Medtronic

Evolut™ TAVR platform

Patient FRALEY, RICHARD L SR, 7/19/1943 **Implant Team** Bleszynski/Jahangir **Hospital** Mountainview **Date** 2/2/2026

PATIENT DEMOGRAPHICS (provided by hospital)

	Age: 82	**Sex:** Male	**Height:** 1.73 **m**	**Weight:** 70.4 **kg**	**BSA:** 1.84 **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: 1.56 cm²** **LVEF %:** **Creatinine Clearance (cc/min):** **Mitral Regurgitation:** Mild ☐ Moderate ☐ Severe ☐ **Previous BAV** Y ☐ N ☐ **Date:** **Pre-existing conduction disturbance:**				
Implant Date		**(DD-MM-YYYY)**					
Comments	Annulus perimeter of 74.6mm and mean SOV of 33.5mm indicates a 29mm EvolutFX+ with 22% oversizing						

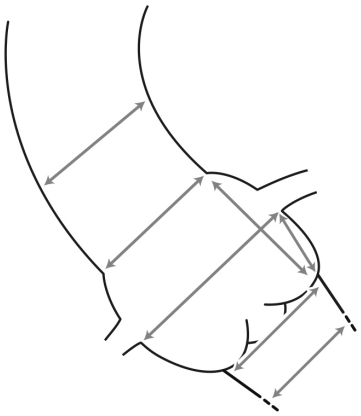
MEDTRONIC ANALYSIS

ANNULUS

Diameter (mm)	20.4 (Min)	x	26.2 (Max)	,	23.3 (Mean)
Perimeter (mm)	**74.6**	, Derived Ø (mm)	**23.8**		
Area (mm²)	429.1	, Derived Ø (mm)	23.4		

LVOT

Diameter (mm)	20.1 (Min)	x	27.3 (Max)	,	23.7 (Mean)
Perimeter (mm)	75.0	, Derived Ø (mm)	23.9		
Area (mm²)	431.6	, Derived Ø (mm)	23.4		



Max Ascending Aorta Diameter (mm)	39.3		
Sinotubular Junction Diameter (mm)	32.8 (Min)	x	33.8 (Max)
Sinus of Valsalva Diameter (mm)	33.9 (LCC)	32.8 (RCC)	33.9 (NCC)
Sinus of Valsalva Height (mm)	17.0 (LCC)	20.0 (RCC)	20.8 (NCC)
Coronary Ostia Height (mm)	8.6 (Left)	17.0 (Right)	

VIEWS

Cusp Overlap View	RAO: 16°, Caudal: 37°
3 Cusp Coplanar View	LAO: 4°, Caudal: 17°
Near Cusp Overlap View	RAO: 8°, Caudal: 29°

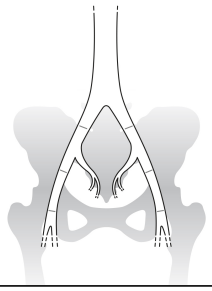
SMART Trial†

RIGHT

CIA Min Diameter (mm): 7.5 x 8.0

EIA Min Diameter (mm): 6.0 x 6.1

Femoral Min Diameter (mm): 7.0 x 8.1



LEFT

CIA Min Diameter (mm): 8.0 x 8.7

EIA Min Diameter (mm): 5.9 x 6.5

Femoral Min Diameter (mm): 7.0 x 8.4

Calcium: Mild ☐ Moderate ☐ Severe ☐

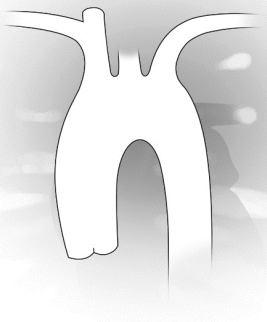
RIGHT

Subclavian Min Diameter (mm): x

Aortic Root Angle: 44°

LEFT

Subclavian Min Diameter (mm): x



Please review images for direct aortic evaluation.

