Medtronic Evolut Pro: System Overview

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Disclosure Eberhard Grube, MD

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- G — Grant and or Research Support
- E — Equity Interests
- S — Salary, AB — Advisory Board
- C — Consulting fees, Honoraria
- R — Royalty Income
- O — Ownership
- OF — Other Financial Benefits
- SB — Speaker’s Bureau
PROVEN PLATFORM PERFORMANCE
MEDTRONIC COREVALVE™ AND EVOLUT™ SYSTEMS

Medtronic CoreValve and Evolut R Systems have an extensive history of proven platform performance:

- > 120,000 Implants
- > 1,000 Centers
- > 100 Countries
MEDTRONIC EVOLUT PRO SYSTEM
DESIGN GOALS

The Evolut PRO system is a next generation self-expanding transcatheter aortic valve (TAV) that is intended to achieve two primary performance goals:

1. **Provide Advanced Sealing**
   - Greater surface area contact
   - Low PVL Rates

2. **Maintain Proven Platform Performance**
   - Unsurpassed Hemodynamics
   - Control During Deployment
   - Low Delivery Profile
MEDTRONIC EVOLUT PRO SYSTEM
SYSTEM COMPONENTS

16 Fr Equivalent Delivery System

23/26/29 mm TAVs

23 and 26/29 mm Loading Systems
Together, the Evolut PRO and Evolut R Systems treat the widest annulus range of any commercially available TAVR system*

* Based on CT measurement
**Measurement for TAV in SAV only.  |  † Annulus Perimeter = Annulus Diameter x π
EVOLUT PRO
DESIGN GOAL 1:
ADVANCED SEALING
Building on Proven Design for **Advanced Sealing**

- **Conformable Frame**
  Self-expanding nitinol frame conforms to annulus

- **Consistent Radial Force**
  Frame oversizing and cell geometry provide consistent radial force across treatable annulus range

- **External Wrap**
  External wrap increases surface contact with native anatomy

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CoreValve | Evolut R | Evolut PRO
EVOLUT PRO
WRAP DESIGN AND CONSTRUCTION

- Evolut R TAV with added external porcine pericardial wrap
  - Identical frame and inner tissue as Evolut R
  - External wrap covers first 1½ inflow cells and extended skirt
- Sutures secure inner skirt and outer wrap together to the frame
  - Same number and location of sutures as Evolut R TAV
External Tissue Wrap Increases Surface Contact with Native Anatomy

- Surface contact between a transcatheter aortic valve and the native anatomy is critical for effective sealing
- Evolut PRO TAV’s conforming frame and consistent radial force provide contact at multiple levels
- The external wrap provides added tissue volume between the TAV and native anatomy to help reduce gaps and increase surface contact area

*Bench top evaluation of the frame contacting the annulus based on a CT analysis of 1 patient; Image Courtesy of Dr. Piazza and Prof. Lange, German Heart Center, Munich Germany
NOTE: Images are for illustrative purposes only and may not be indicative of clinical performance.
Animal Studies Suggest Favorable Response and Interaction with Native Tissue

- Low inflammatory response
- Stable and mature tissue growth observed at 90 days post implant
  - Thin and even layer of endothelial cells on inner lumen of device

Evolut PRO explanted from Porcine Model at 60 Days Cross Section between Nodes 1 and 2, example picture from MDT research study on file illustrating tissue interaction.

1. Medtronic data on file. 90 day porcine GLP Evolut R study, results may not be indicative of clinical performance
2. Medtronic, data on file. 60 day porcine research study model, results may not be indicative of clinical performance.
EVOLUT PRO
DESIGN GOAL 2:
PROVEN PLATFORM PERFORMANCE
Proven Platform Performance

- Supra-annular valve function provides **unsurpassed hemodynamics**
- Controlled, accurate deployment with the ability to recapture and reposition
- **Lowest delivery profile** with integrated InLine Sheath

Evolut R TAV

Evolut PRO TAV
PROVEN PLATFORM PERFORMANCE
EVOLUT FAMILY TAV DESIGN

SUPRA ANNULAR VALVE DESIGN
- Maximizes leaflet coaptation
- Promotes single digit gradients and large EOAs

PORCINE PERICARDIAL TISSUE
- Thin for low profile delivery
- Strength and pliability for durability

SELF-EXPANDING FRAME
- Conforms and seals to the annulus
- The foundation for recapturability
EnVeo™ R 16Fr Equivalent DCS enables controlled 1:1 Response with ability to Recapture
EnVeo R InLine™ Sheath allows treatment of trans-arterial access vessel diameters $\geq 5.5\text{ mm}$ across all Evolut PRO valve sizes.
Lowest delivery profile across all valve sizes with InLine Sheath

