Foldax Biopolymer Valves: An Alternative to Tissue Based Leaflet Valves

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Disclosures:
None
Heart Valve Development Timeline

Address longstanding conundrum of tissue valve limited durability vs. mechanical valve lifetime anticoagulation
Novel Biopolymer Heart Valve Goals

➢ Superior durability
   - No rejection, calcification
   - Strong polymer leaflets

➢ Superior hemodynamics
   - Thinner, more pliable leaflets

➢ No long-term anticoagulation

➢ Precision manufacturing
   - Complete robotic manufacturing

➢ Potential lifetime valve

Address longstanding conundrum of tissue valve limited durability vs. mechanical valve lifetime anticoagulation
Valve Design
New Biopolymer Specifically for Heart Valve Function*

Patented Silicone Poly(urethane urea) Formulation

- Formulated to exceed functional stresses of human heart valves
- Enables computer optimized design
- Not limited by constraints & variability of animal tissue

- Thinner, lighter leaflets than tissue - less inertia, lowest opening/closing resistance
- Stronger material - highly fatigue, tear resistant
- Biostable, biocompatible
- Non-calcific#

# In sheep studies
# Edwards Aortic Valve Nominal Dimensions

## Table 1. Nominal Dimensions

**INSPIRIS RESILIA Aortic Valve, Model 11500A**

<table>
<thead>
<tr>
<th>Size (mm)</th>
<th>19</th>
<th>21</th>
<th>23</th>
<th>25</th>
<th>27</th>
<th>29</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>A. Tissue Annulus Diameter (Stent Diameter, mm)</strong></td>
<td>19</td>
<td>21</td>
<td>23</td>
<td>25</td>
<td>27</td>
<td>29</td>
</tr>
<tr>
<td><strong>B. Internal Diameter (Stent ID, mm)</strong></td>
<td>18</td>
<td>20</td>
<td>22</td>
<td>24</td>
<td>26</td>
<td>28</td>
</tr>
<tr>
<td><strong>C. Profile Height (mm)</strong></td>
<td>13</td>
<td>14</td>
<td>15</td>
<td>16</td>
<td>17</td>
<td>18</td>
</tr>
<tr>
<td><strong>D. External Sewing Ring Diameter (mm)</strong></td>
<td>25</td>
<td>27</td>
<td>29</td>
<td>32</td>
<td>34</td>
<td>36</td>
</tr>
<tr>
<td><strong>Geometric Orifice Area (mm²)</strong></td>
<td>236</td>
<td>293</td>
<td>357</td>
<td>424</td>
<td>500</td>
<td>579</td>
</tr>
</tbody>
</table>
## Foldax Tria Aortic Valve Dimensions

<table>
<thead>
<tr>
<th>Valve Size</th>
<th>19</th>
<th>21</th>
<th>23</th>
<th>25</th>
<th>27</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stent ID</td>
<td>19.0 mm</td>
<td>21.0 mm</td>
<td>23.0 mm</td>
<td>25.0 mm</td>
<td>27.0 mm</td>
</tr>
<tr>
<td>Cuff OD</td>
<td>28.0 mm</td>
<td>30.0 mm</td>
<td>32.0 mm</td>
<td>34.0 mm</td>
<td>36.0 mm</td>
</tr>
<tr>
<td>Total Height</td>
<td>13.5 mm</td>
<td>14.5 mm</td>
<td>15.5 mm</td>
<td>16.5 mm</td>
<td>17.5 mm</td>
</tr>
<tr>
<td>Aortic Protrusion</td>
<td>11.0 mm</td>
<td>12.0 mm</td>
<td>13.0 mm</td>
<td>14.0 mm</td>
<td>15.0 mm</td>
</tr>
</tbody>
</table>
Nominal Dimensions: 25 mm Inspiris and Tria Aortic Valves

