

Advances in Structural Heart Disease

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Disclosure

I have no financial conflicts of interest to disclose



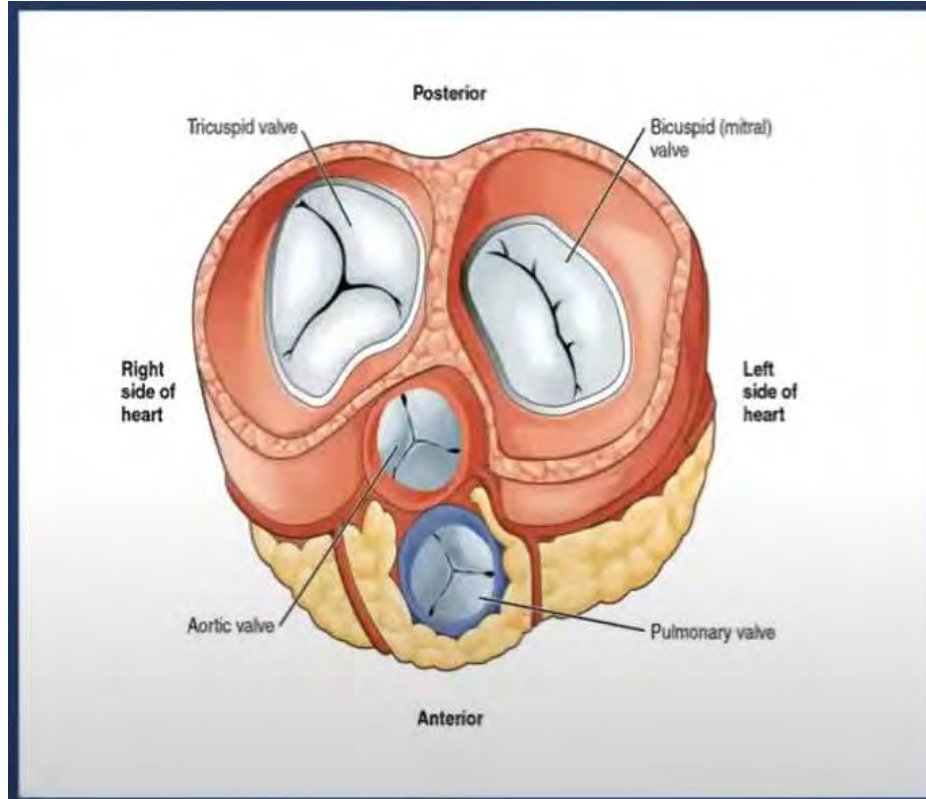
Objectives



- Review state of the art of structural heart disease therapies in 2024
- The Heart Team in 2024
- Currently available transcatheter, minimally invasive surgical options for valvular heart disease



Transcatheter Therapies for Valvular Heart Diseases



Aortic

Mitral

Pulmonic

Tricuspid



“A valve is a device or natural object that regulates, directs or controls the flow of a fluid by opening, closing, or partially obstructing various passageways”

How do valves fail?

- Stenosis
- Regurgitation

How to fix a broken valve?

- Repair
- Replacement

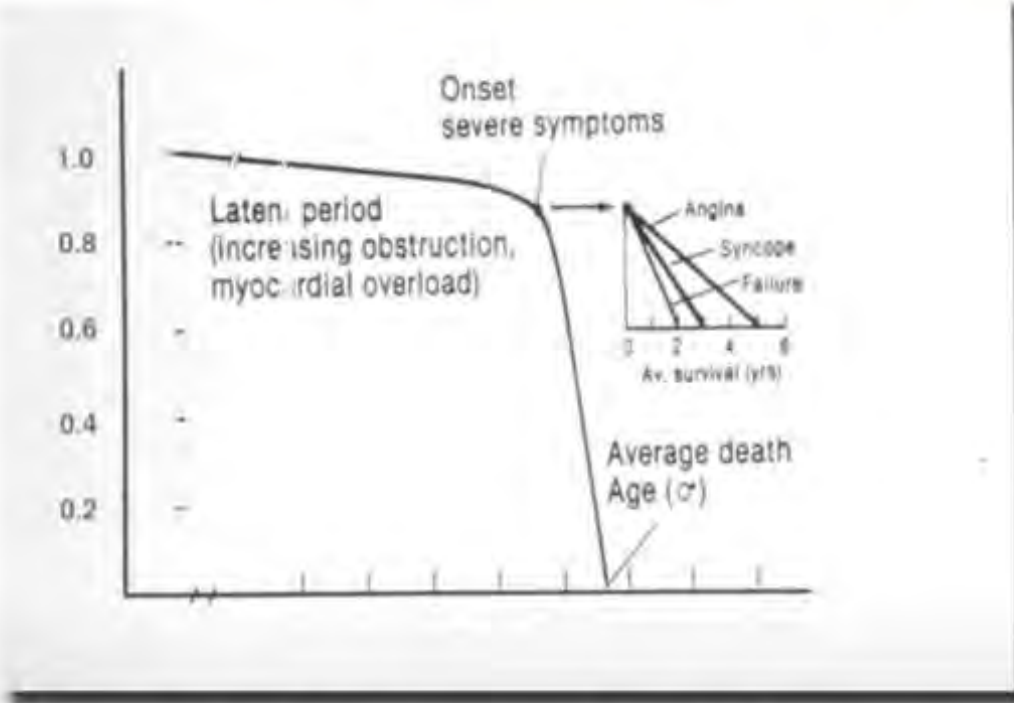


Aortic Valve



AS

Natural History of Aortic Stenosis



“Surgical intervention should be performed Promptly once ... minor symptoms occur”

Surgical AVR improves survival, symptoms, and LV function

Sources: Ross J Jr, Braunwald E. Aortic stenosis. *Circulation* 1968;38
C.M. Otto. Valve Disease: Timing of Aortic Valve Surgery. *Heart* 2000.



April 16, 2002 – First in Man TAVR via Transseptal Approach

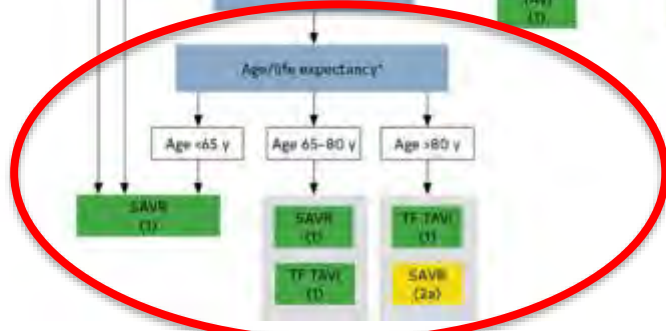
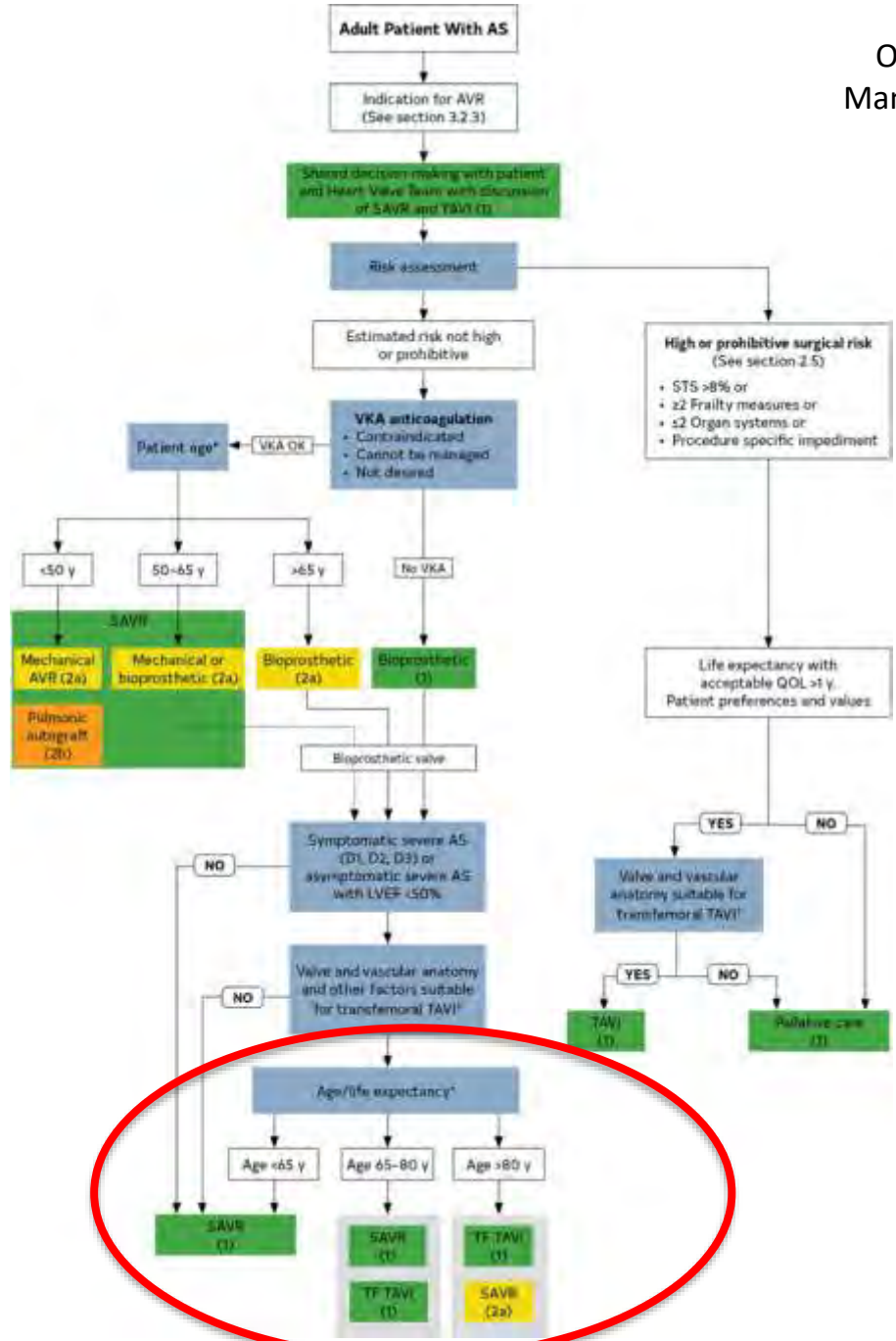
On April 16, 2002, at the Charles Nicolle University Hospital in Rouen, France, the Interventional Cardiologist, Professor Alain Cribier performed the first transcatheter aortic valve replacement procedure in the world. He used a Percutaneous Valve Technology (PVT) percutaneous heart valve.



Finalized device
Tri-leaflet valve (polymer, then bovine pericardium)
Stainless steel stent, single \varnothing 23mm



Otto C, Nishimura R, et al. 2020 ACC/AHA Guideline for the Management of Patients With Valvular Heart Disease. J Am Coll Cardiol. 2021 Feb, 77 (4) e25–e197



The Heart Team – Then and Now



Now – The Role of The Heart Team has Gotten More Complicated!

- ❖ Treatment focus has now shifted from the first to the second aortic intervention (i.e., to the treatment of bioprosthetic failure), regardless of whether the first intervention is SAVR or TAVR.
- ❖ **Anatomy:**
 - Will redo TAVR be straightforward or complex (i.e., require leaflet modification)?
 - Will coronary access be an issue, both now and with future THV in THV?
- ❖ **Durability:**
 - Bioprosthetic vs mechanical valve
 - How long will a bioprosthetic valve last?
- ❖ **Hemodynamics:**
 - What size (ID) and type of SAVR will be used?
 - Will the SAVR be compatible with future VIV TAVR?
- ❖ **Other Considerations:**
 - Significant mitral or tricuspid valve disease
 - Multivessel or significant CAD
 - Patient preference



Mature Space (20th anniversary of TAVR)
New Transcatheter Heart Valves (THV) for AS
Indication Expansion
New Transcatheter Heart Valves (THV) for AR



April 16, 2002; FIM-TAVI; Rouen, FR



EDWARDS SAPIEN


Medtronic Evolut



4 FDA-approved TAVR valves expected to be in the US market in 2024-2025!!



Navitor THV



Curved Aortic Cells
Reduces risk of injury to native structures

Inner NaviSeal™ Cuff
Fabric material maintains low profile and improved durability

Outer NaviSeal Cuff
Actively synchronizes to the cardiac cycle to seal and mitigate PVL

Large Cell Design
Minimizes coronary obstruction and improves coronary access and flow

Optimized Radial Force
For improved opening, expansion, anchoring, stability and sealing

Increased Sealing Zone
Mitigates PVL

Annulus Treatment Range
Treats 19 mm to 30 mm Annulus Diameters



ACURATE neo 2 THV

ACURATE neo2™

- Self-expanding nitinol frame with porcine pericardium leaflets
- Supra-annular positioning; two-step top-down deployment
- Treats annuli from 21mm to 27mm
- Sizes S – 23 mm, M – 25 mm, L – 27 mm, XL-29

Stabilization Arches

- Axial; self-aligning

Upper Crown

- Captures native leaflets and provides coronary clearance

Lower Crown

- Minimal protrusion into LVOT



ACURATE neo2™ Valve incorporates “Active PVseal” technology

- Inner and outer pericardial skirts (outer skirt covers to waist of stent)
- Designed to conform to native aortic annulus, actively seals to prevent PVL



Sapien X4

Enhancing versatility and control to provide personalized TAVR treatment

Adjustable valve sizes to optimize the index procedure while enabling lifetime therapy management (PCI, TAV in TAV)

SAPIEN 3 Ultra

4 valve sizes (3 mm increments)



20 mm



23 mm



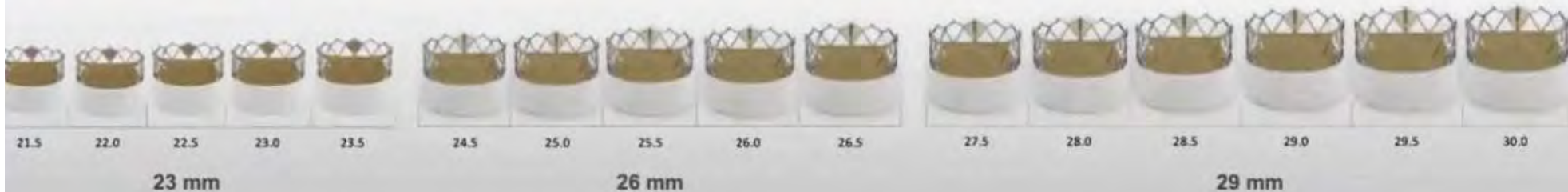
26 mm



29 mm

SAPIEN X4

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



Expanding TAVR Indications – Asymptomatic and Moderate AS


Interpreting Symptoms is Difficult

Interpreting symptoms is difficult, especially in elderly and sedentary populations.

up to
49%

Up to 49% of patients that report no symptoms at time of diagnosis have an abnormal stress test.⁴

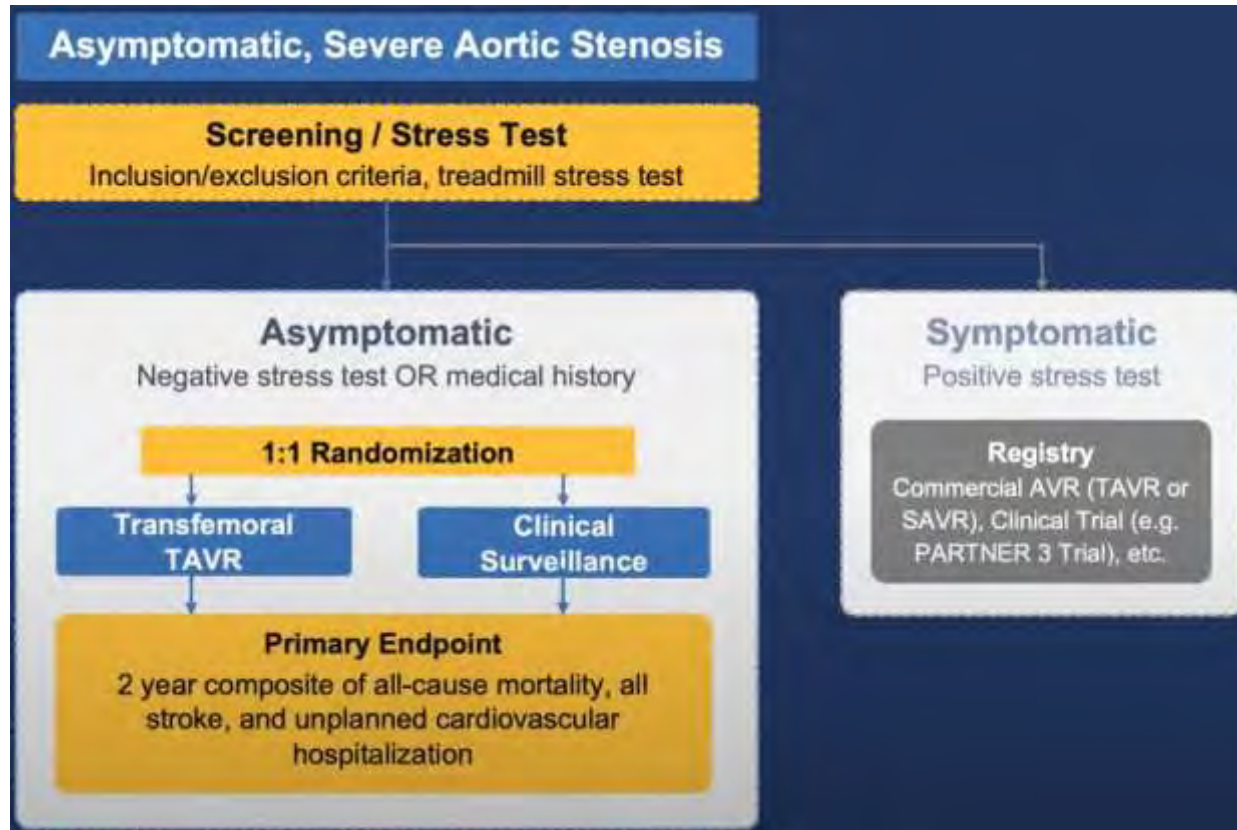
These patients have a 6-fold increased risk of cardiac death. AVR is recommended.



