**EVOLUTION® mechanical dilator sheath set for intravascular lead extraction: a single center experience**

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**Introduction**

Intravascular extraction of dysfunctional or infected cardiac leads can be difficult when fibrous adhesions fix the leads to venous endothelium, endocardium, or to one another. Electrocautery and laser cutting sheaths help to disrupt these adhesions, but the use of these devices can be cumbersome. A new lead extraction device (EVOLUTION® mechanical dilator sheath set, Cook Medical/Cook Vascular Inc., PA, USA) provides mechanical cutting power without the need for increased venous traction force, instrument calibration, or an electrosurgical or laser power source.

**Study Objective**

To retrospectively analyze the clinical outcomes of lead extraction using the EVOLUTION® mechanical dilator sheath set in 22 consecutive patients.

**Study Method**

Medical records were reviewed for lead extraction in consecutive patients between July and December in 2007 at a single center. All extractions were performed with the EVOLUTION® device.

**The Device**

**EVOLUTION® Mechanical Dilator Sheath Set**
Cook Medical/Cook Vascular Inc.

- A flexible inner sheath contains a threaded barrel tip at its distal end.
- The inner sheath advances forward over the target lead, progressing through the fibrous tissues by rotating the threaded barrel tip.
- A telescoping outer sheath dilates the tissue around the target lead.
- An ergonomic handle triggers the rotation of the inner sheath.

**Advantages**
- Four sizes with inner diameter dimensions of 7, 9, 11 and 13 French.
- Mechanical cutting mechanism without the need for any power source.
- No forward depth of cut as used by energized power sheaths.
- No calibration protocol, no cumbersome power or laser unit.

**Results**

Fluoroscopy images: During lead retrieval, the EVOLUTION® dilator sheath set was used to separate adhesions between two leads.

**Summary of Results**

- 22 patients (8 female and 14 male)
- 41 leads (15 atrial, 19 ventricular and 7 dual coil ventricular defibrillator leads)
- Median patient age range: 80-84 years
- Mean implant duration: 7.3 years (range: 0.1-18.8)
- Reasons for extraction: infection (16 patients, 28 leads) and damaged leads (6 patients, 13 leads)
- Of 41 leads, 39 (95%) were successfully and completely removed. One lead was partially extracted and left a 2 cm tip in the right ventricular apex with no sequelae. The remaining lead could not be extracted because the occluded inner lumen prevented insertion of a locking stylet.
- One patient (1/22) required periarteritis for pericardial tamponade one week post procedure, with subsequent mild pericarditis that resolved in two weeks. No other complications were observed.

**Conclusion**

Review of this small patient cohort demonstrates acceptable safe and effective performance of the EVOLUTION® mechanical dilator sheath set for the extraction of acute and chronic cardiac leads.