Medtronic

Evolut™ TAVR platform

Patient	WATSON, BARRY	**Height**	**m**	**Physician**	ROGERS, JAMES F,, DR,,, L	**Received Date**	
Sex	Male	**Weight**	**kg**	**Hospital**	RNSH	**Reviewed Date**	30.6.25
Year Of Birth (Age)	1952 (72)	**BMI**		**City**			
		EOA needed to achieve an iEOA > 0.85 cm²/m²		**Country**			

Clinical History

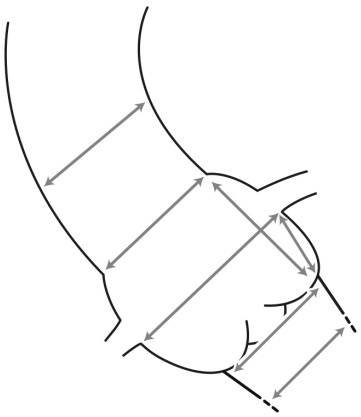
MEDTRONIC ANALYSIS

ANNULUS

Diameter (mm)	26.5 (Min)	x	31.1 (Max)	,	28.8 (Mean)
Perimeter (mm)	89.8	, Derived Ø (mm)	28.6		
Area (mm²)	630.7	, Derived Ø (mm)	28.3		

LVOT

Diameter (mm)	27.0 (Min)	x	33.6 (Max)	,	30.3 (Mean)
Perimeter (mm)	94.4	, Derived Ø (mm)	30.1		
Area (mm²)	687.2	, Derived Ø (mm)	29.6		



Max Ascending Aorta Diameter (mm)	36.4		
Sinotubular Junction Diameter (mm)	30.6 (Min)	x	31.0 (Max)
Sinus of Valsalva Diameter (mm)	32.9 (LCC)	34.3 (RCC)	35.5 (NCC)
Sinus of Valsalva Height (mm)	23.0 (LCC)	24.2 (RCC)	23.0 (NCC)
Coronary Ostia Height (mm)	16.3 (Left)	19.4 (Right)	

VIEWS

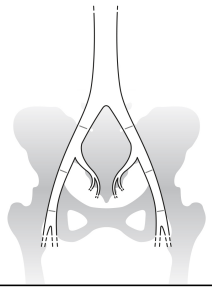
3 Cusp Coplanar View	LAO: 6°, Caudal: 3°
Cusp Overlap View	RAO: 18°, Caudal: 24°
Near Cusp Overlap View	

RIGHT

CIA Min Diameter (mm): 9.0 x 9.6

EIA Min Diameter (mm): 6.7 x 7.5

Femoral Min Diameter (mm): 7.9 x 8.4



LEFT

CIA Min Diameter (mm): 9.6 x 9.8

EIA Min Diameter (mm): 6.2 x 8.6

Femoral Min Diameter (mm): 7.3 x 8.6

Calcium: Mild ☐ Moderate ☐ Severe ☐

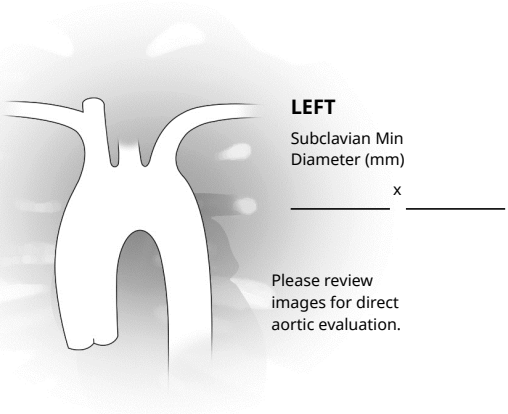
RIGHT

Subclavian Min Diameter (mm): x

Annular Angulation: ≈41°

LEFT

Subclavian Min Diameter (mm): x



Please review images for direct aortic evaluation.

