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PHILIPS

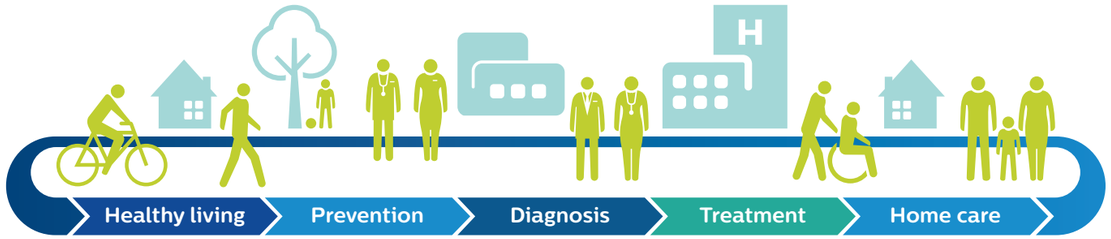
Image Guided Therapy

Lead management products

A full portfolio of safe and effective lead management technologies

International version

Philips and Spectranetics merging our strengths



The Spectranetics acquisition enables the treatment arm of the Philips Health Continuum

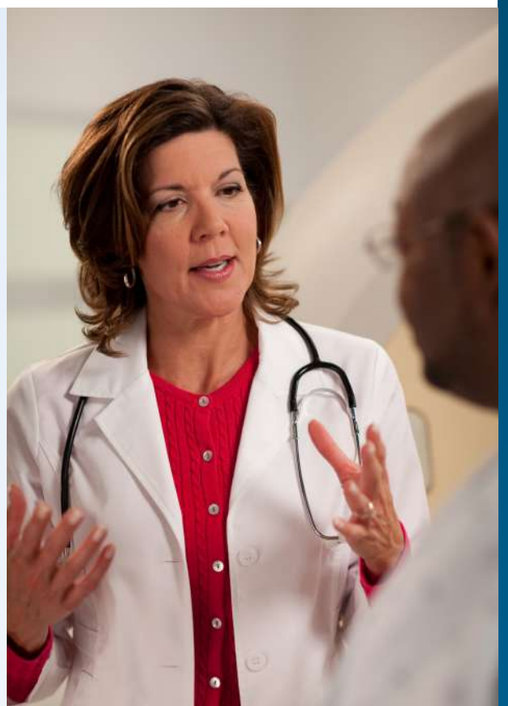
Delivering more effective healthcare by enhancing workflow, improving outcomes and reducing the cost of care. The following represents the Philips and Spectranetics combined product portfolio and the power of us coming together:

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

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

Prepare. Extract. Secure.

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



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Lead management: Making the right decision at the right time, for every patient.

Managing cardiac implanted electronic device (CIED) leads has never been more important. Patients with CIEDs are on a life-long journey, and you're there to make sure it's a healthy one. As your profession advances and more lives are saved with these devices, proactive lead management is essential for your patients, your practice and your hospital. It means partnering with your patients to make the right decision at the right time. There are 13 million cardiac implanted electronic device (CIED) leads worldwide, and another 1.4 million are implanted every year.[14-15]

To cap or not to cap?

There are many reasons to consider lead extraction for your patients living with cardiac devices. CIED patients are enjoying longer lives than ever before, and at some point in time their leads may need to be replaced. Leads may malfunction, or there may be advisories. Capped leads may be a nidus for infection, and infection rates are rising dramatically.[1,2] Understanding the potential clinical implications of capping leads is essential to informing a sound decision about whether to cap and abandon a lead.

Abandoned leads:

- May have abnormalities or insulation failures that allow electrical conductors to move entirely outside the outer lead insulation.
- May cause lead-on-lead interaction[3-5]
- Can be more difficult to extract in the future[6,7]
- Can increase the risk of deadly infection[8], occlusion, thrombosis, and SVC syndrome.[9]

Wait, refer or remove?

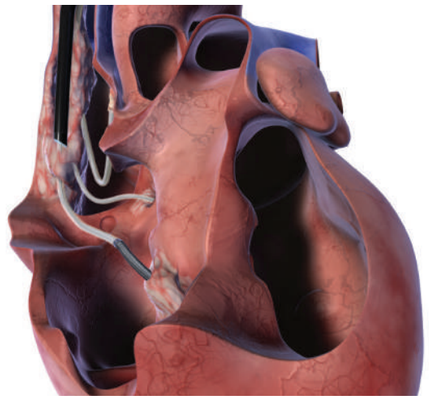
The presence of a systemic infection, pocket infection or endocarditis is a Class I indication for removal of all hardware, including leads.[6, 13] 6 in 10 device infections may be undertreated.[11]

Multiple studies show patients are 2 times more likely to die with a device infection compared to patients without infections.[1,12] When treated with antibiotics alone, mortality rates can be as high as 66% in device-related endocarditis cases. Laser lead removal has a 97.7% success rate.[8]

Proven extraction solutions

Laser lead extraction is proven to be a safe and effective way to manage leads. Multiple clinical studies demonstrate predictable success: 97.7% clinical success rate in lead removal, with only 1.4% of patients experiencing a major adverse event during laser lead extraction.[8-10] This major adverse event rate is lower than with many cardiovascular procedures, including AFIB.[16-19]

At Spectranetics, we firmly believe in managing every lead, safely, predictably and responsibly. Every patient is different, and every case is different. When extraction is the right choice for your patient, Spectranetics is here to support your lead management decisions with a broad portfolio of tools designed for safety and predictability, includings both laser lead extraction and next-generation mechanical devices.



