Lead Extraction Workshop

By Cook Medical
Lead Extraction

• Lead Extraction is the removal from the body of implanted cardiac leads.

• Cardiac leads:
  • They are conductor wires that “electrically” connect the implanted pacemaker or defibrillator and the heart. They are most commonly placed “transvenously”.
Early Methods

Pulleys & Weights
History of interventional lead extraction

- **1985 – 1987** Early research published by Dr Jorgen Meibom (*Locking Stylet*) and Dr Charles Byrd (*Telescoping Dilators*)
- **1988** Development of Cook extraction system began
  Lead Extraction Registry/database established
- **Sept, 1990** Commercial release of Cook lead extraction system
- **March, 1993** Lead Extraction Registry analysed
History of interventional lead extraction

- 1998 First European experience with Excimer Laser extraction techniques published by Charles Kennergren (PACE)
- 1999 Results of PLEXES trial published (Pacing Lead Extraction with the Excimer Sheath)
- March, 1999 EXCL Clinical study commences (Electrosurgical Extraction of Cardiac Leads)
- 2001 Results of EXCL Multicenter Clinical Study presented at NASPE 2001
History of interventional lead extraction

- Aug, 2007 Cook Medical Launches “An Evolution® for Lead Extraction”

  - Oct, 2007 Introduction of EVN into Europe
  - Aug, 2008 Introduction of Evolution® Shortie into USA
  - Jan, 2009 Introduction of Evolution®-Shortie into Europe
  - 2009 New tip design for all Evolution® models
## Ten Years of Lead Extraction™ Procedures

<table>
<thead>
<tr>
<th>Analysis Group</th>
<th>Number of Cases</th>
<th>Years Implanted</th>
<th>Removal Outcome</th>
<th>Major Complications</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Complete</td>
<td>Partial</td>
</tr>
<tr>
<td>1988 – 93 Early cases</td>
<td>1251 patients 2110 leads</td>
<td>4.7 ± 3.8</td>
<td>86%</td>
<td>8%</td>
</tr>
<tr>
<td>1994 – 95 Accufix</td>
<td>985 patients 1237 leads</td>
<td>3.1 ± 2.0</td>
<td>94%</td>
<td>4%</td>
</tr>
<tr>
<td>1994 – 95 Non-Accufix</td>
<td>1011 patients 1743 leads</td>
<td>4.5 ± 4.1</td>
<td>91%</td>
<td>6%</td>
</tr>
<tr>
<td>1996 – 97 Mechanical</td>
<td>1456 patients 2279 leads</td>
<td>4.2 ± 3.8</td>
<td>93%</td>
<td>5%</td>
</tr>
<tr>
<td>1996 – 97 Laser</td>
<td>636 patients 1155 leads</td>
<td>5.8 ± 4.0</td>
<td>94%</td>
<td>4%</td>
</tr>
<tr>
<td>1999 – 2000 Electro surgical</td>
<td>265 patients 459 leads</td>
<td>8.4 ± 5.0</td>
<td>95.9%</td>
<td>3.5%</td>
</tr>
</tbody>
</table>

Data presented at XIth World Symposium on Cardiac Pacing and Electrophysiology in Berlin, Dr Bruce Wilkoff (Cleveland Clinic Foundation, Cleveland, OH) on behalf of U.S. Database participants
Pacemaker & Leads
ICD & leads
Types of Leads

Active-fixation lead

Passive-fixation lead
Transvenous Lead Extraction

HRS Lead Extraction Consensus – 2009
HRS Expert Consensus on Facilities, Training, Indications, and Patient Management

This document was developed in collaboration with the American College of Cardiology (ACC) and the American Heart Association (AHA).

