Medtronic

Evolut™ TAVR platform

Patient	THORPE, ROBIN	**Height**	**m**	**Physician**	Dr Ravinay Bhindi	**Received Date**	07-Aug-25
Sex	Male	**Weight**	**kg**	**Hospital**	North Shore Private Hospital	**Reviewed Date**	07-Aug-25
Year Of Birth (Age)	1946 (78)	**BMI**		**City**			
		EOA needed to achieve an iEOA > 0.85 cm²/m²		**Country**	Australia		

Clinical History

Case 31610009

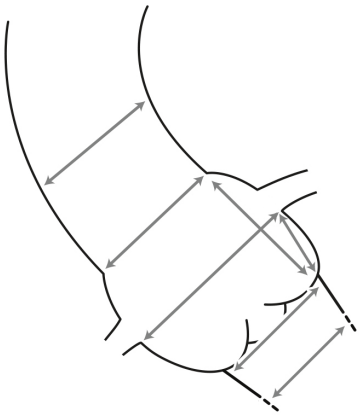
MEDTRONIC ANALYSIS

ANNULUS

Diameter (mm)	26.2 (Min)	x	37.6 (Max)	,	31.9 (Mean)
Perimeter (mm)	102.5	, Derived Ø (mm)	32.6		
Area (mm²)	795.1	, Derived Ø (mm)	31.8		

LVOT

Diameter (mm)	25.0 (Min)	x	38.2 (Max)	,	31.6 (Mean)
Perimeter (mm)	101.6	, Derived Ø (mm)	32.3		
Area (mm²)	759.6	, Derived Ø (mm)	31.1		



Max Ascending Aorta Diameter (mm)	38.6		
Sinotubular Junction Diameter (mm)	36.5 (Min)	x	37.2 (Max)
Sinus of Valsalva Diameter (mm)	42.3 (LCC)	36.0 (RCC)	43.0 (NCC)
Sinus of Valsalva Height (mm)	26.2 (LCC)	30.3 (RCC)	28.3 (NCC)
Coronary Ostia Height (mm)	17.5 (Left)	19.8 (Right)	

VIEWS

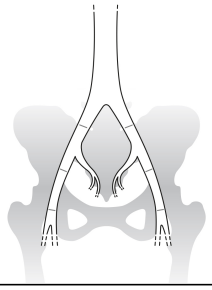
Cusp Overlap View	RAO: 46°, Caudal: 49°
3 Cusp Coplanar View	
Near Cusp Overlap View	

RIGHT

CIA Min Diameter (mm): 12.3 x 12.7

EIA Min Diameter (mm): 9.9 x 10.0

Femoral Min Diameter (mm): 10.0 x 10.8



LEFT

CIA Min Diameter (mm): 12.2 x 12.9

EIA Min Diameter (mm): 10.1 x 10.1

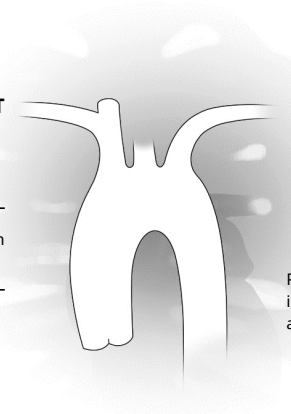
Femoral Min Diameter (mm): 9.8 x 10.3

Calcium: Mild ☐ Moderate ☐ Severe ☐

RIGHT

Subclavian Min Diameter (mm): --- x ---

Annular Angulation: 62°



LEFT

Subclavian Min Diameter (mm): --- x ---

Please review images for direct aortic evaluation.

VIV ADDITIONAL MEASUREMENTS

Valve to Coronary Distance (mm)	--- (To LCA)	--- (To RCA)
Valve to STJ Distance (mm)	--- (LCC)	--- (RCC)

Procedural Considerations

Possible bicuspid AoV - RCC / LCC appear fused

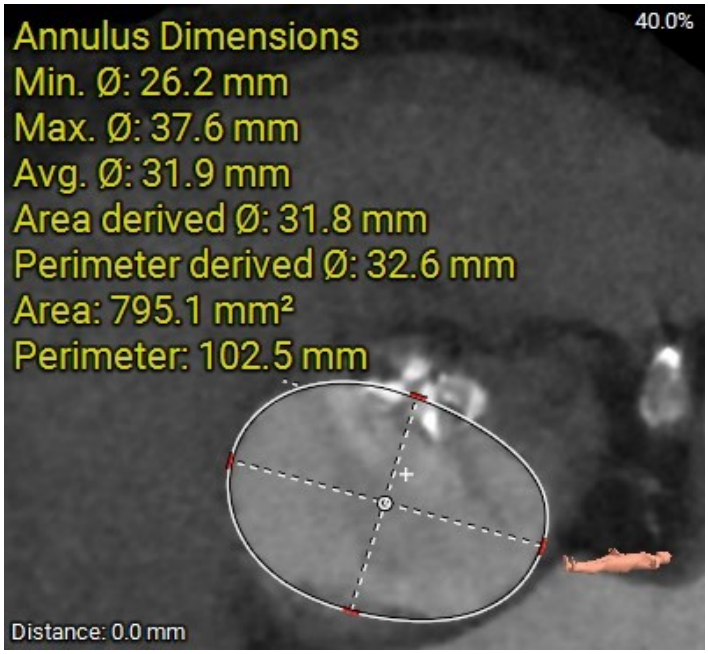
Aortic Annulus measures **>30mm**

Please note: Native aortic annulus size < 18 mm or > 30 mm per the baseline diagnostic imaging is listed as a precaution in the Commercial IFU

