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

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

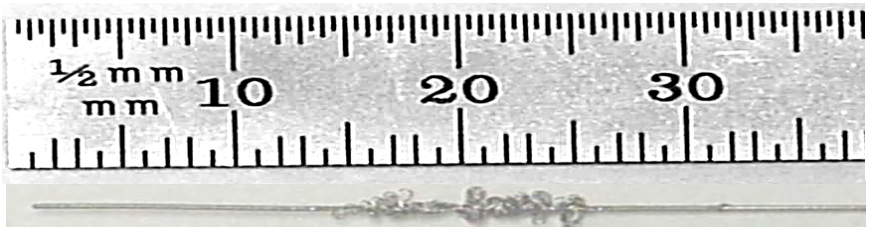
- Lead Extraction without Sheaths
  - Adhesions occur along the length of the lead
    - Venous entry
    - Subclavian vein
    - Superior vena cava (SVC)
    - Distal segment
  - Adhesions are less likely to be overcome if traction is not producing shear force directly at the adhesion site

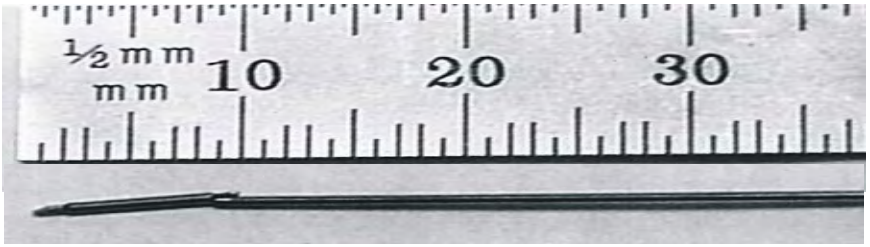
Challenges in Lead Traction for Extraction