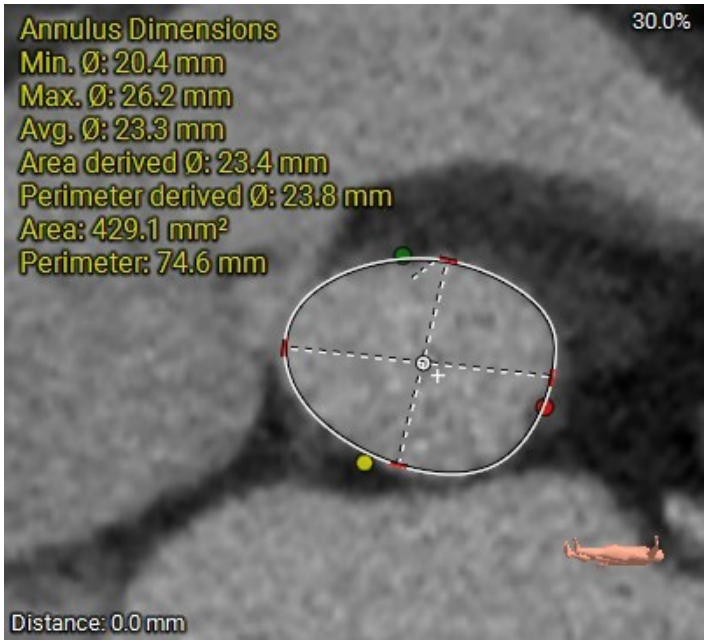
VIV ADDITIONAL MEASUREMENTS

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

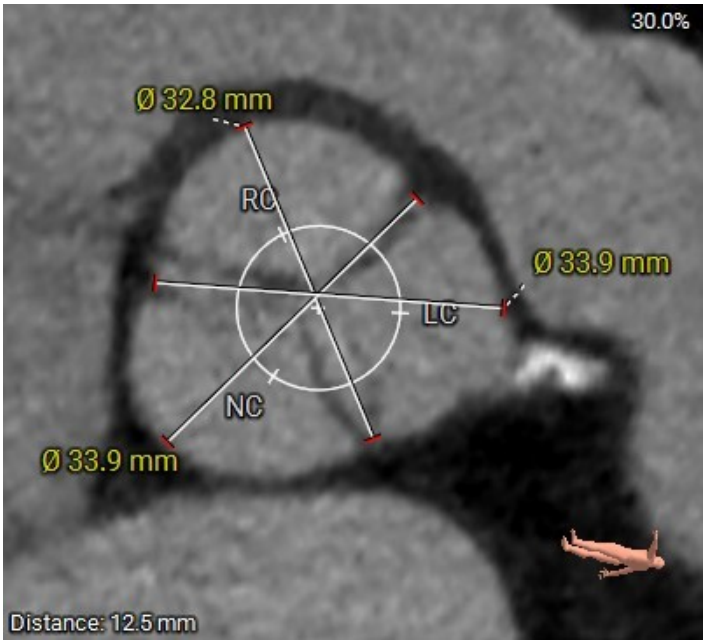
Procedural Considerations

Aorta

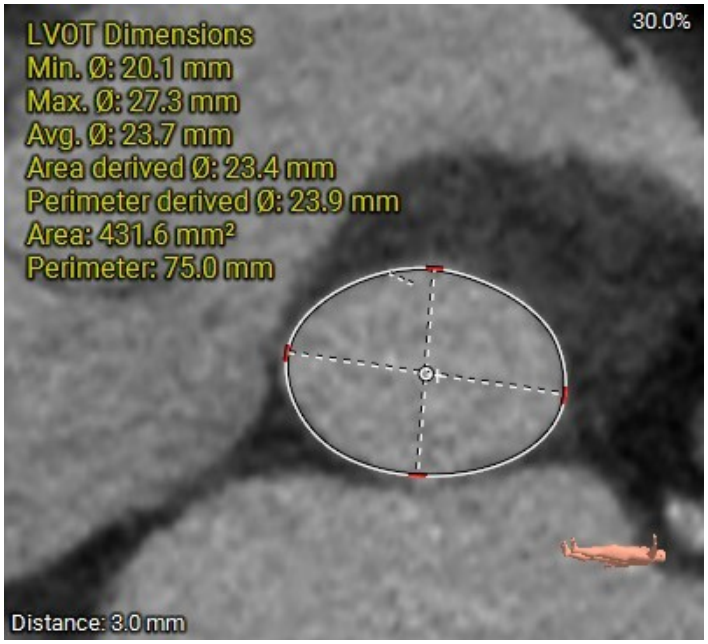
ANNULUS



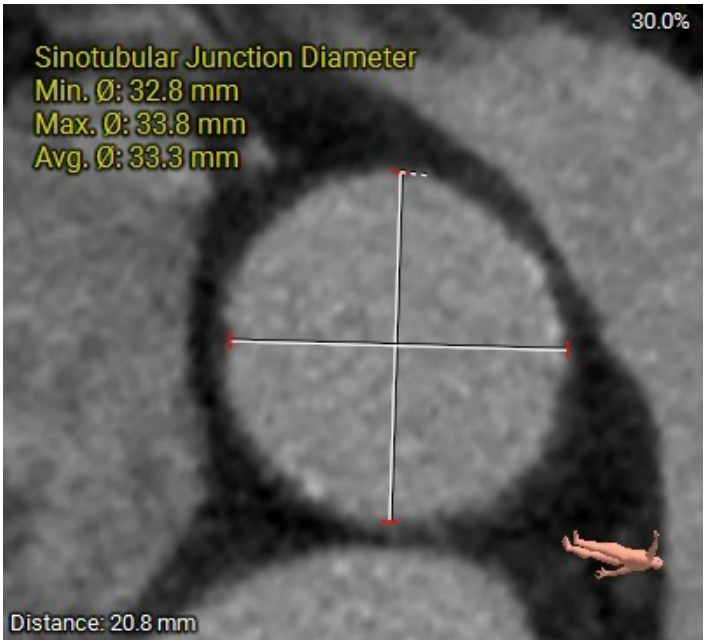
SOV DIAMETER



LVOT

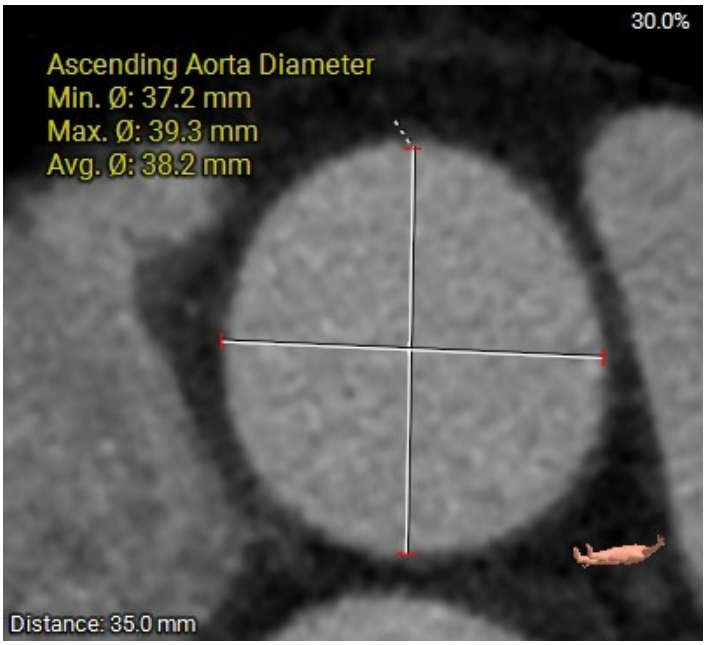


STJ

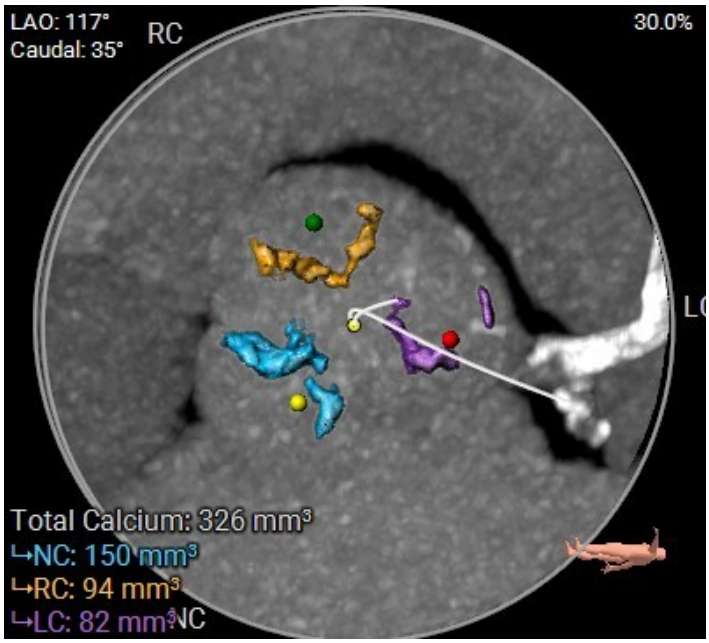


Aorta

ASCENDING AORTA

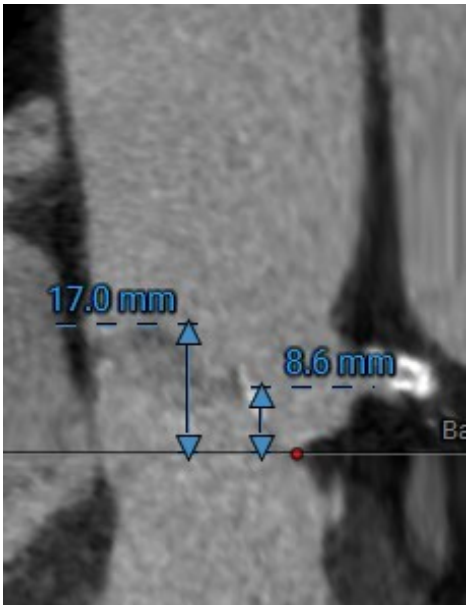


AORTIC VALVE CALCIFICATION