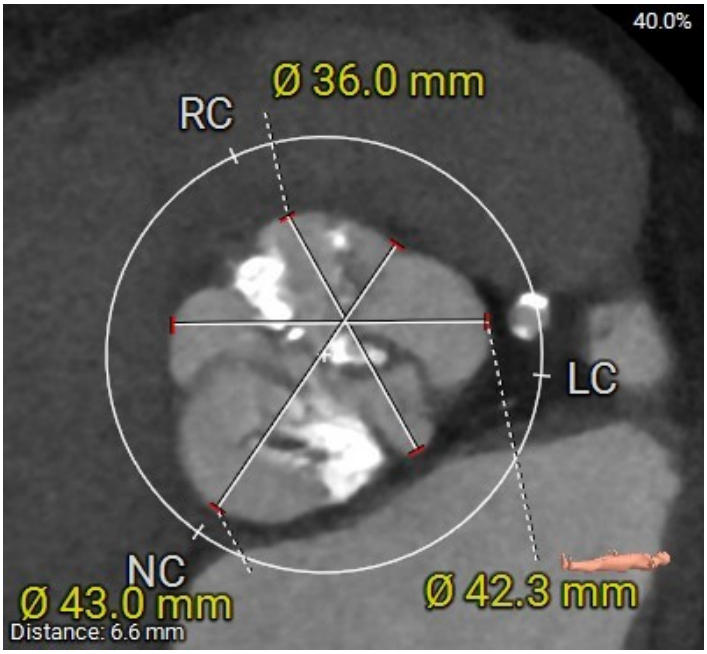
Annular calcification under the RCC extending into the LVOT

