

VitaFlow Liberty introduction and clinical results

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Klinik hal:

- ❖ 69 yaş kiři
- ❖ BKİ 29 kq/m²
- ❖ řD, HT
- ❖ 4 il əvvəl KAQ - OMT
- ❖ Ciddi Aort darlıđı

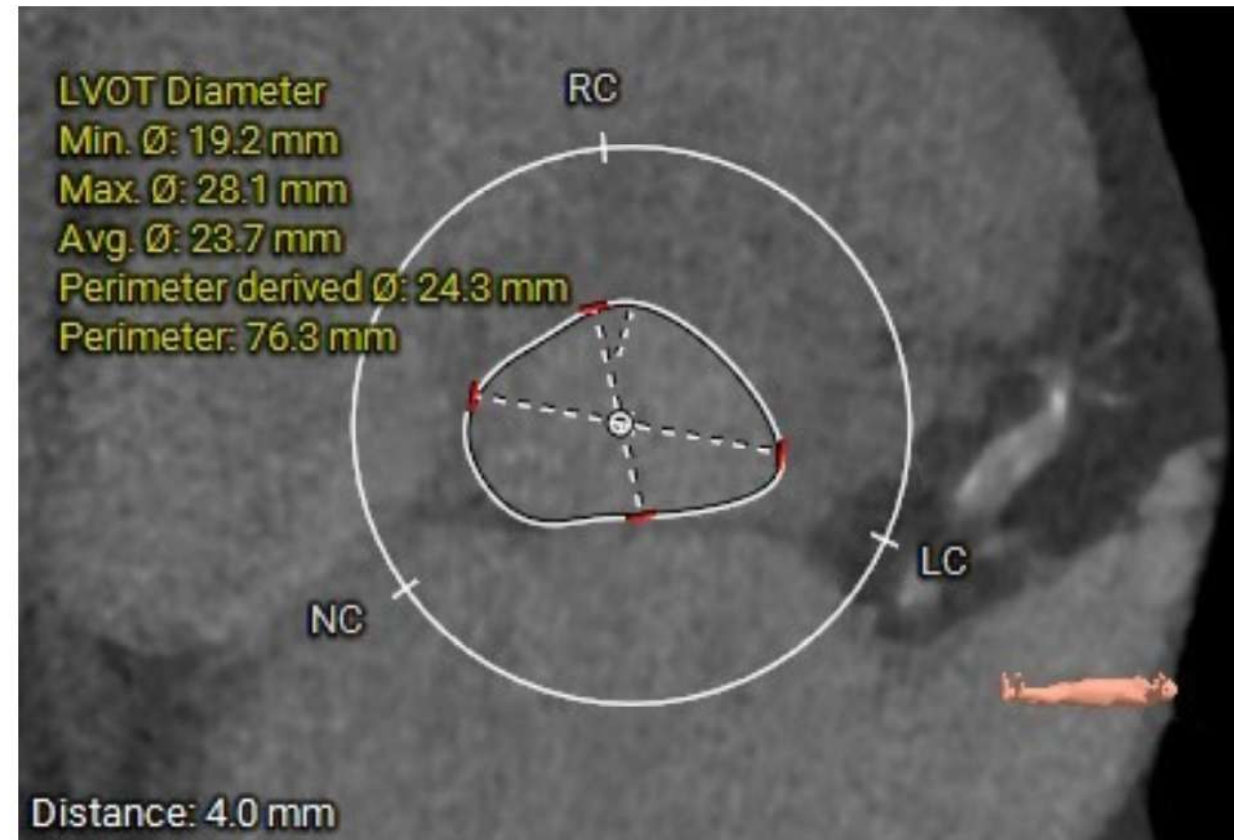


Klinik hal:

Annulus



LVOT



Klinik hal:

Phase: 38.0%

Aortic Annulus

Perimeter: 78.1 mm
Perimeter Derived Ø: 24.9 mm
Area: 464.6 mm²
Area Derived Ø: 24.3 mm

LVOT Ø: 23.7 mm

Asc. Aorta Ø: 40.8 mm

STJ Ø: 31.3 mm

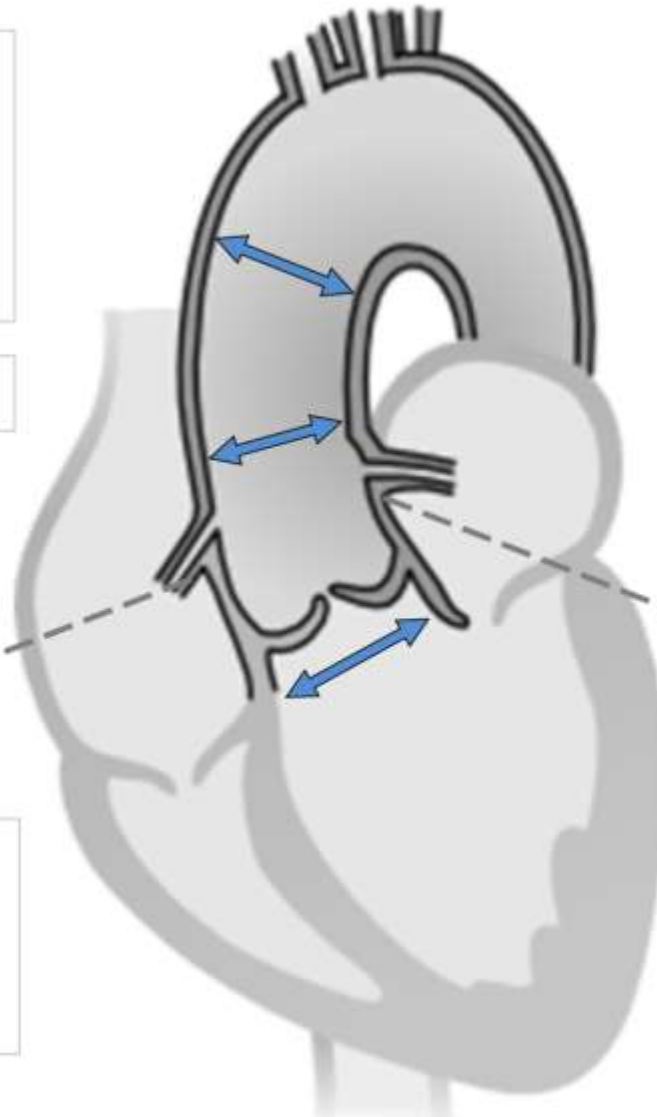
RCA Height: 19.1 mm

LCA Height: 15.7 mm

Sinus Of Valsalva Diameters:

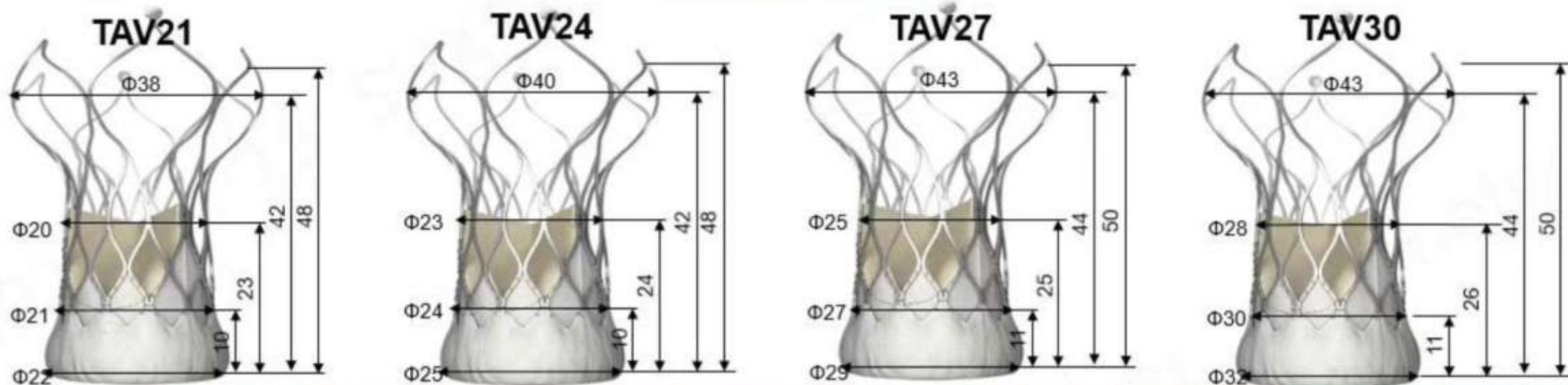
Left: 33.2 mm
Right: 31.1 mm
Non: 33.3 mm

