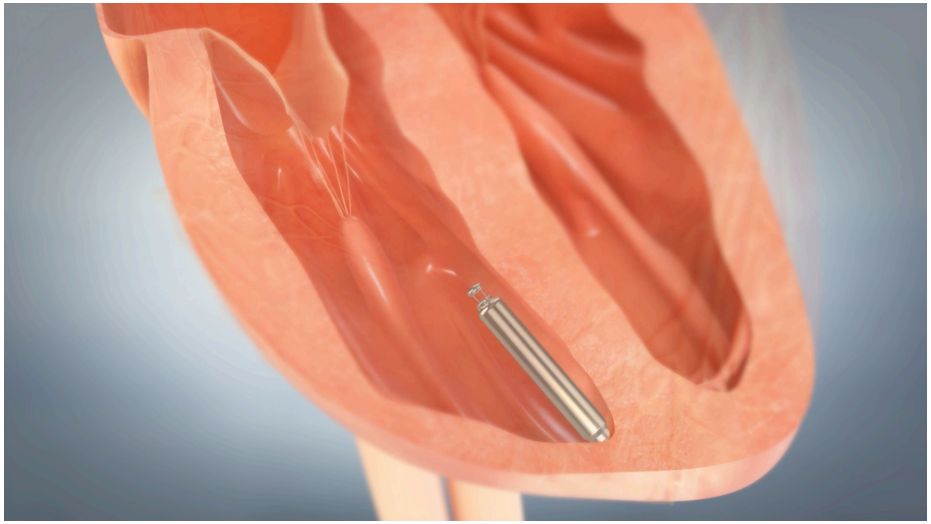
Therapeutiques du futur : Stimulation Cardiaque sans sonde



APPAC/Biarritz
4/6/2014

Pascal Defaye, CHU Grenoble

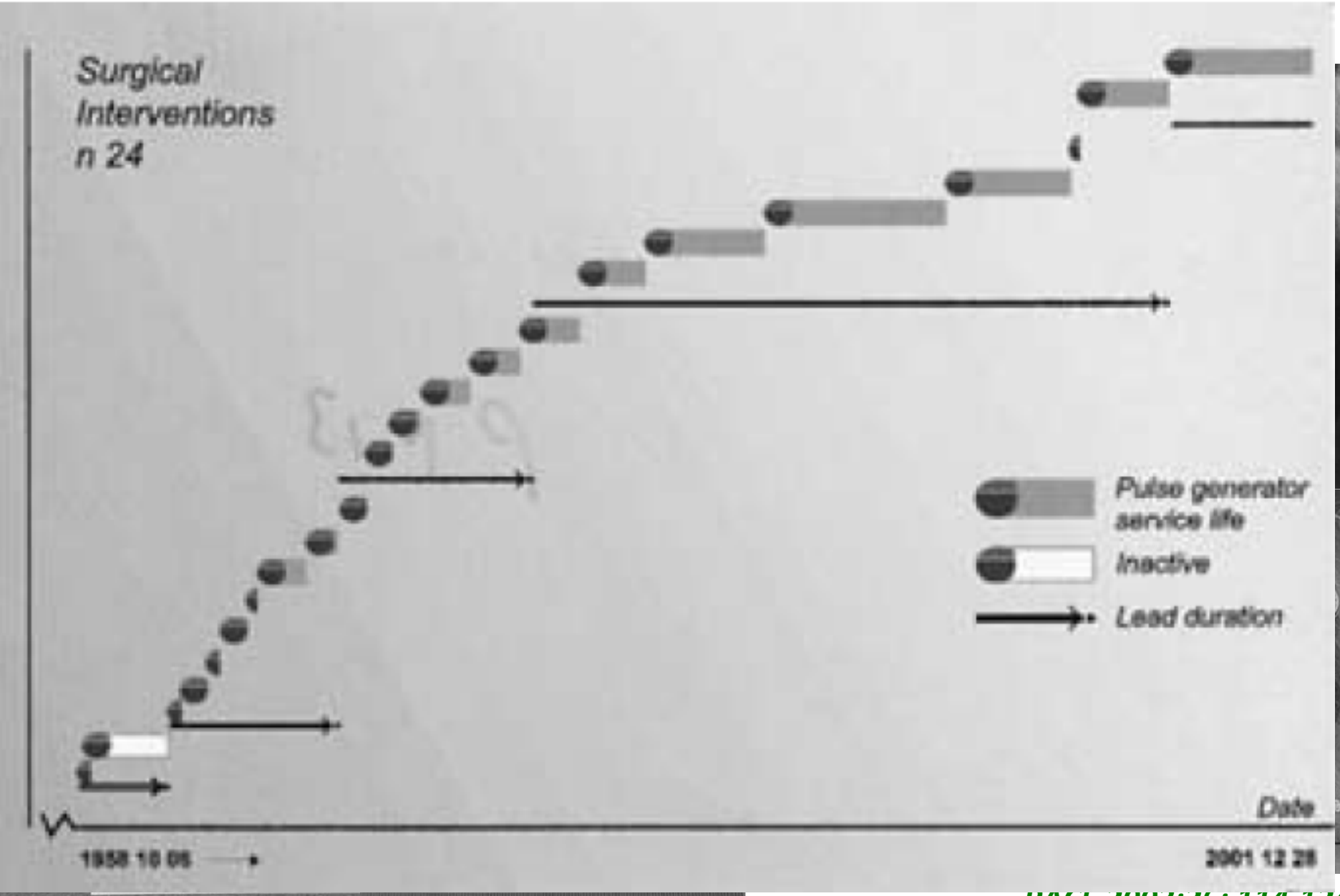
Liens d’intérêts :

Subventions de recherche/honoraires

Boston Scientific/Medtronic/ St Jude Medical/ Sorin

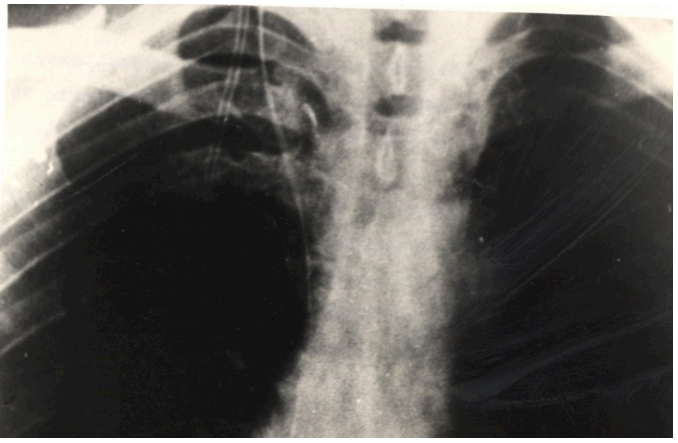
Bayer/ Böhringer Ingelheim

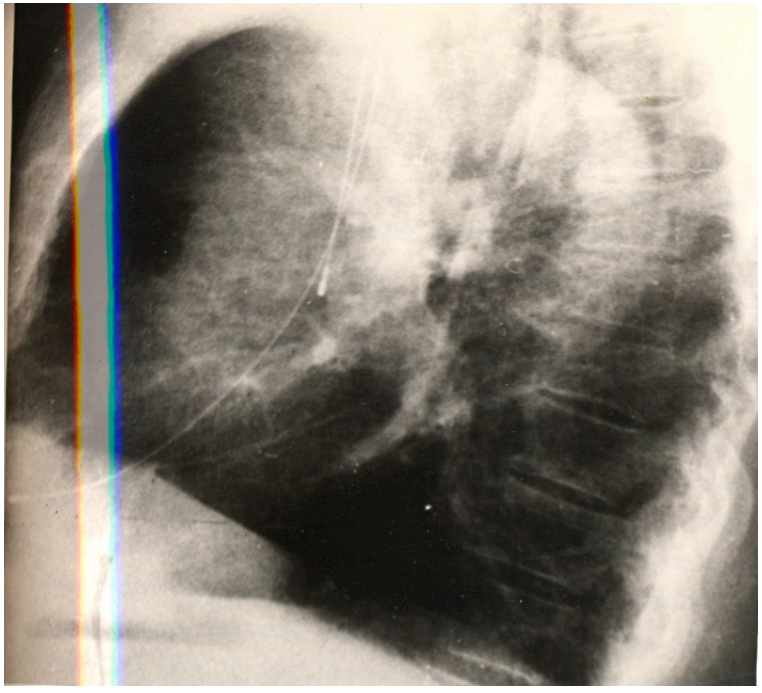
October 8, 1958, PM first implantation
Karolinska Hospital Stockholm



PACE 2003;26: 114-124

Lead through external jugular vein (1965)





endocavitary « synchronous » pacing

Non programmable PM : V pacing after A sensing

Courtesy, Dr B. Dodinot

J. ELECTROCARDIOLOGY, 3 (3-4) 325-331, 1970

Special Article

Totally Self-Contained Intracardiac Pacemaker*

J. WILLIAM SPICKLER, PH.D., NED S. RASOR, PH.D.†, PAUL KEZDI, M.D.
S. N. MISRA, M.D., K. E. ROBINS, P.E., AND CHARLES LeBOEUF, P.E.

SUMMARY

Recent developments in miniature long-life power sources and electronics, such as nuclear batteries and integrated circuits make feasible a new generation of pacemakers, the intracardiac pacemaker (IC), i.e., a completely self-contained pacemaker implanted inside the right ventricle by transvenous insertion. Since the IC pacemaker eliminates all leads, problems associated with the leads such

circuits have been improved substantia
addition, the development of the endo
catheter electrode has broadened the
of operative procedures to include a
portion of the patient population. Two
problems that still exist with conver
pacemakers are perforation or dislocat
the transvenous electrode and the short
the batteries that are presently used. Ir
tion, there is a certain physical and p
logical discomfort involved wit

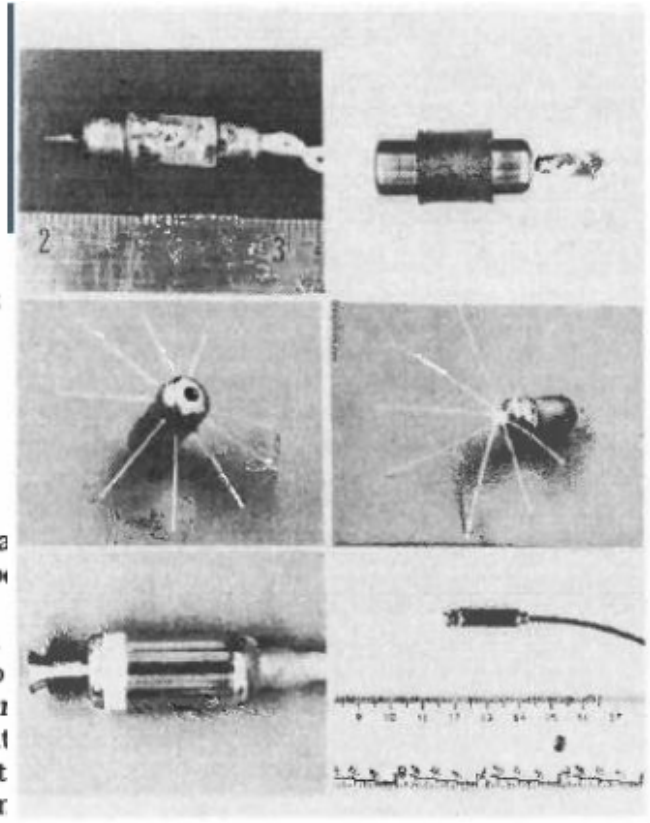


Fig. 2. Some early unsatisfactory dummy capsules

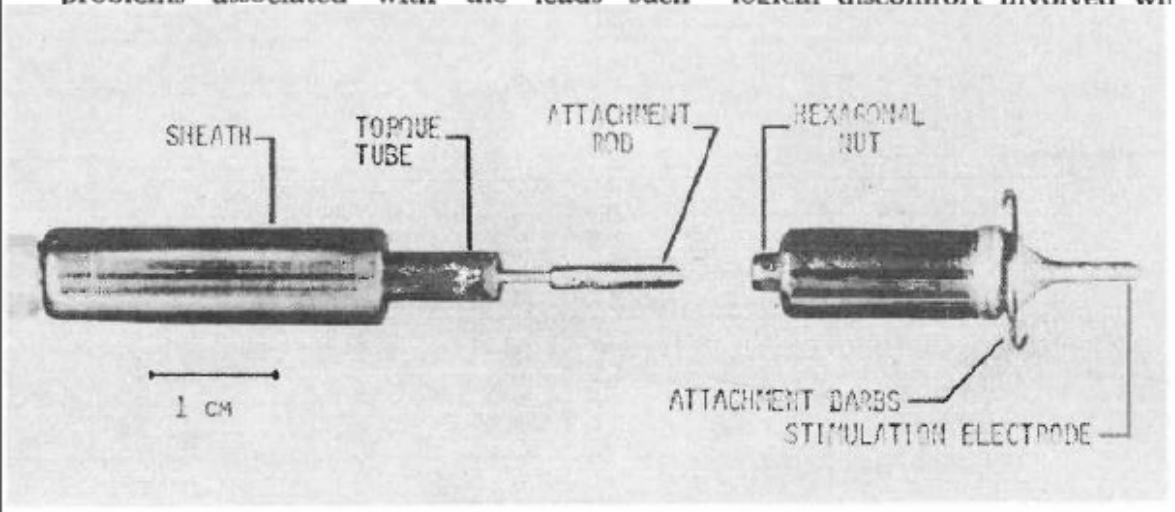


Fig. 4. Intracardiac pacemaker with catheter for transvenous insertion.

