Novel Cardiac Support Devices:

Indications, Functions, and Imaging Appearances

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Disclosures

Bioventrix Inc.: Consultant

Objectives

- Categories of cardiac devices
- Select individual devices: Indications, functions, imaging appearances
- Emerging devices
- *Beyond Scope: Long-term circulatory assist, CT planning, Complications*

Category	Devices	Examples (Manufacturer)
Cardiac Conduction	Leadless Pacemaker	Nanostim Leadless Pacemaker (Abbott) Micra Transcatheter Pacing System (Medtronic)
	Subcutaneous Implantable Defibrillator	Subcutaneous ICD (Boston Scientific)
	Wearable Cardioverter Defibrillator	Life Vest (Zoll Medical Corporation)
Cardiac Monitoring	Insertable Cardiac Monitor/Loop Recorder	Reveal XT, Reveal LINQ (Medtronic) Confirm, Confirm RX (Abbott) BioMonitor2 (Biotronik)
	Wireless PA Pressure Monitor	CardioMEMS System (Abbott)
Left Ventricular Restoration	Ventricular Partitioning	Parachute (Cardiokinetix)
	Volume Reduction/Enhancement	Revivent (Bioventrix)
Left Atrial Appendage Closure	Extravascular Closure Devices	Atriclip (Atricure) Lariat (SentreHeart Inc)
	Percutaneous Endovascular Closure Devices	Watchman (Boston Scientific) Amplatzer Amulet, Plug (Abbott)
Septal Closure/Partitioning	Percutaneous Septal Closure Devices	Amplatzer Closure Device (Abbott) Gore Helex (WL Gore & Associates)
Circulatory Assist	Short-term	Impella, Tandem Heart
	Intermediate and Long-term	Beyond Scope (LVAD, TAH, Tandem Heart)
Valvular Repair	Transcatheter Valve Prostheses	Sapien (Edwards Life Sciences) Melody, Core (Medtronic)
	Mitral Regurgitation Repair	Mitraclip (Abbott)

Cardiac Conduction

Leadless Pacemaker

- >200K pacemakers annually in US and growing [1]
- Lead and subcutaneous pocket
  - 9.5% complication rate [2]
  - pneumothorax, cardiac perforation, hematoma, lead dislodgement/fracture, infection (local, systemic), tricuspid valve dysfunction
- Miniaturized high-density energy sources, electronics, and communication technology
- Indications [3]:
  - Single chamber pacing
  - ESRD

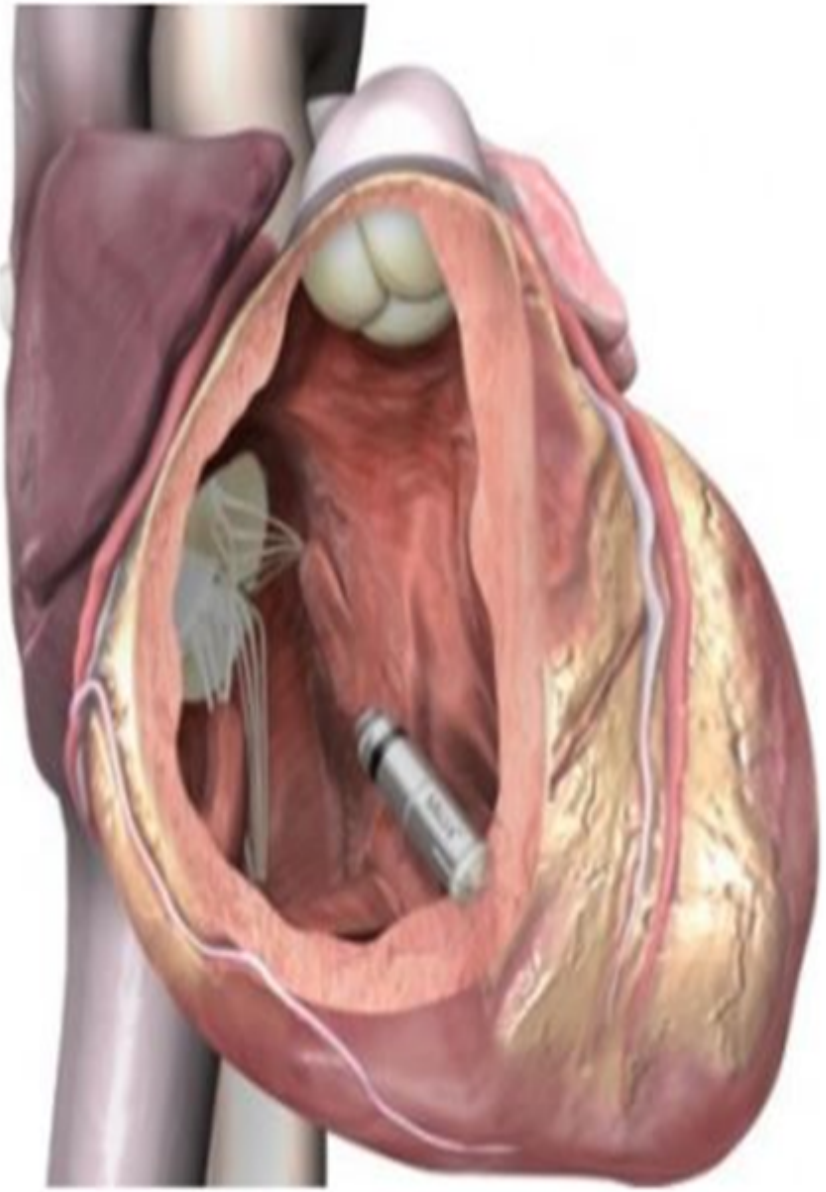
Subcutaneous ICD

- Eliminates lead-related drawbacks of transvenous systems
- Indications:
  - Limited or no venous access
  - Prior intravascular infection
  - Younger patients
- Device: Pulse generator + single electrode
- Non-randomized trials: Equally effective in terminating Vfib as transvenous [4]
- Limatation: No pacing (no resynchronization therapy)

Leadless Pacemaker

- Single-component, single chamber system
- Via femoral vein, RV implantation under fluoro guidance
- Currently one model available in US: Micra (Nanostim recently recalled)

Image courtesy of Jeffery Luebbert, MD



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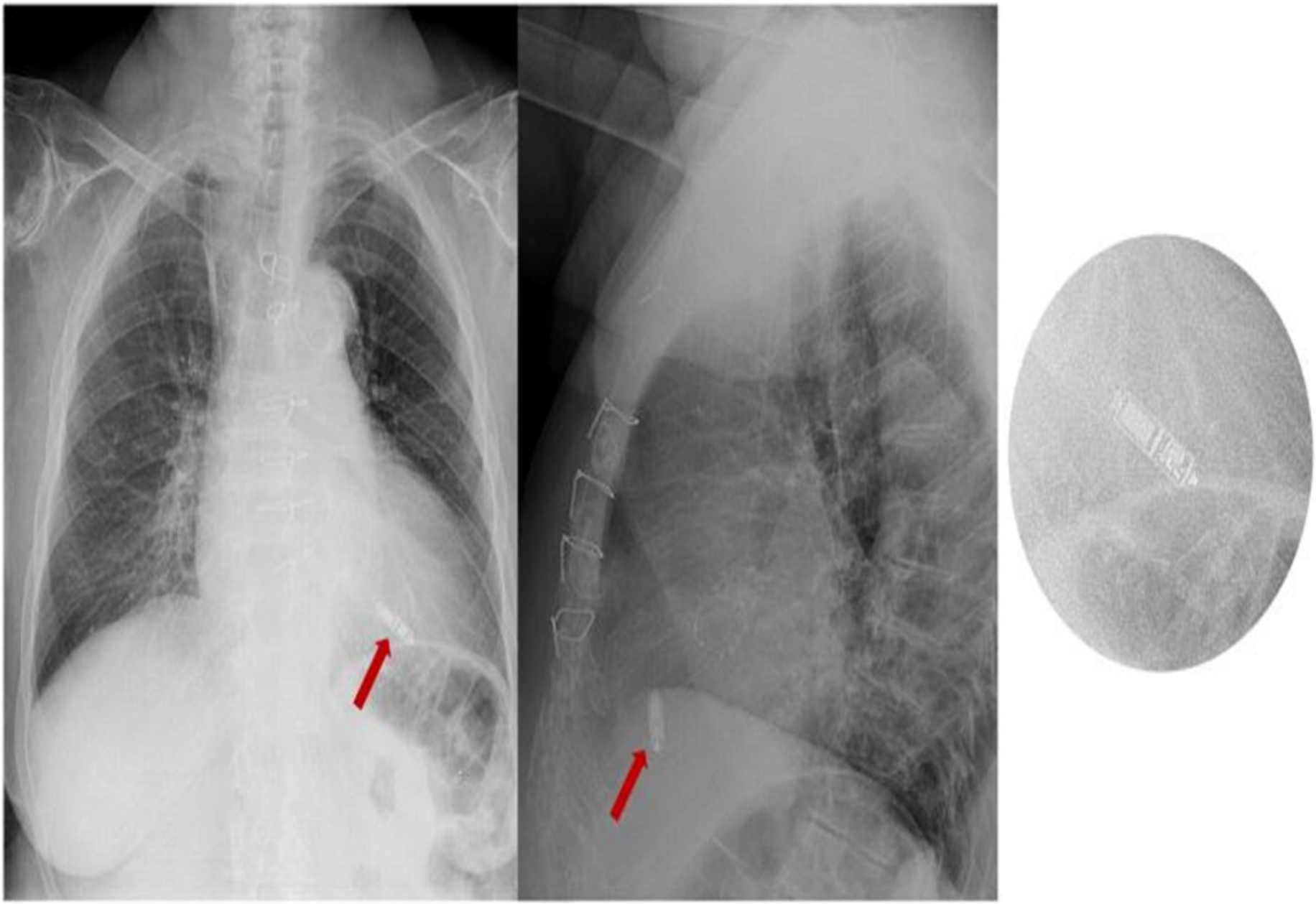
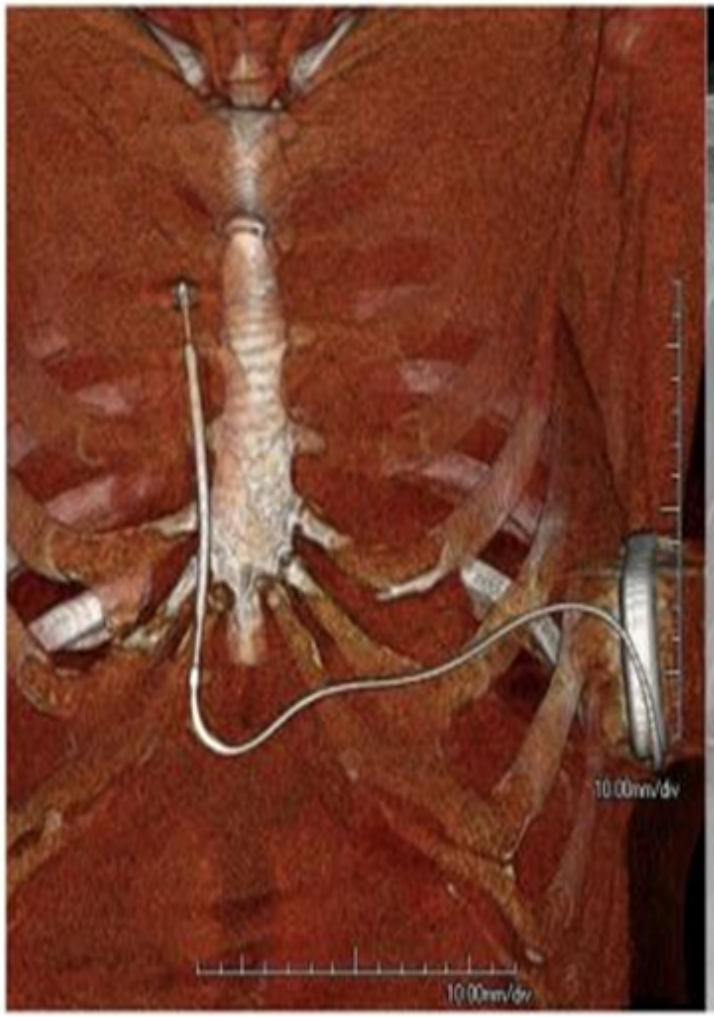
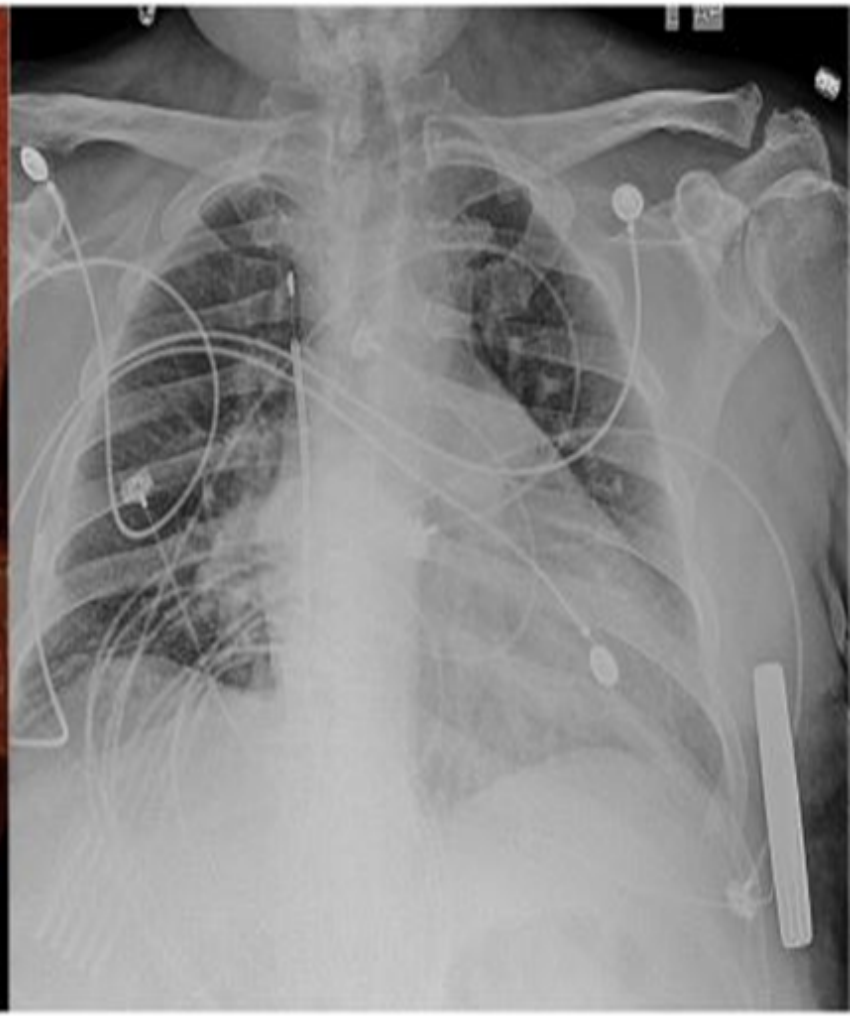
Leadless Pacemaker



