



Spedali Civili
Brescia

Extravascular ICD: dalla teoria alla pratica clinica

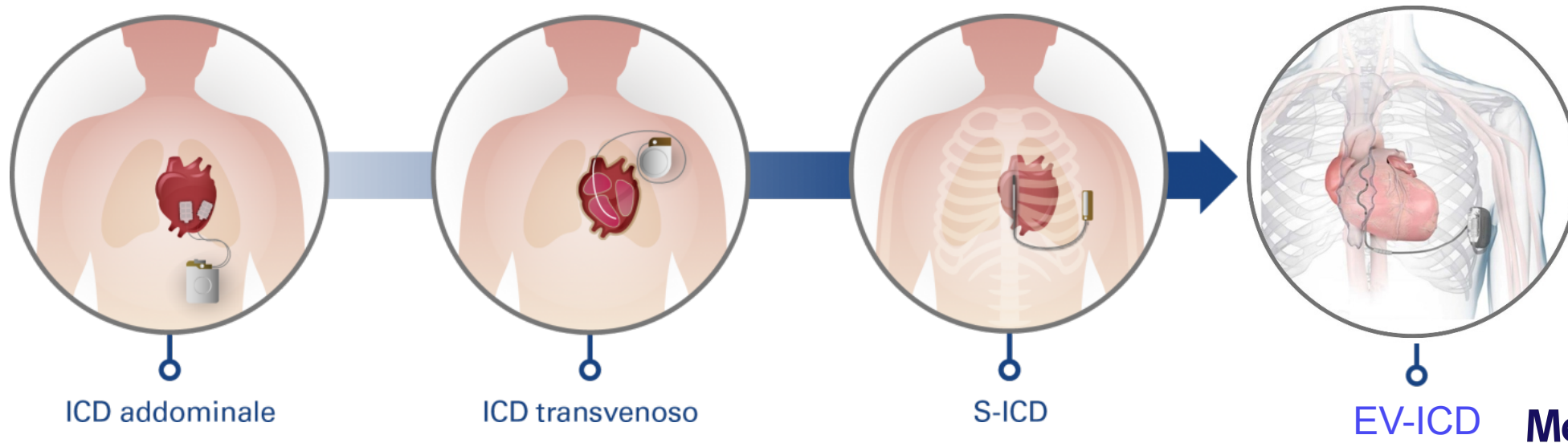
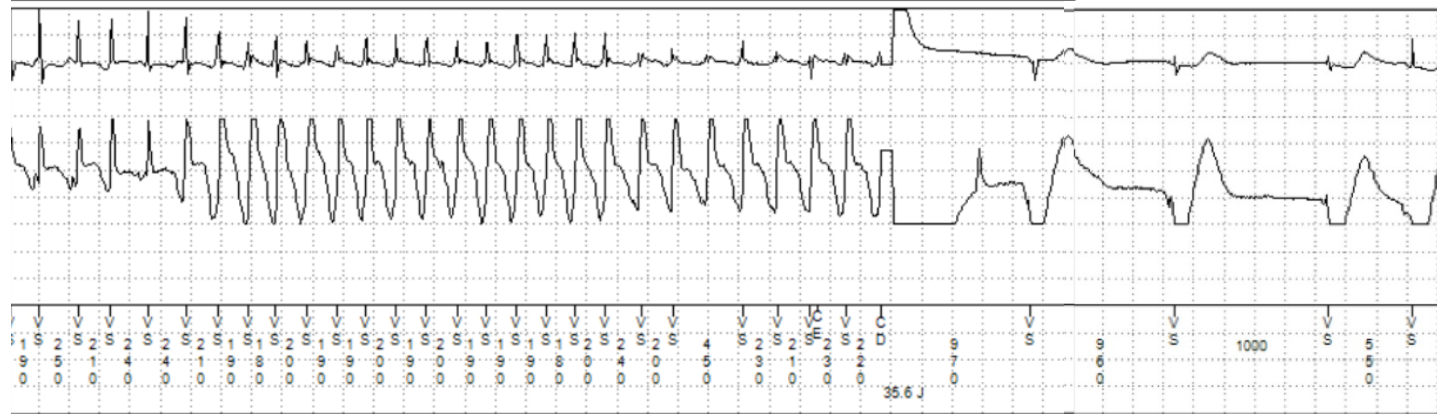
Prof. Antonio Curnis, MD

*Electrophysiology and Cardiac Pacing Unit
Spedali Civili Hospital - University of Brescia*

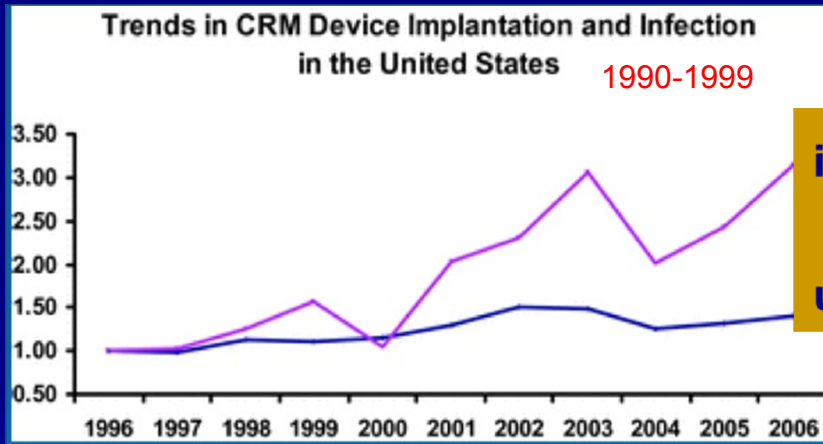
PLACE Roma 27-6-2026

MORTE CARDIACA IMPROVVISA

Trattamento – defibrillatore cardiaco impiantabile
(ICD)

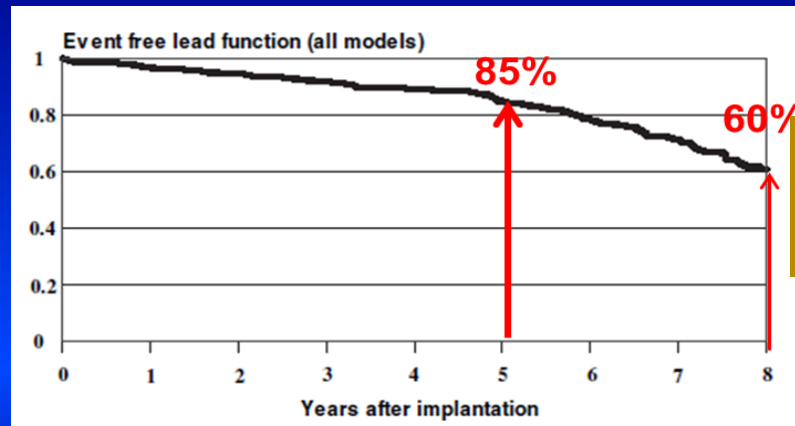


Implant's complications



infections : + 124% ($P < 0.001$ for trend)

use : + 42% ($P < 0.001$ for trend)



PM 28% at 10 years

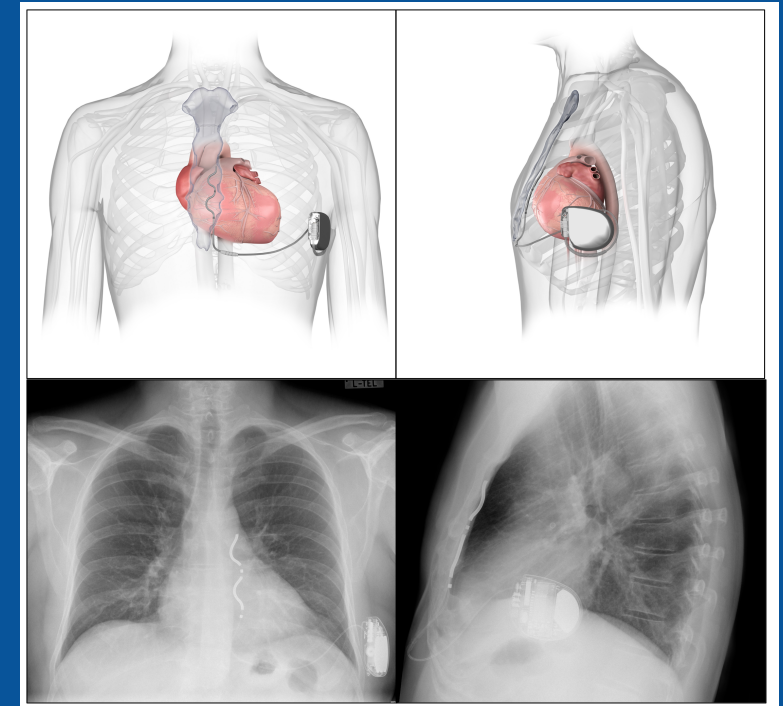
ICD 40% at 8 years

Venous trombosis

15 - 40%

Extravascular ICD (EV-ICD)

- Transvenous ICDs have been the gold standard for sudden cardiac death prevention
- Placing leads outside the heart/vasculature may reduce complications and increase ICD accessibility
- Subcutaneous ICDs were developed to overcome risks of conventional transvenous ICDs, but still have limitations:
 - reduced bradycardia pacing support
 - no anti-tachycardia pacing (ATP)
 - high defibrillation energy
 - large size and comfort issues
 - reduced battery longevity
 - Patient not always suitable



History of EV-ICD Development

- **2012: R&D started after early feasibility work evaluating pacing**
 - Optimize pacing, evaluate sensing, assess defibrillation energy, characterize anatomy
- **5: First human trials for defibrillation (ASD) and pacing (SPACE)**
- **2016 Verify therapy parameters and develop procedure guidance**
- **2017: ASD2 study**
 - Validate S-shaped lead design, gather info for algorithm design, insights for procedure
- **2018: Pilot study**
 - Evaluate performance in chronic setting
- **2022: Pivotal study**
 - Clinical confirmation in real-world application

IMPIANTO EV-ICD



ORIGINAL ARTICLE

Efficacy and Safety of an Extravascular Implantable Cardioverter–Defibrillator

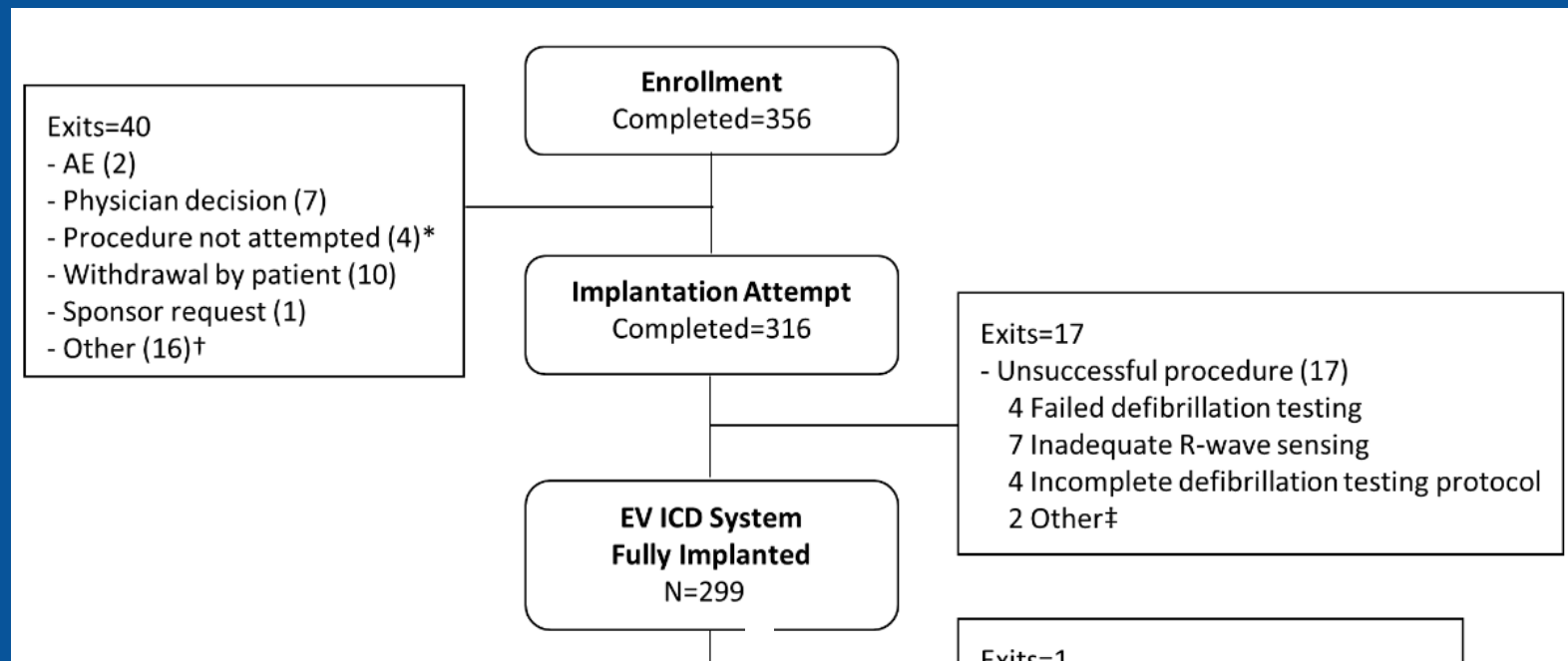
P. Friedman, F. Murgatroyd, L.V.A. Boersma, J. Manlucu, D. O'Donnell, B.P. Knight, N. Clémenty, C. Leclercq, A. Amin, B.P. Merkely, U.M. Birgersdotter-Green, J.Y.S. Chan, M. Biffi, R.E. Knops, G. Engel, I. Muñoz Carvajal, L.M. Epstein, V. Sagi, J.B. Johansen, M. Sterliński, C. Steinwender, T. Hounshell, R. Abben, A.E. Thompson, C. Wiggenhorn, S. Willey, and I. Crozier, for the Extravascular ICD Pivotal Study Investigators*

Conclusions

In this prospective global study, we found that extravascular ICDs were implanted safely and were able to detect and terminate induced ventricular arrhythmias at the time of implantation. (Funded by Medtronic; ClinicalTrial.gov number, [NCT04060680](#).)

