

Trattamenti Interventistici di Estrazione Elettrocateri

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Department of Cardiac, Thoracic and Vascular Sciences



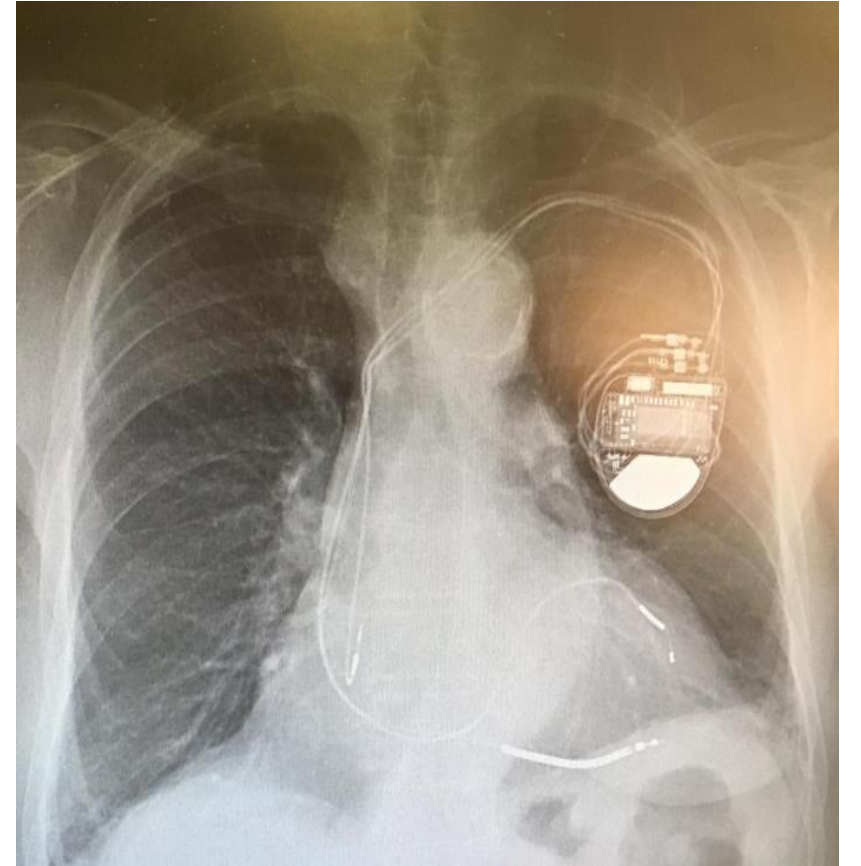
- 75 yr, Male

- 2001 CRT-D implantation

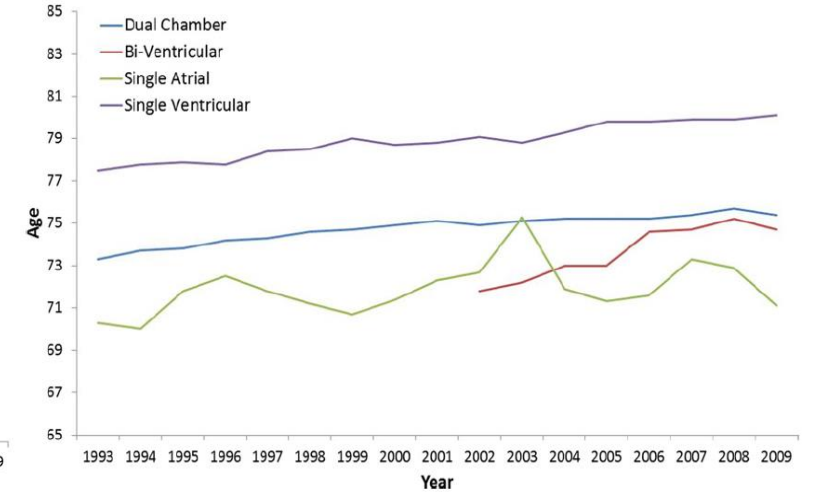
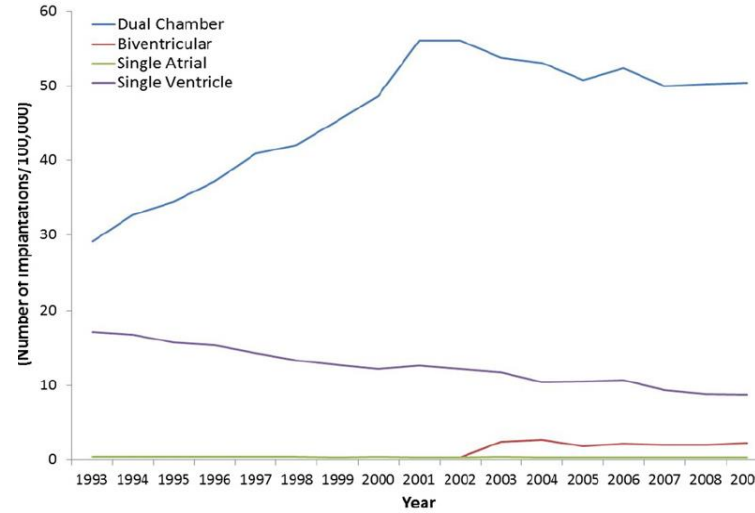
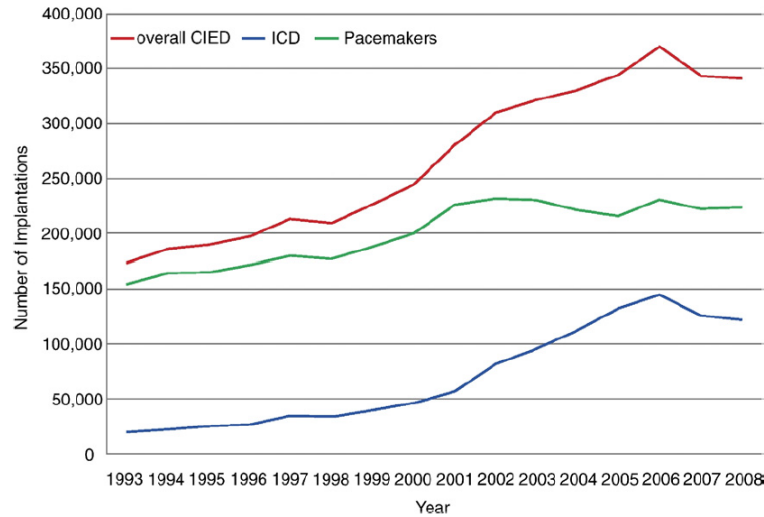
- No-responder

- Fever

- Emergency Room



Trends in Cardiac Implantable Electronic Device Implantation Over Recent Years

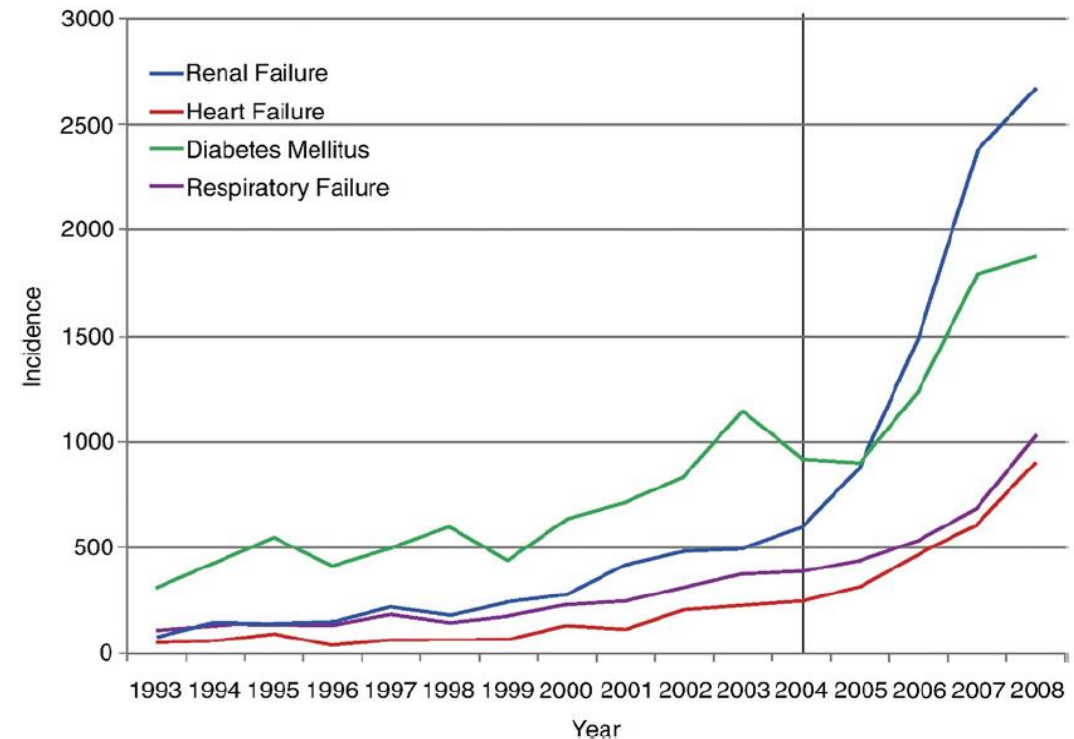
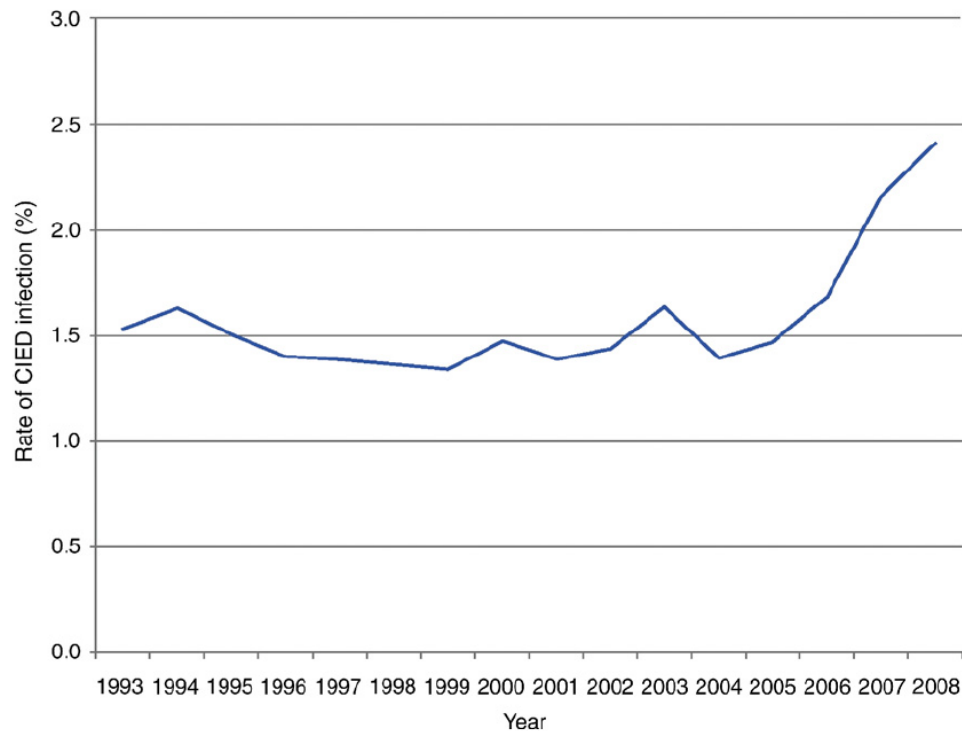


- ✓ The number of CIEDs implantations has increased as a result of population growth, increasing life expectancy, adoption of guidelines, and better access to healthcare
- ✓ ICD, CRT-P/D, DDD device use is increasing
- ✓ Single-chamber use is decreasing
- ✓ Patients are becoming older and have more medical comorbidities

*Greenspon AJ et al. JACC 2012;60:1540
Greenspon AJ et al JACC 2011;58:1001*

16-Year Trends in the Infection Burden for Pacemakers and Implantable Cardioverter-Defibrillators in the United States

1993 to 2008



A marked increase was observed, which coincided with an increase in the incidence of major comorbidities

Current practice in transvenous lead extraction: a European Heart Rhythm Association EP Network Survey

Maria Grazia Bongiorni^{1*}, Carina Blomström-Lundqvist², Charles Kennergren³, Nikolaos Dages⁴, Laurent Pison⁵, Jesper Hastrup Svendsen⁶, and Angelo Auricchio⁷, conducted by the Scientific Initiative Committee, European Heart Rhythm Association

Lead extraction as a part of an overall lead management strategy



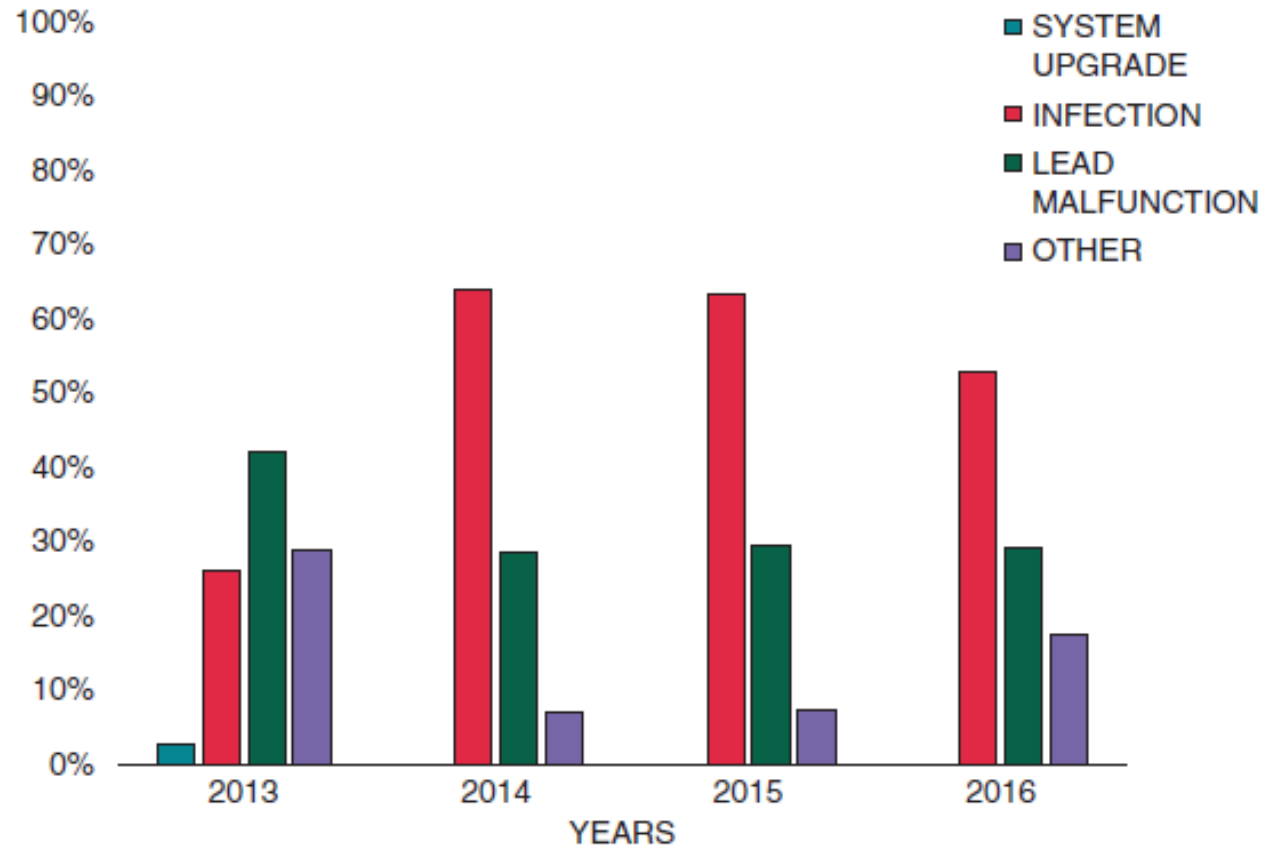
- ✓ Overall increasing experience of widespread involvement of cardiac centres in LEAD EXTRACTION
- ✓ Increasing experience of managing various techniques of LEAD EXTRACTION
- ✓ Undoubtedly lead extraction is already a vital and necessary part of modern CIED treatment in Europe

The European Lead Extraction ConTRolled (ELECTRa) study: a European Heart Rhythm Association (EHRA) Registry of Transvenous Lead Extraction Outcomes

Indications, N/Total N (%)	
Infections	1872/3543 (52.8)
Systemic infection	684/3543 (19.3)
Local infection	1173/3543 (33.1)
No infection ^a	1683/3555 (47.3)

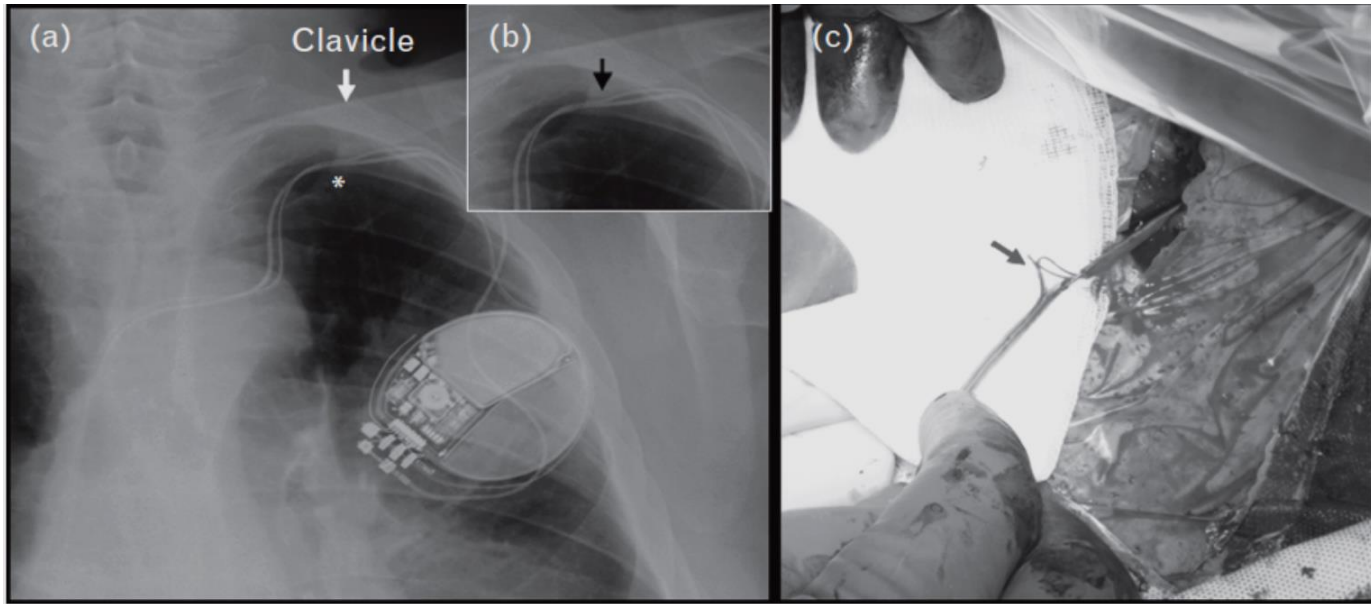
^aNon-infective indications: non-functional leads 38.1%, functional leads 3.7%, chronic pain 5.1%, thrombosis or venous stenosis 4.5%, recalled lead 5.7%, signs and symptoms of venous occlusion 4.8%, system upgrading 7.1%, MRI indication 0.7%, malignancy treatment 0.5%, cardiac perforation 2.1%, redundant lead 0.4%, stretched lead 0.2%, system no more indicated 0.7%, and other indications 1.0%.

