

The leadless pacemaker: Safety and cost-effectiveness



C. W. Israel
Dept. of Cardiology
Evangelical Hospital Bielefeld
Germany
C.W.Israel@em.uni-frankfurt.de





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CONFLICTS OF INTEREST

Medtronic, St. Jude Medical

**(Speaker's bureau, honoraria, safety
advisory board, travel grants)**



First Concepts

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

Special Article

Totally Self-Contained Intracardiac Pacemaker*

J. WILLIAM SPICKLER, PH.D., DON L. BROWN, PH.D., PAUL WITBE, M.D.,
S. N. MISHA, M.D., E. E. ROSSON, P.E., AND CHARLES LAUDER, D.D.

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 intra-cardiac pacemaker (ICP), i.e., a completely self-contained pacemaker implanted inside the right ventricle by transvenous insertion.

discula have been improved substantially. In addition, the development of the endocardial cathodic electrode has broadened the class of operative procedures to include a large portion of the patient population. Two major problems that still exist with conventional pacemakers are perforation or dislodging of the transvenous electrode and the short life of the battery that are presently used. In addition, there are some with conventional devices implanted

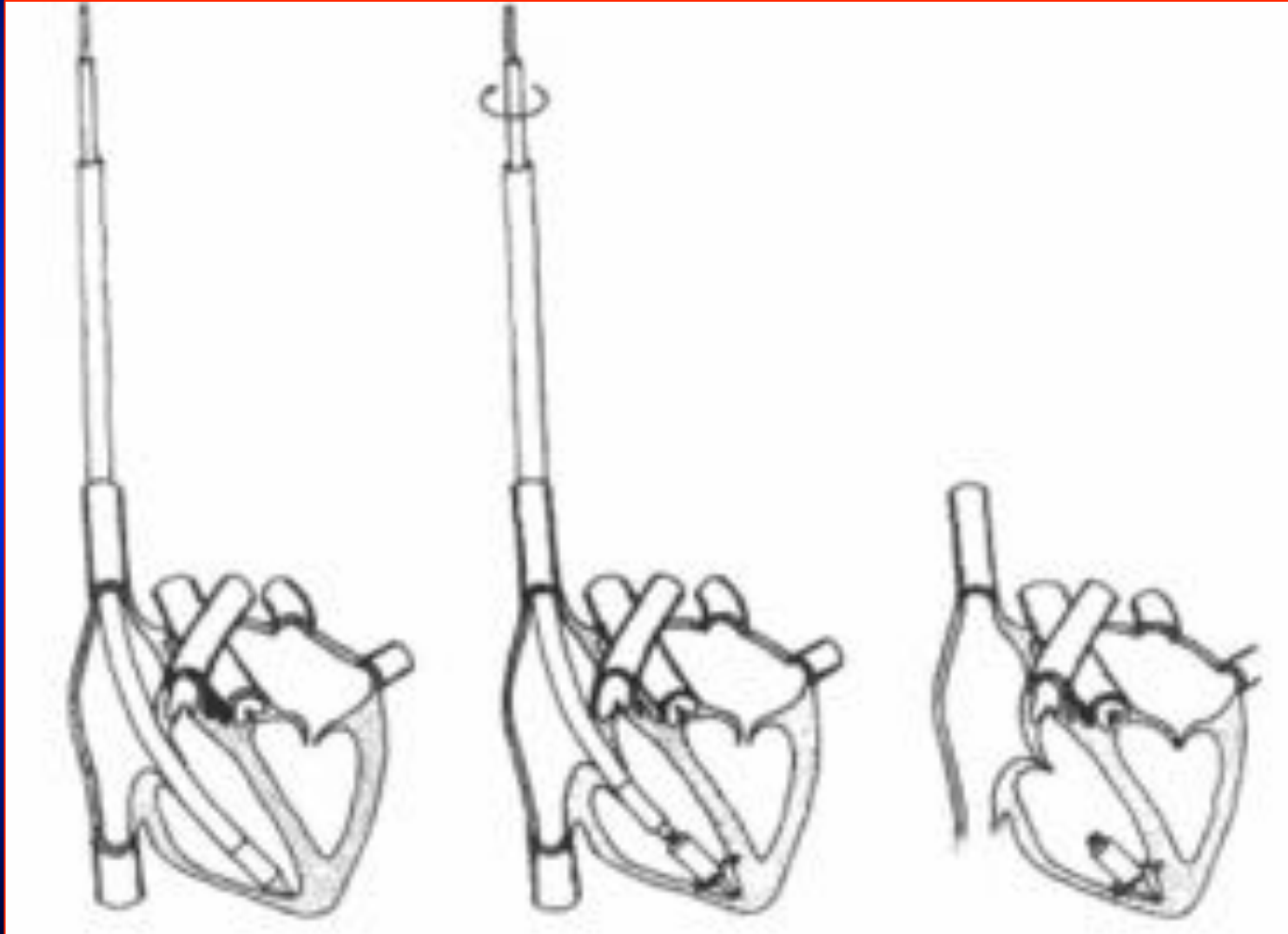


Fig. 6. Intracardiac pacemaker with catheter for transvenous insertion.

Fig. 7. Nuclear-powered intracardiac pacemaker.

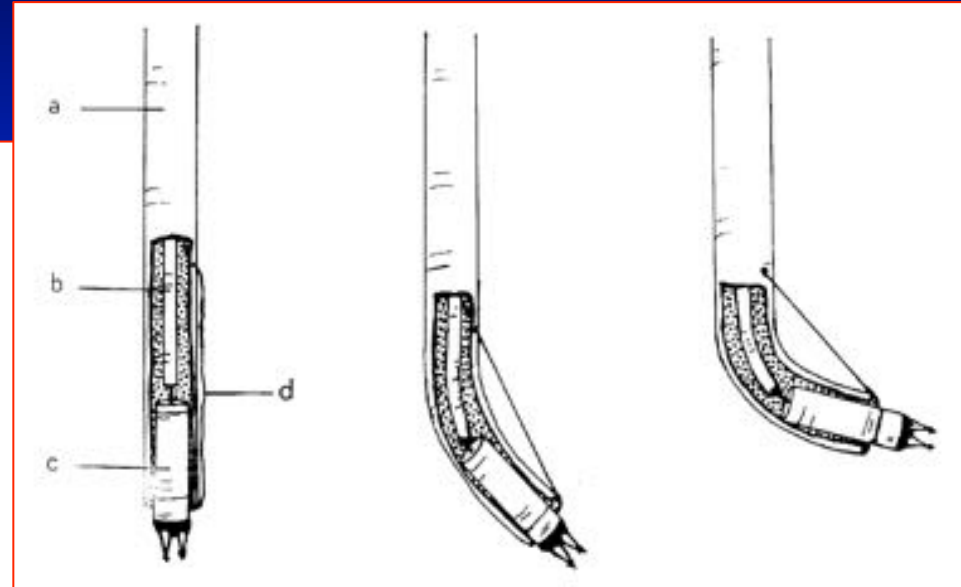
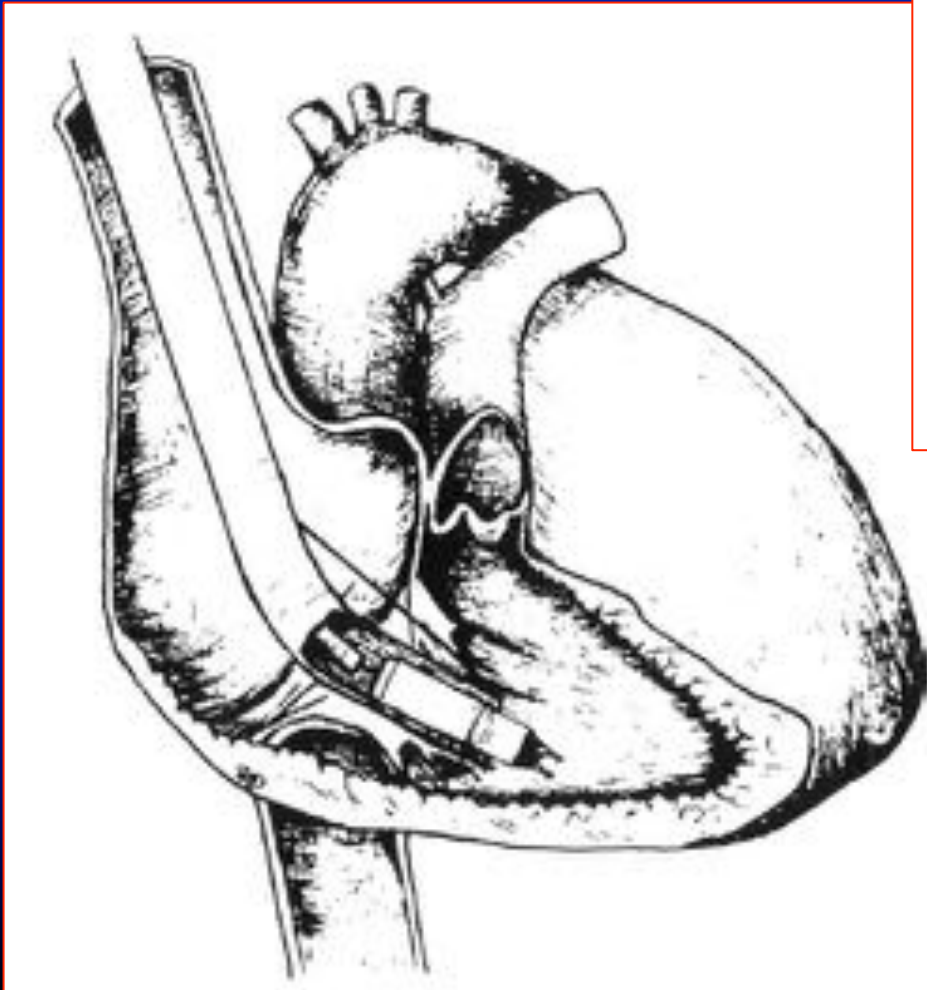


First Concepts





First Concepts





Nanostim (St. Jude Medical)



screw,
tip electrode



docking
interface

Ring electrode

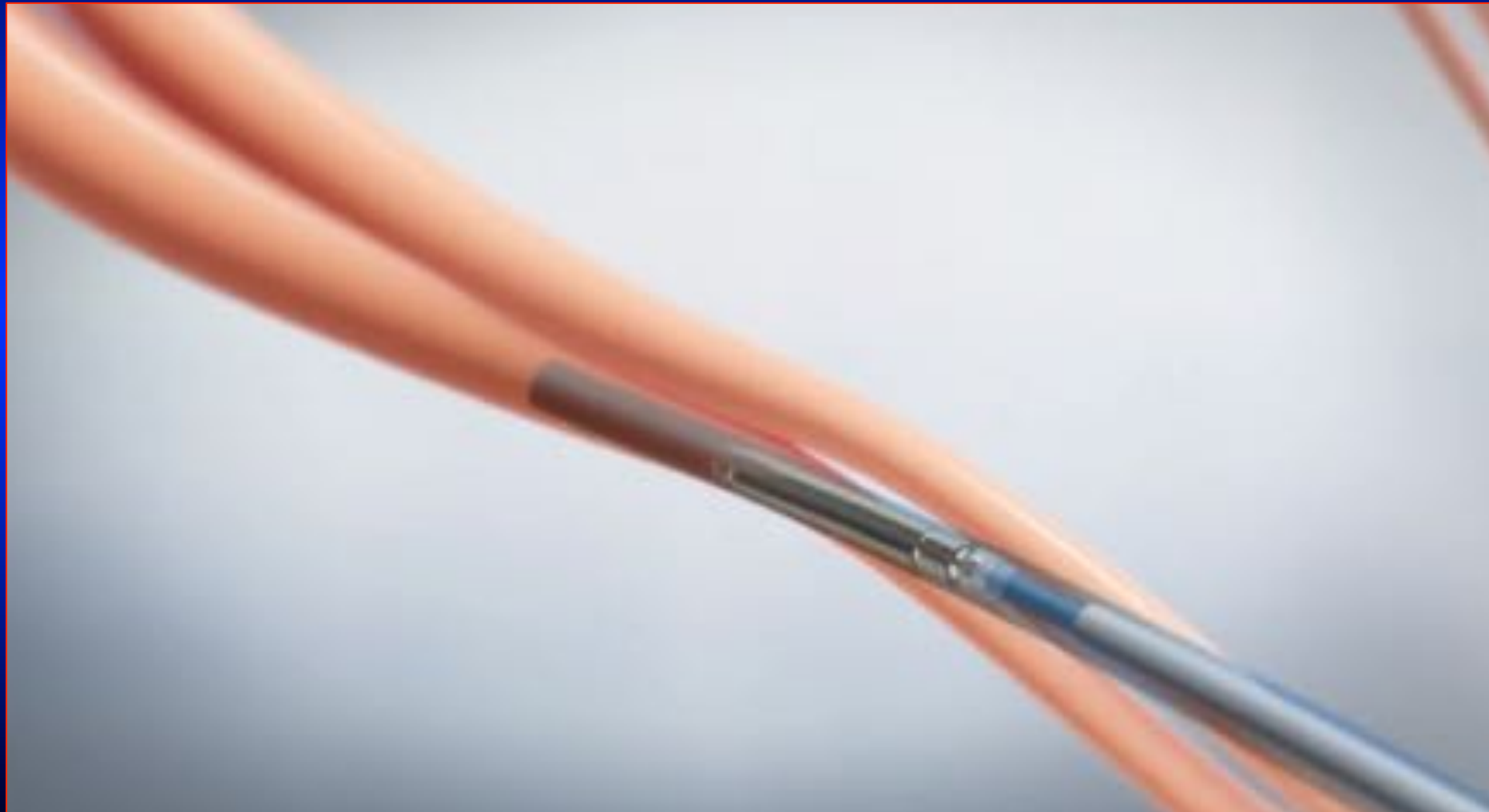
Nanostim (St. Jude Medical)

- Delivery catheter
 - Soft, flexible, deflectable catheter tip designed to minimize complications
 - Tethered feature
 - Integrated protective sleeve
 - 18 F
- Handle with four functions:
 - Steering the deflectable tip
 - Docking/undocking
 - Rotating the device
 - Releasing tether
- 18 F introducer



