

The Splitter: Enabler of transcatheter aortic valve-in-valve implantation

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I have the following relevant financial relationships

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HVT Medical Ltd

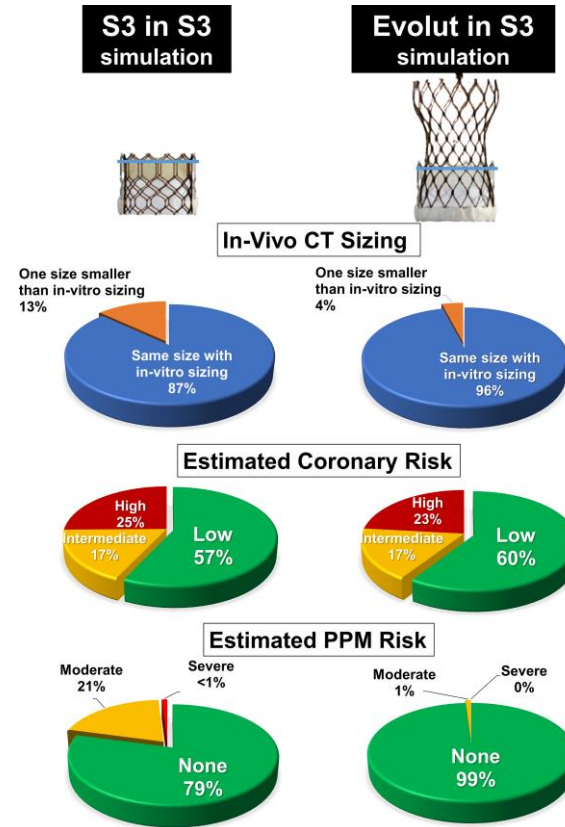
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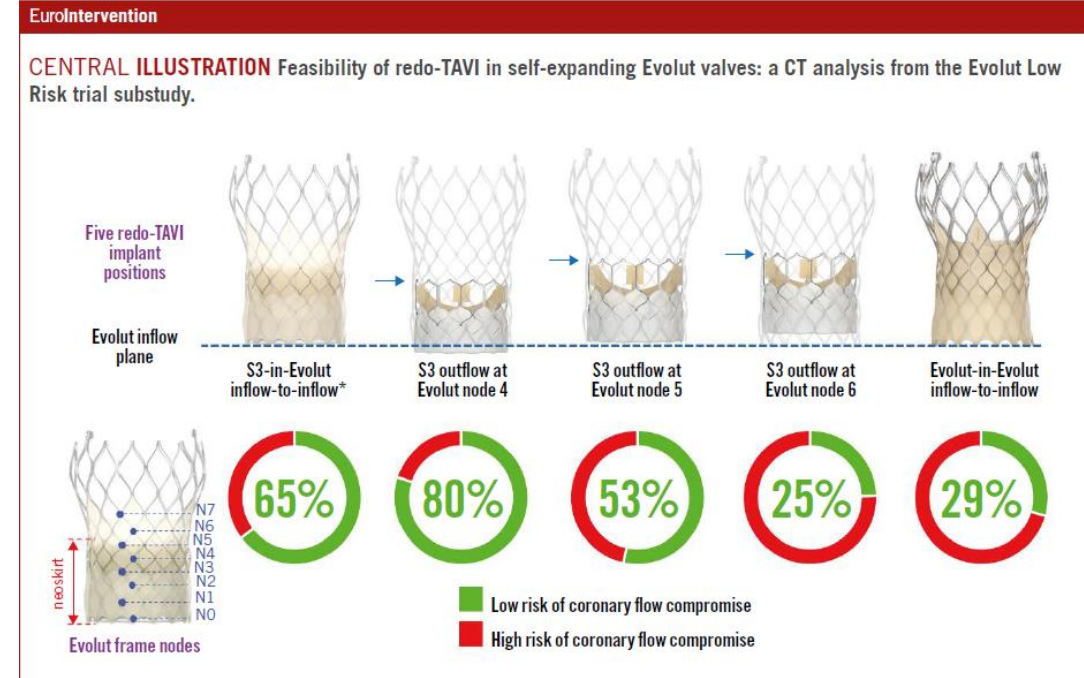
Cathalert

Redo-TAV replacement with S3-in-S3 and Evolut-in-S3 could be feasible with low risk to coronaries in ≈60% of patients, while the remaining 40% will be at intermediate or high risk.

Miho Fukui. Circulation: Cardiovascular Interventions. Feasibility of Redo-Transcatheter Aortic Valve Replacement in Sapien Valves Based on In Vivo Computed Tomography Assessment, Volume: 16, Issue: 11, Pages: e013497, DOI: (10.1161/CIRCINTERVENTIONS.123.013497)

