VisiSheath™

Dilator Sheath

Instructions for Use

Spectranetics®

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VisiSheath™

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Instructions for Use

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Spectranetics®

VisiSheath™ Dilator Sheath

Instructions for Use

English / English

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US Only CAUTION: Federal law restricts this device to sale by or on the order of a physician.

1. DESCRIPTION

The VisiSheath Dilator Sheath is a single lumen sheath used independently or as a support for an inner sheath to facilitate tissue dilation. One end is terminated with a 45° angle cut, while the other end is blunt, see Figure 1. Both ends contain a radiopaque marker band to enable fluoroscopic identification of tip location and orientation. An additional exterior mark aligned with the tip of the 45° angle cut permits visual identification of sheath orientation. There are multiple diameter and length options available, see Table 1.

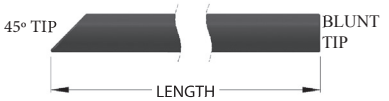

Figure 1: VisiSheath Dilator Sheath Tip Configuration

2. INDICATIONS FOR USE

The VisiSheath Dilator Sheath is intended for use in patients requiring the percutaneous dilation of tissue surrounding cardiac leads, indwelling catheters and foreign objects. The device is also intended for use in the introduction and support of intravascular catheters.

3. CONTRAINDICATIONS

None known.

4. WARNINGS

- Dilator sheaths should be used only at institutions with thoracic surgical capabilities by physicians knowledgeable in the techniques and devices for lead or catheter removal.
- When using dilator sheaths, do not insert sheaths over more than one lead or catheter at a time. Severe vessel damage, including venous wall laceration requiring surgical repair, may occur.
- Do not maintain a stationary position with the VisiSheath tip at the Superior Vena Cava (SVC)-right atrial (RA) junction as it may result in damage to this delicate area during subsequent lead extraction and reinsertion procedures (e.g., manipulating the dilator sheath or implanting a new lead).
- Weigh the relative risks and benefits of intravascular lead/catheter dilation procedures especially in cases when:
  - the object to be dilated away from adherent tissue is of a dangerous shape or configuration,
  - the likelihood of lead/catheter disintegration may result in increased risk of fragment embolization,
  - vegetations are attached directly to the lead/catheter body.

5. PRECAUTIONS

For single use only. The VisiSheath Dilator Sheath must not be resterilized and/or reused.

- DO NOT resterilize or reuse this device, as these actions can compromise device performance or increase the risk of cross-contamination due to inappropriate reprocessing. Reuse of this single use device could lead to serious patient injury or death and voids manufacturer warranties.
- Do not alter the sheath from its original state prior to use.
- When the VisiSheath Dilator Sheath is in the body, it should be manipulated only under fluoroscopic observation with radiographic equipment that provides high quality images.
- Prior to the procedure, evaluate the physical dimensions of the lead, catheter, or inner sheath in relation to the specifications of the dilator sheath to determine possible incompatibility.
- If selectively removing leads/catheters with the intent to leave one or more chronic leads/catheters implanted intact, the non-targeted leads/catheters must be subsequently tested to ensure that they were not damaged or dislodged during the procedure.
- When advancing dilator sheaths, use proper sheath technique. Maintain adequate tension and coaxial alignment on the lead/catheter to minimize the risk of vessel wall damage.

- If excessive scar tissue or calcification prevents safe advancement of dilator sheaths, consider an alternate approach.
- Excessive force with dilator sheaths used intravascularly may result in damage to the vascular system requiring emergency surgical repair.
- If the lead/catheter breaks, evaluate fragment for retrieval.
- If hypotension develops, rapidly evaluate; treat as appropriate.
- Due to rapidly evolving lead/catheter technology, this device may not be suitable for dilation of tissue around all types of leads/catheters. If there are questions or concerns regarding compatibility of this device with particular leads/catheters, contact the lead/catheter manufacturer.
- Do not pull on the lead/catheter because it may stretch, distort, or break, making subsequent removal more difficult. Damage to a lead may prevent passage of a lead locking device through the lumen and/or make dilation of scar tissue more difficult.
- If a lead locking device has not been used, be aware that damage to the lead caused by pulling on it may prevent subsequent passage of a lead locking device through the lumen and/or make dilation of scar tissue more difficult.
- If removing a chronic pacing lead, be aware that if it is freed spontaneously during the extraction procedure, the lead tip may become trapped in the upper vasculature. Dilator sheaths, advanced at least to the innominate vein, are often necessary to extract the lead tip through the scar tissue at the site of venous entry, and to avoid a venotomy.
- If the dilator sheath fails to progress after initial success, or if advancing the sheath was difficult, remove the sheath to inspect the tip. If the tip is distorted or frayed, exchange the damaged sheath for a new sheath before continuing treatment.
- When advancing a sheath around a bend, keep the point of the sheath's beveled tip oriented toward the inside of the bend.