Aortic Valve Calcification: Moderate



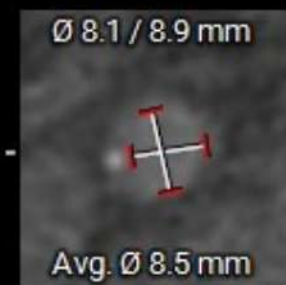
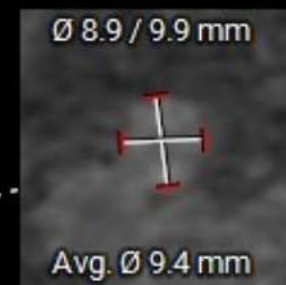
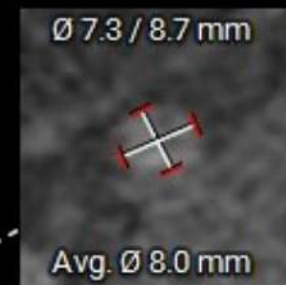
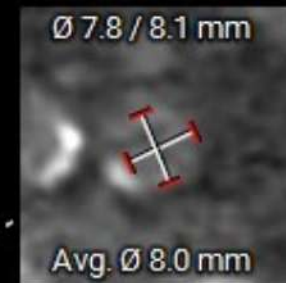
Klinik hal:

VitaFlow liberty TAVI Systems treat the *annulus diameter range from 17-29mm.*

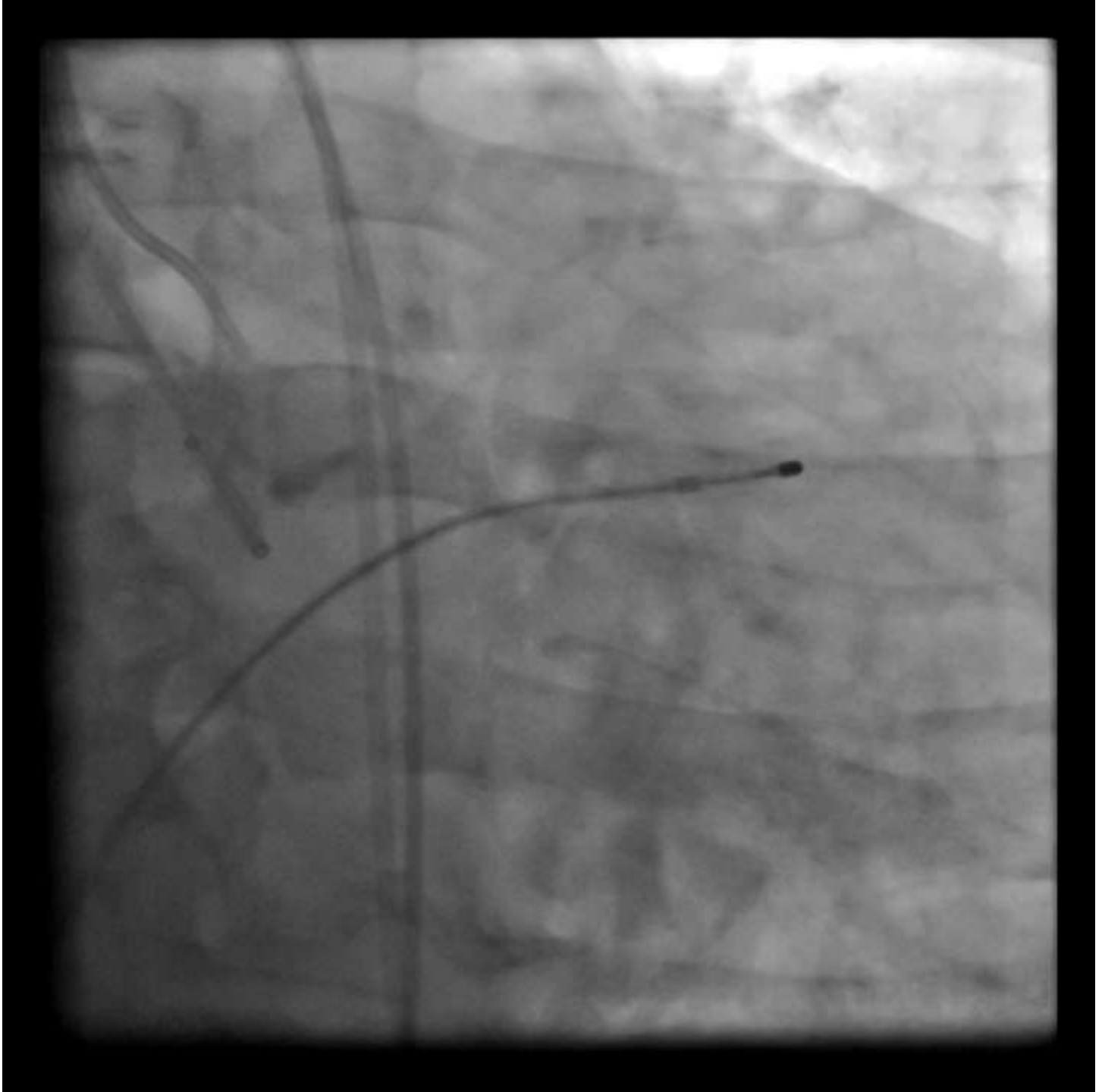


Model	TAV21				TAV24				TAV27				TAV30				
Skirt height: 11-12mm, Frame height: 48- 50mm (without paddles)	Diameter/mm	17	18	19	20	20	21	22	23	23	24	25	26	26	27	28	29
	Perimeter/mm	53.4	56.5	59.6	62.8	62.8	65.9	69.1	72.2	72.2	75.4	78.5	81.6	81.6	84.8	87.9	91.1
	Area/ mm²	226.8	254.5	283.5	314.2	314.2	346.4	380.1	415.5	415.5	452.4	490.9	530.9	530.9	572.6	615.8	660.5

RAO: 0°
Caudal: 0°



Klinik hal:



■ VitaFlow Liberty Aortic Valve



- Hybrid Density Frame
- Exceptional Hemodynamics

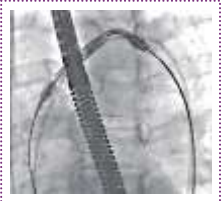
■ VitaFlow Liberty Delivery System



- Motorized Handle
- Stable Delivery



VitaFlow™ Liberty Aortic Valve



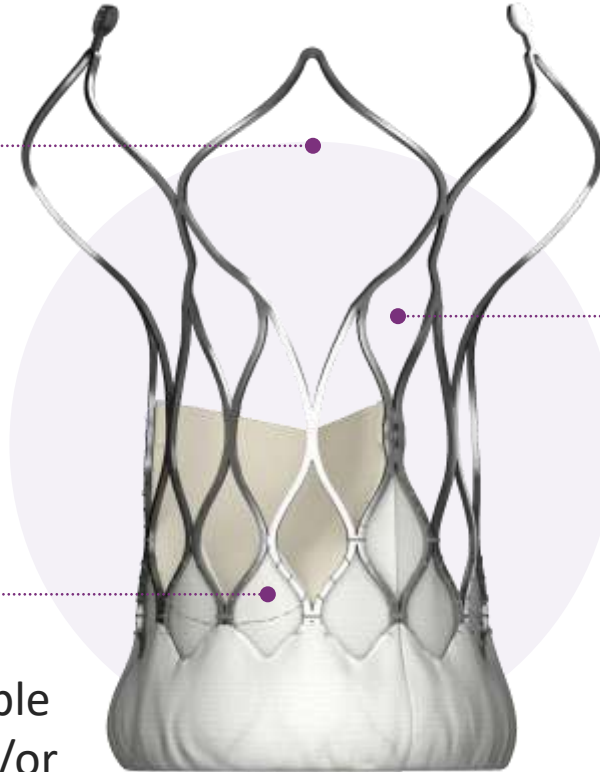
Low Density Cells

- Enhanced deliverability
- Coaxial alignment



High Density Cells

- Strong radial force, suitable for severely calcified and/or bicuspid valves
- Strengthens valve anchoring



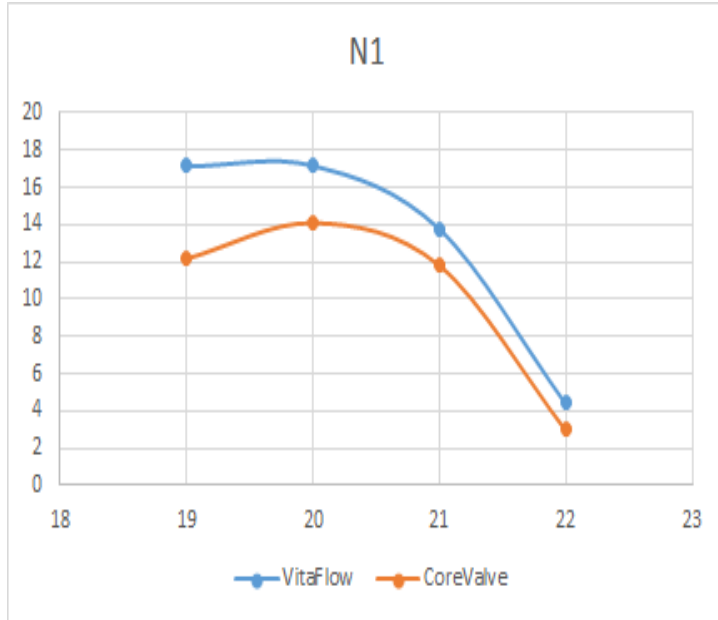
Large Cells

- Preserves coronary access
- Able to simultaneously pass-through two 12F catheters*



