LEAD MANAGEMENT

VASCULAR INTERVENTION

PRODUCT CATALOG

Spectranetics®

Always Reaching Farther

ABOUT SPECTRANETICS

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:

Telephone: 1-800-231-0978
Fax: 1-877-447-2022 / 719-447-2022

Address: The Spectranetics Corporation
9965 Federal Drive
Colorado Springs, CO 80921-3617

German Customer Service and Product Orders:

Product Orders: +49 931/4520080
Fax: +49 931/45200811

Address: Spectranetics Deutschland GmbH
Schweinfurter Str. 7
97080 Würzburg, Germany

International Customer Service and Product Orders:

Telephone: +31 33 4347 050
Fax: +31 33 4347 051

Address: Spectranetics International B.V.
Plesmanstraat 6, 3833 LA Leusden
The Netherlands

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

TERMS AND CONDITIONS

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.

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Spectranetics®
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CVX-300® and CVX-300-P®
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.

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[1,2]
- The laser sheath enables fast and predictable lead removal procedures[1]
- Laser technology enables higher success rates than mechanical sheaths[1]

1 Wilkoff, Bruce L., et al. (May 1999). Pacemaker Lead Extraction with the Laser Sheath: Results of the Pacing Lead Extraction with Excimer Sheath (PLEXES) Trial. *Journal of the American College of Cardiology*, 33, 6.

2 Byrd, Charles, et al. (May 2002). Clinical Study of the Laser Sheath for Lead Extraction: The Total Experience in the United States. *Journal of Pacing and Electrophysiology*, 125, 5.

Vascular Intervention and Lead Management

CVX-300® and CVX-300-P® EXCIMER LASER SYSTEM

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.

SERVICE LEVEL	ANNUAL CUSTOMER BENEFITS
Premium Plus Service Agreement*	• Complete service coverage of the laser system, including replacement of the laser vessel, non-consumable and consumable parts. • Includes emergency calls and preventative maintenance. • On-site labor, M-F. • Meets JCAHO requirements. • Ensures maximum up-time and optimal operation of the laser. • Multi-year discounts available. • 24/7 technical support assistance.
Premium Service Agreement	• Coverage for consumable and non-consumable parts. • Does not include replacement of the laser vessel. • On-site labor, 8:00 a.m.-5:00 p.m., M-F. • Includes emergency calls and preventative maintenance. • Meets JCAHO requirements. • Ensures high-uptime and operation of the laser. • Multi-year discounts available. • 24/7 technical support assistance.
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.

* 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.

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TURBO ELITE®
LASER ATHERECTOMY CATHETER

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

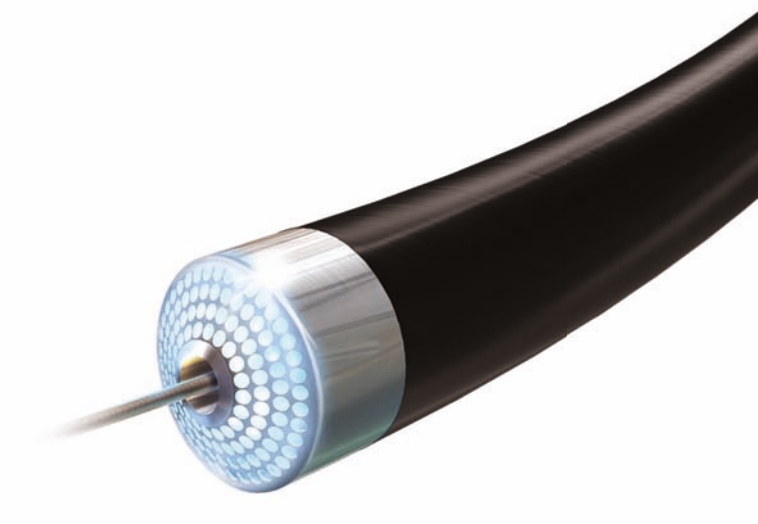
Using UV laser technology that ablates multiple lesion morphologies at the molecular level, the Turbo Elite Laser Catheter provides the precision, control and versatility required to preserve and treat vessels in even the most challenging cases. The system offers proven performance with a single catheter 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

Catheter Diameter	0.9mm	1.4mm	1.7mm	2.0mm	2.3mm	2.5mm	2.3mm	2.5mm
Model Number	410-152	414-151	417-152	420-006	423-001	425-001	423-135	425-135
Vessel Diameter (mm)	≥ 1.4	≥ 2.1	≥ 2.6	≥ 3.0	≥ 3.5	≥ 3.8	≥ 3.5	≥ 3.8
Max Guidewire Compatibility (in)	0.014	0.014	0.018	0.018	0.018	0.018	0.035	0.035
Sheath Compatibility (F)	4	5	5	6	7	8	7	8
Max Tip Outer Diameter (in)	0.038	0.055	0.068	0.080	0.091	0.101	0.091	0.101
Max Shaft Outer Diameter (in)	0.047	0.056	0.069	0.081	0.091	0.102	0.091	0.102
Working Length (cm)	150	150	150	150	120	110	125	112
Fluence (mJ / mm²)	30-80	30-60	30-60	30-60	30-60	30-45	30-60	30-60
Repetition Rate (Hz)**	25-80	25-80	25-80	25-80	25-80	25-80	25-80	25-80

RX Peripheral Rapid Exchange Catheters

0.9mm	1.4mm	1.7mm	2.0mm
410-154	414-159	417-156	420-159
≥ 1.4	≥ 2.1	≥ 2.6	≥ 3.0
0.014	0.014	0.014	0.014
4	5	6	7
0.038	0.057	0.069	0.080
0.049	0.062	0.072	0.084
150	150	150	150
30-80	30-60	30-60	30-60
25-80	25-80	25-80	25-80

* Shammas, N.W. (2009). Commentary: Taking femoropopliteal excimer laser photoablation therapy to the next level: Defining the role of the TURBO-Booster guiding catheter in the CELLO Registry. *Journal of Endovascular Therapy, 16* (6), 676-679.

Laird, J., Zeller, T., Gray, B., Scheinert, D., et al. (February 2006). Limb salvage following laser-assisted angioplasty for critical limb ischemia: Results of the LACI multicenter trial. *Journal of Endovascular Therapy, 13,* 1-11.

Allie, D., Herbert, C., Walker, C., et al. (October 2004). Excimer laser-assisted angioplasty in severe infrapopliteal disease and CLI: The CIS "LACI Equivalent" experience. *Vascular Disease Management, 1,* 1-8.

Bosiers, M., Peeters, P., et al. (June 2009). Excimer laser-assisted angioplasty for critical limb ischemia: Results of the LACI Belgium study. *European Journal of Vascular and Endovascular Surgery, 29,* 613-619.

** Based on software version.

Vascular Intervention

TURBO ELITE® LASER ABLATION CATHETER

Important Safety Information

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:

Software	Catheter Maximum Rep Rate
V3.8XX	80 Hz
V3.7XX	40 Hz

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.

PRECAUTIONS (continued)

Read the Operator's Manual thoroughly before operating the CVX-300® Excimer Laser. Pay particular attention to the Warnings and Responsibility section of the manual which explains Notes, Cautions, and Warnings to be followed to ensure safe operation of the system.

During the procedure, appropriate anticoagulant and vasodilator therapy should be provided to the patient per the institution's protocol.

Saline must be infused throughout the entire lasing process.

ADVERSE EVENTS

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

Events Observed during Clinical Studies

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.