EV-ICD – Pivotal Study Overview

- 356 pts. with class I or IIa ICD indication enrolled in 46 centres (55 implanters) in 17 countries
- Implant success 99.7% (315/316 pts.), median implant time 66 minutes
- Follow-up 10.6 months



The EV ICD defibrillation efficacy at implant is 98.7% in the EV ICD Pivotal Clinical study¹

EV ICD ¹	Transvenous ICDs ²⁻⁵	S-ICD ⁶
98.7%	90.5 %–93.0%	100.0%

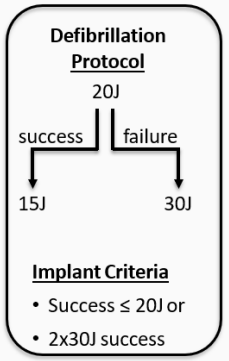
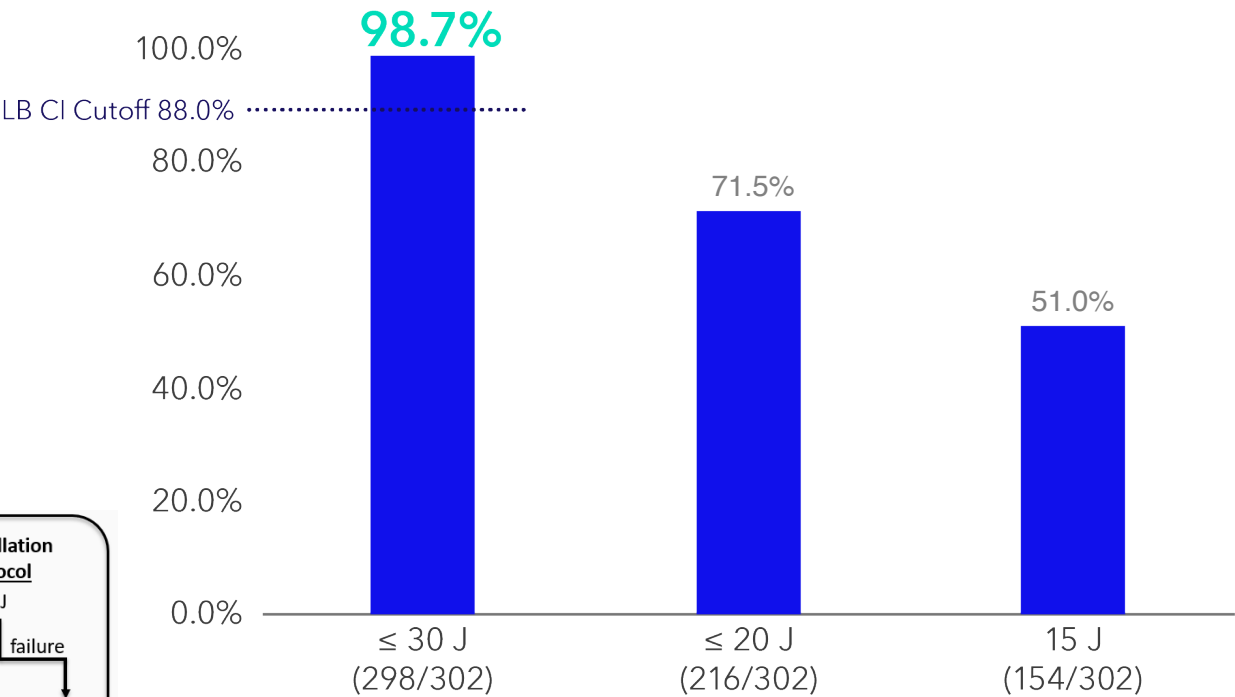
EV ICD defibrillation efficacy at implant was 98.7%¹

No statistical difference was observed in the implant defibrillation success by BMI tertiles (ranging from 17.9 to 45.6 kg/m²)⁷

100% (36/36) patients passed 6-month chronic DFT testing¹

100% (18/18) conversion of discrete[†] spontaneous episodes through average 10.6-month follow-up¹

EV ICD Patients with Successful Defibrillation at Implant (%)¹



Implant defibrillation success rate: 98.7%
One-sided 97.5% CI: 96.6%; P < 0.001 vs. performance of 88%

[†]Discrete episodes are defined as less than or equal to two events within 24 hours.
¹ Friedman P, et al. *N Engl J Med*. 2022;387:1292-1302.
² Michowitz Y, et al. *Europace*. 2011;13:683-688.
³ Leong-Sit P, et al. *Am Heart J*. 2006;152:1104-1108.
⁴ Pires LA, et al. *J Cardiovasc Electrophysiol*. 2006;17:140-145.
⁵ Healey JS, et al. *Lancet*. 2015;385:785-791.
⁶ Weiss R, et al. *Circulation*. 2013;128:944-953.
⁷ Leclercq C, et al. Efficacy and Safety of the Extravascular Implantable Cardioverter Defibrillator by Body Habitus. Late Breaking Clinical Trial Presentation at APHRS 2022. Singapore and online.

EV ICD freedom from major complication rate in-line with S-ICD IDE and transvenous ICD studies

Medtronic EV ICD Pivotal Study

92.6% of patients (Kaplan-Meier estimate) free from major complication at 6 months ($p < 0.001$ compared to the safety performance goal of 79%)¹

- **S-ICD IDE study: 92.1%**²
- **Transvenous ICD studies: 85.4%-93.8%**³⁻⁸

Adverse events to 6 months; 25 events in 23 patients

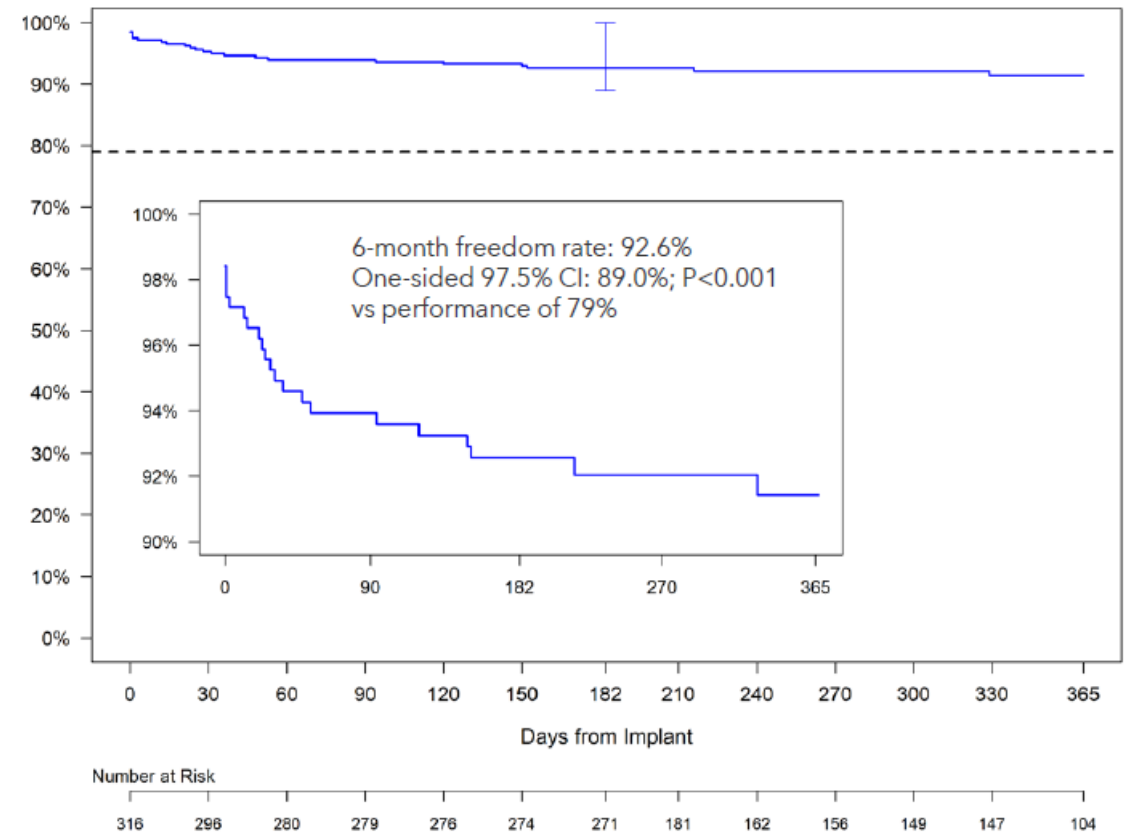
- System revision required: 18
- No revision required: 7

No major intraprocedural or unique complications due to EV ICD

No reports of mediastinitis, sepsis, or endocarditis related to EV ICD

No procedure or system related deaths

Freedom from Major Complication (%)



1. Friedman P, et al. NEJM. In press August 28, 2022. 2. Weiss R, et al. Circulation. 2013;128:944-53. 3. Bardy GH, et al. NEJM. 2005;352:225-37. 4. Sweeney MO, et al. Heart Rhythm. 2010;7:1552-60. 5. Curtis AB, et al. NEJM. 2013;369:579. 6. Linde C, et al. JACC. 2008;52:1834-43. 7. Gold MR, et al. JACC. 2015;65:2581-8. 8. Auricchio A, et al. Heart Rhythm. 2015;12:926-36.

Medtronic EV ICD system is not commercially available and is under clinical evaluation.

EV-ICD Pivotal Study – Other Endpoints

Appropriate therapies:

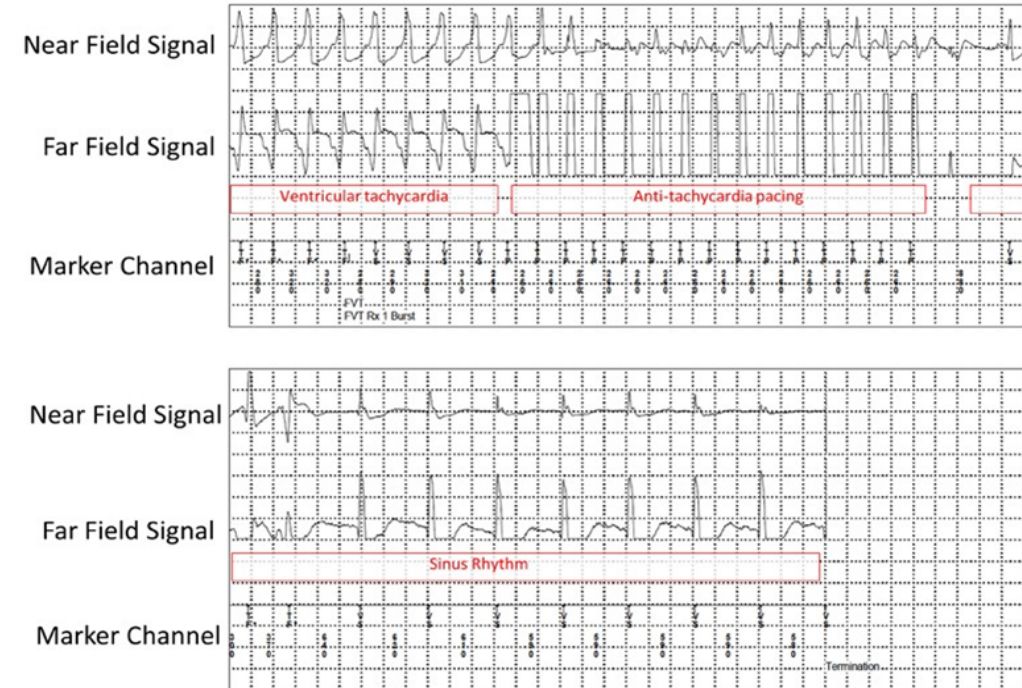
- 100% (18/18 episodes) events successfully treated by shock
- ATP terminated 70% (32/46, 10 pts.) monomorphic VT episodes
- Chronic defibrillation testing: 100% successful (36/36 pts.)

Inappropriate shocks:

- 29 out of 299 pts. (9.7%, 81 episodes) received inappropriate shocks after 10.6 months
 - P-wave oversensing (34), lead noise (19), T-wave oversensing (11), AF/Afl (10), EMI (4)
 - Decrease in P-wave oversensing from 28 to 6 episodes (1st vs 2nd half of study) → **80% reduction**

Pacing:

- Pacing threshold: $4.9 \pm 2.0V$
- Successful at implant: 98.3% of pts.



Learning:

In the first half of the study we had to stop and enroll due to Covid for a certain period of time and then studied all the data P wave at implants.

They stressed that P wave must be 0.2 mV (in the first period it was not so emphasized)

EV-ICD Pivotal Study – Major Complications

25 major complications in 23 pts.

Most commonly lead dislodgement: 10 events in 9 pts → we have seen that a common issue was the fact that anchoring sleeve was not tightly fixated to the lead or the tissue

A learning that we will implement in the training

Table 2. Summary of Major Complications in Patients with an Implantation Attempt through 6 Months.

Event Type	Death	Permanent Loss of Defibrillation Function*	Hospitalization	Hospitalization Prolonged by ≥48 Hours	System Revision	Total	
			no. of events†			no. of events	no. of patients with event (%)‡
Procedure-related only	0	0	7	1	6	9	9 (2.8)
Hemorrhage at implantation site	0	0	0	0	1	1	1 (0.3)
Infection at implantation site	0	0	2	0	2	2	2 (0.6)
Pain at implantation site	0	0	0	1	0	1	1 (0.3)
Impaired healing at incision site	0	0	1	0	0	1	1 (0.3)
Postoperative wound infection	0	0	4	0	3	4	4 (1.3)
System-related only	0	0	6	0	4	7	7 (2.2)
Inappropriate shock delivery	0	0	3	0	0	3	3 (0.9)
Lead dislodgement	0	0	3	0	4	4	4 (1.3)
System- and procedure-related	0	1	1	2	8	9	8 (2.5)
Device software–hardware interaction	0	1	0	0	1	1	1 (0.3)
Device placement issue	0	0	0	0	1	1	1 (0.3)
Lead dislodgement	0	0	1	2	5	6	5 (1.6)
Discomfort at medical device site	0	0	0	0	1	1	1 (0.3)
Total major complications§	0	1	14	3	18	25	23 (7.3)

Antitachycardia pacing (ATP)

Aurora EV-ICD™ is the only available extravascular ICD to offer ATP

As with Medtronic transvenous ICDs, ATP therapy in Aurora includes Burst and Ramp pacing pulses, each with a programmable number of sequences. In the EV ICD Pivotal Clinical study, ATP successfully terminated 70% of episodes (32 of 46), even with an extended detection interval (VF NID = 30/40).¹ This is in the range of the ATP efficacy reported in transvenous ICD publications, 52% to 87%.²⁻⁵

Aurora EV-ICD has three pacing vector options for ATP:

- 1 Coil 2 to coil 1
- 2 Ring 1 to coil 2
- 3 Ring 1 to ring 2

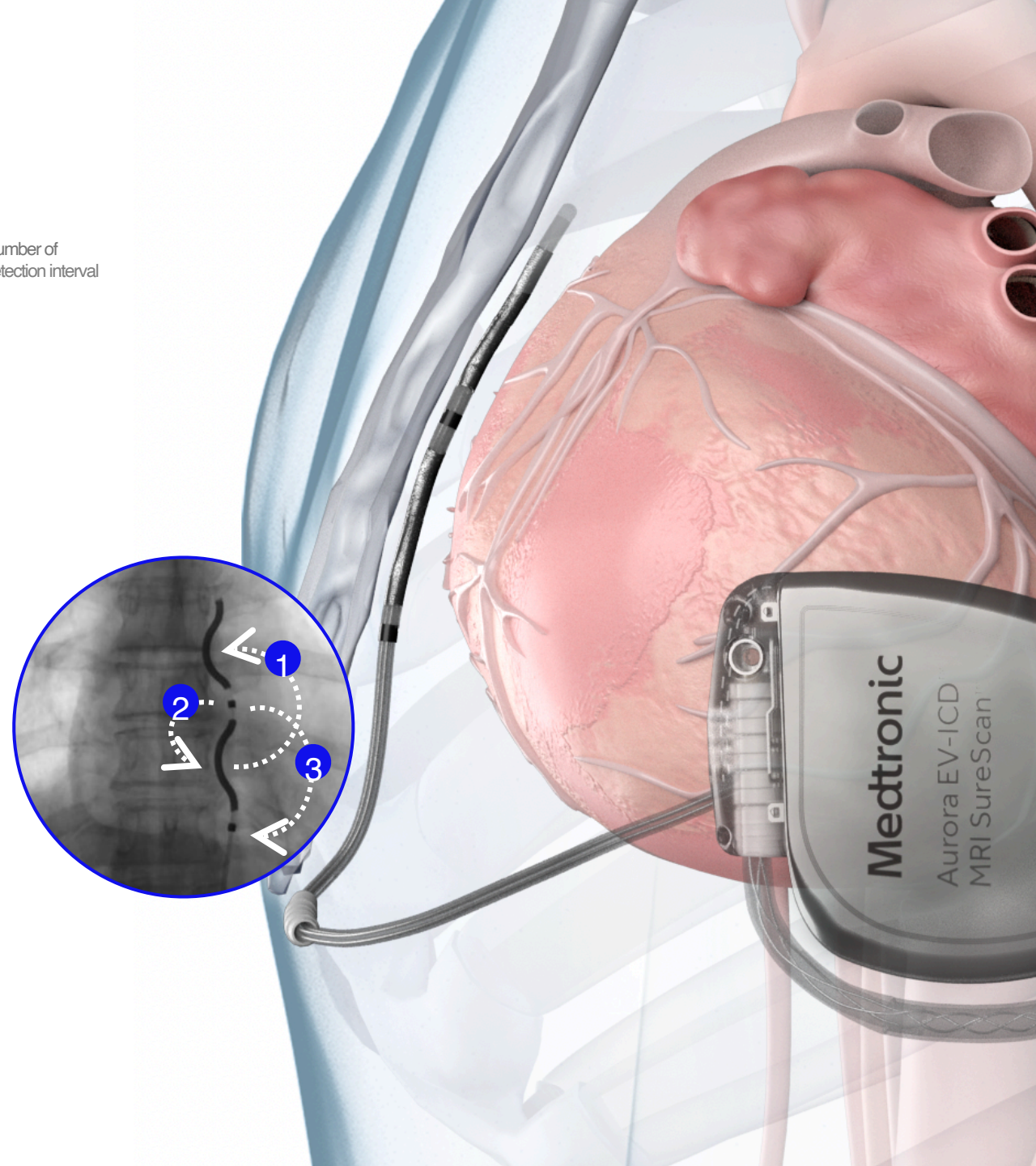
¹ Friedman P, et al. *NEJM*. 2022;386(12):1292-1302.

