TightRail™

Rotating Dilator 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.

1. DEVICE DESCRIPTION

The TightRail Rotating Dilator Sheath (TightRail sheath) is an intra-operative device designed to facilitate the percutaneous removal of cardiac leads from the vasculature. TightRail is used in conjunction with conventional lead extraction tools (e.g., locking stylets, outer sheaths). The components of the Spectranetics TightRail device include an inner and outer shaft and a handheld drive mechanism (Figure 1.).

Figure 1. TightRail Device

The inner shaft (drive shaft) is able to rotate within the outer shaft to activate the rotary dilating feature at the tip.

The stationary outer shaft is contained within a polymer jacket. The handheld drive mechanism attached to the proximal end of the device is used to rotate the inner shaft. Rotation of the distal cam of the inner shaft causes dilation of the tissue and fibrous attachments surrounding the lead, facilitating the removal of said lead.

An outer sheath is also provided that can be used in conjunction with the device to support the device shaft facilitating additional tissue dilation effect and serve as a conduit for re-implant.

The package includes either one 9F, one 11F, or one 13F TightRail sheath, along with one compatible outer sheath.

Use with other devices

The TightRail Sheath may be used in conjunction with the Spectranetics Lead Locking Device (LLD™). Follow the "Instructions for Use" for other devices used. Table 1 provides TightRail Sheath models and sizing specifications.

Table 1. Model Specifications

Model Number	Tip Inner Diameter			Device Outer Diameter			Outer Sheath Inner Diameter		
	(F)	(in.)	(mm)	(F)	(in.)	(mm)	(F)	(in.)	(mm)
545-509	9.2	0.119	3.0	15.9	0.207	5.3	16.6	0.216	5.5
545-511	11.2	0.145	3.7	18.0	0.234	5.9	18.7	0.243	6.2
545-513	13.2	0.171	4.3	20.0	0.260	6.6	20.7	0.269	6.8

2. INDICATIONS FOR USE

The TightRail Rotating Dilator Sheath is intended for use in patients requiring the percutaneous dilation of tissue to facilitate removal of cardiac leads.

3. CONTRAINDICATIONS

None known

4. WARNINGS

- Lead removal devices should be used at institutions with cardiothoracic surgical capabilities by physicians knowledgeable in the techniques and devices for lead removal. Complication prevention and management protocols should be 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 highly recommended for best results.
- When using a locking stylet:
  - Do not abandon a lead in a patient with a locking stylet still in place inside the lead. Severe vessel or endocardial wall damage may result from the stiffened lead or from fracture or migration of the abandoned stylet wire.
  - Do not apply weighted traction to an inserted locking stylet as myocardial avulsion, hypotension, or venous wall tearing may result.
  - Be aware that leads with a J-shape retention wire occupying their inner lumen (rather than being outside of the coil) may not be compatible with the locking stylet. Insertion of the locking stylet into such a lead may result in protrusion and possible migration of the J-shape retention wire.
- Do not insert more than one TightRail sheath or outer sheath into a vein at a time. Do not insert more than one lead into a TightRail device at a time. Severe vessel damage, including venous wall laceration requiring surgical repair may occur.

- Maintain appropriate traction on the lead being extracted during advancement of the TightRail sheath or outer sheath.
- Excessive advancement force may result in device or vessel wall damage.
- Do not leave the outer sheath tip at the SVC-atrial junction as it may damage this delicate area during subsequent procedures. (e.g., manipulating the outer sheath, implanting a new lead).
- Do not activate device when at the myocardial wall.

