Medtronic

Evolut™ TAVR platform

Clark, Nelson Robert,

MR

Sex Male

Year Of Birth (Age) 1947 (78)

Height

Weight BMI

EOA needed to achieve an iEOA > 0.85 cm²/m²

Physician Brereton, Russell m

John, Dr

Hospital RNSH

City Country

kg

Received Date

Reviewed Date 30.7.25

Clinical History

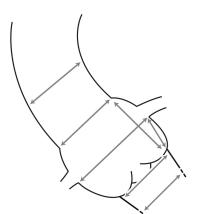
MEDTRONIC ANALYSIS

ANNULUS

Diameter (mm)	23.5	x 27.8 ,	25.7
	Min	Max	Mean
Perimeter (mm)	80.6	, Derived Ø (mm)	25.7
Area (mm²)	502.1	, Derived Ø (mm)	25.3

LVOT

Diameter (mm)	23.4	x 28.5 ,	25.9
	Min	Max	Mean
Perimeter (mm)	80.2	, Derived Ø (mm)	25.5
Area (mm²)	499.2	, Derived Ø (mm)	25.2



Max Ascending Aorta Diameter (mm)

Sinotubular Junction Diameter (mm)

Sinus of Valsalva Diameter (mm)

Sinus of Valsalva Height (mm)

Coronary Ostia Height (mm)

35.2

LCC

Left

31.5 31.5 Min Max

41.0 40.0 40.6 LCC NCC RCC 25.9 26.0 25.2

RCC

Right

NCC

21.5

VIEWS

3 Cusp Coplanar View

LAO: 1°, Cranial: 11°

Cusp Overlap View

RAO: 24°, Caudal: 18°

Near Cusp Overlap View

CIA Min Diameter (mm) 11.1

EIA Min Diameter (mm)

Femoral Min Diameter (mm) 8.2 8.7



LEFT

CIA Min Diameter (mm)

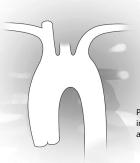
EIA Min Diameter (mm)

Femoral Min Diameter (mm) 8.6

RIGHT

Calcium: Mild ☐ Moderate ☐ Severe ☐

RIGHT Subclavian Min Diameter (mm) Annular Angulation ≈51°



LEFT

Subclavian Min Diameter (mm)

Please review images for direct aortic evaluation.

VIV ADDITIONAL MEASUREMENTS

Valve to Coronary Distance (mm)

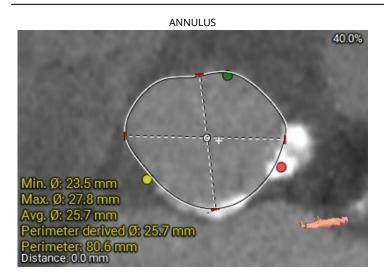
Valve to STI Distance (mm)