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This document was approved by the Board of Trustees of the Heart Rhythm Society on May 6, 2009.
It can be found on the Heart Rhythm Society website at www.HRSonline.org/Policy/ClinicalGuidelines.
History

• NASPE Policy Conference – 1997

• HR 2008 Satellite Symposium
  • Lead Extraction 2008: Critical Review and Implementation of HRS Guidelines, HR 2008 satellite symposium co-Guidelines, co-sponsored by CCF & HRS

• Expert Consensus task force formed
  • Symposium feedback, literature, new research, face-to-to-face, teleconference, email

• HRS Consensus Document
  • HR BOT Approval May 2009
  • Online available, Full publication July 2009 in Heart Rhythm
Definitions

- **Lead Removal**: Removal of a pacing or defibrillator lead using any technique.

- **Lead Explant**: A lead removal using simple traction techniques: (no locking stylet, telescoping sheaths or femoral extraction, tools).

- **Lead Extraction**: Removal of a lead that has been **implanted for more than one year**, or a lead regardless of duration of, implant requiring the assistance of specialized equipment that is not included as part of the typical implant package, and/or removal of a lead from a **route other than via the implant vein**. ICD leads may require specialized extraction equipment even when implantation duration is less than one year.
Definitions

• **Complete Procedural Success:** Removal of all targeted leads and all lead material from the vascular space, with the absence of any permanently disabling complication or procedure related death.

• **Clinical Success:** Removal of all targeted leads and lead material from the vascular space, or retention of a small portion of the lead that does not negatively impact the outcome goals of the procedure.

• **Failure:** Inability to achieve either complete procedural or clinical success, or the development of any permanently disabling complication or procedure related death.
Definitions

• Procedural success rate = Number of clinically successful procedures / Number of procedures performed.
  • Complete
  • Clinical

• Lead clinical success rate = Number of leads removed with clinical success / Total number of leads attempted
Clinical Goals

• Elimination of infection
  • Pocket infection, device related endocarditis
• Venous access in an occluded vessel
• Elimination of an identified risk:
  • Lead or portion of a lead
  • Perforation, arrhythmia
• Preservation of desired pacing mode
• Removal of all non-functional leads
• Resolution of pocket related symptoms
  • Pain
Definitions – Complications

- **Intra-procedural complications:** Any event related to the performance of a procedure that occurs or becomes evident from the time the patient enters the operating room until the time the patient leaves the operating room.

- **Post-procedural complications:** Any event related to the procedure that occurs or becomes evident within 30 days following the intra-procedural period.

- **Major complication:** Any of the outcomes related to the procedure which is life threatening or results in death. In addition, any unexpected event that causes persistent or significant disability, or any event that requires, significant surgical intervention to prevent any of outcomes listed above.

- **Minor complication:** Any undesired event related to the procedure that requires medical intervention or minor procedural intervention to remedy, and does not limit persistently or significantly the patient’s function, nor does it threaten life or cause death.
Major Complications

- Death
- Cardiac avulsion or tear requiring
  - thoracotomy, pericardiocentesis, chest tube, or surgical repair
- Vascular avulsion or tear requiring
  - thoracotomy, pericardiocentesis, chest tube, or surgical repair
- Pulmonary embolism requiring
  - surgical intervention
- Respiratory arrest or anesthesia related complication
  - leading to prolongation of hospitalization
- Stroke
- Pacing system related infection
  - previously non-infected site
Minor Complications

• Pericardial effusion not requiring
  • Pericardiocentesis or surgical intervention
• Hemothorax not requiring
  • chest tube
• Hematoma at the surgical site requiring
  • reoperation for drainage
• Arm swelling or thrombosis of implant veins
  • resulting in medical intervention
• Vascular repair
  • near the implant site or venous entry site
Minor Complications

- Air embolism
  - hemodynamically significant
- Lead fragment migration without sequelae
- Blood transfusion
  - blood loss during surgery
- Pneumothorax requiring a chest tube
- Pulmonary embolism not requiring surgical intervention
Extraction Environment Personnel

• Team approach
• Spectrum of Tools
• Spectrum of Techniques
• Plan, Train & Practice for an emergency
Extraction Environment Personnel

