Aortic Regurgitation:
The Need for and Status of Dedicated TAVR Devices

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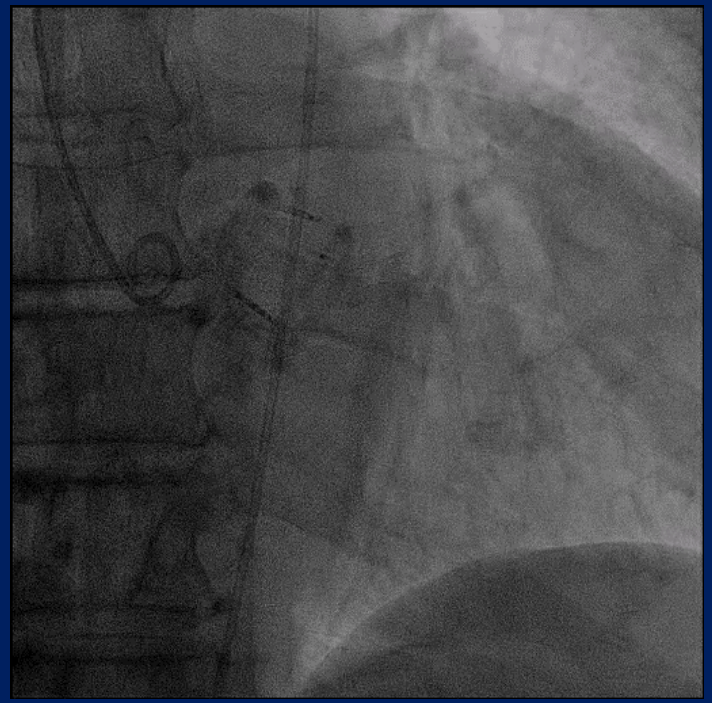
TAVR with Commercial Devices

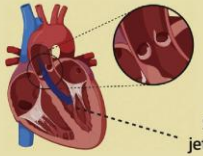


CENTRAL ILLUSTRATION: Meta-Analysis Overview and Findings

Meta-analysis of Dedicated Versus Off-Label TAVR for Native Aortic Valve Regurgitation

Challenges of TAVR in native AR

TAVR and THV design specific solutions



- Aortic annulus dilation → Larger valve sizes, Over-sizing THVs
- Absence of calcium for anchoring and stability → Clipping/grasping of leaflets, Sealing ring
- Severe aortic regurgitant jet causing "suction effect" → Rapid pacing >120 beats/min

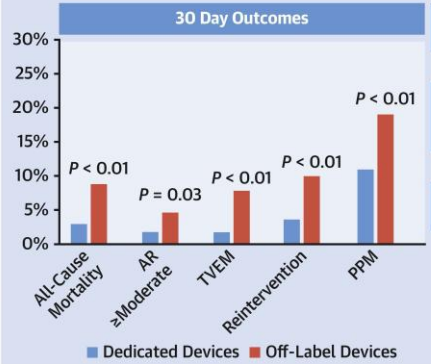
34 Studies

2,162 Patients

1,193 Dedicated Devices

969 Off-label Devices

Mean age = 75.4 ± 0.2 years
STS score = 5.6 ± 0.1 %
Log EuroSCORE = 24.2 ± 0.3%



Device Success
93% vs 82%

Similar risk of:
Stroke
Vascular complications

Mortality at 1 year
6% vs 24%

Samimi S, et al. JACC Cardiovasc Interv. 2024;10.1016/j.jcin.2024.08.042

JenaValve Trilogy

Salient Features:

- 3 sizes (S-M-L)
- Range of perimeters 66-90 mm
- Porcine Pericardial Leaflets
- Nitinol stent
- Flared sealing ring

