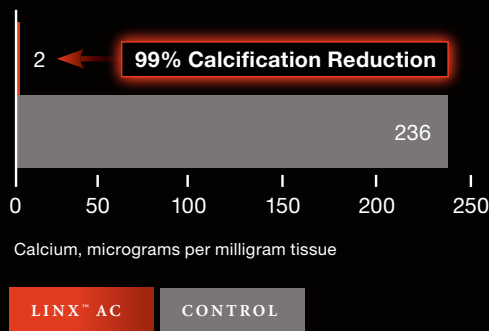


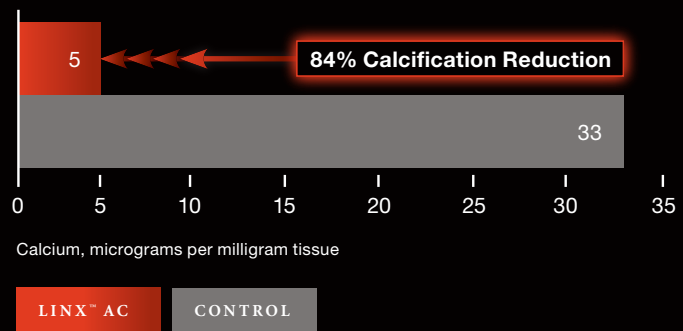
**The Epic™ Valve offers Linx™ AC Technology with the design of the Biocor™ Valve. The Biocor™ Valve is supported by 17-year published durability data, and 25 years of clinical experience.**

Tissue valve calcification occurs after implantation because of the presence of phospholipids, lipid deposits, deterioration of tissue collagen, and elevated calcium metabolism. **Linx™ AC Technology** is a patented, proprietary valve treatment that significantly reduces calcification in animal studies.<sup>1</sup>

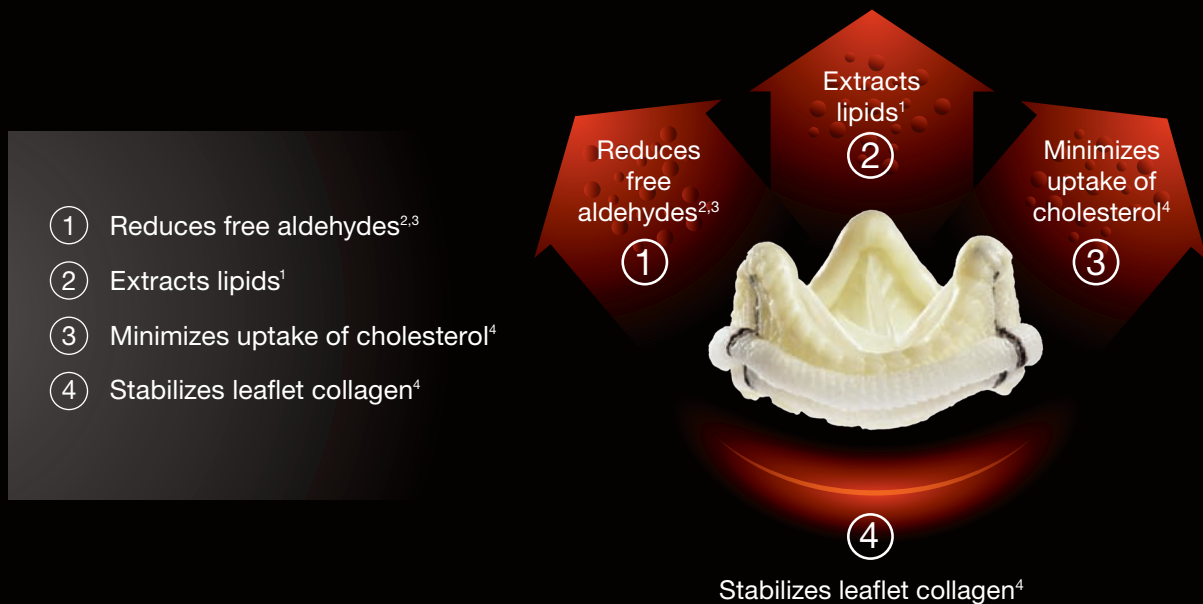
Rat Subdermal Study (60 days) demonstrates 99% reduction in calcification.



