

INFLOW

Novel transcatheter aortic heart
valve implants (TAVI)

proprietary polymeric and biological variants
with a unique self-positioning delivery system



UNMET CLINICAL PROBLEMS TO BE SOLVED

Problems unsolved by current biological valve technologies



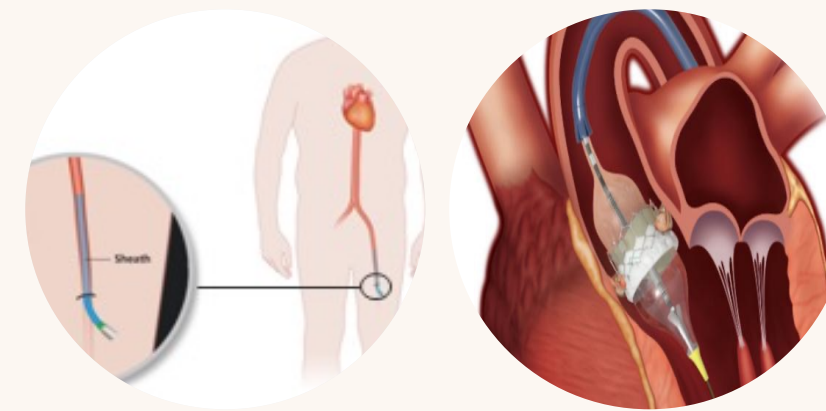
01.
Ageing population
with rising prevalence
of aortic heart valve
disease: 17% in
population >70 y.o.

02.
TAVI not available
for younger
patients <75 y.o.

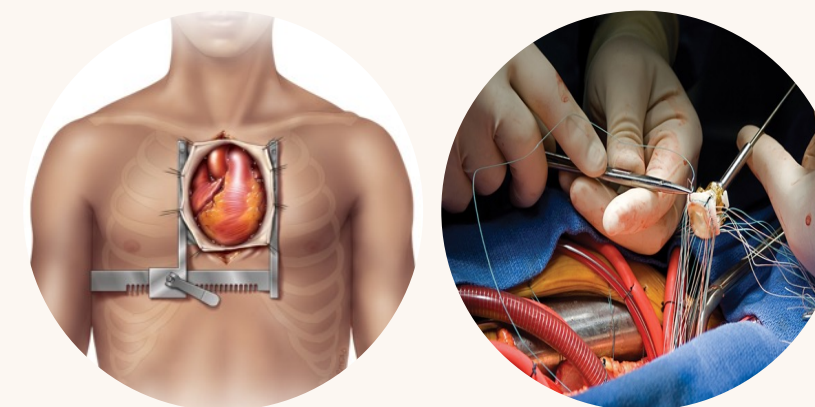
03.
Limited durability of
currently available
TAVI systems

04.
High price of TAVI
systems

TAVI



SAVR



05.
Ineligibility of
many patients for
SAVR due to high
perioperative risk

06.
Limited availability
of biological
material;
costly and time
consuming
manufacturing
process

07.
Long waiting time
for the procedure
(23.3% patients
dying on the
waiting list)

BREAKTHROUGH CONCEPT AND SOLUTION WITH STRONG IP PROTECTION

01.

Biocompatible polymer

02.

Unique biological material

03.

True 14Fr profile

04.

Self-positioning implantation system

05.

Atraumatic tip

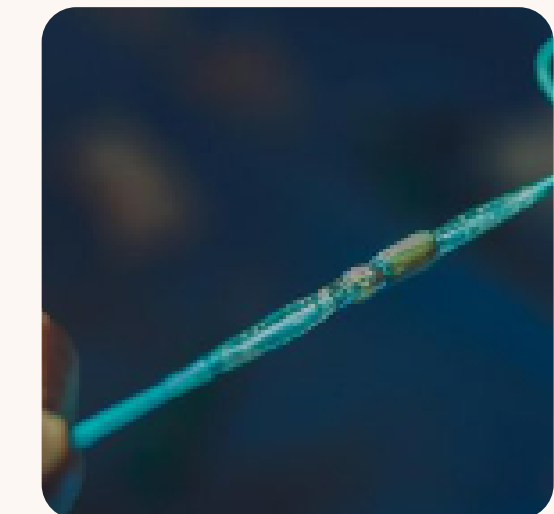
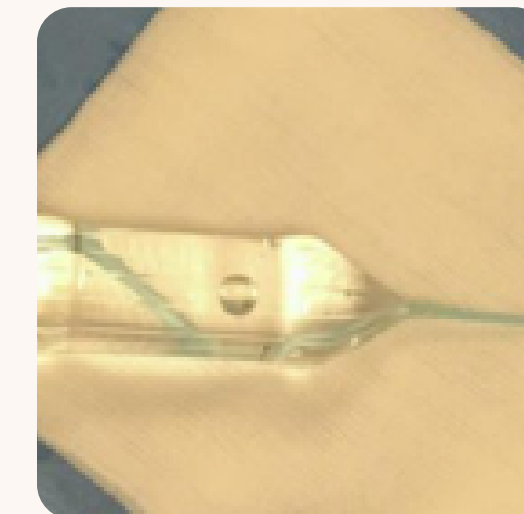
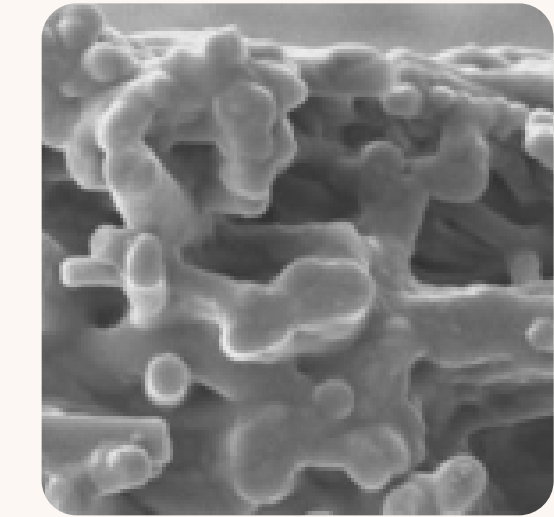
06.

