COMSOL CONFERENCE
2018 LAUSANNE

MicroPort™
CRM

Shanghai
MicroPort Medical (Group) Co., Ltd.

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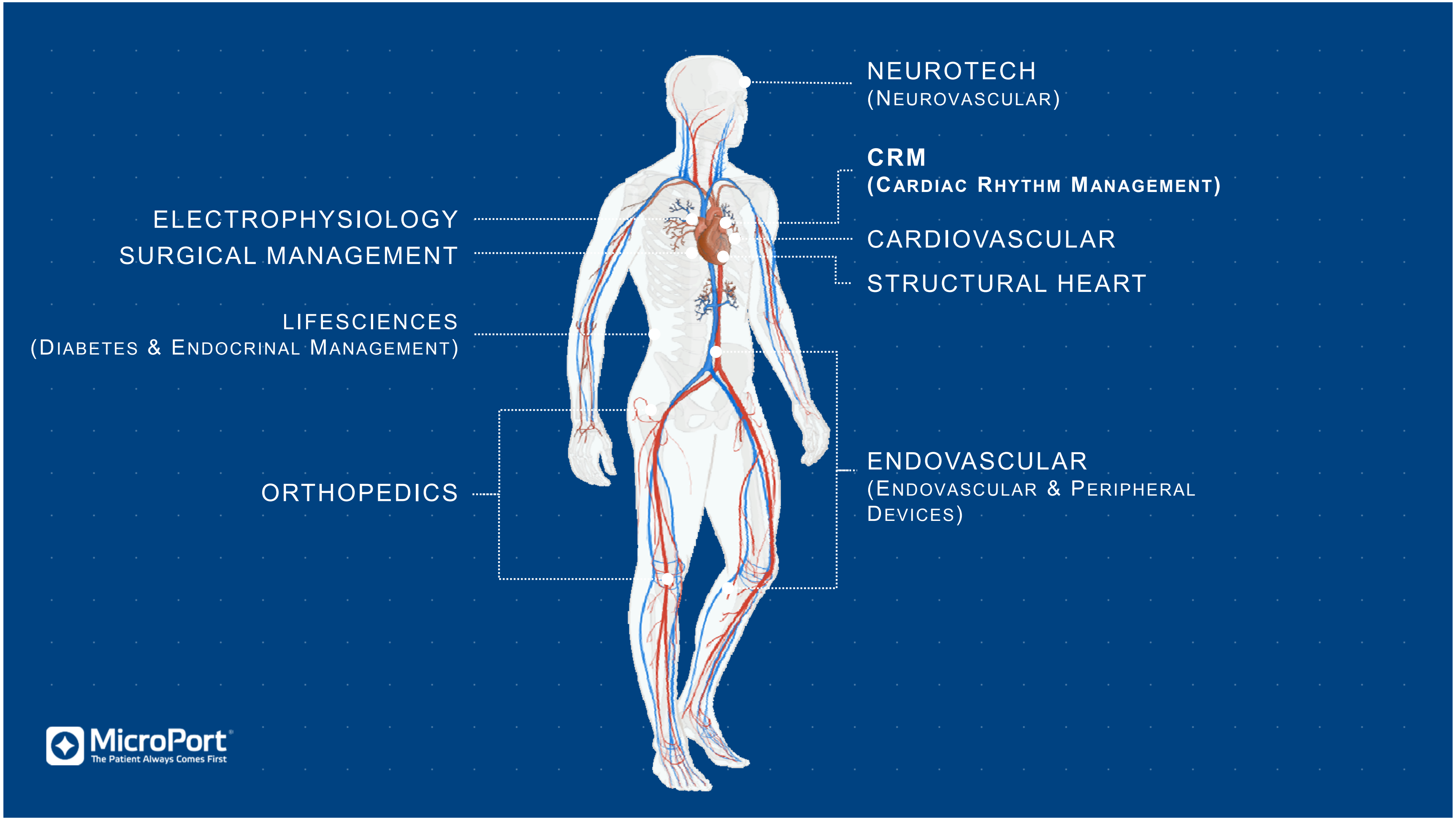
MicroPort
The Patient Always Comes First

Company Overview

Every 12 seconds MicroPort products are used to provide lifesaving medical intervention and life-quality improving care to patients around the world.

- Nearly 4,500 employees worldwide
- Over 260 products offered
- Over 5,000 hospitals product coverage
- Nearly 1,400 applied trademarks
- Over 100 ongoing R&D projects


NEUROTECH
(NEUROVASCULAR)
CRM
(CARDIAC RHYTHM MANAGEMENT)
ELECTROPHYSIOLOGY
SURGICAL MANAGEMENT
CARDIOVASCULAR
STRUCTURAL HEART
LIFESCIENCES
(DIABETES & ENDOCRINAL MANAGEMENT)
ORTHOPEDICS
ENDOVASCULAR
(ENDOVASCULAR & PERIPHERAL DEVICES)
MicroPort
The Patient Always Comes First

CRM Business Overview

3 Major Manufacturing Facilities

- One of the top 5 worldwide cardiac rhythm management device manufacturers, focusing on development and manufacturing of systems to treat cardiac rhythm disorders and heart failure.
- Global workforce of over 900 employees, with major facilities across Europe and in over 10 countries
- Provided over 1 million CRM products for the past 40 years
- Innovation is in our DNA

CRM Business Products & Therapies

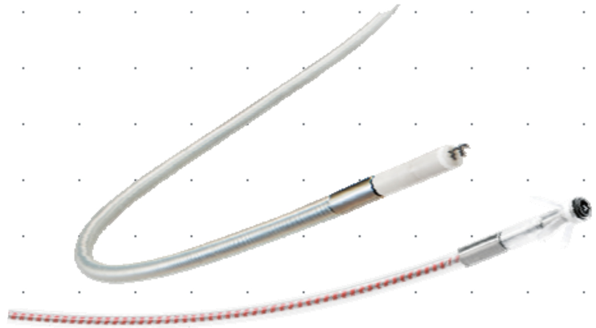
Pacemaker (PM)

Treatment of Bradycardia
(heart rate slower than normal rate)

Defibrillator (ICD)

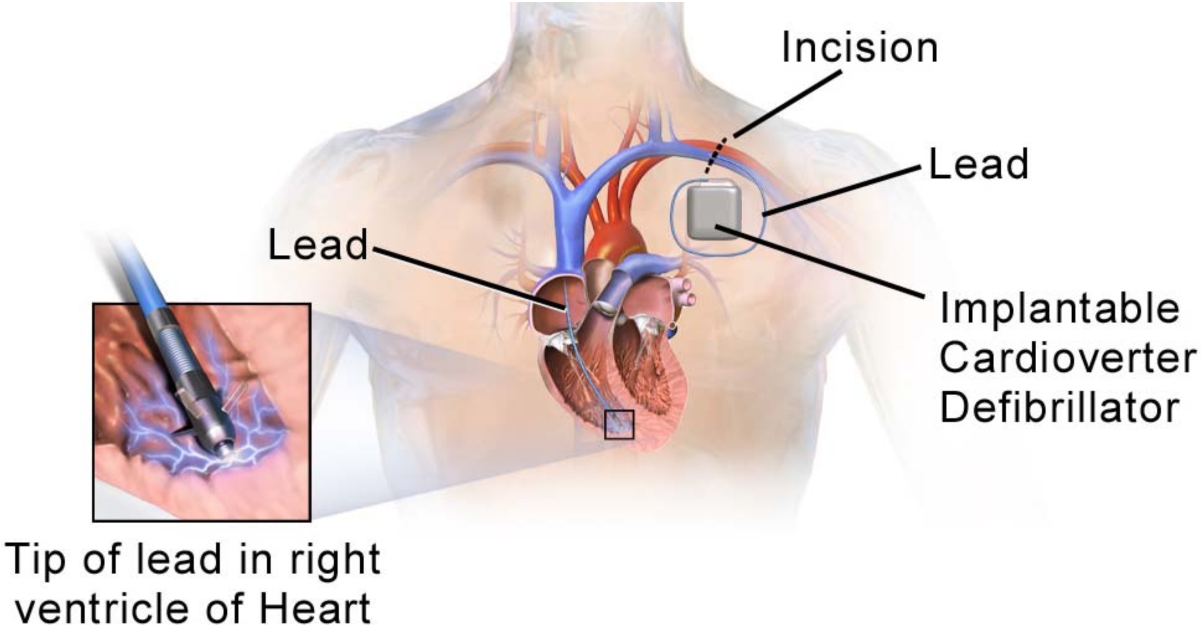
Treatment of Bradycardia & Tachycardia
(heart rate faster or improper)

