Medtronic

Evolut™ TAVR platform

Patient [redacted] **Implant Team** [redacted] **Hospital** [redacted] **Date** 11/24/2022

PATIENT DEMOGRAPHICS (provided by hospital)

	Age: 69 **Sex:** Male **Height:** m **Weight:** kg **BSA:** m²	
Patient Comorbidities and Potential Incremental Risk Factors	**CABG** Y ☐ N ☐ **PPM** Y ☐ N ☐ **Porcelain Aorta** Y ☐ N ☐ **AAA** Y ☐ N ☐ **TAA** Y ☐ N ☐	**EOA needed to achieve an iEOA > 0.85 cm²/m²:** **LVEF %:** **Creatinine Clearance (cc/min):** **Mitral Regurgitation:** Mild ☐ Moderate ☐ Severe ☐ **Previous BAV** Y ☐ N ☐ **Date:** **Pre-existing conduction disturbance:**
Implant Date	TBD **(DD-MM-YYYY)**	
Comments	Patient appears to meet all sizing criteria for a **29mm Evolut** valve. Bilateral transfemoral access appears ≥ 5.0mm. Suitable for **14F FX** delivery system. Overlap = RAO: 13°, CAUD: 27° - Coplane = LAO: 10°, CAUD: 3°	

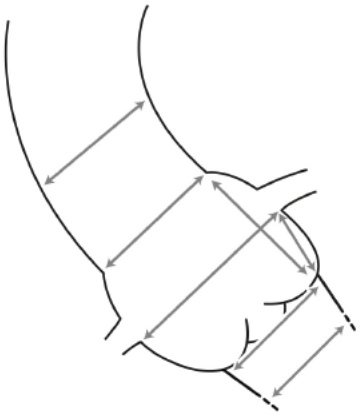
MEDTRONIC ANALYSIS

ANNULUS

Diameter (mm)	21.6	x	26.2	,	23.9
	Min		Max		Mean
Perimeter (mm)	75.1	, Derived Ø (mm)			23.9
Area (mm²)	440.2	, Derived Ø (mm)			23.7

LVOT

Diameter (mm)	18.7	x	25.7	,	22.2
	Min		Max		Mean
Perimeter (mm)	70.6	, Derived Ø (mm)			22.5
Area (mm²)	375.9	, Derived Ø (mm)			21.9



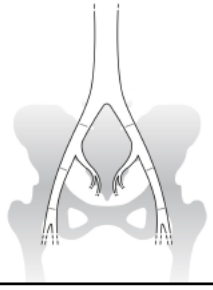
Max Ascending Aorta Diameter (mm)	30.2		
Sinotubular Junction Diameter (mm)	27.3 (Min) x	27.7 (Max)	
Sinus of Valsalva Diameter (mm)	32.4 (LCC)	29.6 (RCC)	30.6 (NCC)
Sinus of Valsalva Height (mm)	22.6 (LCC)	20.9 (RCC)	21.8 (NCC)
Coronary Ostia Height (mm)	16.5 (Left)	17.2 (Right)	

RIGHT

CIA Min Diameter (mm): 9.0 x 9.6

EIA Min Diameter (mm): 7.9 x 8.3

Femoral Min Diameter (mm): 8.2 x 8.3



LEFT

CIA Min Diameter (mm): 9.2 x 9.6

EIA Min Diameter (mm): 7.5 x 7.7

Femoral Min Diameter (mm): 7.9 x 8.2

Calcium: Mild ☐ Moderate ☐ Severe ☐

RIGHT

Subclavian Min Diameter (mm): x

Aortic Root Angle: 47.9°

LEFT

Subclavian Min Diameter (mm): x

Please review images for direct aortic evaluation.