JenaValve Trilogy™ THV Sizing Matrix‡

JenaValve Trilogy™ THV Dimensions & Sizing Recommendations*

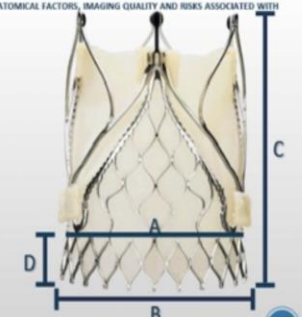
JenaValve Trilogy™ THV Dimensions				Trilogy™ THV Sizing Recommendations (MDCT Scan)				
THV Size	Model Number	Stent Diameter at Sealing Ring* (mm)	Stent Perimeter at Sealing Ring* (mm)	Perimeter-Derived Annulus Diameter Range† (mm)	Indicated Annulus Perimeter Range† (mm)	LVOT Perimeter† (mm)		
						2mm	4mm	6mm
23	TRILOGY-THV-S	26	81.7	21.0 – 24.2	66 – 76	78	80	82
25	TRILOGY-THV-M	28	88.0	23.2 – 26.4	73 – 83	85	87	89
27	TRILOGY-THV-L	30	94.2	25.5 – 28.6	80 – 90	92	94	96

* The top of the Sealing Ring, which interfaces with the native annulus upon implant. Shown as nominal dimensions.

† Comprehensive interpretation of annular dimensions, overall aortic root dimensions & anticipated THV size should be performed in context with anatomical factors, imaging quality and risks associated with undersizing and oversizing when determining anatomical suitability.

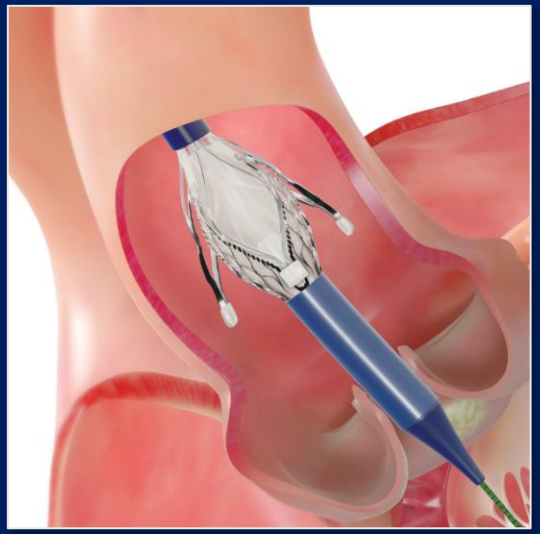
‡ Failure to implant a device within sizing matrix could lead to PVL, dissection/ tear/ rupture, or migration.

THV Model Number	A. Stent Diameter at Sealing Ring (mm)	B. Stent Diameter at Sealing Ring Flare (mm)	C. Valve Height (mm)	D. Sealing Ring Height (mm)
TRILOGY-THV-S	26	28	31.3	5.6
TRILOGY-THV-M	28	30	33.7	5.6
TRILOGY-THV-L	30	32.4	35.7	6.3



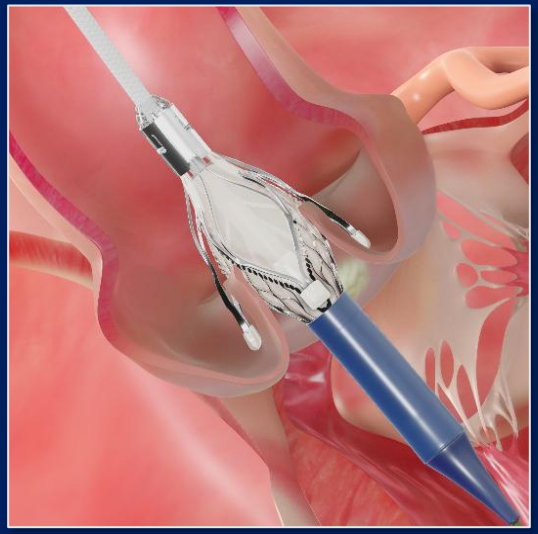
JenaValve® Technology, Inc. | 2022 | Confidential

