



Novel Ultra Low Profile Geminus TAVR System

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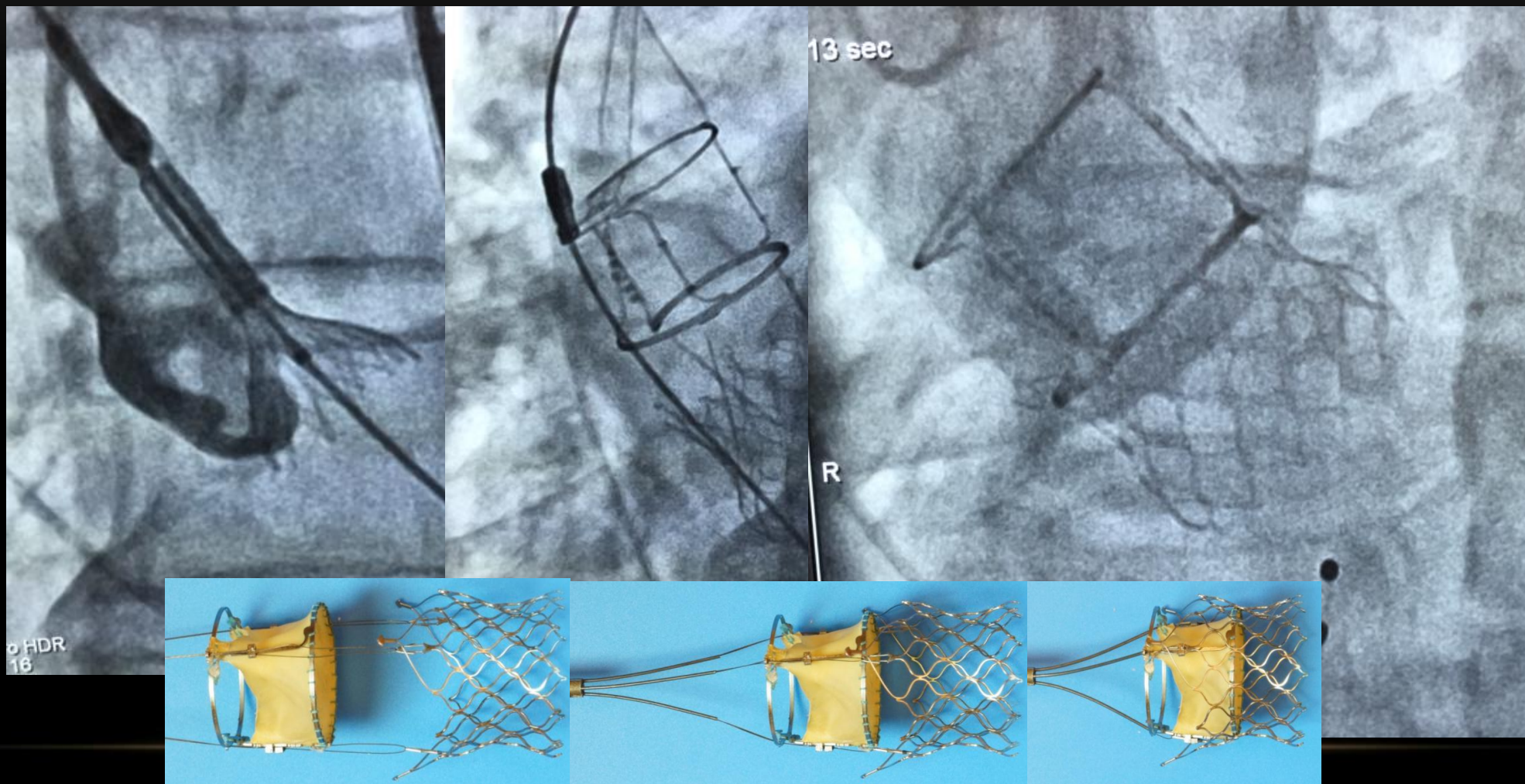
Financial Disclosure

I, Eberhard Grube have the following financial interest/arrangement that could be perceived as a real or apparent conflict of interest in the context of the subject of this presentation

Speaker Bureau/ SAB: Medtronic, Boston Scientific, HighLife, Jena Valve, Protembis, Valve Medical, Anteris

Equity Interest: Cardiovalve, Claret, Shockwave, Valve medical, CardioMech, Millipede, Imperative Care, Pi-Cardia, Ancora, Laminar, ReNiva Medical

First Successful 12 French VM TAVR Modular Implant

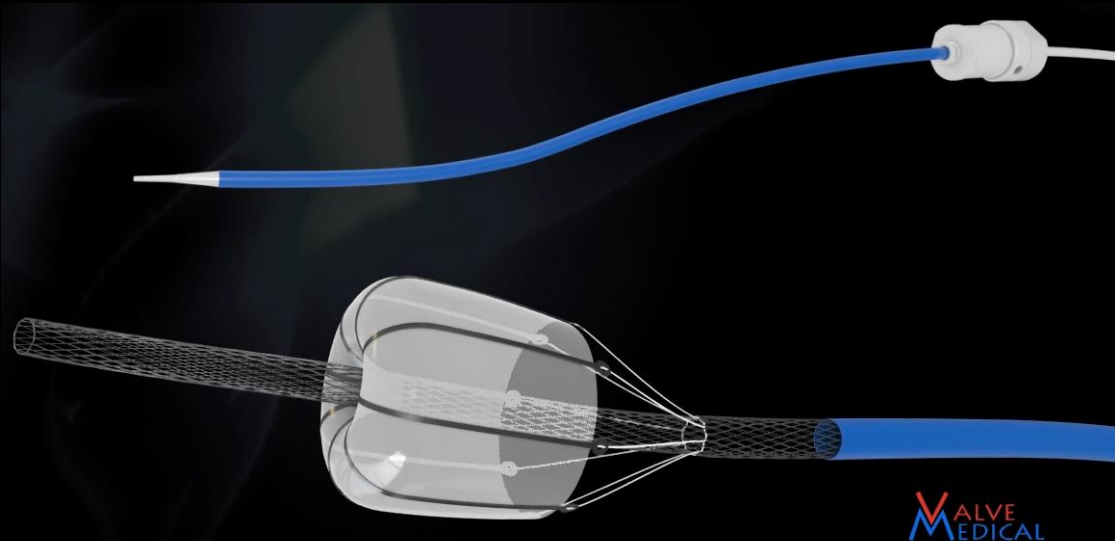


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Grube E, Abizaid A, Leon MBL

