

Innovation in TAVR: ***What can expect from the next decade?***

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Disclosures

Research Grant Support

- Edwards Lifesciences
- Boston Scientific
- Corvia
- CathWorks
- Zoll/Therox
- JenaValve
- Abbott Vascular
- Medtronic
- Philips
- I-Rhythm
- JC Medical

Consulting/Advisory Boards

- Medtronic
- Boston Scientific
- HeartBeam
- Edwards Lifesciences
- Abbott Vascular

NEW TECHNOLOGIES IN TAVR DESIGN

LECTURE SUMMARY

1 Aortic Regurgitation

- Dedicated TAVR Systems for AR
- ALIGN AR Trial

2 Leaflet Modification Techniques

- Concept and Rationale
- Electrosurgery - BASILICA
- The SHORTCUT Device and EFS

3 New Leaflet and Valve Designs

- DurAVR concept
- FOLDAX polymer leaflets
- SIEGEL Rhenium-Molybdenum Valve

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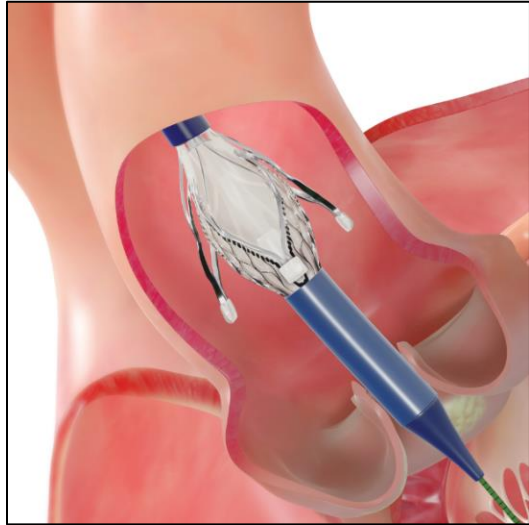
TAVR in Aortic Regurgitation

Unmet Need

- Moderate/Severe AR is common in older patients → prevalence 4.5% in New Ulm (Minnesota) study
- Severe AR is bad → Mortality ~10% per year with severe, symptomatic AR (~25% with NYHA III/IV symptoms)
- AR is undertreated → <25% of patients with severe, symptomatic AR undergo SAVR
- Off-label TAVR with currently approved devices suboptimal → high rates of embolization and PVR

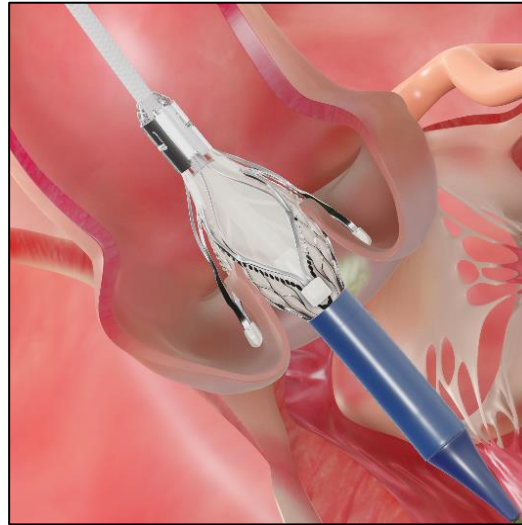
Aortic Regurgitation

TRILOGY and ALIGN AR



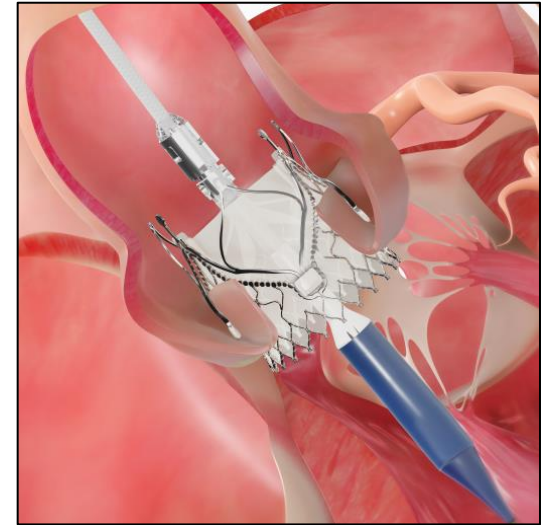
Alignment

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

Aortic Regurgitation

TRILOGY and ALIGN AR (n = 180 pts)

