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.

**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

†By CT measurement.
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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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<th>SUPERIOR EOAs at 1 year</th>
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**LARGER EOAs**

**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
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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.

The views or opinions presented in this document are solely those of Medtronic and do not represent those of the American College of Cardiology, The Society of Thoracic Surgeons, or the STS/ACC TVT Registry™.

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.

†By CT measurement.

**Measurement is for TAVI-in-SAV only.
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TREAT MORE 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 Evolut R Low Risk Study included here is based on the primary analysis, as published in the Journal of the American College of Cardiology. An additional supplemental analysis was performed, which included additional follow-up data on the same cohort. These data are summarized in the Instructions for Use and product listings 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 judged by a heart team, including a cardiac surgeon, to be appropriate for transcatheter heart valve replacement therapy. The Medtronic 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 active infections.

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 replacement 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 bioprosthetic aortic valve may occur in children, adolescents, or young adults; patients with altered calcium metabolism (e.g., chronic renal failure or hyperthyroidism).

PRECAUTIONS

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, PRO, and PRO+ systems, including the transfemoral delivery catheter system, have not been evaluated in the pediatric population. The safety and effectiveness of the bioprosthesis for aortic valve replacement have not been demonstrated. Implanting a CoreValve Evolut R, Evolut PRO, or Evolut PRO+ transcatheter aortic valve should be avoided in the following conditions: The degenerated surgical bioprosthetic valve presents with severe stenosis or regurgitation in patients with aortic valve replacement between the TAVI 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 in the aortic prosthesis, the leaflet is not fully seated within the prosthetic valve ring (i.e., a paravalvular leak); the transcatheter valve is undersized or oversized by more than 15% (risk of paravalvular leakage at 30%).

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 active infections.

POTENTIAL ADVERSE EVENTS

Potential adverse events may occur after deployment of a transcatheter aortic valve prosthesis. These 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); systemic or peripheral embolization or dissection; stroke (ischemic or hemorrhagic), transient ischemic attack (TIA), or other neurological deficits; infection; myocardial infarction, cardiac arrest, cardiogenic shock, or cardiac tamponade. Please refer to the “POTENTIAL ADVERSE EVENTS” in the 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, or for use by, a physician.