



Latest Adjunctive Technologies in TAVR

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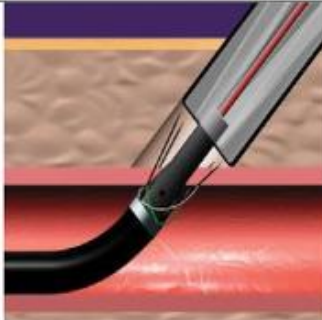
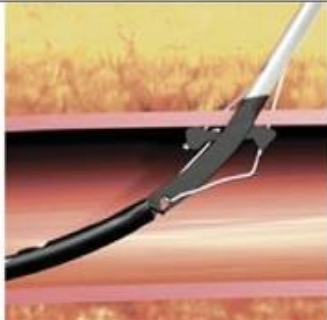
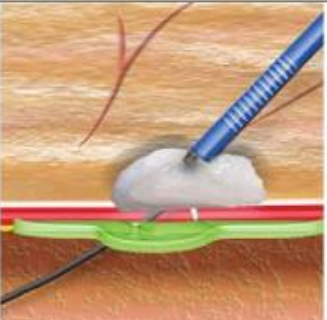
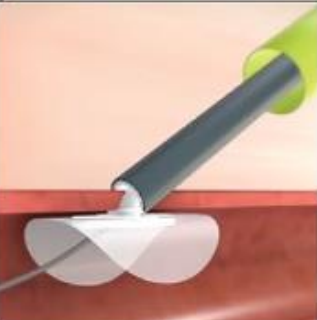
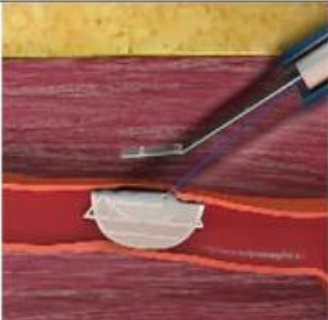
Latest Adjunctive Technologies in TAVR

- ✓ Femoral Closure
- ✓ Special Ballons
- ✓ Pacemaker wires
- ✓ Embolic Protection
- ✓ Leaflet Modification

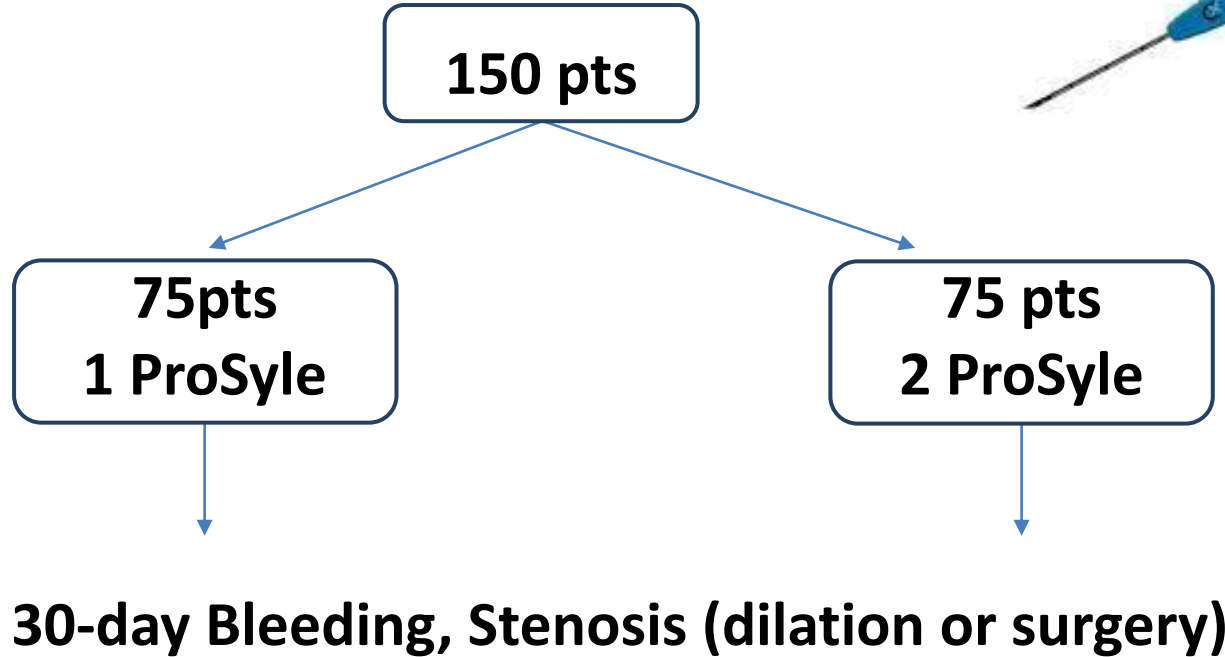
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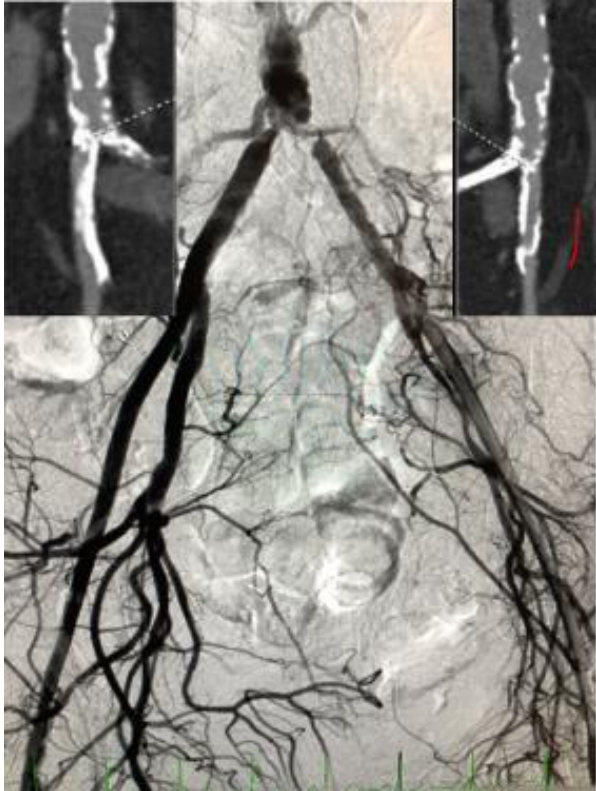
Femoral Closure Devices