Lead Extraction Indications Over Time

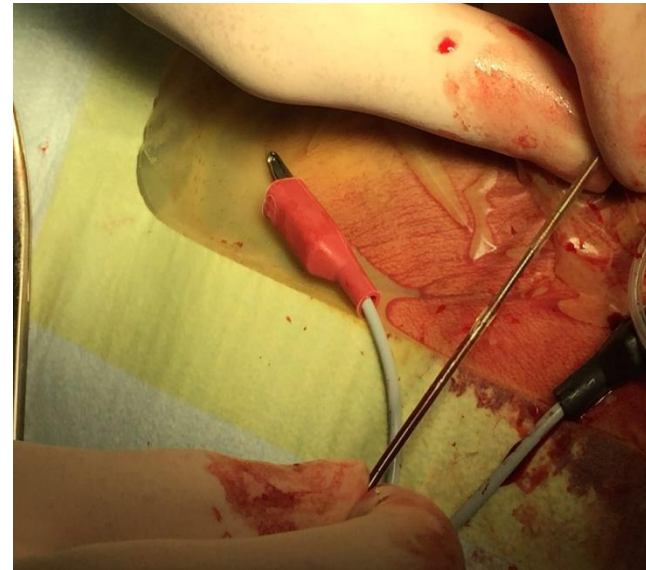


Preparatory Phase

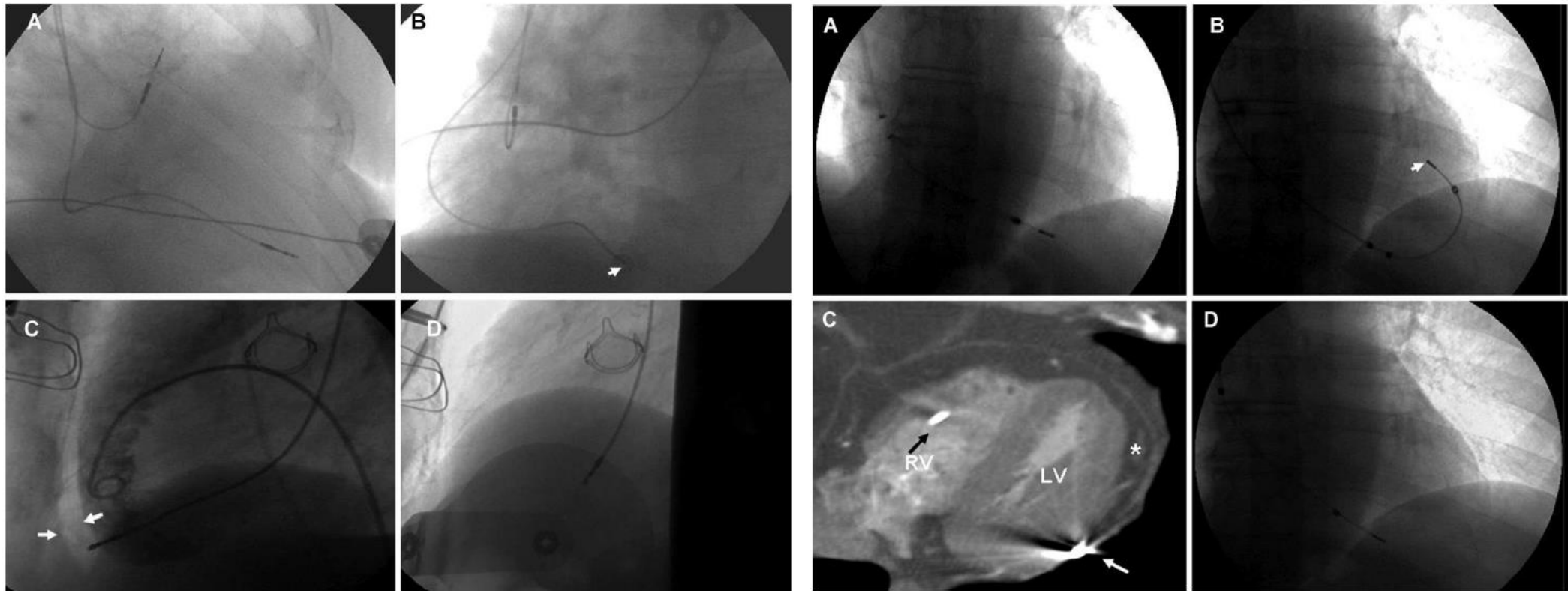
- Perform a comprehensive history and physical exam:
 - Perform anticoagulation management
 - Optimize hemodynamics
- Confirm the appropriate indications for extraction
- Perform the CIED interrogation:
 - Indicate lead model numbers, noting any lead that requires special consideration
 - Confirm lead implant dates
 - Identify prior abandoned leads and implant dates
 - Assess pacemaker dependency
 - Turn off rate-adaptive programming
- Obtain the preprocedural imaging when clinically appropriate. Options include the following:
 - Chest radiography (both posteroanterior and lateral) to assess lead position, identify the presence of abandoned leads, and confirm lead type
 - Echocardiogram to assess LV function, identify intracardiac masses/vegetations, evaluate valve function and whether a patent foramen ovale is present, and identify intracardiac lead course and presence of pleural or pericardial effusions
 - Cardiac CT to assess extravascular or extracardiac lead positioning and potentially identify sites of venous adhesions
 - Fluoroscopy to identify sites of venous occlusion or stenosis and assess regions of lead mobility and adherence
- Define the extraction approach and procedure goals:
 - Percutaneous vs open extraction
 - Hybrid approach to the extraction
 - Goal of single vs multiple lead removal or complete system removal
 - Minimizing damage to nontargeted leads
- Determine the postextraction plan:
 - Indications for CIED reimplantation
 - Timing of CIED reimplantation
- Obtain the patient's informed consent

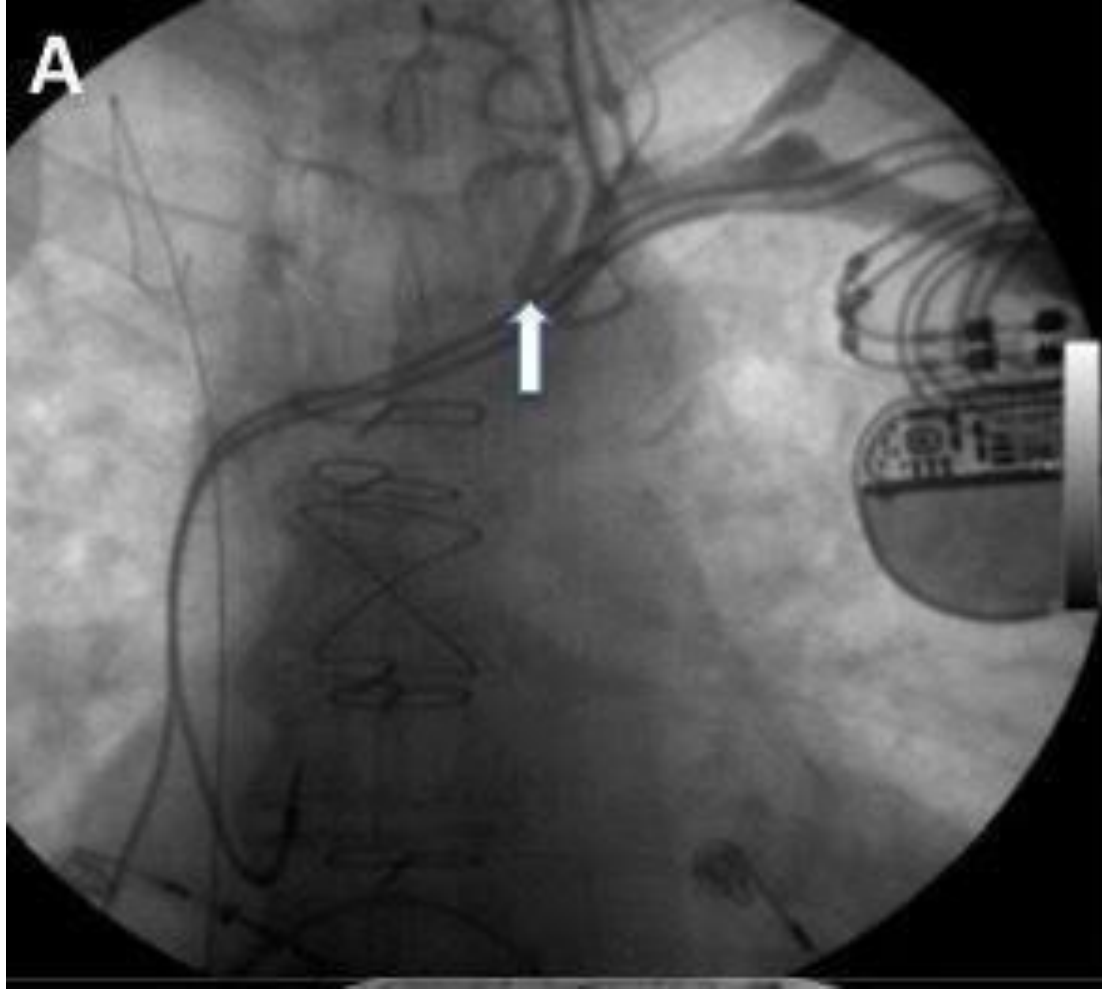


Migliore F, Curnis A, Bertaglia E. J Cardiovasc Med 2016;17:309-13




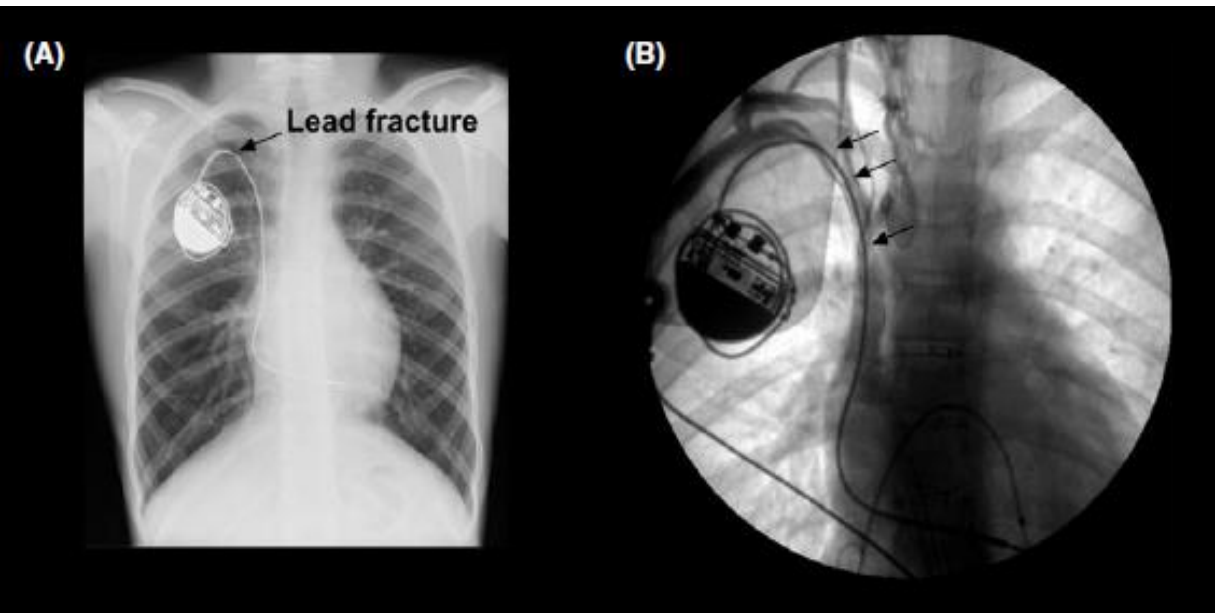
Incidence, Management, and Prevention of Right Ventricular Perforation by Pacemaker and Implantable Cardioverter Defibrillator Leads





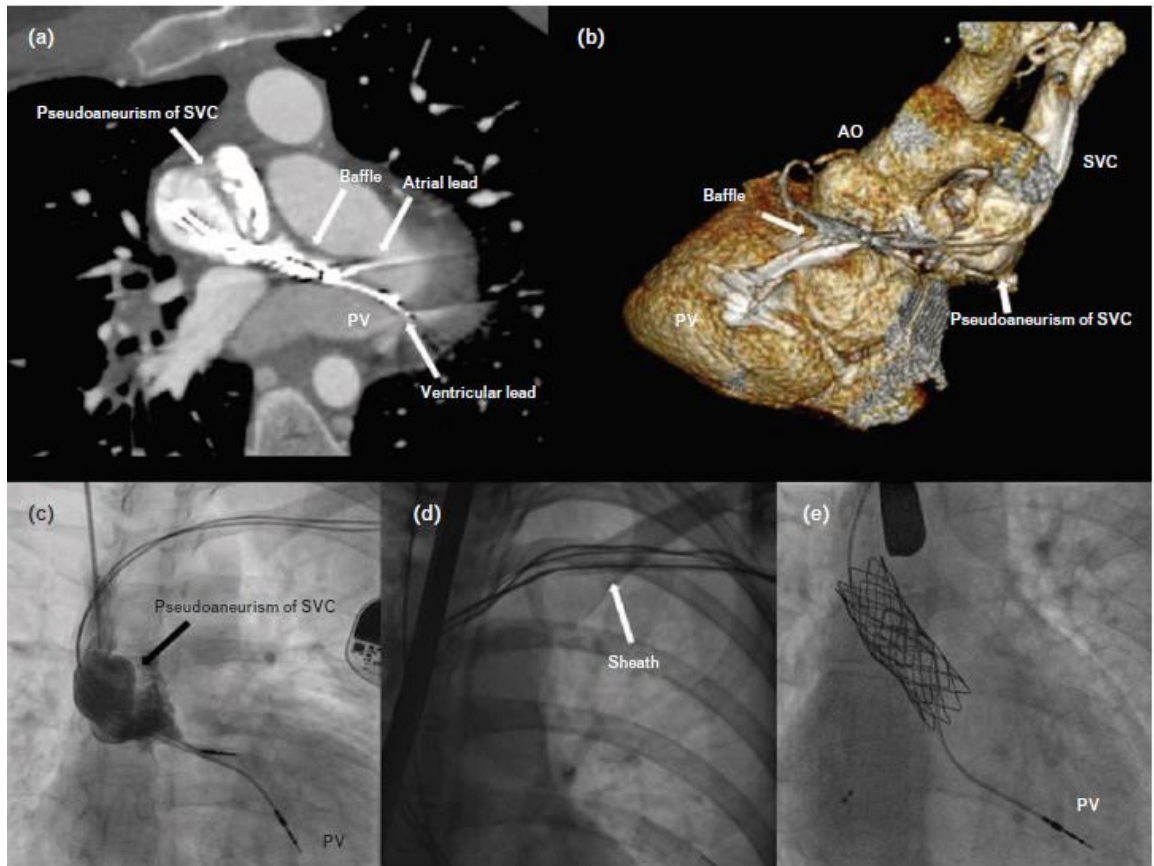
Effective and safe lead extraction using the bidirectional rotational Evolution[®] sheath in a child with congenital heart disease

Federico Migliore MD, PhD  | Alberto Cipriani MD | Sonia Ferretto MD | Dan Hadas MD | Sabino Iliceto MD | Loira Leoni MD, PhD



Successful transvenous mechanical lead extraction and stent implantation in a patient after Mustard palliation for D-transposition of great arteries and superior vena cava syndrome

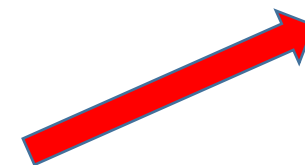
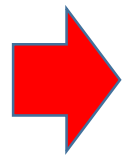
Federico Migliore^a, Sonia Ferretto^a, Biagio Castaldi^b, Nicola Maschietto^b and Loira Leoni^a



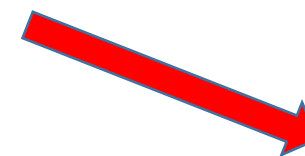
No Fever, Negative Blood Cultures: eco TEE ?



72 years-old, Female
CRT-D



Open Surgery



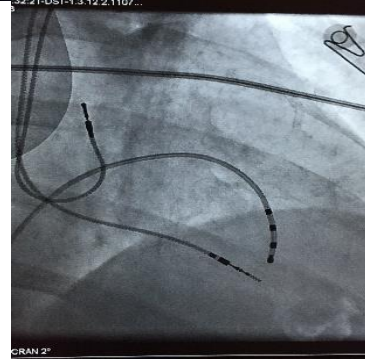
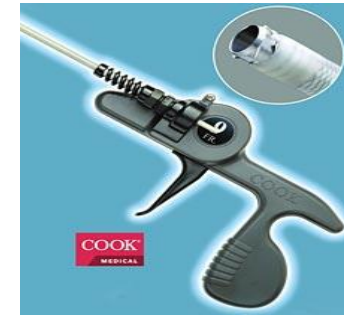
Transvenous Lead Extraction



Setting And Preparatory Phase

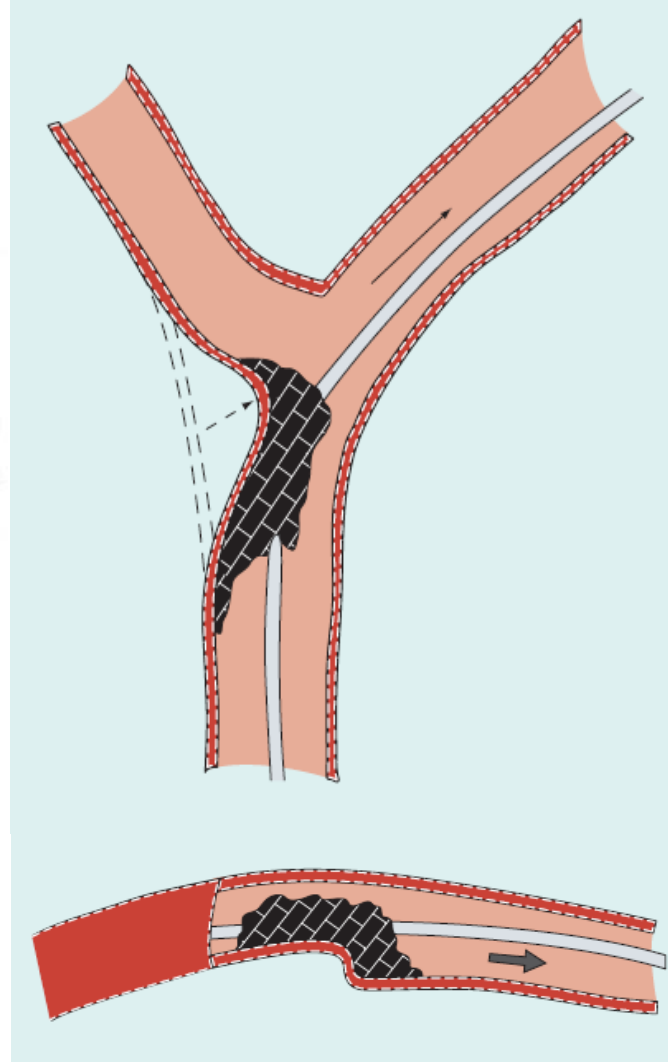
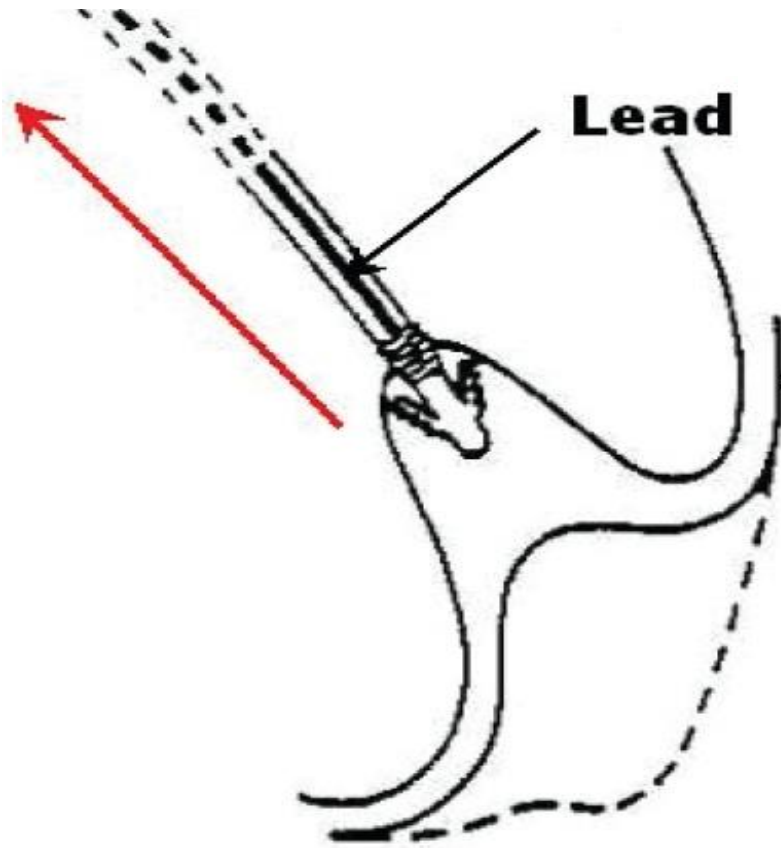
Required Facility and Equipment for Lead extraction Procedures

