Dedicated Technologies for Treatment of Aortic Regurgitation (AR)

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Within the prior 24 months, I have had a financial relationship with a company producing, marketing, selling, re-selling, or distributing healthcare products used by or on patients:

Nature of Financial Relationship	Ineligible Company
Grant/Research Support	Edwards Lifesciences, JenaValve, Vdyne, Tricares, P&F
Consultant Fees/Honoraria	Abbott, Boston Scientific, Edwards Lifesciences, JenaValve, Vdyne, Egnite, EastEnd Medical
Individual Stock(s)/Stock Options	Nininger Medical
Royalties/Patent Beneficiary	n/a
Executive Role/Ownership Interest	n/a
Other Financial Benefit	n/a

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Aortic Regurgitation – The Problem

- Annulus size often large

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ORIGINAL ARTICLE - CLINICAL SCIENCE

WILEY

Clinical journey for patients with aortic regurgitation: A retrospective observational study from a multicenter database

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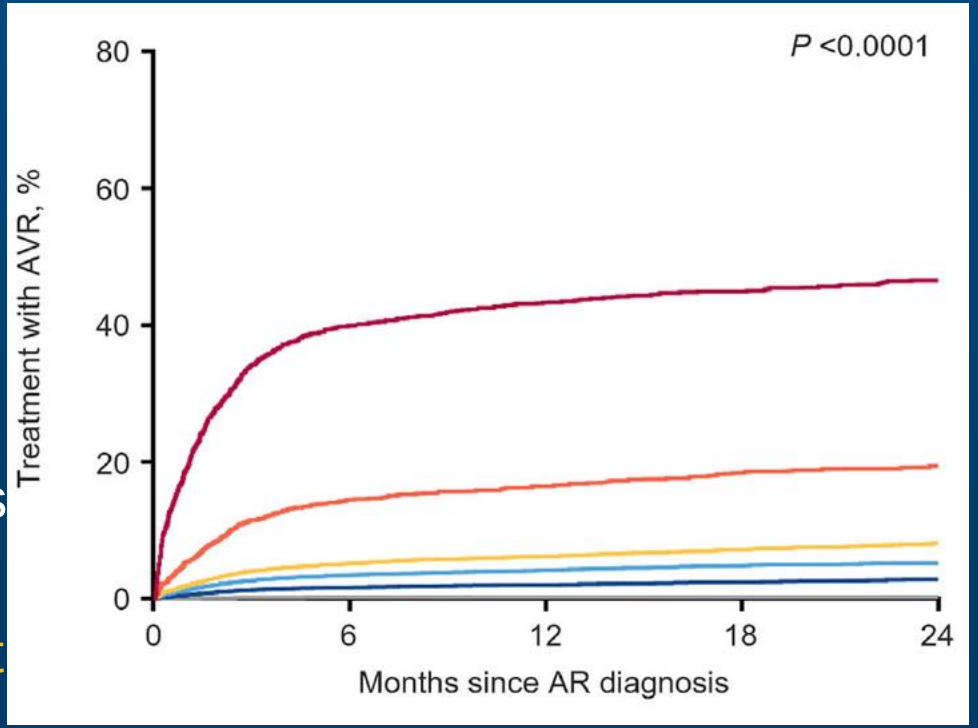
conventional AS TAVR devices

- Younger patients than aortic stenosis; Lifetime management (valve & aneurysms)



