Next innovations in transcatheter valve interventions: new techniques and new valves

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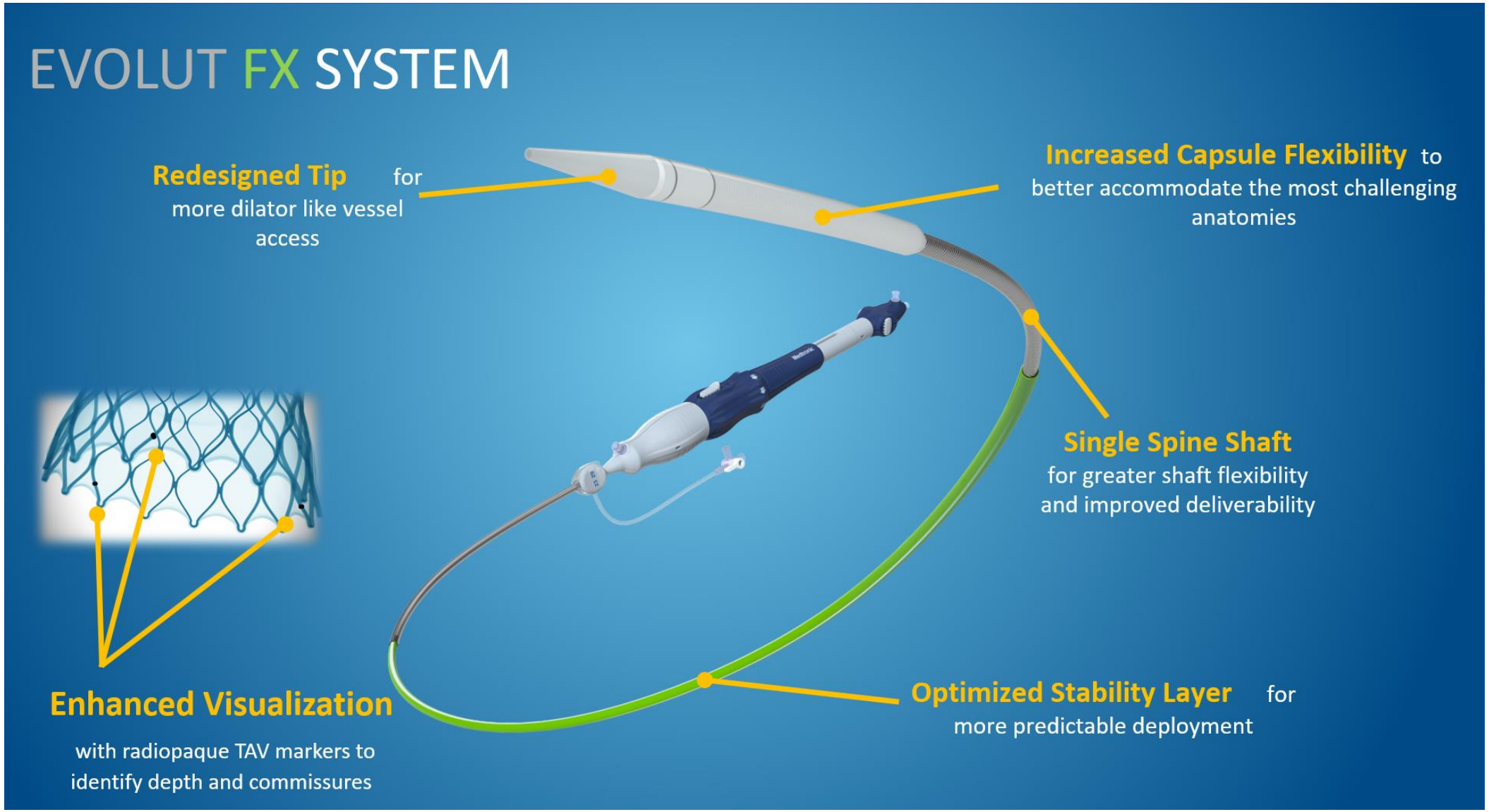
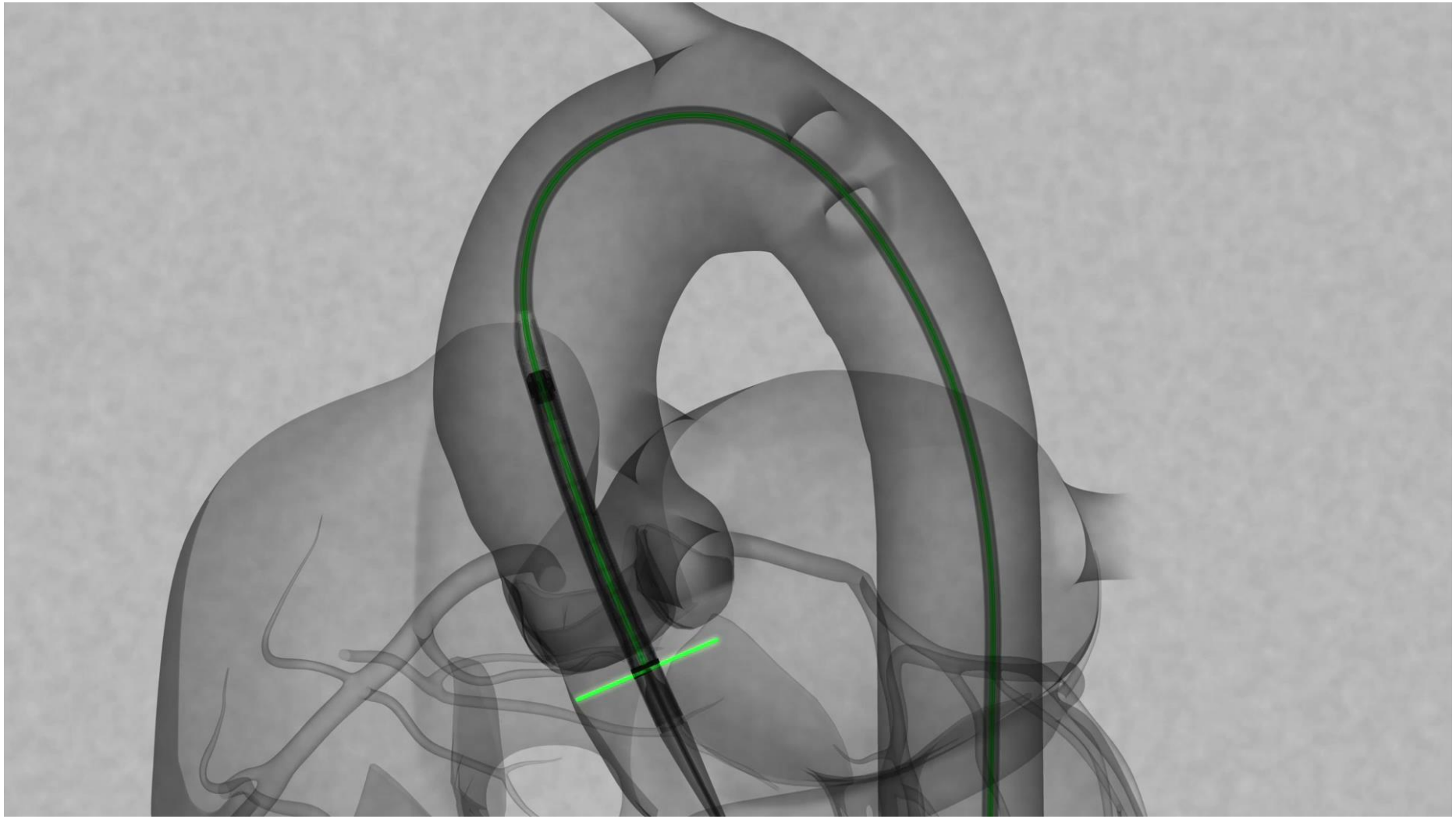
Next generation THV design

