

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

Raymond H. M. Schaerf, MD, Barry E. Norlander and Louis Goode
Providence St. Joseph Medical Center, Burbank, CA; Cook Medical, Inc., Vandergrift, PA

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

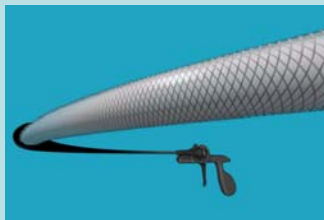
To retrospectively analyze the clinical outcomes of lead extraction using the EVOLUTION® mechanical dilator sheath set in 22 consecutive patients.

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.

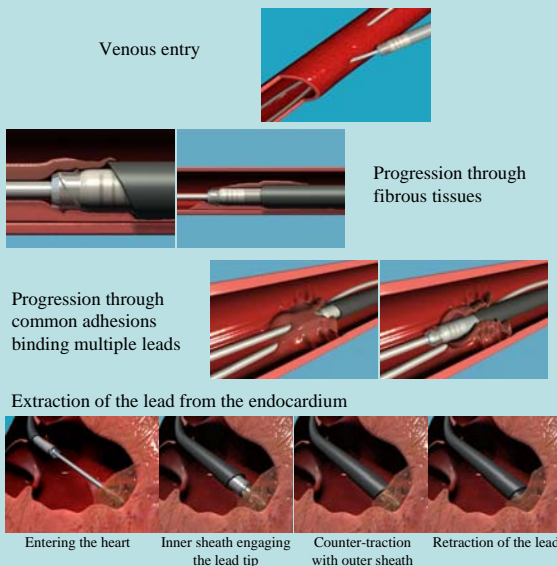


- A flexible inner sheath contains a threaded barrel tip at its distal end.
- The inner sheath advances forward over the target lead, progressing through the fibrous tissues by rotating the threaded barrel tip.
- A telescoping outer sheath dilates the tissue around the target lead.
- An ergonomic handle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

Advantages

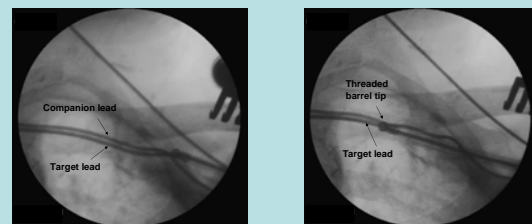
- Four sizes with inner diameter dimensions of 7, 9, 11 and 13 French.
- Mechanical cutting mechanism without the need for any power source.
- No forward depth of cut as used by energized power sheaths.
- No calibration protocol, no cumbersome power or laser unit.

Lead Extraction with the EVOLUTION® Device



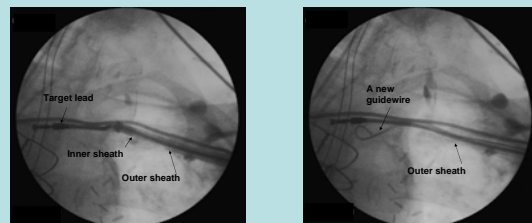
Results

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



A. Adhesion of the target lead to a companion lead during retrieval.

B. Separation of the target lead from the companion lead by rotating the inner sheath.



C. Progression of the EVOLUTION® sheath through the fibrous adhesions between leads.

D. The outer sheath in place to provide access of a guidewire for new lead implantation.

Patient information			Lead Information			Extraction Procedure			
Case #	Gender	Age Range (yr)	Manufacturer	Model	Implant Duration (yrs)	Implant Location	Evolution Size Used (Fr)	Reason for Extraction	Outcome
1	M	75-79	MEDTRONIC	5076	1.3	A	11	D	S
2	F	80-84	GUIDANT	4635	8.0	A	11	D	S
			INTERMEDIC	71195	8.0	V	11	D	S
			UNK	UNK	11.0	V	9	D	S
3	F	45-49	ST. JUDE	1580	3.2	DEFIB	13	D	S
4	M	85-89	MEDTRONIC	4558M	10.7	A	11	I	S
			ST. JUDE	1246T	10.7	V	11	I	S
5	M	90-94	MEDTRONIC	4024	8.3	V	9	I	S
6	M	90-94	MEDTRONIC	4068	8.5	A	9	I	S
			MEDTRONIC	4068	8.5	V	9	I	S
7	M	80-84	INTERMEDIC	432.04	7.9	A	9	I	S
			GUIDANT	4459	7.9	V	9	I	S
8	M	80-84	GUIDANT	4457	0.1	A	9	I	S
9	M	55-59	GUIDANT	4456	1.1	A	11	I	S
			GUIDANT	4035	3.3	V	11	I	S
			GUIDANT	4037	3.3	V	11	I	S
10	F	75-79	ST. JUDE	1388	7.0	A	11	I	S
			ST. JUDE	1590	2.3	DEFIB	13	I	S
			ST. JUDE	1346	7.0	V	11	I	S
11	F	85-89	ST. JUDE	1364	9.0	V	11	I	<3 CM TIP
12	M	85-89	MEDTRONIC	4524	6.1	A	11	I	S
			MEDTRONIC	4024	6.1	V	11	I	S
13	M	80-84	MEDTRONIC	4592	5.3	A	11	I	S
			MEDTRONIC	6944	5.3	DEFIB	13	I	US
			MEDTRONIC	6944	3.3	DEFIB	13	I	S
14	F	45-49	MEDTRONIC	4524	13.5	A	11	D	S
			MEDTRONIC	4024	13.5	V	11	D	S
			ST. JUDE	1012	18.8	A	11	D	S
			ST. JUDE	1226	16.0	V	11	D	S
15	M	65-69	MEDTRONIC	4012	16.0	V	11	D	S
16	F	85-89	MEDTRONIC	5034	10.4	V	11	I	S
			MEDTRONIC	5534	10.4	A	11	I	S
17	M	85-89	GUIDANT	4551	7.4	A	9	D	S
			GUIDANT	4269	7.4	V	11	D	S
			MEDTRONIC	5076	5.3	V	11	D	S
18	F	75-79	GUIDANT	158	5.4	DEFIB	13	I	S
19	M	70-74	GUIDANT	4456	0.3	V	9	I	S
20	M		MEDTRONIC	6949	2.5	DEFIB	13	I	S
21	M	75-79	GUIDANT	4479	4.7	A	11	I	S
			GUIDANT	147	4.7	DEFIB	13	I	S
22	F	80-84	UNK	UNK	10.0	V	9	I	S

UNK: unknown
A: Atrial; V: Ventricular
DEFIB: Defibrillator leads
D: Defective
S: Successful
I: Infection
US: Unsuccessful

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 pericardiocentesis 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.