PRODUCT CATALOG
Spectranetics is dedicated to managing every lead and eradicating restenosis and amputation. We do this by helping physicians, patients, and hospitals maximize cardiovascular health.

Our company is committed to inventing, selling, and supporting technology that enables success during the most challenging minimally invasive cardiovascular procedures. We provide expert physician training, including the only lead removal simulator in the industry, as well as extensive patient and physician education.

The Company’s Lead Management (LM) division is dedicated to helping physicians safely manage every lead. We provide the expert tools, training and ongoing support – including the only available lead extraction simulator – 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.

The Vascular Intervention (VI) division is dedicated to helping physicians address the challenges of peripheral and coronary artery disease. We provide expert tools, training, ongoing support, and patient education so that you can help eradicate restenosis and amputation.

Here’s how to contact us:

**North American Customer Service and Product Orders:**

<table>
<thead>
<tr>
<th>Telephone: 1-800-231-0978</th>
<th>Address: The Spectranetics Corporation 9965 Federal Drive Colorado Springs, CO 80921-3617</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fax: 1-877-447-2022 / 719-447-2022</td>
<td></td>
</tr>
</tbody>
</table>

**German Customer Service and Product Orders:**

<table>
<thead>
<tr>
<th>Product Orders: +49 931/4520080</th>
<th>Address: Spectranetics Deutschland GmbH Schweinfurter Str. 7 97080 Würzburg, Germany</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fax: +49 931/45200811</td>
<td></td>
</tr>
</tbody>
</table>

**International Customer Service and Product Orders:**

<table>
<thead>
<tr>
<th>Telephone: +31 33 4347 050</th>
<th>Address: Spectranetics International B.V. Plesmanstraat 6, 3833 LA Leusden The Netherlands</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fax: +31 33 4347 051</td>
<td></td>
</tr>
</tbody>
</table>

**To Report an Adverse Event**

North America: Please call 1-800-231-0978, or e-mail us at complaints@spnc.com

International: Please call +31 33 4347 050, or e-mail us at customerservice@bv.spnc.com

*The Spectranetics Corporate Headquarters in Colorado Springs, Colorado*
1. **Purchasing**
   - **Shipping:** Customer is responsible for freight/delivery charges. Unless the customer specifies otherwise, product will ship FedEx 3-Day Select (Third Afternoon). All products are shipped FOB Origin (Colorado Springs, CO).
   - **Terms:** Net 30 days.

2. **Unused/Unopened Product Returns**
   Customer must obtain authorization prior to returning any unused products. Customer can obtain a Return Material Authorization (RMA) number and shipping address by calling Customer Service at (800) 231-0978. Customer must include the RMA number on the front of the package being returned. Customer must pay return shipping charges. All returned items are subject to a 20% restocking fee. Authorization to return does not assure that Customer will be issued a monetary credit for the returned items(s). Customer may receive credit only on items that are returned in a saleable condition, prior to expiration, and within 90 days of purchase.

3. **Used or Opened Product Returns**
   As a manufacturer and distributor of medical devices, Spectranetics has a special responsibility to the patients, physicians, and hospital staff members who use its devices. Spectranetics needs to be able to analyze any device that is thought to be faulty in order to assure that its products are as efficacious as possible and to pursue improvements. If Customer is returning a product because of a complaint with the product’s performance, Customer must return any allegedly faulty device for analysis together with information regarding its use in order to be eligible for credit for the product’s cost. Customer must contact Post Market Surveillance at the following contacts for instructions on how to return used or opened product: Phone: 888-341-0035 or Email: complaints@spnc.com

4. **Limited Warranty**
   Spectranetics warrants that all of its disposable products are free from defects in material and workmanship when used by the stated “Use By” date and when package is unopened and undamaged immediately before use. Spectranetics’ liability under this warranty is limited to replacement or refund of the purchase price of any defective product. Spectranetics will not be liable for any incidental, special, or consequential damages resulting from use of its products. Damage to the disposable products caused by misuse, alteration, improper storage or handling, or any other failure to follow the Instructions for Use will void this limited warranty. **THIS LIMITED WARRANTY IS EXPRESSLY IN LIEU OF ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING THE IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.** No person or entity, including any authorized representative or reseller of Spectranetics, has the authority to extend or expand this limited warranty and any purported attempt to do so will not be enforceable against Spectranetics.

5. **No Laser Terms**
   These terms and conditions relate only to the disposable products. Information on Spectranetics’ warranty relating to the CVX-300® Excimer Laser can be found in the Operator’s Manual.
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.

Spectranetics Vascular Intervention markets and sells the excimer laser platform and disposable laser catheters to interventional cardiologists and radiologists and vascular surgeons for the following Indications for Use in both peripheral and coronary interventional procedures:

**Peripheral Procedures**
- Treatment of infrainguinal stenoses and occlusions
- Critical Limb Ischemia (CLI)
- Total occlusions crossable by guidewires

**Coronary Procedures**
- Moderately calcified stenoses
- Occluded saphenous vein bypass grafts
- Long diffuse disease
- Restenosis in 316L stainless steel stents, prior to the administration of intravascular brachytherapy
- Lesions that previously failed balloon angioplasty
- Balloon-refractory and balloon-resistant lesions
- Ostial lesions

Additionally, the laser and fiber optic catheter system has FDA-cleared individualization of treatment for the following:
- In coronary procedures, excimer laser treatment may be considered in the presence of acute myocardial infarction, acute thrombus, and ejection fraction of less than (<) 30%
- In peripheral procedures, excimer laser treatment may be considered if a guidewire crossing attempt is unsuccessful, the proximal occlusion cap deflects the guidewire into a subintimal path or collateral branch, and if calcification obstructs the complete passage of the guidewire through the lesion
- Additionally, in peripheral procedures, recanalization of native arteries may be considered when presented with occluded bypass grafts

Spectranetics Lead Management provides the excimer laser platform and disposable laser sheaths for transvenous removal of chronically implanted pacing and defibrillator leads.

**Lead Management Procedures**
- 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

For more information, visit [www.spnc.com](http://www.spnc.com) • To order, call 1-800-231-0978, international: +31 33 4347 050

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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</td>
<td>• Complete service coverage of the laser system, including replacement of the laser vessel, non-consumable and consumable parts.</td>
</tr>
<tr>
<td>Agreement*</td>
<td>• Includes emergency calls and preventative maintenance.</td>
</tr>
<tr>
<td></td>
<td>• On-site labor, M-F.</td>
</tr>
<tr>
<td></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>
<tr>
<td>Premium Service</td>
<td>• Coverage for consumable and non-consumable parts.</td>
</tr>
<tr>
<td>Agreement</td>
<td>• Does not include replacement of the laser vessel.</td>
</tr>
<tr>
<td></td>
<td>• On-site labor, 8:00 a.m.-5:00 p.m., M-F.</td>
</tr>
<tr>
<td></td>
<td>• Includes emergency calls and preventative maintenance.</td>
</tr>
<tr>
<td></td>
<td>• Meets JCAHO requirements.</td>
</tr>
<tr>
<td></td>
<td>• Ensures high-uptime and 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>
<tr>
<td>Preventive Maintenance</td>
<td>• Coverage for two (2) preventive maintenance calls, including consumable parts.</td>
</tr>
<tr>
<td>Agreement</td>
<td>• Excludes replacement of the laser vessel and failed non-consumable parts.</td>
</tr>
<tr>
<td></td>
<td>• Excludes emergency calls.</td>
</tr>
<tr>
<td>Time and Materials</td>
<td>• 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.</td>
</tr>
<tr>
<td>Coverage</td>
<td></td>
</tr>
</tbody>
</table>

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

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.
Turbo Elite® Laser Atherectomy Catheter: The innovative, safe and proven way to cost-effectively cross, prepare and preserve vessels above and below the knee.

Using UV laser technology that ablates multiple lesion morphologies at the molecular level, the Turbo Elite Laser Catheter provides the precision, control and versatility required to preserve and treat vessels in even the most challenging cases. The system offers proven performance with a single catheter that is capable of both crossing and debulking long, diffuse lesions and total occlusions at multiple sites within the peripheral vasculature.

