



### **Important safety information**

#### **TightRail Sub-C Rotating Dilator Sheath**

#### **Indications for Use**

The TightRail Sub-C 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.