Proprietary stent design

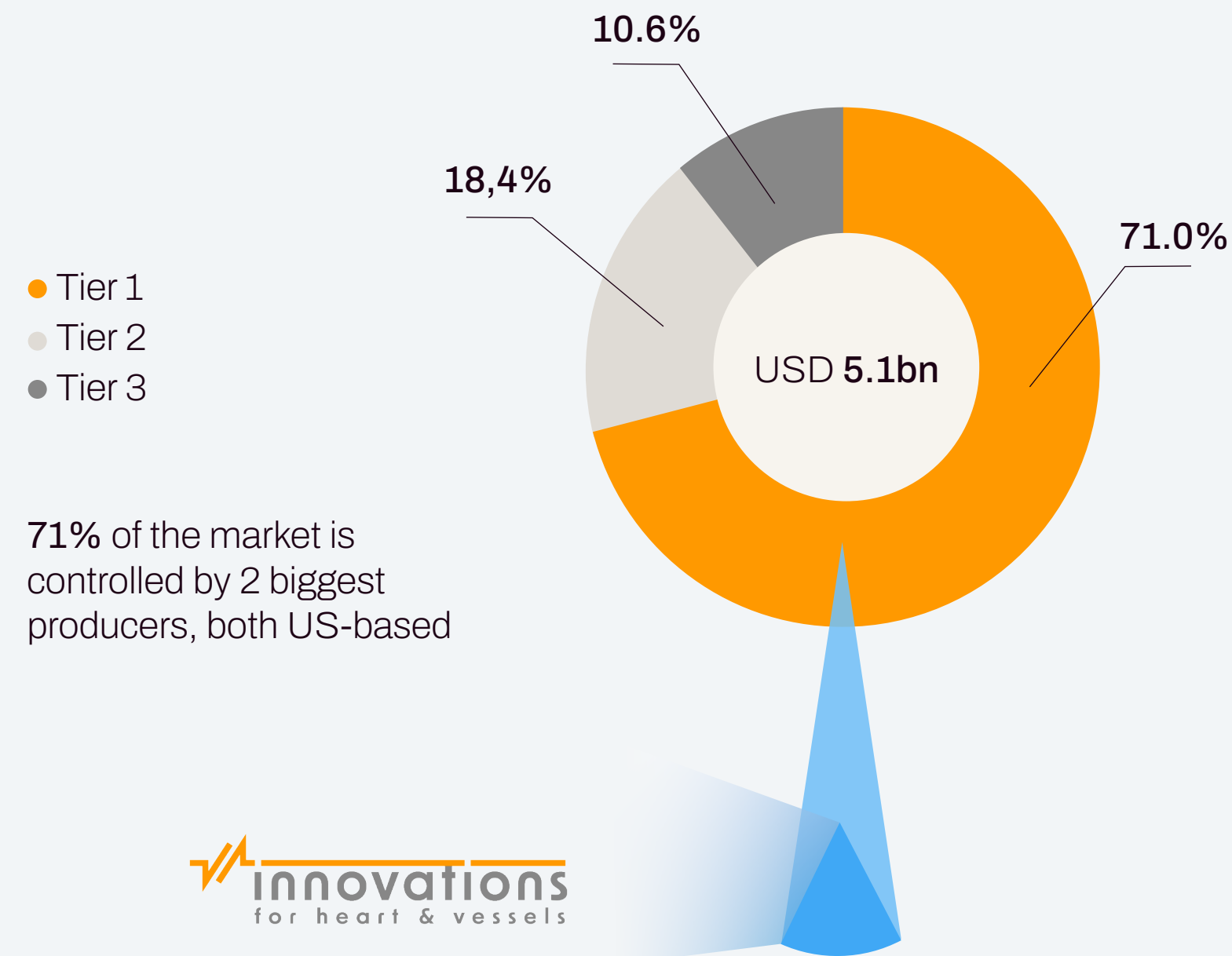
07.

Simplified TAVI procedure

The **INFLOW polymeric valve** stands as a **groundbreaking innovation**, offering extended **durability exceeding 20 years**, surpassing traditional biological valves. The polymeric valve allows to approach a broader market, by making the valves **applicable for younger patients**.

