# Successful Implantation Techniques of Extravascular ICD

**Pil-Sung Yang**

CHA University, Korea

# Korean Heart Rhythm Society
## COI Disclosure

*Pil-Sung Yang*

The authors have no financial conflicts of interest to disclose concerning the presentation

# Why the EV-ICD instead of the S-ICD?

## Subcutaneous ICD

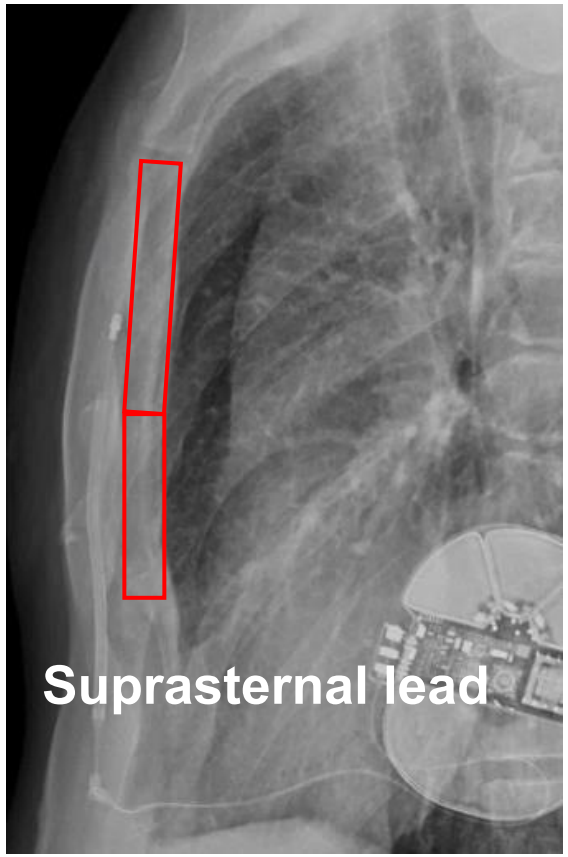

- No anti-tachycardia pacing (ATP)
- Post-shock pacing only
- It need high defibrillation energy, 80J
- Large size
- Reduced battery longevity

## Extravascular ICD

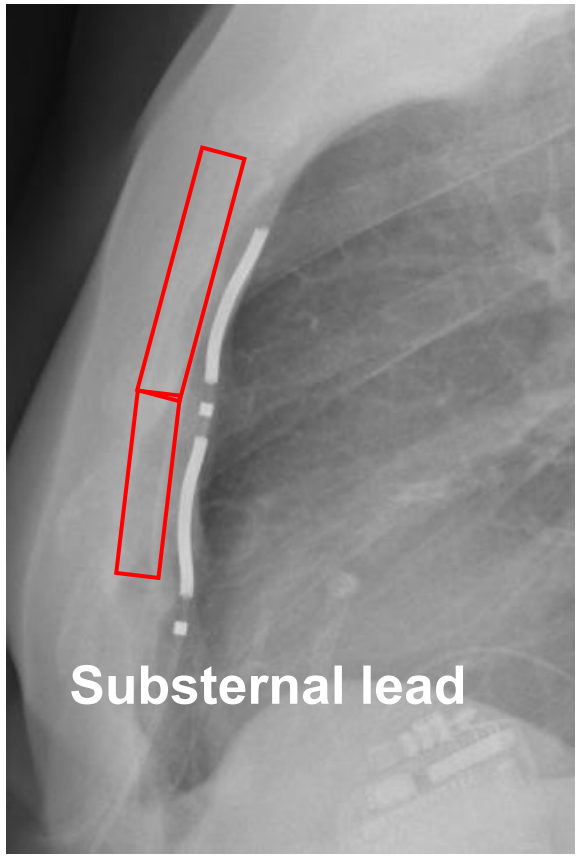

- Anti-tachycardia pacing (ATP)
- Asytole pacing / Post-shock pacing
- Lower defibrillation energy, 40J
- Smaller size (33cc)
- Greater battery longevity (11 year)

# S-ICD and EV-ICD

## Subcutaneous


## Extravascular

# The Pivotal Study (1)

The NEW ENGLAND JOURNAL of MEDICINE

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*

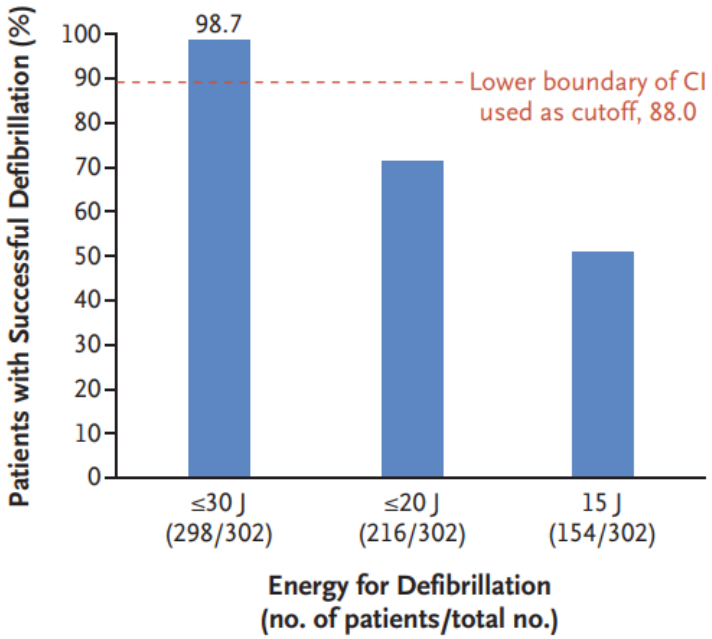
*N Engl J Med 2022;387:1292-302*

- ✓ Prospective, non-randomized approval study
- ✓ 45 centers, 17 countries
- ✓ 356 enrolled: attempted 316, fully implanted 299 (94%)
- ✓ Age: mean 54 years old
- ✓ Primary prevention 82% / Secondary prevention 18%
- ✓ Ischemic CMP: 47%

## ✓ Procedural outcomes

- 315/316 (99.7%) leads successfully implanted
- No major intraprocedural complication
- Procedure duration: medial 66 mins
- Pacing threshold: 4.9 ± 2.0V

### Defibrillation efficacy

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# The Pivotal Study (2)

