COREVALVE® AND EVOLUT® R SYSTEMS

OVERVIEW

THE INFORMATION IN THIS DOCUMENT IS INTENDED FOR EDUCATIONAL PURPOSES AND IS NOT MEANT AS A SUBSTITUTE FOR THE INSTRUCTIONS FOR USE OR PRODUCT TRAINING. PRACTICE MAY VARY BASED ON CLINICAL JUDGMENT.

INTERNATIONAL. CAUTION: FOR DISTRIBUTION ONLY IN MARKETS WHERE COREVALVE EVOLUT R HAS BEEN APPROVED. NON DESTINE AU MARCHE FRANCAIS. ©MEDTRONIC, INC. 2015. ALL RIGHTS RESERVED.
CONSISTENT DESIGN
PROVEN IN MORE THAN 130,000 IMPLANTS WORLDWIDE

Self-Expanding Frame
• Conforms and seals to the annulus
• The foundation for recapturability

Supra Annular Valve Design
• Maximize flow and optimize coaptation

Porcine Pericardial Tissue
• Thinness for low profile delivery
• Strength and pliability for long-term durability
Superelasticity

- Compact designs and low delivery profile
- Conformable to patient anatomy

Shape Retention

- Self-anchoring
- Controlled retraction for precise delivery and placement
- Maintains valve shape

Performance

- Highly biocompatible
- MR Conditional*
- Proven fatigue performance

* Refer to IFU for list of safe operating parameters
SELF-EXPANDING FRAME DESIGN

Frame cells comprised of struts and nodes:

- Smallest cell accommodates a **10 Fr catheter** for coronary access
- Nodes appear as bands when compressed into the delivery system and are used to assess valve depth
CLINICAL NEED: STRONG HEMODYNAMIC PERFORMANCE
MINIMIZING PARAVALVULAR LEAK

PRODUCT DESIGN:
Conforming Frame

The nitinol frame conforms and seals to the non-circular annulus.

Images courtesy of Drs. De Jaegere and Schultz, Erasmus MC, Rotterdam, The Netherlands
CLINICAL NEED: STRONG HEMODYNAMIC PERFORMANCE
MAXIMIZING BLOOD FLOW

PRODUCT DESIGN:
Supra-annular Valve Design

The supra-annular leaflet position optimizes orifice area and flow while preserving circularity and coaptation.
TISSUE SELECTION: **PORCINE PERICARDIUM**

Porcine pericardium ensures optimal valve performance in a low delivery profile:

- Approximately half as thick as bovine pericardium
- Prevents tissue damage during loading, crimping, tracking, and deployment
- Allows for low-profile delivery across all valve sizes

---

PRODUCT DESIGN:

**14Fr Equivalent Delivery Profile Across All Evolut R Valve Sizes**

The low profile of the CoreValve and Evolut R systems helps minimize trauma during delivery, allowing physicians to treat patients with small or calcified vasculature.

Larger sheath size has been shown to increase the rate of major vascular complications\(^1\) and mortality.\(^2\)

---


---

MEDICAL EDUCATION ACADEMIA
EVOLUT R SYSTEM
# Device & Patient Selection Criteria

<table>
<thead>
<tr>
<th>Valve Size Selection</th>
<th>CoreValve® Evolut® R Bioprosthesis</th>
<th>CoreValve® Bioprosthesis</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Size</strong></td>
<td>23 mm</td>
<td>26 mm</td>
</tr>
<tr>
<td><strong>Annulus Diameter</strong></td>
<td>18-20 mm</td>
<td>20-23 mm</td>
</tr>
<tr>
<td><strong>Annulus Perimeter</strong></td>
<td>56.5-62.8 mm</td>
<td>62.8-72.3 mm</td>
</tr>
<tr>
<td><strong>Sinus of Valsalva Diameter (Mean)</strong></td>
<td>≥ 25 mm</td>
<td>≥ 27 mm</td>
</tr>
<tr>
<td><strong>Sinus of Valsalva Height (Mean)</strong></td>
<td>≥ 15 mm</td>
<td>≥ 15 mm</td>
</tr>
</tbody>
</table>

*Annulus Perimeter = Annulus Diameter x TT
Note: Measurements provided are approximate based on engineering specifications.
**DELIVERY CATHETER SYSTEMS**

**Evolut R DCS**

The Enveo R Delivery System with 14Fr-Equivalent In-Line Sheath is indicated for vessels down to **5.0 mm**

18Fr OD (14Fr-Equivalent)

- 7.6 cm InLine™ Sheath = 30 cm
- Working Length = 107 cm

**CoreValve DCS**

The 18 Fr CoreValve Accutrak Delivery system is indicated for vessels down to **6.0 mm**

AccuTrak Stability Layer

- 15 Fr
- 90.9 cm
- 12 Fr
- 2.5 cm
- 7.3 cm
- Working Length = 112.5 cm
LOADED CAPSULE UNDER FLUOROSCOPY

Note: Measurements provided are approximate based on engineering specifications.
TARGET IMPLANT DEPTH

**Evolut R**

Target implant depth is **3 - 5 mm**

Midway between nodes 0 and 1 to just below node 1

**CoreValve**

Target implant depth is **4 - 6 mm**

Between nodes 1 and 1.5
LOWEST DELIVERY PROFILE
14FR-EQUIVALENT SYSTEM WITH INLINE SHEELATH

Minimum Transarterial Access Vessel Diameters ≥ 5.0 mm
LOWEST DELIVERY PROFILE
NEARLY ALL PATIENTS TREATED VIA TRANSFEMORAL ACCESS

14-Fr Equivalent In-Line Sheath

Evolut R Global Clinical Trial Results (US IFU).

Implants by Access Route

94.7%
Patients Treated via Transfemoral Access

MEDICAL EDUCATION ACADEMIA
CONTROL DURING DEPLOYMENT
1:1 RESPONSE

Catheter shaft ‘spines’ provide stability to reduce stretching or compressing of shaft to enable 1:1 Response
EnVeö™ R DCS’s capsule flare and flexible catheter design enable uniform and controlled valve expansion and self-centering of the valve in the annulus.
CONTROL DURING DEPLOYMENT

SELF-CENTERING
CONTROL DURING DEPLOYMENT
ABILITY TO RECAPTURE AND REPOSITION

EnVeо R DCS provides option to recapture and reposition up to three times before reaching the ‘Point of No Recapture’*

* Up to 80% deployment
1. Accurate Positioning
   - 1:1 response with the ability to recapture and reposition the valve
2. More Consistent Radial Force*
3. Atraumatic Inflow
   - Redesigned inflow to reduce force applied by the inflow tip

13.3% 30 Day New Pacemaker**

*Comparison to CoreValve device
**Evolut R Global Clinical Trial
EXCEPTIONAL VALVE PERFORMANCE
ENHANCED SEALING

Enhanced Sealing with a More Conformable Frame
1. Increased Oversizing
2. More Consistent Radial Force
3. Extended Sealing Skirt *

6.8% Moderate & 0% Severe PVL**

*CoreValve Evolut R 26 and 29 mm only
**Evolut R Global Clinical Trial Results (US IFU).

Note: images may not be to exact scale and are for illustration purposes only.
EASE OF USE
IMPROVED FRAME RELEASE

- Paddle attachment incorporates a nested paddle and pocket mechanism for release
- Rounded paddle design provides a reliable release
- Metal paddle attachment helps assess paddle detachment under fluoroscopy
Packaging with Integrated Rinsing and Loading Bowls

Removable Rinsing Bowls

Integrated Loading Bath
MUCHAS GRACIAS!