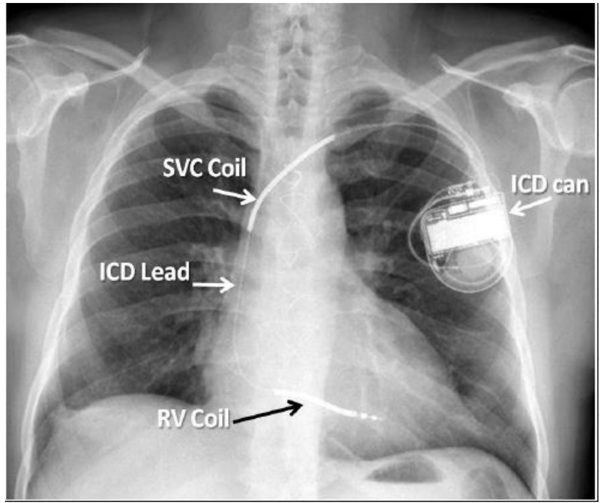
Lead



Placing electrodes in different parts of the body/h

CRM Therapy

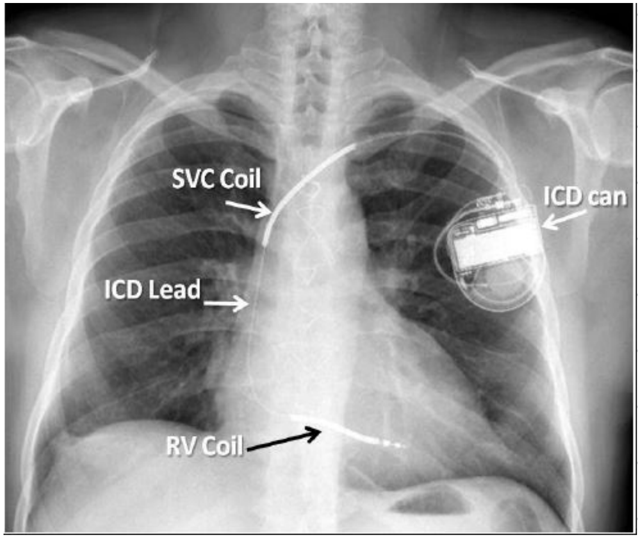

Incision
Lead
Lead
Implantable Cardioverter Defibrillator
Tip of lead in right ventricle of Heart

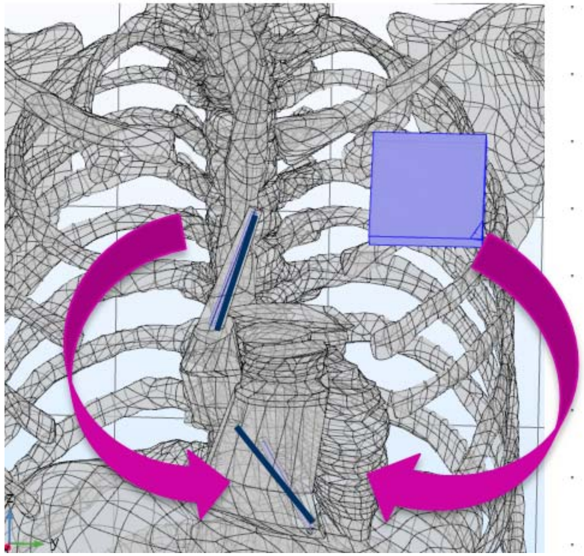

SVC Coil
ICD can
ICD Lead
RV Coil

Defibrillation Therapy

2 Configurations:

RV to CAN — RV to CAN & to SVC



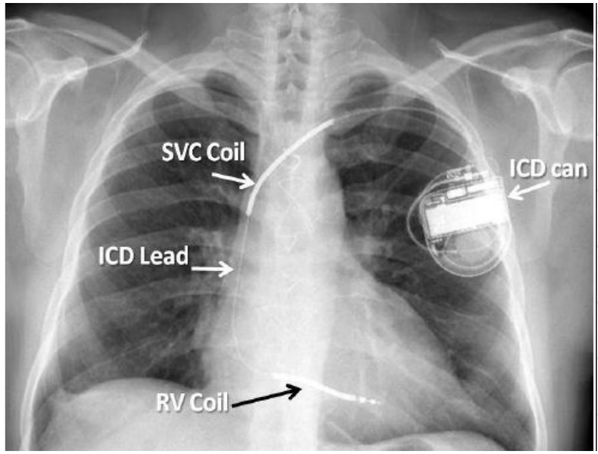


Typical Parameters:

- Voltage 200 ÷ 600 V
- Current 2 ÷ 6 A
- Time 5 ÷ 10 ms
- Energy 5 ÷ 40 J

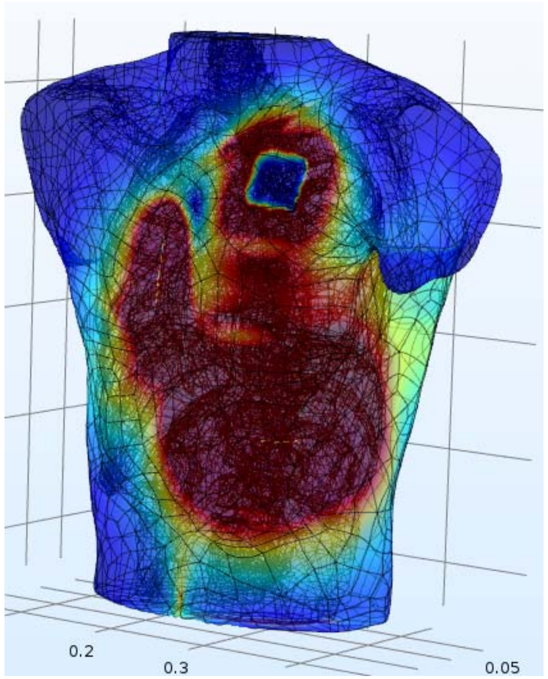
CRM Clinical Testing

From Animal To Human



- Minimum 3 runs of animal testing (15 pigs/dogs per run) and 3 runs of human testing (15 patients per run)
- Time consuming, approx 1 year for 3 runs
- Expensive, hundreds k€ per run
- **Trials repetition in case of failure (iterative approach) → Multiplications of Time, Cost & Risk for the patient**
- ~~**Reducing the Animal testing preserving the same reliability is ethical**~~
- **Reducing the risk of failure of the run (animal or human) is ethical**

Simulation as alternative to Animal Testing



- Reducing the Animal Testing preserving the same reliability is ethical
- Reducing the risk of failure of the run (human or animal) is ethical
- Simulation is used to select the best promising configurations
- **Simulation reduces the risk of failure of the animal and human testing trials**
- **Simulation decreases the need of animal testing**
- **Do it right the first time reducing the burden of the animal and human testing**

SYNOPSYS®
Silicon to Software™

COMSOL CONFERENCE
2018 LAUSANNE

Synopsys Simpleware

Microport CRM Torso model generation

Dipl.-Ing. Denis Feindt (Business Development Manager, Sr. Staff)

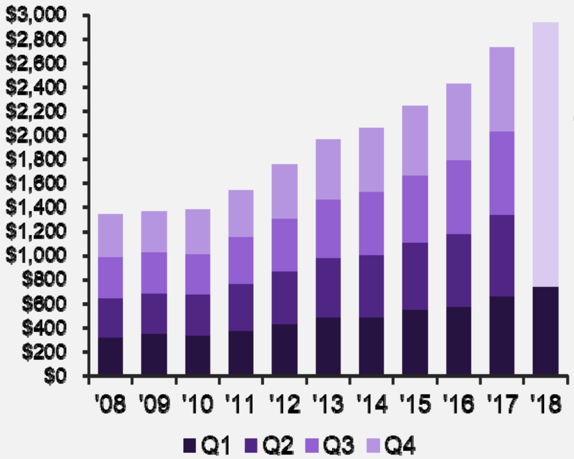
October 23rd - 2018

Synopsys Today

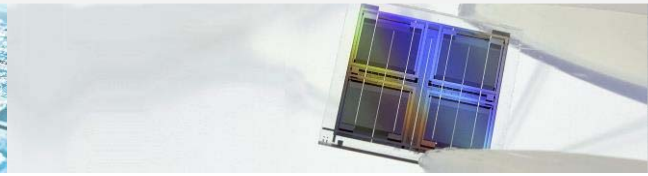
FY17 Revenue:
~$2.7B

Employees:
>12,200

Years: 30+



- **#1** electronic design automation tools & services
- **Broadest IP portfolio** and **#1** interface, analog, embedded memories & physical IP
- **'Leader'** in Gartner's Magic Quadrant for application security testing

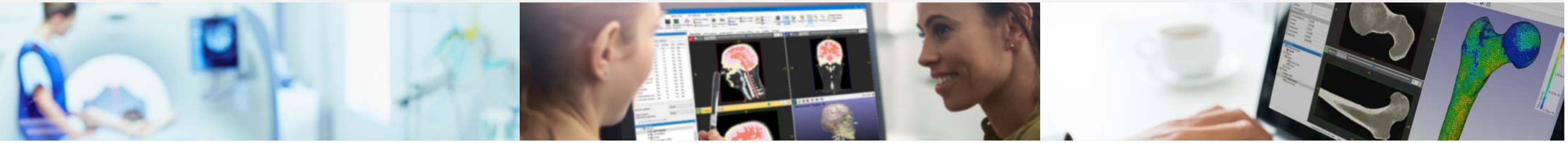


SYNOPSYS

Synopsys - Simpleware Product Group

- Developers of high-end 3D image processing software
- Dedicated sales, support and service teams
- Global presence
- Clinical and broader life sciences / materials applications

SYNOPSYS® | SIMPLEWARE PRODUCT GROUP



SYNOPSYS®

Simpleware Software Solutions & Applications

GUI-based high-end 3D image processing platform which provides comprehensiverange of tools for:

- Visualization including animation 3D data
- Filtering and segmentation
- Measurement and quantification
- CAD and image integration
- 3D print, CAD and simulation model generation