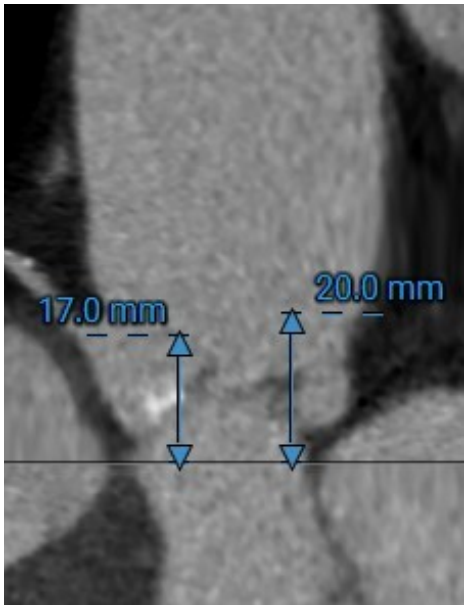


SINUS HEIGHT

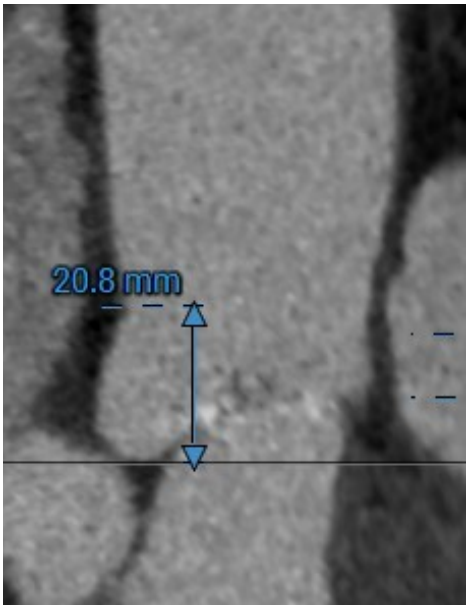
LCC



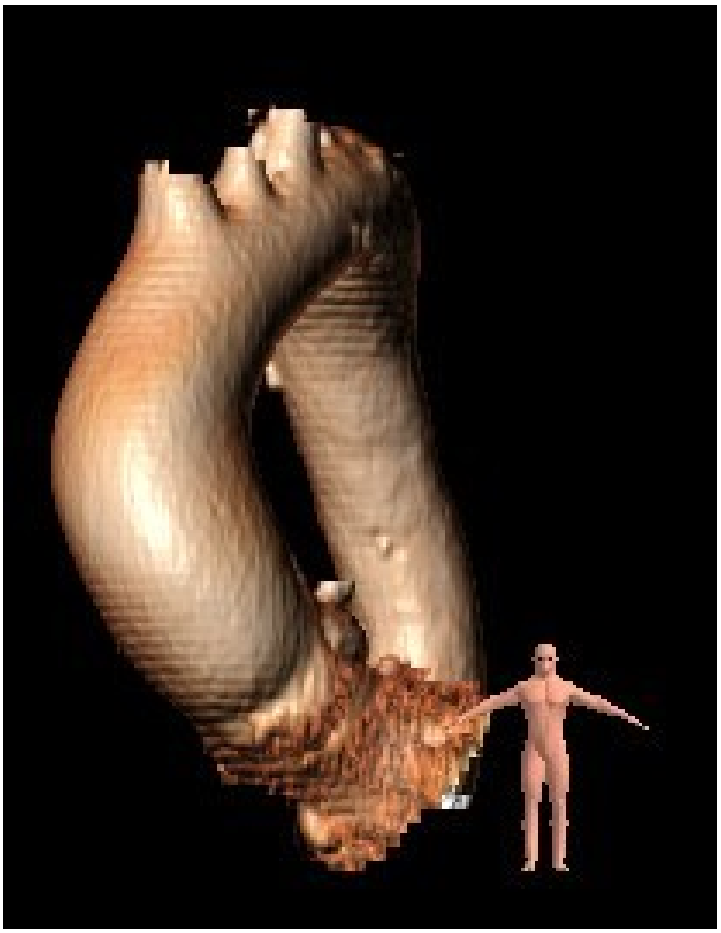
RCC



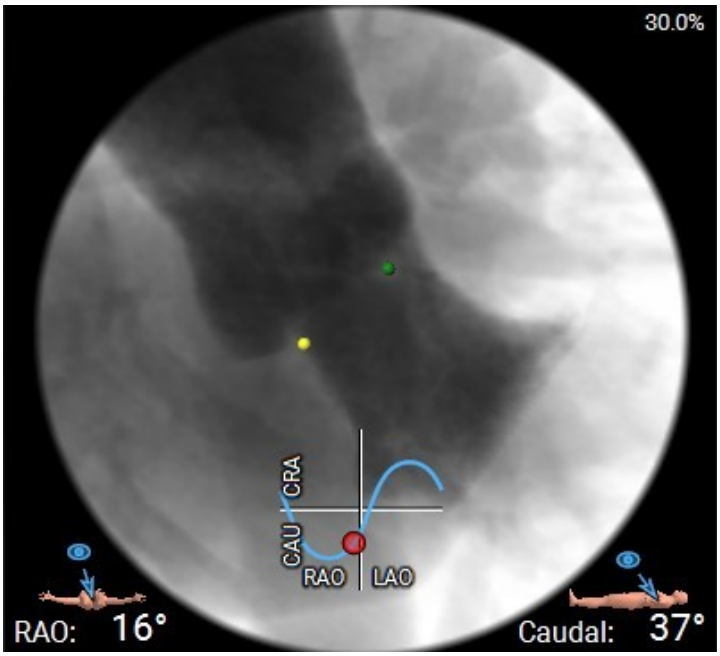
NCC



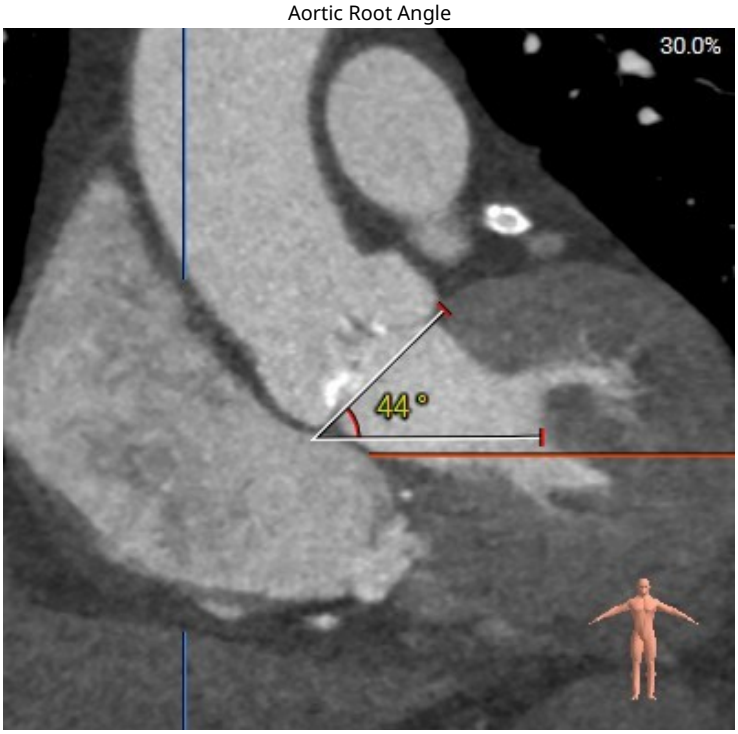
AORTIC ROOT



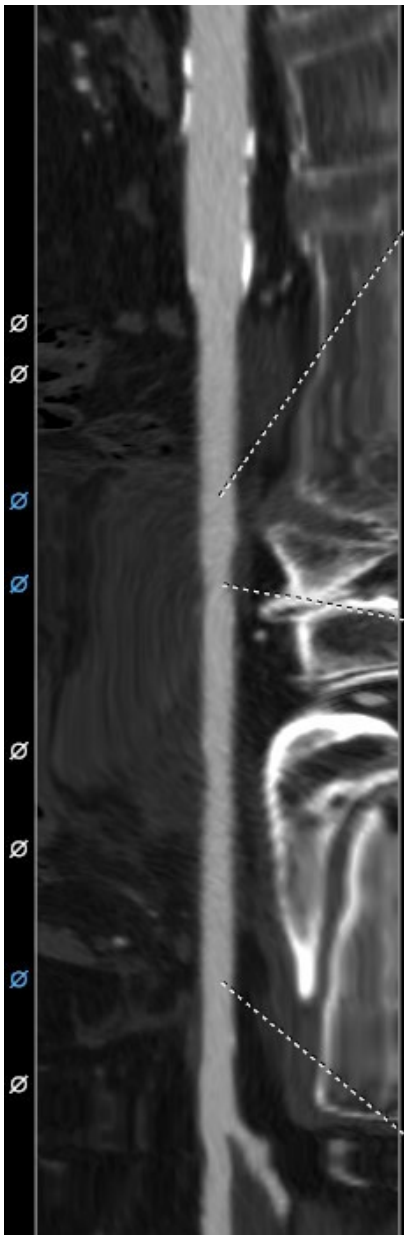
IMPLANTER'S VIEW



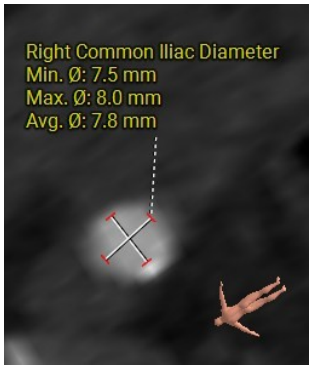
Aortic Root Angle



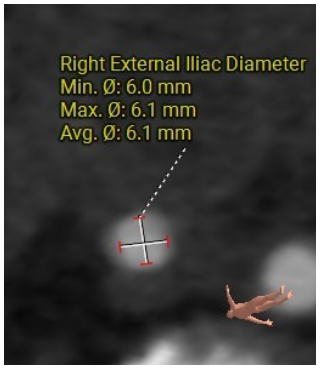
Femoral Access - Right



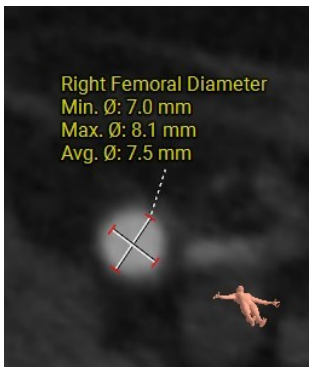
CIA (R)

