2017 HRS Expert Consensus Statement on Cardiovascular Implantable Electronic Device Lead Management and Extraction

Developed in collaboration with and endorsed by the American College of Cardiology (ACC) (endorsement pending), American Heart Association (AHA) (endorsement pending), Asia Pacific Heart Rhythm Society (APHRS), American Society of Anesthesiologists (ASA) (endorsement pending), European Heart Rhythm Association (EHRA), Infectious Diseases Society of America (IDSA) (endorsement pending), Latin American Heart Rhythm Society (LAHRS), Pediatric and Congenital Electrophysiology Society (PACES), and Society of Thoracic Surgeons (STS)

Fred M. Kusumoto, MD, FHRS, FACC (Chair),[1] Mark H. Schoenfeld, MD, FHRS, FACC, FAHA, CCDS (Vice-Chair),[2] Bruce L. Wilkoff, MD, FHRS, CCDS (Vice-Chair),[3] Charles I. Berul, MD, FHRS,[4*] Ulrika M. Birgersdotter-Green, MD, FHRS,[5] Roger Carrillo, MD, MBA, FHRS,[6] Yong-Mei Cha, MD,[7] Jude Clancy, MD,[2] Jean-Claude Deharo, MD, FESC,[8] Kenneth A. Ellenbogen, MD, FHRS,[9] Derek Exner, MD, MPH, FHRS,[10] Ayman A. Hussein, MD, FACC,[11] Charles Kennergren, MD, PhD, FETCS, FHRS,[12‡] Andrew Krahn, MD, FRCPC, FHRS,[13] Richard Lee, MD, MBA,[14§] Charles J. Love, MD, CCDS, FHRS, FACC, FAHA,[15¶] Ruth A. Madden, MPH, RN,[11] Hector Alfredo Mazzetti, MD,[16#] JoEllyn Carol Moore, MD, FACC,[17] Jeffrey Parsonnet, MD,[18**] Kristen K. Patton, MD,[19‡‡] Marc A. Rozner, PhD, MD, CCDS,[20†,§§] Kimberly A. Selzman, MD, MPH, FHRS, FACC,[21] Morio Shoda, MD, PhD,[22] Komandoor Srivathsan, MD,[23] Neil F. Strathmore, MBBS, FHRS,[24¶¶] Charles D. Swerdlow, MD, FHRS,[25] Christine Tompkins, MD,[26] Oussama Wazni, MD, MBA[11]

From the [1]Mayo Clinic, Jacksonville, Florida, [2]Yale University School of Medicine, New Haven, Connecticut, [3]Cleveland Clinic Lerner College of Medicine of Case Western Reserve University, Cleveland, Ohio, [4]Children's National Medical Center, Washington, District of Columbia, [5]UC San Diego Health, La Jolla, California, [6]University of Miami, Coral Gables, Florida, [7]Department of Cardiovascular Diseases, Mayo Clinic School of Medicine, Rochester, Minnesota, [8]CHU La Timone, Service de Cardiologie, Marseille, France, and AMU, UMR MD2, Faculté de Médecine Nord, Marseille, France, [9]Virginia Commonwealth University Medical Center, Richmond, Virginia, [10]University of Calgary, Calgary, Canada, [11]Cleveland Clinic, Cleveland, Ohio, [12]Sahlgrenska University Hospital, Gothenburg, Sweden, [13]The University of British Columbia, Vancouver, Canada, [14]Saint Louis University, St. Louis, Missouri, [15]Johns Hopkins Hospital, Baltimore, Maryland, [16]Hospital Fernandez, Buenos Aires, Argentina, [17]Minneapolis Heart Institute, Abbott Northwestern Hospital, Part of Allina Health, Minneapolis, Minnesota, [18]Dartmouth-Hitchcock Medical Center, Lebanon, New Hampshire, [19]University of Washington, Seattle, Washington, [20]The University of Texas MD Anderson Cancer Center, Houston, Texas, [21]George E. Wahlen Department of Veterans Affairs Medical Center, Salt Lake City, Utah, [22]Tokyo Women's Medical University, Shinjuku, Japan, [23]Mayo Clinic, Phoenix, Arizona, [24]Royal Melbourne Hospital, Parkville, Victoria, Australia, [25]Cedars-Sinai Medical Center, Los Angeles, California, [26]University of Colorado School of Medicine, Aurora, Colorado

†Deceased (see In Memoriam at the end of this document)

*Representative of the Pediatric and Congenital Electrophysiology Society (PACES)
‡Representative of the European Heart Rhythm Association (EHRA)
§Representative of the Society of Thoracic Surgeons (STS)
¶Representative of the American College of Cardiology (ACC)
#Representative of the Latin American Heart Rhythm Society (LAHRS)
**Representative of the Infectious Diseases Society of America (IDSA)
‡‡Representative of the American Heart Association (AHA)
§§Representative of the American Society of Anesthesiologists (ASA)
¶¶Representative of the Asia Pacific Heart Rhythm Society (APHRS)

Document Reviewers: Adrian M. Baranchuk, MD, FACC, FRCPC, FCCS; Carina Blomström-Lundqvist, MD, PhD; Frank A. Fish, MD; James M. Horton, MD; Roberto Keegan, MD; Miguel A. Leal, MD, FACC, FHRS; Nigel Lever, MBChB, FRACP; Aman Mahajan, MD, PhD, MBA; Marc R. Moon, MD; Siva K. Mulpuru, BS, MB, MBBS, MD, FHRS, CCDS

KEYWORDS Lead management; Extraction; Defibrillator, Pacemaker; Infection

ABBREVIATIONS **(^{99m})Tc-HMPAO-WBC =** (^{99m})Tc-hexamethypropylene amine oxime–labeled autologous white blood cell; **CIED =** cardiovascular implantable electronic device; **CRT =** cardiac resynchronization therapy; **CS =** coronary sinus; **CT =** computed tomography; **ECG =** electrocardiogram; **EGM =** electrogram; **FDG =** fluorodeoxyglucose; **HR =** hazard ratio; **ICD =** implantable cardioverter defibrillator; **ICE =** intracardiac echocardiography; **INR =** international normalized ratio; **IV =** intravenous; **LIA =** lead integrity alerts; **LNA =** Lead Noise Algorithm; **LV =** left ventricular; **LVAD =** left ventricular assist device; **MAUDE =** Manufacturer and User Facility Device Experience; **MR =** magnetic resonance; **MRI =** magnetic resonance imaging; **NCDR =** National Cardiovascular Data Registry; **NIS =** National (Nationwide) Inpatient Sample; **OR =** odds ratio; **PADIT =** Prevention of Arrhythmia Device Infection Trial; **PET =** positron emission tomography; **RA =** right atrium; **RLES =** Riata Lead Evaluation Study; **RV =** right ventricle; **S-ICD =** subcutaneous implantable cardioverter defibrillator; **SVC =** superior vena cava; **TEE =** transesophageal echocardiography; **TR =** tricuspid regurgitation; **TTE =** transthoracic echocardiography; **UDI =** unique device identification; **VF =** ventricular fibrillation; **VT =** ventricular tachycardia.

Address reprint requests and correspondence: Heart Rhythm Society, 1325 G Street NW, Suite 400, Washington, DC 20005. E-mail address: clinicaldocs@hrsonline.org.

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1. Introduction and Methodology

Most cardiovascular implantable electronic devices (CIEDs) currently use leads that connect the generator to cardiac tissue. Lead management is an important issue, given the lead failures, generator changes, and clinical conditions that can directly affect CIEDs, such as infection. This document is intended to help clinicians in their decision-making process for managing leads. The document also builds on the *2009 Transvenous Lead Extraction: Heart Rhythm Society Expert Consensus on Facilities, Training, Indications, and Patient Management* (2009 HRS Extraction) document,[1] which provides detailed recommendations on facilities and training for lead extraction that remain appropriate. The main focus of this consensus statement is to provide practical clinical guidance in the broad field of lead management, including extraction.

This consensus statement is the result of an international collaboration among 10 professional organizations, including the Heart Rhythm Society (HRS), American College of Cardiology (ACC), American Heart Association (AHA), Asia Pacific Heart Rhythm Society (APHRS), American Society of Anesthesiologists (ASA), European Heart Rhythm Association (EHRA), Infectious Diseases Society of America (IDSA), Latin American Heart Rhythm Society (LAHRS), Pediatric and Congenital Electrophysiology Society (PACES), and Society of Thoracic Surgeons (STS).

This document follows the policies of the Heart Rhythm Society, with the required disclosures from all committee members regarding their industry relationships. Of the writing committee's 29 members, 18 had no or minimal financial relationships (<$10,000) with industry. Literature searches were performed, and initial drafts were authored by the writing committee members with no relevant industry relationships. Recommendations were developed from the available data, and commonly encountered clinical situations were identified by the writing committee members. The recommendations follow the Class and Level of Evidence system and methodology developed by the AHA and the ACC (Figure 1).[2] The level of evidence was assessed by writing committee members with no relevant relationships with industry. All recommendations are supported by a short summary of the evidence or specific reasoning for the recommendation. The recommendations required a predefined threshold of >80% consensus by anonymous vote. The actual average consensus vote was 96%.

The recommendations for this document underwent a public comment period, and the document underwent internal peer review by the HRS Scientific and Clinical Documents Committee and external review by the participating societies.

2. Background

Over the past 60 years, CIEDs have become established as an important therapeutic modality of cardiovascular care for the treatment of patients with bradycardia, tachycardia, and heart failure. Although recent technological advances have eliminated the need for transvenous or epicardial leads for CIEDs used in selected patient groups, lead management remains critical for a variety of reasons. Recent estimates suggest that 1.2–1.4 million CIEDs are implanted annually worldwide (Medmarket Diligence LLC Report C500). Questions on lead management arise in several situations, including when changes in a patient's clinical condition make a different functionality more or less important, if a lead becomes nonfunctional, and if the presence of a lead is thought to interfere with the patients' optimal treatment.

3. Definitions

The definitions used in the document are provided in Table 1. The definitions relevant to extraction are similar to those developed by the 2009 HRS Extraction document.[1] As in that document, lead extraction is defined as any lead removal procedure in which at least one lead requires the assistance of equipment not typically required during implantation or at least one lead was implanted for longer than 1 year. Definition of outcomes also closely follows the 2009 HRS Extraction document.[1] In that document, clinical success could include the retention of a small part of the lead that did not affect the desired outcome of the procedure. After discussion, the writing committee reached consensus and specifically defined "small" as <4 cm for any residual lead portion. In addition, the <4-cm remnant cannot affect the desired outcome of the procedure; thus, an extraction procedure would not be defined as a clinical success if the remnant needed to be surgically removed due to continued concern for infection. More detail on clinical outcomes is provided in Section 12.

4. Lead Survival

Recommendation

IIa	C-EO	**A lead model and clinical scenario-specific strategy of increased surveillance and management can be useful for CIED leads that have been identified with higher-than-expected failure rates.**	
Identifying an acceptable annual performance target should take into account the lead's intended use, complexity, and patient factors that influence durability. Extensive data from currently available pacing and implantable cardioverter defibrillator (ICD) leads are available from real-world registry data and product performance reports, based on extensive remote monitoring data.[3–5] These data, comprising several available leads with robust 5- to 10-year follow-up data, support a target annual failure rate of ≤0.4% for ICD leads and ≤0.2% for pacing leads.			

4.1 Historical Background

The integrity and reliability of CIED leads are critical for the proper function of these devices and their ability to deliver life-sustaining therapies. The leads must survive the hostile biological environment of the human host and retain electrical integrity and chemical inertia while enduring repetitive mechanical stress with millions of cardiac cycles each year. As such, improving lead design and performance have been targets of significant scientific and engineering efforts in recent decades, but CIED leads continue to occasionally fail, potentially leading to adverse clinical outcomes.

Multiple studies have addressed lead failure rates and modes of failure.[3–11] The reported lead failure rates have varied, with certain leads being more prone to failure and certain patient populations more vulnerable to lead failure.[3] The comparison of failure rates across a wide range of manufacturers and lead designs is complicated by varying definitions and study designs, patient and operator characteristics, venous access and implant technique, duration of follow-up, and methods employed to detect lead failure but, most importantly, by the differences in the leads' structural properties.

Lead failure can represent the breakdown of any of the lead components, including insulation, conductors, connectors, terminal pins, electrodes, and coils. The clinical consequences depend on the failure mode and can lead to the system's inability to deliver appropriate therapy or to the delivery of inappropriate and potentially harmful therapy.

The manufacturers' product performance reports indicate a survival probability for most CIED leads in adult patients in the range of 92% to 99% 5 years after implantation.[12–16] The interpretation of these survival estimates is potentially limited by the under-reporting of failures, lack of uniform definitions, reliance on self-reporting, and insufficient follow-up.

Pacing leads have shown better overall survival rates than ICD leads due to a simpler design and fewer components, which reduce the risk of failure. In the 2006 Danish Pacemaker Register (a longitudinal registry of all leads implanted in Denmark), the 10-year survival rates for unipolar and bipolar pacemaker leads were 96.5% and 97.8%, respectively; the data also suggested that pacemaker lead performance had improved over time.[4] Studies from the past decade have reported lower ICD lead survival rates: ranging from 91% to 99% at 2 years, 85% to 95% at 5 years, and 60% to 72% at 8 years.[17–25] However, many of these studies included leads known to have unacceptably high failure rates or leads subject to safety communications or recalls (Sprint Fidelis [Medtronic] and Riata [Abbott]) (Section 6).[6]

Currently, the 4 most commonly implanted ICD lead families are the Endotak Reliance (Boston Scientific), Sprint Quattro (Medtronic Corp), Protego (Biotronik), and the 7F Durata (St. Jude Medical, Inc.) leads. In a recent meta-analysis of 17 studies, which included a total of 49,871 patients with a follow-up of 136,509 lead-years, the failure rates were 0.29% per year for the Quattro lead family, 0.36% per year for the Endotak Reliance lead family, and 0.45% per year for the Durata lead family (P=NS between families).[11] A caveat when interpreting these observations: The mean follow-up duration of the studies included in this meta-analysis was 2 to 3 years, and none of the studies had an average follow-up longer than 6 years. The failure rates with Sprint Fidelis and Riata/Riata ST leads appear to have increased over time.[24,25] Studies with longer duration follow-ups are therefore needed to further assess the long-term performance of currently implanted leads and all future leads. Lead failure might be more likely in children due to somatic growth and high levels of physical activity.[26,27]

4.2 New Technology

Due to the clinical challenges and morbidity inherent in lead management, significant research efforts have focused on improving lead design and developing devices that do not require intravascular leads. The former aims to develop smaller, yet more durable and easily extractable leads. The latter has resulted in the introduction of the subcutaneous ICD and leadless pacemaker systems.

4.2.1 Single-Component Leadless Pacemakers

Two single-component leadless pacemakers have been implanted in humans in recent years: the Nanostim (Abbott) and the Micra Transcatheter Pacing System (TPS) (Medtronic).[28,29] These systems contain the pulse generator and pace-sense electrodes in one unit and are delivered to the right ventricle through a femoral vein. The Nanostim system uses an active screw-in helix and secondary fixation with three angled nitinol tines perpendicular to the helix. The Micra system employs four self-expanding nitinol tines for fixation. Both devices are reportedly retrievable, but available data are very limited.

4.2.2 Subcutaneous Implantable Cardioverter Defibrillators

An entirely subcutaneous ICD (S-ICD) has been recently introduced, which prevents the inherent problems related to transvenous leads.[30] The S-ICD consists of a pulse generator implanted in a left mid-axillary position connected to an entirely subcutaneous lead with a shocking coil electrode that is positioned in a parasternal position.

5. Diagnostic Approach to Suspected Lead Failure

This section discusses the clinical presentation and diagnostic approach to suspected lead failure. The primary focus is on ICD leads due to their higher failure rates compared with pacing leads and the clinical challenges pertaining to lead management in patients with Sprint Fidelis and Riata ICD leads. Generally, the same diagnostic principles apply to pacemaker leads, with the exceptions that oversensing in ICD leads results in inappropriate shocks and pacing inhibition and that high-voltage failure modes do not apply to pacing leads.

5.1 Clinical Presentation

The lead failure modes are pace-sense malfunction and shock component malfunction, with the former accounting for the clear majority (>90%) of diagnosed lead failures in clinical practice.[7] In pace-sense circuits, conductor failure or insulation breach typically present as oversensing of rapid, nonphysiological signals, resulting in inappropriate shocks or pacing inhibition.[24,31]

In the past, the most common presentation of pace-sense lead fracture was inappropriate shocks.[32,33] Due to device diagnostics that incorporate the detection of short intervals and changes in impedance and the widespread use of remote monitoring, an increasing number of patients in recent years are presenting with lead alerts, enabling early recognition of lead failure before the onset of adverse clinical events.[34] Despite these advances, patients can still present with multiple shocks, because fracture might only become apparent after high-voltage therapy. Health care providers who provide initial care for patients should understand the use of magnets for suspending therapy.

The true incidence of shock-component malfunction is difficult to ascertain due to a lack of specific diagnostic tools. These malfunctions typically present with shock impedance change and, less commonly, as failed defibrillation or in association with coexisting pace-sense failures. Insulation failure with shorting of the high-voltage circuit can result in catastrophic failure of the pulse generator. The introduction of remote monitoring and enhanced lead diagnostics will likely improve the early recognition of shock-component malfunction.

5.2 Device Electrograms in Pace-Sense Failures

Device electrogram (EGM) analysis is important in the diagnostic approach to suspected lead failure, especially pace-sense circuit failures, because oversensing (noise) is the most common observation in this failure mode. It is important to distinguish lead failure–related oversensing from other sources, such as electromagnetic interference, myopotentials, P- or T-wave oversensing, R-wave double counting, and lead-lead interactions. Cyclical oversensing, which refers to sensing non-QRS components with every cardiac cycle, typically indicates an intracardiac source of oversensed signals.

The morphology and pattern of typical nonphysiological EGMs in conductor fractures have been validated by returned product analysis of explanted leads.[34] The typical characteristics of conductor-fracture EGMs are signals that are (1) intermittent with a high dominant frequency; (2) highly variable (amplitude, morphology, frequency); and (3) not recorded on the high-voltage or shock channel. The EGMs are typically noncyclical, exhibit extremely short nonphysiological R-R intervals (<160 ms), are unlikely to represent ventricular depolarization, and might saturate the sensing amplifier, resulting in a truncated signal on the near-field sensing channel. Atypical EGM patterns can, however, occur in pace-sense conductor fractures, including oversensing that is precipitated by pacing and cyclical oversensing patterns.[35–37] Lead connection problems present with similar EGM patterns and are difficult to distinguish from conductor fractures. However, connection problems are most often temporally associated with an invasive CIED procedure such as implantation or generator replacement.

Data regarding EGM characteristics in insulation breaches of pace-sense circuits are limited to observational clinical series, and returned product analysis validation is limited to case reports.[31,38] In contrast to conductor fractures, insulation failures do not themselves typically generate abnormal signals but result in sensing of physiological signals from surrounding structures or nonphysiological signals, which are typically generated from the interaction of conductors. As such, EGM patterns in insulation breaches vary, reflecting the signal source.[37]

5.3 Impedance and Impedance Trends in Lead Failure

CIEDs periodically measure the entire circuit's resistance to direct current, which applies Ohm's law (R=V/I) and reflects the electrical circuit integrity. The pace-sense conductors' resistance to current typically contributes less than 15% of the entire circuit's resistance; therefore, impedance assessment and monitoring lacks sensitivity in pace-sense failures. In fact, impedance abnormalities occur in only a minority of pace-sense lead failures before the abnormalities are identified by oversensing diagnostics or inappropriate detection of ventricular tachycardia (VT) or ventricular fibrillation (VF). In contrast, the observation of abrupt, relative changes in impedance trends is more specific and is about as sensitive as an out-of-range impedance.[24,34,38] A single abrupt change could, however, be spurious, and a gradual rise in impedance without oversensing typically reflects increased resistance to current at the lead-myocardium interface, which by itself does not require lead revision in the absence of sensing and pacing abnormalities. A pacing impedance of less than 200 Ω can indicate an insulation breach of the pace-sense component.

Impedance measurements remain the primary diagnostic tool for high-voltage conductors. There are numerous considerations for the low-voltage, painless measurement of shock circuit impedance, including (1) typical low impedances for high-voltage cables and shock electrodes; (2) tissue resistance, which is inversely proportional to voltage, thereby affecting the estimate of high-voltage impedance based on painless measurement; and (3) the greater effect of respiratory variability with low-voltage measurements. An abrupt increase in shock impedance (typically >75%) or a shock-impedance value greater than 100 Ω likely indicates shock conductor fracture, based on the returned product analysis of Medtronic leads connected to Medtronic generators.[39] The applicability of these specific threshold values for diagnosing conductor fractures in other manufacturers' leads has not been reported. Elevated shock-impedance values could also reflect a faulty connection of shock components. High-voltage insulation breaches result in low impedance values, but shock impedance trends in this setting have not been studied systematically, and no threshold values have been defined. Case reports have shown that shocks can short-circuit despite normal low-voltage painless measurements of shock impedance.[40,41]

5.4 Device Diagnostics to Mitigate Adverse Consequences of Pace-Sense Failure

5.4.1 Counts of Extremely Short R-R Intervals

Intervals near the ventricular blanking period are unlikely to represent successive ventricular activation, even in VF. Some devices keep track of nonphysiological sensed intervals in place of lead integrity. The utility of this feature has been studied systematically with the Medtronic Sensing Integrity Count, which stores the count of R-R intervals that are shorter than 130 ms. However, the most common cause of isolated, extremely short sensed R-R intervals are benign combinations of oversensed physiological signals or detection of environmental electromagnetic interference.[34] A rapidly increasing sensing integrity count is a sensitive indicator of conductor fracture, which in isolation has low specificity. It has been noted that elevated sensing integrity count values are more common with intact integrated bipolar leads than with intact dedicated bipolar leads.[42] Increasing episodes of nonsustained VT, particularly if characterized by rapid rates, should arouse suspicion for possible lead failure.

5.4.2 Algorithms That Incorporate Both Rapid Sensing and Impedance Monitoring

Lead Integrity Alert (Medtronic)
This was the first lead-alert algorithm to incorporate oversensing metrics and is the most extensively studied. The algorithm combines a rapidly-increasing sensing integrity count with repetitive rapid oversensing and abrupt impedance changes.[34,42] Monitoring both rapid oversensing and impedance trends provides earlier warning of lead failure than a fixed impedance threshold.[9,42] This algorithm has been validated by returned product analysis, and multiple studies have assessed its clinical utility.[34,42] The false-positive rates have been generally low and even lower for dedicated-bipolar leads compared with integrated-bipolar leads, primarily due to more frequent triggering by electromagnetic interference in integrated-bipolar leads.[31,34,42] Prospective and retrospective observational data indicate that lead integrity alerts (LIA) improve early detection of Fidelis lead fractures and reduce inappropriate shocks compared with monitoring impedance alone.[34,42] Other published studies have indicated that LIA also improve detection of conductor fractures in other models of Medtronic leads, which has been confirmed by returned product analysis.[35] Retrospective, observational, clinical studies have found that this algorithm identifies failures in defibrillation leads from various manufacturers.[38,43]

Latitude Lead Check (Boston Scientific)
This algorithm is qualitatively similar to Medtronic's LIA and alerts for either rapid, repetitive oversensing or out-of-range pace-sense impedance. A potential advantage of this algorithm is that it is incorporated within the remote monitoring system network, not the ICD; thus, it can be regularly updated for all patients. To date, no peer-reviewed publications have assessed this algorithm's clinical performance.

5.4.3 Algorithms That Compare Sensing and Shock EGMs

Two currently employed algorithms—Medtronic's Lead Noise Algorithm (LNA) and St. Jude Medical's SecureSense—identify oversensed, nonphysiological, pace-sense signals as those that do not correlate temporally with EGMs on the shock channel. There are differences in the design of LNA and SecureSense, but both withhold shocks if sufficient evidence of oversensing occurs.[44,45] Algorithm failures can be caused by a false negative assessment, resulting in failure to withhold inappropriate therapies for true lead failure or a false positive assessment with the algorithm being triggered by conditions other than lead failure. In the latter, failure to deliver appropriate therapy for life-threatening arrhythmia is of greatest concern. Neither algorithm identifies right ventricular (RV) coil fractures in integrated bipolar leads or simultaneous nonphysiological signals on sensing and shock channels, such as those caused by cable-coil abrasions. The differences in design of these algorithms might account for the variability in algorithm failure modes.

In bench testing, SecureSense identified simulated lead failure signals (97.1% of sustained episodes, 90.4% of nonsustained episodes) and did not withhold shocks from 100% of induced VF episodes.[45] A systematic analysis of this algorithm's clinical performance has not been reported. Case reports and small series have documented false positives, mostly for clinically insignificant events.[46]

In bench testing, LNA identified 83% of simulated lead failure signals and did not withhold shocks from 100% of stored EGMs of spontaneous VT and VF episodes.[44] In a prospective clinical study, the maximum delay for detecting 196 episodes of induced VF episodes was 2 seconds.[47] In the PainFree SST trial, this algorithm withheld all shocks from only 3 of 11 patients (27%) with clinically diagnosed lead failure and did not withhold therapy from any of the 3901 adjudicated and treated VT/ and VF episodes.[48]

5.5 Device Diagnostics to Mitigate Adverse Consequences of Shock-Component Failure

Shock-component failure is monitored primarily by standard shock impedance assessment.[39] In in vitro studies, new high-frequency measurements of impedance appear to be able to detect partial, high-voltage insulation breaches.[49] One manufacturer (St. Jude Medical) provides an automatic shock-vector adjustment algorithm (Dynamic Tx) that removes a shorted high-voltage pathway from shock delivery in a dual-coil lead, but no systematic data have been published to date about this feature.

5.6 Role of Remote Monitoring

Devices with wireless telemetry automatically detect and transmit stored data, including lead alerts.[50] Observational studies support the use of remote monitoring to facilitate diagnosis of lead failure.[51] Limited observational data suggest that wireless remote monitoring, when combined with LIA, reduces inappropriate shocks more than LIA alone.[52] The role and importance of remote monitoring in the diagnosis of lead failure and monitoring at-risk leads have been endorsed by consensus statements from HRS and the Canadian Heart Rhythm Society.[53,54]

5.7 Caveats in Diagnosis of Lead Failure

In suspected lead failure diagnosis, it is important to differentiate true lead failure from other causes of false-positive impedance rises and rapid oversensing that could be mistaken for lead failure.

Swerdlow et al analyzed leads that were clinically diagnosed as failures, were explanted, and were subjected to returned product analysis.[35] Their study analyzed normally functioning leads with impedance rises and compared impedance trends and EGMs in leads that were confirmed to have failed versus leads that were confirmed to be normal and intact except for explant damage. The study included 40 fractured leads, 30 with connection problems, and 21 functioning leads that triggered high-impedance alerts. An algorithm was developed in this study to distinguish failed leads from both header-connection problems and benign impedance changes at the electrode-myocardial interface. This algorithm was subsequently validated prospectively in a set of 100 leads. Briefly, (1) either extremely high maximum impedance or noise oversensing with a normal impedance trend indicated a fracture; (2) short temporal interval from surgery to impedance rise or prolonged stable impedance after an abrupt rise indicated a connection problem; and (3) gradual impedance increase or stable, high impedance indicated a functioning lead. The algorithm was found to correctly classify 100% of fractures and 87% of connection problems that had been misdiagnosed as fractures.

Case reports have documented rare occurrences of lead interactions and perioperative air in the header, each of which can trigger lead alerts.[55,56] Multiple recent reviews have discussed the approach for patients with suspected lead failure.[31,37]

6. Lead Recalls and Advisories

6.1 Background

6.1.1 Introduction

Lead advisories or recalls refer to notifications to patients, providers, and regulators that a lead has failed to meet the prespecified expectations for performance.[57] Malfunction (or more often failure) exceeding expected rates is based on returned product analysis, customer reported failures, postmarketing registry reports, or remote monitoring. The precise terminology is primarily determined by regulator language, given the vast majority of leads are not extracted from patients and returned to the manufacturer.[57,58] Random component failure is the term used to describe an unavoidable rare failure that does not reflect a systematic failure mechanism over-represented in a particular lead model. Advisories are typically reported when a lead manifests a specific mechanism of component failure, attributed to a component or an assembly flaw that leads to lead failure, which can involve any of the lead components (insulation, conductors, connectors).

6.1.2 Lead Surveillance History

The growth of CIED implants with increasingly complex lead systems has led to a greater need for surveillance and reporting. Lead manufacturers generate product performance reports that have evolved over time to become in-depth online reports that detail lead performance. The degree of rigor of review and reporting has increased over time, often prompted by lead recalls/advisories that have led regulators and physicians to increase the sample size of prospective registries.[57,58] Remote monitoring has transformed the oversight and reporting of lead performance, because the scale of observations has increased exponentially. Rare but life-threatening performance concerns are readily placed in context when information on hundreds of thousands of comparable leads can be readily accessed. Manufacturers have also markedly enhanced their internal quality processes at the component and assembly level and continue to request input from expert physicians at “arm’s length” when concern is raised over lead performance metrics.

6.1.3 Historical Lessons

Several notable examples of lead performance advisories have shaped the evolution of lead design and performance management, including the Telectronics Accufix pacing leads, which were recalled in November 1994 after two deaths and two nonfatal injuries were reported.[59] The failure mechanism was protrusion of an electrically inactive J retention wire, which fractured and protruded from the polyurethane insulation, resulting in laceration of the right atrium (RA) and rare embolization to the pulmonary circulation. This landmark recall prompted the formation of a multicenter clinical study and a global registry that tracked clinical failure-related events and complications of interventions when leads were extracted. Notably, more deaths were reported from interventions than from lead-related trauma or embolization.[59]

Around the same time, a widespread lead problem focused on the durability of a type of polymer used in bipolar polyurethane pacing leads such as the Medtronic 4004 model. This polymer was associated with an increased risk of stress fracture and insulation breach, particularly evident when the subclavian vascular access approach was used.[60] This problem highlighted the roles of lead component materials and surgical technique on lead performance.

Since then, most concerns about leads have stemmed from ICD leads, whose more complex design and high-voltage components have been associated with systematically higher failure rates than those of pacing leads.[31] Kleemann et al reported on 990 ICD leads (from multiple generations and manufacturers) that were implanted between 1992 and 2005, finding a 20% failure rate at 10 years.[8] Ellenbogen et al evaluated the long-term reliability of the Medtronic 6936 coaxial polyurethane ICD lead in the 1990s, reporting a striking 37% failure rate at 69 months of follow-up.[61] This study reported a late failure mechanism after acceptable performance in the first 3 years, thus launching the development of lead failure recognition algorithms characterized by detection of nonphysiological short sensing intervals.[38]

The next major lead advisory took place in 2007, affecting the Medtronic Fidelis lead, whose malfunction was characterized by a higher-than-expected lead failure rate related to conductor fractures attributed to features designed to reduce the lead's size and enhance the lead's flexibility, which permitted bending with a short curvature radius. More than 90% of Fidelis fractures were caused by fracture of one of the two pace-sense conductors, the inner coil near the tie-down sleeve or the cable to the ring electrode near the distal shocking coil.[33,34,52] Initial clinical presentations were characterized by a high incidence of inappropriate shocks, which was markedly attenuated by the LIA algorithm.[34,38] Fracture rate estimates have ranged from 1.5% to 3% per year, a clear excess in relation to several other concurrent lead models.[33,52,62]

The most recent major advisory concerned the St. Jude (now Abbott) Riata ICD leads, characterized by frequent externalization of conductor coils and an increased risk of lead malfunction.[63] The root cause of externalization was attributed to a design that included redundant cables with stiff ethylene tetrafluoroethylene insulation in large channels, which resulted in cable sliding, "inside-out" erosion, and insulation that did not use an outer "jacket." The Riata family of leads exemplifies the decision-making challenges faced by clinicians because the mechanical externalization rate for select models can be as high as 25%–30%, whereas electrical failure rates range from 2% to 4%.[63] The long-term risk for mechanical failure due to extruded cables is unknown. These leads also represent an inherently more complex and high-risk extraction challenge because of the externalization of the coils, although the data suggest that extraction outcomes are comparable to other lead models in experienced hands.[64]

6.2 Thresholds and Targets for Lead Performance

Lead performance has steadily improved over time, and regulators have set targets for the extent of data necessary for prospective lead follow-up to ensure postmarketing surveillance detects evidence of unsatisfactory lead function.[65] Despite these stringent standards, a clear consensus has not arisen regarding acceptable thresholds for annual failure rates for pacing or ICD leads to guide manufacturers, regulators, or clinicians. Defining these targets would benefit all stakeholders when responding to data from surveillance, assisting the decision-making process when notifying the relevant parties and when removing a lead from ongoing use. By definition, these targets are empirical, although they are informed by historic lead performance that sets targets based on currently available lead models. The current long-term lead performance of currently available ICD leads suggests that annual failure rates should not exceed 0.4% per year and that annual failure rates for pacemaker leads should not exceed 0.2% per year in the first 10 years of the leads' implanted life cycle.[3-5,11] Many currently available leads from the range of manufacturers meet these targets, though data beyond 10 years are limited. These data have been generated from leads using DF-1 connectors and not the DF-4 connector that is now in common use. Data on long-term performance of left ventricular (LV) leads are also less plentiful, especially with the advent of quadripolar leads that currently dominate implant practice. These targets therefore primarily apply to right-sided leads, until further data on quadripolar LV leads set target performance standards.

6.3 Food and Drug Administration

6.3.1 Food and Drug Administration Determination of Lead Safety and Effectiveness

The Office of Device Evaluation in the Center for Devices and Radiological Health (CDRH) within the Food and Drug Administration (FDA) is responsible for overseeing the market approval of all pacemaker and defibrillator leads and all CIEDs in the United States. The focus of premarket assessment of any device, including leads, is to ensure that it has a reasonable assurance of safety and effectiveness.

Premarket testing often includes some variation of bench, animal, and clinical investigations. The FDA requires bench testing of all pacemaker and defibrillator leads, which includes standardized testing recognized by the International Organization for Standardization that assesses the leads' mechanical and electrical performance, biocompatibility, and interchangeability. To assess potential failure mechanisms, other bench testing is also performed, such as flex-fatigue testing, which can simulate the stress of a transvenous lead, flexing with each myocardial contraction over several patient years. The required animal studies vary in size and duration, depending on the particular safety or handling issues for a given lead. The FDA is collaborating with a number of stakeholders, including industry, physicians, and the American Association of Medical Instrumentation, to provide new lead testing standards.

The FDA requirement for premarket clinical data is determined on a case-by-case basis and is based on design differences with a similar lead that is already market approved. The nature and significance of the lead modifications factor into whether a premarket clinical study is necessary. Although the lack of a blanket requirement for clinical data on every lead prior to approval has been controversial, the size and duration of a study to detect certain failures, particularly those that occur infrequently or late, can be prohibitive.[66,67] Over the past several years and in part due to the ICD lead recalls during this timeframe, the FDA has continued to adjust both its premarket requirements and postmarketing surveillance data collection requirements for all new ICD and pacemaker leads.

6.3.2 Food and Drug Administration Postmarketing Surveillance

The FDA is also responsible for postmarketing surveillance to monitor for safety signals in any given device or lead. The focus of postmarketing surveillance is to ensure that all devices, including leads, perform as intended and do not harm the patient. The failure mode for leads is often not entirely new or previously unidentified but rather occurs at a higher rate than with other similar leads. Hospitals and device manufacturers are required to report lead-related failures that clearly caused (or might have caused) death or serious injury. Under-reporting can occur, however, because physicians are not required to report these failures, particularly when there was no serious harm. Devices and leads are frequently not returned to the manufacturer to allow for root-cause testing. When the leads are returned, they are often severely damaged from the extraction procedure, limiting the ability to perform a returned product analysis on the leads.[66] The FDA receives several hundred thousand reports annually on device-related adverse events, which are submitted and saved to the Manufacturer and User Facility Device Experience (MAUDE) database.

Postmarketing lead surveillance requirements have changed over the past several years. Since 2008, manufacturers have been required to conduct a 5-year, 1000-patient minimum, postapproval study on all new or substantially modified ICD leads to reliably capture all lead failures in a large patient cohort and to hopefully detect failures that either occur late or occur relatively infrequently.[66]

6.3.3 Unique Device Identification

The FDA has been working to establish the unique device identification (UDI) system, which requires all medical devices and packages to carry a unique numeric or alphanumeric code. The UDI code includes a device identifier, which identifies the model and includes the production identifier, which identifies the manufacturer lot number, serial number, expiration date, and manufacturing date. This requirement will be phased in over the next 5 years. The UDI system will enable a more streamlined and accurate collection of lead-related adverse events and facilitate the use of large registries for postmarketing data surveillance. The UDI system will enhance the management of lead recalls by recording all leads implanted in the United States in a searchable central database.[57,65–67]

6.4 Lead Recalls

If a device manufacturer determines that a device recall is warranted, the FDA will be notified and may issue a public notification along with the manufacturer's notification to ensure widespread awareness of the recall. Information on recalled leads will be posted on the FDA website, the manufacturer's website, and the HRS website.

The FDA classifies recalls as class I, II, or III, depending on the recall's severity and nature.[65–67] The classification depends on the severity and likelihood of the health risk. Both the Fidelis and Riata ICD lead recalls were classified as class I. A recall indicates that the lead model is being removed from the shelf immediately and can no longer be implanted; however, the recall does not necessarily indicate that the lead needs to be removed or replaced. For implanted leads, a recall may involve patient monitoring and management strategies. The FDA does not regulate the practice of medicine. However, the FDA will make general recommendations based on the available information at the time of the recall and will update the recommendations as new information is received. The manufacturers and professional societies will also issue their own recommendations to patients and physicians.

When the Fidelis ICD lead recall was announced on October 15, 2007, the FDA classified it as a class I recall and stated that they concur with Medtronic's recommendations to adjust the ICD settings.[66] Medtronic recommended several specific programming changes to optimize the lead impedance alert efficacy and to turn on the patient alert to reduce the likelihood of an inappropriate shock. The FDA strongly recommended against the routine extraction of these leads and stated in the recall notice that "neither FDA, Medtronic, nor representatives of the Heart Rhythm Society, recommend the routine surgical removal of a fractured lead because removal carries risks."

Occasionally, the FDA will update its recommendations regarding a lead recall or will ask the manufacturer to gather additional information. An example of this is the St. Jude (now Abbott) Riata ICD lead recall in November 2011, which was also classified as a class I recall. The FDA, however, believed there was insufficient information to answer the following important lead management questions: (1) How frequently does the Riata lead insulation fail? (2) What is the typical time to failure? (3) Does externalization of the electrical conductors increase the risk of future ICD lead electrical failure? (4) What are the risk factors that contribute to insulation failure or externalization of the electrical conductors? The FDA therefore released a safety communication in 2012 with updated recommendations and a public notification that Abbott will be conducting a 3-year postmarketing surveillance study. This safety communication recommended that physicians perform baseline imaging of Riata and Riata ST leads to assess externalization. The imaging assessment could also be performed when changing the generator. For patients with known externalized leads, assessment could be performed at repeated intervals to determine progression. This surveillance study, also known as the Riata Lead Evaluation Study (RLES), was intended to gather data on externalization and electrical failures and to enroll a minimum of 300 Riata and 200 Riata ST leads. The study was then expanded in 2013 to include the Quick Site, Quick Flex and Durata leads (the Cardiac Lead Assessment Study). All patients enrolled in these studies also underwent annual imaging as a required part of the study.

Similar to the Fidelis recall notice, this safety communication stressed that "The FDA, St. Jude Medical [now Abbott], and the Heart Rhythm Society do not recommend routine removal of any leads due to the risks of explantation surgery." The FDA did not recommend routine replacement of leads with abnormal imaging and normal electrical function. Although an association between externalization of cable conductors and electrical failure has been identified in some studies, the Riata Lead Evaluation Study, which was the largest prospective assessment of patients implanted with Riata or Riata ST leads (n=776), showed no association between externalization and electrical failure.[58] The most recent product performance report from St. Jude Medical (now Abbott) stated that as of February 28, 2017, a total of 346 (45%) patients from the Cardiac Lead Assessment Study completed at least 3 years of follow-up with fluoroscopy evaluation. To date, the electrical failure rate for the Riata and Riata ST leads is 5% (10 of 195) for externalized leads and 3% (18 of 581) for leads without externalization (P=.19, NS).[68]

HRS issues general recommendations regarding lead advisories, recalls and factors to consider when formulating a plan for individual patients.[68] Professional societies such as HRS can provide clinical guidance to, as well as partner with, regulatory agencies and industry to help notify its members and educate clinicians on the causes and recommendations for any given lead recall. The current recommendations for Fidelis and Riata leads issued by the FDA and supported by HRS are listed in Appendix 3.

7. Existing Cardiovascular Implantable Electronic Device Lead Management

I	C-EO	**Leaving the lead in a condition that will permit future extraction and prevents retraction into the vessel is recommended for any abandoned lead.**	
If an abandoned lead is transected and allowed to retract into the vascular system, it could move to the ventricle or pulmonary artery, triggering arrhythmias or thrombosis. If transected, suturing the lead stump in the pocket facilitates future access to the lead and might reduce the risk of retraction into the vessel. In leads prone to developing inside-out erosion, transection could facilitate cable extrusion. If a lead is transected, it might not be possible to subsequently disengage an active fixation mechanism if the lead needs to be removed. Preserving the lead terminal connector could enable future disengagement of the active fixation mechanism but increases the amount of hardware in the pocket.			
I	C-EO	**Careful consideration with the patient on the decision on whether to abandon or remove a lead is recommended before starting the procedure. The risks and benefits of each course of action should be discussed, and any decision should take the patient's preference, comorbidities, future vascular access, and available programming options into account.**	
When a lead is replaced due to failure of function, supplanted by an alternate lead (eg, pacemaker advanced to an ICD), or not used due to a change in the clinical situation (eg, atrial lead in atrial fibrillation) or when a lead becomes nonfunctional, a decision needs to be made as to whether the lead should be removed or left in situ, weighing the risks and benefits of each strategy. The risks of removal include venous or cardiac perforation requiring emergency surgery and depend on multiple factors, including the duration of the lead implant, the number and types of lead (ICD vs pacing), the patient's age and health, the presence of prior sternotomy, and the experience of the operator and their team. The benefits of removal include removal of unnecessary hardware that might be harder to remove in the future for a mandatory extraction indication such as infection; allowing magnetic resonance imaging (MRI), which is generally contraindicated in the presence of abandoned leads; and creation of an access channel through an occluded vein to allow a lead to be implanted.			
IIa	B-NR	**Lead abandonment or removal can be a useful treatment strategy if a lead becomes clinically unnecessary or nonfunctional.**	**69–71**
Single-center observational studies have compared outcomes in patients undergoing lead abandonment vs extraction in the setting of lead malfunction.[69,70] Over average follow-up times of approximately 3 years, there were no differences in the complication rates or clinical outcomes. In an analysis of the National Cardiovascular Data Registry (NCDR), there was a small increase in risk of procedural complications and mortality in the extraction group compared with patients who underwent a lead abandonment strategy.[71] Data are limited by the observational nature and limited follow-up.			