Primary Product Features:
• Enhanced fiber configuration precisely and reliably delivers UV light direct from the tip of the catheter to the lesion
• Multiple size options accommodate various anatomical and procedural challenges
• Laser settings for use in multiple lesion types

Primary Product Benefits:
• Safe & Proven Technology – Demonstrated clinical safety and efficacy in both the ability to treat multiple morphologies and the ability to treat above and below-the-knee*
• Versatile Solution – Innovative laser technology directly vaporizes lesions composed of varying morphologies with a single catheter
• Cost-Effective Option – The most cost effective atherectomy solution on a case-by-case basis as compared to other atherectomy competitors

OTW Peripheral Over-the-Wire Catheters

<table>
<thead>
<tr>
<th>Catheter Diameter</th>
<th>0.9mm</th>
<th>1.4mm</th>
<th>1.7mm</th>
<th>2.0mm</th>
<th>2.3mm</th>
<th>2.5mm</th>
<th>2.3mm</th>
<th>2.5mm</th>
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</thead>
<tbody>
<tr>
<td>Model Number</td>
<td>410-152</td>
<td>414-151</td>
<td>417-152</td>
<td>420-006</td>
<td>423-001</td>
<td>425-001</td>
<td>423-135</td>
<td>425-135</td>
</tr>
<tr>
<td>Vessel Diameter (mm)</td>
<td>≥ 1.4</td>
<td>≥ 2.1</td>
<td>≥ 2.6</td>
<td>≥ 3.0</td>
<td>≥ 3.5</td>
<td>≥ 3.8</td>
<td>≥ 3.5</td>
<td>≥ 3.8</td>
</tr>
<tr>
<td>Max Guidewire Compatibility (in)</td>
<td>0.014</td>
<td>0.014</td>
<td>0.018</td>
<td>0.018</td>
<td>0.018</td>
<td>0.018</td>
<td>0.035</td>
<td>0.035</td>
</tr>
<tr>
<td>Sheath Compatibility (F)</td>
<td>4</td>
<td>5</td>
<td>5</td>
<td>6</td>
<td>7</td>
<td>8</td>
<td>7</td>
<td>8</td>
</tr>
<tr>
<td>Max Tip Outer Diameter (in)</td>
<td>0.038</td>
<td>0.055</td>
<td>0.068</td>
<td>0.080</td>
<td>0.091</td>
<td>0.101</td>
<td>0.091</td>
<td>0.101</td>
</tr>
<tr>
<td>Max Shaft Outer Diameter (in)</td>
<td>0.047</td>
<td>0.056</td>
<td>0.069</td>
<td>0.081</td>
<td>0.091</td>
<td>0.102</td>
<td>0.091</td>
<td>0.102</td>
</tr>
<tr>
<td>Working Length (cm)</td>
<td>150</td>
<td>150</td>
<td>150</td>
<td>150</td>
<td>120</td>
<td>110</td>
<td>125</td>
<td>112</td>
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<tr>
<td>Fluence (mJ / mm²)</td>
<td>30-80</td>
<td>30-60</td>
<td>30-60</td>
<td>30-60</td>
<td>30-45</td>
<td>30-60</td>
<td>30-60</td>
<td>30-60</td>
</tr>
</tbody>
</table>

RX Peripheral Rapid Exchange Catheters

<table>
<thead>
<tr>
<th>Catheter Diameter</th>
<th>0.9mm</th>
<th>1.4mm</th>
<th>1.7mm</th>
<th>2.0mm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Model Number</td>
<td>410-154</td>
<td>414-159</td>
<td>417-156</td>
<td>420-159</td>
</tr>
<tr>
<td>Vessel Diameter (mm)</td>
<td>≥ 1.4</td>
<td>≥ 2.1</td>
<td>≥ 2.6</td>
<td>≥ 3.0</td>
</tr>
<tr>
<td>Max Guidewire Compatibility (in)</td>
<td>0.014</td>
<td>0.014</td>
<td>0.014</td>
<td>0.014</td>
</tr>
<tr>
<td>Sheath Compatibility (F)</td>
<td>4</td>
<td>5</td>
<td>6</td>
<td>7</td>
</tr>
<tr>
<td>Max Tip Outer Diameter (in)</td>
<td>0.038</td>
<td>0.057</td>
<td>0.069</td>
<td>0.080</td>
</tr>
<tr>
<td>Max Shaft Outer Diameter (in)</td>
<td>0.049</td>
<td>0.062</td>
<td>0.072</td>
<td>0.084</td>
</tr>
<tr>
<td>Working Length (cm)</td>
<td>150</td>
<td>150</td>
<td>150</td>
<td>150</td>
</tr>
<tr>
<td>Fluence (mJ / mm²)</td>
<td>30-80</td>
<td>30-60</td>
<td>30-60</td>
<td>30-60</td>
</tr>
<tr>
<td>Repetition Rate (Hz)**</td>
<td>25-80</td>
<td>25-80</td>
<td>25-80</td>
<td>25-80</td>
</tr>
</tbody>
</table>


** Based on software version.

For more information, visit www.spnc.com • To order, call 1-800-231-0978, international: +31 33 4347 050
**INDICATIONS FOR USE**

**US Only:** For use in the treatment, including atherectomy, of infrainguinal stenoses and occlusions.

Note: Successful step-by-step passage of guidewires does not necessarily ensure relief of critical limb ischemia. Additional procedures may be required.

**OUS:** For atherectomy of infrainguinal arteries.

**CONTRAINDICATIONS**

No known contraindications.

**WARNINGS**

Federal (USA) law restricts this device to sale by or on the order of a physician with appropriate training.

Spectranetics' Turbo Elite® Laser Atherectomy Catheters CVX-300® Excimer Laser software requirements:

<table>
<thead>
<tr>
<th>Software</th>
<th>Catheter Maximum Rep Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>V3.8XX</td>
<td>80 Hz</td>
</tr>
<tr>
<td>V3.7XX</td>
<td>40 Hz</td>
</tr>
</tbody>
</table>

When the laser catheter is in the body, it should be manipulated only while it is under fluoroscopic observation with radiographic equipment that provides high quality images.

**PRECAUTIONS**

This catheter has been sterilized using Ethylene Oxide and is supplied STERILE. The device is designated and intended for SINGLE USE ONLY and must not be resterilized and/or reused.

DO NOT resterilize or reuse this device, as these actions can compromise device performance or increase the risk of cross-contamination due to inappropriate reprocessing.

Reuse of this single use device could lead to serious patient injury or death and voids manufacturer warranties.

Store in a cool, dry place. Protect from direct sunlight and high temperatures (greater than 60°C or 140°F).

The sterility of the product is guaranteed only if the package is unopened and undamaged. Prior to use, visually inspect the sterile package to ensure that the seals have not been broken. Do not use the catheter if the integrity of the package has been compromised. Do not use catheter product if its “Use Before Date,” found on package labeling, has passed.

Before use, examine carefully all of the equipment to be used in the procedure for defects. Do not use any equipment if it is damaged.

After use, dispose of all equipment in accordance with applicable specific requirements relating to hospital waste, and potentially biohazardous materials.

**ADVERSE EVENTS**

Use of the Spectranetics Turbo Elite® in conjunction with the CVX-300® Excimer Laser may contribute to the following complications:

- **Procedural Complications**
  - Spasm
  - Major dissection
  - Thrombus
  - Distal embolization
  - Perforation

- **Other Serious Adverse Events**
  - Death
  - Reintervention
  - ALI
  - Major amputation
  - Bypass surgery
  - Hematoma with surgery

**Potential Adverse Events NOT Observed during Clinical Studies**

- Nerve injury
- AV fistula formation
- Endarterectomy
- Infection
- Stroke
- Myocardial infarction
- Arrhythmia

No long-term adverse effects on the arterial vessel wall, due to peripheral excimer laser recanalization, are known at this time.
Turbo-Tandem® Laser Guide Catheter with Laser Atherectomy Catheter integrates proven Spectranetics technologies to ablate plaque above the knee in vessels 5mm or greater, restoring blood flow to the lower extremities.

Turbo-Tandem is a laser atherectomy catheter constrained within a guiding catheter to facilitate the offset (biased position) of the laser atherectomy catheter. Turbo-Tandem is designed to be used to directionally ablate infrainguinal concentric and eccentric lesions in vessels >5mm with the 7F Turbo-Tandem or >5.5mm with the 8F Turbo-Tandem. Turbo-Tandem is not designed to be used in total or sub-total occlusions.