Subcutaneous ICD





Wearable Cardioverter Defibrillator

Sudden cardiac death:

- Most common cause of natural death (40-50% all CV mortality
- Immediate implantation of ICD not always possible

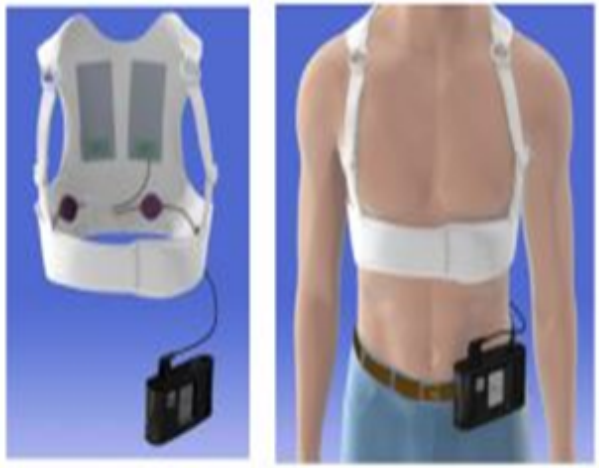
Indication: Bridge to Therapy

- Immediate period following coronary revascularization
- Nonischemic cardiomyopathies with potential for recovery (peripartum, stress cardiomyopathy, others)
- ICD infection warranting extraction, with long wait before re-implantation

Design and Function:

- Single manufacturer (Zoll Medical Corp), Life Vest
- Customized, 4 electrodes, 3 defibrillator pads, <1.5kg
- Holster: Battery, processor senses and analyzes, monitor
- Triggered by LV arrhythmias: Gel injected onto skin, 75 and 150J delivered; can be manually aborted
- Success rate of appropriate shock therapy 75-80% [5]

lifevest.zoll.com



46 yo M, Brugada syndrome, s/p ICD removal due to bacteremia, ESRD on HD via right thigh graft.

Cardiac Monitoring

Insertable Cardiac Monitor/Loop Recorder

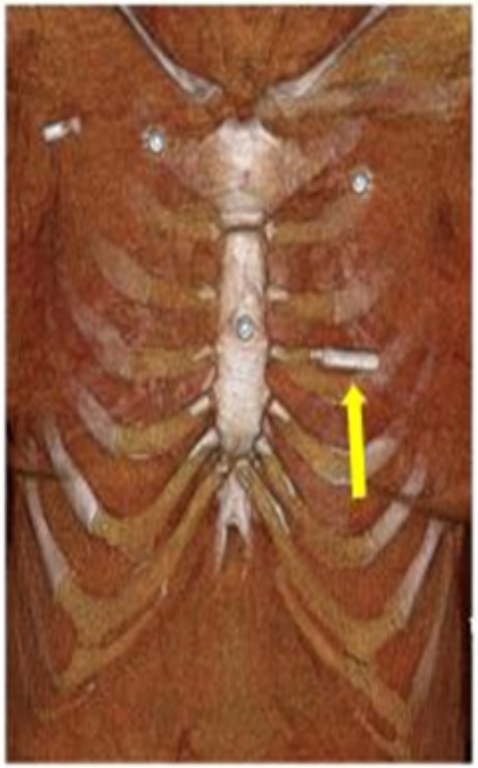
- Indications [6]:
  - Unexplained Syncope
  - Cryptogenic stroke in subclinical Afib
  - Unexplained palpitations: severe and infrequent
- Device: <3g, inserted near left 4th intercostal space, V2-V3 ECG lead location, ECG tracing measured between electrode at each end
- Remote monitoring systems, transmits ECG waveform data via wireless network; automatic "care alerts"
- High sensitivity and specificity (>90%) for Afib, favorable safety profile [7]
- 3 year device life span

Wireless PA Pressure Monitor

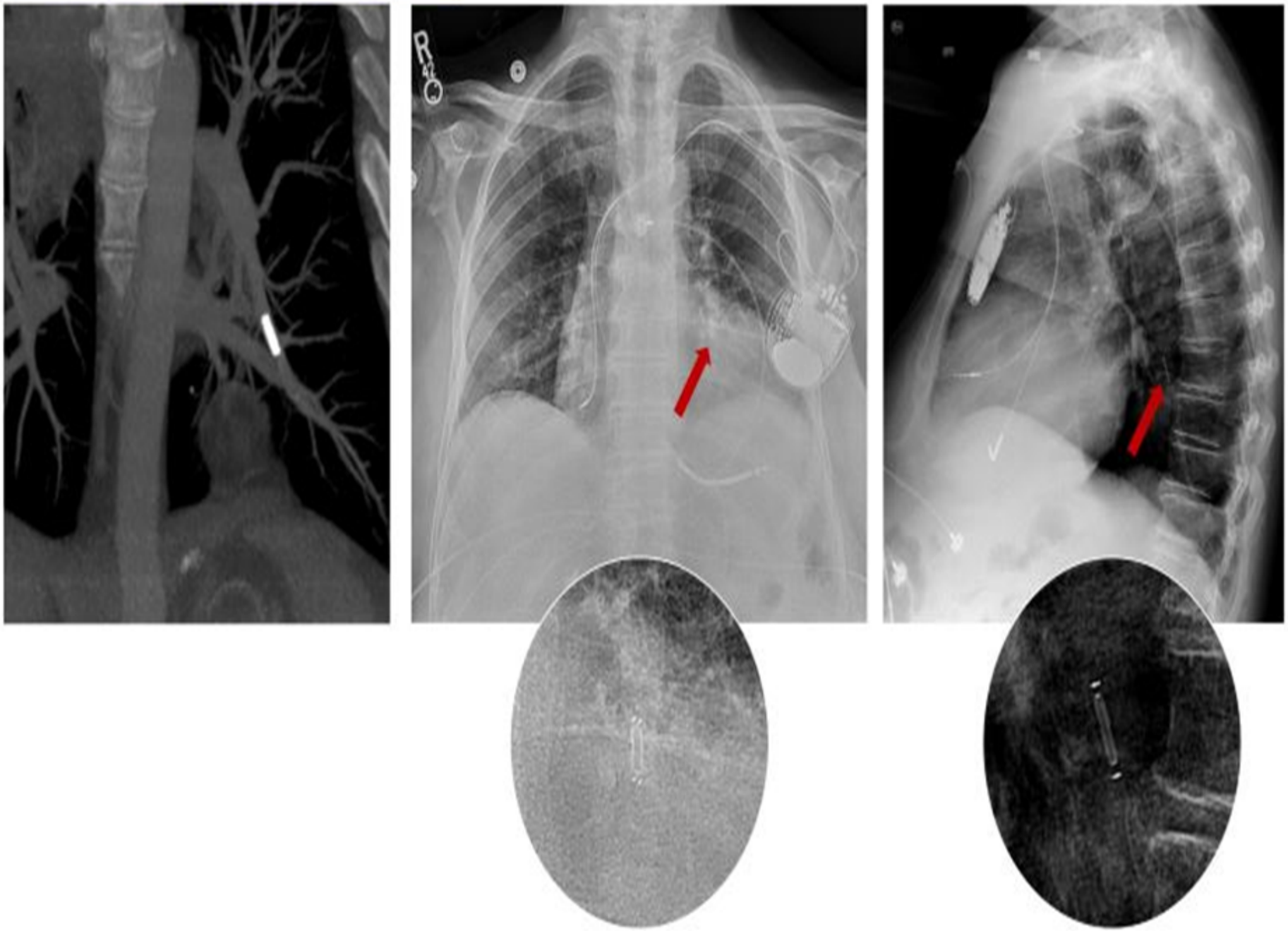
- NYHA class III Heart Failure
- Reduction in HF-related hospital admissions; improved quality of life [8], substantial health care cost savings [9]
- Batteryless, leadless sensor implanted in >7mm branch LPA, anchored by 2 nitinol loops
- Micro-electromechanical ("MEMS") system: RF energy emitted from external antenna to empower device and measure PA pressures, HR
- Patient electronics unit: antenna in pillow, patient lies supine, button to activate interrogation sequence; Remote data monitoring

Loop Recorder

Top left: Image courtesy of Jeffery Luebbert, MD.
Top right: Images courtesy of Medtronic ©2019 .



Wireless PA Pressure Monitor



Left Atrial Appendage Closure

- Afib: most common arrhythmia, prevalence to double by 2050; greatly increased risk stroke and mortality [10]
- LAA main reservoir for LA thrombi in >90% patients with non-valvular AF
- Large # of AF patients still fail to achieve adequate stroke prophylaxis (anticoag)
- Closure Devices: Address risks of anticoagulation therapy: D/C warfarin, Rx with anti-platelet Rx
- Indications:
  - Patients with strict contraindication to systemic anticoagulation therapy, bleeding risk disproportionately higher than risk systemic embolism
  - Middle ground of patients may also be appropriate

LAA Closure

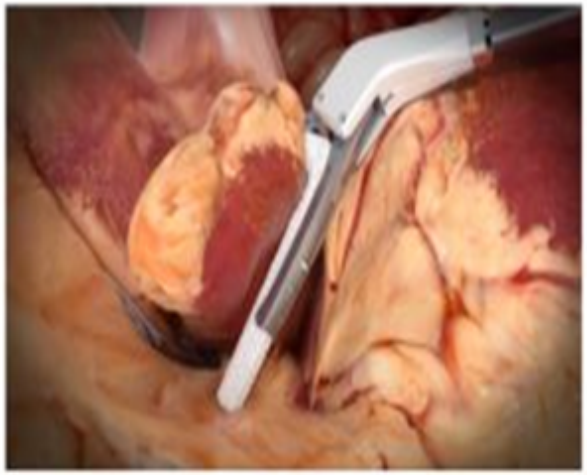
Intravascular/Percutaneous

- Watchman ™: 2nd LAAC device
  - Most rigorously studied (RCT's)
  - Non-inferior to warfarin in preventing stroke, systemic embolism, CV death [11]
  - Planning: TEE preferred, 2DTEE or CT