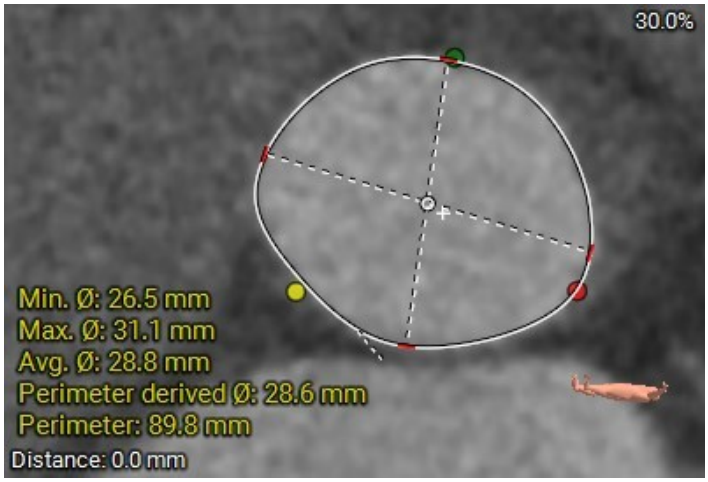
VIV ADDITIONAL MEASUREMENTS

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

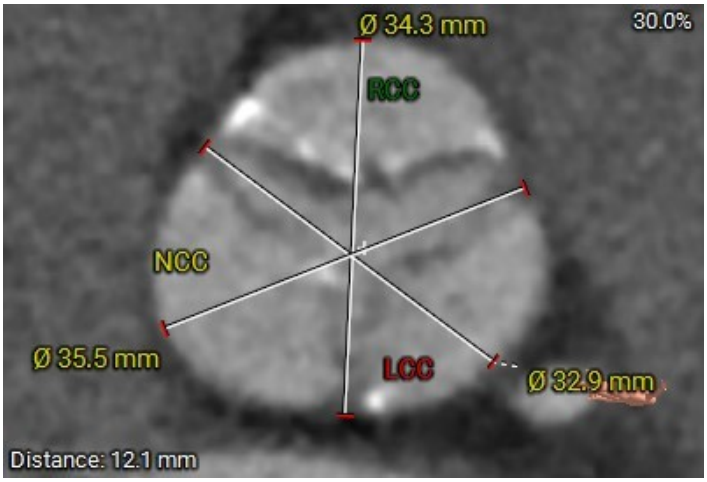
Procedural Considerations

Aorta

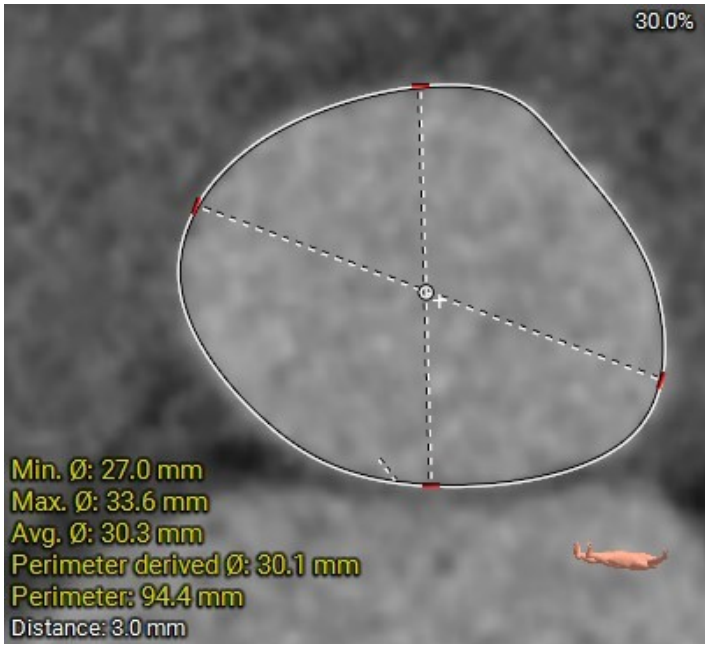
ANNULUS