	Stage 0	Stage 1	Stage 2	Stage 3	Stage 4
Stages/Criteria	No Cardiac Damage	LV Damage	LA or Mitral Damage	Pulmonary Vasculature or Tricuspid Damage	RV Damage
Echocardiogram		Increased LV Mass Index >115 g/m ² (Male) >95 g/m ² (Female)	Indexed LA Volume >35 mL/m ²	Systolic Pulmonary Hypertension >60 mm Hg	Moderate-Severe Right Ventricular Dysfunction
		E/e' >14	Moderate-Severe Mitral Regurgitation	Moderate-Severe Tricuspid Regurgitation	
		LV Ejection Fraction <50%	Atrial Fibrillation		



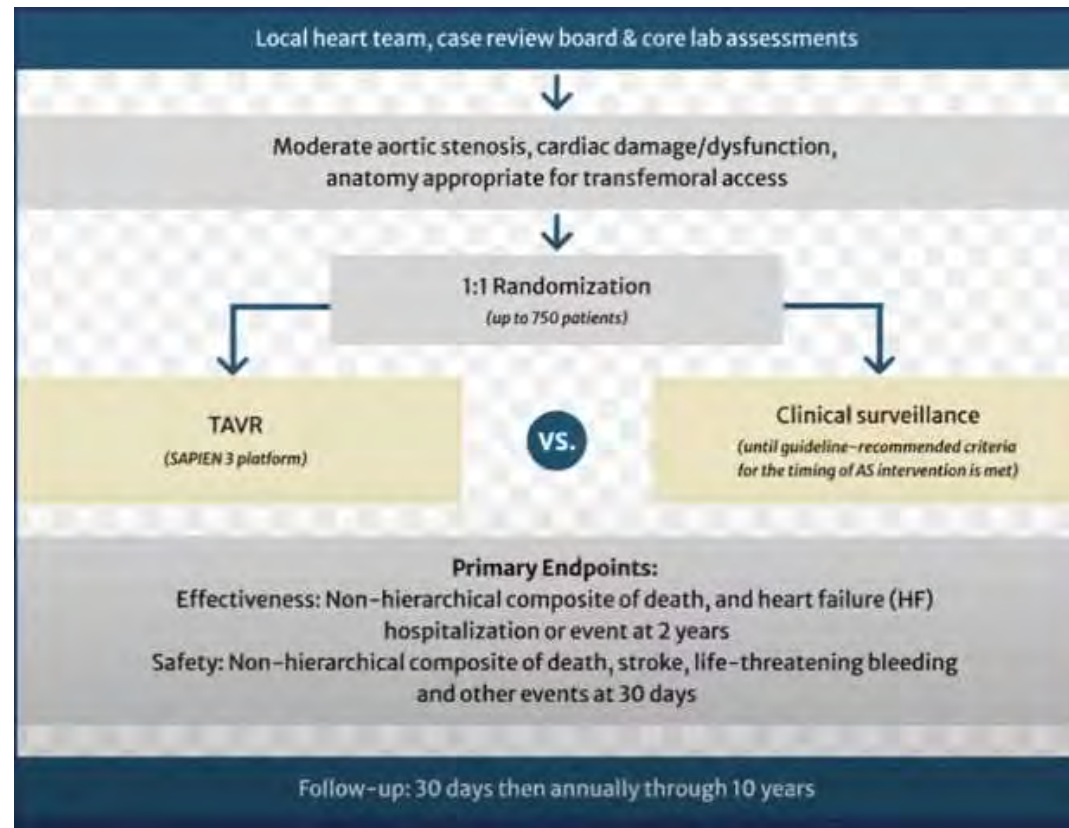
Early TAVR Trial



Généreux P, Schwartz A, Oldemeyer B, Cohen DJ, Redfors B, Prince H, Zhao Y, Lindman BR, Pibarot P, Leon MB. Design and rationale of the evaluation of transcatheter aortic valve replacement compared to surveillance for patients with asymptomatic severe aortic stenosis: The EARLY TAVR trial. *Am Heart J.* 2024 Feb;268:94-103. doi: 10.1016/j.ahj.2023.11.019. Epub 2023 Dec 4. PMID: 38056546.

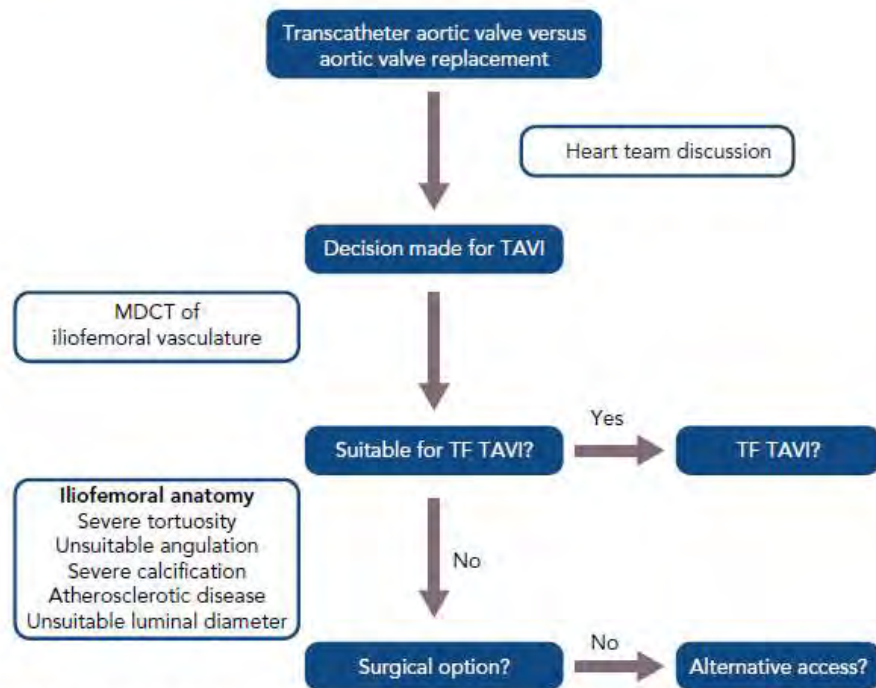


Moderate AS



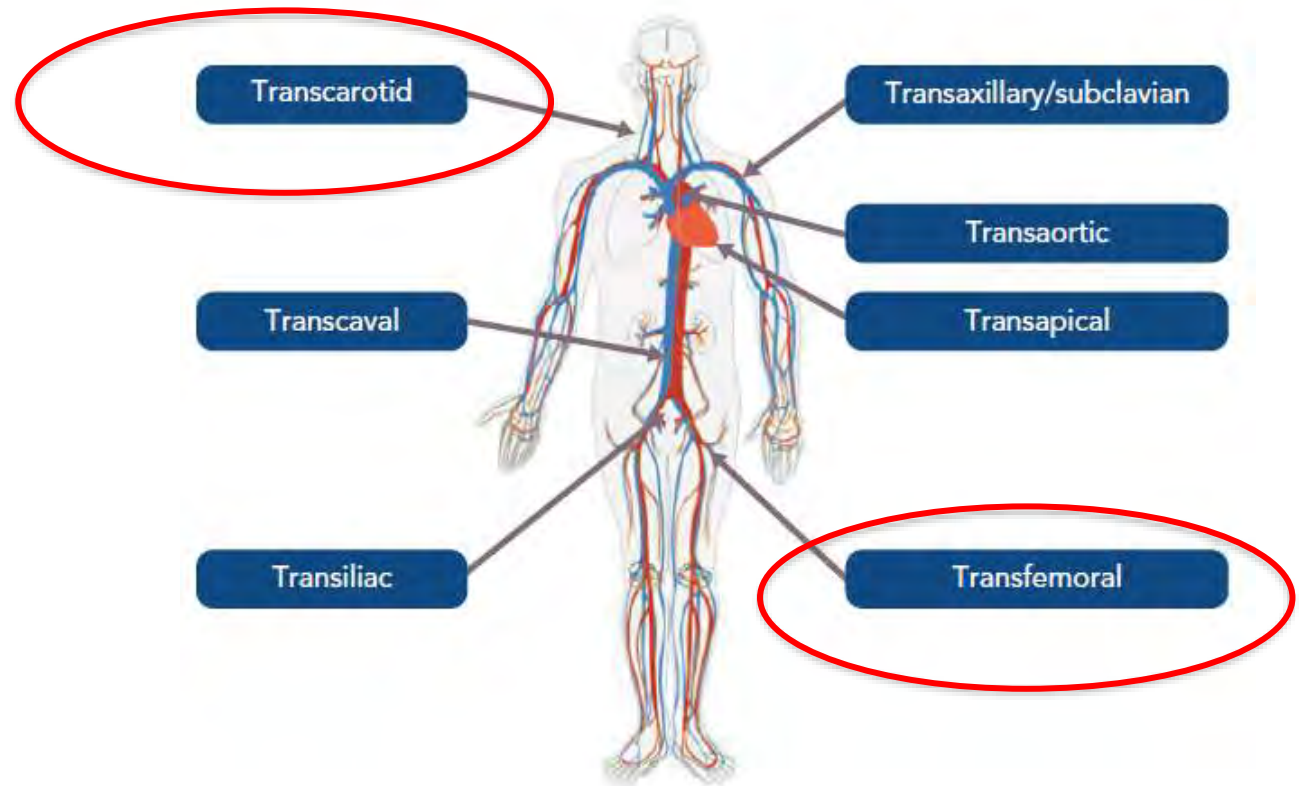
Access Sites for TAVR & Alternative Access TAVR

Figure 1: Algorithm for Deciding if Patient is a Candidate for Alternative Access Transcatheter Aortic Valve Implantation



MDCT = multiple detector CT; SAVR = surgical aortic valve replacement; TAVI = transcatheter aortic valve implantation; TF = transfemoral.

Figure 2: Access Options in Modern Transcatheter Aortic Valve Implantation



Alternative Access TAVR via the Carotid Artery

Room setup: L



DEFIBRILLATOR



ANESTHESIA



MONITOR 2



RAPID PACER



POWER INJECTOR

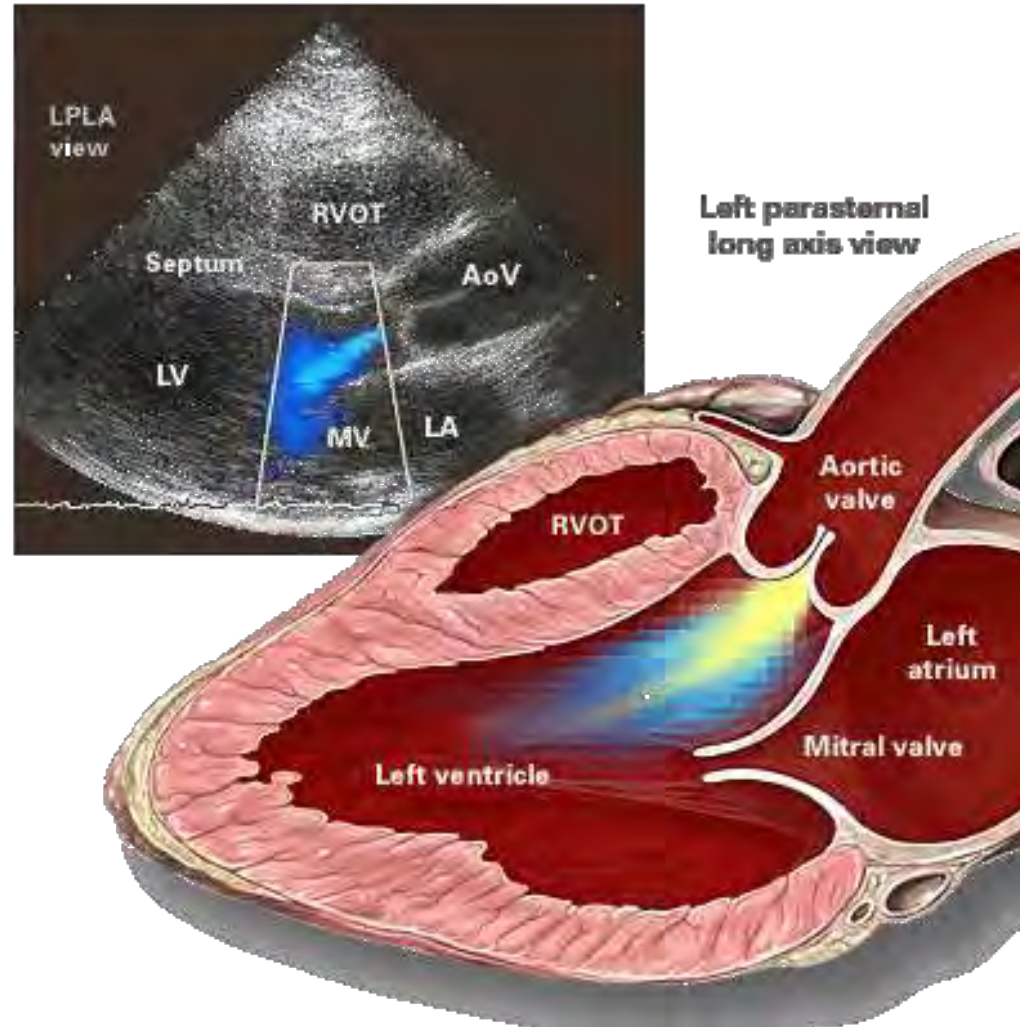
MONITOR 1

MONITOR 2

TABLE (+139 cm)

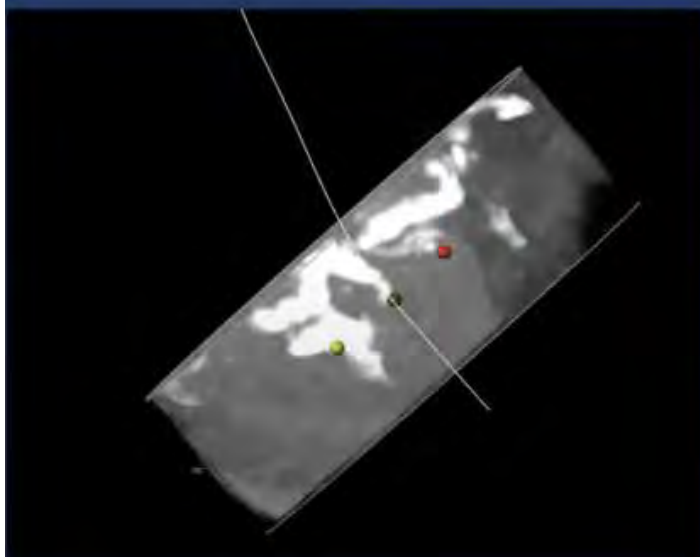


Aortic Regurgitation



Why Do We Need Dedicated THVs for Aortic Regurgitation

Aortic Stenosis = Calcium = Device Landing Zone




Aortic Regurgitation = No Calcium = Risk of Embolization



JenaValve

Trilogy THV System for Aortic Regurgitation



The diagram illustrates the components of the Trilogy THV System for Aortic Regurgitation. The central image shows the valve structure with labels for the 27-31 French Open Cell, Nitinol Frame, Flared Sealing Skirt, Porcine Pericardial Tissue, and Locator. The valve is available in three sizes with a perimeter ranging from 66-90mm.

27-31 French Open Cell


Nitinol Frame

Flared Sealing Skirt

Porcine Pericardial Tissue

Locator

Available in 3 sizes with a perimeter rang from 66-90mm



The diagram also shows the catheter deflector and preshaped sheath components. The catheter deflector is labeled as the Controller (Advance and Rotate Valve) and the Catheter Deflector. The preshaped sheath is labeled as the Preshaped Sheath.