VitaFlow üçün daha qüvvətli radial güc

Higher radial force compared to competitors in market
Important for calcified annulus

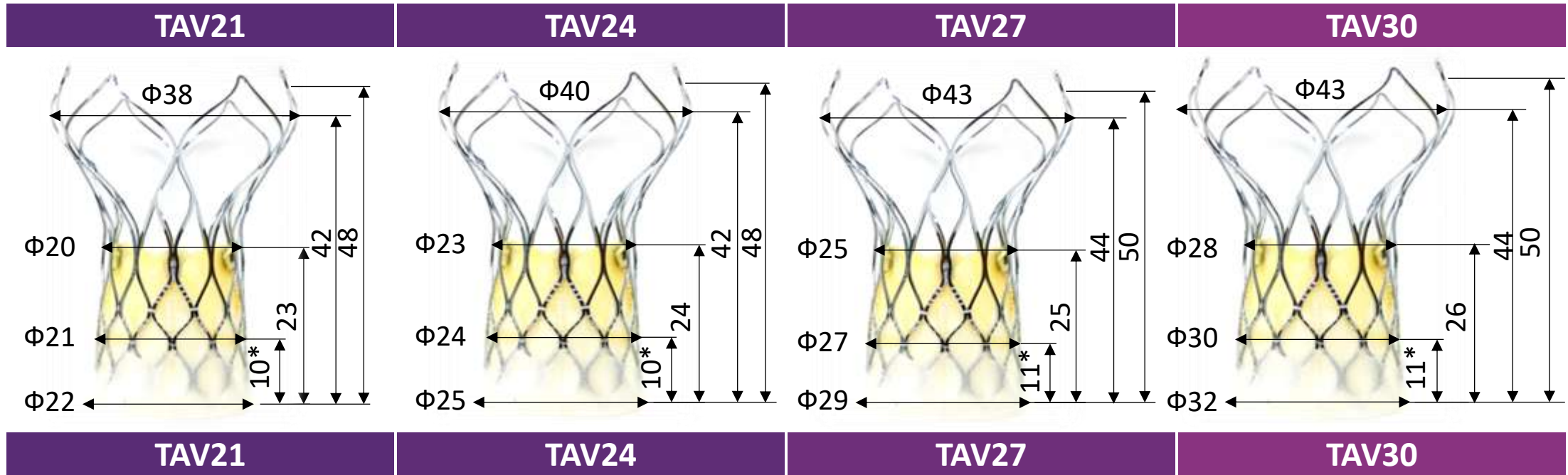


Üstünlükləri :

- PVL-nin daha yaxşı önlənməsi
- Kalsifikasiyanın daha yaxşı idarə edilməsi
- Bicuspid xəstələrində önəmli olan dairəvin annulusun daha yaxşı formalaşması
- Post dilatsiya ehtiyacı daha azdır-implantasiya zamanı lefletlərdəki gərginliyi azaldır

VitaFlow Valve Dimensions

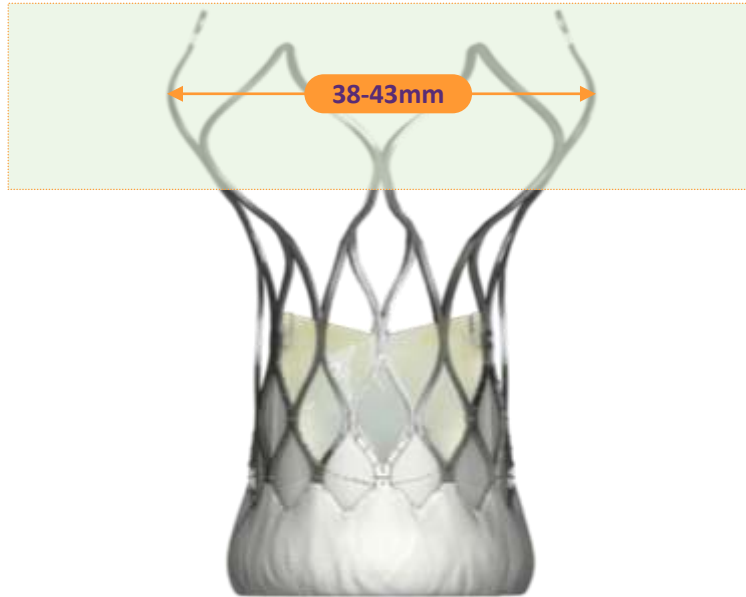
- VitaFlow liberty TAVI Systems treat the **annulus diameter range from 17-29mm**.



	TAV21				TAV24				TAV27				TAV30			
Diameter (mm)	17	18	19	20	20	21	22	23	23	24	25	26	26	27	28	29
Perimeter (mm)	53.4	56.5	59.6	62.8	62.8	65.9	69.1	72.2	72.2	75.4	78.5	81.6	81.6	84.8	87.9	91.1
Area (mm ²)	226.9	254.5	283.5	314.2	314.2	346.4	380.1	415.5	415.5	452.4	490.9	530.9	530.9	572.6	615.8	660.2

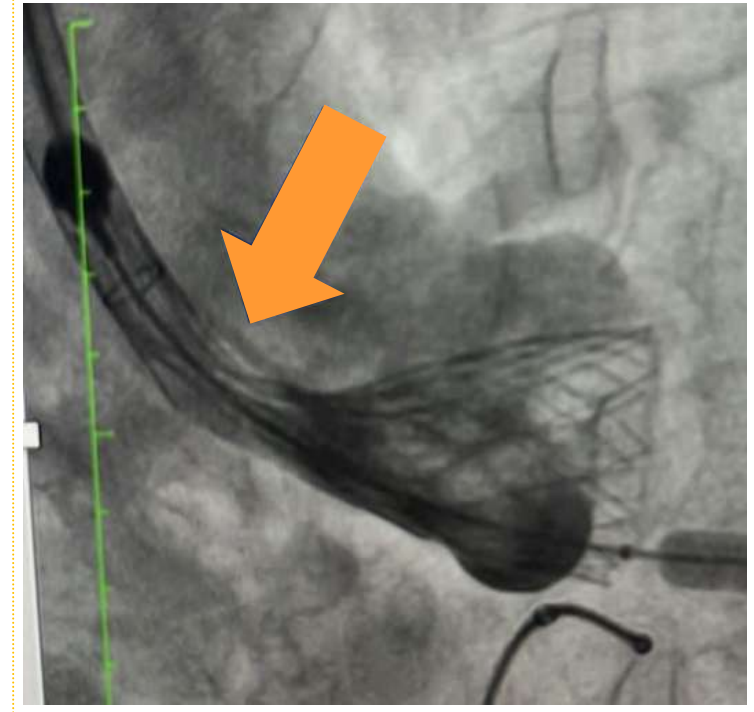
Hybrid Frame Density – Low Density Outflow, provides the flexibility and support that is required for coaxial release

Large Curve



- Large outflow diameter enhances anchoring force and coaxial stability
- Curvature at outflow end protects ascending aorta, minimizes dissection