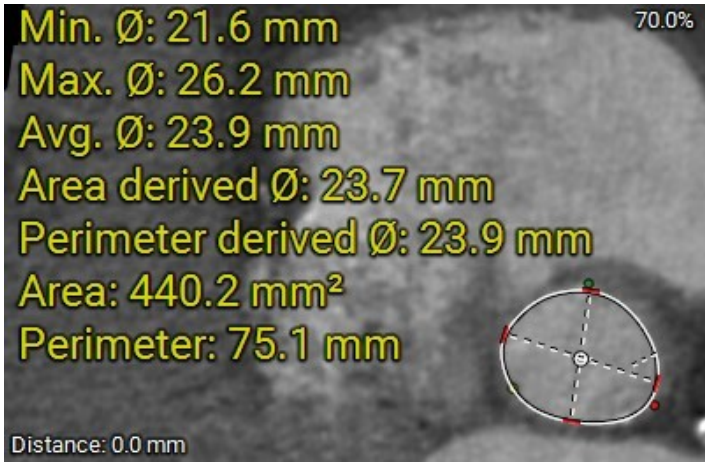
VIV ADDITIONAL MEASUREMENTS

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

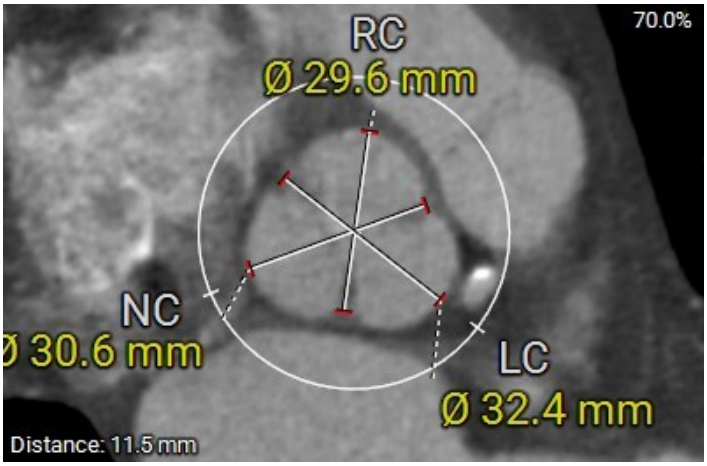
Procedural Considerations

Aorta