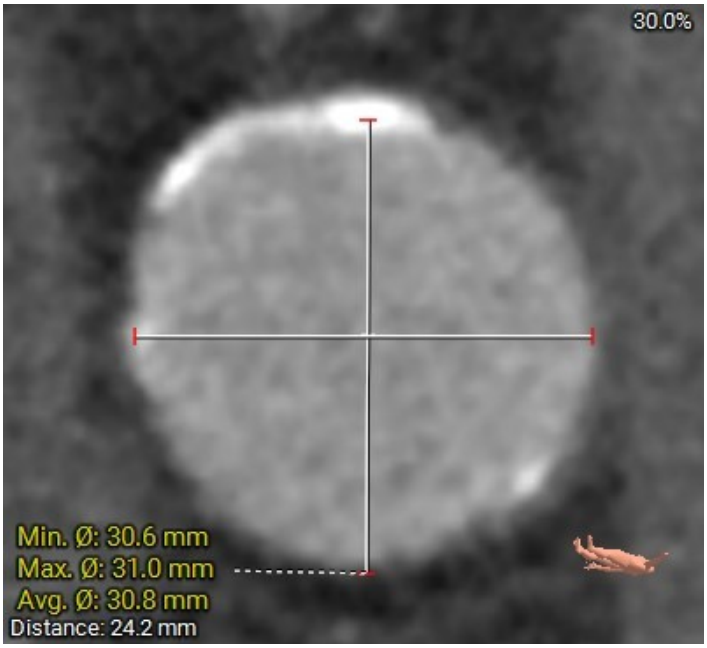
SOV DIAMETER



LVOT

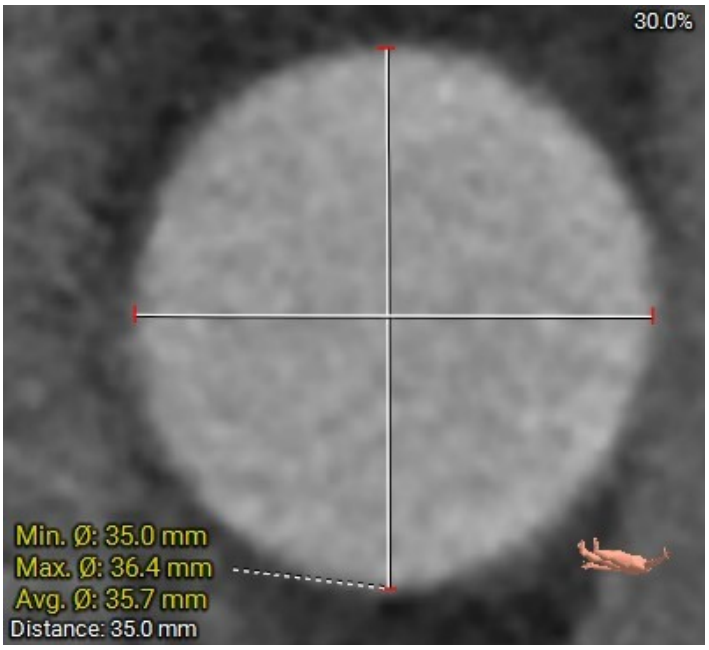


STJ

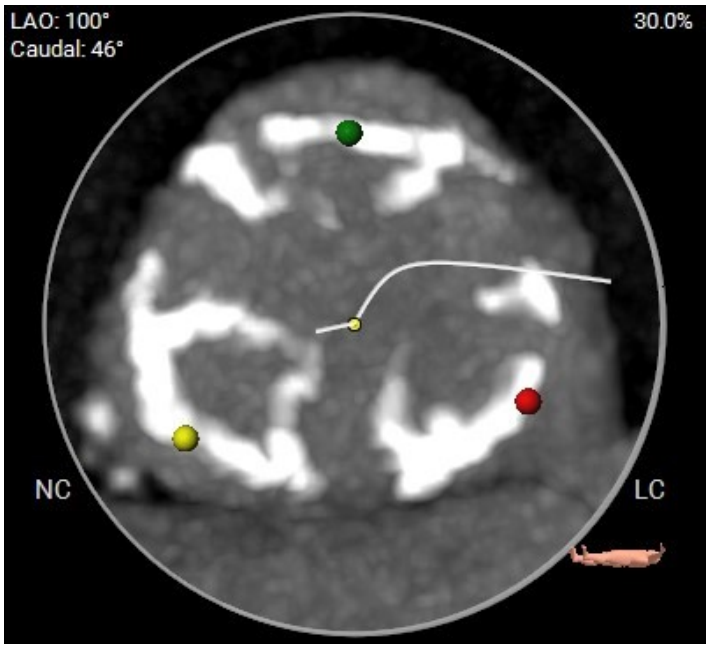


Aorta

ASCENDING AORTA

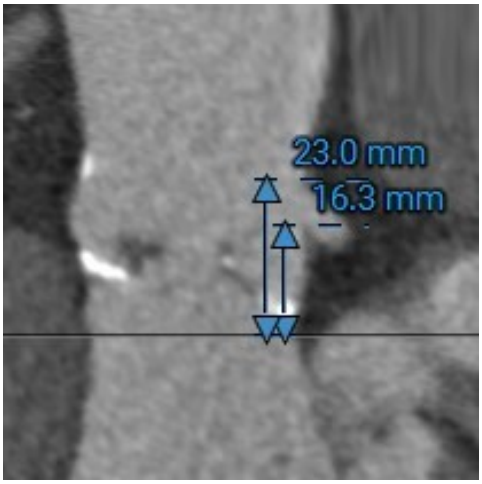


AORTIC VALVE CALCIFICATION

