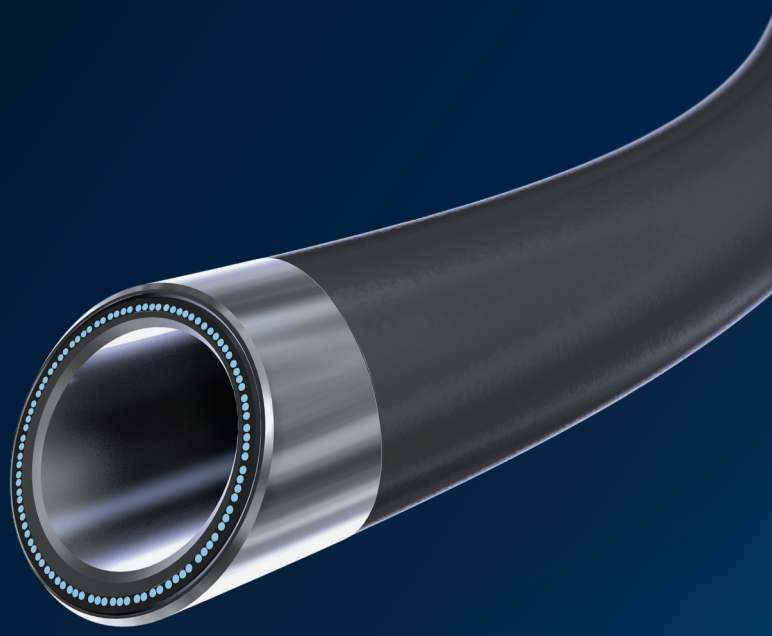
PHILIPS

GlideLight

Laser sheath



Versatility, efficiency, **control**

Unprecedented advances in laser lead removal technology

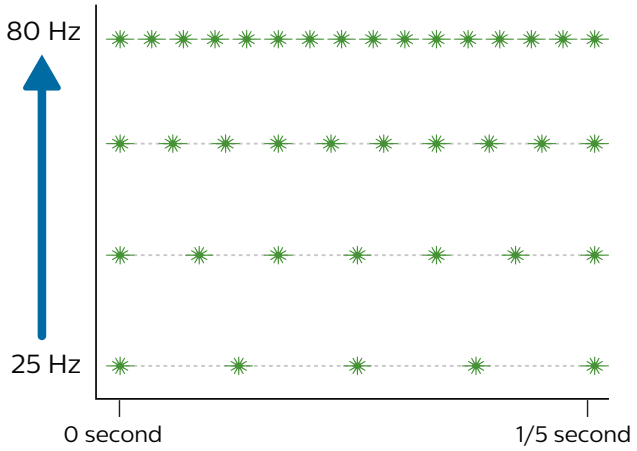
Safely and efficiently removing leads depends on tools that give you versatility and control. Philips GlideLight laser sheath offers the unprecedented ability to customize the laser's repetition rate throughout a procedure. When GlideLight laser sheath is set at 80Hz, you can use up to 55% less advancement force[1], and you can smoothly advance up to 62% more efficiently through tough binding sites[2].

Versatility

No two lead removal procedures are the same. Each binding site is unique, lead designs vary, and every patient's anatomy is different.

GlideLight laser sheath allows you to adjust from 25Hz to 80Hz based on anatomical and procedural considerations.

Flexible pulse repetition rate[8]



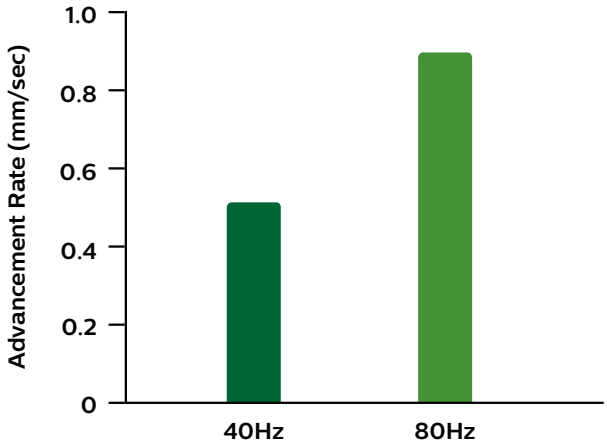
GlideLight laser sheath allows you to customize the repetition rate.