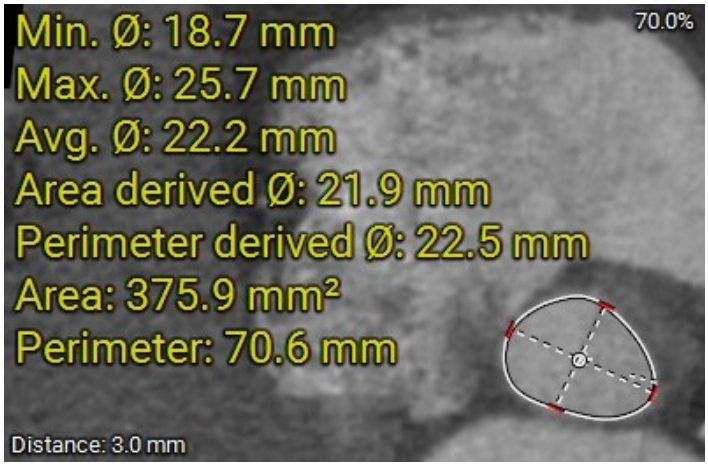
ANNULUS



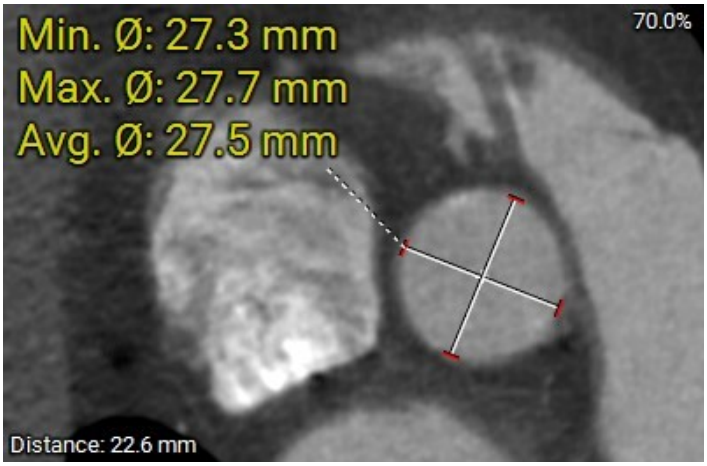
SOV DIAMETER



LVOT

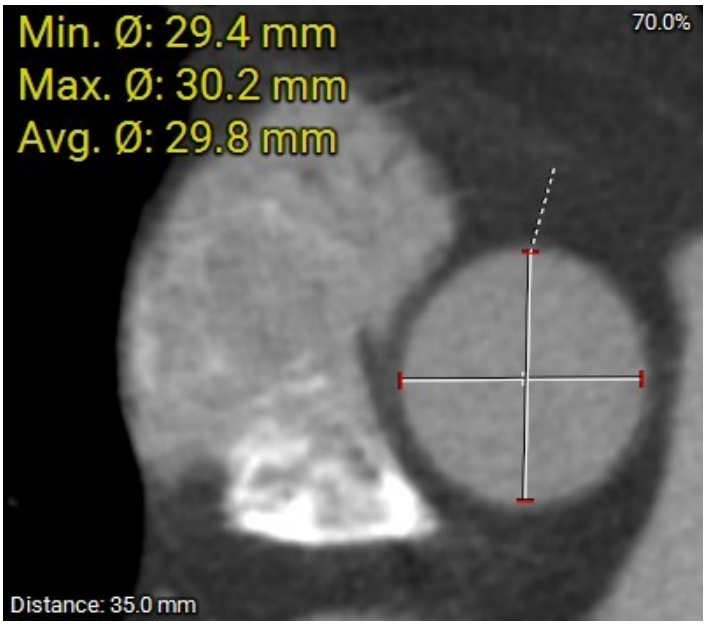


STJ

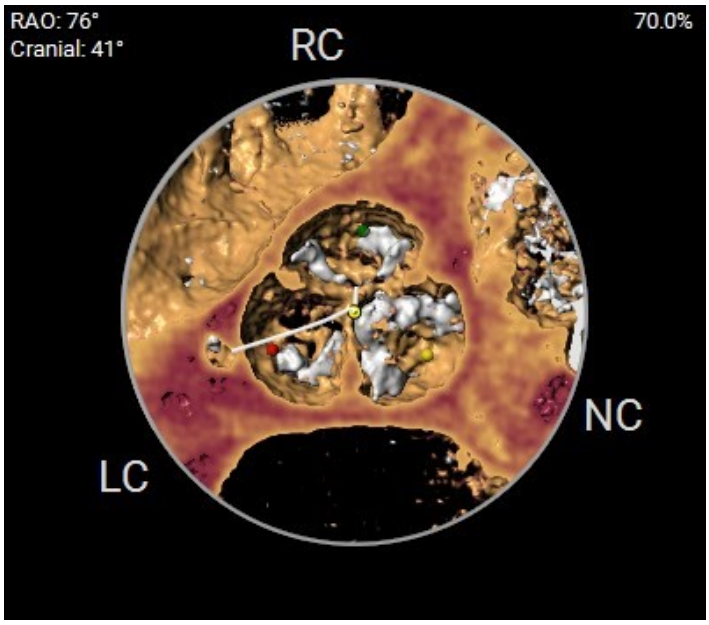