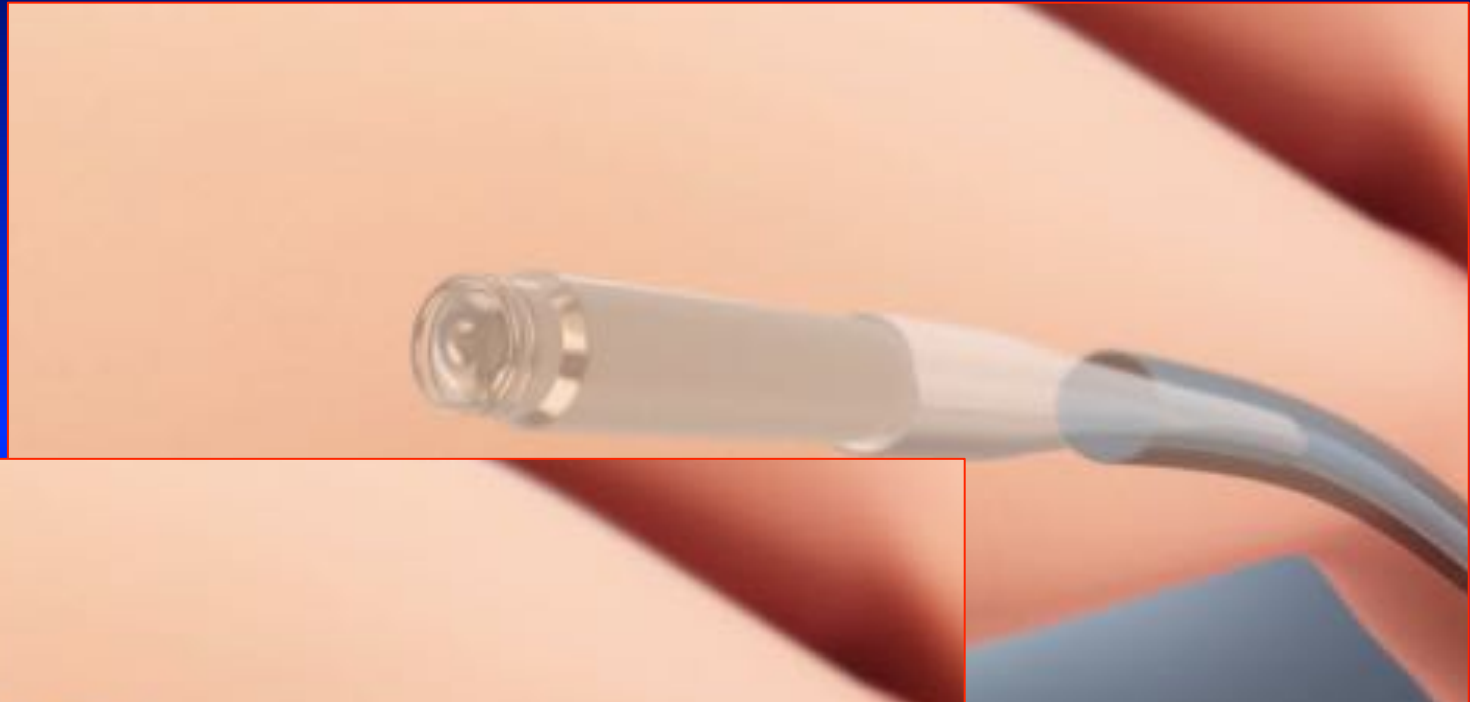


Nanostim (St. Jude Medical)





Nanostim (St. Jude Medical)



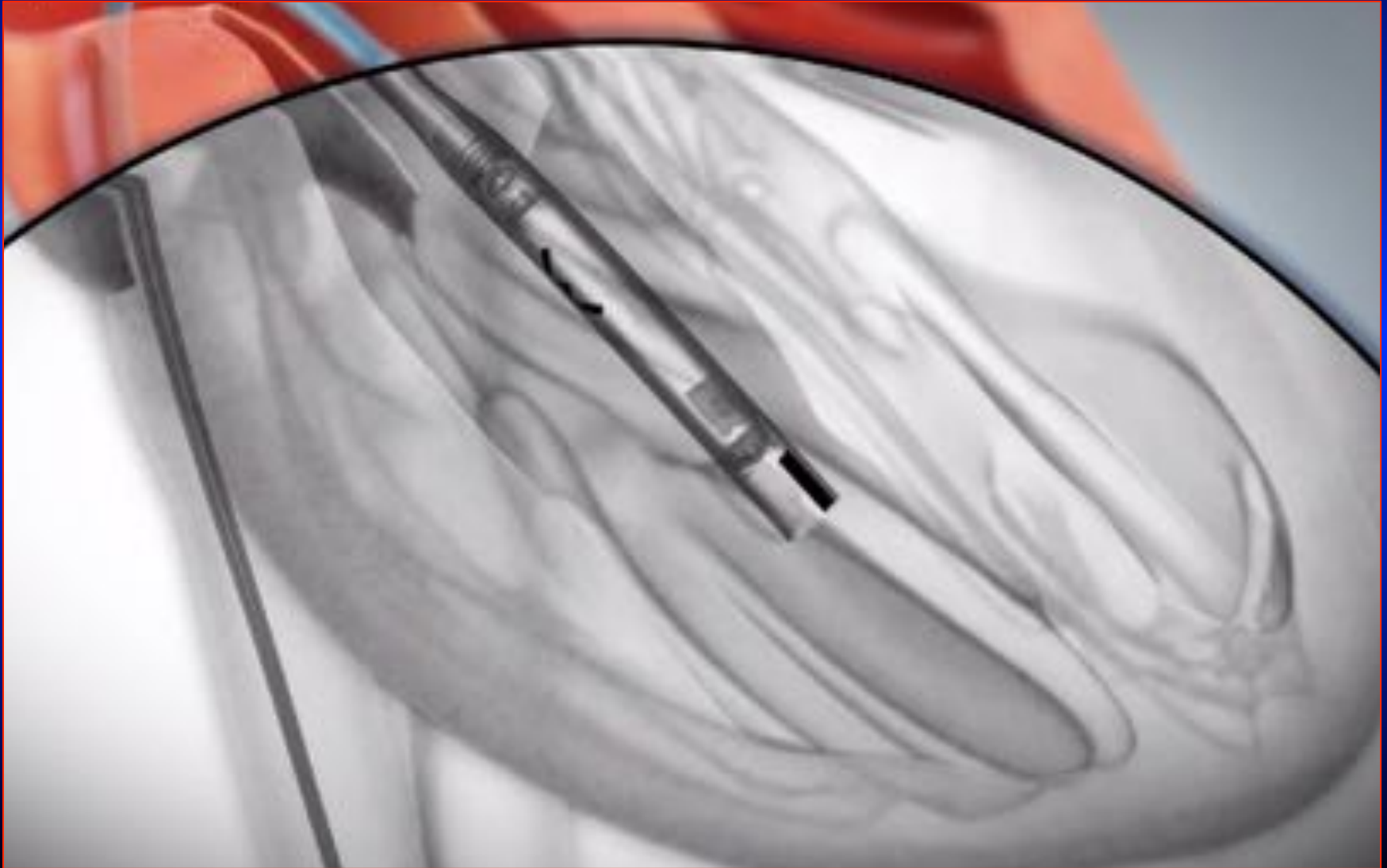


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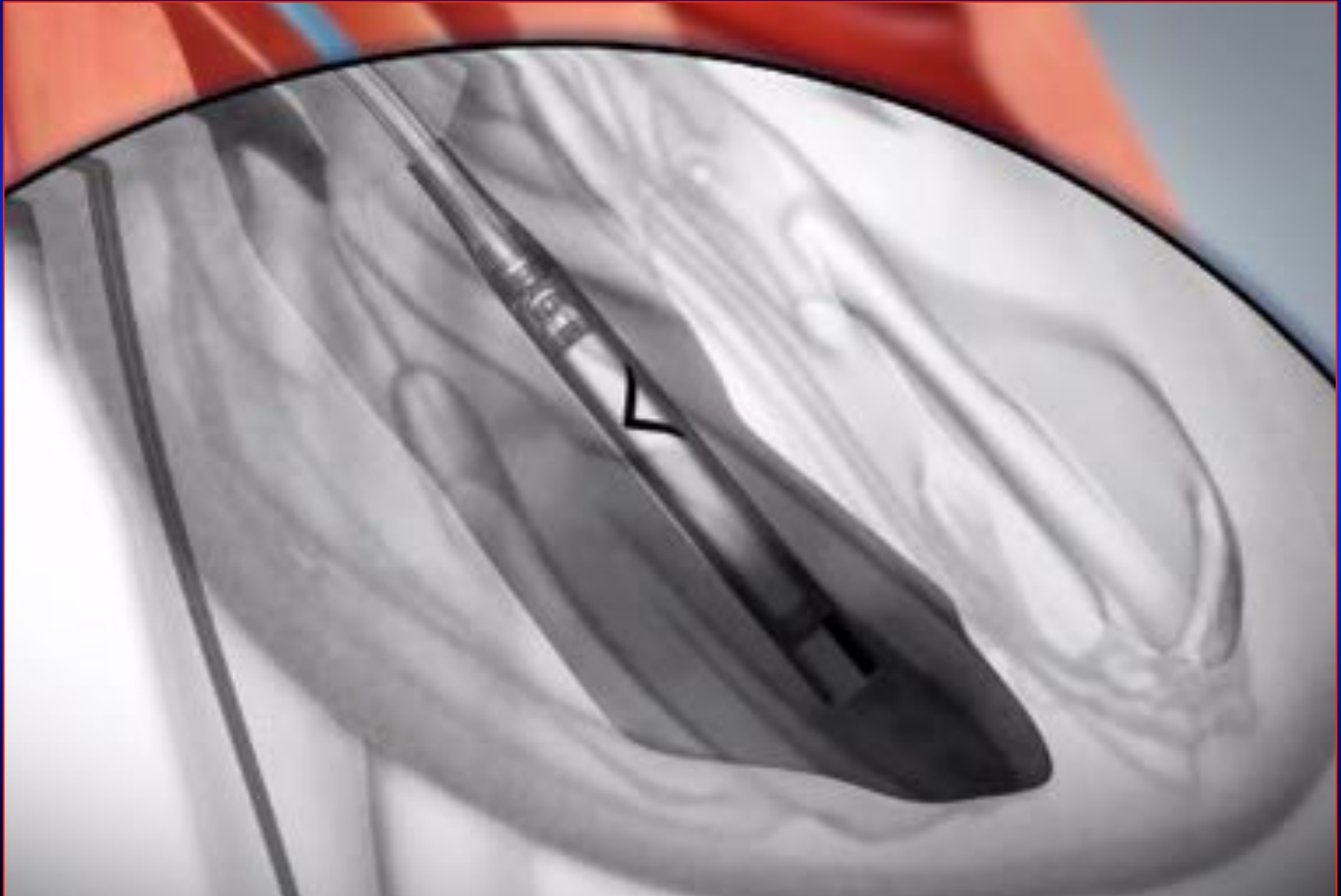


Nanostim (St. Jude Medical)



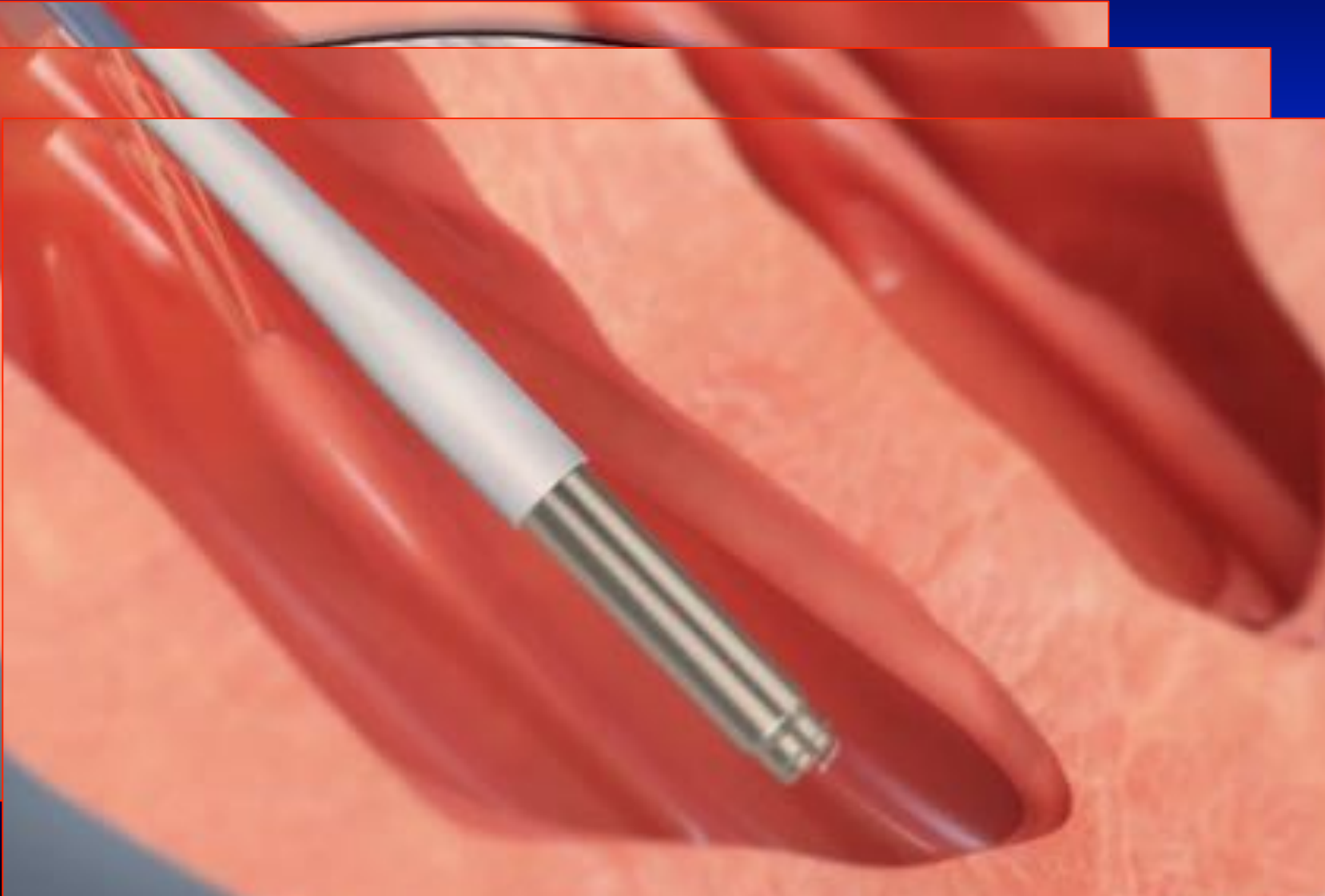


Nanostim (St. Jude Medical)