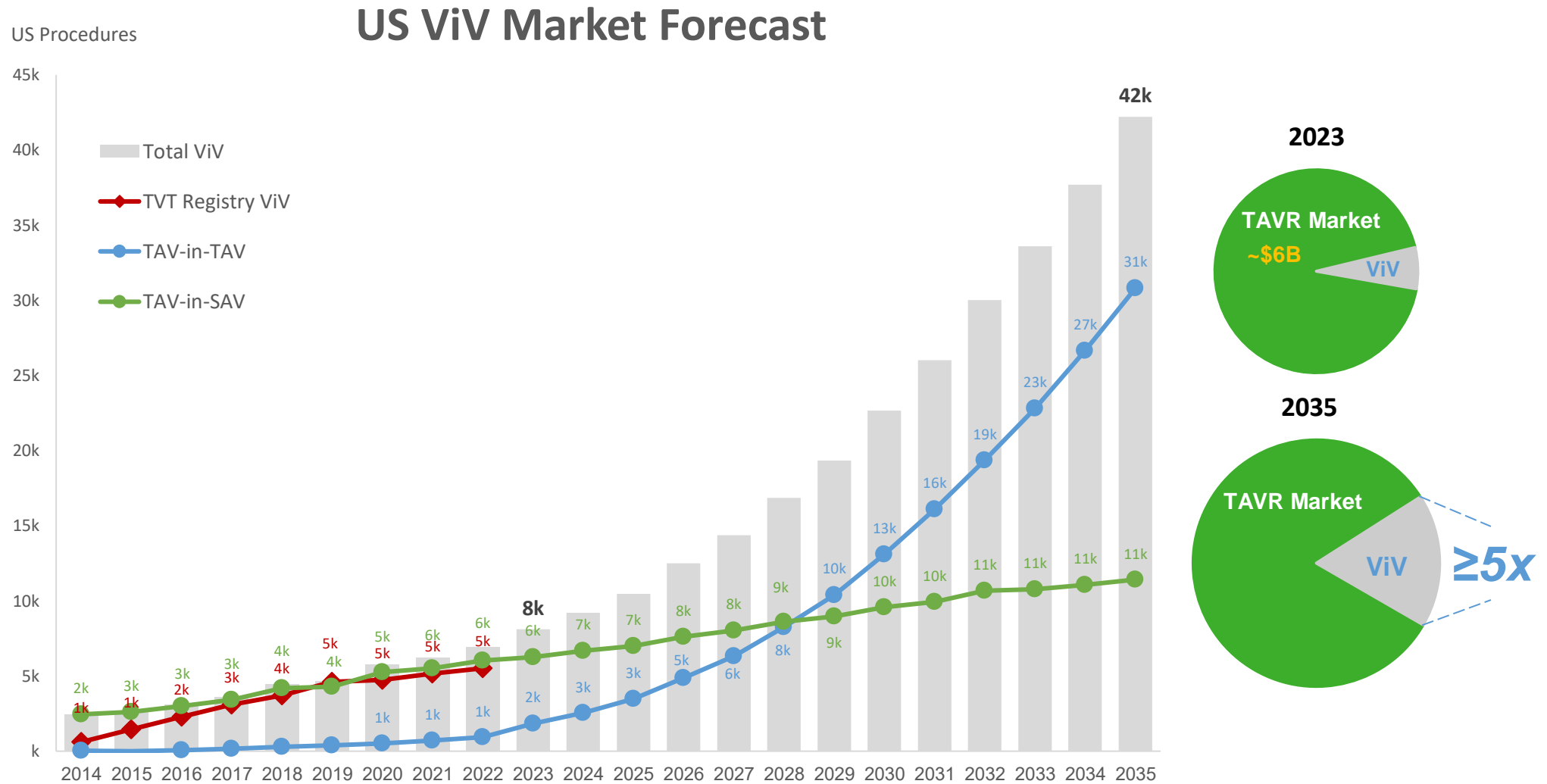


Feasibility of redo-TAVI in self-expanding Evolut valves



Source: "Feasibility of redo-TAVI in self-expanding Evolut valves: a CT analysis from the Evolut Low Risk Trial substudy" *Euro-Intervention* April 2023

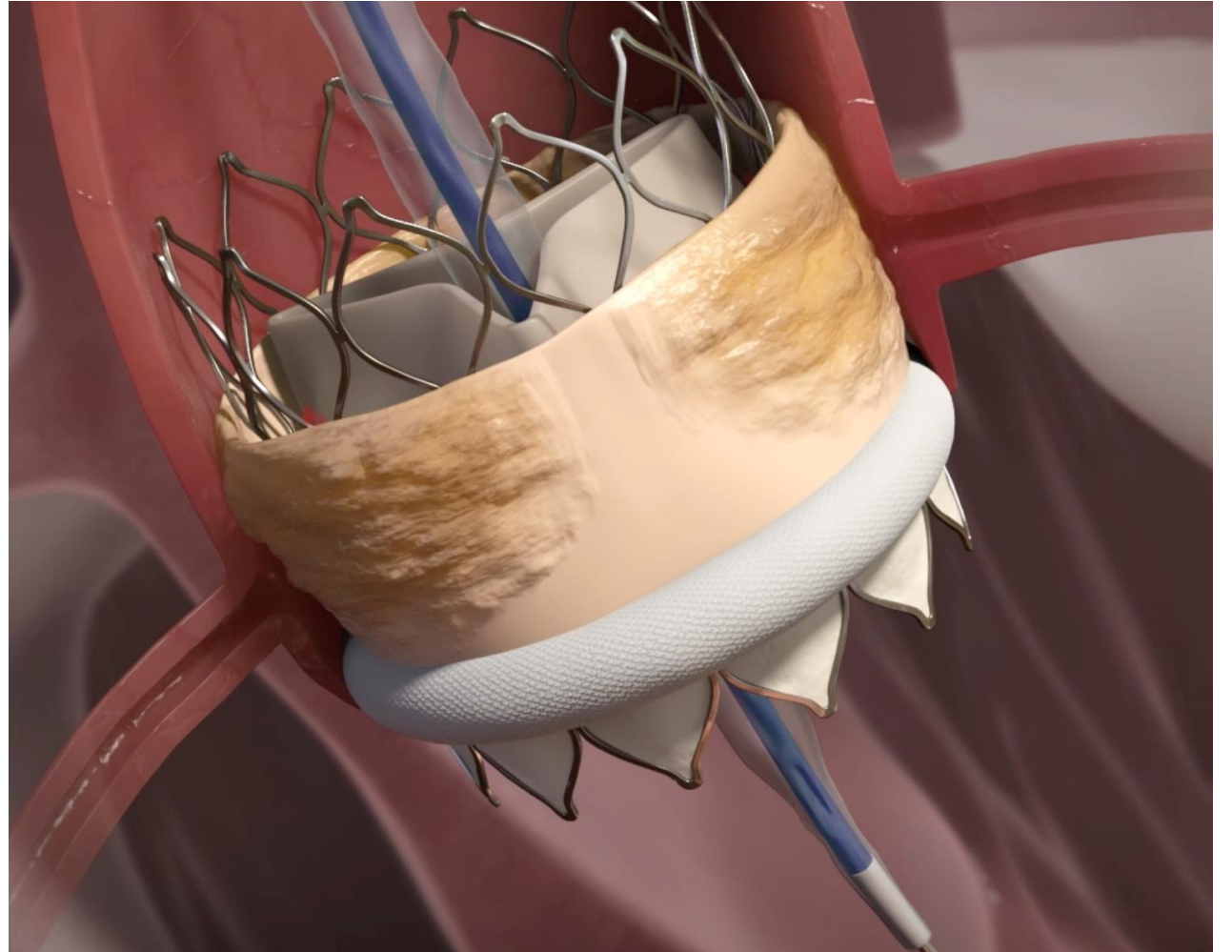
Need for Leaflet Modification will Grow Significantly



Courtesy: P Genereux, R Puri, MB Leon, M Szerlip, R Dar, D Dvir - Publication in Progress

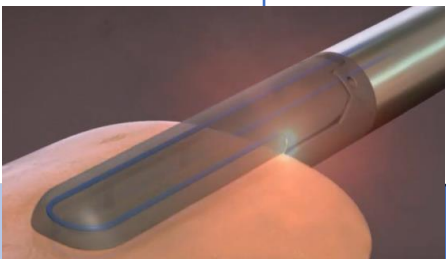
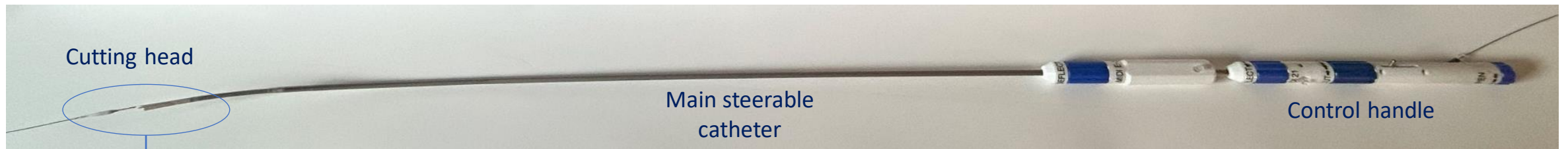
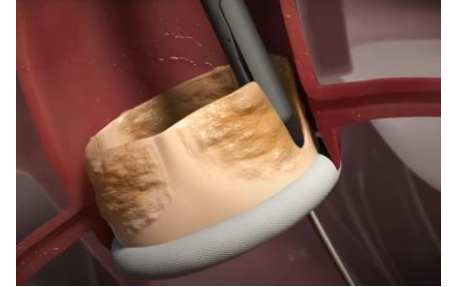
Coronary obstruction is not the whole story

What about Coronary access?

