Lead management products
A full portfolio of safe and effective lead management technologies
Philips and Spectranetics merging our strengths

The Spectranetics acquisition enables the treatment arm of the Philips Health Continuum
Delivering more effective healthcare by enhancing workflow, improving outcomes and reducing the cost of care. The following represents the Philips and Spectranetics combined product portfolio and the power of us coming together:

- Physiology
- Intravascular ultrasound
- Laser atherectomy
- Scoring balloon
- IVUS guided true lumen re-entry
- Mechanical atherectomy
- Thrombectomy
- Drug-coated balloons
- Lead management

Improving lives through meaningful innovation we’re aiming to improve the lives of three billion people a year by 2025.


Philips IGT Devices is dedicated to helping physicians safely manage every lead. We provide the expert tools, training and ongoing support that allow physicians precision, control and versatility while extracting leads, so they can focus more on the patient’s overall status while generating positive outcomes.
Lead management: Making the right decision at the right time, for every patient.

Managing cardiac implanted electronic device (CIED) leads has never been more important. Patients with CIEDs are on a life-long journey, and you’re there to make sure it’s a healthy one. 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. There are 13 million cardiac implanted electronic device (CIED) leads worldwide, and another 1.4 million are implanted every year.14-15

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 in time their leads may need to be replaced. Leads may malfunction, or there may be advisories. Capped leads may be a nidus for infection, and infection rates are rising dramatically.1,2 Understanding the potential clinical implications of capping leads is essential to informing a sound decision about whether to cap and abandon a lead.

Abandoned leads:
- May have abnormalities or insulation failures that allow electrical conductors to move entirely outside the outer lead insulation.
- May cause lead-on-lead interaction.3,4
- Can be more difficult to extract in the future.3,7
- Can increase the risk of deadly infection, occlusion, thrombosis, and SVC syndrome.9

Wait, refer or remove?
The presence of a systemic infection, pocket infection or endocarditis is a Class I indication for removal of all hardware, including leads.6,13 In 60% of device infections may be undertreated.11

Multiple studies show patients are 2 times more likely to die with a device infection compared to patients without infections.12 When treated with antibiotics alone, mortality rates can be as high as 66% in device-related endocarditis cases. Laser lead removal has a 97.7% success rate.8 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.8-10 This major adverse event rate is lower than with many cardiovascular procedures, including AFIB.16-19

At Spectranetics, 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, Spectranetics 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 next-generation mechanical devices.
Indications for lead extraction

HRS indications for lead extraction apply only to those patients in whom the benefits of lead removal outweigh the risks when assessed based on individualized patient factors and operator specific experience and outcomes. See HRS consensus document Class III indications for when lead removal is not recommended.

Indications for lead extraction

1. **Infectious**

   **Indications for lead extraction**

   See HRS consensus document Class III indications for when lead removal is not recommended.

   **Indications for lead extraction**

   See HRS consensus document Class III indications for when lead removal is not recommended.

   **Indications for lead extraction**

   See HRS consensus document Class III indications for when lead removal is not recommended.

   **Class Definitions**

   **Class I (Strong), Benefit >> Risk**
   Conditions for which treatment A should be chosen over treatment B.

   **Class IIa (Moderate), Benefit > Risk**
   Conditions for which it is reasonable to choose treatment A over treatment B.

   **Class IIb (Weak), Benefit ≥ Risk**
   Conditions for which it is reasonable to choose treatment A over treatment B.

   **Class III (Non-infectious)**

   **Indications for lead extraction**

   See HRS consensus document Class III indications for when lead removal is not recommended.

   **Indications for lead extraction**

   See HRS consensus document Class III indications for when lead removal is not recommended.

   **Indications for lead extraction**

   See HRS consensus document Class III indications for when lead removal is not recommended.

   **Indications for lead extraction**

   See HRS consensus document Class III indications for when lead removal is not recommended.

   **Indications for lead extraction**

   See HRS consensus document Class III indications for when lead removal is not recommended.

   **Indications for lead extraction**

   See HRS consensus document Class III indications for when lead removal is not recommended.

   **Indications for lead extraction**

   See HRS consensus document Class III indications for when lead removal is not recommended.

   **Indications for lead extraction**

   See HRS consensus document Class III indications for when lead removal is not recommended.

   **Indications for lead extraction**

   See HRS consensus document Class III indications for when lead removal is not recommended.

   **Indications for lead extraction**

   See HRS consensus document Class III indications for when lead removal is not recommended.

