Aortic Pericardial Bioprosthesis

DOKIMOS PLUS

BEYOND RELIABLE
Patients demand a reliable heart valve that improves quality of life. Cardiac surgeons demand reliable and consistent performance both intra and post-operatively.

**DOKIMOS** = Trustworthy + Reliable

**DOKIMOS Plus** = Beyond Reliable

### Why Dokimos Plus?

For the past 20 years, Dokimos Plus Pericardial Heart Valves have been successfully implanted in numerous cardiac institutions in its country of manufacture, Brazil, as well as other international markets.

Over this period, Dokimos Plus Aortic Bioprosthesis has consistently demonstrated to be a reliable alternative to the well-established traditional pericardial heart valves in use today.

### Key Features

1. Dokimos Plus® allows for versatility and ease of implantability.
   - Dokimos Plus profile provides ample clearance from the coronary Ostia. Its low profile facilitates visibility and ease of suturing when implanting the device.

2. Treated with Reducer® Advanced tissue process.


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Labcor
Commitment to life
**Reliable Design**

- **Ease of implantation** with its low profile stent and ample suture cuff.
- **Profile height** optimizes coaptation area and reduce the potential prolapse and leakage.
- **Designed for both**: Supra-annular or intra-annular placement.
- **Larger EOA comparable to other pericardial valves**, providing superior hemodynamic performance.

**The pericardial thickness is determined for each valve diameter.**
Proprietary pericardium thickness, fiber, structure, elasticity evaluation and strength, as well as leaflets desing matching to appropriate size valve, optimizing coaptation and maximizing flow.

- Externally mounted **leaflets allows for** optimum blood flow.
- **Pre-molded tissue-to-tissue** interface minimizes the risk of leaflet abrasion and structural valve deterioration.

**Reducer®**

Reducer® special treatment is a process to reduce antigenicity and lipidic content, as well as major binding calcium sites, hence, reducing calcification. Reducer® also optimizes the cross-link increasing the tissue’s biological stability. Furthermore, it does not submit the tissue to fixation stresses (zero pressure), thus preserving structural integrity, while keeping mechanical properties.

* No clinical data are available which evaluate the long-term impact of the Reducer® tissue treatment in patient.
Accessories

Labcor provides valves sizers for accurate valve selection. Handles are also provided for attachment to the valve holder.

The ease of attachment-detachment for the ease click system of the Dokimos handle and Dokimos holder are optimized for ease of use and implantability.

Dokimos introduces the all-in-one true-fit sizer. The lower portion of the sizer is a cylindrical conical shape for determining annuli fit. The upper portion, is an exact dimensional replica of the Dokimos Plus, it reflects the sewing ring dimensions as well as the profile height of the commissures for optimal sizing. Its Design provides an excellent view of the coronary Ostia.

The true-fit sizers are made from stainless steel handles and nitinol shafts which are flexible and returns to its original form after each steam sterilization.

Sizers are available 19 to 27 mm.
Comparative Hemodynamics

Hemodynamic data for Dokimos Plus obtained from 6 clinical sites, as part of a multicenter clinical study. Comparative data analysis performed by independent echocardiography laboratory.

Effective Orifice Area (EOA)

Implant data
Patients implanted valve from Jan/2009 to Nov/2011. Echo performed after 6 months.
Total of Patients: 121  Mean age: 63 +/- 13 years
Male: 57%  Female: 43%
Average Mean EOA: 1.80 cm²
Average Mean Gradient: 11.74 mmHg  Average Max Gradient: 22.06 mmHg
EOA Index: ≥0.85 cm²/m² total: 76%  <0.85 cm²/m² total: 24%
DOKIMOS PLUS
AORTIC PERICARDIAL BIOPROSTHESES

With more than 15,000 implants.

BEYOND RELIABLE

Product Specifications

- Low valve profile allows ease of insertion through small incisions or in small aortic roots;
- Coronary ostia clearance achieved with low cusp height.

<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>External Sewing Ring Diameter (in millimeters)</td>
<td>23</td>
<td>25</td>
<td>27</td>
<td>29</td>
<td>31</td>
</tr>
<tr>
<td>External Stent Diameter (in millimeters)</td>
<td>19</td>
<td>21</td>
<td>23</td>
<td>25</td>
<td>27</td>
</tr>
<tr>
<td>Internal Stent Diameter (in millimeters)</td>
<td>16</td>
<td>18</td>
<td>20</td>
<td>22</td>
<td>24</td>
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<tr>
<td>Projection (in millimeters)</td>
<td>8</td>
<td>9</td>
<td>10</td>
<td>11</td>
<td>12</td>
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<tr>
<td>EOA (cm²) *</td>
<td>1.5</td>
<td>1.8</td>
<td>2.3</td>
<td>2.5</td>
<td>2.7</td>
</tr>
<tr>
<td>Profile Height</td>
<td>11</td>
<td>12</td>
<td>13</td>
<td>15</td>
<td>16</td>
</tr>
</tbody>
</table>

* Heart valve function test - VivoBio System - Aarlid Formula - CO - 4. L/min.
* Picture and drawings not to scale. Dimensions taken from valve specifications referenced below.
* No clinical data are available which evaluate the long-term impact of the Labcor tissue treatment in patients.
* Not available for sale in the United States.

References
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