SLS™II

Laser Sheath

Instructions for Use

Spectranetics®

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

1. Description

The Spectranetics Laser Sheath Kit includes a 12F, 14F, or 16F Laser Sheath, two Outer Sheaths, and a Fish Tape. The Laser Sheath is an intra-operative device used to free a chronically implanted pacing or defibrillator lead.

The laser sheath consists of optical fibers arranged in a circle, sandwiched between inner and outer polymer tubing. The fibers terminate at the distal end within a polished tip and at the proximal end within the coupler that mates with the excimer laser system. At the distal tip, the fibers are protected by inner and outer stainless steel bands, which form a radiopaque marker. The inner lumen of the device is designed to allow a pacing lead to pass through it, as the device slides over the lead towards the tip of the lead in the heart.

The laser sheath is designed for use only with the Spectranetics CVX-300® Excimer Laser System or the Philips Laser System. The multifiber laser sheaths transmit ultraviolet energy from the laser system to the tissue at the distal tip of the device. When the laser fires, a small amount of the tissue is ablated, thereby freeing the lead from overgrowth in a controllable fashion.

The laser sheath is used in conjunction with conventional lead extraction tools (e.g., locking stylets, outer sheaths).

The Spectranetics Outer Sheath is a 43 cm long single-lumen tubing designed to fit over the laser sheath. The tube is cut at a 45-degree angle on one end and the edges are beveled on both ends. The Outer Sheath is used during the extraction procedure as an introducer and to support and align the Laser Sheath. It is used as a conduit to remove the laser sheath with the extracted lead and can be used as a conduit to implant a new lead.

The Fish Tape is an accessory to assist in the loading of the laser sheath over an implanted lead. The Fish Tape is a stainless steel mandrel with a wire loop handle on one end and a closed wire hook on the other end.

2. 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.

3. Contraindications

Use of the Laser Sheath is contraindicated:

- When emergency thoracotomy with cardiopulmonary bypass can not 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.

4. 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 laser system should be used only by physicians who have received adequate training (See Section 12.3).

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 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[1] (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 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.

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[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.**

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.

This device is designated for use solely as a component of the Spectranetics CVX-300® Excimer Laser System or the Philips Laser System.

Adequate instructions for the safe installation of the Spectranetics CVX-300® Excimer Laser System and the Philips Laser System are provided in servicing information provided by Spectranetics and should be followed.

5. 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.

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

6. Adverse Events

6.1 Observed Adverse Events

Adverse events observed for the 12F, 14F, and 16F Laser Sheaths in clinical studies are reported in Tables 1 and 2 below. Table 1 reports adverse event information from the 301-patient randomized study of lead removal with the 12F Device (LASER) and conventional lead extraction tools (Non-LASER). Table 2 reports adverse event information from a 180-patient registry study of lead removal with the 14F and 16F devices. Adverse event rates for the 12F device from the randomized study is included in Table 2 for comparison to the larger devices.

Table 1. Acute Complications and Complications at 1-month
All Randomized Patients (n=301)
Laser Device: 12F

	LASER (N=153)		Non-LASER (N=148)		TOTAL (N=301)	
Complications – Acute	**n**	**%**	**n**	**%**	**n**	**%**
Perioperative Death	1	0.7%	0	0	1	0.3%
Hemopericardium tamponade	2	1.3%	0	0	2	0.7%
Hemothorax	1	0.7%	0	0	1	0.3%
Complications – One Month	**LASER (N=145)**		**Non-LASER (N=140)**		**TOTAL (N=285)**	
Death	2	1.4%	1	0.7%	3	1.1%
Complications – any	4	2.8%	3	2.1%	7	2.5%
Pain at cut-down site	1	0.7%	0	0.0%	1	0.4%
Arm swelling	1	0.7%	1	0.7%	2	0.7%
Infection	1	0.7%	1	0.7%	2	0.7%
SVC thrombosis	0	0.0%	1	0.7%	1	0.4%
Tricuspid regurgitation	1	0.7%	0	0.0%	1	0.4%