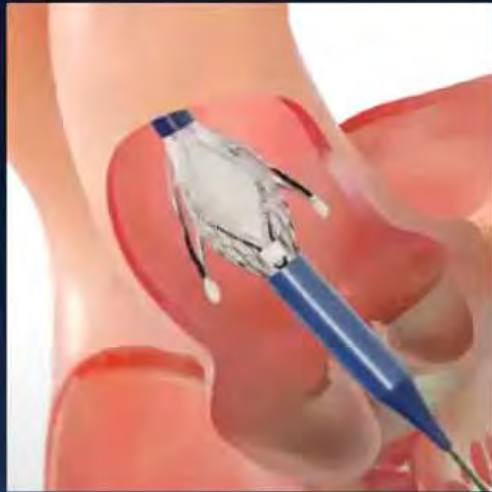
Controller (Advance and Rotate Valve)

Catheter Deflector

Preshaped Sheath



JenaValve Trilogy TAVR System



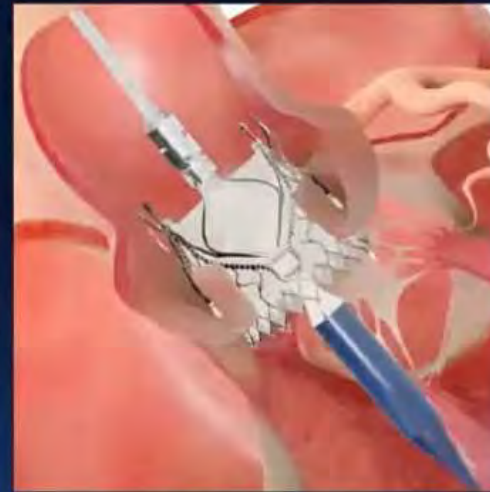
Alignment

- 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
- Flared sealing ring conforms to annulus



JenaValve Trilogy TAVR System

Procedural Outcomes

Outcome	% (n)
In-procedural Death	0
Annular Rupture	0
Ventricular Perforation	0
Coronary Obstruction	0
Valve Embolization	2.2% (4)
Aortic Dissection	0.6% (1)
Femoral Access Site Intervention	2.2% (4)
Success	
Technical Success	95.0% (171)
Device Success	96.7% (174)
Procedure Success	92.8% (167)

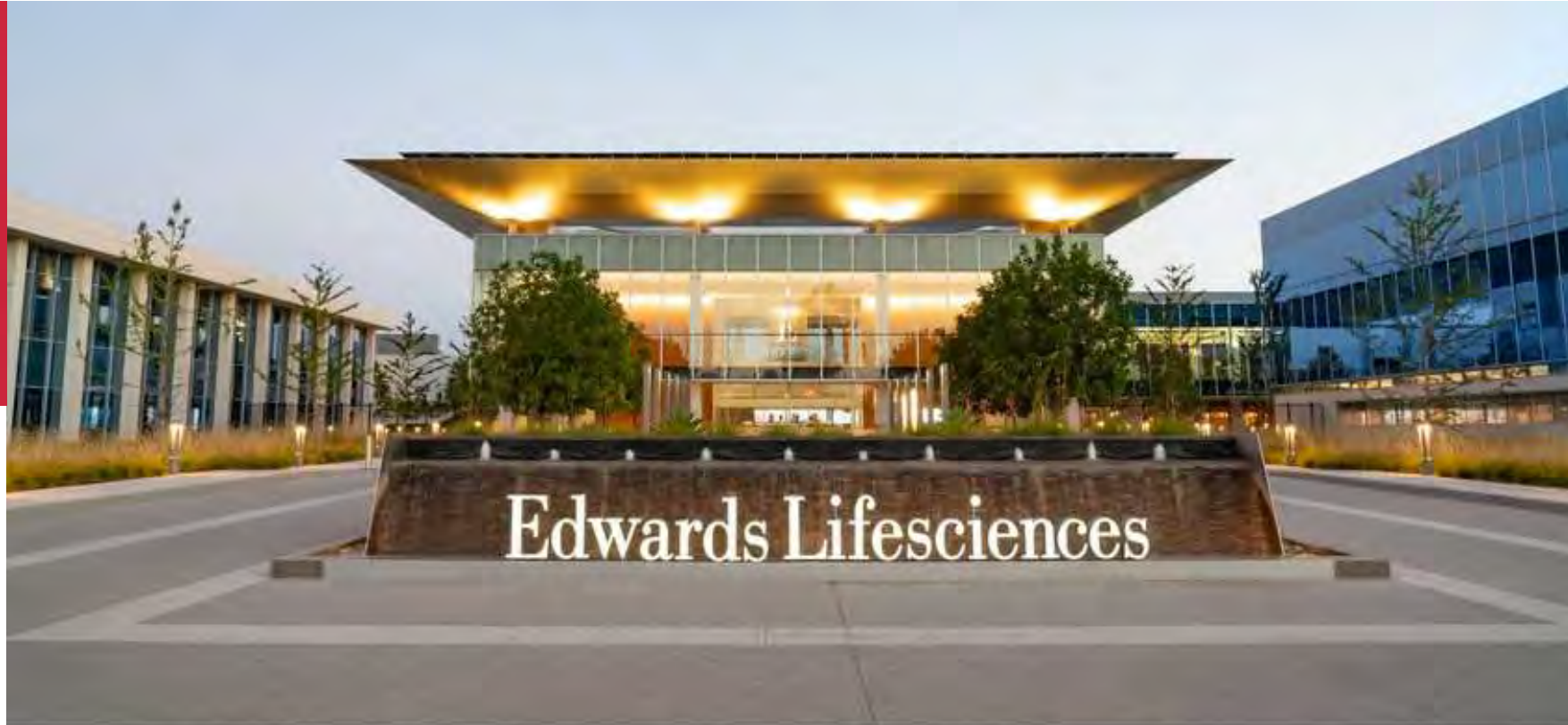
Primary Safety Endpoint at 30 Days

Variable	% (n)
All Cause Mortality	2.2% (4)
Cardiovascular Mortality	2.2% (4)
Any Stroke	2.2% (4)
Disabling Stroke	1.1% (2)
Nondisabling Stroke	1.1% (2)
Major/Life Threatening Bleeding	4.4% (8)
Major Vascular Complication	3.9% (7)
Acute Kidney Injury Stage 2 or 3 or Dialysis (7 Days)	1.1% (2)
Surgery/Intervention Related to the Device	2.8% (5)
New Pacemaker Implantation	24.0% (36)
Pre-existing PPM	16.7% (30)
≥ Moderate Paravalvular Regurgitation	0.6% (1)
Total	26.7% (48)



JenaValve

Press releases



Edwards Lifesciences reported its second-quarter earnings results this week, with growth coming in below expectations for its mainstay transcatheter aortic valve replacement business. (Edwards Lifesciences)

Edwards Lifesciences is dropping about \$1.6 billion on a pair of acquisitions to bolster its structural heart portfolio.



J-Valve

Bioprosthesis: self-expanding nitinol frame, bovine pericardial leaflets

Delivery System: steerable, flexible catheter, designed for TF access (18, 21 Fr)

Locating Feature: 3 anchor rings designed to conform to the native anatomy

Size matrix: 5 sizes, can treat wide range of anatomies (perimeters 57-104)

J-Valve TF Bioprosthesis

J-Valve TF Delivery Device

J-Valve Locating Feature

Valve Size	Annulus Diameter	Annulus Perimeter	Height
22 mm	18-21 mm	57-67 mm	17 mm
25 mm	21-24 mm	65-76 mm	19 mm
28 mm	24-28 mm	73-88 mm	22 mm
31 mm	27-30 mm	85-94 mm	25 mm
34 mm	30-33 mm	94-104 mm	25 mm

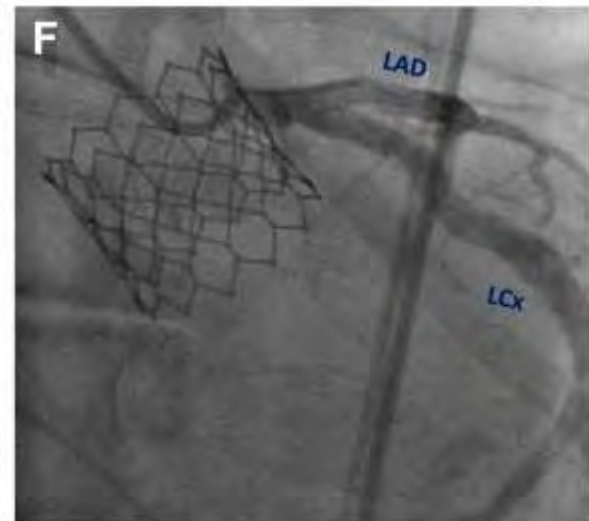
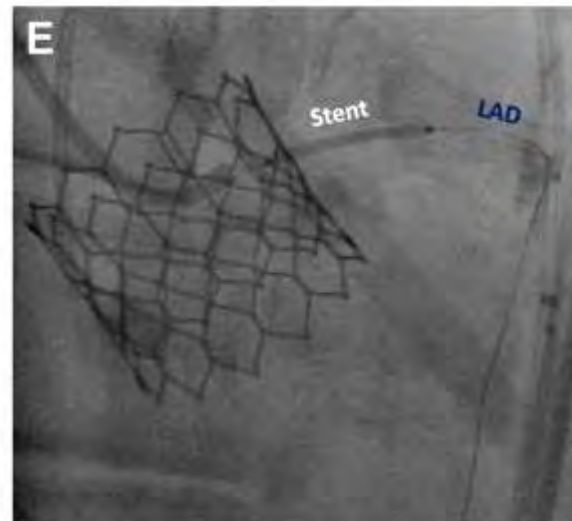
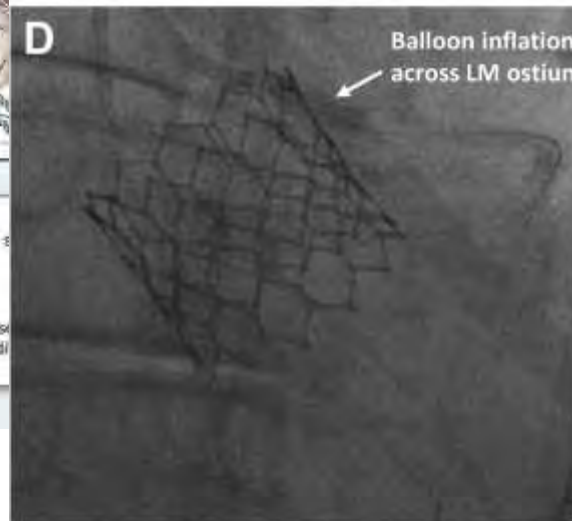
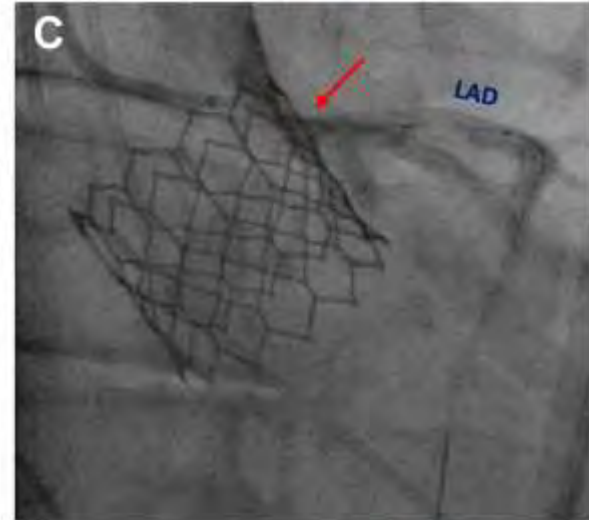
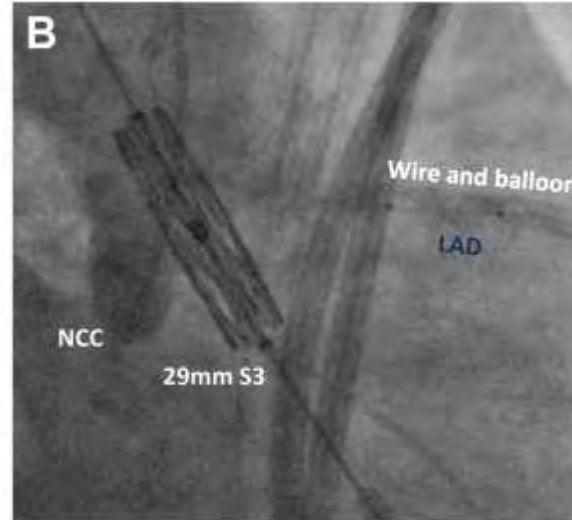
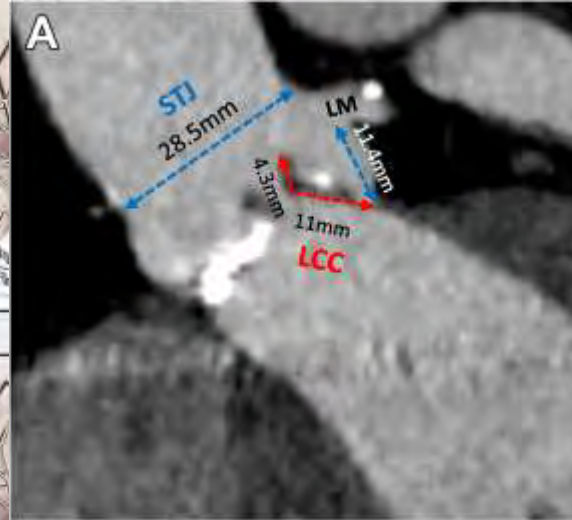
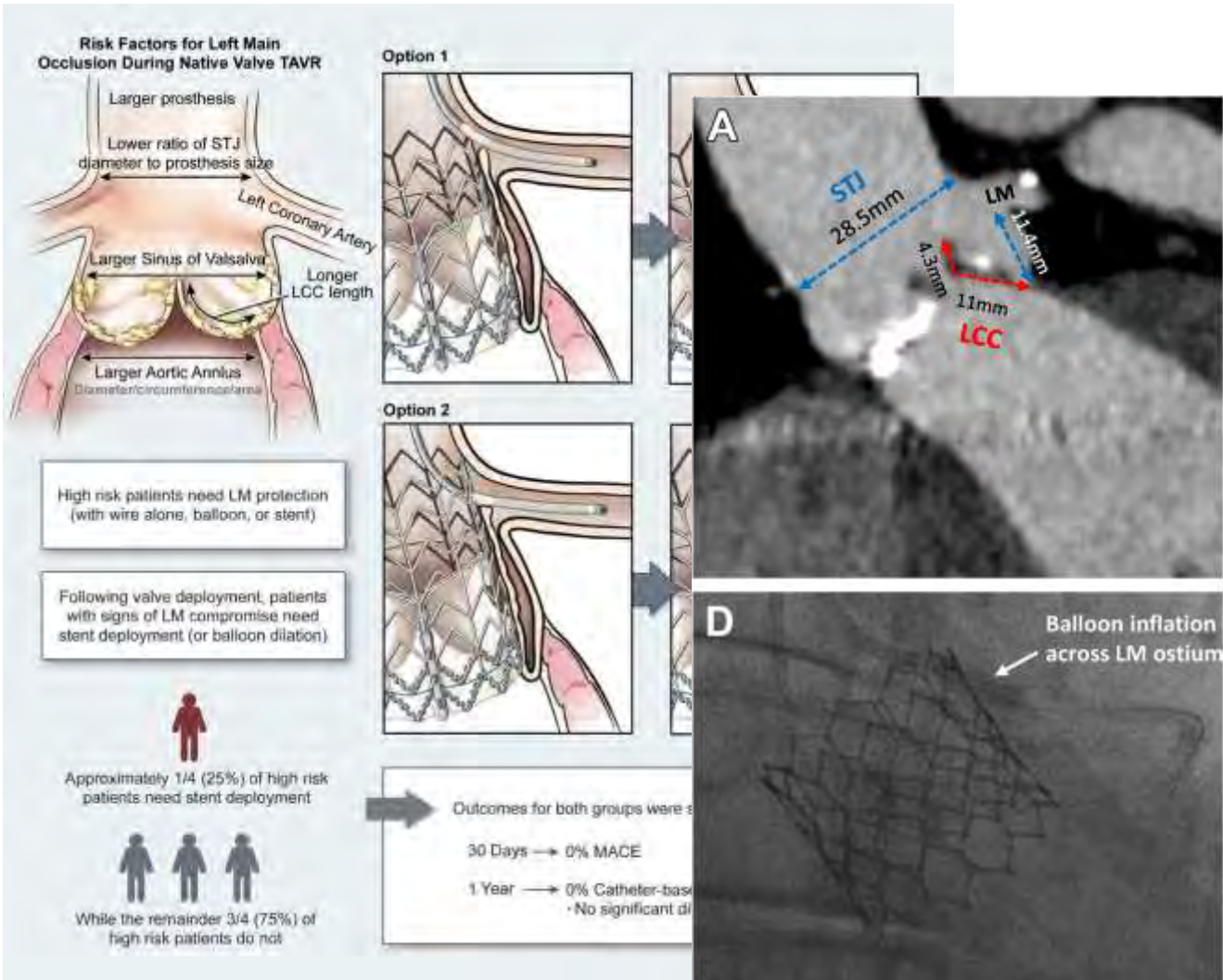
J-Valve Anchor Ring conforms to the native sinuses

