



Optimal Lead Selection: An Extractor's Guide to Lead Choice and Implant Technique

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Disclosures

- Honoraria, research support and/or consulting with:
 - ◆ Boston Scientific
 - ◆ Cook Medical
 - ◆ Leadexx
 - ◆ Lake Region Medical
 - ◆ Medtronic
 - ◆ Spectranetics
 - ◆ St. Jude Medical

No off label uses of devices or drugs will be part of this presentation.



Extraction "Experts" Have Learned!

- Those that do a lot of extraction begin to think!
 - ◆ What causes the problems to arise that result in a need for an extraction
 - ◆ How to modify our implant techniques and device choices
 - Avoid increased risk of mechanical, vascular and infectious complications.
 - ◆ What hardware might result in an easier and safer extraction experience (for patient AND doctor).

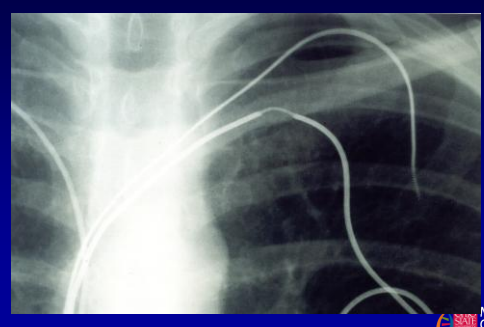


Many choices for many issues

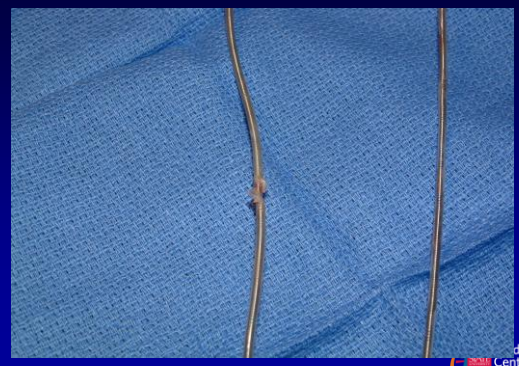
- First, understand where and how complications occur
 - ◆ This will affect
 - Implant site
 - Venous Access Techniques
 - Lead choice
 - Pocket tissue plane



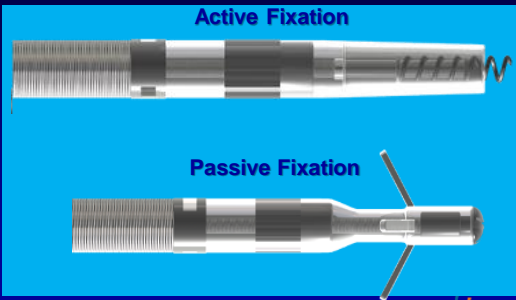
Lead Crush



Lead Crush



Fixation – Active versus Passive



Medical Center

Lead Choice

■ Fixation

◆ Passive

- Tine Length
 - Longer tines are more difficult to extract
- Tined leads in general more difficult to extract due to fibrosis around tines!



Medical Center

LV Lead Designs



Medical Center

Lead Choice

■ Active

◆ Retractable Helix

- Tissue may grow into the fixation mechanism

◆ Fixed Helix

◆ 4195 "Starfix"

* Note active fixation is NOT necessarily isodiametric in all cases



Fixation: Active — Extensible/Retractable Helix



Fixation: Active — Fixed Helix

■ Design Attribute

- Helix fixed to lead body



■ Extraction Considerations

- Ex. Fixed Helix
 - BSC FINELINE[®]
 - BSC THINLINE[®]
 - BSC SWEET TIP[®]

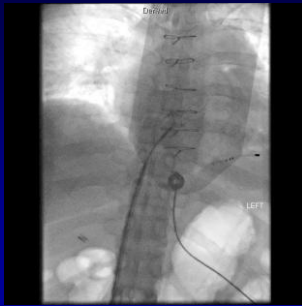
* - cordial



4195 Starfix



Starfix Extraction



Starfix Extraction



Courtesy Dr. Laurence Epstein



4195 Starfix



Connector

- IS-1 / DF-1
 - ◆ Has a “yoke” around which tissue grows and has to be dissected before the lead can be pulled through the tissues
- IS-4/DF-4
 - ◆ Eliminates yoke and reduces need for more extensive dissection of the lead from the pocket



Lead Length

- Leads that are longer than necessary create a “plate of spaghetti” in the pocket. Leads that are just the right length need much less work to free them from the fibrous pocket tissue.
- Excess lead also causes additional pressure points and may lead to “Cold Flow”



Silicone Failure: Mechanical

Abrasion: 4 years



Abrasion: 11 Months



Cold Flow: 1 year



Lead Mounted Sensors

- Sensors (such as pressure and oxygen saturation) are being mounted onto the lead body.
 - ◆ Typically NOT isodiametric
 - ◆ May get hung up on fibrous sheath around lead in vasculature preventing removal by simple traction



ICD Leads

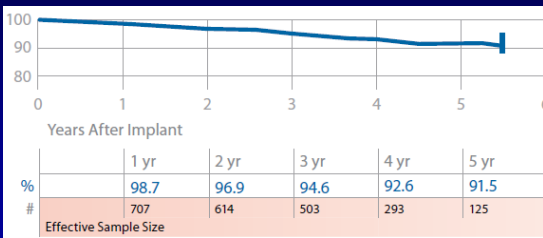
- Single vs Dual Coil
 - ◆ 2nd coil typically positioned at most vulnerable spots in the venous system
 - Curve from innominate into the SVC
 - Junction of RA and SVC
 - ◆ Coils are the site of most aggressive fibrotic ingrowth; why add more "trouble"
 - ◆ Proximal coil may "jam" in the sheath, preventing forward or reverse movement



ICD Coil Attachment to the Venous System



Medtronic 6949 "Fidelis"

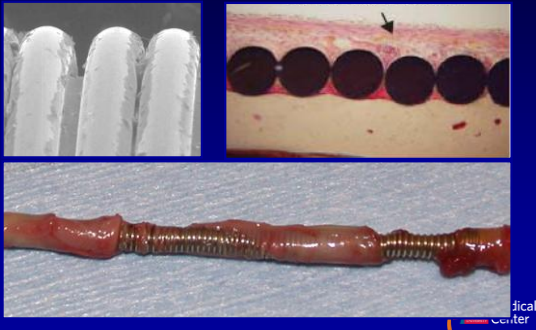


Lead Construction and Reliability

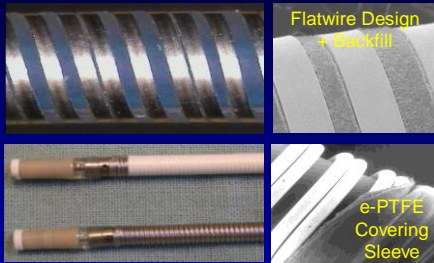
- Lead integrity
 - ◆ General reliability (chronic lead surveillance)
 - ◆ Some models inherently more robust
 - Have high tensile strength
 - Don't pull apart into components easily
 - Tips don't pop off from crimp/weld easily
- Medical Adhesive Backfilled Coils (ICD)
- ePTFE coated Coils (ICD)



