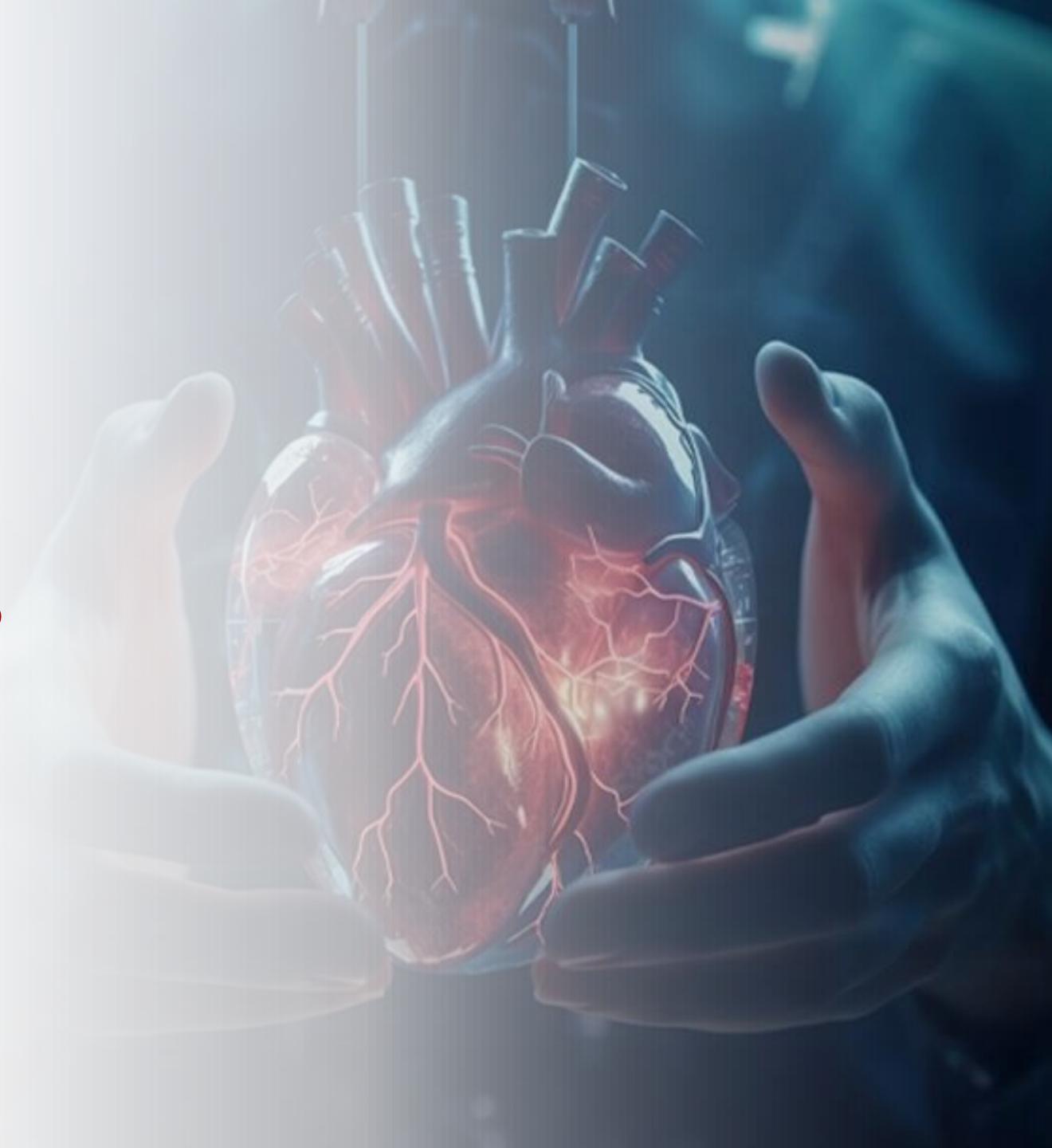


# **Advancing Patients' Care**

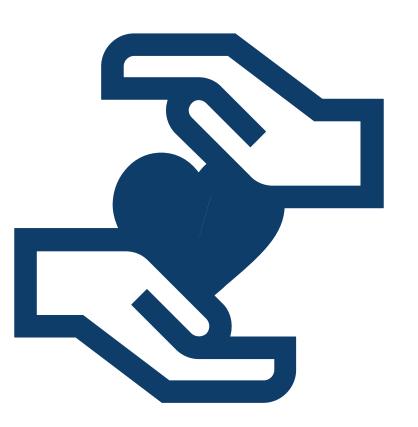
PacePress | CoolCryo | MiniMax | AtriClamp

# Corporate presentation 2025





# We develop advanced solutions to support patients with cardiovascular diseases



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#### WHO WE ARE



Sanjeev Choudhary
Co-Funder
Chief Executive Officer

Piotr Suwalski MD PhD Proffesor of medinice
Co-Funder / Co-Inventor
Chairman of the Scientific Board

Established in 2012 by renowned medical professionals and seasoned entrepreneur.

Innovates, develops, and commercializes advanced cardiovascular care technologies.

Listed on the Warsaw Stock Exchange since 2018.

Holds ISO 13485 and CE MDR for PacePress.

The 510(k) pathway was confirmed with the FDA and the submission is now under review.

Pre-Submission meetings for AtriClamp.





Sanjeev Choudhary
CEO & CO-FOUNDER

Graduate of Wroclaw University of Technology, Ashridge Business School, MBA, INSEAD and Centre for Creative Leadership programmes



Piotr Suwalski
MD PhD Prof
CO-FOUNDER CO-INVENTOR

First LAAO in 2009 in Poland. The only surgeon in Europe with 500+ robotic surgeries. Member of 21st Century Club Ex-President of the ISMICS.



Piotr Lozinski CFO

15+ years of experience Finance in FMCG and medical devices sectors. M&A advisory. Successful equity and debt rounds. Fellow member of ACCA and Institute of Internal Auditors



Greg Wróblewski Med. Eng. PhD CTO

Inventor of technology integrated by Medtronic. Developed 4 medical devices (2nd and 3rd class), 15+ years of experience in R&D, >50 scientific papers



#### **CARDIAC SURGERY**





Piotr Suwalski MD, PhD, Prof

