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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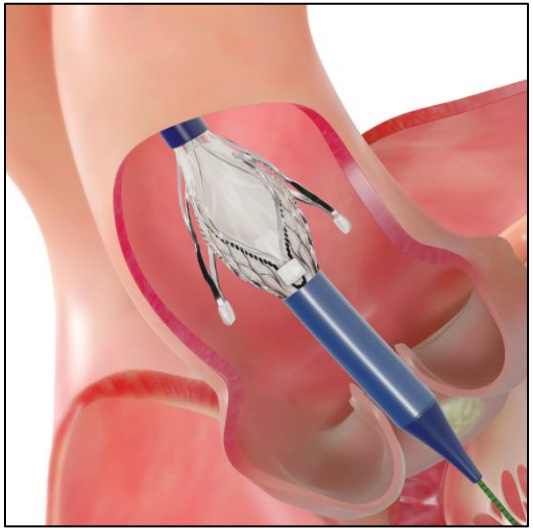
TAVR in Aortic Regurgitation
Unmet Need

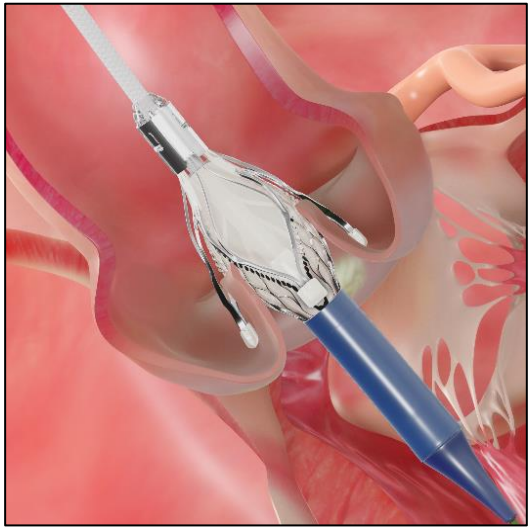
- Moderate/Severe AR is common in older patients → prevalence 4.5% in New Ulm (Minnesota) study
- Severe AR is bad → Mortality ~10% per year with severe, symptomatic AR (~25% with NYHA III/IV symptoms)
- AR is undertreated → <25% of patients with severe, symptomatic AR undego SAVR
- Off-label TAVR with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

Aortic Regurgitation
TRILOGY and ALIGN AR



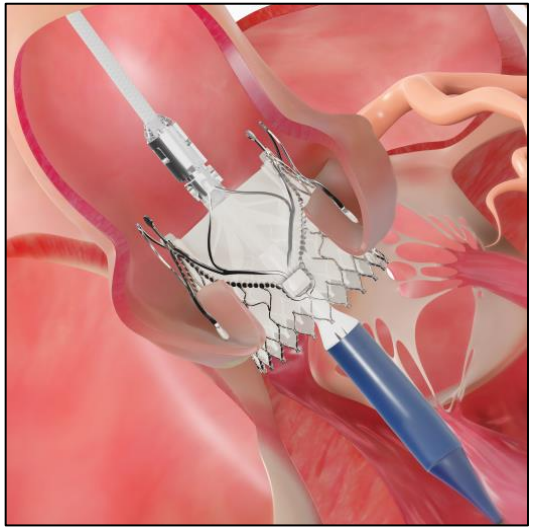
Alignment

Aligns THV with native cusps



Positioning/Anchoring

Locators “clip” onto native leaflets forming a natural seal and stable securement

