String-Shaped Subcutaneous Defibrillator

„First in Man“ Feasibility Study

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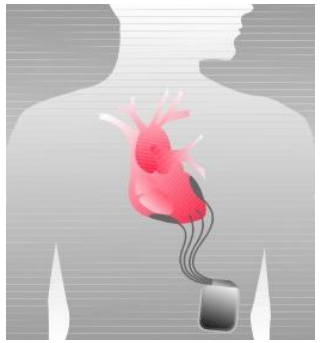
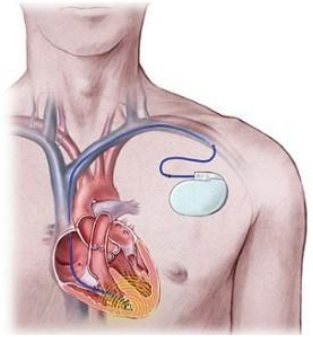
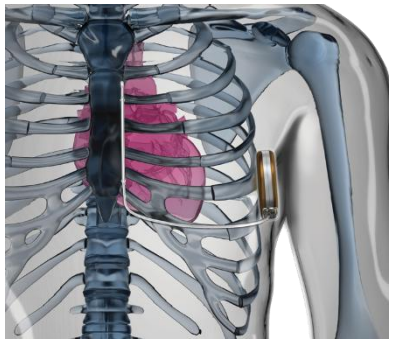
NA HOMOLCE HOSPITAL

KARDIOCENTRUM

ICD Evolution







?

