



Patient-specific 3D holographic platform for planning and navigation in structural heart interventions

Filippo Piatti CEO & co-founder

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# Company&Team



#### C-level





Filippo Piatti, PhD CEO & co-founder Bioengineer at Politecnico di Miland Research at University of Oxford, Stony Brook University





Giovanni Rossini, PhD COO & co-founder Bioengineer at Politecnico di Milano Research at Sorbonne Université Paris, University of Texas at Austin





Omar Pappalardo, PhD CTO & co-founder Bioengineer at Politecnico di Milano Research at Mayo Clinic, Leiden University Medical Center

#### Offices

- o EU (HQ) <u>Milano,</u> Viale Cassala 57, 20143
- USA (partner corp)New York, 745 5th Ave,NY 10151

#### Team: 12 FTE



S. Pozzi, PhD Research & Clinical activities manager



V. Russo
Data protection &
cybersecurity



J. Monti Training & client success manager



M. Pasquali Product & Regulatory manager



C. Grullero Quality manager

#### Advisors / Consultants



C. Fontana, MBA Senior advisor with more than 20 years in Medtech strategic and m&a



A. Radaelli Senior advisor with more than 15 years in Medtech technology and business development



D. Shockley Founder and CEO of Movair, more than 30 years in USA medtech commercialization

IP protection and corporate law





Regulatory and reimbursement



# Company purpose



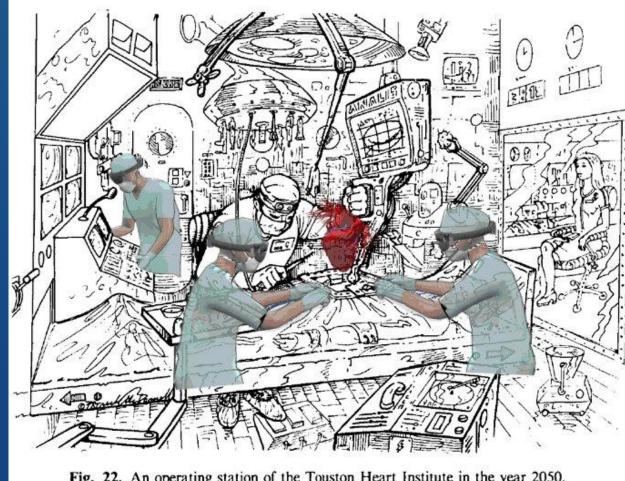


Fig. 22. An operating station of the Touston Heart Institute in the year 2050.

An easy-to-use and user operative guidance

future\*

to make accessible, safe and effective transcatheter structural heart procedures

## Target: structural Heart interventions





Complexity is common for SH interventions, mainly because of

- o <u>Anatomical</u> variations
- o <u>Imaging data</u> heterogeneity
- o <u>Medical devices</u> specificities



## Clinical pains

- o Operators/Imagers complex communication
- o Steep learning curves (months, years)
- o Issues/complications (up to 30-60%)
- o Procedural times (up to 3-4 hours)

## Current solutions





- No pro-active discussion
- Not integrated in the cath-lab



- $\circ$  (Con-)fusion of information (3D to 2D)
- No assistance on the device implant

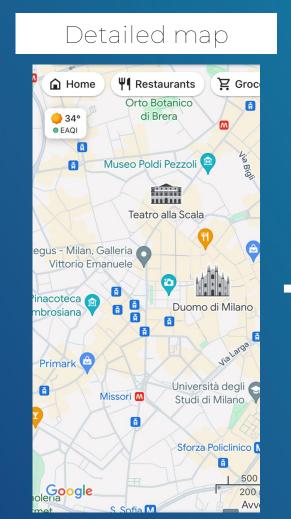


Do not provide simple visualizations for device localization Do not provide active Guidance/Navigation

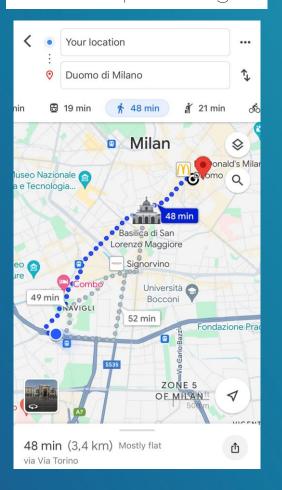
# From information to advanced navigation



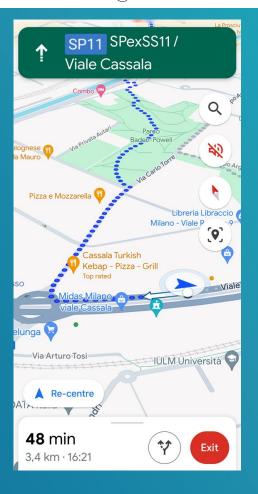
## The analogy.....