Table 2. Acute Complications and Complications at 1-month
Laser-Treated Patients: 14F, 16F, and 12F Devices

	14F (N=97)		16F (N=83)		12F (N=153)		TOTAL (N=333)	
Complications – Acute	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Perioperative Death	2	2.1%	1	1.2%	1	0.7%	4	1.2%
Hemopericardium tamponade	3	3.1%	3	3.6%	2	1.3%	8	2.4%
Hemothorax	0	0%	0	0%	1	0.7%	1	0.3%
Perforation	0	0%	1	1.2%	0	0%	1	0.3%
Other	1	1.0%	1	1.2%	0	0%	2	0.6%
	14F (N=78)		**16F (N=72)**		**12F (N=145)**		**TOTAL (N=295)**	
Complications – One Month	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Death	1	1.3%	0	0%	2	1.4%	3	1.0%
Complications – any	2	2.6%	0	0%	4	2.8%	6	2.0%
Pain at cut-down site	0	0%	0	0%	1	0.7%	1	0.3%
Arm swelling	1	1.3%	0	0%	1	0.7%	2	0.7%
Infection	0	0%	0	0%	1	0.7%	1	0.3%
Tricuspid regurgitation	0	0%	0	0%	1	0.7%	1	0.3%
Phlebitis	1	1.3%	0	0%	0	0%	1	0.3%

6.2 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

7. Clinical Study

The Laser Sheaths in these studies were used with the CVX-300® Excimer Laser System. The Philips Laser System provides the same output and operates at the same parameters as the CVX-300® Excimer Laser System; therefore, no new clinical data has been collected for the Laser Sheath with the Philips Laser System.

7.1 Randomized Trial

Purpose: The use of standard tools (NonLASER) only (locking stylets, polymer and stainless steel sheaths, grips, snares, etc.) to explant chronically implanted pacing and defibrillator leads was compared to standard tools plus the 12F laser sheath (LASER). The primary effectiveness measure was the proportion of complete extractions (per lead basis). The primary safety measure was complication rate (per patient basis).

Methods: Patients with mandatory or necessary indications for lead removal and with the targeted lead implanted at least one year prior were randomized into the LASER or NonLASER groups in nine US centers between 11/95 and 10/96. The primary endpoint was reached if the lead was completely explanted. If the lead fractured, leaving the tip and possibly a portion of the conductor in the patient, the removal was judged a "partial success." The extraction was judged a procedural failure if any of five events occurred: change to femoral or transatrial approach, failure to gain venous entry, failure of sheaths to pass a binding site, lead breakage, or onset of complication. A crossover from NonLASER tools to laser tools was allowed after failure. Crossover patients were analyzed separately. Procedure time, defined as wall-clock time from the moment sheaths were applied until an endpoint was reached, was also recorded.

Description of Patients: 365 patients were enrolled. Five patients were found to meet exclusion criteria after enrollment and were disqualified from the study before any treatment was administered; thus 360 patients were treated. 59 nonrandomized patients were enrolled for investigator training. The remaining 301 patients (with 465 leads) presented with mandatory or necessary indications for lead removal. Mean patient age was 65 years (range 4 to 94) with 36% females and mean implant duration of 67 months (range 1 to 286). Patient characteristics were similar between the two randomized groups.

Results:

Table 3. Principal Effectiveness and Safety Results

Laser vs. Non-Laser

Effectiveness: Leads	Laser				Non-Laser				Difference In
~	N	Complete	Partial	Failure	N	Complete	Partial	Failure	Failure [95% CI]
Of First Treatment	244	230 (94.3%)	6 (2.4%)	8 (3.3%)	221	142 (64.2%)	4 (1.9%)	75 (33.9%)	-29.8%* [-23%,-36%]
Of Crossover Treatment	~	~	~	~	72	63 (87.5%)	3 (4.2%)	6 (8.3%)	~
Of Final Treatment	244	230 (94.3%)	6 (2.4%)	8 (3.3%)	221	205 (92.8%)	7 (3.1%)	9 (4.1%)	-0.8% [-2.8%,4.2%]
Total Proc. Time	244	11.2	±13.9 min	~	221	14.2	±21.6 min	~	-3.05* [-3.12,-2.97]
Safety Results: Patients	**N[a]**	**Laser**			**N[b]**	**Non-Laser**			**Difference**
Acute Complications	218	3 (1.4%) [0.3%, 4.0%]			83	0 (0.0%) [0.0%, 4.4%]			1.4% [-0.2%, 2.9%]
Complications 1mo.	218	6 (2.8%) [1.0%, 5.9%]			83	1 (1.2%) [0.0%, 6.5%]			1.5% [-1.7%, 4.7%]
Death, perioperative	218	1 (0.5%) [0.0%, 2.5%]			83	0 (0.0%) [0.0%, 4.4%]			0.5% [-0.3%, 1.1%]
Death 1mo.	218	2 (0.9%) [0.1%, 3.3%]			83	1 (1.2%) [0.0%, 6.5%]			-0.3% [-3.0%, 2.4%]

Total Proc. Time (mean ± s.d.) = procedure time for First Treatment + time for Crossover Treatment (if any)
CI = Confidence intervals via binomial approximation (Effectiveness) or exact binomial method (Safety)
* = difference statistically significant ($p < 0.001$) by Chi-Square with continuity correction, or t-test
[a] includes patients randomized to LASER plus Crossover patients
[b] includes patients randomized to NonLASER less Crossover patients
Difference = LASER-NonLASER; SEM = sqrt(p1*q1/n1 + p2*q2/n2); 95% CI = Diff ± 1.96*SEM

7.2 Registry Trial

Purpose: Registry usage of the 14F and 16F laser sheaths to explant chronically implanted pacing and defibrillator leads was compared to the outcomes of the 12F laser sheath randomized study. Primary effectiveness measure was the proportion of complete extractions (per lead). The primary safety measure was complication rate (per patient).

Methods: Patients with mandatory or necessary indications for lead removal and with the targeted lead implanted at least one year prior were treated at 32 US centers between 6/97 and 2/98. The primary endpoint was reached if the lead was completely explanted. If the lead fractured, leaving the tip and possibly a portion of the conductor in the patient, the removal was judged a "partial success." The extraction was judged a procedural failure if any of four events occurred: change to

femoral or transatrial approach, failure to gain venous entry, failure of sheaths to pass a binding site, or onset of complication. Procedure time, defined as wall-clock time from the moment sheaths were applied until an endpoint was reached, was also recorded.

Description of Patients: 180 registry patients were enrolled and treated (97 for 14F , 83 for 16F). Mean patient age for the 14F group was 69 years (range 13 to 86) with 57% males; this did not differ significantly from the 12F randomized group. Implant duration of leads treated with the 14F device was significantly longer than the control group (85 ± 50 months vs. 65 ± 42 months). For the 16F group mean patient age was 62 years (range 9 to 85) with 77% males; these values were also not significantly different from the control group. Implant duration of leads treated with the 16F device was 68 ± 60 months and was not significantly different from the control group.

Results:

Table 4. Principal Effectiveness and Safety Results
14F vs. 12F

14F					
Effectiveness: leads	**N**	**Complete**	**Partial**	**Failure**	
Outcome	164	142 (86.6%)	12 (7.3%)	10 (6.1%)	
Safety: patients	**N**	**Observed**	**Confidence Interval**		
Acute Complications	97	4 (4.1%)	[0.2%, 8.1%]		
Complications, 1 mo.	78	2 (2.6%)	[0.0%, 6.1%]		
Death, perioperative	97	2 (2.1%)	[0.0%, 4.9%]		
Death, 1 mo.	78	1 (1.3%)	[0.0%, 3.8%]		
12F					**Difference in Failure**
Effectiveness: leads	**N**	**Complete**	**Partial**	**Failure**	**[95% CI]**
Outcome	244	230 (94.3%)	6 (2.5%)	8 (3.3%)	2.8% [-1.5%, 7.1%]
Safety: patients	**N**	**Observed**	**Confidence Interval**		**Difference[95% CI]**
Acute Complications	218	3 (1.4%)	[0.3%, 4.0%]		2.7% [-2.2%, 7.7%]
Complications, 1 mo.	218	6 (2.8%)	[1.0%, 5.9%]		1.6% [-2.1%, 5.3%]
Death, perioperative	218	1 (0.5%)	[0.0%, 2.5%]		1.6% [-2.1%, 5.3%]
Death, 1 mo.	218	2 (0.9%)	[0.1%, 3.3%]		0.4% [-3.3%, 4.0%]