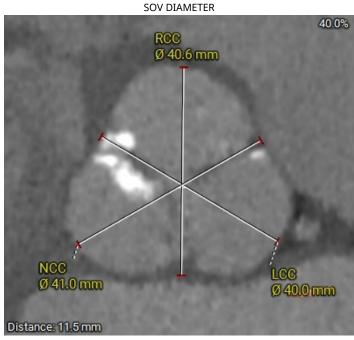
To LCA To RCA

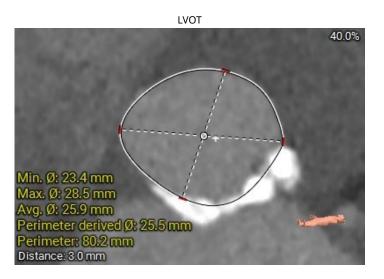
LCC RCC

Procedural Considerations

Aorta



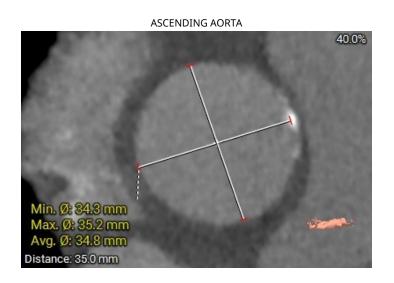


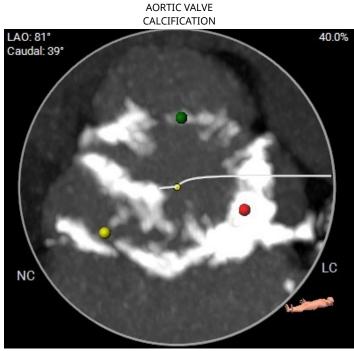




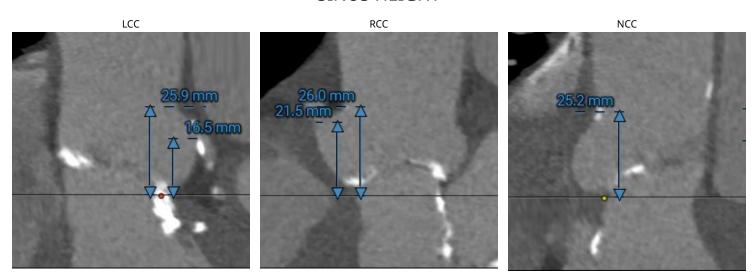
STJ

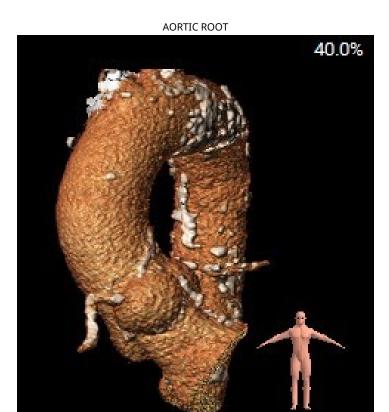
Aorta



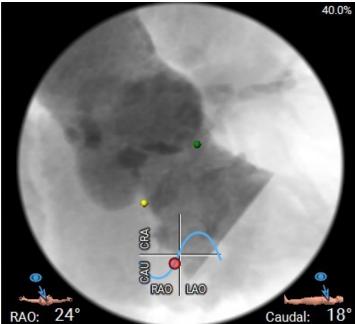


SINUS HEIGHT









2 Cusp View



Femoral Access - Right



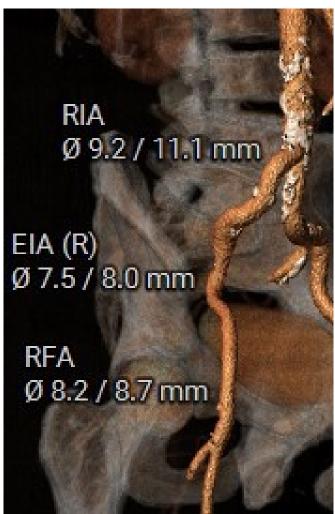


EIA (R)

