

Lead Extraction and
Pocket Management for
Devices

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Disclosures

- Consultant
Philips Lead Management

Generic names used unless
no comparable product
available

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Comprehensive
Lead
Management
Center
Aurora St.
Luke's

8 CV Operating Rooms
3 Hybrid EP/CV Operating Rooms

Since 1996 over 1500
patients have
undergone lead
extraction at ASLMC

- **Transvenous extraction tools**
 - 308 nM Xenon Chloride Excimer Laser sheath
 - Rotating mechanical endarterectomy sheath(es)
 - Telescoping Polypropylene sheaths
- **Femoral access extraction tools**
 - Snares and biopsy forceps
- **Venoplasty and venous stenting**
- **Surgical Program**
 - Surgical placement of epicardial leads and patches
 - Open removal of complex infected systems

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Outline

- Device Pocket Infections
- Crash Course in Surgery
- Creating a New Device Pocket
- Pocket Management during Device Changes
- Learn from Complications

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Outline

- Lead Management
- Lead Extraction Pitfalls
- Surgical Standby
- Lead Extraction Injuries

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Device Pocket Infections

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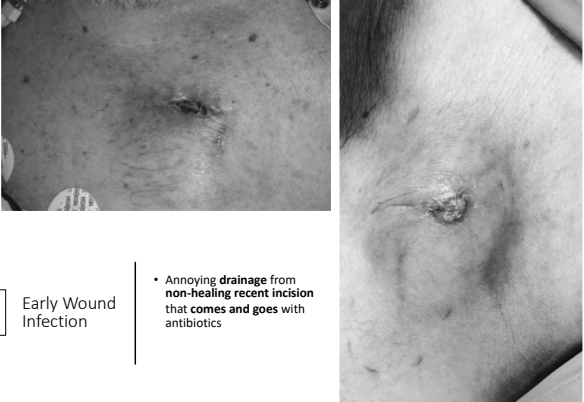
The Many Faces of Pocket Infection

- Brawny indurated skin adherent to generator
- Diffuse erythema that comes and goes with antibiotics
- Annoying drainage from recent incision that comes and goes with antibiotics

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Early Wound Infection

- Annoying **drainage** from **non-healing recent incision** that **comes and goes** with antibiotics

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Early Wound Infection

- **Incision** heals but develops **diffuse erythema** that **comes and goes** with antibiotics



Eventually the underlying abscess will “point” through the incision or pocket

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Late wound infection

- **Brawny indurated skin** **adherent to generator**

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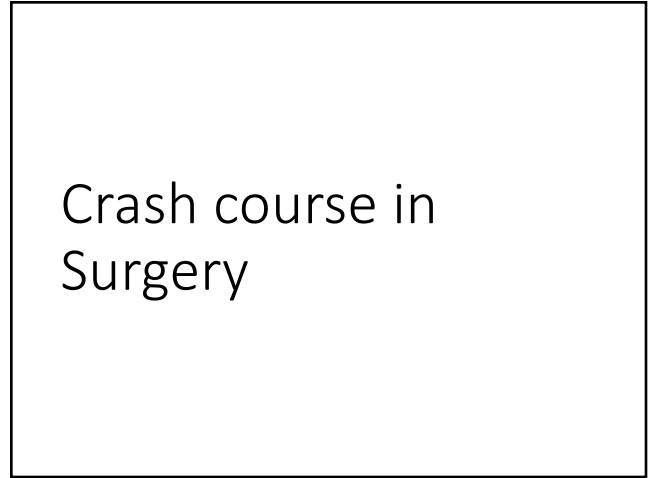
Pocket Erosion



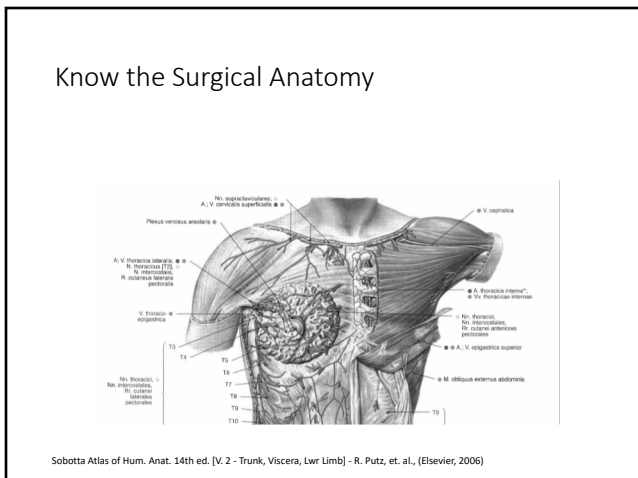
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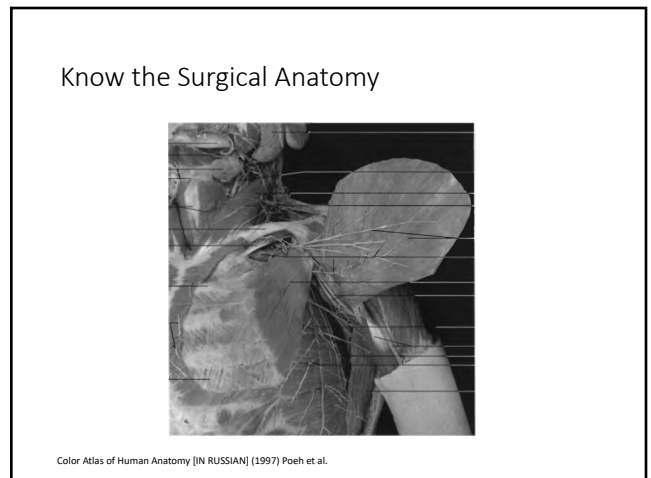
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Prep and drape surgical site well

-  Shave and tape away beards
-  Prep to **costal margin, halfway down arm, well into axilla and neck up to chin** on both sides
-  **Iodine impregnated adhesive skin drape** unless iodine allergy
-  Use **towel clips on towels** if not going to use sticky drape so they stay put **EXPOSE AS LITTLE SKIN AS POSSIBLE**

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Use Instruments
Not your fingers!