6. ADVERSE EVENTS

Potential Adverse Events

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

- dislodging or damaging non-targeted lead/catheter
- chest wall hematoma
- thrombosis
- arrhythmias
- bacteremia
- hypotension
- pneumothorax
- migrating fragment from lead/catheter
- migration of vegetation from lead/catheter
- pulmonary embolism
- laceration or tearing of vascular structures or the myocardium
- hemopericardium
- cardiac tamponade
- hemothorax
- stroke
- death

7. HOW SUPPLIED

7.1 Sterilization

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

7.2 Device / Packaging Care

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

7.3 Inspection Prior to Use

Prior to use, visually inspect the sterile package to ensure that seals have not been broken. The sheath should be examined carefully for defects or damage. Do not use if it has apparent defects or is damaged.

8. COMPATIBILITY

Use with other devices

The VisiSheath Dilator Sheath may be used as a support sheath for compatibly sized inner sheaths, including the Spectranetics Laser Sheath (SLS™II) used for removal of cardiac leads. It may also be used in conjunction with a Spectranetics Lead Locking Device (LLD®).

Be sure to closely follow the "Instructions for Use" for each device used.

Table 1 provides physical dimensions and specifications for use in determining VisiSheath compatibility with other devices.

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Table 1: VisiSheath Dilator Sheath Size Compatibility Specifications

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

9. DIRECTIONS FOR USE

9.1 Procedure Setup

- Obtain a thorough patient history, including blood type. Appropriate blood products should be readily available.
- Determine the manufacturer, model number, physical dimensions, and implant date of the target lead/catheter. Perform radiographic evaluation of position, type and condition of target lead/catheter.
- Use a procedure room that has high quality fluoroscopy, pacing equipment, defibrillator, and thoracotomy and pericardiocentesis trays.
- Prep and drape the patient's chest for possible thoracotomy.
- Arrange for immediate surgical back-up.
- Establish back-up pacing as needed.
- Using sterile technique, open the sterile package.
- Make available, and open as needed, any other adjunct devices such as inner sheaths (laser or non-laser), lead locking devices, or related accessories.

9.2 Clinical Technique

1. Surgically expose the proximal end of the target lead/catheter(s) and remove the lead/catheter from its connections (if connected).
2. Remove all suture and tie-down materials.
3. Cut off all proximal fittings, if present, using clippers or other cutters. It is important to cut the lead/catheter very close to the connector (but past any crimp joints) leaving as long a portion of the target catheter/lead(s) to work with as possible. Avoid closing off the interior lumen (or coil) of the lead/catheter when cutting it.

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

4. Advance a lead locking device down the lead lumen as distal as possible and deploy the locking mechanism.
5. Unless the lead/catheter exterior is damaged, degraded or too thin, tie a suture at the proximal end of the lead/catheter to use as a traction element (the suture may be attached to the proximal portion of a lead locking device).
6. For an active fixation lead/catheter, attempt to unscrew the lead/catheter fixation mechanism via counterclockwise rotation by rotating the catheter/lead (and lead locking device if used) counterclockwise.
7. Gently apply traction to the lead/catheter to determine if it is still engaged in tissue. If the lead is sufficiently free of binding tissue, gently pull on the lead locking device (if used) and catheter/lead to remove it.

PRECAUTION: If a lead locking device has not been used, be aware that damage to the lead caused by pulling on it may prevent subsequent passage of a lead locking device through the lumen and/or make dilation of scar tissue more difficult.