Trilogy Porcine Pericardial Valve



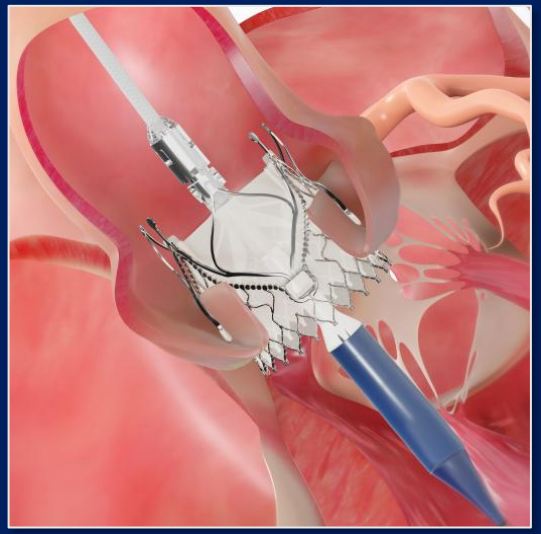
Alignment

Aligns THV with native cusps



Positioning/Anchoring

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

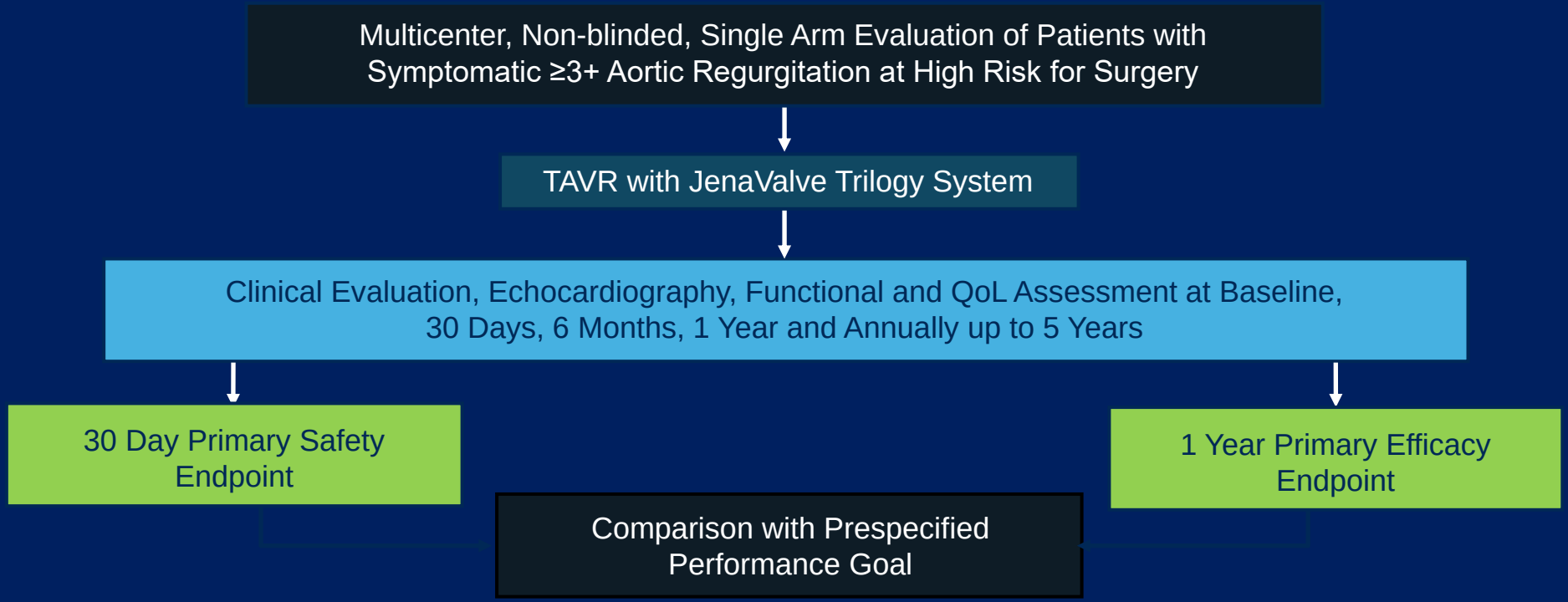


Deployment

Large open cells provide access to low coronaries. Flared sealing ring conforms to annulus

The Trilogy THV System is for Investigational Use Only in the United States and is Limited by Federal (or United States) law for this use.

