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

Yair Feld M.D., Ph.D., Arthur Kerner M.D

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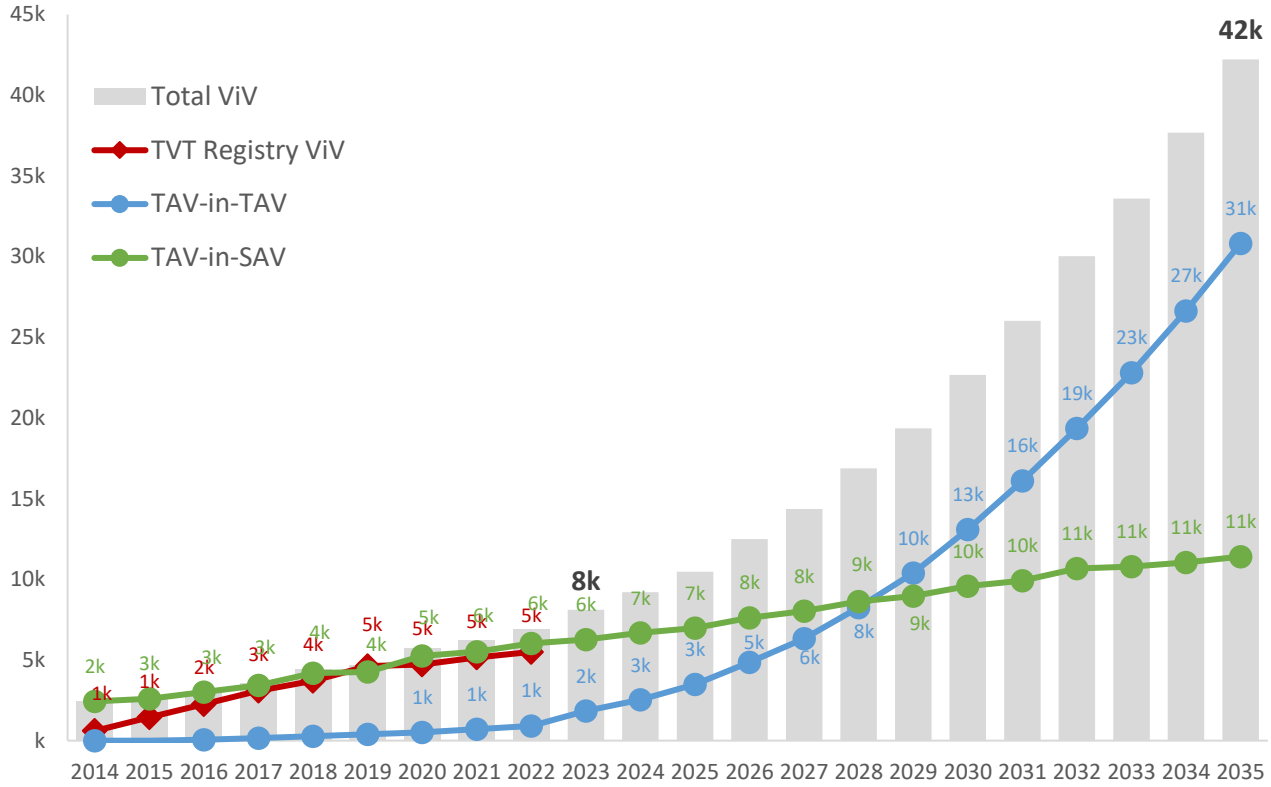
Disclosure of Relevant Financial Relationships

Within the prior 24 months, I have had a financial relationship with a company producing, marketing, selling, re-selling, or distributing healthcare products used by or on patients:

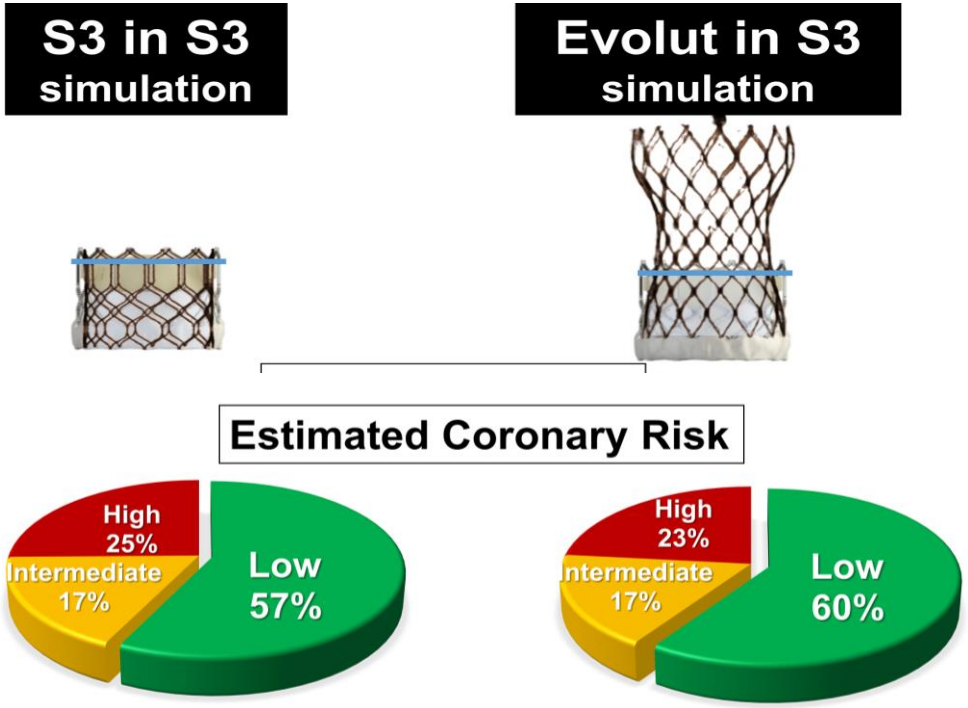
Nature of Financial Relationship	Ineligible Company
Consultant Fees/Honoraria	Medtronic, Edwards(s)
Individual Stock(s)/Stock Options	Cathalert, Cuspa, HVT, Paragate
Royalties/Patent Beneficiary	HVT

All relevant financial relationships have been mitigated.
Faculty disclosure information can be found on the app