Brain Stimulation

Protective Gear

Implants

Wearable Electronics

Surgical Guides

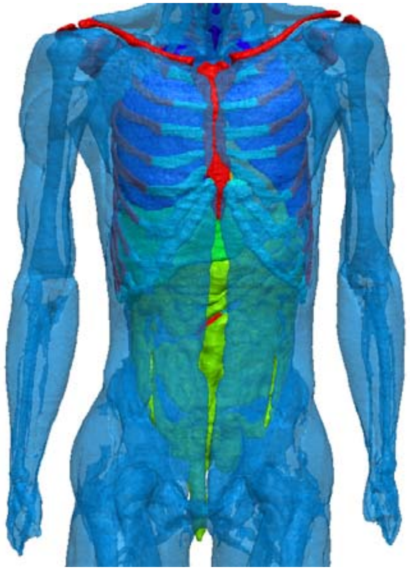
Consumer Products

Drug Delivery

Shoes / Clothing

Geometry: Duke Body Model

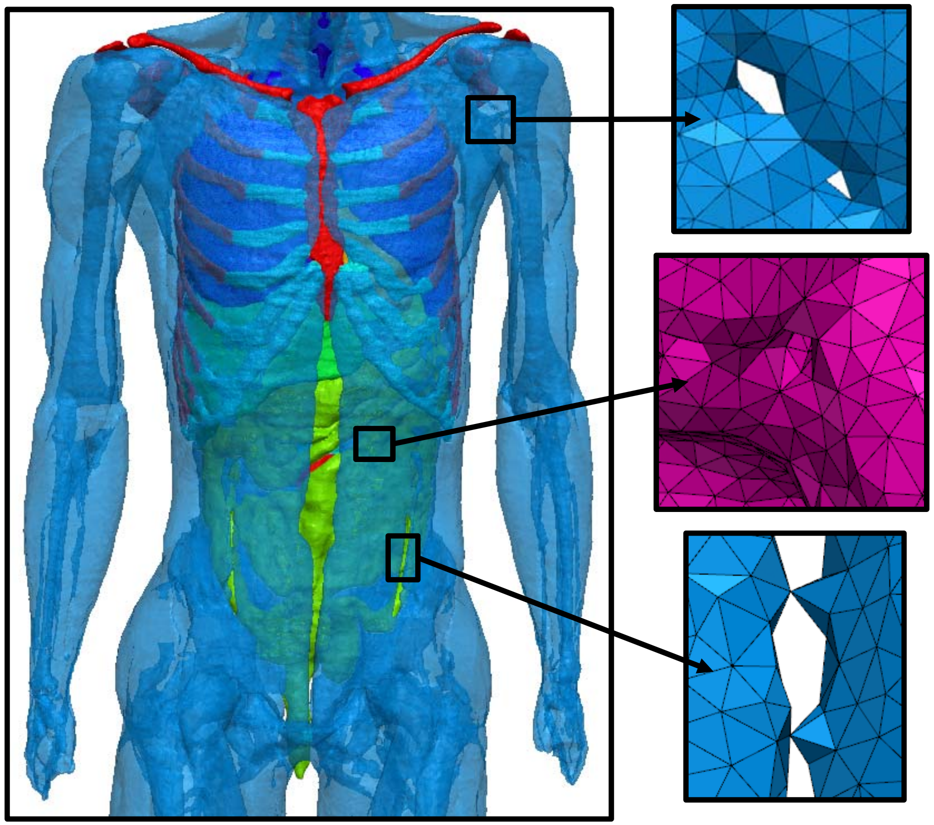
Torso



- The body is “Duke” from the virtual family of ETH Zurich and FDA.
- https://www.itis.ethz.ch/news-events/news/virtual-population/enhanced-virtual-family-models-ella-duke-billie-thelonious/

Simpleware model generation

Processing original STLs



Original geometries – Issues for Simulation

Original geometries in STL format

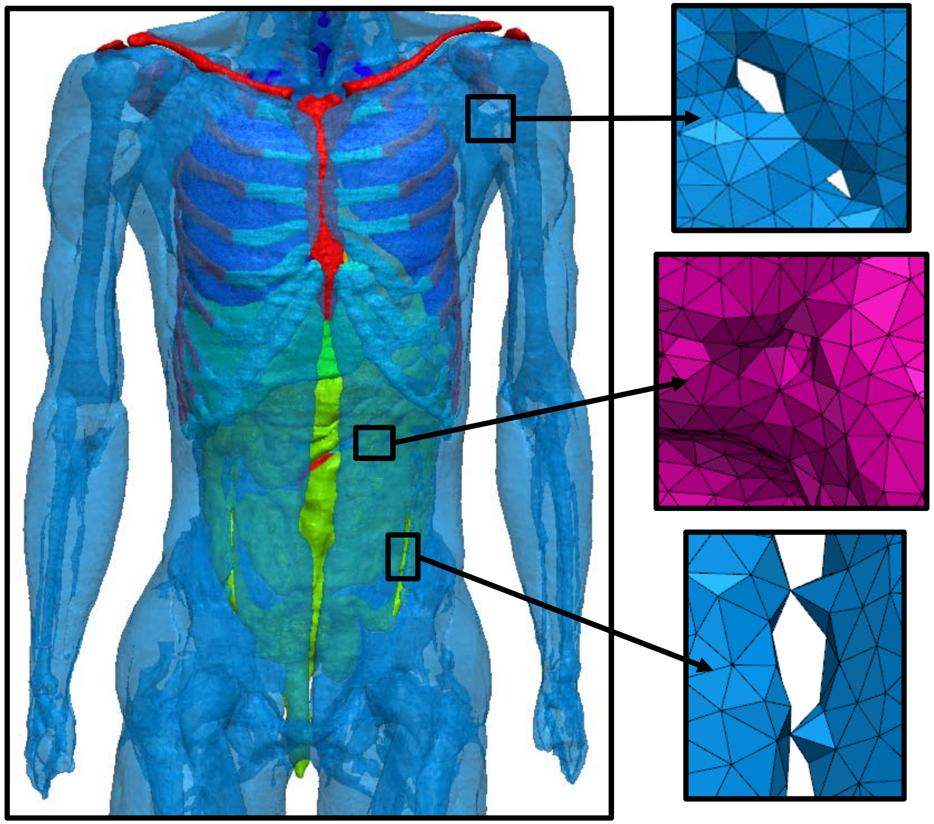
Some issues with individual part triangulation

- Holes
- Vertex-vertex connections
- Non-manifold triangle edges

Many parts with complicated interaction

- Small gaps
- Overlaps

Not possible to use for meshing



Simpleware model generation

Processing original STLs

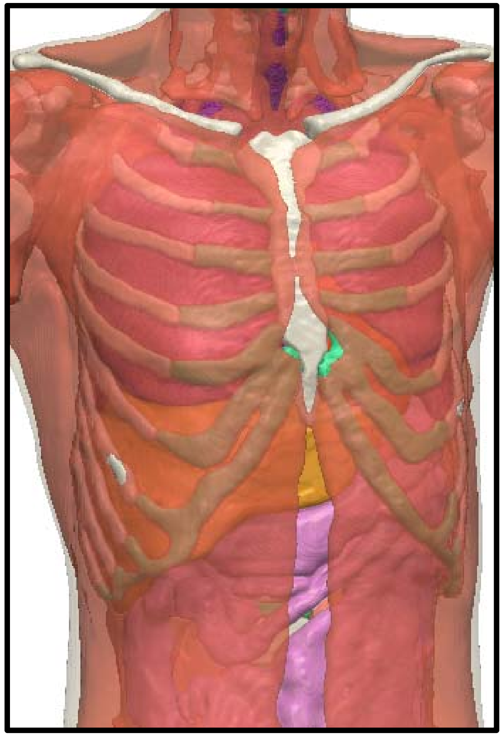
Models produced by Simpleware:

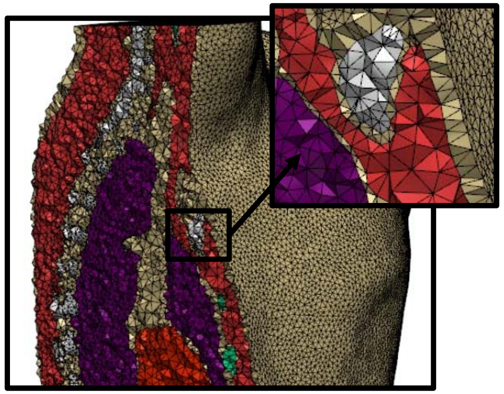
- Simulation-ready volume meshes for COMSOL Multiphysics
- NURBS IGES files for geometry editing and re-meshing

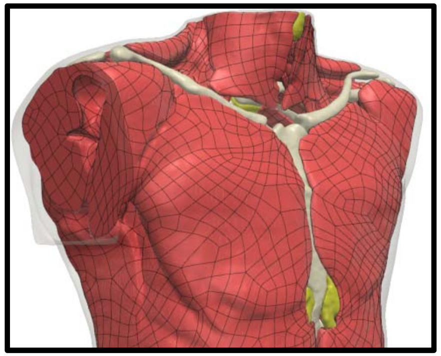
Smooth, accurate geometries

Correct topology, no gaps

Suitable for EM simulations in COMSOL Multiphysics



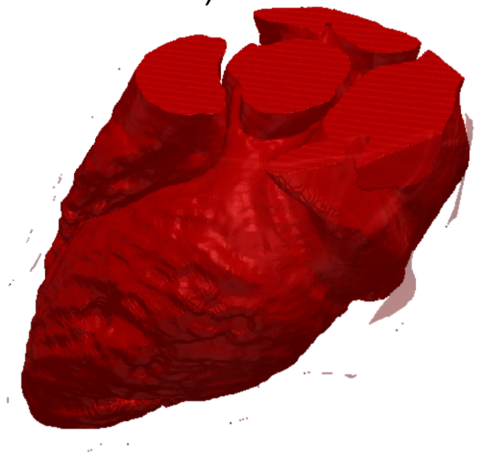




Simpleware – Detailed Heart Model from separate dataset

Original heart model (no chambers)