ALIGN-AR Study Design

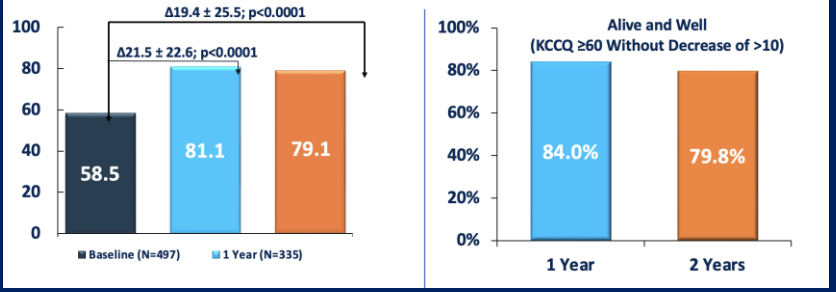


Primary Safety Endpoint at 30 Days

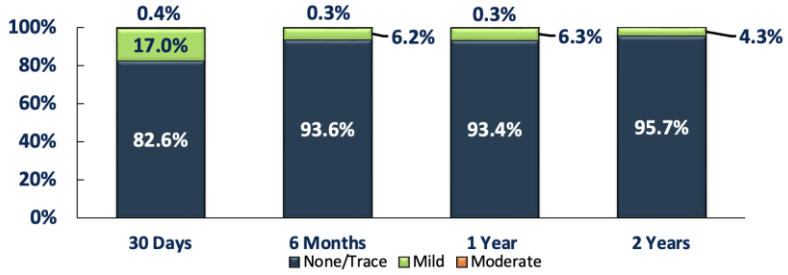
	ALIGN-AR (n=180)	ALIGN-AR CAP (n=320)
Primary Safety Composite Endpoint	**26.7% (48)**	**25.9% (83)**
All Cause Mortality	**2.2% (4)**	**0.9% (3)**
Cardiovascular Mortality	1.7% (3)	0.9% (3)
Any Stroke Disabling Stroke Non-disabling Stroke	2.2% (4) 1.1% (2) 1.1% (2)	1.9% (6) 0.6% (2) 1.3% (4)
Major/Life Threatening Bleeding	**4.4% (8)**	**2.5% (8)**
Major Vascular Complication	**3.9% (7)**	**2.2% (7)**
Surgery/Intervention Related to the Device	5.0% (9)	4.1% (13)
New Pacemaker Implantation Pre-existing Pacemaker	**24.0% (36)** 16.7% (30)	**23.0% (63)** 14.4% (46)
≥ Moderate Total Regurgitation	0.6% (1)	0.7% (2)

