There are 13 million cardiac implanted electronic device (CIED) leads worldwide, and another 1.4 million are implanted every year.[19-24]

Patients with CIEDs are on a life-long journey.
Make it a healthy one.

Managing cardiac implanted electronic device (CIED) leads has never been more important. As your profession advances and more lives are saved with these devices, proactive lead management is essential for your patients, your practice and your hospital. It means partnering with your patients to make the right decision at the right time.

Important Safety Information

GlideLight, SLS II, LLD, and VisiSheath

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.

The Philips Lead Locking Device (LLD) is intended for use in patients who are suitable candidates for removal of implanted pacemaker and defibrillator leads. The use of the LLD 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. Ask your doctor if you are a candidate for lead extraction with the Philips LLD.

The Philips VisiSheath Dilator Sheath is intended for use in patients requiring pacemaker or defibrillator lead extraction or removal of other catheters or foreign objects that have become attached to the wall of the blood vessel. The device is also intended to help place new intravascular catheters. Rarely a patient undergoing lead or catheter extraction may require urgent surgical treatment for a complication; therefore, patients should not undergo lead or catheter extraction 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 VisiSheath.

Potential minor adverse events associated with lead extraction procedures that may or may not require medical or surgical treatment include: a tear or damage to the blood vessels, the heart or its structures; bleeding at the surgical site; or collapsed lung. Rare but serious adverse events that require emergency medical or surgical procedures may include: a tear or damage to the blood vessels, the heart, lungs or their structures; blood clot or obstruction of the blood vessels or lungs by debris or lead fragments. Other serious complications may include: irregular heartbeat, weakened heart muscle, infection, respiratory failure or complications associated with anesthesia, stroke or death.

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

TightRail rotating dilator sheath, TightRail mini-manual dilator sheath, and SightRail dilator sheath set

Indications: The Philips TightRail, TightRail Mini, and SightRail are intended for use in patients requiring the percutaneous dilation of tissue to facilitate the removal of cardiac leads, indwelling catheters, and foreign objects.

Contraindications: None known.

Warnings: Lead removal devices and dilator sheaths should be used at institutions with cardiothoracic surgical capabilities by physicians knowledgeable in the techniques and devices for lead or catheter removal. Complication prevention and management protocols should be in place and routinely practiced. The recommendations for lead management of the Heart Rhythm Society (HRS) and European Heart Rhythm Association (EHRA) are highly recommended for best results.

When using a locking stylet: Do not abandon a catheter/lead in a patient with a locking stylet still in place inside the catheter/lead. Severe vessel or endocardial wall damage may result from the stiffened catheter/lead or from fracture or migration of the abandoned stylet wire.

When using dilator sheaths: Do not insert sheaths over more than one lead or catheter at a time. Severe vessel damage, including venous wall laceration requiring surgical repair, may occur.

Maintain appropriate traction on the lead being extracted during advancement of the inner or outer sheath.

Do not maintain a stationary position with SightRail Dilator Sheath tips at the Superior Vena Cava (SVC)–right atrial (RA) junction as it may result in damage to this delicate area during subsequent lead extraction and reinsertion procedures (e.g., manipulating the dilator sheath or implanting a new lead).

Refer to the IFU for additional information

Bridge Occlusion Balloon

The Philips Bridge Occlusion Balloon is indicated for use for temporary vessel occlusion of the superior vena cava in applications including perioperative occlusion and emergency control of hemorrhage. Use of the Bridge Occlusion Balloon in procedures other than those indicated is not recommended.

The adverse events associated with an occlusion balloon procedure include, but are not limited to allergic reactions, death, embolization, hematoma, hemorrhage, sepsis/infection, short-term hemodynamic deterioration, thromboembolic episodes, vascular thrombosis, vessel dissection, vessel perforation, vessel spasm.