Director of National Medical Institute of MIA in Poland. Former president of ISMICS, member of ESC i EACTS, 21CCSS



Valavanur Subramanian MD, PhD

Head of Lenox Hill Cardiac Surgery -Manhattan. Pioneer of minimally invasive cardiac surgery. Founder of ISMICS.



Paul Gründeman MD, PhD

Former Director
of the Experimental
Cardiothoracic and
Vascular Surgery
at Utrecht Medical
Center. Co-inventor
of the Octopus
device



Paweł
Balsam
MD, PhD, Prof

Head of Clinical
Electrophysiology
Department at WUM,
professor of medical
sciences, specialist
in arrhythmia ablation
and cardiovascular
disease prevention



Michael Glikson MD, PhD, Prof

Director of Jesselson Integrated Heart Center, professor at Hebrew University and Mayo College, former president of Israel Heart Society



Adam Budzikowski MD, PhD

Downstate Director at SUNY Downstate, New York. Over 30 years of experience in clinical medicine. Member of the PSC and ESC and HRS



# Pipeline of wide range innovative medical devices

#### **AtriClamp**

epicardial LAAO device

### **MiniMax**<sup>®</sup>

RF ablation catheter offering 3D mapping and cooling

## . CoolCryo®

quick & powerful epi- & endocardial cryoablation

#### **PacePress**®

prevention of hematoma after CIED implants









PROTOTYPING R&D PRECLINICAL TESTING

CLINICAL TRIALS CERTIFICATION

Market entry

MARKET
Licencing / Selling
/ Partnership



# PacePress<sup>®</sup>







# Safer and faster recovery after implantations of Cardiac Implantable Electronic Devices

PacePress is pneumatic therapeutic medical device designed to minimize the risk of complications after CIED implantations, while ensuring patient comfort, mobility and recovery.