Vahl et al. Lancet 2024, Makkar ACC 2025

KCCQ-Overall Summary

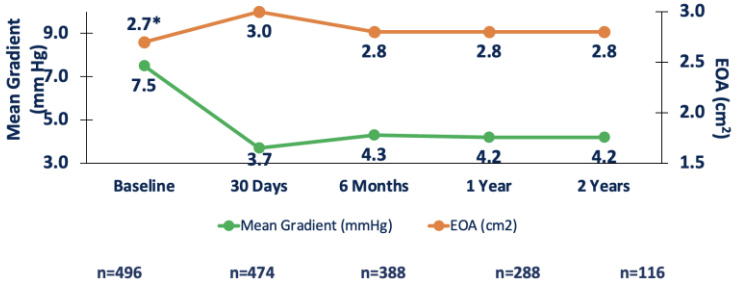


Paravalvular Regurgitation



NYHA Functional Class

Hemodynamic Valve Performance



The ARTIST Trial

Aortic Regurgitation Trial Investigating Surgery and Trilogy

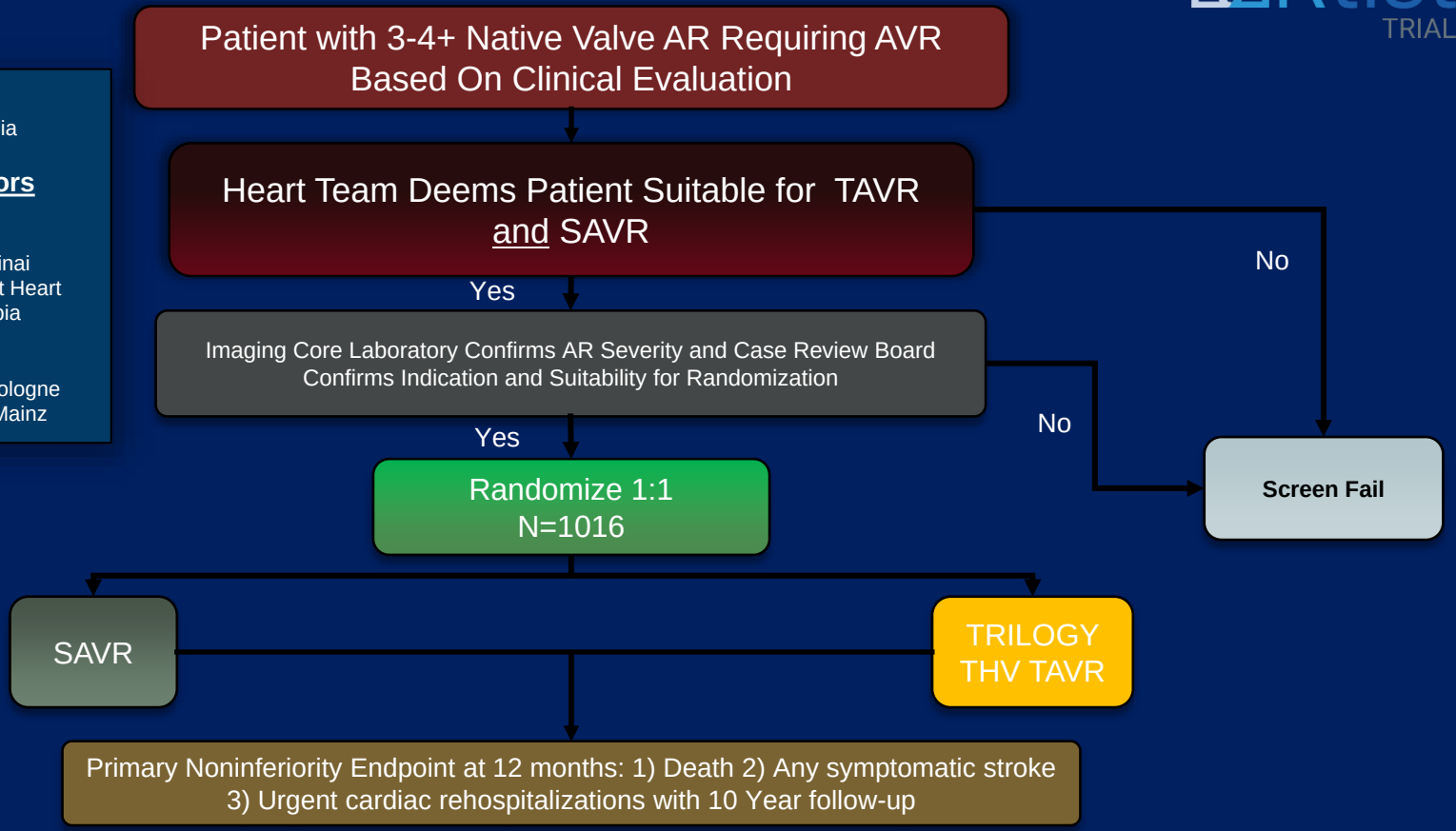
MRtist TRIAL

Study Chair
Martin Leon MD, Columbia

Principal Investigators

US
Raj Makkar MD, Cedars Sinai
Vinod Thourani MD, Piedmont Heart
Torsten Vahl MD, Columbia

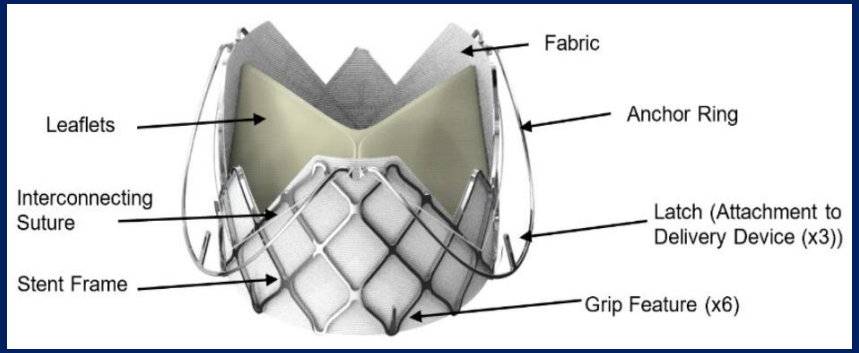
OUS
Stephan Baldus, University Cologne
Hendrik Treede, University Mainz



J-Valve: A Novel TAVR Design to Treat AR

Comprised of bovine pericardium leaflets, nitinol frame, and a fabric skirt to mitigate PVL