- Leaflet technology (valve durability and extension of indication to younger patients)
- Valve performance (better deliverability, reduced rates of PPM and PVL, commissural alignment for better coronary access)
- Pure aortic regurgitation
- Plan for THV in THV

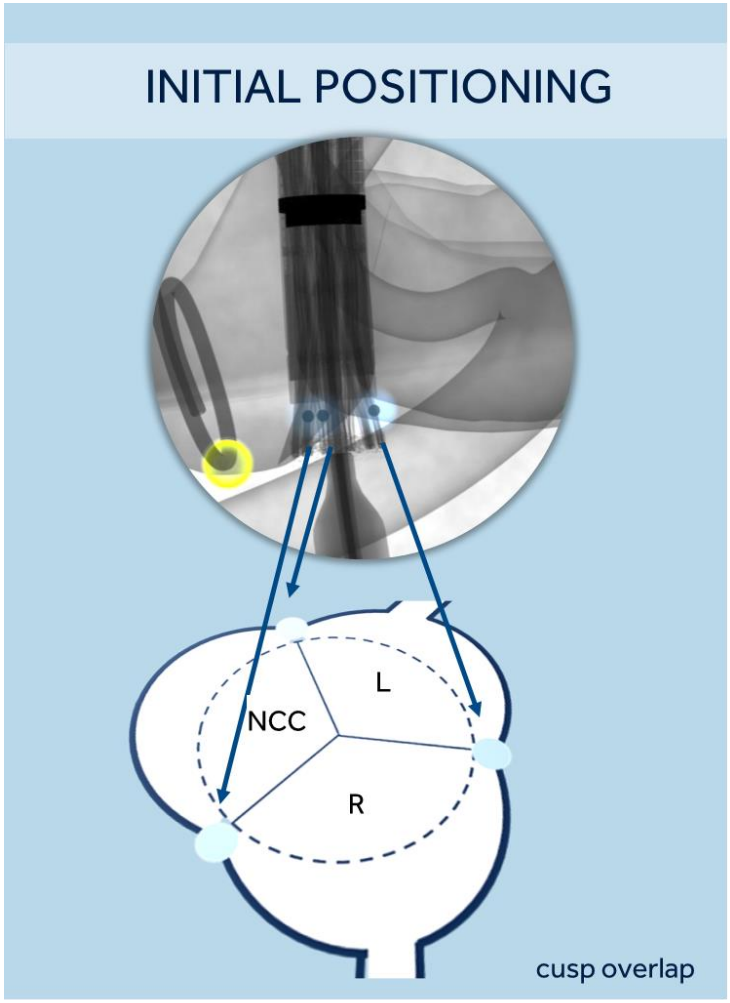
The new is coming from the old

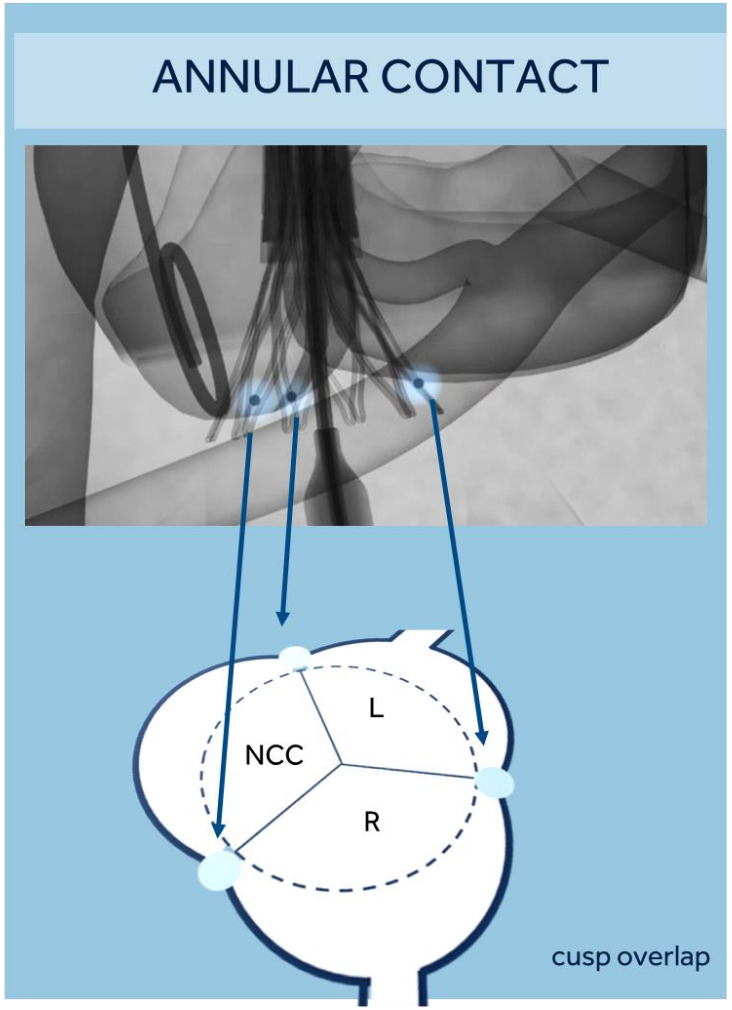


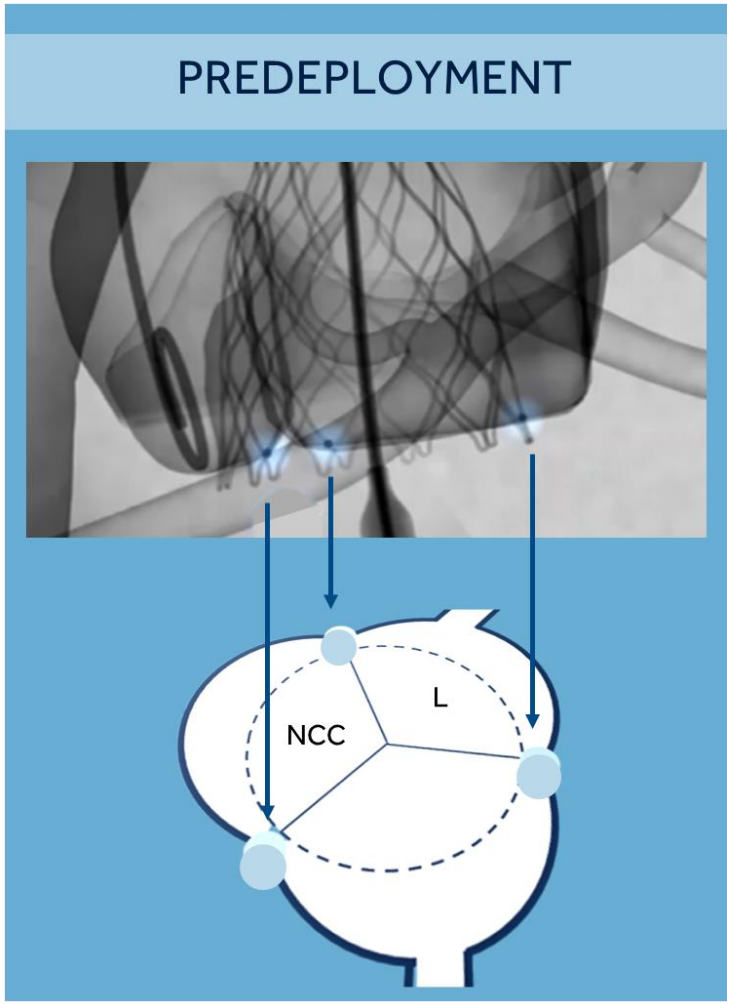
Enhanced stability during deployment



Marker orientation identifies alignement







Sapien X 4

