PHILIPS

Important safety information
Lead Locking Devices, LLD EZ and LLD

Indications for Use

The Spectranetics Lead Locking Devices, LLD, are intended for use in patients suitable for transvenous removal of chronically implanted pacing or defibrillator leads having an inner lumen and using a superior venous approach.

Contraindications

Use of the LLD 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 LLD will not fit into the inner lumen of the device to be extracted.

Potential Adverse Events

Commonly observed adverse events during lead removal procedures have included: hemopericardium tamponade, hemothorax, thrombosis, tricuspid regurgitation, infection, death.

The following adverse events or conditions may also occur during lead removal (listed in alphabetical order): bacteremia, low cardiac output, migration of lead fragments, migration of vegetation, myocardial avulsion, premature ventricular contractions, pulmonary embolism, stroke, venous avulsion, ventricular tachycardia.

Additional information may be found in the articles referenced in the bibliography of the Instructions for Use.

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