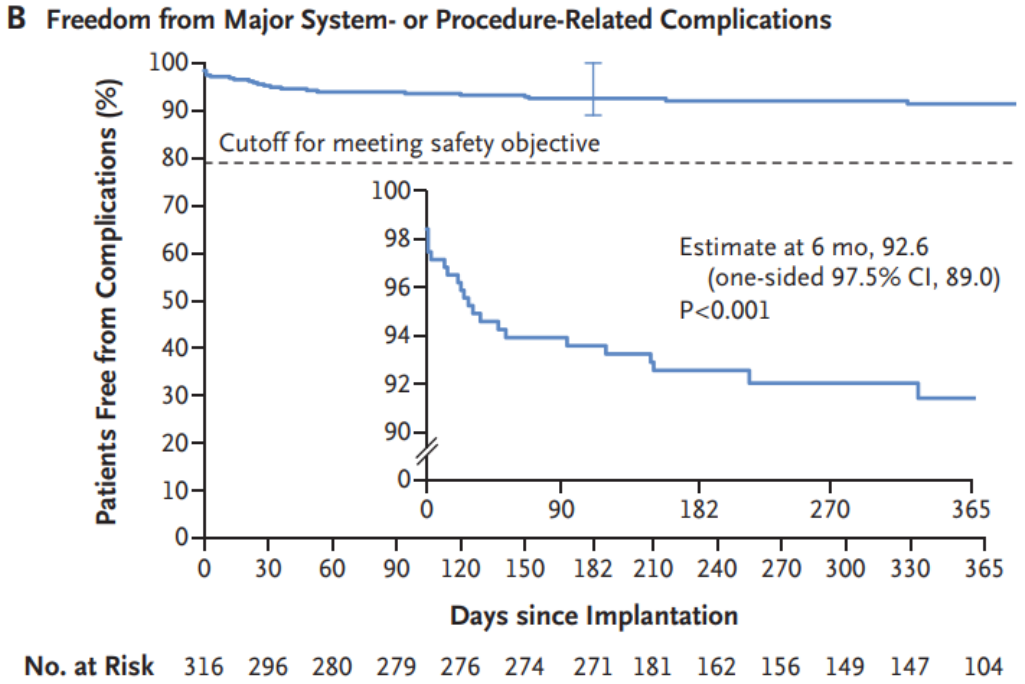


Table 2. Summary of Major Complications in Patients with an Implantation Attempt through 6 Months.

| 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) |

**The estimated percentage of patients free from complications at 6 months is 92.6%**

- **Overall complication rate: 7.3% (25 cases)**
- **No death**
- **Most common - lead dislodgement, 10 of 25 (40%)**
- **System revision: 18 of 25 (72%)**

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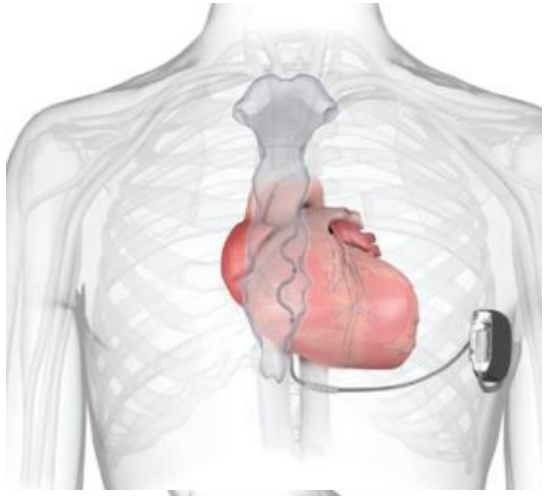
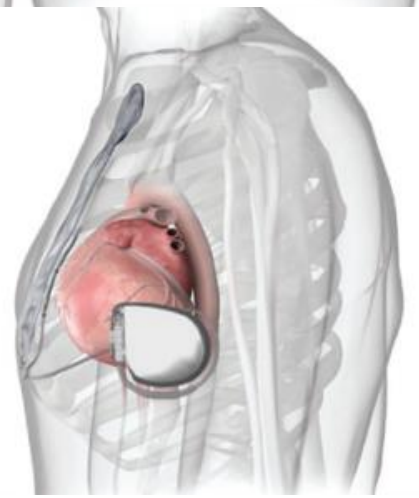
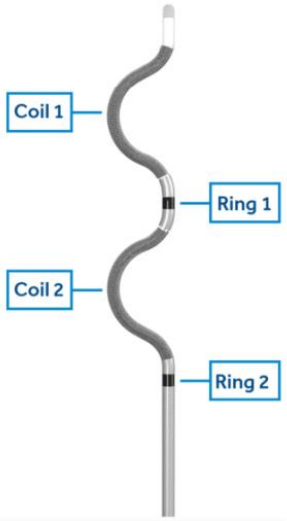
# The Extravascular ICD system and implant tool





