



Important safety information
TightRail Rotating Dilator Sheath

Indications for Use

The TightRail Rotating Dilator Sheath is intended for use in patients requiring the percutaneous dilation of tissue to facilitate removal of cardiac leads.

Contraindications

None known

Potential Adverse Events

Potential adverse events related to the procedure of intravascular removal of leads include (listed generally in order of increasing potential effect): dislodging or damaging non-targeted lead; chest wall hematoma, thrombosis; arrhythmias; bacteremia; hypotension; pneumothorax; migrating fragment from lead; migration of vegetation from lead; pulmonary embolism; laceration or tearing of vascular structures or the myocardium; hemopericardium; cardiac tamponade; hemothorax; stroke; death.

Caution: Federal law restricts this device to sale by or on the order of a physician.

