GlideLight™

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

GlideLight Laser Sheath is similar in construction to the SLS® II Laser Sheath family of products with the addition of 80Hz maximum repetition rate capability. The 80Hz maximum repetition rate capability is designed to improve ease-of-use by reducing advancement force through tissue during laser photoablation. After calibration, GlideLight Laser Sheath defaults to 80Hz repetition rate.

The 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. The multifiber Laser Sheaths transmit ultraviolet energy from the Spectranetics CVX-300® laser 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 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.

4. 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[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.

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 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 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.

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

Adequate instructions for the safe installation of the Spectranetics CVX-300® Excimer Laser System are provided in servicing information provided by Spectranetics and should be followed. Possible electromagnetic interference should be avoided in use. Portable and mobile RF communications equipment may affect the normal operation of the console. Please use the Laser System and accessory laser sheaths under recommended electromagnetic environment.

[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.

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.

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.

6. Adverse Events

All devices used to evaluate lead removal in these clinical studies were the SLS, which used a maximum repetition rate of 40Hz. No clinical data has been collected using the GlideLight Laser Sheath, which operates using a maximum repetition rate of 80Hz. Therefore, complication rates presented in Tables 1 and 2 below are reflective of the complication rates observed with the use of the 40Hz Laser Sheath model (SLS).

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

All devices used to evaluate lead removal in these clinical studies were the SLS, which used a maximum repetition rate of 40Hz. No clinical data has been collected using the GlideLight Laser Sheath, which operates using a maximum repetition rate of 80Hz. Therefore, effectiveness and safety data presented in Tables 3, 4 and 5 below are reflective of the data obtained with the use of the 40Hz Laser Sheath model (SLS).

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	**Nª**	**Laser**			**Nᵇ**	**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 (88.6%)	12 (7.3%)	10 (6.1%)	
Safety: Patients	**N**	**Observed**	**Confidence Interval**		
Acute Complications	97	4 (4.1%)	[0.2%, 8.1%]		
Complications, 1mo.	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 Internal**		**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, 1mo.	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% [-2.0%, 12.2%]
Safety: Patients	**N**	**Observed**	**Confidence Internal**		**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®:

Device	Fluence (mJ)	Repetition Rate (Hz)
12F	30-60	25-80
14F	30-60	25-80
16F	30-60	25-80

Default energy settings following calibration: 60 Fluence, 80 Hz.

Following calibration, fluence and repetition rate are adjustable throughout the above ranges at the physician's discretion.

Version 3.X18 or higher software for the CVX-300® is necessary to operate this device. CVX-300®'s with V3.7XX software will limit the repetition rate to 40Hz.

The CVX-300® 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.

10. How Supplied

10.1 Sterilization

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

The Laser Sheaths are supplied sterile. Sterility is guaranteed only if the package is unopened and undamaged. Do not open before use.

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 #	**500-301**	**500-302**	**500-303**
Minimum Tip ID, in. / F /mm	0.109 / 8.3 / 2.8	0.134 / 10.2 / 3.4	0.164 / 12.5 / 4.2
Maximum Tip OD, in. / F / mm	0.164 / 12.5 / 4.2	0.192 / 14.7 / 4.9	0.225 / 17.2 / 5.7
Lead: Maximum OD, F / mm	7.5 / 2.5	9.5 / 3.2	11.5 / 3.8
Outer Sheath: Minimum ID, F/mm	13 / 4.3	15.5 / 5.2	18.2 / 6.1

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 of the CVX-300®.
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).

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 and sever any suture holding the anchoring sleeve suture. Debride overgrowth from the lead as required to expose the venous entry site. Sever the lead terminal pin and remove the anchoring sleeve.
5. For active fixation leads, unscrew the lead helix.
6. Sever the lead terminal pin connector and remove the anchoring sleeve.
7. Insert and lock a locking stylet or Lead Locking Device into the lead as distal as possible and deploy the locking mechanism. Secure a length of suture material approximately 60 cm long to the proximal end of the lead insulation and high voltage cables to provide additional traction.
8. 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, wet the outer jacket of the Laser Sheath.

9. When using an outer sheath, wet the inner lumen and place over the Laser Sheath.
10. 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.
11. Extraction technique:
    a. Advance the Laser Sheath over the lead until an obstruction is met. When using an outer sheath, use an "inchworm" technique to alternately advance the outer sheath and the laser sheath over the lead.

PRECAUTION: 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.

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.

    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 and coaxial 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.

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.

- Advance the outer sheath to the new position of the Laser Sheath.

    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 11 (a-c) above.

WARNING: 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.

12. 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.

13. To retain venous access for re-implant, keep outer sheath in place for guidewire insertion when removing lead and Laser Sheath. Remove the outer sheath from the body after guidewire is inserted.

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.

All equipment should be disposed of following special requirements applicable to hospital waste and potential biohazard materials.

