PHILIPS

Rotating Dilator Sheaths

TightRail
TightRail Sub-C

Flexibility meets control in mechanical lead extraction

Safe, effective, unparalleled control when it counts

Philips provides a complete solution for mechanical lead extraction. Philips Rotating Dilator Sheaths – TightRail and TightRail Sub-C – are next-generation designs providing the appropriate flexibility, control and safety required for effectively extracting cardiac leads.

For more information about TightRail, contact your Philips representative or visit www.philips.com/IGTdevices

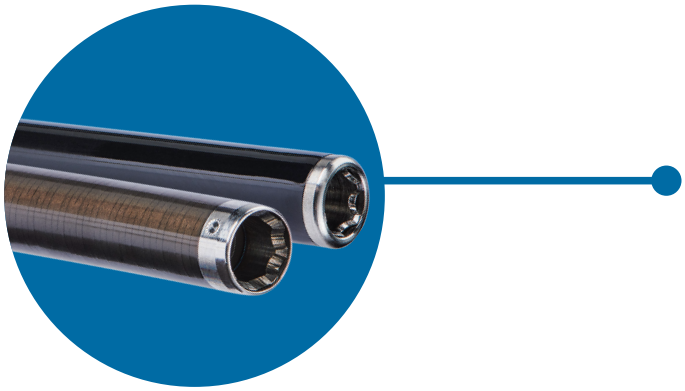
The portfolio of TightRail Rotating Dilator Sheaths puts you in control.
Their next generation design provides important new features: By extending the blade only when the handle is pulled, you can choose when to activate the cutting mechanism. The portfolio of TightRail sheaths offers a static shaft with an optional outer sheath depending on your preference. The TightRail Sub-C enables enhanced pushability for use in the sub-clavicular region, while the TightRail has a flexible shaft, helping to maintain forward progression through tortuous vasculature.

Bidirectional mechanism

The bi-directional mechanism is designed to effectively dilate commonly encountered, fibrosed and calcified lesions. With each full activation of the trigger the mechanism extends just 0.02 inches (0.5 mm) and rotates through 287°, with each subsequent activation it then rotates through 287° in the counter direction giving a total cutting range of 574°.

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.



Left: Re-designed blade and low profile tip of the TightRail Sub-C is intended for efficient dilation in the subclavian region

Right: TightRail features a shielded bi-directional blade

Shielded dilating blade

The dilating blade remains shielded until activated, putting you in control and allowing you to safely provide counter-traction at the targeted lead's distal tip.

Backed by Philips

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 Philips service, support and access to specialized training.

Philips Rotating Dilator Sheaths
TightRail and TightRail Sub-C – Ordering information

TightRail

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
545-509	9F	9.2 / 0.119 / 3.0	15.9 / 0.207 / 5.3	20.0 / 0.266 / 6.8	18.7 / 47.5
545-511	11F	11.2 / 0.145 / 3.7	18.0 / 0.234 / 5.9	23.0 / 0.293 / 7.4	18.7 / 47.5
545-513	13F	13.2 / 0.171 / 4.3	20.0 / 0.260 / 6.6	25.0 / 0.319 / 8.1	18.7 / 47.5

TightRail Sub-C

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
The TightRail and TightRail Sub-C Rotating Dilator Sheaths are intended for use in patients requiring the percutaneous dilation of tissue to facilitate the removal of cardiac leads.

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 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 or TightRail Sub-C sheath or outer sheath into a vein at a time. Do not insert more than one lead into a TightRail or 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 being extracted during advancement of the TightRail or TightRail Sub-C sheath or outer sheath.

Excessive advancement force may result in device or vessel wall damage.

For TightRail Sub-C only:
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.

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 manipulating the outer sheath, implanting a new lead).

Do not activate device when at the myocardial wall.

Refer to the IFU for additional information.

Products subject to country availability. Please contact your local sales representative.

1. Kusumoto et al. 2017 HRS Expert Consensus Statement on Cardiovascular Implantable Electronic Device Lead Management and Extraction
2. EHRA CONSENSUS DOCUMENT Europace (2018) 20, 1217 doi:10.1093/europace/euy050

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