Flexible Outflow



- Support coaxial valve release
- Minimize Micro-dislodgement

Design selection that maximizes haemodynamics

Supra-annular design

- Preserves annulus circularity
- Large EOAs and low gradients



Tubular Shaped Frame

- Allowing for a large EOA



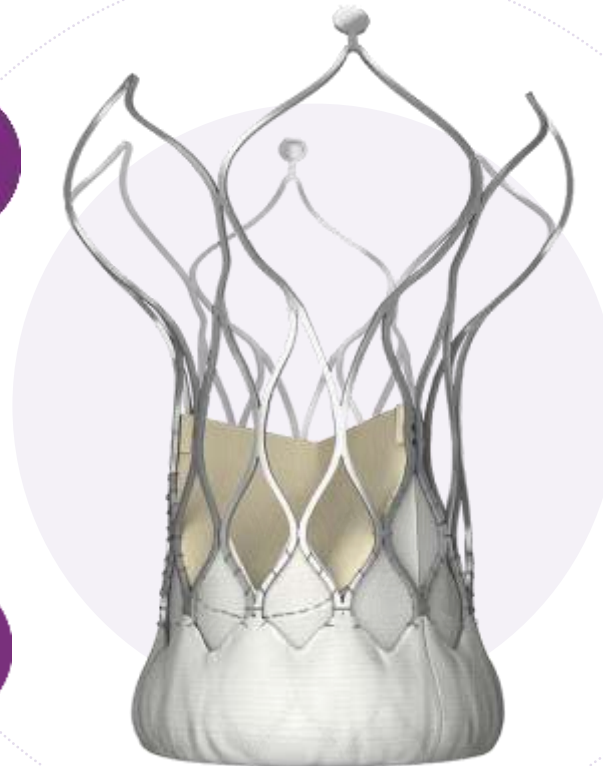
PET double layer skirt design

- Reducing perivalvular leakage and tissue damage



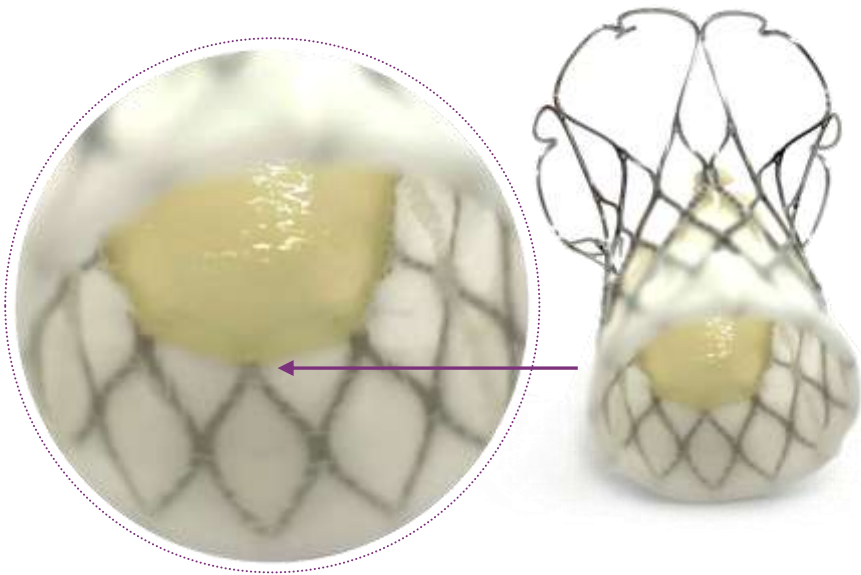
Bovine pericardial leaflets

- Proven longevity



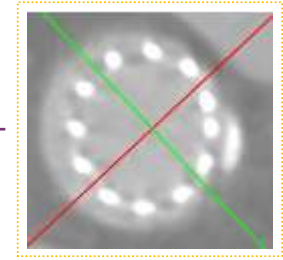
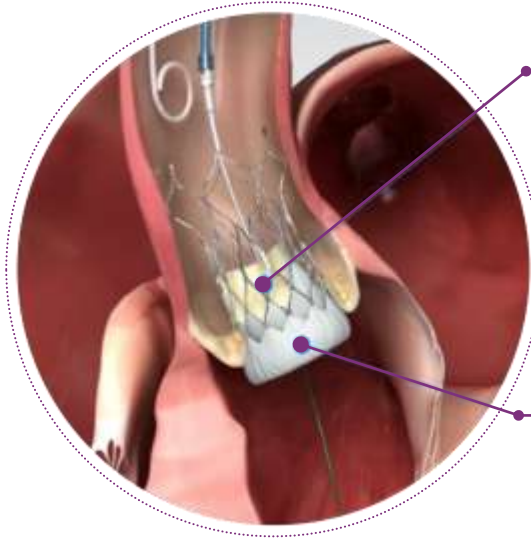
Supra-annular Leaflet – no adaption needed to fit original annulus anatomy

- Do not need to adapt to original anatomy
- Preserves annulus circularity

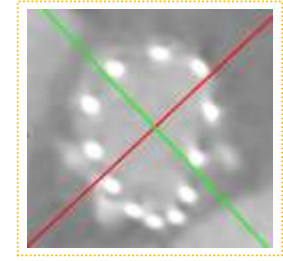


The lowest point of VitaFlow leaflet is at the second node, at a height 10-11mm above the bottom of the frame

Supra-annulus design Optimize valve morphology



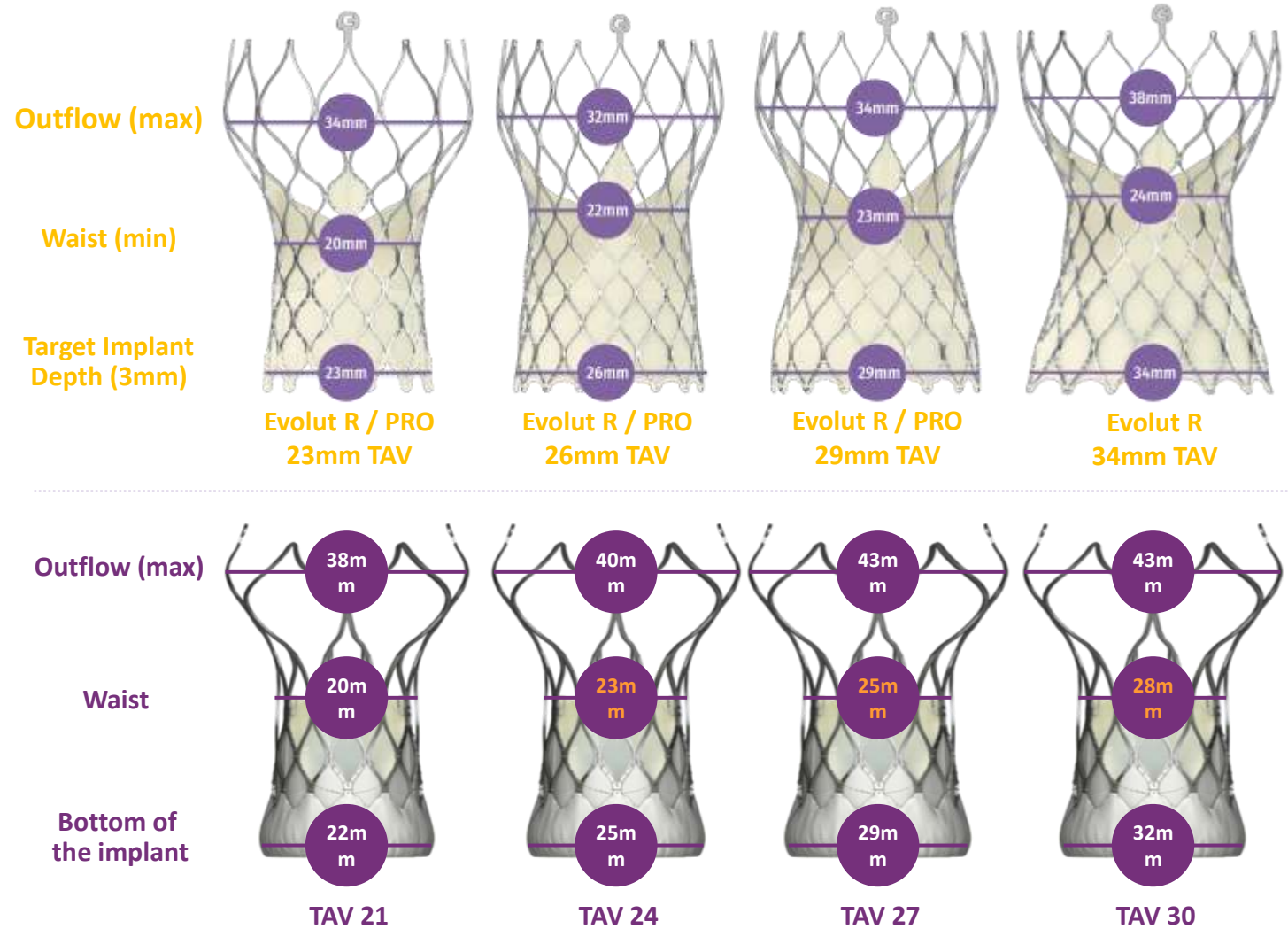
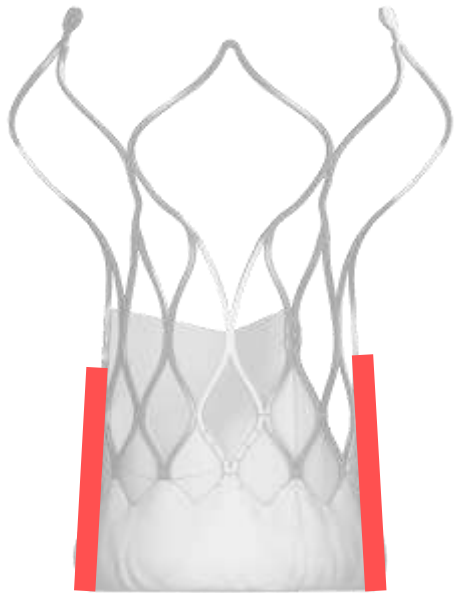
Supra-annulus:
Ensure the maximum opening of the lobe



Annulus:
Fit the original anatomy

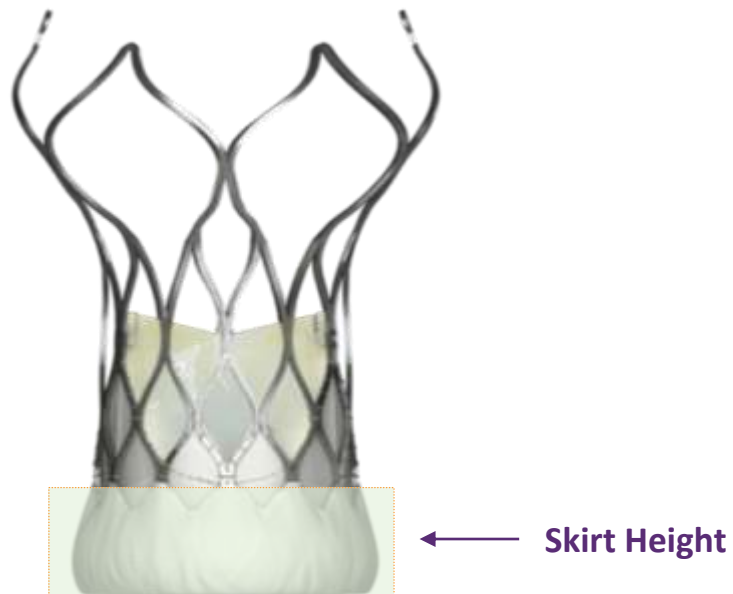
Tubular Shaped Frame – Allowing for a larger orifice area

