Extraction of transvenous Pacing and ICD leads "2009 HRS Consensus"

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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.

Definitions

Lead Extraction Approach: Leads are usually removed via the same transvenous access by which they were inserted, termed the implant vein. However, sometimes alternative venous access is required from a non-implant vein.

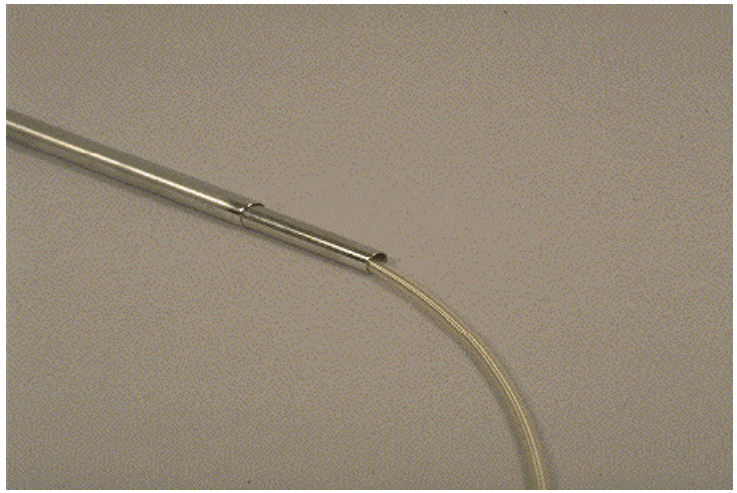
Simple Traction: Manipulation of the lead so that the lead exits the vasculature via the implant vein using tools typically supplied for lead implant, with the addition of traction. These tools include such items as standard stylets (nonlocking), and fixation screw retraction clips.

Extraction tools: *locking stylets*

A **special type of a traction device designed to hold onto the inside of the conductor coil along its length or near the distal stimulating electrode, improve tensile properties and prevent elongation of the lead body during traction.**

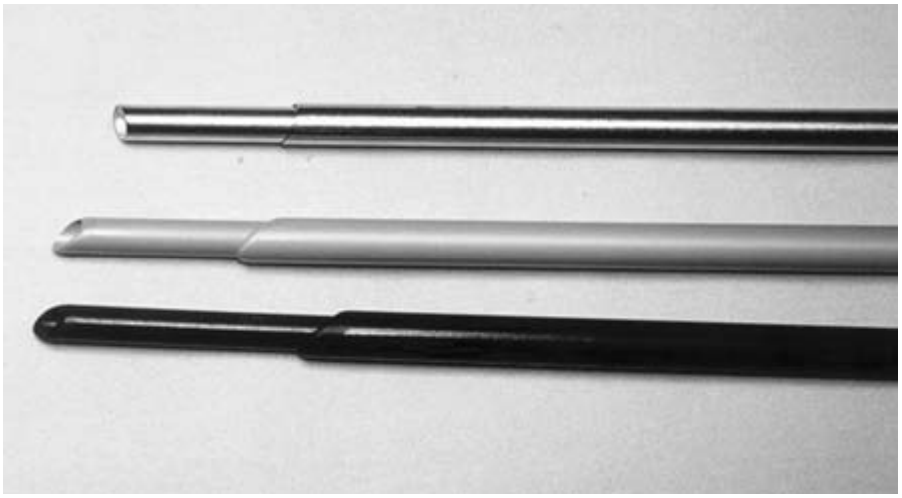
Extraction tools: *Mechanical Sheaths*

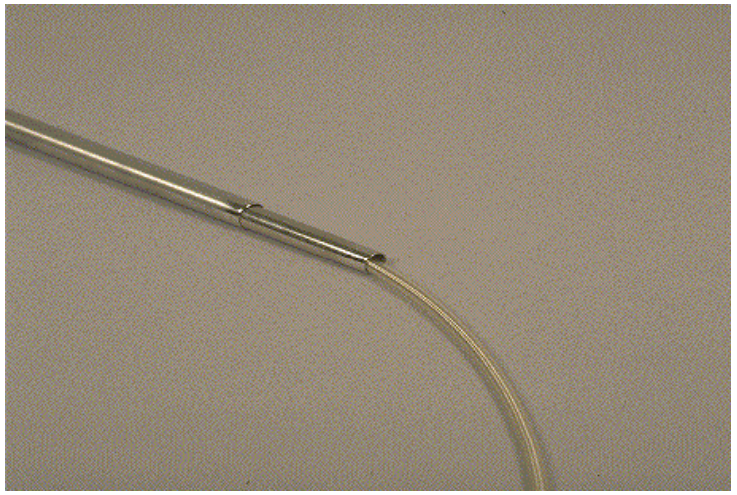
Sheaths composed of metal, Teflon™, polypropylene or other materials that require manual advancement over the lead and rely on the mechanical properties of the sheath to disrupt fibrotic attachments.



Extraction tools: *Telescoping Sheaths*

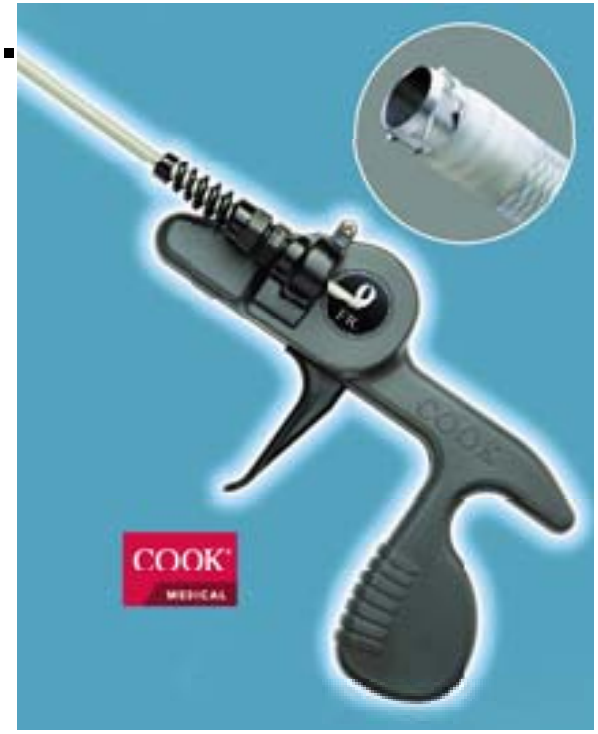
: Any extraction sheath that can be used as a single sheath or may be paired with a second sheath. The use of two sheaths takes advantage of the flexibility of the inner sheath and the stiffness of the outer sheath to prevent kinking and to improve the effectiveness of advancement over the lead without overstressing the lead. The outer sheath is usually mechanical, even when the inner sheath uses some other technology such as laser, electrosurgical or rotating threaded tip.





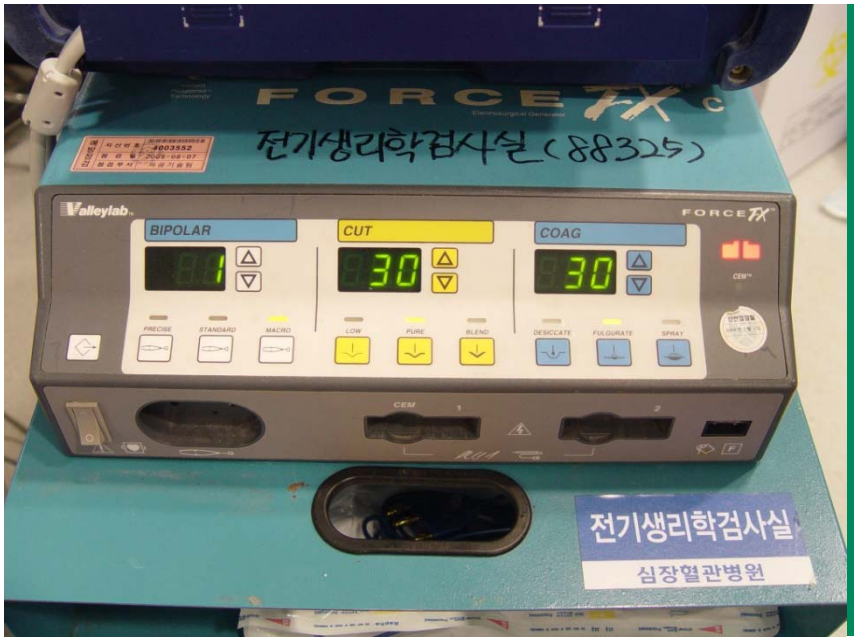
Rotating Threaded Tip Sheath

Sheaths that are equipped with a rotationally powered mechanism that bore through and disrupt fibrotic attachments with a threaded screw mechanism at the sheath tip.



