



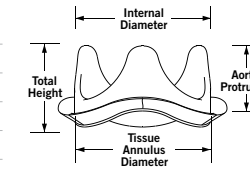
## PROVEN 20-YEAR DURABILITY FOR LONG-TERM FREEDOM FROM REOPERATION.

Backed by 25 years of clinical experience and two decades of in-depth research, the Biocor stented tissue valve from St. Jude Medical offers 20-year durability to reduce the risk of reoperation. In addition, the exclusive FlexFit™ System is designed to facilitate implant from sizing through seating and suturing.

### Ordering Information Reference Dimensions\* (U.S. Model Numbers ONLY)

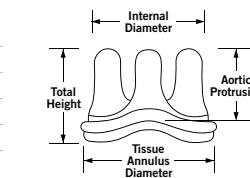
#### Supra (Aortic)

Model Number	Valve Size (mm)	Tissue Annulus Diameter (mm)	Internal Diameter (Stent ID mm)	Aortic Protrusion (mm)	Total Height (mm)
BSP100-19	19	19	19	11	14
BSP100-21	21	21	21	11	15
BSP100-23	23	23	23	13	16
BSP100-25	25	25	25	13	17
BSP100-27	27	27	27	14	19



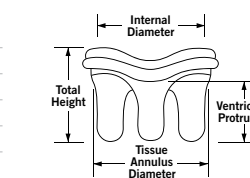
#### Aortic

Model Number	Valve Size (mm)	Tissue Annulus Diameter (mm)	Internal Diameter (Stent ID mm)	Aortic Protrusion (mm)	Total Height (mm)
B100-21A-00	21	21	19	9	14
B100-23A-00	23	23	21	9	15
B100-25A-00	25	25	23	10	16
B100-27A-00	27	27	25	11	17
B100-29A-00	29	29	27	12	19



#### Mitral

Model Number	Valve Size (mm)	Tissue Annulus Diameter (mm)	Internal Diameter (Stent ID mm)	Ventricular Protrusion (mm)	Total Height (mm)
B100-25M-00	25	25	23	9	16
B100-27M-00	27	27	25	9	17
B100-29M-00	29	29	27	10	19
B100-31M-00	31	31	29	10	20
B100-33M-00	33	33	31	11	20



#### Accessories

Model Number	Description
B1000	Bioprosthetic Heart Valve Sizer Set One (1) malleable handle Six (6) double-ended aortic/Supra sizers (19, 21, 23, 25, 27, 29) Five (5) mitral sizers (25, 27, 29, 31, 33) One (1) autoclavable tray for storage of components One (1) autoclavable tray cover
B1000-H	Replacement Handle One (1) malleable holder handle

Recommended Storage Temperature: 5° -25° C (41° -77° F)  
Storage Solution: 0.5% formaldehyde solution.  
Resterilization: Biocor valves must not be resterilized.  
Shelf Life: Four years.  
Radiopaque Marker for X-ray: A stainless steel wire located under the sewing cuff allows the valve to be seen under X-ray.

- Eichinger WB, Hettich IM, Ruzicka DJ, et al. Twenty-year experience with St. Jude medical Biocor bioprosthesis in the aortic position. *Ann Thorac Surg.* 2008;86(4):1204-1210.
- Mykén PS, Bech-Hansen O. A 20-year experience of 1712 patients with the Biocor porcine bioprosthesis. *J Thorac Cardiovasc Surg.* 2009;137(11):76-81.
- St. Jude Medical Instructions for Use: Stented Porcine Tissue Valves.
- St. Jude Medical, Inc. Engineering Report 05-04-01.
- Mosaic Marketing Materials, UC200103933b EN (2002). Hancock II Marketing Materials, UC200001201 EN (1999).
- Carpentier-Edwards PERIMOUNT Magna Pericardial Bioprosthesis model 7000 TFX mitral Instructions for Use.
- Reference Dimensions - St. Jude Medical Instructions for Use: Stented Porcine Tissue Valves Biocor/Biocor Supra, 681925-001. Internal diameter measurements from St. Jude Medical, Inc. Part number 300211.