## Route planning



## Navigation



# Our solution: 3D real-time navigation

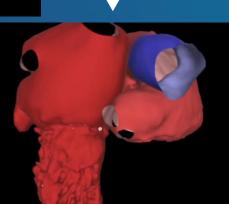


Steps already developed and with commercial traction

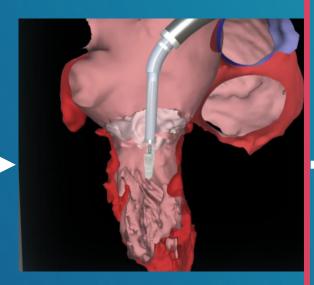
Detailed map







Al-based 3D heart reconstruction from CT scan



3D virtual planning of device trajectories, implants, imaging

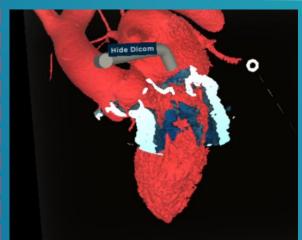
Next technology iteration

## Navigation









Live 3D fusion of TEE-CT for realtime guidance/navigation

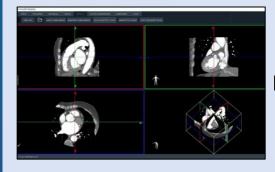
# Product portfolio: ARTICOR® platform



# ARTICOR

#### Full software platform for Intra-procedural guidance

#### Module 1 - ".imaging"



Pre-operative imaging 3D elaboration

#### Module 2 – ".real"



3D procedural analysis

# \_\_\_

#### 4odule 3 – ".xrfusion"



Intra-operative CT-Echo 3D navigation

Sub-modules for Pre-operative planning

#### TARGET MARKETS (with customers

General platforn

Specific additional Software plu

General cardiovascular surgery/interventions



Congenital	TeeR (Mitral)
LAA closure	TeeR (Tricuspid)

#### REGULATORY STATUS

- FDA 510k, under submission
- CE Mark (MDR), submission in 2025 (timeline under assessment based on definition of Class certification)

TARGET MARKETS (under development)

#### Echo guided procedures

- Mitral/Tricuspid repair/replacement
- LAA closure

First prototype for Mitral repair/replacement

- Preliminary in-vitro tests/validation
- Interest from KOLs for clinical activities (USA and EU)

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# Competitive scenario



						Current solutions in the market	
		MxR platforms				Image-fusion systems	3D planners
		ARTINESS.	echopixel 🖔	MediView	apo@lar	SIEMENS PHILIPS	LARALAB materialise ostrick  FEOPS
d map	Patient-specific 3D planning general purpose				<b>&gt;</b>		
Detailed map	Cardiac (heart valves) dynamic 3D planning						
plan	Imaging-device simulation/preparation						
Route plan	Automatic sizing measurements						
Navigation	Real-time 3D image fusion (CT + echo)						
	Live 3D navigation and Albased implant assistance						

# Market drivers: AR/XR and AI



## AUGMENTED/MIXED REALITY



Augmented/Mixed Reality in Healthcare market is on a trajectory of significant growth, estimated at USD 18.5 Billion \$ by 2032 with a CAGR of 21% from 2023 to 2032

https://www.gminsights.com/industry-analysis/augmented-and-virtual-reality-in-healthcare-market?gclid=Cj0KCQjwwuG1BhCnARlsAFWBUC0fXdBHuQqae7qrQJj8wwtVqzBgilz0Pc0DHQGMrBACG3kRXdslQqcaAghsEALw\_wcE