Animated lead management procedure with GlideLight™ laser sheath

Indications for lead extraction[1] - infectious

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

Infection diagnosis

Class I indications

1. Evaluation by physicians with specific expertise in CIED infection and lead extraction is recommended for patients with documented CIED infection. (LOE C-EO)
2. If antibiotics are going to be prescribed, drawing at least two sets of blood cultures before starting antibiotic therapy is recommended for all patients with suspected CIED infection to improve the precision and minimize the duration of antibiotic therapy. (LOE C-LD)
3. Gram stain and culture of generator pocket tissue and the explanted lead(s) are recommended at the time of CIED removal to improve the precision and minimize the duration of antibiotic therapy. (LOE C-LD)
4. Pre-procedural transesophageal echocardiography (TEE) is recommended for patients with suspected systemic CIED infection to evaluate the absence or size, character, and potential embolic risk of identified vegetations. (LOE B-NR)

Class II indications

1. TEE can be useful for patients with CIED pocket infection with and without positive blood cultures to evaluate the absence or size, character, and potential embolic risk of identified vegetations. (LOE B-NR)
2. Evaluation by physicians with specific expertise in CIED infection and lead extraction can be useful for patients with suspected CIED infection. (LOE C-EO)

Class IIb indications

1. Additional imaging may be considered to facilitate the diagnosis of CIED pocket or lead infection when it cannot be confirmed by other methods. (LOE C-LD)

Infection management recommendations

Class I indications

1. Complete device and lead removal is recommended for all patients with definite CIED system infection. (LOE B-NR)
2. A complete course of antibiotics based on identification and in vitro susceptibility testing results after CIED removal is recommended for all patients with definite CIED system infection. (LOE B-NR)
3. Complete removal of epicardial leads and patches is recommended for all patients with confirmed infected fluid (purulence) surrounding the intrathoracic portion of the lead. (LOE C-EO)
4. Complete device and lead removal is recommended for all patients with valvular endocarditis without definite involvement of the lead(s) and/or device. (LOE B-NR)
5. Complete device and lead removal is recommended for patients with persistent or recurrent bacteremia or fungemia, despite appropriate antibiotic therapy and no other identifiable source for relapse or continued infection. (LOE B-NR)
6. Careful consideration of the implications of other implanted devices and hardware is recommended when deciding on the appropriateness of CIED removal and for planning treatment strategy and goals. (LOE C-EO)

Class Definitions

Class I (Strong). Benefit >>>Risk	Class IIa (Moderate). Benefit >>Risk	Class IIb (Weak). Benefit ≥ Risk
Conditions for which treatment A should be chosen over treatment B.	Conditions for which it is reasonable to choose treatment A over treatment B.	Conditions for which it might be reasonable to choose treatment A over treatment B.

Recommendations for lead extraction apply only to those patients in whom the benefits of lead removal outweigh the risks when assessed based on individualized patient factors and operator specific experience and outcomes.

Indications for lead extraction[1] – non-infectious

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

Chronic pain

Class IIa indication

1. Device and/or lead removal can be useful for patients with severe chronic pain at the device or lead insertion site or believed to be secondary to the device, which causes significant patient discomfort, is not manageable by medical or surgical techniques, and for which there is no acceptable alternative. (LOE C-EO)

Thrombosis/vascular issues

Class I indications

1. Lead removal is recommended for patients with clinically significant thromboembolic events attributable to thrombus on a lead or a lead fragment that cannot be treated by other means. (LOE C-EO)
2. Lead removal is recommended for patients with SVC stenosis or occlusion that prevents implantation of a necessary lead. (LOE C-EO)
3. Lead removal is recommended for patients with planned stent deployment in a vein already containing a transvenous lead, to avoid entrapment of the lead. (LOE C-EO)
4. Lead removal as part of a comprehensive plan for maintaining patency is recommended for patients with SVC stenosis or occlusion with limiting symptoms. (LOE C-EO)

Class IIa indication

1. Lead removal can be useful for patients with ipsilateral venous occlusion preventing access to the venous circulation for required placement of an additional lead. (LOE C-LD)