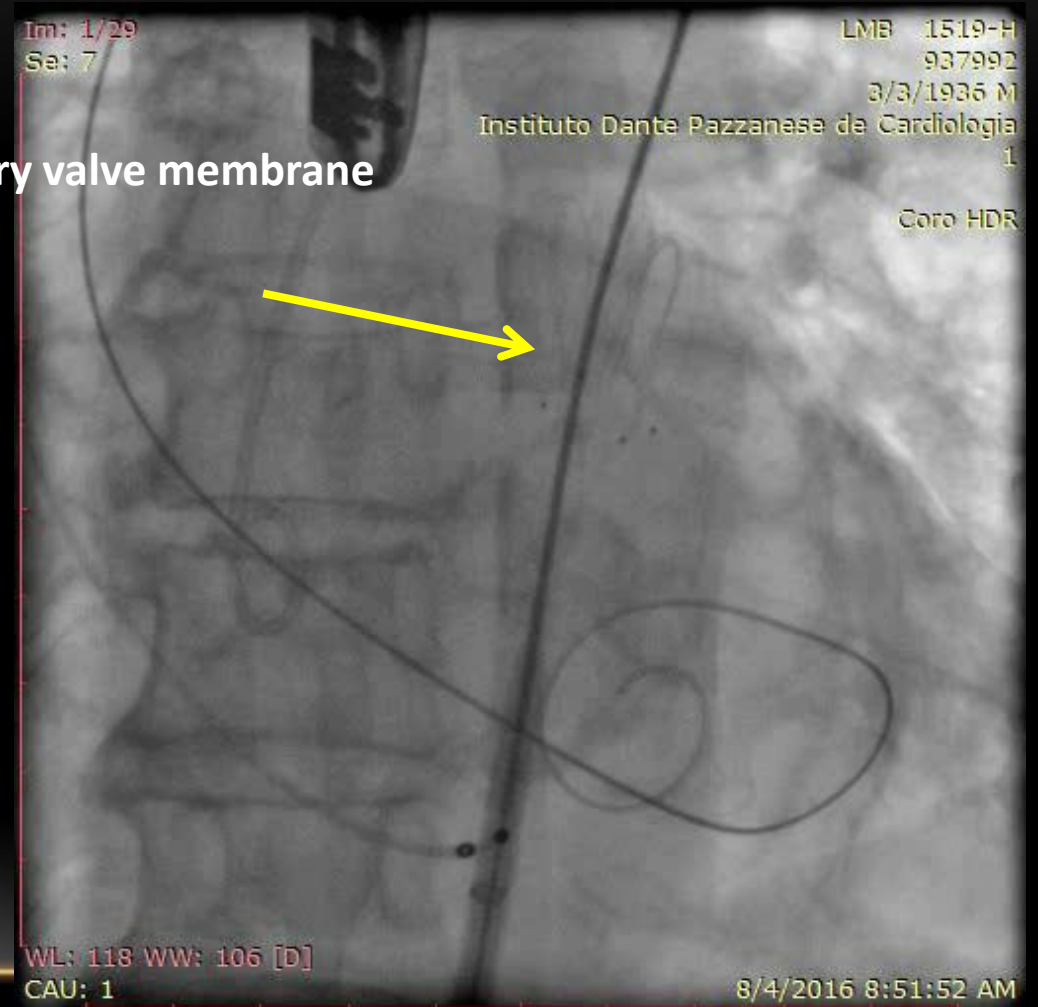
VM TAVR Modular Implant

Temporary Valve (due to docking in the native Annulus)

- OD: 12 Fr.
- Femoral insertion after pre-close
- Temporary valve membrane deploys from inside sheath