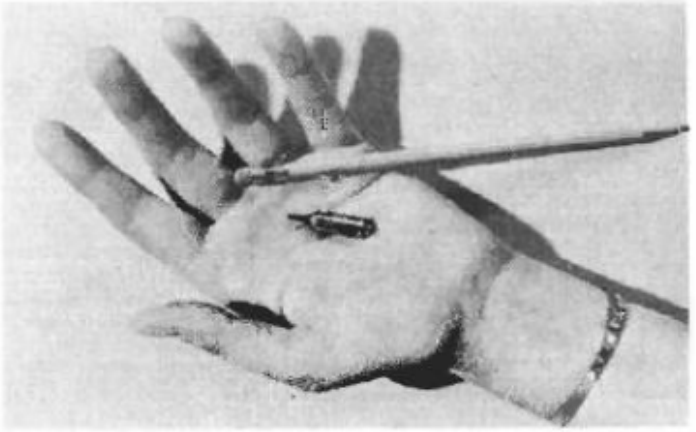
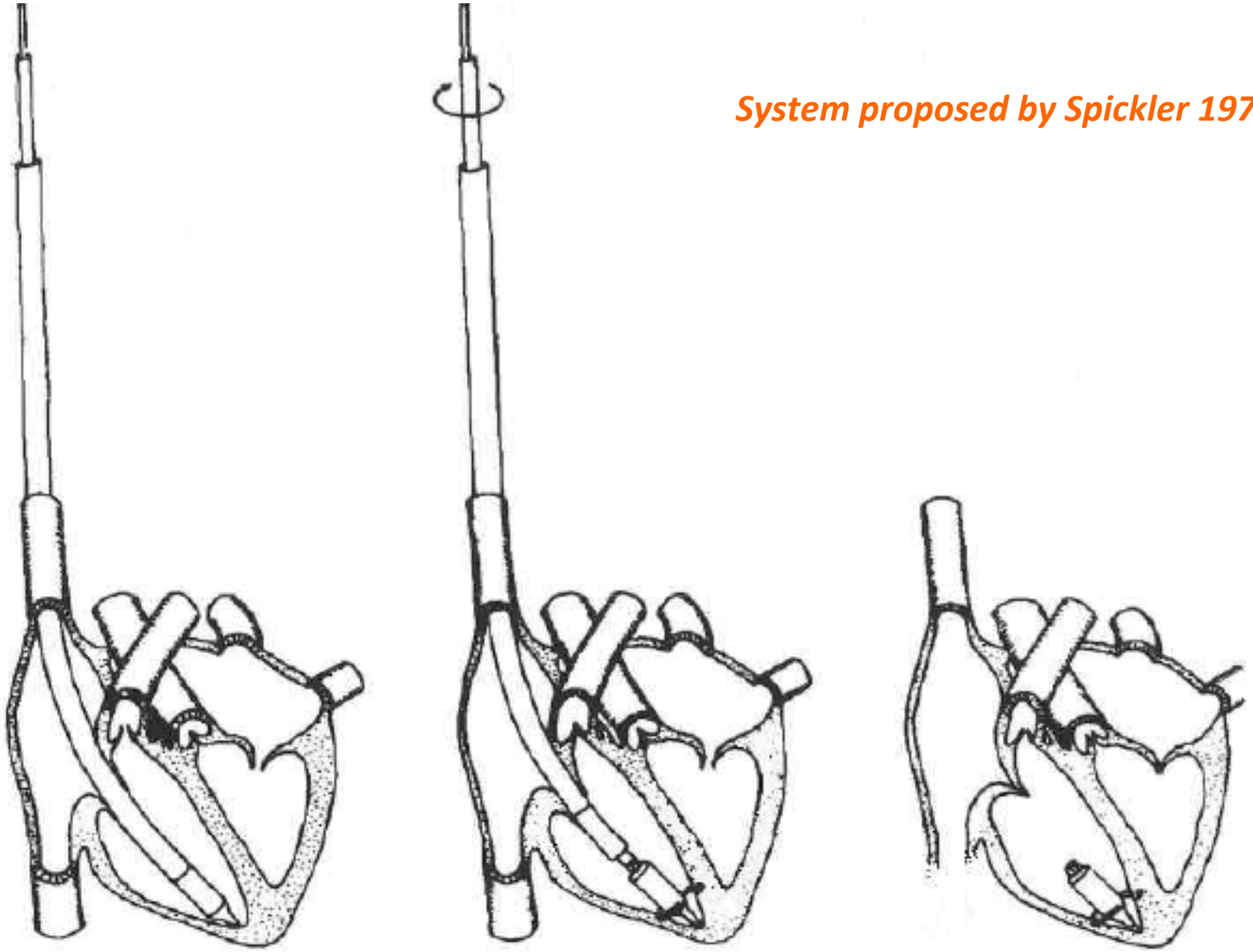


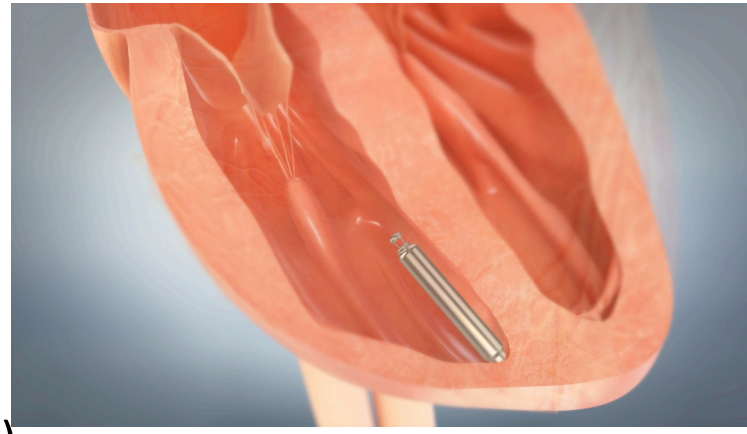
Fig. 8. Nuclear-powered intracardiac pacemaker.

System proposed by Spickler 1970



Leadless pacemaker : Potential advantages

- ***Less Invasive***
  - No surgery
  - Fewer complications (no lead)
  - Less radiation exposure for implanter
  - More cosmetic for patient (« invisible »)



- ***Improved Efficiency :***
  - No surgery; less infection risk
  - **NO LEAD +++++**
  - Femoral venous access
  - No system connections
  - More readily MRI compatible (no antenna)

- ***More Cost-Effective :***
  - Reduced length of hospital stay (1 day)
  - Fewer acute and chronic complications (infection, erosion)

Leadless pacemakers

LCP™ Nanostim/SJM

December 2012

Micra™ Medtronic

December 2013

WICS™ EBR

May 2011

Complications Associated with Pacemakers

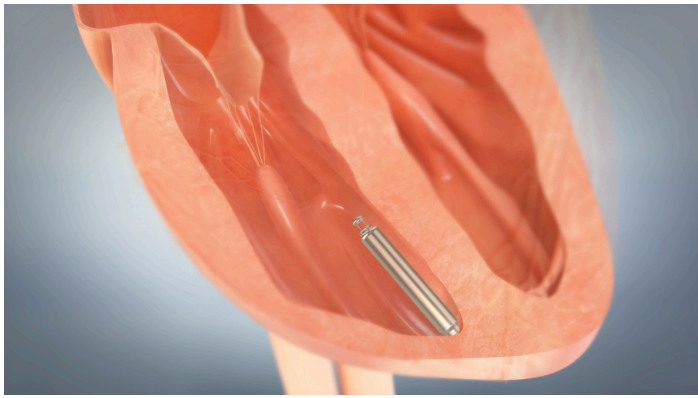
Complication	Occurrence	Implications
Lead dislodgement	2.2% to 3.7%	Increase pacing threshold, failure to capture or sense
Pneumothorax	1.6% to 2.6%	Respiratory distress and prolonged hospitalization (80% require chest tube)
Lead perforation	Less than 1%	Cardiac tamponade, death
Venous thrombosis	1%-3%	Mostly asymptomatic
Chronic Lead failure	2%-4% at 5 years	Failure to pace or sense Need intervention
Hematoma requiring surgical evacuation	<0.5%	Prolonged hospitalization/reoperation Increased rate of infection
Skin erosion (generator change)	0.8-0.9%	Entire system (device and leads) needs to be removed
Infection	1% - 2%	Removal of the complete system to treat effectively

Leadless Pacemaker : Potential Limits??

- **Only VVIR** available for the moment

- Multiple chamber pacing more complex and under development :
  - Wireless communication between leadless PMs
  - Shape of the leadless in the RA?
  - Possibility in the LV?

- **Implantation risks?**
  - Large diameter sheaths : 18 F
  - Embolization/ retrieval
  - Repositionning, extraction
- **Removal/replacement**
  - Longevity?
  - Abandon vs explant



Design for repositionning and removal

Comparison with Conventional Lead-Based System

	Lead-based Pacemaker	Leadless Pacemaker
Implant procedure	Surgical pocket + lead (7Fr)	Percutaneous femoral based delivery (18Fr)
Implant time	30 – 40 minutes	Average 28 mn
X-ray exposure	**For implanter: Next to the X-ray tube**	**For implanter: Further away from the source**
Connections	Lead-can connectors	None
lead in vascular system (chronic)	Yes (lead)	No (leadless)
Lead through tricuspid valve (chronic)	Yes (lead)	No (leadless)
System removal	Risky and difficult removal process for patient and physician	Tools available and have been used acutely
Longevity (2.5V, 500 Ω, 60 bpm)	10-12 years	100% pacing – 9.3 years 75% pacing – 11.0 years 50% pacing – 13.4 years
Battery Replacement	Pocket access	Femoral access: removal+ new implant Option for another adjacent implant
MRI compatibility	±	MRI conditionnal

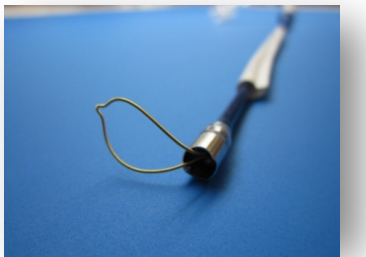
Nanostim™ Leadless Pacemaker

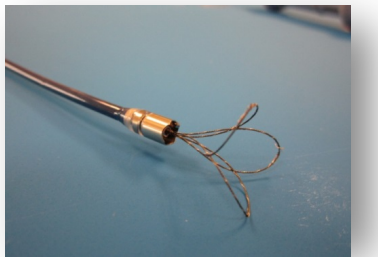
- Introduction through the femoral vein into the right ventricle.