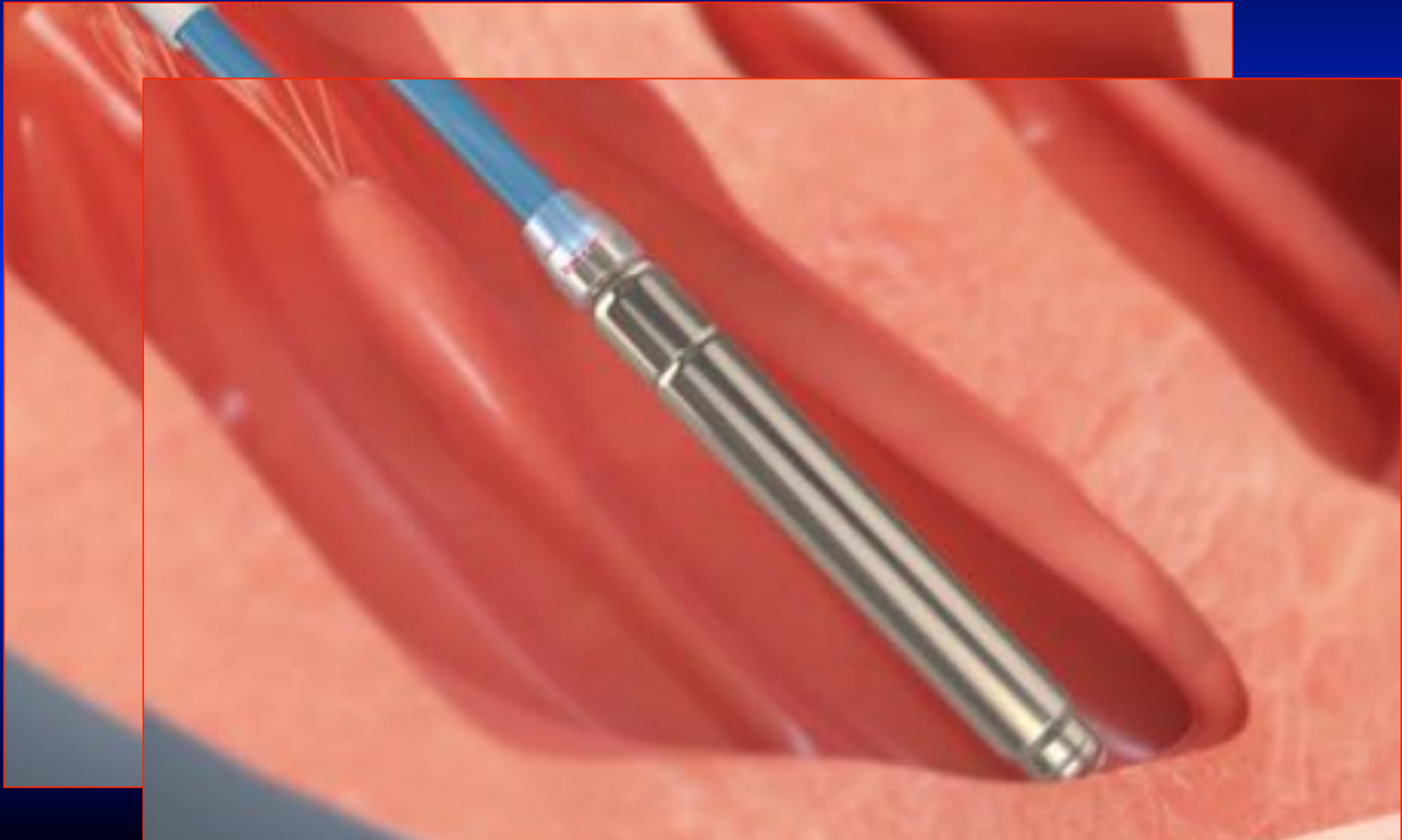


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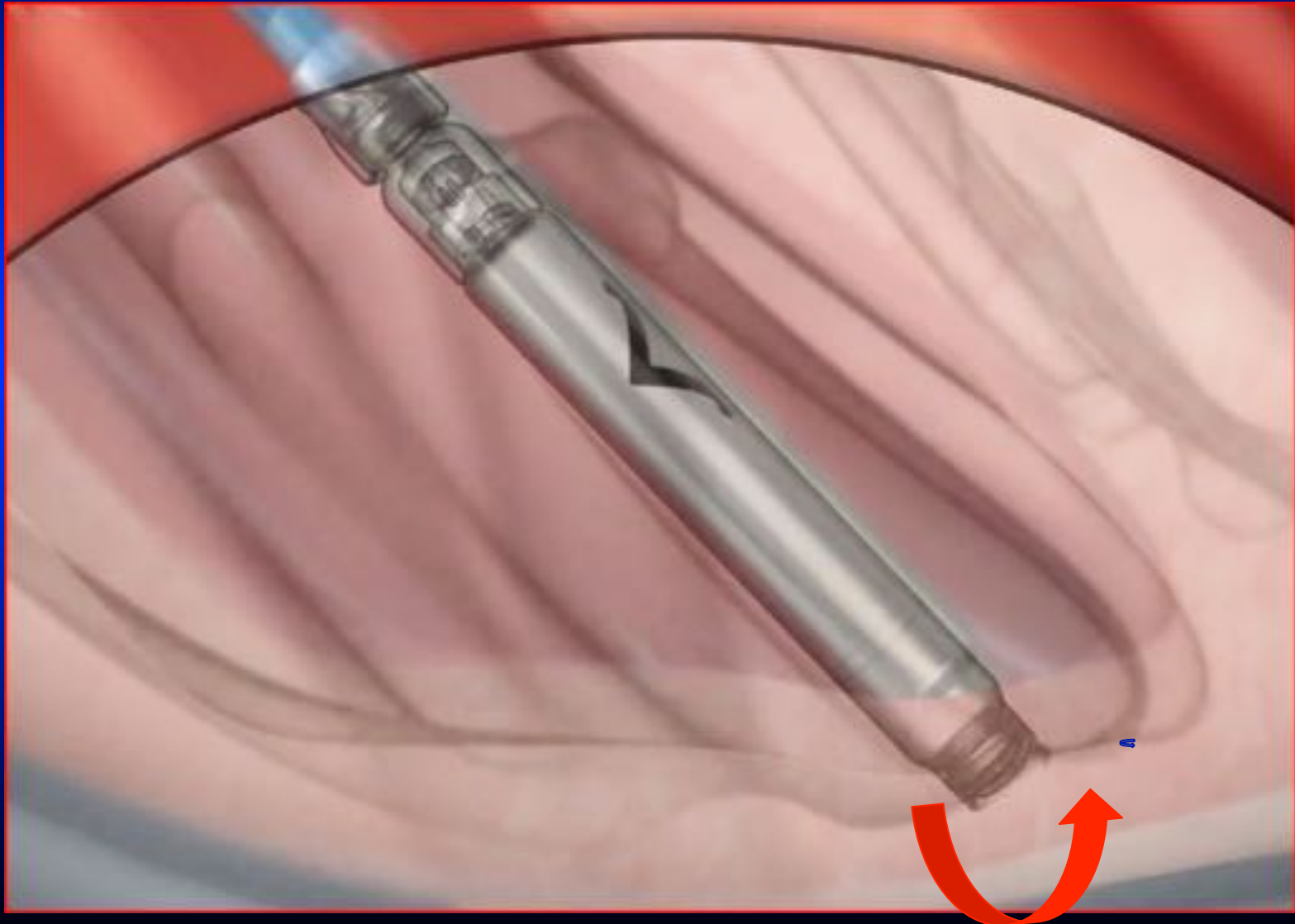


Nanostim (St. Jude Medical)



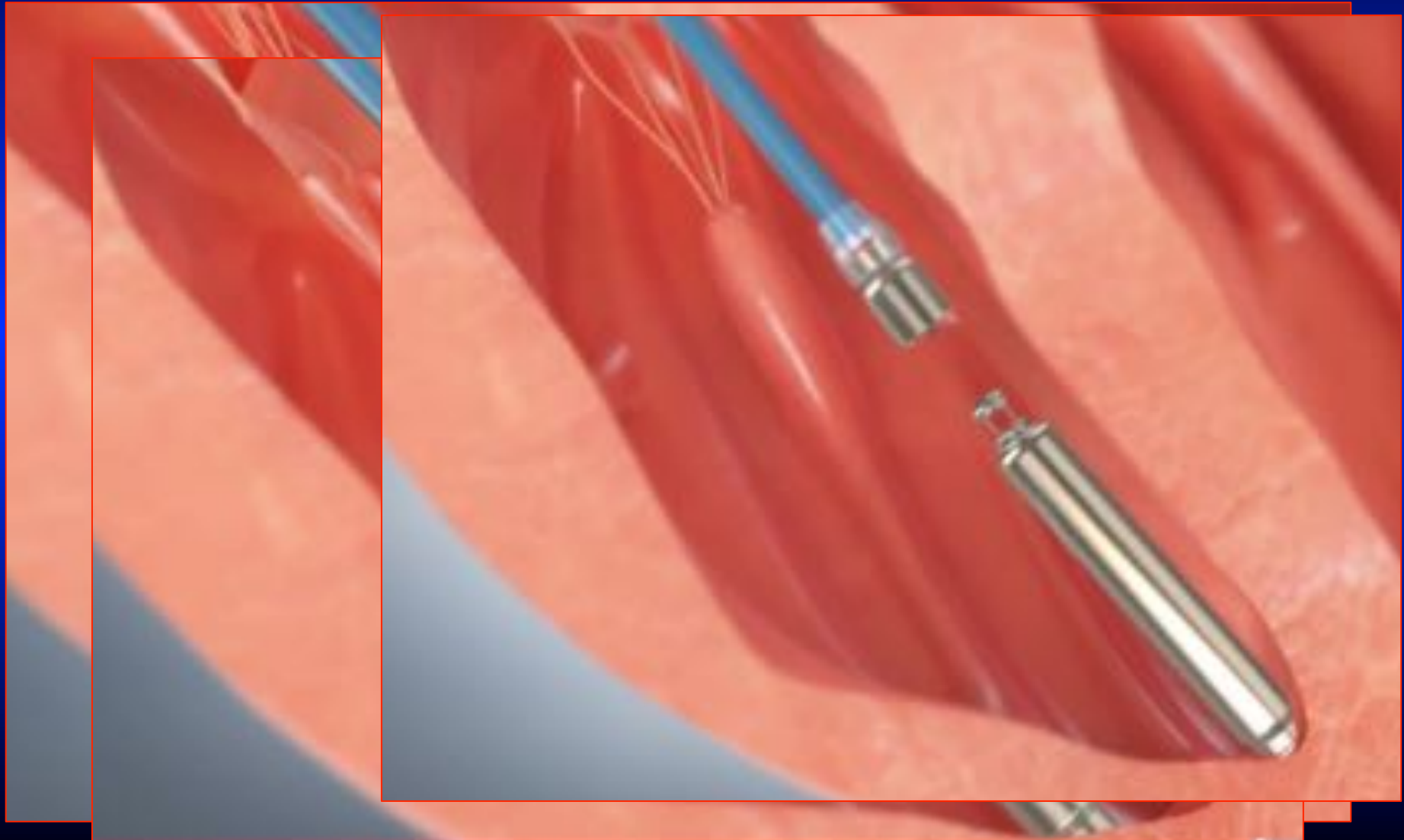


Nanostim (St. Jude Medical)



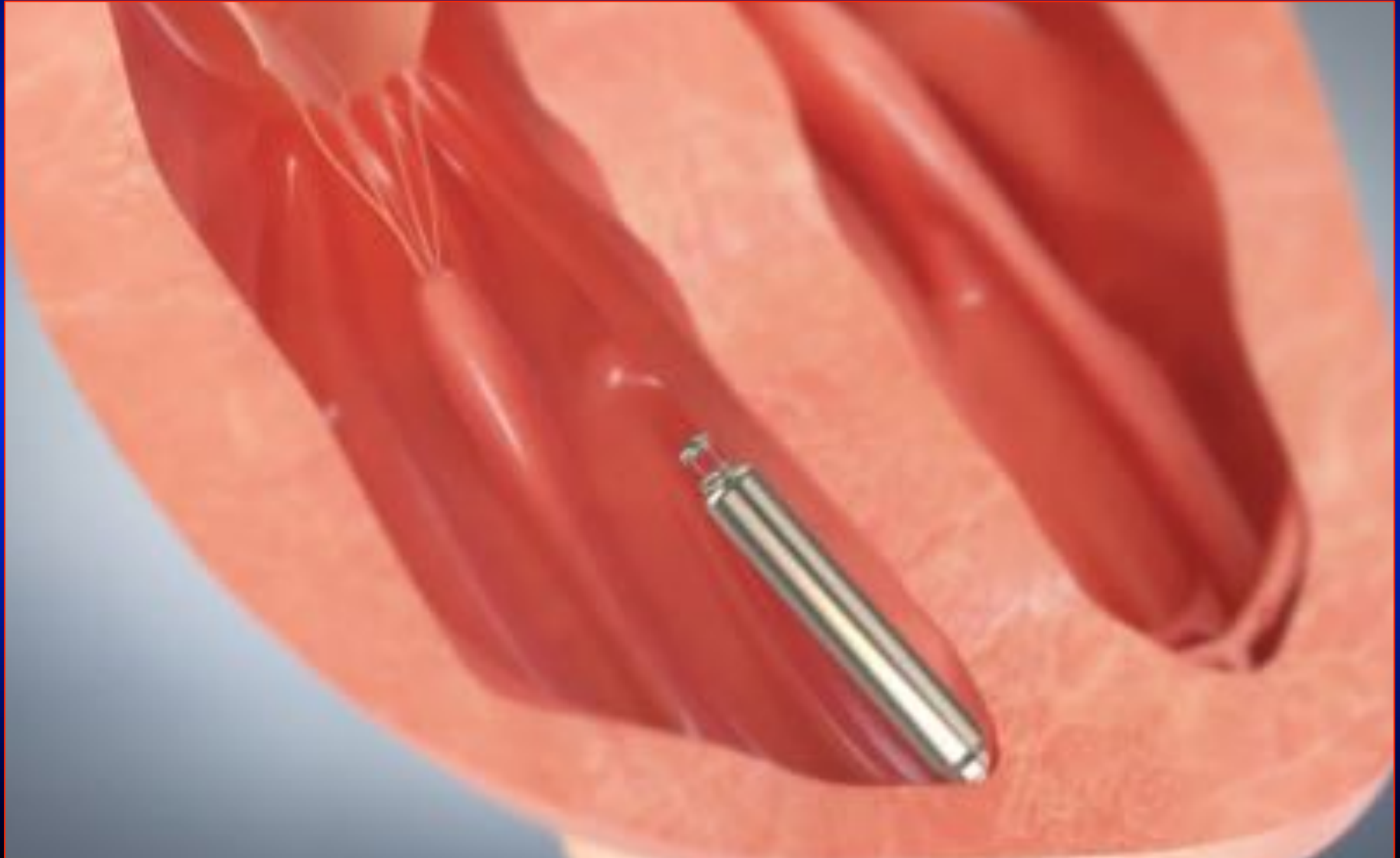


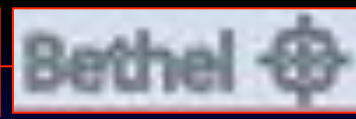
Nanostim (St. Jude Medical)