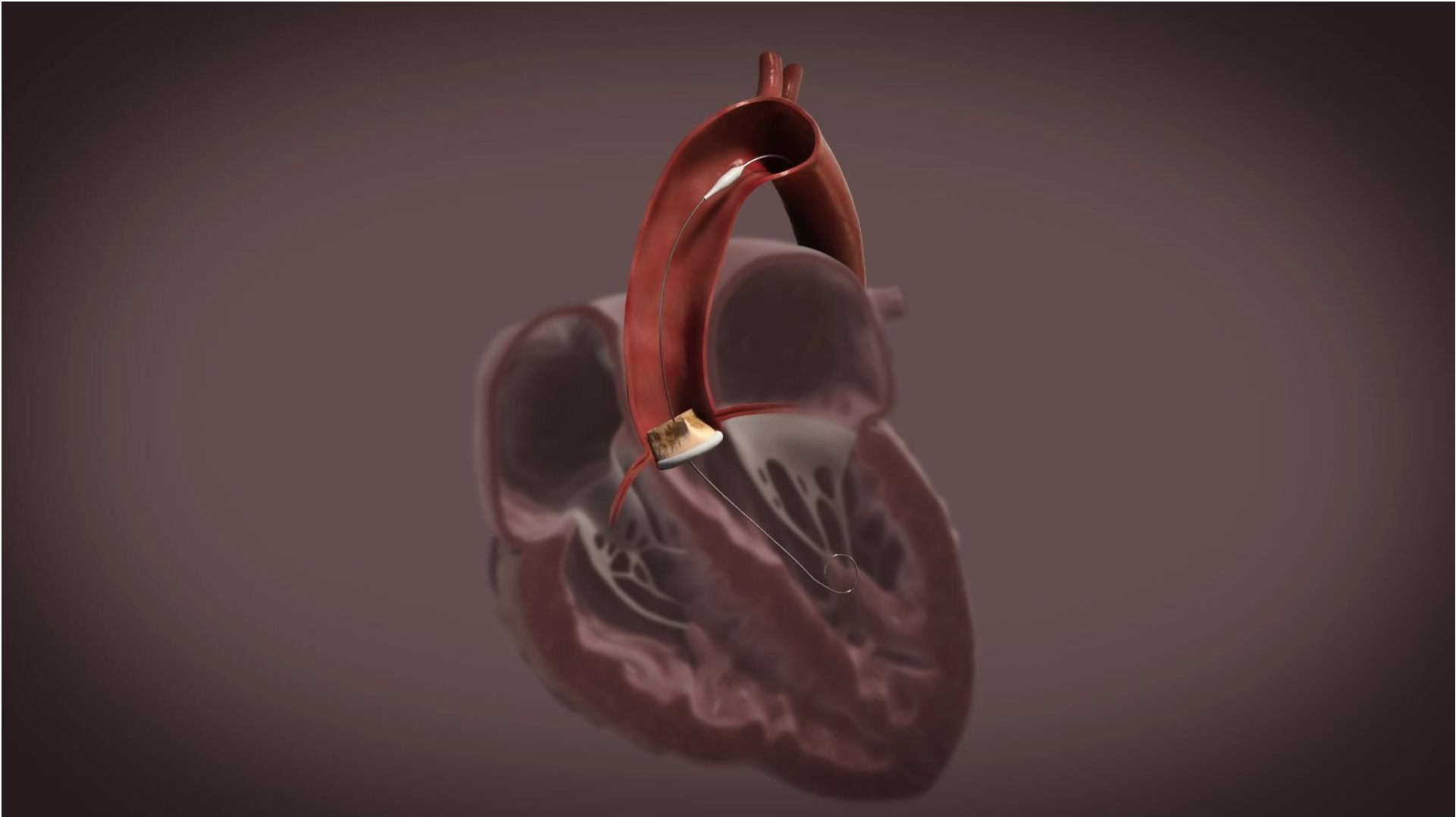


The Splitter

- The Splitter device performs cusp splitting and partial leaflet excision
- The device creates an intentional excision of valve's cusp tissue by using a steerable catheter with an electro-cutting wire loop running through a cutting head that mimics alligator jaws
- The Splitter is advanced over a standard 0.035" stiff guidewire, hence it is streamlined and integrated into the workflow of the valve implantation procedure.