² Arenal A, et al. *Europace*. 2016;18(17):1719-1725.

³ Luo S, et al. *Heart Rhythm*. 2009;6(3):334-339.

⁴ Sami D, et al. *Heart Rhythm*. 2009;6(10):150-157.

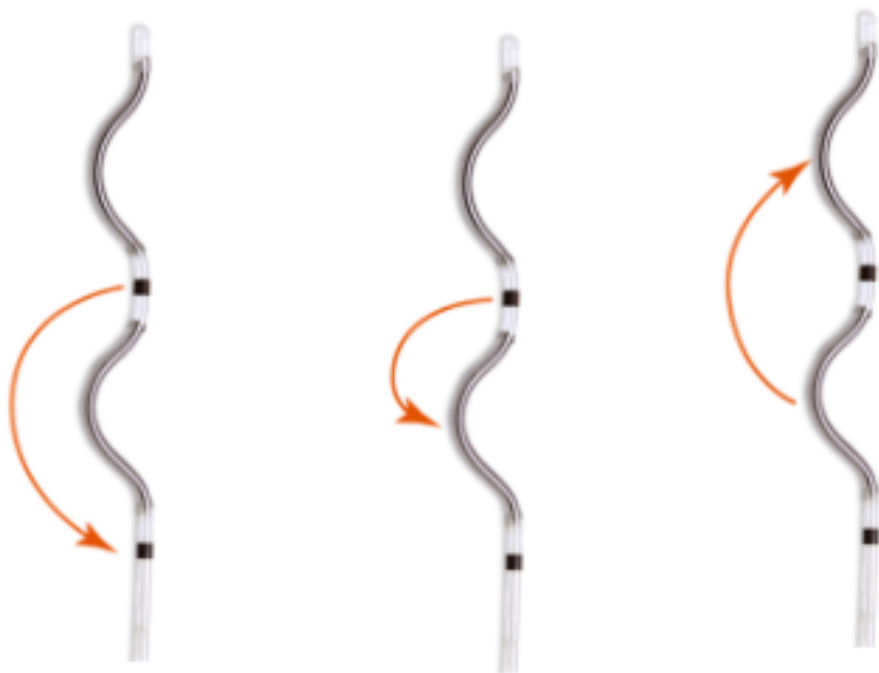
⁵ Schuger C, et al. *Heart Rhythm*. 2001;15:359-363.



System overview

Pacing and sensing vector options

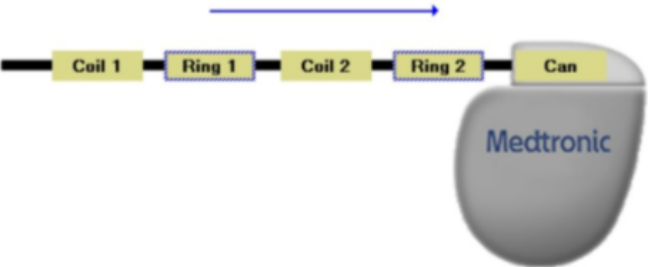
Pacing vector options



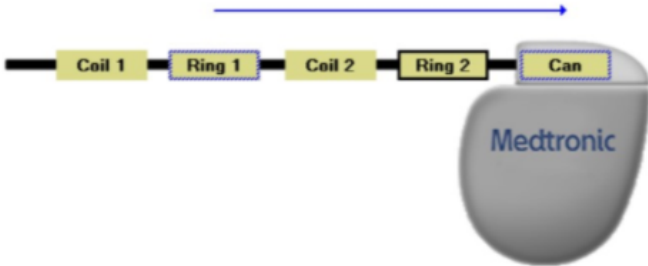
Ring 1 to Ring 2 Ring 1 to Coil 2 Coil 2 to Coil 1

Sensing vector options

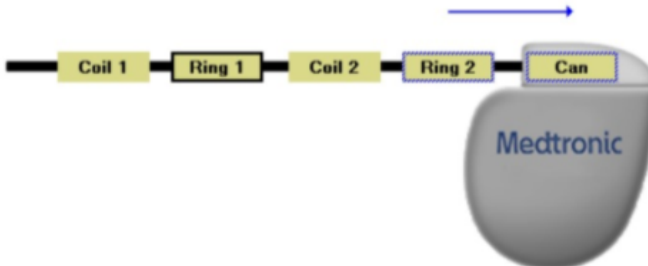
Ring 1 to Ring 2



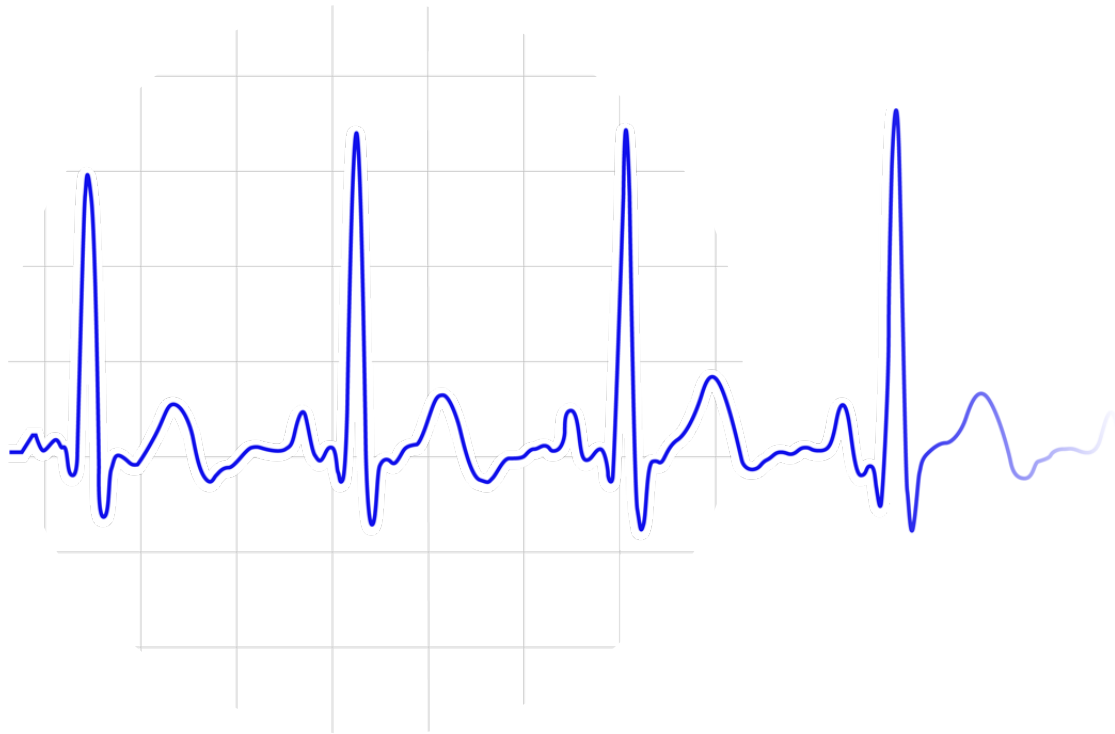
Ring 1 to Can



Ring 2 to Can



Post-shock pacing



Aurora EV-ICD™ can be programmed to deliver temporary post-shock pacing following a defibrillation or cardioversion therapy, as there may be a temporary bradycardia or asystole after the heart receives a high-voltage therapy

- **Paces at 40 bpm for up to 30 seconds**
- Can be enabled before performing defibrillation threshold testing

Diagnostics — to provide insights for patient management

Aurora EV-ICD™ stores episodes that it does and does not treat.

This includes:

- Non-sustained VTs in all therapy zones
- Supraventricular tachycardia (SVT) episodes with heart rates in the monitored and treated therapy zones
- Stored episode EGM
- Rate histograms
- Cardiac Compass™ features:
 - Therapy
 - Day/night heart rate
 - % pacing
 - Heart rate variability
- Remaining longevity estimator

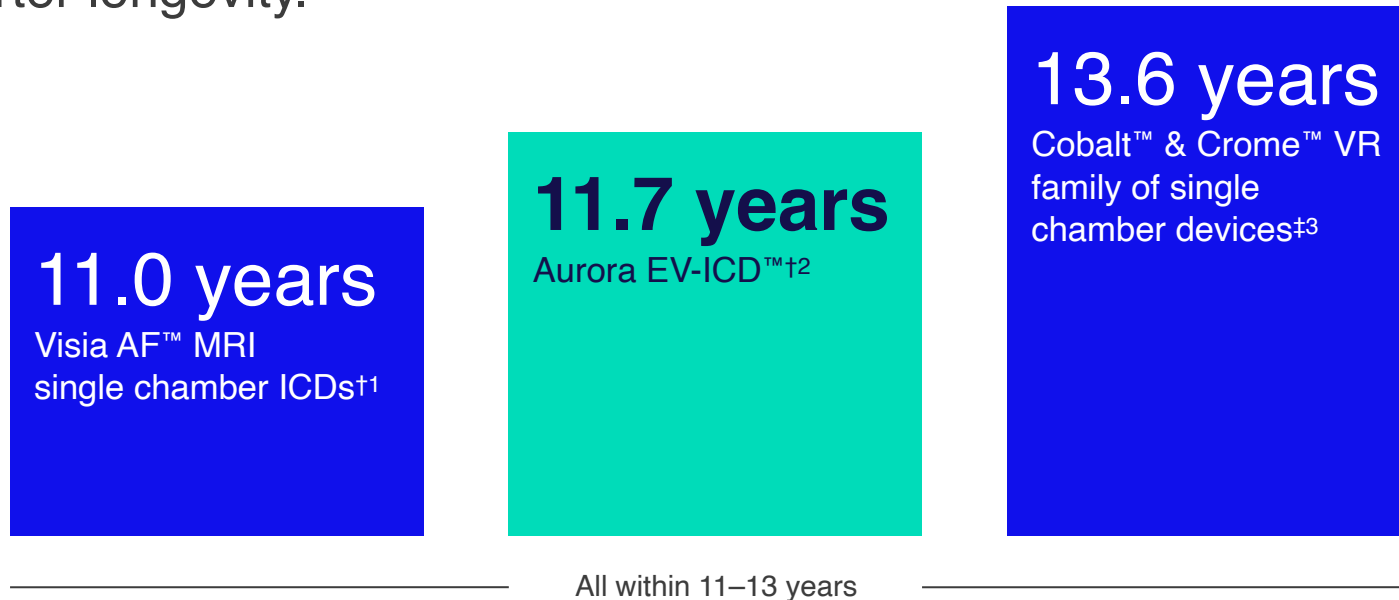
Aurora EV-ICD diagnostics include:



Similar projected longevity while maintaining device size and exclusive PhysioCurve™ design

Projected longevity is similar to other Medtronic single chamber ICDs

Greater device longevity can result in fewer device replacements and lower total product costs than shorter longevity.



[†]Projected longevity for Visa AFMIRI and Aurora EVACD are based on WM with 0% pacing from the manuals of the models listed.

*Mean longevity projection based on median CareLink™ settings in the Cobalt manual. This value should not be interpreted as precise numbers. Individual patient results may vary based on their specific programming and experience.

1. Medtronic Veia AF-MPI™ VR Site Scan™ DVEB2D4 device manual M980310A001A. Available at: https://manuals.medtronic.com/content/dam/manuals/bdm/M980310A001A_view.pdf. Accessed November 2022.

²Medtronic Aurora EVICDMRI SureScan Model DVEA354 device manual.

³Medtronic Cobalt™ XT VRI CD MRI SureScan™ Model DVP42D4 device manual.

PhysioCurve™ design

With its PhysioCurve design, the Aurora EV-ICD™ showed a 27% average reduction in tissue pressure relative to the subcutaneous ICD across the three implant locations modeled¹



- Tapered at the head and bottom of device to reduce skin pressure and promote patient comfort
- Smaller footprint for a smaller incision
- Same size (33 cm³) and shape as Medtronic transvenous ICDs (Cobalt™, Crome™, Visia AF MRI™, Evera MRI™)

¹Mathiesen D, et al. AHA Abstract 13385. *Circulation* 2021;144(A13385).



Performance of a Novel P-wave Oversensing Rejection Algorithm to Reduce Inappropriate Detections in the Extravascular ICD

Charles D. Swerdlow MD

Smidt Heart Center, Cedars Sinai Medical Center, CA

May 20, 2023

Xusheng Zhang PhD¹, Yuanzhen Liu MS¹, Saul Greenhut PhD¹, Yan Zhang MS¹, Lucas V.A. Boersma MD, PhD^{2,3}, Francis Murgatroyd FRCP⁴; on behalf of the EV ICD Pivotal Study Investigators.