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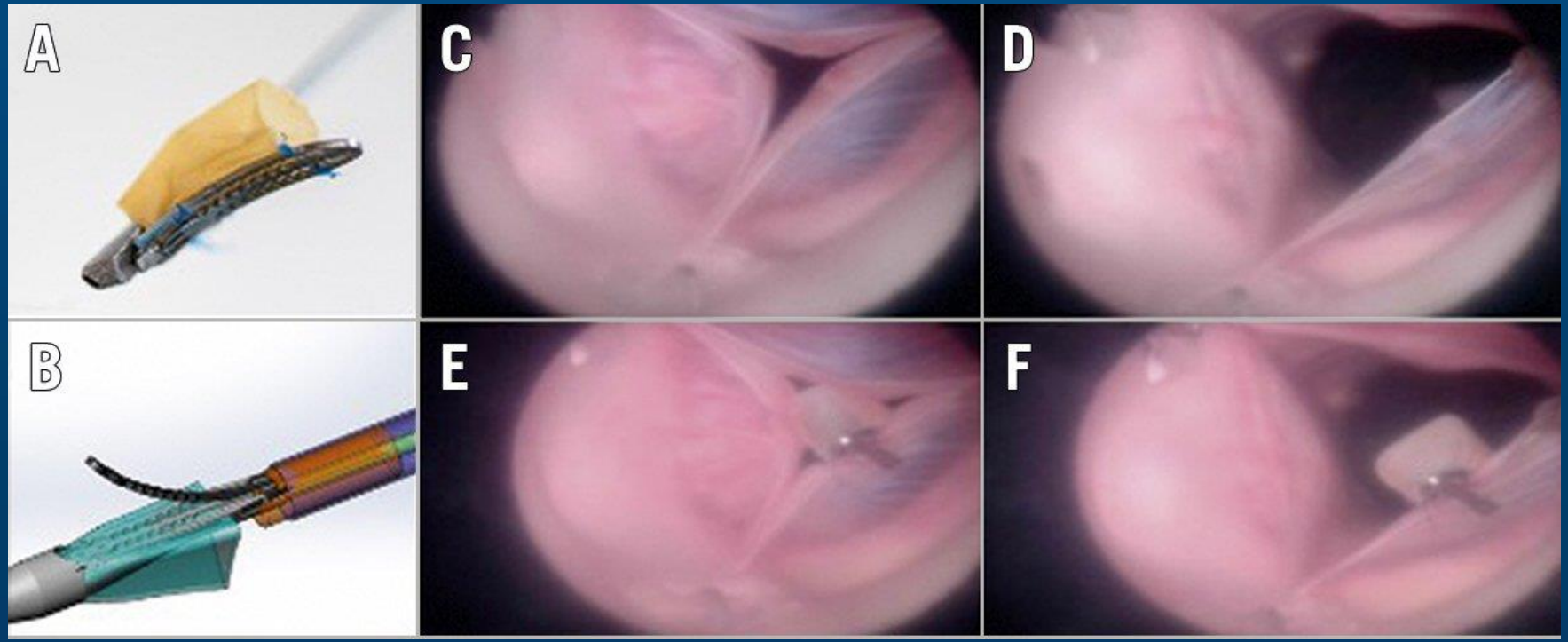
Preclinical Device - Cusper



Accessed 12 Oct 2025: https://eurointervention.pcronline.com/article/transcatheter-aortic-valve-repair-for-aortic-regurgitation-with-the-cusper-device

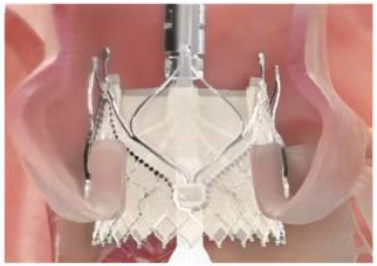
TAVR Devices

	J-Valve	Trilogy
Manufacturer	JC Medical	JenaValve Technology
Approval	NMPA (2017)	CE (2021)
Mechanism of expansion	Self-expanding	Self-expanding
Leaflet material	Bovine pericardial	Porcine pericardial
Leaflet position	Intra-annular	Supra-annular
Frame material	Nitinol	Nitinol
Frame height	17–25 mm*	32–36 mm†
Frame cell size	Sinus cut-outs	27–31 Fr
Native leaflet interaction	U-shaped anchor rings	Locator
Commissural alignment	Self-aligning design	Self-aligning design
Sealing	Fabric, anchor rings	Flared sealing ring, locators
Access	Transfemoral	Transfemoral
Sizes	22, 25, 28, 31 and 34 mm	23, 25 and 27 mm
Target annular diameter range	18.0–33.1 mm	21.0–28.6 mm
Target annular perimeter range	57–104 mm	66–90 mm
Delivery system flexibility/ steerability	+/++	++/++
Repositionable system	+	+
Retrievable system	–	–
Delivery sheath size compatibility	18–22 Fr (ID) or 16 Fr Edwards ESheath+‡	Dedicated 20 Fr (ID)§

to
3))

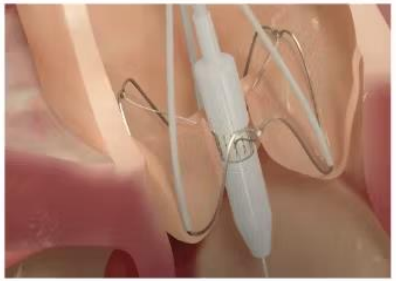
JenaValve Trilogy TAVR Device

Locator grasping of leaflets



Valve Deployment

J-Valve TAVR Device



U-shaped anchor rings positioned on the leaflets

Valve Deployment

Leone PP, Latib A. Transcatheter Heart Valves with Labelling for Aortic Regurgitation. Interventional Cardiology 2025;20:e25.