Efficiency

Stalled progression during lead removal procedures can lengthen the time they take to complete. GlideLight laser sheath may enable smoother and more consistent progression.

GlideLight laser sheath enables you to advance up to 62% more efficiently through tough binding sites[2].

Advancement rate at constant force[8]



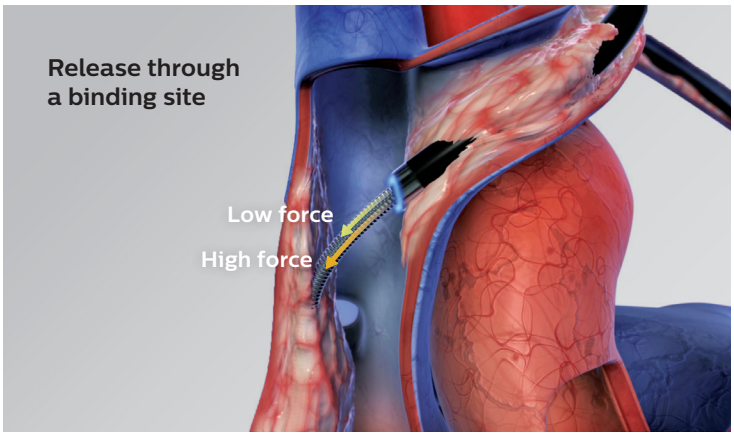
Rate of progression through binding sites at 40Hz and 80Hz.

Control

Using a high degree of mechanical force when removing leads can compromise lead integrity[3-6]. GlideLight laser sheath provides critical control when progressing through binding sites[7].

GlideLight laser sheath allows physicians to use up to 55% less advancement force[1].

Less Unintended Forward Motion



GlideLight laser sheath provides a high degree of control when progressing through binding sites[7].

GlideLight ordering information

Model Number	500-301	500-302	500-303
Sheath size	12F	14F	16F
Maximum target lead diameter (F/inches/mm)	7.5/0.098/2.50	9.5/0.124/3.17	11.5/0.150/3.83
Minimum tip inner diameter (F/inches/mm)	8.3/0.109/2.77	10.2/0.134/3.40	12.5/0.164/4.17
Maximum tip outer diameter (F/inches/mm)	12.5/0.164/4.17	14.7/0.192/4.88	17.2/0.225/5.72
Working length (cm)	50	50	50
Repetition rate (Hz)	25-80	25-80	25-80
Clinical energy setting (mJ/mm)	30-60	30-60	30-60

GlideLight laser sheath important safety information

GlideLight laser sheath is 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 GlideLight laser sheath 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 GlideLight laser sheath.

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.

References

1. Comparison of average peak push forces required to advance Laser Sheath at 40Hz vs. 80Hz Pulse Repetition Rate through simulated fibrosis material at an advancement rate of 1.0 mm/second. D015722, Data on file at Spectranetics.
2. Comparison of ablation force vs. advancement rate of Laser sheath 40Hz vs. 80Hz by use of the data collected in D015786, Data on file at Spectranetics.
3. Maytin M, Epstein, L (2011). The challenges of transvenous lead extraction. Heart, 97(5): 425-34.
4. Henrikson, C.A., et al. (2008). How to prevent, recognize, and manage complications of lead extraction. Part III: Procedural factors Heart Rhythm. Jul;5(7):1083-7. Epub 2007 Oct 9.
5. Smith MC, Love CJ. Extraction of transvenous pacing and ICD leads. Pacing Clin Electrophysiol 2008:31:736-52.
6. Wilkoff, B.L., et al. (1999). Pacemaker lead extraction with the laser sheath: Results of the Pacing Lead Extraction with Excimer Sheath (PLEXES) trial. JACC, 33(6), 1671-1676.
7. Reduced advancement force lowers the forces applied to leads during extraction, D015861-01, Data on file at Spectranetics.
8. Design Verification Report for Ablation Force Testing. D015722, Data on file at Spectranetics.

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