ALIGN AR Study Design

Multicenter, Non-blinded, Single Arm Evaluation of Patients with Symptomatic $\geq 3+$ Aortic Regurgitation at High Risk for SAVR

Trilogy THV Implantation

Clinical Evaluation, Echocardiography, Functional and QoL Assessment at 30 Days, 6 Months, 1 Year and Annually up to 5 Years

30 Day Primary Safety Endpoint

1 Year Primary Efficacy Endpoint

Comparison with Prespecified Performance Goal

Aortic Regurgitation

TRILOGY and ALIGN AR

Primary Safety Endpoint at 30 Days*

Enrolled Population
N=180

10%

$P_{non-inferiority}$

Non-inferiority criteria met



*Composite of 30 day all-cause mortality, all stroke complications, AKI ≥ 2 or dialysis, valve intervention

Primary Efficacy Endpoint at 1 Year*

Enrolled Population
N=180

25% prespecified non-inferiority margin

Rate
7.8%

Upper 1-sided
97.5% CI

12.3%

10%

20%

30%

$P_{non-inferiority} < 0.0001$

Non-inferiority criteria met for primary efficacy endpoint



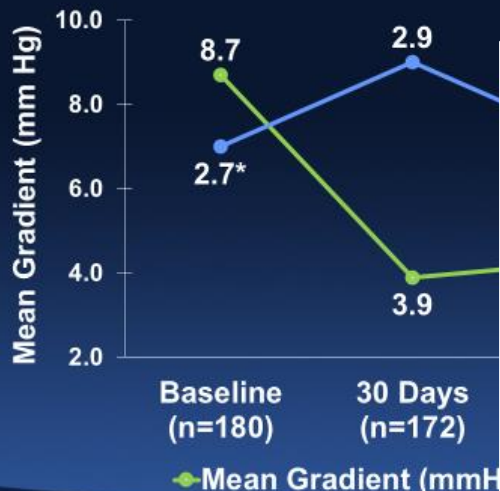
*All-cause mortality



Aortic Regurgitation

TRILOGY and ALIGN AR

Hemodynamic Valve Performance



Baseline (n=180) 30 Days (n=172)

◆ Mean Gradient (mmHg)

CRF
TCT

*AVA (cm²)

Paravalvular Regurgitation



30 Days (n=172)

6 Months (n=154)

1 Year (n=141)

None/Trace

Mild

Moderate

Severe

CRF
TCT

THE
ALIGN
AR TRIAL

Aortic Regurgitation

TRILOGY and ALIGN AR

Quality of Life: KCCQ-OS



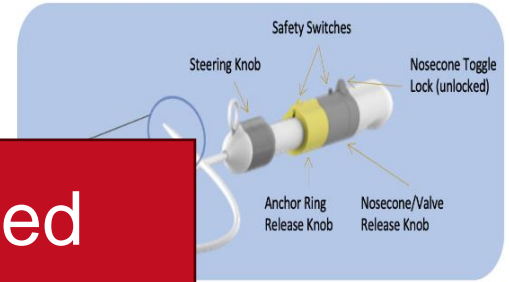
Aortic Regurgitation J-Valve (from China)

- **Bioprosthesis:** self-expanding nitinol frame, bovine pericardial leaflets
- **Delivery System:** steerable, flexible catheter, femoral access (18, 20, 22 Fr)
- **Locating Feature:** J-Valve is designed to locate in the aortic root anatomy
- **Size matrix:** 5 sizes, can treat wide range of anatomies (perimeters 57-104)