   **Indications for lead extraction**

   See HRS consensus document Class III indications for when lead removal is not recommended.

   **Indications for lead extraction**

   See HRS consensus document Class III indications for when lead removal is not recommended.

   **Indications for lead extraction**

   See HRS consensus document Class III indications for when lead removal is not recommended.

   **Indications for lead extraction**

   See HRS consensus document Class III indications for when lead removal is not recommended.

   **Indications for lead extraction**

   See HRS consensus document Class III indications for when lead removal is not recommended.

   **Indications for lead extraction**

   See HRS consensus document Class III indications for when lead removal is not recommended.

   **Indications for lead extraction**

   See HRS consensus document Class III indications for when lead removal is not recommended.

   **Indications for lead extraction**

   See HRS consensus document Class III indications for when lead removal is not recommended.

   **Indications for lead extraction**

   See HRS consensus document Class III indications for when lead removal is not recommended.

   **Indications for lead extraction**

   See HRS consensus document Class III indications for when lead removal is not recommended.

   **Indications for lead extraction**

   See HRS consensus document Class III indications for when lead removal is not recommended.

   **Indications for lead extraction**

   See HRS consensus document Class III indications for when lead removal is not recommended.

   **Indications for lead extraction**

   See HRS consensus document Class III indications for when lead removal is not recommended.

   **Indications for lead extraction**

   See HRS consensus document Class III indications for when lead removal is not recommended.

   **Indications for lead extraction**

   See HRS consensus document Class III indications for when lead removal is not recommended.

   **Indications for lead extraction**

   See HRS consensus document Class III indications for when lead removal is not recommended.

   **Indications for lead extraction**

   See HRS consensus document Class III indications for when lead removal is not recommended.

   **Indications for lead extraction**

   See HRS consensus document Class III indications for when lead removal is not recommended.

   **Indications for lead extraction**

   See HRS consensus document Class III indications for when lead removal is not recommended.

   **Indications for lead extraction**

   See HRS consensus document Class III indications for when lead removal is not recommended.

   **Indications for lead extraction**

   See HRS consensus document Class III indications for when lead removal is not recommended.

   **Indications for lead extraction**

   See HRS consensus document Class III indications for when lead removal is not recommended.

   **Indications for lead extraction**

   See HRS consensus document Class III indications for when lead removal is not recommended.

   **Indications for lead extraction**

   See HRS consensus document Class III indications for when lead removal is not recommended.

   **Indications for lead extraction**

   See HRS consensus document Class III indications for when lead removal is not recommended.

   **Indications for lead extraction**

   See HRS consensus document Class III indications for when lead removal is not recommended.

   **Indications for lead extraction**

   See HRS consensus document Class III indications for when lead removal is not recommended.

   **Indications for lead extraction**

   See HRS consensus document Class III indications for when lead removal is not recommended.

   **Indications for lead extraction**

   See HRS consensus document Class III indications for when lead removal is not recommended.

   **Indications for lead extraction**

   See HRS consensus document Class III indications for when lead removal is not recommended.

   **Indications for lead extraction**

   See HRS consensus document Class III indications for when lead removal is not recommended.

   **Indications for lead extraction**

   See HRS consensus document Class III indications for when lead removal is not recommended.

   **Indications for lead extraction**

   See HRS consensus document Class III indications for when lead removal is not recommended.

   **Indications for lead extraction**

   See HRS consensus document Class III indications for when lead removal is not recommended.

   **Indications for lead extraction**

   See HRS consensus document Class III indications for when lead removal is not recommended.

   **Indications for lead extraction**

   See HRS consensus document Class III indications for when lead removal is not recommended.
References

11. Spectranetics. Data on file
15. Eucomed (2012)
18. Periole, J. et al., Complication Rates Associated with Pacemaker and ICD Generator Replacements when Combined with Planned Lead Addition or Revision, American Heart Association, November 15, 2009.
**LLD EZ® and LLD®**

**Lead locking devices**

The LLD EZ® and LLD® Lead Locking Devices are used to secure implanted pacing and defibrillation leads along the inner lumen to provide traction for lead removal. The LLD consists of two wire loop handles and a core mandrel with a stainless steel mesh locking mechanism. The braided mesh expands to provide traction along the entire lead lumen.