Prostar® XL	ProGlide®	MANTA™	PerQseal®	InSeal
				
				
Suture-based 8.5–10 Fr	Suture-based 5–8 Fr	Collagen-based 10–14 Fr (14 Fr system)	Patch-based < 24 Fr	Membrane-based 14–21 Fr

1 ProStyle Randomized vs 2 ProStyle



Shockwave M5



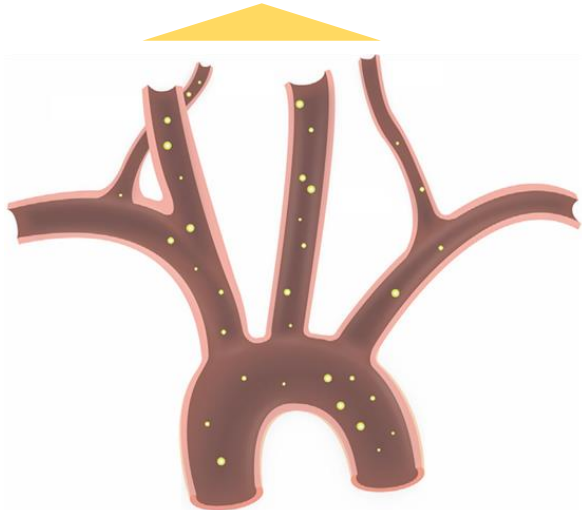
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Clinical Need – Brain injury during left-sided heart procedures

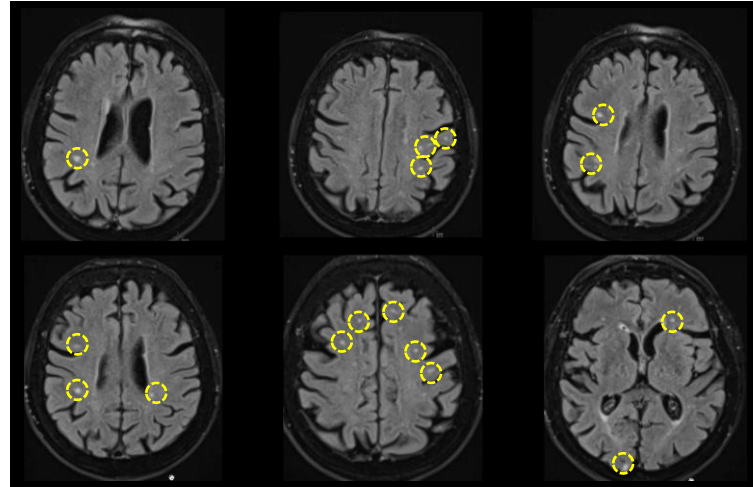
- Debris migration to brain during heart valve procedures leads to stroke (3-5%) and silent infarcts (up to 100%)
- Brain injury is among most feared complication for patients and leads to high cost for health care systems
- Silent infarcts are associated with 2-4-fold risk of future stroke, >3-fold risk of mortality, >2-fold risk of dementia