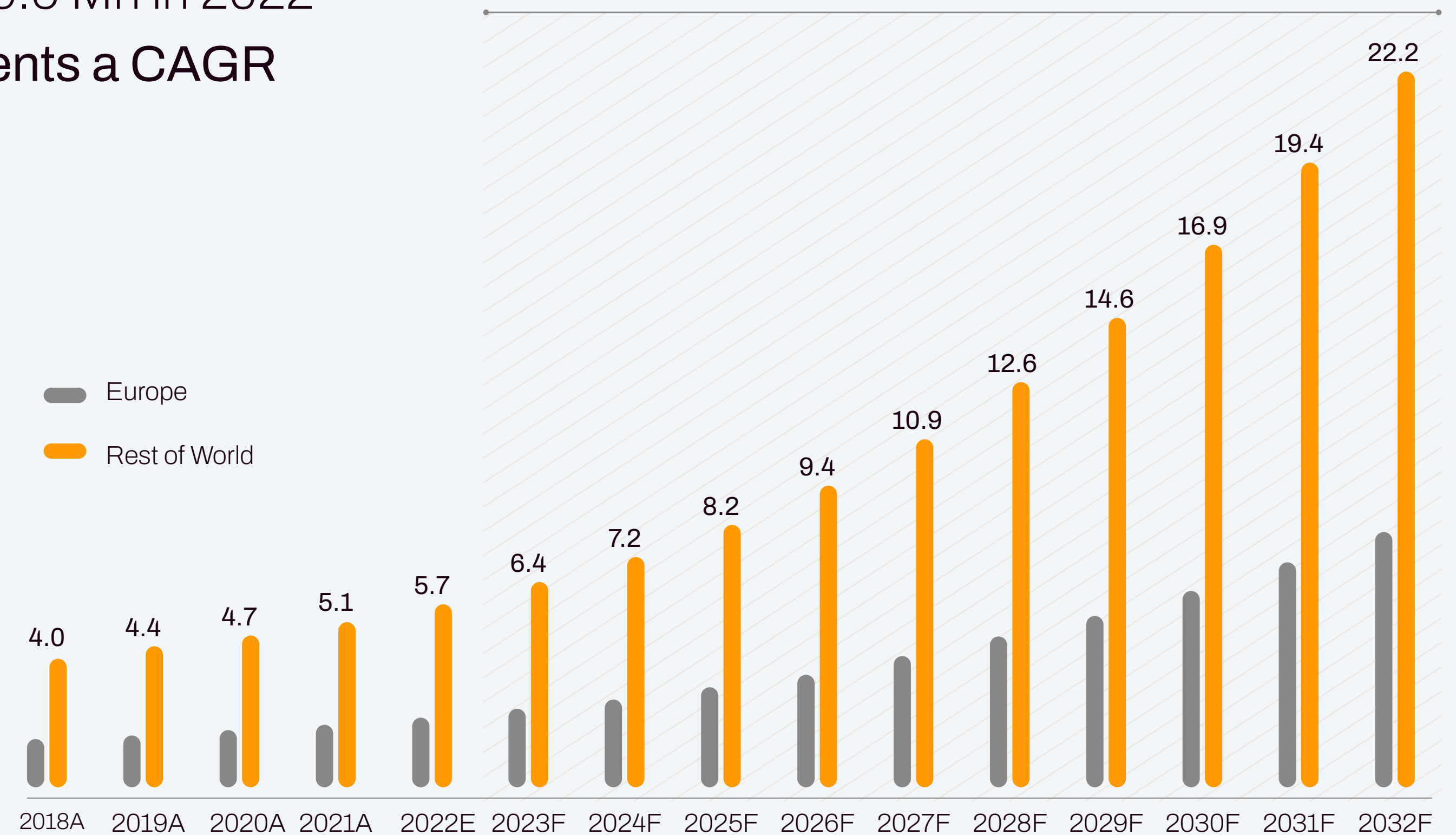


The global transcatheter heart valve implantation (TAVI) market is expected to grow from US\$ 5,709.6 Mn in 2022 to US\$ 22,235.1 Mn by 2032. This represents a CAGR of 14.6% over the forecast period.