In order to facilitate rapid delivery, it is recommended that a guidewire is in place in the superior vena cava prior to beginning the lead extraction procedure. Attempting to place the guidewire after a tear has occurred may:

- Result in an inability to traverse the superior vena cava with the guidewire
- Result in the guidewire exiting the vasculature at the tear site
- Result in an inability to place the Bridge Occlusion Balloon catheter
- Delay or prevent the ability to achieve occlusion

1. Voigt, Andrew, et al. Rising Rates of Cardiac Rhythm Management Device Infections in the United States: 1996 through 2003. JACC Vol. 48, No. 3, 2006: 590–1.
2. Voigt, Andrew, et al. Continued Rise in Rates of Cardiovascular Implantable Electronic Device Infections in the United States: Temporal Trends and Causative Insights. PACE Vol. 33, No. 4, 2010: 414–9.
3. Sweeney, M., et al., Differences In Effects of Electrical Therapy Type for Ventricular Arrhyth-mias on Mortality in Implantable Cardioverter-Defibrillator Patients, Heart Rhythm, Volume 7, Issue 3, March 2010: 353–60.
4. Raltt, M., Implantable Cardioverter-Defibrillator Shocks; A Double-Edged Sword? JACC, Volume 51, Issue 14, April 8, 2008; 1366–8.
5. Kallinen L, et al., Lead Integrity alert decreases inappropriate shocks in patients who have Fidelis pace–sense conductor fractures, Heart Rhytm, Vol.7, No. 8, August 2010, pp. 1048–55.
6. Kusumoto et al. 2017 HRS Expert Consensus Statement on Cardiovascular Implantable Electronic Device Lead Management and Extraction. Heart Rhythm, 2017.
7. Byrd, CL, et al. Intravascular extraction of problematic or infected permanent pacemaker leads: 1994–1996. U.S. Extraction Database, MED Institute. PACE 1999; 22:1348–1357.
8. Wazni, O. et. al. Lead Extraction in the Contemporary Setting: The LExICon Study: A Multi-center Observational Retrospective Study of Consecutive Laser Lead Extractions, J Am Coll Cardiol, 55:579–586.
9. Cock CC, et al. Long-term outcome of patients with multiple (> or = 3) noninfected leads: a clinical and echocardiographic study. PACE, Vol 23, No 4, 2000, 423–6.
10. Mattei, E., Gentili, G., Censi, F., et al (2015), Impact of capped and uncapped abandoned leads on the heating of an MRI-conditional pacemaker implant. Magn Reson Med, 73:390–400. doi: 1002/mrm.25106.
11. Le KY, Sohail MR, Friedman PA, et al. Impact of timing of device removal on mortality in pa-tients with cardiovascular implantable electrophysiologic device infections. Heart Rhythm 2011;8:1678 – 85.
12. Data on file, see infographic references.
13. de Ble, Mihály K., et al. "Cardiac device infections are associated with a significant mortality risk." Heart Rhythm 9.4 (2012): 494–498.
14. Deharo, J. C., et al. "Pathways for training and accreditation for transvenous lead extraction: a European Heart Rhythm Association position paper." Europace 14.1 (2012): 124–134.
15. Documentation on File D027562.
16. Documentation on File D027561.
17. Documentation on File D026197.
18. Roger G. Carrillo, MD; Darren C. Tsang, BS; Ryan Azarra y, BA; Thomas A. Boyle, BS. Multi-Year Evaluation of Compliant Endovascular Balloon in Treating Superior Vena Cava Tears During Transvenous Lead Extraction. EHRA late-breaking trial, March 19, 2018.
19. Medtronic CRDM Product Performance Report, Mar 2013.
20. Boston Scientific CRM Product Performance Report, Q1 2013.
21. St. Jude Medical CRM Product Performance Report, Apr 2013.
22. Biotronik Product performance Report, Jan 2013.
23. Millennium Research Group, Global Markets for Cardiac Rhythm Management Devices 2013.
24. Eucomed (2012).
25. Pokorney et al. Outcomes Associated with Extraction versus Capping and Abandoning Pacing and De brillator Leads Circulation 2017 Oct 10;136(15):1387–1395. doi: 10.1161/CIRCULATIONAHA.117.027636. Epub 2017 Aug 22.
26. Hussein, Ayman A., et al. "Cardiac Implantable Electronic Device Infections: Added Complexity and Suboptimal Outcomes With Previously Abandoned Leads." JACC: Clinical Electrophysiology (2016).
27. Sohal, M. et al. (2014). Laser lead extraction to facilitate cardiac implantable electronic device upgrade and revision in the presence of central venous obstruction. Europace, 16(1), 81–87.
28. Oginosawa Y, Abe H, Nakashima Y. The incidence and risk factors for venous obstruction after implantation of transvenous pacing leads. Pacing Clin Electrophysiol 2002;25:1605–1611.
29. Kutarski, A., Pietura, R., Młynarczyk, K., Małecka, B., & Głowniak, A. (2012). Pacemaker lead extraction and recapture of venous access: technical problems arising from extensive venous obstruction. Cardiology journal, 19(5), 513–517.