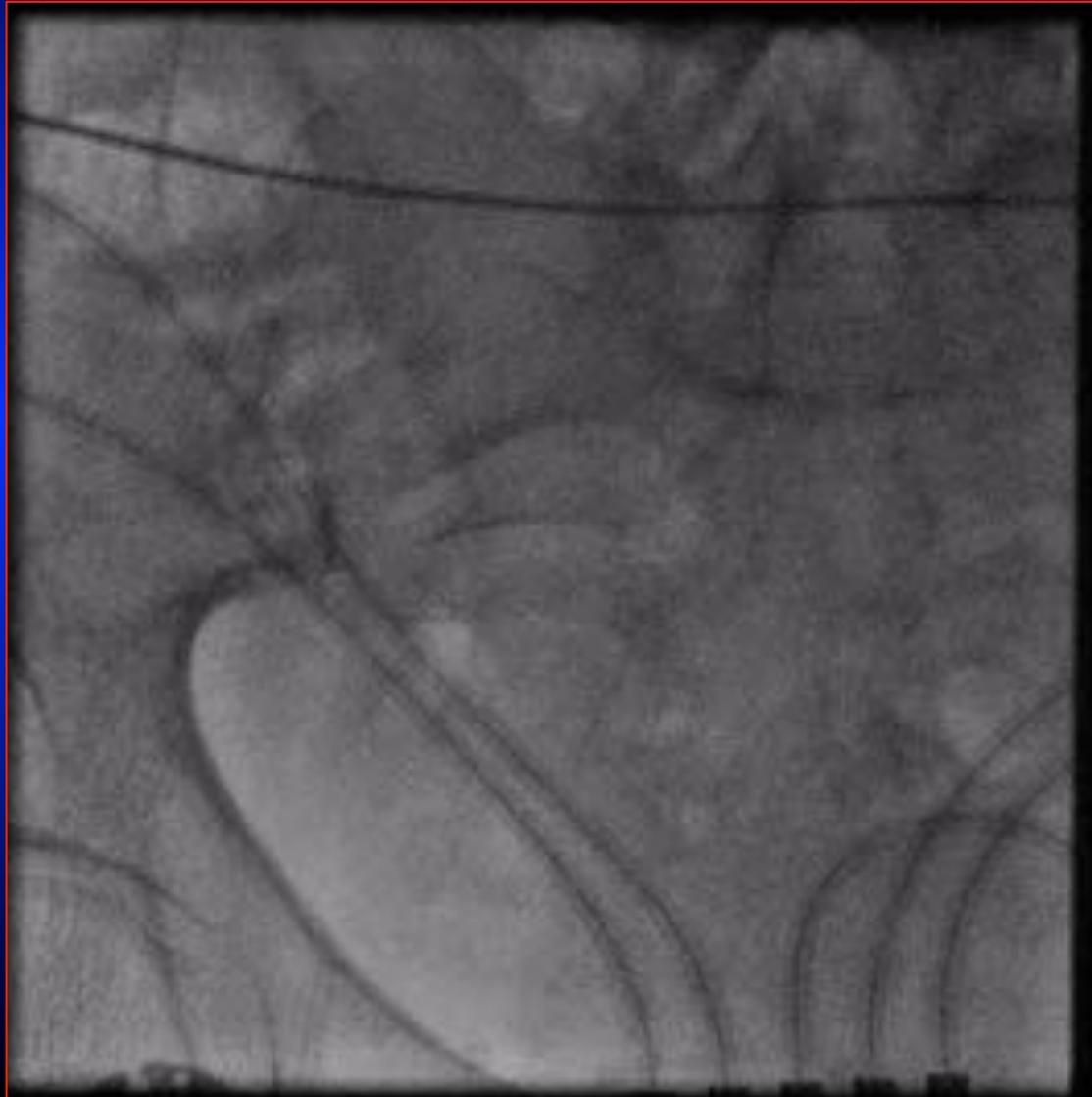


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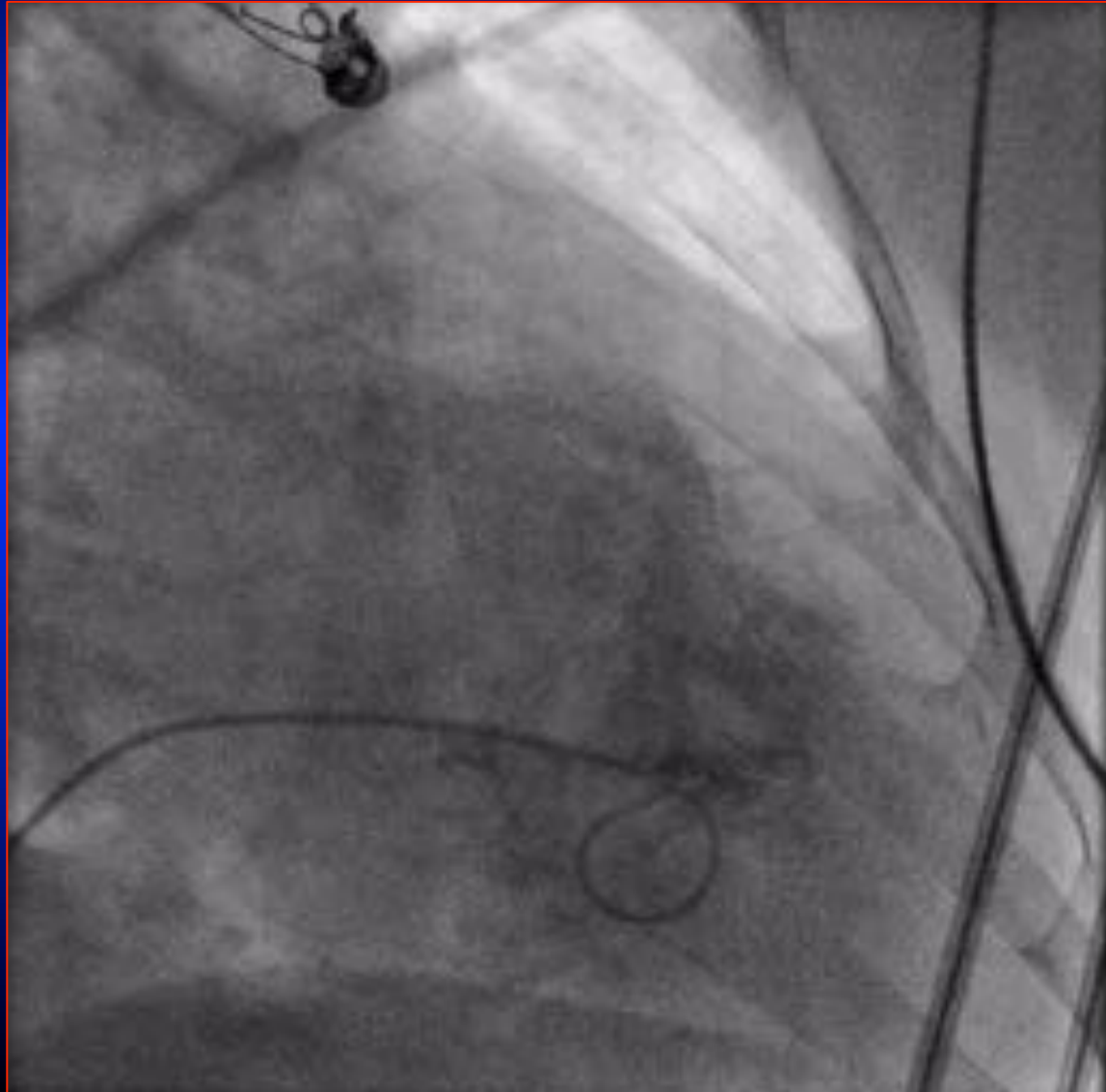
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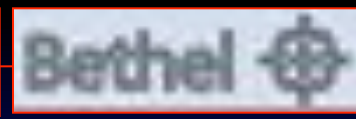
Cortesy Johannes
Sperzel, Bad
Nauheim, Germany