¹Medtronic, Inc. Mounds View Minnesota, US; ²Cardiology Department of St. Antonius Hospital Nieuwegein Netherlands; ³Amsterdam University Medical Centers Amsterdam, Netherlands; ⁴King's College Hospital, London, England

EV-ICD Pivotal Study – Complications

- **Revisions:**

- 22 system modifications in 22 pts.
 - Explant without replacement in 8 pts.
 - Reasons: Lead dislodgement (9)
 - 15 lead explantation: all removed with manual traction without complications

- **Infection:**

- 13 system/procedure-related infections in 13 pts. (4.1%)
 - Medication with/without wound care (9)
 - System removal (4), all related to lateral device pocket
- No cases of mediastinitis, sepsis or endocarditis were reported
- Note: TYRX was used in 55 pts. (17.4%)

Sensing

Morphology

1 Alternating Amplitudes

2 R & R, P & P have Similar Amplitude

3 Morphology not like VT/VF

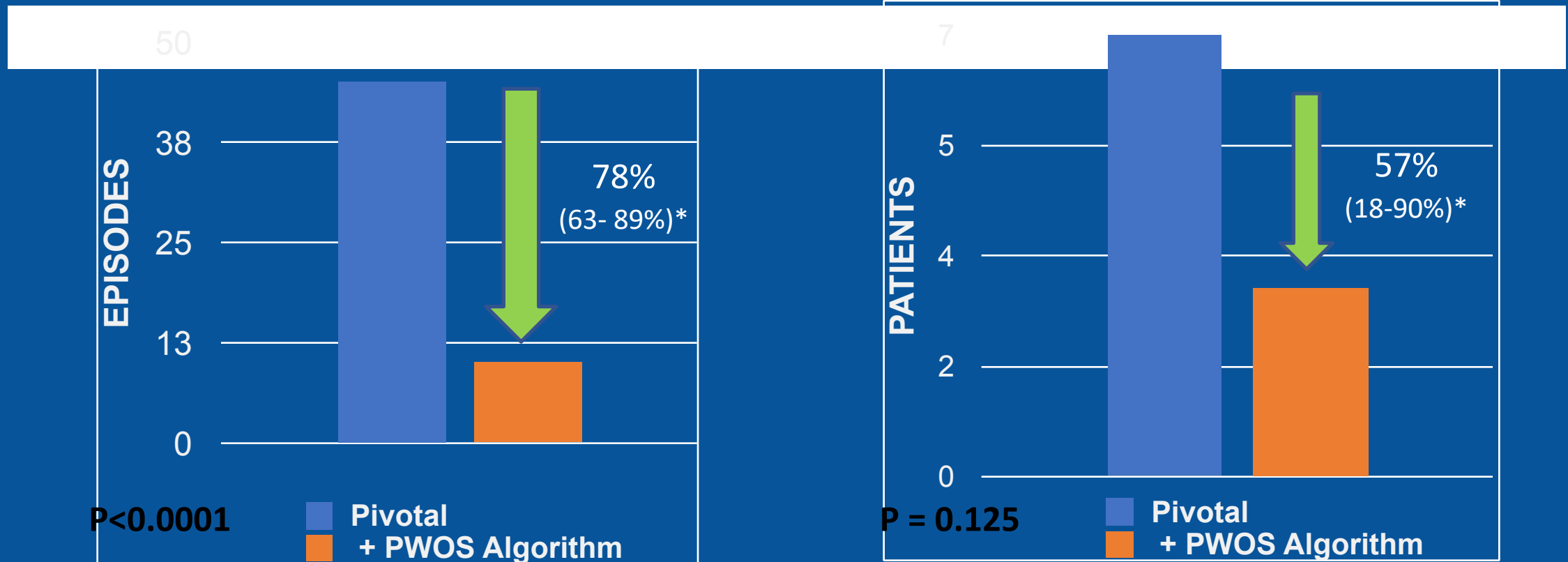
Sensing Markers

Pivotal (No PWOS Algorithm)

VF
VF Rx 1 Defib

N N N N N N

Effect of PWOS Algorithm on Inappropriate Detection of VT/VF due to P-Wave Oversensing

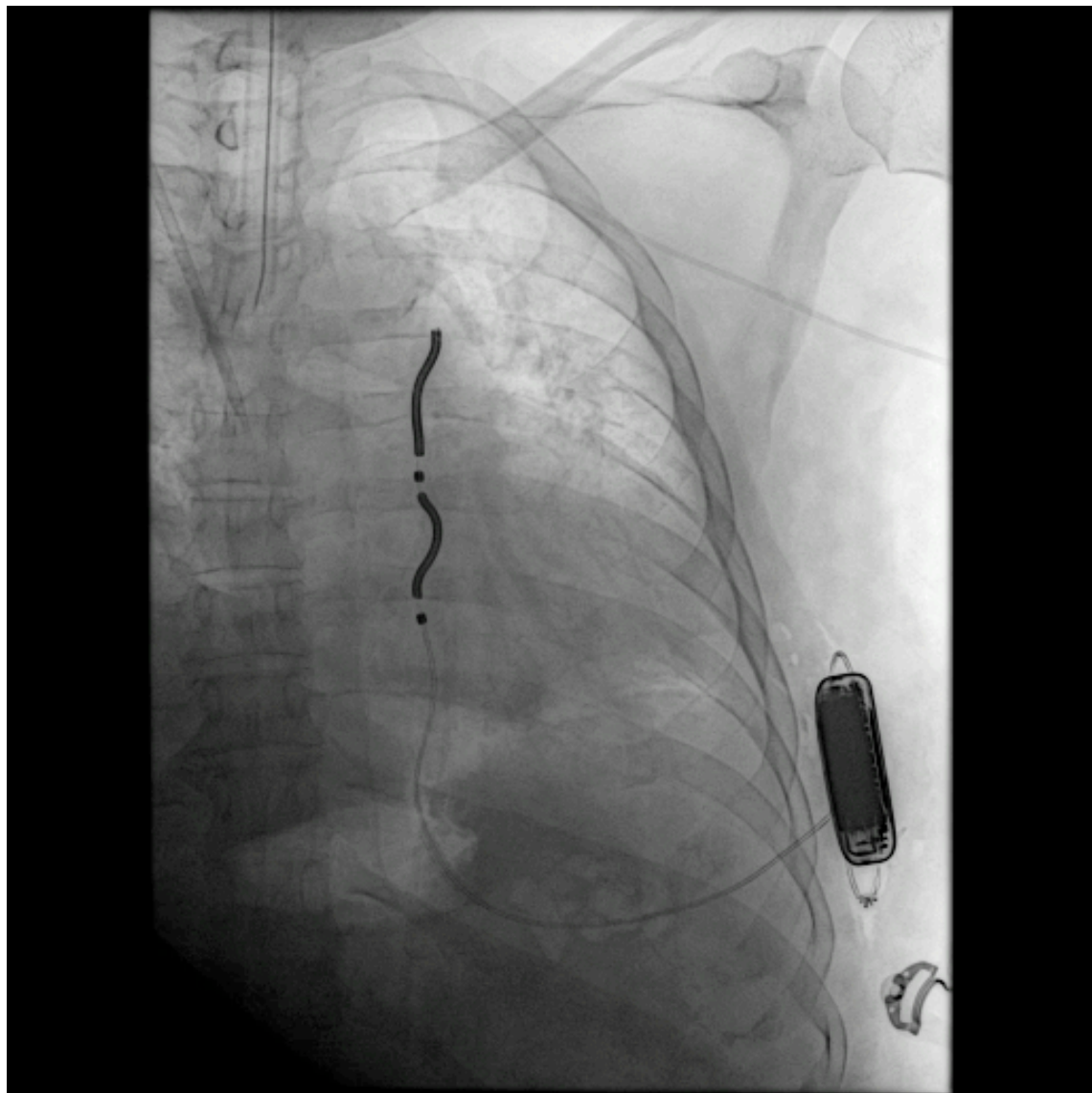
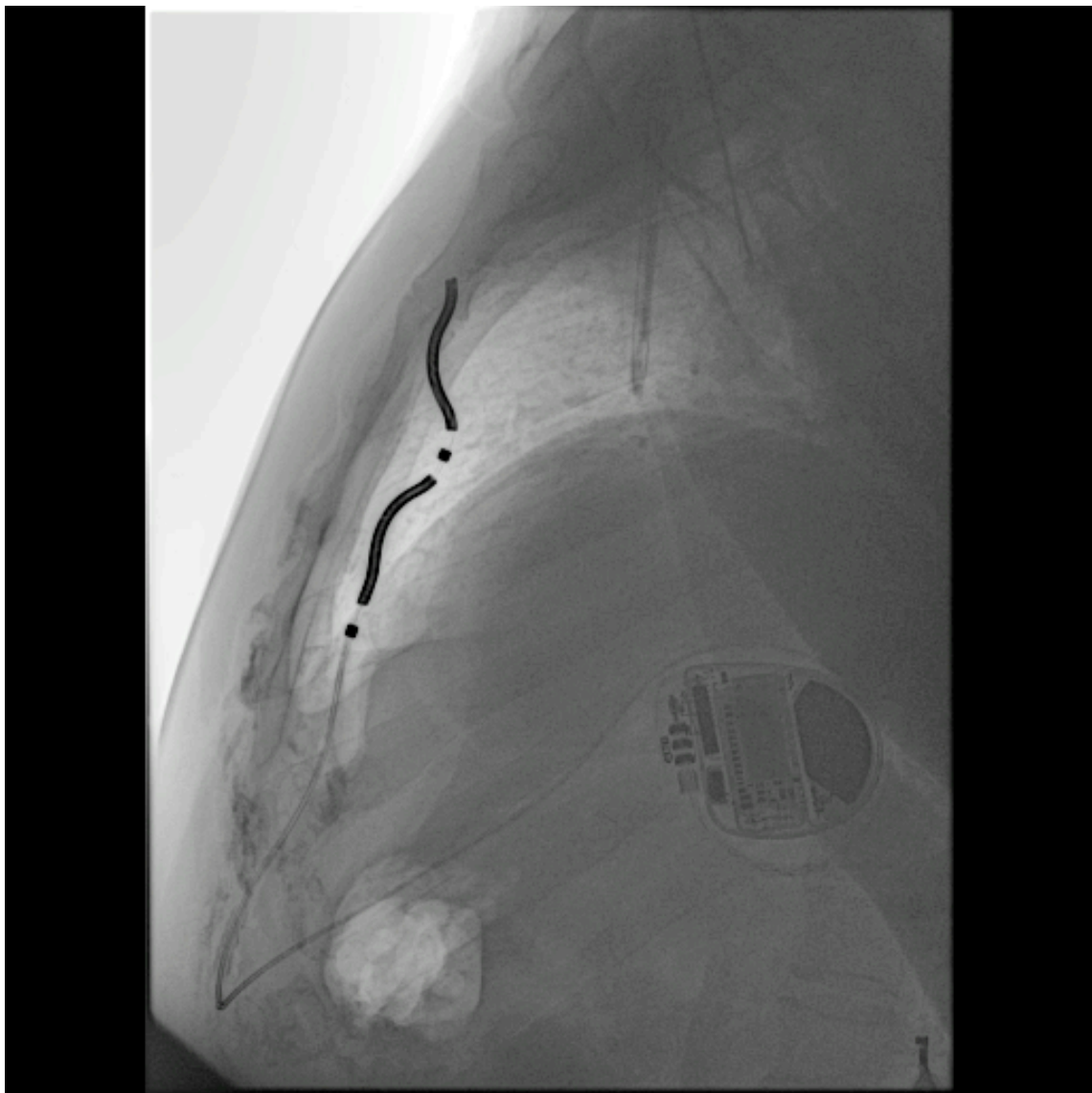


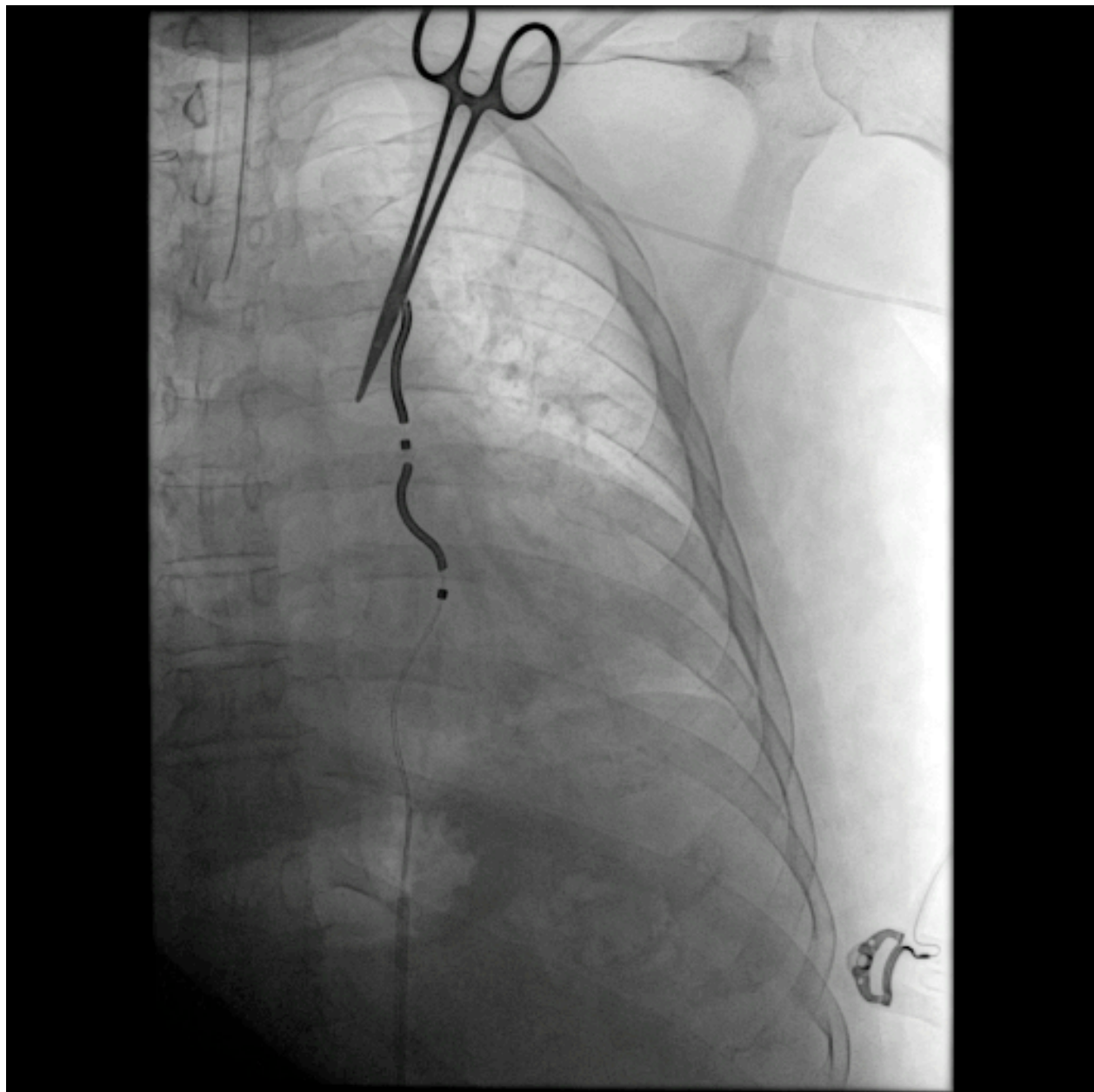
- Risk of inappropriate detection not statistically different between software emulation and device bench testing (p=0.31).

* 95% Confidence Interval

EV-ICD Pivotal Study – Conclusions

- **Primary safety and efficacy endpoints met:**
 - High defibrillation efficacy at implant: 98.7%
 - Freedom from major system & procedure related complications at 6 mo: 92.6%
 - No major intraprocedural complications
 - Safety: comparable to TV-ICD and S-ICD
- **Inappropriate Shock Rate: 9.7% patients at 10.6 months**
 - P-wave oversensing primary case; addressable
- **Spontaneous arrhythmias were successfully treated**
 - Shock 100%. No arrhythmic deaths due to undetected arrhythmias or unsuccessful Tx
 - ATP 70%. By programming ATP, shock was avoided in 33 episodes.
- **EV ICD provides pacing and low energy defibrillation whilst avoiding vascular space**