Embolitic Debris Migration






















Picture: Illustration of aortic arch and hemodynamic flow with embolic debris.

New Cerebral Lesions in the brain



Picture: MR Images of cerebral lesions in the brain.

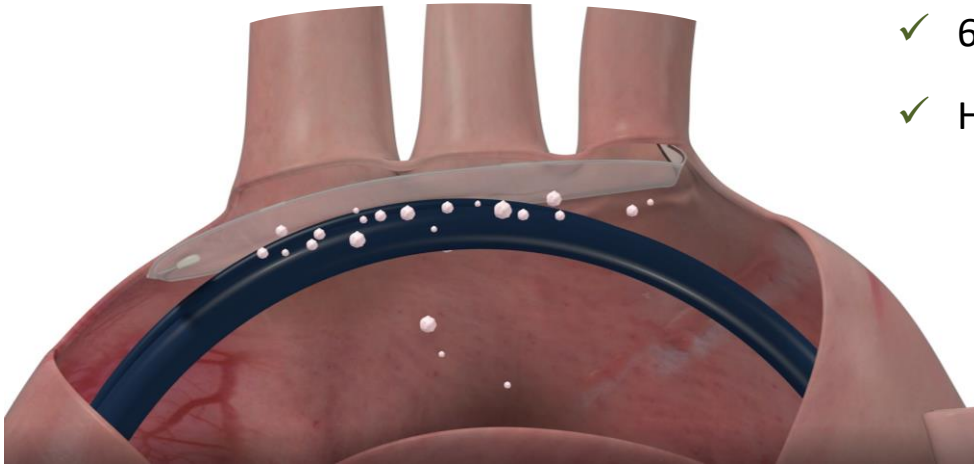
Market – Competitive Landscape

	 	 	 	 	 	 	 	 	 
	ProtEmbo®	Sentinel™	TriGUARD ₃ ™	Emboliner™	FLOWer™	Emblok™	Point-Guard™	CAPTIS™	F2 Filter™
Concept:	Deflect	Capture	Deflect	Capture	Capture	Capture	Deflect	Capture	Deflect
Status:	CE	CE 	CE	IDE	SIH	SIH	SIH	FIH	FIH
Pore size:	60 µm	140 µm	115x145 µm	150 µm	70 µm	125 µm	105 µm	115x150 µm	N/A
Access:	Left-radial	Right-radial	Femoral	Femoral	Femoral	Femoral	Femoral	Femoral	Femoral
Access size	6 Fr	6 Fr	8 Fr	10 Fr	12 Fr	11 Fr	10 Fr	16 Fr	N/A
Head vessels:	3/3	2/3	3/3	3/3	3/3	3/3	3/3	3/3	3/3
Coating:	Yes	No	Yes	Yes	N/A	No	No	N/A	N/A

ProtEmbo[®]