Primary Product Features:
- Now in two sizes!
  - Available for 7F and 8F sheath sizes
- Short-tapered distal tip
  - Easy passage through stenotic lesions
- 12 degree ramp
  - Consistent positioning of laser catheter
  - Precise targeting of lesion
- Spring-loaded handle
  - Quick and easy laser catheter advancement

Primary Product Benefits:
- Creates larger lumens
- Debulks lesions composed of multiple morphologies
- Maximum laser deflection

Turbo-Tandem Laser Guide Catheter with Laser Atherectomy Catheter

<table>
<thead>
<tr>
<th>Model Number</th>
<th>Working Length (cm)</th>
<th>Wire Compatibility (in / mm)</th>
<th>Sheath Compatibility (F / in / mm)</th>
<th>Min Retracted Crossing Profile (in / mm)</th>
<th>Max Extended Crossing Profile (in / mm)</th>
<th>Laser Catheter</th>
</tr>
</thead>
<tbody>
<tr>
<td>472-110</td>
<td>110</td>
<td>0.014 / 0.35</td>
<td>7 / ≥ 0.098 / 2.5</td>
<td>0.094 / 2.4</td>
<td>0.160 / 4.0</td>
<td>2mm OTW</td>
</tr>
<tr>
<td>482-110</td>
<td>110</td>
<td>0.014 / 0.35</td>
<td>8 / ≥ 0.113 / 2.9</td>
<td>0.107 / 2.7</td>
<td>0.185 / 4.7</td>
<td>2mm OTW</td>
</tr>
</tbody>
</table>
INDICATIONS FOR USE
Indicated for atherectomy of infrainguinal arteries.

CONTRAINDICATIONS
No known contraindications. See complete IFU for more information before attempting use of Turbo-Tandem.

WARNINGS
Do not use without a guidewire, as vessel injury may result. Always advance and manipulate the Turbo-Tandem System under fluoroscopic guidance to confirm the location and orientation of the tip. Do not attempt to advance or retract the laser catheter against resistance until the reason for the resistance has been determined by fluoroscopy or other means. Confirm the laser catheter is in the retracted state when advancing or retracting the Turbo-Tandem System without lasing. Do not inject contrast media through the Turbo-Tandem System or guidewire lumen as this could cause the system to lock-up and may lead to complications.

PRECAUTIONS
Read the CVX-300® Excimer Laser System Operator’s Manual thoroughly before operating the CVX-300 Excimer Laser System to ensure safe operation of the system. This catheter has been sterilized using Ethylene Oxide and is supplied STERILE. The device is designated and intended for SINGLE USE ONLY and cannot be re-sterilized and/or reused. During the procedure, appropriate anticoagulant and vasodilator therapy should be provided to the patient per the institution’s interventional protocols. The proximal coupler of the laser catheter connects only to the CVX-300 Excimer Laser System and is not meant to have any patient contact. Do not use the Turbo-Tandem System if any damage is observed. Advancement, manipulation, withdrawal of the Turbo-Tandem System, and advancement, re-positioning or retraction of the laser catheter should always be performed under fluoroscopic guidance.
The ELCA® Coronary Laser Atherectomy Catheter is a versatile treatment option for recanalizing occluded coronary arteries.

The catheter is constructed of an arrangement of optical fibers contained within a flexible shaft surrounding an 0.014" guidewire lumen. With seven indications and nine different product offerings, this product allows physicians to treat even the most complex lesions with precision. ELCA laser catheters are offered in rapid exchange and over-the-wire designs, concentric and eccentric laser fiber configurations, and four different catheter sizes.

**Primary Product Features:**
- Optimally spaced fibers for improved performance
- Adjustable laser energy settings to meet many clinical needs
- Automatic shut-off feature for advanced patient safety

**Primary Product Benefits:**
- Proven patient safety
- Precise treatment of concentric or eccentric lesions
- Broad clinical applications via seven indications

<table>
<thead>
<tr>
<th>Model Number</th>
<th>0.9mm</th>
<th>1.4mm</th>
<th>1.7mm</th>
<th>1.7mm E*</th>
<th>2.0mm</th>
<th>2.0mm E*</th>
<th>0.9mm</th>
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</thead>
<tbody>
<tr>
<td>Guidewire Compatibility (in)</td>
<td>0.014</td>
<td>0.014</td>
<td>0.014</td>
<td>0.014</td>
<td>0.014</td>
<td>0.014 / 0.018</td>
<td>0.014</td>
</tr>
<tr>
<td>Guide Catheter Compatibility (F)</td>
<td>6</td>
<td>6 / 7</td>
<td>7</td>
<td>7</td>
<td>8</td>
<td>8</td>
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<tr>
<td>Minimum Vessel Diameter (mm)</td>
<td>1.5</td>
<td>2.2</td>
<td>2.5</td>
<td>2.5</td>
<td>3.0</td>
<td>3.0</td>
<td>1.5</td>
</tr>
<tr>
<td>Max Tip Outer Diameter (in)</td>
<td>0.038</td>
<td>0.057</td>
<td>0.069</td>
<td>0.066</td>
<td>0.080</td>
<td>0.079</td>
<td>0.038</td>
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<tr>
<td>Max Shaft Outer Diameter (in)</td>
<td>0.049</td>
<td>0.062</td>
<td>0.072</td>
<td>0.072</td>
<td>0.084</td>
<td>0.084</td>
<td>0.049</td>
</tr>
<tr>
<td>Minimum Working Length (cm)</td>
<td>130</td>
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<td>130</td>
<td>130</td>
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<tr>
<td>Fluence (mJ / mm²)</td>
<td>30-60</td>
<td>30-60</td>
<td>30-60</td>
<td>30-60</td>
<td>30-60</td>
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<tr>
<td>Laser On/Off Time (sec)</td>
<td>5 / 10</td>
<td>5 / 10</td>
<td>5 / 10</td>
<td>5 / 10</td>
<td>5 / 10</td>
<td>5 / 10</td>
<td>5 / 10</td>
</tr>
</tbody>
</table>

**For more information, visit www.spnc.com**
INDICATIONS FOR USE

The Laser Catheters are intended for use either as a stand-alone modality or in conjunction with Percutaneous Transluminal Coronary Balloon Angioplasty (PTCA) in patients who are acceptable candidates for coronary artery bypass graft (CABG) surgery. The following Indications for Use, Contraindications and Warnings have been established through multicenter clinical trials. The Spectranetics CVX-300® Excimer Laser System and the multifiber laser catheter models are safe and effective for the following indications:

• Occluded saphenous vein bypass grafts.
• Ostial lesions.
• Long lesions—(greater than 20mm in length).
• Moderately calcified stenoses.
• Total occlusions traversable by a guidewire.
• Lesions which previously failed balloon angioplasty.
• Restenosis in 316L stainless steel stents, prior to the administration of intravascular brachytherapy.

These lesions must be traversable by a guidewire and composed of atherosclerotic plaque and/or calcified material. The lesions should be well defined by angiography.

CONTRAINDICATIONS

• Lesion is in an unprotected left main artery.
• Lesion is beyond acute bends or is in a location within the coronary anatomy where the catheter cannot traverse.
• Guidewire cannot be passed through the lesion.
• Lesion is located within a bifurcation.
• Patient is not an acceptable candidate for bypass graft surgery.

See complete IFU for more information before attempting use of ELCA.

WARNINGS

Federal (USA) law restricts this device to sale by or on the order of a physician with appropriate training. A clinical investigation of the Spectranetics CVX-300® Excimer Laser System did not demonstrate safety and effectiveness in lesions amenable to routine PTCA or those lesions not mentioned in the Indications for Use, above. The effect of adjunctive balloon angioplasty on restenosis, as opposed to laser alone, has not been studied. The use of the CVX-300® Excimer Laser System is restricted to physicians who are trained in the use of the product.