<table>
<thead>
<tr>
<th>Valve Size</th>
<th>25 Inspiris</th>
<th>25 Tria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stent Inside Diameter</td>
<td>24 mm</td>
<td>25 mm</td>
</tr>
<tr>
<td>Total Height</td>
<td>16 mm</td>
<td>16.5 mm</td>
</tr>
<tr>
<td>Cuff Outside Diameter</td>
<td>32 mm</td>
<td>34 mm</td>
</tr>
</tbody>
</table>
Computer Optimized Design

- Polymer allows optimal leaflet shape design
- Leaflet shape maximizes opening/closing efficiency & minimizes leaflet stresses
- Applicable to both surgical & transcatheter valves
Foldax Polymer Valves
Polymer Technology Enables Robotic Manufacturing

Highly precise
   Single digit micron tolerances

Consistent, reproducible process

No human assembly
   No COVID-type impact on manufacturing

Not possible with tissue
Durability
In-Vivo Sheep Aortic Study

Tria valves show:

- No calcification
- No pannus formation
Hemodynamics
Foldax Aortic trial
30 Day Echo Results

Corelab echo results

EOA at 30 Days - Expanded Cohort

<table>
<thead>
<tr>
<th>Valve Size</th>
<th>EOA (cm²)</th>
<th>n</th>
</tr>
</thead>
<tbody>
<tr>
<td>19</td>
<td>1.5</td>
<td>1</td>
</tr>
<tr>
<td>21</td>
<td>1.72</td>
<td>5</td>
</tr>
<tr>
<td>23</td>
<td>1.92</td>
<td>5</td>
</tr>
<tr>
<td>25</td>
<td>2.17</td>
<td>6</td>
</tr>
<tr>
<td>27</td>
<td>3.75</td>
<td>2</td>
</tr>
</tbody>
</table>
Case Study

HPI: 62 yo male o/w healthy male
played football in college, then in marines, now heavy equipment operator
NYHA Class III symptoms

Echo: Probable bicuspid valve
Peek Vel - EF > 60%, 5.88 m/s, Mean gradient – 75 mmHg, EOA – 0.43 cm²

CTA : LVOT – 34 mm
Sinus of Valsalva – 3.7 mm
Sinotubular Jxn – 3.0 mm

Catherization: 60% left main disease

Surgery: AVR/Cabg x2
25 mm Foldax Tria aortic valve
Lima – LAD, SVG – Circumflex

Discharged on Postoperative Day # 5, NSR, no issues
6 month follow-up off anticoagulation, doing well
## Hemodynamics
### 25 mm Tria Valve

<table>
<thead>
<tr>
<th>ECHO</th>
<th>Mean gradient (mmHg)</th>
<th>Effective Orifice Area (cm²)</th>
<th>Insufficiency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intra-operative</td>
<td>6</td>
<td></td>
<td>none</td>
</tr>
<tr>
<td>One month</td>
<td>6</td>
<td>2.5</td>
<td>none</td>
</tr>
<tr>
<td>Three month</td>
<td>6</td>
<td>2.0</td>
<td>none</td>
</tr>
<tr>
<td>Six month</td>
<td>8</td>
<td>2.5</td>
<td>none</td>
</tr>
</tbody>
</table>
Tria Aortic Valve Echoes
Tria Valve Development

- Validate Tria technology
  - Material, design, process

- Designed to withstand mitral pressures
  - Address unmet durable mitral valve need

- Better durability for low-risk pts
  - Coronary access
  - Lower profile

- Meets all FDA testing requirements

- Early Feasibility Studies
  - Aortic nearing completion
  - Mitral enrolling
  - TAVR 2022
Foldax TAVR Design

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Foldax TAVR Animal Data

Angiogram at 30 Days

No Calcification at 30 Days

Fully functioning leaflets
No thrombus at 30 days
## Conclusions

- Polymer formulated for heart valve function – thinner, lighter leaflets
- Computer modeling optimizes hemodynamics & durability
- Bench & animal hemodynamics - Tria superior to pericardial valves
- Robotics ensure precise & repeatable manufacturing of each valve
- Early surgical valve clinical results are encouraging
- TAVR planned to move into clinicals in 2022