- Tubular Frame reduces tapering, maintains orifice area especially for larger valve sizes



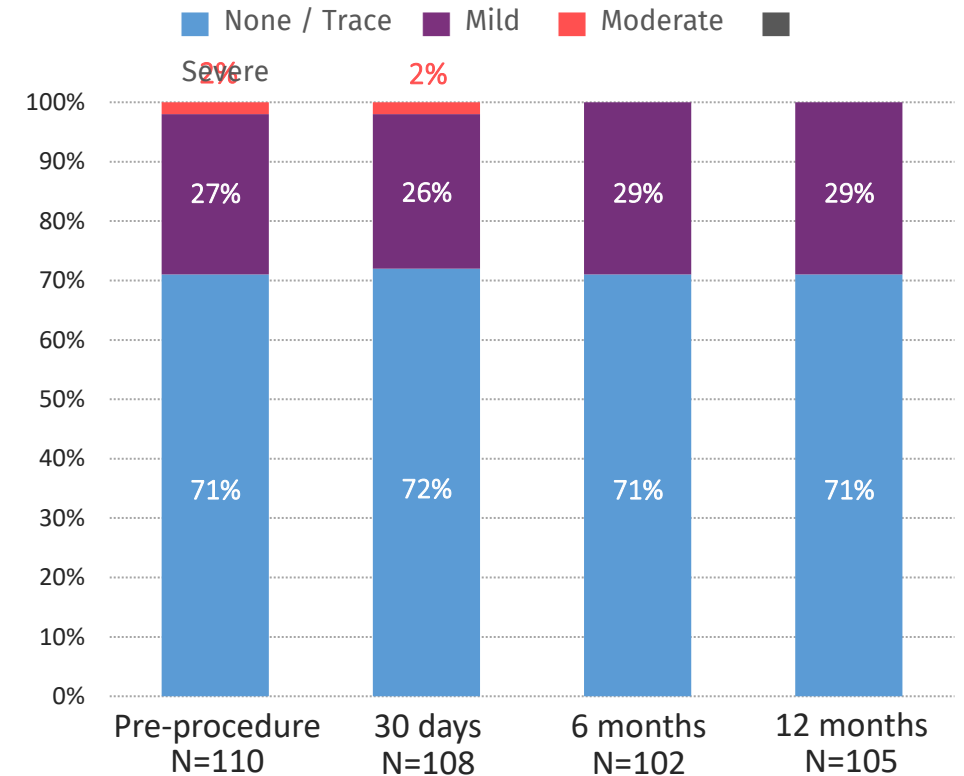
Double Layer PET Skirt – No > Mild PVL at 6 month in Pivotal Trial

- VitaFlow 11-12mm PET double layer skirt, provides a large functional area which reduce peri-valvular leakage and provides friction at the landing zone to minimize valve dislodgement



VitaFlow Premarket Clinical Trials

Clinical results showed that there was no moderate to severe perivalvular leakage 6 months after procedure.



■ VitaFlow Liberty Aortic Valve



- Hybrid Density Frame
- Exceptional Hemodynamics

■ VitaFlow Liberty Delivery System



- Motorized Handle
- Stable Delivery



VitaFlow™ Liberty Delivery System

- The only motorized delivery system approved for marketing

Motorized handle

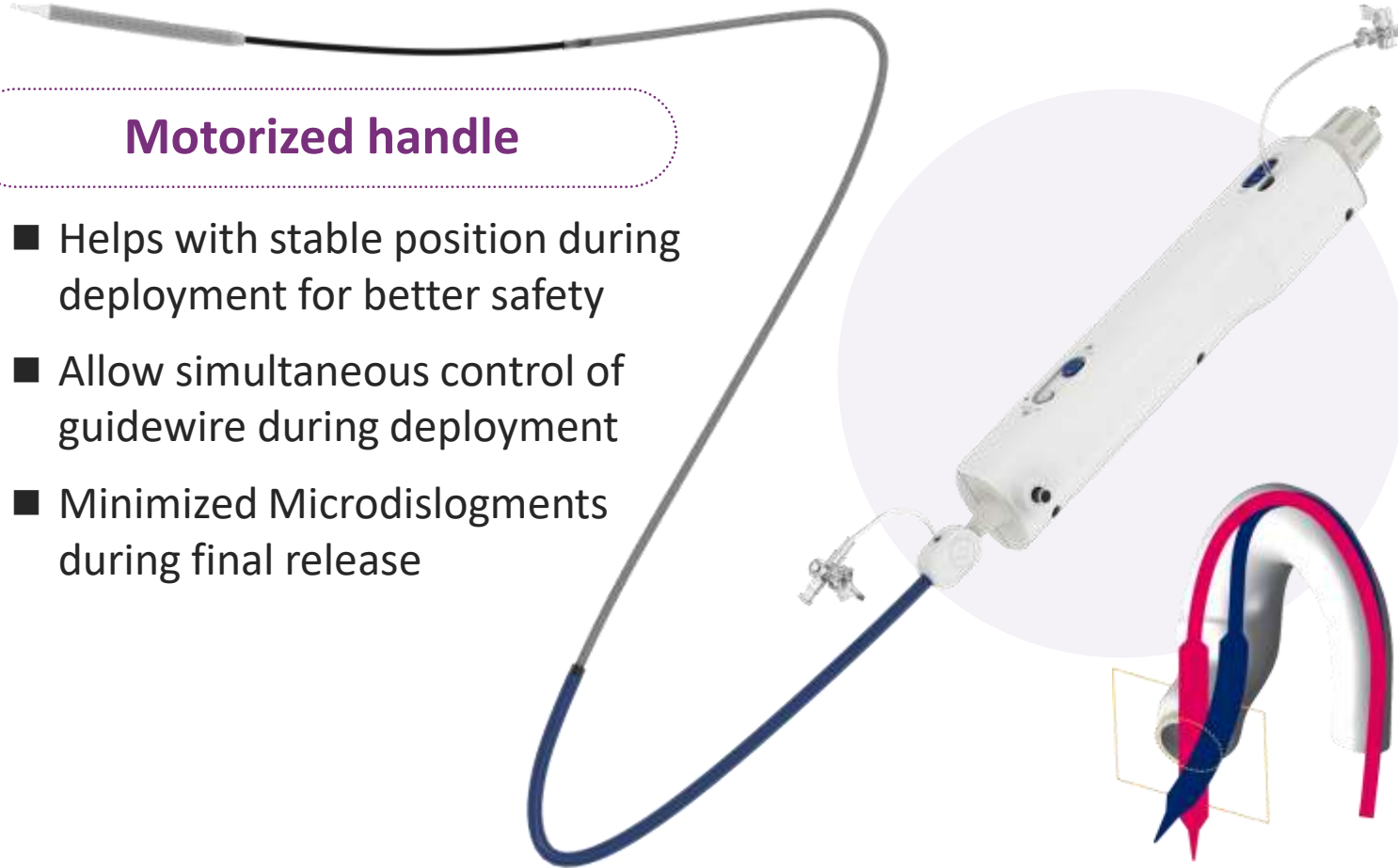
- Helps with stable position during deployment for better safety
- Allow simultaneous control of guidewire during deployment
- Minimized Microdislodgments during final release

Accurate repositioning

- Fully recapturable and repositionable
- up to 75% release
- Fully recapturable 3 times

Capsule with 360° range of motion

- Flexibility for coaxial alignment and valve positioning
- Enhanced deliverability well suited to complex anatomies