- 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*

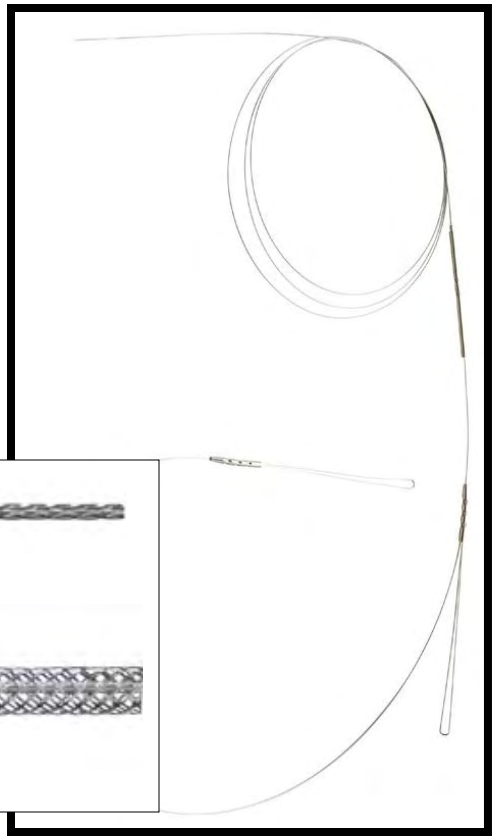


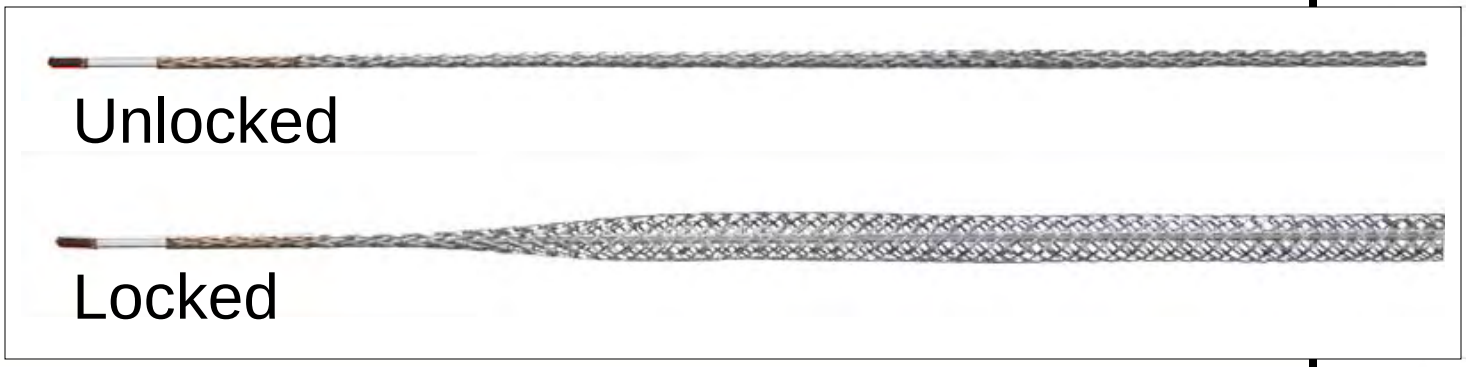


* Sellers, T. Duncan, MD, et al. New Tools for Extraction of Pacemaker and Defibrillator Leads: Advancement in Stylet Technology. *Cardiovascular Review & Reports*, Vol 21, No 10, Oct 2000.

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



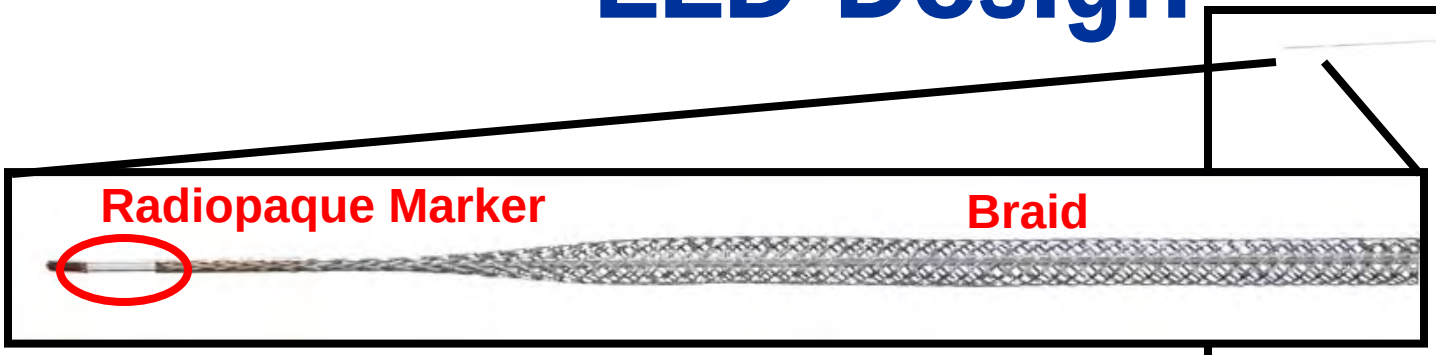


LLD Data

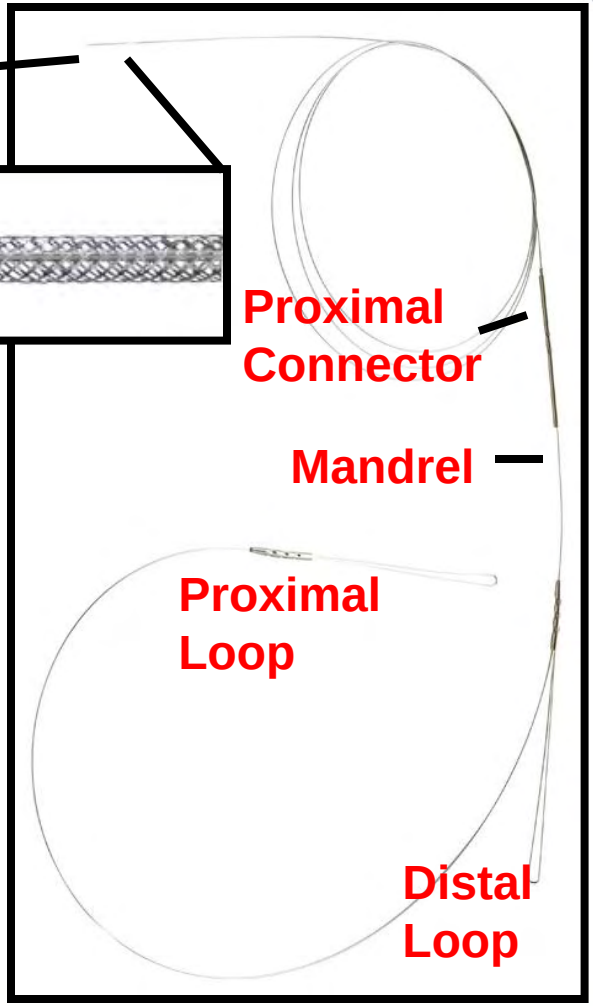
- Study of 57 patients, 99 leads*
- 100% lock success after successful insertion
  (4 leads had damaged lumen or were fragmented, preventing LLD insertion)
- 96% Complete lead removal + 2% Partial lead removal
- 9 cases where LLD was deliberately unlocked and either repositioned in same lead or deployed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