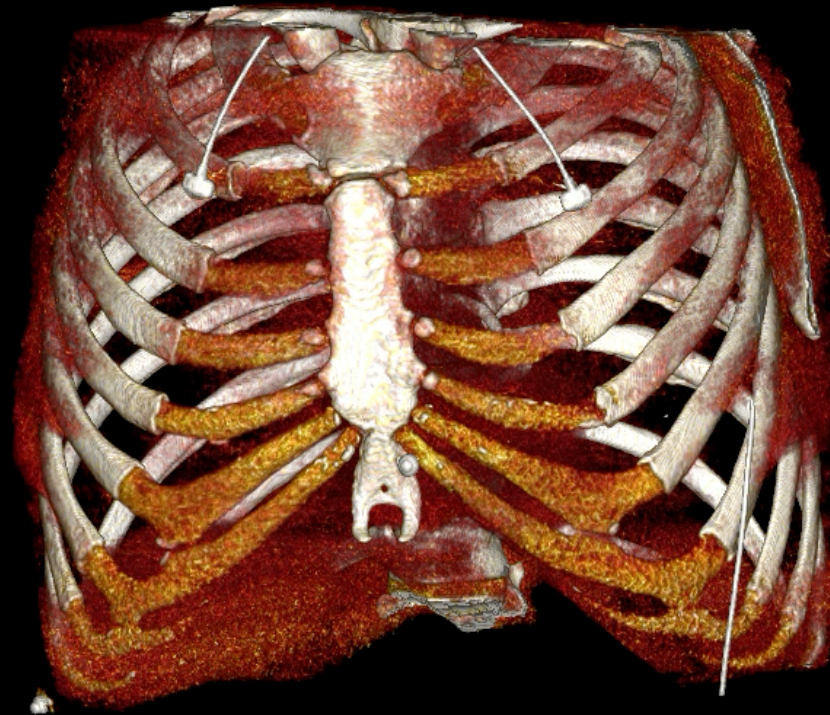
WL: 92 WW: 100

S

A

RA

LP



S-I: 6.6
L-R: 14.3
Roll: 1.2

WL: 203 WW: 426

S

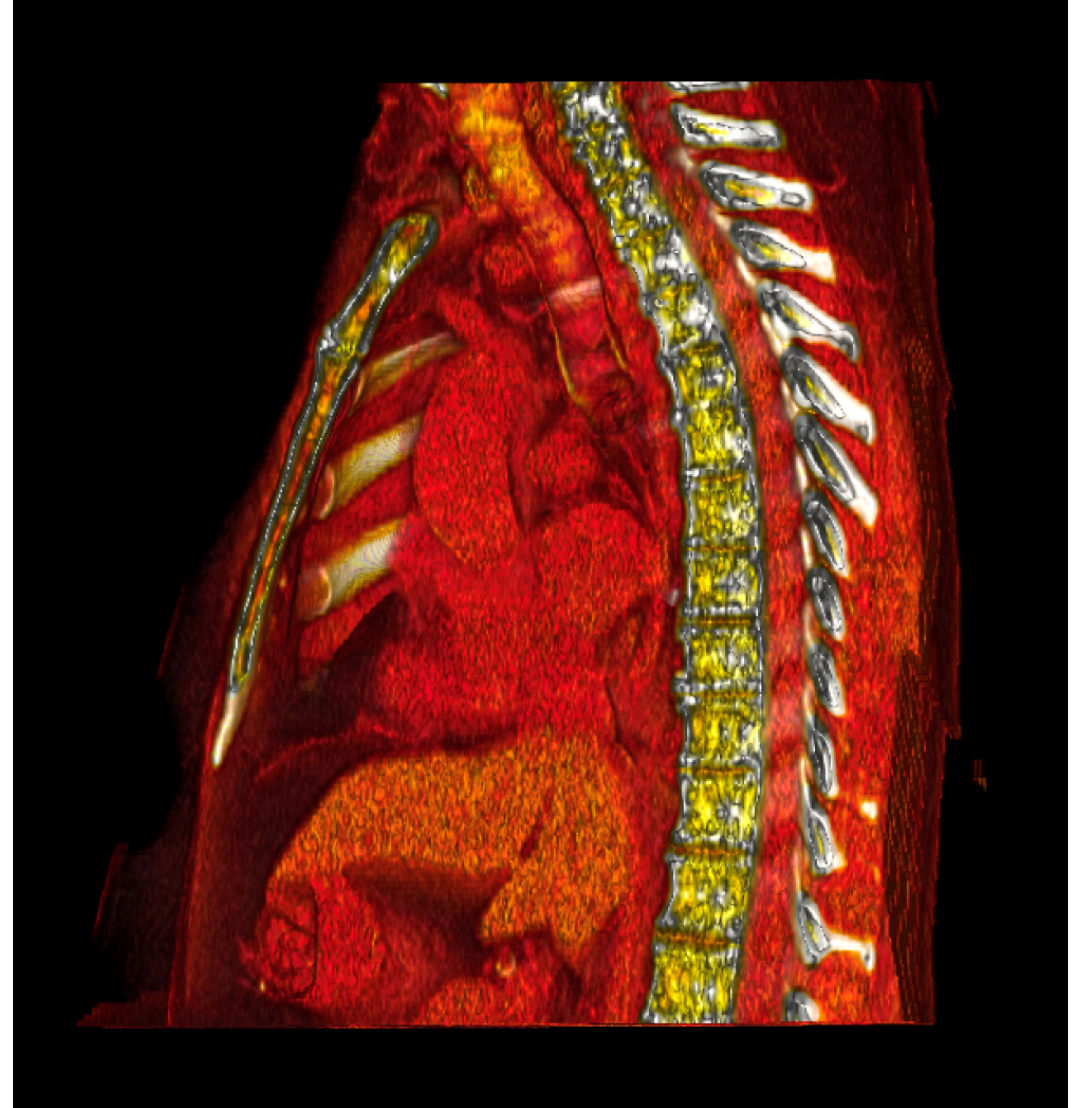
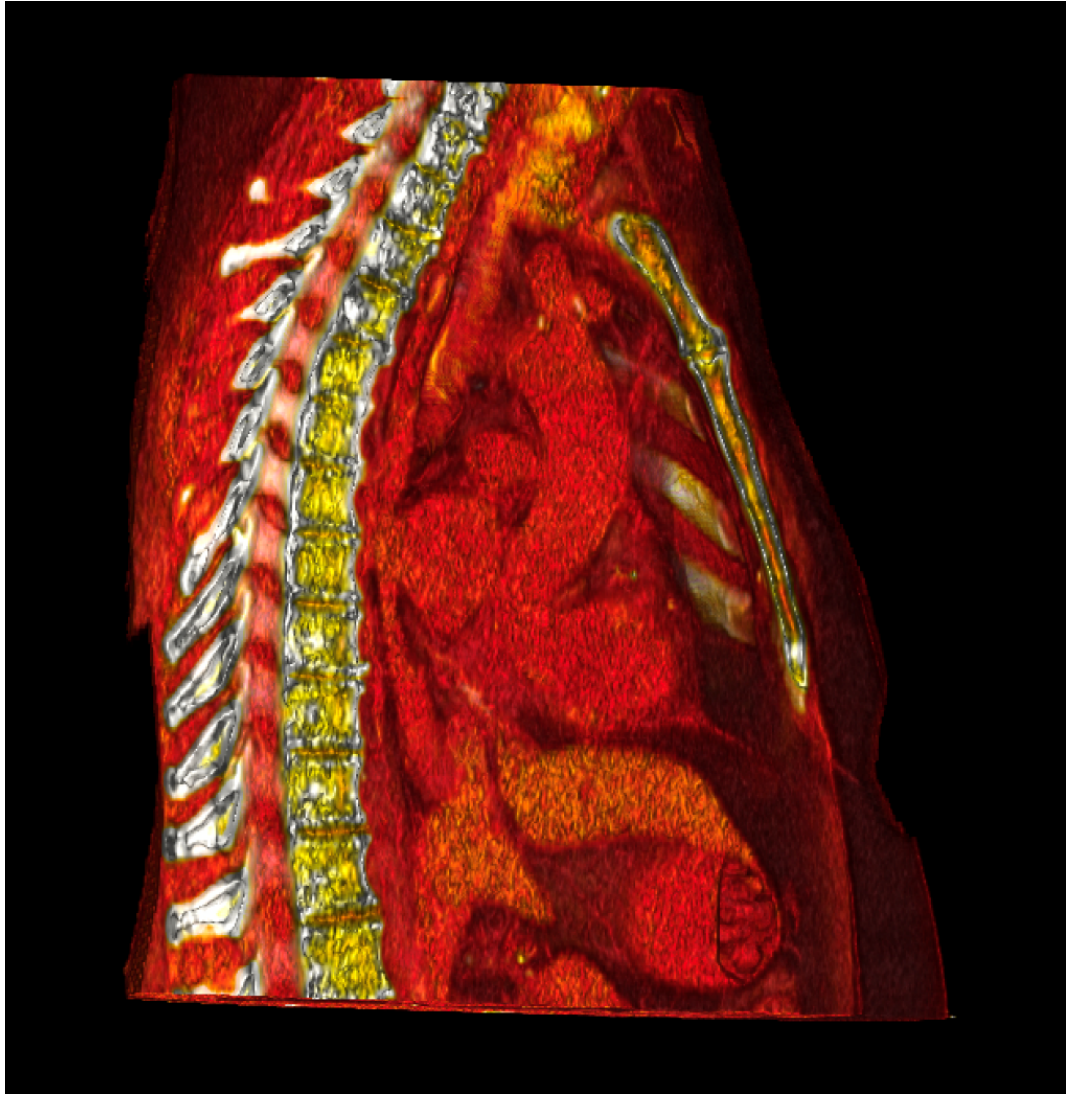
A