Tissue In-growth



Tissue In-Growth Solutions

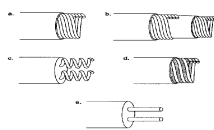


Extraction Considerations

- Non-backfilled coils may have more tissue ingrowth possibly resulting in snowplowing of tissue: Try upsizing extraction sheath

Lead Construction and Reliability

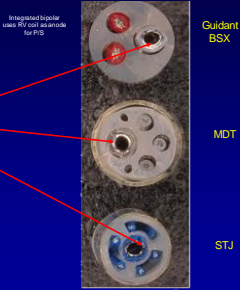
- General construction
 - ◆ Unipolar
 - ◆ Bipolar
 - ◆ Multipolar
- Conductor construction
 - ◆ Coil
 - Coradial vs Coaxial
 - ◆ Cable



Lead Body Design: Multi-Lumen Design

- Design Attribute**
- ICD leads have multiple lumens for High Voltage Cables, Electrode conductors and Crush lumens

- Extraction Considerations**
- Strip back insulation to verify distal electrode conductor lumen insert lead locking device for Lead Locking Deployment.



Ellenbogen, Kenneth A., et al. "Engineering and Clinical Aspects of Defibrillation Leads." *Clinical Cardiac Pacing and Defibrillation*, 2nd Ed. 151-165. W.B. Saunders Company, Philadelphia 2000.

SJM Medical Center

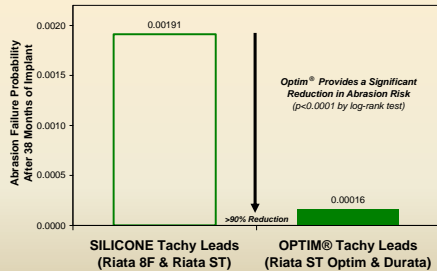
Insulation

- Silicone
- Polyurethane
- Hybrids
- New compounds



Optim[®] performance (as of Q1 2010)

Optim[®] Effects on SJM Tachy Lead Abrasion
(Kaplan-Meier Analysis of US Data)



Courtesy Dr. Mark Carlson



Sterile Technique

- Meticulous attention to Sterile Technique
 - ◆ All involved in the lab or admitted to the lab during the operation should be thoroughly educated in sterile technique
 - ◆ This is NOT Cathlab sterile technique, it is Operating Room sterile technique
 - ◆ Minimize personnel traffic in and out of the room, as well as number of people in the room



Sterile Technique

- Proper use of prophylactic antibiotics
 - ◆ Type
 - ◆ Time of administration
- Irrigation
 - ◆ Not clear whether this helps or not
 - ◆ However: Every person on the jury during your malpractice trial will know you were an idiot for not irrigating with antibiotic solution
 - ◆ TyRx antibiotic pouch



Conclusion

- Planning prospectively for an extraction can make the subsequent operation more rapid and safe, and may reduce the need for counter-traction and cutting sheaths
- Lessons learned from why leads fail can lead to lead choices and implant techniques that reduce the need for subsequent lead extraction



Early Lead Failures and Recalls

Andrew E. Epstein, MD

Professor of Medicine, Cardiovascular Division
University of Pennsylvania

Chief, Cardiology Section
Philadelphia VA Medical Center
Philadelphia, PA

The Bilitch Registry

In 1974 three centers, represented by Drs. Michael Bilitch, Victor Parsonnet, and John Hollander, established the response to a US Food and Drug Administration (FDA) Request for Proposal (RFP) concerning monitoring and evaluating the quality of cardiac pacemaker pulse generators. The RFP response was successful and a grant was awarded, funding continued at year renewals intervals until 1983 when an issue involving use of the device, a situation that existed in the general press, the cessation of funding and awareness of associations with the FDA, the new independent Registry was based on the integrity, reputation, and industry of its participant centers and institutions. The list of centers as established by the Registry has occasionally been revised. The Bilitch Registry has always provided the emergency response for inoperable device, pacemakers, and implantable cardioverter defibrillators (ICDs), and has been published. From data on the largest independent patient group, have additional data that provided for a retrospective analysis and have also provided to be confidential. How several hundred studies of ICD patient outcomes are in place, and one under the auspices of the National Heart, Lung, and Blood Institute and the National Institutes of Health in a high profile journal. All of them will provide data that the public and profession require.

The three teaching institutions, University of Southern California, Newark Beth Israel Medical Center, and Massachusetts General Hospital have continued to participate in the Registry. Dr. Bilitch died in 1987 and in 1988 the Registry was moved to his home and renamed. Other institutions and workers have joined. The listing of past and current participants. The actual operations of the Registry has been under the careful and painstaking direction of Brian Song and his assistant Joe Harkness who, for the past several years, have represented the operating core. From the beginning to the present, all ICD work has been reported, including case reports, case presentations at all forums, and published. In May of 1983, The Bilitch Registry, published in PACE over three years, published a major retrospective summary in April of each year, has set the standard of providing data to patients, industry, and regulators for the past 30 years. For more than the past 11 years no funding, external to the Registry participants, has

been available (despite tremendous requests). The Registry has always been maintained in honor of the wish or without external support.

There are two forms in medical background. One is the large portion of national recognition that the United States research on health care, achievement for such a wide array of health care specialties. The other is the small, more and more difficult to control number, that will affect and severely, make it difficult and generally less possible to provide services that are supported by clinical facts, simply because the professional engineers involved believed that that was the right thing to do. The comparison for the effort is increasing great about difficult. Simultaneously, with the presence of the Bilitch Registry, the various organizations who serve the community have been able to provide the Bilitch Registry with its response to the New Medical Device Act of 1990 (FDA's 510K), reference to the Bilitch Registry as frequent in medical literature (published data, literature, and in advertising, possibly to demonstrate that the data provided may be independent, but is credible, reliable, and suitable for clinical judgment. It is the only long, hard independent information remaining in the place. Probably there is no need for the Bilitch Registry at present.

The new group also has changed its center activities. The absence of funding in a general sense of what we are doing means that it is difficult to recruit new members and maintain them (even as it is difficult for the same participants to maintain their involvement with the passage of time. Effort must be expended in writing a living rather than a written work. The Bilitch 1987 will be a demonstration of what can be accomplished to provide the public and inform the profession, and to demonstrate. It is hoped that the Bilitch will be in progress.

For all of the reasons the Bilitch Registry will end. The present plan is to operate through the end of 1993 if funding and then publish a final retrospective report in April 1994.