12.3 Physician Training

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

- Classroom training in laser safety and physics;
- A didactic presentation of laser operation followed by a demonstration of the CVX-300® Excimer Laser System;
- Hands-on training in the use of the CVX-300® Excimer 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 GlideLight Laser Sheath is 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. Manufacturer's liability under this warranty is limited to replacement or refund of the purchase price of any defective GlideLight Laser Sheath. Manufacturer will not be liable for any incidental, special, or consequential damages resulting from use of the GlideLight Laser Sheath. Damage to the GlideLight Laser Sheath 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 Manufacturer.

This limited warranty covers only the GlideLight Laser Sheath. Information on Manufacturer's warranty relating to the CVX-300® Excimer Laser 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.

目录

警告:美国联邦法律规定,本器械仅限接受过适当培训的医生销售或谨遵医嘱订购。

1. 产品描述

GlideLight植入性电极导线激光拔除鞘套件在结构上与SLS® II系列植入性电极导线激光拔除鞘套件产品相似,只是增加了80Hz最大重复频率的功能。 80Hz最大重复频率功能的设计旨在通过降低激光消蚀期间穿越粘连组织所需的推进力而提高易用性。经校准后,GlideLight植入性电极导线激光拔除鞘套件的重复频率默认为80Hz。

该植入性电极导线激光拔除鞘套件由一个12F、14F或16F植入性电极导线激光拔除鞘、两个外鞘以及一个穿线器组成。植入性电极导线激光拔除鞘套件是一种外科手术使用装置,用于移除长期植入的起博器或除颤器导线。

植入性电极导线激光拔除鞘套件由环形排列的光学纤维组成,夹在内部和外部聚合物管之间。配合准分子激光系统,纤维远端在抛光的尖端内终止,近端在耦合器内终止。在远端,纤维受内部和外部不锈钢带保护,形成一个射线显影标记。设备的内腔设计使得在设备朝向心脏中导线的尖端滑过导线时,起搏器导线能够在其中穿过。

植入性电极导线激光拔除鞘套件设计仅供与Spectranetics CVX-300®准分子激光系统一起使用。复型纤维植入性电极导线激光拔除鞘套件从 Spectranetics CVX-300®激光器向设备远端处的组织传输紫外线能量。发射激光时,少量软组织就会消融,因而,以一种可控的方式将导线拔出增生组织。

植入性电极导线激光拔除鞘套件与传统导线拔除工具结合在一起使用(例如,锁定钢丝、外鞘)。

Spectranetics外鞘是一个长43cm的单腔管,设计用于安上植入性电极导线激光拔除鞘套件。该管一端以45度角切割,且两端边缘为斜面。在拔除程序中,外鞘用做一个导引器,且用于支持和对齐植入性电极导线激光拔除鞘套件。它用做一个导管,以便使用拔除导线移除植入性电极导线激光拔除鞘套件,且还可以用做植入新导线的导管。

穿线器是协助植入性电极导线激光拔除鞘套件加载到一个植入导线上的配件。穿线器是一个不锈钢芯轴,一端是线圈把手,另一端是封闭的线钩。

2. 适应症

植入性电极导线激光拔除鞘套件适用于经静脉移除长期植入的硅聚氨酯外绝缘起搏器或除颤导线的病人,可以作为传统移除工具的辅助手段。

3. 禁忌症

使用植入性电极导线激光拔除鞘套件的禁忌症：

- 如果出现的并发症危及生命，无法立即进行体外循环紧急开胸术时；
- 无法进行X-射线检查时；
- 病人的上腔静脉无法使用时；
- 操作员难以接近起博导线近端时；
- 导线无法被套入植入性电极导线激光拔除鞘套件内腔时。

4. 警告

若不能使用传统导线移除工具，请勿尝试使用植入性电极导线激光拔除鞘套件。

导线移除设备仅能在具有紧急心脏手术能力、并发症预防和管理协议就位且经常应用的机构中使用。强烈推荐美国心律协会[1] (HRS) 和欧洲心律协会[2] (EHRA) 的导线管理建议。

上市后监控观察到的大多数不良反应包括SVC中双线圈ICD导线近端卷曲。 因此，在移除这些导线时必须特别注意。此外，伴随所有的拔除，应为每个患者考虑这些导线移除的风险-获益评估。

在采用伸缩扩张器移除起博导线的技术方面，医师必须具有丰富经验，方可使用植入性电极导线激光拔除鞘套件。

使用CVX-300®准分子激光系统的医师，必须接受过适当培训（见章节12.3）。

使用激光时，必须配戴护目镜。避免眼睛或皮肤曝露在直接或散射辐射环境。参考CVX-300®准分子激光系统的照射标记。

请勿将多个植入性电极导线激光拔除鞘或外鞘同时插入静脉。这可能导致严重的血管损伤（包括静脉壁破裂），而且可能需要进行修复手术。

请勿将外鞘尖端放置于SVC－心房交界处，原因是在随后过程中（比如移动外鞘、植入新导线等）可能损伤这一脆弱的区域。

植入性电极导线激光拔除鞘或外鞘的推进过程中，移除导线时保持适当的牵引力。

当采用荧光镜透视，看到标记钙化物伴随移除导线一同移动时，特别是在心房内，如果出现由于移除过程引发的问题，那么能否立即进行手术救助就显得极为重要。而且，还应当考虑开胸术移除导线的适应症。