Improved heart model (with chambers)



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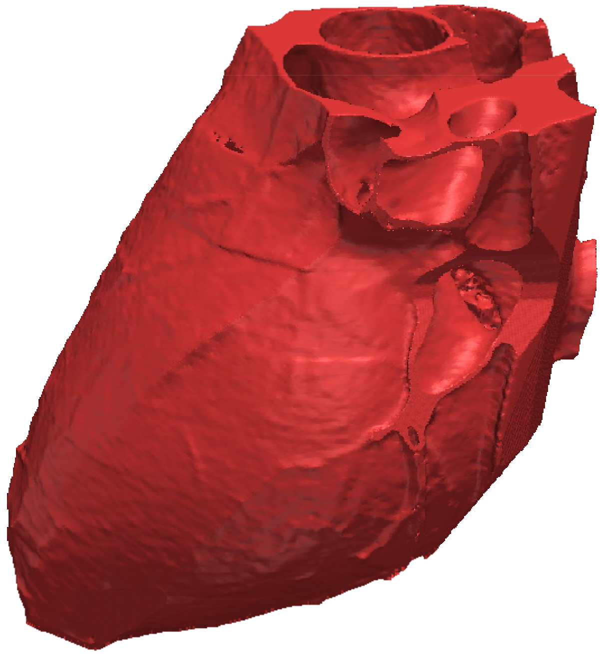
Voxelise STL, use image processing tools to remove unnecessary details.



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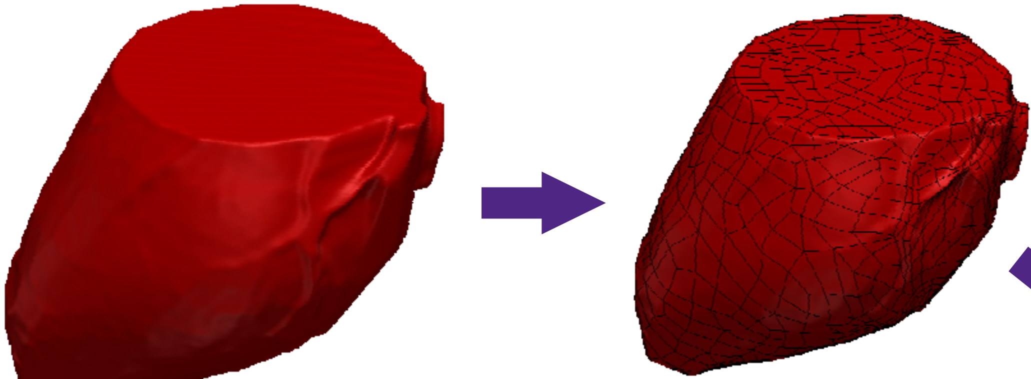
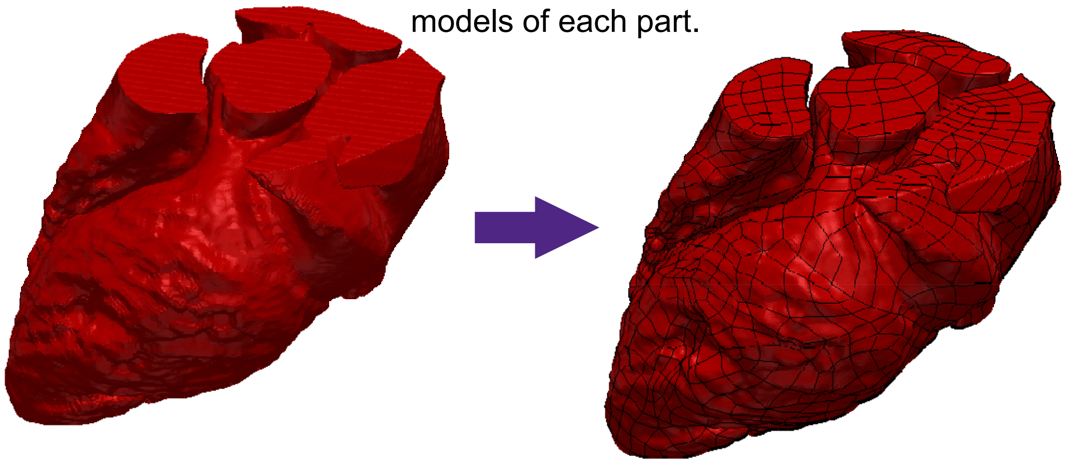
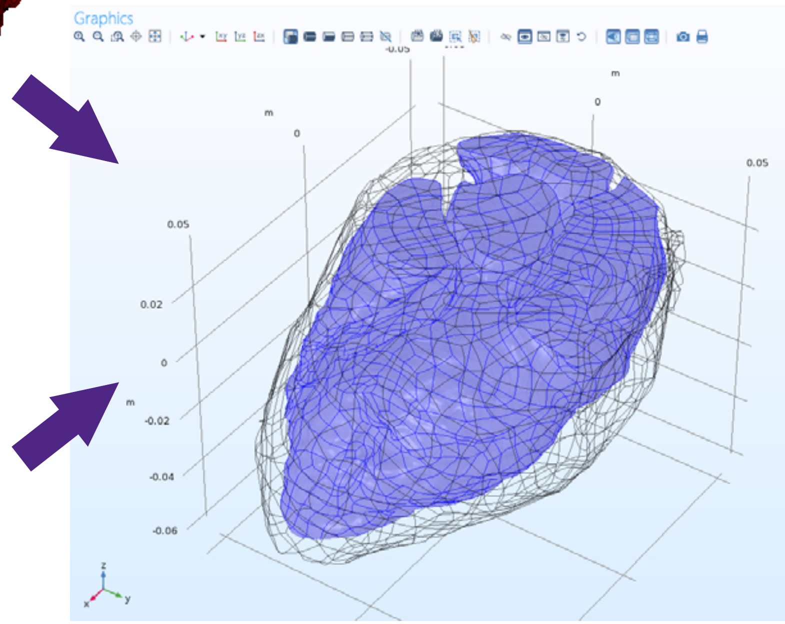


Close outer surface into a solid. Segment chambers. Generate individual NURBS models of each part.





Import into COMSOL

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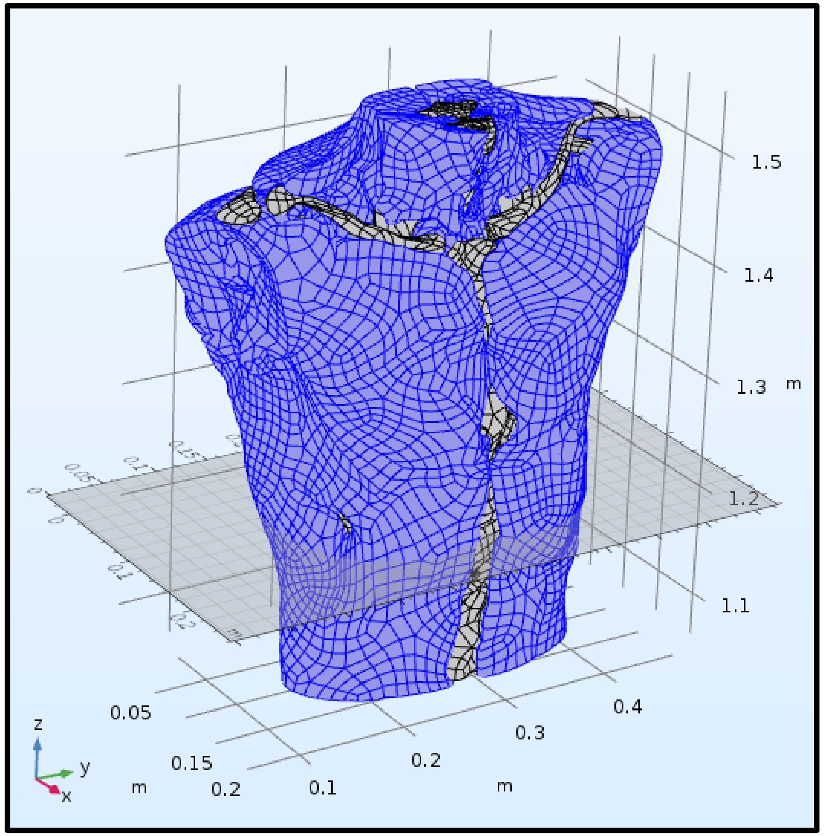
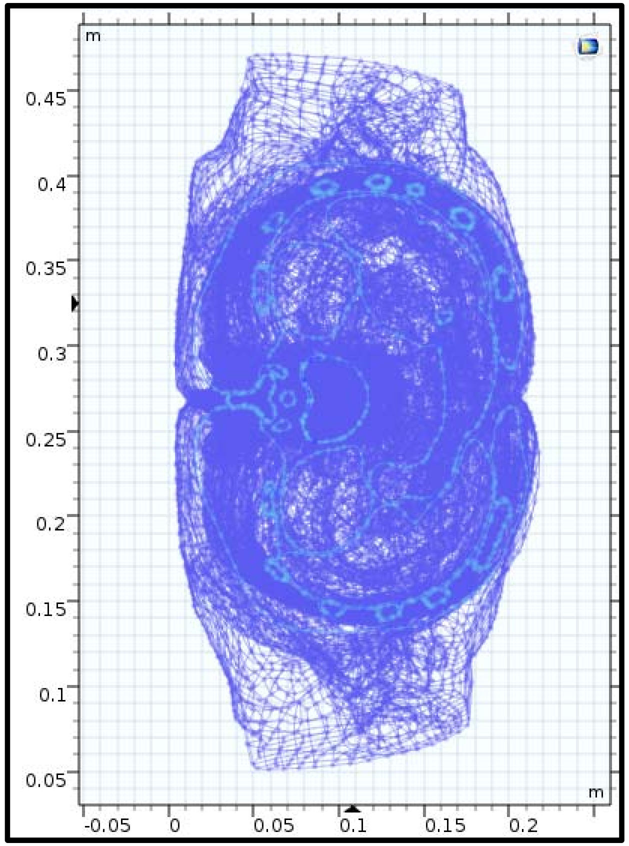
Simpleware models in COMSOL Multiphysics





