Medtronic

Evolut™ TAVR platform

Patient	RIGGS, KEVIN	Height	m	Physician	Dr. HANSEN, PETER	Received Date 29-Jun-2025
Sex	Male	Weight	kg	Hospital	Royal North Shore	Reviewed Date 30-Jun-2025
					Hospital	
Year Of Birth (Age) 1945 (79)		вмі		City	Sydney	
		EOA needed to achieve		Country	Australia	
		an iEOA > 0.85 cm²/m²				

Clinical History

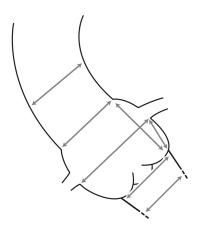
Case: 31570835

MEDTRONIC ANALYSIS

Diameter (mm) 22.5 x 23.6 , 23.0 Min Max Mean Perimeter (mm) 72.4 , Derived Ø (mm) 23.0 Area (mm²) 415.6 , Derived Ø (mm) 23.0

LVOT

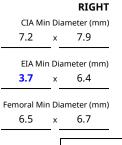
Diameter (mm)	22.6	x 28.1 ,	25.3
	Min	Max	Mean
Perimeter (mm)	80.6	, Derived Ø (mm)	25.7
Area (mm²)	492.5	, Derived Ø (mm)	25.0



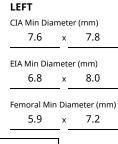
Max Ascending Aorta Diameter (mm)	31.8	•	
Sinotubular Junction Diameter (mm)	28.1 Min	x 28.7	
Sinus of Valsalva Diameter (mm)	36.1	30.3	31.2
Diameter (mm)	LCC	RCC	NCC
Sinus of Valsalva Height (mm)	20.1	19.1	23.4
rieight (iiii)	LCC	RCC	NCC
Coronary Ostia Height (mm)	7.0	12.0	
- 3 - (Left	Right	

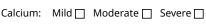
VIEWS

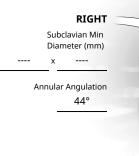
Cusp Overlap View	RAO: 8°, Caudal: 15°		
3 Cusp Coplanar View			
Near Cusp Overlap View			

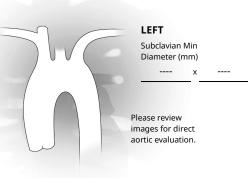












VIV ADDITIONAL MEASUREMENTS

Valve to Coronary Distance (mm)	5.5	6.3	
Distance (iiiii)	To LCA	To RCA	
Valve to STJ Distance (mm)	0.6	2.4	
	LCC	RCC	

Procedural Considerations

Site reports patient has a 25 mm Perimount surgical aortic valve (SAV) - Patient appears to have a 25 mm Magna Ease 3300 surgical aortic valve (SAV) - Recommend obtaining Op report for specific SAV information

Heavy MAC

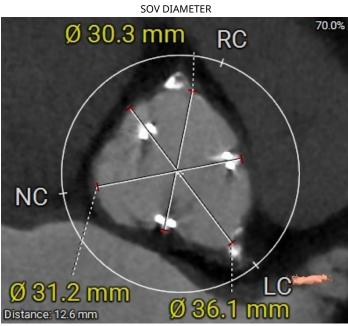
Ca++ seen in LVOT under RCC, LCC and NCC

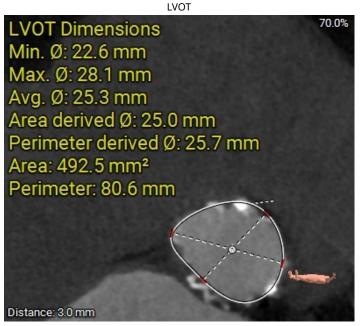
Ca++ seen in proximal RCA and LCA

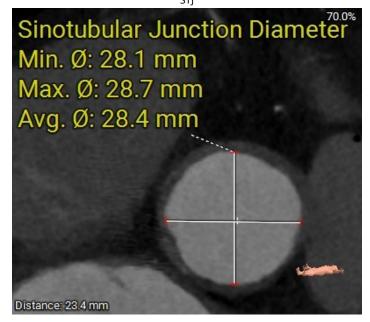
Possible short segment dissection seen in REI with regions of narrowing < 5 mm

Aorta



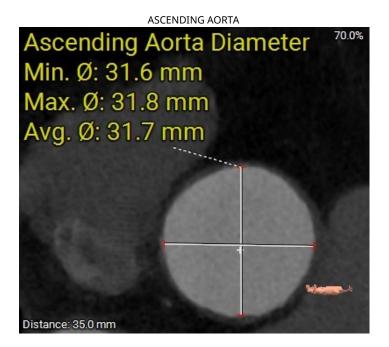






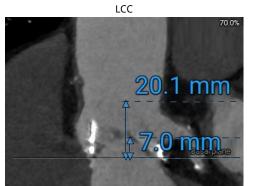
Ca++ seen in LVOT under RCC, LCC and NCC