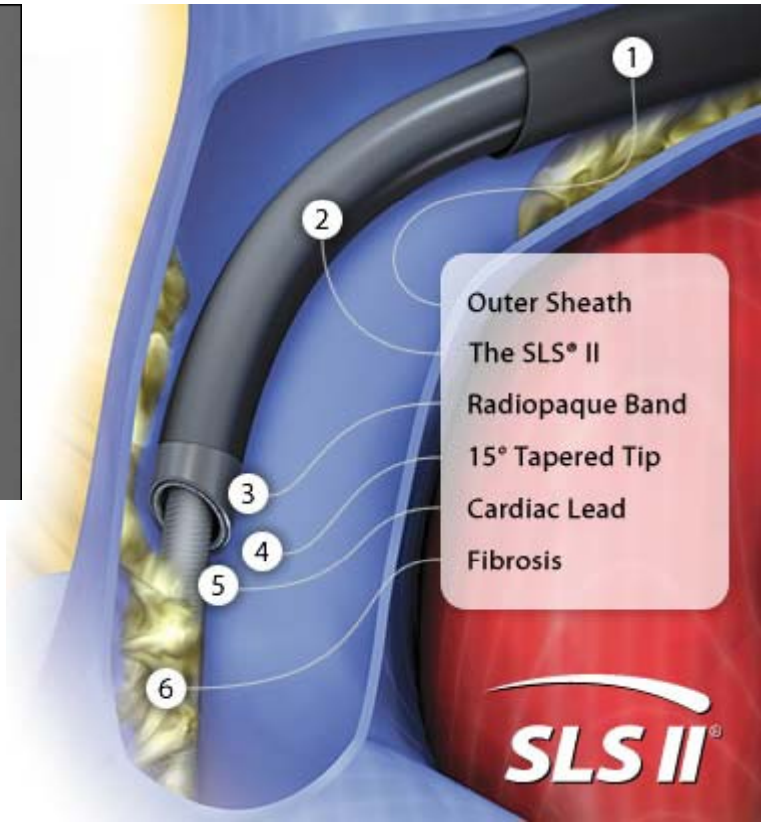
Extraction tools: *Electrosurgical Sheaths*

Sheaths that use radiofrequency energy (such as found in an electrosurgical unit) emitted between two electrodes at the sheath tip to disrupt the fibrotic attachments.



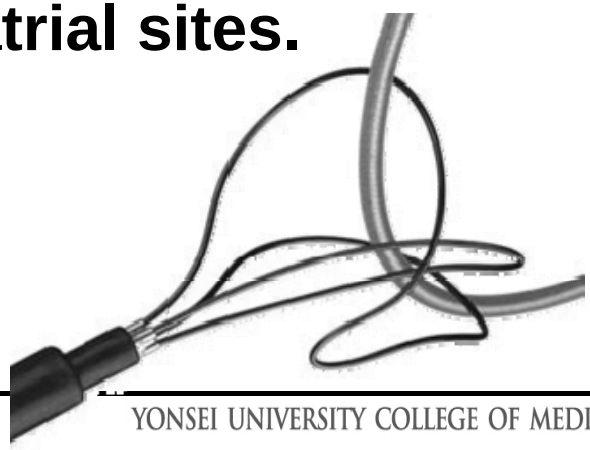
Extraction tools: *Laser Sheaths*

Sheaths that employ fiberoptics to transmit laser light to disrupt the fibrotic attachments.

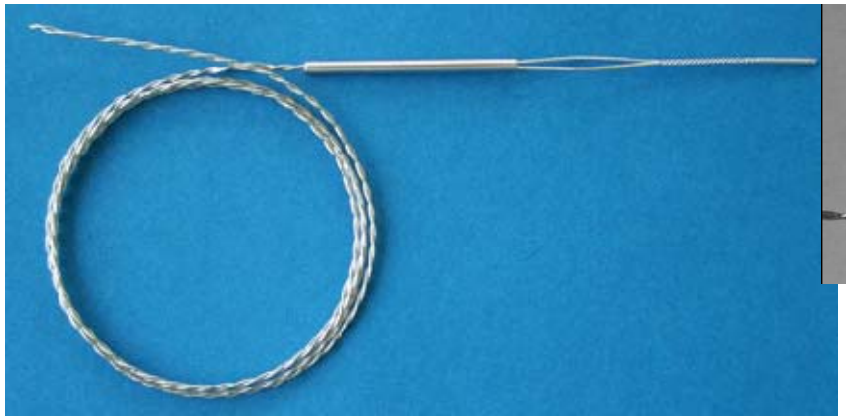


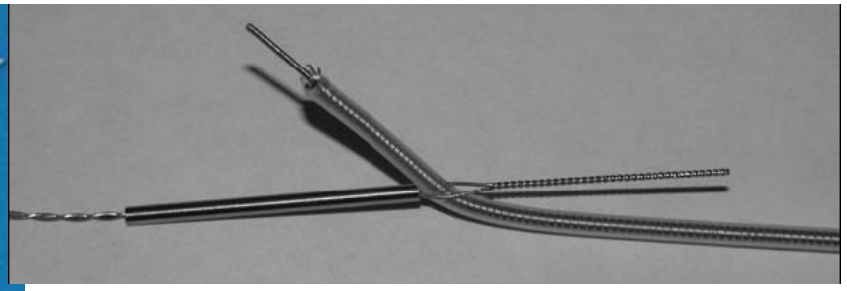
Extraction tools: *Extraction Snares*

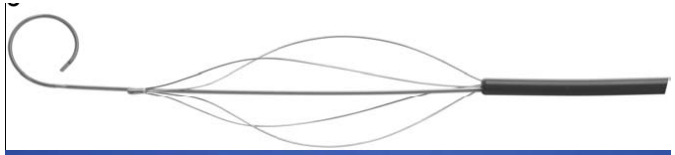
In cases with “free floating” leads, an approach from other than the implant vein is required. This is also true when lead disruption occurs during the procedures. Tools for retrieval from the non-implant vein must be available. These include large sheaths (workstations) with a hemostatic valve, and a variety of grasping and snaring devices. Venous access for these snares can be from the femoral, internal jugular, subclavian or trans-atrial sites.

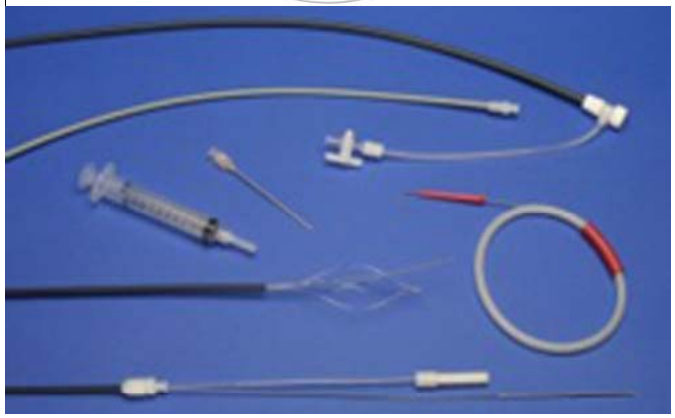


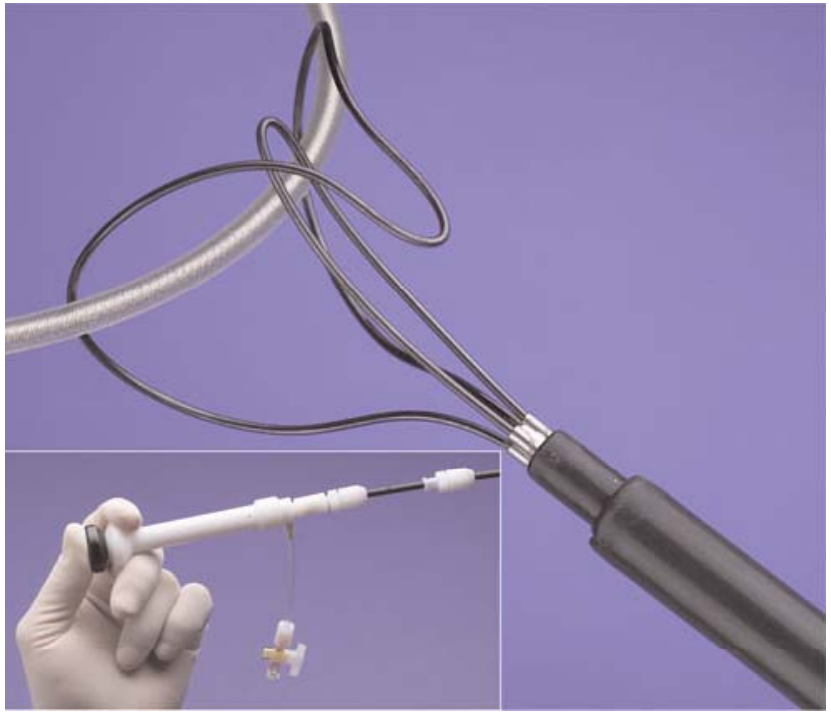
Extraction tools: *Extraction Snares*











Technical and Clinical Success

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. This may be the tip of the lead or a small part of the lead (conductor coil, insulation, or the latter two combined) when the residual part does not increase the risk of perforation, embolic events, perpetuation of infection or cause any undesired outcome.

Targeted Clinical Outcomes

These may include one or more of the following:

1. **Elimination of infection (pocket infection, device related endocarditis)**
2. **Creation of venous access in an occluded vessel**
3. **Elimination of an identified risk (perforation, arrhythmia) produced by a lead or portion of a lead**
4. **Preservation of desired pacing mode**
5. **Removal of all non-functional leads**
6. **Resolution of all pocket related symptoms (i.e. pain)**

Required personnel*

Primary Operator: A physician performing the lead extraction who is properly trained and experienced in device implantation, lead extraction and the management of complications.

Cardiothoracic surgeon well versed in the potential complications of lead extraction and techniques for their treatment, on site and immediately available

Anesthesia support

Personnel capable of operating fluoroscopic equipment

“Scrubbed” assistant (nurse/technician/physician)

Non “scrubbed” assistant

Echocardiographer

*Depending on the environment, one person can hold expertise in several areas and satisfy the requirements (eg. the extractor could be the cardiothoracic surgeon), but at least 5 people (1 – airway and sedation management 2 - scrubbed and 2 - non scrubbed) need to be in the room at all times with the immediate availability of additional personnel as needed.