The Splitter - Animation



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Bench Test – Cutting Tissue

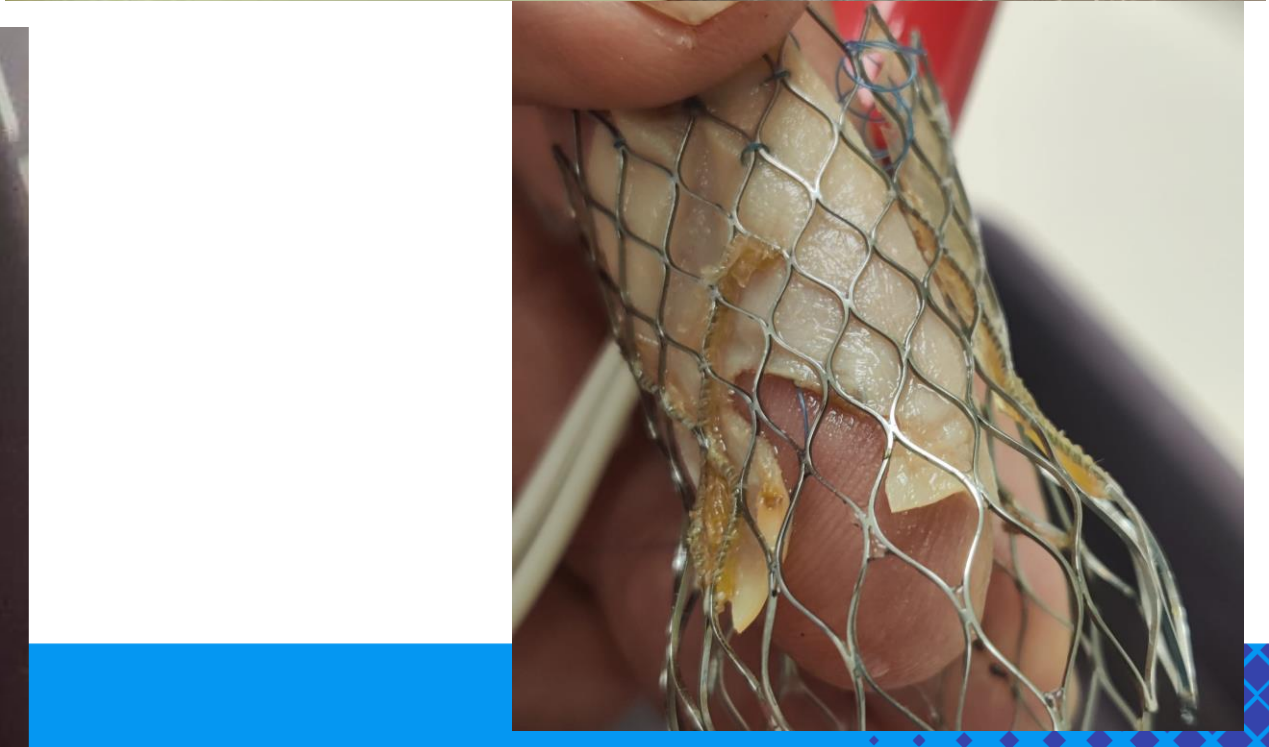
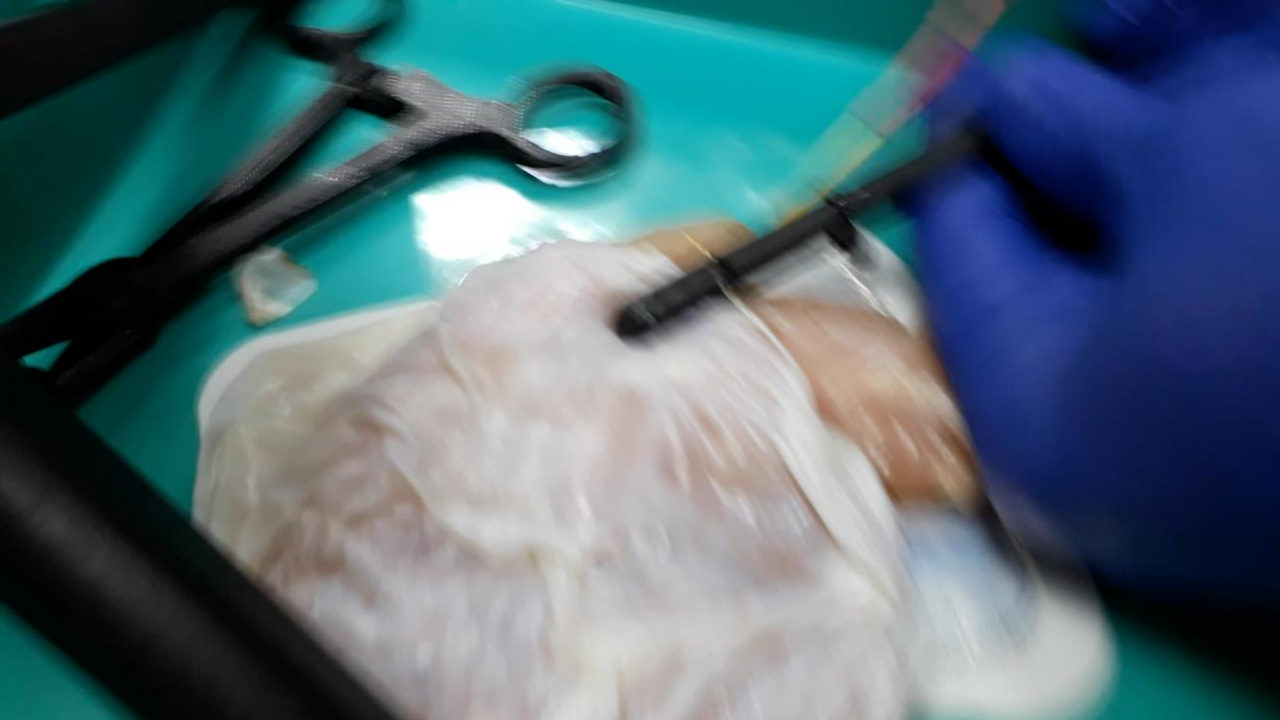


The excised segment

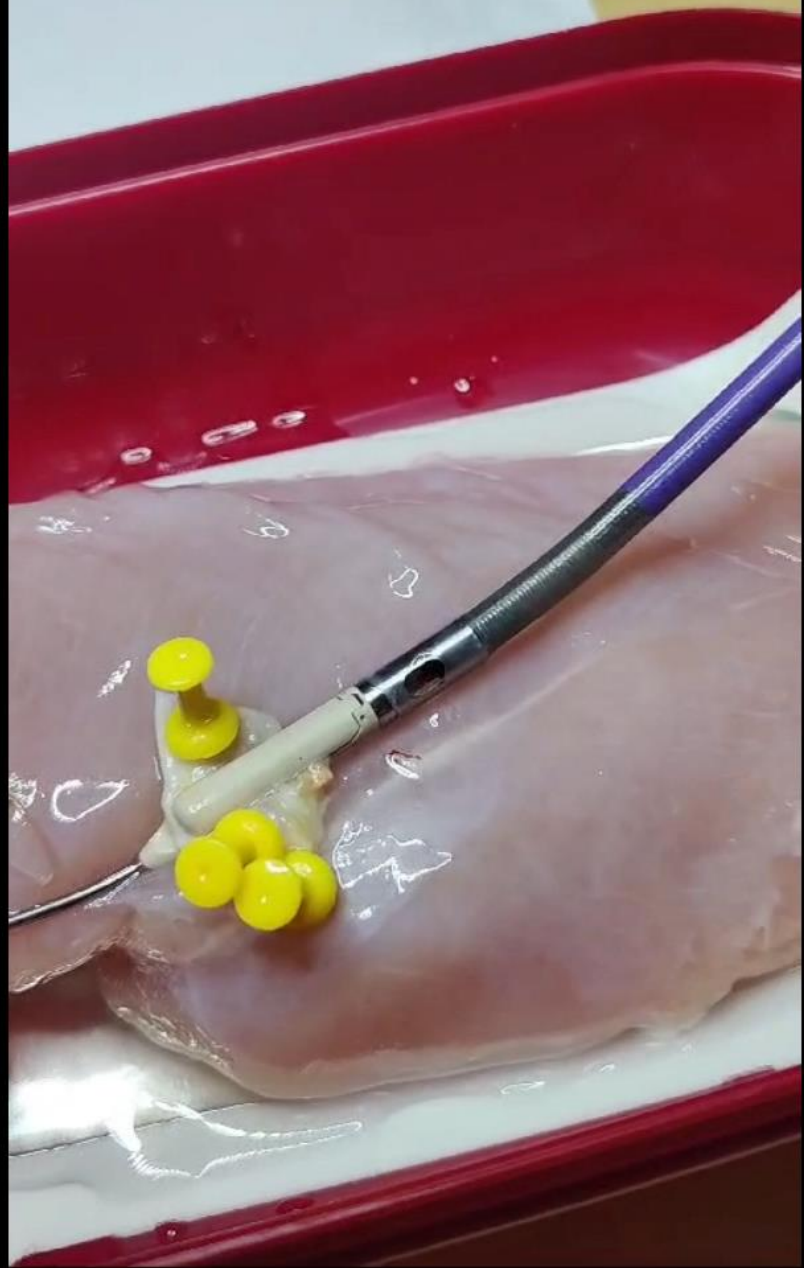
- Precise excision of leaflet tissue and creation of a large u-shaped window in the cusp
- The excised tissue is trapped inside the cutting head and removed through the catheter