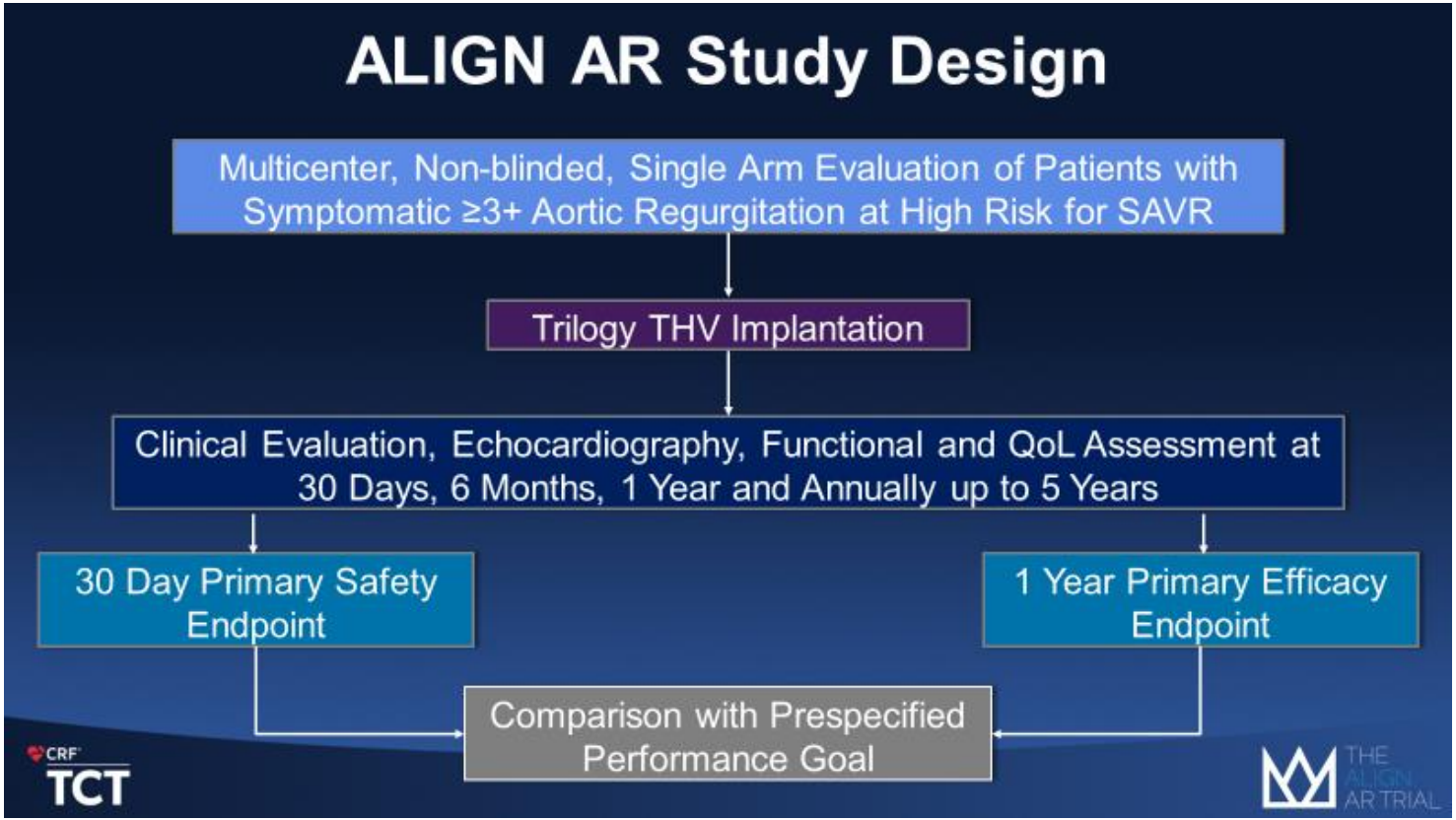


Deployment

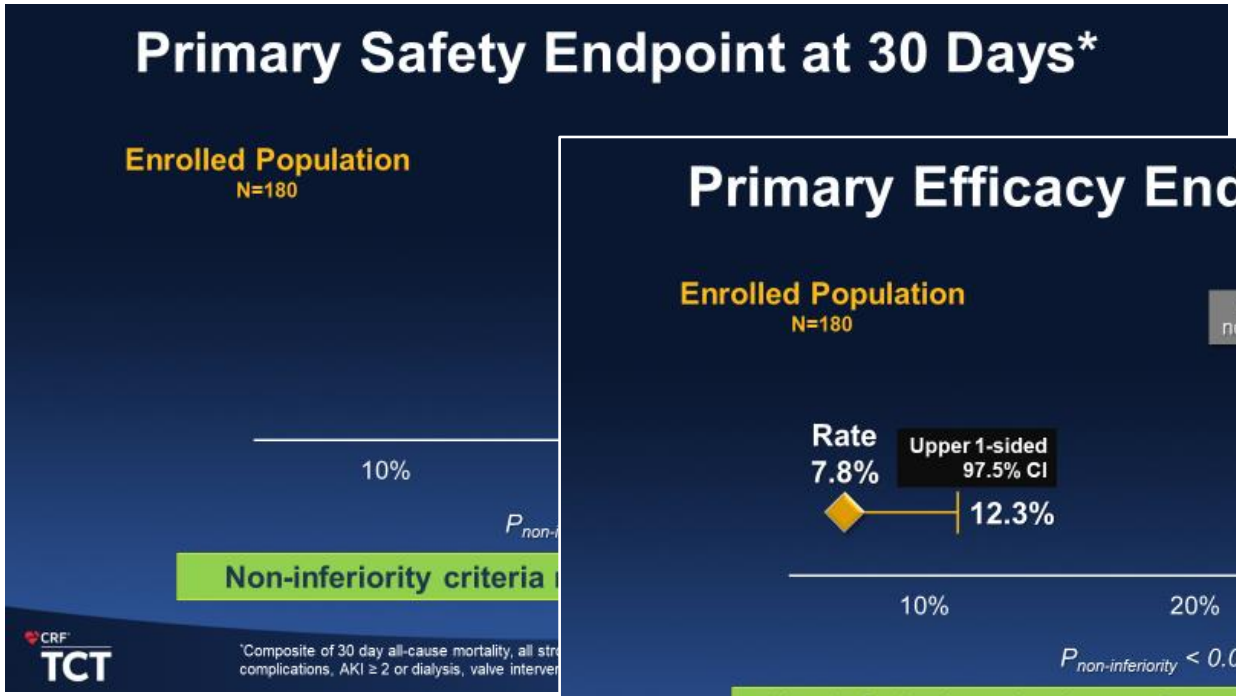
Large open cells provide access to low coronaries; flared sealing ring conforms to annulus