AZERBAIJAN CARDIOLOGY FESTIVAL

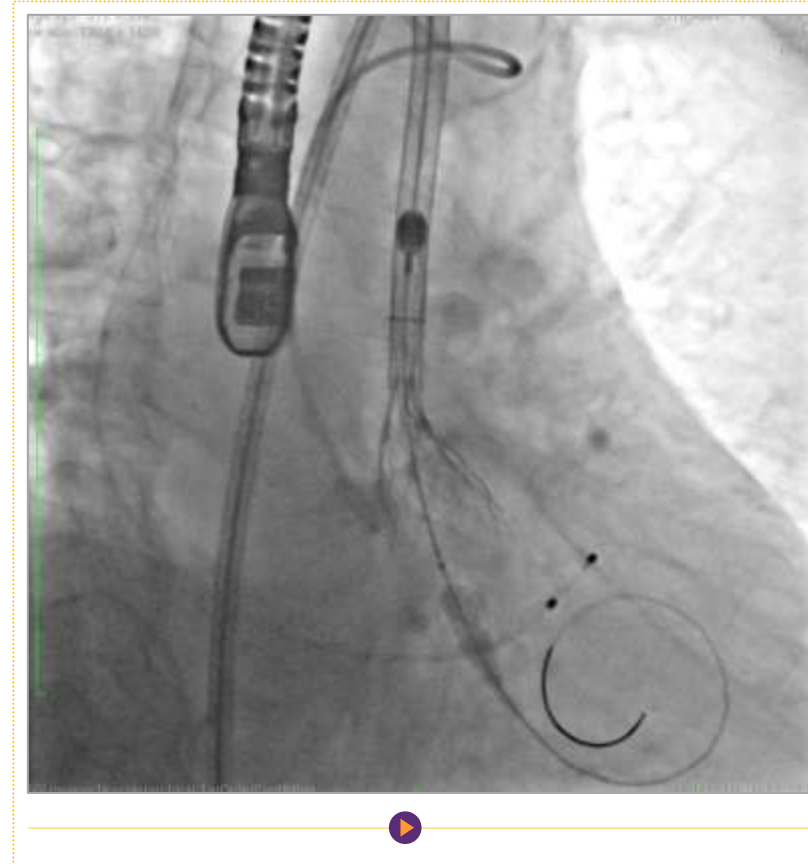
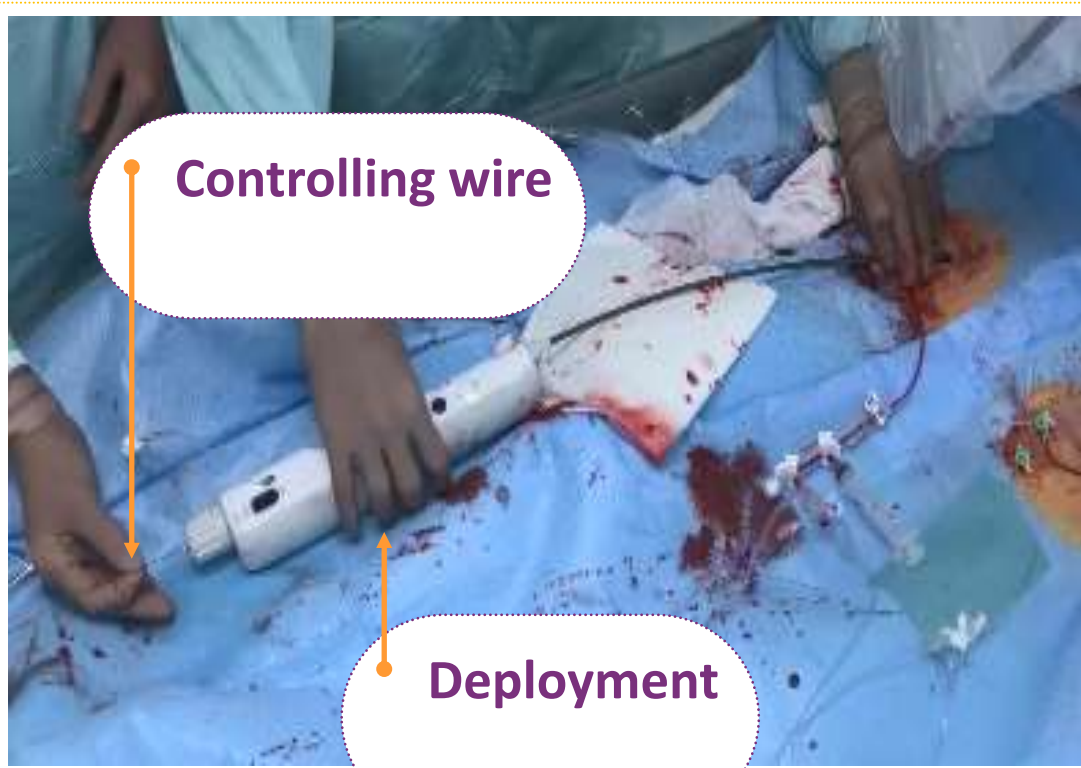


13-14-15 DECEMBER, 2024
THE RITZ-CARLTON HOTEL, BAKU



Motorized handle simplifies the valve release process, providing greater control

- Simultaneous control of the guidewire and delivery system during valve release
- Minimal valve movement provides stable positioning during deployment



Capsule with 360° range of motion for torturous anatomies

- Flexibility for coaxial alignment and valve positioning
- Enhanced deliverability well suited to complex anatomies

Rigorous anatomical structures



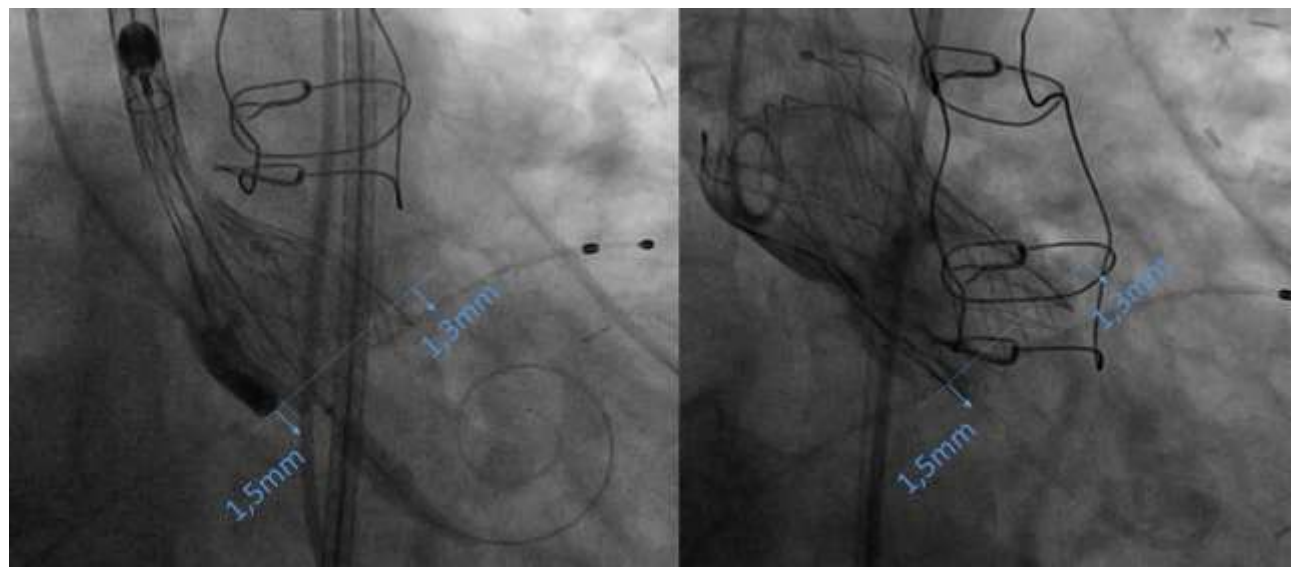
3D Aortic arch case



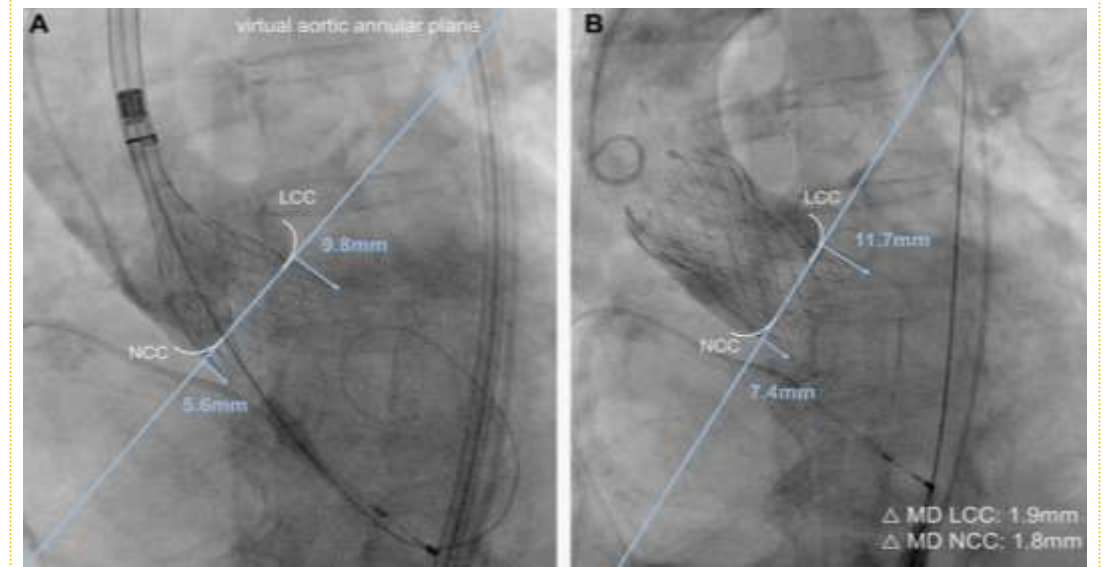
Stable Release – Minimized valve moment during deployment

- No Microdislodgments during final release


VitaFlow



Competitor



VitaFlow™ transcatheter valve system in the treatment of severe aortic stenosis: One-year results of a multicenter study

Daxin Zhou¹ | Wenzhi Pan¹ | Jianan Wang² | Yongjian Wu³  | Mao Chen⁴  |
Thomas Modine⁵ | Darren Mylotte⁶ | Piazza Niccolo⁷ | Junbo Ge¹

Results: One hundred and ten symptomatic aortic stenosis patients (60 men, 50 women; mean age 77.73 ± 4.78 years) at prohibitive or high risk for surgery were enrolled. Mean society of thoracic surgeons score was $8.84 \pm 5.58\%$. All-cause mortality was 2.7% at 1-year. Major stroke, major vascular complication, coronary artery obstruction, new pacemaker implantation occurred in 2.7, 2.7, 1.8, and 19.1% at 1-year follow-up, respectively. No patients had moderate or severe paravalvular leak at 1-year. At 1 year follow-up, 97% of patients had New York heart association \leq II. Patients with bicuspid valves had similar outcomes as those patients with tricuspid aortic valve stenosis.