Ranard LS, Vahl T. *Cardiac Interventions Today*. 2024;18(2):40-44.

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

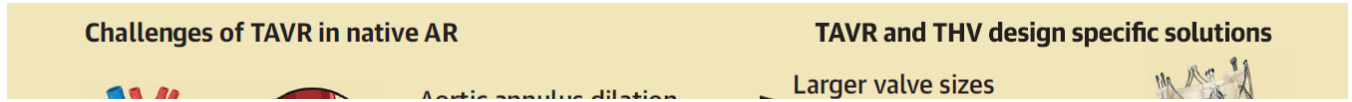


Table 2 Subgroup analysis of clinical outcomes in on-label devices, off-label SE and off-label BE: a meta-analysis

	On-label devices			Off-label SE			Off-label BE				
Outcomes	Event rate (95% CI)	I^2 (%)	P value*	Event rate (95% CI)	I^2 (%)	P value*	Event rate (95% CI)	I^2 (%)	P value*	χ^2	P value†
In-hospital Outcomes											
All cause mortality	0.02 (0.01 to 0.03)	4.7	0.398	0.04 (0.02 to 0.08)	11	0.346	0.04 (0.02 to 0.07)	0	0.797	5.52	0.063
Technical success	0.97 (0.94 to 0.98)	11.8	0.329	0.85 (0.78 to 0.90)	26.7	0.234	0.92 (0.88 to 0.95)	21.4	0.280	17.46	0.000
Device success	0.95 (0.92 to 0.97)	0	0.598	0.83 (0.76 to 0.87)	66.6	0.001	0.89 (0.76 to 0.96)	88.9	0.003	19.75	0.000
PPI	0.10 (0.06 to 0.15)	74.3	0.000	0.19 (0.14 to 0.24)	34.3	0.133	0.18 (0.10 to 0.29)	80.7	0.006	6.18	0.046
Moderate or severe AR	0.02 (0.01 to 0.03)	0	0.745	0.04 (0.02 to 0.07)	31.6	0.156	0.08 (0.06 to 0.12)	1.1	0.364	27.05	0.000‡§
SVI	0.02 (0.01 to 0.03)	18.4	0.269	0.15 (0.11 to 0.21)	46.2	0.053	0.05 (0.03 to 0.08)	0	0.382	50.92	0.000‡§¶
Valve migration	0.02 (0.01 to 0.04)	10.8	0.346	0.10 (0.05 to 0.22)	84.7	0.000	0.07 (0.04 to 0.11)	42.1	0.178	10.89	0.004‡§
Major bleeding	0.04 (0.02 to 0.06)	0.2	0.439	0.05 (0.03 to 0.09)	74.2	0.000	0.03 (0.01 to 0.08)	76.9	0.005	0.86	0.651
AKI **2 or 3**	0.02 (0.01 to 0.04)	0	0.647	0.04 (0.01 to 0.17)	50.1	0.138	0.03 (0.01 to 0.18)	81.9	0.019	57.9	0.006
30-days Outcomes											
All cause mortality	0.03 (0.02 to 0.05)	41.7	0.080	0.06 (0.03 to 0.11)	20.3	0.285	0.06 (0.03 to 0.11)	0	0.537	4.14	0.162
Stroke	0.02 (0.01 to 0.05)	0	0.938	0.05 (0.03 to 0.07)	0	0.938	–	–	–	2.07	0.151
Moderate or severe AR	0.01 (0.00 to 0.03)	0	0.870	0.09 (0.03 to 0.23)	75.1	0.007	–	–	–	8.02	0.005

Peng Y, Lin Y, Su Z, et al. Comparative outcomes of on-label and off-label transcatheter aortic valve replacement for aortic regurgitation: a systematic review and meta-analysis. Open Heart 2025;12:e003482.

Samimi S, et al. JACC Cardiovasc Interv. 2025;18(1):44–57.

Regurgitation. Interventional Cardiology 2025;20:e25.

