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Heart Rhythm Society SM

HRS Consensus Statement

2026 HRS/AHA/APHRS/EHRA/IDSA/LAHRS/PACES/STS expert consensus statement update on cardiovascular implantable electronic device lead management and extraction

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ABSTRACT

AIM The "2026 HRS Expert Consensus Statement Update on Cardiovascular Implantable Electronic Device Lead Management and Extraction" provides updated recommendations to guide clinicians in the management of cardiovascular implantable electronic device (CIED) leads.

BACKGROUND Since the publication of the "2017 HRS Expert Consensus Statement on Cardiovascular Implantable Electronic Device Lead Management and Extraction," the field has evolved quickly. New evidence on CIED lead management and the blooming development of new CIED technologies, including leadless pacing and implantable cardioverter-defibrillator leads implanted outside the vascular system and new lumenless pacing leads and lead extraction tools, have contributed to the field's rapid evolution.

METHODS AND RESULTS A comprehensive literature search was conducted in accordance with the Institute of Medicine standards. The writing committee reviewed evidence gathered through electronic literature searches encompassing clinical trials, original studies, and meta-analyses conducted on human subjects published in English from MEDLINE, PubMed, Embase, and the Cochrane Library up to December 2024. The comprehensive literature review supports each evidence-based recommendation and is compiled in the evidence tables. A predefined threshold of >70% approval for each recommendation was required, with a quorum of two-thirds of the writing committee. The final mean consensus of 108 recommendations was 93.61%.

DISCUSSION The recommendations from the "2017 Expert Consensus Statement on Cardiovascular Implantable Electronic Device Lead Management and Extraction" have been updated with new evidence to guide clinicians. The new recommendations address the latest CIED technologies with the advantages over transvenous leads; new evidence supporting diagnosis, treatment, and prevention for CIED infection; appropriate lead management in transcatheter tricuspid valve replacement for tricuspid regurgitation; and standardization of transvenous lead extraction approach, protocol, and facilities to improve the outcomes of CIED lead management and extraction.

KEYWORDS Lead management; Extraction; Transvenous leads; Leadless pacing; CIED infection

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ABBREVIATIONS ACC = American College of Cardiology; AHA = American Heart Association; APHRS = Asia Pacific Heart Rhythm Society; ATP = antitachycardia pacing; CIED = cardiovascular implantable electronic device; COR = class of recommendation; CRT = cardiac resynchronization therapy; CT = computed tomography; EGM = electrogram; EHRA = European Heart Rhythm Association; ePTFE = expanded polytetrafluoroethylene; EV-ICD = extravascular implantable cardioverter-defibrillator; FDA = Food and Drug Administration; FDG = ^{18}F-fluorodeoxyglucose; HRS = Heart Rhythm Society; HVSI = high-voltage shock impedance; ICD = implantable cardioverter-defibrillator; IDSA = Infectious Diseases Society of America; LAHRS = Latin American Heart Rhythm Society; LOE = level of evidence; LVEF = left ventricular ejection fraction; LVSI = low-voltage shock impedance; MRI = magnetic resonance imaging; non-SA GPC = non-*Staphylococcus aureus* gram-positive cocci; PACES = Pediatric and Congenital Electrophysiology Society; PET = positron emission tomography; PREDICT = Predicting Risk of Endovascular Device Infection; RV = right ventricular; RWI = relationships with industry; SAB = *Staphylococcus aureus* bacteremia; S-ICD = subcutaneous implantable cardioverter-defibrillator; STS = Society of Thoracic Surgeons; SVC = superior vena cava; TEE = transesophageal echocardiography; TLE = transvenous lead extraction; TTE = transthoracic echocardiography; TTVR = transcatheter tricuspid valve replacement; VF = ventricular fibrillation; VT = ventricular tachycardia

TABLE OF CONTENTS

Top 10 take-home messages e1719
Section 1 Introduction and methodology e1719
1.1 Preamble e1719
1.2 Document scope and rationale e1720

1.3 Funding and editorial independence e1720
1.4 Organization of the writing committee and stakeholder involvement e1720
1.5 Evidence reviews and formulation of recommendations e1720
1.6 Class of recommendation and level of evidence e1721
1.7 Document review and approval e1722
1.8 Document updates e1722
1.9 Relevant clinical practice documents e1722
Section 2 General concepts e1722
Section 3 Definitions e1722
Section 4 New technologies e1724
4.1 New technologies e1724
4.1.1 Nonvascular ICD therapies e1724
4.1.2 Leadless pacing therapies e1726
4.2 Extraction of CIEDs in newer CIED technologies e1726
4.2.1 Extraction of nonvascular ICDs e1726
4.2.2 Retrieval and extraction of leadless pacemakers e1727
Section 5 Diagnostic approach to suspected lead failure e1728
5.1 Clinical presentation e1729
5.2 Special populations: Children and patients with congenital heart disease e1730
5.3 Device electrograms in pace-sense failures .. e1730
5.4 Impedance and impedance trends in lead failure e1731
5.5 Device diagnostics to mitigate adverse consequences of pace-sense failure e1732
5.5.1 Counts of extremely short R-R intervals e1732
5.5.2 Algorithms that incorporate sensing and impedance monitoring e1732
5.5.3 Algorithms that compare sensing and shock EGMs e1732
5.6 Role of remote monitoring e1733
Section 6 Lead recalls and advisories e1733
6.1 Terminology and recall framework e1734
6.2 Lead surveillance and performance thresholds e1734
6.3 US FDA e1735
6.3.1 Premarketing assessment e1735
6.3.2 Postmarketing surveillance e1735
6.4 Selected examples of lead recalls and advisories e1735
6.4.1 Accufix leads e1735
6.4.2 Sprint Fidelis and Riata leads e1735
6.4.3 Nanostim leadless pacemaker e1736
6.4.4 Model 3501 S-ICD lead e1736
6.4.5 RELIANCE ePTFE lead e1736
Section 7 Clinical considerations in CIED lead management e1737
7.1 Lead management during CIED replacement e1738
7.1.1 Complications of generator exchange e1738
7.1.2 Risk factors for complications and mortality e1738
7.1.3 Risk of lead failure after generator exchange e1738
7.1.4 Shared decision making e1738
7.2 Lead management during CIED upgrade e1738
7.2.1 Upgrade procedure preparation e1738
7.2.2 Complications of lead upgrade and revision procedures e1739
7.2.3 Venous occlusion e1740
7.2.4 Lead choices e1740
7.2.5 Incorporating preexisting leads e1740
7.2.6 Addition of a pace-sense lead e1740
7.3 Device downgrade e1740
7.4 Nonfunctional and abandoned leads e1741
7.5 Lead management at the time of tricuspid valve replacement e1741
Section 8 Diagnosis, management, and prevention of CIED infection e1743
8.1 Initial evaluation and diagnosis of CIED infection e1744
8.2 Management of CIED pocket infection e1745
8.3 Management of patients with a CIED and *S aureus* bacteremia or endocarditis e1747
8.4 Management of patients with a CIED and non-SAB or endocarditis e1749
8.5 Management of patients with a CIED and fungemia e1751
8.6 Procedural management for infection indication of CIED removal e1753
8.7 Pacing management at CIED removal e1755
8.8 Management of reimplantation timing after CIED removal for infection e1756
8.9 CIED infection antimicrobial therapy e1757
8.10 Prevention of CIED infection e1758
Section 9 Indications for lead extractions (noninfectious) e1759
9.1 Chronic pocket pain e1759
9.2 Thrombosis (vascular obstruction/occlusion) e1760
9.3 Lead malfunction/recalled leads: Extraction vs abandonment e1761
9.4 CIED upgrade and downgrade e1762
9.5 MRI e1763
9.6 CIED management in tricuspid valve disease e1764
9.7 Radiation therapy e1765
9.8 Other issues e1766
Section 10 Management of patients undergoing lead extraction e1766
10.1 Preprocedural considerations e1767
10.2 Intraoperative considerations e1769
10.2.1 Anesthetic and intraoperative management e1770
10.2.2 Approach, technique, and equipment necessary for lead extraction e1771
10.2.3 Management of complications e1772
10.3 Postprocedural considerations e1773
Section 11 Implant lead selection: Approach and techniques to mitigate lead malfunction e1774
11.1 Venous access e1774
11.2 Lead choice e1775
11.3 Tricuspid valve regurgitation e1776
11.4 Number of leads e1777
Section 12 Knowledge gaps and future directions e1778
12.1 Nonvascular CIED e1778
12.2 Standardization of TLE e1778
12.3 Early extraction in infected CIEDs e1779
12.4 Lead management in conduction system pacing e1779
12.5 Transvenous lead and tricuspid valve function e1779

12.6 CIEDs in congenital heart disease e1779
12.7 Uninterrupted anticoagulation during TLE . e1779
12.8 The safety of MRI in patients with CIEDs e1779
Acknowledgments e1779
References e1780
Appendix 1. Writing committee member disclosure of relationships with industry and other entities e1789
Appendix 2. Reviewer disclosure of relationships with industry and other entities e1792

Top 10 take-home messages

1. Cardiovascular implantable electronic device (CIED) new technology: Nonvascular implantable cardioverter-defibrillators and leadless pacemakers have emerged as significant parts of our device practice. Their main advantages are related to the elimination of transvenous leads, hence reducing lead-related complications (venous obstruction and systemic infection) and extraction-related complications and playing a major role in the treatment of patients with limited vascular access.
2. Risk stratification and prevention for CIED infection: 1-time systemic antibiotics delivered before the procedure significantly reduce the incidence of device infection. Additional periprocedural antibiotics, including multicomponent antibiotic regimens or postoperative antibiotics (PADIT trial), provide no significant advantage in preventing device-related infections and are not recommended; however, the adjunctive use of an antibacterial envelope reduces the incidence of CIED infection in selected high-risk patients and is a new class 2a recommendation.
3. New strategies for CIED infection diagnosis: New diagnostic paradigms emphasize using a probabilistic framework that integrates pathogen-specific virulence and biofilm-forming capacity, duration of positive cultures, and careful interpretation of imaging findings. This approach reflects the recognized limitations of imaging modalities: transesophageal echocardiography, although highly sensitive, is nonspecific and may not reliably differentiate infection from noninfectious echo densities; similarly, ^{18}F-fluorodeoxyglucose positron emission tomography/computed tomography has limited sensitivity for isolated lead involvement, particularly in the absence of pocket infection.
4. Thoughtfulness on initial lead selection and implantation techniques: When selecting and implanting transvenous leads, it is critical to consider the risk of lead fracture, infection, pocket complications, and the need for future extraction. The updated document recommends minimizing the number of leads as appropriate, selecting single vs dual implantable cardioverter-defibrillator coils, and practicing meticulous techniques for vascular access and lead placement to mitigate procedural complications, enhance lead longevity, and facilitate future extraction.
5. Early extraction for infected CIED: In patients with CIED infection undergoing system removal, newer evidence demonstrates that early removal (<7 days) is beneficial compared with delayed extraction, including a reduction in in-hospital mortality, major adverse events, and post-procedural length of stay. Therefore, early removal is a new class 1 indication.
6. Lead vegetation debulking and removal: A surgical approach has historically been considered when a very large vegetation (>2.5–3.0 cm) was attached to the lead owing to a concern for massive pulmonary embolism. Percutaneous mechanical aspiration of vegetations in medium and large sizes using new thrombectomy tools has a high rate of procedural success and a low risk of complications and, therefore, is a new class 2a recommendation.
7. Lead management in the setting of tricuspid regurgitation: Transcatheter tricuspid valve replacement (TTVR) has evolved as an effective alternative treatment to surgical valve replacement, especially in high-risk patients for surgery, and can result in right ventricular (RV) lead entrapment between the tricuspid valve and the implanted valve, potentially causing lead malfunction. The updated document recommends RV lead removal in patients with transvenous leads crossing the tricuspid valve and planned transvenous tricuspid valve intervention to avoid entrapment of the lead and facilitate the TTVR procedure as a class 1 indication.
8. Shared decision making for lead extraction or abandonment: When a CIED lead malfunctions or becomes unnecessary, shared decision making with the patient as to whether to abandon or remove the lead is recommended.
9. Standardization of multidisciplinary approach, transvenous lead extraction protocol, and facility/equipment for lead extraction: The updated document emphasizes prompt referral and access for patients with indications for lead removal to an experienced extraction center and establishing an institutional protocol and a multidisciplinary team approach to guide preprocedural planning and periprocedural management. The standardized, multidisciplinary team approach for transvenous lead extraction and establishing an extraction program with all the necessary equipment and expertise required to manage all potential complications are class 1 recommendations.
10. Remote monitoring should be mandatory: Modern CIED technology has advanced algorithms for the detection of electrical abnormalities, which can provide early warning for an impending lead malfunction and failure and mitigate adverse events and hospitalization. Therefore, we emphasize that remote monitoring is a class 1 recommendation for all patients and CIED systems that have this capability.

Section 1 Introduction and methodology

1.1 Preamble

The Heart Rhythm Society (HRS) has developed expert consensus documents that have guided clinical care in the

management of cardiac arrhythmias since 1996. This HRS-led expert consensus statement was developed with international collaboration with the American College of Cardiology (ACC), the American Heart Association, the American Society of Anesthesiologists, the Asia Pacific Heart Rhythm Society, the European Heart Rhythm Association, the Infectious Diseases Society of America, the Latin American Heart Rhythm Society, the Pediatric and Congenital Electrophysiology Society (PACES), and the Society of Thoracic Surgeons.

1.2 Document scope and rationale

Cardiovascular implantable electronic devices (CIEDs) traditionally use leads that connect the pulse generator to cardiac tissue. Since the publication of the "2017 HRS Expert Consensus Statement on Cardiovascular Implantable Electronic Device Lead Management and Extraction,"[1] the field has evolved quickly with the publication of new evidence on CIED transvenous lead management, development of new CIED technologies that are leadless or use leads implanted outside the vascular system, wide adoption of leads that do not have a lumen, new lead extraction tools, and new cardiac and vascular procedures that have lead management implications. A holistic approach to CIED selection and use is required, as is, by extension, consideration of potential lead management implications over a patient's lifetime. This document is intended to help clinicians in their decision-making process for managing leads and CIED implant considerations and updates the 2017 expert consensus statement.[1]

Scientific evidence was systematically reviewed and translated into recommendations to improve the quality of care in CIED lead management. The document was developed in international collaboration and is intended to be relevant to medical practice worldwide. Although expert consensus statements may be used to inform regulatory or payer decisions, the intent is to improve the quality of care, support the appropriate use of therapeutics, and align with patients' interests. Expert consensus statements are intended to define practices that meet the needs of patients in most, but not all, circumstances, and are not meant to replace clinical judgment.

The focus of this current expert consensus statement is to provide an update on practical clinical guidance in the broad field of lead management, including the extraction and management of traditional CIEDs that use transvenous leads, CIEDs with extravascular or subcutaneous leads, and leadless CIEDs.

1.3 Funding and editorial independence

This expert consensus statement is sponsored by the HRS and was developed without commercial support. All writing committee members volunteered their time to the writing and review efforts.

1.4 Organization of the writing committee and stakeholder involvement

The writing committee consisted of internationally recognized experts from 5 countries in the fields of clinical electrophysiology, pediatric electrophysiology, cardiothoracic anesthesiology, cardiothoracic surgery, and infectious diseases. Each writing committee member served as a representative of either HRS or the collaborating society and was nominated according to each organization's processes. HRS strives to ensure that the writing committee contains both requisite expertise and diverse representation from the broader medical community. This is achieved by selecting participants from a wide range of backgrounds representing different geographic regions, genders, races, ethnicities, intellectual perspectives, and scopes of clinical practice and by inviting organizations and professional societies with related interests and expertise to participate as collaborators. In addition, a patient partner was included in the writing committee to ensure a focus on delivering optimal patient care that is in alignment with patients' wants, needs, and preferences.

HRS has rigorous policies and methods to ensure that documents are developed without bias or improper influence. The HRS policy on relationships with industry (RWI) and other entities can be found in the HRS Code of Ethics and Professionalism: Appendix D and in the HRS Clinical Document Development Methodology Manual and Policies. Most of the writing committee was free of relevant RWI throughout the development of the document, and sections with recommendations were written by the writing committee members who were free of relevant RWI. For full transparency, a comprehensive list of RWI (both relevant and nonrelevant to the document topic) disclosed by the writing committee members is presented in Appendix 1. A comprehensive list of RWI disclosed by the peer reviewers is presented in Appendix 2.

1.5 Evidence reviews and formulation of recommendations

This expert consensus statement was developed in accordance with the clinical practice methodology processes detailed in the HRS Clinical Document Development Methodology Manual and Policies[2] and with the standards issued in 2011 by the Institute of Medicine (now National Academy of Medicine).[3]

The writing committee reviewed evidence gathered by electronic literature searches (MEDLINE, PubMed, Embase, and Cochrane Library). Literature searches focused whenever possible on randomized controlled trials, but systematic reviews, nonrandomized and registry studies, cohort studies, and case series were included. Evidence tables are presented in Supplemental Appendix 3 and summarize the evidence used by the writing committee to formulate recommendations. References are representative of the totality of data and are not meant to be all-inclusive. The limitations of the evidence base are discussed in individual sections.

The consensus process was facilitated using a software tool based on the modified Delphi technique, which allows voting committee members to indicate their agreement or disagreement with each recommendation and provide comments for consideration. A predefined threshold of 70% approval for each recommendation was required, with a

minimum quorum of two-thirds of the writing committee. Any initial failure to reach consensus was resolved by subsequent discussions, revisions as needed, and revoting. Writing committee members with RWI did not vote on recommendations concerning relevant topics.

1.6 Class of recommendation and level of evidence

Recommendations in this expert consensus statement are designated with both a class of recommendation (COR) and a level of evidence (LOE). The COR denotes the strength of the recommendation based on the assessment of the magnitude and certainty of the benefits in proportion to the risks. The LOE reflects the quality of the evidence that supports the recommendation based on the type, quantity, and consistency of data from clinical trials and other sources. This COR/LOE system is based on the framework developed by the American Heart Association and the ACC (Table 1).[4]

Table 1 ACC/AHA recommendation system: applying class of recommendation and level of evidence to clinical strategies, interventions, treatments, and diagnostic testing in patient care (updated May 2019)

CLASS (STRENGTH) OF RECOMMENDATION	
CLASS 1 (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 2a (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 2b (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 3: No Benefit (MODERATE) **(Generally, LOE A or B use only)**	**Benefit = Risk**
Suggested phrases for writing recommendations: • Is not recommended • Is not indicated/useful/effective/beneficial • Should not be performed/administered/other	
CLASS 3: Harm (STRONG)	**Risk > Benefit**
Suggested phrases for writing recommendations: • Potentialy 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 1 and 2a; 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.

Adapted with permission from the ACC and the AHA.
ACC = American College of Cardiology; AHA = American Heart Association.

For clarity and usefulness, each recommendation is linked to the supportive evidence through the specific references from the literature used to justify the LOE rating, which are also summarized in their evidence tables (Supplemental Appendix 3). Each recommendation is accompanied by explanatory text. Flow diagrams and appropriate tables provide a summary of the recommendations and are intended to assist clinicians at the point of care.

1.7 Document review and approval

The HRS invites public and stakeholder involvement in document development. Draft recommendations were posted for public comment, and contributions were solicited from regulatory agencies and patient organizations.

This expert consensus statement was approved by the writing committee and underwent an internal review by the HRS Clinical Guidelines Committee. The document underwent an external peer review by reviewers appointed by HRS and each of the collaborating societies, and revisions were made by the chairs. A record of writing committee response to reviewer comments and rationale is maintained by the HRS.

1.8 Document updates

The HRS Clinical Guidelines Committee reviews each clinical practice document for currency at least every 5 years, or earlier in the event of newly published data. The literature is routinely monitored to evaluate the continued validity of recommendations.

1.9 Relevant clinical practice documents

Clinical practice documents relevant to managing leads and CIED implant considerations were used to inform the development of this consensus statement. The relevant clinical practice guidelines and consensus statements that the writing committee considered fundamental to the development of this document are presented in Table 2.

Section 2 General concepts

Over the past 70 years, CIEDs have become an established treatment option for selected patients with bradycardia, tachycardia, and heart failure. In addition, new cardiac and vascular procedures such as transvenous tricuspid valve interventions and central venous stenting have evolved with concurrent lead management implications. It is estimated that, in 2022, 800,000 CIEDs were implanted in the United States.[10] The most recent report from Europe found a median number of 607 pacemaker implants and 121 implantable cardioverter-defibrillators (ICDs) per million people in 2023, with higher numbers observed in more economically advanced countries.[11] The increasing population age in all economically advanced countries suggests that future CIED implant rates will be higher, particularly for permanent pacemakers.[12] When any CIED (including a leadless pacemaker) is implanted, future lead management considerations must be considered. At initial CIED implant or subsequently when a generator or lead needs to be replaced or revised, device choice and lead management issues include clinical indication, patient comorbidities, predicted patient lifespan, lead performance, consequences of any future CIED complication, and potential clinical benefits and risks.

Section 3 Definitions

The definitions used in the current document are similar to those developed in the 2017 document[1] and are presented in Table 3. In that document, clinical success of

Table 2 Relevant clinical practice documents

Title	Publication year
^{18}F-FDG PET/CT and radiolabeled leukocyte SPECT/CT imaging for the evaluation of cardiovascular infection in the multimodality context: ASNC Imaging Indications (ASNC I^2) series expert consensus recommendations from ASNC, AATS, ACC, AHA, ASE, EANM, HRS, IDSA, SCCT, SNMMI, and STS[5]	2024
Update on cardiovascular implantable electronic device infections and their prevention, diagnosis, and management: A scientific statement from the American Heart Association: Endorsed by the International Society for Cardiovascular Infectious Diseases[6]	2024
2021 PACES expert consensus statement on the indications and management of cardiovascular implantable electronic devices in pediatric patients[7]	2021
European Heart Rhythm Association (EHRA) international consensus document on how to prevent, diagnose, and treat cardiac implantable electronic device infections-endorsed by the Heart Rhythm Society (HRS), the Asia Pacific Heart Rhythm Society (APHRS), the Latin American Heart Rhythm Society (LAHRS), International Society for Cardiovascular Infectious Diseases (ISCVID) and the European Society of Clinical Microbiology and Infectious Diseases (ESCMID) in collaboration with the European Association for Cardio-Thoracic Surgery (EACTS)[8]	2020
2017 HRS expert consensus statement on cardiovascular implantable electronic device lead management and extraction[1]	2017
Transvenous lead extraction: Heart Rhythm Society expert consensus on facilities, training, indications, and patient management: This document was endorsed by the American Heart Association (AHA)[9]	2009

Table 3 Definitions

Term	Definition
Nonfunctional lead	A lead that is not usable owing to electrical dysfunction, 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 leads 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 y
Lead extraction	The lead removal procedure, where at least 1 lead removal required the assistance of equipment not typically used during lead implantation or at least 1 lead was implanted for more than 1 y
Intracardiac leadless CIED extraction	Removal of a leadless CIED that has been placed in the heart during a previous implant procedure
Intracardiac leadless CIED retrieval	Removal of a macrodislodged leadless CIED that is no longer attached to the myocardium
Surgical lead removal	Lead removal procedure that requires planned surgical epicardial access
Lead entrapment	Any cardiac or intravascular implant that results in fixation of a portion of a transvenous lead against a vascular wall, cardiac structure, or previously implanted valve
Definitions for transvenous and/or permanent epicardial lead extraction procedure outcomes	
Complete procedural success	Transvenous and/or permanent epicardial 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	Transvenous and/or permanent epicardial lead extraction procedures where there is complete procedural success / total number of extraction procedures
Clinical success	Transvenous and/or permanent epicardial 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 affect the outcome goals of the procedure
Clinical success rate	Transvenous and/or permanent epicardial lead extraction procedures where there is clinical success / total number of transvenous lead extraction procedures
Failure	Transvenous and/or permanent epicardial lead extraction procedures when there is the inability to achieve either complete procedural or clinical success or the development of any permanently disabling complication or procedure-related death
Failure rate	Transvenous and/or permanent epicardial lead extraction procedures that failed / total number of transvenous and/or permanent epicardial lead extraction procedures
Definitions for CIED-related tricuspid regurgitation	
Lead-induced severe tricuspid regurgitation	New finding of severe tricuspid regurgitation after implantation of a transvenous lead crossing the tricuspid valve with imaging evidence of leaflet impingement by the lead, limiting valve coaptation, and an eccentric jet of tricuspid regurgitation
Lead associated with severe tricuspid regurgitation	Severe tricuspid regurgitation in the setting of a dilated tricuspid annulus and right atrial dilation, along with the presence of a transvenous lead crossing the tricuspid valve with no imaging evidence of interaction of the lead with the tricuspid valve leaflets

CIED = cardiovascular implantable electronic device.

lead extraction could include the retention of a small part of the lead that did not affect the desired outcome of the procedure. The writing committee defined "small" as <4 cm for any residual lead portion and unlikely to be clinically significant. This definition was arbitrary and unchanged from the previous expert consensus statement, with no evidence to support a clinical difference compared with longer or shorter retained lead fragments. To provide an accurate and consistent description of a clinical procedure that involves the removal of a lead, a lead removal procedure can be further classified as either a lead explant or lead extraction. Lead extraction is defined as a lead removal procedure where at least 1 lead removal requires the assistance of equipment not typically used during lead implantation and/or at least 1 lead was implanted for more than 1 year. Lead removal can involve transvenous leads or any lead not placed in the vascular system.

To account for new technologies and better account for potential consequences of transvenous leads that pass through the tricuspid valve, several new definitions have been added to the current document. The first is intracardiac leadless CIED extraction; this strategy has become more widely used, with a current estimated growth rate of 13%–14%.[13] New and established cardiac and vascular interventional procedures, such as transcatheter tricuspid valve replacement (TTVR), can potentially result in lead injury or lead entrapment ("jailing"). This document defines lead entrapment as when the deployment of an intravascular or cardiac device results in fixation of a transvenous lead against a vascular wall, cardiac structure, or a previously implanted bioprosthetic valve (TTVR is

sometimes deployed on a previous bioprosthetic valve). Finally, lead-induced severe tricuspid regurgitation is a situation where new severe tricuspid regurgitation is identified after transvenous lead implant and imaging documents leaflet impingement by the lead. Lead-associated tricuspid regurgitation is identified in the absence of imaging evidence of leaflet-transvenous lead interaction, with multifactorial potential causes including enlargement or poor function of the right-sided chambers or pulmonary hypertension.

Section 4 New technologies

4.1 New technologies

Newer technologies in CIED offer the potential to decrease the clinical challenges and morbidity associated with intravascular devices.[14] Since the previous consensus statement in 2017, the use of leadless pacing and nonvascular ICDs (nontransvenous ICDs, eg, subcutaneous ICD [S-ICD] and extravascular ICD [EV-ICD]) has increased substantially, ushering in a new paradigm of nonvascular cardiac rhythm management.

4.1.1 Nonvascular ICD therapies

Recommendations for nonvascular ICD therapies

COR	LOE	Recommendations
1	C-EO	1. In patients who meet indications for primary or secondary prevention ICD therapy and without an indication for bradycardia pacing or cardiac resynchronization therapy (CRT), shared decision making is recommended to choose the type of ICD (transvenous vs nonvascular) based on a patient-centered approach.
1	B-R	2. In patients who meet indications for primary or secondary prevention ICD therapy and without an indication for bradycardia pacing or CRT, who have inadequate vascular access, a mechanical tricuspid valve, high risk of infection, or a history of CIED infection, an S-ICD is recommended.[15–18]
2a	C-LD	3. In patients who meet indications for primary or secondary prevention ICD therapy and without an indication for bradycardia pacing or CRT or a history of sternotomy, who have inadequate vascular access, high risk of infection, or a history of CIED infection, an EV-ICD is reasonable.[19–22]
1	B-NR	4. In patients who meet indications for primary or secondary prevention ICD therapy, and without an indication for bradycardia pacing and CRT, where avoiding a transvenous lead might be beneficial (eg, younger patients), an S-ICD is recommended.[23,24]
2a	C-LD	5. In patients who meet indications for primary or secondary prevention ICD therapy, and without an indication for bradycardia pacing and CRT or a history of sternotomy, where avoiding a transvenous lead might be beneficial (eg, younger patients), an EV-ICD is reasonable.[19,23]

Synopsis

Nonvascular ICD therapies, including S-ICD and EV-ICD, are both approved by the US Food and Drug Administration (FDA) as primary and secondary prevention strategies to mitigate sudden cardiac death. The use of a nonvascular ICD may be of particular interest for patients with a history of CIED infection or high risk of infection, those with inadequate vascular access, younger patients requiring long lead dwell time, or those with a mechanical tricuspid valve.

Recommendation-specific supportive text

1 and 2. The S-ICD is an entirely subcutaneous system appropriate for candidates who are at risk of sudden cardiac death who do not require bradycardia pacing or antitachycardia pacing (ATP) or CRT.[15] Several studies have demonstrated the safety and effectiveness of the S-ICD in both clinical trial settings and real-world practice.[16,18,24] Knops et al,[17] in an international randomized noninferiority trial of S-ICD vs transvenous defibrillator therapy, showed that S-ICD was noninferior with respect to the primary endpoint of the composite of device-related complications and inappropriate shocks after a median follow-up of 49.1 months (hazard ratio [HR] 0.99; 95% confidence interval [CI] 0.71–1.39; $P = .01$ for noninferiority; $P = .995$ for superiority). In a multinational, prospective, nonrandomized study of primary prevention patients undergoing de novo implant of an S-ICD who had a left ventricular ejection fraction (LVEF) of $\leq$35%, Gold and colleagues[25] demonstrated among 1116 patients who had an attempted S-ICD implant that the 18-month freedom from inappropriate shock was 95.9% (lower confidence limit 94.8%); the 18-month all-cause shock-free rate was 90.6% (lower confidence limit 89.0%). The conversion success rate for appropriate, discrete episodes was 98.4%; the complication-free rate at 18 months was 92.7%. The decision to pursue treatment with a nonvascular CIED for sudden cardiac death prevention should be based on a detailed discussion between patient and clinician, including an assessment of preferences and values for treatment in the context of a shared decision-making encounter,[26] while reviewing key treatment considerations including patient age, need for CRT, and bradycardia pacing or ATP.

In general, the risk of infection with S-ICD is lower than transvenous ICD systems. In a secondary analysis of the PRAETORIAN trial,[18] S-ICD was associated with a lower rate of overall device-related complications than transvenous ICDs, including a lower risk of overall infections (11.1% [4 of 36] vs 16.3% [8 of 49]) and systemic infections (48-month Kaplan-Meier cumulative incidence [0 vs 1.2%; $P = .030$]). In an analysis from the S-ICD postapproval study,[22] Gold and colleagues demonstrated that, over a 3-year postimplantation follow-up period, S-ICD infection occurred in 55 of 1637 patients (3.3%), with 69% of the infections occurring within 90 days after implant; 92.7% of the infections occurred within 1 year after device implantation. Predictors of S-ICD infection included diabetes (HR 1.91; $P = .022$), younger age (HR 0.98; $P = .021$), previous transvenous ICD implant (HR 4.84; $P < .0001$), and lower LVEF (HR 0.98; $P = .038$).

3. The EV-ICD, approved by the FDA in October 2023, is indicated to prevent sudden cardiac death and treat ventricular arrhythmias with defibrillation and ATP in a single device. The EV-ICD uses a substernal lead that can offer ATP and postshock and pause-prevention pacing.[19,21] Limited data exist on the safety and effectiveness of the EV-ICD in real-world clinical practice.[20] Friedman and colleagues[27] in long-term follow-up from the PIVOTAL study evaluated freedom from major system- or procedure-related complications and appropriate and inappropriate therapy rates through 3 years of follow-up. ATP was successful in 77.1% of episodes (37 of 48), and shock therapy was successful in 100% of discrete, spontaneous ventricular arrhythmias (27 of 27). No major intraprocedural complications were reported, and the estimated freedom from system- or procedure-related major complications was 91.9% in 1 year and 89.0% in 3 years.

Both nonvascular ICD systems (S-ICD and EV-ICD) are associated with increased rates of inappropriate shocks/therapies compared with transvenous ICD systems. Inappropriate shocks with the S-ICD have been well documented and largely addressed using Smart Pass filter (Boston Scientific) and dual zone programming.[28,29] Results from the PIVOTAL EV-ICD trial[21] demonstrated an inappropriate shock rate of 9.7% of patients (29 of 299) and a Kaplan-Meier estimate for inappropriate shocks at 8.5% at 6 months; the most common causes of inappropriate shocks were P-wave oversensing.

4 **and 5.** In certain clinical scenarios, avoiding a transvenous lead may be beneficial. Young age is a known risk factor for premature transvenous lead failure.[23,30] These patients are typically more active and expose the lead to more stress. In addition, their life expectancy is higher, and hence, they are expected to require multiple lead revisions, which may necessitate repeated transvenous lead extraction (TLE). Moreover, TLE is typically more challenging in this group of patients owing to fibrosis.[23,30] The use of nonvascular ICDs is advantageous in this setting. The S-ICD has been available for a decade longer than the EV-ICD; hence, there is a difference in the COR. An algorithm for ICD selection, including transvenous and nonvascular ICDs, is presented in Figure 1.

