
# TRANSCATHETER MITRAL VALVE PROSTHESIS....

## ....PREPARING FOR THE NEXT REVOLUTION

Stefano Salizzoni, MD, PhD

CLINICAL RESEARCH

# Development of transcatheter aortic valve implantation (TAVI): A 20-year odyssey

## Implantation de valves aortiques par voie percutanée : une odyssée de 20 ans

**Alain Cribier**

**1993**

Post mortem studies validated the concept of intravalvular stenting in calcific aortic stenosis.

**2000**

first prototypes of balloon-expandable valves were tested in an animal model

**2002**

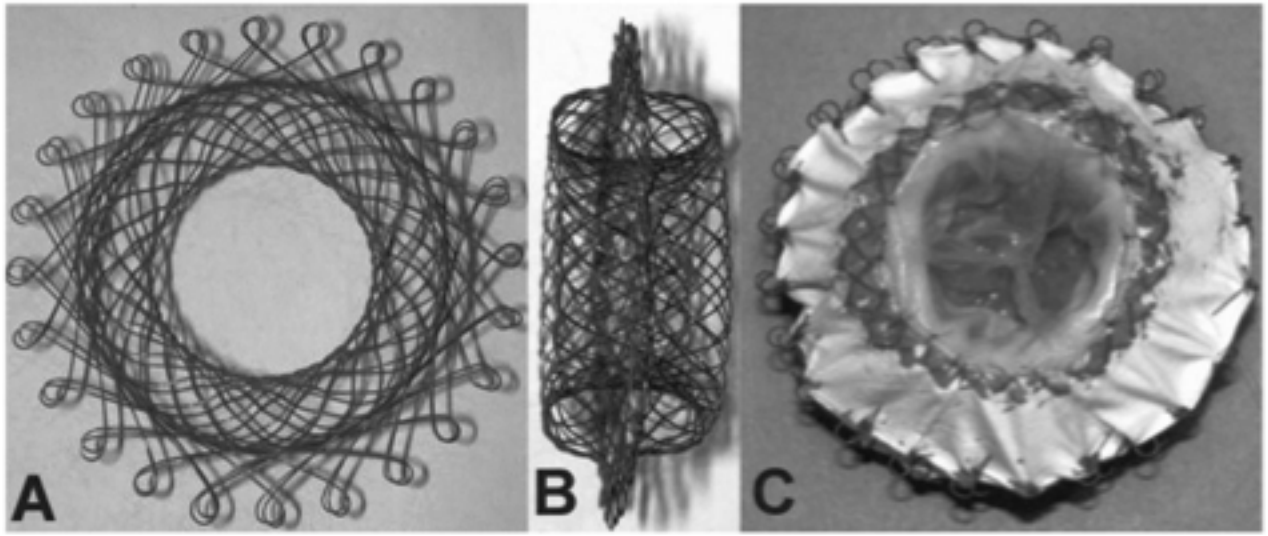
first-in-man

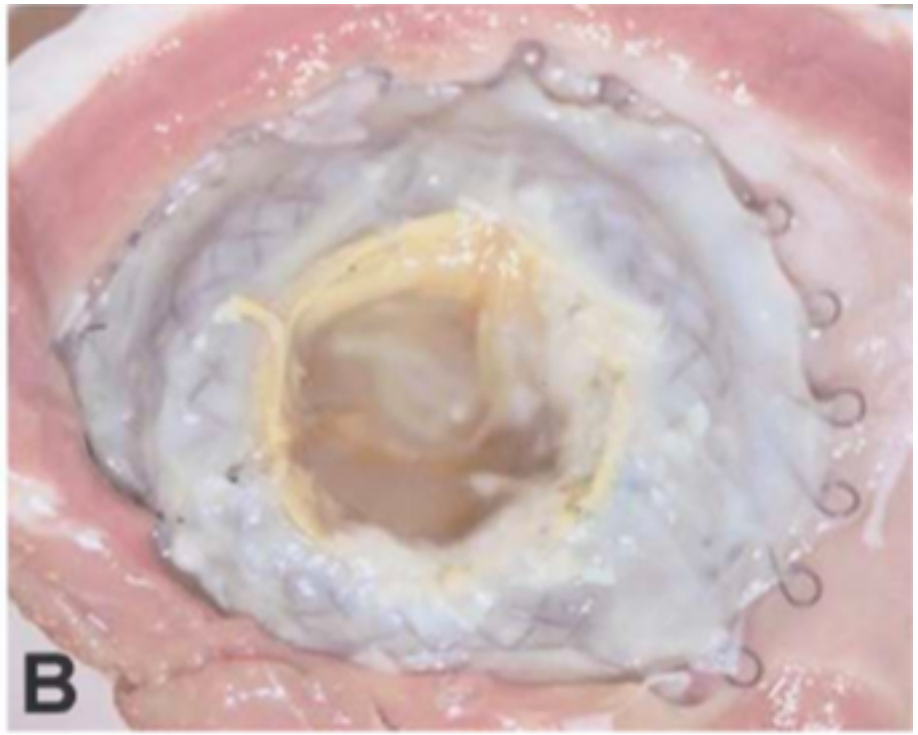
Over a 4-year period, the search for a biomedical company that was interested in the project failed completely. A long list of engineering issues and potential complications was consistently pointed out, including coronary obstruction, aortic and mitral valve complication, early dislodgement of the device, stroke, mechanical complications, etc. The project was even considered ''the most stupid ever heard''!

# Steps Toward the Percutaneous Replacement of Atrioventricular Valves

## An Experimental Study

Younes Boudjemline, MD,*† Gabriella Agnoletti, MD,* Damien Bonnet, MD,*†
Luc Behr, DVM,‡ Nicolas Borenstein, DVM,‡ Daniel Sidi, MD,*† Philipp Bonhoeffer, MD§
*Paris, France; and London, England*



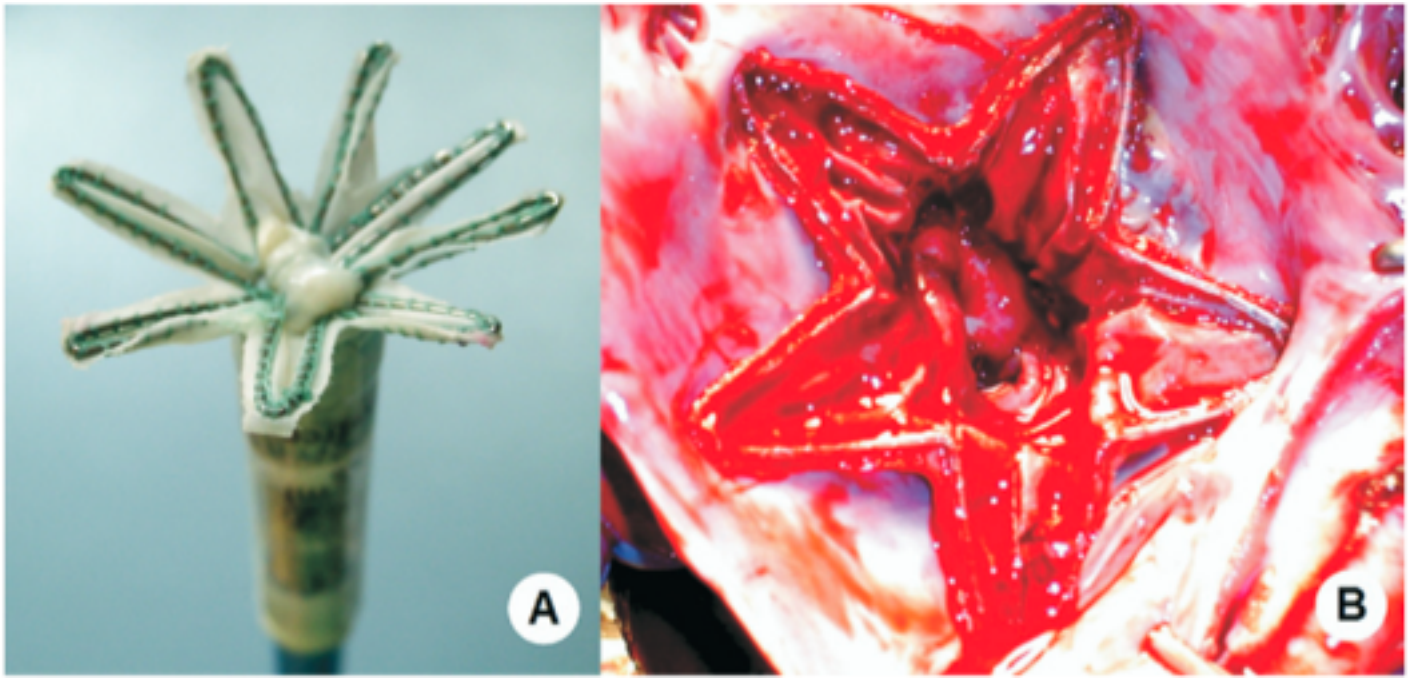




JACC 2005

# Transapical Mitral Valved Stent Implantation

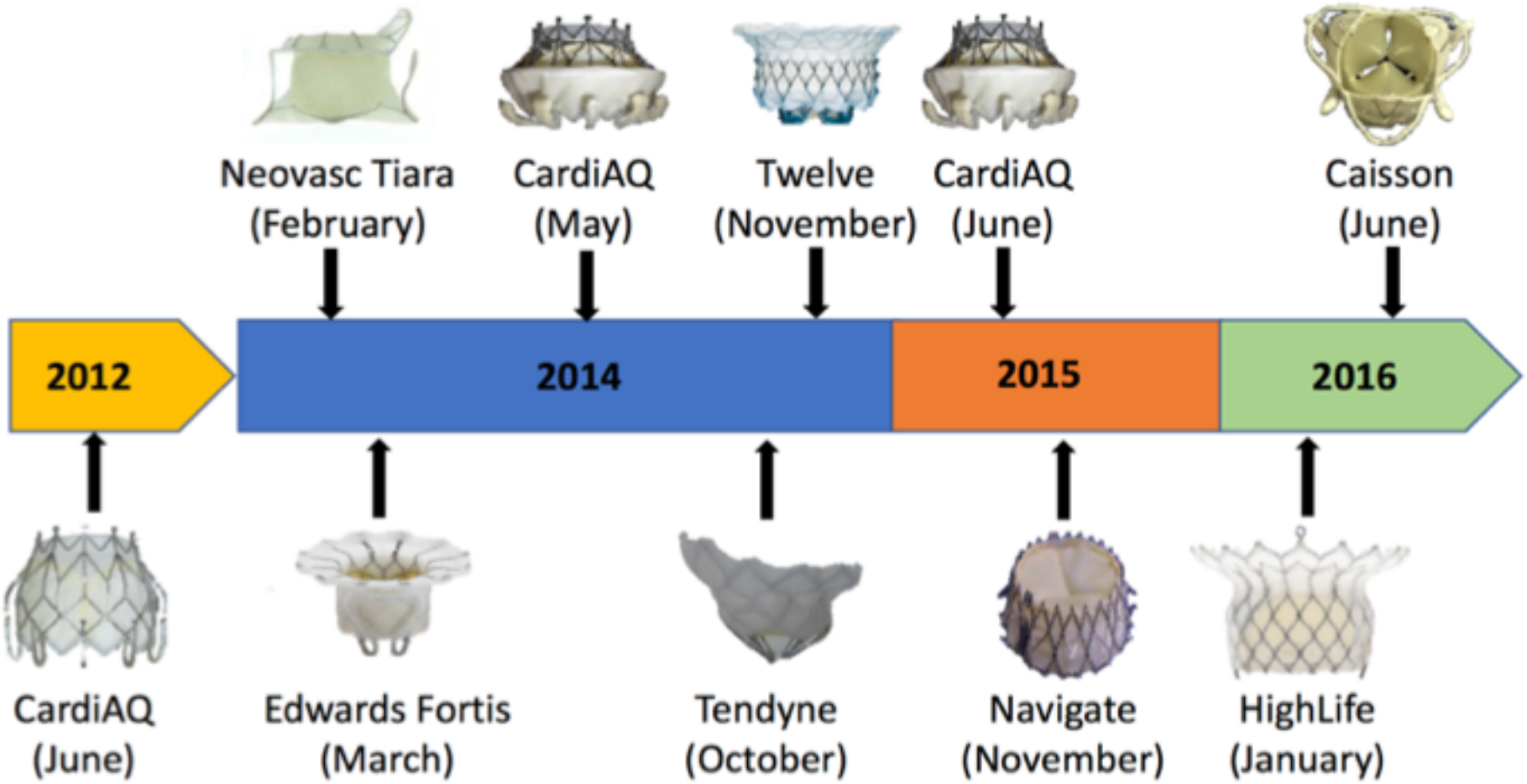
Lucian Lozonschi, MD,* Rene Quaden, MD,* Niloo M. Edwards, MD,
Jochen Cremer, MD, PhD, and Georg Lutter, MD, PhD

Department of Cardiothoracic Surgery, University of Wisconsin School of Medicine and Public Health, Madison, Wisconsin; and
Department of Cardiovascular Surgery, University Hospital Schleswig-Holstein, Campus Kiel, Kiel, Germany




Annals of Thoracic Surgery 2008

# First-in-human timeline for TCMV replacement



2002 FIRST IN MAN 2012

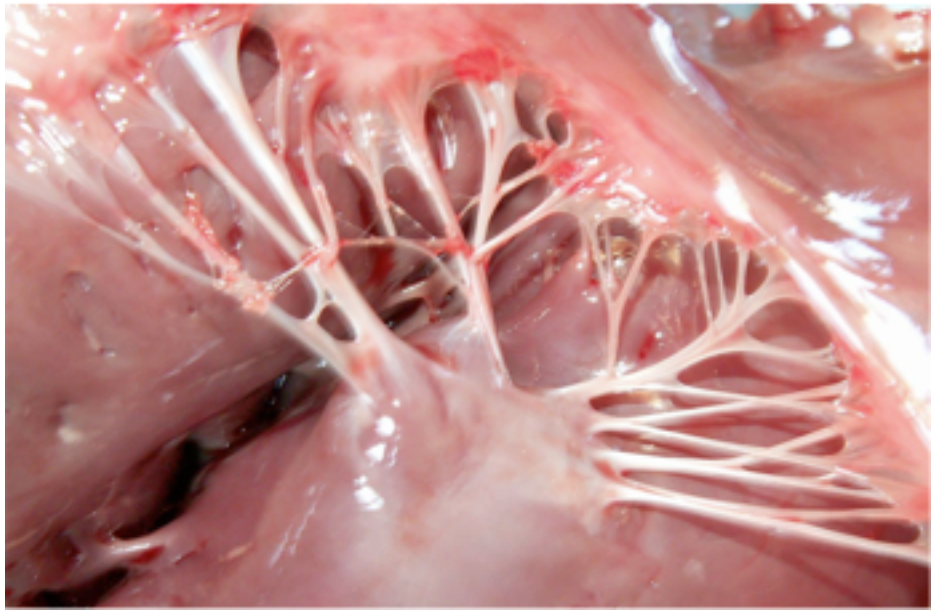
2007 CE MARK 202X

LVOTO

THROMBOSIS

DURABILITY

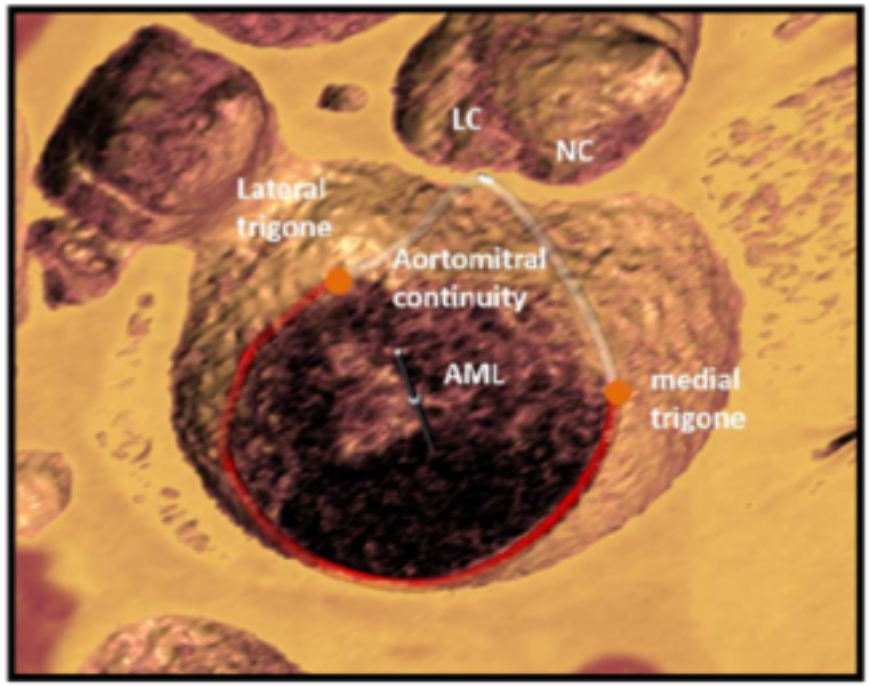
DIFFERENT PATHOLOGY

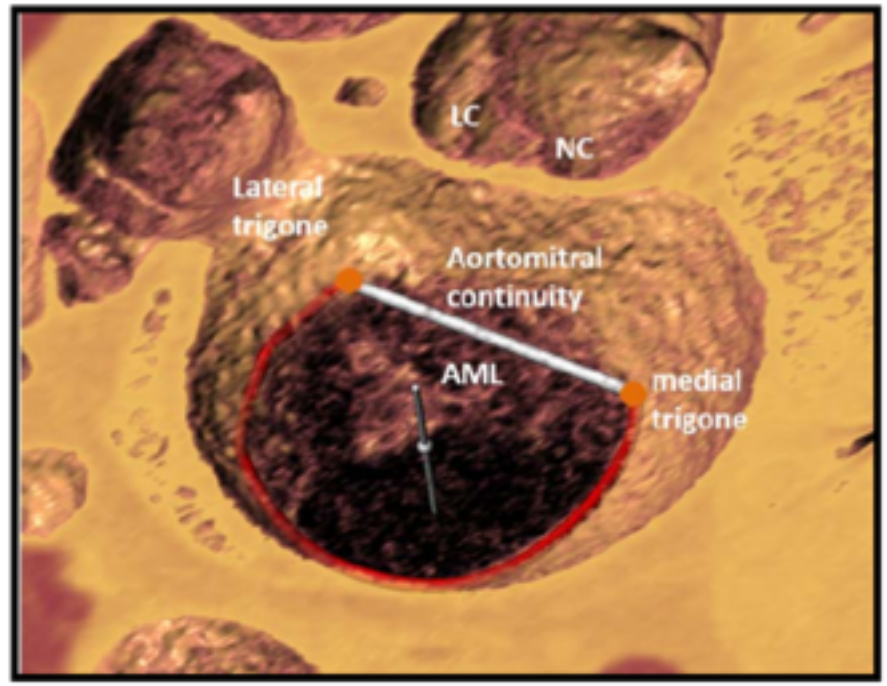


iASD

ASYMMETRIC ANATOMY

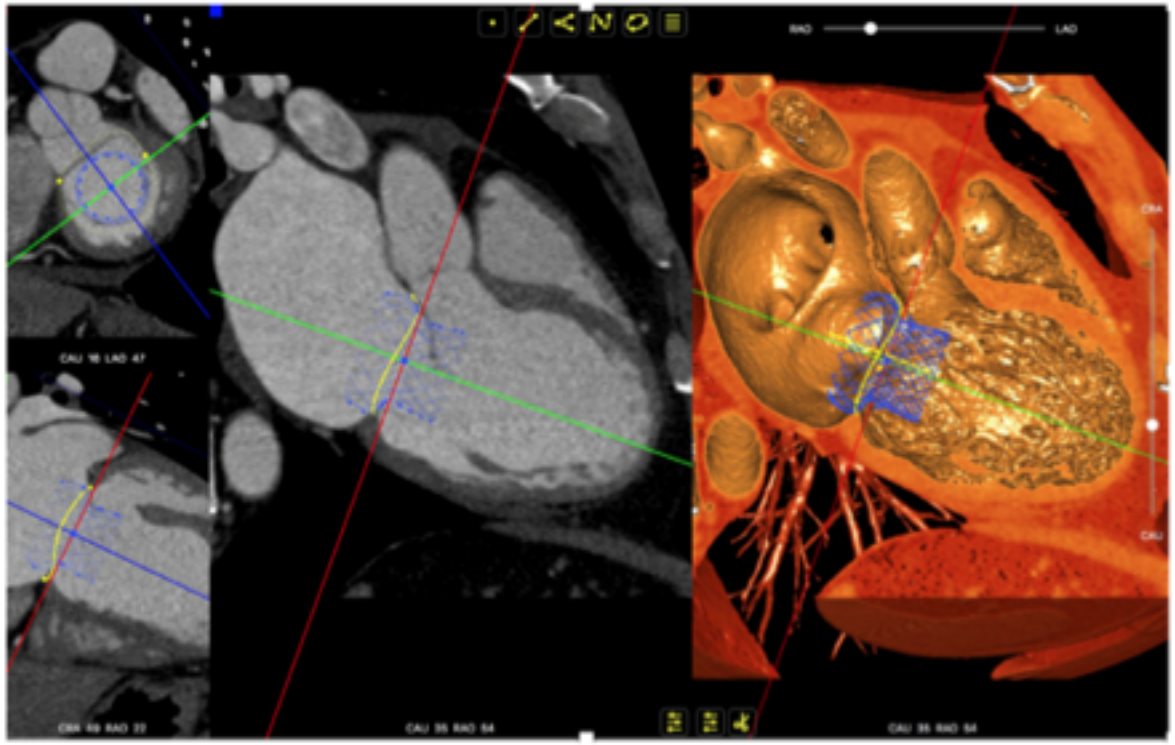
# How to measure the mitral annulus?



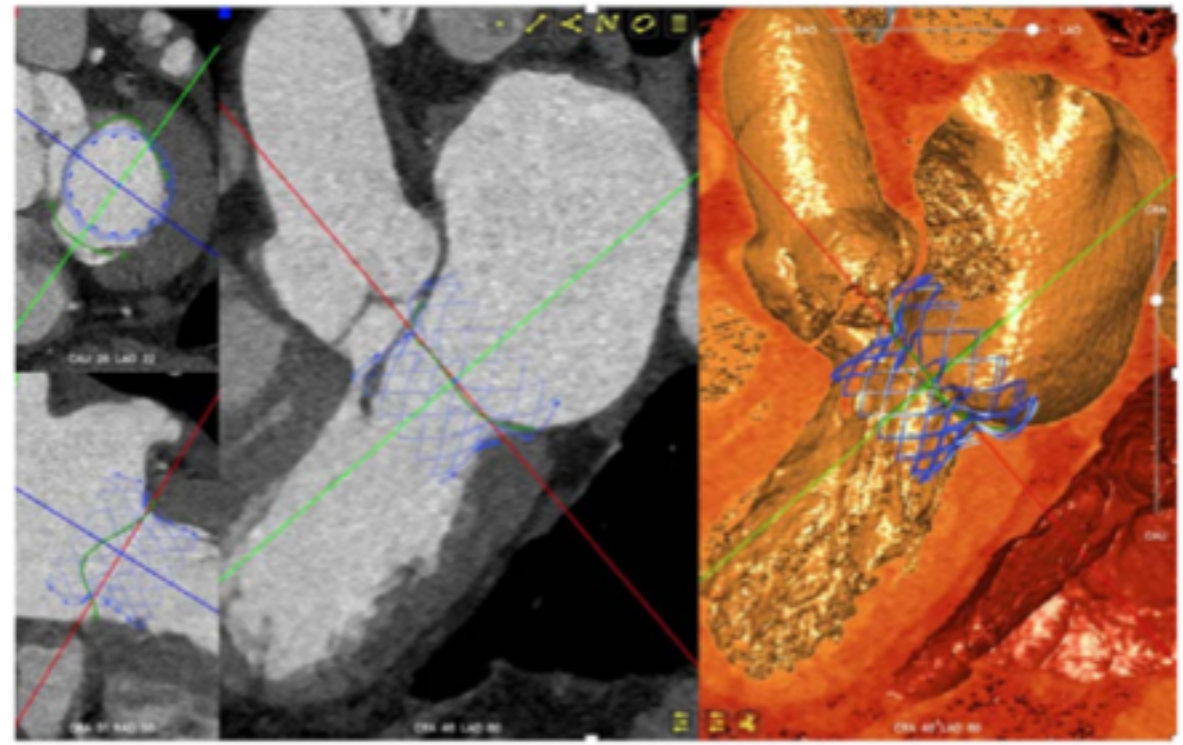




Courtesy Dr. J Leipsic

# Risk of LVOT obstruction

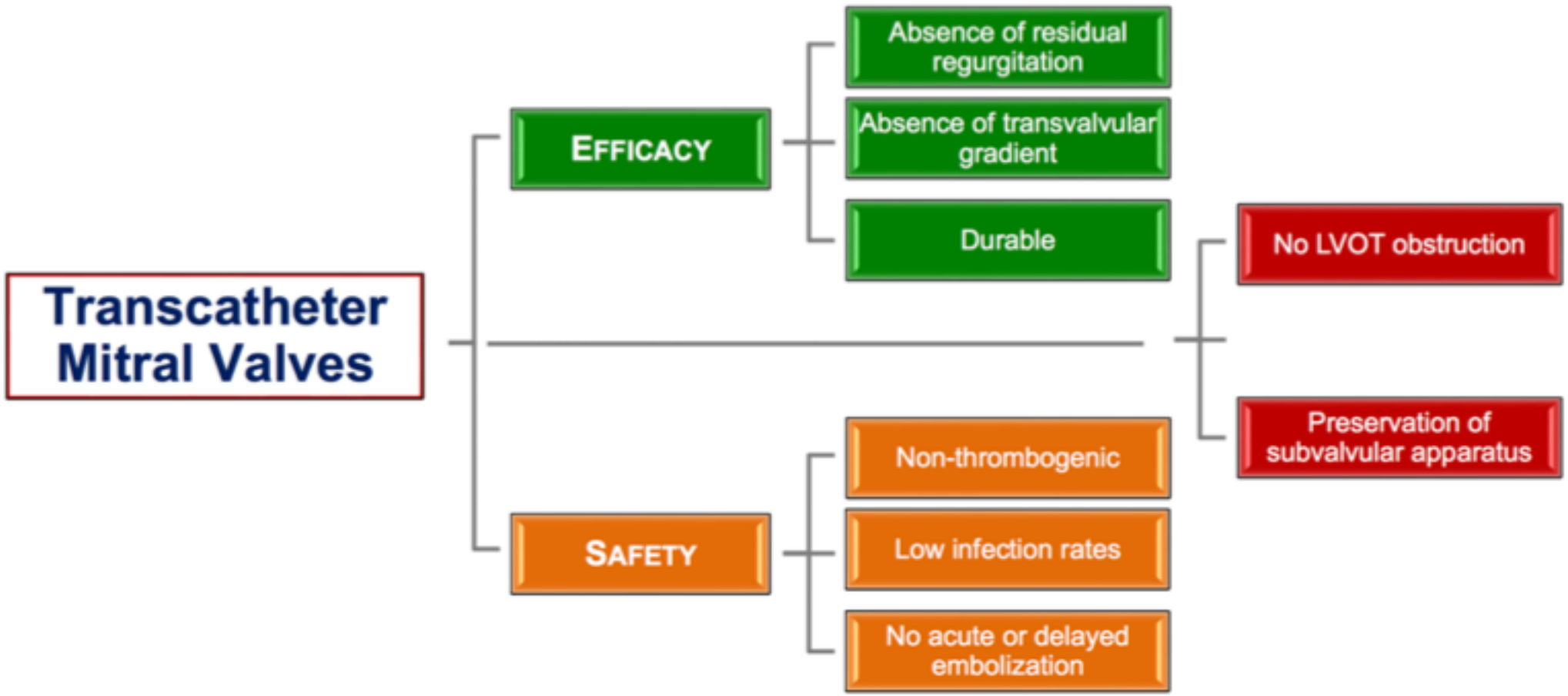


Extremely low risk



Prohibitive risk

# Design Goals of Transcatheter Mitral Valves




Shopping List
1. Milk
2. Eggs
3. Cheese
4. Butter

# TMVR LANDSCAPE

Braile Biomedica

Braile Biomedica

CardiAQ 1st G

CardiAQ Edwards

Cephea

Direct Flow Medical

Twelve Medtronic

M-Valve

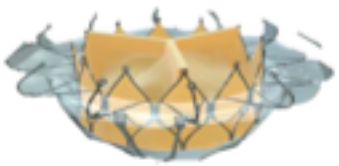
Edwards Fortis

HighLife

Navigate

Neovasc Tiara

PermaValve MID



Sinomed

Tendyne Abbott

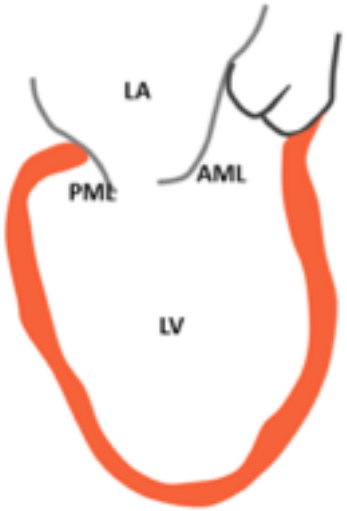
SATURN TMVR

Valtech CardioValve

Caisson

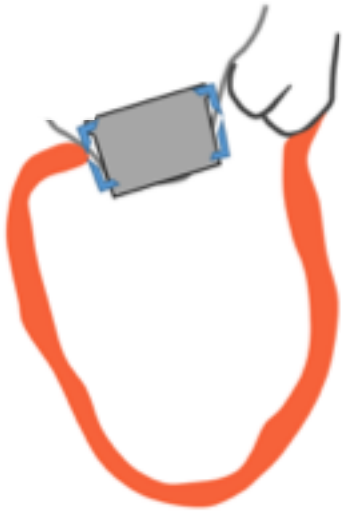
**Others:** MitraHeal, Mitrassist, Mitraltech, Mehr Medical, Mitracath, Mitralix MAESTRO, Nakostech, St. George ATLAS, Transcatheter Technologies Tresillo