Physician qualifications and training

Lead extraction is an invasive procedure that requires training and experience to consistently deliver safe and effective care. Physicians wishing to perform this procedure should be properly trained in extraction techniques and management of complications.

Physicians who have already extracted over 40 leads as a primary operator and maintain the minimum volume of 20 leads extracted annually are considered as meeting the training and volume requirements.

Equipment

High-quality fluoroscopy, Extraction tools, Extraction snares CIED implantation tools, TTE and TEE

Surgical instruments: These include instruments to perform vascular repairs, thoracotomy, sternotomy and CP bypass must be immediately available.

Anesthesia cart for general anesthesia, invasive and noninvasive arterial pressure monitoring, oxygen saturation and CO2 monitoring, pericardiocentesis tray, water seal/vacuum containers for chest tube drainage (2 recommended), temporary transvenous pacemaker and connectors, transcutaneous temporary pacing and defibrillation equipment, intravenous contrast agents, fluids, pressors, and other emergency medications in the procedure room and equipment for cardio-pulmonary bypass must be readily available.

HRS Indications

Class I: conditions for which there is a general agreement that leads should be removed

Class II: conditions for which leads are often removed, but there is some divergence of opinion with respect to the benefit vs risk of removal

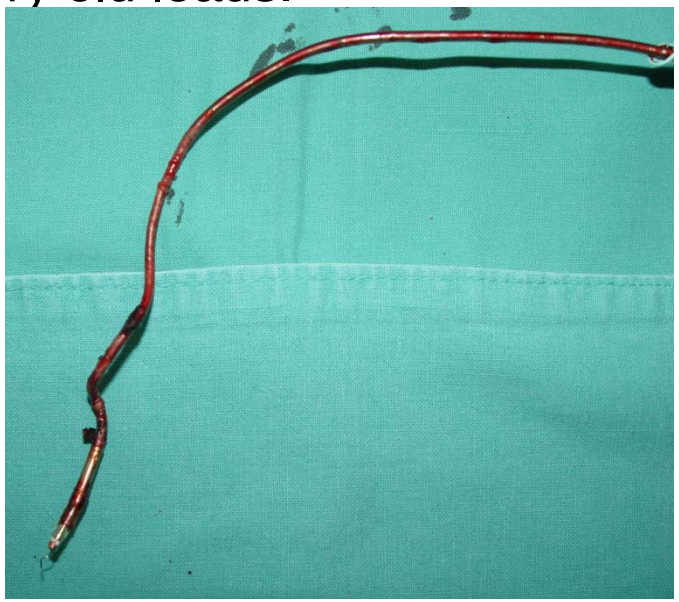
Class III conditions for which there is general agreement that removal of leads is unnecessary

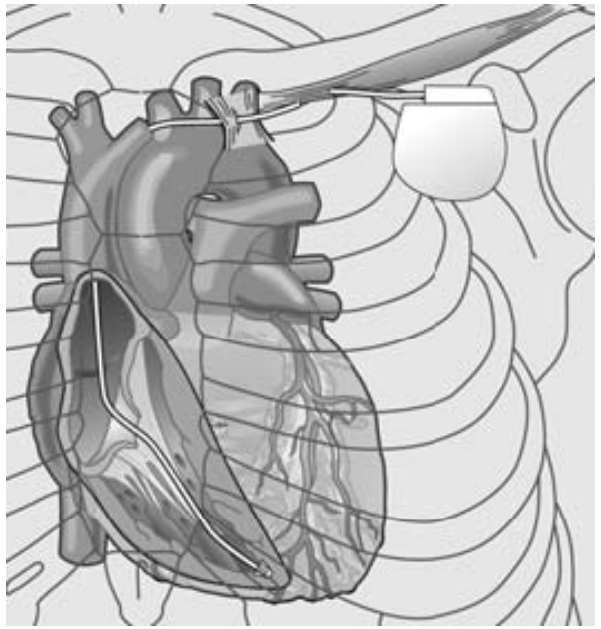
Pathophysiology

The thrombus eventually organizes with fibrosis occurring predominantly on areas of lead that contact the vascular endothelium or endocardium.

The venous entry site, The curve into SVC, and in the region from the anode ring to the lead tip are sites most likely to develop severe fibrosis.

Calcium may incorporate into the fibrous matrix, especially in young patients and very old leads.





Indications for transvenous lead extraction

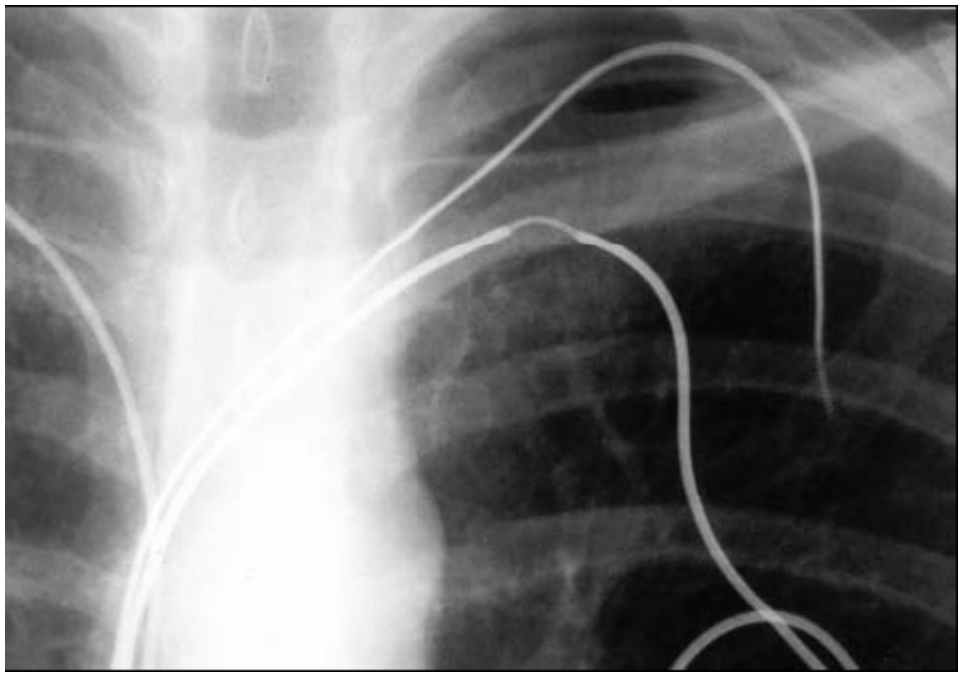
Infection

Multiple Leads

Venous Thrombosis

Migrated Leads

Crush



Indications for transvenous lead extraction: *Infection*

Class I *(Level of evidence: B)*

Complete device and lead removal is recommended in all patients with

1. **Definite CIED system infection, as evidenced by valvular endocarditis, lead endocarditis or sepsis.**
2. **CIED pocket infection as evidenced by pocket abscess, device erosion, skin adherence, or chronic draining sinus without clinically evident involvement of the transvenous portion of the lead system.**
3. **Valvular endocarditis without definite involvement of the lead(s) and/or device.**
4. **Occult gram-positive bacteremia (not contaminant).**

Indications for transvenous lead extraction: *Infection*

Class IIa *(Level of evidence: B)*

1. **Complete device and lead removal is reasonable in patients with persistent occult gram-negative bacteremia.**

Class III *(Level of evidence: C)*

1. **CIED removal is not indicated for a superficial or incisional infection without involvement of the device and/or leads**
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.**

Indications for transvenous lead extraction: *Chronic Pain*

Class IIa *(Level of evidence: C)*

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.**

Indications for transvenous lead extraction: *Thrombosis or Venous Stenosis*

Class I *(Level of evidence: C)*

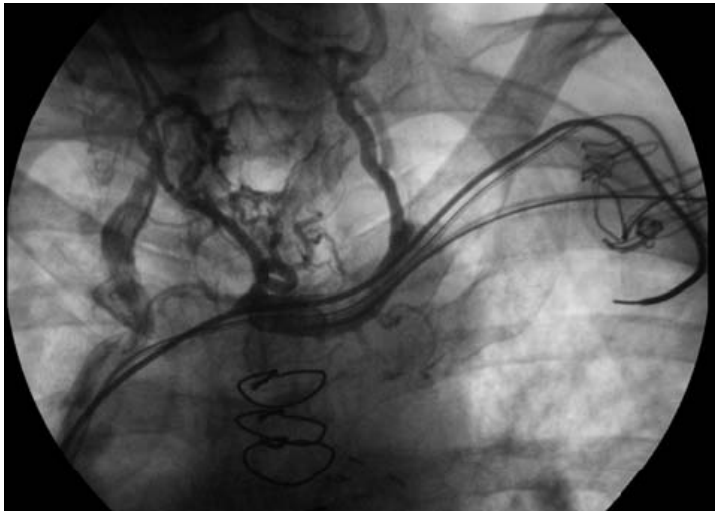
Lead removal is recommended in patients with

1. **Clinically significant thromboembolic events associated with thrombus on a lead or a lead fragment.**
2. **Bilateral subclavian vein or SVC occlusion precluding implantation of a needed transvenous lead.**
3. **Planned stent deployment in a vein already containing a transvenous lead, to avoid entrapment of the lead.**
4. **Superior vena cava stenosis or occlusion with limiting symptoms.**
5. **Ipsilateral venous occlusion preventing 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).**

Indications for transvenous lead extraction: *Thrombosis or Venous Stenosis*

Class IIa *(Level of evidence C)*

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.