US ViV Market Forecast

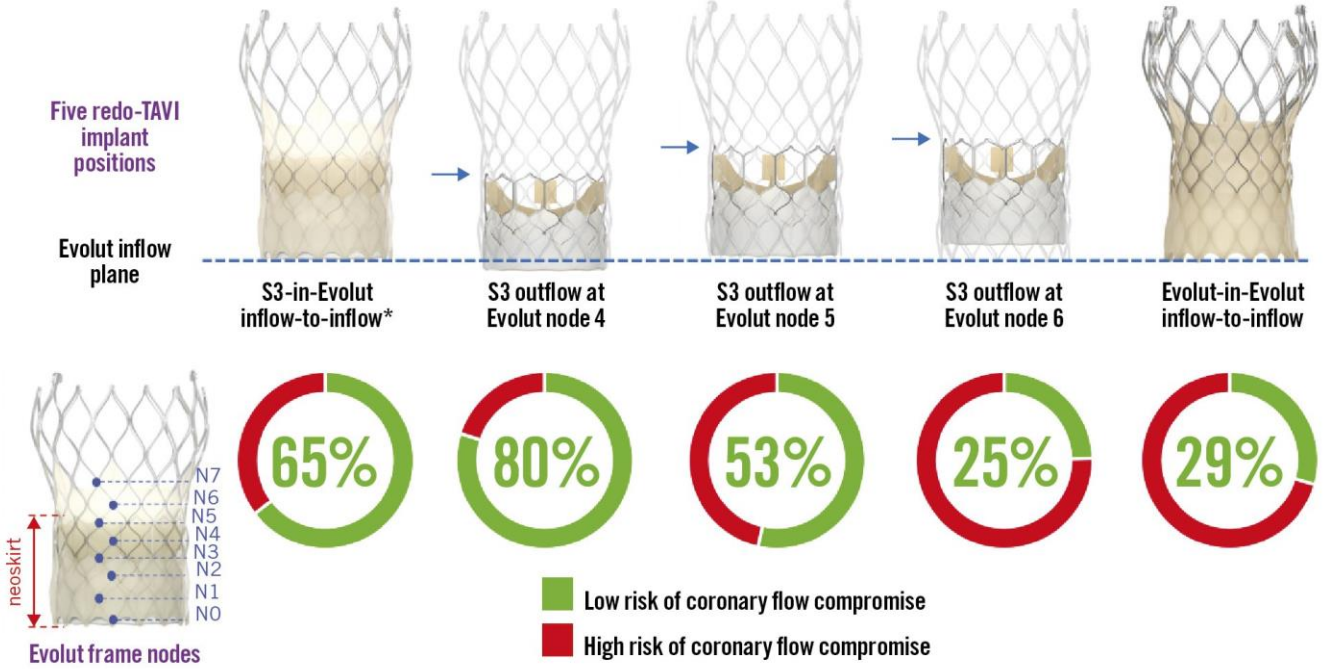


Redo-TAV replacement with S3-in-S3 and Evolut-in-S3 associated in 40% with intermediate or high risk for coronary obstruction



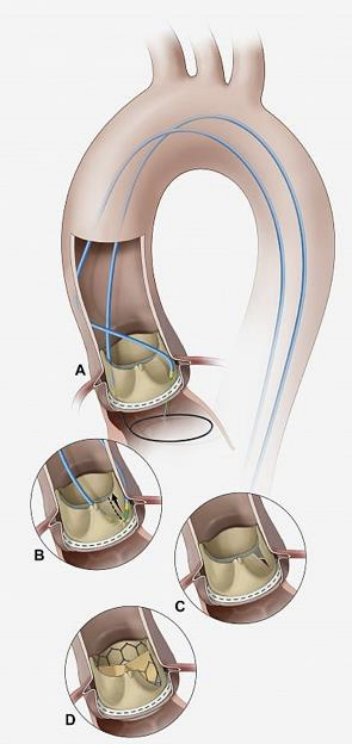
Miho Fukui. Circulation: Cardiovascular Interventions. Feasibility of Redo-Transcatheter Aortic Valve Replacement in Sapien Valves Based on In Vivo Computed Tomography Assessment, Volume: 16, Issue: 11, Pages: e013497, DOI: (10.1161/CIRCINTERVENTIONS.123.013497)

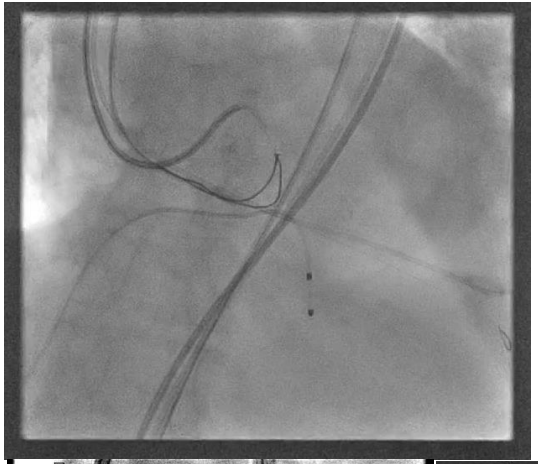
S3 in Evolut 20-70% high risk for coronary obstruction

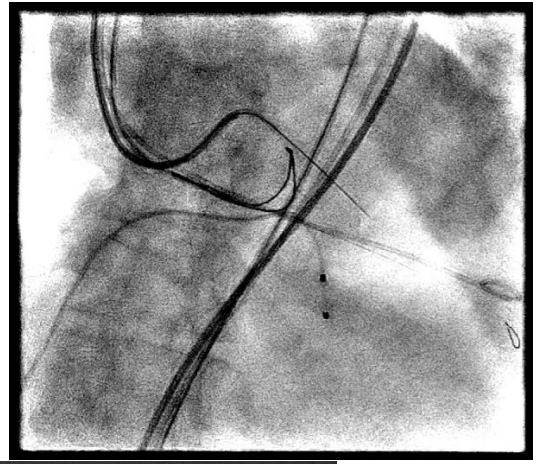


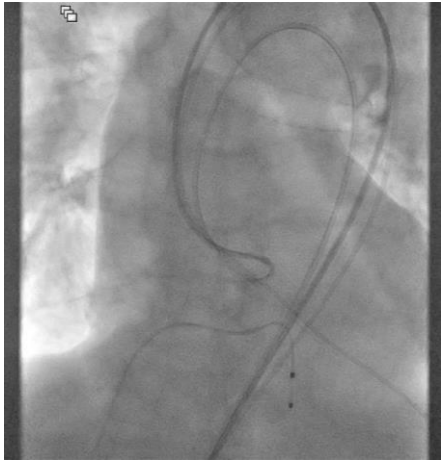
Feasibility of redo-TAVI in self-expanding Evolut valves: a CT analysis from the Evolut Low Risk Trial substudy" *Euro-Intervention* ***April 2023***