PRECAUTIONS

This device has been sterilized using Ethylene Oxide and is supplied STERILE. The device is designated and intended for SINGLE USE ONLY and must not be resterilized and/or reused. Store in a cool, dry place. Protect from direct sunlight and high temperatures (greater than 60°C or 140°F). During the procedure, appropriate anticoagulant and coronary vasodilator therapy must be provided to the patient. Anticoagulant therapy should be administered per the institution’s PTCA protocol for a period of time to be determined by the physician after the procedure. Percutaneous Excimer Laser Coronary Atherectomy (ELCA) should be performed only at hospitals where emergency coronary bypass graft surgery can be immediately performed in the event of a potentially injurious or life-threatening complication. The results of clinical investigation indicated that patients with the following conditions are at a higher risk for experiencing acute complications:

• Patients with diabetes.
• Patients with a history of smoking.
• Lesions with tortuous vessels.
The ELCA® Coronary Laser Atherectomy Catheter is a versatile treatment option for recanalizing occluded coronary arteries. The catheter is constructed of an arrangement of optical fibers contained within a flexible shaft surrounding an 0.014" guidewire lumen. With seven indications and nine different product offerings, this product allows physicians to treat even the most complex lesions with precision. ELCA laser catheters are offered in rapid exchange and over-the-wire designs, concentric and eccentric laser fiber configurations, and four different catheter sizes.

**Primary Product Features:**
- Optimally spaced fibers for improved performance
- Adjustable laser energy settings to meet many clinical needs
- Automatic shut-off feature for advanced patient safety

**Primary Product Benefits:**
- Proven patient safety
- Precise treatment of concentric or eccentric lesions
- Broad clinical applications via seven indications

---

**RX Rapid Exchange Catheter**

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<td>0.014</td>
</tr>
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<td><strong>Guide Catheter Compatibility (F)</strong></td>
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<tr>
<td><strong>Minimum Vessel Diameter (mm)</strong></td>
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<tr>
<td><strong>Max Tip Outer Diameter (in)</strong></td>
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<tr>
<td><strong>Max Shaft Outer Diameter (in)</strong></td>
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</tr>
<tr>
<td><strong>Minimum Working Length (cm)</strong></td>
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<td>130</td>
</tr>
<tr>
<td><strong>Fluence (mJ / mm^2)</strong></td>
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<tr>
<td><strong>Laser On/Off Time (sec)</strong></td>
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**OTW Over-the-Wire Catheter**

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<tr>
<td><strong>Max Tip Outer Diameter (in)</strong></td>
<td>0.038</td>
<td>0.038</td>
</tr>
<tr>
<td><strong>Max Shaft Outer Diameter (in)</strong></td>
<td>0.049</td>
<td>0.049</td>
</tr>
<tr>
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<td>25-80</td>
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<tr>
<td><strong>Laser On/Off Time (sec)</strong></td>
<td>10 / 5</td>
<td>10 / 5</td>
</tr>
</tbody>
</table>

*ELCA is available one per package.*

For more information, visit [www.spnc.com](http://www.spnc.com)  
To order, call **1-800-231-0978**, international: **+31 33 4347 050**
INDICATIONS FOR USE
The X-80 Laser Catheters are intended for use as a stand-alone modality or in conjunction with Percutaneous Transluminal Coronary Balloon Angioplasty (PTCA) in patients who are acceptable candidates for coronary artery bypass graft (CABG) surgery. The following Indications for Use, Contraindications and Warnings have been established through multicenter clinical trials. The Spectranetics CVX-300® Excimer Laser System and the multifiber laser catheter models are safe and effective for the following indications:
• Occluded saphenous vein bypass grafts
• Ostial lesions
• Long lesions – (greater than 20mm in length)
• Moderately calcified stenoses.
• Total occlusions traversable by a guidewire.
• Lesions which previously failed balloon angioplasty—(This includes those lesions that were treated unsuccessfully by PTCA. Lesions that have undergone a complicated PTCA procedure are not included in this category.)
These lesions must be traversable by a guidewire and composed of atherosclerotic plaque and/or calcified material. The lesions should be well defined by angiography.

CONTRAINdications
• Patient has acute thrombosis.
• Lesion is in an unprotected left main artery.
• Patient has experienced an acute myocardial infarction.
• Patient has ejection fraction of less than 30%.
• Lesion is beyond acute bends or is in a location within the coronary anatomy where the catheter cannot traverse.
• Guidewire cannot be passed through the lesion.
• Lesion is located within a bifurcation.
• Patient is not an acceptable candidate for bypass graft surgery.
See complete IFU for more information before attempting use of ELCA X-80.

WARNINGS
Federal (USA) law restricts this device to sale by or on the order of a physician with appropriate training. A clinical investigation of the Spectranetics CVX-300® Excimer Laser System did not demonstrate safety and effectiveness in lesions amenable to routine PTCA or those lesions not mentioned in the Indications for Use, above. The effect of adjunctive balloon angioplasty on restenosis, as opposed to laser alone, has not been studied. The use of the CVX-300® Excimer Laser System is restricted to physicians who are trained in the use of the product.

PRECAUTIONS
This device has been sterilized using Ethylene Oxide and is supplied STERILE. The device is designated and intended for SINGLE USE ONLY and must not be resterilized and/or reused. Store in a cool, dry place. Protect from direct sunlight and high temperatures (greater than 60°C or 140°F). During the procedure, appropriate anticoagulant and coronary vasodilator therapy must be provided to the patient. Anticoagulant therapy should be administered per the institution's PTCA protocol for a period of time to be determined by the physician after the procedure. Percutaneous Excimer Laser Coronary Atherectomy (ELCA) should be performed only at hospitals where emergency coronary bypass graft surgery can be immediately performed in the event of a potentially injurious or life-threatening complication. The results of clinical investigation indicated that patients with the following conditions are at a higher risk for experiencing acute complications:
• Patients with diabetes.
• Patients with a history of smoking.
• Lesions with tortuous vessels
The QuickCat™ Extraction Catheter is an aspiration catheter uniquely designed to combine the best features of other aspiration catheters. Because deliverability is critical in acute cases, the QuickCat Extraction Catheter is designed with a flexible distal and an increasingly stiffer, proximal end.

**Primary Product Features:**
- Optimized catheter material selection
- Hydrophilic coating
- Consistent inner lumen size
- 4.5F crossing profile

**Primary Product Benefits:**
- Excellent deliverability
- High rate of thrombus removal and low rate of clogging\(^1\)
- Easy advancement through tortuous anatomy\(^2\)
- Easy access to small, distal vessels

---

### QuickCat Extraction Catheter

<table>
<thead>
<tr>
<th>Model Number</th>
<th>Guide Catheter Compatibility (F / in)</th>
<th>Guidewire Compatibility (in / mm)</th>
<th>Catheter Crossing Profile (F / in)</th>
<th>Working Length (cm)</th>
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<tbody>
<tr>
<td>60090-01</td>
<td>6 / ≥ 0.068</td>
<td>0.014 / 0.36</td>
<td>4.5 / 0.059</td>
<td>145</td>
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</tbody>
</table>

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1 As compared to the competitive aspiration catheters currently available. Data on file.

2 Using 0.070" guide catheters. Data on file.
**INDICATIONS FOR USE**

QuickCat is indicated for removal of fresh, soft emboli and thrombi from vessels in the arterial system. Product is intended for single use by physicians trained and experienced in diagnostic and interventional techniques. Standard techniques for placement of vascular access sheath, angiographic catheters and guidewires may be employed.

**CONTRAINDICATIONS**

- Use in vessels with a diameter < 1.5 mm.
- Use the venous system.
- The removal of fibrous, adherent or calcified material (e.g., chronic clot, atherosclerotic plaque).

See complete IFU for more information before attempting use of the QuickCat.

**WARNINGS**

Do not use without a guidewire, as vessel injury may result. Do not attempt to advance or retract the catheter against resistance until the cause of resistance has been determined by fluoroscopy or other means. Manipulation of the catheter against resistance may result in kinking of the catheter and/or vessel damage. If excessive slack or a loop in the guidewire is observed between the guide catheter and the monorail segment of the QuickCat Extraction Catheter during the procedure, the guidewire may become kinked within the vessel during catheter advancement or retraction. If flow into the syringe stops or is restricted, do NOT attempt to flush the extraction lumen of the QuickCat Extraction Catheter while the catheter is inside the patient. Serious injury or death may result. Do not use a bent, kinked or damaged catheter as this may lead to vessel injury and/or an inability to advance or withdraw the catheter. Do not use for delivery or infusion of diagnostic, embolic or therapeutic materials into blood vessels.

