LLD™

Lead Locking Device

Instructions for Use

Spectranetics®

Instructions for Use - Sections by Language

Spectranetics®

Lead Locking Device (**LLD™**) Accessory Kit Lead Cutter

Instructions for Use

English / English

Table of Contents

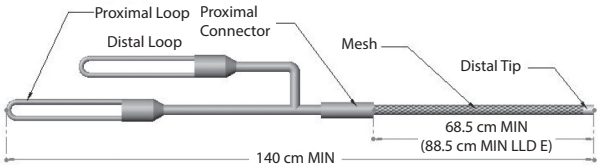
Caution: Federal (USA) law restricts this device to sale by or on the order of a physician with appropriate training.

1. Description

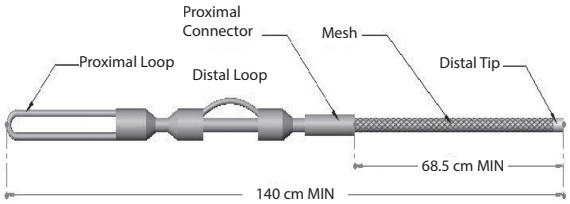
1.1 LLD and Clearing Stylet

The Spectranetics Lead Locking Device or LLD is comprised of two wire loop handles and a core mandrel that has a stainless steel mesh fixation mechanism. This mesh is attached at the distal end within a radiopaque marker for visibility under fluoroscopy. The proximal end of the mesh is attached to a proximal connector which is used to deploy and lock the device into the pacing or defibrillator lead. The proximal connector is seated on a crimped section of the core mandrel until it is deployed. The connector slides distally from the crimped section and deploys the mesh inside the lead.

Figure 1: Non-Deployed LLD, "Insertion" Configuration

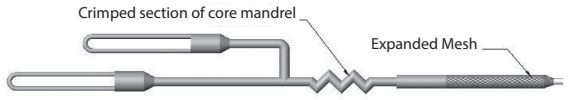


LLD #1, #2, #3, &E

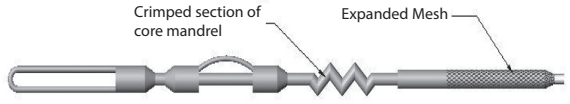


LLD EZ

Figure 2: Deployed LLD, "Locked" Configuration



LLD #1, #2, #3, &E



LLD EZ

The LLD is packaged with a clearing stylet. The clearing stylet consists of a stainless steel mandrel attached to a proximal handle. Table 1 identifies LLD device ranges and Clearing Stylet sizes.

Table 1: Device Range

Model Number	Device Number	Lead Internal Diameter Range (in / mm)	Clearing Stylet Number Diameter (in/mm)
518 – 018 518 – 021	LLD #1	0.013 – 0.016 / 0.33 – 0.41	1 (0.012 / 0.30)
518 – 019 518 – 022	LLD #2	0.017 – 0.026 / 0.43 – 0.66	2 (0.015 / 0.38)
518 – 020 518 – 023	LLD #3	0.027 – 0.032 / 0.69 – 0.81	2 (0.015 / 0.38)
518 – 039	LLD E	0.015 – 0.023/ 0.38 – 0.58	1 (0.012 / 0.30)
518 – 062 518 – 067	LLD EZ	0.015 – 0.023 / 0.38 – 0.58	1 (0.012 / 0.30)

1.2 Lead Cutter (Model Number 518-024)

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.

1.3 Accessory Kit (Model Number 518-027)

The Spectranetics Accessory Kit contains a Coil Expander and two Pin Gauges.

Coil Expander: Used to restore the proximal end of lead coils to a circular profile. The Coil Expander contains a stainless steel tapered pin inserted into a polycarbonate handle. The Coil Expander opens the proximal end of the lead coil. This process promotes an accurate measurement by the Pin Gauges.