Significant share of the global market to be captured

14.6% 2022E-2032F CAGR

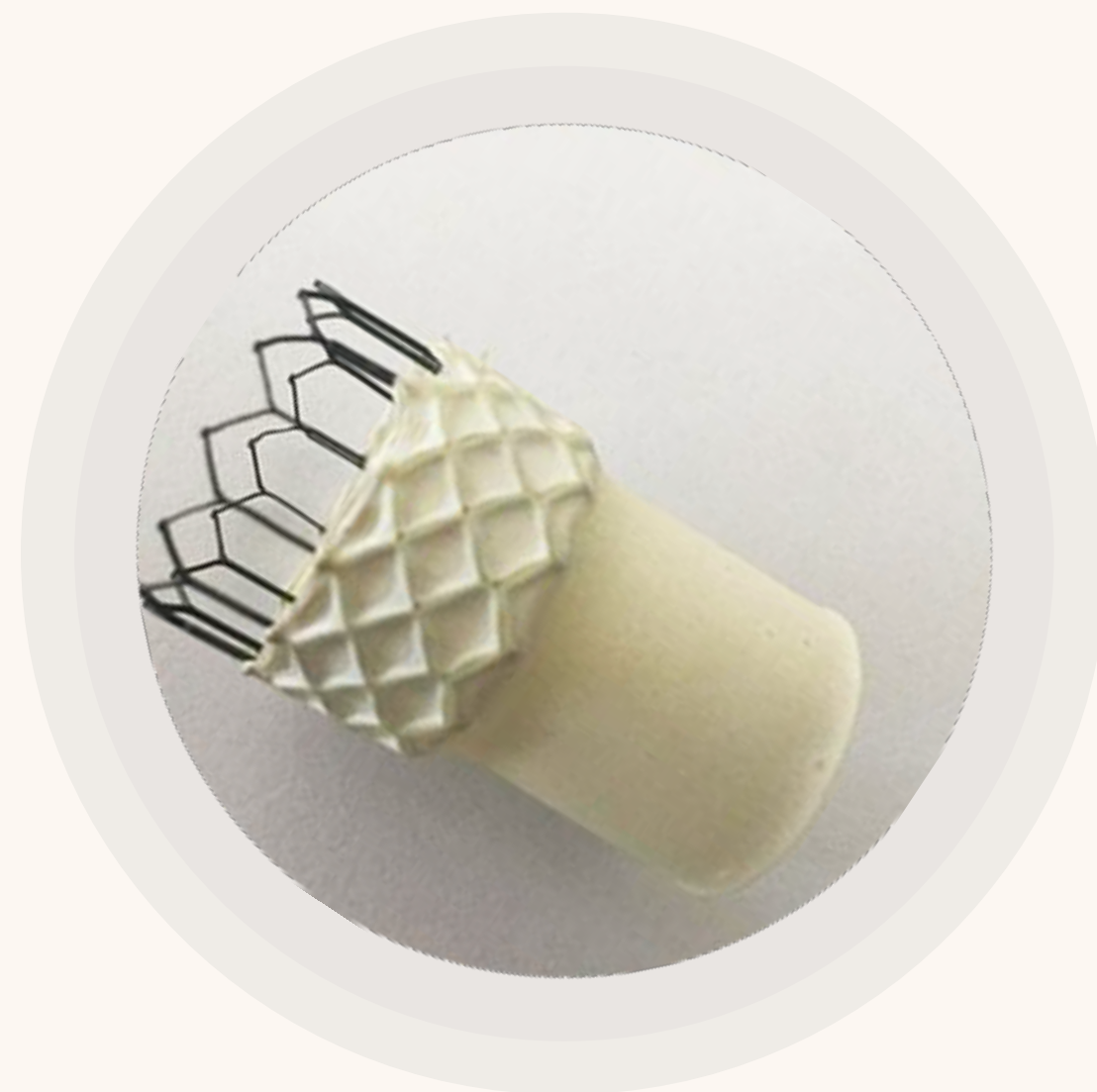


Source: Trigon analysis, Future Market Insights

(1) Tier 1 comprises of: Edwards Lifesciences and Medtronic, tier 2 comprises of: Boston Scientific, Abbott, MicroPort, Sahajanad Medical Technologies, Blue Sail Medical and Venus Medtech, tier 3 comprises of: JenaValve Technology, Suzhou Jiecheng Medical, Peijia Medical, Meril Life Sciences and others

INFLOW POLYMERIC VALVE – DISRUPTIVE TECH

Medical-grade polymer material, low production costs. **No polymeric TAVI competitors** present on the market



POLYMER MATERIAL REMOVES THE NEED FOR ANIMAL HUSBANDRY – PRODUCTION IS EXTREMELY SIMPLIFIED, MUCH CHEAPER AND ENVIRONMENT-FRIENDLY

INFLOW polymeric valve features

01.

Medical-grade polymer material

02.

Proven biocompatibility and mechanical strength (preclinical studies)

03.

Potential for endothelialization of leaflet surface

04.

Exceptional durability – over 20 years, specifically suitable for younger patients

Technology for production

01.

Vent like concept for aortic valve

02.

Sutureless – polymer attached to the metal frame using proprietary electrospinning method

03.

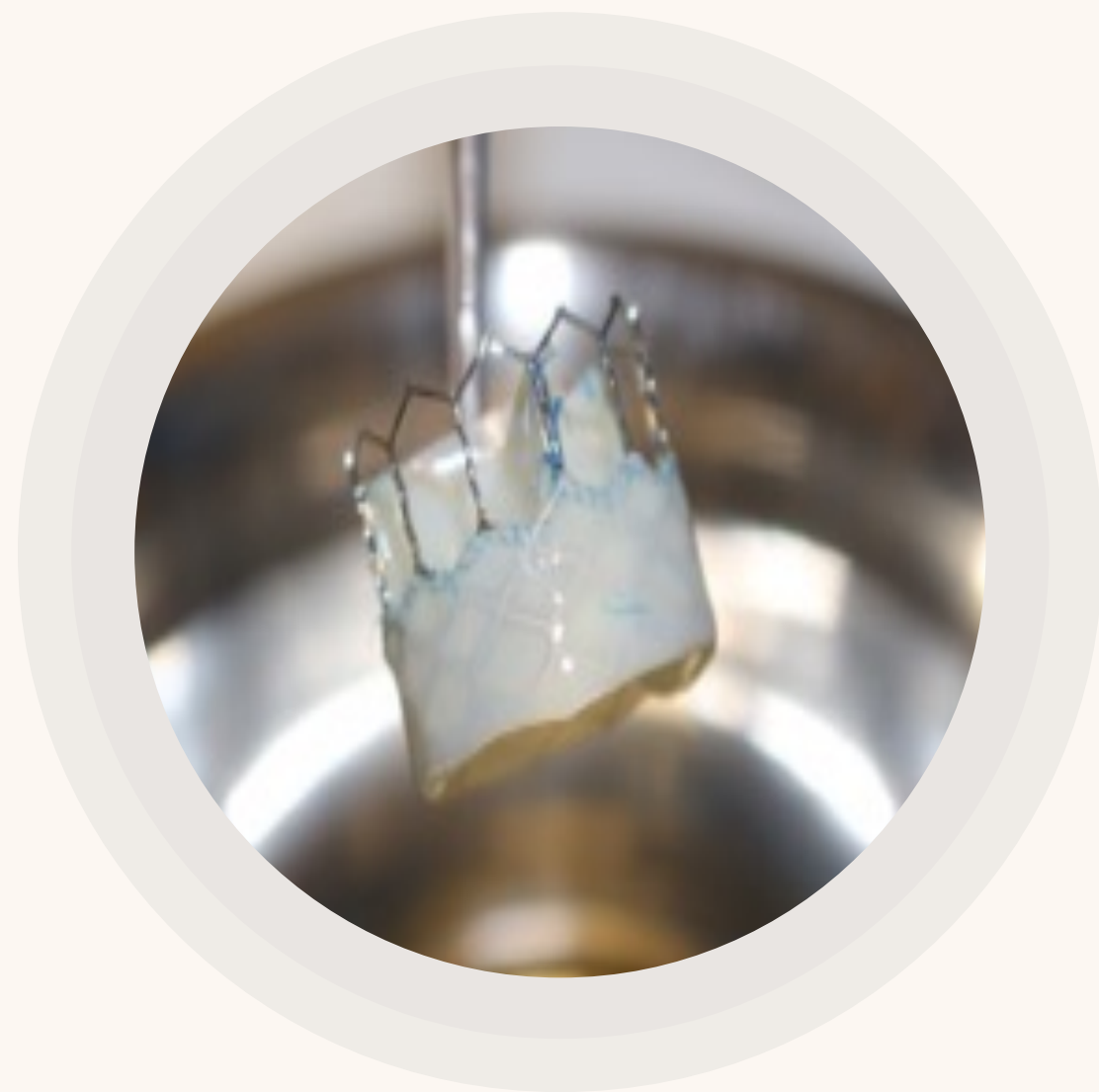
Simple commissure formation by attachment of suspensions to the stent frame

04.

Low production costs with high profit margin

INFLOW BIOLOGICAL VALVE – UNIQUE SOLUTION

Our INFLOW biological valve is characterized by **high biocompatibility and resistance to degeneration**.