There is only ONE surgical plane –

- between SQ and pectoral muscle, OR
- between pectoral major and minor

MUST SEE everything you cut or cauterize

- Retractor and LIGHT

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Use the right Forceps


Adson – Skin Edge



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Use the right Forceps

DeBakey – Subcutaneous/Soft Tissue



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Use the right Forceps

Ferris-Smith - Capsule



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Retractors



Senn
Skin edges



Army Navy
Subcutaneous pocket



Appendiceal
Submuscular pocket

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Self-retaining Retractors

• Weitlaner



NML size or obese patients

• Cerebellar



Morbidly obese patients

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Minimize Foreign Bodies

Cut knots with **short tails**
3 throws for silk, more than 5 throws for braided synthetic
Turn knot down toward wound so it doesn't stick out

2-0 instead of 0 to tie in lead sleeves and generator
TIE IN EACH LEAD SLEEVE SEPARATELY

Avoid routine use of pouch
Permanent fabric pouch for Twiddler or repositioned migration

Avoid leaving in **hemostatic materials**

SPONGE COUNTS ACCURATE!

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Skin closure

<p>Virgin Incision</p> <p>2 layer SQ (Deep SQ/Pectoral Fascia and Scarpa's Fascia)</p> <p>Subcuticular Absorbable braided or monofilament</p> <p>If use Steristrips on skin, space at least 5 mm apart</p>	<p>Redo Incision – Old Same as Virgin Incision unless only 1 layer in SQ possible</p> <p>Redo Incision - Recent Find and take out old SQ and skin sutures</p> <p>Interrupted absorbable 1 layer and skin staples</p>
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Excise skin edges that are of questionable viability


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If it looks unlikely to heal...
it won't heal!

- Closed too tight
- Burnt or macerated skin edges
- Leathery tissue from prior irradiation
- Washout and sub-muscular relocation for infection

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Closed too Tight



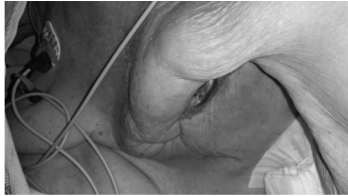
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Unhealthy skin edges



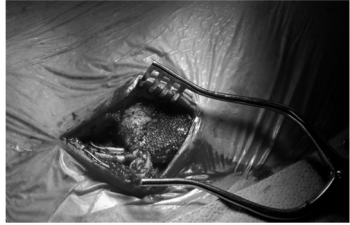
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Prior mastectomy and radiation
Subpectoral erosion



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Failed Sub-muscular Relocation

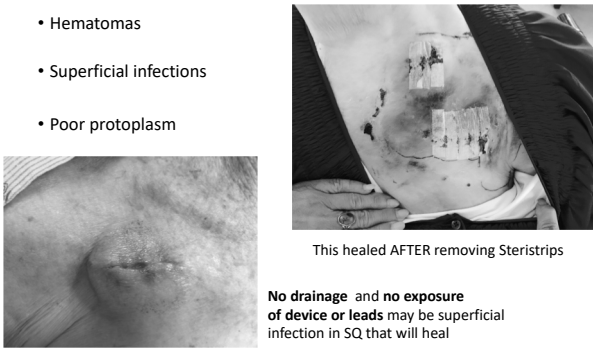


Antibiotic pouch unlikely to help if already infected

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See in Clinic Until it Heals!

- Hematomas
- Superficial infections
- Poor protoplasm



This healed AFTER removing SteriStrips

No drainage and no exposure of device or leads may be superficial infection in SQ that will heal

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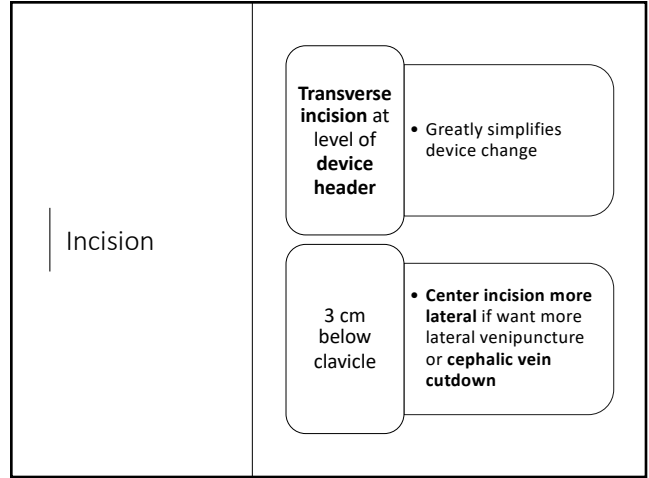
Dilution is the solution to pollution

- Remember **serial dilutions** from physical chemistry in college
- Ten 50 cc irrigations better than one 500 cc irrigation
- Don't leave dead tissue in wound for bacteria to eat
 - Including **old capsule** material when possible!
- Consider using commercially available jet lavage system containing CHLORHEXIDINE GLUCONATE 0.05% in 450 cc sterile water for irrigation

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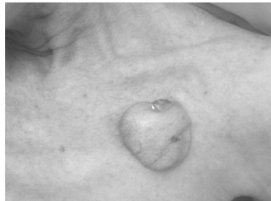
Creating a New Device Pocket

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Suboptimal Incisions



Really?



Vertical?