Pin Gauges: The Pin Gauges are used to determine which Lead Locking Device (LLD) is appropriate for the pacing/defibrillator lead to be extracted. The Pin Gauges are made with stainless steel pins inserted into a polycarbonate handle. Each Pin Gauge contains two pins. One Pin Gauge has the #1 and E/EZ pins, the second Pin Gauge has the #2 and #3 pins.

1.4 LLD Size Selection

The appropriate LLD is selected by using the Spectranetics Pin Gauges as described on Table 2 below.

Table 2: Selection Chart

Pin Number	Select LLD
Pin #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

* For leads with internal diameter greater than 0.023" / 0.58mm, select LLD #2

The LLD may be used in conjunction with the Spectranetics Laser Sheath Kit or other necessary extraction devices.

Closely follow the Instructions for Use for any device used during the extraction procedure.

NOTE: The LLD is a single use disposable device and is intended to be used in one lead.

NOTE: Any device used over the lead to be extracted must have an ID greater than the target lead maximum diameter.

2. Indications for Use

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

3. Contraindications

Use of the LLD is contraindicated:

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

4. Warnings

Do not attempt to use the LLD without the availability of the Spectranetics Laser Sheath or other necessary lead removal tools.

The LLD should be used only by physicians who are experienced in lead removal techniques.

Do not insert more than one LLD into a lead lumen at a time.

Lead removal devices should be used only at institutions with emergency cardiac surgical capabilities.

Weigh the relative risks and benefits of intravascular lead removal procedures particularly when:
- The item to be removed is of a dangerous shape or configuration.
- The likelihood of lead disintegration resulting in fragment embolism is high.
- Vegetations are attached to the lead body.

When using the LLD:
- Do not abandon a lead in a patient with a LLD still inside the lead. Severe vessel or endocardial wall damage may result from the stiffened lead or from fracture or migration of the abandoned device.
- Do not apply weighted traction to an inserted LLD as myocardial avulsion, hypotension, or venous wall tearing may result.
- Excessive applied traction forces may impact the LLD's ability to disengage from a lead.

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

Do not use a Metal Reinforced Flexible Dilator Sheath to apply myocardial countertraction.

When the LLD is in the body, it should be manipulated only under fluoroscopic observation.

Maintain appropriate traction on the LLD and device being extracted during advancement of the Spectranetics Laser Sheath.

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

5. Precautions

Thoroughly review appropriate package inserts for the Spectranetics Laser Sheath (SLS™) before attempting to use the SLS™ with the LLD.

For single use only. Do not resterilize and/or reuse. The LLD is intended to be used in one lead.

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 LLD:
- If the tamper-evident seal is broken;
- If the LLD has been damaged.

When the LLD is in the body, it should be manipulated only under fluoroscopic observation.

Prior to the procedure, consider the size of the lead to be extracted in relation to the size of the Lead Extraction Devices and LLD. Any device used over the lead to be extracted must have an ID greater than the target lead maximum outer diameter.

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

If selectively removing leads with the intent to leave one or more chronically implanted leads intact, these nontargeted leads must be subsequently tested to ensure that they were not damaged or dislodged during the extraction procedure.

6. Adverse Events

Commonly observed adverse events during lead removal procedures have included:
- Hemopericardium Tamponade
- Hemothorax
- Thrombosis
- Tricuspid Regurgitation
- Infection
- Death

The following adverse events or conditions may also occur during lead removal (listed in alphabetical order):
- bacteremia
- low cardiac output
- migration of lead fragments
- migration of vegetation
- myocardial avulsion
- premature ventricular contractions
- pulmonary embolism
- stroke
- venous avulsion
- ventricular tachycardia

Additional information may be found in the articles referenced in the bibliography.

7. Individualization of Treatment

Weigh the relative risks and benefits of intravascular lead removal procedures in cases where:
- 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 to the lead body.

When an outer sheath is left in place following lead removal, it may then be used as a conduit to facilitate the implantation of a new lead.

The 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 during all extraction attempts. If appropriate levels of traction cannot be maintained to offset the counter-pressures that distort the lead body, changing to an alternative extraction procedure should be considered.

