Aortic Pericardial Bioprosthesis

Dokimos Plus

beyond Reliable

CE 1023

Labcor
Commitment to life

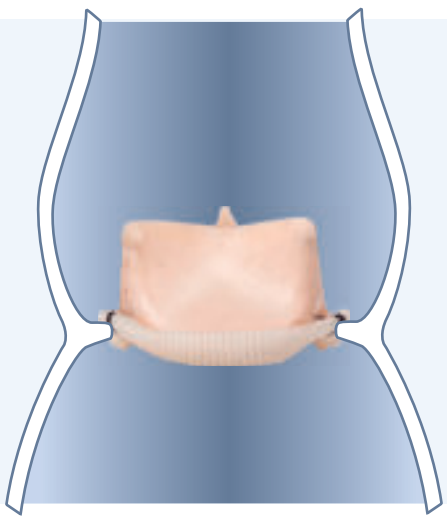
Patients demand a reliable heart valve that improves quality of life. Cardiac surgeons demand reliable and consistent performance both intra and post-operatively.

DOKIMOS = Trustworthy + Reliable

DOKIMOS Plus = Beyond Reliable

Why Dokimos Plus?

[1] 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.
2. Dokimos Plus profile provides ample clearance from the coronary Ostia. Its low profile facilitates visibility and ease of suturing when implanting the device.
3. Treated with Reducer® Advanced tissue process.
4. Proprietary pre-molded porcine pericardium providing Tissue-to-Tissue interface.

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Reliable Design

Ease of implantation with its low profile stent and ample suture cuff.

Profile heigth otimizes coaptation area and reduce the potencial the 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 strenght, as well as leaftets desing matching to appropriate size valve, optimizing coaptation and maximizing flow.

Externally mounted **leaflets allows for** optimum blood flow .

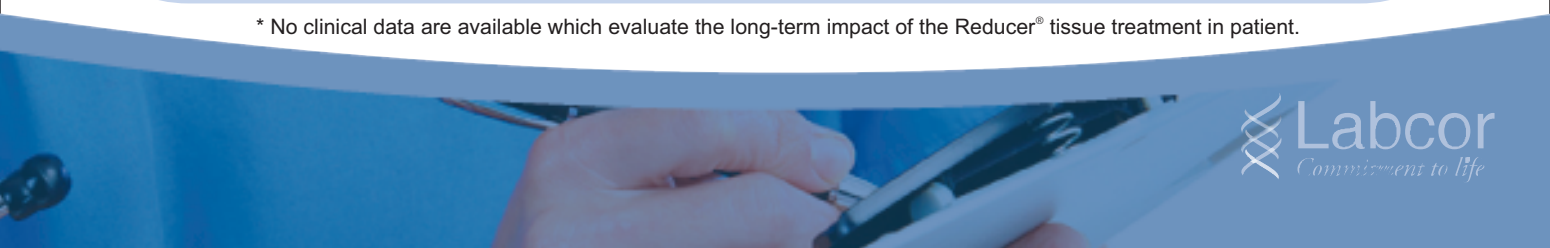
Pre-molded tissue-to-tissue interface minimizes the risk of leaflet abrasion and structural valve deterioration.

Flexible and resilient copolymer stent.

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.

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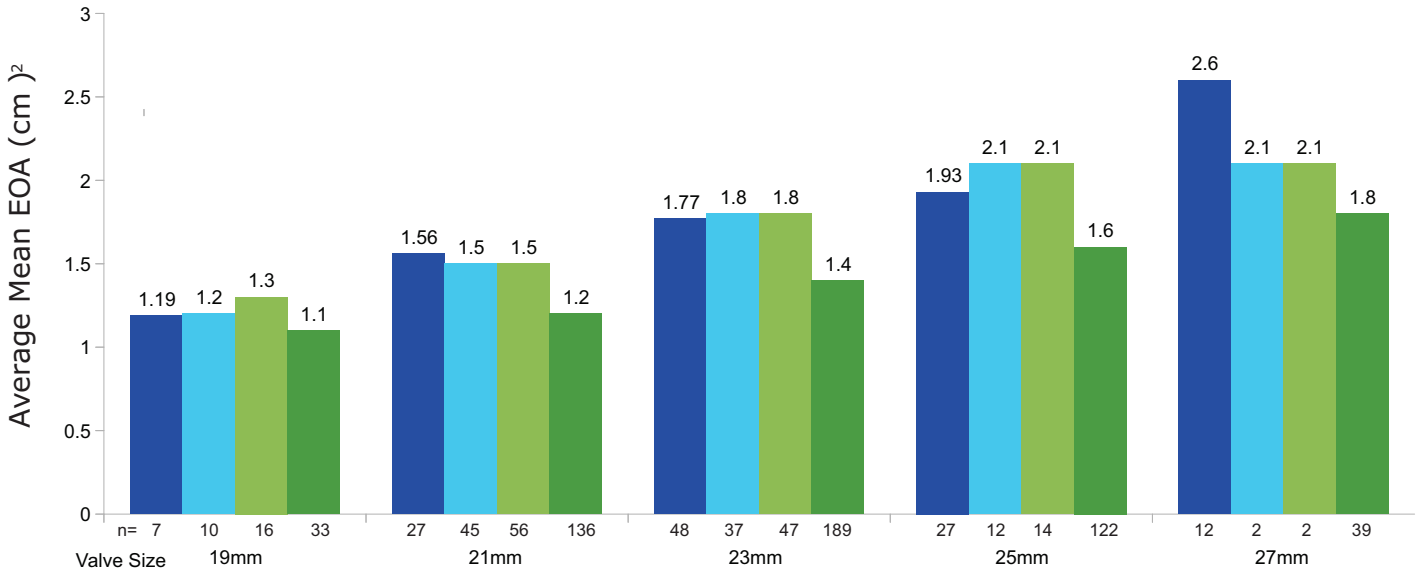
Comparative Hemodynamics

Hemodynamic data for Dokimos Plus obtained from 6 clinical sites, as part of a multicenter clinical study.