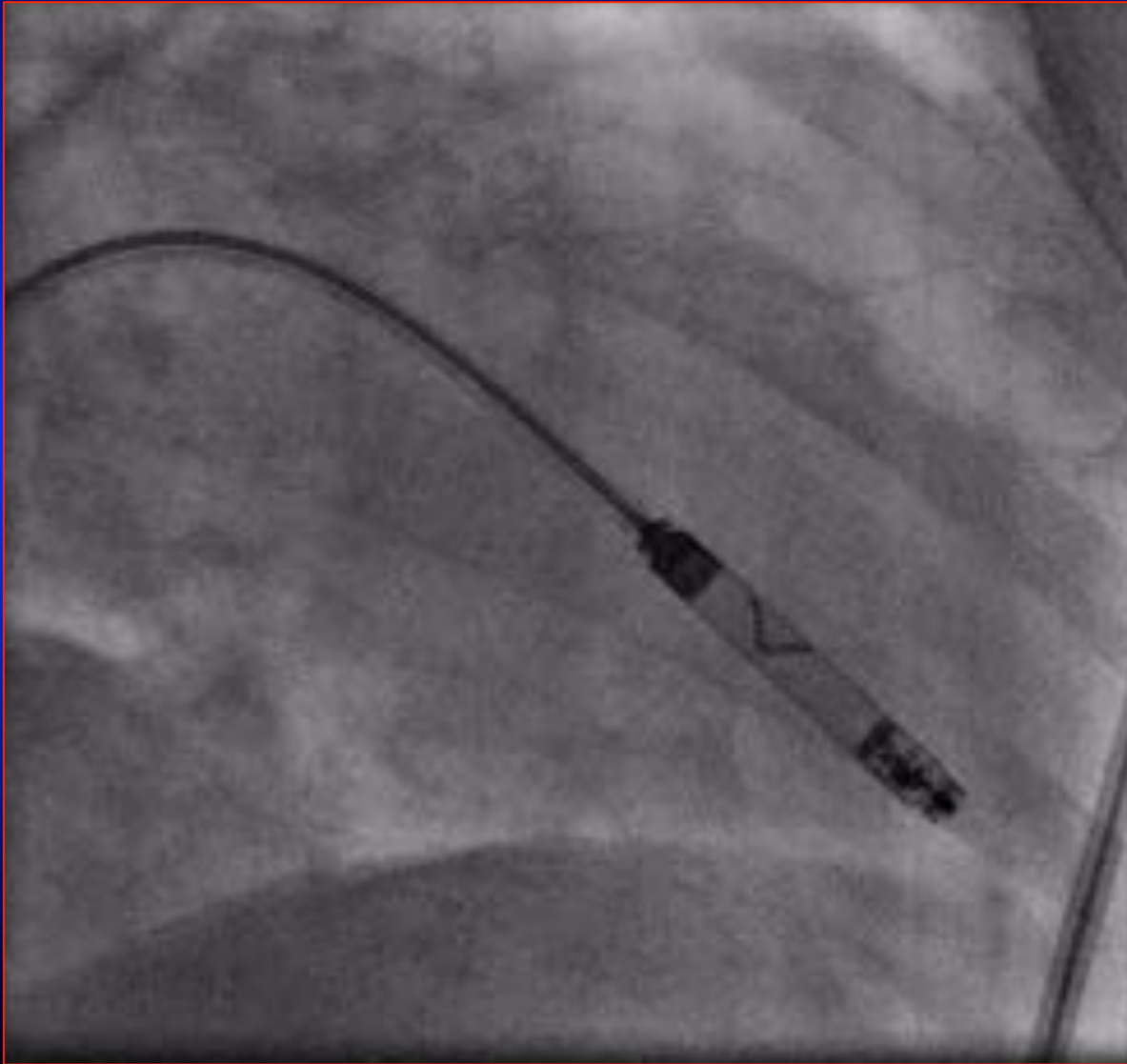
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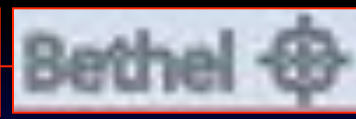
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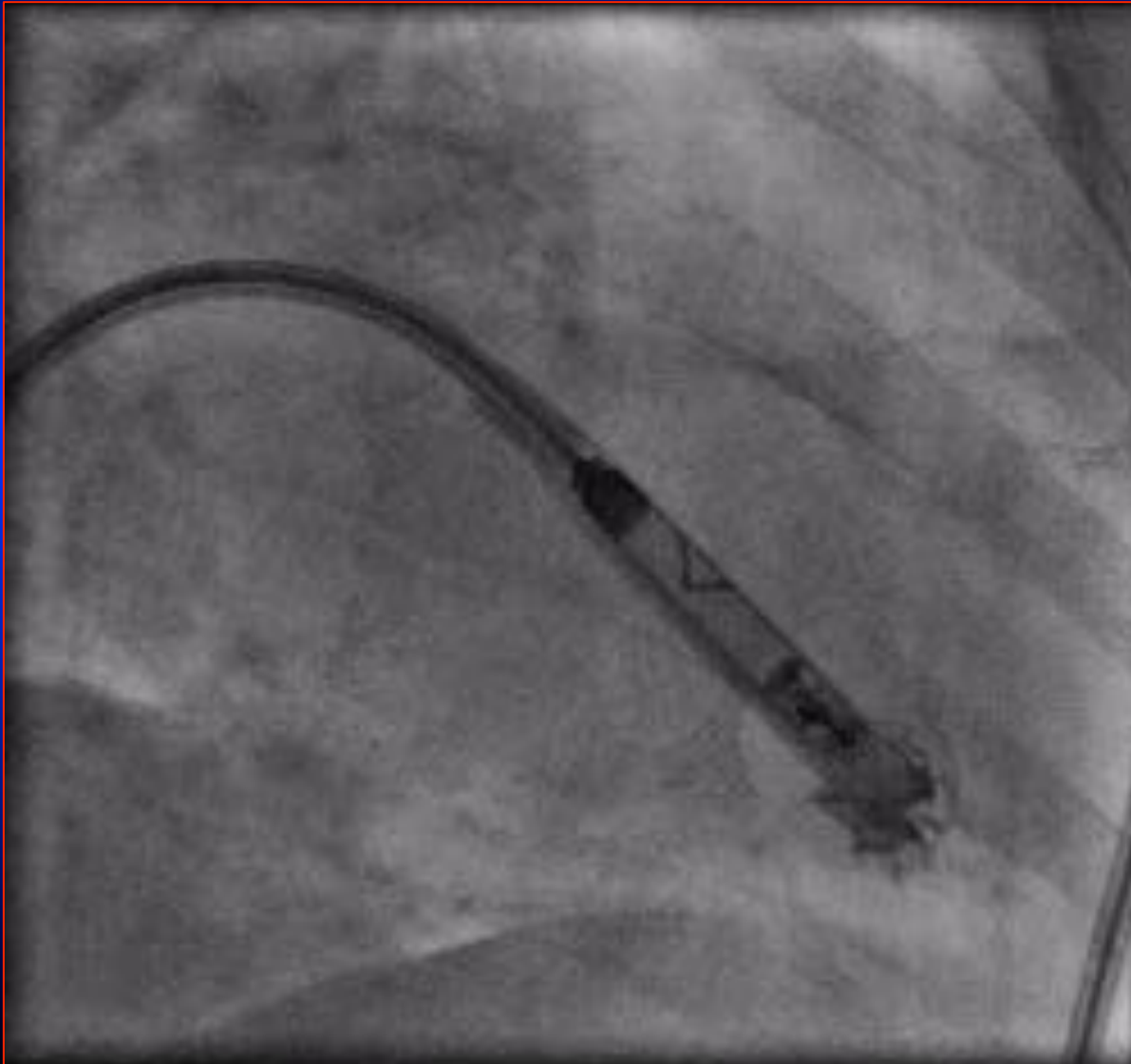
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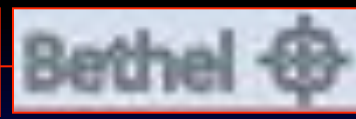
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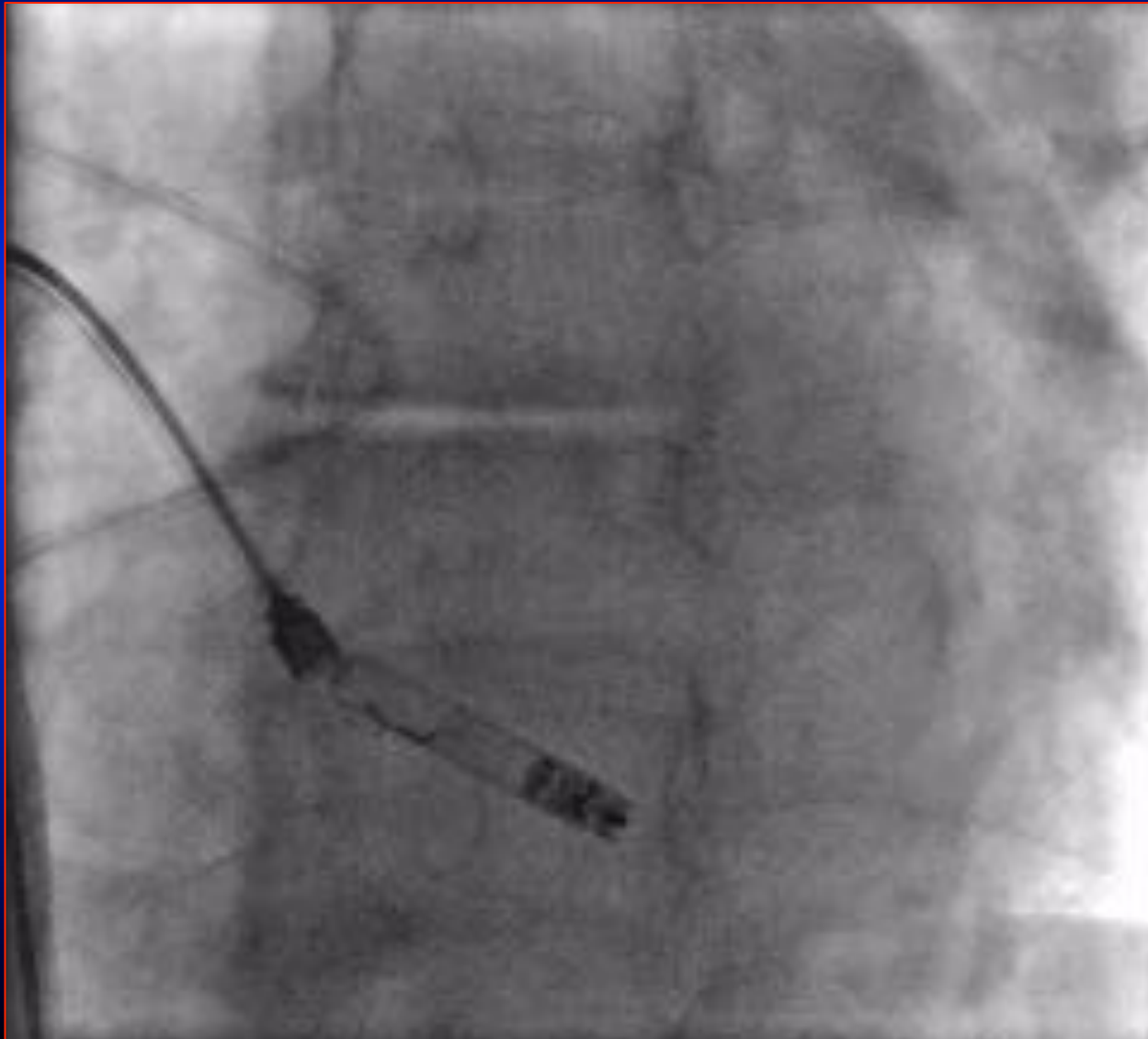
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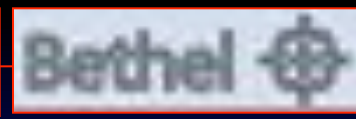
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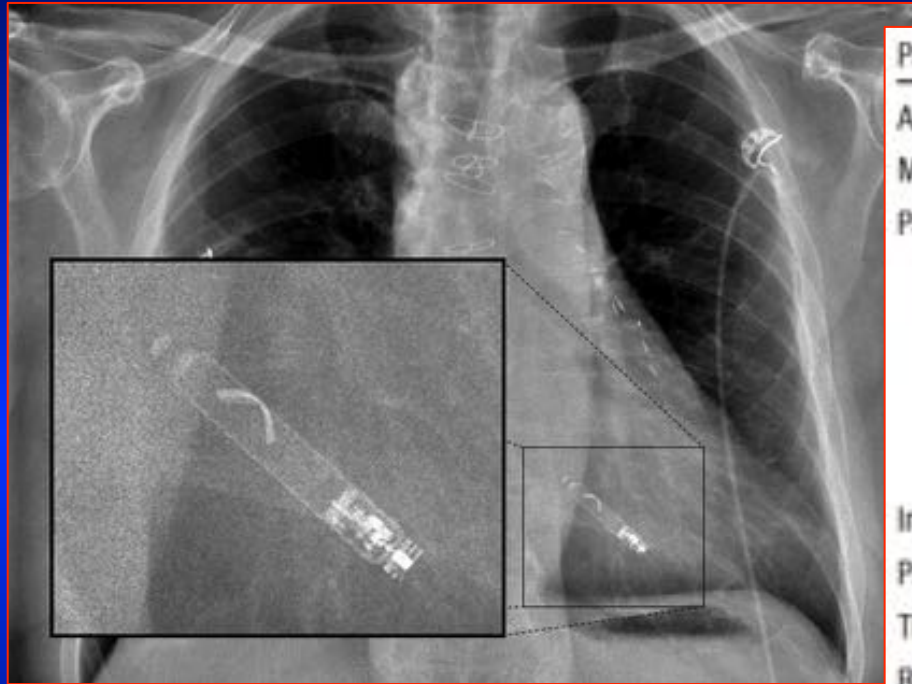
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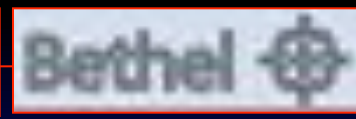


LEADLESS-Trial



Parameter	(n=33)
Age, y	76.5±8.4
Male, n (%)	22 (67)
Pacing indication, n (%)	
Permanent AF with AV block (including AF with a slow ventricular response)	22 (67)
Sinus rhythm with 2nd/ 3rd degree AV block and significant comorbidities	6 (18)
Sinus bradycardia with infrequent pauses or unexplained syncope	5 (15)
Implant success rate, n (%)	32 (97)
Procedure duration, min	28±17
Time to hospital discharge, h	31±20
Repositioning attempts (to achieve final implant position), n (%)	
0	23 (70)
1	4 (12)
2	4 (12)
3	2 (6)
Rehospitalized within 90 days, n (%)	3 (9)
Complication-free rate, %	94