Juvenile Sheep Study (150 days) demonstrates 84% reduction in calcification.



**Linx™ AC Technology** in animal studies has been demonstrated to resist calcification in four ways:

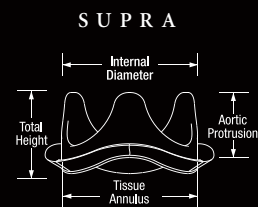


There is no clinical data currently available which evaluates the long-term impact of anticalcification tissue treatment in humans.

# Reference Dimensions<sup>13</sup> International Model Numbers ONLY

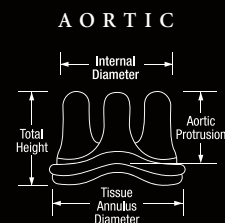
## SUPRA

Model Number	Valve Size (mm)	Tissue Annulus Diameter (mm)	Internal Diameter (Stent ID mm)	Aortic Protrusion (mm)	Total Height (mm)
ESP100-19	19	19	19	11	14
ESP100-21	21	21	21	11	15
ESP100-23	23	23	23	13	16
ESP100-25	25	25	25	13	17
ESP100-27	27	27	27	14	19
ESP100-29	29	29	29	15	20



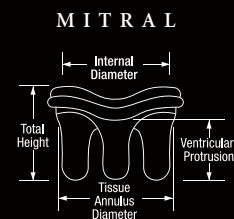
## AORTIC

Model Number	Valve Size (mm)	Tissue Annulus Diameter (mm)	Internal Diameter (Stent ID mm)	Aortic Protrusion (mm)	Total Height (mm)
E100-21A	21	21	19	9	14
E100-23A	23	23	21	9	15
E100-25A	25	25	23	10	16
E100-27A	27	27	25	11	17
E100-29A	29	29	27	12	19
EL-31A*	31	31	29	12	20



## MITRAL

Model Number	Valve Size (mm)	Tissue Annulus Diameter (mm)	Internal Diameter (Stent ID mm)	Ventricular Protrusion (mm)	Total Height (mm)
E100-25M	25	25	23	9	16
E100-27M	27	27	25	9	17
E100-29M	29	29	27	10	19
E100-31M	31	31	29	10	20
E100-33M	33	33	31	11	20



\* This size not available with all product enhancements. Please speak with a St. Jude Medical representative for further detail.

## Accessories

Model Number	Description
B1000	Bioprosthetic Heart Valve Sizer Set One (1) click-in holder 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) click-in holder handle

