

DOMENICA 3 MARZO

PROTESI VALVOLARI MITRALICHE PER VIA PERCUTANEA: UPDATE 2019

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The mitral valve is not as simple as the aortic valve

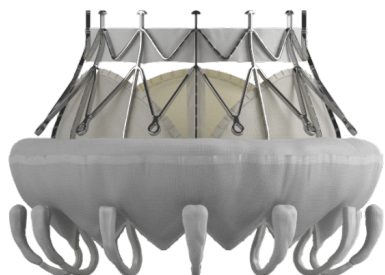
- While aortic valve replacement is the most common solution and **IS** the solution
- Mitral repair, mitral replacement, medical therapy have specific indications and all need to be available
- Transcatheter mitral valve replacement will not become a dominant approach

Why we need a transcatheter mitral valve

- The valve is severely damaged to be repaired
- Surgical risk with standard valve surgery is too high
- A transcatheter approach can be performed with less invasiveness (transapical or transeptal) without extracorporeal circulation

TMVR

CardiaQ



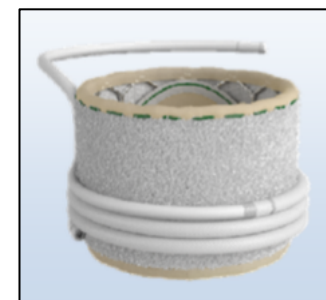
Tiara



Intrepid



Edwards M3



M Valve



Tendyne



Navigate



Caisson

Tendyne

Tendyne CE Mark Study

30 day outcomes of the first 100 patients

Tendyne Device

- Tri-leaflet porcine pericardial valve
- Self-expanding nitinol double frame
 - Outer frame contoured to fit mitral annulus
- Multiple outer valve frame sizes
- Transapical access, valve tethered to apex
 - Adjustable tension provides valve stability
- Epicardial pad assists in access closure
- Valve fully retrievable and repositionable
- No requirement for bypass or rapid pacing