# Mitral valve anchoring – some investigated approaches




Tabs to anchor at
myocardial shelf
and fibrous trigones

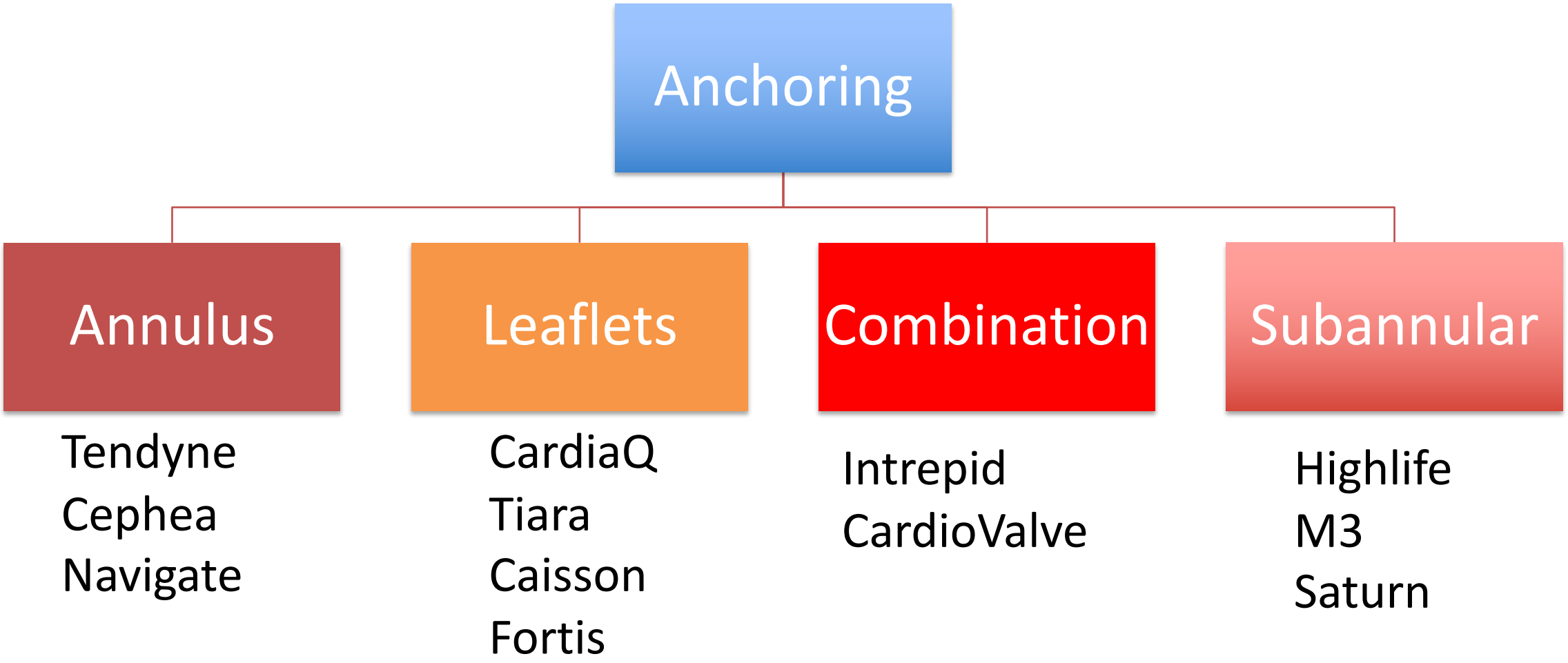
Paddles for attachment
anchoring to leaflets

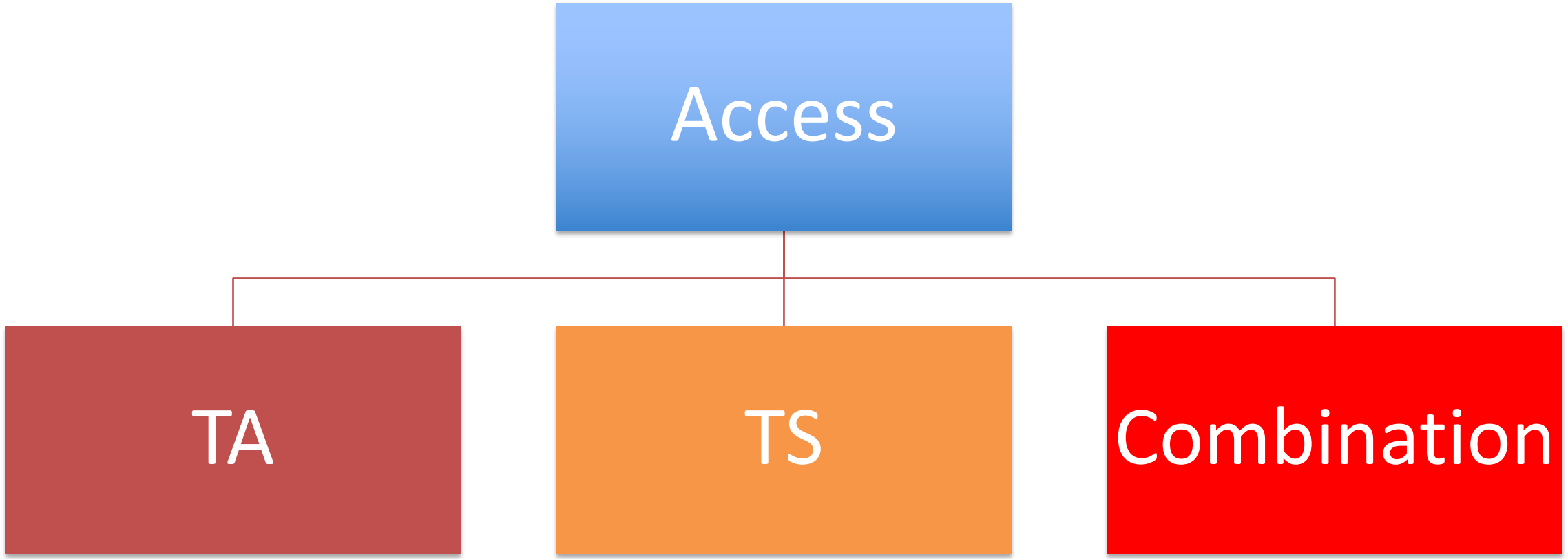


Barbs
(here opposing)

Apical tether
(Neochord)

# TMVR - classification




Access
TA
TS
Combination
Tendyne
Intrepid
Tiara
Fortis
Saturn
4C
CardiAQ
Caisson
M3
Cephea
CardioValve
Highlife

# CardiAQ TA and TS Systems

1st generation

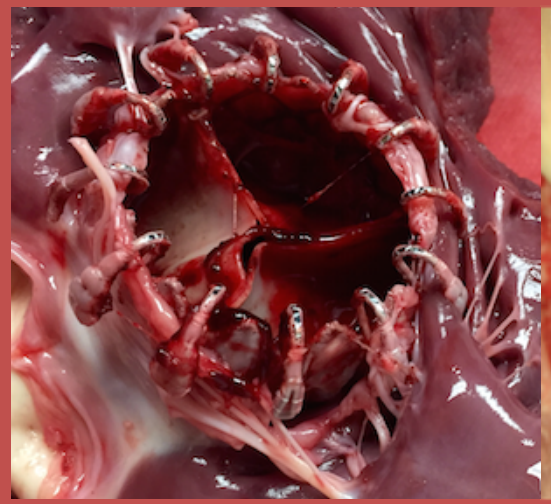
Annular Flap Introduction

New Nitinol Stent Shape

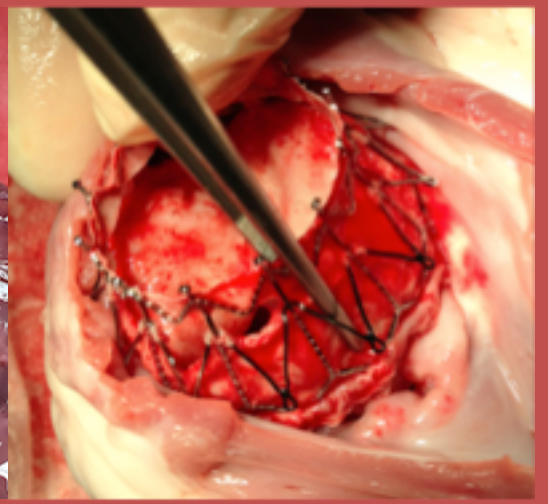
2nd generation

- Designed to be implanted both via TS and TA
- Symmetric design requires no rotational alignment
- Intra-annular and Supra-annular placement
- LV anchors engage annulus and chords

Acute Necropsy (LV)

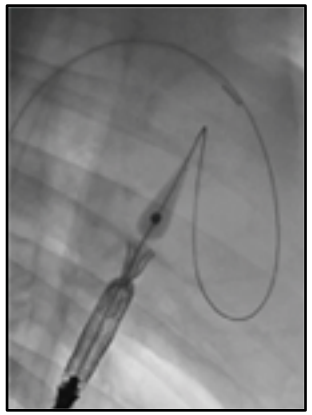


Acute Necropsy (LA)

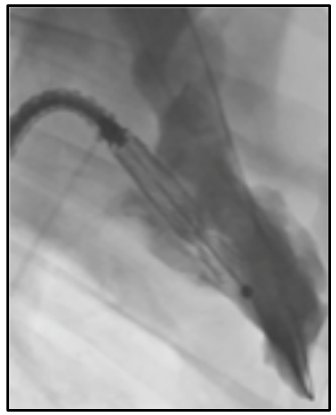


# CardiAQ TA and TF System – TA & TF implantation system

## Transeptal approach



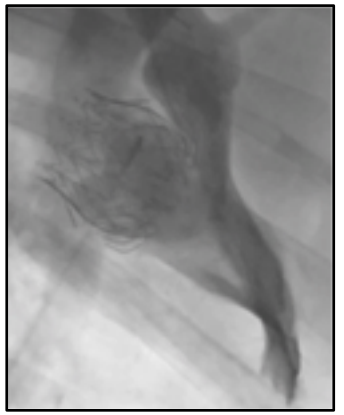
1. Track into LV



2. Depth and Angle

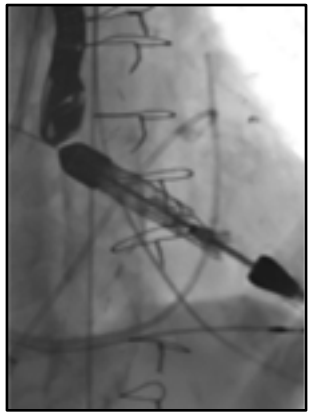
3. Flip LV Anchors

4. Engage + Expand

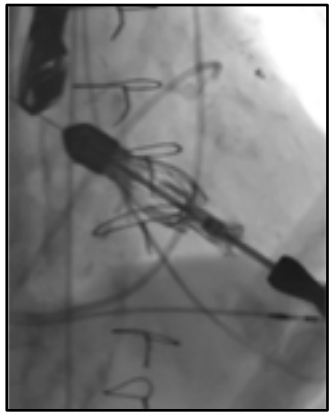


5. Confirm + Release

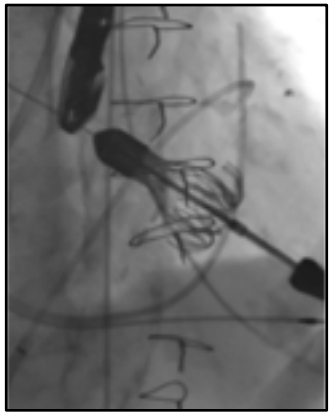
## Transapical approach



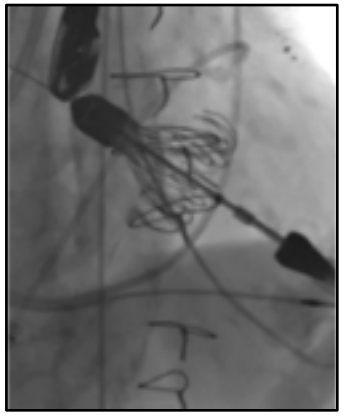
1. Track into LV



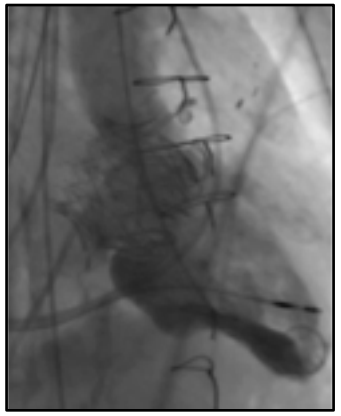
2. Depth and Angle



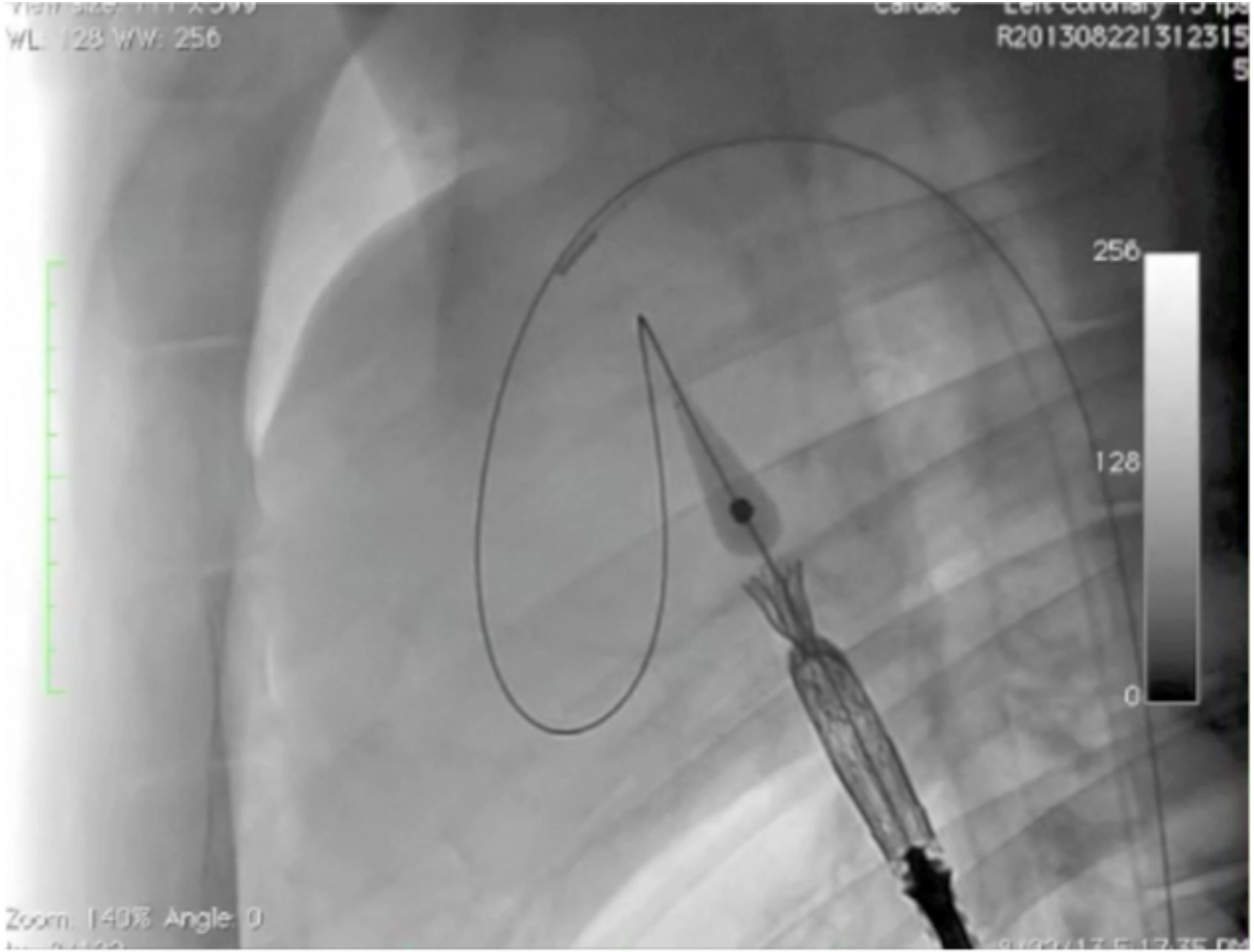
3. Flip LV Anchors



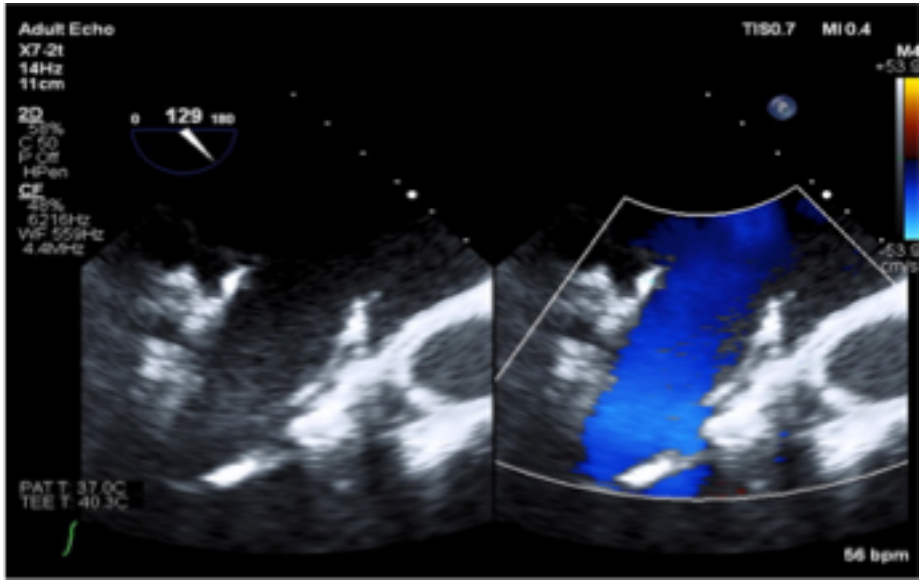
4. Engage + Expand

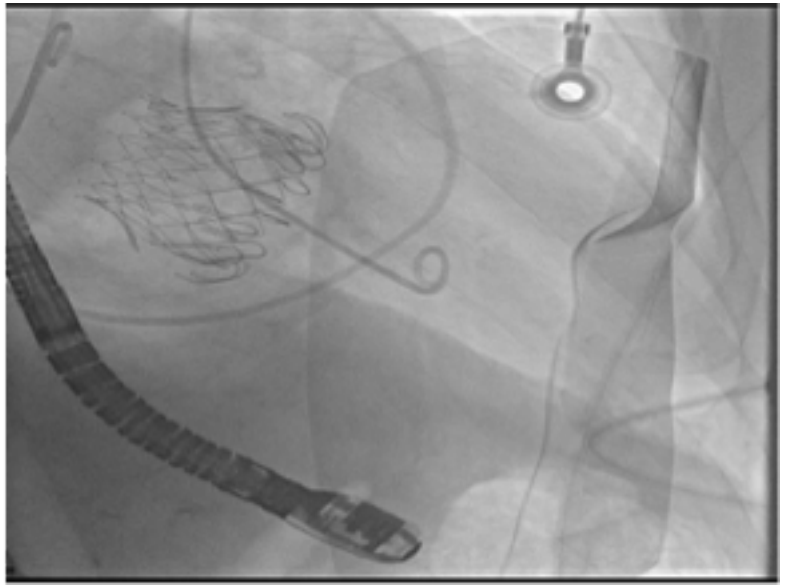


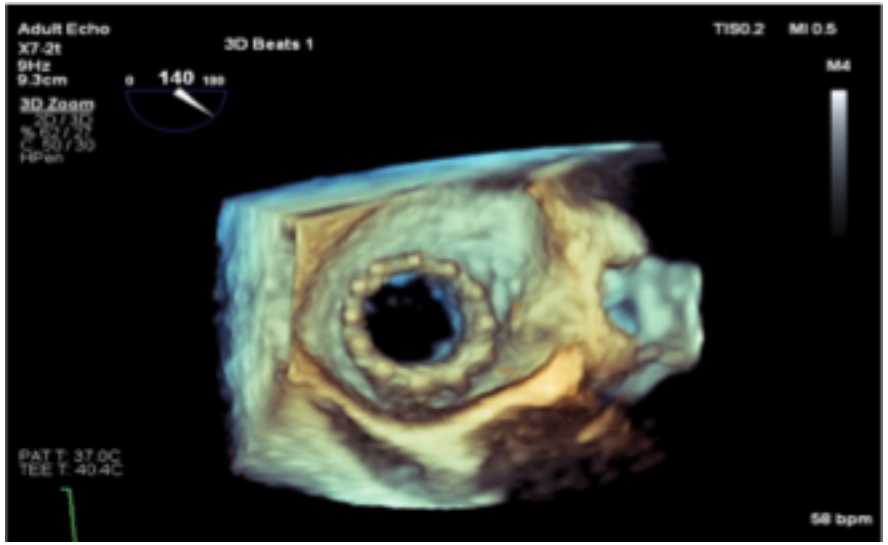
5. Confirm + Release

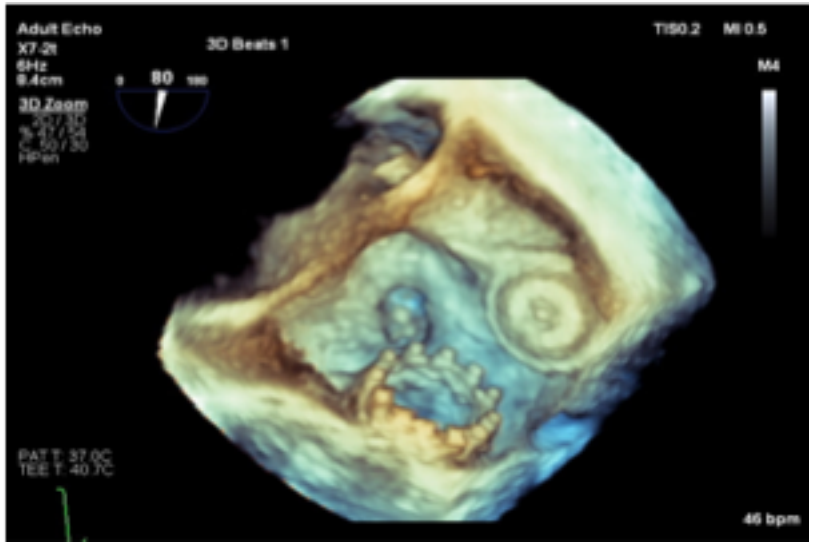

WL: 128 WW: 256
R20130822131231
256
128
0
Zoom: 140% Angle: 0

# Post-implant evaluation






Courtesy of H. Herrmann and W. Szeto,
Hospital of the University of Pennsylvania

# CardiAQ MV Replacement System

| Procedural Factors | N=12<br>% or Mean ± SD |
|---|---|
| **Technical Success**[a] | 75% |
| - Overall | 88% |
| - Streamlined/optimized procedure, n=8 | |
| **Device Time** | |
| - Device insertion to valve deployment, min. | 35±13 |
| **MR Grade 0-1+** | 100% |

**30 day survival = 83% (2 deaths, one procedure-related)**

[a]Technical success, assessed at exit from procedure room, definition: Patient alive with successful access, delivery and retrieval of the transcatheter valve delivery system; and deployment and correct positioning of the single intended device; and no need for additional emergency surgery or re-intervention related to the device or access procedure.

Presented by Howard Herrmann, MD, at TVT 2018.