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

8. If the lead/catheter is not removed from the vessel with gentle pulling, dilator sheaths (or other retrieval devices) may help separate the lead/catheter from any tissue encapsulation by advancing the dilator sheath over the target lead/catheter and any accompanying lead locking device.
9. A size-compatible inner sheath, including a laser sheath, may be used with a VisiSheath Dilator Sheath acting as a support sheath. The VisiSheath Dilator Sheath is loaded over the inner sheath by inserting the distal end of inner sheath through the proximal end of the dilator sheath until it appears beyond the proximal end of the

dilator sheath. The inner sheath and VisiSheath Dilator Sheath may be advanced in alternating fashion to progressively dilate tissue along the length of the lead/catheter.

10. Always maintain adequate tension and coaxial alignment on the lead/catheter to support the maneuvering of the dilator sheaths and any accompanying inner sheaths to properly guide them within the patient anatomy.

    With too little tension, the sheaths may damage the vein. Too much tension may cause a myocardial avulsion. The size of the dilator sheath should be large enough that the sheath can be advanced over the lead/catheter without causing the lead/catheter to buckle or its exterior jacket to distort, but the sheaths should not be overly loose.

    Rotating the sheaths during advancement may facilitate progress through resistant scar tissue.

    Always use fluoroscopic monitoring when manipulating the dilator sheath within the vascular system. Never use sheaths on more than one lead/catheter at a time.

PRECAUTION: If the dilator sheath fails to progress after initial success, or if advancing the sheath was difficult, remove the sheath to inspect the tip. If the tip is distorted or frayed, exchange the damaged sheath for a new sheath before continuing treatment.

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

11. For cardiac leads, if the lead has not been freed by the time the dilator sheath nears the myocardial lead fixation point, position the sheath end against the myocardium, with any inner sheath retracted several centimeters into the dilator sheath. Countertraction may be applied to dilate the remaining tissue at the lead tip. This is accomplished by holding the dilator sheath about one centimeter from the myocardium while steadily and gently applying tension to the lead. Rotation of the sheath may help dilate remaining tissue at the lead tip.
12. When all binding tissue surrounding the target lead/catheter has been successfully dilated, the lead/catheter may slide freely out of the body with applied traction.

10. MANUFACTURER'S LIMITED WARRANTY

Manufacturer warrants that the VisiSheath 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.

11. NON-STANDARD SYMBOLS

Working Length		**Non-Pyrogenic**	
Inner Diameter		**Outer Diameter**	
Sterilized Using Ethylene Oxide	STERILE EO	**Do not use if package is damaged**	
Upper Limit of Temperature	**60°C/140°F**	**Consult Instructions for Use**	
Single Use		**Keep Dry**	
Quantity	**QTY**	**Catalog Number**	REF
CAUTION: Federal law restricts this device to sale by or on the order of a physician.			**Rx ONLY**

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1. Verma A, Wilkoff BL. Intravascular pacemaker and defibrillator lead extraction: A state-of-the-art review. Heart Rhythm, Vol. 1, No. 6, December 2004; 739-745.
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4. Byrd CL, et al. Intravascular techniques for extraction of permanent pacemaker leads. J Thorac Cardiovasc Surg 1991:101:989-997.
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VisiSheath™ Dilator Sheath

Instructions for Use

English / English

【Registrant】
Name of the Registrant: Spectranetics Corporation
Residence：9965 Federal Drive, Colorado Springs, Colorado 80921, USA
Contact Information：1-800-231-0978

【Manufacturer】
Name of the Manufacturer：Spectranetics Corporation
Residence：9965 Federal Drive, Colorado Springs, Colorado 80921, USA
Production Address：9965 Federal Drive, Colorado Springs, Colorado 80921, USA
Contact Information：1-800-231-0978

【Agent】
Name of Agent： Philips (China) Investment Ltd. Co.
Residence： Building A1, #718 Lingshi Road, JingAn District, Shanghai
Contact Information：8008100038

【Validity】2 year

【After Sales Service Unit】Philips (China) Investment Ltd. Co.
Residence： Building A1, #718 Lingshi Road, JingAn District, Shanghai
Contact Information：8008100038

【Production Date】See the Label
【Expiration Date】See the Label
【Medical Device Registration Number】国械注进20173776979
【Product Technical Requirement Number】国械注进20173776979