牵引植入性电极导线激光拔除鞘套件时，与导线尖端的距离不得小于1厘米。移除导线尖端时，不得在心肌层发射激光。

该器械仅作为Spectranetics CVX-300®准分子激光系统的组件单独使用。

在Spectranetics提供的维修信息中列有Spectranetics CVX-300®准分子激光系统安全安装的充分说明，应该加以遵守。使用中应避免可能的电磁干扰，便携式和移动式射频通信设备可能会影响主机的正常使用，请在推荐的电磁环境下使用主机及配套使用的激光拔除鞘。

5. 注意事项

尝试使用植入性电极导线激光拔除鞘套件之前，彻底检查插入传统导线移除工具的包装。

仅限单次使用。请勿再次灭菌或重复使用。

请勿对本装置进行再次灭菌或重复使用，原因是由于不适当的再处理，可能会损害装置的性能，增加交叉感染的危险。

重复使用这种一次性装置，可能会造成病人的严重伤亡，使得生产商的担保失效。

若发生以下情况，请勿使用植入性电极导线激光拔除鞘套件：

- 如果防启封皮破裂；
- 如果植入性电极导线激光拔除鞘套件损坏。

当植入性电极导线激光拔除鞘套件处于人体内，操作时应当采用配备X光线照相设备的荧光镜透视进行观察，这样可以提供高清图像。

以与40Hz操作相同的速率进行80Hz操作大约需要一半的向前推进力。推荐推进速率为每秒1mm。

[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.

6. 不良事件

在这些临床研究中用于评价电极导线移除的所有器械均为SLS，其所使用的最大重复频率为40Hz。对于使用GlideLight植入性电极导线激光拔除鞘套件（以80Hz的最大重复频率运行），并未收集任何临床数据。因此，下表1和表2中列出的并发症发生率反映了使用40Hz植入性电极导线激光拔除鞘套件型号（SLS）观察到的并发症发生率。

6.1. 观察到的不良事件

临床研究中观察到的12F、14F和16F植入性电极导线激光拔除鞘套件不良反应，已经记录在表1和2中。表1记录的不良反应信息来源于301位病人，采用12F装置（激光）和传统导线移除工具（非激光）进行导线移除的随机对照研究。表2记录的不良反应信息来源于对180位病人，采用14F和16F器械进行导线移除的注册研究。随机对照研究中，12F器械的不良反应比率包含于表2中，用于与较大规格的器械进行比较。

表1. 急性并发症和1个月时的并发症
所有随机化病人（n=301）激光装置：12F

	激光装置 (N=153)		非激光装置 (N=148)		总计 (N=301)	
并发症－急性	n	%	n	%	n	%
围术期死亡	1	0.7%	0	0	1	0.3%
心包积血填塞	2	1.3%	0	0	2	0.7%
血胸	1	0.7%	0	0	1	0.3%
并发症－1 个月	激光装置 (N=145)		非激光装置 (N=140)		总计 (N=285)	
死亡	2	1.4%	1	0.7%	3	1.1%
并发症－所有	4	2.8%	3	2.1%	7	2.5%
切除点疼痛	1	0.7%	0	0.0%	1	0.4%
臂部肿胀	1	0.7%	1	0.7%	2	0.7%
感染	1	0.7%	1	0.7%	2	0.7%
SVC 血栓症	0	0.0%	1	0.7%	1	0.4%
三尖瓣反流	1	0.7%	0	0.0%	1	0.4%

表2. 急性并发症和1个月时的并发症
激光治疗病人：14 F、16 F和12 F装置

	14F (N=97)		16F (N=83)		12F (N=153)		总计 (N=333)	
并发症－急性	n	%	n	%	n	%	n	%
围术期死亡	2	2.1%	1	1.2%	1	0.7%	4	1.2%
心包积血填塞	3	3.1%	3	3.6%	2	1.3%	8	2.4%
血胸	0	0%	0	0%	1	0.7%	1	0.3%
穿孔	0	0%	1	1.2%	0	0%	1	0.3%
其他	1	1.0%	1	1.2%	0	0%	2	0.6%
	14F (N=78)		16F (N=72)		12F (N=145)		总计 (N=295)	
并发症－1 个月	n	%	n	%	n	%	n	%
死亡	1	1.3%	0	0%	2	1.4%	3	1.0%
并发症－任何	2	2.6%	0	0%	4	2.8%	6	2.0%
切除点疼痛	0	0%	0	0%	1	0.7%	1	0.3%
臂部肿胀	1	1.3%	0	0%	1	0.7%	2	0.7%
感染	0	0%	0	0%	1	0.7%	1	0.3%
三尖瓣反流	0	0%	0	0%	1	0.7%	1	0.3%
静脉炎	1	1.3%	0	0%	0	0%	1	0.3%