# CardiAQ-Edwards™ TMVR Early Feasibility Study

30 patients

Estimated Study Completion Date June 2022

ClinicalTrials.gov Identifier: NCT02718001

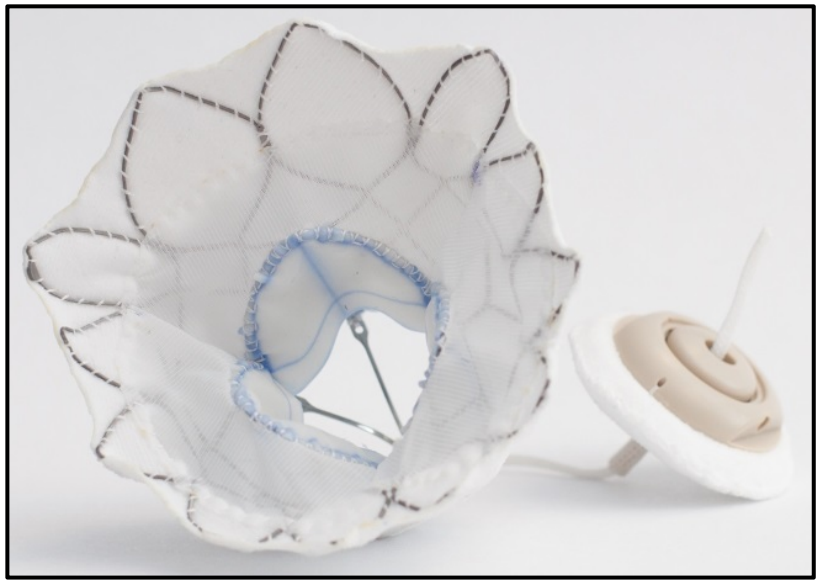
Abbott

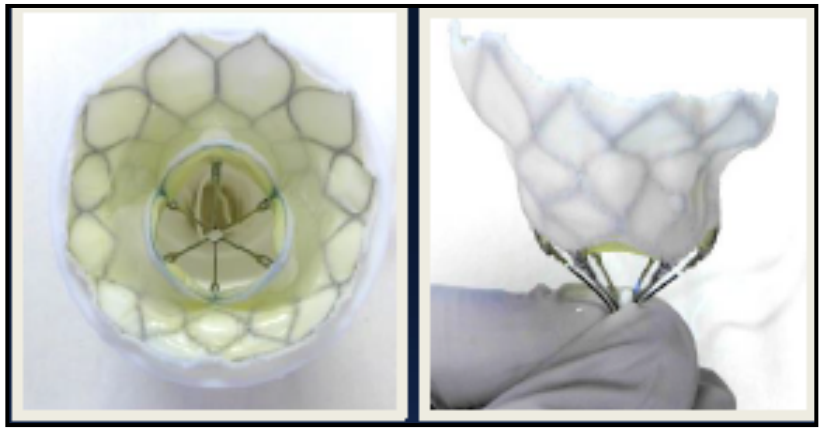
# Tendyne

# Tendyne Transcatheter Mitral Valve

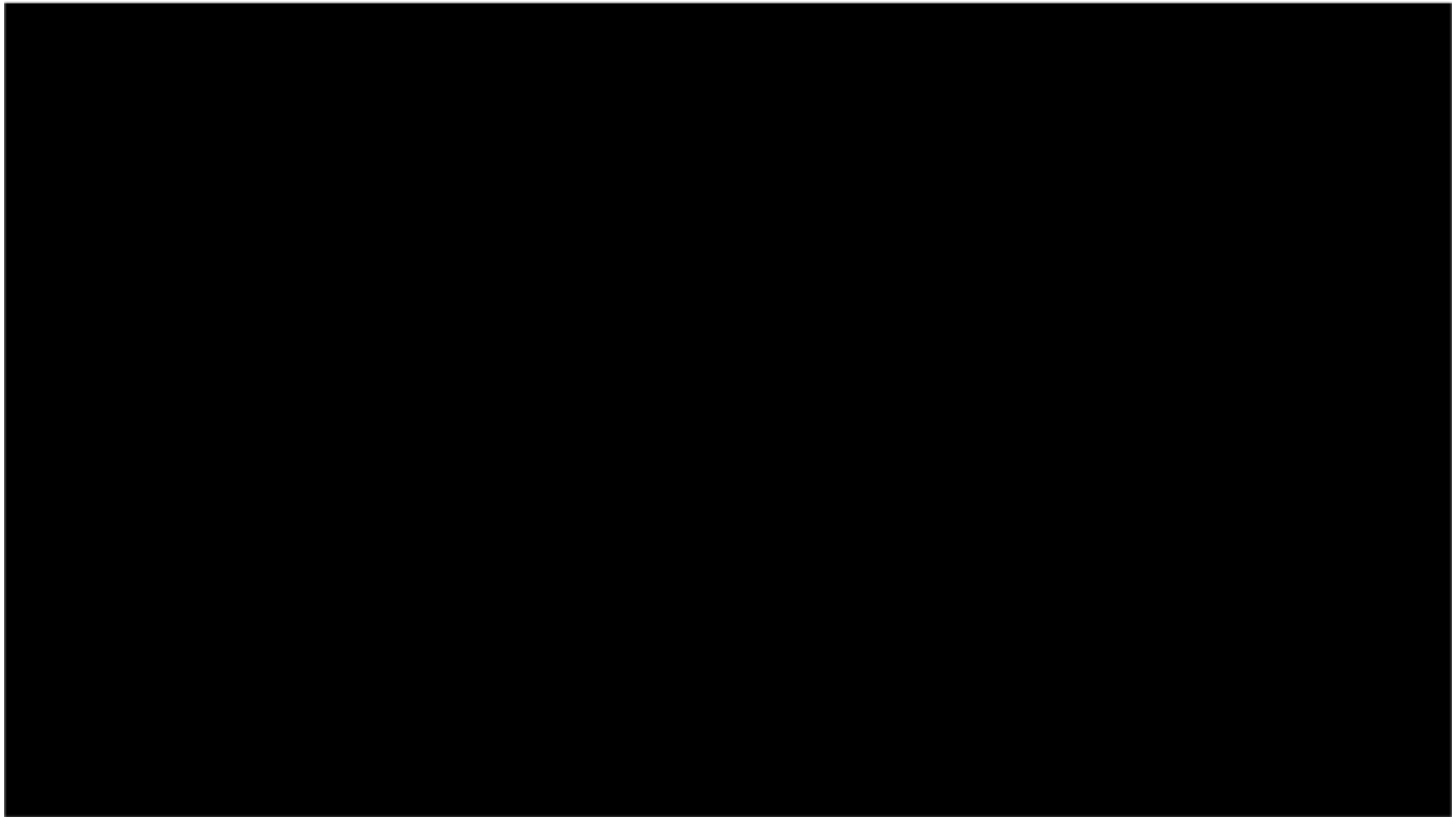
**Tendyne Device**

- D-Shaped Self-Expanding Nitinol Outer Frame
  - Designed to Conform to Native MV Anatomy
- Circular Self-Expanding Nitinol Inner Frame
  - Large Effective Orifice Area (>3.0cm2)
  - Larger EOA than any Surgical Valve
- Porcine Pericardial Tri-Leaflet Valve
- Large Valve Size Matrix to Treat Varying Anatomies
  - Outer Frame Sizes: 30-43mm AP x 34-50mm CC
- Valve Tether to Apex
  - Provides Valve Stability - Designed to Reduce PVL
- Apical Pad Assists in Access Closure





Tendyne product is currently in development at Abbott. Neither approved or available for sale.

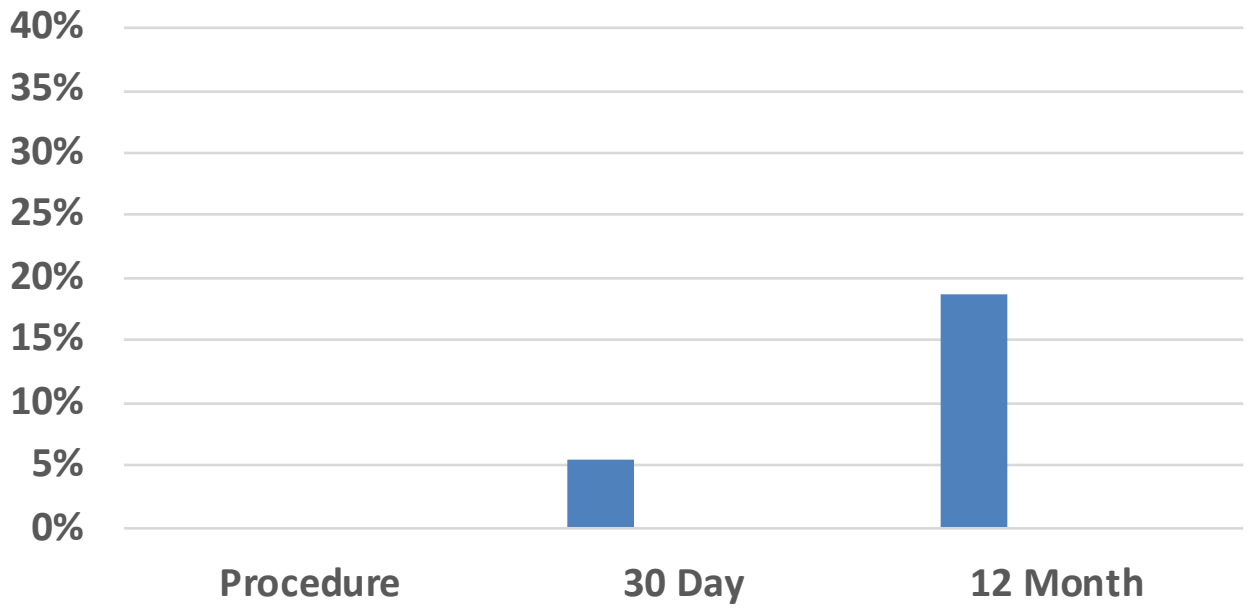


# Outcomes

| Procedure Outcome | N=90 |
|---|---|
| Device Implant Success | 87 (96.7%) |
| LVOTO (Retreival) | 1 (1.1%) |
| Valve Seating (Retreival) | 1 (1.1%) |
| Procedure (no valve attempt) | 1. (1.1%) |
| Procedure Mortality | 0 (0.0%) |

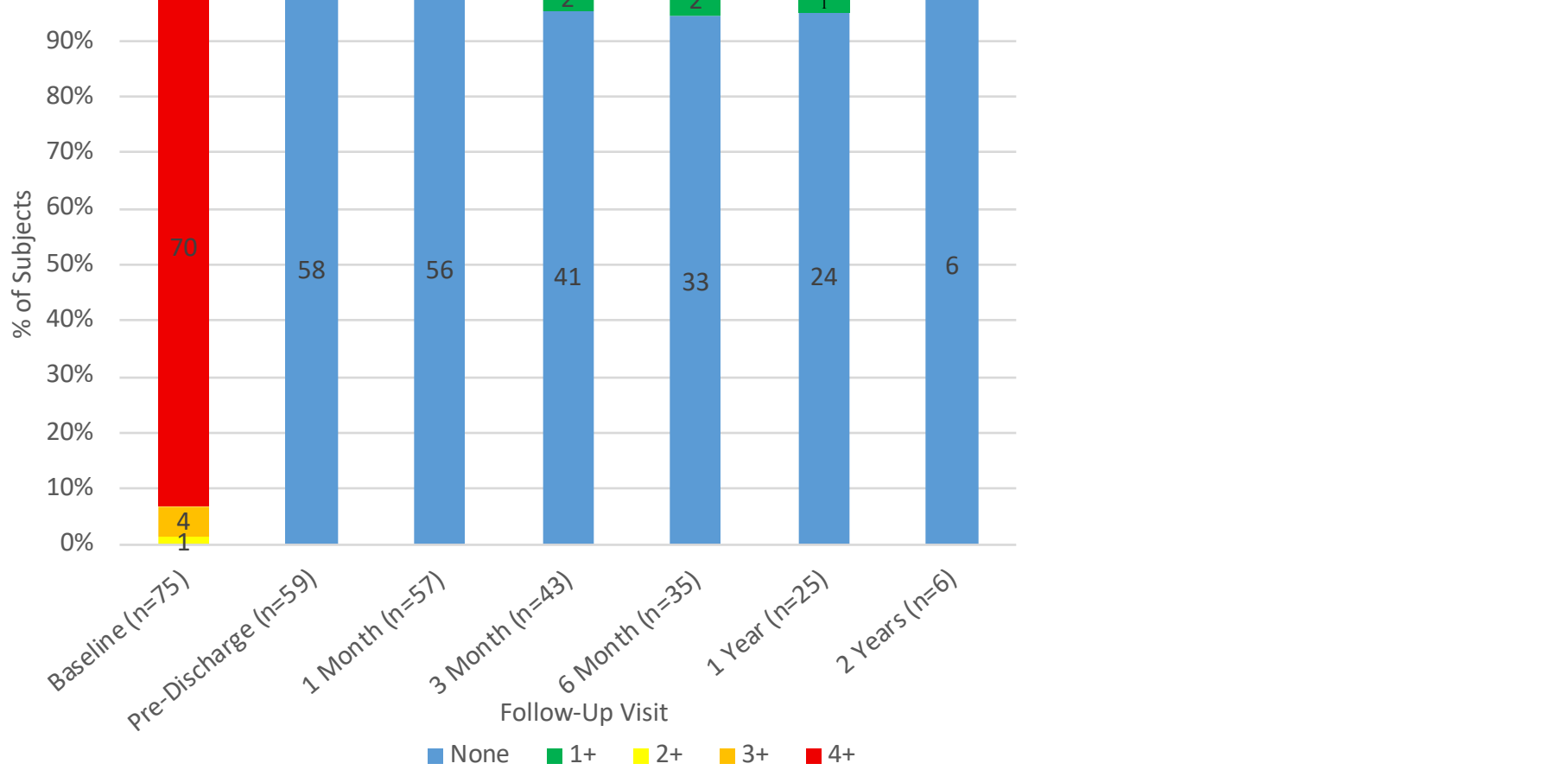
| 30 Day Outcome | N=90 |
|---|---|
| Death | 5 (5.5%) |
| Disabling Stroke | 1 (1.1%) |
| MI | 1 (1.1%) |
| MV Surgery | 0 (0.0%) |

# Mortality: Procedure, 30 days, 12 months




| Tendyne | N=90 | |
|---|---|---|
| Procedure | 0/90 | 0.0% |
| 30 Day | 5/90 | 5.5% |
| 12 Month | 17/90 | 18.8% |

# CS-03 Study – Core Lab Adjudicated MR Gr[illegible]




Data as of 25 Sept 2017

# Treatment of Symptomatic Mitral Regurgitation (**SUMMIT**) Tendyne randomized Trial

1010 Ptz, Functional high risk

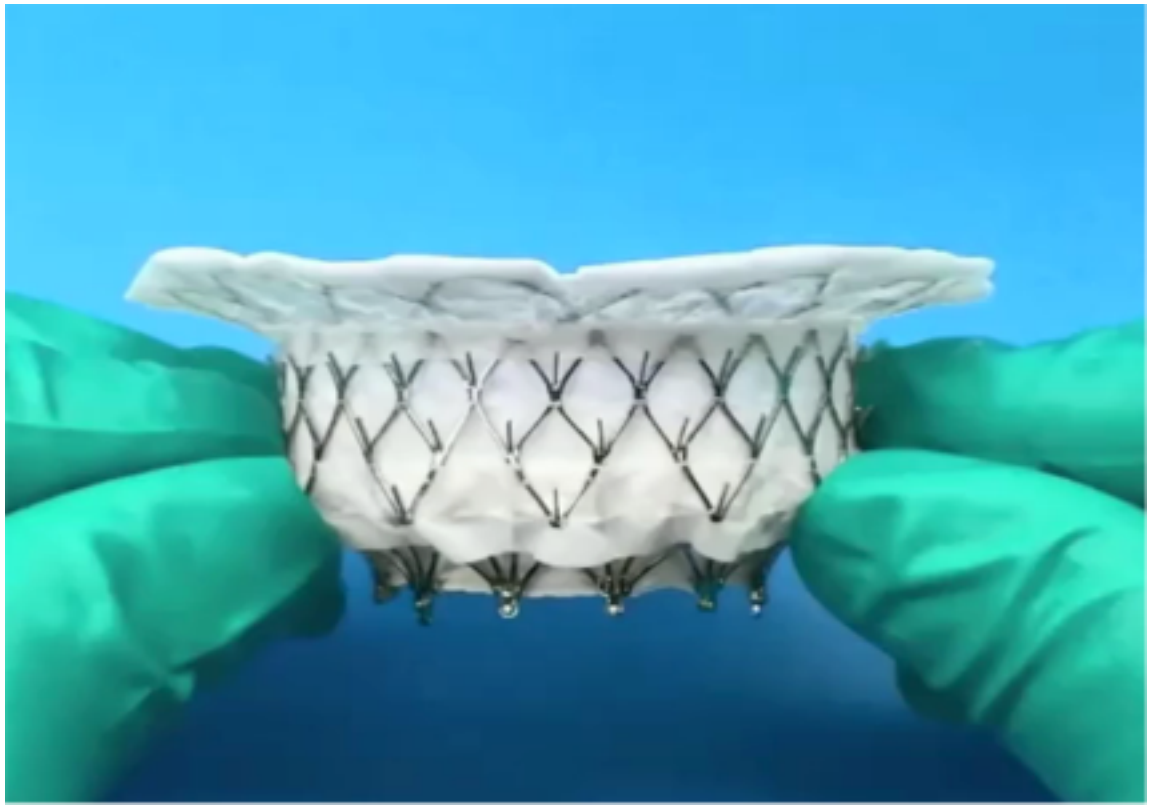
- Surgical candidate

  standard surgery (control) Vs. Tendyne

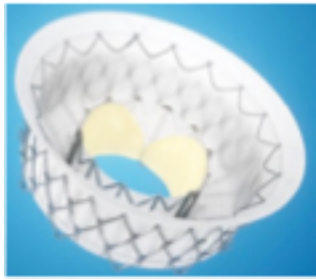
- Non surgical candidate → Tendyne

ClinicalTrials.gov Identifier: NCT03433274

# Intrepid TMVR Dual-Stent System

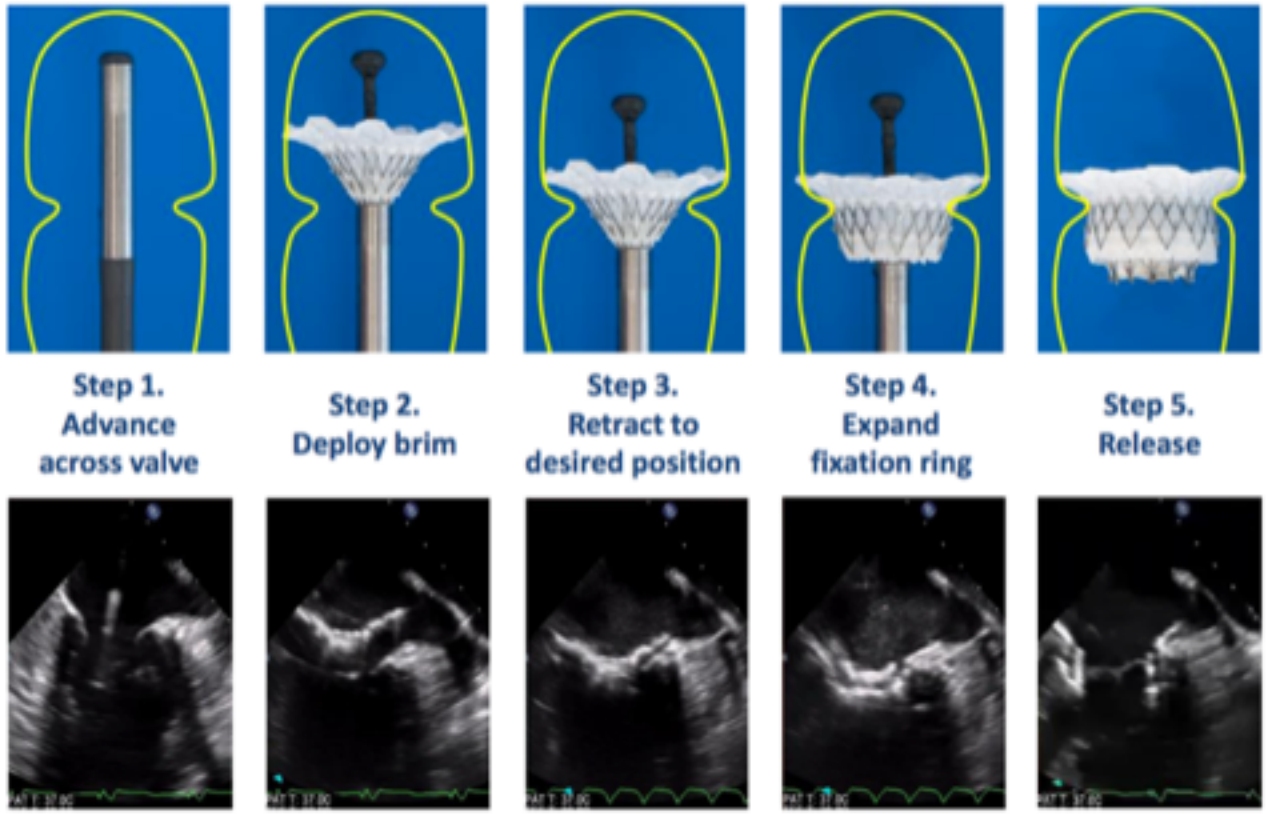


- Conformable Outer Stent engages annulus and leaflets providing fixation and sealing
- Circular Inner Stent houses a 27 mm tricuspid bovine pericardium valve
- Flexible Brim aids imaging during implantation & subsequent tissue in-growth



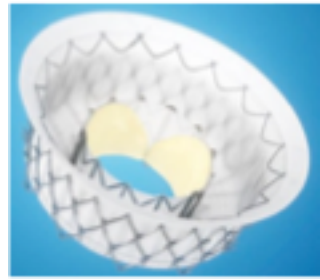
# Medtronic Intrepid TMVR

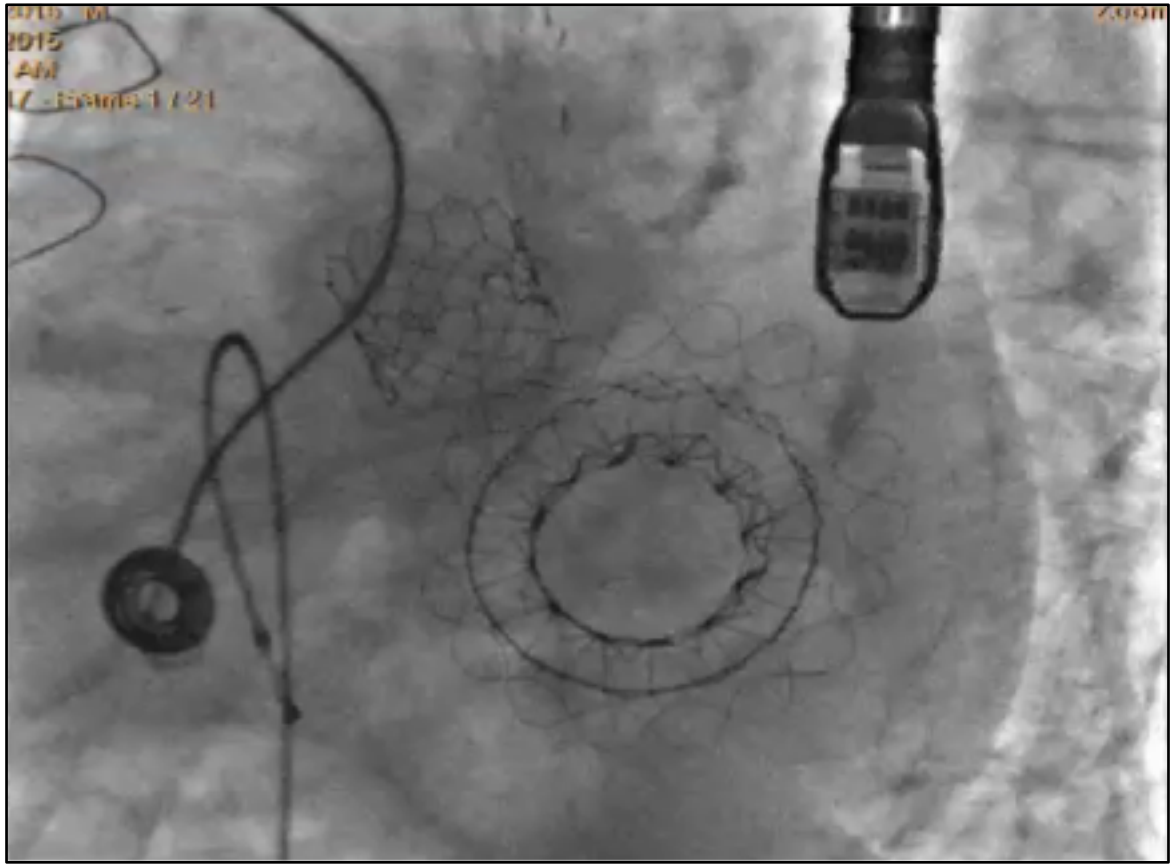
## Hydraulic Deployment of Self-Expanding Stent

