Bioengineered PERIMOUNT Design

- Mathematically modeled bioengineered design is intended to optimize implantability, hemodynamics and long-term durability\(^1\)\(^-\)\(^8\)
- Flexible cobalt-chromium alloy stent absorbs energy during the cardiac cycle
- Three independent symmetrical pericardial leaflets matched for thickness and elasticity are mounted under a flexible stent

Mitral Design

- Low-profile height,\(^9\) to reduce the risk associated with ventricular wall protrusion and LVOTO
- Black suture markers indicate proper orientation

Implantability

The Tricentrix holder system provides ease of implant. When fully deployed, the commissures should deflect towards the center of the valve, guiding sutures into their correct position to minimize the risk of suture entrapment.
The PERIMOUNT mitral valve design consistently demonstrates long-term endurance, as reported in numerous studies.

**Tissue Treatment***

The PERIMOUNT Theon valve is treated with the Carpentier-Edwards ThermaFix process, which confronts both major calcium binding sites: residual glutaraldehydes and phospholipids.

The PERIMOUNT Plus valve is treated with the XenoLogiX treatment, a two-step process targeting residual phospholipids.

*No clinical data are available which evaluates the long-term impact of the Edwards Lifesciences tissue treatments in patients.*
Carpentier-Edwards PERIMOUNT Theon Mitral Pericardial Bioprostheses, Model 6900PTFX
Carpentier-Edwards PERIMOUNT Plus Mitral Pericardial Bioprostheses, Model 6900P

### Nominal Specifications (mm)

<table>
<thead>
<tr>
<th>Size</th>
<th>25 mm</th>
<th>27 mm</th>
<th>29 mm</th>
<th>31 mm</th>
<th>33 mm</th>
</tr>
</thead>
<tbody>
<tr>
<td>A. Stent Diameter (Wireform)</td>
<td>26</td>
<td>27</td>
<td>29</td>
<td>31</td>
<td>33</td>
</tr>
<tr>
<td>B. External Stent Post Diameter (Base)</td>
<td>28.0</td>
<td>29.5</td>
<td>31.5</td>
<td>33.5</td>
<td>33.5</td>
</tr>
<tr>
<td>C. External Stent Post Diameter (Tip)</td>
<td>29</td>
<td>31</td>
<td>34</td>
<td>35</td>
<td>35</td>
</tr>
<tr>
<td>D. External Sewing Ring Diameter</td>
<td>34</td>
<td>36</td>
<td>39</td>
<td>41</td>
<td>43</td>
</tr>
<tr>
<td>E. Ventricular Projection</td>
<td>12</td>
<td>13</td>
<td>14</td>
<td>14</td>
<td>15</td>
</tr>
<tr>
<td>F. Total Profile Height</td>
<td>17</td>
<td>18</td>
<td>19</td>
<td>20</td>
<td>20</td>
</tr>
</tbody>
</table>

### Accessories Information

**Model 6900PTFX**
- Individual Sizers (specify size): 1169HP or 1169P
- Reusable handle: 1111
- Flexible, reusable mitral handle: 1117
- Longer, single-use handle: 1126

**Model 6900P**
- Individual Sizers (specify size): 1169P
- Reusable handle: 1111
- Longer, single-use handle: 1126

### References

17. Carpentier-Edwards PERIMOUNT pericardial bioprosthesis 16-year results. Data on file at Edwards Lifesciences, 2003. (Freedom from explant due to structural valve deterioration; n = 435; mean age = 60.7 ± 11.6 yrs)

### Brief Summary: Mitral Bioprostheses

**Indications:** For use in patients whose mitral valvular disease warrants replacement of their natural or previously placed prosthetic valve and when the valve cannot be repaired. **Contraindications:** Do not use if surgeon believes it would be contrary to the patient’s best interests. **Complications and Side Effects:** Stenosis, regurgitation, endocarditis, hemolysis, thromboembolism, valve thrombosis, nonstructural dysfunction, structural valve deterioration, anemia, arrhythmia, hemorrhage, transient ischemic attack/stroke, congestive heart failure, myocardial infarction, angina, ventricular perforation by stent posts, any of which could lead to reoperation, explantation, permanent disability and death. **Warnings:** Alternative therapies should be considered in the presence of conditions affecting calcium metabolism or when calcium containing chronic drug therapies are used, including children, adolescents, young adults and patients on a high calcium diet or maintenance hemodialysis. Should be used with caution in the presence of severe systemic hypertension or when anticipated patient longevity is longer than the known longevity of the prosthesis.

**CAUTION:** Federal (United States) law restricts this device to sale by or on the order of a physician. See instructions for use for full prescribing information, including indications, contraindications, warnings, precautions and adverse events.

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