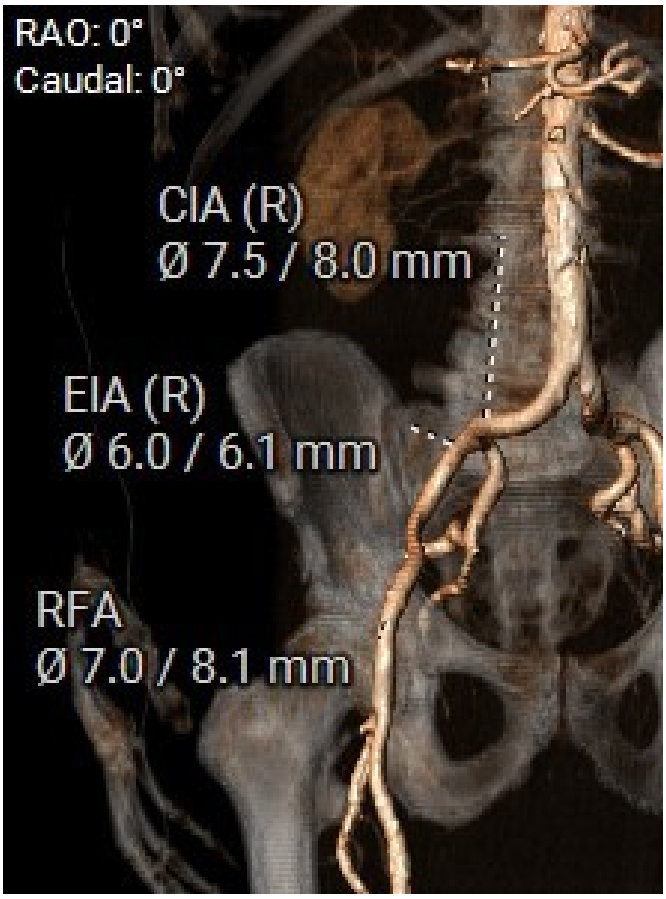


EIA (R)

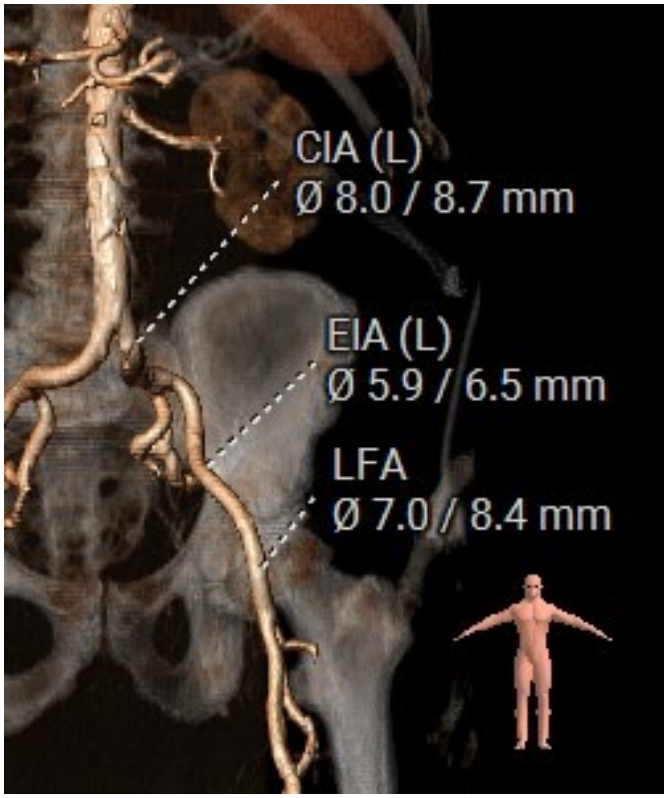


RFA

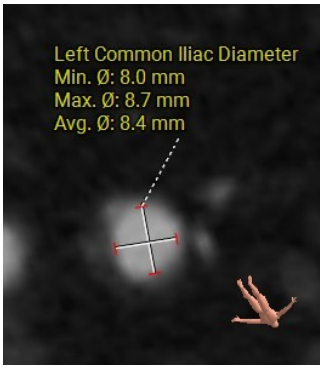




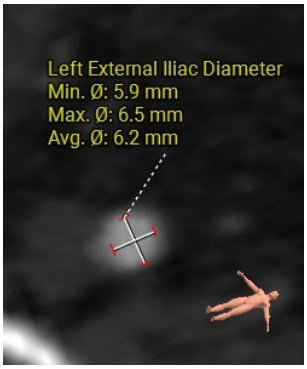
Femoral Access - Left



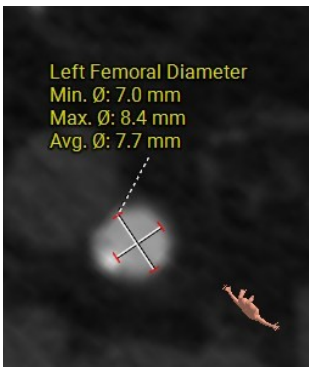
CIA (L)

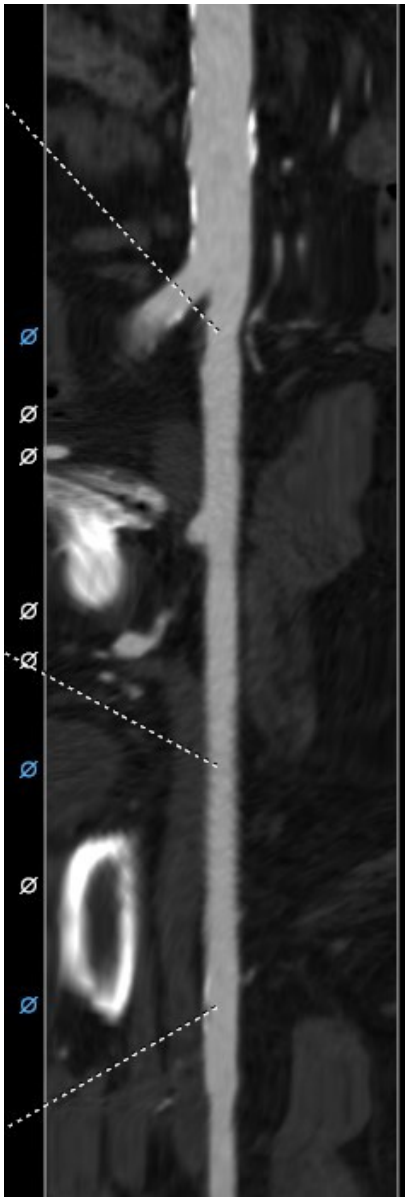


EIA (L)