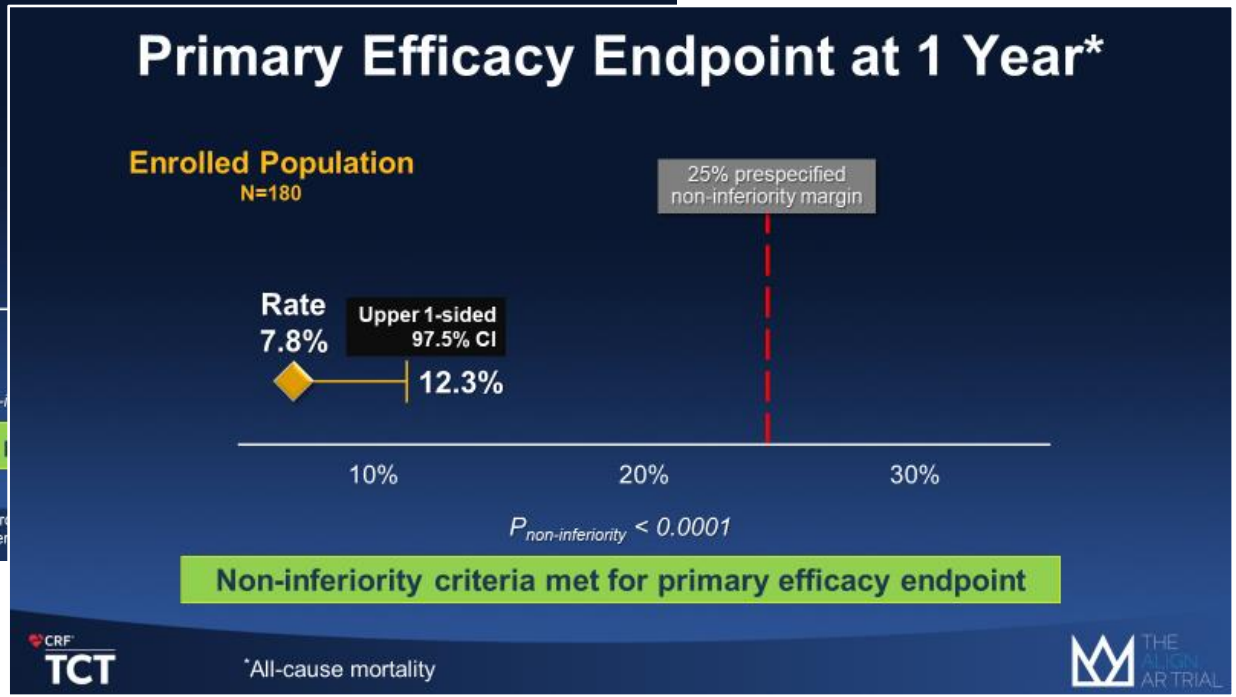
Aortic Regurgitation

TRILOGY and ALIGN AR (n = 180 pts)



Aortic Regurgitation
TRILOGY and ALIGN AR





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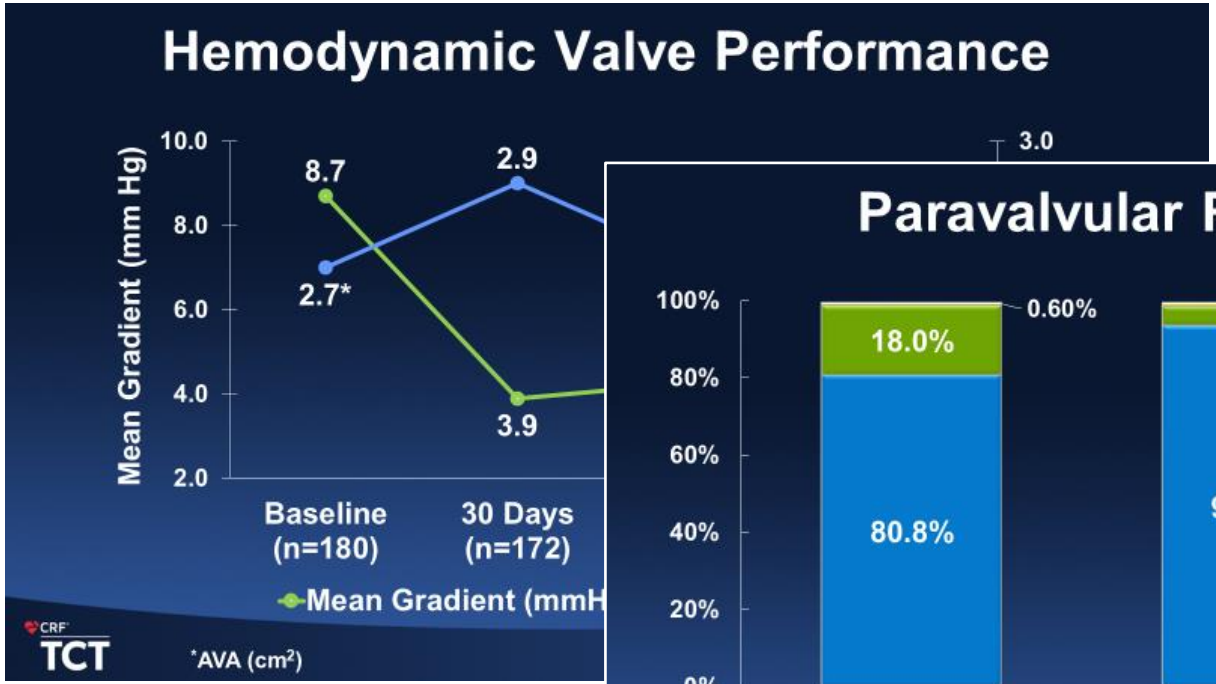