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

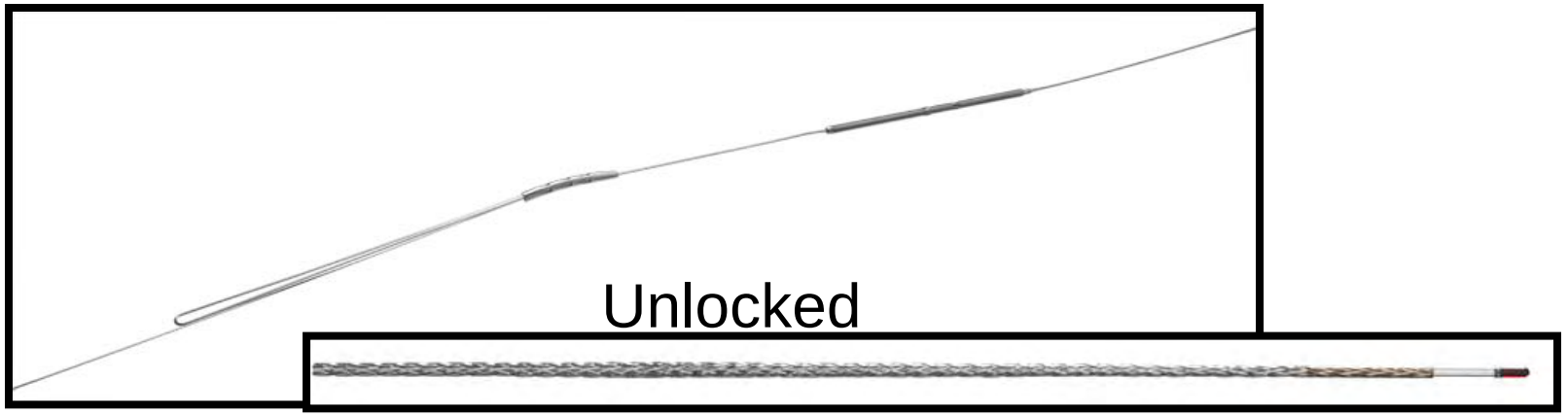
LLD Design

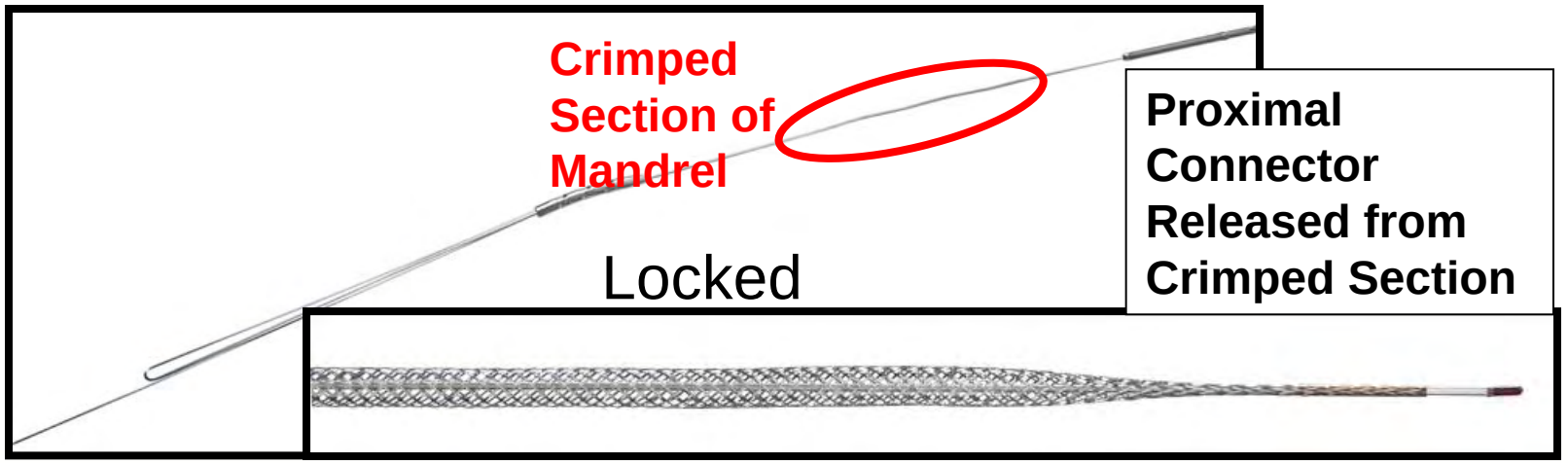


Device	Locking Range	Avg. Tensile Force
LLD #1 (518-018)	0.013” - 0.016” 0.33 mm – 0.41mm	12 lb
LLD #2 (518-019)	0.017” - 0.026” 0.43 mm – 0.66 mm	24 lb
LLD #3 (518-020)	0.027” to 0.032” 0.69 mm – 0.81 mm	45 lb



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

Addressing the unique needs of coronary sinus (CS) lead removal

- CS leads often traverse tortuous LV venous anatomy
- Most CS lead have an open lumen design making stylet tip visibility very important
- CS leads are generally longer than other pacing or defibrillation leads

Providing a flexible option for common lead removal challenges