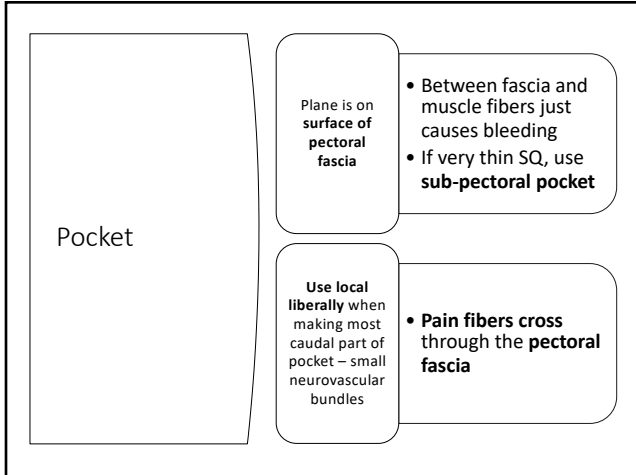
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Suboptimal Incisions

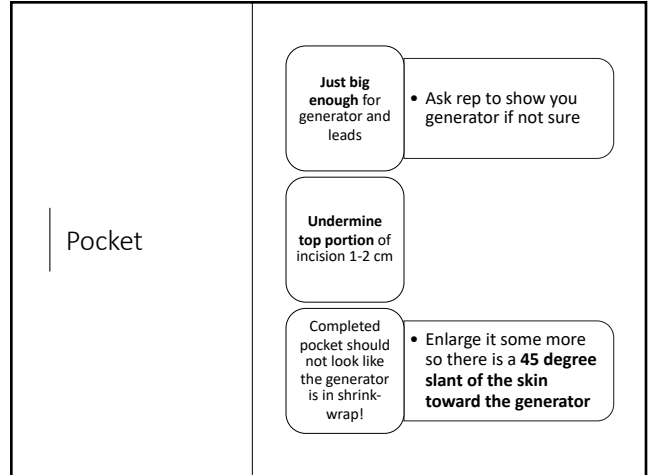


Make up your mind!

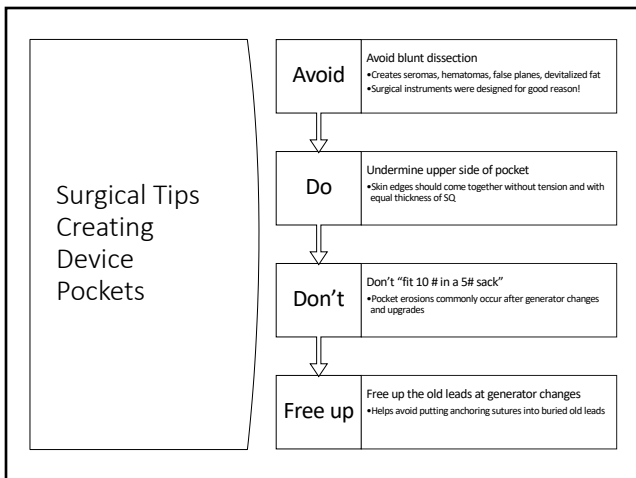
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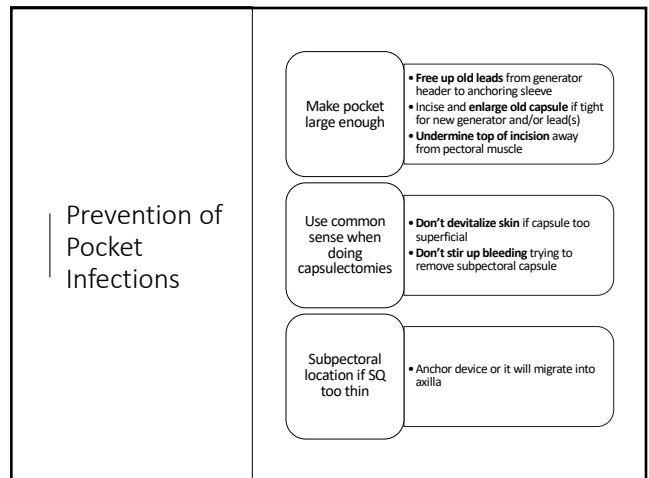
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Prevention of Pocket Infections

- Hemostasis**
 - Prompt drainage of pocket hematomas that are tense
- Incision and closure**
 - Avoid close parallel incisions
 - Close skin with staples if skin edges compromised
 - Steri-strips should breathe (1 cm apart)

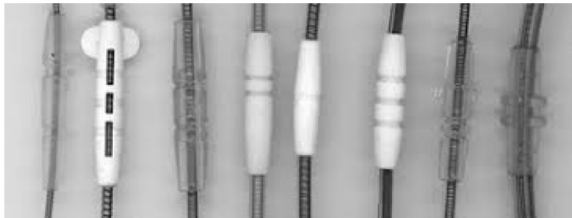
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Anchoring

- Prefer 2-0 non-absorbable synthetic multifilament suture for lead sleeves and generator**
 - Avoid silk – intense reaction and then absorbs by proteolysis and often disappears by 1 year
- 2 or 3 anchoring ties each sleeve individually**
 - Simple sutures: into muscle on one side, under sleeve, and out of muscle on other side
 - Tie snugly but “Don’t kill it”
 - Tug on lead to know it is secure
- Push device down a little when figuring out where to place device anchoring suture**
 - Simple suture through muscle, then through notch and tie

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Anchoring Sleeves



If wings stick out, trim them!

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Back-Bleeding at Lead Insertion Site

May lead to **pocket hematoma**

High CVP in heart failure or tricuspid regurgitation	Multiple leads through single venipuncture	New lead through site of lead extraction
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Absorbable purse string suture in pectoral fascia around lead sleeve to prevent

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Pocket Management during Device Change

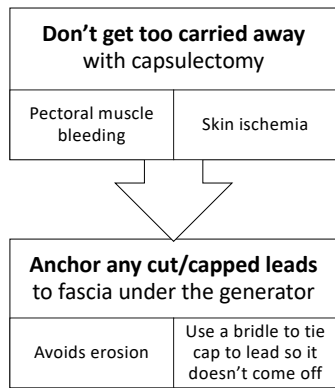
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Basic Principals

- **Go through old incision** whenever possible
 - Avoid unnecessary skin ischemia between close parallel incisions
- **Free all of the old leads**
 - Don't stick anchoring sutures through them
 - Low wattage cautery
 - Repair insulation breaks
 - **Re-coil all the leads under the generator** at the end