Table 5. Principal Effectiveness and Safety Results
16F vs. 12F

16F					
Effectiveness: leads	**N**	**Complete**	**Partial**	**Failure**	
Outcome	97	86 (88.7%)	2 (2.1%)	9 (9.3%)	
Safety: patients	**N**	**Observed**	**Confidence Interval**		
Acute Complications	83	5 (6.0%)	[0.9%, 11.1%]		
Complications, 1 mo.	72	0 (0.0%)	[0.0%, 0.0%]		
Death, perioperative	83	1 (1.2%)	[0.0%, 3.6%]		
Death, 1 mo.	72	0 (0.0%)	[0.0%, 0.0%]		
12F					**Difference in Failure**
Effectiveness: leads	**N**	**Complete**	**Partial**	**Failure**	**[95% CI]**
Outcome	244	230 (94.3%)	6 (2.5%)	8 (3.3%)	6.0% [-0.2%, 12.2%]
Safety: patients	**N**	**Observed**	**Confidence Interval**		**Difference[95% CI]**
Acute Complications	218	3 (1.4%)	[0.3%, 4.0%]		4.6% [-1.5%, 10.8%]
Complications, 1 mo.	218	6 (2.8%)	[1.0%, 5.9%]		-2.8% [-5.8%, 0.3%]
Death, perioperative	218	1 (0.5%)	[0.0%, 2.5%]		0.7% [-2.6%, 4.1%]
Death, 1 mo.	218	2 (0.9%)	[0.1%, 3.3%]		-0.9% [-3.1%, 1.3%]

8. 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.

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

9. Operator's Manual

Energy Parameters

The devices described in this document can be operated within the following energy ranges on the CVX-300® or the Philips Laser System:

Device	Fluence (mJ)	Repetition Rate (Hz)
12F	30-60	25-40
14F	30-60	25-40
16F	30-60	25-40

Recommended calibration settings: 60 Fluence, 40 Hz.
The laser system will allow these devices to operate for a period of 10 seconds, after which a 5 second wait will be imposed before lasing can resume.

Spectranetics' SLS II Laser Sheath software requirements:

Laser System	Software	Laser Sheath Maximum Rep Rate
CVX-300® Excimer Laser System	V3.7XX / V3.8XX	40 Hz
Philips Laser System	V1.0 (b5.0.3 and above)	

10. How Supplied

10.1 Sterilization

For single use only. Do not re-sterilize and/or reuse.

The Spectranetics laser sheaths are supplied sterile. Sterility is guaranteed only if the package is unopened and undamaged.

10.2 Inspection Prior to Use

Before use, visually inspect the sterile package to ensure that seals have not been broken. All equipment to be used for the procedure, including the laser sheath, should be examined carefully for defects. Examine the laser sheath for bends, kinks or other damage. Do not use if it is damaged.

11. Compatibility

Compatibility of Laser Sheath and Pacemaker/ICD Lead

The table below shows the dimensional compatibility between the Laser Sheath, the Pacemaker/ICD Lead to be removed and the Outer Sheath. It is vital that the physician determines the maximum outside diameter (OD) of the lead before extraction with the laser sheath is attempted. This information should be obtained from the lead manufacturer.