Novel frame and leaflet design

- *Enables adjustable sizing while maintaining valve performance over the deployment diameter range*
- *Maintains high radial strength cobalt chromium balloon-expandable design*

Low frame height and large cells

- *Facilitates future coronary access*

Integrity preservation technology

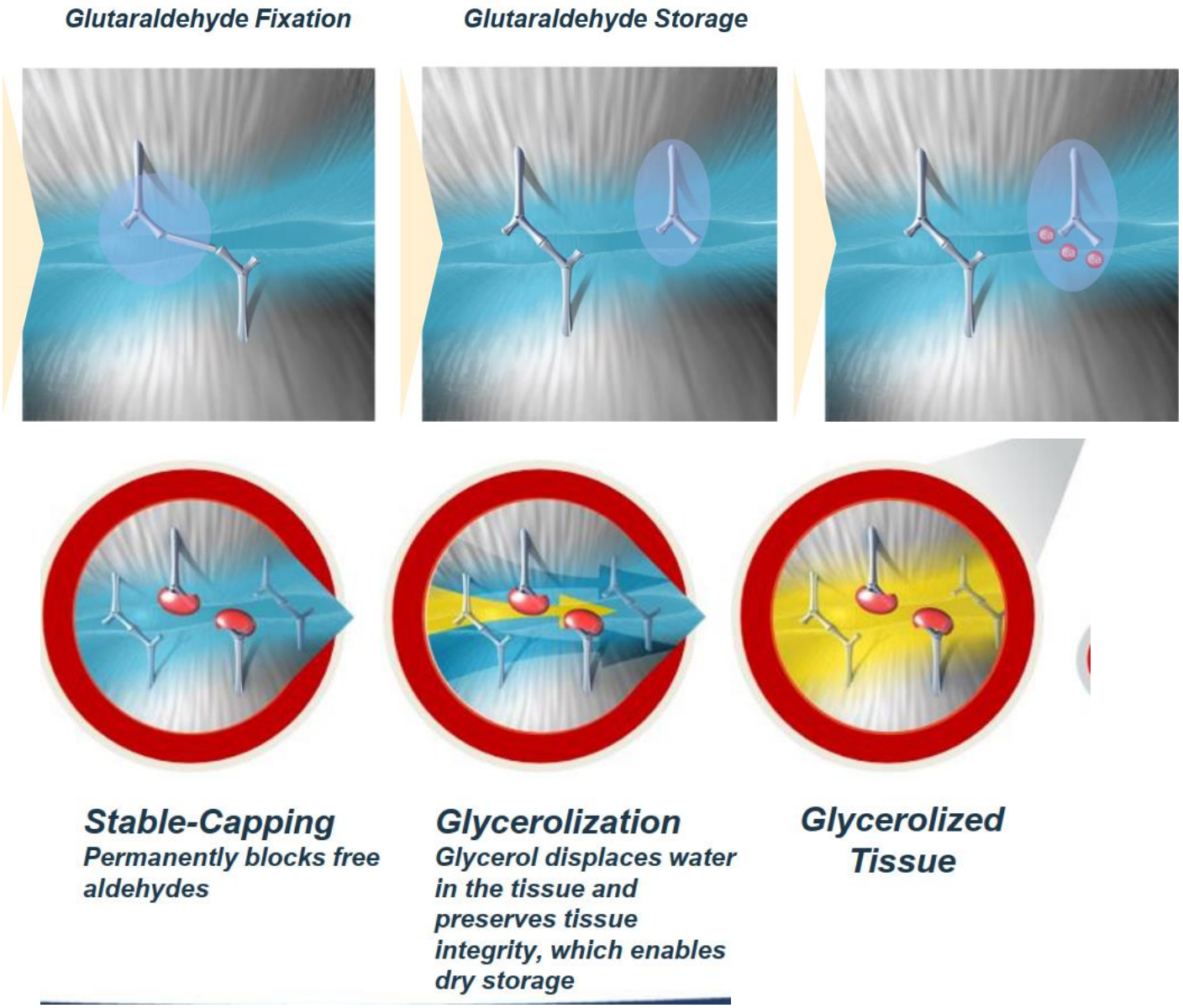
RESILIA tissue

- *Offers enhanced anti-calcification technology and enables dry storage*
- *Maintains bovine pericardial leaflets matched for thickness and elasticity*