CEREBRAL PROTECTION SYSTEM

Protection of the 3 vessels

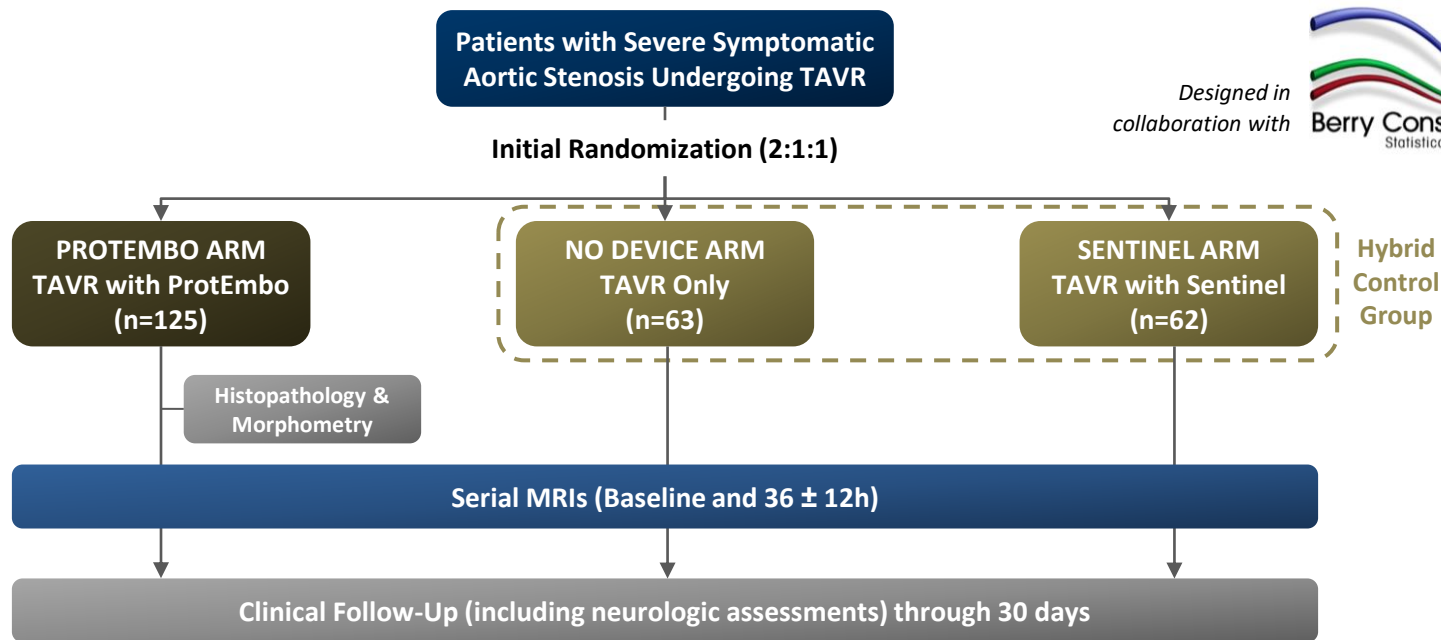


- ✓ Protects all 3 vessels to the brain
- ✓ Smallest filter pores – 60 μm
- ✓ Quick implantation time (left radial access)
- ✓ 6 Minimal interference with the TAVR procedure
- ✓ Heparin coating for optimal blood compatibility





IDE Trial – Adaptive Study Design



Adaptive study design with group sequential boundaries to assess outcomes at sequential interim analyses; First interim analysis at 250 patients with decision about conduct of trial based on predefined definitions of success or futility (by independent DSMB). After 250 patients further interim analyses each time 50 additional patients complete study up to maximum of 500 patients. **510(k) clearance based on superiority versus No Device Arm/ Hybrid Control Group.**



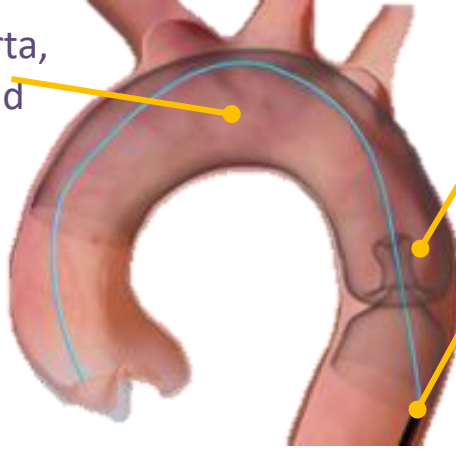
Emboliner



Conformable, cylindrical filter lines aorta, protecting all three cerebral vessels and descending aorta