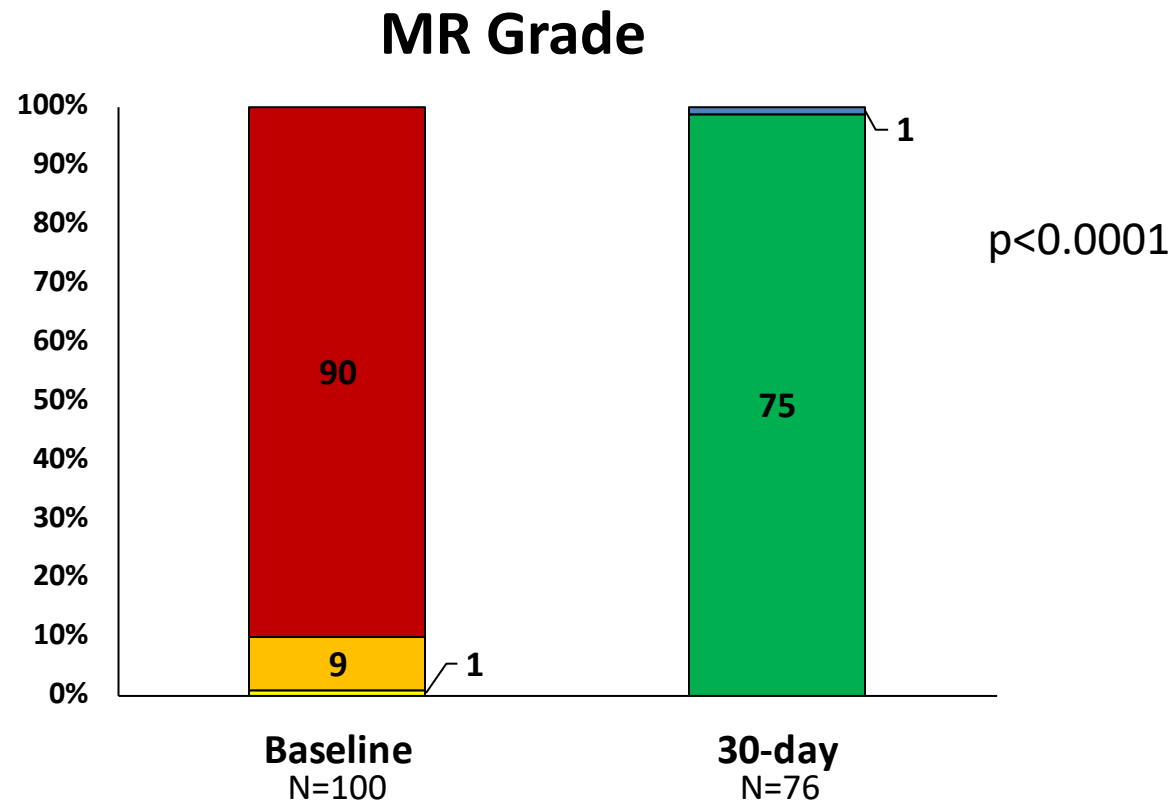
Tendyne CE Mark: Procedural Outcomes

Variable	
Outcome	N=100
Technical success	97 (97%)
Implant retrieved/abandoned	3 (3%)
- retrieved (SAM, LVOT obstruction)	1 (1%)
- retrieved (non-orthogonal)	1 (1%)
- abandoned (pulmonary edema)	1 (1%)
Procedural mortality	0 (0%)
Procedural stroke	0 (0%)
Emergency surgery	0 (0%)
ECMO	0 (0%)

Tendyne CE Mark Study: MR grade

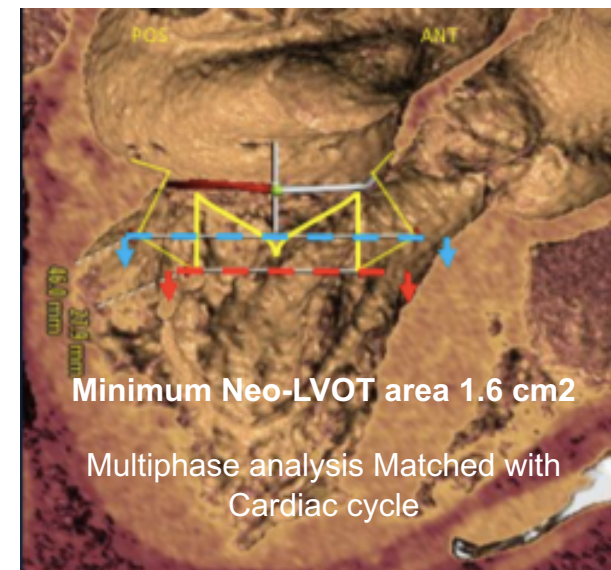
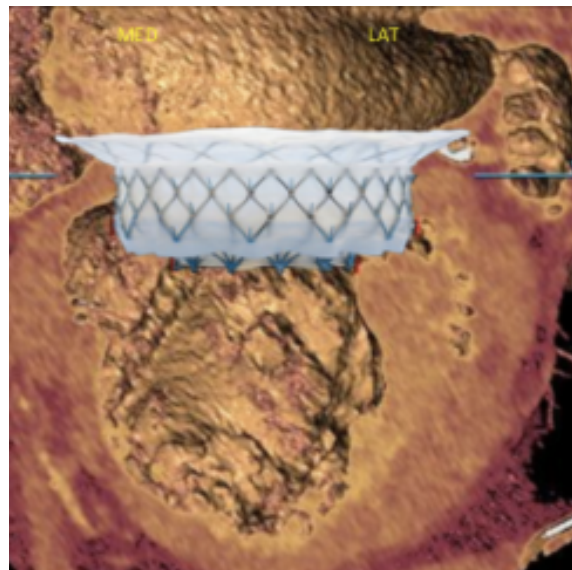
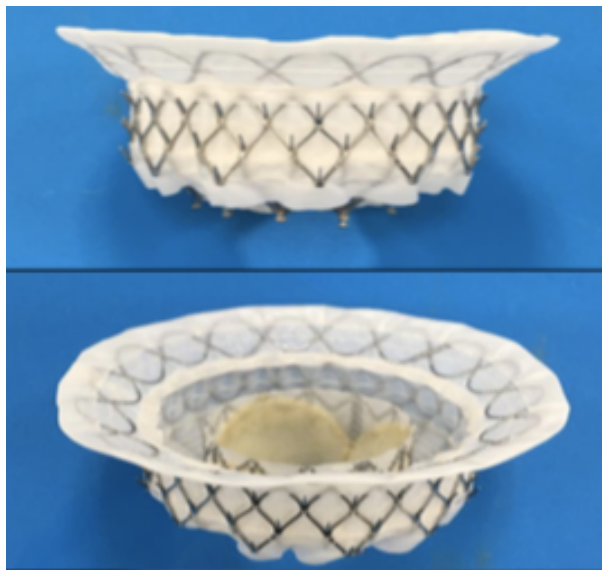
99.0% \geq 3+ MR at baseline to 98.7% none/trace at 30 days

