PHILIPS

Rotating Dilator Sheath

TightRail Sub-C

9 pirkimo dalis: Sistema implantuotam elektrodui atpalaiduoti nuo sąaugų

https://www.philips.lt/healthcare/product/HCIGTDTRSCRDS/tightrail-sub-c-mechanical-rotating-dilator-sheath

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When removing a lead from the sub-clavian region, the presence of calcium and fibrosis can present significant challenges. The next generation design of Philips Rotating Dilator Sheath – TightRail Sub-C – provides the pushability, control and safety required for effectively extracting cardiac leads.

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

## A breakthrough in lead extraction

TightRail Sub-C Rotating Dilator Sheath enhances Philips' portfolio of mechanical devices for lead extraction. TightRail 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.

## 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°.

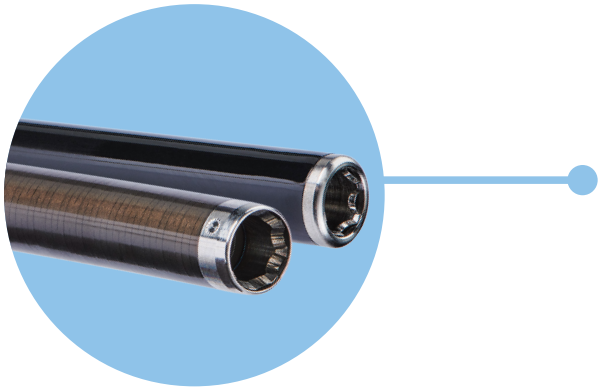
Dvipusis mechanizmas sukurtas efektyviai išplėsti dažniausiai pasitaikančias fibrozines ir kalcifikuotas pažeistas vietas. Kiekvieno pilno mygtuko paspaudimo metu mechanizmas išsipleči a tik 0,02 colio (0,5 mm) ir pasisuka 287°. Kito aktyvavimo metu jis pasisuka 287° priešinga kryptimi, suteikda mas bendrą 574° pjovimo diapazoną.


## Backed by Philips

With its pushability, shielded blade and static shaft, TightRail Sub-C provides the critical control and precision you're looking for in challenging lead extraction procedures. extraction procedures. TightRail Sub-C is backed by Philips service, support and access to specialized training.

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

## TightRail Sub-C features include

- A short, stiff shaft at the base for pushability
- A flexible tip for trackability and ease of navigation under the clavicle
- The dilating blade remains shielded until activated, minimizing risk to vessels and adjacent leads by putting you in control of the blade activation.

TightRail Sub-C can be used alone or in conjunction with Philips Laser Sheath – GlideLight – or other TightRail sheaths to safely and efficiently remove cardiac leads.

# Philips Rotating Dilator Sheath – TightRail Sub-C – ordering information

Pjaunančio vamzdelio vidinis diametras 9 arba 11 F (+- 0,2 F)

| 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 |

Vidinis diametras

Darbinis ilgis 15,5 cm

Darbinis pjaunančio vamzdelio ilgis 13-16 cm.

# Important safety information

**Indications**
The TightRail Sub-C Rotating Dilator Sheath is 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 Sub-C sheath or outer sheath into a vein at a time. Do not insert more than one lead 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 being extracted during advancement of the TightRail Sub-C sheath or outer sheath.

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

The TightRail Sub-C Rotating 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.

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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