Nitinol filter, 150 μ m pore size

Compatible with all TAVR systems



Expandable access port for TAVR delivery system

Integrated 6 Fr lumen for pigtail

Contralateral transfemoral access via integrated 9.5 Fr sheath



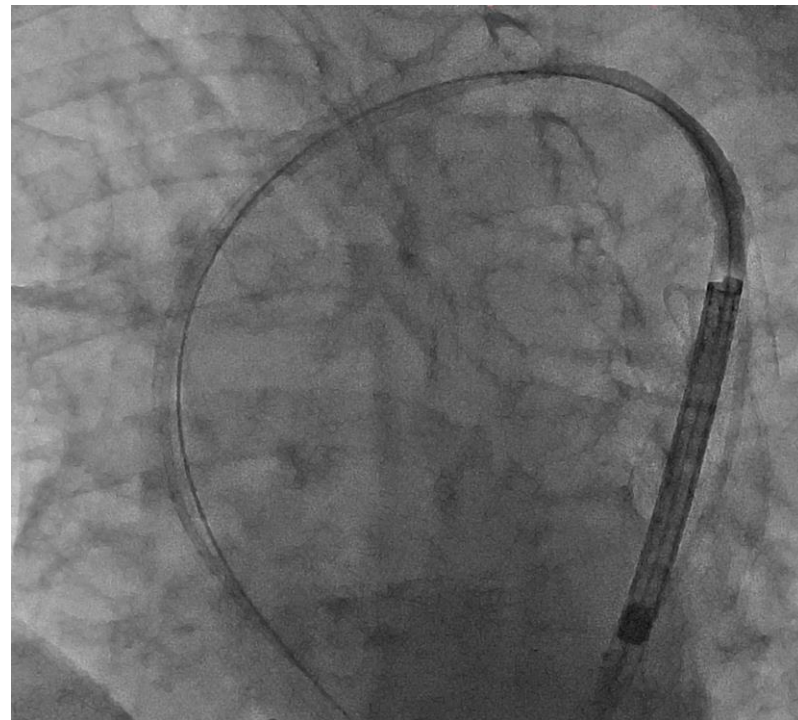


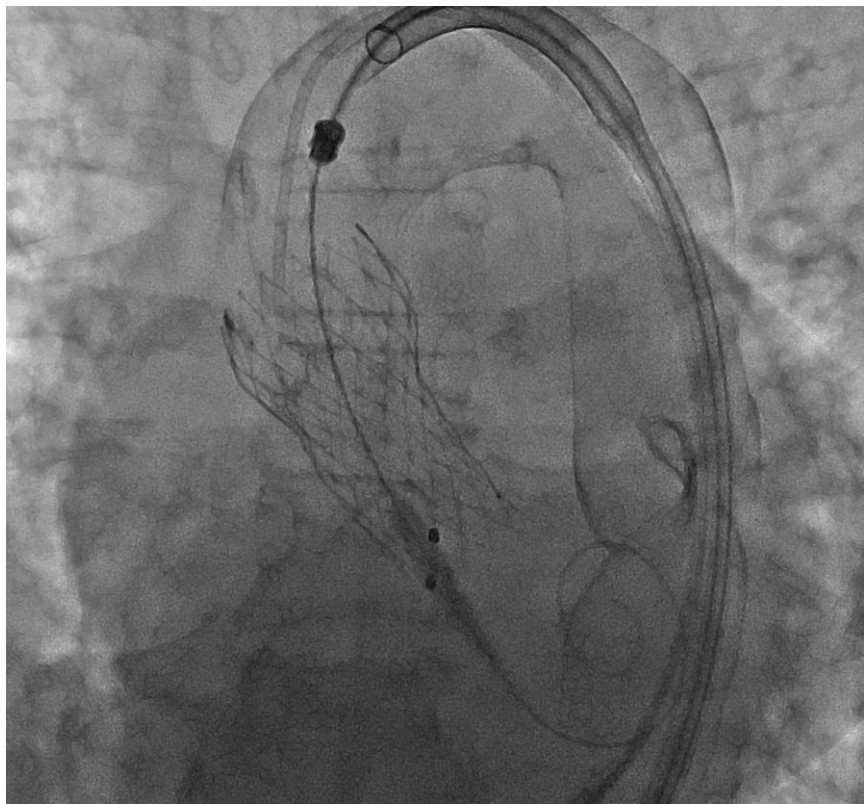
Full Body Embolic Protection

Initial Port Crossing



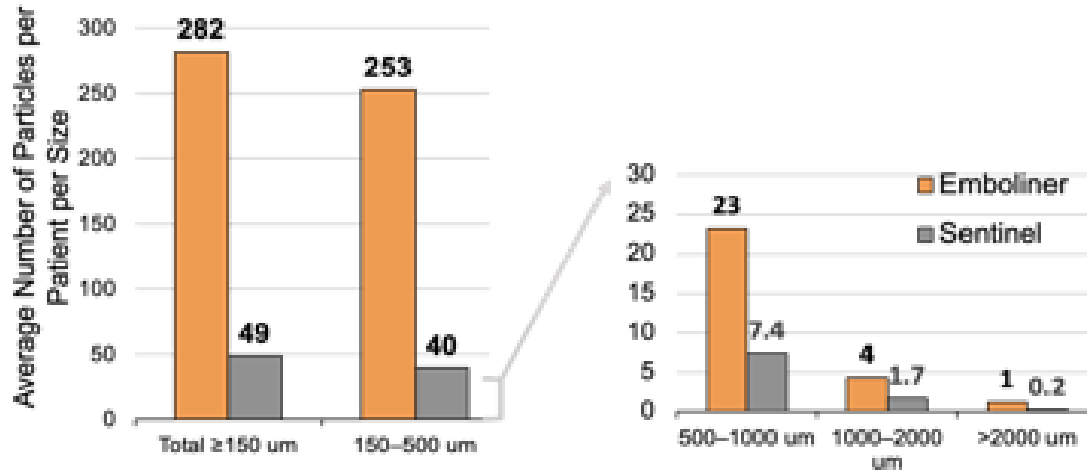
Advancement over Arch



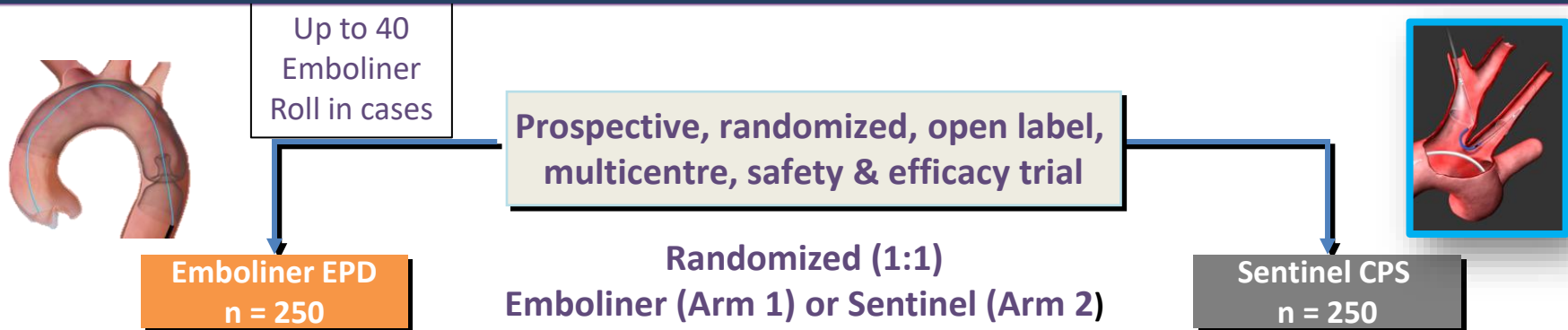


Debris Capture

- SafePass 2 trial at 3 sites in New Zealand
 - Filters collected from SafePass 3 currently under analysis at CVPPath Histopathology Laboratory
 - Emboliner captured >5x number of clinically relevant debris compared to Sentinel data



Protect Head-to-Head Study



Randomization stratified by (a) site and (b) TAVR device type (Edwards or Medtronic)
History of stroke patients randomized per device type throughout study cohort

Primary Endpoint: 30-day combined MACCE: all death, stroke* and stage 3 AKI (non-inferiority)

Secondary Endpoints:

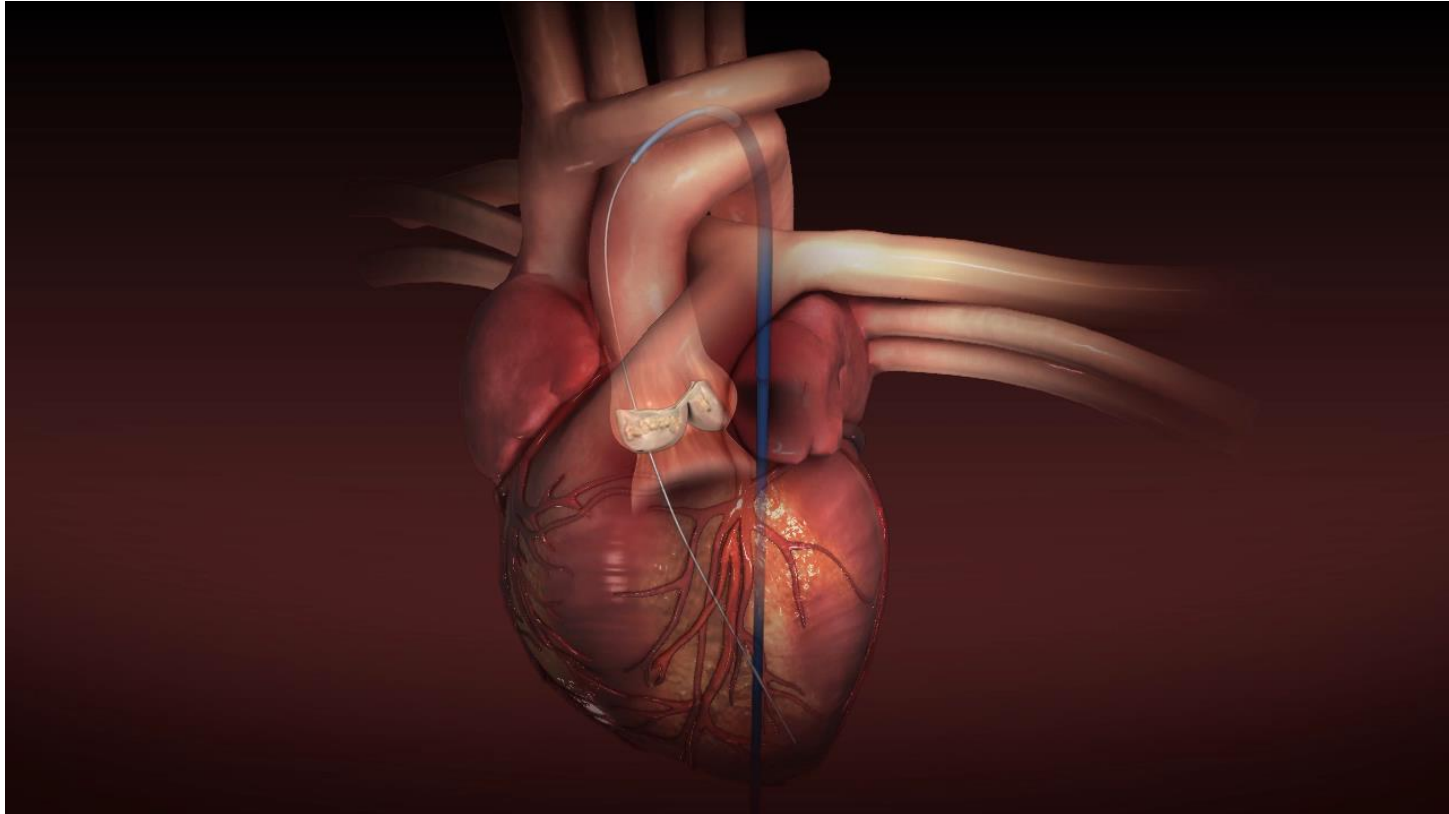
- 30-day stroke* (non-inferiority)
- Number of particles captured >150 μm (superiority)