- **Primary Operator**: trained & qualified
  - single physician vs. team approach
  - well versed in CIED implantation and management.
- **Cardiothoracic Surgeon**: familiar with all potential complications of lead extraction and re-implantation
  - required surgical approach to each anatomic injury
- **Anesthesia Support**: immediate anesthesia support including
  - emergency open-heart surgery.
- **Fluoroscopic Support**: operate and troubleshoot
- **Scrub Personnel**: two “scrubbed” personnel
  - primary operator and assistant primary assistant
- **Non-Scrub Personnel**: ≥ two “non-scrubbed” personnel
- **Echocardiography**: emergent echocardiography
  - transthoracic and/or transesophageal & Interpretation
- **Administrative Support**: Extraction Coordinator and Protocol Coordinator
Experience

• Complete procedural success improves dramatically
  • after first 10–20 procedures
• Experienced physicians have reduced complete procedural success
  • 60 or fewer laser assisted procedures were done over prior 4 years
• Lower complication rates with ≥30 cases
• Continue to decline with up to 400 cases
• Medicare ICD database review:
  • Decreased mechanical complications with ≥10 implantations per year
  • Reduced infections with ≥30 implants per year
Facilities & Equipment

• Institutional support for lead extraction is essential to create and maintain the lead extraction team.

  • High Quality Fluoroscopy
  • Surgical Instruments (Scalpel to CPB)
  • Spectrum of extraction snares
  • CIED implantation tools
  • Echo (Transthoracic, Transesophageal, ICD)

CPB = Cardiopulmonary bypass
CIED = Cardiovascular implantable electronic devices
Indications for Transvenous Lead Extraction

Recommendations for lead extraction apply only to those patients in whom the benefits of lead extraction outweigh the risks when assessed based on individualized patients factors and operators specific experience and outcomes.

INFECTION
Class I

1. Complete device and lead removal is recommended in all patients with definite CIED system infection, as evidenced by valvular endocarditis, lead endocarditis or sepsis (Level of evidence: B)

2. Complete device and lead removal is recommended in all patients with CIED pocket infection as evidenced by pocket abscess, device erosion, skin adherence, or chronic draining sinus without clinically evident involvement of transvenous portion of the lead system. (Level of evidence: B)

3. Complete device and lead removal is recommended in all patients with valvular endocarditis without definite involvement of the lead(s) and/or device. (Level of evidence: B)

4. Complete device and lead removal is recommended in patients with occult gram-positive bacteremia (Not contaminant). (Level of evidence: B)
Indications for Transvenous Lead Extraction

Recommendations for lead extraction apply only to those patients in whom the benefits of lead extraction outweigh the risks when assessed based on individualized patients factors and operators specific experience and outcomes.

INFECTION
Class II
1. Complete device and lead removal is reasonable in patients with persistent occult gram – negative bacteremia (Level of evidence: B)

Class III
1. CIED removal is not indicated for superficial or incisional infection without involvement of the device and/or leads (Level of evidence: C)
2. CIED removal is not indicated to treat chronic bacteremia due to a source other than the CIED, when long term suppressive antibiotics are required. (Level of evidence: C)
Indications for Transvenous Lead Extraction

Recommendations for lead extraction apply only to those patients in whom the benefits of lead extraction outweigh the risks when assessed based on individualized patients factors and operators specific experience and outcomes.

CHRONIC PAIN

Class IIa

1. Device and/or lead removal is reasonable in patients with severe chronic pain, at the device or lead insertion site, that causes significant discomfort for the patient, is not manageable by medical or surgical techniques and for which there is no acceptable alternative. (Level of evidence: C)
Indications for Transvenous Lead Extraction

Recommendations for lead extraction apply only to those patients in whom the benefits of lead extraction outweigh the risks when assessed based on individualized patients factors and operators specific experience and outcomes.

