Foldax® Tria:
First in Human Implant of a Totally Synthetic Polymeric Aortic Valve

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Foldax Tria Valve Technology

**Material**
- Specifically for heart valves
- Patented polymer
- Biocompatible/biostable
- No need for AC therapy

**Design**
- Leaflets, stent & polymer FEA engineered
- More durable than tissue
- 1-2 size larger EOA than tissue valves

**Process**
- Robotic manufacturing
**Tria Valve Development**

- **Surgical AVR**
  - Validate Tria technology
  - Material, design, process

- **Surgical MVR**
  - Designed to withstand mitral pressures
  - Address unmet durable mitral valve need

- **TAVR**
  - Better durability for low-risk pts
  - Lower profile

- **Meets all FDA testing requirements**
- **Initiated Aortic Early Feasibility Study (EFS)**
Development Testing

Chronic Sheep Calcification

Tria Valve

Pericardial Valve

Animal Pressure Gradients

- Foldax 23mm, n=8
- Edwards Perimount 25mm, n=2, Control

4.7mo.
Clinical Experience: Surgical Aortic EFS First-in-Human Patient #1

- **Patient #1**
  - Age: 68 yrs
  - Height: 69 in
  - Weight: 190 lbs
  - Med Hx: Hypertension, Hyperlipidemia, Asthma
  - NYHA: Class II

- Surgery: July 30, 2019
  - 21mm valve

- Beaumont Health

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<thead>
<tr>
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<th>Pre-op</th>
<th>Post-op (30 day)</th>
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<tbody>
<tr>
<td>EF</td>
<td>65%</td>
<td>70%</td>
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<tr>
<td>Gradient</td>
<td>Mean 44mmHg Peak 74mmHg</td>
<td>Mean 19mmHg CO = 7l/m</td>
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<tr>
<td>Symptoms</td>
<td>SOB &amp; DOE</td>
<td>Resolved</td>
</tr>
</tbody>
</table>
Clinical Experience: Surgical Aortic EFS Patient #2

• **Patient #2**
  - Age: 50 yrs
  - Height: 68 in
  - Weight: 212 lbs
  - Med Hx: Murmur, DOE, Tonsillectomy

• Surgery: Sept. 19, 2019
  - 23mm valve

• Riverside Methodist

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<tr>
<th></th>
<th>Pre-op</th>
<th>Post-op</th>
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<tbody>
<tr>
<td>EF</td>
<td>60-65%</td>
<td>70%</td>
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<tr>
<td>Gradient</td>
<td>Mean 45mmHg</td>
<td>Mean 10mmHg</td>
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<tr>
<td></td>
<td>Peak 79mmHg</td>
<td>CO = 9l/m</td>
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Clinical Experience: Surgical Aortic EFS Patient #2
Clinical Experience: Surgical Aortic EFS Patient #2

- Mean gradient = 10mmHg
Tria TAVR Development

• Same polymer as SAVR clinical valve
• FEA engineering optimizes polymer leaflet & stent design
• Potential for significantly better durability for low-risk TAVR patients
• Design goal - lower profile crimped valve and delivery system
TAVR - Proprietary Design

- Self-expanding nitinol frame - supra annular leaflets
- Maintains coronary access
- Controlled deployment - resheathable
- Sealing skirt – 10mm

Bench Testing:
- Accelerated wear: ~100 million cycles
- 27mm valve
- Mean gradient: 3.6mmHg
- EOA: 2.9cm²
Acute Animal Feasibility

- Implanted in aortic position to acutely assess in-vivo performance
- Delivered via ascending aorta, on-pump procedure

Deployment

Confirmation of proper placement & leaflet function
Acute Animal Feasibility

- Fully functioning valve under in-vivo conditions
Summary

- New polymer technology engineered to potentially last a patient’s lifetime
- Eliminates all animal tissue constraints
- Larger EOA for better hemodynamics
- Lower profile & more durable TAVR goal

2019 Milestones

- Met FDA requirements Aortic EFS approval
- Successful first-in-human experience in Aortic EFS
- Successful TAVR animal proof of concept