5. PRECAUTIONS

- Thoroughly review the package insert for conventional lead extraction tools before attempting to use the TightRail sheath.
- Do not re-sterilize 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 TightRail sheath if the tamper-evident seal is broken.
- Do not use the TightRail sheath if any component has been damaged.
- Prior to the procedure, evaluate the physical dimensions of the lead in relation to the specifications of the dilator sheath to determine compatibility.
- Due to rapidly evolving lead technology, this device may not be suitable for dilation of tissue around all types of leads. If there are questions or concerns regarding compatibility of this device with particular leads, contact the lead manufacturer.
- Do not pull on the lead 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.
- When the TightRail sheath is in the body, it should be manipulated only under fluoroscopic observation with radiographic equipment that provides high quality images.
- As in all extraction procedures, use proper sheath technique. Maintain sturdy traction and a stable "rail" position with the lead while keeping coaxial alignment of the TightRail sheath to minimize the risk of vessel wall or cardiac structure damage.
- When advancing an outer sheath around a bend, keep the point of the sheath's beveled tip oriented toward the inside of the bend.
- Advancing the TightRail sheath through heavily calcified tissue may require more activations of the dilating mechanism than through fibrous scar overgrowth.
- If unable to advance the TightRail sheath despite repeated activations of the dilating mechanism, consider an alternate approach. Be prepared to upsize to a larger TightRail sheath, move to another lead, try a femoral approach or consider an open procedure.
- Excessive advancement force may cause temporary binding of the device mechanism.
- If the lead breaks, evaluate fragment for retrieval.
- If hypotension develops, rapidly evaluate; treat as appropriate.
- When 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.
- Upon removal of a lead, the outer sheath tip should be either.
  a) fully into the atrium, or
  b) retracted into the brachiocephalic or innominate 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.
- If selectively removing leads with the intent to leave one or more chronic leads implanted intact, the non-targeted leads must be subsequently tested to ensure that they were not damaged or dislodged during the procedure.
- If the TightRail sheath is removed from the body for any reason, thoroughly flush the device shaft, inner lumen and tip with saline to remove particles and prevent blood from sticking before reinserting the TightRail sheath back into the patient.
- If the TightRail 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.

6. POTENTIAL ADVERSE EVENTS

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

- Dislodging or damaging non-targeted lead
- Chest wall hematoma
- Thrombosis
- Arrhythmias
- Bacteremia
- Hypotension
- Pneumothorax
- Migrating fragment from lead
- Migration of vegetation from lead
- Pulmonary embolism
- Laceration or tearing of vascular structures or the myocardium
- Hemopericardium
- Cardiac tamponade
- Hemothorax
- Stroke
- Death

7. INDIVIDUALIZATION OF TREATMENT

Weigh the relative risks and benefits of intravascular lead removal procedures in cases when:

- Dual coil ICD leads are being removed with proximal coil located in SVC
- 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

8. HOW SUPPLIED

8.1 Sterilization

- For single use only. Not for re-sterilization or reprocessing.
- Ethylene Oxide Sterilized
- Non-pyrogenic
- Sterility guaranteed if package is unopened and undamaged.
- Store device in a dry cool place (below 60° C / 140° F) until use.

8.2 Inpsection 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 TightRail sheath, should be examined carefully for defects. Examine the TightRail sheath for kinks or other damage. Do not use the product if it is damaged or if the Use-by Date has been exceeded.

9. COMPATIBILITY

Information for determining TightRail sheath dimensional compatibility is shown in Table 1.

10. DIRECTIONS FOR USE

10.1 Procedure Set Up

TightRail Sheath Preparations:

Using sterile technique, open the sterile package. Remove the lid from the tray and gently lift the device from the tray while supporting the handle and shaft.

Patient Preparations:

1. Obtain a thorough patient history, including patient blood type. Appropriate blood products should be readily available.
2. Determine the manufacturer, model number and implant date of the lead to be removed. Perform radiographic/echocardiographic evaluation of 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. Arrange for immediate surgical back-up.
6. Establish back-up pacing as needed.
7. Have available additional TightRail sheaths, other sheaths, locking stylets, stylets to unscrew active fixation leads, snares (femoral workstation) and any other accessory equipment deemed necessary.