J-Valve TF Bioprosthesis

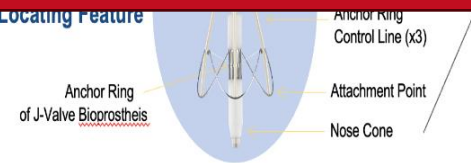


J-Valve TF Delivery Device



Pivotal Clinical Trial Expected to Start in 2024

J-Valve Locating Feature



J-Valve Anchor Ring conforms to the native sinuses

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

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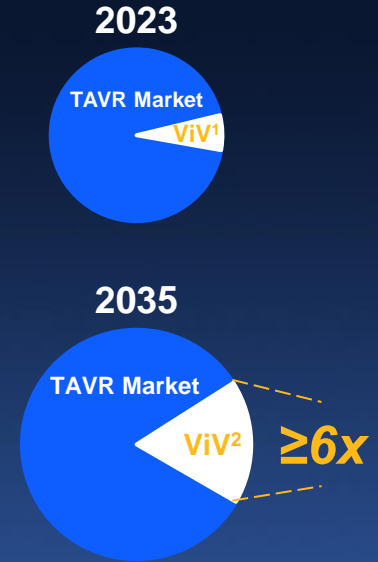
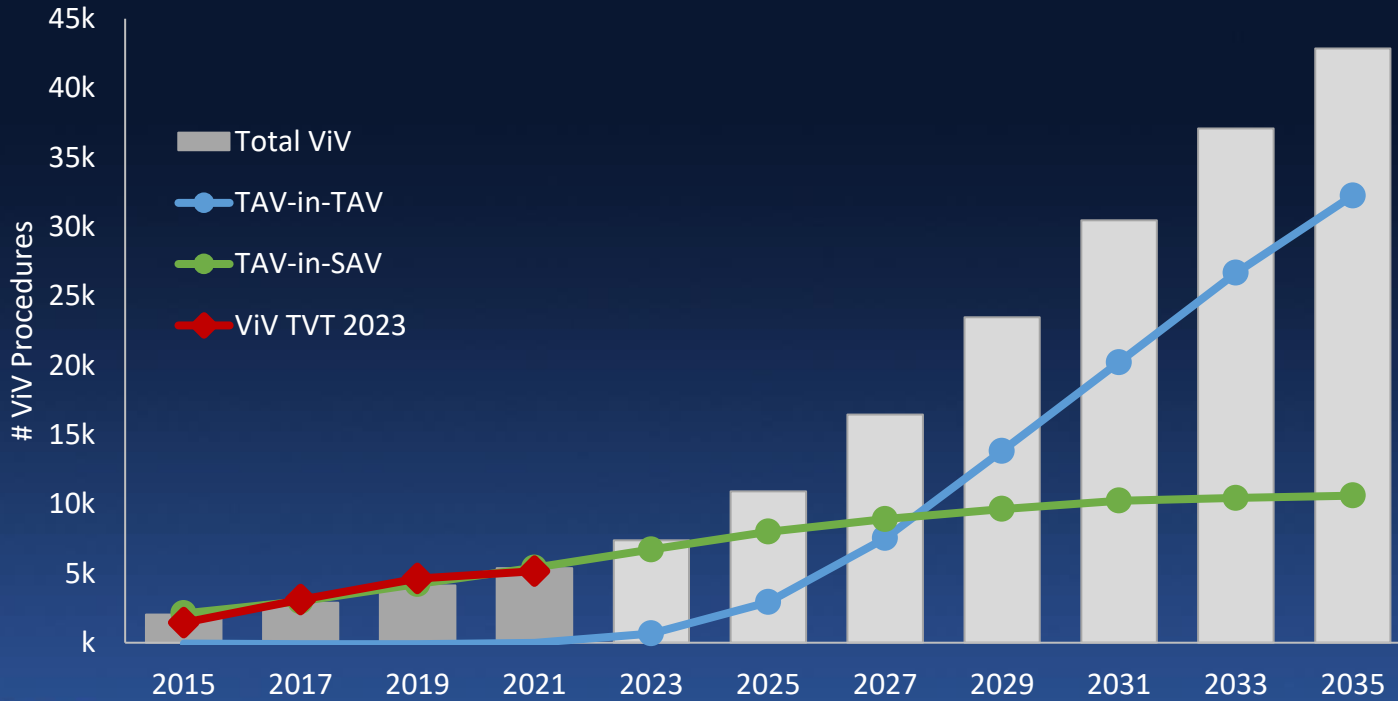
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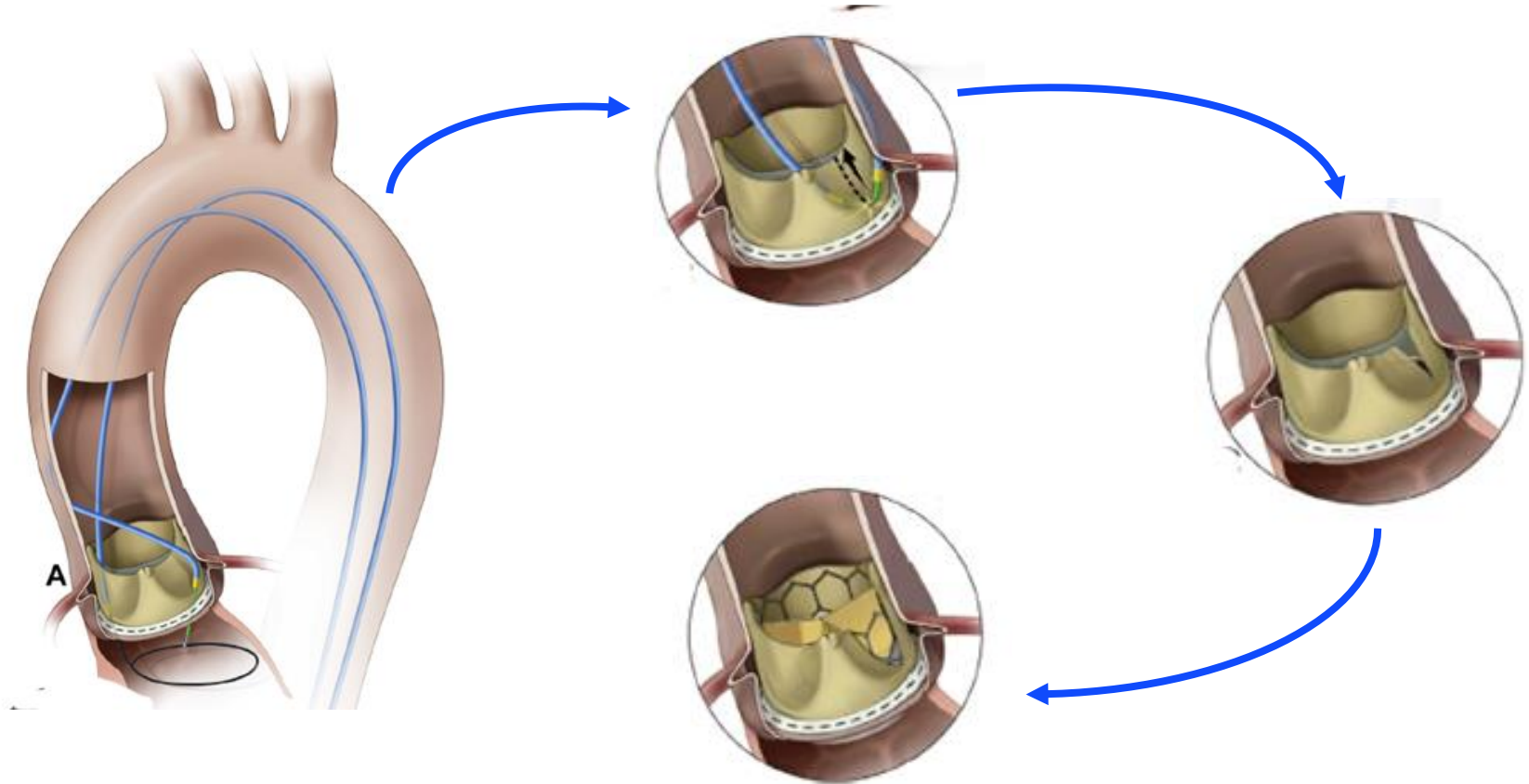
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U.S. ViV TAVR Projections