**PRECAUTIONS**

Use caution when crossing or retracting the QuickCat Extraction Catheter across a freshly deployed drug-eluting stent. Do not re-sterilize, re-process, or re-use the device. Do not replace system components with alternate components.
Quick-Cross® Support Catheters help thousands of physicians cross tortuous anatomy stenoses.

Constructed of high-density polyethylene and featuring three radiopaque marker bands, Quick-Cross catheters are intended for use in both coronary and peripheral procedures. Multiple configurations are available for improved treatment versatility.

**Primary Product Features:**
- Tapered, translucent shaft
- Low-profile tapered tip and hydrophilic coating
- Multiple lengths and diameters
- Three radiopaque markers

**Primary Product Benefits:**
- Excellent guidewire support and seamless catheter-to-guidewire transition
- Facilitates crossing of challenging lesions
- Easy visualization of blood within the catheter confirms luminal access
- Allows for assessment of lesion length and catheter position confirmation

Quick-Cross Support Catheter

<table>
<thead>
<tr>
<th>Model Number</th>
<th>0.014&quot;</th>
<th>0.014&quot;</th>
<th>0.018&quot;</th>
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<th>0.018&quot;</th>
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<td>518-066</td>
<td>518-036</td>
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<td>518-038</td>
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<table>
<thead>
<tr>
<th>Distal Tip Profile (F / in)</th>
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<th>1.5 / 0.020</th>
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<th>1.8 / 0.023</th>
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<td>Guidewire Compatibility (in)</td>
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<td>Guide Compatibility (F)</td>
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<tr>
<td>Proximal Shaft Diameter (in)</td>
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<td>50</td>
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</tr>
</tbody>
</table>

For more information, visit [www.spnc.com](http://www.spnc.com) • To order, call 1-800-231-0978, international: +31 33 4347 050
INDICATIONS FOR USE
Quick-Cross Support Catheters are guidewire exchange and infusion devices designed for use in the vascular system. The catheters are intended to support a guidewire during access of vasculature, allow for exchange of guidewires and provide a conduit for the delivery of saline solutions or diagnostic contrast agents.

CONTRAINDICATIONS
None known.

WARNINGS
Maximum infusion pressure is 300 psi. The catheter is designed and intended for intravascular use only. This catheter is designed and intended for one-time use only. Do not re-sterilize and/or reuse. Careful inspection before use should verify that the catheter has not been damaged in shipment and that its condition is suitable for the procedure. The catheter should not be advanced through an area of resistance unless the source of resistance is identified by fluoroscopy and appropriate steps are taken to reduce or remove the obstruction. Catheter manipulation should occur only under fluoroscopy. If the catheter is used for infusion, reference the table of flow rates and ensure infusion pressure does not exceed the recommendations. Avoid introducing air or any other gas through the catheter into the vascular system.
The proven performance of Quick-Cross® now with the ability to navigate and select.

Constructed of a PTFE inner lining, stainless steel inner braid and a nylon and Pebax® outer coating, the Quick-Cross Select Support Catheter guides and supports a guidewire during access of the vasculature, allows for wire exchanges and provides a conduit for the delivery of saline solutions or diagnostic contrast agents. Quick-Cross Select combines two technologies to allow a physician to select vascular branches and cross tortuous anatomy.

**Primary Product Features:**
- Braided stainless steel reinforcement design
- Angled, tapered tip
- Low crossing profile and hydrophilic coating
- Three radiopaque markers

**Primary Product Benefits:**
- Provides torque control and additional strength*
- Facilitates access into vascular branches and allows for seamless guidewire-to-catheter transition
- Aids in crossing the most challenging lesions and facilitates crossing of CTOs
- Assists in assessment of lesion and allows confirmation of catheter positioning

Quick-Cross Select Support Catheter

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<tr>
<th>Model Number</th>
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<td>2.2 / 0.029</td>
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</tbody>
</table>

* Data on file.
INDICATIONS FOR USE
Quick-Cross Select Support Catheters are intended to guide and support a guidewire during access of the vasculature, allow for wire exchanges and provide a conduit for the delivery of saline solutions or diagnostic contrast agents.

CONTRAINdications
None known.

WARNINGS
Store in a cool, dry place. Protect from direct sunlight and high temperature (greater than 55° C or 131° F). Maximum Infusion Pressure: 500 psi for the 0.035 catheter, and 300 psi for the 0.014 and 0.018 catheters. The catheter is designed and intended for one-time use only. Do not re-sterilize and/or reuse.
QUICK-CROSS® EXTREME®
SUPPORT CATHETER

Specifically designed for extreme cases, our trusted Quick-Cross® Extreme® Support Catheter has a new level of strength and control.

Constructed of a PTFE inner lining, stainless steel inner braid and a nylon and Pebax® outer coating, the Quick-Cross Extreme Support Catheter guides and supports a guidewire during access of the vasculature, allows for wire exchanges and provides a conduit for the delivery of saline solutions or diagnostic contrast agents. Quick-Cross Extreme combines two technologies to allow a physician to cross tortuous anatomy.

Primary Product Features:
- Braided stainless steel reinforcement design
- Low profile, tapered tip
- Low crossing profile and hydrophilic coating
- Three radiopaque markers

Primary Product Benefits:
- Provides additional strength, pushability and torque control*
- Allows for seamless guidewire-to-catheter transition
- Aids in crossing the most challenging lesions and facilitates crossing of CTOs
- Assists in assessment of lesion and allows confirmation of catheter positioning

Quick-Cross Select is available five per package

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<tr>
<th>Quick-Cross Extreme Support Catheter</th>
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<tr>
<td>Working Length (cm)</td>
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<td>150</td>
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<td>90</td>
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<tr>
<td>Proximal Shaft Diameter (in)</td>
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<td>0.042</td>
<td>0.044</td>
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<td>0.044</td>
<td>0.059</td>
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<tr>
<td>Radiopaque Marker Spacing (mm)</td>
<td>15</td>
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<td>15</td>
<td>15</td>
<td>50</td>
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</tr>
</tbody>
</table>

* Data on file.

For more information, visit www.spnc.com • To order, call 1-800-231-0978, international: +31 33 4347 050
QUICK-CROSS® EXTREME® SUPPORT CATHETER

INDICATIONS FOR USE
Quick-Cross Extreme Support Catheters are intended to guide and support a guidewire during access of the vasculature, allow for wire exchanges and provide a conduit for the delivery of saline solutions or diagnostic contrast agents.

CONTRAINDICATIONS
None known.

WARNINGS
Store in a cool, dry place. Protect from direct sunlight and high temperature (greater than 55° C or 131° F). Maximum Infusion Pressure: 500 psi for the 0.035 catheter, and 300 psi for the 0.014 and 0.018 catheters. The catheter is designed and intended for one-time use only. Do not re-sterilize and/or reuse.
Safe, precise vessel access during retrograde procedures.

The Quick-Access™ Needle Holder is an innovative, easy-to-use device that helps you access vessels safely and efficiently, particularly during challenging retrograde procedures and when faced with small vessels. It keeps your hands away from the point of needle insertion and the associated radiation risk, and it fits any standard needle.

Primary Product Features:
- Connects to any standard needle via its luer tip
- Allows the guidewire to be preloaded and anchored via its wire lock
- Can accommodate any size guidewire

Primary Product Benefits:
- Minimize radiation exposure by keeping hands away from point of needle insertion
- Enhances needle stability by enabling controlled advancement of the guidewire
- Provides precise control over needle trajectory during vessel puncture, particularly in small vessels

Quick-Access Needle Holder

<table>
<thead>
<tr>
<th>Model Number</th>
<th>Product Description</th>
<th>Length (cm)</th>
<th>Guidewire Compatibility (in)</th>
<th>QTY</th>
</tr>
</thead>
<tbody>
<tr>
<td>519-001</td>
<td>Needle Holder 23</td>
<td>23</td>
<td>up to 0.035</td>
<td>Box of 1</td>
</tr>
<tr>
<td>519-005</td>
<td>Needle Holder 23</td>
<td>23</td>
<td>up to 0.035</td>
<td>Box of 5</td>
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<tr>
<td>U201</td>
<td>Needle Holder 23</td>
<td>23</td>
<td>up to 0.035</td>
<td>Box of 10</td>
</tr>
</tbody>
</table>

Quick-Access is available ten per box

For more information, visit [www.spnc.com](http://www.spnc.com) • To order, call 1-800-231-0978, international: +31 33 4347 050
QUICK-ACCESS™ NEEDLE HOLDER

Important Safety Information

INDICATIONS FOR USE
The Quick-Access Needle Holders are intended to facilitate the placement of guidewires into the vascular system.