Aorta

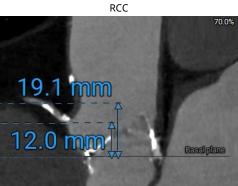




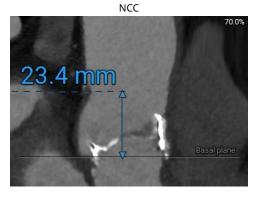
SINUS HEIGHT

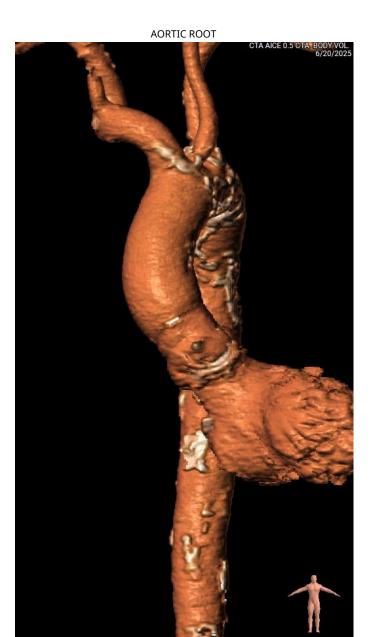


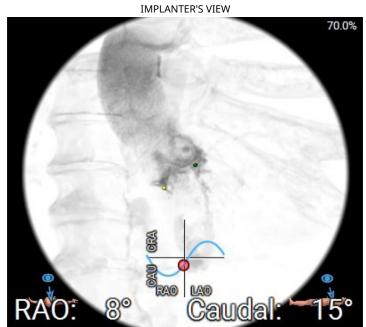
Ca++ seen in proximal LCA



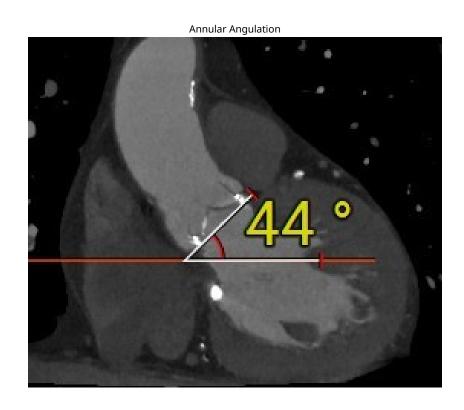
Ca++ seen in proximal RCA



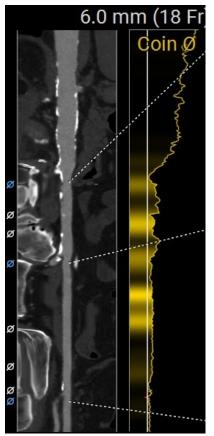


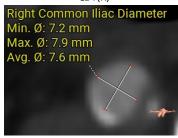


Cusp Overlap View

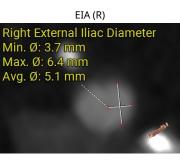


Femoral Access - Right



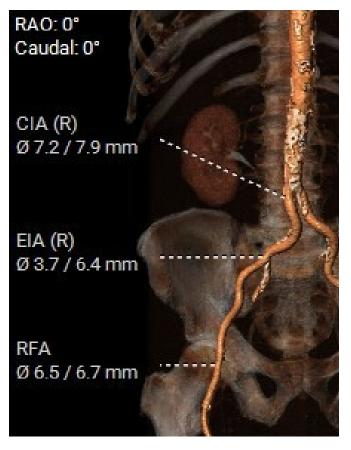


CIA (R)