Facility/equipment	Description
Facility	Operating theatre or room or a cardiac catheter/EP lab
High-quality fluoroscopy	'Angiographic quality' equipment with image storage, either as an integral part of a lab or a mobile C-arm
Surgical instruments	Appropriate for transvenous lead extraction, device implantation, vascular repairs, thoracotomy, sternotomy, and cardio-pulmonary bypass—must be in good functional order and in the room or immediately available
Extraction tools	Depending on the operator(s) preferences, a selection of extraction stylets, sheaths, and femoral tools
CIED implantation tools	All standard implantation equipment as well as a variety of stylets, guidewires, wrenches, lead end caps
Echocardiography	'On-line' during the procedure for immediate use
Drainage sets	For emergency pericardiocentesis and for drainage of haemothorax
Temporary pacing	Venous sheath for temporary pacing electrode placement



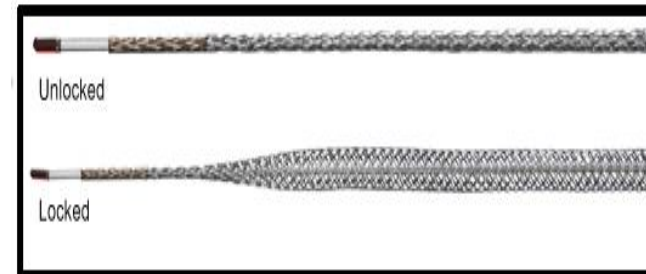
Which Technique ?

Manual Traction



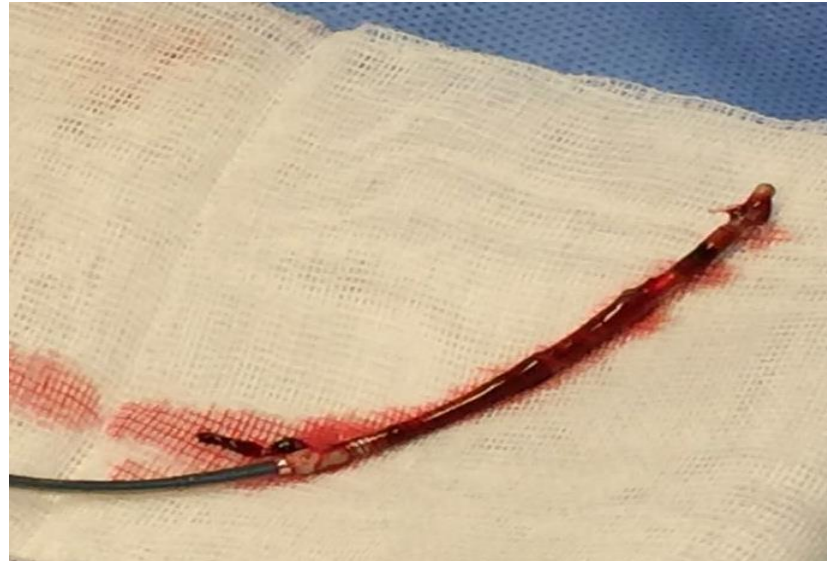
Locking Stylet Device

- ◆ Provides stable traction by locking along the entire contacted lead lumen
- ◆ Can be unlocked and repositioned

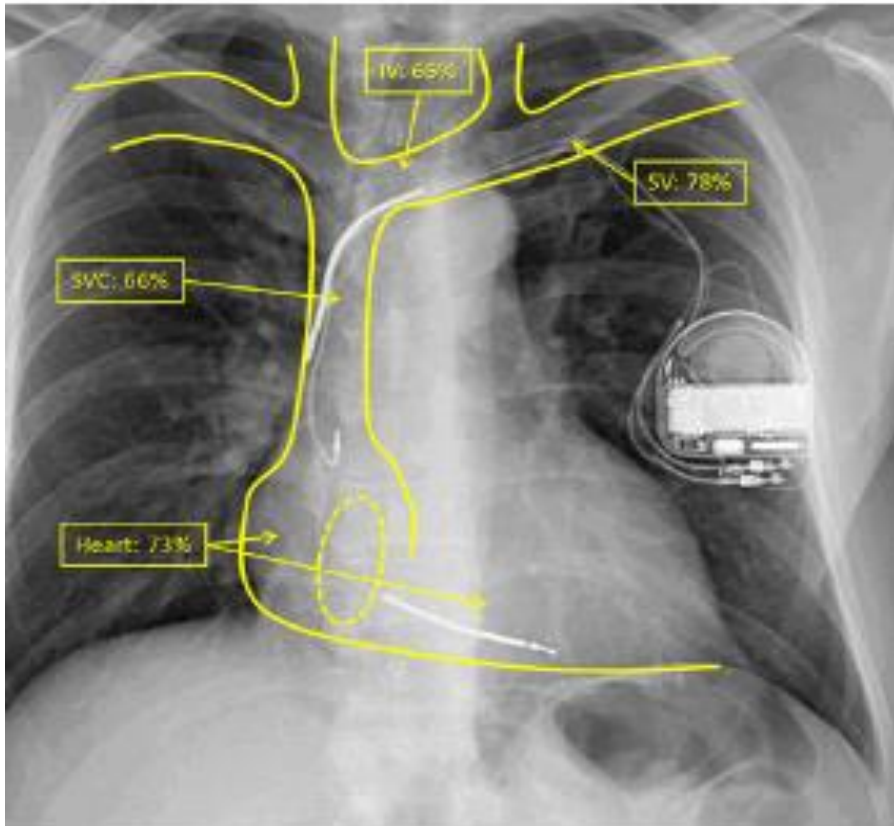


Chronically implanted leads develop fibrous adherences

Although *manual traction* is an effective technique for removing recently implanted leads, chronically implanted leads develop fibrous adherences around surrounding structures and *require additional extraction tools*



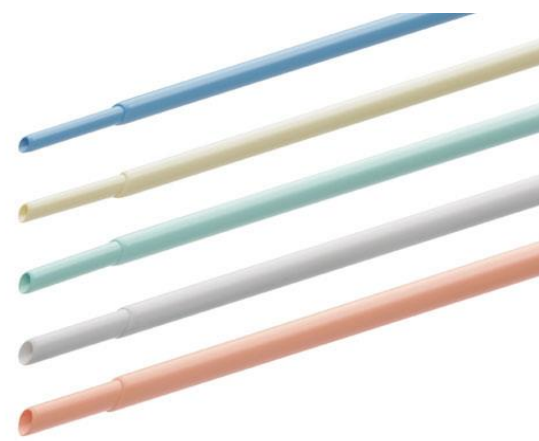
Location and Rate of Fibrous Adherences



	Univariate analysis		Multivariate analysis	
	OR (95% CI)	P value	OR (95% CI)	P value
Male gender	0.81 (0.36-1.80)	.617	—	—
Age	0.99 (0.97-1.01)	.632	—	—
Body mass index	1.02 (0.92-1.14)	.636	—	—
Creatinine	1.00 (0.49-2.01)	.994	—	—
Previous cardiac surgery	1.06 (0.41-2.70)	.899	—	—
Time from implant	1.10 (1.06-1.14)	<.001	1.10 (1.06-1.14)	<.001
No. of cardiac leads	0.80 (0.60-1.07)	.139	—	—
Removal for infection	1.24 (0.63-2.43)	.532	—	—
Passive fixation	6.01 (3.07-11.74)	<.001	3.25 (1.41-7.53)	.006
Lead size	1.55 (1.15-2.09)	.001	1.15 (0.77-1.72)	.480
Dual coil	4.50 (2.41-8.41)	<.001	2.94 (1.27-6.78)	.011
No expandable polytetrafluoroethylene-coated coil/medical adhesive back-filled coil	5.80 (3.07-10.96)	<.001	1.82 (0.79-4.19)	.156
Subclavian access	1.19 (0.55-2.54)	.661	—	—
Right-sided implantation	0.23 (0.10-0.51)	.001	0.66 (0.22-1.98)	.460

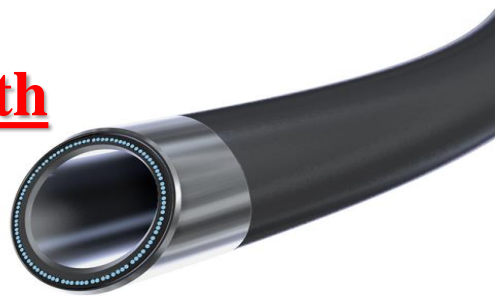
Tools & techniques for lead extraction

Mechanical Extraction Sheath

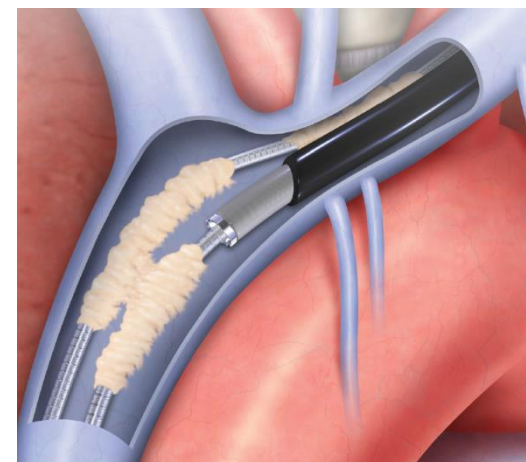


Telescopic Mechanical Sheaths, Cook Medical

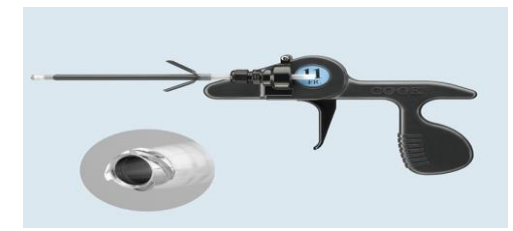
Powered Extraction Sheath



Laser, Spectranetics



Mechanical Rotational Sheaths



Mechanical Sheath ,Evolution Cook Medical



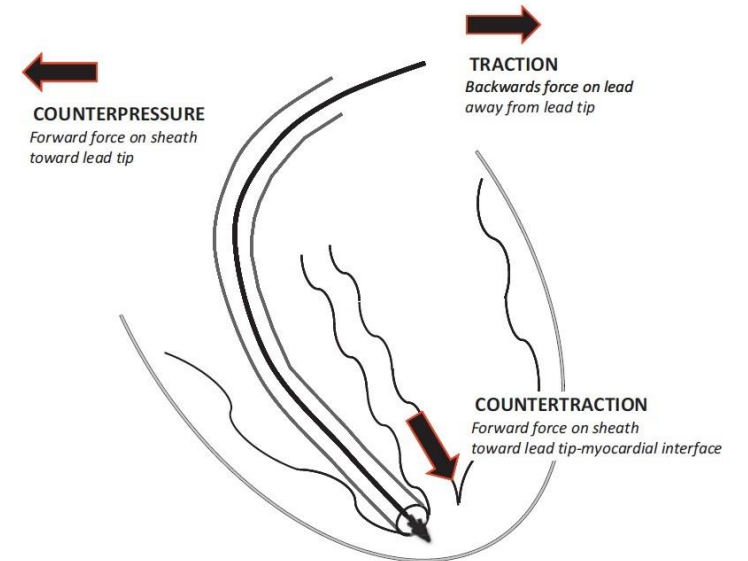
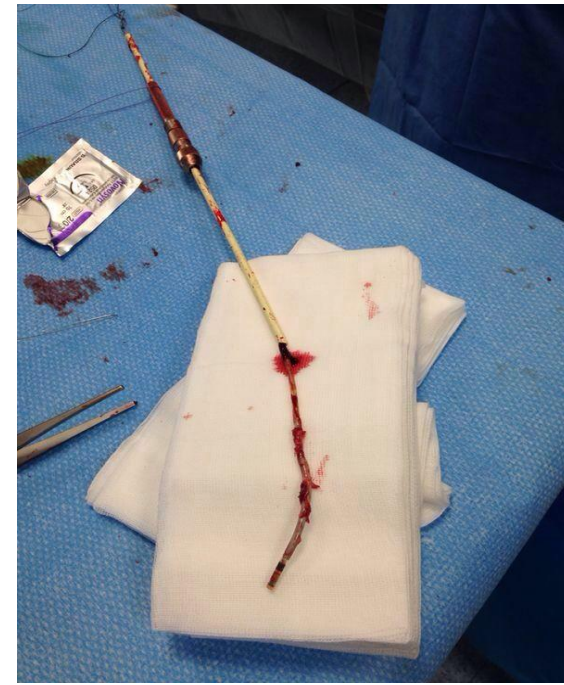
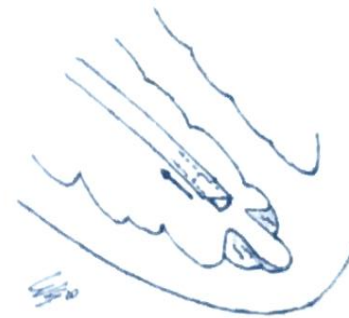
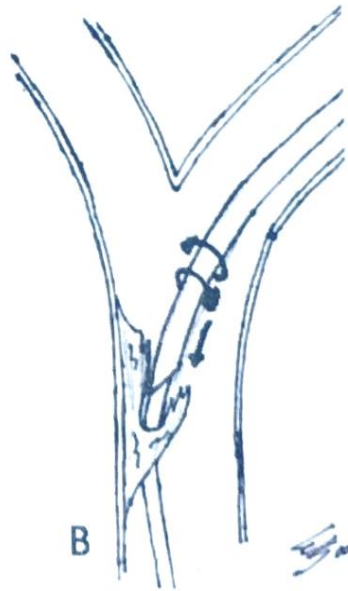
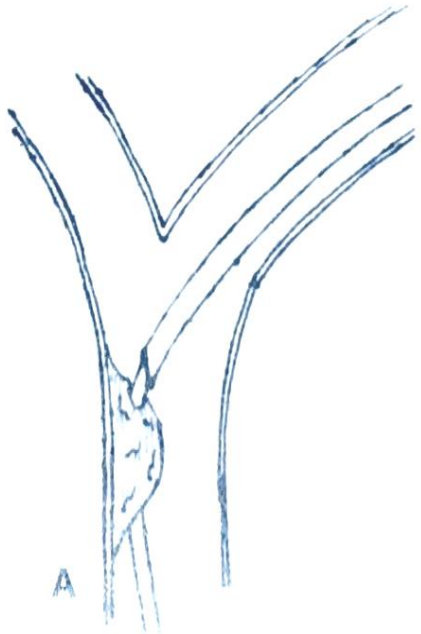
Mechanical Sheath ,RL Evolution Cook Medical



Mechanical Sheath, TightRail, Spectranetics

Mechanical Extraction Sheath

Progressive dissection
and
mechanical dislodgement



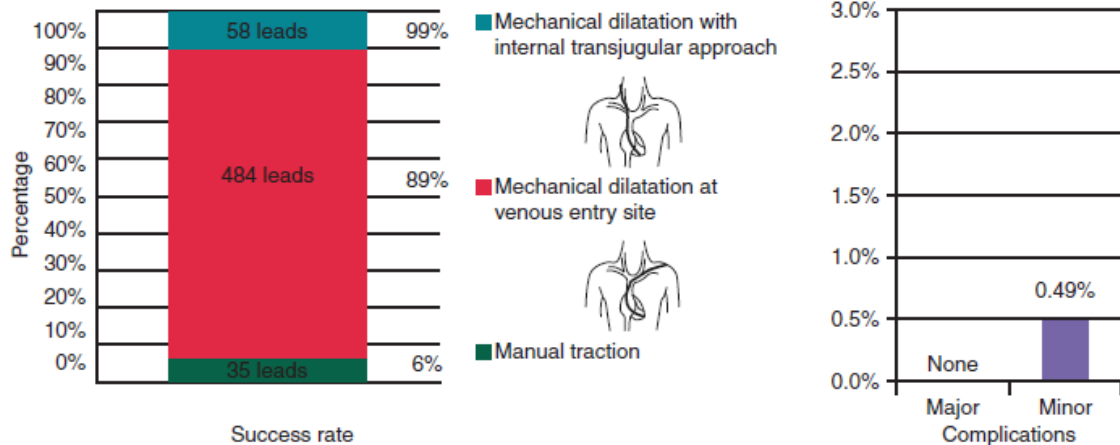
Transvenous removal of pacing and implantable cardiac defibrillating leads using single sheath mechanical dilatation and multiple venous approaches: high success rate and safety in more than 2000 leads

Maria Grazia Bongiorno*, Ezio Soldati, Giulio Zucchelli, Andrea Di Cori, Luca Segreti, Raffaele De Lucia, Gianluca Solarino, Alberto Balbarini, Mario Marzilli, and Mario Mariani

Safety and efficacy of internal transjugular approach for transvenous extraction of implantable cardioverter defibrillator leads

