



**University of Brescia Medical School  
Electrophysiology and Cardiac Stimulation Laboratory  
Division of Cardiology  
Spedali Civili Brescia  
Italy**



# ***Subclavian vein obstruction during device upgrading***

***A. Curnis MD FESc***

***M. Cerini MD***

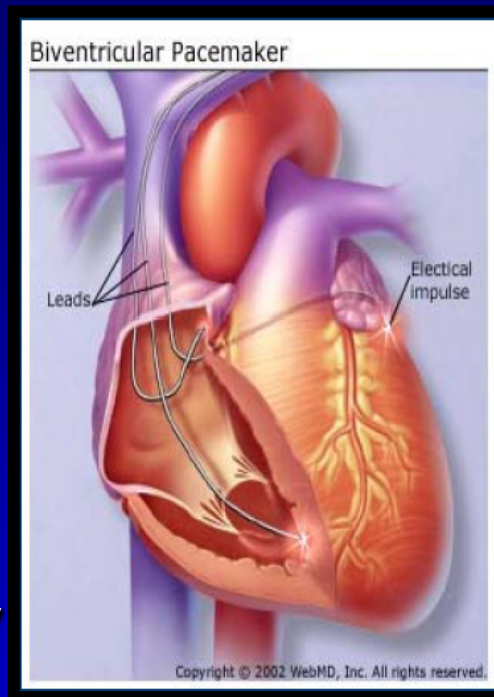
**XXVIII GIORNATE CARDIOLOGICHE TORINESI**

**Turin, October 13-15, 2016**

# Cardiac Resynchronization Therapy

**Widely accepted for treatment**

- Pts with systolic heart failure
- Impaired LVEF
- Electrical asynchrony



**It improves**

- Systolic LV function
- Peak oxygen uptake
- Exercise tolerance
- NYHA Class
- Reverses the remodeling
- Neurohormonal changes accompanying HF

*Large randomized trials also showed improved survival with CRT*

MIRACLE  
(n=453)

CONTAK-CD  
(n=490)

COMPANION  
(n=1520)

CARE-HF  
(n=813)

REVERSE  
(n=610)

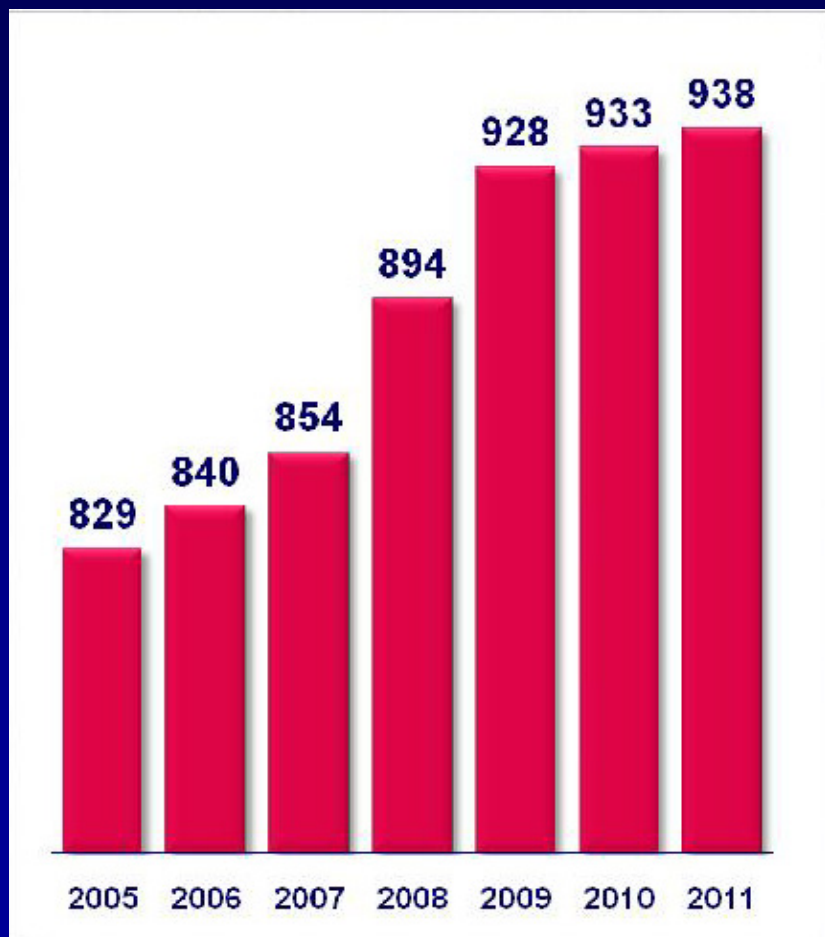
MADIT-CRT  
(n=1820)

RAFT  
(n=1798)

# Cardiac Resynchronization Therapy

PM

(Units per milion inhabitants/year)



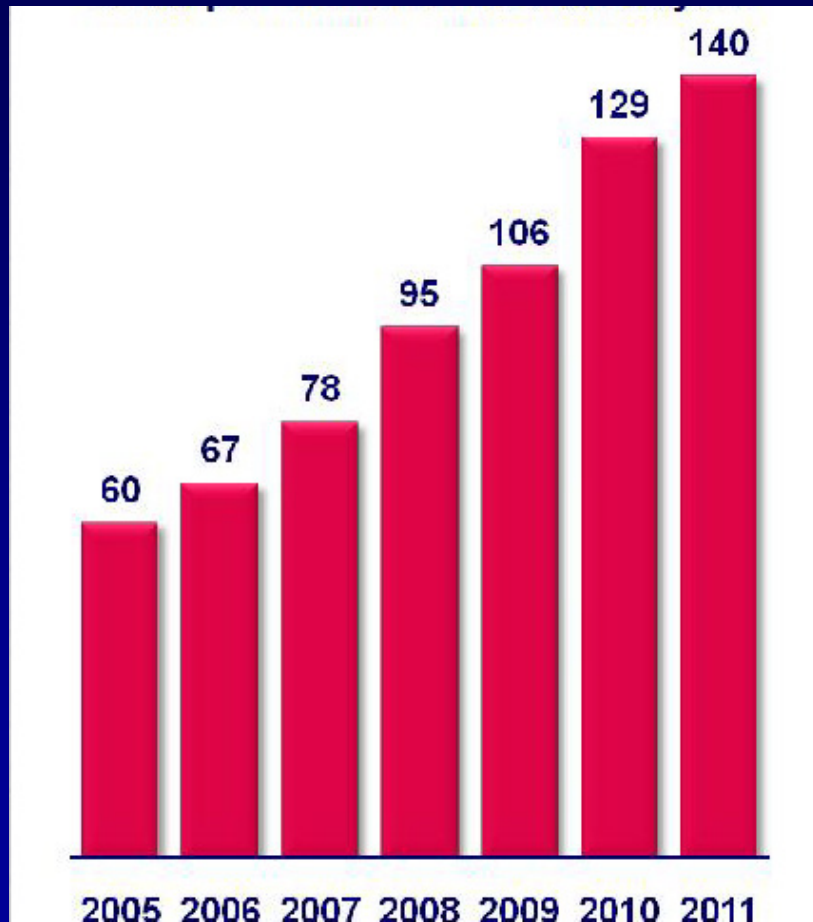
PM 2011

(Units per milion inhabitants/year)



# Cardiac Resynchronization Therapy

Units per million inhabits/years

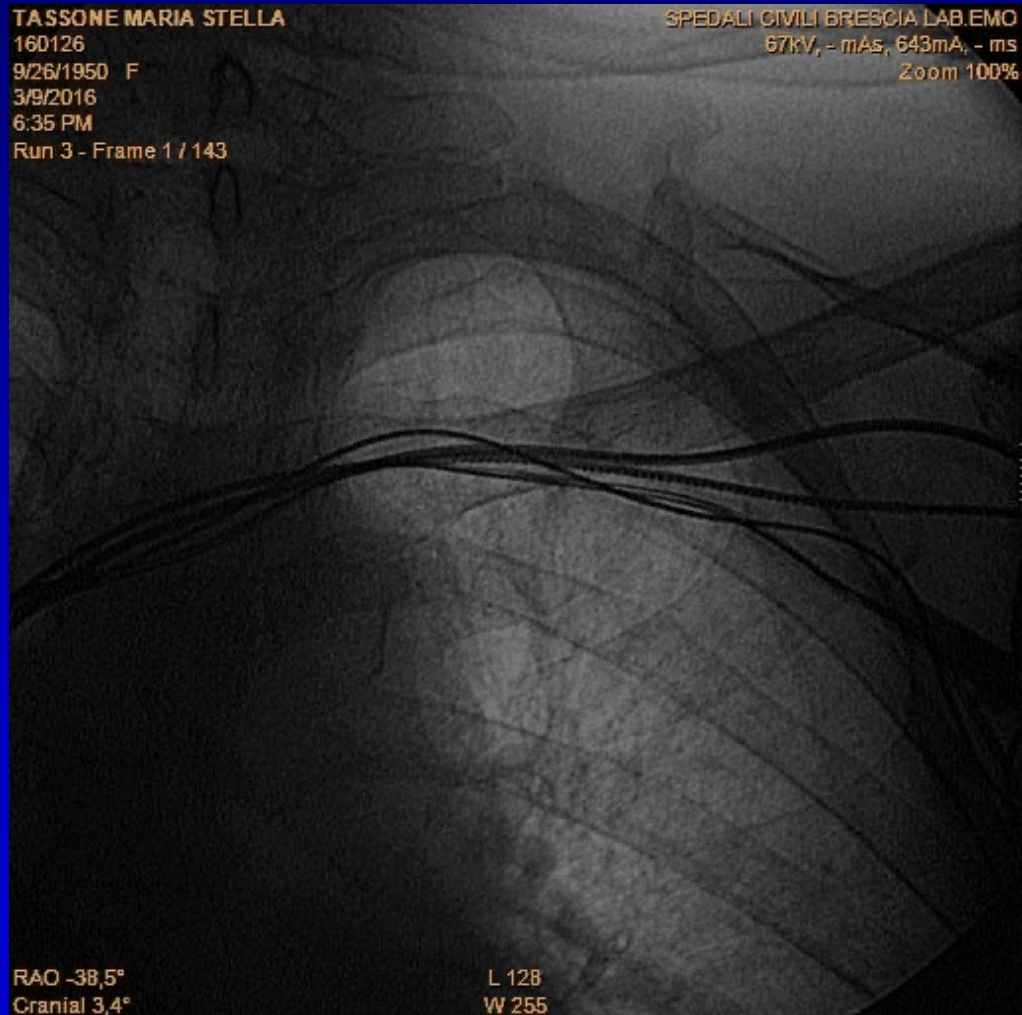


Units per million inhabits/years in





# PREIMPLANTATION ANGIOGRAPHY



# Vein Thrombosis

*A possible complication during implant of devices consists of thrombotic occlusion of the axillary or subclavian vein demonstrated up to 23% of cases \*.*

- *Asymptomatic (feedback during upgrading pacing system)*
- *Symptomatic (5%)*
- *Superior Vena Cava Syndrome (2 per 1000):*
  - number of leads
  - time slot
  - occurrence of infection.

*>>> They are frequent but often of little clinical weight*

\*Incidence and risk factors of early venous thrombosis associated with permanent pacemaker leads. J Cardiovasc Electrophysiol. 2004 Nov;15(11):1258-62

Venous thrombosis and stenosis after implantation of pacemakers and defibrillators. J Interv Card Electrophysiol. 2005 Jun;13(1):9-19.