Manual Revision Date：October 25, 2016

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VisiSheath™ 扩张鞘

使用说明

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1. 说明

VisiSheath扩张鞘是一种单腔鞘，可以单独使用，也可以作为内鞘的支撑物使用，以帮助组织扩张。该鞘的一端是带有45度切角的形状，另一端是是钝角，如图1所示。两端均有一个不透射线标志带，便于在荧光镜监视下确定顶端位置和定位。另外还有一个外部标志与45度切角的顶端对齐，便于目视确认扩张鞘的定位。该器械具有多个可选直径和长度，如表1所示。

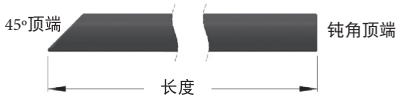

图1：VisiSheath扩张鞘顶端结构

2. 适应症

VisiSheath扩张鞘用于为有需要的病人的心脏导线、植入导管或外来物周围组织进行经皮扩张，也可以用于血管内导管的引入和支撑。

3. 禁忌症

无已知禁忌症。

4. 警告

- 扩张鞘仅应由具有导线或导管移除技术和器械操作知识的医生在具有胸外科手术资质的机构使用。
- 使用扩张鞘时，请不要将其同时插在多个导线或导管上。否则可能出现严重的血管损伤，包括静脉壁破裂，需要进行修复手术。
- 请不要将VisiSheath顶端停滞在上腔静脉（SVC）–右心房（RA）连接处，否则在随后导线移除和重新插入的过程中，可能会对该脆弱区域造成损伤（例如，操作扩张鞘或植入新的导线）。
- 尤其是当出现下列情况时，应当权衡血管内导线/导管扩张程序的相对风险和利益：
  - 需要从附着组织上剥离的对象具有危险的形状或结构；
  - 导线/导管老化的可能性会增加碎片栓塞的危险；
  - 赘生物直接附着在导线/导管体上。

5. 注意事项

限一次性使用。不能对VisiSheath扩张鞘重新灭菌和/或重复使用。

- 请勿对本器械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器械的性能，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。
- 使用之前，请不要改变扩张鞘的原状。
- 当VisiSheath扩张鞘在体内时，仅可使用能够提供优质影像的射线照相设备在荧光镜监视下对其进行操作。
- 操作之前，先评估导线、导管或内鞘相对于扩张鞘规格的物理尺寸，以判断可能的不兼容性。
- 如果需要有选择地移除一部分导线/导管，而保留一个或多个长期导线/导管原封不动时，操作完成后，必须对非目标导线/导管进行检查，以确保它们在操作过程中未受损坏或移动。
- 当推进扩张鞘时，请使用恰当的技术。要保持足够的拉力，并且要与导线/导管保持在同一轴线上，使血管壁损伤的风险降至最低。
- 如果有过多的瘢痕组织或钙化组织妨碍了扩张鞘的安全推进，请考虑更改推进路线。
- 如果对用于血管内的扩张鞘用力过大，可能导致血管系统损伤，而这种损伤需要紧急外科手术来修复。
- 如果导线/导管破碎，请对碎片进行评估以便将其取出。
- 如果出现血压过低的情况，请立即评估，根据情况作适当处理。
- 由于导线/导管技术的迅速发展，该器械可能不适用于某些导线/导管周围组织的扩张。如果对本器械与特定导线/导管的兼容性存在问题或忧虑，请联系导线/导管生产商。
- 请不要拉动导线/导管，因为这可能会导致它们拉伸、扭曲或损坏，增加随后移除工作的困难。导线的损坏可能会阻碍导线锁定系统装置通向内腔的通道，和/或使瘢痕组织的扩张更加困难。

- 如果没有使用导线锁定装置，请当心由于拉动导线而对其造成损坏，因为导线的损坏可能会阻碍导线锁定系统装置随后通向内腔的通道，和/或使瘢痕组织的扩张更加困难。
- 如果要移除一个长期起搏器导线，在移除的过程中，其注意该导线是否处于自然脱离状态，因为导线顶端可能会卡在上部的脉管系统。扩张鞘至少要进入到头臂静脉，通常需要从静脉切口处的瘢痕组织将导线顶端抽出，以避免静脉切开术。
- 取得初步的成功后，如果扩张鞘不能顺利前进，或者推进该鞘非常困难，请移除该鞘并检查其顶端。如果其顶端已经扭曲或散开，请更换新的扩张鞘之后再继续治疗。
- 如果在弯曲部位推进该鞘，请保持鞘的带有斜面的顶端朝着弯曲部位的内侧方向。