Human heart, ex-vivo



Leaflet cutting (1)



Leaflet cutting (2)

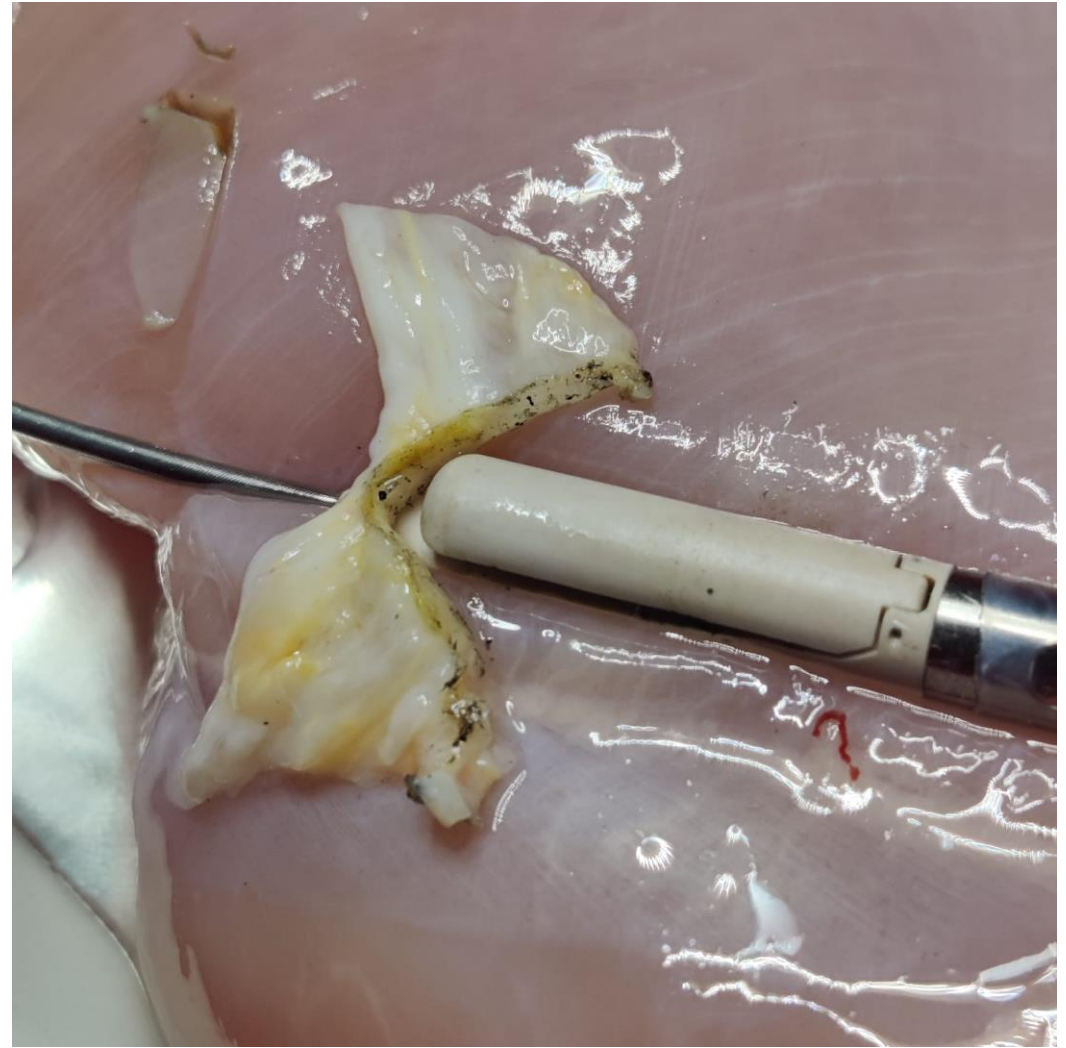


jaws release after leaflet cutting





leaflet before cutting



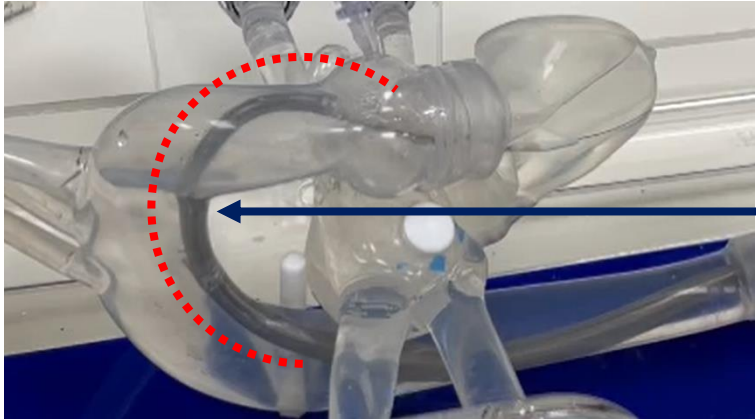
window in leaflet

Bench Test - Silicone Heart Model

The Splitter inside silicone model of human heart – access to valve plane and distal tip maneuvering