### **Key features**

- Reduces the risk of complications: infection and hematomas
- Shortens hospitalization
- Increases patient control and safety







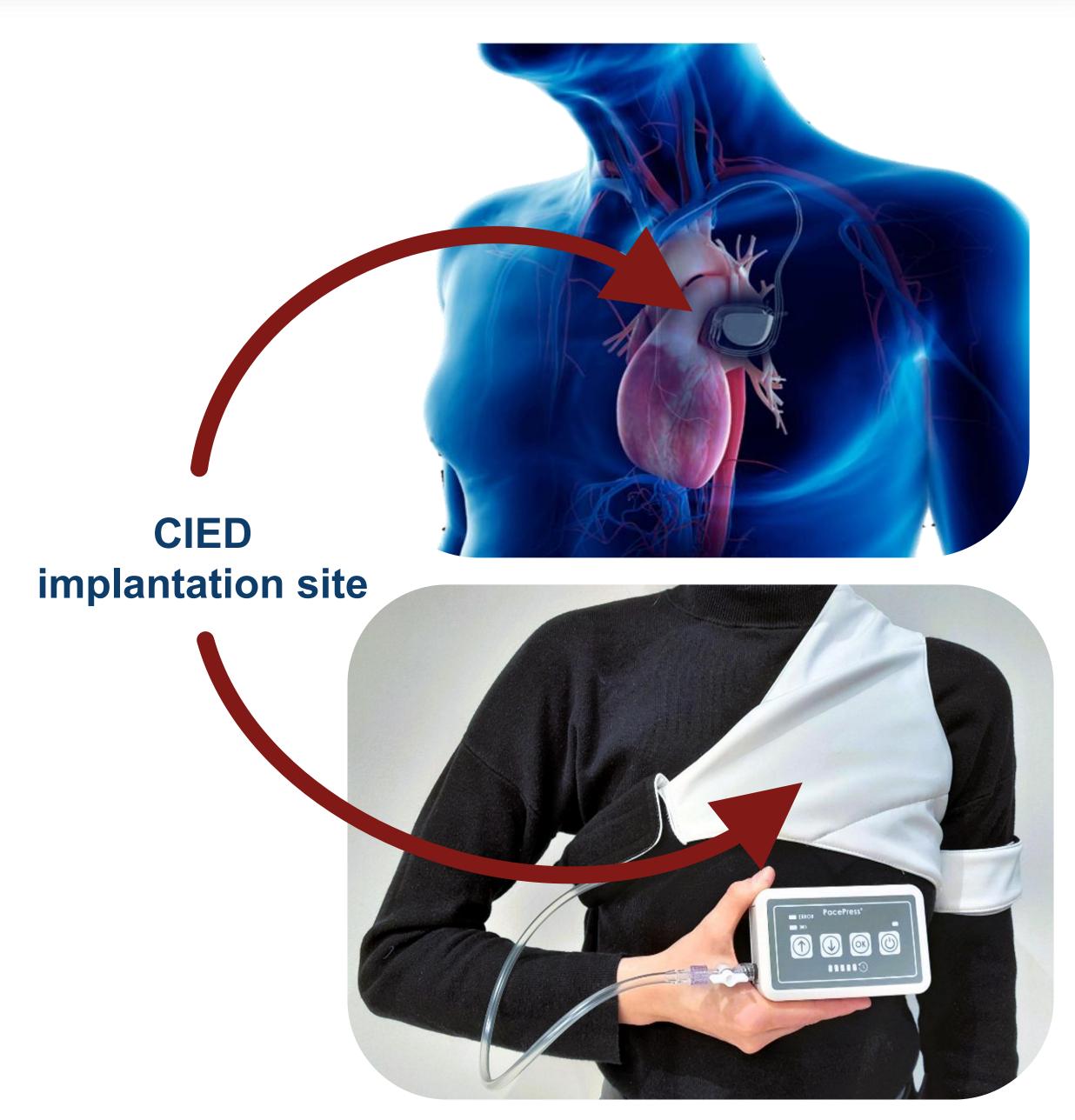
# 1.5 million procedures performed annually worldwide

About 60% of patients undergoing CIED implantation procedures are at risk of postoperative complications.