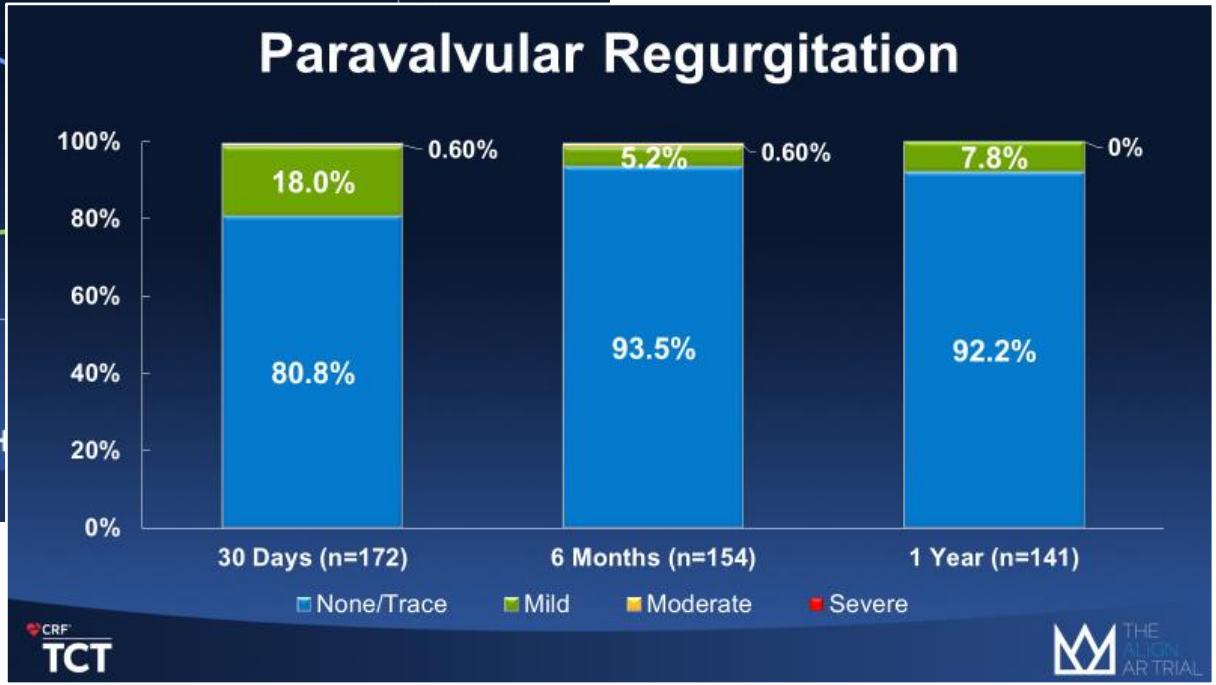

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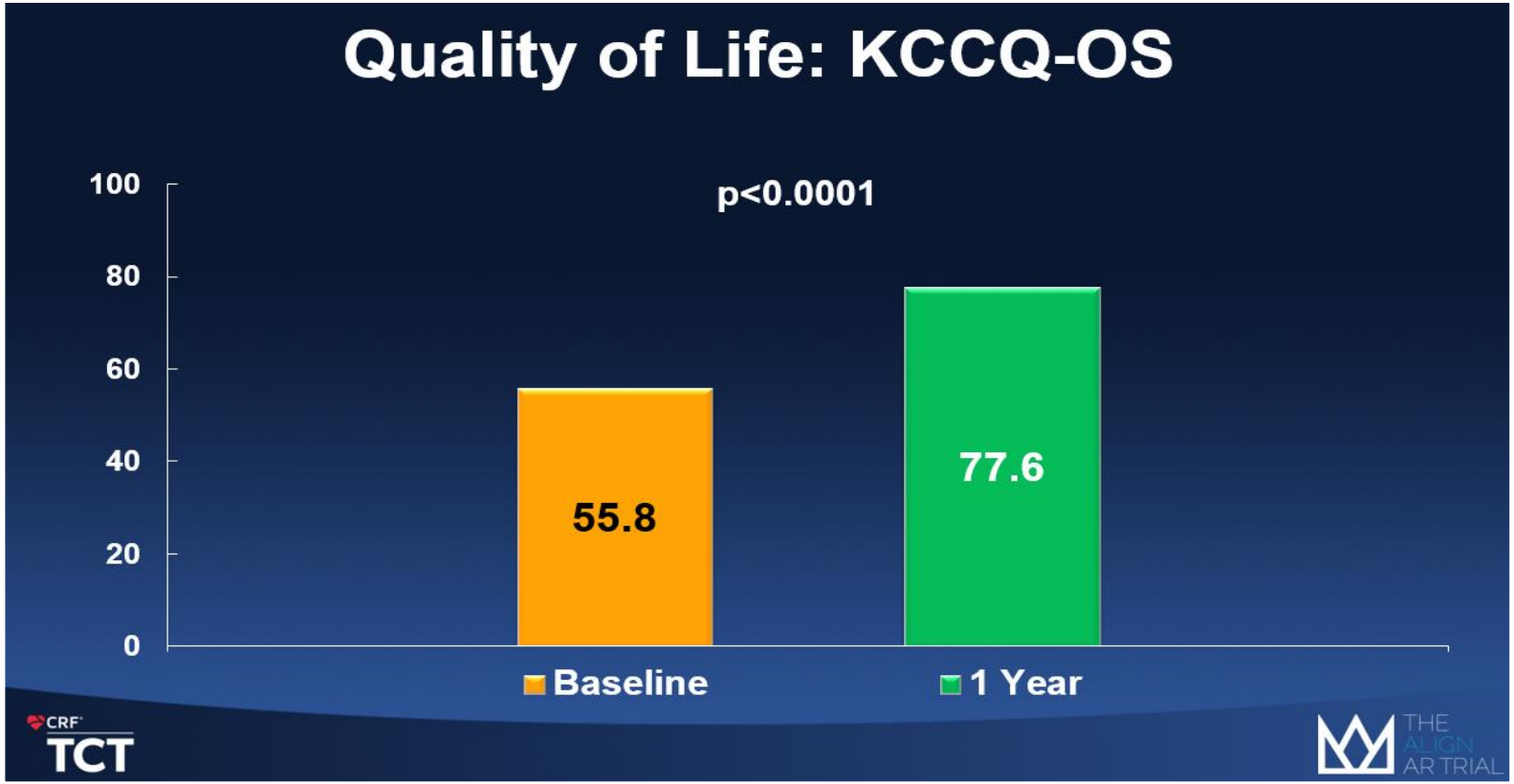
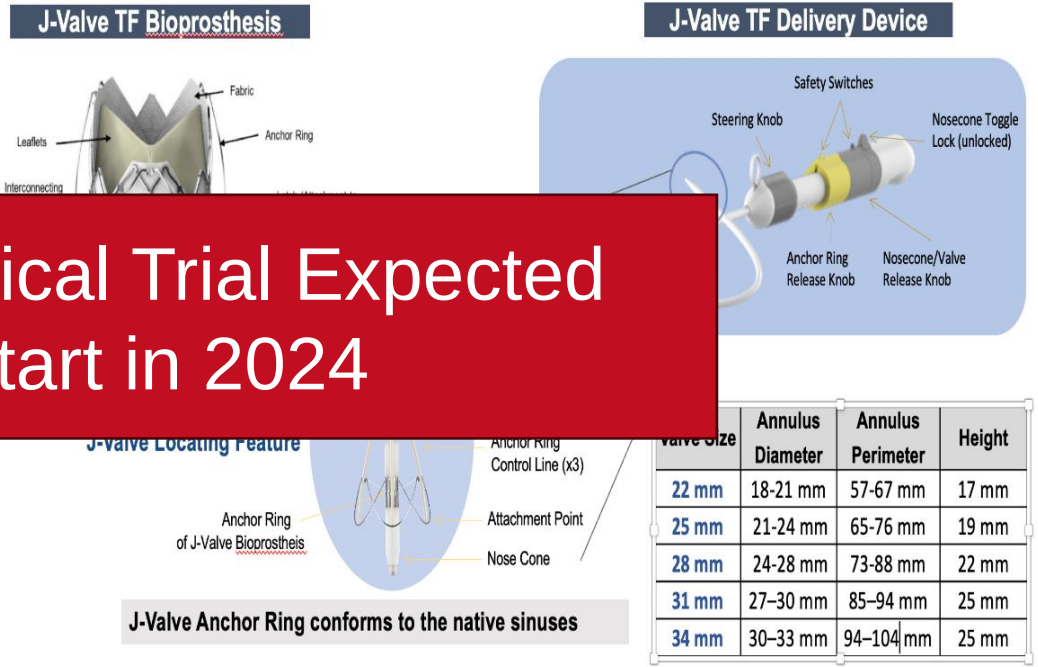