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TURBO-TANDEM®

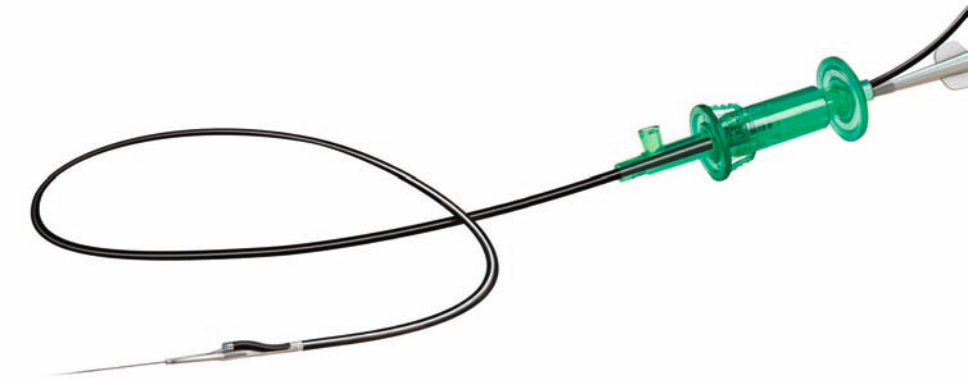
LASER GUIDE CATHETER WITH LASER ATHERECTOMY CATHETER

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



Turbo-Tandem is available one per package

Primary Product Benefits:

- Creates larger lumens
- Debulks lesions composed of multiple morphologies
- Maximum laser deflection

Turbo-Tandem Laser Guide Catheter with Laser Atherectomy Catheter

Model Number	Working Length (cm)	Wire Compatibility (in / mm)	Sheath Compatibility (F / in / mm)	Min Retracted Crossing Profile (in / mm)	Max Extended Crossing Profile (in / mm)	Laser Catheter
472-110	110	0.014 / 0.35	7 / ≥ 0.098 / 2.5	0.094 / 2.4	0.160 / 4.0	2mm OTW
482-110	110	0.014 / 0.35	8 / ≥ 0.113 / 2.9	0.107 / 2.7	0.185 / 4.7	2mm OTW

Vascular Intervention

TURBO-TANDEM®

LASER GUIDE CATHETER WITH LASER ATHERECTOMY CATHETER

Important Safety Information

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.

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ELCA®

CORONARY LASER ATHERECTOMY CATHETER

The ELCA® Coronary Laser Atherectomy Catheter is a versatile treatment option for recanalizing occluded coronary arteries.

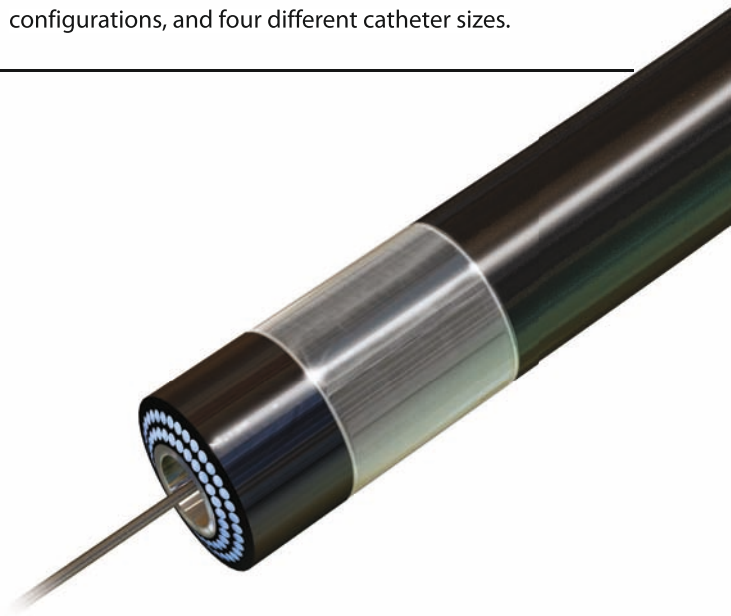
The catheter is constructed of an arrangement of optical fibers contained within a flexible shaft surrounding an 0.014" guidewire lumen. With seven indications and nine different product offerings, this product allows physicians to treat even the most complex lesions with precision. ELCA laser catheters 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



ELCA is available one per package

RX Rapid Exchange Catheters

OTW Over-the-Wire Catheters

	0.9mm	1.4mm	1.7mm	1.7mm E*	2.0mm	2.0mm E*	0.9mm
Model Number	110-003	114-009	117-016	117-205	120-009	120-008	110-001
Guidewire Compatibility (in)	0.014	0.014	0.014	0.014	0.014	0.014 / 0.018	0.014
Guide Catheter Compatibility (F)	6	6 / 7	7	7	8	8	6
Minimum Vessel Diameter (mm)	1.5	2.2	2.5	2.5	3.0	3.0	1.5
Max Tip Outer Diameter (in)	0.038	0.057	0.069	0.066	0.080	0.079	0.038
Max Shaft Outer Diameter (in)	0.049	0.062	0.072	0.072	0.084	0.084	0.049
Minimum Working Length (cm)	130	130	130	130	130	130	130
Fluence (mJ / mm^2)	30-60	30-60	30-60	30-60	30-60	30-60	30-60
Repetition Rate (Hz)	25-40	25-40	25-40	25-40	25-40	25-40	25-40
Laser On/Off Time (sec)	5 / 10	5 / 10	5 / 10	5 / 10	5 / 10	5 / 10	5 / 10

Vascular Intervention

ELCA® CORONARY LASER ATHERECTOMY CATHETER

Important Safety Information

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.

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Spectranetics®
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ELCA® X-80

CORONARY LASER ATHERECTOMY CATHETER

The ELCA® Coronary Laser Atherectomy Catheter is a versatile treatment option for recanalizing occluded coronary arteries.

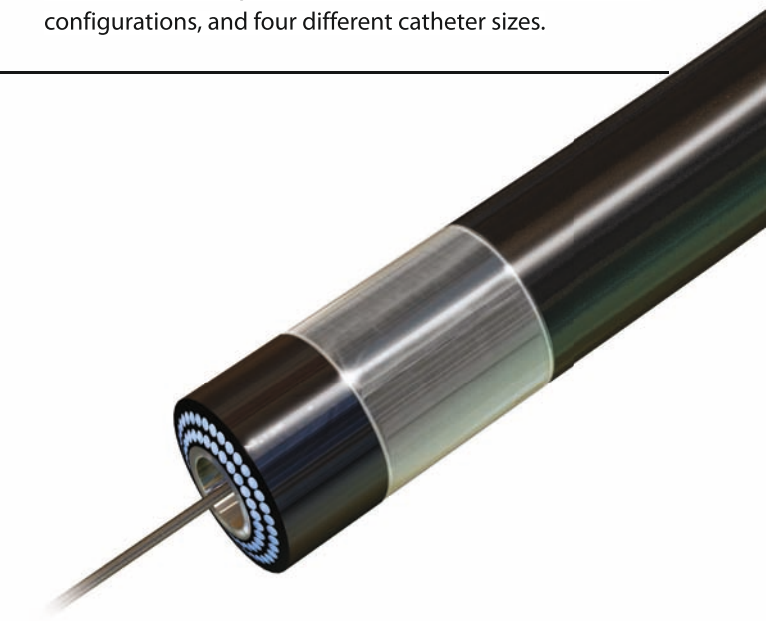
The catheter is constructed of an arrangement of optical fibers contained within a flexible shaft surrounding an 0.014" guidewire lumen. With seven indications and nine different product offerings, this product allows physicians to treat even the most complex lesions with precision. ELCA laser catheters 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



ELCA is available one per package

RX Rapid Exchange Catheter

	0.9mm X-80
Model Number	110-004
Guidewire Compatibility (in)	0.014
Guide Catheter Compatibility (F)	6
Minimum Vessel Diameter (mm)	2.0
Max Tip Outer Diameter (in)	0.038
Max Shaft Outer Diameter (in)	0.049
Minimum Working Length (cm)	130
Fluence (mJ / mm^2)	30-80
Repetition Rate (Hz)	25-80
Laser On/Off Time (sec)	10 / 5

OTW
Over-the-Wire Catheter

0.9mm X-80
110-002
0.014
6
2.0
0.038
0.049
130
30-80
25-80
10 / 5

Vascular Intervention

ELCA® X-80 CORONARY LASER ATHERECTOMY CATHETER

Important Safety Information

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

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Vascular Intervention

QUICKCAT™
EXTRACTION CATHETER

The QuickCat™ Extraction Catheter is an aspiration catheter uniquely designed to combine the best features of other aspiration catheters.