Approximately 10% of CIED procedures result in chest cavity haematomas, potentially leading to infection and re-operation.

Current prevention methods include:

- patient immobilization
- applying pressure to the implantation site





# CoolCryo®







## Faster and more efficient cardiac cryoablation system

The CoolCryo® system is designed for the cryosurgical treatment of arrhythmic cardiac tissue ablation by freezing target tissues, inducing an inflammatory response (cryonecrosis) that blocks the electrical conduction pathway. Using liquid nitrogen makes cryoablation faster and more cost-effective.

## **Key features**

- at least four times faster and more efficient cryoablation
- possibility of minimally invasive endoscopic surgery
- possibility of continuous cryoablation and defrosting
- possibility of full-wall ablation of even thick tissues
- cheaper and more efficient cooling medium

# Ongoing clinical trials & FDA 510K submission







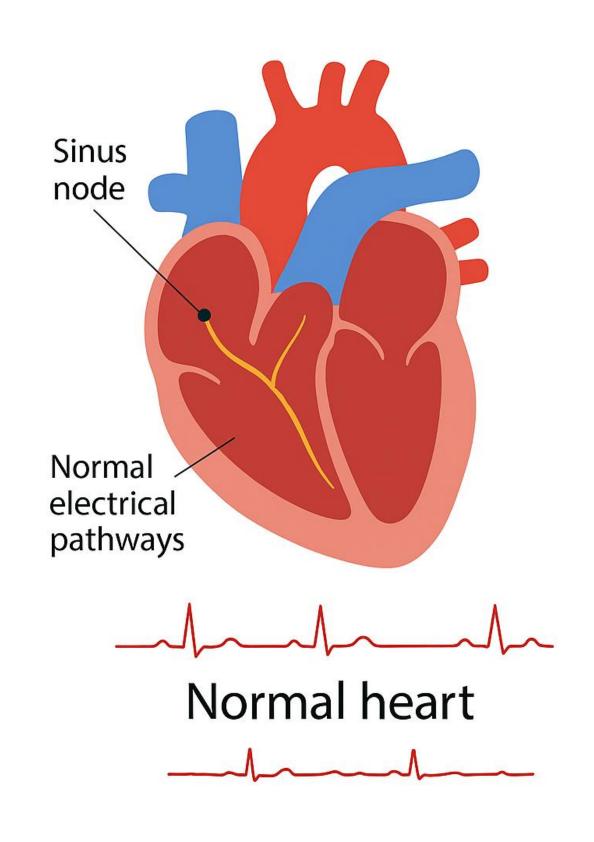
# 59 mln people worldwide suffer from arrhythmia

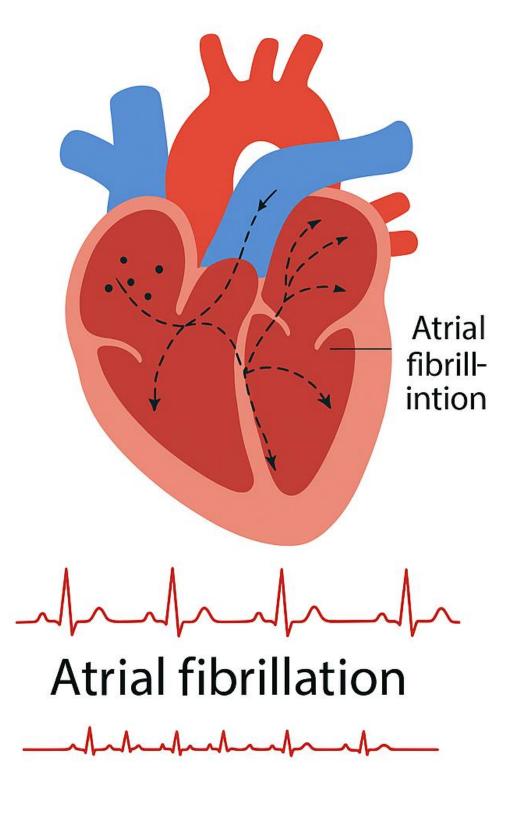
Arrhythmia ranks among the most prevalent heart conditions. It can result in circulatory failure and strokes.

