



The Spectranetics® Lead Locking Device LLD® & LLD® E

Refer to the end of this presentation for Important Safety Information

Overview

- Challenges in Lead Traction for Extraction
- The Solution: Spectranetics Lead Locking Device (LLD[®])
- The Enhanced Lead Locking Device – LLD[®] E

Note: LLD[®] and LLD[®] E are 510K market released. See *Instructions for Use* for complete prescribing information.
All product claims are supported by data on file.

Challenges in Lead Traction for Extraction

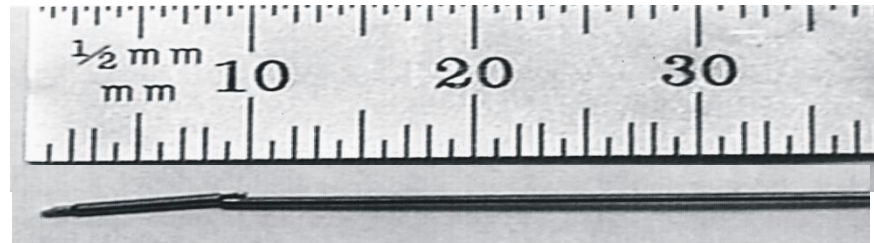
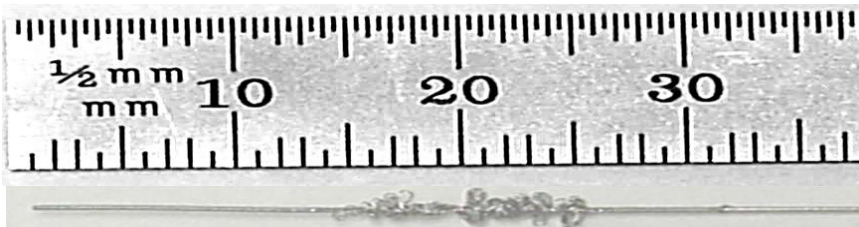
- Lead Extraction without Sheaths
 - Adhesions occur along the length of the lead
 - Venous entry
 - Subclavian vein
 - Superior vena cava (SVC)
 - Distal segment
 - Adhesions are less likely to be overcome if traction is not producing shear force directly at the adhesion site

Challenges in Lead Traction for Extraction

- Lead Extraction with Sheaths
 - Fractured or damaged leads pose a challenge to establishing a stable traction platform for sheath advancement
 - Sometimes older leads can begin to come apart due to traction forces applied during the extraction process

Challenges in Lead Traction for Extraction

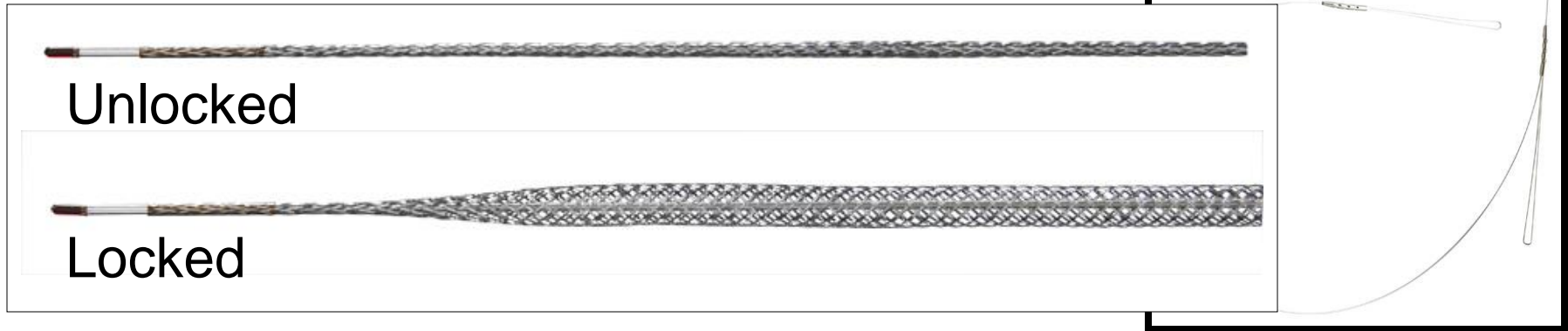
- Common locking stylets have limitations
 - As many as 25%-35%* fail to stay locked for a variety of reasons
 - Locking area is confined to a very small distal portion of lead
 - Locking process may be difficult to reverse*



* Sellers, T. Duncan, MD, et al. (2000). New Tools for Extraction of Pacemaker and Defibrillator Leads: Advancement in Stylet Technology. *Cardiovascular Review & Reports*, 21 (10), 549-553.