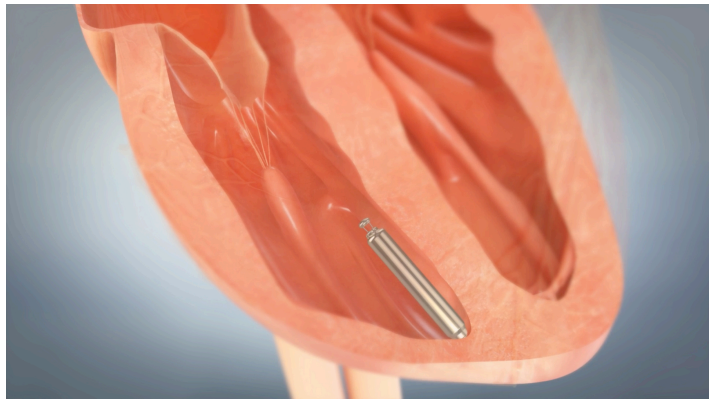
- Energy efficient
  - High-capacity CFx battery
  - Lower resistance due to lack of lead
  - Low-power conductive communication

- Fixation
  - Helix
  - Radiographic indicator to ensure proper number of turns

- Designed for retrievability
  - Catheter-based retrieval system







Permanent Leadless Cardiac Pacing
Results of the LEADLESS Trial

Vivek Y. Reddy, MD; Reinoud E. Knops, MD; Johannes Sperzel, MD; Marc A. Miller, MD; Jan Petru, MD; Jaroslav Simon, MD; Lucie Sediva, MD; Joris R. de Groot, MD, PhD; Fleur V.Y. Tjong, MD; Peter Jacobson, BS; Alan Ostrosff, MS; Srinivas R. Dukkipati, MD; Jacob S. Koruth, MD; Arthur A.M. Wilde, MD, PhD; Josef Kautzner, MD, PhD; Petr Neuzil, MD, PhD

First-in-man LEADLESS study

- Objective: Evaluate the safety and performance

- 33 patients enrolled
  - Mean age : 75 years (53-91 years); 64% male

- Successful delivery in 32/33 patients (97%)
  - 1 groin hematoma : no treatment
  - 1 cardiac perforation and tamponade → required surgical repair,
    D+ 5 patient : large right-sided stroke and later expired

- Procedure Times

  28 mn (range 11 – 74 min)

- Time from procedure to hospital discharge: Mean 1 day (1 – 4)

Circulation. 2014;129:1466-1471

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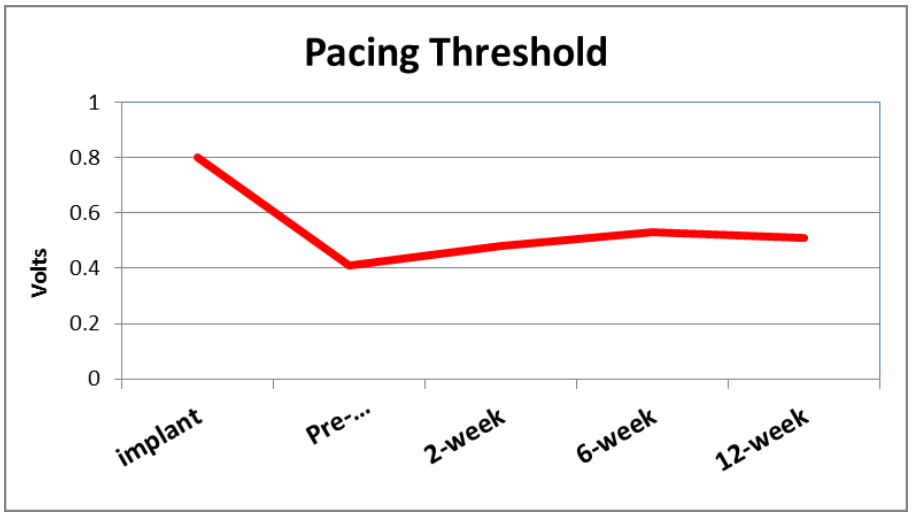
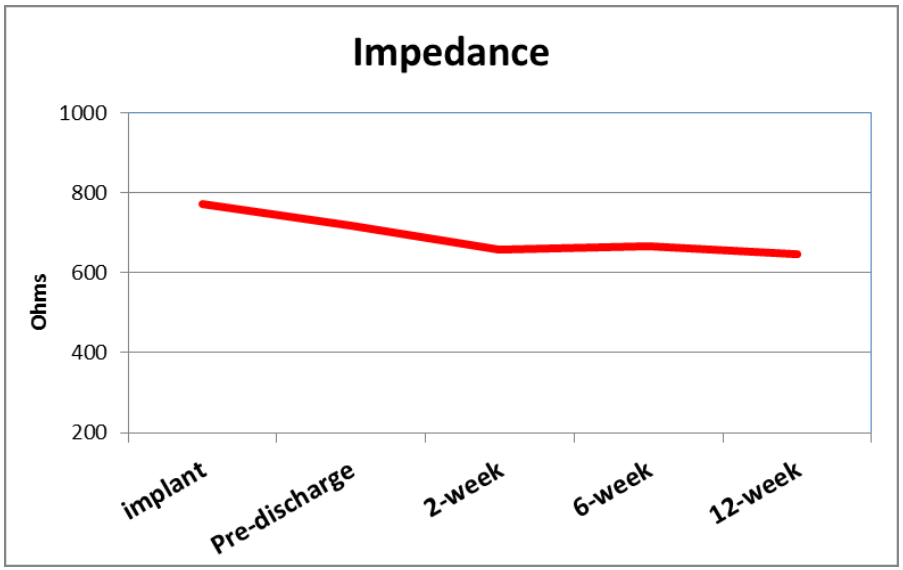
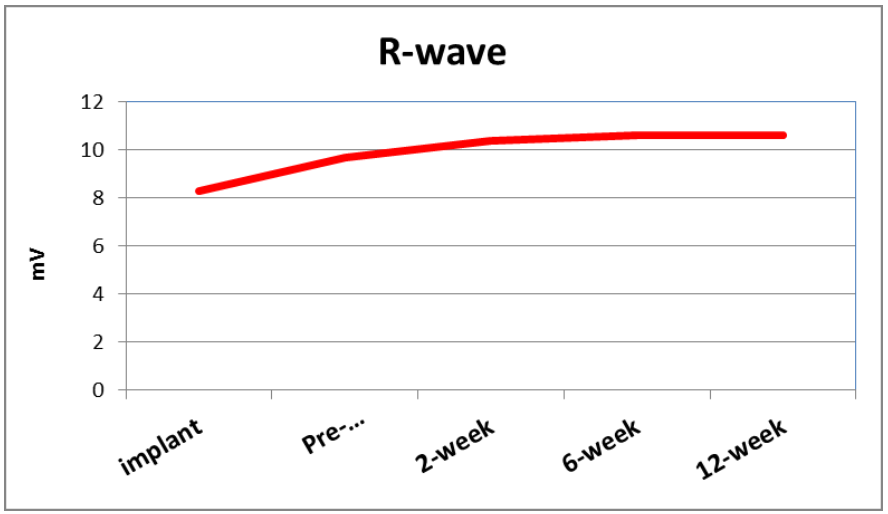
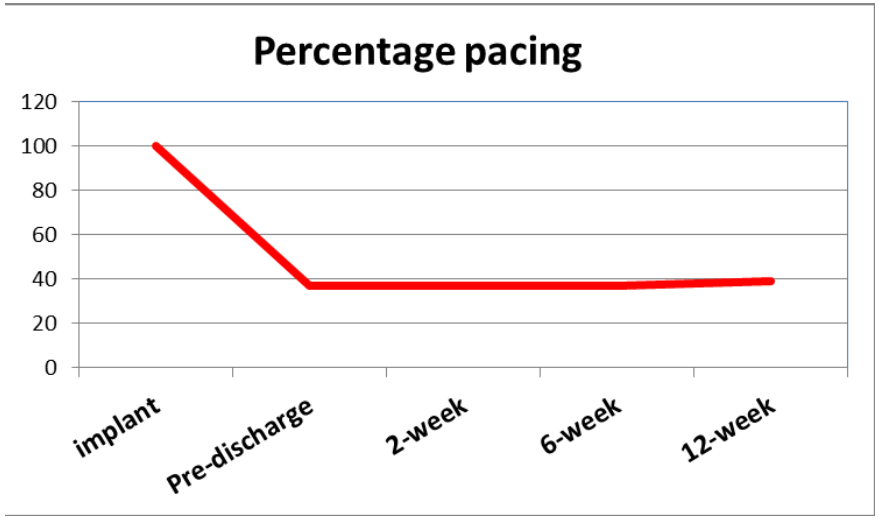
LEADLESS Study:





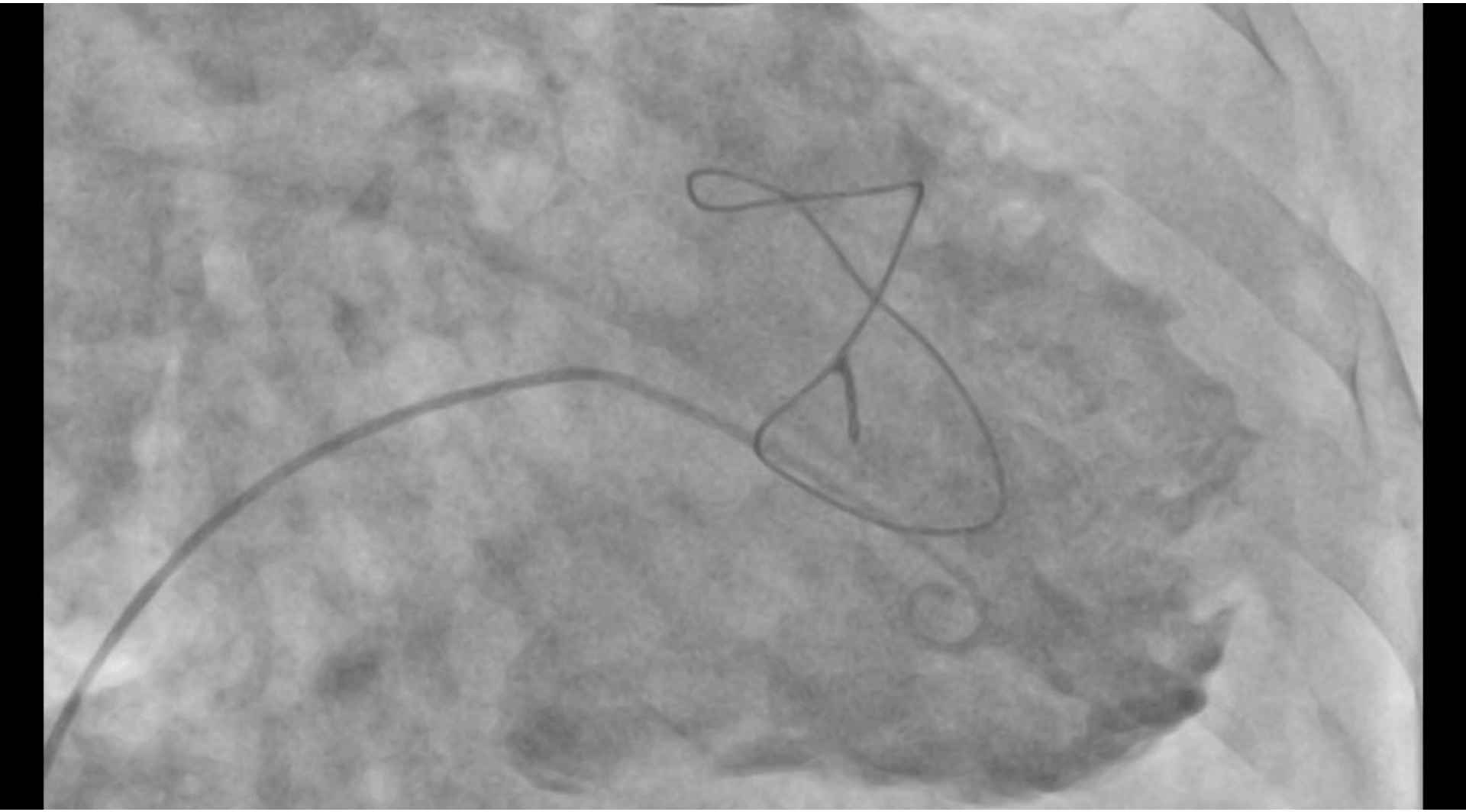


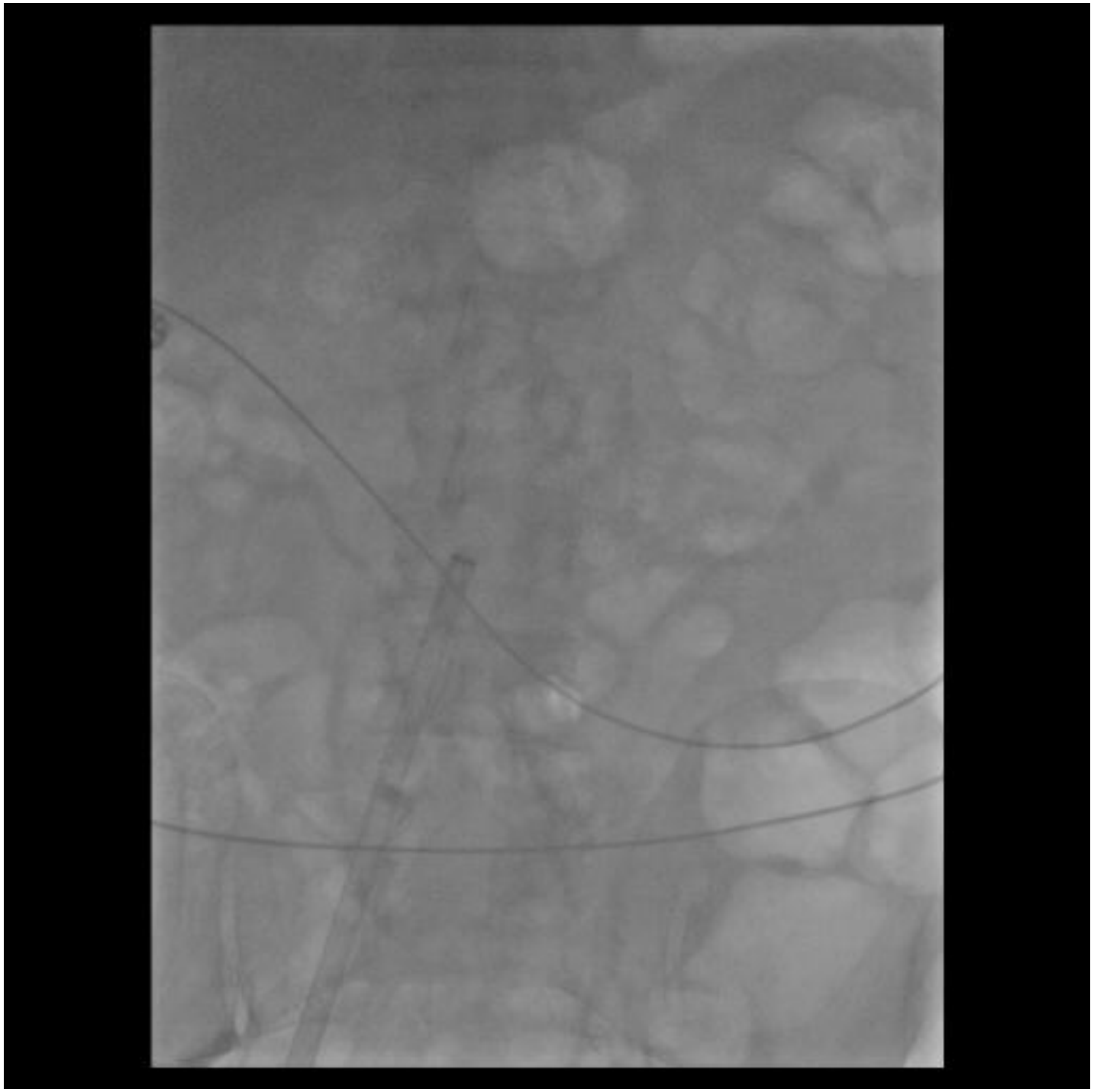


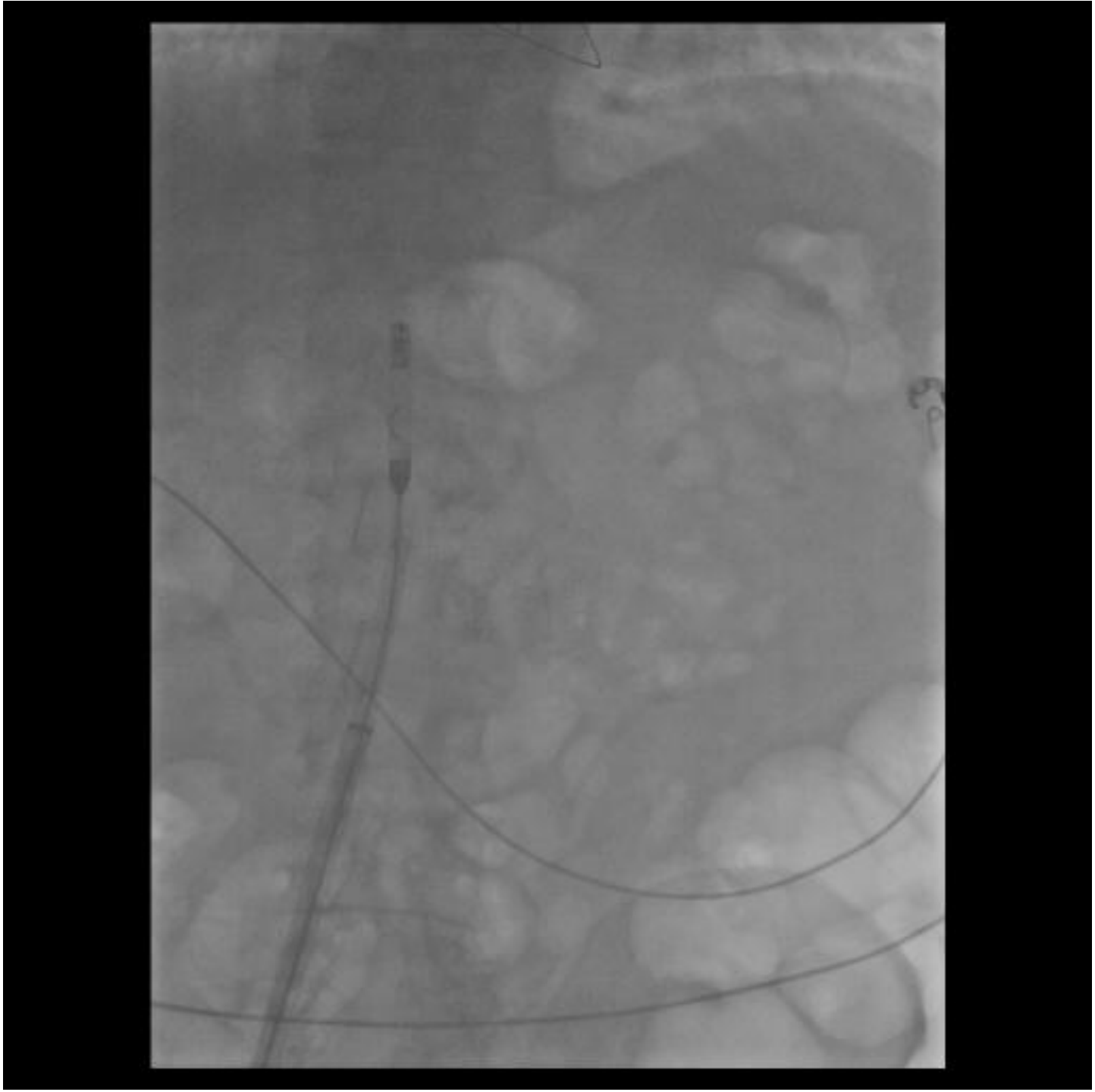
Circulation. 2014;129:1466-1471

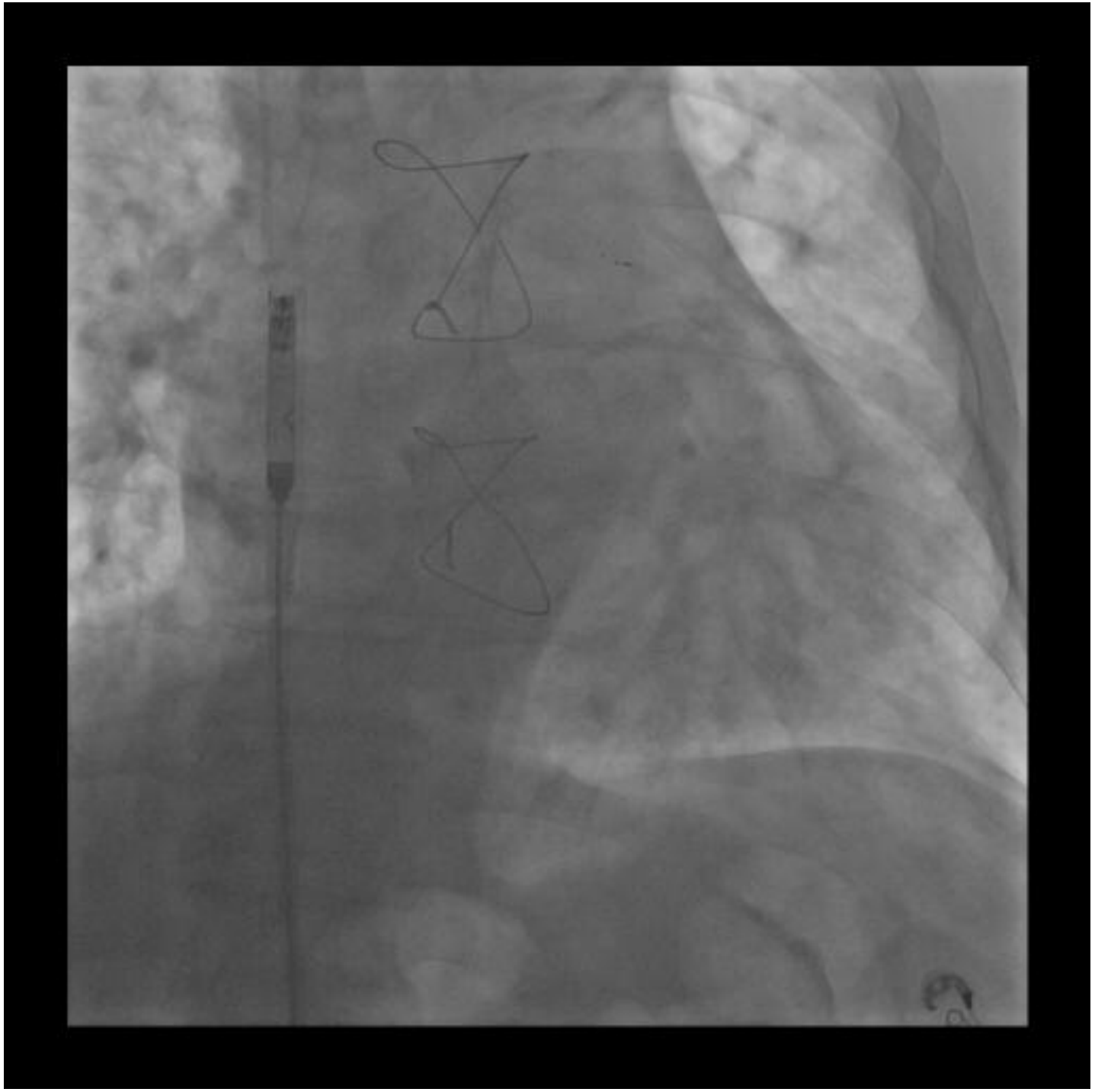
First 2 implantations in Grenoble 19/11/2013/ 15 implantations since November 2013