OUR OWN SUPPLY OF HIGH QUALITY BIOLOGICAL MATERIAL FOR VALVE PRODUCTION IS A KEY COMPETITIVE ADVANTAGE

INFLOW biological valve features

01.

High resistance to degeneration

02.

Proven biocompatibility and mechanical strength

03.

Potential for endothelization of leaflet surface

Technology for production

01.

Vent like concept for aortic valve

02.

Simple commissure formation by attachment of suspensions to the stent frame

03.

Proprietary biological material derived from the pericardium of genetically modified domestic pig

BENEFITS OF OUR INFLOW BIOLOGICAL & POLYMERIC VALVES



Benefits for patients



Faster recovery, shorter stay at the hospital, reduced trauma and pain, less noticeable scars



Shorter waiting time for the procedure



A lower risk of perioperative complications and death rate



Personalized valve implant

Benefits for cardiologists



Simplified procedures to be performed immediately after diagnosis



Low risk of the procedure, short hospitalization with low side effect rate



Easier re-operation and more straightforward procedures

Benefits for cardiac centers



Facilitation and simplification of the procedure



Larger scope of procedures delivered without any delay



Decrease in procedure costs for hospitals and cardiac centers

The **INFLOW Polymeric Valve** stands as a **revolutionary innovation**, which can be applied for a larger patient population due to its **extended durability >20 years – especially applicable for younger patients.**

POLYMERIC INFLOW VALVE PRECLINICAL STUDY RESULTS

01.

Optimal hemodynamic performance and healing, with no valve degenerations at 6 month follow-up in an ovine preclinical study

02.