THROMBOSIS OR VENOUS STENOSIS
Class I
1. Lead removal is recommended in patients with clinically significant thrombo-embolic events associated with thrombus on a lead or a lead fragment. (Level of evidence: C)
2. Lead removal is recommended in patients with bilateral subclavian vein or SVC occlusion precluding implantation of a needed transvenous lead. (Level of evidence: C)
3. Lead removal is recommended in patients with planned stent deployment in a vein already containing a transvenous lead, to avoid entrapment of the lead. (Level of evidence: C)
4. Lead removal is recommended in patients with superior vena cava stenosis or occlusion with limiting symptoms. (Level of evidence: C)
Indications for Transvenous Lead Extraction

Recommendations for lead extraction apply only to those patients in whom the benefits of lead extraction outweigh the risks when assessed based on individualized patients factors and operators specific experience and outcomes.

THROMBOSIS OR VENOUS STENOSIS

Class I
5. Lead removal is recommended in patients with ipsilateral venous occlusion reventing access to the venous circulation for required placement of an additional lead when there is a contraindication for using the contralateral side (e.g. contralateral AV fistula, shunt or vascular access port, mastectomy). (Level of evidence: C)

Class IIa
1. Lead removal is reasonable in patients with ipsilateral venous occlusion preventing access to the venous circulation for required placement of an additional lead, when there is no contraindication for using the contralateral side. (Level of evidence C)
Indications for Transvenous Lead Extraction

Recommendations for lead extraction apply only to those patients in whom the benefits of lead extraction outweigh the risks when assessed based on individualized patients factors and operators specific experience and outcomes.

FUNCTIONAL LEADS
Class I
1. Lead removal is recommended in patients with life-threatening arrhythmias secondary to retained leads. (Level of evidence: B)
2. Lead removal is recommended in patients with leads that, due to their design or their failure, may pose an immediate threat to the patients if left in place. (e.g. Telectronics ACCUFIX J wire fracture with protrusion). (Level of evidence: B)
3. Lead removal is recommended in patients with leads that interfere with the operation of implanted cardiac devices. (Level of evidence: B)
4. Lead removal is recommended in patients with leads that interfere with the treatment of a malignancy (radiation/reconstructive surgery). (Level of evidence: C)
Indications for Transvenous Lead Extraction

Recommendations for lead extraction apply only to those patients in whom the benefits of lead extraction outweigh the risks when assessed based on individualized patients factors and operators specific experience and outcomes.

FUNCTIONAL LEADS
Class IIb

1. Lead removal may be considered in patients with an abandoned functional lead that poses a risk of interference with the operation of the active CIED system. (Level of evidence: C)

2. Lead removal may be considered in patients with functioning leads that due to their design or their failure pose a potential future threat to the patient if left in place. (e.g. Telectronics ACCUFIX without protrusion) (Level of evidence: C)

3. Lead removal may be considered in patients with leads that are functional but not being used. (i.e. RV pacing lead after upgrade to ICD) (Level of evidence: C)

4. Lead removal may be considered in patients who require specific imaging techniques (e.g. MRI) that can not be imaged due to the presence of the CIED system for which there is no other available imaging alternative for the diagnosis. (Level of evidence: C)
Indications for Transvenous Lead Extraction

Recommendations for lead extraction apply only to those patients in whom the benefits of lead extraction outweigh the risks when assessed based on individualized patients factors and operators specific experience and outcomes.

FUNCTIONAL LEADS

Class IIb

5. Lead removal may be considered in patients in order to permit the implantation of an MRI conditional CIED system. (Level of evidence: C)

Class III

1. Lead removal is not indicated in patients with functional but redundant leads if patients have a life expectancy of less than one year. (Level of evidence: C)

2. Lead removal is not indicated in patients with known anomalous placement of leads through structures other than normal venous and cardiac structures, (e.g. subclavian artery, aorta, pleura, atrial or ventricular wall or mediastinum) or through a systemic venous atrium or systemic ventricle. Additional techniques including surgical backup may be used if the clinical scenario is compelling. (Level of evidence: C)
Indications for Transvenous Lead Extraction

Recommendations for lead extraction apply only to those patients in whom the benefits of lead extraction outweigh the risks when assessed based on individualized patients factors and operators specific experience and outcomes.