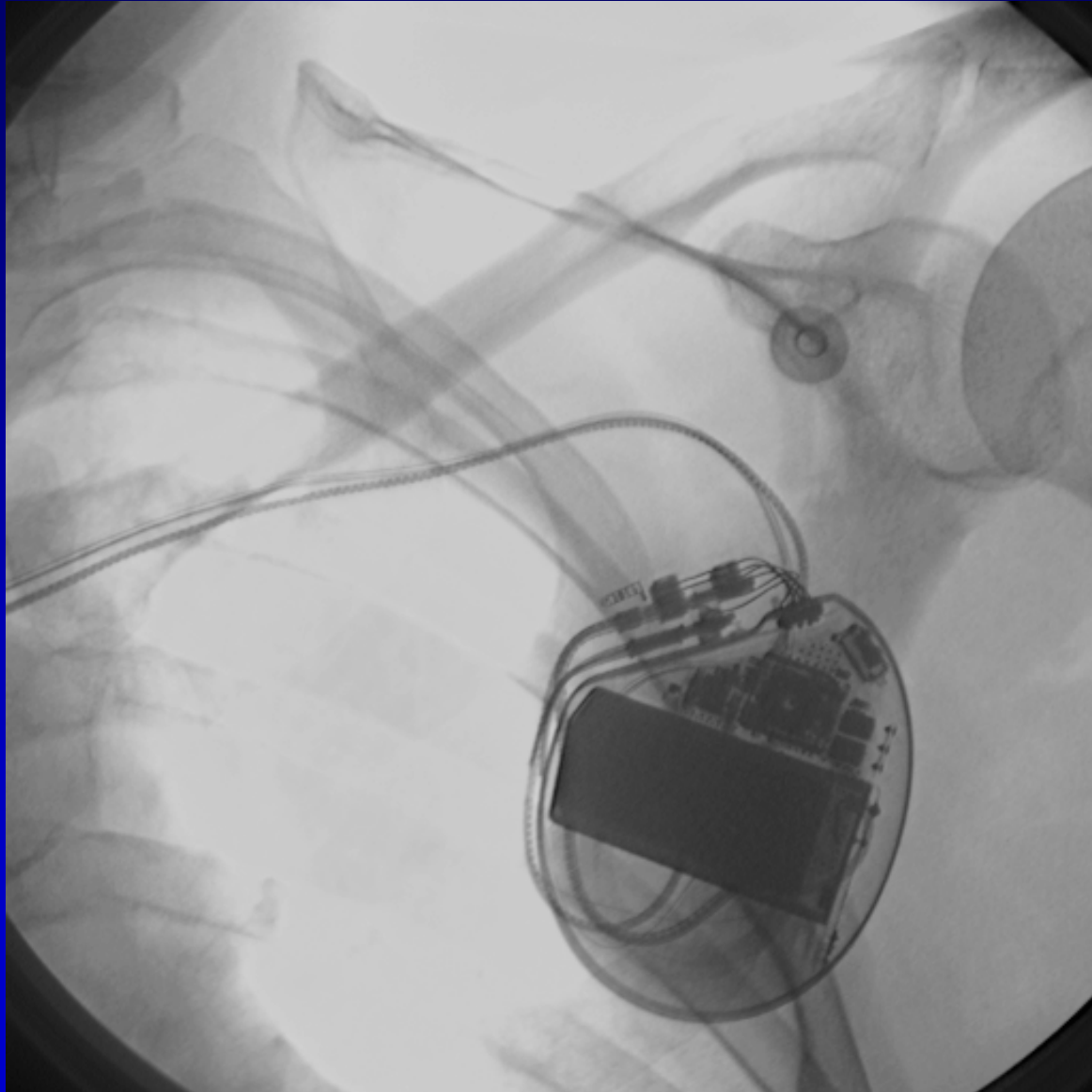
# Vein Thrombosis in PM/ICD

Author	Patients	Time after implant	Abnormal venography	Vein occlusion	Symptoms	Factors statistically significant	Factors statistically nonsignificant
da Costa et al. [15]	202	6mos	129(64%)	12 (6%)	12 (6%)	<ul style="list-style-type: none"> <li>- previous transvenous temp leads (P .001)</li> <li>-LV EF &lt; 40%</li> </ul>	<ul style="list-style-type: none"> <li>-age</li> <li>-sex</li> <li>-underlying heart disease</li> <li>-NYHA Functional Class</li> <li>-site of access</li> <li>-number of leads</li> <li>-leads material</li> </ul>
Bracke et al. [16]	56						<ul style="list-style-type: none"> <li>-age</li> <li>-sex</li> <li>-the number of leads,</li> <li>-the procedure of implantation</li> <li>-the time from implantation</li> <li>-lead insulation,</li> <li>-the polarity of the electrode</li> <li>-the route of entry</li> </ul>
Zuber et al. [19]	56						<ul style="list-style-type: none"> <li>-age,</li> <li>-sex,</li> <li>-the number of leads,</li> <li>-the procedure of implantation</li> <li>-the time from implantation</li> <li>-lead insulation,</li> <li>-the polarity of the electrode</li> <li>-the route of entry</li> </ul>
Antonelli et al. [17]	40	9 ± 3 mos	9 (23%)	2 (5%)	2 (5%)	NONE	<ul style="list-style-type: none"> <li>-age,</li> <li>-sex,</li> <li>cardiothoracic ratio,</li> <li>-left atrial dimension,</li> <li>-LVEF,</li> <li>-baseline heart disease</li> <li>-number and body</li> <li>-size of pacing leads</li> </ul>
Oginosawa et al. [14]	131(enrolled) 79 (follow-up DSA)	44 ± 6 mos	26 (32.9%) 18 (13.7%) had sig. narrowing before implantation	10(12.6%)	All patients asymptomatic	NONE	<ul style="list-style-type: none"> <li>-age,</li> <li>-sex,</li> <li>cardiothoracic ratio,</li> <li>-left atrial dimension,</li> <li>-LVEF,</li> <li>-baseline heart disease</li> <li>-number and body</li> <li>-size of pacing leads</li> </ul>
Van Rooden et al. [20]	145 mixed data (48% pacing, 52% ICD leads)	12 mos	34(23.4%) abnormal Doppler US	14 (10%)	3 (2%)	<ul style="list-style-type: none"> <li>-absence of anticoagulation tx RR 2.7 (95% CI 1.4-5.0)</li> <li>-use of hormone tx RR 3.7 (95% CI 2.2-6.2)</li> <li>-personal history of venous thrombosis RR 2.4 (95% CI 1.2-4.6)</li> <li>-presence of multiple leads RR 3.8 (95% CI 1.0-15.0)</li> </ul>	<ul style="list-style-type: none"> <li>-sex, age, BMI</li> <li>-active cancer</li> <li>-factor V Leiden</li> <li>-acute MI</li> <li>-CHF</li> <li>-COPD</li> <li>-limb paralysis</li> <li>-family hx of DVT</li> </ul>
<b>Total</b>	<b>711</b>		<b>275 (38%)</b>	<b>78(11%)</b>	<b>19 (2.6%)</b>		

The venous thrombotic complication rate for ICD is very similar to that for pacemakers

Rozmus et al J of Intervent Cardiac Electrophysiol 2005;13:9-19

# Vein Thrombosis



# Controlateral implant and tunneling

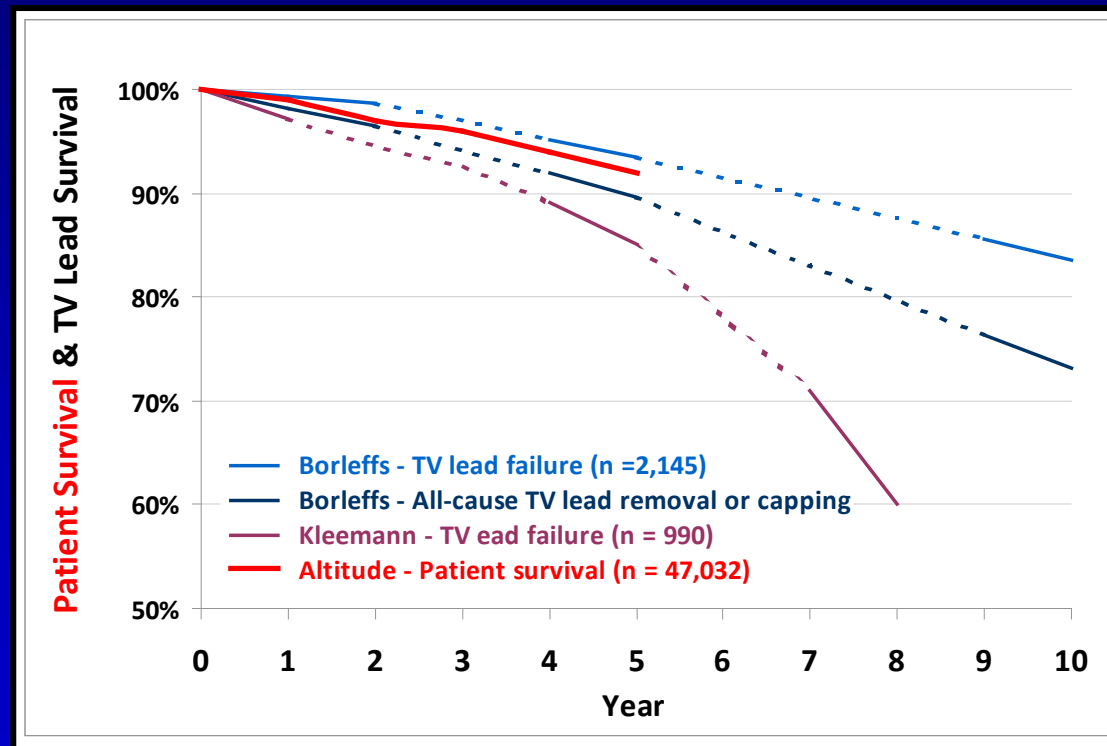
- ✓ *Bilateral incision*
- ✓ *Pain*
- ✓ *Increased risk of failure*
- ✓ *Increased risk of thrombosis and superior vena cava syndrome*





# Complications and failure of leads

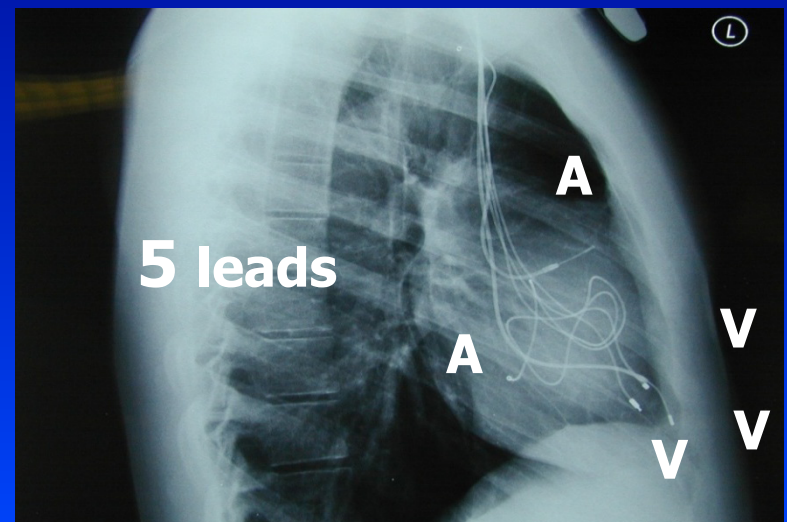
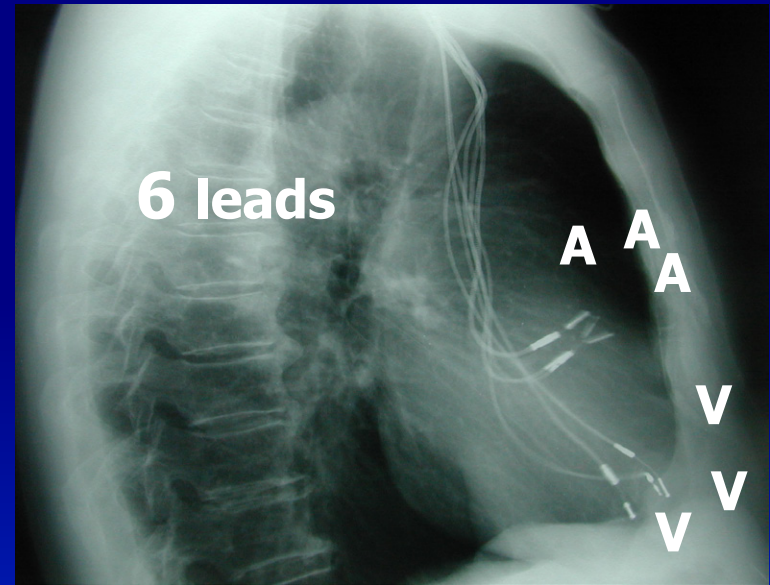
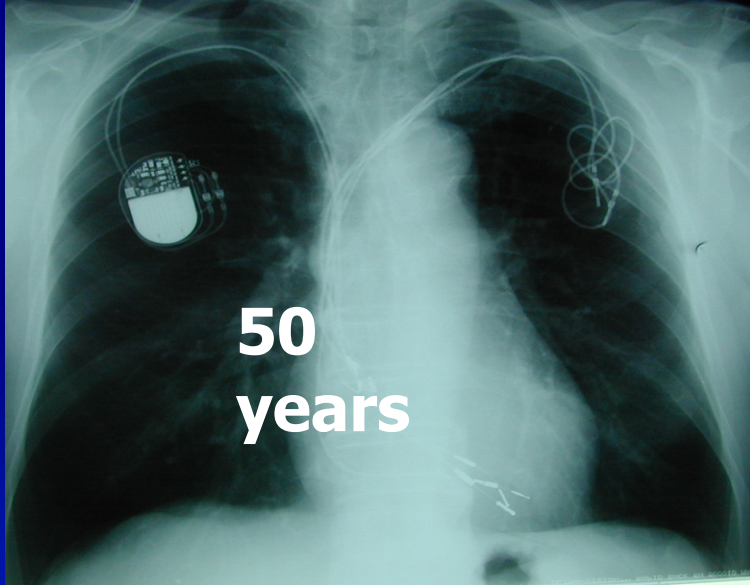
*10%-15% leads within 5 years after implant*  
*20%-40% leads within 8 years after implant*



T.Kleeman T, et al. Annual rate of transvenous defibrillation lead defects in implantable cardioverter-defibrillators over a period of >10 years. *Circulation* 2007;115:2474-80.

