



# SLS<sup>®</sup> II LASER SHEATH

Precision Lead Management Technology

# SLS® II LASER SHEATH

## Safe

The low-temperature excimer laser operates in the ultraviolet spectrum at 308nm to ablate target tissue at a depth of 50 microns.

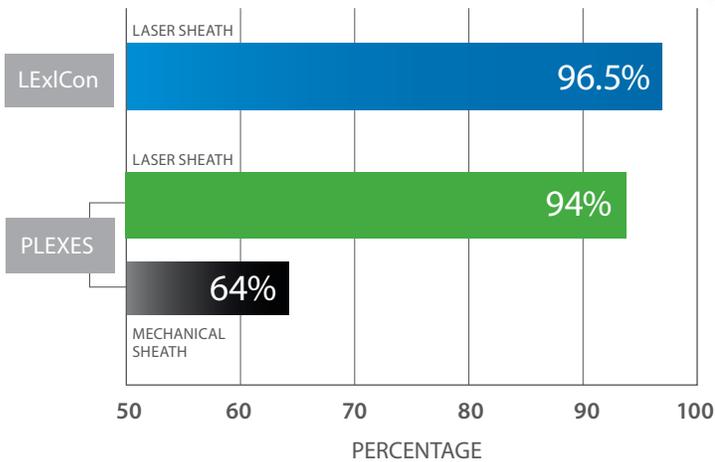
## Efficient

A ring of laser energy ablates contacted tissue around the circumference of the lead.

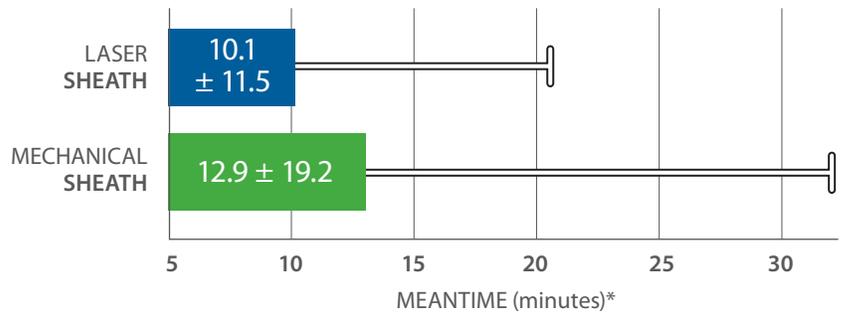
- In a study of the SLS II in 46 leads<sup>3</sup>, fast extraction times were observed (time from sheath application until lead removed).