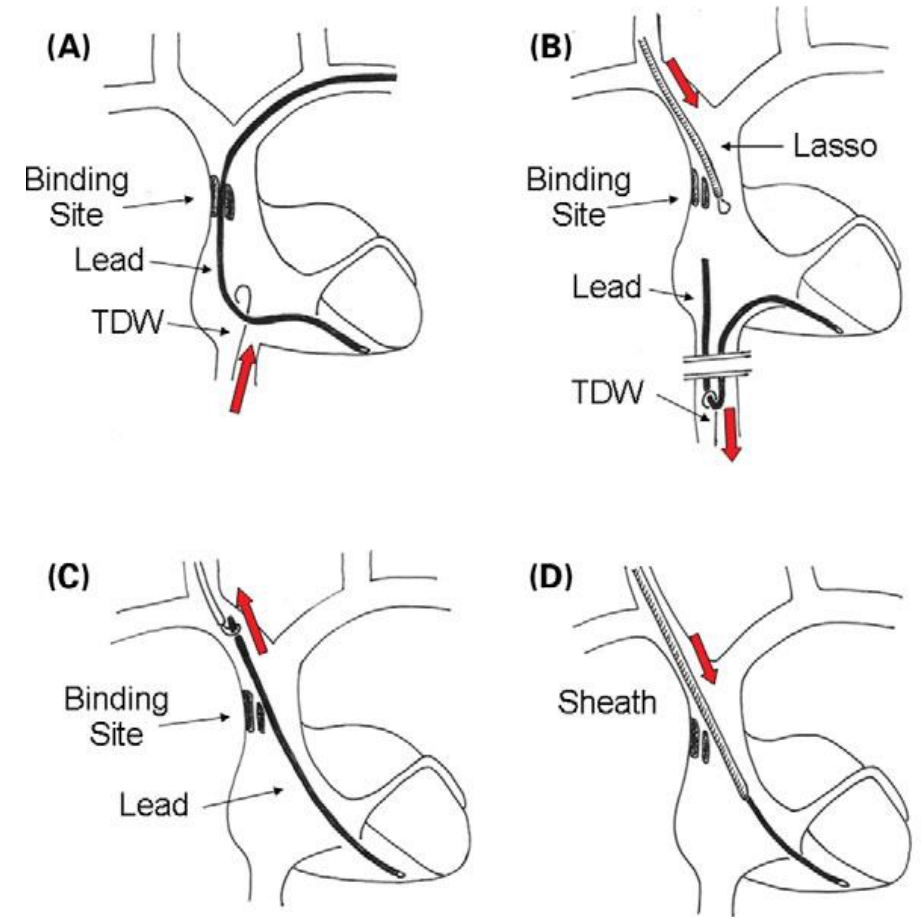
Maria Grazia Bongiorno*, Luca Segreti, Andrea Di Cori, Giulio Zucchelli, Stefano Viani, Luca Paperini, Raffaele De Lucia, Adriano Boem, Dianora Levorato, and Ezio Soldati

ICD lead extraction: outcome and approaches (582 leads — 545 patients)



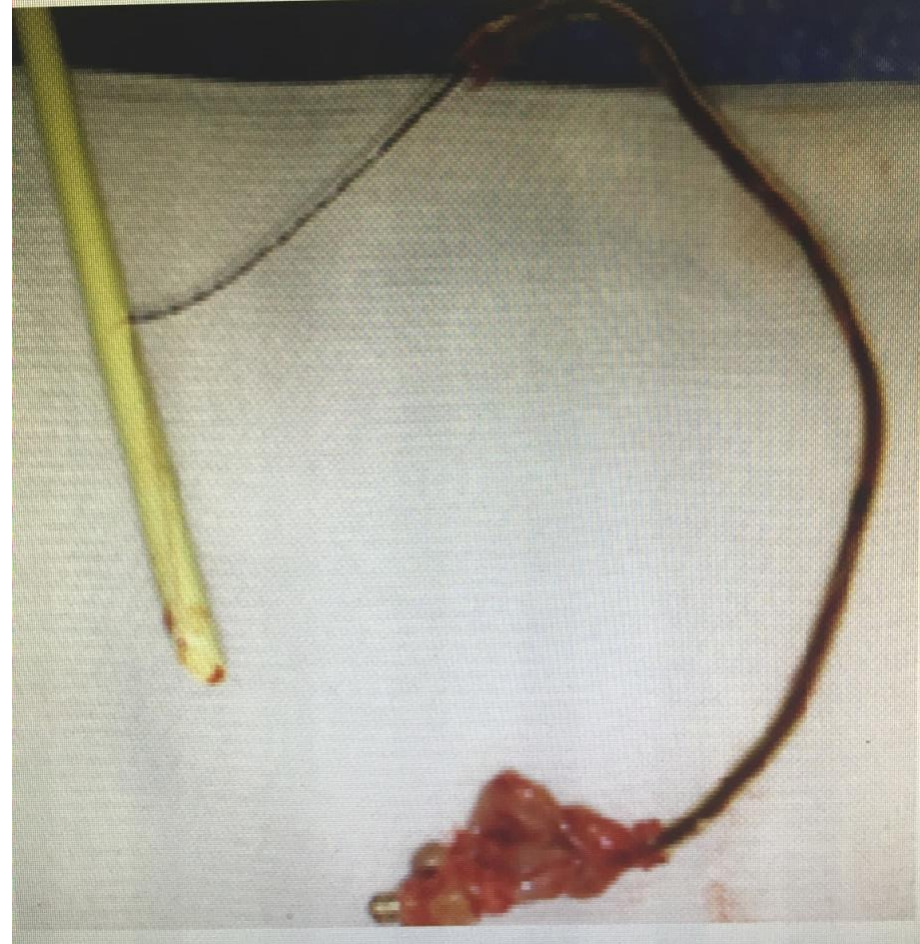
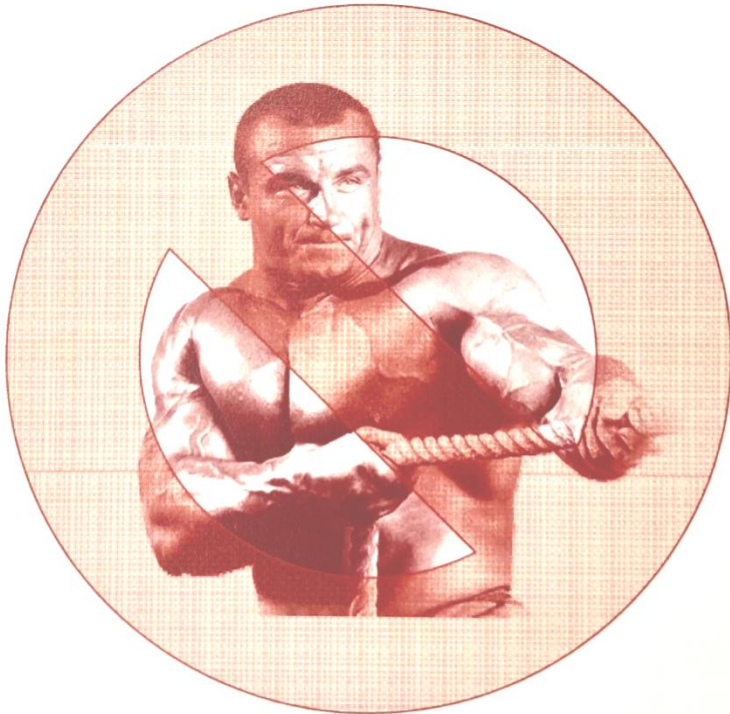
“The Pisa Approach”

Mechanical single-sheath technique with multiple venous entry-site approach
No locking stylet

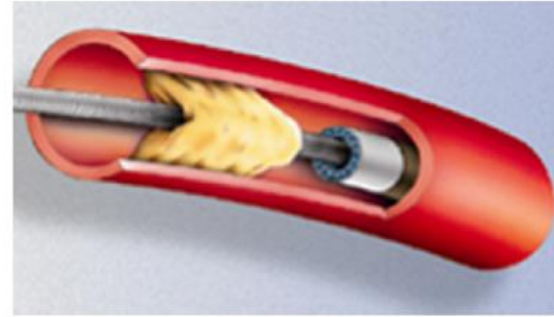
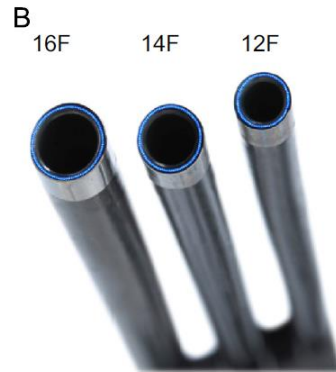


*European Heart Journal 2008;29;2886
Europace 2014;16;1356*

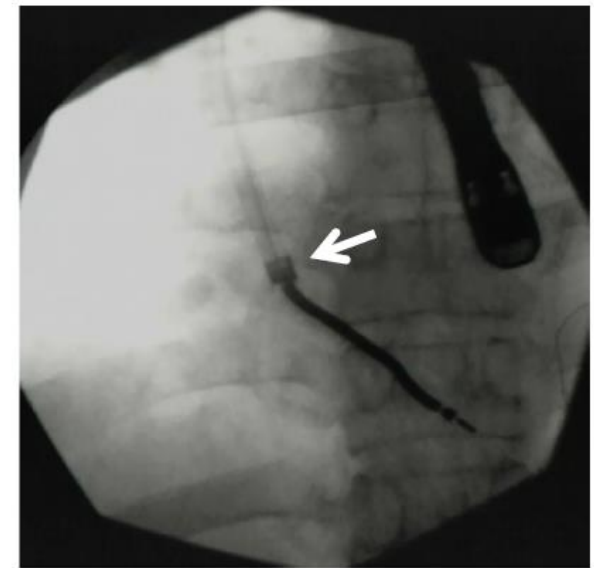
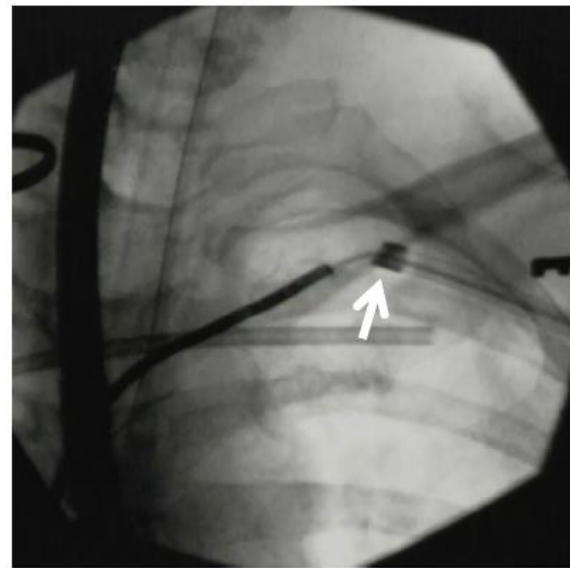
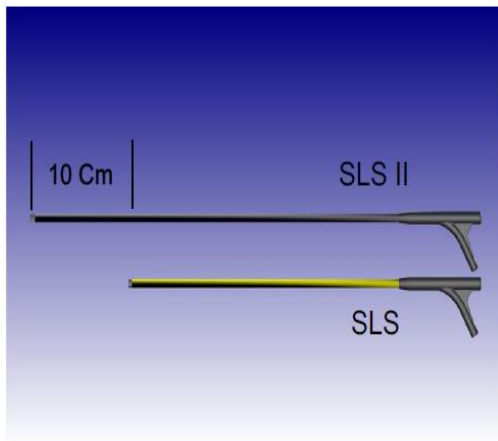
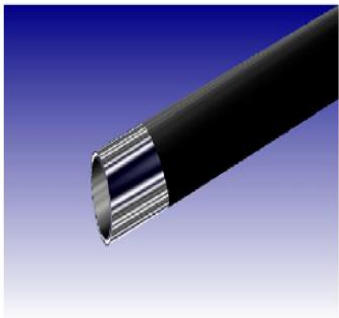
**There is no Place
for Strong Men !**



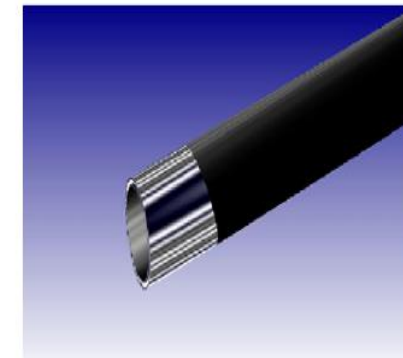
Laser Extraction Sheath



SLS II



Laser Extraction Sheath



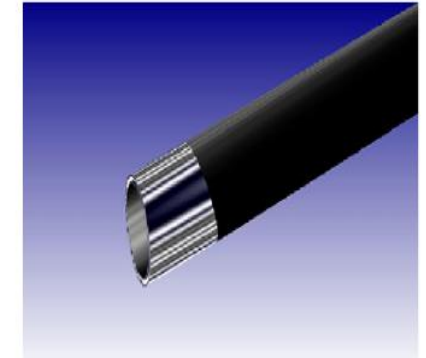
Pacemaker Lead Extraction With the Laser Sheath: Results of the Pacing Lead Extraction With the Excimer Sheath (PLEXES) Trial

	Nonlaser	Laser	p Value
Leads (n)	221	244	
Complete extraction*	142 (64%)	230 (94%)	< 0.001
Partial extraction	4 (1.8%)	6 (2.5%)	0.87
Failure*	75 (34%)	8 (3.3%)	< 0.001
Failed venous entry	14 (6%)	0	< 0.001
Binding site impasse	42 (19%)	3 (1.2%)	< 0.001
Lead disruption	14 (6%)	2 (0.8%)	0.003
Lead diameter	3 (1.4%)	0	0.21
Acute complication†	0	3 (1.2%)	0.28
Crossover to 12-F laser	72 (33%)	—	—
Crossover to 16-F laser	1 (0.5%)	—	—
Crossover to femoral	2 (0.9%)	5 (2.0%)	0.53
Clinical success of procedure (patients)	142 of 148 (95.9%)	145 of 153 (94.8%)	0.83

The mean time to achieve a successful lead extraction was significantly reduced for patients randomized to the laser tools (p<0.04)

Complication	Randomization	Result	Description
Tamponade	Laser	Thoracotomy, death	Laceration of the lateral right atrial wall produced cardiac tamponade and consequent death. The atrial lead was tightly bound by densely calcified scar tissue observed on chest radiography and fluoroscopy.
Tamponade	Laser	Thoracotomy	Laser removal of another lead was complete. Occurred during femoral tool removal of a lead not eligible for randomization due to preoperative retraction into the brachiocephalic vein.
Hemothorax	Laser	Chest tube	Laser sheaths had been advanced to the distal electrode and had been withdrawn. Polymer sheath advancement lacerated the SVC due to inadequate tension on the lead during counterpressure.
Valve damage	Laser	Medical treatment	Peripheral edema and severe tricuspid insufficiency were noted after a difficult and failed extraction with the laser and other tools.
Thrombosis	Nonlaser	Anticoagulation	SVC occlusion.
Thrombosis	Laser	Anticoagulation	Arm edema.
Thrombosis	Nonlaser	Observation	Arm edema.

Laser Extraction Sheath



Clinical Study of the Laser Sheath for Lead Extraction: The Total Experience in the United States

Radiographic Outcomes for 2,561 Leads

Radiographic Outcomes	
Complete success	90%
Partial success	3%
Failure	7%
Mean treatment time, minutes	15.7 ± 26 (0–300)
Tip freed by	
Traction	40%
Countertraction	46%
Other/unknown	14%
Reasons for failure	
Lead breakage	17
Impassable lead	12
Impassable binding site	35
Complications	29
Change of approach	50
Other	24

	n	%
Major		
Tamponade	23	1.4
Hemothorax	6	0.4
Pulmonary embolism	2	0.1
Migrating lead fragments	1	0.06
Subtotal: major	32	1.9
Minor		
Perforation	5	0.3
Myocardial avulsion	2	0.1
Venous avulsion	1	0.06
Other	15	0.9
Subtotal: minor	23	1.4
Any complication	55	3.3

Potential Limitation of Laser Sheath

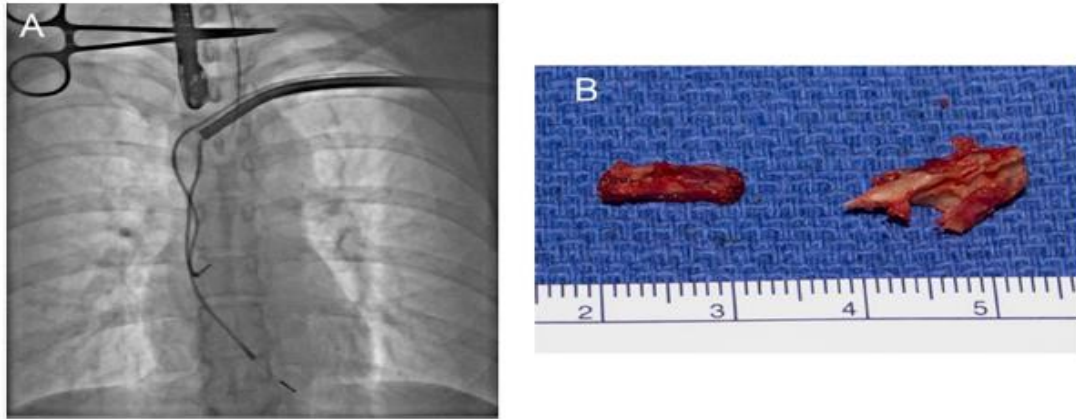


Fig. 1. A: Lead extraction using a rotating mechanical sheath. B: Bone-like tissue lodged in the sheath lumen.