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.

8. How Supplied

8.1 Sterilization

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

The Spectranetics LLD, Accessory Kit, and Lead Cutter are supplied sterile and Non-Pyrogenic. Sterility is guaranteed only if the package is unopened and undamaged.

8.2 Device / Packaging Care

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

8.3 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 LLD, should be examined carefully for defects. Examine the LLD for bends, kinks or other damage. Do not use if it is damaged.

9. Compatibility

See "Description" section.

10. Directions for Use

NOTE: "LLD" refers to all LLD devices (#1, #2, #3, E, and EZ).

WARNING: Do not abandon a lead in a patient with a LLD still in place. Severe vessel or endocardial wall damage may result from the stiffened lead or from fracture or migration of the abandoned LLD body.

WARNING: Be aware that a lead that has a J-shape retention wire that occupies its inner lumen (rather than being outside the coil) may not be compatible with the LLD. Insertion of the LLD into such a lead may result in protrusion and possible migration of the J-shape retention wire.

WARNING: Excessive applied traction forces may impact the LLD's ability to disengage from a lead.

WARNING: Do not apply weighted traction to an inserted LLD as myocardial avulsion, hypotension, or venous wall tearing may result.

10.1 Clinical Technique

Thoroughly review appropriate package inserts for Spectranetics Laser Sheaths or other necessary lead extraction tools before attempting to use the LLD.

10.2 Procedure Set Up

LLD Preparations:
Using sterile technique, open the sterile package.

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 lead to be removed. Perform radiographic / echo-cardiographic evaluation of lead condition, type and position.
3. Use a procedure room that has 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. If a femoral approach becomes necessary, the LLD is contraindicated.
5. Establish back-up pacing as needed.

10.3 Procedure

1. After the proximal end of the lead has been exposed, sutures and tie-down materials removed, and the proximal fittings (if present) cut off, using the Spectranetics Lead Cutter or other suitable instrument, expose the inner coil of the lead.

NOTE: For a unipolar lead, if the lead is long enough, use a scalpel to circumscribe the insulation two centimeters from the cut proximal end of the lead (do this carefully to avoid deforming the coil), then pull the insulation off to expose the inner coil.

For a bipolar lead with coaxial coils, remove the outer coil and inner insulation to expose the inner coil and prevent it from being pushed deeply into the outer coil.

Once the inner lumen of the lead is exposed, insert the Spectranetics Coil Expander to ensure that there is no obstruction to insertion of the Spectranetics Pin Gauges used to size the appropriate LLD.

NOTE: Examine the lumen to be sure the interior coil is not flattened and there are no burrs that would inhibit passage of the Spectranetics Pin Gauges or the LLD into the lumen.

2. Determine the appropriate size of LLD based on the inside diameter of the lead coil. The Spectranetics Pin Gauges are used to determine the inner diameter of the coil. The size of the largest pin that fits freely in the coil indicates the size of the appropriate LLD.
3. Check patency of the coil lumen. Pass the Clearing Stylet (provided in the LLD package) through the inner lumen of the lead to clear any blood, coagulation, or blockage in the lumen prior to insertion of the LLD. After confirmation of a clear lumen, remove the Clearing Stylet.

NOTE: It may be helpful to mark the depth of penetration of the Clearing Stylet into the lead by placing a mosquito clamp at that point where the Clearing Stylet exits the cut end of the lead. Knowing the depth of penetration will be useful later in monitoring progress during insertion of the LLD.

4. Grasp the appropriately sized LLD within the mesh section and advance the LLD into the inner coil of the lead, using the radiopaque marker for fluoroscopic monitoring.

CAUTION: Do not attempt to advance or rotate the LLD via the proximal connector as premature deployment or damage to the mesh may result.

CAUTION: Do not attempt to rotate the LLD via the proximal loop as damage to the device may result.

5. Lock the LLD in place by:

Releasing the proximal connector from the crimped core mandrel by sliding the connector off the crimped section after the LLD has reached the distal end of the lead or the position indicated by the Clearing Stylet.