## REFERENCES:

- Vyavahare N, Hirsch D, Lerner E, Baskin JZ, Schoen FJ, Bianco R, Kruth HS, Zand R, Levy RJ. Prevention of Bioprosthetic Heart Valve Calcification by Ethanol Preincubation. *Circulation* 1997;95:479-488.
- Frater RWM, Seifert E, Liao K, Wasserman F. Advances in Anticalcific and Antidegenerative Treatment of Heart Valve Bioprostheses. Edited by Gabbay S, and Wheatley D. First Edition, Silent Partners, Inc. 1997;8:105-113.
- Kelly SJ, Ogle MF, Carlyle WC, Mirsch MW. Biocompatibility and Calcification of Bioprosthetic Heart Valves. Society for Biomaterials, Sixth World Biomaterials Congress Transaction, 2000;1353.
- Vyavahare N, Hirsch D, Lerner E, Baskin J, Zand R, Schoen F, Levy R. Prevention of calcification of glutaraldehyde-crosslinked porcine aortic cusps by ethanol preincubation. *J Biomed Mater Res*, 1998;40:577-585.
- St. Jude Medical Instructions for Use Stented Porcine Tissue Valves Epic™ / Epic™ Supra, 681935-001 or 681934. Internal Diameter measurements from St. Jude Medical, Inc. Part Number 300211.
- St. Jude Medical, Inc. Engineering Report 05-04-01.
- Mosaic Marketing Materials, UC200103933b EN (2002). Hancock II Marketing Materials, UC200001201 EN (1999).
- Carpenter-Edwards PERIMOUNT Magna Pericardial Bioprosthesis Model 7000TFX Mitral Instructions for Use.
- Bottio T, Rizzoli G, Thieme G, Nesseris G, Casarotto D, Gerosa G. Hemodynamic and clinical outcomes with the Biocor valve in the aortic position: An 8-year experience. *J Thorac and Cardiovasc Surg* 2002;127:6:1616-23. Study size = 257. n at 8 years = 17. Implant years (1992-2001). Mean age 75 years.
- Mykén P. Seventeen-Year Experience with the St. Jude Medical Biocor Porcine Bioprosthesis. *JHVD* 2005;14:486-92. Study size=1,283 AVR; 172 MVR. n at 16 years estimated to be <=5 AVR; n at 15 years not stated MVR. Implant years (1983-2000). Mean age 70 years AVR; 64 years MVR.
- Mykén Pia S. Two Decades With The St. Jude Med. Biocor Bioprosthesis. Department of Thoracic and Cardiovascular Surgery, Sahlgrenska University Hospital, Gothenburg, Sweden. Third Biennial Meeting of the Society for Heart Valve Disease, 2005.
- Rizzoli G, Bottio T, Vida, V, et al. Intermediate results of isolated mitral valve replacement with a Biocor porcine valve. *J Thorac Cardiovasc Surg*. 2005 Feb;129(2):332-9. Study size=154. n at 8 years = 20. Implant years (1992-2004). Mean age 72.3 years.
- ST. Jude Medical Instructions for Use Stented Porcine Tissue Valves Epic™ Epic™ Supra, 681935-001 or 681934. Internal Diameter measurements from St. Jude Medical, Inc. Part Number 300211.

Brief Summary: Please review the Instructions for Use prior to using these devices for a complete listing of indications, contraindications, warnings, precautions, potential adverse events and directions for use. Not all product models or indications for use may be applicable for Canada or other countries. Please consult your St. Jude Medical, Inc. representative for licensed product availability in Canada or your country. ©2008 St. Jude Medical, Inc. All Rights Reserved.



**St. Jude Medical**  
Global Headquarters  
One Lillehei Plaza  
St. Paul, MN 55117, USA  
651 483 2000  
651 482 8318 Fax

**St. Jude Medical Europe, Inc.**  
The Corporate Village  
Avenue Da Vinci laan, 11 - Box F1  
B-1935 - Zaventem  
Belgium  
+32 2 774 68 11  
+32 2 772 83 84 Fax

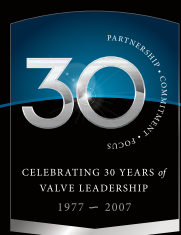
**St. Jude Medical Brasil, Ltda.**  
Rua Frei, Caneca 1380-9° A-CJ91/92  
Sao Paulo - SP - Brasil  
CEP 01307-002  
+55 11 5080 5400  
+55 11 5080 5423 Fax

**St. Jude Medical (Hong Kong) Ltd.**  
Unit 2701-07, COSCO Tower  
Grand Millennium Plaza  
183 Queen's Road  
Central, Hong Kong  
+852 2996 7688  
+852 2956 0622 Fax

[www.sjm.com/implantable](http://www.sjm.com/implantable)

# ImplantAbility.™

Redefining performance through implant and durability.  
With the addition of anticalcification treatment.