Borleffs et al. Risk of failure of transvenous implantable cardioverter-defibrillator leads. *Circ Arrhythmia Electrophysiol.* 2009;2:411-416.

# Overcrowding of leads



# Lead extraction

## *PURPOSE:*

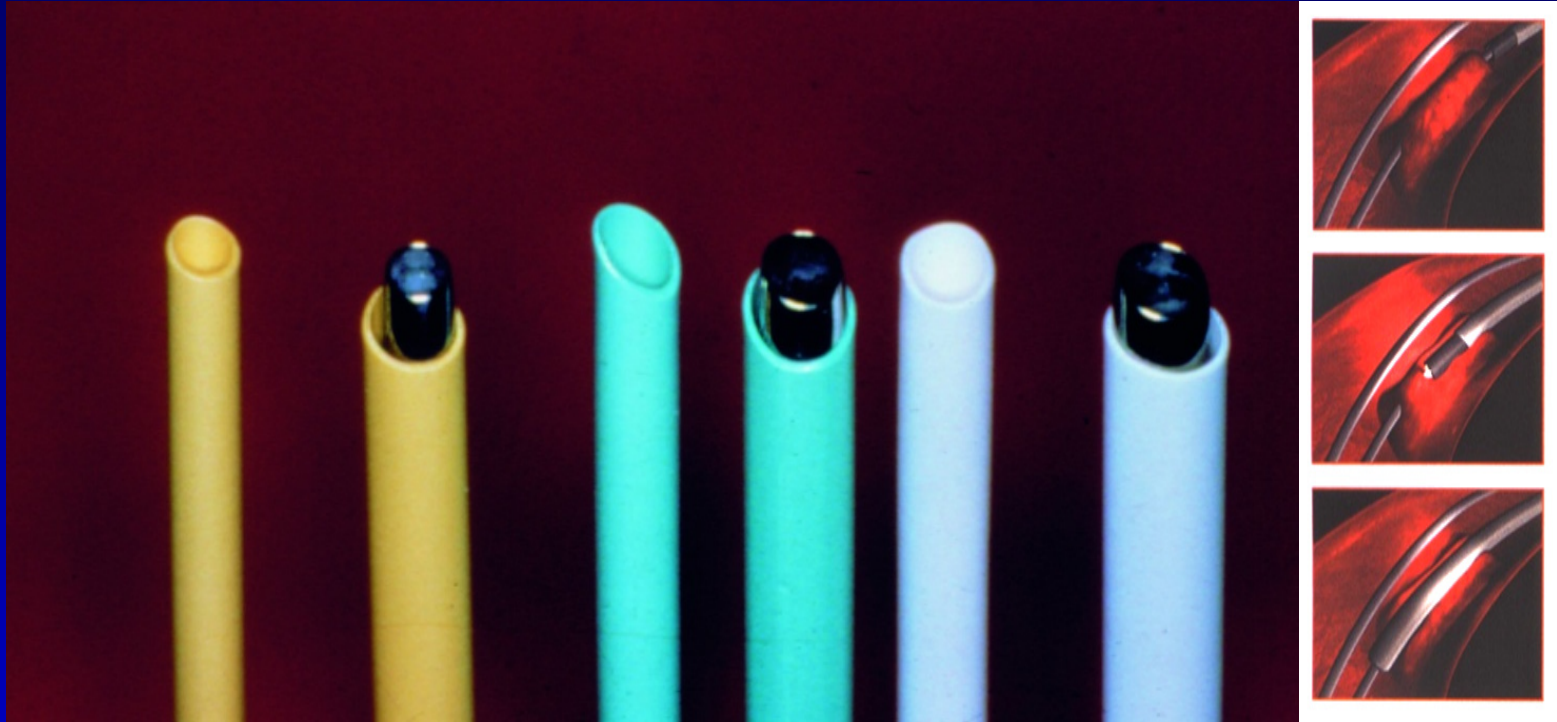
- ✓ *Use the sheath instead of introducer to advance the wires*

## *DISADVANTAGES:*

- ✓ *Surgical risk*
- ✓ *Risk of impairment of other leads*
- ✓ *Long procedure and increased risk of infection*



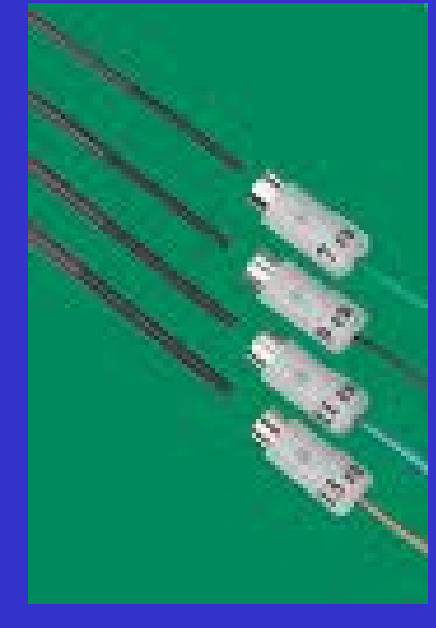
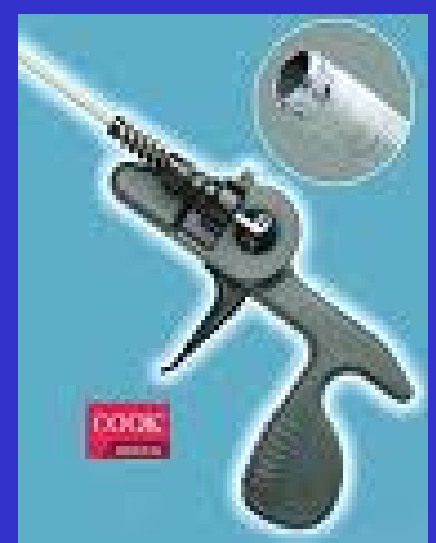
# Mechanical Sheaths



metal /teflon/ polypropylene: require manual advancement over the lead and rely on the mechanical properties of the sheath to disrupt fibrotic attachments

# Powered Sheath

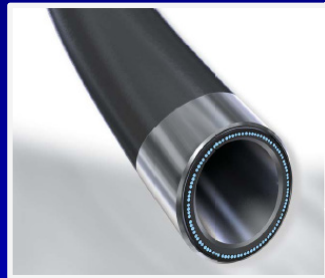
- *Rotating Threaded Tip Sheath* :  
rotationally powered mechanism on the tip
- *Electrosurgical dissection sheath (EDS)*:  
radiofrequency energy emitted between two electrodes at the sheath tip to disrupt the fibrotic attachments



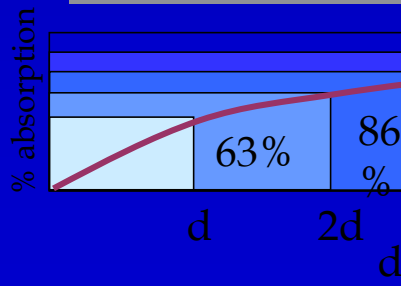
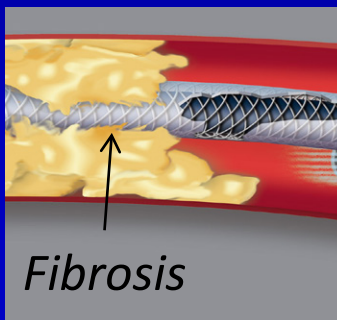


# Powered Sheath 80 Hertz for Laser Spectranetics CVX-300<sup>®</sup>

Re-calibrate your hands to **control** the advancement rate and **lower** the force applied



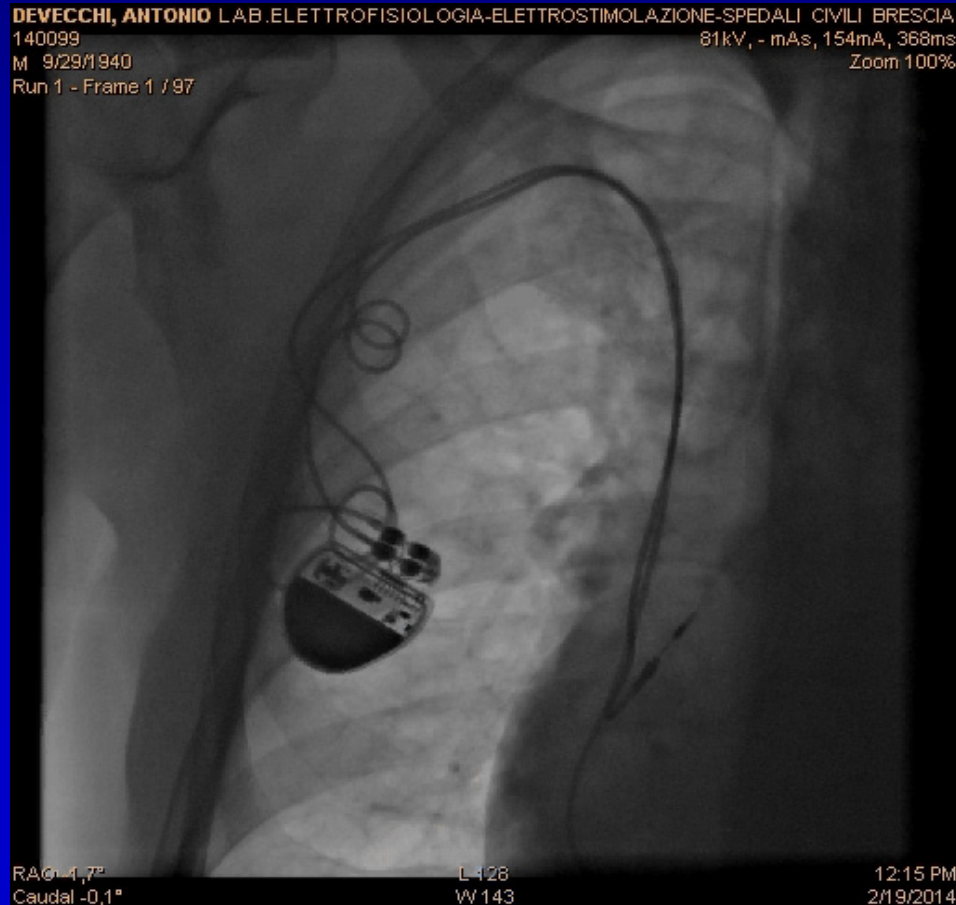
Size
12
14
16



absorbed in 0.6 mm

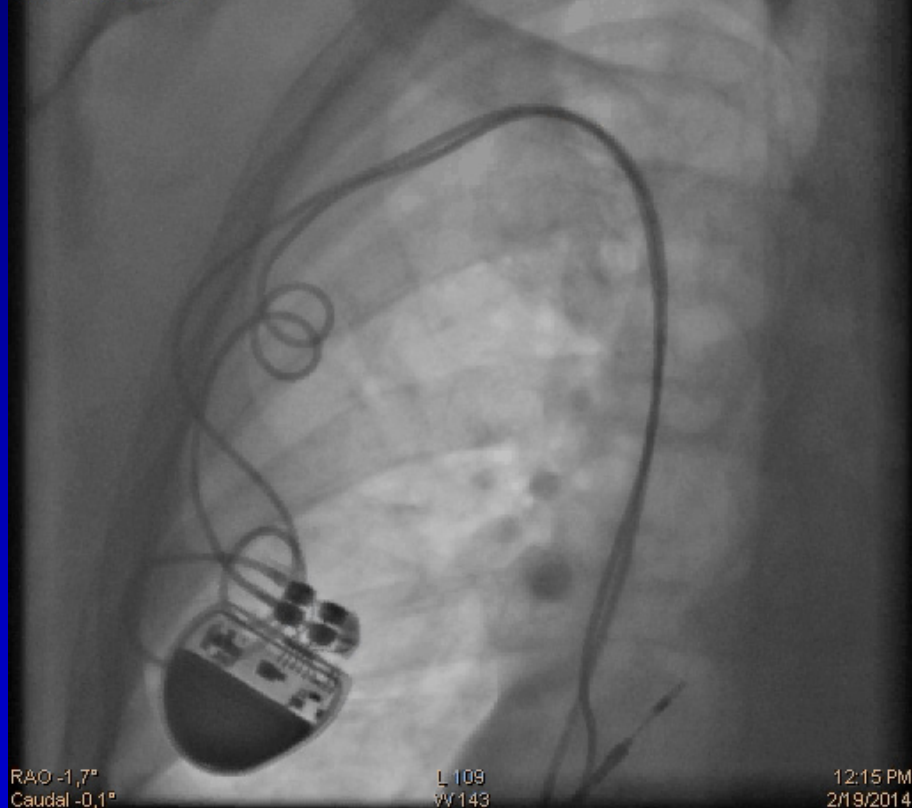
# Leads extraction and reimplant (1)