Aorta

ANNULUS

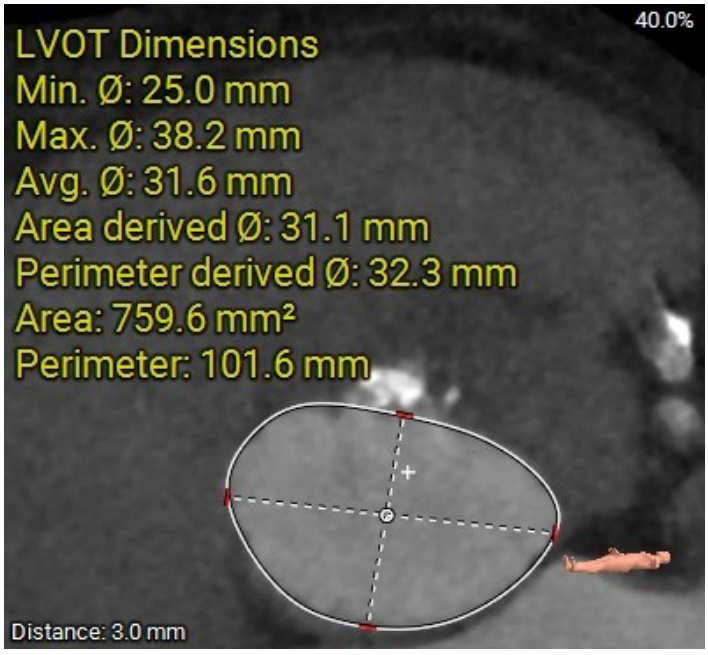


SOV DIAMETER

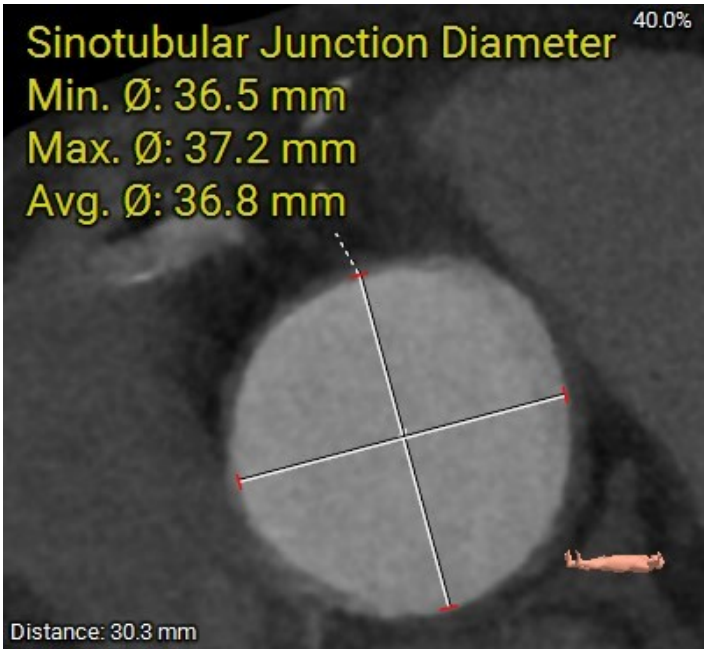


Aortic Annulus measures **>30mm**
Annular calcification under the RCC

LVOT

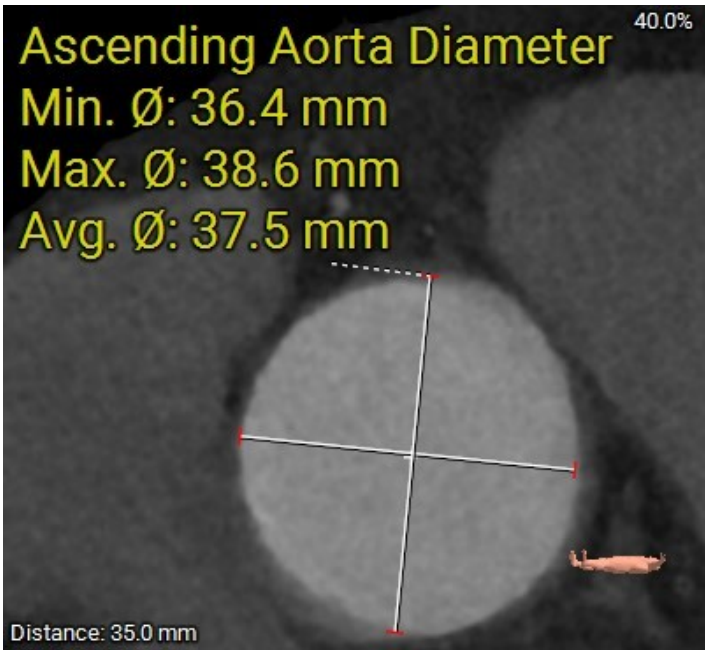


STJ

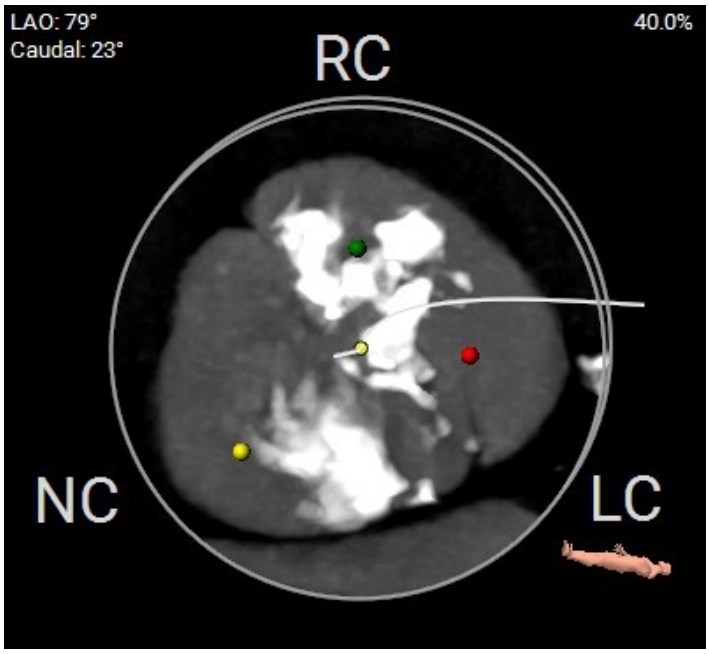


Aorta

ASCENDING AORTA

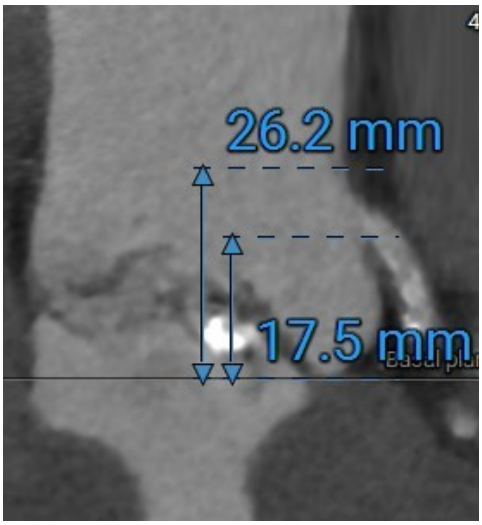


AORTIC VALVE CALCIFICATION

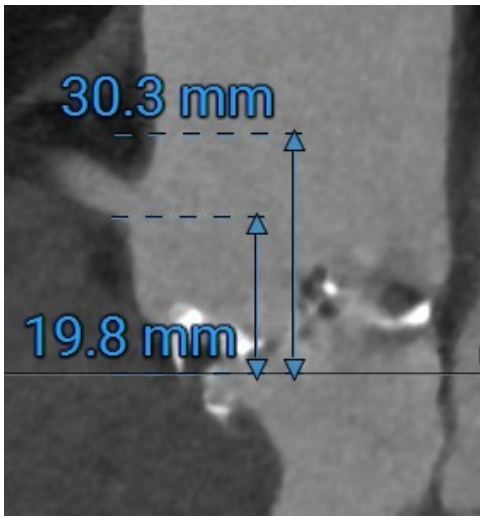