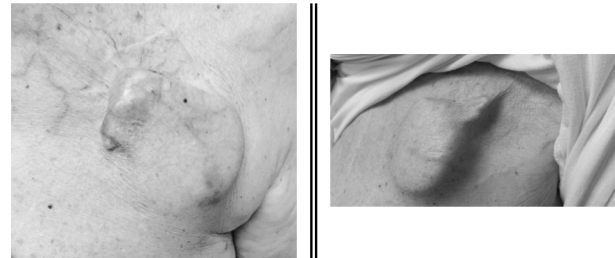
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Basic Principals



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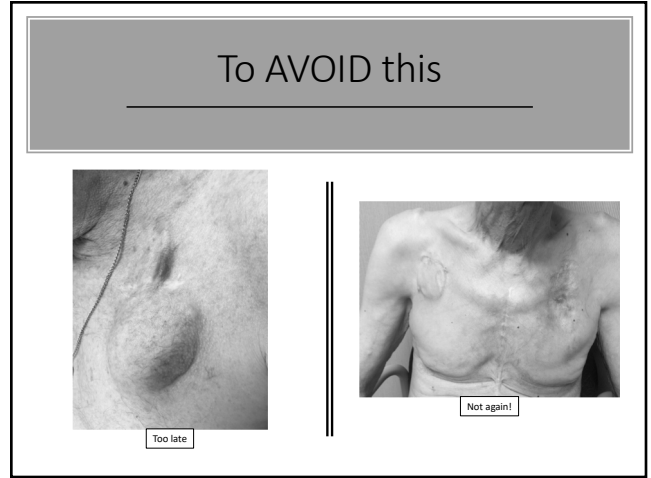
Sub-pectoral Pocket Revision



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Sub-pectoral pocket

- Divide pectoral major **in direction of fibers**
 - May be over 2 inches deep in athletes
- Divide neurovascular bundles that appear at base of pectoral muscle
 - Silk ties and/or medium clips (be careful!)

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Sub-pectoral pocket

If venipuncture below pectoral major	<ul style="list-style-type: none"> • Absorbable purse-string to prevent back-bleeding
If venipuncture already on surface of pectoral major	<ul style="list-style-type: none"> • Divide pectoral muscle fibers at site of lowest lead sleeve • Close 1st layer of SQ to close over lead sleeves if possible

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Sub-pectoral pocket

- **Anchor device well** on pectoral minor or intercostal muscle fascia or **may slide into axilla**
- Impractical in petite patients with small thorax (= small pectoralis major)
- Unless very elderly and frail use **general anesthesia with muscle relaxant**

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Learn from Each Complication

Try to assign blame to yourself

"Learn from your mistakes or you will keep repeating them"

Anon

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Lessons all Surgeons Learn

- Two main categories of error in surgery
 - Error in technique
 - Conduct of operation led to complication
 - Error in judgement
 - Poor patient selection
 - Poor preop planning
 - Wrong operation

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Error in Technique

Not using Instruments

- Avoid **blunt dissection**
 - Creates seromas, hematomas, false planes, devitalized fat
- **Can't anchor generator** properly if not on a fascial plane
 - Lead Migration
 - Generator migration

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Error in Technique

Not Understanding Anatomy

- Be in the **right plane**
- If don't go down to pectoral muscle in morbidly obese, **device will migrate**
- Undermine **upper side of pocket**
- Skin edges should come together without tension and with equal thickness of SQ

- "Surgery is like flying – It's easy if you're in the right plane"
- Anon

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Error in Technique

Pocket Sizing

Make pocket large enough

- Incise and **enlarge old capsule** if tight for new generator and/or lead(s)

Tissue under tension loses local capillary bed perfusion

- **Subcutaneous followed by skin dermis** dies from an internally created capillary bed compression
- **Pocket erosions commonly occur** after generator changes and upgrades

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Errors in Technique

Leaving Leads Buried

- **Free up old leads** from generator header to anchoring sleeve at generator changes
 - Helps **avoid putting anchoring sutures** into buried old leads
 - May be able to **cut and cap abandoned leads** to reduce mass

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Errors in Technique

Lead Anchoring

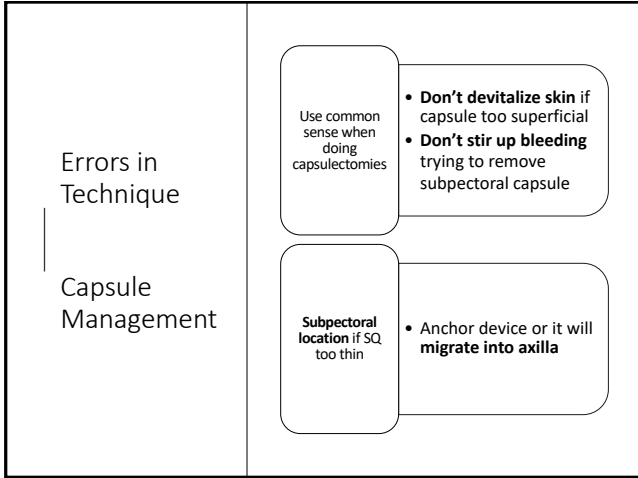
Avoid unnecessary early reoperations to **reposition lead**

Tug on lead at lead sleeve and at generator header

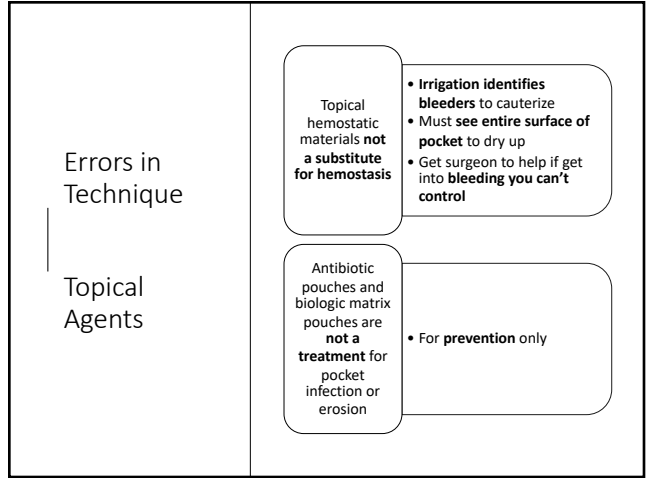
- Some sleeves are not optimal diameter for lead and need extra ties