Aortic Regurgitation
J-Valve (from China)

- **Bioprosthesis**: self-expanding nitinol frame, bovine pericardial leaflets
- **Delivery Sy** flexible cath access (18,
- **Locating Fe** designed to anatomy
- **Size matrix:** 5 sizes, can treat wide range of anatomies (perimeters 57-104)

Pivotal Clinical Trial Expected to Start in 2024



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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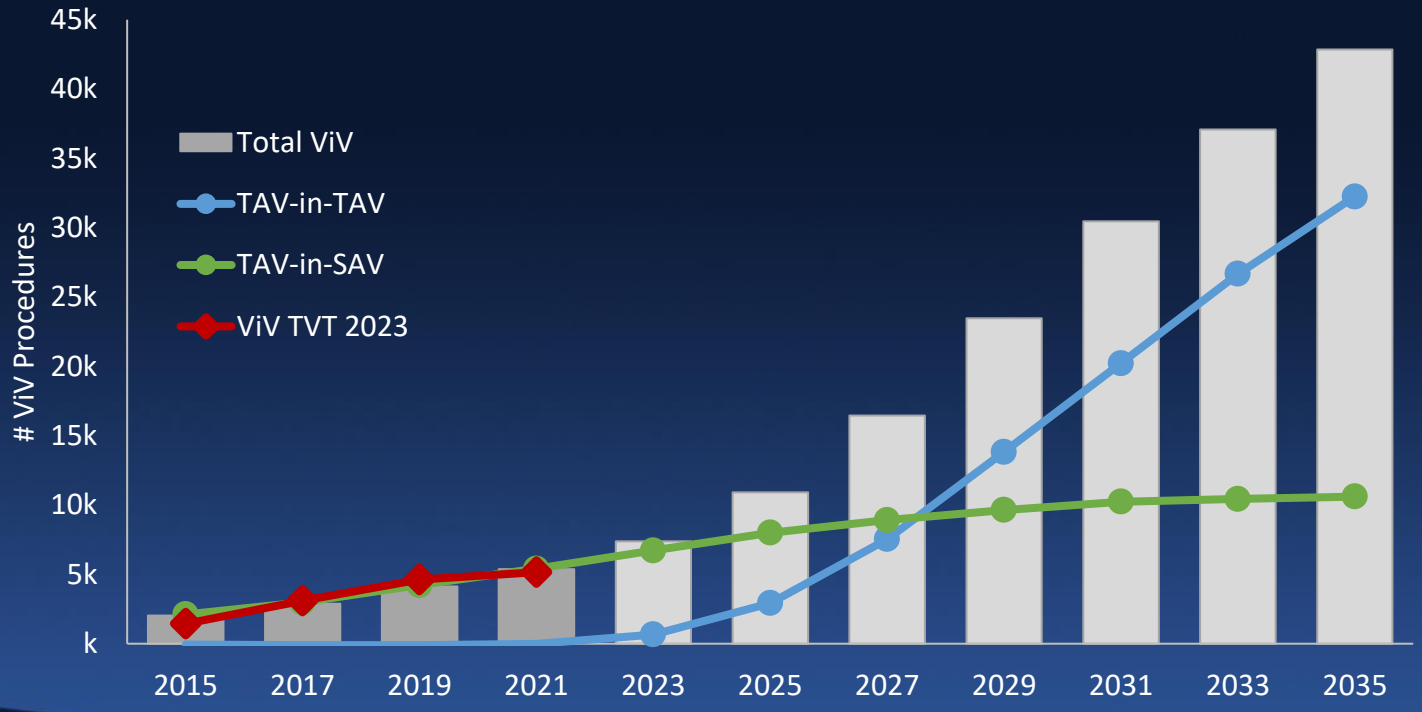
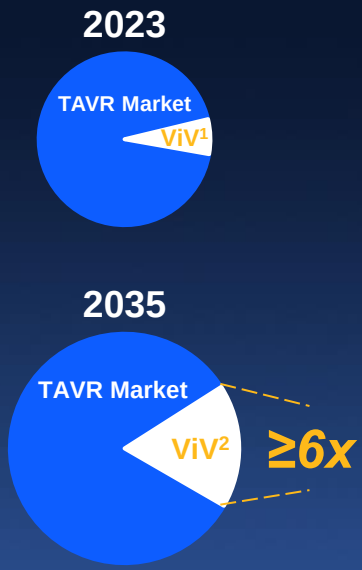
U.S. ViV TAVR Projections

