LIFE IS DIFFERENT WITH PRO

Evolut™ PRO System

Medtronic
The Evolut™ PRO system combines exceptional valve design and advanced sealing with an excellent safety profile.
Supra-annular valve design
Self-expanding nitinol frame

BUILT ON A PROVEN PLATFORM.

1.7% Mortality
1.7% Stroke
11.7% Permanent Pacemaker

Forrest, et al., TCT, 2017 Evolut PRO 6-month data.
ADVANCED SEALING.

Evolut PRO 30-day and 6-month Outcomes

0% Moderate or Severe PVL

Forrest, et al., TCT, 2017 Evolut PRO 6-month data.

<table>
<thead>
<tr>
<th>30 DAYS</th>
<th>N = 58</th>
<th>6 MONTHS</th>
<th>N = 50</th>
</tr>
</thead>
<tbody>
<tr>
<td>MILD</td>
<td>28%</td>
<td>MILD</td>
<td>12%</td>
</tr>
<tr>
<td>NONE/TRACE PVL</td>
<td>72%</td>
<td>NONE/TRACE PVL</td>
<td>88%</td>
</tr>
</tbody>
</table>
Supra-annular valve design maximizes leaflet coaptation and promotes single digit gradients and large EOAs.

**UNSURPASSED HEMODYNAMICS.**

6.4 mmHg single digit gradients
2.0 cm² large EOA

Evolut PRO Clinical Study, 60 patients, 30-day outcomes.
CONTROL.
ACCESS.
CONFIDENCE.

Recapture and Reposition
Lowest Delivery Profile
Acute Performance
At Medtronic, we are committed to collaborating with TAVR Heart Teams to improve patient outcomes, expand access, and improve efficiencies. As a global leader in medical technology, services, and solutions, we’re working with others to take on the industry’s greatest challenges.
INDICATIONS: The Medtronic CoreValve® Evolut™ R and CoreValve® Evolut™ PRO systems are indicated for relief of aortic stenosis in patients with symptomatic heart disease due to severe native aortic stenosis who are judged by a heart team, including a cardiac surgeon, to be intermediate or greater risk for open surgical therapy (i.e., predicted risk of mortality ≥ 3% at 30 days, based on the Society of Thoracic Surgeons risk model) and who are not eligible or suitable candidates for open surgical therapy. The CoreValve Evolut™ R and CoreValve Evolut™ PRO systems are indicated for use in patients with symptomatic heart disease due to severe native aortic stenosis; aortic stenosis in transcatheter bioprosthetic aortic valve (including Sapien™ and Edwards SAPIEN™) with known valve damage). Do not attempt to reload a damaged bioprosthesis. Do not load the bioprosthesis onto the catheter more than two times or after it has been recommended in the Instructions for Use, is mandatory before implantation. During rinsing, do not touch the leaflets or squeeze the bioprosthesis. If a misload is

During Use

General

The Medtronic CoreValve® Evolut™ R and CoreValve® Evolut™ PRO systems are intended for use by physicians who have received Medtronic CoreValve® Evolut™ R and Evolut™ PRO training and performed open heart surgery and transcatheter bioprosthetic valve implantation. Open heart surgery must be performed by a cardiac surgeon who has adequate experience in mitral valve interventions (PCI), balloon valvuloplasty

CONTRAINDICATIONS

The CoreValve Evolut R and PRO systems are contraindicated for patients presenting with any of the following conditions: a history of severe allergic reaction to aspirin, heparin (HIT/HITTS) and bivalirudin, ticlopidine, clopidogrel, Nitinol (Titanium or Nickel), or any components of the delivery system (e.g., the guidewire, and inspect the catheter and confirm that it is complete. Clinical long-term durability has not been established for the bioprosthesis.

POTENTIAL ADVERSE EVENTS

• Potential risks associated with the implantation of the CoreValve Evolut R or CoreValve Evolut PRO transcatheter aortic valve systems include stroke, myocardial infarction, death, and vascular complications. Prior to use Exposure to Glutaraldehyde may cause irritation of the skin, eyes, nose, and throat. Avoid prolonging or repeated exposure to the vapors. Damage may result from forceful degradation of the catheter. Prevent kinking of the catheter when removing it from the packaging. This device is suitable for re-use, re-caps, or re-sterilization. Before use, inspect the catheter and confirm that it is complete. The Medtronic CoreValve® Evolut™ R and CoreValve® Evolut™ PRO transcatheter aortic valve systems are intended to be used for patients with symptomatic native aortic stenosis with severe native aortic stenosis; aortic stenosis in transcatheter bioprosthetic aortic valve (including Sapien™ and Edwards SAPIEN™) with known valve damage). Do not attempt to reload a damaged bioprosthesis. Do not load the bioprosthesis onto the catheter more than two times or after it has been recommended in the Instructions for Use, is mandatory before implantation. During rinsing, do not touch the leaflets or squeeze the bioprosthesis. If a misload is

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In the event the catheter is in the patient, ensure the guidewire is extending from the tip. Do not remove the guidewire from the catheter while the catheter is in the patient. During the procedure, take care to ensure the aortic valve is not displaced or damaged. If there is some resistance when the catheter is advanced through the vasculature. If there is a significant increase in resistance, stop advancement and reposition the catheter. If there is some resistance when the catheter is advanced through the vasculature. If there is a significant increase in resistance, stop advancement and reposition the catheter.

Please refer to the CoreValve Evolut R and Evolut™ PRO Instructions for Use for more information regarding the delivery system.

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician.

The CoreValve Evolut R and Evolut™ PRO Systems are Medtronic CoreValve® Evolut™ PRO System.