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

Approved for external distribution
D022573-02 022019

Philips
3721 Valley Centre Drive, Suite 500
San Diego, CA 92130 USA
www.philips.com/IGTdevices

PHILIPS

Lead Management

Make the right decision at the right time, for every patient.

Safe and effective lead management

To cap or not to cap?

There are many reasons to consider lead extraction for your patients living with cardiac devices. CIED patients are enjoying longer lives than ever before, and at some point their leads may need to be replaced. In 2017, the Heart Rhythm Society established a Class I indication for discussing the risks of lead abandonment and the risks of lead extraction with patients.[6] Understanding both courses of action is essential to making the right decision at the right time, for every patient.

Risks of lead abandonment:

- Increased risk of infection 5 years post-procedure[25]
- Risk of more difficult future extraction, which requires more tools and has worse outcomes[26]
- Risk of developing venous occlusion[27-29] and tricuspid regurgitation[9]
- Contraindicate a patient for MRI - even if patients have received an MRI-compatible implant[10]

Proven extraction solutions

Laser lead extraction is proven to be a safe and effective way to manage leads. Multiple clinical studies demonstrate predictable success: 97.7% clinical success rate in lead removal, with only 1.4% of patients experiencing a major adverse event during laser lead extraction.[8,9,11]

At Philips, we firmly believe in managing every lead, safely, predictably and responsibly. Every patient is different, and every case is different. When extraction is the right choice for your patient, Philips is here to support your lead management decisions with a broad portfolio of tools designed for safety and predictability, including both laser lead extraction and mechanical devices.

No better time

There's no better time to remove a lead than today. Capping and abandoning leads poses significant long-term risks that can be mitigated proactively with safe lead removal.

Infection + device = removal

The presence of a systemic infection, pocket infection or endocarditis is a Class I indication for removal of all hardware, including leads.[6, 14]

6 in 10 device infections may be undertreated.[12]

Multiple studies show patients are 2 times more likely to die with a device infection compared to patients without infections.[1,13]

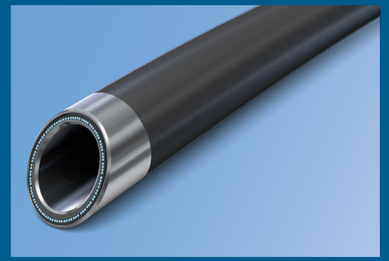
When treated with antibiotics alone, mortality rates can be as high as 66% in device-related endocarditis cases.[6]

A full portfolio of lead management **solutions**

Philips provides a broad portfolio of tools to address a wide range of clinical scenarios, including laser and mechanical devices.

Laser lead extraction

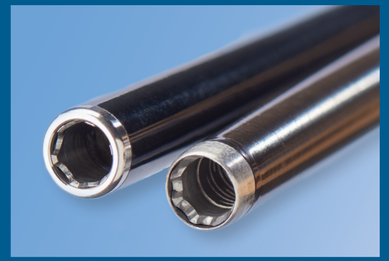
Philips Glidelight laser sheath offers the only excimer laser for lead extraction available in the world. It produces pulsed bursts of UV light energy that are capable of gently dissolving fibrous tissue into microscopic particles that are easily absorbed by the bloodstream.