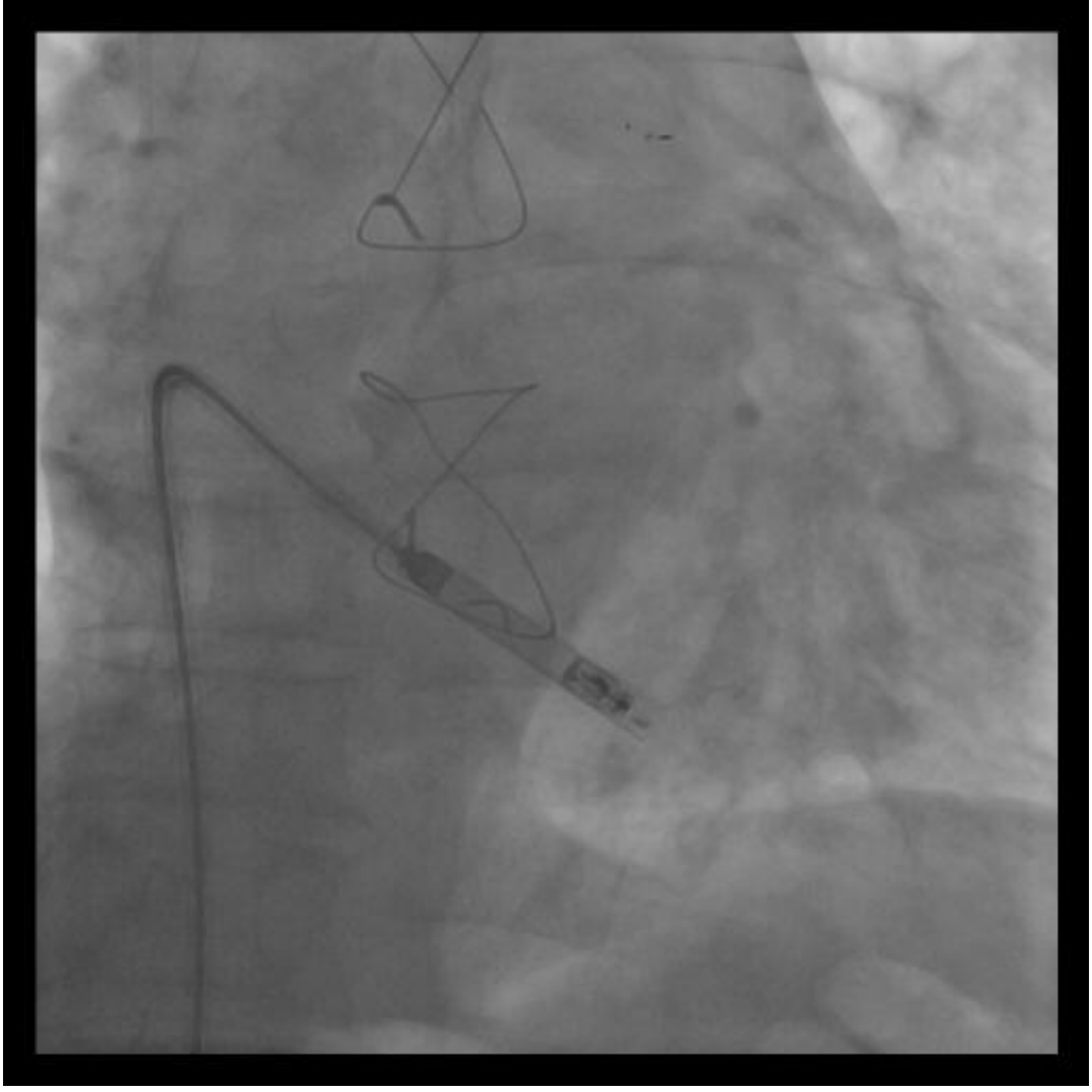
Right ventriculography
RAO

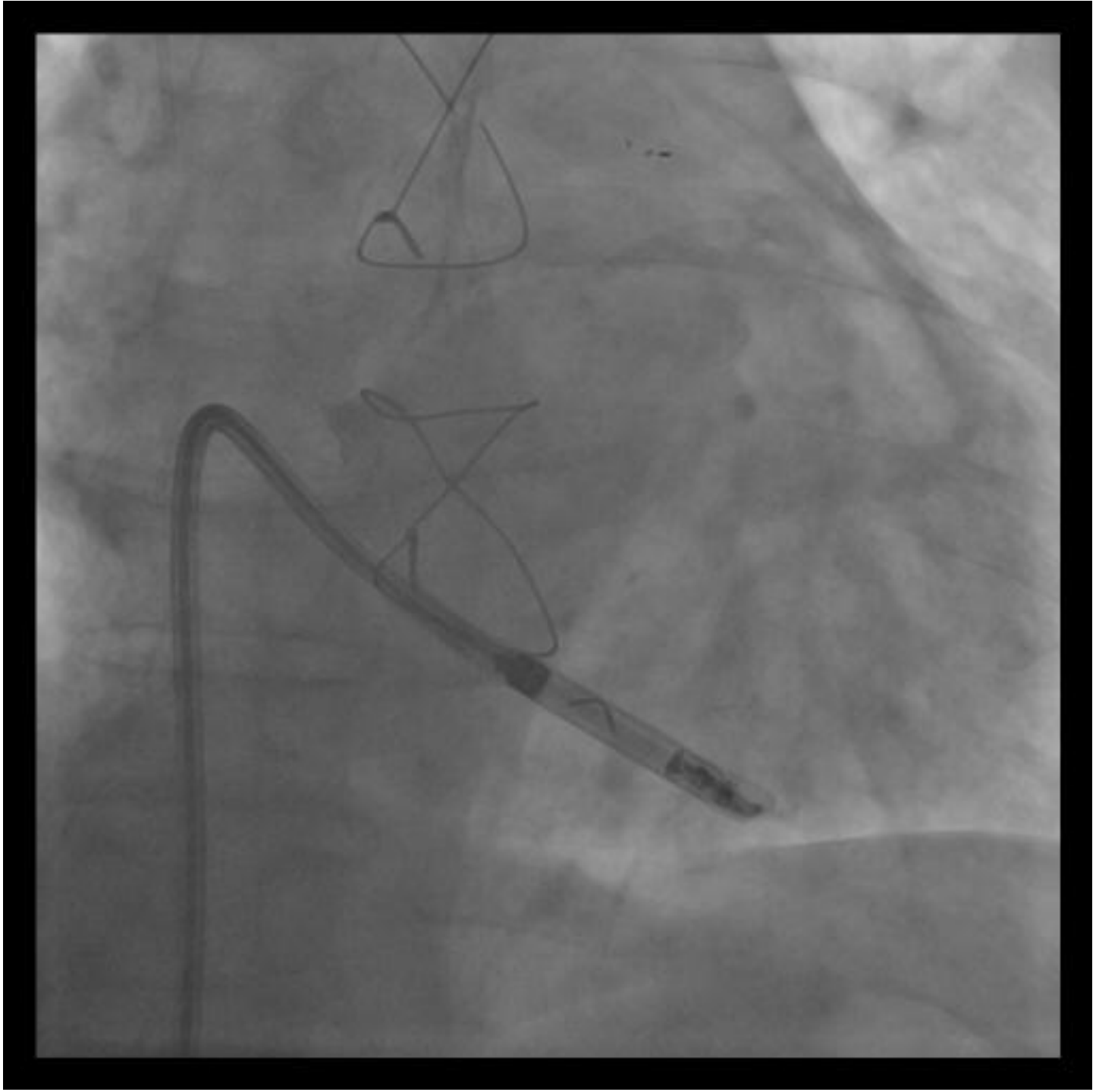


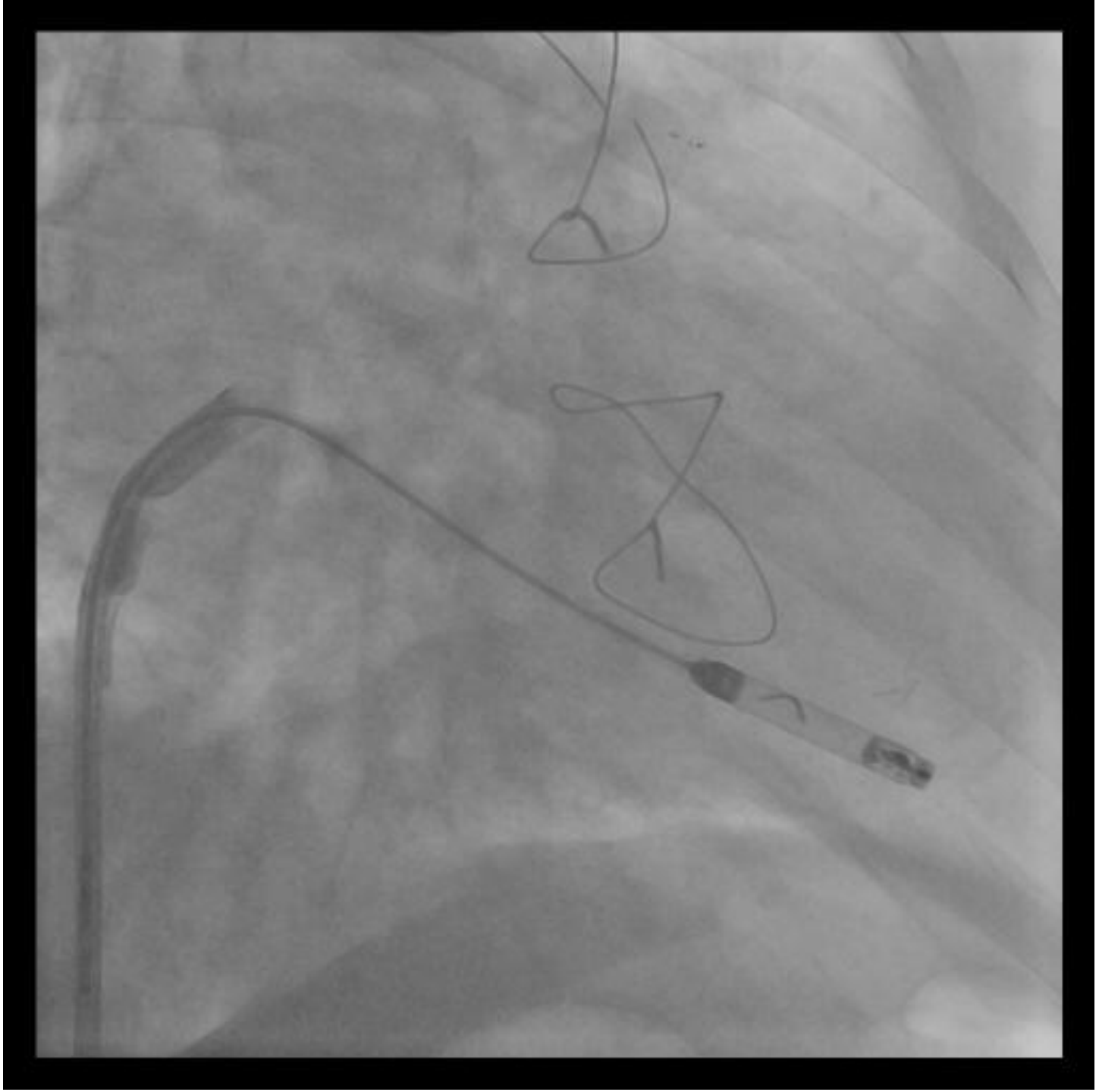


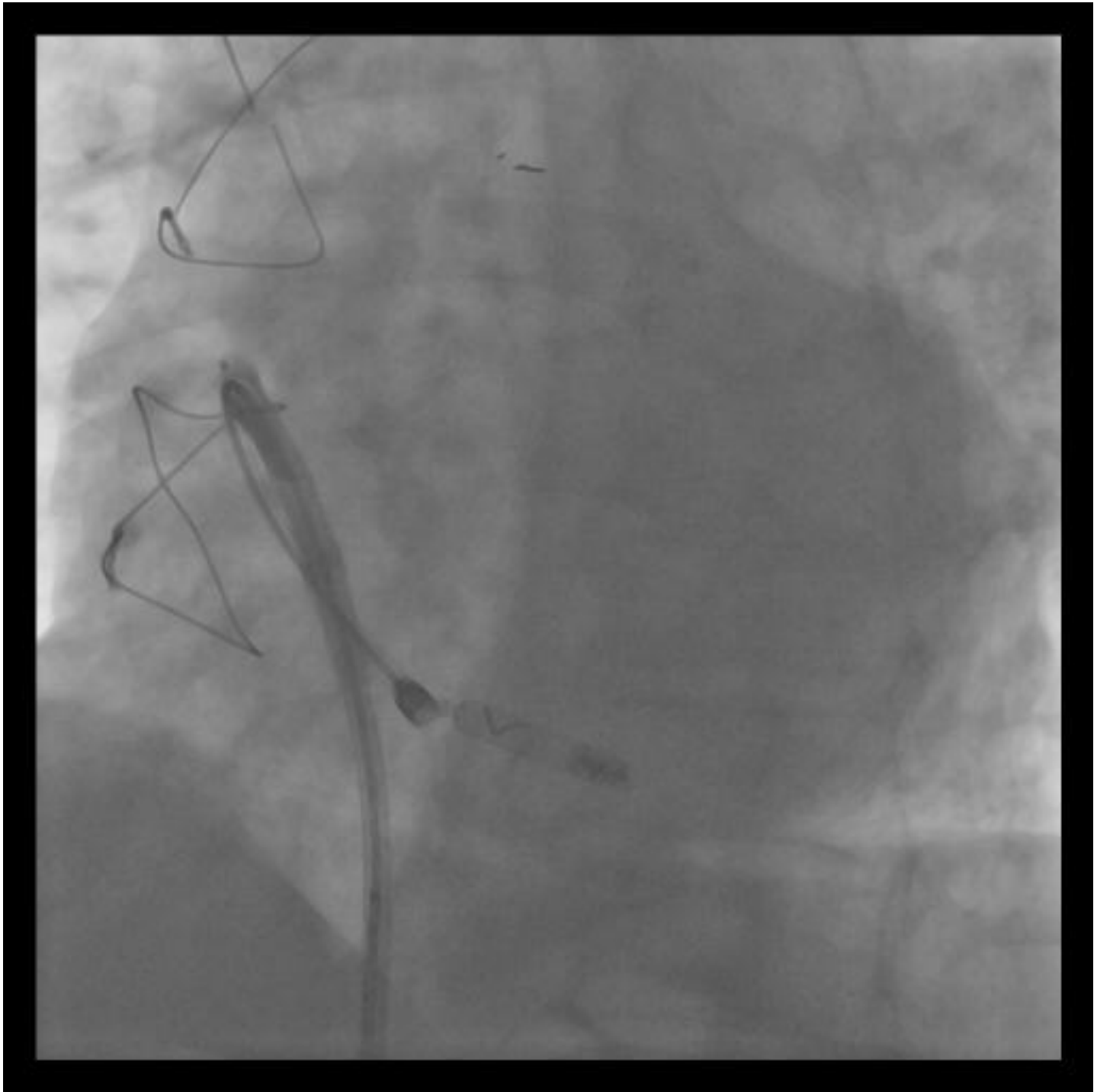