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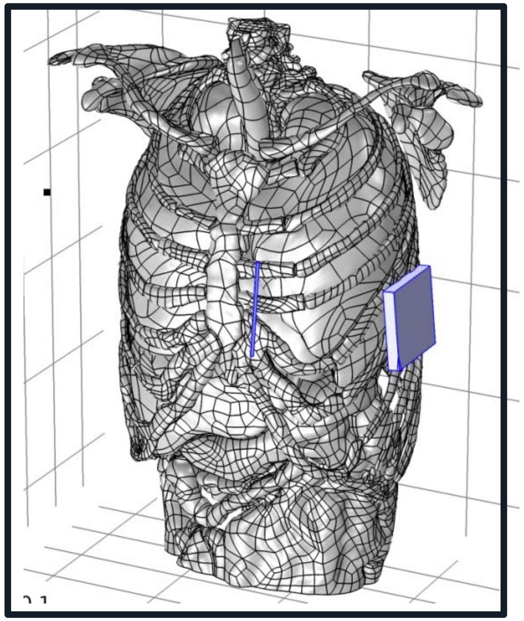
Simulation procedure



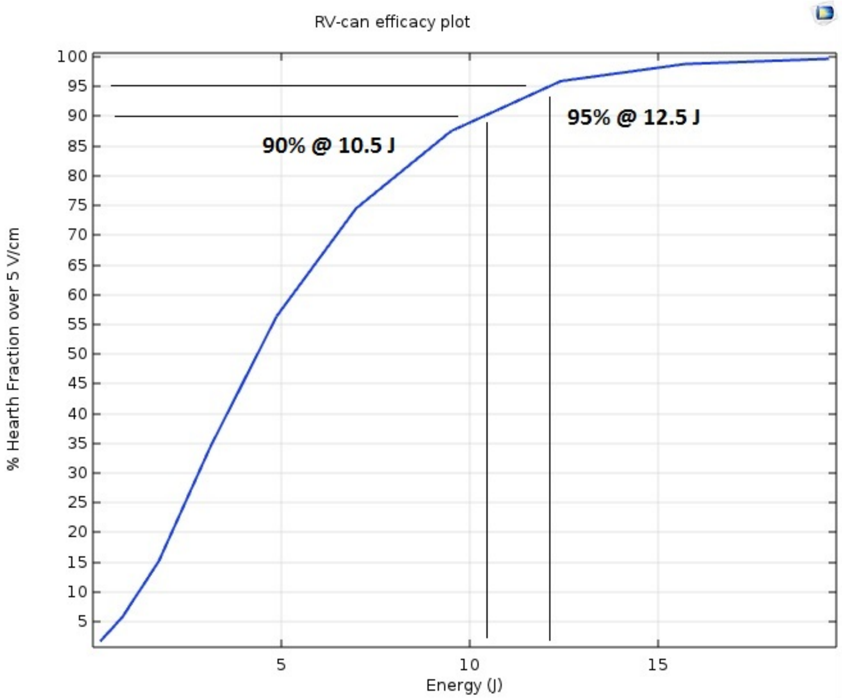
1) Place the electrodes in the body

2) Assign conductivity to tissue

3) Apply Voltage

4) Output is the current pathway and the electric field inside the heart

Shock Efficacy Plot



Efficacy plot correlates:

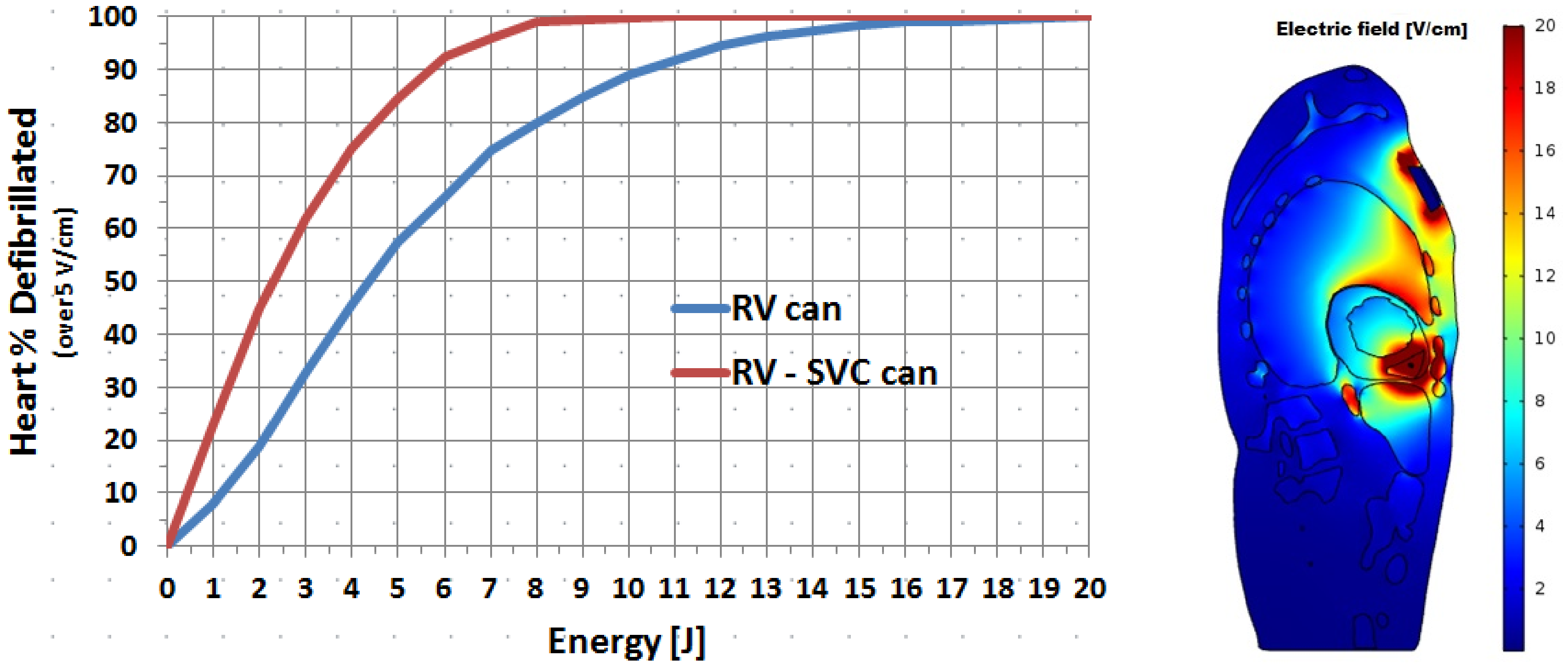
the **Energy** delivered

WITH

the **Heart %** defibrillated (>5V/cm).

Energy is calculated as:
Energy [J] = Voltage [V] * Current [A] * shock duration [ms]
Shock duration is set to 10 ms

Shock Results

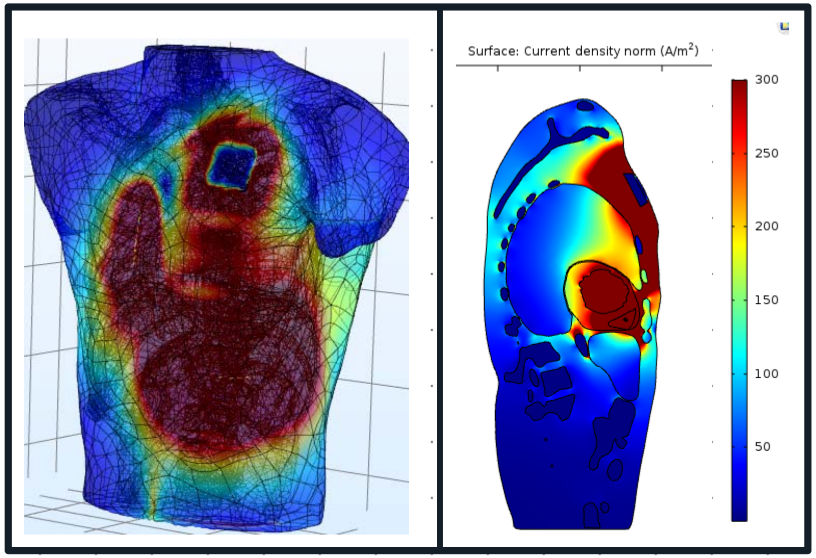


Model Validation ICD versus literature

Configuration Model Literature	Energy [J] for 90-95%	Voltage [V] for 90-95%
Single coil	11.25 ± 1.25 (10 ÷ 12.5)	380 ± 20 (360 ÷ 400)
Single coil	10.1 ± 5 (5.1 ÷ 15.1)	355 ± 87 (268 ÷ 442)
Double coil	6.3 ± 0.7 (5.6 ÷ 7)	235 ± 15 (220 ÷ 250)
Double coil	8.7 ± 4 (4.7 ÷ 12.7)	312 ± 71 (241 ÷ 383)

Error between 7-20% depending on the configuration

Conclusions



- **The model is mature to compare different configurations:** it can determine which configuration is better
- **The model can determine the optimal position of the electrodes (Capability of penetration depends on the position of the electrodes)**
- **The model can determine optimal pathways to maintain the defibrillation at acceptable level simplifying the implant procedure and the patient comfort**

End of presentation

Thanks for your attention:

- Questions
- Additional slides available in dedicated Annex at the end.