- Ischemic DCM (EF 25%)
- Previous PM-DDD implant

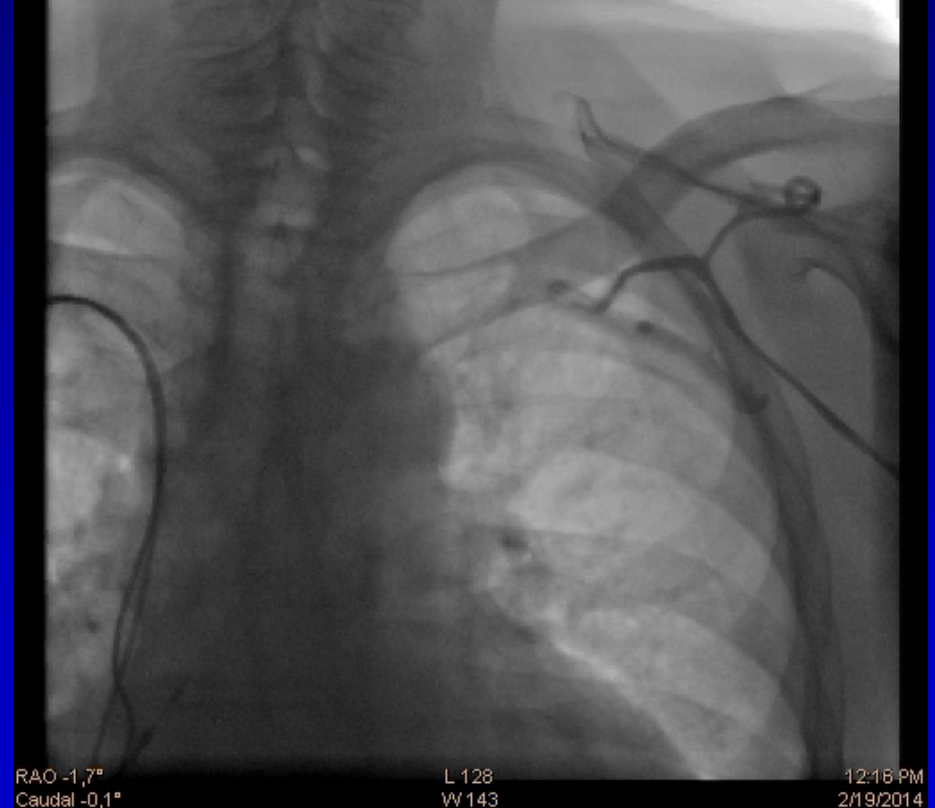


# Leads extraction and reimplant

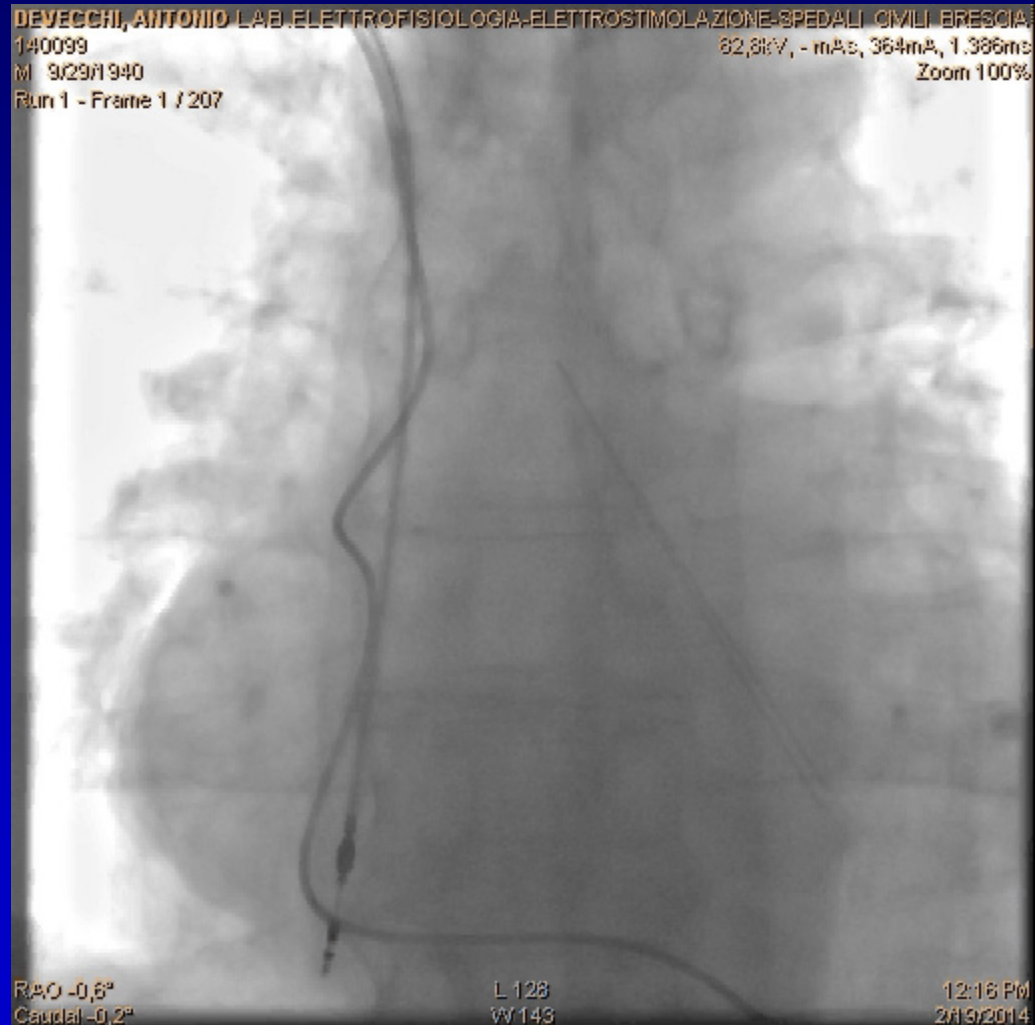
DEVECCHI, ANTONIO LAB.ELETTROFISIOLOGIA-ELETTROSTIMOLAZIONE-SPEDALI CIVILI BRESCIA  
140099 81kV, -mA, 29mA, 1.044ms  
M 9/29/1940 Zoom 100%  
Run 1 - Frame 1 / 290



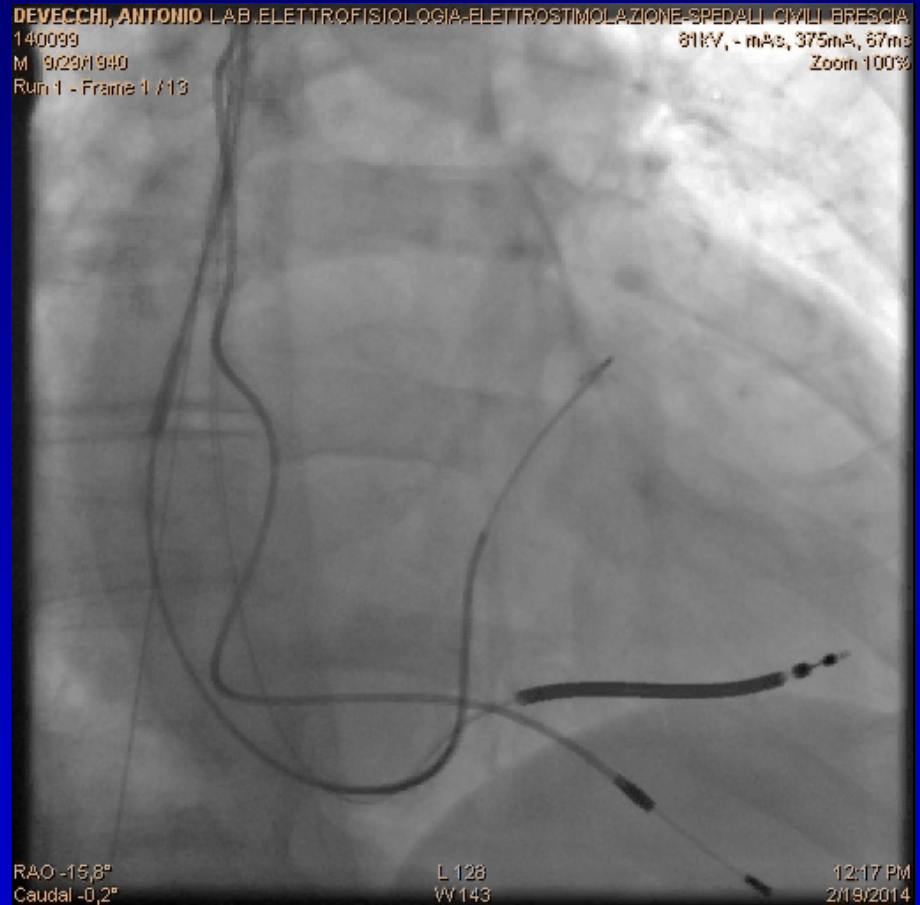
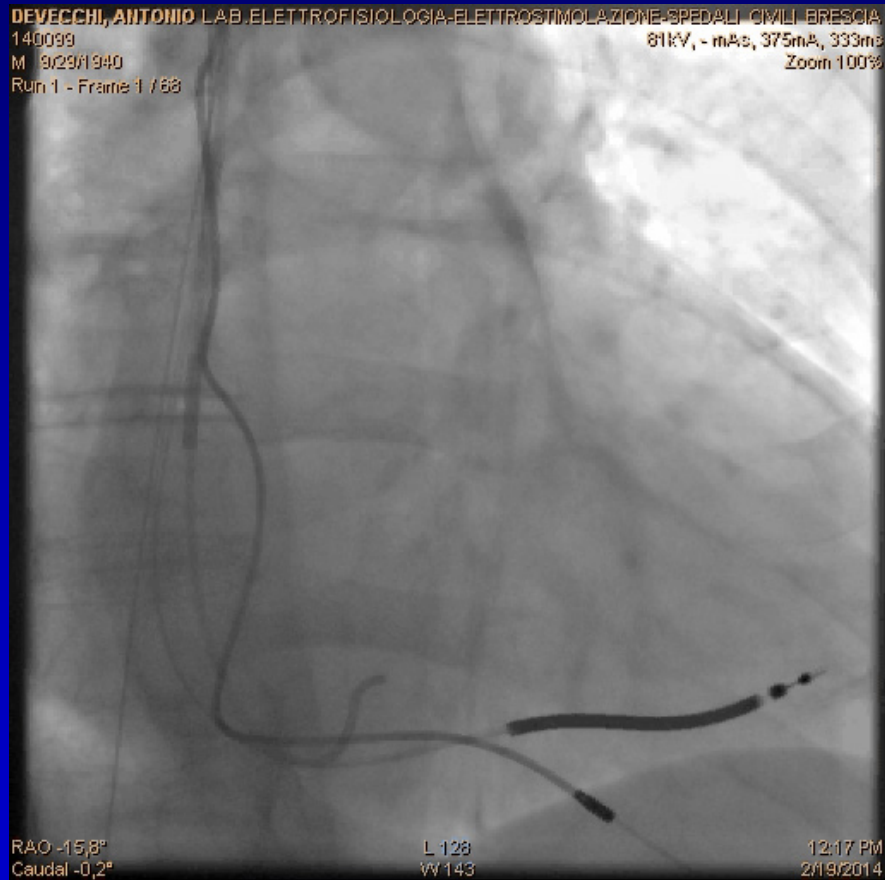
DEVECCHI, ANTONIO LAB.ELETTROFISIOLOGIA-ELETTROSTIMOLAZIONE-SPEDALI CIVILI BRESCIA  
140099 81kV, -mA, 37mA, 898ms  
M 9/29/1940 Zoom 100%  
Run 1 - Frame 1 / 194