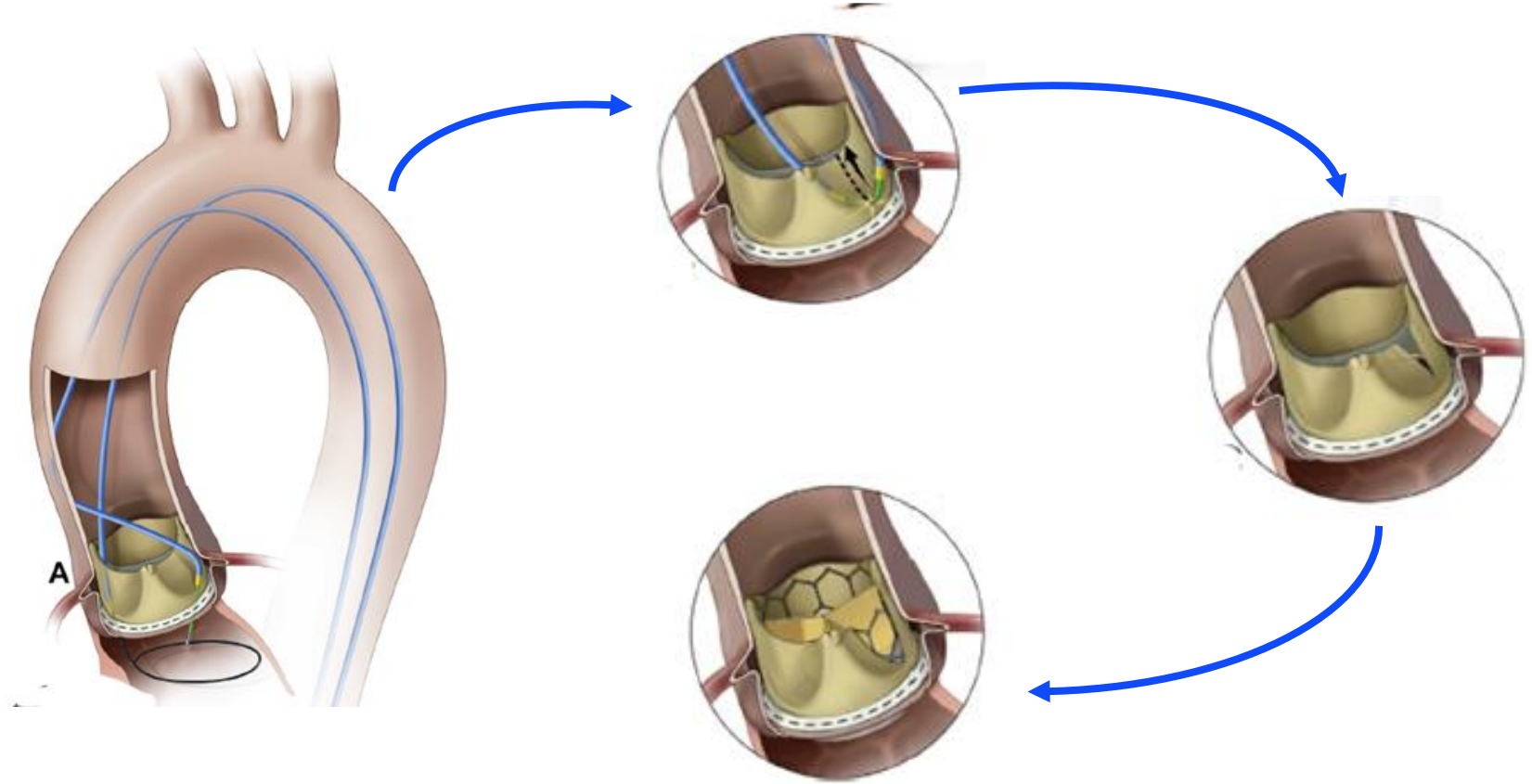




CRF TCT

Genereux P, et al. JSCAI 2024

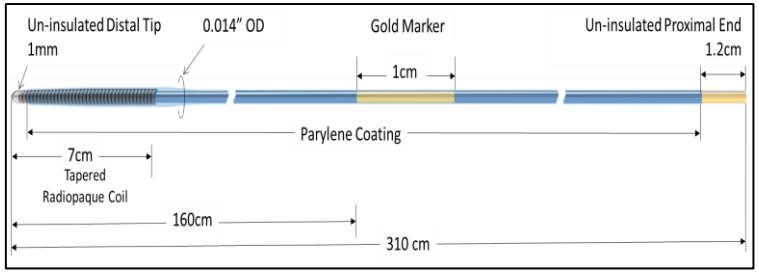
Leaflet Modification: BASILICA



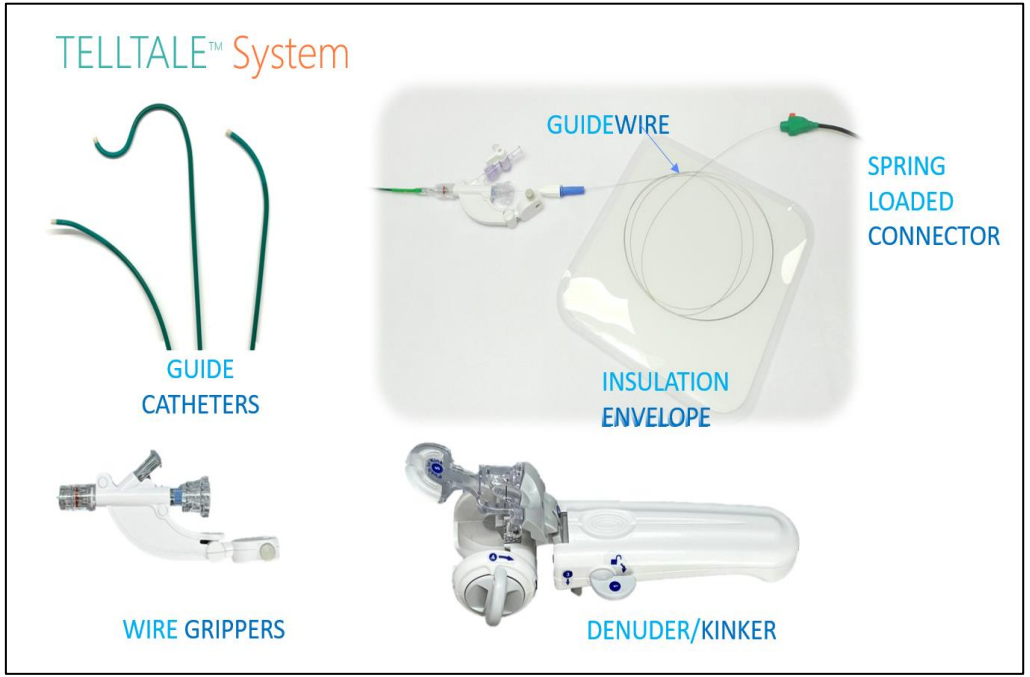
Khan JM, et al. JACC Intv 2018

