Strategies towards active implants for cardiology

Department of Digital Design and Processing (PLD)

Institute of Active Polymers, Helmholtz-Zentrum Hereon

Dr. Katarzyna Polak-Kraśna

Institute of Active Polymers, Helmholtz-Zentrum Hereon

14/11/2023 MSE Day

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Background – active implants

inert material

"do no harm"

immunological response

vs

active

sensing

feedback

stimulation

mechanical

chemical

electrical

support healing

endothelialisation

reduce thrombogenicity

functionalisation

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PLD Research

Department of Digital Design and Processing (PLD)
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applying active materials and sensors towards medical devices

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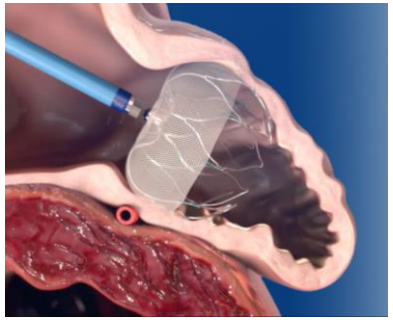
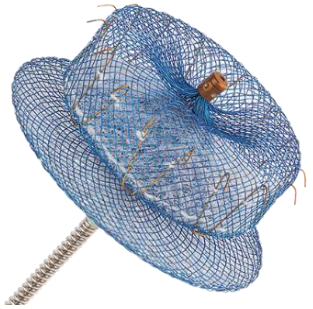
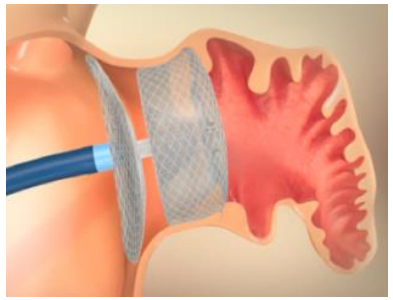
60 mln people
worldwide have
Atrial Fibrillation
Left Atrial Appendage
source of clots
➔ STROKE

Current LAA Occluders

Occluders on the US and EU market: Watchman from Boston Scientific, Amplatzer Amulet from Abbott

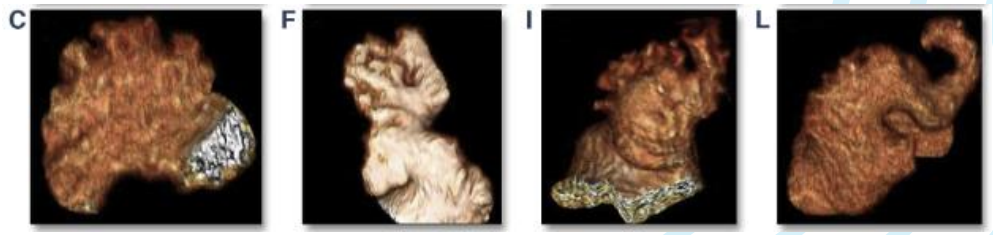
Limited positioning control	Suboptimal occlusion
Instantaneous deployment	Placement / tissue damage
Rapid hooks penetration	Tissue damage
Limited placement information	Low certainty on correct placement
Critical device and size selection	Success of the procedure
Hemocompatibility issues	Inflammation / body reactions
Leaks in 25-54% of cases	Stroke, anticoagulation need

Major issues with LAA occluders: Leaks

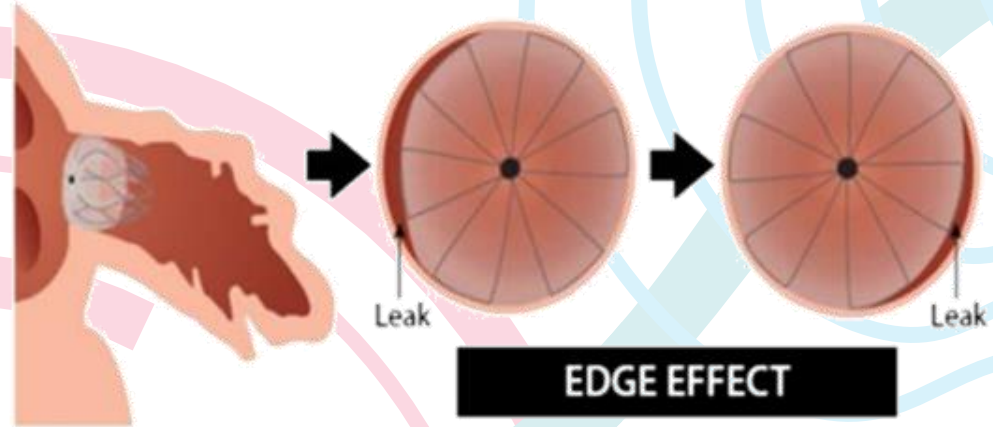
Up to **50%** of patients experience leaks after implantation