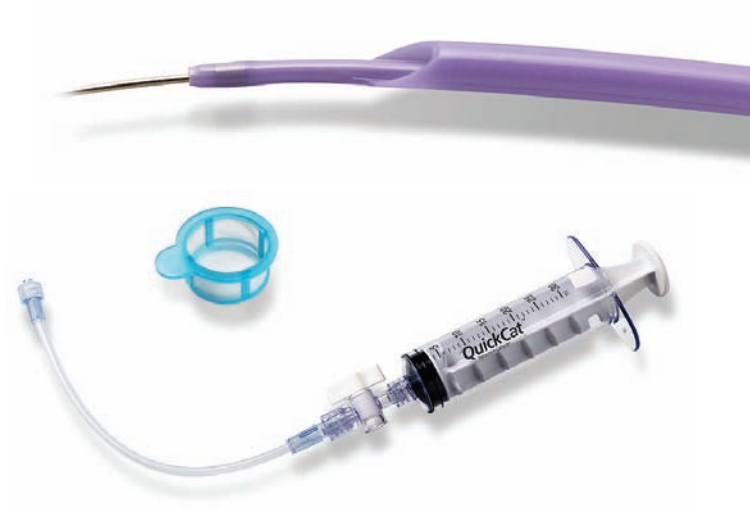
Because deliverability is critical in acute cases, the QuickCat Extraction Catheter is designed with a flexible distal and an increasingly stiffer, proximal end.

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 is available one per package

QuickCat Extraction Catheter

Model Number	Guide Catheter Compatibility (F / in)	Guidewire Compatibility (in / mm)	Catheter Crossing Profile (F / in)	Working Length (cm)
60090-01	6 / ≥ 0.068	0.014 / 0.36	4.5 / 0.059	145

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

2 Using 0.070" guide catheters. Data on file.

Vascular Intervention

QUICKCAT™ EXTRACTION CATHETER

Important Safety Information

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.

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Spectranetics®
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Crossing Solutions

QUICK-CROSS®
SUPPORT CATHETER

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 is available five per package

Quick-Cross Support Catheter

	0.014″	0.014″	0.018″	0.018″	0.018″	0.035″	0.035″	0.035″	0.035″
Model Number	518-032	518-065	518-033	518-034	518-035	518-066	518-036	518-037	518-038
Distal Tip Profile (F / in)	1.5 / 0.020	1.5 / 0.020	1.8 / 0.023	1.8 / 0.023	1.8 / 0.023	3.1 / 0.041	3.1 / 0.041	3.1 / 0.041	3.1 / 0.041
Distal Shaft Outer Diameter (in)	0.026	0.026	0.030	0.030	0.030	0.050	0.050	0.050	0.050
Working Length (cm)	135	150	90	135	150	65	90	135	150
Guidewire Compatibility (in)	0.014	0.014	0.018	0.018	0.018	0.035	0.035	0.035	0.035
Guide Compatibility (F)	5	5	5	5	5	6	6	6	6
Sheath Compatibility (F)	4	4	4	4	4	5	5	5	5
Proximal Shaft Diameter (in)	0.039	0.039	0.044	0.044	0.044	0.063	0.063	0.063	0.063
Radiopaque Marker Spacing (mm)	15	15	15	15	15	50	50	50	50

Crossing Solutions

QUICK-CROSS® SUPPORT CATHETER

Important Safety Information

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.

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Spectranetics®
Always Reaching Farther

QUICK-CROSS® SELECT
SUPPORT CATHETER

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 is available five per package

Quick-Cross Select Support Catheter

	0.014″	0.014″	0.018″	0.018″	0.018″	0.035″	0.035″	0.035″	0.035″
Model Number	518-085	518-087	518-089	518-091	518-093	518-077	518-079	518-081	518-083
Distal Tip Profile (F / in)	2.0 / 0.026	2.0 / 0.026	2.2 / 0.029	2.2 / 0.029	2.2 / 0.029	3.5 / 0.046	3.5 / 0.046	3.5 / 0.046	3.5 / 0.046
Distal Shaft Outer Diameter (in)	0.034	0.034	0.038	0.038	0.038	0.052	0.052	0.052	0.052
Working Length (cm)	135	150	90	135	150	65	90	135	150
Guidewire Compatibility (in)	0.014	0.014	0.018	0.018	0.018	0.035	0.035	0.035	0.035
Guide Compatibility (F)	5	5	5	5	5	N/A	N/A	N/A	N/A
Sheath Compatibility (F)	4	4	4	4	4	5	5	5	5
Proximal Shaft Diameter (in)	0.042	0.042	0.044	0.044	0.044	0.059	0.059	0.059	0.059
Radiopaque Marker Spacing (mm)	15	15	15	15	15	50	50	50	50
Throw Angle	45˚	45˚	45˚	45˚	45˚	45˚	45˚	45˚	45˚
Throw Length (mm)	4	4	4	4	4	7	7	7	7

* Data on file.

Crossing Solutions

QUICK-CROSS® SELECT SUPPORT CATHETER

Important Safety Information

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.**

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Spectranetics®
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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.

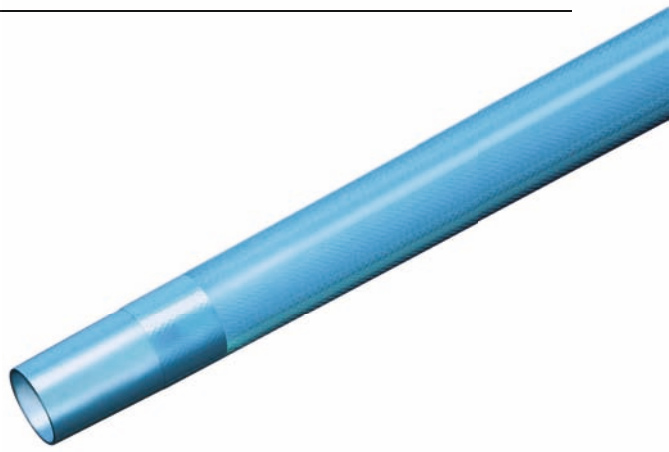
Constructed of a PTFE inner lining, stainless steel inner braid and a nylon and Pebax® outer coating, the Quick-Cross Extreme Support Catheter guides and supports a guidewire during access of the vasculature, allows for wire exchanges and provides a conduit for the delivery of saline solutions or diagnostic 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

Quick-Cross Extreme Support Catheter

	0.014″	0.014″	0.018″	0.018″	0.018″	0.035″	0.035″	0.035″	0.035″
Model Number	518-084	518-086	518-088	518-090	518-092	518-076	518-078	518-080	518-082
Distal Tip Profile (F / in)	2.0 / 0.026	2.0 / 0.026	2.2 / 0.029	2.2 / 0.029	2.2 / 0.029	3.5 / 0.046	3.5 / 0.046	3.5 / 0.046	3.5 / 0.046
Distal Shaft Outer Diameter (in)	0.034	0.034	0.038	0.038	0.038	0.052	0.052	0.052	0.052
Working Length (cm)	135	150	90	135	150	65	90	135	150
Guidewire Compatibility (in)	0.014	0.014	0.018	0.018	0.018	0.035	0.035	0.035	0.035
Guide Compatibility (F)	5	5	5	5	5	N/A	N/A	N/A	N/A
Sheath Compatibility (F)	4	4	4	4	4	5	5	5	5
Proximal Shaft Diameter (in)	0.042	0.042	0.044	0.044	0.044	0.059	0.059	0.059	0.059
Radiopaque Marker Spacing (mm)	15	15	15	15	15	50	50	50	50

Crossing Solutions

QUICK-CROSS® EXTREME® SUPPORT CATHETER

Important Safety Information

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.**

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Spectranetics®
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QUICK-ACCESS™ NEEDLE HOLDER

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 is available ten per box

Quick-Access Needle Holder

Model Number	Product Description	Length (cm)	Guidewire Compatibility (in)	QTY
519-001	Needle Holder	23	up to 0.035	Box of 1
519-005	Needle Holder	23	up to 0.035	Box of 5
U201	Needle Holder	23	up to 0.035	Box of 10

Vessel Access

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.

