TAVR EVIDENCE UPDATE

SURTAVI five-year results

Consistently good outcomes.

CoreValve™ and Evolut™ TAVR platforms maintained hemodynamic benefits and stable valve performance at five years in intermediate risk patients.

Compared to SAVR at five years, CoreValve and Evolut TAVR platforms demonstrated:

1. No statistical difference in all-cause mortality
   30.0% (TAVR); 28.7% (SAVR) p = 0.55

2. Numerically lower disabling stroke
   4.1% (TAVR); 5.8% (SAVR) p = 0.12

3. Statistically better hemodynamics with stable low gradients

Mean gradient and EOA over time implanted set

All post-implant p-values are < 0.001

Source: Van Mieghem NM. 5-Year Clinical and Echocardiographic Outcomes from the Randomized SURTAVI Trial. Presented at TCT 2021; November 5, 2021; Orlando, FL.
INDICATIONS The Medtronic CoreValve™ Evolut™ R, CoreValve™ Evolut™ PRO, and Evolut™ PRO+ systems are intended for use in patients with symptomatic aortic stenosis 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, CoreValve Evolut PRO, and Evolut PRO+ systems are indicated for use in patients with symptomatic heart disease due to failure (stenosed, insufficient, or combined) of a biological bioprosthetic aortic valve which 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 ≥ 15% risk of mortality at 30 days). CONTRAINDICATIONS The CoreValve Evolut R, CoreValve Evolut PRO, and Evolut PRO+ systems are contraindicated in patients who cannot tolerate Nitinol (titanium or nickel), an anticoagulation/antiplatelet regimen, or who have active bacterial endocarditis or other local infection or inflammation. WARNINGS General Implantation of the CoreValve Evolut R, PRO, and PRO+ systems should be performed only by physicians who have received Medtronic CoreValve Evolut R, PRO, or PRO+ 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 hyperparathyroidism). PRECAUTIONS General Clinical long-term durability has not been established for the bioprostheses, although clinical data have been collected during patient follow-up. The safety and effectiveness of the CoreValve Evolut R, PRO, and PRO+ systems have not been evaluated in the pediatric population. The safety and effectiveness of the bioprostheses for aortic stenosis in patients with an accessible native aortic valve area index ≤ 0.6 cm²/m² has not been evaluated in the pediatric 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 cm² or 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 cm² or aortic valve area index ≤ 0.6 cm²/m², 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 structure in either the mitral or pulmonary position if either the preexisting prosthetic heart valve could impair 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, PRO, or PRO+ bioprosthesis implanted within a failed preexisting transcatheter bioprosthesis has not been demonstrated. Implanting a CoreValve Evolut R, PRO, or PRO+ transcatheter bioprosthesis has not been demonstrated. Implanting a CoreValve Evolut R, PRO, or PRO+ transcatheter aortic 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 prostheses and the native annulus), is not securely fixed in the native annulus, or is not structurally intact (e.g., wire 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 bioprosthesis 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/mm³), thrombocytopenia (platelet count < 50,000 cells/mm³), hemorrhagic diathesis, or history of bleeding diatheses; congenital unicupid valve; mixed aortic valve disease (aortic stenosis and aortic regurgitation with predominant aortic regurgitation [3+ to 4+]); severe (moderate to severe 3+ or 4+) mitral or tricuspid regurgitation; mitral valve-degenerative; new or untreated echocardiographic evidence of intracardiac mass, thrombus, or vegetation; native aortic annulus size < 18 mm or > 30 mm for Evolut R/Evolut PRO+ and < 18 mm or > 26 mm for CoreValve Evolut PRO. For the baseline diagnostic imaging or surgical bioprosthetic aortic annulus size < 17 mm or > 30 mm for CoreValve Evolut R/Evolut PRO+ or < 17 mm or > 26 