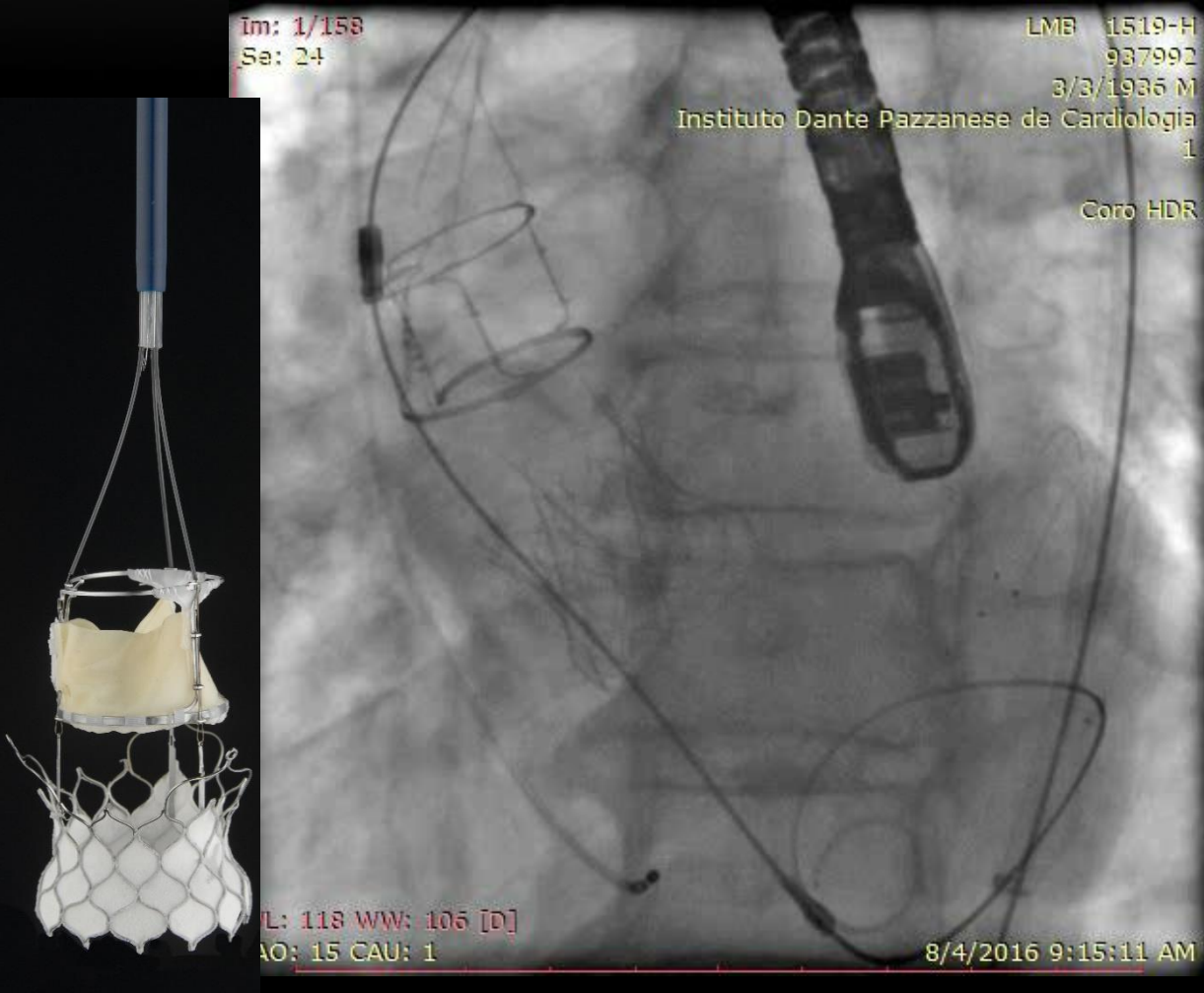
Temporary valve membrane



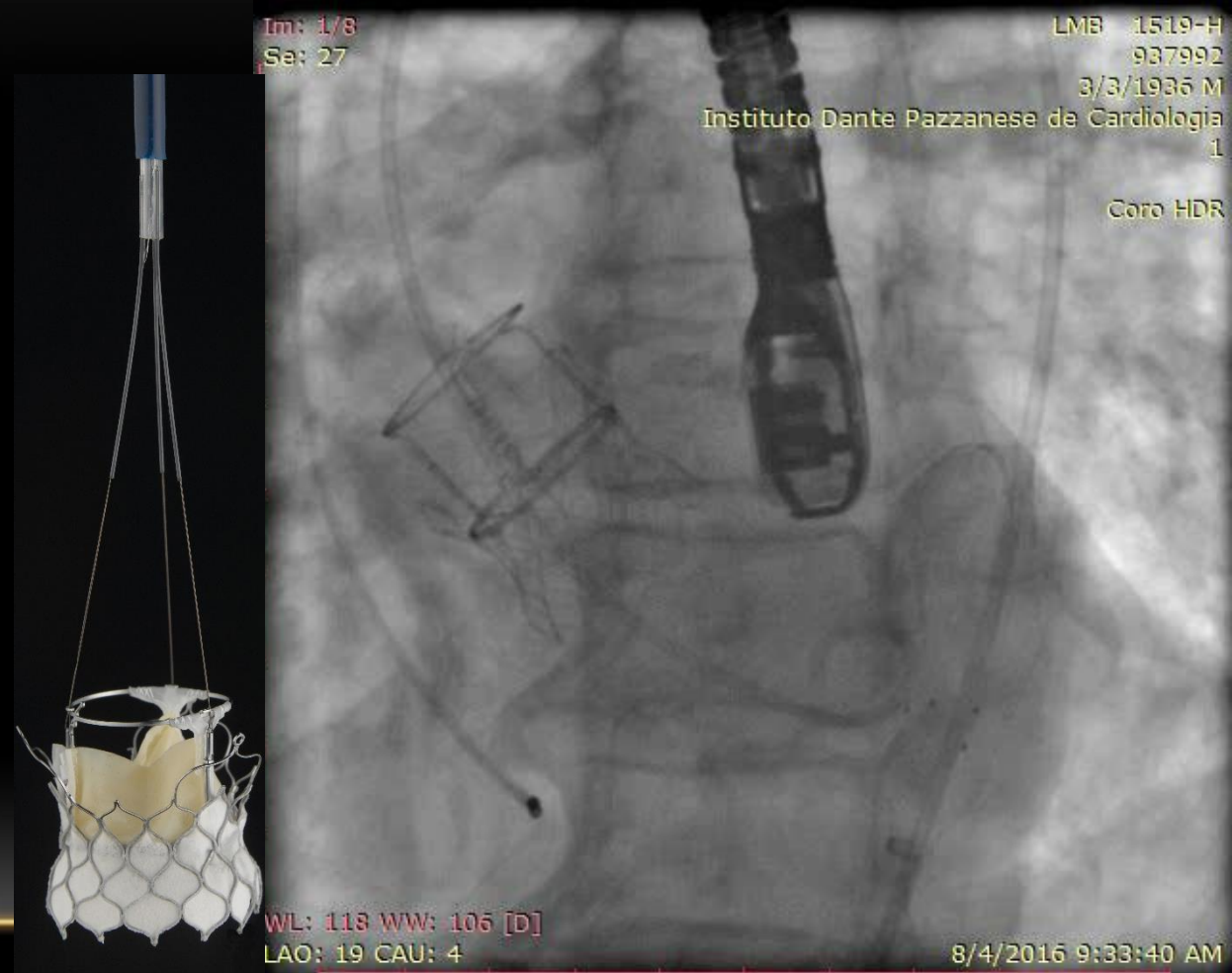
VM TAVR Modular Implant

Docking of 2 Modules

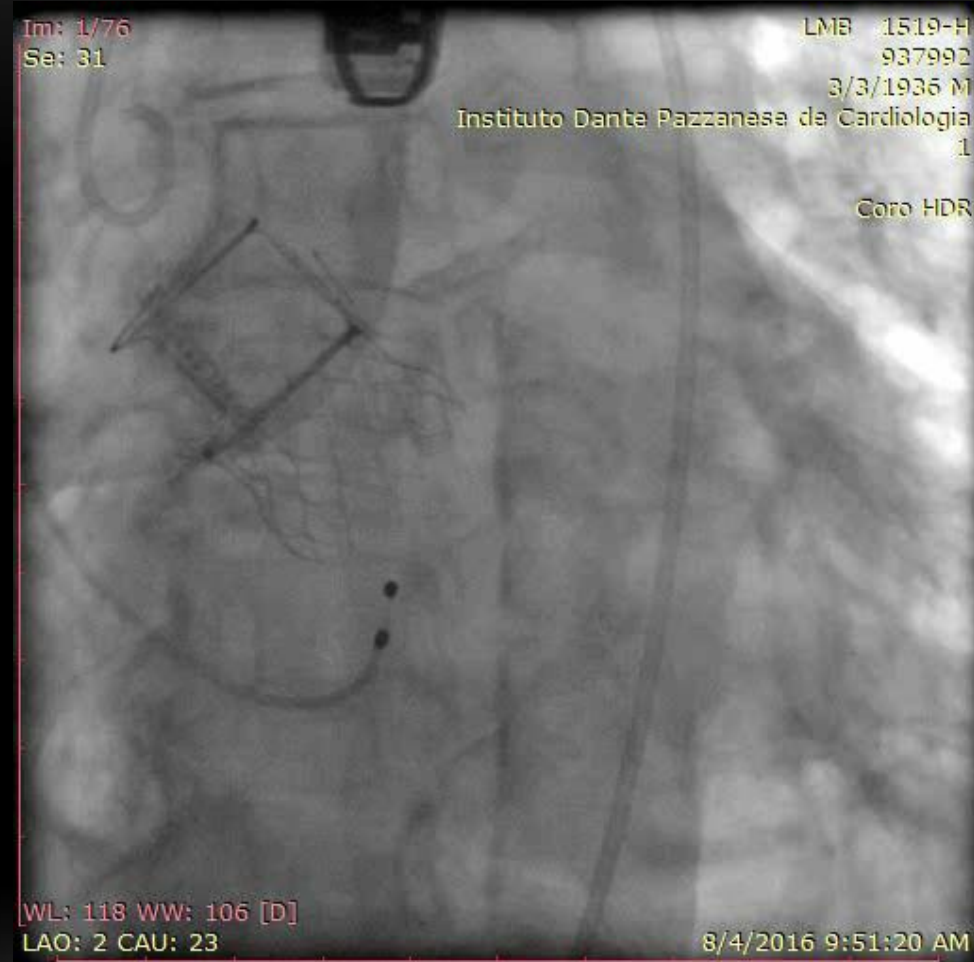
Docking



Fully Assembled Valve



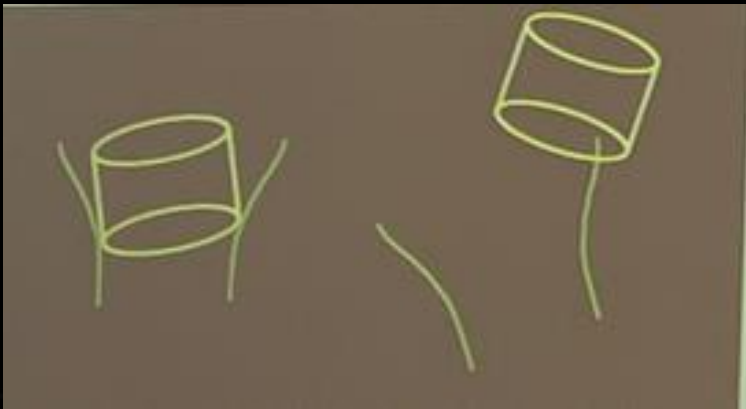
VM TAVR Modular Implant Final Implant



Limitations of Gen 1

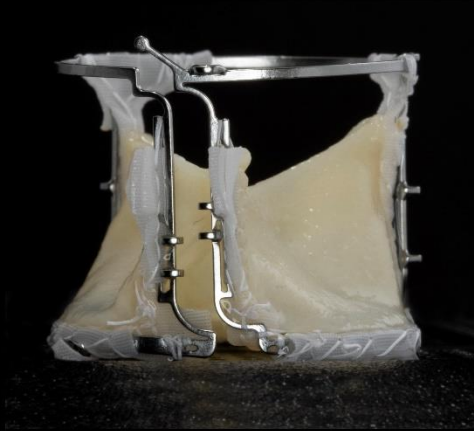
Docking within the native Annulus:

- requires the use of a temporary Valve
- creates a high stress environment
- creates a linkage between docking maneuver and the valvular native anatomy