SINUS HEIGHT

LCC



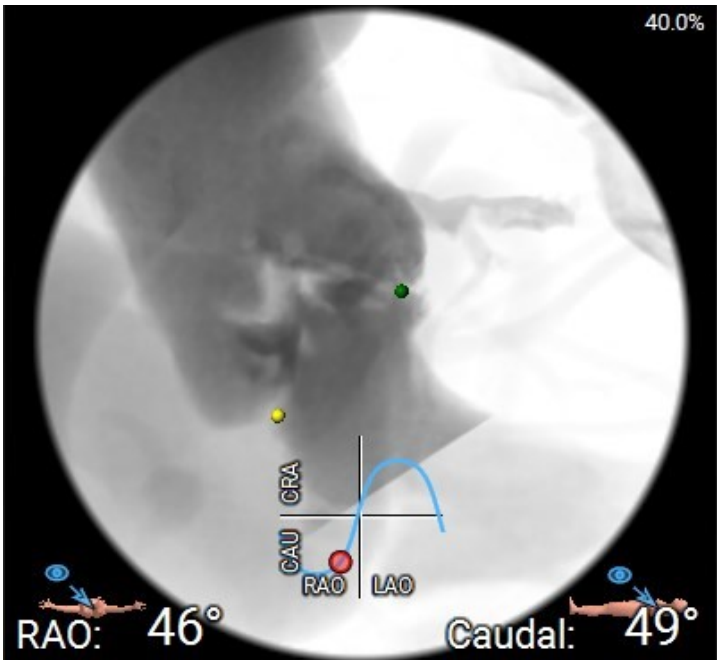
RCC



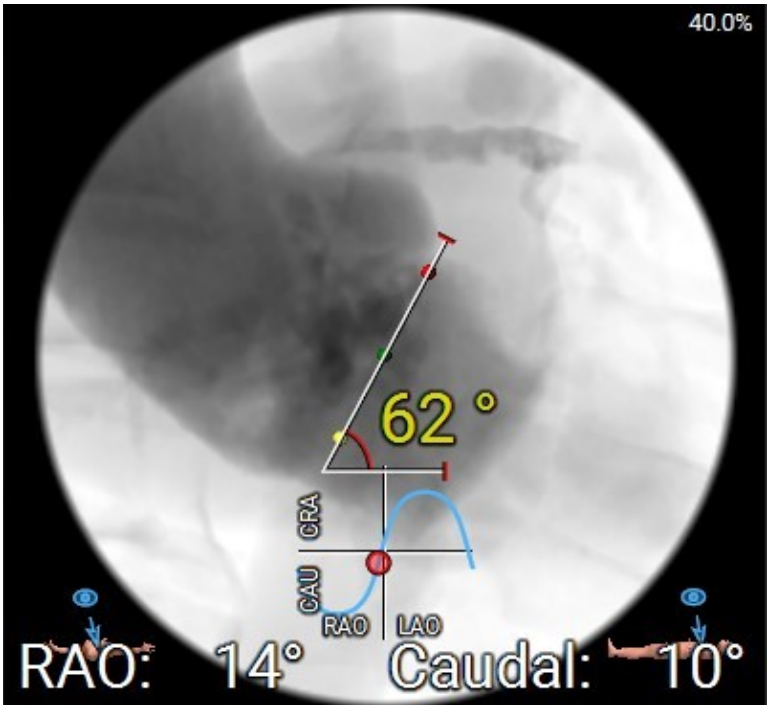
NCC

AORTIC ROOT

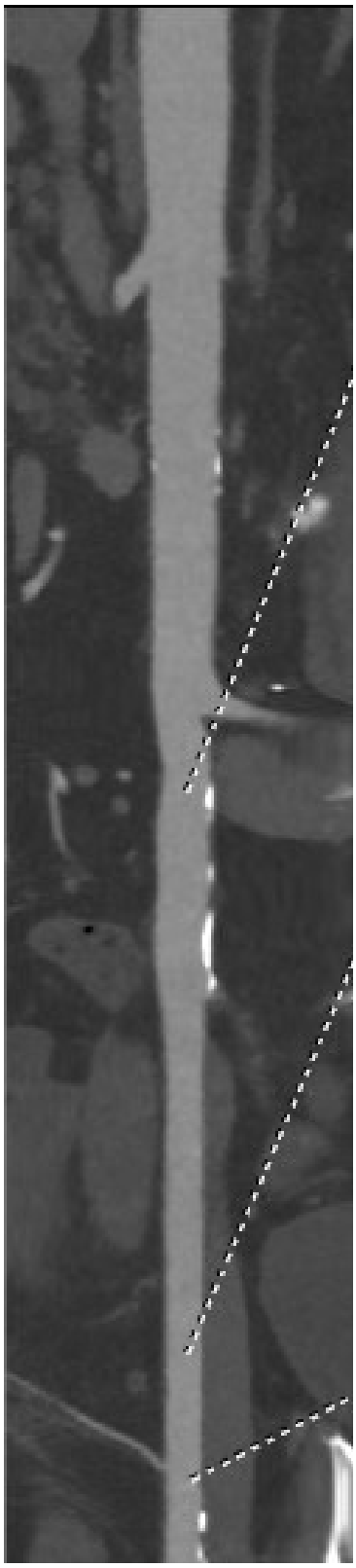
IMPLANTER'S VIEW



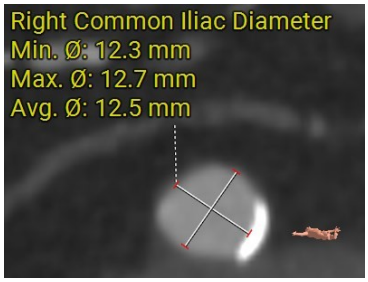
Annular Angulation



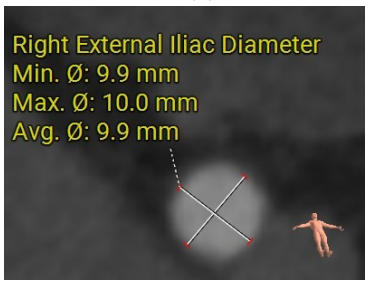
Femoral Access - Right



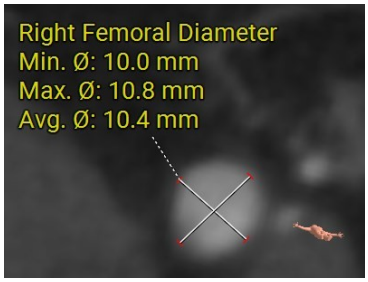
CIA (R)

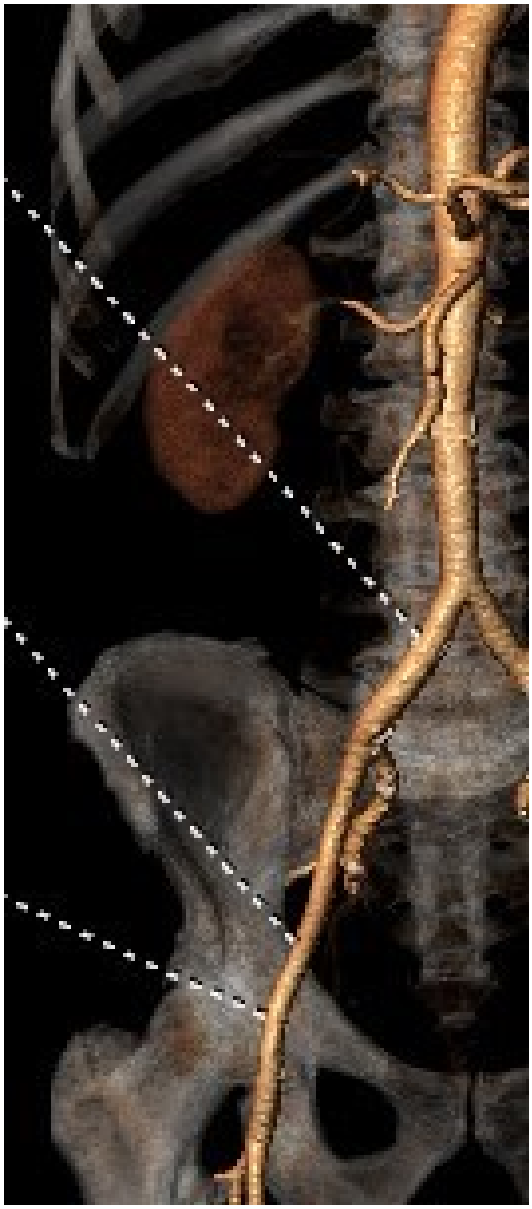


EIA (R)