6.2 潜在不良事件

在使用植入性电极导线激光拔除鞘套件移除导线过程中，可能会出现下列不良反应或情况，但是在临床研究中并未观察到（按字母排序）：

- 菌血症
- 心输出量下降
- 导线碎片移动
- 赘生物移动
- 心肌撕脱／穿孔
- 心室早发性收缩
- 肺栓塞
- 中风
- 静脉撕脱／穿孔
- 室性心动过速

7. 临床研究

在这些临床研究中用于评价导线移除的所有器械均为SLS，其所使用的最大重复频率为40Hz。对于使用GlideLight植入性电极导线激光拔除鞘套件（以80 Hz的最大重复频率运行），并未收集任何临床数据。因此，下表3、表4和表5中列出的并发症发生率反映了使用40Hz植入性电极导线激光拔除鞘套件型号（SLS）观察到的并发症发生率。

7.1 随机试验

目的：仅用于外植长期植入的起博和除颤导线标准工具（非激光）（锁定钢丝、聚合与不锈钢鞘、夹具、勒除器等），其用法与添加12F植入性电极导线激光拔除鞘套件（激光）的标准工具相比较。采用完全移除（以导线为基础）的比例进行初步有效性测量。采用并发症率（以病人为基础）进行初步安全性测量。

方法：于11/95和10/96之间，在九个US中心，将强制性或必要性移除导线适应症及事先植入目标导线至少一年的病人，随机分成激光或非激光组。如果导线完全移除，则达到了主要目的。如果导线断裂，其尖端和导线的一部分滞留于病人体内，则该移除术可判定为“部分救助成功”。如果出现五种事件的其中之一，则该移除术可判定为操作失败：转变为股动脉或经心房入路，无法进入静脉，鞘无法通过结合位置，导线折断，并发症发作。失败后，非激光工具和激光工具可以进行交换。对交换后的病人分别进行分析。同时还记录操作时间，即：从鞘安插时开始，直至达到终结点的挂钟时间。

病人情况说明：共有365位病人参与研究。登记之后，发现有五位病人符合排除标准，因而在实施治疗之前，取消了这五位病人的资格；因此，共有360位病人接受治疗。其中有59位非随机安排的病人供调查员培训之用。剩余301位病人（安插465根导线）呈现强制性或必要性移除导线适应症。病人的平均年龄为65岁（范围是4到94），其中女性占36%，平均植入时间为67个月（范围是1到286）。两个随机化小组之间的病人特征相似。

结果：

表3. 基本有效性和安全性结果

激光VS非激光

有效性：导线	激光				非激光				差异
~	N	完全	部分	失败	N	完全	部分	失败	失败 [95% CI]
首次处理	244	230 (94.3%)	6 (2.4%)	8 (3.3%)	221	142 (64.2%)	4 (1.9%)	75 (33.9%)	-29.8%* [-23%,-36%]
交换处理	~	~	~	~	72	63 (87.5%)	3 (4.2%)	6 (8.3%)	~
最终治疗	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%]
总操作时间	244	11.2	±13.9 min	~	221	14.2	±21.6 min	~	-3.05* [-3.12,-2.97]
安全性结果：病人	N[a]	激光			N[b]	非激光			差异
急性并发症	218	3 (1.4%) [0.3%, 4.0%]			83	0 (0.0%) [0.0%, 4.4%]			1.4% [-0.2%, 2.9%]

并发症1 个月	218	6 (2.8%) [1.0%, 5.9%]	83	1 (1.2%) [0.0%, 6.5%]	1.5% [-1.7%, 4.7%]
死亡，围术期	218	1 (0.5%) [0.0%, 2.5%]	83	0 (0.0%) [0.0%, 4.4%]	0.5% [-0.3%, 1.1%]
死亡 1 个月	218	2 (0.9%) [0.1%, 3.3%]	83	1 (1.2%) [0.0%, 6.5%]	-0.3% [-3.0%, 2.4%]

总操作时间（平均+标准差）＝首次处理的操作时间+交换后处理时间（如有）
CI＝通过二项近似（有效性）或精确二项式方法（安全性）获得的置信度区间
* = 采用卡方连续校正或T试验a获得统计上的显著差异（P＜0.001）
[a] 包括随机安排到激光组的病人，加上交换后的病人
[b] 包括随机安排到非激光组的病人，减去交换后的病人
差异＝激光－非激光；SEM＝sqrt (p1*q1/n1 + p2*q2/n2)；95% CI = Diff ± 1.96*SEM