This action expands the wire mesh inside the lead and locks it in place (the device is now deployed). Tension can be applied to the core mandrel or proximal loop for traction.

6. It is recommended that a suture be tied to the proximal end of the targeted lead insulation as an additional traction source. The other end of the suture can be secured to the LLD via the Distal Loop immediately above the Proximal Connector. Fastening the suture to the Distal Loop will facilitate the insertion of the LLD with the suture through the Spectranetics Laser Sheath. Closely follow the Instructions for Use for the Spectranetics Laser Sheath Kit.
7. If for some reason lead removal is unsuccessful or becomes medically contraindicated, removal or repositioning of the LLD may be facilitated as follows:

Reset the proximal connector onto the crimped section of the core mandrel.

This action reduces the diameter of the wire mesh inside the lead, unlocking it from the inner lead body.

WARNING: Excessive applied traction forces may impact the LLD's ability to disengage from a lead.

Withdraw or reposition the LLD by grasping the proximal mesh of the locking device.

If the LLD is still secured within the lead the following actions are recommended:

A. Grasp the mesh near the proximal end of the lead coil and gently smooth the mesh by stretching it towards the proximal connector.
B. Grasp the mesh again near the proximal end of the lead coil, advance the LLD within the lead and then simultaneously rotate and pull the LLD from the lead body.

11. Manufacturer's Limited Warranty

Manufacturer warrants that the LLD 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 LLD. Manufacturer will not be liable for any incidental, special, or consequential damages resulting from use of the LLD. Damage to the LLD 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.

12. Bibliography

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Byrd, C. L.: Extracting Chronically Implanted pacemaker Leads using the Spectranetics Excimer Laser; Initial Clinical Experience: NASPE Abstract, PACE April 1996

Byrd, C. L.: Laser System Improves Success at Removing pacemaker Leads: NASPE News Brief (Abstract #1687), PACE April 1996

Byrd, C. L.: Extraction of Telectronics 330-808 and 329-701 Leads, NASPE Abstract, PACE April 1996

Smith, H. J., et. al.: Five-Year Experience with Intravascular Lead Extraction: PACE 1994:17:2016-2020

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Spectranetics® Laser Sheath (SLS™)Instructions For Use

13. Non-Standard Symbols

Non-Pyrogenic		**Kit Includes**	
Lead Internal Diameter Range		**Clearing Stylet Outer Diameter**	
Size		**Contents**	
Pin Gauge		**Coil Expander**	
Kit Contents		**Clearing Stylet**	
Quantity	**QTY**	**Lead Cutter**	
Sterilized Using Ethylene Oxide		**Do not use if package is damaged**	
Upper Limit of Temperature	 **60°C/140°F**	**Consult Instructions for Use**	
Single Use		**Keep Dry**	
CAUTION: Federal law restricts this device to sale by or on the order of a physician.			**Rx ONLY**

电极导线锁紧装置
配件套件
导线切割器

使用说明

Chinese/中文

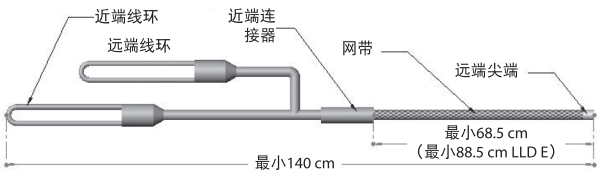
目录

1. 说明

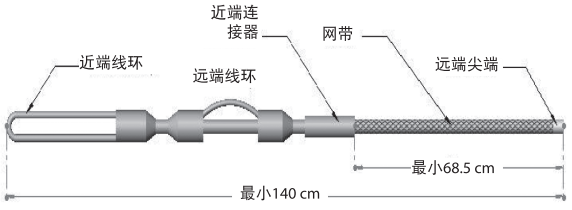
1.1 LLD和清除探针

Spectranetics电极导线锁紧装置由两个线环把手和一个带有不锈钢网带固定机制的芯轴组成。网带的远端有一个不透射线标志，以便在荧光透视下可见。网带近端装有一个近端连接器，用于将装置置入起搏或除颤导线并与之锁定。近端连接器位于芯轴的卷曲部分直至置入导线。连接器从卷曲部分向远侧滑动并将网带送至导线内部。