Extravascular

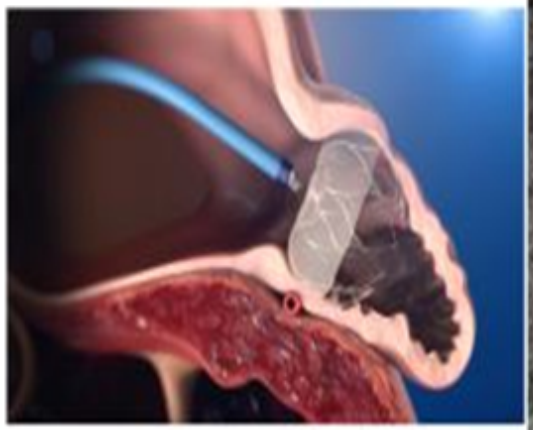
- Atriclip®:
  - Effective for complete LAA occlusion during surgery
  - Reduced relative risk of stroke 93%, no device-related complications in first prospective trial [12]
  - RCT's underway

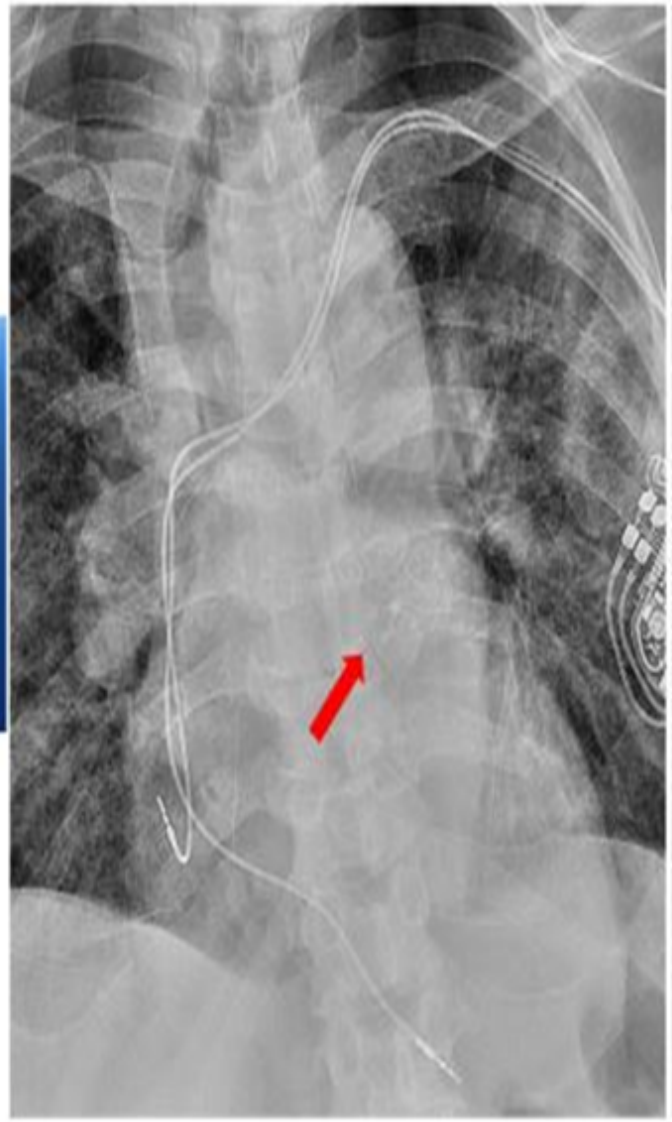
Extravascular: Atriclip®

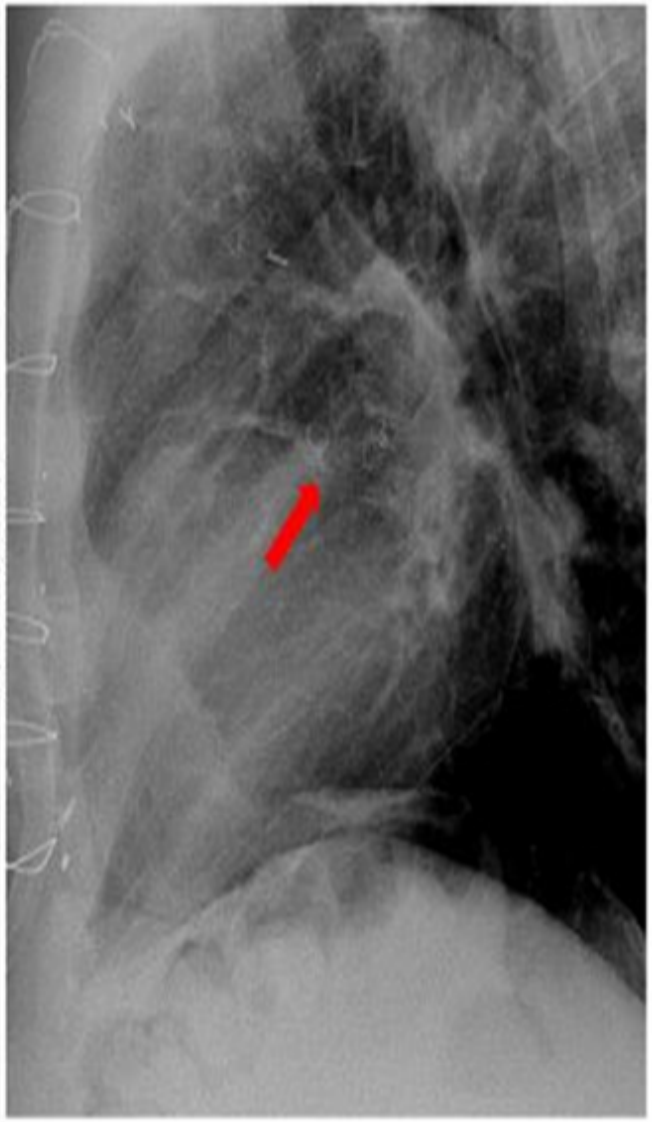


Above images provided courtesy of AtriCure, Inc. ©2019.

Endovascular: Watchman

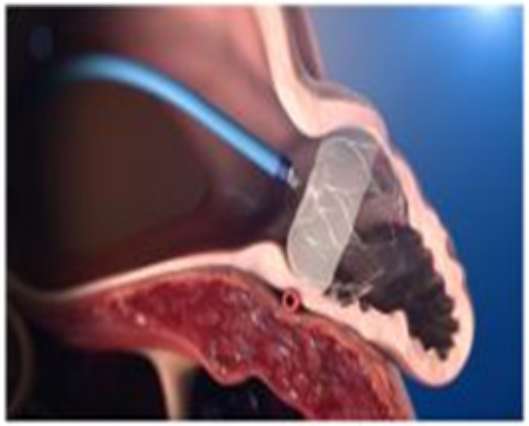






Above images provided courtesy of Boston Scientific.

Endovascular: Watchman



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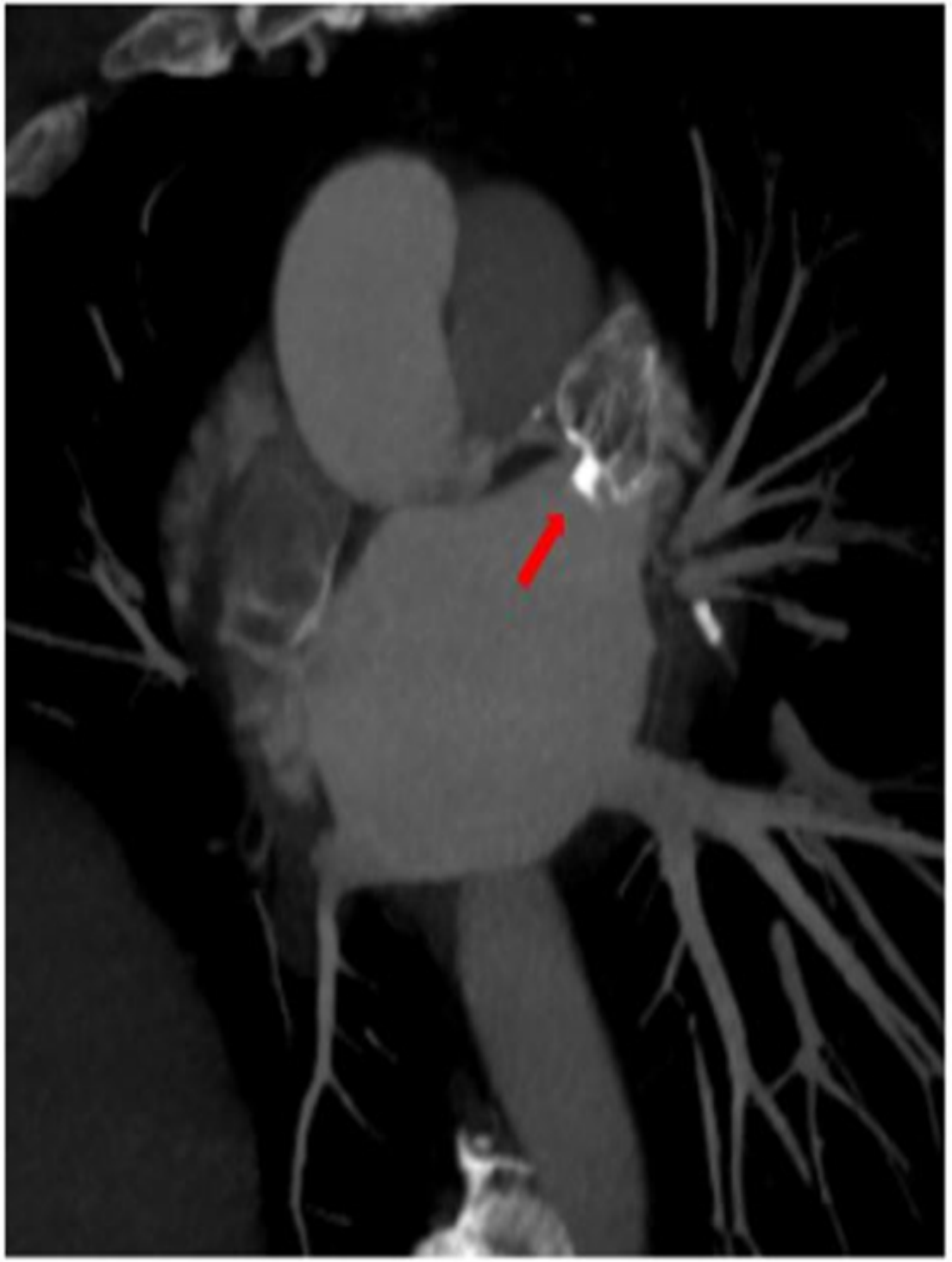
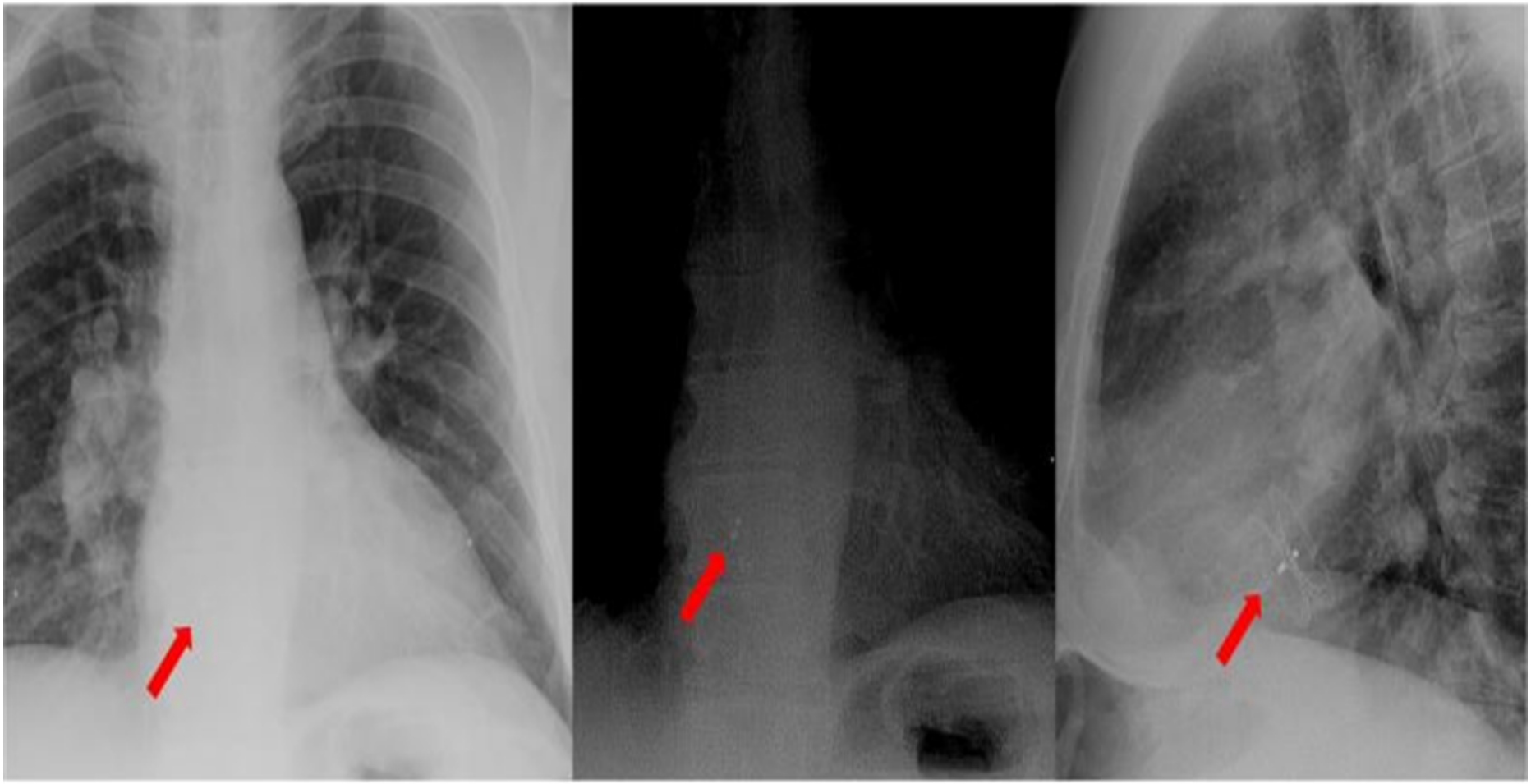