No patients with more than mild (1+) MR at 30 days



Intrepid

Intrepid: Transapical Dual stent system

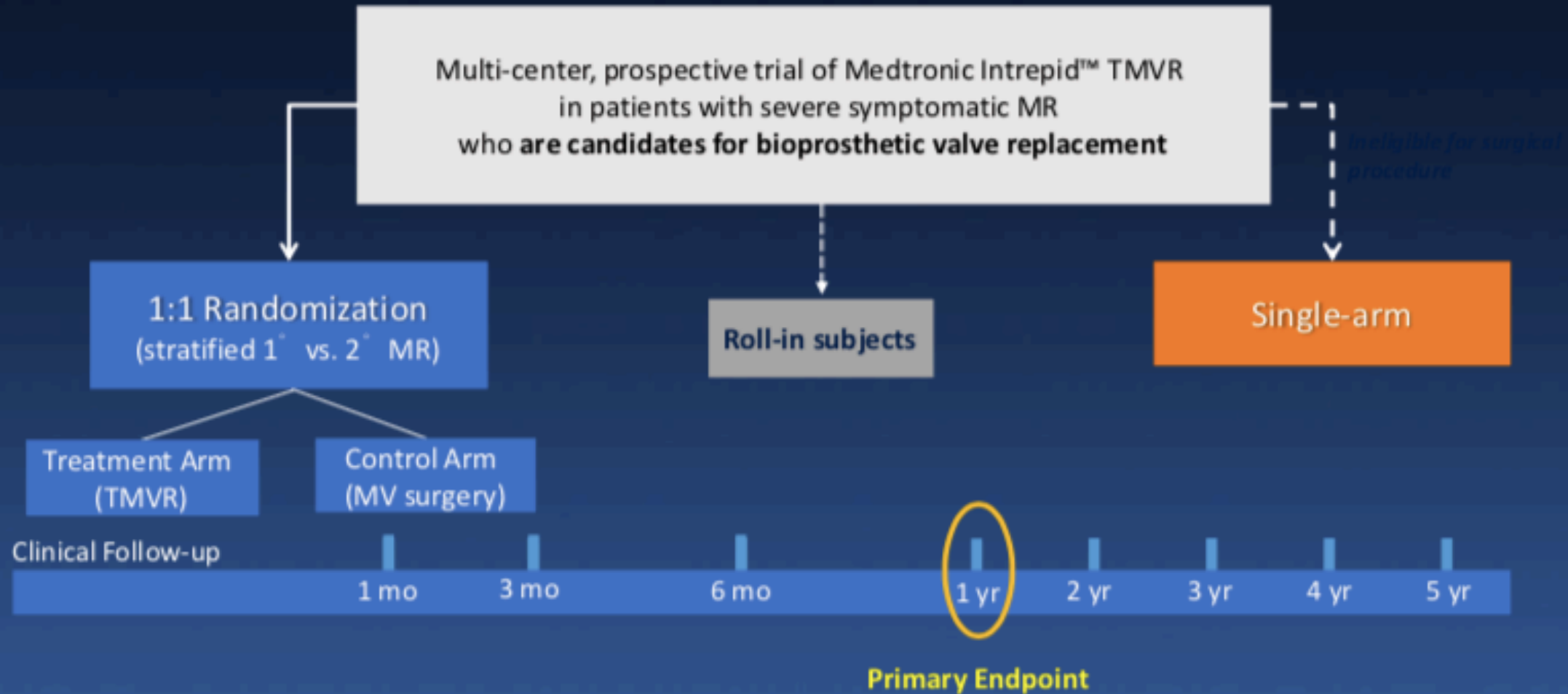


- **Conformable Outer Stent** engages annulus and leaflets providing fixation and sealing while isolating the inner stent from the dynamic anatomy
- **Circular Inner Stent** houses a 27 mm tricuspid bovine pericardium valve
- **Flexible Brim** aids imaging during implantation & subsequent tissue in-growth