Implant Release unpredictable

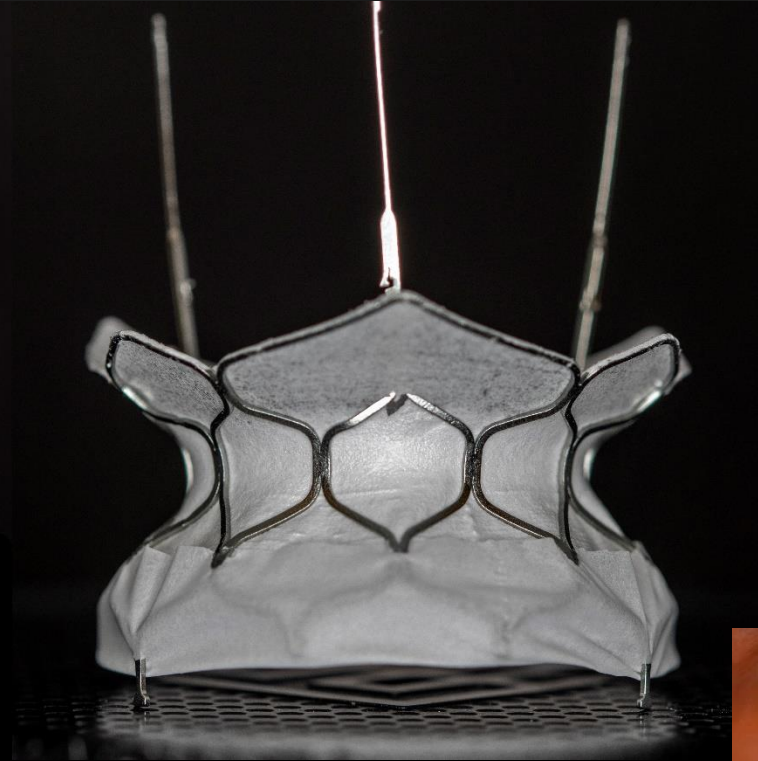
Geminus Gen II System



Valve Module

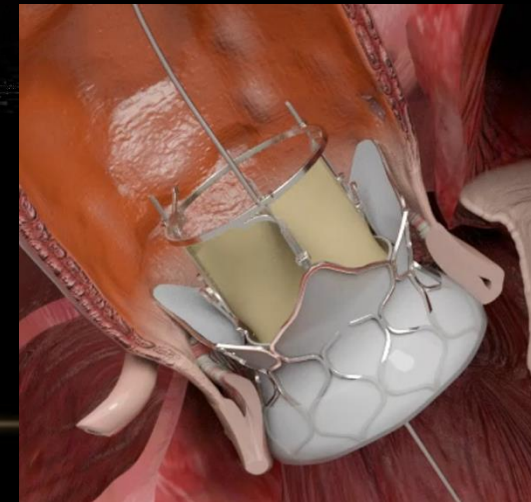


Assembled device



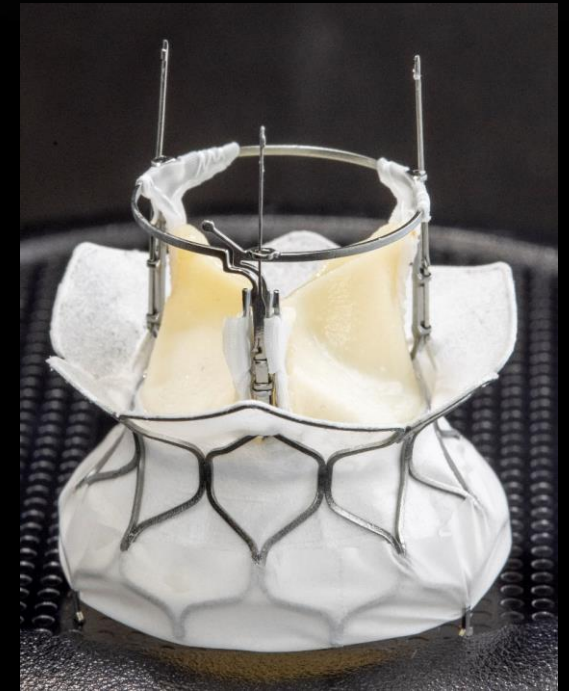
Anchor Module

- Modular (2-piece)
- Bioprosthetic
- Trans-femoral implantation
- 12 Fr OD

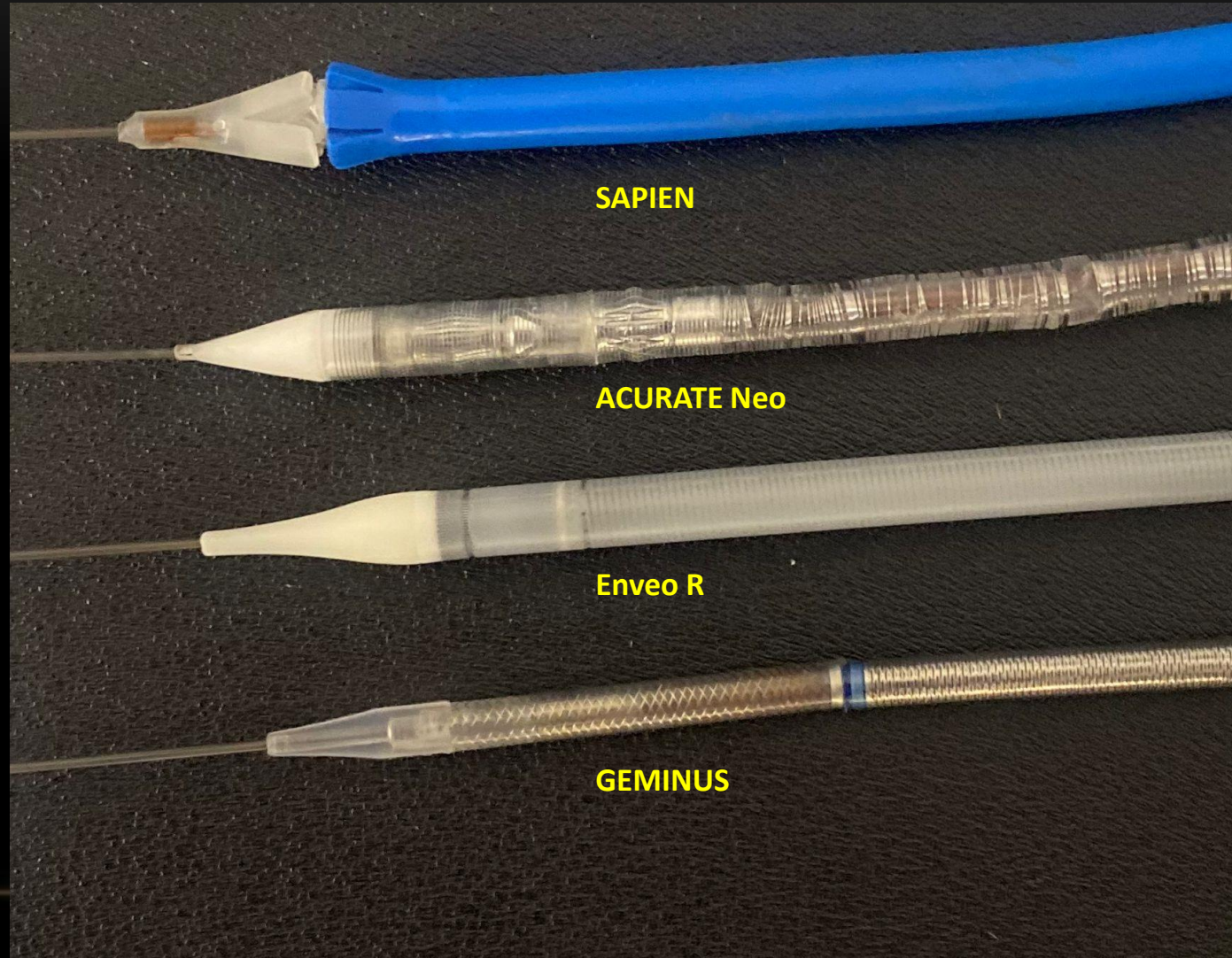


The Ultra Low Profile Geminus TAVR Valve (2nd Gen) System Properties

- **True 12Fr OD profile:**
 - Reduced vascular complications, increased deliverability & availability to more patients
- **Optimized frame:**
 - Minimal interference with conduction system and mitral valve
 - Self seating
 - Facilitate coronary access
 - High radial force
- **Optimized leaflets:**
 - Full thickness pericardium
 - Reduced crimping force on leaflets
 - Durability & manufacturability
- **PVL reduction**