## Lead



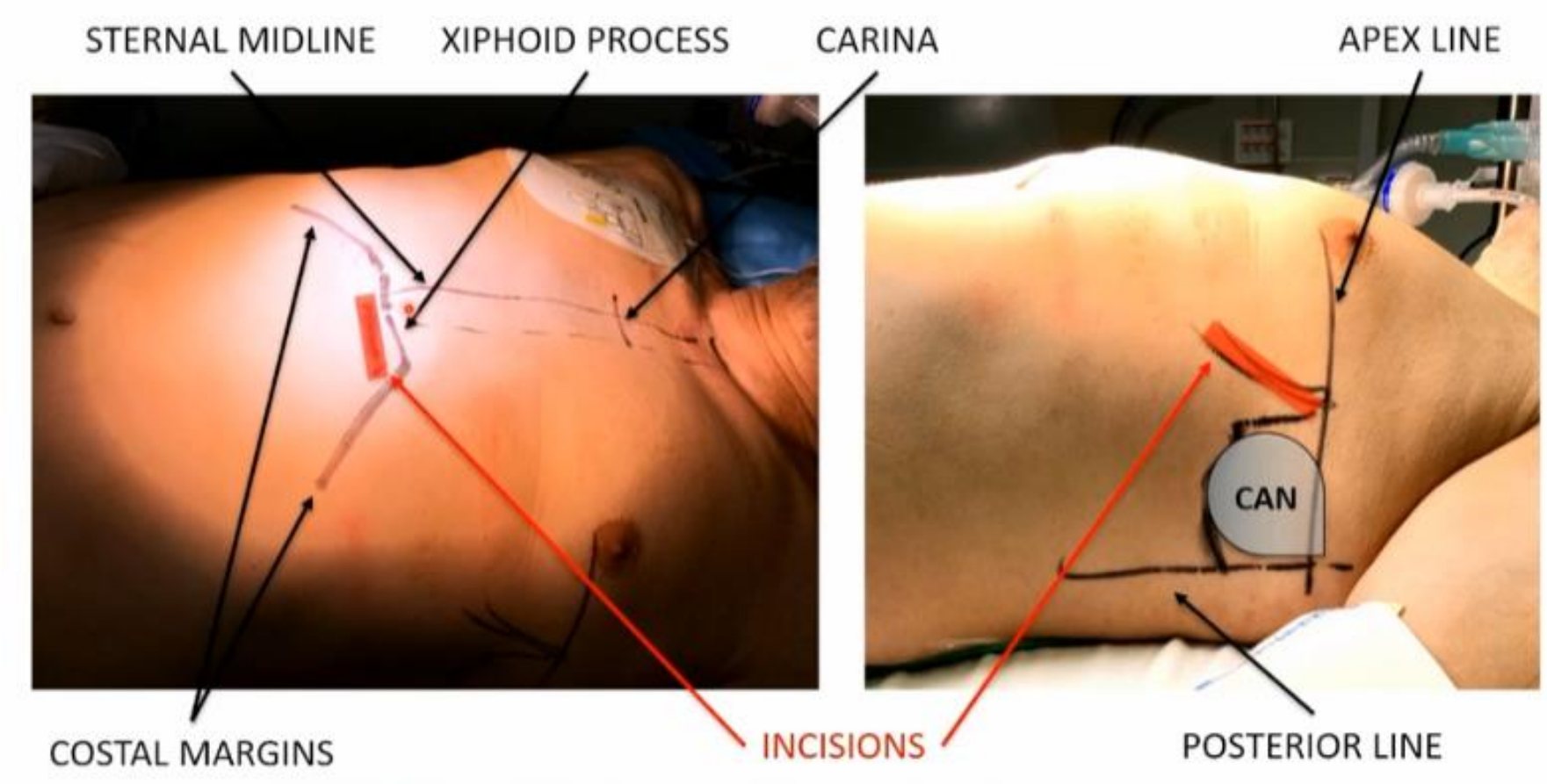

- Epsilon shape
- passive fixation
- Multiple pace/sense vectors

## Generator


- Volume: 33cc
- Shock: 40J

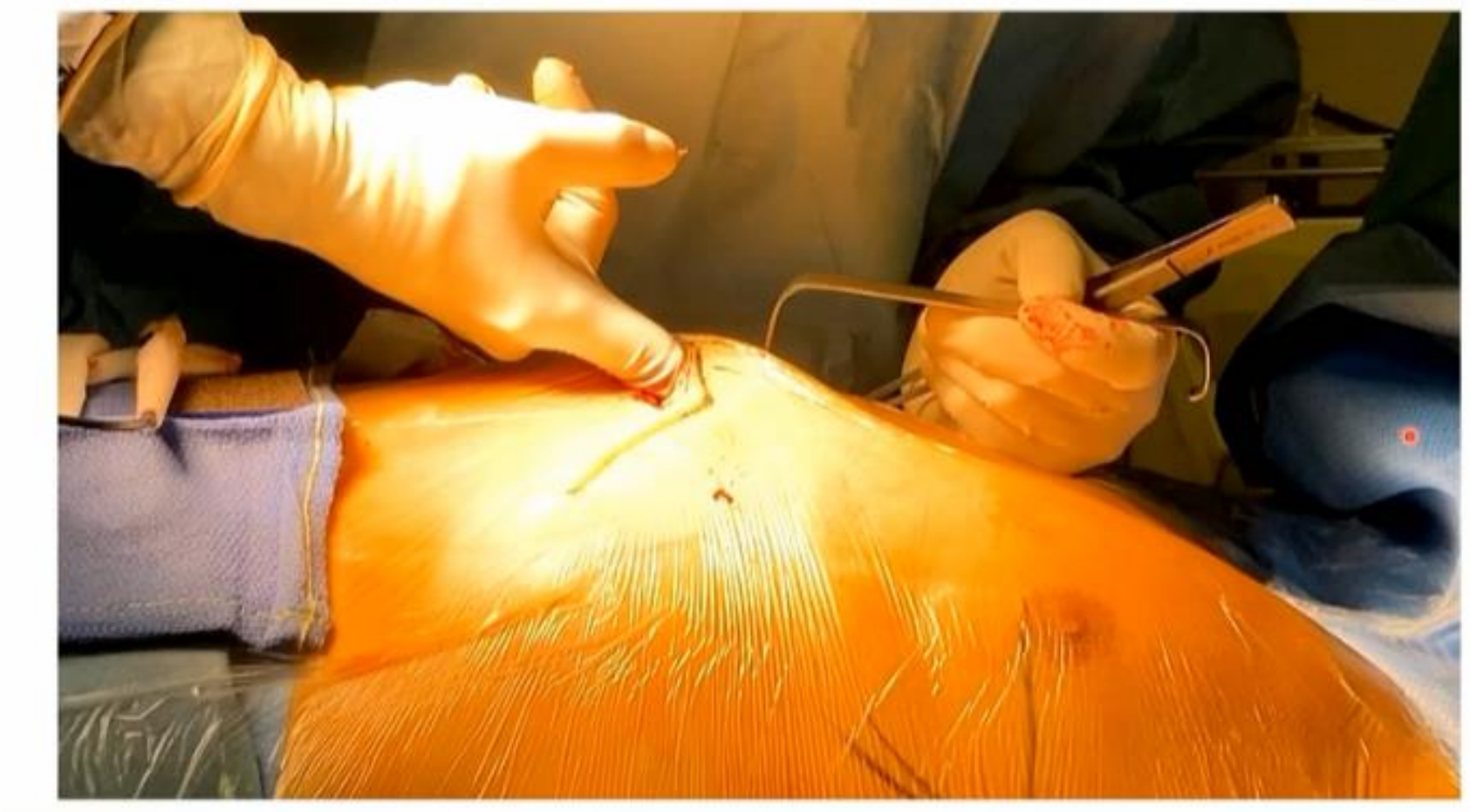
## Implant tool

# Implantation step: Anatomical landmarks




***From Dr. Nicolas Clemety's presentation EHRA 2022***

# Implantation step: Finger