Raymond Furman
Edwin LeClair
Meredith Medical Center
Victor Parsonnet
Newark Beth Israel Medical Center
Steven Saxe
University of Southern California

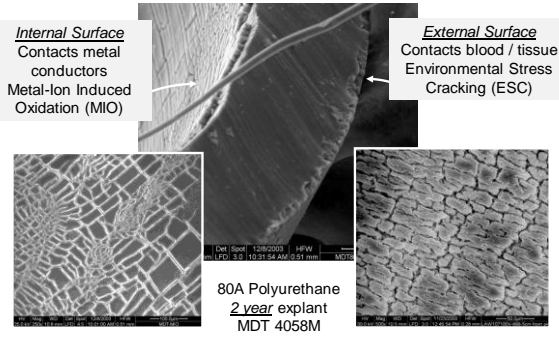
- In response to a FDA RFP, registry founded in 1974 by Drs. Bilitch, Parsonnet and Furman.
- Maintained data on devices, leads and programmers.
- Funding ceased 1981.
- Registry continued at USC, NBIMC, and Montefiore.
- Dr. Bilitch died in 1987.
- Registry ceased in 1994.

Major CRM Lead Advisories / Recalls

| Manufacturer | Lead / Lead Family | Issue |
|--------------|--|---|
| Medtronic | 6972 Family 80A Poly U Leads | 80A Poly U degradation |
| | 4002 Family 80A Poly U Leads | 80A Poly U degradation |
| | 4012 Family 80A Poly U Leads | 80A Poly U degradation |
| | 4004 Family 80A Poly U Leads | 80A Poly U degradation |
| | 4504 & 4504M / 4582 Poly U CapSure / Target Tip Tined Atrial J Leads | 80A Poly U degradation |
| St Jude Med. | 1016 & 1026 Pacing Leads | 55D Poly U (very thin) inner insulation degradation |
| Telectronics | AccuFix & Encor "J" lead Family (The "801" lead) | J shape retention wire extruded thru insulation |
| Medtronic | Transvene ICD family leads | 80A Poly U degradation |
| BSI | Endotak DSP Family ICD Leads | IS-1 connector failures |
| Medtronic | Fidelis Family ICD Leads | Pace-sense & high V cables and coil fractures |
| St Jude Med. | Riata & Riata ST silicone ICD leads | Inside-out silicone abrasion externalized cables |
| St Jude Med. | QuickSite & QuickFlex Bipolar Lds | Inside-out silicone abrasion externalized cables (distal) |

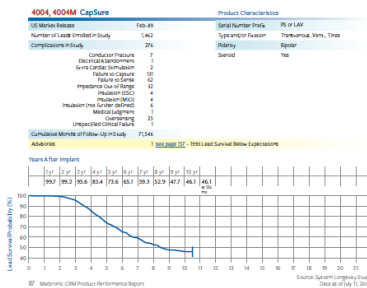
Courtesy of Mr. John Helland

Polyurethane Failure Mechanisms



Courtesy of Mr. John Helland

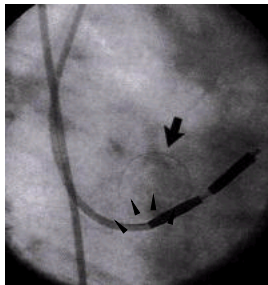
MDT 4004 Pellethane 80A



MDT CRM Product Performance Report, 2006.

Telectronics AccuFix Lead

- Recalled in November 1994 after 2 deaths, 2 non-fatal injuries
- 45,000 worldwide implants
- Risk of wire fracture/protrusion
- Issue: More deaths documented due to extraction than lead malfunction



Risks of Spontaneous Injury and Extraction of an Active Fixation Pacemaker Lead

Report of the Accufix Multicenter Clinical Study and Worldwide Registry

G. Neal Kay, MD; Jeffrey A. Brinker, MD; David T. Kawanishi, MD; Charles J. Love, MD; Margaret A. Lloyd, MD; Russell C. Reeves, MD; Guy Poger, MD; JoAnn Fee, RN, BSN; Mary K. Overland, PhD; Lisa Gansey-Ensign, MS; Gary L. Grunkekreier, PhD; for the Accufix Multicenter Clinical Study Investigators

TABLE 5. Complications of Lead Extraction*

| Extraction Complication | MCS (n=818) | | WWR (n=3404) | | Primary Thrombolysis (n=116) | |
|-------------------------|-------------|-----|--------------|-----|------------------------------|-----|
| | n | % | n | % | n | % |
| Minor | 20 | 3.2 | 138 | 4.1 | 9 | 7.8 |
| Fatal | 1 | 0.2 | 15 | 0.4 | 2 | 1.7 |
| Life threatening | 1 | 0.2 | 20 | 0.6 | 2 | 1.7 |
| Other | 18 | 2.9 | 103 | 3.0 | 5 | 4.3 |
| Minor | 26 | 4.2 | 122 | 3.6 | 2 | 1.7 |
| Total complications | 46 | 7.4 | 260 | 7.8 | 11 | 9.5 |

*Patients with known extraction outcome data.

260

TABLE 3. WWR Reported Accufix Injuries Related to J Retention Wire

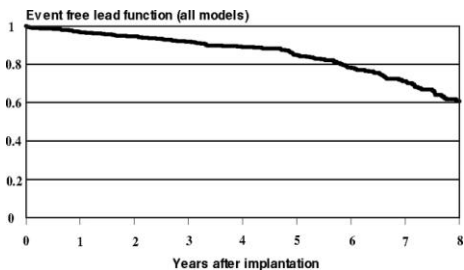
| Injury | n |
|--|----|
| Death | 6 |
| Pericardial tamponade (nonfatal) | 19 |
| Pericardial effusion without tamponade | 5 |
| Atrial perforation with pericarditis | 3 |
| Embolism of J-wire fragment | 4 |
| Tricuspid valve perforation and insufficiency | 1 |
| Acute right atrial failure | 1 |
| Right atrial thrombus with pulmonary thromboembolism | 1 |

Total injuries=40

40

Kay GN, et al. *Circulation* 1999;100:2344-2352.

Event-free Lead Function (n=990)



Kleemann T, et al. *Circulation* 2007;115:2474-2480.