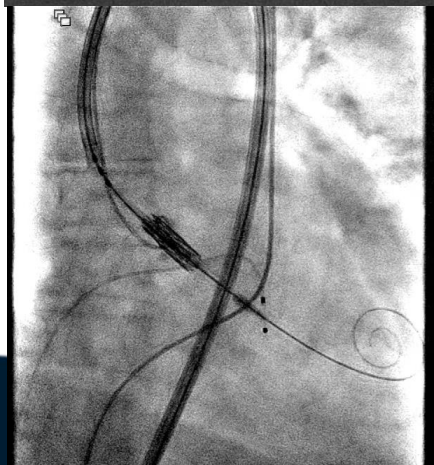
Leaflet modification (BASILICA)

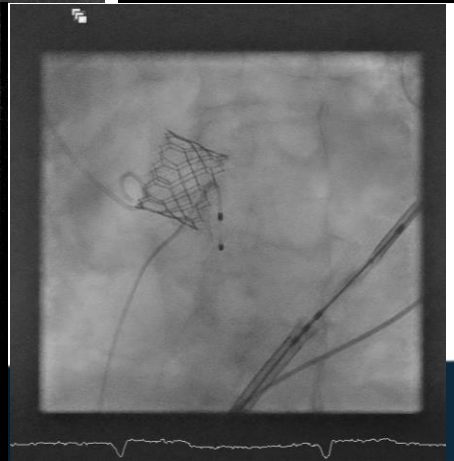












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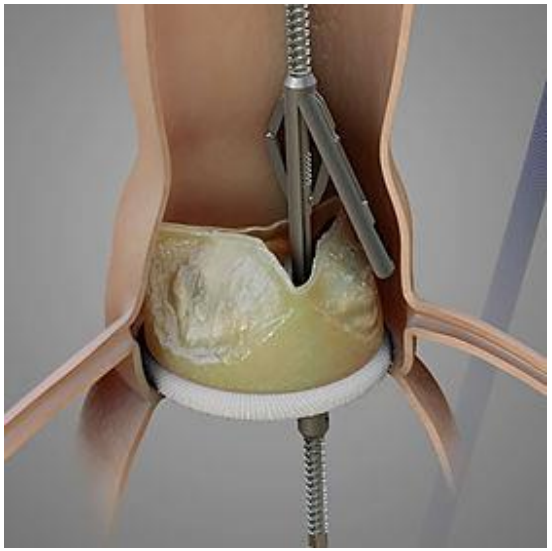
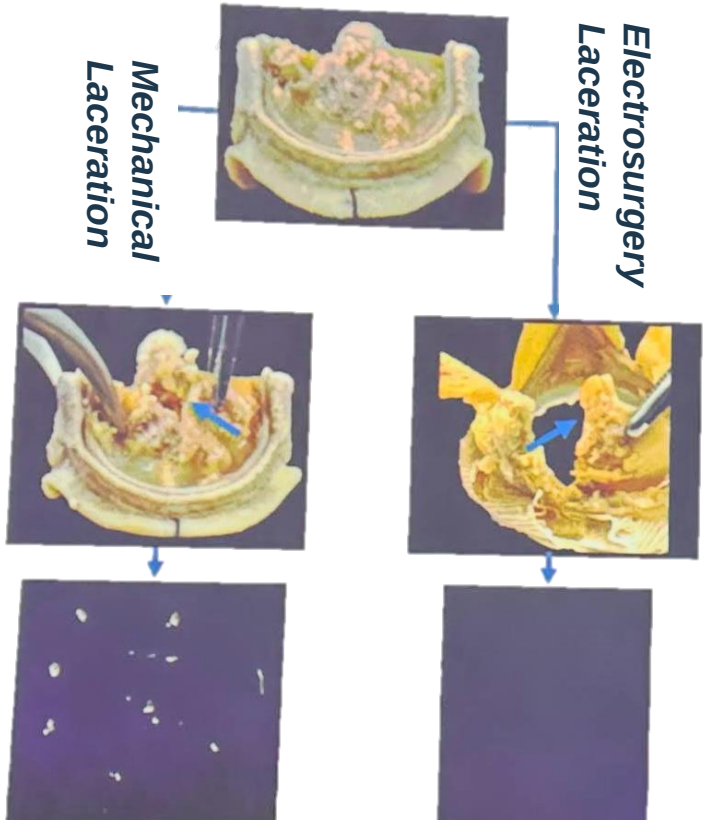
Mechanical Vs. Electrosurgical