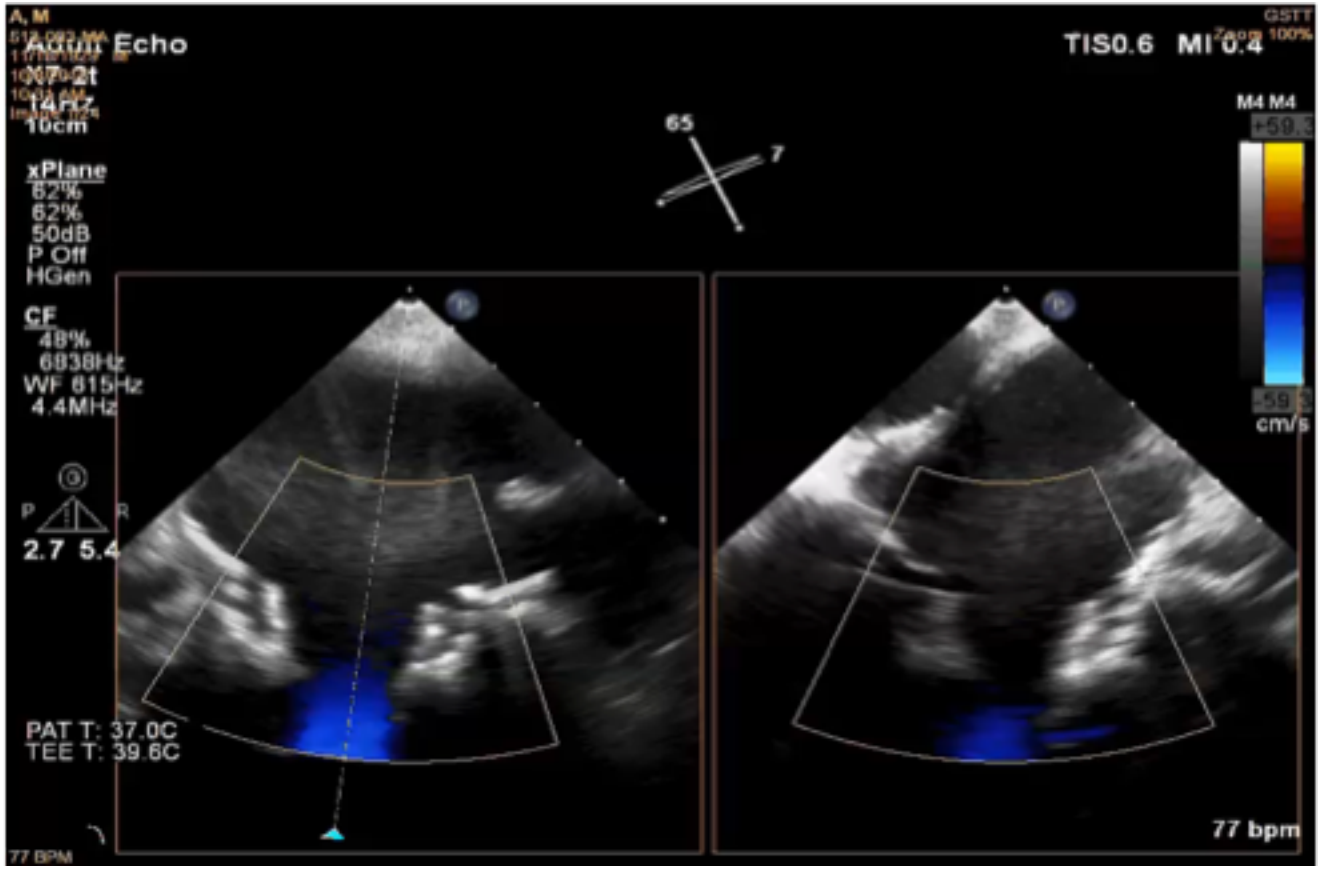



No need for rotational alignment - No need to search for leaflets

# Implant Result

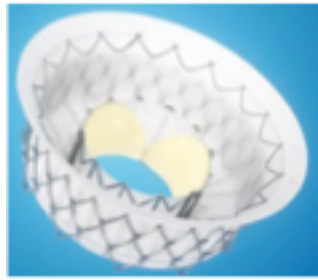


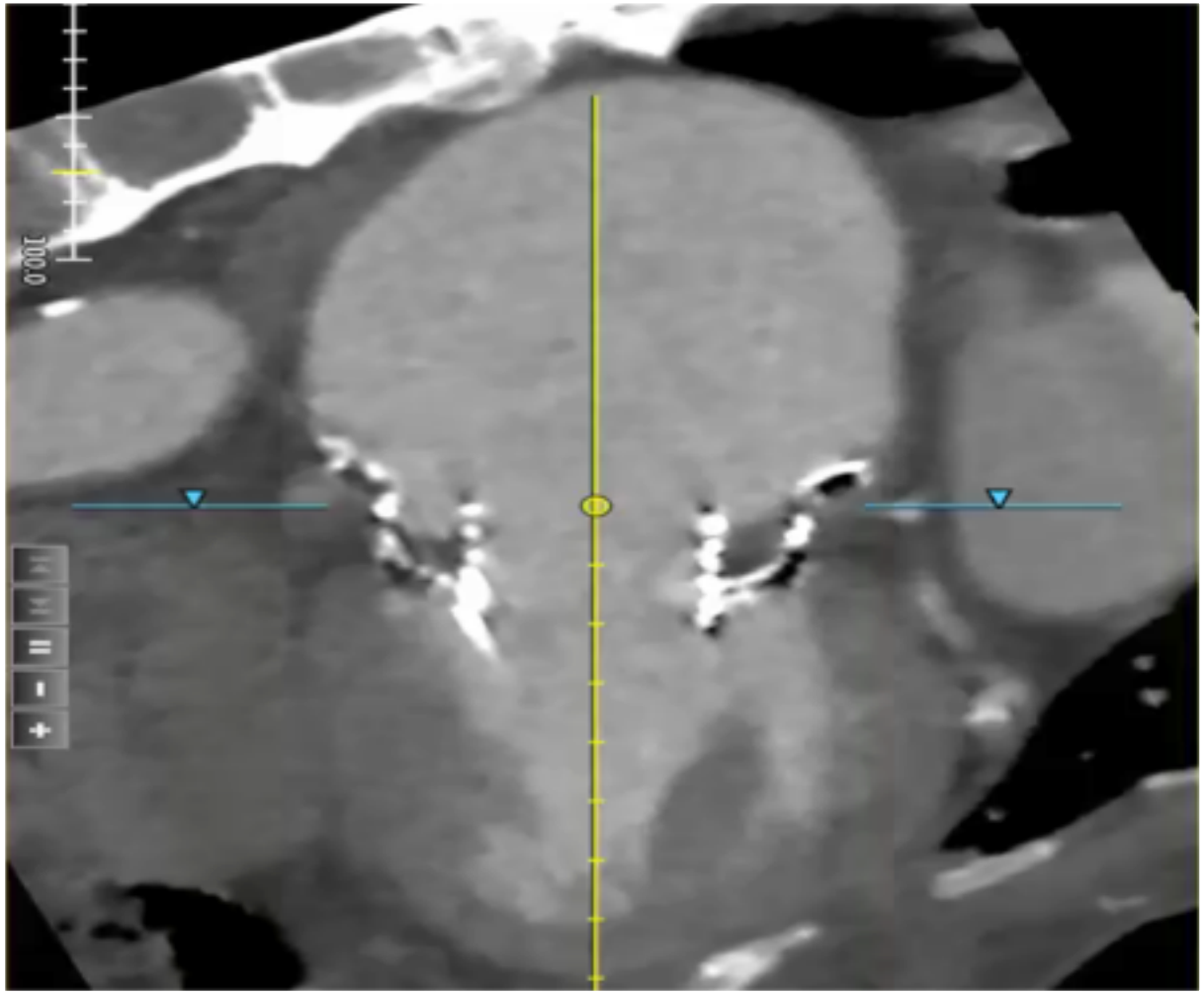




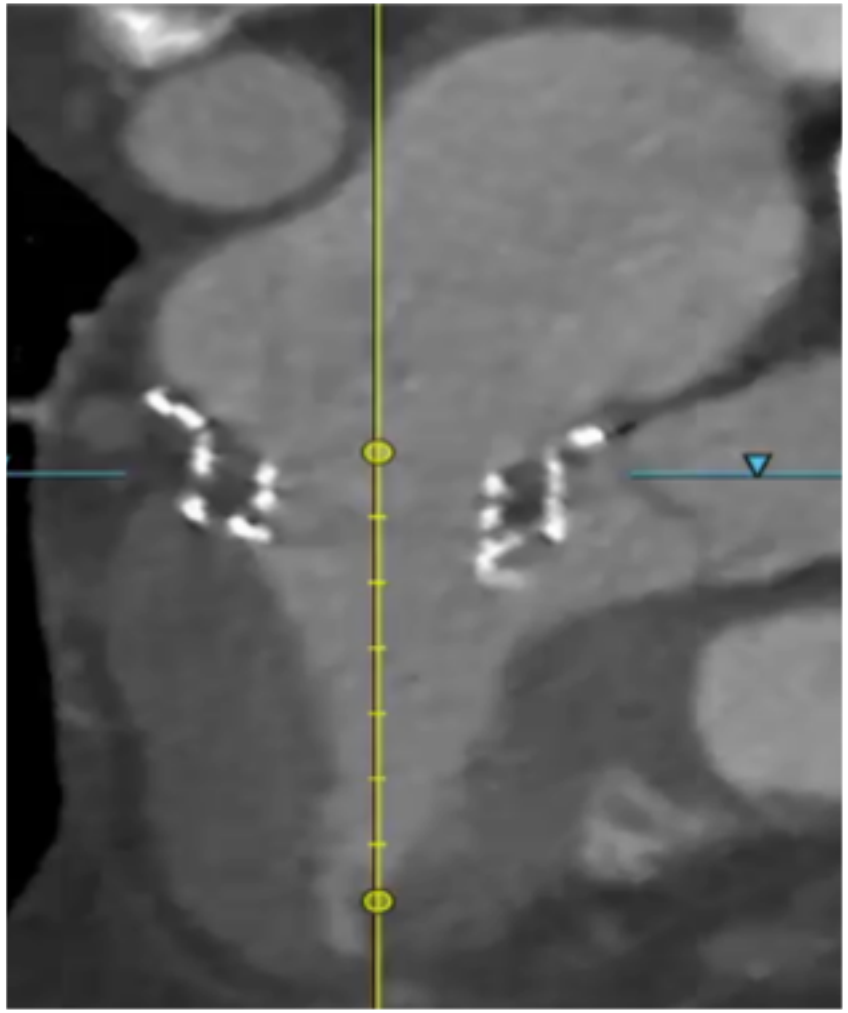

Trans-mitral pressure gradient is 2 mmHg (mean)

# Intrepid TMVR
## Case Examples (12 month FU CT)



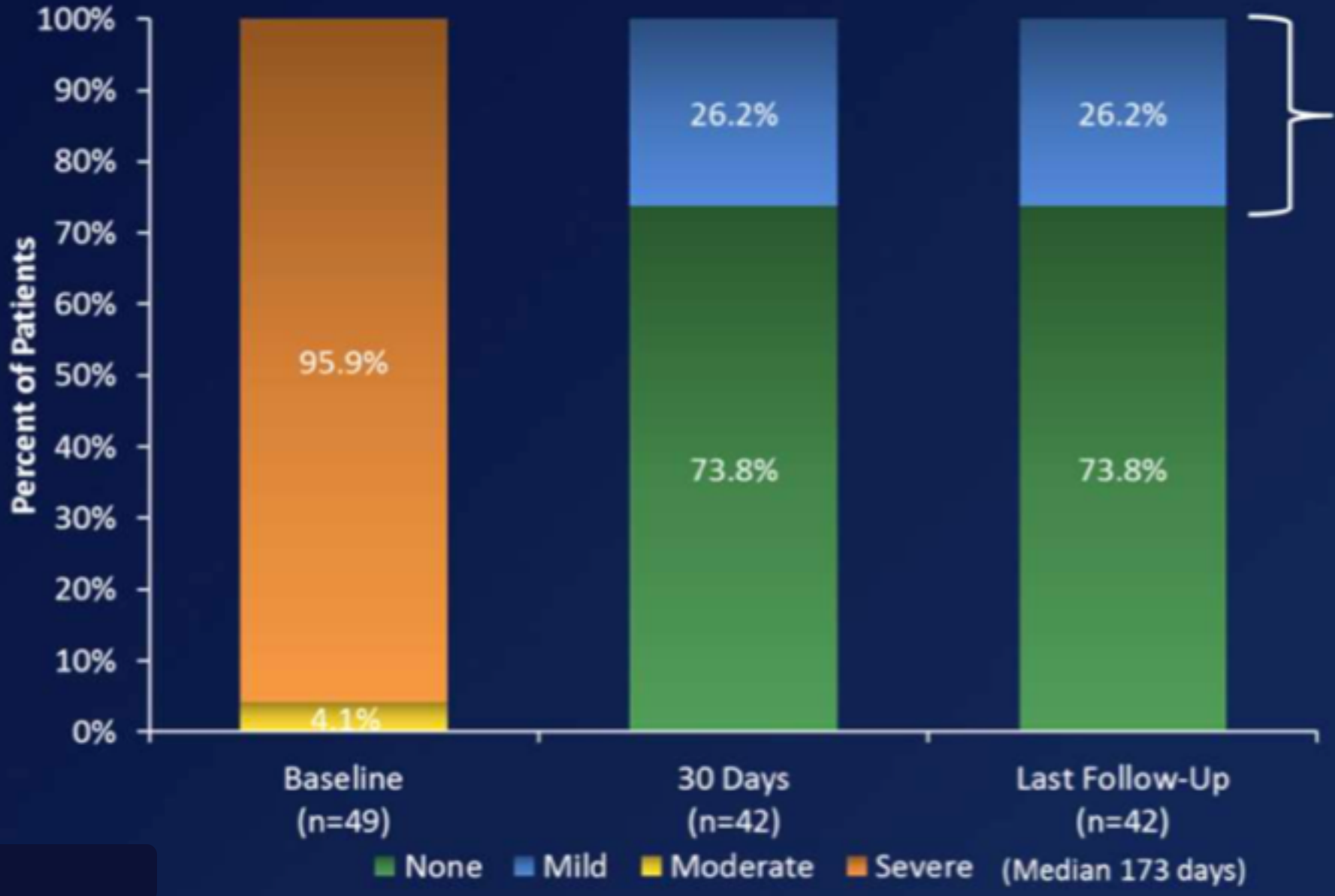


Patient #4: 12-month FU



Patient #6: 12-month FU

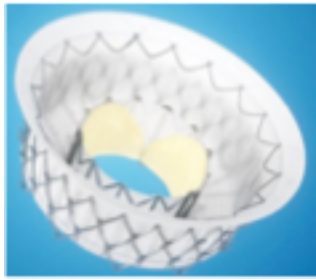
# Mitral Regurgitation Severity




Mild MR
Paravalvular: 3 (7.1%)
Transvalvular: 8 (19.0%)

All patients with mild or no MR in follow-up

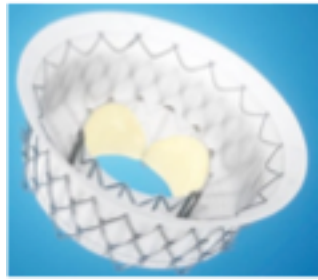
Intrepid Global Pilot Study



# Data Summary (n=50)

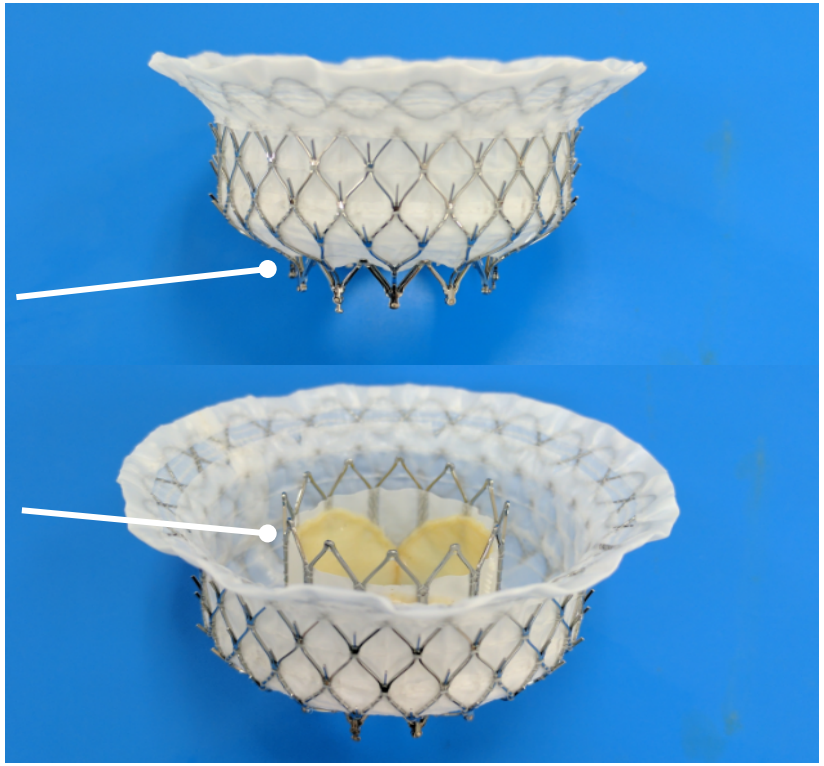
- Device implant success in 48/49 (98%)
- 30-day mortality = 14%
  - 3 from apical bleeding, 3 from CHF, 1 from malposition
- One-year survival = 77%
  - 3 SCDs in patients with low EF and no ICDs
  - No death after 180 days
- No device malfunction, hemolysis, or thrombosis
- No or mild MR in all survivors
- 79% of patients in NYHA class I or II in follow-up

# Intrepid TMVR
# Next Generation Systems
# 1. Recoverable Design

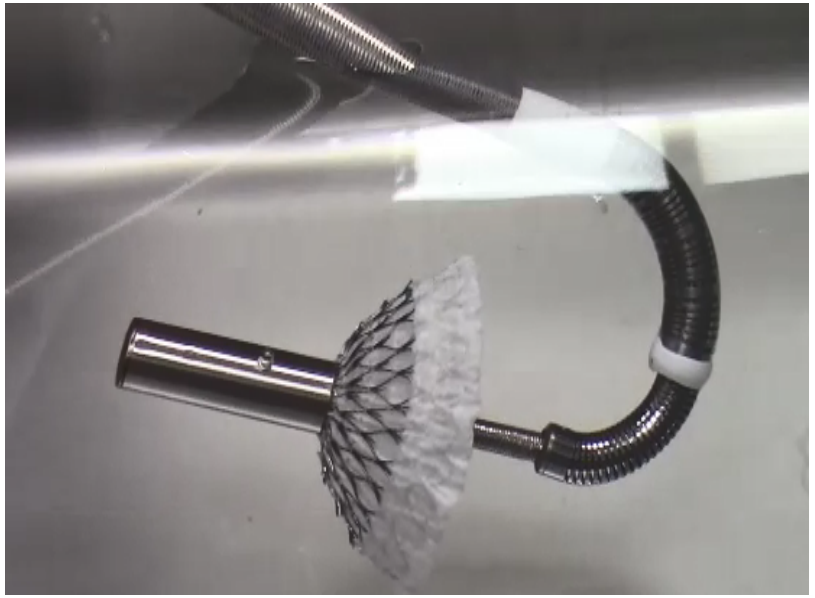


Ventricular section allows recoverability

Closed-cell inner structure facilitates recoverability

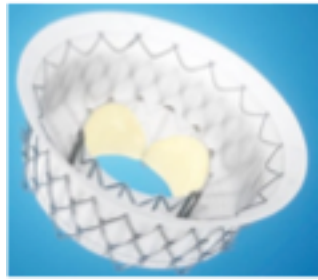


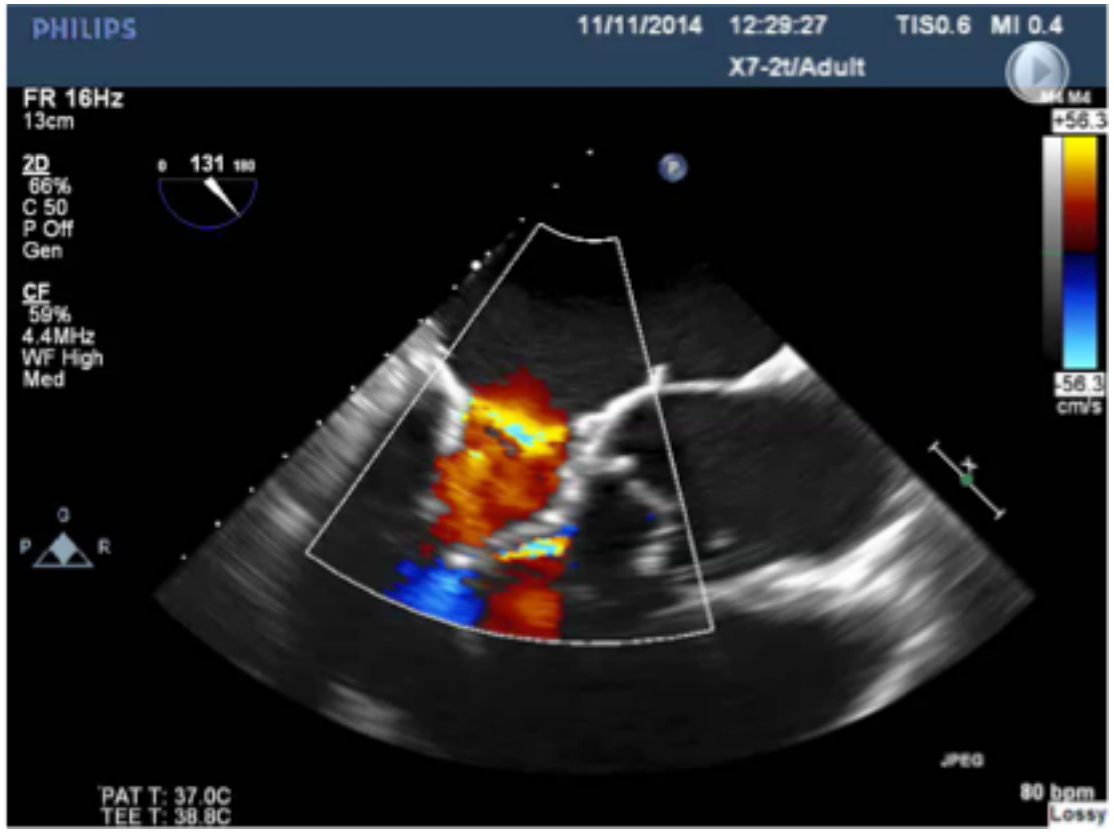
# Intrepid TMVR
# Next Generation Systems

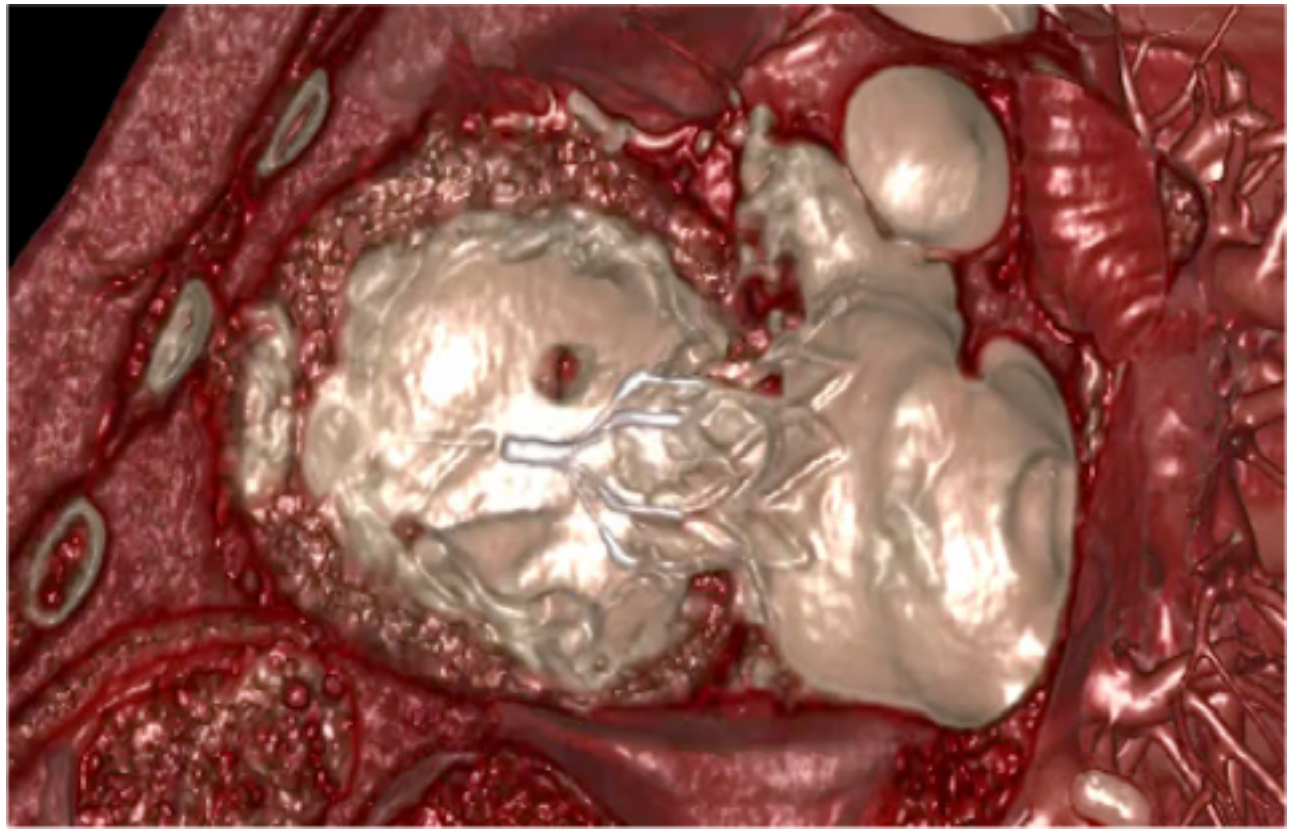



- Trans-septal, trans-femoral system in development (enabled by implant design not requiring rotational alignment or need to capture leaflets)
- One implant platform regardless of delivery approach: TS or TA

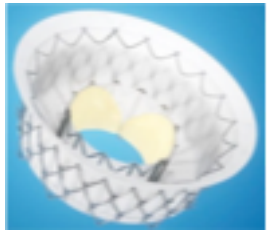
# Case Example





# Apollo Trial



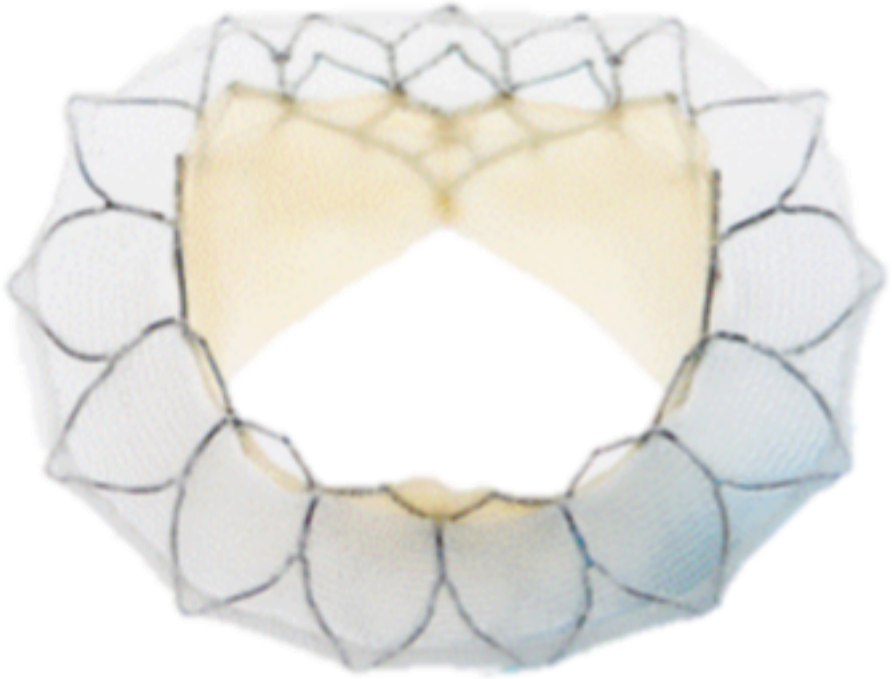
- 1380 pts randomized
- Surgical candidate

  surgical mitral valve **replacement** (control) Vs. Intrepid
- Non surgical candidate → Intrepid

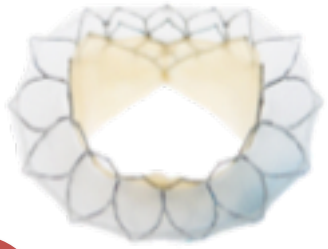
- All-cause mortality, all-stroke, reoperation or reintervention and cardiovascular hospitalization at 1 year
- Non inferiority 1 Years
- Secondary endpoints in the trial include quality of life measures and valve performance in patients with severe symptomatic mitral regurgitation