RA

LP



S-I: 3.1
L-R: 12.0
Roll: 2.3



WL: 445 WW: 851

SP



RA

LP

IA



S-I: 14.0
L-R: 22.2
Roll: 5.6

WL: 643 WW: 1398

S



RA

LP



S-I: 8.3
L-R: 17.1
R-ll: 4.4

WL: 750 WW: 1529

S

A

RA

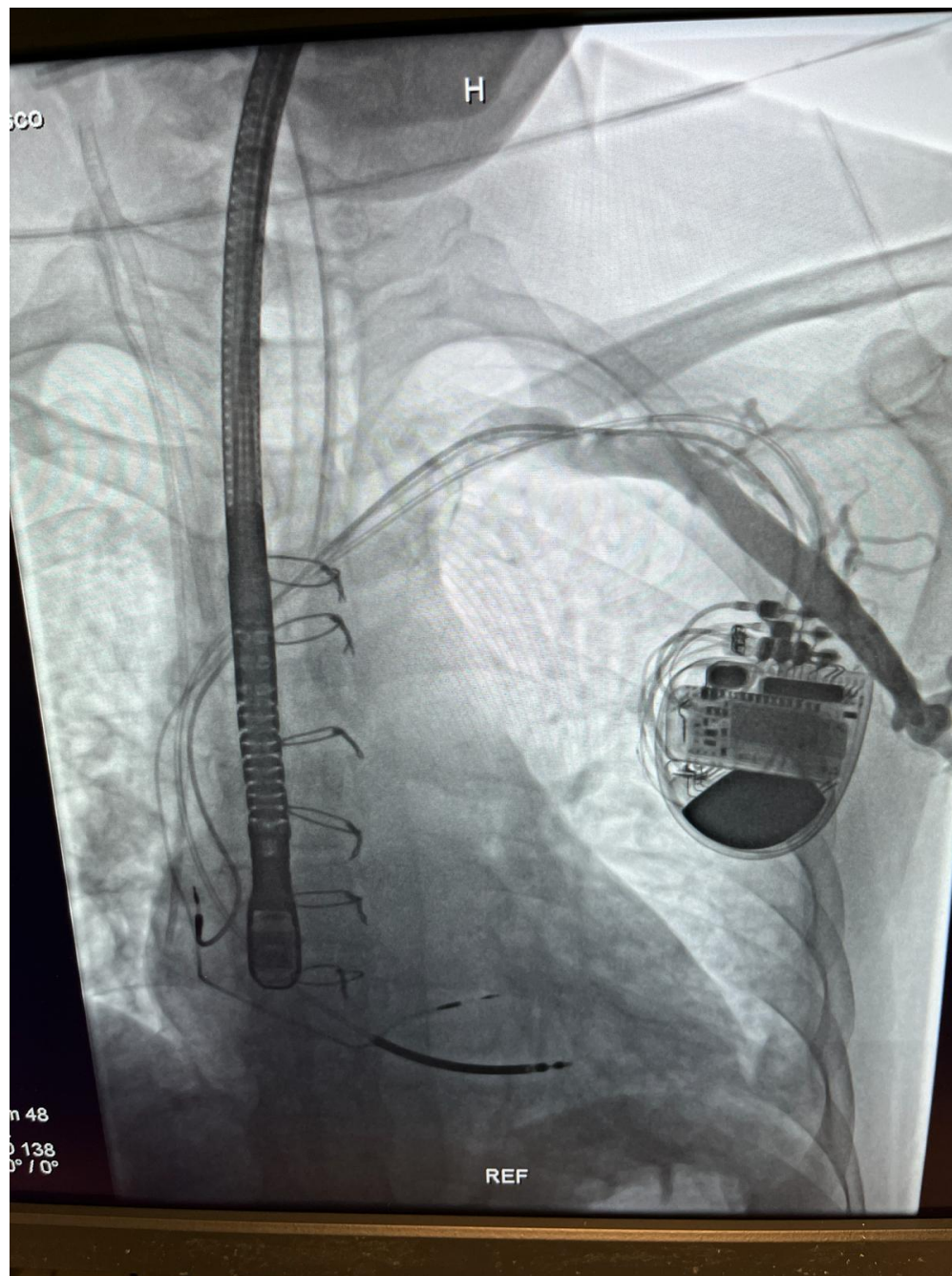
LP



I

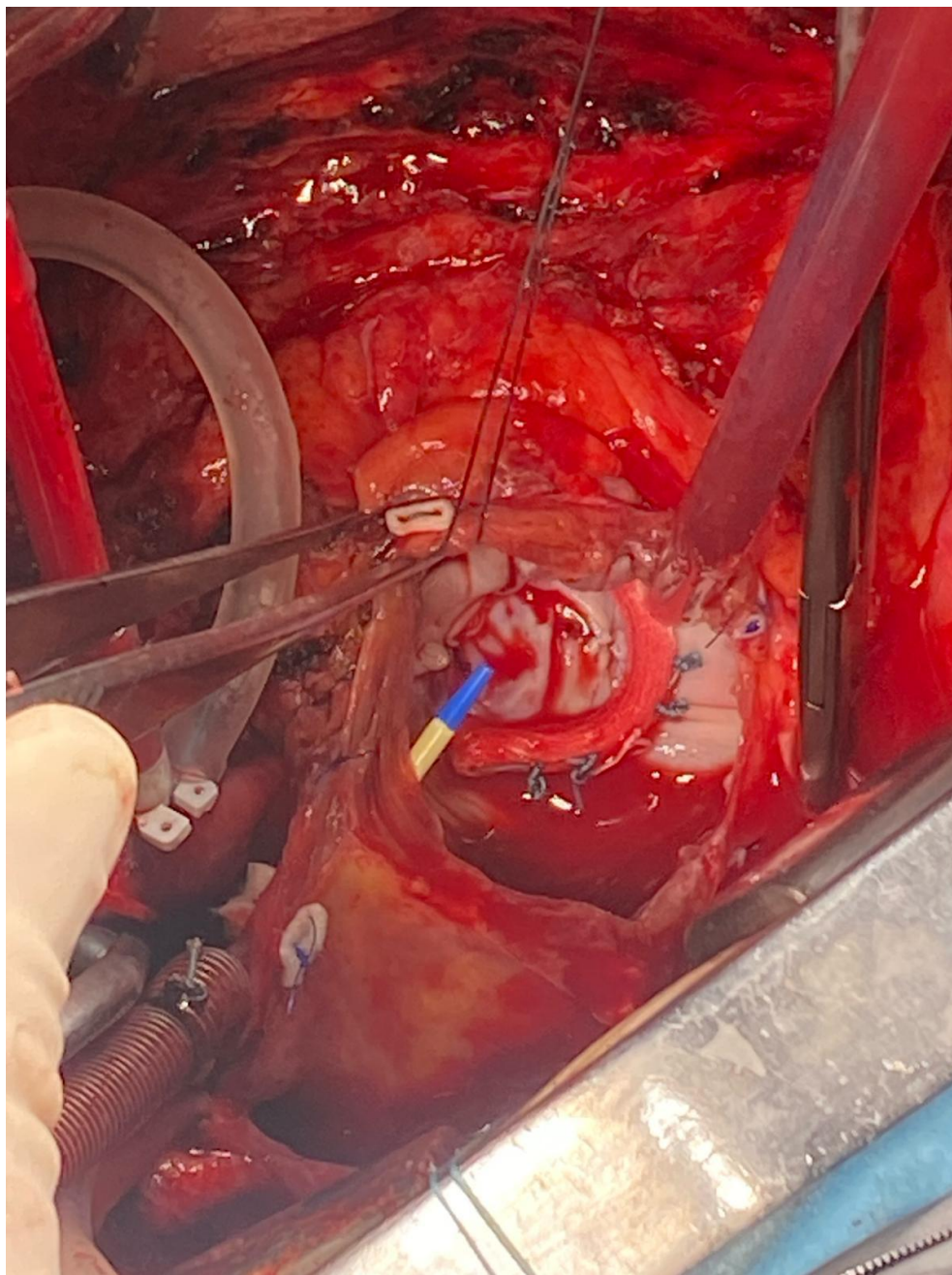


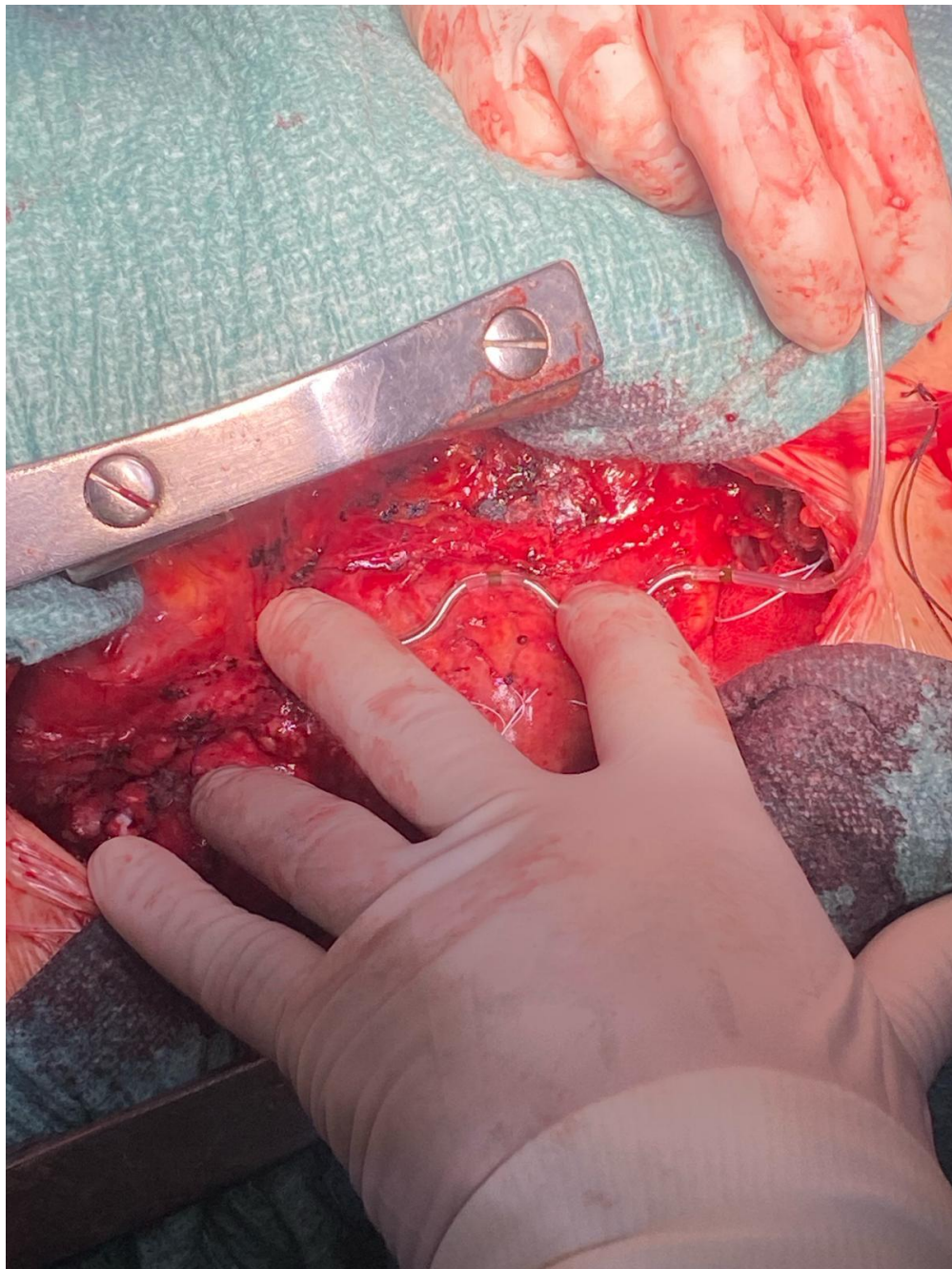
S-I: 2.9
L-R: 17.9
Roll: 1.1

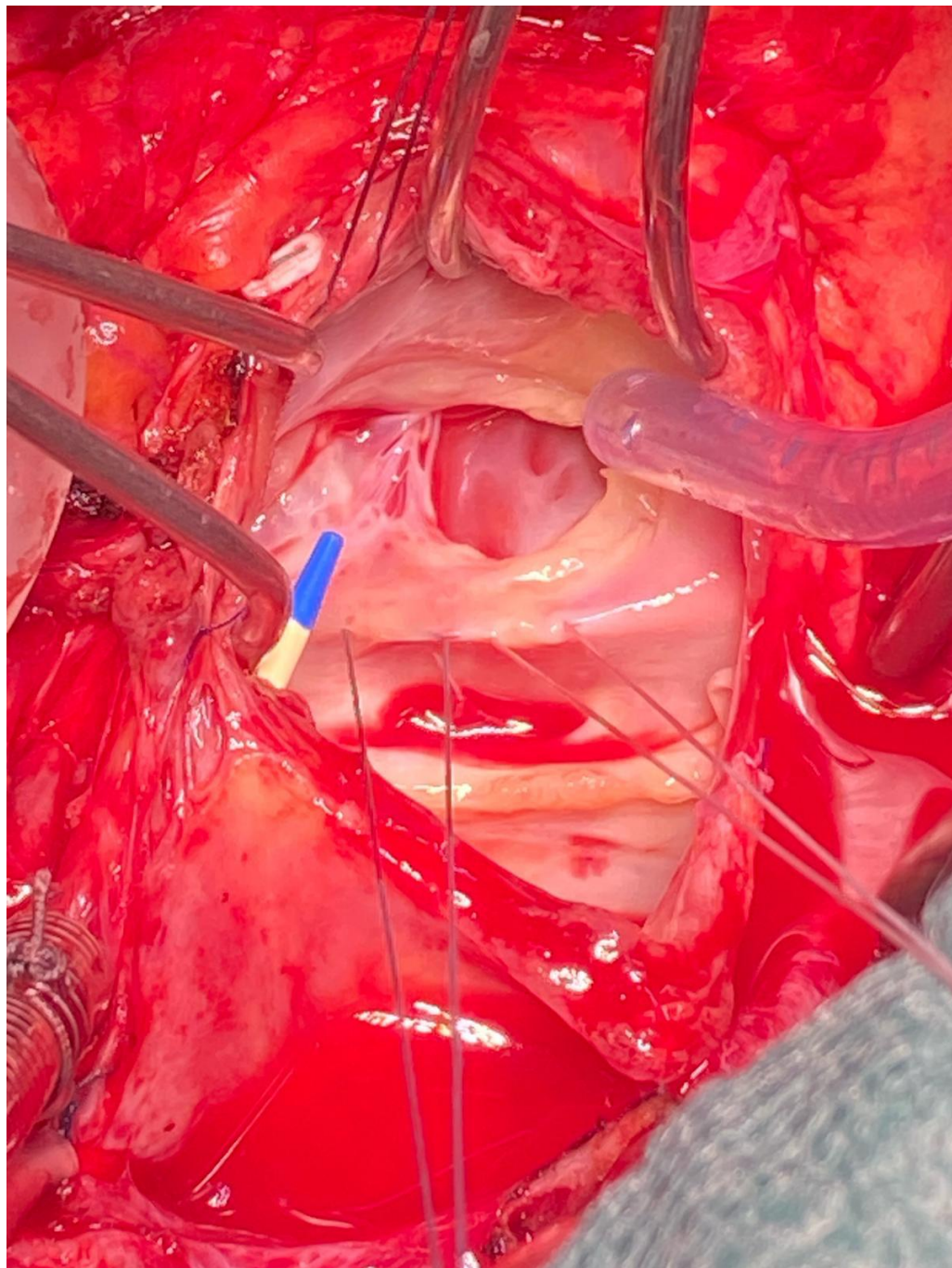


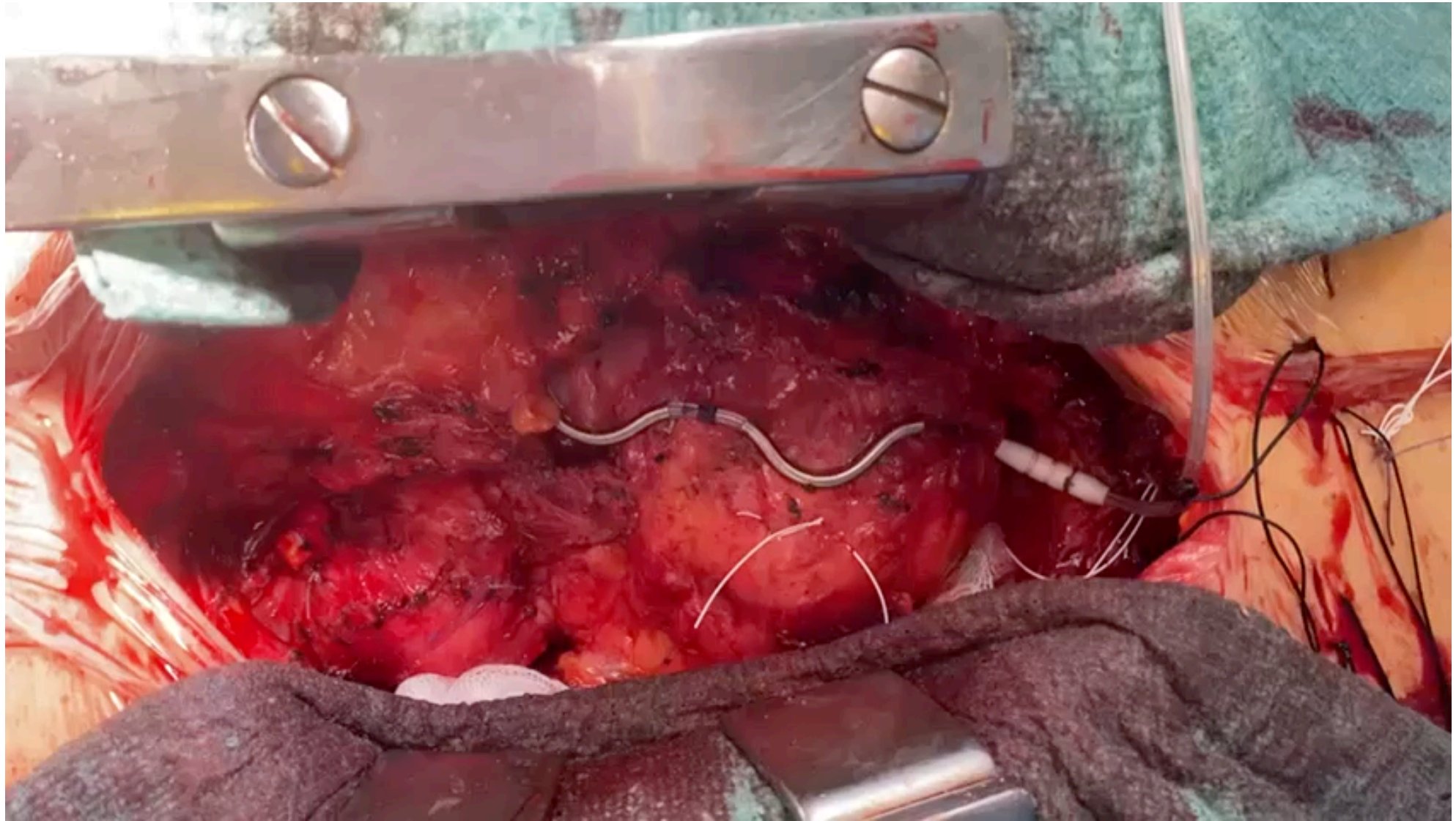




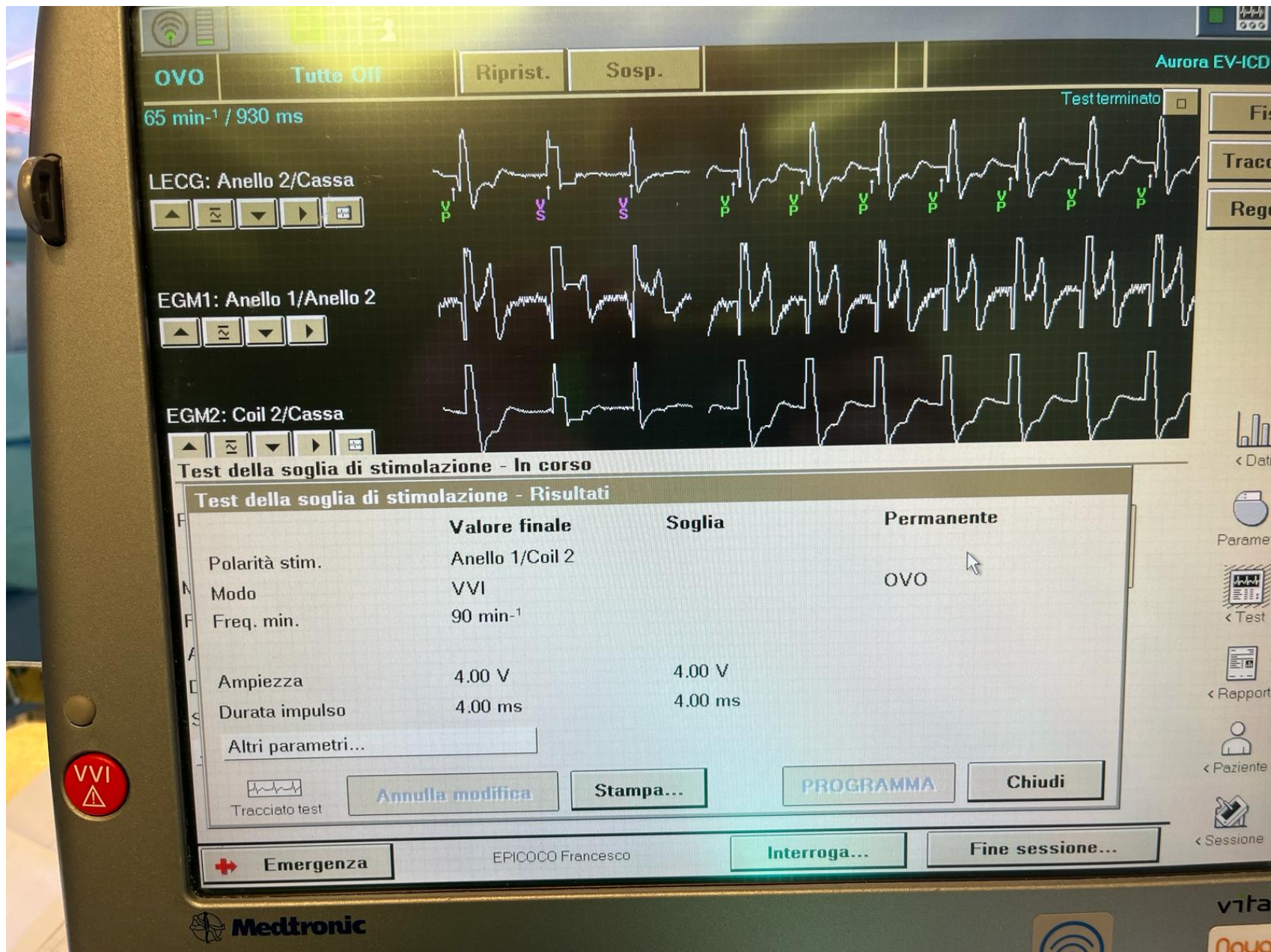










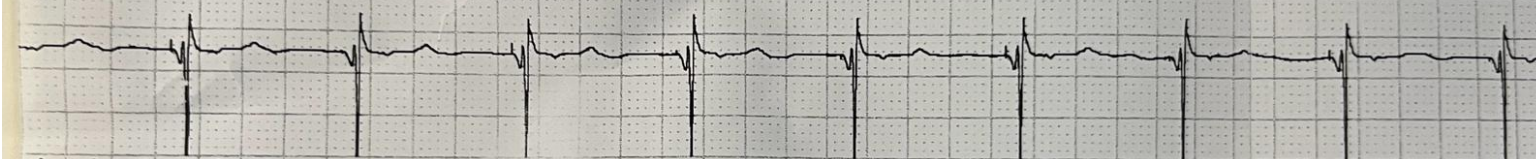
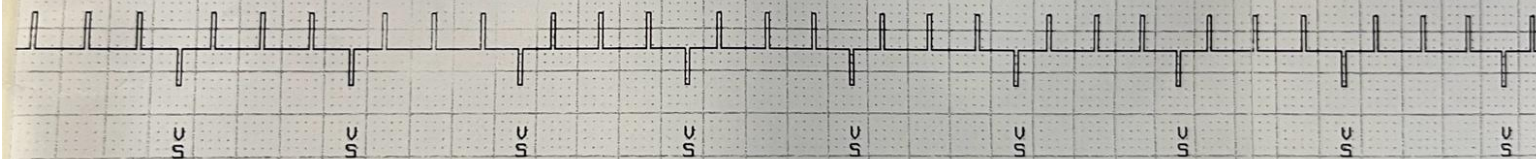