(Alkhouli 2022, Lakkireddy 2021)

Aim: detect and eliminate leaks



Different LAA anatomies from left: cauliflower, windsock, cactus and chicken wing (Beigel, 2014)



Leak Mechanism in Endocardial Plug Placement (Pillarisetti, 2015)

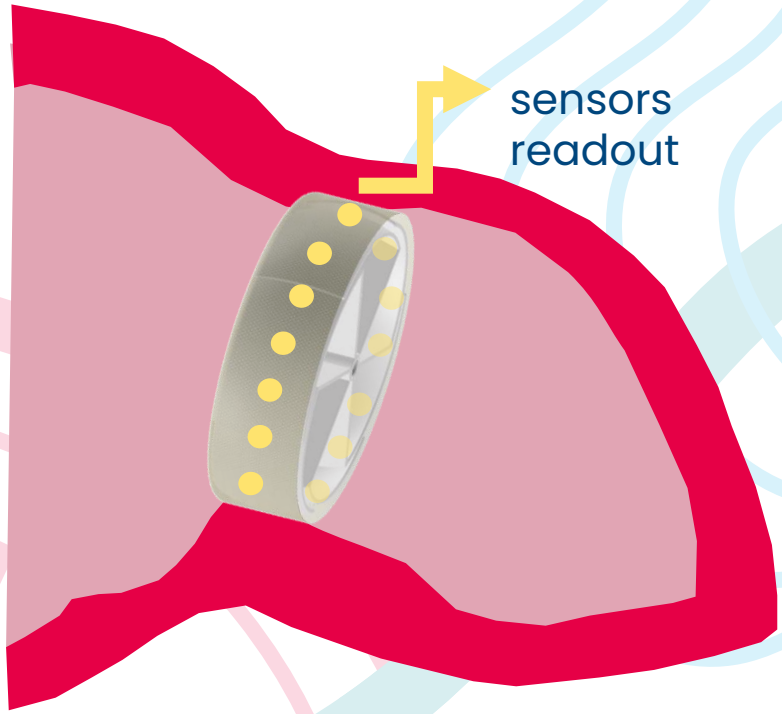
Our solution
new design and sensor driven implantation

Controlled deployment and size

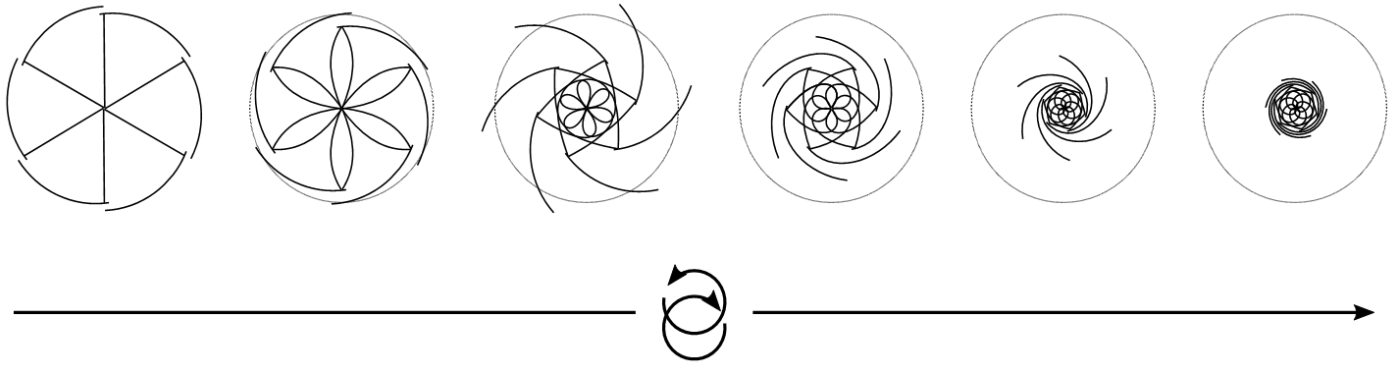
Sensor-based leak detection and procedure **guidance**