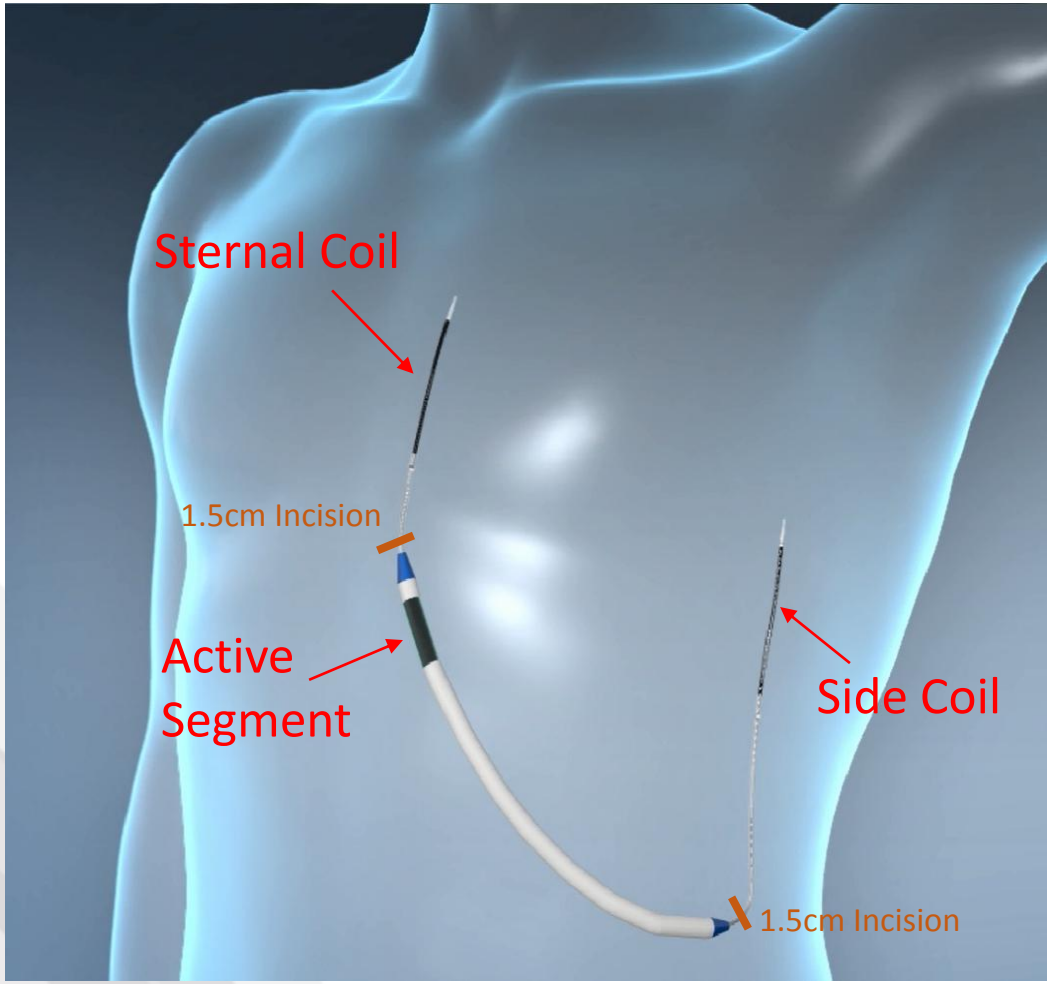
Abdominal IPG
Epicardial patches

Subcutaneous IPG
Intra-cardiac leads

Subcutaneous IPG
Subcutaneous lead

Implantable Subcutaneous String Defibrillator (ISSD)

Basic Concept



Configuration:

1. A unitary (integrated) and flexible structure (“string”) having two shocking coils and an active part (“active segment”)
2. Implanted subcutaneously

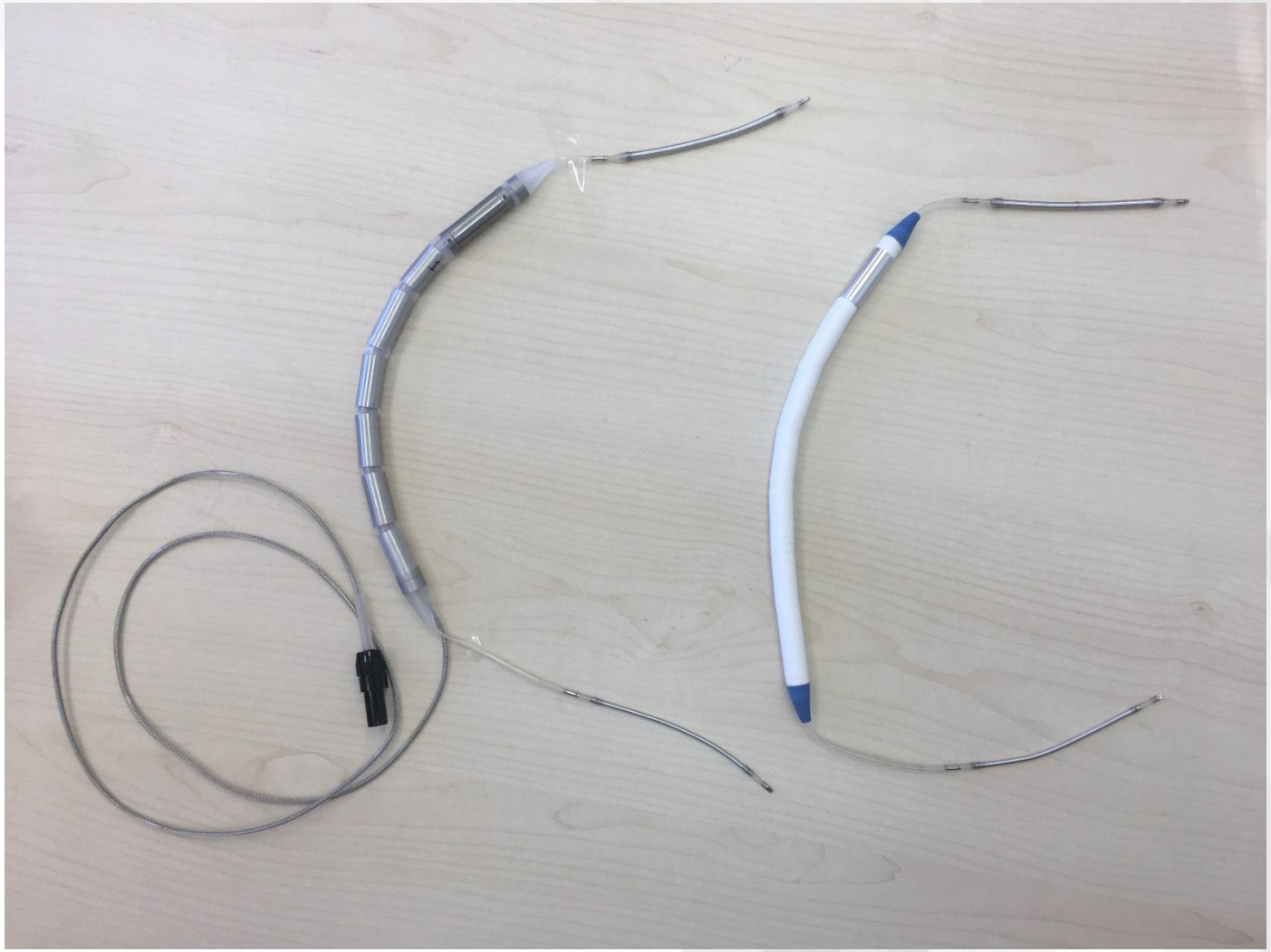
Feasibility questions:

1. Can this configuration defibrillate?
2. How complex is the implant procedure?

ISSD Clinical Trial: *Rationale*

- Use a Passive ISSD Mock-Up
  - Same size and placement
  - Connects via cable to:
    1. External defibrillator
    2. External sense signal recorder

- Acute DFT Study
  - ICD patients, pre-implant



ISSD Mock-up with external connector used in the trial

ISSD – Implantable Subcutaneous String Defibrillator

ISSD Clinical Trial: *Definitions*

Trial design:

- Acute, non randomized, single arm, single center study
  (Homolka Hospital, Prague)

Patient population:

- patients indicated for ICD implantation, prior to implant

Sample size:

- Size: 20-30 size depends on statistics

Endpoint:

- DFT values

Study was approved by hospital IRB and Czech Republic SUKL

ISSD Clinical Trial: *Criteria*

Main Inclusion:

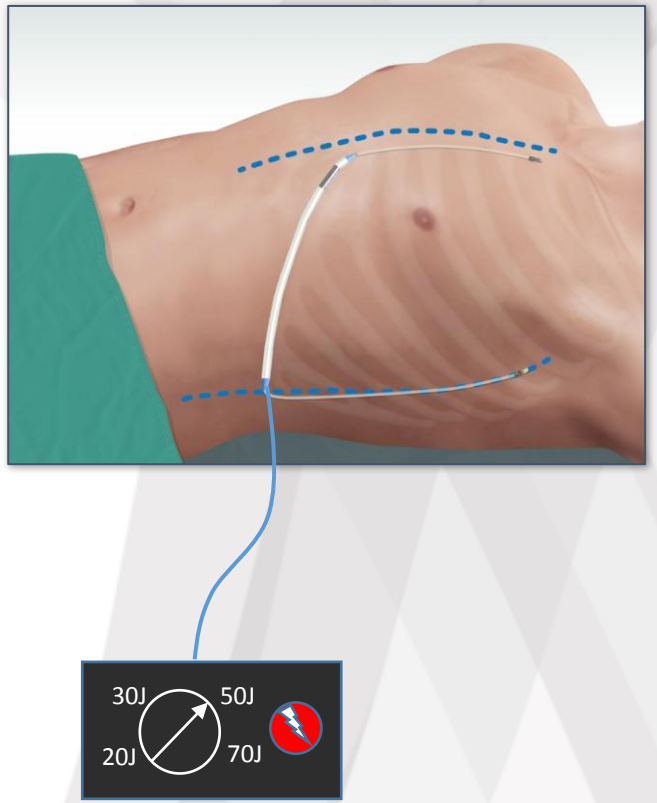
- Subjects meeting class I, IIa or IIb indication for ICD implantation
- Age >18
- 32 > BMI > 25
- 190 > Height > 165 cm
- 120 > Waist size > 90 cm

Main Exclusion:

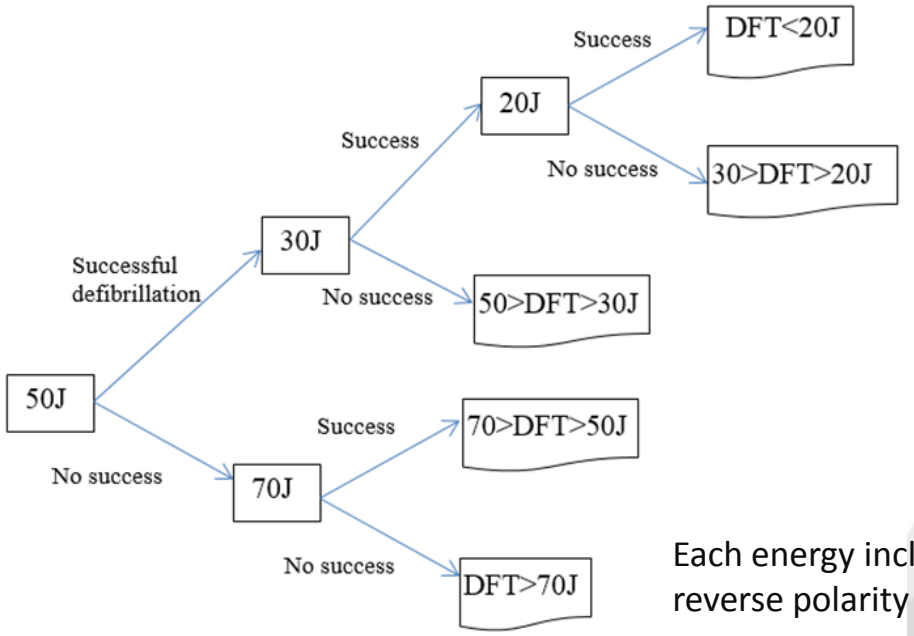
- Epicardial electrodes, >3 endocardial electrodes or other metal objects in the upper part of the body
- prior abdominal surgery in the upper abdomen, previous upper abdominal trauma or anatomical deformities of the chest or upper abdomen
- NYHA III or IV , LVEF ≤ 20% or an enlarged or hypertrophied heart
- Pulmonary hypertension, COPD, renal failure, bleeding disorders
- Antiarrhythmic drugs, Antibiotics

ISSD Clinical Trial: *Design*

- Insert & connect ISSD mock-up device
- Perform DFT search tree
  - Induce by rapid pacing
  - External shock through ISSD mock-up
  - 10 min. break between energy levels
- Extract device



DFT testing tree



Each energy include reverse polarity too

ISSD Clinical Trial: *Demographics*

- 22 ICD implant patients
- 18 male, 4 females
- 91% primary prevention patients

	AVG	STD	Min	Max
Age	69.5	8.9	46	87
BMI	26.9	3.5	20.6	34.1
LVEF	28.9	8.2	10	50

- 18% non ischemic cardiomyopathy
- 14% with prior cardiac surgery

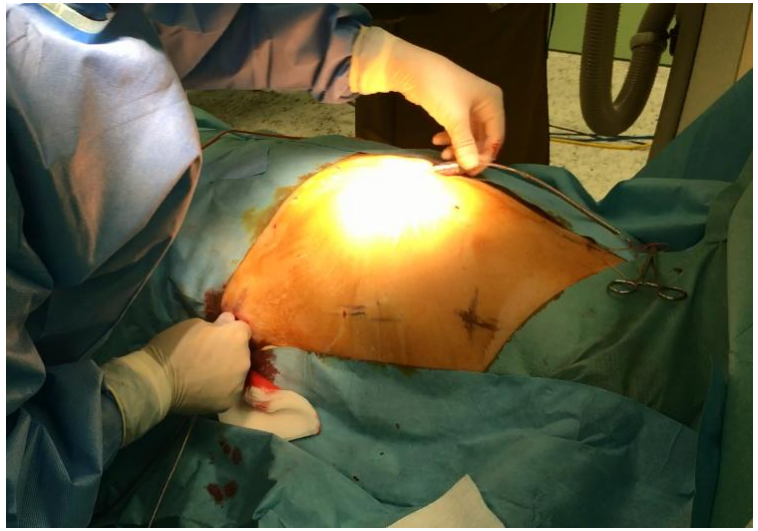
Implanting Procedure: *Position Marking*