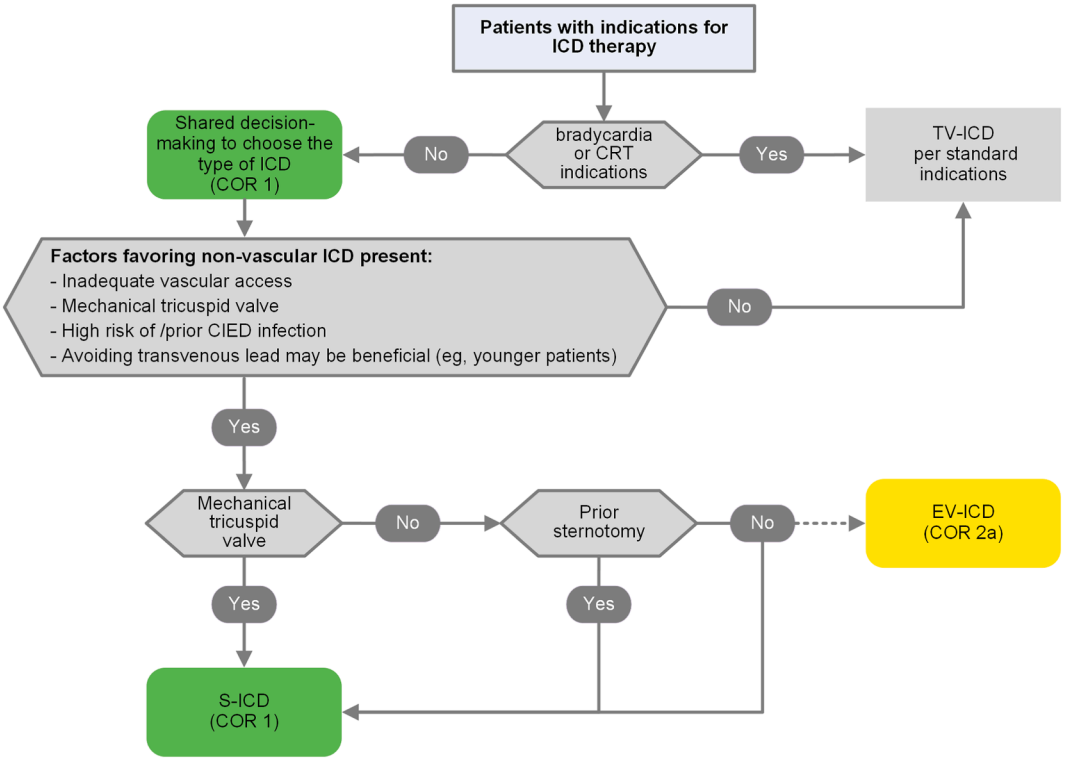


Figure 1
Algorithm for nonvascular ICD selection. Colors correspond to the class of recommendation (COR) in Table 1. CIED = cardiovascular implantable electronic device; CRT = cardiac resynchronization therapy; EV-ICD = extravascular implantable cardioverter-defibrillator; ICD = implantable cardioverter-defibrillator; S-ICD = subcutaneous implantable cardioverter-defibrillator; TV-ICD = transvenous implantable cardioverter-defibrillator.

4.1.2 Leadless pacing therapies

Recommendations for leadless pacing therapies		
COR	LOE	Recommendations
1	C-EO	1. In patients who require bradycardia pacing support, shared decision making is recommended to choose the type of pacemaker based on a patient-centered approach.

Synopsis

Bradycardia pacing with leadless pacing systems has rapidly expanded since the initial FDA approval in 2016. Given the advantages and growing use of leadless pacing, contemporary leadless pacing systems have become an important alternative in the pacing armamentarium for select populations. The data from leadless pacemaker studies and registries have shown a common theme of reduction in device-related complications predominantly owing to a lower incidence of need for reintervention.[31–35] These devices are associated with a low risk of device infection.[32,33,36,37] Hence, they might be beneficial in certain clinical situations, such as in patients at high risk of infection and patients who have undergone CIED extraction because of device infection.[33,38,39] Patients with limited vascular access such as hemodialysis patients are another group that might benefit from leadless pacemakers.[40,41] For detailed recommendations regarding the indications and selections of leadless pacing systems, refer to the HRS consensus statement on leadless pacing for bradycardia indications in adults and pediatric patients (in development at the time of this publication).

Recommendation-specific supportive text

1. 2 right ventricular (RV) and an atrial and dual-chamber leadless pacemakers are currently available for implant: the Micra Transcatheter Pacing System (Micra VR and Micra AV) (Medtronic) and the AVEIR VR and AVEIR AR (Abbott). The Micra system and the AVEIR system have a comparable battery longevity of approximately 12 years.[36,37,42,43] A common theme to all leadless pacemaker studies is the reduction in complications during follow-up, driven by the reduction in need for reintervention. Numerous studies[31,35] have demonstrated the safety and effectiveness of the Micra VR system compared with either historical controls or a contemporary cohort of patients receiving transvenous single-chamber ventricular pacemakers.[35] El-Chami et al,[32] in a 2-year follow-up from the Micra CED study, demonstrated that leadless VVI patients had significantly fewer reinterventions (adjusted HR 0.62; 95% CI 0.45–0.85; $P = .003$) and chronic complications (adjusted HR 0.69; 95% CI 0.60–0.81; $P < .0001$) than transvenous VVI patients. In addition, data from the Micra Transcatheter Pacing System postapproval registry[33] demonstrated that, among 1809 patients with a median follow-up period of 51.1 months, the major complication rate was 4.5% at 60 months (95% CI 3.6–5.5) and 4.1% at 36 months, which is significantly lower than the 8.5% rate for transvenous systems (HR 0.47; 95% CI 0.36–0.61; $P < .001$). Importantly, there were no Micra system removals owing to infection noted over the duration of follow-up. Although the real-world data of AVEIR are limited, data are accumulating. Early reports demonstrate comparable success and safety for Micra.[37] Knops et al[36] demonstrated the safety and effectiveness of a dual-chamber leadless pacemaker implantation (AVEIR DR). This dual-chamber leadless pacemaker was implanted with a 98.3% success rate and low complication rate (1.7% postprocedural dislodgment and 0.7% pericardial effusion rates). The mean atrioventricular synchrony was 95%.[36] A conduction system leadless pacemaker (AVEIR CSP) has shown promising results in a small study.[44] This device has not been studied in a large cohort with long-term follow-up. This evolving leadless and physiological pacing technology will gain further evidence.

4.2 Extraction of CIEDs in newer CIED technologies

4.2.1 Extraction of nonvascular ICDs

Both the S-ICD and EV-ICD use a tunneling tool for defibrillator coil deployment, either in a subcutaneous parasternal location or below the sternum, respectively. Several retrospective, observational analyses have demonstrated the efficacy of using manual traction in removing the defibrillator lead of the S-ICD and EV-ICD. De Filippo and colleagues[45] demonstrated among 71 consecutive patients who underwent complete S-ICD extraction that simple manual traction of the S-ICD lead through the xiphoid incision was sufficient to remove the lead in 59 (84%), whereas 11 patients (15%) required the use of a nonpowered mechanical sheath (eg, Byrd dilator sheath) to remove lead adhesions around the coil. Sagi et al[46] demonstrated that, of the 347 patients who underwent successful EV-ICD implantation across the 3 studies, 29 underwent lead removal with a primary indication for lead dislodgment. Lead removal was successful in 27 of 29 (93.1%) cases; simple traction was used in 22 of 26 (84.6%), and extraction tools were used in 4 of 26 (15.4%). Based on the limited available data, the use of manual traction should be the initial strategy when removing the EV-ICD or S-ICD lead in patients who require explant or extraction owing to infection, lead malfunction/failure, replacement with a transvenous ICD/CRT device, or lead malposition.

4.2.2 Retrieval and extraction of leadless pacemakers

Recommendations for the retrieval and extraction of leadless pacemakers		
COR	LOE	Recommendations
1	B-NR	1. In patients with a proven leadless device infection, device removal using contemporary extraction techniques is recommended.[45–47]
1	B-NR	2. In patients with micro- or macrodislodgement of a leadless pacemaker, device removal is recommended.[48]
2a	B-NR	3. In patients with suboptimal pacing parameters early after implantation, device removal is reasonable.[48]
2a	C-LD	4. In patients with a leadless pacemaker who require battery replacement or device upgrade years after implantation, a strategy of either device removal or abandonment is reasonable using a patient-centered approach and shared decision making.[35,49]
1	C-EO	5. In patients undergoing leadless pacemaker extraction, the extraction procedure should be performed in a center with expertise in snaring and contemporary extraction techniques.

Synopsis

The widespread adoption of leadless pacemakers in routine clinical practice has concurrently led to an increase in scenarios where these devices need to be retrieved or extracted. Data on the safety and efficacy of techniques needed to retrieve or extract these devices are accumulating. In addition, the appropriateness of device retrieval and/or extraction will be based on clinical and patient characteristics, including indication for retrieval/extraction, patient demographics, and medical comorbidities.

Recommendation-specific supportive text

1. Leadless pacemaker infection is a rare event. Data from the 5-year follow-up Micra postapproval registry[33] showed no device-related infection requiring device removal. However, several case reports have described infections with leadless pacemakers.[50–52] When proven, leadless pacemaker infection is an absolute indication for extraction.

2 and 3. Experience with Micra and AVEIR leadless pacemaker early retrieval is well described. A multicenter study by Afzal et al[48] described the successful retrieval of 40 Micra devices. The most common indication was elevated pacing thresholds. Another multicenter study[49] of 40 patients reported a 100% success rate for Micra removal. The mean age of extracted Micra leadless pacemakers was 46 days, and no complications were encountered. Neužil et al[53] and Morita et al[54] documented successful retrieval of the Nanostim leadless pacemaker and AVEIR, using the AVEIR retrieval system and the double-snare technique, respectively. Given the mounting evidence of the success and safety of early retrieval of leadless pacemakers, extraction is recommended in the context of dislodgment and is preferable when early suboptimal pacing characteristics are encountered.

4. The Micra postapproval registry[33] reported nearly 1800 patients implanted and followed for 5 years. 82 patients required a device modification (upgrade to CRT, battery at end of life, etc). Most (72 patients) were managed with device abandonment and the remainder by device extraction.[33] No complications were observed with either approach. Evidence regarding the extraction of leadless pacemakers with long dwell times continues to mount. In a study from the Czech Republic,[55] chronically implanted Micra leadless pacemakers were successfully extracted in 88.9% (8 of 9 patients), despite dwell times of 7–9 years; extraction success was not affected by duration of implant. In addition, several case reports[55–61] have similarly described the successful extraction of chronically implanted Micra leadless pacemakers. In an investigation of worldwide chronic extraction experience of the discontinued Nanostim device,[62] the extraction success rate was 87.6% (205 of 234 devices). The average dwell time of the Nanostim device was 3.2 years (range 0.2–9 years). Although this device has been withdrawn from the market, these results might indicate that the extraction of AVEIR devices with long dwell time is feasible and safe.[62] Examples of clinical scenarios to help guide leadless pacing management and decision making are presented in Table 4.
5. Extraction of leadless pacemakers requires a unique skill set of snaring. Physicians who perform these procedures should have expertise in TLE, particularly in different snaring techniques, including the double-snare technique.[58,63]

Table 4 Clinical scenarios and LP management options

Clinical vignette	Management options	Preferred management
An 86-y-old patient with a history of permanent atrial fibrillation and complete heart block received a leadless pacemaker 12 y ago, and the device has reached ERI.	Option 1: Abandon the old LP and reimplant a new LP. Option 2: Abandon the old LP and reimplant a permanent transvenous pacemaker. Option 3: Extract the LP and reimplant a new LP.	Option 1 or 2 would be more reasonable because this patient is 86 y old and is unlikely to require a third device.
A 65-y-old patient with a history of mitral valve replacement 8 y ago and postoperative complete heart block has LP with atrioventricular synchrony that has reached ERI.	Option 1: Abandon the old LP and reimplant a new LP. Option 2: Abandon the old LP and reimplant a permanent transvenous pacemaker. Option 3: Extract the LP and reimplant a new LP.	Options 1, 2, and 3 are all reasonable. The patient is 65 y old and will likely require more than 1 device during their lifetime. The previous sternotomy is likely protective during LP extraction. Shared decision making is an essential step in the decision-making process.
A 78-y-old patient with a history of heart block who had an LP implantation 7 y ago with RV pacing of >40% has developed a decline in her ejection fraction to 40%.	Option 1: Abandon the old LP and upgrade to CRT-P or CSP. Option 2: Extract the LP and upgrade to CRT-P or CSP.	The patient is 78 y old, and it might be more reasonable to abandon the LP and implant a CRT-P/CSP. Option 2 is reasonable after the shared decision-making process. Leaving the LP in place would not be appropriate.
A 75-y-old patient with a history of sinus node dysfunction after dual-chamber LP 5 y ago has an atrial LP that has reached ERI, but his ventricular LP still has 6 y left on the battery.	Option 1: Abandon the atrial LP and reimplant a new atrial LP. Option 2: Extract the atrial LP and implant a new atrial LP. Option 3: Extract the LP and reimplant a permanent transvenous pacemaker.	This scenario has the potential to become a common situation in the future. The right atrium has limited space for multiple LPs. Therefore, LP extraction (option 2 or 3) might be reasonable in this situation.

CRT-P = cardiac resynchronization therapy-pacemaker; CSP = conduction system pacing; ERI = elective replacement indicator; LP = leadless pacemaker; RV = right ventricular.

Section 5 Diagnostic approach to suspected lead failure

Pacemaker lead failure can occur because of conductor fractures or insulation breaches, causing either failure to capture or inappropriate inhibition of pacing owing to oversensing of electrical noise. Defibrillation high-voltage lead failure can result in catastrophic failure to shock or ineffective shock, inappropriate shocks owing to oversensing or undersensing, and failure to detect tachyarrhythmias and/or successfully defibrillate owing to conductor fracture.

Recommendations for remote monitoring		
COR	LOE	Recommendations
1	B-NR	1. In patients with CIEDs, remote monitoring with lead monitoring algorithms is recommended, if available.[64–68]
2a	C-EO	2. In patients with abnormal findings on remote monitoring, it is reasonable to have an in-person clinic evaluation or close remote follow-up.

Synopsis

Pacemaker and defibrillator lead failure can present in various ways, from asymptomatic detection on remote monitoring or in-person device interrogation to symptoms caused by abnormal performance of the CIED system to failure to pace or defibrillate. Understanding the basic mechanisms of conductor fractures or insulation breaches, as well as the value of embedded software algorithms and remote monitors, can mitigate the potential clinical consequences of lead failure.

Recommendation-specific supportive text

1. The availability of remote monitoring capabilities for most pacemakers and defibrillators allows for easy access to care in addition to early warning of potential lead

abnormalities. Remote monitoring can provide reassurance, increase patient satisfaction, and correlate rhythm and device functionality with perceived symptoms or arrhythmias. It can also offer more frequent CIED electrical parameter assessments between in-person clinical visits. Remote monitoring has been shown to improve detection of lead failure; in a study by Caughron et al,[69] 67% of lead failure was detected by remote monitoring. Multiple different algorithms to detect lead noise have been shown to accurately detect lead failure and potentially reduce the rate of inappropriate shocks. In a study by Beau et al,[64] the SecureSense algorithm accurately withheld therapy in 97% of lead noise events that otherwise would have been classified as ventricular fibrillation (VF). Another algorithm, the Lead Integrity Alert, was shown to reduce the rate of inappropriate shocks and resulted in more than 3 days of warning between the alert and the first inappropriate shock.[70] Most importantly, combining these algorithms and remote monitoring resulted in better detection of lead failure than remote monitoring alone (77% vs 25%)[69]; in this study, the combination of remote monitoring and lead noise algorithm was associated with a 16-fold reduction in inappropriate therapy.

2. The early warning value of remote monitoring can be followed up with an in-person clinic visit for device evaluation or a close follow-up remotely, based on the urgency and severity of the lead malfunction. Currently, CIED parameters cannot be reprogrammed remotely for most devices, and in-person device evaluation may be beneficial to further determine the etiology of remote monitor-detected abnormalities.

5.1 Clinical presentation

The lead failure modes are pace-sense malfunction and shock component malfunction. In pace-sense circuits, insulation breach can present as oversensing of rapid, nonphysiological signals, resulting in inappropriate shocks or pacing inhibition, whereas conductor fracture can lead to failure to capture.[71] In older-generation ICDs, the most common presentation of pace-sense lead fracture was inappropriate shocks.[72,73] Owing to improvements in device diagnostics that incorporate the detection of short intervals and changes in impedance and the more widespread use of remote monitoring, an increasing number of patients are now presenting with presymptomatic lead alerts, enabling early recognition of lead failure before the onset of adverse clinical events.[74] Despite these advances, patients can still present with multiple inappropriate shocks, given that the fracture may only become apparent after the first shock therapy. Fortunately, high-voltage coil conductor failure is quite rare, but it can result in failure to deliver an appropriate (potentially lifesaving) shock when needed.

Shock component malfunction typically presents with shock impedance change and less commonly as failed defibrillation or in association with coexisting pace-sense failures. Insulation failure with a shorting of the high-voltage circuit can result in catastrophic failure of the defibrillator pulse generator. The introduction of remote monitoring and enhanced lead diagnostics has fortunately improved the early recognition of both pace-sense lead failure and shock component malfunction.

Family members and health care providers who provide initial care for patients with CIEDs should understand the urgent use of magnets for suspending therapy. Placing a magnet over a pacemaker will inhibit the sensing part, leading to asynchronous pacing (AOO, VOO, and DOO) while the magnet is immediately present over the device. Magnet application over an ICD will inhibit shock therapies without disabling sensing or altering the pacing mode. Once the magnet is removed from the field, the pacemaker or ICD will revert to its previous nonmagnet programmed parameters and therapies.

Several studies have aimed to determine the prevalence of pacing or defibrillator lead failures, including the impact of electrical abnormalities on mortality. In 1 large prospective observational study,[75] all consecutive adult patients undergoing CIED implantation were included over a 3-year period. During follow-up (median 57 months), 283 complications were observed in 263 of 2811 consecutive patients (71 $\pm$ 14 years of age; 67% male). Early complications ($\leq$30 days) were associated with significantly lower cumulative survival from cardiovascular death than late complications and with freedom from complications. On multivariate analysis, early complication, pneumothorax, and pocket hematoma were significantly associated with a higher risk of all-cause death, whereas device infection remained the only complication significantly associated with a higher risk of cardiovascular death.[75] In a large retrospective chart-review study over 8 years,[76] patients were identified with lead failure and segregated by patient clinical characteristics and device manufacturer. There were 2996 unique patients (35% female) included with 4600 leads (57% Abbott and 43% Medtronic). Electrical lead abnormalities were observed in 135 (3%) leads over a 4.5-year follow-up, including 124 Abbott (92%) and 10 Medtronic leads (7%) (HR 9.25; $P < .001$).[76] Risk factors associated with electrical abnormalities included smaller lead French size, atrial location, and Abbott leads. Lead revision was required in 28% of cases. Patients with lead abnormalities had 38% more in-clinic visits per patient year of follow-up than those without ($P < .001$).[76] To assess the clinical and radiographic factors associated with lead failure,[77] subjects with lead failure within 10 years of implantation were compared with an implant-year-matched group without lead failure. Among the failure group, the mean time from implantation to device lead failure was 4.7 $\pm$ 2.9 years. Older age at implantation was associated with a lower likelihood of lead failure (odds ratio [OR] 0.28 [75 vs 42 years old]; 95% CI 0.12–0.63; $P = .002$).[77] A larger smallest-loop diameter on the chest radiograph was also associated with a lower likelihood of lead failure (OR 0.51 [31 vs 14 mm]; 95% CI 0.27–0.97; $P = .04$).[77] CIED type (defibrillator vs pacemaker) was not significantly associated with lead failure. Among lead-specific parameters, defibrillation lead vs pace-sense

lead was associated with lead failure (OR 3.91; 95% CI 1.95–7.81; $P < .001$).[77] Younger age, defibrillation leads, and small lead loops are associated with lead failure in CIEDs. Techniques to avoid tight loops in the pocket could potentially reduce the risk of lead failure and have important implications for the implanting physician.[77] The Tendril family of pacing leads (Abbott) has been shown in several studies to have an increased risk of insulation breach leading to lead failure.[78] In a single-center observational study[79] following 1111 leads in 700 patients over an average of 54 months, the Tendril leads had significantly higher failure rates, manifested by low impedances and electrical noise. Similarly, a single-center study[80] of 408 Tendril 2088 leads implanted in 335 patients revealed a failure rate of 6.2% at 4-year follow-up, which is significantly higher than results in published product performance reports.

A propensity-matched survival analysis[81] of the ACC National Cardiovascular Data Registry ICD Registry was performed to evaluate 4 ICD leads in patients aged ≥18 years who underwent an implant of an ICD between April 2011 and March 2016. Monitoring safety continued for up to 5 years. A difference was defined as twice (or more) the lead failure rate observed in the propensity-matched comparator patients. Among 374,132 patients who received a new ICD implant, no safety alerts were triggered for the primary safety endpoint of lead failure for any of the high-energy leads studied. Estimated rates of freedom from lead failure at 5 years ranged from 97.7% to 98.9% for the 4 high-energy leads.[81]

A single-connector defibrillator lead (DF4) is more streamlined by removing the separate yoke joining the 2 defibrillation conductors into an inline format, reducing the bulk and complexity at the pin end. The chronic performance of DF4 leads has been evaluated and demonstrates relatively stable reliability over 3–5 years dwell time and 96%–98% lead survival at follow-up.[82,83]

5.2 Special populations: Children and patients with congenital heart disease

Implanting a device in children or in young adults with congenital heart disease has special considerations, including patient size, longitudinal growth, level of physical activity, and the need for a potentially decades-long requirement for pacing, defibrillation, and lead management. The Pediatric Lead Extractability and Survival Evaluation (PLEASE) study[23] was a 24-center international registry of 878 pediatric and congenital heart disease patients (44% with congenital heart disease) with ICDs. The mean age at implantation was 18.6 ± 9.8 years. Of 965 total leads, 54% were thin (≤7F), of which 57% were Fidelis, and 23% were coated with expanded polytetrafluoroethylene (ePTFE).[23] There were 139 ICD lead failures (14%) in 132 patients (15%) at a mean lead age of 2.0 ± 1.4 years, causing shocks in 53 patients (40%). Independent predictors of lead failure included younger implantation age and Fidelis leads. Actuarial analysis showed an incremental risk of lead failure with younger age at implantation: <8 years compared with >18 years ($P = .01$).[23] Extraction was performed on 143 leads (80% thin and 7% ePTFE coated), with lead age as the only independent predictor for advanced extraction techniques. There were 6 major extraction complications (4%) but no procedural mortality. This study demonstrates that ICD leads in children and congenital heart disease patients have an age-related suboptimal performance, further compounded by a high failure rate of thin ICD leads.[23] Lead failure may be higher in younger patients; this is likely caused by multiple factors including increased levels of physical activity and continued linear growth after lead implantation.[84]

It is critically important to consider the implications of implanting a device in young patients who will have a lifetime need for cardiac rhythm management. Children and patients with congenital heart disease may have a life expectancy of 50–100 years after their first CIED implantation; therefore, it is imperative to preserve venous patency and maintain vascular access for future device needs.[7,85] Epicardial systems may be preferable in the smallest patients and in those with intracardiac shunts or other congenital abnormalities that preclude transvenous access to the heart. Novel pediatric epicardial devices are currently under clinical investigation.[86] Lead extraction has a higher relative risk in young patients owing in part to greater fibrosis and lower volumes for extractors and centers.[87] Cardiac surgical backup is mandatory for pediatric lead extractions. The role of leadless pacemakers and nontransvenous defibrillator systems (S-ICD, EV-ICD, and pericardial and hybrid approaches) may reduce the reliance on transvenous endocardial systems in the young.[88]

5.3 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 (electrical 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-to-lead interactions. Cyclical oversensing, which refers to sensing non-QRS components with every cardiac cycle, typically indicates an intracardiac source of oversensed signals. An ICD-recorded EGM for a patient who had an ICD lead fracture with nonphysiological cyclical oversensing is presented in Figure 2A, and an example of physiological T-wave oversensing is presented in Figure 2B. The morphology and pattern of typical nonphysiological EGMs in conductor fractures have been validated by returned product analysis of explanted leads.[89] 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

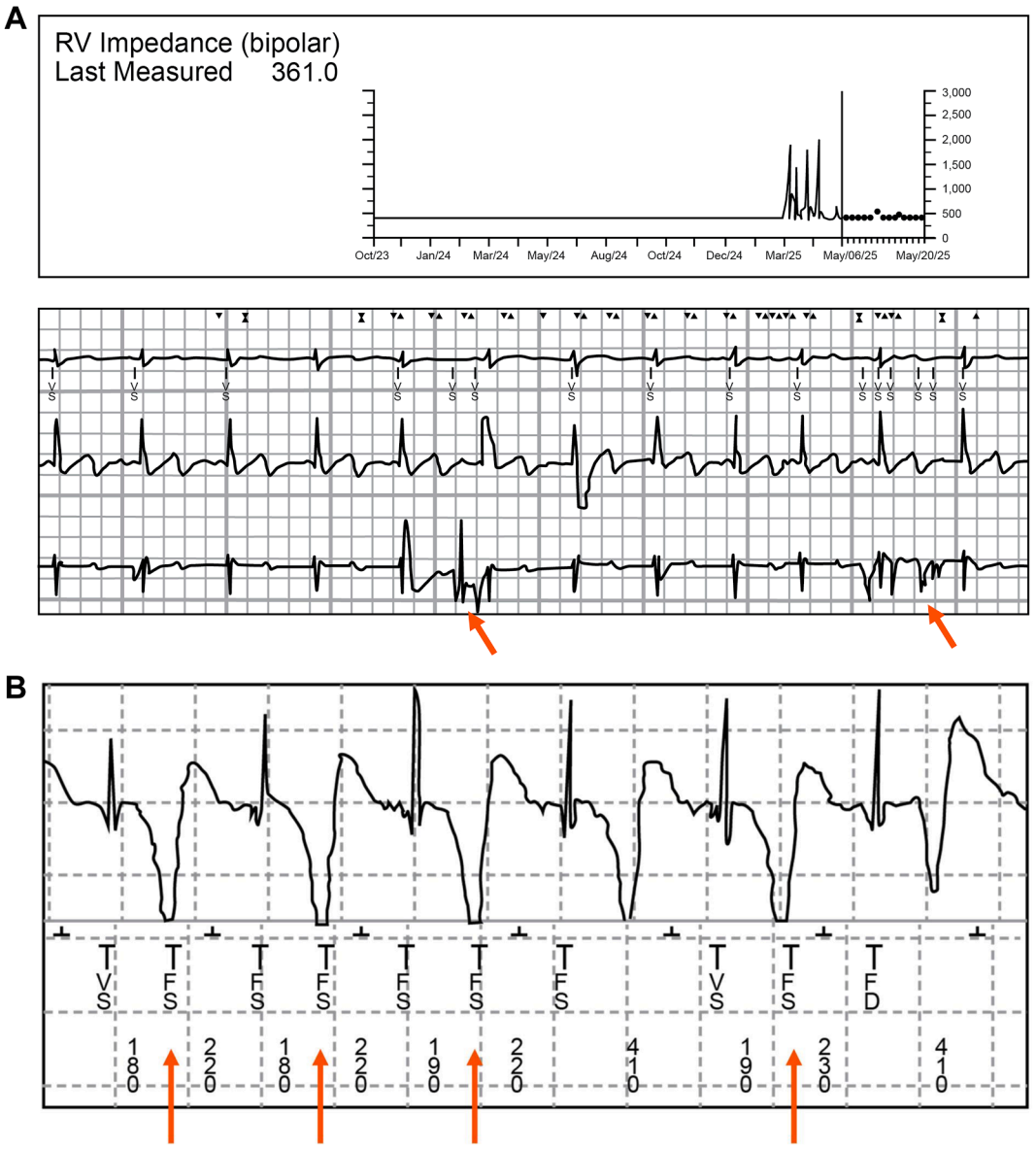


Figure 2

Examples of ventricular oversensing in ICDs. A: Shown is an electrogram for a 41-year-old patient who received an ICD for long-QT syndrome. 10 years later, the remote monitor showed intermittent elevated lead impedance and inappropriate noise detection. The ventricular sensing is nonphysiological, with features of high-frequency, short-interval (150 ms) oscillation, consistent with oversensing the noise owing to lead fracture. *Orange arrows* point out the noise detection. B: Shown is an electrogram from a patient who developed T-wave oversensing, double counting the R wave and T wave (*orange arrows*), resulting in ventricular fibrillation detection because the rate met the criteria for ventricular fibrillation. This is consistent with inappropriate physiological T-wave oversensing. ICD = implantable cardioverter-defibrillator; FS = fibrillation sense; RV = right ventricular; VS = ventricular sense.

amplifier, resulting in a truncated signal on the sensing channel. Atypical EGM patterns can occur in pace-sense conductor fractures, including oversensing that is precipitated by pacing and cyclical oversensing patterns.[89,90] Lead-header connection problems can also 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. In contrast to conductor fractures, insulation failures do not typically generate abnormal signals but result in sensing of physiological signals from surrounding structures, which are typically generated from the interaction of conductors. As such, EGM patterns in insulation breaches vary depending on the signal source.[91]

5.4 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 20% of the entire circuit's resistance; therefore, impedance

assessment and monitoring lack sensitivity in pace-sense failures. In fact, gradual 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 VF—often leading to inappropriate shock in ICD systems. 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. However, a single abrupt change could 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 in a bipolar configuration or an abrupt significant decrease in lead impedance can indicate an insulation breach of the pace-sense component. An abrupt increase in pacing lead impedance, especially when greater than 2000 Ω, suggests impending conductor failure, and >3000 Ω impedance indicates pace-sense conductor fracture. 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 or a shock impedance value of greater than 120 Ω likely indicates shock conductor fracture, based on the returned product analysis.[92] 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 may be variable, and no threshold values have been defined.

5.5 Device diagnostics to mitigate adverse consequences of pace-sense failure

5.5.1 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 shorter than 130 ms. The most common cause of isolated, short-sensed R-R intervals is benign oversensed physiological signals or detection of environmental electromagnetic interference. A rapidly increasing sensing integrity count is a sensitive early 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.[93] Increasing episodes of nonsustained VT, particularly if characterized by rapid rates, should also arouse suspicion for possible lead failure, and careful review of intracardiac EGM is essential to differentiate true nonsustained VT from electrical noise oversensing.

5.5.2 Algorithms that incorporate sensing and impedance monitoring

Lead Integrity Alert (Medtronic)

Lead Integrity Alert 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.[70] Monitoring both rapid oversensing and impedance trends provides earlier warning of lead failure than a fixed impedance threshold. This algorithm has been validated by returned product analysis, and multiple studies have assessed its clinical utility and shown relatively low false-positive rates.

Prospective and retrospective, observational data indicate that lead integrity alerts improve early detection of the now-recalled thin defibrillator (Fidelis) lead fractures and reduce inappropriate shocks compared with monitoring impedance alone.[94,95] Retrospective, observational, clinical studies have found that this algorithm identifies failures in defibrillation leads from various manufacturers.[96]

Latitude Lead Check (Boston Scientific)

The Latitude Lead Check algorithm is qualitatively similar to Medtronic's Lead Integrity Alert 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.[71,97,98]

5.5.3 Algorithms that compare sensing and shock EGMs

2 currently used algorithms—Medtronic's Lead Noise Algorithm and Abbott'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 the Lead Noise Algorithm and SecureSense, but both withhold shocks if sufficient evidence of oversensing occurs.[65,99] 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 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% of sustained episodes, 90% of nonsustained episodes) and did not withhold

shocks from 100% of induced VF episodes.[32] These sensing algorithms have been tested in small series, with rare delay in delivering shock therapies and even rarer withholding of ICD shocks.[64,66]

5.6 Role of remote monitoring

Devices with wireless telemetry automatically detect and transmit stored data, including lead alerts. Observational studies support the use of remote monitoring to facilitate diagnosis of lead failure, and data suggest that wireless remote monitoring, when combined with lead integrity alerts, reduces inappropriate shocks more than lead integrity alerts alone.[67] 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 the HRS[100] and the Canadian Heart Rhythm Society.[68] The value of routine remote monitoring has been evaluated and shown to be effective at identifying lead failures earlier than in-office visits, although compliance with regular use may be affected by external factors such as patient age and location. However, a substantial portion of remote monitoring warnings and abnormalities may not represent true lead failure necessitating intervention.[69] When patients go on vacation, they often leave their bedside transmitters at home and thereby lose remote monitoring capabilities.[101] A recent survey[102] from the Pediatric and Congenital Electrophysiology Society showed high variation in compliance with remote monitoring in young patients. A total of 15 of 22 reporting centers (68%) reported that >80% of their CIED patients are enrolled in remote monitoring, and only 2 centers reported <50% participation.[102] The number of centers achieving high compliance differed by device type: 36% for pacemakers, 50% for ICDs, and 55% for implantable cardiac monitors. All centers reported at least 50% adherence to recommended follow-up for pacemakers and ICDs.[102] In a large prospective study[74] evaluating remote monitoring strategies for ICD lead failure across 5 manufacturer alert algorithms, the use of lead noise alerts significantly improved early identification of lead malfunction and reduced inappropriate therapies. Most lead failures were detected remotely before any clinical complication occurred. Pace-sense component failures were correctly identified by a dedicated lead noise alert in 77% vs 25% of the control group ($P = .002$).[74] The absence of a lead noise alert was associated with a 16-fold increase in the likelihood of initiating either a shock or ATP (OR 16.0; 95% CI 1.8–143.3; $P = .01$). Another multicenter evaluation also demonstrated favorable clinical performance of ICD lead monitoring diagnostics across contemporary systems.[103]

Section 6 Lead recalls and advisories

Lead recalls or advisories confer a safety concern to the patient, health care professional, manufacturer, and regulatory agencies that a lead has failed to meet the prespecified expectations for performance.[1] This failure notification is based on returned product analysis, customer-reported failures, postmarketing registry reports, or remote monitoring.[104,105] Unlike device generator recalls, lead recalls pose greater clinical challenges, given that extraction can carry significant procedural risk. Management strategies should emphasize enhanced surveillance, patient counseling, and shared decision making rather than routine lead replacement or extraction.