# Leads extraction and reimplant

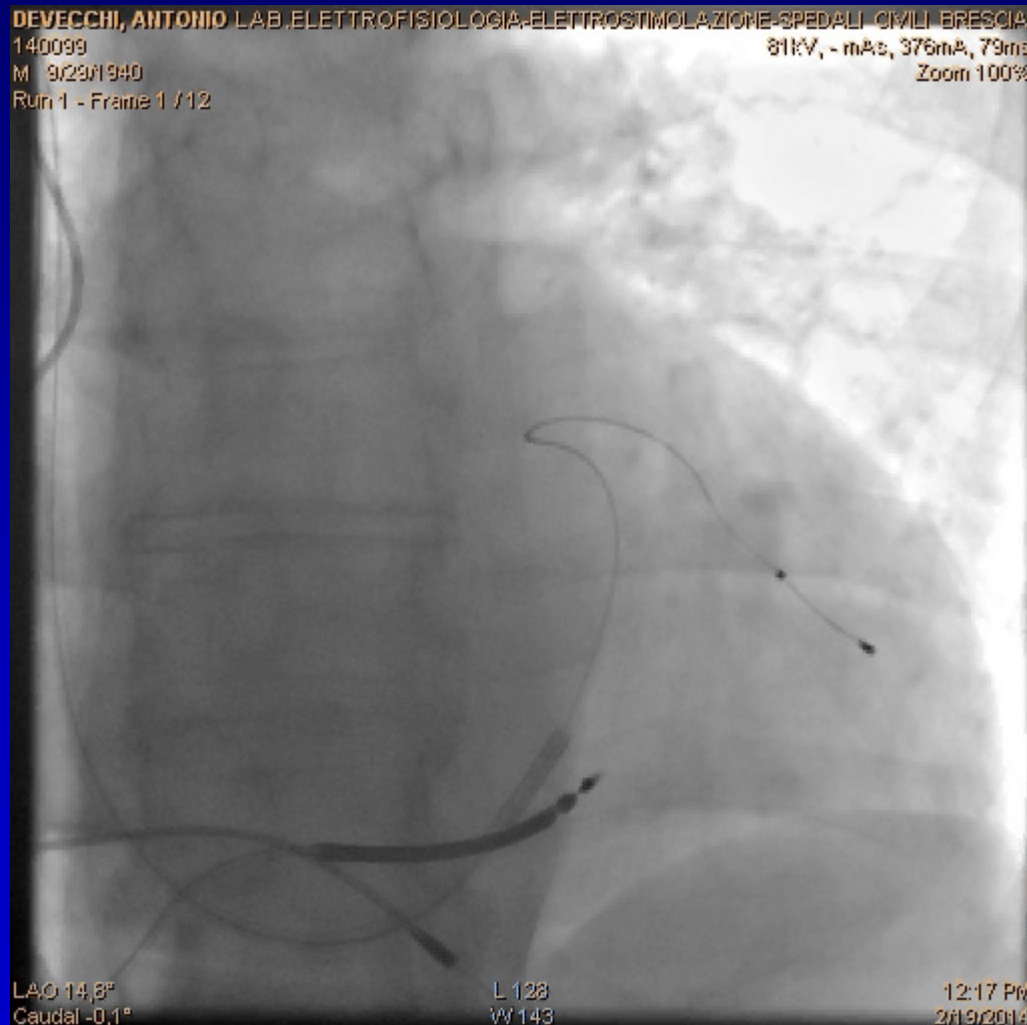


# Leads extraction and reimplant

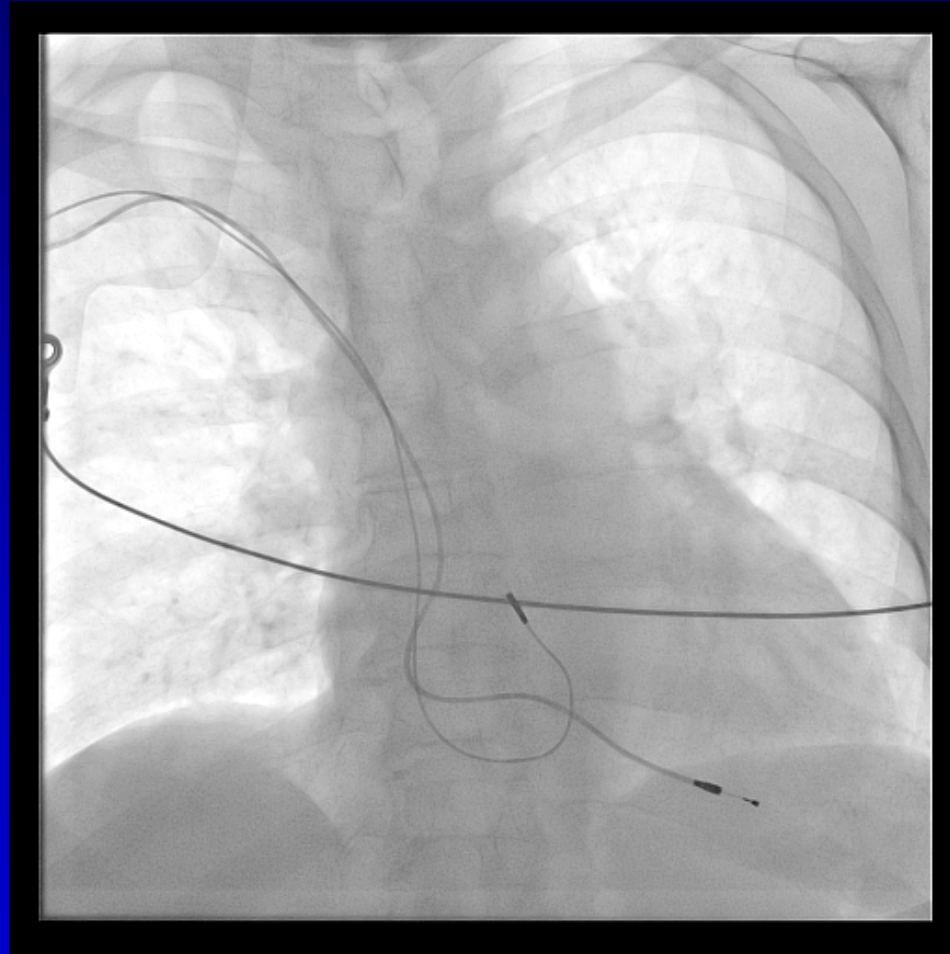




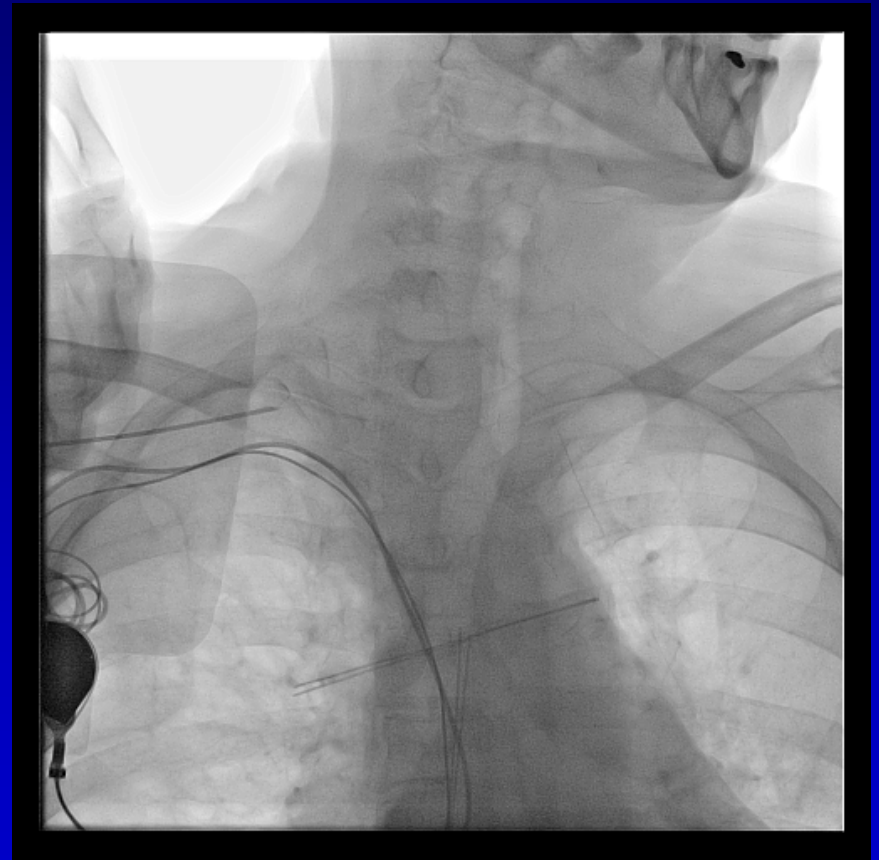
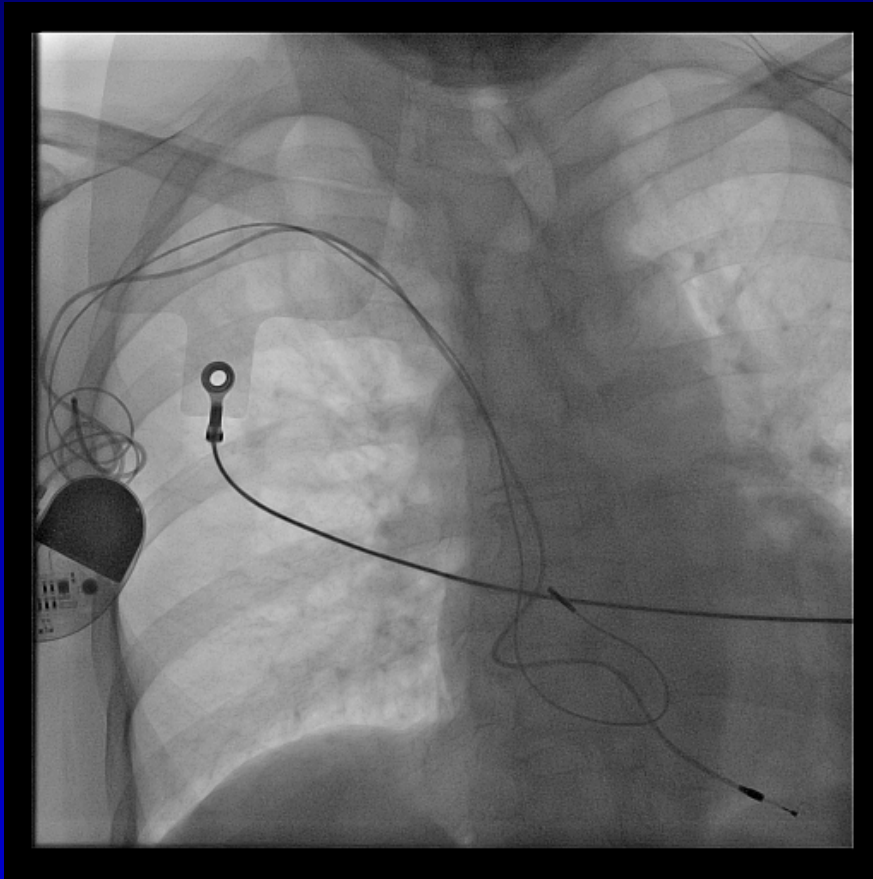
# Leads extraction and reimplant