<table>
<thead>
<tr>
<th>Device</th>
<th>Model number</th>
<th>Locking range (in/mm)</th>
<th>Average tensile force (lbs)</th>
<th>Working length (cm)</th>
<th>Clearing stylet number / diameter</th>
</tr>
</thead>
<tbody>
<tr>
<td>Single</td>
<td>Pack of 3</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>#1</td>
<td>518-021</td>
<td>0.012 / 0.33</td>
<td>12</td>
<td>65</td>
<td>1 (0.012 / 0.30)</td>
</tr>
<tr>
<td></td>
<td>518-018</td>
<td>0.015 / 0.38</td>
<td>19</td>
<td>85</td>
<td>1 (0.012 / 0.30)</td>
</tr>
<tr>
<td>E</td>
<td>518-019</td>
<td>0.017 / 0.43</td>
<td>24</td>
<td>65</td>
<td>2 (0.015 / 0.38)</td>
</tr>
<tr>
<td>EZ</td>
<td>518-067</td>
<td>0.027 / 0.69</td>
<td>45</td>
<td>65</td>
<td>2 (0.015 / 0.38)</td>
</tr>
<tr>
<td>#2</td>
<td>518-022</td>
<td>0.019 / 0.42</td>
<td>19</td>
<td>65</td>
<td>1 (0.012 / 0.30)</td>
</tr>
<tr>
<td>#3</td>
<td>518-023</td>
<td>0.015 / 0.38</td>
<td>19</td>
<td>65</td>
<td>1 (0.012 / 0.30)</td>
</tr>
</tbody>
</table>

Diameter of inner lumen of the lead

- **EZ or E**
- **#1**
- **#2**
- **#3**

**Accessories**

<table>
<thead>
<tr>
<th>LLD accessory kit</th>
<th>Model number</th>
<th>518-027</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lead cutter</td>
<td>Model number</td>
<td>518-024</td>
</tr>
</tbody>
</table>

**Package content:** LLD Accessory Kit: 1 Coil expander, 2 Pin Gauges Lead Cutter: 1 Lead Cutter

For important safety information, please see IFU: www.spnc.com/ifu

---

**Prepare**

- **1 cm Radiopaque marker**
- **To lock, release proximal connector from crimped section of mandrel**
- **To unlock after initial deployment**
- **Highly visible radiopaque marker assists identification of LLD EZ and LLD E tip location under fluoroscopy**
- **Low-profile loop handles (LLD EZ)**

**Pin number**

- **Pin #1 fits, but not E/EZ**
- **Pin E/EZ fits, but not #2**
- **Pin #2 fits, but not #3**
- **E or EZ**
- **Pin #3 fits**

The Spectranetics Lead Cutter is used to gain access to the inner lumen of a pacing/defibrillator lead by cutting through the insulation and coils cleanly. The lead cutter is constructed with stainless steel.

CVX-300® and CVX-300p®
Excimer laser system

Spectranetics excimer laser technology treats complex cardiovascular conditions through the unique mechanism of pulsed photoablation.

Indicated treatments using the CVX-300 and excimer laser catheters include removing lesions comprising atheroma, fibrosis, calcium, thrombus, and neointimal hyperplasia in the coronary and peripheral vasculature and include transvenous removal of problematic pacing and defibrillator leads. Operators—both physicians and hospital staff—can anticipate an easy-to-use system with simple set-up.

The Spectranetics excimer laser platform coupled with excimer laser catheters is indicated for use in several applications within the minimally invasive interventional cardiovascular market.

Laser-assisted lead removal has an established safety profile and has proven effective in multiple clinical trials:

- The laser sheath enables fast and predictable lead removal procedures.
- Laser technology enables higher success rates than mechanical sheaths.

Excimer Laser System Maintenance

The CVX-300 Excimer Laser System is a precision instrument that will provide years of service with a very low failure rate when properly serviced and maintained.

Spectranetics offers a full complement of factory-certified service options for the laser to meet our customers’ needs. These programs, designed with our customers in mind, eliminate the need for institutions to purchase any specialty tools or equipment required for servicing.