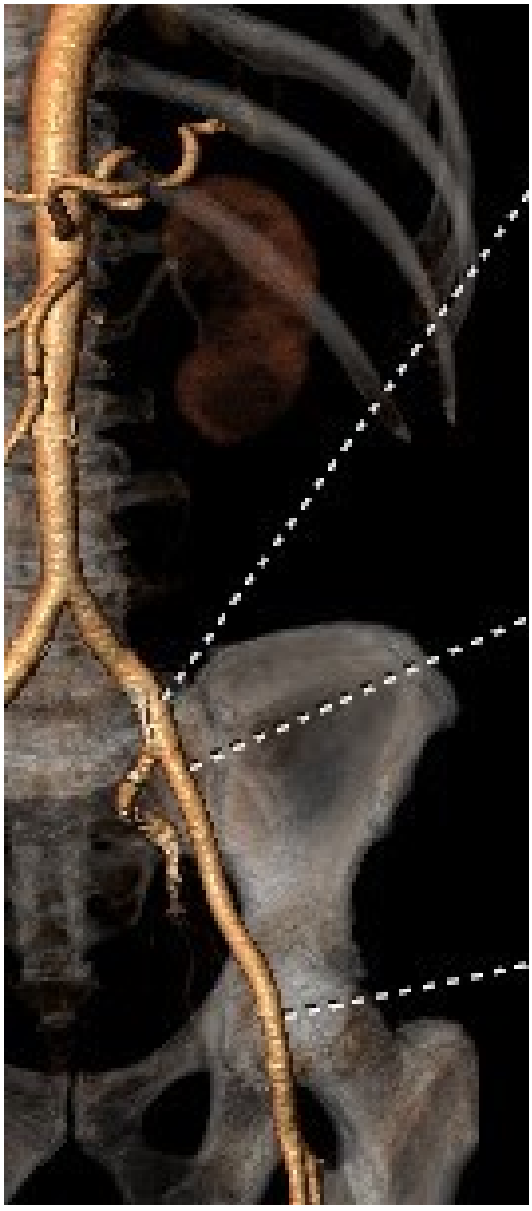


RFA

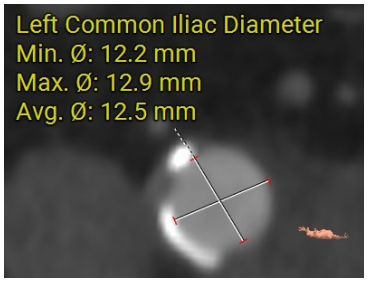




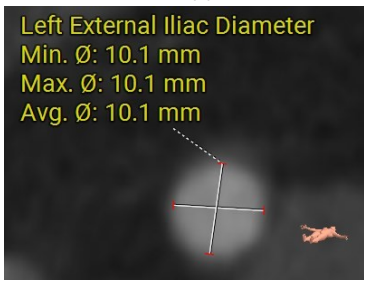
Femoral Access - Left



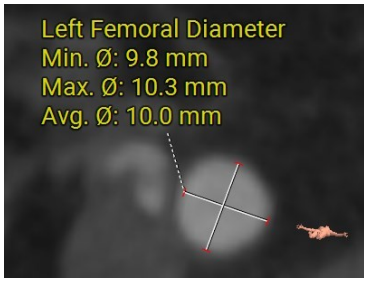
CIA (L)

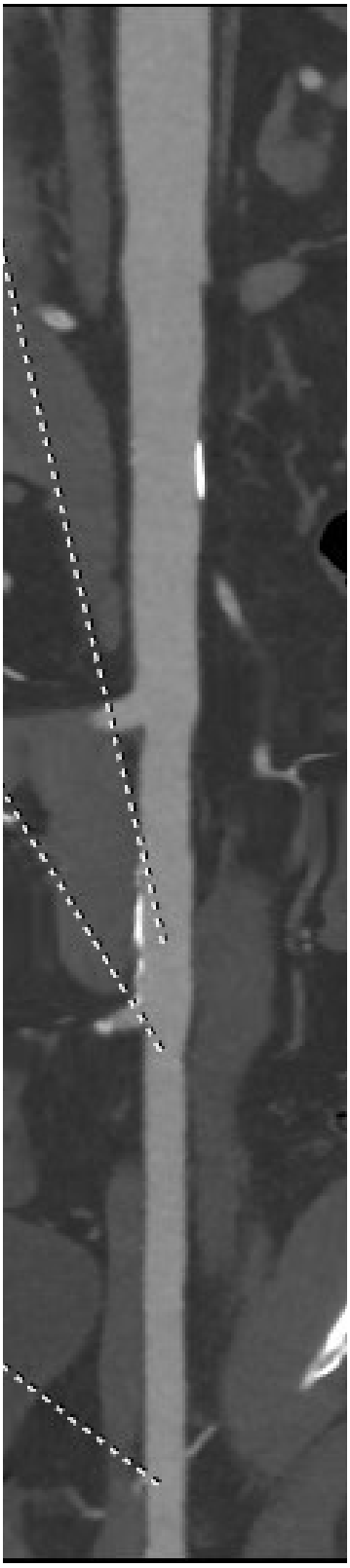


EIA (L)