Cutting head



Aortic arch



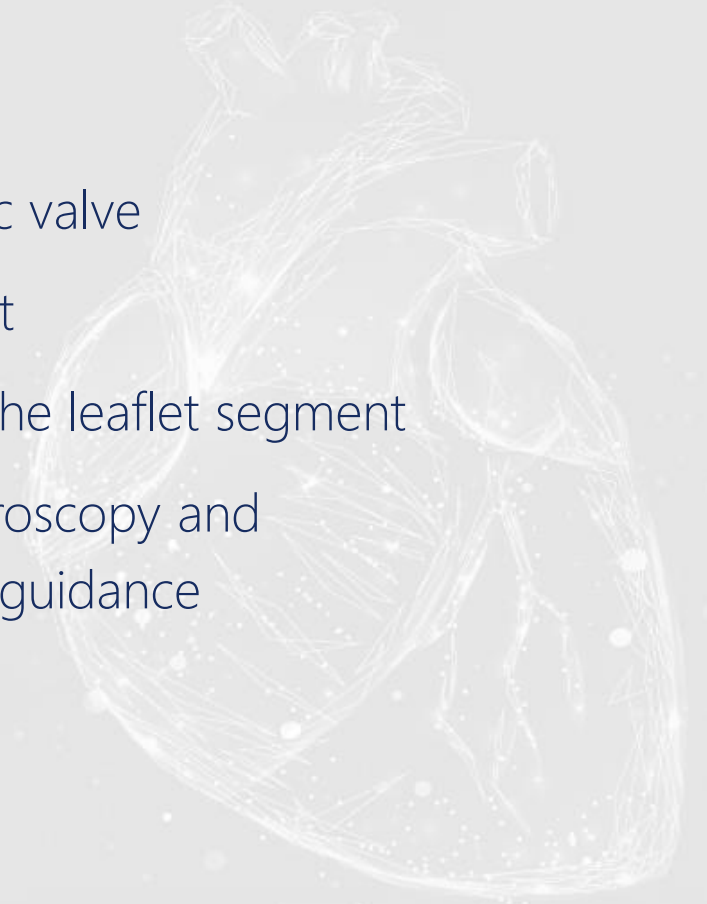
Cutting head

Control handle

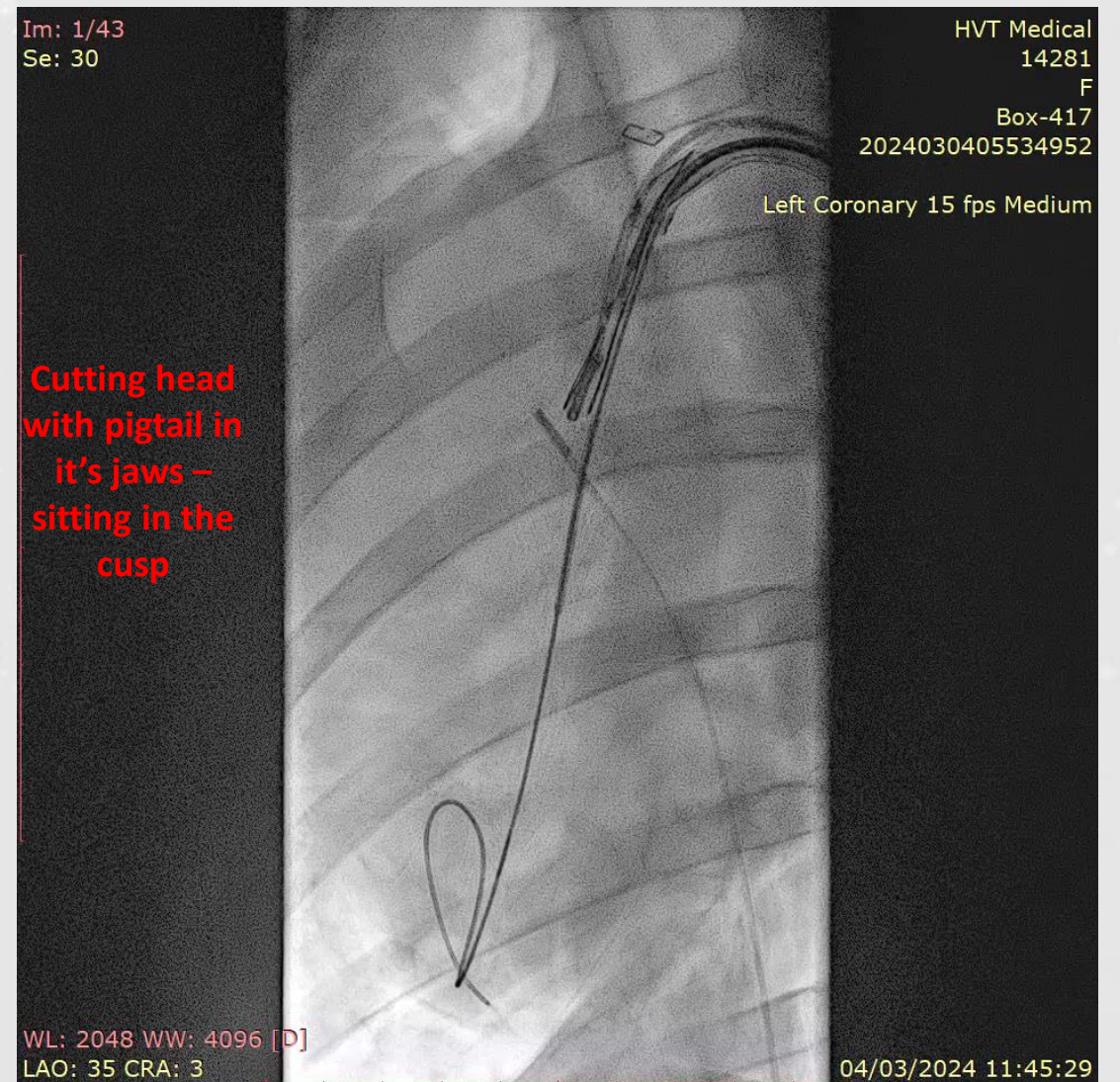
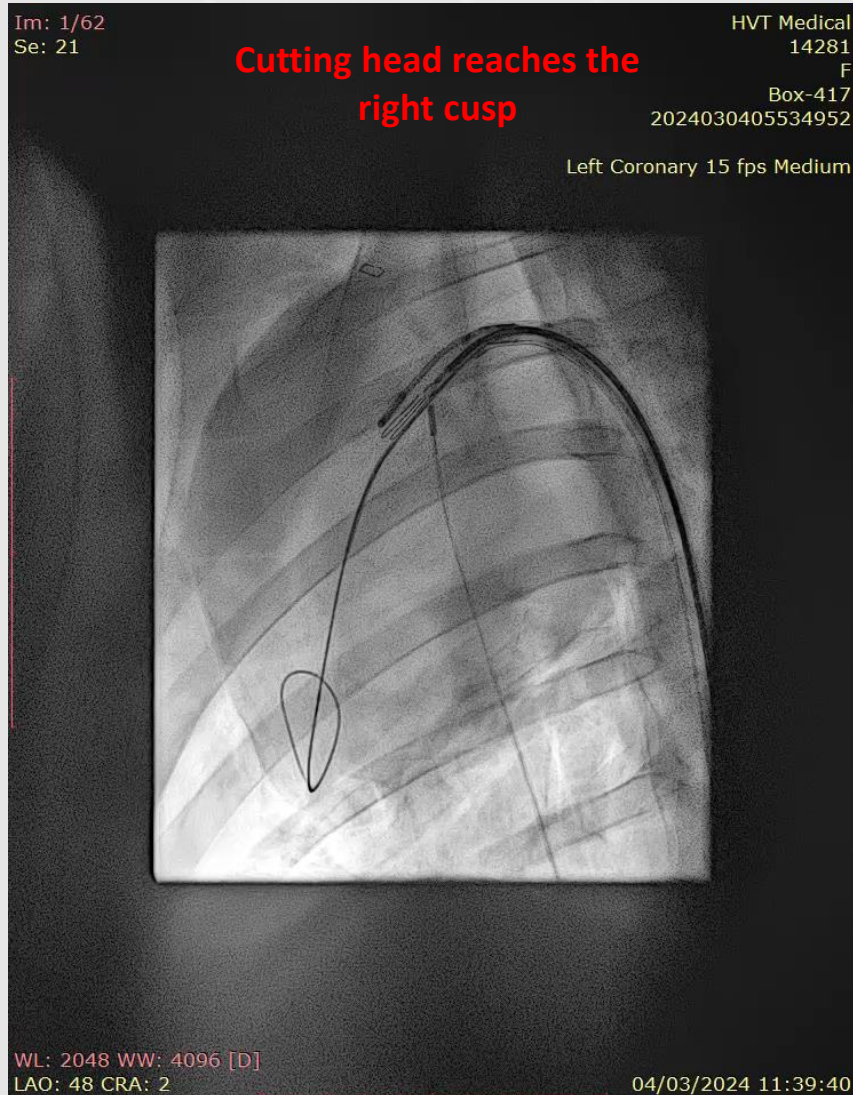
Pre-Clinical Studies: Pig Study