<table>
<thead>
<tr>
<th>Service level</th>
<th>Annual customer benefits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Premium plus service agreement*</td>
<td>- Complete service coverage of the laser system, including replacement of the laser vessel, non-consumable and consumable parts.</td>
</tr>
<tr>
<td></td>
<td>- Includes emergency calls and preventative maintenance.</td>
</tr>
<tr>
<td></td>
<td>- On-site labor, M-F</td>
</tr>
<tr>
<td>Premium service agreement</td>
<td>- Meets JCAHO requirements.</td>
</tr>
<tr>
<td></td>
<td>- Ensures maximum up-time and optimal operation of the laser.</td>
</tr>
<tr>
<td></td>
<td>- Multi-year discounts available.</td>
</tr>
<tr>
<td></td>
<td>- 24/7 technical support assistance.</td>
</tr>
</tbody>
</table>

| Preventive maintenance agreement | - Coverage for two (2) preventive maintenance calls, including consumable parts. |
|                                | - Excludes replacement of the laser vessel and failed non-consumable parts.             |
|                                | - Excludes emergency calls.                                                             |

| Time and materials coverage | - Customer elects to pay the hourly rate for travel and labor in addition to the current list price for all consumable and non-consumable parts required. |

Service excellence guarantee

Spectranetics guarantees that all service completed on your system will be performed by factory-trained and certified Field Service Engineers utilizing only authorized and approved components. Spectranetics is the only authorized service group for the CVX-300 Excimer Laser Systems.


* Not all systems qualify for PLUS coverage; please call Spectranetics Field Service for specific details.
**GlideLight™ Laser sheath**

The GlideLight™ Laser Sheath is used to remove implanted pacing and defibrillator leads.

Safely and efficiently removing leads depends on tools that give you versatility and control. The GlideLight Laser Sheath offers the unprecedented ability to customize the laser’s repetition rate throughout a procedure. The GlideLight Laser Sheath incorporates optical fibers arranged in a circle. The fibers terminate at the distal end within a polished tip and the fibers are also connected at the proximal end within the coupler that mates with the CVW-300® Excimer Laser System. The energy emitted from the tip ablates the tissue holding the lead, thereby freeing the lead in a controlled fashion.

### Specification Table

<table>
<thead>
<tr>
<th>Model number</th>
<th>500-301</th>
<th>500-302</th>
<th>500-303</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sheath size</td>
<td>12F</td>
<td>14F</td>
<td>16F</td>
</tr>
<tr>
<td>Max target lead diameter (F/in/mm)</td>
<td>7.5/0.098/2.50</td>
<td>9.5/0.124/3.17</td>
<td>11.5/0.150/3.83</td>
</tr>
<tr>
<td>Min tip inner diameter (F/in/mm)</td>
<td>8.3/0.109/2.77</td>
<td>10.2/0.134/3.40</td>
<td>12.5/0.164/4.17</td>
</tr>
<tr>
<td>Max tip outer diameter (F/in/mm)</td>
<td>12.5/0.164/4.17</td>
<td>14.7/0.192/4.88</td>
<td>17.2/0.225/5.72</td>
</tr>
<tr>
<td>Working length (cm)</td>
<td>50</td>
<td>50</td>
<td>50</td>
</tr>
<tr>
<td>Repetition rate (Hz)</td>
<td>25-80</td>
<td>25-80</td>
<td>25-80</td>
</tr>
<tr>
<td>Clinical energy setting (mJ/mm²)</td>
<td>30-60</td>
<td>30-60</td>
<td>30-60</td>
</tr>
</tbody>
</table>

Package content: 1 laser sheath, 2 outer sheaths, 1 fish tape.

- Low-temperature excimer laser has a 50–micron penetration depth
- 15˚ bevel tip
- Flexible distal segment
- Lubricious coating along inner lumen
- Customizable repetition rate from 25Hz to 80Hz, based on anatomical and procedural considerations

### Diagrams

**Flexible pulse repetition rate**

**Advancement rate at constant force**

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 10 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.

For important safety information, please see IFU: www.spnc.com/ifu

---

**Less unintended forward motion**

GlideLight Laser Sheath allows you to customize the repetition rate.

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

GlideLight Laser Sheath enables you to advance up to 62% more efficiently through tough binding sites.

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 10 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.

For important safety information, please see IFU: www.spnc.com/ifu
The SLS® II Laser Sheath is used to remove implanted pacing and defibrillator leads.

The SLS II incorporates optical fibers arranged in a circle. The fibers terminate at the distal end within a polished tip and at the proximal end within the coupler that mates with the CVX-300® Excimer Laser System. The energy emitted from the tip ablates the tissue holding the lead, thereby freeing the lead in a controlled fashion.