- Unique anchor rings designed to self-center the valve for optimal alignment
- Five valve sizes available intended to treat perimeters 57-104mm
- Rounded, atraumatic rings designed to easily locate and position in the annulus



J-Valve TF Size	Annulus Diameter (mm)	Annulus Perimeter (mm)	Annulus Area (mm^2)
22 mm	18 - 21	57 – 66	254 - 346
25 mm	21 - 24	66 - 75	346 - 452
28 mm	24 - 27	75 - 85	452 - 573
31 mm	27 - 30	85 - 94	573 - 707
34 mm	30 - 33	94 - 104	707 - 855

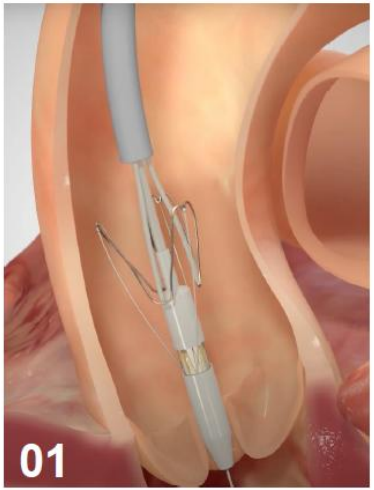
Valve size recommendations are based on native valve annulus size, as measured by computed tomography (CT). Patient anatomical factors and imaging modality should be considered during valve size selection.

Low Profile

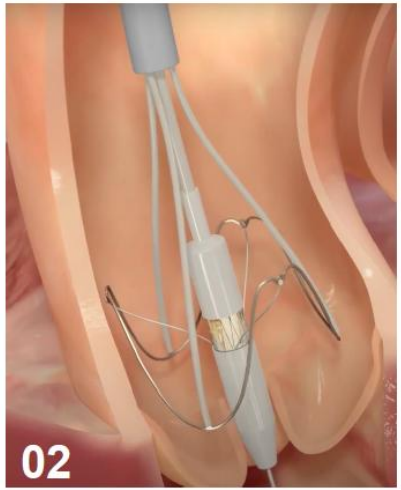
Valve Size	Height
22 mm	17 mm
25 mm	19 mm
28 mm	22 mm
31 mm	25 mm
34 mm	25 mm

CAUTION: Investigational device. Limited by Federal (United States) law to investigational use.

