TightRail™
ROTATING MECHANICAL DILATOR SHEATH
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 enables you to maintain forward progression through tortuous vasculature and commonly encountered fibrotic and calcified lesions.

**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.

**Bidirectional mechanism**
The bidirectional mechanism is designed to effectively dilate commonly encountered fibrosed and calcified lesions by rotating 540° with each full trigger activation—270 degrees clockwise and 270 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 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.
**TightRail™**

**Mechanical Extraction Device**

<table>
<thead>
<tr>
<th>Model Number</th>
<th>Size</th>
<th>Device Inner Diameter F / in. / mm</th>
<th>Device Outer Diameter F / in. / mm</th>
<th>Outer Sheath Outer Diameter F / in. / mm</th>
<th>Working Length in. / cm</th>
</tr>
</thead>
<tbody>
<tr>
<td>545-509</td>
<td>9F</td>
<td>9.2 / 0.119 / 3.0</td>
<td>15.9 / 0.207 / 5.3</td>
<td>20.0 / 0.266 / 6.8</td>
<td>18.7 / 47.5</td>
</tr>
<tr>
<td>545-511</td>
<td>11F</td>
<td>11.2 / 0.145 / 3.7</td>
<td>18.0 / 0.234 / 5.9</td>
<td>23.0 / 0.293 / 7.4</td>
<td>18.7 / 47.5</td>
</tr>
<tr>
<td>545-513</td>
<td>13F</td>
<td>13.2 / 0.171 / 4.3</td>
<td>20.0 / 0.260 / 6.6</td>
<td>25.0 / 0.319 / 8.1</td>
<td>18.7 / 47.5</td>
</tr>
</tbody>
</table>

C-code: 1773

**Important Safety Information**

**INDICATIONS**
The TightRail Mechanical 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 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 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.

---

**Corporate Headquarters**
The Spectranetics Corporation
9965 Federal Dr., Colorado Springs, CO 80921
Tel: 719-447-2000 • Fax: 719-447-2022 • Customer Service: 800-231-0978

**German Office**
Spectranetics Deutschland GmbH
Schweinfurter Str. 7
97080 Würzburg, Germany
Phone: +49 931/4520080 • Fax: +49 931/45200811

**Spectranetics International B.V.**
Plesmanstraat 6, 3833 LA Leusden
The Netherlands
Tel: +31 33 4347 050 • Fax: +31 33 4347 051

©2014 Spectranetics. All rights reserved. Approved for external distribution. D022638-00 042014