ShortCut Catheter | Pi Cardia / UNICORN



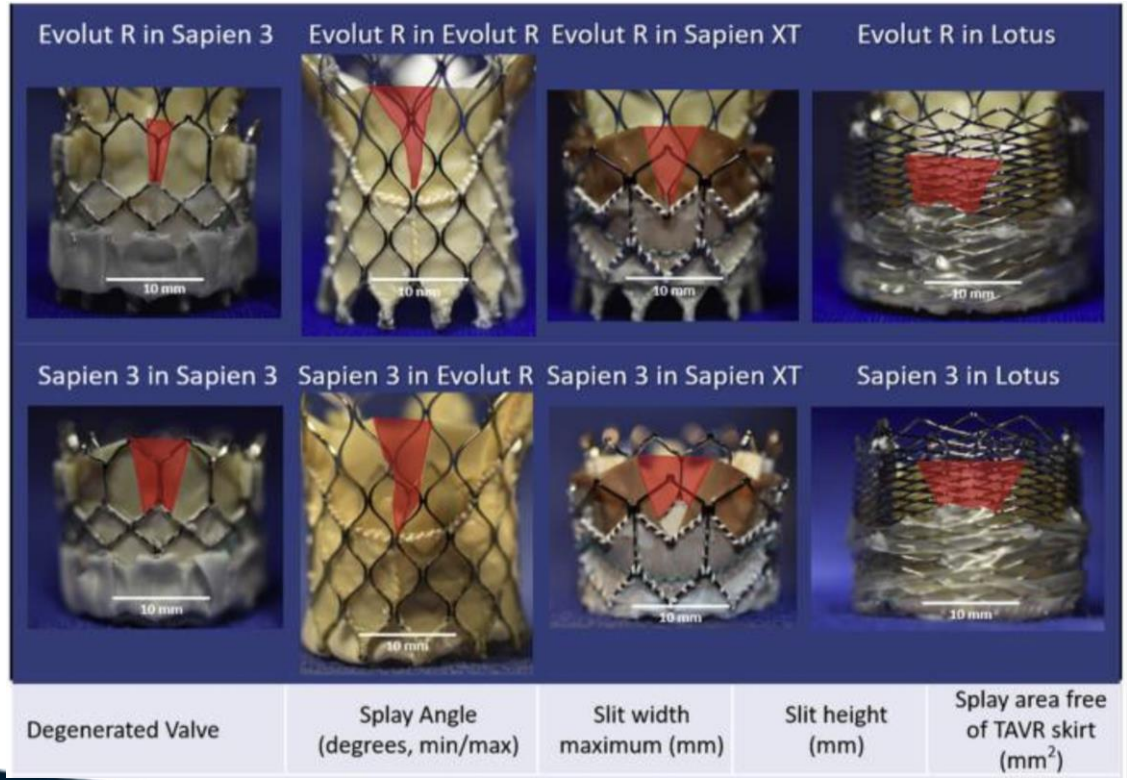


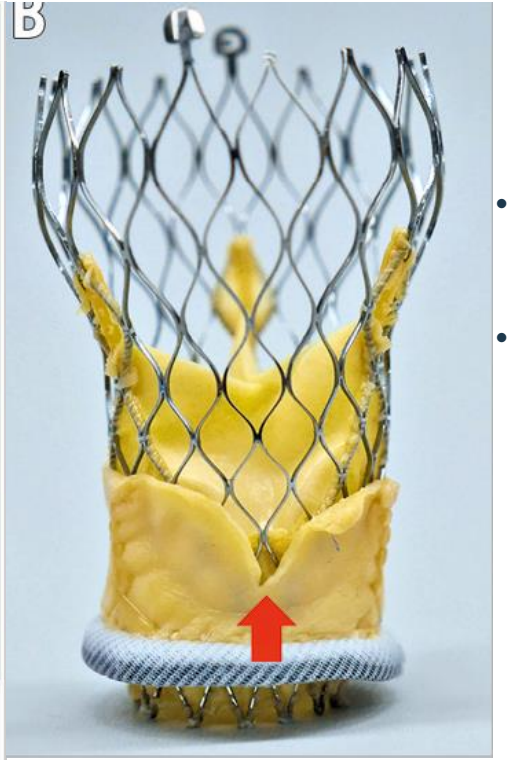
Liberated debris

Absence of Liberated debris

Courtesy of J Sathananthan and Stephanie Sellars

Making a cut is not enough



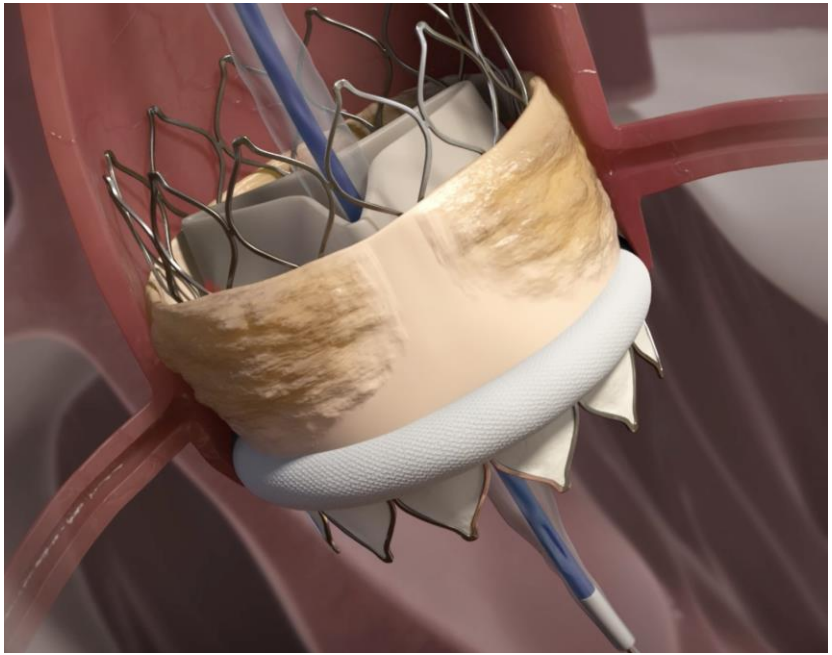


- ***Narrow Splay with newer devices***
- ***Commissures need to be aligned***

Khan et al. JACC Cardiovasc Interv. 2020 March 23; 13(6): 787–789.

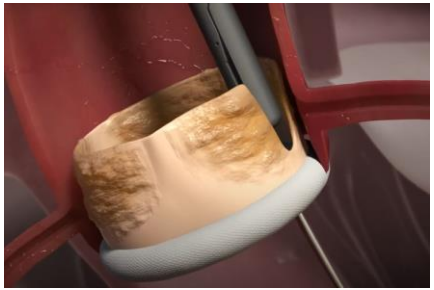
Coronary obstruction is not the whole story

What about Coronary access?