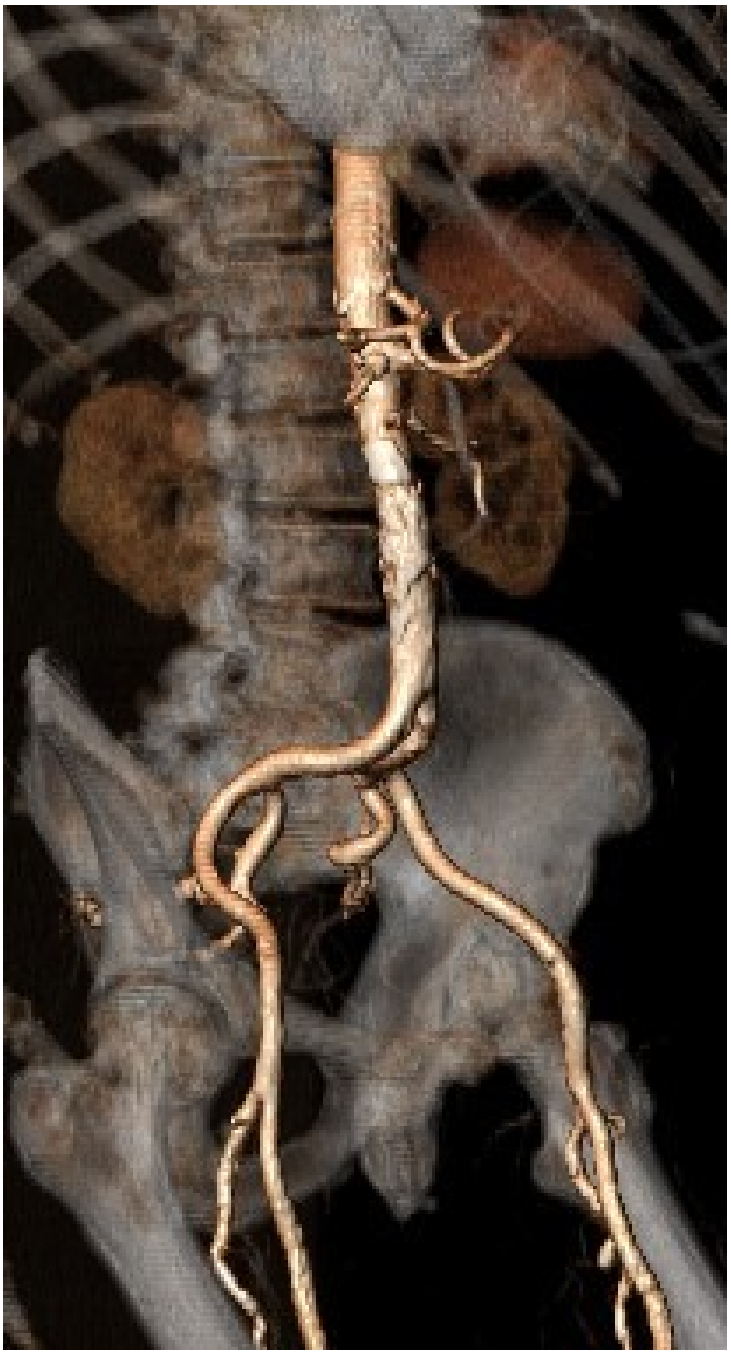
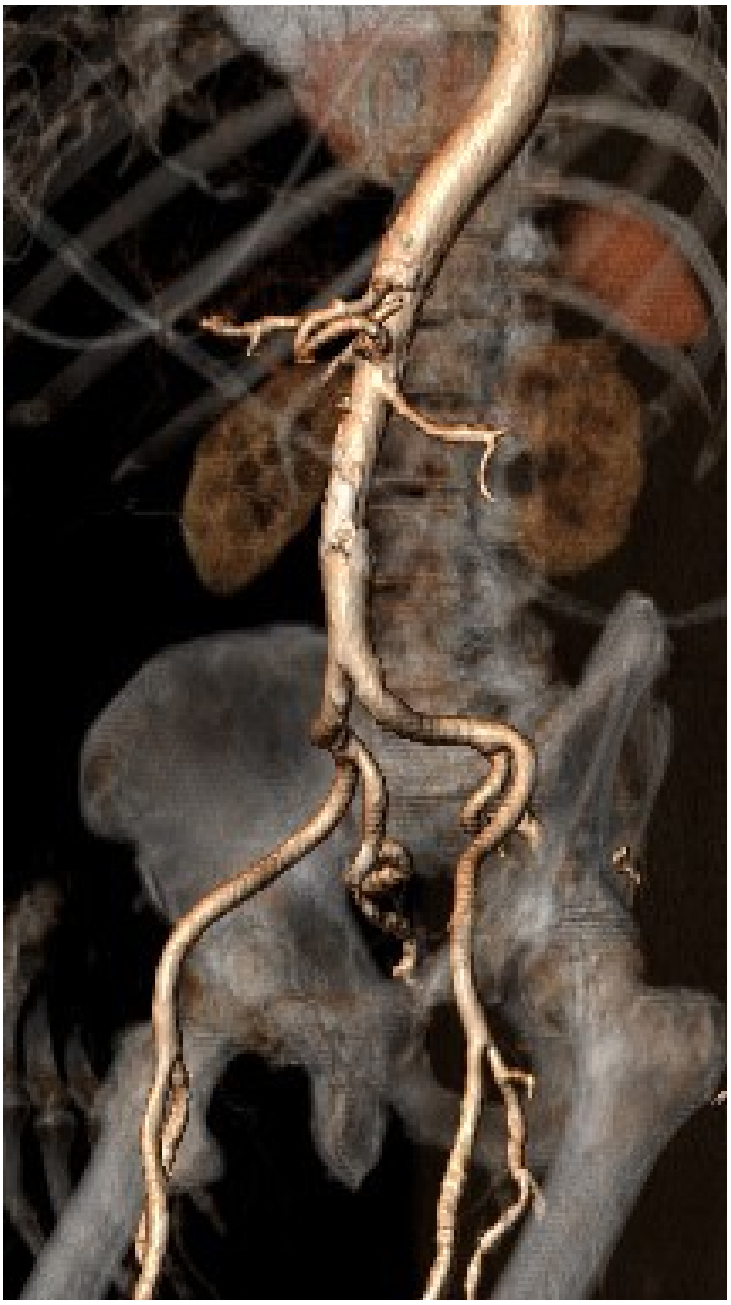