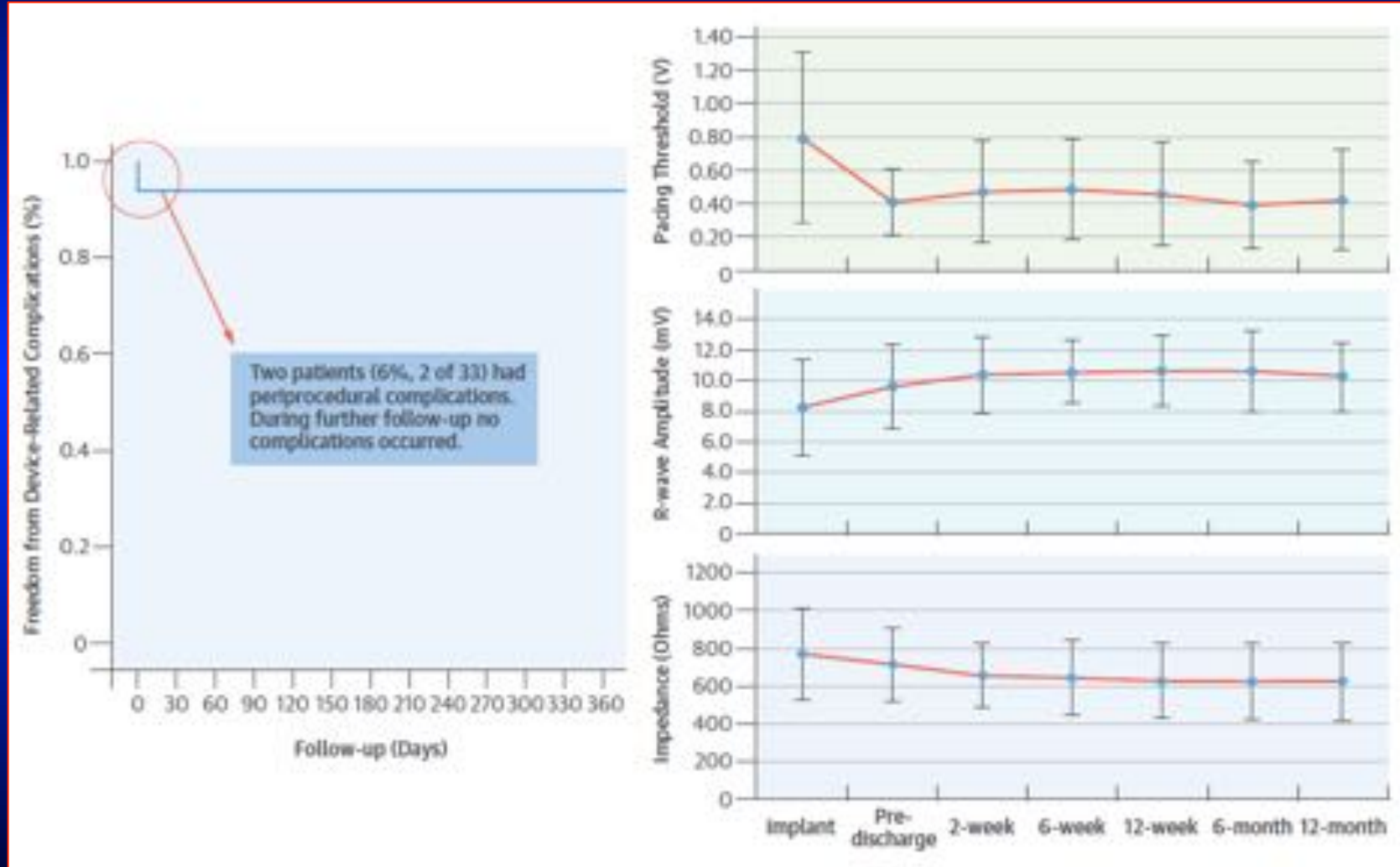
94% (31/33) free of complications



LEADLESS-Trial: Complications

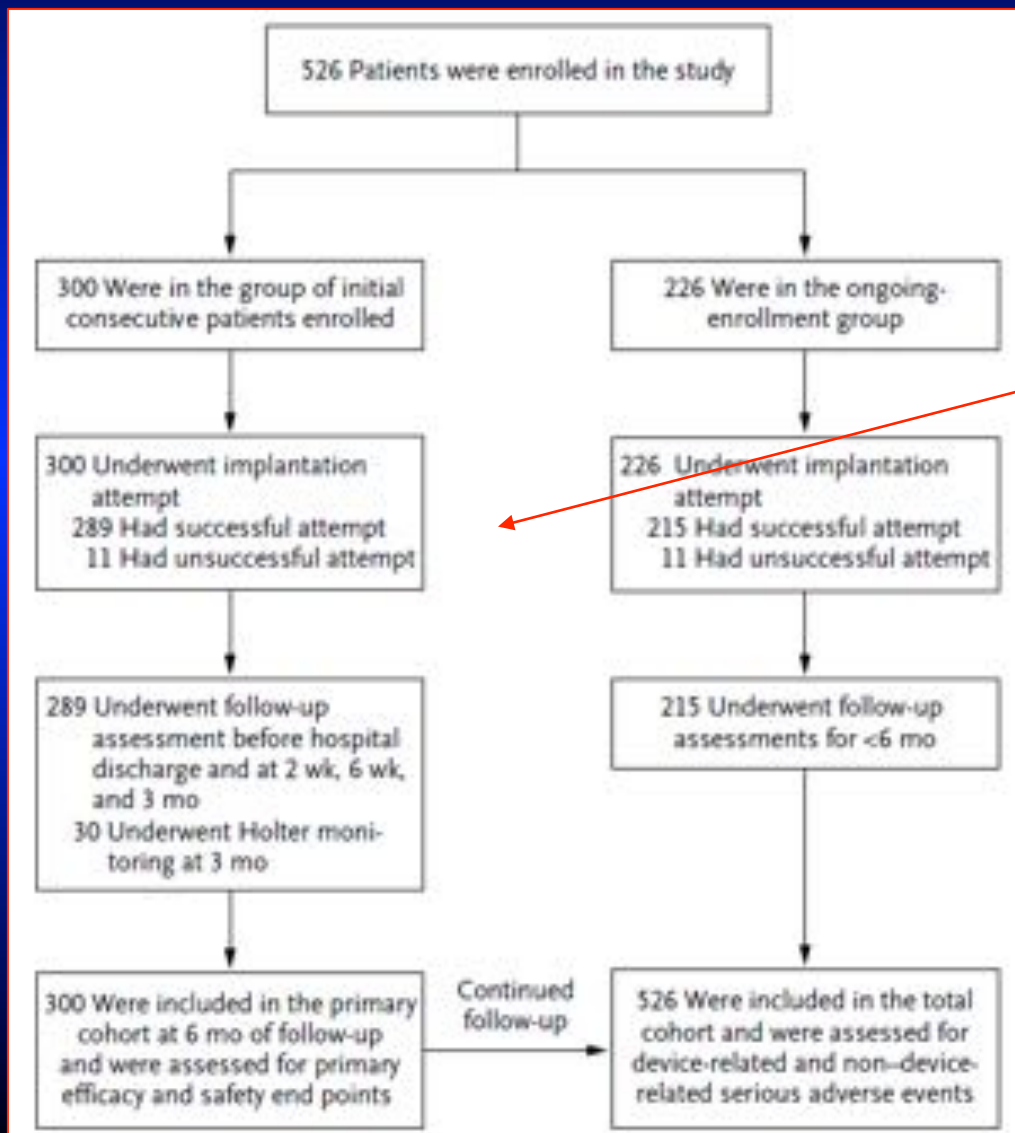
- 1 cardiac tamponade with hemodynamic collapse after repositioning of the LCP + manipulation of the delivery catheter in the RV apex
- pericardial drainage, sternotomy on cardiopulmonary bypass, surgical repair of perforation of the RV apex
- on day 5 hemiplegia due to ischemic infarct, progressive cerebral edema, died on postprocedure day 18
- 1 inadvertent LV positioning via a patent foramen ovale,
- Retrieval by a trilooped snare through the patent foramen ovale, new device implanted in the RV apex. Retrieval took 6 minutes

LEADLESS Trial: 1 year Data





LEADLESS II Trial



Successful implantation:
95.8%



LEADLESS II Trial

Characteristic	Primary Cohort (N = 300)	Total Cohort (N = 526)
Procedural characteristics		
Duration of implantation — min		
Total: sheath insertion to removal	50.0±27.3	46.5±25.3
Procedure: insertion of delivery catheter to removal	30.4±18.2	28.6±17.8
Duration of fluoroscopy — min	14.9±9.4	13.9±9.1
Device repositioning — no. of patients/total no. (%)		
None	199/289 (68.9)	354/504 (70.2)
1	53/289 (18.3)	89/504 (17.7)
2	24/289 (8.3)	39/504 (7.7)
>2	13/289 (4.5)	22/504 (4.4)
Final device position in right ventricle — no. of patients/ total no. (%)		
Apex	140/289 (48.4)	192/504 (38.1)
Apical septum	5/289 (1.7)	96/504 (19.0)
Outflow, septum, or other	144/289 (49.8)	215/504 (42.7)
Missing data	0/289	1/504 (0.2)



LEADLESS II Trial

Event	Primary Cohort (N = 300)			Total Cohort (N = 526)		
	No. of Events	No. of Patients	Event Rate	No. of Events	No. of Patients	Event Rate
			%			%
Total	22	20	6.7	40	34	6.5
Cardiac perforation						
Cardiac tamponade with intervention	1	1	0.3	5	5	1.0
Cardiac perforation requiring intervention	1	1	0.3	1	1	0.2
Pericardial effusion with no intervention	2	2	0.7	2	2	0.4
Vascular complication						
Bleeding	2	2	0.7	2	2	0.4
Arteriovenous fistula	1	1	0.3	1	1	0.2
Pseudoaneurysm	1	1	0.3	2	2	0.4
Failure of vascular closure device requiring intervention	0	0	0	1	1	0.2



LEADLESS II Trial

Event	Primary Cohort (N = 300)			Total Cohort (N = 526)		
	No. of Events	No. of Patients	Event Rate	No. of Events	No. of Patients	Event Rate
			%			%
Arrhythmia during device implantation						
Asystole	1	1	0.3	1	1	0.2
Ventricular tachycardia or ventricular fibrillation	1	1	0.3	2	2	0.4
Cardiopulmonary arrest during implantation procedure	0	0	0	1	1	0.2
Device dislodgement	5	5	1.7	6	6	1.1
Device migration during implantation owing to inadequate fixation	0	0	0	2	2	0.4
Pacing threshold elevation with retrieval and implantation of new device	4	4	1.3	4	4	0.8
Other						
Hemothorax	0	0	0	1	1	0.2
Angina pectoris	0	0	0	1	1	0.2
Pericarditis	1	1	0.3	1	1	0.2
Acute confusion and expressive aphasia	0	0	0	1	1	0.2
Dysarthria and lethargy after implantation	0	0	0	1	1	0.2
Contrast-induced nephropathy	0	0	0	1	1	0.2
Orthostatic hypotension with weakness	1	1	0.3	1	1	0.2
Left-leg weakness during implantation	0	0	0	1	1	0.2
Probable pulmonary embolism	1	1	0.3	1	1	0.2
Ischemic stroke	0	0	0	1	1	0.2

2 procedure-related deaths (groin hematoma, perforation)

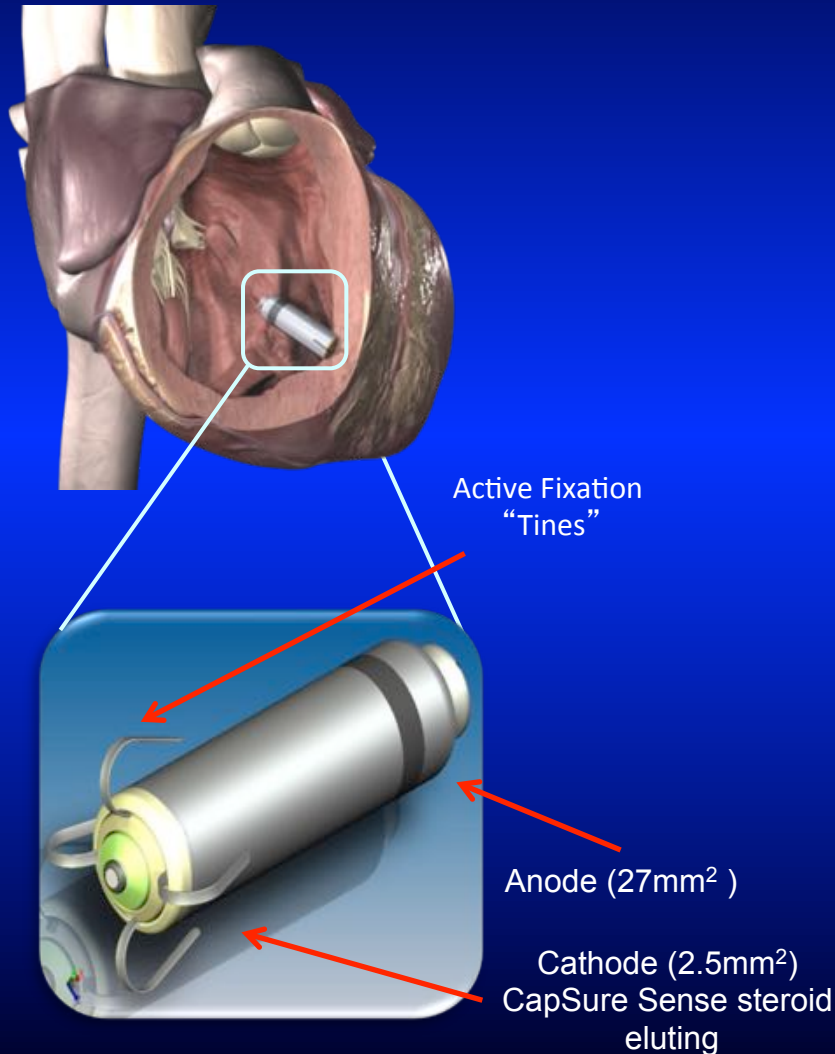
Reddy,
New Engl J Med 2015;
73:1125-35

Micra (Medtronic)





Micra (Medtronic)



- **Size**
 - 0.8 cm³, 2.0 g
 - Length: 25.9 mm
 - Outer diameter: 6.7 mm
- **Bipolar sensing/pacing**
- **Fixation mechanism: Nitinol tines**
- **Battery**
 - Lithium silver vanadium oxide/Carbon monofluoride
 - Longevity: 7.4/10.1 year (2.0/1.5V output, 60 bpm, 100% paced)
- **Capabilities**
 - VVIR
 - RV capture management
 - Sensing assurance
 - Diagnostics
- **Deactivated to OOO at EoL**



Micra (Medtronic)



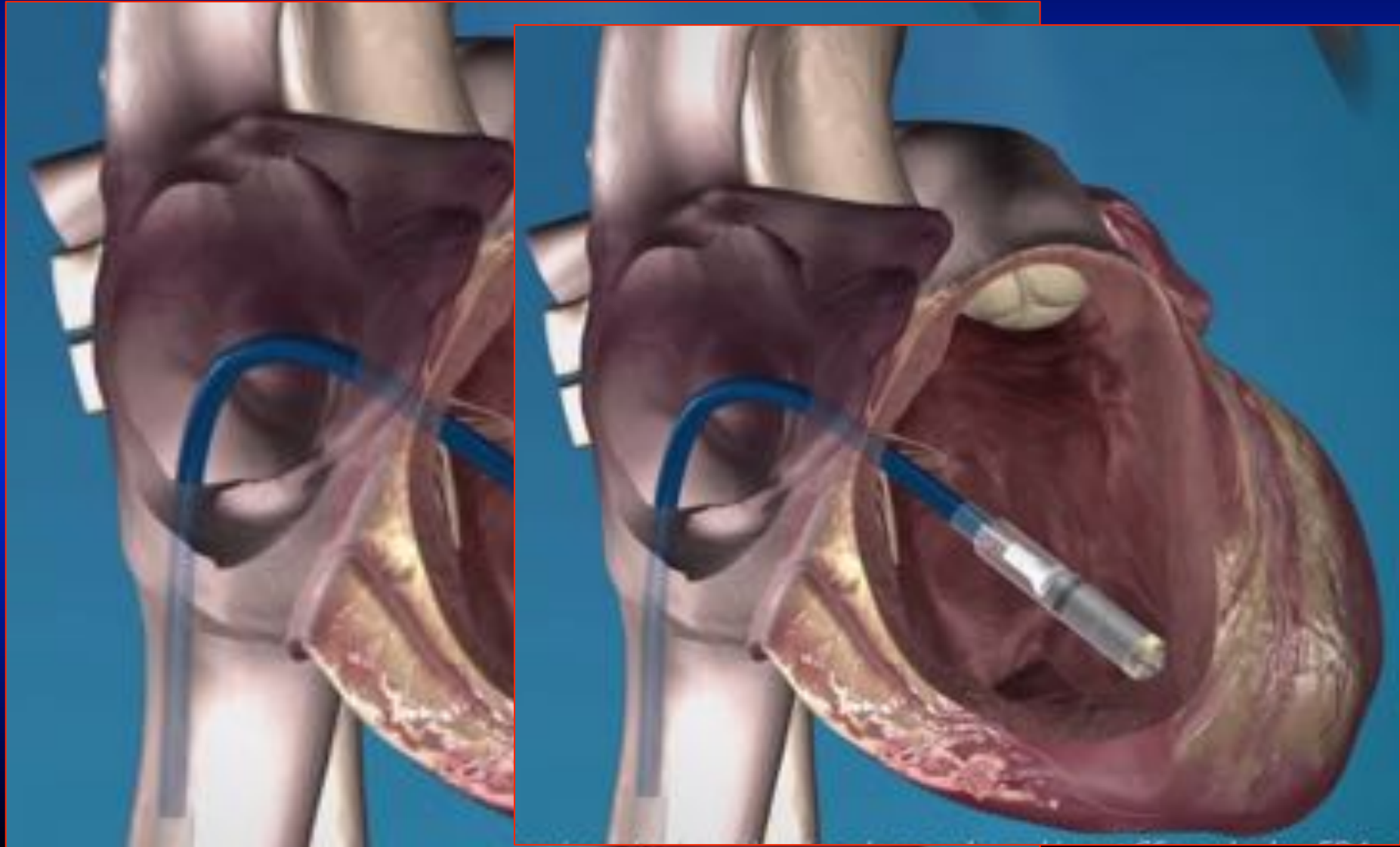
27 French outer diameter introducer

Micra (Medtronic)