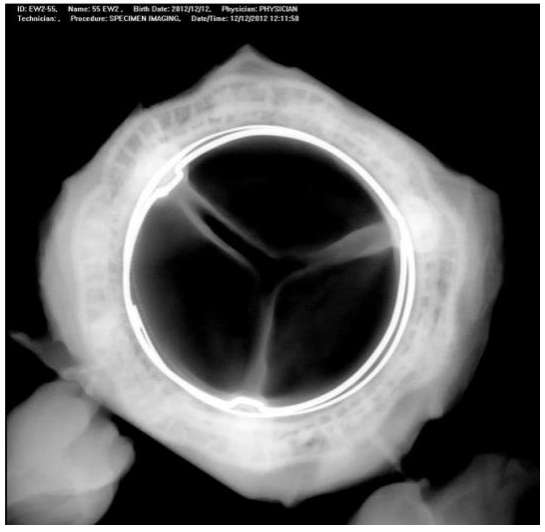
Enhanced PET outer skirt

- *Designed to further minimize PVL*
- *Maintains low profile access*

Resilia tissue valve: integrity preservation technology



RESILIA Tissue Valve



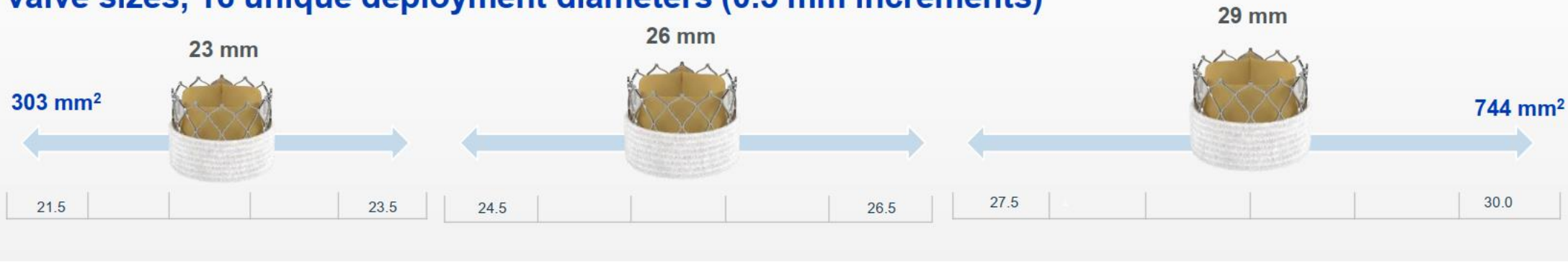
Sapien Ultra versus Sapien X4

SAPIEN 3 Ultra

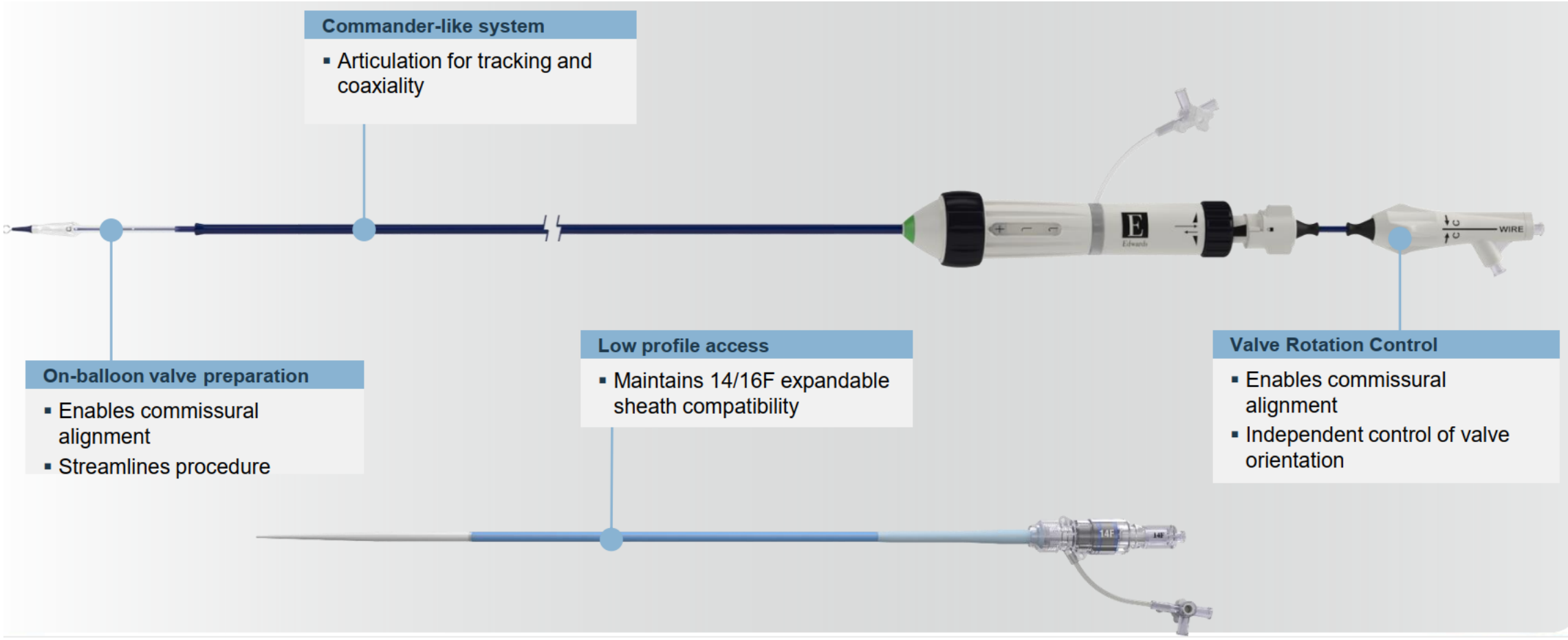
4 valve sizes (3 mm increments)