CONTRAINDICATIONS
No known contraindications.
For additional information, please see the IFU.

WARNINGS
The device is intended for one time use. DO NOT resterilize and/or reuse it, as this can potentially result in compromised device performance and increased risk of inappropriate resterilization and cross contamination.

Do not use any unit if its package is open or damaged.

Use the catheter prior to the “Use Before” date specified on the package label.

Do not advance the guidewire or the Quick-Access Needle Holder if resistance is met.

Use only appropriate guidewires of size 0.035” and below.

CAUTION: Federal (USA) Law restricts this device to sale by or on the order of a physician with appropriate training. Read all instructions prior to use.

PRECAUTIONS

Procedures should be conducted under fluoroscopic guidance with appropriate x-ray equipment.

The sealed needle container should be inspected prior to opening. If the seal is broken, or the container has been damaged, sterility cannot be assured.

Careful attention must be paid to maintain tight connection between the Quick-Access Needle Holder and needle.

DO NOT resterilize or reuse this device, as these actions can compromise device performance or increase the risk of cross-contamination due to inappropriate reprocessing.

Reuse of this single use device could lead to serious patient injury or death.

POTENTIAL COMPLICATIONS
Potential complications related to angioplasty include, but are not limited to clot formation and embolism, nerve damage, vascular perforation requiring surgical repair, damage to the vascular intima, or death.
Quick-Cross Capture Guidewire Retriever

Easy, reliable, safe guidewire retrieval and exchange during complex retrograde procedures.

During complex retrograde procedures, retrieving and exchanging guidewires can be difficult, time-consuming and frustrating. The Quick-Cross Capture™ Guidewire Retriever easily, reliably and safely helps you retrieve and exchange guidewires with no damage either to the wire or to the vessel. It can even retrieve prolapsed or damaged guidewires.

Primary Product Features:
• Can be used in diseased vessels without the dangers of manipulating a snare
• Low-pressure balloon centers the device within the vessel
• Can retrieve even prolapsed or damaged wires
• Retrograde wire access and retrieval with Quick-Cross Capture is safe and less costly than using a re-entry device when crossing total occlusions

Primary Product Benefits:
• Delivers predictably shorter procedure times¹
• Increases the predictably of successful guidewire retrieval
• Is effective in multiple vessels, including iliac, femoral, popliteal and tibial

Quick-Cross Capture is available one per package

<table>
<thead>
<tr>
<th>Model Number</th>
<th>Product Description</th>
<th>Funnel and Size (mm)</th>
<th>Catheter Length (cm)</th>
<th>Guidewire Compatibility (in)</th>
<th>Catheter Size (F)</th>
<th>Sheath Compatibility (F)</th>
<th>Nominal Pressure (ATM)</th>
<th>Rated Burst Pressure (ATM)</th>
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<tbody>
<tr>
<td>519-106</td>
<td>6mm Guidewire Retriever Catheter</td>
<td>6</td>
<td>100</td>
<td>up to 0.035</td>
<td>5.5</td>
<td>6</td>
<td>1.0</td>
<td>5.0</td>
</tr>
<tr>
<td>519-108</td>
<td>8mm Guidewire Retriever Catheter</td>
<td>8</td>
<td>100</td>
<td>up to 0.035</td>
<td>5.9</td>
<td>6</td>
<td>3.0</td>
<td>5.0</td>
</tr>
</tbody>
</table>

¹ Data on file.

For more information, visit www.spnc.com • To order, call 1-800-231-0978, international: +31 33 4347 050
INDICATIONS FOR USE
The Quick-Cross Capture Guidewire Retriever is intended to be used in conjunction with a steerable guidewire to access discrete regions of the vasculature and for guidewire exchange. The Quick-Cross Capture Guidewire Retriever is not intended for use in the coronary, cerebral or carotid vasculature.

CONTRAINDICATIONS
None known.
For additional information, please see the IFU.
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.

**Primary Product Features:**
- 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

**Primary Product Benefits:**
- Offers versatility for unique binding sites, lead designs and patient’s anatomy
- Advances up to 62% more efficiently\(^1\) than SLS II
- Provides a high degree of control when progressing through binding sites\(^2\)

**GlideLight Laser Sheath**

<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/mm(^2))</td>
<td>30-60</td>
<td>30-60</td>
<td>30-60</td>
</tr>
</tbody>
</table>

For pacemaker and defibrillator lead manufacturers, models and GlideLight size compatibility, go to [www.spnc.com/LeadLookup](http://www.spnc.com/LeadLookup)

For more information, visit [www.spnc.com](http://www.spnc.com) • To order, call 1-800-231-0978, international: +31 33 4347 050
GLIDELIGHT™ LASER SHEATH

Important Safety Information

INDICATIONS FOR USE
The Laser Sheath is intended for use as an adjunct to conventional lead extraction tools in patients suitable for transvenous removal of chronically implanted pacing or defibrillator leads constructed with silicone or polyurethane outer insulation.

CONTRAINDICATIONS
Use of the Laser Sheath is contraindicated:
• When emergency thoracotomy with cardiopulmonary bypass cannot be performed immediately in the event of a life threatening complication;
• When fluoroscopy is not available;
• In patients in whom superior venous approach cannot be used;
• When the proximal end of the pacing lead is not accessible to the operator;
• When the lead will not fit into the inner lumen of the Laser Sheath

WARNINGS
Do not attempt to operate the Laser Sheath without the availability of conventional lead extraction tools. Lead removal devices should be used only at institutions with emergency cardiac surgical capabilities and complication prevention and management protocols in place and routinely practiced. The recommendations for lead management of the Heart Rhythm Society® (HRS) and European Heart Rhythm Association® (EHRA) are strongly suggested. The majority of adverse events observed in post market surveillance have involved the proximal coil of the dual coil ICD leads in the SVC. Therefore, particular care must be taken when removing these leads. In addition, as with all extractions, a risk to benefit assessment for the removal of these leads should be considered for each patient. The Laser Sheath should be used only by physicians who are experienced in pacing lead removal techniques using telescoping dilator sheaths. The CVX-300™ Excimer Laser System should be used only by physicians who have received adequate training (See Section 9.6 of the IFU). Protective glasses are required when the laser is in use. Avoid eye or skin exposure to direct or scattered radiation. Refer to exposure label on the CVX-300 Excimer Laser System. Do not insert more than one Laser Sheath or Outer Sheath into a vein at a time. Severe vessel damage, including venous wall laceration requiring surgical repair, may occur.

Do not place the outer sheath tip at the SVC-atrial junction as it may damage this delicate area during subsequent procedures, e.g., moving the outer sheath, implanting a new lead.

Maintain appropriate traction on the lead being extracted during advancement of the Laser Sheath or outer sheath. When marked calcification that moves with the lead to be extracted is seen on fluoroscopy, particularly in the atrium, the availability of immediate surgical assistance is paramount if a problem presents itself as a result of the extraction procedure. Also, an indication for thoracotomy removal of the lead(s) should be considered.

Do not advance the Laser Sheath any closer than 1 cm from the lead tip. Do not lase at the myocardium to free the lead tip.

PRECAUTIONS
Thoroughly review the package insert for conventional lead extraction tools before attempting to use the Laser Sheath.

For single use only. Do not resterilize and/or reuse.

DO NOT resterilize or reuse this device, as these actions can compromise device performance or increase the risk of cross-contamination due to inappropriate reprocessing.

Reuse of this single use device could lead to serious patient injury or death and voids manufacturer warranties.

Do not use the Laser Sheath:
• If the tamper-evident seal is broken;
• If the Laser Sheath has been damaged.

PRECAUTIONS (continued)
When the Laser Sheath is in the body, it should be manipulated only under fluoroscopic observation with radiographic equipment that provides high quality images. Approximately half the forward advancement force is needed to progress with 80 Hz operation at the same rate as with 40 Hz operation. The recommended advancement rate is 1 mm per second.