NON FUNCTIONAL LEADS

Class I
1. Lead removal is recommended in patients with life-threatening arrhythmias secondary to retained leads or lead fragments. (Level of evidence: B)
2. Lead removal is recommended in patients with leads that, due to their design or their failure, may pose an immediate threat to the patients if left in place. (e.g. Telectronics ACCUFIX J wire fracture with protrusion) (Level of evidence: B)
3. Lead removal is recommended in patients with leads that interfere with the operation of implanted cardiac devices. (Level of evidence: B)
4. Lead removal is recommended in patients with leads that interfere with the treatment of a malignancy (radiation/reconstructive surgery). (Level of evidence: C)
Indications for Transvenous Lead Extraction

Recommendations for lead extraction apply only to those patients in whom the benefits of lead extraction outweigh the risks when assessed based on individualized patients factors and operators specific experience and outcomes.

NON FUNCTIONAL LEADS

Class IIa

1. Lead removal is reasonable in patients with leads that due to their design or their failure pose a threat to the patient, that is not immediate or imminent if left in place. (e.g. Telectronics ACCUFIX without protrusion) (Level of evidence C)

2. Lead removal is reasonable in patients if a CIED implantation would require more than 4 leads on one side or more than 5 leads through the SVC. (Level of evidence C)

3. Lead removal is reasonable in patients that require specific imaging techniques (e.g. MRI) and can not be imaged due to the presence of the CIED system for which there is no other available imaging alternative for the diagnosis. (Level of evidence: C)
Indications for Transvenous Lead Extraction

Recommendations for lead extraction apply only to those patients in whom the benefits of lead extraction outweigh the risks when assessed based on individualized patients factors and operators specific experience and outcomes.

NON FUNCTIONAL LEADS
Class III
1. Lead removal is not indicated in patients with non-functional leads if patients have a life expectancy of less than one year. (Level of evidence C)
2. Lead removal is not indicated in patients with known anomalous placement of leads through structures other than normal venous and cardiac structures, (e.g. subclavian artery, aorta, pleura, atrial or ventricular wall or mediastinum) or through a systemic venous atrium or systemic ventricle. Additional techniques including surgical backup may be used if the clinical scenario is compelling. (Level of evidence: C)
Why does an implanted cardiac lead pose such a problem at time of removal?
The Chronic Lead

1. Binding scar tissue
2. Poor lead design
3. Fragile Materials
4. Implant technique and lead entry location
5. Patient anatomy and physiology
The Chronic Lead

- Binding scar tissue
The Chronic Lead

1. Binding scar tissue – Location
2. Poor lead design
3. Fragile Materials
4. Implant technique
5. Patient anatomy

72% 48%
36% 41%
16% 71%
The Chronic Lead

1. Binding scar tissue
2. Poor lead design
3. Fragile Materials
4. Implant technique
5. Patient anatomy and physiology
The Chronic Lead

1. Binding scar tissue
2. Poor lead design
3. Fragile Materials
4. Implant technique and lead entry location
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The Chronic Lead

1. Binding scar tissue
2. Poor lead design
3. Fragile Materials
4. Implant technique and lead entry location
5. Patient anatomy and physiology
Indications for Extraction

- Infection (sepsis)
- Damaged leads (arrhythmias, venous trauma)
- Unable to implant additional leads
- Thromboembolic events resulting from a retained lead
- Lead that interferes with the operation of another implanted device
Infection

- Reported in 4-7% of implants
- Erosion occurs when the generator and/or leads exit through the skin
- Staph Epi is the most common microbe while Staph Aureus (MRSA) and related are more virulent
- Can be located in:
  - The pacemaker pocket
  - Along the lead (in biofilm)
  - Within a compromised lead
Damaged Lead

Can be caused by:

- Trauma to the lead
- Lead reaction to the “hostile” human body and subsequent material degradation
- Faulty implant technique
- Result of a lead extraction of another lead
Fractured Lead
Damaged Lead

What are the problems?