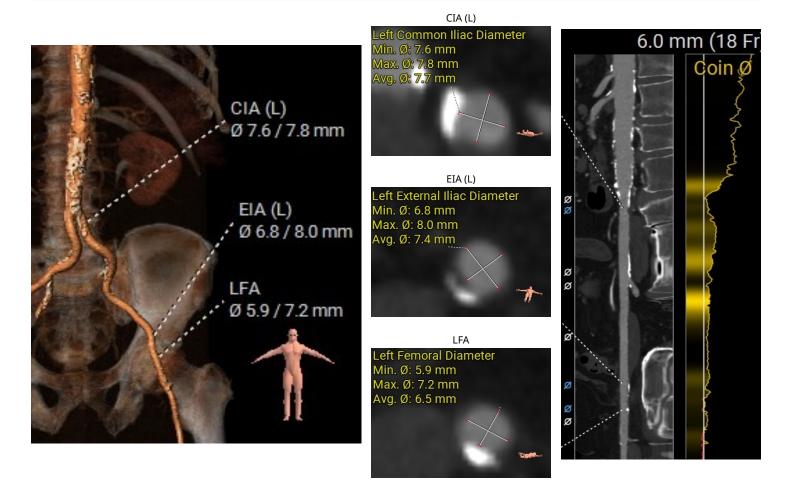


Possible short segment dissection seen in REI

RFA
Right Femoral Diameter
Min. Ø: 6.5 mm
Max. Ø: 6.7 mm
Avg. Ø: 6.6 mm



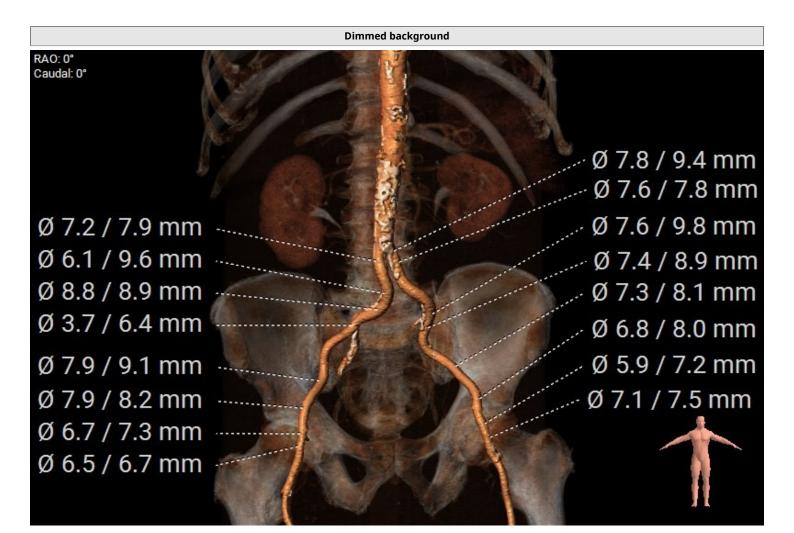
Femoral Access - Left



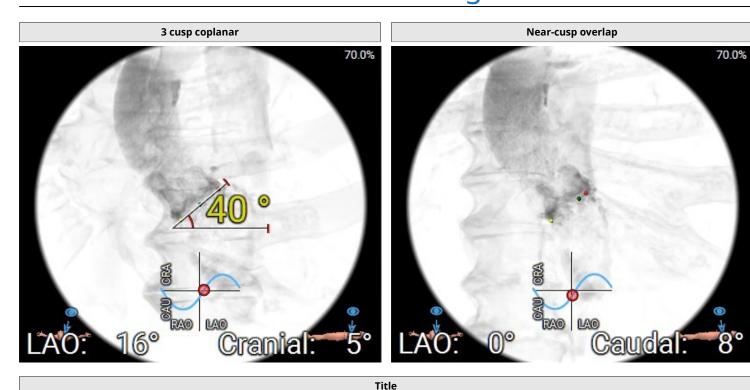
Additional Femoral Images



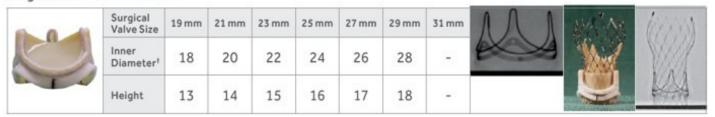




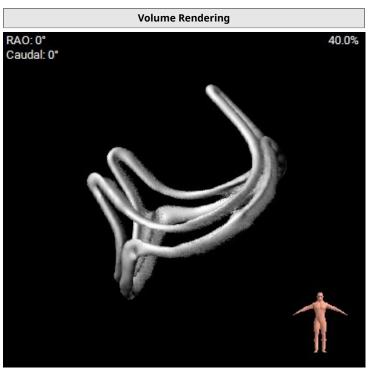
Additional Images

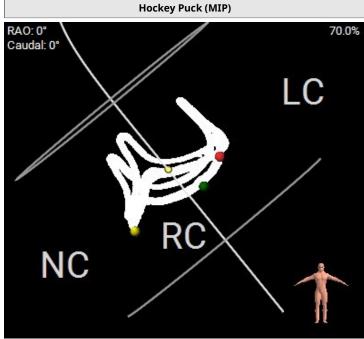


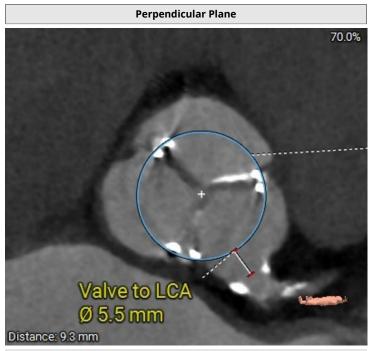
Magna Ease™ 3300 Valve10

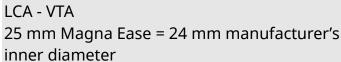


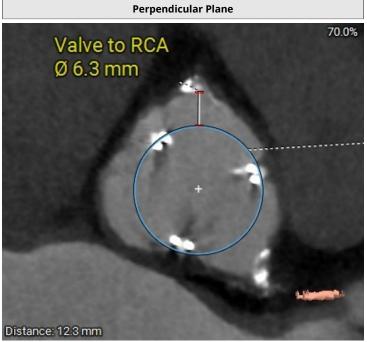
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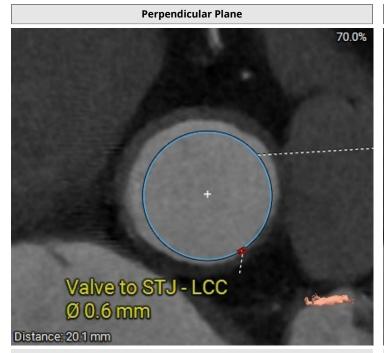




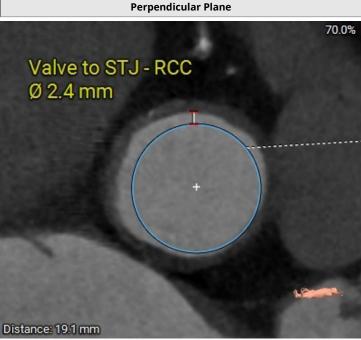




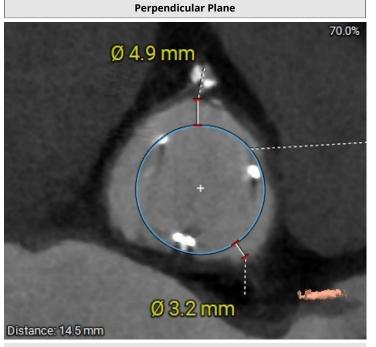
RCA - VTC 25 mm Magna Ease = 24 mm manufacturer's inner diameter



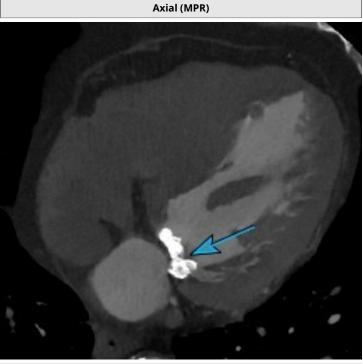