<table>
<thead>
<tr>
<th>Evolut R 23/26/29 mm TAV</th>
<th>Evolut PRO /Evolut R 34 mm TAV</th>
</tr>
</thead>
<tbody>
<tr>
<td>≥ 5.0 mm</td>
<td>≥ 5.5 mm</td>
</tr>
<tr>
<td>Treatable Access Vessel Diameter</td>
<td></td>
</tr>
<tr>
<td>18 Fr OD</td>
<td>20 Fr OD</td>
</tr>
<tr>
<td>14 Fr Equivalent</td>
<td>16 Fr Equivalent</td>
</tr>
</tbody>
</table>

The Evolut System retains its outer diameter as it enters the vessel and remains at this diameter as it is advanced to the annulus.
EVOLUT PRO
CLINICAL PERFORMANCE
<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Mean ± SD or %</th>
<th>N=60</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, years</td>
<td>83.3 ± 7.2</td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>65.0</td>
<td></td>
</tr>
<tr>
<td>BSA, m²</td>
<td>1.8 ± 0.2</td>
<td></td>
</tr>
<tr>
<td>STS – PROM, %</td>
<td>6.4 ± 3.9</td>
<td></td>
</tr>
<tr>
<td>NYHA Class III or IV</td>
<td>70.0</td>
<td></td>
</tr>
<tr>
<td>Peripheral vascular disease</td>
<td>43.3</td>
<td></td>
</tr>
<tr>
<td>Atrial fibrillation / atrial flutter</td>
<td>18.6</td>
<td></td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td>43.3</td>
<td></td>
</tr>
<tr>
<td>Severe aortic calcification</td>
<td>20.5</td>
<td></td>
</tr>
<tr>
<td>LV ejection fraction, %</td>
<td>58.9 ± 12.4</td>
<td></td>
</tr>
<tr>
<td>Pre-existing pacemaker</td>
<td>15.0</td>
<td></td>
</tr>
</tbody>
</table>

Forrest, et al., ACC, 2017
## EVOLUT PRO SYSTEM CLINICAL TRIAL
### PROCEDURAL OUTCOMES

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>% or mean ± SD</th>
<th>N = 60</th>
</tr>
</thead>
<tbody>
<tr>
<td>General anesthesia</td>
<td>58.3</td>
<td></td>
</tr>
<tr>
<td>Iliofemoral access approach</td>
<td>98.3</td>
<td></td>
</tr>
<tr>
<td>Valve Size Implanted</td>
<td></td>
<td></td>
</tr>
<tr>
<td>26 mm</td>
<td>40.0</td>
<td></td>
</tr>
<tr>
<td>29 mm</td>
<td>60.0</td>
<td></td>
</tr>
<tr>
<td>Pre-TAVR balloon dilation</td>
<td>51.7</td>
<td></td>
</tr>
<tr>
<td>Post-implant balloon dilation</td>
<td>26.7</td>
<td></td>
</tr>
<tr>
<td>Percentage of patients repositioned</td>
<td>35.0</td>
<td></td>
</tr>
<tr>
<td>Average implant depth, mm</td>
<td>4.3 ± 1.6</td>
<td></td>
</tr>
</tbody>
</table>

Forrest, et al., ACC, 2017
Low rates of PVL while maintaining low rates of mortality, stroke, and need for pacemaker

Forrest, et al., ACC, 2017
Supra-annular valve function provides single-digit gradients and large effective orifice areas.
87.9% of survivors improved NYHA class at 30 days
EVOLUT PRO TRANSFEMORAL PROCEDURE & CASE EXAMPLE
# EVOLUT PRO/ EVOLUT R PATIENT SELECTION
## AORTIC ROOT CRITERIA

<table>
<thead>
<tr>
<th>Valve Size Selection</th>
<th>Evolut PRO TAV</th>
<th>Evolut R TAV</th>
</tr>
</thead>
<tbody>
<tr>
<td>Size</td>
<td>23 mm</td>
<td>26 mm</td>
</tr>
<tr>
<td>Annulus Diameter</td>
<td>17*/18 – 20 mm</td>
<td>20 – 23 mm</td>
</tr>
<tr>
<td>Annulus Perimeter (π x Diameter)</td>
<td>53.4*/ 56.5 – 62.8 mm</td>
<td>62.8 – 72.3 mm</td>
</tr>
<tr>
<td>Sinus of Valsalva Diameter (Mean)</td>
<td>≥ 25 mm</td>
<td>≥ 27 mm</td>
</tr>
<tr>
<td>Sinus of Valsalva Height (Mean)</td>
<td>≥ 15 mm</td>
<td></td>
</tr>
</tbody>
</table>