图1：未置入的LLD，“插入”结构



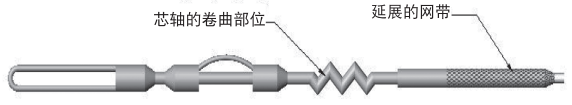
LLD #1，#2，#3，&E



LLD EZ

图2：已置入的LLD，“锁定”结构

LLD #1，#2，#3，&E



LLD EZ

LLD的包装中还有一根清除探针。该清除探针包括一个连接至近端把手的不锈钢芯轴。表1确定了LLD装置的范围及清除探针的尺寸大小。

表1：装置范围

型号	装置序号	导线内径范围（in/mm）	清除探针编号及直径（in/mm）
518 – 018 518 – 021	LLD #1	0.013 – 0.016 / 0.33 – 0.41	1 (0.012 / 0.30)
518 – 019 518 – 022	LLD #2	0.017 – 0.026 / 0.43 – 0.66	2 (0.015 / 0.38)
518 – 020 518 – 023	LLD #3	0.027 – 0.032 / 0.69 – 0.81	2 (0.015 / 0.38)
518 – 039	LLD E	0.015 – 0.023 / 0.38 – 0.58	1 (0.012 / 0.30)
518 – 062 518 – 067	LLD EZ	0.015 – 0.023 / 0.38 – 0.58	1 (0.012 / 0.30)

1.2 导线切割器（型号518-024）

Spectranetics导线切割器用于割透绝缘层和线圈，进而进入起搏/除颤导线的内腔。该切割器由不锈钢制成。

1.3 配件套件（型号518-027）

Spectranetics配件套件包括一个线圈扩展器和两个针规。

线圈扩展器：用于将导管线圈的近端恢复为圆形剖面。该线圈扩展器包括一个插入聚碳酸酯把手的不锈钢锥形针销。线圈扩展器打开导线线圈的近端。此程序有助于针规的正确测量。

针规：针规用于确定对于将要移除的起搏/除颤导线，哪个电极导线锁紧装置合适。针规由插入一个聚碳酸酯把手的不锈钢针销制成。每个针规包含两个针销。一个针规包括#1和E/EZ针销，第二个针规包括#2和#3针销。

1.4 LLD尺寸选择

通过如下表2所示的Spectranetics针规，选择合适的LLD。

表2：选择表

针销序号	选择LLD
针销#1合适，针销E/EZ不合适	#1
针销E/EZ合适，针销#2不合适	E或EZ
针销#2合适，针销#3不合适	#2、E或EZ*
针销#3合适	#3

* 对于内径大于0.023”/0.58 mm的导线，选择LLD #2。

LLD可与Spectranetics激光鞘套件或其他必要的移除设备结合使用。

在移除过程中，应严格遵守所使用的任何设备的使用说明。

注意：LLD是仅供单次使用的一次性装置，且仅可用于一根导线。

注意：用于将要移除的导线上的任何设备，其内径必须大于目标导线的最大直径。

2. 适应症

Spectranetics电极导线锁紧装置，适用于为适合经静脉移除的病人移除长期植入的带有内腔、经上腔静脉植入的起搏或除颤导线。

3. 禁忌症

以下情况禁忌使用LLD：

- 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；
- 无法进行荧光检查时；
- 病人的上腔静脉通路无法使用；
- 手术者难以接近起博导线近端时；
- 当LLD不能装入将要移除的装置的内腔时。