10.2 Clinical Technique

1. Patients are prepared for multiple lead extraction approaches, including an emergency cardiac surgical intervention. 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. 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 Lead Locking Device into the lead as distal as possible and deploy the locking mechanism. Secure appropriate lengths of suture material to the proximal end of the lead insulation and high voltage cables to provide additional traction.
8. Hydrate the inner lumen of the TightRail sheath and wet the outer jacket.
9. If using an outer sheath, flush the inner lumen and place over the TightRail sheath.
10. Support the handle and shaft of the TightRail device while loading the device onto the locking stylet and target lead.
11. Extraction technique:
    a. Apply sturdy traction on the lead and/or its locking stylet to maintain a stable "rail" position with the lead while keeping coaxial alignment of the TightRail sheath. This is critical to safe passage of the TightRail sheath over the lead. If traction is inadequate, the lead may buckle, precluding the TightRail sheath from advancing along the appropriate path.
    b. With the lead in tension, advance the TightRail 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 TightRail sheath over the lead.
    c. Use the following guidelines to determine if a tissue obstruction is met:
        - The TightRail sheath will not advance into the vein.
        - The TightRail sheath bows when longitudinal pressure is applied.
        - Fluoroscopy shows that the sheath tip does not advance relative to the lead body.
        - Fluoroscopy shows that the TightRail sheath tip is not caught on a lead electrode, a lead bend, or another lead.
    d. When an obstruction is met and the TightRail sheath cannot be advanced:
        - Use AP and oblique fluoroscopic views to ensure that the tip of the TightRail sheath is aligned and coaxial with the longitudinal axis of the lead.
        - If the optional outer sheath is being used, retract the outer sheath so that its distal end does not overlap the tip of the TightRail sheath. Press the TightRail sheath gently into the obstructing tissue.
        - Use gentle pressure on the TightRail sheath to advance the device while squeezing the trigger to activate the inner shaft's dilating mechanism. Apply traction to the locking stylet while advancing and dilating tissue.
        - With each full squeeze of the trigger, the dilating mechanism will extend, rotate, and retract. The dilating mechanism retracts into the sheath tip when the trigger is fully released.
        - If the trigger is partially squeezed the rotational direction of the dilation mechanism may not change directions.
        - Return the trigger to a fully forward position between each subsequent squeeze.
        - When the TightRail sheath breaks through the obstruction you may stop activating the dilating mechanism while advancing to the next point of binding tissue.
        - Monitor all device maneuvers and activations by fluoroscopy.
        - If needed, advance the outer sheath to the new position of the TightRail sheath.

e. If the traction device unlocks its grip on the lead, it is necessary to remove the TightRail sheath and outer sheath, and apply a new traction device, before proceeding again with the TightRail sheath.
f. After the resistance has been relieved, advance the TightRail sheath and optional outer sheath to the next desired location or point of resistance on the lead and repeat the process as described in 11 (a-d) above.
g. If necessary, use countertraction to free the lead tip from the heart wall while applying traction to the locking stylet until the lead tip is free.
   - Countertraction may be applied by positioning the TightRail sheath, without actuation of the trigger, at or near the myocardial wall.
   - As an alternative, the blunt end of the outer sheath may also be used to apply counter traction at or near the myocardial wall.

12. Withdrawal of the TightRail sheath and optional outer sheath can be accomplished at any time during the procedure. If the lead is free, it should be drawn into the TightRail sheath before the lead, the TightRail sheath, and the outer sheath are removed from the body.
13. To retain venous access for re-implant, remove the lead through the TightRail sheath, keeping the TightRail sheath in place for guidewire insertion. Remove the TightRail device from the body after guidewire is inserted. If the optional outer sheath is being used, an alternative is to keep the outer sheath in place for guidewire insertion when removing lead and TightRail sheath. Remove the outer sheath from the body after guidewire is inserted.
14. At the completion of the extraction, withdraw the TightRail sheath and outer sheath from the patient and inspect the TightRail sheath for damage prior to any additional use.
15. Dispose of the used products according to local biological handling and disposal procedures.

References

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3. 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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5. Byrd CL, et al. Lead extraction: indications and techniques. Cardiol Clin 1992: 10:735-748.
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11. MANUFACTURER'S LIMITED WARRANTY

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

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