PHILIPS

Motorized Dilator Sheath

TightRail Guardian

A shielded, motorized, dual-mode dilator sheath for lead extraction

Control in hand. Safety at heart.

Safe, effective, unparalleled control when it counts

Philips Motorized Dilator Sheath – TightRail Guardian – is a breakthrough in lead extraction that puts the power of innovation in your hands. A shielded, motorized, dual-mode dilator sheath, TightRail Guardian gives you greater confidence when responding to ever-changing clinical needs. With shielded mode as the primary operating mode, and extended mode for stalled progression, TightRail Guardian delivers the safety, versatility and ease-of-use you need to deliver the positive outcomes your patients deserve.

For more information about TightRail Guardian, contact your Philips representative or visit Philips.com/TightRail-Guardian

Dual-mode selection

Shielded mode

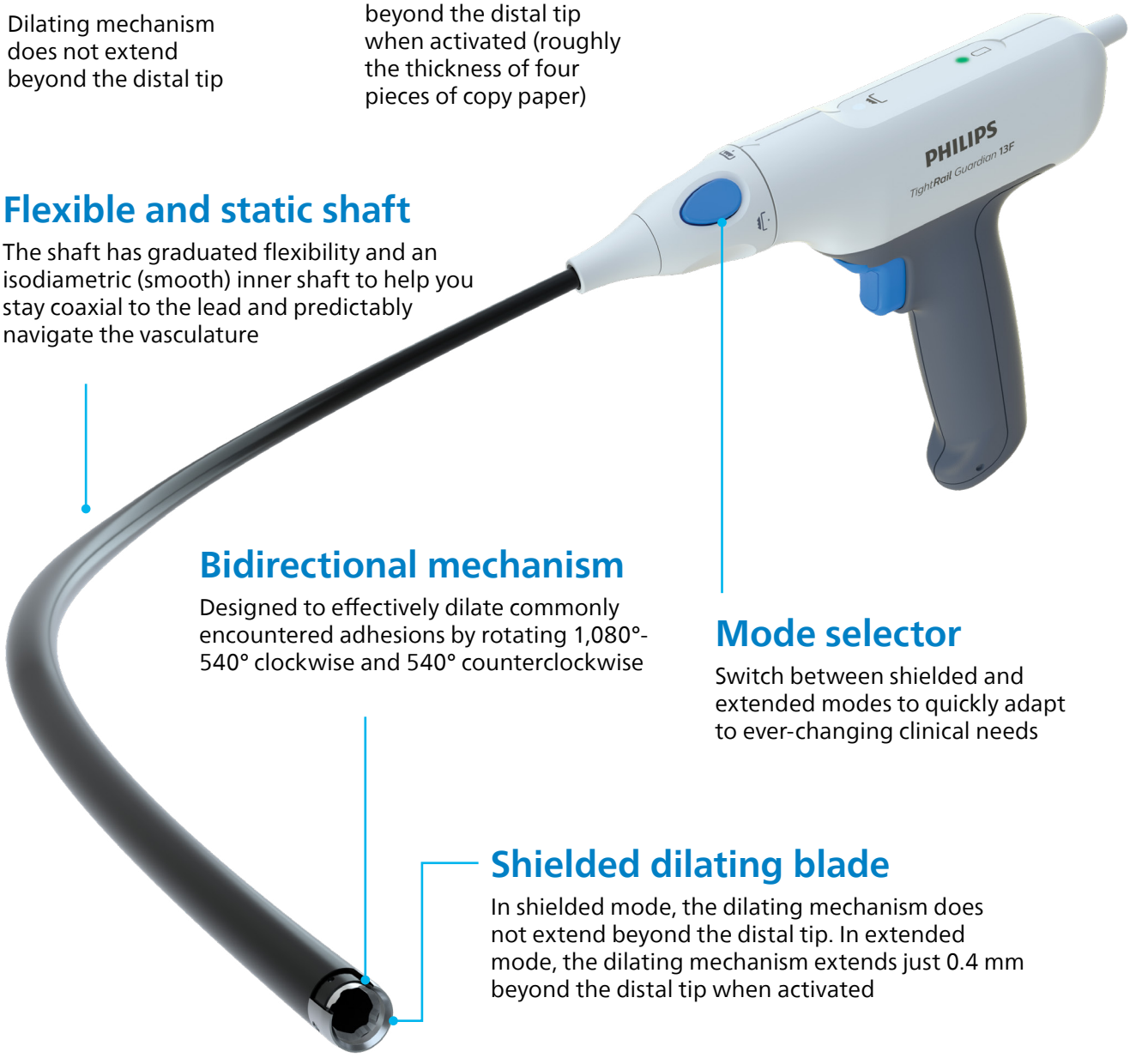
- Primary mode of operation
- Dilation in sensitive areas to limit contact with the vessel wall
- Dilating mechanism does not extend beyond the distal tip