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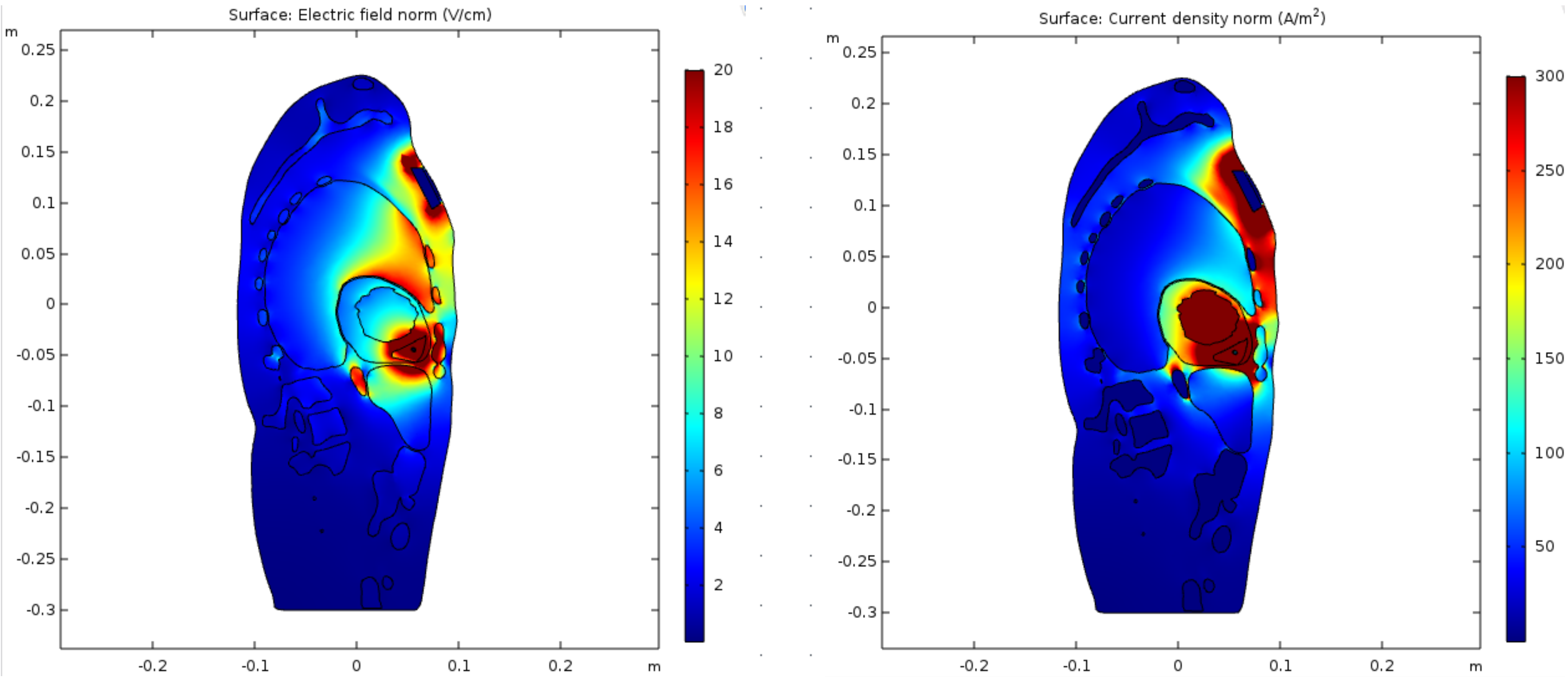
22nd of June 2018

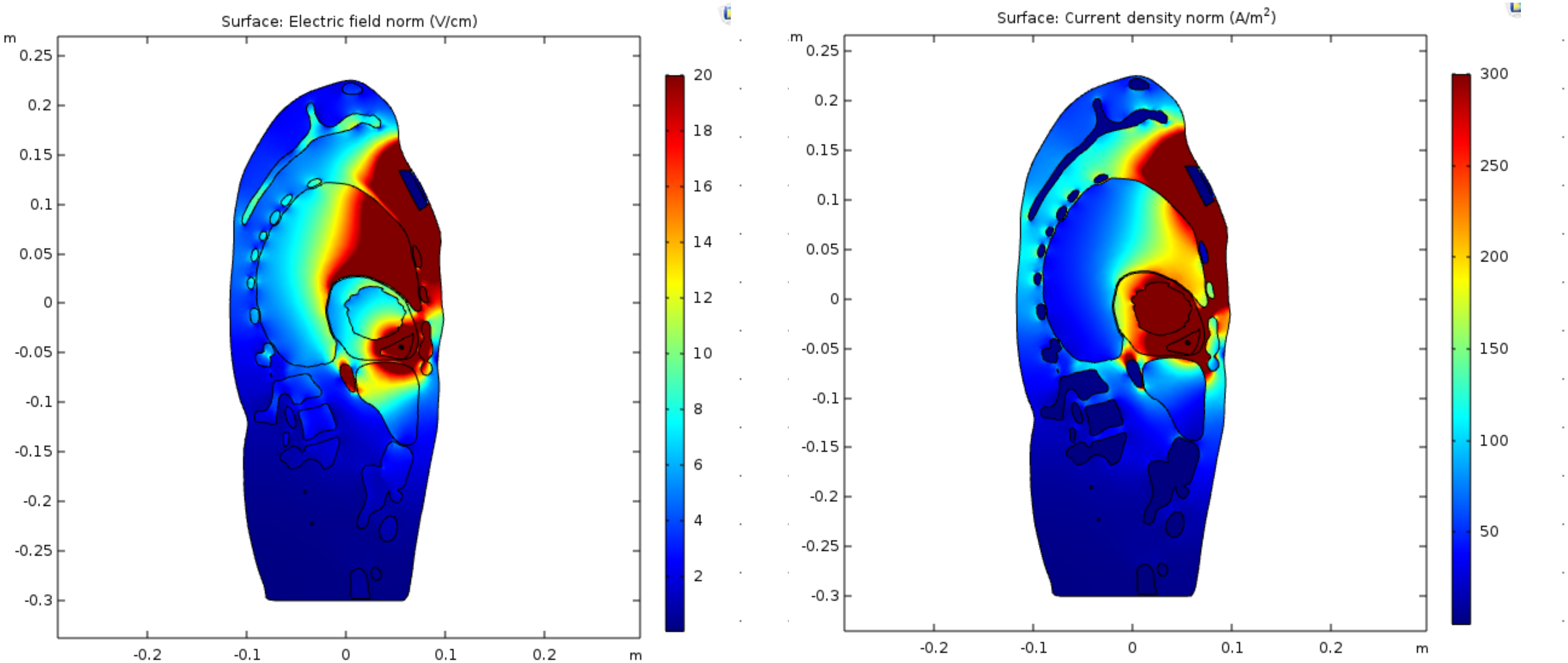
Annex
Additional slides

RV to SVC & can – Pathways of Electric field and Current Density



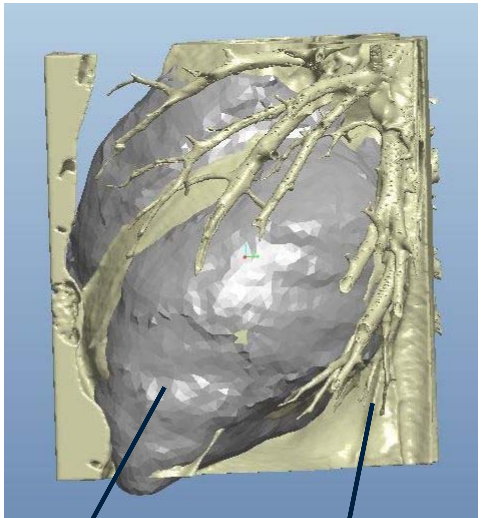
RV TO SVC&CAN ELECTRIC FIELD AND CURRENT DENSITY

RV to can – Pathways of Electric field and Current Density



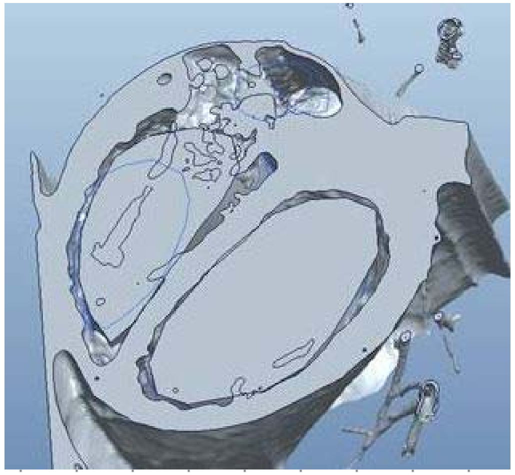
Geometry: Heart cavities

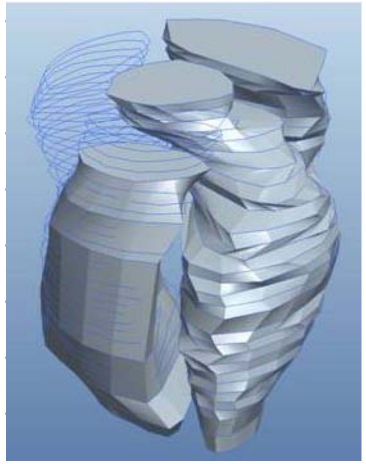
The cavities have been reconstructed from a CAT of another heart, freely available on the web.