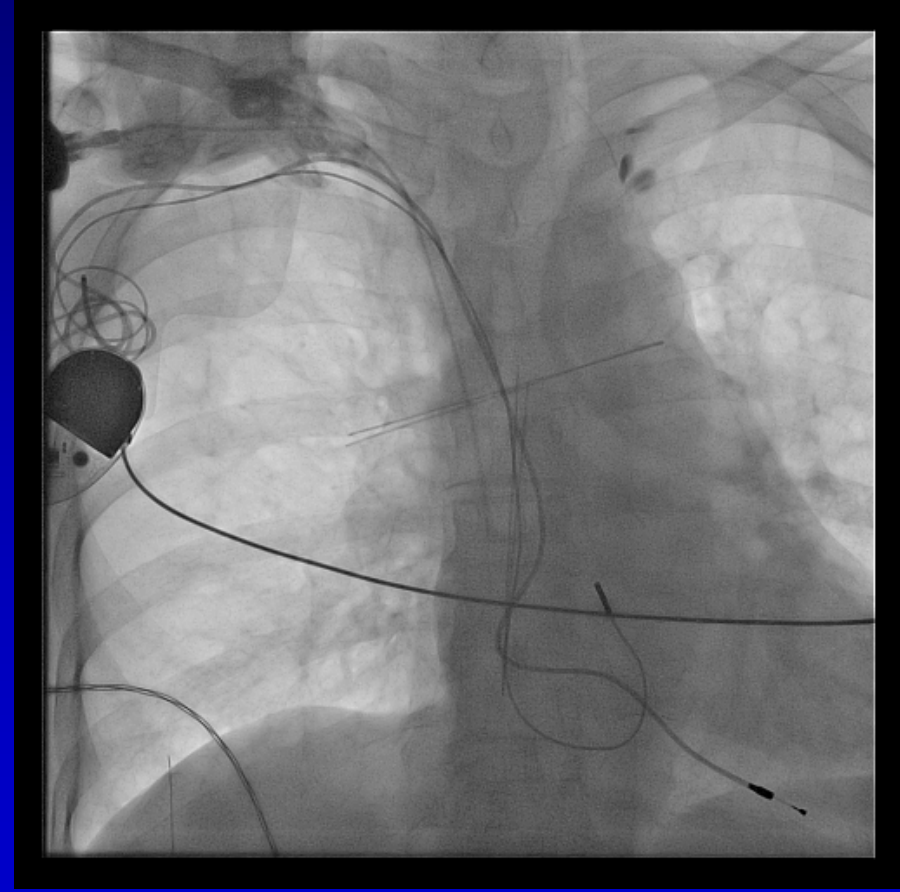
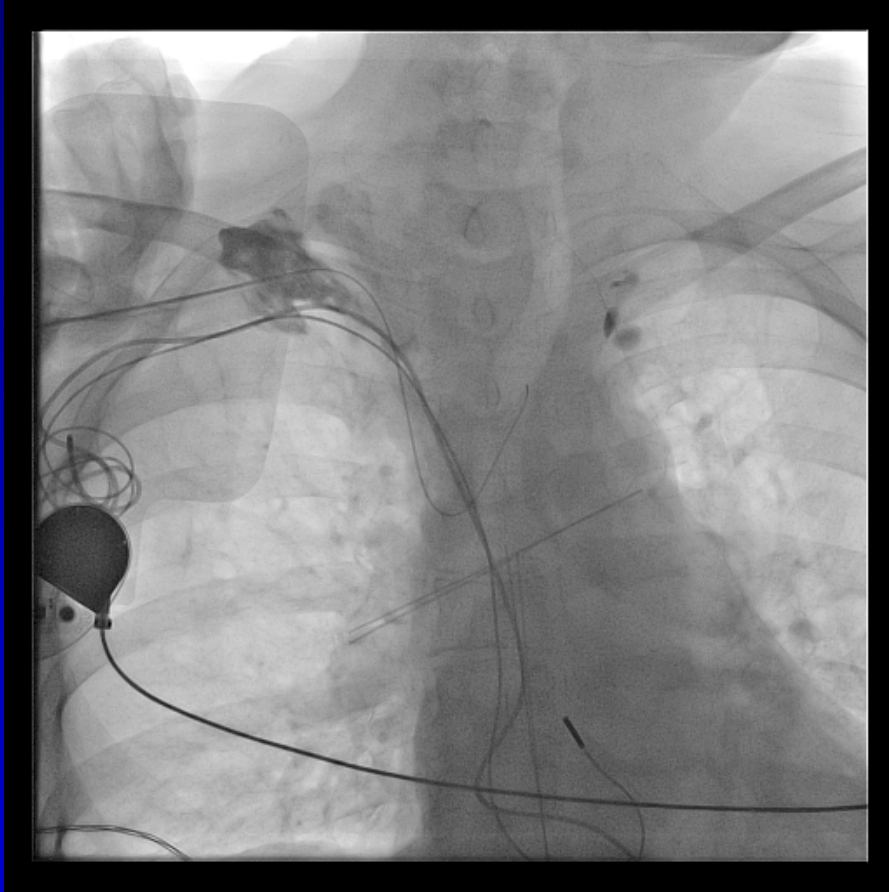
# Leads extraction and reimplant (2)



# Leads extraction and reimplant



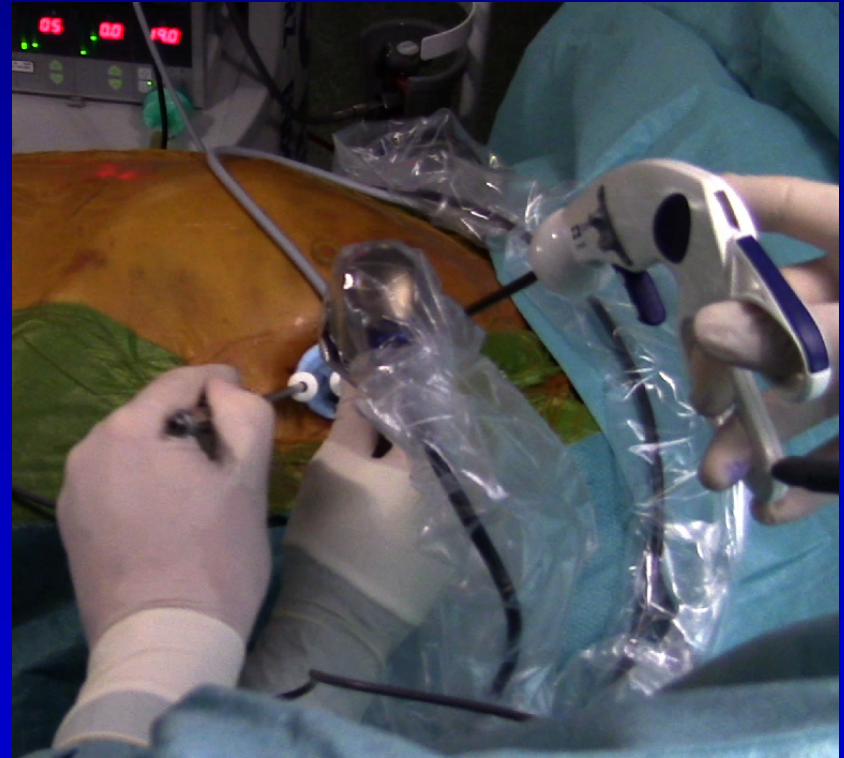
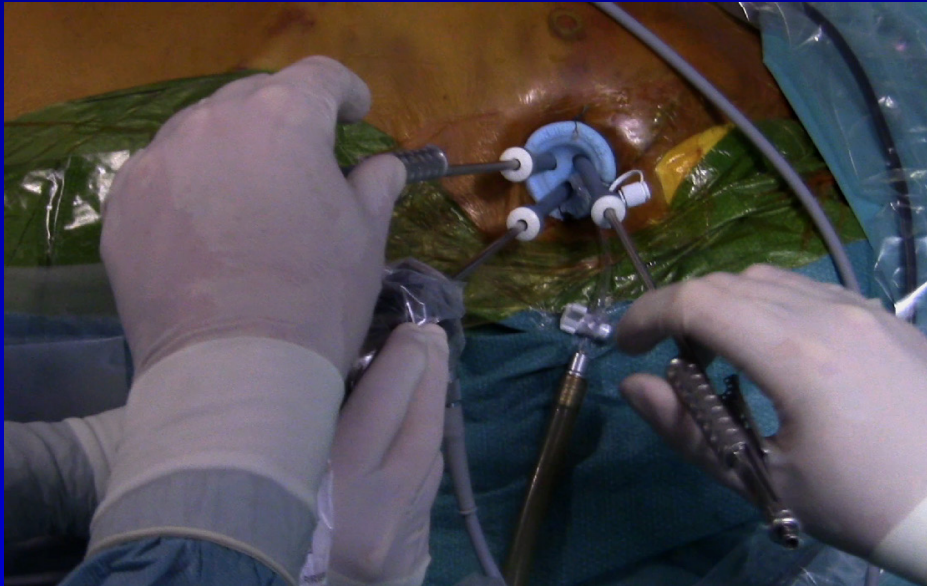
# Leads extraction and reimplant