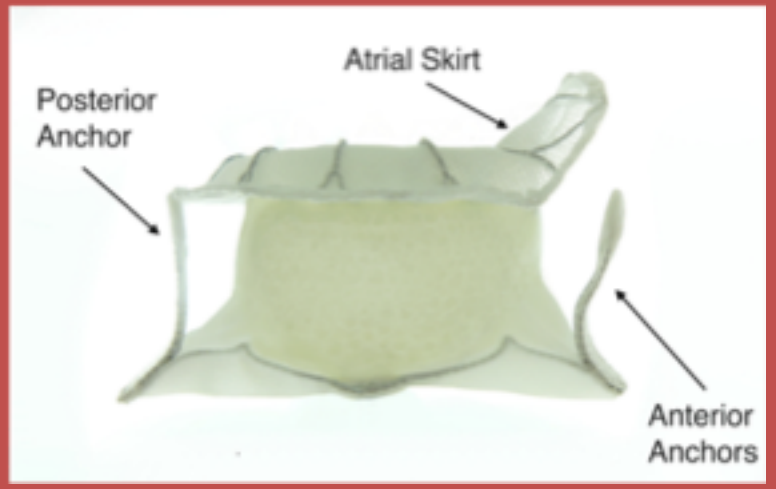
ClinicalTrials.gov Identifier: NCT03242642

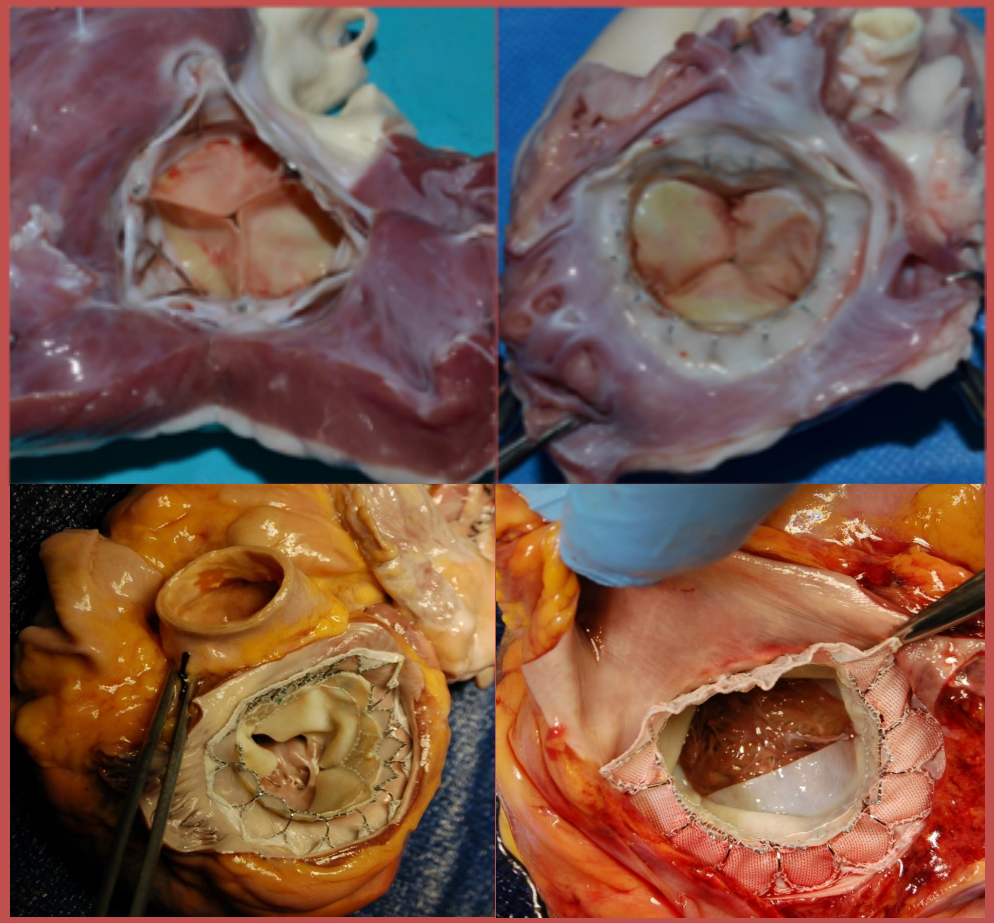
# Tiara



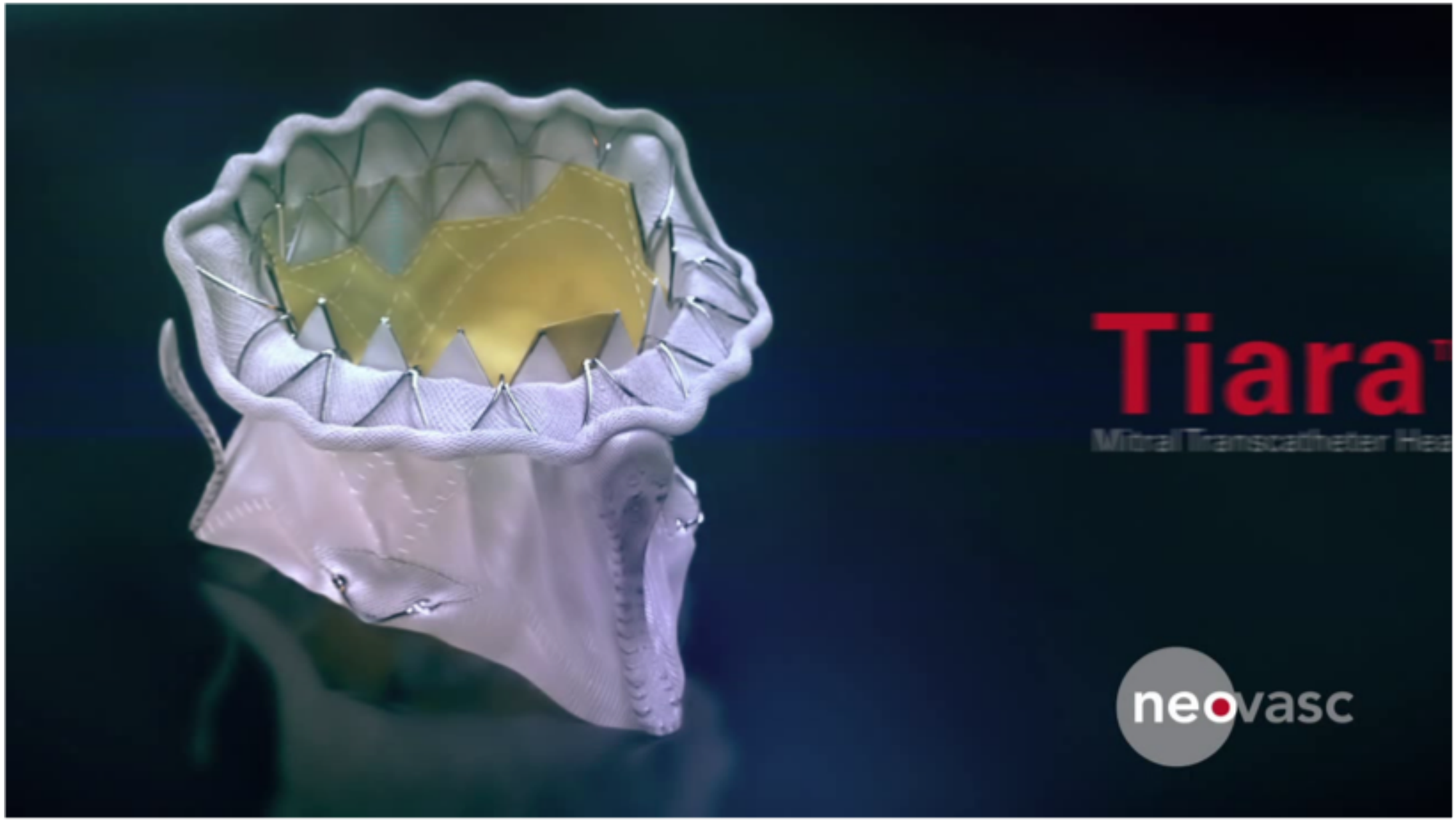
# Tiara Transapical System



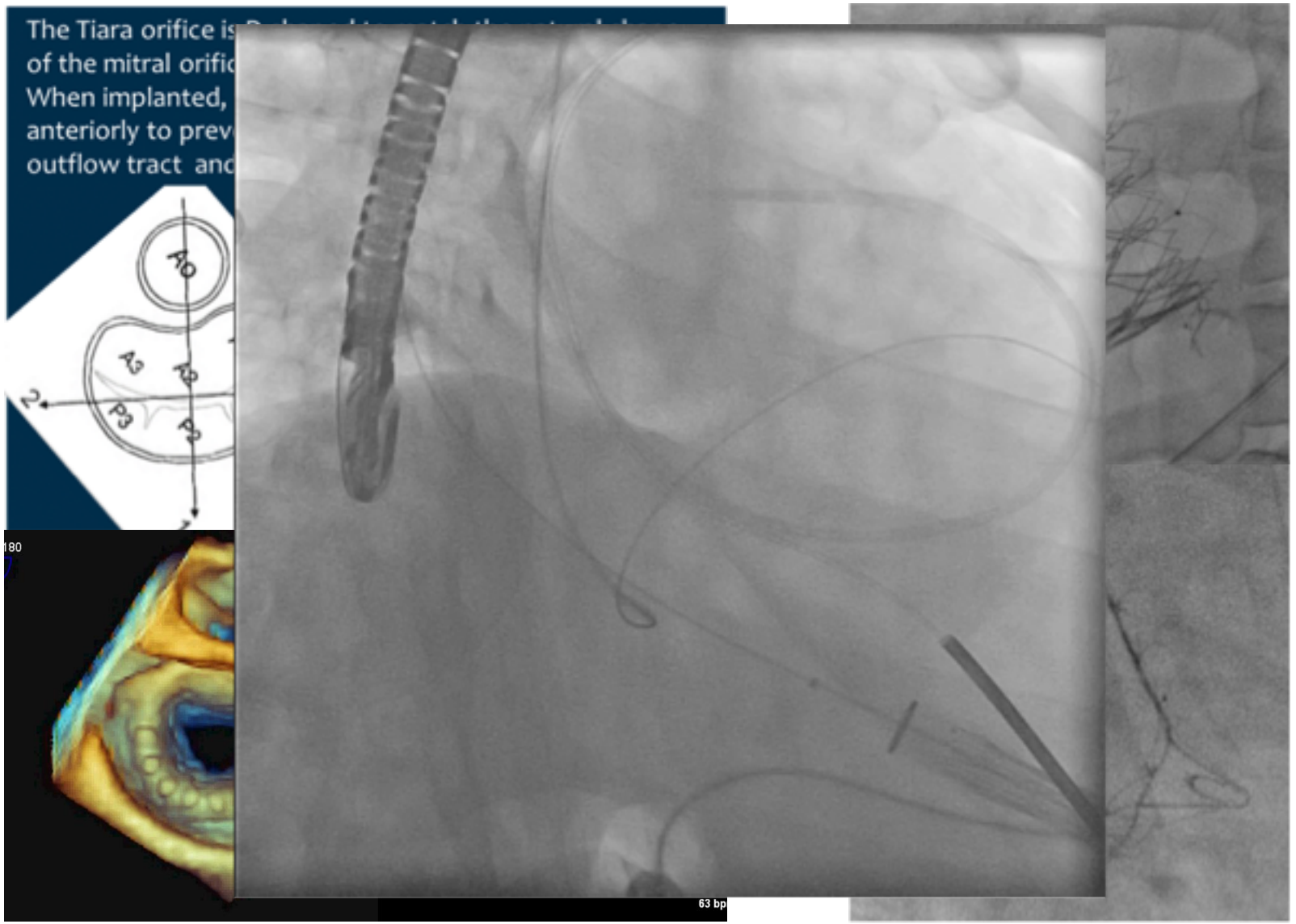


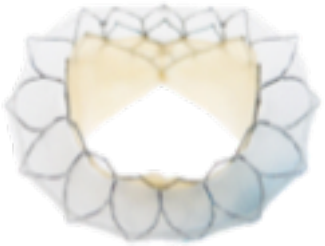
- Transapical access
- Anatomically shaped (D-shaped)
- Nitinol based, self-expanding frame
- Full Atrial skirt
- Ventricular anchors to fix the valve


Tiara
neovasc

# Tiara Transapical System – The D-shape feature



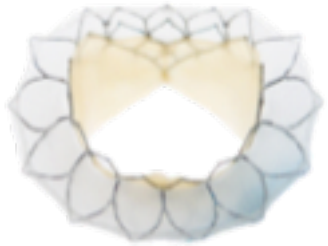
# TIARA Clinical Program



Currently, 34 patients have been treated with Tiara TMVR

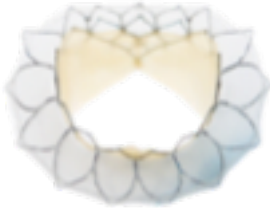
- **Special Access/Compassionate Use** (n=20)
  (Canada, Italy, Germany, Switzerland, Israel)
- **TIARA-I Early Feasibility Clinical Study** (n=30)
  ClinicalTrials.gov Identifier: NCT02276547
  (USA, Canada, Belgium)
- **TIARA-II European CE Mark Clinical Study** (n=115 pts)
  ClinicalTrials.gov Identifier: NCT03039855
  - First implant in Italy occurred on 28 Apr 2017
  - Investigational sites/countries: Italy, Germany, UK

# Procedural and 30 Day Outcomes (n=34)



| | |
|---|---|
| Peri-procedural Death | 0 |
| Cerebrovascular Event | 0 |
| Myocardial Infarction | 0 |
| Access Site Complication | |
| -Minor | 0 |
| -Major | 1 (3%) |
| Paravalvular Leakage (>2+) | 0 |
| LVOT obstruction | 0 |
| Acute Kidney Injury | 0 |
| Device migration | 2 (6%) |
| Conversion to open heart surgery | 3 (9%) |
| All-cause 30-Day Mortality | 4 (12%) |
| Cardiac 30-Day Mortality | 2 (6%) |

# TIARA Clinical Experience

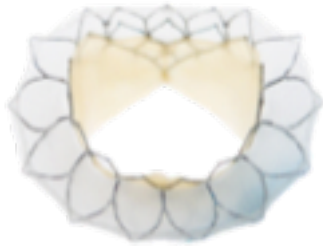


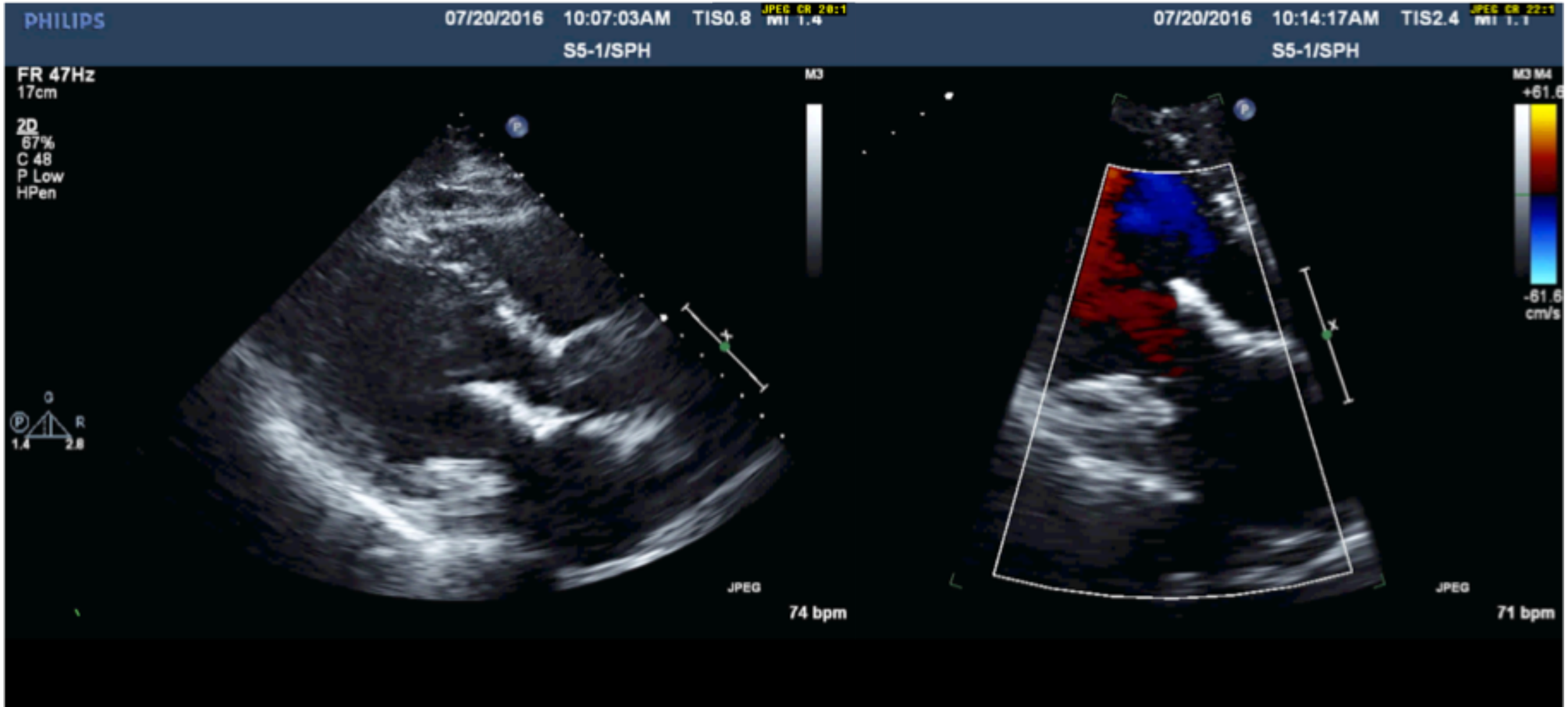
- 34 patients treated in Canada, Belgium, Germany, Italy, Switzerland, USA and Israel:
  - 31 successful implants, with excellent acute results
  - 3 patients were converted to open MVR due to valve malposition
- 30-day mortality 12%
- Longest follow up over 3 years – excellent valve function, no MR
- All available follow up imaging show none to mild-moderate MR
- No fractures detected in follow up CTA