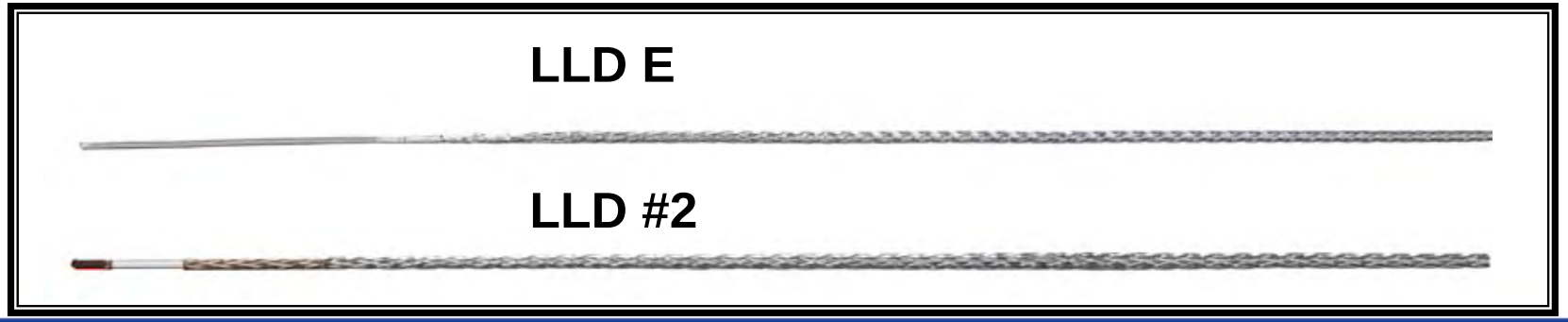
- Tortuous or highly curved pacing and defibrillation leads
- Difficulty passing a locking device through a damaged lumen

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

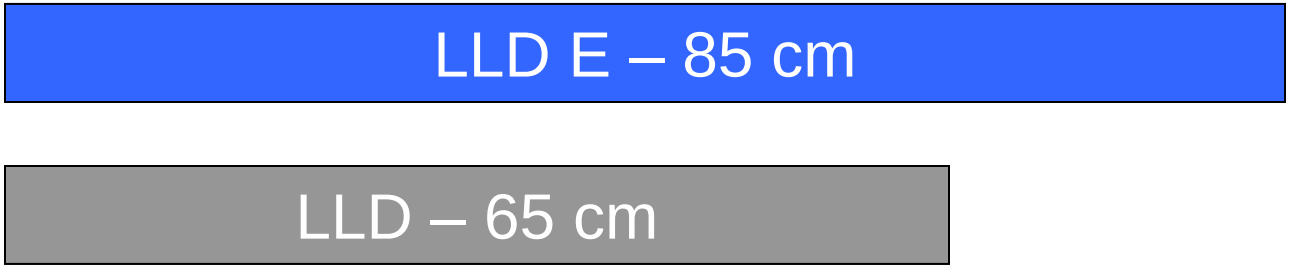


LLD E

- 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 coronary sinus (CS) pacing leads



LLD E

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

LLD E – 0.015” to 0.026”

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: 32 lb**	**Not published in IFU**
Locking Range (Diameter)	**0.015” to 0.026”**	**#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**

* Internal data on file. ** Cook Liberator brochure and Instructions for Use.