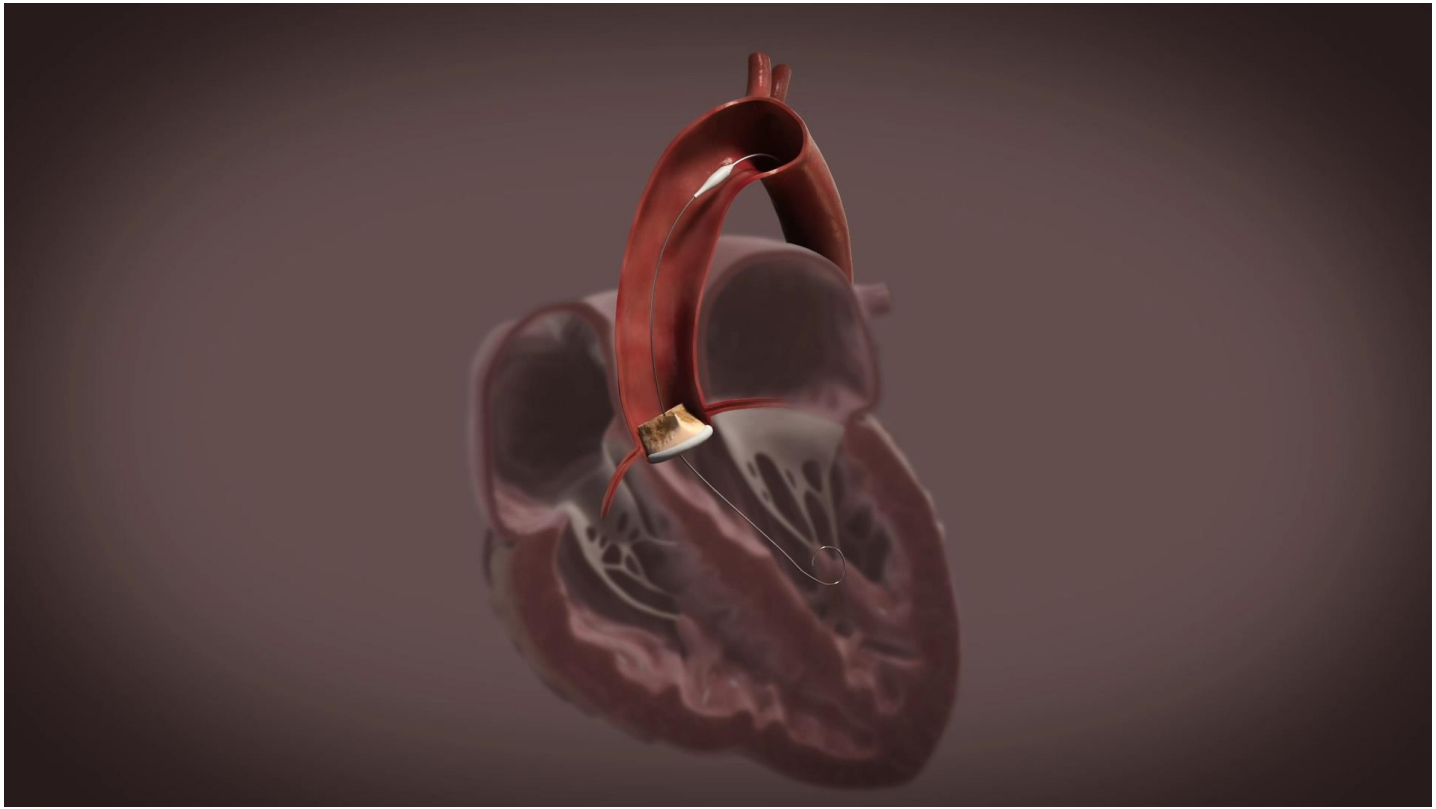


The Splitter

- 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.

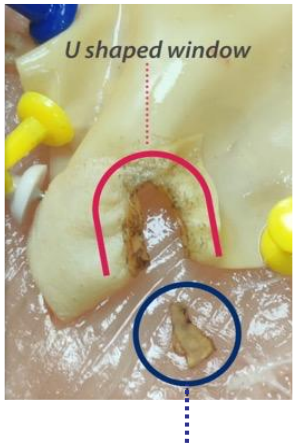


The Splitter - Animation



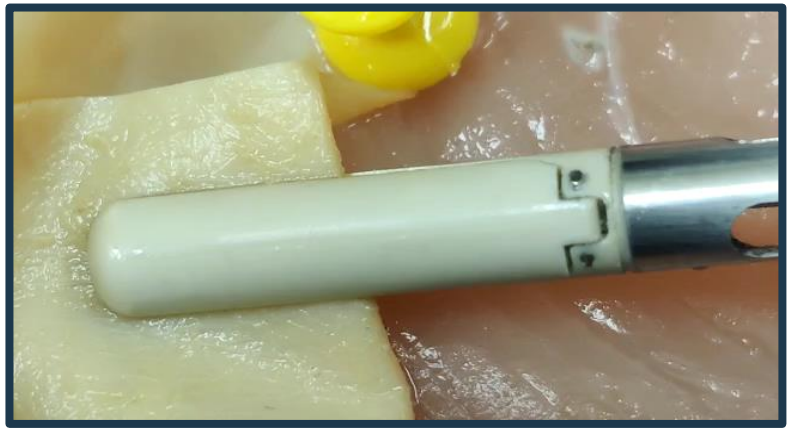
Bench Test – Cutting Tissue

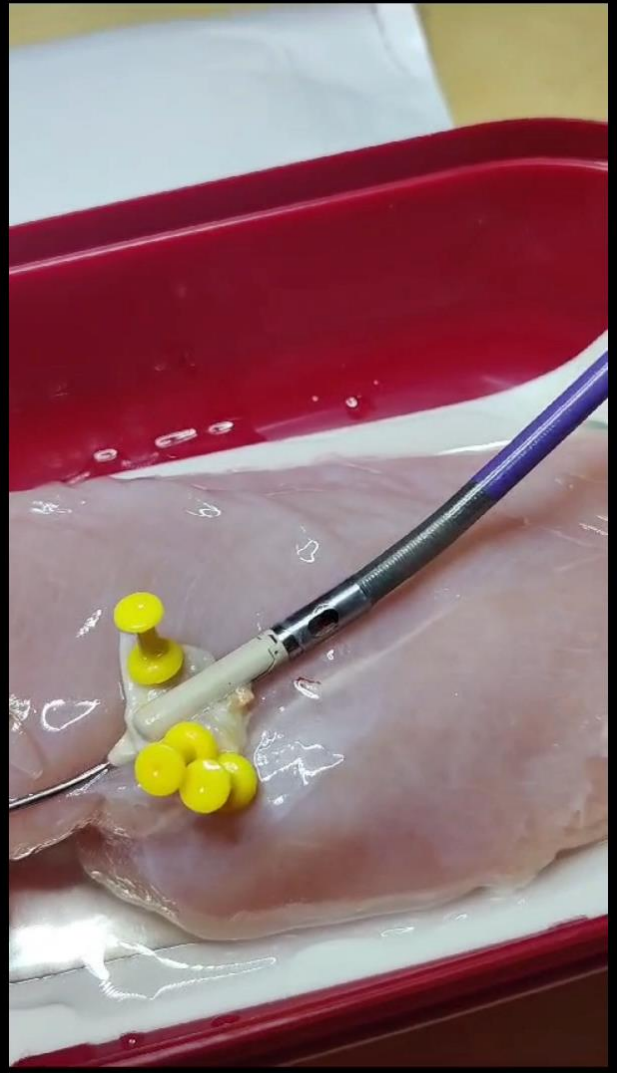
- Precise excision of leaflet tissue and creation of a large u-shaped window in the cusp
- The excised tissue is trapped inside the cutting head and removed through the catheter