SAPIEN X4

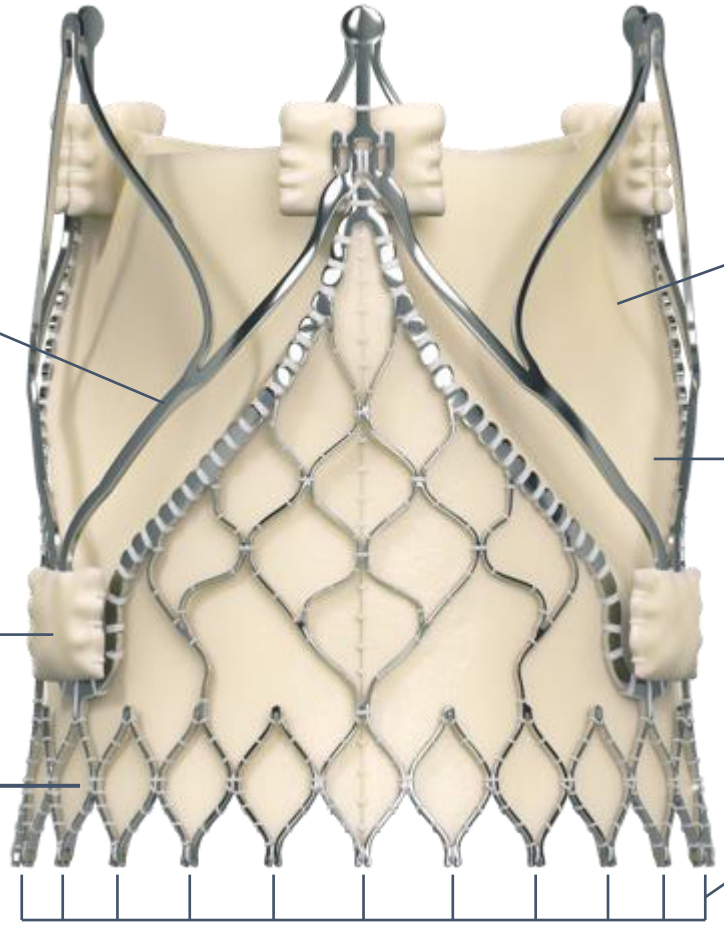
3 valve sizes, 16 unique deployment diameters (0.5 mm increments)



Sapien X 4 delivery system



Jena valve for pure aortic regurgitation



Supra-annular, self-expanding nitinol frame

Large, open cell design enables future coronary access

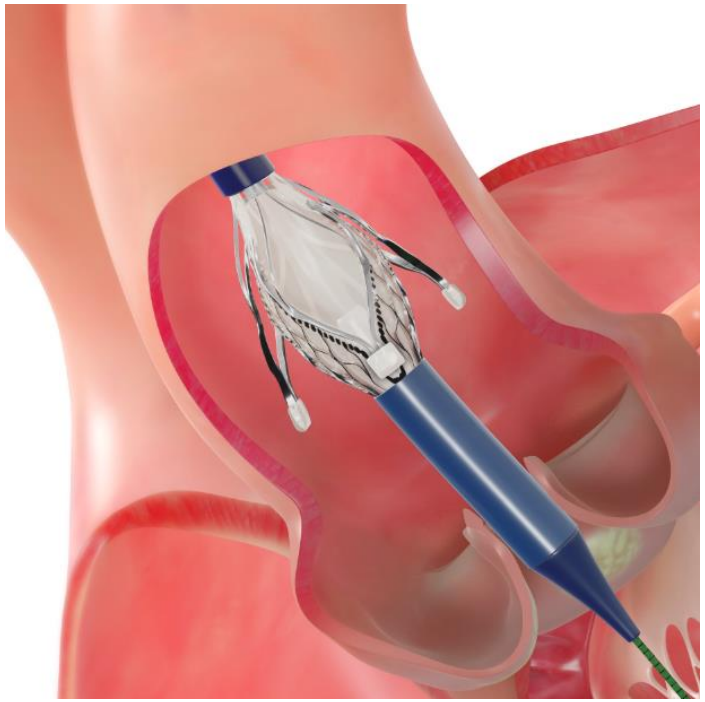
Porcine pericardial tissue

Locators to align and attach to native leaflets

Sealing ring

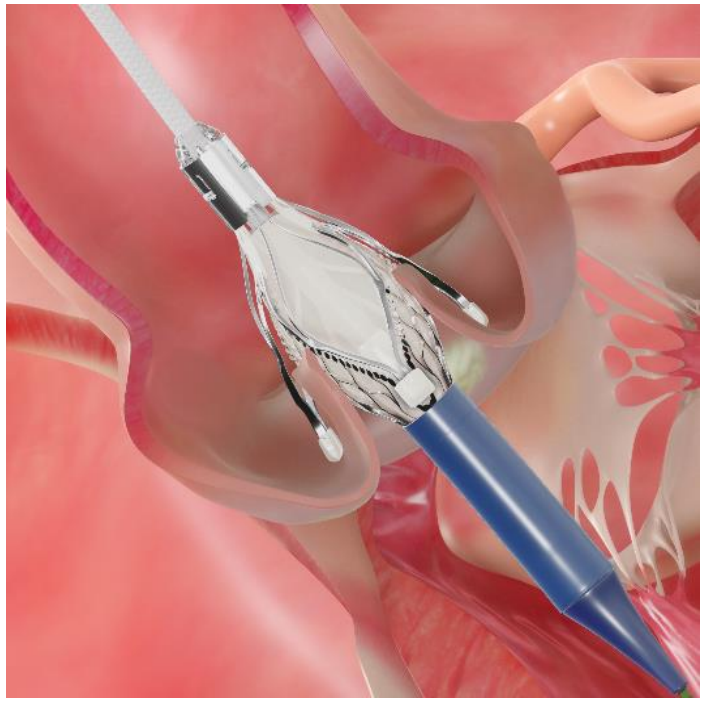
Sealing ring for annular conformability and anchoring