Transvene ICD Lead

6936, 6966 Transvene

| US Market Release | | Product Characteristics | | US Returned Product Analysis | |
|------------------------------|--------|-------------------------|---|------------------------------|-----|
| Registered US Implants | 23,600 | Type and/or Fixation | Transvenous, Ventr, Deltis and Pacemaker, Screen-In | Conductor Fracture | 176 |
| Estimated Active US Implants | 2,400 | Polarity | True Bipolar/One Coil | Comp/Weld/Bond | 0 |
| Advisories | None | Sensid | No | Insulation Breach | 142 |
| | | | | Other | 7 |

System Longevity Study Results

| Qualifying Complications | 167 | Total | |
|-----------------------------------|--------|----------------------------------|-----|
| Number of Leads Enrolled in Study | 1,340 | Failure to Capture | 15 |
| Cumulative Months of Follow-Up | 75,072 | Conductor Fracture | 21 |
| Number of Leads Active in Study | 19 | Failure to Sense | 7 |
| | | Insulation (not further defined) | 14 |
| | | Impedance Out of Range | 7 |
| | | Unspecified Circuit Failure | 3 |
| | | Extra Cardiac Stimulation | 6 |
| | | Overensing | 112 |

Years After Implant: 1 yr, 2 yr, 3 yr, 4 yr, 5 yr, 6 yr, 7 yr, 8 yr, 9 yr, 10 yr, 11 yr, 12 yr, 13 yr, 14 yr, 15 yr, 16 yr, 17 yr, 18 yr, 19 yr, 20 yr, 21 yr

%: 100, 99.2, 99.2, 98.3, 97.3, 96.3, 95.3, 94.3, 93.3, 92.3, 91.3, 90.3, 89.3, 88.3, 87.3, 86.3, 85.3, 84.3, 83.3, 82.3, 81.3, 80.3, 79.3, 78.3, 77.3, 76.3, 75.3, 74.3, 73.3, 72.3, 71.3, 70.3, 69.3, 68.3, 67.3, 66.3, 65.3, 64.3, 63.3, 62.3, 61.3, 60.3, 59.3, 58.3, 57.3, 56.3, 55.3, 54.3, 53.3, 52.3, 51.3, 50.3

n: 1340, 956, 607, 639, 530, 414, 284, 210, 142, 104, 75, 56, 40

Effective Sample Size

Medtronic Product Performance Report, 2012.

Analysis of OPTIMUM, SCORE, and SJ4 Registries of Patients with Durata and Riata ST Optim ICD Leads

| Parameter | OPTIMUM | SCORE | SJ4 | TOTAL |
|----------------------|-----------|-----------|-----------|--------|
| Enrollment years | 2006-2009 | 2007-2012 | 2009-2010 | — |
| Enrolled (n) | 5929 | 3357 | 1534 | 10 820 |
| Unique leads (n) | 6016 | 3416 | 1573 | 11 005 |
| Median follow-up (y) | 3.5 | 2.3 | 2.7 | 3.0 |

Cairns J, et al. HRS LBCTs, May 9, 3013.

PHRI Analysis of St Jude Medical Registries of Patients with Optim-insulated ICD Leads

| End point | Failure Rate (%) | Freedom from Failure at 5 y (%) |
|------------------------------|------------------|---------------------------------|
| All-cause mechanical failure | 0.35 | 99.4 |
| Conductor fracture | 0.22 | 99.6 |
| Insulation abrasion | 0.07 | 99.9 |
| Externalized conductor | 0 | 100 |

Cairns J, et al. HRS LBCTs, May 9, 3013.

Risk of Overreaction: Complications Associated with ICD Replacement in Response to Advisories

- 17 Canadian centers, 2915 recalled devices
 - 533 (18.3%) replaced
 - 66% primary prevention
- Complications in 43 pts (8.1%)
 - Major requiring reoperation: 31 pts (5.8%)
 - Death: 2 pts
 - Minor complications: 12 pts (2.3%)
 - Of explanted devices, 3 (0.1%) had malfunction (early battery depletion), none with clinical consequence

Gould PA, et al. JAMA 2006;295:1907-1911.

Lessons Learned

- All leads have a finite failure rate.
- Goal of zero failure rate is unattainable.
- Resolution is in how failures are managed.
- Need post-marketing surveillance, not absence of approval of new technology by requiring long-term follow-up before approval.
- Our responsibilities are to weigh the evidence and make judgments of risk benefit ratios. This requires data and understanding.

Techniques for Lead Extraction

Oussama M. Wazni

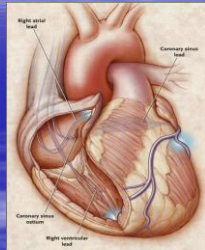
Cardiac Electrophysiology
Cleveland Clinic

Scope

- 250,000-275,000 ICD devices are implanted yearly throughout the world.
- Up to 10% of all leads implanted may require removal.

EPS: A growing demand

- 3 million implanted ICDs
- 180,000 pacing systems
- Increasing indications
- Aging population



Complications of Implantable Cardiac Devices

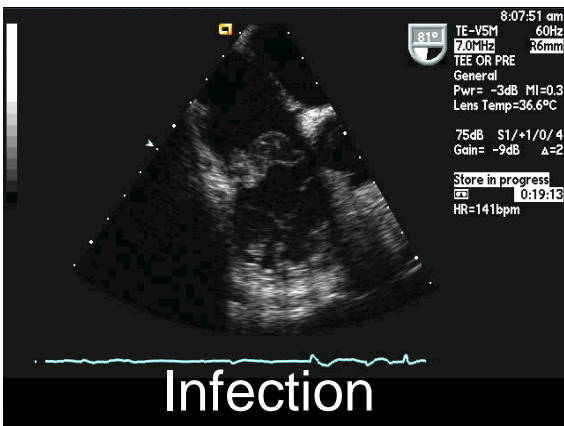
- Non infectious
 - Hematoma (5%)
 - Lead dislodgement (2%)
 - Pacing threshold evaluation (1%)
 - Lead fracture (<1%)
- Infectious
 - Erosion or incipient erosion (0.75 per 100 pts)
 - All other infections (0.7 per 100 pts)