4. 警告

在Spectranetics激光鞘或其他必要的导线移除工具不可用的情况下，切勿试图使用LLD。

LLD只应由在导线移除技术方面经验丰富的医生使用。

一次切勿将多个LLD插入同一个导线腔中。

使用导线移除装置的机构必须具备紧急心脏手术能力。

衡量血管内导线移除手术的相对风险和利益，尤其是当：
- 将要被移除的导线具有危险形状或结构时。
- 导线解体引起碎片栓塞的可能性较高时。
- 赘生物与导线体相连时。

使用LLD时：
- 切勿将内含LLD的导线滞留于患者体内。变硬的导线或遗留装置断裂或移位会导致严重的血管或心内膜壁损伤。
- 切勿对插入的LLD施力牵引，否则可能导致心肌撕裂、低血压或静脉壁撕裂。
- 过度施力可能影响LLD从导线脱离的能力。

注意，如果导线中有J型固位丝占据其内腔（而不是在线圈外部），则可能与LLD不兼容。将LLD插入这样的导线可能引起J型固位丝突出或可能移位。

切勿使用金属强化柔性扩张鞘施加心肌对抗牵引力。

当LLD位于体内时，仅可在荧光镜监视下对其进行操作。

在Spectranetics激光鞘推进期间，在LLD及将要移除设备上保持适当牵引力。

当在荧光镜透视下看到标记钙化物伴随装置一同移动时，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是至关重要的。此外，应考虑该装置的开胸手术移除。

5. 注意事项

在试图与LLD一起使用Spectranetics Laser Sheath (SLS™)之前，详细查看SLS™的相关包装说明书。

限一次性使用。请勿重新灭菌或重复使用。LLD仅可用于一根导线。

请勿对本装置进行重新灭菌或重复使用，因为不适当的再处理可能会损害装置的性能，或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，使得生产商的担保无效。

如果出现以下情况，切勿使用LLD：
- 如果防揭密封包装破裂；
- 如果LLD已被损坏。

当LLD位于体内时，仅可在荧光镜监视下对其进行操作。

进行手术前，先对比考虑待移除导线的尺寸与导线移除装置和LLD的尺寸。任何用于待移除导线的装置的内径必须大于目标导线的最大外径。

由于导线技术的迅速发展，本装置可能不适用于某些类型的导线。如果对本装置与特定导线的兼容性存在问题或忧虑，请联系导线生产商。

如果需要有选择地移除一部分导线，而保留一个或多个长期植入导线原封不动时，操作完成后，必须对非目标导线进行检查，以确保它们在移除过程中未受损坏或移动。

6. 不良事件

导线移除术期间观察到的常见不良事件包括：
- 心包积血填塞
- 血胸
- 血栓形成
- 三尖瓣反流
- 感染
- 死亡

在导线移除术中，还可能会出现下列不良事件或状况（按字母顺序列举）：
- 菌血症
- 低心排血量
- 导线碎片移动
- 赘生物移动
- 心肌撕裂
- 心室早发性收缩
- 肺栓塞
- 中风
- 静脉撕裂
- 室性心动过速

更多详细信息可以在参考书目中提到的文章中找到。

7. 治疗的个性化

出现下列情况时，应衡量血管内导线移除术的风险和益处：
- 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；
- 赘生物与导线体相连时。

在导线移除之后，如果外鞘留在原位，可将其用作植入新导线的导管。

鞘尖端应当完全插入心房，或缩进头臂静脉。

不建议将外鞘尖端放置于SVC－心房交界处，因为在后续操作中，比如移动外鞘或植入新导线，可能会对该脆弱部位造成损伤。

在所有的移除尝试过程中，务必在将要移除的导线上保持适当的牵引力。如果无法在导线上保持适当的牵引力，用以抵消扭曲导线体的背压，则需要考虑换用其他移除手术。

当在荧光镜透视下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是至关重要的。而且，还应当考虑行开胸术移除导线的指征。