- Device steering to the aortic valve
- Grasping the selected leaflet
- Laceration and removal of the leaflet segment
- Procedure done under fluoroscopy and echocardiography imaging guidance

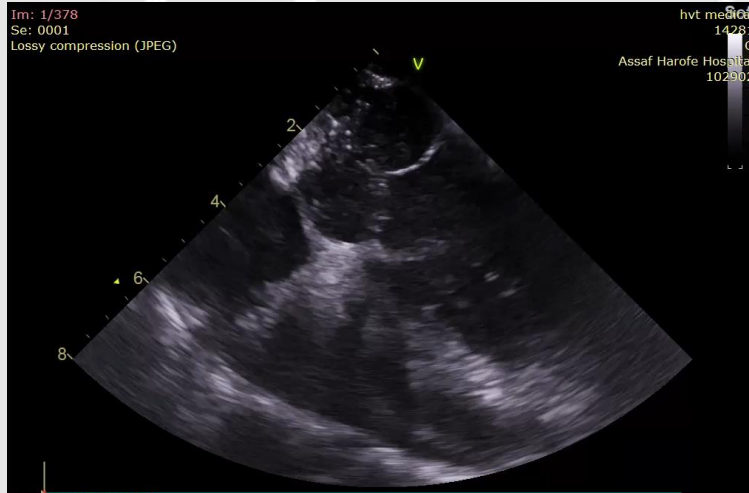


Pre-Clinical Studies: Pig Study – Fluoroscopy Imaging Movies

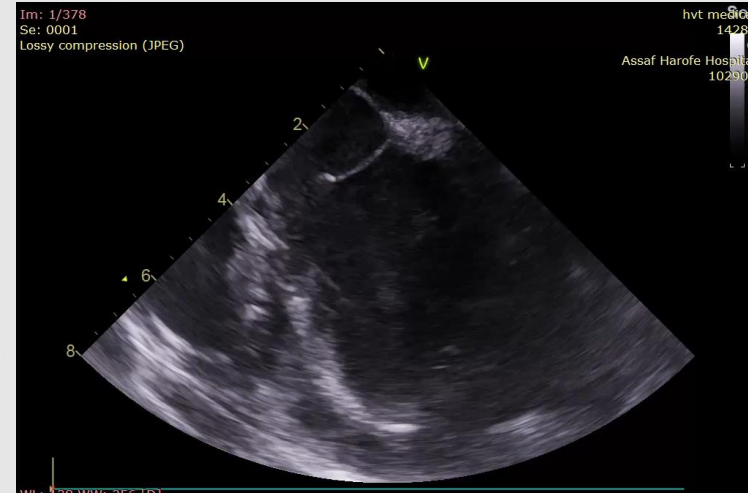


Pre-Clinical Studies: Pig Study – Echo Imaging Movies

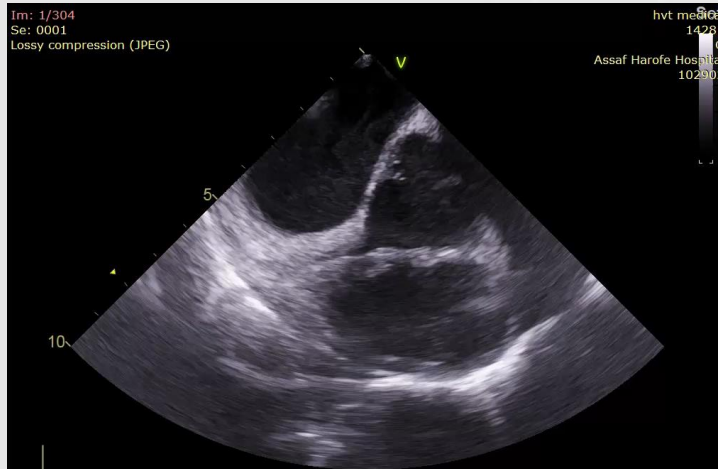
Native Aortic Valve
Cutting head is
above valve
(long axis view, ICE)



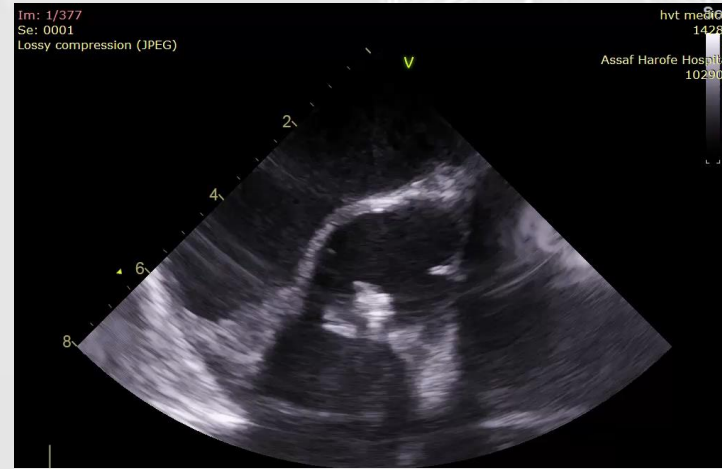
Leaflet captured
by the cutting head
(long axis view, ICE)



Native Aortic Valve
Cutting head is above
valve
(short axis view, ICE)