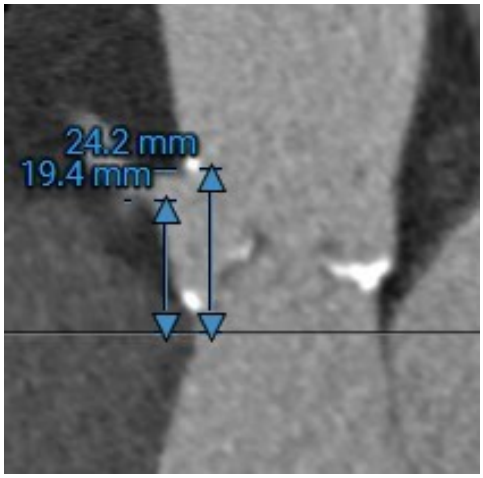


SINUS HEIGHT

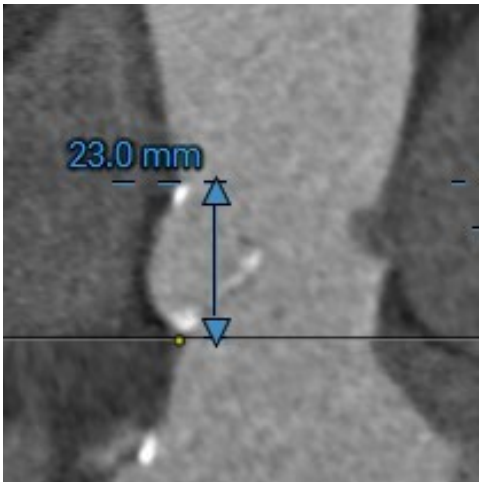
LCC



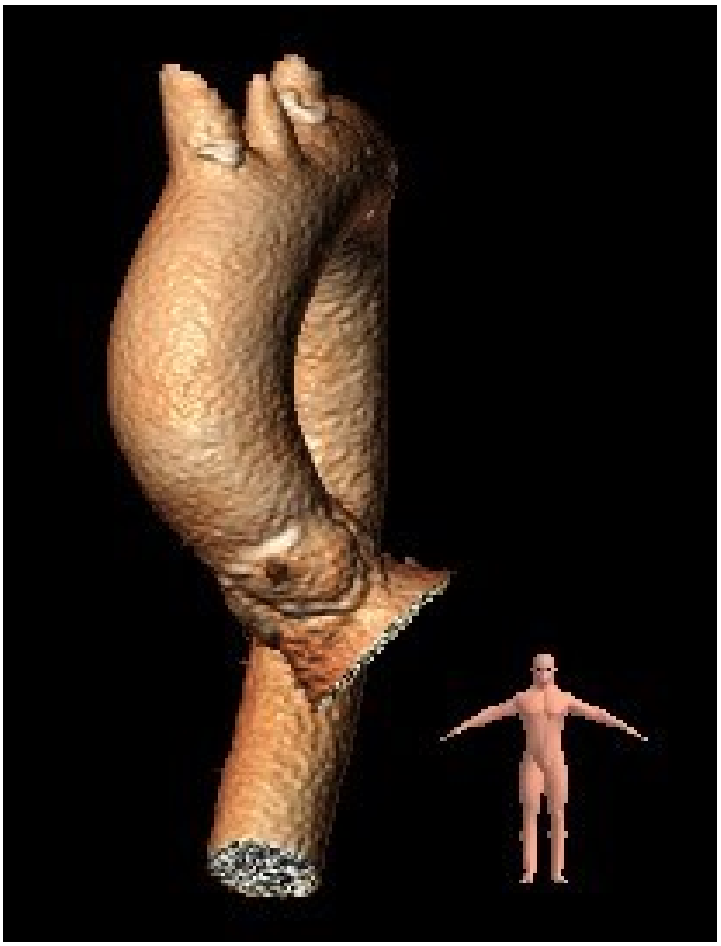
RCC



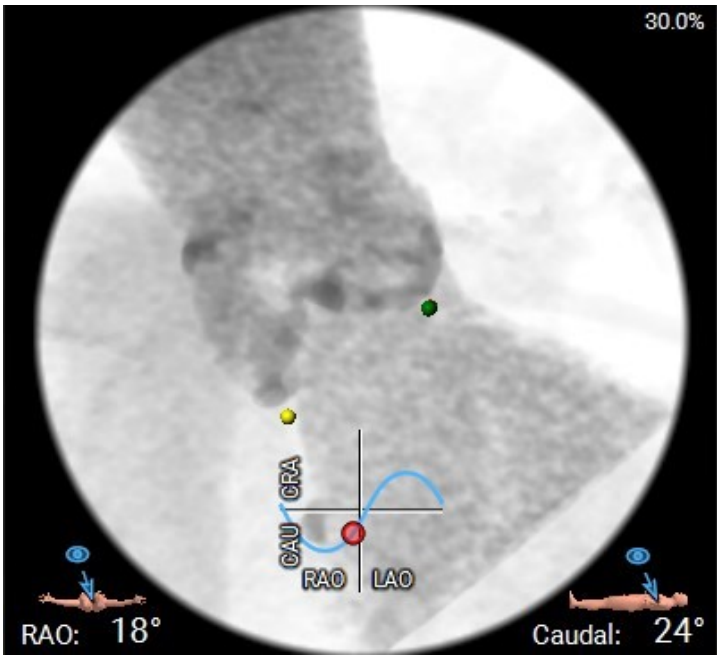
NCC



AORTIC ROOT

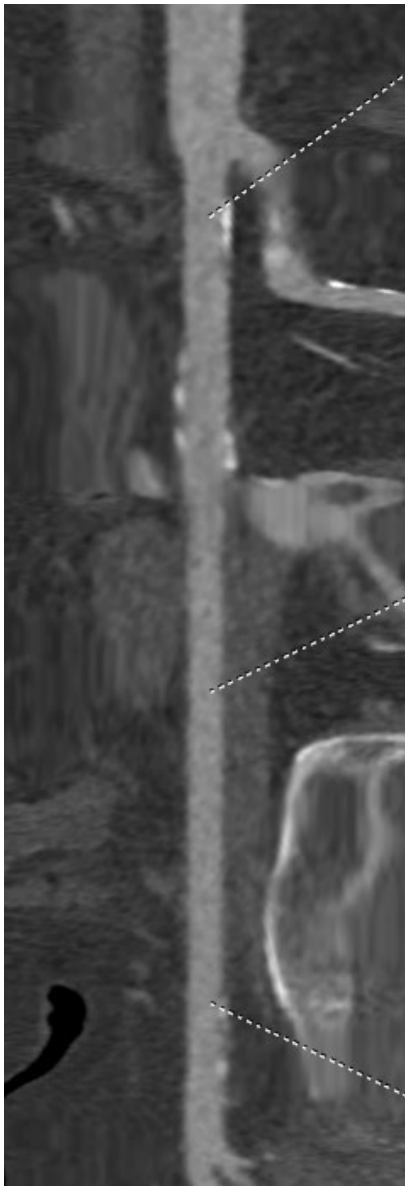