Other

Class I indications

1. Lead removal is recommended for patients with life-threatening arrhythmias secondary to retained leads. (LOE C-EO)

Class IIa indications

1. Lead removal can be useful for patients with a CIED location that interferes with the treatment of a malignancy. (LOE C-EO)
2. Lead removal can be useful for patients if a CIED implantation would require more than 4 leads on one side or more than 5 leads through the SVC. (LOE C-LD)
3. Lead removal can be useful for patients with an abandoned lead that interferes with the operation of a CIED system. (LOE C-EO)

Class IIb indications

1. Lead removal may be considered for patients with leads that due to their design or their failure pose a potential future threat to the patient if left in place.
2. Lead removal may be considered for patients to facilitate access to MRI.* (LOE C-EO) *Removal of leads to prevent their abandonment, removal of broken or abandoned leads, or removal of leads to allow implantation of an MRI conditional system.
3. Lead removal may be considered in the setting of normally functioning non-recalled pacing or defibrillation leads for selected patients after a shared decision-making process. (LOE C-EO)

Abbreviations

CIED	cardiovascular implantable electronic device
AFIB	atrial fibrillation
EO	expert opinion
LD	limited data available
NR	non-randomized studies
LOE	level of evidence
MRI	magnetic resonance imaging
SVC	superior vena cava
TEE	transesophageal echocardiography

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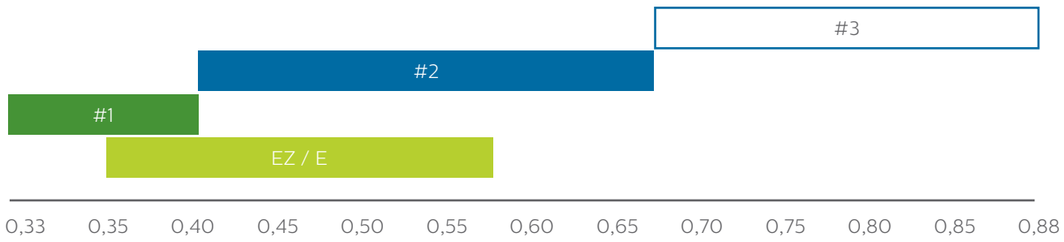
LLD EZ® and LLD®
Lead locking devices

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.

Device	Model number		Locking range	Average tensile force	Working length	Clearing stylet number / diameter
	Single	Pack of 3	(in/mm)	(lbs)	(cm)	(in/mm)
#1	518-021	518-018	0.013 / 0.33 to 0.016 / 0.41	12	65	1 (0.012 / 0.30)
E	--	518-039	0.015 / 0.38 to 0.023 / 0.58	19	85	1 (0.012 / 0.30)
EZ	518-067	518-062	0.015 / 0.38 to 0.023 / 0.58	19	65	1 (0.012 / 0.30)
#2	518-022	518-019	0.017 / 0.43 to 0.026 / 0.66	24	65	2 (0.015 / 0.38)
#3	518-023	518-020	0.027 / 0.69 to 0.032 / 0.81	45	65	2 (0.015 / 0.38)