Indications for transvenous lead extraction
Functional Leads

Class I *(Level of evidence)*

Lead removal is recommended in patients with

1. Life threatening arrhythmias secondary to retained leads. *(B)*
2. 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). *(B)*
3. Leads that interfere with the operation of implanted cardiac devices. *(B)*
4. Leads that interfere with the treatment of a malignancy (radiation/reconstructive surgery). *(C)*

Indications for transvenous lead extraction
Functional Leads

Class IIb *(Level of evidence: C)*

Lead removal may be considered in patients

1. With an abandoned functional lead that poses a risk of interference with the operation of the active CIED system.

2. 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)

3. With leads that are functional but not being used. (i.e. RV pacing lead after upgrade to ICD)

4. 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.

5. In order to permit the implantation of an MRI conditional CIED system.

Indications for transvenous lead extraction
Functional Leads

Class III *(Level of evidence: C)*

Lead removal is not indicated in patients with

1. **Functional but redundant leads if patients have a life expectancy of less than one year.**
2. **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.**

Indications for transvenous lead extraction
Non Functional Leads

Class I *(Level of evidence)*

Lead removal is recommended in patients with

1. Life threatening arrhythmias secondary to retained leads or lead fragments. *(B)*

2. 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) *(B)*

3. Leads that interfere with the operation of implanted cardiac devices. *(B)*

4. Leads that interfere with the treatment of a malignancy (radiation/reconstructive surgery). *(C)*

Indications for transvenous lead extraction
Non Functional Leads

Class IIa *(Level of evidence)*

Lead removal is reasonable in patients

1. 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) *(C)*

2. If a CIED implantation would require more than 4 leads on one side or more than 5 leads through the SVC. *(C)*

3. 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. *(C)*

Indications for transvenous lead extraction
Non Functional Leads

Class IIb *(Level of evidence:C)*

1. **Lead removal may be considered at the time of an indicated CIED procedure, in patients with non-functional leads, if contraindications are absent.**
2. **Lead removal may be considered in order to permit the implantation of an MRI conditional CIED system.**

Indications for transvenous lead extraction
Non Functional Leads

Class III *(Level of evidence:C)*

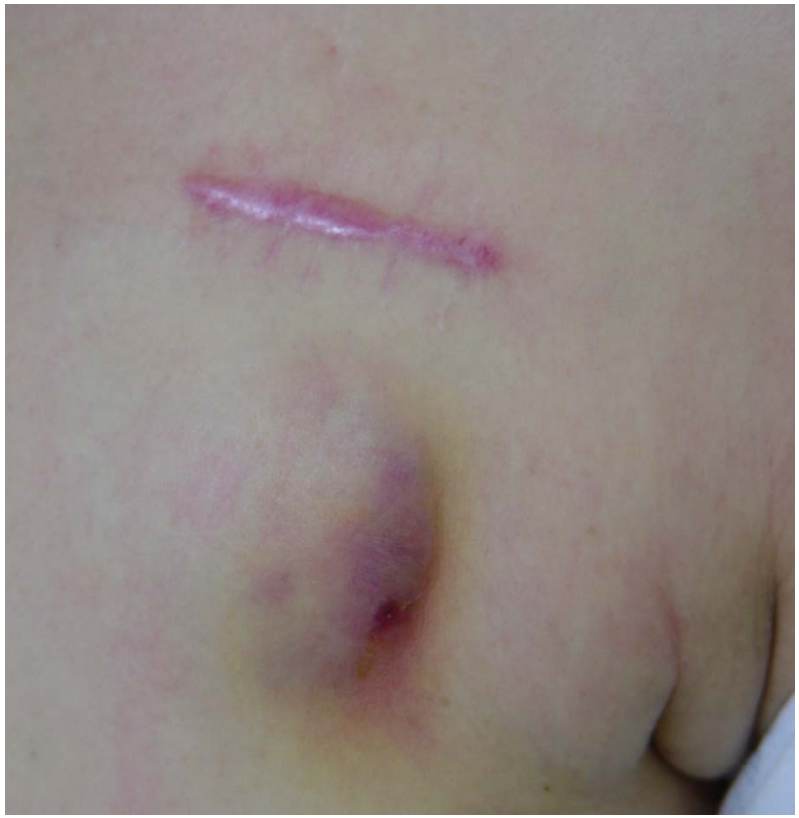
Lead removal is not indicated in patients with

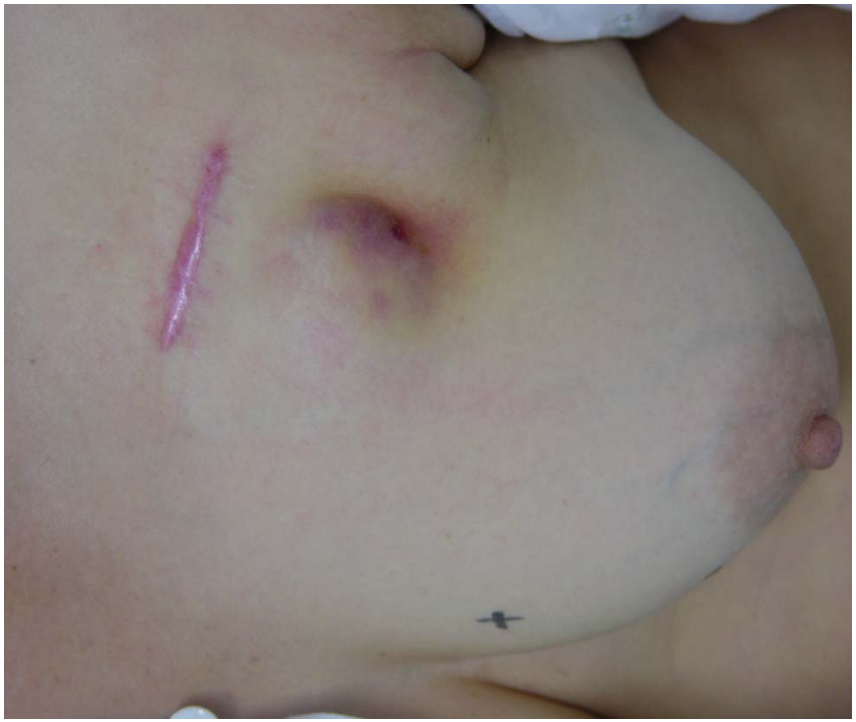
1. **Non-functional leads if patients have a life expectancy of less than one year.**
2. **Known anomalous placement of leads through structures other than normal venous and cardiac structures, (e.g. subclavian artery, aorta, pleura, atrial or ventricular wall or mediastinum) or through a systemic venous atrium or systemic ventricle. Additional techniques including surgical backup may be used if the clinical scenario is compelling.**

55 F

Pain and swelling at pacemaker insertion site

1996-10 : dizziness ➔ CAVB ➔ DDD
2005-3 : Generator change (E Hospital)

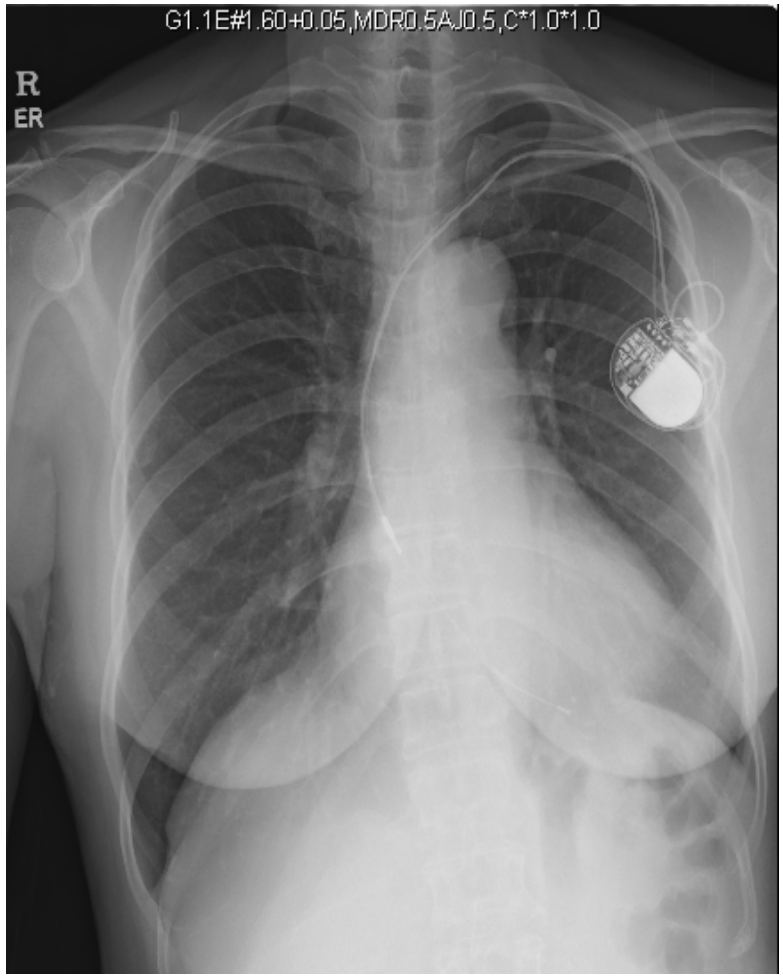




2005-9-15

Chest PA

On admission (HD #1)