7.1 Lead Management during Cardiovascular Implantable Electronic Device Replacement

In the setting of planned CIED generator replacement or exchange, expectant management of normally functioning, nonrecalled leads is usually preferable to routine lead revision or extraction procedures due to the comparatively lower risk of complications in generator exchange procedures compared with lead extractions. Nevertheless, as in any area of medicine, the unexpected does occur, and the proceduralist should be prepared to respond to unexpected findings that require lead revision or extraction.

7.1.1 Complications of Generator Exchange

Substantial clinical data over the past decade have revealed a surprisingly high risk of complications associated with generator exchange procedures, particularly when systematically assessed, or when including a several-month follow-up. Direct periprocedural complications occur in 1%–2% of cases, but the overall short-term complication rate is substantially higher (approximately 4%; range 0.6%–8.2%).[72–75] Common major complications include lead dislodgement requiring revision (0.07%–3.2%), infection (0%–5.2%), and hematoma requiring evacuation (0%–1.6%).[72–75] Procedure-related death is rare, occurring in only 0%–0.4%.[72–75] Minor complication rates range from 2.3% to 7.4%, and include infections treatable with antibiotics, hematoma, pain, and other minor surgical wound problems. It is important to note that not only is generator exchange associated with a 2.2-fold increased risk of pocket-related complications compared with an initial CIED implant, a marked increase in the complication rate occurs over subsequent procedures, ranging from 1.5% for the first to 8.1% for the fourth implanted ICD generator.[76]

These findings highlight the importance of minimizing adverse events by making every effort to reduce overall generator exchanges per patient. This goal can be best accomplished by choosing devices with superior battery longevity, ensuring best possible thresholds at lead implant, avoiding placement of unnecessary leads, and using programming strategies that decrease current drain and minimize unnecessary pacing and the use of ICD therapies.[77,78] Determining the optimal battery choice can be challenging; there are significant differences in battery longevity among manufacturers, and past battery longevity from one manufacturer does not necessarily predict future performance in another.[78]

7.1.2 Risk Factors for Complications and Mortality

Patient, proceduralist, and CIED system factors influence the risk of complications. Adverse periprocedural events are associated with patient comorbidities such as worsening angina, heart failure, antiarrhythmic drug use, valvular disease, renal failure, diabetes, anticoagulation or antiplatelet use, corticosteroid use, chronic pulmonary disease, cerebrovascular disease, prior CIED infection, malignancy, fever, and dermatologic disorders.[74,79]

There are a considerable number of procedural factors that increase the complication rate for generator exchange and include reoperation for dislodgement, hematoma, lack of antibiotic prophylaxis, temporary pacing, low implanter volume (<60–70 CIED procedures per year), procedural complications, greater number of leads, the use of defibrillators compared with pacemakers, and the use of biventricular devices.[73,74,79] Unsurprisingly, comorbidities influence the mortality risk for generator exchange. Older age, atrial fibrillation, heart failure, diabetes, renal dysfunction, lung disease, and cerebrovascular disease are associated with an increased risk of death.[75]

7.1.3 Evaluation of Defibrillator System at Generator Exchange

The *2015 HRS/EHRA/APHRS/SOLAECE Expert Consensus Statement on Optimal Implantable Cardioverter-Defibrillator Programming and Testing* provided recommendations on the intraprocedural analysis of ICDs, including the use of defibrillation threshold testing.[80]

7.1.4 Risk of Lead Failure After Generator Exchange

There are limited data on whether the risk of lead failure increases after generator exchange. In a large series of 60,219 ICD patients followed on the Boston Scientific's LATITUDE platform, the incidence of lead alerts markedly increased after generator exchange compared with the control population (hazard ratio [HR] 5.19 [95% CI 3.45–7.84]), many within the first 3 months of generator exchange.[81] Two series of patients with Fidelis leads reported conflicting results associated with generator exchange (20.8% failure rate after generator exchange vs 2.54% in matched controls, P<.001 in one study, and in another study a 3.6% incidence of lead failure after generator exchange compared with 3.5% in controls, P=.962).[82,83] The lead failure rate did not increase in the first year after generator exchange in a series of patients with Riata leads (1.5% vs 2%, P=.32).[84]

7.1.5 Shared Decision Making

It is increasingly clear that ICD generator replacement should not be an automatic decision but one that warrants careful thought and discussion with the patient about values and goals. This is of particular relevance in the elderly ICD population, in which age and increasing comorbidities might reduce the benefit of sudden death prevention, and neither the operative risks of the procedure itself nor the short-term risk of complications is small.[85]

7.2 Lead Management during Cardiovascular Implantable Electronic Device Upgrade

7.2.1 Upgrade Procedure Preparation

Many of the clinically important circumstances described in the generator exchange section above are applicable to CIED upgrade and revision procedures, particularly awareness of the risks of complications and ways to avoid adverse events. This section focuses on clinical issues specific to procedures in which a lead is added to an existing CIED system. These procedures include upgrading single-chamber systems to dual chamber, pacemakers to ICDs, and either pacemakers or ICDs to systems that provide biventricular pacing, as well as lead revision procedures that require addition of a new lead due to lead malfunction or dislodgement.

7.2.2 Complications of Lead Upgrade and Revision Procedures

The risk of immediate procedural and short-term adverse events in upgrade procedures is strikingly higher than in generator exchange procedures. In the REPLACE Registry, the overall risk of major and minor complications at the 6-month follow-up in the 713-patient upgrade cohort was 15.3%, compared with 4% in the 1081-patient generator exchange cohort, and the rate was higher in procedures involving a LV lead (18.7%).[73] The most frequent complication was lead dislodgement (7.9%), followed by prolonged hospitalization (2.5%), hematoma (1.5%), death (1.1%), hospital readmission (1.1%), infection (0.8%), and perforation (0.7%).[73] Similarly, in a large two-center series of new implants (n=1511), generator exchange, (n=1034) and upgrade (n=126), pacemaker implantation and generator exchange had a similar risk of major complications (1.7%), with higher complication rates for ICD implantation (3.5%) and upgrade procedures (6.1%), particularly if an LV lead was implanted (9.5%).[86]

Likewise, increased and unexpectedly high complication rates in pacemaker upgrade procedures (when compared with initial implantation) have been reported for patients with pacemakers, although focused studies were reported in the late 1990s, when upgrade procedures were less common.[87] The incidence of major complications was high (16.7%) in patients undergoing atrial, ventricular, or LV lead upgrade in the Danish Multicenter Randomized Study on Single-Chamber Atrial Pacing Vs Dual-Chamber Pacing in Sick Sinus Syndrome study.[88]

7.2.3 Venous Occlusion

A relatively high rate of subclavian venous occlusions has been reported for patients with chronically indwelling leads. Single-center observational series of up to 356 patients undergoing planned upgrade CIED procedures have shown complete occlusion rates of 3%–26%, a >75% stenosis rate of 10%, and moderate (50%–75%) stenosis rates of 6%–37%.[89–91] Clinical factors associated with stenosis include number of leads, ICD leads vs pacemaker leads, lead dwell time, and multiple procedures. A preparatory venogram or noninvasive ultrasound prior to opening the pocket to assess venous patency should be considered.[89–91]

7.2.4 Lead Choices

When choosing to add a lead to an already existing CIED system, there are numerous clinical decisions regarding the type of lead, whether to include a single- or dual-coil ICD lead, whether to use a passive or active fixation mechanism, whether to add a pacing lead or a new ICD lead in the setting of a pace-sense component malfunction, and the optimal positioning of a new lead in the chamber.[80]

7.2.5 Incorporating Preexisting Leads

Given the limitations of venous access and space in both the central venous system and the heart, a minimalist strategy aimed at reducing the risks of lead additions is practical, and previously placed functioning leads should be integrated into new systems. Data suggest a low risk of lead-related complications when suitable pre-existing leads are combined in an upgrade procedure.[91]

7.2.6 Addition of a Pace-Sense Lead

If an ICD lead failure can be localized to the pace-sense portion and the high-voltage component is known to be reliable, the addition of a pace-sense lead would be a potentially viable strategy that reduces complexity and bulk in the ICD pocket. An observational comparison of 24 patients who underwent a pace-sense lead addition and a contemporaneous group of 13 patients requiring addition of a new ICD lead had no substantial differences in outcomes. However, the long-term recurrent lead failure rate was high in both groups (16% of patients at 3 years of follow-up).[92] In a series of 151 patients undergoing ICD revision with the addition of a pace-sense lead in localized defects, 28% of patients experienced a lead-related complication, and the event-free cumulative survival rate of the added lead was 89.6%, 82.0%, and 60.0% at 1, 2, and 5 years, respectively, for pectoral leads.[93] A follow-up study from this group comparing the outcomes of a nonrandomized series of patients undergoing pace-sense lead addition to those undergoing lead extraction and ICD lead replacement in 85 patients showed no statistically significant differences in complications, mortality, or lead survival after up to 3 years.[94] Long-term lead survival rates of 100%, 93%, and 87% at 1, 2, and 3 years, respectively, were reported in a series of 45 patients undergoing pace-sense lead addition.[95] Single-center studies have reported that ICD lead abandonment does not appear to be associated with an increased risk of overall complications, lead defects, defibrillation failures, or venous occlusion.[96] These older studies evaluated this strategy in nonadvisory leads. Recent modeling studies suggest that, due to the progressive failure rate, implanting a new ICD lead in patients with Sprint Fidelis leads (with or without extraction) is cost-effective and associated with fewer adverse outcomes than adding a pace-sense lead.[97,98]

7.3 Device Downgrade

When the generator is exchanged due to battery depletion, there is an opportunity to review the indication and appropriateness of the device in relation to the patient's current clinical status, prognosis, and wishes. Discussion with the patient and, if appropriate, their family is important to achieve shared clinical decision making.[1,80,99]

When considering replacement of a primary prevention ICD with no history of relevant ventricular arrhythmias, the patient's prognosis, original indication for the ICD, and current LV function should be considered. There are data suggesting that our current significant dependence on LV ejection fraction for assessing risk has limitations.[100,101] Patients who receive an ICD for primary prevention and subsequently have a significant improvement in ejection fraction experience reduced mortality and appropriate ICD therapies, but not complete freedom from significant ventricular arrhythmias.[100–103] If there have been no ventricular arrhythmias and the ventricular function has significantly improved or if the patient has a prognosis of less than 1 year or has developed significant comorbidities, it might be appropriate to not replace the ICD generator or, for pacemaker-dependent patients, replace the ICD with a pacemaker.[100–103] For patients with an ICD that also provides cardiac resynchronization therapy (CRT-D) and who have severe, intractable symptomatic heart failure with no prospect of transplantation or a ventricular assist device, it might be appropriate to downgrade the device from CRT-D to a device that provides cardiac resynchronization therapy without ICD capabilities (CRT-P).

When changing from an ICD to a pacemaker, the issue of lead compatibility should be carefully considered before the operation. The ICD lead connector should be identified as DF-1 or DF-4. For a CRT device, the terminal connector of the LV lead should be identified. With a DF-1 ICD lead, the ICD coil terminal pins can be capped, and the IS-1 pace-sense terminal pin connected to a replacement pacemaker. There is currently no DF-4 to IS-1 connector for a DF-4 lead. Alternatives are to implant a new IS-1 pace-sense lead, use the DF-4 lead in the left ventricle port with a CRT-P device, or replace with a DF-4 ICD generator with the shock function disabled. Given that the device is being downgraded because of the patient's condition, it might be reasonable to avoid a new lead implant, particularly if the venous system is occluded. In these cases, replacing with a new ICD (with shock function disabled) might be simpler, safer, and possibly cheaper overall, even though the device cost will be higher.

In general, a pacemaker should be replaced with a similar generator. However, for patients with a dual-chamber device, who have developed permanent atrial fibrillation, the alternatives when replacing the generator due to battery depletion are to implant a single-chamber device and cap the atrial lead (which can affect access to MRI) or to implant a new dual-chamber device programmed to a ventricular pacing mode (which might be more expensive but could have a larger battery with a longer interval until the next generator change).

7.4 Nonfunctional and Abandoned Leads

With older ICD lead models, failure is increasingly common over time, with reported failure rates of 7%–16% at 8–10 years.[8,104] Implantation of a new lead might be indicated, particularly if, at the moment when the generator is exchanged, the existing indwelling lead has not failed if the risk of future failure of that lead outweighs the risks of a new lead implant. The clinician should also consider the patient's age, physical and mental condition, prognosis, and wishes. If a lead does fail, is replaced for some other reason, or becomes nonfunctional, a decision needs to be made as to whether the lead should be removed or remain in situ, weighing the risks and benefits of each strategy.

The risks of removal include venous or cardiac perforation requiring emergency surgery and depends on multiple factors, including the lead implant technique, duration of the lead implant, the number and types of lead (ICD vs pacing), the patient's age and health, the presence of prior sternotomy, and the experience of the operator and that of their team.[1] Nomograms to estimate the risk of removal have been developed, and the factors that affect the extraction risk are detailed in Section 10.[105] The benefits of removal include removal of unnecessary hardware that might be harder to remove in the future for a mandatory extraction indication such as infection ("a lead will never be easier to extract than it is today"), preservation of access to MRI, and creation of an access channel through an occluded vein to allow a lead to be implanted.

The risks of abandonment include inability to implant a new lead due to lack of venous access, lead-lead interaction, tricuspid valve damage, and traditionally contraindication to MRI.[1] An experimental study reported excessive heating of an abandoned lead with MRI, although preliminary clinical studies have reported no adverse effects associated with MRI and abandoned leads or remnants.[106–110] Interactions between an abandoned lead and a functional lead rarely cause oversensing, although leads can rub together causing an insulation break. The incidence of tricuspid insufficiency can increase with more than one transvalvular lead.[111] The mechanical consequences of extruded cables in Riata leads is unknown. The major benefits of abandonment are the prevention of risks from removal and that of a simpler procedure, which can be performed by an operator who is not trained in extraction in an environment that is not set up for extraction.

Both present and potential future vascular access issues could affect the decision as to whether to abandon a lead or extract. Venous stenosis and obstruction due to leads is generally asymptomatic because it occurs gradually and collaterals develop, although severely limiting symptoms due to obstruction of the superior vena cava (SVC) or the large central veins do occur and are difficult to resolve. Venous obstruction to any degree has been found in 25% of patients at their first ICD generator replacement, with complete occlusion in 9%.[112] There is an association between the number of leads and the sum of their diameters in contributing toward venous stenosis.[113] However, no study has directly linked abandoned leads to venous thrombosis. The maximum number of leads that can be implanted in a vein with an acceptably low risk of complications is controversial. In a recent survey, European electrophysiologists had a wide variety of responses to the question of how many leads could be implanted in a vein, depending on the patient's age, with 3 to 4 leads considered reasonable in the SVC of a younger patient and up to 5 in the SVC of an older patient, with as many as 3 to 4 leads implanted in the subclavian vein.[114]

Single-center studies have reported their experience with abandoning leads and have found either a low rate of complications for abandoned leads or no difference in outcomes between abandoning and extracting.[69,70,113,115,116] Several authors have addressed this controversy, and surveys of pediatric electrophysiologists and European extraction centers have shown a wide divergence of opinion.[117,118] A recent analysis of the NCDR linked to the Medicare database using propensity matching found a higher in-hospital complication rate with lead explantation when compared with lead abandonment, with no significant differences in mortality detected at 1 year.[71] The decision on whether to abandon or extract a lead is complex, and some of the nuances that should be considered in individual patient care are highlighted in Table 2. Some of the most important clinical considerations affecting the decision are the patient's age, projected longevity and comorbid conditions, the number of leads currently implanted, the leads' physical characteristics, the battery status, and the strength of the indication for surgical intervention.

8. Indications for Lead Extraction (Infectious)

8.1 Cardiovascular Implantable Electronic Device Infection Recommendations

I	C-LD	**If antibiotics are going to be prescribed, drawing at least 2 sets of blood cultures before starting antibiotic therapy is recommended for all patients with suspected CIED infection to improve the precision and minimize the duration of antibiotic therapy.**	**119**
Microbial growth can be suppressed by antibiotics and can mislead or mask CIED-related bloodstream infection. Early identification of the pathogen will guide appropriate selection and duration of antimicrobial therapy. Blood culture should include two sets of aerobic and anaerobic bacterial cultures. Multiple positive blood cultures might be needed to distinguish bloodstream infection versus contamination in cases of infection due to skin flora, in particular, coagulase-negative staphylococci.[119]			
I	C-LD	**Gram stain and culture of generator pocket tissue and the explanted lead(s) are recommended at the time of CIED removal to improve the precision and**	**120**

		minimize the duration of antibiotic therapy.	
Collecting device pocket tissue for Gram stain and culture at the time of device removal is useful for identifying the causative organism. The sensitivity of tissue culture (69%) is higher than that of the swab culture (31%) of the pocket.[120] The entire explanted leads or lead tips should also be sent for culture, although lead contamination can occur when leads are extracted through the generator pocket. Pathogen-guided therapy enhances antimicrobial drug selection by targeting the causal microbe, guiding appropriate treatment duration to minimize recurrent infection, and identifying potential drug resistance.			
I	B-NR	**Preprocedural transesophageal echocardiography (TEE) is recommended for patients with suspected systemic CIED infection to evaluate the absence or size, character, and potential embolic risk of identified vegetations.**	**121–125**
TEE is a useful imaging modality for establishing the diagnosis of CIED-related endocarditis and/or lead infection. The sensitivity of TEE for endocarditis and perivalvular extension of infection is superior to that of transthoracic echocardiography (TTE). The sensitivity of TTE for detecting endocarditis was only 32%, and the specificity was 100% when compared with TEE.[121] TEE benefits include the confirmation of native or prosthetic valve endocarditis and identifying the presence and the size of vegetation(s) on the valve or lead(s), valvular malfunction, and perivalvular abscess. This information can help guide antibiotic therapy and provide additional information on the risk of CIED removal.[122–125]			
I	C-EO	**Evaluation by physicians with specific expertise in CIED infection and lead extraction is recommended for patients with documented CIED infection**.	
When the diagnosis of CIED infection is documented, consulting physicians who have the expertise in CIED infection, including infectious disease specialists, cardiologists, and surgeons who specialize in managing device-related infection and/or performing lead extraction is beneficial. Delayed, inappropriate, or incomplete therapy can result in significant morbidity and mortality for patients with CIED infection.			
IIa	B-NR	**TEE can be useful for patients with CIED pocket infection with and without positive blood cultures to evaluate the absence or size, character, and potential embolic risk of identified vegetations.**	**126**
Device pocket infection might or might not be accompanied by bloodstream infection. In one study, intravascular lead involvement was present in 88% of patients presenting with pocket infection despite lack of symptoms of systemic infection.[126]			
IIa	C-EO	**Evaluation by physicians with specific expertise in CIED infection and lead extraction can be useful for patients with suspected CIED infection.**	
When CIED infection is suspected, consulting physicians who have expertise in CIED infection (including infectious disease specialists, cardiologists, and surgeons who			

specialize in managing device-related infection and/or performing lead extraction) can be useful for facilitating the diagnosis and further management.			
IIb	C-LD	**Additional imaging may be considered to facilitate the diagnosis of CIED pocket or lead infection when it cannot be confirmed by other methods.**	**127–132**
18-Fluorodeoxyglucose (^{18}F-FDG) positron emission tomography (PET)/computed tomography (CT) scanning might provide helpful evidence when diagnosis of CIED pocket or lead infection is doubtful.[127–129] One study showed that PET/CT had a high sensitivity of 87% and a specificity of 100% for device pocket infection but a low sensitivity of 31% and a specificity of 62% for endocarditis.[130] In another single-center, prospective, controlled study of 86 patients, patients with suspected generator pocket infection requiring CIED extraction had significantly higher ^{18}F-FDG activity (4.80 [3.18–7.05]) compared with those who did not have the infection (1.40 [0.88–1.73]) and compared with controls (1.10 [0.98–1.40]).[131] The diagnostic performance of ^{99m}Tc-hexamethypropylene amine oxime–labeled autologous white blood cell (^{99m}Tc-HMPAO-WBC) scintigraphy had a sensitivity of 94% for both detection and localization of CIED-associated infection.[132]			

With the increase in CIED clinical applications for bradycardia, tachyarrhythmia, and heart failure, CIED infection has become increasingly prevalent in cardiac disease management.[133–140] Among Medicare beneficiaries, the prevalence of cardiac device infections increased from 0.94 to 2.11 per 1000 beneficiaries between 1990 and 1999, a 124% increase during the study period.[133] Similarly, in a community-based study of Olmsted County, Minnesota, from 1975 to 2004, the incidence (defined as the probability of occurrence of a given medical condition in a population within a specified period of time) of CIED infection was 1.9 per 1000 device-years, with an incidence of pocket infection alone of 1.37 per 1000 device-years and an incidence of pocket infection with blood stream infection of 1.14 per 1000 device-years.[134] The probability of CIED infections was higher among patients with ICDs than among those with pacemakers.[135] Using the National (Nationwide) Inpatient Sample (NIS) discharge records from the United States, Greenspon et al reported that during the study period between 1993 and 2008, the incidence of CIED infection was 1.61%. The annual rate of infections remained constant until 2004, when a marked increase was observed, coinciding with an increase in the incidence of major comorbidities in patients undergoing CIED procedures.[139] Furthermore, another report from the same data source indicated an increase in lead extraction for CIED infection from nearly 30% in 2006 to 50% in 2012, while lead extraction for non-CIED infection decreased from approximately 70% to 50% in the same period of time.[140] Developing effective means for preventing device infection and early diagnosis are therefore important in reducing the mortality, morbidity, and medical cost related to CIED infection.

8.1.1 Diagnosis

8.1.1.1 Definitions of Cardiovascular Implantable Electronic Device–Related Infection

A correct definition for CIED-related infections will guide diagnosis and appropriate management. CIED-related infections can be categorized as follows[141,142]:

- Isolated generator pocket infection: localized erythema, swelling, pain, tenderness, warmth, or drainage with negative blood cultures
- Isolated pocket erosion: device and/or lead(s) are through the skin, with exposure of the generator or leads, with or without local signs of infection
- Bacteremia: positive blood cultures with or without systemic infection symptoms and signs
- Pocket site infection with bacteremia: local infection signs and positive blood cultures
- Lead infection: lead vegetation and positive blood cultures
- Pocket site infection with lead/valvular endocarditis: local signs and positive blood cultures and lead or valvular vegetation(s)
- CIED endocarditis without pocket infection: positive blood cultures and lead or valvular vegetation(s)
- Occult bacteremia with probable CIED infection: absence of alternative source, resolves after CIED extraction
- Situations in which CIED infection is not certain: impending exteriorization, isolated left heart valvular endocarditis in a patient with a CIED
- Superficial incisional infection: involves only skin and subcutaneous tissue of the incision, not to the deep soft tissues (eg, fascia and/or muscle) of the incision

A general algorithm outlining the steps for diagnosis of CIED infection and management is shown in Figure 2.

8.1.1.2 Clinical Presentation

The device pocket can become infected at the time of implantation, at replacement, or during subsequent surgical manipulation of the pocket. A pocket infection, either as the primary source or secondary source disseminated from bloodstream infection, manifests with local inflammatory changes, which can include pocket erythema (41%), swelling (38%), pain and tenderness (28%), warmth (18%), drainage (38%), and device exposure (21%).[143]

Device cutaneous erosion can occur through fat necrosis and migration from the deep layers through the skin. Usually this occurs at a time remote from the CIED procedure, proceeding slowly through progressive migration and loss of tissue from outward pressure of the generator. In some cases, when the pocket is not closed appropriately due to loose sutures or large gaps between the sutures, the incision can become dehisced. Once the implanted device is exposed, it is considered to be infected, because it is in direct contact or communication with the skin and local bacterial pathogens.[144]

Initial signs of erythema, tenderness, and swelling after a CIED procedure can represent a superficial infection or a true pocket infection (Figure 3). Pocket infection can track along the intravascular portion of the lead to involve the intravascular and intracardiac portion of the CIED.[144] Therefore, patients might present with systemic symptoms, such as fever, chills, malaise, fatigue, or anorexia, similarly to those patients who present with primary bloodstream infection. However, some patients with CIED lead vegetations do not have systemic signs and symptoms. Although early CIED infection, defined as less than 6 months, was more likely to present with pocket infection, while late CIED infection was more attributable to bacteremia and/or endocarditis, the timing of the infection after CIED placement alone does not reliably suggest whether an infection is localized or systemic.[145]

Patients can present with primary bloodstream infection (bacteremia, lead infection, or endocarditis) with or without generator pocket involvement (Figure 4). In such circumstances, systemic symptoms are often prominent. The severity and onset of symptoms and physical signs are related to microbial and host factors. Staphylococcal species are responsible for 60%–80% of CIED infections.[120,126,146] *Staphylococcus aureus* is a notably virulent bacterium accounting for 25% of CIED infections, which often result in acute onset of fever and rigors. Coagulase-negative staphylococcus is the most common cause of device pocket-related infection but is less virulent and has fewer systemic symptoms.[147,148] Staphylococcal pathogens can be resistant to antimicrobial therapy and the host defense system because they form a protective biofilm.[148,149] A biofilm is defined as a device surface-associated community of 1 or more microbial species that are layered together by the product of polysaccharide intercellular adhesion, firmly attached to one another, and encased in an extracellular polymeric matrix that holds the biofilm together. Biofilm prevents the eradication of CIED infection by antibiotics alone without device system removal. Nonstaphylococcal CIED-related infections are prevalent and diverse, with a relatively low virulence and mortality rate.[150] Among 30 patients who presented with Gram-positive nonstaphylococcal bacteremia—most commonly the enterococcus species, viridans group streptococci, and *Streptococcus pneumoniae*—6 had confirmed CIED site infection. The remaining 24 patients underwent antibiotic therapy only, 2 of whom ultimately required CIED extraction for persistent bacteremia.[122] Less than 10% of CIED infections are caused by Gram-negative bacilli, such as *Klebsiella pneumonia* and *Serratia marcescens*.[146] CIED fungal infection is uncommon, identified in only 2% of 189 documented CIED infections.[146] Gram-negative bacteremia uncommonly results in secondary seeding of the device. Empirical and broad antimicrobial coverage against Gram-positive and Gram-negative bacteria is recommended until the infecting pathogen is identified.[151]

The S-ICD involves no hardware exposure to the intravascular system, which is the unique innovative feature of this technology. Pocket infection and erosion rates were 1.7% and 1.2%, respectively.[152,153] Device pocket infection requiring surgical intervention is the most common infectious complication for S-ICD, and no systemic infection case has been identified from the EFFORTLESS registry.[153]

8.1.1.3 Blood and Device Pocket Culture

At least 2 sets of blood culture should be obtained before starting antimicrobial therapy in patients with suspected CIED infection. Microbial growth can be suppressed by antibiotics, which can mislead or mask the clinical diagnosis of device infection. Blood cultures should include both aerobic and anaerobic bacterial cultures. Patients with bloodstream infection might manifest systemic leukocytosis.

Device pocket swabs for Gram stain/culture and tissue culture at the time of device removal are useful in identifying the causative organism and to support a diagnosis of CIED infection. The sensitivity of tissue culture (69%) is higher than that of the swab culture (31%) of the pocket.[120] A connector culture provides a more than 90%

positive yield.[154] If the Gram stain is negative, a tissue culture should be sent for mycobacteria and fungal stains. The entire lead or lead tip should also be sent for culture, although lead contamination might occur when leads are extracted through the generator pocket. Use of the vortexing-sonication technique increases culture sensitivity and enhances microbial detection.[155] When a CIED infection is suspected, performing percutaneous pocket aspiration should be carefully considered because the diagnostic yield is low and there is the potential risk of introducing microorganisms into the pocket, thereby causing infection.[156]

8.1.1.4 Imaging Diagnosis

TEE is a useful imaging modality in establishing the diagnosis of CIED-related endocarditis and/or lead infection. The sensitivity of TEE for endocarditis and perivalvular extension of infection is superior to that of transthoracic echocardiography. Fowler et al reported that the sensitivity of TTE for detecting endocarditis was only 32%, and the specificity was 100% when compared with TEE. The addition of TEE resulted in one false-positive result (specificity 99%).[121] TEE is critically important for patients with *Staphylococcus aureus* bacteremia, because the rate of lead-associated endocarditis is substantial. TEE should be considered for all patients who have documented or suspected bloodstream infection or CIED pocket infection. Device pocket infection often demonstrates evidence of intravascular lead involvement in 88% of patients presenting with pocket infection and might not always be associated with systemic infection symptoms.[126] TEE is helpful in assessing unrecognized bloodstream infection. The benefits of TEE include confirmation of systemic involvement of CIED infection (endocarditis, vegetation on the valve or lead(s), valvular malfunction, perivalvular abscess), guidance of reimplantation timing strategy, antibiotic therapy duration, and extraction approach, such as in the presence or absence of patent foramen ovale, tricuspid valve regurgitation or lead impingement, and the size and shape of lead vegetation(s).[122–124]

When the diagnosis of CIED pocket or lead infection is doubtful, ^{18}F-FDG PET/CT scanning might provide helpful evidence. One prospective study showed PET/CT had a high sensitivity of 87% and a specificity of 100% for device pocket infection but a low sensitivity of 31% and a specificity of 62% for endocarditis.[130] In another single-center, prospective, controlled study of 86 patients, patients with suspected generator pocket infection requiring CIED extraction had significantly higher ^{18}F-FDG activity (4.80 [3.18–7.05]) compared with those who did not have the infection (1.40 [0.88–1.73]) and compared with the controls (1.10 [0.98–1.40]).[131] These findings have been supported by other authors.[127,128] Furthermore, PET/CT imaging can disclose undiagnosed alternate sources of infection, such as occult spondylodiscitis.[127] The diagnostic performance of ^{99m}Tc-HMPAO-WBC scintigraphy had a sensitivity of 94% for both detection and localization of CIED-associated infection.[132]

8.1.2 Predictors for Cardiovascular Implantable Electronic Device Infection and Prognosis

Device-related infection is the result of the interaction between the device, the microbe, and the host (Table 3).[156]

8.1.2.1 Patient Risk Factors

Older age and concomitant comorbidities are associated with CIED infections. Approximately 70% of device recipients are 65 years of age or older, and more than 75% had 1 or more coexisting medical conditions in a community-based study.[157,158] Data from the community-based practice and NCDR have consistently shown that patients older than 60 years of age receive ICDs more often than young patients (70% vs 30%).[159] Increased implantation in older patients with increased comorbidities has set the stage for higher rates of CIED infection. In the REPLACE registry, a higher Charlson Comorbidity Index predicted the risk of infection (2.79 vs 2.32 [95% CI 0.08–0.86]; P=.019).[160] A meta-analysis of 180,004 patients from 60 prospective and retrospective studies concluded that the significant host-related risk factors for infection included diabetes mellitus (odds ratio [OR] 2.08 [95% CI 1.62–2.67]), end-stage renal disease (OR 8.73 [95% CI 3.42–22.31]), chronic obstructive pulmonary disease (OR 2.95 [95% CI 1.78–4.90]), corticosteroid use (OR 3.44 [95% CI 1.62–7.32]), history of previous device infection (OR 7.84 [95% CI 1.94–31.60]), renal insufficiency (OR 3.02 [95% CI 1.38–6.64]), malignancy (OR 2.23 [95% CI 1.26–3.95]), heart failure (OR 1.65 [95% CI 1.14–2.39]), preprocedural fever (OR 4.27 [95% CI 1.13–16.12]), anticoagulant drug use (OR 1.59 [95% CI 1.01–2.48]), and skin disorders (OR 2.46 [95% CI 1.04–5.80]).[161] Other studies have reported similar findings.[14] Once CIED infection is diagnosed, women have a higher risk of death than men.[162,163]

Chronic renal disease is very common in patients with an existing CIED. Among a series of 503 patients who underwent lead exaction, predominantly for CIED infection, 54% had class III-V chronic renal disease.[164] In a study group of 1440 patients, Tompkins et al found the CIED infection rate to be 12.5% in patients with end-stage renal disease, which was significantly higher than the rate of 0.2% in patients without end-stage renal disease.[165] An analysis from the United States Renal Data System, which included 546,769 patients with end-stage renal disease, showed that 6.4% of this study cohort had CIEDs in place and 8.0% of those with CIEDs developed CIED infection. Notably, only 28.4% of infected CIEDs were removed. Patients with end-stage renal disease and infected CIEDs had a poor prognosis. Although the rate of device extraction was low, this strategy appears to be associated with a modest improvement in survival.[166]

8.1.2.2 Procedure-Related Factors

Apart from the host-related factors, the procedure itself and related complications are also strongly associated with the risk of CIED infection. Reopening the pocket, including generator change, CIED upgrade, and lead or pocket revision or manipulation increases the opportunity of introducing bacteria into the pocket. In a meta-analysis, the following procedure-related factors were identified: postoperative hematoma (OR 8.46 [95% CI 4.01–17.86]), reintervention for lead dislodgement (OR 6.37 [95% CI 2.93–13.82]), device replacement/revision (OR 1.98 [95% CI 1.46–2.70]), temporary pacing (OR 2.31 [95% CI 1.36–3.92]), operator inexperience (defined as <100 prior CIED procedures) (OR 2.85 [95% CI 1.23–6.58]), and procedure duration (weighted mean difference 9.89 [95% CI 0.52–19.25]).[161] In the REPLACE registry, all 1774 patients received preoperative intravenous (IV) antibiotics before the CIED generator change, and 68.7% received postoperative antibiotics. CIED infection developed in 22 patients (1.3%), and patients with infections were more likely to have had postoperative hematomas (5 of 22 [22.7%] vs 17 of 1722 [0.98%]; *P*=.002).[160]

8.1.2.3 Microbes

Prospective surveillance microbiology and genetic analysis have shown the surprising finding that positive bacterial DNA can be identified in 23% of device pockets, on 29.5% of device surfaces, and in both locations in 14%. Despite the common nature of pocket colonization, only a subset develop clinical infection.[163] *Staphylococcus aureus* and coagulase-negative staphylococcus are the most common and virulent causes of CIED infection within and beyond 1 year of CIED implant.[167,168] As compared with coagulase-negative staphylococcus, *Staphylococcus aureus* has a longer bacteremia duration of more than 3 days, longer hospital stay, and increased mortality (25% vs 9.5%).[147] Nonstaphylococcal CIED infection has relatively low virulence and has lower mortality than that of staphylococcus.[151]

8.2 Management Recommendations

I	B-NR	**A complete course of antibiotics based on identification and in vitro susceptibility testing results after CIED removal is recommended for all patients with definite CIED system infection.**	**1,143,156, 169–171**
A complete course of antibiotics is recommended to treat device pocket and/or bloodstream infection and/or valvular endocarditis.[1,143,156,169–171] After device and lead removal, antibiotics are more effective for eradicating the infection. Selection of the appropriate antimicrobial agent should be based on identification and in vitro susceptibility testing results. Patients with infections due to oxacillin-susceptible staphylococcal strains can be administered cefazolin or nafcillin. Vancomycin should be administered to patients with infection due to oxacillin-resistant staphylococci. Although there are no clinical trials that have tested the minimum duration of antibiotic therapy, in general, a 2-week antibiotic therapy after lead extraction is recommended for CIED pocket infection and 10 days for pocket erosion.[156] For patients with bloodstream infection without valvular involvement, a minimum 2-week course of antimicrobial therapy is recommended after extraction of the infected CIED. Antimicrobial therapy should be at least 4–6 weeks for complicated infection including endocarditis. The duration of antimicrobial therapy should be calculated from the day of completion of the lead extraction or negative blood cultures (whichever occurred last).			
I	B-NR	**Complete device and lead removal is recommended for all patients with definite CIED system infection.**	**172–174**
Early diagnosis of CIED infection and performing lead extraction within 3 days of diagnosis is associated with lower in-hospital mortality.[172] A multivariate analysis found a 7-fold increase in 30-day mortality if the CIED was not removed. Although CIED removal resulted in fatal complications, the mortality associated with a delay in removal was even higher.[173] Therefore, CIED-associated infections are the strongest indication for complete CIED system removal and should not be delayed, regardless of the timing of the start of antimicrobial therapy.[1,174]			

I	C-EO	**Complete removal of epicardial leads and patches is recommended for all patients with confirmed infected fluid (purulence) surrounding the intrathoracic portion of the lead.**	
Infection can occur in patients with surgical epicardial leads and/or patches that are connected to a pectoral or abdominal generator. Complete removal of infected portions of epicardial leads and patches is recommended to eradicate the infection after weighing the risk of surgery and mortality from infection.[175]			
I	B-NR	**Complete device and lead removal is recommended for all patients with valvular endocarditis without definite involvement of the lead(s) and/or device.**	**156,172**
Complete CIED removal should be performed when patients undergo valve replacement or repair for infective endocarditis, because the CIED could serve as a nidus for relapsing infection and subsequent seeding of the surgically treated heart valve.[156] A recent study has shown that complete CIED removal appears curative for patients with CIED infection in the presence of prosthetic heart valves and thus might prevent repeat valve surgery.[172]			
I	B-NR	**Complete device and lead removal is recommended for patients with persistent or recurrent bacteremia or fungemia, despite appropriate antibiotic therapy and no other identifiable source for relapse or continued infection.**	**156,168**
Persistent or relapsing bacteremia or fungemia after a course of appropriate antibiotic therapy when there is no other identified source for bacteremia or fungemia suggests CIED and lead infection. In this scenario, the retained intravascular lead(s) are very likely to be the source of infection. Complete removal of hardware is recommended to eradicate the infection.[156,168]			
I	C-EO	**Careful consideration of the implications of other implanted devices and hardware is recommended when deciding on the appropriateness of CIED removal and for planning treatment strategy and goals.**	
Patients who have received a CIED might have other implanted devices and hardware. For example, left ventricular assist device (LVAD) recipients often have a CIED in place (up to 87%). In a large series of 247 LVAD patients, 2.8% had CIED infection. Patients with an LVAD and CIED infection should undergo CIED removal to eliminate a potential source of microbial seeding and infection. Chronic suppressive antibiotic therapy is warranted in concomitant LVAD infection.[176]			

8.2.1 Antimicrobial Therapy

For patients who present with bacteremia, a broad empiric antimicrobial therapy to cover both Gram-positive and Gram-negative microbes is recommended until the causative organism is identified.[151,177] Ninety-seven percent or more of patients who present with either pocket infection or endocarditis can be cured after combined lead extraction and antibiotics therapy.[143,169–171]

A complete course of antibiotics is recommended to treat the device pocket and/or bloodstream infection and valvular endocarditis.[156,171] After the device and lead removal, antibiotics are more effective in eradicating the infection. Selection of the appropriate antimicrobial agent should be based on identification and in vitro susceptibility testing results. Given that staphylococci are the most common microbe and nearly half of these are methicillin resistant, vancomycin should be administered initially as an empirical antibiotic coverage until the microbiological etiology is identified.[143] Patients with infections due to oxacillin-susceptible staphylococcal strains can be administered cefazolin or nafcillin, with discontinuation of vancomycin. Vancomycin should be continued in patients with infection due to oxacillin-resistant staphylococci. Although no clinical trials have tested the minimal duration of antibiotic therapy, in general, a 2-week antibiotic therapy after lead extraction is recommended for CIED pocket infection, and 10 days is recommended for pocket erosion.[156] For patients with bloodstream infection without valvular involvement, a minimum of 2 weeks of parenteral antimicrobial therapy is recommended after extraction of the infected CIED. The duration of antimicrobial therapy should be at least 4–6 weeks for complicated infection, including endocarditis, septic thrombophlebitis, osteomyelitis, and persistent bacteremia, despite device removal and appropriate initial antimicrobial therapy; the duration of antimicrobial therapy should be calculated from the day of lead extraction or negative blood cultures (whichever occurred last). In particular, patients with staphylococcal bacteremia need repeated blood cultures to document the clearance of infection.

Under certain circumstances, long-term antimicrobial suppressive therapy and local wound care strategies are used as a palliative therapy in selected patients with CIED infection who are excessively high-risk candidates for device removal.[178] These patients usually have a stable cardiovascular status, clinical improvement with initial antimicrobial therapy, and clearance of bloodstream infection. The choice of antimicrobial therapy and its dosing are empirical, given the limited available study results. The long-term outcome of this approach is unknown, and this approach is only considered when conventional management is contraindicated or is less favorable to an individual patient who has a high risk for CIED extraction, such as a high likelihood of requiring surgical extraction, inability to reimplant, loss of CRT, ongoing risk of reinfection due to other sources of infection that cannot be eradicated, or a life expectancy shorter than a year. Long-term antimicrobial suppression therapy is a palliative approach, which should be the last option compared with the recommended curative lead extraction approach.

8.2.2 Cardiovascular Implantable Electronic Device Extraction

Early diagnosis of CIED infection, including pocket abscess, erosion, bacteremia, lead vegetation, and endocarditis, and performing lead extraction within 3 days of diagnosis are associated with lower in-hospital mortality.[172] In a large CIED infection cohort, the 30-day mortality rate was 5.5%, and 1-year mortality was 14.6%. A multivariate analysis indicated a 7-fold increase in 30-day mortality if the CIED was not removed. Although CIED removal resulted in fatal complications, the mortality associated with delayed removal was significantly higher.[173] Therefore, CIED-associated infections are the strongest indication for complete CIED system removal and should not be delayed, regardless of the timing of the start of antimicrobial therapy. Furthermore, infection relapse could occur due to retained hardware.[1,174]

Erosion of any part of the CIED indicates contamination of the entire system, and complete device removal should be performed. Complete CIED removal should be performed when patients undergo valve replacement or repair for infective endocarditis, because the CIED could serve as a nidus for relapsing infection and subsequent seeding of the surgically treated heart valve. A recent study showed that complete CIED removal appears curative for patients with CIED infection in the presence of prosthetic heart valves and can spare valve surgery.[170]

Infection can occur in patients with surgical epicardial leads and/or patches that are connected to a pectoral or abdominal generator. Complete removal of infected epicardial leads and patches is recommended to eradicate the infection after balancing the risk of surgery and mortality from infection.[175] However, in patients with epicardial leads and patches and a localized pocket infection, a separate incision away from the pocket where the epicardial leads or patches enter the thoracic cavity can be used to access and cut the lead(s). The proximal portion of the epicardial lead or patch can be removed from the infected pocket.