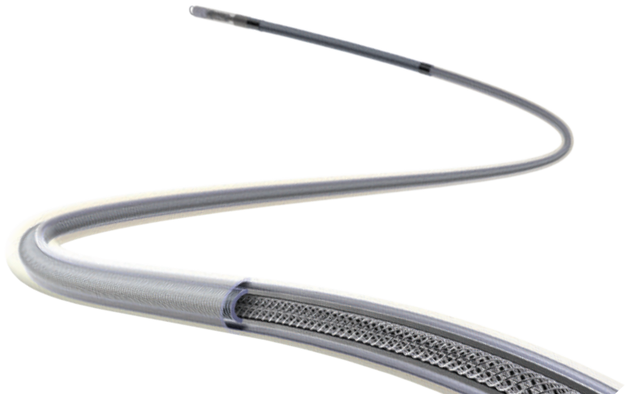
Diameter of inner lumen of the lead

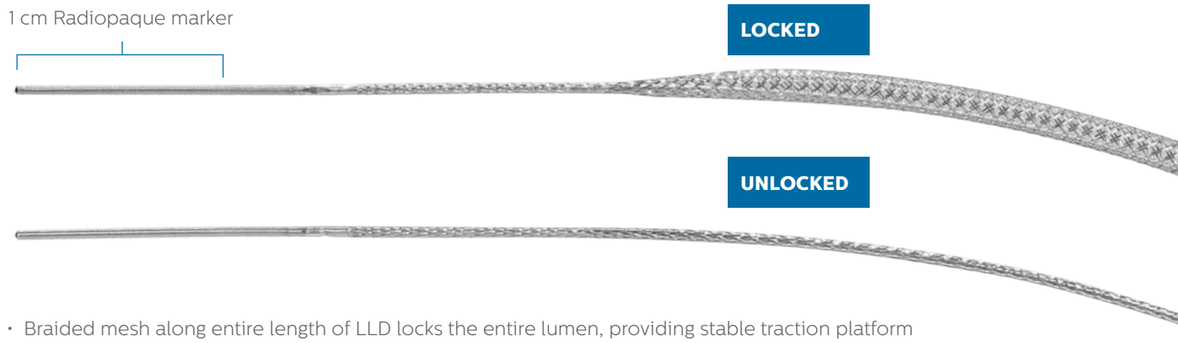


Accessories	Model number
LLD accessory kit	518-027
Lead cutter	518-024

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

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





- Braided mesh along entire length of LLD locks the entire lumen, providing stable traction platform
- LLD provides proven capability to unlock after initial deployment[1]
- Highly visible radiopaque marker assists identification of LLD EZ and LLD E tip location under fluoroscopy
- Low-profile loop handles (LLD EZ)

- Accessories are used to facilitate reliable insertion of the LLD Lead Locking Device.
- The Lead Cutter provides clean access to the inner lumen of the lead. The Accessory Kit provides a Coil Expander to restore the proximal end of the lead coils to a circular shape and tow Pin Gauges for determination which LLD size is appropriate.

Pin number	Select LLD
Oin #1 fits, but not E/EZ	#1
Pin E/EZ fits, but not #2	E or EZ
Pin #2 fits, but not #3	#2, E, or EZ*
Pin #3 fits	#3

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

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

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

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

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

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

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

Extract

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.

Service excellence guarantee

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

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

GlideLight™ Laser sheath

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

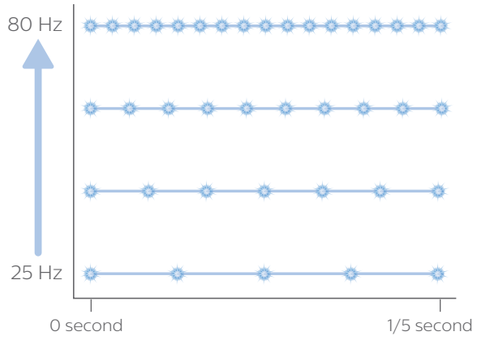
Safely and efficiently removing leads depends on tools that give you versatility and control. The GlideLight Laser Sheath offers the unprecedented ability to customize the laser's repetition rate throughout a procedure. The GlideLight Laser Sheath incorporates optical fibers arranged in a circle. The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

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/mm2)	30-60	30-60	30-60

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

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

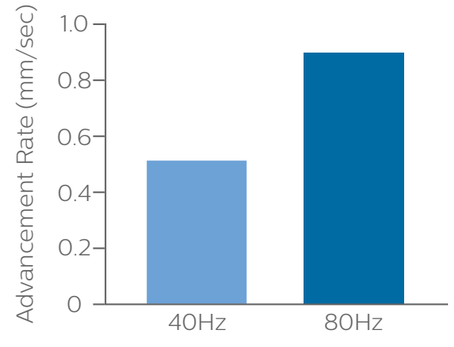
Flexible pulse repetition rate*



GlideLight Laser Sheath allows you to customize the repetition rate.

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

Advancement rate at constant force



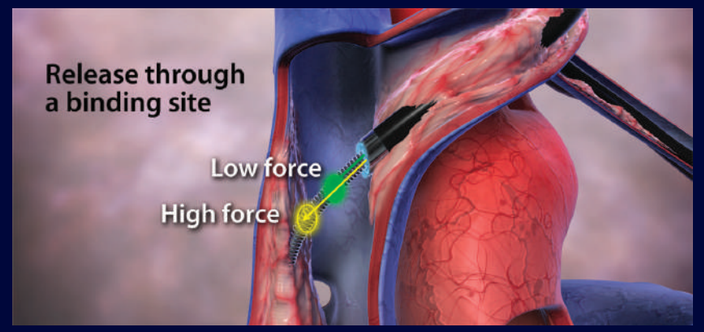
Rate of progression through binding sites at 40Hz and 80Hz.

GlideLight Laser Sheath enables you to advance up to 62% more efficiently through tough binding sites 2.

1. Comparison of average peak push forces required to advance Laser Sheath at 40Hz vs. 80Hz Pulse Repetition Rate through simulated fibrosis material at an advancement rate of 1.0 mm/second. D015722, Data on file at Spectranetics.
2. Comparison of ablation force vs. advancement rate of Laser sheath 40Hz vs. 80Hz by use of the data collected in D015786, Data on file at Spectranetics.

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

Less unintended forward motion



GlideLight Laser Sheath allows physicians to use up to 55% less advancement force[1].

GlideLight Laser Sheath provides a high degree of control when progressing through binding sites[1].