dissection



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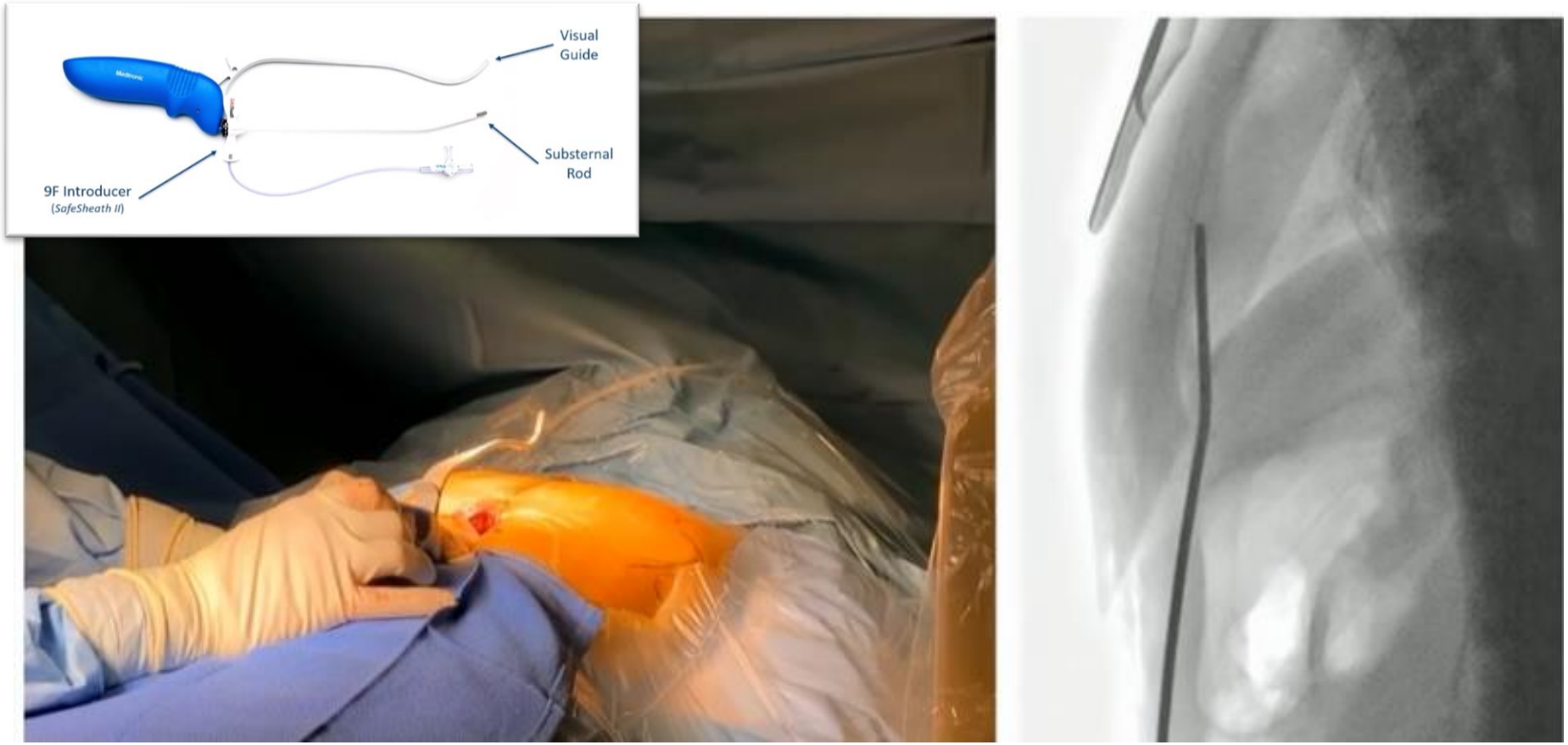
# Implantation step: Substernal tunneling

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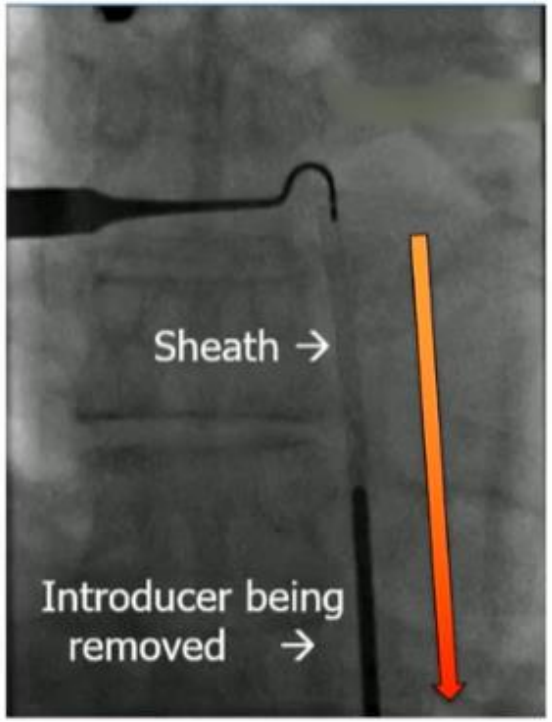
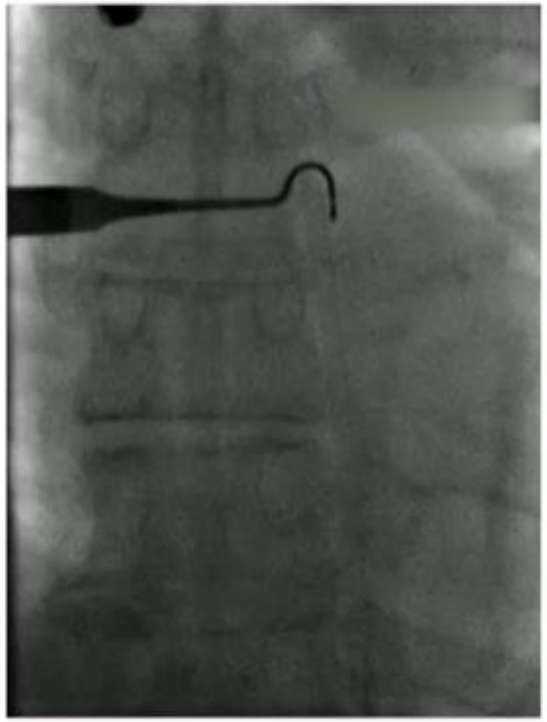
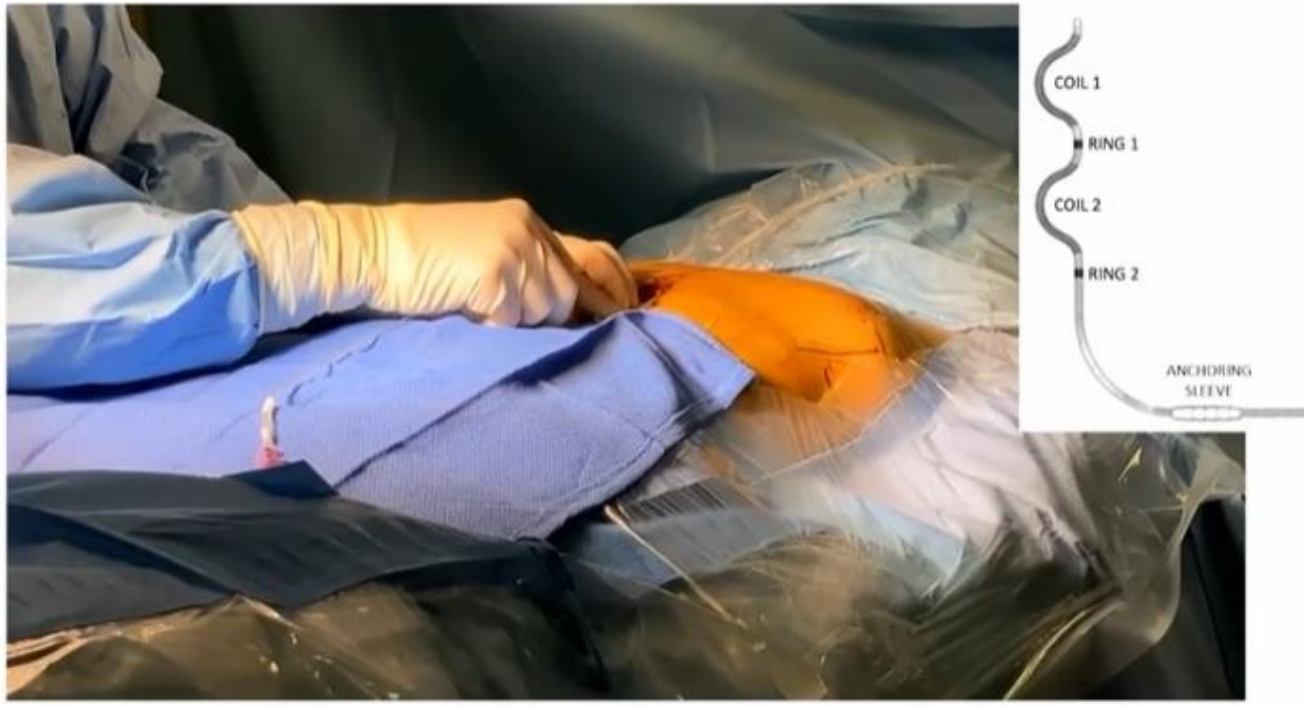
# Implantation step: Lead insertion