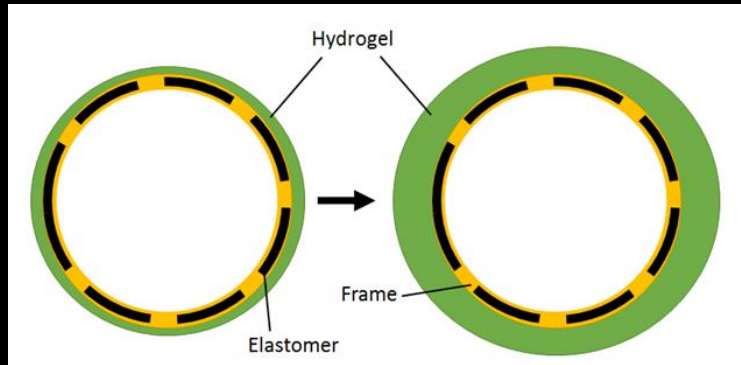


Comparison of Delivery Systems



PVL Prevention - Sealing Hydrogel

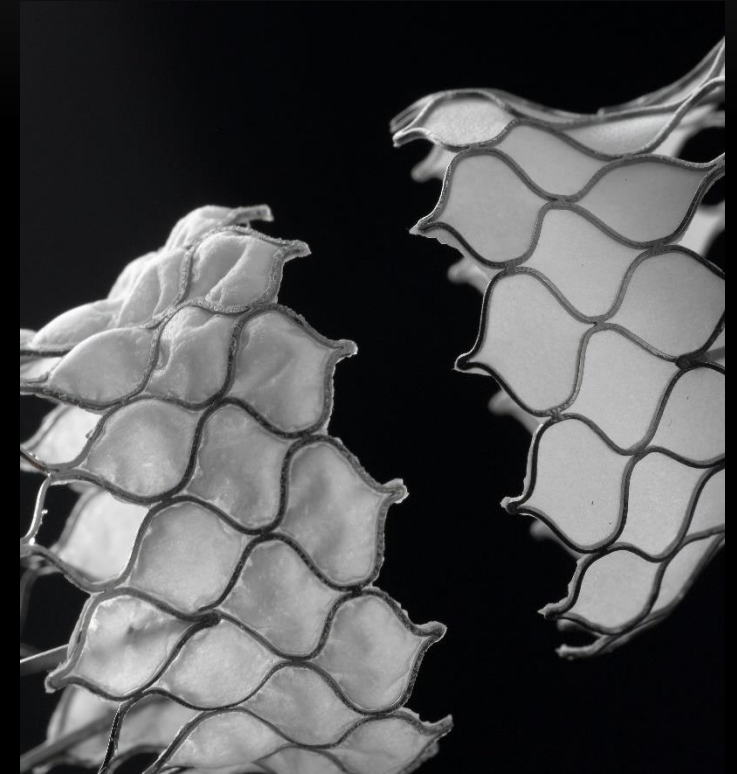
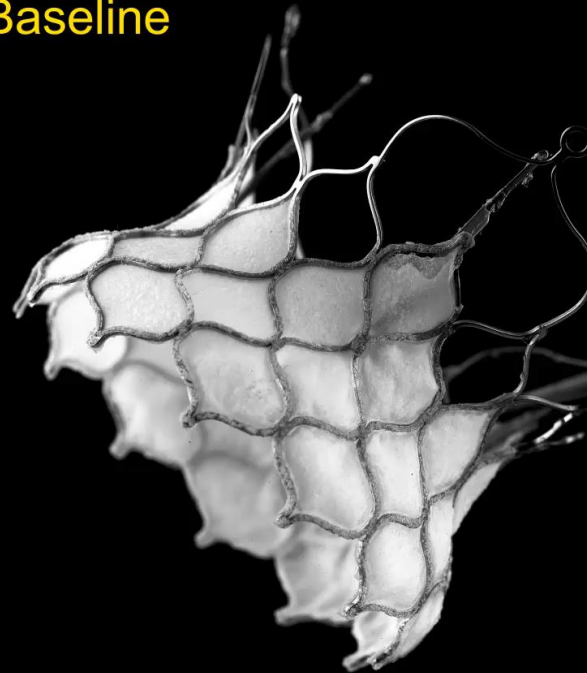
Para valvular leak prevention



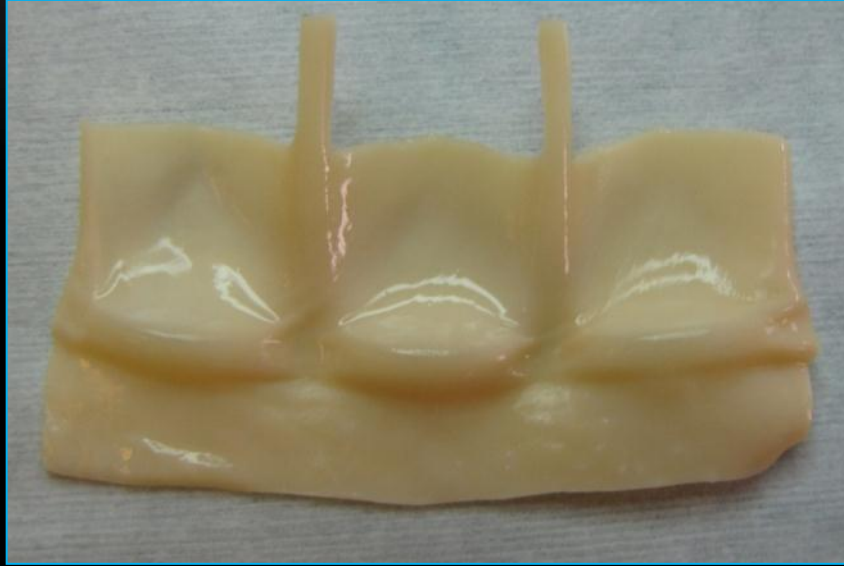
Inflatable coating

- A two layer polymer coat
- External hydrogel-based layer
- Frame stored dry
- Following implantation, the hydrogel swells outwards