LFA

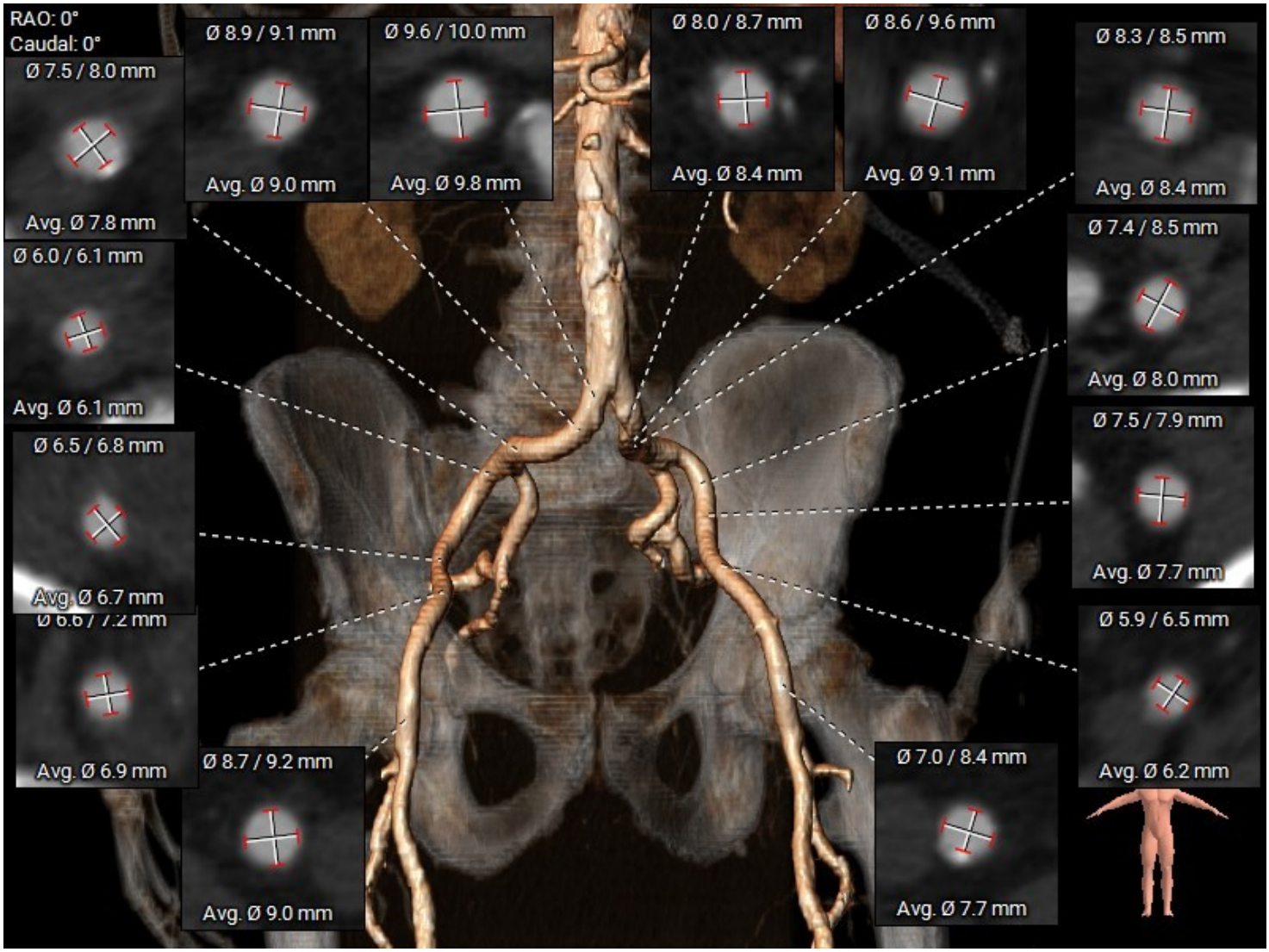


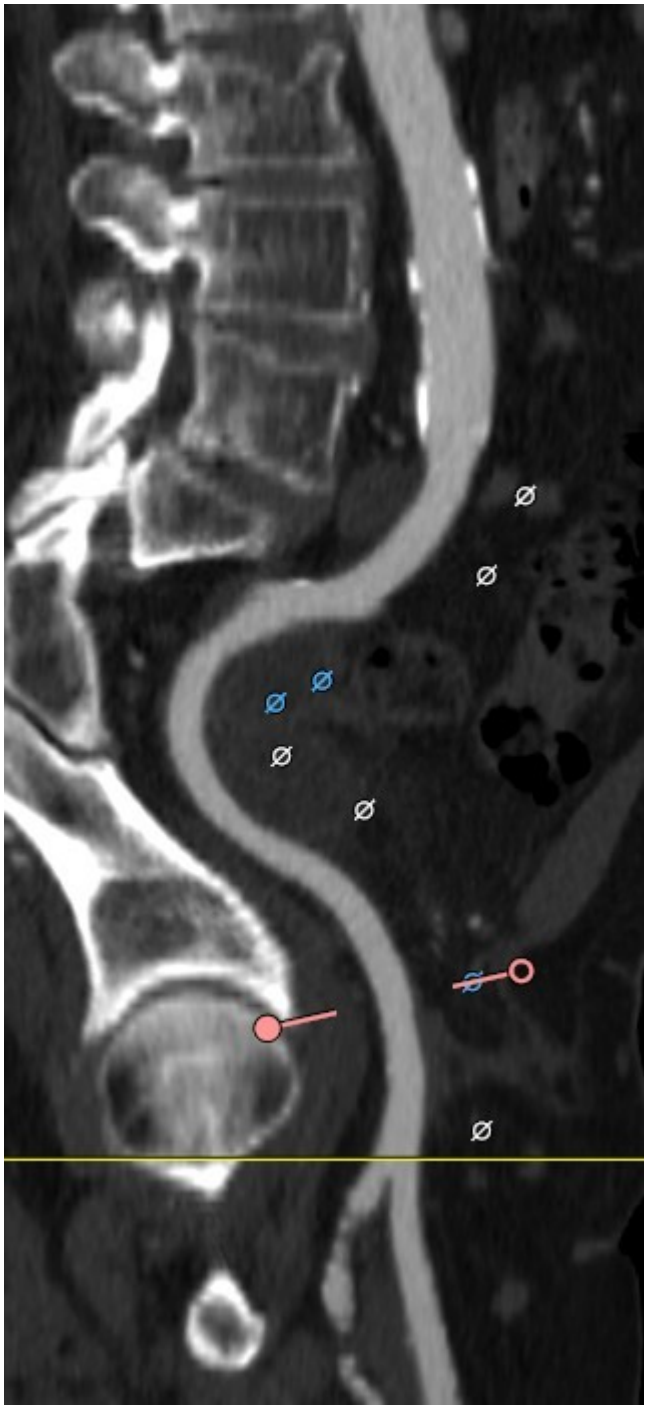
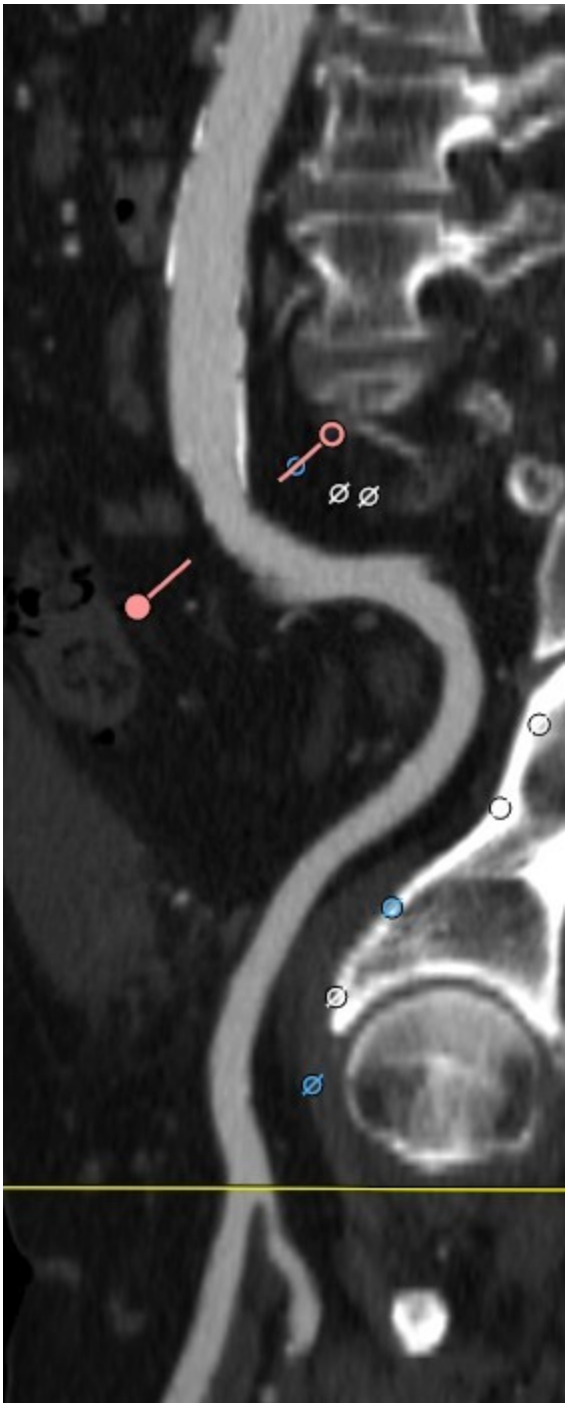