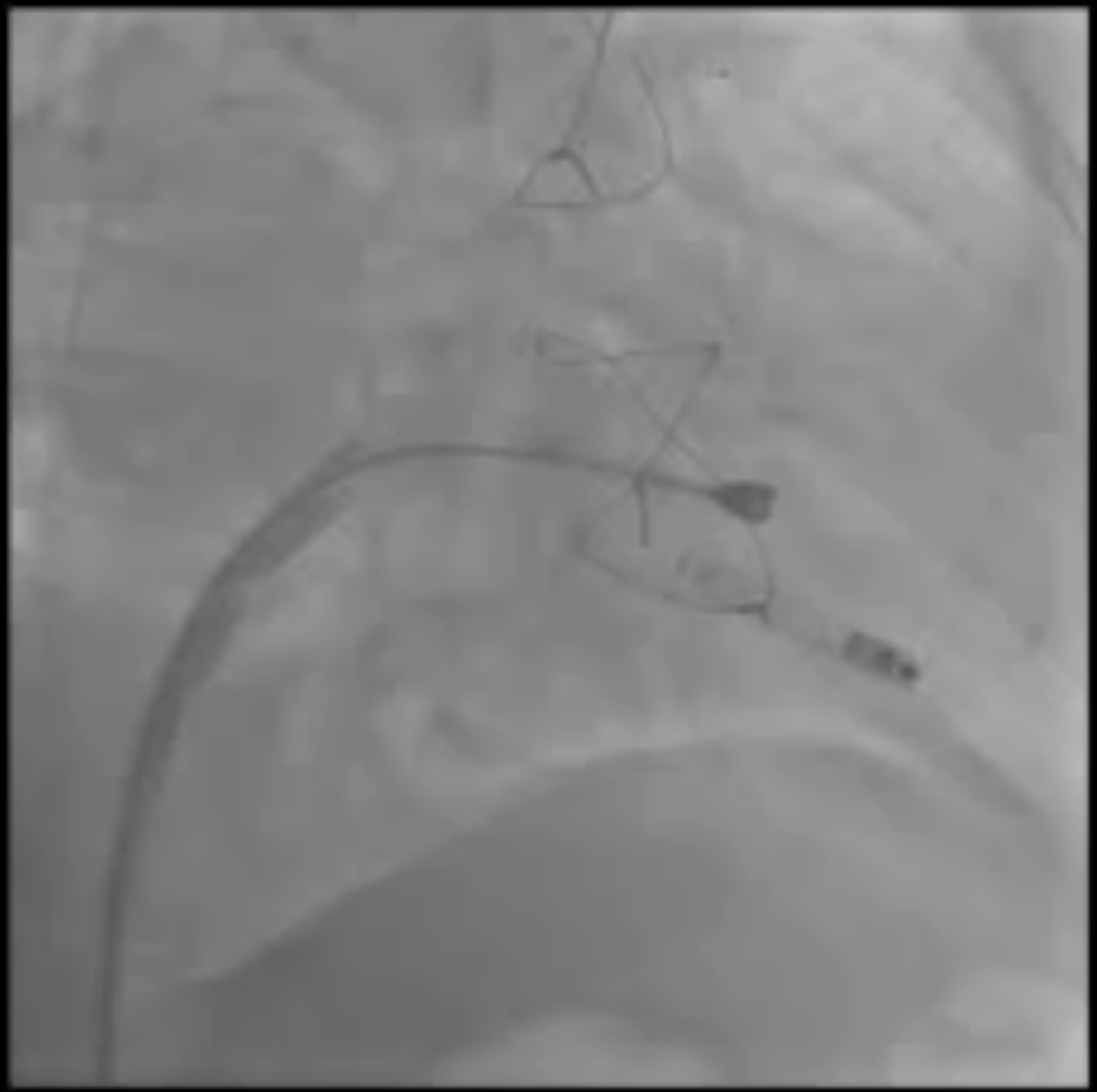


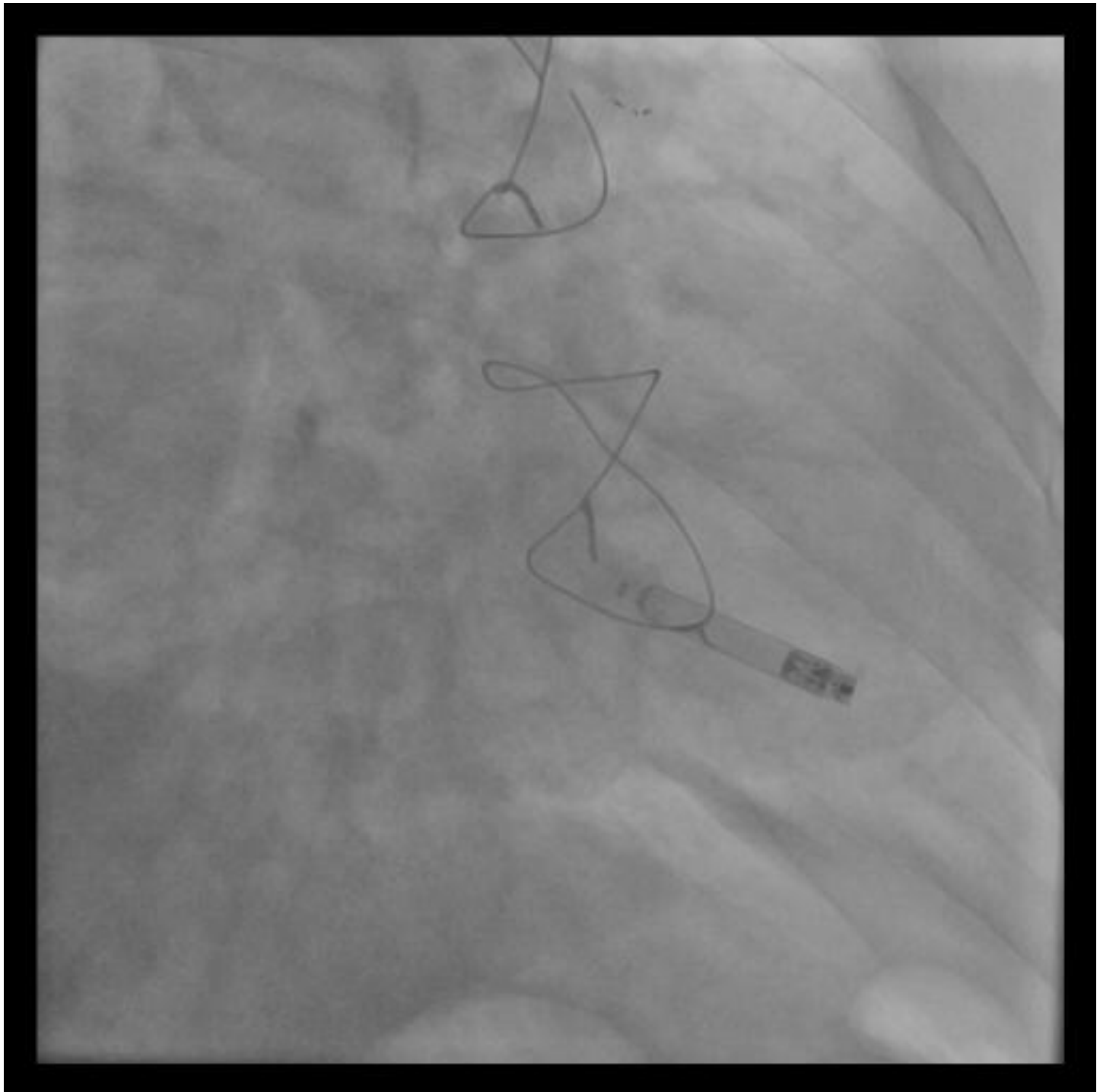


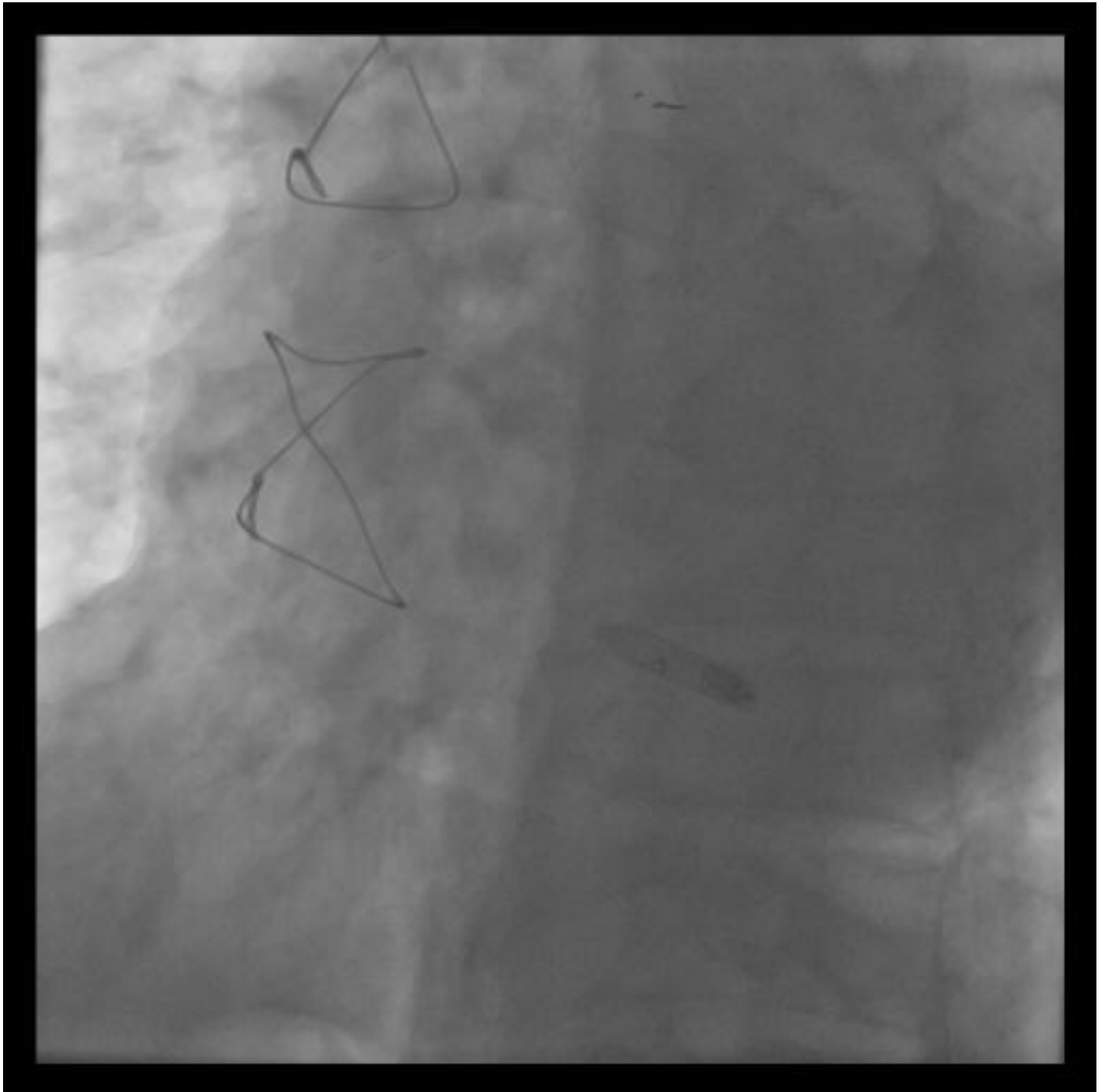




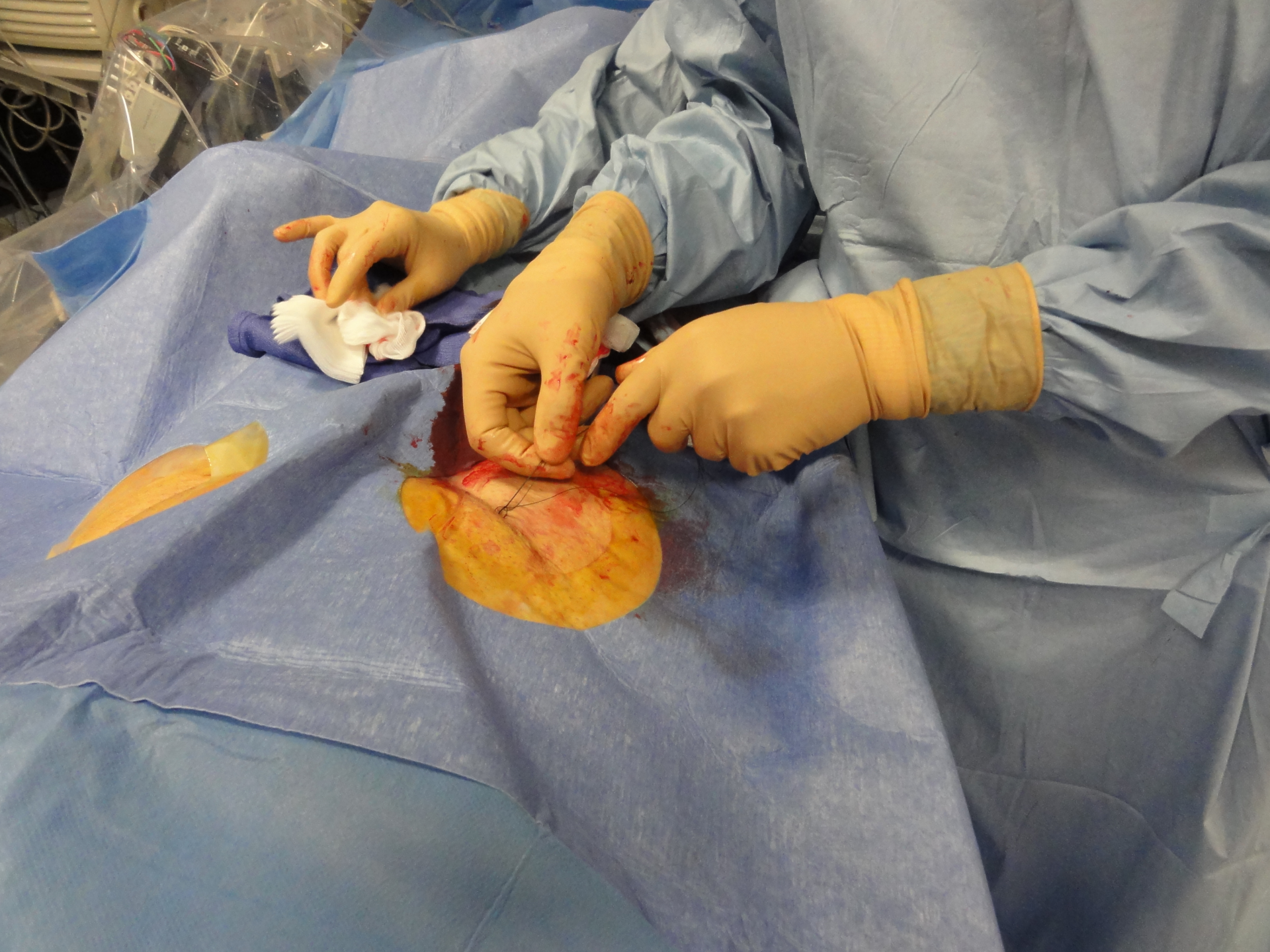








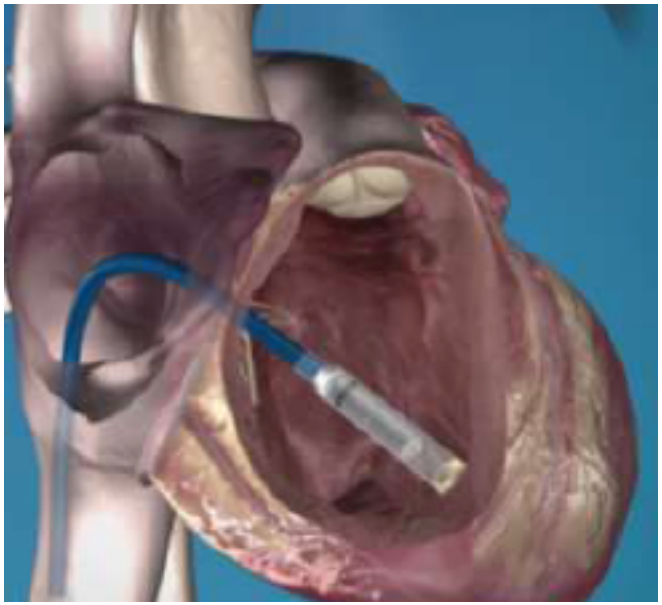
% Pacing	500 Ω Load	600 Ω Load