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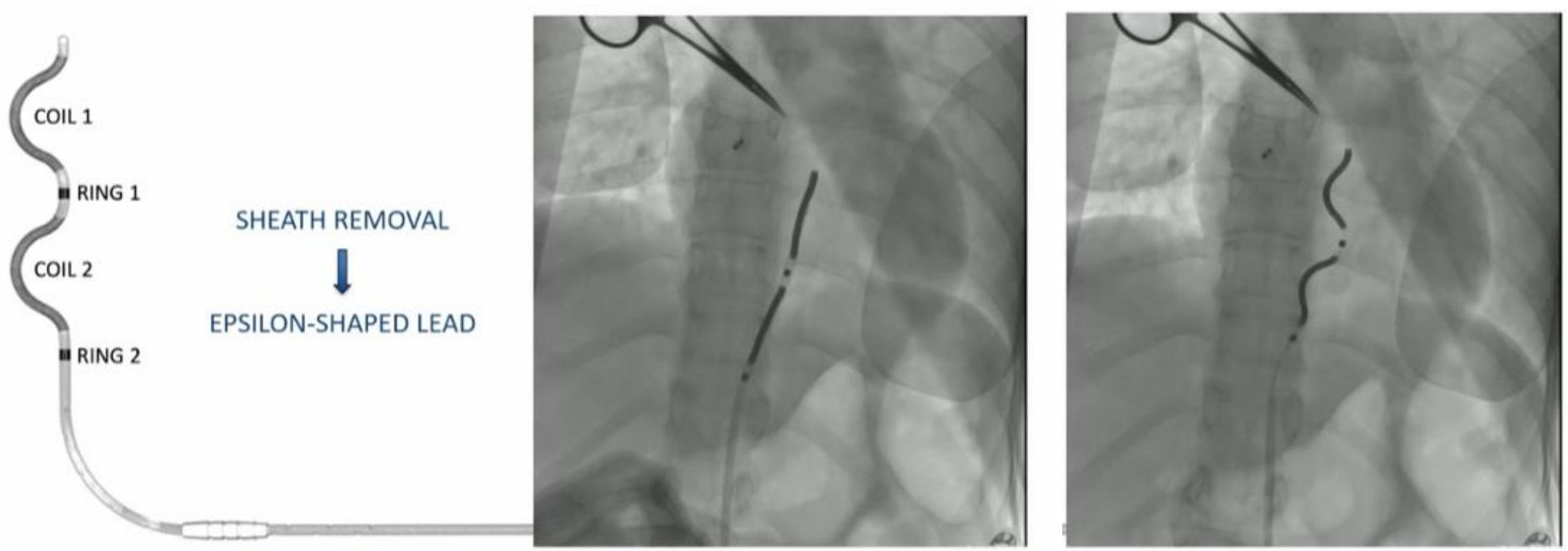
# Implantation step: Lead insertion