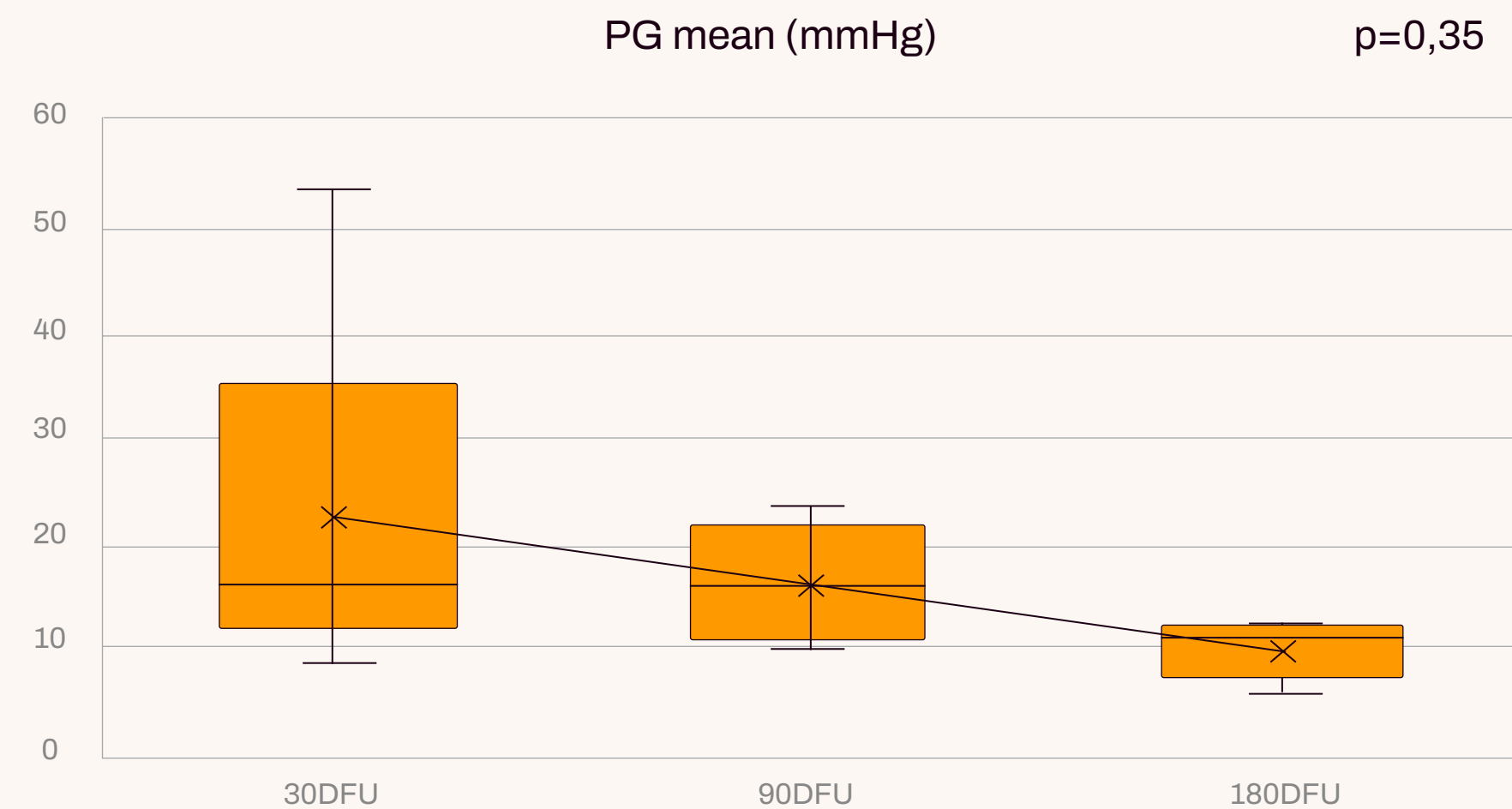
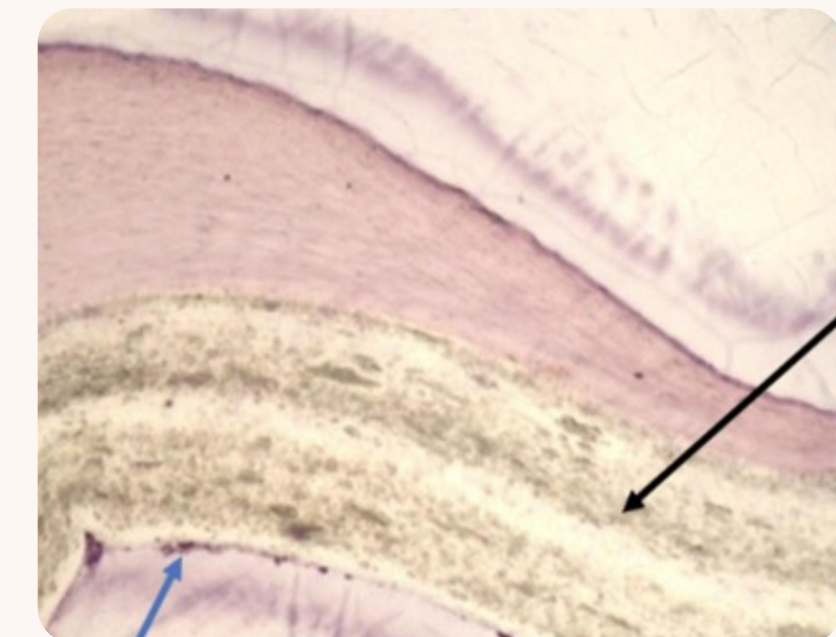
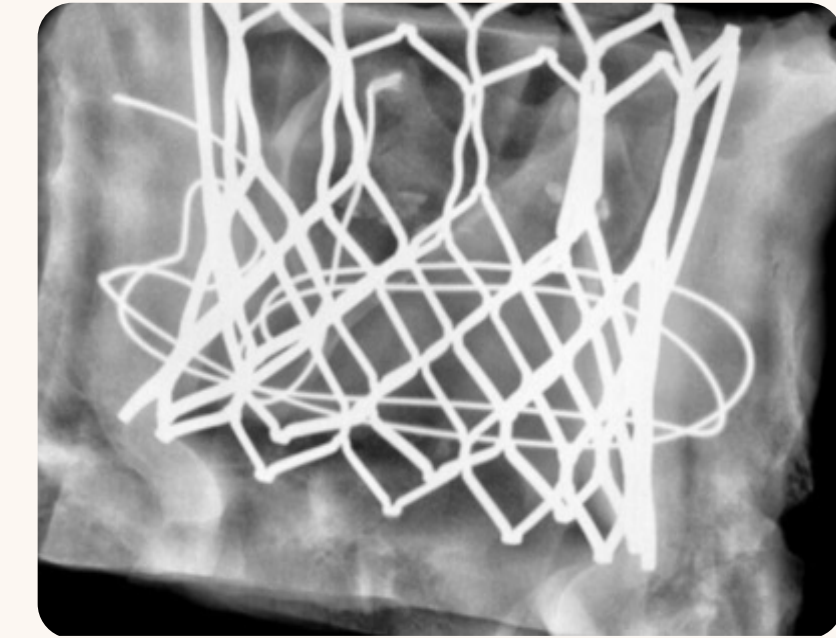
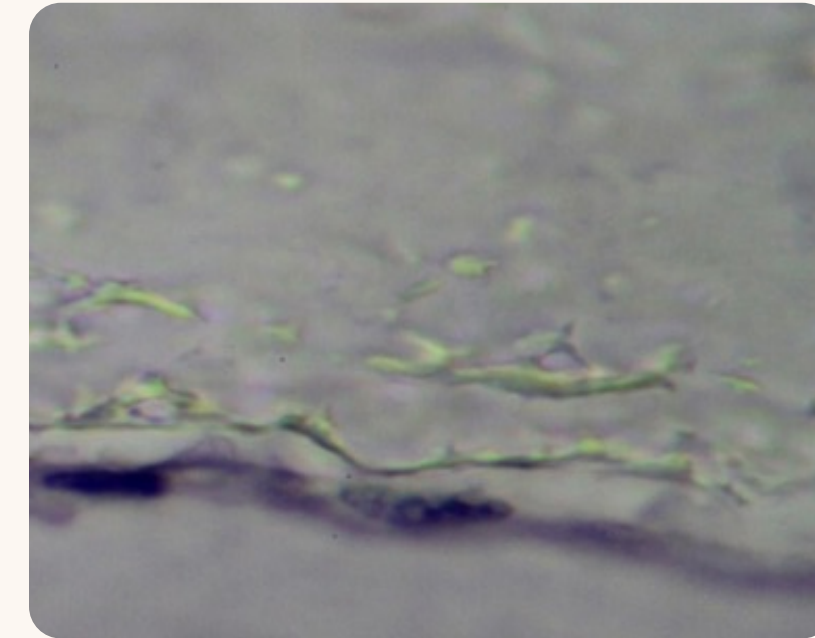
No calcifications or significant stenosis, regurgitation or peri-valvular leak in echocardiography

03.

Leaflets remained free from thrombi and calcifications in all cases

04.

Complete material endothelialisation



Source: Mateusz Kachel, Piotr Buszman et al.,
Frontiers in Cardiovascular Medicine, 2022

BIOLOGICAL INFLOW VALVE PRECLINICAL STUDY RESULTS

01.

Long-term (6-month) observation was feasible with low mortality and no valve degeneration at 6 month follow-up in an ovine preclinical study

02.