Up to 87% of LVAD recipients have a CIED. In a large series of 247 patients with an LVAD, 2.8% developed a CIED infection. Patients with LVADs and CIED infection should be considered for CIED removal. Chronic suppressive antibiotic therapy might be required for patients with concomitant LVAD infection.[176]

Generally, a single positive blood culture with no other clinical evidence of infection should not result in removal of the CIED system. However, *Staphylococcus aureus* should always be considered a pathogen, and evaluation for a likely source should be undertaken. Superficial or incisional infection without device involvement is not an indication for CIED removal. Superficial incisional infection involves only skin and the subcutaneous tissue of the incision, not penetrating to the deep soft tissues (eg, fascia and/or muscle) of the incision, and does not present late after a CIED intervention. Patients with superficial incisional infection or hematoma can present early after CIED intervention with signs of inflammation, such as pain, tenderness, erythema, and local warmth. The patient should be closely followed for progression to a deeper infection, which would require extraction. Seven to 10 days of oral antibiotic therapy with activity against staphylococci is reasonable.[156]

8.2.3 Post Lead Extraction Wound Care

After removal of infected leads and generator, a thorough debridement of the device pocket is necessary to remove all infected and fibrotic tissue, including the entire capsule. The wound should be irrigated using sterile normal saline solution to remove small debris. There are several strategies that can be employed for postextraction wound management, including primary closure with or without the use of a drain, or staged closure using a drain or wound vacuum.

8.2.4 New Device Implantation

Reassessment of the need for a new CIED is imperative after removal of an infected CIED. Some patients might have had interval improvement in rhythm or cardiac function and no longer meet a guideline indication for permanent pacemaker, ICD, or CRT, or a patient might not wish to receive a new device. The optimal timing of device replacement is unknown. There are no prospective trial data on the timing of new device replacement and risk of relapsing infection. A new implantation can reasonably be postponed until blood cultures are negative for 72 hours, although implantation should be delayed if the patient has another undrained source of infection, such as a psoas abscess.[1,146,156] Replacement device implantation should be performed in an alternative location such as the contralateral side, the iliac vein, or using epicardial or subcutaneous implantation. Single-center studies have suggested that same-day implantation is feasible for patients with isolated pocket infections and is not associated with adverse outcomes.[1] Figure 2 shows an algorithm of diagnosis, management, and CIED reimplantation for suspected CIED infection.

For pacemaker-dependent patients, temporary pacing is required as a bridge to reimplanting a new permanent device. Epicardial pacing is an option but has been associated with higher mortality.[171] A commonly adopted alternative is temporary pacing using a screw-in pacing lead connected to an external re-used can, sometimes called "semi-permanent" pacing.[179,180] This approach allows patients to safely await implantation of a new device for the recommended 72 hours to 14 days, depending on clinical status. For ICD patients with a high risk of short-term, sudden cardiac death, the wearable defibrillator (LifeVest, Zoll) is an option as a bridge to reimplantation.

8.3 Prevention

Performing an evaluation before implanting the device is important to ensure that patients do not have clinical signs of infection. The implantation should be postponed if signs of infection are present. Observational studies have consistently found that perioperative systemic antibiotics delivered 1 hour before the procedure significantly reduced the incidence of device infection compared with no antibiotics, with a relative risk reduction of 40%–95%.[161,181] In a double-blind, randomized, prophylactic antibiotics versus placebo study of 1000 patients who presented for primary device implantation or generator replacement, the safety committee interrupted the trial after 649 patients were enrolled due to a significant difference in favor of the antibiotic arm (infection rate, 0.63%) compared with the placebo group (3.28%; relative risk 0.19; P=.016).[182] In addition to surgical area sterilization and antiseptic preparation of the skin at the surgical site, systemic antibiotic use is a standard therapy and should be administered before the surgical incision is performed. A first-generation cephalosporin, such as cefazolin (within 1 hour before the incision) or vancomycin (within 2 hours before the incision) is commonly administered. Vancomycin or clindamycin are alternatives to a first-generation cephalosporin for patients who are allergic to cephalosporins. Using an antibiotic solution to irrigate the device pocket has not been shown to decrease device pocket infection when compared with saline irrigation.[183] Postoperative antibiotic therapy is not currently recommended, because there are no convincing data to support the administration of postoperative antibiotic therapy. Furthermore, there is a potential risk of adverse drug events and selection of drug-resistant organisms. To determine whether additional measures during or after device implantation would further reduce the risk of

CIED infection, the Prevention of Arrhythmia Device Infection Trial (PADIT) has completed the enrollment of over 12,500 patients who underwent generator change, system upgrade, or new CRT CIED, and is now in the follow-up stage. The study is designed to assess (1) the effect of alternate or additional preoperative antibiotics, especially vancomycin; (2) the role of using intraoperative, wound pocket irrigation (with an antibiotic); and (3) the benefit of postoperative antibiotics.[184] In a randomized, single-center, single-operator study of 1008 patients, povidone iodine ointment, neomycin ointment, and antiseptic pads showed no benefit in preventing CIED infection when compared with placebo.[185] Another new technology using a nonabsorbable antibacterial envelope placed around the device generator has shown a significant reduction in CIED infection from 1.5% to 0.6% in a nonrandomized study when compared with historical controls.[186] The absorbable antibacterial envelope also appears to be associated with a lower incidence of CIED-related pocket infections in high-risk patients.[187] A randomized study is currently underway to provide further evidence for the clinical utility of antibacterial envelope use.[188]

The predominance of staphylococci as pathogens in CIED infection rather than oral flora suggests that antibiotic prophylaxis for dental procedures is of little or no value.[189] Antimicrobial prophylaxis is not recommended for dental or other invasive procedures not directly related to device manipulation to prevent CIED infection.

9. Indications for Lead Extraction (Noninfectious)

Recommendations

		Chronic Pain	
IIa	**C-EO**	**Device and/or lead removal can be useful for patients with severe chronic pain at the device or lead insertion site or believed to be secondary to the device, which causes significant patient discomfort, is not manageable by medical or surgical techniques, and for which there is no acceptable alternative.**	
Chronic pain at the device site or lead insertion site is an infrequent indication for lead extraction.[190,191] The scope of this problem has not been well defined and is likely multifactorial, ranging from indolent infection to musculoskeletal conditions.[120,192–196] An individualized treatment plan is clearly necessary, but removal of the device and lead extraction is reasonable for patients with severe chronic pain in which alternative management strategies are not available or have failed.			
		Thrombosis/vascular issues	
I	C-EO	**Lead removal is recommended for patients with clinically significant thromboembolic events attributable to thrombus on a lead or a lead fragment that cannot be treated by other means.**	
Clinically significant thromboembolic events related to transvenous leads occur infrequently, but have been reported and are of particular concern in patients with intracardiac shunts.[197,198]			
I	**C-EO**	**Lead removal is recommended for patients with SVC stenosis or occlusion that prevents implantation of a necessary lead.**	

Lead-induced venous thrombosis can occur early or late after implantation of a transvenous pacemaker.[199] Thrombosis can cause an occlusion of the SVC, making placement of additional transvenous leads difficult. Under these circumstances, removal of an existing lead is recommended to gain access and allow for placement of the necessary lead.			
I	C-EO	**Lead removal is recommended for patients with planned stent deployment in a vein already containing a transvenous lead, to avoid entrapment of the lead.**	
Percutaneous stent implantation has now become first-line treatment for pacemaker-induced SVC syndrome.[199,200] Existing leads should be removed prior to stent placement, thus preventing entrapment of these leads behind the stent.			
I	C-EO	**Lead removal as part of a comprehensive plan for maintaining patency is recommended for patients with SVC stenosis or occlusion with limiting symptoms.**	
Although lead-related venous thrombosis occurs relatively commonly, the incidence of pacemaker-induced SVC syndrome has been reported to be less than 0.1%.[199,200] However, patients who do become symptomatic might have debilitating symptoms requiring treatment. Lead removal and subsequent stent placement have emerged as the most effective treatment and should be part of the overall treatment strategy.			
IIa	C-LD	**Lead removal can be useful for patients with ipsilateral venous occlusion preventing access to the venous circulation for required placement of an additional lead.**	**201,202**
In the context of a device upgrade or requirement of an additional lead, venous access can become an issue due to venous occlusion of the desired venous access point. Management options include contralateral lead implantation with tunneling across the chest, extraction of a redundant lead, or subclavian venoplasty. An individualized approach should be taken based on operator and center expertise. Use of extraction as a first-line approach to device upgrades for patients with venous occlusion is well described and can be a useful strategy in experienced centers.[201,202]			
		Other	
I	C-EO	**Lead removal is recommended for patients with life-threatening arrhythmias secondary to retained leads.**	
There are reports in the literature of refractory ventricular arrhythmias that occurred after an RV lead placement that resolved with extraction.[203]			
IIa	C-EO	**Lead removal can be useful for patients with a CIED location that interferes with the treatment of a malignancy.**	
CIED relocation is recommended when the CIED is situated in the path of planned radiation beam therapy that would interfere with adequate tumor treatment.[204] There are limited clinical data on CIED relocation options but could include removal or tunneling of existing leads or the use of lead extenders. Radiation exposure to the device itself is, however, not a primary concern and should not prompt a CIED relocation.			
IIa	C-LD	**Lead removal can be useful for patients if a CIED implantation would require more than 4 leads on one side or more than 5 leads through the SVC.**	**113,202,206**
Analysis of extraction registries has reported higher complication rates with extraction when there are large numbers of leads that need to be removed.[202] Studies have reported increased shoulder pain and other complications in patients with higher numbers of leads from the same shoulder.[113,206]			
IIa	**C-EO**	**Lead removal can be useful for patients with an abandoned lead that interferes with the operation of a CIED system.**	

<table>
<tr><td colspan="4">Isolated case reports have described adverse lead-lead interactions that require removal of an abandoned lead.[207,208]</td></tr>
<tr><td>IIb</td><td>C-LD</td><td>Lead removal may be considered for patients with leads that due to their design or their failure pose a potential future threat to the patient if left in place.</td><td>64,66,135,209</td></tr>
<tr><td colspan="4">Sprint Fidelis (Medtronic, Minneapolis, MN) and Riata (Abbott, Sylmar, CA) ICD leads and the Accufix Atrial J Leads (Telectronics) have all had recalls due to concern for early failure or potential for patient harm. There is evidence that extraction of these leads does not pose a higher risk to patients than that of other nonrecalled leads.[64,135] Nonetheless, there is a potential for adverse events, which should always be considered when deciding on an extraction plan.[66] Thus, when there is a safety alert for the lead, there should be an additional clinical indication for opening the pocket when the lead is still functional and does not therefore pose a manifest risk to the patient. This is supported by the experience with the Telectronics Accufix extraction.[209]</td></tr>
<tr><td>IIb</td><td>C-EO</td><td>Lead removal may be considered for patients to facilitate access to MRI.*
*Removal of leads to prevent their abandonment, removal of broken or abandoned leads, or removal of leads to allow implantation of an MRI conditional system</td><td></td></tr>
<tr><td colspan="4">Recommendations for managing CIEDs in the MRI setting have been addressed in a recent consensus document.[204] Substantial evidence has been accumulated to demonstrate that MRI can be safely performed in most magnetic resonance (MR) nonconditional CIED systems without abandoned or epicardial leads; however, discussions regarding the risks and benefits should be held prior to imaging due to the risks, particularly in the setting of pacemaker-dependent patients with an ICD or those with battery voltages near the elective replacement indicator.[210-214]</td></tr>
<tr><td>IIb</td><td>C-EO</td><td>Lead removal may be considered in the setting of normally functioning nonrecalled pacing or defibrillation leads for selected patients after a shared decision-making process.</td><td></td></tr>
<tr><td colspan="4">There are rare clinical situations in which lead removal of a normally functioning lead may be considered after discussion with the patient. For example, lead survival of nonrecalled defibrillator leads in younger patients was 89% at 5 years, characterized by a progressively decreasing survival curve.[27] It is possible that removal and reimplantation of a new defibrillator lead might represent a strategy associated with less long-term risk when compared with generator change.</td></tr>
</table>

Although the indication for lead extraction to clear a cardiac device-related infection is relatively uncontroversial (ie, there is a mortality benefit to removing an infected device), the decision-making process regarding lead extraction for noninfectious indications is frequently less straightforward. Not only are there no randomized data to guide treatment, but it is unclear in many cases whether the risk of extraction would outweigh the benefit of having the lead(s) removed. If the litmus test of whether to offer a medical treatment or procedure is to make a patient feel better or live longer, many of the noninfectious indications below are in a relatively gray zone. For each of the indications listed for noninfected lead extraction, there should be a clinical goal that balances the risk of removal, and reasonable alternatives should be considered (Table 2). The recommendations are also made with the understanding that extraction is performed in conformance with the standards in the 2009 HRS Extraction document and the current document.

9.1 Chronic Pain

Chronic pain at the device site or at the lead insertion site is an infrequent indication for lead extraction, and the scope of this problem has not been well defined. The incidence of chronic pain following a CIED implantation has not been fully established but generally represents about 1%–3% of lead extraction cases.[190,191]

Pain and tenderness at the device site represent a wide range of clinical scenarios, from an underlying infection to possible CIED allergies or musculoskeletal problems. The presentation of a device infection is often variable. It is conceivable that chronic pain at the device site might be a manifestation of an indolent, chronic infection by a slow-growing organism, but the direct relationship between subclinical device infections and chronic pain remains to be elucidated.

CIED contact dermatitis has been well established, with many case reports illustrating a wide spectrum of possible symptoms, ranging from pain and tenderness to dermatological manifestations.[193,194] The diagnosis of CIED contact dermatitis is confirmed with positive skin patch testing of any of the components of the CIED system, together with an absence of proof of infection.

Implantable cardiac defibrillators have been associated with postoperative discomfort and pain.[195] Chronic shoulder pain and disability were described in 131 (54%) patients more than 3 years after ICD implantation.[196] The only predictor of shoulder pain was the number of implanted leads. Another possible cause for musculoskeletal pain at the device site and shoulder region is thoracic outlet syndrome, which can cause pain, numbness, and fatigue of the shoulder and arm due to compression of the brachial plexus and subclavian vessels.

Although these are possible etiologies for chronic pain at the device site and/or lead insertion site, it is important to keep in mind that this clinical scenario can be multifactorial, and a careful and individualized treatment plan is necessary. Removal of the device and lead extraction are reasonable for patients with severe chronic pain after discussion with the patient and when alternative management strategies are not available or have failed to resolve the problem.

9.2 Thrombosis/Vascular Issues

Venous thrombosis after pacemaker or ICD system implantation is a known, although often under-recognized, condition that can challenge system revision and device upgrades, contribute to the development and symptoms from SVC syndrome, and infrequently lead to thromboembolic complications.

In the context of a device upgrade or requirement of an additional lead, venous access could become an issue. Previously placed leads might have caused a venous obstruction, and an assessment of patency is recommended either through venous ultrasound or a chest CT prior to the procedure. A peripheral IV contrast injection can also be performed at the time of the procedure. Knowledge of venous patency prior to the procedure is preferable because this could impact the procedural strategy.

In case of an obstruction/occlusion, options include a contralateral lead implantation with tunneling across the chest, extraction of a redundant lead, and subclavian venoplasty. An individualized approach should be taken based on operator and center expertise. In the case of tunneling, a standard tunneling tool is used, set to cross the sternum subcutaneously. This procedure can be somewhat more difficult in a patient with a previous sternotomy but is essentially always achievable. Although this could be the most straightforward option at the time of the upgrade, there are some drawbacks to keep in mind. Lead(s) are now added without removal of potentially unnecessary leads, with the result that future lead revisions are made more challenging, and venous access is further compromised.

Alternatively, a subclavian venoplasty can be considered. Percutaneous balloon venoplasty is typically applied by interventional radiology in many different clinical scenarios but is less well documented in cardiac device cases. The subclavian venoplasty approach was successful in 371 of 373 patients as reported by Worley et al in 2011.[215] Total angiographic occlusion was demonstrated in 65% of cases by peripheral venogram but in only 20% of cases by contrast injection at the site of obstruction, demonstrating the importance of additional contrast injections at the site of the occlusion to fully assess patency. The authors also reported successful crossing of a hydrophilic wire in 86% of cases, allowing for balloon dilatation of the partially occluded segment and subsequent lead placement. Similar success rates were reported in a smaller, single-center experience of subclavian venoplasty in upgrade cases.[216] The venoplasty approach preserves contralateral venous access and can be performed in an electrophysiology laboratory, provided there is operator and staff expertise and appropriate equipment available. As with the tunneling approach, venoplasty adds to overall lead burden by leaving redundant lead(s) behind and is not applicable in cases of a complete occlusion that cannot be crossed.

Use of lead extraction in cases of unsuccessful wire crossing and complete obstruction has been described, as well as a first-line approach to device upgrades in patients with venous occlusion.[201,202,215,217] Under these circumstances, an existing lead is extracted with specific extraction tools such as laser or a mechanical rotational tool, allowing for venous access through the sheath after the lead has been removed. Lead extraction to regain venous access of an occluded vein preserves the contralateral side for potential future use and minimizes overall lead burden.

SVC occlusion in the setting of well-developed collateral flow might preclude placement of additional, required leads in a patient with existing leads. Under these circumstances, an extraction of an existing lead is one approach to gain access to endocardial tissue. Patients can also present with symptoms related to the SVC obstruction, consistent with SVC syndrome. In a literature review, anticoagulation, thrombolysis, and venoplasty alone were all associated with high recurrence rates. Surgery and stenting were more successful: recurrence rates were 12% and 5% over a median follow-up of 16 (range 2–179) and 9.5 (range 2–60) months, respectively.[199,200] When a stenting strategy is deployed, it is important to keep in mind that all existing transvenous leads will need to be extracted prior to the stent placement to avoid entrapment of leads behind the stent.

CIED-related thromboembolic complications can also occur. Lead-related thrombus is commonly observed in patients with transvenous CIED leads; however, clinical pulmonary embolus appears to occur with a low incidence.[215] The risk clearly increases in patients with intracardiac shunts, as observed in a large retrospective study of patients with transvenous leads who had an increased risk of cardioembolic stroke/transient ischemic attack in the presence of a diagnosed patent foramen ovale.

9.3 Abandoned Leads

It is often possible to abandon a failed or no longer required lead and/or implant the needed leads through the same or alternative implantation route. It is less common for a patient to exhibit symptoms or be at risk of death from the abandonment of noninfected leads. It is therefore harder to calculate the risk-to-benefit ratio of lead extraction in these patients. When this indication is considered, it is crucial to balance the risk of the intervention (including the lead extraction operator's experience) with the patient's situation.[64,70,209] Nonetheless, the presence of an abandoned lead is a common reason for extraction; as many as 38% of all leads extracted were removed for this reason, according to one registry.[27,219] Several other important observations favor earlier lead extraction instead of abandonment. Leads are more difficult to remove when left behind; when removed, the leads are associated with an increased risk of major complications, which progresses as the implantation duration increases. This situation could be of particular relevance in a pediatric population in which there is some evidence that the mortality rate could be lower, albeit with arguably higher stakes.[27,210] It is therefore difficult to anticipate how taking the risk now vs later is best assessed. These extraction risks increase as the interlead fibrosis thickens and covers more of the surface of the lead, especially when there are multiple leads.[70,221] Lead fragility is also proportional to implant duration and increases with the body's chemical and mechanical stresses, reducing the likelihood of complete lead removal.[219] The risks are further increased with even modest calcification of the fibrosis. Therefore, in a 20-year-old patient with complete heart block and 2 failed leads, implanting new leads without extracting the old ones, although feasible, is usually inadvisable. Alternatively, in a 90-year-old patient with 1 failed lead or an occluded vessel precluding the reuse of the ipsilateral subclavian vein, it might be more reasonable to consider that failure to remove the lead would never become a clinical issue for the patient. It is also important to consider how long the lead had been implanted, the fragility or tensile robustness of each particular lead, and the ease or difficulty of extracting the particular lead model. These issues are particularly important for lead management in children and young adults and highlight the importance of thoughtful input from pediatric cardiologists, pediatric electrophysiologists, and lead extraction specialists with patients and their families at the initial CIED implant or subsequently when lead management issues arise.

9.4 Magnetic Resonance Imaging

Recommendations for the management of CIEDs in the setting of MRI have been addressed in a recent HRS consensus document.[204] Currently, there are several FDA-approved MR-conditional CIED systems that are safe for use in the MRI environment when managed according to specific labeling requirements, which includes reprogramming.[222–225] The definition of "MR nonconditional" comprises all CIED systems that have not been FDA-labeled as "MR conditional." This also includes CIED systems with leads from differing manufacturers, whether or not the leads have been approved as part of another MR-conditional system, as well as CIED systems with abandoned or epicardial leads.[204] However, because MR-conditional technology is relatively new, there are substantially more MR-nonconditional systems in the population.[226] Not all patients with MR-nonconditional CIED systems have reasonable imaging alternatives. Substantial evidence has accumulated to demonstrate that MRI can be safely accomplished in most MR-nonconditional CIED systems without abandoned or epicardial leads, yet discussion regarding the risks and benefits should be held prior to imaging due to the risks, particularly in the setting of pacemaker-dependent patients or those with battery voltages near the elective replacement indicator.[210-213] The evidence base for the safety of MRI in CIED systems with abandoned, epicardial, or fractured leads or at field strengths of >1.5 tesla is far less robust.[106–110,227] Studies suggesting the feasibility of MRI with abandoned leads, epicardial leads, or fragments have been confined to single centers using rigorous imaging protocols. For the individual patient, shared decision making regarding the risks of MRI vs the risks of lead extraction in this setting is therefore paramount.[106-110,227]

9.5 Recalled Leads

As discussed in Section 6, Fidelis and Riata ICD leads and the Accufix Atrial J Leads (Telectronics) have all been recalled due to concern for early failure or potential for patient harm. Nonetheless, the potential for adverse events associated with extraction also exists.[66] There should therefore be an additional clinical indication for opening the pocket when there is a safety alert for the lead while the lead is still functional and therefore does not pose a manifest risk to the patient. This is supported by the experience with the Telectronics Accufix extraction, in which the mortality associated with extraction was higher than the risk of mortality from leaving the lead in place.[209]

9.6 Lead Perforation

Although lead perforation is usually a relatively acutely presenting complication of device placement, delayed perforation has been reported even years after implantation.[228] It is likely that many leads have some degree of microperforation, given imaging findings of this, but they are usually not clinically significant. Clearly, if a lead perforation causes pain, bleeding, or other complications, extraction will be an important component for the patient’s overall management strategy.

9.7 Severe Tricuspid Regurgitation

RV pacing and defibrillator leads are known to frequently lead to some degree of tricuspid regurgitation (TR), but this condition is usually clinically silent. Tricuspid valve dysfunction can result when leaflets fail to coapt due to excess lead loops traversing the valve orifice, retraction of the septal leaflet by the lead, or lead impingement on the valve apparatus.[229] The severity of tricuspid regurgitation following lead implantation varies from study to study, with one study reporting an increase by >1 grade in 24.2% of patients, whereas another reported an increase ≥2 grades in 18.3%.[230] Risk factors associated with lead-induced tricuspid valve dysfunction include older age, defibrillator leads, location of leads (posterior and septal leaflets), and leads passing between chordae.[230] A recent study found that significant TR associated with pacemaker leads was associated with increased mortality.[231]

Polewczyk et al reported 63% improvement in TR severity and 75% clinical improvement in patients referred for lead extraction due to symptomatic TR.[229] Conversely, Nazmul et al reported no improvement in the severity of symptomatic TR following percutaneous extraction of RV leads (with reimplantation of ventricular leads into the coronary sinus [CS]).[232] The authors reported that dilation of the tricuspid valve annulus persisted following lead removal and suggested the presence of preprocedural annular dilation might be helpful in predicting patients less likely to improve following percutaneous lead revision.[228] Consequently, these patients could benefit from an open extraction that permits tricuspid valve annuloplasty at the time of lead extraction. Thus, a combined evaluation and approach, in conjunction with cardiothoracic surgery, is optimal with either percutaneous extraction followed by open tricuspid surgery or, more commonly, open surgery with removal of all visible lead portions followed by percutaneous removal of the remnants.

The risk of traumatic tricuspid valve injury during lead extraction varies from 3.5% to 19%.[233–235] Features associated with the development of postextraction TR include advanced age, extraction of two or more leads, use of powered sheaths, female sex, and defibrillator leads.[233–235] Outcomes following traumatic tricuspid valve injury are less clear; one study indicated that 26% of patients developed new right heart failure symptoms, and 11% required surgical repair.[235]

9.8 Arrhythmias

Operators routinely assess for an increase in the degree of ventricular ectopy when implanting RV leads, with concern that frequent premature ventricular contractions might be predictive of that lead location being proarrhythmic. There are reports in the literature of refractory ventricular arrhythmias that occurred after an ICD lead placement, which resolved with extraction.[203]

9.9 Radiation Therapy

The primary clinical concern occurs when the CIED is situated in the path of the planned radiation beam and might interfere with adequate tumor treatment. Under these circumstances, a CIED relocation is recommended by the recent HRS consensus statement.[204] Options for CIED relocation include device placement on the contralateral side, with tunneling of existing leads using adapters/lead extenders, placement of the new device system on the contralateral side while abandoning the existing leads, and placement of a new device system on the contralateral side with extraction of the existing leads. There are potential risks and benefits with each approach. Clinical factors such as the patient’s overall prognosis and ability to tolerate procedures clearly need to be taken into account, and a shared decision-making process between the patient and the treating physicians should take place.

There is little evidence to substantiate a practice of CIED relocation with potential lead extraction to minimize radiation exposure to the device.[204,236,237] A number of studies have documented tolerance of the CIED generator well above the commonly recommended 2 Gy threshold and have established that the strongest predictor of CIED malfunction is exposure to neutron-producing beam energies >10 MV, not cumulative doses to the device.[204,236,237] Enhanced CIED monitoring without invasive measures is appropriate under these circumstances and should again involve an informed discussion between the patient and the treating physicians.

10. Periprocedural Management

10.1 Preprocedural Evaluation and Lead Management Strategy

The major risks associated with lead extractions can be attributed to the body's response to the foreign implanted material. Within a year, fibrosis encapsulates the leads and cardiac structures in direct contact with the lead. These sites of fibrosis can fuse, leading to dense adhesions between the endocardial structures and the lead that calcify over time. Sites of adhesion commonly occur at the site of venous entry, the SVC, and the electrode-myocardial interface.[238] Dense adhesions and calcified fibrotic lesions significantly affect the ease of extraction.[238,239] In addition to intravascular and intracardiac adhesions, lead-to-lead binding often occurs, further complicating the complexity of extraction. Lead dwell time and lead characteristics, including passive fixation and dual shocking coils correlate with fibrous adherences.[238] Conversely, SVC and intracardiac adhesions are lower in leads with backfilled shocking coils and those treated with expanded polytetrafluoroethylene.[238] Interestingly, significant adhesions within the device pocket can be a marker for challenging extractions.[240]

An area that warrants consideration is the development of strategies to reduce the risk of difficult future extraction at the time of initial CIED implant or generator exchange. In addition to assuring appropriate indications for CIED implantation, methods for minimizing the need for future lead revisions and reduce the risk of future extraction include the following:

- Using implant techniques that minimize the risk for lead perforation and/or lead fracture
- Minimizing the risk of infection:
    - Proper administration of periprocedural antibiotics
    - Appropriate anticoagulation management[241]
    - Minimizing the use of temporary pacing[161]
    - Assessing the need for prophylactic capsulectomy, because this can increase the risk for pocket hematomas without decreasing pocket infections[242]
    - Considering epicardial lead placement or subcutaneous defibrillators in patients at elevated risk for infection
- Ensuring proper postimplantation wound management
- Optimal lead selection:
    - Dual-coil defibrillator leads are more dangerous to extract and can have higher failure rates (due to more components) than single-coil ICD leads[243]
    - Coated and backfilled shocking coils have less tissue ingrowth than ICD shocking coils that allow tissue to grow under the coils[244]

Choosing the best lead management strategy warrants a thoughtful and patient-centered assessment of lead management options. Extraction should be offered when alternative lead management options appear less favorable to the patient's immediate and long-term risks. These alternatives include device reprogramming, lead abandonment, or, in the case of venous occlusion, venoplasty or contralateral lead placement.[215,216,245] The clinical factors associated with an increased risk of extraction are listed in Table 4. Several investigators have developed extraction risk models that consider factors such as lead dwell time, number of leads, patient age, and other comorbidities.[64,143,219,246–257] Age is often an important consideration for lead extraction. Higher risk of lead malfunction and longer exposure to potential complications from abandoned leads are often cited as a justification for lead extraction in younger patients.[26,27,220] Although lead extraction in elderly patients can be associated with higher overall risk of mortality, particularly in the presence of comorbidities, the procedural risk does not increase with age, and successful extraction can be performed when clinically appropriate.[64,254,255] Cumulative mortality rates following lead extraction range from 2.1%–3.3% at 30 days to 8.4%–10% at 1 year and 33%–46.8% at 10 years, with higher rates in patients with infected leads.[64,143,219,254–257]

10.2 Management of Patients Undergoing Lead Extraction

Management can be divided into 3 phases (preparatory, procedure, and postprocedure phases), each containing distinct components aimed at minimizing the risk of procedure-related complications and facilitating the diagnosis and management of complications when they occur. As with any invasive procedure, complications will occur, and it is paramount that the extraction team is prepared to handle catastrophic complications to prevent unnecessary deaths.

10.2.1 Preparatory Phase

The purpose of the preparatory phase is to confirm appropriate indications for lead extraction, assess procedure complexity, define extraction approach and goals, and optimize the patient's clinical status in preparation for the procedure. The following key components should be addressed during this phase:

- Perform a comprehensive history and physical exam:
  - Perform anticoagulation management
  - Optimize hemodynamics
- Confirm the appropriate indications for extraction
- Perform the CIED interrogation:
  - Indicate lead model numbers, noting any lead that requires special consideration
  - Confirm lead implant dates
  - Identify prior abandoned leads and implant dates
  - Assess pacemaker dependency
  - Turn off rate-adaptive programming
- Obtain the preprocedural imaging when clinically appropriate. Options include the following:
  - Chest radiography (both posteroanterior and lateral) to assess lead position, identify the presence of abandoned leads, and confirm lead type
  - Echocardiogram to assess LV function, identify intracardiac masses/vegetations, evaluate valve function and whether a patent foramen ovale is present, and identify intracardiac lead course and presence of pleural or pericardial effusions
  - Cardiac CT to assess extravascular or extracardiac lead positioning and potentially identify sites of venous adhesions
  - Fluoroscopy to identify sites of venous occlusion or stenosis and assess regions of lead mobility and adherence
- Define the extraction approach and procedure goals:
  - Percutaneous versus open extraction

    - Hybrid approach to the extraction
    - Goal of single versus multiple lead removal or complete system removal
    - Minimizing damage to nontargeted leads
- Determine the postextraction plan:
    - Indications for CIED reimplantation
    - Timing of CIED reimplantation
- Obtain the patient's informed consent

A comprehensive history and physical examination are necessary when assessing patients referred for lead extraction, including a review of the patient's comorbidities, medications, allergies, cardiac device history, indications, and implant dates. The physical exam should identify signs of decompensated heart failure and sequelae of CIED-related endocarditis; assess chest wall venous collaterals, which are suggestive of venous occlusion or high-grade stenosis; examine the device pocket for signs of infection (eg, fluctuance, cellulitis, draining sinuses, skin dimpling); and determine device location (eg, subpectoral, submammary). The cardiac device needs to be interrogated to obtain lead information, confirm malfunctioning leads, and assess pacemaker dependency. Patients who are not pacemaker-dependent should have their device reprogrammed to backup pacing modes (VVI 40 bpm) prior to the procedure to confirm lack of dependency. Information regarding abandoned leads can be obtained by reviewing prior operative reports, contacting device manufacturers, or performing chest radiography. Hemodynamic status should be optimized prior to the extraction procedure.

10.2.2 Anticoagulation

Patients who are implanted cardiac devices are frequently undergoing oral anticoagulation or dual antiplatelet therapy. Continuation of anticoagulation and avoidance of heparin bridging when implanting the cardiac device are relatively recent changes in practice.[258–260] The decision to withhold antiplatelet or anticoagulation therapy when implanting the CIED is a matter of weighing the risks of exposing patients to thromboembolic events during unprotected periods vs periprocedural bleeding complications.[258–260] Unlike CIED implantation, potentially life-threatening hemorrhagic events are a common complication of lead extraction procedures. Anticoagulation management should therefore be considered separately from cardiac device implantation. Observational studies have shown an approximately 3-fold increased risk of major complications and 1.3- to 1.8-fold increased risk of death in patients with an elevated international normalized ratio (INR; >1.2) at the time of lead extraction, although a preliminary study described a patient cohort in whom extraction was performed with a therapeutic INR.[64,261] Anticoagulation therapy is usually conducted in the perioperative phase, but periprocedural anticoagulation strategies should be considered on a case-by-case basis, after assessing the thromboembolic risk during unprotected periods.[259,260]

10.2.3 Preprocedural Imaging

Preprocedural imaging is important to confirm the number and location of indwelling leads. This information can be easily obtained from a chest radiography or fluoroscopy. However, advanced imaging modalities can provide the same information and potentially identify extravascular or extracardiac lead positioning. Electrocardiogram (ECG)-gated cardiac CT is commonly used to identify ventricular lead perforation and appears more accurate, with greater interobserver agreement, than chest radiography for the diagnosis of lead perforation.[262,263] The use of ECG-gated multidetector CT altered the approach to lead extraction in 3% of cases at one institution and was useful in predicting challenging extractions based on the presence of venous adhesions in 43% of cases at one center.[239] Lead artifacts, however, remain an impediment to the diagnostic accuracy of determining intravascular lead positioning.

Fluoroscopy with venography can also be helpful in the preparatory phase, identifying regions of venous stenosis or occlusion and adhesion sites. The incidence of venous stenosis following initial device implantation can be as high as 61%, with complete occlusion at the venous entry site in one-fourth of patients.[90] The brachiocephalic vein and the SVC are common sites of stenosis. Venous occlusion increases the complexity of extraction, as demonstrated by the greater use of advanced tools, longer procedures, and fluoroscopy times.[264]

Transthoracic echocardiography can provide useful information regarding LV function, presence of intracardiac masses or vegetations, valvular disorders (including TR severity), intracardiac lead course (including anomalies such as inadvertent LV lead positioning), intracardiac adhesions or lead perforation, and pre-existing pleural or pericardial effusions. Using transthoracic color Doppler echocardiography, Yakish et al demonstrated that turbulent flow in the SVC was more common in patients with lead dwell times of 2 years or more. Turbulent flow correlated with significant fibrosis in the SVC in a subset of patients who underwent transvenous lead extraction and correlated with more complex extractions.[265]

10.2.4 Extraction Approach: Open Versus Percutaneous Extraction

The percutaneous approach to lead extractions is generally preferred over open extractions because it is inherently less invasive and significantly reduces patient morbidity.[1,181] Conversely, open extractions are generally favored in high-risk extractions to avoid potentially life-threatening complications that can be encountered during percutaneous extractions.[1] The challenge then becomes predicting which extractions are sufficiently high-risk to justify the inherent morbidities associated with open-heart surgery. In general, open extractions are considered when the patient has failed a prior extraction procedure, has another reason for cardiac surgery, or when cardiac imaging identifies large lead masses (vegetation or thrombus >2.5 cm).[1]

Case reports that discuss different ways of "debulking" lead-associated vegetations identified by preprocedural imaging prior to proceeding with lead extraction might offer options for patients with large vegetations that are deemed too high-risk for either transvenous or open extraction. Patel et al described 3 cases in which AngioVac was used to debulk lead vegetations.[266] This resulted in clinical improvement (including weaning of vasopressors) and permitted lead extraction to be safely performed 2–7 days later without complications. Thrombolytics have also been used to reduce vegetation size in patients with CIED-associated infective endocarditis.[267]

Once the optimal extraction approach has been defined, the next important step is to define the procedure goal. The procedure goal for CIED-related infection (including isolated pocket, bacteremia, or CIED-endocarditis) should be complete system removal.[1]

The procedure goal for lead malfunction differs on a case-by-case basis and should be determined in the preprocedure phase.

10.2.5 Cardiac Device Reimplantation

Reassessment of appropriate indications for CIED reimplantation is imperative and should be part of the preparatory phase. Over time, clinical indications are updated, the patient's clinical status can change, such that device therapy is no longer necessary, or the patient's wishes can change, particularly regarding ICD therapy. In observational studies, over one-third of patients did not have devices reimplanted after undergoing system extraction for CIED infection.[143,146]

10.2.6 Informed Consent

The final step in the preparatory phase is informed consent, which ideally, takes place with the patient in the presence of family members or other social support. A review of this discussion, including alternatives to extraction, and potentially life-threatening complications, should be discussed with the patient and his or her family members and clearly documented in the patient's chart.

10.3 Procedure Phase

10.3.1 Patient Preparation

Routine preoperative blood work, including complete blood counts and metabolic and coagulation panels, should be obtained prior to the procedure. The type and cross for 2–4 units of packed red blood cells should be obtained prior to the procedure, especially for those patients with a higher complication risk during extraction, and the blood products should be readily available in the procedure room. External patches that permit transcutaneous pacing and defibrillation should be placed on the patient outside of the sterile working field. Device reprogramming to inactivate tachytherapies and/or enable asynchronous pacing, when appropriate, can be performed once the patient is connected to a cardiac monitor. Patients should be sterilely prepped for possible emergent sternotomy, creating a sterile field that covers the entire anterior chest and bilateral groin areas. An arterial line should be placed to permit continuous blood pressure monitoring and pulse oximetry to monitor oxygenation. Given that most complications involve vascular tears of the upper extremities, intravenous access to permit rapid infusion of fluid, vasopressors, and blood products should be placed in the femoral veins. Some centers routinely place sheaths in the common femoral artery and vein to serve as access sites for rapid placement of perfusion cannulas if cardiopulmonary bypass is necessary. Most centers perform lead extractions under general anesthesia to minimize patient discomfort and facilitate the use of intraprocedural TEE, which also eliminates the need for urgent intubation should complications occur and allows the anesthesia team to focus on resuscitation rather than intubation.

For transient rate support during the extraction, isoproterenol may be considered, but temporary transvenous pacing is usually employed if longer periods of rate support are required. Temporary pacing using the femoral approach is generally preferred when a superior extraction approach is planned to minimize interaction between the temporary pacing catheter and extraction tools. Temporary pacing might be required at the beginning of the operation for patients who are not pacemaker-dependent, particularly those with baseline left bundle branch block. If longer periods of continued temporary pacing are required after the lead extraction procedure, the femoral venous temporary pacing catheters can be exchanged for externalized temporary pacemakers using active fixation leads placed typically via the superior veins. Alternatively, if clinically appropriate, a permanent pacing system can be immediately implanted after the extraction is complete.

10.3.2 Intraprocedural Imaging

Both TEE and intracardiac echocardiography (ICE) have been used intraprocedurally to assist with lead localization and characterization of masses and to provide clinically relevant information during periods of hemodynamic instability. ICE can be particularly helpful for imaging right-sided cardiac structures, because the catheter can be advanced to the chamber of interest. Conversely, visualization of right-sided structures using TEE can be somewhat challenging given their relative anterior position.

The safety and efficacy of preprocedural and intraprocedural ICE was first described by Bongiorni et al. Preprocedural axial images were obtained from the lead venous entry site to the RA and used to distinguish between free-floating and adherent leads.[268] Fibrotic adhesions were visualized in the subclavian vein (80%), innominate vein (68%), RV (68%), and SVC (56%). Additionally, SVC and subclavian vein occlusion were identified by the inability to pass the ICE catheter in 2 patients. This imaging modality might be preferred by centers that routinely use ICE for other procedures.

A number of observational studies have reported the efficacy of TEE in identifying or excluding cardiovascular causes of hemodynamic instability during lead extraction.[269–271] Single-center observational studies indicate that TEE identified critical findings that prompted surgical intervention in 6%–40% of cases, prevented premature procedure termination in approximately 10%, and excluded cardiovascular causes of hypotension in approximately 50%.[269–271] TEE was placed at the beginning of the extraction procedure or as a rescue diagnostic procedure for managing refractory hypotension. Three-dimensional TEE is an emerging technology that can be useful for identifying adhesion sites.

Both modalities are helpful for characterizing lead vegetations, monitoring tricuspid valve function, and documenting pericardial effusions before and during lead extraction.[269,272] Narducci et al compared the diagnostic yield of ICE vs TEE in detecting vegetations in patients undergoing extraction for CIED-related infections. ICE was more sensitive than TEE at detecting vegetations in patients with definite (100% vs 73%) or probable (27% vs 12%) infective endocarditis using the modified Duke criteria, with an overall positive predictive value of 65.6% and negative predictive value of 100%.[272]

Intraprocedural imaging provides clinically relevant information that can enhance the safety of lead extraction, and its use during extractions is strongly recommended. The preferred imaging modality should be center specific, based on the operator’s familiarity and comfort with image interpretation.

10.3.3 Extraction Tools

Extractions can be successfully completed using a variety of approaches and tools, including simple manual traction, locking stylets, telescoping sheaths, femoral snares, mechanical cutters, and laser sheaths. At a minimum, extractors should have a working knowledge of these tools and the situations in which the tools are particularly helpful. Lead extraction is usually performed via a superior approach at the lead insertion site. Simple traction with either a standard or locking stylet is usually attempted first. This approach is generally successful in removing leads that move freely within the vein but remain attached at the tip to the myocardium, which can be observed with infected leads or those with a short lead dwell time. Use of a locking stylet that allows application of traction force more distally within the lead is crucial for determining the ease of extraction, whether using either simple traction or specialized sheaths.