THE EPIC™ STENTED TISSUE VALVE  
WITH LINX™ AC TECHNOLOGY

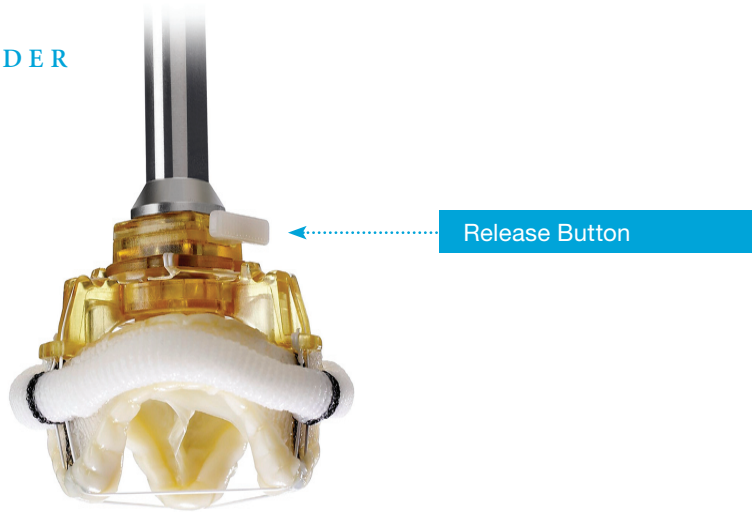
# THE *FlexFit*<sup>™</sup> SYSTEM

The *FlexFit*<sup>™</sup> System facilitates the entire implant procedure.

## FLEXFIT<sup>™</sup> MITRAL VALVE HOLDER

The *FlexFit*<sup>™</sup> Mitral Valve Holder provides stent deflection.

- Reduces potential for suture looping
- Maximizes visibility and access to cuff
- Enables valve seating without handle
- Facilitates MIS procedures with lowest combined valve + holder height



## FLEXFIT<sup>™</sup> AORTIC VALVE HOLDER

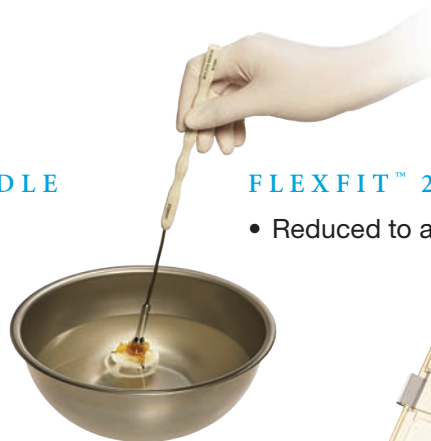
The *FlexFit*<sup>™</sup> Aortic Valve Holder is a compact holder that maximizes visibility and cuff access for suturing.



## FLEXFIT<sup>™</sup> CLICK-IN HANDLE

Both the *FlexFit*<sup>™</sup> Mitral and Aortic Valve Holders provide quick click-in attachment and removal.

- Stabilizes valve and minimizes risk of unseating
- Facilitates access and release for MIS
- Malleable nitinol handle straightens during sterilization



## FLEXFIT<sup>™</sup> 20 SECOND RINSE

- Reduced to a 2 x 10 second rinse



## FLEXFIT<sup>™</sup> VALVE SIZERS

The *FlexFit*<sup>™</sup> System Sizers are optimized for valve selection.

## FLEXFIT<sup>™</sup> VALVE SYSTEM TRAY

The *FlexFit*<sup>™</sup> System provides one convenient tray for all of the valve accessories.

# ImplantAbility.™

The implantability leader in *both* aortic and mitral positions.

THE EPIC™ STENTED VALVE SYSTEM WITH LINX™ AC TECHNOLOGY

## AORTIC POSITION

### SUPRA VALVE

13mm aortic protrusion



23mm valve

### AORTIC VALVE

9mm aortic protrusion

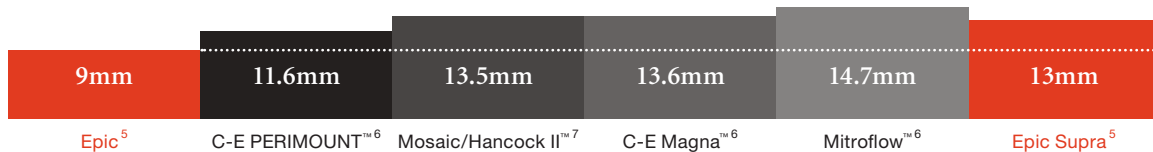


23mm valve

### Advantages and benefits

- Industry's lowest implant profile facilitates valve positioning
- Low profile provides optimal coronary ostia clearance
- Valve adapts easily to the annulus and enhances knot positioning
- Low profile facilitates closure of aortotomy
- Scalloped inflow edge optimizes valve seating
- Supra optimizes stent to annulus ratio, maximizing flow
- Supra cuff designed for supra-annular implant