#### ARTIFICIAL INTELLIGENCE



Al in medical imaging market size was estimated at USD 762.84 million in 2022 to reach 14 billion in 2032 with a <u>CAGR of 33.1% from 2023 to 2032</u>

https://www.biospace.com/ai-in-medical-imaging-market-will-grow-to-14-423-15-million-over-next-10-years#.~:text=2023%20to%202032.-,The%20global%20Al%20in%20medical%20imaging%20market%20is%20estimated%20grow,the%20field%20of%20healthcare%20diagnostic

## Clinical validation and use



Massimo Chessa, pediatric cardiologist

Jenny E. Zablah, pediatric cardiologist Gareth Morgan, cardiothoracic surgeon

Paolo Denti, cardiac surgeon Edoardo Zancanaro, cardiac surgeon

Giuseppe Sangiorgi, int. cardiologist Michela Bonanni, cardiologist

M. Bergmann, int. cardiologist

M. Joner, int. cardiologist

C. Skurk, int. cardiologist

Marianna Adamo, int. cardiologist Fabrizio Rosati, cardiac surgeon

Francesco Petrella, thoracic surgeor

Mauro Pepi, cardiologist Laura Fusini, cardiologis

Alfredo Giuseppe Cerillo, cardiac surgeor

Carlo Pace, cardiothoracic surgeor







Children's Hospital Colorado



Ospedale Careggi



IRCCS Ospedale San Raffaele



Centro Cardiologico Monzino



Policlinico Tor Vergata



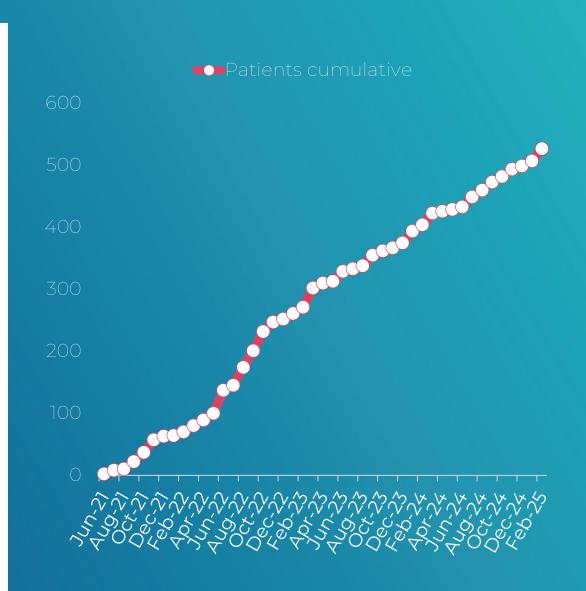
Ospedale Infantile Regina Margherita



Istituto Europeo di Oncologia







## Advisory board



### CLINICAL



Massimo Chessa, MD IRCCS Policlinico San Donato, IT Coordinator of Congenital Heart Disease, specialist in Cardiology and in Pediatric



Paolo Denti, MD
IRCCS Ospedale San Raffaele, IT
Coordinator Transcatheter Heart Valve
Interventions, skilled operator of
percutaneous approaches to structural heart.



Jenny Zablah, MD Children's Hospital Colorado, US Expert in congenital heart disease with a minimally invasive approach through cardiac catheterization



Nina Marsan Ajmone, MD, PhD, FESC Leiden University Medical Center, NL Cardiologist, specialized in non-invasive cardiovascular imaging and FESC for scientific excellence

## SCIENTIFIC/TECHNOLOGY

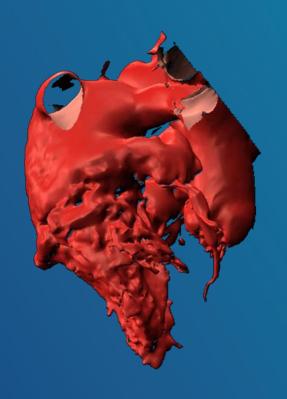


Alberto Redaelli, Prof. Board member & co-founder Full Professor at Politecnico di Milano 25+ years of experience in Cardiovascular Field



Emiliano Votta, Prof. Board member & co-founder Associate Professor at Politecnico di Milano 15+ years of experience in Cardiovascular Field

# THANKYOU



















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