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J-Valve Early Feasibility Study – 15 patients

- No procedural mortality, coronary obstruction, embolization, migration, or ViV
- One convert to surgery for failed device release with tortuous aorta
- One 30-day noncardiac death
- LV remodeling at 30-days

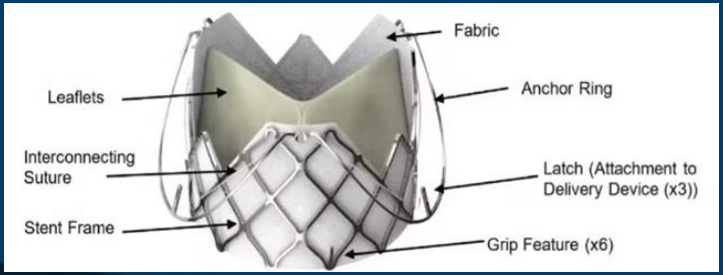

TABLE 1 Echocardiographic Characteristics

	Full Cohort Baseline (n = 15)	Paired Cohort[a] Baseline (n = 14)	Paired Cohort[a] 30 d (n = 14)	*P* Value[b]
LVEF, %	53.84 ± 7.97	54.10 ± 8.20	49.06 ± 9.31	0.064
AV mean gradient, mm Hg	5.38 ± 2.20	5.13 ± 2.05	5.57 ± 2.04	0.625
EOA, cm^2	3.04 ± 0.68	3.11 ± 0.65	2.90 ± 0.68	0.444
Residual AR severity ≥mild	NA	NA	0	NA
Paravalvular regurgitation	NA	NA	0	NA
LVEDD, cm	6.00 (5.10-6.70)	5.90 (5.10-6.20)	5.20 (4.80-5.50)	0.014
LVESD, cm	4.20 (4.00-5.60)	4.20 (4.00-5.20)	3.95 (3.00-4.50)	0.088
LVEDV, mL	167.70 (131.80-232.10)	166.95 (131.80-229.00)	133.10 (109.50-201.10)	0.017
LVESV, mL	87.70 (53.70-115.90)	80.00 (53.70-105.50)	65.60 (51.30-116.50)	0.241[c]
LV mass, g	222.00 (157.00-287.00)	219.50 (157.00-272.00)	189.00 (165.00-236.00)	0.056

Garcia S et al. Research Letter: Treatment of Aortic Regurgitation With a Novel Device Results of the J-Valve Early Feasibility StudyJACC Intv VOL. 17, NO. 17, 2024

JenaValve ALIGN AR

Transcathe

Death	
Any stroke	
Disabling stroke	
Non-disabling stroke	
Major or life-threatening bleeding	
Major vascular complication	
Acute kidney injury stage 2 or 3 or dialysis (7 days)	
Surgery or intervention related to the device	
Aortic Endograft and Commercial THV for aortic dissecti	
Surgical aortic valve replacement for Trilogy transcathete	
Commercial transcatheter heart valve for Trilogy transcath	
Trilogy transcatheter heart valve for Trilogy transcathete	
New pacemaker implantation	
Moderate or greater aortic regurgitation	
Total	

Data are n (%) or n/N (%). [illegible] patients had a new or [illegible]

Table 2: Primary safety endpoint at 30 days

- Achieved the
- Achieved the

(7.8% vs. 25

346 patient

ALIGN-AR 2024[40]	
n	180
Age, years	75
Female, %	47
STS-PROM, %	4
THV	Trilogy
Procedural/ device success	95
Residual AR >moderate	6
THV migration/ embolisation	2
Second THV	2
Surgical conversion	1
New PPM	24
Stroke/TIA	2[ll]
Major vascular complication	4
Major bleeding	4
30-day mortality	2

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mm Hg)
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length <55 mm

180 enrolle

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177 Trilogy
valve su

177 included in 1-year valve implantati
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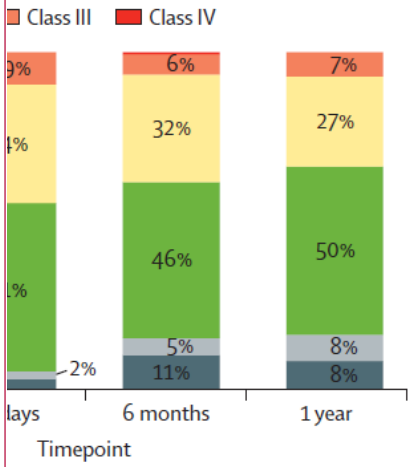