A number of single-center retrospective studies have reported their experience using various extraction tools designed to disrupt fibrous adhesions (Appendix 7). Optimal tool selection varies based on the lead-tissue interface, fibrotic lesion characteristics, lead characteristics, lead dwell time, and operator experience. Telescoping sheaths and femoral snares can effectively disrupt fibrous adhesions but tend to fail when confronted with dense fibrotic or heavily calcified lesions. Laser sheaths can handle fibrous lesions efficiently but can be less effective when confronted with heavily calcified lesions.[273] Mechanical cutters, on the other hand, can be more efficient at traversing densely calcified fibrotic lesions. Suffice it to say, no one tool is adept at negotiating all types of fibrous adhesions encountered during lead extractions. Switching between extraction tools and approaches might be necessary.

Not uncommonly, the operator must change the approach to salvage extractions. For example, Starck et al noted that adding femoral snaring to the superior approach increased complete success by 10% and clinical success by 13%.[274] Similarly, de Bie et al reported that clinical success increased from 84.8% with manual traction alone to 93.5% when combined with femoral snaring.[275] The femoral approach can also be helpful in snaring lead fragments and in older (OR 1.16 per year) or passive-fixation leads (OR 2.52), which are prone to fracture.[275,276]

Some centers prefer a strictly femoral approach. Bracke et al reported their experience using the Needle’s Eye snare (Cook Medical) as the primary tool for pacing lead extraction.[276] Complete procedural success was reported in 94.4% of cases, with a mean pacing lead dwell time of 9.2 ± 5.8 years. Complete success using the snare was affected by lead location (CS 100%; RA 99.3%; and RV 90.1%). Failure and partial failures occurred in 1.8% and 3.8% of cases. The clear majority of these leads were RV leads with lead dwell times exceeding 10 years. Two (0.9%) RA perforations occurred that required surgical intervention. There were no procedure-related deaths. In a registry study of 3510 consecutive patients undergoing lead explantation, a femoral approach either as a primary strategy (9.09%) or secondary strategy (3.46%) was associated with a higher complication rate when compared with other approaches (1.43%).[277] In contrast to extracting via the implant vein, a strictly femoral approach does not maintain superior venous access.

A modified mechanical dilatation technique using multiple venous entry sites was described by Bongiorni et al.[268] This approach begins at the venous entry site with the introduction of telescoping countertraction sheaths, followed by transfemoral retraction of the lead to allow for snaring from an internal transjugular approach if the physician is unable to extract the lead fully from the venous entry site. The overall complete success rate at the author’s center was 98.4% (manual traction 14.3%), with a 0.9% partial success rate and a 0.6% failed extraction rate. Major complications occurred in 0.7% of cases, all due to tamponade, and 3 (0.3%) cases resulted in death.

10.3.4 Extraction of Coronary Sinus Leads

Unlike atrial or ventricular leads, CS leads can often be removed with manual traction.[278] Fibrous adhesions are less common in the CS, perhaps due to smaller lead diameters and lack of direct (active or passive) fixation mechanisms.[279] However, as with other leads, longer dwell times and the larger lead diameters increase the need for mechanical or powered sheaths.[280] Complete and clinical success are similar to other leads, averaging 98%–99% (range 91%–100%).[278,280,281] The rate of major complications is low, ranging from 0% to 3.9%, excluding complications associated with the active fixation Medtronic StarFix lead.[278,280,281]

As with all extractions, CS lead reimplantation should be evaluated to ensure that appropriate indications exist. Whether to replace a CS lead in nonresponders to CRT is controversial and beyond the scope of this document. However, reimplantation can prove challenging due to thrombosis or occlusion of the main body of the CS or its tributaries as a result of direct vascular injury during the extraction.[280,281] Retaining access to the main body of the CS with a guide wire delivered through the working sheath's lumen is one way to retain access in noninfectious cases, when the plan includes reimplantation following extraction. Balloon occlusive venography can also be helpful to visualize the status of the branch through which extraction was performed and identify alternative targets.

10.3.5 Leads that Require Special Consideration

10.3.5.1 Medtronic Starfix (Model 4195)

Extractors should be mindful of the unique challenges posed during extraction of the Medtronic Starfix model 4195.[275–281] This is the only active-fixation CS lead that is currently available and is among the most difficult leads to extract. Inexperienced operators should probably avoid extracting this lead unless performed in consultation with an experienced extractor. At a minimum, extractors should have a working knowledge of the various techniques that have been used to facilitate extraction of this lead. Importantly, implanting physicians should have a compelling reason to implant this lead, particularly with the advent of quadripolar leads.

Successful removal of StarFix leads varies by study, ranging from as low as 50% to 100%.[282–285] Given that significant tissue ingrowth occurs around the fixation lobes, successful extraction is more likely with shorter implant times.[281,283] Major complications, including CS tears and pericardial tamponade, have been reported in 15%–17% of cases.[283,284]

10.3.5.2 Small-diameter Pacing Leads

The SelectSecure lumenless pacing lead (model 3830, Medtronic, Minneapolis, MN) is a 4.1F diameter, nonretractable active-fixation lead that is delivered through a catheter. The lead's small diameter is particularly attractive for use in children who need pacing leads. The lead does not permit placement of locking stylets but can be successfully extracted with simple traction while simultaneously employing counterclockwise rotation on the lead.[286] Manual traction alone successfully removed 40.9% of SelectSecure leads with a mean lead implant duration of 4.1 ± 2.6 years. The remaining leads were removed using polypropylene countertraction sheaths (31.8%) and the Evolution mechanical sheath (27.3%).[287] Care should be taken when using powered sheaths with this lead, because establishing a rail can be challenging due to the differences in size between the sheath and lead. Small-diameter leads using a coaxial design (eg, Boston Scientific FINELINE 4469-4474) also require special care when extracting and are probably more difficult to completely extract. In some cases, using a combined femoral and superior approach will minimize the tension required to remove the lead.

10.3.5.3 Abbott Riata ICD Leads (Riata 1500 and Riata ST 7000 series)

Extractors should be aware of the differences in lead design between Riata and conventional ICD leads and understand how these differences affect lead extraction. The 1500-series Riata leads are larger in diameter (8Fr) and lack backfilled shocking coils. As a result, these leads are susceptible to significant tissue ingrowth. The 7000-series Riata leads are smaller in diameter (7Fr) and contain backfilled shocking coils. Both leads are susceptible to the inside-out insulation defect that results in conductor cable externalization. Cable externalization rates are higher for the 1500 series than for the 7000 series (31.4% vs 6.3%, respectively; $P<.001$) Riata leads and increase over time (0% at <3 years; 13% at 3–5 years; 26% at >5 years).[72,288] By design, the externalized conductor cables are welded to the distal rather than the proximal edge of the shocking coil, which increases the likelihood of "snowplowing" during extraction.

During the extraction procedure, the operator should maintain equal traction on the defibrillator lead body and the externalized cables while advancing the working sheath to avoid dragging and prolapsing the cables proximal to the extraction sheath. Reduction of externalized conductor cables should be attempted before advancing the working sheath, otherwise it might be impossible to advance the sheath over the externalized cables. Use of a larger sheath to accommodate externalized cables could be beneficial. Extractors should also be aware of the potential for thrombus formation on externalized cables and consider preprocedural or intraprocedural imaging prior to lead extraction.[289]

10.3.6 Special Considerations

10.3.6.1 Management of Isolated Pocket Infections in Patients Who Refuse Lead Extraction

Centers have reported various approaches to managing isolated pocket infection in patients who refuse lead extraction.[290–292] Lopez et al described the use of a closed irrigation system that consisted of pulse irrigation and suction, using a solution of vancomycin and gentamycin for 72 hours following pocket debridement and washout in 5 patients with isolated pocket infection. Patients remained free of infection during a mean follow-up of 19 months.[290] Puri et al described a similar closed irrigation system using povidone-iodine solution infused 4 times daily for 1 week, in addition to a 2-week course of oral antibiotics.[292] The authors reported no recurrent infection over a 2-year follow-up period. Poller et al used an alternative approach to manage isolated pocket infections in 5 people who refused lead extraction.[292] In these cases, the generator was removed and the leads were cut, allowing them to retract into the vascular space. A vacuum-assisted wound closure dressing was placed to promote wound closure, and devices were implanted on the contralateral side when appropriate. One patient in this study developed recurrent pocket infection at 69 days.

10.3.6.2 Leads Inadvertently Placed in the Left Ventricle

Inadvertent placement of leads into the left ventricle is a rare complication of device implantation that presents unique management challenges. Thromboembolism resulting in stroke is a potential complication, as is mitral valve dysfunction due to lead impingement or adhesion. Preprocedural and intraoperative TEE should be performed to evaluate the presence of thrombus and adherence to the mitral valve. In the absence of thrombus or adherence, the lead may be removed with simple manual traction. Open extraction is otherwise preferred, particularly in the presence of thrombi or mitral valve dysfunction.

10.3.6.3 Management of Retained Lead Fragments

Another area with emerging data is the consequence of retained fragments following a partial or failed extraction. A direct correlation between longer lead implant duration and retained lead fragments was observed by Rusanov et al.[175] One-third of patients with failed or partial extraction, initially referred for transvenous lead extraction due to infection, subsequently required an open extraction for endocarditis involving the retained lead fragment.[293] Gomes et al reported similar findings, noting an increased incidence of recurrent infection following initial extraction for infection in patients with retained fragments vs complete removal (13.5% vs 3%, P=.001).[295] Calvagna et al reported their experience retrieving retained fragments using femoral snaring, citing a 93% success rate with no major complications.[295] Therefore, the goal of extraction for patients with CIED-related infections should be complete system removal.[296]

10.3.6.4 Ghosts

Not infrequently, small residual fibrinous strands or masses remain within the RA or SVC following lead extraction. These so-called ghosts have an incidence ranging from 8% to 14% and are most commonly observed in patients with infectious indications for extraction.[297,298] Ghosts were more common in patients with CIED-related endocarditis (OR 7.63; P=.001) or positive blood cultures (OR 2.98; P=.048), and patients with ghosts had a higher mortality than those without ghosts (HR 3.47; P=.002).[298] The approach for these residual masses is unclear. Given the potential association between ghosts and adverse outcomes, their presence should probably be noted on postextraction imaging and might warrant closer postextraction follow-up. No specific therapy is indicated for patients with this finding.

10.3.7 Management of Complications

Prompt recognition and management of life-threatening complications is paramount in preventing catastrophic outcomes. To ensure optimal quality assurance, extraction programs should document all intraprocedural and postprocedural complications encountered during lead extractions. A review of the complications provides an opportunity for the extraction team to learn from the adverse events and identify ways to improve the safety and efficacy of extraction procedures.

Complications should be differentiated by severity into major and minor. Major complications are those that pose an immediate threat to life or that result in death. Minor complications are undesired adverse events that require medical intervention, including minor procedural interventions, but do not significantly affect the patient's function.

Some complications can be attributed to suboptimal implant techniques. One assumption of lead extraction is that the lead courses within the venous system, from the venous entry site to the cardiac attachment point. Unfortunately, this is not always the case. Identifying extravascular leads remains a diagnostic challenge. Extractors should have a high clinical suspicion for arteriovenous fistulas or leads inadvertently traversing the artery before entering the vein.[299] A breakdown of procedure-related complications and incidences reported in the literature is provided in Table 5.

10.3.8 Vascular Tears

Vascular tears involving the subclavian and innominate veins can result in ipsilateral hemothorax but can be difficult to identify or accurately localize. Awareness of the position of the working sheath and imaging with TEE or fluoroscopy can be helpful in identifying potential sites of injury. More importantly, about two-thirds of life-threatening vascular tears occur in the SVC, half of which are below and half of which are above the pericardial reflection.[300] This results in pericardial effusion and tamponade when below the pericardial reflection and in hemothorax and rapid demise when above the pericardial reflection unless the bleeding is immediately controlled. Deployment of an occlusive compliant balloon can control the severity of bleeding while the chest is opened and definitive repair is pursued. Although venography, coated stent implantation, and pericardiocentesis have been successfully employed, the time lost in avoiding opening the chest often results in avoidable mortality in many patients. Positioning an introducer sheath and a stiff guide wire that extends from the femoral vein to the right internal jugular or subclavian vein at the beginning of the extraction procedure allows for rapid deployment of an occlusive balloon to minimize bleeding as the patient is rapidly prepared for definitive repair. Initial studies have suggested that the occlusive balloon is safe and associated with improved survival in the setting of vascular tears of the SVC.[301,302]

Temporary measures to minimize blood loss can be critical to survival while awaiting definitive repair. It is critical that the surgical team responds immediately and provides backup in the surgical management of transvenous lead complications. In patients with a prior sternotomy, a right-sided thoracotomy and double-lumen endotracheal tube might be required for surgical access to a lateral tear above the pericardial reflection, emphasizing the importance of preprocedural planning involving the entire extraction team. Unfortunately, few studies have reviewed the surgical management of extraction-related complications.

10.4 Postprocedure Phase

The main goal of the postextraction phase is to monitor for postprocedure complications and ensure close follow-up for the prompt management of late complications. Physical examinations, including listening for arteriovenous fistula bruits over the subclavian areas, are important for all patients. Following extraction, most centers will obtain chest radiography and transthoracic echocardiograms within 24 hours of the procedure. The purpose of chest radiography is to rule out occult hemothorax or pneumothorax and document lead positions following implantation of either a temporary or permanent pacemaker. The echocardiogram is useful for screening unrecognized adverse events such as tricuspid valve injury, detecting the presence or stability of pericardial effusion, and documenting any remaining intracardiac masses (either retained fragments or so-called ghosts). For patients who undergo extraction for CIED-related infection, the postprocedure phase focuses on wound care management, appropriate selection and duration of antibiotics, and determining the appropriate timing for device reimplantation.

11. Facilities, Equipment, and Training

Given the potential for life-threatening complications, lead extractions should only be performed in centers with an environment fully supportive of a lead extraction program, which includes a collaborative lead extraction team, appropriate facilities, and all necessary equipment and facilities to perform extractions and manage complications.

A 2010 study specifically evaluated whether extractions can be performed safely in the electrophysiology laboratory with surgical backup.[303] The investigators reported similar success rates (93.1% vs 91.4%, *P*=.227), overall complication rates (2.2% vs 2.8%, *P*=.431), major complication rates (1.0% vs 2.1%, *P*=.794), and procedure-related mortality rates (0.12% vs 0.18%) when comparing procedures in the electrophysiology laboratory vs the operating room. Regardless of whether the extraction is performed in the electrophysiology laboratory or the operating room, the most important condition is that the location provides all necessary equipment to safely perform lead extractions and manage complications. It is essential that a cardiac surgeon and surgical team are immediately available, with access to equipment to perform emergent sternotomy or thoracotomy within 5 to 10 minutes. The primary focus of a lead extraction program should be to maximize procedure safety and efficacy. Recommendations for facilities and training have not changed from the requirements outlined in the 2009 HRS Extraction document.[1]

11.1 Personnel

The importance of a collaborative, multidisciplinary team cannot be overstated. For programs in which the primary operator is not a surgeon, the involvement of a cardiothoracic surgeon and surgical staff familiar with the management of lead extraction complications is critical to ensure safe outcomes.[1] Some centers have also included interventional radiologists and/or vascular surgeons as members of the multidisciplinary team to assist with percutaneous management of vascular tears. For centers that perform extraction in children and young adults, close collaboration between pediatric cardiologists, pediatric electrophysiologists, and lead extraction specialists is essential.

11.2 Operator Training and Maintenance of Skills

Appropriate training of all staff involved in the extraction team is required to maximize procedural safety and efficacy. Physicians performing extractions should be properly trained in all aspects of extraction techniques (superior and femoral approaches) and in recognizing and managing complications.

In general, procedure success and complication rates are influenced by extractor experience and overall center volume.[304,305] Recommendations for training have not changed from those outlined in the 2009 HRS Extraction document.[1] That document recommended that physicians undergoing training in lead extractions should extract a minimum of 40 leads as the primary operator under the direct supervision of a qualified physician and a minimum of 20 leads should be extracted annually to maintain competency and were also adopted by a subsequent EHRA position paper.[305a] More recently, the *2015 ACC/AHA/HRS Advanced Training Statement on Clinical Cardiac Electrophysiology (a Revision of the ACC/AHA 2006 Update of the Clinical Competence Statement on Invasive Electrophysiology Studies, Catheter Ablation, and Cardioversion)* noted that the minimal procedural volume to achieve and demonstrate clinical competence is 30 lead extractions.[306]

11.3 Simulators

Maytin et al evaluated the effect of virtual-reality lead-extraction simulations on electrophysiology fellows undergoing training for lead extractions.[307] In this study, 8 fellows were randomized to simulator or conventional training and then compared based on procedural competency. All fellows underwent 4 hours of didactic training. The fellows randomized to the simulator group underwent 4 additional hours of simulator training. The fellows then participated in 5 months of clinical training in transvenous lead extraction, after which both groups underwent simulator case-based testing. All 4 fellows randomized to the conventional group experienced a simulator complication (2 SVC tears, 3 RV avulsions), whereas only 1 complication (SVC tear) occurred in the simulator group (P=.02). Lead removal time was significantly longer in the conventionally trained group (12.5 ± 4.5 vs 5.5 ± 1.3, P=.02), and a trend toward excess pushing vs pulling forces was observed in the conventional group (push-pull: 1.3 ± 3.6 vs -1.0 ± 1.7, P=.31).[307]

When extractors who had performed over 40 lead extractions were asked to apply simple manual traction to a phantom torso, a significant range of applied forces emerged (3.0 N–24.7 N; median 10.9 N).[308] The investigators also found that the forces applied at the proximal end of the lead were 10% higher than those measured at the tip. These studies suggest that simulator training can provide valuable feedback to physicians and can represent important tools for maintaining competency and training physicians who are new to lead extractions.

11.4 Surgeon Training

The training of cardiothoracic surgeons who support percutaneous lead extractions has received little focus. Surgeons play a vital role in managing major complications that occur during lead extractions that directly affect patient outcomes. It is therefore imperative that surgeons engage in continuing educational activities that focus on the surgical management of lead complications and remain abreast of significant developments within the field of lead extraction.

12. Outcomes and Follow-up

I	C-EO	**Extraction programs and operator-specific information on volume, clinical success rates, and complication rates for lead removal and extraction should be available and discussed with the patient prior to any lead removal procedure.**	

Data collection is a critical component for all lead extraction programs and complete transparency of the data and analyses should be available to the patient and all other stakeholders.

Outcomes following lead management interventions, which include not only lead extraction but also interventions such as venoplasty, pocket debridement, and lead abandonment, can be divided into two phases: procedure and postprocedure outcomes. By definition, outcomes consider both the perceived success of the procedure and procedure-related complications identified over a predefined period. Accordingly, lead intervention procedure outcomes are defined by the extraction procedure success and, where applicable, complications that occur during the extraction procedure and the inpatient hospitalization period. Postprocedure complications can be divided into 2 phases: early complications that occur within the first 30 days and late complications that occur within the first year. With regard to lead management interventions, the primary postprocedure complication of significance is infection, which presents well beyond 30 days in 43%–75% of patients.[146,257] To adequately capture these events, postprocedure outcomes should include infections that occur during each of the time periods: 30 days, 1–6 months and >6 months.

Complications that can trigger medical attention following discharge include upper extremity swelling due to venous thrombosis; recurrent infection, particularly in patients who underwent incomplete extraction for CIED infection; new pocket or systemic infection; lead perforation; lead dislodgement; heart failure; symptoms associated with tricuspid valve injury; pneumonia; and complications from thromboemboli, including pulmonary embolism. Prompt recognition and management of these complications is the responsibility of the providers who care for patients after CIED implant or after extraction. Thus, proper communication between the provider performing the CIED lead management procedure and the provider who assumes the longitudinal care of the patient is paramount when the 2 are distinct, exchanging any pertinent information about the procedure and hospital course.

There are 3 aspects to consider when defining the procedural success of lead extraction. The first addresses whether the initial clinical goals of the procedure were achieved; the second considers whether a retained fragment was left behind; and the third requires that there were no procedure-related permanent or disabling complications or death. Complete procedural success indicates that all targeted leads and all lead material were successfully removed from the vascular space and is defined for the entire procedure, with no permanent, disabling complications or procedure-related death. Clinical success is defined as removal of all targeted leads with retention of no more than a small portion of lead material (<4 cm) that does not negatively impact the outcome goals of the procedure.[309] Conversely, procedure failure is defined as an inability to achieve either complete procedural or clinical success or the development of any permanently disabling complications or procedure-related death.

Lead extraction program-specific success and failure metrics should be prospectively collected and communicated to patients during the decision and consent process prior to each potential lead extraction procedure. Information discussed with patients during the shared decision-making process should at least include (1) the annual lead extraction volume at that center, (2) the lead extraction clinical success rate, and (3) major procedure-related complication/death rates during hospitalization. Writing committee members firmly believe this information should be made publicly available and should be communicated to patients during the shared decision-making and informed consent process to ensure complete transparency. Additional information is likely to be valuable to the patient, including (1) personal lead extraction volume and personal number of leads removed during lead extraction procedures (yearly and lifetime), clinical success rate, and complication rate; (2) volume broken down between ICD and pacing leads; and (3) extraction indications (eg, infection, lead malfunction, and superfluous leads). More complete data collection is desirable and useful to promote quality outcomes and identify opportunities for process improvement but is not required.

13. Data Management

It is the opinion of the writing committee that centers performing lead extraction procedures maintain or participate in a multicenter data capture system that includes the ability to calculate site-specific metrics for procedure success, failure, and complications for all lead removal procedures. Procedure success and complications should be categorized according to the definitions outlined earlier to ensure standardization of data. Periodic review of complications often highlights opportunities for procedure and system improvements and demonstrates a commitment to quality improvement. Center-specific databases should include patient demographic information, operator information, indications for extraction (eg, infection, lead malfunction, and superfluous leads), type of lead removed (ICD vs pacing), lead extraction clinical success rates, procedure success rates (complete and clinical), major and minor complications, and deaths that occur during the procedure or within the early or late postprocedure phases.

14. Registries, International Collaboration, and the Future

Registries will be critical to our further understanding of how best to manage leads in the setting of infection, lead failure, and changing clinical conditions. The AHA, ACC, STS, HRS, ESC, and EHRA have all embraced clinical registries as a way of capturing "real-world" clinical practices. The European Society of Cardiology-sponsored European Lead Extraction Controlled Registry (ELECTRa) is already yielding important results that can serve as benchmarks for clinical success rates, complication rates, and mortality using the definitions from the 2009 HRS Extraction document (https://www.escardio.org/Sub-specialty-communities/European-Heart-Rhythm-Association-(EHRA)/partner-organisations-networks/ELECTRa-Registry).[1,277] The Extract Registry and Study Group currently has six centers in the United States and one in Australia and is actively recruiting additional centers (http://www.extractstudygroup.org). A more widespread use of registries offers the opportunity to monitor trends in lead extraction procedures, compare extraction techniques, define characteristics of leads undergoing extraction, assess procedure success and complication rates, and provide a venue to conduct observational research.

Beyond extraction-specific registries, larger device-based registries will be able to provide information on lead management strategies in general. Information from the NCDR and the National Inpatient Sample has already contributed to our understanding of clinical outcomes with lead abandonment and extraction in patients with ICDs.[71,310] The use of a medical device surveillance tool with the NCDR could be useful for early real-time identification of failure-prone ICD leads.[311]

Interactions on technique and methodology can now be shared worldwide via the Internet. Although discussions at this point are informal, this type of information could be systematically collected and evaluated to help identify best practices, taking individual clinical situations into account. Although new technologies will be able to obviate the requirement for transvenous and epicardial leads for future CIEDs, lead management issues will likely remain important for the next decade of clinical medicine. New technologies have reduced the periprocedural risks of lead extraction, but all extraction programs require a multidisciplinary approach with the commitment of significant resources.

In Memoriam

This document is dedicated to Marc A. Rozner, PhD, MD, CCDS (1952–2016), and the entire writing committee wishes to honor his integrity and commitment to science and patient care.

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Figure 1 Applying Class of Recommendation and Level of Evidence to clinical strategies, interventions, treatments, or diagnostic testing in patient care (Halperin et al. Circulation 2016;133:1426–1428).

Figure 2 Management of suspected CIED infection.
*Refer to text and table for specific recommendations depending on microbiology. Antimicrobial therapy should be at least 4–6 weeks for endocarditis (4 weeks for native valve, 6 weeks for prosthetic valve or staphylococcal valvular endocarditis). If lead vegetation is present in the absence of a valve vegetation, 4 weeks of antibiotics for *Staphylococcus* aureus and 2 weeks for other pathogens is recommended.
†Usually the contralateral side; a subcutaneous ICD may also be considered.
**2010 AHA CIED Infection Update distinguishes between pocket infection and erosion (Baddour et al. Circulation 2010;121:458–477).

Figure 3 Management of suspected pocket infection.
*See text for examples.

Figure 4 Management of bacteremia without evidence of CIED infection.
*Important to distinguish between blood stream infection and contamination in bacteremia involving skin flora.

Table 1 Definitions

Term	Definition
Nonfunctional lead	A lead that is not usable due to electrical dysfunction, regardless of whether it is connected to the CIED or not.
Abandoned lead	A functional or nonfunctional lead that is left in place and is not connected to the CIED.
Lead removal procedure	A procedure involving the removal of a pacing or defibrillator lead using any technique, regardless of time since implantation.
Lead explant procedure	Lead removal procedure where all leads were removed without tools or with implantation stylets and all removed leads were implanted for less than 1 year.
Lead extraction	Lead removal procedure where at least one lead removal required the assistance of equipment not typically employed during lead implantation or at least one lead was implanted for greater than 1 year.
Definitions for extraction procedures	
Complete procedural success	Lead extraction procedure with removal of all targeted leads and all lead material from the vascular space, with the absence of any permanently disabling complication or procedure-related death.
Complete procedural success rate	Extraction procedures where there is complete procedural success/total number of extraction procedures.
Clinical success	Lead extraction procedures with removal of all targeted leads and lead material from the vascular space or retention of a small portion of the lead (<4 cm) that does not negatively impact the outcome goals of the procedure.
Clinical success rate	Extraction procedures where there is clinical success/Total number of extraction procedures.
Failure	Lead extraction procedures in which complete procedural or clinical success cannot be achieved, or the development of any permanently disabling complication, or procedure-related death.
Failure rate	Failed extraction procedures/total number of extraction procedures.
Lead removal with clinical success	Leads with attempted removal where the entire lead is taken out of the body or with retention of a small portion of the lead material (<4 cm) that does not negatively impact the outcome goals of the procedure.
Lead removal with clinical success rate	Number of leads removed with clinical success during a lead extraction/total number of leads with attempted removal.

CIED = cardiac implantable electronic device.

Table 2 Lead abandonment clinical scenarios

Patient scenario	**Management strategies**	**Key points**
An 86-year-old man with complete heart block who underwent dual-chamber pacemaker implantation 14 years ago, with most recent generator replacement 3 years ago. Two leads are in place. His medical history is significant for chronic lymphocytic lymphoma and recently diagnosed prostate cancer. He presents with noise on the right ventricular lead and inhibition of ventricular pacing consistent with lead malfunction.	• Assess possibility of reprogramming to unipolar. • Consider likelihood of ipsilateral venous occlusion, which would require contralateral lead placement for addition. • Management options discussed included extraction of 14-year-old pacemaker lead with new lead implantation vs abandonment of old lead and placement of new right ventricular lead. • Values elicited in discussion included patient's desire to avoid hospitalization and not wanting to be dependent on his children. • Although the risks of lead addition and lead extraction are comparable in the literature, the risk of major complications and a more prolonged hospital stay appear higher for an extraction procedure, particularly given the patient's advanced age, comorbidities, and older leads. The decision was made to add a new pace-sense lead and abandon the previously placed lead.	• Age and medical comorbidities contribute to the lead management decision making. • Lead type and dwell time contribute to the risk and benefit analysis in lead management decision making. • Abandoned leads are a contraindication for MRI, which is often used in the follow-up of cancer.
A 46-year-old woman with a history of mechanical mitral valve replacement complicated by complete heart block, who underwent placement of a dual-chamber pacemaker 3 years ago. She presents with dislodgement of the atrial lead associated with symptoms of loss of AV synchrony.	• Management options discussed included extraction and replacement of atrial lead, attempt to reposition, and addition of a new atrial lead. • Values elicited in discussion included the desire to have the best possible functional CIED system and not have abandoned leads, even if this resulted in a longer hospital stay due to anticoagulation management. • Despite the mechanical mitral valve, the ease of extraction of a 3-year-old pacemaker lead is reasonable. The decision was made to extract and replace the lead.	• Young age and long-term need for functional CIED therapy and the desire to avoid an abandoned lead contributed to the decision-making process.
A 25-year-old man who underwent a secondary prevention ICD placement with a dual-coil lead 14 years ago for a ventricular fibrillation cardiac arrest. His ICD lead fractured 6 years ago, and he underwent addition of a new ICD lead and abandonment of his first ICD lead. During the follow-up, the new ICD lead was found to be fractured, with inappropriate detections due to noise.	• Management options discussed included adding a third lead; abandoning both transvenous ICD leads and implanting a subcutaneous ICD; extracting both leads and adding a new ICD lead; extracting both leads and implanting a subcutaneous ICD. • Primary concerns elicited were the potential for long-term complications from the ICD leads and the possibility of needing an MRI in his lifetime. The decision was made to extract both leads	• The lead extraction procedure was higher risk due to the previous decision to abandon a malfunctioning lead in a young patient.

	and implant a subcutaneous ICD lead, after discussing the risks and benefits of a subcutaneous ICD system vs a transvenous ICD system.	
A 40-year-old woman with familial LQT2 who underwent primary prevention ICD placement with a dual-coil lead 8 years ago due to pregnancy, concerns about increased risk of arrhythmias during the postpartum setting, and strong family history of peripartum sudden death. She has two children, will not have future pregnancies, and has never had ICD therapies. ICD generator is ERI, and she no longer wants ICD therapy.	• Management options discussed included abandoning lead and generator; removing generator and abandoning lead; and extracting lead and generator. • Values elicited included a desire to not have a prolonged hospitalization or recovery and not wanting a generator in the pocket. • The patient did not want to undergo extraction. At her request, the decision was made to remove the generator and abandon the lead.	• The option of removing only the generator would leave the patient with a contraindication for MRI. • The patient remains at ongoing risk for lead infection, which would require a higher risk extraction in the future. • Opening the pocket to remove the generator exposed the patient to a risk of infection.
A 52-year-old man with a history of complete heart block, leading to a diagnosis of cardiac sarcoidosis, underwent dual-chamber ICD with a single-coil ICD lead 4 years ago. He has had ATP therapy for VT. Remote interrogation shows impedance of 150 and episodes of noise on RV lead. Noise is reproducible on exam with pocket manipulation.	• Management options discussed included addition of new RV pace-sense lead; and ICD lead extraction and replacement. • Values elicited during discussion included his desire for a reliable system, concerns about the effect of more leads in his vasculature, and his desire to be able to easily undergo MRI in the future. • The decision was made to extract and reimplant a new ICD lead.	• Should the strategy of an additional lead be applied, vein patency would need to be considered. In case of extraction and reimplantation, the lead's original insertion point would need to be evaluated in case this represents damage from the costoclavicular ligaments. • Adding a pace-sense lead is sometimes a suboptimal choice, because the ICD shock coil can also be at high risk of failure in the setting of a pace-sense component fracture.

ATP = antitachycardia pacing; AV = atrioventricular; CIED = cardiovascular implantable electronic device; ERI = elective replacement indicator; ICD = implantable cardioverter defibrillator; MRI = magnetic resonance imaging; VT = ventricular tachycardia.

Table 3 Risk factors for cardiac implantable electronic device infection[157–169]

Patient-related factors	Procedure-related factors	Microbe-related factors
Age Chronic kidney disease Hemodialysis Diabetes mellitus Heart failure Chronic obstructive pulmonary disease Preprocedure fever Malignancy Skin disorder Immunosuppressive drug Prior CIED infection Anticoagulation	Pocket reintervention (generator change, upgrade, lead or pocket revision) Pocket hematoma Longer procedure duration Inexperienced operator ICD (compared with PM) Lack of use of prophylactic antibiotics	Highly virulent microbes (eg, staphylococci)

CIED = cardiovascular implantable electronic device; ICD = implantable cardioverter defibrillator; PM = pacemaker.

Table 4 Factors associated with extraction procedure complications and longer-term mortality

Factor	Associated risk
Age	1.05-fold ↑ mortality[285]
Female sex	4.5-fold ↑ risk of major complications[205]
Low body mass index (<25 kg/m^2)	1.8-fold ↑ risk of 30-day mortality[64] ↑ no. of procedure-related complications[219]
History of cerebrovascular accident	2-fold ↑ risk of major complications[64]
Severe LV dysfunction	2-fold ↑ risk of major complications[64]
Advanced HF	1.3- to 8.5-fold ↑ risk of 30-day mortality[64] 3-fold ↑ 1-year mortality[257]
Renal dysfunction	ESRD: 4.8-fold ↑ risk of 30-day mortality[64] Cr ≥2.0: ↑ in-hospital mortality[216] and 2-fold ↑ risk of 1-year mortality[257]
Diabetes mellitus	↑ in-hospital mortality[219] 1.71-fold ↑ mortality[285]
Platelet	Low platelet count: 1.7-fold ↑ risk of major complications[64]
Coagulopathy	Elevated INR: 2.7-fold ↑ risk of major complications and 1.3-fold ↑ risk of 30-day mortality[64] Anticoagulant use: 1.8-fold ↑ 1-year mortality[257]
Anemia	3.3-fold ↑ risk of 30-day mortality[64]
Number of leads extracted	3.5-fold ↑ risk of any complication[249] 1.6-fold ↑ long-term mortality[250]

Presence of dual-coil ICD	2.7-fold ↑ risk of 30-day mortality[64]
Extraction for infection	2.7- to 30-fold ↑ risk of 30-day mortality[64,249] 5- to 9.7-fold ↑ 1-year mortality[64,250] CRP >72 mg/L associated with ↑ 30-day mortality[252] 3.52-fold ↑ mortality[285]
Operator experience	2.6-fold ↑ no. of procedure-related complications[299]
Prior open heart surgery	↓ risk of major complications[249]

Cr = creatinine; CRP = C-reactive protein; ESRD = end-stage renal disease; HF = heart failure; ICD = implantable cardioverter defibrillator; INR = international normalized ratio; LV = left ventricular.

Table 5 Extraction procedure-related complications

	Incidence, %
Major[64,216,246,247,278,287,307]	0.19%–1.80%
Death[64,216,246,247,287,307]	0.19%–1.20%
Cardiac avulsion[64,216 ,287,307]	0.19%–0.96%
Vascular laceration[64,216,246,247,307]	0.16%–0.41%
Respiratory arrest[64]	0.20%
Cerebrovascular accident[64,216]	0.07%–0.08%
Pericardial effusion requiring intervention[64,278,307]	0.23%–0.59%
Hemothorax requiring intervention[64,216]	0.07%–0.20%
Cardiac arrest[64]	0.07%
Thromboembolism requiring intervention[216]	0.07%
Flail tricuspid valve leaflet requiring intervention[64]	0.03%
Massive pulmonary embolism[310]	0.08%
Minor[64,216,246,247,287,307]	0.60%–6.20%
Pericardial effusion without intervention	0.07%–0.16%
Hematoma requiring evacuation[64,216,287]	0.90%–1.60%
Venous thrombosis requiring medical intervention[64,216]	0.10%–0.21%
Vascular repair at venous entry site[64,216,246]	0.07%–0.13%
Migrated lead fragment without sequelae[64]	0.20%
Bleeding requiring blood transfusion[64,246,287]	0.08%–1.00%
AV fistula requiring intervention[64]	0.16%
Coronary sinus dissection[64]	0.13%
Pneumothorax requiring chest tube[287]	1.10%
Worsening tricuspid valve function[287]	0.32%–0.59%
Pulmonary embolism[246]	0.24%–0.59%

Figure 1

CLASS (STRENGTH) OF RECOMMENDATION

CLASS I (STRONG) — **Benefit >>> Risk**

Suggested phrases for writing recommendations:
- Is recommended
- Is indicated/useful/effective/beneficial
- Should be performed/administered/other
- Comparative-Effectiveness Phrases†:
  - Treatment/strategy A is recommended/indicated in preference to treatment B
  - Treatment A should be chosen over treatment B

CLASS IIa (MODERATE) — **Benefit >> Risk**

Suggested phrases for writing recommendations:
- Is reasonable
- Can be useful/effective/beneficial
- Comparative-Effectiveness Phrases†:
  - Treatment/strategy A is probably recommended/indicated in preference to treatment B
  - It is reasonable to choose treatment A over treatment B

CLASS IIb (WEAK) — **Benefit ≥ Risk**

Suggested phrases for writing recommendations:
- May/might be reasonable
- May/might be considered
- Usefulness/effectiveness is unknown/unclear/uncertain or not well established

CLASS III: No Benefit (MODERATE) — **Benefit = Risk**
(Generally, LOE A or B use only)

Suggested phrases for writing recommendations:
- Is not recommended
- Is not indicated/useful/effective/beneficial
- Should not be performed/administered/other

CLASS III: Harm (STRONG) — **Risk > Benefit**

Suggested phrases for writing recommendations:
- Potentially harmful
- Causes harm
- Associated with excess morbidity/mortality
- Should not be performed/administered/other

LEVEL (QUALITY) OF EVIDENCE‡

LEVEL A
- High-quality evidence‡ from more than 1 RCT
- Meta-analyses of high-quality RCTs
- One or more RCTs corroborated by high-quality registry studies

LEVEL B-R — **(Randomized)**
- Moderate-quality evidence‡ from 1 or more RCTs
- Meta-analyses of moderate-quality RCTs

LEVEL B-NR — **(Nonrandomized)**
- Moderate-quality evidence‡ from 1 or more well-designed, well-executed nonrandomized studies, observational studies, or registry studies
- Meta-analyses of such studies

LEVEL C-LD — **(Limited Data)**
- Randomized or nonrandomized observational or registry studies with limitations of design or execution
- Meta-analyses of such studies
- Physiological or mechanistic studies in human subjects

LEVEL C-EO — **(Expert Opinion)**

Consensus of expert opinion based on clinical experience

COR and LOE are determined independently (any COR may be paired with any LOE).

A recommendation with LOE C does not imply that the recommendation is weak. Many important clinical questions addressed in guidelines do not lend themselves to clinical trials. Although RCTs are unavailable, there may be a very clear clinical consensus that a particular test or therapy is useful or effective.

* The outcome or result of the intervention should be specified (an improved clinical outcome or increased diagnostic accuracy or incremental prognostic information).

† For comparative-effectiveness recommendations (COR I and IIa; LOE A and B only), studies that support the use of comparator verbs should involve direct comparisons of the treatments or strategies being evaluated.

‡ The method of assessing quality is evolving, including the application of standardized, widely used, and preferably validated evidence grading tools; and for systematic reviews, the incorporation of an Evidence Review Committee.

COR indicates Class of Recommendation; EO, expert opinion; LD, limited data; LOE, Level of Evidence; NR, nonrandomized; R, randomized; and RCT, randomized controlled trial.