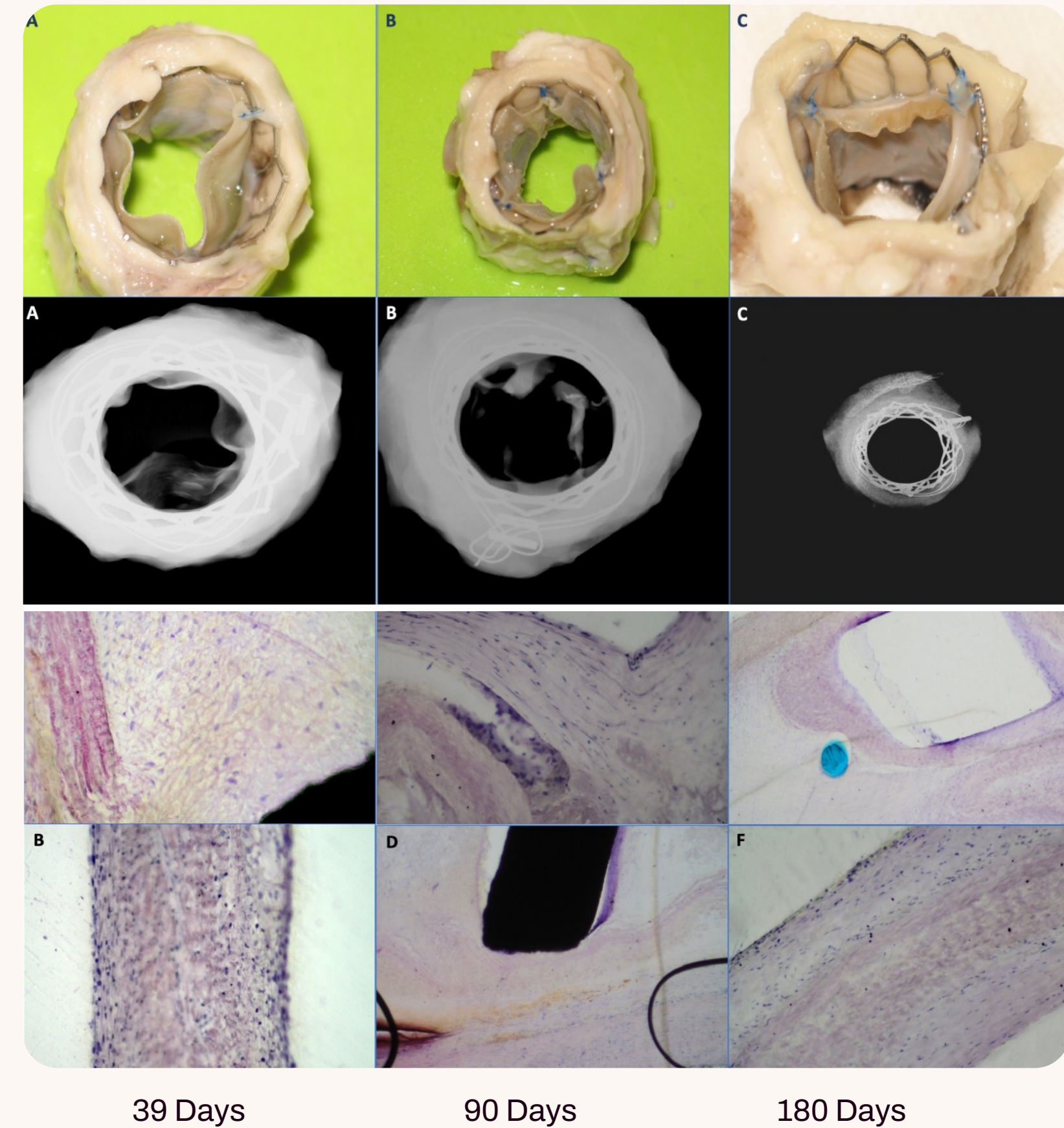
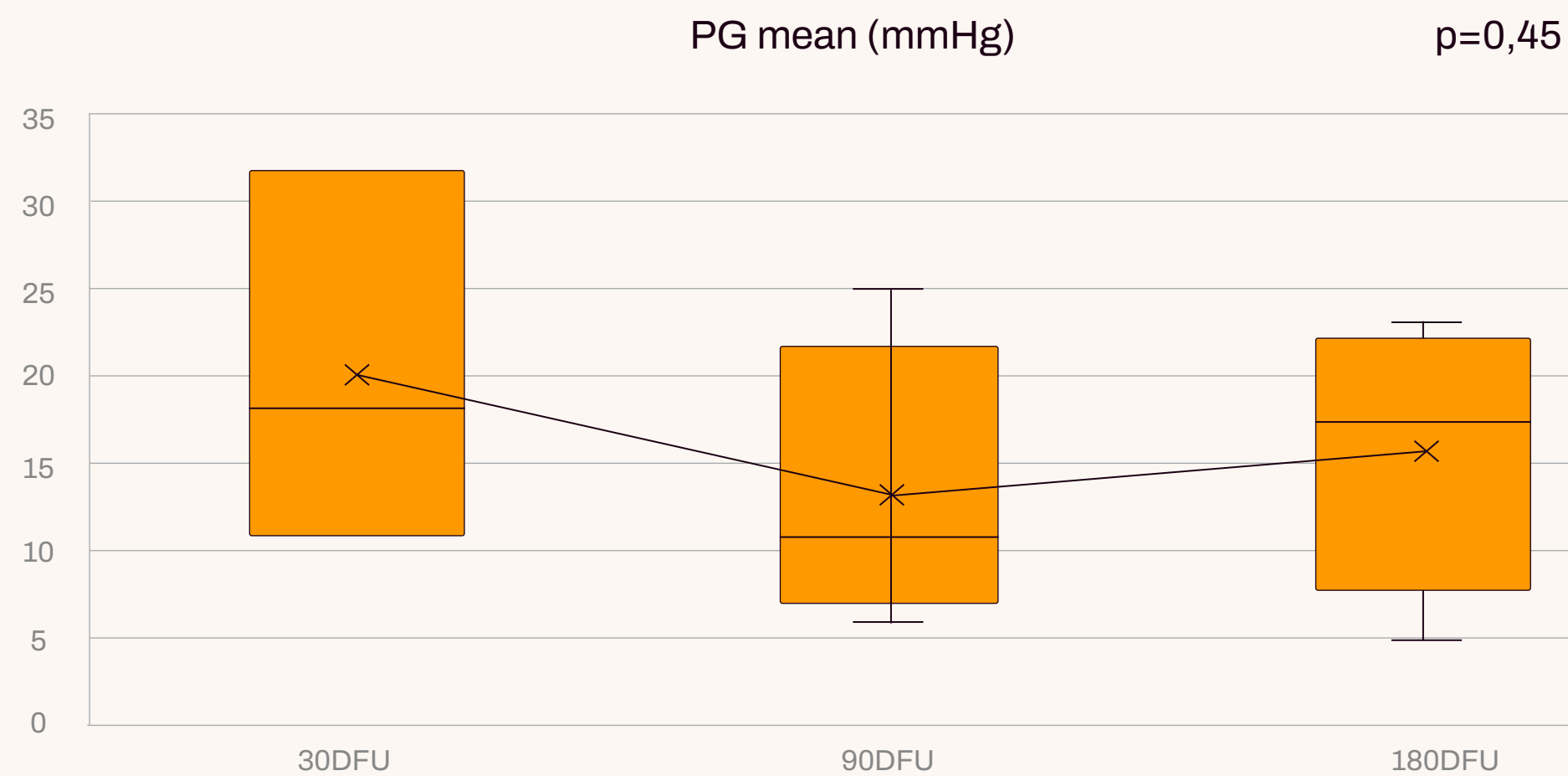
Echocardiography showed good hemodynamic outcomes and no structural valve deterioration