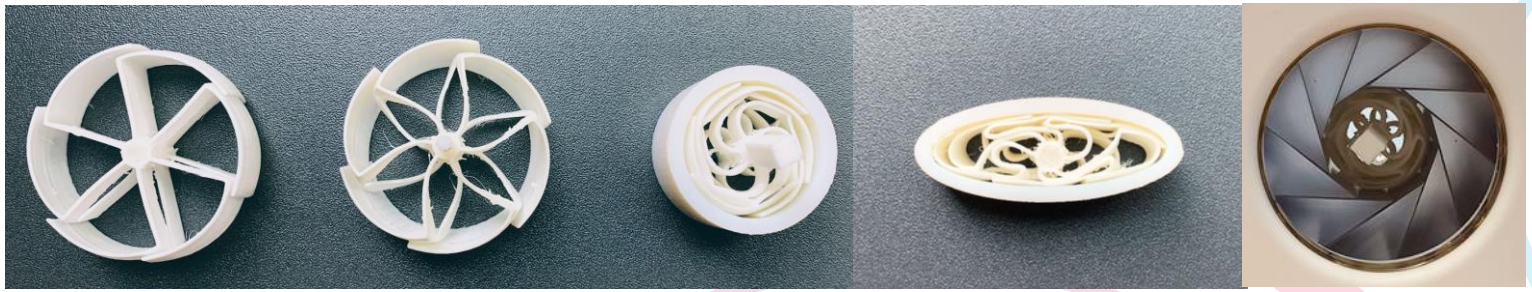
Hemocompatible covering

➔ **Improved outcomes**



Novel design of polymer based LAA occluder

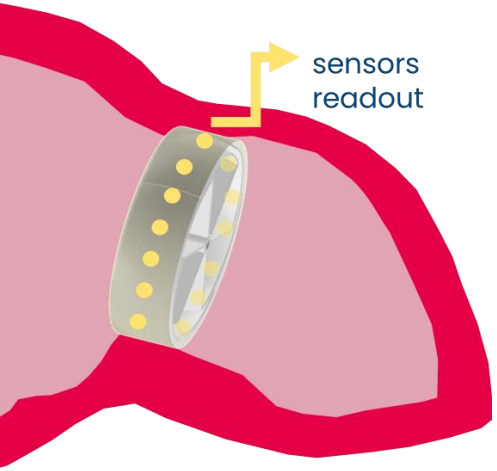




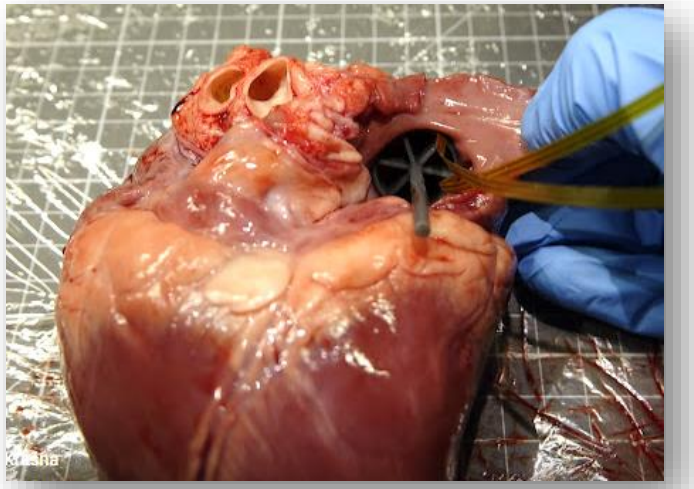
Implantation in mock LAA

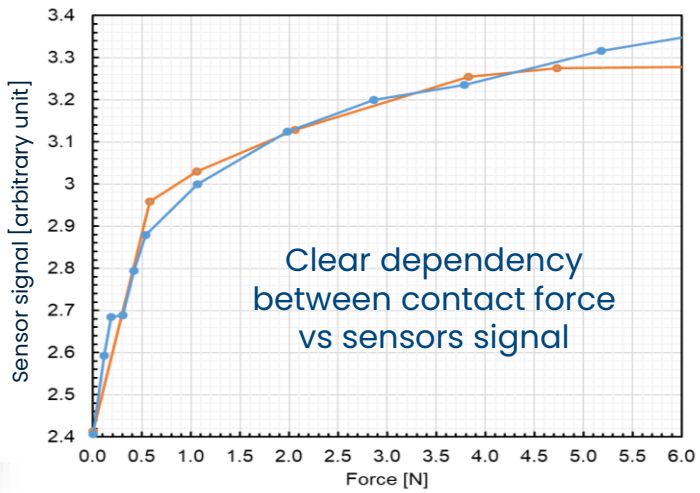
3D printed concept device, CAD design, Finite Element mesh, and displacement analysis in the structure

Implant Digital Twin