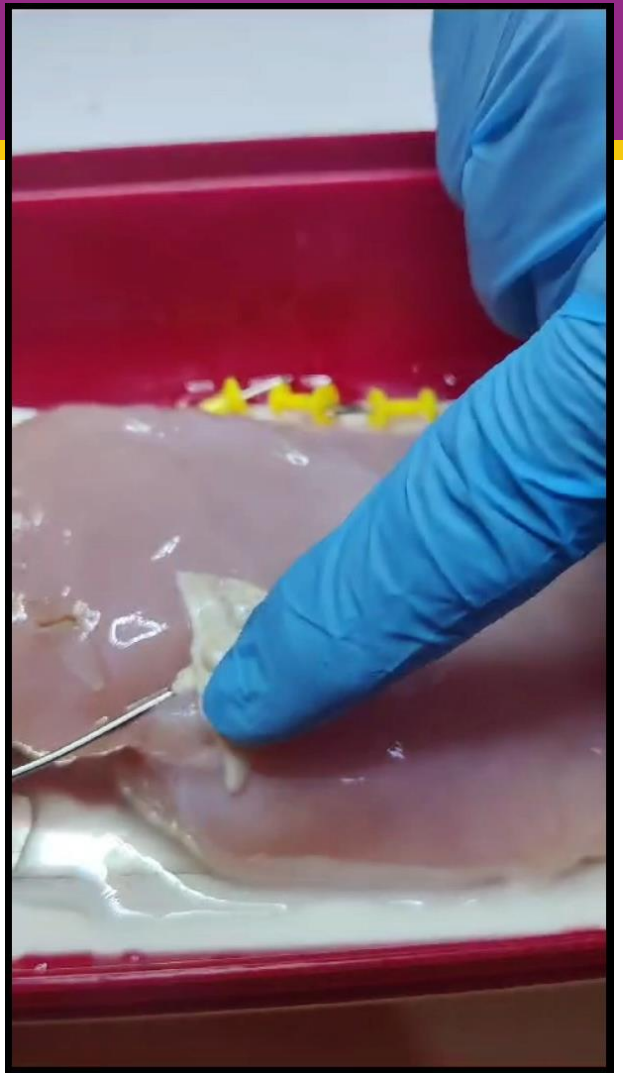


The excised segment

Human heart, ex-vivo

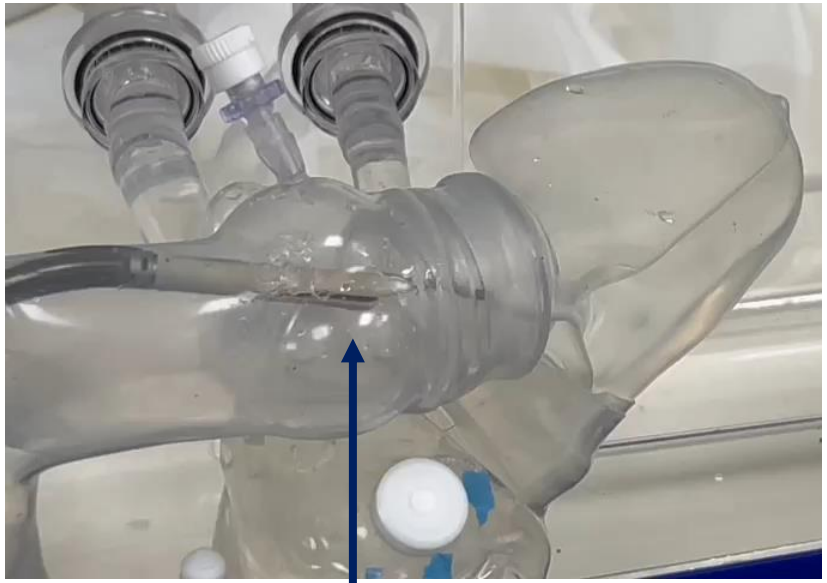




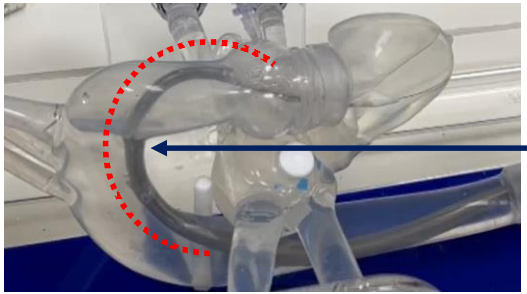


Bench Test - Silicone Heart Model

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



Cutting head



Aortic arch

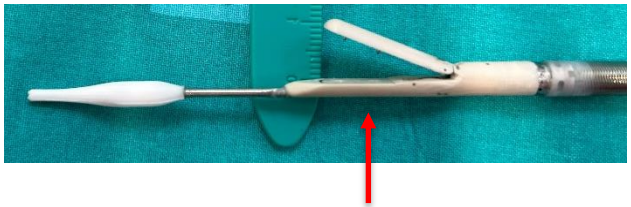
Control handle

Cutting head

Pre-Clinical Studies: Pig Study