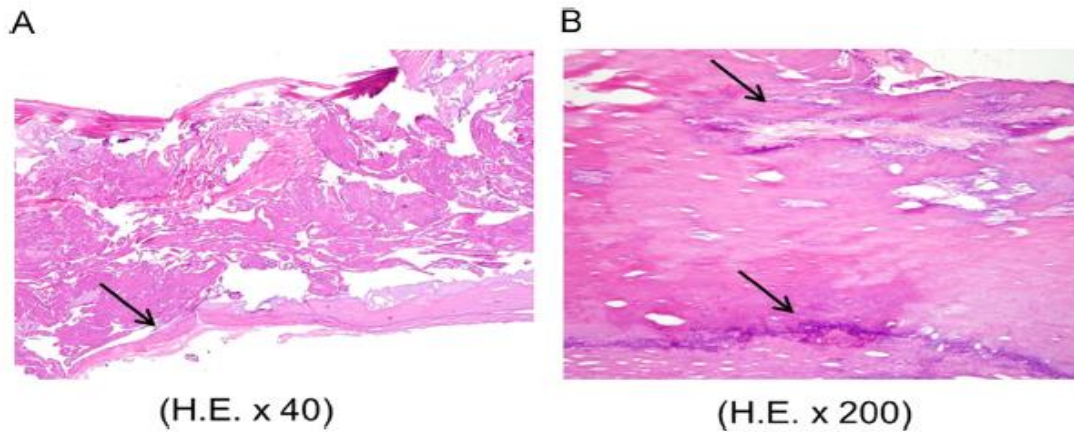
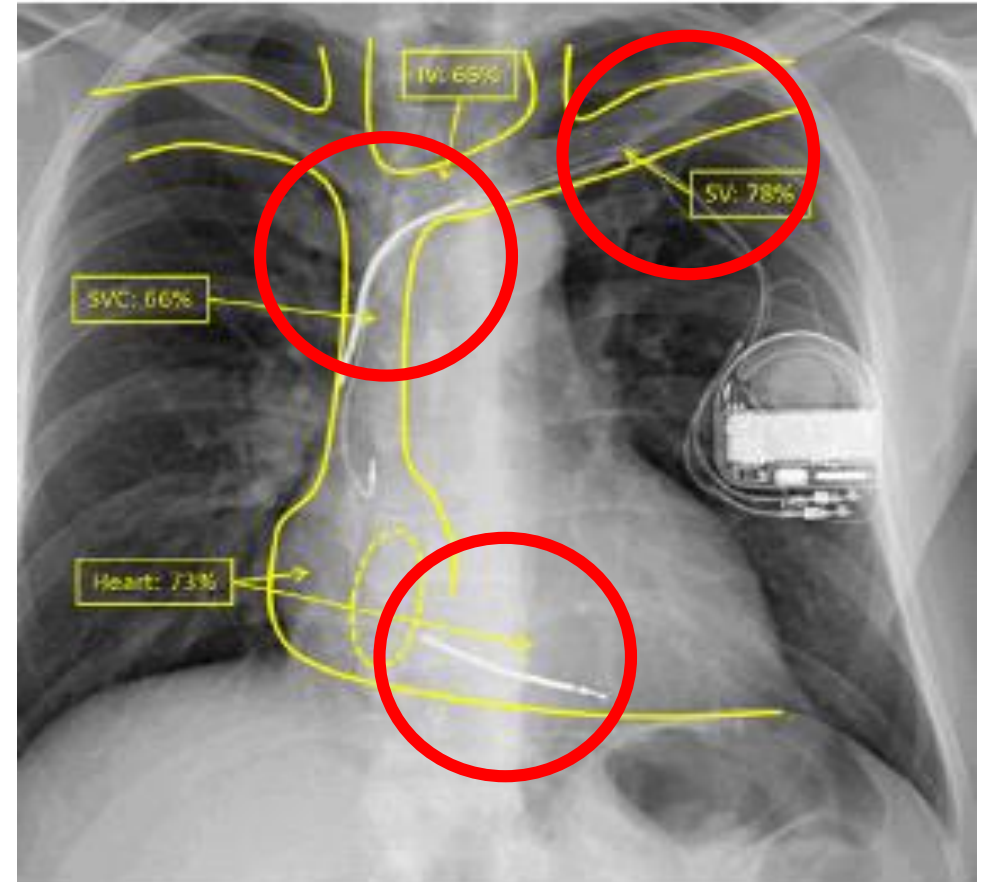
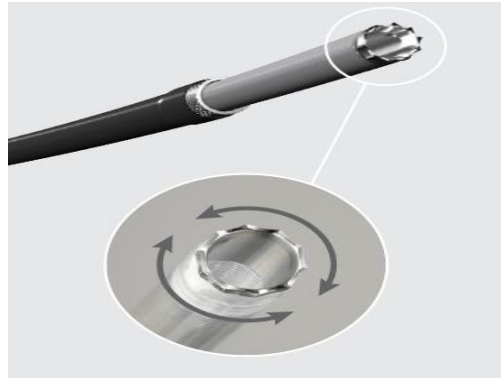


Fig. 2. Photomicrograph of the bone-like tissue stained by hematoxylin & eosin. A: $\times 40$. B: $\times 200$.

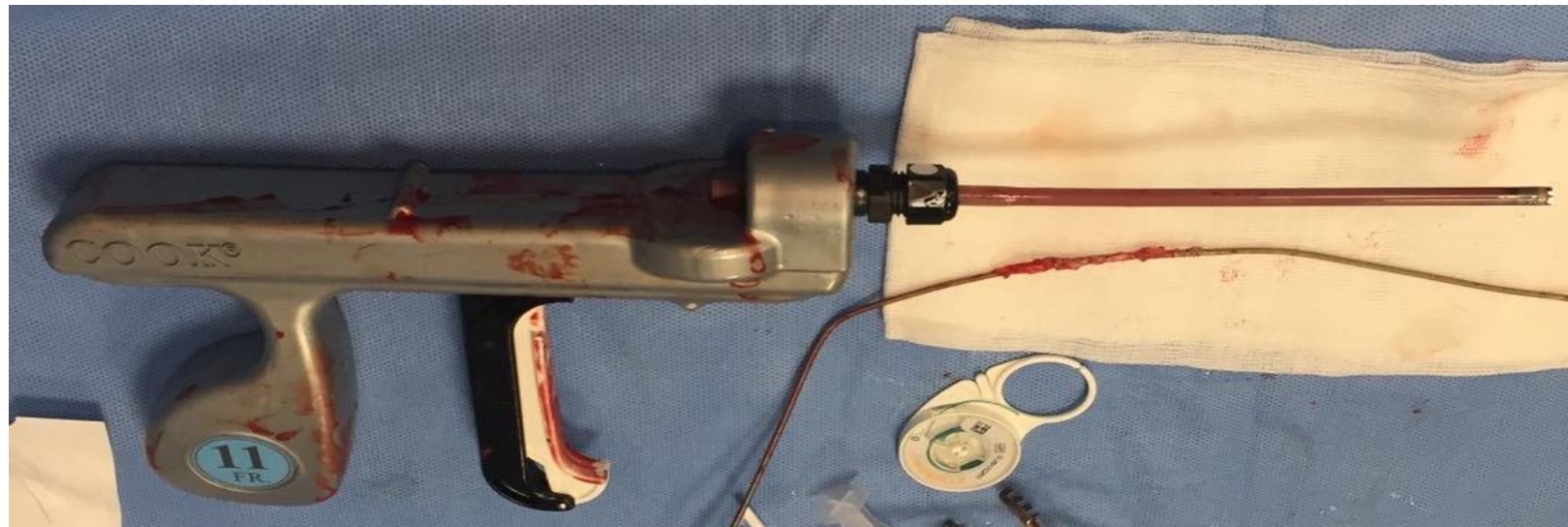
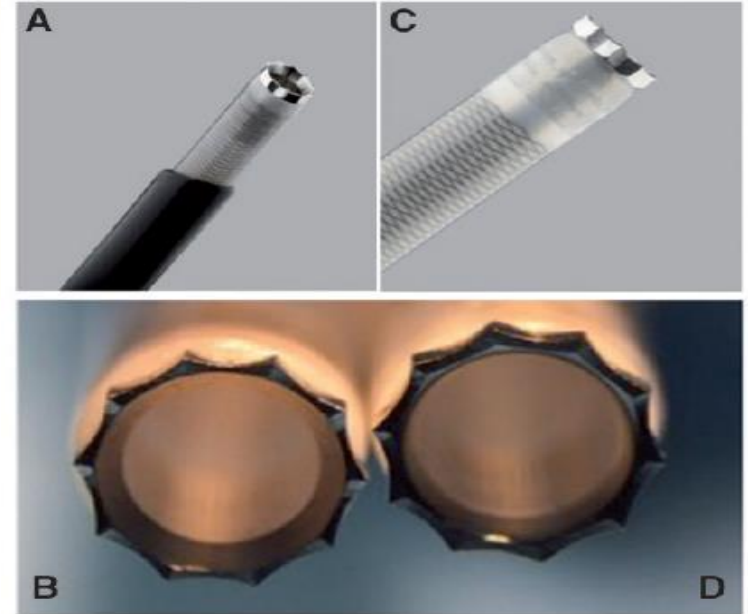
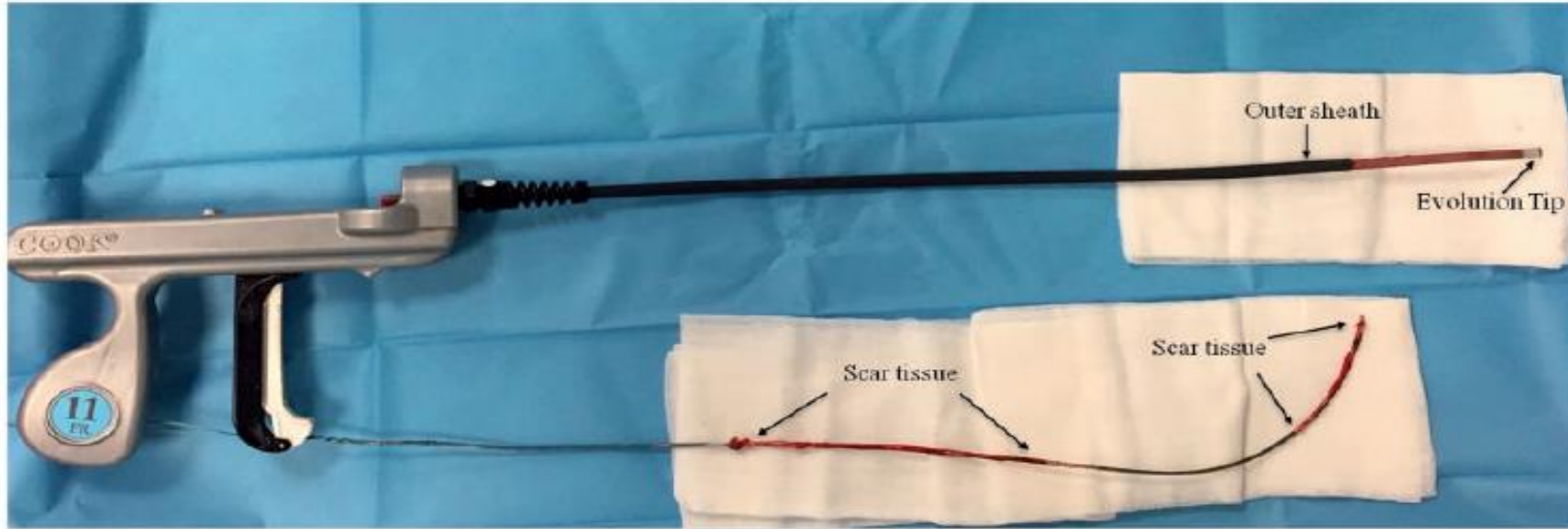


Powered Rotational Mechanical Extraction Sheaths

The New Bidirectional Rotational Evolution (Cook Medical) Mechanical Extraction Sheath



Powered Rotational Mechanical Extraction Sheaths



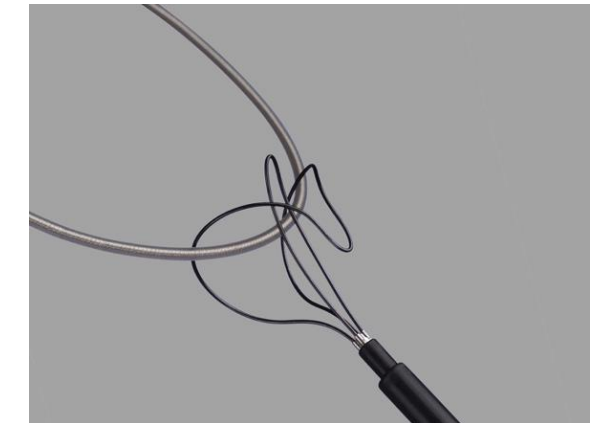
Powered Rotational Mechanical Extraction Sheaths

Safety and efficacy of the new bidirectional rotational Evolution[®] mechanical lead extraction sheath: results from a multicentre Italian registry

Patrizio Mazzone^{1†}, Federico Migliore^{2*†}, Emanuele Bertaglia², Domenico Facchin³, Elisabetta Daleffe³, Vittorio Calzolari⁴, Martino Crosato⁴, Francesco Melillo¹, Francesco Peruzza², Alessandra Marzi¹, Nicoleta Sora¹, and Paolo Della Bella¹



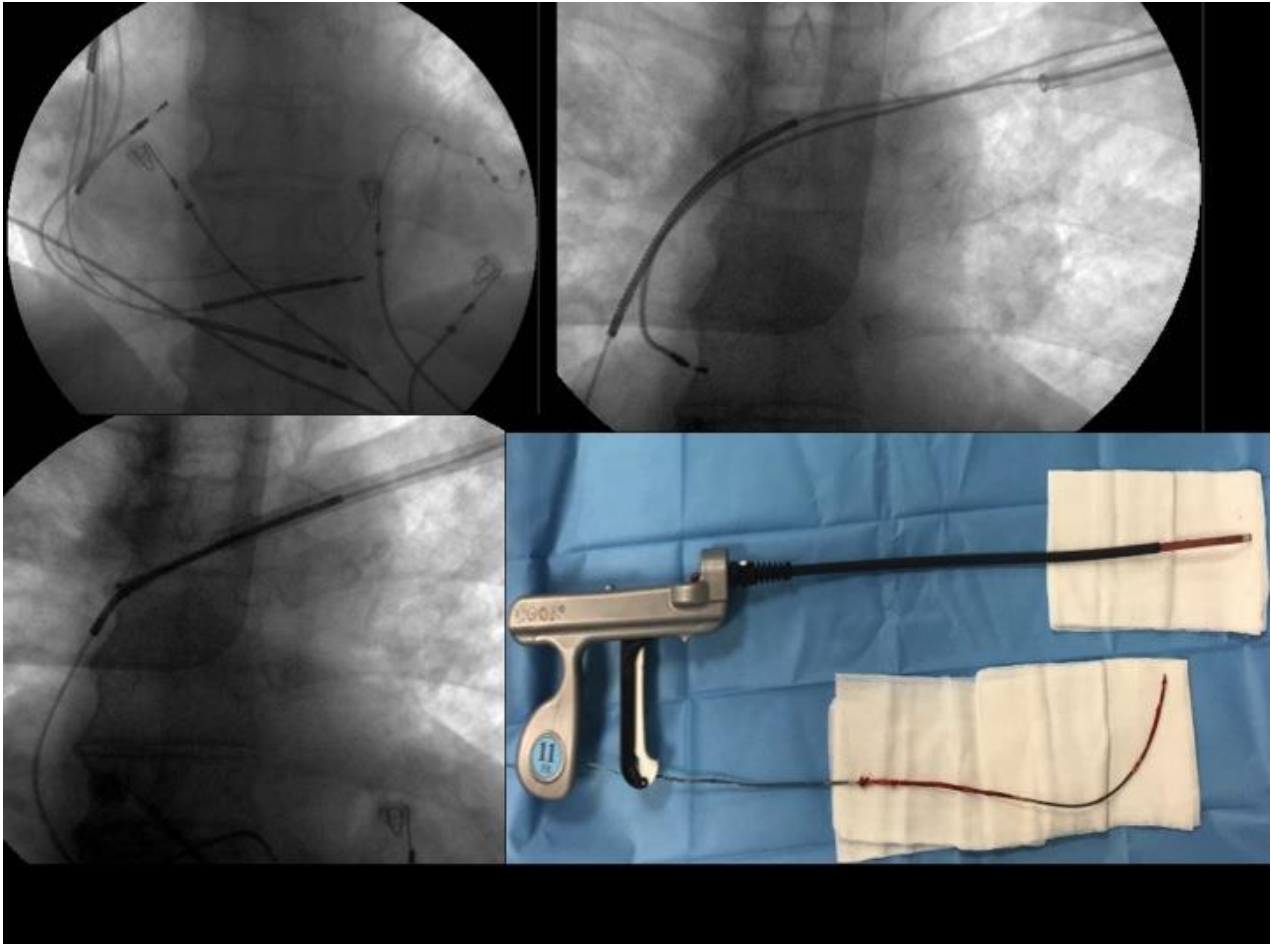
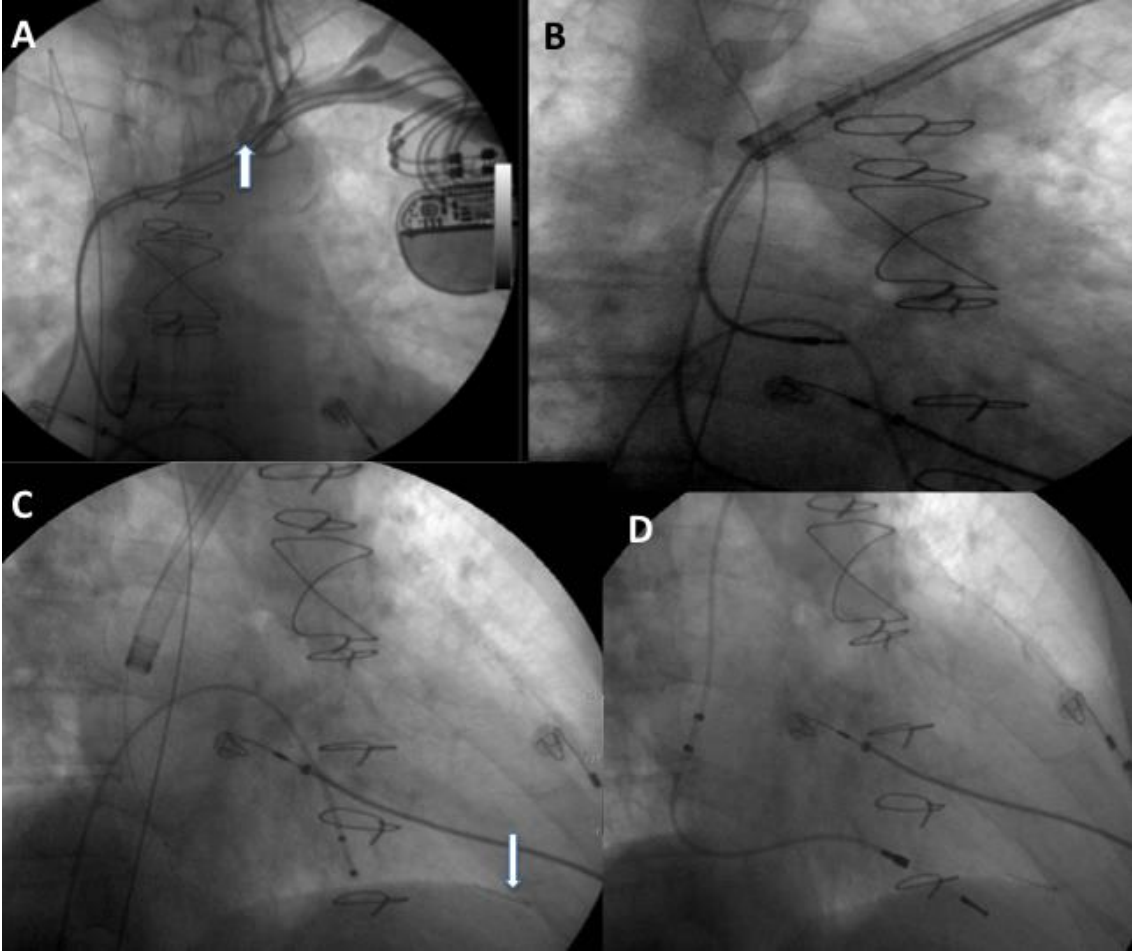
91.6% of the leads (218/238) were extracted completely with the Evolution RL alone