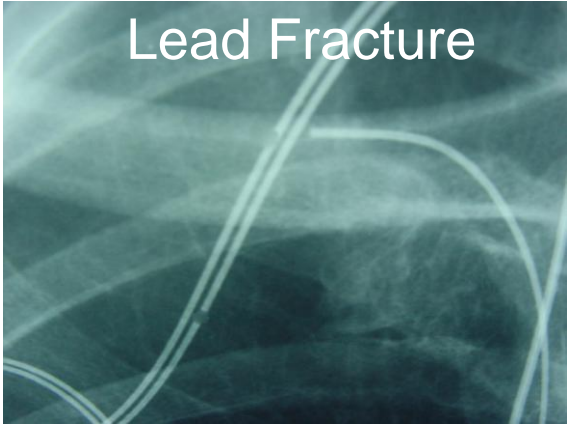
Klug et al Circulation 2007;116

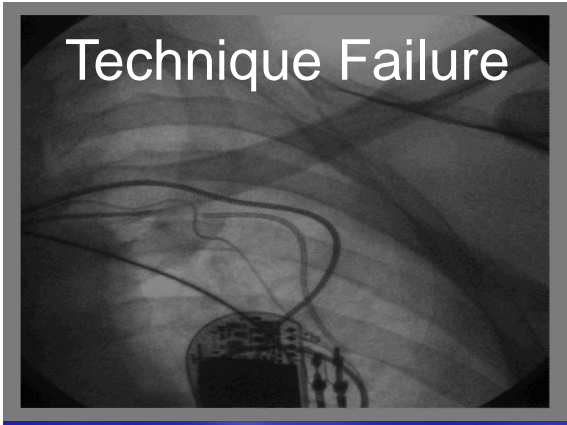
Infection

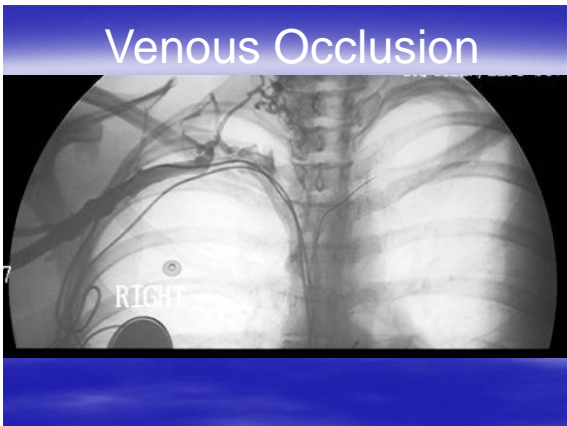


Infection

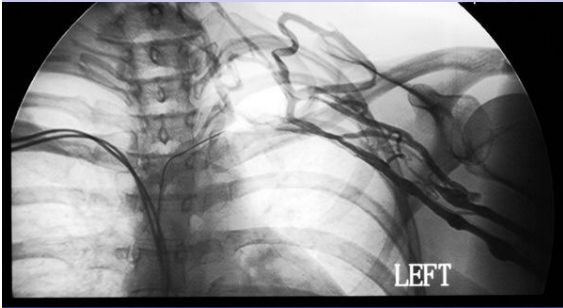








Bilateral Occlusion

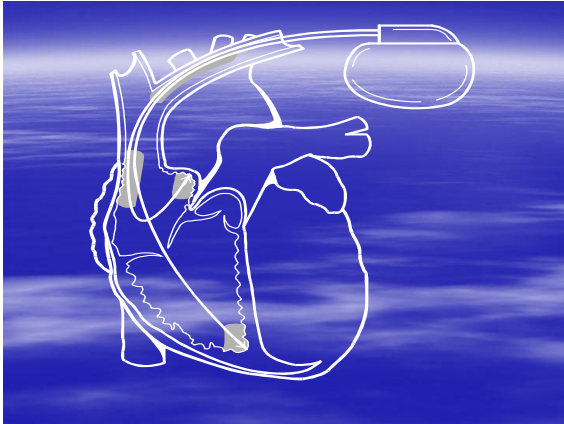


Poor Judgment

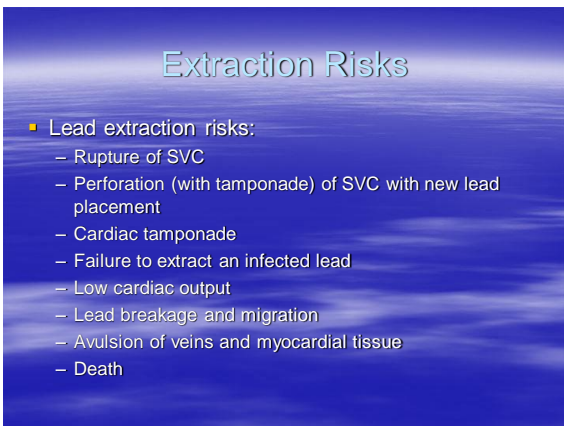


Fibrotic Attachments

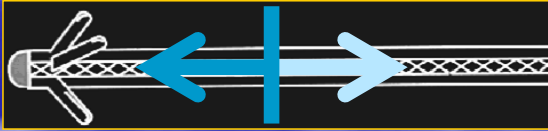




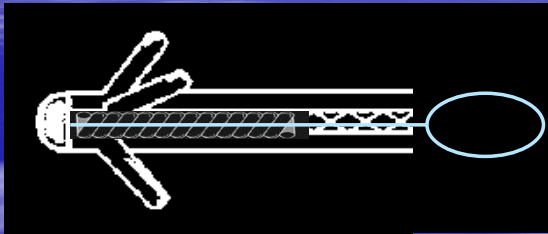




Tensile Strength



Locking Stylets



Apply Suture

Connect suture from lead outer insulation to closest LLD loop.

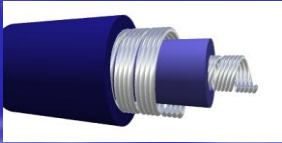


Example: 0 Ethibond tied with 2 "throws" for low profile

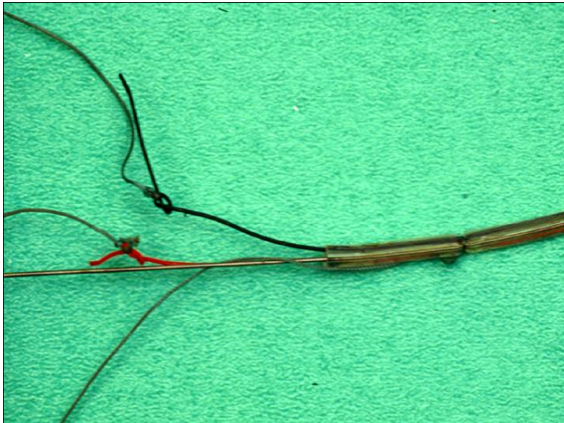


Prepare the Target Lead(s)

- Exposing the inner coil
 - Bipolar lead: must remove outer insulation, outer coil, and inner insulation to expose inner coil