# ***EPICARDIAL LEADS IMPLANTATION***

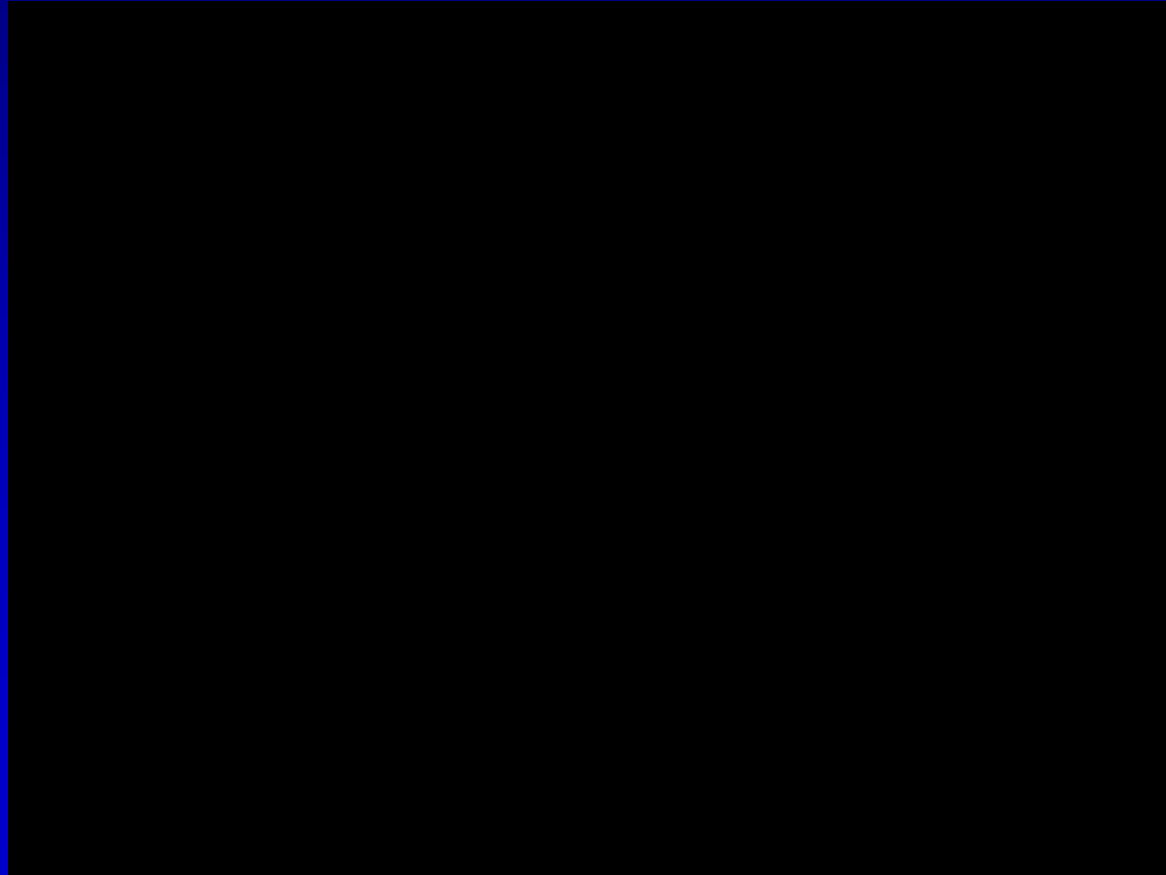
***- Thoracoscopic approach -***



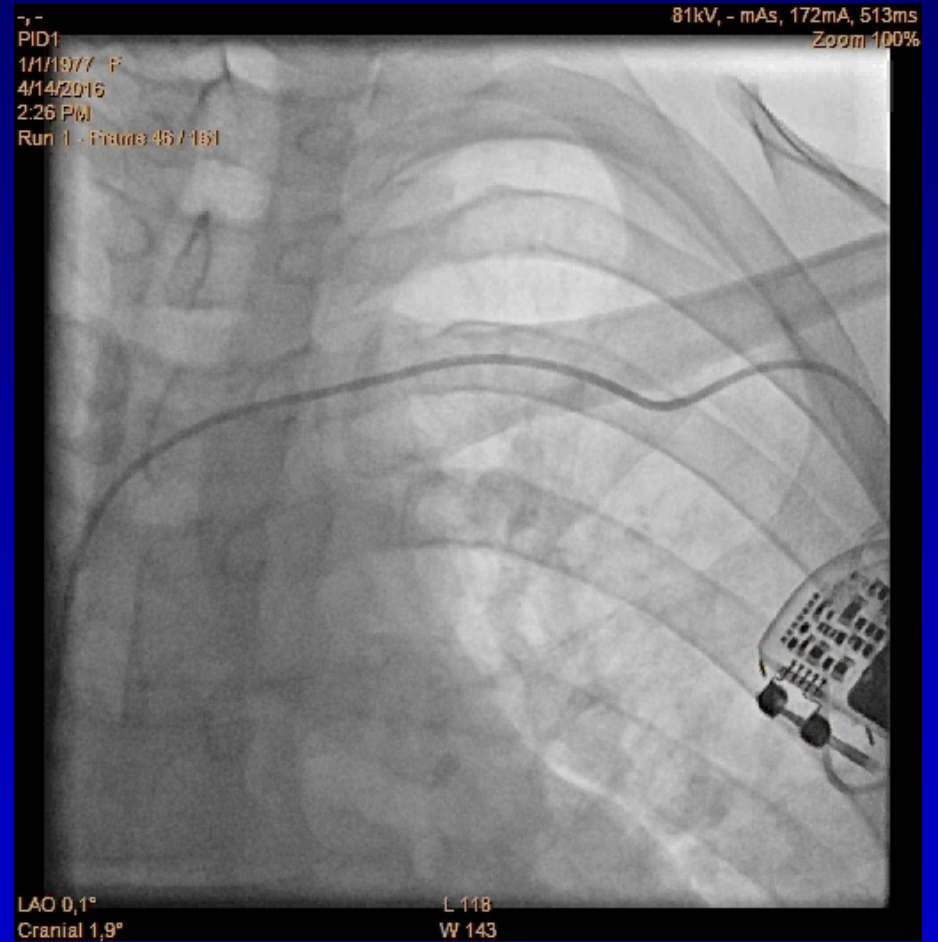
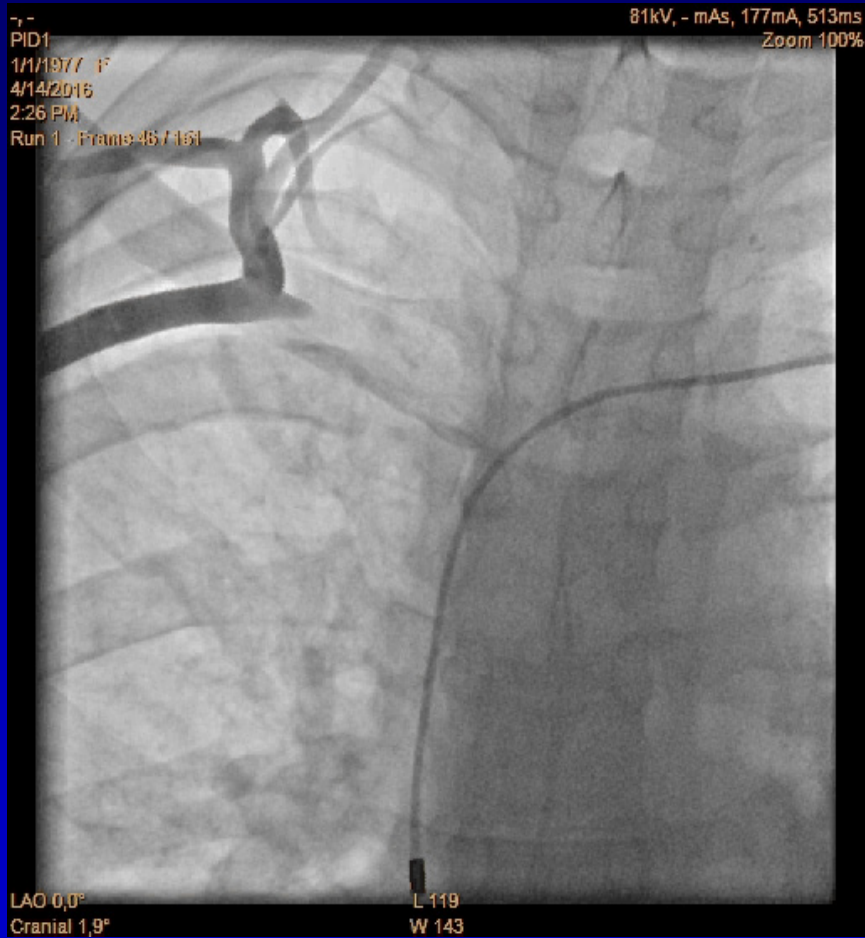


# ***EPICARDIAL LEADS IMPLANTATION***

***- Mini-thoracotomy approach -***



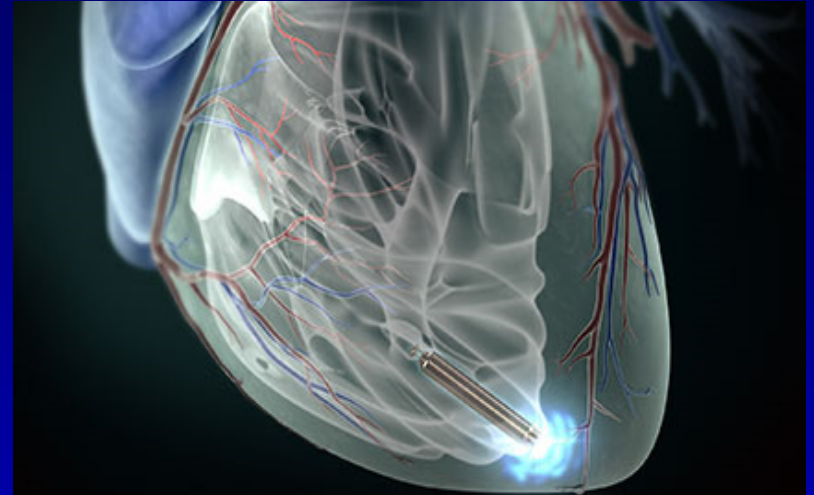
# LEADLESS



# Nanostim™ Leadless Pacemaker

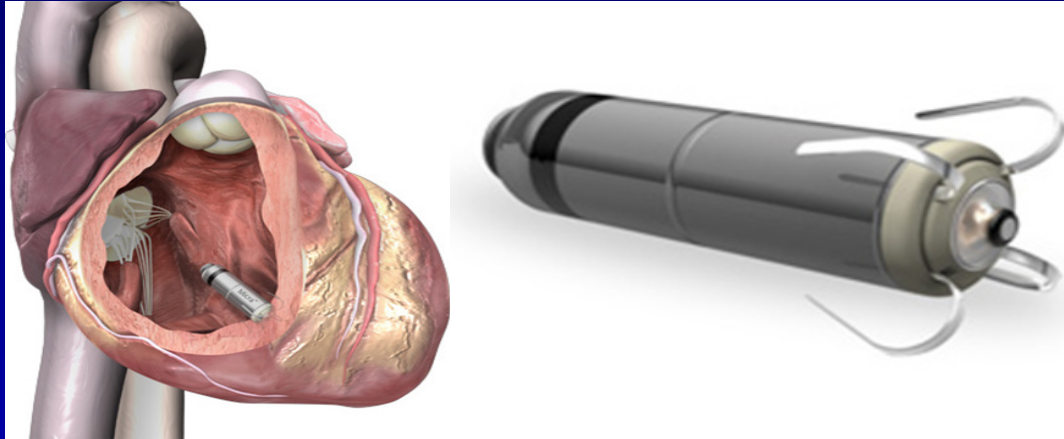
- VVIR\* Pacemaker
- Miniaturized: 1 cc, 2 g
- Entirely lies into RV
- Contains battery and electrodes
- Inserted by femoral approach

\* Temperature sensor



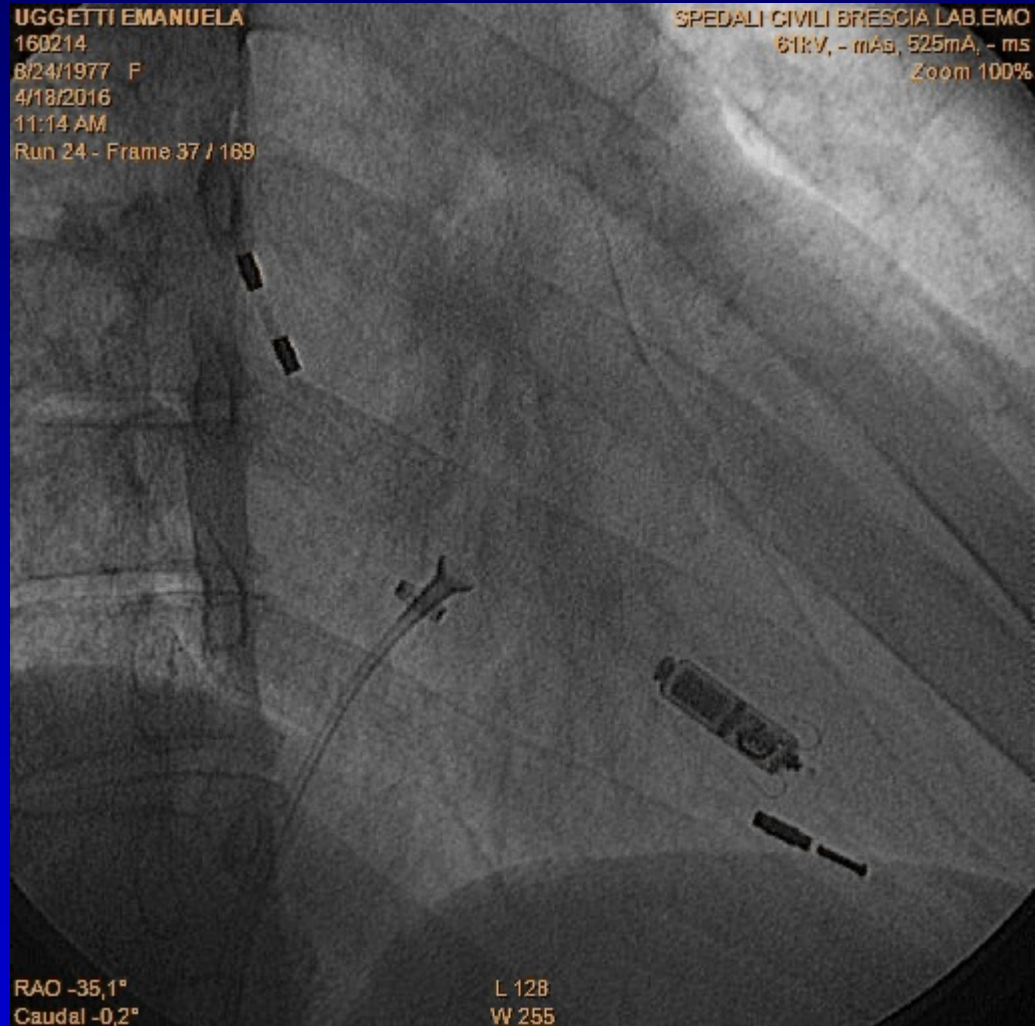
# Micra TPS

## (Transcatheter Pacing System)



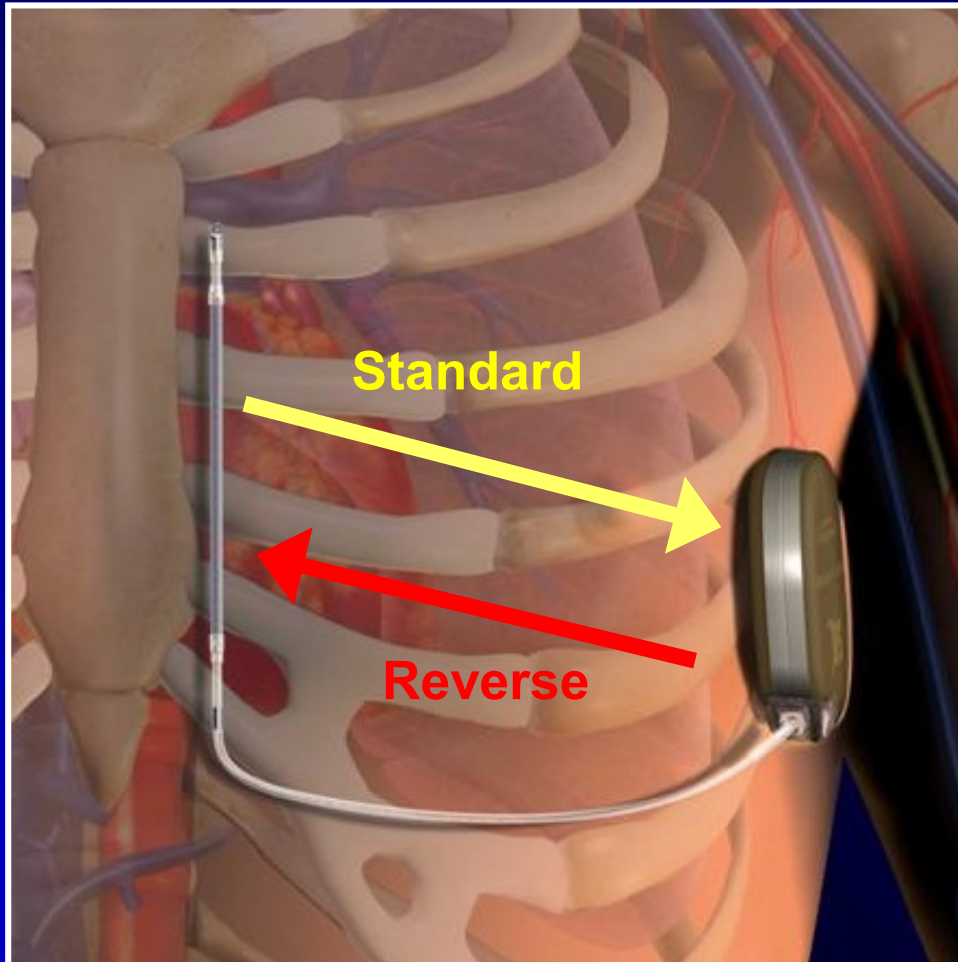
- ✓ *VVI(R)*
- ✓ *Cylinder Shape (24 mm long / 0.75 cc volume) Placed within RV*
- ✓ *Titanium capsule with 4 active fixation nitinol tines*
- ✓ *7-10 years longevity*
- ✓ *MR-conditional*
- ✓ *RF communication with programmer and remote f-u capability*