J-valve. JC Medical. Burlingame, CA



LM Protection During TAVR

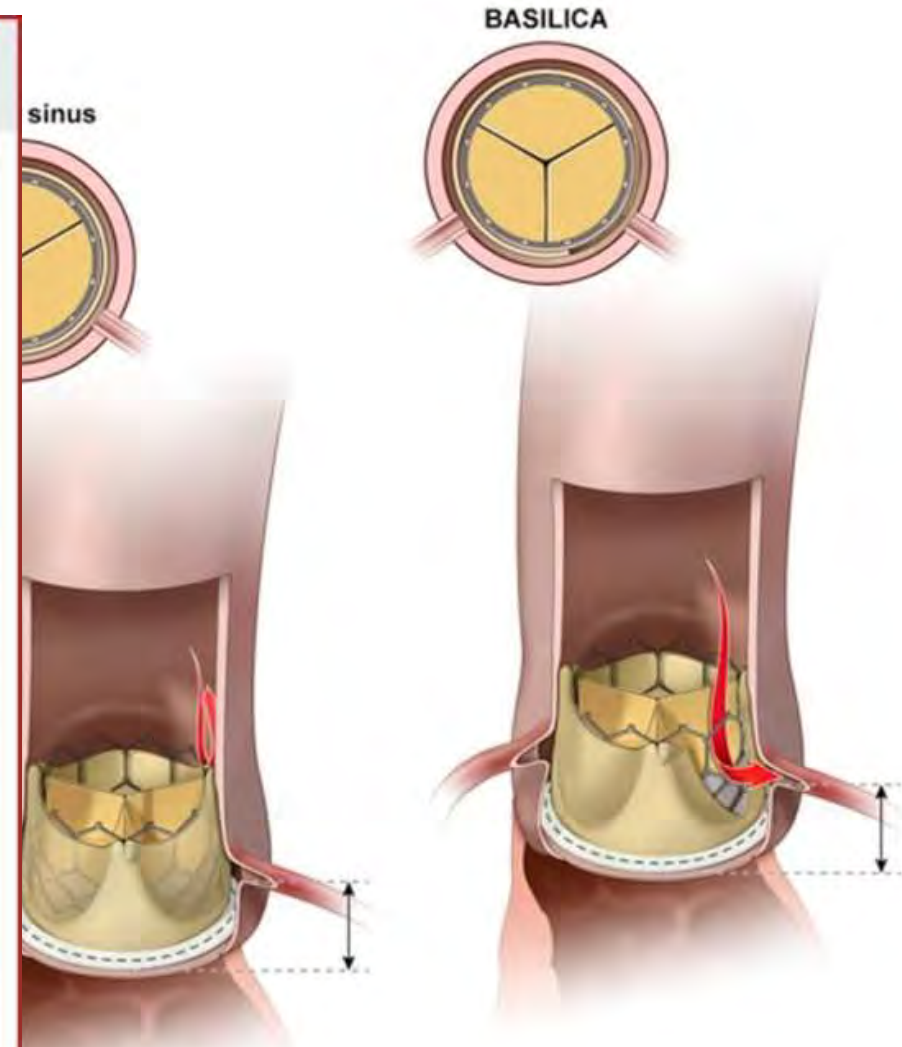
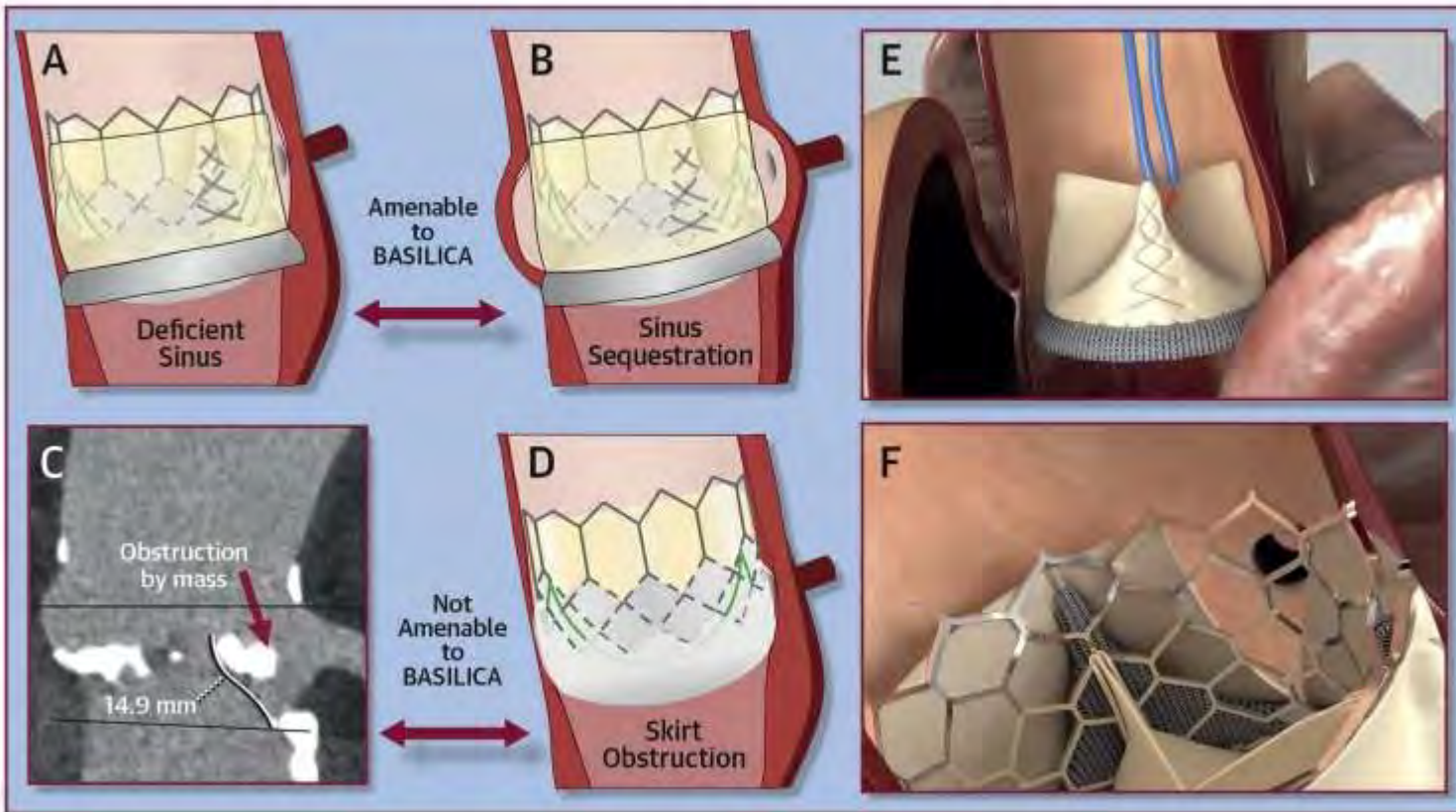
Left Main Protection During Transcatheter Aortic Valve Replacement With a Balloon-Expandable Valve
 Hsiung, Ingrid et al.
 Journal of the Society for Cardiovascular Angiography & Interventions, Volume 1, Issue 4, 100339



BASILICA (Bioprosthesis or native Aortic Scallop Intentional Laceration to prevent Iatrogenic Coronary Artery obstruction)

Capacious sinus Transcatheter







CENTRAL ILLUSTRATION: Mechanisms of Transcatheter Aortic Valve Replacement-Induced Coronary Obstruction and Mitigation by BASILICA



Mitral Valve

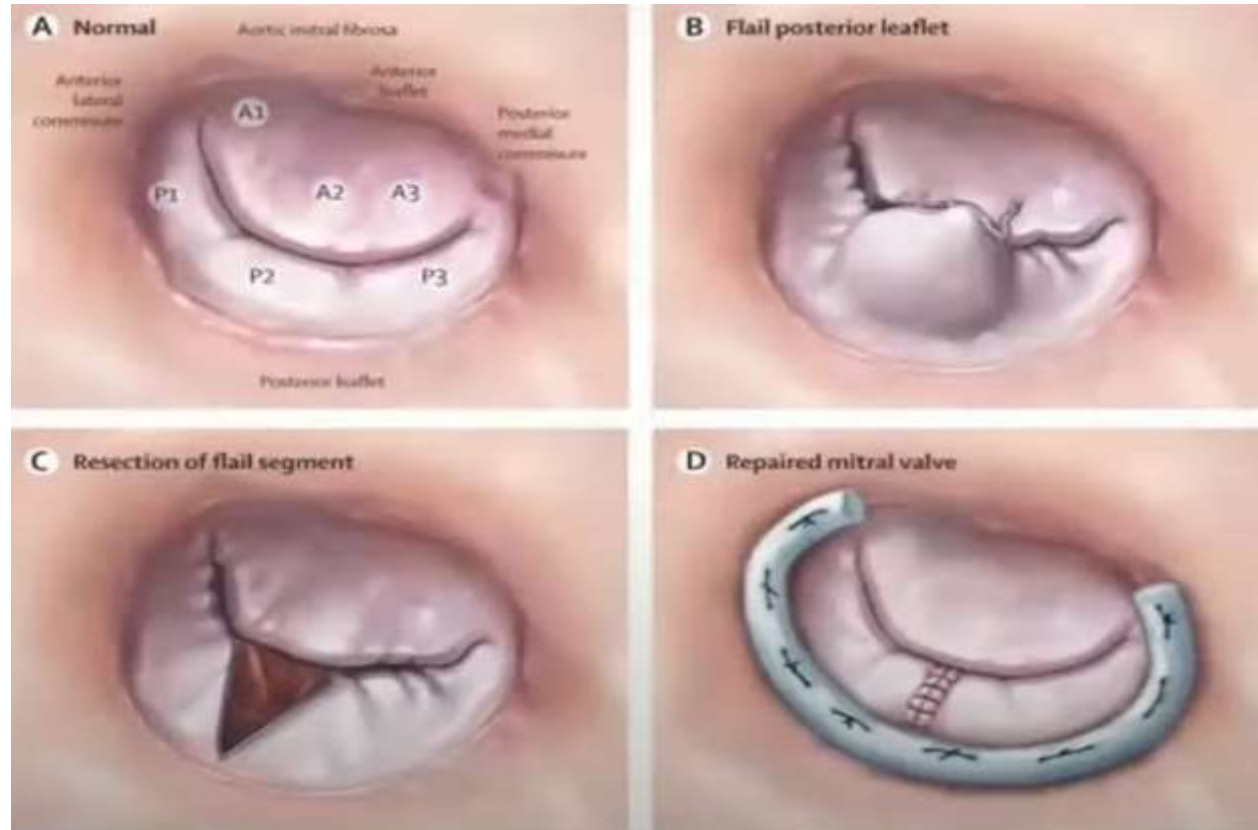


Classification of MR

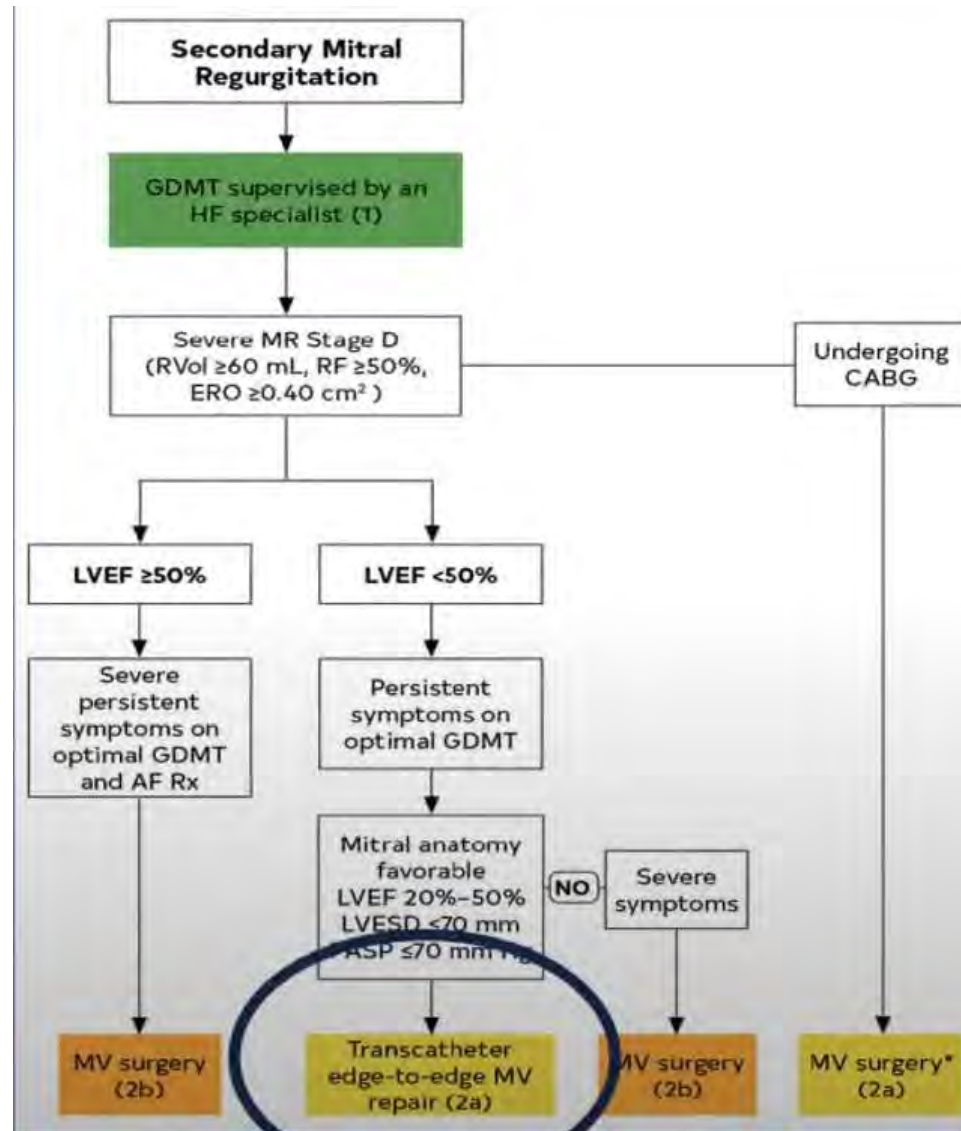
	Carpentier Type I <i>(normal leaflet motion and position)</i>	Carpentier Type II <i>(excess leaflet motion)</i>	Carpentier Type IIIa <i>(restricted leaflet motion in systole and diastole)</i>	Carpentier Type IIIb <i>(restricted leaflet motion in systole)</i>
PRIMARY MR	 <p>Leaflet Perforation Cleft</p>	 <p>Mitral Valve Prolapse</p>	 <p>Rheumatic Valve Disease Mitral Annular Calcification Drug Induced MR</p>	
SECONDARY MR	 <p>Atrial MR</p>	 <p>Nonischemic Cardiomyopathy</p>		 <p>Ischemic Cardiomyopathy</p>



Standard of Care for Primary MR with Acceptable Surgical Risk

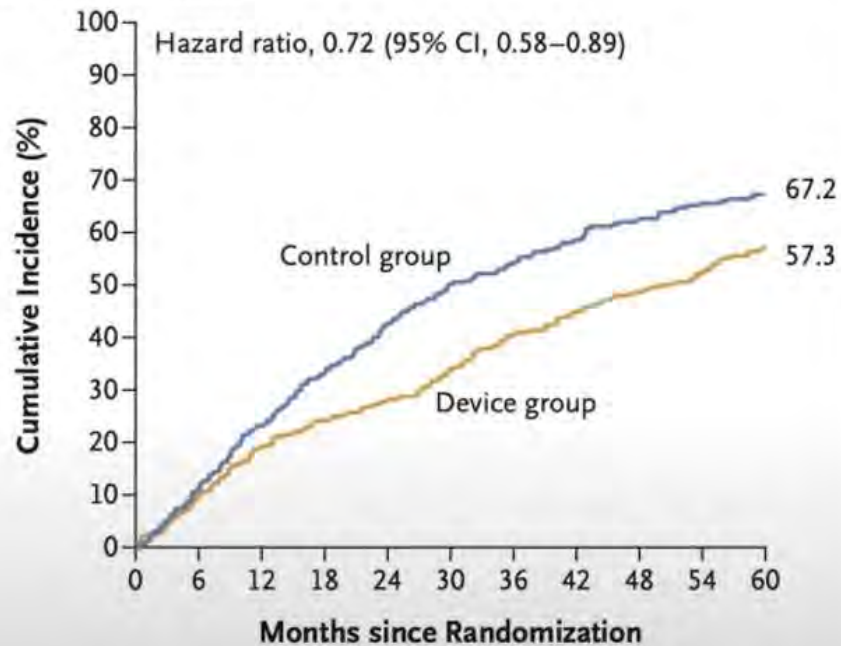


Guidelines



COAPT Trial 5-year Outcomes

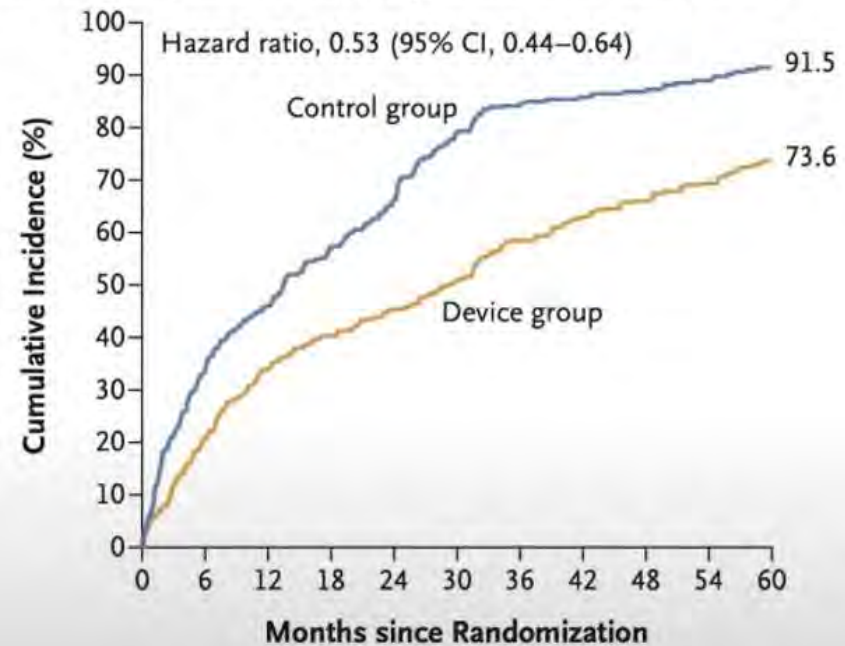
C Death from Any Cause



No. at Risk

Control group	312	272	224	189	157	135	122	107	94	84	59
Device group	302	269	238	219	205	186	167	151	138	124	79