Recommendations for lead recalls and advisories

COR	LOE	Recommendations
1	C-EO	1. In patients with leads under FDA advisory/recalls, the patient should be informed about the potential for lead malfunction/abnormalities and advised about the different management strategies in a shared decision-making process. Patients who do not need urgent/immediate intervention should be monitored remotely or in person.

Synopsis

ICDs and pacemaker leads are critical components of the CIED system with mechanisms to ensure proper sensing, pacing, and defibrillation therapy. Over time, certain lead models have been subject to recalls or advisories owing to lead malfunction/abnormalities that may lead to inappropriate shocks or ineffective therapy. Collaboration among clinicians, patients, and device manufacturers is essential to ensure informed decision making and optimal management. An awareness of lead performance trends, adherence to surveillance recommendations, and shared decision making remain the foundation of safe and effective care in the setting of lead recalls and advisories.

Recommendation-specific supportive text

1. To optimize therapeutic engagement and transparency, patients should be informed about the advisory with an emphasis on individualized risk assessment and shared decision making with regard to lead management. Lead recall language from manufacturers and regulatory bodies may be difficult for patients to interpret; therefore, clinicians play a central role in explaining the advisories, the potential implications, and the relative risks and benefits of the available management strategies, based on the patient's condition(s). Enhanced surveillance with remote monitoring allows for early detection of lead abnormalities and should help to maintain patient confidence in their implanted CIED system.

6.1 Terminology and recall framework

The terminology used to describe lead performance is primarily defined by regulatory language, given that the vast majority of leads are not extracted and returned to the manufacturer for analysis. A *component failure* refers to a rare, unavoidable failure that does not reflect a systematic failure mechanism over-represented in a particular lead model. In contrast, *advisories* are typically issued when a lead manifests a reproducible mechanism of failure related to a component or an assembly flaw, which may involve any of the lead components (insulation, conductors, or connectors). The advisory typically outlines the nature of the problem, recommended clinical actions, and any required follow-up.

A *recall* is a regulatory action used by the FDA to describe actions taken by a manufacturer to correct or remove from the market an FDA-regulated product that violates US laws and regulations. Most recalls involve removing violative FDA-regulated products from the market, but there are instances where a violation can be corrected without removing the products from distribution. In the context of implanted products, including CIEDs, a recall has complex implications, given that clinicians and patients then need to decide whether to continue to use the product, place a new implant, and/or remove the recalled implant.

The FDA classifies recalls as class I, II, or III depending on the severity and likelihood of the health risk.[106–109] Class I recalls represent the highest risk and demand immediate attention owing to the reasonable probability that using or being exposed to the defective product will cause serious adverse health consequences or even death. Class II recalls may result in temporary or medically reversible adverse health consequences, but the probability of serious health consequences is low. Class III recalls are the least serious, are not likely to cause any adverse health consequences, and generally focus on addressing minor defects or quality issues. Given that some recalls do not necessitate cessation of the use of the device or removal from the market and do not dictate a change in clinical management in all cases, the term *advisory* may be used in clinical practice to emphasize surveillance, risk mitigation, and possible intervention. 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. Medtronic Sprint Fidelis, St. Jude Medical (now Abbott) Riata ICD lead, St. Jude Medical (now Abbott) Nanostim, and, most recently, Boston Scientific's Model 3501 advisories were classified as class I recalls. As of the writing of this document, Boston Scientific issued a safety advisory for its RELIANCE Gore-coated ICD leads, but an official recall has yet to be issued (the lead models are no longer on the market as of 2021).

Consistent and routine patient monitoring and management strategies are required for class I recalls. The FDA can 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. In summary, health care professionals, manufacturers, and regulatory agencies work together to manage recalls effectively and ensure patient safety. Information on recalled leads is posted on the FDA website, the manufacturer's website, and HRSonline safety alerts, which contain physician-written recommendations regarding lead advisories, recalls, and factors to consider when formulating a plan for individual patients.

6.2 Lead surveillance and performance thresholds

Remote monitoring and postmarket surveillance enable ongoing detection and reporting of lead performance issues. Manufacturer performance reports, registry data, and in-person device interrogation provide the basis for identifying emerging failure mechanisms and informing clinical management strategies. Therefore, all removed/extracted malfunctioning leads should be returned to the manufacturer for analysis.

Monitoring of lead performance has steadily improved over time. Robust data gathering and extensive lead follow-up provide information for postmarketing surveillance so that evidence of unsatisfactory lead function is detected expeditiously.[108] Despite these advances, there is no clear consensus regarding acceptable thresholds for annual failure rates for pacing or ICD leads. Although perfect lead performance is not expected, there is a performance threshold that is acceptable owing to the risk of malignant bradycardia and tachyarrhythmias. Historical data for the long-term performance of available transvenous leads suggest that annual failure rates should not exceed 0.4% and 0.2% per year for the first 10 years of ICD and pacemaker leads, respectively.[110–113]

A recalled S-ICD lead illustrates how a recall may be issued despite acceptable overall performance when a systematic failure mechanism is identified. Approximately 47,000 Emblem 3501 S-ICD leads have been implanted worldwide. The cumulative occurrence rate for this specific electrode body fracture location is reported to be 0.2% at 41 months, with a potential for life-threatening harm of 1 in 25,000 (0.004%) at 10 years.[114] The probability of longevity of the S-ICD lead was higher than transvenous leads and not significantly lower than that of its predecessor, Model 3401 (not subjected to safety notification).[115] Even though this failure rate would be considered acceptably low and comparable with the standard transvenous leads, the fact that a systematic failure mechanism was identified led to the recall of this lead (see below in section 6.4.4).

6.3 US FDA

6.3.1 Premarketing assessment

In the United States, the FDA is responsible for premarket evaluation of CIEDs and CIED leads to ensure the reasonable safety and effectiveness of leads. Premarketing assessment includes bench testing and may include mechanical and electrical performance, biocompatibility, interchangeability, and flex-fatigue testing. Premarket requirements are not standardized and are determined on a case-by-case basis based on lead-specific concerns and differences to products already in the market. In response to historical lead recalls, the FDA has continued to modify both its premarket requirements and postmarketing surveillance expectations.

6.3.2 Postmarketing surveillance

The FDA oversees postmarketing surveillance through mandatory manufacturer reporting of lead-related adverse events and analysis of data submitted to the Manufacturer and User Facility Device Experience database. 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 with relative infrequency.[107] In 2022, the FDA established a Unique Device Identification system, which requires all medical devices and packages sold in the United States to carry a unique device identifier. With full implementation, the label of most devices will include a unique device identifier in human- and machine-readable form, which will ultimately improve patient safety, modernize device postmarket surveillance, and facilitate medical device innovation.[105,107,109,115]

6.4 Selected examples of lead recalls and advisories

The following examples illustrate how lead recalls and advisories are communicated and managed in clinical practice, emphasizing surveillance, patient counseling, and individualized decision making. In most cases, recalls do not mandate routine lead extraction but instead rely on enhanced monitoring and risk mitigation strategies.

6.4.1 Accufix leads

The landmark recall of the Teletronics Accufix leads in 1994 was the impetus for 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, given that there were 2 fatal events and nonfatal injuries with the lead.[116] Not too long after, there was an unacceptable rate of failure in a specific bipolar tined polyurethane ventricular pacing lead, such as the Medtronic 4004/4004M lead. This failure was manifested by failure to capture, sensing abnormalities, early battery depletion, and abnormal impedance measurements.[117] These early experiences highlighted the importance of lead design, component materials, and procedural risk in lead management decisions.

6.4.2 Sprint Fidelis and Riata leads

ICD leads are considered the "weakest link" in a defibrillator system because of the high rates of failure and recall.[118] A retrospective study[72] evaluating the Medtronic 6936 in the 1990s was pivotal in the identification of the late failure mechanism. This has led to the development of lead failure recognition algorithms characterized by the detection of nonphysiological short sensing intervals.[96] The last 2 major lead advisories were the Medtronic Fidelis and the St. Jude (now Abbott) Riata ICD leads. In October 2007, the Medtronic Sprint Fidelis lead was recalled by the FDA. The reason for the recall was chronic conductor fractures occurring at 2 primary locations, leading to inappropriate shocks and several deaths.[94,119,120] In 2011, there was a class I recall of the St. Jude (now named Abbott) Riata ICD lead (multiple models exist). This recall was characterized by insulation breaches resulting in an increased risk of lead malfunction.[121]

The approach to the management of the recalled Sprint Fidelis and Riata leads has previously been documented. In summary, patients should be followed with remote monitoring. All patients with Medtronic ICDs should have the Lead Integrity Alert turned on to prevent inappropriate therapies and high-voltage lead impedance alert programmed "on" with a maximum setting of 100 Ω (pace-sense impedance alerts can also be narrowed from nominal) to facilitate earlier detection of lead failure.[94,96] If a lead fracture is suspected or confirmed, immediate patient attention is strongly recommended to discuss the approach of lead management. Implantation of a new high-voltage lead is recommended. If the decision is made to extract the affected lead, the HRS and Medtronic Independent Physician Quality Panel recommend that this be performed by a physician with extensive lead extraction experience.[96,108,119,121] If the lead is normally functioning, the recommendation is to continue remote monitoring. Similarly, if there is no evidence of a lead fracture at the time of generator change or device upgrade, multiple approaches should be considered regarding the Fidelis lead. This includes continuing to use the 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 previous pace-sense conductor fracture), or extraction of the Fidelis lead and implantation of a new lead, depending on the clinical scenario. Similarly, patients with the St. Jude Medical (now Abbott) Riata leads should be followed with remote monitoring. Strategies to monitor for lead compromise (eg, short, nonphysiological R-R intervals) include using the SecureSense noise discrimination to monitor for lead noise, programming the pacing lead impedance range to 200–1000 Ω and the high-voltage lead impedance to 25 Ω above

and below the stable high-voltage impedance range, programming an unused EGM channel to RV coil to the superior vena cava (SVC) to store EGMs that might detect noise, increasing detection criteria for VF detection intervals from 24 to 30 intervals, turning off the SVC coil in dual-coil leads, turning RV autocapture to "on" or to "monitor" to closely monitor the pacing lead thresholds, turning "on" vibratory patient alert triggers, and ensuring that the episode trigger for VT and VF episodes are set to "high." If conductor externalization is noted but the lead is electrically intact, continued monitoring is recommended without replacement. This is true at the time of generator change, but the operator should consider implanting a device that has an automatic vector switching capability that allows the shock vector to be automatically changed if a short circuit is detected. The Riata lead should be replaced if it exhibits electrical failure by implanting a new ICD lead and either capping or extraction of the Riata lead (depending on the shared decision making based on underlying comorbidities and the expertise of the medical center and the physician). Externalized conductor cables could also develop associated thrombus that may complicate their management.[122] Extraction of Riata leads with externalized conductors can be difficult and would require a commensurate operator skill set.

6.4.3 Nanostim leadless pacemaker

The Nanostim leadless pacemaker was offered as an alternative to traditional transvenous pacemakers. The device was recalled 4 years after its launch owing to premature battery depletion, with failure of output and communication from the device. Failure rates approached 41%. It should also be noted that, in 94% of the cases of premature battery depletion, patients had normal lead parameters 3 months before battery failure, and therefore, the changes were sudden and unexpected.[123] A second advisory was also released stating that there was a 0.28% docking button detachment rate, rendering the device irretrievable.[123,124] The batteries that were retrieved for premature depletion showed an increase in resistance caused by insufficient electrolyte availability at the cathode-anode interface. Retrieval of these devices can be safely performed with a demonstrated success rate of approximately 90%.[125] In patients who need removal, the overall success of Nanostim leadless pacemaker extraction is high, with a low risk of extraction attempt. The average time of extraction of Nanostim was 1040 $\pm$ 467 days, noted in 1 series,[123] and 256 days in others.[49] 2 of 73 patients had serious adverse events with Nanostim extraction in 1 series.[49] It is a reasonable approach to retrieve or abandon the leadless pacemaker with the implantation of a new pacing system in high-risk device-dependent patients. Among low-risk patients without device dependence, watchful monitoring is recommended. Patients should be followed remotely with remote monitoring (Merlin.net) with a suggested frequency of every 3 months.

6.4.4 Model 3501 S-ICD lead

There have been marked advancements in ICD therapy, 1 of which has been heralded by the use of a nonvascular (subcutaneous) ICD lead (S-ICD). This S-ICD system is an effective alternative for the prevention of sudden cardiac death.[17] In December 2020, the FDA issued a class I recall of the Boston Scientific Emblem Model 3501 S-ICD lead following 27 reports of lead fracture not related to trauma and 1 reported death.[126] Mechanical stress at a location just distal to the proximal ring electrode on the lead may potentially cause a "fatigue crack" that initiates from the outer lumen. Over time, this crack may propagate inward toward the distal sense conductor, eventually leading to a fracture of both high-voltage conductors.[126]

6.4.5 RELIANCE ePTFE lead

The latest class I lead recall issued in 2025 involves the Boston Scientific RELIANCE ICD lead models with ePTFE (GORE)-coated coils that were on the market for 19 years. These leads were found to exhibit a gradual rise in shock impedance owing to shock coil calcification, possibly compromising high-voltage shock delivery. Although no longer on the market or available for implantation, Boston Scientific estimates that approximately 354,000 remain in service, of which 250,000 are in the United States. The ePTFE (GORE) leads were initially developed to prevent tissue ingrowth. However, its presence on the lead coil may cause a gradual change in low-voltage shock impedance (LVSI) or high-voltage shock impedance (HVSI) owing to shock coil calcification. High out-of-range LVSI and/or HVSI measurements have the potential for reduced shock efficacy. There is a natural and acceptable rise in LVSI in the postimplantation period, and it can also be seen in other lead performance issues (eg, lead fractures and insulation issues). Therefore, it is crucial to identify a gradual rise in LVSI consistent with lead calcification. This includes a 20-Ω rise from baseline, at least 3 years after implant, to a minimum of 90 Ω for single-coil leads, 70 Ω for dual-coil leads, excluding rises in excess of 30 Ω per quarter.

If HVSI exceeds 145 Ω, Boston Scientific defibrillators, by design, limit the shock duration of the first shock phase to 20 ms. If this occurs, the shock's biphasic waveform is truncated, and a monophasic shock is delivered, potentially reducing shock efficacy. A high delivered shock impedance alert (Fault Code 1005) is seen on the device check after these shock instances. This phenomenon can occur irrespective of lead polarity. However, Fault Code 1005 is 4.5 times more likely in reversed (RV+) polarity than initial (RV−) polarity. The caveat is that this applies to ePTFE RELIANCE defibrillation leads connected to Boston Scientific generators. Presently, the criteria for leads connected to ICD generators from other manufacturers remain less certain. The current recommendations for the Model RELIANCE ePTFE lead issued by Boston Scientific and supported by the HRS are available online (HRSonline safety alert).

Section 7 Clinical considerations in CIED lead management

Careful consideration is required when patients with existing CIED systems require additional procedures, including generator changes, lead revisions, and device upgrades. Patient device needs can evolve over time, and alternate management strategies have different risks and benefits. 1 hallmark of existing CIED management is shared decision making with patients, reviewing not only the acute risks and benefits of various strategies but also the potential long-term ramifications.

Recommendations for management of patients with existing CIEDs		
COR	LOE	Recommendations
1	C-EO	1. In patients with CIEDs, leaving the lead in a condition that will permit future extraction and prevent retraction into the vessel is recommended for any abandoned lead.
1	C-LD	2. In patients with CIEDs, when considering whether to abandon or remove a nonfunctional or unnecessary lead, shared decision making with the patient is recommended to include immediate and long-term risks and benefits of each option, taking into account the patient's preference, comorbidities, future vascular access, and available programming options.[127–136]
1	C-EO	3. In patients with CIED leads across the tricuspid valve who are referred for transvenous or surgical tricuspid valve replacement, it is recommended that they be evaluated by a multidisciplinary heart team, including an electrophysiologist with lead extraction and lead management expertise.

Synopsis

In patients with CIEDs, lead management should be guided by an assessment of current and future risks, anticipated benefits, and the clinical significance of potential outcomes. Shared decision making is essential in determining whether a lead is best retained, abandoned, or extracted.

Recommendation-specific supportive text

1. Transected leads should not be allowed to retract into the vasculature, given that they may put patients at risk of arrhythmias or thrombosis and make future extraction more difficult. Capping and suturing the stump of a transected lead in the pocket would improve future access to the lead as well as shield the lead stump from possible magnetic resonance imaging (MRI) heating. Capping a transected lead may prevent future helix retraction in active fixation leads. However, transection could facilitate cable extrusion in leads prone to inside-out erosion or make future extraction more difficult in coradial lead designs. Preserving the lead terminal connector may prevent these challenges with future extraction, but it increases the amount of hardware in the pocket.
2. Shared decision making with the patient, reviewing the risks and benefits of each strategy, is required before the decision to extract or abandon a lead owing to malfunction, replacement by an alternate lead (eg, pacemaker upgrade to ICD), or change in clinical situation (eg, atrial lead in patients with permanent atrial fibrillation). The risks of extraction include venous or cardiac perforation and depend on multiple device and patient factors, including quantity of leads, lead type, lead manufacturer, duration of implant, patient's age and health, presence of previous sternotomy, and operator and team experience. The benefits of removal include the elimination of unneeded hardware that might be more difficult to remove in the future for mandatory extraction indications, such as infection; to facilitate MRI at some institutions; and to allow for access in patients with vascular occlusions. Several studies have suggested that abandonment of unnecessary leads has long-term outcomes similar to those for extraction.[127,129] A study from the Danish prospective national registry following abandoned ICD leads over a mean of 4.4 years showed only 8.8% of leads required extraction (most often for infection), with low complication rates.[129] A large retrospective Medicare claims study[135] showed that patients undergoing lead extraction for noninfectious indications had long-term survival similar to that of those who pursued an abandonment approach, although extraction was associated with a lower risk of device infection at 5 years.[135] In addition to retained hardware and risk of infection, a number of studies have shown that abandoned leads are associated with increased procedural complexity, complications, and clinical failure in subsequent extraction attempts.[128,130–136] Overall, studies are limited by their observational nature, and many are single-center.
3. In patients with transvenous RV leads, surgical or percutaneous tricuspid valve procedures can "jail" the lead. This may affect the lead function and prevent extraction even in the event of infection. Management of these patients is complex and requires evaluation of many patient and device factors, such as the patient's age and health, device type, pacemaker dependency, and surgical risk. In patients with RV CIED leads, the multidisciplinary team devising a comprehensive treatment plan should include

an electrophysiologist or surgeon who has expertise in lead extraction and management, given that this is an important consideration for these patients.

7.1 Lead management during CIED replacement

Normally functioning, nonrecalled leads are generally retained during routine generator exchange procedures. There is a lower rate of complications for routine generator exchanges than for lead extraction or revision procedures. Proceduralists should be prepared to respond to unexpected findings that may require lead removal or revision during the planned generator exchange.

7.1.1 Complications of generator exchange

The risks associated with routine generator exchange procedures are substantial, both in the acute perioperative period and during the first several months of follow-up. Minor complications include superficial infections treatable with antibiotics, hematoma, and pain. Major complications include lead dislodgment requiring revision (0.07%–3.2%), pocket or lead-related infections (0%–5.2%), and hematoma requiring evacuation (0%–5.2%). Direct periprocedural complications occur in approximately 1%–2% of cases. This risk increases to approximately 4% (0.6%–8.2%) during short-term follow-up. The risk of death at the time of a generator change is negligible (0%–0.4%).[137–139]

Generator exchange is associated with a 2.2-fold increased risk of pocket-related complications compared with initial CIED implantation procedures. In addition, the risk of pocket complications rises with each subsequent procedure. In a population of ICD procedures, the rate increased to 8.1% by the fourth subsequent procedure.[140] Based on these findings, a basic premise of CIED and lead management is that the number of required generator exchanges or other pocket procedures in a patient should be minimized. Devices with superior battery longevity may help achieve this goal. Optimal thresholds should be attained during the original device implantation, and unnecessary leads should be avoided. Appropriate attention should be given to device programming using strategies to decrease current drain and minimize unnecessary pacing and the use of ICD therapies. Battery longevity can vary greatly based on a variety of factors, including device type, device manufacturer, lead parameters, and patient usage, and may be difficult to predict.[141,142] S-ICDs seem to have a low risk of complications at the time of generator change.[137] There are no data yet regarding substernal ICDs.

7.1.2 Risk factors for complications and mortality

Risk factors for complications and mortality at the time of generator exchange depend on patient, procedural, and CIED system characteristics. Patient factors and comorbidities that have been associated with adverse procedural events include angina, heart failure, antiarrhythmic drug use, valvular heart disease, renal failure, diabetes, anticoagulation/antiplatelet use, corticosteroid use, chronic pulmonary disease, cerebrovascular disease, malignancy, fever, recent hospitalization, and dermatologic disorders. Previous CIED infection is also associated with an increased risk of future infection.[7] Although mortality is extremely low around the time of generator changes, in 1 large registry study, older age, atrial fibrillation, heart failure, diabetes, renal dysfunction, lung disease, and cerebrovascular disease were associated with an increased risk of death.[137,139,143,144] In addition, low implant volume, lack of antibiotic prophylaxis, temporary pacing, and ICDs or CRT devices (compared with single- or dual-chamber pacemakers) raise the risk of adverse events.[139]

7.1.3 Risk of lead failure after generator exchange

Data are limited and conflicting as to whether patients have an increased risk of lead failure after a generator exchange. In a series of more than 60,000 ICD patients in the Boston Scientific Latitude remote monitoring platform,[145] lead alerts significantly increased after generator change compared with the remainder of the population, most within the first 3 months after generator change (HR 5.19; 95% CI 3.45–7.84). Risks are likely associated with procedural technique and the specific lead models.[77,146] A study of the recalled Riata defibrillator lead did not show increased risks of lead malfunction after generator changes.[147] 2 series of patients with recalled Sprint Fidelis leads reported conflicting results, with 1 showing a significant increase in lead failures at the time of generator exchange and the other showing no difference compared with the general population.[148,149]

7.1.4 Shared decision making

The decision to replace an ICD generator should involve a comprehensive discussion between the patient and the providers regarding the risks and benefits of the procedure, as well as the patient's values and preferences.[150] This is particularly important in patients who are of advanced age or who have significant comorbidities. In these patients, the benefits of the device may not justify the potential procedural complications. In addition, tachyarrhythmia therapies may no longer be in line with the patient's wishes.[151] An observational study[152] of ICD generator changes in septuagenarians and octogenarians showed the procedure to be safe, although more patients died during follow-up from noncardiac causes than had appropriate shocks. Rarely, there may be select pacemaker patients who do not elect for pacemaker generator change after shared decision making (eg, those with minimal pacing). Small observational studies have shown that pacemaker generator changes can be performed with an acceptable safety profile in those of advanced age.[153]

7.2 Lead management during CIED upgrade

7.2.1 Upgrade procedure preparation

A CIED system is upgraded when 1 or more leads are added to an existing system. This can include converting a single-chamber device to a dual-chamber device, a pacemaker to

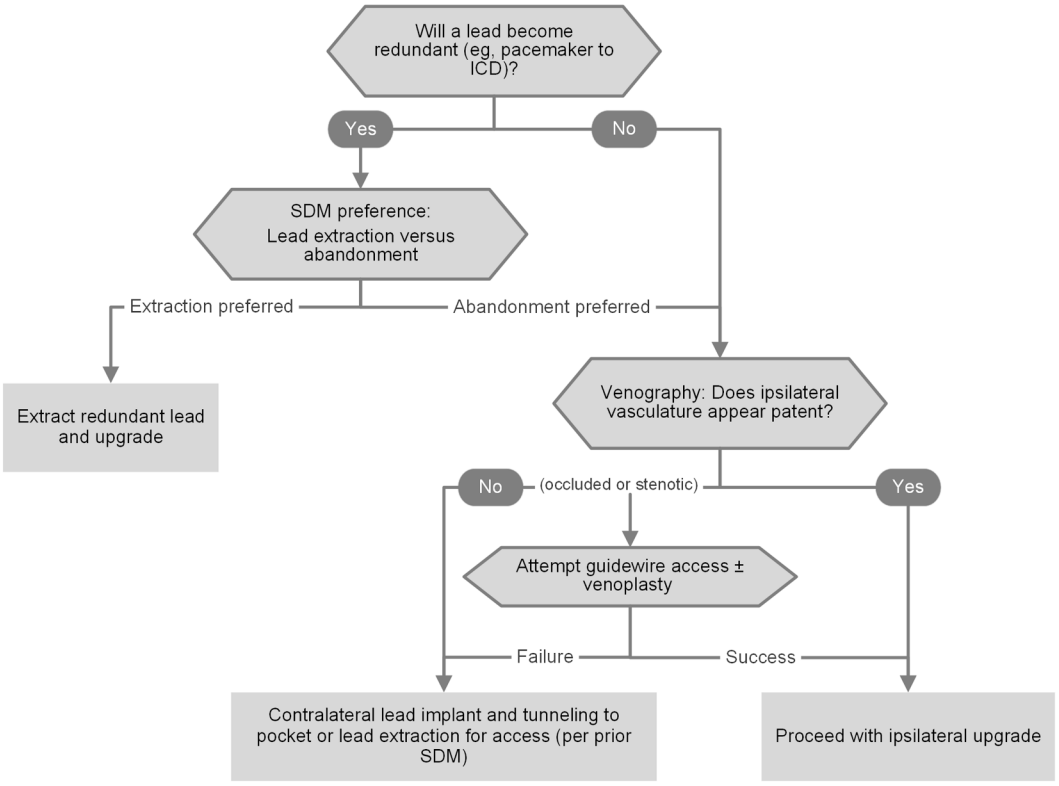


Figure 3
Illustrative flowchart of decision points during CIED upgrade procedure preparation. The flowchart highlights common considerations related to redundant leads, venous patency, and procedural planning. Key clinical decision points are supported by the recommendations for CIED upgrade and downgrade (section 9.4). Procedural approaches may vary based on patient factors, anatomy, and operator and center expertise. CIED = cardiovascular implantable electronic device; ICD = implantable cardioverter-defibrillator; SDM = shared decision making.

an ICD, or a standard pacemaker or ICD to a cardiac resynchronization device. Many of the risks and considerations reviewed in the generator exchange section are applicable to patients undergoing upgrade procedures. The process through which an upgrade procedure proceeds depends on whether a lead will become redundant, the presence of venous patency, patient age and comorbidities, and shared decision making in light of patient values (Figure 3). Key clinical decision points illustrated in Figure 3 are supported by the recommendations for CIED upgrade and downgrade in section 9.4; procedural details are intended to illustrate common practice patterns and may vary based on patient- and center-specific factors.

When a CIED is upgraded, intentional lead management is paramount and clinical decision making is potentially very complex with many considerations. In the event that a lead will become redundant, extraction of that lead will often be considered, as guided by a shared decision-making conversation. If extraction was not planned but the vasculature appears occluded by venogram, then several options exist. It is important to recognize that a peripheral venogram will often suggest occlusion when a wire is actually able to pass to the central circulation. In this scenario, a sheath might pass without difficulty, although sometimes balloon venoplasty will be needed for ipsilateral implant. If there is the possibility of terminating the procedure without upgrade if the vein is indeed occluded and/or not able to undergo venoplasty, then an attempt may be made to pass a wire into the vein of interest before opening the pocket to avoid unnecessary pocket infection risk. If ipsilateral implant access is not achieved, then options include extraction for access, tunneling of a contralaterally implanted lead, and occasionally epicardial lead placement. Because of many variations in potential anatomic findings, patient factors, and the operator's equipment and skills, Figure 4 can only serve as a rough guide.

7.2.2 Complications of lead upgrade and revision procedures

The risk of acute and short-term procedural complications is higher for upgrade procedures than for generator exchanges. This is true for both pacemaker and ICD upgrade procedures. In the Danish Multicenter Randomized Study on AAI Versus DDD Pacing in Sick Sinus Syndrome (DANPACE),[154] the incidence of complications in patients undergoing addition of an atrial, RV, or coronary sinus lead to an existing system was 16.7%. In the REPLACE Registry,[139] the rate of all complications was 15.3% in the upgrade population and 4% in the generator exchange population. The most common complication was lead dislodgement (7.9%), which may account for the increased complication rate in upgrades compared with generator exchanges. Other

complications included prolonged hospitalization (2.5%), hematoma (1.5%), death (1.1%), hospital readmission (1.1.%), infection (0.8%), and perforation (0.7%).[139] The rate of lead dislodgement is now lower in the era of quadripolar leads.[155]

A large, 2-center study[156] comparing de novo implants, generator exchanges, and upgrades found that there were similar rates of complications in patients with new pacemaker implants and generator changes (1.7%), but ICD implants (3.5%) and upgrade procedures (6.1.%) had higher rates of complications, with a much higher rate in patients receiving a left ventricular (LV) lead (9.5%). However, in a more recent single-center, retrospective study comparing patients undergoing de novo CRT implantation with those undergoing upgrade, the procedure success and 90-day complications were similar despite a higher rate of vascular occlusion in the upgrade population.[157]

7.2.3 Venous occlusion

Single-center and observational studies have shown a high rate of central venous stenosis in patients with indwelling pacemakers and ICD systems. Complete occlusion is seen in 3%–26%, more than 75% stenosis in 10%, and 50%–75% stenosis in 6%–37%.[158,159] Clinical factors that are associated with stenosis include lead number, lead type (eg, ICD vs pacemaker), lead dwell time, and number of procedures.[158,159] Venogram can be considered before device upgrades and should be performed before pocket incision so that plans for necessary access options can be made.[158–160] With a stepwise approach, ipsilateral access may often be salvaged in patients with significant stenosis or occlusion.[161]

7.2.4 Lead choices

The decision to add a lead to an existing CIED system requires careful consideration of multiple patient and device factors. The risks and benefits to the patient should be assessed with consideration of long-term management of the CIED system and potential long-term complications. Patient considerations include age, comorbidities, and specific CIED needs. Lead considerations include active vs passive fixation leads, location of the new lead, the chamber, and single-coil vs dual-coil ICD leads. In general, dual-coil ICD leads should be avoided, given that the risks of future extraction outweigh the benefits for defibrillation efficacy in most patients.[162] MRI conditionality is reasonable to preserve whenever possible.

7.2.5 Incorporating preexisting leads

As described earlier, upgrades have a higher risk of complications than generator exchanges, and much of this additional risk is related to the addition of new leads. Increased numbers of leads are associated with higher risks of future infection and vascular occlusion. Thus, it is prudent to include functional indwelling leads in an upgraded system when practical. Small observational studies have shown that patients do well with this approach.[160]

7.2.6 Addition of a pace-sense lead

When ICD leads malfunction, the failure mechanism may sometimes be localized to the pace-sense portion while the high-voltage components remain intact. For DF-1 connector ICD leads, there are separate connector pins for the pace-sense components and high-voltage components. For these leads, a new pace-sense lead can be added and connected to the generator along with the high-voltage components of the ICD lead, and the pace-sense portion of the ICD lead can be capped.[163] It should be recognized that ICD leads with pace-sense failure remain at an increased risk of high-voltage component failure, and this strategy is usually reserved for those of advanced age with a prohibitively high risk of extraction. Many DF-1 leads are still in service, but DF-4 connector ICD leads have become the standard for new implantations with the pace-sense and high-voltage components integrated such that the addition of a pace-sense lead is not an option.

In the past, small observational studies in patients with nonadvisory ICD lead malfunction evaluating pace-sense lead addition and ICD lead replacement have suggested that both strategies are feasible.[164–166] Modeling data of the recalled Sprint Fidelis lead suggest that replacing the ICD lead is associated with fewer adverse outcomes and is cost-effective.[167]

7.3 Device downgrade

Planned generator exchanges owing to battery depletion present an opportunity to reevaluate CIED needs with the patient in a shared decision-making process. Factors that may influence the decision to "downgrade" a device include patient comorbidities and longevity, changes in pacing needs, and, for ICD patients, changes in LV systolic function.[1] For patients with permanent atrial fibrillation, a single-lead ventricular pacemaker can be placed and the atrial lead capped. However, this may affect MRI access. The use of a dual-chamber generator, programmed to a ventricular pacing and sensing mode, can facilitate MRI access and may provide increased battery longevity. Some models of pacemaker generators have greater battery life than others, and patient age and comorbidities should be considered when selecting those devices.[168]

At the time of generator exchange for primary prevention ICDs, important considerations include the original indication, LVEF, patient comorbidities and prognosis, and patient preferences. There are limitations in using ejection fraction as the main indication for ICD implantation.[169,170] There is controversy as to the risk of sudden death in patients who experience improvement in their ejection fraction after placement of primary prevention ICDs. Available evidence summarized in appropriateness criteria and expert consensus documents noted that these patients have lower rates of tachyarrhythmia therapies and mortality, but residual risk remains.[171,172] If exchange for an ICD is deferred, the patient's pacing needs,

including cardiac resynchronization, should be assessed. In general, even if the ejection fraction has improved, cardiac resynchronization should be maintained.