mm for Evolut PRO; transarticular access unable to accommodate an 18 Fr sheath or the 14 Fr equivalent EnVeo InLine™ sheath when using Model ENVEOR-US/N-ENVPOR-14-US, or transarterial access unable to accommodate a 22 Fr introducer sheath or the 18 Fr equivalent Model EVPO2329US or transarticular access unable to accommodate a 20 Fr introducer sheath or the 16 Fr equivalent InLine sheath when using Model ENVEOR-US/N-ENVPOR-14-US or transarterial access unable to accommodate a 22 Fr introducer sheath or the 18 Fr equivalent Model EVPO2329US; prohibitive left ventricular outflow tract calcification; sinus of Valsalva aneurysm that would prevent adequate coronary perfusion; significant aortopathy requiring ascending aortic replacement; moderate to severe mitral regurgitation; severe mitral stenosis, aortic stenosis, severe tricuspid regurgitation, or 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 bioprostheses size must be appropriate to fit the patient’s anatomy and allow proper sizing of the conduit for the patient. The bioprostheses size is the responsibility of the physician. Please 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 transarticular access vessel diameters of ≥ 5 mm when using Model ENVEOR-US/ ENVPOR-14-US-D/EVPO2329US or ≥ 5.5 mm when using Model ENVEOR-US-16-US or ≥ 6 mm when using Model ENVEOR-US-16-US or ≥ 6 mm when using Model ENVEOR-US-16-US or ≥ 6 mm when using Model ENVEOR-US-16-US or ≥ 6 mm when using Model D-EVPO347US, or patients must present with an ascending aortic (direct aortic) access site ≥ 60 mm from the basin 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-14-US/ENVEOR-1-US-D/EVPO232929US or ≥ 6 mm when using Models ENVEOR-16-US and ENVEOR-R-US or ≥ 6 mm when using Model D-EVPO347US. Use caution when using models with the patient having 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 pre-existing patent RIMA graft. For emergent surgical or or use cases, patients who present with patients who present with patients who present with aortic stenosis (transcatheter aortic valve replacement) or severe aortic regurgitation, a transcatheter bioprosthesis has been demonstrated. Implantation of the bioprosthesis may not be evaluated in patient populations presenting with the following: Blood dyscrasias as defined as leukopenia (WBC < 1,000 cells/mm³), thrombocytopenia (platelet count < 50,000 cells/mm³), hemorrhagic diathesis, or history of bleeding diatheses; congenital unicupid valve; mixed aortic valve disease (aortic stenosis and aortic regurgitation with predominant aortic regurgitation [3+ to 4+]); severe (moderate to severe 3+ or 4+) mitral or tricuspid regurgitation; mitral valve-degenerative; new or untreated echocardiographic evidence of intracardiac mass, thrombus, or vegetation; native aortic annulus size < 18 mm or > 30 mm for Evolut R/Evolut PRO+ and < 18 mm or > 26 mm for CoreValve Evolut PRO; for the baseline diagnostic imaging or surgical bioprosthetic aortic annulus size < 17 mm or > 30 mm for CoreValve Evolut R/Evolut PRO+ or < 17 mm or > 26 mm for Evolut PRO; transarticular access unable to accommodate an 18 Fr sheath or the 14 Fr equivalent EnVeo InLine™ sheath when using Model ENVEOR-US/N-ENVPOR-14-US/D/EVPO2329US or transarterial access unable to accommodate a 20 Fr introducer sheath or the 16 Fr equivalent InLine sheath when using Model ENVEOR-US/N-ENVPOR-14-US or transarterial access unable to accommodate a 22 Fr introducer sheath or the 18 Fr equivalent Model EVPO2329US; prohibitive left ventricular outflow tract calcification; sinus of Valsalva aneurysm that would prevent adequate coronary perfusion; significant aortopathy requiring ascending aortic replacement; moderate to severe mitral regurgitation; severe mitral stenosis, aortic stenosis, severe tricuspid regurgitation, or with left ventricular ejection fraction (LVEF) < 20%; symptomatic carotid or vertebral artery disease; and severe basal septal hypertrophy with an outflow gradient.

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