Aorta

ASCENDING AORTA

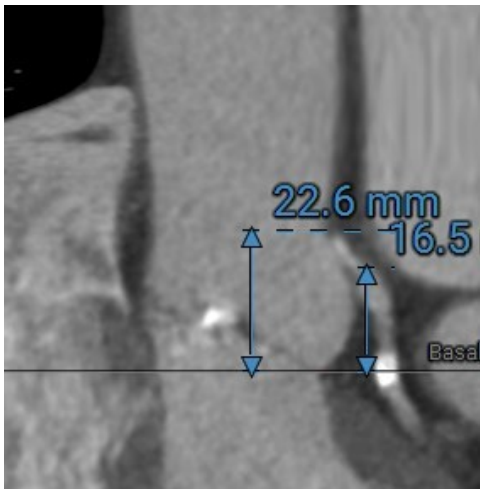


AORTIC VALVE CALCIFICATION

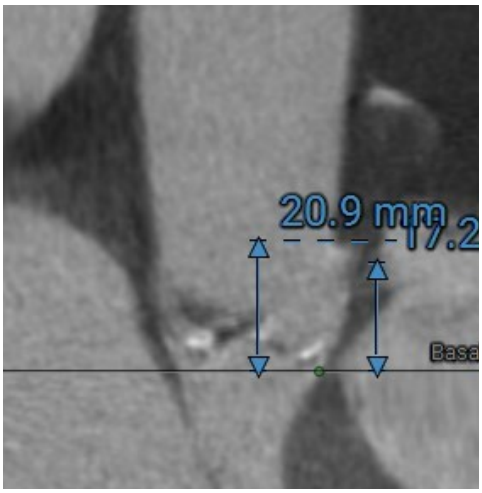


SINUS HEIGHT

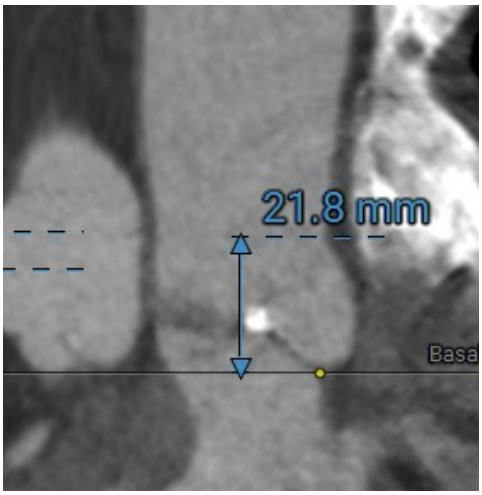
LCC



RCC

