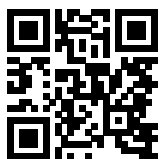


There is no better time to discuss cardiac lead management with your doctor. Be a proactive advocate for your health and know the facts to be a part of the shared decision-making process with your healthcare provider regarding your CIED.



To learn more about managing your heart device, visit upbeat.org/cied-management

Important safety information

The Philips laser sheaths (GlideLight and SLS II) are intended for use with other lead extraction tools in patients who are suitable candidates for removal of implanted pacemaker and defibrillator leads. The use of the laser sheaths may be unsafe in some patients, or with certain leads, or when the leads cannot be extracted through the superior veins (that is, when groin or surgical extraction is required). Rarely a patient undergoing lead extraction may require urgent surgical treatment for a complication; therefore, patients should not undergo lead extraction with a laser sheath in centers where emergency surgical procedures cannot be performed. Leads not intended for extraction may be damaged during the procedure and may require replacement. Ask your doctor if you are a candidate for lead extraction with the laser sheaths.

This information is not intended to replace a discussion with your healthcare provider on the benefits and risks of this procedure to you.

Caution: Federal law restricts this device to sale by or on the order of a physician.

1. Sohail MR, Henrikson CA, Braid-Forbes M, Forbes K, Lerner DJ. Mortality and cost associated with cardiovascular implantable electronic device infections. Arch Intern Med/Vol 171 (No. 20). Nov 14, 2011
2. Kusumoto et al. 2017 HRS Expert Consensus Statement on Cardiovascular Implantable Electronic Device Lead Management and Extraction. Heart Rhythm, 2017
3. Pokorney et al. Outcomes Associated with Extraction versus Capping and Abandoning Pacing and Defibrillator Leads. Circulation 2017 Oct 10;136(15):1387-1395. doi: 10.1161/CIRCULATIONAHA.117.027636. Epub 2017 Aug 22
4. Hussein, Ayman A., et al. "Cardiac Implantable Electronic Device Infections: Added Complexity and Suboptimal Outcomes With Previously Abandoned Leads." JACC: Clinical Electrophysiology (2016).
5. Kutalek et al. HRS 2018 presentation: Yikes! The Veg is Bigger than I Thought! Drexel University Experience and Clinical Results. <http://education.hrsonline.org/common/media-player.aspx/30/35/2565/21097>
6. Kalin R, Stanton MS. Current clinical issues for MRI scanning of pacemaker and defibrillator patients. PACE. April 2005;28(4):326-328.
7. Kutarski, A., Pietura, R., Młynarczyk, K., Malecka, B., & Główniak, A. (2012). Pacemaker lead extraction and recapture of venous access: technical problems arising from extensive venous obstruction. Cardiology journal, 19(5), 513-517.
8. 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.
9. Wilkoff, Bruce, L., et al. Pacemaker Lead Extraction with the Laser Sheath: Results of the Pacing Lead Extraction with Excimer Sheath (PLEXES) Trial. JACC, Vol 33, No. 6, May 1999.
10. Ryan Azarrafiy, 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.

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PHILIPS

Image Guided Therapy

Lead Management



Managing your cardiac leads

Signs and solutions to help you make informed decisions



Heart Rhythm Society

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

Your doctor may recommend cardiac lead removal or replacement. Here's why:

- An infection has developed in the body
- The lead is not functioning properly
- The lead is interfering with blood flow to the heart
- The manufacturer of the lead has issued a safety advisory
- The presence of the lead is preventing you from getting an MRI
- Your CIED is being upgraded or changed and requires new or different types of leads
- There is not enough room in your veins and heart to add more leads
- Your device is causing you chronic pain

The risks associated with leaving infected or unused cardiac leads in place

Infection

- A device infection can be life-threatening¹
- An infection can be systemic or localized to the pocket (where the device is located)²
- When a device becomes infected, antibiotics are an important part of treatment, and typically the device and all of the leads will need to be removed to help clear the infection²
- There may be an increased potential for future infection³

Vegetation (an infected mass)

- A greater potential for developing vegetations, or an infected mass, on your lead⁴
- The vegetations can break off and travel to other parts of your body, possibly causing new infections or blocking blood flow resulting in a pulmonary embolism or stroke⁵

More difficult removal

- The longer unused and abandoned leads are in your body, the more difficult they are to remove³

MRI denial

- Unused and abandoned leads may complicate your ability to get an MRI
- 75% of patients with a CIED will need an MRI in their lifetime⁶

Other risks

- The vein that leads to your heart could become blocked, interfering with blood flow to your heart⁷

What happens during the procedure?

Your doctor(s) will determine before your procedure which leads will be removed. During the procedure, your doctor will advance a flexible tube (sheath) over the lead, gently freeing the lead by removing scar tissue. Some of these sheaths can deliver laser energy to the scar or use precise surgical blades designed to safely remove the lead. Your doctor will continue this process until all targeted leads are safely extracted.



There is no better time to discuss management of all the components of your CIED with your doctor. Unused and abandoned leads may increase long term health risks that can be mitigated with safe, effective lead removal. A lead extraction is generally a very safe procedure. However, as with any invasive procedure, there are risks. Although results and risks vary from patient to patient, several large studies show clinical success rates around 98%.⁸ The risk of internal bleeding, tear in a vein or the heart, or death is less than 0.5%.¹⁰ Lead removal may not be appropriate for some patients depending on their health factors. Treatment decisions should be based on consultation with your physician.

Learn more about the risks of leaving a capped lead in place:

upbeat.org/cied-management