Baseline

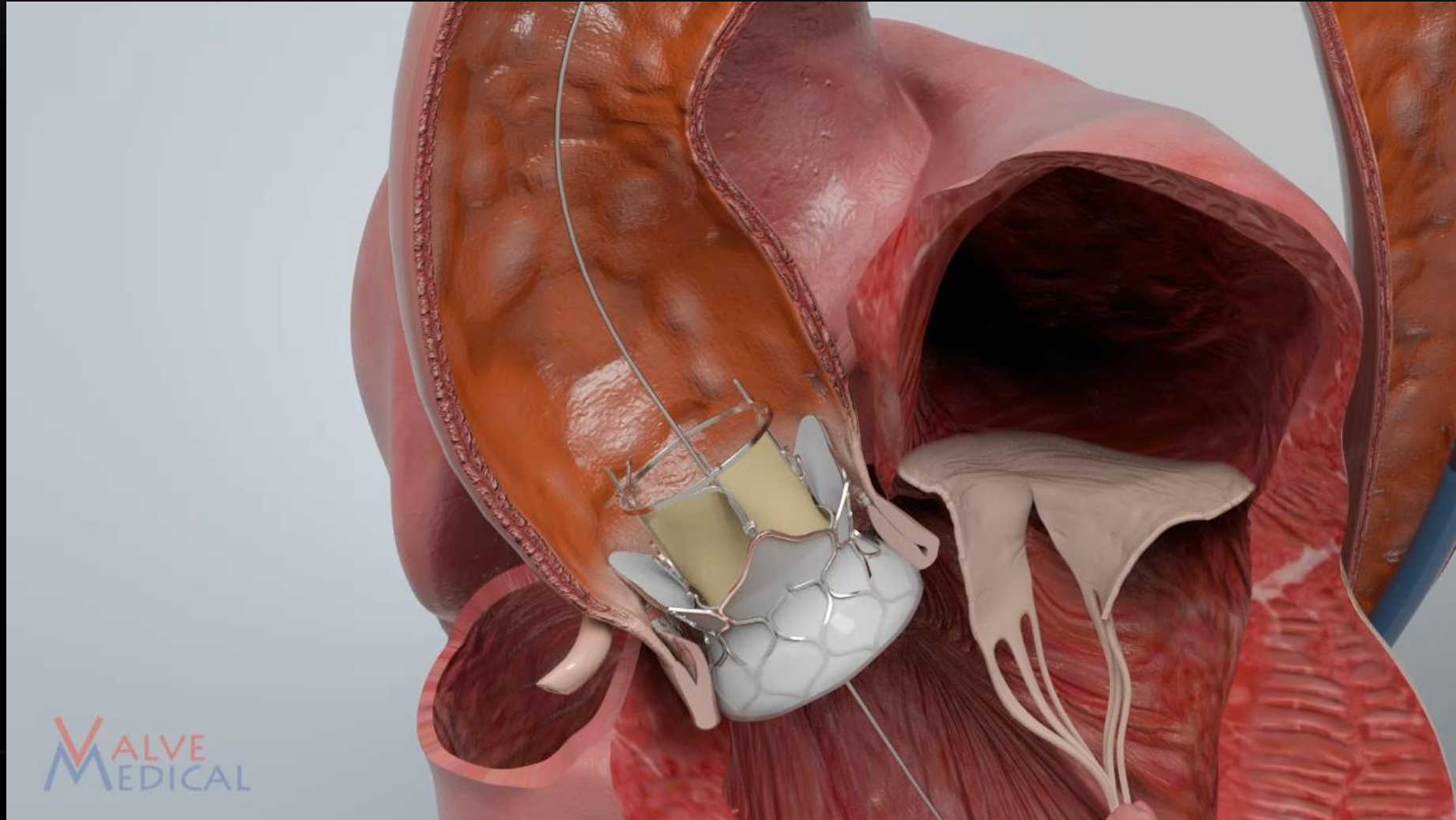


3 D Valve Leaflets



- Single piece of pericardium is fixed 3D on a mandrel
- Fewer stitches → improved manufacturability and durability
- Enhanced coaptation → wider opening and improved hemodynamics
- Full thickness bovine pericardium (500 microns)

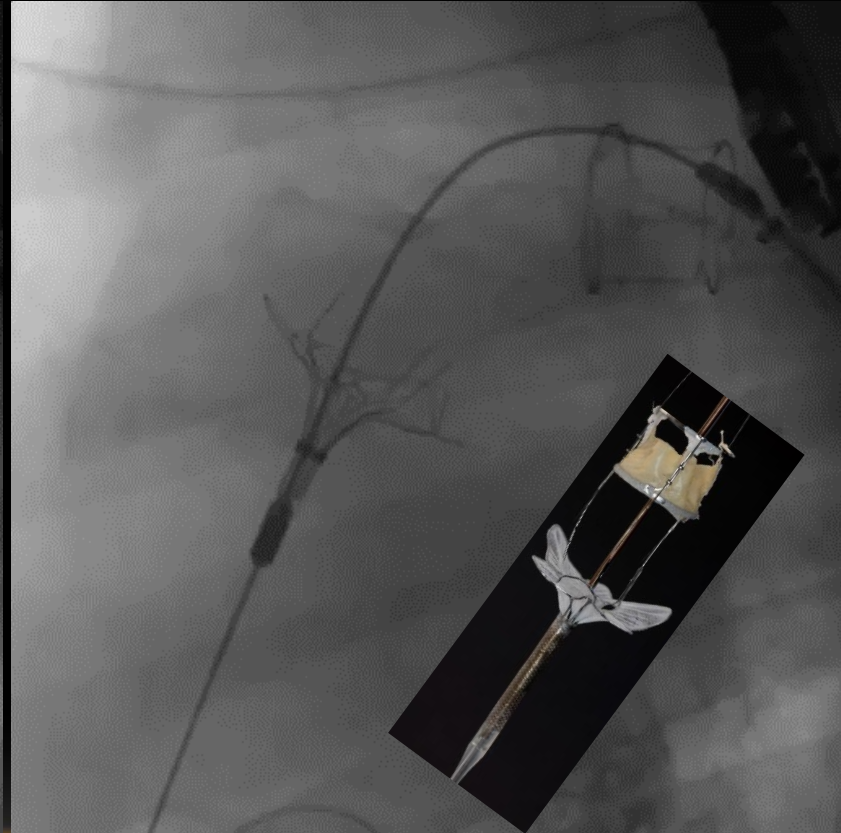
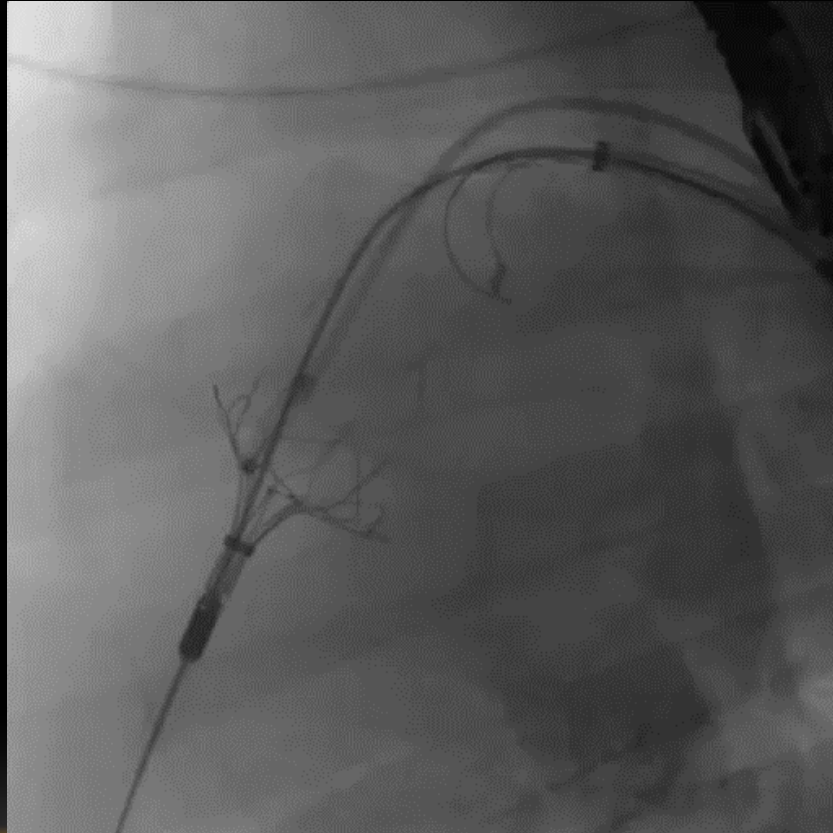
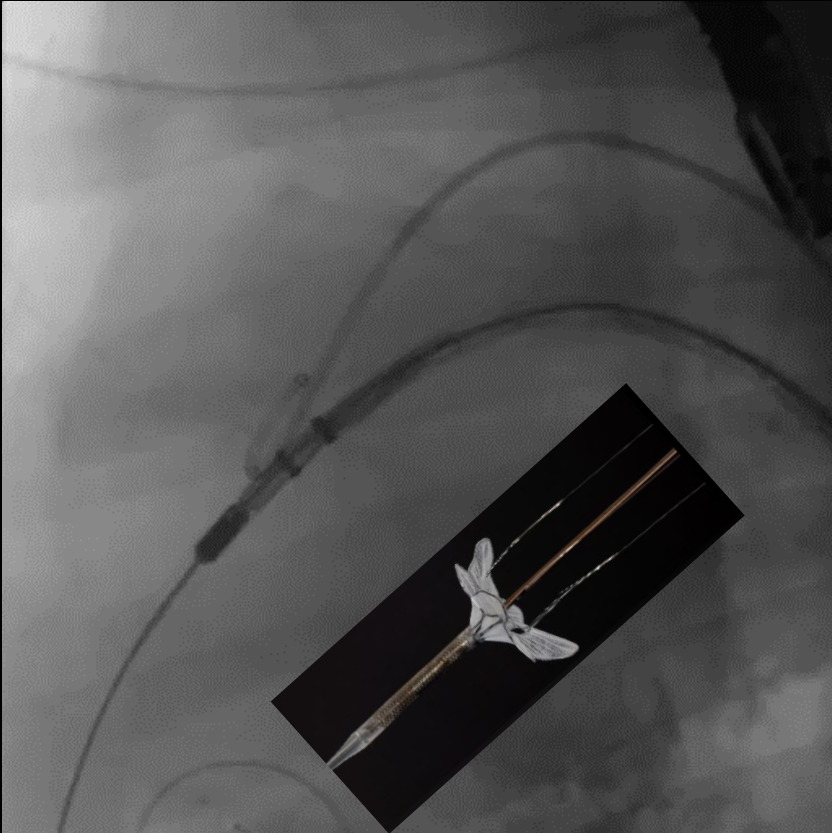
Geminus Gen II - Implantation



