Cardiac laser lead removal

The scar tissue around your leads can prevent your doctor from being able to safely remove them. "Cool" laser technology – the same kind that's used in LASIK eye surgery – gently vaporizes scar tissue so that your doctor can safely extract your leads.

This method has been proven safe and effective:

- There is a 97.7% clinical success rate^{9,10}
- Only 1.4% of patients experience a major adverse event (MAE)

97%

procedural success rate^{9, 10*}

Laser lead extraction has been proven safe in multiple clinical trials, including Pacemaker Lead Extraction with the Laser Sheath (PLEXES), and a retrospective study: Lead Extraction in Contemporary Settings (LExICon).

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.

References

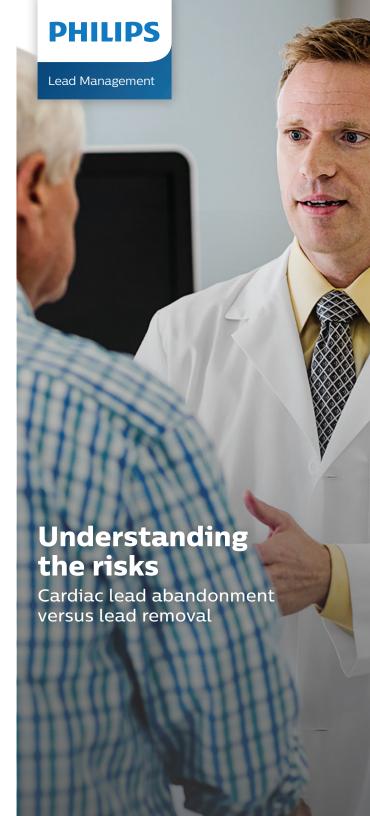
- Kusumoto et al. 2017 HRS Expert Consensus Statement on Cardiovascular Implantable Electronic Device Lead Management and Extraction. Heart Rhythm, 2017.
- Pokorney et al. Outcomes Associated with Extraction versus Capping and Abandoning Pacing and Defibrillator Leads Circulation 2017 Oct 10;136(15):1387-1395. doi: 10.1161/CIRCULATIONAHA.117.027636. Epub 2017 Aug 22.
- Sohail MR, et al. Management and outcome of permanent and implantable cardioverter-defibrillator infections. J Am Coll Cardiol. 2007;49:1851–1859.
- Hussein, Ayman A., et al. "Cardiac Implantable Electronic Device Infections: Added Complexity and Suboptimal Outcomes With Previously Abandoned Leads." JACC: Clinical Electrophysiology (2016).
- Mattei, E., Gentili, G., Censi, F., Triventi, M. and Calcagnini, G. (2015), Impact of capped and uncapped abandoned leads on the heating of an MR-conditional pacemaker implant. Magn Reson Med, 73: 390–400. doi: 10.1002/mrm.25106
- Kalin R, Stanton MS. Current clinical issues for MRI scanning of pacemaker and defibrillator patients. PACE. April 2005;28(4):326-328.
- de 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.
- 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.
- 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.
- 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.



Philips

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

©2019 Koninklijke Philips N.V. All rights reserved. Some or all products manufactured by Spectranetics, a Philips company. Approved for external distribution. D023608-02 012019



Why consider cardiac lead removal?

Cardiac leads may need to be removed for several reasons, such as:1

- · An infection has developed
- The lead is not functioning properly
- The lead is interfering with blood flow to the heart
- There is a manufacturer's advisory on the lead
- The lead prevents you from getting an MRI
- Your cardiac device has been or is being upgraded or changed and may require new leads
- There is n ot enough room to add more leads
- You experience severe chronic pain from your device

The risks of leaving cardiac leads in place

Higher risk of developing an infection²

- A device infection is life-threatening, and is likely to require an extraction to clear the infection³
- Infection can lead to erosion in your pocket as well as endocarditis, which is an infection in your heart³
- You are also at higher risk to develop infected clumps, called vegetations, which can break off and travel to other parts of your body possibly causing new infections or blocking blood flow⁴

Harder and riskier future extraction4

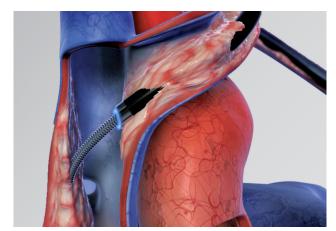
 The procedure may be more difficult and have worse outcomes if postponed⁴

MRI denial

 You are contraindicated for an MRI with capped and abandoned leads in place, even if you have a MRIcompatible device⁵, however, there is a 75% chance you will need an MRI in your lifetime⁶

Other risks

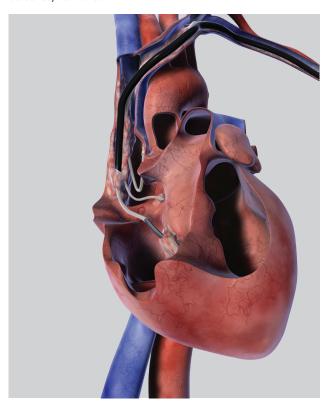
- The vein that leads to your heart could become blocked, possibly resulting in what's called SVC syndrome⁷
- Risk of increased tricuspid regurgitation, a disorder where your heart valve does not close tightly enough and blood flows backward in your heart, possibly leading to atrial fibrillation or right-sided heart failure?
- Leads can interact with each other, interfering with how well your cardiac device works and resulting in unwanted conduction of electricity⁸



The laser gently vaporizes scar tissue into particles smaller than a red blood cell.

What happens during the procedure?

Your doctor inserts the lead into the center of a flexible laser sheath, and then slowly advances the sheath over the lead, gently freeing the lead by vaporizing scar tissue into particles smaller than a red blood cell. These particles are carried away by your bloodstream. Your doctor will repeat this process until all unused leads can be safely removed.



No better **time**

There's no easier time to remove a lead than today. Capping and abandoning leads poses significant risks that can be mitigated proactively with safe lead removal. Laser lead removal has a 99.72% procedural survival rate. Talk to your doctor about cardiac lead removal; learn more using the resources below.

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

www.deviceinfection.com