The preferred treatment approach is ablation.

Currently, ablation treatments include:

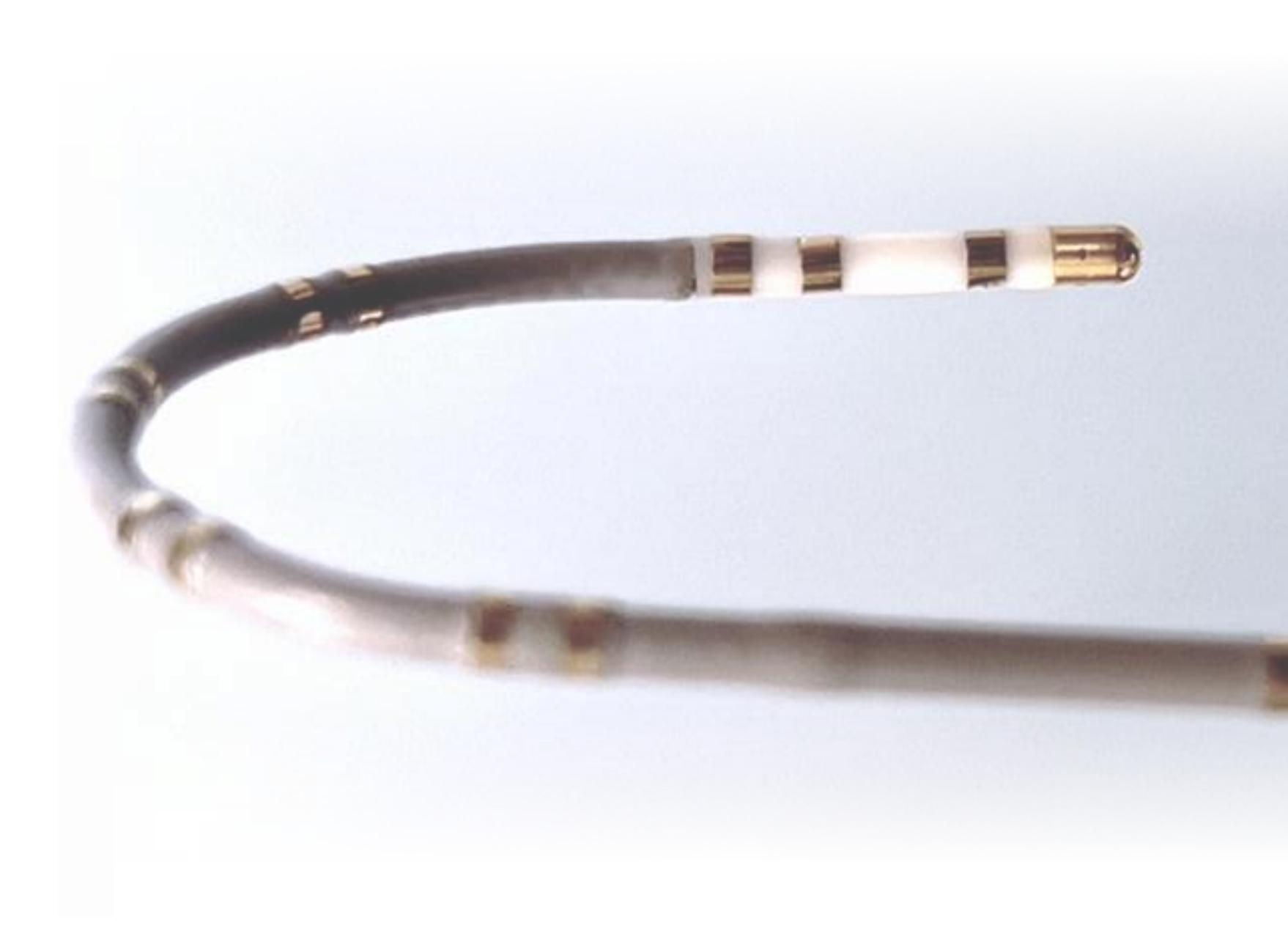
- •Cryoablation (CoolCryo®) freezing method
- •Radiofrequency (MiniMax®) or Pulsed Field burning method





