PHILIPS

TightRail

Rotating dilator sheath

Flexibility meets control

in mechanical lead extraction

Safe, effective, unparalleled control **when it counts**

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

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

Flexible shaft

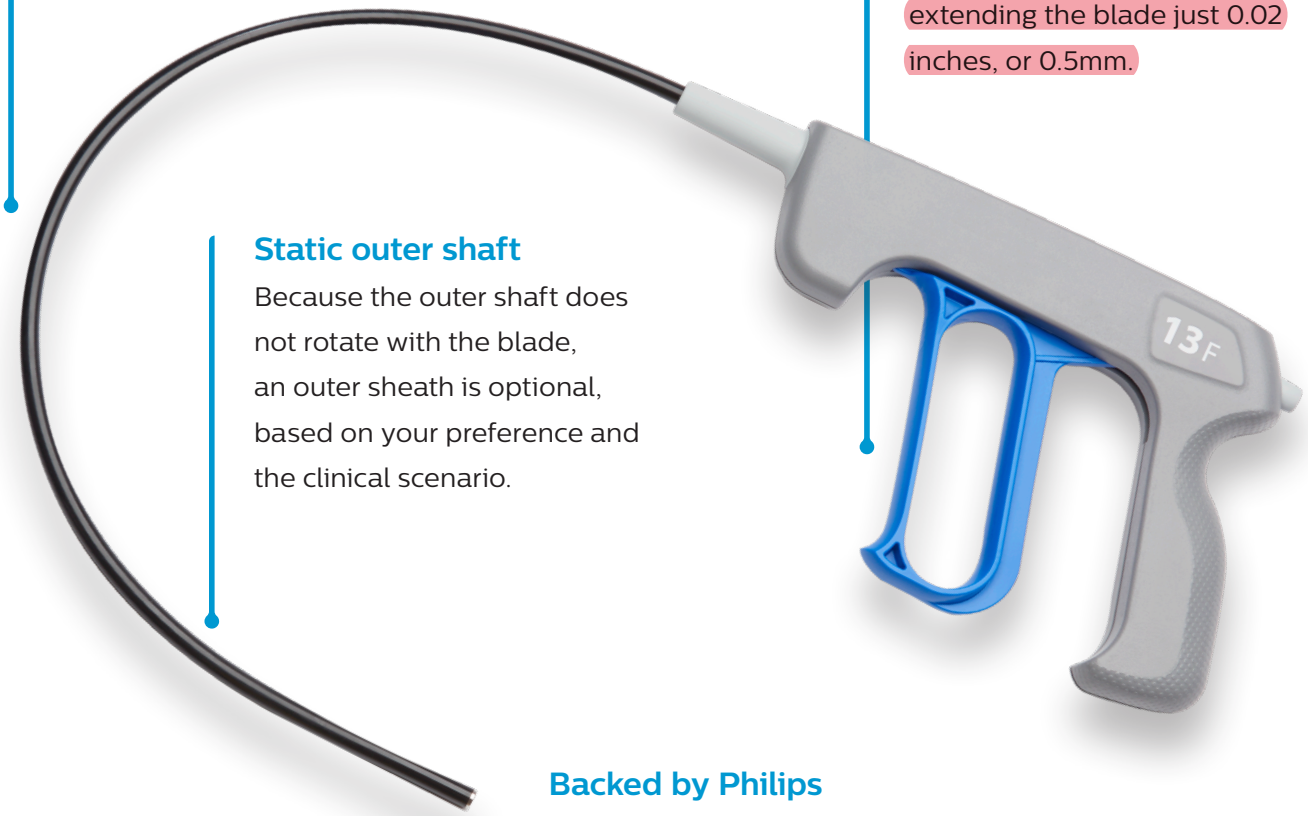
TightRail was designed with a more flexible shaft than other mechanical sheaths, so you can remain coaxial to the lead. The unique shaft technology enables you to maintain forward progression through tortuous vasculature and commonly encountered fibrotic and calcified lesions.

Bidirectional mechanism

The bidirectional mechanism is designed to effectively dilate commonly encountered fibrosed and calcified lesions by rotating 574° with each full trigger activation— 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.



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.

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.

Ordering information

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

Important safety information

Indications

The TightRail rotating dilator sheath is 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 only 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[1] (HRS) and European Heart Rhythm Association[2] (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. Do not insert more than one lead or catheter 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/catheter 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., moving the outer sheath, implanting a new lead).

Do not activate device when in contact with cardiac wall.

Refer to the IFU for additional information.

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