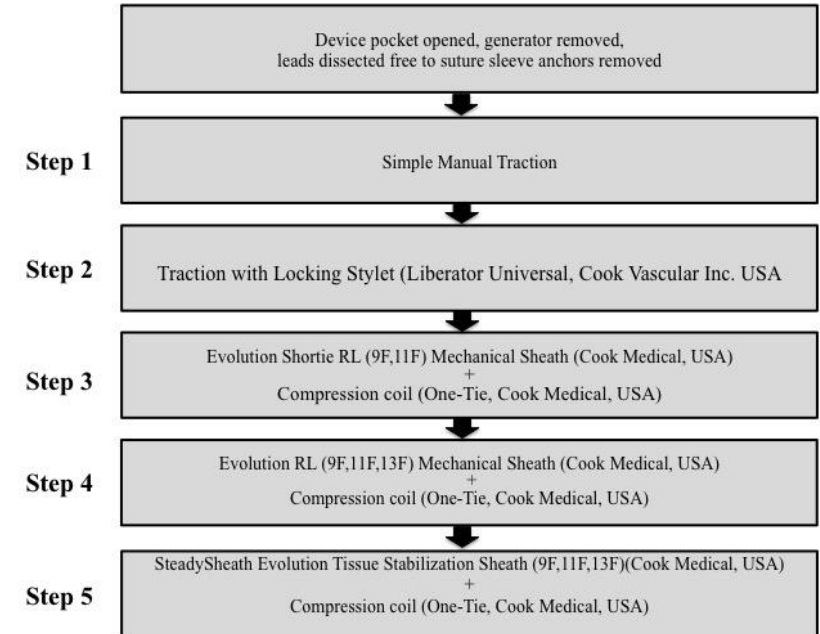
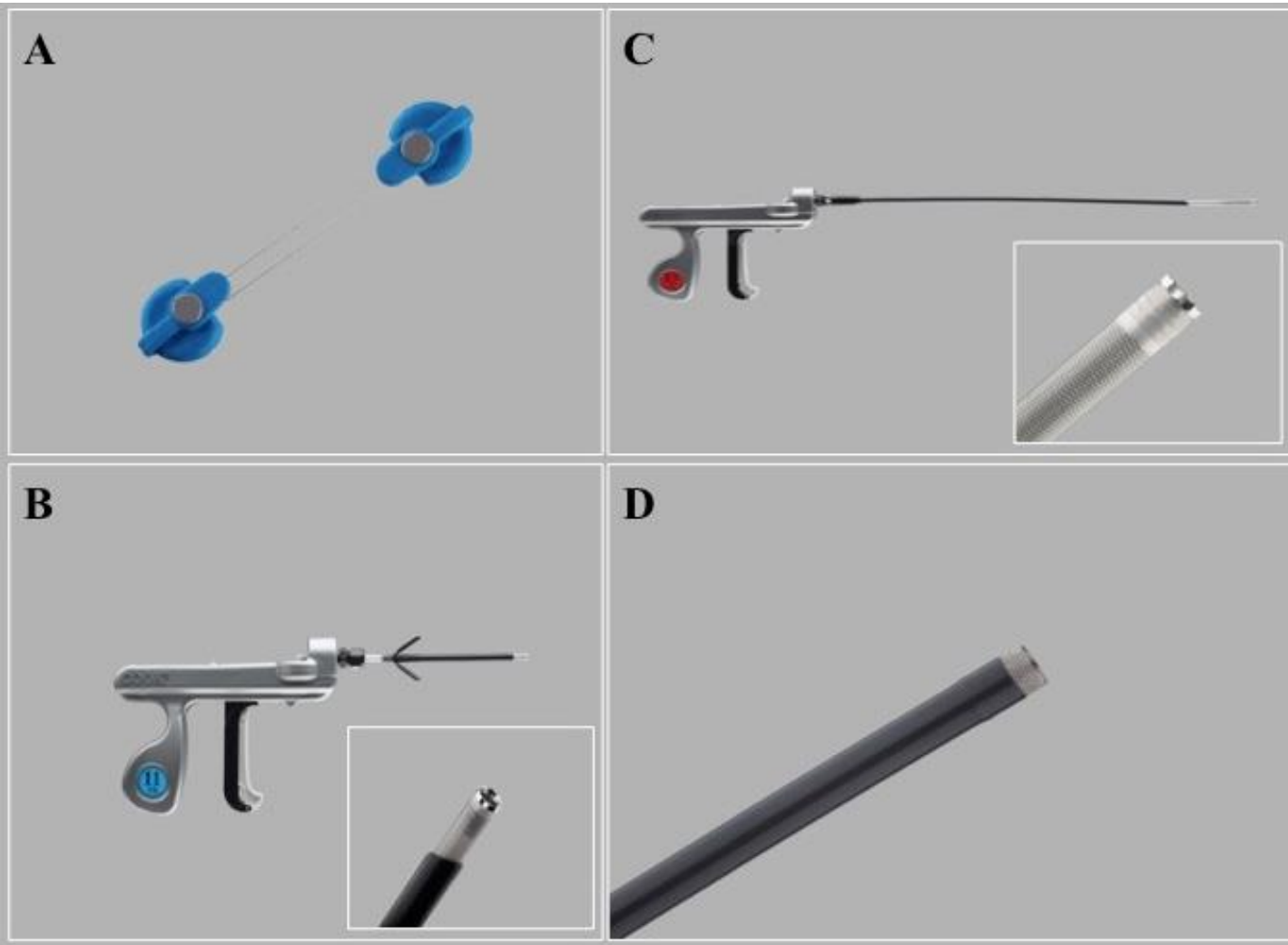
Use of a snare was required for six patients (seventeen leads; **7%**)

Number of leads extracted with Evolution RL sheath, <i>n</i>	238		
Mean number of leads extracted per patient ± SD, range	1.92 ± 0.44 (1–3)	Clinical success, <i>n</i> (%)	100%
➔ Mean implant duration ± SD, range (months)	92.2 ± 52.9 (12–336)	Complete procedural success per lead/per patient, <i>n</i> (%)	235/238 leads (98.7%)/121/124 (97.6%)
Distribution of lead implant duration (months), <i>n</i> (%)		Minor complications, <i>n</i> (%)	5 (4%)
12–24	11/238 (4.6%)	Major complication, <i>n</i> (%)	0
24–48	26/238 (11%)	Dilator sheath diameter, <i>n</i> (%)	
48–72	60/238 (25.2%)	9 F	36 (15%)
72–96	49/238 (20.5%)	11 F	191 (80%)
96–120	29/238 (12.2%)	13 F	16 (7%)
>120	63/238 (26.5%)		
➔ Passive fixation, <i>n</i> (%)	135 (56.3%)		
Lead type, <i>n</i> (%)			
Right atrium	86 (36.1%)		
Right ventricle	38 (16%)		
Coronary sinus	23 (9.7%)		
➔ Defibrillator	91 (38.2%; 81 dual coil vs. 10 single coil)		

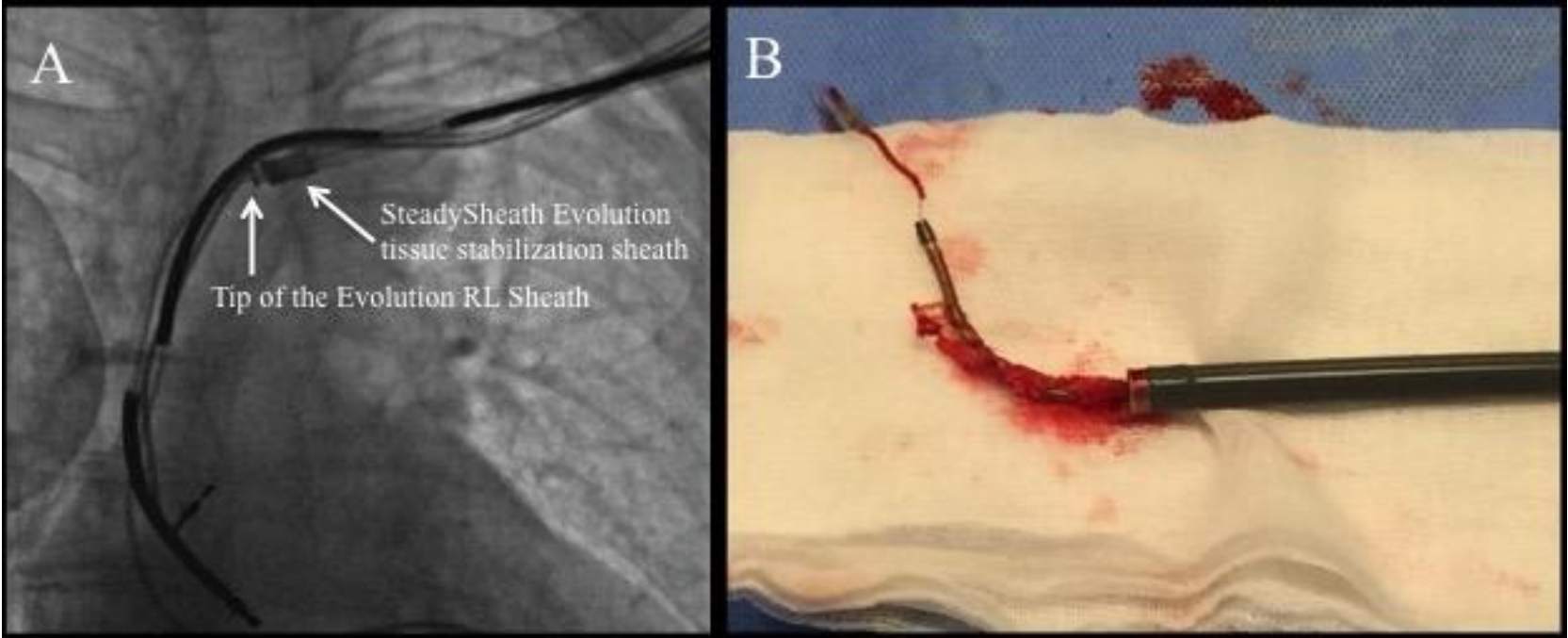
Powered Rotational Mechanical Extraction Sheaths



Mechanical Extraction Sheaths: stepwise approach with the available extraction tools

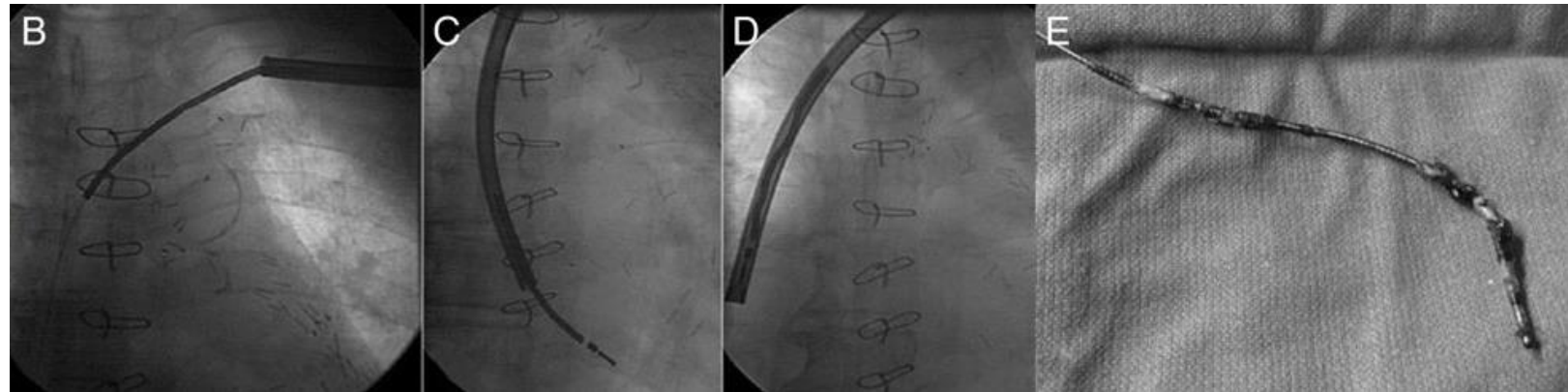


Complete procedural success rate (%)	192/198 (96.9%)
Clinical success rate (%)	196/198 (99%)
Lead removal with clinical success rate (%)	387/393 (98.4%)
Failure rate (%)	2/198 (1%)
Minor complications, n (%)	10 (5%)
Major complications, n (%)	1 (0.5%)



Initial experience with the TightRail™ Rotating Mechanical Dilator Sheath for transvenous lead extraction

Kudret Aytemir, Hikmet Yorgun, Uğur Canpolat*, M. Levent Şahiner, Ergün Barış Kaya, Banu Evranos, and Necla Özer



✓ **Complete procedural success** 95.7% patients (41/42 leads)

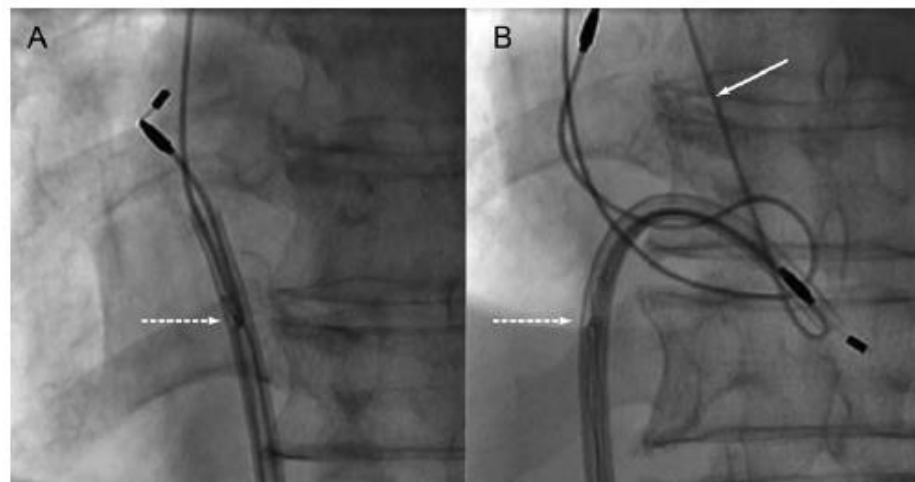
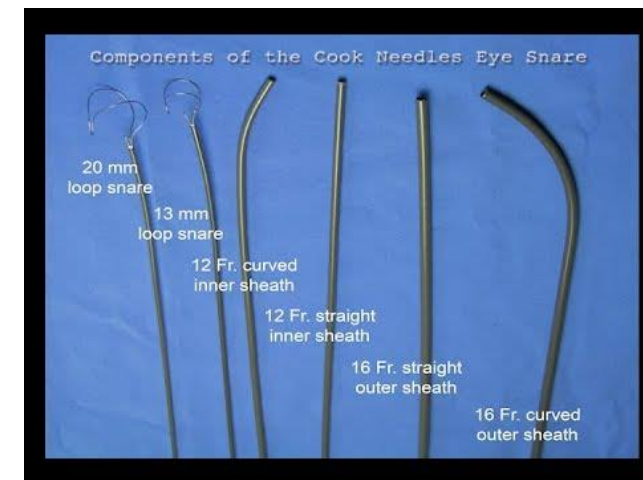
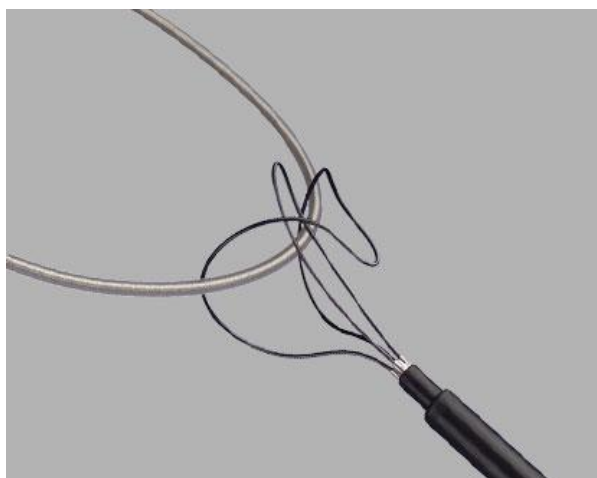
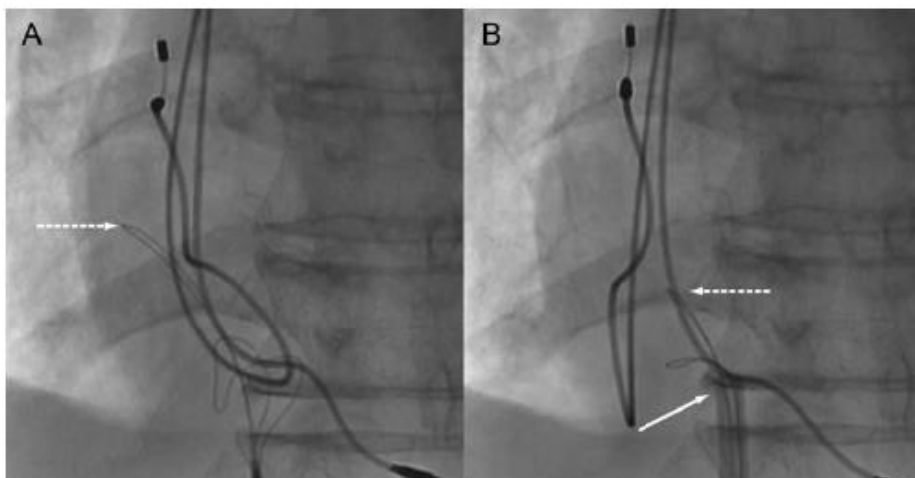
✓ **Clinical success** was 100%

While TightRail™ system has an **advantage** of more flexible shaft that follows the curvature of the lead and maintains alignment with the lead, such a property might be **disadvantageous** in severely calcified lesions

Femoral Snare

The Needle's Eye Snare as a primary tool for pacing lead extraction

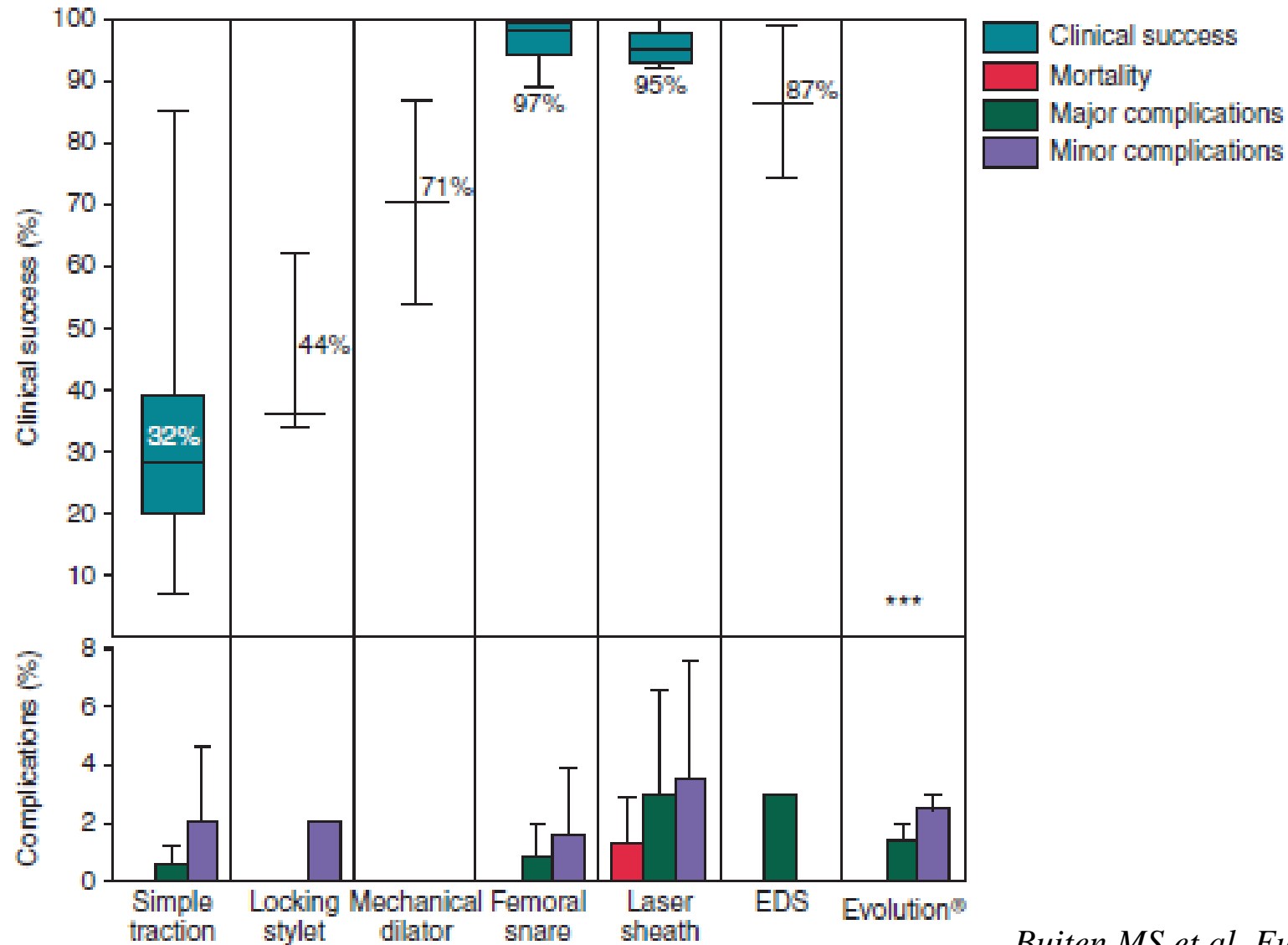
Frank A. Bracke*, Lukas Dekker, and Berry M. van Gelder



