The Evolut Pro+ TAVR System Advantage

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†

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

†By CT measurement.
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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

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

LARGER EOAs

LOWER GRADIENTS

Evolut TAVR

Superiority vs. SAVR

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Superior EOAs at 1 year

Evolut TAVR

2.3 cm²

vs.

SAVR 2.0 cm²

15%

Superior Gradients at 1 year

Evolut TAVR

8.6 mm Hg

vs.

SAVR 11.2 mm Hg

23%
Superiority vs. SAVR

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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.

Low Rates of Moderate/Severe PVL

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

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LEADERSHIP IN VALVE DESIGN

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<table>
<thead>
<tr>
<th>Percentage of Available Echos (%)</th>
<th>Evolut PRO</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N = 1,444</td>
</tr>
<tr>
<td>0%</td>
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<tr>
<td>10%</td>
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<td>70%</td>
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<td>80%</td>
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<tr>
<td>90%</td>
<td>2.8</td>
</tr>
<tr>
<td>100%</td>
<td></td>
</tr>
</tbody>
</table>

Total Aortic Regurgitation at 30 Days

- **Moderate**: 2.8%
- **Mild**: 31.6%
- **None/Trace**: 65.6%
- **Severe**: 0.0%

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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 TAVR-in-SAV only.
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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 data here is based on the primary analysis, as published in the Journal of Interventional Cardiology. A supplemental analysis was performed, which included additional follow-up data on the same cohort. These data are summarized in the Instructions for Use and are additional findings 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 aortic stenosis who are judged by a cardiac surgeon, to be appropriate for the transcatheter aortic valve replacement.

The Medtronic CoreValve Evolut R, CoreValve Evolut PRO, and Evolut PRO+ systems are indicated for use in patients with symptomatic severe aortic valve disease 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 > 15% or predicted mortality > 30% 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/antiplaquette regimen, or who have active bacterial endocarditis or acute 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 when it is clear that the conditions, including the use of a disease-specific periprocedural antibiotic regimen, are met.

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

Prolonged exposure to high-frequency energy (e.g., Doppler ultrasound) may result in tissue damage to the aortic valve and surrounding structures. Use caution when performing fluoroscopy. Fluoroscopic procedures are associated with the risk of radiation exposure.

Prior to Use

To prevent infection, use aseptic technique during the delivery of the CoreValve Evolut R, PRO, or PRO+ system. Bacterial endocarditis or other active infections.

Evolut PRO+ systems have not been evaluated in the pediatric population. The safety and effectiveness of the CoreValve Evolut R, PRO, or PRO+ training. This procedure should only be performed by physicians who have received Medtronic CoreValve Evolut R, PRO, or PRO+ training. Instructions for Use and are additional findings of the primary analysis.

INDICATIONS

The degenerated surgical bioprosthesis presents a lower profile and a lower profile compared to the fluoroscopy of the preexisting prosthetic heart valve; patients with liver failure (Child-Pugh B/C); with cardiogenic shock manifested by low cardiac output, vasopressor dependence, or mechanical hemodynamic support; patients who are pregnant or breastfeeding, and patients with known or suspected coated bioprostheses or a previous bioprosthetic valve.

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