1. Arrhythmias (Due to broken leads striking the epicardial wall)
2. Muscle stimulation
3. Endothelial wall damage
4. Potential puncture of heart wall and large vessel (J-wire design)
Unable to implant additional lead

- Too much implanted hardware
- Large vein occlusion

Re-implanting through the same tract as that of the removed lead is the
Thromboembolic events resulting from retained lead

- Pulmonary emboli
- Especially troubling with congenital heart disease patients and those with PFO
Lead Interference

- Inadvertent shocks (Defib.)
- Over-sensing resulting in inhibition of pacing
Implanted Device Lead Extraction

Intervention for failed and/or infected pacemaker/ICD leads or where venous obstruction is considered possible

- Infected or potentially infected ICD or pacemaker lead
  - Take blood/wound cultures, swab implant area before commencing antibiotics
  - TOE (if available) to assess vegetations on lead(s)
  - Refer to specialist centre for management and extraction
  - Consider percutaneous or surgical extraction

- Failed or redundant ICD/pacemaker lead
  - Any evidence of infection?
    - Yes
      - Is the lead causing arrhythmias or other mechanical problems?
        - Yes
          - Abandon/bury lead, no further action
        - No
      - No

- Venous obstruction plus ICD or pacemaker lead
  - Obstruction confirmed with venography?
    - No
    - Yes
Lead Extraction Techniques

Minimal invasive transvenous approach

• Superior approach
  • Access by the subclavian vein
  • Access by the jugular vein
• Femoral Approach
  • Access by the femoral vein
Lead Extraction Categories

- Lead Control
  - Locking stylet – Liberator®
  - Lead extender – Bulldog™
- Vessel Entry
  - Evolution® Shortie
- Superior Approach
  - Dilator Sheath Poly & TFE
  - Evolution® Mechanical
  - Needle’s Eye Snare®
- Femoral Approach
  - Needle’s Eye Snare®
- Accessories
Lead Extraction Categories

Lead Control
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Vessel Entry
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- Dilator Sheath Poly & TFE
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Femoral Approach
- Needle’s Eye Snare®

Accessories
Liberator® Locking stylet

- Traction (pulling on a lead) is a fundamental and essential component of all lead extraction procedures. Without some form of traction a lead extraction cannot be performed.
- Traction on a lead is defined as a pulling force (force along the long axis) creating tension. Ideally, this tension stiffens the lead (rail effect) providing support for guiding sheaths and applying pressure to binding sites.
Liberator® Locking stylet

• The most effective method for controlling traction on a lead is the locking stylet. A locking stylet is deployed and locked near the distal electrode. The tension caused by the traction is confined to the locking stylet, preventing destruction of the lead body.

• It also stiffens the lead, supporting the manipulation of sheaths (rail effect).

• The purpose of this work is to show how traction is controlled using a Liberator Locking Stylet. The correct applications of the underlying principles governing traction are exhibited by this stylet.
Liberator® Locking stylet

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- It also stiffens the lead, supporting the manipulation of sheaths (rail effect).
- The purpose of this work is to show how traction is controlled using a Liberator Locking Stylet. The correct applications of the underlying principles governing traction are exhibited by this stylet.
Liberator® Locking stylet

- Universal size: Single model is compatible with all known leads possessing an inner-lumen. [.016 - .032 inch]
Liberator® Locking stylet
Liberator® Locking stylet
Liberator® Locking stylet
Liberator® Locking stylet
Liberator® Locking stylet

- The Liberator will always lock at the very end of the Tip.
- This secures that traction will be applied to the Tip and not somewhere inbetween. This can be crucial to the success of the Lead Extraction Procedure.
Liberator® Locking stylet
Lead Extraction Categories

- Lead Control
  - Locking stylet – Liberator®
  - Lead extender – Bulldog™

- Vessel Entry
  - Evolution® Shortie

- Superior Approach
  - Dilator Sheath Poly & TFE
  - Evolution® Mechanical

- Femoral Approach
  - Needle’s Eye Snare®

- Accessories
Bulldog™ Lead extender
Bulldog™ Lead extender

- Secures lumenless leads, defibrillator lead’s shocking coil conductor cables and broken or damaged leads during the extraction procedure
Bulldog™ Lead extender