Duke model no cavities

CAT model from web





Cavities reconstruction from CAT model

Shock
Stimulation Threshold

The mass criterion for cardiac defibrillation is defined as 90% of the myocardium with a voltage gradient >5 V/cm.

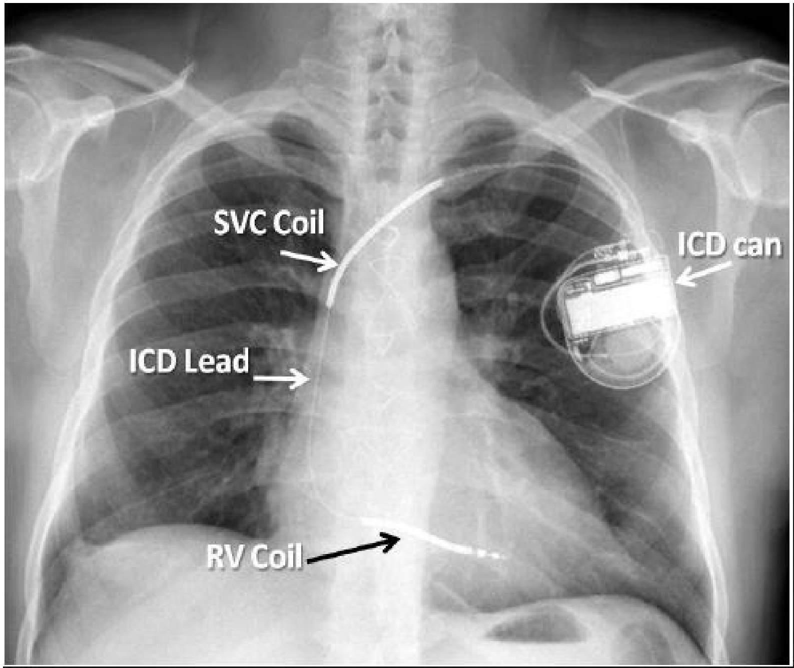
https://www.jstage.jst.go.jp/article/circj/80/4/80_CJ-15-1258/_html

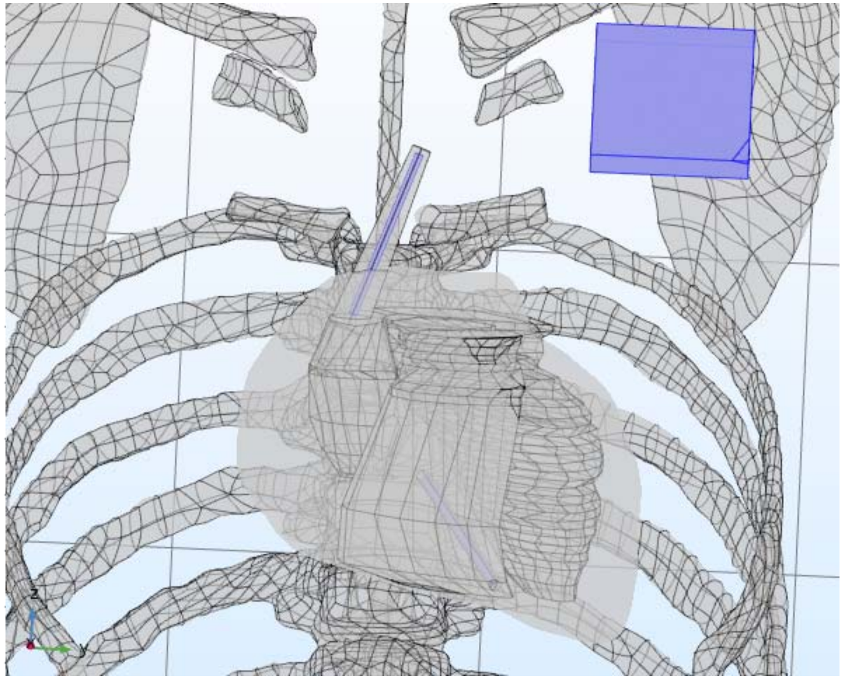
The assumption in the model is that the defibrillation is effective when the 90÷95% of the myocardium is over 5 V/cm.

Considering the conductivity of the cardiac mass of 0.3 S/m, **5 V/cm is correlated with a Current Density of 150 A/m^2.**

V=R I ; V= (x I) / (A σ) → dV/dx = E = I / (A σ) = J / σ → **J = E σ**

Geometry: SVC coil positioning

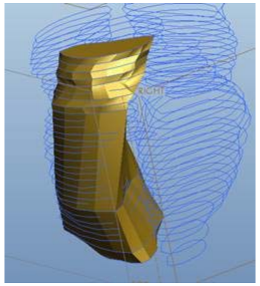


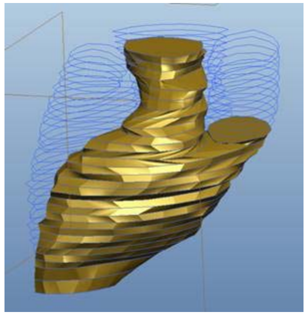


Geometry: Cavities characterization

Configuration	RV	LV
Real volume systolic [cc]	47	50
Real volume diastolic [cc]	142	144
Real Average [cc]	94,5	97
Model Volume [cc]	91	107

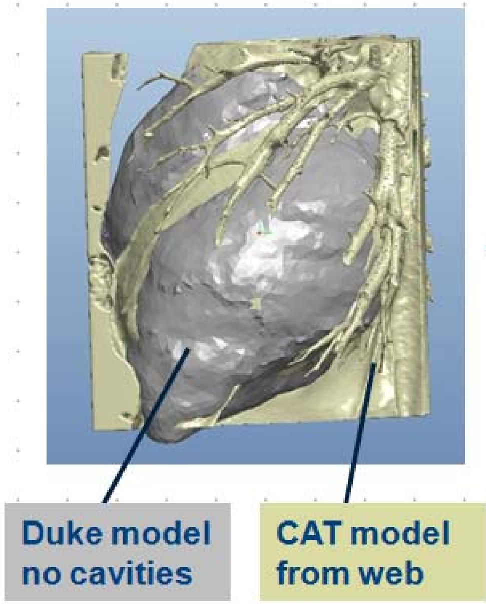
https://en.wikipedia.org/wiki/Ventricle_(heart)





Geometry
possible improvements

Reconstruction of the external shape of the heart that seems "larger " compared to the cavities and the torso