D Death from Any Cause or First Hospitalization for Heart Failure



No. at Risk

Control group	312	206	157	122	95	58	43	37	33	26	17
Device group	302	236	194	174	158	141	118	105	93	81	52



M-TEER Suitability Stratification

Repair!		Replacement?	
Anatomical suitability for M-TEER		Centre experience	
Non-complex Ideal for M-TEER	Complex Suitable for M-TEER	Very complex Challenging for M-TEER	Criteria favouring replacement M-TEER hard or impossible
<ul style="list-style-type: none"> - Central pathology - No calcification - MVA >4.0 cm² - Posterior leaflet >10 mm - Tenting height <10 mm - Flail gap <10 mm - Flail width <15 mm 	<ul style="list-style-type: none"> - Isolated commissural lesion (A1/P1 or A3/P3) - Annular calcification without leaflet involvement - MVA 3.5-4.0 cm² - Posterior leaflet length 7-10 mm - Tenting height >10 mm - Asymmetric tethering²⁶ - Coaptation reserve <3 mm²⁴ - Leaflet-to-anulus index <1.2²⁵ - Flail width >15 mm - Flail gap >10 mm - Two jets from leaflet indentations 	<ul style="list-style-type: none"> - Commissural lesion with multiple jets - Annular calcification with leaflet involvement - Fibrotic leaflets - Wide jet involving the whole coaptation - MVA 3.0-3.5 cm² - Posterior leaflet length 5-7 mm - Barlow's disease - Cleft - Failed surgical annuloplasty 	<ul style="list-style-type: none"> - Concentric MAC with stenosis - MVA <3.0 cm² - Relevant mitral valve stenosis (mean gradient >5 mmHg) - Posterior leaflet <5 mm - Calcification in the grasping zone - Deep regurgitant cleft - Leaflet perforation - Multiple/wide jets - Rheumatic mitral stenosis



4th Generation MitraClip

WIDER CLIP ARMS, 4 CLIP SIZES

CONTROLLED GRASPING ACTUATION

CONTINUOUS LAP MONITORING

DELIVERY SYSTEM DESIGNED FOR THE MITRAL VALVE

MitraClip™ G4
1.0g mm

4 mm 6 mm

50% wider in the grasping area

4 mm 6 mm

50% wider in the grasping area

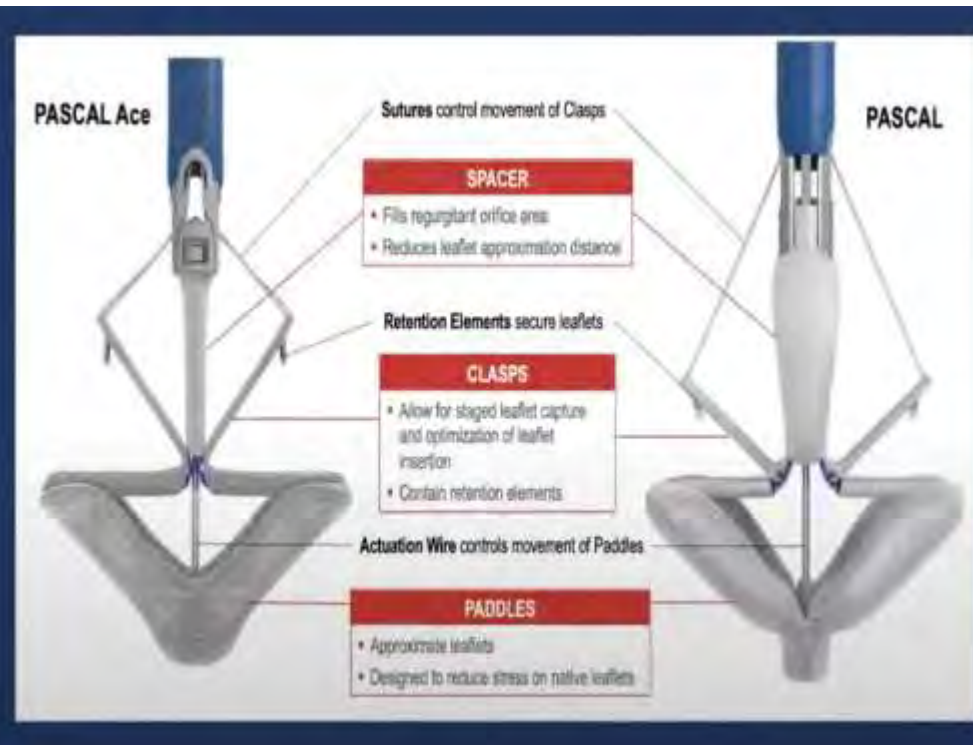
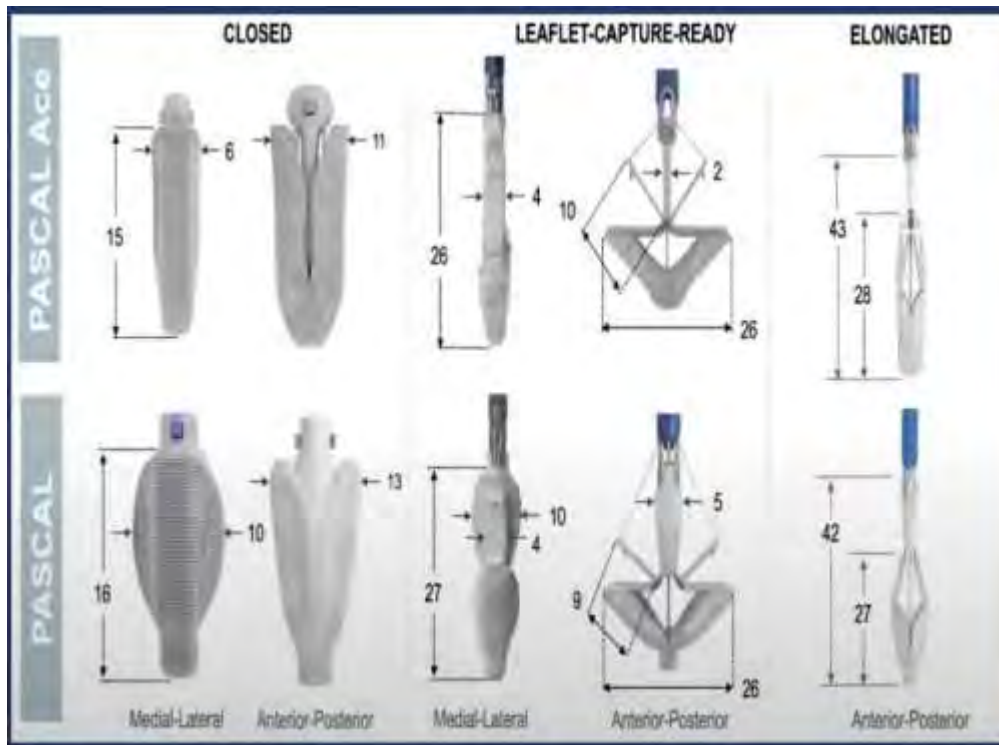
5 mm 12 mm

17 mm at 120 degrees
20 mm at 180 degrees

22 mm at 120 degrees
25 mm at 180 degrees



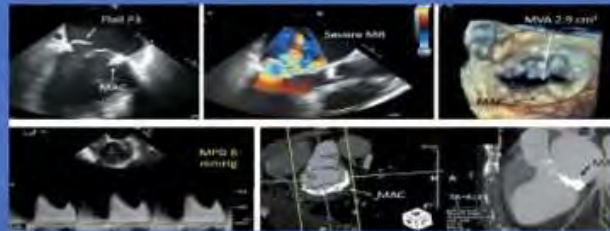
PASCAL



Anatomies Unsuitable for M-TEER

1. Anatomic classification associated with mitral stenosis following TEER (Carpentier Class IIIA)

Rheumatic disease, radiation, MAC, rings, small mitral valve area



2. Anatomic classification associated with inadequate reduction in MR

Perforation, active endocarditis, severe Barlow's, short or restricted posterior leaflet < 5 mm, clefts

3. Patient Factors associated with inability to perform TEER

Inability to perform TEE, inadequate grasping views, insufficient height, hostile IAS

4. Clinical Factors Associated with Futility

Limited life expectancy, insufficient MR, inotropic dependency



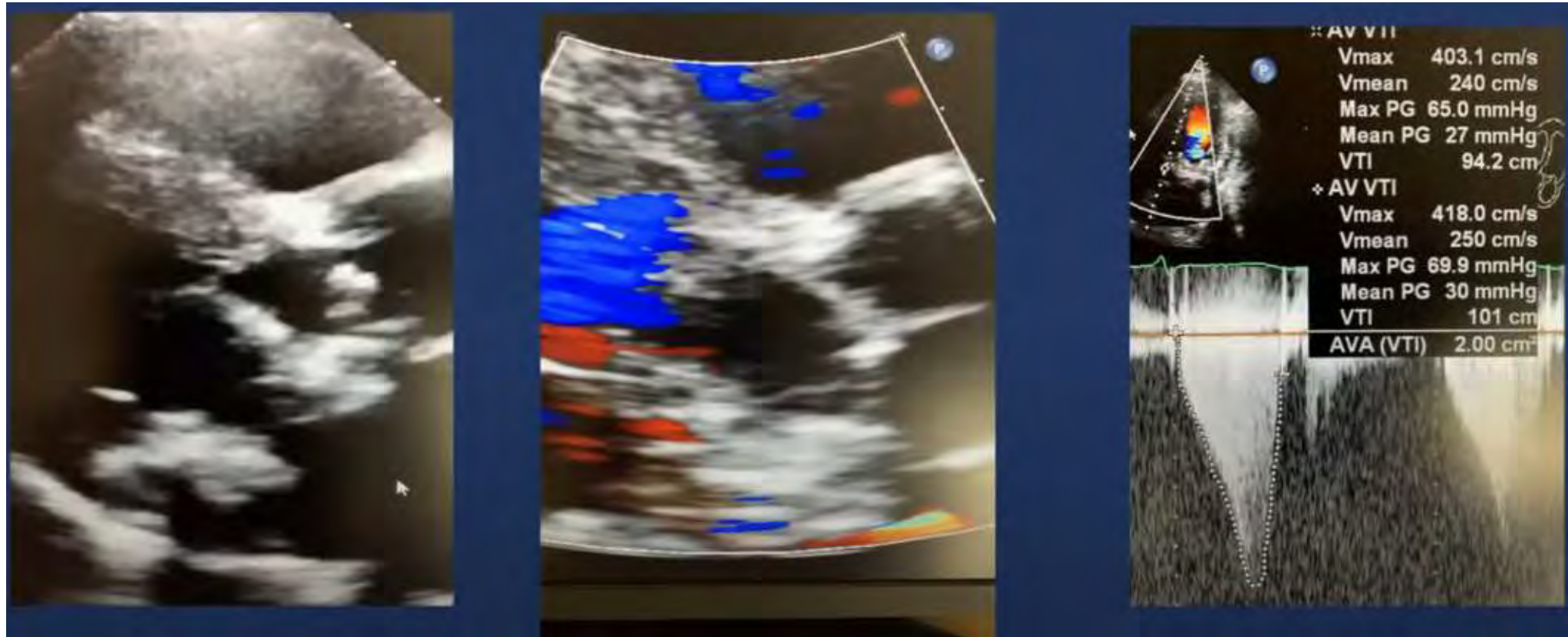
Enter - TMVR



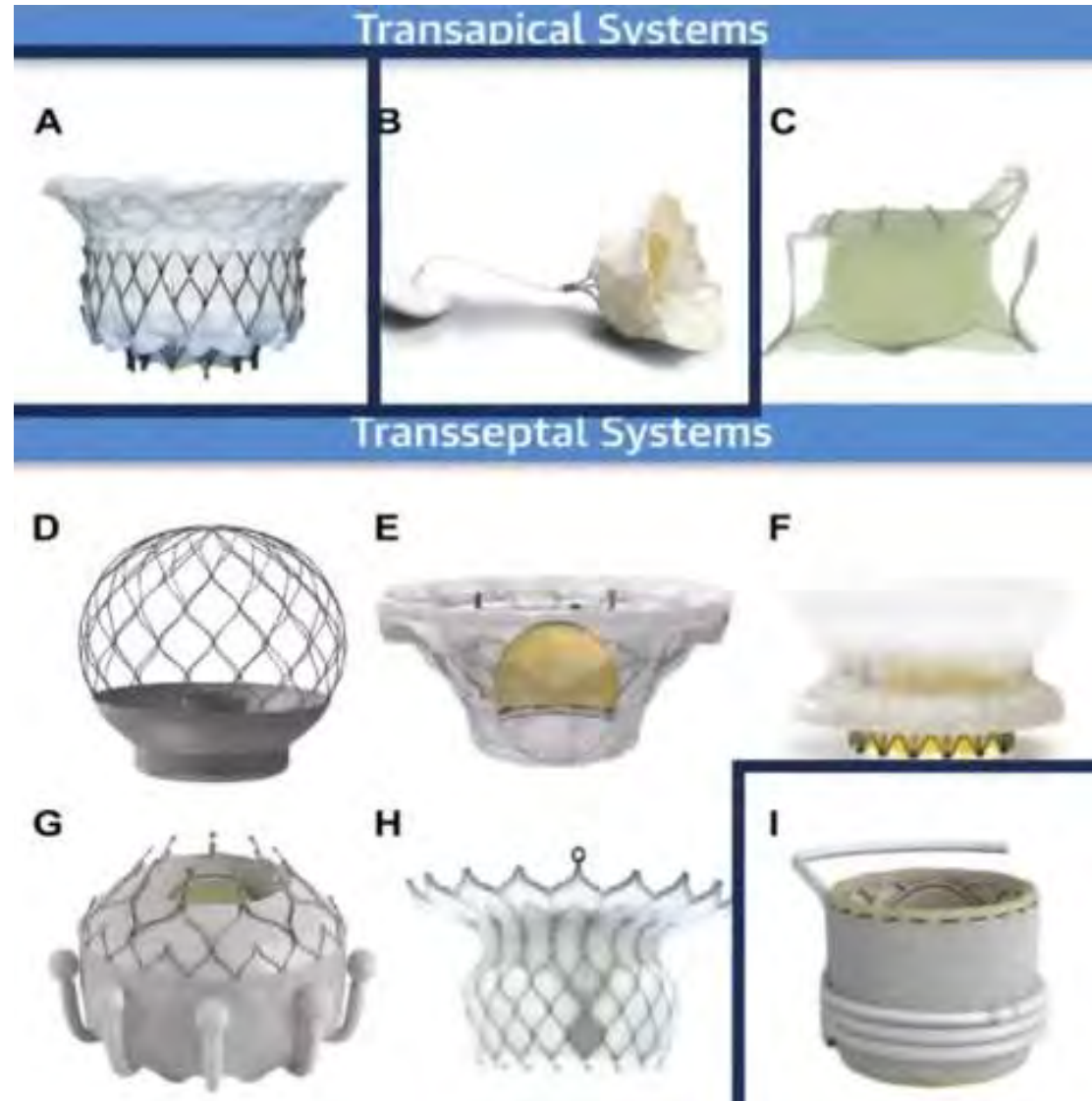
80% Screen Failure in Pivotal RCTs
Mostly due to anatomical limitations



LVOTO after TMVR



Current TMVR Device Landscape



Intrepid TMVR

Device Size (mm)	Perimeter (mm)	Diameter (mm)	Annulus Area (cm ²)
42	99 - 117	28 - 39	7.3 - 10.4
48	114 - 134	29 - 45	9.6 - 13.8

INTREPID™ TMVR SYSTEM
TRANSFEMORAL PRODUCT OVERVIEW

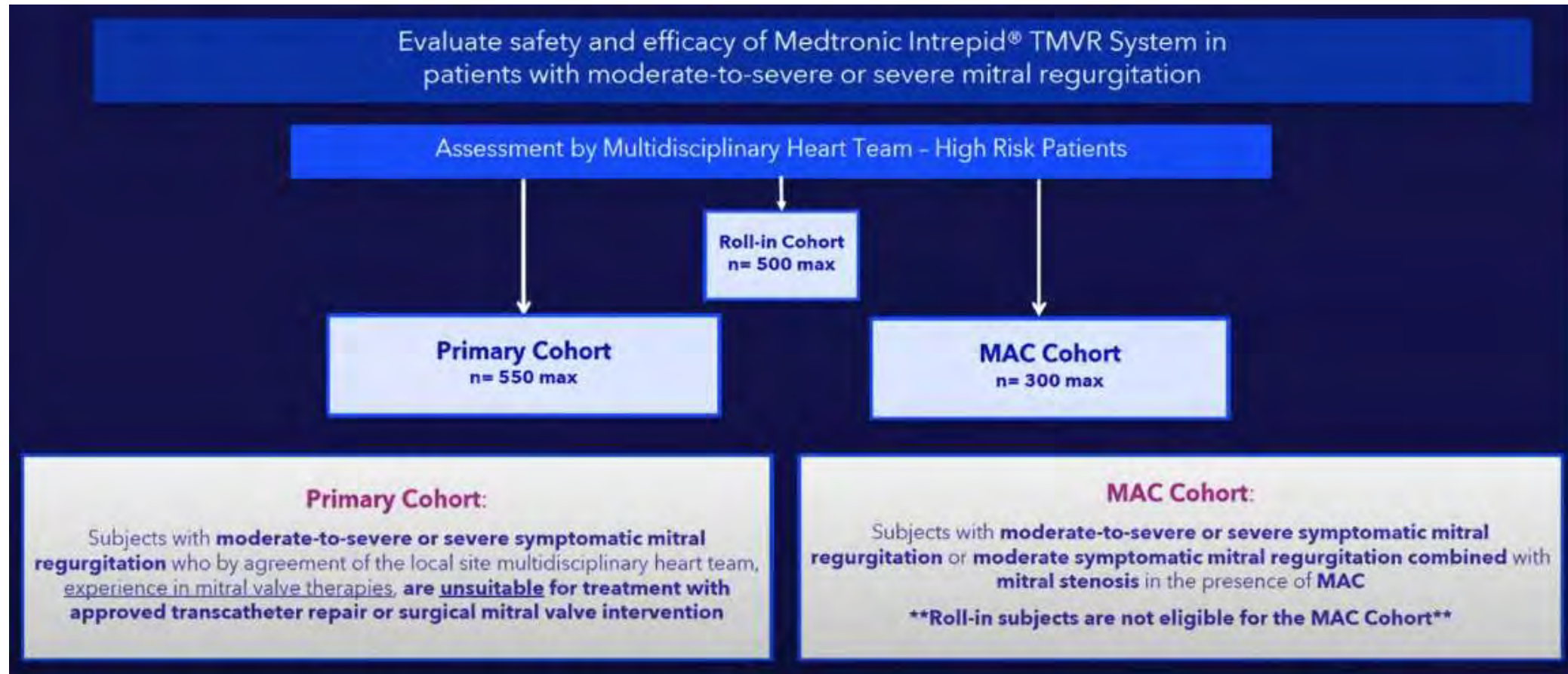
The Intrepid TMVR Intrepid Transfemoral System is comprised of the following components:

- Dual-stent, self-expanding nitinol
- Bovine pericardium valve (27 mm)
- Fixation: cork effect, small cleats
- 35 Fr system

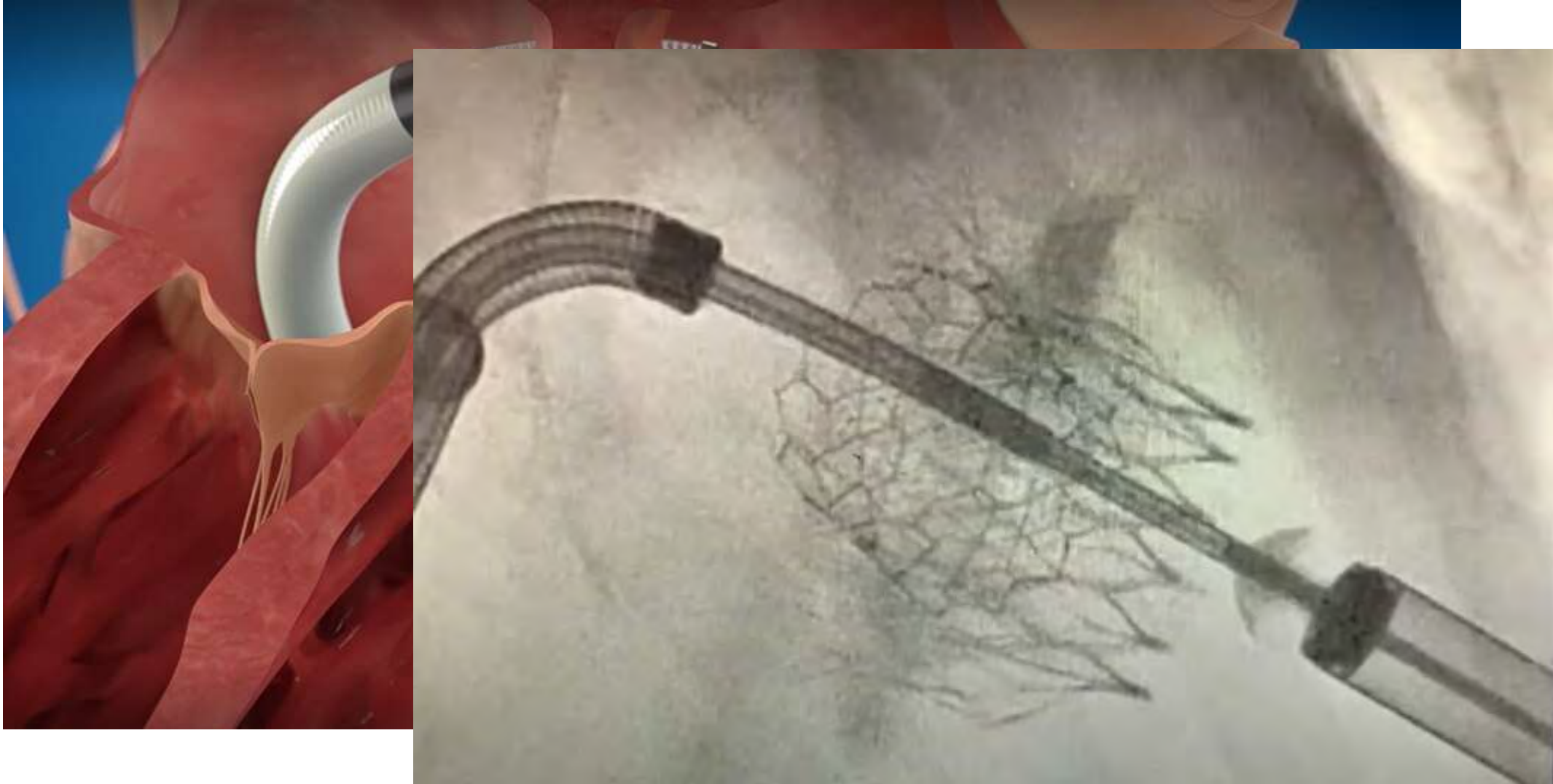
- Started as a transapical system but is now evolving to a TF system to allow for a TS approach
- Plan to bring down catheter size to 29 F thereby limiting iatrogenic ASD creation



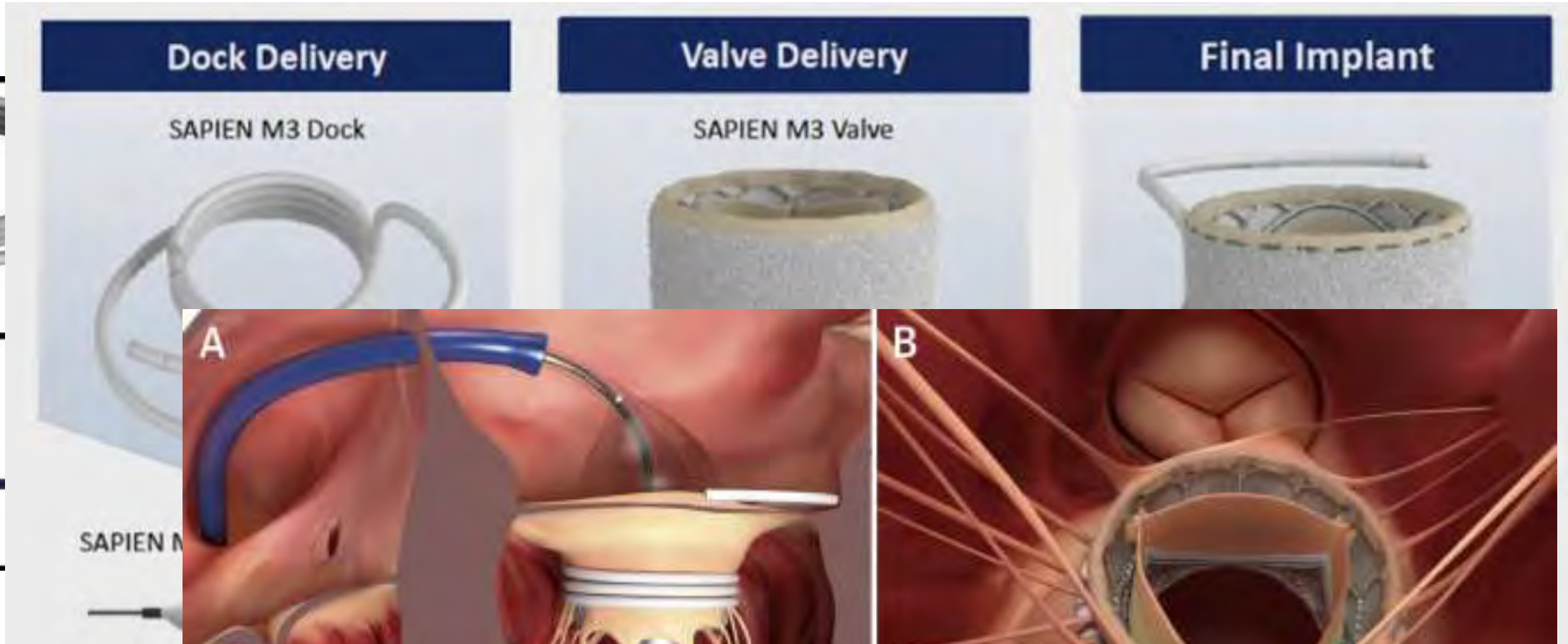
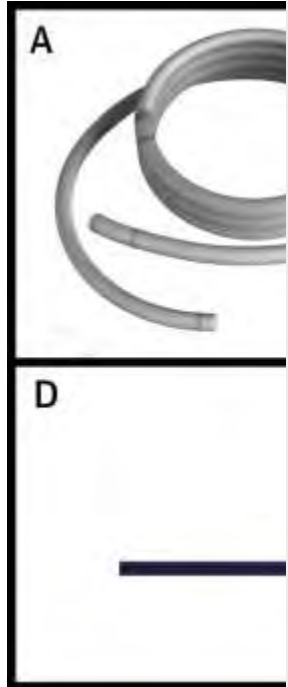
Intrepid TMVR – APOLLO Trial



Intrepid TMVR



Sapien M3 TMVR System (Edwards Lifesciences)



Sapien M3 TMVR System

Dock



Atrial turn

Functional turns

Ascending segment

PVL guard seating marker bands (double marker)

PVL guard

Retention braid

Encircling turn

Deployment marker band (single marker band) (under PVL guard)

SAPIEN M3 Valve

- Leverages 29 mm SAPIEN 3 valve tissue and frame
- Woven PET outer sealing skirt
- Covered apices

	29 mm
Tissue	Bovine pericardium, Therafix tissue process ¹
Frame	Cobalt-chromium alloy
Crimped height	31 mm
Expanded height	22.5 mm
Foreshortening	8.5 mm



Apex covers

Woven skirt

Essentially mimicking a 'valve-in-ring' implant



ENCIRCLE Trial

Subjects deemed unsuitable for commercial treatment options
as assessed by Heart Team

Main Study
(n = Up to 300)

MAC Registry
(n = 100)

Failed TEER Registry
(n = 100)

PRIMARY ENDPOINT:
Death & Heart Failure Rehospitalization at 1 year

Follow-up: 30 days, 6 mos, 1 year and annually through 5 years



Tendyne TMVR (Abbott)

UNIQUE VALVE-TETHER-PAD DESIGN

- Repositionable
- Fully retrievable
- No need for CPB or rapid ventricular pacing



APICAL PAD

- Placed over ventricular access site

TETHER DESIGN

- Separates sealing from securement
- Enables full retrievability

VALVE DESIGN

- Tri-leaflet, bioprosthetic valve
- Outer frame contoured to mitral annulus
- Variety of valve sizes and profiles to address broad range of patient anatomies



Tendyne TMVR (Abbott)

Valve

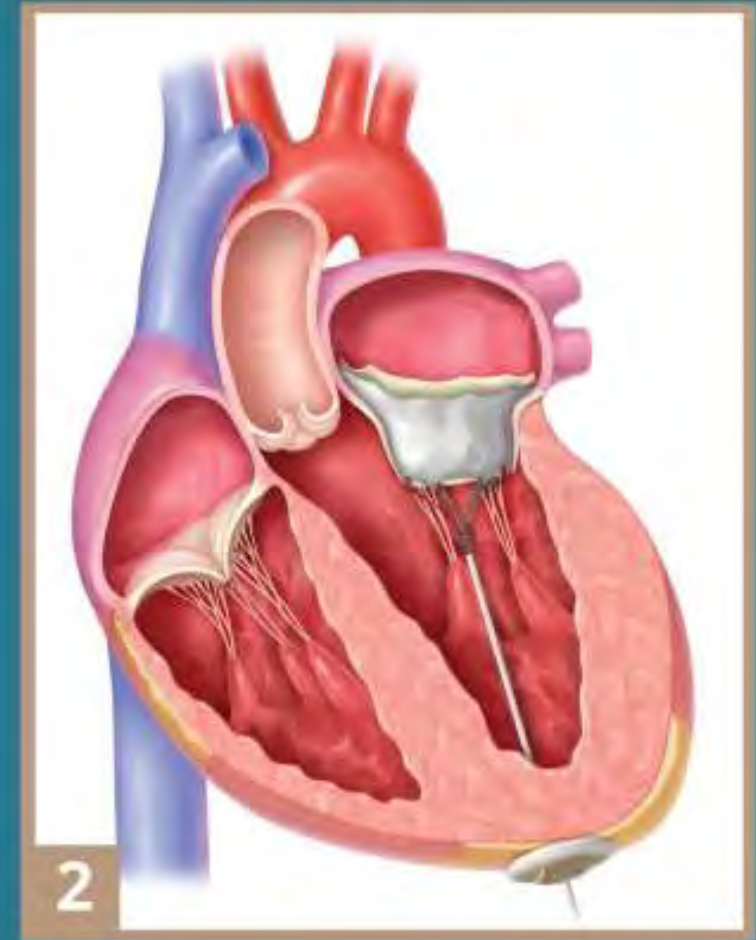
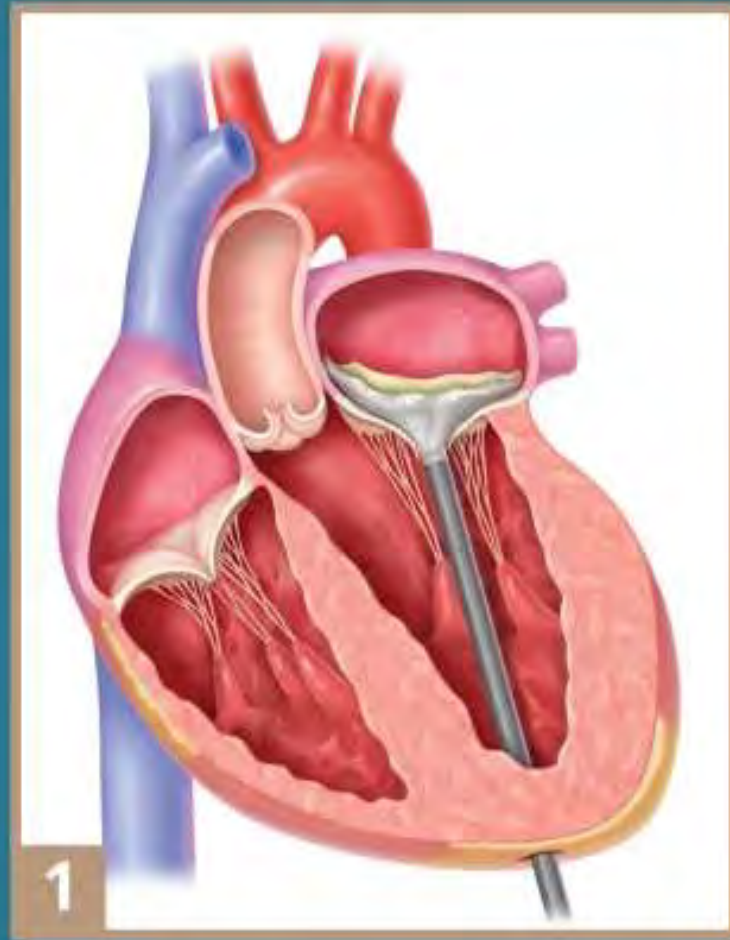
Dual-frame design provides customized anatomic fit and stable hemodynamic performance.

Inner frame

Circular self-expanding tri-leaflet, bioprosthetic valve.

Outer frame

Contoured design respects shape of the native mitral annulus for secure fixation and stability.