When converting an ICD to a pacemaker, including a cardiac resynchronization pacemaker, the lead types and compatibility must be carefully considered. A DF-1 connector ICD lead can easily be converted to a standard RV pacing lead by placing the pace-sense pin in the ventricular port of a pacemaker generator and capping the high-voltage pins. DF-4 connector ICD leads do not have this option, given that there are no available DF-4 to IS-1 connectors. A new pace-sense lead can be placed. Another option may be to connect this lead to the LV port of a cardiac resynchronization pacemaker if it is a quadripolar connector. Finally, the lead can be connected to an ICD generator with the shock therapies disabled. Factors including the risks of abandoned leads, device size, and patient condition and preference will determine the best choice for any individual patient.

7.4 Nonfunctional and abandoned leads

All transvenous leads have some rate of malfunction, with older models showing failure rates of 7%–16% at 8–10 years of follow-up.[173,174] When a lead malfunctions, a decision must be made regarding management, specifically whether the lead will be removed and replaced or abandoned when a new lead is implanted. This decision depends on many patient and device factors. The acute risks of extraction must be balanced with the long-term risks of abandonment. There may be settings in which replacement of functional leads may be considered, particularly for very old leads or leads under advisory. The potential risks of abandonment include limiting access to MRI, venous thrombosis and stenosis, lead-to-lead interaction, tricuspid regurgitation, and increased risk of infection. Historically, MRIs have not been performed in patients with abandoned leads, particularly owing to concerns about lead heating.[175] However, observational studies and registries have not found adverse effects in the clinical setting.[176,177] Interactions between an abandoned lead and a new lead causing oversensing are rare. Friction between the 2 leads can lead to erosion of the insulation. Adding a second lead across the tricuspid valve is associated with increased tricuspid regurgitation.[178,179]

Both present and future vascular access affect the decision to abandon or extract a lead. At the time of the first ICD generator change, 25% of patients had some form of stenosis, with 9% having complete occlusion.[180] In 227 patients referred for CIED revision or upgrade after a median implant time of 67 months, 27% had stenosis of >75% of the vessel diameter, with 6% having total occlusion.[161] The rate of venous stenosis rises with increased numbers of transvenous leads.[181,182] Patients are generally asymptomatic owing to the formation of collateral vessels, but, in severe cases, patients can develop peripheral edema or SVC syndrome, which can be challenging to resolve.[183] There is no set number of leads that is considered the maximum for all patients to prevent venous stenosis.

Patients with abandoned leads may be at a higher risk of infection. A large retrospective Medicare claims study showed that patients who had undergone lead extraction had a lower risk of device infection at 5 years than those who had leads abandoned, although the overall long-term mortality was the same in both groups.[135] There is a discrepancy in many of the smaller observational studies. Some, particularly those with shorter follow-up times, show a low risk associated with lead abandonment.[127,129,132,184] Others suggest an increased risk of infection and subsequent difficulty in future device management, particularly if future extraction is needed.[128,130,131,133,134,136]

The decision regarding whether to abandon a lead or extract is a complex one, and there is divergence of opinion among experts as to the risks and benefits of each strategy. Clinical scenarios highlighting the nuances in caring for individual patients are presented in Table 5. Important device considerations include lead age, number, type (pacemaker vs ICD), and model. Important patient considerations include age, comorbidities, prognosis, status of vascular access, and preference. Patient age is a key factor, with many physicians preferring to remove leads in younger patients with a normal expected lifespan to spare them the long-term complications of transvenous leads, which are no longer providing benefit. Conversely, a lead that is already at a very high risk of extraction (eg, Medtronic 4195 Starfix) may be abandoned if it is no longer functional in an older patient, given that high-risk extraction of this lead may never be necessary.

7.5 Lead management at the time of tricuspid valve replacement

Newer TTVR options have raised awareness regarding transvenous RV leads, including both their influence on tricuspid valve function and lead management around the time of these procedures.[185,186] If an RV lead is left in place at the time of a TTVR, it can be "jailed" by the valve. This has important implications for lead function and future extraction, especially if the patient develops a class 1 indication for extraction, such as infection.[187] Data are incomplete as to the long-term outcomes of TTVR-jailed leads, but there seems to be a significant short-term lead complication rate. 1 database review showed that, of 28 jailed leads, 1 patient experienced RV lead dislodgement during the procedure and 2 patients had lead failure during follow-up of 15.2 months.[188] Another single-center study[189] showed that, of 14 patients with jailed leads, 3 had major lead-related complications (2 lead fractures and 1 infection) during 10.5 months of follow-up, with an additional patient dying suddenly at home in the setting of high-grade heart block. Finally, in a series of 32 patients with transvenous RV leads

receiving Evoque valves,[190] 31% of patients developed significant lead dysfunction.

TTVR is an evolving field, and an understanding of the different valve models and how they interact with the conduction system and CIEDs will be critical. The influence of various valves on lead function is likely different. In addition, models are available that may jail other leads (in the SVC) in addition to the RV lead or restrict access to the coronary sinus.[191] Given that this patient population is often quite ill, patient management is complex. A multidisciplinary team approach is needed to ensure that a comprehensive treatment plan is in place. This team should include an electrophysiologist with lead extraction experience, given that this is an important consideration for these patients.[192] Options for new or revised CIED implant after TTVR may include leadless pacing, coronary sinus lead implant, or a lead across the valve. Each option has benefits and drawbacks, and all could potentially be made more complex by the presence of the valve itself. In general, the same considerations apply to patients undergoing surgical tricuspid valve replacement or repair.

Patient scenarios that may help with a case-by-case assessment and management of leadless pacing at the end of life, lead malfunction, lead extraction vs abandonment, device upgrade or downgrade, and lead interaction with TTVR are presented in Table 5.

Table 5 Lead management clinical scenarios and strategies

Patient scenario	Management strategies	Key points
An 85-y-old woman with previous back surgery, sick sinus syndrome, complete heart block, and normal ejection fraction initially underwent pacemaker implantation 23 y ago, and the most recent generator change was 1 y earlier. She developed an abrupt increase in impedance associated with an elevated pacing threshold in the 23-y-old RV pacing lead and episodic electrical noise leading to inhibition of pacing.	■ Assess the possibility of reprogramming to unipolar. ■ Consider the likelihood of ipsilateral venous occlusion, which would limit management options. ■ Options include attempting to continue to use the lead, possibly in unipolar pacing and sensing mode, adding a new RV lead and abandoning the old lead, extracting and replacing the old lead, and abandoning the system and placing a leadless pacemaker. ■ The patient preferred to avoid unnecessary short-term risk and selected lead addition without extraction, even if it required lead tunneling from the right. This was completed via a severely stenosed left subclavian vein facilitated by balloon venoplasty.	■ Age and comorbidities contribute to the lead management shared decision making. ■ Long dwell time increases the risk and complexity of lead extraction, which influences the risk side of the risk-benefit analysis. ■ If the ipsilateral venous system is occluded, tunneling increases the risk of jeopardizing both prepectoral accesses in the event of future infection. ■ A 1-y-old pulse generator factors into the cost consideration of switching to a leadless pacemaker. ■ Lead abandonment may restrict access to MRI at some centers.
A 50-y-old man with complete heart block after a previous mechanical mitral valve replacement who had a His bundle pacemaker placed after valve replacement 5 y earlier presents with high pacing threshold and generator at the elective replacement interval. Myocardial capture threshold is 4.0 V at 1.0 ms with QRS duration 165 ms. His bundle capture is not present at maximal output, and left ventricular ejection fraction has decreased from 70% to 52% in the intervening 5 y with continuous ventricular pacing.	■ Management options include generator change only, pacing lead addition with abandonment of the His bundle lead, and extraction and replacement of the lead. ■ The patient preferred to have the best long-term pacing system, even if this resulted in more short-term risk and complexity. ■ Based on all of this, the decision was made to proceed with the extraction of the lead with placement of a left bundle pacing lead on continuous anticoagulation with an INR of 2–2.5, with no postprocedural bridging if possible.	■ Although His bundle pacing is potentially an attractive option for chronic ventricular pacing in young patients, this patient now has a very short battery life and no longer has His capture. ■ This patient's young age suggests a large potential benefit of reducing future generator changes and achieving improved ventricular synchrony if possible. ■ Extraction on continuous anticoagulation can be considered in those at high risk of stopping anticoagulation, given that heparin bridging may be associated with worsened outcomes after CIED interventions.

Table 5 Continued

Patient scenario	Management strategies	Key points
A 42-y-old woman with long-QT syndrome type 1 presents with RV ICD lead fracture. She has never had a ventricular arrhythmia or syncope and is taking nadolol. She had a single-chamber ICD placed at 17 y of age, and her dual-coil Sprint Fidelis lead was abandoned and replaced owing to fracture 3 y later with another dual-coil ICD lead. She has voiced increasing dissatisfaction with the experience of having an ICD. She was recently denied an MRI owing to the presence of the abandoned lead.	■ Management options include placement of a third ICD lead, extraction of both indwelling leads with replacement, and abandoning the leads with or without generator removal and with or without placement of a nonvascular ICD. ■ The patient is very clear that she does not want an ICD of any sort. She also does not want any remaining ICD hardware. Her referring genetic arrhythmia specialist is understanding of the situation and believes that she is at low risk of cardiac arrest with nadolol therapy. ■ She understands that extraction will be relatively high risk but that future extraction, if needed, would likely be of higher risk. ■ She would like to have no barrier to future MRI. ■ The decision was made to proceed with extraction, which was complex and eventually required removal of a lead fragment via the femoral route.	■ In a scenario of multiple potential reasonable options, patient preference is key. ■ 2 dual-coil leads with a combined lead age of 47 y will be a high-risk extraction, and the operator should be prepared to use many different strategies and manage complications. ■ This lead extraction is higher risk owing to the decision to abandon a lead that was only indwelling for 3 y in a young patient; this would rarely be a prudent decision. ■ Although MRI could likely be performed with leads or lead fragments left in place, access to MRI may be limited in many centers. Complete system extraction would obviate this potential restriction. ■ Removal of only the ICD generator is an option, although the risk of lead-related infection (among others) would be lifelong.
An 82-y-old woman with permanent atrial fibrillation, severe tricuspid regurgitation, and complete heart block with a pacemaker placed 7 y earlier presents as part of a heart team discussion during workup for transcatheter tricuspid valve intervention. She is not a candidate for open surgical repair. No escape rhythm is found on underlying rhythm check.	■ Transcatheter valve replacement would jail the pacing lead on which this patient is dependent. ■ If it is determined that transcatheter valve replacement is her only option, then management considerations will first need to consider whether the lead will be extracted or jailed. ■ Because she is dependent on the lead, the risk of lead failure was deemed too great to rely on a jailed lead. ■ She elected to undergo lead extraction and replacement with a leadless pacemaker before the planned tricuspid valve replacement.	■ Jailing RV pacing leads during transcatheter tricuspid valve replacement carries a high risk of lead fracture and makes future extraction potentially impossible. ■ Transcatheter edge-to-edge repair is favored in these scenarios if possible. ■ If the RV lead were not essential (eg, sick sinus syndrome with no ventricular pacing), then the decision making would hinge primarily on future extraction considerations in the event of infection. ■ CIED endocarditis without the possibility of lead removal may very well prove fatal.

CIED = cardiovascular implantable electronic device; ICD = implantable cardioverter-defibrillator; INR = international normalized ratio; MRI = magnetic resonance imaging; RV = right ventricular.

Section 8 Diagnosis, management, and prevention of CIED infection

CIED infection is 1 of the most feared and serious complications of device therapy owing to associated morbidity, prolonged hospitalizations, need for costly and repeated interventions, and increased mortality.[6] Although removal of infected hardware has been the fundamental and logical cornerstone of CIED infection management for several decades, establishing a clear diagnosis can be challenging owing to the lack of any single diagnostic test that is considered definitive. In the setting of obvious CIED pocket abnormalities (eg, incisional dehiscence, purulence, drainage, erosion), device infection may be a relatively straightforward diagnosis. However, when a patient presents with bacteremia and no local signs of pocket infection, confirming CIED involvement can be difficult. Reliance on transthoracic echocardiography (TTE) or transesophageal echocardiography (TEE) imaging must be constrained by the inability to reliably distinguish noninfected echo densities from infectious vegetations.[193] Further complicating the diagnostic challenges, CIED lead infection may be present in the absence of abnormalities on echocardiographic or nuclear medicine imaging, and abnormal pocket findings overlap with superficial infection or inflammation owing to noninfectious causes.[194] Establishing the diagnosis is time sensitive, given that evidence shows that early definitive antimicrobial treatment combined with system removal is associated with improved outcomes. This includes early involvement by expert centers with multidisciplinary extraction teams.

8.1 Initial evaluation and diagnosis of CIED infection

Recommendations for initial evaluation and diagnosis of CIED infection		
COR	LOE	Recommendations
1	C-LD	1. In patients with a suspected CIED pocket or systemic infection, drawing ≥2 sets of blood cultures before initiation of antibiotic therapy is recommended to enhance microbial detection and distinguish true bloodstream infection from blood culture contamination from skin flora.[195–197]
2b	C-LD	2. In stable patients with suspected CIED pocket infection (without fever, hypotension, leukocytosis, or other systemic signs and symptoms), it may be reasonable to withhold antibiotic therapy until device removal to improve the yield of pocket tissue culture.[198]
1	C-LD	3. In patients with suspected CIED pocket or bloodstream infection, TTE is recommended as initial imaging to assess lead-related echo densities and concurrent native or prosthetic valvular involvement.[197,199,200]
1	C-LD	4. In patients with suspected CIED infection, TEE is recommended to identify the presence, size, and mobility of lead vegetation if findings on TTE are negative or inconclusive and there is high suspicion of systemic infection.[193,197,201,202]
2a	B-NR	5. In patients with suspected CIED infection and inconclusive echocardiographic imaging findings, ^{18}F-fluorodeoxyglucose (FDG) positron emission tomography (PET)/computed tomography (CT) is reasonable to improve diagnostic accuracy, particularly for pocket involvement.[203,204]

Synopsis

Timely and accurate diagnosis is the foundational principle for optimal management of suspected CIED infection, yet there is no gold standard for diagnosis, and establishing definite CIED infection is often challenging. Initial evaluation should include a focused history, including the timeline and scope of device interventions, symptoms, physical examination, and laboratory evaluation consisting of infectious and inflammatory markers. Blood cultures are essential in all patients with suspected CIED infection, even if the origin of infection is the CIED pocket. Blood cultures should be obtained before the initiation of antibiotic therapy for the best yield. Obtaining ≥2 blood cultures enhances diagnostic accuracy and helps differentiate true bacteremia from contamination, particularly when the organism detected in blood culture is an uncommon cause of CIED infection or part of normal skin flora. Imaging, whether echocardiographic or nuclear, has assumed increasing importance in establishing the diagnosis of CIED infection.

Recommendation-specific supportive text

1. Although no studies specific to CIED infection and timing or number of blood cultures have been performed, standard clinical care and extrapolated evidence support obtaining ≥2 sets of blood cultures before administration of antibiotic therapy to optimize the diagnostic yield of cultures. A multicenter observational study of patients with sepsis showed that blood culture positivity decreased by nearly 50% within 2 hours of antibiotic administration (31% positive vs 19% positive).[195] Although not specific to CIED infection, these data highlight the importance of early blood culture acquisition. In CIED infection, bloodstream involvement is common; in a retrospective cohort of 39 CIED infections among 3105 device implants, 90% of patients had abnormal pocket findings and 54% had positive blood cultures.[196] However, concordance between blood and lead tip cultures was only 35%. In a cohort of patients with clinical signs of pocket infection, 65% had evidence of lead-associated endocarditis, highlighting the risk of systemic infection in patients presenting with pocket infection.[197] Early blood cultures are critical for the diagnosis of bloodstream infection and guidance of antimicrobial therapy. The approximate risk of CIED infection during bacteremia is presented in Figure 4.

2. In a retrospective series of 95 patients with CIED pocket infection, patients without evidence of bloodstream infection who did not receive pre-extraction antibiotics were found to have a trend of higher frequency of positive intraoperative pocket and device cultures than patients treated with antibiotics before extraction (79.4% vs 58.6%; $P = .06$).[198] Importantly, evidence of a systemic inflammatory response (tachycardia, tachypnea, fever, hypothermia, or hypotension) was an independent predictor of bloodstream infection, allowing identification of patients requiring immediate antibiotic therapy. In clinically stable patients with pocket infection without systemic signs of infection, deferring antibiotics until the time of CIED removal may improve the diagnostic yield of pocket and hardware culture and facilitate pathogen identification, which is essential for targeted antimicrobial therapy after extraction.

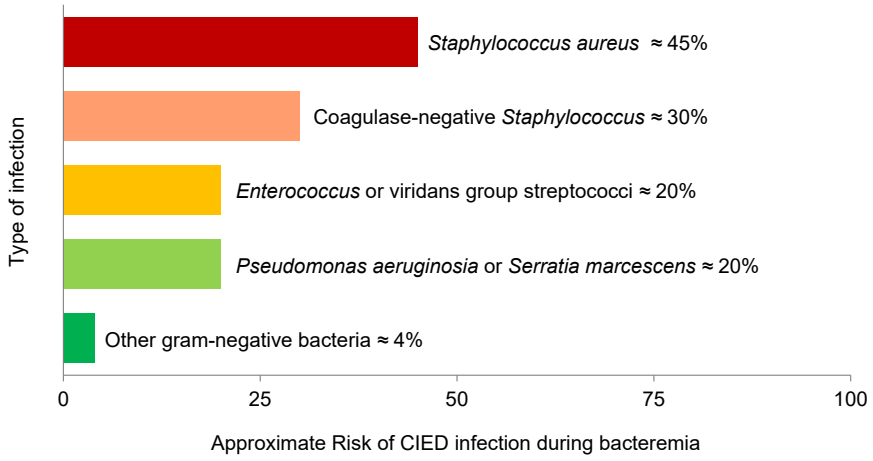


Figure 4
Approximate risk of CIED infection during bacteremia. CIED = cardiovascular implantable electronic device.

3. Although TTE has limited sensitivity for detecting CIED lead infection, it is a useful imaging modality for detecting lead-related or valvular echo densities, particularly given its wide availability and low risk. TTE may provide additional information in establishing or excluding left-sided valvular vegetations or abscess. In a retrospective series of patients with CIED infection, TTE identified vegetations in 23%–30%.[199,200] In the multicenter MEDIC registry, TTE detected lead-related vegetations in only 7%–10% of patients with CIED-related endocarditis, mostly when the vegetation size was greater than 1 cm.[197] TEE not only has substantially higher sensitivity for lead involvement but can also provide valuable information with respect to the presence, size, and mobility of echo densities and can guide planning of further diagnostic or management steps. Both TTE and TEE are limited by their inability to accurately discern whether a given echo density is a vegetation or represents thrombotic or fibrotic material.[193]
4. TEE offers greater sensitivity than TTE for detecting CIED lead echo densities and vegetations. In patients with a CIED and *Staphylococcus aureus* bacteremia (SAB), the sensitivity of TTE was 63% and TEE was substantially better at 88%.[202] In a retrospective review of 160 patients with non-*S aureus* bloodstream infection, TEE identified lead or valvular vegetations in 54% of patients compared with only 5% by TTE.[201] Similarly, in the MEDIC registry, only 8% of patients with confirmed CIED-related endocarditis had vegetations detected by TTE, whereas all had findings on TEE.[197] However, it is important to recognize that echo densities seen on TEE are not specific for infection and echocardiographers are unable to reliably distinguish infected from noninfected echo densities in blinded review.[193] Therefore, although TEE enhances detection and can support diagnosis in high-suspicion cases, interpretation of results must be integrated with clinical and microbiological data.
5. FDG PET/CT has emerged as a valuable adjunctive imaging modality in the evaluation of suspected CIED infections, particularly when echocardiographic imaging is inconclusive. A systematic review and meta-analysis of 14 studies involving 492 patients reported an overall pooled sensitivity of 83% and specificity of 89%. Diagnostic accuracy for CIED-related endocarditis was lower than for pocket infections (76% vs 96% sensitivity).[203] A larger systematic review and meta-analysis of subtypes of infective endocarditis, including 26 studies and 1358 patients, reported an overall sensitivity of 72% and specificity of 83% for CIED-related endocarditis. Notably, pooled sensitivity and specificities were higher for studies published since 2015, suggesting improved performance over time.[204] Caution must be applied in cases of recent pocket intervention, given that healing may result in FDG avidity. Although comparative data are sparse, radiolabeled white blood cell, single-photon emission CT has been shown to have high sensitivity and specificity for CIED infection as an alternative to FDG PET/CT and may improve the diagnostic accuracy of the modified Duke-International Society for Cardiovascular Infectious Diseases criteria.[205]

8.2 Management of CIED pocket infection

A CIED pocket can become infected at the time of implantation, during subsequent surgical access, or during seeding from a secondary source that results in disseminated bloodstream infection, which infects the hardware. Patients with a CIED pocket infection can present with localized erythema (41%), swelling (38%), pain (28%), warmth (18%), drainage (38%), or device erosion with exposure (21%).[1] In the acute setting after device implant or reintervention, erythema, tenderness, and swelling can represent healing, hematoma, a superficial infection, or a true pocket

infection. Patients with pocket infection may have bloodstream lead involvement leading to fever, chills, malaise, fatigue, or anorexia, yet can present without systemic symptoms or signs even in the presence of lead vegetations or bacteremia. Device erosion usually occurs quite late after a CIED procedure. Once hardware is exposed through the skin, it is deemed infected because it is in direct contact with skin pathogens. Patients who present with device erosion are less likely to have associated systemic infection.[206]

Recommendations for the management of CIED pocket infection

COR	LOE	Recommendations
1	B-NR	1. In patients with CIED pocket infection (clinical signs of pocket purulence, abscess, dehiscence, erosion), complete device system removal is recommended for effective infection management.[207–209]
2b	C-LD	2. In patients with CIED pocket infection who are at a prohibitively high risk of complications from lead extraction or who decline complete system removal, a salvage strategy that includes pocket debridement and chronic suppressive antibiotic therapy may be considered.[210,211]
1	C-LD	3. In patients with CIED pocket infection, gram stain and culture of pocket tissue and leads are recommended at device removal to improve identification of causative pathogens and guide antimicrobial therapy.[212,213]
2b	C-LD	4. In patients with CIED pocket infection, the use of advanced diagnostic technology such as vortexing-sonication or 16S/18S ribosomal RNA polymerase chain reaction sequencing of pocket tissue or explanted device components (generator or leads) may be considered to increase identification of causative pathogens.[214–216]

Synopsis

Removal of all CIED hardware (generator, leads, anchoring sleeves, sutures, etc) is consistently associated with improved outcomes in CIED pocket infection. In addition to hardware removal, thorough debridement and irrigation of the pocket are warranted. Device system removal provides the opportunity for pocket and removed hardware cultures that can guide antimicrobial therapies. Advanced microbial identification techniques can improve diagnostic accuracy, particularly in culture-negative cases or after antibiotic exposure. Many small series of operative salvage strategies have shown good clinical success for managing patients whose lead extraction poses a prohibitive risk or who decline extraction, albeit with higher recurrence rates.

Recommendation-specific supportive text

1. Complete removal of all CIED hardware is a cornerstone of the management of CIED pocket infections. Observational studies consistently demonstrate an association between device removal with improved outcomes compared with medical therapy with antibiotics alone. Although specific surgical management strategies are not discussed in these publications, debridement, removal of all infected material, and irrigation are the standard of care in the surgical management of infections.[217,218] In a single-center observational cohort study of 189 patients with CIED infection, 69% of whom had pocket infection, 98% underwent complete device removal. When combined with antibiotic therapy, this resulted in a 96% cure rate.[207] A systematic review and meta-analysis of 32 studies, including 1100 patients with a CIED infection or endocarditis with an indwelling CIED, reported an association with a lower risk of relapse and a lower risk of mortality (OR 0.52; 95% CI 0.34–0.78; $P = .002$) with complete device removal.[209] However, a Medicare cohort study of 11,304 patients with CIED infection showed that device removal rates were only 18.6% within 30 days of diagnosis. Earlier vs later extraction was associated with an adjusted HR of 0.82 for mortality.[208]
2. In selected patients with CIED pocket infection who either are not candidates for complete hardware removal or who decline extraction, limited observational evidence supports salvage strategies such as pocket debridement and generator relocation[219] or negative pressure wound therapy combined with chronic suppressive antibiotic therapy. In a nonrandomized observational series of 80 patients with pocket infection, continuous in situ targeted ultrahigh concentration of antibiotics was curative in 85% at a median follow-up of 3 years compared with a 96% cure rate for 81 patients who underwent extraction.[210] Rates of serious complications were higher in the extraction group (15% vs 1.5%; $P = .005$), and all-cause mortality at 1 year was similar between the 2 groups. More than 15 small series report successful outcomes with surgical salvage approaches, including the "Removal, Excision, Sterilization and Quarantine" method,[220] negative pressure wound therapy,[221] flap coverage,[222] and varying pocket revision techniques.[219,223,224] However, long-term success rates vary, ranging from <50% to 100% at 1 year, and failure is unsurprisingly more common in cases with lead vegetations or *S aureus* infection.[210,211,219–224]

Overall, these data support salvage as a reasonable palliative or bridging option in selected patients, although recurrence rates are higher than those of extraction. Most studies included only patients with localized pocket involvement, and patient-specific risks must be carefully weighed.

3. Gram stain and culture of pocket tissue and lead tips at the time of CIED removal increase detection of pathogens and guide antimicrobial therapy in patients with CIED pocket infection. In a prospective, single-center, observational study of 71 patients undergoing lead extraction for infection, pocket tissue cultures were positive in 69% compared with a 31% positivity rate for pocket swab cultures.[212] Importantly, 28% of patients without clinically evident pocket infection had positive cultures, suggesting that pocket infection may be present even when clinical abnormalities are absent. Similarly, in a multicenter observational study of 105 patients with CIED infection, cultures from the pocket segment and tips were positive in 92% and 79%, respectively, whereas wound swabs were positive in 38% of cases.[213] Pocket contamination of intravascular lead segments/tips during the extraction process remains a possibility. Of note, positive tissue culture also does not always represent infection. In a series of 122 patients without evidence of CIED infection undergoing generator replacement or lead intervention, 33% had positive cultures from pocket tissue or leads. After a median follow-up of 203 days, device infection was diagnosed in 3 patients (7.5%) with a positive culture and 2 patients with a negative culture.[225]
4. Microbial detection may be improved by sonication of explanted CIED components and pocket tissue, particularly in patients with negative conventional cultures or who have had previous antibiotic exposure. 2 recent systematic reviews and meta-analyses have evaluated the diagnostic utility of sonication in addition to traditional cultures. Martín-Gutiérrez et al[214] included 9 studies reviewing 1838 cultures and reported an overall higher sensitivity (76% vs 49%) and a lower specificity (77% vs 87%) than nonsonicated cultures. False positives were more common with sonication (24% vs 17%), but the use of a threshold could decrease this rate. Similarly, Araújo et al[215] included 8 studies with 519 patients and found that sonication resulted in an overall sensitivity of 82% and specificity of 63% in sonicated cultures. This study also reported a higher false-positive rate with sonication, particularly in patients without a clinical infection. In a study of 322 specimens of sonicate fluid from extracted CIEDs, 16S ribosomal RNA gene polymerase chain reaction sequencing had a higher sensitivity than fluid culture (64% vs 56%; $P = .003$) and detected a pathogen in 28 of 118 culture-negative cases of clinical infection.[216] An evaluation, diagnosis, and management algorithm for patients with suspected CIED pocket infection is presented in Figure 5.

8.3 Management of patients with a CIED and S aureus bacteremia or endocarditis

Recommendations for management of patients with CIED and S aureus bloodstream infection or endocarditis		
COR	LOE	Recommendations
1	C-LD	1. In patients with CIED and *S aureus* bacteremia with lead involvement by imaging, CIED system removal is indicated to reduce infectious complications and improve outcomes.[226–229]
1	B-NR	2. In patients with persistent *S aureus* bacteremia for more than 4 days, CIED system removal is indicated to reduce the risk of relapse.[226,230]
2a	C-LD	3. In patients with CIED and *S aureus* bacteremia without conclusive evidence of lead infection, CIED system removal is reasonable to reduce the risk of relapse.[231,232]
2a	C-LD	4. In patients with *S aureus* bacteremia and no signs of pocket infection or vegetation by TEE, validated risk scores, including Predicting Risk of Endovascular Device Infection (PREDICT)–*S aureus* bacteremia (SAB), can be useful to determine the risk of associated CIED infection and guide CIED management decisions.[226]

Synopsis

S aureus is a notably virulent bacterium that accounts for 25% of CIED infections. Staphylococcal pathogens are resistant to antimicrobial therapy and host defenses because they form a protective biofilm of layers of extracellular polymeric matrix that limits the penetrability of antibiotics coupled with creating a protective microclimate that allows bacteria to persist in a dormant state, relatively impervious to antibiotic bactericidal effect and host defenses.[233] When SAB occurs in patients with a CIED, there should be a high index of suspicion for infection, and evaluation should be timely and comprehensive. For patients with definite or possible CIED infection in the setting of SAB, complete CIED system removal is associated with a reduction of infectious complications and improved mortality. In cases where CIED involvement is indeterminate, empirical device removal or risk

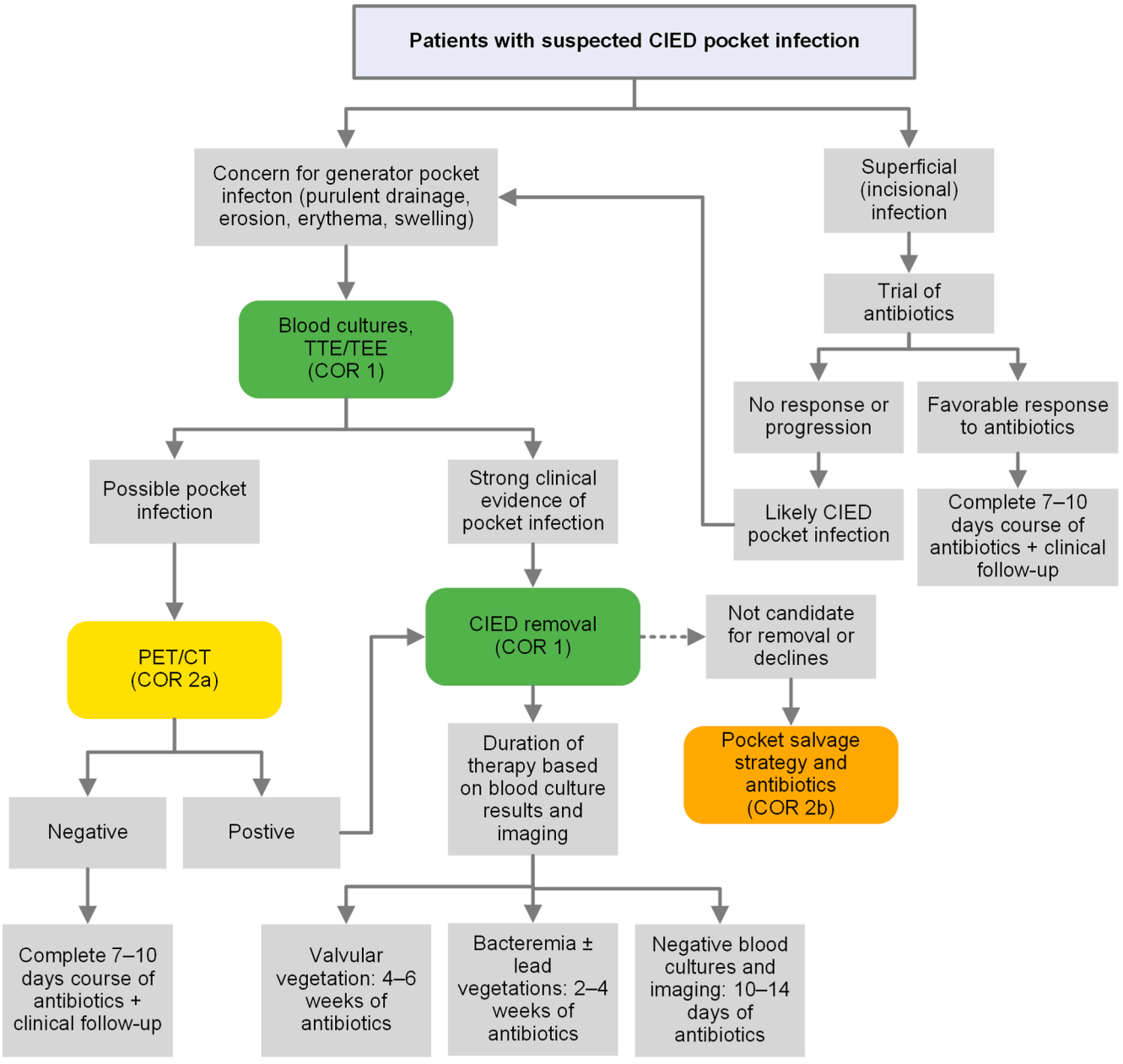


Figure 5
Algorithm for the evaluation, diagnosis, and management of suspected CIED pocket infections. Colors correspond to the COR in Table 1. CIED = cardiovascular implantable electronic device; COR = class of recommendation; PET/CT = positron emission tomography/computed tomography; TEE = transesophageal echocardiography; TTE = transthoracic echocardiography.

stratification using the PREDICT-SAB score is supported by observational evidence.