# MiniMax®





# Versatile RF ablation catheter offering 3D mapping and cooling

MiniMax® is a steerable, minimally invasive 2-in-1 catheter developed for the treatment of cardiac arrhythmias during RF ablation procedure. It combines ablation and 3D mapping functions to reduce both the risk and duration of the procedure. Additionally, it features cooling system using NaCl.

#### **Key features:**

- 2 in 1 Ablation + 3D electro-anatomical mapping
- Safer procedure shorter time and lower risk
- Advanced NaCl cooling
- Flexible and steerable tip
- X-ray free modern visualization









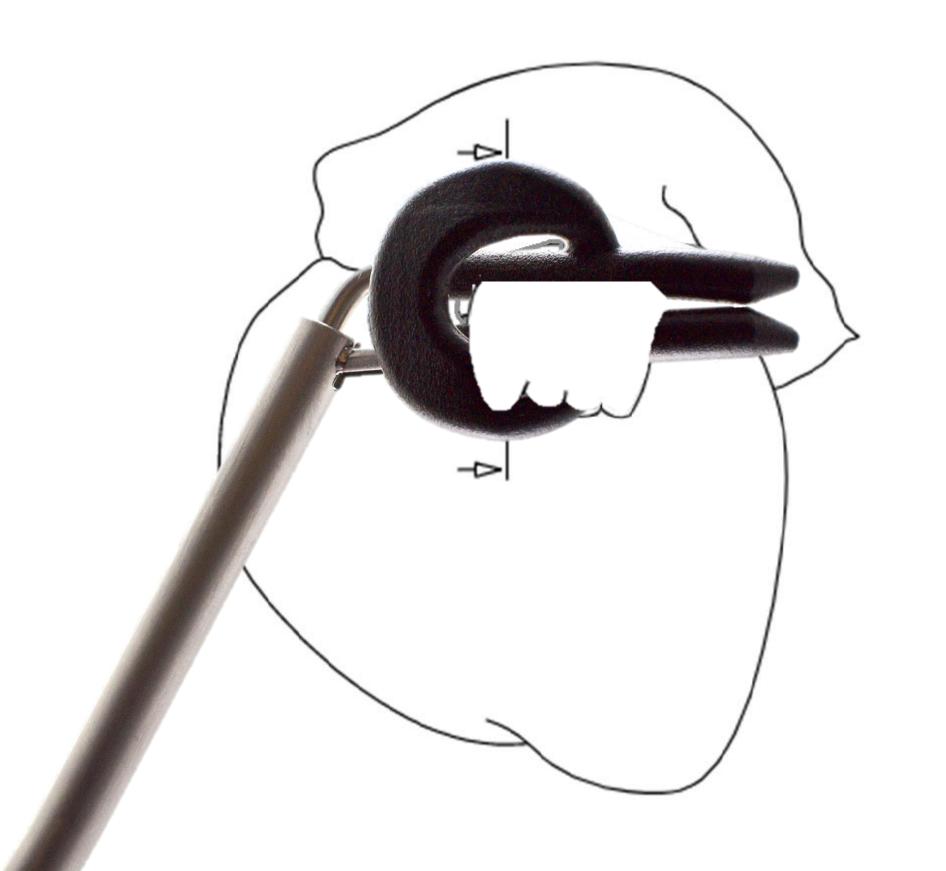
# Scalable Left Atrial Appendage Closure system

AtriClamp is a cardiothoracic clamp designed for the LAAC procedure. Utilizing an epicardial approach, it eliminates the need for threading through the appendage, keeping blood clots sealed within the appendage.