Defect Closure/Partitioning

- Congenital and acquired defects: ASD, VSD, PFO, unroofed coronary sinus
- Septum secundum type septal defect most common ASD, one of most common adult congenital defects
- Closure indicated:
  - Pulmonary HTN, RV dysfunction, atrial arrhythmias, exertional dyspnea, Qp:Qs=1.5:1, paradoxical embolism
- Percutaneous closure currently preferred if amenable
- Evolution of devices since first percutaneous closure (1976): low complication rates, good long-term outcomes [13]

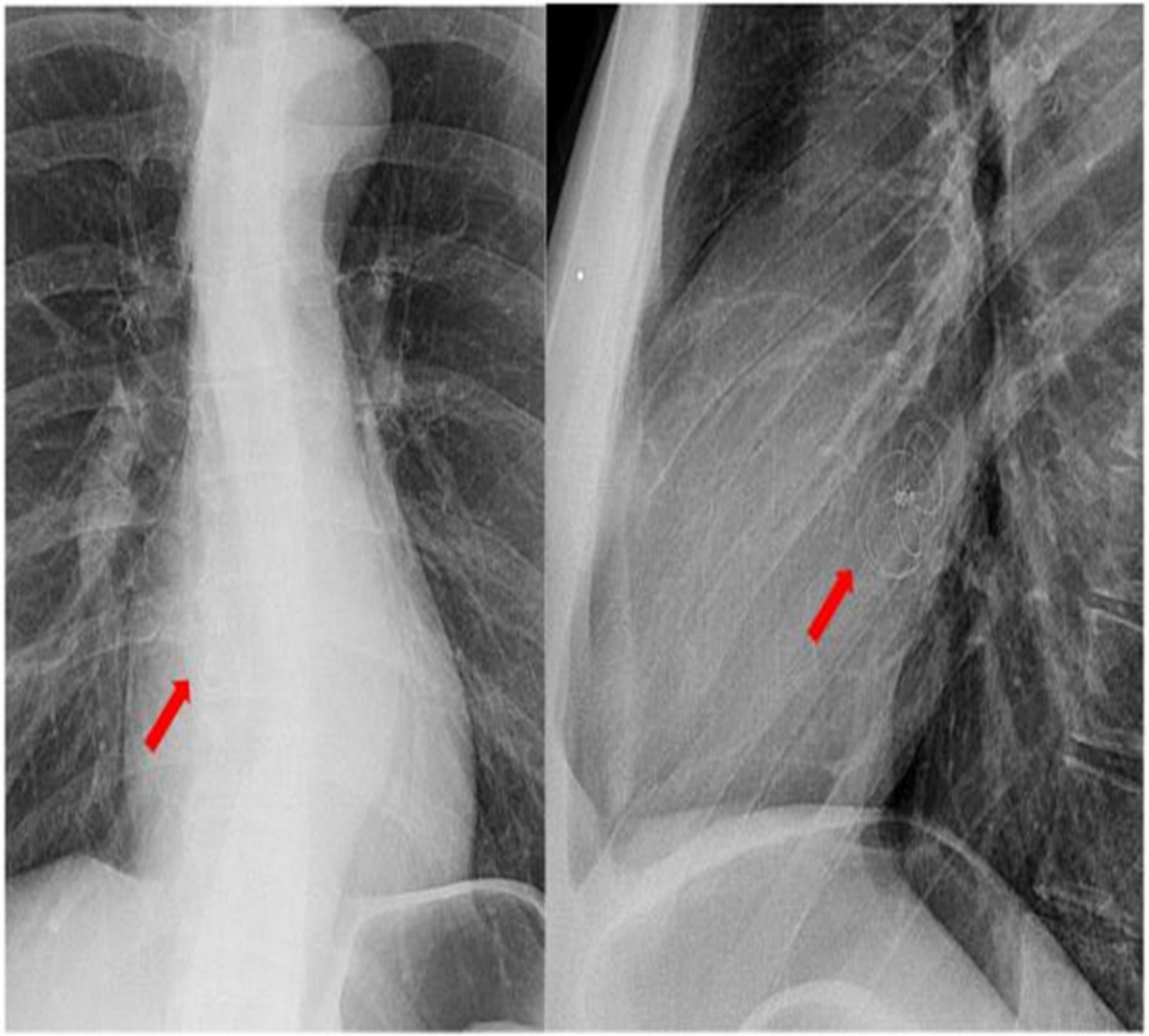
Amplatzer ™ PFO ASD Occluder



64 yo M with shortness of breath found to have L to R shunt, associated RV dilation and elevated pulmonary arterial pressures due to ASD.

Gore Helex/Cardioform Septal Occluder

www.goremedical.com/products/cardioform



Amplatzer ™ Closure Devices

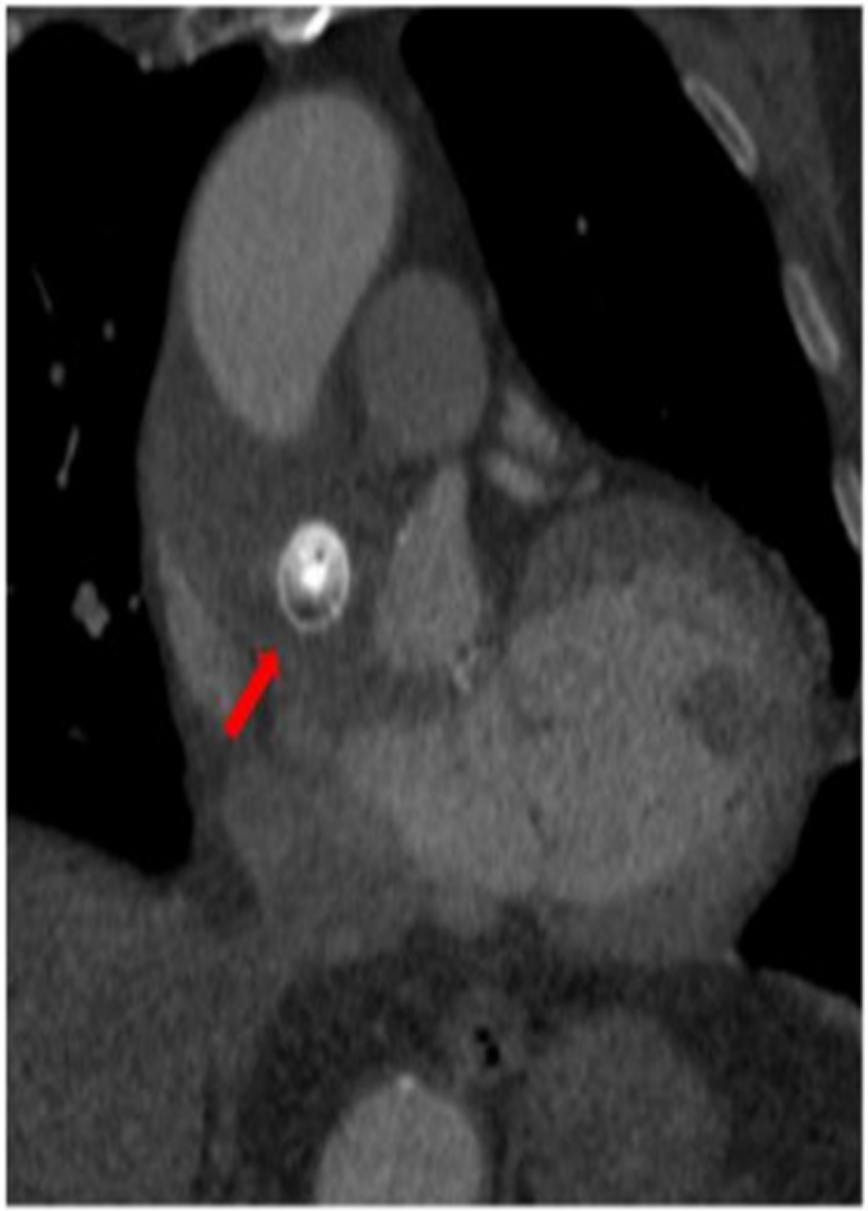
Amplatzer ™ Duct Occluder

Amplatzer ™ Plug

Amplatzer ™ Vascular Plug II

Amplatzer ™ Vascular Plug 4

Endovascular: Amplatzer ™ Vascular Plug



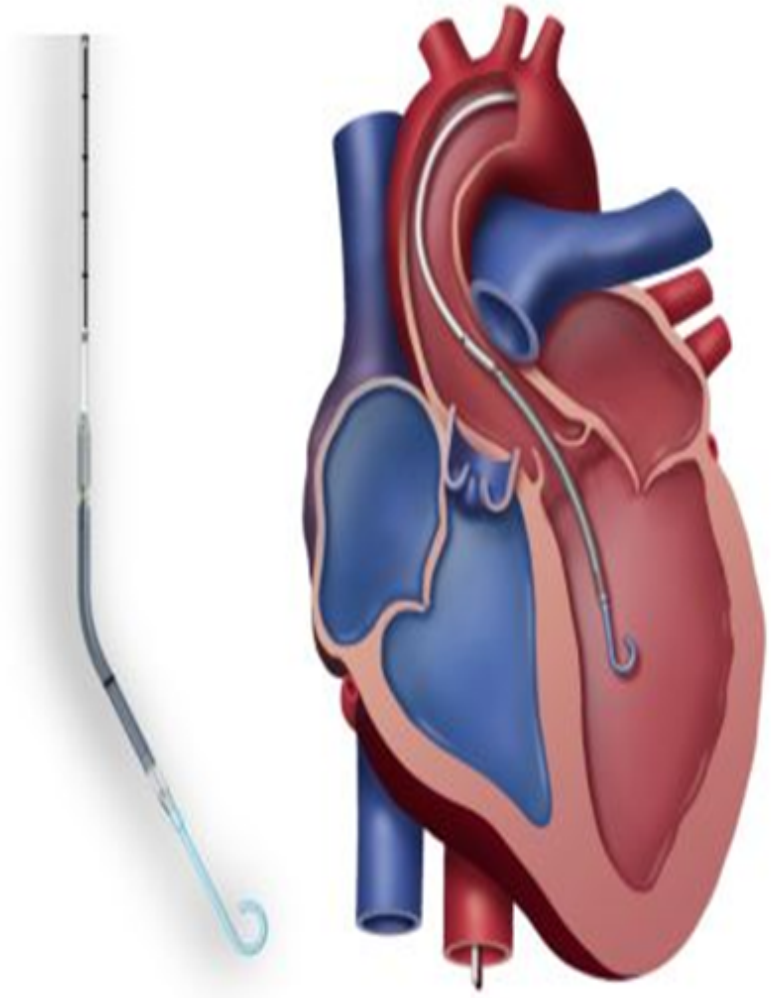
85 yo M, s/p endovascular aortic repair for bicuspid valve. Subsequent ascending aortic pseudoaneurysm repaired with Amplatzer plug.

