Design
- Mathematically modeled bioengineered design is intended to optimize implantability, hemodynamics and long-term durability
- Flexible cobalt-chromium stent absorbs energy during the cardiac cycle
- Three independent symmetrical pericardial leaflets matched for thickness and elasticity are mounted under a flexible stent
- Compact sewing ring to facilitate implant in small aortic roots and supra-annular design to maximize valve orifice area

Indications
The Carpentier-Edwards PERIMOUNT pericardial aortic bioprosthesis is intended for use in patients whose aortic valvular disease is sufficiently advanced to warrant replacement of their natural valve with a prosthetic one. It is also intended for use in patients with a previously implanted aortic valve prosthesis that is no longer functioning adequately and requires replacement. In the latter case, the previously implanted prosthesis is surgically excised and replaced by the replacement prosthesis.

Materials List
- Valve leaflets: Bovine pericardium
- Stent: Cobalt-chromium
- Fabric covering stent: Polyester cloth

Tissue Treatment
- Model 3000TFX features the Carpentier-Edwards ThermaFix process*, which confronts both major calcium binding sites: residual glutaraldehydes and phospholipids
- Model 3000 features the XenoLogiX treatment*, a two-step process targeting residual phospholipids

General Product Information
- Storage Temperature: 10 °C to 25 °C (50-77 °F)
- Storage Solution: Glutaraldehyde
- Rinse Procedure: 500 ml (sterile physiological saline solution) x 60 seconds Repeat once using new saline solution
- MRI Safety Information: The device has been shown not to have magnetic interactions at up to 8 tesla. It is also safe with respect to RF heating at 1.2 w/kg for up to 15 minutes. Artifacts have been determined at 1.5 tesla

*No clinical data are available which evaluates the long-term impact of the Edwards Lifesciences tissue treatments in patients.
Specifications

**Model 3000/ 3000TFX**

<table>
<thead>
<tr>
<th>Size</th>
<th>19 mm</th>
<th>21 mm</th>
<th>23 mm</th>
<th>25 mm</th>
<th>27 mm</th>
<th>29 mm</th>
</tr>
</thead>
<tbody>
<tr>
<td>A. Stent Diameter (TAD)</td>
<td>19</td>
<td>21</td>
<td>23</td>
<td>25</td>
<td>27</td>
<td>29</td>
</tr>
<tr>
<td>B. Internal Diameter (Stent I.D.)</td>
<td>18</td>
<td>20</td>
<td>22</td>
<td>24</td>
<td>26</td>
<td>28</td>
</tr>
<tr>
<td>C. Profile Height</td>
<td>14</td>
<td>15</td>
<td>16</td>
<td>17</td>
<td>18</td>
<td>19</td>
</tr>
<tr>
<td>D. External Sewing Ring Diameter</td>
<td>24</td>
<td>26</td>
<td>28</td>
<td>30</td>
<td>32</td>
<td>34</td>
</tr>
</tbody>
</table>

Significant dimensions in millimeters (nominal values)

Sizers and Accessories

**Model 1130**  Complete sizer set

**Model 1111**  Reusable handle

**Model 1126**  Single-use handle (extended length)

References


Brief Summary: Aortic Bioprostheses

**Indications**: For use in patients whose aortic valvular disease warrants replacement of their natural or previously placed prosthetic valve. **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, 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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