STUDY DESIGN

MEDTRONIC INTREPID™ TMVR **APOLLO TRIAL**

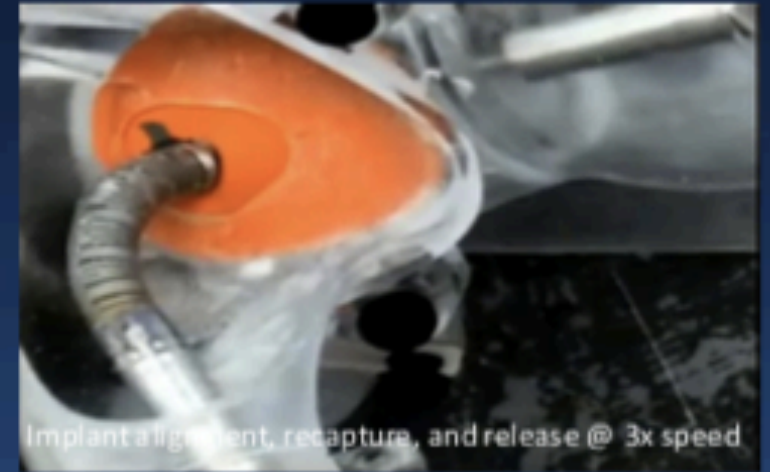
1380 pts



Intrepid TMVR

Next Generation Systems

2. Trans-septal Design

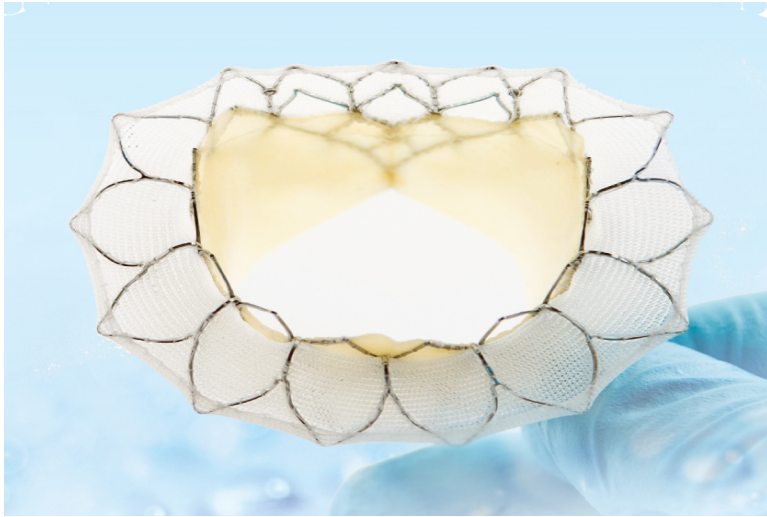


Implant alignment, recapture, and release @ 3x speed

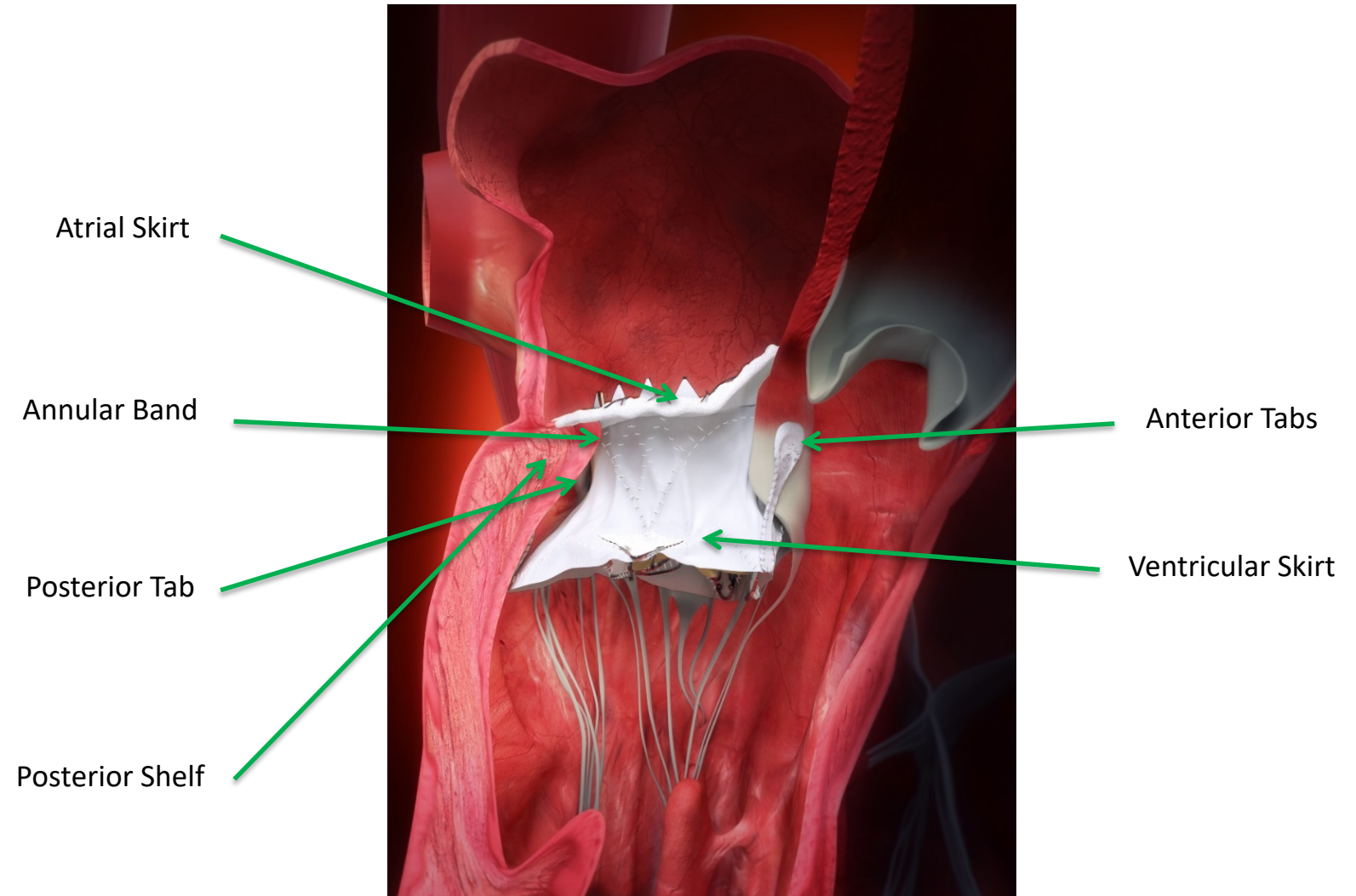


- Trans-septal, trans-femoral system in development (enabled by implant design not requiring rotational alignment or need to capture leaflets)
- One implant platform regardless of delivery approach: TS or TA

Tiara



Tiara



Edwards SAPIEN M3

Edwards SAPIEN M3 System

Dock Delivery

SAPIEN M3 Dock