1. Comparison of average peak push forces required to advance Laser Sheath at 40Hz vs. 80Hz Pulse Repetition Rate through simulated fibrosis material at an advancement rate of 1.0 mm/second. D015722, Data on file at Spectranetics.
2. Comparison of ablation force vs. advancement rate of Laser sheath 40Hz vs. 80Hz by use of the data collected in D015786, Data on file at Spectranetics.

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

SLS® II
Laser sheath

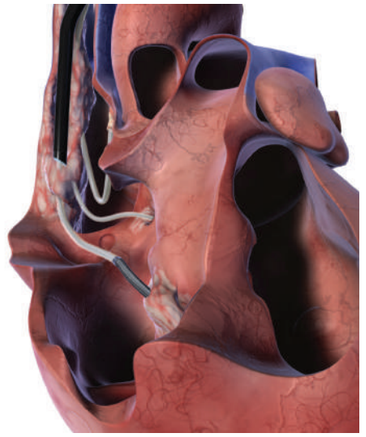
The SLS® II Laser Sheath is used to remove implanted pacing and defibrillator leads

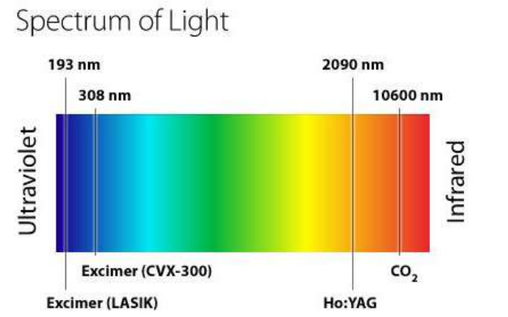
The SLS II incorporates optical fibers arranged in a circle. The fibers terminate at the distal end within a polished tip and at the proximal end within the coupler that mates with the CVX-300® Excimer Laser System. The energy emitted from the tip ablates the tissue holding the lead, thereby freeing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

	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	15,5/0,203/6,43	18,2/0,238/6,07
Max outer sheath inner diameter (F/in/mm)	16,4/0,215/5,47	19,3/0,253/6,43	22,4/0,294/7,47
Working length (cm)	50	50	50
Repetition rate (Hz)	25-40	25-40	25-40
Clinical energy setting (mJ/mm2)	30-60	30-60	30-60

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

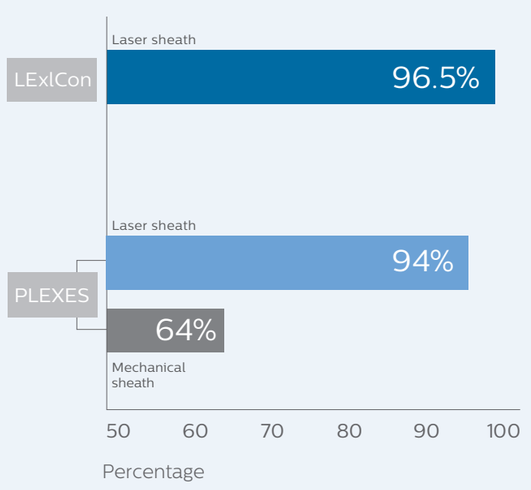
- Low-temperature excimer laser has a 50-micron penetration depth
- 15˚ bevel tip
- Flexible distal segment
- Lubricious coating along inner lumen



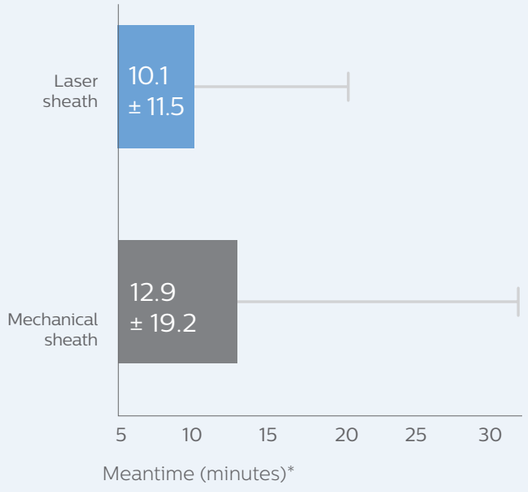


A ring of laser energy ablates contacted tissue around the circumference of the lead. The low-temperature excimer laser operates in the ultraviolet spectrum at 308nm to ablate target tissue at a depth of 50 microns.

Lead removal success rates[1,2]



Lead removal time



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

1. Wilkoff, B., et al. (2009). Pacemaker lead extraction with the laser sheath: Results of the Pacing Lead Extraction with Excimer Sheath (PLEXES) Trial. Journal of the American College of Cardiology, 33(6).
2. Wazni, O., et al. The LExICon study: A multicenter observational retrospective study of consecutive laser lead extractions. (2010). Journal of the American College of Cardiology, 55(6).