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Spectranetics®
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QUICK-CROSS CAPTURE™ GUIDEWIRE RETRIEVER

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

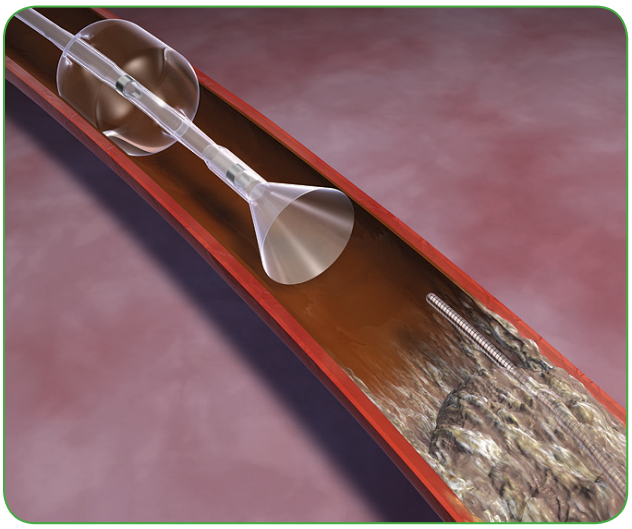
During complex retrograde procedures, retrieving and exchanging guidewires can be difficult, time-consuming and frustrating. The Quick-Cross Capture™ Guidewire Retriever easily, reliably and safely helps you retrieve and exchange guidewires with no damage either to the wire or to the vessel. It can even 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 times[1]
- 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

Quick-Cross Capture Guidewire Retriever

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

[1] Data on file.

Crossing Solutions

QUICK-CROSS CAPTURE™ GUIDEWIRE RETRIEVER

Important Safety Information

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.

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Spectranetics®
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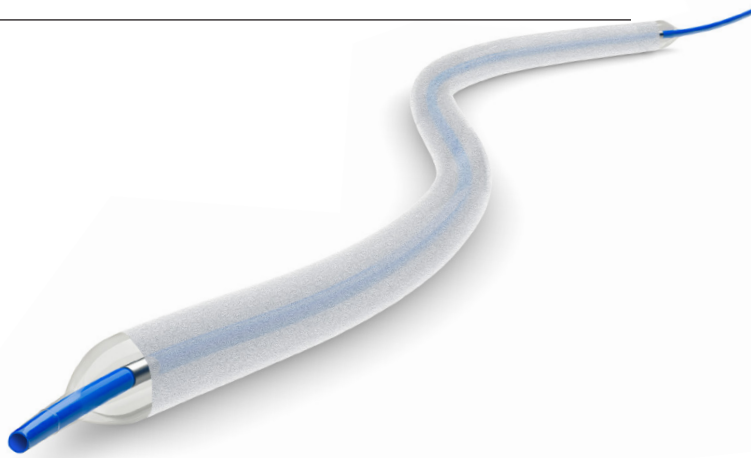
Stellarex™
Drug-coated Angioplasty Balloon

The Next-generation Drug-coated Balloon

The Stellarex Drug-coated Angioplasty Balloon features the Spectranetics' proprietary Enduracoat Technology and a low drug load (2 microgr/mm^2). Enduracoat technology features high coating uniformity and stability while maximizing drug transfer efficiency.

Key features:

- Spectranetics proprietary Enduracoat technology
- Drug load of 2 µg/mm^2
- PEG* (Polyethylene Glycol) Excipient
- High coating stability; low drug loss
- High transfer efficiency
- Sustained drug residency at 28+ day



Stellarex Drug-coated Angioplasty Balloon

Product Catalog Number	Sheath Size (Fr)	Balloon Diameter (mm)	Balloon Length (mm)	Shaft Length (cm)	Nominal Pressure (atm)	Rated Burst Pressure (atm)
A35SX040040080	6	4	40	80	10	20
A35SX040080080	6	4	80	80	10	20
A35SX040120080	6	4	120	80	10	20
A35SX050040080	6	5	40	80	10	18
A35SX050080080	6	5	80	80	10	18
A35SX050120080	6	5	120	80	10	16
A35SX060040080	6	6	40	80	8	14
A35SX060080080	6	6	80	80	8	14
A35SX060120080	6	6	120	80	8	12
A35SX040040135	6	4	40	135	10	20
A35SX040080135	6	4	80	135	10	20
A35SX040120135	6	4	120	135	10	20
A35SX050040135	6	5	40	135	10	18
A35SX050080135	6	5	80	135	10	18
A35SX050120135	6	5	120	135	10	16
A35SX060040135	6	6	40	135	8	14
A35SX060080135	6	6	80	135	8	14
A35SX060120135	6	6	120	135	8	12

Treatment Solutions

Stellarex™ Drug-coated Angioplasty Balloon

Important Safety Information

Indications, contraindications, warnings and instructions for use can be found in the product labelling supplied with each device. All claims and descriptions are for CE regulated countries. Availability of these products may vary in countries outside EU.

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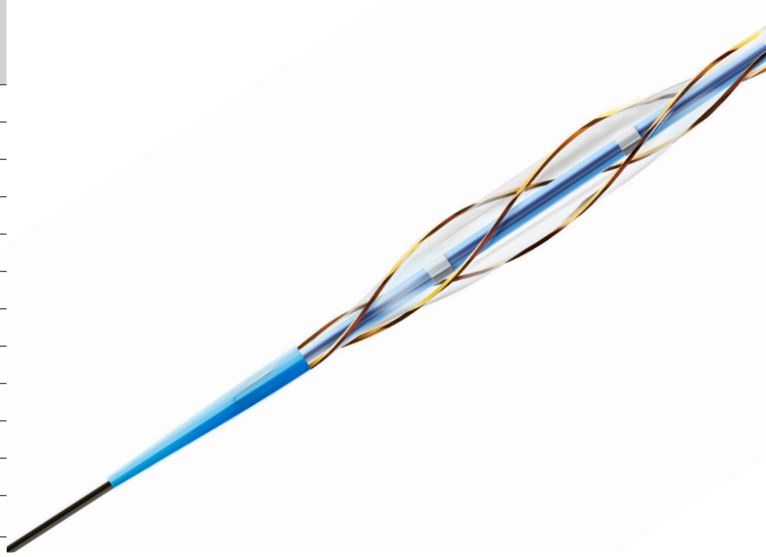
Spectranetics®
Always Reaching Farther

AngioSculpt® XL

PTA Scoring Balloon Catheter

AngioSculpt® XL: The longer length of AngioSculpt XL provides more coverage and convenience for infrainguinal artery procedures, but it's the unique advantage of the AngioSculpt scoring technology that really delivers.

Number	Balloon Diameter (mm)	Balloon Length (mm)	Catheter Length (cm)	Guidewire Compatibility	Sheath Size (F)
2039-2010	2.0	10	137	0.014″	5F
2039-2020	2.0	20	137	0.014″	5F
2155-2040	2.0	40	155	0.014″	5F
2215-20100	2.0	100	137	0.014″	6F
2216-20100	2.0	100	155	0.014″	6F
2039-2520	2.5	20	137	0.014″	5F
2155-2540	2.5	40	155	0.014″	5F
2215-25100	2.5	100	137	0.014″	6F
2216-25100	2.5	100	155	0.014″	6F
2039-3020	3.0	20	137	0.014″	5F
2155-3040	3.0	40	155	0.014″	5F
2215-30100	3.0	100	137	0.014″	6F
2216-30100	3.0	100	155	0.014″	5F
2039-3520	3.5	20	137	0.014″	5F
2155-3540	3.5	40	155	0.014″	5F
2215-35100	3.5	100	137	0.014″	6F
2216-35100	3.5	100	155	0.014″	6F
2076-40204	4.0	20	137	0.018″	6F
2092-40404	4.0	40	90	0.018″	6F
2076-40404	4.0	40	137	0.018″	6F
2290-40100	4.0	100	90	0.014″	6F
2237-40100	4.0	100	137	0.014″	6F
2249-40200	4.0	200	137	0.014″	6F
2076-50205	5.0	20	137	0.018″	6F
2092-50405	5.0	40	90	0.018″	6F
2076-50405	5.0	40	137	0.018″	6F
2290-50100	5.0	100	90	0.014″	6F
2237-50100	5.0	100	137	0.014″	6F
2249-50200	5.0	200	137	0.014″	6F
2105-6020	6.0	20	50	0.018″	6F
2092-6020	6.0	20	90	0.018″	6F
2076-6020	6.0	20	137	0.018″	6F
2105-6040	6.0	40	50	0.018″	6F
2092-6040	6.0	40	90	0.018″	6F
2076-6040	6.0	40	137	0.018″	6F
2290-60100	6.0	100	90	0.014″	6F
2237-60100	6.0	100	137	0.014″	6F
2249-60200	6.0	200	137	0.014″	6F



Primary Product Features:

The AngioSculpt XL is now available in even longer lengths, providing a greater array of sizes to meet the needs of treating diffuse disease in the lower extremities.