Sensing approach to guide implantation





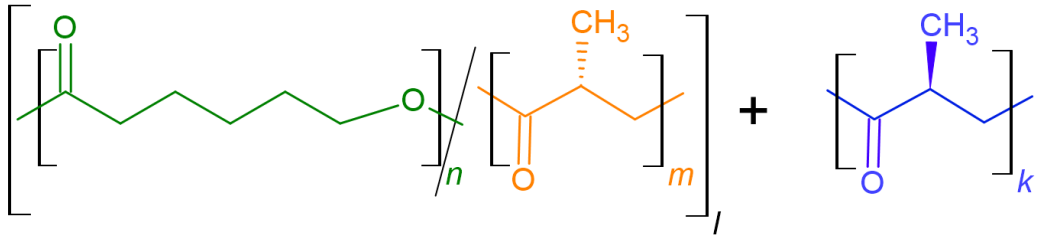
Signal measurement of sensors in contact with tissue in blood model with varying **contact force**

Tissue **contact detection** in porcine heart LAA

Feedback provided directly to interventional cardiologist during procedure

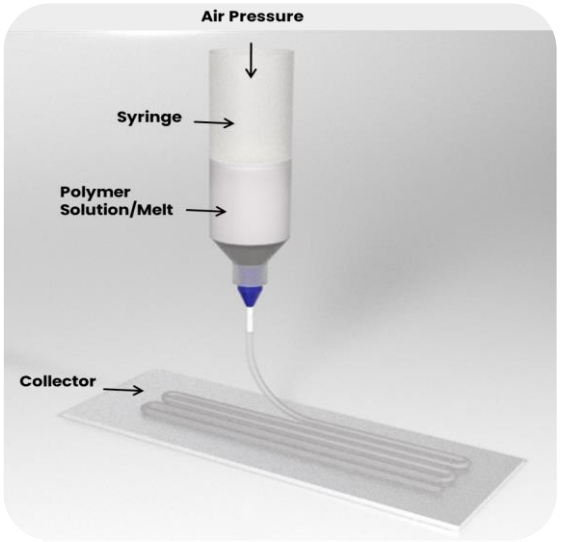
Novel materials for cardiac implants and implants covering (PLD+WGC)

See Hanin's poster for more!