TABLE 2 Clinical end-points at different follow up time point (% , n)

Clinical end-points	Discharge N = 110	30-day N = 110	6-month N = 110	1-year N = 110
All-cause mortality	0.9% (1)	0.9% (1)	2.7% (3)	2.7% (3)
Cardiovascular mortality	1.8% (2)	1.8% (2)	1.8% (2)	1.8% (2)
All stroke (Major and Minor)	1.8% (2)	2.7% (3)	4.5% (5)	4.5% (5)
Major stroke	0% (0)	0% (0)	0% (0)	0% (0)
Major vascular complication	1.8% (2)	1.8% (2)	1.8% (2)	2.7% (3)
Coronary artery obstruction	1.8% (2)	1.8% (2)	1.8% (2)	1.8% (2)
New PPM ^a	15.5% (18) ^a	16.4% (19) ^a	19.1% (21) ^a	19.1% (21) ^a
New PPM for ≥2nd degree atrioventricular block	10% (12)	10.9% (13)	13.6% (16)	13.6% (16)

^aA total of 5.5% (6) patients had I° atrioventricular block and complete left bundle branch block; PPM, permanent pacemaker.

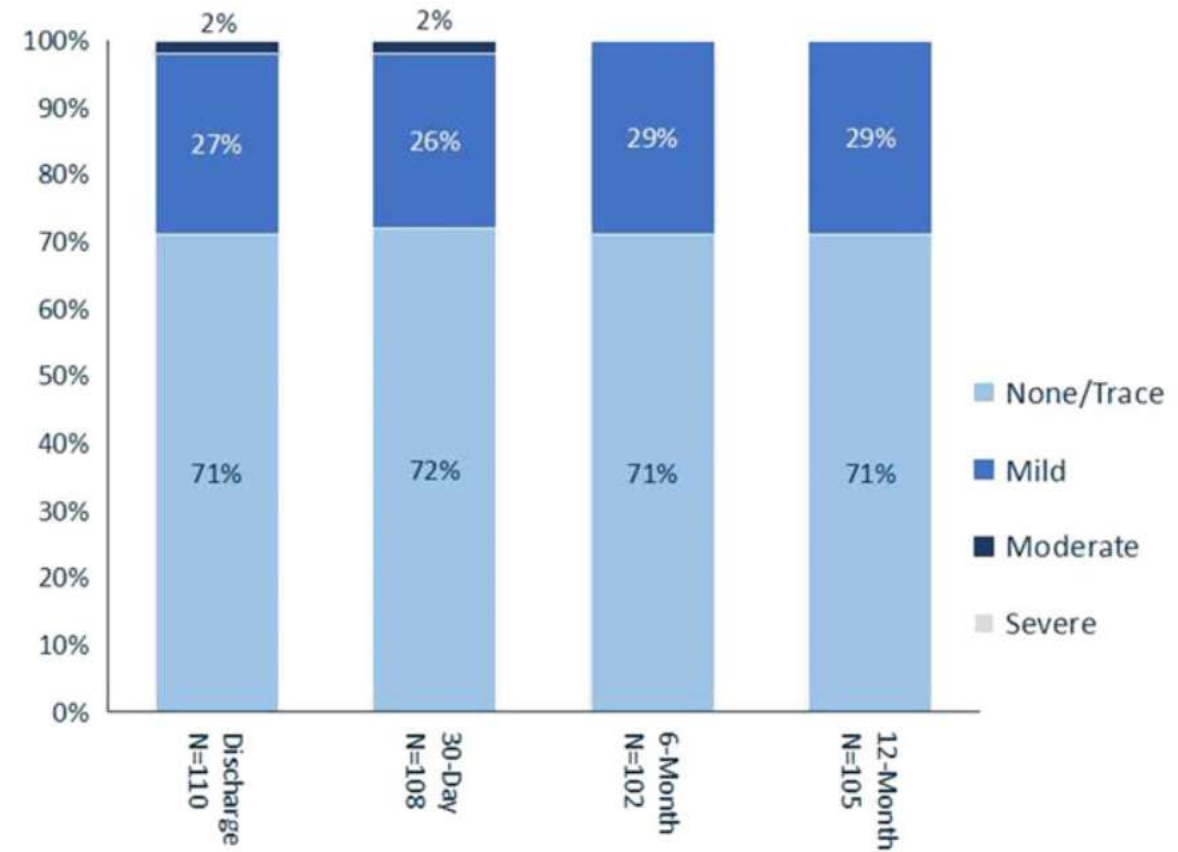
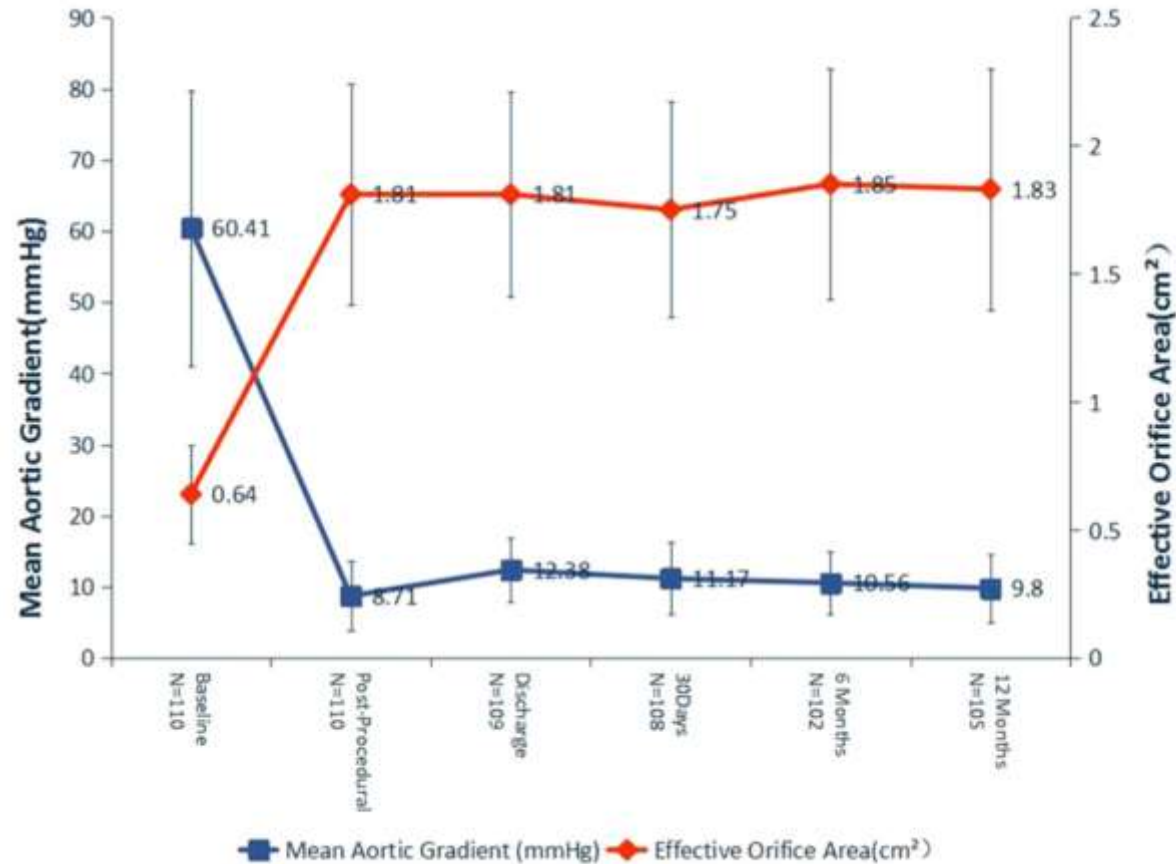