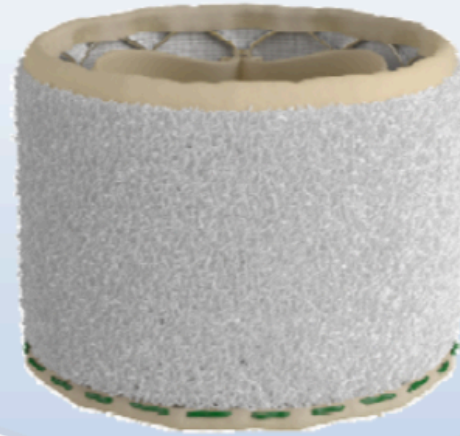


SAPIEN M3 Dock Delivery System



Valve Delivery

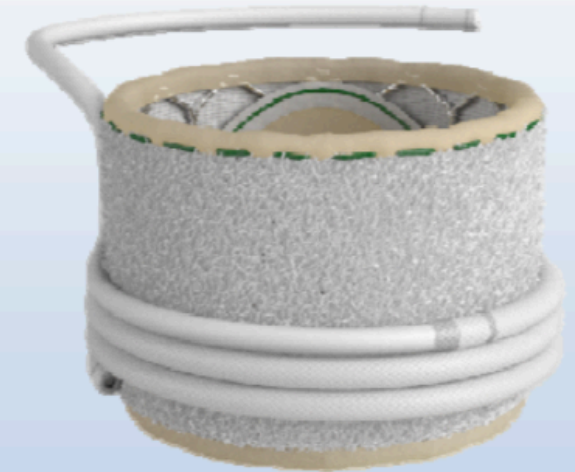
SAPIEN M3 Valve



Commander Delivery System



Final Implant



SAPIEN M3 System

First 10 Cases - Data Summary

	N=10
Technical Success*	9
Alive	10
Successful access/Delivery	10
Deployment	10
Freedom from Reintervention	9 ⁽¹⁾

Clinical Outcomes at 30 days*	N=10
All-cause Mortality	0
All Stroke	1 ⁽¹⁾
Rehospitalization (device/procedure related)	0
Hemolysis	0
LVOT Obstruction	0

There was no Conversion to Surgery, Device Embolization, Device Migration or Implantation of more than one valve.