6. 不良事件

潜在的不良事件

与血管内导线/导管移除手术相关的潜在不良事件包括（按照潜在危险递增顺序概括列出）：

- 非目标导线/导管的移位或损坏
- 胸壁血肿
- 血栓形成
- 心律失常
- 菌血症
- 低血压
- 气胸
- 碎片从导线/导管中移出
- 赘生物从导线/导管中移出
- 肺栓塞
- 血管结构或心肌层的裂伤或撕裂
- 心包积血
- 心包填塞
- 血胸
- 中风
- 死亡

7. 供货方式

7.1 灭菌

限一次性使用。请勿重新灭菌和/或重复使用。VisiSheath扩张鞘出厂时为无菌无热原器械。只有在包装未打开且未损坏的情况下，才能保证本器械的无菌性。

7.2 器械/包装注意事项

使用之前，请将器械保存在干燥凉爽之处（60摄氏度/140华氏度以下）。

7.3 使用前的检查

使用之前，目视检查无菌包装，确保其密封性未被破坏。请仔细检查扩张鞘是否有缺陷或损坏，如果已经有明显的缺陷或已经被损坏，请不要使用。

8. 兼容性

与其他器械配套使用

VisiSheath扩张鞘可以配合相应尺寸的内鞘作为支撑鞘使用，包括用于移除心脏导线的Spectranetics Laser Sheath（SLS™II），也可以与Spectranetics 导线锁定装置（LLD®）结合使用。

严格按照使用说明书使用各设备。

表1提供了相关物理尺寸和规格，用于确定VisiSheath与其他设备的兼容性。

表1：VisiSheath扩张鞘尺寸兼容规格

型号（参考）	长度 (cm)	扩张鞘尺寸（直径）	最小内径 (mm/in/F)	最大外径 (mm/in/F)	SLS™II兼容性
501-012	43	S	4.2 / 0.168 / 12.8	5.5 / 0.215 / 16.4	12 F
501-112	33				
501-212	23				
501-014	43	M	5.0 / 0.198 / 15.0	6.5 / 0.253 / 19.3	14 F
501-114	33				
501-214	23				
501-016	43	L	5.9 / 0.236 / 17.9	7.5 / 0.293 / 22.4	16 F
501-116	33				
501-216	23				

9. 使用说明

9.1 手术安排

- 取得包括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。
- 确定目标导线/导管的生产商、型号、物理尺寸和植入日期，用放射摄像技术对目标导线/导管的位置、类型和状况进行评估。

- 使用的手术室需要具备高质量荧光镜、起博设备、除颤器、开胸手术和心包穿刺术托盘。
- 准备遮布并盖住病人的胸部，为可能的开胸手术做准备。
- 安排紧急手术后备工作。
- 按需要，配备备用起博器。
- 运用灭菌技术，打开无菌包装。
- 根据需要，准备和打开所有其他附属设备，如内鞘（激光的或非激光的）、导线锁定装置或相关配件。

9.2 临床技术

1. 用外科手术的方法露出目标导线/导管的近端，然后从其连接部位将它们移除（如果已连接）。
2. 移除所有的缝合线和固定材料。
3. 如果在近端有接头，用剪刀或其他刀具将其切除。尽可能在靠近接口处切断导线/导管（但要越过任何褶皱接头），这样可以尽量留下较长的目标导管/导线部分来操作，这一点非常重要。切割时，要避免封闭导线/导管的内腔（或圈）。

注意事项：请不要拉动导线/导管，因为这可能会导致它们拉伸、扭曲或损坏，增加随后移除工作的困难。导线的损坏可能会阻碍导线锁定系统装置通向内腔的通道，和/或使瘢痕组织的扩张更加困难。