The Solution: Spectranetics Lead Locking Device (LLD)

- Only LLD delivers stable traction along the entire lead length
- LLD provides the ability to unlock and reposition after initial deployment

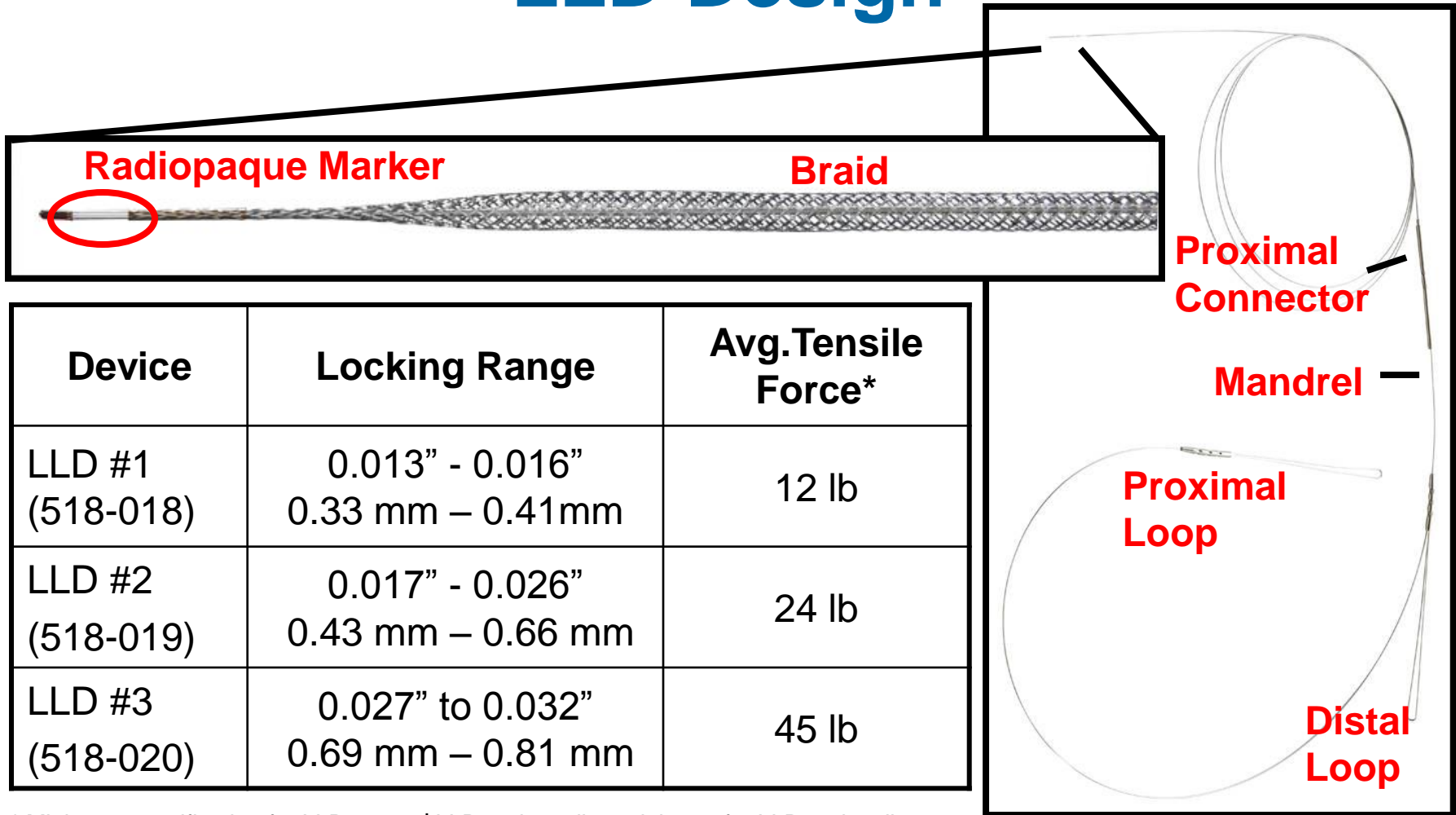


LLD Data

- Study of 57 patients, 99 leads*
- 100% lock success after successful insertion (4 leads had damaged lumen or were fragmented, preventing LLD insertion)
- 96% Complete lead removal + 2% Partial lead removal
- 9 cases where LLD was deliberately unlocked and either repositioned in same lead or deployed in another lead
- 3 leads removed with 1 LLD