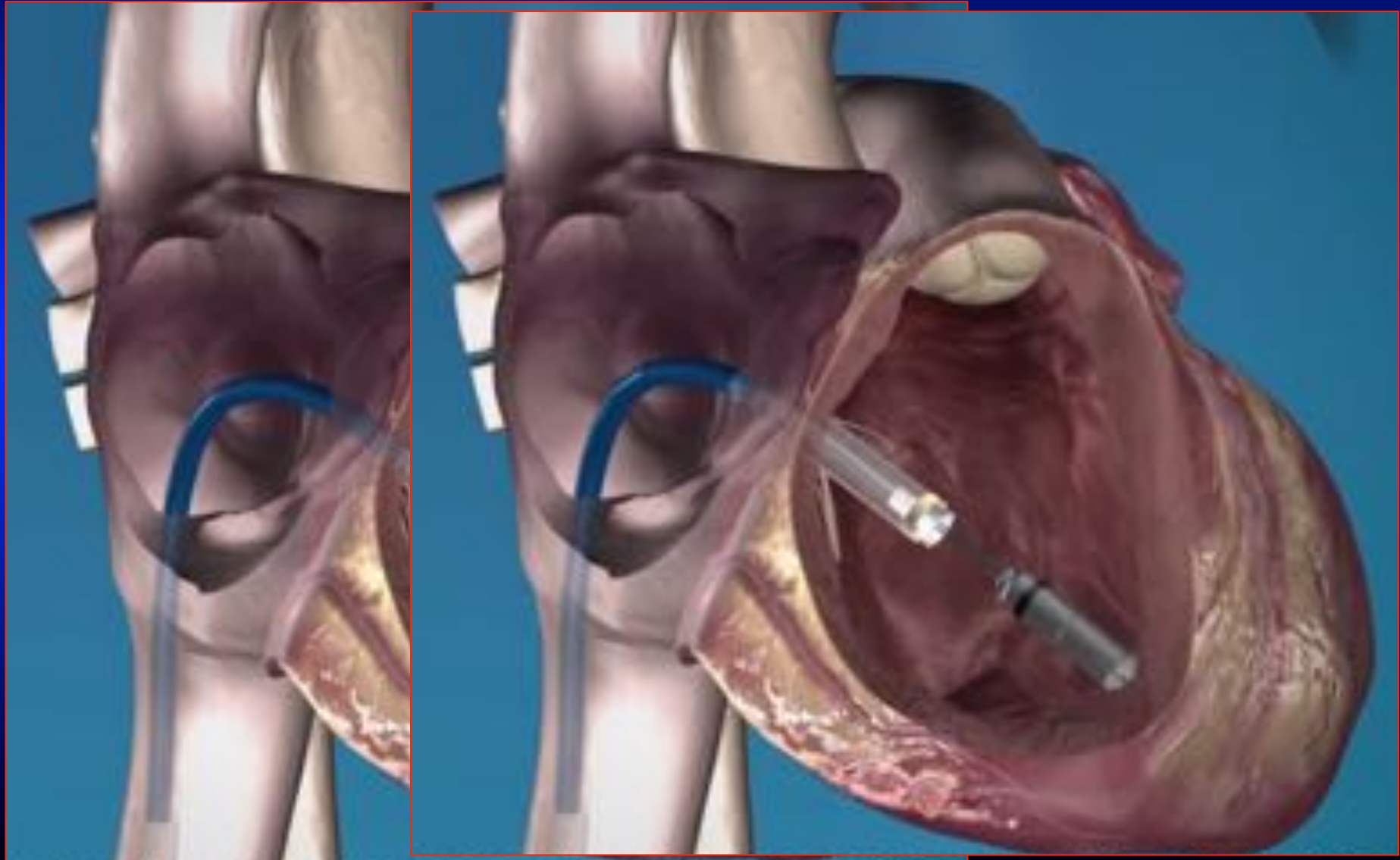


Micra (Medtronic)



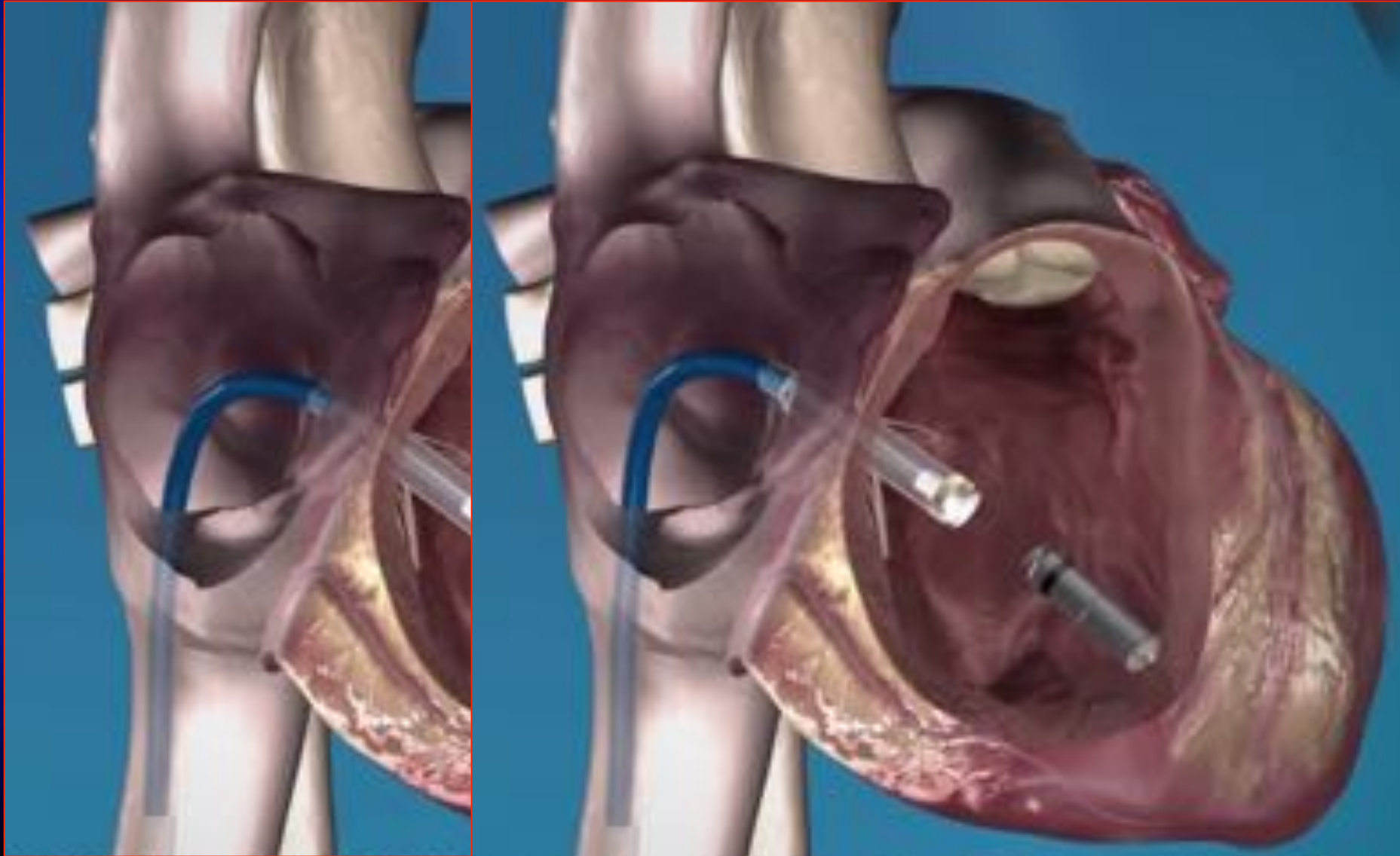


Micra (Medtronic)



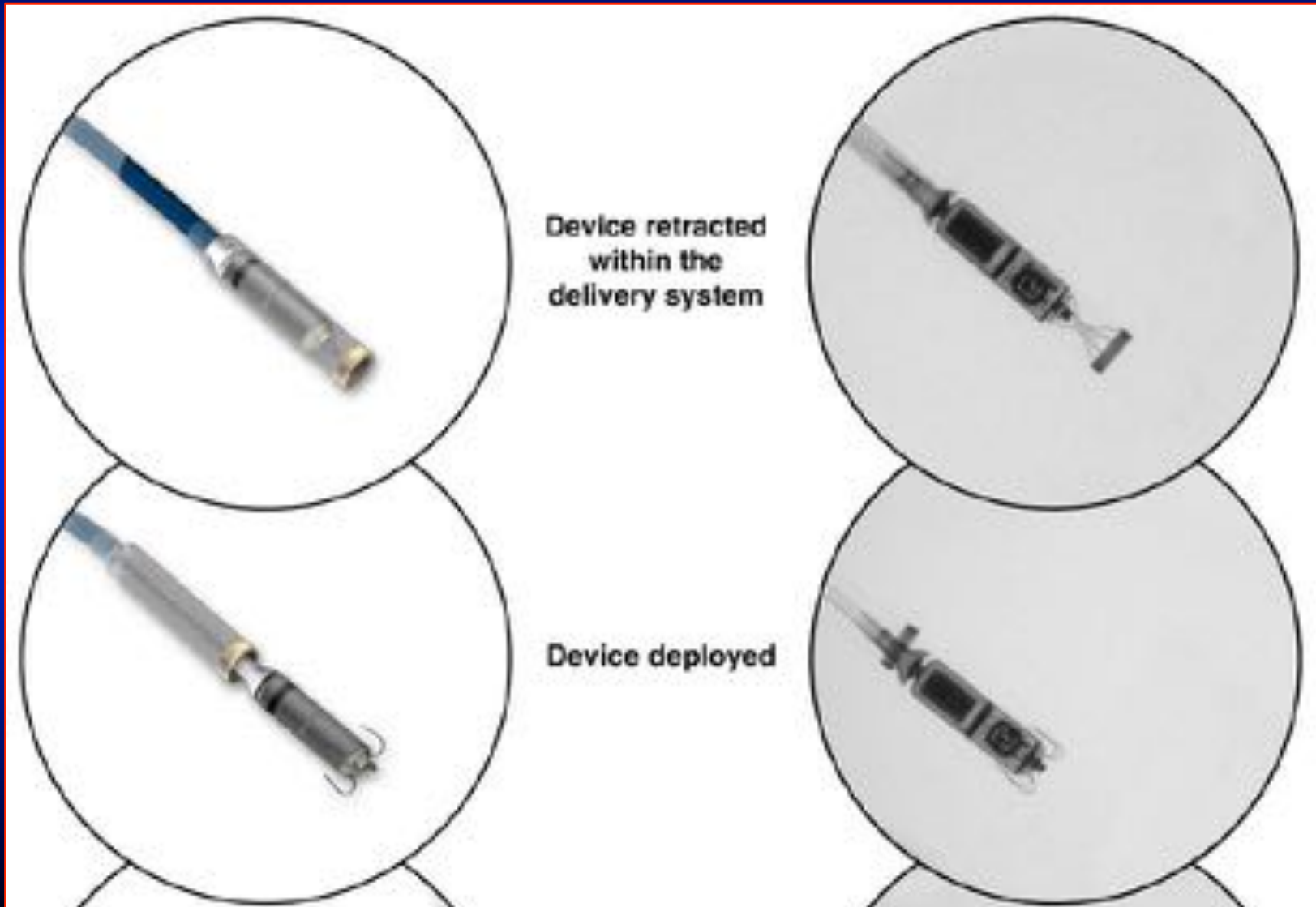


Micra (Medtronic)





Micra (Medtronic)





First Data from Micra®

Implant attempted ($n = 140$)

Received TPS ($n = 140$)

Did not receive TPS ($n = 0$)



Follow-up

Death ($n = 1$)

Lost to follow-up ($n = 0$)

Discontinued intervention ($n = 0$)



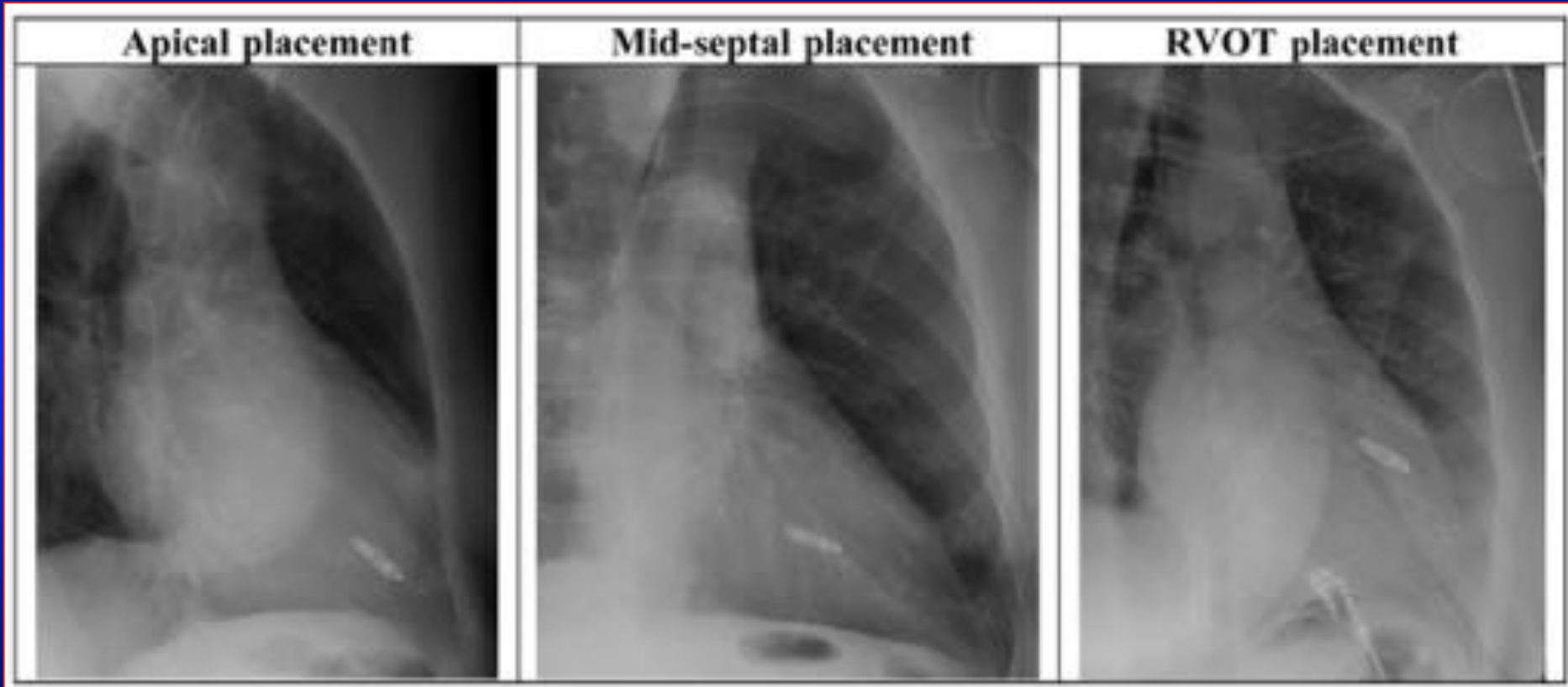
Analysed for early performance objectives