7.2 注册研究

目的：在注册研究中，使用14F和16F植入性电极导线激光拔除鞘套件移除长期植入的起博和除颤导线，其用法与随机试验中12F植入性电极导线激光拔除鞘套件的结果相比较。采用完全拔除（以导线为基础）的比例进行初步有效性测量。采用并发症率（以病人为基础）进行初步安全性测量。

方法：于6/97和2/98之间，在32个US中心，对强制性或必要性移除导线适应症及事先植入目标导线至少一年的病人进行治疗。如果导线完全移除，则达到了主要目的。如果导线断裂，其尖端和导线的一部分滞留于病人体内，则该移除术可判定为“部分救助成功”。如果出现四种事件的其中之一，则该拔除术可判定为操作失败：转变为股动脉或经心房入路，无法进入静脉，鞘无法通过结合位置，并发症发作。同时还记录操作时间，即：从鞘安插时开始，直至手术结束的时间。

病人情况说明：180位注册病人参与研究并接受治疗（97位采用14F，83位采用16F）。14F组病人的平均年龄为69岁（范围是13到86），女性占57%；这种情况与12F的随机组没有显著差异。14F装置组的导线安插时间，明显长于对照组（85+50个月 VS 65+42个月）。16F组病人的平均年龄为62岁（范围是9到85），男性占77%；这些数值与对照组没有明显差异。16F装置组的导线安插时间为68+60个月，与对照组没有明显差异。

结果：
表4. 基本有效性和安全性结果
14F vs. 12F

14F					
有效性：导线	N	完全	部分	失败	
结果	164	142 (88.6%)	12 (7.3%)	10 (6.1%)	
安全性：病人	N	观察值	置信度区间		
急性并发症	97	4 (4.1%)	[0.2%, 8.1%]		
并发症，1个月时	78	2 (2.6%)	[0.0%, 6.1%]		
死亡，围术期	97	2 (2.1%)	[0.0%, 4.9%]		
死亡，1个月时	78	1 (1.3%)	[0.0%, 3.8%]		
12F					失败的差异
有效性：导线	N	完全	部分	失败	[95% CI]
结果	244	230 (94.3%)	6 (2.5%)	8 (3.3%)	2.8% [-1.5%, 7.1%]
安全性：病人	N	观察值	置信度区间		差异 [95% CI]
急性并发症	218	3 (1.4%)	[0.3%, 4.0%]		2.7% [-2.2%, 7.7%]
并发症，1个月	218	6 (2.8%)	[1.0%, 5.9%]		1.6% [-2.1% 5.3%]
死亡，围术期	218	1 (0.5%)	[0.0%, 2.5%]		1.6% [-2.1%, 5.3%]
死亡，1个月	218	2 (0.9%)	[0.1%, 3.3%]		0.4% [-3.3%, 4.0%]

表5. 基本有效性和安全性结果
16F vs. 12F

16F				
有效性:导线	N	完全	部分	失败
结果	97	86 (88.7%)	2 (2.1%)	9 (9.3%)
安全性:病人	N	观察值	置信度区间	
急性并发症	83	5 (6.0%)	[0.9%, 11.1%]	
并发症,1个月时	72	0 (0.0%)	[0.0%, 0.0%]	
死亡,围术期	83	1 (1.2%)	[0.0%, 3.6%]	
死亡,1个月时	72	0 (0.0%)	[0.0%, 0.0%]	

12F					失败的差异
有效性:导线	N	完整	部分	失败	[95% CI]
结果	244	230 (94.3%)	6 (2.5%)	8 (3.3%)	6.0% [-2.0%, 12.2%]
安全性:病人	N	观察值	置信度区间		差异 [95% CI]
急性并发症	218	3 (1.4%)	[0.3%, 4.0%]		4.6% [-1.5%, 10.8%]
并发症1个月时	218	6 (2.8%)	[1.0%, 5.9%]		-2.8% [-5.8%, 0.3%]
死亡,围术期	218	1 (0.5%)	[0.0%, 2.5%]		0.7% [-2.6%, 4.1%]
死亡,1个月时	218	2 (0.9%)	[0.1%, 3.3%]		-0.9% [-3.1%, 1.3%

8. 个性化治疗

如果出现下列情况,则权衡血管内导管／导线移除过程的相对风险与受益:

- 正在移除双线圈ICD导线;
- 需要移除的导线具有锐弯或出现断裂迹象;
- 导线出现绝缘体分解迹象,增加肺栓塞危险;
- 增生物直接与导线体相连。

在导线移除过程中,外鞘配合植入性电极导线激光拔除鞘一同使用,一旦植入性电极导线激光拔除鞘和导线从病人体内拔出时,外鞘留在原处,则可以作为牵引导丝的导管,有助于安插新导线。

外鞘尖端应当完全插入心房,或缩进头臂静脉。将外鞘尖端放置于SVC—心房交界,可能在后序操作中,比如移动外鞘或安插新导线,对脆弱区域造成损伤,因而不建议此做法。

在激光辅助和标准拔除过程中,保持导线上施加适当的牵引力显得极为重要。如果导线承受的牵引力无法保持适当程度,用以抵消扭曲导线体的背压,则需要变换方法,采用另一种拔除法,比如股动脉入路。