# Patient (3 year post Tiara implant)

NYHA II

Good valve function, no PVL, no LVOT obstruction, MG-2mmHg

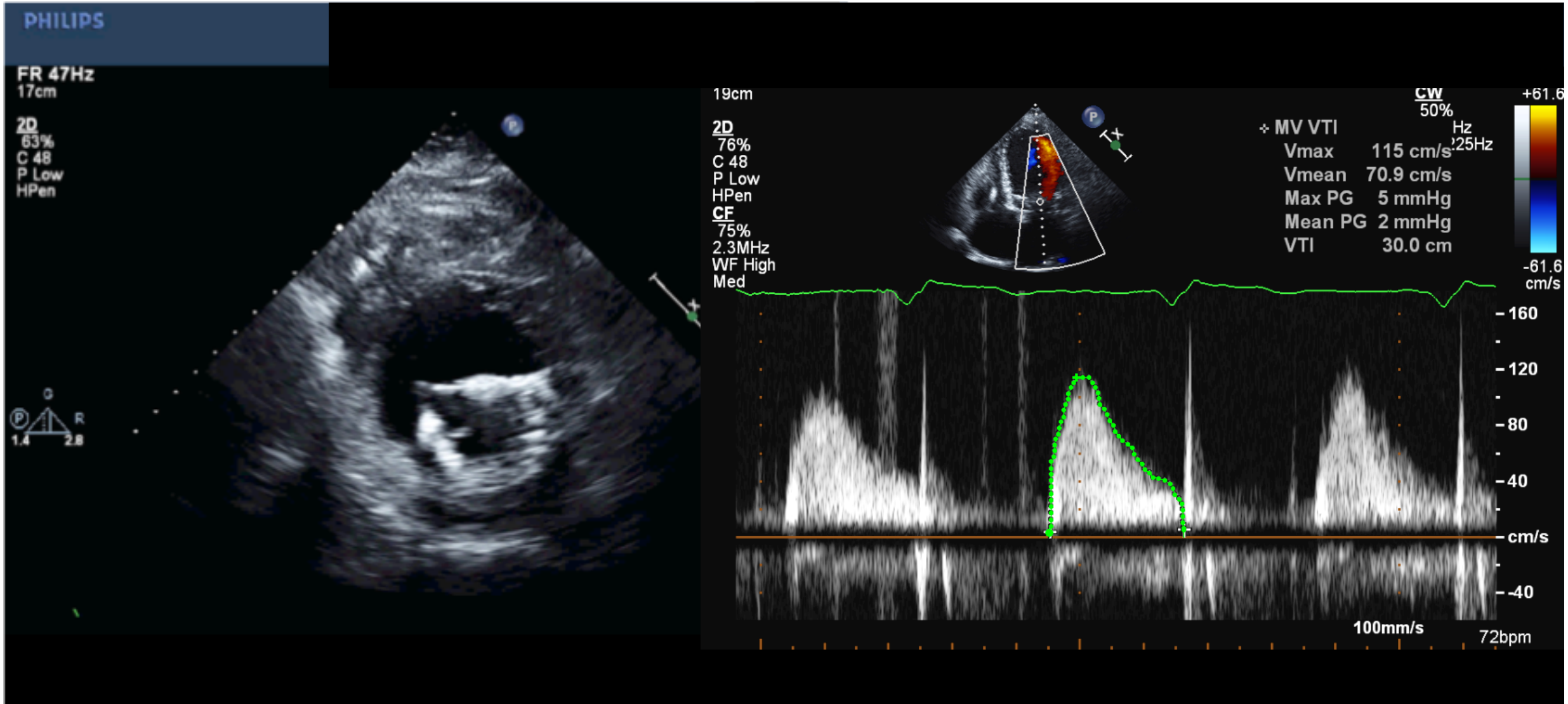




# Patient (3 year post Tiara implant)

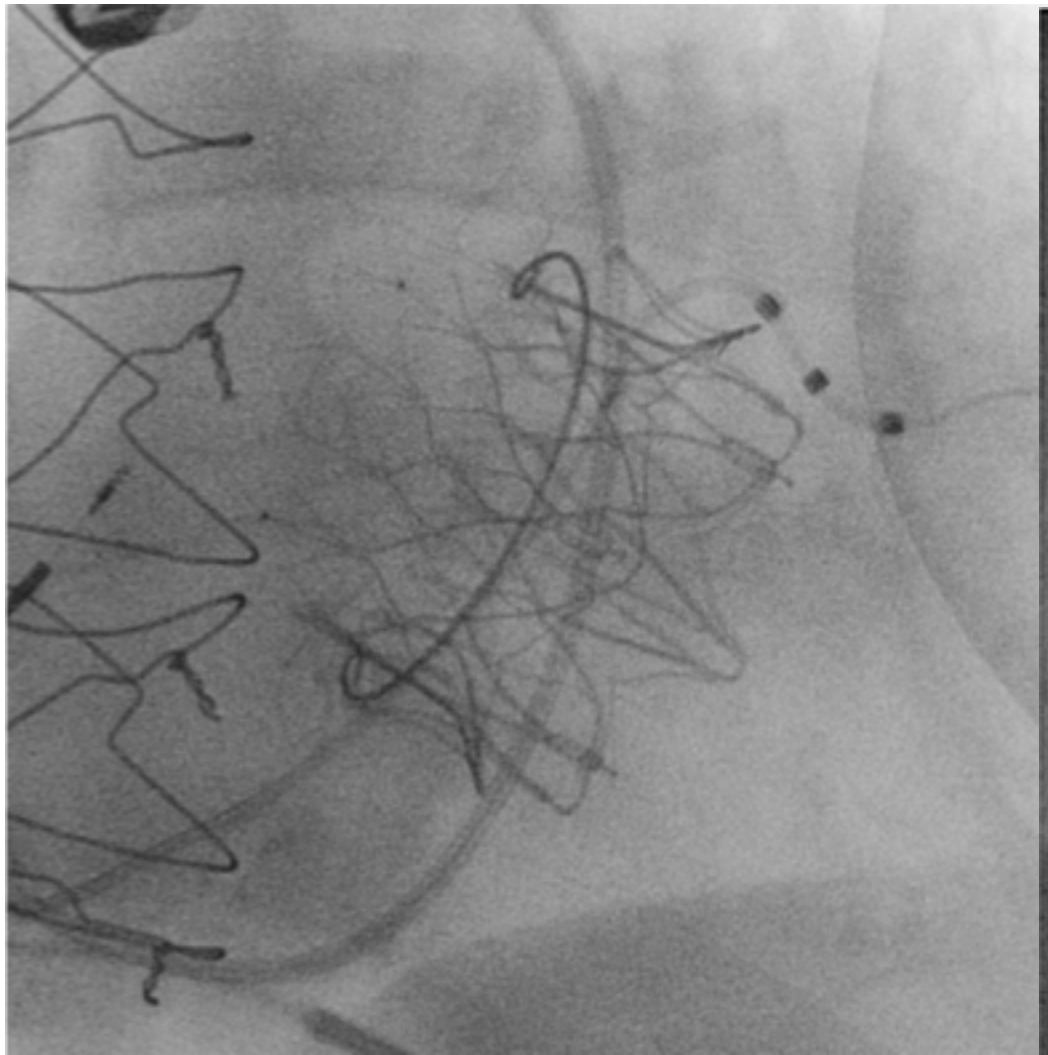
## NYHA II

## Good valve function, no PVL, no LVOT obstruction, MG-2mmHg

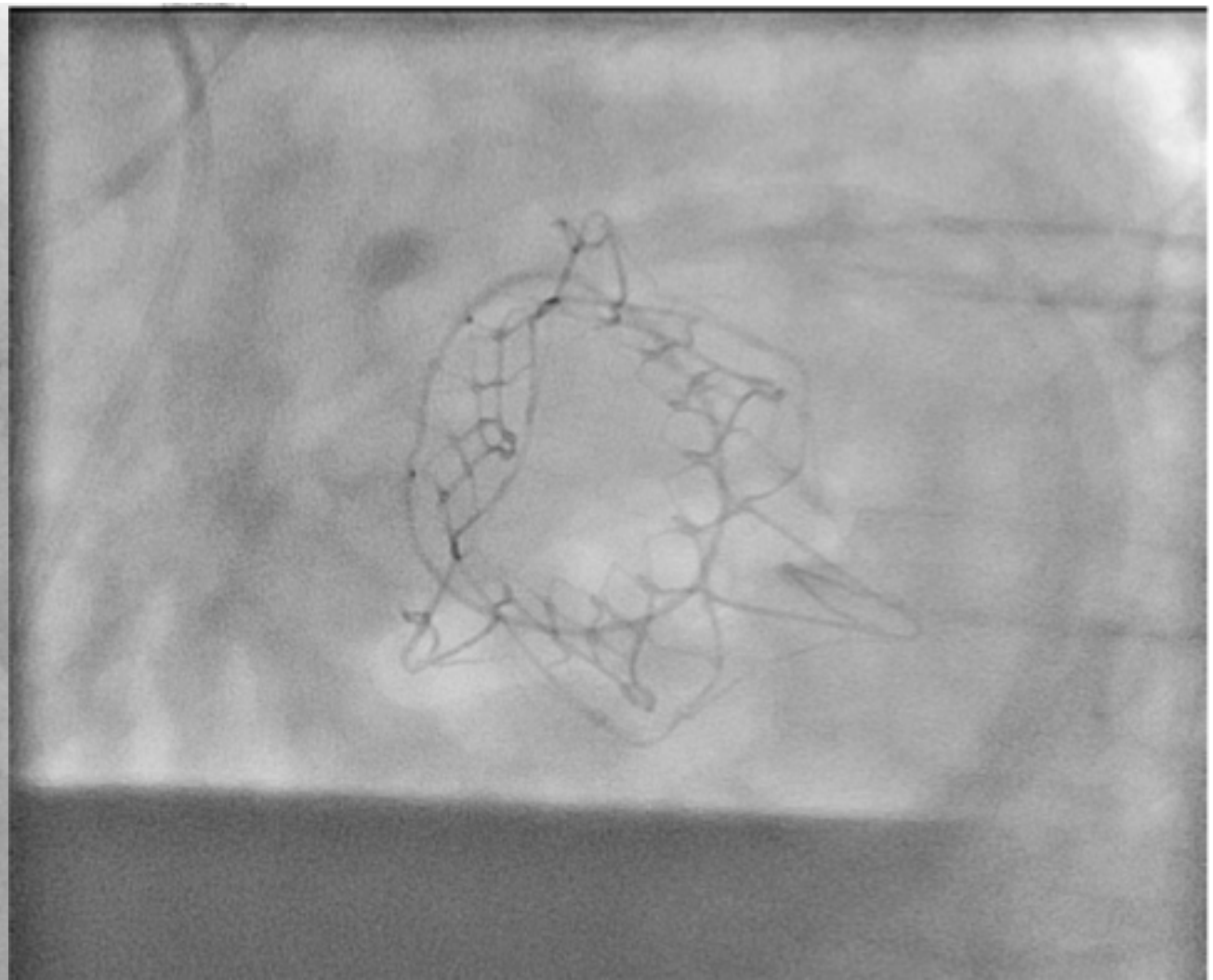


# Feasible in patients with mitral valve repair

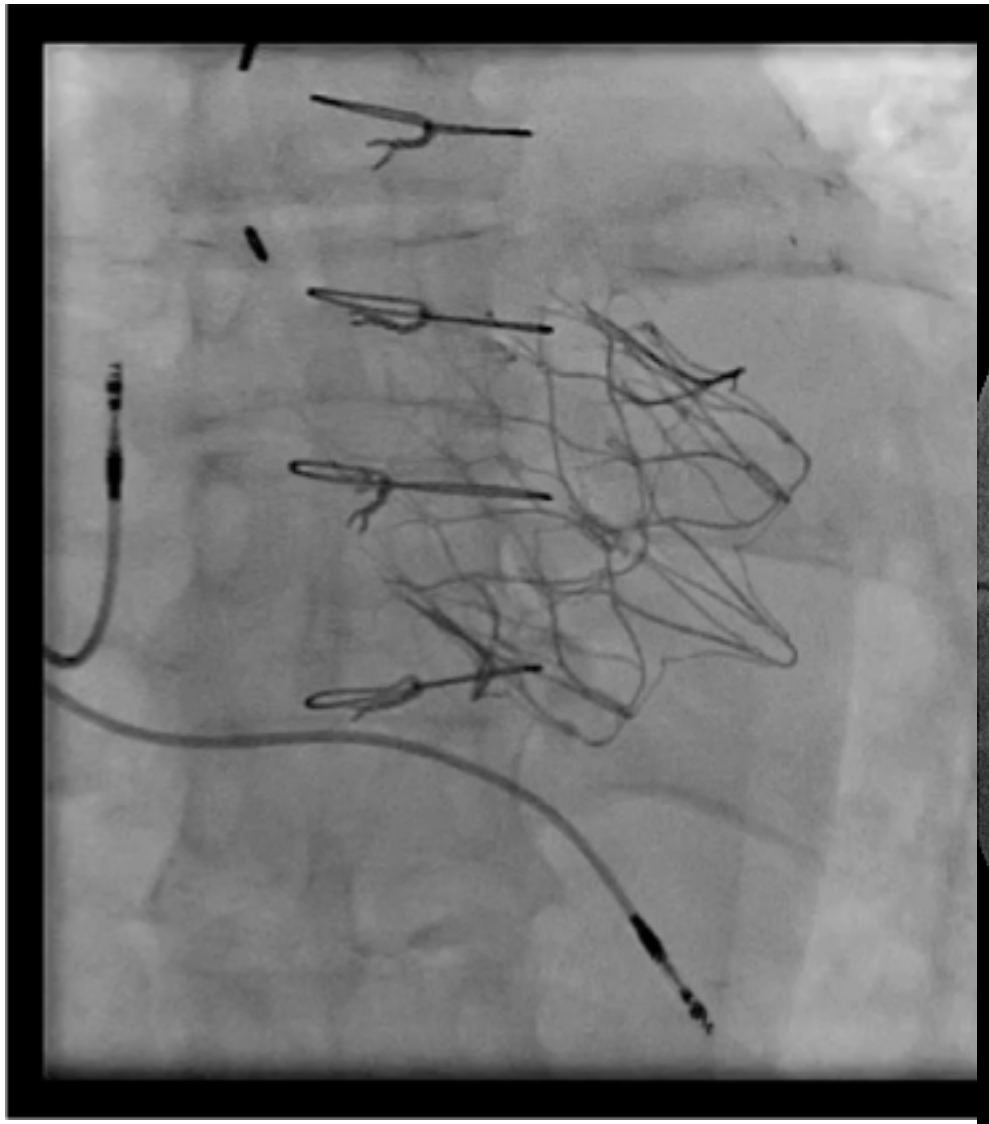
Tiara in partial ring (Medtronic Future band 34mm)

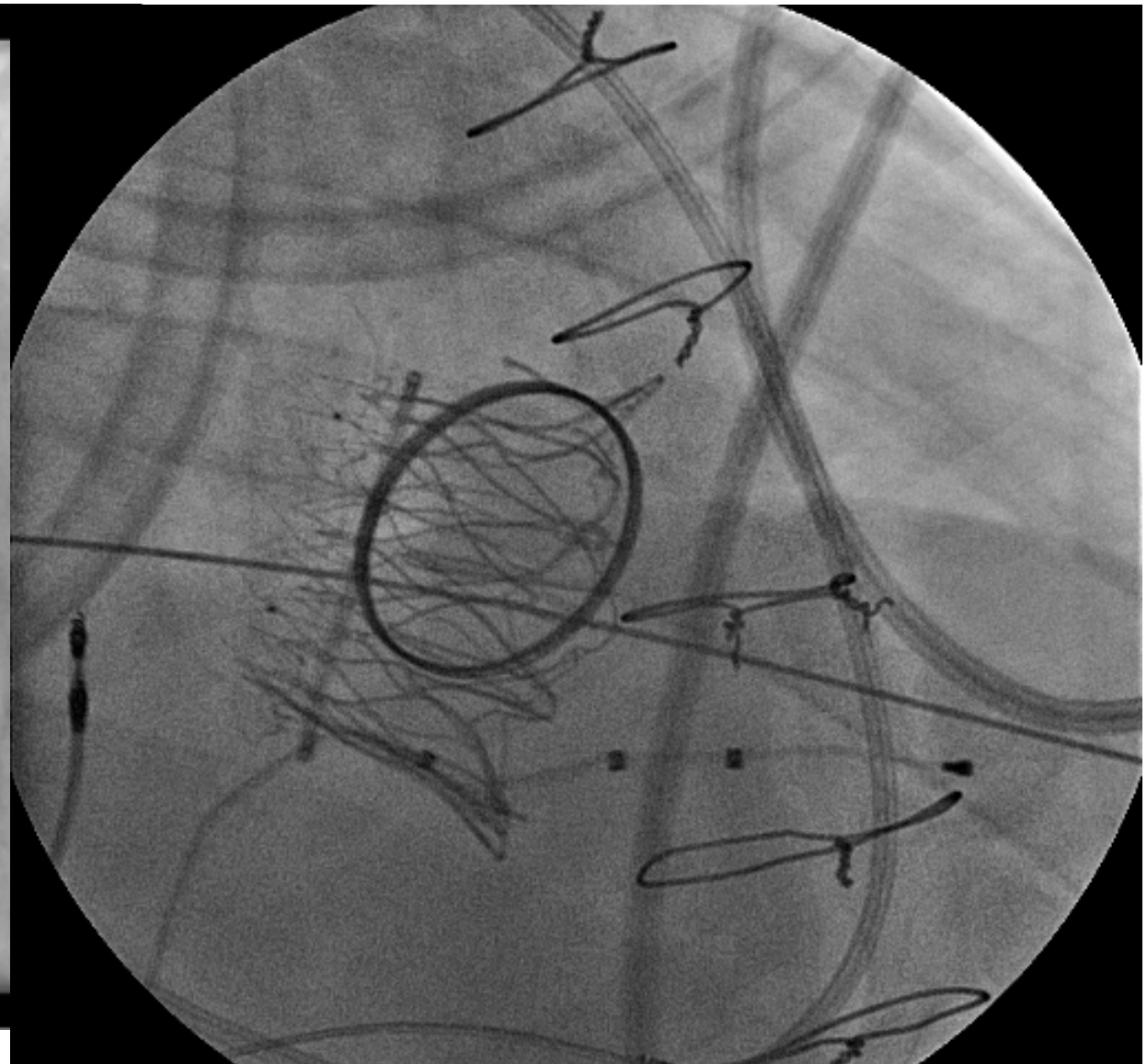


Incomplete flexible ring (Medtronic Duran 29mm)



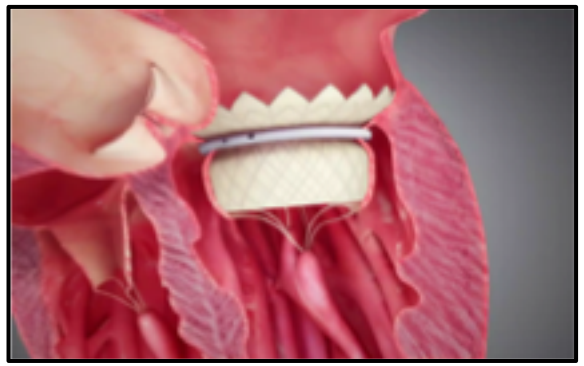
# Feasible in patients with Mechanical and biological AVR





# Highlife: 2-step procedure

“Valve-in-Ring”



=

Ring

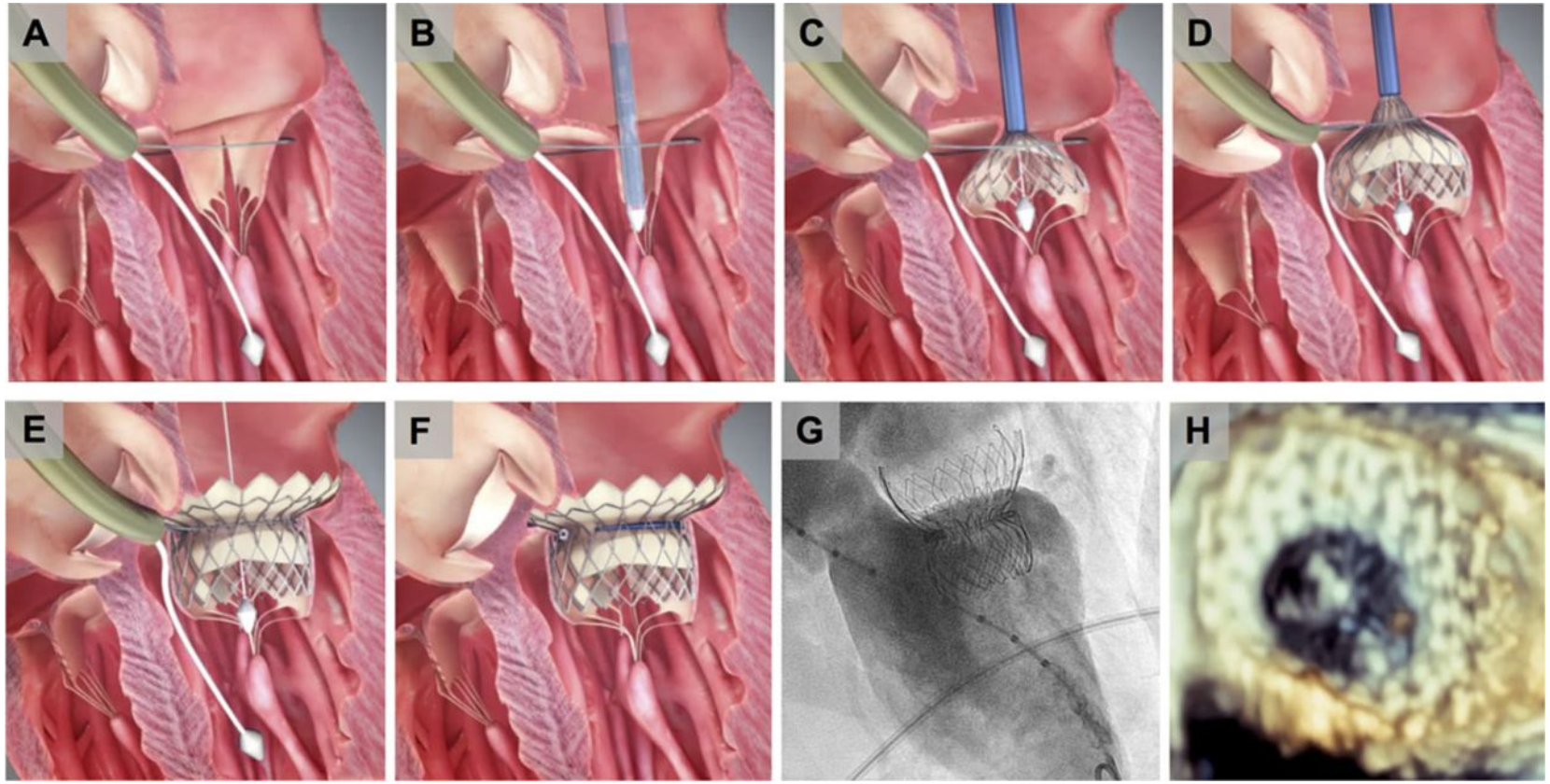
Transfemoral artery

+

Valve

Transseptal or transapical

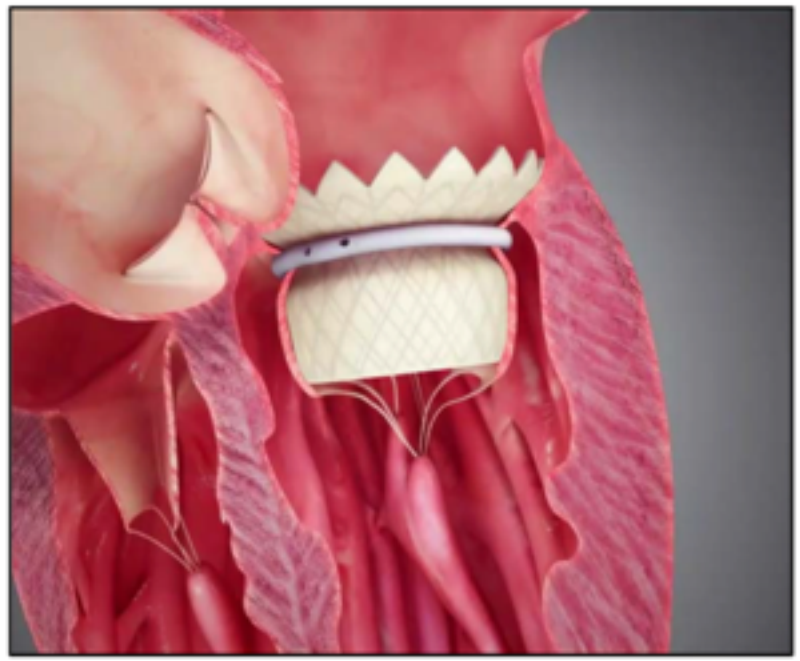
# High Life System – Advantages of valve in ring approach



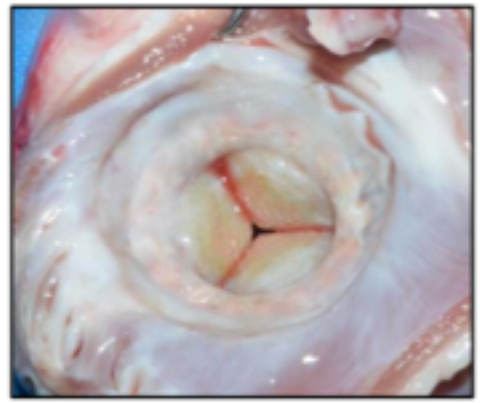

- **Two component system**
- **Self-centering and self-positioning upon release**
- **Range of “One size fits all“**
- **Short valve stent for uncompromised LVOT**
- **Fixation of anterior leaflet**
- **No concern with posterior leaflet tethering**

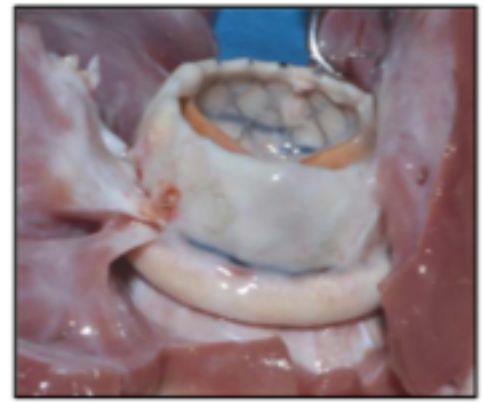

HighLife

# HighLife “Valve-in-Ring” concept



Chronic animal explant 3 months

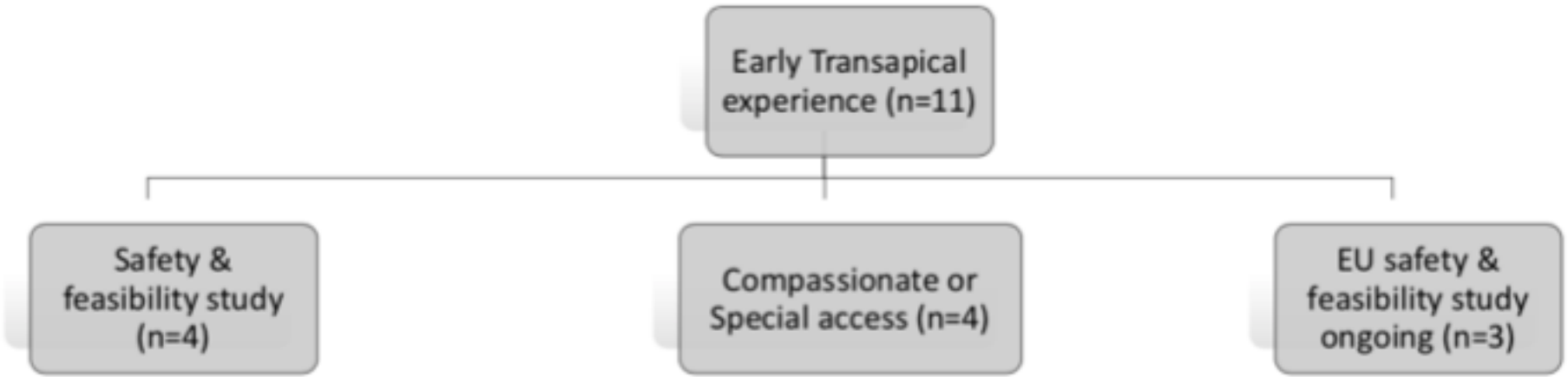




Atrial

Ventricular

# Early transapical experience




- **100% success**
- **4 patients with > 1 year follow-up**

- **n= 1 successful implant**
  **(poor LV function 25%, in-hospital death)**
- **n = 1 successful implant**
  **(> 6 months follow-up)**
- **n= 1 conversion to surgery**
  **(for chordal entanglement, in-hospital death)**
- **n = 1 conversion to surgery**
  **(chordal entanglement, > 12 months follow-up)**

- **2 successful implants with > 30 days follow-up**
- **1 patient with LVOTO and in-hospital death**

# HighLife Transapical Clinical Outcomes

| | 30 Days (n=11) | 1 Year (n=4) |
|---|---|---|
| Death | 3** | 0 |
| Stroke | 0 | 0 |
| MI | 0 | 0 |
| LVOT obstruction | 1 | 0 |
| PVL > grade I | 0 | 0 |
| Mean Transvalvular gradient > 5 mmHg | 0 | 0 |
| Structural valve dysfunction | 0 | 0 |

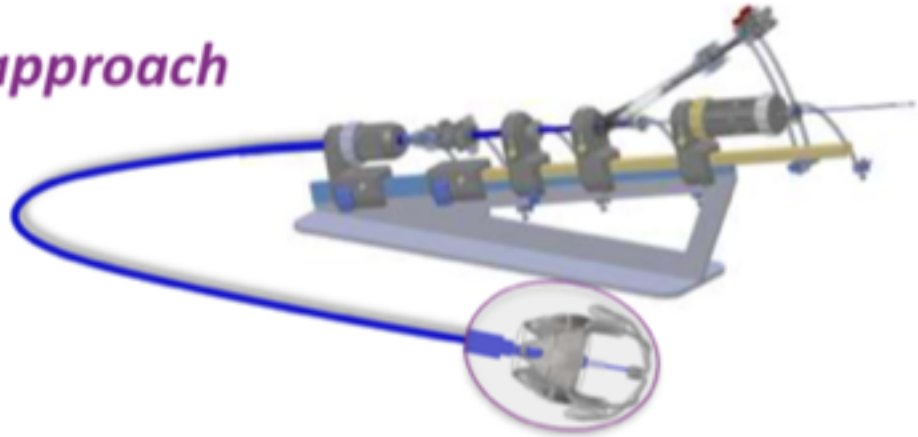
** Patient selection (severe LV dysfunction, LVOT obstruction from small left ventricular cavity) and technical learning curve (chordal entanglement)

# Caisson TMVR Concept

LivaNova
Health innovation that matters

## Delivery System

- Completely *transvenous percutaneous approach*
- 2-step implant
- Fully reversible

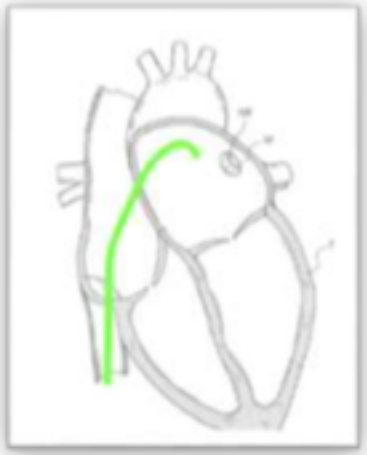


## Anchor

- Nitinol Self-Expanding Frame
- Covered with Polyester and ePTFE
- 4 Sub-annular Anchoring Feet
- SAM Management Feature

## Valve

- 3 Leaflet Circular Valve, EOA>3.0cm$^2$
- Porcine Pericardium
- D-shaped Outer Stent
- Nitinol Self-Expanding



# Early Clinical Data n=12

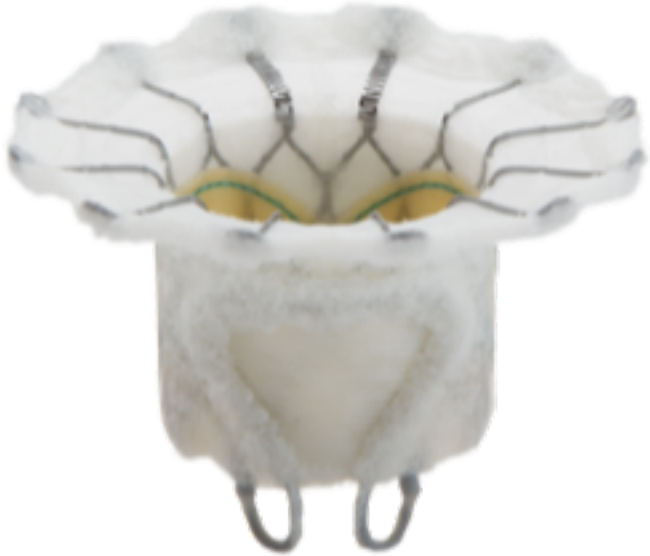
| Patient Number | Study | Days Since Implant (1 Year) | MR Grade | | Ejection Fraction % | | NYHA | |
|---|---|---|---|---|---|---|---|---|
| | | | Baseline | Last FU | Baseline | Last FU | Baseline | Last FU |
| 01 (1) | Prelude | 28 | 4 | - | 32.6 | | III | |
| 02 | Prelude | 587 | 3 | 0 | 57.3 | 60.2 | III | I |
| 03 | Prelude | 560 | 4 | 0 | 57.9 | 61.6 | II | I |
| 04 | Prelude | 456 | 3 | 0 | 58.9 | 46.7 | III | I |
| 05 | Prelude | 434 | 4 | 0 | 47.6 | 26.8 | IV | I |
| 06 (3) | Prelude | 20 | 3 | - | 56.0 | | III | |
| 07 | Prelude | 314 | 3 | 0 | 29.4 | 30.0 | IV | I |
| 08 (4) | Prelude | 3 | 4 | - | 36.4 | | III | |
| 09 | Interlude | 209 | 4 | 1 | 46.0 | 40.0 | III (5) | II |
| 10 | Prelude | 196 | 3 | 0 | 47.5 | 41 | III | III |
| 11 | Prelude | 154 | 3 | 0 | 29.07 | 19.9 | III | I |
| | SAP | 567 | 4 | 0 (2) | 28 | | III | |