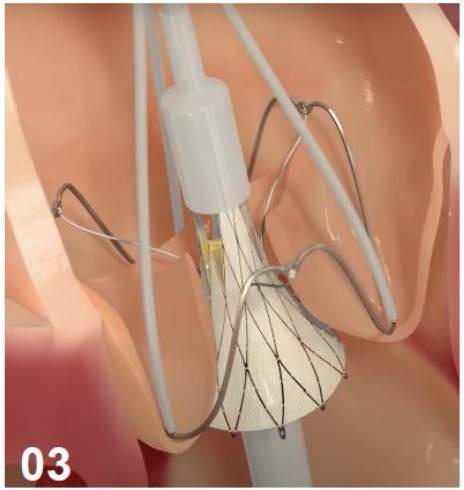
J-Valve Deployment Steps



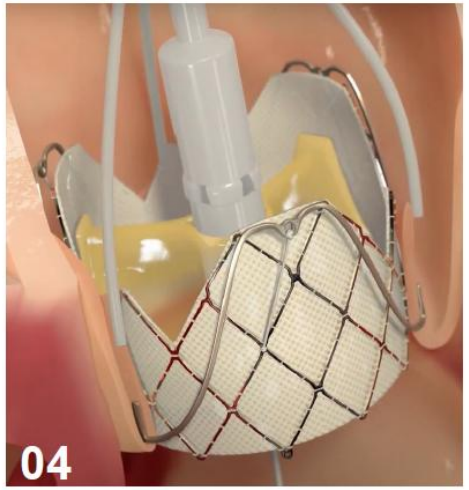
Unsheath Anchor Rings



Expand anchor rings into sinuses



Position and deploy the valve



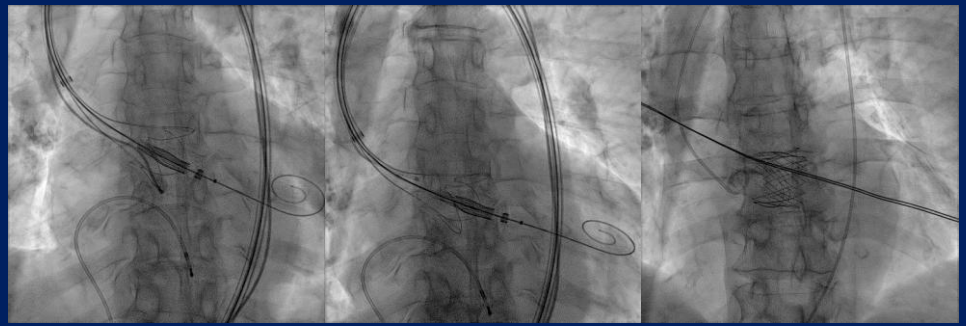
Disengage anchor rings from control lines to release the valve

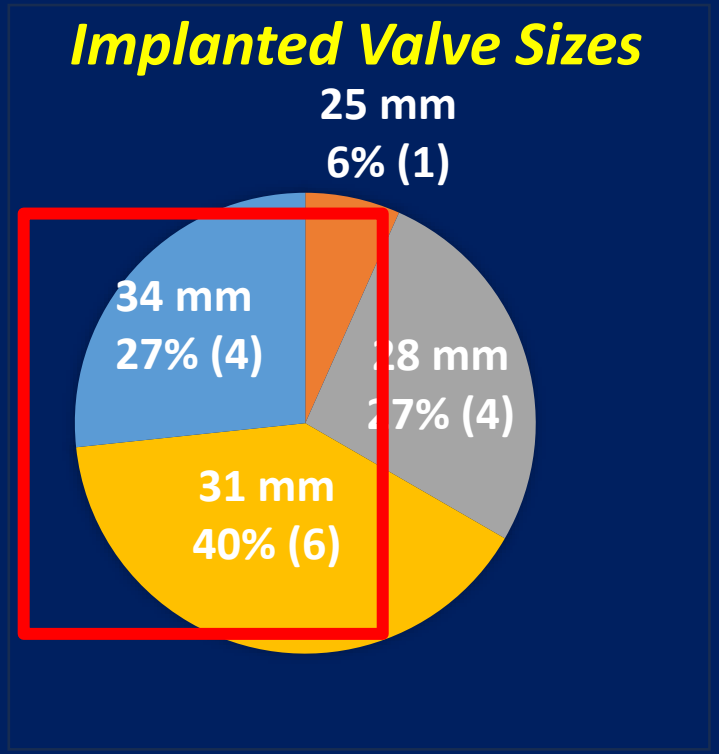
CAUTION: Investigational device. Limited by Federal (United States) law to investigational use.

J-Valve® TF EFS Results (n=15)