2290 Analyzer

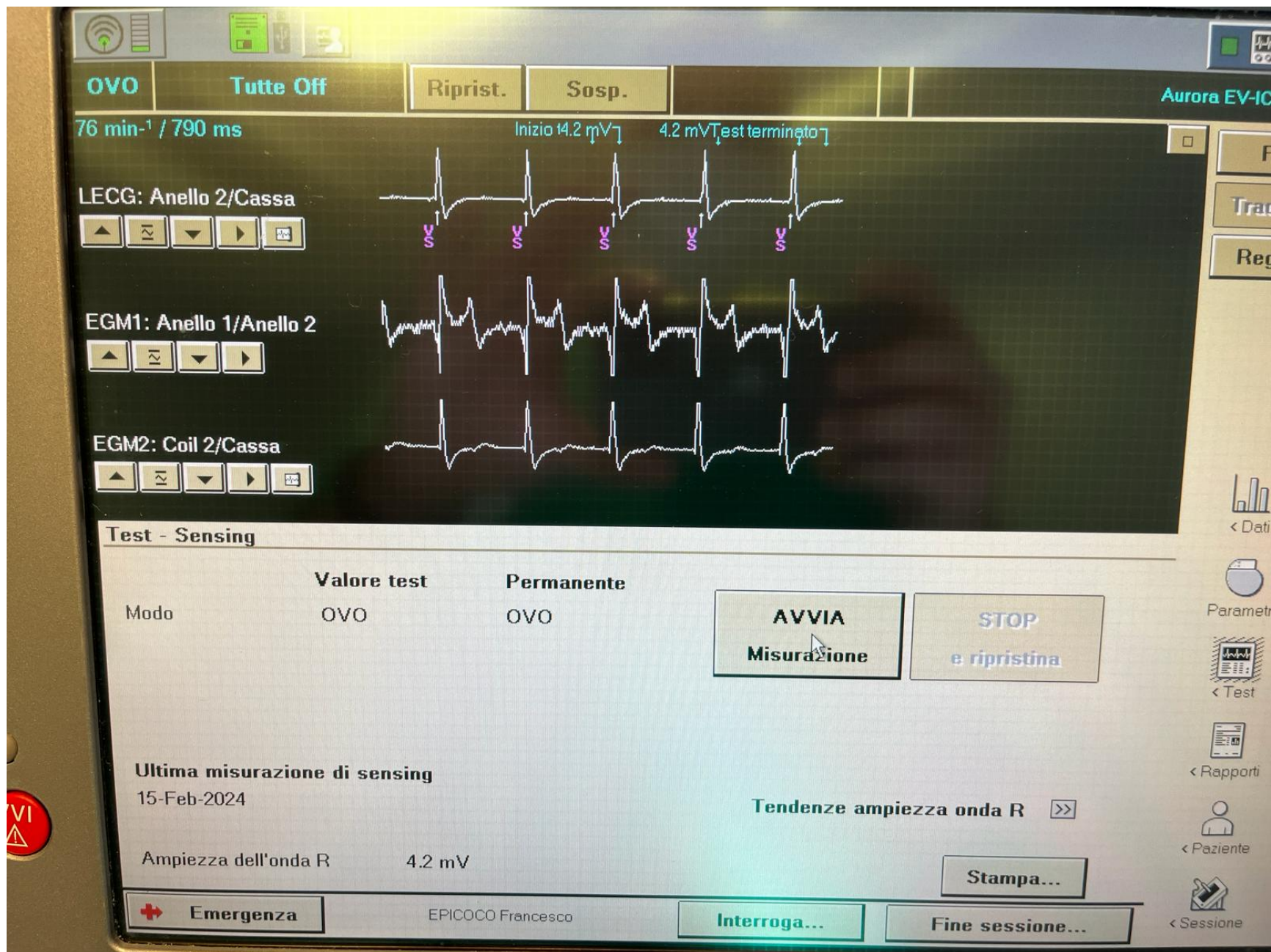
15.02.24 16:10:59

VELOC. CARTA 25.0 mm/s

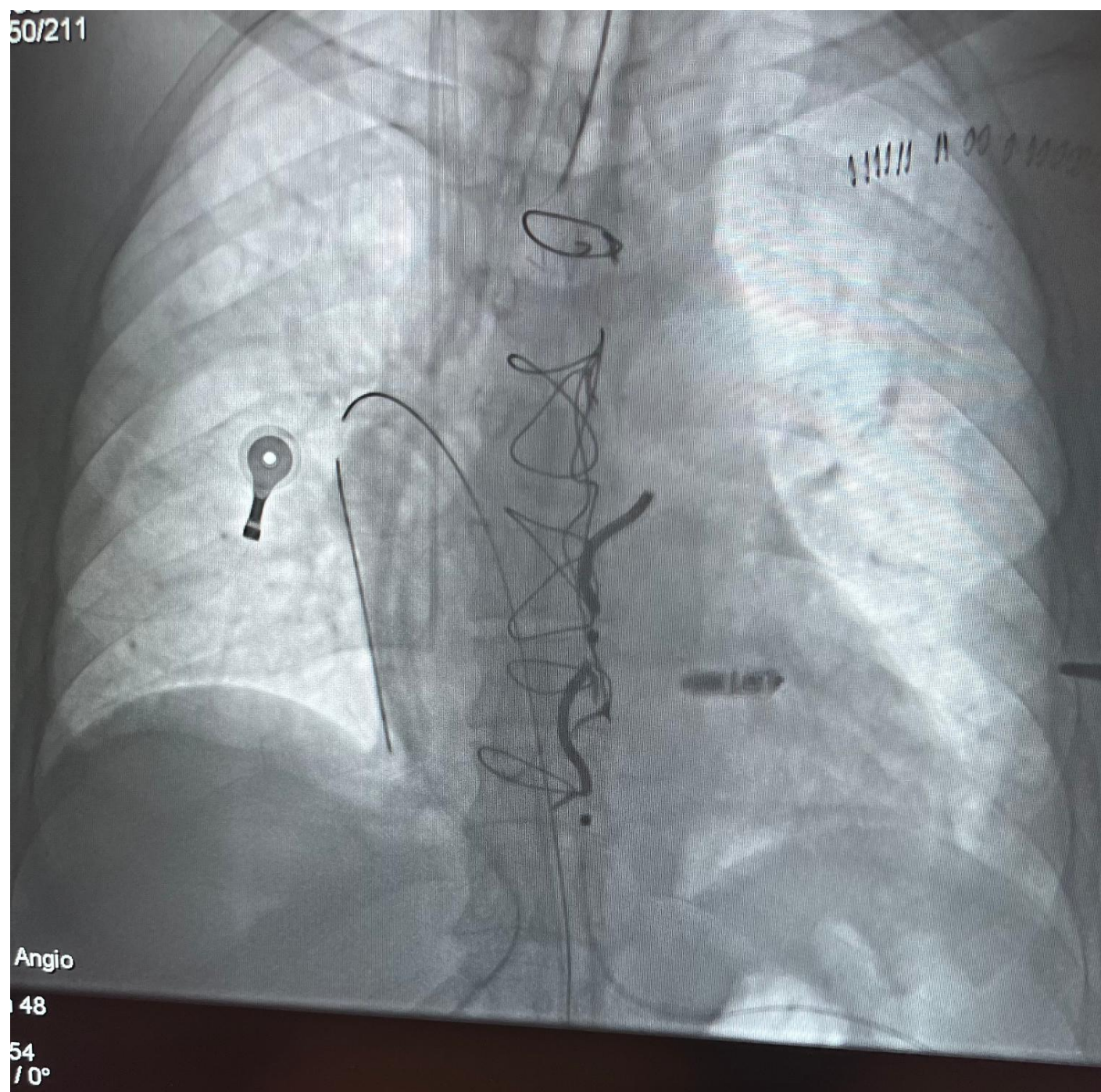
EGM V. 0.5 mV/mm

[illegible]

ECG DER. I 0.2 mV/mm



50/211



Angio

48

54
/ 0°

RISULTATI - prospettive future

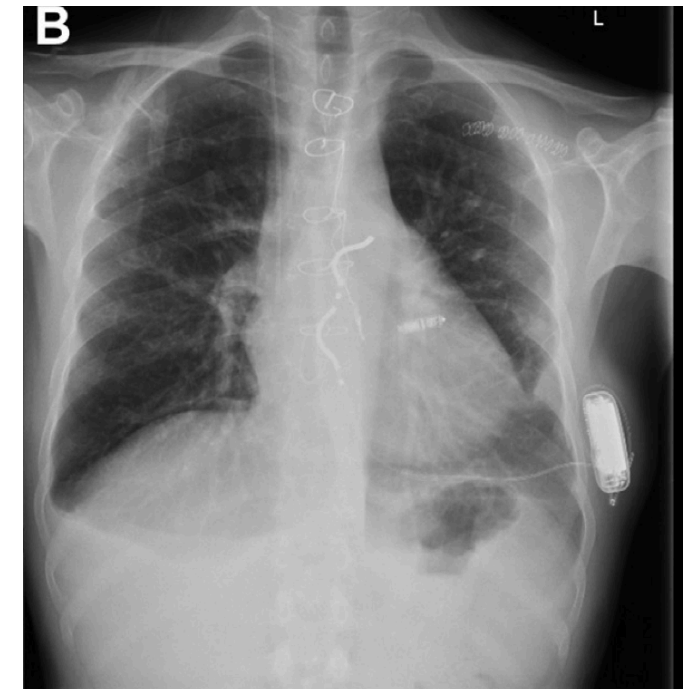
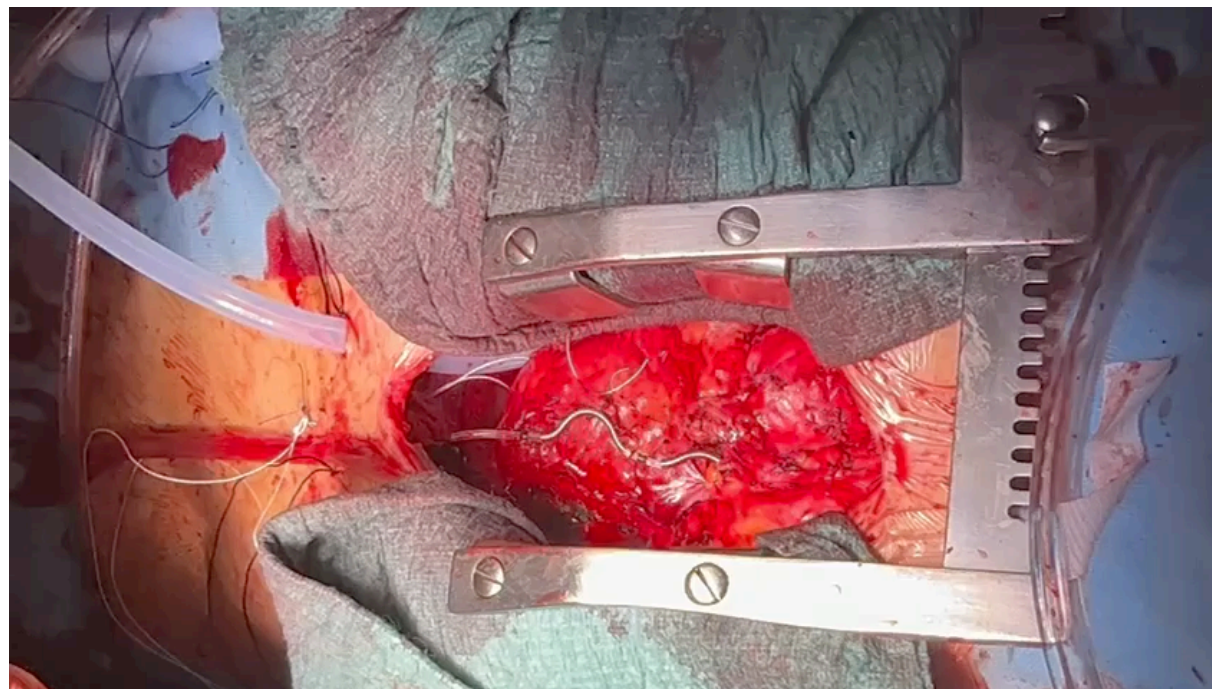
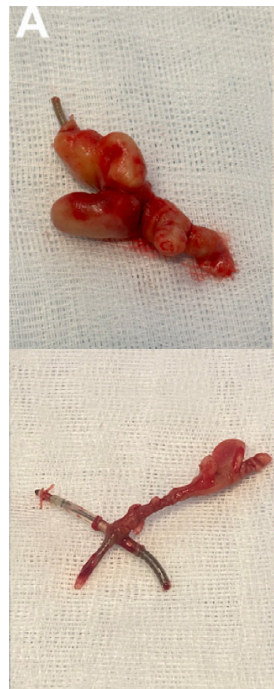
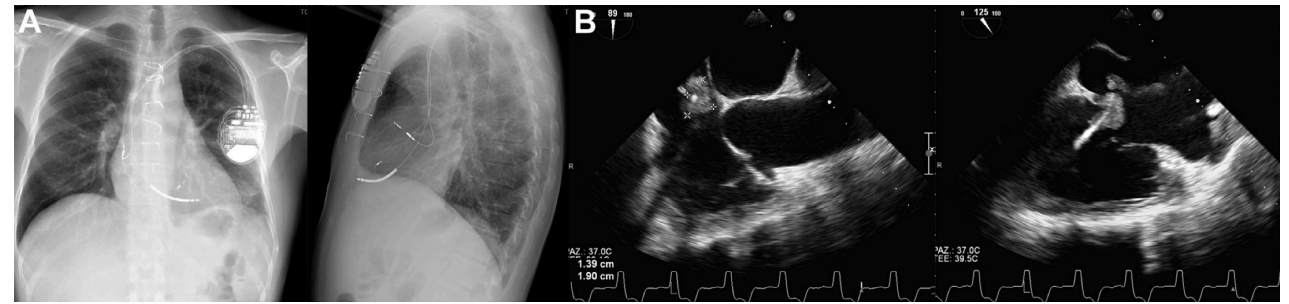
RHYTHM DISORDERS AND ELECTROPHYSIOLOGY