Deployment of Components

1. Upper frame deployment

2. Valve Module deployment

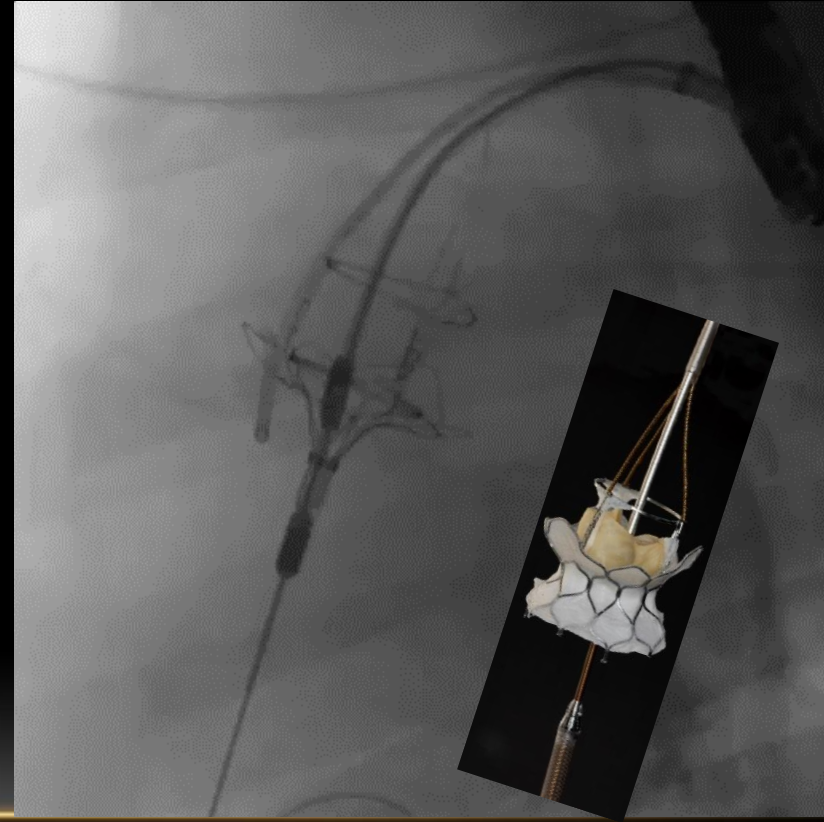


Docking and Implantation

3. Docking of modules

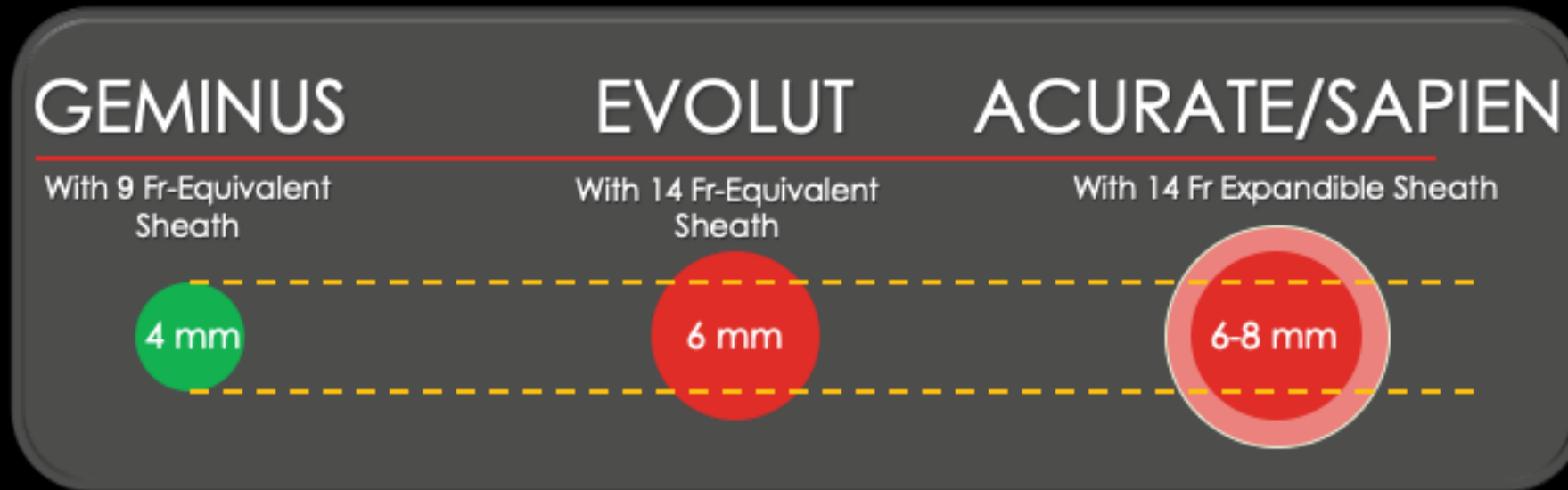


4. Implantation



Coming Up Q2 2023

- FIH (for Gen II system) Q2 2023
- 9 Fr. equivalent in-line sheath system Q4 2023



SYSTEMS TRUE OD (“The size of the hole in the¹⁶ groin”)

Gemini Ultra Low Profile TAVR System

Summary

- Ultra-low profile – 12F OD delivery system for all valve sizes (9F OD to come in Q3/2023)
- Modular design (frame and valve separate)
- Folded valve design (not crimped)
- 3-D (one-piece) valve leaflet construction (bovine pericardium)
- *In-situ* docking (valve to frame in ascending Ao)
- Two-component hydrogel coating on frame to reduce para-valvular regurgitation

Thank you for your kind Attention