Tendyne TMVR

Valve

Dual frame design with ability to customize fit to individual patient anatomy

Inner frame

Self-expanding, tri-leaflet, bioprosthetic valve

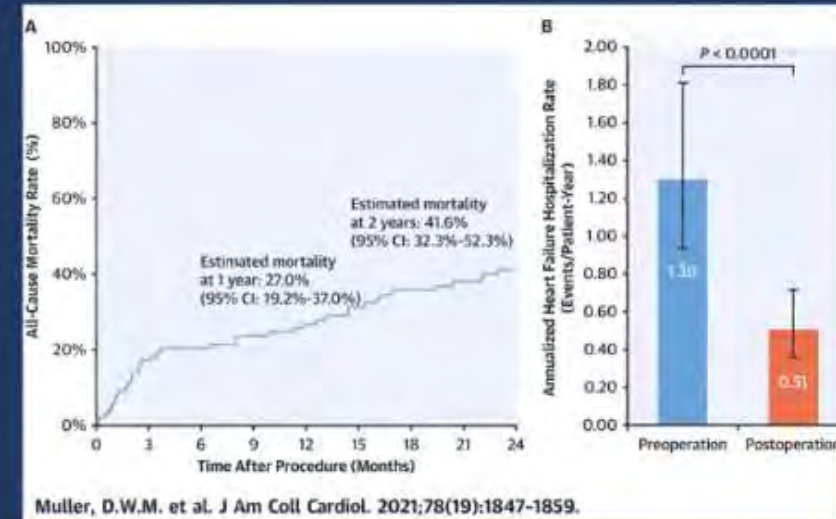
Outer frame

Conformed design supports a secure seal over native anatomy



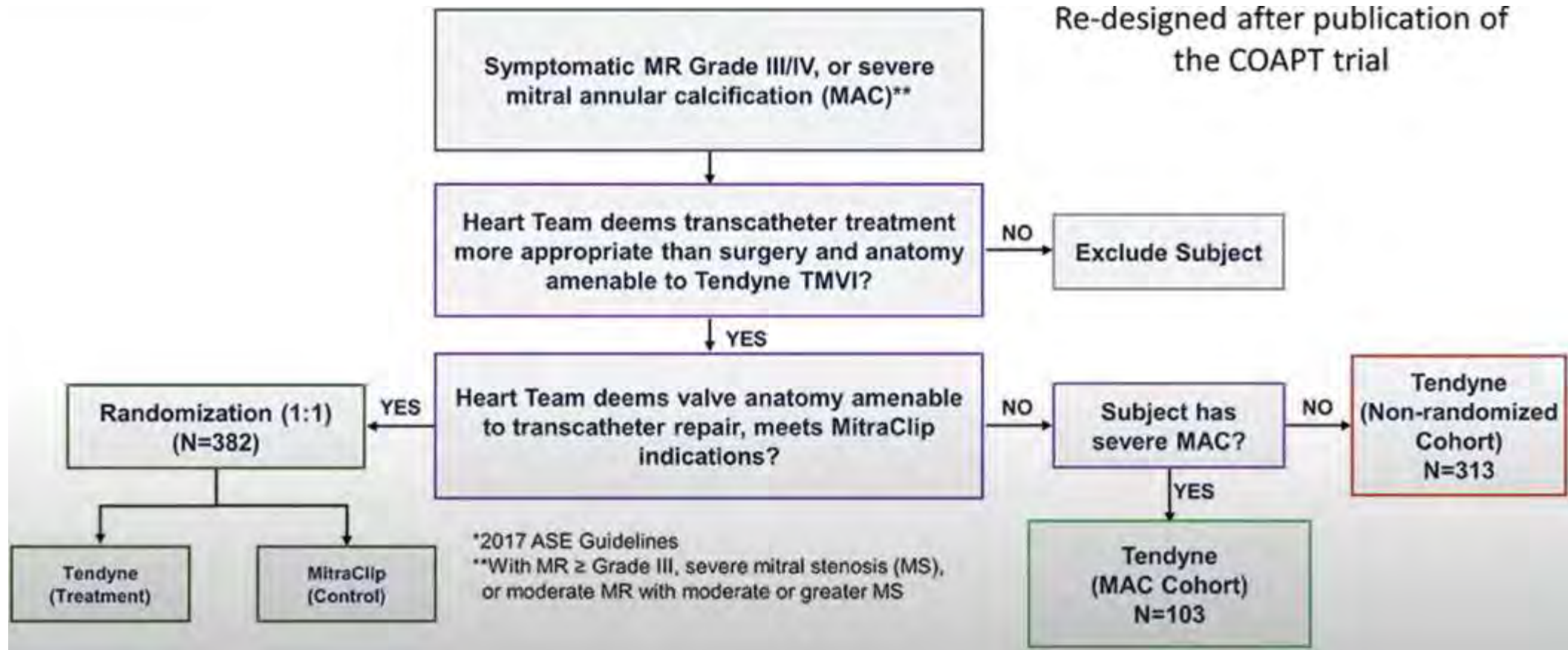
Anchoring system

Tether and pad



J Am Coll Cardiol. 2021

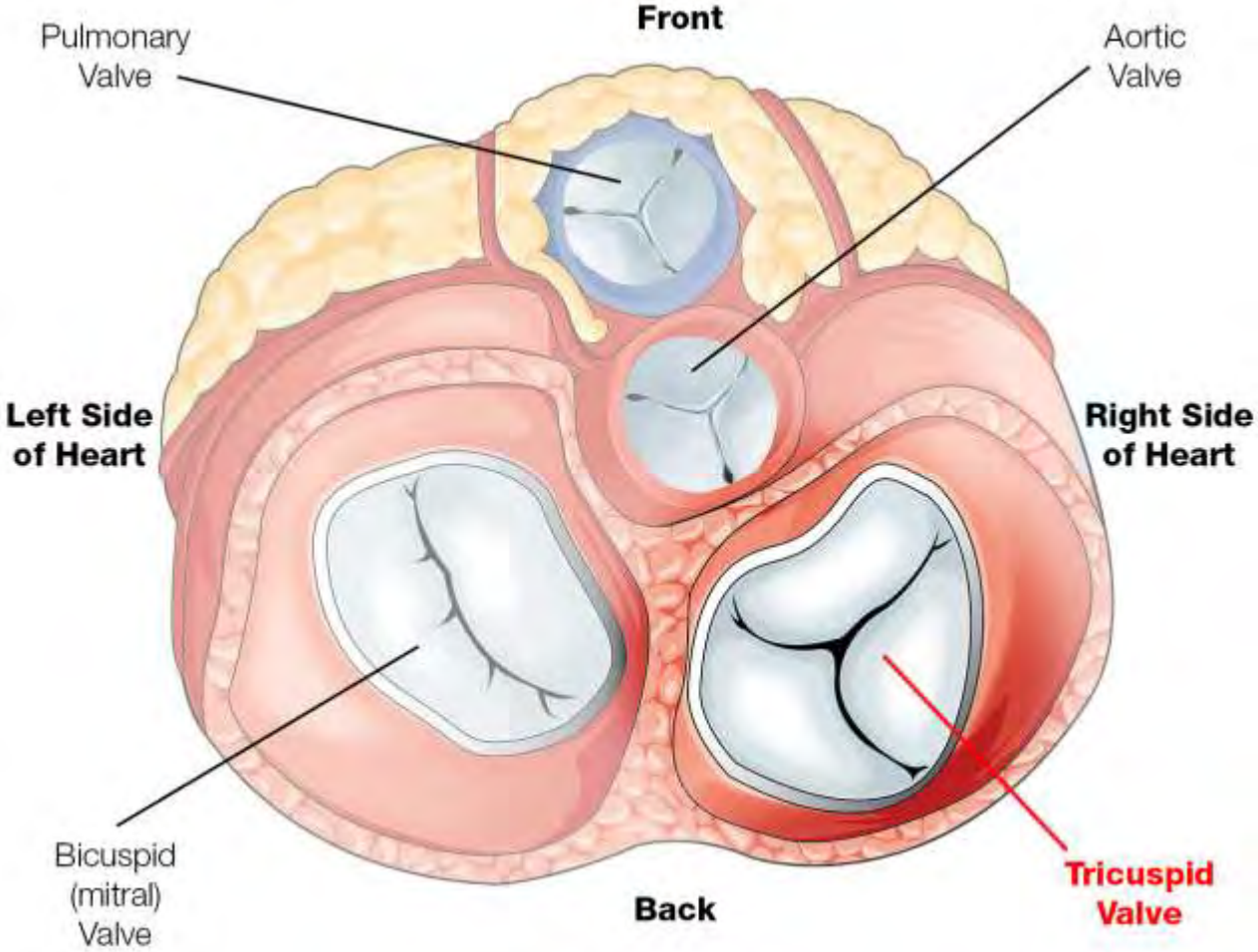
SUMMIT Trial



Tricuspid Valve

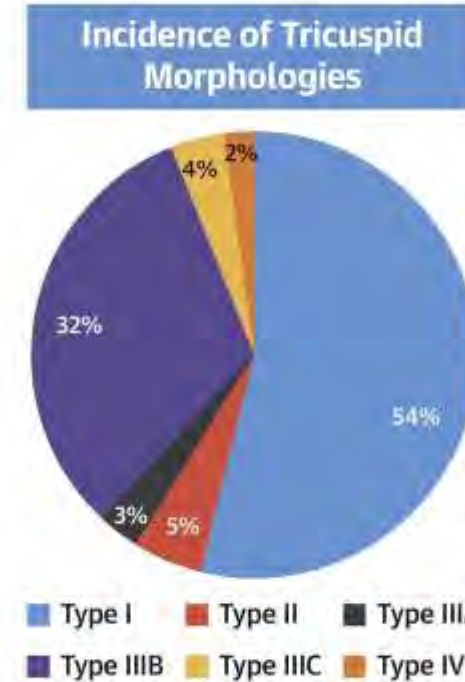
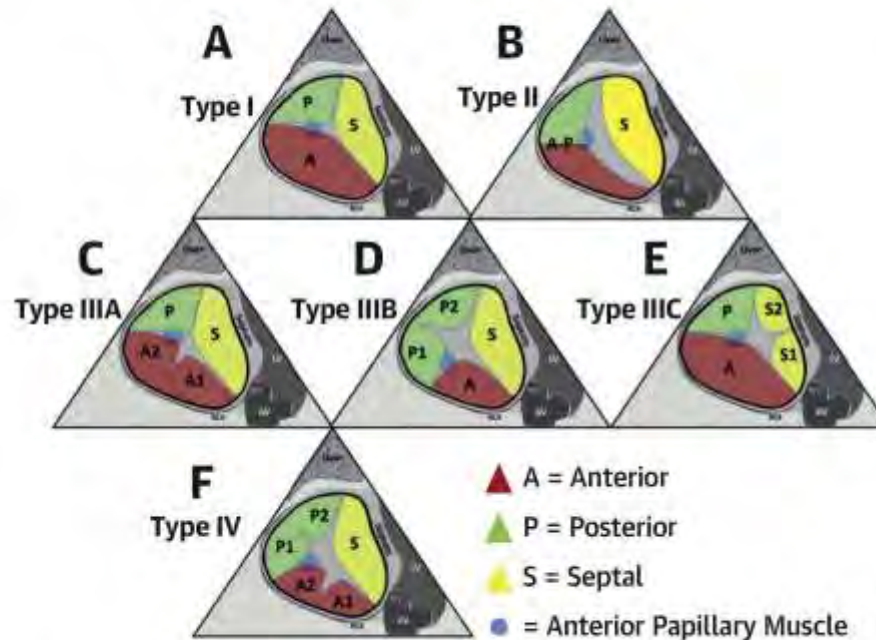


The "Forgotten" Valve



Not Often Tricuspid

CENTRAL ILLUSTRATION: Tricuspid Valve Nomenclature Classification Scheme



Hahn, R.T. et al. J Am Coll Cardiol Img. 2021;14(7):1299-305.

Approx only 54% of Tricuspid Valves are actually tricuspid



Tricuspid Regurgitation Causes

CIED Related TR

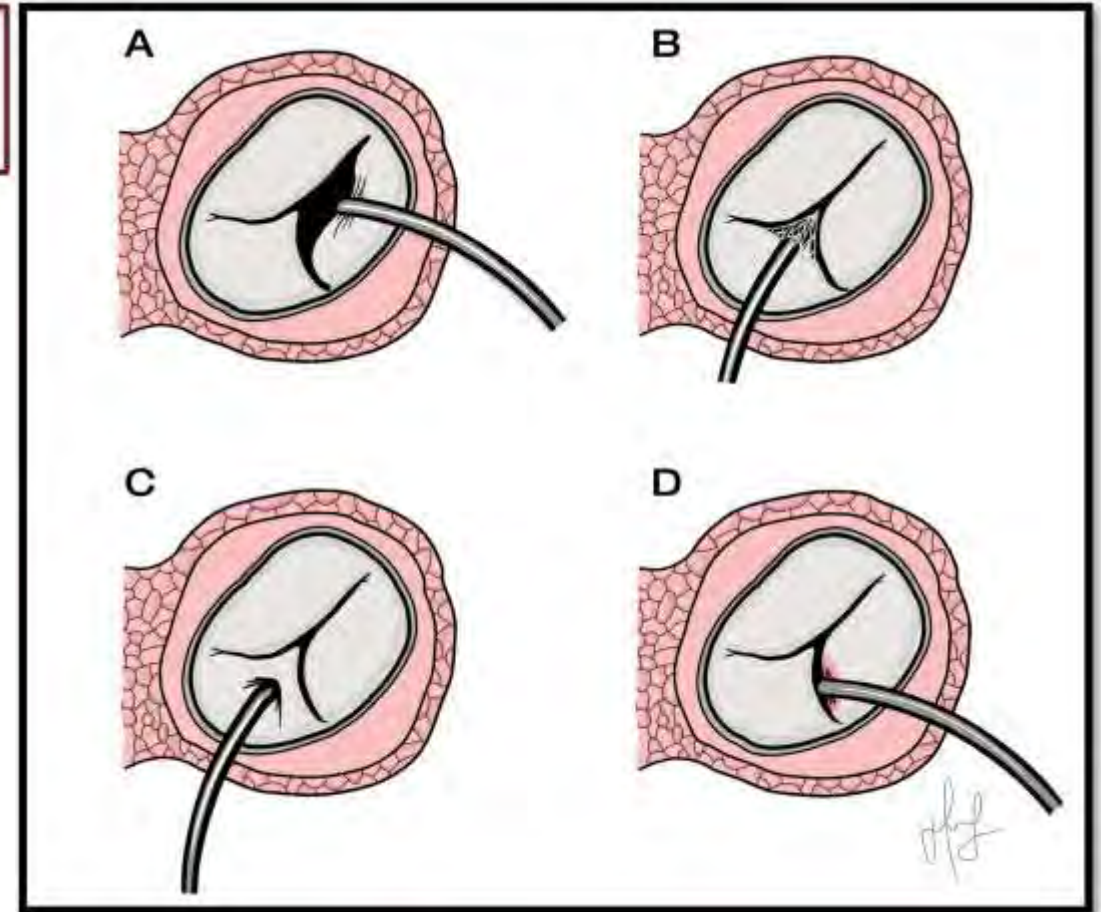
Causes of Primary and Secondary Tricuspid Regurgitation

- **Primary causes (25%)**

- Rheumatic
- Myxomatous
- Ebstein anomaly
- Endomyocardial fibrosis
- Endocarditis
- Carcinoid disease
- Traumatic (blunt chest injury, laceration)
- Iatrogenic (pacemaker/defibrillator lead, RV biopsy)

- **Secondary (Functional) causes (75%)**

- Left heart disease (LV dysfunction or valve disease) resulting in pulmonary hypertension
- Any cause of pulmonary hypertension (chronic lung disease, pulmonary thromboembolism, left to right shunt)
- Any cause of RV dysfunction (myocardial disease, RV ischemia/infarction)



- (A) Lead impingement causing mechanical interference on leaflet mobility and coaptation.
- (B) Lead entanglement in the subvalvular apparatus, even with chordal entrapment.
- (C) TV leaflet perforation during implantation.
- (D) Lead adherence or leaflet laceration causing scarring and fibrosis, with or without leaflet tethering

Tricuspid Regurgitation Related to Cardiac Implantable Electronic Devices: An Integrative Review

Julio Cesar Moreira MD, PhD, Roberto de Jesus MD, PhD, Marcelo de Souza e Silva MD, PhD, Luis Dominguez MD, PhD, Carlos Felipe Ferreira MD, PhD, Walter Helder Mendes MD, PhD, Felipe de Souza MD



Tricuspid Regurgitation Evaluation Pathway



Welle, G, Hahn, R, Lindenfeld, J. et al. New Approaches to Assessment and Management of Tricuspid Regurgitation Before Intervention. J Am Coll Cardiol Intv. 2024 Apr, 17 (7) 837–858.
<https://doi.org/10.1016/j.jcin.2024.02.034>



Landscape

Tricuspid Regurgitation: Available Devices for the Interventionalist

Transcatheter Edge to Edge Repair

- Devices: TriClip, PASCAL
- Favorable Indications
 1. Small leaflet coaptation gap (<7 mm)
 2. "True" tricuspid (3 leaflets) morphology
 3. Confined prolapse or flail of any leaflet
 4. Jet location: Anteroseptal



TriClip



PASCAL

Tricuspid Valve Replacement

- Devices: Evoque, LuxValve, GATE
- Favorable Indications
 1. Greater leaflet coaptation gap (>8.5 mm)
 2. Valve tethering (more than moderate)
 3. Previous Tricuspid Valve Replacement (ViV)
 4. Thickened leaflets (heavily calcified)



LuxValve

Evoque

GATE

Annuloplasty

- Devices: Cardioband
- Favorable Indications
 1. Dilated tricuspid annulus as the key pathophysiological mechanism
 2. Valve tethering preferably mild
 3. Jet location: Central



Cardioband

Heterotopic Caval Valve Implantation

- Devices: Tricento, TricValve
- Favorable Indications
 1. Venous congestion – significant backflow in caval veins
 2. Not suitable for orthotopic valve implantation
 3. Appropriate cava anatomy-size