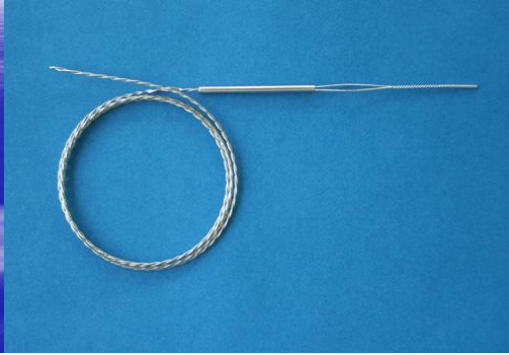
Inner Coil



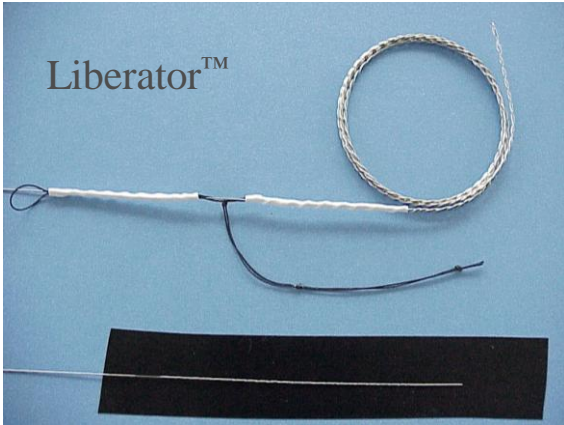
One Tie



Bull Dog



Liberator™



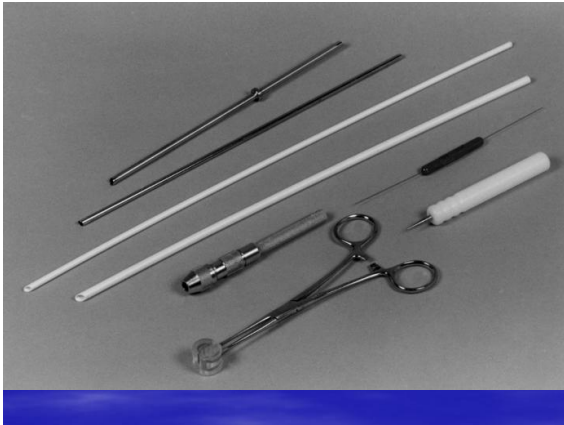
Wilkoff & Spectranetics Lead Locking Devices



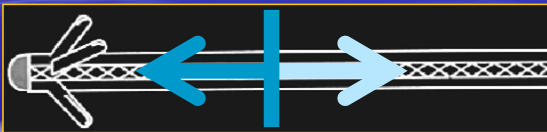
Lead Locking Device® (L.L.D)

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

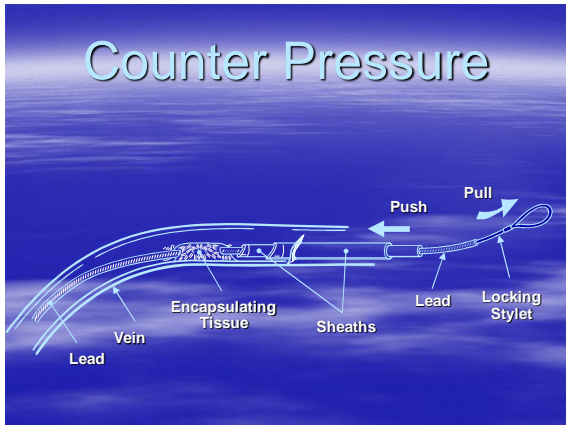


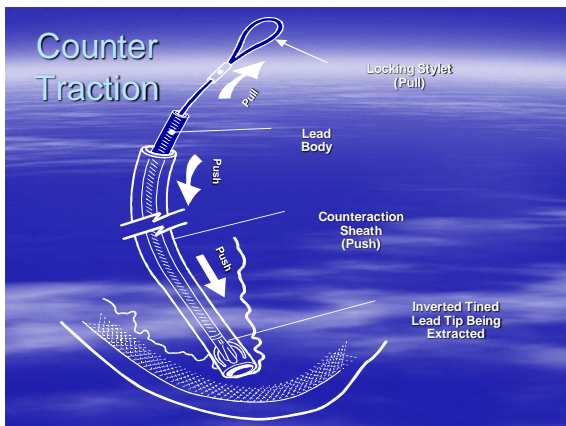


Tensile Strength

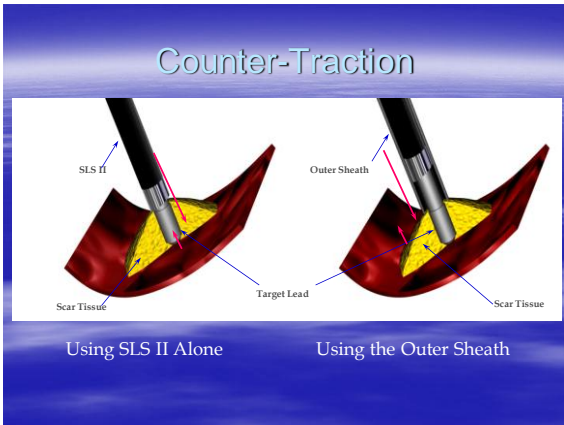










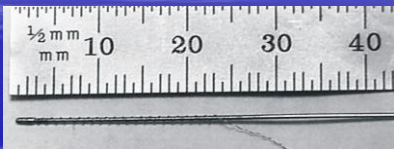


- ### Lead Extraction Tools
- Locking Stylets
 - Cook Locking Stylet - 1989
 - Liberator Locking Stylet - 2000
 - Mechanical sheaths
 - Mechanical Sheaths
 - Polypropylene (1989)
 - Teflon (1990)
 - Steel (1992)
 - Byrd Femoral Workstation - 1990
 - Dotter Basket/Tip Deflecting Guidewire -1990
 - Needles-Eye-Snare - 1996
 - Evolution - 2006
 - One tie
 - Bull dog

Powered Lead Removal Technologies

- 12F - Excimer Laser – 1994 (Clinical Trial)
- 12F – Excimer Laser – 1997 (FDA approval)
- Lead Locking Device (LLD™) –1999
- 14F & 16F Excimer Laser -
- Electrosurgical Dissection Sheaths - 2001
- SLSII – 12F, 14F, 16F – 2003

Locking Stylet™ by COOK®



CVX-300® Excimer Laser

- Generates light at 308 nm wavelength in the ultraviolet spectrum
- Excimer laser enables photoablation of lipids and proteins
- Laser Medium = XeCl gas

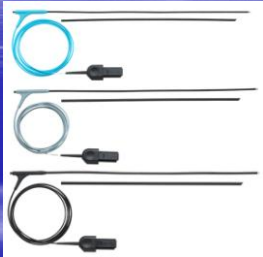


Mechanisms of Action

| ● Photochemical | ● Photothermal | ● Photomechanical |
|---|---|---|
| Dissolving molecular bonds | Produces photo-thermal energy | Creating kinetic energy |
|  |  |  |