* Measure for TAV in SAV only
**Controlled, Accurate Deployment via Familiar Evolut Procedure and Best Practices**

### Pre-Deployment
- Vascular Access via 16FR InLine Sheath or 20Fr Introducer
- Inspected Loaded Capsule under Fluoro
- BAV According to Standard Practice
- Advance and Align System within Native Annulus
- Align annulus/catheter marker band

### Deployment
- Begin Deployment at Target Depth (3 – 5 mm)
- Very Slow First 1/3 Deployment
- Consider Controlled Pacing (90 – 110 bpm)
- Release System Tension Prior to Release

### Assessment
- Assess Valve Performance; if PVL ≥ Mild, Wait 10 minutes to Reassess
- Address PVL ≥ Mild According to Standard Practice
- Close Vascular Access
EVOLUT PRO CASE EXAMPLE
AORTIC ROOT MEASUREMENTS

35% cardiac phase

Ao Annulus mean diameter 21.2 mm

<table>
<thead>
<tr>
<th>Measurement</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Major x Minor aortic annulus diameter</td>
<td>23.8 x 18.6</td>
</tr>
<tr>
<td>Aortic Annulus perimeter</td>
<td>67.0</td>
</tr>
<tr>
<td>Max Ascending Aorta diameter</td>
<td>34.8</td>
</tr>
<tr>
<td>Sinus of Valsalva diameter (Mean)</td>
<td>28.4 – 29.0</td>
</tr>
<tr>
<td>Sinus of Valsalva height (Mean)</td>
<td>20.2 – 20.8</td>
</tr>
<tr>
<td>Sinotubular Junction Diameter (STJ)</td>
<td>25.9 – 26.9</td>
</tr>
</tbody>
</table>

Sinus Height

Left Coronary Cusp

SOV diameter

60% cardiac phase

Right Coronary Cusp

LVOT

Non Coronary Cusp
EVOLUT PRO CASE EXAMPLE
ACCESS MEASUREMENT AND ASSESSMENT

Clinical Analyst’s Image

Right Femoral Diameter
Min. Ø: 7.6 mm
Max. Ø: 8.9 mm
Avg. Ø: 8.2 mm

Left Femoral Diameter
Min. Ø: 8.1 mm
Max. Ø: 8.1 mm
Avg. Ø: 8.1 mm

Right External Iliac Diameter
Min. Ø: 7.7 mm
Max. Ø: 8.3 mm
Avg. Ø: 8.0 mm

Left External Iliac Diameter
Min. Ø: 7.5 mm
Max. Ø: 8.1 mm
Avg. Ø: 7.8 mm

Tortuous

7.6 x 8.9
RFA min. diameter

7.7 x 8.3
RIA min. diameter

8.1 x 8.1
LFA min. diameter

7.5 x 8.1
LIA min. diameter
EVOLUT PRO CASE EXAMPLE
ANNULAR AND LVOT CALCIFICATION ASSESSMENT
EVOLUT PRO CASE EXAMPLE
SYSTEM TRACKING
EVOLUT PRO CASE EXAMPLE
VALVE DEPLOYMENT TO POINT OF NO RECAPTURE

Controlled, 1:1 Response with Ability to Recapture*

*Able to recapture up to three times before reaching the point of no recapture; upon third recapture the system must be removed from the patient and replaced with a new delivery system and TAV.
Conformable frame, Consistent Radial Force, and External Wrap for Advanced Sealing
EVOLUT PRO CASE: LVOT CALCIFICATION
AR AT DISCHARGE AND 30 DAYS

Unsurpassed Hemodynamics

Site Reported AR*:
• Discharge = None
• 30 Days = None

*Represents one case only and may not be indicative of clinical performance in other patients.
MEDTRONIC EVOLUT PRO SYSTEM

SUMMARY

Intended for Advanced Sealing

- Conforming frame and consistent radial force provide contact at multiple levels in various annulus shapes
- External tissue wrap increases surface contact area

Proven Platform Performance

- Controlled, accurate deployment with the ability to recapture
- Supra-annular valve function provides unsurpassed hemodynamics
- Lowest delivery profile with integrated InLine Sheath
Thank you for your kind attention!