- Low-temperature excimer laser has a 50-micron penetration depth
- 15˚ bevel tip
- Flexible distal segment
- Lubricious coating along inner lumen

### Model number

<table>
<thead>
<tr>
<th>12F Kit</th>
<th>14F Kit</th>
<th>16F Kit</th>
</tr>
</thead>
<tbody>
<tr>
<td>500-001</td>
<td>500-012</td>
<td>500-013</td>
</tr>
</tbody>
</table>

| Max target lead diameter (F/in/mm) | 7.5/0.098/2.50 | 9.5/0.124/3.17 | 11.5/0.150/3.83 |
| Min tip inner diameter (F/in/mm) | 8.3/0.109/2.77 | 10.2/0.134/3.40 | 12.5/0.164/4.17 |
| Max tip outer diameter (F/in/mm) | 12.5/0.164/4.17 | 14.7/0.192/4.88 | 17.2/0.225/5.72 |
| Min outer sheath inner diameter (F/in/mm) | 13.0/0.170/4.33 | 15.5/0.203/6.31 | 18.2/0.238/6.07 |
| Max outer sheath inner diameter (F/in/mm) | 16.4/0.215/5.47 | 19.3/0.253/6.43 | 22.4/0.294/7.47 |
| Working length (cm) | 50 | 50 | 50 |
| Repetition rate (Hz) | 25-40 | 25-40 | 25-40 |
| Clinical energy setting (mJ/mm²) | 30-60 | 30-60 | 30-60 |

Package content: 1 laser sheath, 2 outer sheaths, 1 fish tape.

- Low-temperature excimer laser has a 50-micron penetration depth
- 15˚ bevel tip
- Flexible distal segment
- Lubricious coating along inner lumen

A ring of laser energy ablates contacted tissue around the circumference of the lead. The low-temperature excimer laser operates in the ultraviolet spectrum at 308nm to ablate target tissue at a depth of 50 microns.

### Lead removal success rates

![Graph showing lead removal success rates: PLEXES 64%, LExiCon 94%, Laser Sheath 96.5%]

### Lead removal time

![Graph showing lead removal time: Mechanical Sheath 12.9 ± 19.2 minutes, Laser Sheath 10.1 ± 11.5 minutes]

*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.


For important safety information, please see IFU: www.spnc.com/ifu
When removing a lead is the right decision, turn to TightRail. Its next-generation design advances provide the flexibility, control and safety required to effectively extract cardiac leads.

<table>
<thead>
<tr>
<th>Model number</th>
<th>Size</th>
<th>Device inner diameter (F/in/mm)</th>
<th>Device outer diameter (F/in/mm)</th>
<th>Outer sheath inner diameter (F/in/mm)</th>
<th>Working length (in/cm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>545-009</td>
<td>9F</td>
<td>6.2/0.159/3.7</td>
<td>15.8/0.207/5.3</td>
<td>20.0/0.266/6.8</td>
<td>18.7/47.5</td>
</tr>
<tr>
<td>545-011</td>
<td>11F</td>
<td>11.2/0.145/3.7</td>
<td>18.0/0.234/5.9</td>
<td>23.0/0.293/7.4</td>
<td>18.7/47.5</td>
</tr>
<tr>
<td>545-013</td>
<td>13F</td>
<td>13.2/0.171/4.3</td>
<td>20.0/0.260/6.6</td>
<td>25.0/0.319/8.1</td>
<td>18.7/47.5</td>
</tr>
</tbody>
</table>

Package content: 1 TightRail sheath, 1 compatible outer sheath.

Flexible shaft
To remain coaxial to the lead. The unique shaft technology combines flexibility with column strength, enabling forward progression through vasculature and commonly encountered fibrotic lesions.

Shielded dilating blade
The dilating blade remains shielded until activated, allowing safe counter-traction at the targeted lead’s distal tip.

Bidirectional mechanism
designed to effectively dilate commonly encountered fibrotic lesions by rotating 574 degrees—287 degrees clockwise and 287 degrees counterclockwise—while extending the blade just 0.02 inches, or 0.5mm.

Static outer shaft
Because the outer shaft does not rotate with the blade, an outer sheath is optional, based on your preference and the clinical scenario.

The subclavian region presents a variety of clinical challenges, including vessel entry when fibrosis and calcium are present. The TightRail Sub-C Rotating Dilator Sheath can be used alone or in conjunction with laser or other TightRail sheaths to safely and efficiently move through subclavian fibrosis and calcium for predictable vessel entry. It is designed for the subclavian region, featuring:
• A specialized cutting tip for subclavian vessel entry
• A short, stiff shaft at base for pushability
• A flexible tip for trackability
• A shielded rotational blade to minimize risk to vessels and adjacent leads