– Median: 4 min – Mean: 5.3 min

Lead Removal Success Rates<sup>1,2</sup>



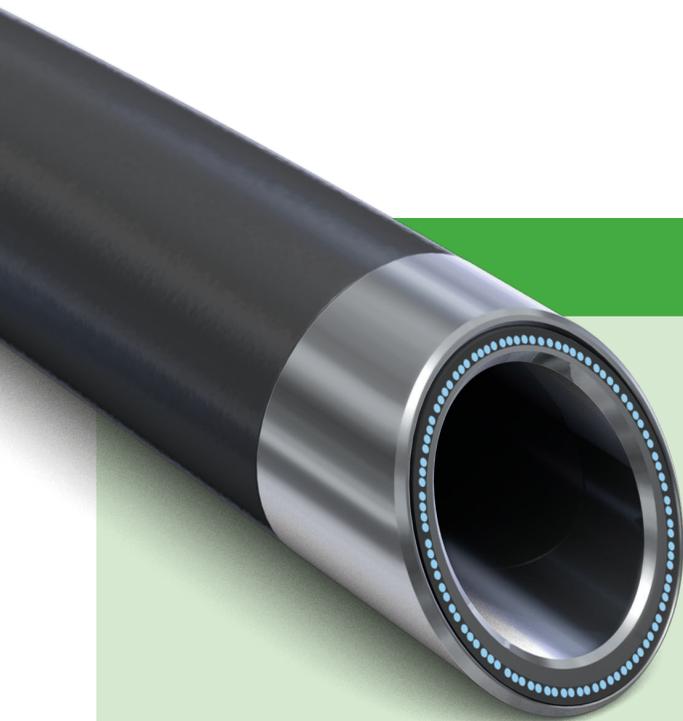
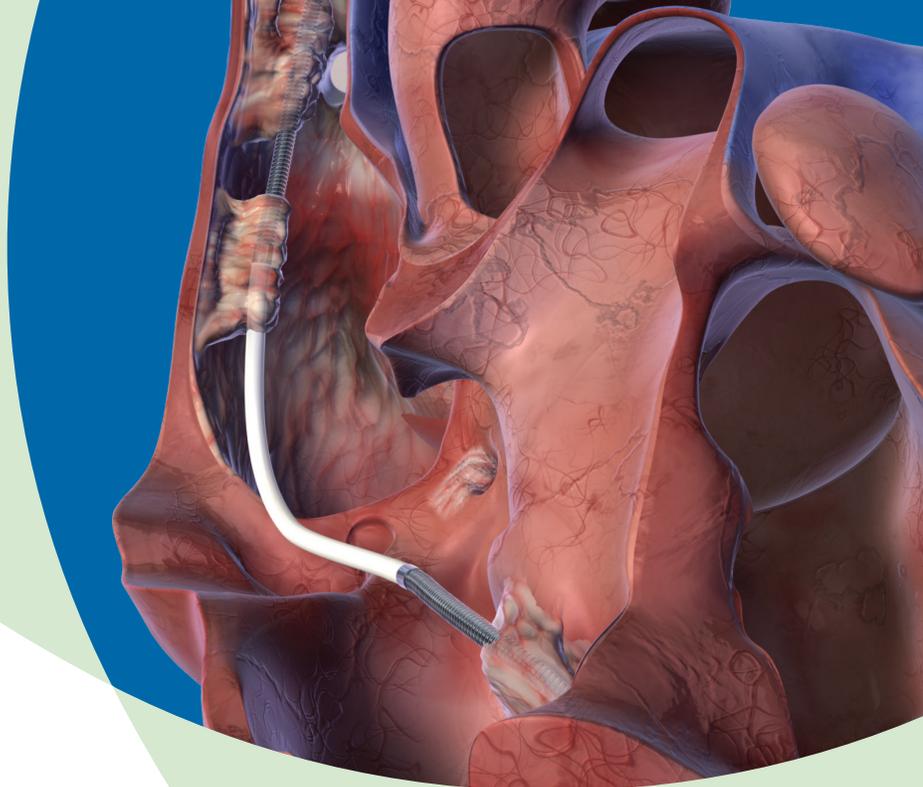
Lead Removal Time



**p < 0.04**

\* In the PLEXES trial, the Spectranetics Laser Sheath (SLS) had a maximum 5 sec. activation period with a 10 sec rest period. SLS II operates with a maximum 10 sec activation period with a 5 sec rest period.

*Any surgical procedure has certain risks. For more information, please see the SLS II IFU.*



## Spectranetics Laser Sheath

Second-generation laser sheath ablates binding tissue safely and effectively.

- Flexible distal segment and 15° bevel tip for advancement over acute lead angles
- Internal lubricious coating for easy passage
- Improved torque capacity
- Comes with Teflon® outer sheath, which acts as a low-friction conduit

## SLS® II PRODUCT SPECIFICATIONS

	12F Kit	14F Kit	16F Kit
<b>Model Number</b>	500-001	500-012	500-013
<b>Max. Target Lead Diameter (F/inches/mm)</b>	7.5/0.098/2.50	9.5/0.124/3.17	11.5/0.150/3.83
<b>Min. Inner Tip Diameter (F/inches/mm)</b>	8.3/0.109/2.77	10.2/0.134/3.40	12.5/0.164/4.17
<b>Max. Outer Tip Diameter (F/inches/mm)</b>	12.5/0.164/4.17	14.7/0.192/4.88	17.2/0.225/5.72
<b>Working Length (cm)</b>	50	50	50
<b>Repetition Rate (Hz)</b>	25-40	25-40	25-40
<b>Clinical Energy Setting (mJ/mm<sup>2</sup>)</b>	30-60	30-60	30-60

### Important Safety Information

#### SLS® II Laser Sheath

The Spectranetics Laser Sheath (SLS II) 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 the SLS II 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 the SLS II 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.

For additional information, please see the IFU located at [www.spnc.com/IFU](http://www.spnc.com/IFU).

### References

1. Wilkoff, B., et al. (2009). Pacemaker lead extraction with the laser sheath: Results of the Pacing Lead Extraction with Excimer Sheath (PLEXES) Trial. *Journal of the American College of Cardiology*, 33(6).
2. Wazni, O., et al. The LExCon study: A multicenter observational retrospective study of consecutive laser lead extractions. (2010). *Journal of the American College of Cardiology*, 55(6).
3. Kennergren, C., et al. (2002). Lead extraction: Initial experience using a new laser sheath. *Abstract 101892. NASPE*.

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