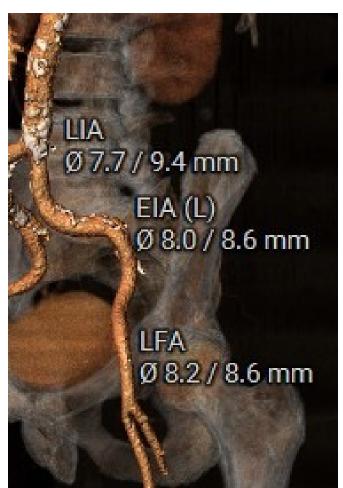








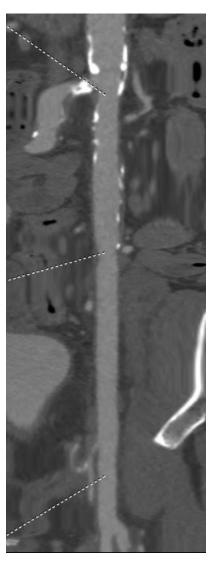
Femoral Access - Left





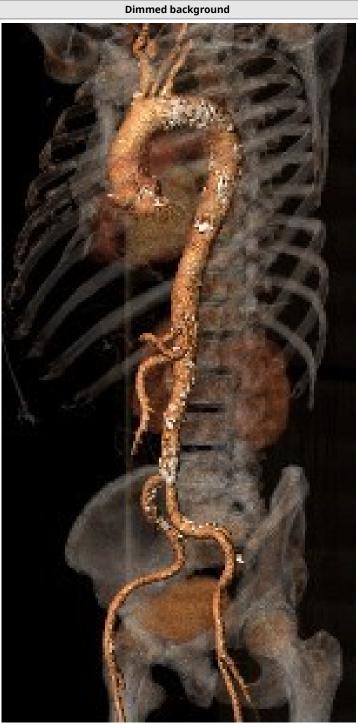




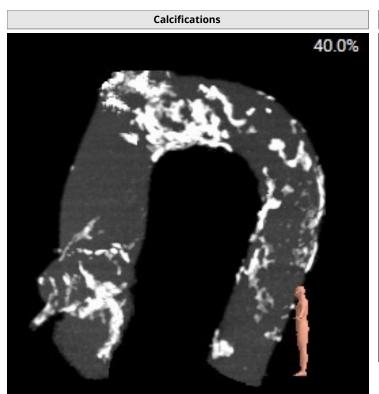


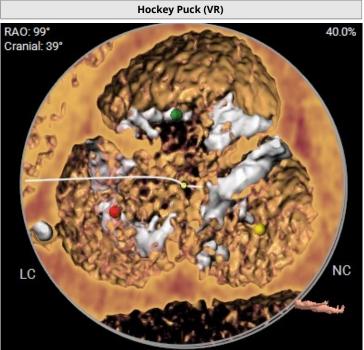
Additional Femoral Images

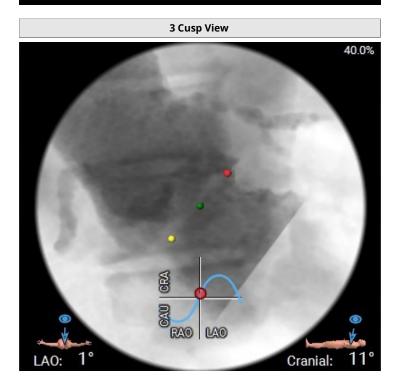




Additional Images







Medtronic

Evolut™ FX TAVR System

Patient valve selection criteria

Evolut FX bioprosthesis valve size selection



25.7 mm ≥ 15 mm

-11%







Size

Annulus diameter (A)

Annulus perimeter‡

Sinus of Valsalva diameter (mean) (B) 40.5 mm ≥ 25 mm Sinus of Valsalva height (mean) (C) **Oversizing Percentage**

> *Measurement for TAV-in-SAV only. *Annulus perimeter = annulus diameter x π.

26 mm 25.7 mm 17[†]/18-20 mm

20-23 mm 80.6 mm 53.4[†]/56.5-62.8 mm 62.8-72.3 mm ≥ 27 mm

> ≥ 15 mm 1%

23-26 mm 72.3-81.7 mm

≥ 29 mm ≥ 15 mm 13%

26-30 mm 81.7-94.2 mm ≥ 31 mm

≥ 16 mm 32%

-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 ≥ 6.0 mm

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

Ascending aorta access site ≥ 60 mm from basal plane.º

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.

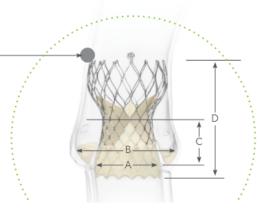
"For direct aortic access, ensure access site and trajectory are free of patent RIMA or preexisting patent RIMA graft.

Note the position of any SVGs -(A) Annulus diameter (B) Sinus of Valsalva diameter

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

Illustration not to scale.

(C) Sinus of Valsalva height



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.

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 acrtic 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

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.

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 sortic 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).

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 acritic valve replacement have not been evaluated in the pediatric population. The safety and effectiveness of the bioprostheses for acritic valve replacement have not been evaluated in the following patient populations: Patients who do not meet the criteria for symptomatic severe native sortic stenosis a cartic valve area S 1.0 cm² or acritic valve area index S 0.6 cm²/m², a mean acritic stenosis a cartic valve gradient 2 40 mm Hg, or a peak sortic-jet velocity 2 4.0 m/s; (2) symptomatic severe low-flow, low-gradient acritic stenosis — acritic valve area s 1.0 cm² or acritic valve area index S 0.6 cm²/m², a mean acritic valve gradient 4 40 mm Hg, and s peak sortic-jet velocity < 4.0 m/s; with untreated, clinically significant coronary artery disease requiring revascularization; with a preexisting prosthetic heart valve acritic precedition in 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 Evoluta R, Evolut PRO+, or Evolut FRO+, or Evolut

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710 Medtronic Parkway Minneapolis, MN 55432-5604

Toll-free: 800.633.8766 Tel: +1 763 514 4000

medtronic.com

CardioVascular Technical Support Toll-free: 877.526.7890 Tel: +1.763.526.7890 rs.structuralheart@medtronic.com 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 models ENVEOR-US/D-EVPROP2329US/D-EVOLUTFX-2329 or ≥ 5.5 mm when using models 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 sortic 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 sortic 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 access, ensure the access site and trajectory are free of patent RIMA or a p

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.

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 sortic 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 sorta 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 trame; 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 sortic 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 regurgitation or injury * conduction system disturbances (e.g., active and the incomplete in ode 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

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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Conclusion:

Reviewer Name: Raquel Hughes **Review Date:** 30.7.25