<b>Global Headquarters</b> One St. Jude Medical Drive St. Paul, Minnesota 55117 USA +1 651 756 2000 +1 651 756 3301 Fax	<b>Cardiovascular Division</b> 177 East County Road B St. Paul, Minnesota 55117 USA +1 651 490 4470 +1 651 490 4466 Fax	<b>St. Jude Medical Brasil Ltda.</b> Rua da Paisagem, 310B - Vila da Serra Nova Lima-MG CEP: 34.000-000 Brazil + 55 31 3055 5200 + 55 31 3055 5252 Fax	<b>U.S. Division</b> 807 Las Cimas Parkway Suite 400 Austin, Texas 78746 USA +1 512 732 7400 +1 512 732 2418 Fax
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CAUTION: FEDERAL LAW RESTRICTS THESE DEVICES TO SALE BY OR ON THE ORDER OF A PHYSICIAN OR PROPERLY LICENSED PRACTITIONER.

**Brief Summary:** Please see the Instructions for Use (IFU) for a full description of indications, contraindications, side effects, precautions, warnings and Instructions for Use. St. Jude Medical Stented Tissue Valves are indicated for use as a replacement for malfunctioning native or prosthetic aortic and/or mitral valves. Adverse events potentially associated with the use of bioprosthetic heart valves include: angina, cardiac arrhythmia, endocarditis, heart failure, hemolysis, hemolytic anemia, hemorrhage (anticoagulant/antiplatelet-related), leak (transvalvular or paravalvular), myocardial infarction, nonstructural dysfunction (e.g., pannus, suture, inappropriate sizing or other), prosthesis regurgitation, stroke, structural deterioration (e.g., calcification, leaflet tear, or other), thromboembolism and valve thrombosis. It is possible that these complications could lead to: reoperation, explantation, permanent disability or death. Long-term anticoagulation and/or antiplatelet therapy should be considered in patients with dilated left atrium, a history of thrombotic events or a cardiac rhythm of atrial fibrillation or flutter.

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Biocor™  
Stented Tissue Valve



## Designed for Durability

Backed by 25 years of clinical experience and reinforced by two published studies,<sup>1,2</sup> the Biocor tissue valve from St. Jude Medical provides demonstrated long-term durability, which contributes to lower reoperation rates. With a triple composite design, unique pericardial shield and the FlexFit™ stent, the Biocor valve provides a powerful combination of durability and control during implant.



### Triple Composite Design

Three separate porcine leaflets are matched to optimize leaflet coaptation and reduce stress.

### Unique Pericardial Shield

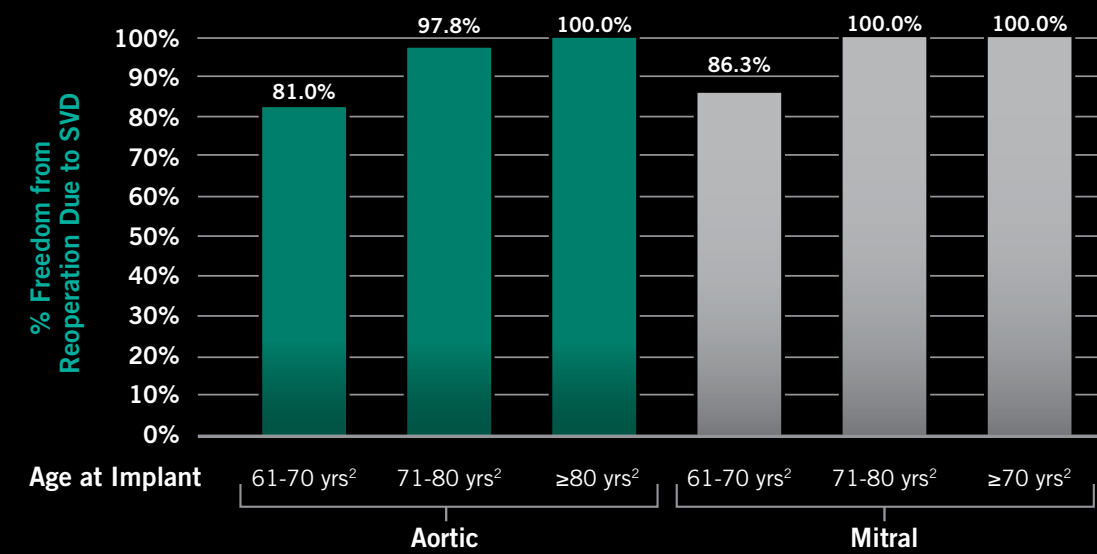
The outflow edge of the Biocor valve is covered with a pericardial shield, providing a tissue-to-tissue interface to help prevent the risk of abrasion.

### FlexFit Stent

The FlexFit stent reduces leaflet stress.

### Proven 20-year Durability

The Biocor valve delivers proven 20-year durability results in the aortic and mitral positions.