POTENTIAL ADVERSE EVENTS
The following adverse events or conditions may also occur during lead extraction with the Laser Sheath, but were not observed during the clinical study (listed in alphabetical order):
• bacteremia
• low cardiac output
• migration of lead fragments
• migration of vegetation
• myocardial avulsion/perforation
• premature ventricular contractions
• pulmonary embolism
• stroke
• venous avulsion/perforation
• ventricular tachycardia

INDIVIDUALIZATION OF TREATMENT
Weigh the relative risks and benefits of intravascular catheter/lead removal procedures in cases when:
• There are Dual Coil ICD leads being removed;
• The lead to be removed has a sharp bend or evidence of fracture;
• The lead shows evidence of insulation disintegration raising the concern of pulmonary embolism;
• Vegetations are attached directly to the lead body.
When an outer sheath, used in conjunction with the Laser Sheath during the lead extraction procedure, is left in place once the Laser Sheath and lead are removed from the patient, the outer sheath may then be used as a conduit for a guidewire to facilitate the implantation of a new lead. The outer sheath tip should be either (a) fully into the atrium, or (b) retracted into the brachiocephalic vein. Placing the outer sheath tip at the SVC-atrial junction risks damage to this delicate area during subsequent procedures, such as moving the outer sheath or implanting a new lead and is thus not recommended.

It is vital that appropriate traction be maintained on the lead being extracted both during laser assisted and standard extraction attempts. If appropriate levels of traction cannot be maintained on the lead in order to offset the counter-pressures that distort the lead body, then changing to an alternative extraction methodology such as the femoral approach would be indicated. When marked calcification that moves with the lead to be extracted is seen on fluoroscopy, particularly in the atrium, the availability of immediate surgical assistance is paramount if a problem presents itself because of the extraction procedure. Also, an indication for thoracotomy removal of the lead(s) should be considered.

The safety and effectiveness of the Laser Sheath has not been established for the following:
• Patients with recent history of pulmonary embolus
• Laser sheath advancement into the coronary sinus

1 Marketing Claims Summary Report, D015861, Data on file at Spectranetics.
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.

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

**Primary Product Benefits:**
- Enables precision lead removal procedures
- Easy to pass the sheath over acute lead angles
- Ablates through multiple tissue types with circumferential laser tip

---

**SLS II Laser Sheath**

<table>
<thead>
<tr>
<th></th>
<th>12F Kit</th>
<th>14F Kit</th>
<th>16F Kit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Model Number</td>
<td>500-001</td>
<td>500-012</td>
<td>500-013</td>
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<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>Min Outer Sheath Inner Diameter (F/in/mm)</td>
<td>13.0 / 0.170 / 4.33</td>
<td>15.5 / 0.203 / 5.17</td>
<td>18.2 / 0.238 / 6.07</td>
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<tr>
<td>Max Outer Sheath Outer Diameter (F/in/mm)</td>
<td>16.4 / 0.215 / 5.47</td>
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<tr>
<td>Working Length (cm)</td>
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<td>50</td>
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<tr>
<td>Repetition Rate (Hz)</td>
<td>25-40</td>
<td>25-40</td>
<td>25-40</td>
</tr>
<tr>
<td>Clinical Energy Setting (mJ/mm²)</td>
<td>30-60</td>
<td>30-60</td>
<td>30-60</td>
</tr>
<tr>
<td>Energy Range (mJ) at 60 Fluence</td>
<td>38.4-46.8</td>
<td>38.4-46.8</td>
<td>43.7-53.5</td>
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For pacemaker and defibrillator lead manufacturers, models and SLS size compatibility, go to www.spnc.com/SLSref.
Important Safety Information

INDICATIONS FOR USE
The Laser Sheath is intended for use as an adjunct to conventional lead extraction tools in patients suitable for transvenous removal of chronically implanted pacing or defibrillator leads constructed with silicone or polyurethane outer insulation.

CONTRAINDICATIONS
Use of the Laser Sheath is contraindicated:
- When emergency thoracotomy with cardiopulmonary bypass cannot be performed immediately in the event of a life threatening complication;
- When fluoroscopy is not available;
- In patients in whom superior venous approach cannot be used;
- When the proximal end of the pacing lead is not accessible to the operator;
- When the lead will not fit into the inner lumen of the Laser Sheath

WARNINGS
Do not attempt to operate the Laser Sheath without the availability of conventional lead extraction tools.

The Laser Sheath should be used only by physicians who are experienced in pacing lead removal techniques using telescoping dilator sheaths. The CVX-3000 Excimer Laser System should be used only by physicians who have received adequate training (See Section 9.6 of the IFU).

Protective glasses are required when the laser is in use. Avoid eye or skin exposure to direct or scattered radiation. Refer to exposure label on the CVX-3000 Excimer Laser System.

Do not insert more than one Laser Sheath or Outer Sheath into a vein at a time. Severe vessel damage, including venous wall laceration requiring surgical repair, may occur.

Lead extraction devices should be used only at institutions with emergency cardiac surgical capabilities and complication prevention and management protocols in place and routinely practiced. The recommendations for lead management of the Heart Rhythm Society (HRS) and European Heart Rhythm Association (EHRA) are strongly suggested.

The majority of adverse events observed in post market surveillance have involved the proximal coil of the dual coil ICD leads in the SVC. Therefore, particular care must be taken when removing these leads. In addition, as with all extraction methodology such as the femoral approach would be indicated.

When marked calcification that moves with the lead to be extracted is seen on fluoroscopy, particularly in the atrium, the availability of immediate surgical assistance is paramount if a problem presents itself as a result of the extraction procedure. Also, an indication for thoracotomy removal of the lead(s) should be considered.

Do not place the outer sheath tip at the SVC-atrial junction as it may damage this delicate area during subsequent procedures, e.g., moving the outer sheath, implanting a new lead.

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

When marked calcification that moves with the lead to be extracted is seen on fluoroscopy, particularly in the atrium, the availability of immediate surgical assistance is paramount if a problem presents itself as a result of the extraction procedure. Also, an indication for thoracotomy removal of the lead(s) should be considered.

Do not advance the Laser Sheath any closer than 1 cm from the lead tip. Do not lase at the myocardium to free the lead tip.

PRECAUTIONS
Thoroughly review the package insert for conventional lead extraction tools before attempting to use the Laser Sheath.

For single use only. Do not resterilize and/or reuse.

DO NOT resterilize or reuse this device, as these actions can compromise device performance or increase the risk of cross-contamination due to inappropriate reprocessing.

Reuse of this single use device could lead to serious patient injury or death and voids manufacturer warranties.

CONTRAINDICATIONS (continued)
- Do not use the Laser Sheath:
  - If the tamper-evident seal is broken;
  - If the Laser Sheath has been damaged.

When the Laser Sheath is in the body, it should be manipulated only under fluoroscopic observation with radiographic equipment that provides high quality images.

POTENTIAL ADVERSE EVENTS
The following adverse events or conditions may also occur during lead extraction with the Laser Sheath, but were not observed during the clinical study (listed in alphabetical order):
- bacteremia
- low cardiac output
- migration of lead fragments
- migration of vegetation
- myocardial avulsion/perforation
- premature ventricular contractions
- pulmonary embolism
- stroke
- venous avulsion/perforation
- ventricular tachycardia

INDIVIDUALIZATION OF TREATMENT
Weigh the relative risks and benefits of intravascular catheter/lead removal procedures in cases when:
- There are Dual Coil ICD leads being removed;
- The lead to be removed has a sharp bend or evidence of fracture;
- The lead shows evidence of insulation disintegration raising the concern of pulmonary embolism;
- Vegetations are attached directly to the lead body.

When an outer sheath, used in conjunction with the Laser Sheath during the lead extraction procedure, is left in place once the Laser Sheath and lead are removed from the patient, the outer sheath may then be used as a conduit for a guidewire to facilitate the implantation of a new lead.

The outer sheath tip should be either (a) fully into the atrium, or (b) retracted into the brachiocephalic vein. Placing the outer sheath tip at the SVC-atrial junction risks damage to this delicate area during subsequent procedures, such as moving the outer sheath or implanting a new lead and is thus not recommended.