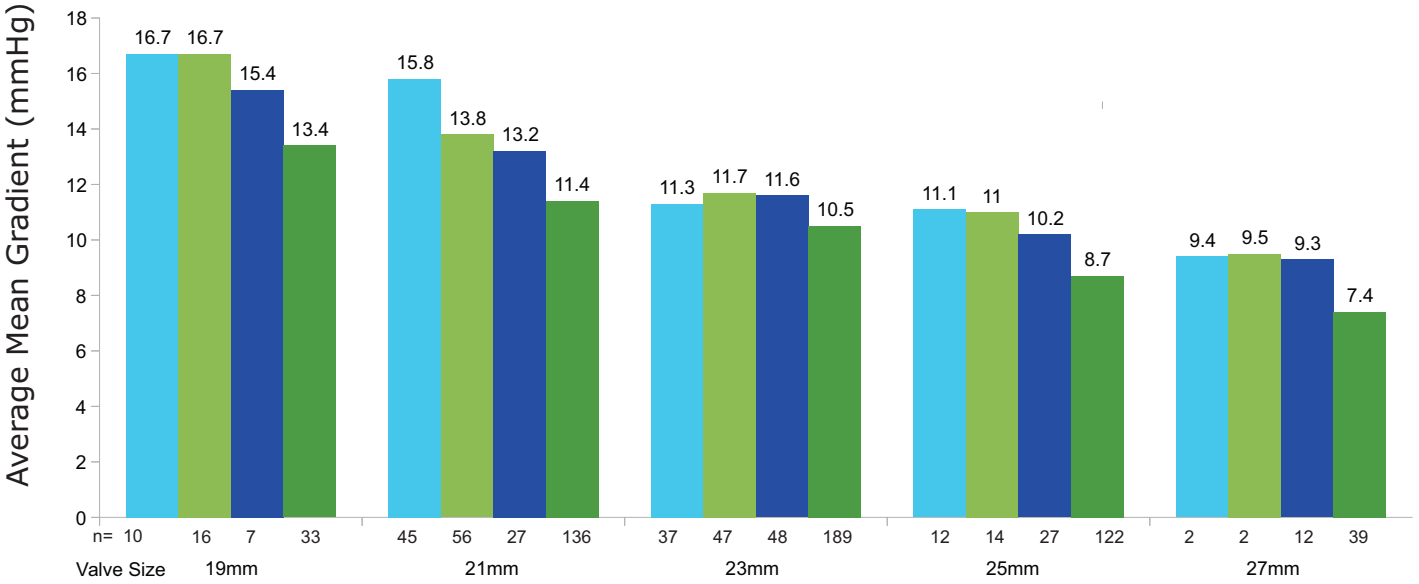
Comparative data analysis performed by independent echocardiography laboratory.

Effective Orifice Area (EOA)



■ Labcor Dokimos Plus Aortic Valve ■ Perimount Magna Ease with ThermaFix ■ Sorin Mitroflow ■ Perimount Magna Ease with and without ThermaFix

Mean Gradient



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 cm^2
Average Mean Gradient: 11,74mmHg / Average Max Gradient: 22.06mmHg
EOA Index: ≥0.85cm^2/m^2 total: 76% / <0.85cm^2/m^2 total: 24%

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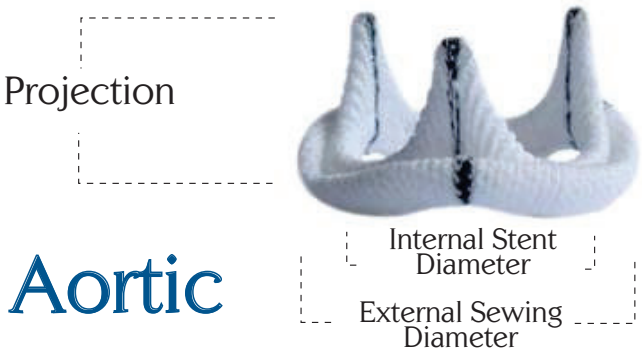
Dokimos Plus

Aortic Pericardial Bioprosthesis

With more than 15.000 implants.

BEYOND RELIABLE



Aortic

Product Specifications

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

Valve Size	19	21	23	25	27
External Sewing Ring Diameter (in millimetters)	23	25	27	29	31
External Stent Diameter (in millimetters)	19	21	23	25	27
Internal Stent Diameter (in millimetters)	16	18	20	22	24
Projection (in millimetters)	8	9	10	11	12
EOA (cm^2)*	1.5	1.8	2.3	2.5	2.7
Profile Height	11	12	13	15	16

* Heart valve function test - Vivitro System - Aaslid 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 avaiable for sale in the United States.

References

1. Garcia-Bengochea, et al - The New Labcor - Santiago Pericardial Valves Bioprosthesis 1991; 6 suppl. 4 6 13-619
2. Edwards Lifesciences Corporation, Carpentier-Edwards Magna Ease Pericardial Aortic Bioprosthesis Model 3300TFX, Instructions for use, 2009. Echo follow-up at one year.
3. CarboMedics, Inc., A Sorin Group Company. Mitroflow Aortic Pericardial Heart Valve, Pre-Market Approval Application Summary of Safety and Effectiveness Data, P060038, 2007. Echo follow-up at one year.
4. Conte J. Weissman N, Dearani JA, etal. A North American, prospective, multicenter assessment of Mitroflow aortic pericardial prosthesis. Ann Thorac. Surg. 2010;90(1)144-152.e1-3

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