- Longer balloon length can lead to fewer inflations and reduced procedure times
- Only 100mm and 200mm devices to feature the proprietary AngioSculpt Scoring Technology
- Large working range (2–up to 20 atm) allows physician to tailor device to vessel size*
- Nitinol-enhanced balloon deflation for excellent rewrap and recross capabilities
- Electropolished, helical scoring element safely scores lesion circumferentially4
- Rectangular edges provide a predictable dilatation resulting in low dissection rates
- Available in a wide range of balloon sizes

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AngioSculpt® XL PTA Scoring Balloon Catheter

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Important Safety Information

INDICATIONS

The AngioSculpt PTA Scoring Balloon Catheter is intended for dilatation of lesions in the iliac, femoral, ilio-femoral, popliteal, infra-popliteal, and renal arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. Not for use in the coronary or neuro-vasculature.

CONTRAINDICATIONS

None known for percutaneous transluminal angioplasty (PTA) procedures.

WARNINGS

This device is intended for single (one) patient use only. Do not resterilize and/or reuse, as this can potentially result in compromised device performance and increased risk of inappropriate resterilization and cross contamination. The inflated diameter of the balloon should approximate the diameter of the vessel just proximal and distal to the stenosis, in order to reduce potential vessel damage. When the catheter is exposed to the vascular system, it should be manipulated while under high-quality fluoroscopic observation. Do not advance or retract the catheter unless the balloon is fully deflated under vacuum. If resistance is met during manipulation, determine the cause of the resistance before proceeding. Balloon pressure should not exceed the rated burst pressure (RBP). Refer to product label for device-specific information. The RBP is based on results of in-vitro testing. At least 99.9% of the balloons (with a 95% confidence level) will not burst at or below their RBP. Use of a pressure monitoring device is recommended to prevent over-pressurization. Use only the recommended balloon inflation medium. Never use air or any gaseous medium to inflate the balloon. Proceed cautiously when using the AngioSculpt catheter in a freshly deployed bare metal or drug-eluting stent. The AngioSculpt catheter has not been tested for post-dilation of stents or in lesions distal to freshly deployed stents in clinical studies. Bench testing has shown no additional risk when inserting or withdrawing the AngioSculpt catheter through stents (no interference with stent struts, no retention of or damage to the AngioSculpt catheter). Use the catheter prior to the "Use Before" (expiration) date specified on the package.

PRECAUTIONS

A thorough understanding of the principles, clinical applications and risks associated with PTA is necessary before using this product.

Any use for procedures other than those indicated in these instructions is not recommended. The device is not recommended for use in lesions that may require inflation pressures higher than those recommended for this catheter. Do not use if package is opened or damaged. Prior to angioplasty, the catheter should be examined to verify functionality, device integrity and to ensure that its size and length are suitable for the specific procedure for which it is to be used. During and after the procedure, appropriate anticoagulants, antiplatelet agents and vasodilators should be administered to the patient according to institutional practice for peripheral angioplasty of similar arteries. Pass the AngioSculpt catheter through the recommended introducer sheath size or minimum size guiding catheter indicated on the product label.

ADVERSE EFFECTS

Possible adverse effects include, but are not limited to, total occlusion of the treated artery, arterial dissection or perforation, arterial spasm, pseudoaneurysm, restenosis of the dilated artery, embolism, thrombus, retained device components, hemorrhage or hematoma, arteriovenous fistula.

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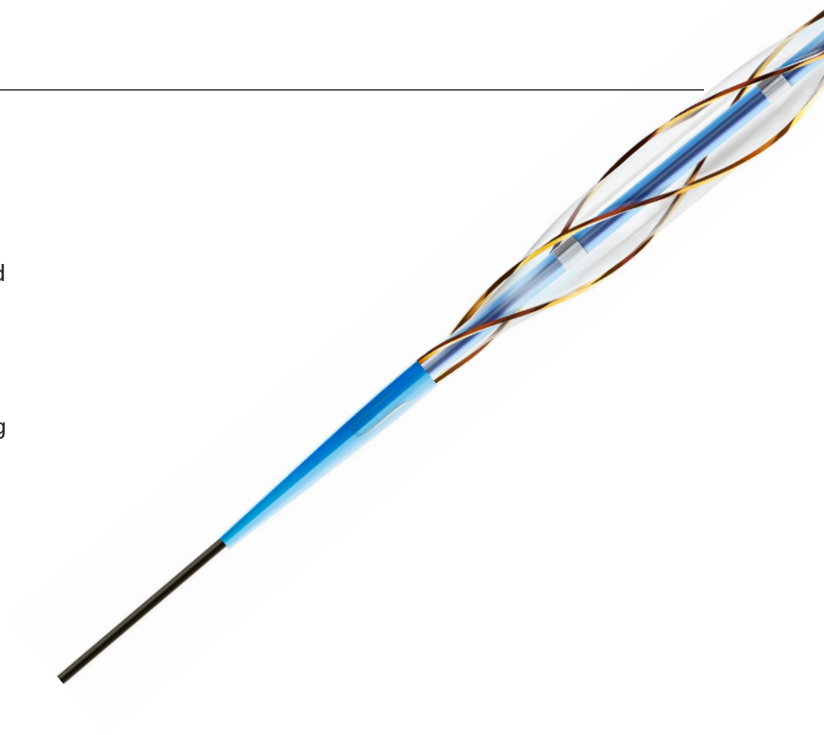
AngioSculpt® RX
PTCA Scoring Balloon Catheter

The new AngioSculpt® RX PTCA Scoring Balloon Catheter features an advanced molded, tapered tip that facilitates reliable catheter delivery.

- Smooth transitions throughout the distal end of the catheter for improved crossing
- The most agile and nimble AngioSculpt design ever
- Elevates procedural confidence



ADVANCED TECHNOLOGY DELIVERS BIG RESULTS

- Large working range (2 atm up to 20 atm) allows physician to tailor device to vessel size*
- Nitinol-enhanced balloon deflation for excellent rewrap and recross capabilities
- Electropolished, helical scoring element safely scores lesion circumferentially[1]
- Rectangular edges provide a predictable dilatation resulting in low dissection rates and minimal device slippage[2]

* Please refer to AngioSculpt RX PTCA product labeling, including the instructions for use, to select the appropriate device size.

AngioSculpt® PTCA Scoring Balloon Catheter

Number	Balloon Diameter (mm)	Balloon Length (mm)	Catheter Length (cm)	Guidewire Compatibility	Guide Catheter Compatibility
2200-2006	2	6	137	0.014″	6F
2200-2010	2	10	137	0.014″	6F
2200-2015	2	15	137	0.014″	6F
2200-2506	2.5	6	137	0.014″	6F
2200-2510	2.5	10	137	0.014″	6F
2200-2515	2.5	15	137	0.014″	6F
2200-3006	3	6	137	0.014″	6F
2200-3010	3	10	137	0.014″	6F
2200-3015	3	15	137	0.014″	6F
2200-3506	3.5	6	137	0.014″	6F
2200-3510	3.5	10	137	0.014″	6F
2200-3515	3.5	15	137	0.014″	6F

References

1. Fonseca A, Costa JR, Abizaid A, et al. Intravascular ultrasound assessment of the novel AngioSculpt Scoring Balloon Catheter for the treatment of complex coronary lesions. J Invasive Cardiol. 2008;20:21-27.