IMPLANTER'S VIEW



Annular Angulation

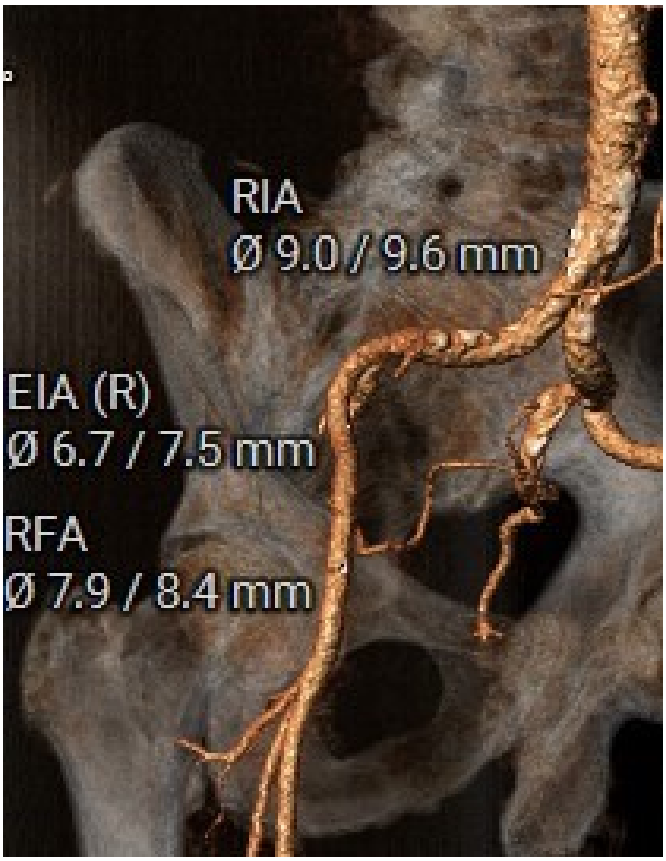
Femoral Access - Right



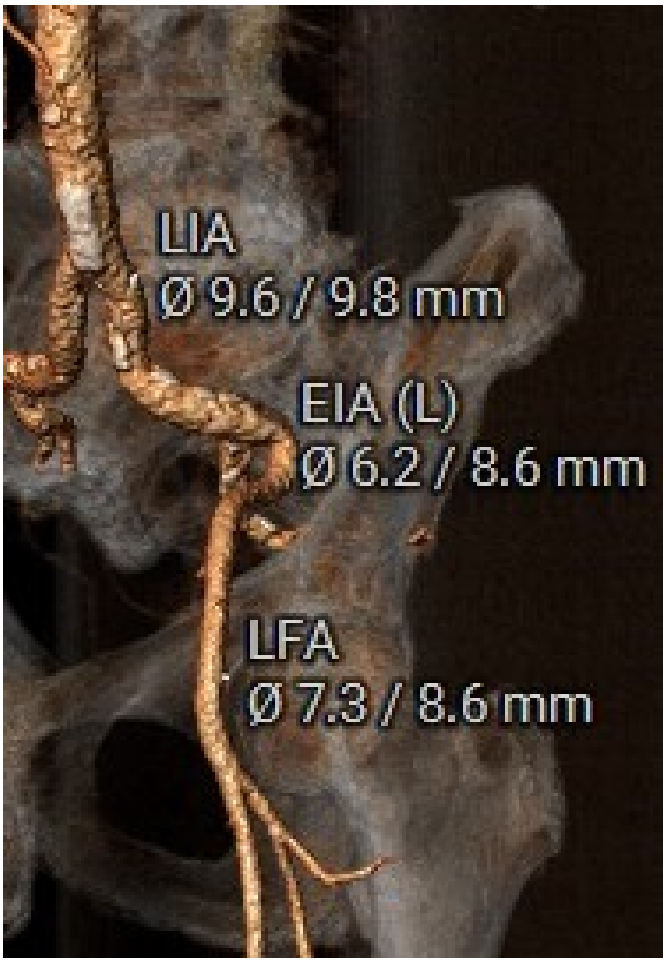
RIA

EIA (R)

RFA



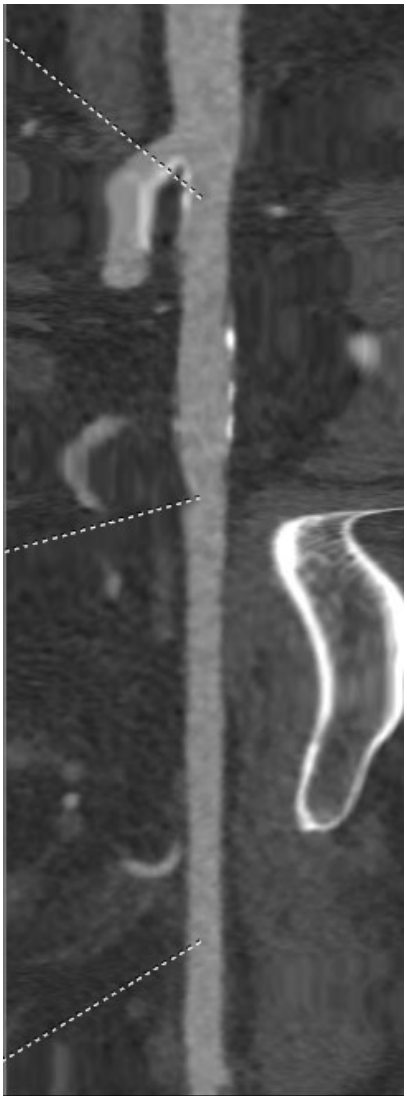
Femoral Access - Left



LIA

EIA (L)