- Used to extract lumen-less pacemaker and defibrillator leads.
- Compatible with ALL Cook extraction sheaths

Other uses for Bulldog™…

- To “extend” a broken lead
- To extend a broken Liberator
- To “grasp” the shocking coil cables of ICD leads to prevent them from becoming “disrupted” during advancement of “sheaths”.
Evolution® Shortie

**Problem:**
Challenging vein access associated with lead removal.

**Solution:** Shortie.

**Problem:**
Maintaining access when removing acute cardiac leads.

**Solution:** Shortie.
Some key points:

✓ Use the **EVOLUTION® SHORTIE** during difficult venous entry procedures
Evolution® Shortie

Some key points:

✔ Always ensure that the pacing lead and EVOLUTION® SHORTIE are “co-axial” or “in line” when attempting to access the vessel.
Evolution® Shortie

Some key points:

✅ Do not attempt to pass EVOLUTION® SHORTIE too deeply into the vessel and take extra caution when approaching a bend in the vessel
Evolution® Shortie

1. Initial incision showing generator and leads.

2. Counter-incision is created. Liberator® Locking Stylets secured within leads and exit through counter-incision.
Evolution® Shortie

Counter-incision utilized for optimal approach angle for Evolution® Shortie tip insertion.

**INCORRECT**

Attention: Using the original generator removal incision site may result in a sub-optimal angle for inserting the Evolution® Shortie device.
Lead Extraction Categories

- Lead Control
  - Locking stylet – Liberator®
  - Lead extender – Bulldog™
- Vessel Entry
  - Evolution® Shortie
- Superior Approach
  - Dilator Sheath Poly & TFE
- Femoral Approach
  - Needle’s Eye Snare®
- Accessories
  - Evolution® Mechanical
  - Needle’s Eye Snare®
Dilator Sheath Poly & TFE

- Manual Mechanical Telescoping Dilator Sheath Sets
Lead Extraction Categories

- Lead Control
  - Locking stylet – Liberator®
  - Lead extender – Bulldog™

- Vessel Entry
  - Evolution® Shortie

- Superior Approach
  - Dilator Sheath Poly & TFE
  - Evolution® Mechanical

- Femoral Approach
  - Needle’s Eye Snare®

- Accessories
Evolution® Mechanical

- Sheath rotates when the trigger handle is squeezed for maximum operator control

- The patented threaded barrel tip provides succinct passage past fibrous binding sites without the “forward depth of cut” of other powered sheaths

- Available in four sizes that are compatible with both pacing and defibrillator leads: 7, 9, 11 & 13 Fr. (I.D.)
● When sizing the Evolution™ choose a sheath that is at least 2 French sizes but preferably 3 French sizes larger than the lead to be removed.
Evolution® Mechanical

- Slight forward pressure will allow the Evolution™ tip to engage into the area of fibrosis and then “pulling” on the handle (trigger) will cause the sheath to rotate and advance forward through the lesion.
Evolution® Mechanical

• Rotational speed is directly controlled by the Physician (speed at which he squeezes the “trigger”).

• Some Physicians like Dr. Byrd prefers to rapidly squeeze (in short “bursts”) to produce a “pulsing” movement of the Evolution.
Evolution® Mechanical

- Movement through the lesion is caused mainly by the tip of the Evolution™ sheath "pulling" itself forward as it rotates.
Evolution® Mechanical

- There is no “depth of cut” ahead of the metal tip of Evolution™
- Evolution’s continuous helical tip and flexible rotating sheath efficiently separate fibrous binding adhesions from the target lead.
The inner surface of the metal tip is designed with a slight radius so that it will not cut into the lead.