Recommendation-specific supportive text

1. In a single-center cohort of patients with SAB, the incidence of confirmed CIED infection by imaging or microbiology was 15 of 33 (45%), and no local pocket signs or symptoms were evident in 60% of those with infected CIED systems.[227] Although not randomized, treatment failure was reported in 52% of patients not undergoing extraction compared with 25% in those who underwent extraction.[227] In a more recent single-center survey of 110 patients with CIED who developed SAB and underwent TEE, 52% were diagnosed as having definite and 28% possible CIED infection.[229] Of those with definite CIED infection, 80% underwent CIED extraction, and there was an association with reduced mortality in the extraction group. However, there was no overall difference in 1-year mortality among the 3 groups, comprising definite infection, probable, and rejected.[229] In a Swedish county hospital cohort, of 61 cases of SAB in patients with a CIED, 21% were diagnosed as having CIED-related endocarditis.[228] Death occurred in the hospital in 31%, 56% were discharged with a retained CIED, and 13%

were discharged after CIED removal. No recurrences were seen in the removal group; in 4 cases with CIED endocarditis, discharged with a device, 1 had a recurrence. Among 30 patients discharged with a retained CIED and no evidence of endocarditis, 73% had no further related events.[228] The heterogeneity within the population of SAB with a CIED suggests that a management strategy based on an individual risk-benefit analysis could be an alternative to mandatory device removal. However, in addition to its potential for antibiotic resistance, *S aureus* is a particularly challenging pathogen to eradicate from implanted devices owing to its ability to form a protective biofilm matrix that hinders antibiotic penetration and normal immune response,[234] resulting in a reduced risk of recurrent infection with hardware removal.

2. Persistent SAB is strongly associated with CIED infection, even in the absence of overt clinical findings.[230] In a single-center, retrospective review of SAB of 131 patients with CIED and no clinical signs of pocket infection, 34% were found to have CIED infection by clinical or echocardiographic criteria.[226] A duration of SAB of ≥4 days was an independent predictor of CIED infection.[226]
3. *S aureus* accounts for most CIED endovascular infections, and underlying CIED infection should always be considered in patients with SAB.[226,235] Limited observational data support consideration of empirical CIED removal to reduce the risk of recurrent infection. In a single-center study of 360 patients with CIED and SAB, 178 (49%) had no evidence of CIED infection, yet 10% underwent empirical CIED removal.[231] In those who did not undergo removal, SAB relapse was reported in 19% and was associated with the duration of SAB. 1-year mortality for the entire cohort was 35%, and empirical CIED removal was associated with a decreased risk of mortality (HR 0.28; 95% CI 0.08–0.95; $P = .04$).[231] Similarly, in a Swedish cohort of 274 patients with CIED and SAB, endocarditis was diagnosed in 14% (50% with CIED involvement, but 92% with left heart involvement).[232] Extraction was performed in 14% of patients, half of whom had definite endocarditis and half who did not. Recurrence was seen in 6%: 2 in the extraction group (5%) and 14 who had not undergone extraction (6%).[232]
4. Accurately determining whether a CIED is infected in the setting of SAB can be challenging and poses a critical clinical dilemma in the clinical care of CIED patients. The PREDICT-SAB score, developed from a retrospective cohort of 131 patients with CIED and SAB without signs of pocket infection, assists in identifying patients at the highest and lowest risk of CIED infection.[226] Patients without any of the 3 high-risk features of (1) presence of a permanent pacemaker, (2) history of more than 1 CIED procedure, and (3) SAB persisting for ≥4 days have a low risk of CIED infection and may be managed without device extraction but with close follow-up and monitoring (see Table 6).[226] The suggested algorithm for the evaluation and management of SAB is presented in Figure 6.

Table 6 Predicted probability of CIED infection by PREDICT-SAB score

PREDICT-SAB score	Probability of CIED infection
0.0	0.07
3.5	0.20
4.0	023
5.0	0.29
7.5	0.49
8.5	0.58
9.0	062
12.5	0.84

PREDICT-SAB scoring: SAB lasting ≥4 days = 5 points; pacemaker = 4 points; >1 device procedure = 3.5 points. Adapted with permission from Sohail et al.[226] CIED = cardiovascular implantable electronic device; PREDICT = Predicting Risk of Endovascular Device Infection; SAB = *Staphylococcus aureus* bacteremia.

8.4 Management of patients with a CIED and non-SAB or endocarditis

Recommendations for management of patients with CIED and non-SAB or endocarditis

COR	LOE	Recommendations
1	C-LD	1. In patients with a CIED and bloodstream infection with non-*S aureus* gram-positive organisms (coagulase-negative *Staphylococcus* [CoNS], *Enterococcus*, viridans group streptococci [VGS]) and CIED lead vegetation or involvement by advanced imaging, CIED system removal is recommended to reduce the risk of relapse.[201,236]
2a	C-LD	2. In patients with a CIED and high-risk nonstaphylococcal bloodstream infections (CoNS, *Enterococcus*, VGS, *Pseudomonas aeruginosa*, *Serratia marcescens*) and absence of an alternative source of bacteremia, CIED removal can be useful to reduce the risk of relapse.[201,236]
2b	C-LD	3. In patients with a CIED and bloodstream infection with non-*S aureus* gram-positive organisms but without signs of CIED infection or suggestive imaging, the usefulness of CIED system removal is not well established.[201,236]
2a	C-LD	4. In patients with a CIED and gram-negative bacteremia without pocket involvement, suggestive imaging, or known alternative source of bacteremia, conservative management with antibiotics is reasonable.[237,238]

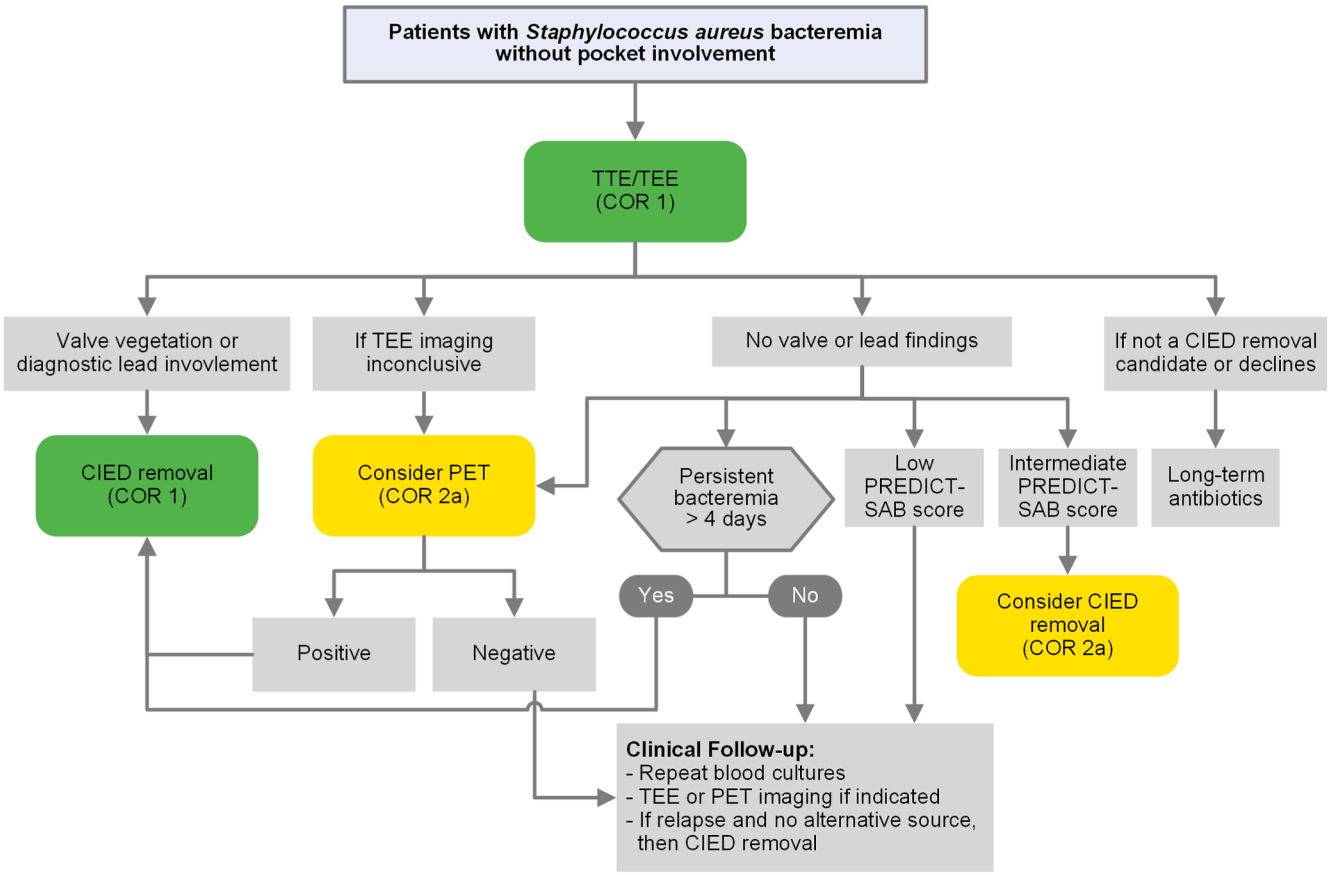


Figure 6
Algorithm of recommendations for evaluation in SAB without pocket abnormality. Colors correspond to the COR in Table 1. CIED = cardiovascular implantable electronic device; COR = class of recommendation; PET = positron emission tomography; PREDICT = Predicting Risk of Endovascular Device Infection; SAB = *Staphylococcus aureus* bacteremia; TEE = transesophageal echocardiography; TTE = transthoracic echocardiography.

Synopsis

The likelihood of CIED infection in the setting of bacteremia varies substantially by the organism type and species. Therefore, understanding the pathogenicity of the specific microbe is critical to assessing the risk of infection and the benefit of hardware removal. Non-*S aureus* bloodstream infections with CoNS, *Enterococcus*, or VGS demonstrate a higher risk of secondary CIED infection, and therefore, a higher level of concern is warranted in the setting of bacteremia. Similarly, *P aeruginosa* and *S marcescens* have a substantially higher likelihood of indwelling CIED infection than other gram-negative bacteria.

Recommendation-specific supportive text

1. A retrospective single-center review of 74 patients with non-*S aureus* gram-positive cocci (non-SA GPC) bacteremia and a CIED found that 30% were diagnosed as having a CIED infection.[236] The most common agent was CoNS, and a lead vegetation was noted in 68% of those with CIED infection. Patients without evidence of CIED infection who did not undergo CIED system removal had a recurrence rate of 15%, and all relapses occurred in CoNS infections. However, none of these patients had demonstrable CIED infection at the time of relapse, and several had alternative sources of infection.[236] There was no difference in the mortality rate of those who underwent CIED removal vs those who did not. These findings suggest routine device removal in the absence of imaging-based evidence of CIED infection is not required for patients with GPC bacteremia not caused by *S aureus*. However, TEE imaging is necessary in patients with a CIED and GPC bacteremia for the diagnosis of CIED infection. A more recent observational study from the same center of 160 patients with a CIED and non-SA GPC bacteremia reported infection in 56%.[201] The adjusted odds of CIED infection in cases owing to CoNS, *Enterococcus*, and VGS were 19-, 14-, and 15-fold higher than other non-SA GPC, respectively.[201] There were no differences in mortality between the group of patients who underwent CIED removal for infection and the group that did not.[201] Given the differences in CIED infection rates based on microbiology, treatment decisions should be guided by organism-specific data.

2. In a retrospective, observational series of 160 patients with a CIED and non-SA GPC bacteremia, CIED infection was

diagnosed in 56%.[201] In cases caused by CoNS (46%), *Enterococcus* (33%), and VGS (14%), the adjusted odds of CIED infection were substantially higher than in other non-SA GPC (19-, 14-, and 15-fold, respectively).[201] However, there were no differences in mortality between the group of patients who underwent CIED removal for infection and the group that did not.[201] In some series, a higher rate of CIED infection has been described in patients with *S marcescens* bacteremia than in those with other gram-negative bacteremia.[237] Notably, a prospective cohort study of 284 patients with CIED and bacteremia showed that the risk of CIED infection varied by species and that patients with *P aeruginosa* and *S marcescens* had an elevated risk of CIED infection compared with other species of gram-negative bacteria.[238] These data support stratifying CIED infection risk by infecting organism.

3. A retrospective single-center study of 74 patients with non-SA GPC bacteremia and a CIED reported a 30% rate of CIED infection.[236] Among those patients who did not have diagnosed CIED involvement and did not undergo device removal, the relapse rate was 15% within 3 months, but relapses were largely attributable to alternative sources of infection rather than CIED infection.[236] Mortality rates were similar regardless of whether device extraction was performed or not.[236] In a later series of 160 patients with CIED and non-SA GPC bacteremia, mortality did not differ between patients with CIED infection and non-GPC bacteremia who underwent extraction or did not undergo extraction.[201] These findings suggest that although a risk of relapse exists, particularly with CoNS bacteremia, routine extraction in the absence of imaging or clinical evidence of CIED infection may not always be necessary. Therefore, treatment decisions should be individualized, balancing the risks of extraction for that patient against the relatively low rate of proven device-related relapse.
4. A retrospective, single-center, observational series of 126 patients with a CIED and gram-negative bacteremia without clinical pocket infection reported definite CIED infection in 3% and probable CIED infection in 8%. CIED extraction was performed in 4 patients: 2 with possible and 2 with rejected CIED infection.[237] None of the patients in the definite or possible CIED infection groups had relapsing gram-negative bacteremia, despite no device extraction. There was no difference in 1-year survival between the definite/possible and the rejected CIED infection groups.[237] These findings support that routine removal of CIED hardware may not be necessary in all cases of gram-negative bacteremia owing to low rates of relapse in the setting of device retention and that clinical decision making must take species into account when considering risk and benefit.

The algorithm for evaluation and management of non-*S aureus* gram-positive bacteremia without pocket abnormality is presented in Figure 7. The algorithm for evaluation and management of gram-negative bacteremia without a pocket abnormality is presented in Figure 8.

8.5 Management of patients with a CIED and fungemia

Recommendations for management of patients with a CIED and fungemia		
COR	LOE	Recommendations
1	C-LD	1. In patients with CIED and fungal bloodstream infection with suspected CIED involvement, CIED system removal is recommended in addition to antifungal therapy.[239,240]

Synopsis

The management of fungemia in a patient with a CIED can pose a significant clinical challenge, owing to the wide variability in presentation and the limited data available to guide care. Although rare, *Candida* species are the most commonly described fungal pathogen in device-related infections. Published data are limited and consist of case reports, small series, and a systematic review of cases. Mortality is high regardless of the selected treatment strategy; device and vegetation cultures are frequently negative when the CIED is removed, yet relapses can occur in patients managed without device removal. Higher-risk findings include findings on imaging consistent with infection and persistent bloodstream infection without an alternative source. Given the lack of definitive diagnostic criteria and high mortality rate, management decisions must be individualized in weighing specific procedural risk and uncertain benefit in the context of limited data.

Recommendation-specific supportive text

1. A systematic review of 48 cases from 41 studies of systemic fungal infections in the setting of a CIED reported that *Candida* and *Aspergillus* species were most common.[239] There was significant heterogeneity in antifungal medication selection and duration of treatment. There was an association between CIED extraction and survival to discharge (92% vs 56%), although data were observational and limited to individual case reports and 1 small case series.[239] In a single-center series of 23 patients with a CIED and candidemia, 17.4% were ultimately confirmed to have CIED infection.[240] Only 2 patients with lead masses underwent extraction, but device cultures were negative. Of 6 patients managed as having candidemia without CIED infection, 2 subsequently relapsed and underwent CIED removal; device cultures were positive in both. Prognosis was poor in all groups; overall, 74% of patients died within 90 days of diagnosis of candidemia.[240]

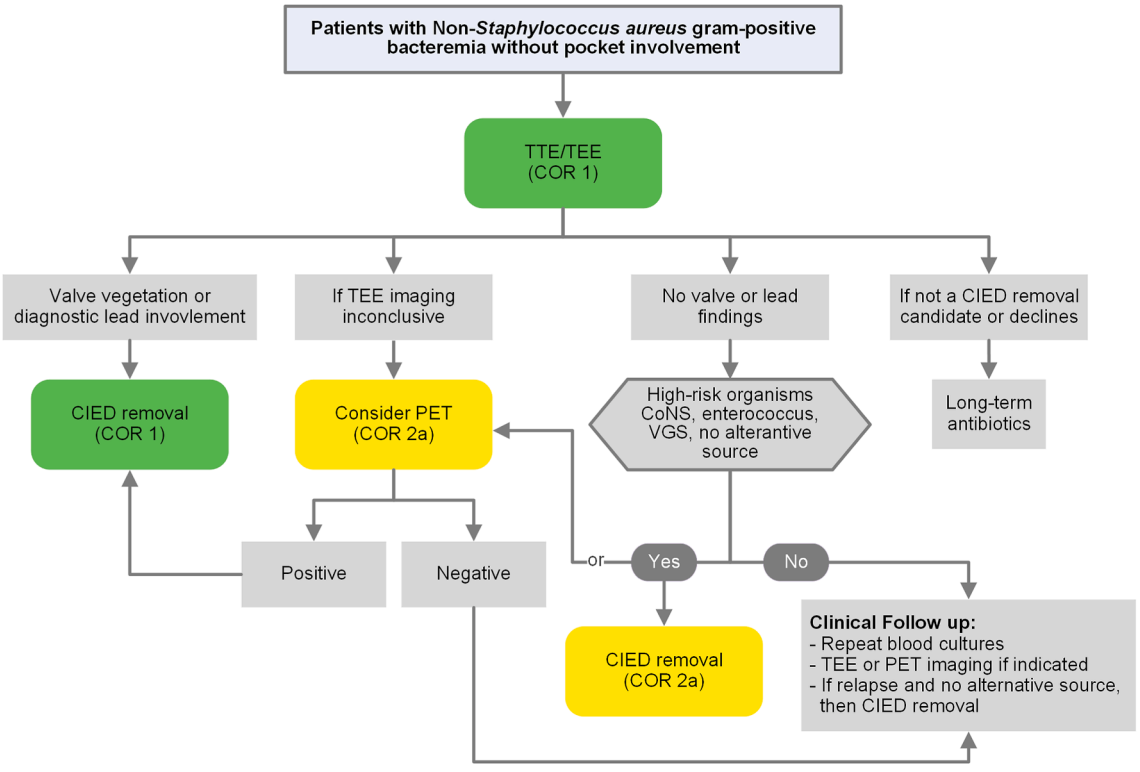


Figure 7
Algorithm for evaluation and management of non-*Staphylococcus aureus* gram-positive bacteremia without pocket abnormality. Colors correspond to the COR in Table 1. CIED = cardiovascular implantable electronic device; CoNS = coagulase-negative *Staphylococcus*; COR = class of recommendation; PET = positron emission tomography; TEE = transesophageal echocardiography; TTE = transthoracic echocardiography; VGS = viridans group streptococci.

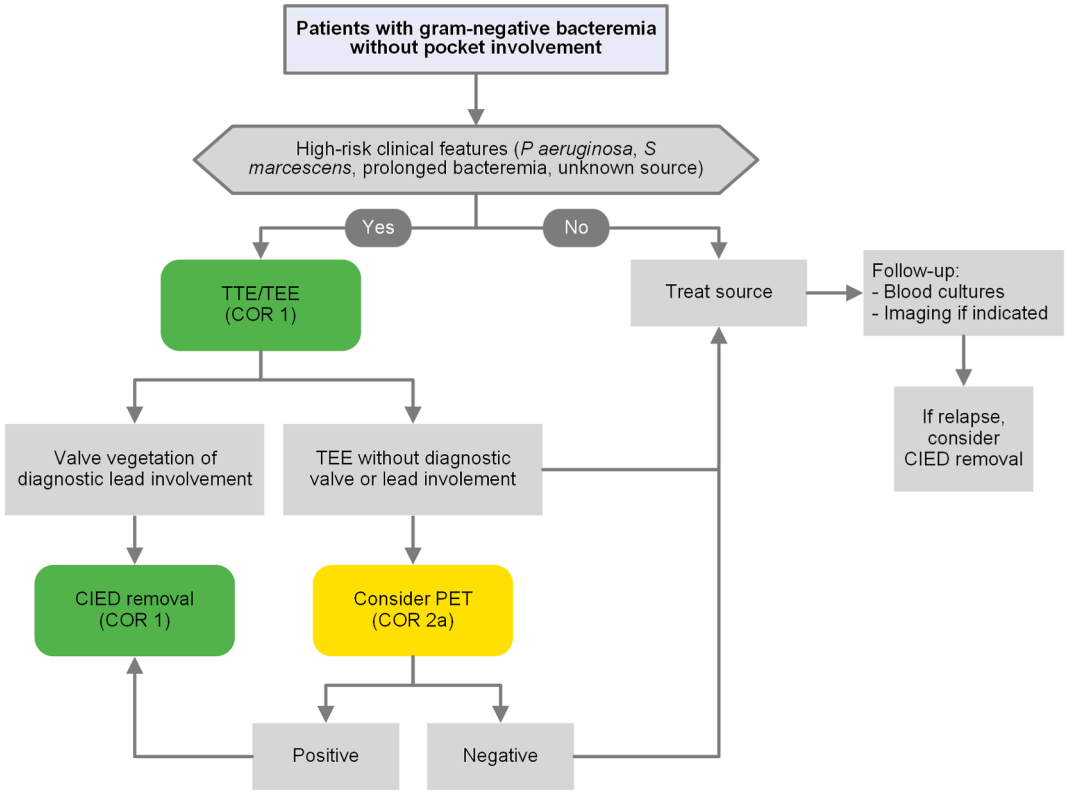


Figure 8
Algorithm for evaluation and management of gram-negative bacteremia without a pocket abnormality. Colors correspond to the COR in Table 1. CIED = cardiovascular implantable electronic device; COR = class of recommendation; *P aeruginosa* = *Pseudomonas aeruginosa*; PET = positron emission tomography; *S marcescens* = *Serratia marcescens*; TEE = transesophageal echocardiography; TTE = transthoracic echocardiography.

8.6 Procedural management for infection indication of CIED removal

Recommendations for procedural management for infection indication of CIED removal		
COR	LOE	Recommendations
1	C-LD	1. In patients with CIED bloodstream infection, gram stain and culture of pocket tissue and lead tips are recommended at device removal to guide antimicrobial therapy.[212,213]
1	B-NR	2. In patients with CIED infection undergoing system removal, early removal is beneficial compared with delayed extraction, particularly for virulent organisms such as *S aureus*.[208,241,242]
2a	C-LD	3. In patients with CIED infection and lead vegetation who are undergoing CIED system removal, transvenous lead removal is reasonable, even in the presence of a larger vegetation.[207,243]
2a	C-LD	4. In patients with CIED infection and vegetation of >1–2 cm, percutaneous mechanical aspiration can be effective to debulk lead and valve-associated vegetations.[244]
2b	C-LD	5. In patients who are at a very high risk of complications from TLE (eg, very large vegetations, >4 leads, long duration of dwell time, high-risk leads, low body mass index, female sex, and no previous cardiac surgery), surgical lead extraction may be considered.[245–248]
1	B-NR	6. In patients with a CIED who are undergoing cardiac surgery for valvular endocarditis, particularly with high-risk organisms such as *S aureus*, complete CIED system removal is indicated to reduce the risk of recurrent infection.[202,209,227,246]
2b	C-LD	7. In patients with both a CIED and a ventricular assist device who present with systemic or pocket infection, complete removal of the CIED system while leaving the LV assist device in situ may be considered.[249,250]

Synopsis

The timing of extraction is critical for patients with overwhelming *S aureus* or infection with other virulent microbes. Earlier removal of infected hardware is associated with a substantially improved outcome in observational analyses. CIED system removal in the setting of infection affords the opportunity for enhanced diagnostic accuracy by the use of tissue or lead material culture or using advanced microbial detection techniques in pocket and hardware materials. Similarly, percutaneous mechanical aspiration at the time of CIED removal allows for debulking of large vegetations, which may improve infection outcomes, and for culture of infected material.

Recommendation-specific supportive text

1. In a series of 71 patients with a CIED undergoing extraction, 49% of whom were diagnosed as having infection, positive pocket tissue cultures were more frequent than swab cultures (69% vs 31%).[212] Of note, patients without clinical infection had positive cultures at a similar rate by tissue culture (28%) and swab culture (22%). Patients who did not have a clinically diagnosed infection were not treated with additional antibiotics and did not develop subsequent infection.[212] In a series of 105 patients with CIED pocket infection undergoing extraction, the intravascular parts of the lead had positive cultures in 79%, and the extravascular parts were positive in 92%, in contrast to a 38% positivity rate in pocket swab cultures.[213] These data support the routine culture of pocket tissue and lead components at CIED removal for infection to guide antimicrobial therapy, although careful clinical interpretation of culture results is essential.[212]
2. In a single-center observational series of 233 patients undergoing CIED removal, most of whom had *S aureus* or CoNS bloodstream or pocket infection, delayed extraction (15 days) in the setting of bloodstream infection was associated with adverse outcomes of septic shock, acute kidney injury, respiratory failure, and heart failure.[241] Delayed extraction (11 days) in patients with pocket infection was associated with acute kidney injury.[241] Although observational, delayed extraction in both groups was associated with lower survival.[241] Similarly, a Nationwide Readmissions Database observational analysis of 13,000 patients undergoing extraction for CIED infection showed an association of delayed extraction (>7 days) and in-hospital mortality, major adverse events, and postprocedural length of stay.[242] In a large Medicare cohort study of more than 1 million patients diagnosed as having CIED infection using claims data, only 19% underwent CIED removal.[208] Undergoing extraction within 30 days of infection diagnosis, and particularly within 6 days, was associated with lower mortality than delayed or no extraction.[208]
3. TLE can be safely performed in patients with CIED infection and lead vegetations, including larger vegetation

sizes. Observational studies have shown that although pulmonary embolization events may occur in the setting of vegetations, they are usually not clinically relevant. In a single-center observational series of 25 consecutive patients with vegetations of >10 mm undergoing extraction, pre-extraction CT showed subclinical pulmonary emboli in 72% and subclinical pulmonary emboli in 78% of those postextraction.[243] There were no patients with new pulmonary emboli.[243] In a series of 9 patients undergoing extraction with lead vegetations of 10–38 mm, 5 of 9 patients had evidence of pulmonary emboli, all of whom had a full recovery without a longer hospitalization.[251] In a series of 189 patients with CIED infection undergoing extraction, 23% had vegetations with a size ranging from 0.3 to 7 cm in the longest dimension. None of these patients had clinical manifestations of pulmonary emboli at or after lead extraction.[207] In a series of 100 patients with vegetations ranging from 0.2 to 4 cm undergoing extraction, 2 patients had embolization and did not have clinical sequelae.[252] A publication from the MEDIC registry reported similar outcomes in 129 patients with vegetations < or >1 cm, although major complications were associated with an open surgical approach for CIED removal.[197] In patients with very large vegetations (eg, >3–4 cm), percutaneous aspiration[253] or open surgical extraction can be pursued when clinically indicated.

4. Observational series reported adjunctive vegetation debulking with percutaneous mechanical aspiration in the setting of CIED infection with a high rate of procedural success (88%–94%) and a low risk of complications (3%).[254] Multiple tools have been developed, and comparative studies are not available. In a multicenter observational study of 101 patients with a mean vegetation size of 30.7 ± 13.5 mm, complete procedural success was reported in 94% and partial in 5%, with a complication rate of 3% (death from shock, iliac vein perforation, and hemodynamic collapse before aspiration).[244] A scoping review of 51 studies including 294 patients (152 of whom had debulking of CIED vegetations) noted inconsistent reporting of patient outcomes but a reasonably low risk of procedural complications of 2.7%, including worsening tricuspid regurgitation.[254] Concurrent lead extraction success rates do not seem to differ from historical series when percutaneous mechanical aspiration is used.[254] Although the available data do not extend to improvement of clinical outcomes, these studies support percutaneous aspiration as a reasonable adjunct in select patients.
5. Surgical extraction offers a reasonable alternative to TLE when the risks are very high. A multicenter study of 2325 patients undergoing lead extraction identified clinical variables associated with perforation (no previous cardiac surgery, female sex, an LVEF of ≥40%, lead age of >8 years, >2 leads, and diabetes).[245] Clinical variables associated with mortality included infection as an indication for extraction, anemia, and older age.[245] A single-center study of outcomes of a heart team approach reported that 21 of 384 patients underwent primary open surgical extraction (for high risk of bleeding, anticipated difficult condition, or large vegetations) and 10 transvenous extraction patients required surgical intervention (5 for failed lead extraction, 5 for bleeding). There were no deaths in the planned surgical group and 1 death in a patient with an SVC laceration.[246] In a single-center series of 29 patients undergoing elective open surgical extraction, 41% had an infectious indication for CIED removal and 38% had an additional indication for open extraction. The rate of both major complications and procedural failure was 3%. Length of stay was longer in patients with infectious indications.[247] In another single-center observational study of 24 patients undergoing surgical extraction and 329 undergoing transvenous extraction, surgical patients were more likely to have positive blood cultures, larger vegetations, and higher Charlson comorbidity index scores.[248] 1-year mortality rates were higher in the surgical group, even after adjustment for other comorbidities, but patients were not randomized.[248] Data from the Canadian registry suggest that surgical extraction can reduce the risk of major procedural complications associated with large vegetations and other high-risk features, with no significant difference in mortality compared with TLE.[245]
6. Although there is no specific evidence to support CIED system removal at the time of cardiac surgery for infective endocarditis, data support removal of potentially infected hardware, particularly in the setting of high-risk infectious agents, given that the risk associated with surgical extraction is low. A systematic review and meta-analysis of patients in 32 studies of CIED infection or infective endocarditis showed an association with a lower risk of relapse and a lower mortality risk in those who underwent hardware removal (n = 905) than antibiotic therapy (n = 195).[209] In a single-center study of patients who underwent open surgical extraction, most required valve surgery and outcomes were excellent.[246] SAB is a particularly high-risk clinical setting, and retention of CIED hardware is associated with a substantial risk of recurrent infection.[227]
7. Data to support specific management strategies in patients with CIED infection and LV assist devices are very limited. Small observational studies from 2 high-volume extraction centers of 6–27 patients support the safety and efficacy of TLE in this patient population for either pocket or bloodstream infection.[249,250,255] Patients with bloodstream infection or endocarditis were usually treated with chronic suppressive antibiotic therapy after CIED removal. Recurrent or persistent infection after CIED extraction was associated with a high mortality rate. In the largest series, 21 of 27 patients (78%) were free of recurrent infection at 1 year, with 83% treated with oral suppressive antibiotics after extraction. Persistent infection after extraction occurred in 4 patients (15%) and was associated with a 50% mortality rate.[249] Individualized decision making with consideration of clinical circumstances, the severity of infection, and institutional expertise is essential.

8.7 Pacing management at CIED removal

Recommendations for pacing management at CIED removal		
COR	LOE	Recommendations
1	C-LD	1. In patients who are pacing dependent and undergoing CIED removal for infection, temporary pacing using a standard implanted pacemaker lead and externalized generator is an effective means to provide stable pacing during a course of antibiotic therapy before permanent device reimplantation.[256,257]
2b	C-LD	2. In patients who are pacing dependent and undergoing CIED removal for infection, the usefulness of implanting a permanent epicardial pacing system as an adjunct to transvenous lead removal is not well established.[258,259]
1	C-LD	3. In patients undergoing cardiothoracic surgery for valvular or CIED-related endocarditis who require pacing therapy, implantation of an epicardial pacing system is recommended.[258–260]
1	C-LD	4. In patients who are pacing dependent and undergoing CIED removal for infection, implantation of a leadless pacemaker during or after CIED removal is useful to reduce the risk of recurrent infection.[261–263]

Synopsis

Effective management of pacing needs in dependent patients after CIED removal for infection requires balancing the needs for safe and reliable pacing with controlling infection, a particular challenge in the setting of endocarditis or bloodstream infection. Temporary-permanent pacing systems using an externalized standard permanent pacing lead and generator offer a bridge to reimplantation of a permanent device with a low rate of complications, even with hospital discharge. A permanent epicardial CIED system, particularly in patients already undergoing cardiac surgery, also offers stable long-term pacing. Increasingly, a leadless pacemaker system has become a preferred option owing to the low risk of reinfection.