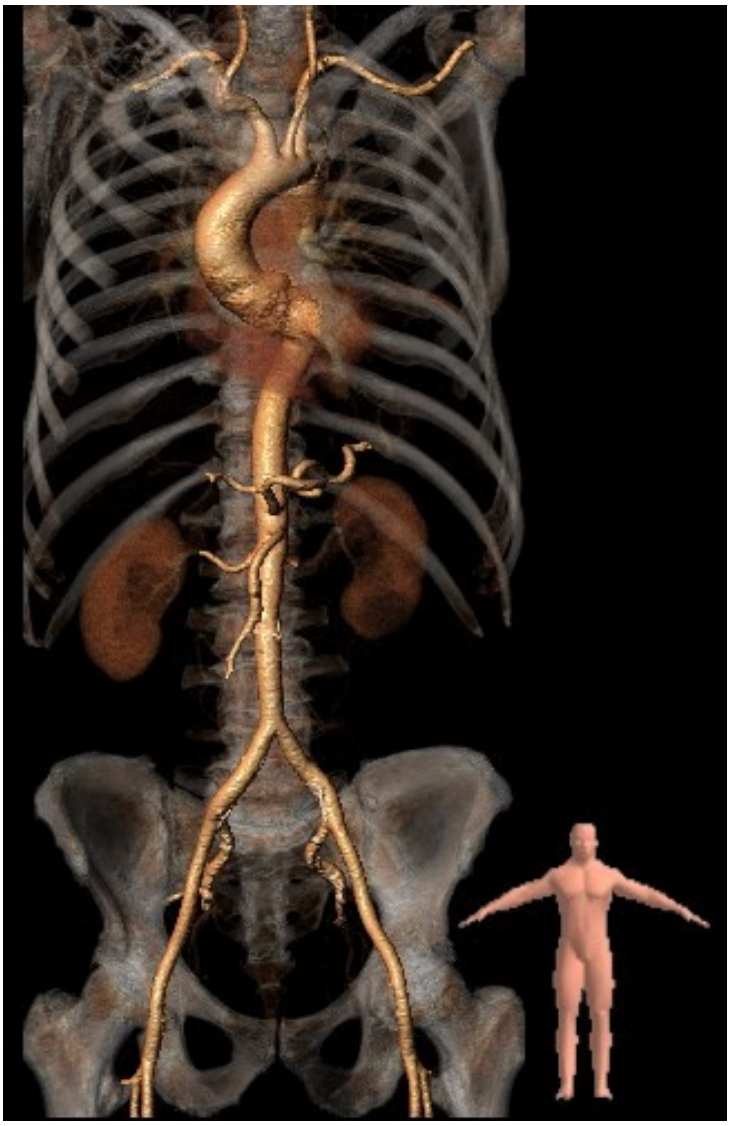


LFA

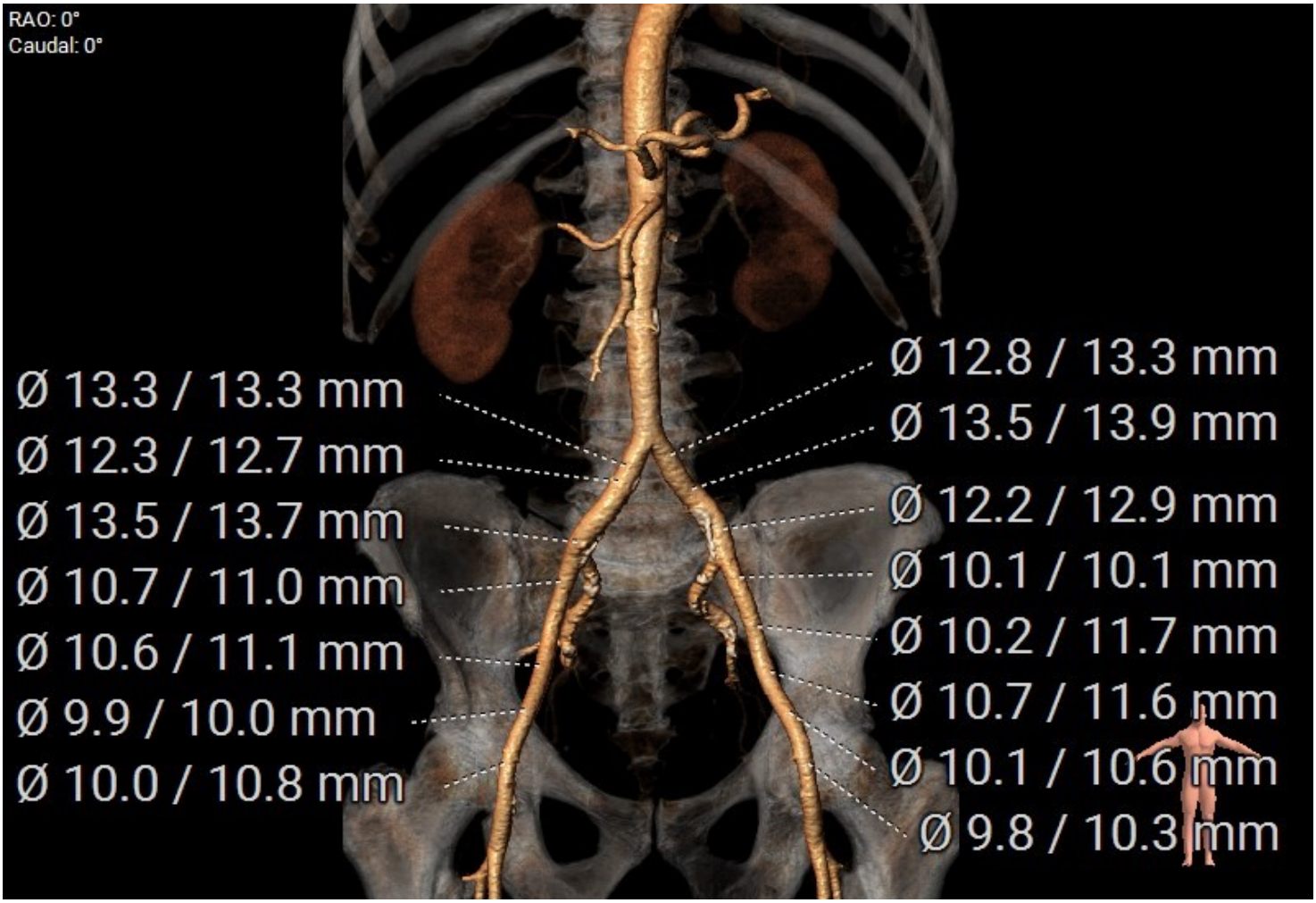




Additional Femoral Images

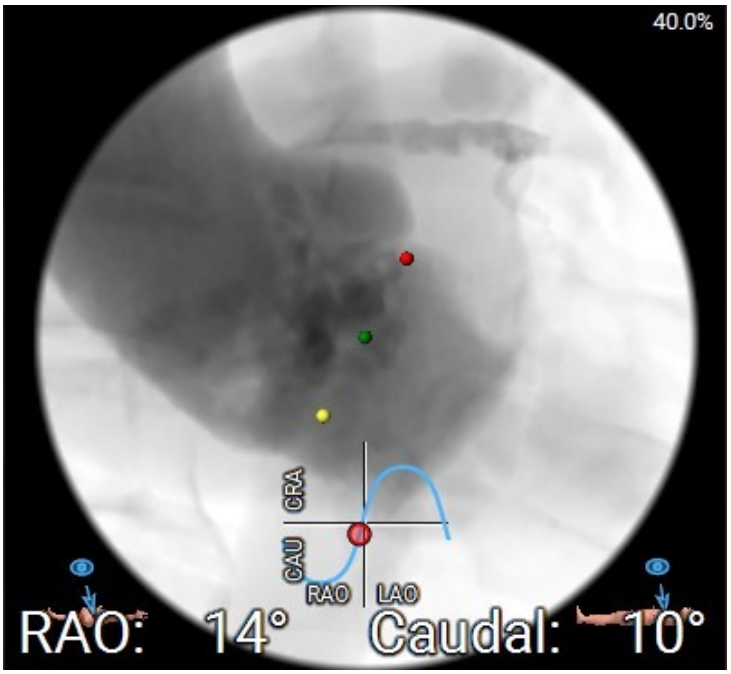
Title	Title
	

Dimmed background

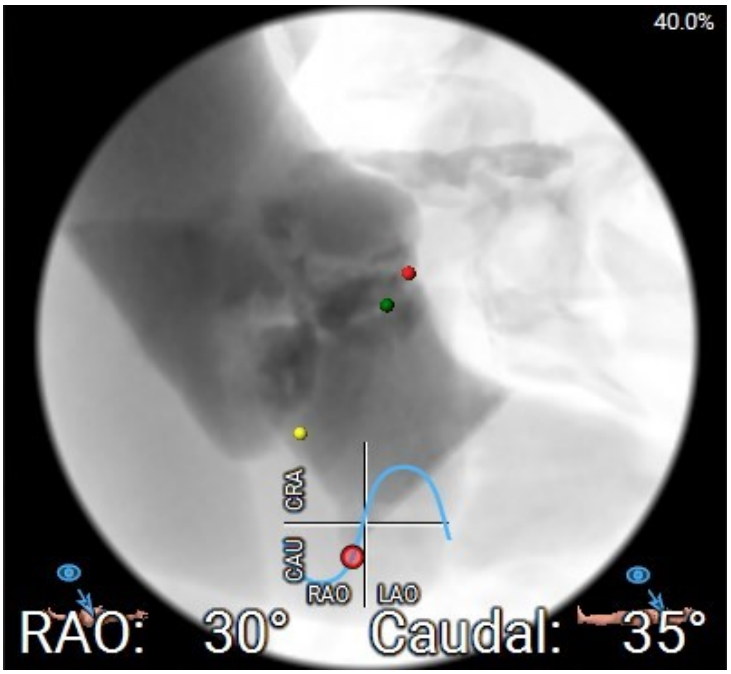


Additional Images

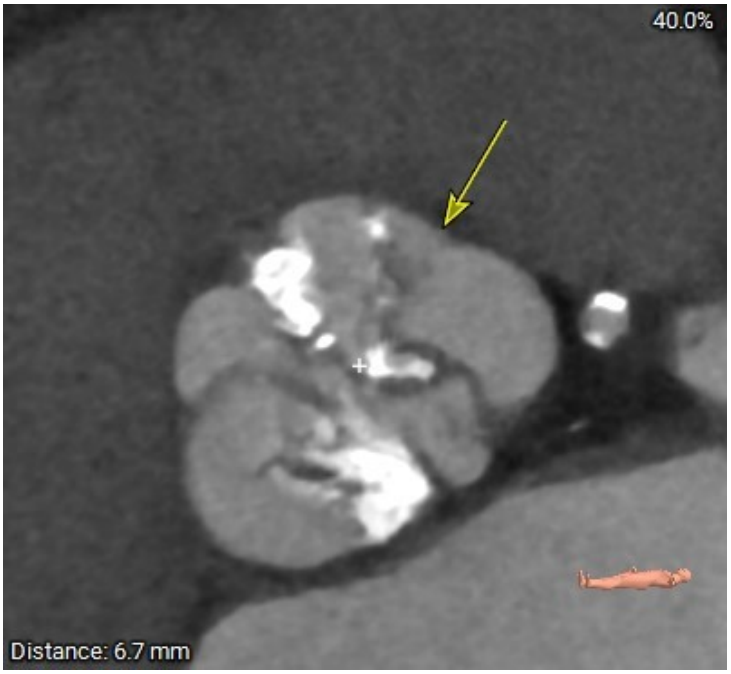
3 Cusp Co-Planar



Near Overlap View

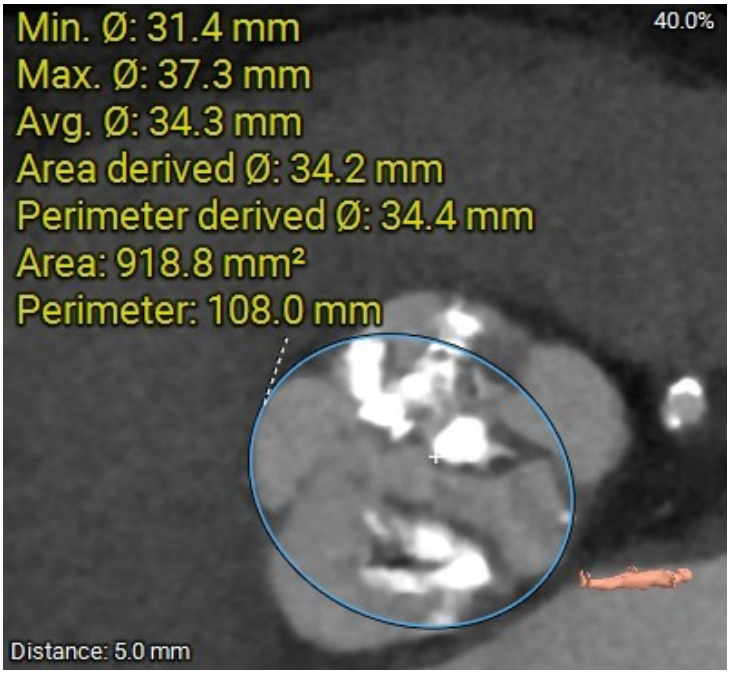


Perpendicular Plane



Possible bicuspid AoV - RCC / LCC appear fused

Perpendicular Plane



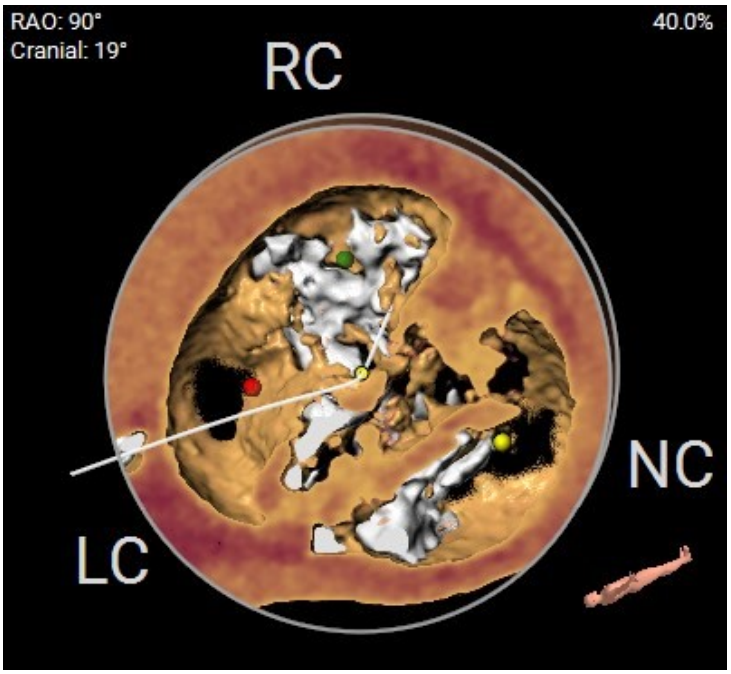
Estimated orifice area of possible bicuspid AV – 5 mm above basal plane

NOTE

The methodology for supra-annular measurement is variable and has not been standardized. No prospective clinical evidence has been reported comparing clinical results using supra-annular technique to basal plane annulus measurement results. Supra-annular measurements may be provided for anatomical consideration in case planning only and are not intended to replace annular sizing guidance. Refer to the product IFU for annular sizing guidance.