Figure 2

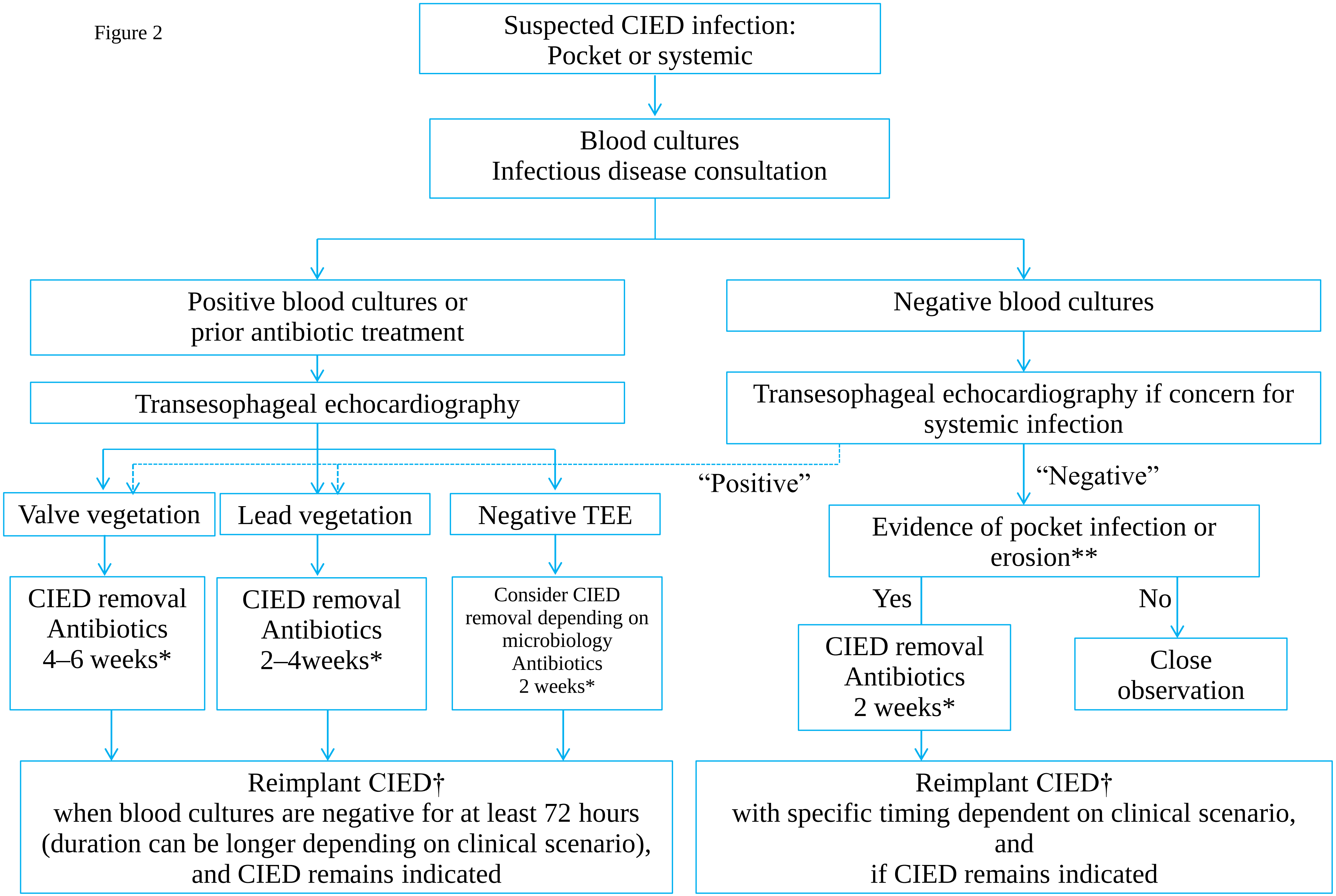

Suspected CIED infection:
Pocket or systemic
Blood cultures
Infectious disease consultation
Positive blood cultures or
prior antibiotic treatment
Negative blood cultures
Transesophageal echocardiography
Transesophageal echocardiography if concern for
systemic infection
"Positive"
"Negative"
Valve vegetation
Lead vegetation
Negative TEE
Evidence of pocket infection or
erosion**
Yes
No
CIED removal
Antibiotics
4–6 weeks*
CIED removal
Antibiotics
2–4weeks*
Consider CIED
removal depending on
microbiology
Antibiotics
2 weeks*
CIED removal
Antibiotics
2 weeks*
Close
observation
Reimplant CIED†
when blood cultures are negative for at least 72 hours
(duration can be longer depending on clinical scenario),
and CIED remains indicated
Reimplant CIED†
with specific timing dependent on clinical scenario,
and
if CIED remains indicated

Figure 3

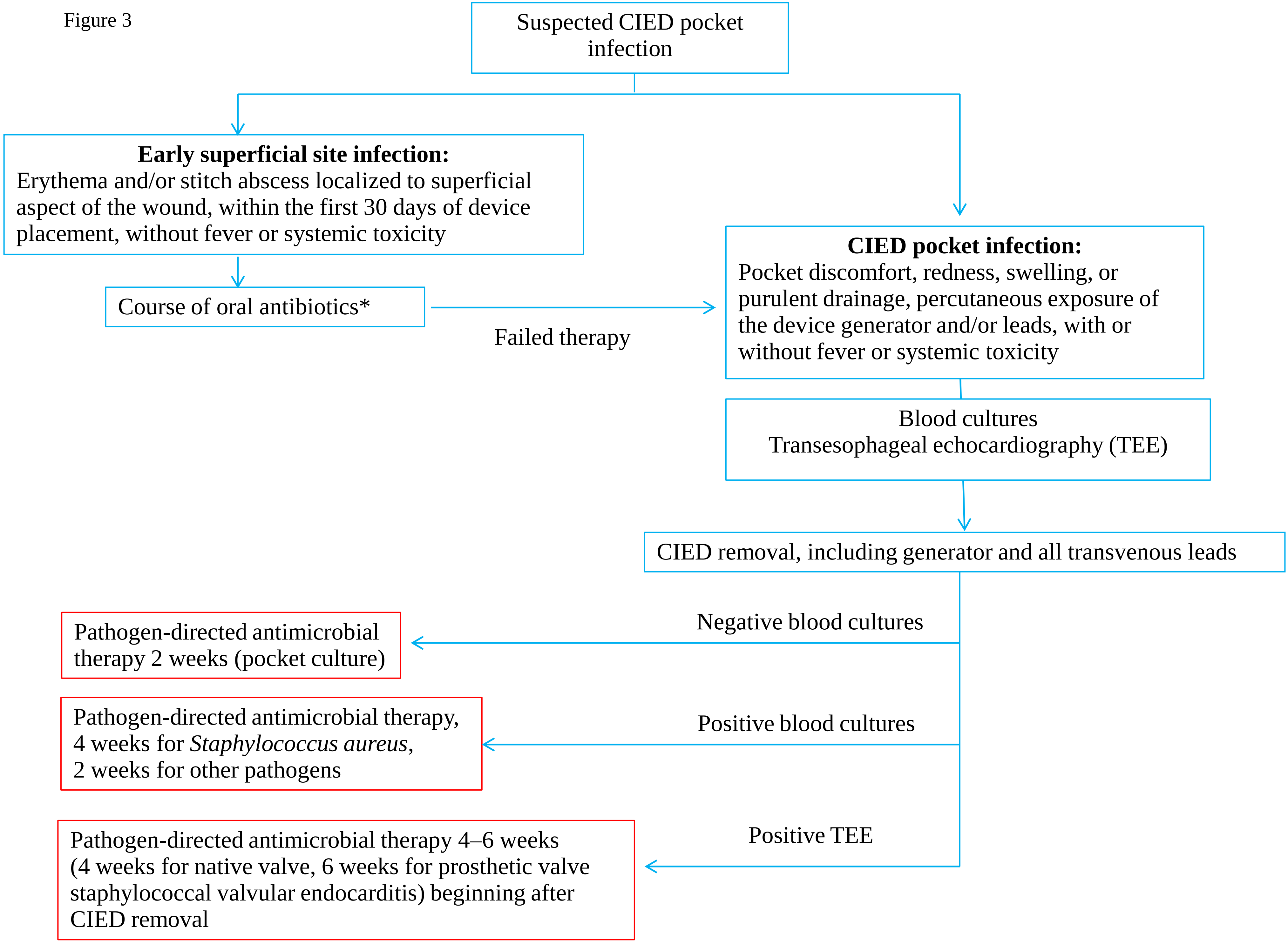
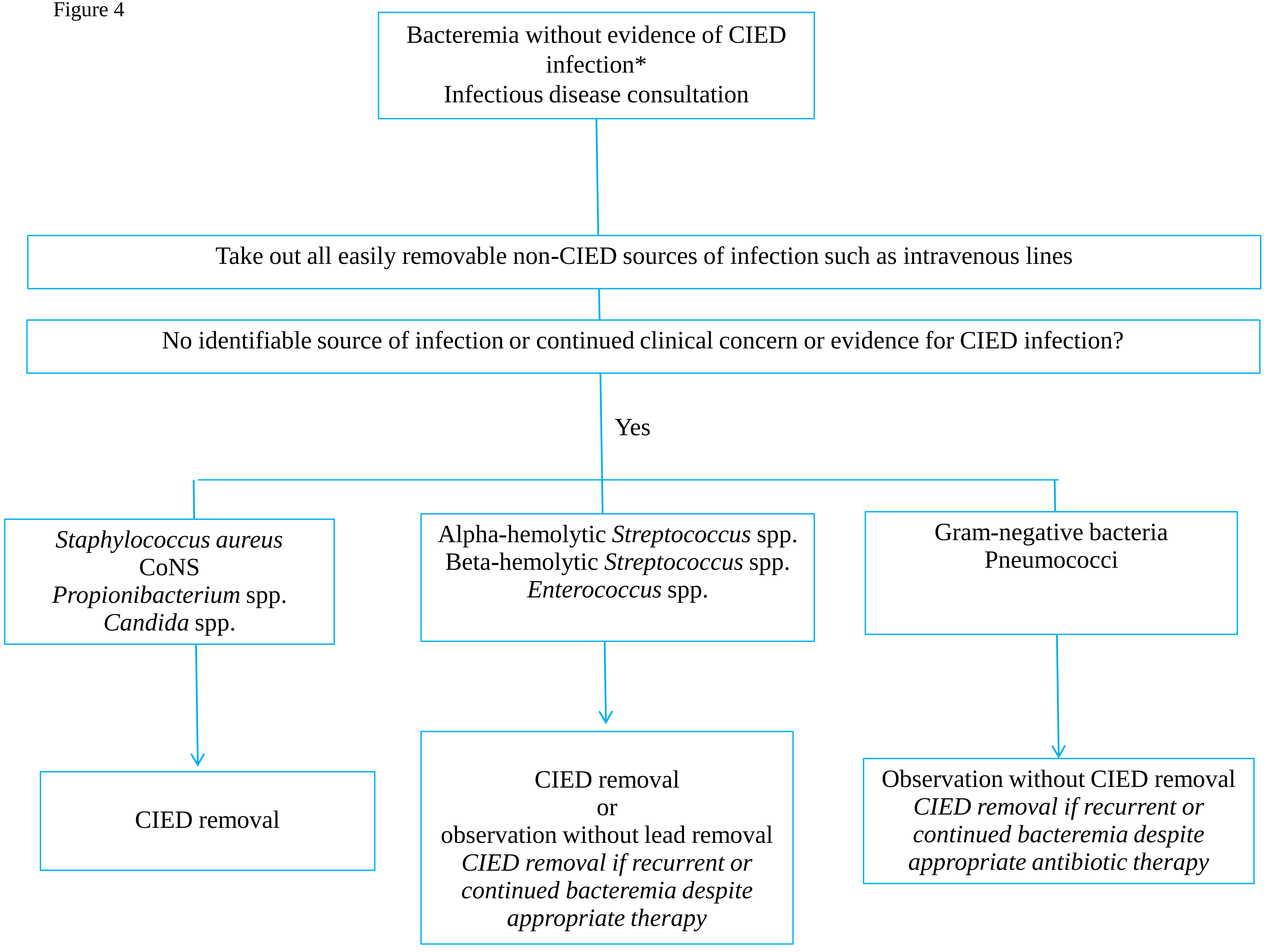

Suspected CIED pocket infection
Early superficial site infection:
Erythema and/or stitch abscess localized to superficial aspect of the wound, within the first 30 days of device placement, without fever or systemic toxicity
Course of oral antibiotics*
Failed therapy
CIED pocket infection:
Pocket discomfort, redness, swelling, or purulent drainage, percutaneous exposure of the device generator and/or leads, with or without fever or systemic toxicity
Blood cultures
Transesophageal echocardiography (TEE)
CIED removal, including generator and all transvenous leads
Negative blood cultures
Pathogen-directed antimicrobial therapy 2 weeks (pocket culture)
Positive blood cultures
Pathogen-directed antimicrobial therapy, 4 weeks for *Staphylococcus aureus*, 2 weeks for other pathogens
Positive TEE
Pathogen-directed antimicrobial therapy 4–6 weeks (4 weeks for native valve, 6 weeks for prosthetic valve staphylococcal valvular endocarditis) beginning after CIED removal

Figure 4



Bacteremia without evidence of CIED infection*
Infectious disease consultation
Take out all easily removable non-CIED sources of infection such as intravenous lines
No identifiable source of infection or continued clinical concern or evidence for CIED infection?
Yes
Staphylococcus aureus
CoNS
Propionibacterium spp.
Candida spp.
Alpha-hemolytic *Streptococcus* spp.
Beta-hemolytic *Streptoccocus* spp.
Enterococcus spp.
Gram-negative bacteria
Pneumococci
CIED removal
CIED removal
or
observation without lead removal
CIED removal if recurrent or continued bacteremia despite appropriate therapy
Observation without CIED removal
CIED removal if recurrent or continued bacteremia despite appropriate antibiotic therapy

Appendix 1 Author disclosure table

Writing group member	Institution	Consultant/Advisory board/Honoraria	Speakers' bureau	Research grant	Fellowship support	Stock options/Partner	Board Mbs/Other
Fred M. Kusumoto, MD, FHRS, FACC (Chair)	Mayo Clinic, Jacksonville, Florida	None	None	None	None	None	None
Mark H. Schoenfeld, MD, FHRS, FACC, FAHA, CCDS (Vice-Chair)	Yale University School of Medicine, New Haven, Connecticut	1: United HealthCare Services	None	None	None	None	None
Bruce L. Wilkoff, MD, FHRS, CCDS (Vice-Chair)	Cleveland Clinic Lerner College of Medicine of Case Western Reserve University, Cleveland, Ohio	2: Abbott; 2: Medtronic; 2: Spectranetics	None	None	None	3: Medtronic	None
Charles I. Berul, MD, FHRS	Children's National Medical Center, Washington, District of Columbia	1: Medtronic; 2: American Heart Association	None	2: Medtronic	None	None	1: Up to Date
Ulrika M. Birgersdotter-Green, MD, FHRS	UC San Diego Health, La Jolla, California	1: BIOTRONIK; 2: Abbott; 2: Medtronic	1:Medtronic; 2: Abbott	2: Boston Scientific	None	None	None
Roger Carrillo, MD, MBA, FHRS	University of Miami, Coral Gables, Florida	1: Sensormatic; 1: Sorin Group; 1: Medtronic; 1: Boston Scientific; 4: Spectranetics	None	4: Abbott	None	None	None
Yong-Mei Cha, MD	Department of Cardiovascular Diseases, Mayo Clinic School of Medicine, Rochester, Minnesota	None	None	None	None	None	None
Jude Clancy, MD	Yale University School of Medicine, New Haven,	1: Spectranetics	1: Abbott; 1: Boston Scientific; 2: Spectranetics	None	None	None	None

Writing group member	Institution	Consultant/Advisory board/Honoraria	Speakers' bureau	Research grant	Fellowship support	Stock options/Partner	Board Mbs/Other
	Connecticut						
Jean-Claude Deharo, MD, FESC	CHU La Timone, Service de Cardiologie, Marseille, France, and AMU, UMR MD2, Faculté de Médecine Nord, Marseille, France	1: Livanova; 1: Abbott; 1: BIOTRONIK; 1: Boston Scientific; 1: Medtronic	None	None	None	None	None
Kenneth A. Ellenbogen, MD, FHRS	Virginia Commonwealth University Medical Center, Richmond, Virginia	1: Capricor; 1: Heart Rhythm Society; 1: American Heart Association; 2: Boston Scientific; 3: Merit Medical	1: Abbott; 1: AtriCure; 1: BIOTRONIK; 1: ZOLL Medical Corporation; 2: Biosense Webster; 2: Boston Scientific; 2: Medtronic	2: Daiichi-Sankyo; 2: National Institutes of Health; 3: Biosense Webster; 3: Medtronic; 3: Baim Institute for Clinical Research; 4: Boston Scientific	None	None	1: Elsevier; 1: Wiley-Blackwell
Derek Exner, MD, MPH, FHRS	University of Calgary, Calgary, Canada	1: Abbott; 1: GE Healthcare; 1: Medtronic	None	5: Abbott; 5: GE Healthcare; 5: Medtronic	5: Medtronic	3: HelpWare; 5: Analytics 4 Life	0: Analytics 4 Life; 0: GE Healthcare; 0: HelpWare
Ayman A. Hussein, MD, FACC	Cleveland Clinic, Cleveland, Ohio	None	None	None	None	None	None
Charles Kennergren, MD, PhD, FETCS, FHRS	Sahlgrenska University Hospital, Gothenburg, Sweden	1: BIOTRONIK; 2: Medtronic; 3: Boston Scientific; 3: Spectranetics	None	None	None	None	None

Writing group member	Institution	Consultant/Advisory board/Honoraria	Speakers' bureau	Research grant	Fellowship support	Stock options/Partner	Board Mbs/Other
Andrew Krahn, MD, FRCPC, FHRS	The University of British Columbia, Vancouver, Canada	0: Medtronic; 0: Boston Scientific	None	1: Boston Scientific; 2: Medtronic	None	None	0: Canadian Cardiovascular Society
Richard Lee, MD, MBA	Saint Louis University, St. Louis, Missouri	None	None	None	None	None	None
Charles J. Love, MD, CCDS, FHRS, FACC, FAHA	Johns Hopkins Hospital, Baltimore, Maryland	1: Abbott; 1: ConvaTec; 2: Medtronic; 2: Spectranetics	None	None	None	None	None
Ruth A. Madden, MPH, RN	Cleveland Clinic, Cleveland, Ohio	1: Medtronic	None	None	None	None	None
Hector Alfredo Mazzetti, MD	Hospital Fernandez, Buenos Aires, Argentina	None	None	None	None	None	None
JoEllyn Carol Moore, MD, FACC	Minneapolis Heart Institute, Abbott Northwestern Hospital, Part of Allina Health, Minneapolis, Minnesota	None	None	None	None	None	None
Jeffrey Parsonnet, MD	Dartmouth-Hitchcock Medical Center, Lebanon, New Hampshire	None	None	5: Procter & Gamble	None	None	None
Kristen K. Patton, MD	University of Washington, Seattle, Washington	1: American Board of Internal Medicine; 1: FDA Circulatory System Devices Panel	None	None	None	None	0: American Heart Association

Writing group member	Institution	Consultant/Advisory board/Honoraria	Speakers' bureau	Research grant	Fellowship support	Stock options/Partner	Board Mbs/Other
Marc A. Rozner, PhD, MD, CCDS	The University of Texas MD Anderson Cancer Center, Houston, Texas	None	None	None	None	None	None
Kimberly A. Selzman, MD, MPH, FHRS, FACC	George E. Wahlen Department of Veterans Affairs Medical Center, Salt Lake City, Utah	None	None	None	None	None	None
Morio Shoda, MD, PhD	Tokyo Women's Medical University, Shinjuku, Japan	1: Abbott; 1: Boston Scientific; 1: Cook Medical	None	None	None	None	None
Komandoor Srivathsan, MD	Mayo Clinic, Phoenix, Arizona	0: Abbott	None	None	None	None	None
Neil F. Strathmore, MBBS, FHRS	Royal Melbourne Hospital, Parkville, Victoria, Australia	None	None	None	None	None	None
Charles D. Swerdlow, MD, FHRS	Cedars-Sinai Medical Center, Los Angeles, California	1: Boston Scientific; 1: Medtronic	None	None	None	None	1: Medtronic
Christine Tompkins, MD	University of Colorado School of Medicine, Aurora, Colorado	1: Medtronic; 1: Spectranetics	None	None	None	None	None

Writing group member	Institution	Consultant/Advisory board/Honoraria	Speakers' bureau	Research grant	Fellowship support	Stock options/Partner	Board Mbs/Other
Oussama Wazni, MD, MBA	Cleveland Clinic, Cleveland, Ohio	None	None	None	None	None	None

Number Value: 0 = $0; 1 = ≤ $10,000; 2 = > $10,000 to ≤ $25,000; 3 = > $25,000 to ≤ $50,000; 4 = > $50,000 to ≤ $100,000; 5 = > $100,000

Appendix 2 Reviewer disclosure table

Peer reviewer	Institution	Consultant/Advisory board/Honoraria	Speakers' bureau	Research grant	Fellowship support	Stock options/ Partner	Board Mbs/ Other
Adrian M. Baranchuk, MD, FACC, FRCPC, FCCS	Queen's University, Kingston, Ontario, Canada	0: Bayer HealthCare; 0: Boehringer Ingelheim; 0: Medtronic	None	1: Bayer HealthCare; 5: Medtronic	None	None	None
Carina Blomström-Lundqvist, MD, PhD	Uppsala University, Uppsala, Sweden	1: Bayer Schering Pharma; 1: Biosense Webster; 1: Boston Scientific; 1: Bristol-Myers Squibb; 1: Medtronic; 1: Merck Sharp & Dohme; 1: Pfizer; 1: Sanofi	None	1: Cardiome Pharma Corp./Astellas; 1: Medtronic	None	None	None
Frank A. Fish, MD	Vanderbilt Heart and Vascular Institute, Nashville, Tennessee	None	1: Abbott	None	None	None	None
James M. Horton, MD	Carolinas Medical Center, Charlotte, North Carolina	None	None	None	None	None	None
Roberto Keegan, MD	Hospital Privado del Sur, Bahía Blanca, Argentina	1: Abbott	None	None	None	None	None
Miguel A. Leal, MD, FACC, FHRS	University of Wisconsin, Madison, Wisconsin	None	None	None	None	None	None
Nigel Lever, MBChB, FRACP	Green Lane Cardiovascular Service, Auckland City Hospital; University of Auckland, Auckland, New Zealand	None	None	None	None	None	None
Aman Mahajan, MD, PhD, MBA	UCLA Perioperative Services, UCLA Cardiac Arrhythmia Center and UCLA Neurocardiology Research Center, UCLA Health, Los Angeles, California	None	None	None	None	None	None
Marc R. Moon, MD	Washington University, St. Louis, Missouri	None	None	None	None	None	None
Siva K. Mulpuru, BS, MB, MBBS, MD, FHRS, CCDS	Mayo Clinic, Tucson, Arizona	None	None	2: National Institutes of Health	None	None	None

Number Value: 0 = \$0; 1 = ≤ \$10,000; 2 = > \$10,000 to ≤ \$25,000; 3 = > \$25,000 to ≤ \$50,000; 4 = > \$50,000 to ≤ \$100,000; 5 = > \$100,000

Appendix 3 Current recommendations for Medtronic Fidelis and Abbott Riata leads
Abbott Riata Leads

- Programming Changes
  - Use SecureSense right ventricular (RV) lead noise discrimination to monitor for lead noise.
  - Program an unused electrogram (EGM) channel to RV coil to superior vena cava to store EGMs that might detect noise.
  - Program the Pacing Lead impedance range to 200–1000 Ω. Program the high-voltage (HV) lead impedance to 25 Ω above and below the stable HV impedance range.
  - Ensure episode trigger for ventricular tachycardia (VT)/ventricular fibrillation (VF) episodes is set to "high."
  - Vibratory patient alert triggers should be on (eg, out-of-range lead impedance, lead noise detected).
  - Turn RV autocapture to "on" or to "monitor" in order to closely monitor the pacing lead thresholds.
  - Increase detection criteria for VF detection intervals from 24 to 30 intervals.
- At the time of generator change, examine the visible portion of the lead for any insulation damage. A high-voltage shock may be performed to ensure integrity and functionality of the ICD system. Also consider implanting a device that has automatic vector switching capability that allows the shock vector to be automatically changed if a short circuit is detected.
- At the time of a remote transmission or clinic visit, review stored EGMs and any VT/VF EGMs to assess for noise, and review the heart rate histogram to assess for short, nonphysiological RR intervals. Review the pacing and HV lead impedance trends. Review the R sensing amplitude trend and the RV autocapture trend.
- Patients should be followed remotely with remote monitoring (Merlin.net).
- If lead externalization is present, but the lead is electrically intact and functional, the lead does not require replacement.
- If the lead exhibits electrical failure, it should be replaced. The decision to cap the lead or extract should be based upon multiple factors, including the patient's preferences, the patient's comorbidities, the expertise of the medical center, and the physician.

Medtronic Fidelis leads

- Patients should be followed remotely with remote monitoring (CareLink).
- All patients with a Sprint Fidelis lead should have the Lead Integrity Alert (LIA) turned on to prevent inappropriate therapies.
- Ensure that the high-voltage lead impedance alert is programmed "on" with a maximum setting of 100 Ω.
- If a lead fracture is suspected or confirmed, immediate patient attention is strongly recommended.
- If a Fidelis lead fracture of any type has occurred, implantation of a new high-voltage lead with or without extraction of the fractured Fidelis lead is recommended. If a Fidelis

lead has a pace-sense conductor fracture, there is an increased risk of a future high voltage conductor fracture in that lead. Therefore, placement of a new pace-sense lead does not mitigate this potential future risk.

- If the lead has normal function and there is no evidence of a lead fracture, the recommendation is to take no action
- At the time of a generator change or device upgrade, if the lead has normal function and there is no evidence of a lead fracture, multiple factors should be considered and taken into consideration when determining the treatment strategy. The 4 possible treatment options include reusing the Fidelis lead; implanting a new ICD lead and capping the Fidelis lead; implanting a new pace-sense lead (although there is an increased risk of subsequent high-voltage conductor fracture in a lead with a prior pace-sense conductor fracture); and extraction of the Fidelis lead and implantation of a new lead if warranted by individual patient circumstances.
- If the decision to extract the Fidelis lead has been made, the Medtronic Independent Physician Quality Panel recommends that it be performed by a physician with extensive lead extraction experience.[i]

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[i] Wilkoff BL, Love CJ, Byrd CL, et al. Transvenous lead extraction: Heart Rhythm Society expert consensus on facilities, training, indications, and patient management. Heart Rhythm 2009;6:1085–1104.

Appendix 4 Lead Survival Evidence Table

Study name or author	Year	PubMed PMID	Study type	Study size	Inclusion criteria	Endpoints	Findings	Outcome results	Statistical values	Limitations	Comments
General											
Aizawa	2015	26218183	Retrospective	735 with CIED	All single center	Lead failure	38 lead failures in 31 patients after a mean follow-up of 5.8 years	Age: HR 0.969 (95% CI 0.95–0.988) Recalled: HR 7.22 (95% CI 3.025–17.22)	95% CI; *P*<.5	Retrospective, single center	Lead failures more common in ICD leads. Lead failure with certain lead models.
Cohen	2015	26028656	Retrospective	3802 with CIED	All, single center	Lead failure Mortality	153 leads failed (3.5%)	Increased mortality with recalled leads (*P*=.01)	*P*<.05	Retrospective single center limited follow-up data	Variability in lead performance among different manufacturers. Recalled ICD lead associated with higher mortality.
Ellenbogen	2013	24099976	Retrospective	12,793	ICD with LIA	Lead alerts	LIA identified 179 alerts with 84 lead system events	LIA identified >66% more lead system events than impedance monitoring alone	*P*<.05 Exact binomial 95% CI	Remote monitoring data only, limited clinical data	Use of LIA increased detection rate of lead system events
Fazal	2013	23138013	Retrospective	229 ICD leads: 113 Fidelis, 106 Riata	Riata/Fidelis	Lead failure	Comparable failure rates: Riata 2.71%/year; Fidelis 2.60%/year	Similar failure rates and death with Riata and Fidelis	*P*<.05	Single center	No differences in outcomes between Riata and Fidelis
Good	2016	26990515	Prospective, nonrandomized registry	3933 leads in 3840 patients	ICD, CRT-D	Adverse events	The most common AEs were oversensing (23, 0.58%), conductor fracture (14, 0.36%), failure to capture (13, 0.33%), lead dislodgement (12, 0.31%), insulation breach (10, 0.25%), and abnormal pacing impedance (8, 0.20%).	The estimated cumulative survival probability was 96.3% at 5 years after implantation for Linox leads	*P*<.05	Limited clinical data	Linox lead family with few lead-related adverse events
Janson	2014	24140671	Single center, retrospective	120 leads	ICD leads	Lead failure	47 small diameter ≤8F, 73 >8F Fidelis leads with lower 3-year (69% vs 92%, *P*<.01) and 5-year (44% vs 86%, *P*<.01) survival rates	Lead design (Fidelis) rather than small diameter affected lead performance	*P*<.05	Single center	Lead design rather than lead diameter important
Kramer	2015	2651866	Retrospective, multicenter	2653 patients: (median age, 65 years; males, 73%) included 445 St. Jude, 1819 Medtronic, and 389 Boston Scientific leads.	ICD leads	Lead failure	After a median of 3.2 years, lead failure was 0.28%/year (95% CI, 0.19–0.43), with no statistically significant differences among manufacturers.	Current ICD leads are reliable	*P*<.05		Current ICD leads are reliable
Lovelock	2014	24953380	Retrospective, ALTITUDE registry	60,219 ICD patients with 37 months of follow-up, 7458 with generator exchange	ICD leads	Lead failure	After generator replacement, the rate of lead alerts was more than 5-fold higher than in the controls with leads of the same age without generator	Routine generator replacement is associated with a 5-fold higher risk of lead alerts compared with age-matched leads without generator replacement.	*P*<.05; Cox proportional hazards model	Registry, limited clinical data	Increased surveillance after generator replacement and the development of techniques to minimize the risk of lead damage during generator replacement.

							replacement (HR 5.19 [95% CI 3.45–7.84]). A large number of leads alerted within 3 months of generator replacement. Lead alerts were more common in patients with single-chamber ICDs than in dual-chamber ICDs and in younger patients.				
Noti	2016	26738946	Single center, retrospective	485 ICD leads (93 Biotronik Linox, 190 Boston, and 202 Medtronic Quattro)	ICD or CRT-D	Lead failure	8 cases of lead failures in the Biotronik group (index case of conductor externalization, 6 cases of nonphysiological high-rate sensing, and 1 case of high-voltage conductor fracture).	5-year lead survival: Biotronik 88%, Boston 97.5%, and Medtronic 100%	Cox proportional hazards model A 2-sided *P* value <.05 was considered statistically significant	Single center	Biotronik Linox with higher failure rates
Providencia	2015	26518666	Meta-analysis	17 studies with 49,871 ICD leads	ICD leads	Lead failure	Fidelis: 2.23%/year; Riata: 1.17%/year, Durata: 0.45%/year, Endotak: 0.36%/year; Quattro: 0.29%/year	A higher event rate was documented with the Riata (1.0% per year increase) and Sprint Fidelis (>2.0%/year increase) leads compared with nonrecalled leads	Raw mean difference of the incidence of lead failure and respective 95% CIs. The Mantel-Haenszel random-effects model was used	Observational studies, heterogeneity-Tau 0.86	Currently used ICD leads with low similar failure rates
Rordof	2013	23063430	Single center, retrospective	890 ICD leads: 190 Sprint Fidelis, 182 Riata/Riata ST, 99 Optim (Riata Optim/Durata) and 419 standard-diameter leads	ICD leads	Lead failure	During a median follow-up of 33 months, the overall failure rate was 6.3%. The failure rate was significantly higher in Sprint Fidelis leads than in both standard-diameter (4.8%/year vs 0.8%/year; *P*<.001) and Riata/Riata ST (4.8%/year vs 2.6%/year; *P*=.03) leads.	Small-diameter (HR 5.03, 2.53–10.01, *P*<.001), Sprint Fidelis (HR 6.3, 95% CI 3.1–13.3; *P*<.001), or Riata/Riata ST (HR 4.5, 95% CI 1.9–10.5; *P*=.001) leads and age <60 years (HR 2.3, 95% CI 1.3–4.3; *P*=.005) were found to independently increase the risk of lead failure.	*P*<.05	Single center, retrospective	Small diameter leads with higher failure rates
Sprint Fidelis											
Birnie	2012	22311781	23 Canadian centers	3169 Fidelis leads	Fidelis leads	Lead failure	A total of 3169 Sprint Fidelis leads were implanted in 11 centers, with a total of 251 failures. Lead failure rates at 3, 4, and 5 years were 5.3%, 10.6%, and 16.8%, respectively.	Women had a higher risk of failure (HR 1.51, 95% CI 1.14–2.04; *P*=.005). The rate of Fidelis failure continues to increase over time, with failures approaching 17% at	*P*<.05	Retrospective	Accelerating lead failure rate with Fidelis

							The rate of lead failure continues to accelerate (*P*<.001).	5 years.			
Hauser	2012	22396584	3 center databases	2710 ICD leads	Fidelis or Quattro leads	Lead failure	84 of 1035 Fidelis (8.1%) and 23 of 1675 Quattro (1.4%) leads failed.	In the propensity-matched analysis, the automated alert algorithm triggered 22 months after the first Fidelis implant and more than 1 year before the lead was recalled.	Simulated prospective propensity matched, *P*<.05	Simulated	Algorithm could be useful for identifying lead failure.
Hauser	2011	21242478	3 center databases	2691 ICD leads: 1023 Fidelis and 1668 Quattro leads	Fidelis or Quattro leads	Lead failure	The failure rate for Fidelis leads was 2.81%/year compared with 0.43%/year for Quattro leads (*P*<.0001) The survival of Fidelis leads at 4 years was 87.0% (95% CI, 83.6–90.1) compared with 98.7% (95% CI, 97.9–99.4) for Quattro leads (*P*<.0001).	Multivariate predictors of Fidelis failure were younger age (HR 0.98, 95% CI 0.96–0.99), female sex (HR 0.61, 95% CI 0.40–1.00), and cardiac disease (*P*=.041).	Survival probabilities were estimated by the Kaplan-Meier method with 95% CI. Cox proportional hazards	Retrospective	Survival of Fidelis leads continues to decline over time and failure more likely in women, younger patients, and better LV function.
Krahn	2016	27154229	21,500 Fidelis leads from a remote monitoring cohort	21,500 ICD leads, 2988 with a generator change	Fidelis leads, remote monitoring	Lead failure	Of the 2988 implanted leads in each group, there was no statistical difference in the number of lead fractures between cases and controls (replacement, n=227; no replacement, n=257; Fisher's exact, *P*=.169). Lead survival analysis demonstrated that lead performance since the first replacement procedure did not differ from that of the matched control group.	86.5% survival at 5 years after device replacement and 83.1% in no device replacement matched cohort	Kaplan Meier survival curves	Propensity matching	Generator change does not affect Fidelis survival.
Morrison	2011	21737019	3 center databases	2671 patients (1030 Fidelis, 1641 Quattro)	Fidelis/Quattro ICD	Survival	No deaths were associated with 85 Fidelis and 23 Quattro failures. At 4 years, survival was diminished in patients with Fidelis compared with Quattro leads (80.7% vs 83.9%, *P*=.025).	After adjustment for factors associated with mortality, survival was similar between groups. One hundred percent pacing was not associated with mortality.	Cox proportional hazards; *P*<.05	Retrospective	Similar survival between Fidelis and Quattro groups
Parkash	2012	23159551	Post-hoc analysis of the RAFT study	818 patients received Fidelis: 405 ICD, 413 CRT-D	Fidelis lead	Lead failure	47 confirmed defibrillation lead fractures; 45 were Fidelis leads (5.5% of Fidelis leads).	Fracture more likely with ≥2 leads	Cox proportional hazards	Retrospective	Fidelis fracture is more likely with CRT-D implant.

							The overall rate of fracture in the ICD group was 3.2% compared with 7.8% in the ICD-CRT group (HR 2.42, 95% CI 1.27–4.61; *P*=.006).				
Parkash	2010	20497979	25 Canadian centers	6237 Fidelis leads and 310 lead failures	Fidelis lead	Lead failure and complications	310 lead failures found in 6237 Sprint Fidelis leads in Canada (4.97%) over a 40-month follow-up. The lead was removed in 248 cases (53%), by simple traction in 61% and by laser lead extraction in 33%. Complications were encountered in 14.5% of the lead revisions; 7.25% of these were major, whereas 7.25% were minor.	The overall risk of complications (19.8%) was greater in those who underwent lead removal at the time of revision than in those whose leads were abandoned (8.6%; *P*=.0008).	*P*<.05	Retrospective	The overall rate of major complications that arose from lead revision due to the Sprint Fidelis advisory was significant.
Piot	2015	25858538	Multicenter registry, retrospective	986 Fidelis	Fidelis lead	Lead failure	Over a mean follow-up of 51.4±20 months, the mean fracture rate was 11.2%, and increased over time: 1.2% at 1 year, 3.8% at 2 years, 7.4% at 3 years, 13.9% at 4 years, and 20.7% at 5 years.	Younger age (<40 years) was associated with a higher risk of fracture compared with patients <40 years. Patients aged 40–60 years had a relative risk of 0.53 (95% CI 0.29–0.98), and patients >60 years had a relative risk of 0.45 (95% CI 0.24–0.84) and subpectoral implantation (at 3 years) with a relative risk of 2.35 (95% CI 1.29–4.28).	*P*<.05 HRs and their 95% CIs are provided for both univariate and multivariable analyses.	Retrospective	Lead fracture increases with dwell time. Fracture more common in younger patients (<40 years old), subpectoral implant.
Verlato	2013	23434626	Multicenter, retrospective	976 ICD leads (508 Fidelis; 468 Quattro	Fidelis lead	Lead failure, survival	Kaplan-Meier patient survival differed between the 2 lead groups (80±2% in Fidelis leads vs 70±4% in the Sprint Quattro leads at 4 years, *P*=.002). Multivariate analyses showed that mortality was neither associated with lead type nor with diagnosed failed lead. The annual rate of lead failure was	Over a mean follow-up of 27±18 months, 141 deaths occurred in the overall population. There were no deaths among the patients with diagnosed failing lead.	Kaplan Meier for lead survival	Retrospective	Low failure rate (0.2%/year) for Quattro

							1.8%/ patient-year for Fidelis leads and 0.2% for the Sprint Quattro leads.				
Riata											
Abdelhadi	2013	23128017	Multicenter (7 centers), retrospective	1081 Riata leads	Riata lead	Lead failure	62 of 774 Riata (8.0%) and 5 of 307 Riata ST (1.6%) leads failed. 47 of 67 lead failures (70.1%) were caused by electrical malfunction, and 20 lead failures (29.9%) were due to externalized conductors (ECs) that were electrically intact.	Of 110 leads examined fluoroscopically, externalized conductors were found in 26 of 81 Riata (32%) and 1 of 29 Riata ST (3.4%) leads. Of 26 Riata leads with externalized conductors, 7 (27%) were malfunctioning.	Kaplan Meier for survival, *P*<.05	Retrospective	
Bennett	2013	23973950	15 Canadian centers	3981 leads (3477 Durata, 504 Riata ST Optim)	Optim coated leads	Lead failure	The annual rate of lead failure was 0.27%/year for Riata ST Optim leads and 0.24%/year for Durata leads.	2 inappropriate shocks but no deaths	*P*<.05, 2-sided	Retrospective	Optim covering appears to prevent externalized conductors.
Cairns	2014	25131665	Prospective registry	11,016 leads in 10,835 patients	Optim coated leads	Lead failure	During a median follow-up of 3.2 years, there were 51 mechanical failures (0.46%), with 99.0% survival free of this outcome by 5 years of follow-up.	Freedom from conductor fracture was identified in 99.4% and from all-cause abrasion in 99.8% of the leads, and there were no reports of externalized conductors.	*P*<.05	Retrospective	Optim covering appears to prevent externalized conductors.
Cheung	2013	23792596	Single center, retrospective	314 patients	Riata	Lead failure	During a median follow-up of 4.1 years, the Riata lead electrical failure rate was 6.6%. The rate of externalized conductors among failed leads was 57%.	Female sex (HR 2.7, 95% CI 1.1–6.7; *P*=.04) and age (HR 0.95, 95% CI 0.92–0.97; *P*<.001) were multivariate predictors of lead failure.	*P*<.05, survival with Kaplan Meier	Retrospective	Externalization of conductors is associated with electrical failure.
Forleo	2014	24042736	Single center, retrospective/prospective (fluoroscopy)	234 patients with 413 Optim coated leads	Optim coated leads	Lead failure	The overall incidence of lead failure was 1.2 vs 0.3 per 100 lead-years, for high- and low-voltage leads, respectively (*P*=.1).	151 patients agreed to undergo fluoroscopy screening; none of the 264 analyzed. Optim leads were found to have no fluoroscopically visible structural defects after an average of 31 months postimplant.	*P*<.05	Retrospective	Optim with few lead failures and no cable externalization
Hauser	2013	23871705	MAUDE inquiry	59 leads with fractures in the IS-1 leg	MAUDE listing	Lead failure	Outer coil conductor fractures accounted for the majority (51 of 59, 86%). Oversensing and noise were common	Young age and subpectoral implant appeared to be associated with failure.	NA	Database search	Design changes improved lead performance.

							signs, and 81% of the patients received inappropriate				
Liu	2013	24012025	Single center, retrospective	329 patients with Riata and 76 with externalized conductors	Externalized conductor	Lead failure	Externalization was present in 76 patients (23%), 24 of whom (32%) had the Riata lead replaced shortly after screening. The remaining 52 patients were followed for 7.9±2.9 months, during which 5 patients were lost to follow-up and 2 patients exhibited electrical lead failure resulting in lead replacement, an electrical failure rate of 6.4%/year in externalized leads.	Externalization associated with a high failure rate (6%/year)	NA-cohort natural history description	Retrospective	Externalization associated with a high failure rate (6%/year) Authors recommend prophylactic replacement.
Lovelock	2015	26285670	Single center, retrospective	1042 Riata leads, 153 underwent generator change	Riata lead	Lead failure	Conductor externalization was noted in 21.5% of Riata leads in the ICD exchange cohort, which did not differ from the control group (19.2%; *P*=.32). Two leads failed in the first year after generator replacement (1.5%), which did not differ significantly from the control group (2.0%; *P*=.57).	Commanded shock at DFT testing did not change the clinical strategy.	Cox proportional hazards and Kaplan Meier	Single center, retrospective	Generator change does not change lead failure rate.
Parkash	2016	27733493	Canadian registry	3763 Riata ICD leads	Riata ICD leads	Lead failure	The overall electrical failure rate was 5.2% at 8 years, with no difference between 7-French and 8-French lead models. Cable externalization was found to be more common in the 8-French model (12.3% vs 5.2%, *P*<.0001) and was associated with a higher risk of electrical failure.	In the multivariate analysis, the presence of active fixation (HR 0.70, 95% CI 0.49–0.98; *P*=.0402) and older age (HR 0.89, 95% CI 0.89–0.99; *P*=.0345) was associated with a lower risk of electrical failure, whereas the presence of cable externalization (HR 2.68, 95% CI 1.72–4.18; *P*<.001), increased body mass index (HR 1.03, 95% CI 1.01–1.06; *P*=.0185), and a higher left ventricular ejection fraction (HR 1.29,	95% CI and HRs	Retrospective	Steady failure rate with some clinical features (better LVEF, younger age, greater BMI, passive fixation) and cable externalization appeared to be associated with electrical failure.

								95% CI 1.11–1.36; *P*<.001) were associated with an increased risk.			
Parkash	2015	25485777	Returned product analysis	263 ICD leads	Returned product	Visual inspection and testing	43 (16.8%) were found to have insulation abrasion that was due to either lead-can or lead-other device interaction (70%) or inside-out abrasion (27.9%). Electrical abnormalities were frequent (20 of 31 [65.4%]) and most often due to electrical noise (45.2%), although inappropriate shocks were present (25.8%).	Death occurred in 1 of 43 (2.3%) of the patients with an insulation defect in the lead-can abrasion group.	NA-descriptive	Descriptive, returned product only	Lead-can abrasion is the most common form of insulation defect in the Riata group of leads under advisory.
Theuns	2012	23091049	National registry (Netherlands)	1029 ICD leads	Riata leads	Lead failure	Externalized conductors were observed in 147 leads (14.3%). Proportion of externalized conductors was higher in 8-F Riata compared with 7-F Riata ST (21.4% vs 8.0%; *P*<.001). Proportion of externalized conductors was higher in 8-F Riata compared with 7-F Riata ST (21.4% vs 8.0%; *P*<.001). Median time from implantation to detection of externalized conductors was 65.3 months.	The estimated rates of externalized conductors were 6.9% and 36.6% 5 and 8 years after implantation, respectively. Of the 147 leads with externalized conductors, 10.9% had abnormal electrical parameters vs 3.5% in nonexternalized leads (*P*<.001).	Rates of externalized conductors were estimated by life-table analysis with 95% CIs *P*<.05	One-time screening	Fluoroscopic screening identifies externalized conductors in 14.3% of Riata leads.

AE = adverse event; CRT-D = cardiac resynchronization therapy defibrillator; CI = confidence interval; CIED = cardiovascular implantable electronic device; DFT = defibrillation threshold; HR = hazard ratio; ICD = implantable cardioverter defibrillator; LIA = lead integrity alert; LVEF = left ventricle ejection fraction.

