TightRail™ & TightRail Mini™
ROTATING DILATOR SHEATHS
The Next Generation in Mechanical Lead Extraction Sheaths
FLEXIBILITY MEETS CONTROL IN MECHANICAL LEAD EXTRACTION

When removing a lead is the right decision, turn to TightRail. Its next-generation design advances provide the flexibility, control and safety required for effectively extracting cardiac leads.

Flexible shaft
TightRail was designed with a more flexible shaft, so you can remain coaxial to the lead. The unique shaft technology combines flexibility with column strength, enabling forward progression through vasculature and commonly encountered fibrotic lesions.

Shielded dilating blade
The dilating blade remains shielded until activated, allowing safe counter-traction at the targeted lead’s distal tip.

Bidirectional mechanism
The bidirectional mechanism is designed to effectively dilate commonly encountered fibrotic lesions by rotating 574°—287 degrees clockwise and 287 degrees counterclockwise—while extending the blade just 0.02 inches, or 0.5mm.
Static outer shaft
Because the outer shaft does not rotate with the blade, an outer sheath is optional, based on your preference and the clinical scenario.

TightRail Mini™ Rotating Dilator Sheath
This companion product featuring a shorter shaft is designed to gain vascular access.

Backed by Spectranetics
With its flexibility, shielded blade and static shaft, TightRail provides the critical control and precision you’re looking for in lead extraction procedures. And it’s backed by Spectranetics’ unparalleled service, support and access to specialized training.

For more information about TightRail, contact your Spectranetics representative or visit www.spnc.com/TightRail.
** Important Safety Information

**INDICATIONS**
The TightRail and TightRail Mini are intended for use in patients requiring the percutaneous dilation of tissue to facilitate the removal of cardiac leads, indwelling catheters, and foreign objects.

**CONTRAINDICATIONS**
None known.

**WARNINGS**
- Lead removal devices should be used at institutions with cardiothoracic surgical capabilities by physicians knowledgeable in the techniques and devices for lead or catheter removal. Complication prevention and management protocols should be in place and routinely practiced. The recommendations for lead management of the Heart Rhythm Society (HRS) and European Heart Rhythm Association (EHRA) are highly recommended for best results.
- When using a locking stylet:
  - Do not abandon a catheter/lead in a patient with a locking stylet still in place inside the catheter/lead. Severe vessel or endocardial wall damage may result from the stiffened catheter/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. Severe vessel damage, including venous wall laceration requiring surgical repair may occur.
  - Maintain appropriate traction on the lead/catheter being extracted during advancement of the TightRail sheath or outer sheath.
- **For TightRail Mini only:** The TightRail Mini Sheath should only be used to minimally enter the vessel. Do not attempt to enter the vessel or attempt to navigate the TightRail Mini sheath into bends beyond the convergence of the innominate and brachiocephalic veins as vessel wall or cardiac lead damage may occur.
- Excessive advancement force may result in device or vessel wall damage.
- **For TightRail only:** Do not leave 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).
- **For TightRail only:** Do not activate device when in contact with cardiac wall.

Refer to the IFU for additional information.

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