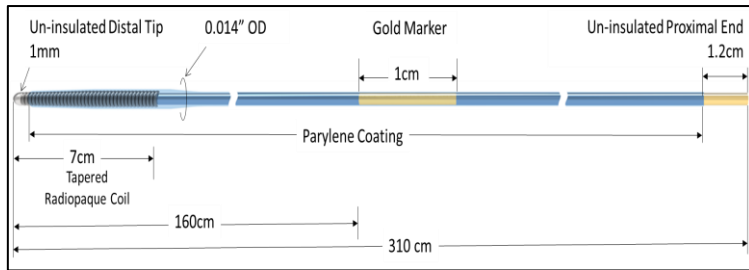


Leaflet Modification: BASILICA

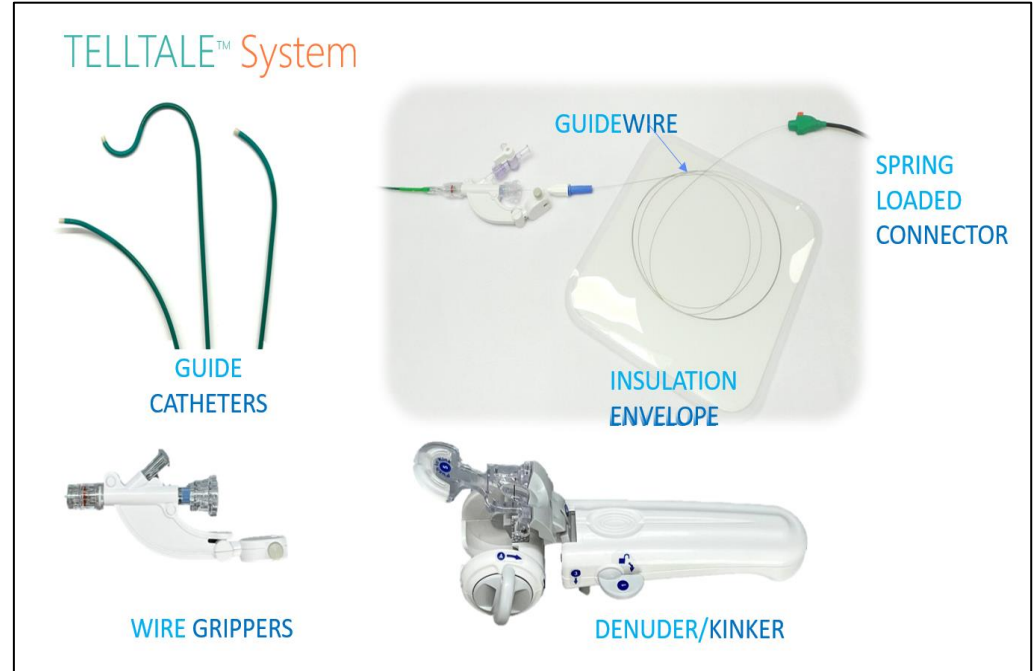


CAN WE MAKE LEAFLET MODIFICATION EASIER?

TELLTALE SYSTEM



Dedicated electrosurgery wire



Accessories

Leaflet Modification Techniques

Mechanical Splitting (SHORTCUT)



Designed to **enable coronary access & prevent coronary obstruction** during TAVI