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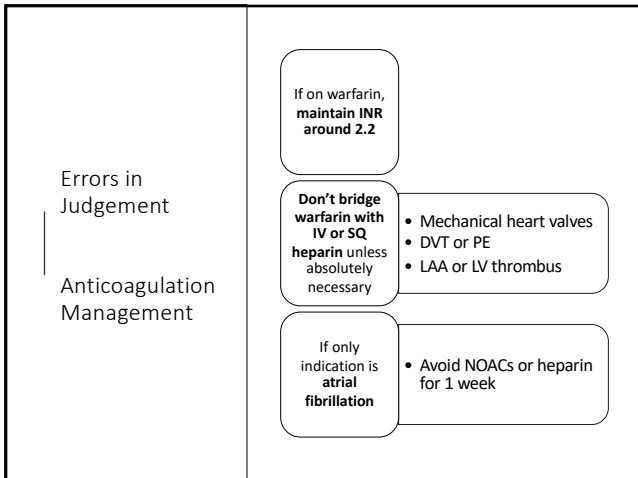
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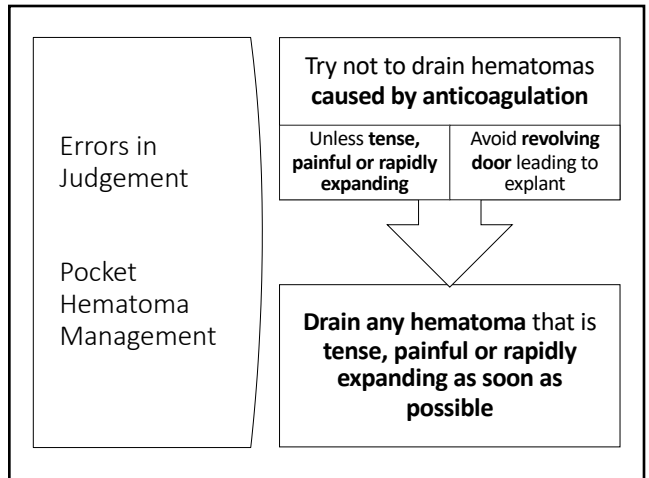
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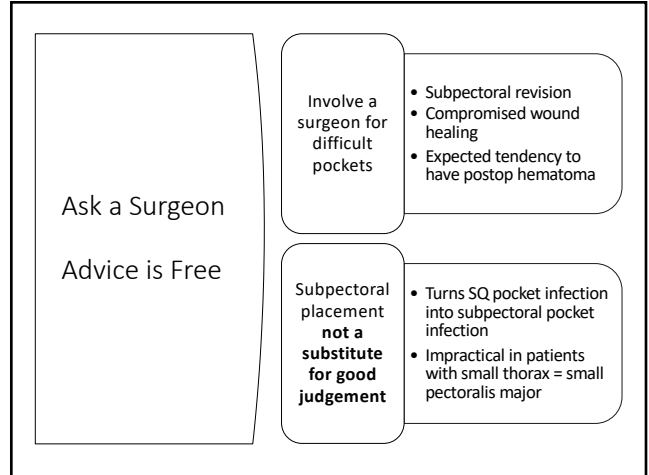
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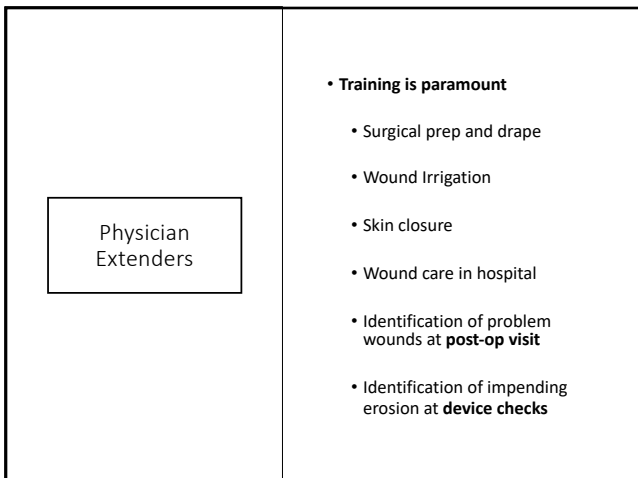
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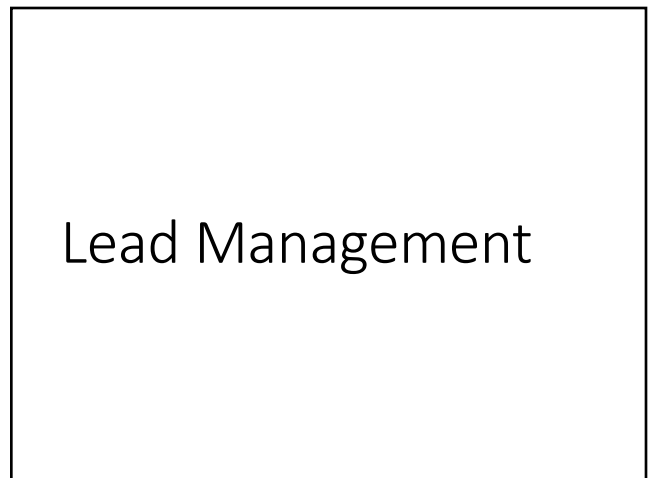
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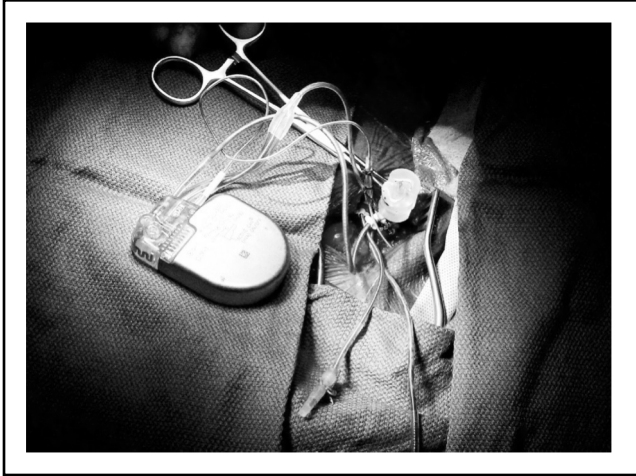
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Lead Management