ID = Inside Diameter OD = Outside Diameter	12F Laser Sheath	14F Laser Sheath	16F Laser Sheath
Model #	**500-001**	**500-012**	**500-013**
Minimum Tip ID, in. / Fr /mm	0.109 / 8.3 / 2.77	0.134 / 10.2 / 3.40	0.164 / 12.5 / 4.17
Maximum Tip OD, in. / Fr / mm	0.164 / 12.5 / 4.17	0.192 / 14.7 / 4.88	0.225 / 17.2 / 5.72
Lead: Maximum OD, Fr / mm	7.5 / 2.50	9.5 / 3.17	11.5 / 3.83
Outer Sheath: Minimum ID, Fr/mm	13 / 4.33	15.5 / 5.17	18.2 / 6.07

12. Directions for Use

12.1 Procedure Set Up

Laser Sheath preparations:

1. Using sterile technique, open the sterile package. Remove the packaging wedges from the tray and gently lift the device from the tray while supporting the proximal coupler.
2. Connect the proximal end of the device to the connector on the laser system.
3. Calibrate the Laser Sheath following the instructions in the "Operational Modes" section of the CVX-300® Operator's Manual (7030-0035 or 7030-0068) or the "Screen Guided Workflow" section of the Philips Laser System Operator's Manual (P018730).

Patient preparations:

1. Obtain a thorough patient history, including patient blood type. Appropriate blood products should be readily available.
2. Ascertain the manufacturer, model number and implant date of the catheter/lead to be removed. Perform radiographic/echocardiographic evaluation of catheter/lead condition, type and position.
3. Use a procedure room that has high quality fluoroscopy, pacing equipment, defibrillator, and thoracotomy and pericardiocentesis trays.
4. Prep and drape the patient's chest for possible thoracotomy; prep and drape the patient's groin for a possible femoral approach extraction procedure.
5. Establish back-up pacing as needed.
6. Have available additional Laser Sheaths, Outer Sheaths, locking stylets, stylets to unscrew active fixation leads, snares (femoral workstation) and any other accessory equipment deemed necessary.

12.2 Clinical Technique

1. Patients prepared for lead extractions are prepared for multiple approaches, including an emergency cardiac surgical procedure. Preparations may include: general endotracheal anesthesia or conscious sedation, shave and preparation of both the chest and groin areas, ECG monitoring, insertion of an arterial line and a Foley catheter, presence of instruments for pacing and defibrillation, an electrosurgical unit, and a sternal saw for emergencies.
2. A temporary pacing lead is inserted in all patients needing a pacemaker. An exception is made for patients with an implanted permanent pacemaker whose

leads are not to be extracted.

3. Fluoroscopy will be used to monitor all transvenous maneuvers.
4. Expose the proximal end of the lead. Debride overgrowth from the lead as required to expose the venous entry site. Sever the lead connector and remove the anchoring sleeve.
5. Insert and lock a locking stylet into the lead. Alternatively, a length of suture material approximately 60 cm long may be attached to the proximal end of the lead to act as a traction device.
6. Fill a sterile syringe with 10 cc of saline solution. Inject the saline into the inner lumen of the Laser Sheath. Using another 10 cc of saline, moisten the outer jacket of the laser sheath.
7. Place an outer sheath over the laser sheath.
8. Using a "Fish Tape" device, thread the handle of the traction device through the inner lumen of the Laser Sheath. Remove the "Fish Tape" after the traction device handle emerges from the proximal end of the laser sheath. Thread the proximal end of the lead into the inner lumen of the laser sheath.
9. Extraction technique:

PRECAUTION: When advancing a Laser Sheath or outer sheath around a bend, keep the point of the sheath's beveled tip oriented toward the inside of the bend.

PRECAUTION: As in all extraction procedures using a laser sheath, but particularly when removing dual coil ICD leads, maintain sturdy traction and a stable "rail" position with the lead while keeping coaxial alignment of the laser sheath and the bevel on the inside curvature of the SVC.