Circulatory Assist (Short-term): Impella Devices

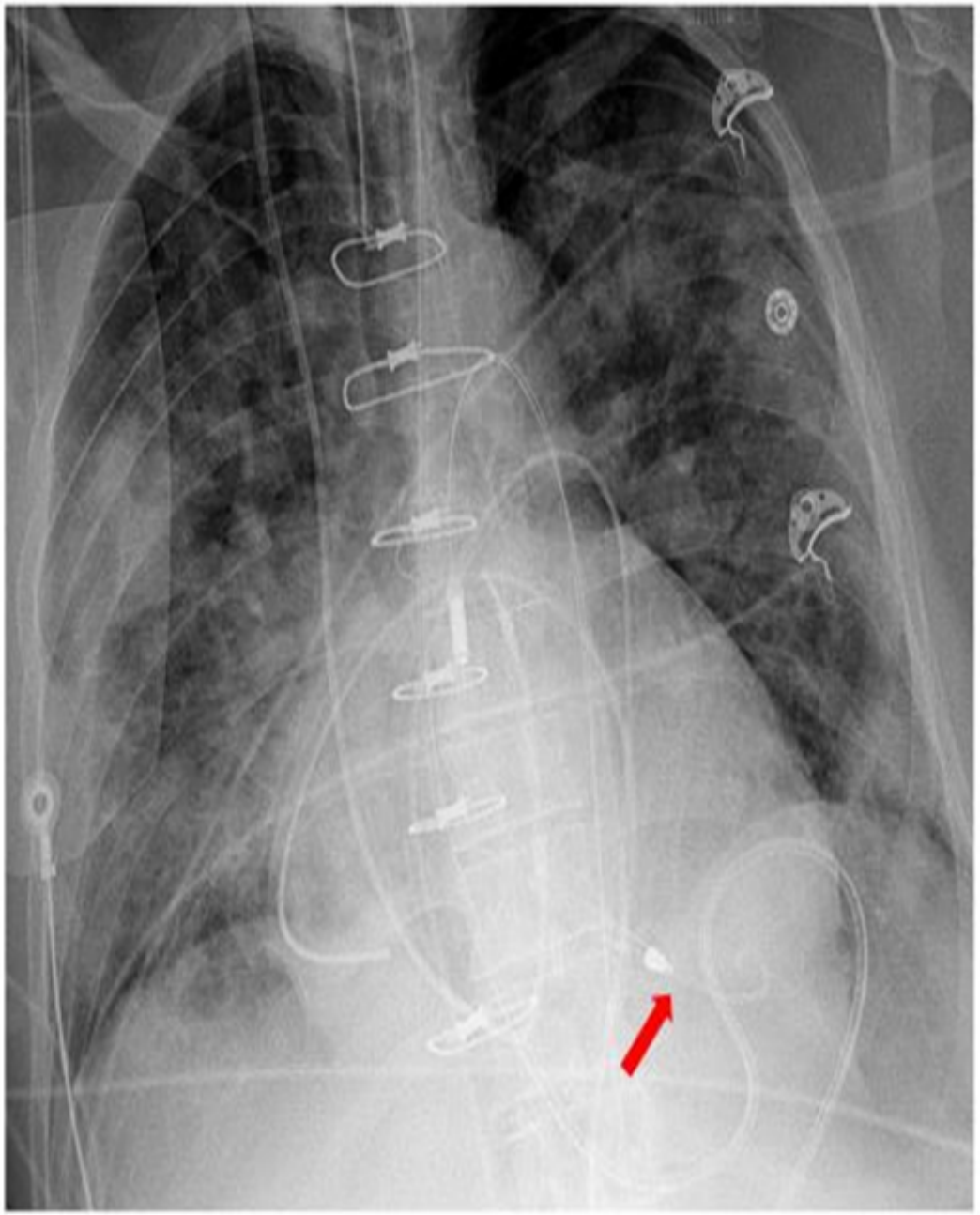
- Short-term assist in setting of acute or acute on chronic HF [14]:
  - Acute decompensated HF failing maximal medical therapy
  - Multiorgan failure, sepsis
  - To optimize hemodynamics on vent-dependent patients
  - RV Impella: postop RV failure refractory to maximal medical therapy after LV assist placement

- Goals:
  - Increase vital organ perfusion
  - Augment coronary perfusion
  - Reduce ventricular volume, filling pressures→ decrease wall stress, myocardial O2 consumption, stroke work

Impella



Images provided courtesy of Abiomed®, Impella 2.5® heart pump, 2019



Valvular Repair: TAVR, TPVR, TMVR

TAVR

- Surgical AVR standard of care
- TAVR well established
- Self-expanding bioprostheses
- Several access approaches
- CT angiography
- Consideration if moderate risk:
  - Recently Surgical Replacement and transcatheter aortic valve implantation (SURTAVI), non-inferior to surgery

TPVR

- Congenital heart disease (tetralogy of Fallot, pulmonary atresia)
- Indications: Chronic post-op setting
  - Failing RV to PA conduit
  - Failing PA bioprosthesis
- Similar outcomes to surgical PVR, shorter hospital stay
- Femoral venous approach

TMVR

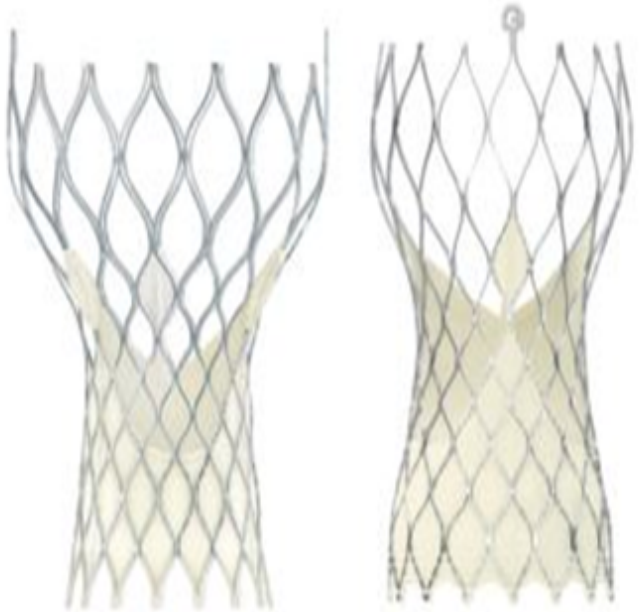
- MR, infrequently MS
- Early stages of use
- Transapical approach; transseptal increasingly adopted
- CT angiography complements echo for pre-procedural planning
- Challenges:
  - Complex anatomy
  - Large device and catheter sizes
  - Large spectrum of disorders causing MR

Transcatheter Valves

Sapien 3™
Bovine pericardial leaflets, cobalt chromium alloy frame.
Sizes from 20-29mm

Image provided courtesy of Edwards LifeSciences LLC, Irvine, CA ©2019 . All rights reserved.

CoreValve™ and Evolut R™
Porcine pericardial leaflets, nitinol frame.
Sizes from 23-34mm.



Melody ™
Bovine jugular vein leaflets, platinum iridium frame.
Sizes 16 to 22mm.

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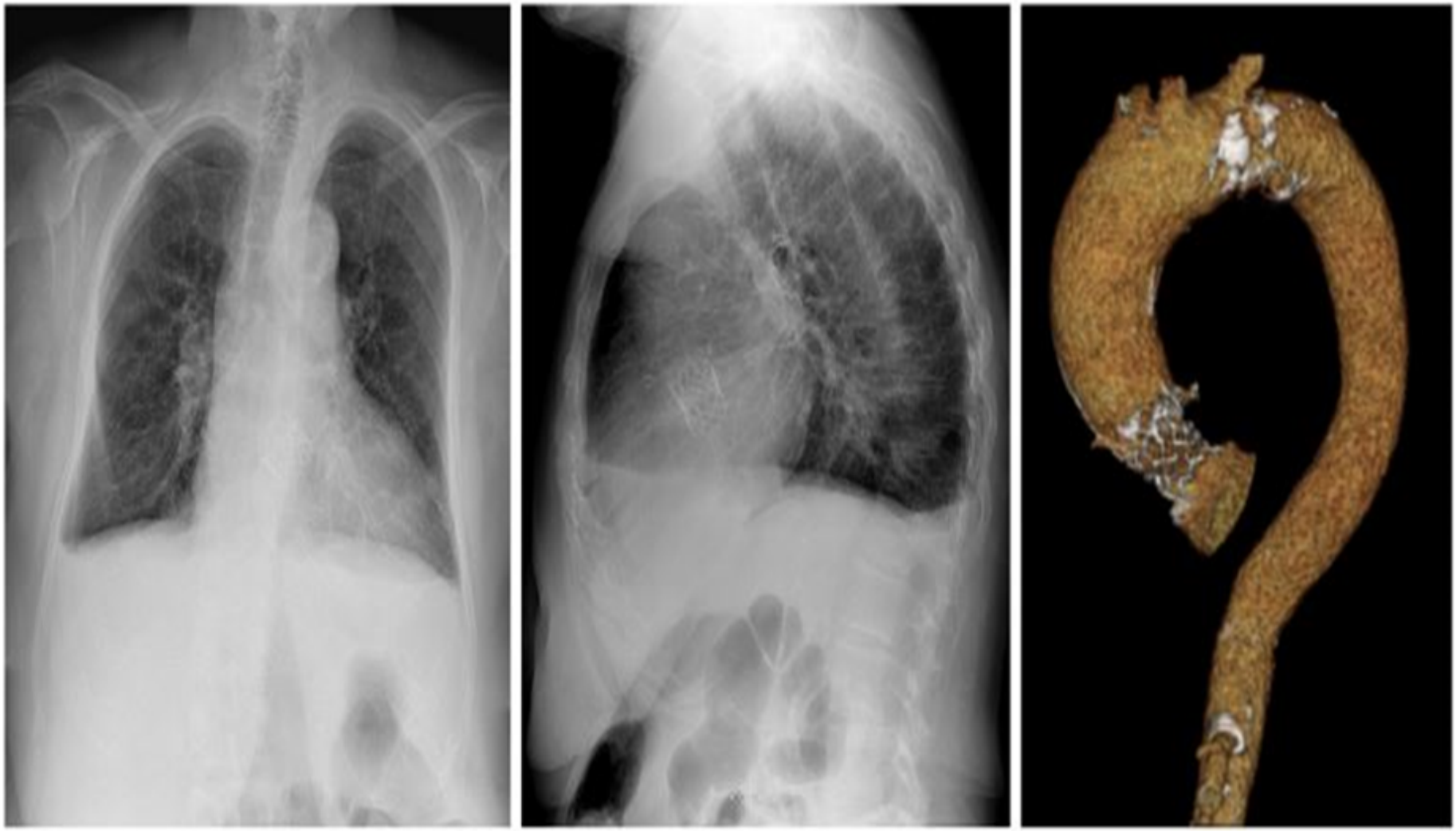
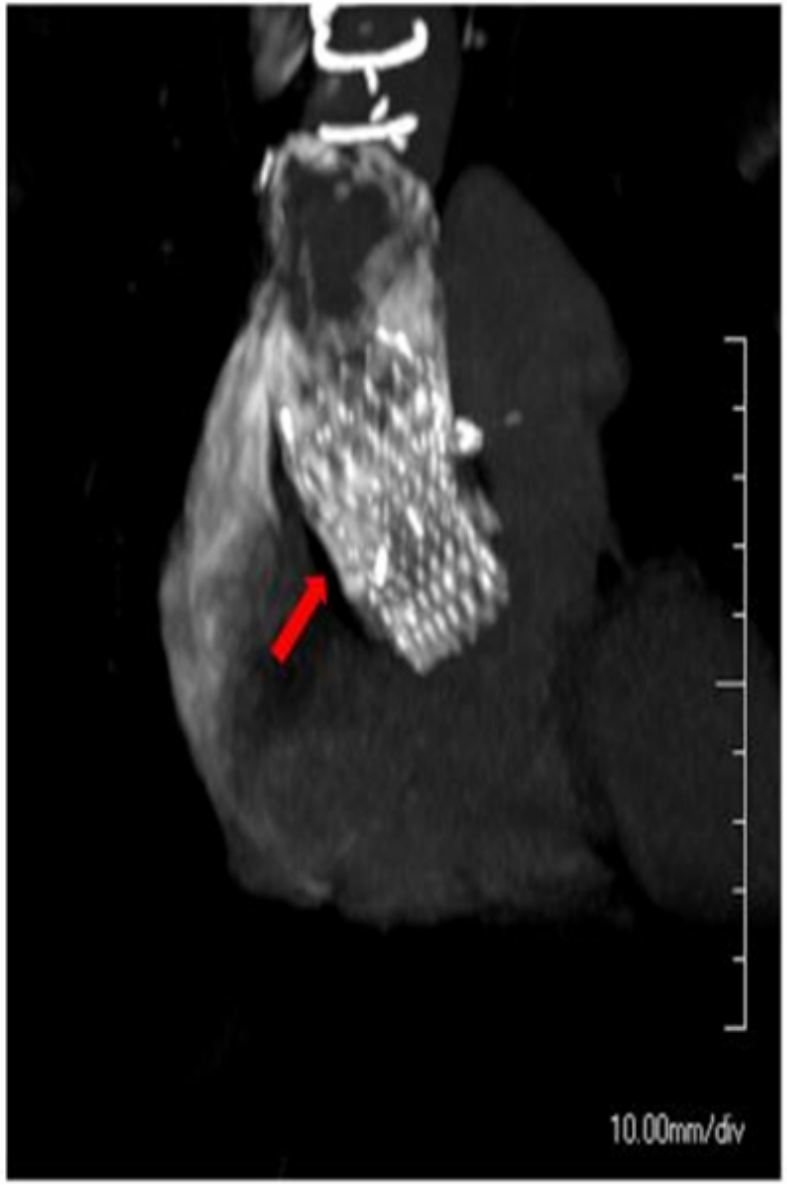
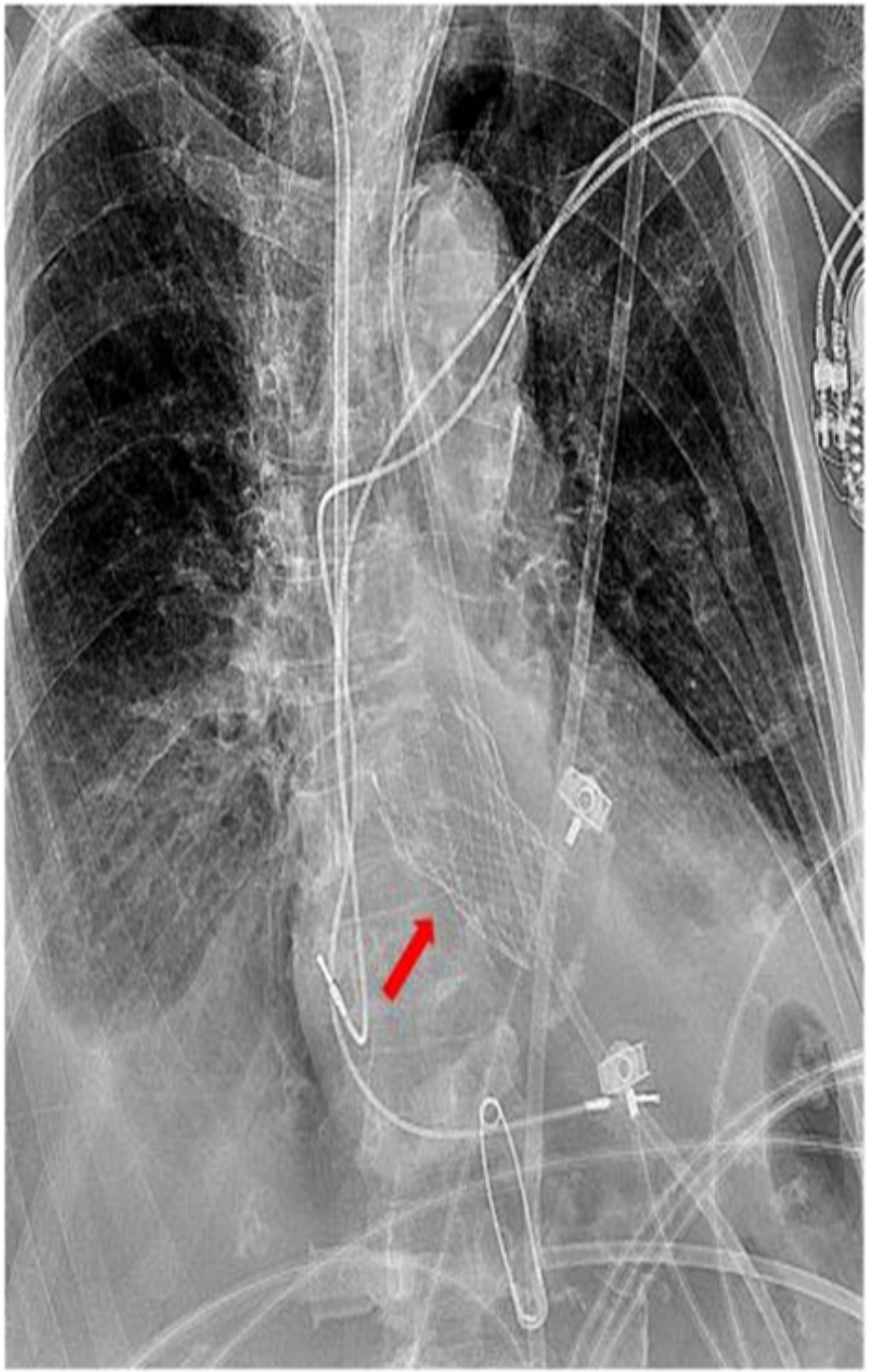
TAVR: Sapien ™