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

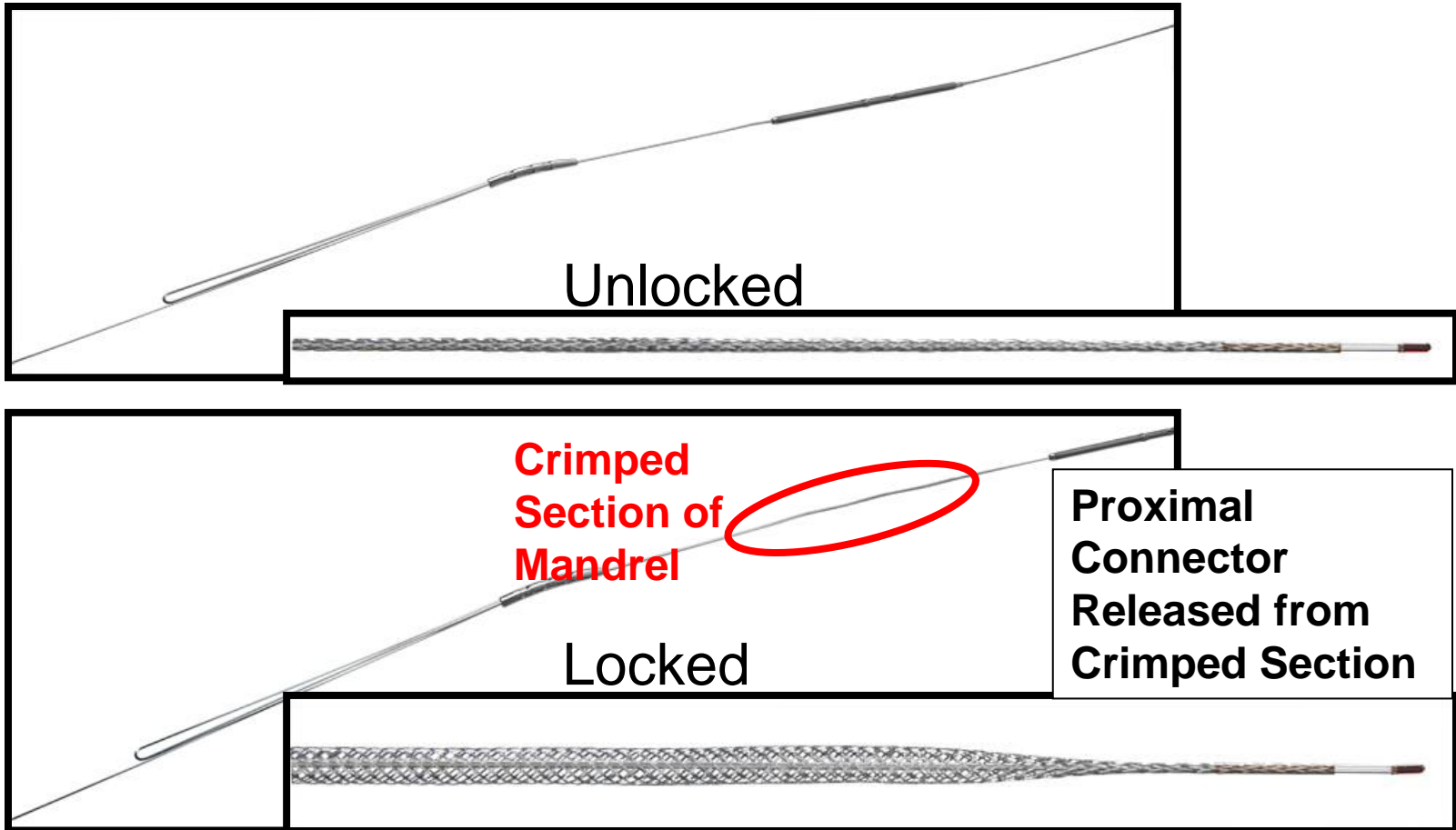
LLD Design



Device	Locking Range	Avg. Tensile Force*
LLD #1 (518-018)	0.013" - 0.016" 0.33 mm – 0.41mm	12 lb
LLD #2 (518-019)	0.017" - 0.026" 0.43 mm – 0.66 mm	24 lb
LLD #3 (518-020)	0.027" to 0.032" 0.69 mm – 0.81 mm	45 lb