LCC – VTSTJ 25 mm Magna Ease = 24 mm manufacturer's inner diameter



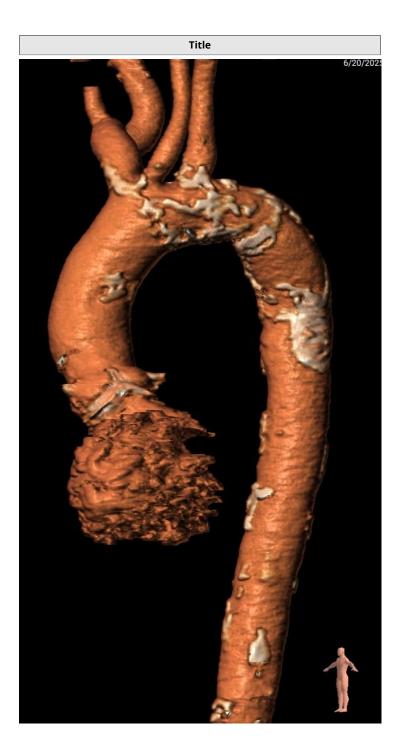
RCC – VTSTJ 25 mm Magna Ease = 24 mm manufacturer's inner diameter



LCC/RCC - VTA at top of SAV stent posts (3 posts seen)
25 mm Magna Ease = 24 mm manufacturer's inner diameter



Heavy MAC



Medtronic

Evolut™ FX TAVI System

Patient valve selection criteria

Evolut FX bioprosthesis valve size selection









Size Annulus diameter (A) Annulus perimeter‡ Sinus of Valsalva diameter (mean) (B) 32.5 mm ≥ 25 mm

Sinus of Valsalva height (mean) (C) **Oversizing Percentage**

23 mm 23.0 mm 18-20 mm 72.4 mm 56.5-62.8 mm $20.9 \ mm \ge 15 \ mm$ 0%

26 mm 20-23 mm 62.8-72.3 mm ≥ 27 mm ≥ 15 mm 13%

29 mm 23-26 mm 72.3-81.7 mm ≥ 29 mm ≥ 15 mm 26%

34 mm 26-30 mm 81.7-94.2 mm ≥ 31 mm ≥ 16 mm 48%

 ‡ Annulus perimeter = annulus diameter x π .