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

TightRail™ / TightRail™ Sub-C

Rotating dilator sheath

Flexibility meets control with TightRail™ lead removal

When removing a lead is the right decision, turn to TightRail. Its next-generation design advances provide the flexibility, control and safety required to effectively extract cardiac leads.

Model number	Size	Device inner diameter (F/in/mm)	Device outer diameter (F/in/mm)	Outer sheath inner diameter (F/in/mm)	Working length (in/cm)
545-009	9F	9,2/0,119/3,0	15,9/0,207/5,3	20,0/0,266/6,8	18,7/47,5
545-011	11F	11,2/0,145/3,7	18,0/0,234/5,9	23,0/0,293/7,4	18,7/47,5
545-013	13F	13,2/0,171/4,3	20,0/0,260/6,6	25,0/0,319/8,1	18,7/47,5

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

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

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

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

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

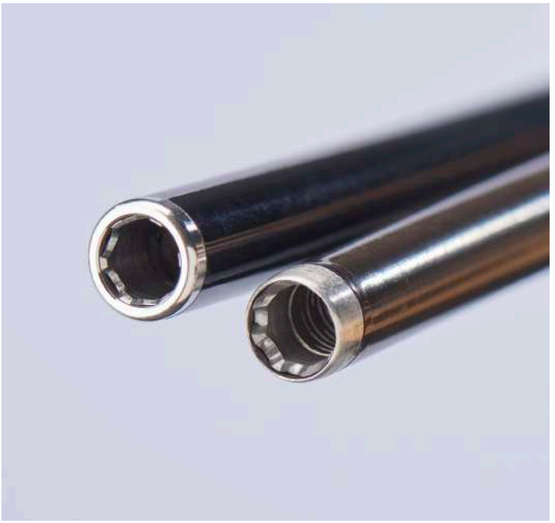
The subclavian region presents a variety of clinical challenges, including vessel entry when fibrosis and calcium are present. The TightRail Sub-C Rotating Dilator Sheath can be used alone or in conjunction with laser or other TightRail sheaths to safely and efficiently move through subclavian fibrosis and calcium for predictable vessel entry. It is designed for the subclavian region, featuring:

- A specialized cutting tip for subclavian vessel entry
- A short, stiff shaft at base for pushability
- A flexible tip for trackability
- A shielded rotational blade to minimize risk to vessels and adjacent leads

Model number	Size	Device inner diameter (F/in/mm)	Device outer diameter (F/in/mm)	Outer sheath inner diameter (F/in/mm)	Working length (in/cm)
560-009	9F	9,1/0,119/3,0	14,4/0,187/4,8	18,9/0,245/6,3	6,1/15,5
560-011	11F	11,1/0,145/3,7	16,4/0,213/5,5	20,9/0,271/6,9	6,1/15,5
560-013	13F	13,1/0,171/4,3	18,4/0,239/6,1	22,9/0,297/7,6	6,1/15,5

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

TightRail™ features a shielded, bi-directional blade.



TightRail Sub-C's lower profile cutting tip is specifically designed for the subclavian region.

SightRail™ and TorqMax®
Dilator sheath set and accessory

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

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

				Inner sheath diameter		Outer sheath diameter	
Model number	**Size**	**Inner/outer length (cm)**	**Color**	**Min. Inner diameter (F/in/mm)**	**Max. outer diameter (F/in/mm)**	**Min. inner diameter (F/in/mm)**	**Max. 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

Package Content: 1 inner sheath and 1 outer sheath

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

Model number	Minimum sheath outer diameter	Maximum sheath outer diameter	Sheath grip length
501-001	11,9 F/0,155 in/4,0 mm	22,5 F/0.296 in/7,5 mm	64 mm

Package content: 1 sheath

Easy to position

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

Easy to manipulate

- The inner sheath length is 10 centimeters longer than the outer sheath, making the device easy to manipulate.
- SightRail™ reduces the resistance between the inner sheath and the outer sheath by 14%[1].

Bevel orientation indicators

Ergonomic grip

- Contoured polymer shell with soft over-mold construction designed for comfortable user interface.
- Provides mechanical advantage to more easily rotate the body of an associated sheath.
- Distributes forces along the sheath body to aid in sheath advancement.

