PHILIPS

LLD

Lead-locking device

Stable, flexible, and visible

lead removal

See how easy
lead management can be.

LLD E and LLD EZ combine the best of the original LLD family and enhanced tip design with new ease-of-use features to provide a flexible traction solution for leads targeted for removal today.

Sizing

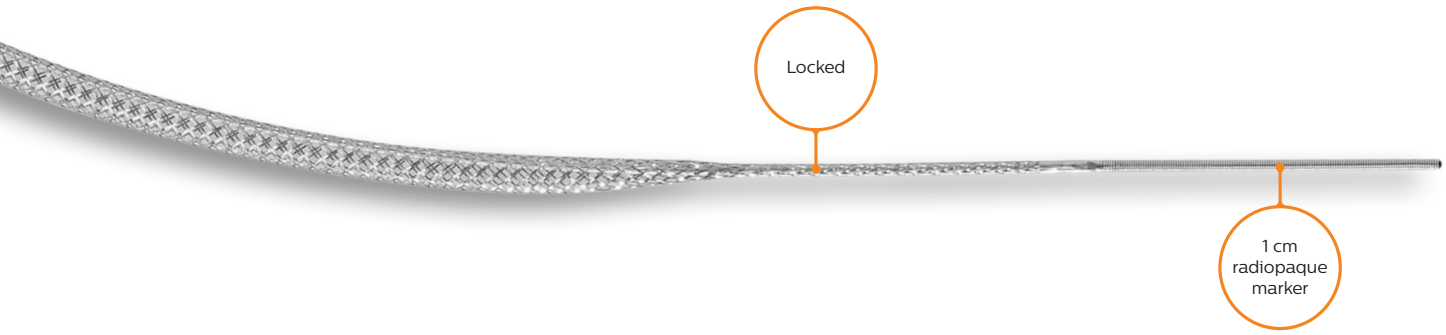
LLD E and LLD EZ accommodate a wide range of leads with inner lumen diameters from 0.015” (0.38mm) to 0.023” (0.58mm).

Tracking

Flexible platinum iridium tip design and sleek profile facilitate tracking and passage through tightly curved leads and past some points of lead lumen damage.

Visibility

Permits Longer and highly visible radiopaque marker assists identification of both the LLD EZ and LLD E tip location under fluoroscopy.



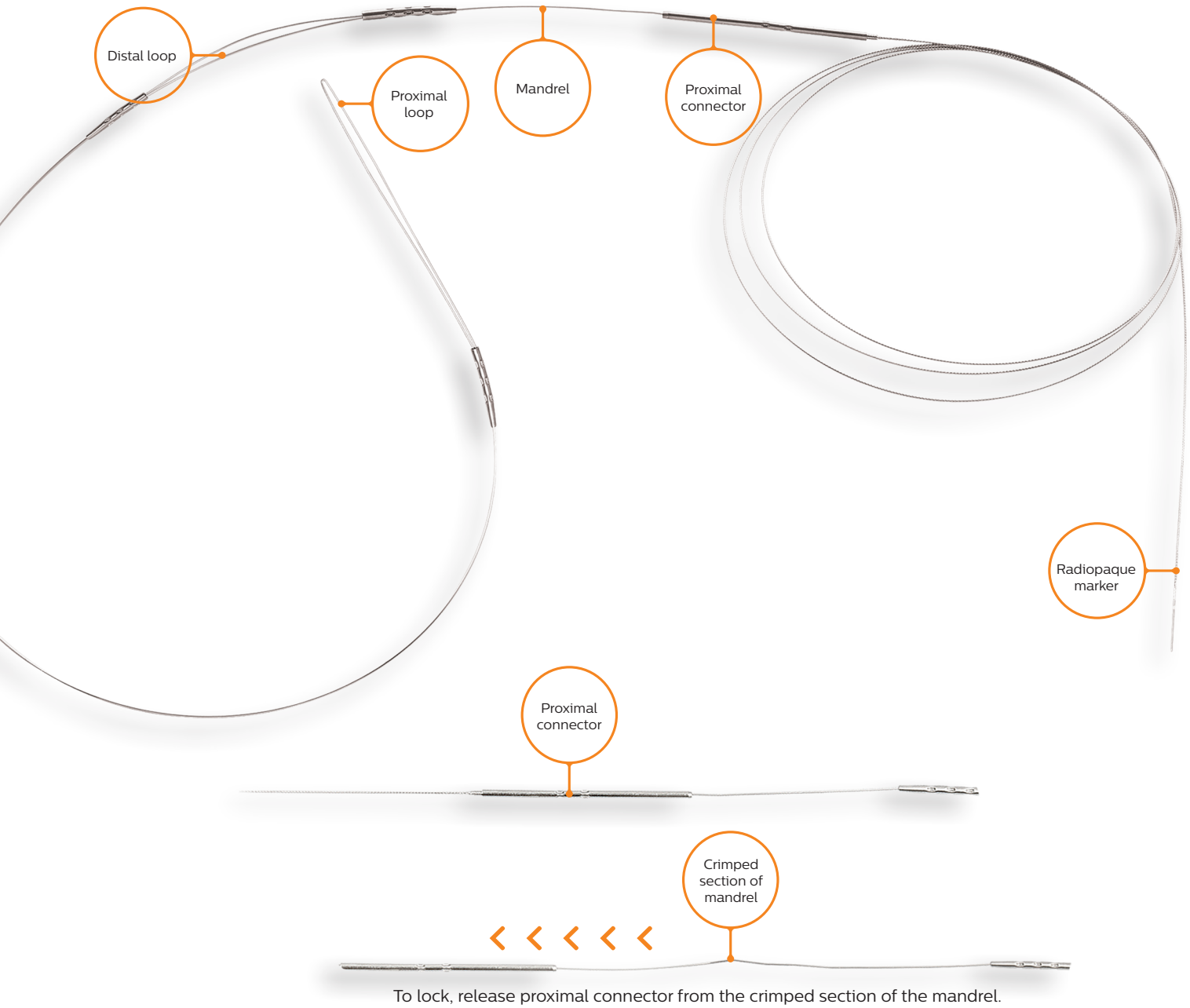
LLD E Treatment versatility for longer leads