*Site reported

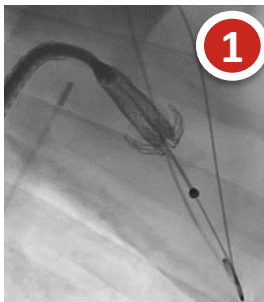
¹Case #2: Chordal rupture during dock deployment resulted in severe PVL; closed intra-procedurally with plugx2; stroke (POD 02)

CardiAQ-Edwards TMVR

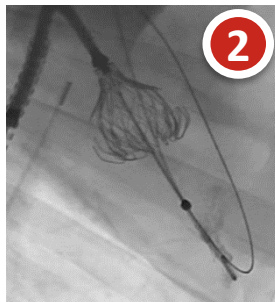
CardiAQ-Edwards Transcatheter Mitral Valve Replacement

Transseptal

Left ventricular
Anchor Release



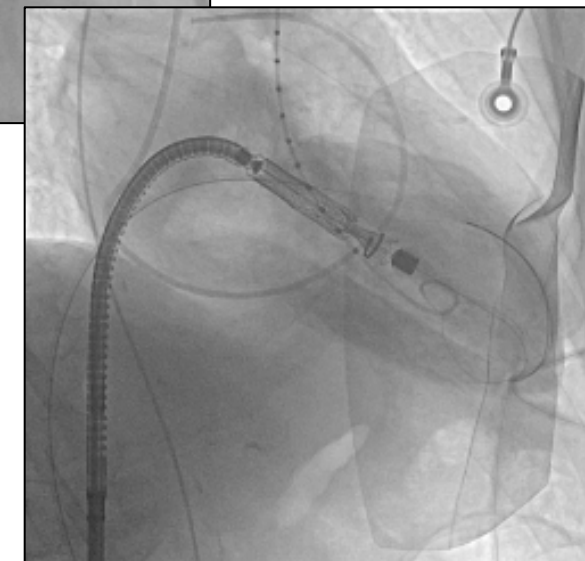
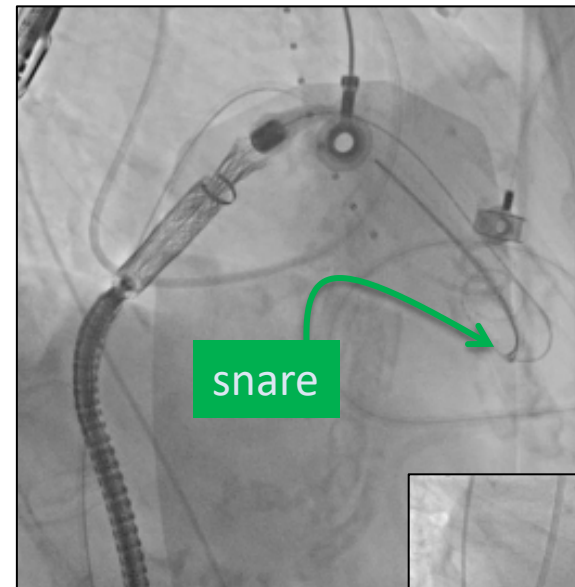
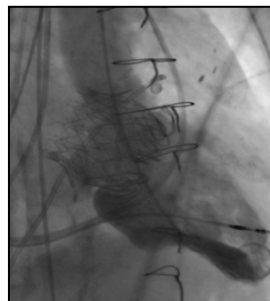
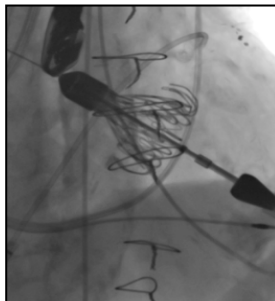
Valve Expansion &
Leaflet Capture



Valve Release



Transapical



CAUTION: Investigational device, limited by Federal (or United States) law to investigational use. Exclusively for Clinical Investigation. Not approved for sale in any country.