AVR: Study size = 1618 (female = 554; male = 964). Mean age = 70.8 years.  
MVR: Study size = 194 (female = 99; male = 95). Mean age = 64.9 years.

## Designed for Implantability

With the industry's lowest implant profile, the Biocor stented tissue valve with the FlexFit system offers optimal implantability in both the aortic and mitral positions.

### Aortic Valves and Biocor Supra

- Low profile provides optimal coronary ostia clearance.
- Scalloped inflow edge optimizes valve seating.
- Design adapts easily to annulus and enhances knot positioning.

### Aortic Valve

9 mm aortic protrusion



23 mm valve

### Supra Valve

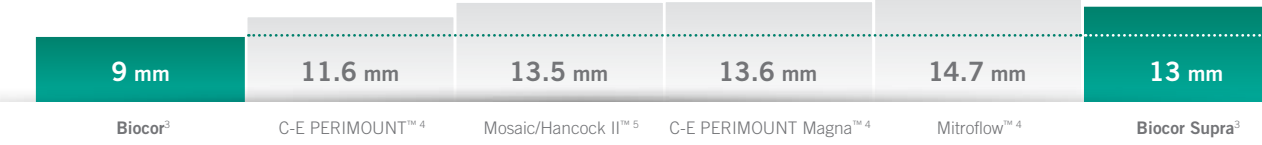
13 mm aortic protrusion



23 mm valve

### Protrusion Heights

Aortic Position (23 mm valves)



### Biocor Mitral Valve

- Low profile reduces risk of LV outflow tract obstruction.
- Mitral ratcheting minimizes potential for suture looping.
- Lowest combined valve and holder height facilitates minimally invasive surgical procedures.

### Mitral Valve

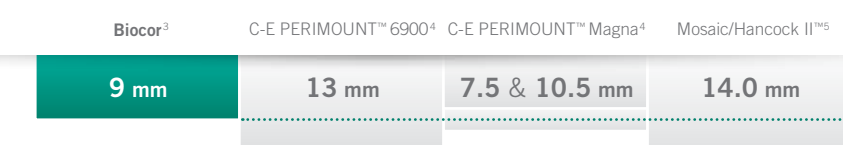
9 mm ventricular protrusion



27 mm valve

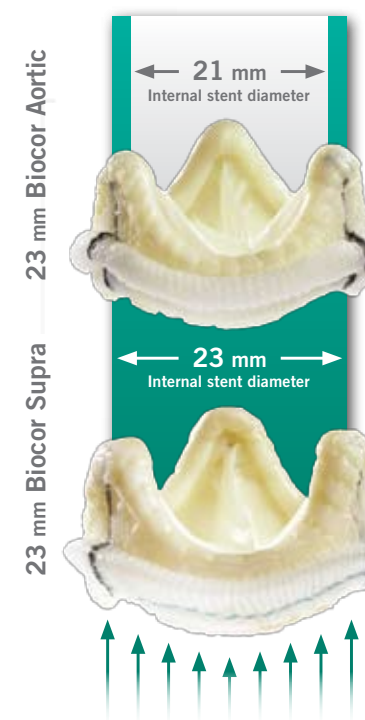
### Ventricular Protrusion Heights

Mitral Position (27 mm valves)



### Optimal Stent to Annulus Ratio: Biocor Supra

The Biocor Supra provides a larger stent-to-annulus ratio than the Biocor Aortic valve.



## The FlexFit System

The FlexFit system from St. Jude Medical includes several components that facilitate the entire valve implant procedure.

### FlexFit Mitral Valve Holder

The FlexFit mitral valve holder provides stent deflection, which reduces the potential for suture looping and maximizes visibility and access to the valve cuff.

### FlexFit Aortic Valve Holder

The FlexFit aortic valve holder improves visibility and cuff access for suturing.

### FlexFit 20-second Rinse

Rinse time is reduced to 2 x 10 seconds.

### FlexFit Click-in Handle

Both the aortic and mitral valve holders provide quick handle attachment and removal to stabilize the valve and minimize the risk of unseating.

### FlexFit Valve Sizers and System Tray

FlexFit system sizers are optimized for valve selection, and the tray provides one convenient location for all valve accessories.



**St. Jude Medical** is committed to putting more control into the hands of physicians and thereby reducing risk. As part of a comprehensive portfolio that delivers on this promise, the Biocor stented tissue valve provides proven 20-year durability and enhanced flexibility during implant, to help reduce the risk of reoperation.