Safety ($n = 140$)

Three-month efficacy ($n = 60$)



First Data from Micra®

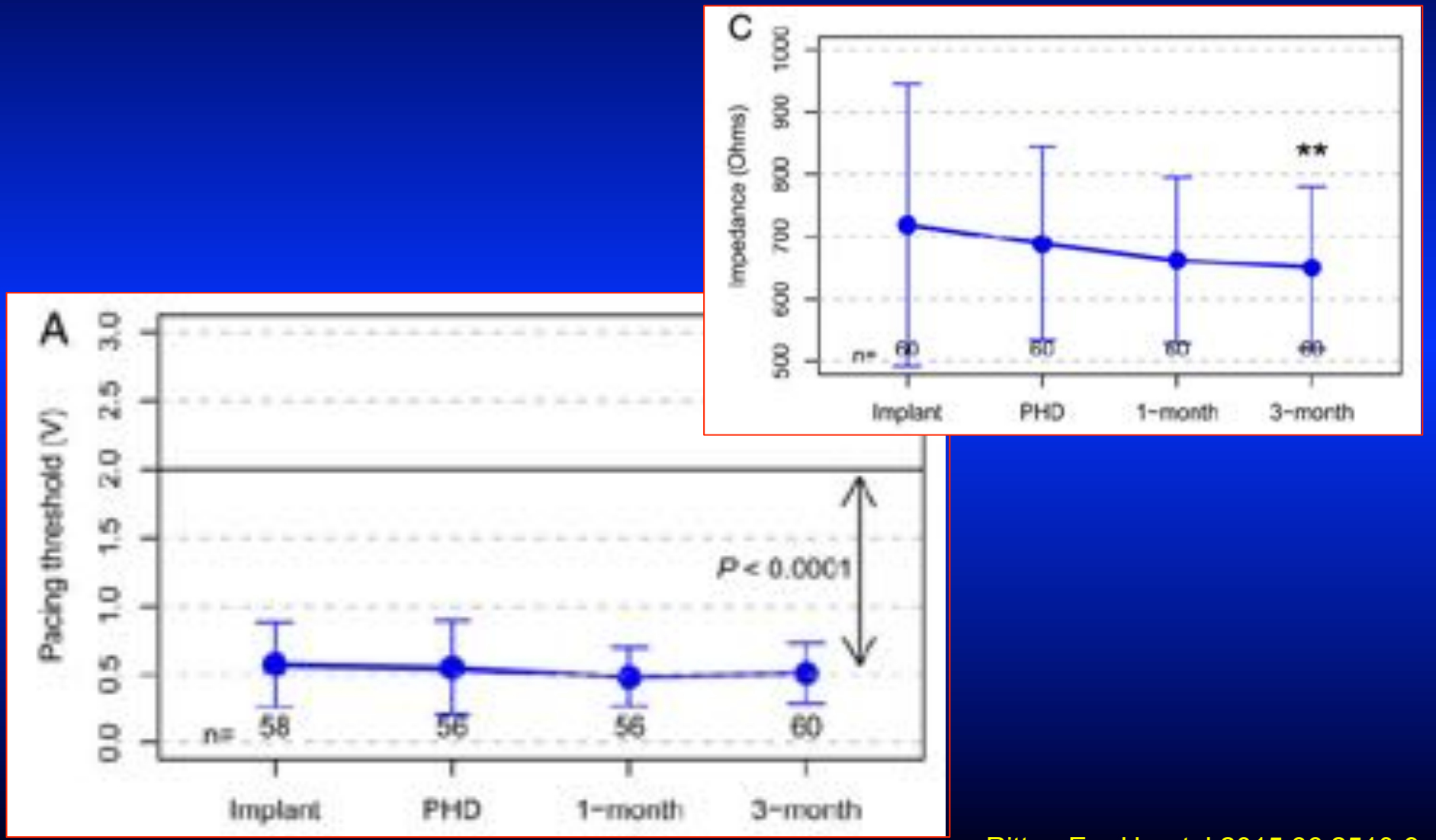




First Data from Micra®

30 total related adverse events		Resulted in death, re-operation, or hospitalization?	Total event rate, n (%) 30 (26 patients, 18.6%)
Dysrhythmias	Transient atrioventricular block	No	4 (4, 2.9)
	Right bundle branch block	No	2 (2, 1.4)
	Ventricular tachycardia	No	2 (2, 1.4)
	Ventricular fibrillation	No	1 (1, 0.7)
Events at device placement site	Pericardial effusion without tamponade	1 hospitalization prolonged >48 h	1 (1, 0.7)
	Acute myocardial infarction	for both events in same patient	1 (1, 0.7)
	Pericarditis	No	2 (1, 0.7)
	Non-cardiac chest pain	No	1 (1, 0.7)
	Angina pectoris	No	2 (2, 1.4)
Events at groin puncture suite	Arterial pseudoaneurysm	1 hospitalization prolonged >48 h	2 (2, 1.4)
	Incision site haemorrhage	No	3 (3, 2.1)
	Incision site haematoma	No	2 (2, 1.4)
	Incision site pain	No	1 (1, 0.7)
	Incisional drainage	No	1 (1, 0.7)
	Vaso-vagal presyncope	No	2 (2, 1.4)
Other	Dysuria following procedure	No	1 (1, 0.7)
	Osteoarthritis following procedure	No	1 (1, 0.7)
	Back pain during procedure	No	1 (1, 0.7)

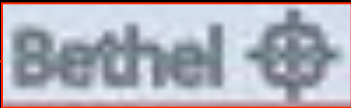
First Data from Micra®



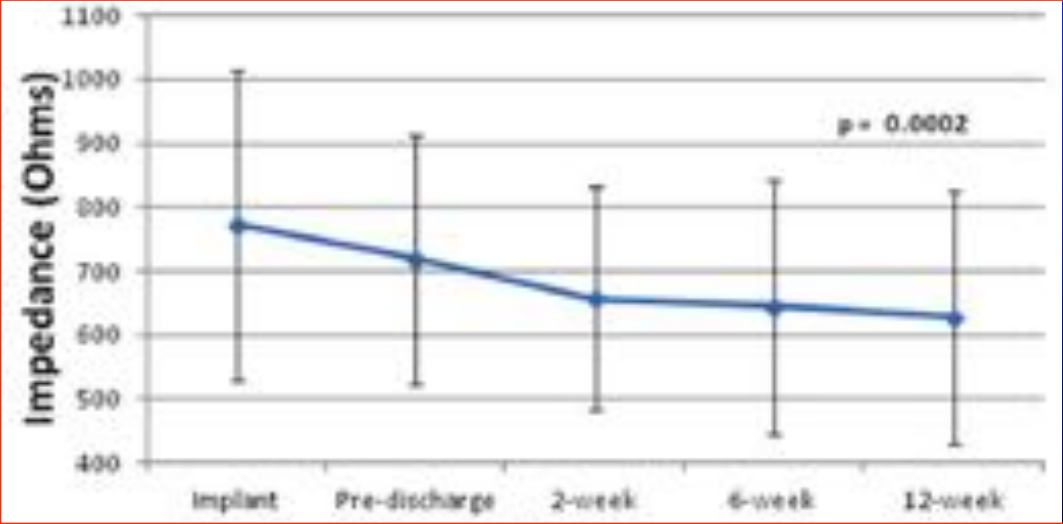
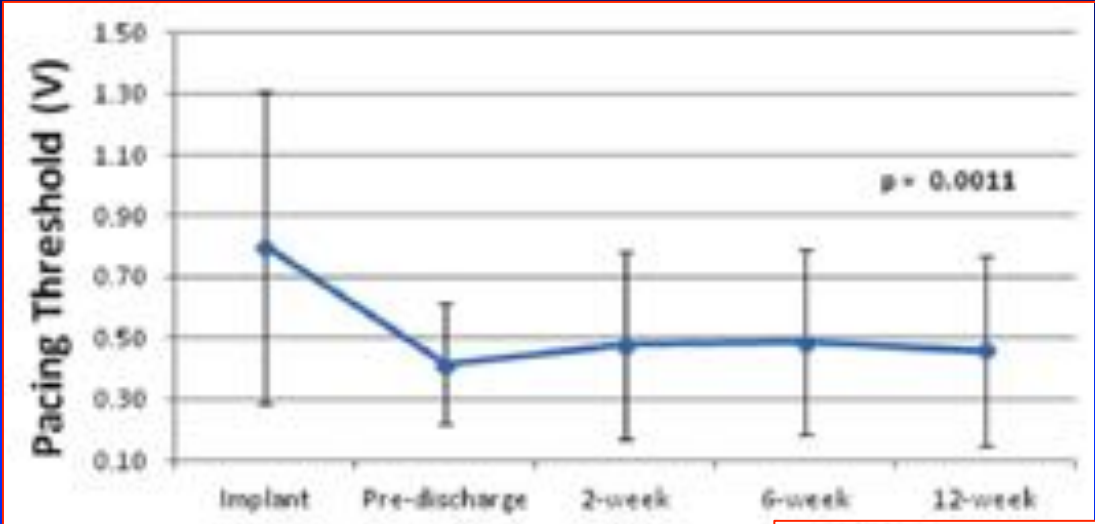


Micra Study

- ◆ Single-arm, multi-center global clinical trial
- ◆ Up to 780 patients
- ◆ At ~50 centers
- ◆ Primary Outcomes at 6 months:
 - Safety: Major complication-free rate
 - Efficacy: Low and stable pacing capture thresholds
- ◆ Initial results Expected:
 - First 60 patients followed to 3 months
 - Expected in 2nd half of 2014



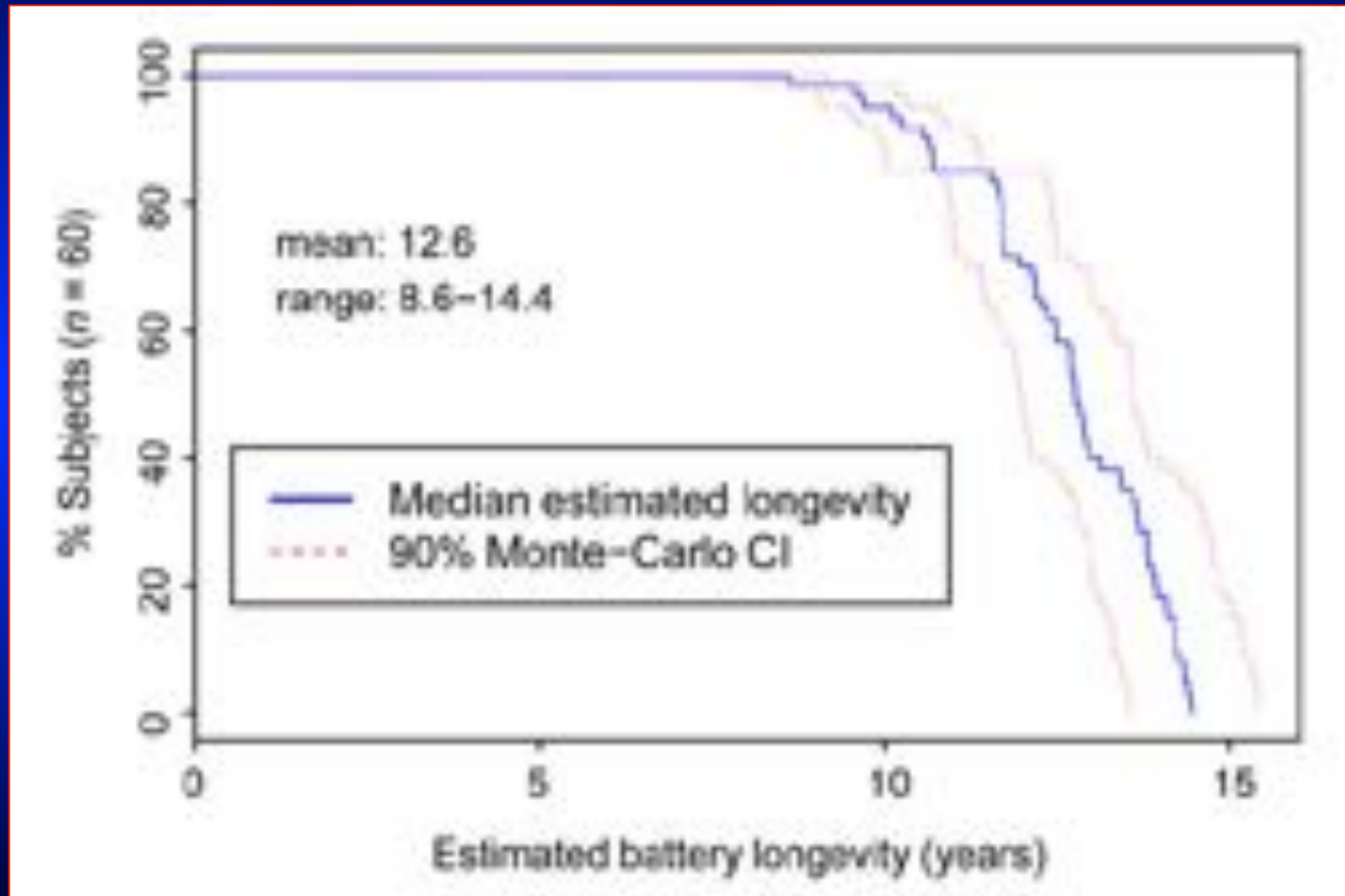
LEADLESS-Trial



% 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



First Data from Micra®





**Thank you very
much for your
attention!**