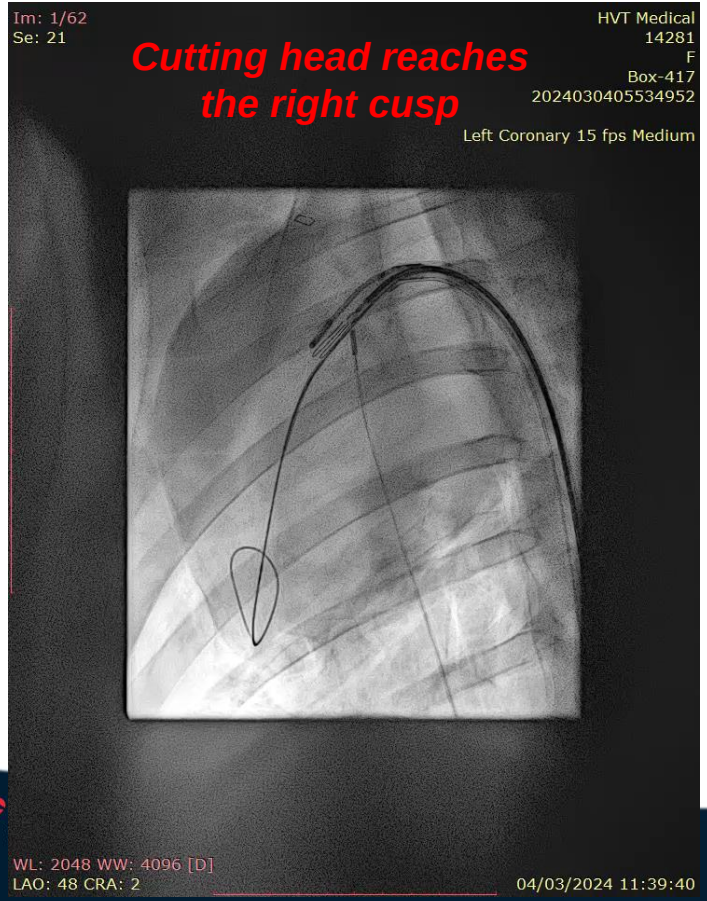
- Device steering to the aortic valve
- Grasping the selected leaflet
- Laceration and removal of the leaflet segment
- Procedure done under fluoroscopy and echocardiography imaging guidance

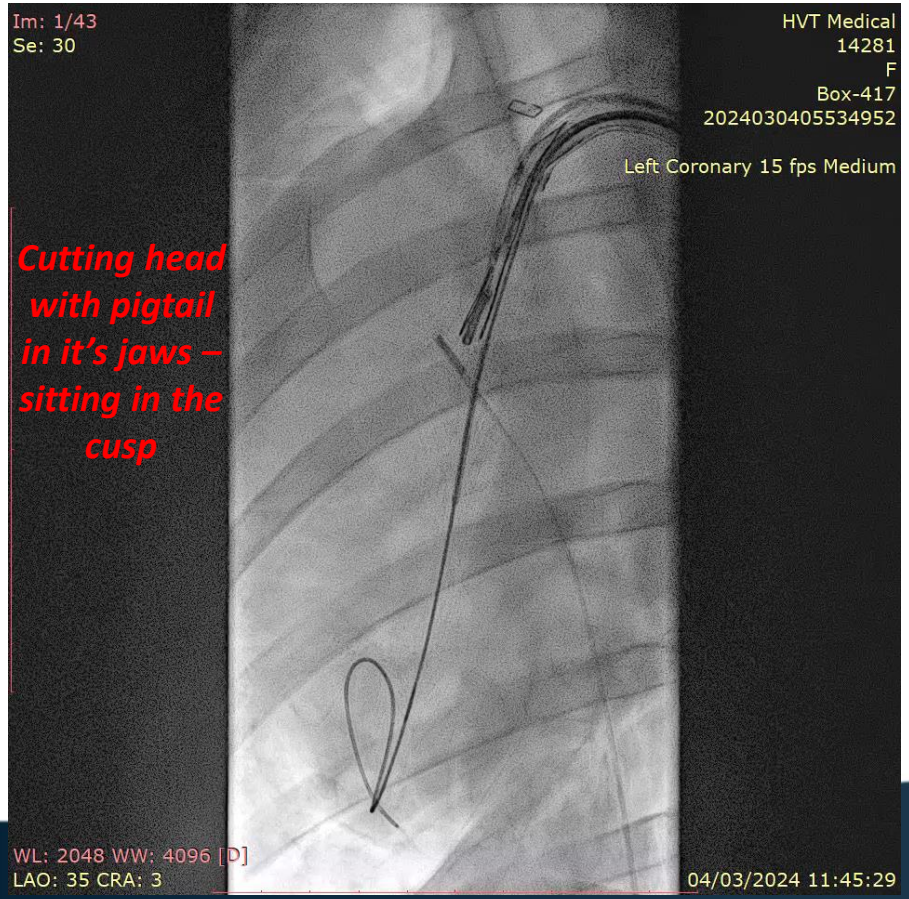
Distal end of the Splitter device



Cutting head

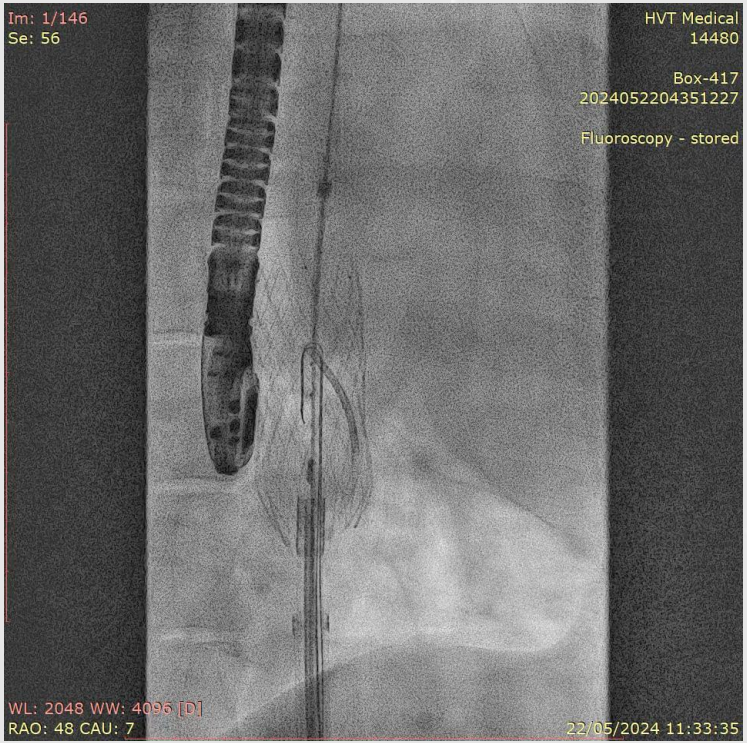
Pre-Clinical Studies: Pig Study – Fluoroscopy Imaging Movies