-Selection criteria-

Access consideration by MSCT

Minimum transarterial access vessel diameter

Aortic root angulation, femoral access Aortic root angulation, left subclavian Aortic root angulation, right subclavian

Vascular access location, direct aortic access

IFU guidance by MSCT

Evolut FX 23/26/29 mm TAVs ≥ 5.0 mm Evolut FX 34 mm TAV \geq 6.0 mm

Not recommended if > 70 degrees. Not recommended if > 70 degrees.§ Not recommended if > 30 degrees.§

Ascending aorta access site \geq 60 mm from basal plane.^{Ω}

 5 Patients with a patent LIMA or RIMA graft must present with access vessel diameters that are either ≥ 5.5 mm when using model D-EVOLUTFX-2329 or ≥ 6.5 mm when using model D-EVOLUTFX-34.

 $^{
m Q}$ For direct aortic access, ensure access site and trajectory are free of patent RIMA or preexisting patent RIMA graft.

Note the position of any SVGs (A) Annulus diameter (B) Sinus of Valsalva diameter (C) Sinus of Valsalva height (D) Frame height (≈ 45 mm, not including paddles) Illustration not to scale.

CAUTION: For distribution only in markets where CoreValve™ Evolut™ R, CoreValve™ Evolut™ PRO, Evolut™ PRO+, Evolut™ FX Systems and Evolut™ FX+ Systems are approved. See the CoreValve™ Evolut™ R, the CoreValve™ Evolut™ PRO, the Evolut™ PRO+, the Evolut™ FX and the Evolut™ FX+ device manuals for detailed information regarding the instructions for use, the implant procedure, indications, contraindications, warnings, precautions, and potential adverse events. For further information, contact your local Medtronic representative and/or consult the Medtronic website at medtronic.eu. For applicable products, consult instructions for use on manuals.medtronic.com. Manuals can be viewed using a current version of any major internet browser. For best results, use Adobe Acrobat® Reader with the browser. The commercial name of the Evolut™ R device is Medtronic CoreValve™ Evolut™ R System, the commercial name of the Evolut™ PRO device is Medtronic CoreValve™ Evolut™ PRO System, the commercial name of the Evolut™ PRO+ device is Medtronic CoreValve™ Evolut™ PRO+ System, the commercial name of the Evolut™ FX device is Medtronic Evolut™ FX System and the commercial name of the Evolut™ FX+ device is Medtronic Evolut™ FX+ System.

CAUTION: This report is provided based on information and images provided by the physician to Medtronic. This report is intended to be a resource to support physicians in their determination of proper case selection, device sizing and procedure planning, and is in no way intended to constitute medical advice or in any way replace the independent medical judgment of a trained and licensed physician with respect to any patient needs or circumstances. Physicians must conduct their own measurements and make their own medical judgments based on all of their patient's clinical and diagnostic records and images. Physician is solely responsible for all decisions and any medical judgments relating to patient diagnosis and treatment, including case selection and sizing of the device. Please see the complete Instructions of Use for all product indications, contraindications, precautions, warnings, and adverse events.

See the CoreValve™ Evolut™ R, the CoreValve™ Evolut™ PRO, the Evolut™ PRO+ device and the Evolut™ FX device manuals for detailed information regarding the instructions for use, the implant procedure, indications, contraindications, warnings, precautions, and potential adverse events. For further information, contact your local Medtronic representative and/or consult the Medtronic website at medtronic.eu.

For applicable products, consult instructions for use on manuals.medtronic.com. Manuals can be viewed using a current version of any major internet browser. For best results, use Adobe Acrobat® Reader with the browser.

The commercial name of the Evolut™ R device is Medtronic CoreValve™ Evolut™ R System, the commercial name of the Evolut™ PRO device is Medtronic CoreValve™ Evolut™ PRO System, the commercial name of the Evolut™ PRO+ device is Medtronic Evolut™ PRO+ System, and the commercial name of the Evolut™ FX device is Medtronic Evolut™ FX System.

С€ 0344

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Notes:

Conclusion:

Reviewer Name: #42

Review Date: 30-Jun-2025