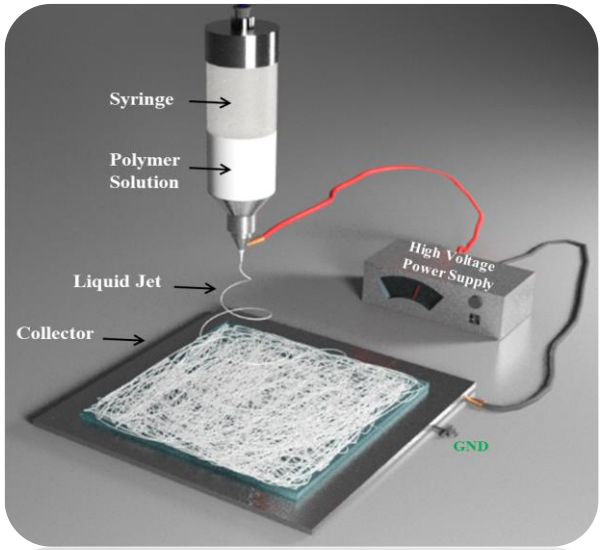


Chemical structure of P(LLA-co-CL)/PDLA

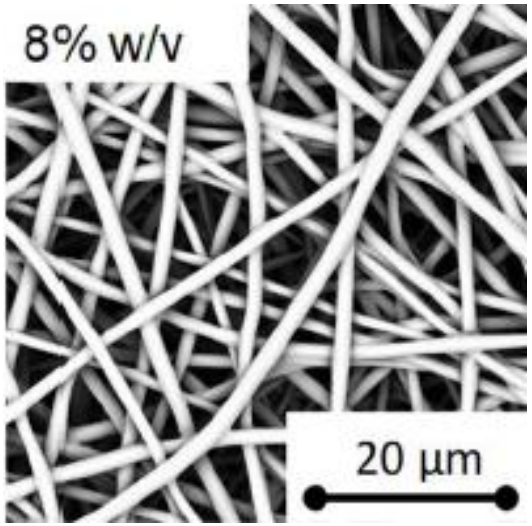
Thorough experimental characterisation + development of **materials' digital twins**