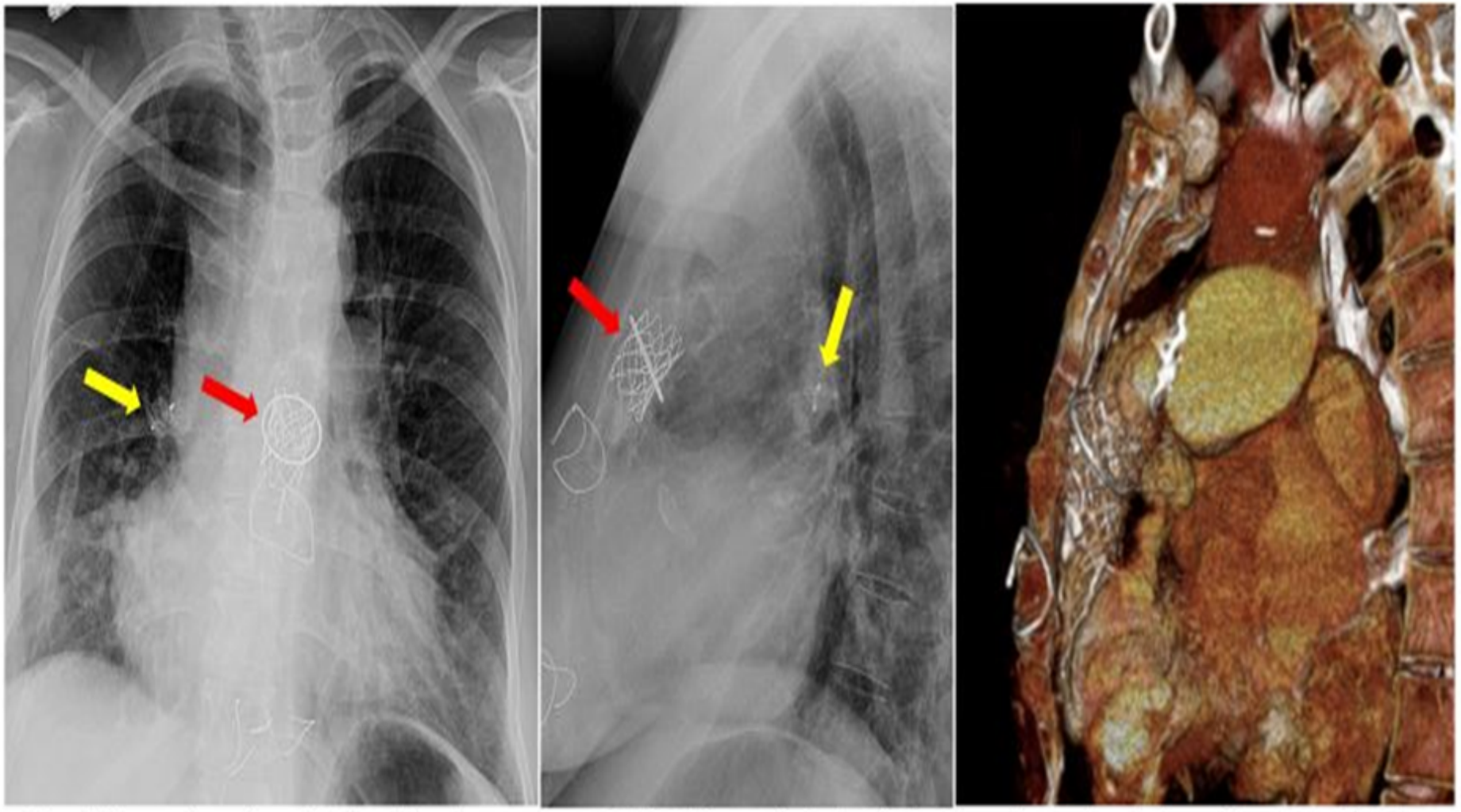
79 yo F status post Edwards Sapien TAVR for severe aortic stenosis.

TAVR: CoreValve ™



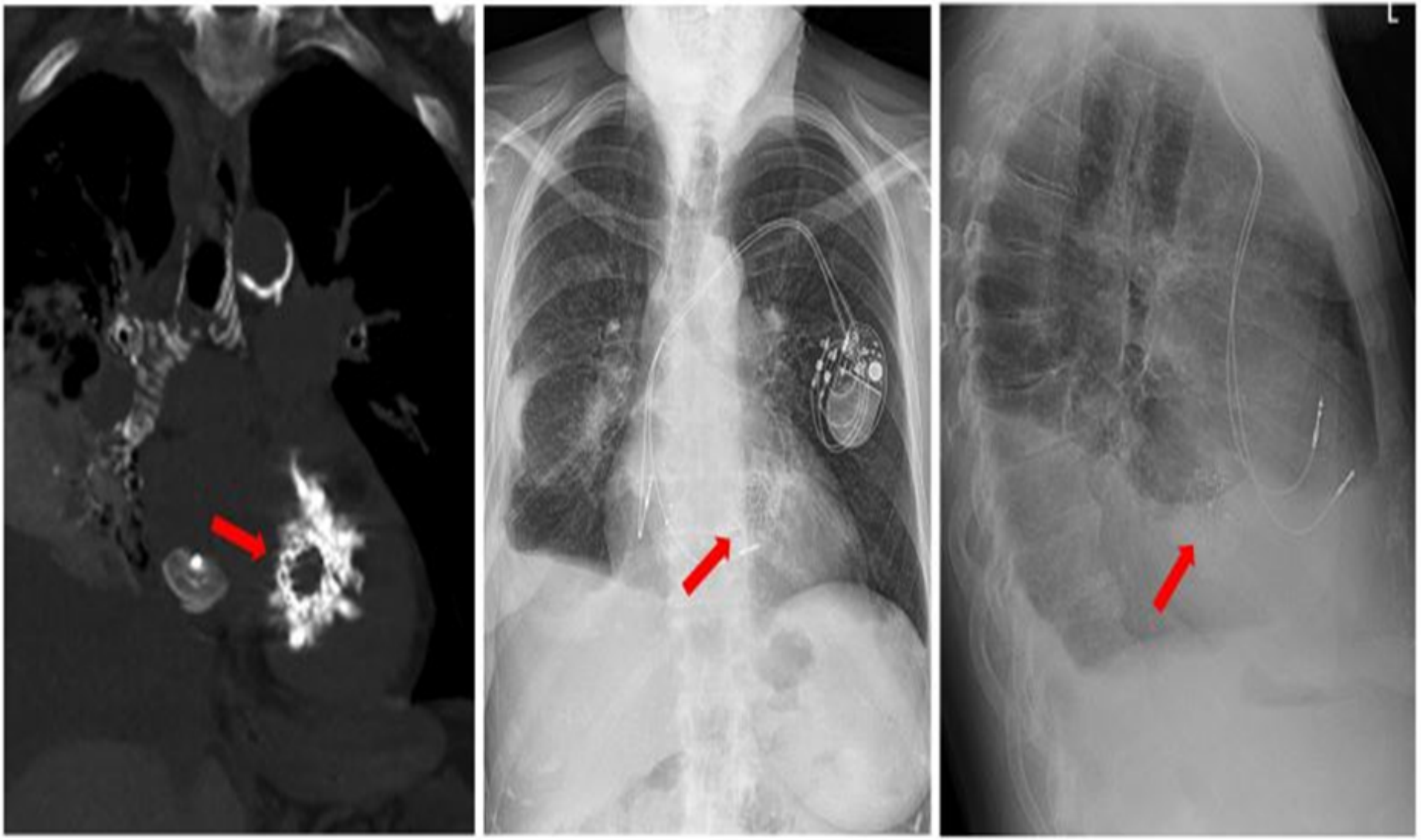


TPVR: Melody ™



56 yo F, history of tetralogy of Fallot with pulmonary atresia, VSD, RV hyperplasia s/p classic Glenn shunt and valved conduit to LPA with VSD and ASD closure. Melody valve placed within conduit. Amplatzer plug in right middle lobe PA due to AVM.