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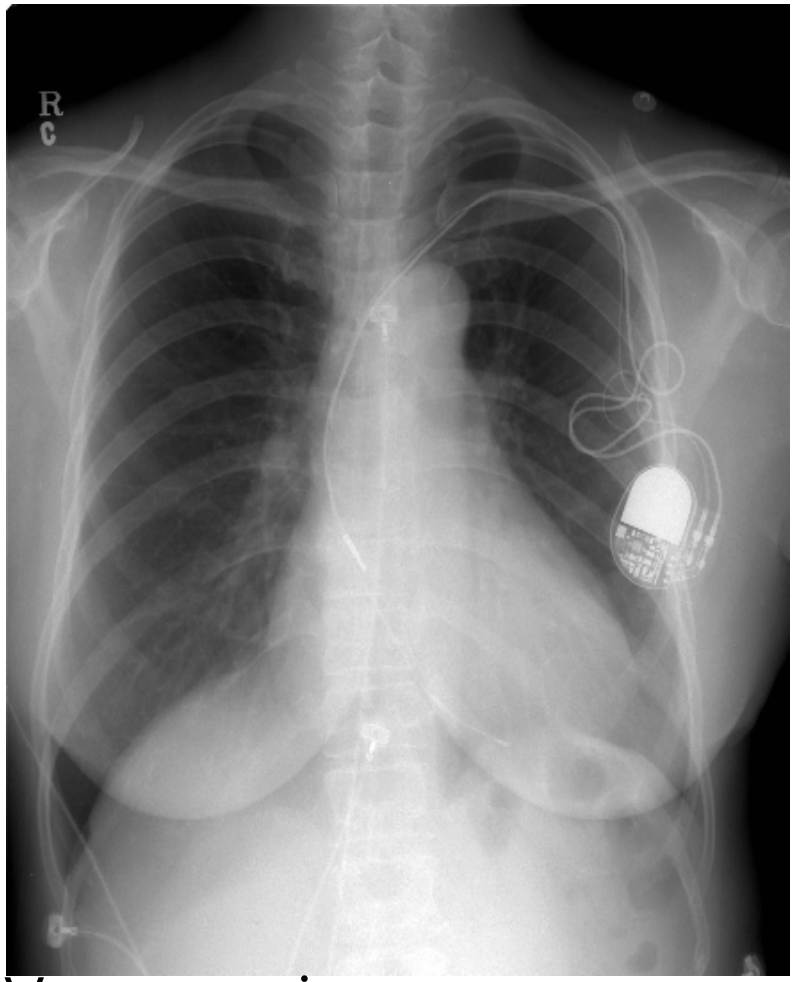
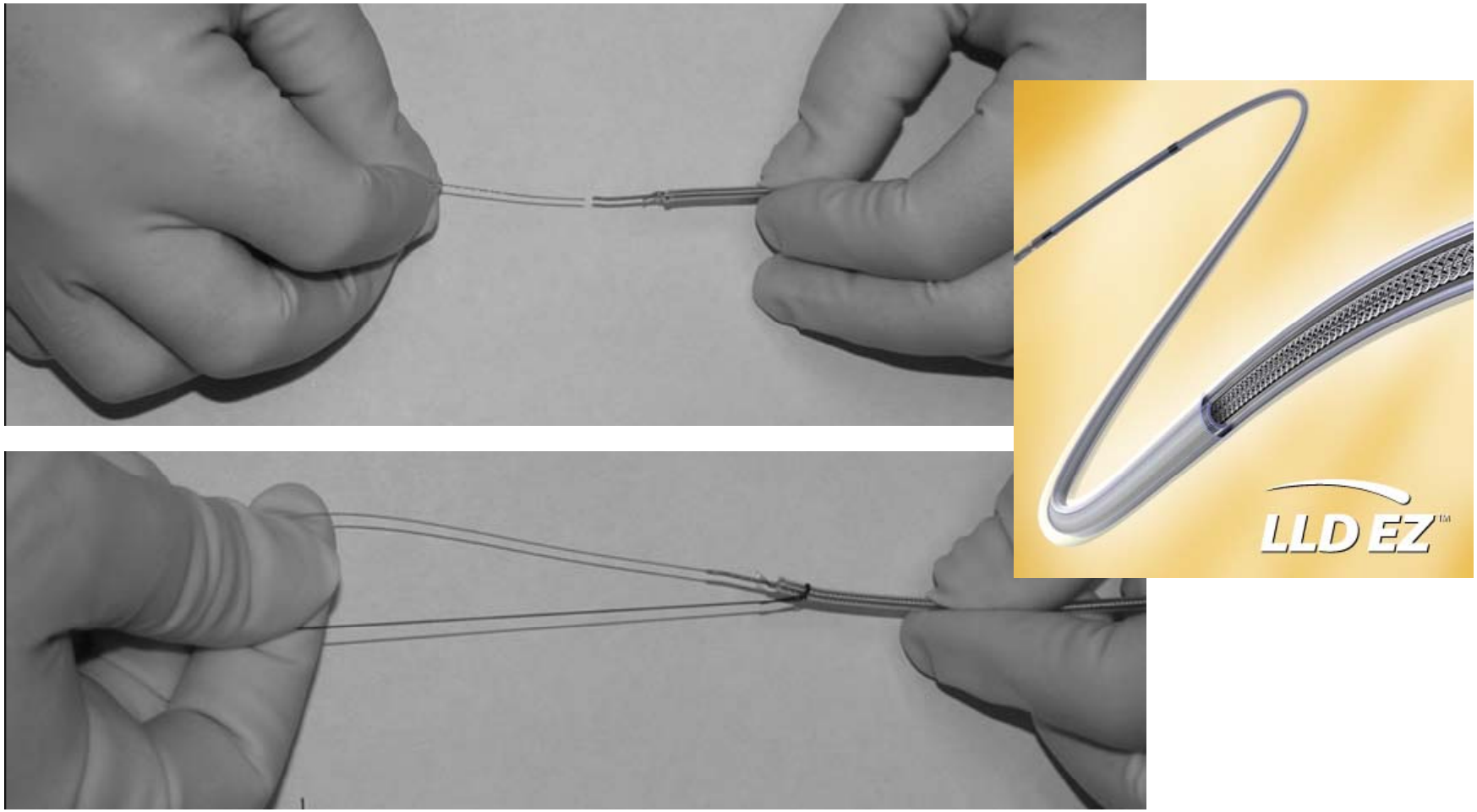
After I & D (HD #3)