Recommendation-specific supportive text

1. Temporary transvenous pacing using a standard active fixation lead and an external pacemaker generator can provide a stable option for pacemaker-dependent patients that allows for hospital discharge while completing a course of antibiotics for CIED infection. In 1 of the larger of several single-center series, 334 patients underwent temporary-permanent pacing system placement after CIED removal for infection.[256] The most common access site was the ipsilateral subclavian or axillary vein.[256] Complications occurred in 1.5%, including lead dislodgement in 0.6% and infection in 0.3%.[256] In a nationwide cohort study not restricted to CIED infection, 2952 patients were treated with a temporary-permanent pacing system.[257] There was an increased rate of infection of the subsequent device, which was no longer significant after adjustment for clinical risk factors.[257] The temporary-permanent pacemaker also allows patients to ambulate, reducing the length of their cardiac care unit stay and complications related to immobility.
2. In a single-center observational study of pacemaker-dependent patients who underwent lead extraction, either epicardial reimplantation (n = 59) or active fixation temporary pacing (n = 52) was performed.[258] In-hospital complication rates were similar (37% vs 33%). In the active fixation temporary pacing cohort, 25% required an epicardial implant for infection.[258] No difference was seen in mortality by reimplantation strategy, but the use of temporary pacing was associated with a reduced risk of late endocarditis and device reintervention compared with an epicardial device.[258] In a series of 66 patients who underwent CIED extraction, 42 patients underwent epicardial pacemaker placement and 24 active fixation temporary systems.[259] The patients who received an epicardial device were discharged earlier, and complication rates were similar between the 2 groups.[259]
3. Implantation of a surgical epicardial pacemaker system in the setting of CIED infection and transvenous extraction is supported by several small observational case series.[258–260] The largest study, which comprised 160 pacemaker-dependent patients undergoing CIED extraction for infection at 2 centers, showed equivalent outcomes at both the center using a strategy of delayed transvenous pacemaker implant and a second center that performed a concurrent surgical epicardial pacemaker implant at the time of extraction.[260] In this observational

study, epicardial pacemaker implantation was associated with a shorter hospital length of stay. Limited data have been published regarding the outcomes of surgical epicardial devices implanted after valve surgery for endocarditis,[264] although concurrent epicardial device placement is suggested by current surgical guidelines owing to a lower risk of infection.[265] Collectively, these findings support an epicardial pacing strategy in patients undergoing cardiac surgery for valvular endocarditis.

4. In patients who undergo CIED removal for infection (and are no longer bacteremic), implantation of a leadless pacemaker system can provide stable pacing, with a low risk of recurrent infection. Multiple observational studies and several systematic reviews have reported a low rate of infection after leadless pacemaker implantation in this setting. In the Micra postapproval registry, 105 patients with previous CIED infection underwent leadless pacemaker placement 30 days after removal of a previous system.[261] During follow-up, 2 patients died of sepsis, and no Micra devices were explanted for infection.[261] A systematic review of 22 studies, including 657 patients, reported that 45% of patients underwent concurrent leadless pacemaker implantation.[262] A total of 194 patients (30%) had systemic CIED infections, and 153 (23%) had pocket infections. Only 3 patients (0.46%) experienced persistent or recurrent infection.[263] Although studies differ in their assessment of the best timing of leadless pacemaker implantation and include implantation at the time of extraction or later, overall rates of complications and recurrent infections are low.[262,263,266]

8.8 Management of reimplantation timing after CIED removal for infection

Recommendations for reimplantation timing after CIED removal for infection		
COR	LOE	Recommendations
1	C-LD	1. In patients who are pacemaker dependent and undergoing CIED removal for infection, the timing of reimplantation and device selection should be individualized based on clinical status and risk of reinfection.[262,267–269]

Synopsis

After CIED system extraction, a significant number of patients no longer require CIED reimplantation. In a study of 300 patients who underwent extraction for infection, 41% continued to have an indication for the same device, 23% received a different kind of CIED, and 37% were discharged without the need for CIED.[270] Timing of reimplantation varies depending on the clinical circumstance, including the virulence of the infecting microbe and the extent of infection.

Recommendation-specific supportive text

1. In a retrospective single-center observational review of 109 patients treated for CIED-related infective endocarditis requiring reimplantation, patients with valve vegetation and reimplantation in <14 days had an association with reduced survival.[271] A MEDIC registry report of 220 patients who underwent extraction for infection and later implant showed a repeat infection rate of 1.8% with a broad range of reimplantation strategies.[267] A systematic review and meta-analysis of 8 studies, including 96 patients with CIED infection, reported a pooled incidence rate of device reinfection of 0.45%. There was no difference in reinfection rates when time to reimplantation was stratified at 1 week, but significant heterogeneity in the studies limited interpretation.[268] A systematic review of 22 studies, including 657 patients who underwent leadless pacemaker implantation after CIED removal for infection, reported a 0.46% rate of recurrent or persistent infections.[262] In a multicenter observational study of 229 patients who underwent ICD extraction and subsequent S-ICD or transvenous ICD implantation, no lead failures, systemic infection, or system-related deaths occurred in the S-ICD group. In the transvenous ICD group, 1 lead fracture and 2 infections occurred, 1 of which resulted in death.[269] A flowchart on the timing of CIED reimplantation after the CIED system removal in select scenarios is presented in Figure 9.

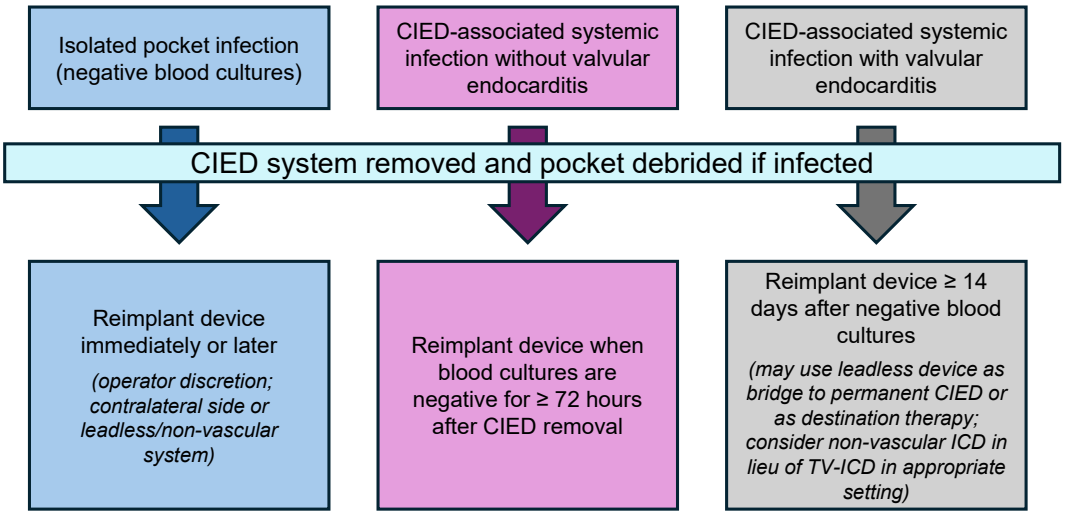


Figure 9
Illustrative flowchart for the timing of CIED reimplantation after CIED system removal for infection in select scenarios. CIED = cardiovascular implantable electronic device; ICD = implantable cardioverter-defibrillator; TV-ICD = transvenous implantable cardioverter-defibrillator.

8.9 CIED infection antimicrobial therapy

Recommendations for antimicrobial therapy		
COR	LOE	Recommendations
1	C-EO	1. In patients with CIED presenting with systemic infection, initiation of empirical broad-spectrum antimicrobial therapy targeting both gram-positive and gram-negative organisms is recommended until pathogen identification and susceptibility results are available.
1	C-EO	2. In patients with CIED infection, a complete course of antimicrobial therapy (typically 4–6 weeks for bloodstream infection and 7–14 days for pocket infection) guided by pathogen identification and in vitro susceptibility testing is recommended after complete device removal.
2a	C-EO	3. In select patients with CIED infection who are at prohibitively high risk or who decline device removal, long-term suppressive antibiotic therapy and local wound management may be reasonable as palliative treatment.
2b	C-LD	4. In stable patients who undergo CIED removal for device infection, transitioning to oral antibiotic therapy after an initial course of intravenous treatment may be reasonable.[272,273]

Synopsis

Antimicrobial choice and duration for CIED infections vary based on the causative pathogen and clinical presentation. Once the infected CIED is removed, most pocket infections can be treated with 1–2 weeks of antibiotic therapy, often transitioning to an oral agent at discharge. For systemic infections, most patients with uncomplicated bacteremia can be managed with 2 weeks of antibiotic therapy. Switching to an oral agent at discharge may be appropriate in select patients—particularly when bacteremia clears quickly, the infection is caused by an organism susceptible to a highly bioavailable oral antibiotic, and outpatient adherence is reliable. Complicated CIED infections with lead or valvular vegetations are typically treated with 4–6 weeks of antibiotics. Long-term suppressive therapy is reserved as a palliative option for patients in whom the infected CIED cannot be removed, although it carries a high risk of relapse.

Recommendation-specific supportive text

1. In 1 study involving 429 cases of CIED infection, 68 cases (71.6%) were categorized as nonbloodstream infection and 27 (28.4%) as bloodstream infection. Patients with CIED pocket infection who meet systemic inflammatory response syndrome criteria and/or are hypotensive at admission are more likely to have underlying bloodstream infection and should be started on empirical antibiotics

after blood cultures are obtained.[198] Another study aimed to compare empirical treatment with antistaphylococcal penicillin or cefazolin with other treatments in methicillin-susceptible *S aureus* endocarditis. In 208 patients, empirical treatment with antistaphylococcal penicillin or cefazolin was more effective than other treatments.[274]

After blood cultures are collected, vancomycin is usually recommended for the empirical treatment of a pocket infection. Empirical antimicrobial coverage for patients with possible CIED infection and a suspected bacteremic presentation should consider clinical findings, epidemiologic factors, and the need for inclusion of coverage for gram-negative bacilli pending blood culture results. Vancomycin (or an equivalent agent) should be administered as initial therapy until the microbiological etiology is identified to ensure robust gram-positive coverage. Antibiotic therapy is the first pillar in CIED infection management. It should be started promptly after blood culture sampling and follow the principles of treatment of infectious endocarditis.[95,275]

2. There are no comparative trials to guide the selection of an optimal antimicrobial treatment for infection. For pocket site erosion without purulence, a 7-day treatment course after extraction is reasonable. For pocket site infection with purulence, a 10-day duration of antibiotics after extraction is reasonable. A longer duration of antimicrobial therapy is suggested in patients with bloodstream infection; patients with valvular infective endocarditis may need up to 4–6 weeks of parenteral treatment, depending on the causative pathogen and whether there is native or prosthetic valve infective endocarditis.[276]
3. Suppressive antimicrobial therapy indication relies to date on local expert opinion rather than clinical evidence (42 patients in 1 study). The choice of antimicrobial therapy should be guided by in vitro susceptibility testing of the causative organism. However, dosing and duration are based on wound tissue blood cultures but may be empirical, given the limited available study results. The long-term outcome of this approach is unknown.[6,277]
4. The randomized multicenter POET trial examining the efficacy and safety of partial oral vs intravenous antibiotic therapy in patients with infective endocarditis, including patients with CIEDs, found that step-down oral therapy was noninferior to continued intravenous antibiotic treatment. This study examined changes in the length of hospital stay (mortality and relapse of bacteremia) before and after the POET publication (3008 patients before POET and 1740 after POET). There was a reduction in the median length of hospital stay of 8 days with no changes in mortality and associated lower rate of relapse of bacteremia.[198,278]

8.10 Prevention of CIED infection

Recommendations for the prevention of CIED infection

COR	LOE	Recommendations
1	A	1. In patients undergoing a CIED procedure with incision, administration of preoperative systemic antibiotics before incision is recommended to reduce the risk of infection.[279–281]
2a	B-R	2. In high-risk patients with a CIED, such as those undergoing generator replacement or system upgrade or with previous device infection, immunosuppression, or renal dysfunction, the use of an antibacterial envelope can be useful to reduce the risk of pocket infection.[282,283]

Synopsis

Systemic antibiotic prophylaxis is the key strategy for preventing CIED infection. Administering antibiotics within 1 hour before the procedure, typically cefazolin, significantly lowers infection risk by 40–95%. For patients allergic to cephalosporins, vancomycin and clindamycin are suitable alternatives. Most CIED infections are pocket related. Antibacterial envelopes are effective in reducing pocket infection and should be considered in higher-risk patients, such as those undergoing generator replacement, revision, or CRT. Risk stratification tools such as the PADIT score[281] can help identify high-risk patients. Despite its frequent use in surgery, wound irrigation has no demonstrated benefit in lowering infection rates. Evidence supports focused, perioperative prophylaxis rather than extended or topical antibiotic use.

Recommendation-specific supportive text

1. Administering systemic antibiotics 1 hour before the procedure has been shown to significantly reduce the risk of device infection, with a relative risk reduction ranging from 40% to 95%; a first-generation cephalosporin such as cefazolin (given within 1 hour before incision) or vancomycin (given within 2 hours before incision) can be administered. For patients who are truly allergic to cephalosporins, vancomycin and clindamycin are considered suitable alternatives. The PADIT trial confirmed that using a dual antibiotic preoperative approach, including

vancomycin, did not provide a significant benefit. Compared with the standard prophylaxis with periprocedural cefazolin in patients undergoing CIED implantation, a more aggressive multicomponent antibiotic regimen did not show a notable advantage in preventing device-related infections. Postoperative antibiotics are not recommended, given that there are no supporting data for their use. The use of povidone iodine ointment, neomycin ointment, and antiseptic pads did not demonstrate any benefit in preventing CIED infections compared with placebo.[279–281,284]

2. Most CIED infections are pocket related. The WRAP-IT randomized study was conducted in a population deemed at a higher risk of pocket infection (CIED generator replacement, device upgrade/revision, or CRT implantation). The use of an antibacterial envelope as an adjunctive measure decreased the occurrence of major CIED infections in this higher-risk population compared with standard infection prevention strategies alone; the absolute infection rates were low and statistically significant (0.7% vs 1.2%, respectively; 40% relative risk reduction; $P = .04$). *Staphylococcus* species were the most common pathogens, and envelope use resulted in a significant decrease in *Staphylococcus*-related pocket infections (both *S aureus* and CoNS), although there were more cases of *Staphylococcus* bacteremia (mostly *S aureus*) in the envelope group.[283] Several risk calculators, including online tools such as the PADIT score, help identify high-risk patients.[281] Although wound irrigation during surgery is common across various surgical fields, there is no evidence that it reduces infection risk. Similarly, postoperative antibiotics have not demonstrated any benefit in preventing infections. Povidone iodine ointment, neomycin ointment, and antiseptic pads did not provide any advantage over placebo in preventing CIED infections.[282,285]

Section 9 Indications for lead extractions (noninfectious)

9.1 Chronic pocket pain

Chronic pain at the device site or 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 after a CIED implantation has not been fully established but generally represents approximately 1%–3% of lead extraction cases.[286,287]

Pain and tenderness at the device site represent a wide range of clinical scenarios, from subclinical infection to possible CIED allergies, poorly formed device pocket, fibromyalgia, or musculoskeletal problems. The presentation of a device infection is often variable. Chronic pain at the device site is an often-overlooked manifestation of an indolent, chronic infection caused by a slow-growing organism. Still, the direct relationship between subclinical device infections and chronic pain remains to be elucidated. CIED contact dermatitis, although rare, has been well established, with many case reports illustrating a broad spectrum of possible symptoms, ranging from pain and tenderness to dermatologic manifestations.[288,289] 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.

CIED has been associated with postoperative discomfort and pain independent of infection.[290] Chronic shoulder pain and disability were described in 131 patients (54%) more than 3 years after ICD implantation.[291] The only predictor of shoulder pain was the number of implanted leads. Another possible cause of 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 owing to compression of the brachial plexus and subclavian vessels. Placement of the device in or very close to the deltopectoral groove may cause pain owing to compression of the tissue and structures in the area during ipsilateral arm adduction.

Recommendations for chronic pocket pain

COR	LOE	Recommendations
2a	C-LD	1. In patients with severe, chronic pain at the CIED site believed to be secondary to the CIED system and that is not manageable by medical therapies or surgical revision, device and lead removal can be beneficial.[292]

Synopsis

Chronic pain at the device implant site or lead insertion site is an infrequent indication for lead extraction.[286,287] The scope of this problem is likely multifactorial, ranging from indolent infection to musculoskeletal conditions.[212,288–293] An individualized treatment plan is necessary, and removal of the device and lead extraction in patients with severe chronic pain may relieve symptoms when other strategies have failed.

Recommendation-specific supportive text

1. Chronic pain at the CIED generator site is variable and can present as persistent or movement triggered and be caused by dermatitis, subclinical infection, thoracic

outlet syndrome, fibromyalgia, or a poorly formed device pocket. In a 27-patient, multicenter, retrospective, observational study, extraction relieved constant and intermittent pain in two-thirds of patients.[292] Although there are various causes of 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. Medical therapy with antinociceptive medications such as amitriptyline, pregabalin, and gabapentin has proved useful in some patients. When alternative management strategies are not available or have failed to resolve chronic pain, removal of the device and leads is reasonable after shared decision making with the patient.

9.2 Thrombosis (vascular obstruction/occlusion)

CIED lead-related vascular stenosis or occlusion is a relatively common finding and is often asymptomatic.[161] Symptomatic patients may have debilitating symptoms requiring treatment. A comprehensive plan including anticoagulation, endovascular treatment with venoplasty and possible stent placement, and/or TLE should be considered.[183,294] Placement of the device in or very close to the deltopectoral groove may cause pain owing to compression of the tissue and structures in the area during ipsilateral arm adduction.

Recommendations for thrombosis (vascular obstruction/occlusion)

COR	LOE	Recommendations
1	C-LD	1. In patients with symptomatic vascular stenosis or occlusion, lead removal as part of a comprehensive plan for maintaining vascular patency is recommended.[161,183]
1	C-LD	2. In patients with clinically significant thromboembolic events attributable to thrombus on a lead or a lead fragment that cannot be treated by other means, lead removal is recommended.[295,296]
1	C-EO	3. In patients with planned stent deployment in a vein already containing a transvenous lead, lead removal is recommended to avoid entrapment of the lead.

Synopsis

CIED lead-related venous occlusion is common and, fortunately, most often asymptomatic owing to the development of collateral blood vessels. Venous occlusion/thrombosis after pacemaker or ICD system implantation can make system revision and device upgrades challenging; contribute to the development of symptomatic venous occlusion, including SVC syndrome; and, rarely, lead to thromboembolic complications.[296]

Endovascular treatment with subclavian percutaneous balloon venoplasty offers symptom relief with a high rate of technical success; however, restenosis is common. When used in the setting of failed leads with venous occlusion, venoplasty adds to the overall lead burden by leaving redundant leads behind. Furthermore, this approach is not applicable in cases of a complete occlusion that cannot be crossed. Alternatively, TLE to regain venous access to an occluded vein preserves the contralateral side for potential future use and minimizes overall lead burden and the long-term risks of abandoned leads.

Asymptomatic SVC occlusion in the setting of well-developed collaterals might preclude the placement of additional leads in a patient with existing leads. Under these circumstances, the extraction of an existing lead is 1 approach to regain access. In patients with symptomatic SVC syndrome, venoplasty alone often resolves symptoms; however, the benefit is frequently short-lived owing to near-inevitable reocclusion. In experienced extraction centers, lead extraction offers a safe and effective method for symptom resolution and long-term maintenance of SVC patency.[294] When a stenting strategy is used, all existing transvenous leads should be extracted before the stent placement to avoid entrapment of leads behind the stent.[297,298]

Recommendation-specific supportive text

1. Combining TLE with percutaneous treatment of symptomatic vascular stenosis is a safe and effective treatment strategy.[294] Several observational studies of TLE in patients with SVC syndrome support this management approach. Gabriels et al[294] described their experience with patients undergoing TLE for symptomatic SVC syndrome at a single high-volume center. A total of 37 leads were extracted from 16 patients. Periprocedural management included SVC stenting after TLE in 6 patients with antecedent balloon angioplasty in 5 of the 6 cases; 11 patients underwent CIED reimplantation. There was 1 major complication owing to an SVC tear that was managed surgically. Importantly, most patients (75%) remained free of SVC restenosis and symptoms over long-term follow-up (median 5.5-year follow-up).[294] Arora and Carrillo[183] reported similar outcomes in their experience of CIED-related SVC syndrome. Among 17 patients, management included TLE and venoplasty in 13 patients, venoplasty alone in 3

patients, and surgical SVC reconstruction in 1 patient. 10 patients underwent CIED reimplantation. Symptom resolution was achieved and maintained in all patients at both 6- and 12-month follow-ups. Compared with controls, there was no significant difference in the rate of complications associated with TLE for SVC syndrome.[183]

2. Clinically significant thromboembolic events related to transvenous leads occur infrequently but have been reported and are of particular concern in patients with intracardiac shunts.[295,296,299] In a multicenter, retrospective study of 202 patients with intracardiac shunts,[295] 64 patients had transvenous leads (group 1), 56 had epicardial leads (group 2), and 82 had right-to-left shunts but no pacemaker or ICD leads (group 3). Multivariate, stepwise regression analyses indicated that transvenous leads were an independent predictor of systemic thromboembolic events (HR 2.6; $P = .027$).[295]
3. Endovascular treatment with stent placement is often used for the treatment of lead-induced symptomatic venous occlusion (eg, SVC, subclavian, brachiocephalic). Existing leads should be removed before stent placement to prevent entrapment of leads behind the stent (potentially causing lead malfunction and completely precluding future lead removal for any indication, including infection).[296,297]

9.3 Lead malfunction/recalled leads: Extraction vs abandonment

Recommendations for lead malfunction/recalled leads: Extraction vs abandonment

COR	LOE	Recommendations
2a	B-NR	1. In patients with malfunctioning leads, when the benefits outweigh the risks, it is reasonable to choose lead removal over lead abandonment.[300–302]
2b	C-LD	2. In patients with normally functioning advisory leads and/or devices that, owing to a design failure, pose a potential future threat to the patient if left in place, lead and leadless device removal may be considered.[127,303]

Synopsis

Transvenous leads are the weak link in the CIED system. Leads are engineered to withstand various unique and complex forces, including implantation manipulation, twisting and torquing with upper body movement, and bending with myocardial contraction with each cardiac cycle, while enduring the harsh in vitro environment.[304,305] Failure of a transvenous lead, whether on advisory or not, can result in serious clinical events, including premature battery depletion, failure to capture or defibrillate, and oversensing leading to inappropriate shocks or pacing inhibition. Reported failure rates vary widely, with estimates as high as 17% at 12 years,[306] but more recent observations of lead survivability at 8 years report 94% for contemporary nonadvisory leads and 81% for advisory leads.[307] However, specific lead advisories have demonstrated significantly higher failure rates of nearly 4% per year.[308] In addition, lead electrical parameters may not always predict physical lead integrity.[309]

Recommendation-specific supportive text

1. There are no randomized studies comparing TLE with abandonment for failed leads. Multiple observational studies have suggested the safety of lead abandonment, but they are limited by selection bias and a lack of long-term follow-up.[135,300–302] Conversely, other observational studies have demonstrated an increased incidence of venous occlusion and infection.[128] Moreover, if TLE is required, abandoned leads are associated with an increased risk of incomplete extraction and major complications.[128,130,166] In fact, abandoned leads are frequently cited as a risk factor for lead extraction complications.[310,311] TLE has become safer with growing experience, newer technology, and the rescue balloon (see section 10). Each patient must be considered as an individual, and the risks and benefits of each approach should be weighed. When the benefits of TLE outweigh the risks and TLE is considered, it should be performed at an experienced center with appropriate safety protocols.
2. Management of CIED advisories needs to be individualized to the advisory and the patient. When the lead failure incidence is low with a low risk of patient harm, regular and close surveillance via a remote monitoring system is advised. In certain cases, lead extraction may be considered for functional advisory leads to prevent patient harm, such as inappropriate shocks, symptomatic device failure (eg, symptomatic bradycardia and/or syncope), and mechanical complications. In addition, the difficulty of TLE increases with increasing implant duration, and removal of a relatively young advisory lead with a significant failure risk will be technically easier when performed earlier rather than at some time in the future if the lead fails.[312] Extraction registries have reported higher complication rates or clinical failure when there are large numbers of leads requiring removal.[310,311,313,314] Therefore, abandoning leads

could complicate future TLE and potentially lead to an increased risk of major complications.[132,315] In a large registry study of 2962 procedures, patients with multiple abandoned leads had an increased risk of infection and all-cause mortality vs controls without abandoned leads matched by age, sex, device type, and device revision/removal date.[132] For advisory leads that have failed, the decision regarding abandonment vs extraction should follow the same guiding principles as for nonadvisory leads. The risk-benefit ratio of lead or leadless device removal on a normally functioning lead or device must be considered in a shared decision-making process with the patient when the lead management plan is discussed.[127,303]

9.4 CIED upgrade and downgrade

Recommendations for CIED upgrade and downgrade		
COR	LOE	Recommendations
2a	C-LD	1. In patients with vascular stenosis or occlusion that prevents implantation of a necessary lead, lead removal to achieve central venous access is reasonable.[132,316,317]
2a	B-NR	2. In patients undergoing a CIED upgrade that would result in a superfluous lead, it is reasonable to choose removal of superfluous leads over abandonment when upgrading, downgrading, or revising a CIED system when the benefit outweighs the risk.[313–316]
2a	C-LD	3. In patients undergoing a CIED upgrade, when inserting additional leads would result in an excessive number of leads that exceed the capacity of the vasculature, it can be useful to remove superfluous leads.[132,182,291]

Synopsis

Procedural options for device system upgrade necessitate knowledge of ipsilateral venous patency. Thus, assessment of vascular patency before the procedure is preferable, given that this knowledge may affect the procedural strategy. In case of an obstruction/occlusion, options include a contralateral lead implantation with tunneling across the chest, attempted venoplasty, or extraction of a superfluous or functional lead to gain vascular access. An individualized approach should be taken based on operator and center expertise and an assessment of the risk and benefit of each option.

In patients with ipsilateral venous patency and leads that are no longer required (eg, upgrading a pacemaker to an ICD), there are the options of abandoning the lead and placing a new lead vs extraction and reimplantation. In each patient, the up-front risk of extraction must be weighed against the long-term risk of lead abandonment. When this indication is considered, it is crucial to balance the risk of the intervention (including the age, number, and model of the lead(s) and the lead extraction center's experience) with the patient factors such as age and life expectancy. TLE has become safer with growing experience, newer technology, and the rescue balloon, and lead abandonment is not without risk; studies have demonstrated an increased incidence of venous occlusion and infection. In addition, if TLE is ultimately required, abandoned leads are associated with an increased risk of incomplete extraction and major complications.

When upgrading or downgrading a CIED system results in a superfluous lead (eg, permanent pacemaker to ICD, or CRT-defibrillator to CRT-pacemaker), the same decision process described for nonfunctional and advisory leads should be undertaken for TLE vs abandonment.

Recommendation-specific supportive text

1. Venous access can become an issue during a device upgrade or requirement for an additional lead owing to venous occlusion at the desired venous access point. Based on operator and center expertise and the patient's condition, an individualized approach should be taken. For example, tunneling may be the only option for operators not skilled in venoplasty or TLE; however, tunneling has the associated limitations of utilization of the only remaining superior access site and the potential discomfort of the tunneled lead. In addition, not all clinical cases may be amenable to all management options. In the setting of complete occlusion, venoplasty might not be possible. TLE as an approach to device upgrade for patients with vascular stenosis or occlusion is well described and has been shown to be a safe and effective strategy.[182,315–318] 1 post hoc study of a large, multicenter registry showed that the clinical success rate of TLE to facilitate CIED upgrade was comparable with that for those who underwent TLE for other reasons (97.6% vs 93.0%; $P = .569$).[316] However, in an older patient with long-dwelling leads and other comorbidities, contralateral lead implantation with tunneling across the chest is, perhaps, a more appropriate option.
2. The same decision process for TLE vs abandonment as described earlier should be undertaken when a CIED

upgrade would result in a superfluous lead (eg, permanent pacemaker to ICD), taking into account the risk of removing the lead vs potential future complications of abandoning the lead. Superfluous leads have been associated with more technically challenging TLE, lower success rates, and higher complication rates.[313,314] In addition, the presence of abandoned leads conferred an increased risk of infection and all-cause mortality compared with matched controls in a large registry series.[132] In fact, infection rates as high as 5.5% have been observed among patients with superfluous leads.[182]

3. Decisions regarding lead abandonment vs extraction of superfluous leads need to be individualized to the patient and the operator, taking into account the overall lead burden relative to the vessel size. Data regarding extraction vs abandonment are limited to retrospective, observational studies, often with limited follow-up. Regardless, increasing transvenous lead burden is not without potential complications, including symptomatic vascular occlusion and infection. Although the accepted number of implanted leads within 1 vessel varies among operators, there is a clear association between the number of leads and the sum of their diameters in contributing toward venous stenosis and an increased incidence of pacemaker-related infection with 3 or more abandoned leads or 4 or more total leads.[308] Increased shoulder pain and other complications have also been reported in patients with a larger number of leads on the ipsilateral side.[291] As always, lead management decisions are an individualized risk vs risk assessment, weighing the up-front risk of extraction against the long-term risk of lead abandonment.

9.5 MRI

Recommendations for managing CIEDs in the MRI setting were addressed in the 2017 HRS consensus document.[2] The safety of MRI in conditional and nonconditional CIED systems has previously been well established. The definition of "MRI nonconditional" comprises all CIED systems that have not been FDA labeled as "MRI conditional." This also includes CIED systems with leads from different manufacturers, whether or not the leads have been approved as part of another MRI-conditional system, as well as CIED systems with abandoned or epicardial leads.[2]

Substantial evidence has accumulated to demonstrate that MRI can be safely accomplished in most MRI-nonconditional CIED systems, including those with abandoned or epicardial leads.[2,319–322] Not all patients with MRI-nonconditional CIED systems have reasonable imaging alternatives. Therefore, for the individual patient, shared decision making regarding the risks of undergoing MRI with a nonconditional CIED vs the risks of lead extraction to achieve an MRI-compatible system in this setting is paramount.[175–177,323,324]

Recommendations for MRI

COR	LOE	Recommendations
1	C-EO	1. In patients with nonconditional CIED systems, the development and use of facility-specific protocols for performing MRI are recommended.
2b	C-LD	2. In select patients with nonconditional CIEDs who require MRI, lead removal may be considered after considering other imaging modalities including off-label MRI.[176,177,319–324]

Synopsis

Many FDA-approved MRI-conditional CIED systems are widely implanted today and are safe for use in the MRI environment when managed according to specific labeling requirements, including reprogramming. Substantial evidence has been accumulated to demonstrate that MRI can be safely performed in most MRI-nonconditional CIED systems, including those with abandoned or epicardial leads.[2,319–322] It must be noted that the use of a multidisciplinary collaborative protocol is advisable. However, currently, there is limited availability of MRI-nonconditional CIED system scans. Therefore, removal of malfunctioning or abandoned leads to allow implantation of an MRI-conditional system may be considered to facilitate MRI, especially for those for whom no other optimal imaging modality is readily available.

Recommendation-specific supportive text

1. Standardized, multidisciplinary protocols for MRI scanning in patients with CIEDs have been developed and implemented to enhance patient safety and procedural consistency. In patients with an MRI-nonconditional system, additional steps are advisable to ensure safety and minimize hazards to the patient. These should include a risk-benefit discussion and consideration of alternative imaging modalities. Substantial evidence has been accumulated to demonstrate that MRI can be safely performed in most MRI-nonconditional CIED systems. There is a growing body of literature that has shown that MRI in nonconditional epicardial implanted leads or abandoned leads in both the pediatric and adult populations does not represent a greater risk than MRI performed on transvenous CIEDs.[2,319–322]
2. Although the large body of evidence shows a low risk when using MRI in patients who have MRI-nonconditional CIEDs

despite the manufacturer's labeling,[175,177,322,324] access to MRI for these patients remains limited in some institutions. Therefore, the class 2b indication for consideration of lead extraction to facilitate obtaining an MRI-conditional CIED status has been maintained. Given that lead extraction can be associated with serious complications, albeit at a very low rate, access to MRI for CIED patients with nonconditional CIEDs should be improved to minimize the need for lead extraction.

9.6 CIED management in tricuspid valve disease

CIEDs and tricuspid valve disease frequently coexist in either an independent or causal relationship. Tricuspid valve dysfunction can occur as a result of CIED implant from mechanical interference of the lead(s) with the valve leaflet function because of lead adhesion or direct trauma to the valve itself or owing to altered RV geometry as a consequence of long-term pacing.[325,326] The reported prevalence of tricuspid regurgitation after CIED implantation varies widely from 7% to 45%[325,327–334] and from 10% to 38% when classified as a ≥2 grade increase in tricuspid regurgitation severity.[328,331,332,335,336] Various risk factors have been associated with CIED-related tricuspid regurgitation; however, none have proven consistent, highlighting the multitude of variables at play.[337]

Recommendations for tricuspid valve disease		
COR	LOE	Recommendations
1	C-LD	1. In patients with transvenous leads crossing the tricuspid valve and planned TTVR, lead removal is recommended to avoid entrapment of the lead and facilitate the TTVR procedure.[188–190,338]
2a	B-NR	2. In select patients with severe tricuspid regurgitation where the mechanism of tricuspid regurgitation is thought to be secondary to the existing transvenous lead(s), lead removal can be beneficial.[330,339]

Synopsis

Reported outcomes of tricuspid valve function with TLE are inconsistent,[186,330,339–347] likely reflecting the interaction between the lead and tricuspid valve and the variability in the tricuspid regurgitation mechanism. The management of lead-related and lead-associated severe tricuspid regurgitation is undergoing an evolution with the advent of TTVR. In recent studies, patients with preexisting transvenous leads represent more than one-third of the TTVR population.[348] Although each case should be individualized, the jailing of transvenous leads by TTVR should be avoided for 2 principal reasons. First, the potential for reduction in tricuspid regurgitation severity with lead removal, especially with younger leads, may obviate the need for TTVR. Second, there are tangible risks associated with jailing leads.