Jenavalve Trilogy System – Positioning and Securing in AR Anatomy



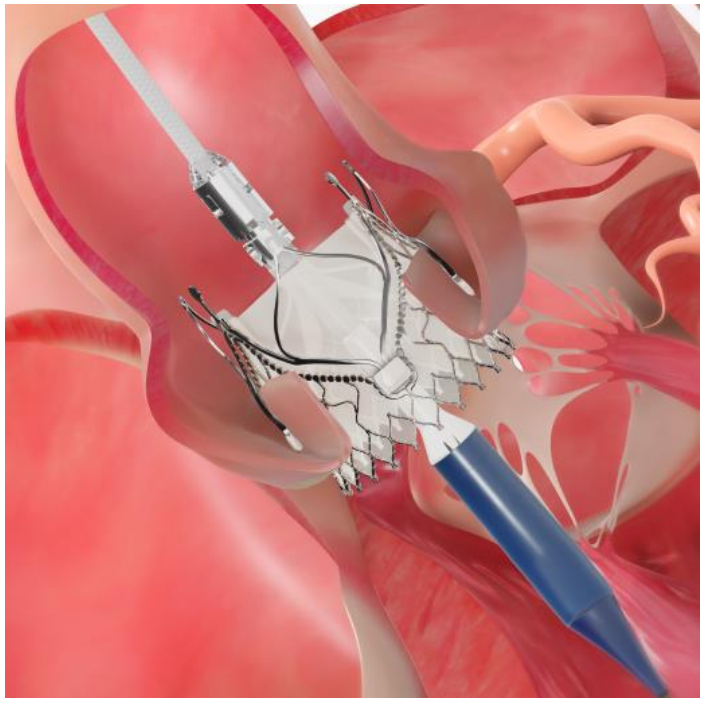
Alignment

- Aligns THV with native cusps



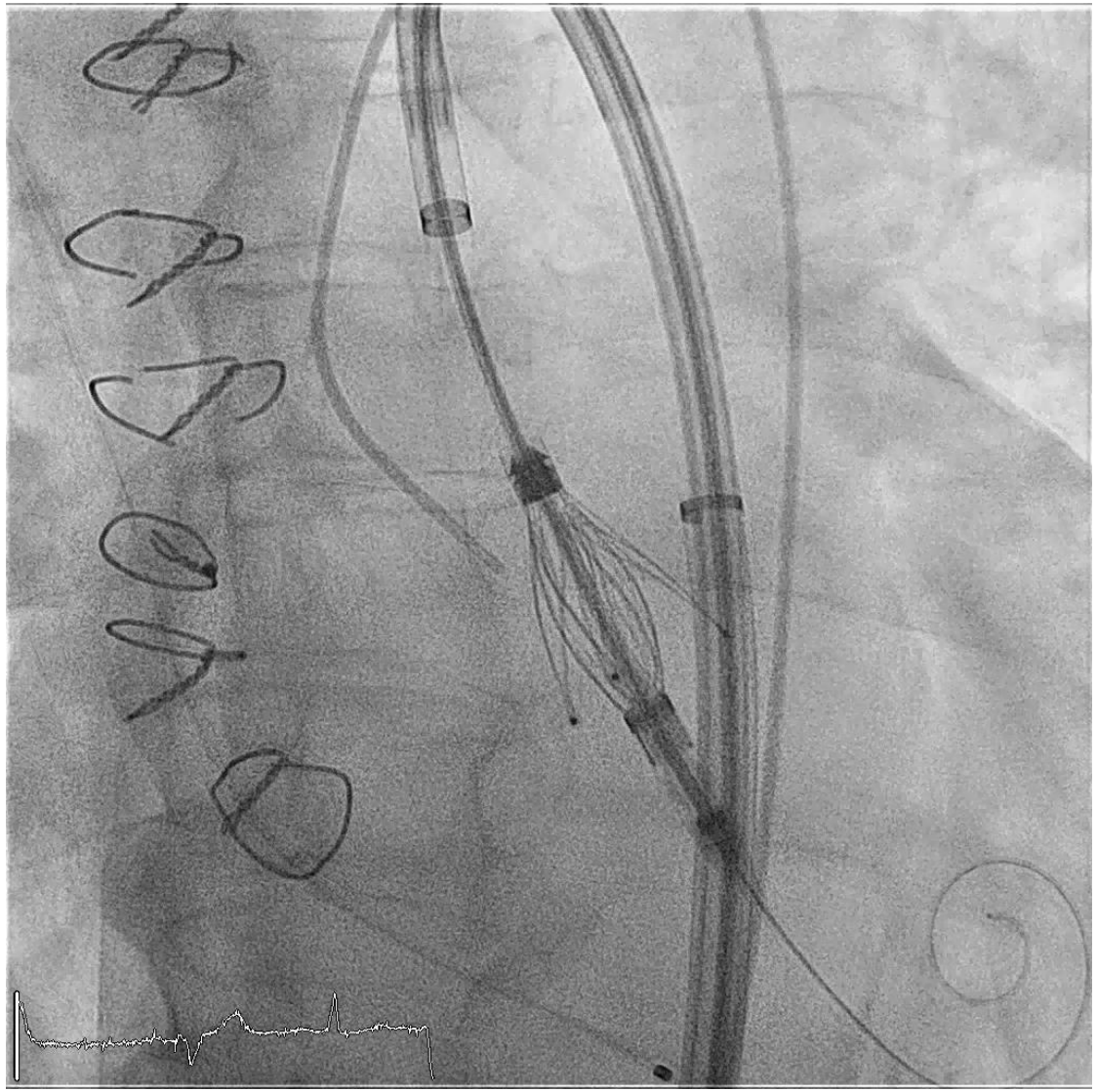
Positioning/Anchoring

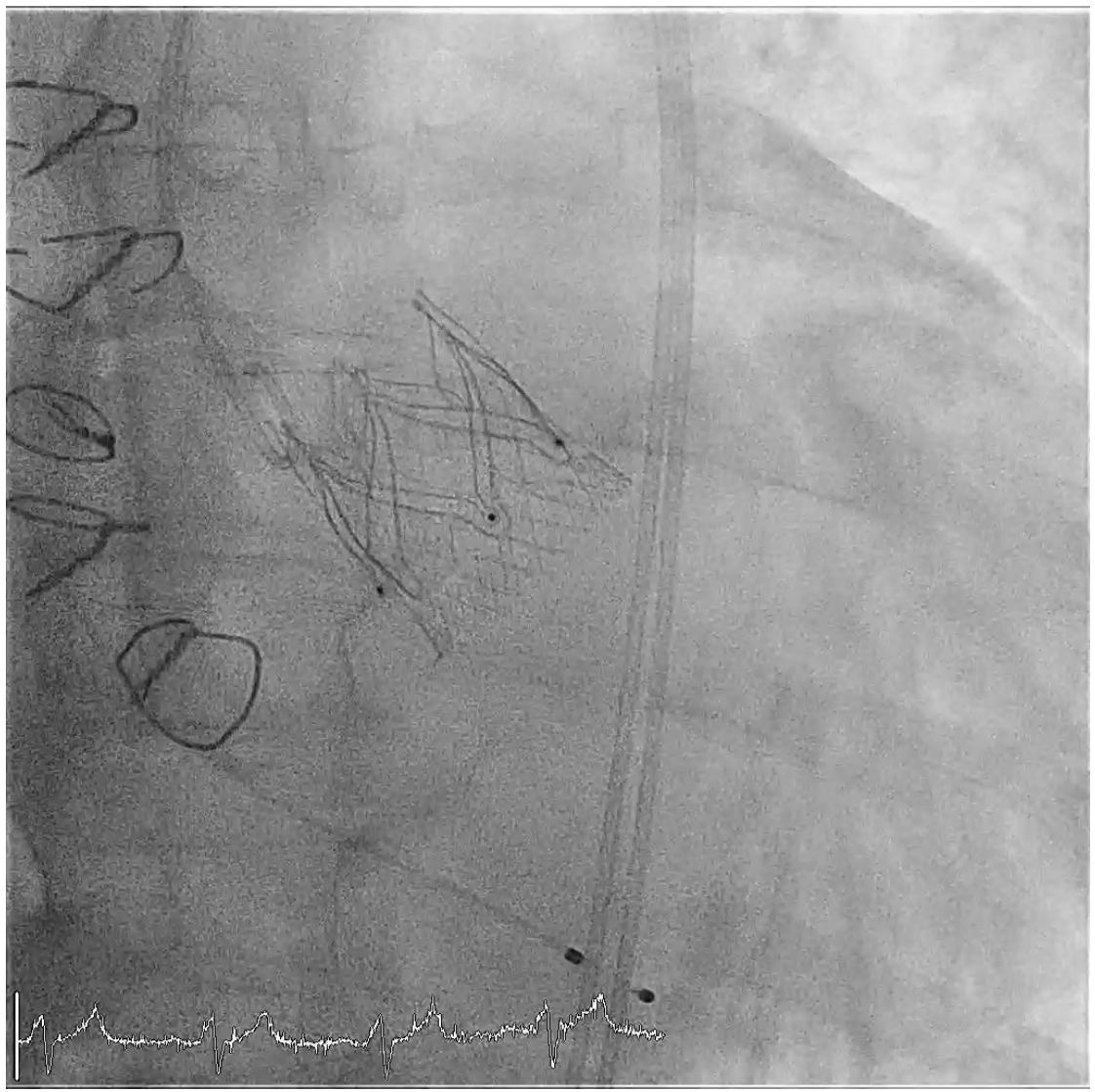
- Locators “clip” onto native leaflets forming a natural seal and stable securement



Deployment

- Large open cells provide access to low coronaries
- 24 diamond-shaped cells provide annular conformability and sealing



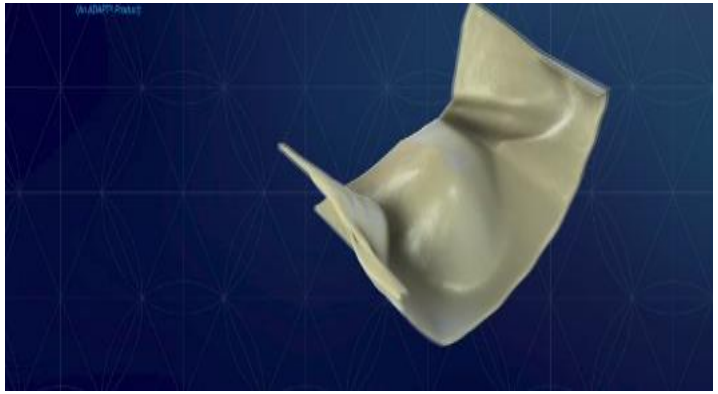


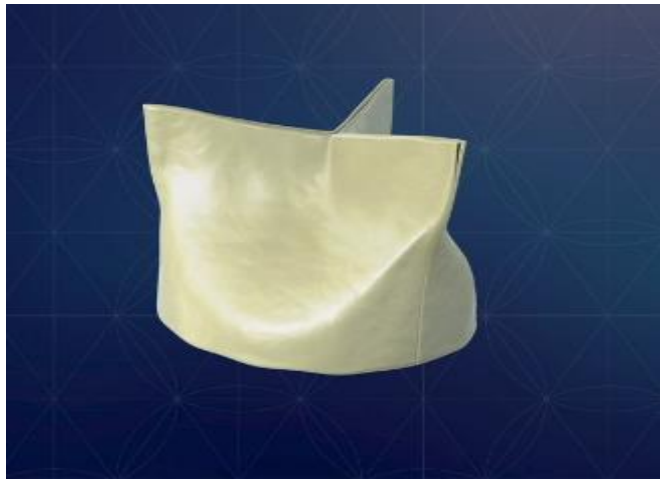
Anteris DurAVR THV

- **Balloon expandable**