CAN WE MAKE LEAFLET MODIFICATION EASIER?

TELLTALE SYSTEM



Dedicated electrosurgery wire



Accessories

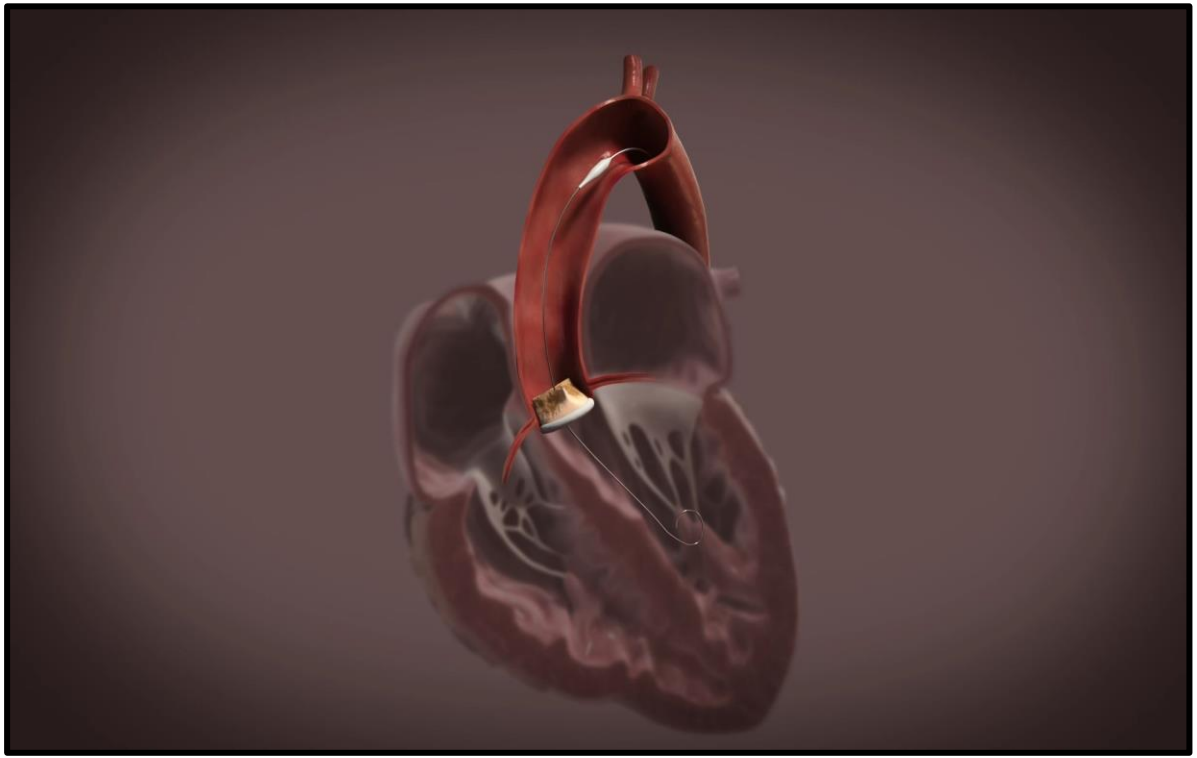
Leaflet Modification Techniques
Mechanical Splitting (SHORTCUT)