Appendix 5 Complications after cardiovascular implantable electronic device implantation

Study name or author	Year	PubMed PMID	Study type	Study size	Inclusion criteria	Endpoints	Findings	Outcome results	Statistical values	Limitations	Comments
Abu El Haija	2015	26231843	Retrospective, single center	212	generator replacement, lead revision or upgrade	Venograms	56 of 212 patients had total occlusion of the subclavian or innominate vein (26%).	Lead diameter, as an independent variable, was not a risk factor; however, a larger sum of the diameters of the implanted leads was a predictor of subsequent venous stenosis (*P*=.009). Multiple-lead implant procedures may be associated with venous stenosis (*P*=.057).	A nominal 2-sided *P* value <.05	Single center, retrospective	There is a significant association between venous stenosis and the number of implanted leads and the sum of the lead diameters.
Alam	2014	24099864	Retrospective, single center	646 patients	Generator replacement CRT-D	Battery longevity/generator replacement	During 2.7±1.5 years of follow-up, 113 (17%) devices had reached ERI (Boston scientific 4%, Medtronic 25%, and St. Jude Medical 7%, *P*<.001). The 4-year survival rates for the device's battery: 94% for Boston scientific, 67% for Medtronic, and 92% for St. Jude Medical (*P*<.001).	Medtronic with reduced battery longevity. The difference in battery longevity by manufacturer was independent of pacing burden, lead parameters, and burden of ICD therapy.	A 2-sided *P* value <.05 Cox proportional hazards	Single center, retrospective	Different manufacturers' batteries have markedly different longevities.
Bonney	2010	20002886	Retrospective, single center	70 patients	ICD	Lead failure	Average age at implant was 14.8 years (range 5.7–19.5).	5-year lead survival at 89.6%.	Kaplan-Meier survival analysis	Single center	Similar lead survival in children when compared with adults
Borne	2014	25095884	NCDR and matched Medicare	117,100	ICD for primary prevention and in Medicare FFS	Mortality, survival	Between 2006 and 2010, there were significant improvements in all outcomes, including 6-month all-cause mortality (7.1% in 2006, 6.5% in 2010; OR 0.88; 95% CI 0.82–0.95), 6-month rehospitalization (36.3% in 2006, 33.7% in 2010; OR 0.87; 95% CI 0.83–0.91), and device-related complications (5.8% in 2006, 4.8% in 2010; OR 0.80; 95% CI 0.74–0.88).	Outcomes after ICD implant improved between 2006 and 2010	Odds ratios with 2006 as the reference	Registry, retrospective	Improvements in outcomes for ICD implants over time
Chung	2014	25221331	Post-hoc analysis of REPLACE	70	Death after CIED replacement/revision	Death	At 6 months, 70 of 1744 (4.0%) patients had died.	Death more likely with prior admission for HF 3.097 (1.795–5.344; *P*<.001), NYHA III/IV: 1.959 (1.122–3.418; *P*=.018); Antiarrhythmic drug use: 1.901 (1.141–3.169; *P*=.014)	Kaplan Meier survival curves, Cox proportional hazards model	Post-hoc	Risk of death higher with older age, prior admission for heart failure, NYHA III/IV, and antiarrhythmic drug use.
Delling	2016	26833208	Single center	93,592 TTE with 1245 with PPM	Serial echocardiography and PPM	Tricuspid regurgitation, mortality	The prevalence of significant tricuspid regurgitation was higher in patients after PPM placement (mean age, 79±3 years; 54% men) compared with those without a PPM (OR 2.32; 95% CI 1.54–3.49; *P*<.0001).	The presence of significant tricuspid regurgitation was associated with increased mortality (HR 1.40; 95% CI 1.04–2.11; *P*=.027, vs no significant tricuspid regurgitation). Compared with having neither a PPM lead nor significant tricuspid regurgitation, adjusted HRs for death were 2.13 (95% CI 1.93–2.34) for significant tricuspid regurgitation but no PPM, 1.04 (0.89–1.22) for PPM without significant tricuspid regurgitation, and 1.55 (1.13–	Cox proportional hazards	Retrospective	Pacemaker-associated tricuspid regurgitation is associated with significant mortality.

								2.14) for PPM with significant tricuspid regurgitation.			
Hoke	2014	24449717	Retrospective, single center	239 CIED	CIED (191 ICD and 48 PPM)	Tricuspid regurgitation, mortality	Before device implantation, most patients had tricuspid regurgitation grade 1 or 2 (64.0%) or no tricuspid regurgitation (33.9%), but after lead placement, significant tricuspid regurgitation was observed in 91 patients (38%).	Patients with significant lead-induced TR had worse long-term survival (HR, 1.687; *P*=.040) and/or more heart failure-related events (HR, 1.641; *P*=.019).	*P*<.05 Differences in echocardiographic variables within and between the patient groups were compared by repeated-measures analysis of variance, including interaction between group and time	Retrospective	Significant lead-induced TR is associated with poor long-term prognosis.
Landolina	2011	21576653	Retrospective, multicenter	3253	CRT-D	Device-related events	Device-related events were reported in 416 patients. Specifically, surgical interventions for system revision were reported in 390 patients. Four years after the implantation procedure, 50% of patients underwent surgical revision for battery depletion and 14% for unanticipated events. For comparison, battery depletion at 4 years occurred in 10% and 13% of patients who received single- and dual-chamber defibrillators at the study centers, and unanticipated events were reported as 4% and 9%, respectively.	CRT-D, infections occurred at a rate of 1.0%/year, and the risk of infections increased after device replacement procedures (HR 2.04; 95% CI 1.01–4.09; *P*=.045). Device-related events were not associated with a poorer clinical outcome. The risk of death was similar for patients with and without surgical revision (HR 0.90; 95% CI 0.56–1.47; *P*=.682).	HRs and their 95% CIs were computed by means of Cox regression models.	Retrospective	The authors concluded that device-related events are more frequent in CRT-D than in single- or dual-chamber defibrillators and are frequently managed by surgical intervention for system revision. Clinical outcome is not worsened in the presence of these events.
Palmisano	2013	23407627	Retrospective	2671	Device implantation (1511), generator replacements (1034), upgrades (126)	Complications	Over a median follow-up of 27 months, the overall rate of complications was 2.8% per procedure-year [9.5% in CRT device implantation, 6.1% in pacing system upgrade, 3.5% in implantable cardioverter defibrillator implantation, 1.7% in pacemaker implantation, and 1.7% in generator replacement). The procedure with the highest risk of complications was CRT device implantation (OR, 6.6; *P*<.001). These complications primarily involved coronary sinus lead dislodgement and device infection.	Patients with complications had a significantly higher number of device-related hospitalizations (2.3±0.6 vs 1.0±0.1; *P*<.001) and hospital treatment days (15.7±25.1 vs 3.6±1.1; *P*<.001) than those without complications. Device infection was the complication with the greatest negative impact on patient outcome.	ORs were reported with their 95% CIs. A *P* value <.05 was considered statistically significant.	Retrospective	Cardiac resynchronization with the highest complication rate
Syska	2010	20132378	Single center, retrospective	104	HCM and an ICD	Appropriate/inappropriate discharges, complications	In the primary prevention group, appropriate ICD discharges occurred in 13 patients (16.7%), and the intervention rate was 4.0%/year. Nonsustained VT	Complications of the treatment included: inappropriate shocks (33.7%), lead dysfunction (12.5%), and infections (4.8%).	Two-sided *P* values were considered statistically significant at the level <.05. Cox	Retrospective	ICD effective in HCM but with significant complications

							was the only predictive risk factor for an appropriate ICD intervention in the primary prevention (positive predictive value 22%, negative predictive value 96%).		proportional hazards model		
Tompkins	2011	21489029	Retrospective	1440	PPM or ICD	Bleeding complications	82 bleeding complications (5.7%) and 7 infections (0.5%) temporally related to device implantation in 1440 patients.	Infection rates were significantly higher in patients with ESRD (defined as GFR <15 mL/min) versus controls (12.5% vs. 0.2%; *P*<.0001). A significant increase in bleeding complications was observed in ESRD versus controls (21.9% vs 3.2%, respectively; *P*<.0001).	*P*<.05	Retrospective	ESRD markedly increases bleeding and device-related infections.
Tseng	2015	26098676	retrospective	22	Sudden death and a PPM or ICD	Autopsy results	6 of 14 pacemaker-related sudden deaths and 7 of 8 ICD-related sudden deaths due to ventricular tachycardia or ventricular fibrillation.	Device concerns were identified in half (4 pacemakers and 7 ICDs), including 3 hardware failures contributing directly to death (1 rapid battery depletion with a sudden drop in pacing output and 2 lead fractures), 5 ICDs with ventricular fibrillation undersensing, 1 ICD with ventricular tachycardia missed due to programming, 1 improper device selection, and a pacemaker-dependent patient with pneumonia and concern about lead fracture.	A 2-tailed *P*<.05 was considered statistically significant.	Retrospective	Concerns about CIED function identified at post-mortem analysis. Passive surveillance efforts could underestimate CIED malfunction.
Van Rees	2011	21867832	Systematic review	11 ICD and 7 CRT trials		In-hospital mortality	The average in-hospital mortality was 2.7% in trials using both thoracotomy and nonthoracotomy ICDs, 0.2% in trials using nonthoracotomy ICDs, and 0.3% in CRT trials. Coronary sinus complications occurred in 2.0% of patients undergoing CRT. Lead dislodgement rates were higher in CRT trials (5.7%) than in nonthoracotomy ICD trials (1.8%).	All included CRT trials used CRTs with transvenously implanted leads. The most common complications included coronary vein dissection (1.3%) and coronary vein perforation (1.3%). The overall incidence of lead dislodgement was 1.8% for nonthoracotomy ICDs.	NA-systematic review	Systematic review	Complication rates higher for CRT-D systems.
Van der Heijden	2015	25749138	Retrospective, single center	3075	ICD (1729) or CRT-D (1346)	Mortality	The cumulative incidence of all-cause mortality was 49% (95% CI, 45%–54%) for ICD recipients after 12 years of follow-up and 55% (95% CI, 52%–58%) in CRT-D recipients after 8 years of follow-up.	A total of 1081 patients (35%) received appropriate defibrillator therapy. The 12-year cumulative incidences of adverse events were 20% (95% CI 18%–22%) for inappropriate shock, 6% (95% CI 5%–8%) for device-related infection, and 17% (95% CI 14%–21%) for lead failure. Device-related infection occurred more frequently in CRT-D than in ICD recipients (8-year cumulative incidence, ICD: 6% [95% CI 4%–7%] vs. CRT-D: 8% [95% CI 5%–10%]; log rank, *P*=.01)	*P*<.05, Multivariate Cox regression analysis	Retrospective	After long-term follow-up of ICD (12 years) and CRT-D (8 years) recipients, 49% of ICD recipients and 55% of CRT-D recipients had died. Many of these patients (58% of ICD and 40% CRT-D) received appropriate therapy

Vehmeijer	2016	26873095	Meta-analysis	2162 patients, 24 studies	Adult congenital heart disease and ICD	ICD interventions	Implantable cardioverter-defibrillators were implanted for primary prevention in 53% (43.5–62.7). Overall, 24% (18.6–31.3) of patients received one or more appropriate ICD interventions (anti-tachycardia pacing or shocks) during 3.7±0.9 years: 22% (16.9–28.8) of patients with primary prevention in 3.3±0.3 years and 35% (26.6–45.2) of patients with secondary prevention in 4.3±1.2 years. Inappropriate shocks occurred in 25% (20.1–31.0) of patients in 3.7±0.8 years and other complications (particularly lead-related) occurred in 26% (18.9–33.6) of patients in 3.8±0.8 years.	All-cause mortality was 10% during 3.7±0.9 years.	Random effects models to calculate proportions and 95% CI	Systematic review	Patients with ACHD have high appropriate ICD therapy rates.
Zanon	2016	27094359	Retrospective	953	ICD replacement	Reason for device replacement	For 813 (85%) patients, the reason for replacement was battery depletion, while 88 (9%) devices were removed for clinical reasons, with the remaining 52 removed because of system failure (eg, lead or ICD generator failure and safety advisory indications).	Among single- and dual-chamber ICDs, the median survival from replacement for battery depletion was 5.3 years (95% CI 5.0–5.5) for Biotronik, 6.3 years (95% CI 6.2–6.7) for Boston Scientific, 6.4 years (95% CI 6.2–6.9) for Medtronic, 6.7 years (95% CI 6.2–6.8) for St. Jude Medical, and 6.4 years (95% CI 5.8–6.7) for Sorin.	Multivariate Cox proportional hazards. $P<.05$		CRT-D, percentage of ventricular pacing, and development of system failure all contribute to shorter service life. Differences among manufacturers identified.

ACHD = adult congenital heart disease; AE = adverse event; CRT-D = cardiac resynchronization therapy defibrillator; CI = confidence interval; CIED = cardiovascular implantable electronic device; ERI = elective replacement interval; ESRD = end-stage renal disease; GFR = glomerular filtration rate; HF = heart failure; HR = hazard ratio; ICD = implantable cardioverter defibrillator; NYHA = New York Heart Association; OR = adjusted odds ratio; PPM = permanent pacemaker; TTE = transthoracic echocardiography.

Appendix 6 Cardiovascular implantable electronic device infection evidence table

Study name or author	Year	PubMed PMID	Study type	Study size	Inclusion criteria	Endpoints	Findings	Outcome results	Statistical values	Limitations	Comments
Archarya	2016	26810859	Retrospective	197	Stage D heart failure discharged on inotropes	Death, transplant, LVAD, complications	Fifty-seven patients (29%) had one or more infections during follow-up. Bacteremia was the most common type of infection.	Implanted electrophysiology devices did not confer an increased risk of infection.	ORs are presented with 95% CI and *P* values. *P*<.05	Retrospective	Presence of a CIED did not impact infection rate.
Ahson	2014	24919539	Retrospective, then prospective	2779	CIED implant	Infection	Following the introduction of the infection control protocol, there was a 54% reduction in the incidence of CDI, from 1.3% to 0.6% (*P*<.03; 95% CI 0.25–1.36). Most patients with CDI had negative blood cultures or grew *Staphylococcus sp.* The average cost was £30,958.40 per infection incident, and the cost of the new ICP was minimal.	Infection decreased despite longer procedure time (92 minutes vs 73 minutes; *P*<.01), higher use of anticoagulation (11.9% vs 5.4%; *P*<.01), and trend toward increased use of temporary pacing (9.03% vs 5.02%; *P*=.07).	Continuous data were summarized using mean and SD or 95% CI.	Retrospective comparison	Infection control protocol had a nominal cost and significant savings.
Amraoui	2016	26897683	Prospective	35	CIED lead endocarditis, PET/CT scanning	Description of PET/CT results	PET/CT scanning identified septic emboli in 10 patients (29%): 7 with spondylodiscitis, 2 with septic pulmonary emboli, and 1 with an infected vascular prosthesis. Among the 7 patients with occult spondylodiscitis, 4 were	PET/CT is a diagnostic tool in the setting of CIED lead endocarditis.	NA-descriptive	No comparison	PET/CT can identify occult/asymptomatic infection and other abnormalities.

							asymptomatic, and 3 had back pain with negative CT imaging.			
Athan	2012	22535857	Prospective cohort	2760 patients, 177 with CIED endocarditis	CIED endocarditis	In-hospital and 1-year mortality	The clinical profile of CDRIE included advanced patient age (median, 71.2 years [interquartile range 59.8–77.6]); causation by staphylococci (62 cases of *S. aureus* [35.0%; 95% CI 28.0%–42.5%], and 56 cases of CoNS [31.6%; 95% CI 24.9%–39.0%]); and a high prevalence of health care-associated infection (81 cases [45.8%; 95% CI 38.3%–53.4%]). There was coexisting valve involvement in 66 (37.3%; 95% CI 30.2%–44.9%) patients, predominantly tricuspid valve infection (43 of 177 [24.3%]), with associated higher mortality.	In-hospital and 1-year mortality rates were 14.7% (26 of 177; 95% CI 9.8%–20.8%) and 23.2% (41 of 177; 95% CI 17.2%–30.1%), respectively. Proportional hazards regression analysis showed a survival benefit at 1 year for device removal during the initial hospitalization (of 141 patients, 28 [19.9%] who underwent device removal during the index hospitalization had died at 1 year, vs 13 of 34 [38.2%] who did not undergo device removal; HR, 0.42 [95% CI 0.22–0.82]).	Two-sided $P<.05$ Proportional hazards regression model	Observational, voluntary participation. Could not evaluate specific risk factors for CIED endocarditis.	Early CIED removal associated with improved survival.
Perez Baztarrica	2012	22213472	Retrospective	8	Large (>20 mm) CIED-related vegetations	Outcomes	Extraction with traction/manual sheaths. Complete procedural success: 100% in large vegetations, 91% in the group with small vegetations or no vegetations. Two of 8 patients with large		Descriptive	Small, descriptive	Transvenous extraction of large vegetations is feasible.

							vegetations found to have PE with "mild" hemodynamic compromise. Microbiology (positive cytology in 7 of 8 in the large vegetation group): *S. aureus* (3) and CoNS (2) most frequent. Seven of 8 cases had a reimplanted device (1 refused), with a median time to implant of 42 days.				
Bloom	2011	20942819	Prospective	624	CIED	Infection, successful implant	Antimicrobial pouch used in a cohort of patients with high-risk features (age 70±13 years, 68.1% men, 27.2% renal insufficiency, 35.4% oral anticoagulant use, 67.8% replacement/revision procedures) utilized pacemakers	There were 3 major infections (0.48%; 95% CI 0.17–1.40) after 1.9±2.4 months follow-up. The infections followed 1 ICD revision and 2 CRT-D replacements.	NA	Descriptive of new technology	Antimicrobial pouch does not impede implant and is associated with a low infection rate.
Bongiorni	2012	22399202	Prospective	1204	Removed CIED leads and material	Culture results	Electrodes from 1204 patients were analyzed, with 854 (70.9%) testing positive. In 663 (77.6%) cases, only 1 species was isolated; in 175 (20.5%) cases, 2 species were isolated, and in 14 (1.8%) cases, >2 species were isolated.	Gram-positive organisms were most frequently isolated (92.5% of isolates), particularly CoNS: mainly *S. epidermidis*, in 69% of cases, and *S. aureus* in 13.8%. Gram-negative rods were isolated in 6.1%, yeasts in 1%, and molds in 0.4%.	NA-descriptive	Descriptive	Electrodes are an excellent source for identifying microbiology of a CIED infection.
Boersma	2016	26341604	Prospective	866 (119	S-ICD	Mortality	Mean follow-up	Major infection	Continuous data	Observational	S-ICD implant after

				after TV-ICD extraction)			duration was 651 days, and all-cause mortality was low (3.2%). Patients previously explanted for TV-ICD infection were older (55.5±14.6, 47.8±14.3, and 49.9±17.3 years in the infection, noninfection, and de novo cohorts, respectively; *P*=.01), were more likely to have received the ICD for secondary prevention (42.7%, 37.2%, and 25.6% in the infection, noninfection, and de novo cohorts, respectively; *P*<.0001), and had higher percentages of comorbidities, including atrial fibrillation, congestive heart failure, diabetes mellitus, and hypertension, in line with the highest mortality rate (6.7%).	after S-ICD implantation was low in all groups, with no evidence that patients implanted with the S-ICD after TV-ICD explantation for infection were more likely to experience a subsequent reinfection.	were compared by Student *t* test. Categorical variables are summarized as frequencies and percentages and were compared with the chi-squared test		extraction for infection reasonable, with low or no infection rate.
Cautela	2013	23148119	Prospective	21	CIED infection and PET/CT	PET/CT results	In patients with pocket site infection, the sensitivity and specificity of FDG PET/CT were 86.7% (95% CI 59.5–98.3) and 100% (95% CI 42.1–100), respectively. The only patient with a superficial skin	FDG PET/CT is highly accurate for the diagnosis of skin and pocket CIED infection but low for infective endocarditis.	*P*<.05; scans interpreted blindly	Small pilot study	PET/CT has a role in CIED infection diagnosis.

							infection was accurately identified by FDG PET/CT. The sensitivity and specificity of FDG PET/CT in patients with CDRIE were 30.8% (95% CI 9.1–61.4) and 62.5% (95% CI 24.5–91.5). Most false-negative results occurred in patients who had undergone previous antimicrobial treatment.				
Chu	2014	25530969	Prospective	78	CIED replacement or upgrade with no evidence of infection.	DNA results	The bacterial-positive rate was 38.5% (30 cases); the CoNS detection rate was the highest (9 cases, 11.5%). Positive bacterial DNA results were obtained from pocket tissue in 23.1% of patients (18 cases), and bacterial DNA was detected on the device in 29.5% of patients (23 cases).	During follow-up (median 24.6 months), 2 of 30 patients (6.7%) became symptomatic with the same species of microorganism, *S. aureus* and *S. epidermidis*.	Student's t-test and chi-squared test	False positives with bacterial DNA	High proportion of colonization in patients with CIEDs.
Da Costa	2015	25917024	Prospective	1326 (32 with infection)	CIED implant	Clinical differences with 2 different skin preparations	Long-term follow-up (26±3 months) revealed no significant difference between the groups: infections were observed in 14 of the 648 patients (2.2%) using povidone-iodine vs 18 of the 678 patients (2.7%)	The occurrence of infection was positively correlated with reintervention (aOR 7.16; 95% CI 2.56–19.99; *P*<.0001), mean number of generator replacements (aOR 3.47; 95% CI 2.22–5.44;	*P*<.05; multiple variable logistic regression	Observational	Aqueous and alcoholic povidone-iodine solutions displayed similar antiseptic effects regarding CIED infection prevention.

							using alcohol povidone iodine (*P*=.9).	*P*<.001), and hematoma (aOR 48.4; 95% CI 13.45–174.25; *P*<.0001).			
Darouiche	2012	22946683	Systematic review	15 studies, 3970 patients	CIED implant and prophylactic antibiotics	Surgical site infection	For patients undergoing a CIED implant, perioperative systemic antibiotics plus antiseptics delivered 1 hour before the procedure significantly reduced the incidence of surgical site infections compared with no antibiotics (RR 0.13; 95% CI 0.05–0.36; *P*<.00001). Furthermore, perioperative systemic infections plus antiseptics significantly reduced the incidence of postoperative infection compared with antibiotics delivered postoperatively (RR 0.14; 95% CI 0.03–0.60; *P*=.008).	The evidence strongly suggests that antibiotic prophylaxis within 1 hour before CIED implantation is effective at reducing surgical site infections.	Each study is reported separately. The results of binary outcomes (ie, infection or not) are descriptively summarized as percentages, and treatment comparisons presented RRs with corresponding 95% CIs.	Bias inherent with systematic reviews.	Preoperative antibiotics effective for reducing surgical site infections.
DeHaro	2012	22523057	Prospective	197	CIED infection	Mortality	Some 197 patients were included and matched 1:1 to controls. Pocket infections were present in 41.1%, and definite or suspected infective endocarditis was present in 58.9%.	Mortality rates in the study group and controls were 14.3% vs 11.0% (NS), respectively, at 1 year; and 35.4% vs 27.0% (*P*=NS), respectively, at 5 years.	Univariate and multivariate predictors of mortality during follow-up were assessed in Cox regression models, from which HRs and 95% CIs were	Bias with matched controls	In patients with CIED infection managed by recommended therapy, long-term mortality rates are similar to comparable controls. Independent predictors include patient- and disease-

							Total or subtotal hardware removal was achieved in 98.5% of cases. Median follow-up was 25 months (12–70).	Independent predictors of long-term mortality were older age (HR=1.09, *P*<.001), cardiac resynchronization therapy (HR=3.70, *P*=.001), thrombocytopenia (HR=5.10, *P*=.003), and renal insufficiency (HR=2.66, *P*=.006).	derived.		related factors, in addition to implantation of right ventricular epicardial pacemakers.
Downey	2011	21303389	Retrospective	177 TEEs in 153 patients	TEE/pacemaker	Masses on imaging	A visible mass on a device lead was observed in 25 (14%) cases, including 11 TEEs showing lead vegetation, 13 TEEs showing lead strands, and 1 study showing both. Seventeen patients were determined to have endocarditis, of which 8 had a mass observed on a lead during TEE. Thus, 72% of patients (18 of 25) with a lead-associated mass did not have evidence of an infection. In TEEs performed for indications other than to rule out endocarditis, lead masses were observed in 13 of 136 studies (10%), with only 1 patient determined to	Masses in 14% of the patients. In 72% of patients, the mass did not prove to be secondary to infection.	NA-descriptive	Observational	Masses identified by TEE must be evaluated in the clinical context.

							clinically have an infected device.				
Erba	2013	24011775	Prospective	63	Suspected infection	Results of white cell scanning	Sensitivity of (^{99m})Tc-HMPAO-WBC SPECT/CT was 94% for both detection and localization of CIED-associated infection. SPECT/CT imaging had a definite added diagnostic value over both planar and stand-alone SPECT. Pocket infection was often associated with lead(s) involvement; the intracardiac portion of the lead(s) more frequently exhibited (^{99m})Tc-HMPAO-WBC accumulation and presented the highest rate of complications, infectious endocarditis, and septic embolism.	None of the patients with negative ^{99m}Tc-HMPAO-WBC scintigraphy developed CIED-related infection during follow-up of 12 months. Echocardiography had a 90% specificity but low sensitivity.	95% CI	Small study; no direct comparison to PET/CT.	Radiolabeled white blood cell scintigraphy helpful for suspected CIED infections and better than FDG PET/CT.
Greenspo n	2012	22322085	Retrospective	145	Lead-associated endocarditis	Mortality	CIED endocarditis: 43 early (<6 months), 102 late (>6 months).	Complete hardware removal in 95% of early and 96% of late infections. In-hospital mortality was 7% for early and 6% for late. Six-month mortality was 25% for early and 29% for late.	Two-sided *P*<.05	Six-month definition was arbitrary; lost follow-up data.	Lead-associated endocarditis should be considered in any patient with systemic signs or symptoms of infection.
Greenspo n	2014	24813965	Retrospective	129	Lead-associated	Microbiology, clinical	A total 129 patients with lead-	Complete removal of lead	Two-sided *P*<.05	1-cm size choice was	CoNS with larger vegetations.

					endocarditis	outcomes	associated endocarditis. Vegetation size <1 cm (61); >1 cm (68) (MEDIC).	and device in 61 of 61 (100%) patients with vegetation <1 cm and 65 of 68 (96%) patients with vegetation >1 cm. Thoracotomy in 4 of 61 (<1 cm) and 13 of 68 (>1 cm). Major procedural complications: <1 cm: 1 of 61 (1.6%); >1 cm: 7 of 68 (12%). Microbiology (<1 cm): *S. aureus*: 27 (44.2%), CoNS : 6 (9.8%). Microbiology (>1 cm): *S aureus*: 22 (32%), CoNS : 21 (30%).		arbitrary; unable to provide additional information on vegetation morphology.	
Guha	2015	26253036	Retrospective	546,769 with ESRD	ESRD and CIED	Mortality	A total 546,769 patients with ESRD. Of these, 34,935 (6.4%) had a CIED; 2,792 (0.5%) had an infected CIED.	Infected CIED more likely if other percutaneous access. African-Americans with an infected CIED: medical prescription, 1999 of 2792 (71.6%); extraction, 793/2792 (28.4%). Infected CIED with higher likelihood of dying from an infectious cause	Cox proportional hazards	Retrospective and cannot compare medical and surgical strategies.	Patients with ESRD and an infected CIED have a poor prognosis.

								(11.7% vs 5.7%). Device extraction within 60 days of infection associated with higher likelihood of survival at 5 years (extracted: 33.8% vs medical: 26.0%) and lengthening median survival time (extracted: 15.9 months vs medical: 9.2 months).			
Habib	2013	23276467	Retrospective	415	CIED infection	Mortality	A total 243 patients with CIED infection with follow-up.	After mean follow-up of 6.9 years, short-term mortality increased with heart failure (OR 9.3), steroid therapy (OR: 1.97), ESRD (OR 1.94), and lead-associated endocarditis (OR 1.68).	Two-sided, *P*<.05	Retrospective	CIED infection with accompanying comorbidities is associated with a poor prognosis.
Herce	2013	23097224	Retrospective	2496	CIED implant with 35 infections	Mortality and outcomes	A total 2496 patients underwent CIED implant and 35 infections were identified (1.2%).	Some 75% of infections developed in the first year after implant. Factors associated with infection: DM (OR 3.5), heart disease: (OR 3.12), >1 lead (OR 4.07).	*P*<.05	Retrospective, small, single-center	Diabetes and underlying heart disease risk factors for developing infection.
Hickson	2014	24388672	Retrospective	415	CIED infection	Mortality and outcomes	A total 415 patients with CIED infection, 17 on long-term HD.	Of the 17 patients on long-term HD, 17 had bloodstream CIED infection and 7 of 17 (41%) had lead	*P*<.05	Small observational study; majority white cohort.	CIED infection in patients receiving HD therapy is usually associated with bloodstream infection and is

								or valve vegetations; 14 of 17 (82%) were treated with complete removal; 90-day survival was 76%.			frequently complicated with device-related endocarditis. Despite complete device removal in the majority of HD patients with infection, mortality remains high.
Jan	2012	22082221	Retrospective	286	CIED infection	Microbiology	Microbiological confirmation in 252 of 286 (88%) patients, most from Staphylococcus (216 of 252 (86%), and of these, 90% CoNS.	Some 31% had methicillin-resistant *S. aureus*	NA-descriptive	No control	Authors recommend vancomycin as first-line empirical therapy.
Khaligh	2014	24164587	Prospective randomized	1008	CIED implant	Infection	A total of 1008 patients received a CIED and was randomized to placebo or 3 different topical ointments; 58 patients developed a CIED infection.	Some 14 patients with culture-positive wound infections. No effect or benefit from any topical skin preparation (povidone-iodine, neomycin, sterile nonadherent pads). Surgical site infection associated with longer procedural time or malignancy.	Not specified	Designed to be blinded, but distinct odor with iodine.	Careful skin preparation critical.
Kim	2014	25060820	Retrospective, single center	80	CIED infection	Microbiology	Total median follow-up was 38 months. Overall mortality was 36% with a median time to death from presentation of 95 days. Complete device extraction in 67 of	All-cause mortality was high with lead-related endocarditis.	*P*<.05	Retrospective, single center	All-cause mortality with lead-related endocarditis remains high.

							80 (84%) patients and conservative approach in 13 of 80 because of overwhelming septic complications or palliative management. Percutaneous extraction unless vegetation >2 cm. Despite device extraction, direct infectious complications accounted for 43% of deaths. Reimplantation in 26 patients after a median of 58 days.				
Kolek	2015	26222980	Retrospective	488	Patients with CIED receiving antimicrobial pouch	Infection	A total 353 patients received a nonabsorbable pouch, and 135 received an absorbable pouch; all with risk factors for infection (diabetes, kidney disease, anticoagulation, corticosteroid use, white blood cells >11,000, abandoned leads, or CRT).	In a propensity score-matched cohort of 316 recipients of either envelope and 316 controls, the prevalence of infection was 0 (0%) and 9 (2.8%), respectively; *P*=.004. When limited to 122 absorbable pouch recipients and 122 propensity-matched controls, the prevalence of CIED infections was 0 (0%) and 5 (4.1%), respectively; *P*=.024.	Propensitiy matching	Retrospective	In high-risk patients, the absorbable pouch is associated with a low rate of surgical site infection.
Kornberger	2011	23718817	Retrospective	59	"Semipermanent" pacing	Complications	A total 60 patients with transvenous semipermanent pacing:	Left in place for a mean period of 14.6 days. Outcome:	NA-descriptive	Small, single center	"Semipermanent" pacing can be useful.

							42 after extraction for infection, 18 due to potentially reversible bradycardia.	bridge to permanent device: 41 (68%); bridge to recovery: 7 (12%); death: 4 (6.7%); transferred to another facility: 7 (11.7%).			
Le	2012	22762715	Retrospective	280	CIED and staphylococcal infections	Clinical characteristics	Of 280 patients, 123 (44%) had *S. aureus*; 157 (56%) had CoNS. *S. aureus* more likely in recently implanted CIEDS (<1 year). Late *S. aureus* cases more likely to be treated with corticosteroids, have longer duration of bacteremia, longer hospitalization, and is associated with higher mortality. CoNS infections more likely with a larger number of abandoned leads.	CoNS CIED infections compared with *S. aureus* were associated with a history of multiple device revisions and a higher number of total and abandoned leads at presentation (P<.001 for all comparisons).	Student *t* test for continuous variables and Pearson's chi-squared or Fisher exact test for categorical variables	Small, retrospective	CoNS and *S. aureus* have different clinical presentations.
Leccisotti	2014	24715624	Prospective	27	Standard and delayed imaging with PET/CT.	Imaging results	A total 27 patients with suspected CIED infection and 15 controls imaged with PET.	Diagnostic accuracy of delayed imaging (70%) was higher than 1-hour scanning (51%) for CIED lead infection. No difference for pocket infection.	P<.05	Small, single-center study.	Delayed imaging useful for lead endocarditis.
Lin	2014	25501080	Retrospective	40,608	CIED implant	Infection	Incidence of infection was 2.45 of 1000 procedures. Risk of infection increased in men,	Risks lower in high-volume centers.	Cox regression	Retrospective, details about procedures not available.	Infection more likely in young men.

							and with younger age, device replacement, and prior infection.				
Madhaven	2010	20852296	Retrospective	74	Gram-positive cocci bacteremia other than *S. aureus.*	CIED infection	A total 74 patients with CIED and Gram-positive cocci bacteremia other than *S. Aureus*.	Some 22 of 74 patients had CIED infection. Duration of symptoms shorter if no CIED infection (no CIED infection: 2 days vs CIED infection: 33 days). Microbiology: CoNS more likely to be associated with CIED infection: 16 of 44 (36%) compared with nonCoNS GPC: 6 of 24 (25%). Relapsing bacteremia more likely with CoNS infection.	Two-tailed *P*<.05	Retrospective	Vegetations more common with CoNS.
Mason	2011	20561226	Prospective	82	CIED replacement	Microbiology	A total 82 patients with generator removal: 66 replacement or upgrade, 16 pocket infection.	Some 15 of 16 with pocket infection had a positive diagnosis: 15 of 16 sonication; 13 of 16 tissue culture; 11 of 16 swab. A total 14 of 66 (21%) without pocket infection had positive microbiology: 11/14 sonication; 8/14 tissue culture; 2/14 swab.			Ultrasonication is useful for increasing yield but identifies a number of patients with asymptomatic colonization.

								After average follow-up of 311 days, no subsequent infections in the 66 patients who did not have evidence of pocket infection.			
McGarry	2014	24127355	Prospective	28	CIED removal for infection treated with negative pressure wound therapy.	Clinical course	Median duration of negative pressure wound therapy was 5 days. Complete healing in 27 of 28 patients.	One patient developed recurrent infection.	NA-descriptive	Small, single center	Negative pressure wound therapy might be a useful strategy for treating wounds after infection.
Nagpal	2015	25779615	Prospective	77	CIED	Microbiology	A total 77 patients: noninfected: 42; infected: 35; swabs, tissues, and sonication.	Infected: 12 of 35 pocket cellulitis; 4 of 35 erosion; 14 of 35 bloodstream; 5 of 35 bloodstream and valve. Noninfected: sonicate: 5% positive; tissue: 5%; swab: 2%. Infected: sonicate: 54%; tissue: 9%; swab: 9–20%.	NA-descriptive	Single center	Sonication improves the sensitivity of culture results compared with tissue or swab.
Polyzos	2015	25926473	Meta-analysis	60 studies	CIED	Infection	The average device infection rate was 1%–1.3%. In the meta-analysis, significant host-related risk factors for infection included DM (OR 2.08; 95% CI 1.62–2.67), end-stage renal disease (OR 8.73; 95% CI 3.42–	Regarding procedure-related factors, postoperative hematoma (OR, 8.46; 95% CI, 4.01–17.86), reintervention for lead dislodgement (OR 6.37; 95% CI 2.93–13.82),	Unadjusted infection data were pooled to OR, WMD, and 95% CIs by the use of the DerSimonian-Laird random-effects mode.	Meta-analysis	Identified risk factors for CIED infection.

							22.31), chronic obstructive pulmonary disease (OR 2.95; 95% CI 1.78–4.90), corticosteroid use (OR 3.44; 95% CI 1.62–7.32), history of previous device infection (OR 7.84; 95% CI 1.94-31.60), renal insufficiency (OR 3.02; 95% CI 1.38-6.64), malignancy (OR 2.23; 95% CI 1.26–3.95), heart failure (OR 1.65; 1.14–2.39), preprocedural fever (OR 4.27; 95% CI 1.13–16.12), anticoagulant drug use (OR 1.59; 95% CI 1.01–2.48), and skin disorders (OR 2.46; 95% CI 1.04–5.80).	device replacement/revision (OR 1.98; 95% CI 1.46–2.70), lack of antibiotic prophylaxis (OR 0.32; 95% CI 0.18–0.55), temporary pacing (OR 2.31; 95% CI 1.36–3.92), inexperienced operator (OR 2.85; 95% CI 1.23–6.58), and procedure duration (weighted mean difference, 9.89; 95% CI 0.52–19.25) were all predictors of CIED infection. Among device-related characteristics, abdominal pocket (OR 4.01; 95% CI 2.48–6.49), epicardial leads (OR 8.09; 95% CI 3.46–18.92), positioning of 2 or more leads (OR 2.02; 95% CI 1.11–3.69), and dual-chamber systems (OR 1.45; 95% CI 1.02–2.05) predisposed to device infection.			
Qintar	2015	25224666	Retrospective	2792	CIED procedure	Infection	Chlorhexidine-alcohol agent was used in 1450 (51.1%) procedures, and povidone-iodine agent was	Chlorhexidine and povidone iodine skin preparation both associated with a 1.1% risk of device	Two-sided *P*<.05	Retrospective, single center. Not randomized.	Antiseptic skin preparation agent did not have an effect on CIED infection.

							used in 1390 (48.9%).	interaction.			
Rickard	2013	24622003	Retrospective	151	CRT extraction for infection	Mortality, clinical outcomes	151 patients with CRT extraction due to infection, with successful reimplant in 81, compared with a matched cohort of 879 patients.	Of the 70 patients who did not receive reimplant, 10 were deemed not fully cured and died after extraction, 21 were felt not to be candidates for CRT, 18 had failed implant, 10 were thought to be too high risk, 6 were lost to follow-up, and 5 refused. In the 81 patients who underwent implant, median time to reimplantation was 8 days. Laser sheath used for 74% right ventricle leads, 38% right atrial leads, and 17% CS leads (2 patients required laser in the CS).	Cox regression model	Single center	Patients with a biventricular device infection who are successfully extracted, treated with antibiotics, and reimplanted with a biventricular device have outcomes similar to those of patients with biventricular devices not known to have become infected.
Saeed	2014	24766634	Retrospective	168	CIED extraction	Clinical outcomes	Median time to reimplantation was 3 days. After mean follow-up of 4.4 years, 9 patients underwent repeat CIED extraction, with 6 in the first year.	Patients with a second infection requiring a repeat CIED extraction were younger (57±20 vs 68±16, P=.046). Pocket infection was the most common presentation of a second infection, occurring in 8 of the 9 patients.	Two-tailed P<.05	Small, retrospective	Risk of infection after a first extraction and reimplant is higher.
Sohail	2011	21911623	Retrospective	5817	Admissions for infection	Clinical outcomes, cost	5817 patients with CIED infection from 200,219 patients	Infection associated with increased rate of	P<.05	Claims data	Device infection associated with increased mortality

							with CIED generator change, revision, or placement.	adjusted admission mortality (rate ratios 4.8–7.7) and adjusted long-term mortality (rate ratios 1.6–2.1). Adjusted incremental costs were $14,360–$16,498.			and cost.
Sohail	2015	25504648	Retrospective	131	*S. aureus* bacteremia	Clinical outcome	131 patients with CIEDs and *S. aureus* bacteremia and no evidence of pocket infection	45 of 131 (34%) patients had a CIED infection. Likelihood of infection more likely with >1 CIED procedure, PPM, duration of *S. aureus* bacteremia ≥4 days.	Logistic regression models and summarized with ORs and 95% CIs.	Single center	Among patients presenting with *S. aureus* bacteremia and no signs of pocket infection, the risk of underlying CIED infection can be calculated.
Sohail	2016	27506820	Retrospective	93031	CIED	Infection	Cumulative incidence of infection at 1-year postimplant was 1.18% for initial CIED implants and 2.37% for replacement.	Median time to infection was 35 days for initial implant and 23 days for replacement. Incremental healthcare expenditures by treatment intensity categories for initial implant patients at 1 year were $16,651, $104,077, $45,291, and $279,744. For replacement implants, incremental expenditures at 1 year by treatment intensity	Kaplan-Meier survival curves	Claims only	CIED infection adds considerable cost.

								categories were $26,857, $43,541, $48,759, and $362,606.			
Tarakji	2014	25087154	Retrospective	502	CIED pocket infection	Clinical course	502 patients with CIED infection: pocket: 289 (58%); endovascular: 213 (42%).	One-year mortality 20%. Endovascular infection with 2-fold increase in risk of death. 100 of 213 patients with endovascular infection had vegetation by TEE. However, vegetation was not associated with increased risk. Some 56% had infection identified >1 year after last implant procedure. Increased risk of death: renal failure, poorer functional class, bleeding requiring transfusion.	*P*<.05, Cox regression analysis	Retrospective; does not include patients who died prior to extraction.	One-year mortality higher with endovascular infection, but not related to vegetation size.
Uslan	2012	22077194	*Post hoc*	1744	CIED replacement	Clinical outcomes	Of 1744 patients, CIED infection developed in 22 (1.3%).	Patients with infection more likely to have a hematoma: 5 of 22 (22.7%) vs 17 of 1733 (0.98%). Sites with infection rate >5% more likely to use povidone iodine topical solution, with lower implantation volume, and	Student *t* test and chi-squared test	6-month follow-up	Infection associated with postoperative hematoma.

								higher Charlson Comorbidity scores.			
Viola	2010	20439783	Retrospective	504	CIED infection	Clinical course	Of 504 patients with CIED infection, 80 (16%) had a nonstaphylococcal infection.	Although not described in prior reports, we identified 3 definite and 2 suspected cases of secondary Gram-negative bacteria seeding of the CIED. Inappropriate antimicrobial coverage was provided in approximately 50% of the cases with a mean period of 2.1 days. The overall mortality rate was 4%.	Not listed (rare)	Low event rate	Nonstaphylococcal infections can seed CIEDs.
Voigt	2010	19793359	Retrospective	222,940	CIED implant	Infection	22,611 patients with CIED from the National Hospital Discharge Database (approximately 1% of hospitalizations in the US).	Infection rate estimate increased from 4.1% in 2004 to 5.8% in 2006. Increased likelihood of comorbid conditions.	*P*<.05	Claims data	Rates of CIED infection increasing.
Welch	2014	24665867	Retrospective	238	CIED infection	Microbiology	238 patients with CIED infection (MEDIC database): early (< 1 year), 132; late (≥1 year), 106.	Early group more likely to be female or on AC Late infections more likely to have device erosion. No difference between the two groups regarding lead number, presence of abandoned leads. 45% of patients	Two-sided P<.05	Descriptive cohort, referral bias	Almost half of the patients with CIED pocket infection presented ≥12 months after their last device-related procedure. Although early-onset pocket infections were more frequently related to a recent CIED pocket manipulation and had overt inflammatory

								with pocket infection presented ≥1 year after last implant procedure. Microbiology (early): positive culture, 117 (89%); *S. aureus*: 46 (40.7%); CoNS: 53 (47%); Other: 18 (15%). Microbiology (late): positive culture, 91 (86%); *S. aureus*: 22 (25.9%); CoNS: 45 (52.9%); Other: 24 (26%).			changes at the pocket site, a significant number of late infections presented with a more indolent manifestation of infection or erosion, presumably due to less virulent organisms.