Additional Femoral Images

Dimmed background	Dimmed background
	

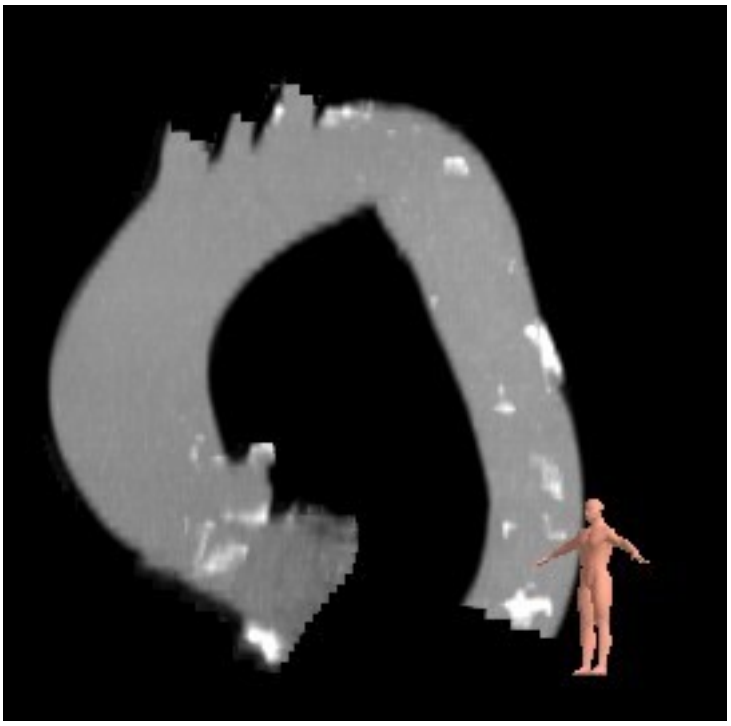
Dimmed background



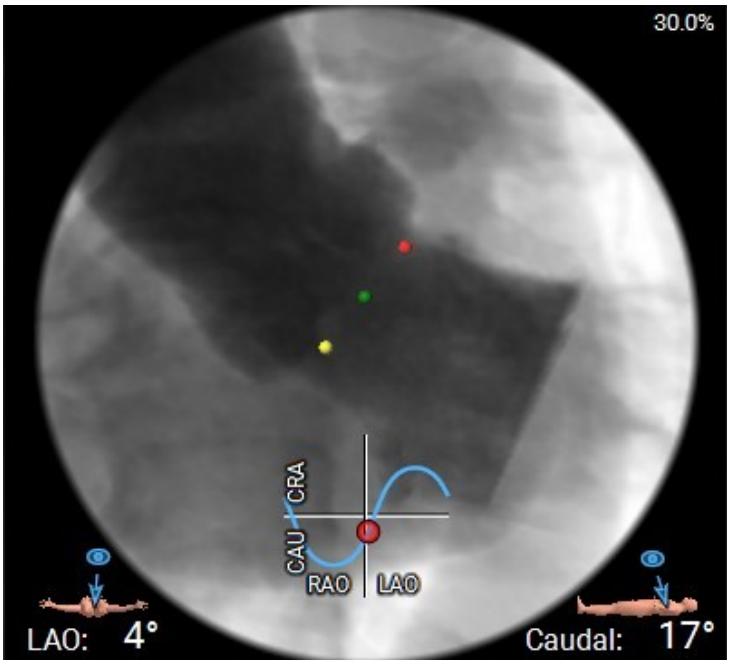
Snake View - Right Iliac	Snake View - Left Iliac
	

Additional Images

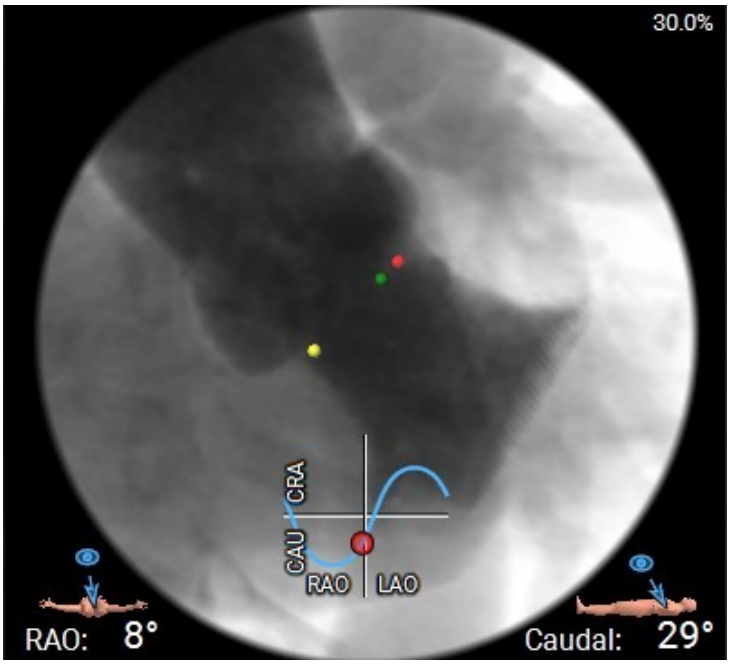
Calcifications



3 CUSP COPLANAR



NEAR CUSP



Evolut™ Hemodynamic Reference Values[1]

Annular Diameter (mm)	≤ 22.3	> 22.3 to ≤ 23.2	> 23.2 to ≤ 24.7	> 24.7 to ≤ 26.2	> 26.2 to ≤ 30.2
Diameter-derived Annular Area (mm²)	≤ 391	391-423	423-479	479-539	539-716
EOA Ref Data (cm²)	1.66 ± 0.42 (n = 53)	1.82 ± 0.43 (n = 38)	1.98 ± 0.56 (n = 62)	1.98 ± 0.59 (n = 49)	2.56 ± 0.77 (n = 53)

Patient BSA (m²)					
1.3	1.28	1.40	1.52	1.52	1.97
1.4	1.19	1.30	1.41	1.41	1.83
1.5	1.11	1.21	1.32	1.32	1.71
1.6	1.04	1.14	1.24	1.24	1.60
1.7	0.98	[illegible]	1.16	1.16	1.51
1.8	0.92	1.01	1.10	1.10	1.42
1.9	0.87	0.96	1.04	1.04	1.35
2	0.83	0.91	0.99	0.99	1.28
2.1	0.79	0.87	0.94	0.94	1.22
2.2	0.75	0.83	0.90	0.90	1.16
2.3	0.72	0.79	0.86	0.86	1.11
2.4	0.69	0.76	0.83	0.83	1.07
2.5	0.66	0.73	0.79	0.79	1.02
2.6	0.64	0.70	0.76	0.76	0.98
2.7	0.61	0.67	0.73	0.73	0.95
2.8	0.59	0.65	0.71	0.71	0.91

In Vivo Indexed Effective Orifice Area (IEOA)

Sapien 3™* Hemodynamic Reference Values[1]

Area-derived Annular Diameter (mm)	≤ 22.1	> 22.2 to ≤ 23.64	> 23.65 to ≤ 24.9	> 24.9 to ≤ 26.2	> 26.2 to ≤ 29.4
Annular Area (mm²)	248-384	385-439	440-488	489-537	538-678
EOA Ref Data (cm²)	1.41 ± 0.27 (n = 189)	1.58 ± 0.33 (n = 191)	1.73 ± 0.36 (n = 192)	1.79 ± 0.35 (n = 191)	1.91 ± 0.42 (n = 188)

Patient BSA (m²)					
1.3	1.08	1.22	1.33	1.38	1.47
1.4	1.01	1.13	1.24	1.28	1.36
1.5	0.94	1.05	1.15	1.19	1.27
1.6	0.88	0.99	1.08	1.12	1.19
1.7	[illegible]	0.93	1.02	1.05	1.12
1.8	0.78	0.88	0.96	0.99	1.06
1.9	0.74	0.83	0.91	0.94	1.01
2	0.71	0.79	0.87	0.90	0.96
2.1	0.67	0.75	0.82	0.85	0.91
2.2	0.64	0.72	0.79	0.81	0.87
2.3	0.61	0.69	0.75	0.78	0.83
2.4	0.59	0.66	0.72	0.75	0.80
2.5	0.56	0.63	0.69	0.72	0.76
2.6	0.54	0.61	0.67	0.69	0.73
2.7	0.52	0.59	0.64	0.66	0.71
2.8	0.50	0.56	0.62	0.64	0.68

In Vivo Indexed Effective Orifice Area (IEOA)

The analysis provided above assesses data from separate clinical studies. These charts are not intended to be a direct comparison of these devices as there is no head-to-head clinical study, but rather are intended to illustrate an analysis of similar trials. Multiple factors, including the use of different echo corelabs, contribute to clinical study outcomes and need to be considered in making any assessments across different studies. Where measurements are derived, conversions assume circularity.

References

[1] Hahn RT, Leipsic J, Douglas PS, et al. Comprehensive Echocardiographic Assessment of Normal Transcatheter Valve Function. *JACC Cardiovasc Imaging*. Published online June 8, 2018.

Indexed Effective Orifice Area (IEOA) = EOA/BSA²

IEOA > 0.85 cm²/m²	mild
IEOA ≤ 0.85 cm²/m²	moderate
IEOA ≤ 0.65 cm²/m²	severe

To Aid Patient-Prosthesis Matching[2]

- First determine patient's body surface area (BSA).
- Second, using the chart, select a valve size with

Medtronic

† This patient fits the anatomical profile similar to those enrolled in the Medtronic SMART Clinical Trial.

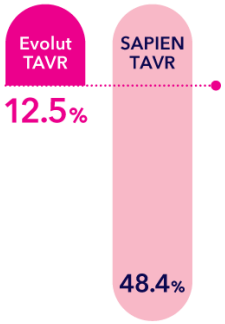
SMART Trial†

AV annulus area measures ≤ 430 mm²

Actual results may vary based on patient characteristics.