Extrusion Printing



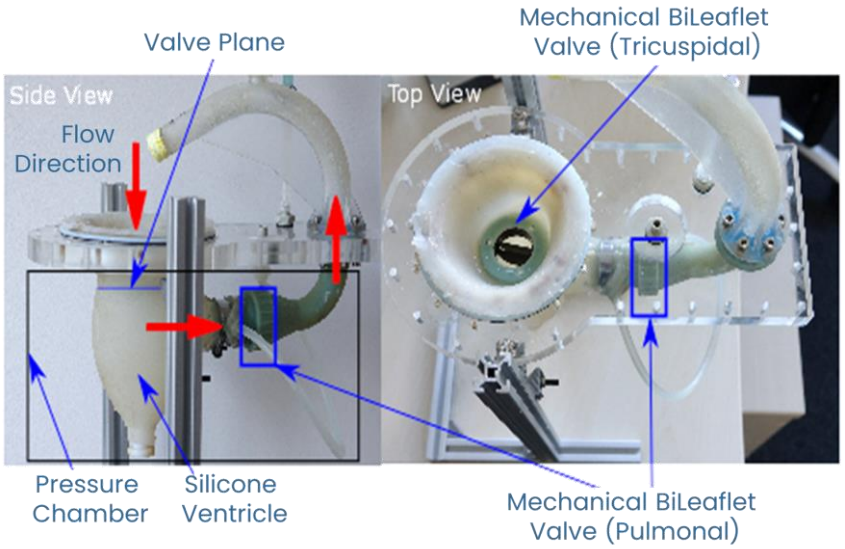
Electrospinning

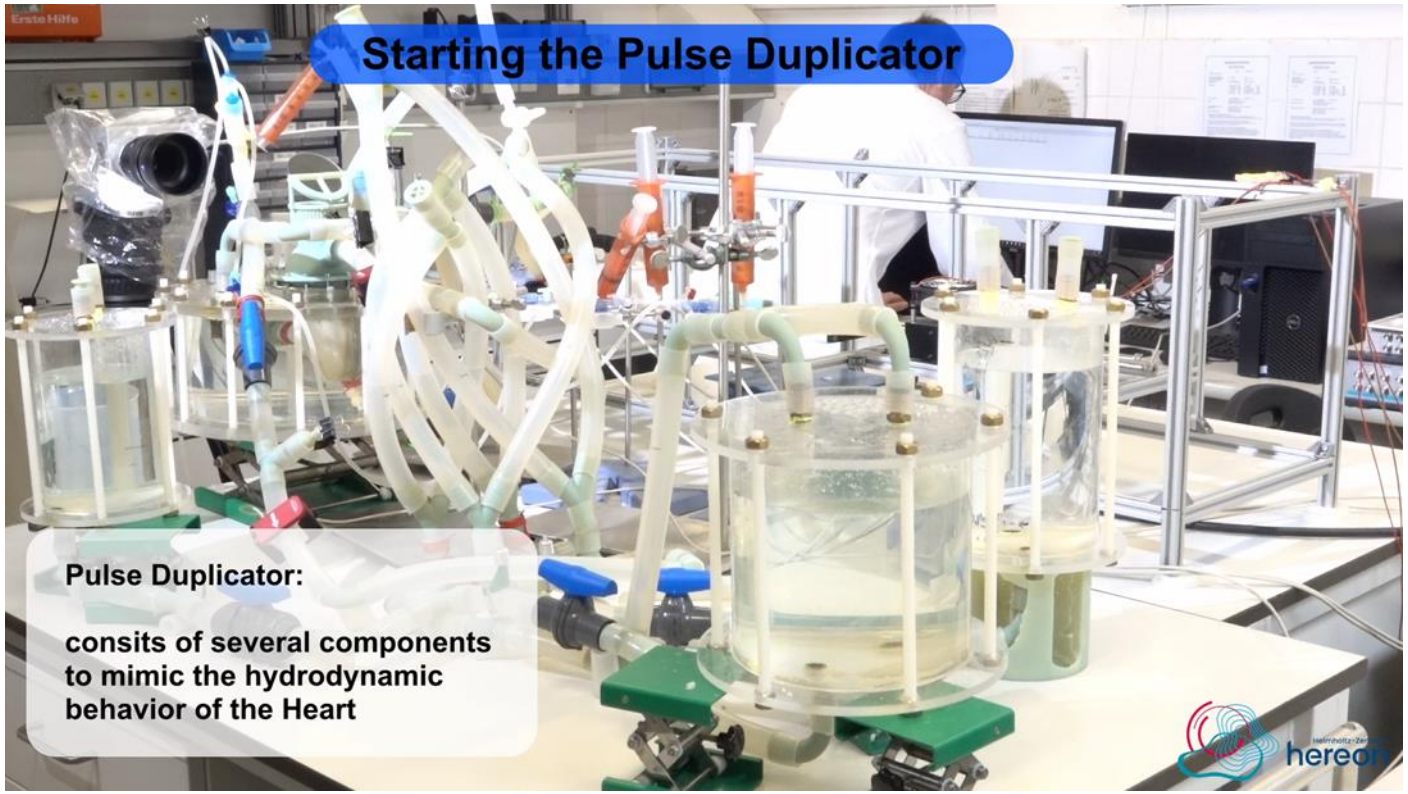


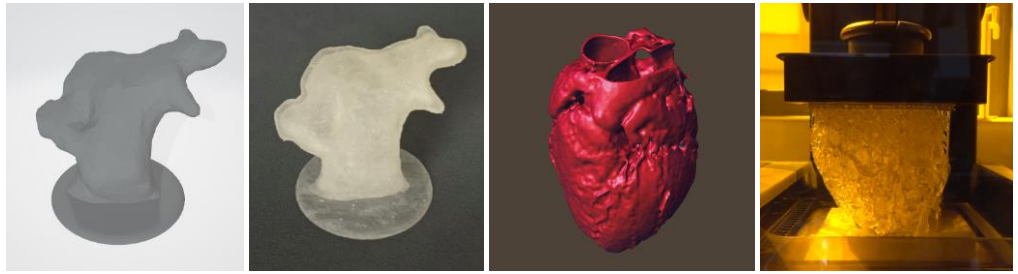
Electrospinning of occluder **covering** material

Bench-top testing of cardiac devices

- 3D printed bench-top testing setups
- Pulse duplicator
- Patient specific anatomical models: mock hearts, LAAs, vessels







Patient specific LAA and heart 3D models reconstructed from patient images and 3D printed models