TMVR: Sapien ™

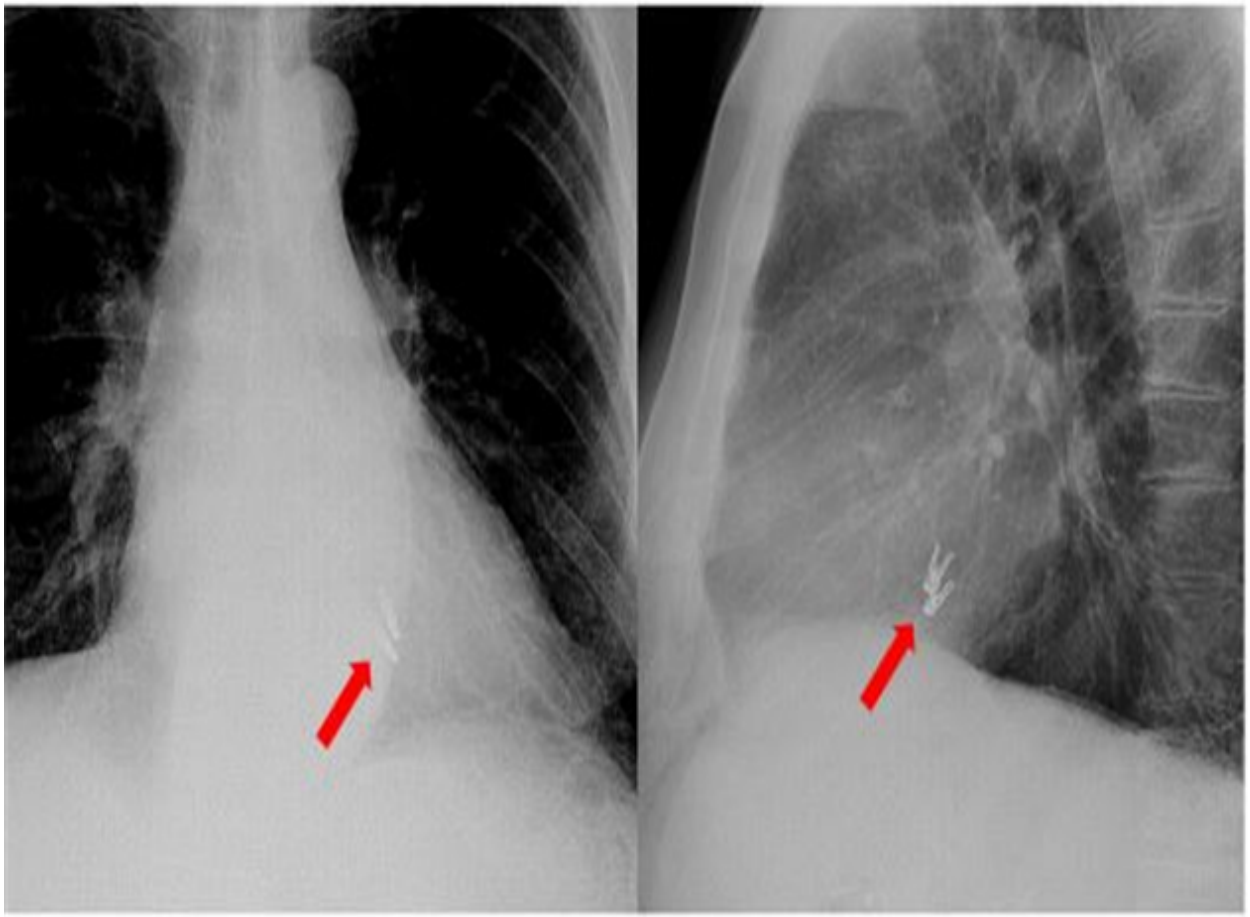


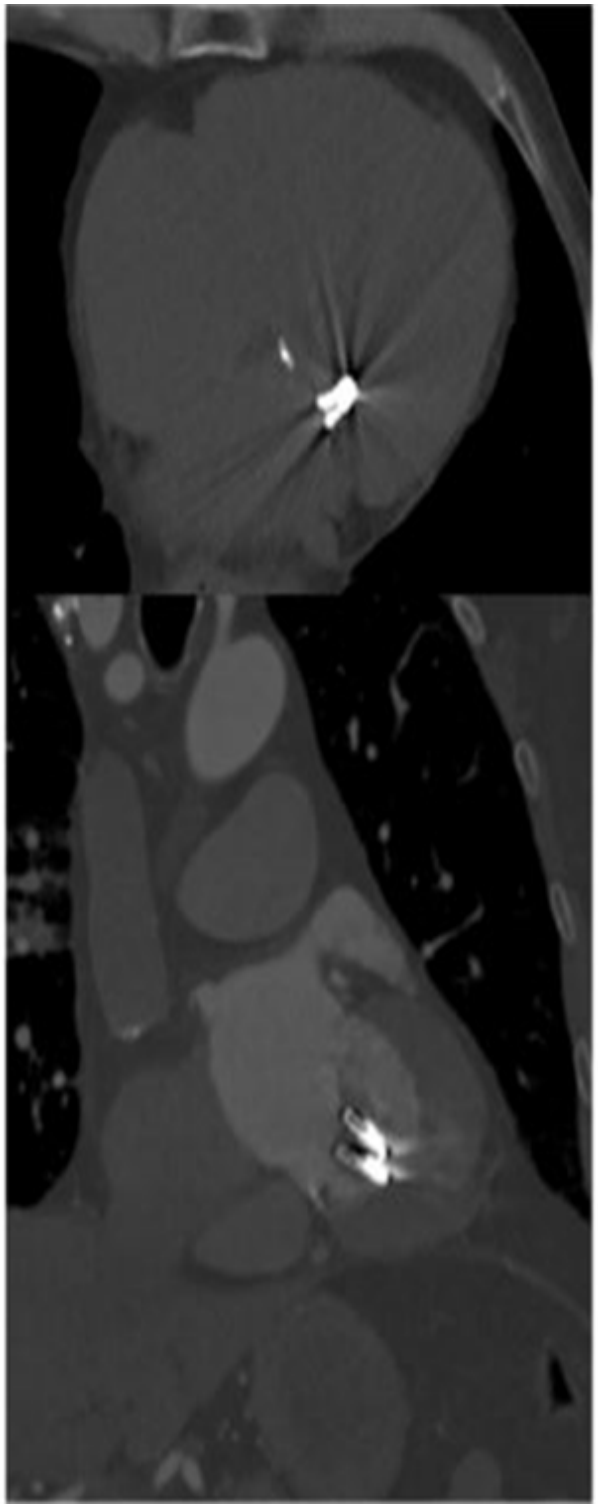
Critical MR and moderate MS, high risk for surgery. TMVR deemed acceptable option. Sapien TMVR performed.

Mitral Valve Regurgitation Repair

- >4 million in US moderate to severe chronic MR
- LV adverse remodeling, HF, LA dilation, pulmonary HTN
- Surgical repair standard of care
- Large number untreated due to high surgical risk, particularly if advanced age and depressed LV function
- MitraClip®:
  - Severe degenerative MR
  - Functional MR: COAPT Trial (Dec 2018) [15]
  - Creates "double orifice" thereby reducing regurgitant jet

Mitraclip®





Future Directions, Emerging Devices

Left Ventricular Restoration

- Parachute (partitioning), Corcap (LV restraint) – withdrawn from market
- Revivent ™
- Biomaterial injection and infusion

Valve Repair and Replacement

- ↑Transcatheter MV Replacement
- MitraClip for functional MR
- Transcatheter annuloplasty via coronary sinus
- Valve-in-Valve TVR

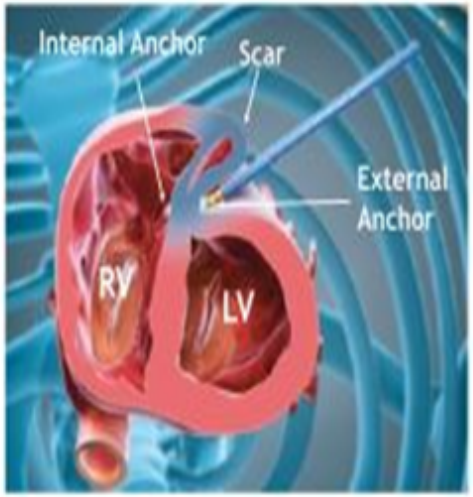
Cardiac Conduction and Monitoring

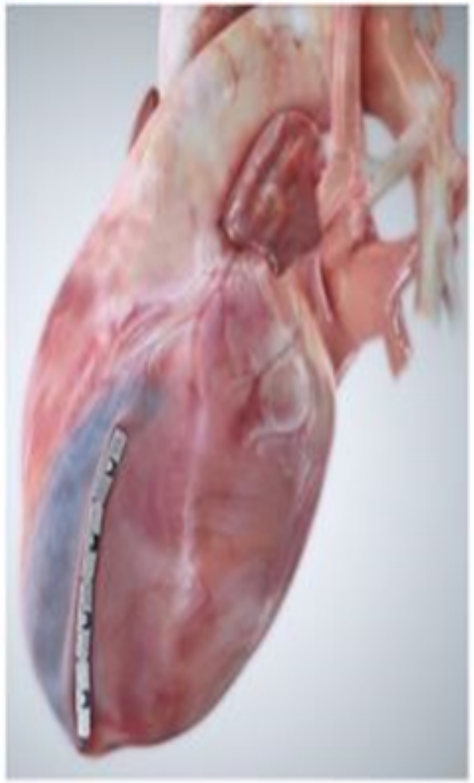
- Combination technology (Subcutaneous ICD + Leadless Pacemaker)
- Endocardial LV Pacing
- Motion-harvesting pacemakers
- Wearable monitors (miniaturized)

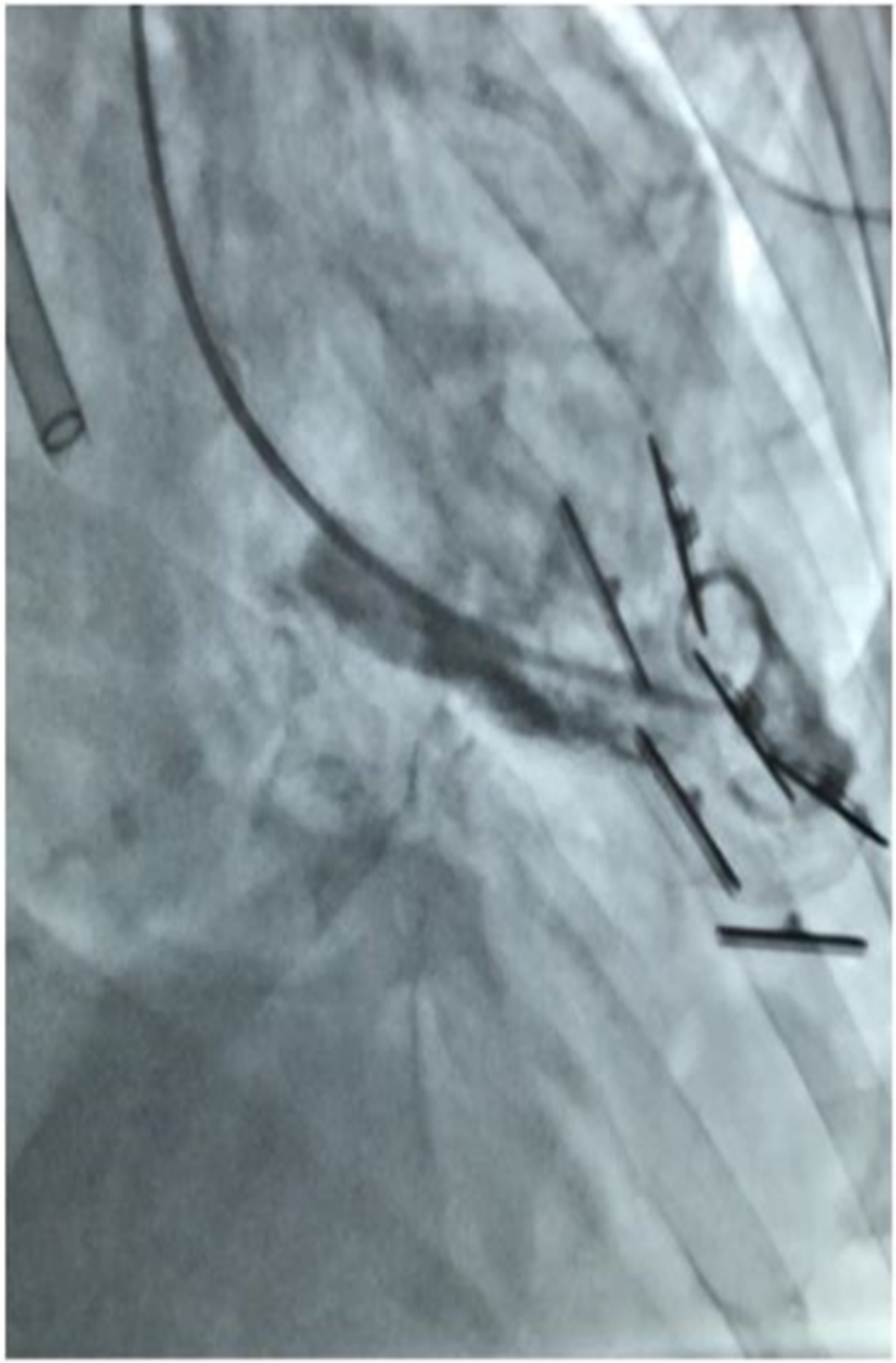
Closure Devices

- Watchman vs. Amulet (Trial underway)
- Many new devices in pipeline, slight variations in design
- Biodegradable devices