8. 供货方式

8.1 灭菌

限一次性使用。请勿重新灭菌和/或重复使用。

Spectranetics LLD、配件套件及导线切割器已经过灭菌，且无热原。只有在包装未打开且未损坏的情况下，才能保证本装置的无菌性。

8.2 装置/包装注意事项

使用之前，请将装置保存在干燥凉爽之处（60摄氏度/140华氏度以下）。

8.3 使用前的检查

使用之前，目视检查灭菌包装，确保其密封性未被破坏。手术中所要使用的所有设备，包括LLD，都应仔细检查是否有缺陷。检查LLD是否存在弯曲、扭结或其他损坏。一旦损坏，请勿使用。

9. 兼容性

参见“说明”部分。

10. 使用说明

注意：“LLD”指所有的LLD装置（#1、#2、#3、E及EZ）。

警告：切勿将内含LLD的导线滞留于患者体内。变硬的导线或遗留的LLD主体断裂或移位会导致严重的血管或心内膜壁损伤。

警告：注意，如果导线中有J型固位丝占据其内腔（而不是在线圈外部），则可能与LLD不兼容。将LLD插入这样的导线可能引起J型固位丝突出或可能移位。

警告：过度施力可能影响LLD从导线脱离的能力。

警告：切勿对插入的LLD施力牵引，否则可能导致心肌撕裂、低血压或静脉壁撕裂。

10.1 临床技术

在尝试使用LLD之前，详细查看Spectranetics激光鞘或其他必要导线移除工具的相关包装说明书。

10.2 手术安排

LLD准备程序：

运用灭菌技术，打开无菌包装。

病人准备程序：
1. 取得包括病人血型在内的完整的病历。应准备好适当的血液制品，以便随时使用。
2. 确定将要移除导线的生产商、型号及植入日期。对导线状况、类型和位置进行射线透视和超声心动图评估。
3. 使用的手术室需要具备荧光镜、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，以便进行可能的股动脉入路移除术。如果必须经股动脉入路，则禁忌使用LLD。
5. 按需要，配备备用起博器。

10.3 程序

1. 导线的近端显露后，将缝合线和固定材料移除，使用Spectranetics导线切割器或其他合适的装置切断近端接头（如果有），露出导线的内部线圈。

注意：对于单极导线，如果导线足够长，使用手术刀，在绝缘层距离导线切割近端两厘米周围划线（小心地进行此操作，以避免线圈变形），然后将绝缘层拉开以显露内部线圈。

对于带有共轴线圈的双极导管，移除外部线圈和内部绝缘层以显露内部线圈，并防止其被过深地推入外部线圈。

一旦导线的内腔显露，插入Spectranetics线圈扩展器以确保不会阻碍用于确定适当LLD尺寸的Spectranetics针规的插入。

注意：检查管腔，以确定内部线圈未变平，且没有可能会妨碍Spectranetics针规或LLD通过管腔的毛刺。

2. 根据导线线圈的内径，确定LLD的适当尺寸。Spectranetics针规用于确定线圈的内径。可在线圈中自由移动的最大针销尺寸表示LLD的适当尺寸。
3. 检查线圈管腔是否保持开放通畅。插入LLD之前，将清除探针（包含在LLD包装中）穿过导线的内腔，以清除管腔内的任何血液、凝血或堵塞。确认已清除管腔之后，移除清除探针。

注意：通过在清除探针退出导线切割端的位置放置一个蚊式血管钳，可能有助于标记清除探针插入导管的深度。知道插入深度对后来LLD插入过程中的监测程序是很有用的。

4. 握住适当尺寸的LLD的网带部位，利用供荧光透视监测的不透射线标志，将LLD推入导线的内部线圈。

警告：切勿尝试通过近端连接器推进或旋转LLD，因为可能导致网带过早置入或损坏。

警告：切勿尝试通过近端线环旋转LLD，因为可能会导致装置损坏。

5. 将LLD锁定入位：

在LLD触到导线远端或者清除探针指示的位置之后，通过将连接器从卷曲部分滑出，将近端连接器从卷曲芯轴上释放。

此操作使得线网在导线内延展，并将其锁定入位（装置现已置入）。可以向芯轴或近端线环施加张力以供牵引。

6. 建议将一条缝合线绑在目标导管绝缘层的近端，以作为额外的牵引力源。缝合线的另一端可以通过近端连接器正上方的远端线环固定至LLD上。将缝合线固定在远端线环上，有助于将带有缝合线的LLD插入Spectranetics激光鞘。严格遵守Spectranetics激光鞘套件的使用说明。
7. 如果由于一些原因导致导线移除失败或者成为医学禁忌，下列方式可能会有助于移除或重新定位LLD：