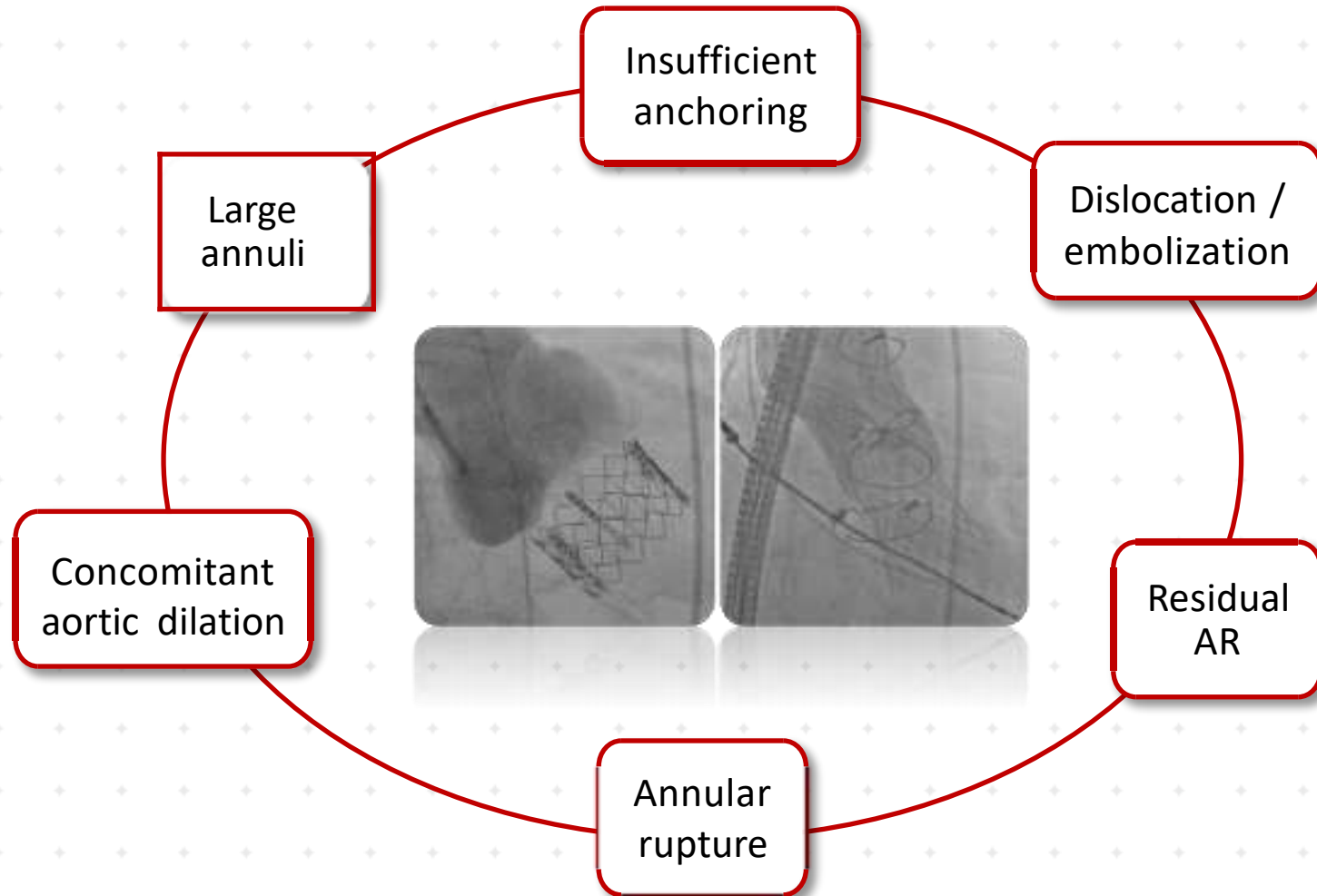
FIGURE 3 Incidence of paravalvular leak thorough 12 months follow-up. There was no moderate or severe PVL at 12 months. PVL, paravalvular leak [Color figure can be viewed at wileyonlinelibrary.com]

TABLE 4 Comparison of 1-year clinical outcomes between tricuspid and bicuspid patients

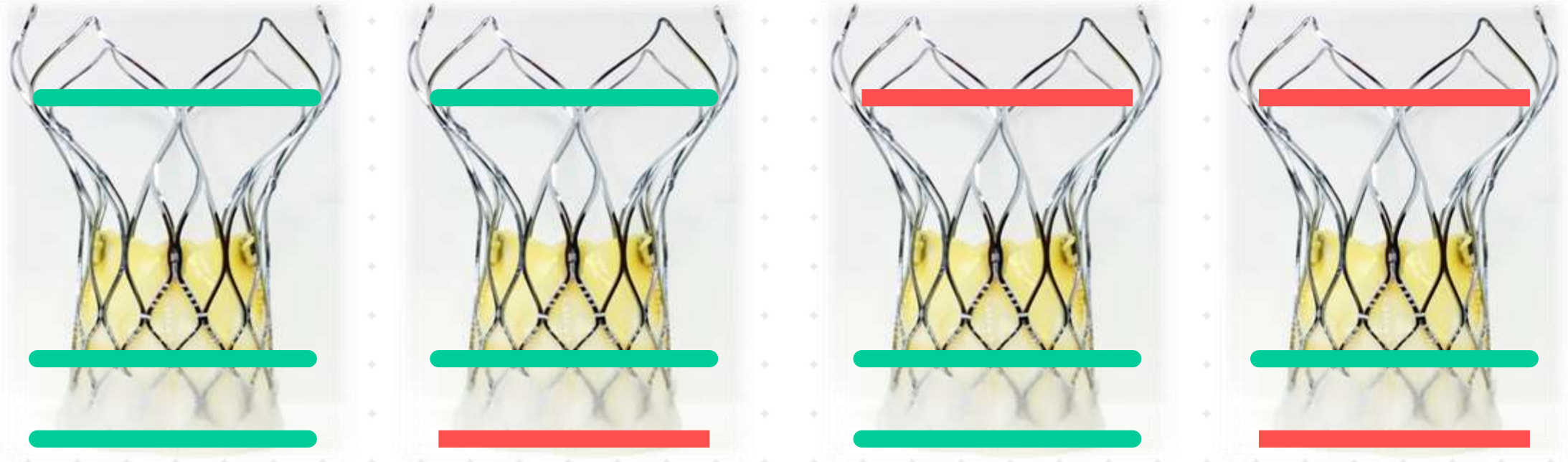
Clinical outcomes	Tricuspid N = 68	Bicuspid N = 42	p Value
All-cause mortality (%)	4.4%	0.0%	.285
Cardiovascular mortality	2.9%	0.0%	.524
Procedure success rate (%)	88.2	90.4	1.000
All stroke (Major and Minor; %)	4.6%	4.8%	1.000
Major vascular complication (%)	4.5%	0.0%	.158
Moderate or severe PVL (%)	0.0%	0.0%	1.000
New pacemaker implantation (%)	22.1%	14.3%	.454
Mean aortic gradient (mmHg)	9.62 ± 4.75	9.92 ± 4.78	1.000
Aortic valve area (cm ²)	1.84 ± 0.48	1.82 ± 0.47	1.000
NYHA class I(%)	67.7%	73.8%	.631

Abbreviations: NYHA, New York heart association; PVL, paravalvular leak.

“Pure AR” –nin müalicəsində çətinliklər



Anchoring Advantages of VitaFlow™ Applied to AR



Optimum

Worst

- Annulus oversize at least $>10\%$ /mean diameter <28 , ideally oversize up to 20%
- Ascending aorta/STJ <35
- Annulus: LVOT >0.96 or LVOT: Annulus <1.05

Comparative Quantitative Aortographic Assessment of Regurgitation in Patients Treated With VitaFlow Transcatheter Heart Valve vs. Other Self-Expanding Systems

Rutao Wang^{1,2,3}, Hideyuki Kawashima^{2,4}, Chao Gao^{1,2,3}, Fangjun Mou¹, Ping Li⁵, Junjie Zhang⁶, Jian Yang⁷, Jianfang Luo⁸, Darren Mylotte², William Wijns^{2,9}, Yoshinobu Onuma², Osama Soliman², Ling Tao^{1*} and Patrick W. Serruys^{2,10*}

Aortic regurgitation

- Moderate or severe (qAR >17%)
- Mild (6% ≤qAR ≤17%)
- None or trace (qAR <6%)



VitaFlow Liberty Aortic Valve Üstünlükləri

1. Bikuspid aort qapaqda istifadə oluna bilər
2. Ciddi aort çatışmazlığında istifadə oluna bilər
3. Paravalvular qaçaq yaranma halı nadirdir
4. Prosedur zamanı koronar arteriyaların sıxılması ehtimalı azaldır
5. Major stroke ehtimalı minimaldir
6. İstifadəsi rahardır. Flexibledir.

תודה

Dankie Gracías

Спасибо

شكراً

Merci Takk

Köszönjük

Terima kasih

Grazie Dziękujemy Dèkojame

Ďakujeme Vielen Dank Paldies

Kiitos

Tänname teid

谢谢

Təşəkkür edirəm Tak

感謝您

Obrigado

Teşekkür Ederiz

감사합니다

Σας ευχαριστούμε

ඔබට ආචාර්ය

Bedankt

Děkujeme vám

ありがとうございます

Tack