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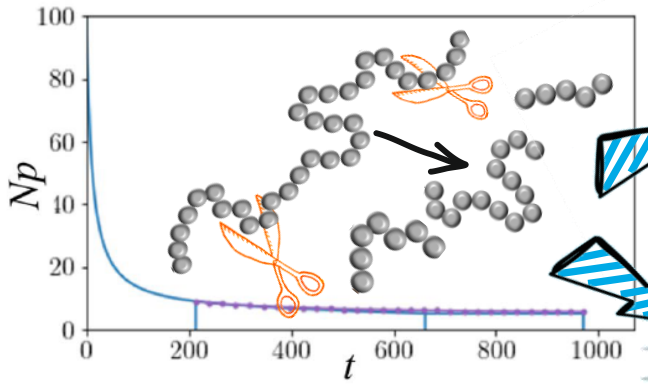
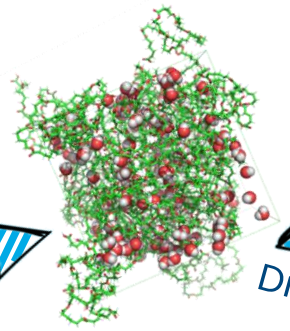
Digital polymer implant design by multiscale material and cardiac models (PLD + PLL + WGS + MS)

(combining MC, MD and FE), validated via novel sensor-based degradation measurement technology and bench-top testing platform

Molecular Level: Reaction kinetics

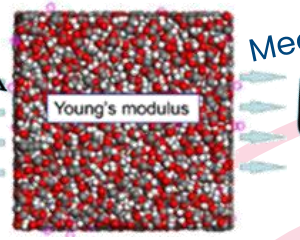




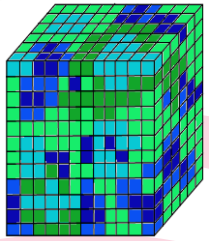
Micro-Level: Monte Carlo Simulation

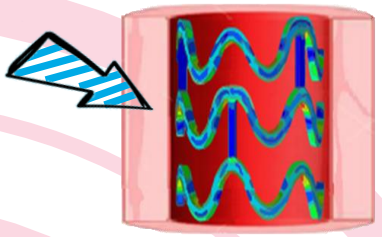
Diffusion

Mechanics



Nano-Level: Molecular Dynamics

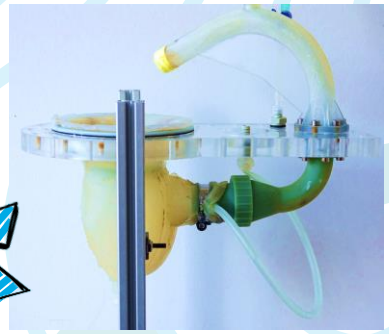




Device-Level: Finite Elements

Simulation of the cardiac environment including mass transport, solid and fluid mechanics (collaboration with Christian Cyron, MS)

In Vitro Experiment



Proprietary pulse duplicator with silicon heart for model verification / calibration

In silico bench-top testing and *in silico* clinical trials will enable development of next generation implants supporting physiological healing and improving patients' outcomes