- **Short frame height**
- **Large open cell geometry**
- **Delivery system can rotate to achieve commissural alignment**
- **ADAPT: anticalcification tissue process (DNA and glutaraldyede free)**
- **PET skirt**

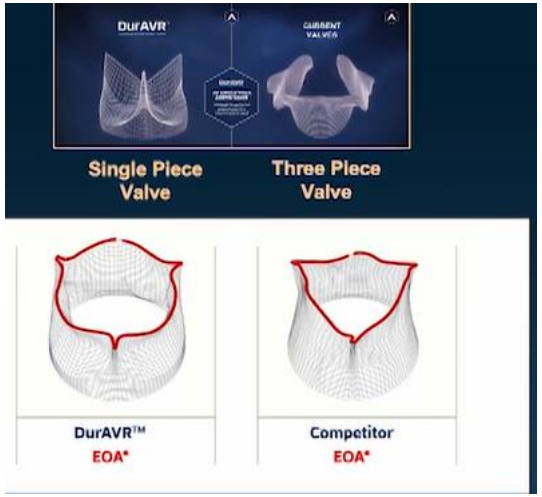
Anteris DurAVR THV

Single-piece of bovine pericardium tissue





- **Near normal hemodinamic function**
- **Better leaflet coaptation**
- **Less leaflet stress**



First in Human

Design

Prospective, non-randomised, single-arm, single-centre

Purpose

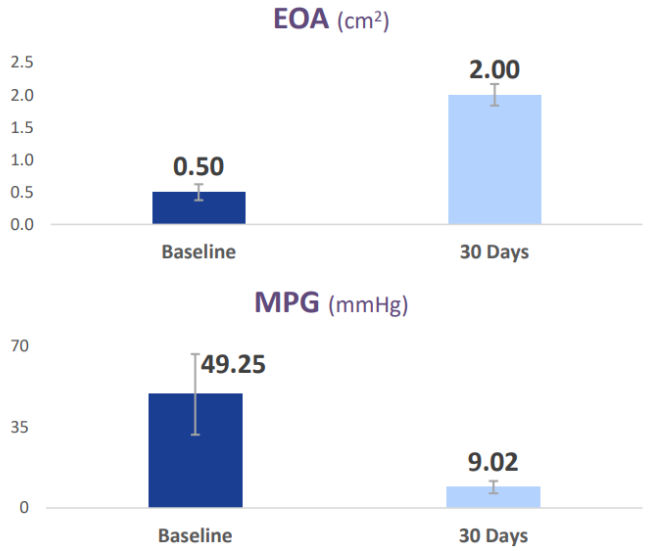
Evaluate the safety and feasibility of the DurAVR™ THV System