- Implanted devices and leads age**
 - Expected slow failure rate for most leads
 - A few leads have had unexpectedly high failure rates
- Infections occur**
 - Cure requires complete lead and generator removal
- Patients age and condition can change**
 - Upgrade requiring placement of new lead(s)
 - Pacemaker to ICD
 - Single to dual chamber device
 - Biventricular pacing
 - Dialysis or chemotherapy can limit options for venous access

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Lead Infection can turn into endocarditis

Pocket	Pocket infection in someone with a new lead can quickly turn into bacteremia
Prompt	Prompt removal of infected leads mandatory in patients with prosthetic heart valves
Assume	Assume coexisting endocarditis in bacteremia until proven otherwise

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Other thoughts

- In the battle between vascular access for dialysis and vascular access for PM or ICD, the dialysis access should get precedence.**
 - Can always place PM or ICD epicardially.
 - If fistulas fail and permacath necessary for dialysis, high risk of bacteremia. **Respect AV fistulas.**
- Don't put in leads that are difficult to extract**
 - Use single coil ICD leads
 - Avoid coaxial leads

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Lead Extraction Pitfalls

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Don't Lose Control of the Lead

Leads can unravel if locking stylet fails to reach end of lead

Consider downsizing locking stylet, using 2 smaller stylets or a different type of stylet

Locking stylets can break or dislodge

Loss of rail changes everything

Leads can snap (rarely)

CS lead inner coil can pinch closed if pull without putting in locking stylet first

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Pacemaker Lead Extraction

Pacemaker lead design went through a phase in which designs favored implantation but made subsequent extraction difficult

Uncoil easily
Tips separate from remainder of lead

This is best managed by treating "older leads" with extra care

Don't attempt to unscrew

Narrows the inner coil, may make locking stylet passage harder or impossible
May break off inner coil from active fixation screw

Don't cut off the pin

Pin serves to keep the inner and outer coils from unwinding
Shave the fins off of the pin

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What to do when you can't establish a rail

- **Non-mandatory** indication: Abandon and cap lead
- **Mandatory** indication: TightRail or surgical removal
 - Use ICD shocking coils as locking stylet surrogate
 - Femoral snare to pull from below

Don't create a mandatory indication for removal by pulling and unraveling the lead into a piano wire

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Don't lose control of the extraction catheter

- There are 2 ways to release the lead from scar
 - **Burn/cut/grind through the scar**
 - **Upsize and go over the scar**
- Push with inner extraction catheter to engage the scar, and to maintain contact as the energy is applied
 - **USE THE RAIL and KEEP IT SNUG**
- The catheter will move easily between regions of scar tissue
 - **Beware a sudden advancement of the catheter during a tough SVC scar**

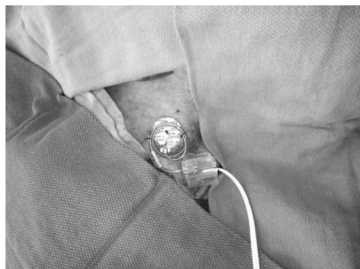
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Don't Lose Pacing

If develop CHB during extraction and don't have TVP, try pacing with Alligator clip on locking stylet in RV lead	AVJ trauma during extraction can initiate CHB
Patient should leave OR with screw-in lead sewn to skin when awaiting re-implant	Keep patient in ICU if any concerns about dislodgement until reimplanted
If Zoll doesn't capture will need CPR until TVP established	Place TVP at beginning if ANY concern <ul style="list-style-type: none"> • Balloon guided femoral TVP catheters dislodge easily during extraction • Consider screw-in RV lead if no underlying rhythm

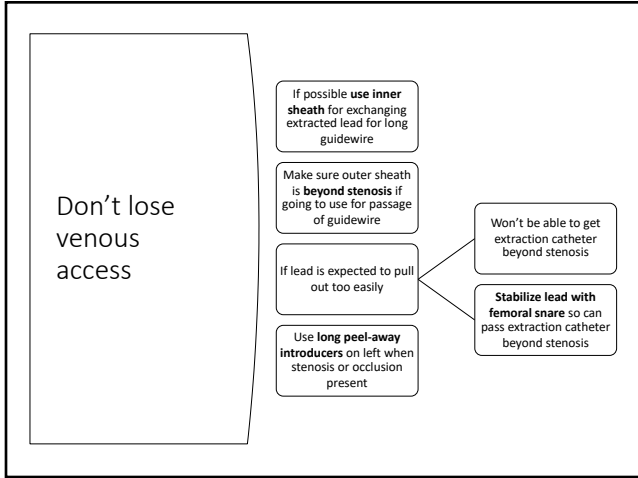
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Temporary Right IJ Lead