Cephea

CEPHEA'S TMVR SYSTEM: DESIGN FEATURES

(1) Antegrade Delivery Approach

- Trans-atrial and trans-septal

(2) Low Profile Frame Structure

- Sub-annular anchoring
- Minimal LVOT interference and sub-valvular injury
- Enables trans-septal delivery

(3) Suspension Leaflet Central Core

- Isolates leaflets function from dynamic annular compression
- Flexibility in design of anchoring elements

(4) Optimized AV Hemodynamics

- Smooth transition from LA to LV



Cephea TMVR

- Novel TMVR platform using the trans-septal approach
- Unique design features
 - Valve retention through axial disk compression
 - Device adaptation to variable anatomy
 - Folding into “low-profile” delivery catheters
- Long term chronic animal data

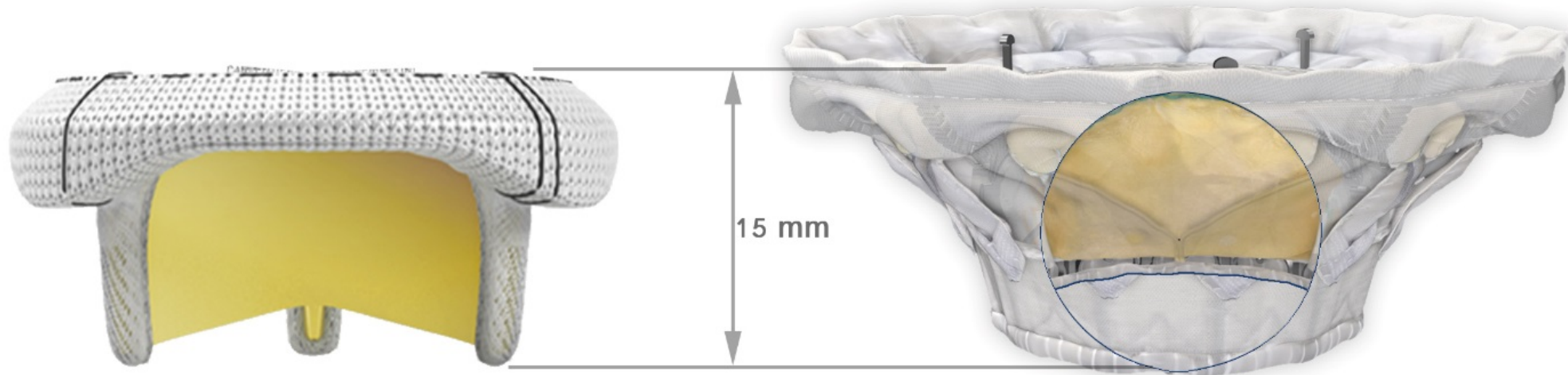
TWO Patients treated

CardioValve TMVR

CardioValve TMVR: 1 valve, 2 frames, 3 steps

– CardioValve follows surgical design, adapted for transcatheter use

- Low presence in the ventricle, no protruding atrial component
- Robust frame and classic leaflet design for durability
- 3 sizes to fit all anatomies
- Proprietary anchoring and sealing element

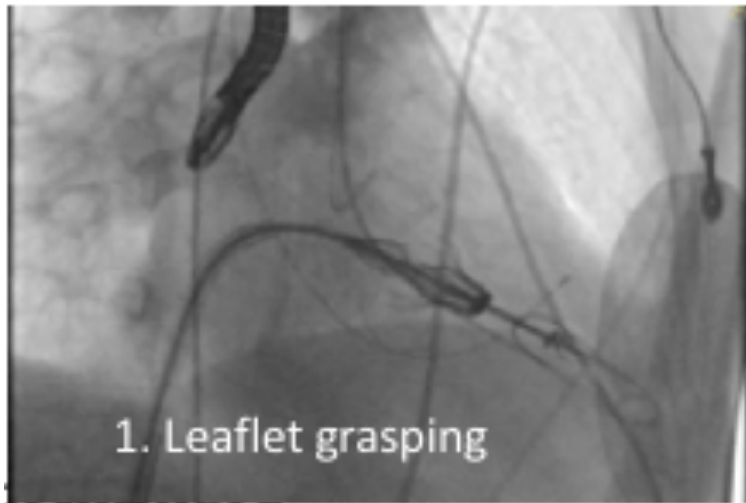
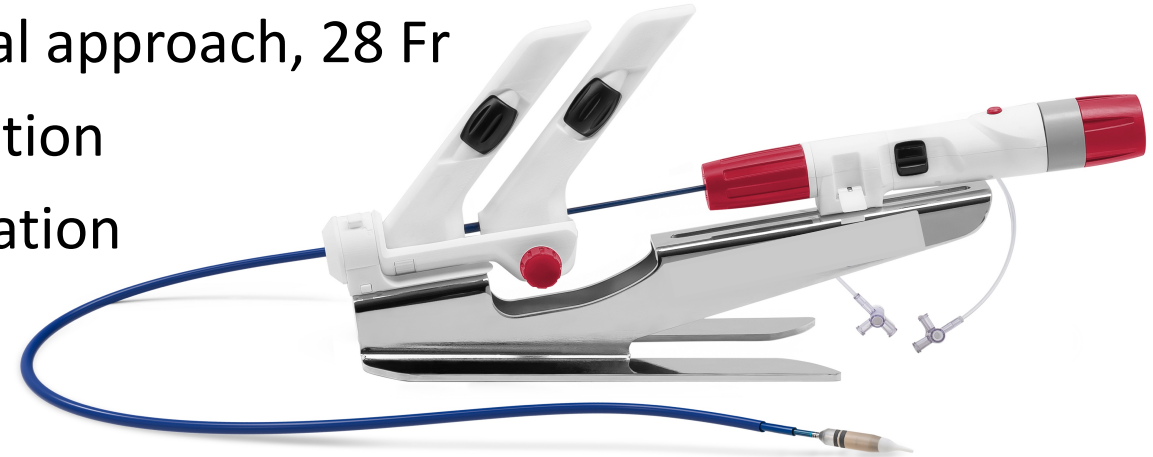


