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.
THE EVOLUT™ HEMODYNAMIC ADVANTAGE

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

**Superior EOA at 1 year**

<table>
<thead>
<tr>
<th>Evolut TAVR</th>
<th>2.3 cm²</th>
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<tbody>
<tr>
<td>vs. SAVR</td>
<td>2.0 cm²</td>
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**Superior Gradients at 1 year**

<table>
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<tr>
<th>Evolut TAVR</th>
<th>8.6 mm Hg</th>
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<tr>
<td>vs. SAVR</td>
<td>11.2 mm Hg</td>
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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 life²-⁴, 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**

15% ↓

23% ↓
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.

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

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™.

Evelut PRO
N = 1,444

Total Aortic Regurgitation at 30 Days

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

Low Rates of Moderate/Severe PVL
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 TAV-in-SAV only.
Purposeful design to provide you with the performance and outcomes you need to help patients live life to the fullest.
Exposure to glutaraldehyde may cause irritation of the skin, eyes, nose, throat. Avoid prolonged or repeated exposure to the vapors. Damage may occur.

**WARNINGS** General implantation of the CoreValve Evolut R, Evolut PRO, or Evolut PRO+ systems should be performed only by physicians who have received Medtronic CoreValve Evolut R, Evolut PRO, or Evolut PRO+ training. This procedure should only be performed when all necessary patient data are available and the proper patient size is known.

**CONTRAINDICATIONS** The CoreValve Evolut R, Evolut Pro, and Evolut PRO+ systems are contraindicated in patients who cannot tolerate Nitinol (Titanium or Nickel), an anticoagulation/antiplatelet regiment, or who have active or chronic renal failure/insufficiency.

**PRECAUTIONS** The 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 area ≤ 1.0 cm² or aortic area index ≤ 0.6 cm²/m², a 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 area ≤ 1.0 cm² or aortic area index ≤ 0.6 cm²/m², a mean aortic valve gradient ≥ 40 mm Hg, and a peak aortic jet velocity < 4.0 m/s; or (3) congenital bicuspid valve patients who are at low surgical risk (predicted mortality score ≥ 8% or at ≥ 15% risk of mortality at 30 days).

**REFERENCES**