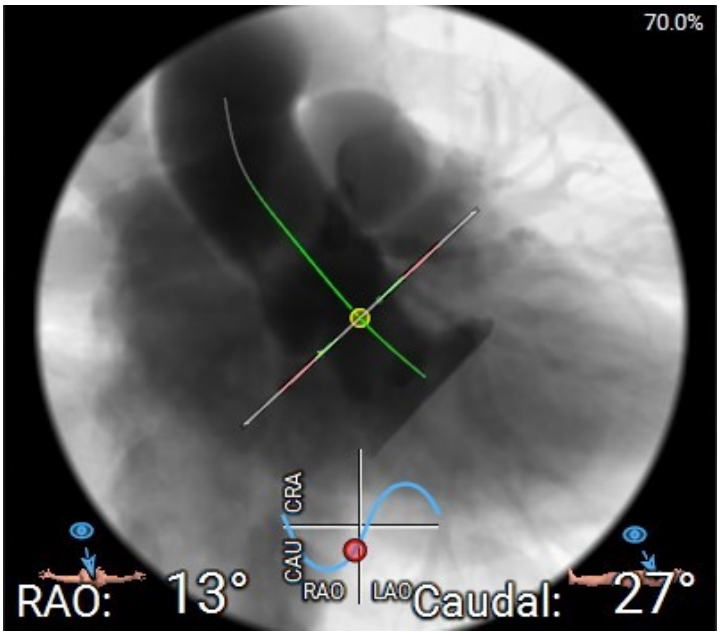


NCC



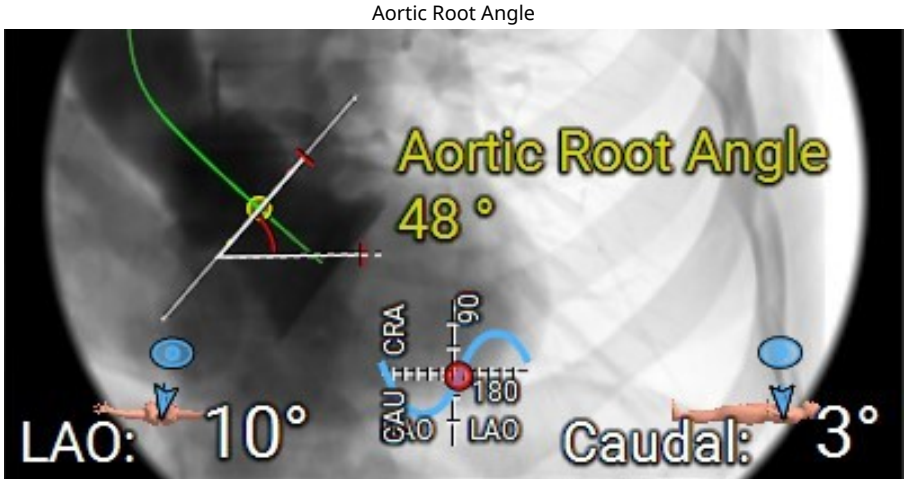
AORTIC ROOT

IMPLANTER'S VIEW



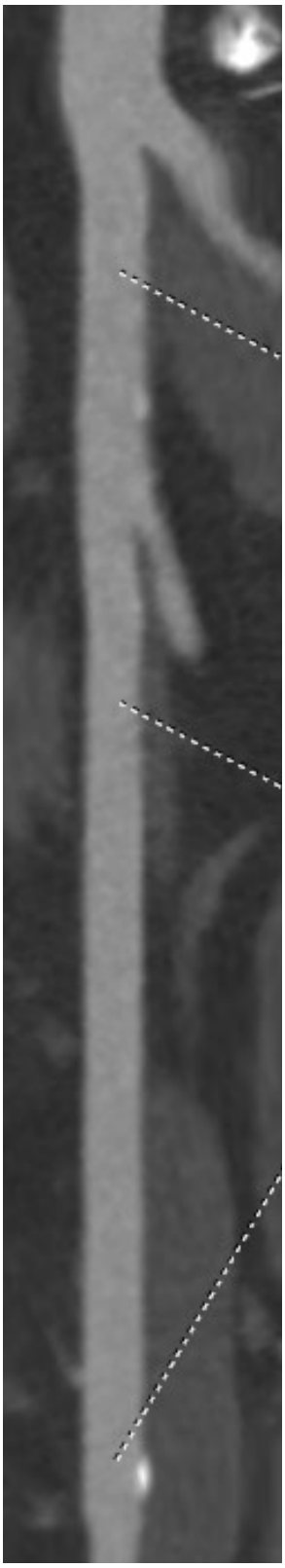
Overlap

Aortic Root Angle