It is vital that appropriate traction be maintained on the lead being extracted both during laser assisted and standard extraction attempts. If appropriate levels of traction cannot be maintained on the lead in order to offset the counter-pressures that distort the lead body, then changing to an alternative extraction methodology such as the femoral approach would be indicated.

When marked calcification that moves with the lead to be extracted is seen on fluoroscopy, particularly in the atrium, the availability of immediate surgical assistance is paramount if a problem presents itself as a result of the extraction procedure. Also, an indication for thoracotomy removal of the lead(s) should be considered.

The safety and effectiveness of the Laser Sheath has not been established for the following:
- Patients with history of pulmonary embolus
- Laser sheath advancement into the coronary sinus
Lead Management

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.

Primary Product Features:
- Braided mesh along entire length of LLD
- LLD provides proven capability to unlock
- Flexible platinum iridium tip design and sleek profile (LLD EZ and LLD E)
- Low-profile loop handles (LLD EZ)

Primary Product Benefits:
- Locks entire lead lumen, providing stable traction platform
- LLD can be unlocked and repositioned after initial deployment*
- Highly visible radiopaque marker assists identification of LLD EZ and LLD E tip location under fluoroscopy
- Easy tracking through tightly curved leads (LLD EZ and LLD E)

LLD EZ Lead Locking Device

<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>
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</thead>
<tbody>
<tr>
<td>LLD EZ</td>
<td>518-062</td>
<td>0.015 / 0.38 to 0.023 / 0.58</td>
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<td>65</td>
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</tbody>
</table>

LLD Lead Locking Device

<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>
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</thead>
<tbody>
<tr>
<td>LLD #1</td>
<td>518-018</td>
<td>0.013 / 0.33 to 0.016 / 0.41</td>
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<td>65</td>
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<tr>
<td>LLD #2</td>
<td>518-019</td>
<td>0.017 / 0.43 to 0.026 / 0.66</td>
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<tr>
<td>LLD #3</td>
<td>518-020</td>
<td>0.027 / 0.69 to 0.032 / 0.81</td>
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<tr>
<td>LLD E</td>
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<td>0.015 / 0.38 to 0.023 / 0.58</td>
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LLD Accessories

<table>
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<td>LLD Accessory Kit</td>
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<tr>
<td>Lead Cutter</td>
<td>518-024</td>
</tr>
</tbody>
</table>


** Minimum specification for LLD #2, LLD #3, LLD E, and LLD EZ is 10 lbs; minimum for LLD #1 is 7 lbs.

For more information, visit www.spnc.com • To order, call 1-800-231-0978, international: +31 33 4347 050
**INDICATIONS FOR USE**

The Spectranetics Lead Locking Device, LLD, is intended for use in patients suitable for transvenous removal of chronically implanted pacing or defibrillator leads having an inner lumen and using a superior venous approach.

**CONTRAINDICATIONS**

Use of the LLD is contraindicated:

- When emergency thoracotomy with cardiopulmonary bypass cannot be performed immediately in the event of a life-threatening complication.
- When fluoroscopy is not available.
- In patients in whom superior venous approach cannot be used.
- When the proximal end of the pacing lead is not accessible to the operator.
- When the LLD will not fit into the inner lumen of the device to be extracted.

**WARNINGS**

Do not attempt to use the LLD without the availability of the Spectranetics Laser Sheath or other necessary lead removal tools. The LLD should be used only by physicians who are experienced in lead removal techniques. Do not insert more than one LLD into a lead lumen at a time. Lead removal devices should be used only at institutions with emergency cardiac surgical capabilities. Weigh the relative risks and benefits of intravascular lead removal procedures particularly when the item to be removed is of a dangerous shape or configuration, the likelihood of lead disintegration resulting in fragment embolism is high, and vegetations are attached.

**WARNINGS (continued)**

- Do not abandon a lead in a patient with an LLD still inside the lead. Severe vessel or endocardial wall damage may result from the stiffened lead or from fracture or migration of the abandoned device.
- Do not apply weighted traction to an inserted LLD as myocardial avulsion, hypotension or venous wall tearing may result.
- Be aware that a lead that has a J-shape retention wire that occupies its inner lumen (rather than being outside the coil) may not be compatible with the LLD. Insertion of the LLD into such a lead may result in protrusion and possible migration of the J-shape retention wire. When the LLD is in the body, it should be manipulated only under fluoroscopic observation. When marked calcification that moves with the device to be extracted is seen on fluoroscopy, particularly in the atrium, the availability of immediate surgical assistance is paramount if a problem presents itself as a result of the extraction procedure. Also, thoracotomy removal of the device(s) should be considered.

**PRECAUTIONS**

For single use only. Do not resterilize and/or reuse. The LLD is intended to be used in one lead. Do not use the LLD: if the tamper-evident seal is broken; if the LLD has been damaged. When the LLD is in the body, it should be manipulated only under fluoroscopic observation. Due to rapidly evolving lead technology, this device may not be suitable for the removal of all types of leads. If there are questions or concerns regarding compatibility of this device with particular leads, contact the lead manufacturer. If selectively removing leads with the intent to leave one or more chronically implanted leads intact, these nontargeted leads must be subsequently tested to ensure that they were not damaged or dislodged during the extraction process.
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 multi-layer construction and robust tip design deliver high performance. Nine sizes provide options for different clinical scenarios and user preferences.

**Primary Product Features:**
- Advanced multi-layer construction with gold-coated, steel marker bands
- Flexibility for tracking
- Exterior orientation line and robust beveled tip design
- Nine sizes: three lengths and three diameters

**Primary Product Benefits:**
- Superior visibility
- Strong torque delivery
- Outstanding flexibility for tracking without kinking
- Resists deformation better than common Teflon construction

**VisiSheath Dilator Sheath**

<table>
<thead>
<tr>
<th>Model Number</th>
<th>Size (diameter)</th>
<th>Minimum Inner Diameter (F/ in / mm)</th>
<th>Maximum Outer Diameter (F/ in / mm)</th>
<th>Length (cm)</th>
<th>SLS II® Laser Sheath Compatibility (F)</th>
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**TorqMax Sheath Grip Accessory**

<table>
<thead>
<tr>
<th>Model Number</th>
<th>Minimum Sheath Outer Diameter (F/ in / mm)</th>
<th>Maximum Sheath Outer Diameter (F/ in / mm)</th>
<th>Sheath Grip Length (in / mm)</th>
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<tr>
<td>502-001</td>
<td>11.9 / 0.155 / 4.0</td>
<td>22.5 / 0.296 / 7.5</td>
<td>2.5 / 64</td>
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* Data on file at Spectranetics.

Teflon is a registered trademark of DuPont®. Pebax is a registered trademark of Arkema.

For more information, visit [www.spnc.com](http://www.spnc.com) • To order, call 1-800-231-0978, international: +31 33 4347 050
VISISHEATH® AND TORQMAX® ACCESSORIES

VisiSheath Important Safety Information

INDICATIONS FOR USE
The VisiSheath Dilator Sheath is intended for use in patients requiring the percutaneous dilation of tissue surrounding cardiac leads, indwelling catheters and foreign objects. The device is also intended for use in the introduction and support of intravascular catheters.

CONTRAINdications
None known.

WARNINGS
Dilator sheaths should be used only at institutions with thoracic surgical capabilities by physicians knowledgeable in the techniques and devices for lead or catheter removal. 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. Do not maintain a stationary position with the VisiSheath tip 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). Weigh the relative risks and benefits of intravascular lead/catheter dilation procedures, especially in cases when the object to be dilated away from adherent tissue is of a dangerous shape or configuration; the likelihood of lead/catheter disintegration may result in increased risk of fragment embolization; vegetations are attached directly to the lead/catheter body.

TorqMax Important Safety Information

INDICATIONS FOR USE
The TorqMax Sheath Grip Accessory is intended for use in providing ergonomic grip on outer support sheaths, dilator sheaths, and Spectranetics laser sheaths.

CONTRAINdications
None known.

See complete IFU for more information before attempting use of TorqMax.

WARNINGS
Observe all warnings for the sheath to be used as indicated in the associated Instructions for Use.

PRECAUTIONS
The TorqMax Sheath Grip Accessory must not be resterilized and/or reused. Do not alter the sheath from its original state prior to use. Observe all precautions for the sheath to be used as indicated in the associated “Instructions for Use.”