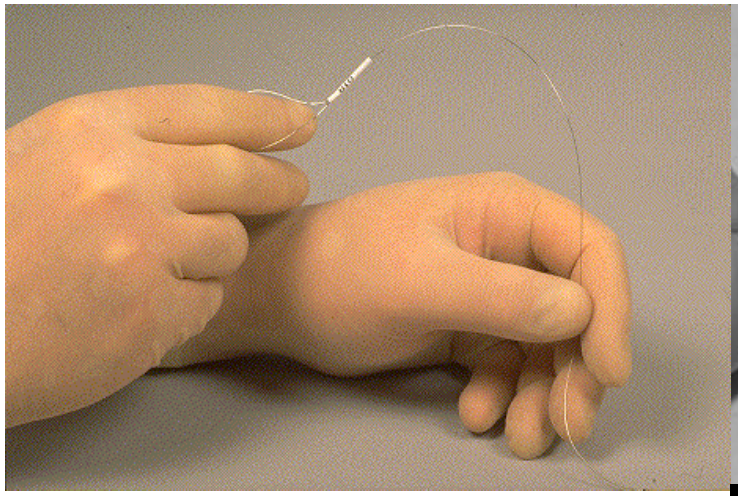


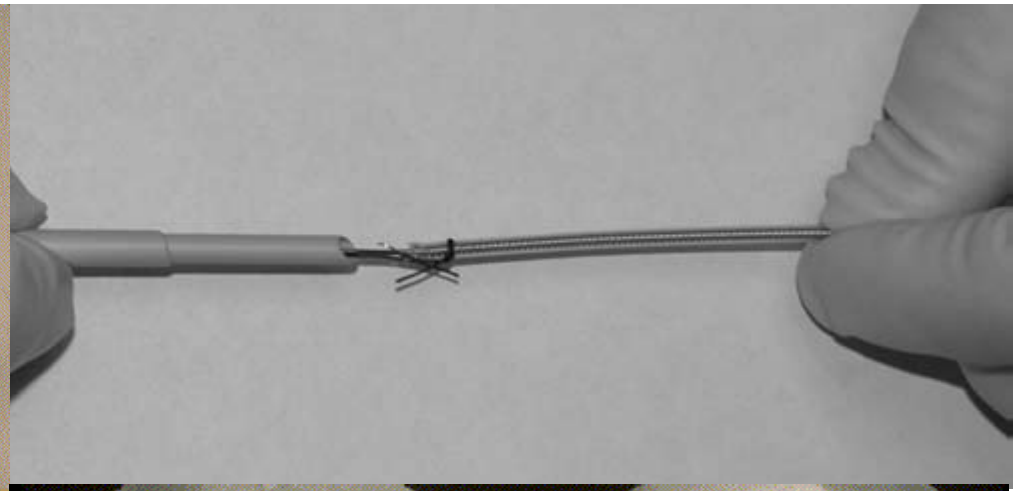
→ Vancomycine **2005-9-17**

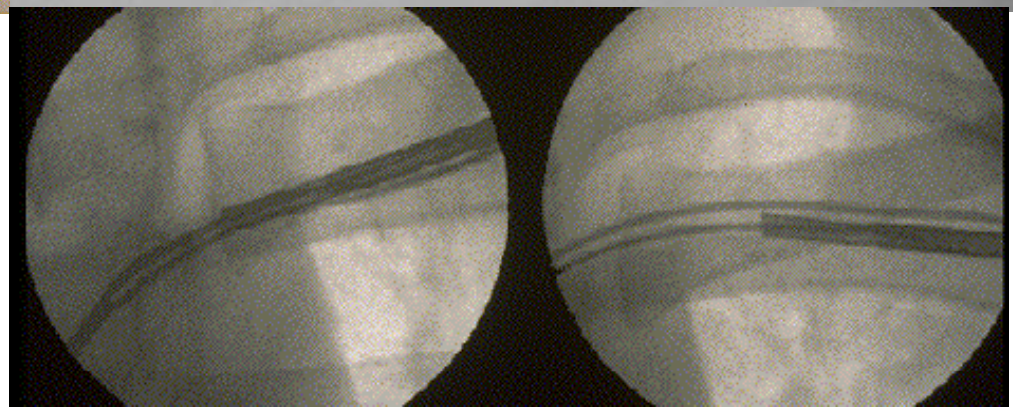
Locking Stylet



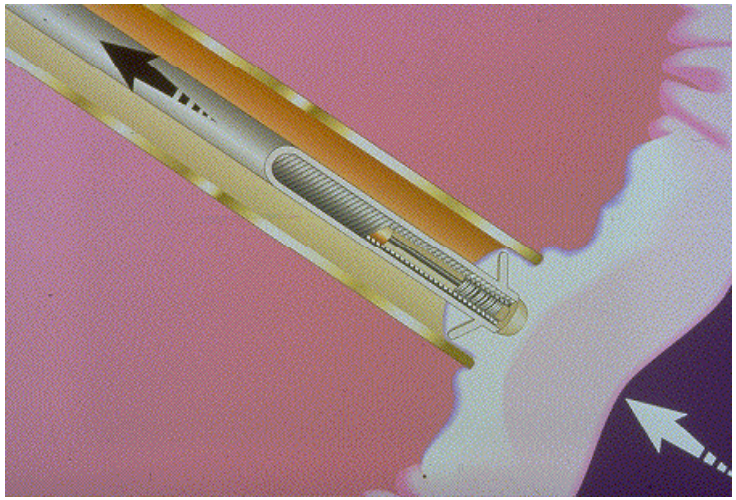
Locking Stylet & Telescopic Sheath

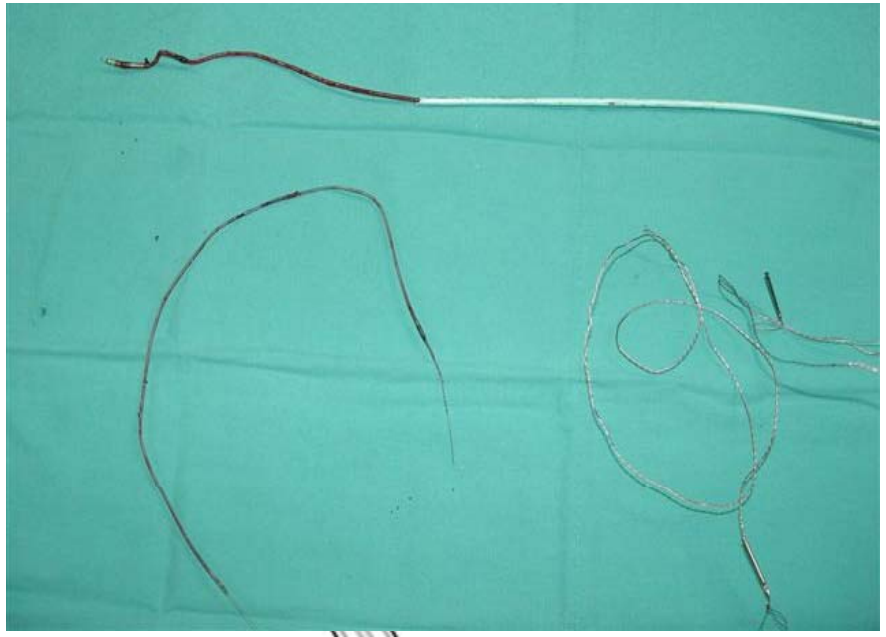


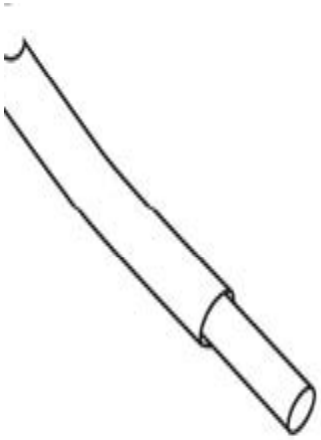


