Medtronic: CoreValve Evolut R and Engager TAVI System

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Within the past 12 months, the presenter or their spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below.

<table>
<thead>
<tr>
<th>Physician Name</th>
<th>Company/Relationship</th>
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<tbody>
<tr>
<td>Eberhard Grube, MD</td>
<td>Medtronic, CoreValve: C, SB, AB, OF</td>
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<td>Sadra Medical: E, C, SB, AB</td>
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<td>Direct Flow: C, SB, AB</td>
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<td>Mitralign: AB, SB, E</td>
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<td>Capella: SB, C, AB</td>
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<td>Valtech: E, SB, Claret: SB</td>
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Medtronic’s Approach to TAVI

• Strategic intent always to offer two complimentary valve platforms
• Multiple valves and multiple access routes needed in order to achieve the best outcome for every TAVI patient
• The right options – valve sizes, access routes – empower heart teams to achieve the best outcomes with every patient
Medtronic’s TAVI Portfolio: Common Factors

- Self-expanding, supra-annular valves for every access route
  - Self-expanding frames conform and seal to varying annular shapes
  - Supra-annular valve function facilitates coaptation in non-circular anatomy
  - Repositionability and controlled deployment enable proper positioning

CoreValve® Family
- Transfemoral
- Subclavian
- Direct Aortic

Engager™
- Transapical
- Direct Aortic
Engager Valve Design

- Control arms
- Self-expanding nitinol frame and polyester skirt
- Supra-annular valve function
- Bovine pericardial tissue
The Engager system is designed to offer both transapical and direct aortic access routes.

**Direct Aortic**
- Multi-center Engager DA Study underway
- Simple three step deployment
- Delivery catheter system with optional stability sheath

**Transapical**
- CE-Mark approved
- Simple three step deployment
- Integrated introducer sheath
CoreValve Design

Outflow
Supports valve commissures and enables controlled deployment

Waist
Promotes circularity, supports supra-annular valve

Inflow
Conforms and seals to the annulus

Low Radial Force
High Hoop Strength
High Radial Force
Nitinol Ideally Suited for Future TAVI

Durable Performance in small package is critical

**Superelasticity**
- Compact design for true low profile delivery

**Shape Retention**
- Self-anchoring
- Controlled retraction for precise delivery and placement
- Maintain valve shape without recoil

**Proven Performance**
- Corrosion resistance
- Low thrombogenicity
- Conformable to patient anatomy
- Fatigue performance
Porcine Pericardium
Optimal TAVI Tissue

Thin
Half the thickness of bovine
Prevents tissue damage during crimping, tracking, and deployment, allowing for low-profile delivery across all valve sizes.¹,²

Strong
Far exceeds physiologic need
Ultimate tensile strength (UTS) and suture pullout force for porcine and bovine pericardium are not statistically different¹,³ and exceed peak physiologic stresses.⁴

Flexible frame conforms to native annulus shape while maintaining the bioprosthesis in a higher position

- This decoupling of the valve from native annulus shape minimizes the impact of ellipticity at the valve level post deployment\(^1\)

1. Data on file at Medtronic

Images courtesy of Drs. de Jaegere and Schultz, Erasmus MC, Rotterdam, The Netherlands
CoreValve Clinical Outcomes

More than 40,000 implants worldwide

- High procedural success
  - Low rates of annular rupture, coronary compromise, valve embolism

- High survival rates

- Significant and persistent hemodynamic improvement

CoreValve ADVANCE, EuroPCR 2013
Use of CoreValve in failed surgical bioprostheses
Supra-annular valve function maximizes blood flow

Low post-procedural gradients

Large potential orifice area
Leaflets sit above the annulus where the frame is least constrained, opening up the valve for greater flow

1. Dvir et al., TCT. Miami, Fl. Oct 2012
Opportunities for Future

1. **Annular sealing**
   Reduces paravalvular leak

2. **Proper positioning**
   Key to achieving superior clinical outcomes, including PVL performance and conduction disturbances

3. **Low OD sheath to femoral artery ratio (SFAR)**
   Reduces major vascular complications

(Images courtesy of Dr. J. Sinning, University of Bonn)

(Hayashida K., Lefevre T., Chevalier B.; et al. Transfemoral Aortic Valve Implantation; New Criteria to Predict Vascular Complications, J Am Coll Cardiol Intv 4 2011 851-858)
Annular Sealing | Valve Design
Valve Height and Extended Skirt

Outflow design
Outflow height reduced by 10% and reshaped for improved fit, especially in angulated anatomy

Extended Skirt
Scalloped skirt creates longer landing plane for better sealing
Annular Sealing | Frame Characteristics
Cell Geometry and Radial Force

**Modified cell geometry**
Improves conformability in non-circular and calcified annulus while preserving anchoring

**Consistent radial force curve across operating zone**
Contributes to improved sealing across indicated annulus range

![Graph showing consistent radial force curve across annulus diameter range.](image)
Effect of Cover Index on PVL for CoreValve patients

<table>
<thead>
<tr>
<th>Authors</th>
<th># Patients</th>
<th>PVL ≥ 2</th>
<th>PVL &lt; 2</th>
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<tbody>
<tr>
<td>Vasa-Nicotera et al. 2012</td>
<td>122</td>
<td>13.5 ± 3.6</td>
<td>16.0 ± 4.4</td>
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<tr>
<td>Gotzmann et al. 2012</td>
<td>198</td>
<td>13.7 ± 6</td>
<td>15.9 ± 6.2</td>
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<tr>
<td>Sinning et al. 2012</td>
<td>146</td>
<td>10.1 ± 6.3</td>
<td>16.0 ± 4.6</td>
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Broad Range from 18–30 mm
First Time Deployment Accuracy
EnVevo Delivery System

1. **Predictable deployment** through an intuitive handle with 1:1 response and improved valve release.

2. Insertion and tracking via a low profile, flexible, 18Fr catheter.

3. Improved valve release mechanism.

4. Redesigned valve loading & packaging.

5. Facilitates delivery with an optional shorter-length catheter for subclavian and direct aortic access.
Resheathing, Repositioning and Deploying

Cadaver: 29mm CoreValve Evolut R

First Time Accuracy
Forced High Implant
Deep Implant
Introducer Sheath Sizing

Recognize inner diameter vs. outer (maximum) diameter measurements

18Fr Cook Introducer Sheath

18Fr

21.8Fr maximum diameter
Reduce Vascular Complication Risk
EnVeo R Delivery System with InLine Sheath

Current

22 FR (OD) | 26.7–29.7FR (OD)

CoreValve w/ 18Fr Cook Sheath | Sapien XT w/ Edwards e-Sheath

Future

18 FR (OD)
14 FR Equivalent

CoreValve Evolut R w/ InLine Sheath
Conclusions

- Reducing procedural complications can, ultimately, improve overall TAVI results
  - New technologies to further reduce delivery profile and avoid ventricular damage can contribute to improved TAVI outcomes
- Self-expanding technology provides platform for innovation
- Supra-annular valve provides optimal coaptation
- New delivery systems will enhance positioning necessary for improved TAVI performance
  - First time accuracy is goal, but recapture and repositionable technology provides back-up
- Continued advancement to downsize valve payload can address access challenges