Tricento

TricValve



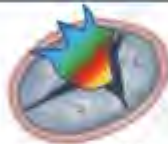
T-TEER

ACC.23
TOGETHER WITH
WCC

Prospective

Populatio

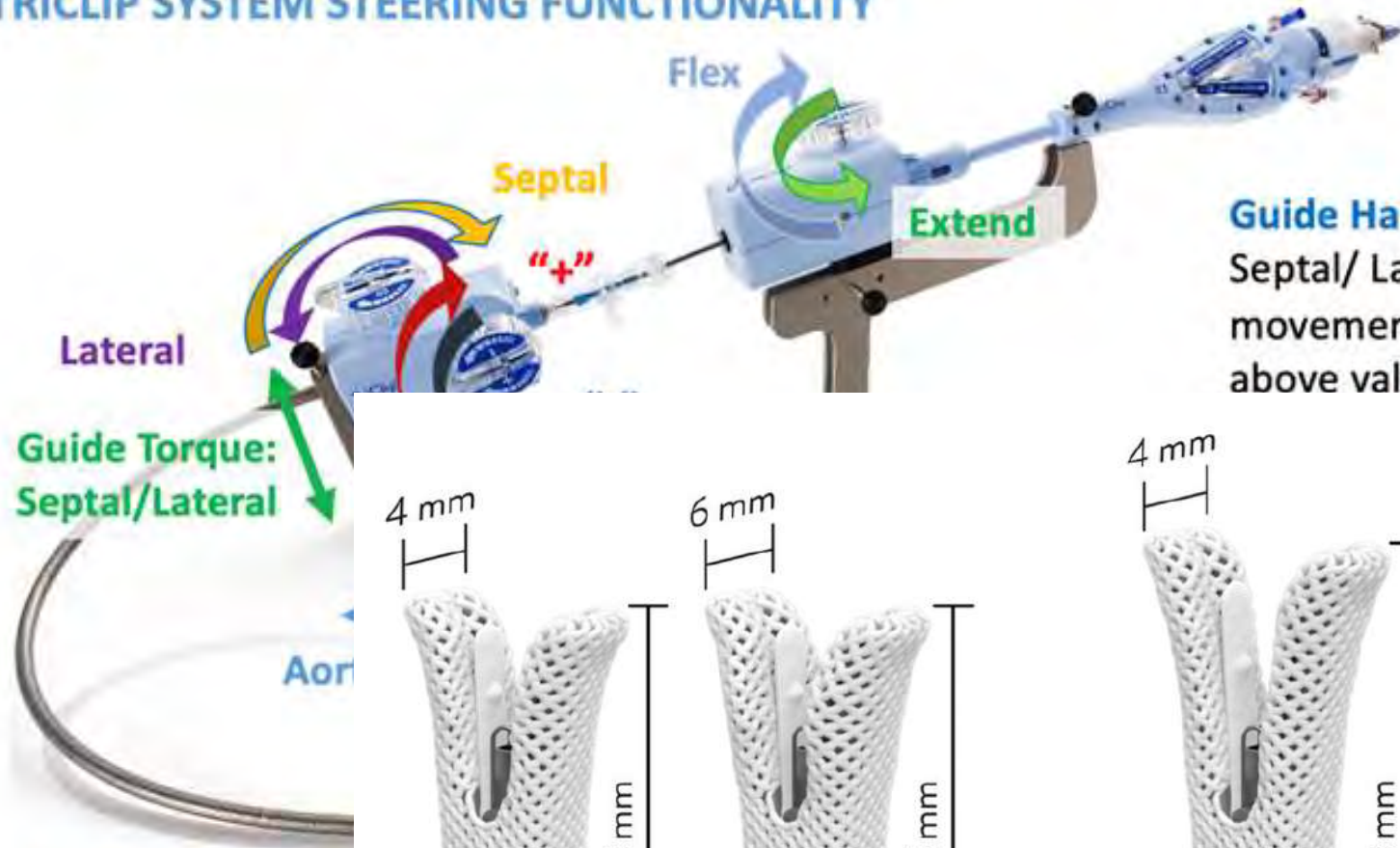
- 350 patients enrolled at sites in the US, Canada, Europe
- Symptomatic, severe and at intermediate greater risk for TV sur
- 175 pts randomized 1 T-TEER (TriClip™ G4) c medical therapy (GDM



Patients with symptomatic severe

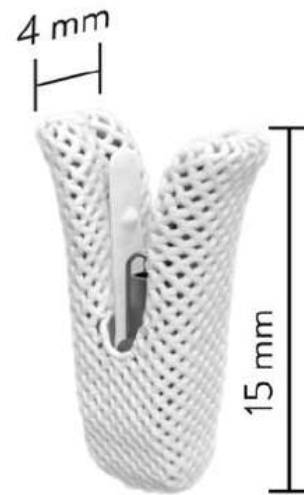
TRILUMINATE at

TRICLIP SYSTEM STEERING FUNCTIONALITY

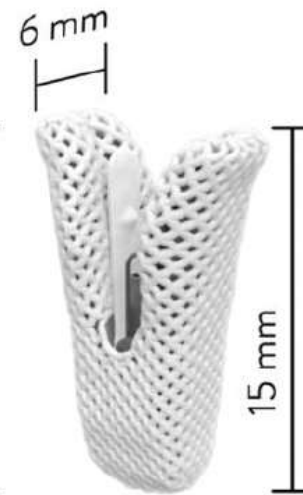


Guide Handle:
Septal/ Lateral
movement; Height
above valve

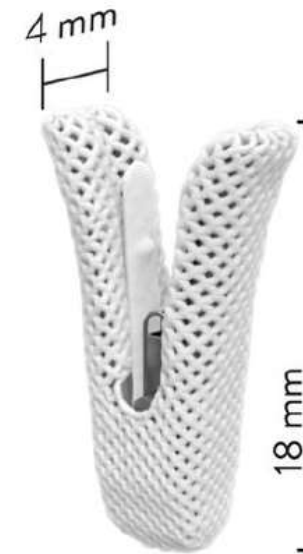
Note: TriClip System
in the non-planar Tri



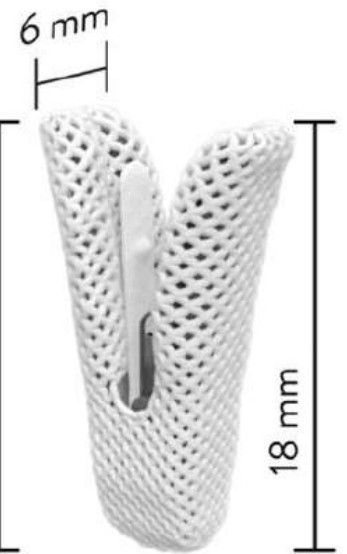
G4 NT



G4 NTW



G4 XT



G4 XTW

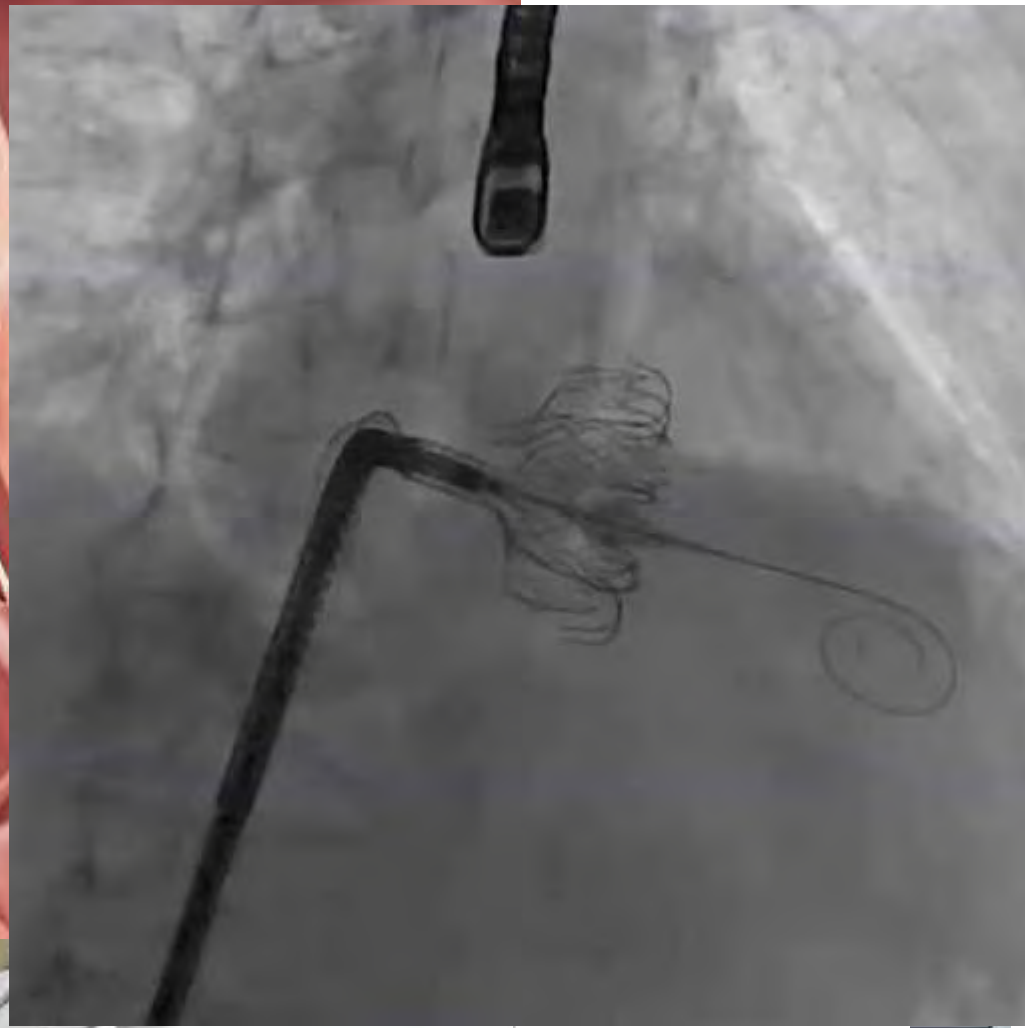
TTVR

Designed for anatomic compatibility

Self-expanding memory nitinol designed to coapt with native valve apparatus

Designed for secure implantation

Nine ventricular engagement leaflets subvalvular anchors



EVOQUE TTVR

TRISCEND II Trial Design



TRISCEND II: Two-Part Study Design Based on the Breakthrough Designation



'First 150'
First 150 patients randomized and treated

Total Cohort
N = 400
All-randomized patients
Enrolled, follow-up ongoing

Primary Endpoints	First 150	Total Cohort
Safety (30 Days)		
• Composite MAE rate	✓	✓
Effectiveness (6 Months)		
• TR grade reduction	✓	✓
• Hierarchical composite of KCCQ, NYHA and 6MWD		
Hierarchical Composite (1 Year)		
1. All-cause mortality		
2. RVAD implant or heart transplant		
3. TV surgery or intervention		
4. Annualized heart failure hospitalization		✓
5. KCCQ, NYHA, 6MWD		

✓ Prespecified analysis



- Median length of stay: 3 days (0.35)
- Composite of MAEs: 18.5%
- Severe bleeding: 17.7%
- Bleeding related to the main procedure: 1.6%
- New permanent pacemaker: 10.5%
- Stroke: 0%
- Myocardial infarction: 0%

- 96±2%
- KM Freedom from HF Hospitalization @6m: 94±2%
- KM composite MAEs: 20±4%

TTVR using the EVOQUE system demonstrated favorable 30-day outcomes sustained at 6-months showing significant TR reduction, 96% of survival, 94% of freedom from HF hospitalization, improvements in NYHA class, KCCQ score and 6MWD

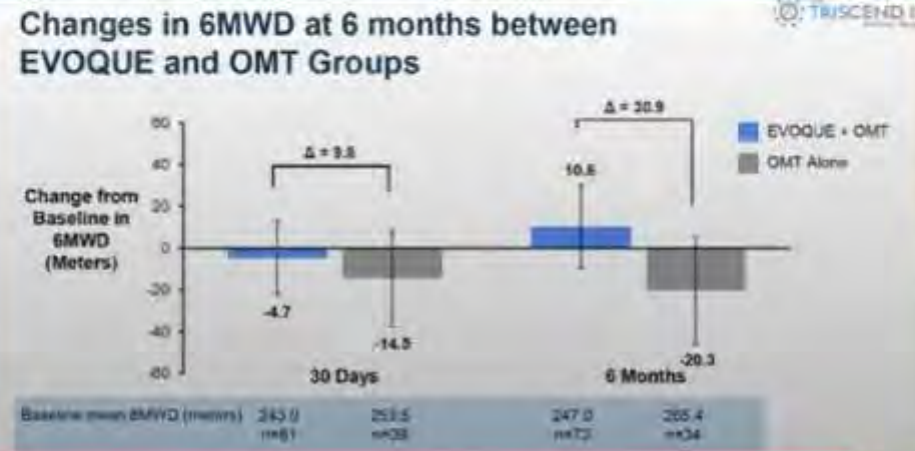
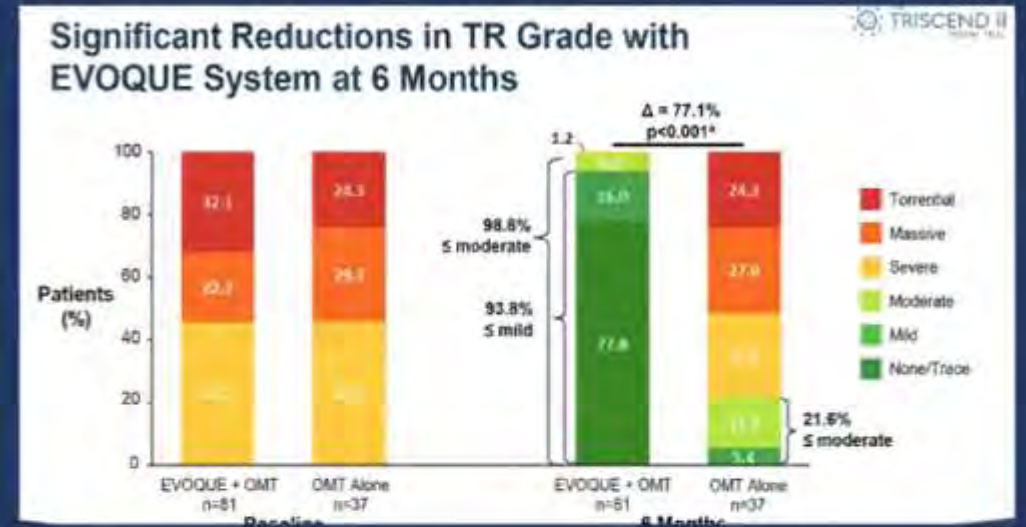
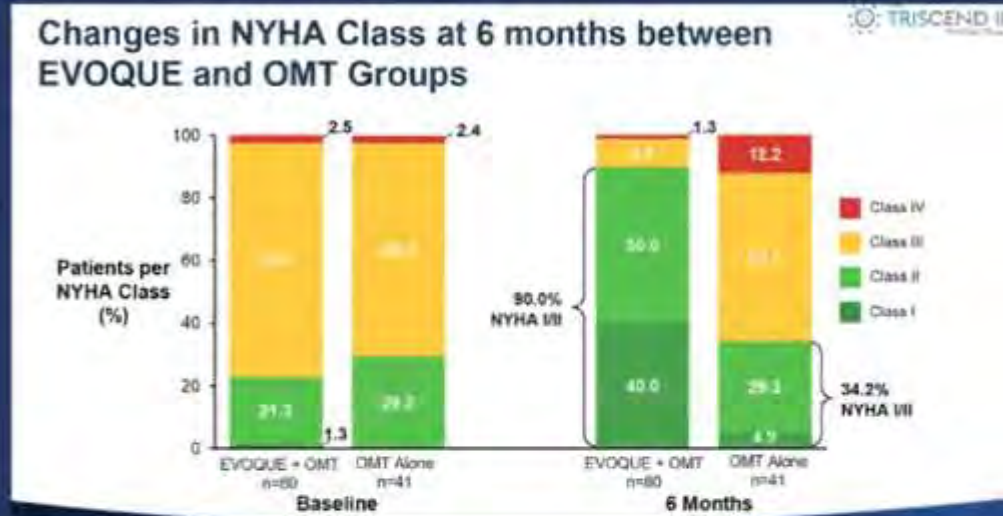
Designed by @Stouff_Alex & @Comousother



TRISCEND II: 150 Patients, 6-month Data

90 % NYHA FC I-II

93.8 % Mild or no TR



Walking distance + Delta 30 mts vs OMT

Pulmonic Valve





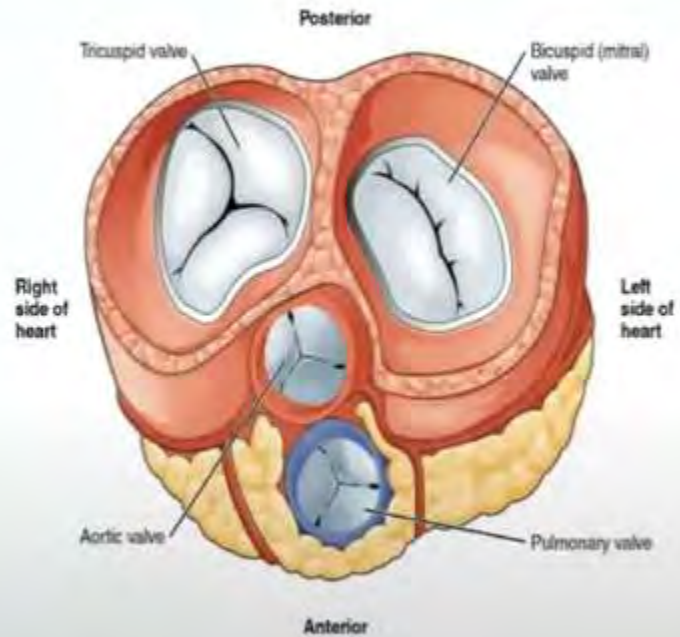
(Call ACHD ...)



Conclusion



---- Approved ---- In Phase 3 clinical trial



Aortic

Replacement AS
Replacement AR

Mitral

Repair (M-TEER)
Replacement (TMVR)

Pulmonic

Replacement

Tricuspid

Repair (T-TEER)
Replacement (EVOQUE)



Thank You