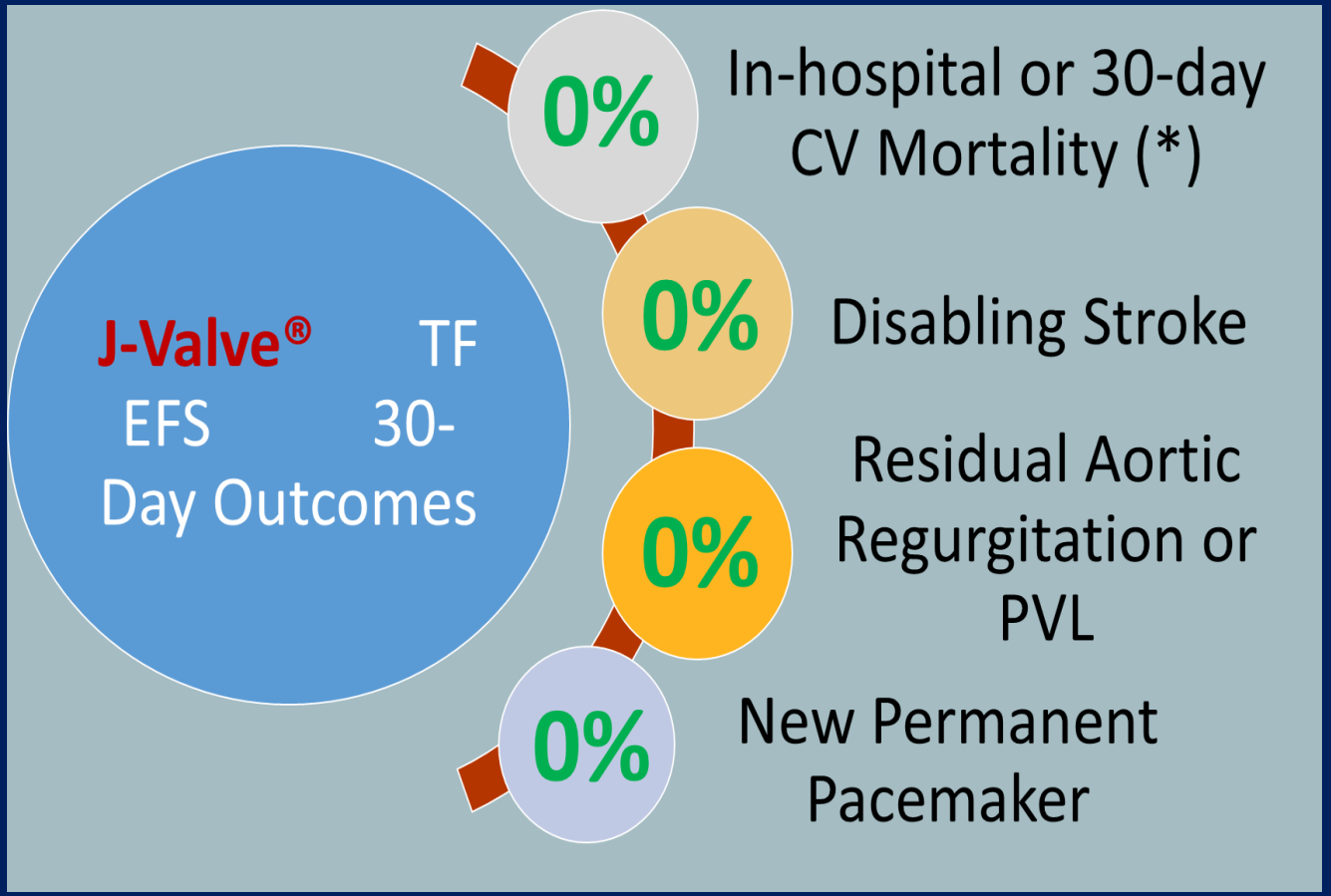
Characteristic	Minutes
Procedure duration (min) Median- IQR	53 (50-65)
Fluoroscopy time (min) Median- IQR	22 (18-28)

67% was 31/34mm J-valve





Garcia, S et al. JACC Int 2024



Garcia, S et al. JACC Int 2024

JOURNEY Pivotal Trial Overview

J-Valve to treat aortic regurgitation via transcatheter therapy

Multicenter, prospective, single-arm evaluation of patients with symptomatic ≥ 3+ aortic regurgitation (AR)* at high-risk for SAVR

***Multimodality diagnostic assessment to determine AR severity by TTE and CMR/TEE criteria for indeterminate AR**

Edwards J-Valve TAVR-AR transcatheter heart valve implantation

Safety Co-Primary Endpoint: Composite early-safety outcomes at 30 days as defined by VARC 3

Efficacy Co-Primary Endpoint: All-cause mortality at 1-year

Pivotal IDE Plan

- 194 subjects
- Up to 40 roll-ins
- Up to 35 sites
- CMR Sub-Study

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

The JOURNEY Trial

JOURNEY Trial Leadership

Co-Principal Investigators

Tsuyoshi Kaneko, MD
Chair, Cardiac Surgery Section

Santiago Garcia, MD,
FSCAI, FACC

Study Chair Persons

Michael Reardon, MD
Professor of Cardiothoracic

Dean J Kereiakes, MD,
FACC, MSCAI

Key Takeaways:

- In native aortic regurgitation, TAVR with dedicated AR devices is safer and more effective than commercial AS devices
- **JenaValve Trilogy System (3 sizes):** CE Mark approval, completed IDE in USA and started low/intermediate risk trial against surgery (ARTIST) + LVAD Registry.
- **J-Valve (5 sizes)**: Completed EFS, pivotal ongoing (JOURNEY trial), imaging sub-study (c-MRI) + LVAD registry.

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