LFA

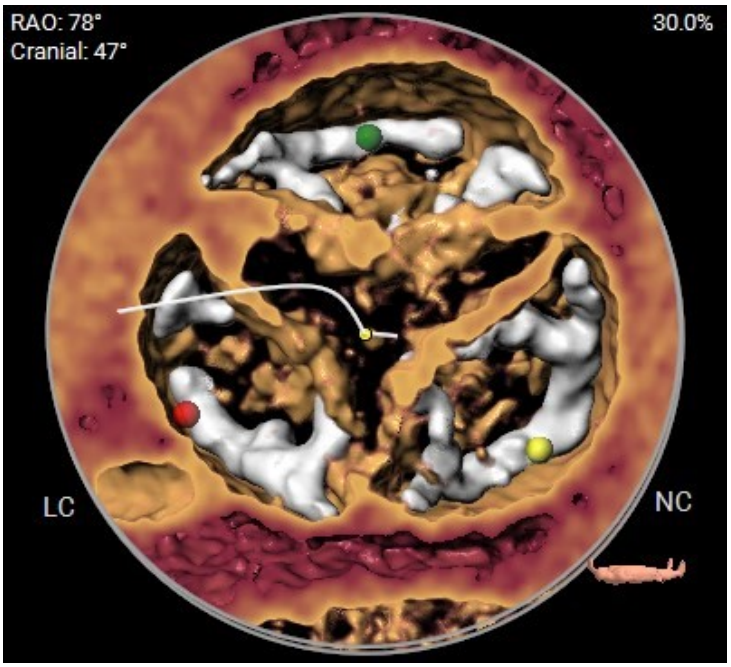


Additional Femoral Images

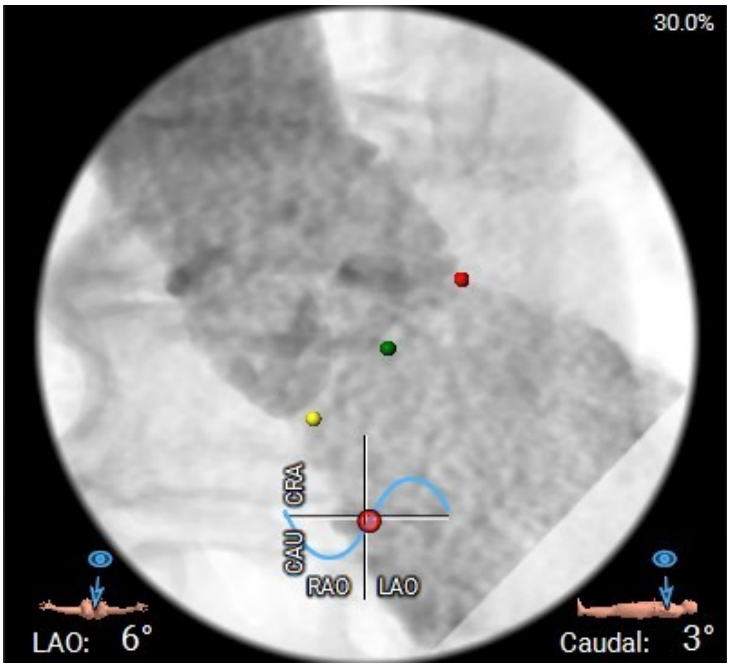
Dimmed background	Dimmed background
	

Additional Images

Hockey Puck (VR)



3 Cusp View



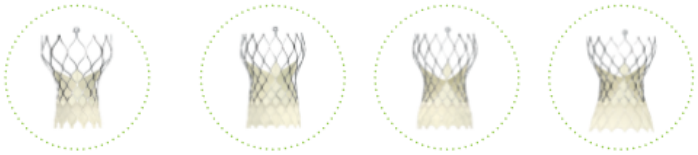
Calcifications

Medtronic

Evolut™ FX TAVR System

Patient valve selection criteria

Evolut FX bioprosthesis valve size selection



Size		23 mm	26 mm	29 mm	34 mm
Annulus diameter (A)	28.6 mm	17†/18–20 mm	20–23 mm	23–26 mm	26–30 mm
Annulus perimeter‡	89.8 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) (B)	34.2 mm	≥ 25 mm	≥ 27 mm	≥ 29 mm	≥ 31 mm
Sinus of Valsalva height (mean) (C)	23.4 mm	≥ 15 mm	≥ 15 mm	≥ 15 mm	≥ 16 mm
Oversizing Percentage		**-20%**	**-9%**	**1%**	**19%**

†Measurement for TAV-in-SAV only.
‡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.¤

§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.
¤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

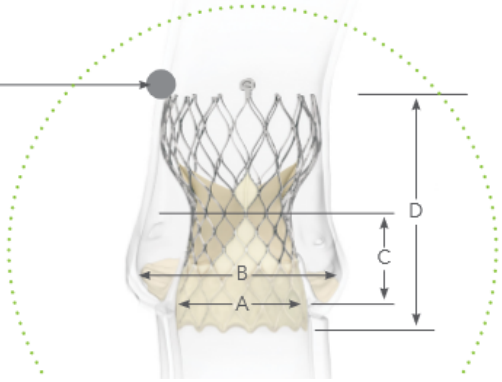
(A) Annulus diameter

(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+, and Evolut™ FX Systems are approved. See the CoreValve™ Evolut™ R, the CoreValve™ Evolut™ PRO, the Evolut™ PRO+ and the 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, 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.

Indications
The Medtronic CoreValve™ Evolut™ R, Evolut™ PRO+, and Evolut™ FX Systems are indicated for relief of aortic stenosis in patients with symptomatic heart disease due to severe native calcific aortic stenosis who are judged by a heart team, including a cardiac surgeon, to be appropriate for the transcatheter heart valve replacement therapy.

The Medtronic CoreValve Evolut R, Evolut PRO+, and Evolut FX Systems are indicated for use in patients with symptomatic heart disease due to failure (stenosed, insufficient, or combined) of a surgical bioprosthetic aortic valve who are judged by a heart team, including a cardiac surgeon, to be at high or greater risk for open surgical therapy (e.g., STS predicted risk of operative mortality score ≥ 8% or at a ≥ 15% risk of mortality at 30 days).

Contraindications
The CoreValve Evolut R, Evolut PRO+, and Evolut FX Systems are contraindicated in patients who cannot tolerate Nitinol (titanium or nickel), gold (for Evolut FX Systems alone), an anticoagulation/antiplatelet regimen, or who have active bacterial endocarditis or other active infections.