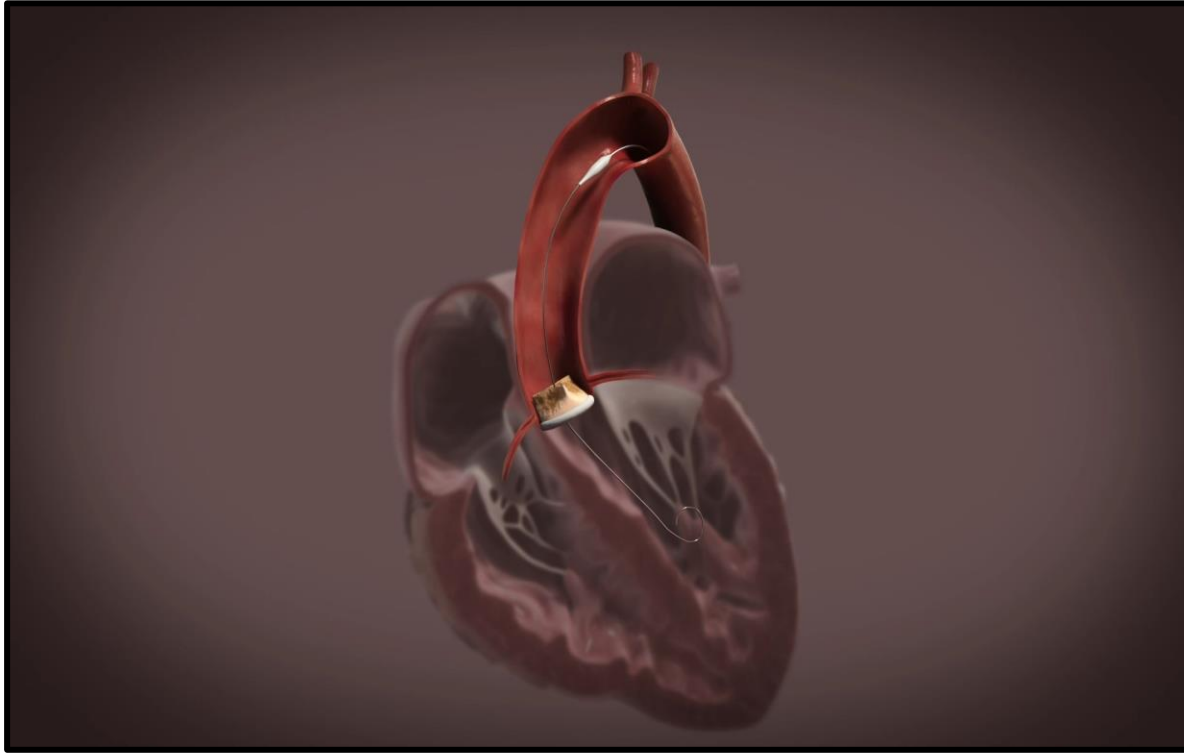


Complete **control over positioning & leaflet splitting location**



Allows for **safe, simple splitting of single or double leaflets** using same device

The Splitter (HVT Medical)



- Electrosurgical partial leaflet excision and removal
- Allows visual confirmation of effective leaflet laceration

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New Leaflet Designs

DurAVR Concept (Anteris)

Single-piece, native-shaped
biomimetic design



ADAPT®
ANTI-CALCIFICATION
TECHNOLOGY



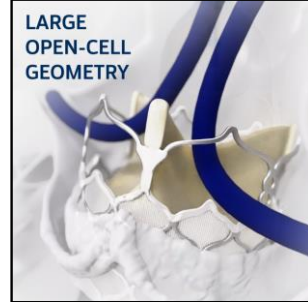
BALLOON
EXPANDABLE
PRECISION



COMMISSURE
ALIGNMENT
TECHNOLOGY



LARGE
OPEN-CELL
GEOMETRY



New Leaflet Designs

DurAVR Concept (Anteris)

**EFS Valve
Performance (n=15)**

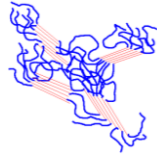
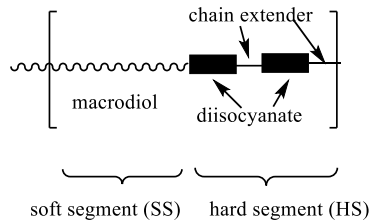
*Mean Annulus
22.2 mm*

Hemodynamic Parameter	Mean (n=15)
Mean Gradient	
Echo	7.8 mmHg
Invasive	1.8 mmHg
DVI	0.71
EOA	2.4 cm ²

New Leaflet Designs

TRIA Polymer Valve + Robotic Manufacturing (Foldax)