Recommendation-specific supportive text

1. TTVR is a rapidly evolving technology for the percutaneous management of tricuspid valve disease, and its popularity and implementation are growing rapidly. The management of CIEDs in tricuspid valve disease is complex and warrants involvement of a multidisciplinary team, including electrophysiologists specifically skilled in CIED management and lead extraction. Existing transvenous leads should be removed before valve placement, thus avoiding entrapment of these leads behind the valve. The adverse events associated with jailed leads include lead dislodgement, lead malfunction, infection, sepsis, and death. In the event of future infection, complete removal of the infected jailed lead may not be possible—certainly not without jeopardizing the overlying valve apparatus. Although studies of TTVR-jailed transvenous leads have limited follow-up to date, the early results are concerning. In just 15 months of follow-up, Anderson et al[188] observed an 11% risk of lead failure among 28 TTVR patients with entrapment of the RV lead in the Valve-in-Valve International Database. More recently, Mekary et al[189] described their experience with TTVR-entrapped leads in a real-world setting. Among 14 TTVR patients with entrapped RV leads, they observed a 21% failure rate with 14% mortality after only 10.5 months of follow-up. Causes of mortality included local CIED infection progressing to endocarditis and, ultimately, death and sudden cardiac death in a pacemaker-dependent patient. The rates of lead failure and death with RV lead entrapment by TTVR are alarming. The TRIPLACE TTVR registry documented a 5.9% failure rate of jailed leads at only 6 months, as well as an increased risk of tricuspid valve reintervention and perivalvular leak.[338] In a cohort of 32 patients undergoing Evoque implantation with preexisting CIED lead crossing the tricuspid valve and left in situ, at a median follow-up of 210 days, 31% developed lead abnormalities.[190]

The management of leads crossing the tricuspid valve, analogous to the recommendations for venous stenting and endovascular leads, seems both logical and prudent. In addition, pacing requirements after transvenous intervention should ideally use transvenous-sparing approaches

such as leadless pacing or coronary sinus lead placement if possible. Finally, any decisions regarding CIED management in this patient population require the involvement of a multidisciplinary team with electrophysiologists specializing in CIED management and shared decision making. As with every TLE decision, an individualized approach must be used. There may be circumstances where jailing a lead might be warranted, such as in cases of palliative TTVR or those in which the risk of extraction is prohibitive.

2. Tricuspid regurgitation can occur as a result of concomitant disease processes that require CIED therapy or as a result of the CIED therapy itself. Among 2678 patients undergoing TLE, Polewczyk et al[330,339] identified 119 patients with lead-related tricuspid regurgitation and observed a 35% reduction in tricuspid regurgitation in this group, emphasizing the importance of accurately evaluating tricuspid regurgitation etiology. In a smaller series, Nazmul et al[349] observed a relationship between tricuspid valve annular dilation and irreversible lead-related tricuspid regurgitation, highlighting the significance of appropriate patient selection for valvular intervention. Finally, severe transvenous injury is a potential yet uncommon complication of TLE. Large series at high-volume centers have reported an incidence of TLE associated with transvenous injury of 0.8%–2.5%,[291,315] whereas smaller series have described incidences of worsening tricuspid regurgitation (defined as ≥1 grade increase) as high as 11.5%–15%.[186,341] Importantly, injuries resulting in tricuspid valve flail leaflets were not observed in leads less than or equal to 7 years old. Consideration of lead removal among patients with severe tricuspid regurgitation, mechanistically related to the existing transvenous lead(s), should be entertained to mitigate valvular regurgitation. However, early intervention (RV lead removal or reposition) within 1–2 years of lead implant is advised, given that late intervention may not restore the tricuspid valve function despite removing the lead.[342]

9.7 Radiation therapy

Recommendations for radiation therapy		
COR	LOE	Recommendations
2b	C-LD	1. In patients with a CIED generator location that interferes with the treatment of a malignancy, in rare instances, lead removal may be considered as part of the management strategy.[350–356]

Synopsis

It is estimated that 1.25 million pacemakers and 410,000 ICDs are implanted worldwide annually.[357] In 2025, it is projected that there will be more than 2 million new cancer cases that will occur in the United States alone, with approximately half requiring radiotherapy as part of their treatment plan.[358] The exponential increase in the intersection of these events is unavoidable. Fortunately, radiation therapy-induced CIED malfunction is uncommon, and the clinical consequences are tempered.[353,355,359–366] In fact, most cases can be managed with device reprogramming and careful monitoring. Thus, the need for preventive complete device system removal is exceedingly rare and indicated only when the CIED is situated in the path of a planned radiation beam, resulting in interference with adequate tumor treatment. In these infrequent situations, device generator relocation can avoid the direct radiation damage to the CIED.

Recommendation-specific supportive text

1. CIED system revision can be considered if the CIED is located directly in the path of the planned radiation therapy beam and its very position would interfere with adequate radiation delivery. The reported rate of radiation-related CIED malfunction is highly variable, with incidences described between 1% and 20%.[351–353,356] However, clinically significant adverse events are infrequent. The most commonly observed CIED malfunctions are software-related issues, either transient effects during the radiation therapy itself or device reset recoverable after reprogramming, whereas permanent device damage occurs less frequently.[367] Risk factors for radiotherapy-induced CIED malfunction include pacemaker dependency, the presence of ICD and CRT devices, photon beam energy of >10 MV, electron energy of >20 MeV, or proton therapy and cumulative generator absorbed dose of >5 Gy. Despite these risk factors, there is substantial evidence documenting the tolerance of the CIED generator to radiation exposure even among those at the highest risk of device malfunction. Risk stratification and enhanced monitoring programs without invasive measures are the preferred management strategy for CIED patients undergoing radiation therapy. Even among patients at high risk of CIED malfunction, patients are often best managed conservatively.

9.8 Other issues

Recommendations for other issues		
COR	LOE	Recommendations
1	C-EO	1. In patients with symptomatic arrhythmias secondary to the device leads and/or lead fragment (s), lead or leadless device removal is recommended.
1	C-EO	2. In patients with an abandoned lead that interferes with the operation of a CIED system, lead removal is recommended.
1	B-NR	3. In patients with complications (eg, pain, bleeding) as a result of lead perforation, lead removal is recommended.[368,369]
1	C-LD	4. In patients undergoing partial lead removal as part of a concomitant open surgical procedure, such as cardiac transplantation or tricuspid valve surgery, lead extraction is recommended to ensure complete hardware removal.[370]

Synopsis

Other noninfectious indications for TLE include refractory lead-induced arrhythmias, abandoned lead-related CIED interference, lead perforation, and as part of a strategy to ensure complete hardware removal.

Recommendation-specific supportive text

1. Reports of lead-induced refractory ventricular arrhythmias with resolution after TLE exist in the literature but are uncommon. Mechanical proarrhythmia from transvenous endocardial leads or leadless devices is a rare but clinically important event.[371] The mechanism is unknown but is believed to be multifactorial. Identification of this form of lead or device proarrhythmia requires a high index of suspicion, particularly in cases where electrophysiological mapping localizes the origin of the arrhythmia to the region of the device or lead tip. Given that TLE is curative, prompt recognition is important. When frequent premature ventricular contractions or VTs are clearly associated with the lead or leadless device and are unable to resolve, removing or repositioning the lead/device should be considered.
2. Adverse lead-to-lead interactions requiring the removal of an abandoned lead may occur. Both electrical and mechanical lead-to-lead interactions have been reported in the literature.[372,373] Although the standard of care is to avoid contact between an abandoned and newly implanted lead, electrode contact can and does occur. Lead removal or repositioning to eliminate lead-to-lead interaction is the definitive treatment of choice.
3. Although lead perforation frequently presents as an acute problem necessitating immediate intervention, cases of delayed perforation do occur.[106,108,109,112–115] When complications such as bleeding and pain develop as a consequence of perforation, lead removal is an integral part of the treatment strategy. Lead removal can often be performed with simple traction,[116] but advanced transvenous extraction techniques may be required.[369,374–376] Several studies have demonstrated the safety and efficacy of both transvenous and surgical lead removal.[256,369,374–378] Conversely, conservative management of lead perforation, vs early lead revision, has been associated with increased complications.[368] Lead removal should be performed for complications related to lead perforation when lead function is compromised and for unresolved chest pain related to the lead perforation. Transvenous or surgical lead removal can be performed safely in most patients.
4. Transvenous lead removal is frequently attempted at the time of planned surgical procedures such as cardiac transplant or tricuspid valve surgery. However, lead removal can be incomplete or not attempted at all, with leads transected and only intracardiac portions removed,[379,380] with up to 39% of patients having remaining lead remnants.[379] Lead remnants are associated with complications such as infection, lead embolization and migration, erosion,[370,379,380] and loss of venous access.[381] When lead remnants remain after cardiac surgery, TLE can be performed successfully and safely but may often require specialized tools and various vascular approaches.[370,381]

   At the time of transplant, for devices older than a few years, cutting the leads in the SVC, removing the device, and pulling the lead from the pocket often result in lead remnants in the subclavian/brachiocephalic veins that are difficult to remove. It is recommended that the lead(s) be cut as high as possible in the SVC and the device and proximal leads be left in place. Before discharge, the device and lead remnants can be safely removed using a standard TLE approach to minimize complications of retained lead fragments.

Section 10 Management of patients undergoing lead extraction

Lead management has become an increasingly important clinical discipline, given the higher prevalence of CIED

patients and the increasing complexity of these devices. Lead extraction procedures are now commonly performed and typically result in successful outcomes without major complications. When the risks and benefits of the procedure have been carefully adjudicated and the patient elects to proceed, a careful preoperative assessment is required. In addition to performing a comprehensive history and physical examination, numerous factors need to be addressed to allow for the procedure to have the highest success rate and lowest risk of complications.

Leads in the vascular system induce a fibrotic reaction that encapsulates the leads and the cardiac and vascular structures in contact with them. Adhesions also frequently develop between leads that are adjacent to each other. Extraction of leads necessitates overcoming these adhesions. Adhesions can develop along any part of the lead or the entire course of the lead. Particularly, common sites for adhesions include areas with minimal lead motions, such as the subclavicular region, the innominate-SVC junction, the SVC, the tricuspid valve, and the lead tip–myocardial interface. In addition, these fibrotic adhesions can calcify over time, posing even greater challenges to extraction.

A host of factors have been identified that indicate a higher risk of unfavorable outcomes. These factors have been associated with either higher procedural complication rates or higher long-term mortality. Most of these factors are associative rather than causal. Every patient has several clinical variables that may affect clinical outcome, and all should be considered when offering specific recommendations. Factors that predict a higher periprocedural complication rate include the number of leads extracted, lead dwell time, low body mass index, thrombocytopenia, coagulopathy, and operator inexperience.[382] Some investigators have noted a higher risk of complications in patients with dual-coil ICDs and passive fixation leads, whereas others have detected little additional risk. Factors that predict longer-term mortality include an infection indication for extraction, end-stage renal disease, anemia, and previous cerebrovascular accident. Data on gender risk are somewhat inconsistent, but it seems that women have a higher risk of periprocedural complications without an increase in 30-day mortality.[383,384] Conversely, elderly patients seem to have very reasonable procedural outcomes but have higher long-term mortality owing to the prevalence of an infection indication for extraction and comorbidities, as noted earlier. Reports vary as to the impact of LV dysfunction on periprocedural outcomes. Open-heart surgery results in scarring around cardiac structures, and although many clinicians have experienced a reduced risk of vascular injury during extractions, if injuries do occur, a previous open-heart procedure would make emergency rescue effort far more complicated and potentially less successful. A few investigators have developed extraction risk models to aid in risk-stratifying individual patients.

10.1 Preprocedural considerations

Recommendations for preprocedural considerations

COR	LOE	Recommendations
1	C-LD	1. In patients with CIEDs undergoing complex TLE procedures, a multidisciplinary team consisting of an electrophysiologist, cardiac surgeon, and cardiac anesthesiologist is recommended for procedural planning.[385–387]
1	C-LD	2. In patients with CIEDs undergoing lead extraction, it is recommended to consider the need for device reimplantation for either continued pacing needs or sudden cardiac death prevention.[388–390]
1	C-LD	3. In patients with CIEDs undergoing elective TLE, it is recommended to interrupt anticoagulation, if possible.[391]
2a	C-LD	4. In select patients requiring uninterrupted therapeutic international normalized ratio (INR) (eg, mechanical valve), it is reasonable to perform TLE.[392,393]
1	C-EO	5. In patients with CIEDs undergoing lead extraction, review of preoperative radiologic imaging to determine the number and location of leads to be extracted is recommended for preprocedural planning.
2b	B-NR	6. In patients with CIEDs undergoing lead extraction, preoperative contrast chest CT may be helpful to visualize lead findings that may alter extraction planning.[394–397]
2b	C-LD	7. In patients with CIEDs undergoing lead extraction, preoperative TEE may be reasonable for assessing leads in relation to cardiac structures and vegetations.[398,399]

Synopsis

Preoperative planning is instrumental in the success of complex procedures. This includes discussion among experienced clinicians about procedural timing in regard to patient optimization and infection risks, if applicable, as well as the need for another device and when it should be reimplanted.

Preoperative planning steps

(1) The extraction plan should be tailored to the procedure indication. An aggressive approach to removing infected hardware is typically required, whereas abandoned hardware removal alone may call for a more measured attempt. (2) Device interrogation should be performed to assess the degree of pacemaker dependence, presence and history of atrial and ventricular arrhythmias, and lead integrity. (3) Preoperative imaging may be performed to determine the number and type of leads. This, along with dwell time, will both affect the strategy for lead removal and help predict the risks of the procedure. (4) It is important to identify specific lead models that engender unique challenges and require modified extraction approaches. Specific tools and approaches can enhance outcomes if the goal is to preserve the function of nontargeted leads. (5) The patient should be optimized medically and hemodynamically before the lead extraction procedure.

Recommendation-specific supportive text

1. Advance procedural planning for complex cases allows discussion of timing, procedural approach, and potential complications. Other team members, such as imaging specialists, infectious disease physicians, or intensive care teams, should be involved as necessary. The outcomes are improved with a collaborative approach.[387] Procedural approach and techniques may be discussed to ensure that the proper equipment is available. Planning also allows for alignment of scheduling for the availability of multiple clinicians, especially in the event of an acute complication. Depending on the circumstances, other team members, such as imaging specialists, infectious disease physicians, cardiac anesthesiologists, cardiothoracic surgeons, plastic surgeons, or intensive care teams, may also serve important roles.
2. Before extraction, assessment of whether device reimplantation will be required for ongoing pacing or sudden cardiac death prevention is an important component of procedural planning. The need for device reimplantation should be determined before the procedure. Information that may be beneficial includes device dependence, LV function, ventricular arrhythmia history, and recurrent infection risk. In a retrospective analysis of more than 3500 patients undergoing TLE, only 4.6% did not have device reimplantation at the time of TLE.[389] Studies have shown that immediate device reimplantation may not be necessary.[388,390]
3. Bleeding risk is higher when procedures are performed in patients who are anticoagulated. However, the risk of bleeding should be weighed against the risk of thromboembolism from anticoagulation discontinuation. Anticoagulation may be discontinued safely in some patients with a low risk of thromboembolic events. A study of more than 700 patients with 51% interrupting their chronic anticoagulation therapy for the TLE procedure showed that TLE may be performed safely when anticoagulation has been temporarily discontinued.[391] There was no significant difference in major adverse events; however, minor events such as blood transfusion and pocket hematoma were greater in the group that bridged the anticoagulation therapy.
4. Certain patients require uninterrupted therapeutic INR, such as those with mechanical valves. In some patients who have mechanical valves, discontinuation of anticoagulation may lead to disastrous consequences. In cases where discontinuation is not an option (eg, mechanical mitral valve), the lowest acceptable INR should be targeted. Some small studies have shown that it is feasible to perform TLE with continuation of anticoagulation without an increased incidence of major complications.[392,393] Bridging may allow for full cessation of anticoagulation during the procedure, but is associated with a higher rate of bleeding complications after the procedure. Similar considerations should be made regarding patients who are receiving antiplatelet therapy.
5. Preoperative posteroanterior and lateral chest radiographs provide essential information on the number, type, and location of leads before extraction. Posteroanterior and lateral chest radiograph views should be obtained to identify the leads present, their type, and location. The number of leads, lead type, and lead dwell will affect the duration and risk of the procedure and extraction planning.
6. The gated CT modality offers more precise information regarding vessel patency, lead binding sites, presence of calcifications, and lead perforation.[394,395] Several investigators have reported how it altered their approach or allowed them to predict more complex procedures.[396,397] Nonetheless, additional information that is obtained does not seem to have a major effect on the course outcome or rate of complications. In particular, lead perforations by CT criteria are often identified, yet extractions seem to be done effectively and safely in this cohort of patients. Venous patency offers the option of new lead insertions without the need for lead extraction. Even a vein that appears occluded may be amenable to venoplasty. Venography also helps identify potential binding sites. Venous stenosis has been reported in 67% of patients with previously implanted leads,[180] and up to 26% manifest total occlusion.[158] The presence of venous occlusion predicts a more complex procedure and the need for more advanced tools.

7. Preoperative TEE can provide a detailed assessment of lead relationships to cardiac structures and identify vegetation(s) or a thrombus relevant to procedural planning. Assessment of ventricular and valvular function with echocardiography, as well as the detection of cardiac shunts, aids in the planning of the procedure. Preoperative TEE can identify vegetations or thrombi that raise consideration for percutaneous aspiration of the vegetation or conversion to an open procedure. In addition, echocardiography can aid in the detection of lead-associated scar tissue, which may add to the complexity of the TLE procedure.[398,399]

10.2 Intraoperative considerations

Recommendations for intraoperative considerations		
COR	LOE	Recommendations
1	C-LD	1. In patients with CIEDs undergoing TLE, a well-established, written, institution-specific protocol for the safe conduct of the procedure and management of any complications is recommended.[400]
1	B-NR	2. In patients with CIEDs undergoing TLE, it is recommended that TLE be performed in appropriate procedural rooms with the necessary equipment and optimal imaging, which allows for immediate surgical rescue if required.[387,401]
1	C-LD	3. In patients with CIEDs undergoing TLE, it is recommended that a multidisciplinary team be readily available during TLE.[385,401]

Synopsis

There is a consensus that lead extraction procedures should be performed in a manner and an environment that delivers a high rate of success while attenuating risks. All extraction procedures carry a degree of potentially serious complications, and case planning should reflect that reality. Extractions should be performed by experienced operators with the appropriate support team and necessary equipment available.

Recommendation-specific supportive text

1. A well-established, written, institution-specific protocol provides a framework for the safe conduct of TLE procedures and the management of any potential complications. A standardized protocol can aid in the identification of complex procedures and patient risks for the TLE procedure, outline the proper steps of operation and potential complications, and provide pathways to activate the collaborating team if a complication does occur. This protocol can help to identify who to contact for emergency backup and ensure that the appropriate equipment is available before the start of the procedure.[400]
2. Appropriate procedural environments with the necessary equipment and optimal imaging are essential to support safe TLE and allow for immediate surgical rescue if required. Such settings typically include experienced operators, high-quality fluoroscopic imaging, ready access to TEE or intracardiac echocardiography, and a full array of TLE tools that may be needed to achieve successful extraction, as well as immediate availability of tools for urgent rescue in case of a catastrophic complication, such as a temporary venous occlusion balloon in the case of an SVC tear,[397,401,402] access to and experience in performing urgent pericardiocentesis, and the ability to undergo cardiopulmonary bypass in a timely manner when rescue cardiac surgery is needed.
3. The multidisciplinary team must work together to care for the patient in a safe environment and monitor and manage any potential complications. Before the intervention, it is essential that the procedural suite (electrophysiology laboratory, operating room, or hybrid room) is evaluated to ensure that all equipment and personnel are fully prepared and operational for cardiopulmonary bypass support. Collaboration with cardiac anesthesiologists who are knowledgeable about the procedure and prepared to help manage related complications greatly enhances the safety and efficacy of the procedure. The cardiovascular surgical backup team should be ready to respond emergently to complications. A joint cardiac surgeon and electrophysiologist team performing TLE achieves excellent outcomes.[385] A multicenter study including 2205 patients who underwent TLE had a clinical success rate of 97% and a major complication rate of 1% using rotational TLE tools.[401]
The other team members, such as imaging specialists, infectious disease physicians, or intensive care teams, may also serve important roles in the perioperative setting.

10.2.1 Anesthetic and intraoperative management

Recommendations for anesthetic and intraoperative management		
COR	LOE	Recommendations
1	B-NR	1. In patients with CIEDs undergoing lead extraction, general anesthesia with endotracheal intubation is recommended.[403]
1	C-EO	2. In patients with CIEDs undergoing TLE, invasive arterial pressure monitoring is recommended.
1	C-LD	3. In patients with CIEDs undergoing TLE, previous placement of femoral venous sheaths is recommended for use as volume lines, temporary pacemakers, femoral TLE tools, or emergency use.[404]
2a	B-NR	4. In patients with CIEDs undergoing lead extraction, when there is significant concern for possible vascular injury, a rescue balloon kit can be useful with the appropriate support wire placed beyond the SVC before extraction.[405,406]
2a	B-NR	5. In patients with CIEDs undergoing lead extraction, when there is a significant concern for possible cardiac and vascular injury, continuous echocardiographic monitoring is reasonable.[407–410]

Synopsis

As the removal of intravascular leads has become more prevalent, the implementation of a thoughtful plan has become necessary. A suitable anesthetic should provide the necessary means to safely perform lead extractions, avoid sudden patient movement, and appropriately monitor for complications. In addition to administering the anesthetic, the anesthesiologist will also monitor for hemodynamic instability. Some complications can result in a sudden hemodynamic change. Invasive blood pressure monitoring, continuous imaging, and a method to rapidly and temporarily tamponade bleeding from an SVC tear are advisable to have a timely diagnosis and subsequent management of vascular tear and cardiac perforation. Communication between the anesthesiologist and the proceduralist is critical when there is any change in a patient's blood pressure or status so that the cause of the change can be investigated promptly.

Recommendation-specific supportive text

1. Although patient comorbidities and extraction difficulty may vary, general anesthesia with endotracheal intubation is recommended for most patients undergoing lead extraction. A retrospective study showed that in 2021, throughout the United States, 92% of lead extractions were performed using general anesthesia.[403] The general trend over the past decade showed that general anesthesia was being used more than monitored anesthesia care or sedation.[403] Even though it is possible to perform some extractions using sedation, it may be advisable to use general anesthesia and a protected airway with endotracheal intubation to facilitate the use of TEE. General anesthesia will also promote immobility of the patient throughout the procedure during the use of the laser and/or mechanical extraction tools. Positive pressure ventilation used during general anesthesia will also reduce the risk of air embolism, through air entrainment, during extraction.
2. Invasive arterial blood pressure monitoring is recommended during lead extraction procedures to monitor for potential rapid decreases in systemic blood pressure or even slowly decreasing blood pressure over time owing to insidious blood loss.[402] Beat-to-beat monitoring could detect changes in hemodynamics more promptly than noninvasive blood pressure monitoring. The instant hemodynamic changes allow immediate action to assess and manage potential complications. Invasive arterial access can also allow for obtaining blood gases for monitoring changes in hematocrit. The radial artery is the primary location usually chosen. The femoral artery may be an additional location, given that it can be used for arterial cannulation for cardiopulmonary bypass or extracorporeal membrane oxygenation.
3. Placement of femoral venous sheaths before TLE is recommended for use as volume lines, temporary pacemakers, femoral TLE tools, or emergency use. Femoral venous access should be obtained to allow for infusion of fluid or blood products in an emergency, insertion of a temporary pacemaker lead when indicated, and insertion of an SVC occlusion balloon.[402,404] Having femoral venous access may also be necessary to allow a femoral approach to TLE in addition to a superior approach. Finally, in higher-risk cases, both femoral venous and arterial access will offer a more rapid approach for emergent cardiopulmonary bypass initiation. This may be especially useful for patients with a previous sternotomy, given that access to the heart may be delayed owing to the presence of sternal wires or adhesions or the need for more careful dissection to avoid damage to bypass grafts.

4. A rescue balloon kit can be useful with the appropriate support wire placed beyond the SVC before extraction when there is significant concern for possible vascular injury. The rescue balloon is commonly advanced over the wire from the femoral venous access to the inferior vena cava to allow for emergent deployment.[406,411] In the case of an injury, an occlusion balloon can reduce blood loss until definitive surgical repair.[405]
5. Continuous echocardiographic monitoring is reasonable in patients undergoing TLE. In addition to standard American Society of Anesthesiologists monitoring, which includes pulse oximetry, capnography, electrocardiography, and intra-arterial blood pressure monitoring, continuous monitoring with echocardiography is beneficial. Continuous imaging can aid in the detection of an accumulating pericardial effusion, volume status, ventricular contractility, tricuspid valve regurgitation, lead location, and lead-associated masses. Echocardiography can assist in the preoperative planning throughout the procedure to detect complications and to monitor the resolution. The use of TEE or intracardiac echocardiography can assist with procedural planning by identifying looped leads or leads adherent to cardiac structures.[407,409,410] Masses adherent to the leads can be mechanically aspirated concurrently but be addressed before extraction. Echocardiography also allows for the rapid identification of acute complications and permits the continuation of procedures where transient hypotension is seen but serious complications are excluded.[409] Possible complications visualized with echocardiography include pericardial effusion, worsening tricuspid regurgitation, and pleural effusions.[408,412] Echocardiography is essential in the detection and guidance of therapy.

10.2.2 Approach, technique, and equipment necessary for lead extraction

Recommendations for approach, technique, and equipment necessary for lead extraction

COR	LOE	Recommendations
1	C-LD	1. In patients with CIEDs undergoing TLE, extraction programs should be familiar with multiple vascular approaches (eg, the femoral and the superior) and have femoral and superior extraction tools available.[413–415]
1	C-LD	2. In patients with CIEDs undergoing lead extraction, extraction programs should have all the necessary equipment and expertise required to manage all potential complications.[413,416–418]
1	C-EO	3. In patients with CIEDs undergoing lead extraction, when powered sheaths are used from a superior approach, continuous traction should be maintained on the lead to provide a rail.
1	C-EO	4. In patients with CIEDs undergoing lead extraction in whom reimplantation is planned, it is recommended that vascular access be obtained during the procedure, before extraction, or by retained access via the extraction sheath.

Synopsis

TLE lead extraction requires the ability to adapt an approach relevant to the clinical scenario and to the progress of the procedure. Although the predominant approach is from the implant vascular access site (using a locking stylet and outer sheath), circumstances may require the use of dedicated and nondedicated tools from other sites (femoral and/or jugular). Familiarity with access to alternate sites[415] and the use of tools from these sites should form part of the training for TLE operators. Routine use of combined approaches[414] or transfer of skills from other cardiology or interventional radiology tools may aid with familiarity and success of nonimplant access site adjunct approaches when required.

Recommendation-specific supportive text

1. Familiarity with multiple vascular approaches (eg, superior and femoral) and access to the appropriate tools allows for procedural flexibility during TLE. Complexities with extraction (eg, multiple intravascular leads, lead fragments, and lack of lead rail or particular lead types) require the ability to adapt the approach and use of alternate tools either as an adjunct or as the primary method for lead extraction.[413,416,418] Familiarity with such tools and access to them are encouraged.
2. Management of complications during TLE requires access to appropriate equipment and teams with expertise in vascular, cardiac, and surgical rescue.[413,416,418] Complications that occur during TLE fall into categories relating to vascular or cardiac injury, lead fragmentation, or the inability to extract. SVC injuries are a particular complication that requires emergency cardiac surgery. These injuries are the main reason for programs to have immediate access to a surgical team. Members of the surgical team should include a cardiac surgeon, a cardiac anesthesiologist, a perfusionist, a circulating operating room nurse, and a cardiac surgical technician. Team members should be ready to intervene if complications arise. Emergency equipment should be available in the

procedural suite, including cardiopulmonary bypass circuit, open-heart surgical instruments, and rescue balloon catheters. The presence of a rescue balloon could be lifesaving if an SVC injury were to occur.[419]

The preferred technique is to place the support wire before the extraction, given that a placement attempt after SVC injury will delay rescue and may result in the wire entering the pleural or pericardial space through the tear. Prestaging of the balloon with marking of the appropriate position on the shaft followed by withdrawal of the balloon to the inferior vena cava just before applying the sheath to the lead is typically done. In lower-risk cases, prepositioning of a stiff wire alone may be a reasonable strategy and avoids unnecessary use of the balloon and the potential for thrombus formation on the balloon and subsequent embolization. Where severe damage to the tricuspid valve has occurred during extraction, the multidisciplinary team should discuss whether surgery is required during that index procedure or not. A decision regarding reimplantation strategy and other factors will be an important part of the decision-making process.

3. When sheaths are used from a superior approach, continuous traction must be maintained on the lead to provide a rail. The central tenet of TLE is to provide a stable lead platform to permit the use of appropriate outer sheaths to release binding points along the vascular tree and cardiac structures. For leads with a lumen, a locking stylet should be placed in all targeted leads before an attempt to extract. This prevents the inability to place the stylet should damage occur to the inner lumen of the lead during the removal of other leads. For lumenless leads, extension to the lead may be required to allow sufficient length to pass the extraction sheath into the vascular access. With a suitable rail, optimum control can be gained to allow the outer sheath to maintain a coaxial relationship to the lead, minimizing potential vascular or cardiac injury and maximizing a controlled extraction of the lead. Maintaining an appropriate amount of tension on the rail is a key factor and requires extensive training and experience.[417] In situations where a locking stylet cannot be passed into the central lumen of the lead or fails to pass sufficiently distal, early consideration of the use of adjunctive tools should occur. Using a femoral approach at an early stage may increase the successful extraction by reducing the force on the vascular structures and on the lead while using a sheath from the superior access. The tandem approach used by centers as the initial mode has been reported to allow a better ability to maintain a coaxial relationship that aids dissection of the binding sites, increasing success rates and minimizing SVC injury.[414]
4. When reimplantation is anticipated, maintaining vascular access during the procedure—either before extraction or via retained access through the extraction sheath—is an important consideration for procedural planning. In cases where failed or redundant leads are being removed and replaced, reimplantation from the same operative site is highly preferred. This approach allows for the utilization of the remaining functional hardware and avoids the need for a totally new implant via the contralateral site. Nonetheless, obtaining venous access via the ipsilateral side after extraction can prove to be complex. If the vein is patent, obtaining access before extraction is advised, given that placement of a guidewire may be complicated by venous occlusions or tears, resulting in the inability to reach the heart. If this cannot be achieved, delivering and retaining guide wires via the extraction sheath (a longer safe sheath over the wire may also be considered) will ensure continued access for new lead insertions.

10.2.3 Management of complications

Recommendations for management of complications		
COR	LOE	Recommendations
1	C-LD	1. In patients with CIEDs undergoing lead extraction, if a vascular injury occurs, deploying a rescue balloon catheter is recommended until surgical evaluation and repair.[405,406]
1	B-NR	2. In patients with CIEDs undergoing lead extraction, pericardiocentesis is recommended to relieve tamponade, provided that it does not delay definitive surgical intervention when needed.[420]
1	B-NR	3. In patients with CIEDs undergoing lead extraction who cannot be managed by alternatives, emergent sternotomy and initiation of cardiopulmonary bypass are recommended to repair cardiac and vascular bleeding.[420]
2a	B-NR	4. In patients with CIEDs who underwent TLE, it is reasonable to evaluate and manage the development of new or worsening significant tricuspid regurgitation.[339]

Synopsis

During lead extraction, operators should carefully monitor hemodynamic changes with arterial line monitoring, ideally with the assistance of intraoperative TEE, especially in higher-risk cases. Operators should be familiar with the insertion of rescue balloons. In the event of hemodynamic compromise, operators should be vigilant for signs of cardiac tamponade, including clinical signs such as respiratory variation and narrow pulse pressure and radiographic signs such as enlargement of the cardiac silhouette or TEE evidence of an enlarging pericardial effusion. Emergent sternotomy with or without the use of cardiopulmonary bypass at the discretion of the surgeon allows for definitive repair of vascular injury.[420] A fluoroscopic evaluation of the right hemithorax should be performed for evidence of opacification that would suggest hemothorax.