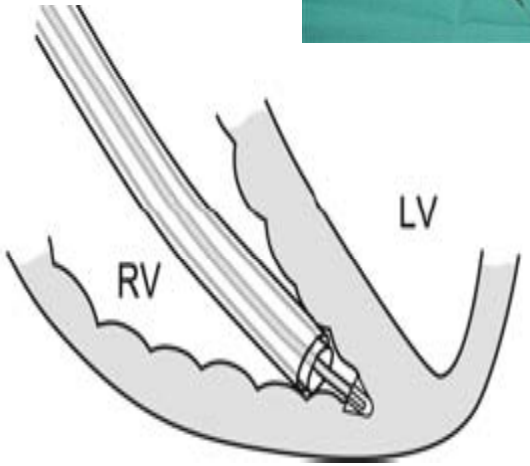


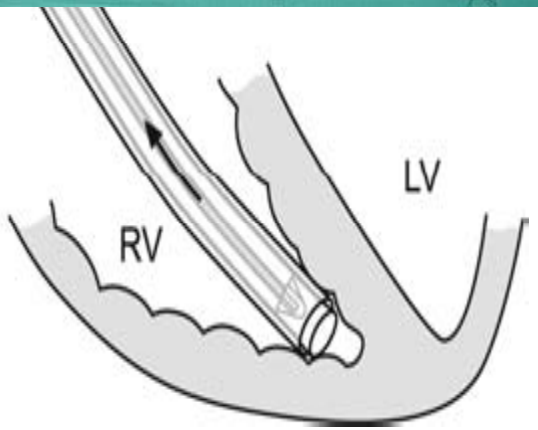
Counter Traction



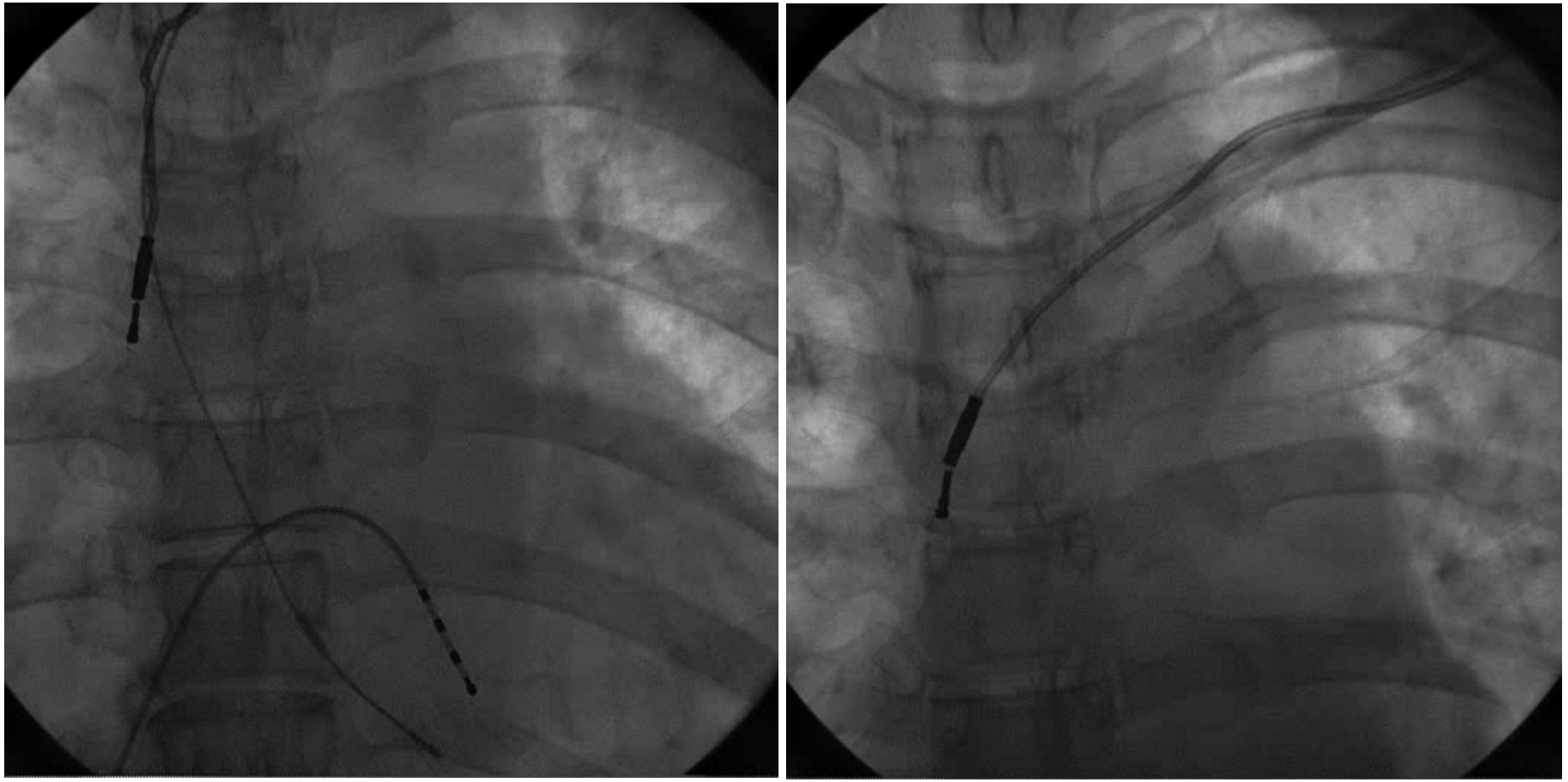






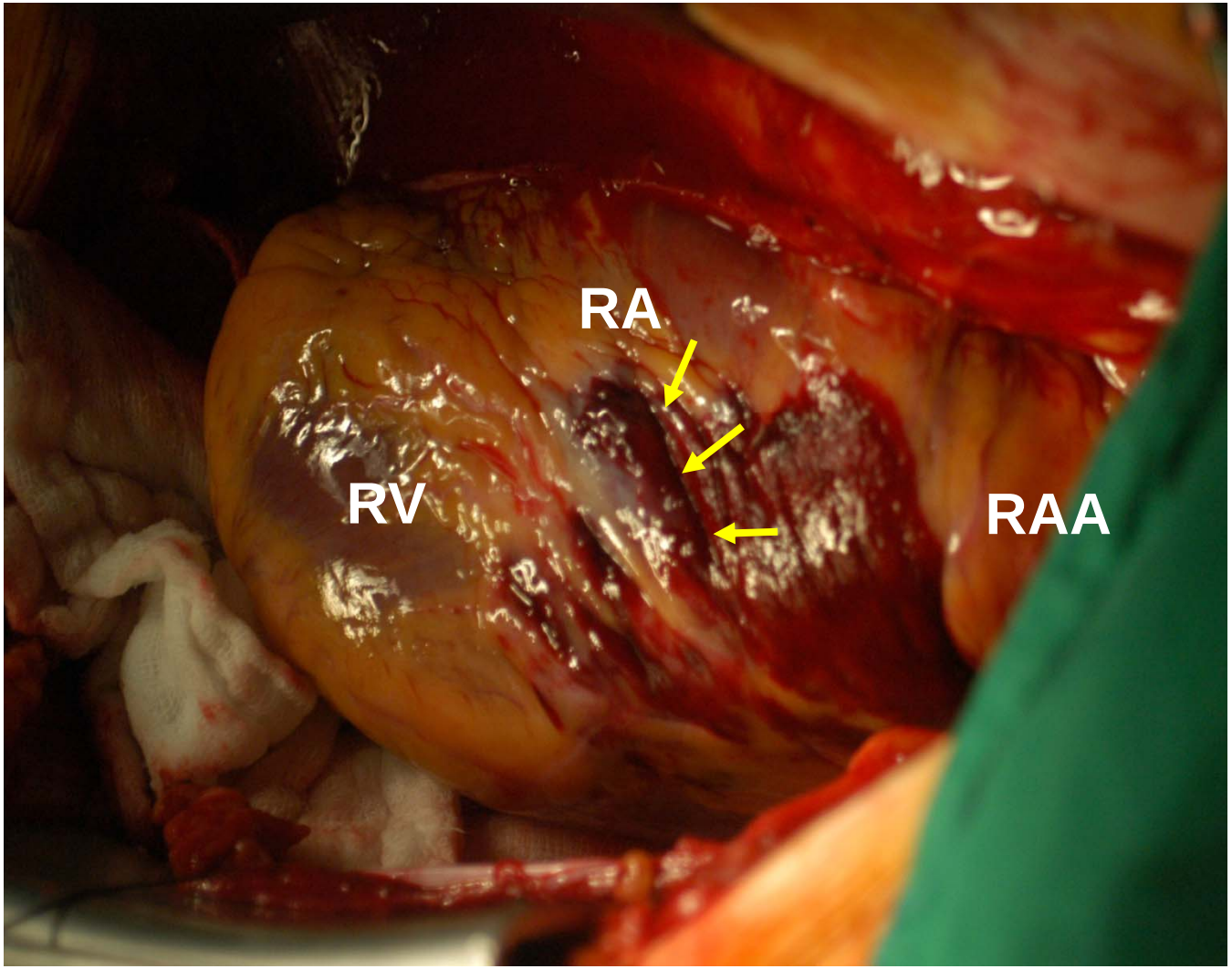


Lead extraction



2005-9-22

Ruptured RA



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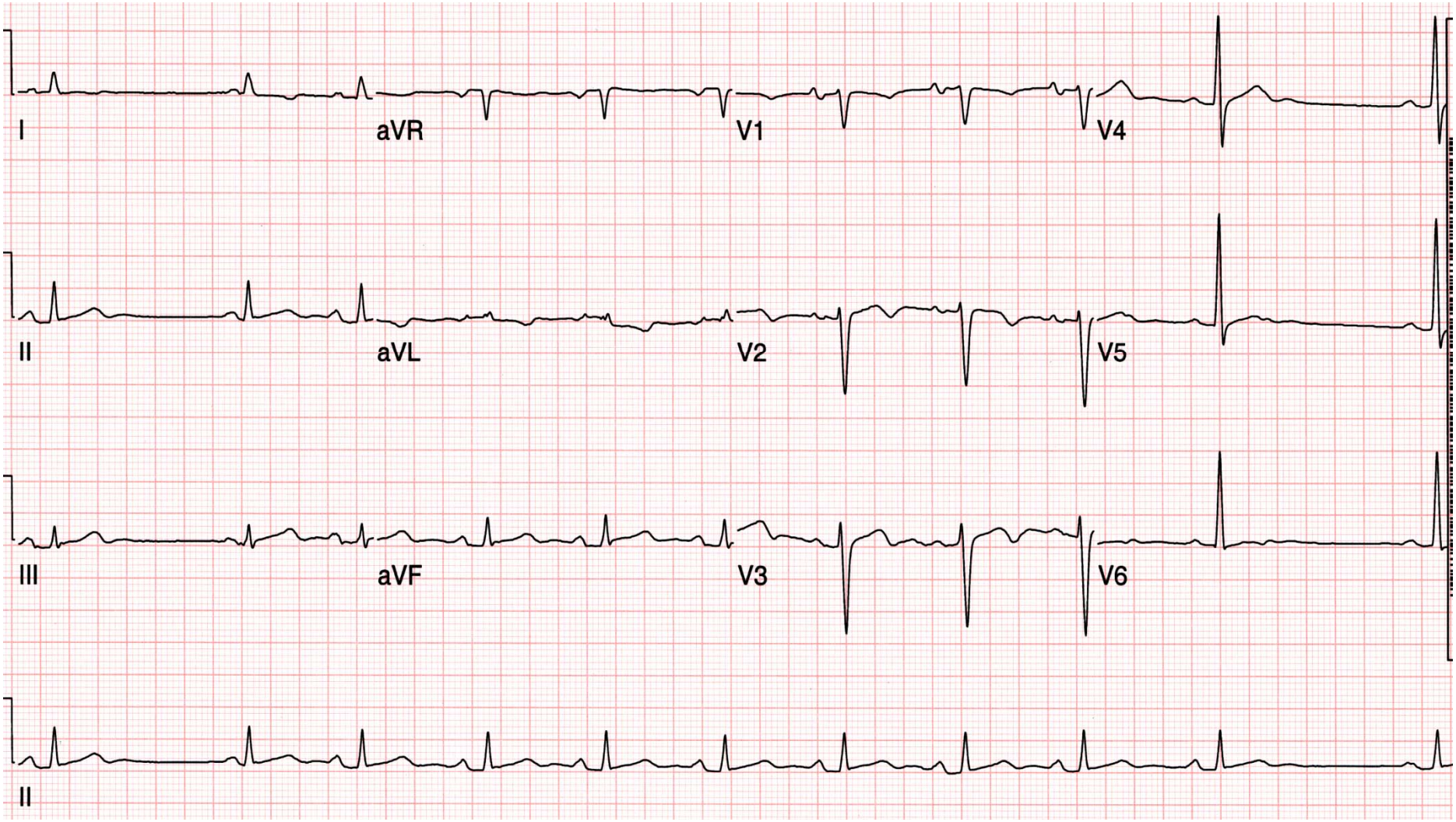
Park SJ, # 4397359