当采用X-射线透视,看到标记钙化物伴随移除导线一同移动时,特别是在心房内,如果出现由于拔除操作引发的问题,那么能否立即进行手术救助就显得极为重要。而且,还应当考虑开胸术移除导线的适应症。

对于属下列情况的病人,植入性电极导线激光拔除鞘套件的安全性和有效性尚未确定:

- 肺栓塞新近发作
- 导线安插在冠状窦内

9. 操作者手册

能量参数
本文件中提及的装置,可以在下列CVX-300®的能量范围内操作:

装置	能量密度 (mJ)	重复频率 (Hz)
12F	30-60	25-80
14F	30-60	25-80
16F	30-60	25-80

建议校准设置：60 能量密度，80Hz。

校准后，医师可酌情调整上述范围内的能量和重复频率。

操作该装置需要CVX-300®的3.X18 版本或更高版本的软件。带有V3.7XX软件的CVX-300®将把重复频率限制为40 Hz。

CVX-300®为这些装置提供的操作时间为10 秒钟，在继续发射激光之前，将有5 秒钟等待时间。

10. 提供方式

10.1 灭菌

仅限单次使用。请勿再次灭菌或重复使用。

该植入性电极导线激光拔除鞘套件属于灭菌产品。当包装未打开和未损坏时，才能保证其无菌性，不可提前拆开。

10.2 使用前的检查

使用之前，请检查灭菌包装，确保封条没有打开。操作过程使用的所有设备，包括植入性电极导线激光拔除鞘，应当仔细检查是否存在缺陷。检查植入性电极导线激光拔除鞘是否弯曲、扭结或其它损坏。一旦损坏，请勿使用。

11. 兼容性

植入性电极导线激光拔除鞘套件和起搏器／ICD 导线的兼容性

下表说明了植入性电极导线激光拔除鞘套件、需要移除的起搏器／ICD 导线和外鞘之间的空间兼容性。采用植入性电极导线激光拔除鞘套件进行拔除之前，医师确定导线的最大外径（OD），这一点至关重要。这方面信息应当由导线生产商提供。

ID = 内径 OD = 内径	12F 植入性电极导线激光拔除鞘	14F 植入性电极导线激光拔除鞘	16F 植入性电极导线激光拔除鞘
型号	500-301	500-302	500-303
最小头内径，in./F/mm	0.109 / 8.3 / 2.8	0.134 / 10.2 / 3.4	0.164 / 12.5 / 4.2
最大头外径，in./F/mm	0.164 / 12.5 / 4.2	0.192 / 14.7 / 4.9	0.225 / 17.2 / 5.7
导线：最大外径，F/mm	7.5 / 2.5	9.5 / 3.2	11.5 / 3.8
外鞘：最小内径，F/mm	13 / 4.3	15.5 / 5.2	18.2 / 6.1

12. 使用说明

12.1 安装程序

植入性电极导线激光拔除鞘套件准备程序：

1. 运用无菌技术，打开无菌包装。从托架上取下包装楔子，轻轻地将装置从托架上抬起，同时支撑近端的耦合器。
2. 将装置的近端接通CVX-300®的接口。
3. 按照CVX-300®操作者手册（7030-0035 或7030-0068）中“操作模式”部分的说明，校准植入性电极导线激光拔除鞘。

病人准备程序：

1. 获取详细病例，包括病人的血型。应随时准备好适当的血液制品。
2. 确定生产商、型号和需要移除导管／导线的安插日期。采用X 光线照相术或心回波描记术，评估导管／导线的情况、类型和位置。
3. 使用的操作室需要具备高质量X-射线设备、起博设备、除颤器、开胸手术和心包穿刺术托盘。
4. 准备并遮盖病人的胸部，为开胸手术做准备，准备并遮盖病人的腹股沟，以便进行股动脉入路拔除操作。
5. 按需要，配备备用起搏器。
6. 有必要额外准备植入性电极导线激光拔除鞘套件、外鞘、锁定钢丝、用于松开主动固定电极的通管针、勒除器（股动脉穿刺套件）及其它辅助装置。