The Enhanced Lead-Locking Device (LLD E) uniquely addresses certain lead removal and lead traction challenges.

Enhanced versatility

- 31% longer working length (85 cm) is more compatible with longer leads.
- 12% smaller unlocked diameter compared to LLD #2

LLD EZ design and operation



To lock, release proximal connector from the crimped section of the mandrel.

LLD Stable and secure traction

Only the Philips LLD design provides a stable traction platform by locking along the entire contacted lead lumen.

Stable Locking

- 100% lock success in leads with undamaged lumens (95 of 99 leads had undamaged lumens)*
- Proven ability to unlock and reposition after initial deployment*.

*Kennergren, C., et al. Cardiac Lead Extraction with a Novel Locking Stylet. Journal of Interventional Cardiac Electrophysiology 4 591-593 (2000).

LLD Lead-locking device

LLD specifications and comparisons

Feature	LLD E	LLD EZ	LLD #1	LLD #2	LLD #3	Cook® Liberator
Model number	518-039	518-062	518-018	518-019	518-020	N/A
Locks along entire lead lumen	•	•	•	•	•	
Proven ability to Unlock and reposition	•	•	•	•	•	•
Average tensile strength**	19 lbs.	19 lbs.	12 lbs.	24 lbs.	45 lbs.	Not published in IFU
Low-profile loop handles		•				N/A
Locking range (diameter)	0.015”/0.38mm to 0.023”/0.58mm	0.015”/0.38mm to 0.023”/0.58mm	0.013”/0.33mm to 0.016”/0.41mm	0.017”/0.43mm to 0.026”/0.66mm	0.027”/0.69mm to 0.032”/0.81mm	0.016”/0.41mm to 0.032”/0.81mm
Working length	85cm	65cm	65cm	65cm	65cm	70cm
Clearing stylet included	0.012”/ 0.30mm diameter	0.012”/ 0.30mm diameter	0.012”/ 0.30mm diameter	0.015”/ 0.38mm diameter	0.015”/ 0.38mm diameter	N/A

LLD accessories

Feature	518-027
Lead cutter	518-024

Liberator is a registered trademark of Cook Medical. Cook Products for Lead Extraction brochure accessed 9-2-10, from http://www.cookmedical.com/lm/content/mmedia/LM-DM-EVOLCAT-EN-201003.pdf and Liberator Instructions for Use on file.

** Minimum specification for LLD E, LLD EZ, LLD #2, and LLD #3 is 10 lbs; minimum for LLD #1 is 7 lbs.

Important safety information

Indications

The Philips Lead Locking Device, LLD, is 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.

Contrindications

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.

Precautions

For single use only. Do not resterilize and/or reuse. The LLD is intended to be used in one lead. Do not use the LLD: if the tamper-evident seal is broken; if the LLD has been damaged. When the LLD is in the body, it should be manipulated only under fluoroscopic observation. Due to rapidly evolving lead technology, this device may not be suitable for the removal of all types of leads. If there are questions or concerns regarding compatibility of this device with particular leads, contact the lead manufacturer. If selectively removing leads with the intent to leave one or more chronically implanted leads intact, these nontargeted leads must be subsequently tested to ensure that they were not damaged or dislodged during the extraction process.

Warnings

Do not attempt to use the LLD without the availability of the Spectranetics Laser Sheath or other necessary lead removal tools. The LLD should be used only by physicians who are experienced in lead removal techniques. Do not insert more than one LLD into a lead lumen at a time. Lead removal devices should be used only at institutions with emergency cardiac surgical capabilities. Weigh the relative risks and benefits of intravascular lead removal procedures particularly when the item to be removed is of a dangerous shape or configuration, the likelihood of lead disintegration resulting in fragment embolism is high, and vegetations are attached to the lead body. When using the LLD, do not abandon a lead in a patient with an LLD still inside the lead. Severe vessel or endocardial wall damage may result from the stiffened lead or from fracture or migration of the abandoned device. Do not apply weighted traction to an inserted LLD as myocardial avulsion, hypotension or venous wall tearing may result. Excessive applied traction forces may impact the LLD’s ability to disengage from a lead. Be aware that a lead that has a J-shape retention wire that occupies its inner lumen (rather than being outside the coil) may not be compatible with the LLD. Insertion of the LLD into such a lead may result in protrusion and possible migration of the J-shape retention wire. When the LLD is in the body, it should be manipulated only under fluoroscopic observation. When marked calcification that moves with the device to be extracted is seen on fluoroscopy, particularly in the atrium, the availability of immediate surgical assistance is paramount if a problem presents itself as a result of the extraction procedure. Also, thoracotomy removal of the device(s) should be considered.

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