This has not been a problem in over 6,000 uses.
The “outer sheath” is used both as a support for the Evolution™ inner sheath and also as a dilator itself when necessary.
Evolution® Mechanical

- Evolution™ can be used throughout the length of the lead… normal care should be taken when working at the tip of the lead (against the myocardium).
“Counter-traction” should be applied with the outer sheath when detaching the lead from the myocardium.
Evolution® Mechanical

- The use of a Liberator™ Locking Stylet is strongly recommended to ensure that constant traction can be applied “throughout” the lead to create a firm platform over which the Evolution™ can advance. “Other” locking stylets may lock more proximally causing limited “support” distally which could cause problems.
When removing more than one lead, it is important to “dress” all leads at the beginning of the procedure. This will reduce any rotational effect that may occur on secondary leads as the primary lead is removed.

(Definition: “dress” means to place a Liberator™ locking stylet down ALL leads from the start and lock in place).
If secondary leads are to be left in place (not removed) then a “normal” (non-locking) stylet should be used as support.
Lead Extraction Categories

Lead Control
- Locking stylet – Liberator®
- Lead extender – Bulldog™

Vessel Entry
- Evolution® Shortie

Superior Approach
- Dilator Sheath Poly & TFE

Femoral Approach
- Needle's Eye Snare®

Accessories
- Evolution® Mechanical
- Needle’s Eye Snare®
Needle’s Eye Snare

- Compatible with the Cook Vascular Inc. Curved Inner Femoral Sheath (LR-CRVFEM 001) for added utility
- Flush port is continuous with the snare’s innermost lumen
- Outer 16 Fr. sheath can be used in counter-traction
- Works with free-floating catheters or with those without free ends
- Formed from a Nitinol® alloy for consistent preservation of shape
- Provides quick-release capability by simply retracting the threader
Lead Extraction Categories

- **Lead Control**
  - Locking stylet – Liberator®
  - Lead extender – Bulldog™

- **Vessel Entry**
  - Evolution® Shortie

- **Superior Approach**
  - Dilator Sheath Poly & TFE
  - Evolution® Mechanical
  - Needle’s Eye Snare®

- **Femoral Approach**
  - Needle’s Eye Snare®

- **Accessories**
Accessories

- Lead Clipper
- Coil Expander
- Sof-Grip Hemostat
- Pin Vise
- Stylet Wires
Superior Approach – Preparation

1. Surgical Team on stand-by
2. Pericardiocentesis Set
3. Typed and crossed blood
4. TEE
5. High quality fluoroscopy
6. Thoracotomy tray (where appropriate)
Superior Approach

1. Open and thoroughly debride pocket.
2. Free proximal lead(s) and remove all tie-down sutures and the lead’s suture collar.
3. Cut-off proximal connector using Lead Clippers.
4. Remove ~ 1-2 cm of lead’s outer insulation using scalpel and isolate the innermost conductor coil.
5. Insert Coil Expander into the cut end of the lead to assure a circular opening.
Superior Approach

7. Advance Stylet wire down the innermost lumen toward the lead tip and Visualize under fluoroscopy.

8. Advance LIBERATOR® Locking Stylet down the innermost lumen toward the lead tip and Visualize under fluoroscopy.

9. Engage the locking stylet.

10. Tie suture around lead proximal end and attach it to the LIBERATOR.
Superior Approach

11. Place appropriate EVOLUTION or manual telescoping dilator sheath set over the locking stylet and advance toward the tip of the lead while maintaining tension on the locking stylet.

12. When the dilator sheath set is within 1-2 cm of the leads distal tip. **STOP**

13. Position the outer dilator sheath so that the blunt or flat end is distal and toward the heart wall. Make sure that the inner sheath is drawn safely into the outer sheath and hold firmly.
Superior Approach

14. Gradually increase tractional force to the locking stylet while holding the sheath firm (Counter-Traction).

15. After the lead detaches from endocardial wall, carefully draw the lead tip into the dilator sheath and slowly remove the lead.

16. If a new lead is to be replaced during this procedure, consider advancing a guidewire through the dilator sheath prior to its removal to maintain the lead tract for a subsequent lead implantation.
THANK YOU