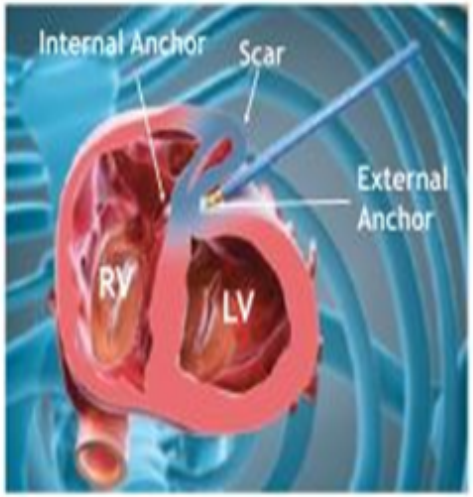
LV Restoration: Revivent TC ™

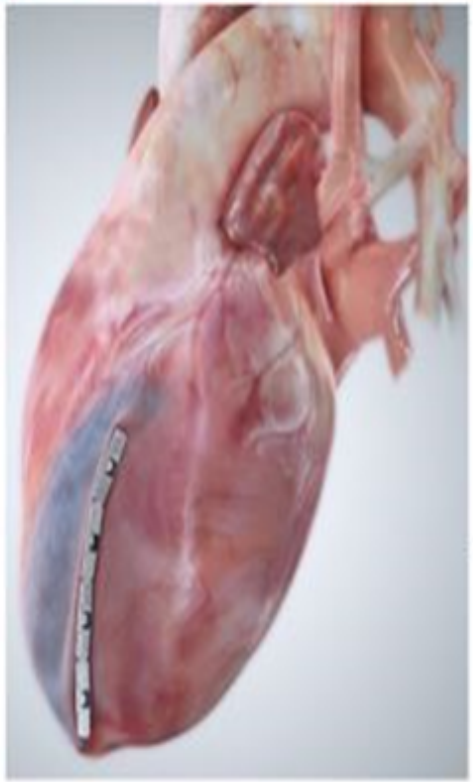


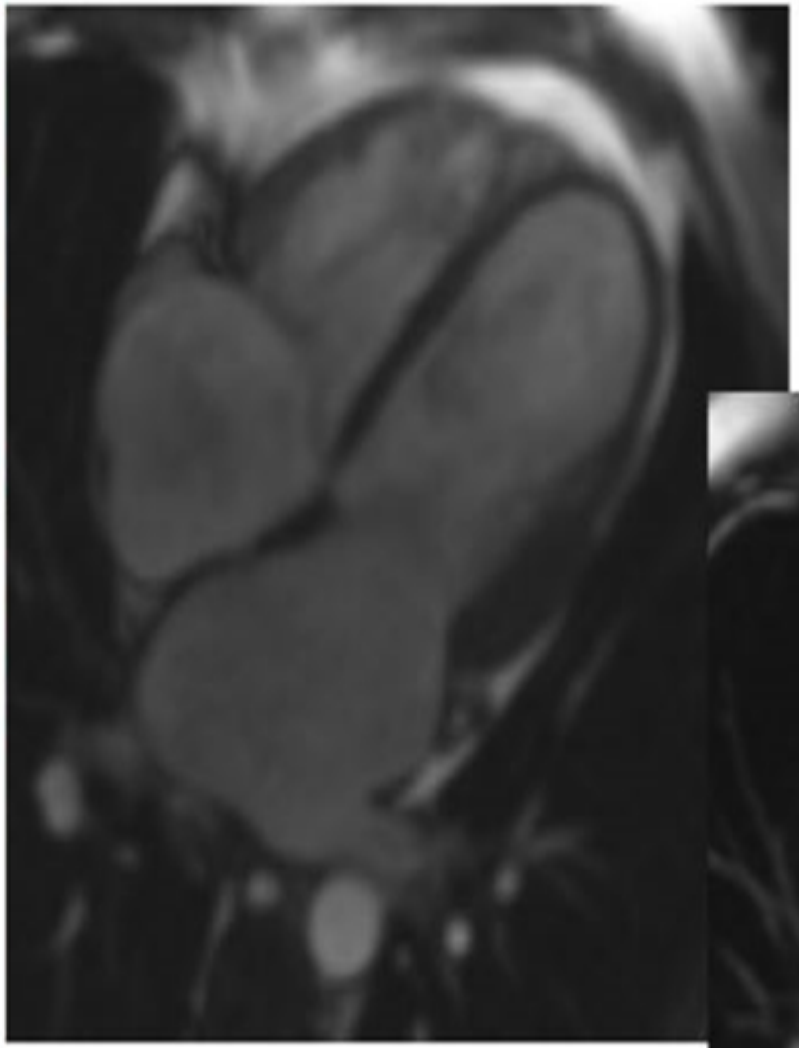


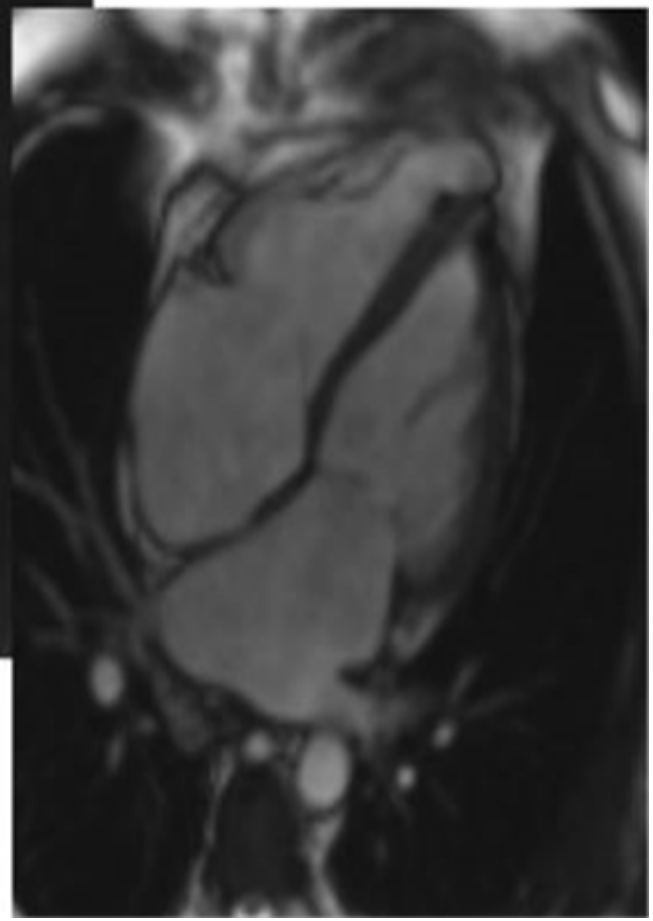


LV Restoration: Revivent TC ™

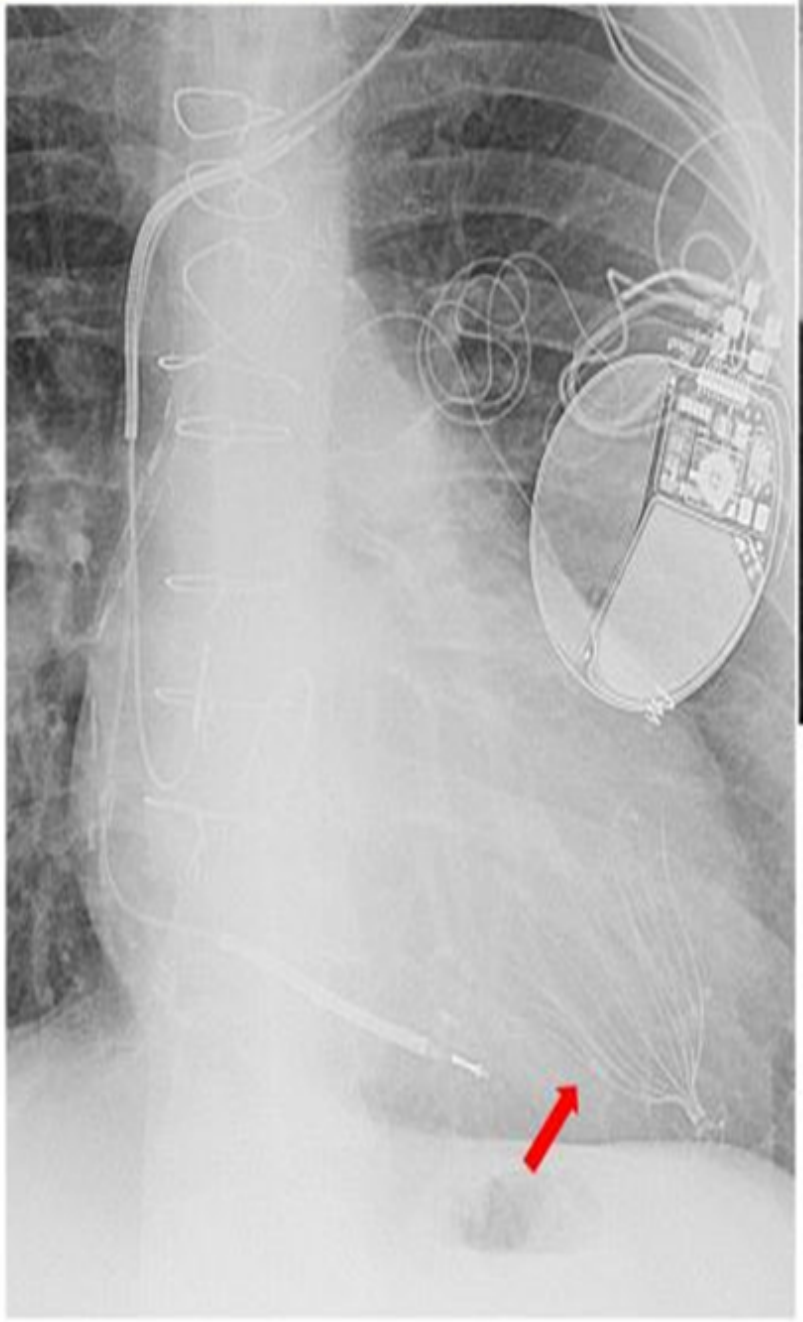


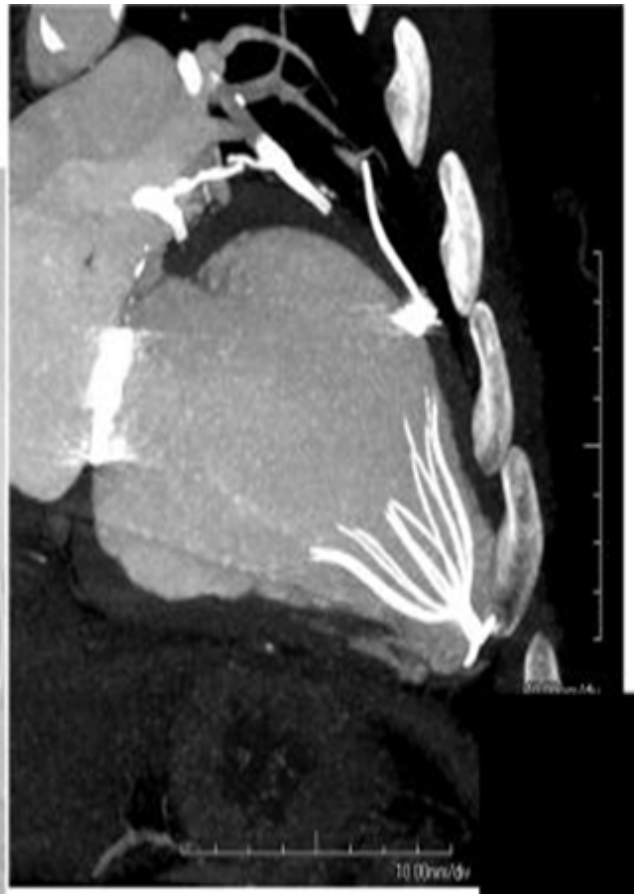






LV Restoration: Parachute





Summary

- Currently wide variety of cardiac devices
- Continuing trend of miniaturization, minimally invasive/catheter-based delivery systems, leadless/batteryless devices
- Expanding applications, number of devices
- Cardiothoracic radiologists
  - Must be familiar with appearances of currently available devices
  - Potential increased role in pre-procedural planning and post-intervention evaluation

Thank you.

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