12.2 临床技术

1. 预备接受导线移除的病人应做好多方面准备，包括紧急心脏外科手术。准备工作包括：全身气管内麻醉或清醒麻醉，修剪胸部和腹股沟区域，ECG监测，安插动脉管路和Foley 导管，准备起搏器和除颤器等装置，电灼器，急救时使用的胸骨锯。
2. 所有需要起搏器的病人均安插了临时起博导线。植入永久起搏器，并且无需移除导线的病人除外。
3. 运用X 光透视监测全部经静脉操作。
4. 露出导线的近端并且切断用于保持固定套管缝线的缝线。因为需要露出静脉插入点，所以清除导线上的增生物。切断导线接头，取下固定套管。
5. 对于有源固定导线，旋松导线螺旋段所用的螺钉。
6. 切断导线接头，取下固定套管。
7. 尽可能将锁定探针或导线锁定装置插入远端导线，并展开锁定机制。将一段约60 cm 长的缝线材料固定在电极导线绝缘和高压电缆的近端，用作牵引装置。
8. 将无菌注射器吸入10cc 盐水。再将盐水注入植入性电极导线激光拔除鞘内腔。另外采用10cc 盐水，润湿植入性电极导线激光拔除鞘套件的外鞘。
9. 使用外鞘时，请润湿内腔并将其放置于植入性电极导线激光拔除鞘上。
10. 运用“穿线器”装置，将牵引装置的操作柄穿入植入性电极导线激光拔除鞘内腔。牵引装置的操作柄从植入性电极导线激光拔除鞘近端露出之后，取下“穿线器”。将导线近端穿入植入性电极导线激光拔除 鞘内腔。
11. 拔除技术：
    a. 沿导线推进植入性电极导线激光拔除鞘，直到遇到阻塞。运用“尺蠖”技术，通过外鞘和植入性电极导线激光拔除鞘交替作用在电极导线上前行。

注意事项：以与40Hz 操作相同的速率进行80Hz 操作大约需要一半的向前推进力。推荐的推进速率为每秒1 mm。

注意事项：当在一个弯道附近推进植入性电极导线激光拔除鞘或外鞘时，保持激光拔除鞘斜面尖端位于弯道内侧。

注意事项：正如使用植入性电极导线激光拔除鞘套件的所有拔除操作，特别是在移除双线圈ICD 导线时，维持导线坚固的牵引以及一个稳定的“轨道”位置，同时保持植入性电极导线激光拔除鞘套件与电极同轴，保持激光拔除鞘斜面尖端位于SVC 弯道内侧 。

注意事项：在进入SVC 之前停止，以确保维持坚固的牵引以及一个稳定的“轨道”。

b. 运用下列准则确定是否符合软组织阻塞：
   - 植入性电极导线激光拔除鞘无法插入静脉。
   - 当纵向施加压力时，植入性电极导线激光拔除鞘稍微向外弯曲。
   - X-射线透视检查显示，相对于导线体，鞘尖端无法前移。
   - X-射线透视检查显示，植入性电极导线激光拔除鞘尖端没有卡住导线电极、导线弯曲或其它导线。

c. 当遇到阻塞时，并且植入性电极导线激光拔除鞘套件无法前移：
   - 运用正交透视视图，确保植入性电极导线激光拔除鞘头端对准导线的纵轴。
   - 缩回外鞘，以便其末端不会与植入性电极导线激光拔除鞘尖端重叠。轻轻地将植入性电极导线激光拔除鞘按入阻塞组织。
   - 将激光器设定为就绪模式。按压脚踏开关，激活激光器。发射激光时，在植入性电极导线激光拔除鞘上轻轻地施加压力，以便该装置每秒钟前移约1 毫米，同时在牵引装置上施加同等大小的反向牵引力。如果在发射激光过程，植入性电极导线激光拔除鞘刺穿了阻塞物，则松开脚踏开关。

注意事项：推进植入性电极导线激光拔除鞘穿过中度钙化组织，可能比穿过纤维瘢痕增生需要更多地激光能量脉冲。

注意事项：如果不能推进植入性电极导线激光拔除鞘，则停止推进。准备好以扩大至一个更大的植入性电极导线激光拔除鞘套件，移动至另一条导线，尝试股静脉方法或者考虑一个开放手术。同时也考虑通过将导线留在原地放弃此手术过程，并且委托给一个更有经验的中心。

- 将外鞘推进至植入性电极导线激光拔除鞘的新位置。
  d. 如果导线上牵引装置的夹子分离，那么就有必要取下植入性电极导线激光拔除鞘和外鞘，并且在继续使用植入性电极导线激光拔除鞘套件之前，安装新的牵引装置。
  e. 将外鞘和植入性电极导线激光拔除鞘牵到导线上的理想位置，如上述11（a-c）所述。

警告：植入性电极导线激光拔除鞘与导线头端的距离不得少于1 厘米。不得在心肌层发射激光以移除导线尖端。

  f. 如有必要，运用外鞘和牵引装置，施加反向牵引力，将导线尖端从心脏侧壁移除。

12. 在操作过程中，随时可以成功地抽回植入性电极导线激光拔除鞘和外鞘。如果导线松开，那么它应当被拉进植入性电极导线激光拔除鞘内，然后导线、植入性电极导线激光拔除鞘和外鞘方可从体内取出。
13. 为保持静脉通路以便重新植入，将外鞘保持在适当位置，以便移除导线和植入性电极导线激光拔除鞘时插入导丝。插入导丝后，从体内取出外鞘。