Easy side-loading

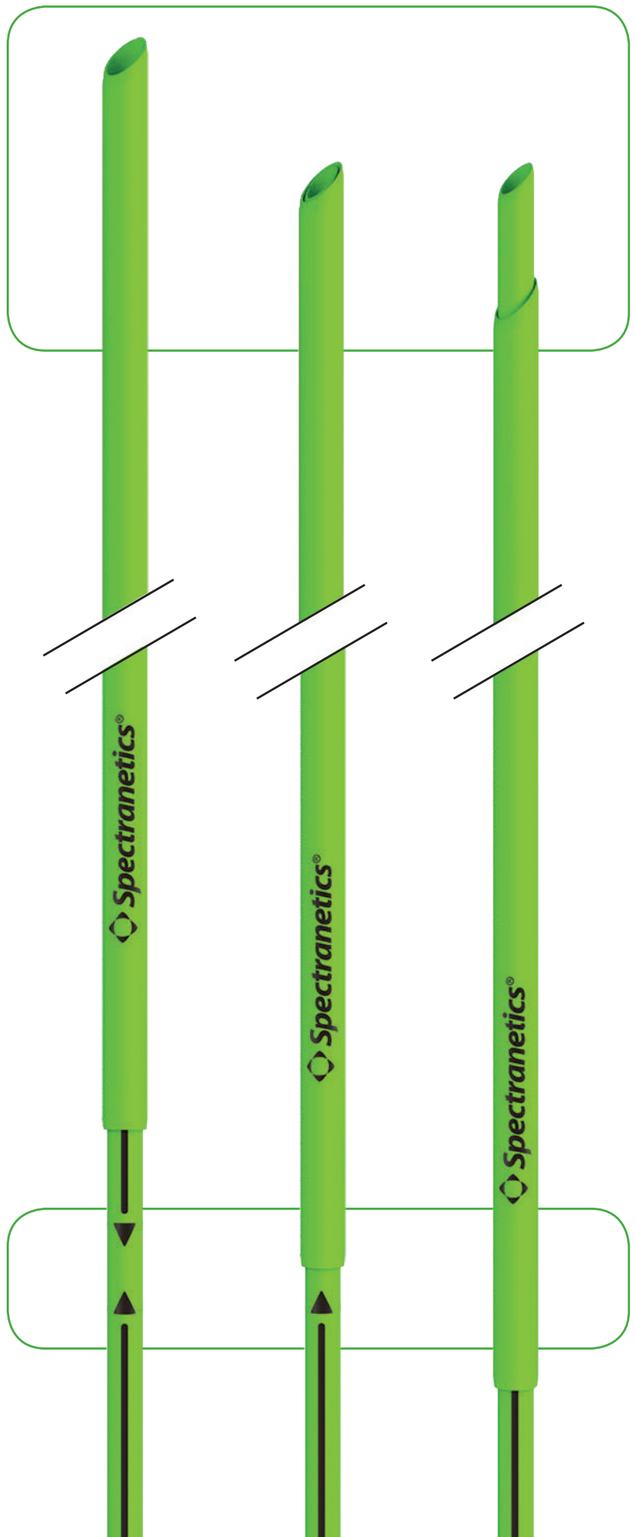
- Loads quickly and easily from the side- permitting easy removal or repositioning during procedures.
- Stays on the sheath where it is positioned, until the user chooses to move it.

Flexible sizing

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

Bevel orientation indicators

- Outer sheath tip is more distal than inner sheath tip.
- Distal tips of inner and outer sheaths are aligned.
- Inner sheath tip is more distal than outer sheath tip.



VisiSheath®
Dilator sheath

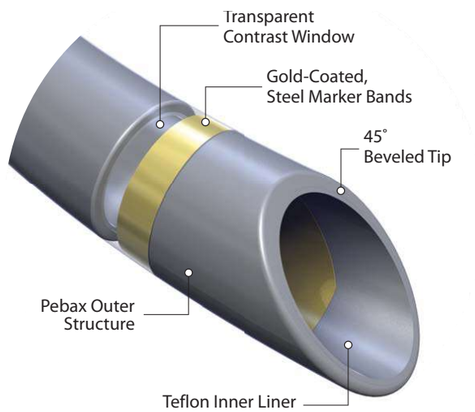
The VisiSheath® Dilator Sheath acts as an independent sheath or outer support sheath for dilating tissue surrounding cardiac leads, indwelling catheters and foreign objects.

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

Model number	Size	Min. Inner diameter (F/in/mm)	Max. outer diameter (F/in/mm)	Length (cm)	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

Package content: 1 sheath

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



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

Advanced multi-layer construction: Pebax® with Teflon® Liner

Outstanding flexibility for tracking without kinking*

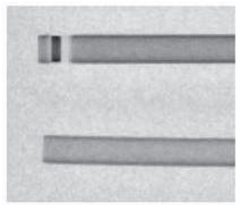
- 85% and 38% more bending deflection without kinking compared to similar sized polypropylene and Teflon sheaths respectively
- 39% better tracking than similar sized polypropylene sheaths

Strong torque delivery*

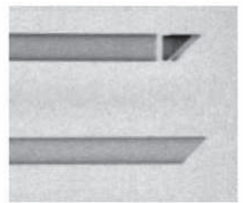
- Over 50% better torque response than Teflon sheaths

Over 200% better fluoroscopic visibility*

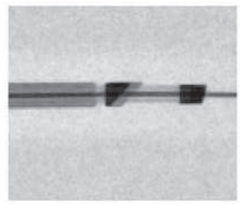
- Enables easy identification of tip location and bevel orientation.