CASE REPORT: CLINICAL CASE

First-in-Man Surgical Extravascular-ICD Implantation

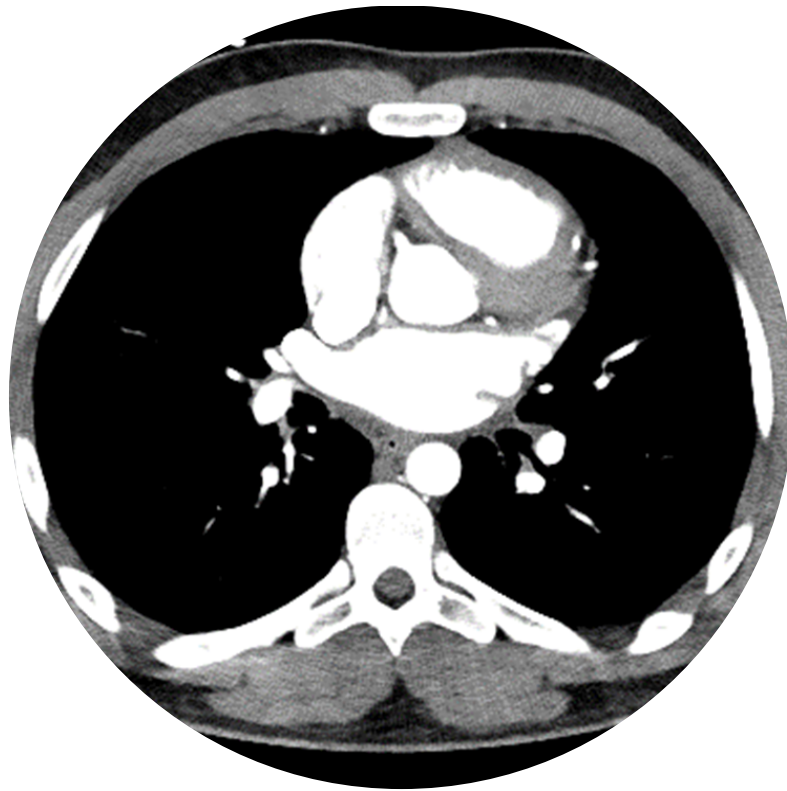
Suturing the Defibrillation Lead to the Heart Wall Post Device-Related Endocarditis

Massimo Moltrasio, MD,^a Matteo Biroli, MD,^b Marco Schiavone, MD,^a Moreno Naliato, MD,^c Marco Zanobini, MD,^d
Fabrizio Tundo, MD, PhD,^a Claudio Tondo, MD, PhD,^{a,c} Antonio Curnis, MD^e

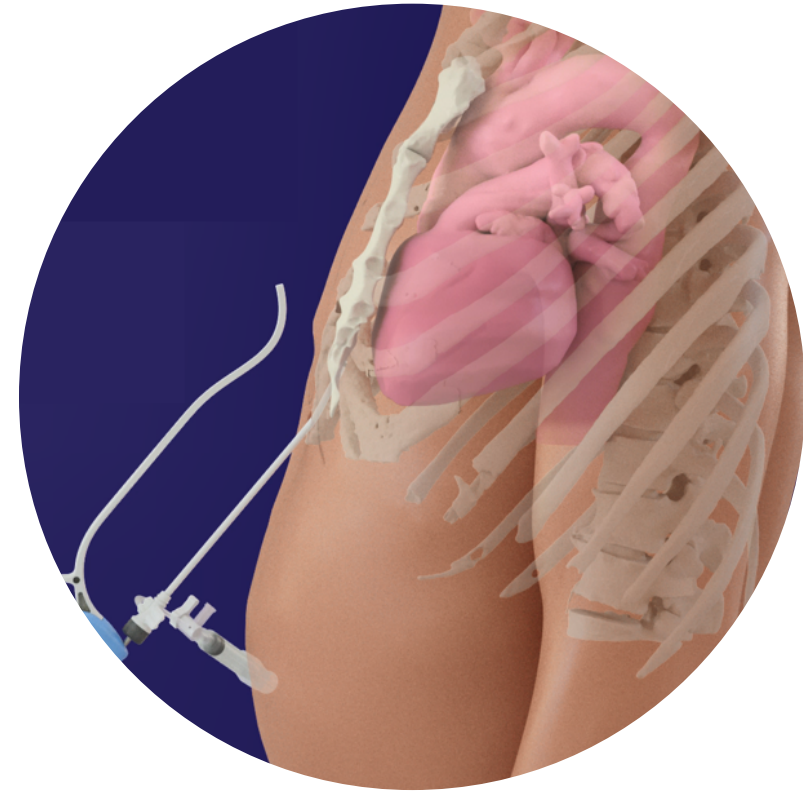


OBIETTIVI DELLO STUDIO

- Valutare l'efficacia e la sicurezza dell'EV-ICD anche in pazienti con anatomie complesse
- Determinare se l'analisi della TC pre-operatoria sia predittiva di buona riuscita dell'impianto



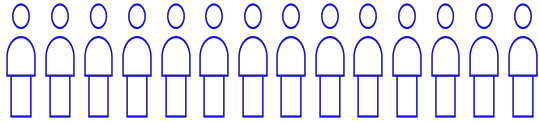
Anatomia & Imaging



Procedura

Medtronic

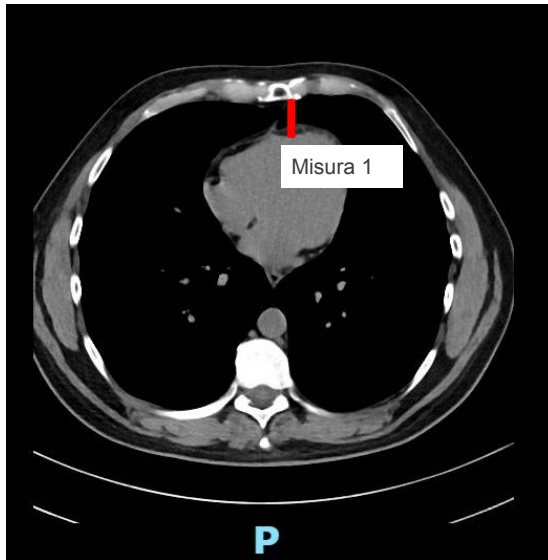
POPOLAZIONE DELLO STUDIO



61 consecutivi arruolati
22 mesi follow-up
medio

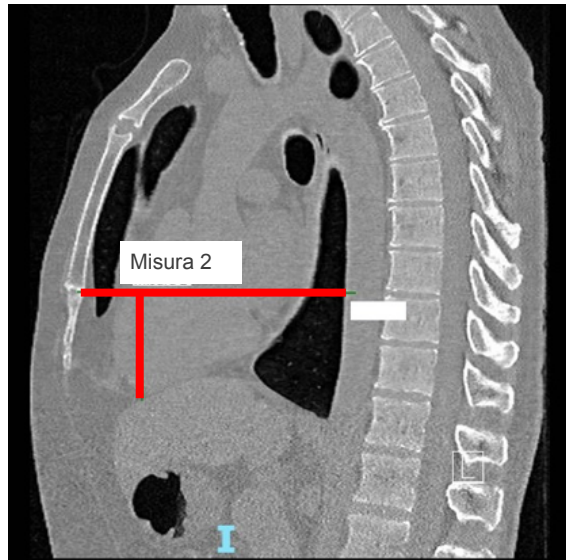
Età, media±dev.standard, anni	47,9±16,3
Sesso, numero (%)	
Donne	6 (28,6)
Indicazione all'impianto ICD, numero (%)	
Prevenzione primaria	13 (61,9)
Prevenzione secondaria	8 (38,1)
LVFE, media±dev.standard, (%)	47,6±15,7
Cardiomiopatia, numero (%)	13 (61,9)
Ischemica	5 (23,8)
Non Ischemica	2 (9,5)
Ipertrofica	2 (9,5)
Altro	4 (19)
Sindrome di Brugada	4 (19)
Aritmie spontanee, numero (%)	
Fibrillazione atriale	1 (4,8)
Aritmie ventricolari	10 (47,6)
Dispositivo precedente estratto per infezione	5 (23,8)
Dispositivo precedente estratto per malfunzionamento	3 (14,3)

MATERIALI E METODI



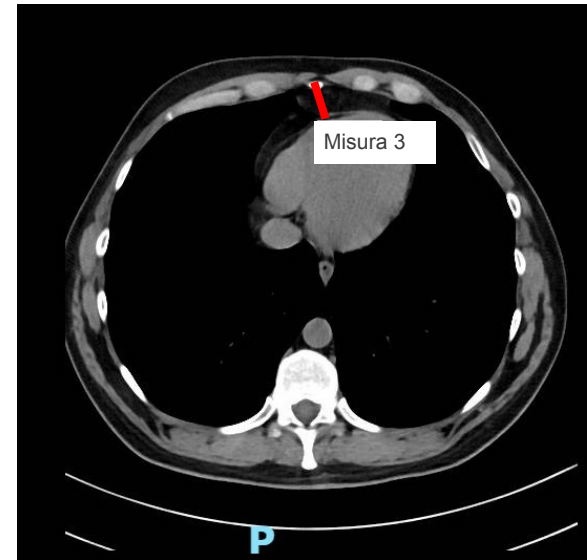
Misura 1

Distanza tra margine inferiore del corpo dello sterno e superficie cardiaca



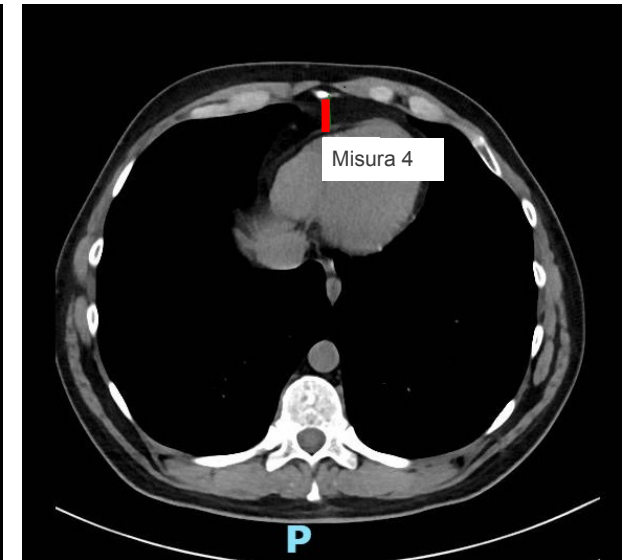
Misura 2

Distanza tra margine inferiore del corpo dello sterno e cupola diaframmatica



Misura 3

Punto di minima distanza tra sterno e cuore



Misura 4

Distanza tra punto distale del processo xifoideo e superficie cardiaca

RISULTATI



Analisi statistica

R² **p-value**

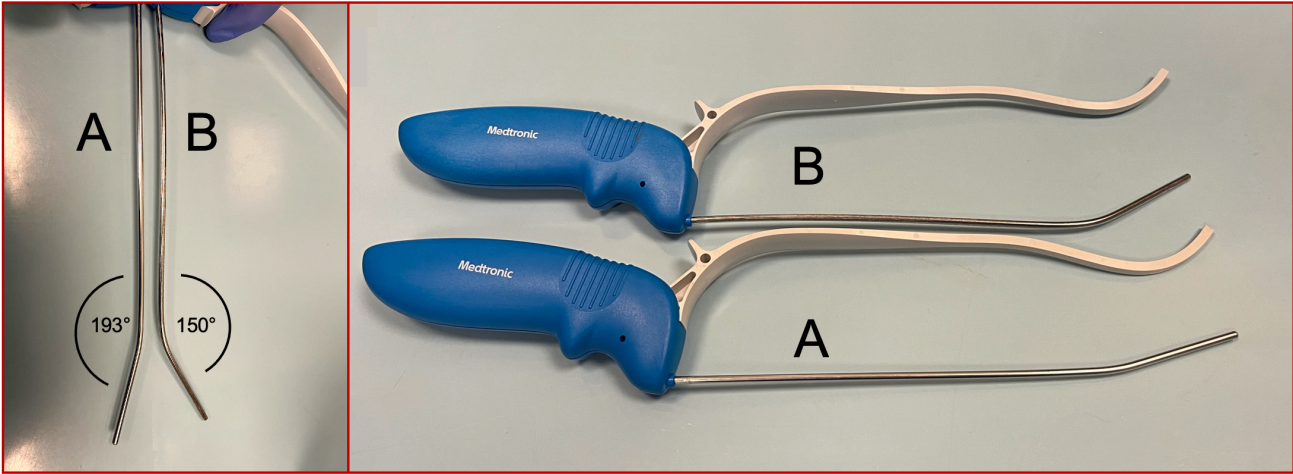
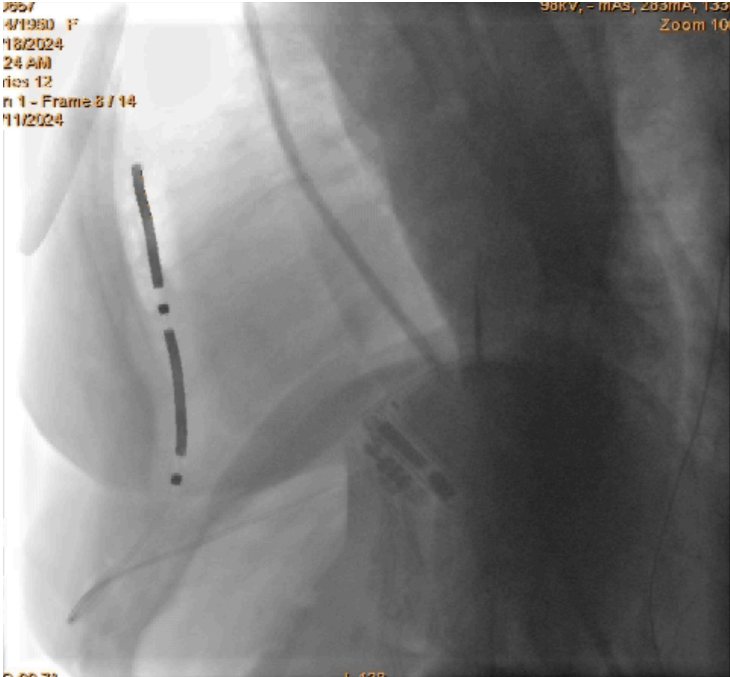
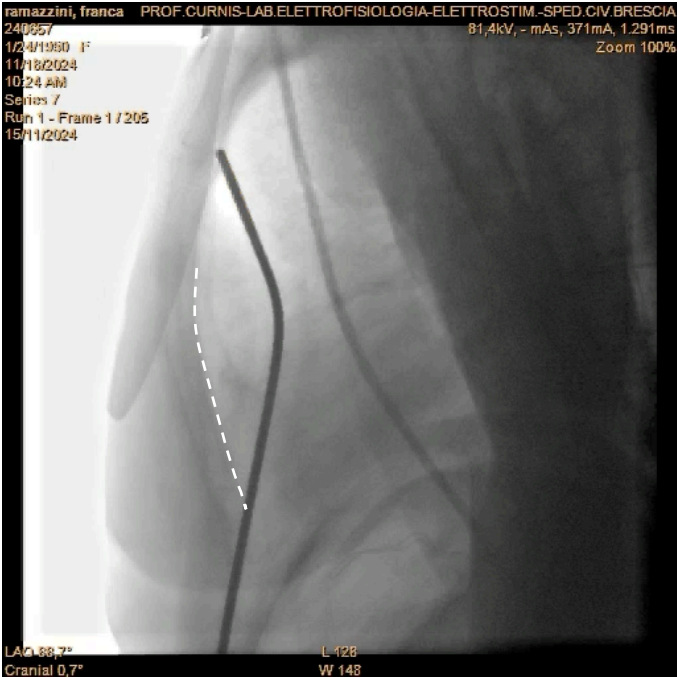
Durata dell'intervento

1. Distanza tra il margine inferiore del corpo dello sterno e il cuore	0.13	0.123
2. Distanza tra il margine inferiore del corpo dello sterno e cupola diaframmatica	0.0026	0.835
3. Punto di minima distanza tra la struttura ossea dello sterno e la superficie cardiaca	0.131	0.128
4. Distanza tra processo xifoideo e cuore.	0.027	0.503

Segnale di sensing

1. Distanza tra il margine inferiore del corpo dello sterno e il cuore	0.257	0.027
2. Distanza tra il margine inferiore del corpo dello sterno e cupola diaframmatica	0.0011	0.894
3. Punto di minima distanza tra la struttura ossea dello sterno e la superficie cardiaca	0.218	0.044
4. Distanza tra processo xifoideo e cuore.	0.128	0.132

RISULTATI - anatomie complesse



Conclusioni:

GRAZIE

- Grazie