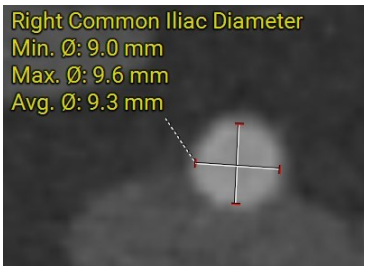


Coplane

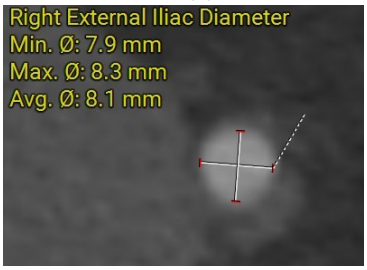
Femoral Access - Right



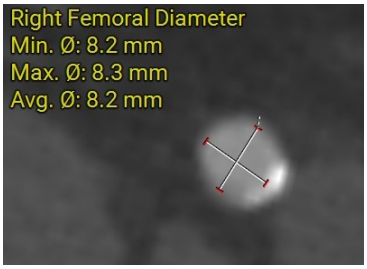
RIA

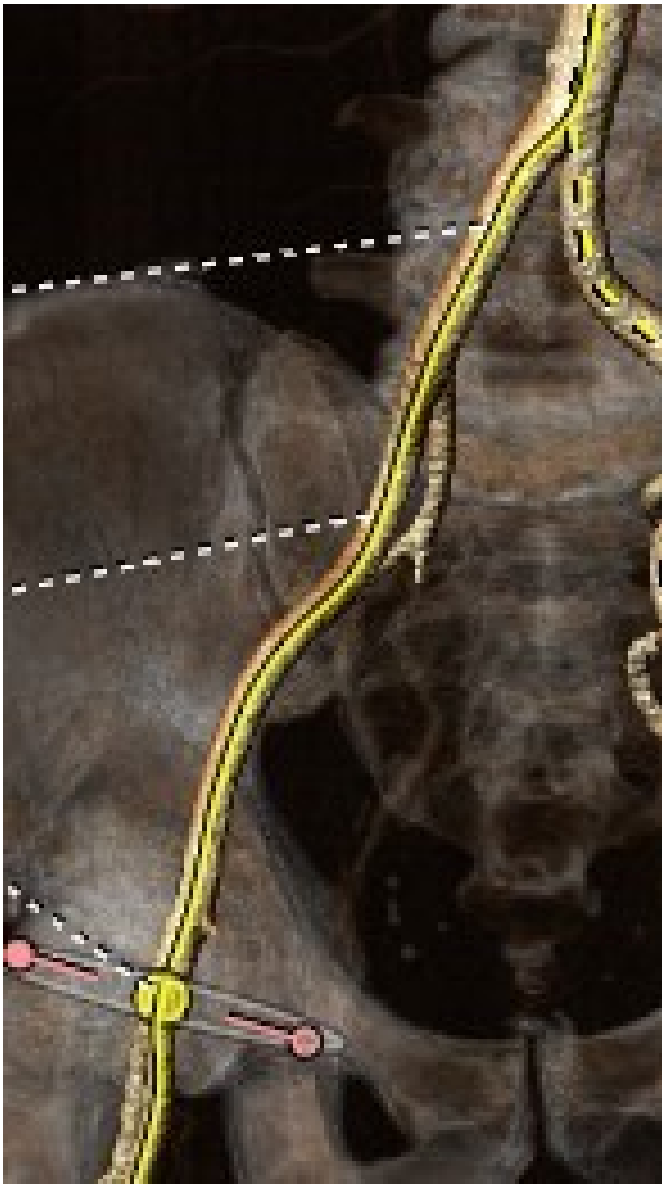


EIA (R)