Polyurethane



Siloxane polyurethane



*Similar structure used in
pacing leads for over 15 years*



TRIA™ Mitral Surgical Valve



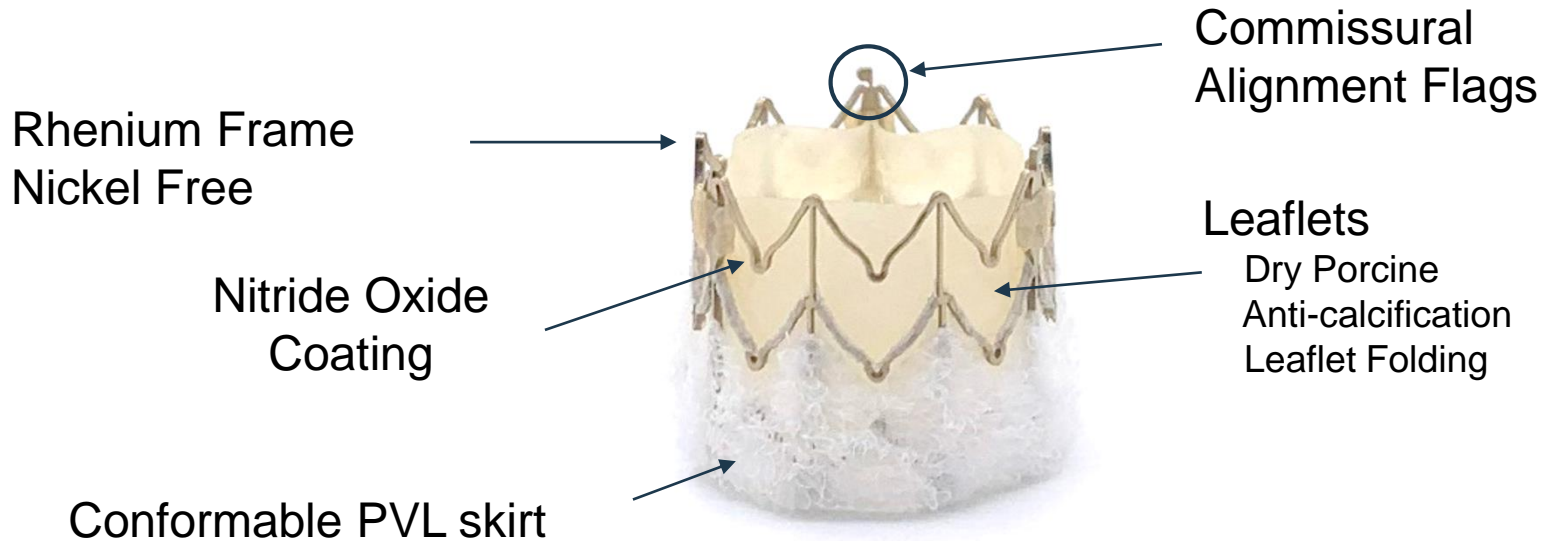
TRIA™ TAVR
Gen 1 Valve

Polymeric Valve

- High tensile strength
- Biologically inert
- ? One valve for life?

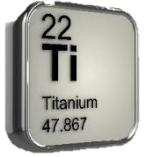
New Valve Designs

Siegel Valve



Delivered Crimped On Balloon Through **8 Fr Expandable Sheath**

Rhenium Superalloy



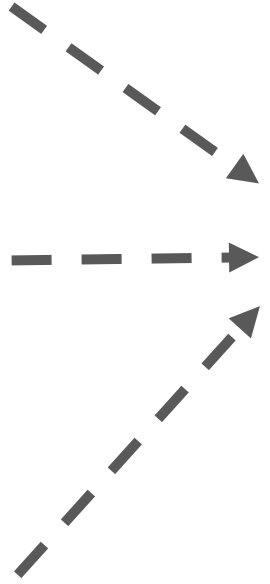
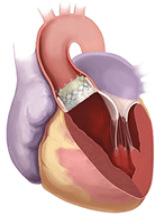
Nickel (Nitinol)
Aluminum-Vanadium

Poor Mechanical &
Biological Properties



Nickel
Chromium

Poor Mechanical &
Biological Properties



- 2-3x Strength
- 2-3x Durability
- <1/3 Recoil
- Superior Biocompatibility
 - Nickel Free
- Improved Radiographic Visibility

Traditional Materials Closed Cell Design

Rhenium Frame Open Cell Design

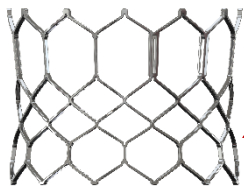
BEV
Cobalt
48 Cells

SEV
Nitinol

Siegel BEV
Rhenium

- Reduced Crimp Profile

5 patient FIM study completed
US EFS expected 2025



Asy
Cells



15 cells per row
9 rows



9 cells per row
2 rows

- Improved Coronary
Access
- Noreshortening

- Minimal Recoil →
Symmetrical Expansion

12 cells per row
4 rows

Innovation in TAVR

Summary

- Despite more than 15 years of commercial application, innovation in the TAVR space remains active
- Areas of innovation are focused on unmet needs and include TAVR for AR, novel approaches to leaflet modification, new leaflet and valve technologies, and expanding “upstream” indications
- Other promising areas include embolic protection systems and AI for procedural planning (including lifetime management)
- Stay tuned... the future is bright for TAVR!