### **Key features:**

- low-cost and scalable production method
- fully retrievable & repositionable
- designed for single-handed operation
- no Dacron<sup>®</sup> used



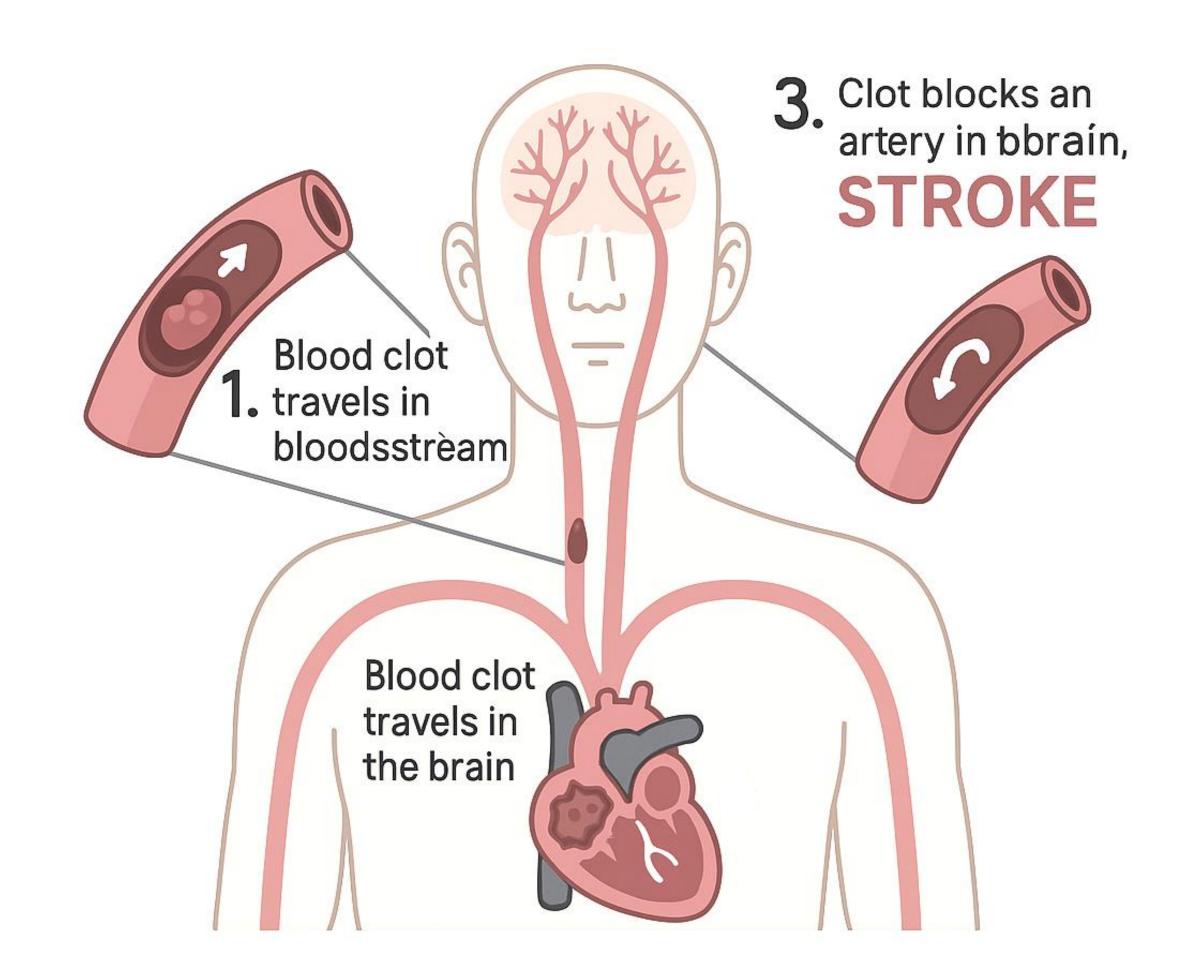




## 15 million people affected annually

According to the World Health Organization, stroke is a leading cause of death, accounting for 11% of all deaths worldwide<sup>[1,2]</sup>.