### AORTIC PROTRUSION COMPARISON (23mm Aortic)



## MITRAL POSITION

### MITRAL VALVE

9mm ventricular protrusion

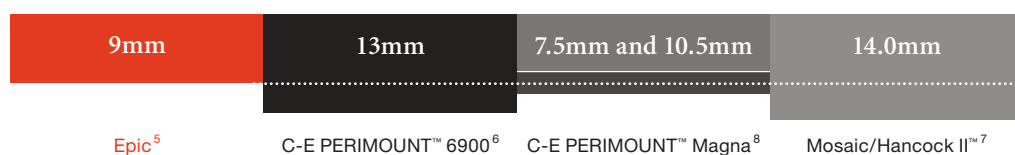


27mm valve

### Advantages and benefits

- Industry's lowest implant profile facilitates valve positioning
- Low profile reduces risk of LV outflow tract obstruction
- Mitral ratcheting minimizes potential for suture looping
- Triple composite design eliminates septal muscle bar leaflet and need for orientation
- Suture-friendly cuff minimizes suture drag and parachuting forces
- Facilitates MIS procedures with lowest combined valve + holder height

### MITRAL (ventricular) PROTRUSION COMPARISON (27mm Mitral)



# Durability.

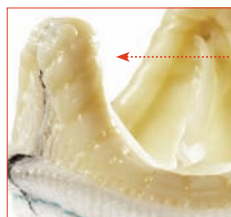
Up to 20-year Biocor durability data and over 25 years of clinical experience.

The Epic™ Valve is designed for durability with the added feature of Linx™ AC Technology.



### TRIPLE COMPOSITE DESIGN

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



### UNIQUE PERICARDIAL SHIELD ON OUTFLOW EDGE

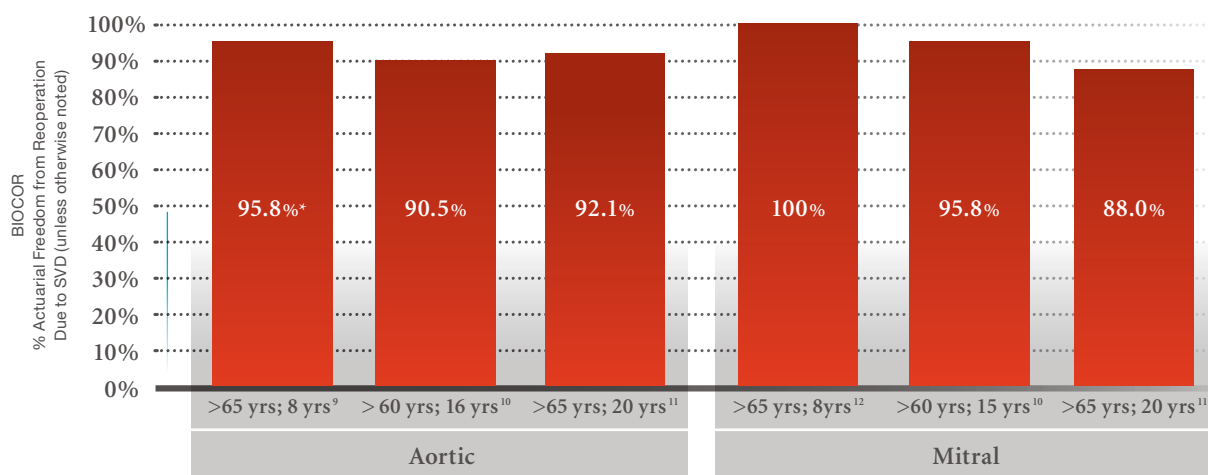
Helps prevent risk of abrasion by providing tissue-to-tissue interface.



### FLEXFIT™ STENT

Reduces leaflet stress.

The Epic™ Valve is identical in design to the Biocor™ Valve, which delivers exceptional durability results in the aortic position and in the even more challenging mitral position.



\*Freedom from SVD

### Optimal stent to annulus ratio: Epic Supra

The Epic™ Supra Valve provides a larger stent to annulus ratio than the Epic™ Aortic Valve.

### 23mm Epic Aortic



### 23mm Epic Supra