Warnings
General Implantation of the CoreValve Evolut R, Evolut PRO+, and Evolut FX Systems should be performed only by physicians who have received Medtronic CoreValve Evolut R, Evolut PRO+, or Evolut FX training. This procedure should only be performed where emergency aortic valve surgery can be performed promptly. Mechanical failure of the delivery catheter system and/or accessories may result in patient complications. *Transcatheter aortic valve (bioprosthesis)* Accelerated deterioration due to calcific degeneration of the bioprostheses may occur in: children, adolescents, or young adults; patients with altered calcium metabolism (e.g., chronic renal failure or hyperthyroidism).

Precautions
General Clinical long-term durability has not been established for the bioprosthesis. Evaluate bioprosthesis performance as needed during patient follow-up. The safety and effectiveness of the CoreValve Evolut R, Evolut PRO+, and Evolut FX Systems have not been evaluated in the pediatric population. The safety and effectiveness of the bioprostheses for aortic valve replacement have not been evaluated in the following patient populations: Patients who do not meet the criteria for symptomatic severe native aortic stenosis as defined: (1) symptomatic severe high-gradient aortic stenosis – aortic valve area ≤ 1.0 cm^2 or aortic valve area index ≤ 0.6 cm^2/m^2, a mean aortic valve gradient ≥ 40 mm Hg, or a peak aortic-jet velocity ≥ 4.0 m/s; (2) symptomatic severe low-flow, low-gradient aortic stenosis – aortic valve area ≤ 1.0 cm^2 or aortic valve area index ≤ 0.6 cm^2/m^2, a mean aortic valve gradient < 40 mm Hg, and a peak aortic-jet velocity < 4.0 m/s; with untreated, clinically significant coronary artery disease requiring revascularization; with a preexisting prosthetic heart valve with a rigid support structure in either the mitral or pulmonic position if either the preexisting prosthetic heart valve could affect the implantation or function of the bioprosthesis or the implantation of the bioprosthesis could affect the function of the preexisting prosthetic heart valve; patients with liver failure (Child-Pugh Class C); with cardiogenic shock manifested by low cardiac output, vasopressor dependence, or mechanical hemodynamic support; patients who are pregnant or breastfeeding. The safety and effectiveness of a CoreValve Evolut R, Evolut PRO+, or Evolut FX bioprosthesis implanted within a failed preexisting transcatheter bioprosthesis have not been demonstrated. Implanting a CoreValve Evolut R, Evolut PRO+, or Evolut FX bioprosthesis in a degenerated surgical bioprosthetic valve (transcatheter aortic valve in surgical aortic valve [TAV-in-SAV]) should be avoided in the following conditions: The degenerated surgical bioprosthetic valve presents with: a significant concomitant paravalvular leak (between the prosthesis and the native annulus), is not securely fixed in the native annulus, or is not structurally intact (e.g., wire form frame fracture); partially detached leaflet that in the aortic position may obstruct a coronary ostium; stent frame with a manufacturer-labeled inner diameter < 17 mm. The safety and effectiveness of the bioprostheses for aortic valve replacement have not been evaluated in patient populations presenting with the following: Blood dyscrasias as defined as leukopenia (WBC < 1,000 cells/mm^3), thrombocytopenia (platelet count < 50,000 cells/mm^3), history of bleeding diathesis or coagulopathy, or hypercoagulable states; congenital unicuspid valve; mixed aortic valve disease (aortic stenosis and aortic regurgitation with predominant aortic regurgitation [3-4+]); moderate to severe (3-4+) or severe (4+) mitral or severe (4+) tricuspid regurgitation; hypertrophic obstructive cardiomyopathy; new or untreated echocardiographic evidence of intracardiac mass, thrombus, or vegetation; native aortic annulus size < 18 mm or > 30 mm per the baseline diagnostic imaging or surgical bioprosthetic aortic annulus size < 17 mm or > 30 mm; transarterial access unable to accommodate an 18 Fr introducer sheath or the 14 Fr equivalent EnVeo InLine™ Sheath when using models ENVEOR-US/D-EVPROP2329US or Evolut FX Delivery Catheter System with InLine™ Sheath when using model D-EVOLUTFX-2329 or transarterial access unable to accommodate a 20 Fr introducer sheath or the 16 Fr equivalent EnVeo InLine Sheath when using model ENVEOR-N-US or transarterial access unable to accommodate a 22 Fr introducer sheath or the 18 Fr equivalent Evolut PRO+ InLine Sheath when using model D-EVPROP34US or Evolut FX Delivery Catheter System with InLine Sheath when using model D-EVOLUTFX-34; prohibitive left ventricular outflow tract calcification; sinus of Valsalva anatomy that would prevent adequate coronary perfusion; significant aortopathy requiring ascending aortic replacement; moderate to severe mitral stenosis; severe ventricular dysfunction with left ventricular ejection fraction (LVEF) < 20%; symptomatic carotid or vertebral artery disease; and severe basal septal hypertrophy with an outflow gradient.