1. Marking location using the ISSD mockup

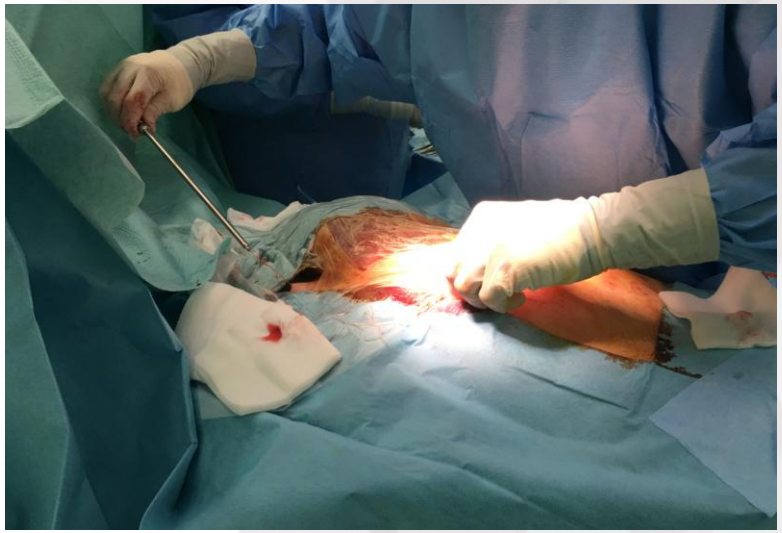
2. Verifying location using static fluoro

Implanting Procedure: *Tunneling and Insertion*

3. Tunneling



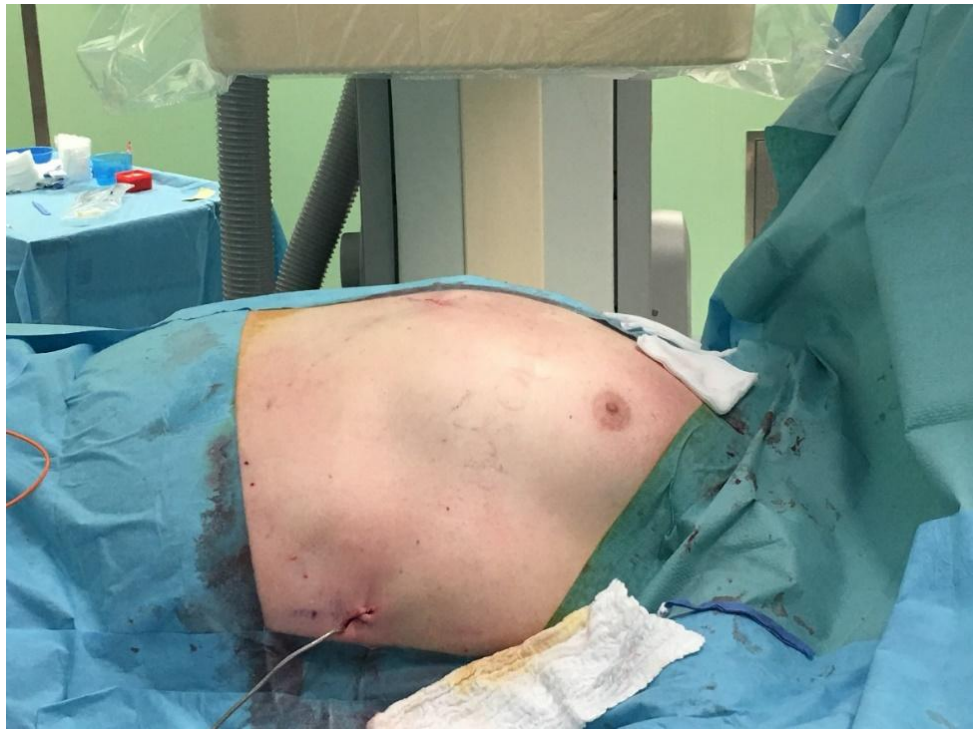
4. Device insertion



5. Lead tunneling and insertion

Tunneling tool by Scanlan International Inc.