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

LLD Deployment



LLD vs. Liberator[®] (Cook[®])

LLD



Locks Along the Entire Contacted Lumen

LIBERATOR



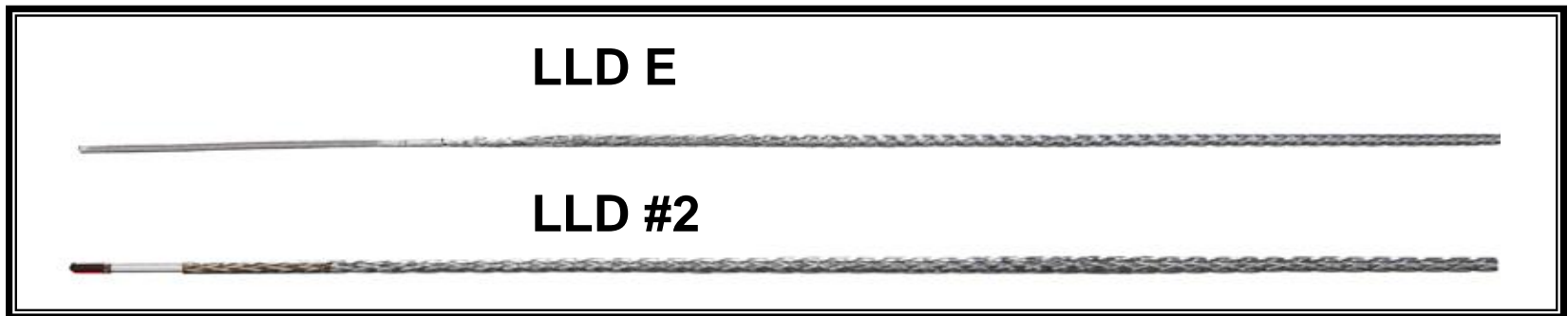
Locks Small Distal Segment

The Enhanced Lead Locking Device LLD E

- Enhanced tracking and passage
- Enhanced visibility
- Enhanced versatility

LLD E

- Enhanced tracking and passage through inner lumen of tortuous or highly curved leads compared to LLD #2
 - More flexible tip
 - Smaller unlocked diameter (0.015" vs. 0.017")
 - Note this tradeoff results in 19 lb. avg. tensile force vs. 24 lb*



* Minimum specification for LLD #2 and LLD E is 10 lbs.

LLD E

- Enhanced visibility due to longer radiopaque marker helps identify when LLD E tip reaches lead tip



LLD E

- Enhanced versatility
 - Longer working length for greater compatibility with longer leads

LLD E – 85 cm

LLD – 65 cm

LLD E

- Enhanced versatility
 - More locking range than LLD #2 to include smaller diameter leads

LLD E – 0.015” to 0.023”

LLD #1 – 0.013” to 0.016”

LLD #2 – 0.017” to 0.026”

LLD E / LLD Comparisons

Feature	LLD E*	LLD*	Cook [®] Liberator ^{®**}
Locks Along Entire Lead Lumen	Yes	Yes	No
Proven Ability to Unlock and Reposition	Yes	Yes	No
Avg. Tensile Strength***	19 lb	#1: 12 lb #2: 24 lb #3: 45 lb	Not published in IFU
Locking Range (Diameter)	0.015" to 0.023"	#1: 0.013" to 0.016" #2: 0.017" to 0.026" #3: 0.027" to 0.032"	0.016" to 0.032"
Working Length	85 cm	65 cm	70 cm
Packaged with Clearing Stylet	Yes	Yes	No

* Data on file at Spectranetics.

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

Important Safety Information

Indications

The Spectranetics 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.

Contraindications

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.

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.

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.