100%	8.4 yr	9.3 yr
75%	10.0 yr	11.0 yr
50%	12.4 yr	13.5 yr
25%	16.3 yr	17.2 yr



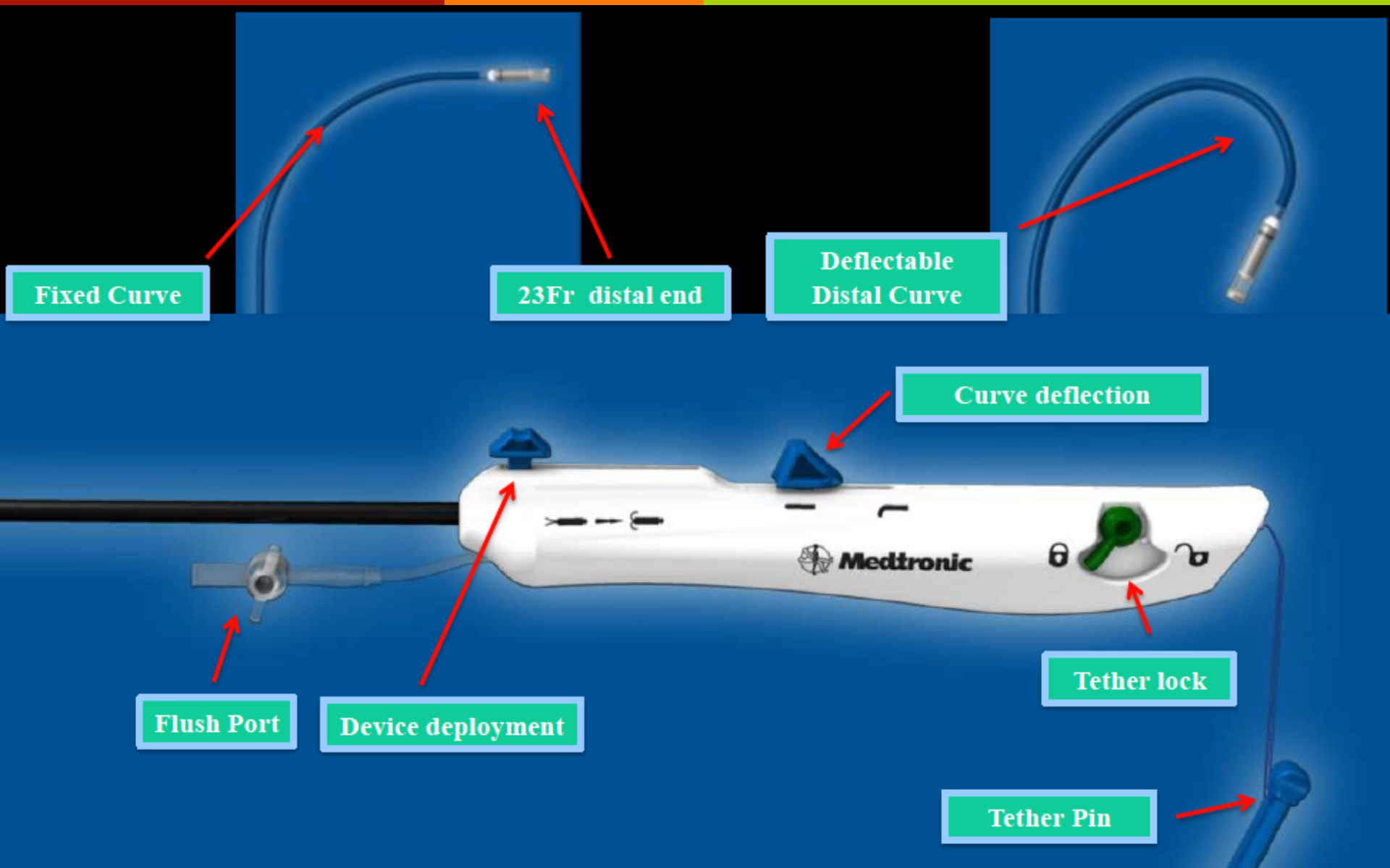

MAVIC
SIEMENS
Dr Martin
JDE ANGIO CURIM

Micra™ Transcatheter Pacing System (TPS)