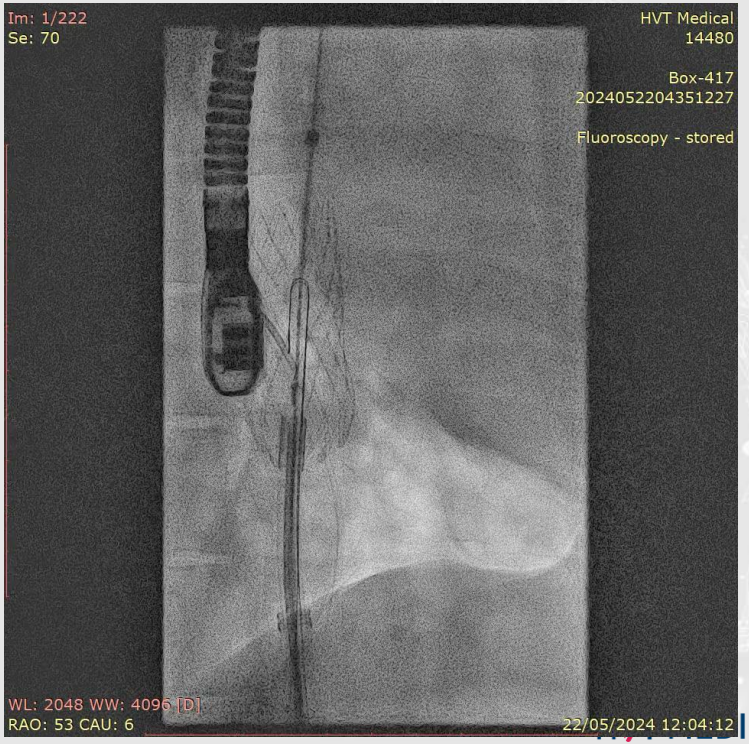
R&D Animal Studies:
Pig Study on an Implanted Prosthetic Valve

Fluoroscopy imaging



Cutting head exists the external unit

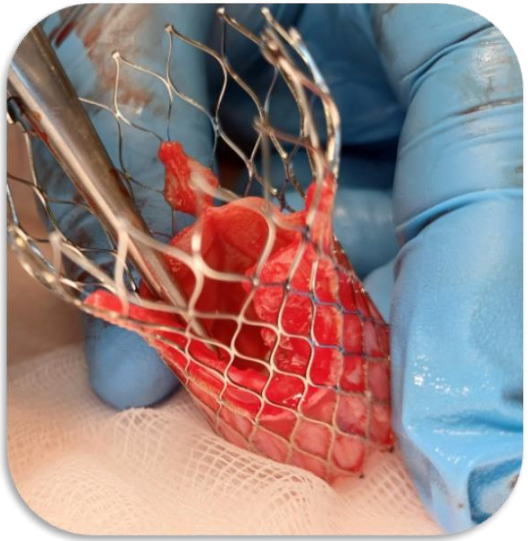
Cine imaging



R&D Animal & Bench Studies: on a Prosthetic Valve

Prosthetic valve* -
post Splitter cutting
(bench test)

Prosthetic valve* -
post Splitter cutting, in-vivo
(explanted from pig post animal study)

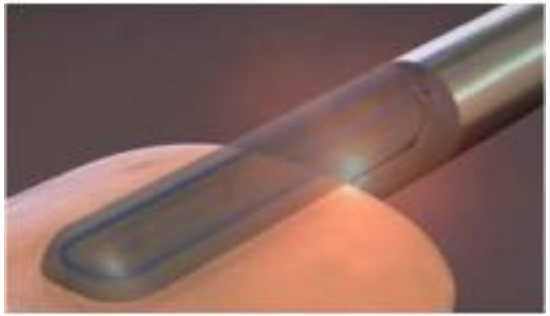


*Tested on Medtronic Evolut FX, 29 mm valve

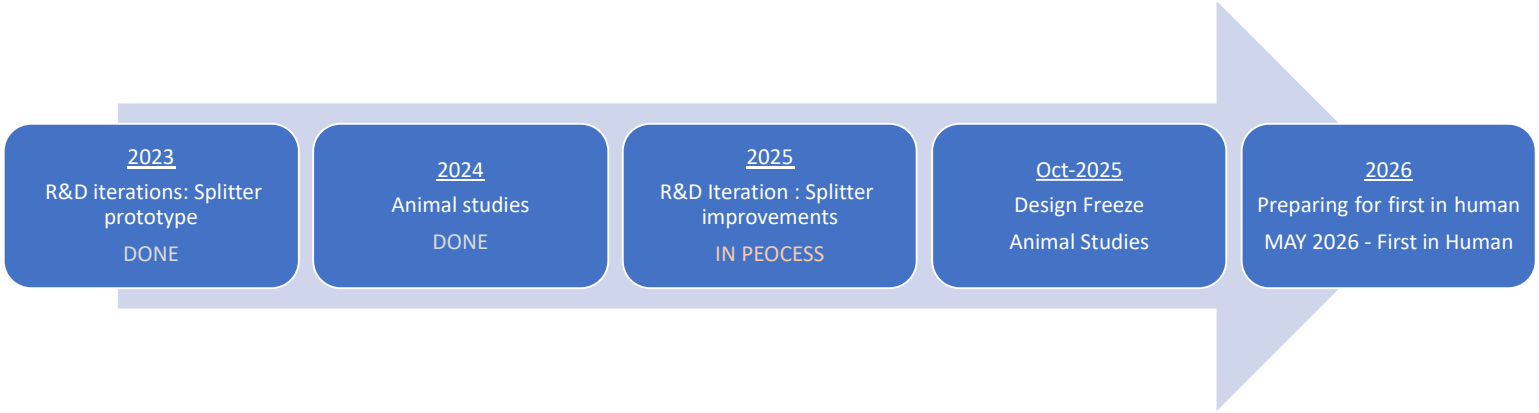
HVT MEDICAL

The Splitter – Essential to Remember

- Benefits:
- 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
- Wide splay
- Electrosurgical cutting
- Fully integrated into the workflow of the TAVI procedure



The Splitter – Status and Expected Timeline



- **Splitter improvements:**
  - **Improved steering**
  - **Improved Positioning & Grasping**

    An adaptive jaw capable of dynamic grasping of both normal & calcified leaflets.
    Verify the optimal leaflet position inside the Splitter jaws
  - **Improved cutting**

Thank You

Yair Feld M.D., Ph.D.

Director – Structural and Interventional Cardiology

Tzafon Medical Center

Israel