<table>
<thead>
<tr>
<th>Model number</th>
<th>Size</th>
<th>Device inner diameter (F/in/mm)</th>
<th>Device outer diameter (F/in/mm)</th>
<th>Outer sheath inner diameter (F/in/mm)</th>
<th>Working length (in/cm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>560-003</td>
<td>9F</td>
<td>8.1/0.191/3.0</td>
<td>14.4/0.213/5.5</td>
<td>18.8/0.245/6.3</td>
<td>6.1/15.5</td>
</tr>
<tr>
<td>560-011</td>
<td>11F</td>
<td>11.1/0.145/3.7</td>
<td>16.4/0.213/5.5</td>
<td>20.9/0.271/6.9</td>
<td>6.1/15.5</td>
</tr>
<tr>
<td>560-013</td>
<td>13F</td>
<td>13.1/0.171/4.3</td>
<td>18.4/0.239/6.1</td>
<td>22.9/0.297/7.6</td>
<td>6.1/15.5</td>
</tr>
</tbody>
</table>

Package Content: 1 TightRail sheath, 1 compatible outer sheath.

TightRail™ features a shielded, bi-directional blade.
TightRail Sub-C’s lower profile cutting tip is specifically designed for the subclavian region.
SightRail™ and TorqMax®

Dilator sheath set and accessory

SightRail™ Dilator Sheath Set: A new solution for confident lead removal

SightRail telescoping manual sheaths are a next-generation design advancement. SightRail sheaths provide ease of positioning and manipulation during cardiac lead removal procedures.

<table>
<thead>
<tr>
<th>Model number</th>
<th>Size</th>
<th>Inner/outer length (cm)</th>
<th>Color</th>
<th>Min. Inner diameter (F/in:mm)</th>
<th>Max. outer diameter (F/in:mm)</th>
<th>Min. Inner diameter (F/in:mm)</th>
<th>Max. outer diameter (F/in:mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>550-008</td>
<td>8.5F</td>
<td>43 / 33</td>
<td>Yellow</td>
<td>8,1/0,107/2,7</td>
<td>10,9/0,143/3,7</td>
<td>11,2/0,147/3,7</td>
<td>14,0/0,183/4,7</td>
</tr>
<tr>
<td>555-508</td>
<td>8.5F long</td>
<td>51 / 41</td>
<td>Yellow</td>
<td>8,1/0,107/2,7</td>
<td>10,9/0,143/3,7</td>
<td>11,2/0,147/3,7</td>
<td>14,0/0,183/4,7</td>
</tr>
<tr>
<td>550-010</td>
<td>10F</td>
<td>43 / 33</td>
<td>Green</td>
<td>9,6/0,127/3,2</td>
<td>12,5/0,163/4,2</td>
<td>12,7/0,167/4,2</td>
<td>15,5/0,203/5,2</td>
</tr>
<tr>
<td>555-510</td>
<td>10F long</td>
<td>51 / 41</td>
<td>Green</td>
<td>9,6/0,127/3,2</td>
<td>12,5/0,163/4,2</td>
<td>12,7/0,167/4,2</td>
<td>15,5/0,203/5,2</td>
</tr>
<tr>
<td>550-011</td>
<td>11.5F</td>
<td>43 / 33</td>
<td>White</td>
<td>11,2/0,147/3,7</td>
<td>14,0/0,183/4,7</td>
<td>14,2/0,187/4,7</td>
<td>17,0/0,223/5,7</td>
</tr>
<tr>
<td>555-511</td>
<td>11.5F long</td>
<td>51 / 41</td>
<td>White</td>
<td>11,2/0,147/3,7</td>
<td>14,0/0,183/4,7</td>
<td>14,2/0,187/4,7</td>
<td>17,0/0,223/5,7</td>
</tr>
<tr>
<td>550-013</td>
<td>13F</td>
<td>43 / 33</td>
<td>Orange</td>
<td>12,7/0,167/4,2</td>
<td>15,5/0,203/5,2</td>
<td>15,7/0,207/5,2</td>
<td>18,6/0,243/6,2</td>
</tr>
<tr>
<td>555-513</td>
<td>13F long</td>
<td>51 / 41</td>
<td>Orange</td>
<td>12,7/0,167/4,2</td>
<td>15,5/0,203/5,2</td>
<td>15,7/0,207/5,2</td>
<td>18,6/0,243/6,2</td>
</tr>
</tbody>
</table>

Package Content: 1 inner sheath and 1 outer sheath

The TorqMax® Sheath Grip Accessory is used to enhance grip on outer support and dilator sheaths and catheter devices.