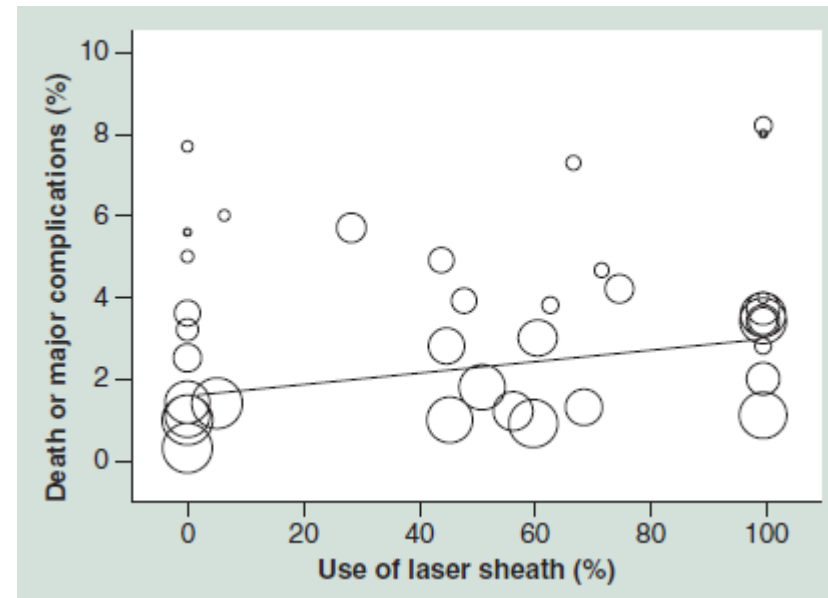
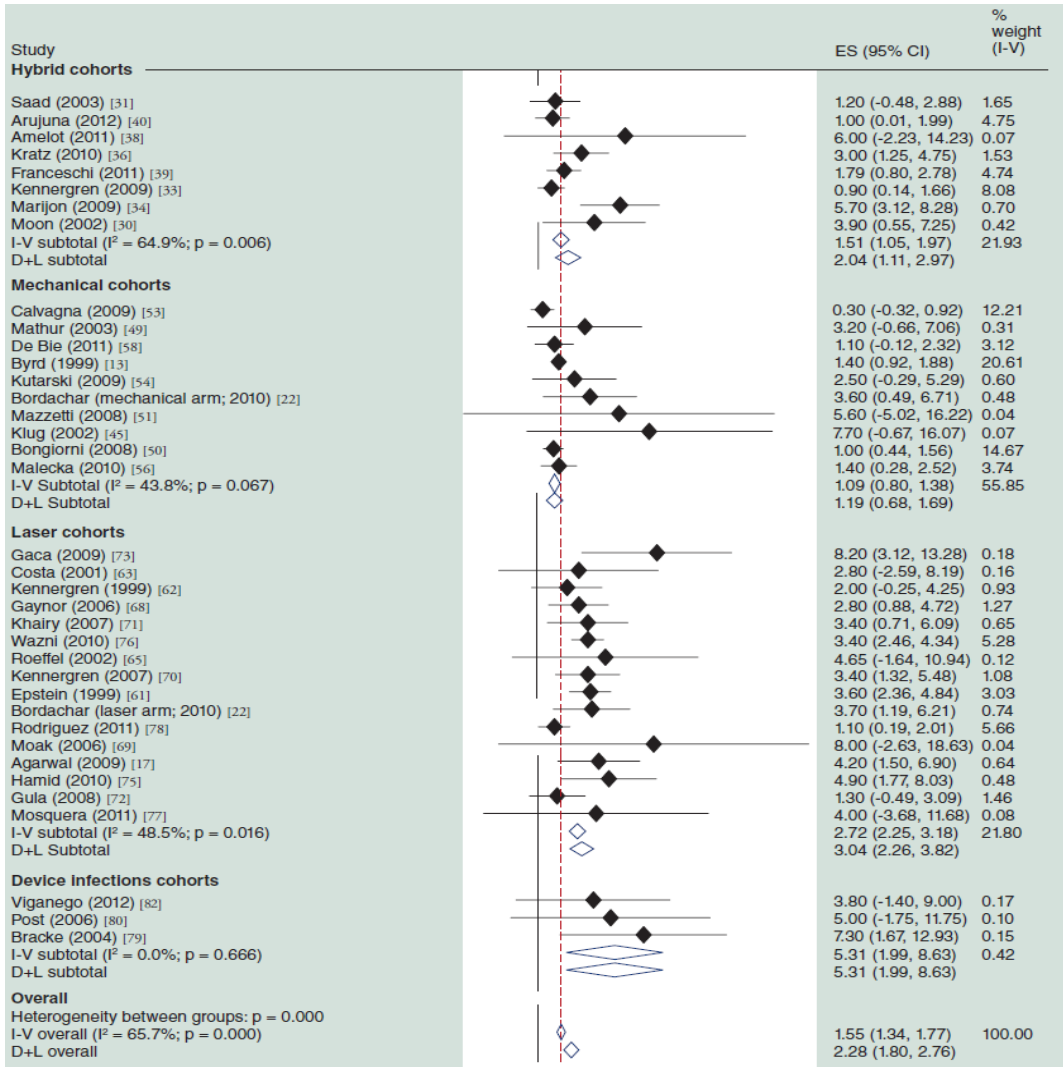
✓ Failure or partial extraction occurred in, respectively, 1.8 and 3.8% of all leads

✓ The overall clinical success rate was 98.2%

Clinical outcomes of different extraction methods



From lead management to implanted patient management: systematic review and meta-analysis of the last 15 years of experience in lead extraction



✓ Use of **laser sheath** was associated with **increased risk of major complications or death** (p = 0.029)

✓ while it was associated with **higher technical success** of extraction (p = 0.003)

Transvenous lead extractions: comparison of laser vs. mechanical approach

Christoph T. Starck^{1*}, Hector Rodriguez¹, David Hürlimann², Jürg Grünenfelder¹, Jan Steffel², Sacha P. Salzberg¹, and Volkmar Falk¹

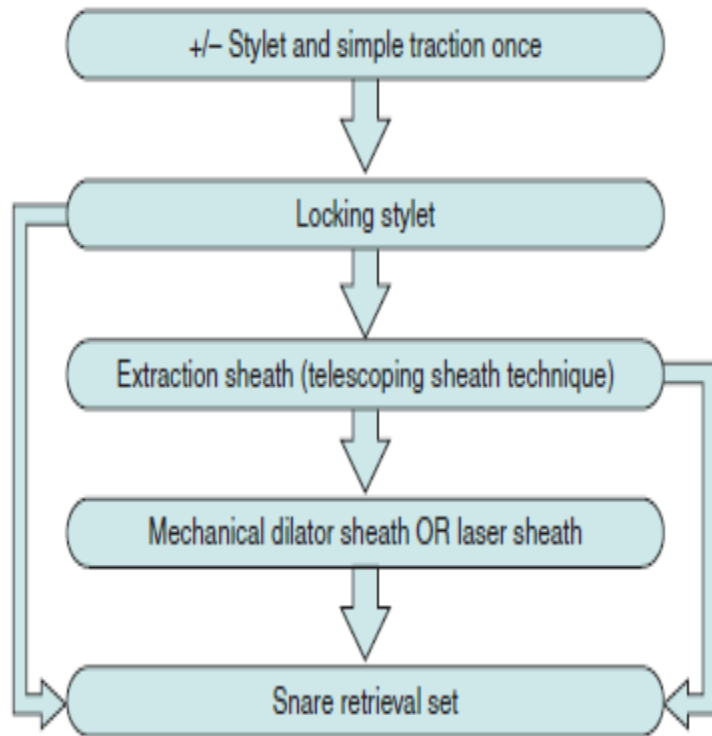
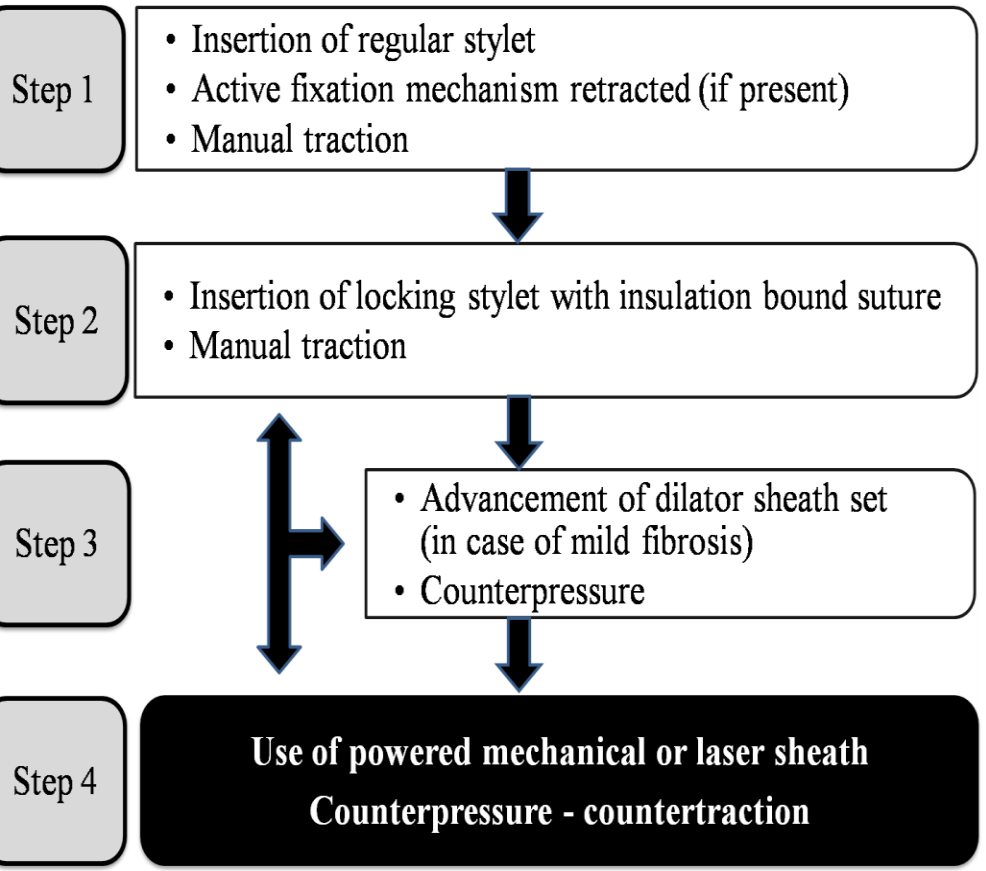


Table 2 Results of leads with an implant duration of 12 months and more with regard to the different groups (group A = no specific extraction tools, Group B = laser extraction approach, Group C = mechanical extraction approach; n.s. = not significant)

	Group A (n = 41)	Group B (n = 39)	Group C (n = 99)	P value
Mean implant duration (months)	38.1 (19–122)	83.1 (13–168)	95.4 (12–384)	A vs. B: $P < 0.0001$ A vs. C: $P < 0.0001$ B vs. C: n.s.
Ratio of ICD leads	26.8%	69.2%	37.4%	A vs. B: $P < 0.0001$ A vs. C: n.s. B vs. C: $P = 0.001$
Complete procedural success	100% (41)	76.9% (30)	88.9% (88)	A vs. B: $P < 0.0001$ A vs. C: $P = 0.005$ B vs. C: n.s.
Clinical success	100% (41)	76.9% (30)	97.0% (96)	A vs. B: $P = 0.001$ A vs. C: n.s. B vs. C: $P = 0.018$
Operative Mortality	0	0	0	n.s.
Minor complications	2	2	3	n.s.
Major complications	0	0	2	n.s.

Clinical success and cost effectiveness analysis favours the mechanical approach

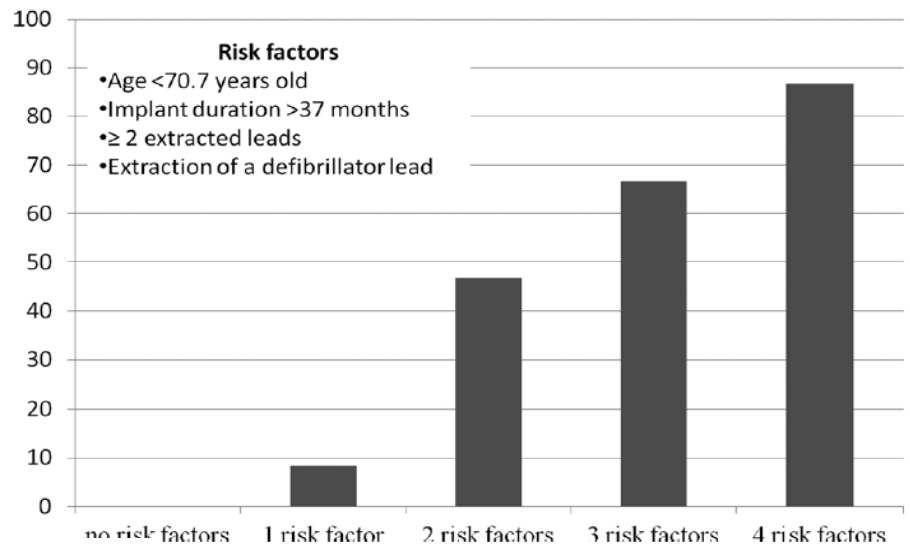
Predictors of Advanced Lead Extraction Based on a Systematic Stepwise Approach: Results from a High Volume Center



And when the going gets tough...



Proceeding into step 4 for lead extraction



A simple prediction tool that helps estimation of the possibilities for using powered sheaths for lead extraction.

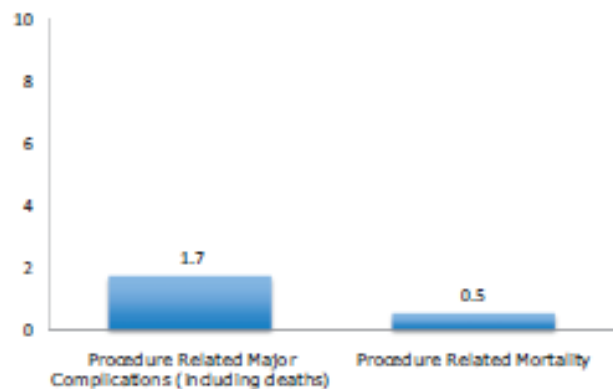
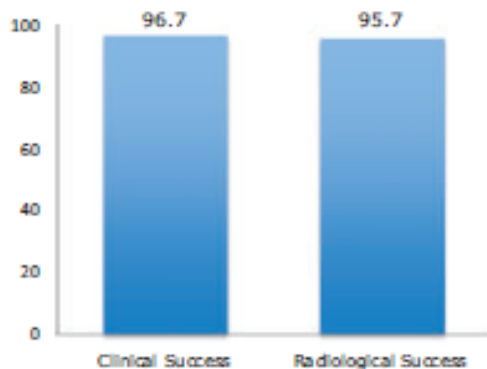
The European Lead Extraction ConTrolled (ELECTRa) study: a European Heart Rhythm Association (EHRA) Registry of Transvenous Lead Extraction Outcomes

ELECTRa
European Lead Extraction ConTrolled Registry

73 centers in 19 European countries
3510 patients with 6493 leads
75.7% pacing leads & 24.3% ICD leads

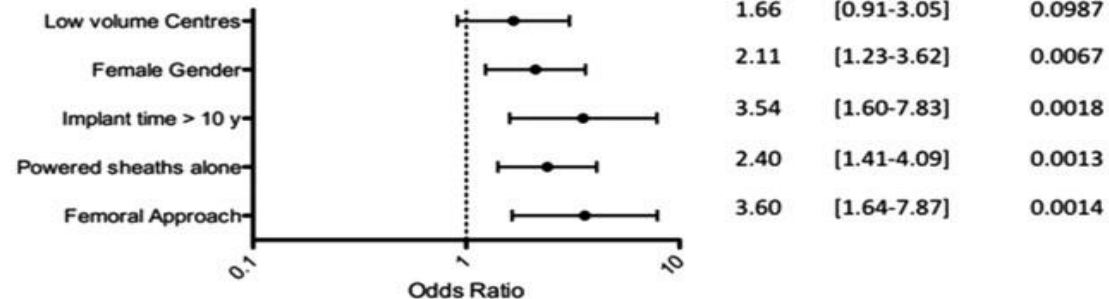
Transvenous Lead Extractions Indications
52.8% infective & 47.3 % non-infective

OUTCOMES

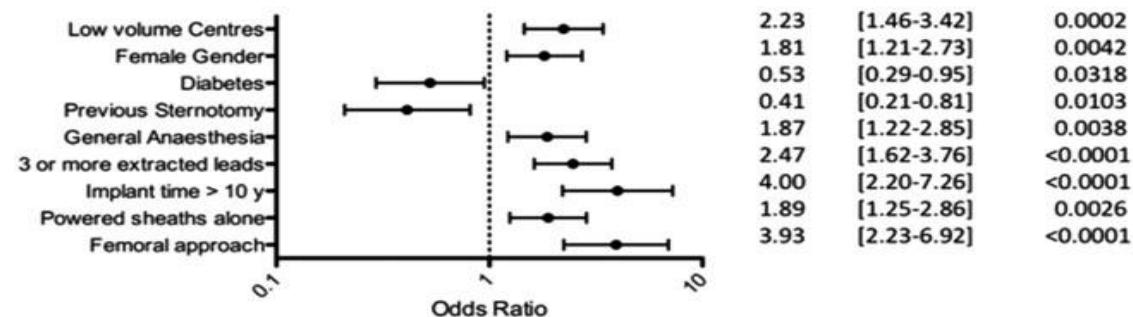


Patient, device/lead characteristics, centre-related factors were associated with both TLE success rate and major complications

