ABOVE AND BEYOND

Evolut™ PRO+
Transcatheter Aortic Valve System
From a design built on a proven platform, the Evolut PRO+ system is taking valve performance and patient outcomes above and beyond.

HEMODYNAMIC PERFORMANCE
for exceptional patient outcomes

ADVANCED SEALING
for all valve sizes and across the broadest annular range!

† By CT measurement.

LOWEST DELIVERY PROFILE
for access down to 5.0 mm vessels with the 23-29 mm valves
From a design built on a proven platform, the Evolut PRO+ system is taking valve performance and patient outcomes above and beyond.

THE EVOLUT PRO+ TAVR SYSTEM ADVANTAGE

HEMODYNAMIC PERFORMANCE for exceptional patient outcomes

ADVANCED SEALING for all valve sizes and across the broadest annular range†

LOWEST DELIVERY PROFILE for access down to 5.0 mm vessels with the 23-29 mm valves

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The Evolut TAVR’s supra-annular, self-expanding valve design delivers exceptional hemodynamics and is the only TAVR device to demonstrate hemodynamic superiority in a low-risk clinical trial vs. SAVR.¹

### Superiority vs. SAVR

<table>
<thead>
<tr>
<th>Superior EOAs at 1 year</th>
<th>Superior Gradients at 1 year</th>
</tr>
</thead>
<tbody>
<tr>
<td>Evolut TAVR 2.3 cm² vs. SAVR 2.0 cm²</td>
<td>Evolut TAVR 8.6 mm Hg vs. SAVR 11.2 mm Hg</td>
</tr>
</tbody>
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- **15%** larger EOA
- **23%** lower gradients

Evolut TAVR has demonstrated large effective orifice areas (EOAs), thereby:

- Lowering risk of severe patient-prosthesis mismatch (PPM) and subsequently reducing risk of mortality and heart failure rehospitalizations²;
- Promoting increased blood flow and minimizing PPM, allowing patients to maintain a higher exercise capacity, helping them return to an active life³,⁴; and
- Suggesting a durable platform given Evolut TAVR is built on the CoreValve™ supra-annular, self-expanding platform, which has consistently sustained large EOAs and low mean gradients over time.⁵
Superiority vs. SAVR

The Evolut TAV’s supra-annular, self-expanding valve design delivers exceptional hemodynamics and is the only TAVR device to demonstrate hemodynamic superiority in a low-risk clinical trial vs. SAVR.¹

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**Superior EOAs at 1 year**

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**Superior Gradients at 1 year**

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**Larger EOAs**

**Lower Gradients**

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LEADERSHIP IN VALVE DESIGN

Advanced Sealing across the Platform

The external tissue wrap on the Evolut PRO valves has shown excellent PVL performance. With the addition of the wrap to the 34 mm PRO+ valve, similar results can be expected — offering advanced sealing across the platform.

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Total Aortic Regurgitation at 30 Days

Low Rates of Moderate/Severe PVL

Real-world commercial experience from the STS/ACC TVT Registry™ demonstrates excellent PVL performance.

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Broadening Access with an Expanded Platform and Expanded Indication

• With a reduced delivery profile for 23–29 mm valves, only Medtronic is indicated to treat patients with vessels as small as 5.0 mm.
• With the ability to treat the broadest annulus range† of any commercially available TAVR system, Evolut PRO+ valves can treat annulus ranges from 17*/18 mm to 30 mm.
• The Evolut PRO+ system is approved for all symptomatic severe aortic stenosis patients.

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Purposeful design to provide you with the performance and outcomes you need to help patients live life to the fullest.
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The Medtronic TAVR Low Risk Study included here is based on the primary analysis, as published in Journal of the American College of Cardiology (JACC) in October 2019. A supplemental analysis was performed, which included additional follow-up data on the same cohort. These findings are provided for use in the context of the primary analysis.

INDICATIONS
The CoreValve Evolut™R, CoreValve™ Evolut™ PRO, and Evolut™ PRO+ systems are indicated for relief of aortic stenosis in patients with symptomatic severe native aortic stenosis who are at high surgical risk (e.g., STS predicted risk of mortality ≥ 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 regime, or who have active bacterial endocarditis (or previous endocarditis). Warnings
General Implantation of the CoreValve Evolut™ R, Evolut™ PRO, and Evolut™ PRO+ systems should be performed only by physicians who have received Medtronic CoreValve Evolut™ R, or Evolut™ PRO or Evolut™ PRO+ training. This procedure should only be performed after completing a successful CoreValve Evolut™ R, Evolut™ PRO, or Evolut™ PRO+ system course.