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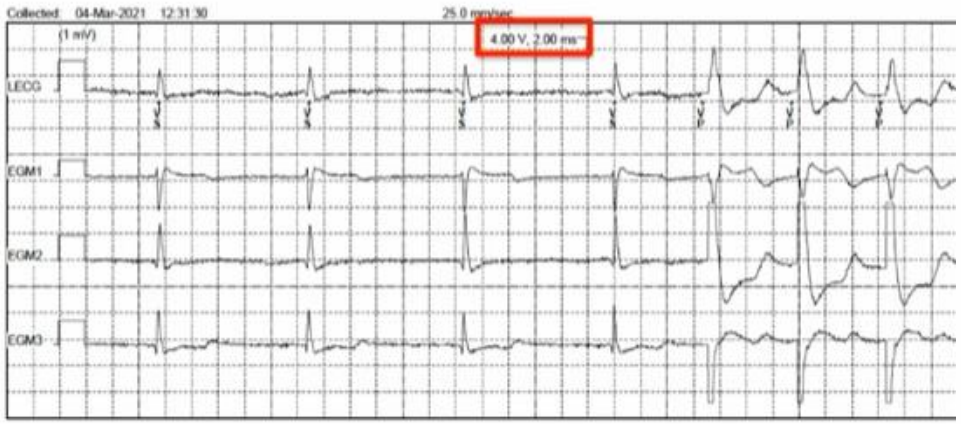
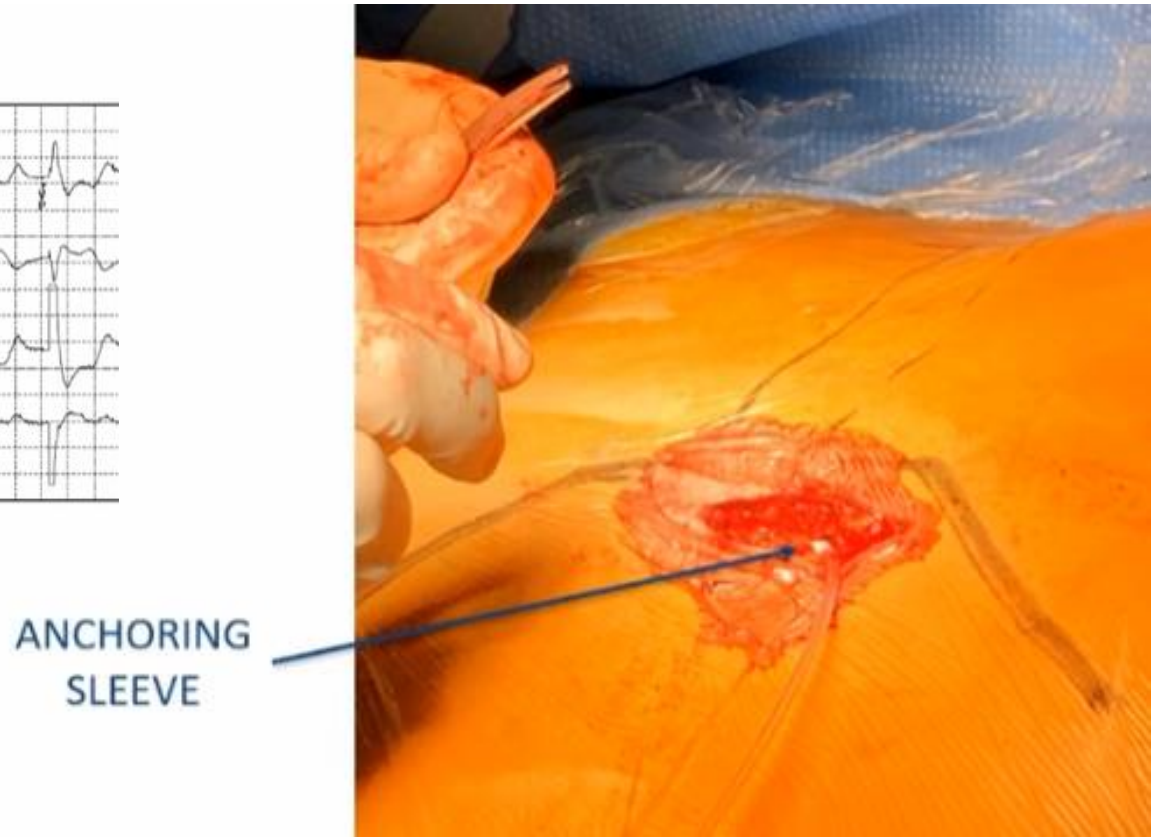
# Implantation step: Sensing/pacing profile / Lead fixation

| | Test Value | Permanent |
|---|---|---|
| Mode | OVO | OVO |
| **Last Sensing Measurement** | | |
| 04-Mar-2021 | | |
| R-Wave Amplitude | 2.4 mV | |
| **Sense Polarity** | | |
| R-wave | Ring 1 to Ring 2 | |




- **Sensing amplitude: >1.0 mV**
- **Pacing threshold in Pivotal study: 4.9 ± 2.0V**