2. Mooney M, Teirstein P, Moses J, et al. Final results from the U.S. multi-center trial of the AngioSculpt Scoring Balloon Catheter for the treatment of complex coronary artery lesions. Am J Cardiol. 2006;98(suppl 8):121M.

AngioSculpt® PTCA Scoring Balloon Catheter

Important Safety Information

SUMMARY OF SAFETY AND EFFECTIVENESS – PTCA CATHETER INDICATIONS

The AngioSculpt Scoring Balloon Catheter is indicated for use in the treatment of hemodynamically significant coronary artery stenosis, including in-stent restenosis and complex type C lesions, for the purpose of improving myocardial perfusion.

CONTRAINDICATIONS

The AngioSculpt catheter should not be used for the following: Coronary artery lesions unsuitable for treatment by percutaneous revascularization. Coronary artery spasm in the absence of a significant stenosis.

WARNINGS

Administer appropriate antiplatelet, anticoagulant and coronary vasodilator therapy, consistent with institutional practice for coronary stent procedures, during and after the procedure. This device is intended for single (one) use only. Do not resterilize and/or reuse, as this can potentially result in compromised device performance and increased risk of inappropriate resterilization and cross contamination. For use in de novo or in-stent restenosis (ISR) lesions, the inflated diameter size of the balloon should approximate the vessel diameter size just proximal and distal to the stenosis, in order to reduce potential vessel damage. When used to pre-dilate the lesion prior to pre-planned stenting, the catheter should be one size smaller than the estimated vessel diameter (e.g., a 2.5 mm diameter device should be used in a vessel estimated to have a 3.0 mm diameter).

PTCA in patients who are not acceptable candidates for coronary artery bypass graft surgery requires careful consideration, including possible hemodynamic support during PTCA, as treatment of this patient population carries special risk. When the catheter is exposed to the vascular system, it should be manipulated while under high-quality fluoroscopic observation. Do not advance or retract the catheter unless the balloon is fully deflated under vacuum. If resistance is met during manipulation, determine the cause of the resistance before proceeding. Do not exceed the rated burst pressure (RBP) during balloon inflation. The RBP is based on results of in-vitro testing. At least 99.9% of the balloons (with 95% confidence) will not burst at or below their RBP. Use of a pressure monitoring device is recommended to prevent over-pressurization. PTCA should only be

performed at hospitals where emergency coronary artery bypass graft surgery can be quickly performed in the event of a potential cardiovascular injury or lifethreatening

complication. Use only the recommended balloon inflation medium. Never use air or any gaseous medium to inflate the balloon. Use the device prior to the expiration date specified on the package.

PRECAUTIONS

Take extra care when using the AngioSculpt catheter to treat a lesion distal to a freshly deployed stent. This precaution is particularly applicable to a drugeluting stent so as to minimize the risk of damage to the stent coating. Prior to angioplasty, examine the catheter to verify functionality, catheter integrity and to ensure that its size and length are suitable for the specific procedure for which it is to be used. Only physicians trained in the performance of percutaneous transluminal coronary angioplasty should use the AngioSculpt catheter. Do not rotate the catheter shaft in excess of 180 degrees when the tip is constrained. Do not rotate the catheter luer hub in excess of five (5) turns during use. Do not advance or retract the AngioSculpt catheter over the floppy portion of the guide wire. Catheter manipulation, including advancement and retraction, should be

performed by grasping the catheter shaft. If unusual resistance is felt when the catheter is being manipulated or if it is suspected that the guide wire has become kinked, carefully remove the entire catheter system (AngioSculpt catheter and steerable guide wire) as a unit. If fluoroscopic guidance indicates that the AngioSculpt catheter has advanced beyond the end of the guide wire, withdraw the catheter and reload the wire before advancing again.

POSSIBLE ADVERSE EFFECTS

Death; Heart Attack (acute myocardial infarction); Total occlusion of the treated coronary artery; Coronary artery dissection, perforation, rupture, or injury; Pericardial tamponade; No/slow reflow of treated vessel; Emergency coronary artery bypass (CABG); Emergency percutaneous coronary intervention; CVA/ stroke; Pseudoaneurysm; Restenosis of the dilated vessel; Unstable angina; Thromboembolism or retained device components; Irregular heart rhythm (hypotension)/high (hypertension) blood pressure; Coronary artery spasm; Hemorrhage or hematoma; Need for blood transfusion; Surgical repair of vascular access site; Creation of a pathway for blood flow between the artery and the vein in the groin (arteriovenous fistula); Drug reactions, allergic reactions to x-ray dye(contrast medium); Infection.

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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.

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 is available one per package

GlideLight Laser Sheath

Model Number	500-301	500-302	500-303
Sheath Size	12F	14F	16F
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
Working Length (cm)	50	50	50
Repetition Rate (Hz)	25-80	25-80	25-80
Clinical Energy Setting (mJ/mm^2)	30-60	30-60	30-60

For pacemaker and defibrillator lead manufacturers, models and GlideLight size compatibility, go to **www.spnc.com/LeadLookup**

Lead Management

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[3] (HRS) and European Heart Rhythm Association[2] (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

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SLS® II LASER SHEATH

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 is available one per package

SLS II Laser Sheath

	12F Kit	14F Kit	16F Kit
Model Number	500-001	500-012	500-013
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 / 5.17	18.2 / 0.238 / 6.07
Max Outer Sheath Outer 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/mm^2)	30-60	30-60	30-60
Energy Range (mJ) at 60 Fluence	38.4-46.8	38.4-46.8	43.7-53.5

For pacemaker and defibrillator lead manufacturers, models and SLS size compatibility, go to **www.spnc.com/SLSref.**

Lead Management

SLS® II 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.

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.

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.

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 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.

PRECAUTIONS (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 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 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

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TIGHTRAIL™
ROTATING DILATOR SHEATH

TightRail™ Rotating Dilator Sheath: The next generation in mechanical lead extraction sheaths.

TightRail mechanical sheaths provide the flexibility, control and safety required for effectively extracting cardiac leads.

Primary Product Features:

- Flexible shaft remains coaxial to the lead
- Dilating blade is shielded until activated
- Bidirectional mechanism
- Static outer shaft

Primary Product Benefits:

- A more flexible shaft remains coaxial to the lead.
- Unique shaft technology combines flexibility with column strength, enabling forward progression through vasculature and commonly encountered fibrotic lesions.
- Dilating blade remains shielded until activated, allowing safe counter traction at the targeted lead's distal tip.
- Designed to effectively dilate commonly encountered fibrotic lesions.
- Bidirectional mechanism rotates 540 degrees with each full trigger activation of the handle – 270 degrees clockwise and 270 degrees counterclockwise – while extending the blade 0.02 inches or 0.5 mm
- Static outer shaft does not rotate with the blade, so using an additional outer sheath is optional.

TightRail Rotating Dilator Sheath

Model Number	Size	Device Inner Diameter F / in / mm	Device Outer Diameter (F / in / mm)	Outer Sheath Outer Diameter (F / in / mm)	Working Length (in / cm)
545-509	9F	9.2 / 0.119 / 3.0	15.9 / 0.207 / 5.3	20.0 / 0.266 / 6.8	18.7 / 47.5
545-511	11F	11.2 / 0.145 / 3.7	18.0 / 0.234 / 5.9	23.0 / 0.293 / 7.4	18.7 / 47.5
545-513	13F	13.2 / 0.171 / 4.3	20.0 / 0.260 / 6.6	25.0 / 0.319 / 8.1	18.7 / 47.5

TIGHTRAIL™ ROTATING DILATOR SHEATH

Important Safety Information

INDICATIONS
The TightRail Rotating Dilator Sheath is intended for use in patients requiring the percutaneous dilation of tissue to facilitate the removal of cardiac leads, indwelling catheters, and foreign objects.

CONTRAINDICATIONS
None known.

WARNINGS
Lead removal devices should be used at institutions with cardiothoracic surgical capabilities by physicians knowledgeable in the techniques and devices for lead or catheter removal. Complication prevention and management protocols should be in place and routinely practiced. The recommendations for lead management of the Heart Rhythm Society[1] (HRS) and European Heart Rhythm Association[2] (EHRA) are highly recommended for best results.