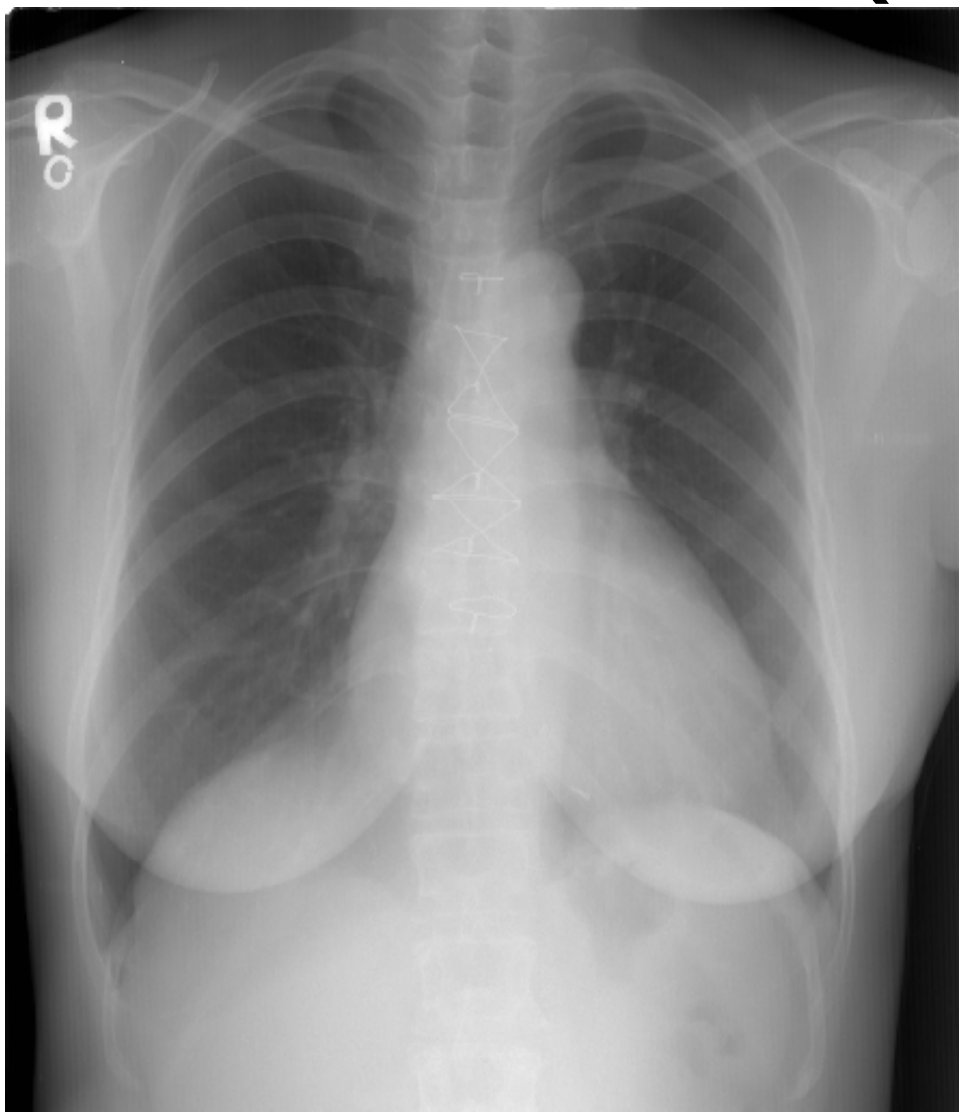
EKG (POD #18)

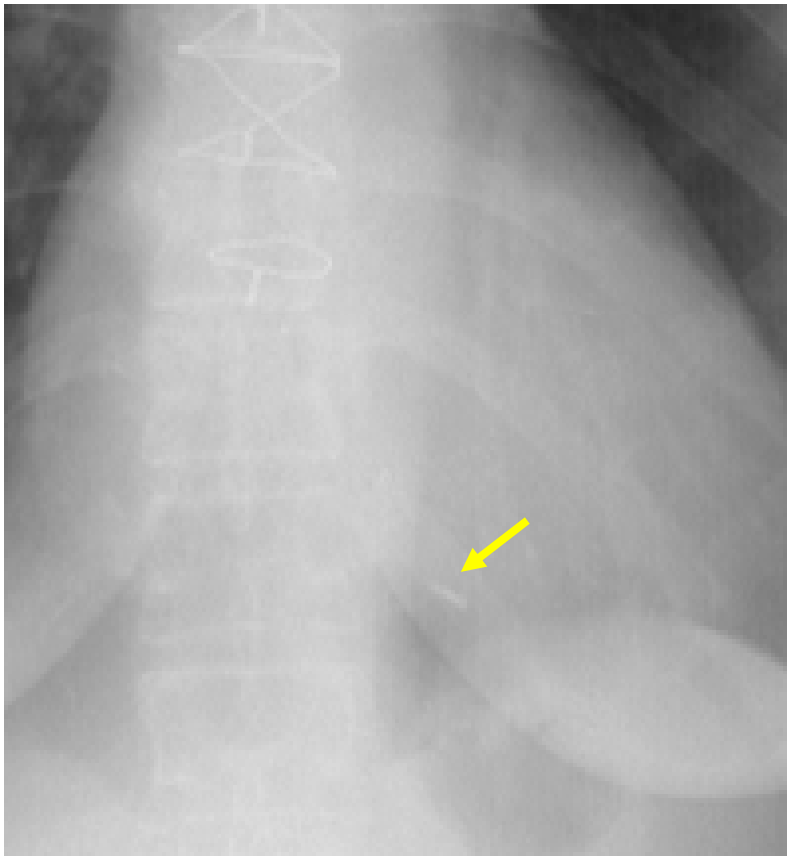
57 bpm



2005-10-10

Chest PA (POD #18)





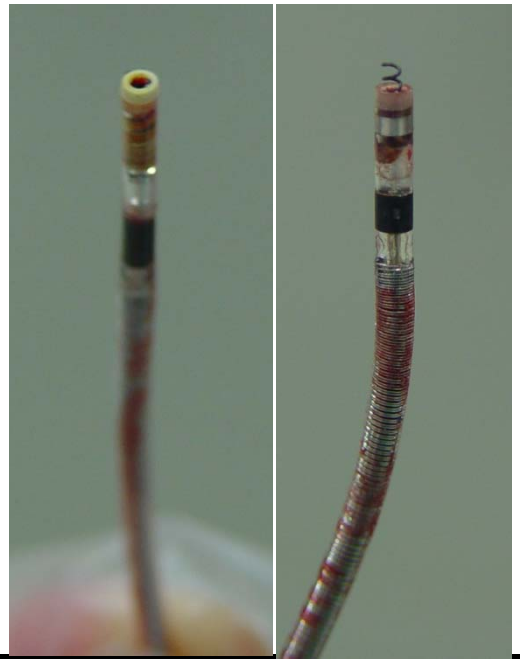
2005-10-10

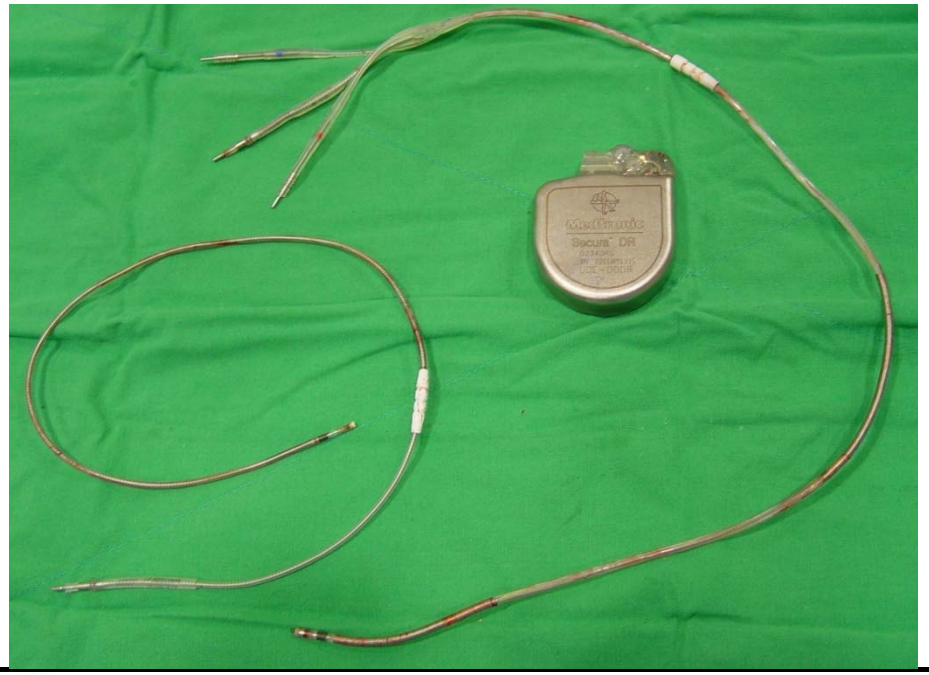
Conclusion

1. **Cardiovascular implantable electronic devise (CIED)** 시술 증가에 따라 제거술이 증가
2. 엄격한 시술 **indication** 적용으로 불필요한 시술억제하고 철저한 감염관리로 제거술 최소화
3. **CIED**의 정확한 시술**(puncture site)**로 기능장애 최소화

Conclusion

1. **Cardiovascular implantable electronic devise (CIED)** 시술 증가에 따라 제거술이 증가
2. 엄격한 시술 **indication** 적용으로 불필요한 시술억제하고 철저한 감염관리로 제거술 최소화
3. **CIED**의 정확한 시술**(puncture site)**로 기능장애 최소화
4. 제거시 편리함을 고려하면 **“screw type”, “single coil”** 권장





Conclusion

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5. 감염시 **curative therapy**는 거의 모든 **foreign bodies**를 제거하는 것이 원칙
6. 완벽한 장비 준비와 완벽한 인적 준비
7. 응급상황에 대한 철저한 준비

Conclusion

한국의 현실은**?**
제도의 미비로 **laser**나 **RF power sheath** 등 다양한 제거용 도구 없음
고난도, 고위험 시술임에도 적절한 수가 보상 안됨

다시

1. 엄격한 시술 **indication** 적용으로 불필요한 시술억제하고 철저한 감염관리로 제거술 최소화
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