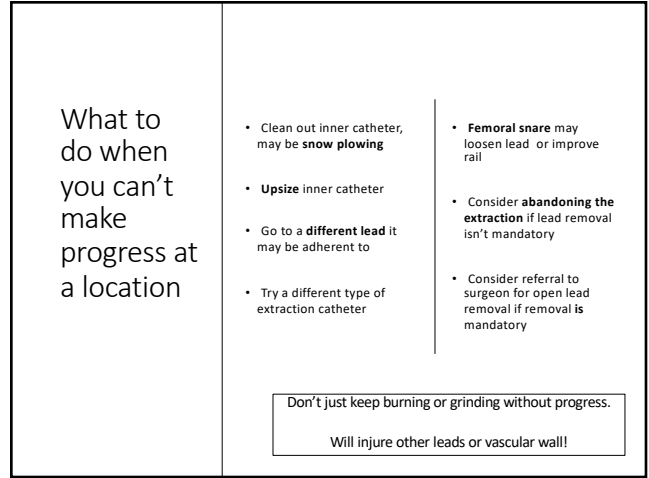


Convert cable box to inexpensive re-usable VVI PM when leave OR

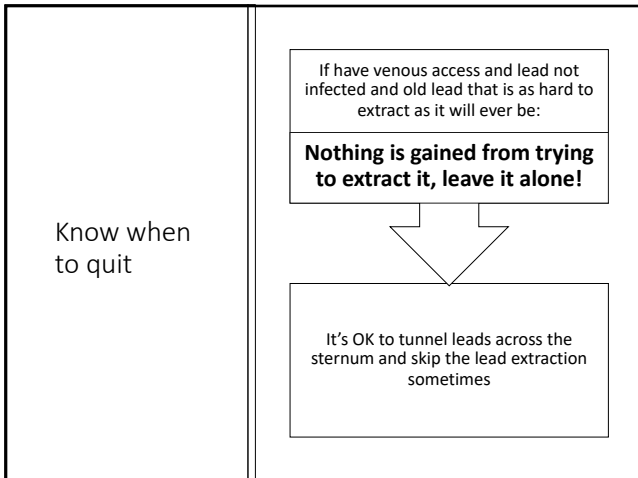
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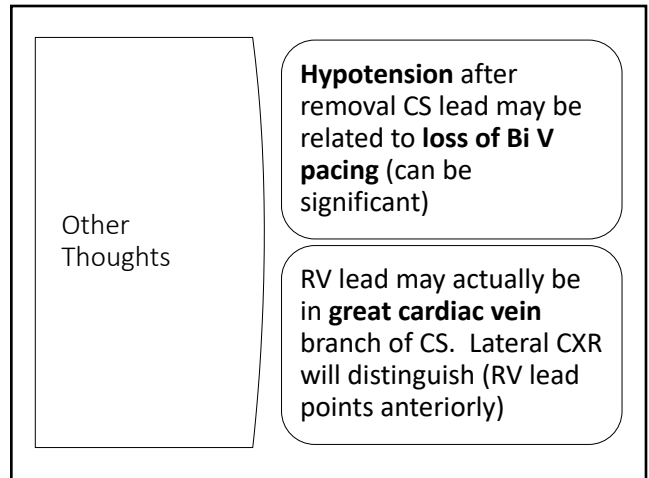
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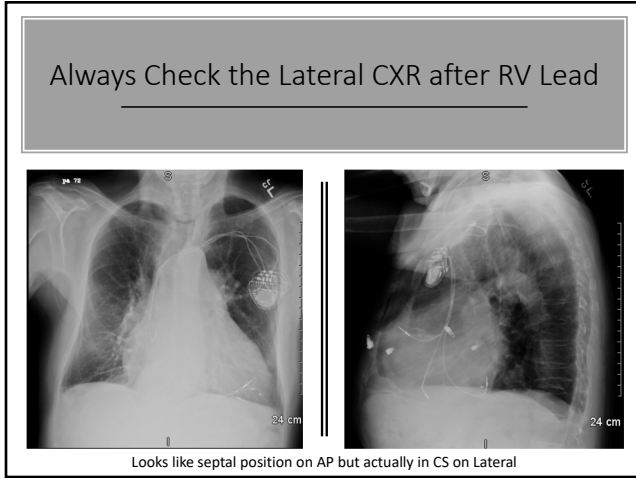
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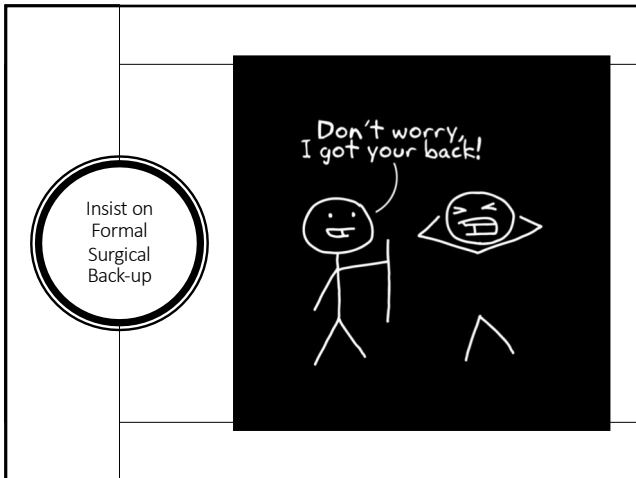
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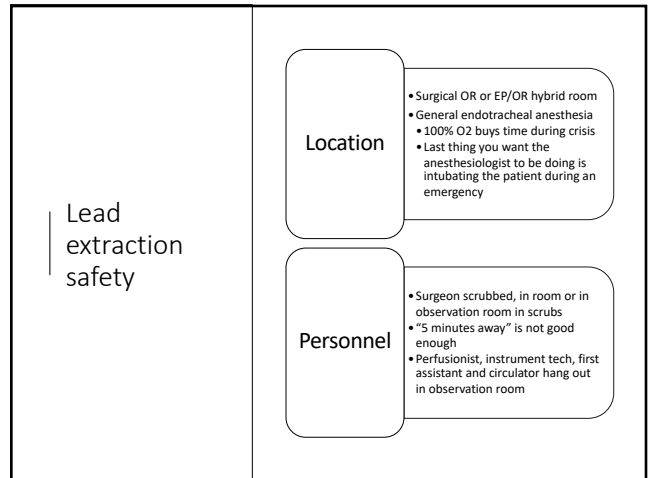
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Lead extraction safety

- Instrument Set-up
 - Back table open and available with with sternal retractor, cannulation sutures, Rommels, pericardial sutures, basic CV instruments, crossclamp
- Aortic, caval, cardioplegia cannulas in room
- Cell saver in room
- Pump in hallway