In Follow-up
Surgical Re-Intervention
Deceased
No Further Follow-up

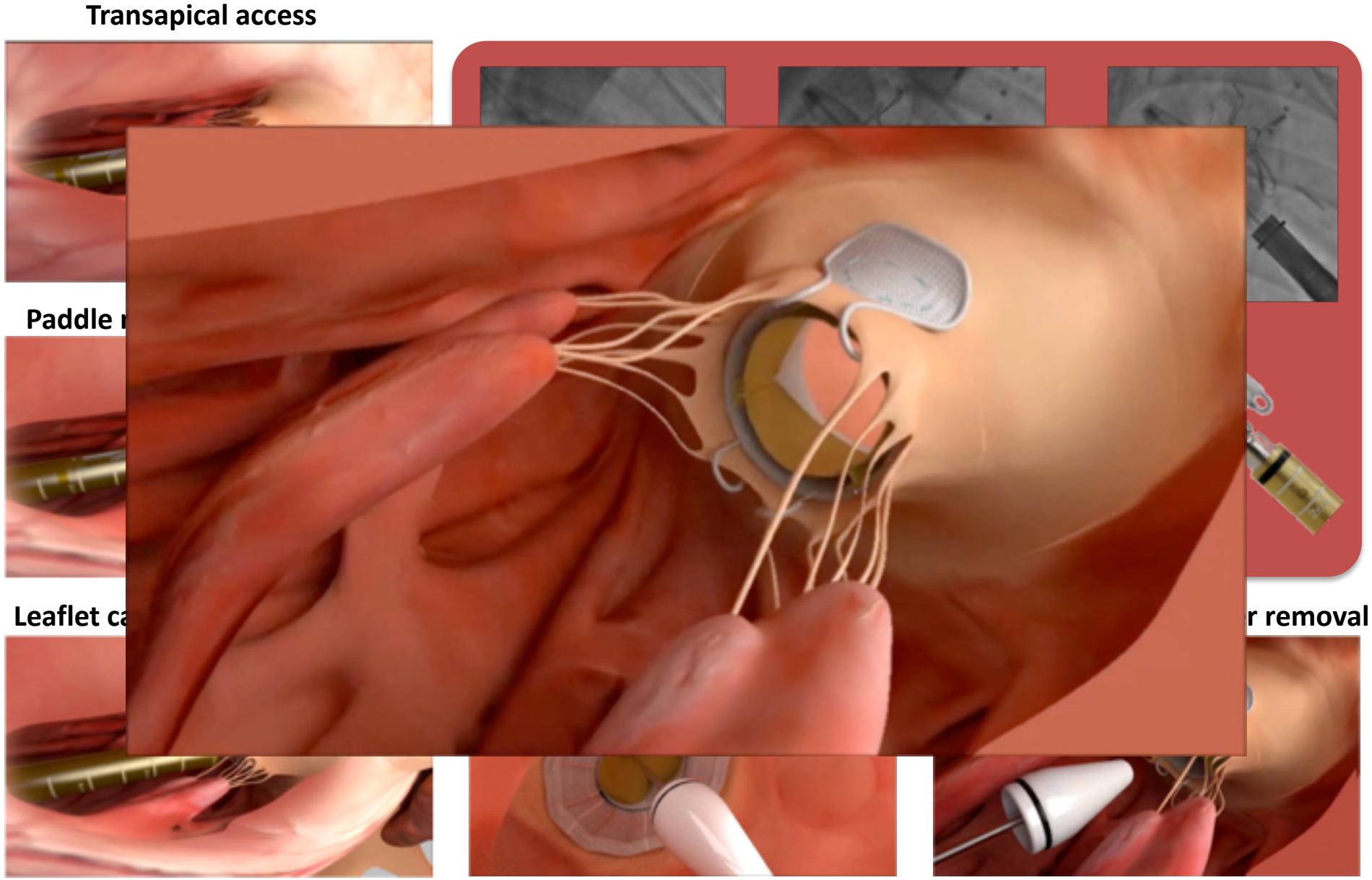
1: Early Death (Day 28) due to Sepsis
2: Last follow-up at the end of procedure
3: Surgical Re-Intervention due to excess PVL
4: Early Death (Day 3) following hypotension and PVL
5: NYHA III-IV at time of screening and later II following medical management

Edwards

# Fortis

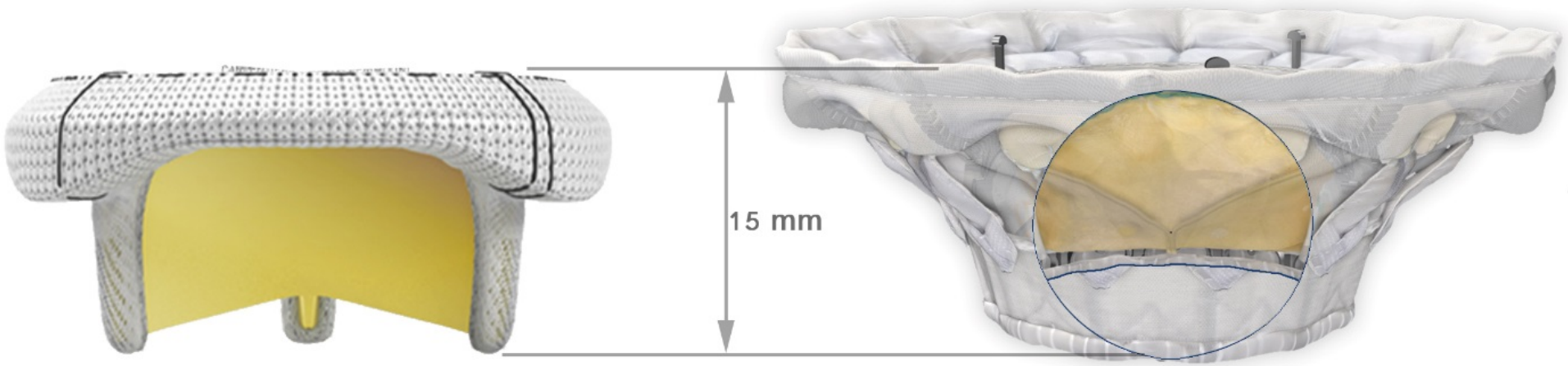


# Fortis Transapical System



# Cardiovalve TMVR (Mitraltech)

- **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



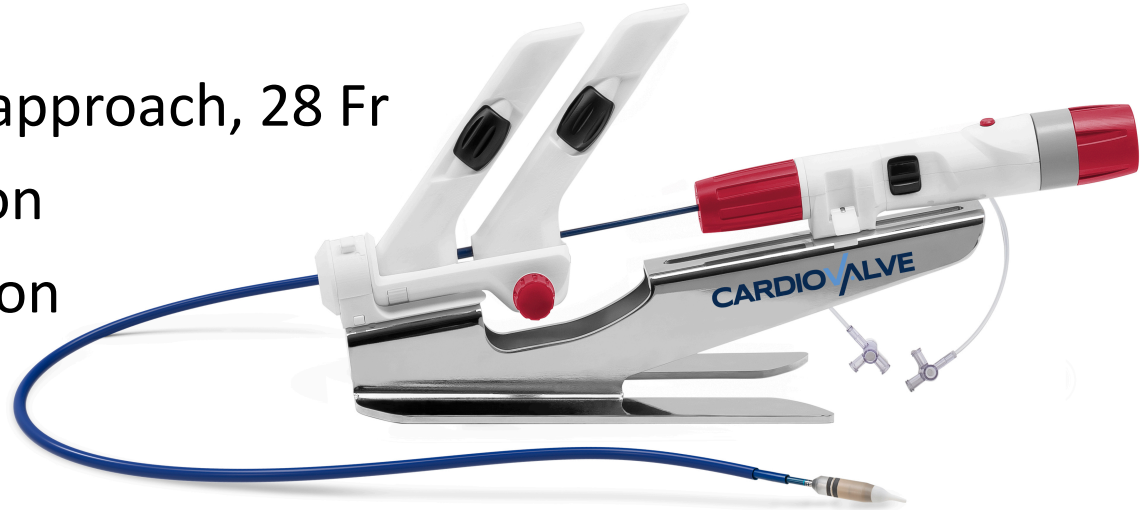

The **Surgical gold-standard**
Edwards Perimount Magna™

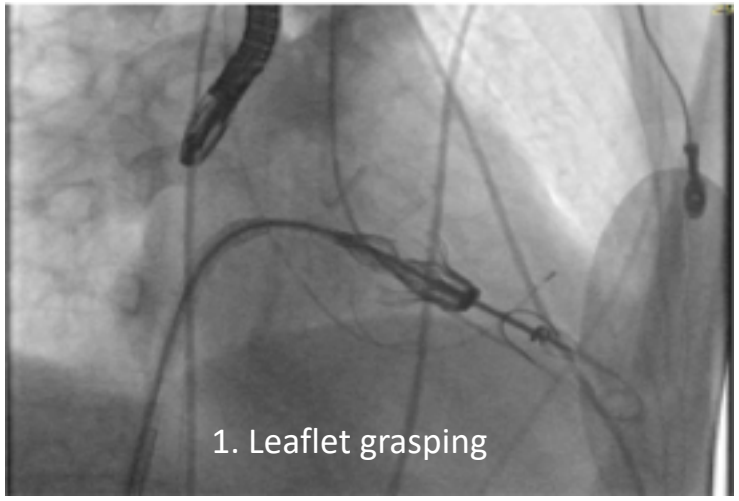
The **Transcatheter solution**
Cardiovalve™

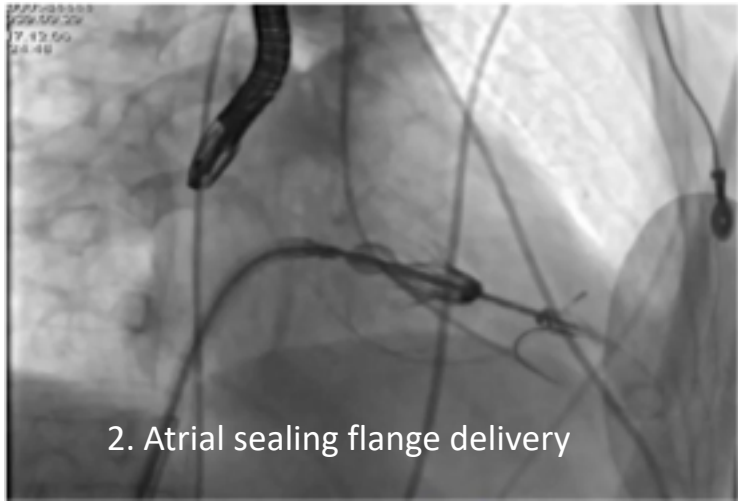
COURTSEY: MAURIZIO TARAMASSO MD, PHD
University Hospital Zürich, Switzerland

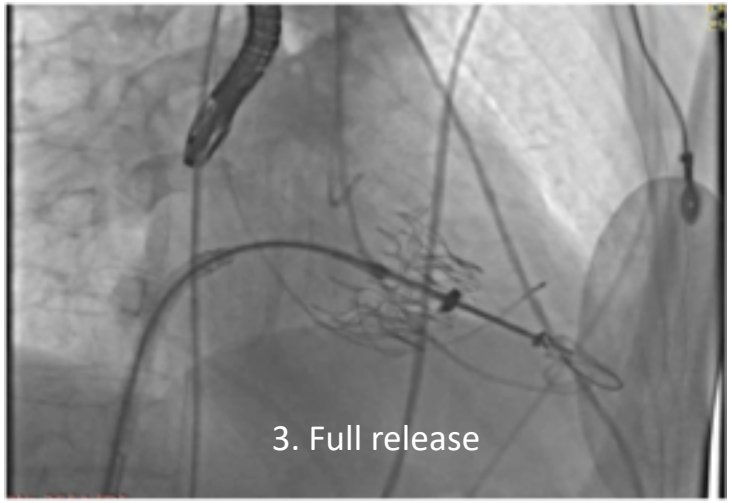
# CardioValve Delivery

- 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



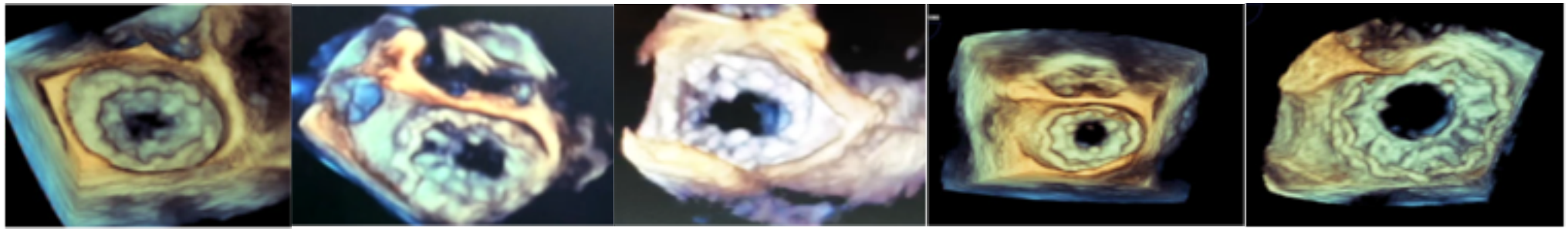


1. Leaflet grasping


2. Atrial sealing flange delivery


3. Full release

# 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 |



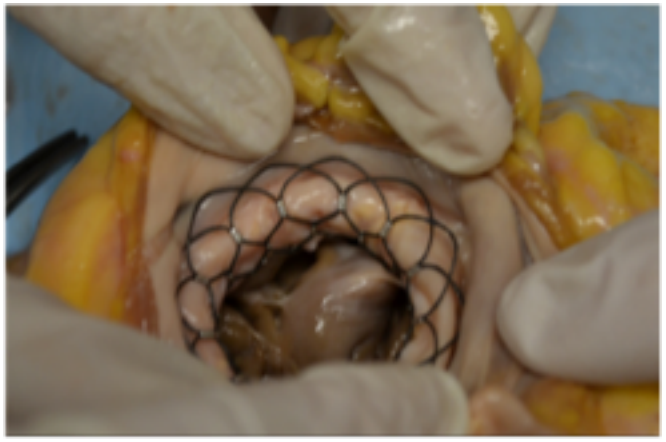
**AHEAD US trial** recruitment will start in early Q4 2018

# Cephea

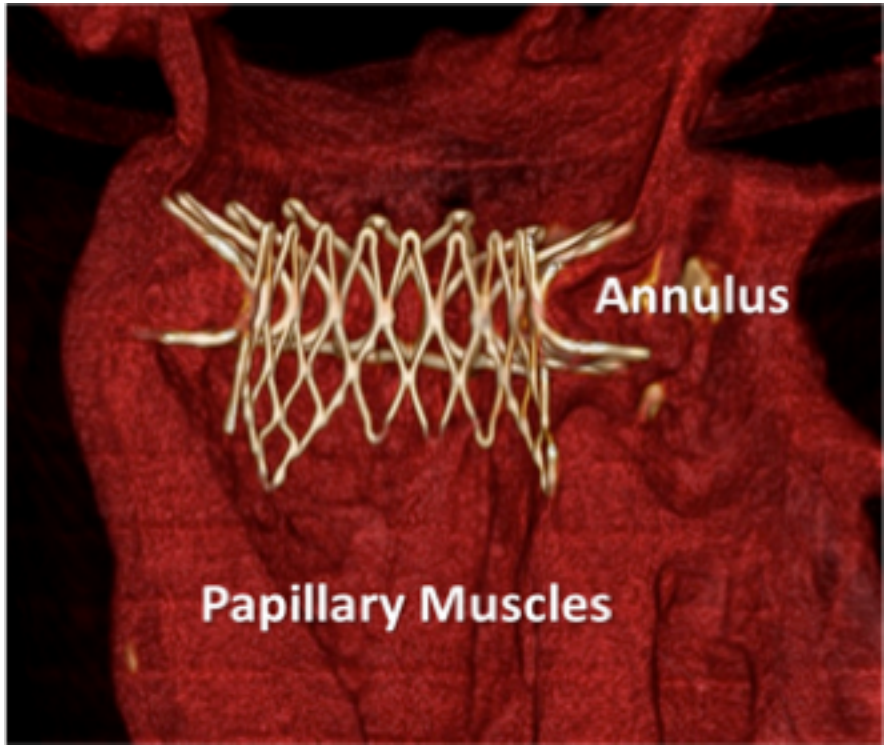
# Cephea TMVR: Attributes

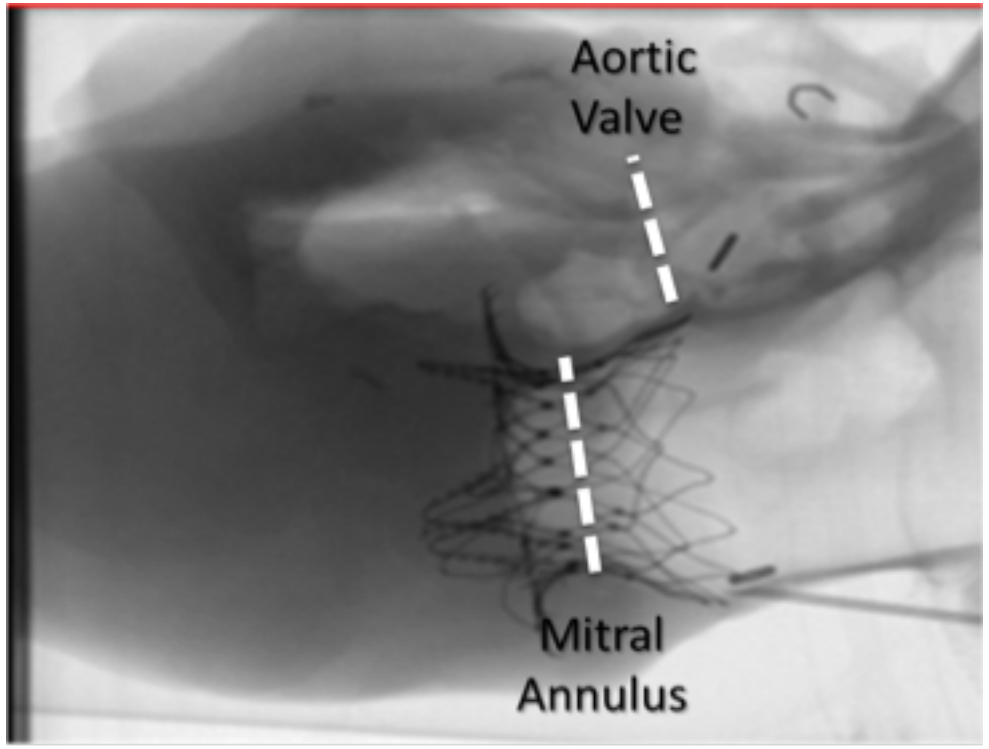
- Double-disk structure, bovine valve
- Frame anchoring decoupled from leaflet function
- Symmetric design, no rotational or orientation issues
- Device adapts to variable anatomy and cardiac motion
- Trans-atrial or trans-septal delivery

# Cephea Trans–Septal approach



- Conformability at Multiple Anatomical Levels
- Low Device Profile (Height)
- Sub-Annular Anchoring
- Minimize LVOT Obstruction

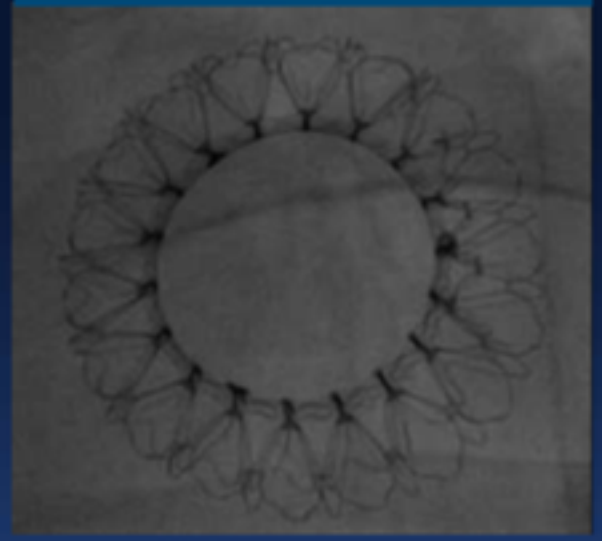


# Cephea's TMVR

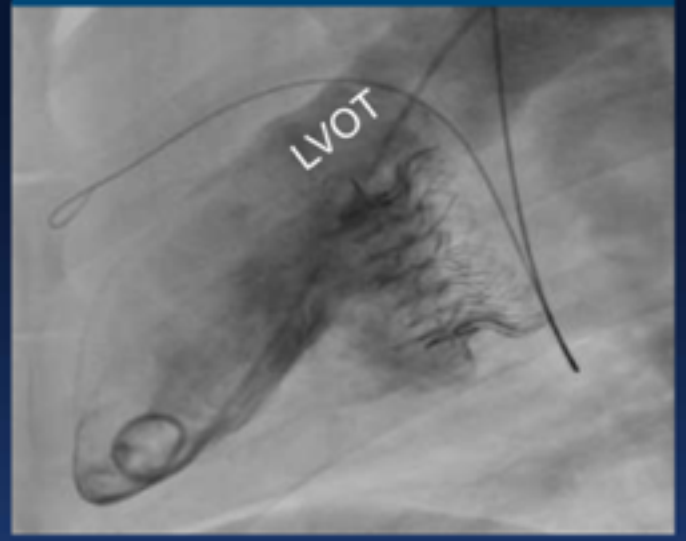
## Trans-Septal System Design Attributes

### Suspension Leaflet Core Technology



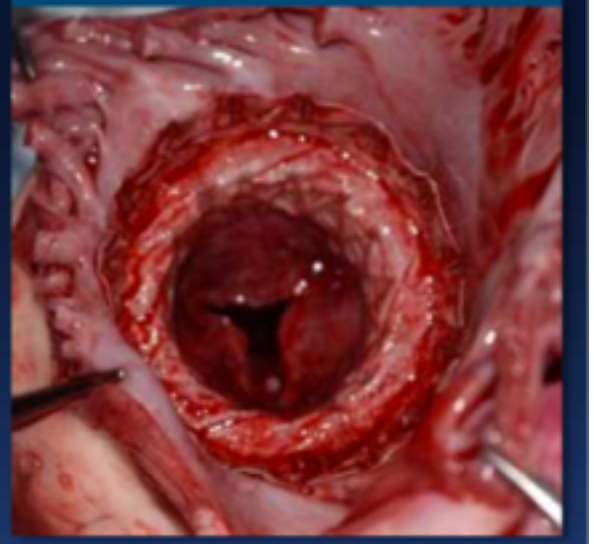
- External frame conforms to variable annular anatomy
- Central core isolates leaflets from external annular compression

### Low Profile Valve Frame Structure




- Minimize interference with LVOT
- Anchoring independent of sub-valvular apparatus

### Reduced Presence of Metal in the Left Atrium

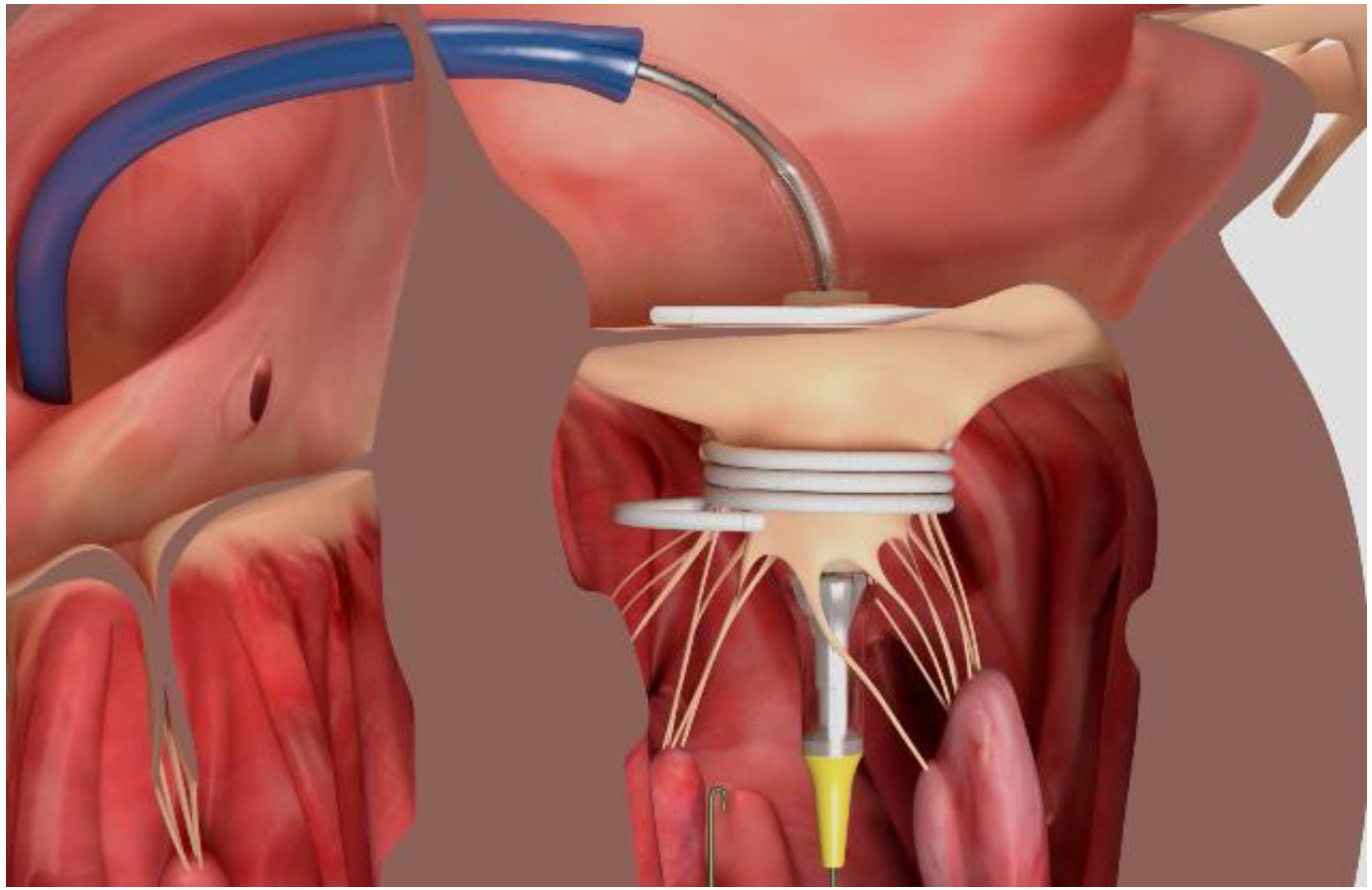


- Surgical-like valve and leaflet architecture
- Low flow disturbance and optimized hemodynamics