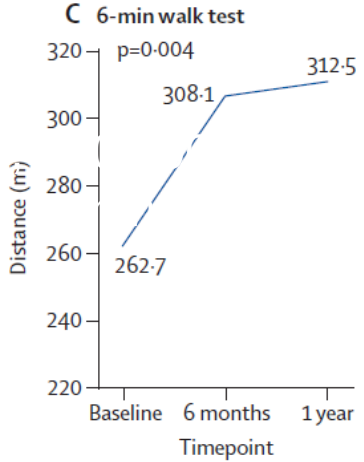

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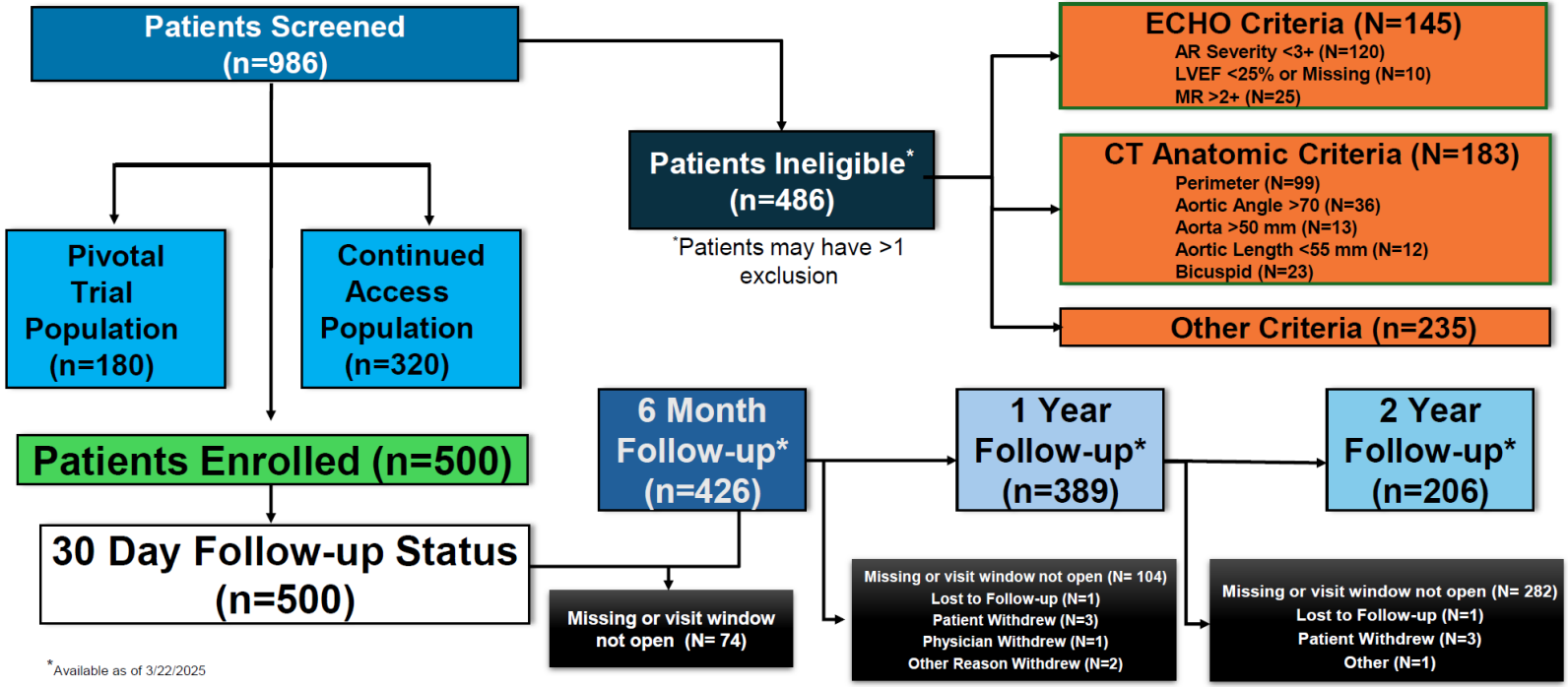
Lancet 20
https://doi.

Courtesy of: Makkar RR. NY Valves 2025
Ranard LS. NY Valves 2025

JenaValve – ALIGN AR Trial + CAP

Screening and Patient Disposition



Take-Home Message

- Continued Unmet Needs for Treatment of Aortic Regurgitation
- Off-label TAVR Suffers Unacceptable Outcomes at Scale
- Dedicated Transcatheter Therapies (e.g. JenaValve, J-Valve)
  - Safer
  - More technical success
  - Less PVL or short-term reintervention
- Needs: Commercial Availability, Pacemaker Avoidance, More Anatomies, Trials of all risk profile, Trials vs surgery