Implanting Procedure: *Device Post Implantation*

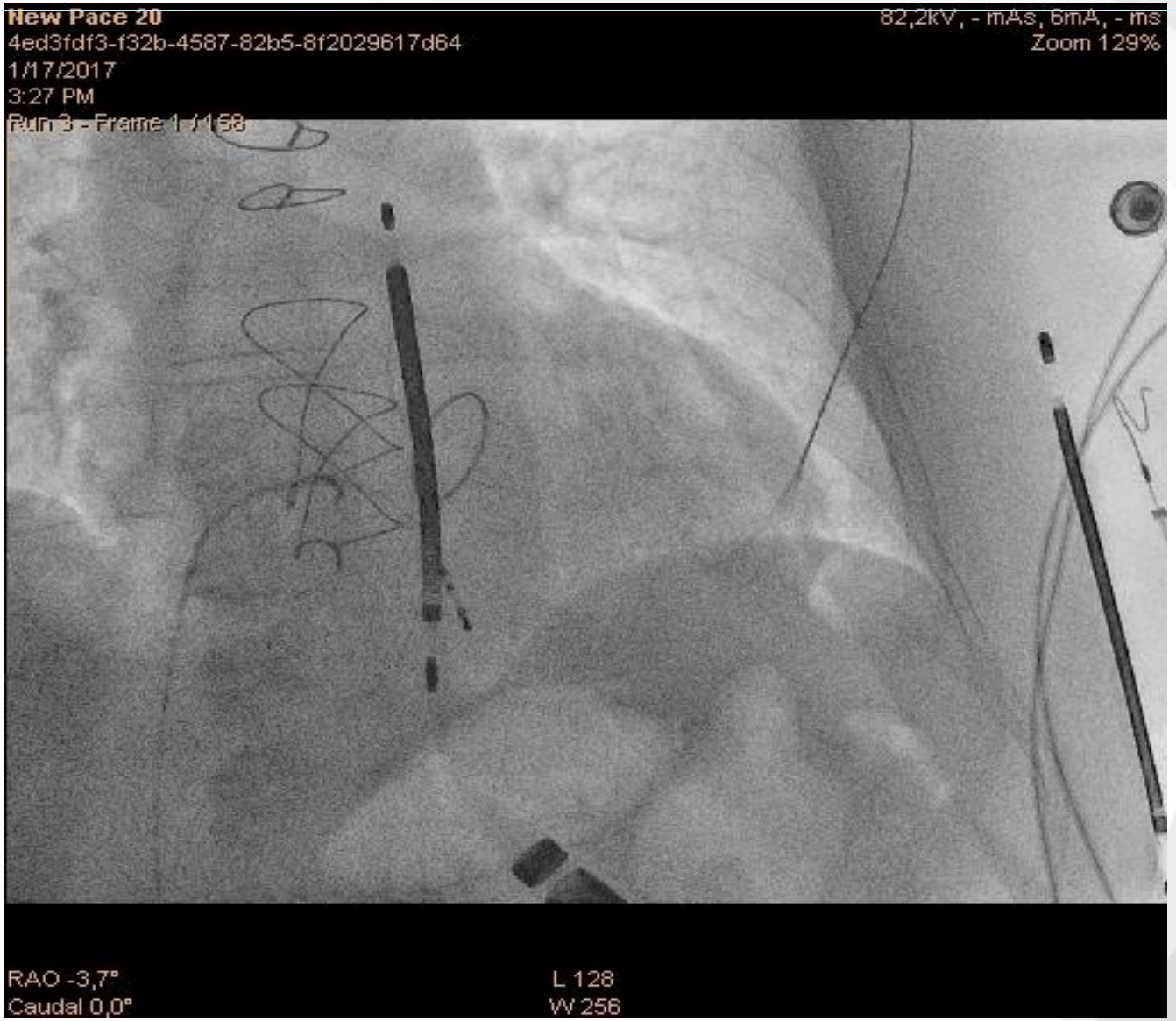


ISSD Mockup fully implanted

Fluoro of ISSD Mockup fully implanted

- Implanted using existing (of-the-shelf) subcutaneous tunneling tools
- Very short implant time

Implanting Procedure: *Device Post Implantation*



ISSD Clinical Trial: *Defibrillation Results*

Minimal energy of successful shock (J)	Number of patients*
20J	**7**
30J	**4**
50J	**7**

* 4 patients excluded from results due to lead misplacements

DFT statistics: **25.8J ± 10.7J**

Thus - 60J defibrillation shock has > 99.87% chance success

Notes: 1. Patient shock impedances between 34Ω and 89Ω

2. No reported complications in any of the patients, did not prolong the stay of patients in the hospital

Conclusions

Q: Can this configuration defibrillate successfully?

1. Yes
2. Device positioning according to guidelines is required
3. Patient screening with 50J defibrillation
4. The sensing trial shows good sensitivity (100%) as well as good specificity (97.6%) with low chance for false shocks

Q: How complex is the implant?

1. Easy and fast (Mostly under 20Min, the fastest took 11Min)
2. Would be shorter with tailored implant tools
3. Positioning using pre-op fluoroscopy is required

Thanks to the team

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