Edwards

NEWS • INTERVENTIONAL | CRT 2018

# Early Results for Dock-Plus-Valve Approach Promising in Transcatheter Mitral Valve Replacement

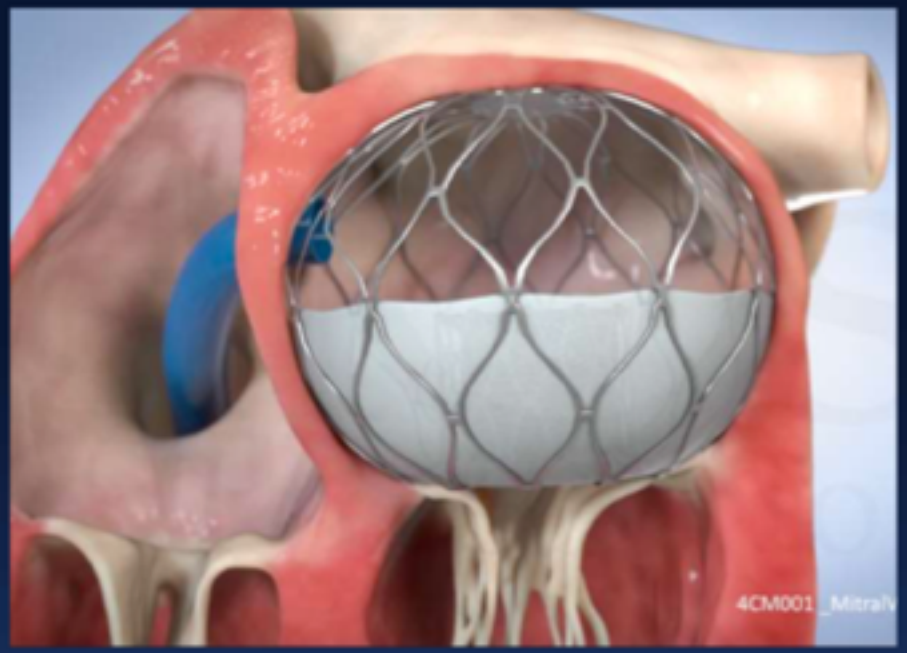


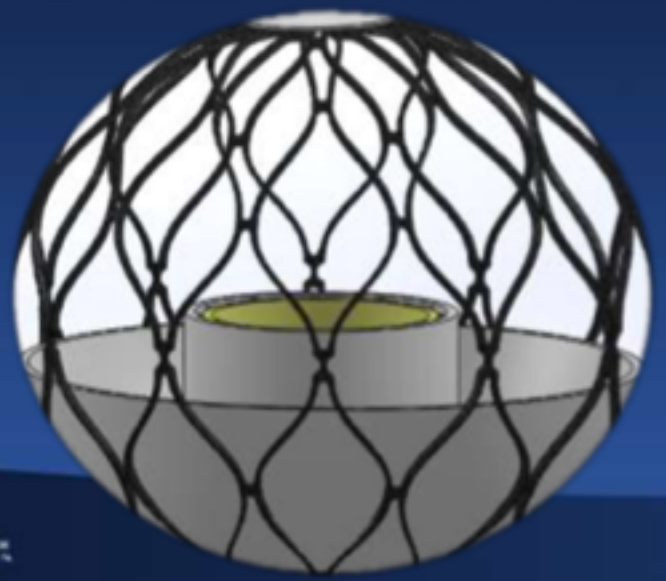
Sapien M3 Valve

10 Patients Treated in Canada

Only one chordal rupture

# 4C TMVR: Attributes

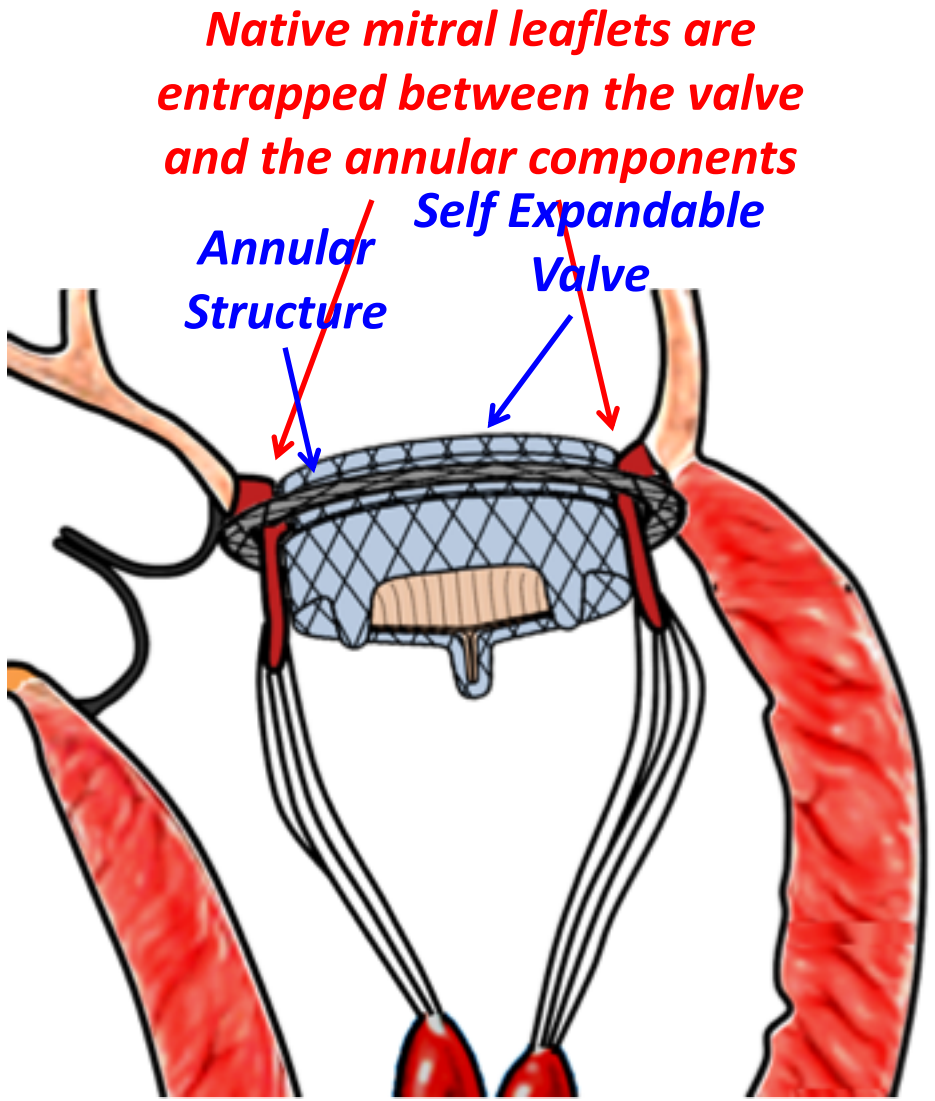




- Pericardial tissue valve with fabric skirt to reduce PVL
- Self-orienting
- Supra-annular fixation; conforms to LA; radial force tailored to preserve atrial compliance
- Leaves native valve and subvalvular apparatus intact
- No LVOT obstruction, SAM or embolization
- Low-profile, trans-septal (or trans-apical) delivery system
- Potential Rx for all MR etiologies (incl MClip failures)

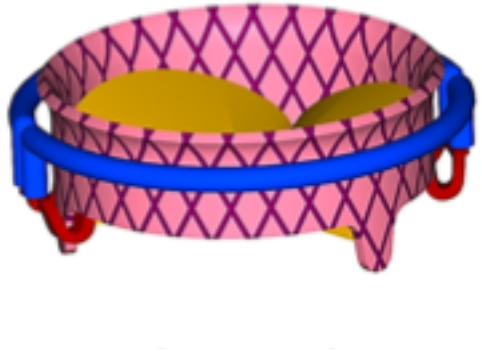
# Saturn Technology

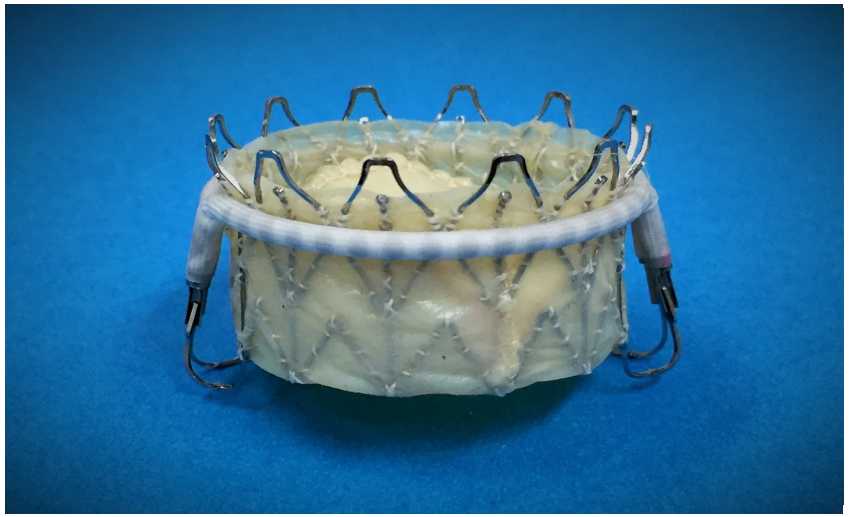
- An **annular structure** is positioned behind the leaflets, in contact with the annulus.
- The **valved central element** is expanded inside the mitral orifice, to lock the native leaflets in between.



# Saturn Technology

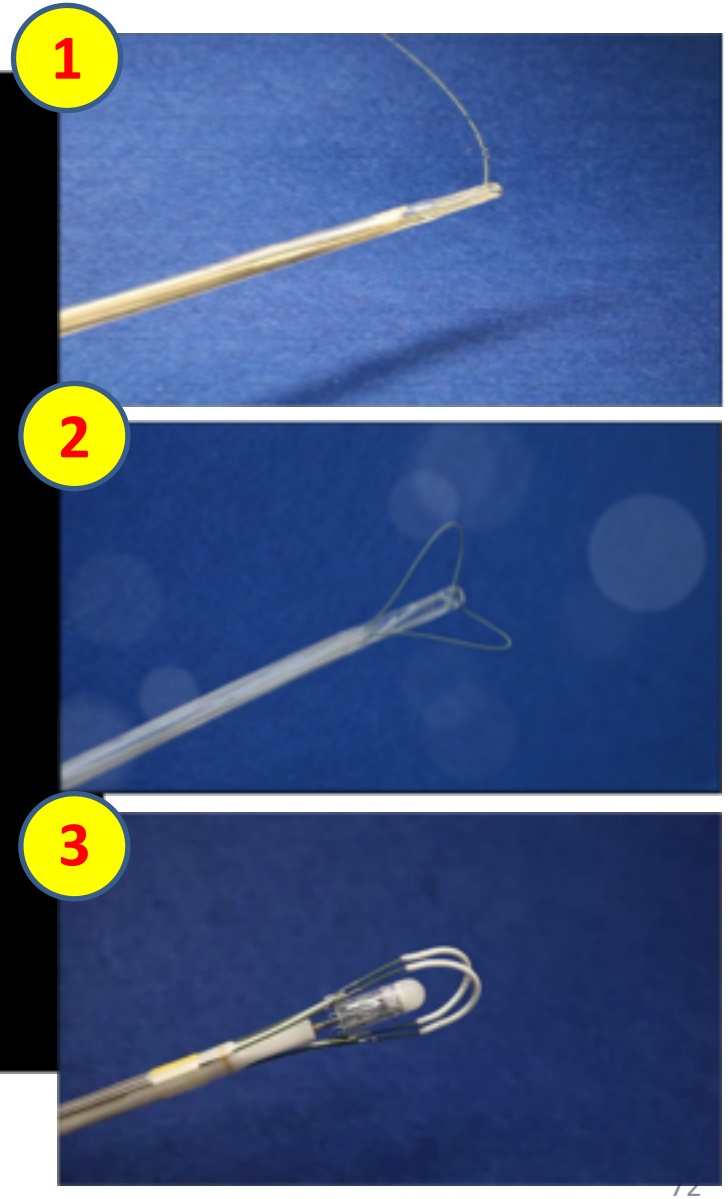
## Saturn Design – single piece / multifunctional parts





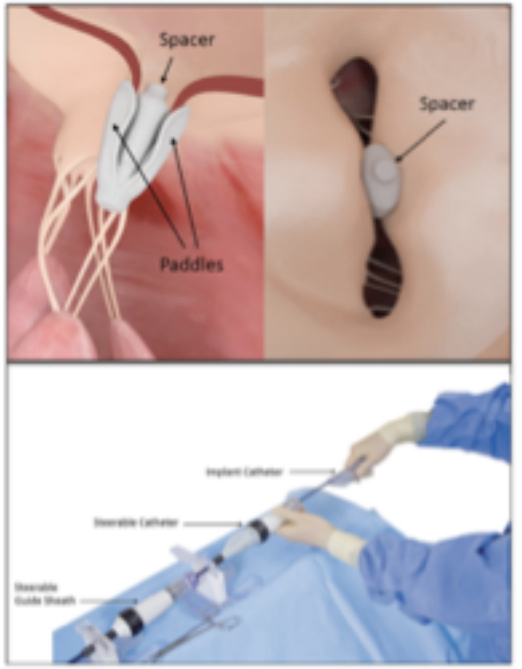
suitable for intracardiac reassembling of the prosthesis before final release

# Saturn Technology: TA - Implant Procedure



# Compassionate use of the PASCAL transcatheter mitral valve repair system for patients with severe mitral regurgitation: a multicentre, prospective, observational, first-in-man study

*Fabien Praz*, Konstantinos Spargias*, Michael Chrissoheris, Lutz Büllesfeld, Georg Nickenig, Florian Deuschl, Robert Schueler, Neil P Fam, Robert Moss, Moody Makar, Robert Boone, Jeremy Edwards, Aris Moschovitis, Saibal Kar, John Webb, Ulrich Schäfer, Ted Feldman, Stephan Windecker*




- First-in-human, 7 sites, 5 countries
- 23 compassionate-use patients
- Moderate-Severe & Severe MR
- Surgical risk high or inoperable

Etiology:
FMR 52%
DMR 26%
Mixed 22%

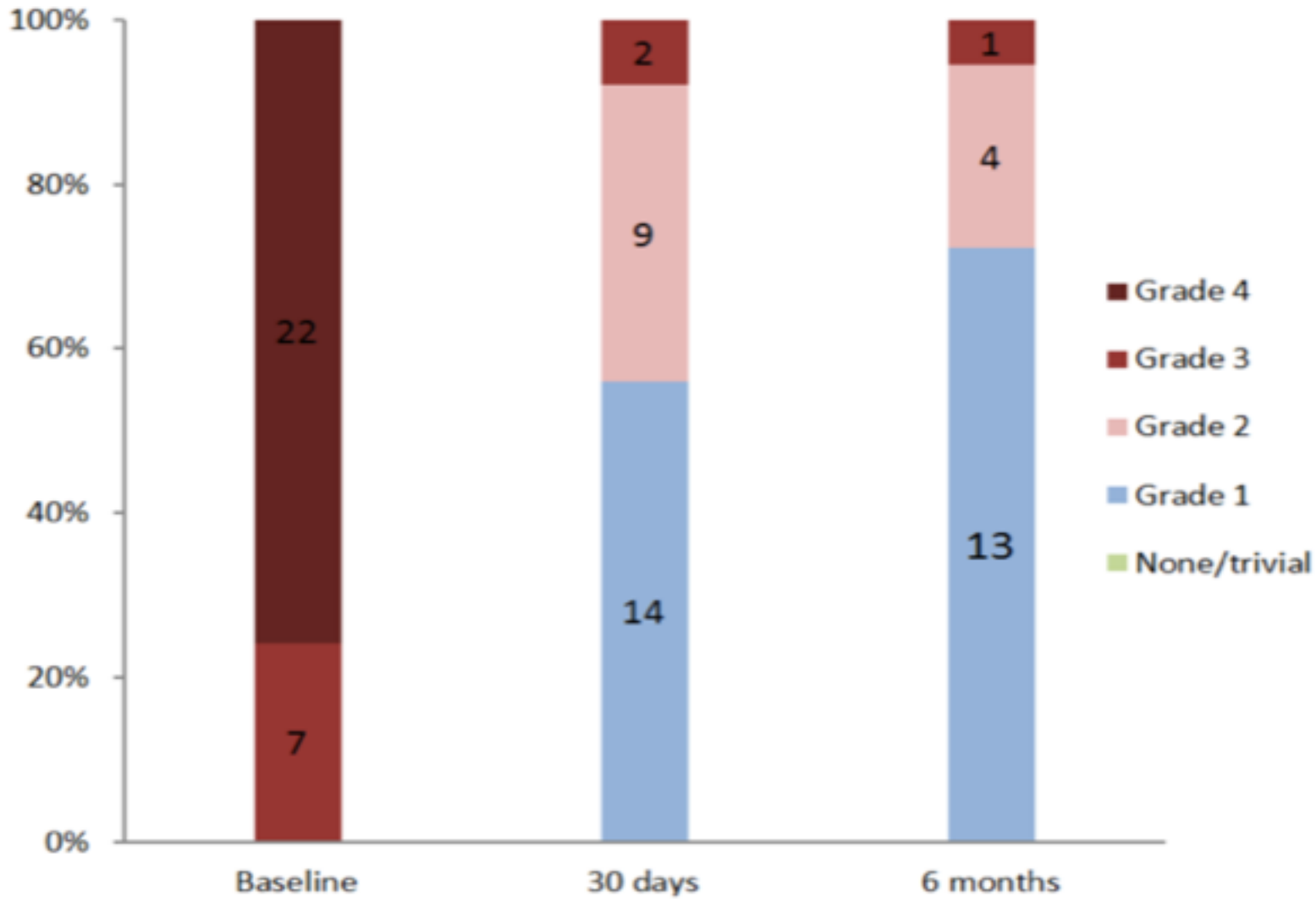
Lancet 2017;390:773-780

# Edwards PASCAL Mitral FIH at 30 Days

| | N=29 | % |
|---|---|---|
| Device success* | 23 | 79% |
| All cause mortality | 3 | 10% |
| Re-hospitalizations for heart failure | 2 | 7% |
| Reintervention for MV dysfunction | 0 | |
| Major bleeding | 0 | |
| Stroke | 0 | |
| Myocardial infarction | 0 | |
| Thrombus formation on device | 0 | |

* according to the MVARC criteria

# Edwards PASCAL: MR Grade

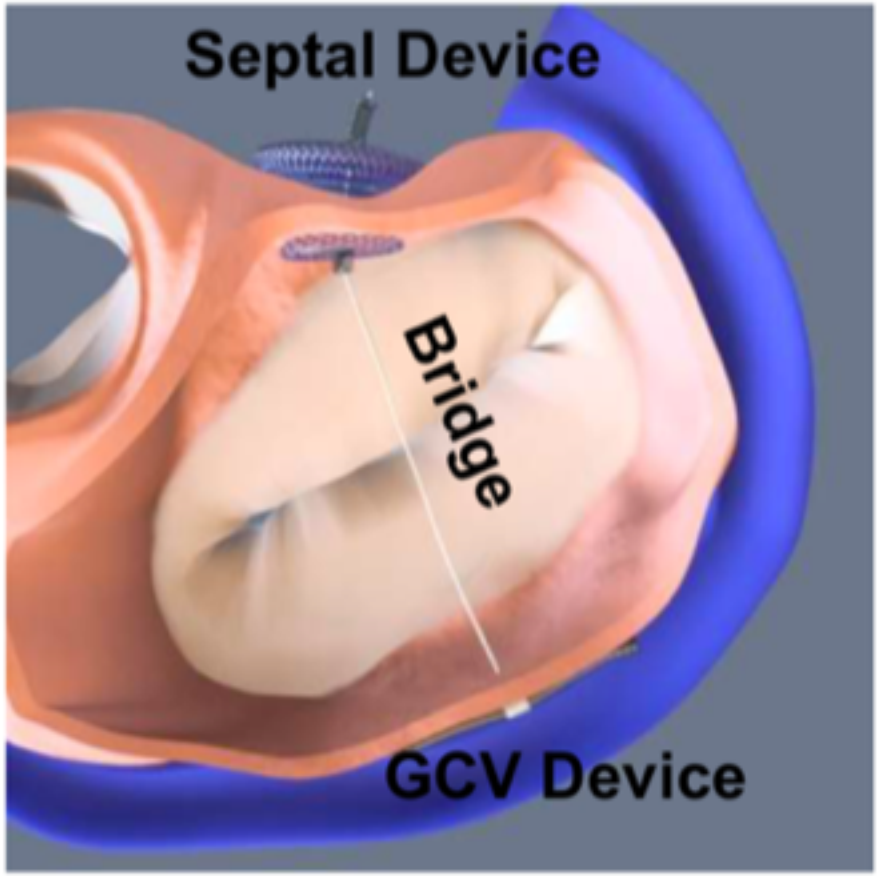



p-values calculated for paired values using the Wilcoxon signed rank test

# Edwards PASCAL Transcatheter Mitral Valve Repair System

- CE mark study (The CLASP Study) is currently enrolling
- U.S. pivotal trial will begin in 2018

# The ARTO System: Procedural Concept




- **Immediate and Direct A-P** Diameter Shortening to Treat FMR
- **No compression of LCX** or other coronary artery
- Venous Based Delivery **Under Fluoroscopic Imaging**
- Acutely **Reversible or Removable**
- **12 Fr** Delivery System
- **No residual ASD**, no trauma to native MV leaflets or chords
- **Ample room** for future septal access
- **Procedure** generally takes <90 mins

# ARTO™ TART PROCEDURE

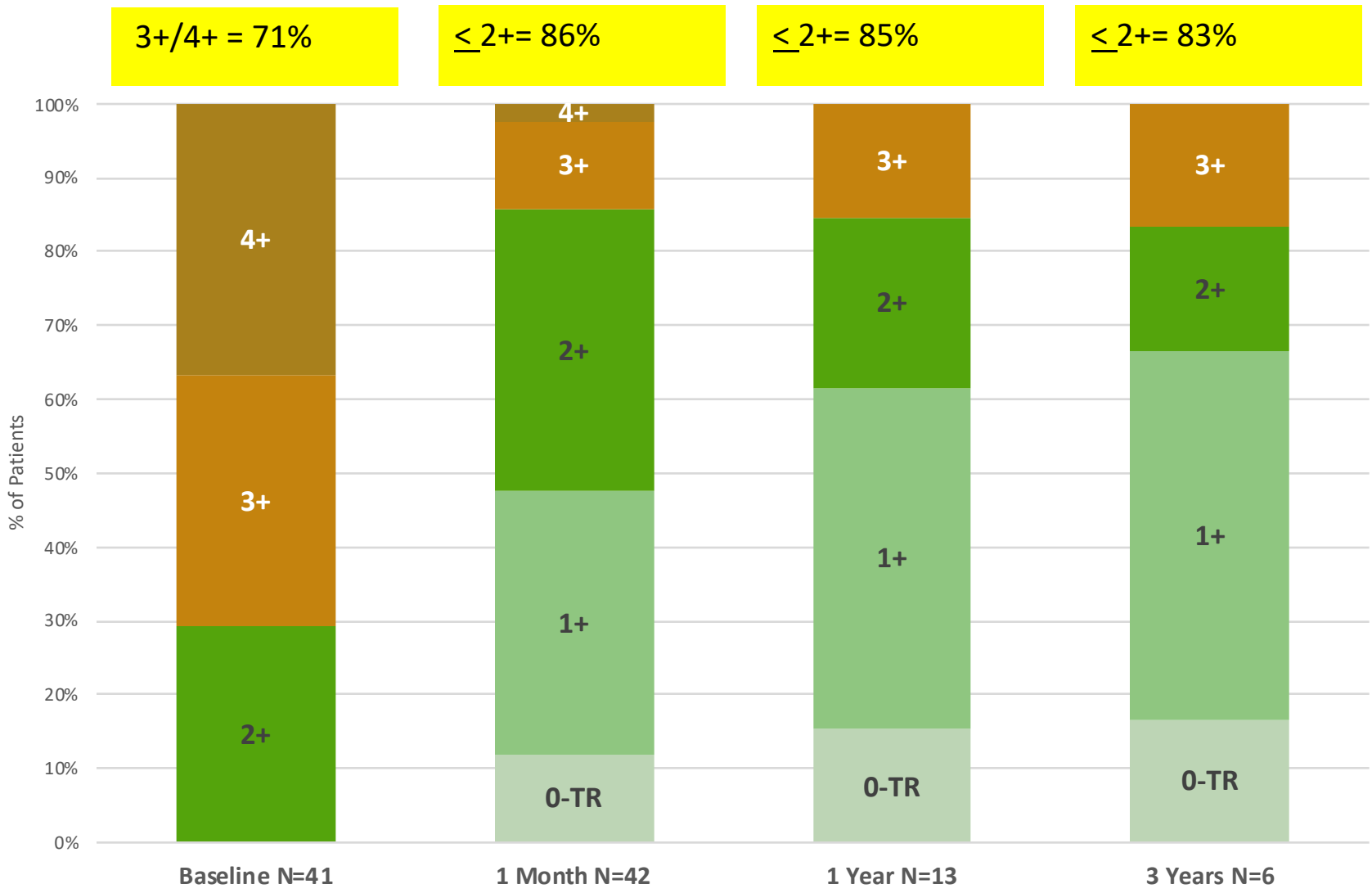
| Characteristic | All Patients (N=45) |
|---|---|
| Device Technical Success (MVARC)*% | 100 |
| Compression of LCX or other coronary artery n (%) | 0(0) |
| New Onset Atrial Fibrillation, n (%) | 0 (0) |
| ARTO procedure time (mins) | 89.0 ± 28.7 |
| Fluoro Time (mins) | 43.5 ± 16.2 |
| Total Contrast Vol (ml) | 96.0 ± 82.0 |
| Days in Hospital (median) (IQR) | 2.0 (1-5) |

Device Technical success defined as: At exit from cath lab, alive, with: 1) Successful access, delivery and retrieval of the device delivery system, and 2)Deployment and correct positioning (including repositioning/recapture if needed) of the single intended device, and 3)No need for additional unplanned or emergency surgery or re-intervention related to the device or access procedure

# MAVERIC 30 day Safety

| **Definition/Event (Cumulative)**<br>**CEC adjudicated** | Procedure<br>N=45<br>n(%) | 0-7 days post<br>N=45<br>n(%) | 0- 30 Days<br>(cumulative)<br>N=45<br>n(%) |
|---|---|---|---|
| Primary Composite Endpoint* | 0(0) | 1(2.2) | 2(4.4) |
| **Death** | **0** | **0** | **0** |
| **Stroke** | **0** | **0** | **0** |
| **Myocardial Infarction** | **0** | **0** | **0** |
| Mitral Operation/Intervention | 0 | 0 | 0 |
| Renal Failure | 0 | 1(2.2) | 1(2.2) |
| Cardiac Tamponade | 0 | 0 | 1(2.2) |
| Major Bleeding | 1(2.2) | 1(2.2) | 2(4.4) |

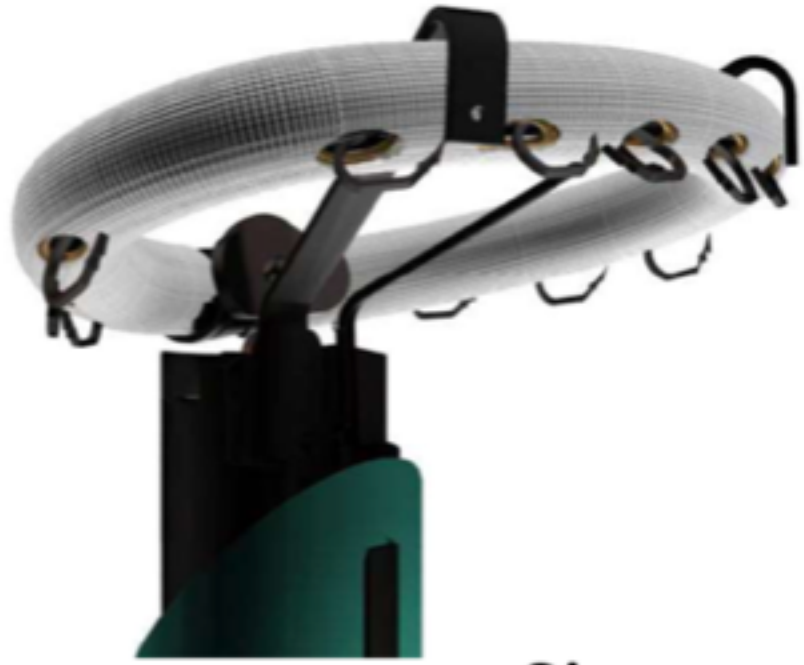
*Death, Stroke, MI, cardiac tamponade, device related cardiac surgery, renal failure




Cardiovascular European Research Center

# AMEND - The Technology

Nitinol Ring & Anchoring system
Delivery system (TA & TS)
Positioning / Alignment
Re-openable
Retreivable



Six zone anchoring system

- 4 Posterior zones
- 2 Anterior zones

# CONCLUSION

- Slow but definite progress
- Still unknown when prosthesis will be available on the market (TMVR is not TAVI)
- Randomised trials have started
- TMVR has a 30 days mortality 5-25% (high risk / inoperable pts)
- High effectiveness but short follow-up