*VARC2-defined

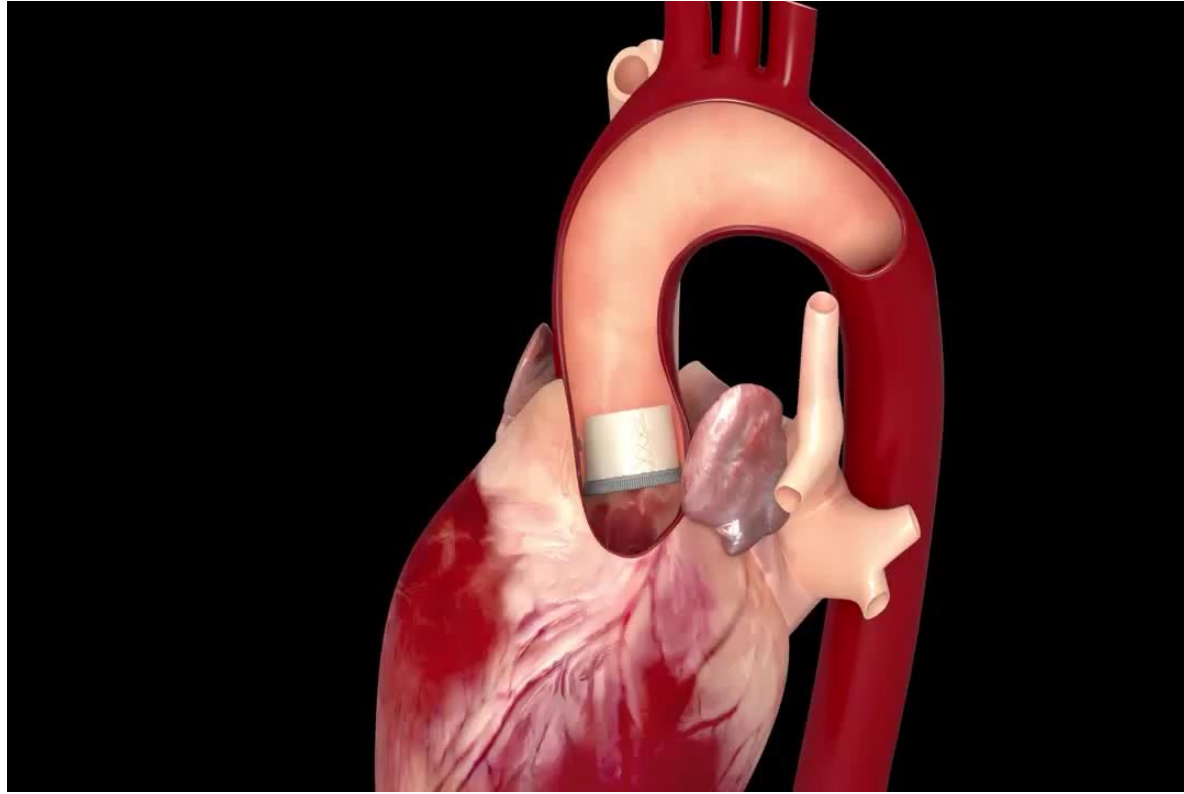
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The Leaflex™ Procedure

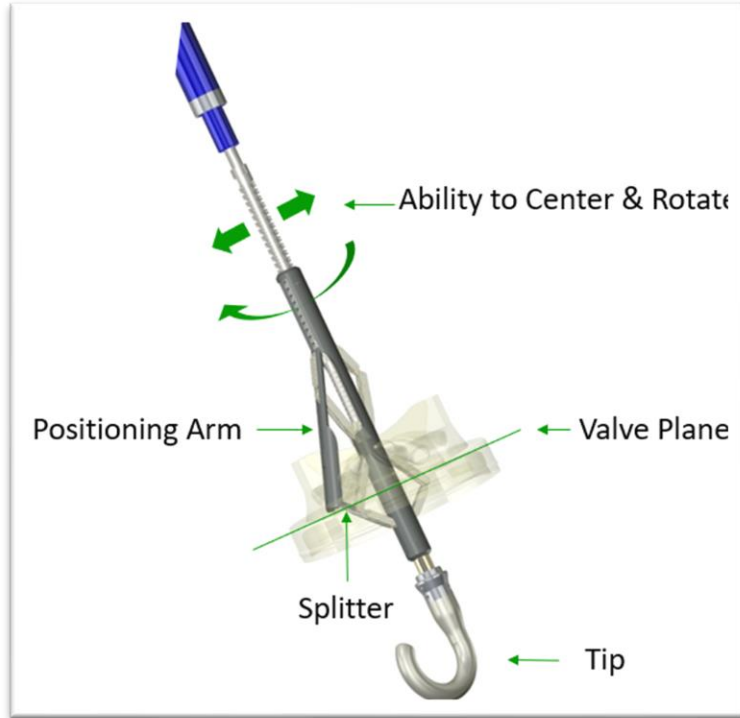


Basilica



ShortCut™

Safe & Simple Coronary Access



Latest Adjunctive Technologies in TAVR

- ✓ Certainly made procedures safer
- ✓ Higher chances of success
- ✓ Less bleeding
- ✓ Less Stroke
- ✓ Shorter hospital stay