NOTE: If the patient presents with a bicuspid aortic valve, the treating physician should consider the patient's age and the need for ascending aorta intervention when determining the appropriate treatment option for the patient.

Hockey Puck (VR)	Title

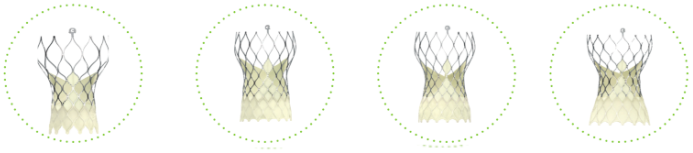


Medtronic

Evolut™ FX TAVI System

Patient valve selection criteria

Evolut FX bioprosthesis valve size selection



Size		23 mm	26 mm	29 mm	34 mm
Annulus diameter (A)	32.6 mm	18–20 mm	20–23 mm	23–26 mm	26–30 mm
Annulus perimeter‡	102.5 mm	56.5–62.8 mm	62.8–72.3 mm	72.3–81.7 mm	81.7–94.2 mm
Sinus of Valsalva diameter (mean) (B)	40.4 mm	≥ 25 mm	≥ 27 mm	≥ 29 mm	≥ 31 mm
Sinus of Valsalva height (mean) (C)	28.3 mm	≥ 15 mm	≥ 15 mm	≥ 15 mm	≥ 16 mm
Oversizing Percentage		**-29%**	**-20%**	**-11%**	**4%**

‡Annulus perimeter = annulus diameter x π.

Selection criteria

Access consideration by MSCT	IFU guidance by MSCT