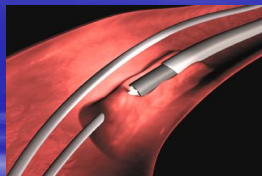
SLS II and Outer Sheath Options

- 12 Fr
- 14 Fr
- 16 Fr

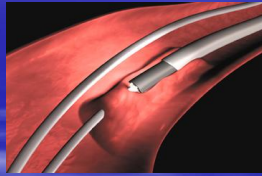


Teflon outer sheath offers blunt and beveled ends

Electrosurgical Dissection System sheath



Electrosurgical Dissection System sheath



Evolution



Evolution

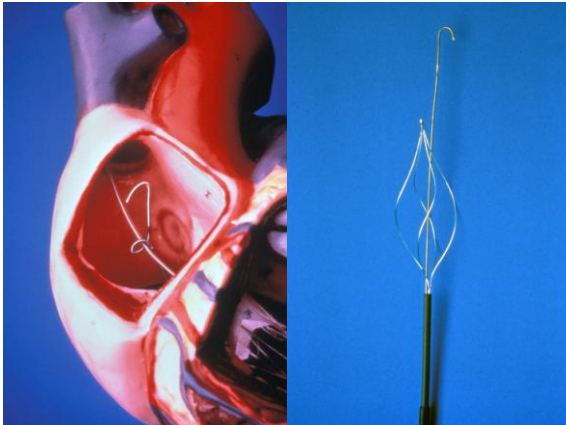


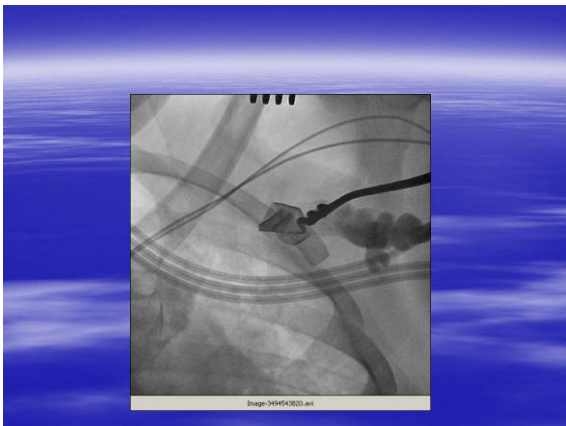


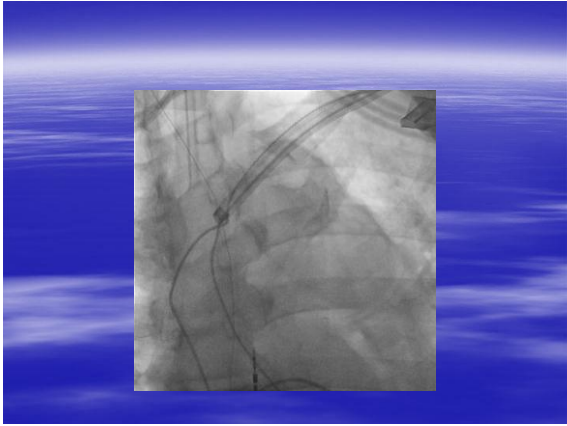


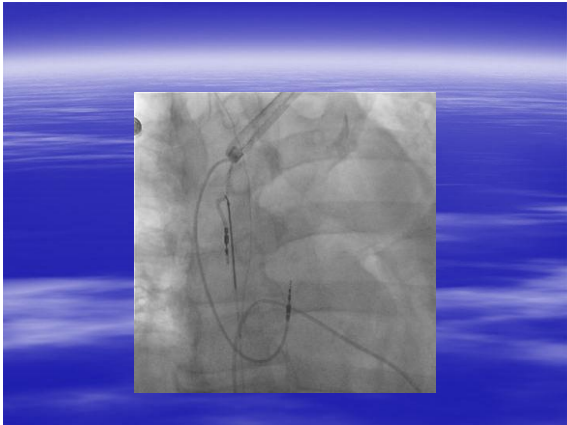


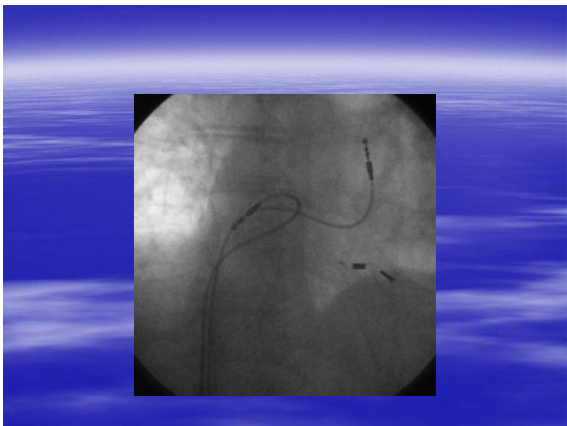


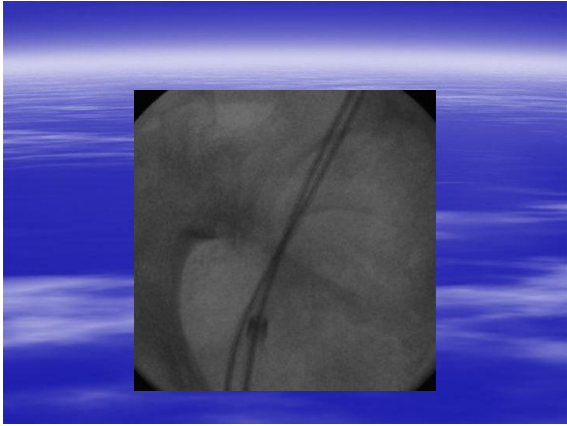