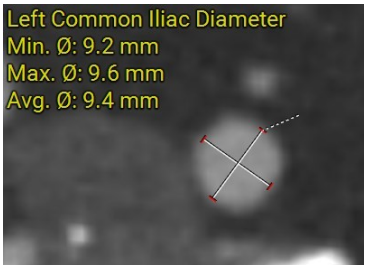
RFA



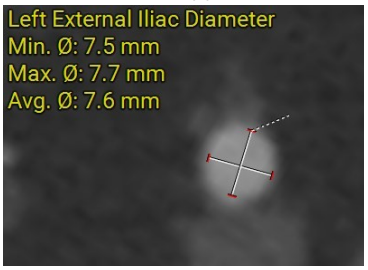


Femoral Access - Left

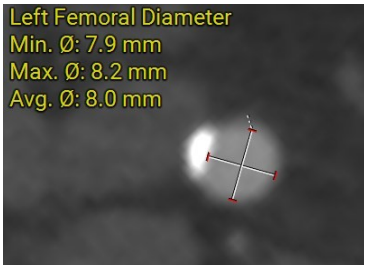
LIA

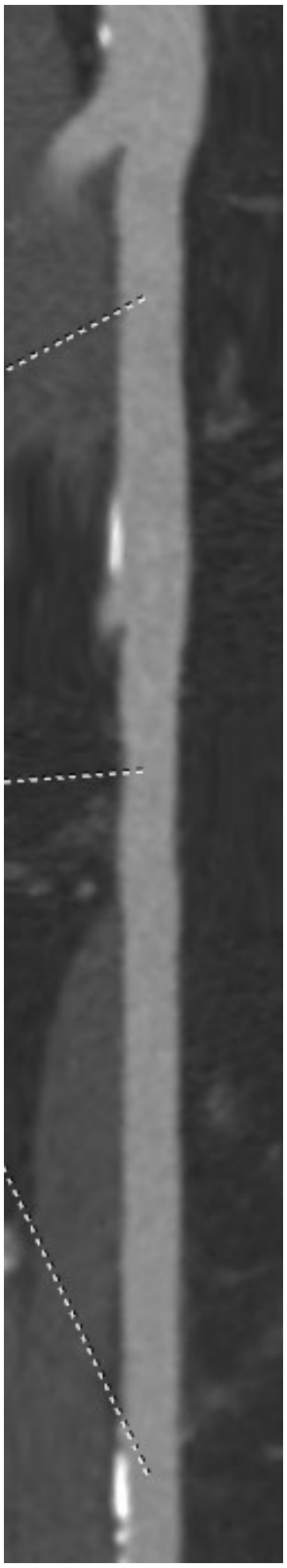


EIA (L)



LFA





Patient Evaluation Criteria

Valve Size Selection		Evolut™ PRO+ Bioprosthesis			
					
Size		23 mm	26 mm	29 mm	34 mm
Annulus Diameter	23.9 mm	17*/18-20 mm	20-23 mm	23-26 mm	26-30 mm
Annulus Perimeter†	75.1 mm	53.4*/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)	30.9 mm	≥ 25 mm	≥ 27 mm	≥ 29 mm	≥ 31 mm
Sinus of Valsalva Height (Mean)	21.7 mm	≥ 15 mm	≥ 15 mm	≥ 15 mm	≥ 16 mm
Oversizing Percentage		-4%	9%	21%	42%

*Measurement for TAV-in-SAV only. | †Annulus Perimeter = Annulus Diameter x π
NOTE: Evolut™ PRO+ valve size selection is identical to Evolut™ R valve size selection criteria

Selection Criteria

Access Consideration by MSCT	IFU Guidance by MSCT
Minimum Transarterial Access Vessel Diameter	Evolut PRO+ and Evolut R 23/26/29 TAVs ≥ 5.0 mm Evolut PRO+ 34 TAV ≥ 6.0 mm Evolut R 34 TAV ≥ 5.5 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.††

**Use caution in patients with a preexisting patent left internal mammary artery/right internal mammary artery (LIMA/RIMA) graft.
††For direct aortic access, ensure access site and trajectory are free of patent RIMA or preexisting patent RIMA graft.

Heart Team Procedure Plan (provided by hospital)

Patient Name	[redacted]		
Planned Evolut™ R/ Evolut™ PRO+ Size	☐ 23 mm	☐ 26 mm	☐ 29 mm ☐ 34 mm
Access Route	☐ Transfemoral	☐ Subclavian	☐ Direct Aortic
Vascular Access	☐ Left ☐ Right ☐ Percutaneous ☐ Cut-down	☐ Left ☐ Right	☐ Mini-Thoractomy ☐ Mini-Sternotomy
Planned Anesthesia		☐ General	☐ Conscious Sedation

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician. The Evolut™ R/ Evolut™ PRO+ transcatheter aortic valve has been approved by FDA for specific patient populations only.

Refer to the Instructions for Use for a full list of warnings, precautions, indications, and adverse events.

CAUTION: This report is provided pursuant to the terms of the Case Planner Physician Use Agreement and is 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.

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UC201402558a EN
07/2018