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Use of TEE

- Look for baseline effusion, monitor development of "minor" effusion
- Document presence of vegetation
- Document condition of TV after extraction
- If it isn't already in, there will not be enough time to place it when a tear occurs

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Prep neck to mid Thighs



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BASICS OF SURGICAL STANDBY

- Surgeon is useless without CV surgery instruments, sutures and cannulas
- Surgeon is useless without heart-lung machine for 90% of injuries
- Surgeon is useless without a surgical assistant
- Surgeon is useless without suckers so he/she can see

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Word to the Wise	Don't do	<p>Don't do lead extractions at night</p> <ul style="list-style-type: none"> • Need intense concentration • Need swarm of qualified personnel in crisis who can be go-fers or scrub in
	Don't do	<p>Don't do lead extractions when you're in a hurry</p>
	Learn	<p>Learn from every injury and change your technique/patient selection accordingly</p>

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Lead Extraction Injuries

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Be Prepared to Open Chest and repair injury in the EP Lab	<p>Once pressure starts to fall, need to immediately heparinize and open chest</p>
	<p>Blood lost in SVC tears usually 30-40% of total blood volume = MUST HAVE BLOOD IN ROOM</p>
	<p>Expect to lose 4-5 units blood because cell saver will not be available in the beginning</p> <ul style="list-style-type: none"> •SVC tear will fill up entire chest and continue obscuring the aorta and right atrial cannulation sites until on bypass •Need 2 assistants (one to hold in aortic cannula until sewn in, one to hold in IVC cannula until sewn in). Will probably start with 1 assistant

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When a Cardiac Injury Occurs... SECONDS COUNT (Not Minutes)	<p>No time for TEE if not already placed</p>
	<p>GIVE HEPARIN</p>
	<p>Open sternum ASAP (THINK GUNSHOT OR STAB WOUND)</p>

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When a Cardiac Injury Occurs...

- Injury site is probably the site where "something happened"
- Catheter suddenly progressed "too easily" several cm beyond site of dense adhesion (SVC or RA tear)
- Tip of lead pulled out about 60 seconds ago (RA or RV perforation)

TELL THE SURGEON WHAT YOU THINK TORE

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Two Main Types of Cardiac Injury during Lead Extraction

- Venous Tear**
 - SVC
 - Tear tends to be 2-3 cm long, associated with thermal injury to surrounding SVC tissue
 - RA
 - From perforation at RA lead tip or unusual adhesion of lead to lateral wall
 - CS
- Ventricular Perforation**

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Courtesy of
Pierce J. Vatterott, MD, FACC
United Heart and Vascular Clinic
Associate Professor, University of Minnesota

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SVC Tear

Most Lethal

- Harder to cannulate for bypass
 - More likely to exsanguinate when chest is opened
- Harder to repair
 - Extensive burning of SVC around tear site may necessitate extensive debridement and reconstruction
- SVC may be like wood rather than a soft pliable tubular structure
- Cardiomyopathy patients with an EF of 20% don't tolerate exsanguinating SVC injuries well

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Why are SVC Tears so Lethal?

- Patients quickly exsanguinate from these tears
 - Blood completely covers heart, aorta and cavae so cannulation is difficult, usually done 1-handed while trying to hold finger or sponge over hole (usually unsuccessfully) with other hand
- Numerous other leads adherent to inside of SVC must be removed before patch can be placed
- Tissue often very tenuous from surrounding thermal injury
- Management of venous return difficult if tear extends into innominate vein (3 sources – RIJ, innominate and right subclavian)

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How to Approach an SVC Tear

- Patients quickly exsanguinate from these tears
 - Patients tamponade until pericardium is opened, then exsanguinate
- After aorta, cannulate IVC, occlude with tape. Pump suckers will need to suffice for CS and SVC return until leads are out and SVC repaired
- Autologous or bovine pericardium makes best patch material. Make sure patch edges are sewn to healthy remaining vein

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Balloon-Assisted Rescue of SVC Perforation



Courtesy Roger Carillo, MD, FACS

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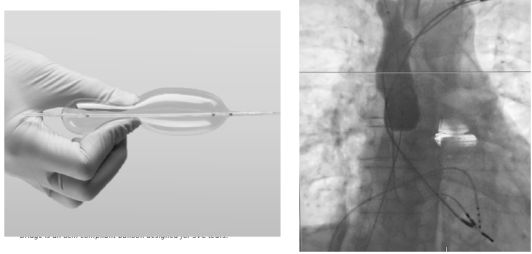
RIGHT ATRIAL APPENDAGE LACERATION



Courtesy of
Roger Carillo, MD, FACS
Associate Professor of Surgery
University of Miami

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Soft Compliant Balloon Bridge For Rapid Deployment in SVC Tear



Bridge is an 8cm compliant balloon designed for SVC tears.

Fluoro of Bridge successfully supporting rescue in an SVC tear. The repair was made without bypass.

Courtesy Philips Lead Management

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FDA Maude Database Study of SVC Tears

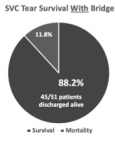
July 1, 2016 to July 31, 2018

Results

116 Confirmed SVC Events

- 51 cases with proper Bridge use
- 65 cases with no Bridge use/improper use

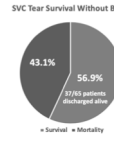
SVC Tear Survival With Bridge



88.2%
46/52 patients discharged alive

• Survival • Mortality

SVC Tear Survival Without Bridge



56.9%
37/65 patients discharged alive

• Survival • Mortality


P = 0.0002

Courtesy Roger Carillo, MD, FACS

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Balloon-Assisted Rescue of SVC Perforation

Average Time to deploy a balloon



- Wire and 12FR: **120 seconds**
- Wire and 6FR: **240 seconds**
- Prophylactic: **14 seconds**

Courtesy Roger Carillo, MD, FACS

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"Lucky for you there was a safety net."

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