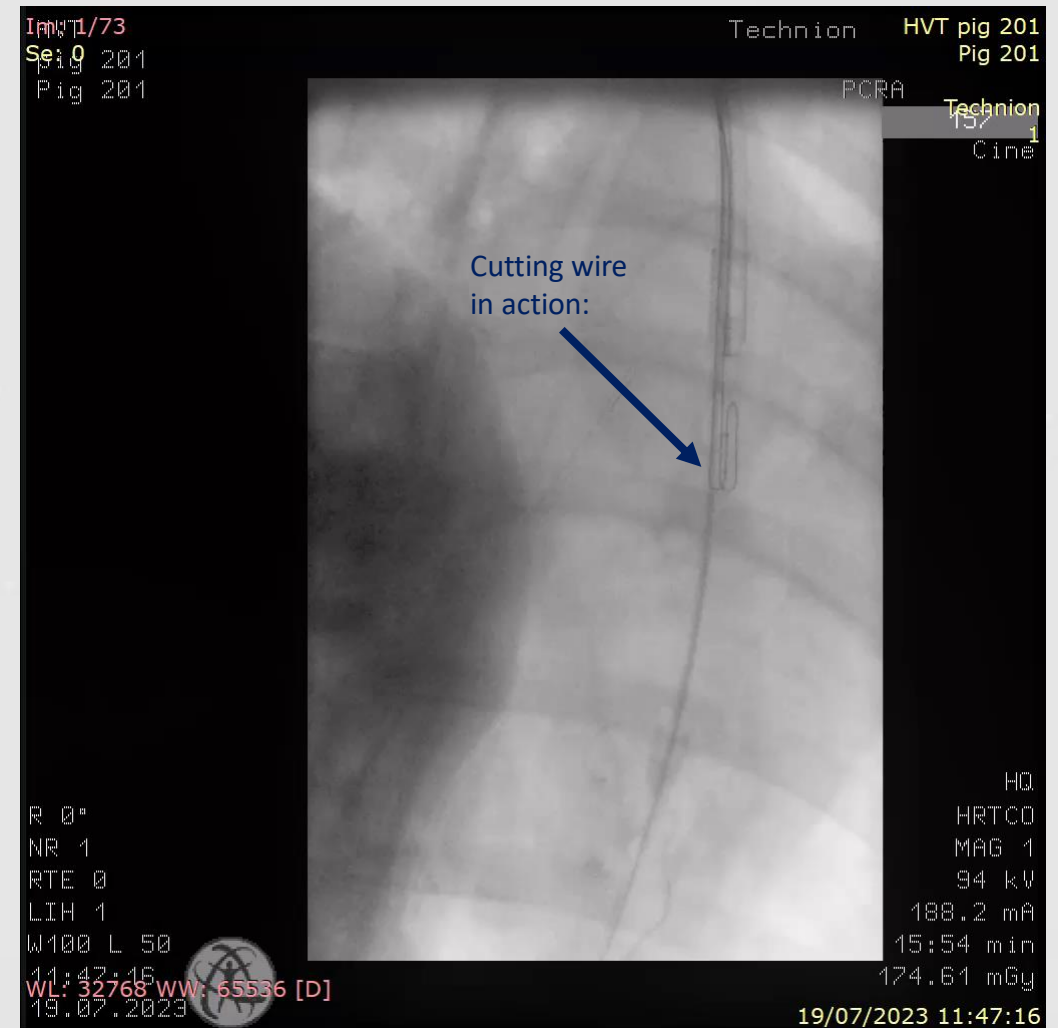
Leaflet captured
by the cutting head
(short axis view, ICE)



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Pre-Clinical Studies – Pig Study

- Activation of the cutting process.
- Note the u-shaped cutting wire moving back through a groove inside the cutting head.
- During the excision, the grasping jaws of the cutting head are stationary and stable (no pulling forces) while a running wire with electrical energy performs precise excision of a horseshoe shape.



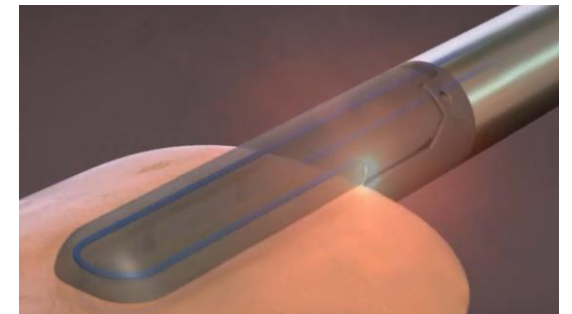
Electrosurgery energy applied by the Splitter's cutting head

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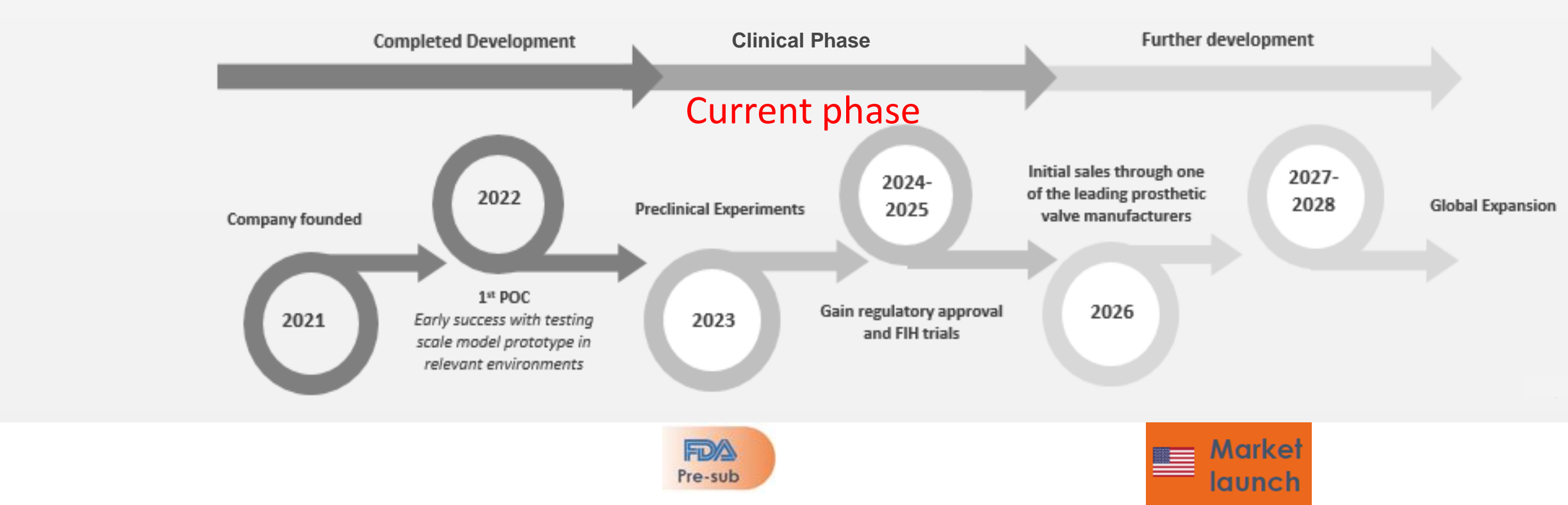
The Splitter – Essential to Remember

Benefits:

- Simple and intuitive to operate
- Precise control of the cutting site
- During the excision, the grasping jaws are stationary and stable (no pulling forces) while a running wire with electrical energy performs precise excision of a horseshoe shape
- Confirmation of a successful cutting
- Fully integrated into the workflow of the TAVI procedure



Roadmap



Thank You

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