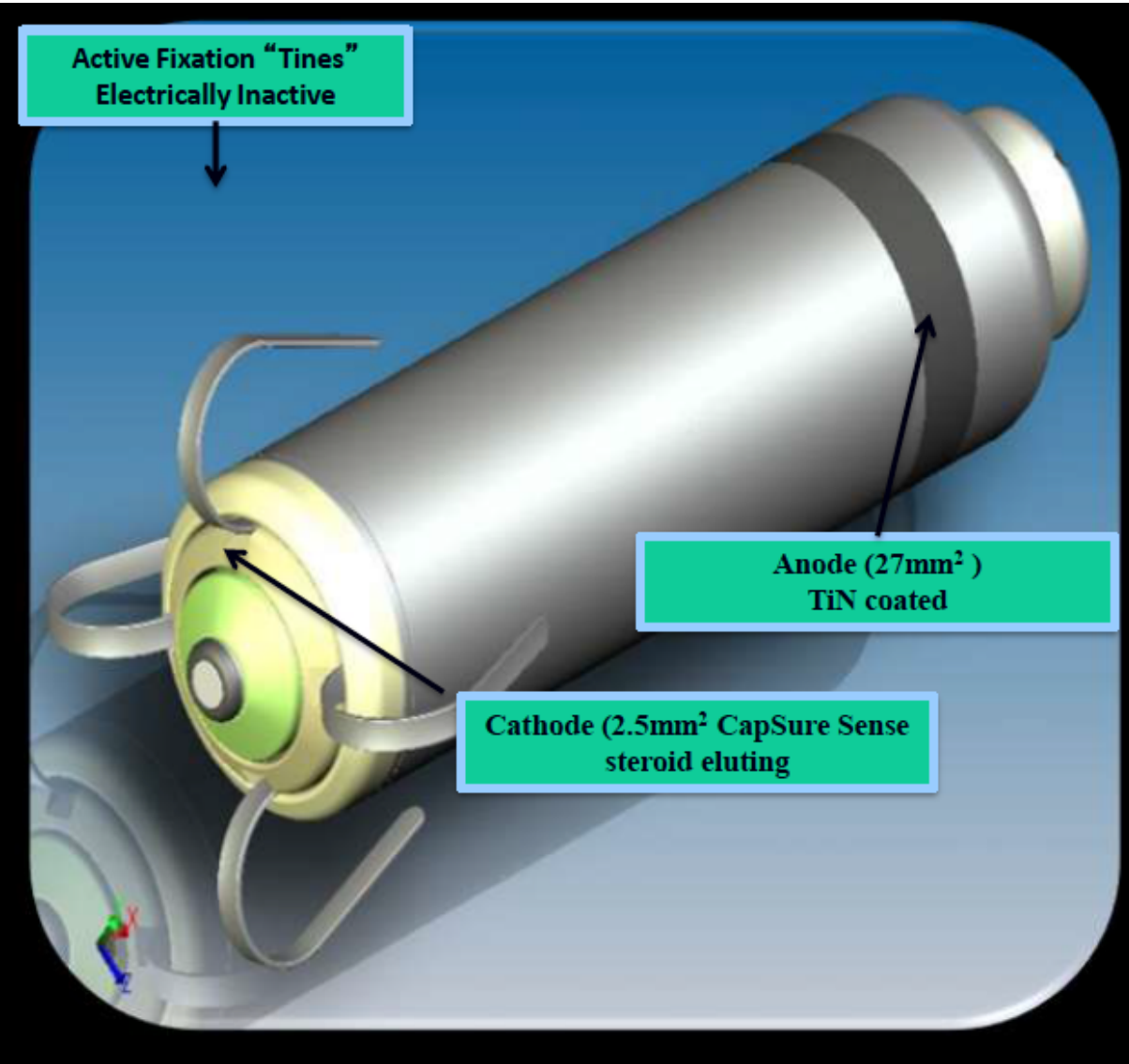
- 25,9 mm, <1cc miniaturized VVIR pacemaker (Adapta pacemaker =10cc
- World's smallest, minimally invasive pacing system
- 10 year longevity
- Percutaneous access to RV apex via femoral vein
- Active fixation via 4 self-expanding « tines »



Micra™ Device



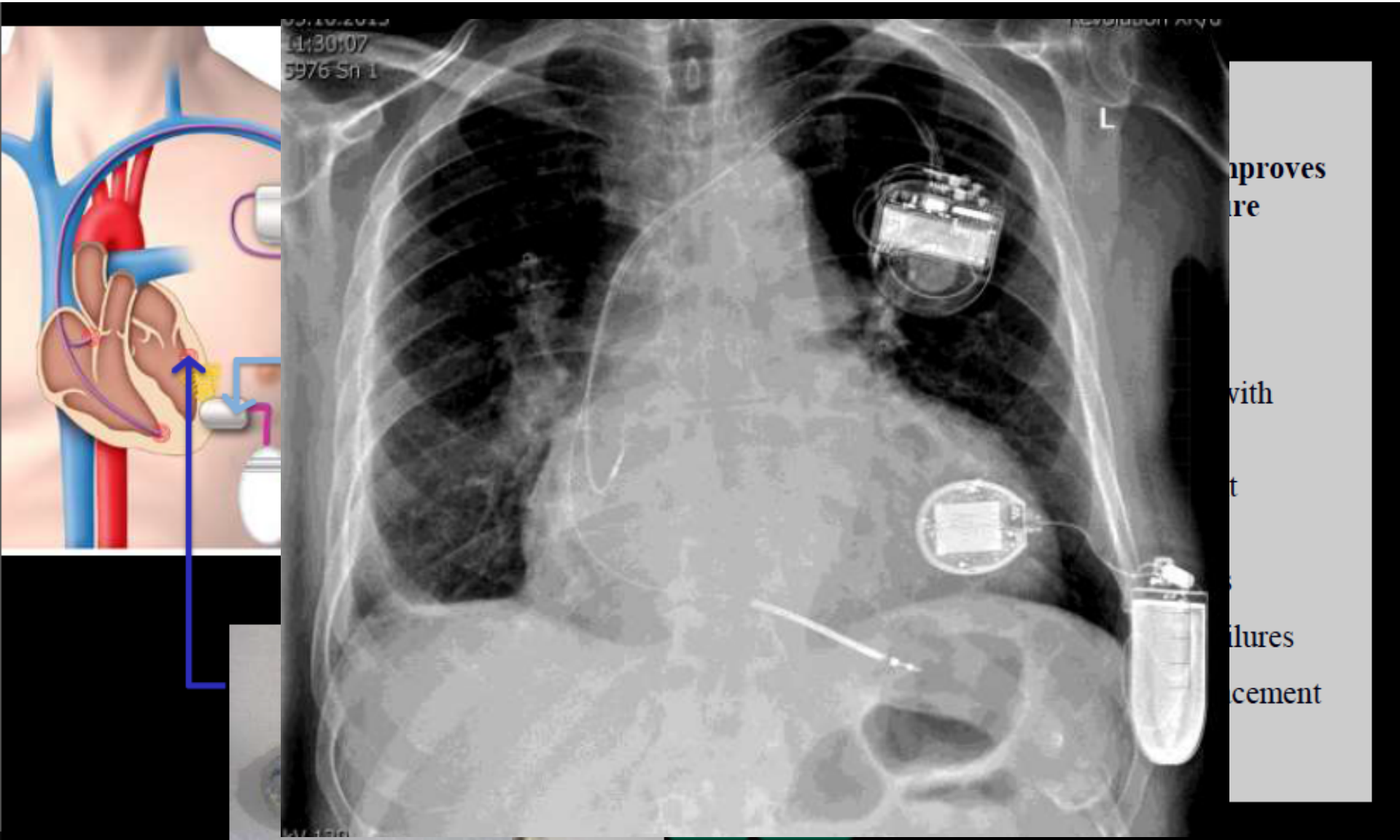
Micra™ Device



- Pacing Mode: VVIR
- Volume: 0.75cc
- Mass: 2g
- Length: 24mm
- Width: 20Fr
- Bipolar sensing (17mm spacing)

- Programmable
- Capture Management
- Rate Response
- Essential Diagnostics: battery status, pacing threshold, pacing impedance, % paced, longevity estimator
- Standard communication with 2090 programmer
- Device will be deactivated at EOL

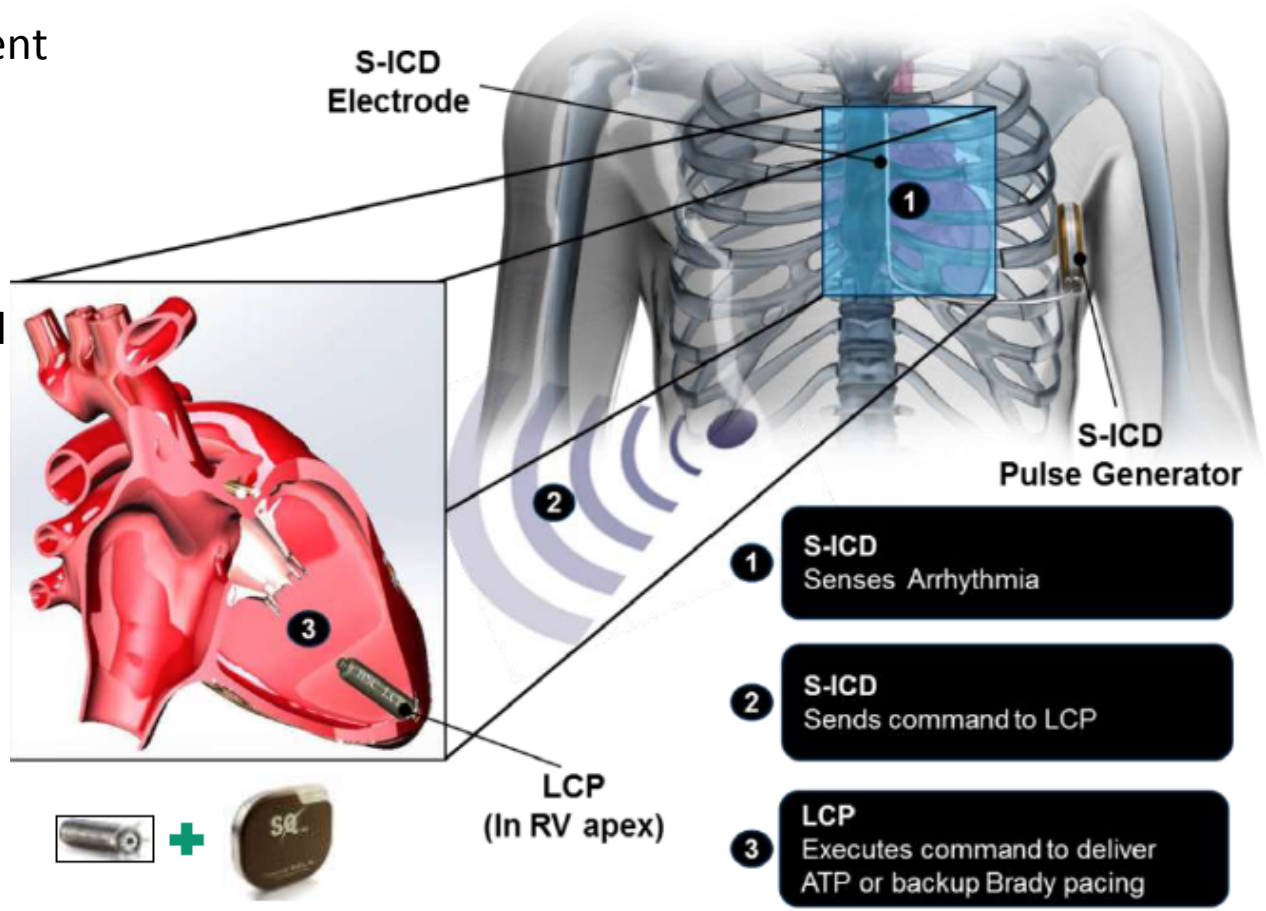
WiCS-LV : Wireless US Pacing



WiCS-LV : Wireless Pacing Clinical Experiences

Leadless pacing as a compliment
To the S-ICD platform

- Option for delivery of commanded ***ATP*** should S-ICD patients exhibit terminal Arrhythmias
- Option for patients that develop future pacing indications or require ***brady-pacing*** support
- Option for enhancement of S-ICD discrimination by providing ***intracardiac sensing***



Leadless pacemaker : conclusion

- **Leadless VVIR PM : 1st implantation in human in 2013**
- ***Technological breakthrough* : new step in cardiac pacing**

→ ***2d revolution since first PM implantation in 1958***

- **Future : 25% of cardiac pacing (VVI market)**
- **Development of DDD pacemaker and CRT : in 5 years**
- **Association between S-ICD and leadless**
- **Development at 10 years : energy harvesting technolog**
  Energy harvester, scavenger