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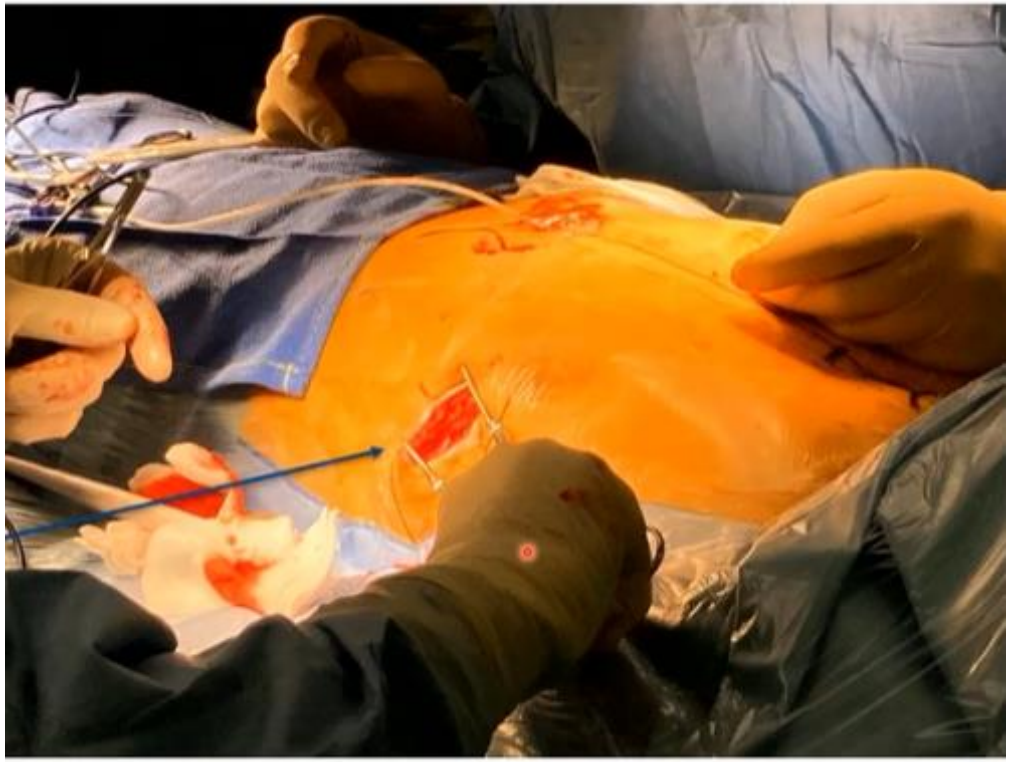
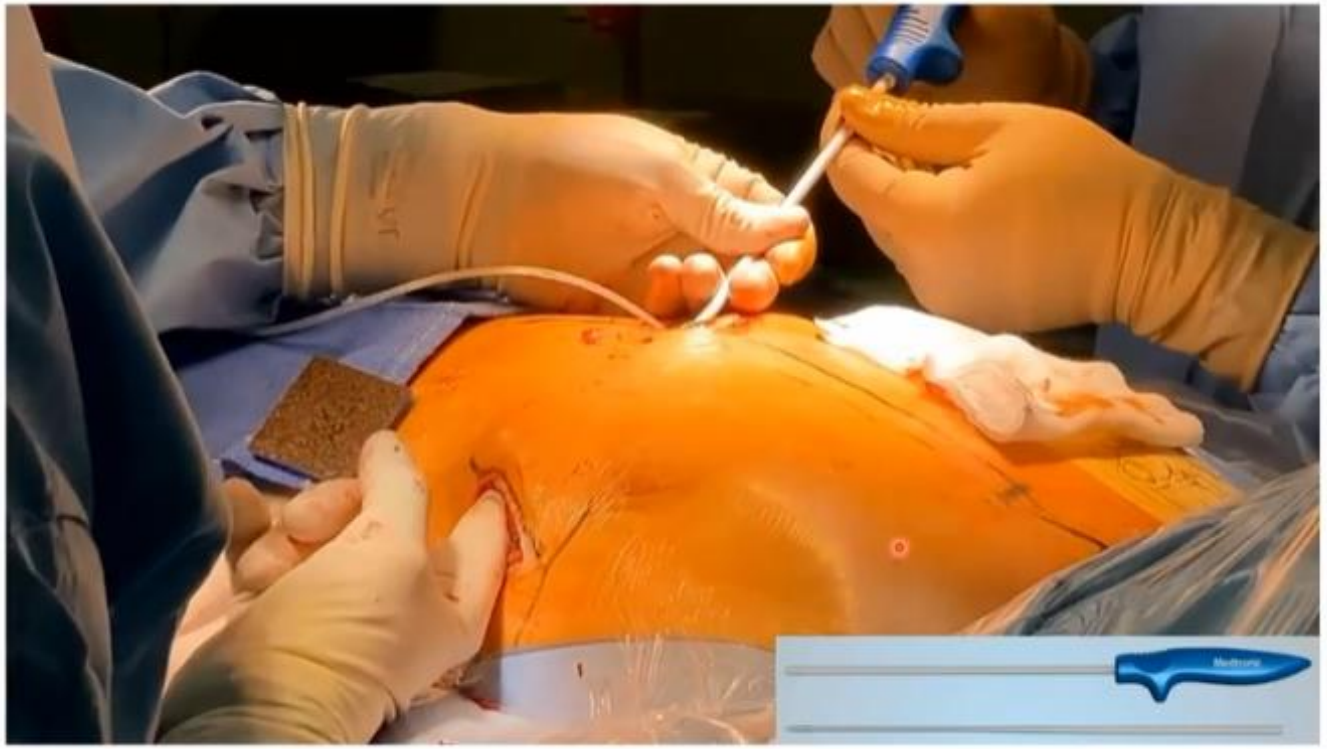
# Implantation step: Axillary pocket / subcutaneous tunneling





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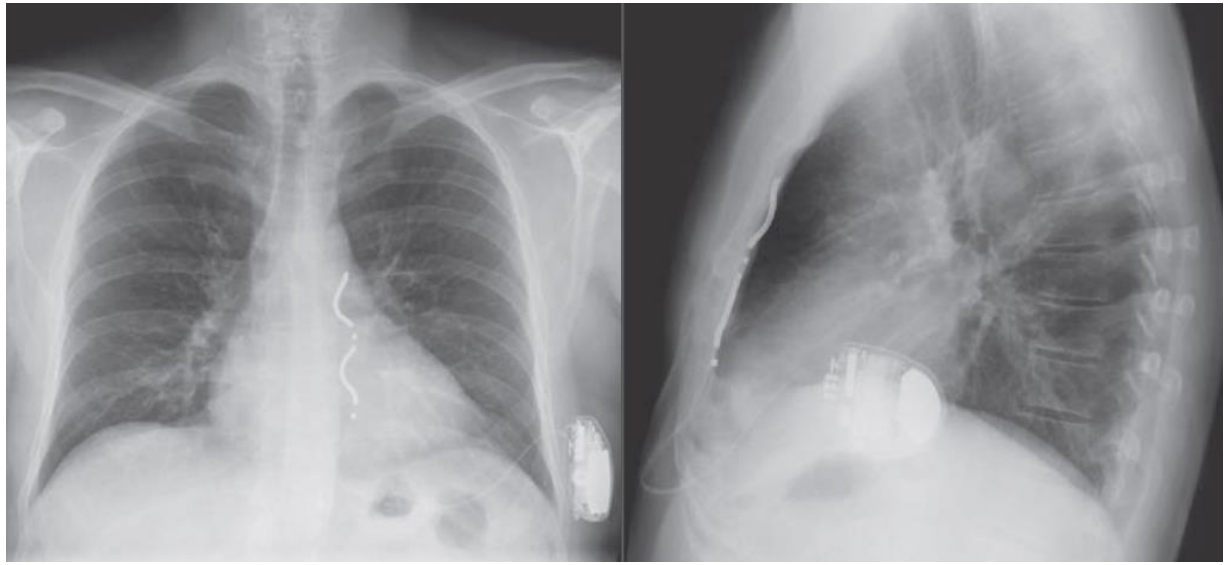
# Implantation step: Generator positioning