Through 2 years,

Evolut™ TAVR maintains superior valve performance‡ vs. SAPIEN™* TAVR in small annulus patients.§,1



Significantly less BVD‡ with Evolut TAVR

vs. SAPIEN TAVR in small annulus patients.§,1

p < 0.001

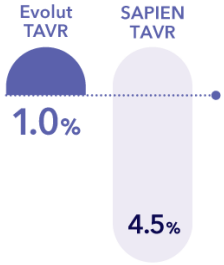
Sustained excellent patient outcomes through 2 years.1

Clinical outcome composite: All-cause mortality, disabling stroke, or heart failure rehospitalization.

Evolut TAVR: 17.8%, SAPIEN TAVR: 17.6%. p = 0.97
Hazard ratio, 1.01
(95% CI 0.71, 1.43)

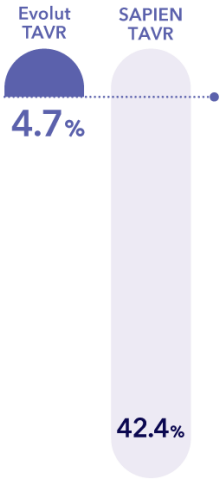
Compared to SAPIEN TAVR,

only Evolut TAVR delivers:



4.5x less prosthetic valve thrombosis◊ through 2 years in small annulus patients.§,1

p = 0.0048



9x less HSVD¶ (mean gradient ≥ 20 mmHg) through 2 years in small annulus patients.§,1

p < 0.001

Evolut TAVR continues to show strong results across these key components of **valve performance.**

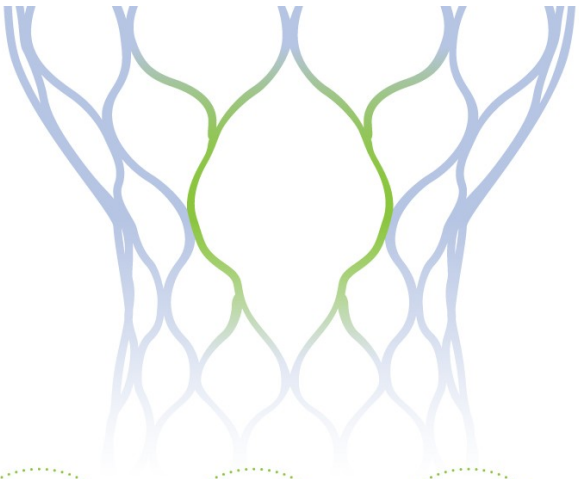
TAVR risks may include, but are not limited to, death, stroke, damage to the arteries, bleeding, and need for permanent pacemaker.
Devices used: Evolut PRO+ 78.0%, Evolut PRO 17.1%, Evolut FX 4.3%, Evolut R 0.6%; SAPIEN 3 Ultra 80.8%, SAPIEN 3 19.2%
‡ Valve performance as defined as freedom from bioprosthetic valve dysfunction (BVD) through 24 months. BVD is defined as a composite including any of the following: hemodynamic structural valve dysfunction (mean gradient ≥ 20 mmHg), non-structural valve dysfunction (severe prothesis-patient mismatch or ≥ moderate aortic regurgitation), clinical thrombosis, endocarditis, and aortic valve reintervention.
§ In patients with small annuli (area ≤ 430 mm²) in all-comers trial, consisting of majority low surgical risk participants (52.1%).
◊ Prosthetic valve thrombosis as defined as a composite of clinical and subclinical valve thrombosis.
¶ Hemodynamic structural valve dysfunction.
1. Herrmann H, et al. SMART 2 Year Data Update. Presented at CRT; March 2025.

Medtronic

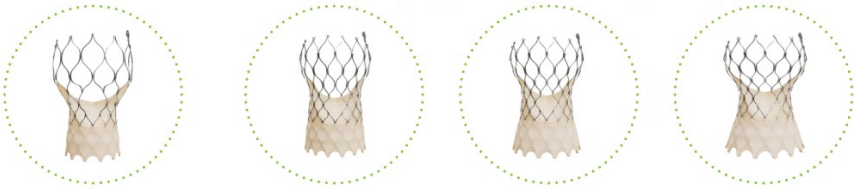
Medtronic

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)	23.8 mm	17†/18–20 mm	20–23 mm	23–26 mm	26–30 mm
Annulus perimeter‡	74.6 mm	53.4†/56.5–62.8 mm	62.8–72.3 mm	72.3–81.7 mm	81.7–94.2 mm
SoV diameter (mean) (B)	33.5 mm	≥ 25 mm	≥ 27 mm	≥ 29 mm	≥ 31 mm
SoV height (mean) (C)	19.3 mm	≥ 15 mm	≥ 15 mm	≥ 15 mm	≥ 16 mm
Oversizing Percentage		-3%	9%	22%	43%

†Measurement for TAV-in-SAV only.

‡Annulus perimeter = annulus diameter x π.

Selection criteria

Access consideration by MSCT

Minimum transarterial access vessel diameter

IFU guidance by MSCT

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

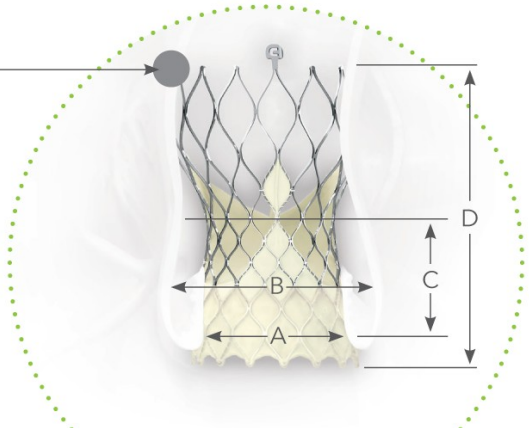
(A) Annulus diameter

(B) Sinus of Valsalva diameter

(C) Sinus of Valsalva height

(D) Frame height (≈ 45 mm, not including paddles)

Illustration not to scale.



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

Warnings
General Implantation of the Evolut PRO+, Evolut FX, and Evolut FX+ Systems should be performed only by physicians who have received Medtronic Evolut PRO+, Evolut FX, 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 Evolut PRO+, Evolut FX, 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 an Evolut PRO+, Evolut FX, or Evolut FX+ bioprosthesis implanted within a failed preexisting transcatheter bioprosthesis have not been demonstrated. Implanting an Evolut PRO+, Evolut FX, 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 Evolut PRO+ inline sheath when using model D-EVPROP2329US or Evolut FX Delivery Catheter System with inline sheath when using model D-EVOLUTFX-2329 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 D-EVPROP2329US/D-EVOLUTFX-2329 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 D-EVPROP2329US/D-EVOLUTFX-2329 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 If a misload is detected during fluoroscopic inspection, do not attempt to reload the bioprosthesis. Discard the entire system. Inflow crown overlap that has not ended before the 4th node within the capsule increases the risk of an infold upon deployment in constrained anatomies, particularly with moderate-severe levels of calcification and/or bicuspid condition. Do not attempt to direct load the valve. 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 an Evolut PRO+, Evolut FX, or Evolut FX+ bioprosthesis implanted within a transcatheter bioprosthesis have not been demonstrated.

Potential adverse events
Potential risks associated with the implantation of the Evolut PRO+, Evolut FX, 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 Evolut PRO+, Evolut FX, 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™ PRO+ device is Medtronic 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.

Medtronic

710 Medtronic Parkway
Minneapolis, MN 55432-5604
USA
Tel: (763) 514-4000
Fax: (763) 514-4879
Toll-free: (800) 328-2518

Europe
Medtronic International Trading Sàrl
Route du Molliau 31
Case Postale
CH-1131 Tolochenaz
Switzerland
Tel: (41 21) 802-7000

Asia
Medtronic International Ltd
49 Changi South Avenue 2
Nasaco Tech Centre
Singapore 486056
Singapore
Tel: (65) 6436-5000

LifeLine
CardioVascular Technical Support
Tel: (877) 526-7890
Tel: (763) 526-7890
Fax: (763) 526-7888
rs.cstechsupport@medtronic.com

Canada
Medtronic of Canada Ltd
99 Hereford Street
Brampton, Ontario L6Y 0R3
Canada
Tel: (905) 460-3800
Toll-free: (800) 268-5346

Latin America
Doral Corporate Center II
3750 NW 87th Avenue, Suite 700
Miami, FL 33178
USA
Tel: (305) 500-9328

www.medtronic.com

UC201402558a EN
07/2018