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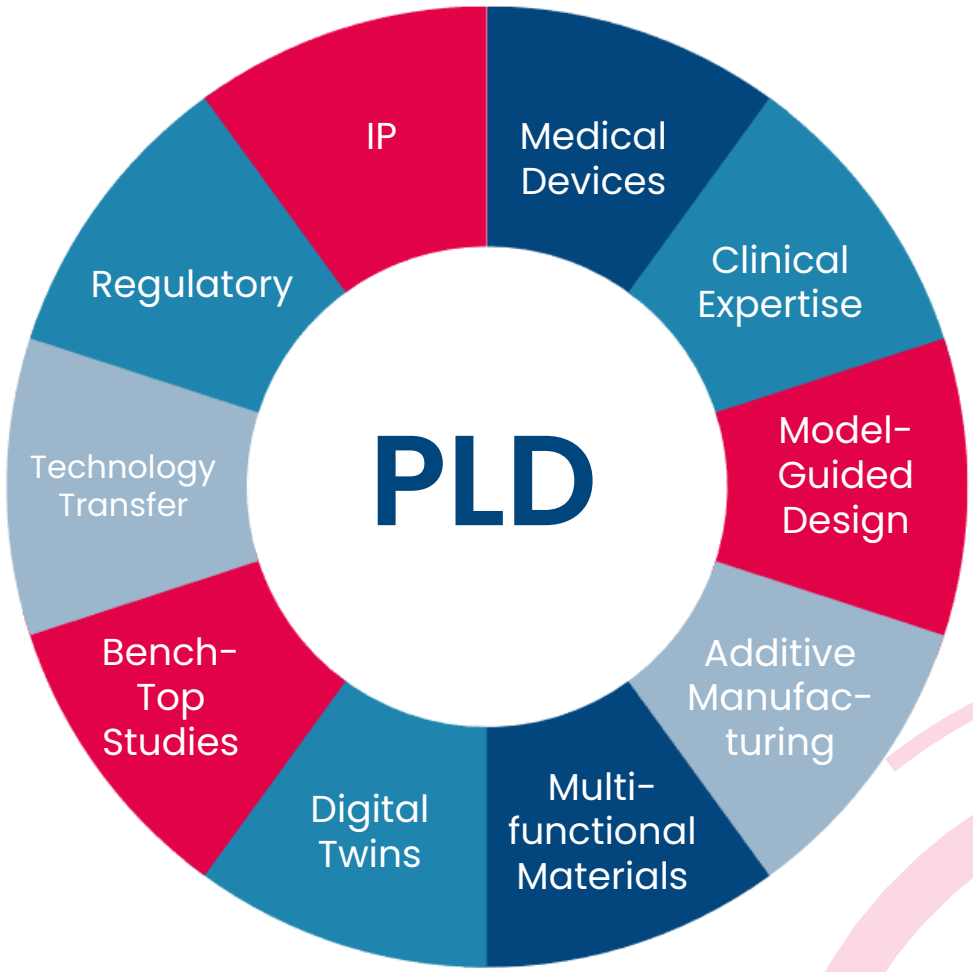
Our Team



Dr. Katarzyna Polak-Kraśna: development of medical devices and smart programmable structures

Experience: biodesign, active materials, 4D printing, FE modelling, biomechanics and materials mechanics, regulatory approval

Dr. Markus Rheinthaler: interventional cardiologist (Charité), medical devices development (Hereon)

Experience: structural heart diseases, minimally invasive procedures, occluders, valves, stents

Hanin Alkhamis: PhD student proprietary materials for medical devices

Experience: biomedical engineering, 3D-printing, electrospinning, cell studies

Mario Rettschlag: technical support

Experience: materials processing and characterisation

Manan Suraiya: intern student 3D printing piezoelectrics

Experience: 3D printing, materials, CAD

Dr. Marcin J. Kraśny: electronics engineer (guest researcher)

Experience: electronics for medical devices, sensors, wireless communication, animal trials

Adalbert Pakura: spin-off manager

Experience: CEO, digital health, business and strategy

Special thanks: Dr. Axel Neffe, Dr. Rainhard Machatschek, Dr. Schivam Saretia, Dr. Manfred Gossen

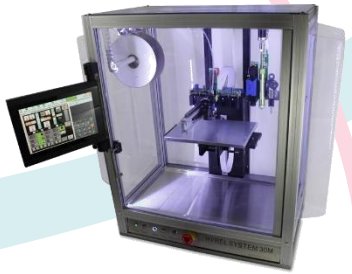






Our Infrastructure

- **3D printers**
  - FDM Printers: MakerBot Method X, MakerBot Replicator 2x
  - **3D-Bioplotter**: melt printing, solution printing, hydrogels, cells printing, piezoelectric materials, pastes, i.e. magnesium
  - Stratasys Connex 3 PolyJet printer: digital materials with desired properties
  - Formlabs 3 SLA printer: for excellent resolution
  - The Box: large scale FDM
  - Hyrel 3D System 30M printer
- **Electrospinning**
- **Piezoelectric characterisation** (poling station, LCR meter, d33 meter, electrometer)



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Thank you for your attention!

Sources

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Schlaganfall - Zahlen, Daten, Fakten – Schlaganfallbegleitung

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