

Summary of significant new HRS indications for non-extracting device managers

Type	Indications	Class
Management	Discuss risk of abandonment vs. risk of extraction with patients	I
	Leave abandoned leads in a condition that permits future extraction	I
	Increase surveillance for leads with higher failure rates	IIa
Infection	Extractor consult in patients with documented infection	I
	At least 2 sets of blood cultures before antibiotics for suspected CIED infection	I
	Additional imaging to diagnose pocket or lead infection	IIb

Bridge occlusion balloon supports improved survival of SVC tears²

As a non-extracting physician, when you refer your patients for lead extraction you want the best clinical outcomes. Lead extraction has a 99.72% procedural survival rate³, and SVC tears occur in <0.5% of lead extractions.² A novel rescue balloon has been shown to increase SVC tear survival from 56.4% to 88.2%²

Manage every lead. Safely, predictably, responsibly.



Class definitions

Class I (Strong). Benefit >>>Risk

Conditions for which treatment A should be chosen over treatment B.

Class IIa (Moderate). Benefit >>Risk

Conditions for which it is reasonable to choose treatment A over treatment B.

Class IIb (Weak). Benefit ≥ Risk

Conditions for which it might be reasonable to choose treatment A over treatment B.

Recommendations for lead extraction apply only to those patients in whom the benefits of lead removal outweigh the risks when assessed based on individualized patient factors and operator specific experience and outcomes.

Abbreviations

CIED, cardiovascular implantable electronic device; COR, class of recommendation; CT, computerized tomography; EGM, electrogram; ERI, elective replacement indicator; ESRD, end-stage renal disease; ICD, implantable cardioverter defibrillator; INR, international normalized ratio; LOE, level of evidence; LV, left ventricle; MRI, magnetic resonance imaging; PM, pacemaker; RV, right ventricle; SVC, superior vena cava; TEE, transesophageal echocardiography; VT, ventricular tachycardia.

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1. Kusumoto et al. 2017 HRS Expert Consensus Statement on Cardiovascular Implantable Electronic Device Lead Management and Extraction. Heart Rhythm, 2017.
2. Ryan Azarrafi, BA; Darren C. Tsang, BS; Bruce L. Wilkoff, MD, FHRS; Roger G. Carrillo, MD, MBA, FHRS. The Endovascular Occlusion Balloon for Treatment of Superior Vena Cava Tears During Transvenous Lead Extraction: A Multi-Year Analysis and An Update to Best Practice Protocol. Circulation: Arrhythmia and Electrophysiology, August 2019.
3. Wazni, O et. al. Lead Extraction in the Contemporary Setting: The LEXIcon Study: A Multicenter Observational Retrospective Study of Consecutive Laser Lead Extractions, J Am Coll Cardiol, 55:579-586.



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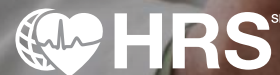
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Lead Management

CIED lead management considerations for the non-extracting device manager¹



Recognized as a quality educational tool by the Heart Rhythm Society.

Overview

The 2017 consensus statement provides practical clinical guidance in lead management, not only for extractors, but also for non-extracting device managers.

This brochure highlights important consensus updates for non-extracting device managers.

Existing CIED management

Class I Indications

New Careful consideration with the patient on the decision on whether to abandon or remove a lead is recommended before starting the procedure. The risks and benefits of each course of action should be discussed, and any decision should take the patient's preference, comorbidities, future vascular access, and available programming options into account. (LOE C-EO)

New Leaving the lead in a condition that will permit future extraction and prevents retraction into the vessel is recommended for any abandoned lead. (LOE C-EO)

Upgrade considerations

When preparing for CIED upgrade, a preparatory venogram or noninvasive ultrasound prior to opening the pocket to assess venous patency should be considered

Lead survival

Class IIa Indications

New A lead model and clinical scenario-specific strategy of increased surveillance and management can be useful for CIED leads that have been identified with higher-than expected failure rates. (LOE C-EO)

Infection diagnosis and management

Class I Indications

New Evaluation by physicians with specific expertise in CIED infection and lead extraction is recommended for patients with documented CIED infection. (LOE C-EO)

New If antibiotics are going to be prescribed, drawing at least 2 sets of blood cultures before starting antibiotic therapy is recommended for all patients with suspected CIED infection to improve the precision and minimize the duration of antibiotic therapy. (LOE C-LD)


Class IIa Indications

New TEE can be useful for patients with CIED pocket infection with and without positive blood cultures to evaluate the absence or size, character, and potential embolic risk of identified vegetations. (LOE B-NR)

New Evaluation by physicians with specific expertise in CIED infection and lead extraction can be useful for patients with suspected CIED infection. (LOE C-EO)

Class IIb Indications

New Additional imaging may be considered to facilitate the diagnosis of CIED pocket or lead infection when it cannot be confirmed by other methods. (LOE C-LD)



“Delayed, inappropriate, or incomplete therapy can result in significant morbidity and mortality for patients with CIED infection.”¹

- Fred M. Kusumoto, M.D.

Key Extraction Indications to be Aware of

There are dozens of indications for lead extraction. As a non-extracting device manager, below are key extraction indications to be aware of.

Type	Lead removal indications	Class
Infection	• Definite CIED system infection	I
	• Persistent or recurrent bacteremia or fungemia	
	• Valvular endocarditis without definite involvement of the lead(s) and/or device.	
Thrombosis/ vascular issues	• Clinically significant thromboembolic events	I
	• SVC stenosis or occlusion that prevents implantation of a necessary lead	
	• Planned stent deployment in a vein already containing a lead	
	Ipsilateral venous occlusion for required placement of an additional lead	IIa
Other	Chronic Pain	IIa
	Facilitate access to MRI	IIb
	Abandoned lead that interferes with the operation of a CIED system	IIa
	Leads that due to their design or their failure pose a potential future threat to the patient if left in place	IIb
	Removal after a shared decision-making process	IIb
	Life-threatening arrhythmias secondary to retained leads	I
	If CIED implantation requires >4 leads on one side or >5 leads through the SVC	IIa