(^{99m})Tc-HMPAO-WBC: (^{99m})Tc-hexamethylpropylene amine oxime–labeled autologous white blood cell; aOR = adjusted odds ratio; CDI = cardiac device infections; CDRIE = cardiac device–related infective endocarditis; CI = confidence interval; CIED = cardiovascular implantable electronic device; CoNS = coagulase-negative staphylococci; CS = coronary sinus; CT = computed tomography; DM = diabetes mellitus; ESRD = end-stage renal disease; FDG = fluorodeoxyglucose; GPC = Gram-positive cocci; HR = hazard ratio; ICD = implantable cardioverter defibrillator; ICP = internal cardiac pacemaker; NA = not applicable; OR = odds ratio; PET = positron emission tomography; PPM = permanent pacemaker; RR = risk ratio; S-ICD = subcutaneous implantable cardioverter-defibrillator; *S. aureus* = *Staphylococcus aureus*; *S. epidermidis* = *Staphylococcus epidermidis*; SD = standard deviation; SPECT = single-photon emission computed tomography; TEE = transesophageal echocardiography; TV-ICD = transvenous implantable cardioverter defibrillator; WMD = weighted mean difference.

Appendix 7

Author	Year	Study Type	Study Size	Inclusion Criteria	Endpoints	Results
Predictors of TLE Success/Complications						
Brunner	2014	Observational - Retrospective (single center)	2999 transvenous lead extractions; 4137 pacing leads, 1384 ICD leads	Consecutive patients undergoing TLE at Cleveland Clinic from 8/1996-8/2011	Extraction success rates; complication rates; risk factors associated with adverse outcomes	95.1% complete procedural success, 98.9% clinical success, 1.1% failure. Minor complications: 3.6%, major complications 1.8%; 30-day all-cause mortality: 2.2%. Predictors of major complications by MVA: cerebrovascular disease, EF ≤15%, low platelets, INR ≥ 2, mechanical and powered sheaths. Predictors of 30-day mortality by MVA: BMI <25 kg/m^2, ESRD, higher NYHA class, lower hemoglobin, higher INR, extraction for infection, extraction of dual-coil ICD lead.
Brunner	2014	Observational - Retrospective (single center)	3258 TLE (5973 pacing, 1537 ICD); n=25 required emergent surgical or endovascular intervention	Consecutive patients undergoing TLE at Cleveland Clinic from 8/1996-9/2012	Incidence, types, outcomes of catastrophic complications	SVC laceration n=15 of 25; RA perforation n=2 of 25; RV perforation n=3 of 25; vascular repair at access site n=2 of 25; 3 of 25 treated with endovascular repair; pericardiocentesis 56%; chest tube 8%; 44% treated in EP lab, 56% in OR; cardiopulmonary bypass in 10 of 25 cases (median pump time 81 min [45–116 min]; in-hospital mortality 36% (6 procedural, and 3 during hospitalization); median length of stay (survivors) 13.5 (10.8–14) days.
Brunner	2015	Observational - Retrospective (single center)	2999 transvenous lead extractions; 4137 pacing leads, 1384 ICD leads	Consecutive patients undergoing TLE at Cleveland Clinic from 8/1996–8/2011	Risk nomogram for predicting 30-day all-cause mortality using baseline clinical variable and multivariate logistic regression modeling	Median lead implant duration 4.7 (2.4–8.3) years; median of 2 leads extracted per procedure; 2.2% died by 30 days after TLE. Variables with highest predictive value of 30-day mortality: age (OR 0.6, *P* =.013), BMI (OR 1.4, *P* =.015), hemoglobin (OR 3.3, *P* <.001), ESRD (OR 5.6, *P* <.001), LVEF (OR 1.7, *P* =.148), NYHA class (OR 1.8, *P* =.084), extraction for infection (OR 2.5, *P* =.005), operator experience (OR 2.0, *P* =.06), extraction of dual coil leads (OR 2.8, *P* <.001).
Wazni	2010	Observational - Retrospective (13 centers); LExiCon	1449 patients	Consecutive patients underwent laser-assisted extraction from 1/2004–12/2007; excluded procedures that used nonlaser, nontraction devices used in same procedure	Safety and efficacy of laser-assisted lead extraction	Median implant duration 82.1 months (0.4–356.8). Indications: infection 57%, nonfunctional leads 26.6%, functional abandoned 11.1%, venous stenosis/occlusion 4.5%, chronic pain 0.8%. Complete removal: 96.5%, clinical success 97.7%. Multivariate predictors of failure to achieve clinical success: BMI <25 kg/m^2, volume ≥60 cases over 4 years by MVA; MAE: 4%, death 1.86% (0.28% directly related to procedure). Multivariate predictor of MAE: BMI <25 kg/m^2; multivariate predictor of in-hospital death: BMI <25 kg/m^2, creatinine ≥2.0 mg/dl, diabetes, and infection as indication.
Franceschi	2011	Observational - Prospective (2 centers)	675 patients: OR= 279, EP lab= 296 (1364 leads: 533 OR, 831 EP lab)	Consecutive TLE at 2 centers either OR or EP lab	Procedure outcomes and complications	EP lab vs OR: Complete success: 93.1% vs 91.4%; Complications: 2.24% vs 2.84%, *P* =.43; Major complications: 1.0% vs 21%, *P* =.794; 2 deaths: 1 OR, 1 EP lab; rapid surgical intervention.
Agarwal	2009	Observational - Retrospective (single center)	212 patients (456 leads)	Consecutive patients underwent TLE 2002–2008 Upitt	Predictors of TLE complications (complications within 30 days)	Complications 11.8% (n=25); 4.2% major, 8% minor; independent predictors of any complication: higher # extracted RV leads (HR 3.51, *P* =.013), trend in ICD vs PM (HR 2.57, *P* =.053); elevated WBC count predictive of major complications (HR 1.52, *P* =.005); history of open heart surgery protective (HR 0.11, *P* =.049).
Byeard	1999	Observational - Prospective registry (226 centers)	2338 patients (3540 leads)	TLE 1/1994–4/1996 (pre-laser)	Procedure success, complications	Complete success 93%; Incomplete or failed extraction associated with: implant duration (*P* <.0001), less experienced operator (*P* <.0001), ventricular leads (*P* <.005), noninfected patients; Major complications 1.4%; risk of complications: # leads removed (*P* <.005), less experienced physicians (*P* <.005); risk of major complications higher in women (*P* <.01).

Roux	2007	Observational - Prospective registry (1 center)	200 patients (270 leads: 23 removed by simple traction; 270 laser)	TLE 9/2009–8/2005; Partial success if ≤4 cm residual lead fragment; failure if >4 cm	Predictors of TLE success	Mean lead dwell time: 7.8±5.5; MVA predictors of failed extraction: longer lead dwell time (OR 1.16 per year; *P* =.0001), history of hypertension (OR 5.2, *P* =.002); Procedure complications in 7.9% (major 3.4%, minor 4.5%); MVA predictor of procedure complications: use of laser on right and left during same procedure (OR 9.4, *P* =.012); 3 of 10 patients who had failed or partial extraction eventually required open extraction due to endocarditis (vegetation on lead fragments with positive blood culture).
Moak	2006	Observational - Retrospective (single center)	25 patients (36 pacing; 7 ICD leads)	Conscutive patients undergoing LLE; median age 13.9 (8.4–39.9) years	Success and complications following LLE	Indications: fracture 86%, remaining had abnormal lead function; median lead dwell time 49.4 (8.4–39.9) months; complete removal in 91%; major complications 8% (cardiac perforation with tamponade; thrombosis of subclavian/innominate vein).
Segreti	2014	Observational - Retrospective (single center)	637 patients required TLE of 679 ICD leads. In addition, 369 atrial leads, 221 coronary sinus leads, and 89 RV pacing leads were extracted	Consecutive patients referred for TLE 01/1997–12/2013. Inability to remove lead with manual traction was interpretted as having ≥1 adhesion point; location identified by operator when uanble to advance	Evaluated regions of lead adherences during TLE and predictors of adherences	Simple traction effective in 6.6%; 99% success rate; 0.9% could not be extracted; fibrous adherences in 94%; average number adherences 2.8±1.2 per patient; subclavian vein 78%, innominate vein 65%, SVC 66%, heart 73%. Multivariate predictors of fibrous adherences: lead dwell time (OR 1.10, *P* <.001), passive fixation (OR 3.25, *P* =.006), dual-coil lead (OR 2.94, *P* =.011); dual-coil predicted innominate (OR 3.93, *P* <.001) and SVC (OR 3.52, *P* <.001) adherences, passive fixation predicted cardiac adhesions (OR 1.72, *P* =.015); coil treatment (polytetrafluoroethylene or back-filled coils) was associated with low rate of SVC (OR 1.75, *P* =.035) and cardiac (OR 2.11, *P* =.005) adherences.
Irfan	2016	Observational - Retrospective (single center)	106 patients (71 conventional, 35 subcostal)	Patients <50 years underwent ICD implantation 01/2007–12/2013	Outcomes following ICD implantation in conventional (pre- or subpectoral) vs subcostal positions	61% had ICD placed conventionally; 33% had subcostal. Procedure complications: conventional 14.1% vs subcostal 8.9%; 84.9% had no adverse events after mean follow-up of 2.1±1.8 years. Lead survival 95% for conventional, 97% subcostal, *P* =NS.
Kong	2015	Observational - Retrospective (single center)	76 patients	Consecutive patients who underwent TLE 2013–2014 using Evolution or Needles Eye Snare		Snare used in 59 (77.6%), Evolution in 17 (22.4%). Procedure (*P* =.034) and fluoro (*P* =.29) times shorter with evolution vs snare; complete extraction better with evolution 94% vs 86% with snare, *P* =.024. Evolution sheath associated with lower total complications (5.9% vs 5.1%, *P* =.024).
Abu-El-Haija	2015	Observational - Prospective	212 patients	Patients who presented for generator change, lead revision, device upgrade 10/2006–2/2014 had venogram at time of procedure	Incidence and risk factors for venous stenosis following transvenous lead placement	Venous stenosis identified in 61%; 26% had complete venous occlusion of subclavian or innominate vein; number of leads implanted was associated with higher risk of venous stenosis by MVA (OR 3.32, *P* =.046, for 3 leads vs 1 lead), age 1.038, *P* =.004. No association between venous stenosis and sex, lead dwell time, type of insulation, individual lead diameter, anticoagulation/antiplatelet medications, vein access.
Polewcyk	2013	Observational - Retrospective (single center)	940 patients for TLE; 24 with LDTD	24 patients referred for TLE due to LDTD; remaining 916 patients referred for TLE served as controls	Define cause and outcomes of lead-dependent tricuspid valve dysfuntion following TLE	More leads in LDTD group (2.04 vs 1.69, *P* =.04); more unnecessary loops in LDTD group (41.7% vs 5.24 %, *P* =.0001), main mechanism of LDTD abnormal leaflet coaptation caused by loop (42%), retraction of septal leaflet (37%), lead impingement (21%); TLE perfomed in 87.5%, with 8.3% referred for surgical extraction because of TLE failure. TR improved in 62.5%; 75% reported improvement in exercise tolerance and peripheral edema in mean follow-up of 1.5 years.

Franceschi	2009	Observational - Prospective	208	Consecutive patients underwent TLE 5/2003–4/2008; echo (TTE or TEE) obtained pre-extraction; TTE obtained prior to discontinuation	Incidence, risk factors, and outcomes of TTR following TLE	Median lead dwell time: 46.4 (95% CI 0.7–260.5) months; 12% had TR prior to TLE, none with mod-severe. Incidence TTR: 19% (moderate 26%; severe 74%); predictors of TTR by MVA: use of laser (OR 9.43; 95% CI 2.03–43.77; *P* =.004); laser + lasso (OR 13.1; 95% CI 1.58–108.9; *P* =.02); female (OR 3.38; 95% CI 1.21–9.41; *P* =.02). Of those with TTR: 26% developed new right HF symptoms; 10.5% required surgical repair; 31.6% died (2 from HF, 6 from noncardiac).
Suga	2000	Observational - Retrospective (single center)	433 patients; 531 abandoned leads	All patients with retained, nonfunctional leads 1977–1998	Abandoned lead complications	Indications for abandoning: capture/sensing failure 45.8%, lead reall 33.3%, fracture 16.2%, device upgrade in remainder. Complications 5.5%: infection 1.8%, venous occlusion prohibiting new lead placement in 3.7%. Incidence of complications higher in patients with 3 abandoned leads vs ≤2 leads (40% vs 4.7%, *P* <.00001); patients with 4+ leads (functional +abandoned) vs ≤ 3 leads (26.2% vs 0.6%, *P* <.00001); and patients with 3+ leads (functional + abandoned) vs ≤2 leads (36.4% vs 3.9%, *P* <.00001). Patients with complications were younger than those without at time of initial implant and lead abandonment; 3.4% required later extraction.
Bohm	2001	Observational - Retrospective (single center)	60 patients (66 abandoned leads)	Reviewed 3445 patients status post PM implant (1/1969-12/1999); 89 lead replacement for noninfectious issues; follow-up available in 60	Complications associated with abandoned leads	Complications: 20%. Lead migration 8.3% (Leads were cut at time of abandonment and allowed to retract. Two of 5 caused serious complications: RA lead perforated septum and migrated to LA, causing stroke; RV lead migrated to right lung; both surgically corrected. Other 3 migrated to pulmonary artery and were managed with chronic anticoagulation); skin erosion 5% (removed surgically); venous thrombosis 3.3%; muscle stimulation 3.3%.
Silvetti	2008	Observational - Retrospective (single center)	18 patients	245 patients received endocardial PM 1982-2006, 19 leads failed and were abandoned	Short-term outcomes with abandoned leads	7% had lead malfunction - failing after median follow-up 10 (3-15) years; median follow-up of abandoned leads: 4 (1-10) years; no increase in TR, no new venous occlusion; 2 (11%) cases of endocarditis at 5 and 10 years
Rijal	2015	Observational - Retrospective (single center)	488 patients (leads extracted = 296; capped=192)	Patients with nonfunctional or recalled CIED leads or device upgrades resulting in superfluous leads who underwent lead capping (LC) vs lead extraction (LE) 2006–2012 at UPitt; Infections excluded	Primary: unanticipated CIED-related procedure; Secondary: Procedure complications, hospitalizations, all-cause mortality	LE vs LC: younger (60±17 vs 67±13 years, *P* <.001); observed by experienced extractor (76% vs 26%), longer lead dwell time (4.2±3.6 vs 0.9±1.1 years). Age influenced extractors decision to cap or extract (66±14 vs 58±17 years, *P* =.003) but not nonextractors (67±13 vs 64±16 years, *P* <.001). Over median follow-up of 3.0 years, adjusted risk of unanticipated CIED procedures was similar for LE vs LC: (HR 1.04; 95% CI 0.62–1.75); similar procedure complications (LE vs LC: major 6% vs 3%, *P* =.13; minor 3% vs 3%, *P* =.63), hospitalizations (49% vs 50%, *P* =.81), and mortality rates (24% vs 27%, *P* =.17).
Poole	2010	Prospective multicenter Registry (REPLACE)	1031 patients generator change; 731 patients generator change + addition of lead	Prospectively assessed procedure complications over 6 months in patients undergoing generator change vs generator change + addition of lead	Complications	Major complications: 4% generator change only, 15.3% generator change + lead; higher in ICD vs PM in both groups. Complications highest in upgrade/revision to CRT 18.7%; no periprocedural deaths; 6-month infection rates 1.4% vs 1.1%.
Device/Lead Complications						
Maisel	2006	Editorial				Reported ICD lead survival varies significantly: 91%-99% at 2 years, 85%–98% at 5 years, and 60%–72% at 8 years. Patients with lead failure who undergo revision have an 8-fold increased risk for another lead failure. Variability likely due to nonstandard definition of lead survival, varying lead model performance, patient characteristics, implantation technique, and physician interpretation of interrogation and imaging.

Kleeman	2007	Observational - Retrospective (single center)	900 patients received 990 ICD leads	Consecutive ICD lead implants (first implant only) 1992–2005	Annual rate of ICD lead defects over median follow-up of 2.55 years	Median time to lead failure 4.7 years; 15% of leads failed. Estimated lead survival: 85% at 5 years and 60% at 8 years. Annual failure rate increased with time: 20% at 10 years. Types of lead complications: insulation defects 56%, fractures 12%, loss of capture 11%, abnormal impedance 10%, sensing failure 10%. Adjusted predictors of lead failure: younger age (age per 10 years [HR 0.84; 95% CI 0.72–0.98]) and female sex (HR 1.61; 95% CI 1.12–2.32).
DeWitt	2015	Observational - Retrospective (single center)	140 patients	Consecutive patients receiving primary prevention ICD, age <21 years	Time-dependent incidence of appropriate therapies and device-related adverse events (inappropriate shocks, lead failure, complications)	Mean follow-up 4 years; 19% experienced appropriate shocks. First adverse event 36%, inappropriate shock 14%, lead failure 11%, need for reintervention 26%. Adverse events more frequent than appropriate therapies over time: first year postimplant: appropriate shock 9%, adverse events 16%; fifth year postimplant: appropriate shock 19%, adverse events 29%.
Gadler	2015	Observational registry (National Swedish PM and ICD registry, 2012 update)	6657 PM, 1298 ICD, 392 CRT-P, 526 CRT-D were implanted in 2012	Registry information regarding first implants	Implantation rates and complications	Mean PM implantation rate 697 per million people; progressive increase since 1970, plateauing in 2009. PM generator survival 98% at 5 years, 33% at 10 years; PM lead survival 98% at 10 years. Mean ICD implantation rate 136 per million, increasing since 2009. ICD generator survival 88% at 5 years; 13% at 10 years; ICD lead survival 92% at 10 years. CRT-P 41 per million, CRT-P generator survival 96% at 5 years, 65% at 10 years. CRT-D 55 per million (slight increases in CRT-D), CRT-D generator survival 86% at 5 years, 69% at 10 years.
Parkash	2015	Observational - Prospective	List of returned products obtained from St. Jude Medical that included primary root cause, presence of abrasion, and lead information. 263 returned Riata leads		Location of abrasions in returned Riata leads	A total 16.3% had insulation abrasion, with mean lead dwell time 4.9±2.5 years. Lead-can abrasion present in 62.8%, abrasion from interaction with another device component 7%, inside-out abrasion 27.9%. Lead-can abrasion tended to be more common with Riata 7-F than Riata 8-F (84.2% vs 58.4%, P=.07), inside-out abrasion tended to be more common with Riata 8-F than 7F (37.5% vs 15.8%, P=.12); electrical abnormalromalities identified in 65.1% due to noise; death occured in 1 patient (2.3%), with evidence of lead-can abrasion.
Kutarski	2013	Observational - Retrospective (single center)	700 patients had 1212 endocardial leads removed	Patients undergoing lead extraction at single center. Lead extraction was performed using mechanical cutters or telescoping sheaths. Excluded PM lead <12 months and ICD <6 months	Assessed abrasion patterns from explanted lead with average lead dwell time 77.3±55.9 months	A total 84.5% were removed via the subclavian approach, 10.6% by simple traction, 2.9% via the femoral approach, and 1.2% combined. Abrasion with metal exposure was found in 25.3% (7.1% occurred during removal); definite lead abrasion was seen in 46.2% with endocarditis, but only 23% without endocarditis (*P* <.001). Lead abrasion was more likely with increased number of leads (patients with abrasions had an average 2.5 leads, vs patients without abrasions, who had an average 1.8 leads, *P* <.001). Predictors of lead abrasion: number of leads removed (OR 2.25, *P* <.001); average lead age (OR 1.007, *P* <.001); lead in CS (OR 2.04, *P* =.007); and excess lead length in RA/TV (OR 4.75, *P* <.0001).
Borne	2014	Observational Registry (NCDR)	117,100 patients	Medicare beneficiaries, age ≥65 years, LVEF ≤35%, primary prevention ICD, including CRT between 2006–2010	Temporal changes in mortality, all-cause hospitalizations, HF hospitalizations at 180 days, device-related complications	Improvements in 6-month all-cause mortalilty (7.1% in 2006 vs 6.5% in 2010; adjusted OR 0.88, *P* <.001); 6-month rehospitalization (36.3% in 2006 vs 33.7% in 2010, adjusted OR 0.87, *P* <.001); 6-month HF hospitalization (13.1% in 2006 vs 11.4% in 2010, adjusted OR 0.80, *P* <.001); device-related complications (5.8% in 2006 vs 4.8% in 2010, adjusted OR 0.80. *P* <.001).
Mendehall	2014	Case Report	1	n/a	n/a	Unusual case of Twiddler's syndrome in which most loops were intracardiac, causing appearance of vegetation; removed by extraction.
AlMohaissen	2013	Review			Association between TR and PM/ICD leads	Pre- and post-implant echo showed >1-grade increase in severity of TR in 24.2% of patients; ≥2-grade increase in 18.3%. RF for lead-induced TR: older age, ICD leads, location of lead (posterior and septal leaflets), leads passing between chordae. Management: surgery probably better than extraction because of potential injury to TV during extraction.

Hayat	2013	Observational Case series (1 center)	24 patients	BS Cognis CRT generator	Reporting on issues with header	Three Cognis headers implanted subpectorally presented initially with intermittent, then persistent increase in shock impedance associated with noise in shock EGMs, due to inadequate bond between header and titanium casing.
Jama	2013	Observational - Retrospective (single center)	268 patients: 134 patients in each group	134 diagnosed with mild cognitive impairment or dementia before or within 1 year of device implantation compared with 134 matched controls	Compared rates of device complications (composite of infection, lead malfunction requiring intervention, or inappropriate shock) between 2 groups	Cognitively impaired vs control: device-related complications (14.4% vs 5.8% at 5 years, P=.268), infections: 4% vs 1%, *P* =.15. Five-year survival was signficantly lower in the cognitively impaired group: 42% vs 67%, *P* =.007.
Varma	2010	Prospective randomized TRUST trial	1339 patients	Patients receiving ICD were randomly assigned to HM vs in-office evaluations	HM vs conventional to detect generator/lead issues	A total 62 device events were observed in 46 patients (4.4% HM vs 1.39% conventional, *P* =.004); 47% were asymptomatic. Generator/lead problems were detected earlier in the HM vs the conventional groups (1 vs 5 days, *P* =.05); 20 device issues required surgical interventions, others managed with device reprogramming.
Goette	2009	Review/commentary				Reported ICD lead survival varies significantly: 91%–99% at 2 years, 85%–95% at 5 years, 60%–72% at 8 years. Approximately 66% are detected during routine device interrogations. Patients with lead failure who undergo revision have an 8-fold increased risk for another lead failure.
Shah	2009	Review of ICD complications in pediatrics				
Eckstein	2008	Observational - Retrospective (3 centers)	1317	ICD implanted 1993–2004	Lead malfunction, death during median follow-up 6.4 years	Cumulative incidence lead malfunction: 1.1% at 1 year, 2.5% at 5 years. Malfunction resulted in inappropriate therapies in 76%; 63% of cases received pace/sense lead; lead failure recurrence 4.4% at 2 years and 19.8% at 4 years. Those who had ICD lead revision due to lead failure had an 8-fold higher incidence of experiencing another failure.
Kazmierczak	2008	Observational - Prospective cohort	133	Consecutive ICD implants 01/1999–03/2003	Readmission rates and causes following ICD implantation	Readmission rates: 54% at mean 22±15 months; 54.5% arrhythmia-related, 32.3% cardiac (nonarrhythmic), and 13.2% non-cardiac. Rehospitalization index per person for total follow-up: 1.26; 0.69 for first year; arrhythmia-related rehospitalization index: 0.37; mean time to first readmission 9±9 months.
Epstein	2009	Observational Registry (ACT, OPTIMUM, RHYTHM, and PAS registries at 373 sites)	7497 patients followed for median 22 months	6141 patients received 8-F, 1356 received 7-F	Riata-related adverse events defined as abnormal lead performance that required lead revision, extraction, or replacement.	Conductor fracture 0.09%, insulation damage 0.13%, dislodgement 0.88%, perforation rate 0.31%; no difference in 8F vs 7F or active vs passive fixation by MVA.

Burri	2014	Decision analysis model				Probability of Fidelis lead fracture requiring reintervention: generator change only: 36% at 5 years; 49% at 10 years; risk of inappropriate shock 11% at 5 years, 15% at 10 years; addition of new pace/sense lead: 8.5% at 5 years, 13.3% at 10 years, with 0% chance of inappropriate shock at 5 years, 0.1% at 10 years; extraction with new ICD lead: 2.1% at 5 years, 3.3% at 10 years; inappropriate shocks 0.5% at 5 years, 0.7% at 10 years; 5- and 10-year mortality estimates were the same for all strategies: approximately 39% at 5 years and 62.5% at 10 years.
Hauser	2007	Observational - Retrospective (single center)	583 Sprint Fidelis 6949 leads vs 285 Sprint Quattro 6947 leads	Consecutive patients who received 6949 leads 9/2004–2/2007 vs 6947 leads 11/2001–2/2007	Lead failure rates, compared with MAUDE database	Fidelis fracture in 1%; average time to failure 14 months (4–23 months). Failure rates for Fidelis vs Quattro: 0.01 per patient year vs 0.001 per patient year.
Stroker	2016	Observational - Retrospective (2 centers)	184 patients (143 with Riata ST, 41 with Riata ST Optim)	Consecutive patients status post Riata ST and Riata ST Optim lead implantation 9/2003–6/2008	Survival analysis for Riata EF	During mean follow-up of 7 years, Riata ST EF was 13%. Riata lead survival rates were 95% at 3 years, 92% at 6 years. The Riata ST lead showed accelerating EF rates over time; the initial exponential trend was followed by linear lead failure pattern for leads surviving >5 years (approximately 7% annual EF rate).
Piot	2015	Observational Registry (French Fidelis registry - 6 centers)	1022 patients	All patients who received Sprint Fidelis ICD leads 12/2004–11/2007	Fidelis fracture rate over time and predictors of lead failure	Mean follow-up 51.4±20 months, mean Fidelis fracture rate 11.2% and increased over time: 1.2% at 1 year, 3.8% at 2 years, 7.4% at 3 years, 13.9% at 4 years, and 20.7% at 5 years. Predictors of fracture by MVA: younger age (age >60 years vs <40 years; HR 0.45, *P* =.0005), subpectoral implant (HR 2.35, *P* =.025), lead 6930 vs 6949 (HR 3.47, *P* =.049).
Cairns	2014	Observational Prospective registry (3 registries: OPTIMUM, SCORE, PAS)	11,016 leads in 10,835 patients		Rates of all-cause mechanical failure in Optim-insulated ICD leads	Median follow-up 3.2 years; mechanical failure 0.46%, failure rate 0.15% per year; conductor failure 0.31%, conductor failure rate 0.10% per year; insulation breach 0.10%; no externalized cables; estimated lead survival 99% at 5 years.
Cheung	2013	Observational - Retrospective (single center)	314 patients with Riata leads 4/2002–5/2007	Consecutive patients who received Riata leads and had ≥90 days follow-up	Mechanisms, temporal patterns, and predictors of Riata lead EFs over median follow-up 4.1 (1.8–5.7) years	Electrical failure rate 6.6% (67% noise, 48% abnormal impedances, 24% abrupt change in pacing threshold, 12% abrupt decrease in R-wave amplitude); 24% had inappropriate shocks due to noise; presence of externalized coils among failed leads 57%;. Predictors of EF: female sex (HR 2.7, *P* =.04); age (HR 0.95, *P* <.001). Log-log analysis demonstrated initial exponential failure rate that became linear after 4 years. Calculated failure rates for leads surviving >4 years was 5.2% per year.
Liu	2013	Observational - Retrospective (single center)	2475 patients: Durata 828, Riata 627, Quattro 1020	Consecutive patients who received Durata, Riata, or Sprint Quattro ICD leads	KM failure-free survival curves	Durata, Riata, Sprint Quattro annual EF rates: 0.3%, 1.7%, 0.3%, respectively (P<.0001 Durata vs Riata, P=1.0 Durata vs Quattro). Failure-free survival of Durata was similar to Quattro (*P* =.94) and better than Riata (*P* <.0001). 7Fr Riata ST had better survival than 8F (*P* =.05) and was comparable to Durata (*P* =.12).

Rordorf	2013	Observational - Retrospective (single center)	890 patients. Small diameter (≤ 8Fr): Fidelis n=190, Riata n=182, Durata n=99; vs standard diameter (>8Fr) n=419	Consecutive patients who received ICD lead 01/2003–12/2010	Incidence of lead failure in small vs standard diameter ICD leads; median follow-up 33 months	Overall lead failure rate 6.3%; failure rate significantly higher in Fidelis lead than standard diameter (4.8% vs 0.8% per year, *P* <.001) and Riata/Riata ST (2.6% per year, *P* =.030); failure higher in Riata/Riata ST vs standard diameter (2.6% per year vs 0.8% per year, *P* =.001). Predictors of lead failure by MVA: small diameter (HR 5.03, *P* <.001), Sprint Fidelis (HR 6.3, P<.001), Riata/Riata ST (HR 4.5, *P* =.001), and age <60 years (HR 2.3, *P* =.005).
Steinberg	2013	Observational - Prospective	284 patients	552 Riata leads implanted 2002–2008, excluded: 24 due to early explant, 146 died, 15 heart transplant; 83 without CXR	Evaluate prevalence and predictors of CE in Riata leads using CXR	Cable externalization identified in 24.3% and increased over time; CE was significantly higher in 1500 than 7000 series (31.4% vs 6.3%, *P* <.001); single-coil vs dual-coil (43.5% vs 29.8%).
Bernstein	2012	Observational - Retrospective (single center)	176 patients	Consecutive patients who received Sprint Fidelis 6931, 6949 leads	Evaluated implant techniques were associated with premature lead failure	Lead malfunction 5.7% over median follow-up 35±11 months. Predictors of lead failure by MVA: right-sided implant (vs left) (HR 18.8, *P* =.01); subpectoral implant (vs prepectoral) (HR 14.31, *P* <.01).
Cheung	2012	Observational - Retrospective (single center)	604 Fidelis implants	Followed Fidelis implants with ≥90 days follow-up	Analysis of log-log plots of cumulative hazard plots was performed to assess changes in lead failure rate over time; average follow-up 3.3±1.7 years	Lead failures 8.4%: 3-year and 5-year Fidelis lead survival rates 93.5% vs 85.3%, respectively. Mathematical modeling of failure demonstrated transition from exponential to linear failure rate at 2.9 years. The 2- and 4- year rate of failure was 4.5% per year. Predictors of lead failure by MVA: female sex (HR 2.1, *P* <.0001).
Liu	2012	Observational - Retrospective (single center)	245 patients with Riata leads	Asymptomatic patients with Riata leads offered fluoroscopic screening and device interrogation with provocative maneuvers	Incidence of conductor coil externalization, abnormal lead parameters	Coil externalization 21.6%. Rate increased with lead dwell time: 0% at <3 years; 13% at 3–5 years; 26% at >5 years. Decrease of ≥25% in R-wave amplitude was more frequent in externalized coil group (28% vs 8.1%, *P* =.018); noise was identified in 1 patient (1.9%) with coil externalization.
Shen	2012	Observational - Retrospective (single center)	84 patients with advisory Riata leads; 23 (27.4%) had evidence of externalization	Patients who had evidence of coil externalization by fluoroscopy	Prevalence and predictors of conductor coil externalization and abnormality. Electrical parameters in Riata leads	Coil externalization 27.4%; adjusted predictors of coil externalization: time since implant (OR 1.03, *P* =.029); multiple RV leads OR 38.9, *P* =.008; no electrical abnormalities identified in patients with coil externalization; 65% had shocks within 12 months of coil externalization, and only 1 demonstrated post-shock electrical abnormalities.
Girerd	2011	Observational - Retrospective (single center)	258 patients received 269 Sprint Fidelis leads	Consecutive patients who received Sprint Fidelis lead 2004–2007	Predictors of Fidelis fracture over median follow-up 2.8 years	Fractures 12.3%; 5-year lead survival 65.6%±7.5%. Age was independent predictor of lead failure: age <62.5 years increased risk of failure (HR 2.80; 95% CI 1.30–6.02; *P* =.009). Annual incidence of lead failure increased for age <62.5 (11.6%±4.9% at fourth year, 22.9% ± 13.2% at fifth year. Incidence was <5% through fourth year for age >62.5.
Hauser	2011	Observational - Retrospective (3 centers)	Fidelis 1023 vs Quattro 1668	Age >18 who received Sprint Fidelis (6931, 6948, 6949) or Quattro (6947) 11/01–01/09	Failure rates	Fidelis vs Quattro average follow-up: 2.78 vs 3.18 years, *P* <.0001. Failure: 7.8% vs 1.4%, *P* <.0001. Failure rate: 2.81% vs 0.43% per year. Pace/sense fractures: 95% Fidelis failures, 83% Quattro; HV conductor fractures: 5% Fidelis, 17% Quattro; no deaths. Of lead failures, 42% associated with inappropriate shocks. Four-year KM-derived lead survival: Fidelis 87% (83.6-90) vs 98.7% (97.9-99.4), *P* <.0001. Variables associated with Fidelis lead failure by MVA: age (HR 0.98, *P* =.007); male sex (HR 0.61, *P* =.048); HCM (HR 3.66, *P* =.041); ARVC + channelopathies (HR 2.5, *P* =.041); ischemic heart disease (HR 2.08, *P* =.041); idiopathic VT/VF (HR 1.97, *P* =.041). Hazard of Fidelis lead failure decreased 3% for every 1-year increase in age; 2% for every 1% increase in EF.

Danik	2007	Observational - Retrospective (single center)	130 Riata 1500 series leads vs 111 Sprint Fidelis	All patients who underwent percutaneous ICD lead placement at MGH in 2005	Incidence of ICD lead perforation and dislodgement	Riata vs Fidelis: Perforation 3.8% vs 0%, $P <.05$ (all within 10 days of implant); RV lead revision: 7.7% vs 0%, $P <.005$.
Hsu	2013	Observational Registry (NCDR)	440251 patients	First-implant ICD between 1/2006–9/2011	Predictors of ICD lead perforation	Perforation in 0.14%. Predictors by MVA: older age (age per 10-year increase, OR 1.37, $P <.0001$); female sex (OR 2.18, $P <.0001$); LBBB (OR 1.80, $P<.0001$); advanced HF class (class III, OR 1.42, $P <.023$); higher LVEF (per 5% increase, OR 1.05, $P =.19$); dual-chamber ICD (OR 1.52, $P <.001$). Patients with ICD perforation have increased risk of other major complications (OR 27.5, $P <.0001$); >3 day LOS (OR 16.2, $P <.0001$); in-hospital death (OR 17.7, $P <.0001$).
Victor	2013	Case report	n/a	n/a		RV lead perforation identified by CXR, confirmed by TTE, best visualized by chest CT.
Rordorf	2011	Observational - Retrospective (single center)	858 patients. Small diameter (≤ 8Fr): Fidelis n=190, Riata n=196, Durata n=51; vs standard diameter >8Fr (n=421)	Consecutive patients who received ICD lead 01/2003–10/2009	Incidence of delayed cardiac perforation in small vs standard diameter ICD leads; median follow-up 421 (2-2150) days	Delayed perforation 0.8%; occurred within 34 days (mean 17±12 days); all were positioned in RV apex, detected by TTE or CXR in 86%, chest CT 14.3%. All occurred in small diameter active fix leads; 1.6% in ≤8Fr vs 0% in >8Fr, $P =.01$; 1.4% active fix vs 0% passive fix, $P =.02$. In the ≤8Fr group, perforation occured in 2.8% active fix vs 0% passive fix, $P =.01$. Predictors of perforation by MVA: active fix + small diameter. Lead dislodgement in 1.6%; younger age was predictive of dislodgement; no difference in active vs passive (1.2% vs 2.2%, $P =.415$); no difference in >8F vs ≤8F (0.9% vs 2.2%, $P =.177$).
Refaat	2010	Case Report	2		Late perforation	Case 1: 2 months postimplant CP with bloody pleural effusion; Chest CT showed RV lead perforation to pleural cavity; open surgical repair. Case 2: 3 years after CRT noise observed during routine device interrogation; chest CT showed RV lead perforation; lead extracted transvenously without incidence.
Carlson	2008	Observational Registry (ACT; OPTIMUM)	ACT: 4721; Optimum: 1207	8F vs 7F Riata	Lead Perforation	8F + 7F: ACT = 0.34%; OPTIMUM=0.33%. 7F: ACT=0%; OPTIMUM 0.35%. 8F: ACT 0.34%; OPTIMUM 0%. RV pacing leads: 0.5%.
Corbisiero	2008	Observational - Retrospective (single center)	8F: 357; 7F: 357	ICD or CRT-D with 8F vs 7F Riata	Lead Perforation	8Fr: 0.28%; 7Fr 0.28%
Laborderie	2008	Observational case series (single center)	11	Consecutive patients referred for management of subacute or delayed RV perforation	Frequency, identification, management of delayed RV perforation	Pacing lead 64%, ICD lead 36%; 91% symptomatic. All had abnormal lead parameters at diagnosis (drop in sensing and lead impedance, including capture threshold). Diagnosed by CXR 55%, TTE 45%; 91% managed with manual traction (surgical backup). One patient developed tamponade immediately and required surgical intervention; 1 required surgical extraction due to suspicion of gastrointestinal perforation.
Polyzos	2015	Meta-analysis	60 studies included 206,176 patients (26,172 patients in prospective studies and 180,004 patients in retrospective studies	Of 2317 articles reviewed, 60 articles met inclusion criteria of CIED infection with *de novo* implants, generator changes, or device upgrades; pediatric populations excluded	Risk factors for CIED-related infection	Clinical factors: history of previous device infection (OR 7.84), ESRD (OR 8.73), pre-procedure fever (OR 4.27), steroid use (OR 3.44), history of CKD (OR 3.02), skin disorder (OR 2.46), malignancy (OR 2.23), COPD (OR 2.95), DM (OR 2.08), HF (OR 1.65), and anticoagulant use (OR 1.59). Procedure factors: procedure duration (OR 9.89), hematoma (OR 8.46), reintervention (OR 6.37), device replacement (OR 1.98), lack of antibiotic prophylaxis (OR 0.32), temporary pacing (OR 2.31).

Greenspon	2014	Observational Registry (MEDIC)	129 Patients, 61 with vegetation <1cm, 68 ≥1cm	Enrolled consecutive patients from MEDIC registry with lead-associated endocarditis 01/2009–05/2011	Assessed effect of vegetation size on presentation and outcomes	Patients with vegetations <1 cm were more likely to present with pocket infection; group with vegetation ≥1 cm more likely to present with systemic symptoms. Positive blood cultures 65% with <1 cm vegetation vs 80% ≥1 cm, *P* =.042. CIED system removed in 100% of the group with <1 cm vegetation vs 96% of the group with ≥1 cm. In-hospital mortality was similar between the two, 9.8% vs 11.7%, *P* =NS. Mortality significantly increased as function of vegetation size.
Kim	2014	Observational - Retrospective (single center)	80 patients	Consecutive patients with CIED-related IE (vegetations on TTE or fulfilling Duke criteria); identified by ICD-9 codes; death confirmed by SSDI	Mortality	Mortality 36%; median time to death 95 days from presentation; 56% had PM, 44% ICD; 86% had positive blood cultures; 69% had vegetations; 84% had devices extracted. Predictors of mortality by MVA: MRSA (OR 0.158, *P* =.003); valve endocarditis (OR 0.141, *P* =.002).
Herce	2013	Case-control (1 center)	2496 patients; 35 infections identified	Underwent cardiac device implantation 10/96–7/2007; identified 35 infections (1.2%). Two controls were matched based on age, sex, and year of device implant.	Risk factors for infection	Some 75% of infections occurred during 1st year of implantation. Factors associated with infection: DM (OR 3.5, *P* =.04), heart disease (OR 3.12, *P* =.03), use of >1 lead (OR 4.07, *P* =.02). All cases treated with hardware removal (all but 1 performed percutaneously).
Osmonov	2013	Observational - Retrospective (single center)	5287 CIED-related proceures; 23 patients with CIED-related infections	Patients with CIED-related infection 1980–2011	Incidence and outcomes of CIED-related infections at single center	CIED-related infection rate 0.38%; 56.5% pocket infection; 26% presented early (<6 months); 74% >6 months. Organism identified in 78%; most common organism *S. aureus* 56%. Complete system removal in 74%; 17.4% died due to CIED-related infections.
Palmisana	2013	Observational - Retrospective (2 centers)	2671 CIED procedures (1511 device implants; 1034 generator changes; 126 upgrades)	Consecutive CIED procedures at 2 centers 1/2006–3/2011	Device-related complications defined as adverse events requiring surgical revision, tamponade, pneumothorax, device infection, pocket hematoma, lead dislodgement, and lead failure, over median follow-up 27 months	Complications in 4.8%, complication rate 2.8% per year. Procedure with highest risk of complications: CRT implantation (OR 6.6, *P* <.001), driven mainly by CS lead dislodgement (OR 5.02, P<.001) and infection (OR 28.5, *P* =.002); 84.5% complications observed within the first year. Complications increased from 1.7% with PM implant to 3.5% with ICD implant to 6.1% with PM upgrade, and 9.5% with CRT implantation.
Greenspon	2012	Observational Registry (MEDIC)	145 patients (lead-associated endocarditis within 6 months, n=43; vs >6 months, n=102)	Enrolled consecutive patients from MEDIC registry with lead-associated endocarditis 01/2009–05/2011	Assessed clinical features and outcomes in 2 groups: early (within 6 months of CIED procedure) vs late (>6 months from CIED procedure)	Median time from CIED procedure: early 1.9 (1–3.5) months, vs late 26.2 (17–41.2) months, *P* =.03. Infection presentation: early=pocket infection (54% vs 11%, *P* =.001); late=bacteremia (38% vs 8%, *P* <.001). Lead vegetation by TTE: early 63% vs late 82%, P<.01. Staphylococcus was most common species in both; all treated with hardware removal and antibiotis; no difference in mortality: early 7% vs late 6%.
Rodriguez	2012	Observational - Retrospective (3 centers)	384 patients with device-related endocarditis; 6 (1.5%) with spinal abscess	Patients with CIED-related infection who also had spinal abscess	Describe association between spinal abscess and CIED-related infection	Spinal abscess diagnosed by MRI or CT, pathogens: MRSA 50%, MSSA 16.7%, CoNS 33.3%, *E. faecalis* 16.7%. All underwent complete hardware removal without complications; 33% died in-hospital; 33% discharged with permanent neurological deficits; 33% discharged with no deficits.