注意事项：如果因为任何原因将植入性电极导线激光拔除鞘套件从身体内移除，使用生理盐水彻底清洗装置轴柄、内腔和头端，以清除颗粒并且防止血液粘黏。

注意事项：如果在使用过程中经透视检查证实植入性电极导线激光拔除鞘套件扭结或损坏，建议不要再使用该装置。衡量装置移除相对于继续使用的相关风险和获益。

用完之后，根据适用于医院废弃物、潜在生物危害材料的特殊要求，处理所有设备。

12.3 医师培训

使用植入性电极导线激光拔除鞘套件和CVX-300®准分子激光系统的医师应当接受下列培训：

- 激光安全性和物理性质的课堂培训；
- 对激光器操作进行讲解性介绍，然后进行CVX-300®准分子激光系统演示；
- 使用CVX-300®准分子激光系统移除导线的实际操作培训；
- 观察有经验的植入性电极导线激光拔除鞘套件操作员运用植入性电极导线激光拔除鞘套件移除至少两根导线；
- 在另一位熟悉导线移除技术的医师和训练有素的Spectranetics 代表监督下，移除至少两根导线。
- HRS[3]和EHRA[4]建议进行并发症管理。

13. 生产商有限担保

生产商保证在有效期内使用的GlideLight 植入性电极导线激光拔除鞘套件，并且使用前包装未打开、没有损坏，其材料和工艺没有缺陷。根据本担保，生产商的责任仅限于更换GlideLight 植入性电极导线激光拔除鞘套件的次品或按购买价格退款。生产商不负责由于使用GlideLight 植入性电极导线激光拔除鞘套件造成的任何偶然性、特殊性或结果性损坏。由于误用、改造、不当贮存或操作造成的损坏，以及按照本使用说明书进行操作而引起其它故障，此时本有限担保无效。本有限担保可以代替其它所有明确或暗含的担保，包括暗含的适销性或特殊目的适合性。任何个人或实体，包括生产商授权的代理或中间商，均无权扩充或延伸本有限担保，任何出于此目的所进行的尝试，对于生产商不具有约束力。

本有限担保仅涵盖GlideLight 植入性电极导线激光拔除鞘套件。在CVX-300®准分子激光系统的相关文件中，可查找该系统的生产商担保信息。

[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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Spectranetics®

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说明书附页

【适用范围】该产品与CVX-300准分子激光器配合使用，用于传输激光，可作为传统移除工具的辅助手段用于移除问题起搏器或除颤器的导线（硅或聚氨酯外绝缘）。

【按防电击的程度分类】CF型应用部分

【按运行模式分类】间歇加载连续运行（激光每发射10秒，停歇5秒）。

【按在与空气混合的易燃麻醉气或与氧或氧化亚氮混合的易燃麻醉气体情况下使用时的安全程度分类】不能在有与空气混合的易燃麻醉气或与氧或氧化亚氮混合的易燃麻醉气情况下使用的设备。

【光纤性能参数表】

光纤总长度：分为两段，有效长度：50-52（cm），尾管部分：269.24±15.24（cm）。

纤芯直径：100 μm。

光纤适用的波长：308nm。

对应波长的最低传输效率：500-301、500-302：21.3%；500-303：24.3%。

最大传输功率（或能量）：500-301、500-302：46.8mj；500-303：53.5mj。

抗拉强度：15N。

灭菌方法：环氧乙烷灭菌。

光纤最小弯曲工作半径：76.2mm。

		植入性电极导线激光拔除鞘				穿线器 型号：518-005		外鞘		
型号、规格	激光拔除鞘尺寸	最小尖端内径，mm	最大尖端外径 mm	工作长度，cm	传输效率（%）	长度 cm	直径英寸（mm）	最小内径 mm	长度，cm	一端**斜度**
500-301	12 Fr	2.8	4.2	50-52	≥ 21.3	62.23-67.31	0.024”（0.61）	4.3	42	45度
500-302	14 Fr	3.4	4.9	50-52	≥ 21.3	62.23-67.31	0.024”（0.61）	5.2	42	45度
500-303	16 Fr	4.2	5.7	50-52	≥ 24.3	62.23-67.31	0.024”（0.61）	6.1	42	45度

【生产企业/注册人名称】Spectranetics Corporation 史派克公司

【生产企业/注册人住所】9965 Federal Drive Colorado Springs Colorado80921 USA

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【代理人/售后服务单位联系方式】800 810 0038

【生产日期】见标签

【使用期限/失效日期】2年

【产品技术要求编号】国械注进20163121385

【医疗器械注册证编号】国械注进20163121385

编制或者修订日期：xxxx年xx月xx日

符号及含义

	制造商	REF	产品编号
	有效期	LOT	批号
	不得二次使用	STERILE EO	经环氧乙烷灭菌
EC REP	欧盟授权代表		怕雨
	无热原		查看使用说明
Rx ONLY	仅凭处方销售		如包装破损切勿使用
CE 0086	CE 标志	60°C/140°F	温度上限60°C/140°F
	CF 型应用部分		