将近端连接器复位至芯轴的卷曲部位。

此操作减少了导线内线网的直径，从而将其从导线体内解锁。

警告：过度施力可能影响LLD从导线脱离的能力。

抓住锁定装置的近端网带，取出或重新定位LLD。

如果LLD仍然固定在导线内，建议进行下列操作：

A. 抓住导线线圈近端附近的网带，并通过向近端连接器拉伸而缓慢地将网带抚平。
B. 再次抓住导线线圈近端附近的网带，在导线内推进LLD，然后同时旋转并将LLD从导线体内拉出。

11. 生产商有限担保

生产商保证，如果在声明的“使用截止日期”之前使用，且在临近使用前包装未打开或破损，则LLD在材料和工艺方面无缺陷。生产商在此担保下的责任限于更换有缺陷的LLD或按购买价格退款。生产商不负责由于使用LLD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，或未按照本使用说明进行的其他操作而引起LLD损坏，此时本有限担保将失效。**本有限担保明确替代所有其他明示或暗示的担保条款，其中包括对适销性和特定用途适用性的任何担保。**任何个人和实体，包括任何生产商授权的代表或零售商，都无权扩展或扩大本有限担保，任何声称扩大担保的行为对生产商均无强制力。

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Spectranetics® Laser Sheath (SLS™)Instructions For Use

13. 非标准符号

Non-Pyrogenic 无热原		**Kit Includes** 套件包括	
Lead Internal Diameter Range 导线内径范围		**Clearing Stylet Outer Diameter** 清除探针外径	
Size 尺寸		**Contents** 内含物	
Pin Gauge 针规		**Coil Expander** 线圈扩展器	
Kit Contents 套件内含物		**Clearing Stylet** 清除探针	
Quantity 数量	QTY	**Lead Cutter** 导线切割器	
Sterilized Using Ethylene Oxide 已使用环氧乙烷灭菌	STERILE EO	**Do not use if package is damaged** 包装如有损坏，请勿使用	
Upper Limit of Temperature 温度上限	60°C/140°F	**Consult Instructions for Use** 参考使用说明	
Single Use 单次使用		**Keep Dry** 保持干燥	
CAUTION: Federal law restricts this device to sale by or on the order of a physician. 警告：联邦法律规定，本装置只能由医生直接销售或遵医嘱销售。		Rx ONLY	

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Spectranetics®

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代理人地址及联系方式 ： 上海市静安区灵石路718号A1幢
电话： 8008100038**中国**

P008251

电极导线锁紧装置（说明书附页）

【型号规格】518-018、518-021、518-019、518-022、518-020、518-023、518-039、518-062、518-067、518-024、518-027

【主要结构组成】产品包括电极导管锁紧装置、清除探针、切割器、线圈扩展器和针规。电极导管锁紧装置由两个线圈环状把手和 一 个带有不锈钢齿轮固定机制的芯杆组成。清除探针和切割器由不锈钢制成 ,线 圈扩展器和针规由不锈钢和聚碳酸酯制成。产品经环氧乙烷灭菌 ,一 次性使用。

【灭菌方式】环氧乙烷灭菌

【有效期】2年

【生产商】Spectranetics Corporation 史派克公司

9965 Federal Drive Colorado Springs Colorado 80921 USA

【代理人】飞利浦(中国)投资有限公司

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【电话】8008100038中国

【生产日期】见标签

【产品标准编号】国械注进 20183771854

【医疗器械注册证书编号】国械注进 20183771854