



Important safety information

GlideLight Laser Sheath

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

Indications for Use

The Laser Sheath is intended for use as an adjunct to conventional lead extraction tools in patients suitable for transvenous removal of chronically implanted pacing or defibrillator leads constructed with silicone or polyurethane outer insulation.

Contraindications

Use of the Laser Sheath is contraindicated:

- When emergency thoracotomy with cardiopulmonary bypass cannot be performed immediately in the event of a life threatening complication;
- When fluoroscopy is not available;
- In patients in whom superior venous approach cannot be used;
- When the proximal end of the pacing lead is not accessible to the operator;
- When the lead will not fit into the inner lumen of the Laser Sheath.

Potential Adverse Events

The following adverse events or conditions may also occur during lead extraction with the Laser Sheath but were not observed during the clinical study (listed in alphabetical order): bacteremia, low cardiac output, migration of lead fragments, migration of vegetation, myocardial avulsion/perforation, premature ventricular contractions, pulmonary embolism, stroke, venous avulsion/perforation, ventricular tachycardia.

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