Minimum transarterial access vessel diameter	Evolut FX 23/26/29 mm TAVs ≥ 5.0 mm Evolut FX 34 mm TAV ≥ 6.0 mm
Aortic root angulation, femoral access	Not recommended if > 70 degrees.
Aortic root angulation, left subclavian	Not recommended if > 70 degrees.§
Aortic root angulation, right subclavian	Not recommended if > 30 degrees.§
Vascular access location, direct aortic access	Ascending aorta access site ≥ 60 mm from basal plane.Ω

§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.

ΩFor direct aortic access, ensure access site and trajectory are free of patent RIMA or preexisting patent RIMA graft.

Note the position of any SVGs

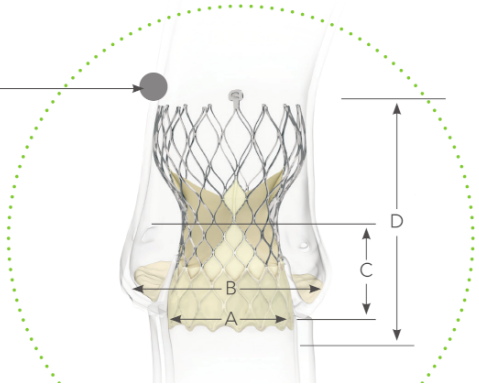
(A) Annulus diameter

(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.

CE
0344

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UC202202685a-evolut-fx-patient-evaluation-criteria-en-we-8664725

medtronic.eu

Notes:

Conclusion:

Reviewer Name: # 17

Review Date: 07-Aug-2025