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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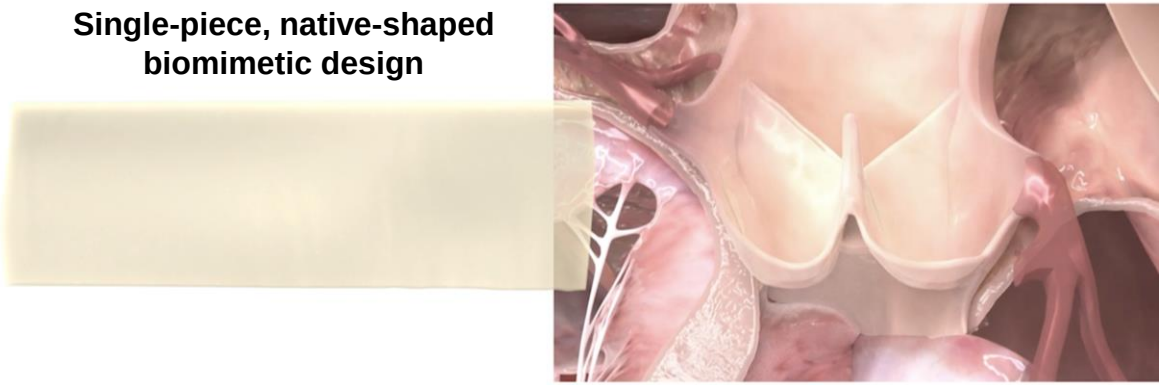
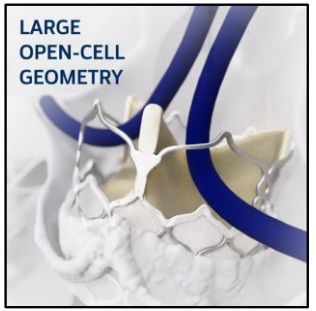
New Leaflet Designs

DurAVR Concept (Anteris)

Single-piece, native-shaped biomimetic design





New Leaflet Designs

DurAVR Concept (Anteris)

EFS Valve Performance (n=15)

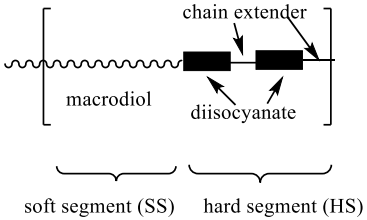
Mean Annulus 22.2 mm

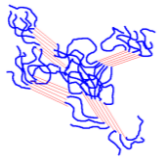
Hemodynamic Parameter	Mean (n=15)
Mean Gradient	
Echo	7.8 mmHg
Invasive	1.8 mmHg
DVI	0.71
EOA	2.4 cm2

New Leaflet Designs

TRIA Polymer Valve + Robotic Manufacturing (Foldax)

Polyurethane





Siloxane polyurethane

Similar structure used in pacing leads for over 15 years

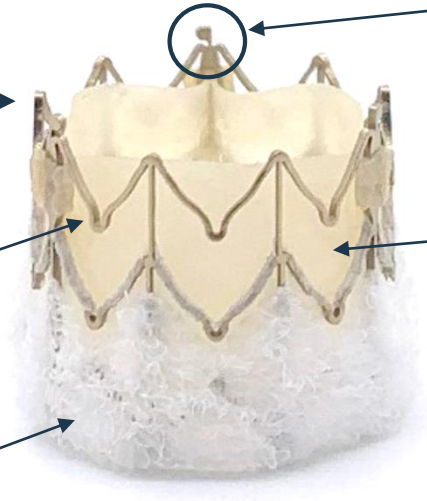
TRIA™ Mitral Surgical Valve

TRIA™ TAVR
Gen 1 Valve

Polymeric Valve

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

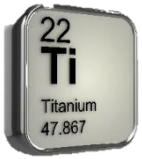
New Valve Designs
Siegel Valve



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

Slides courtesy of Pradeep Yadav, MD

Rhenium Superalloy

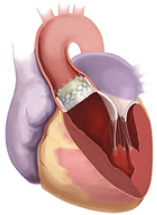


Nickel (Nitinol)
Aluminum-Vanadium

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

Slides courtesy of Pradeep Yadav, MD

Traditional Materials
Closed Cell Design

BEV
Cobalt
48 Cells

12 cells per row
4 rows

SEV
Nitinol

15 cells per row
9 rows

Rhenium Frame
Open Cell Design

Siegel BEV
Rhenium

9 cells per row
2 rows

- Reduced Crimp Profile
- oved Coronary
  ss
- oreshortening
- Minimal Recoil → Symmetrical Expansion

5 patient FIM study completed
US EFS expected 2025

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!