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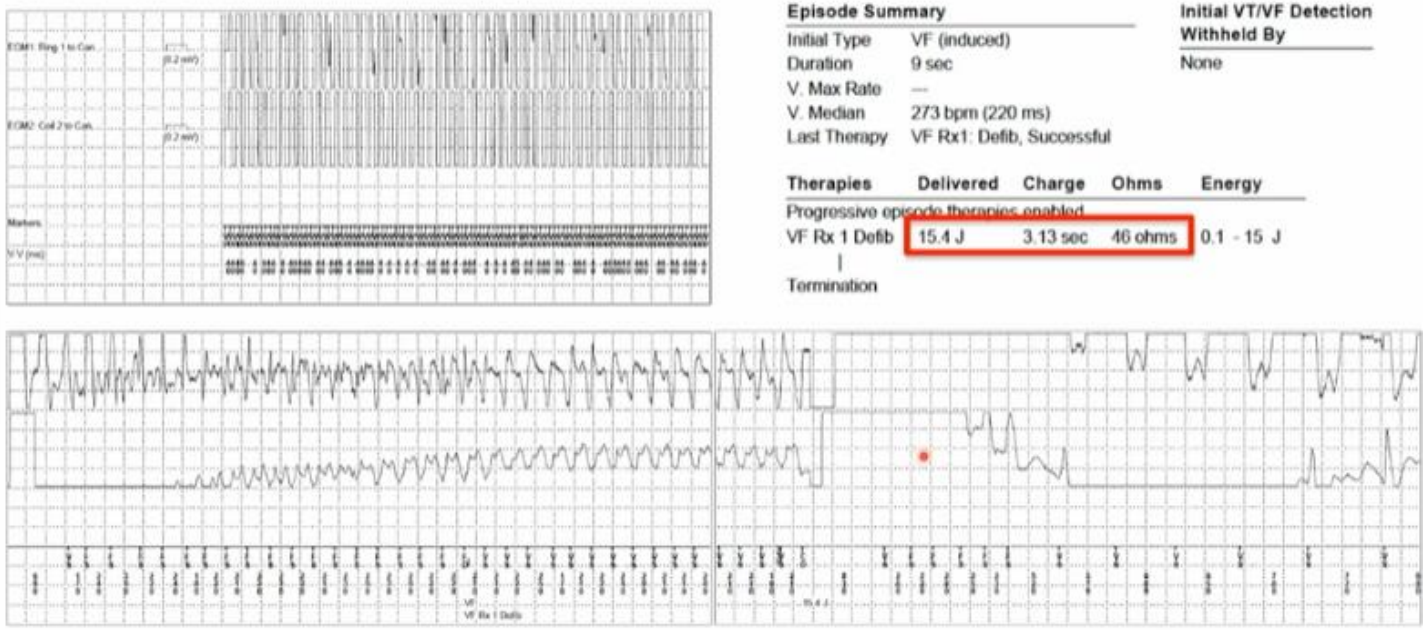
# Implantation step: Defibrillation threshold test / Skin suture



**Episode Summary**

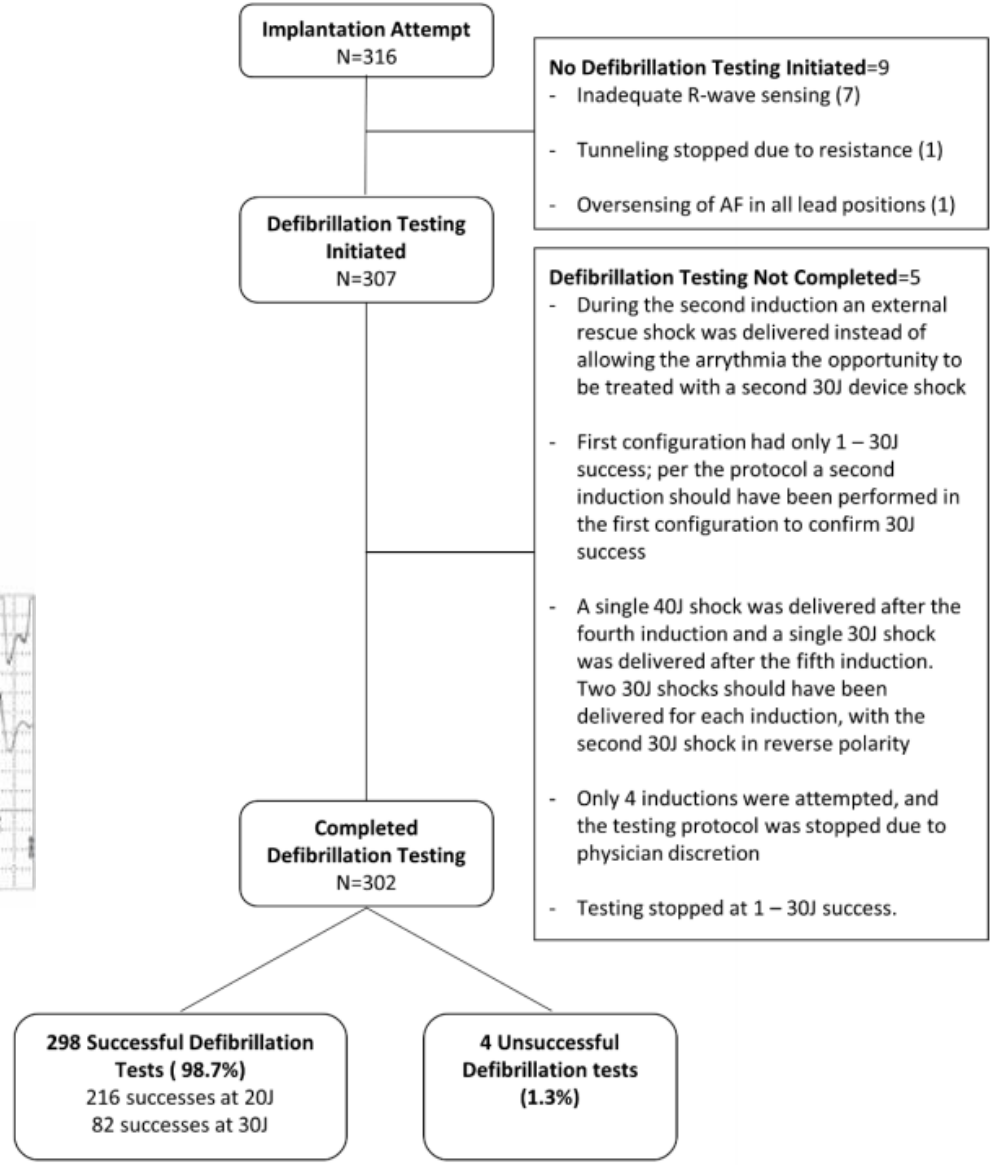
| | |
|---|---|
| Initial Type | VF (induced) |
| Duration | 9 sec |
| V. Max Rate | --- |
| V. Median | 273 bpm (220 ms) |
| Last Therapy | VF Rx1: Defib, Successful |

**Initial VT/VF Detection Withheld By**

None

| Therapies | Delivered | Charge | Ohms | Energy |
|---|---|---|---|---|
| Progressive episode therapies enabled | | | | |
| VF Rx 1 Defib | 15.4 J | 3.13 sec | 46 ohms | 0.1 - 15 J |
| \| | | | | |
| Termination | | | | |



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**Thank you for your attention.**