Recommendation-specific supportive text

1. The SVC is at a particular risk of injury during lead extraction, especially in patients with chronic leads. A large-bore lower extremity (femoral access) should be placed in all patients for immediate resuscitation. Lead extractors should be familiar with rescue balloons that can be placed across the SVC to occlude the site of injury until surgical repair can be performed.[405,406]
2. When pericardial tamponade develops, pericardiocentesis can be attempted as a temporizing measure to relieve tamponade until definitive surgical rescue can be performed.[420] Emergent sternotomy with or without the use of cardiopulmonary bypass would be at the discretion of the surgeon. If a myocardial or vascular injury does occur during lead extraction, pericardiocentesis may be performed to relieve tamponade to improve hemodynamics until surgical repair can be performed but should not delay surgical consultation or rescue.[420]
3. Severe cardiac and vascular bleeding that cannot be managed by alternative measures necessitates emergent sternotomy with initiation of cardiopulmonary bypass for definitive repair. Patients with a major myocardial or vascular injury during lead extraction require surgical intervention at the discretion of the surgeon. For patients without previous cardiac surgery, sternotomy is the most common and effective approach to provide exposure to the heart and SVC. At the discretion of the surgeon, initiation of cardiopulmonary bypass can provide hemodynamic support during repair.[420]
4. Patients with chronic indwelling ventricular leads traversing the tricuspid valve are at risk of tricuspid valve injury. It is advisable to compare and document the function of the tricuspid valve before and after performing a ventricular lead extraction. Intraoperative TEE provides real-time feedback on tricuspid valve function and allows for assessment of the severity of tricuspid valve injury associated with extraction.[339] Efforts should be made to deliver extraction sheaths down to the ventricular lead tip to protect the tricuspid valve, if possible. In some cases, tricuspid valve injury caused by significant lead adhesion to the valvular structure can be significant enough to warrant repair.[339]

10.3 Postprocedural considerations

Recommendations for postoperative considerations

COR	LOE	Recommendations
2a	B-NR	1. In select patients who undergo uncomplicated TLE, same-day discharge is reasonable.[421,422]

Synopsis

Patients undergoing lead extraction for infection indications may typically require extensive surgical debridement, requiring inpatient wound and pain management, ongoing administration of intravenous antibiotics, and the use of bridging systems for managing their rhythm problems. For these patients, ongoing inpatient management may be required for periods of time, depending on local institutional facilities and needs. Patients who have required the extraction of their heart failure devices may also require additional hospital care to optimize their care while awaiting definitive reimplantation.

For other patients requiring lead extraction who are clinically stable and who do not have an ongoing need for inpatient care, a same-day discharge protocol is considered reasonable. Such patients typically have undergone extraction for vascular access or lead failure indications. If the extraction was uncomplicated and the reimplantation procedure was straightforward, discharge on the same day is a safe option. An institutional protocol for post–general anesthetic same-day discharge can be applied, similar to the process for a new device implant.[421] This may help reduce hospital-acquired infections, minimize length of stay and associated costs, and be preferred by patients.

Recommendation-specific supportive text

1. Implementation of same-day discharge after TLE requires careful patient selection and predefined institutional

criteria. Care should be taken to develop prespecified requirements for successful day stay admissions that consider the pacemaker dependency, postdischarge environment, and local follow-up protocols.[421,422] Many of the patients who may be eligible for same-day discharge will have noninfectious indications for TLE. Where patients do not meet these criteria, admission will be required, and institutions must provide for this.

Section 11 Implant lead selection: Approach and techniques to mitigate lead malfunction

When implanting pacemaker or defibrillator leads, there are a variety of factors that must be considered. Although the priority is to place leads that provide optimal pacing or defibrillation, leads should also be implanted in a manner that maximizes their longevity, minimizes the access complications and injury to the heart, and limits the risks of future lead extractions.

11.1 Venous access

Recommendations for venous access		
COR	LOE	Recommendations
1	B-R	1. In patients undergoing transvenous lead implantation, an extrathoracic axillary vein puncture or a cephalic vein cutdown should be performed vs subclavian vein puncture to decrease the risk of pneumothorax and premature lead failure.[146,423,424]
2a	B-R	2. In patients undergoing lead implantation, ultrasound guidance or contrast-guided fluoroscopy can be useful for axillary vein puncture.[425–427]

Synopsis

The method of implanting leads has continued to evolve. Initially, cephalic vein cutdown was the primary method for lead implantation; however, with the advent of peel-away sheaths, the subclavian approach became the preferred route of venous access by most device implanters. Although faster, puncturing the subclavian vein carries a higher risk of lung injury and lead malfunction from "subclavian crush," with leads entrapped between the clavicle and first rib. Axillary vein puncture has become the preferred alternative. As with a cephalic vein cutdown, it provides extrathoracic access, limiting the risks of pneumothorax and subclavian crush, but shares the convenience of subclavian vein access, requiring less surgical time and skill. Ultrasound guidance represents an additional tool to minimize complications (especially inadvertent arterial puncture) and decrease radiation exposure.

Recommendation-specific supportive text

1. Subclavian vein puncture, cephalic vein cutdown, and axillary vein puncture are the most common options for transvenous lead insertion (Figure 10). Subclavian vein puncture has been associated with procedural complications, including pneumothorax and hemothorax, and can result in premature lead failure secondary to the subclavian crush syndrome. Extrathoracic access with cephalic

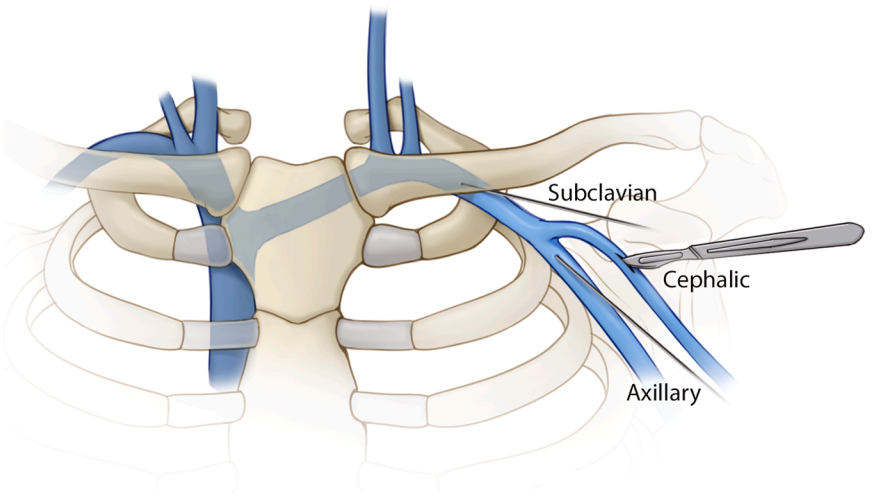


Figure 10
Most common access sites for transvenous lead insertion. Extrathoracic access using a cephalic vein cutdown or axillary vein puncture (over the first or second rib) is recommended. Access within the intrathoracic subclavian vein, medial to the inferior border of the clavicle, has been associated with more complications.

vein cutdown or axillary vein puncture has proven to lower these risks without significantly affecting procedural success.[146,423] Although cephalic vein cutdown used to be the primary method of venous access, axillary vein puncture has become the preferred method of venous access for some providers—complication rates between these 2 techniques are not significantly different, but axillary vein puncture has been associated with faster access and procedural success.[424] Subclavian vein access may still be required in certain scenarios, including for patients with abnormal venous anatomy or venous obstruction. In these instances, accessing the vein as laterally as possible is recommended to minimize the risk of complications.

2. Image guidance can be useful in obtaining axillary access. Both fluoroscopy and ultrasound can be used to decrease the time to obtain access and increase the success in gaining access.[427] Ultrasound guidance has the benefit of decreasing radiation exposure and decreasing the risk of inadvertent axillary artery puncture. In total, these benefits can make axillary vein puncture more efficient than cephalic vein cutdown.[425,426]

11.2 Lead choice

Recommendations for lead choice		
COR	LOE	Recommendations
1	B-NR	1. In patients undergoing transvenous ICD implantation, a single-coil (vs dual-coil) lead is recommended.[428–434]
1	B-NR	2. In patients undergoing transvenous lead implantation, consideration of lead design and fixation mechanisms is recommended to facilitate future extraction if needed.[435–439]

Synopsis

The lead(s) chosen at implant can have a profound impact on future lead management. Some leads are known to have longer longevity than others,[78,440] but the risk of premature lead malfunction should not be the only factor considered when deciding on a lead implant. Lead design and fixation mechanisms should also be considered, given that they can affect the complexity of future lead extractions.

Recommendation-specific supportive text

1. Dual-coil leads, with a coil in the SVC and another in the RV, were once the most common ICD lead implanted. However, studies over the last decade have shown that the presence of an SVC coil does not significantly improve the defibrillation threshold, first-shock efficacy, or mortality.[429,430,432,434] Moreover, the presence of a coil in the SVC can result in more adhesions in the innominate vein and SVC.[136] This can lead to more difficult extractions, with longer procedural times, a need for advanced techniques, and more complications.[428,431] As such, in most cases, single-coil leads should be chosen at the time of implant. Dual-coil leads may be reserved at the operator's discretion for individual patient needs and complex anatomic situations.
2. Multiple factors influence how difficult a lead extraction will be. Among these is lead design. Active fixation leads, with the ability of the screw to retract or straighten out with traction, are more easily extracted than passive fixation leads that anchor more firmly into the trabeculated myocardium. The complication rate when extracting active vs passive fixation leads is similar, but removal of passive fixation leads often requires longer procedures and the need for advanced extraction techniques.[435,437] Passive fixation leads are also more likely to break during extraction.[436,438] Lead break can increase the difficulty of extraction, increasing procedural complexity and complications while also increasing the risk of residual lead fragments remaining after extraction. Leads that are more prone to break include leads that have a coradial (vs coaxial) design and leads with a nonpolyurethane insulation.[438] Leads that do not require a stylet, specifically the Medtronic 3830 lead, may be less likely to break, potentially leading to extractions with lower complexity and a higher rate of complete procedural success.[439]

11.3 Tricuspid valve regurgitation

Recommendations for limiting tricuspid valve regurgitation		
COR	LOE	Recommendations
1	C-LD	1. In patients undergoing ventricular lead implantation, the procedure should be performed in a manner to decrease tricuspid valve regurgitation.[441–446]
1	C-LD	2. In patients undergoing ventricular lead implantation, assessment for lead-related significant tricuspid valve regurgitation is recommended within 1 year after implantation.[339,447]

Synopsis

Tricuspid valve regurgitation is common, but its incidence and severity may be increased in patients with transvenous CIEDs.[443] This can have significant effects on a patient's clinical status, leading to volume overload, heart failure, and death.[325,447] How a lead is implanted and positioned can influence the degree of tricuspid regurgitation (Figure 11). Over time, further interaction with the valve can cause significant binding and adhesions; extraction of these leads can result in severe regurgitation or flail leaflets.[339] Given these concerns, close monitoring of tricuspid valve function should be performed after a lead is implanted across the valve.

Recommendation-specific supportive text

1. Tricuspid valve regurgitation can increase significantly after ventricular lead implantation. Patients with dilated right atria or elevated right-sided pressures may be at higher risk.[443] Ideally, leads should pass directly through the tricuspid valve orifice or site within a commissure (most commonly the posteroseptal commissure) to decrease the risk of tricuspid regurgitation. Leaving an adequate amount of slack is also imperative; however, excess loops in the right atrium can result in prolapse of the loop into the ventricle and affect leaflet motion.[445] Leads may also be too taut, impinging on leaflet motion. Lead impingement and adherence are the most common causes of tricuspid valve regurgitation; lead entanglement and lead perforation may also occur, but are less prevalent.[444,448] Lead location—apical vs septum—has not been found to influence the degree of regurgitation[446]; however, when evaluating septal leads alone, the distance of lead fixation from the

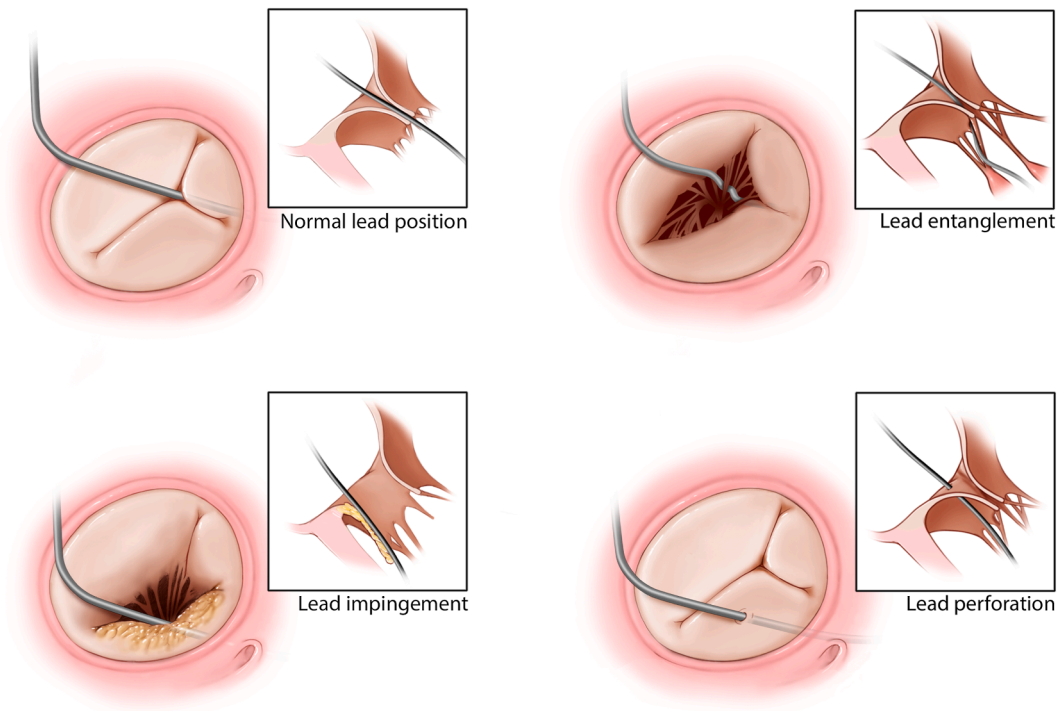


Figure 11
Examples of lead interaction with the tricuspid valve. The lead ideally passes through the central part of the valve, limiting its interaction with the tricuspid valve leaflets. Leads that rest more on the leaflets can result in fibrosis and scar formation, causing lead impingement. Leads can also be trapped within the tricuspid valve apparatus, getting entangled with the chordae or perforating the leaflet itself at implant. Extraction of these leads can result in severe tricuspid regurgitation.

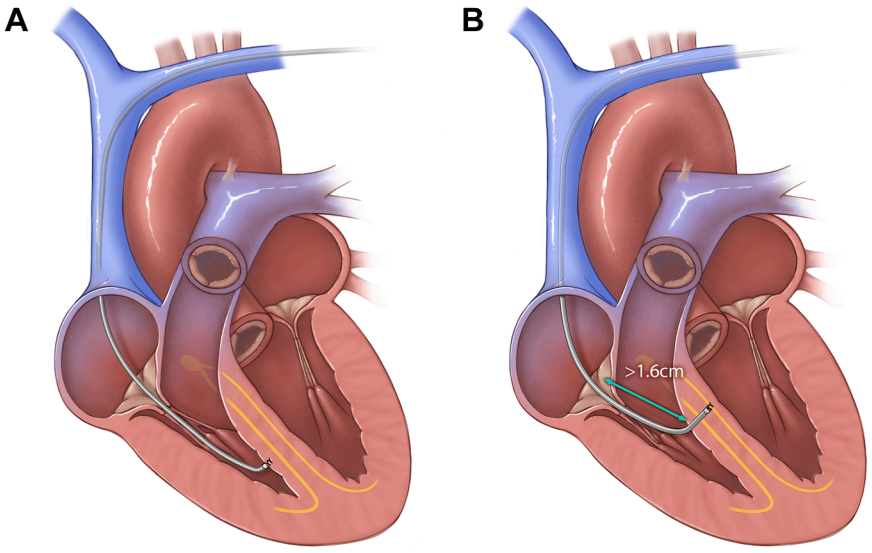


Figure 12
Right ventricular lead positioning relative to the tricuspid valve. A: Placement of leads on the right ventricular septum (vs apical pacing) has not been associated with worsening tricuspid regurgitation. B: When implanting leads for left bundle branch area pacing, a shorter lead to tricuspid annulus distance can result in more tricuspid regurgitation.

tricuspid valve annulus has been found to be significant, with a longer distance associated with less tricuspid regurgitation. Recent data have indicated that a distance of at least 1.6 cm may limit interaction with the tricuspid valve but should be balanced against locations that are too apical and fail to capture the left bundle (Figure 12).[441,442]

2. Tricuspid valve regurgitation can often be underappreciated or unrecognized. Given that tricuspid regurgitation can have a significant effect on a patient's long-term health, close monitoring of valve function is recommended.[447] An evaluation for significant regurgitation secondary to lead interaction is recommended within 1 year of implantation, given that these leads can be removed or repositioned safely to effectively improve valve function. Leads that have been in place for longer durations (>7 years) may cause irreversible valve injury owing to the formation of adhesions that plaster the leaflets in place.[186] Removal of leads at this point is unlikely to improve valve function. These patients often need to undergo some form of tricuspid valve intervention, via either catheterization or open-heart surgery for valve repair or replacement.

11.4 Number of leads

Recommendations for the number of leads		
COR	LOE	Recommendations
1	C-LD	1. In patients receiving a transvenous device, the number of leads implanted should be minimized. Particular consideration should be given to lead burden in special groups such as pediatric patients.[245,449–451]
1	B-NR	2. In patients receiving a transvenous ICD, an atrial lead should be implanted only when atrial pacing or atrioventricular synchrony is beneficial.[314,452,453]

Synopsis

The number of leads implanted is a known risk factor for lead extractions, increasing the complexity of the extraction and complication rate.[314] As such, implanters should consider whether each lead being implanted is necessary, with the number of leads placed kept to a minimum. Each additional lead has the potential to worsen lead-to-lead binding, venous obstruction, and valvular regurgitation.[447,454,455] Although a lead may be beneficial, its true clinical value should be weighed against these complications.[456,457] Finally, the patient's age must be considered when leads are implanted. Transvenous leads placed early in life can be more difficult to extract, complicating lead management in patients who will need many CIED lead revisions over a lifetime.[30,458]

Recommendation-specific supportive text

1. Studies have shown that the number of leads present increases the risks of extraction. This can result in longer procedural times, a need for complex extraction techniques, and a higher risk of major complications.[245,314] Thus, the clinical need for each lead implanted must be assessed. This can range from the need for a ventricular lead in patients with sinus node dysfunction, an atrial lead in patients with complete heart block, or a coronary sinus lead in patients with ventricular dyssynchrony and dysfunction. Special consideration should be taken in children and young adults: not only does their smaller size increase the risk of venous obstruction, but younger patients often require more complex extractions, which is thought to be caused by increased adhesions and dense fibrosis around their leads.[450,455,458] Patients with congenital heart disease may also be more prone to obstruction, and young patients with or without congenital heart disease may be at a higher risk of atrioventricular valve injury during extractions.[449,451] Given that young patients will need their leads managed over a span of many decades, strategies should be taken to minimize the number of leads present.
2. Defibrillator leads can be more difficult to extract than pacing leads, requiring longer procedural times and the need for more extraction tools.[417] Limiting additional risks should be a priority. A primary consideration is whether an atrial lead is required. Atrial leads are often implanted to aid with rhythm discrimination, with the presence of an atrial EGM thought to improve the ability to differentiate between supraventricular tachycardia and VT. This has not proven to be the case.[452,453] An atrial lead should only be implanted if the patient would benefit from atrial pacing (ie, symptomatic sinus bradycardia, tachy-brady syndrome) or to optimize hemodynamics with atrioventricular synchrony. Conversely, a VDD-type lead (a single ICD lead that has an integrated atrial dipole that sits in the right atrium, providing atrial sensing without the need for an additional lead) can be considered. The incremental benefits provided for rhythm discrimination should be weighed against the adhesions that could develop around the dipole, potentially making extraction more difficult.

Section 12 Knowledge gaps and future directions

This section summarizes important knowledge gaps and future needs identified during the development of this consensus statement. These areas reflect limitations in the current evidence base, evolving technologies, and unresolved clinical questions that warrant further investigation. The following subsections highlight priority areas where additional research and data may inform future updates and improve patient care.

12.1 Nonvascular CIED

Some of the major advances since the consensus document in 2017 include the improvements to and expanded clinical application of leadless devices, which provide new options for patients who have experienced CIED infection, lead failure, or lack of vascular access, as well as for pediatric patients. These devices provide alternative treatment options for bradycardia pacing with a reduced infection rate and risk of lead extraction but still have limitations in terms of battery longevity, optimal atrioventricular synchrony, nonphysiological pacing, and safety of removal during the replacement procedure.[459,460] Similarly, defibrillation with nontransvenous devices has limitations, including higher rates of inappropriate therapy and a lack of pacing options for those who require high-burden pacing.[461] A leadless pacemaker coupled with an S-ICD can provide improved options with respect to the delivery of ATP and bradycardia pacing, but such a pacemaker is not yet approved by the FDA and requires a coimplant of 2 devices. S-ICD and EV-ICD have tachycardia-detection limitations to patient candidacy, yet the 2 technologies are complementary alternatives to mitigate the drawbacks. The second generation of leadless pacing has improved battery longevity. Leadless left bundle area pacing based on an active fixation prototype, which could eliminate transvenous lead–related complications and concomitantly achieve physiological pacing, is under initial phase investigation in humans.[44] Atrioventricular sequential DDD leadless conduction system pacing is under investigation in animal studies. Although leadless device extraction has a high reported success rate (up to 9 years in 1 model), its feasibility and safety for the various models after longer dwell time remain to be determined.[62] Further work is required to determine the optimal roadmap for the pacing approach in pediatric patients to mitigate cumulative risks from vascular occlusions, infections, system revisions, and TLE.

12.2 Standardization of TLE

Indications for TLE are increasing in parallel with an aging population, evolving new technologies, and expanded indications. Advancements in lead extraction tools and techniques have made lead removal safer for patients. However, patients have simultaneously become exceedingly more complex. Older patients with a higher comorbidity index, combined with the need for augmented CIED lead survival beyond their expected longevity, have heightened the complexity of the current paradigm of lead management.[384] Concerted efforts to increase perioperative safety through technological innovations and institutional advances have sparked lead extraction practice and active research.[462] CIED lead extraction requires a multidisciplinary team with expertise and collaborative endeavor. Creating a team structure that can accurately identify individuals with CIED infection or malfunction and efficiently channel them to appropriate expert care in a timely fashion could dramatically improve outcomes and unmet needs. Prompt referral and access to extraction would help address and potentially resolve the barriers to care and practice gaps, yet many questions in the field remain unanswered. Quantifying the potential risk of complications with lead extraction remains elusive; it is not

well defined by lead characteristics (model, dwell time, etc), patient characteristics, frailty, comorbidities, and extraction tool type. Further data from well-designed investigations are necessary to better elucidate how to best risk-stratify patients and improve outcomes to refine guideline-based and institutionally endorsed CIED lead management strategies.

12.3 Early extraction in infected CIEDs

Complete and early extraction has been found to be associated with significantly better clinical outcomes than no or late extraction.[463] However, significant gaps in knowledge, barriers to early diagnosis, referral, and appropriate therapy remain challenges. Quality metrics on assessing the efforts to improve access to experts and experienced extraction centers will be beneficial to the outcomes of CIED infection management.

12.4 Lead management in conduction system pacing

Conduction system physiological pacing has opened a new arena for bradycardia pacing and cardiac resynchronization. It mitigates RV pacing–induced cardiomyopathy and achieves comparable outcomes to biventricular pacing resynchronization from small randomized studies. Large randomized clinical trials are on the way. Given that left bundle branch area pacing leads deeply penetrate the ventricular septum toward the LV subendocardium, long-term lead durability and outcomes of lead extraction in this anatomy merit future investigation.[27]

12.5 Transvenous lead and tricuspid valve function

The effect of lead placement on the tricuspid valve is unpredictable in individual patients, and its impact is often underrecognized. Severe tricuspid regurgitation associated with lead impingement or entanglement to the tricuspid structure can occur.[192] The best practice to avoid impingement of the tricuspid valve at the time of lead placement needs to be established and adhered to by implanters. Appropriate and timely assessment of tricuspid regurgitation after transvenous lead placement is necessary and may be considered as standard care to identify patients who have developed significant lead-related tricuspid regurgitation and will benefit from early lead revision, potentially avoiding surgery or TTVR. The risks and benefits of TLE need to be discussed with shared decision making and a multidisciplinary heart team approach. More research evidence is required in this rapidly growing area.

12.6 CIEDs in congenital heart disease

Adult patients with congenital heart disease are an increasing population, many of whom have arrhythmic issues that require bradycardia or tachycardia support by the device. This population may merit special registries to elucidate better how they could be managed.

12.7 Uninterrupted anticoagulation during TLE

The initial experience in patients who undergo TLE with uninterrupted warfarin owing to a mechanical valve in situ and a high risk of thromboembolism has shown no apparent increase in the risk of bleeding in selected patients. However, further investigations are needed to provide more evidence for assessing the risk of TLE-related bleeding with uninterrupted anticoagulation vs heparin bridging.

12.8 The safety of MRI in patients with CIEDs

Insufficient MRI-conditional labeling is an example where patient safety may be compromised by avoiding MRI owing to MRI-nonconditional systems, particularly when data exist to support the safe performance of such imaging, irrespective of MRI-conditional labeling (a limitation based on industry interests and regulatory scope). A larger scope of evidence is needed to demonstrate the safety of MRI in MRI-nonconditional CIEDs and leads, including abandoned leads. It is our hope that, with additional safety data, future guidelines will facilitate MRI across the spectrum of CIEDs so that lead extraction for this indication will grow increasingly rare in future practice.

In summary, these knowledge gaps underscore the need for continued research to inform evidence-based management of CIED leads. Addressing these areas will be critical to optimizing patient outcomes, guiding future recommendations, and supporting the safe integration of emerging technologies into clinical practice.

Appendix

Supplementary data

Supplementary data associated with this article can be found in the online version at https://doi.org/10.1016/j.hrthm.2026.04.015.

Acknowledgments

This document is dedicated to the memory of Dr Bruce L. Wilkoff, MD, CCDS, who had been selected to serve as Vice-Chair of the writing committee before his passing on January 7, 2024. A memorial honoring Dr Wilkoff's life and contributions to the field is published in *Heart Rhythm*.[464]

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Appendix 1 Writing committee member disclosure of relationships with industry and other entities

Writing committee member	Employment	Honoraria/speaking/ consulting	Speakers' bureau	Research*	Fellowship support*	Ownership/ partnership/ principal/majority stockholder	Stock or stock options	Intellectual property/ royalties	Other
Yong-Mei Cha, MD, FHRS, Chair	Mayo Clinic	None	None	Nonrelevant: Medtronic	None	None	None	None	None
Mikhael F. El-Chami, MD, FHRS, Vice-Chair	Emory University School of Medicine	Relevant: Boston Scientific, Medtronic	None	Nonrelevant: Boston Scientific, Medtronic	None	None	None	None	None
Christopher F. Liu, MD, FHRS, Vice-Chair	Weill Cornell Medicine Network/New York-Presbyterian Hospital	None	None	None	None	None	None	None	None
Laura J. Andreychuk, BSN, RN	North Shore Health Network	None	None	None	None	None	None	None	None
Thomas M. Beaver, MD, MPH	University of Florida	Relevant: Cook Medical	None	None	None	None	None	None	None
Kelly M. Bergen, MSN, ACNP, FHRS, CCDS	CaroMont Heart & Vascular	None	None	None	None	None	None	None	None
Charles I. Berul, MD, MS, FHRS, CEPS-P	Children`s National	None	None	Nonrelevant: Medtronic	None	Nonrelevant: PeriCor	None	None	None
Ulrika Maria Birgersdotter-Green, MD, FHRS	UC San Diego Health Systems	Relevant: Abbott, Biotronik, Boston Scientific, Medtronic, Philips Nonrelevant: Vektor Medical	None	None	None	None	None	None	None

(*continued*)

Appendix 1 Continued

Writing committee member	Employment	Honoraria/speaking/consulting	Speakers' bureau	Research*	Fellowship support*	Ownership/partnership/principal/majority stockholder	Stock or stock options	Intellectual property/royalties	Other
Alexander Breitenstein, MD	University Heart Center Zurich	Relevant: Abbott, AngioDynamics, Biosense Webster, Biotronik, Boston Scientific, Cook Medical, Medtronic, Philips Nonrelevant: Bayer Healthcare Pharmaceuticals, Bristol Myers Squibb/Pfizer Alliance, Daiichi Sankyo	None	None	None	None	None	None	None
Laurence M. Epstein, MD	Northwell Health	Relevant: Abbott, Philips, Medtronic	None	None	None	None	None	None	None
Jay N. Gross, MD, CCDS	Montefiore Medical Center	None	None	None	None	None	None	None	None
Larry R. Jackson II, MD, MHS, FHRS	Duke University Medical Center	Nonrelevant: Alliance for Aging Research, Biosense Webster, Bristol Myers Squibb, CME Outfitters, Health Monitor, Johnson & Johnson, Pfizer, PRIME Education, Sanofi	None	None	None	None	None	None	None
Saima Karim, DO, FHRS	Mercy Medical Center	Relevant: Abbott, Medtronic	None	None	None	None	None	None	None
Andrew D. Krahn, MD, FHRS	University of British Columbia	Relevant: Medtronic Nonrelevant: Tenaya Therapeutics	None	None	None	None	None	None	None
Fred M. Kusumoto, MD, FHRS	Mayo Clinic Jacksonville	None	None	None	None	None	None	None	None
Nigel Lever, MBChB, FRACP	Auckland City Hospital	Relevant: Cook Medical	None	None	None	None	None	None	None
Latoya N. Linton-Frazier, MD, MS	Indiana Regional Medical Center	None	None	None	None	None	None	None	None

Charles J. Love, MD, FHRS, CCDS	Johns Hopkins Hospital	Relevant: Boston Scientific, Medtronic, Philips Nonrelevant: Eximo, Orchestra Biomed	None	None	None	None	None	None	None
Douglas Y. Mah, MD, FHRS, CEPS-P	Boston Children`s Hospital	None	None	None	None	None	None	None	None
Pamela K. Mason, MD, FHRS	University of Virginia Health System	Relevant: Boston Scientific, Medtronic, Philips	None	None	None	None	Nonrelevant: Apple	None	None
M. Travis Maynard	Colorado State University	None	None	None	None	None	None	None	None
Melanie Maytin, MD, FHRS	Brigham & Women's Hospital	Nonrelevant: Medtronic	None	None	None	None	None	None	None
Jay A. Montgomery, MD	Vanderbilt University Medical Center	None	None	None	None	None	None	None	None
Jennie Ngai, MD	NYU Langone	None	None	None	None	None	None	None	None
Ratika Parkash, MD, MS, FHRS	QEII Health Sciences Center	None	None	Nonrelevant: Abbott, Medtronic, Novartis	None	None	None	None	None
Kristen K. Patton, MD, FHRS	University of Washington	Nonrelevant: Jama Cardiology	None	None	None	None	None	None	Nonrelevant: ACGME RC Internal Medicine, AHA Clinical Cardiology Council, US FDA
Naga Venkata Krishna Chand Pothineni, MD	Kansas City Heart Rhythm Institute	Relevant: Biosense Webster, Boston Scientific Medtronic	None	None	None	None	None	None	None
Ulises Rojel-Martínez Sr, MD, FHRS	South Medical Center, Puebla, Mexico	None	None	None	None	None	None	None	None
Muhammad Rizwan Sohail, MD	Baylor College of Medicine	Relevant: AngioDynamics, Medtronic, Philips	None	None	None	None	None	None	None

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Appendix 2 Reviewer disclosure of relationships with industry and other entities

Peer reviewer	Employment	Honoraria/speaking/consulting	Speakers' bureau	Research	Fellowship support	Ownership/partnership/principal/majority stockholder	Stock or stock options	Intellectual property/royalties	Other
Joseph Atallah, MDCM, MS, FRCPC	University of Alberta	None	None	None	None	None	None	None	None
Thomas D. Callahan IV, MD, FHRS	Cleveland Clinic	Abbott, Boston Scientific, Medtronic, Philips, Shockwave Medical	None	None	None	None	None	None	None
Roger G. Carrillo, MBA, MD, FHRS	Palmetto General Hospital	Medtronic Inc, Philips	None	None	None	None	None	None	None
Jim Cheung, MD, FACC, FHRS	Weill Cornell Medicine	Biosense Webster	None	None	Abbott, Biosense Webster, Biotronik, Boston Scientific, Medtronic	None	None	None	None
Pascal Defaye, MD	Grenoble University Hospital	Abbott, Boston Scientific, LivaNova, Medtronic	None	None	None	None	None	None	None
Perin Kothari, DO, FASE	Stanford	None	None	None	None	None	None	None	None
Robert D. Schaller, DO, FHRS	Hospital of the University of Pennsylvania	Abbott Medical, Boston Scientific, Cook Medical, Inc, Medtronic Inc, Philips							
Holenarasipur Vikram, MD, FACP, FIDSA	Mayo Clinic	None	None	None	None	None	None	None	None
Gareth Wynn, MBChB, MD, FHRS	Royal Melbourne Hospital	None	None	None	None	None	None	None	None
Emily Zeitler, MD, MHS, FHRS	Dartmouth Health	Biosense Webster, Boston Scientific, Element Science, Inc, Medtronic Inc, Sanofi, V-Wave		Biosense Webster, Boston Scientific, Sanofi					

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