Before Use Exposure to glutaraldehyde may cause irritation of the skin, eyes, nose, and throat. Avoid prolonged or repeated exposure to the vapors. Damage may result from forceful handling of the catheter. Prevent kinking of the catheter when removing it from the packaging. The bioprosthesis size must be appropriate to fit the patient's anatomy. Proper sizing of the devices is the responsibility of the physician. Refer to the Instructions for Use for available sizes. Failure to implant a device within the sizing matrix could lead to adverse effects such as those listed below. Patients must present with transarterial access vessel diameters of ≥ 5 mm when using models ENVEOR-US/D-EVPROP2329US/D-EVOLUTFX-2329 or ≥ 5.5 mm when using model ENVEOR-N-US or ≥ 6 mm when using models D-EVPROP34US/D-EVOLUTFX-34, or patients must present with an ascending aortic (direct aortic) access site ≥ 60 mm from the basal plane for both systems. Implantation of the bioprosthesis should be avoided in patients with aortic root angulation (angle between plane of aortic valve annulus and horizontal plane/vertebrae) of > 30° for right subclavian/axillary access or > 70° for femoral and left subclavian/axillary access. For subclavian access, patients with a patent left internal mammary artery (LIMA) graft must present with access vessel diameters that are either ≥ 5.5 mm when using models ENVEOR-L-US/D-EVPROP2329US/D-EVOLUTFX-2329 or ≥ 6 mm when using model ENVEOR-N-US or ≥ 6.5 mm when using models D-EVPROP34US/D-EVOLUTFX-34. Use caution when using the subclavian/axillary approach in patients with a patent LIMA graft or patent RIMA graft. For direct aortic access, ensure the access site and trajectory are free of patent RIMA or a preexisting patent RIMA graft. For transfemoral access, use caution in patients who present with multiplanar curvature of the aorta, acute angulation of the aortic arch, an ascending aortic aneurysm, or severe calcification in the aorta and/or vasculature. If ≥ 2 of these factors are present, consider an alternative access route to prevent vascular complications. Limited clinical data are available for transcatheter aortic valve replacement in patients with a congenital bicuspid aortic valve who are deemed to be at low surgical risk. Anatomical characteristics should be considered when using the valve in this population. In addition, patient age should be considered as long-term durability of the valve has not been established.

During Use After the procedure, administer appropriate antibiotic prophylaxis as needed for patients at risk for prosthetic valve infection and endocarditis. After the procedure, administer anticoagulation and/or antiplatelet therapy per physician/clinical judgment. Excessive contrast media may cause renal failure. Prior to the procedure, measure the patient's creatinine level. During the procedure, monitor contrast media usage. Conduct the procedure under fluoroscopy. Fluoroscopic procedures are associated with the risk of radiation damage to the skin, which may be painful, disfiguring, and long-term. The safety and efficacy of a CoreValve Evolut R, Evolut PRO+, or Evolut FX bioprosthesis implanted within a transcatheter bioprosthesis have not been demonstrated.

Potential adverse events
Potential risks associated with the implantation of the CoreValve Evolut R, Evolut PRO+, or Evolut FX transcatheter aortic valve may include, but are not limited to, the following: • death • myocardial infarction, cardiac arrest, cardiogenic shock, or cardiac tamponade • coronary occlusion, obstruction, or vessel spasm (including acute coronary closure) • cardiovascular injury (including rupture, perforation, tissue erosion, or dissection of vessels, ascending aorta trauma, ventricle, myocardium, or valvular structures that may require intervention) • emergent surgical or transcatheter intervention (e.g., coronary artery bypass, heart valve replacement, valve explant, percutaneous coronary intervention [PCI], balloon valvuloplasty) • prosthetic valve dysfunction (regurgitation or stenosis) due to fracture; bending (out-of-round configuration) of the valve frame; underexpansion of the valve frame; calcification; pannus; leaflet wear, tear, prolapse, or retraction; poor valve coaptation; suture breaks or disruption; leaks; mal-sizing (prosthesis-patient mismatch); malposition (either too high or too low)/malplacement • prosthetic valve migration/embolization • prosthetic valve endocarditis • prosthetic valve thrombosis • delivery catheter system malfunction resulting in the need for additional recrossing of the aortic valve and prolonged procedural time • delivery catheter system component migration/embolization • stroke (ischemic or hemorrhagic), transient ischemic attack (TIA), or other neurological deficits • individual organ (e.g., cardiac, respiratory, renal [including acute kidney failure]) or multi-organ insufficiency or failure • major or minor bleeding that may require transfusion or intervention (including life-threatening or disabling bleeding) • vascular access-related complications (e.g., dissection, perforation, pain, bleeding, hematoma, pseudoaneurysm, irreversible nerve injury, compartment syndrome, arteriovenous fistula, or stenosis) • mitral valve regurgitation or injury • conduction system disturbances (e.g., atrioventricular node block, left bundle-branch block, asystole), which may require a permanent pacemaker • infection (including septicemia) • hypotension or hypertension • hemolysis • peripheral ischemia • General surgical risks applicable to transcatheter aortic valve implantation: • bowel ischemia • abnormal lab values (including electrolyte imbalance) • allergic reaction to antiplatelet agents, contrast medium, or anesthesia • exposure to radiation through fluoroscopy and angiography • permanent disability.

Please reference the CoreValve Evolut R, Evolut PRO+, and Evolut FX Instructions for Use for more information regarding indications, warnings, precautions, and potential adverse events.

Caution: Federal Law (USA) restricts these devices to the sale by or on the order of a physician.

The commercial name of the Evolut™ R device is Medtronic CoreValve™ Evolut™ R 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.

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UC202202685b EN
06/2022

Notes:

Conclusion:
Reviewer Name: Raquel Hughes
Review Date: 30.6.25