The GlideLight laser sheath offers unprecedented versatility, efficiency and control during lead removal procedures.

Mechanical lead extraction

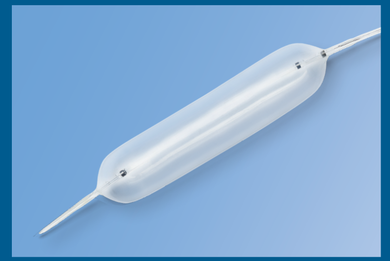
The Philips TightRail and TightRail Sub-C rotating dilator sheaths offer design advances in mechanical lead extraction tools. The flexible shaft, shielded dilating blade and bidirectional mechanism provide flexibility, control and safety during lead extraction procedures.



TightRail's unique shaft technology combines flexibility with column strength, and the shielded tip is one of several built-in safety features.

Occlusion balloon

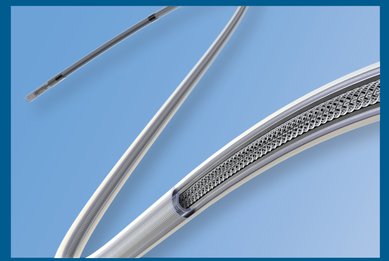
Though rare, SVC tears during lead extraction can happen. The Philips Bridge occlusion balloon can be deployed in less than two minutes via a pre-placed guidewire[15] to stop 90% of blood loss on average[16] and maintain acceptable hemostasis for at least 30 minutes.[17] You maintain uninterrupted control and time to stabilize your patient for transition to surgery.



Bridge occlusion balloon is an 8 cm low-pressure, compliant balloon. With Bridge, SVC tear survival has gone from 56.4% to 91.7%[18]

Lead locking device

The Philips LLD lead locking device provides superior traction, visibility and versatility during challenging lead removal procedures. It's the only lead locking stylet that locks along the entire length of the lead body—from the proximal end to the distal tip—for superior grip and stability during removal. The LLD portfolio provides a variety of locking sizes, providing optimum engagement to the lead.

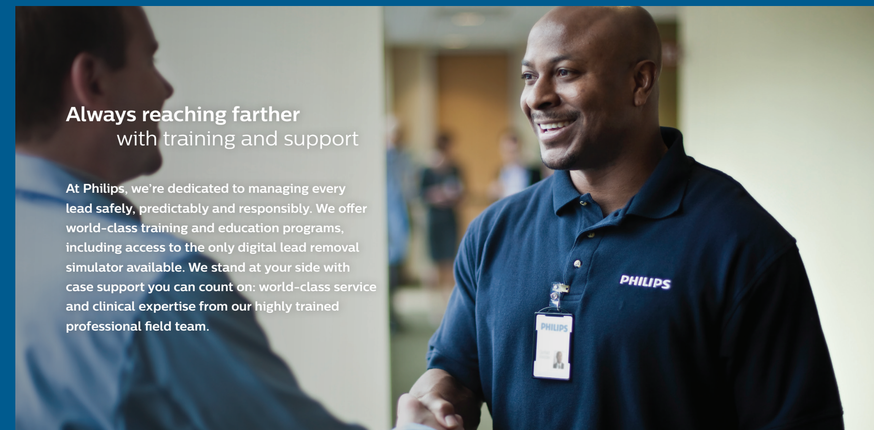


The LLD lead locking device offers total lead control during lead removal procedures.

Manual dilator sheath

The Philips SightRail includes printed indicators for bevel orientation and tip alignment and an inner sheath length that's 10 cm longer than the outer sheath. SightRail is easy to manipulate, and you'll know at a glance that the sheaths are oriented and positioned correctly.

SightRail provides the next generations of manual dilator sheath design that allow for easy positioning, manipulation and use.



Always reaching farther with training and support

At Philips, we're dedicated to managing every lead safely, predictably and responsibly. We offer world-class training and education programs, including access to the only digital lead removal simulator available. We stand at your side with case support you can count on: world-class service and clinical expertise from our highly trained professional field team.