<table>
<thead>
<tr>
<th>Model number</th>
<th>Minimum sheath outer diameter</th>
<th>Maximum sheath outer diameter</th>
<th>Sheath grip length</th>
</tr>
</thead>
<tbody>
<tr>
<td>501-001</td>
<td>11.0 F/0.155 in/4.0 mm</td>
<td>22.5 F/0.295 in/7.5 mm</td>
<td>64 mm</td>
</tr>
</tbody>
</table>

Package content: 1 sheath

Easy to position
- Printed indicators for bevel orientation and tip alignment, so you know that the sheaths are oriented and positioned correctly.
- Though fluoroscopy is the primary method of visualization, SightRail gives you an additional method of directly ensuring the position and orientation of the sheaths.

Easy to manipulate
- The inner sheath length is 10 centimeters longer than the outer sheath, making the device easy to manipulate.
- SightRail™ reduces the resistance between the inner sheath and the outer sheath by 14%.
Ergonomic grip
• Contoured polymer shell with soft over-mold construction designed for comfortable user interface.
• Provides mechanical advantage to more easily rotate the body of an associated sheath.
• Distributes forces along the sheath body to aid in sheath advancement.

Easy side-loading
• Loads quickly and easily from the side—permitting easy removal or repositioning during procedures.
• Stays on the sheath where it is positioned, until the user chooses to move it.

Flexible sizing
• One size spans a wide range of sheath outer diameters – from 11.9F to 22.5F.
• Compatible with all Spectranetics Laser Sheaths and associated outer sheaths.

Bevel orientation indicators
• Outer sheath tip is more distal than inner sheath tip.
• Distal tips of inner and outer sheaths are aligned.
• Inner sheath tip is more distal than outer sheath tip.
VisiSheath®

Dilator sheath

The VisiSheath® Dilator Sheath acts as an independent sheath or outer support sheath for dilating tissue surrounding cardiac leads, indwelling catheters and foreign objects. VisiSheath’s gold-coated steel marker bands provide over 200% better fluoroscopic visibility than standard Teflon or polypropylene sheaths.* An advanced multilayer construction and robust tip design deliver high performance. Nine sizes provide options for different clinical scenarios and user preferences.

<table>
<thead>
<tr>
<th>Model number</th>
<th>Size</th>
<th>Min. Inner diameter (F/in/mm)</th>
<th>Max. outer diameter (F/in/mm)</th>
<th>Length (cm)</th>
<th>Laser sheath compatibility (F)</th>
</tr>
</thead>
<tbody>
<tr>
<td>501-012</td>
<td>S</td>
<td>12.8/0.168/4.2</td>
<td>16.4/0.215/5.5</td>
<td>43</td>
<td>12</td>
</tr>
<tr>
<td>501-014</td>
<td>M</td>
<td>15.0/0.198/5.0</td>
<td>19.3/0.253/6.5</td>
<td>43</td>
<td>14</td>
</tr>
<tr>
<td>501-016</td>
<td>L</td>
<td>17.9/0.236/5.9</td>
<td>22.4/0.293/7.5</td>
<td>43</td>
<td>16</td>
</tr>
<tr>
<td>501-112</td>
<td>S</td>
<td>12.8/0.168/4.2</td>
<td>16.4/0.215/5.5</td>
<td>33</td>
<td>12</td>
</tr>
<tr>
<td>501-114</td>
<td>M</td>
<td>15.0/0.198/5.0</td>
<td>19.3/0.253/6.5</td>
<td>33</td>
<td>14</td>
</tr>
<tr>
<td>501-116</td>
<td>L</td>
<td>17.9/0.236/5.9</td>
<td>22.4/0.293/7.5</td>
<td>33</td>
<td>16</td>
</tr>
<tr>
<td>501-212</td>
<td>S</td>
<td>12.8/0.168/4.2</td>
<td>16.4/0.215/5.5</td>
<td>23</td>
<td>12</td>
</tr>
<tr>
<td>501-214</td>
<td>M</td>
<td>15.0/0.198/5.0</td>
<td>19.3/0.253/6.5</td>
<td>23</td>
<td>14</td>
</tr>
<tr>
<td>501-216</td>
<td>L</td>
<td>17.9/0.236/5.9</td>
<td>22.4/0.293/7.5</td>
<td>23</td>
<td>16</td>
</tr>
</tbody>
</table>

Package content: 1 sheath

- Advanced multi-layer construction with gold-coated, steel marker bands for superior visibility
- Flexibility for tracking without kinking
- Exterior orientation line and robust beveled tip design
- Nine sizes: three lengths and three diameters
- Strong torque delivery
- Resists deformation better than common Teflon construction

Advanced multi-layer construction:

Pebax® with Teflon® Liner

Outstanding flexibility for tracking without kinking*
- 85% and 38% more bending deflection without kinking compared to similar sized polypropylene and Teflon sheaths respectively

Strong torque delivery*
- Over 50% better torque response than Teflon sheaths

90% better fluoroscopic visibility*
- Enables easy identification of tip location and bevel orientation.