When using a locking stylet:
Do not abandon a catheter/lead in a patient with a locking stylet still in place inside the catheter/lead. Severe vessel or endocardial wall damage may result from the stiffened catheter/lead or from fracture or migration of the abandoned stylet wire.

WARNINGS (continued)
Do not apply weighted traction to an inserted locking stylet as myocardial avulsion, hypotension, or venous wall tearing may result.

Be aware that leads with a J-shape retention wire occupying their inner lumen (rather than being outside of the coil) may not be compatible with the locking stylet. Insertion of the locking stylet into such a lead may result in protrusion and possible migration of the J-shape retention wire.

Do not insert more than one TightRail sheath or outer sheath into a vein at a time. Do not insert more than one lead or catheter into a TightRail device at a time. Severe vessel damage, including venous wall laceration requiring surgical repair may occur.

Maintain appropriate traction on the lead/catheter being extracted during advancement of the TightRail sheath or outer sheath. Excessive advancement force may result in device or vessel wall damage.

Do not leave 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).

Do not activate device when in contact with cardiac wall.

Refer to the IFU for additional information.

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Spectranetics®
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SIGHTRAIL™
DILATOR SHEATH SET

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

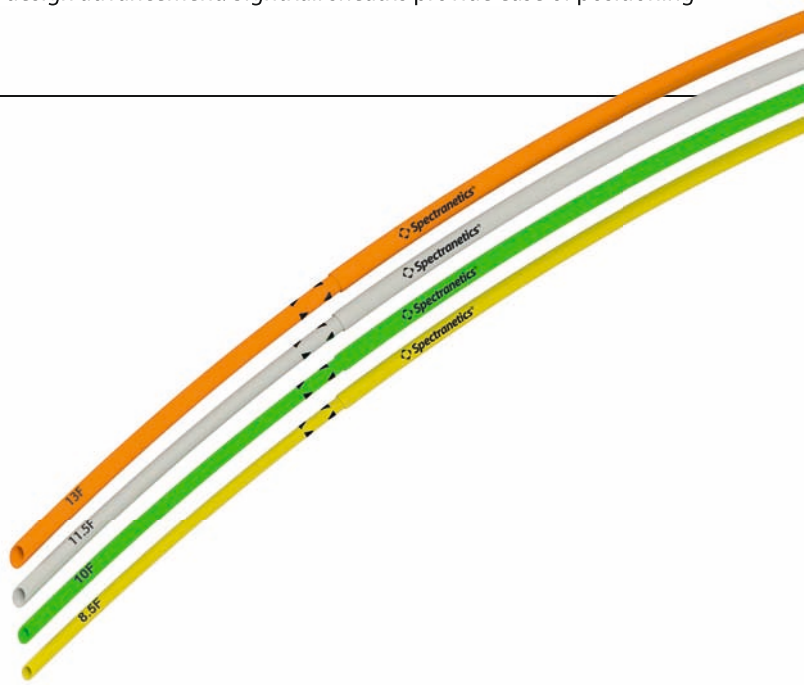
SightRail telescoping manual sheaths are a next-generation design advancement. SightRail sheaths provide ease of positioning and manipulation during cardiac lead removal procedures.

Primary Product Features:

- Printed indicators for bevel orientation and tip alignment
- Additional inner sheath length

Primary Product Benefits:

- **Ease of Positioning** – The device markers make it easier for physicians to know that the sheaths are oriented and positioned as desired and can be adjusted as needed
- **Ease of Manipulation** – The additional inner sheath length makes the device easy to manipulate



SightRail Dilator Sheath Set

MODEL NUMBER	SIZE	INNER / OUTER LENGTH (cm)	COLOR	INNER SHEATH DIAMETER		OUTER SHEATH DIAMETER	
				MINIMUM INNER DIAMETER (F / in / mm)	MAXIMUM OUTER DIAMETER (F / in / mm)	MINIMUM INNER DIAMETER (F / in / mm)	MAXIMUM OUTER DIAMETER (F / in / mm)
550-008	8.5F	43 / 33	Yellow	8.1 / 0.107 / 2.7	10.9 / 0.143 / 3.7	11.2 / 0.147 / 3.7	14.0 / 0.183 / 4.7
555-508	8.5F Long	51 / 41	Yellow	8.1 / 0.107 / 2.7	10.9 / 0.143 / 3.7	11.2 / 0.147 / 3.7	14.0 / 0.183 / 4.7
550-010	10F	43 / 33	Green	9.6 / 0.127 / 3.2	12.5 / 0.163 / 4.2	12.7 / 0.167 / 4.2	15.5 / 0.203 / 5.2
555-510	10F Long	51 / 41	Green	9.6 / 0.127 / 3.2	12.5 / 0.163 / 4.2	12.7 / 0.167 / 4.2	15.5 / 0.203 / 5.2
550-011	11.5F	43 / 33	White	11.2 / 0.147 / 3.7	14.0 / 0.183 / 4.7	14.2/ 0.187 / 4.7	17.0 / 0.223 / 5.7
555-511	11.5F Long	51 / 41	White	11.2 / 0.147 / 3.7	14.0 / 0.183 / 4.7	14.2/ 0.187 / 4.7	17.0 / 0.223 / 5.7
550-013	13F	43 / 33	Orange	12.7 / 0.167 / 4.2	15.5 / 0.203 / 5.2	15.7/ 0.207 / 5.2	18.6 / 0.243 / 6.2
555-513	13F Long	51/ 41	Orange	12.7 / 0.167 / 4.2	15.5 / 0.203 / 5.2	15.7/ 0.207 / 5.2	18.6 / 0.243 / 6.2

SIGHTRAIL™ DILATOR SHEATH SET

Important Safety Information

INDICATIONS FOR USE

The SightRail Dilator Sheath Set is intended for use in patients requiring the percutaneous dilation of tissue to facilitate the removal of cardiac leads, indwelling catheters, and foreign objects.

CONTRAINDICATIONS

None known.

WARNINGS

Dilator sheaths should be used only at institutions with cardiothoracic surgical capabilities by physicians knowledgeable in the techniques and devices for lead or catheter removal. Complication prevention and management protocols should be in place and routinely practiced. The recommendations for lead management of the Heart Rhythm Society[1] (HRS) and European Heart Rhythm Association[2] (EHRA) are strongly suggested.

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.

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

Do not maintain a stationary position with SightRail Dilator Sheath tips 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).

PRECAUTIONS

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 alter the sheath from its original state prior to use.

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

Prior to the procedure, evaluate the physical dimensions of the lead, catheter, or foreign object in relation to the specifications of the dilator sheath to determine compatibility.

If selectively removing leads/catheters with the intent to leave one or more chronic leads/catheters implanted intact, the non-targeted leads/catheters must be subsequently tested to ensure that they were not damaged or dislodged during the procedure.

When advancing dilator sheaths, use proper sheath technique. Maintain adequate tension and coaxial alignment on the lead/catheter to minimize the risk of vessel wall or cardiac structure damage.

If excessive scar tissue or calcification prevents safe advancement of dilator sheaths, consider an alternate approach.

Excessive force with dilator sheaths used intravascularly may result in damage to the vascular system requiring emergency surgical repair.

If the lead/catheter breaks, evaluate fragment for retrieval.

If hypotension develops, rapidly evaluate; treat as appropriate.

Due to rapidly evolving lead/catheter technology, this device may not be suitable for dilation of tissue around all types of leads/catheters. If there are questions or concerns regarding compatibility of this device with particular leads/catheters, contact the lead/catheter manufacturer.

PRECAUTIONS (continued)

Do not pull on the lead/catheter because it may stretch, distort, or break, making subsequent removal more difficult. Damage to a lead may prevent passage of a lead locking device through the lumen and/or make dilation of scar tissue more difficult.

When removing a chronic pacing lead, be aware that if it is freed spontaneously during the extraction procedure, the lead tip may become trapped in the upper vasculature. Dilator sheaths, advanced at least to the innominate vein, are often necessary to extract the lead tip through the scar tissue at the site of venous entry, and to avoid a venotomy.