03.

TAVI and anchoring of valves was achieved in all cases with high procedural success

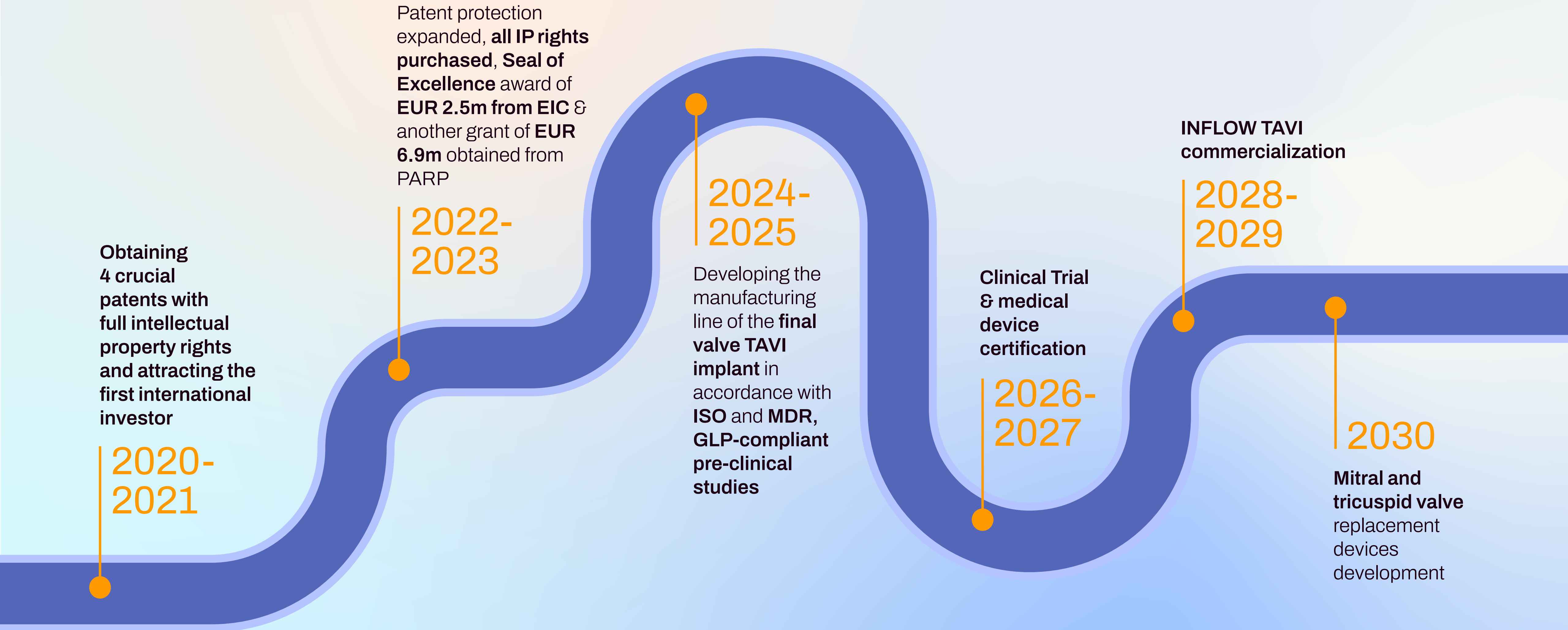
04.




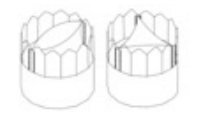


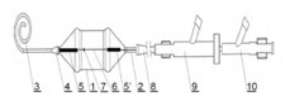


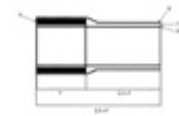
No valve degeneration at 1, 3 and 6 month follow-up



Source: Piotr Buszman, Mateusz Kachel et al., Cardiology Journal, 2023

PRODUCT DEVELOPMENT ROADMAP



IP RIGHTS PROTECTION – INTERNATIONAL PATENTS		APPROVAL DATE [date of patent grant]	PATENT OWNERSHIP	PROTECTION RANGE
<p>WO2020022914</p> 	Biological, low-profile, balloon-expanded prosthetic aortic heart valve, percutaneously implanted, and the method of its manufacturing	PL 11.12.2020	I4HV 100%	 
<p>WO2020022914</p> 	Artificial, low-profile, balloon-expanded specialized aortic heart valve, percutaneously implanted	PL 11.12.2020 EU 21.06.2023	I4HV 100%	 
<p>WO2020022915</p> 	System for introducing implants used in structural heart diseases using a minimally invasive method	PL 25.03.2021	I4HV 100%	 
<p>WO2020022916</p> 	Method of forming prefabricated units used in production of systems of prosthetic aortic valve transcatheter implantation and prosthetic aortic valve prefabricated unit	PL 17.06.2021 EU 09.08.2023	I4HV 100%	