Spectranetics®
Always Reaching Farther

TightRail™ SUB-C
ROTATING DILATOR SHEATH

A Breakthrough in Lead Extraction

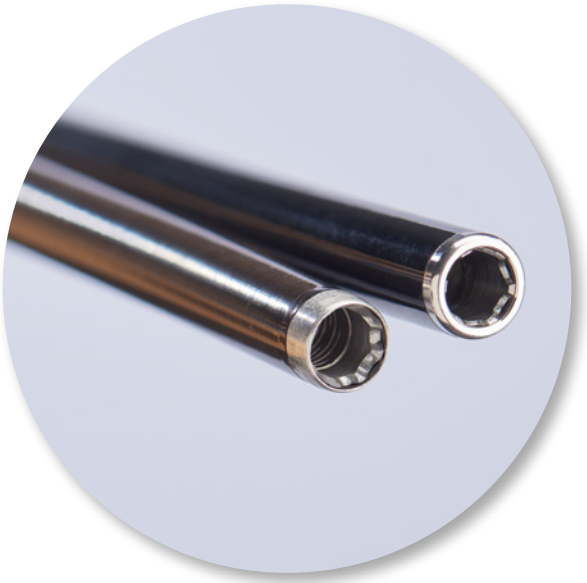
TightRail™ Sub-C Rotating Dilator Sheath completes Spectranetics' portfolio of mechanical devices for lead extraction. Sub-C is specifically designed for the challenges of the subclavian region, including vessel entry when fibrosis and calcium are present.

Tightrail Sub-C helps solve the complex issues surrounding vascular access with an improved cutting tip, lower profile for safe passage under tight clavicular spots and a shielded cutting mechanism that allows you to get through occlusions with lower risk of damaging the targeted lead or adjacent leads.

Features include:

- Re-designed blade and low profile tip for efficient dilation in the subclavian region
- A short, stiff shaft at base for pushability
- A flexible tip for trackability and ease of navigation under the clavicle
- A shielded rotational blade to minimize risk to vessels and adjacent leads

TightRail Sub-C can be used alone or in conjunction with laser or other TightRail Sheaths to safely and efficiently move through fibrosis and calcium for predictable vessel entry.



The right device at the right time. TightRail Sub-C (above left) features a lower profile cutting tip specifically designed for the subclavian region compared to the standard TightRail (above right) with it's shielded-bi-directional blade.

TightRail™ Sub-C

Rotating Dilator Sheath

Model Number	Size	Device Inner Diameter F / in. / mm	Device Outer Diameter F / in. / mm	Outer Sheath Outer Diameter F / in. / mm	Working Length in. / cm
560-009	9F	9.1 / 0.119 / 3.0	14.4 / 0.187 / 4.8	18.9 / 0.245 / 6.3	6.1 / 15.5
560-011	11F	11.1 / 0.145 / 3.6	16.4 / 0.213 / 5.5	20.9 / 0.271 / 6.9	6.1 / 15.5
560-013	13F	13.1 / 0.171 / 4.3	18.4 / 0.239 / 6.1	22.9 / 0.297 / 7.6	6.1 / 15.5

Important Safety Information

INDICATIONS FOR USE
The TightRail Sub-C Rotating Dilator Sheath is intended for use in patients requiring the percutaneous dilation of tissue to facilitate 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 Society1 (HRS) and European Heart Rhythm Association2 (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 Sub-C sheath or outer sheath into a vein at a time. Do not insert more than one lead or catheter into a TightRail Sub-C device 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 Sub-C sheath or outer sheath.

The TightRail Sub-C sheath should only be used to minimally enter the vessel. Do not attempt to enter the SVC structure or attempt to navigate the TightRail Sub-C 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.

Refer to the IFU for additional information.

References

1 D022077 Data on file.

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