Extended mode

- For stalled progression or complex lesions
- Dilating mechanism extends just 0.4 mm beyond the distal tip when activated (roughly the thickness of four pieces of copy paper)

Motorized activation

- Motorized activation and ergonomic handle provide consistency and control for dilation
- May reduce hand fatigue and procedure time



Flexible and static shaft

The shaft has graduated flexibility and an isodiametric (smooth) inner shaft to help you stay coaxial to the lead and predictably navigate the vasculature

Bidirectional mechanism

Designed to effectively dilate commonly encountered adhesions by rotating 1,080°-540° clockwise and 540° counterclockwise

Mode selector

Switch between shielded and extended modes to quickly adapt to ever-changing clinical needs

Shielded dilating blade

In shielded mode, the dilating mechanism does not extend beyond the distal tip. In extended mode, the dilating mechanism extends just 0.4 mm beyond the distal tip when activated

Control in hand. Safety at heart.

Philips Motorized Dilator Sheath – TightRail Guardian – provides the critical control and precision you're looking for in lead extraction procedures and it is backed by Philips service, support and access to specialized training. TightRail Guardian helps you manage every lead safely, predictably, responsibly.

Device specifications

Model number	Sheath	Tip inner diameter			Device outer diameter			Device length	
		(F)	(in)	(mm)	(F)	(in)	(mm)	(in)	(cm)
575-009	TightRail Guardian	9.0	0.119	3.0	16.5	0.215	5.5	18.7	47.5
	Outer sheath	17.4	0.227	5.8	21.0	0.277	7.0	16.0	40.6
575-011	TightRail Guardian	11.1	0.145	3.7	18.3	0.241	6.1	18.7	47.5
	Outer sheath	19.2	0.253	6.4	23.1	0.303	7.7	16.0	40.6
575-013	TightRail Guardian	12.9	0.171	4.3	20.4	0.267	6.8	18.7	47.5
	Outer sheath	21.3	0.279	7.1	25.2	0.329	8.4	16.0	40.6

Important safety information

Indications

The TightRail Guardian Motorized Dilator Sheath is intended for use in patients requiring the percutaneous dilation of tissue to facilitate 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.
- The safety and effectiveness of TightRail Guardian has not been established for the following:
  - Pediatric patients (< 18 years old) and transitional adolescent patients (18 - <= 21 years old)
  - Advancement of the device into the coronary sinus
- When using a lead locking device:
  - Do not abandon a lead in a patient with a lead locking device 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 lead locking device 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 lead locking device. Insertion of the lead locking device into such a lead may result in protrusion and possible migration of the J-shape retention wire.
- Do not submerge the handle of the TightRail Guardian Sheath. Fluid ingress into the enclosure could result in damage to the device and/or injury to the patient.
- Do not insert more than one TightRail Guardian Sheath or Outer Sheath into a vein at a time. Do not insert more than one lead into a TightRail Guardian Sheath 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 Guardian Sheath or Outer Sheath. Excessive advancement force may result in device or vessel wall damage.
- In order to maintain awareness of selected dilation mode and operational status, operate the device in a position that allows for visualization of the icons and LED lights.
- If the device enters an unrecoverable error state while within the patient's vasculature, stop advancement of the device. Rotate the mode selector to shielded mode and remove the device from the patient's vasculature.
- Do not leave the Outer Sheath tip at the SVC-atrial junction as it may damage this delicate area during subsequent procedures. (e.g., manipulating the Outer Sheath, implanting a new lead).
- Do not activate device when at the myocardial wall. Severe injury may occur.
- Device is rated Type CF non-defibrillation proof. Remove dilator sheath from patient vasculature before defibrillation or cardioversion.
- Do not incinerate the TightRail Guardian Sheath, as the enclosed batteries may explode at excessive temperatures.
- Do not open the enclosure, modify the components or change the batteries. Opening or modifying the TightRail Guardian Sheath could result in damage to the device and/or injury to the patient or physician.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the TightRail Guardian device as degradation of the performance of this equipment could result.
- Electromagnetic disturbance from RF emitters cannot be predicted with accuracy. To assess the electromagnetic disturbance of such devices, an electromagnetic site survey should be considered. If the measured field strength in the location in which the TightRail Guardian Sheath is used exceeds the applicable RF compliance level above, the TightRail Guardian Sheath should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the TightRail Guardian Sheath.

Refer to the IFU for additional information.

1. Kusumoto et al. 2017 HRS Expert Consensus Statement on Cardiovascular Implantable Electronic Device Lead Management and Extraction. Heart Rhythm, 2017
2. Maria G Bongiorni, et al. ESC Scientific Document Group, 2018 EHRA expert consensus statement on lead extraction: recommendations on definitions, endpoints, research trial design, and data collection requirements for clinical scientific studies and registries: endorsed by APHRS/HRS/LAHRS, EP Europace, Volume 20, Issue 7, July 2018, Page 1217, https://doi.org/10.1093/europace/euy050

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