PRECAUTION: Before entering the SVC, stop to ensure sturdy traction and a stable "rail" are maintained.

a. Using an "inchworm" technique, alternately advance the outer sheath and the laser sheath over the lead.
b. Use the following guidelines to determine if a tissue obstruction is met:
   - The laser sheath will not advance into the vein.
   - The laser sheath bows outward slightly when longitudinal pressure is applied.
   - Fluoroscopy shows that the sheath tip does not advance relative to the lead body.
   - Fluoroscopy shows that the laser sheath tip is not caught on a lead electrode, a lead bend, or another lead.
c. When an obstruction is met and the laser sheath cannot be advanced:
   - Use orthogonal fluoroscopic views to ensure that the tip of the laser sheath is aligned with the longitudinal axis of the lead.
   - Retract the outer sheath so that its distal end does not overlap the tip of the Laser Sheath. Press the laser sheath gently into the obstructing tissue.
   - Place the laser in READY mode. Depress the foot switch, activating the laser. While the laser is firing, use gentle pressure on the laser sheath to advance the device approximately 1 mm per second while applying equal and opposite traction to the traction device. If the laser sheath breaks through the obstruction during lasing, release the foot switch.

PRECAUTION: Advancing the laser sheath through moderately calcified tissue may require more pulses of laser energy than through fibrous scar overgrowth. Advance the outer sheath to the new position of the laser sheath.

PRECAUTION: Stop if not able to advance the laser sheath. Be prepared to upsize to a larger laser sheath, move to another lead, try a femoral approach or consider an open procedure. Also consider abandoning the procedure by leaving the lead in place and refer to a more experienced center.

d. If the traction device unlocks its grip on the lead, it is necessary to remove the laser sheath and outer sheath, and apply a new traction device, before proceeding again with the laser sheath.
e. Advance the outer sheath and laser sheath to the desired location on the lead, as described in 9 (a-c) above. 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.
f. If necessary, use countertraction, using the outer sheath and the traction device, to free the lead tip from the heart wall.

10. Withdrawal of the laser sheath and outer sheath can be accomplished at any time during the procedure. If the lead is free, it should be drawn into the laser sheath before the lead, the laser sheath, and the outer sheath are removed from the body.

PRECAUTION: If the Laser Sheath is removed from the body for any reason, thoroughly clean the device shaft, inner lumen and tip with saline to remove particles and prevent blood from sticking.

PRECAUTION: If the Laser Sheath becomes kinked or damaged during use as evidenced by fluoroscopy, it is recommended to discontinue use of the device. Weigh the relative risks and benefits of device removal versus continued use.

12.3 Physician Training

Physician training in use of the Laser Sheath and CVX-300® Excimer Laser System or the Philips Laser System should include:

- Classroom training in laser safety and physics;
- A didactic presentation of laser operation followed by a demonstration of the laser system;
- Hands-on training in the use of the laser system in lead removal;
- Observation of the removal of at least two leads with the Laser Sheath performed by an experienced Laser Sheath user;
- Removal of at least two leads in the presence of a second physician experienced in lead removal techniques and a fully trained Spectranetics representative.
- HRS[3] and EHRA[4] recommendations for complication management

13. Manufacturer's Limited Warranty

Manufacturer warrants that the SLS II is free from defects in material and workmanship when used by the stated "Use By" date. Manufacturer's liability under this warranty is limited to replacement or refund of the purchase price of any defective unit of the SLS II. Manufacturer will not be liable for any incidental, special, or consequential damages resulting from use of the SLS II. Damage to the SLS II caused by misuse, alteration, improper storage or handling, or any other failure to follow these 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 Manufacturer, has the authority to extend or expand this limited warranty and any purported attempt to do so will not be enforceable against the Manufacturer. This limited warranty covers only the SLS II. Information on Manufacturer's warranty relating to the CVX-300® Excimer Laser System or the Philips Laser System can be found in the documentation relating to that system.

[3] Wilkoff B.L., et al. Transvenous Lead Extraction: Heart Rhythm Society Expert Consensus on Facilities, Training, Indications, and Patient Management. Heart Rhythm. July 2009.

[4] 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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