Nine size options

Three lengths – available in three diameters – provide options for clinical scenarios and user preferences.

VisiSheath blunt end vs. Teflon
VisiSheath beveled end vs. Teflon
VisiSheath acting as an outer support for an SLS II laser sheath over a pacing lead
VisiSheath beveled end vs. Teflon under simulated low quality fluoroscopy

* Compared to common Teflon or polypropylene sheaths (data on file at Spectranetics). Pebax® is a registered trademark of Arkema. Teflon® is a registered trademark of Dupont®.
Bridge®
Occlusion balloon

Though rare, SVC tears during lead extraction can happen. The Bridge™ occlusion balloon maintains acceptable hemostasis for at least 30 minutes, giving you time to stabilize your patient and transition to surgery.

<table>
<thead>
<tr>
<th>Bridge™ occlusion balloon catheter specifications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Catalog #: 590-001</td>
</tr>
<tr>
<td>Catheter length: 90 cm</td>
</tr>
<tr>
<td>Balloon diameter: (nominal) 20 mm</td>
</tr>
<tr>
<td>Balloon length: (nominal) 80 mm</td>
</tr>
<tr>
<td>Maximum OD: (crossing profile) 4 mm/0.157”</td>
</tr>
<tr>
<td>Minimum tip ID: 0.9 mm/0.035”</td>
</tr>
<tr>
<td>Maximum inflation volume: 60cc</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Bridge™ prep kit specifications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Catalog #: 591-001</td>
</tr>
<tr>
<td>Description: Bridge™ occlusion balloon compatible guidewire, introducer sheath sets, syringe and stopcock</td>
</tr>
</tbody>
</table>

Bridge™ is a low pressure, compliant balloon designed to conform to the SVC.

The Bridge™ occlusion balloon can be deployed in less than two minutes via a pre-placed guidewire. Bridge is easy to use, with no additional balloon preparation required. Radiopaque markers guide proper placement. Bridge is designed to cover the entire length and diameter of the SVC in 90% of patients.

Once deployed, the Bridge™ occlusion balloon can dramatically reduce blood loss. In an animal model of an SVC tear, Bridge reduced blood loss by up to 90% on average in tears up to 3.5 cm, with two pacing leads and one ICD lead in place.

Bridge™ occlusion balloon can provide at least 30 minutes of acceptable hemostasis - time to stabilize your patient and transition to surgery. With Bridge, the surgical team can approach the repair in a controlled setting with a clear field of view.

Fluoroscopy image of Bridge™ balloon in an animal model.

1. Document on file D027562. Bridge can be fully deployed in under one minute (53 seconds) in an animal model when pre-positioned on a guidewire, or in under two minutes (1 minute, 46 seconds) when not pre-positioned.
2. Document on file D027563. The balloon will cover the length and diameter of the SVC in 90% of the population as determined by analysis of 52 patients (N=52, % Male=48.1, Average Age 47.1 ± 16.5, Age Range 63 (18 to 81 years), Average Height 170.8cm ± 10.6, Height Range 40.6cm (152.4 to 193cm), Average BMI 29.8 ± 7.2, BMI Range 32.1 (18.2 to 50.3)).
3. Document on file D027561. When deployed, the Bridge™ occlusion balloon reduces blood loss by up to 90%, on average, in an animal model of an SVC tear. Testing was conducted in a heparinzed porcine model which has shorter SVC length than is typical in humans. A balloon design scaled for use specifically in the porcine model was used in generating this data.

HRS Expert Consensus Statement 2017

Vascular Tears

“Deployment of an occlusive compliant balloon for SVC tears can control the severity of bleeding while the chest is opened and definitive repair is pursued.”

“Positioning an introducer sheath and a stiff guide wire that extends from the femoral vein to the right internal jugular or subclavian vein at the beginning of the extraction procedure allows for rapid deployment of an occlusive balloon to minimize bleeding as the patient is rapidly prepared for definitive repair.”

Secure