# LEADLESS





# S-ICD system



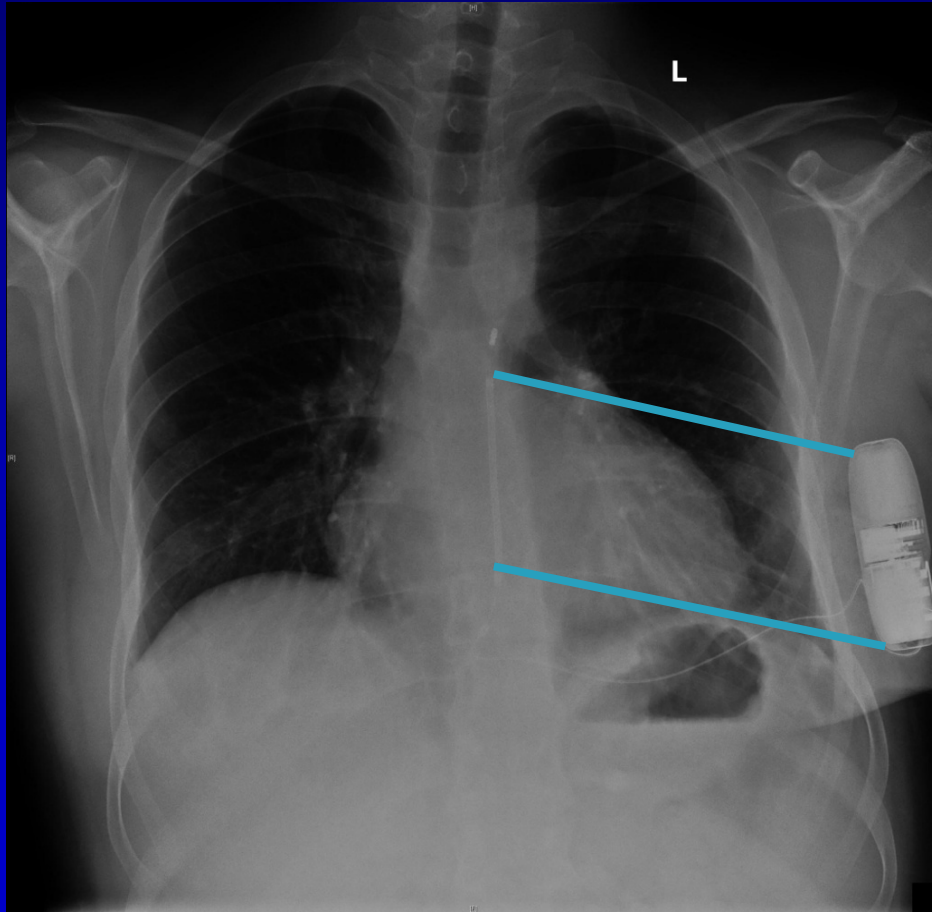
- 80J max output
- Biphasic waveform, polarity adaptive shock
- No ATP
- No anti-brady pacing
- Post shock pacing on demand, max 30s, 50 bpm

*No catheter within or on the heart → venous system preserved*

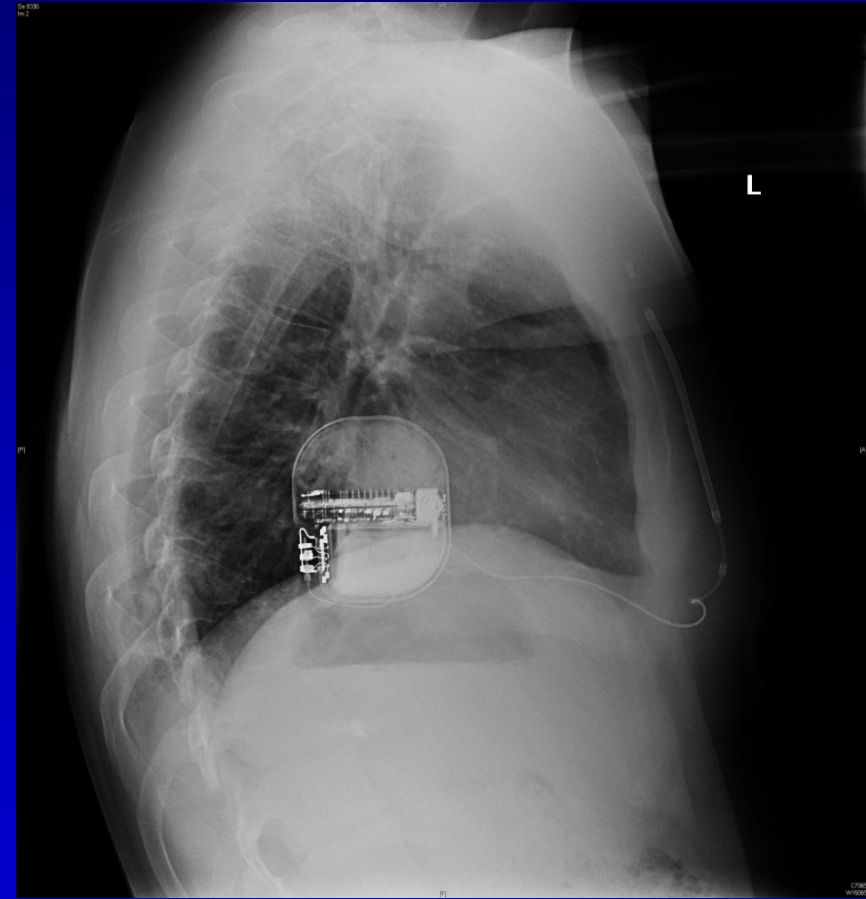


# *S-ICD System: X-RAY*

AP\*

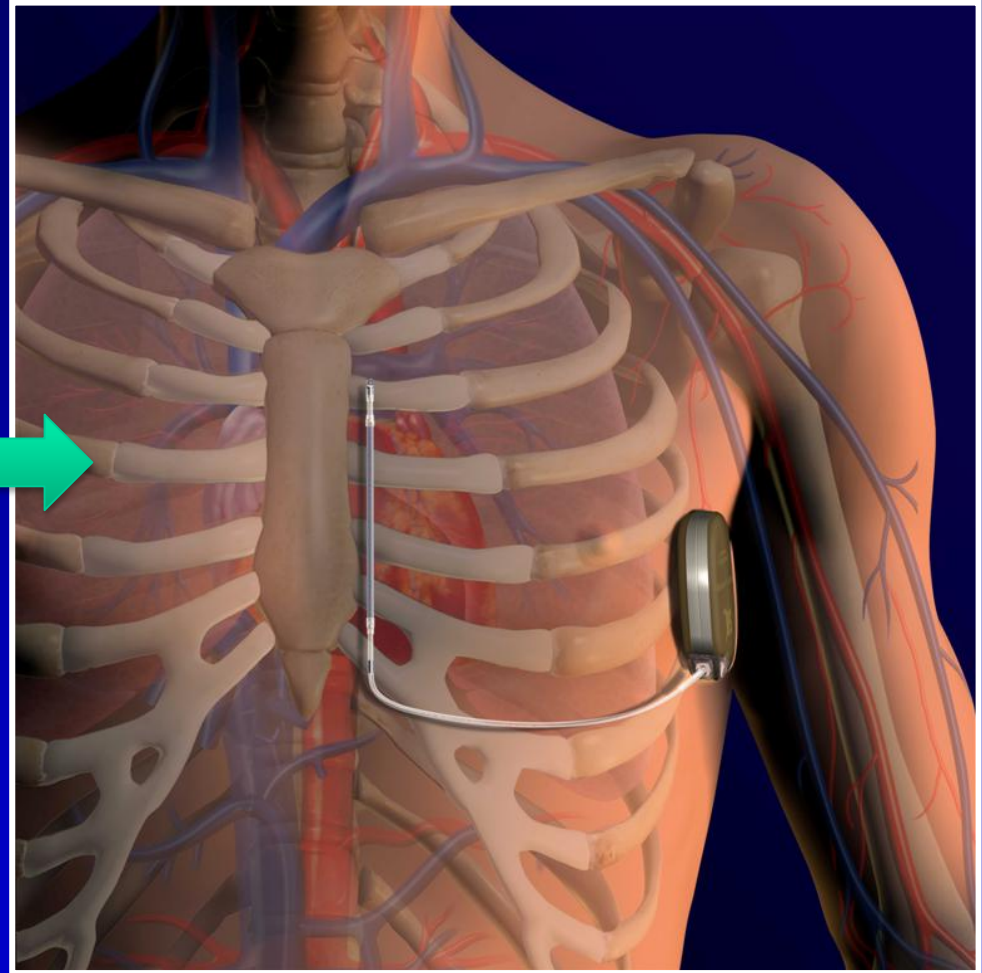
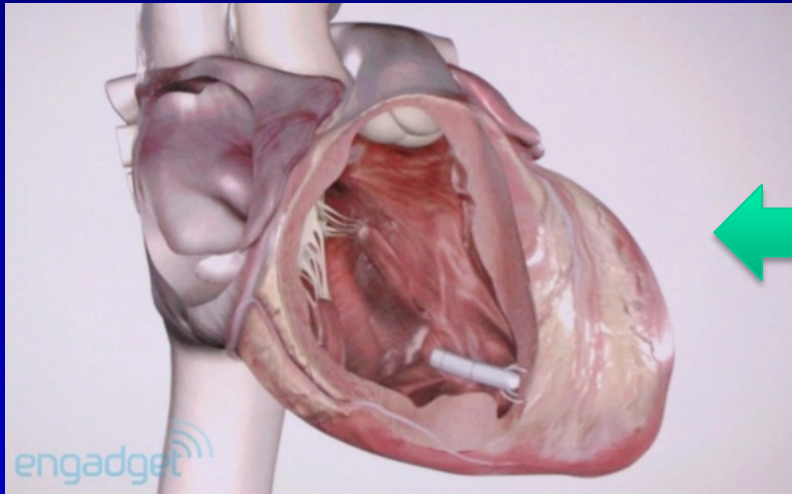


LL\*



\*Courtesy MHH Hannover Medical School

# The future : S-ICD gen 2-3



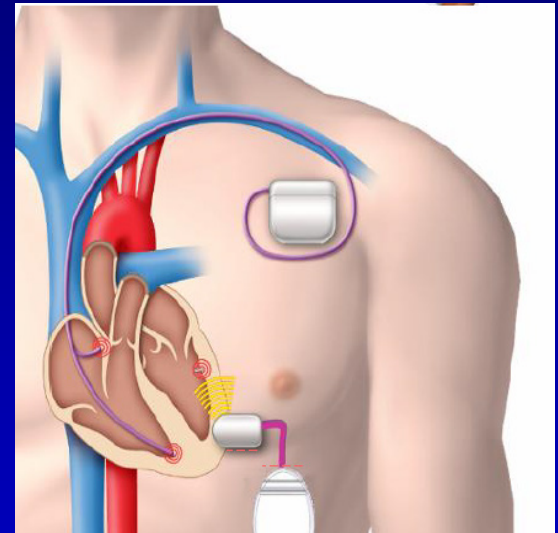
Interaction and communication between S-Icd and leadless device

# Future perspectives

## Dual chamber and Biventricular pacing:

### Challenges:

- Atrial device position and fixation
- LV device position and fixation
- Device shape
- Wireless communication (beat to beat)
  - Energy consumption for communication
  - Avoid external interference on communication



# Conclusions

*Subclavian vein obstruction is a frequent event, often asymptomatic, noticed during device upgrading.*

*Many different approaches are available, with different goals, and they have to be chosen according to the patient characteristics.*

*The new technology should aid to preserve the venous system*



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