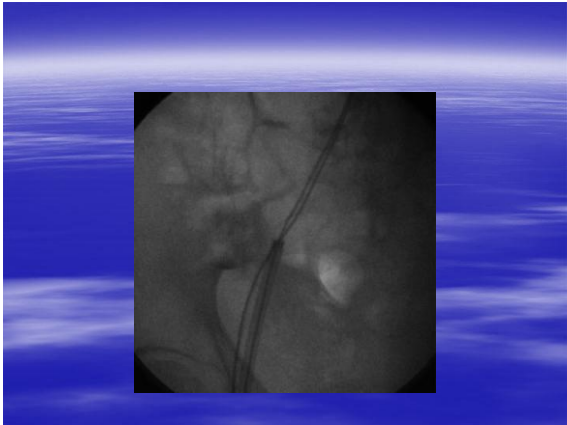


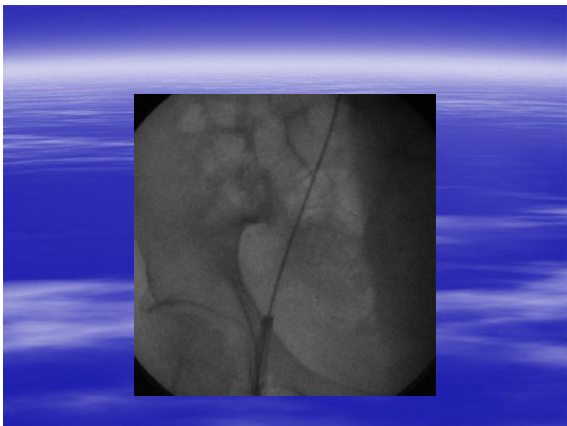


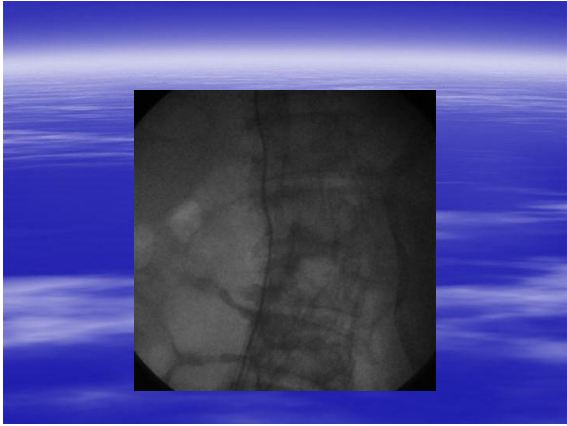


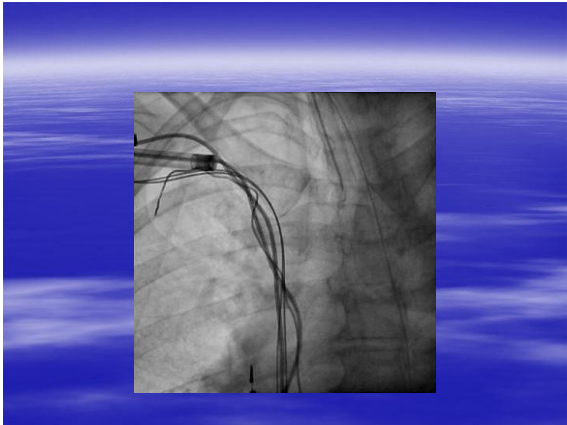


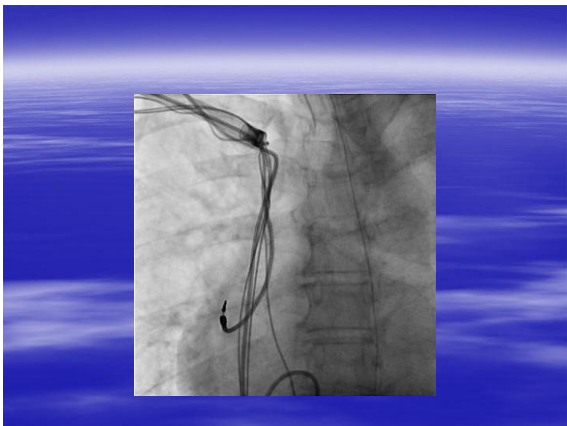


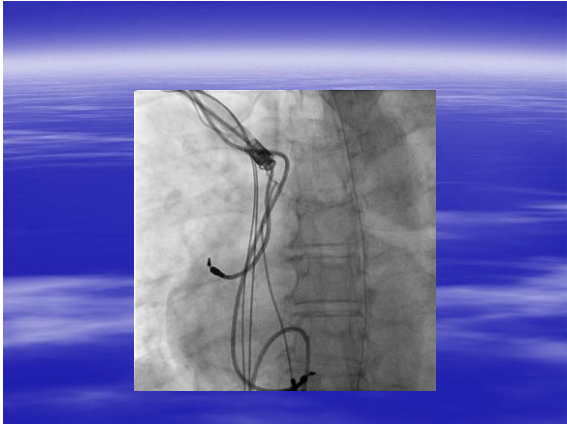


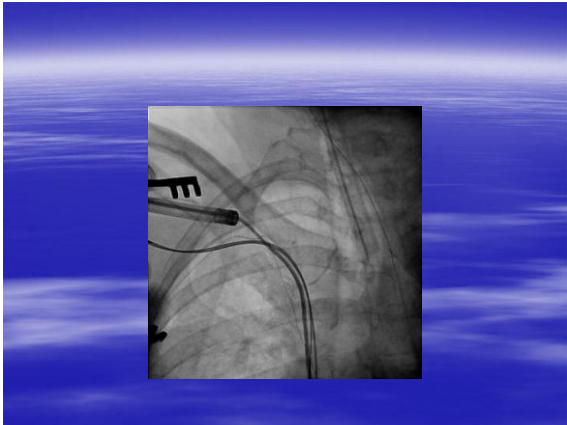


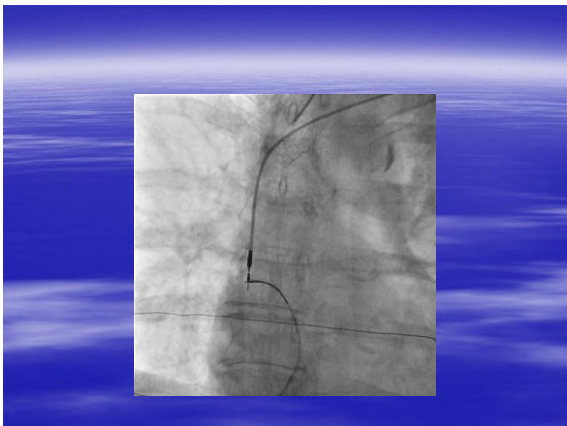


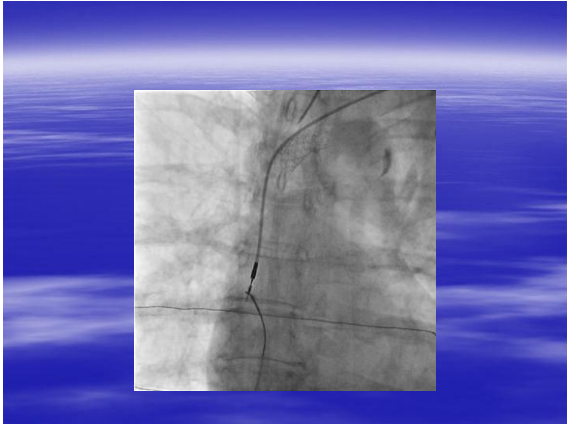


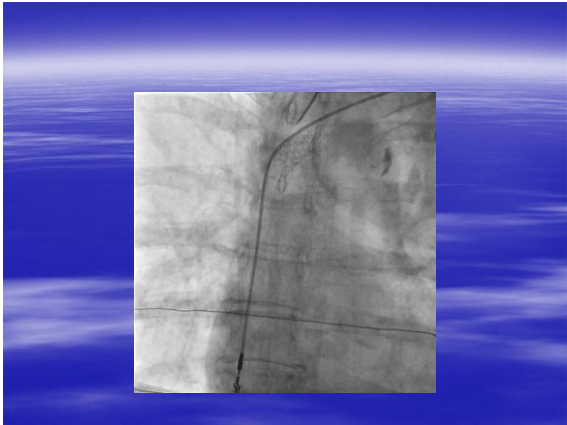
















Conclusion

In the right patients if you know what you are doing extraction is useful and safe