Kleeman	2010	Observational - Prospective	122 patients	Generator change or lead revision 2006–2008, had pocket cultures	Positive cultures	Of 33% positive cultures, most common organism was CoNS at 68%. Device infection occurred in 7.5% with positive culture vs 2.4% with negative culture, P=.33. Time from revision to infection was longer in positive culture vs negative culture group (108±73 days vs 60±39 days).
Greenspon	2008	Observational - Retrospective (single center)	51	CIED-related infection	Clinical presentation, microbiology and course	Some 37.2% presented ≤6 months following implant, 62.7% at >6 months. *S. aureus* 53% (67% of these were MRSA), CNS 22%, streptococci 12%. All leads removed by percutaneous extraction.
Prevention						
Gillis	2014	Review				Discusses ways to optimize RV pacing to avoid deleterious effects of chronic pacing.
Ueda	2016	Observational - Retrospective (2 centers)	205 patients	277 consecutive ICD recipients (11/1994–12/2013) with structural heart disease; excluded those with pacing indication or permanent atrial fibrillation; remaining patients grouped by ICD type: 36 (18%) received SC ICD, 169 (82%) DC ICD	Trends regarding single vs dual ICD	Mean follow-up 56 months; 10% of DC ICD recipients developed need for atrial pacing over 4.5 years; 5% of SC ICD patients underwent device upgrade to add atrial lead. Inappropriate shocks were similar in single vs dual chamber: 19.4% vs 12.4%, *P* =.285. Infection more frequent in dual vs single (5.3% vs 0%, *P* =.155).
Lambiase	2014	Observational Registry (EFFORTLESS S-ICD)	472 patients	Nonrandomized, multicenter registry to collect outcome data from S-ICD	Efficacy of S-ICDs	Mean follow-up 558 days. Complication-free rates: 97% at 30 days, 94% at 360 days; 7.2% experienced appropriate shocks. First shock conversion efficacy 88%, with 100% overall clinical conversion after maximum 5 shocks. The 360-day inappropriate shock rate was 7%, 94% due to oversensing.
Randles	2014	Observational - Prospective	196 patients	All patients with SC or DC ICD were screened (2/2012–10/2012); excluded patients with S-ICD and paced rhythms	Percent passing ECG screening (≥2 qualifying leads), predictors of failure, interobserver variability	Some 85.2% passed screening; 83.7% passed lead III, 82.7% passed Lead II, and 52.6% passed Lead I, with 92.9% interobserver agreement. An independent predictor of failing screening was prolonged QRS duration.
Pettit	2013	Observational - Retrospective (2 centers)	15 patients: 9 received S-ICD, 6 received transvenous ICD	Consecutive patients aged <20 who received ICD over 4-year period	Primary outcome: survival; secondary outcome: survival free from inappropriate shocks or system revision comparing S-ICD vs transvenous ICD	Median follow-up: S-ICD 20 months; transvenous ICD 36 months, *P* =.026; survival 100% for both groups. Survival free of inappropriate therapy or system revision: S-ICD 89% vs 25% transvenous ICD. Three (50%) of the transvenous ICDs were extracted (infection and lead failure), and none of S-ICDs. Inappropriate shocks: 11% for S-ICD, 38% for transvenous ICD.
Saad	2013	Review				Provides recommendation for implantation and management of CIED in patients with CKD and ESRD.
Stazi	2012	Observational - Prospective	43 patients	Traditional indications for ICD received Lexos A+ generator combined ith Kentrox A+ lead	Assessed atrial sensing peformance in single-lead ICD system that uses an atrial sensor with P-wave amplification; mean follow-up 384 ± 244 days	Implant: unfiltered P-wave 2.02 ± 1.49 vs Filtered P-wave 3.85 ± 0.81 mV, *P* <.001; no difference in p-wave amplitued at follow-up, *P* =.48; 30 appropriate VT/VF episode detections occurred in 9 patients - appropriately detected and treated. 2 patients had inappropriate therapies - both unrelated to atrial sensing detection

Bavnbeck	2010	Review				Discusses wound management following cardiac device implantation.
Alternatives to Extraction						
Sadarmin	2016	Case report	2	Patients in need of device upgrade, impaired by venous occlusion		Authors describe a method for device upgrade in setting of ipsilateral venous occlusion. Venous access was accomplished in the contralateral vein and the lead tunneled subcutaneously.
Chung	2014	Observational Registry (REPLACE)	1744 subjects: (cohort 1: n=1031; cohort 2: n=713); 70 patients died in cohort 1, 33 in cohort 2	6-month complication rates after CIED replacement without (cohort 1) or with (cohort 2) addition of lead or revision. Excluded patients with life expectancy of <6 months or planned lead extraction	6-month all-cause mortality; Risk factors associated with mortality following CIED replacement procedures	Six-month mortality 4%. Factors associated with 6-month mortality included recent HF admission (HR 3.1, *P* <.001), NYHA class III/VI (HR1.96, *P* =.018), antiarrhythmics (HR 1.90, *P* =.014), history of cerebrovascular disease (HR 1.80, *P* =.032), and CKD (HR 1.43, *P* =.022).
Lopez	2013	Observational Case series (1 center)	5 patients	Patients with pocket infections who declined extraction	Describe conservative management of pocket infection	Non-viable tissue, chronically inflamed tissue, granulation tissue, and scar tissue were completely removed, and hemostasis obtained. Nonessential foreign materials (old sutures, suture sleeves) were removed. Generator and any hardware in pocket were scrubbed rigorously with antiseptic and soap solution and placed in vancomycin/gentamicin solution; pocket lavaged with vancomycin/gentamicin solution using a pulse irrigation/suction system. JP drains placed superiorly and inferiorly and pocket closed with monofilament nonabsorable suture. Drains attached to closed irrigation system contining vancomycin/gentamicin for up to 72 hours; pocket reopened, drains removed and generator placed in antibiotic pouch. All discharged with oral antibiotics; mean follow-up 19.2 months. Three died of noninfectioius causes, 2 are alive and infection free.
Kelly	2012	Observational - Retrospective (single center)	191 patients with Fidelis leads		Authors challenging MDT advisory to replace complete HV lead (rather than pace/sense components)	Lead failure 17.8% (n=34), median time to failure 920 days. HV conductor failure in 2 patients (6% of lead failures); most patients managed by replacing pace/sense component (n=26). During median follow-up of 22 months, only 1 patient (3.8%) with pace/sense replacement developed HV conductor failure.
Elayi	2011	Observational Case series (1 center)	8 patients	Patients with central venous occlusion in need of additional lead	Describes novel approach to vascular access in patients with central venous occlusion	Patients with entral venous occlusion in the SVC (n=4), brachiocephalic and bilateral subclavian (n=4); underwent inside-out central venous access without procedure-related complications; normal device function at 485 ± 542 days.
Glikson	2009	Observational - Retrospective (single center)	78 ICD patients with 101 abandoned leads	Mayo Clinic ICD database 8/93–5/02 with abandoned leads; mean follow-up 3.1±2 years from lead abandonment	Complications related to abandoned leads	Most common indication for abandonment: device upgrade (28%), oversensing (11%), and high DFT (9%). During 3.1-year follow-up, no abnormal sensing or thromboembolic complications. High DFTs in 17% (not changed before vs after lead abandonment); 18% required ICD-related surgery but not because of abandoned leads; no difference in inappropriate shocks before vs after lead abandonment.

Jaroszewski	2009	Observational - Retrospective (single center)	11 patients	Minimally invasive surgical placement of epicardial pacing leads or ICD coils	Nontraditional surgical approaches for PM/ICD with limited venous access	Indications for epicardial placement: inablility to place CS lead (82%), venous occlusion (18%). VATS epicardial lead placement in 73%, conversion to midanterior thoracotomy in 9%, subxiphoid lead placement in 27%. Mean hospitalization 4.6 days; postop hypotension and pulmonary edema 27%.
Camboni	2008	Observational - Retrospective (single center)	74 (21 open vs 53 percutaneous extraction)		30-day, 6-month, 12-month, 5-year survival	Open: 91%, 91%, 81%, and 71% at 30 days, 6 months, 12 months, and 5 years, respectively. Percutaneous: 100%, 100%, 94%, and 78% at 30 days, 6 months, 12 months, and 5 years, respectively.
Management Decisions Abandon vs Extract						
Bogniorni	2014	European Survey	34 centers with 98.5% response rate		Describes physician treatment strategies for management of malfunctioning and recalled PM/ICD leads	Factors strongly influencing extraction vs redundant lead: age, lead dwell time, malfunctioning leads. Extracting centers more likely to extract malfunctioning or recalled leads than nonextracting centers. Concerns related to lead abandonment: difficulty with future extraction, future infections, interference with functioning leads.
Henrikson	2010	Commentary: extraction vs abandoning leads				Mortality risk in pre-powered sheath eraapproximately 0.4%–0.6%, morbidity 1%–2%. The laser era has seen improved success rates with similar morbidity/mortality; LEXICON 0.28% mortality. Younger patients have higher risk of lead malfunction and longer time for potential complications from abandoned leads.
Priori	2009	Mathmatical model assessing number needed to replace with advisory leads	n/a	Risk/benefit to replace advisory lead depends on expected annual SCD rate, residual device life, difference in failure rate between advisory device and replacement device, and replacement procedure mortality risk		Device with failure rate approximately 1% and probability of needing device intervention ≥25% per year (PM-dependent patients) have an NNR <250. PM-dependent patients, with devices having ≥ 3 years longevity and device failure rates ≥0.5%, have an NNR <100. Patients with arrhythmic risk ≤2.5% per year and devices with failure rates <0.1% have a high NNR and are at greater risk of harm than benefit from device replacement.
Preprocedure Imaging						
Hirschl	2007	Observational - Retrospective (single center)	100	Patients with cardiac device who had non-ECG gated chest CT	Correlated subclinical lead perforation by CT with lead parameters	Some 15% perforated leads shown by CT (15% atrial, 6% ventricular); no difference in lead impedance or pacing threshold.
Amraoui	2016	Observational - Prospective	35 patients	Consecutive patients with lead endocarditis underwent FDG PET/CT scanning;	scans analyzed by blinded nuclear med MD's to assess for septic emboli 2 days prior to extraction	Identified septic emboli in 29%. Group with emboli were more likely to have higher CRP (144±90 vs 67±61, *P* =.011), positive blood cultures (100% vs 68%, *P* =.07) than those without emboli.
Yakish	2015	Observational - Retrospective (single center)	109 patients	Consecutive patients with Doppler echocardiogram	Compared SVC doppler recordings in patients with vs without CIED	There were 38% patients with CIED. Turbulent Doppler flow in SVC with vs without CIED: 6% vs 22%, respectively, *P* <.05. Turbulent flow in those with CIED implanted ≥2 years vs <2 years: 27% vs 0%, respectively; 22% of CIED patients underwent TLE; turbulent flow identified patients with significant SVC fibrosis.

Balabanoff	2014	Observational - Retrospective (single center)	50 patients (116 leads)	Nonrandom subset of 50 patients were selected from retrospective analysis; all had CXR and ECG gated noncontrast chest CT	Compare CXR vs CT to detect lead perforation	Some 14.7% leads were identified as perforated by chest CT; interobserver agreement was good (κ=0.71); 5.2% of leads were identified as perforated by CXR (50% correlated with chest CT); observers did not agree on any cases of perforation on poor Chest X-ray (interobserver agreement: κ=0.12).
Narducci	2013	Observational - Prospective	162 patients	All underwent TLE, 152 had CIED-related infection; 10 with malfunction	Compared efficacy of ICE vs TEE for identification of intracardiac masses	Group 1: definite IE by Duke criteria: ICE+ 100% vs TEE+ 73%; Group 2: probable IE by Duke: ICE+ 26% vs TEE+ 11%; Group 3: No IE: ICD+ 5% vs TEE+ 3%.
Endo	2008	Observational - Retrospective (single center)	108 patients (202 leads)	Consecutive patients who underwent TLE with TEE guidance		Complete extraction 86%; TEE identified critical findings that promoted emergent surgical intervention in 5.6%; eliminated need for premature procedure termination in 10.2%.
Lewis	2014	Observational - Retrospective (single center)	30 patients	"High-risk" patients who had ECG-gated MDCT before TLE	Feasibility of MDCT for detecting lead perforation, central venous adherence, venous thrombosis, or stenosis	TLE cancelled in 3% due to MDCT-detected lead perforation; 6.7% had evidence of RA tenting; leads extracted without complication (one was converted to open due to extraction difficulty, visually no evidence of perforation). MDCT evidence of venous adherence 43%, associated with longer laser times; 15% venous occlusion; pneumothorax was only MAE.
Regoli	2015	Prospective observation (1 center)	168 patients (241 leads)	Consecutive patients underwent TLE 01/2009–01/2014; TEE during entire TLE, post-procedure TTE	Utility of TEE to guide TLE	Pre-TLE TEE diagnosed pericadial effusion in 2.4%, TR 1.2%, endocardial vegetations 4.2%; intraprocedure TEE: new findings 4.5%, new pericardial effusion 3.2%, new moderate-severe TR 1.2%; post-TLE TTE: no additional TLE-related findings.
Henrikson	2006	Observational Case series (1 center)	3	n/a	Use of CT to diagnose extracardiac lead migration	Case 1: Poor sensing and elevated capture 2 weeks post-implant; echo, CXR, fluoro unrevealing; cardiac CT showed extracardiac lead migration. Case 2: Pleuritic CP 2 days postimplant, interrogation normal; CXR and echo suggestive of perforation but not conclusive; chest CT performed through RV apex and pericardium, lead removed with traction; no pericarial bleeding. Case 3: pleuritic CP 2 days postimplant, chest CT to rule out pulmonary embolism showed RV perforation into pericardial space; interrogation revealed poor sensing and elevated capture; lead removed with simple traction; no pericardial bleeding.
Leads That Require Special Consideration during Extraction						
Pecha	2016	Observational - Retrospective (single center)	22	Consecutive patients refered for extraction that included CS lead removal	Extraction failure rates MDT StarFix vs passive fixation CS leads	Indication: infection for all. Mean lead dwell time: MDT Attain StarFix 9.9±11.7 months, passive fixation 48.0±33.6 months, *P* =.02. Complete removal: StarFix 50%, passive fix 100%; no deaths or complications during 30-day follow-up.
Crossley	2016	Observational - Prospective observational	215 patients; StarFix n=50, 40 had lead in >6 months; non-StarFix n=165	Patients with MDT CS leads implanted ≥180 days requiring extraction (class I or II indications)	Safety and efficacy of StarFix extraction vs other MDT leads	Extraction success: StarFix <6 months 100%; Starfix >6 months 92.5%; non-StarFix 98.8%. Major complications: StarFix <6 months 0%; Starfix >6 months 15% (tamponade in 5%); non-StarFix 6.1%.
Maytin	2012	Observational - Retrospective (6 centers)	12 patients	Identified cohort of patients undergoing lead extraction in 6 centers	Safety and efficacy of StarFix extraction	Mean lead dwell time 14.2±5.7 months; 67% removed for infection. Extraction sheaths (laser, mechanical cutter, femoral) were needed in all; 75% into CS body; 41.7% into CS branch. Successful extraction 91.7%; no major complications.

Bongiorni	2015	Observational - Retrospective (single center)	194 patients (134 Riata; 61 Sprint Fidelis)	Consecutive patients with Riata or Sprint Fidelis leads (01/1997– 04/2014) requiring extraction were included	Assess extraction profile of Riata leads with and without CE	Extraction success rate: Riata 97.8% vs Sprint Fidelis 100%; no major complications in either group. Riata leads often required larger sheaths (11.7±1.4 vs 11.3±1.4), internal transjugular approach (14% vs 3%), and longer procedure time (23±33 min vs 12±16 min). Riata leads with vs without CE: required larger sheaths (12.5±1.6 vs 11.3±1.2, *P* <.001); internal transjugular approach (26% vs 10%, *P* =.02); longer extraction time (37±49 vs 18±22, *P* =.001); had lower success rates (93% vs 100%, P=.02), and was a more difficult procedure (62% vs 33%, *P* =.004).
Maytin	2014	Observational - Retrospective (11 centers)	577 patients (Riata 467, Riata ST 89)	Consecutive patients undergoing Riata/Riata ST lead extraction	Safety and efficacy of Riata lead extraction	Complete extraction success 99.1%. Indication for extraction: infection 53%, lead malfunction 35.7%; 34.9% had CE. Leads with CE vs normal appearance: indication for extraction more often for lead failiure (45.6% vs 33.8%, *P* <.0001); more frequently required use of laser sheaths (71.3% vs 54.9%, *P* =.01); no difference in major (0.97% vs 1.04%, *P* =1.00) or minor complications (3.8% vs 3.0%, *P* =1.00). Predictors of need for powered sheaths by MVA: implant duration (OR 1.06, *P* <.0001); externalized cables (0.41, *P* =.07).
Zeitler	2015	Meta-analysis	23 studies (12,393 patients)	Studies with >35 patients that included CE or EF were included	Prevalence of CE and EF	The CE rate was 23%, the EF rate 6.3%. Presence of CE was associated with 6-fold increase in EF rate vs no CE (17.3% vs 2.7%). CE is 3-fold higer for 8F vs 7F, rates of EF similar (4.6% vs 3.9%).
Larsen	2014	Observational - Danish PM and ICD Registry	295 patients	Consecutive patients in registry that have Riata (8F and 7F) leads	Longitudinal and dynamic nature of CE and EF	CE incident rate 3.7 per 100 person-years; EF incident rate 7.1 per 100 person-years. EF rate was significantly higher in those with CE: adjusted incidence rate ratio 4.4, *P* =.002.
Recommendations for Anticoagulation						
Tompkins	2011	Observational - Retrospective (single center)	1440 patients	Consecutive patients who received PM or ICD 8/2004–8/2007	Bleeding or infection complications that occurred within 60 days of index procedure; compared controls (GFR ≥90 mL/min) with stages of CKD and ESRD	Controls vs ESRD (GFR <15 mL/min or on hemodialysis): infection 0.2% vs 12.5%, *P* <.0001; bleeding complications 3.2% vs 21.9% *P* <.0001. Bleeding complications controls vs moderate CKD (GFR 30–59 ml/min): 3.2% vs 7.4%, *P* <.005. Bleeding complications controls vs severe CKD (GFR 15-29 mL/min) 3.2% vs 9.8%, *P* <.005.
Kutinsky	2010	Observational - Prospective	935 consecutive patients underwent PM or ICD implantation 3005; 89 developed pocket hematoma		Clinical factors associated with hematoma formation	Pocket hematoma 9.5%. Predictors of hematoma: clopidogrel use 18.3%, *P* <.001; IV heparin 22%, P<.0001; subcutaneous heparin 22.6%, *P* =.022. No hematoma if clopidogrel held ≥4 days. MVA predictors: clopidogrel (OR 3.63; 95% CI 2.18–6.02; *P* <.0001), heparin (OR 2.32; 95% CI 1.42–3.79; *P* <.001); more common in ICD vs PM; hematoma associated with increased LOS median 4 vs 2 days; *P* =.004.
Zaca	2015	Review	n/a	n/a		Provides recommendations regarding antithrombotic therapy in patients undergoing TLE.
Hanninen	2014	Case report	n/a	n/a		Case with massive thrombosis that occurred shortly after TLE.

Rahbar	2013	Observational - Retrospective (single center)	1086 patients with devices; 15 patients with clot adhered to lead	Included patients with cardiac devices who had TTE following device implant and follow-up	Risk factors and prognosis of lead-related clot	Lead-associated clot identified in 1.4%. Predictor of lead-associated clot by MVA: atrial fibrillation (OR 8.7, *P* =.006). Patients treated with intensification of anticoagulation/antiplatelet therapy after clot discovered; complete resolution was observed in 89%; none had embolic phenomenon.
Psychological Effects of Advisory Leads						
Larsen	2014	Observational - Prospective registry (DANISH ICD)	210 patients with Riata leads, 256 matched nonadvisory controls	Consecutive patients in registry who received ICD; excluded prior Class I recalls, nonresponders and death	Patient-reported outcomes to assess well-being and psychological functioning with advisory lead	Riata patients reported poorer device acceptance (*P* =.001) and increased device-related concerns (*P* <.001) vs nonadvisory controls; device-related concerns decreased over time; female sex was independent predictor of negative impact of advisory lead on general well-being.
Dantono	2013	Observational - Retrospective (single center)	160 patients received Fidelis leads	Recruited within 1.5 years of advisory notification; told lead surveillance implemented was inadequate at warning of impending fracture	Assessed symptoms of depression, anxiety, and QOL in patients who received advisory lead	Depression experienced in 31%, anxiety in 48%; QOL impaired on all subscales.
Heatherly	2011	Observational - Prospective	413 patients: 158 with advisory Fidelis vs 255 nonadvisory ICD leads	Enrolled patients with advisory Fidelis or nonadvisory ICD lead; excluded those who underwent device explants or had lead fracture, active infection, or malfunctioning ICD. patients notified by EP clinic of advisory status	Total Score from ICDC. ICDC survey: 20-item Likert scale inventory that addresses patients' overall perceptions of their device and QOL. Score on ICDC is positively correlated with depression and anxiety.	Advisory Fidelis vs nonadvisory ICD lead: average time from implant: 3.99±2.32 vs 4.29±3.72 years. Shocks: 39.8% vs 32.2%. Average ICDC scores: advisory group vs nonadvisory with shocks, 27.7 vs 18.5, *P* =.0001; advisory group vs nonadvisory without shocks, 18.5 vs 10.8, *P* =.0001. Having any history of shock signficantly increased ICDC scores; having an advisory lead significantly increased ICDC scores regardless of shocks.
Keren	2011	Observational - Retrospective (single center)	416 patients: Fidelis no fracture (249) vs Fidelis with fracture (24) vs control (nonadvisory, n=143)	All patients with Fidelis lead	Generalized anxiety and depression scores between 3 groups: Fidelis no fracture vs Fidelis with fracture vs control (nonadvisory)	No difference in psychological scores between Fidelis no fracture and control. Adverse psychological morbidity in Fidelis with fracture group, associated with receiving inappropriate shock.
Duru	2010	Prospective randomized trial (PANORAMIC)	356 patients	Randomized to patient notifier on vs off		This paper describes the design of the PANORAMIC trial, which assesses use of vibrating patient notifier to alert patients of possible device malfunction to see if this lowers device-related anxiety about receiving an inappropriate shock.

Author	Year	Study Type	Study Size	Inclusion Criteria	Endpoints	Results
Baddour	2010	Scientific statement from AHA				Discusses management of CIED infections, recommended antibiotic duration, and timing for device reimplantation.
Spragg	2006	Case report	1	n/a	n/a	Describes restoring vascular access retrograde from femoral vein to left subclavian after retained access was lost.
Sohail	2007	Observational - Retrospective (single center)	189 patients	Consecutive patients with CIED-related infection	Evaluated management and outcomes in patients with CIED-related infection.	Some 67% of patients required reimplantation; median time to reimplantation was longer in patients with bloodstream infections vs. nonbacteremic cases (13 days vs 7 days, $P < .0001$); 94% had reimplantation performed on contralateral side; epicardial leads placed in 5%.
Mendenhall	2010	Review	n/a	n/a		Describes a method of retaining IV accesss using lead that can be removed with gentle traction, which is backloaded through sheath.
Antonelli	2009	Observational - Retrospective (single center)	16 leads		Outcomes using novel technique to retain venous access during TLE.	Describes a method of retaining IV access by placing a wire through the lead insulation and advancing the lead into the subclavian vein. All were successfully completed within mean time of 2±1 min.
Bracke	2002	Case report	1 patient	n/a	n/a	Describes technique to retain access by advancing the laser and outer sheaths over malfunctioning lead to just beyond area of occlusion. Laser sheath removed while outer sheath retained and long wire passed through outer sheath.
Staniforth	2002	Observational - Retrospective (single center)	34 patients		Outcomes using novel technique to retain venous access during femoral extractions.	PM lead was cut short, guidewire inserted into gap between insulation and coil; PM lead then snared from below; guidewire then drawn into RA and used to retain access for placement of leads.
Fischer	2009	Observational - Retrospective (single center)	5 patients		Outcomes using novel technique to retain venous access during TLE.	Venography performed to identify sites of venous occlusion; laser sheath advanced over lead to free lead body from vessel wall; lead tip pulled free with manual traction; transfemoral snare used to grasp distal lead tip; laser sheath advanced until binding sites addressed; snare removed and lead withdrawn through laser sheath. Wire advance down laser sheath to retain access.

Author	Year	Study Type	Study Size	Inclusion Criteria	Endpoints	Results
Smith	2008	Review				State-of-the-art tools and techniques for lead extractions.
Farooqi FM	2010	Review				Discusses facilities, training, and equipment required for safe lead extraction.
Maus	2015	Observational - Retrospective (single center)	195 pts (351 leads extracted)	Consecutive patients who underent TLE 2010–2014	Evaluated success and complication rates of TLE using multidisciplinary approach.	Clinical success 99.7%; complete success 97.7%; major complications 3.08% (decreased from 12.1% in year 1 to 2.7% at year 4).
Smith	2104	Case report	1	n/a	n/a	Management of exsanguination during TLE.
Raman	2015	Case report	1	n/a	n/a	Successful use of vena caval inflow occlusion during TLE in patient with contraindications to cardiopulmonary bypass.
Bernardes de Souza	2015	Case report	3	n/a	n/a	Discusses utility of joint cardiac surgery; extraperitoneal approach to lead extraction.
Wang	2014	Observational - Retrospective (single center)	140 patients	Consecutive patients who underent TLE 2004–2011	Clinical outcomes compared in patients with and without intraoperative vascular lacerations.	Complete lead removal in 84.3%; potentially fatal complications in 3.6% (SVC or innominate tears); mean time to bypass 6.0±3.6 minutes. All survived without sequelae; dual-coil ICD was independent risk factor for laceration (OR 11.3, *P* =.048).
Maytin	2015	Prospective Randomized	8 fellows	A total of 8 fellows randomized to virtual reality simulator vs conventional training.	Compared procedural skill competency between the groups using simulator competency, tactile measurements, markers of proficiency and attitudes, and cognitive abilities battery.	VR simulator group executed patient preparation and procedure performance better than the conventional group (P<.01). A total 100% of the conventional training group experienced a simulator complication (50% had SVC tears, and 75% had RV avulsions vs 25% in the VR simulator group [SVC tear], *P* =0.02). Tactile measurements revealed a trend toward excess pushing versus pulling forces among the conventionally trained group. The time for lead removal was also significantly longer in the conventional training group (12.46 minutes vs 5.54 minutes, *P* =.02). There was no significant difference in baseline or post-training cognitive ability.
Lou	2015	Case report	1	n/a	n/a	Successful use of a covered stent for SVC laceration.
DiMonaco	2014	Meta-analysis	66 observational studies (18433 patients)	Included studies assessing safety or efficacy of TLE.	Rate of major and minor complications based on center volume.	Major complications or deaths within 48 hours: crude rate 1.6%, proportion meta-analysis 1.8%. Minor complications within 48 hours: crude rate 2.4%, proportion meta-analysis 3.0%. The 30-day mortality crude rate 1.5%, proportion meta-analysis 1.8%. Major complications + death: EHRA classification (<15 extractions, 1.8%; >30 extractions, 1.8%); Lexicon classification (<60 extractions 2.0%; >130 extractions 1.6%). Minor complications: EHRA classification (<15 extractions 7.2%; >30 extractions 2.1%); Lexicon classification: <60 extractions 8.5%; >130 extractions 2.3%). The 30-day mortality: EHRA classification (<15 extractions 5.3%; >30 extractions 1.5%); Lexicon classification (<60 extractions 14.6%; >130 extractions 1.4%).

Wazni	2010	Observational - Retrospective Lexicon (13 centers)	1449 patients	Consecutive patients underwent laser-assisted extraction between 1/2004–12/2007; excluded procedures that used nonlaser, nontraction devices used in same procedure.	Safety and efficacy of laser-assisted lead extraction.	Median implant duration 82.1 months (0.4-356.8). Indications: infection 57%, nonfunctional leads 26.6%, functional abandoned 11.1%, venous stenosis/occlusion 4.5%, chronic pain 0.8%. Complete removal: 96.5%, clinical success 97.7%. Multivariate predictors of failure to achieve clinical success: BMI <25 kg/m^2; volume ≥60 cases over 4 years by MVA. MAE: 4%, death 1.86% (0.28% directly related to procedure). Multivariate predictor of MAE: BMI <25 kg/m^2. Multivariate predictor of in-hospital death: BMI <25 kg/m^2, creatinine ≥2.0 mg/dl, diabetes, and infection as indication.

Author	Year	Study Type	Study Size	Inclusion Criteria	Endpoints	Results
Essebag	2015	Observational - retrospective (subgroup analysis of RAFT)	140 patients underwent CRT upgrade; control group 644 patients	644 patients underwent de novo CRT implant; 80 ICD recipients underwent attempted upgrade to CRT-D during RAFT, 60 after completion of RAFT	Incidence, predictors following upgrade to CRT	Device upgrade successful in 77 of 80 (96.3%) during RAFT, and 54 of 60 (90.0%) after RAFT; success rates were similar in de novo CRT implant group (95.2%). Complications ≤30 days more common in de novo group than upgrade groups (26.2% vs 18.8% [during RAFT] vs 3.3% [after RAFT]); 282 patients (82.5%) in ICD group did not undergo upgrade to CRT-D after RAFT; physicians recommended against upgrade in 129 patients (37.7%) because not LBBB (9.6%), permanent afibrillation (5.3%), QRS <150 ms (13.1%), NYHA class I (17%), LVEF >35% (5.0%).
Kikkenborg	2015	Prospective, randomized (COPE-ICD trial)	196 ICD patients	196 ICD patients randomized 1:1 to rehab (exercise training + nursing psychoeducational training) vs usual care	Emotions and Health Scale	Primary emotions are affected after ICD implantation that improve over time (3 months); no difference in mean emotion scores at baseline or after 3 months between rehab group vs usual care.
Nordkamp	2015	Observational - retrospective (subgroup analysis of EFFORTLESS registry)			Incidence, predictors, and management of inappropriate shocks	Mean follow-up 21±13 months; 8.3% experience inappropriate shocks; most common cause cardiac oversensing 73% (T-wave), SVT 18%. Predictors of inappropriate shocks by MVA: history of atrial fibrillation (HR 2.4, P <.05), HCM (HR 4.6, P <.05); reprogramming and treatment of SVT were effective in preventing further inappropriate shocks.
Fanourgiakis	2015	Observational - Retrospective (single center)	398 patients: 201 initial PM implants, 117 PM replacements, 69 initial ICD implants, 11 ICD replacements	Single-center registry created as part of cost of illness study; includes consectutive patients status post CRMD procedure during 1 year	Evaluated additional costs associated with CRMD complications	There were 2.99% complications following initial PM implantation; 0.85% following PM generator change; no complications in ICD arms; average prolongation in LOS was 7 days (1–35), resulting in £17,422 additional direct hospital costs.
Cairrault	2014	Review				Discusses advances in field of CIEDs
Johansen	2014	Editorial of Burri				
Jordan	2014	Observational Registry (NCDR)	3139 CHD patients	Age <21 years who received ICDs 2006–2012	Indications for ICD in CHD or pediatric ICDs	Primary prevention 61.9%, secondary 35.2%; 97% tranvenous leads, 3% nontransvenous.
Conte	2014	Observational Registry (Brugada, 1 center)	40 patients <12 years of age compared with 465 controls age >12 years	505 patients with ajmaline-induced Brugada syndrome; 40 <12 years of age	Incidence and outcomes of children with drug-induced Brugada syndrome.	Some 75% of patients were referred as part of family screening; 85% had normal ECGs. Findings from EPS: 60% had SND, 8% had inducible VAs. Type I ECG pattern post-ajmaline in 24%; genetic testing positive in 21%; 30% had ICD placed; after mean follow-up 83±51 mths, none died suddenly, 8% had appropriate ICD therapies; 33% had inappropriate shocks.

Rivera	2014	Case report	1	n/a	n/a	CIED-infection (lead vegetation) with C. albicans; status post surgical resection/lead extraction.
Wadhawan	2014	Case report	1	n/a	n/a	Describes LUE occlusive thrombus following ICD placement; symptoms pain, swelling, redness continued despite anticoagulation; underwent mechanical thrombolysis with resolution of symptoms.
Marinskis	2013	Survey				Discussed X-ray equipment used for EP procedures.
Maron	2013	Observational Registry (22 centers)	224 patients: 188 primary prevention; 36 secondary	Multicenter international registry of ICDs implanted 1987–2011 in age <20 years with HCM	Efficacy of ICDs over median follow-up 4.3±3.3 years	Some 19% experienced ≥1 appropriate therapy. ICD intervention rates 4.5% per year overall; rate of ICD interventions was 4-fold higher in secondary vs primary prevention: 14% per year for secondary prevention, 3.1% per year primary prevention. Mean time from implant to first appropriate therapy 2.9±2.7 years. ICD-related adverse events occurred in 41%; 28% experienced inappropriate therapies (rate of 6.5% per year); 4% died during follow-up. in primary prevention arm, appropriate ICD therapies occured in 14% of patients with 1, 2, or 3 high-risk features.
Silvetti	2013	Observational - Prospective	89 patients: 48 patients axillary vein; 41 subclavian vein	Consecutive pediatric patients who underwent PM/ICD lead implantation between 2009–2012 via axillary or subclavian veins	Comparison of axillary vs subclavian approach to lead placement	A total 62 leads placed via axillary vein, 54 via subclavian. Efficacy of lead placement: subclavian 100% vs axillary 93.7% (precluded by smaller diameter); no difference in early or late complications.
Arias	2012	Letter to Editor				Provides definitions for Twiddler vs. Reel syndromes.
Bhatt	2012	Observational Registry (NCDR)	173,616 implants	ICD implant rates between 07/2006 and 12/2008	Performed time-series analysis comparing actual vs predicted implant volumes following Fidelis recall in 10/2007	Monthly average implants: 5952 devices before October 2007 vs 5623 following recall (*P* =.05). Proportion of MDT implants declined from 51.1% in the 15 months prior to recall to 45.8% in the 15 months following recall (*P* <.01).
Ladoucer	2012	Case Report	1			A 15-year-old boy who received multiple inappropriate shocks that continued in ED because magnet not available. Transferred to another facility to inactivate therapies. Subclavian crush was cause of fracture; lead revised.
Healey	2012	Position paper from Canadian Cardiovascular Society, Canadian Anesthesioly Society and Canadian Heart Rhythm Society				Reviews perioperative management of CIEDs

Powell	2011	Observational Registry (Altitude remote monitoring)	81081 patients	Randomly selected 2000 patients with 5279 shock episodes were included	Evaluate inter- and intraobserver variability in adjudication of shocks (appropriate vs inappropriate) using EGMs from remote monitoring	Interobserver Kappa scores: dual chamber 0.84 (0.71–0.91), single chamber 0.61 (0.54–0.67). Intraobserver Kappa scores: dual chamber 0.89 (0.82–0.95), single chamber 0.69 (0.59–0.79). Substantial interreviewer agreement for rhythm classifiation; agreement greater for dual- vs single-chamber devices; nonsustained arrhythmia and polymorphic and monomorphic VT had greatest degree of discordance between reviewers.
Cheng	2010	Observational Registsry (NCDR)	2628 patients	Acute lead dislodgements out of 226,764 patients who had cardiac device placed 4/2006–9/2008	Consequences and predictors of lead dislodgement	Acute dislodgement occurred in 1.2%; highest with CRT-D (1.78%) vs single chamber (0.56%). Some 54.3% of dislodgements occurred with CRT-D; LOS increased 2.3 days with acute dislodgement. MVA predictors of lead dislodgement: NYHA class IV, atrial fibrillation, CRT-D, physicians trained under alternative pathways. Major complications were 5-fold higher (OR 5.62; 95% CI 4.79–6.6; $P < .00001$) and death approximately 3-fold higher (OR 2.66; 95% CI 1.98–3.57) in patients with acute dislodgement.
Hammill	2010	Observational NCDR annual update (2009)	486,025 implants			Implant data: mean age 68.1±12.8 years, 73.8% male, 82.8% white; 65.3% ischemic HD, 11.4% cardiac arrest, 46% NYHA class III, EF 28.6±11.6; 77.9% primary prevention; 22.2% secondary; adverse event rate: 3.22%.
LaRocca	2010	Observational - Retrospective (single center)	235 patients (118 CRT-P, 117 CRT-D)	Consecutive patients who received CRT	CS lead performance	During mean follow-up 41.7±14.7 months: pacing impedance and R-wave amplitude decreased, capture threshold increased.
Syska	2010	Observational - Retrospective (single center)	104 patients	Consecutive patients with HCM who received ICD	Average follow-up 4.6±2.6 years	Primary prevention 75%, secondary 25%; appropriate therapies in 53.8% of secondary prevention group (7.9% per year) vs 16.7% in primary prevention group (4.0% per year). Complications: inappropriate shocks 33.7%, lead dysfunction 12.5%, infection 4.8%.
Boriani	2009	Editorial				
Hammill	2009	Observational Registry NCDR 2008 annual report	339,076 implants			Implant data: mean age 68.1±12.8 years, 74% male, 83% white; 66% ischemic HD, 11.3% cardiac arrest, 46% NYHA class III, EF 28.2±11.4; 78% primary prevention; 21.8% secondary; adverse event rate: 3.36%.
Healy	2009	Commentary				Review of Epstein 2009
Krahn	2009	Commentary				Manuscript announcing development of Canadian Device Advisory Committee.

Lobodzinski	2009	n/a	n/a	n/a	n/a	Discusses electrical and mechanical data on silver-infiltrated gold-plated poly(p-phenylene-2,6-benzobisoxazole) fibers as a potential alternative to conventional metal cardiac leads.
Spenker	2009	Observational - Retrospective (single center)	54 patients undergoing lead revision without	54 patients undergoing lead revision (11 equipped with home monitoring, 43 without)		Remote monitoring diagnosed lead failure in 91%; 90% were asymptomatic at time of 1st report; inappropriate shocks occuried in 27.3% HM vs 46.5% without monitoring; HM gained 56 days of reaction time to prevent adverse events.
Watson	2009	Letter to Editor - Fidelis				
Stone	2009	Review				Discusses perioperative management of cardiac devices for anesthesiologists.
Berul	2008	Observational - Retrospective (4 centers)	443	Children with SHD or primary electrical disease who received ICDs	Inappropriate/appropriate shocks; complications	Some 46% had CHD; 23% primary electrical. Appropriate shocks 26%, inappropriate shocks 21%; 4% all-cause mortality; 64 (in 55 patients) complications within 30 days.
Brinker	2008	Commentary				
Dourakis	2008	Case Report	1	n/a		Brucella CIED
Catanchin	2008	Case Report	1			Death due to inappropriate shock inducing VF.
Hammill	2008	Observatioanl Registry (NCDR 2-year update)	206,604	2-year update on NCDR	Adverse procedure events	Implant data: mean age 68.1±12.7 years, 74% male, 83% white; 66% ischemic HD, 10.8% cardiac arrest, 46% NYHA class III, EF 27.8±11.1; 78.7% primary prevention; 21.3% secondary; adverse event rate: 3.24%.
Theurns	2008	Letter to Editor				
Catanchin	2007	Case Report	1	n/a	n/a	Noise led to inappropriate shock that induced VF; resulted in death.

ARVC = arrhythmogenic right ventricular cardiomyopathy; BMI = body mass index; CIED = cardiovascular implantable electronic device; CKD = chronic kidney disease;
CoNS = coagulase-negative staphylococci; COPD = chronic obstructive pulmonary disease; CP = chest pain; CRT-D = cardiac resynchronization therapy defibrillator;
CS = coronary sinus; CXR = chest X-ray; DC = dual catheter; DFT = defibrillation threshold; ESRD = end-stage renal disease; FDG = fluorodeoxyglucose; GFR = glomerular filtration rate; HCM = hypertrophic cardiomyopathy; HF = heart failure; HM = home monitoring; HR = hazard ratio; HV = high voltage; ICD = implantable cardioverter defibrillator; ICDC = ICD Patient Concerns Questionnaire; IE = infective endocarditis; INR = international normalized ratio; KM = Kaplan-Meier; LBBB = left bundle branch block; LDTD = lead-dependent tricuspid dysfunction; LE = lead extraction; LLE = laser lead extraction; LOS = length of stay; LVEF = left ventricular ejection fraction; MAE = major adverse event; MDCT = multidetector computed tomography; MDT = Medtronic; MRSA = methicillin-resistant *Staphylococcus* aureus; MVA = multivariate analysis; NNR = number needed to replace; NS = not significant; NYHA = New York Heart Association; OR = odds ratio; PM =