The **Surgical gold-standard**
Edwards Perimount Magna™

The **Transcatheter solution**
CardioValve™

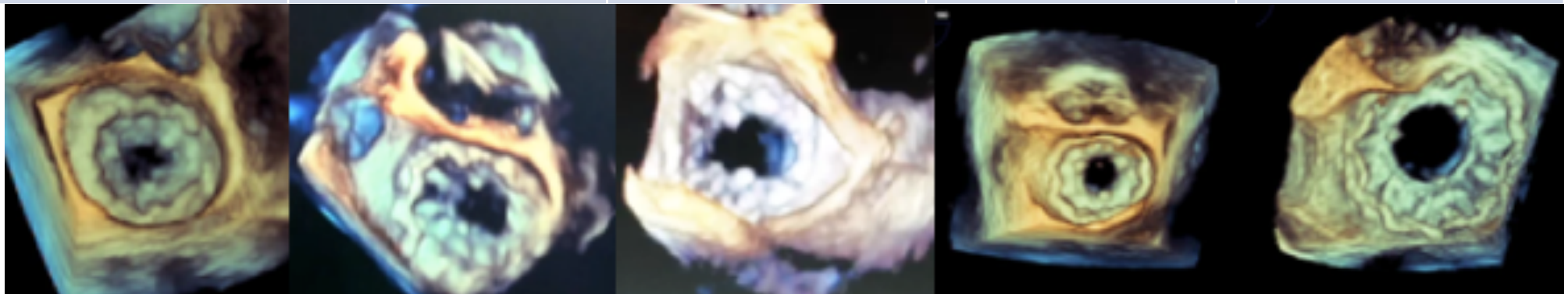
CardioValve Delivery: 1,2,3....

- Transfemoral Access: Femoral vein, transeptal approach, 28 Fr
- Multi-steerable catheter for coaxial implantation
- No AV loop required - Single step TF implantation
- Echo main guidance, Fluoro assistance
- 3 steps procedure



Promising First 5 Cases

	Case 1	Case 2	Case 3	Case 4	Case 5
MR	No	No	No	No	No
PVL	No	Trace	Trace	No	Trace
LVOTO	No	No	No	No	No
Gradients	5 mmHg	6 mmHg	2 mmHg	6 mmHg	3 mmHg
Hemody.	Normal	Normal	Normal	Normal	Normal
DS time	30 min	23 min	40 min	30 min	21 min
Depl. time	13 min	15 min	25 min	17 min	14 min



**Maria Cecilia Hospita in Cotignola (RA) will
partecipate in the CE Mark Study for CardioValve**

Principal Investigator : Antonio Colombo

**Patients not candidate for repair (surgical or
transcatheter) and too high risk for surgical valve
replacement**

FOR SCREENING REFER TO: colombo@emocolumbus.it

Future of TMVR?



Mitral valve is not open to simple solutions such aortic valve

Surgical repair remains the gold standard, when feasible

Trancatheter solutions such as MitraClip and Cardioband are effective in a number of settings

We need a procedure to be applied when surgical or transcatheter repair are not possible and surgical replacement is at high risk