If the dilator sheath fails to progress after initial success, or if advancing the sheath was difficult, remove the sheaths one at a time to inspect the tips. If the inner sheath tip is distorted or frayed, the other end may be used. A new sheath set may also be used to continue treatment.

When advancing a sheath around a bend, be cognizant of the sheath's beveled tip orientation.

ADVERSE EVENTS

Potential adverse events related to the procedure of intravascular removal of leads/catheters include (listed generally in order of increasing potential effect):

- Dislodging or damaging non-targeted lead/catheter
- Chest wall hematoma
- Thrombosis
- Arrhythmias
- Bacteremia
- Hypotension
- Pneumothorax
- Migrating fragment from lead/catheter
- Migration of vegetation from lead/catheter
- Pulmonary embolism
- Laceration or tearing of vascular structures or the myocardium
- Hemopericardium
- Cardiac tamponade
- Hemothorax
- Stroke
- Death

INDIVIDUALIZATION OF TREATMENT

Weigh the relative risks and benefits of intravascular catheter/lead removal procedures in cases when:

- Dual coil ICD leads are 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.

HOW SUPPLIED

For single use only. Do not re-sterilize and/or reuse. The SightRail Dilator Sheath Set is supplied sterile and non-pyrogenic. Sterility is guaranteed only if the package is unopened and undamaged.

Store devices in a dry cool place (below 60° C / 140° F) until use.

REFERENCES

1. Wilkoff B.L., et al. Transvenous Lead Extraction: Heart Rhythm Society Expert Consensus on Facilities, Training, Indications, and Patient Management. Heart Rhythm. July 2009.
2. Deharo J.C., et al. Pathways for training and accreditation for transvenous lead extraction: a European Heart Rhythm Association position paper. Europace (2012) 14, 124-134.

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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.

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 and LLD are available three per package

LLD EZ Lead Locking Device

Device	Model Number	Locking Range (in / mm)	Average Tensile Force (lbs)**	Working Length (cm)
LLD EZ	518-062	0.015 / 0.38 to 0.023 / 0.58	19	65

LLD Lead Locking Device

Device	Model Number	Locking Range (in / mm)	Average Tensile Force (lbs)**	Working Length (cm)
LLD #1	518-018	0.013 / 0.33 to 0.016 / 0.41	12	65
LLD #2	518-019	0.017 / 0.43 to 0.026 / 0.66	24	65
LLD #3	518-020	0.027 / 0.69 to 0.032 / 0.81	45	65
LLD E	518-039	0.015 / 0.38 to 0.023 / 0.58	19	85

LLD Accessories

Device	Model Number
LLD Accessory Kit	518-027
Lead Cutter	518-024

- *The LLD Accessory Kit is available one per package*
- *The Lead Cutter is available one per package*

* Kennergren, C., et al. (2000.) Cardiac Lead Extraction with a Novel Locking Stylet. *Journal of Interventional Cardiac Electrophysiology, 4, 591-593.*

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

LLD EZ® AND LLD® LEAD LOCKING DEVICES

Important Safety Information

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)

to the lead body. When using the LLD, 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.

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VISISHEATH® AND TORQMAX®

DILATOR SHEATH AND SHEATH GRIP ACCESSORY

The VisiSheath® Dilator Sheath acts as an independent sheath or outer support sheath for dilating tissue surrounding cardiac leads, indwelling catheters and foreign objects.

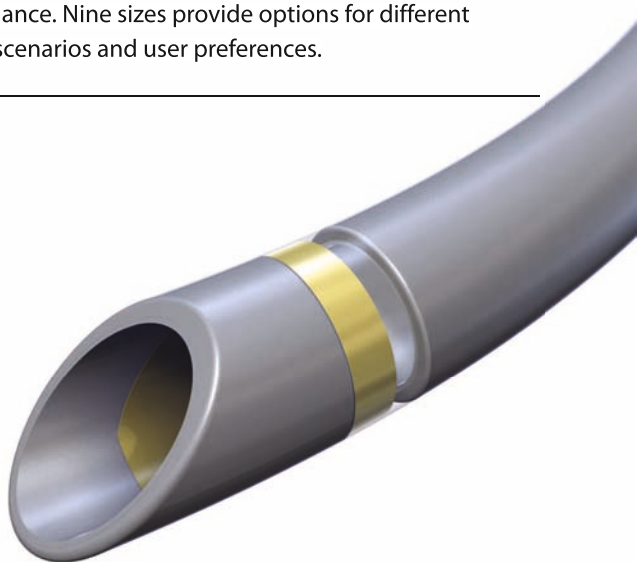
VisiSheath's gold-coated steel marker bands provide over 200% better fluoroscopic visibility than standard Teflon or polypropylene sheaths.* An advanced multi-layer construction and robust tip design deliver high performance. Nine sizes provide options for different clinical scenarios and user preferences.

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 is available one per package

VisiSheath Dilator Sheath

Model Number	Size (diameter)	Minimum Inner Diameter (F / in / mm)	Maximum Outer Diameter (F / in / mm)	Length (cm)	SLS II® Laser Sheath Compatibility (F)
501-012	S	12.8 / 0.168 / 4.2	16.4 / 0.215 / 5.5	43	12
501-014	M	15.0 / 0.198 / 5.0	19.3 / 0.253 / 6.5	43	14
501-016	L	17.9 / 0.236 / 5.9	22.4 / 0.293 / 7.5	43	16
501-112	S	12.8 / 0.168 / 4.2	16.4 / 0.215 / 5.5	33	12
501-114	M	15.0 / 0.198 / 5.0	19.3 / 0.253 / 6.5	33	14
501-116	L	17.9 / 0.236 / 5.9	22.4 / 0.293 / 7.5	33	16
501-212	S	12.8 / 0.168 / 4.2	16.4 / 0.215 / 5.5	23	12
501-214	M	15.0 / 0.198 / 5.0	19.3 / 0.253 / 6.5	23	14
501-216	L	17.9 / 0.236 / 5.9	22.4 / 0.293 / 7.5	23	16

TorqMax Sheath Grip Accessory

Model Number	Minimum Sheath Outer Diameter (F / in / mm)	Maximum Sheath Outer Diameter (F / in / mm)	Sheath Grip Length (in / mm)
502-001	11.9 / 0.155 / 4.0	22.5 / 0.296 / 7.5	2.5 / 64

* Data on file at Spectranetics.

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.

PRECAUTIONS

For single use only. The VisiSheath Dilator Sheath must not be resterilized and/or reused. Do not alter the sheath from its original state prior to use. When the VisiSheath Dilator Sheath is in the body, it should be manipulated only under fluoroscopic observation with radiographic equipment that provides high-quality images. Prior to the procedure, evaluate the physical dimensions of the lead, catheter, or inner sheath in relation to the specifications of the dilator sheath to determine possible incompatibility. If selectively removing leads/catheters with the intent to leave one or more chronic leads/catheters implanted intact, the non-targeted leads/catheters must be subsequently tested to ensure that they were not damaged or dislodged during the procedure. Maintain adequate tension and coaxial alignment on the lead/catheter to minimize the risk of vessel wall damage. If excessive scar tissue or calcification prevents safe advancement of dilator sheaths, consider an alternate approach. Excessive force with dilator sheaths used intravascularly may result in damage to the vascular system requiring emergency surgical repair. If the lead/catheter breaks, evaluate fragment for retrieval. If hypotension develops, rapidly evaluate; treat as appropriate. Due to rapidly evolving lead/catheter technology, this device may not be suitable for dilation of tissue around all types of leads/catheters. Do not pull on the lead/catheter because it may stretch, distort, or break, making subsequent removal more difficult. Damage to a lead may prevent passage of a lead locking device through the lumen and/or make dilation of scar tissue more difficult. If the dilator sheath fails to progress after initial success, or if advancing the sheath was difficult, remove the sheath to inspect the tip. If the tip is distorted or frayed, exchange the damaged sheath for a new sheath before continuing treatment. When advancing a sheath around a bend, keep the point of the sheath's beveled tip oriented toward the inside of the bend.

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 TorqMax Sheath Grip Accessory from its original state prior to use. Observe all precautions for the sheath to be used as indicated in the associated "Instructions for Use."

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