VisiSheath blunt end vs. Teflon



VisiSheath beveled end vs. Teflon

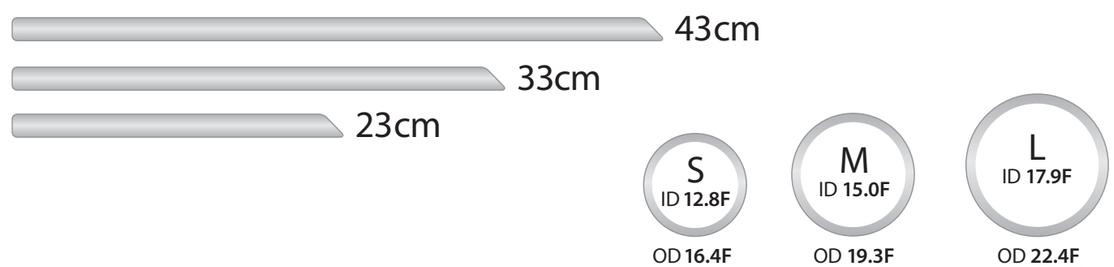


VisiSheath acting as an outer support for an SLS II laser sheath over a pacing lead

VisiSheath beveled end vs. Teflon under simulated low quality fluoroscopy

Nine size options

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



* Compared to common Teflon or polypropylene sheaths (data on file atSpectranetics).

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

Bridge®
Occlusion balloon

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

Bridge™ occlusion balloon catheter specifications	
Catalog #:	590-001
Catheter length:	90 cm
Balloon diameter: (nominal)	20 mm
Balloon length: (nominal)	80 mm
Maximum OD: (crossing profile)	4 mm/0,157"
Minimum tip ID:	0,9 mm/0,035"
Maximum inflation volume:	60cc

Bridge™ prep kit specifiactions	
Catalog #:	591-001
DescrIption:	Bridge™ occlusion balloon compatible guidewire, introducer sheath sets, syringe and stopcock

Secure

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

The Bridge™ occlusion balloon can be deployed in less than two minutes via a pre-placed guidewire.[1] Bridge is easy to use, with no additional balloon preparation required. Radiopaque markers guide proper placement. Bridge is designed to cover the entire length and diameter of the SVC in 90% of patients.[2]

Once deployed, the Bridge™ occlusion balloon can dramatically reduce blood loss. In an animal model of an SVC tear, Bridge reduced blood loss by up to 90% on average in tears up to 3.5 cm, with two pacing leads and one ICD lead in place.[3]

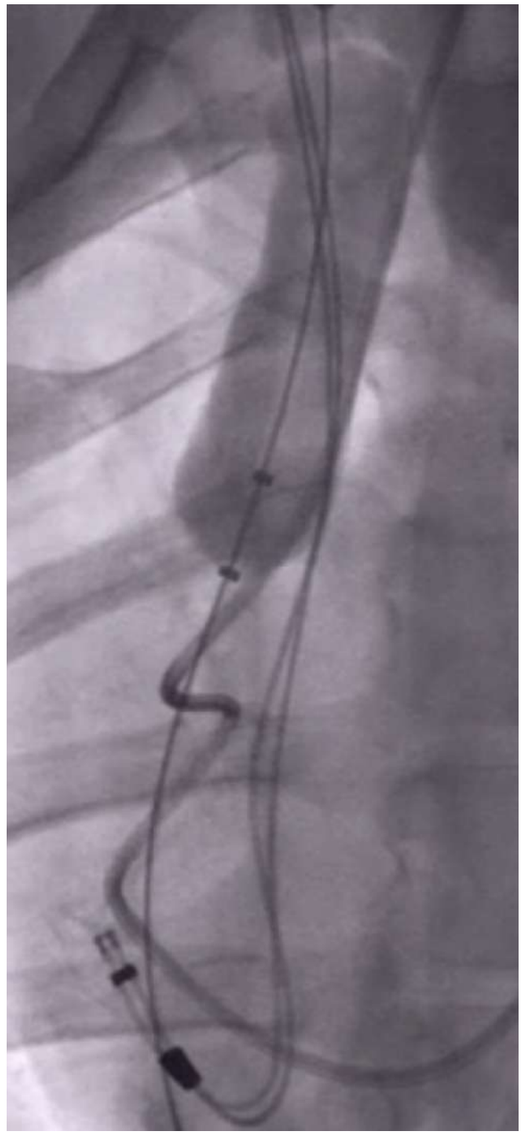
Bridge™ occlusion balloon can provide at least 30 minutes of acceptable hemostasis[4] - time to stabilize your patient and transition to surgery. With Bridge, the surgical team can approach the repair in a controlled setting with a clear field of view.

HRS Expert Consensus Statement 2017

Vascular Tears

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

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



Fluoroscopy image of Bridge™ balloon in an animal model.

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