Precautions
Immunosuppressive therapy may be required in patients with systemic lupus erythematosus, rheumatoid arthritis, or other collagen-vascular diseases. Safety and effectiveness of the bioprosthesis 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 cm²; (2) symptomatic severe aortic valve area ≤ 0.6 cm²/m², a mean aortic valve gradient ≥ 40 mm Hg, or a peak aortic jet velocity ≥ 4.0 m/s; (3) 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; (4) congenital bicuspid valve patients who are at low surgical risk (Child-Pugh Class A) and with cardiogenic shock manifested by low cardiac output; (5) patients requiring urgent or emergency surgery for aortic dissection or rupture, or mechanical or surgical support in either the mitral or pulmonary position; (6) patients with atrial fibrillation who meet the criteria for symptomatic severe native aortic stenosis and in whom anticoagulation therapy is contraindicated; (7) patients with prior history of aortic valve surgery or prior placement of a prosthetic valve. Safety and effectiveness of the bioprosthesis for transcatheter aortic valve replacement have not been evaluated in patients with atrial fibrillation who meet the criteria for symptomatic severe native aortic stenosis as defined: (1) symptomatic severe high-gradient aortic stenosis — aortic valve area ≤ 1.0 cm²/m²,-thrombocytopenia (platelet count < 50,000/mm³), history of bleeding diathesis or coagulopathy, or hypercoagulable states; (2) congenital unicuspid aortic valve with severe aortic regurgitation with predominant aortic regurgitation (≥ 3+); (3) moderate to severe (≥ 4+) or severe (≥ 5+) mitral or severe (≥ 4+ to 5+) tricuspid regurgitation; (4) hypertrophic obstructive cardiomyopathy; or prior graphic evidence for aortic root angulation, intracardiac mass, 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. The baseline diseased native aortic bioprosthetic aortic annulus size ≤ 17 mm or > 30 mm for CoreValve Evolut R/Evolut PRO+ and ≤ 17 mm or > 26 mm for Evolut PRO; transapical systems are contraindicated in patients who cannot tolerate Nitinol (Titanium or Nickel), an anticoagulation/antiplatelet regime, or who have active bacterial endocarditis (or previous endocarditis). Education
Cardiovascular complications may result from forceful handling of the catheter. Prevent kinking of the catheter when removing it from the packaging. The bioprosthetic 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 transapical aortic valve diameters of 3.5 cm or ≥ 4.5 mm when using Medtronic ENVOY-PRO-US/ENVOY-PRO-US/D-ENVOYPRO2329US or transapical access usable to accommodate ≥ 2Fr introducer sheath or the 18 Fr equivalent EnVeo InLine sheath when using Medtronic ENVOY-N-US/ENVOY-PRO-U-US/D-ENVOY-PROUS/D-ENVOY-PRO2329US or transapical access usable to accommodate ≥2 Fr introducer sheath or the 18 Fr equivalent EnVeo PRO+ InLine sheath when using Medtronic EVPRO-14-US/ENVOY-PRO-US/D-ENVOY-PROUS/D-ENVOY-PRO2329US or at least 18 mm peripheral aortic (direct aortic) access ≥ 60 mm from the base line for both systems. Implantation of the bioprosthesis should be avoided in patients with aortic root angulation (angle between the plane of the aortic valve annulus and the horizontal plane/ configuration) of the valve frame > 45° or > 50° right subclavian/axillary access or > 70° for femoral and left subclavian/axillary access. For subclavian access, patients with a patient left subclavian/axillary artery ≤ 6.5 mm in diameter will be addressed with the subclavian/axillary approach in patients with a patient LIMA graft or patient RIMA graft. For direct aortic access, ensure the access site and trajectory are free of vascular disease, such as occlusion, stenosis, or pseudoaneurysm, stent frame with a manufacturer-labeled 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 detached leaflet. 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 bioprosthetic valve may occur in children, adolescents, or young adults; patients with altered calcium metabolism (e.g., chronic renal failure or hyperparathyroidism). Precautions
Precaution: The safety and effectiveness for the bioprosthesis have not been established for the transcatheter aortic valve replacement therapy. Potential adverse events Potential risks associated with the implantation of the CoreValve Evolut™ R, Evolut™ PRO, or Evolut™ PRO+ transcatheter aortic valve 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 (including regurgitation or stenosis) due to fracture (bending and/or out-of-round configuration) of the valve frame; underexpansion of the valve frame; calcification; pannus; leaflet tear, tear, prolapse, or retraction; poor valve coaptation; suture breaks or distortion, leaflet 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 component migration/embolization • stroke (ischemic or hemorrhagic) • peripheral vascular disease • renal injury • acute kidney injury • bleeding (systemic, mucocutaneous, and/or intracranial) • cardiovascular exposure to radiation through fluoroscopy and angiography • permanent disability
Please refer to the CoreValve Evolut™ R, Evolut™ PRO, and Evolut™ PRO+ 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 CoreValve™ Evolut™ PRO System, and the commercial name of the Evolut™ PRO+ device is Medtronic CoreValve™ Evolut™ PRO+ System.