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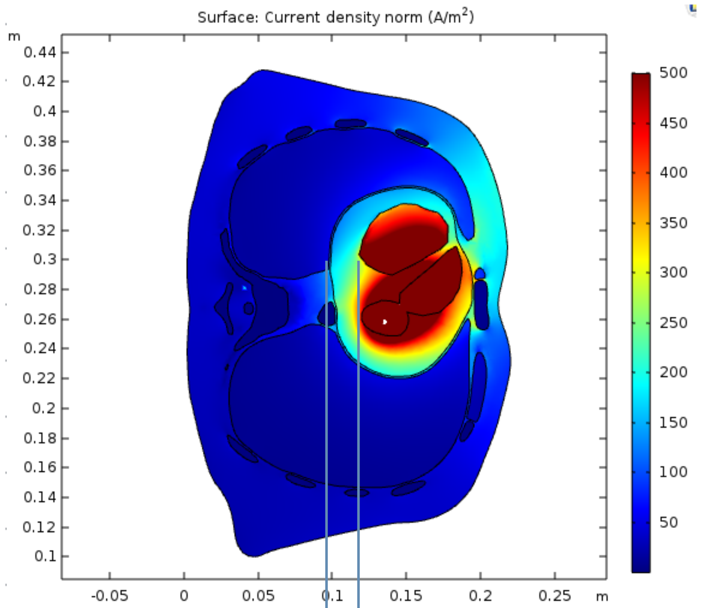
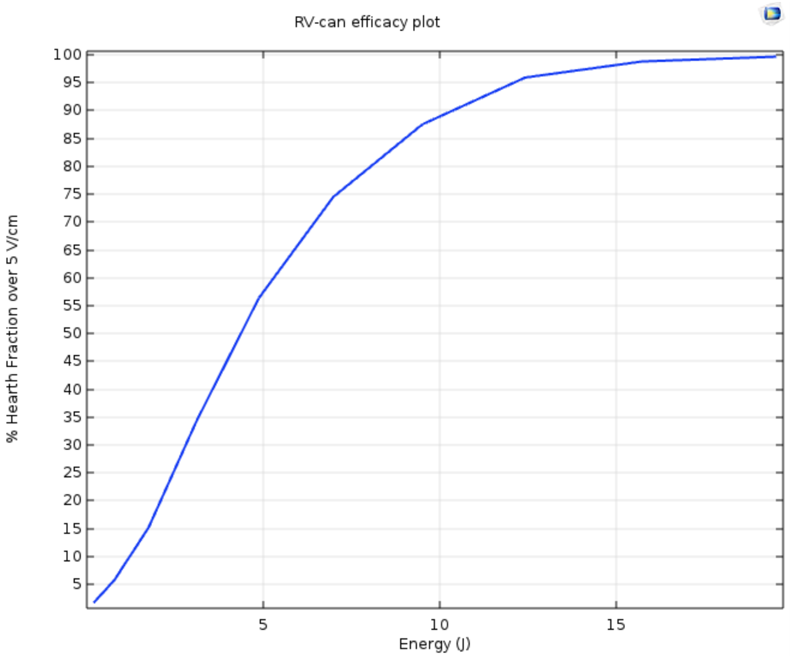
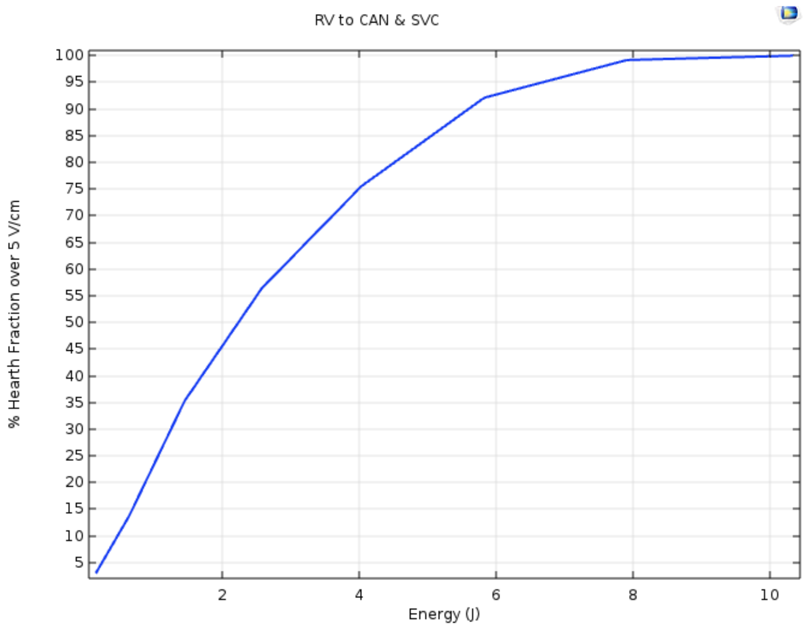


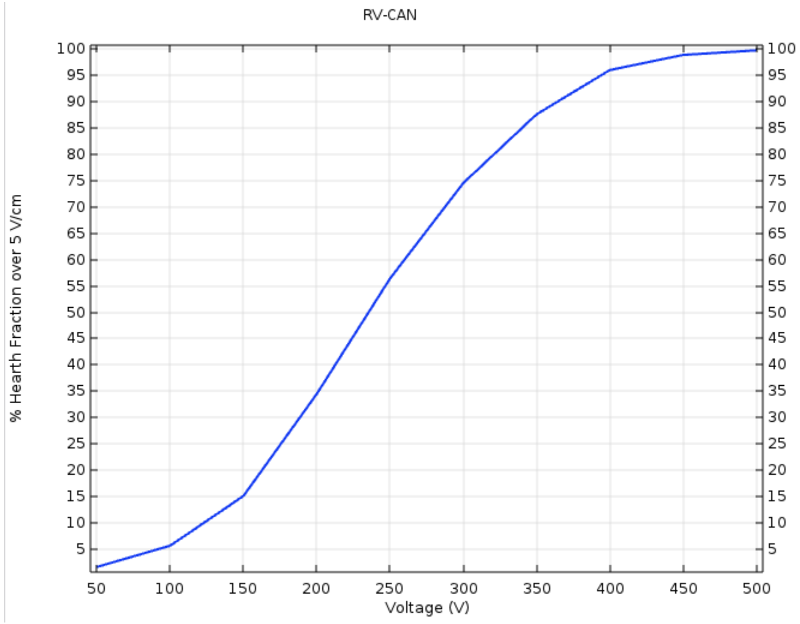
Rescale of the external shape to reduce it

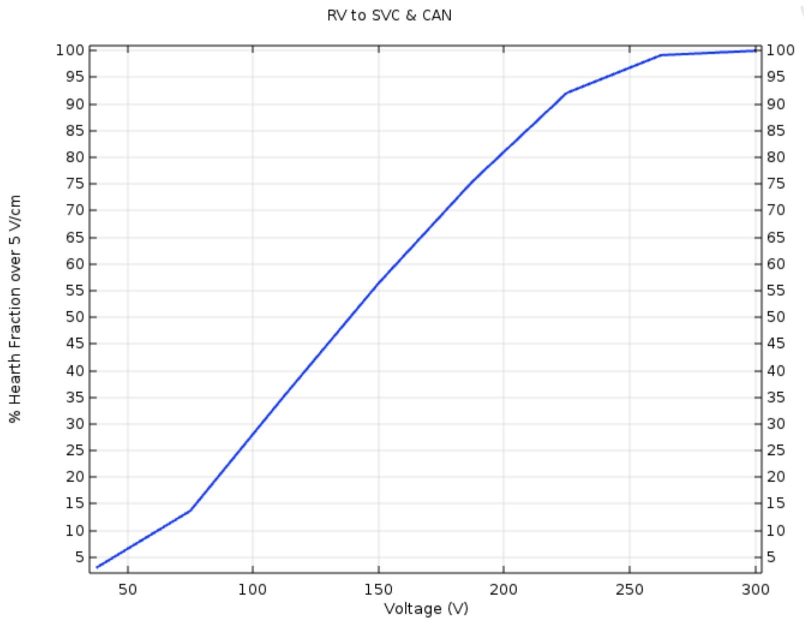
Efficacy plots
RV-CAN % RV –SVC&CAN





Efficacy plots in Voltage
RV-CAN, RV-SVC&CAN





Model Validation & reference data

Configuration Model Literature	Energy [J]	Voltage [V]	Current [A]
Single coil	11.25 ± 5 (10 ÷ 12.5)	380 ± 20 (360 ÷ 400)	2.8 ÷ 3.1
Single coil	10.1 ± 5 (5.1 ÷ 15.1)	355 ± 87 (268 ÷ 442)	literature 4.6 ÷ 8.4 derived: 1.9 ÷ 3.4
Double coil	6.3 ± 0.7 (5.6 ÷ 7)	235 ± 15 (220 ÷ 250)	2.5 ÷ 2.8
Double coil	8.7± 4 (4.7 ÷ 12.7)	312 ± 71 (241 ÷ 383)	literature 5.9 ÷ 10.9 derived: 1.9 ÷ 3.3

ELECTROPHYSIOLOGY

Comparison of Single- and Dual-Coil Active Pectoral Defibrillation Lead Systems

MICHAEL R. GOLD, MD, PhD, FACC, MARY R. OLSOVSKY, MD, MICHAEL A. PELINI, MD, ROBERT W. PETERS, MD, STEPHEN R. SHOROFSKY, MD, PhD, FACC
Baltimore, Maryland

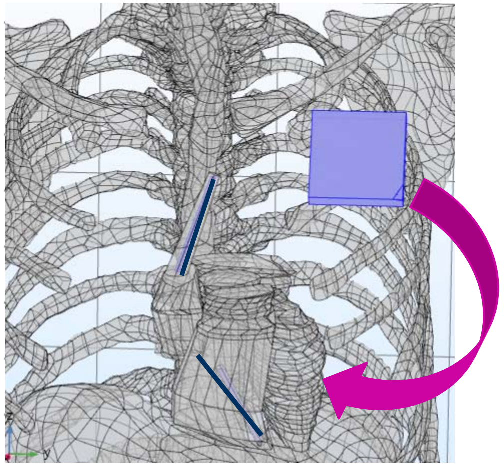
JACC Vol. 31, No. 6
May 1998:1391–4

Table 1. Pulse Characteristics at Defibrillation Threshold

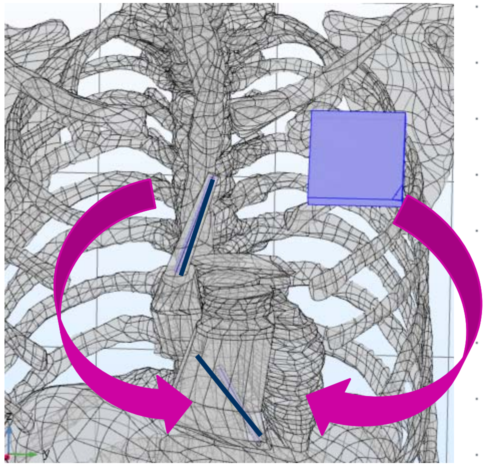
Configuration	Energy (J)	Voltage (V)	Current (A)	Impedance (ohms)
Single coil (mean ± SD)	10.1 ± 5.0	355 ± 87	6.5 ± 1.9	57 ± 11
Dual coil (mean ± SD)	8.7 ± 4.0	312 ± 71	8.4 ± 2.5	39 ± 7
p value	0.012	0.001	< 0.001	< 0.001

Shock Configurations

RV to CAN



RV to CAN & SVC



Shock Results