Population

13 subjects with severe symptomatic AS

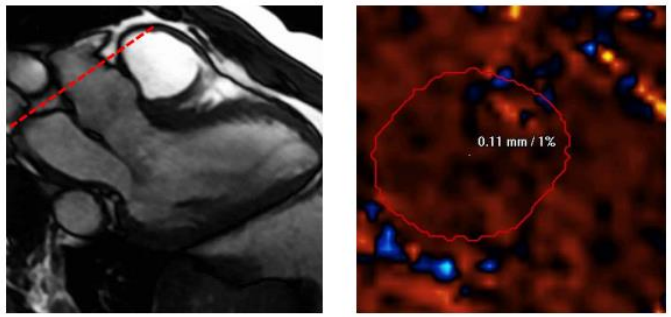
Follow-up

Clinical, echo, MDCT, and cardiac MRI performed. Follow-up to 1 year.



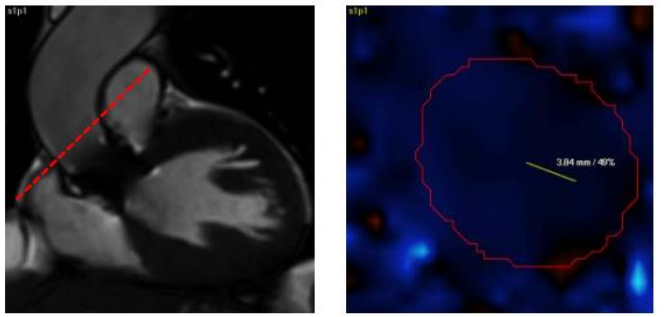
Restoration of normal aortic flow

Healthy Aortic Valve



FD = 10%
FRR = 1%
(n=5)

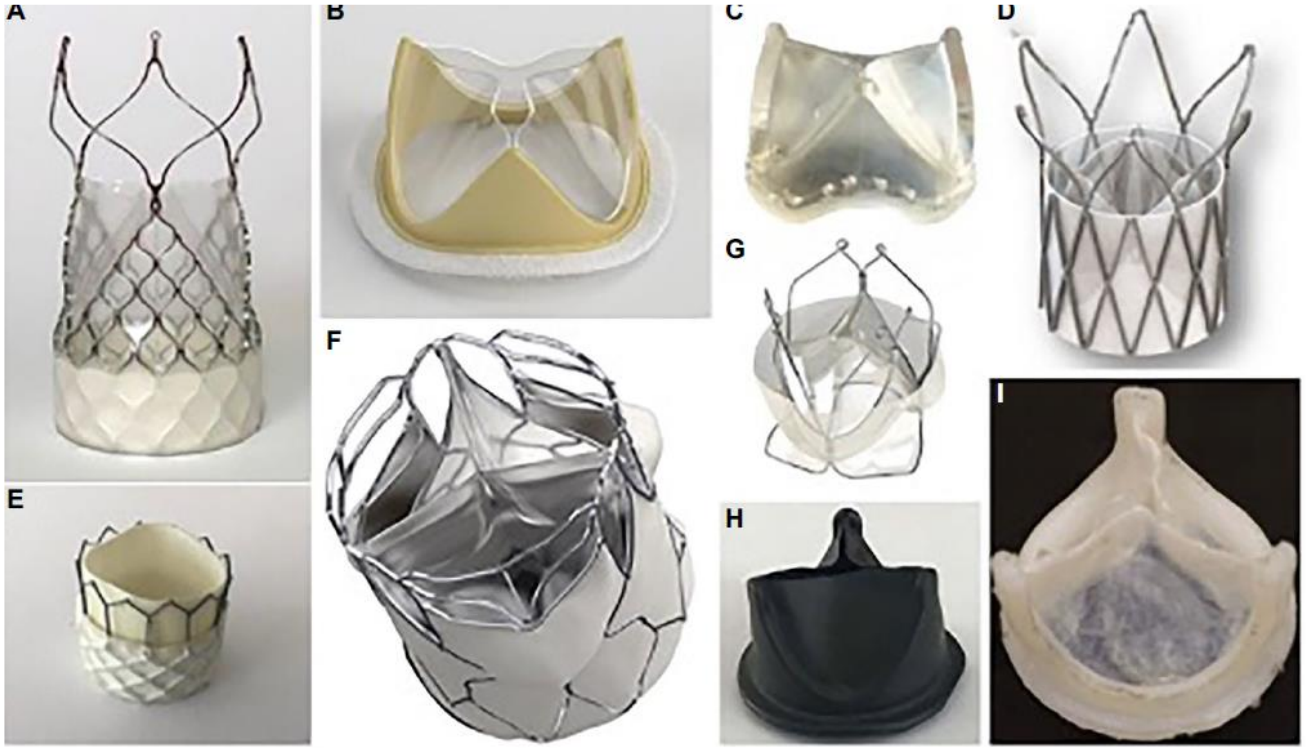
Post DurAVR THV



FD = 14%
FRR = 4%
(n=5)

Meduri; London Valves 2022

Polymeric valves



- **Automated robotic manufacturing**
- **High reproducibility of manufacturing and lower costs**
- **Polymeric compunds may be modified to meet the needs of THV (biostability, biocomaptibility, leaflet strength, and durability)**
- **For TAVI, only tested in animal model**

Foldax Tria Heart valve: the only one tested in humans

- **Surgical valve**
- **Sylicone polyurethane material**
- **Durability of 16 years at Accelerated Wear Testing models**
- **Low ex-vivo thrombogenicity (non-human primate AV shunt models)**

Conclusions

- **Iteration of aortic THV is progressing relentlessy with new devices coming with longer valve durability and better performance in terms of deliverability, PP implantation, PVL, and better commissure alignment for coronary access.**

- **Polymeric heart valves have the potential of long durability, biostability, biocomaptibility, and leaflet strength and therefore clinical trials are needed to prove their safety and efficacy.**