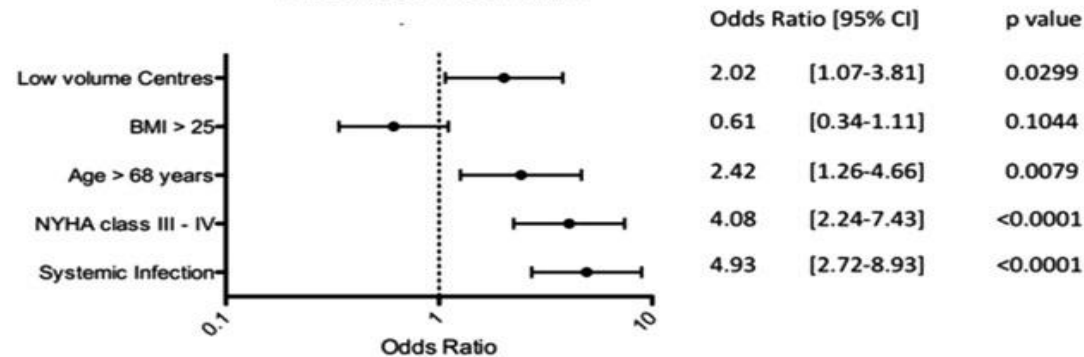
PROCEDURE RELATED MAJOR COMPLICATIONS INCLUDING DEATHS



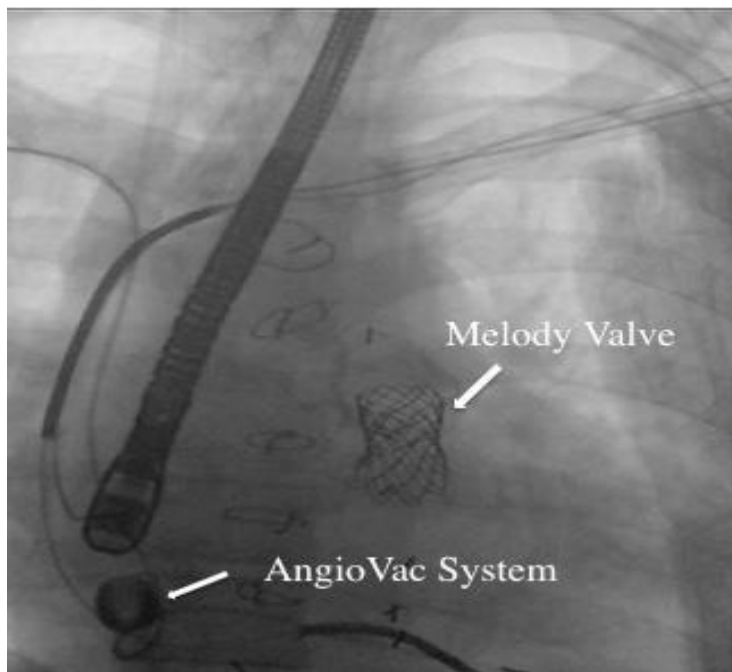
CLINICAL FAILURE




ALL CAUSE MORTALITY

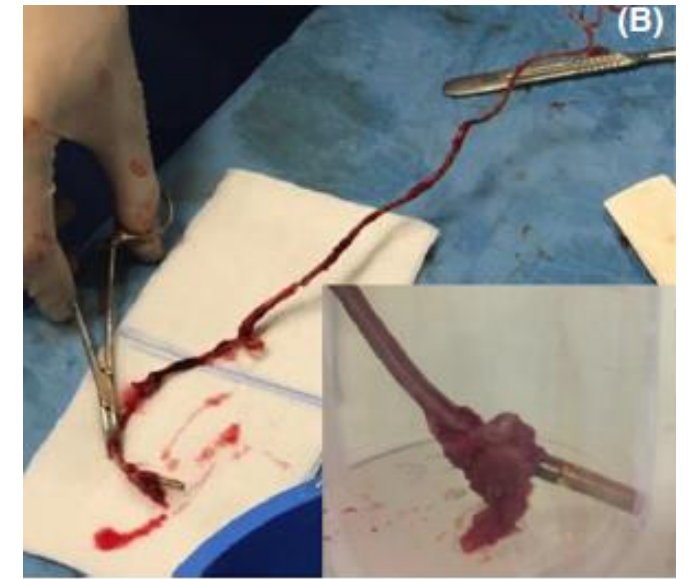
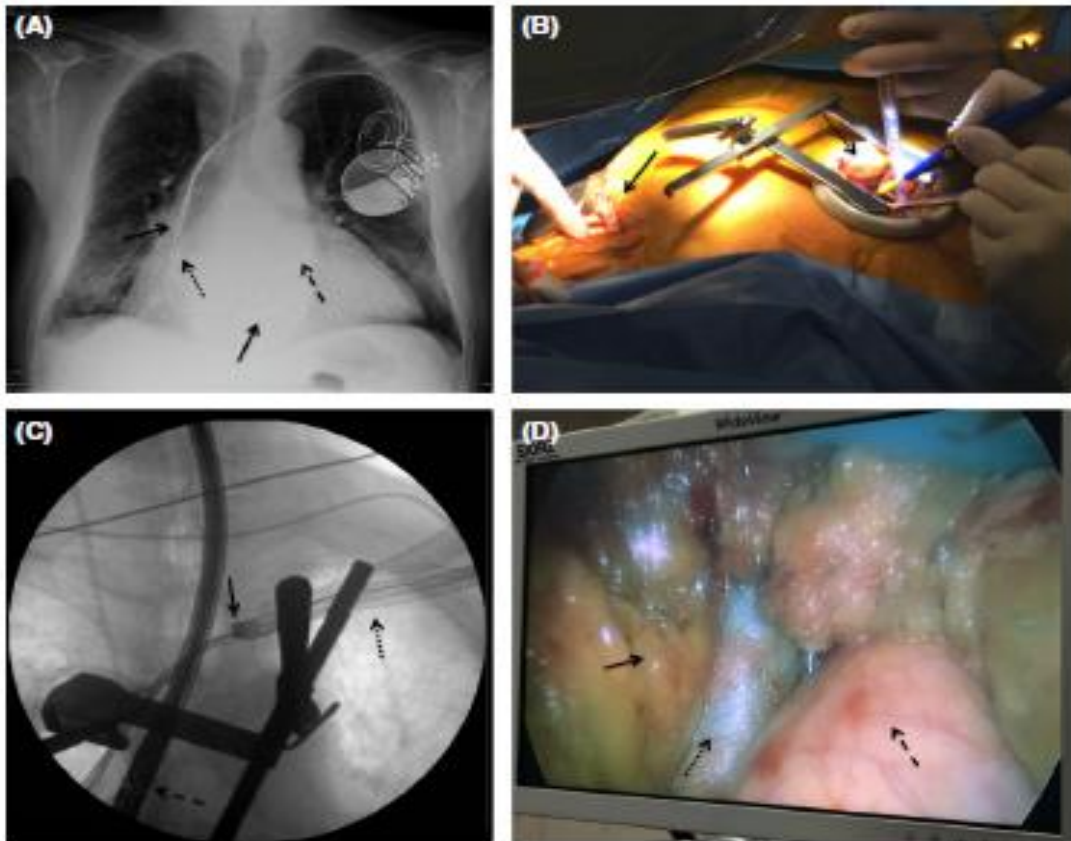


Non-surgical Lead Extrction of large Vegetation by AngioVac System



Hybrid minimally invasive technique with the bidirectional rotational Evolution[®] mechanical sheath for transvenous lead extraction: A collaboration between electrophysiologists and cardiac surgeons

Federico Migliore MD, PhD  | Giacomo Cavalli MD | Tomaso Bottio MD, PhD |
Martina Testolina MD | Manuel De Lazzari MD, PhD | Emanuele Bertaglia MD, PhD |
Sabino Iliceto MD | Gino Gerosa MD



Potential Advantages

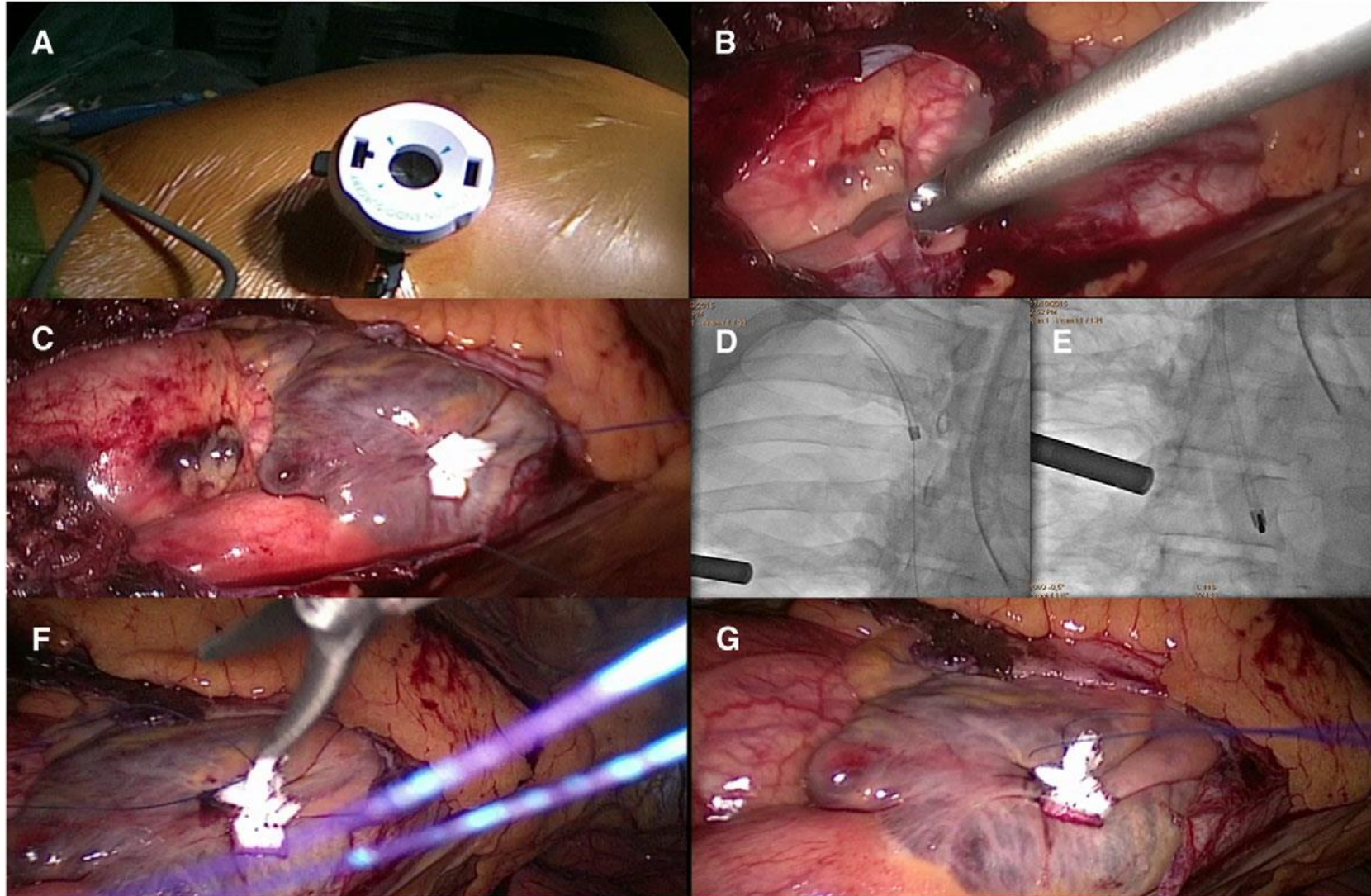
Allows direct visualization of the critical area of potential vascular injury during TLE maneuvers and prompts surgical treatment in case of serious complications

Potential Limitations

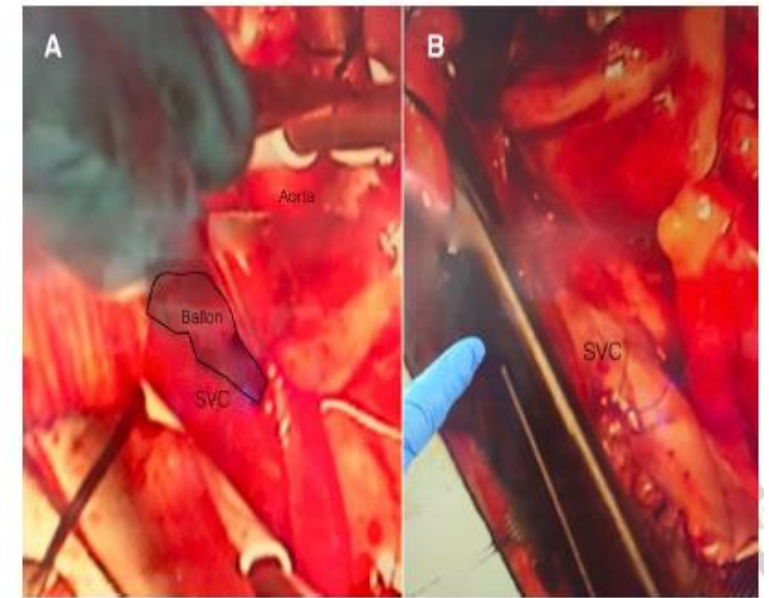
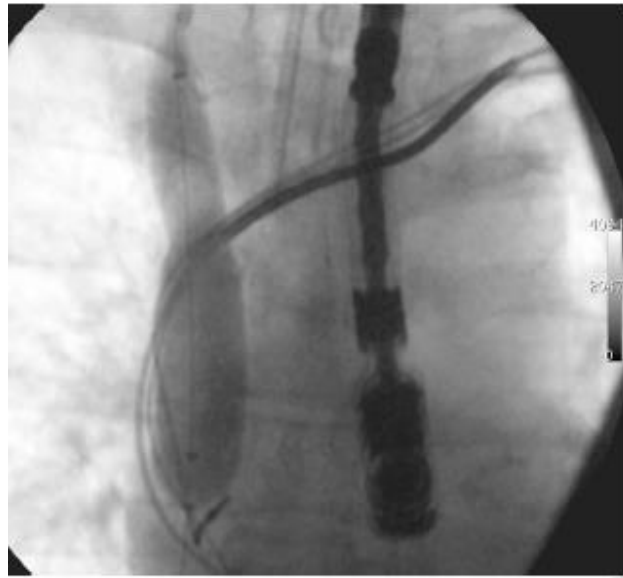
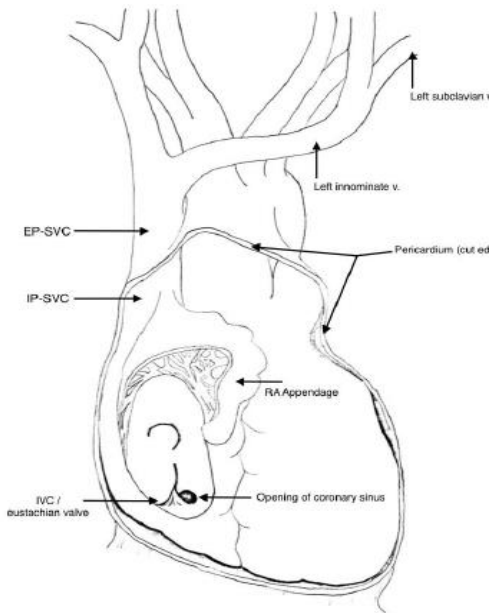
- ✓ Possible approach-related thoracic complication
- ✓ including wound infection and dehiscence
- ✓ not allow adequate treatment of vascular damage, resulting in conversion into thoracotomy and therefore delayed in surgical treatment
- ✓ the treatment of a brachiocephalic or subclavian vein injury (rare)



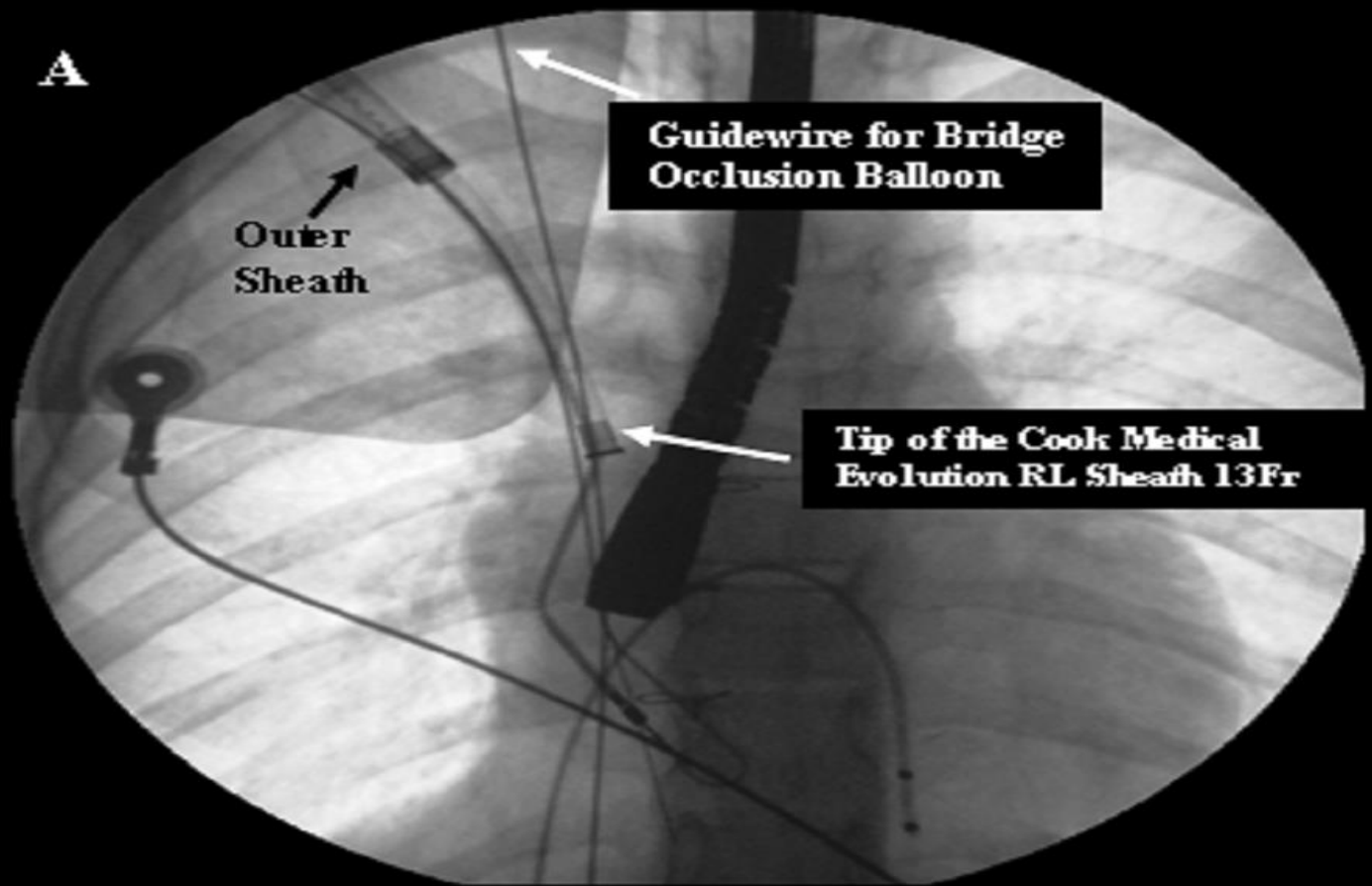
Hybrid Minimally Invasive Approach for Transvenous Lead Extraction: Thoracoscopy



Balloon-Assisted Rescue of Four Consecutive Patients with Vascular Lacerations Inflicted During Lead Extraction



A



Guidewire for Bridge Occlusion Balloon

Outer Sheath

Tip of the Cook Medical Evolution RL Sheath 13Fr

B



*A collaboration between electrophysiologist
AND
Cardiac Surgeon for TLE*