The left atrial appendage closure procedure prevents 90% of embolic material, leading to 87% of strokes. This procedure will now be performed routinely with other cardiac surgeries, and we have therefore prioritized economic aspect of AtriClamp.



[3] <u>Dudzińska-Szczerba</u>, K., <u>Association between left</u> atrial appendage morphology and function and the risk of ischaemic stroke in patients
with atrial fibrillation, *Arrhythmia & Electrophysiology* 

Review 11 (2022).

[1] World Health Organization - Fact sheets

[2] World Health Organization – Definitions: Stroke



# Repeatable revenue model

## **Growing demand**

- Growing demand for minimally invasive technologies
  - Ageing population

# Medinice

## **Competitive advantages**

- Diversified portfolio
- Patent protection future projects for development

# portfolio of potential co Two projects near

## An experienced team

- Scientific Council composed of world-renowned scientists and inventors
- Experienced management and project teams

## Large and healthy target market

- Potential buyers are global corporations
- The technologies under development fit in the portfolio of potential counterparties

commercialisation





Patient friendly smart routing therapies for quality of life

Thank you for your attention

www.medinice.eu



# Medinice

# APPENDIX



In response to the needs of doctors, we break the boundaries of technological innovation.

To ensure the quality of life of patients, we create minimally invasive and safe medical devices.





## Advancing through the development process enhances the product's value

# **LAAO** market 250 K procedures annually \$1.9 B market size **RF Ablation market**



300 mln USD acquisition of SentreHEART by AtriCure in 2019

1.5 M procedures annually \$5.5 B market size



125 mln USD w 2023 MACOM acquisition of Wolfspeed RF portfolio





150 mln USD JapanLifeline acquired CardioFocus in 2020

**CIED** market

1.5 M procedures annually \$1.5 B PacePress market size

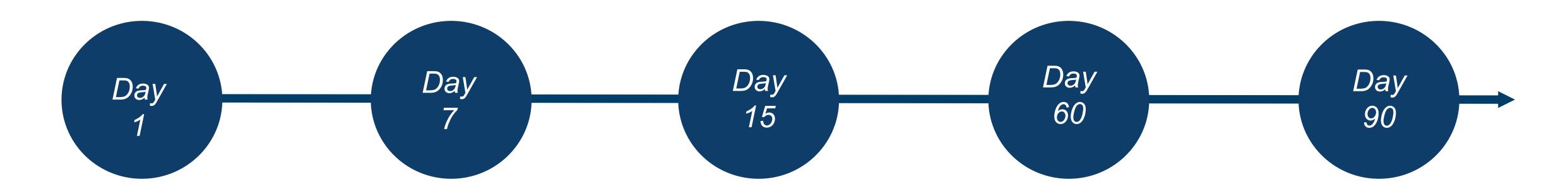


PacePress<sup>®</sup>

125 mln USD ConvaTec acquired Triad Life Sciences in 2022



# 510k Review – Procedure After Submission of the Application



#### **Submission**

The FDA receives our application

#### **Acknowledgement Letter**

The FDA sends a confirmation of receipt of the application or issues a request for additional information (payment, identification)

#### **Acceptance Review**

The lead reviewer checks whether the electronic eSTAR submission is complete and meets the minimum requirements for further review

#### **Substantive Review**

The application undergoes a substantive review, and after 60 days, the FDA communicates whether it will proceed under one of the following pathways:

- 1. Interactive Review
- 2. Additional Information

#### **Decision Letter**

The FDA informs about the decision on whether the device under review is substantially equivalent to the predicate device or not.

Referencje:

1) FDA: 510(k) Submission Process, 10.03.2022