4. 尽可能从远端沿着导线腔推进导线锁定装置，并将其锁定机制打开。
5. 除导线/导管的外部已经损坏、老化或太薄的情况外，请在导线/导管的近端系一根缝合线，用作牵引装置（缝合线可以系在导线锁定装置的近端）。
6. 尝试逆时针旋转导管/导线（和导线锁定装置，如使用），拧松导线/导管的固定机制，可以主动固定导线/导管。
7. 轻轻拉动导线/导管，确认其是否仍然与组织接合。如果导线已经从束缚组织中彻底脱离，轻轻拉动导线锁定装置（如果使用）和导管/导线，将其移除。

注意事项：如果没有使用导线锁定装置，请当心由于拉动导线而对其造成损坏，因为导线的损坏可能会阻碍导线锁定系统装置随后通向内腔的通道，和/或使瘢痕组织的扩张更加困难。

注意事项：如果要移除一个长期起搏器导线，在移除的过程中，其注意该导线是否处于自然脱离状态，因为导线顶端可能会卡在上部的脉管系统。扩张鞘至少要进入到头臂静脉，通常需要从静脉切口处的瘢痕组织将导线顶端抽出，以避免静脉切开术。

8. 如果轻轻拉动无法将导线/导管从血管中移除，可使用扩张鞘（或其他取回器械），沿着目标导线/导管以及附属导线锁定装置推进扩张鞘，将导线/导管从包覆组织中取出。
9. VisiSheath扩张鞘可以作为支撑鞘与包括激光鞘在内的大小兼容的内鞘配套使用。将内鞘的远端插入扩张鞘的近端，并且穿过扩张鞘的近端，从而将VisiSheath扩张鞘安装在内鞘上。可以交替推进内鞘和VisiSheath扩张鞘，沿着导线/导管的纵长逐步扩张组织。
10. 在导线/导管上保持适当的拉力，并且要与导线/导管在同一轴线上，用于支撑扩张鞘和其他附属内鞘的操作，并根据病人的解剖学特点引导其操作。

    如果拉力过小，这些鞘可能损伤血管；如果拉力过大，可能会造成心肌撕裂。扩张鞘的尺寸应当足够大，使其在导线/导管上推进时不会引起导线/导管的弯曲，也不会使其外护套扭曲，但是鞘也不应该过松。

    在推进的过程中旋转鞘，可以帮助穿越具有阻力的瘢痕组织。

    在血管系统内操作扩张鞘时，请始终使用荧光镜进行监视。切勿将鞘同时用于多个导线/导管。

注意事项：取得初步的成功后，如果扩张鞘不能顺利前进，或者推进该鞘非常困难，请移除该鞘并检查其顶端。如果其顶端已经扭曲或散开，请更换新的扩张鞘之后再继续治疗。

注意事项：如果在弯曲部位推进该鞘，请保持鞘的带有斜面的顶端朝着弯曲部位的内侧方向。

11. 对于心脏导线，如果在扩张鞘靠近心肌导线的固定点时导线还没有脱离，请将鞘末端定位在心肌对面，然后将内鞘向扩张鞘中回缩几厘米。可施加对抗牵引力，扩张导线顶端剩余的组织。对导线稳定且缓慢地施加拉力，同时将扩张鞘从心肌中抽出约1厘米，通过这种方式完成上述操作。旋转鞘有助于扩张位于导线顶端的剩余组织。
12. 当目标导线/导管周围的所有束缚组织都已经成功扩张开时，通过施加牵引力，可以将导线/导管滑出体内。

10. 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且未损坏，VisiSheath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VisiSheath或按购买价格退款。

Spectranetics®

VisiSheath™ 扩张鞘

使用说明

Chinese/中文

11. 非标准符号

Working Length 工作长度		**Non-Pyrogenic** 无热原	
Inner Diameter 内径		**Outer Diameter** 外径	
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	
Quantity 数量	QTY	**Catalog Number** 产品型号	REF
CAUTION: Federal law restricts this device to sale by or on the order of a physician. 警告：联邦法律规定，本器械只能由医生直接销售或遵医嘱销售。			Rx ONLY

参考资料

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Spectranetics®
VisiSheath™
Dilator Sheath

Instructions for Use

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【失效日期】见标签
【医疗器械注册证编号】国械注进20173776979
【产品技术要求编号】国械注进20173776979

说明书修订日期：2016 年10 月25 日