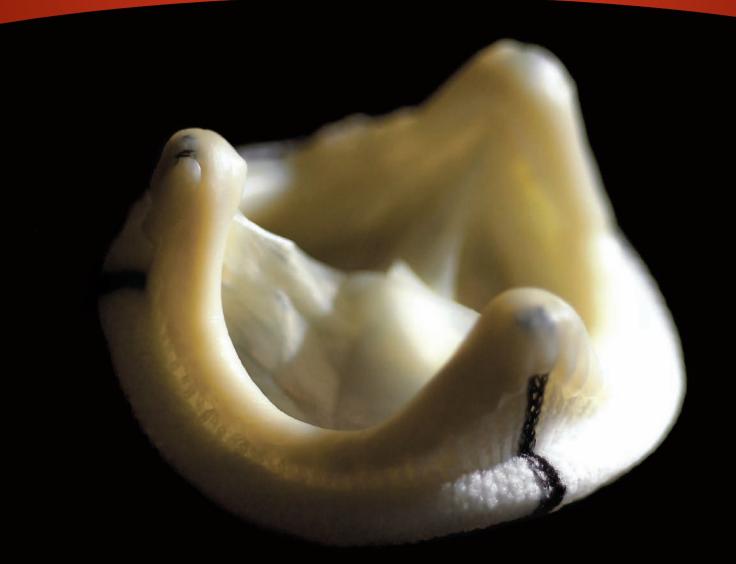
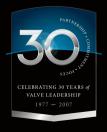
ImplantAbility.

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





THE EPIC[™] STENTED TISSUE VALVE WITH LINX[™] AC TECHNOLOGY

ST. JUDE MEDICAL

THE *FlexFit*[™] SYSTEM

The FlexFit[™] System facilitates the entire implant procedure.

FLEXFIT[™] MITRAL VALVE HOLDER

The *FlexFit*[™] 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



Release Button



FLEXFIT[™] AORTIC VALVE HOLDER

The *FlexFit*[™] Aortic Valve Holder is a compact holder that maximizes visibility and cuff access for suturing.

FLEXFIT[™] CLICK-IN HANDLE

Both the *FlexFit*[™] 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[™] 20 SECOND RINSE

• Reduced to a 2 x 10 second rinse



$\mathbf{F} \mathbf{L} \mathbf{E} \mathbf{X} \mathbf{F} \mathbf{I} \mathbf{T}^{^{\mathsf{TM}}} \mathbf{V} \mathbf{A} \mathbf{L} \mathbf{V} \mathbf{E} \mathbf{S} \mathbf{I} \mathbf{Z} \mathbf{E} \mathbf{R} \mathbf{S}$

The *FlexFit*[™] System Sizers are optimized for valve selection.

FLEXFIT[™] VALVE SYSTEM TRAY

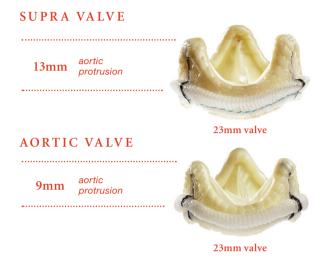
The *FlexFit*[™] System provides one convenient tray for all of the valve accessories.

ImplantAbility.

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

THE EPIC[™] STENTED VALVE SYSTEM WITH LINX[™] AC TECHNOLOGY

AORTIC POSITION



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)

9mm	11.6mm	13.5mm	13.6mm	14.7mm	13mm
Epic⁵	C-E PERIMOUNT ^{™6}	Mosaic/Hancock II ^{™7}	C-E Magna ^{™ 6}	Mitroflow ^{™ 6}	Epic Supra ⁵

MITRAL POSITION

MITRAL 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)

9mm	13mm	7.5mm and 10.5mm	14.0mm	
Epic ⁵	C-E PERIMOUNT [™] 6900 ⁶	C-E PERIMOUNT [™] Magna ⁸	Mosaic/Hancock II ^{™7}	

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.

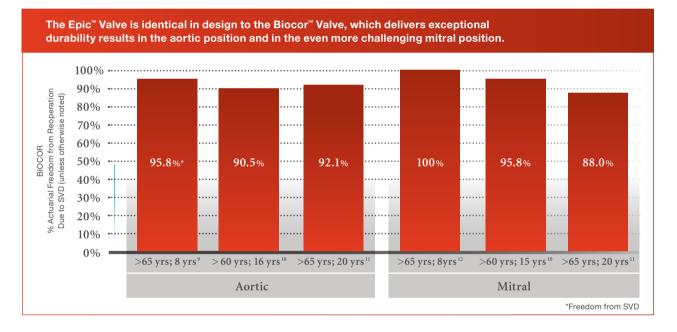


UNIQUE PERICARDIAL SHIELD ON OUTFLOW EDGE

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

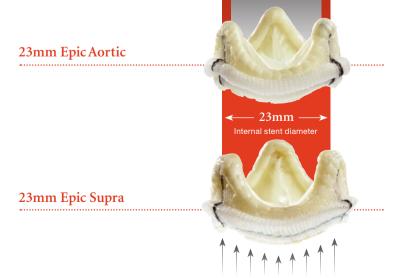


FLEXFIT[™] STENT Reduces leaflet stress.



Optimal stent to annulus ratio: Epic Supra

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

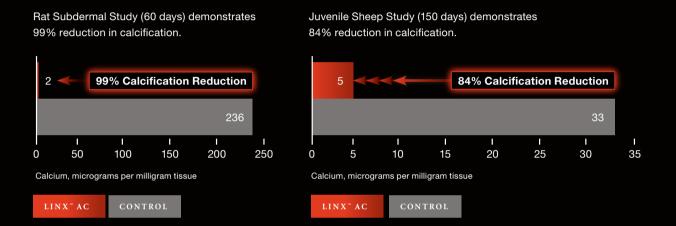


21mm

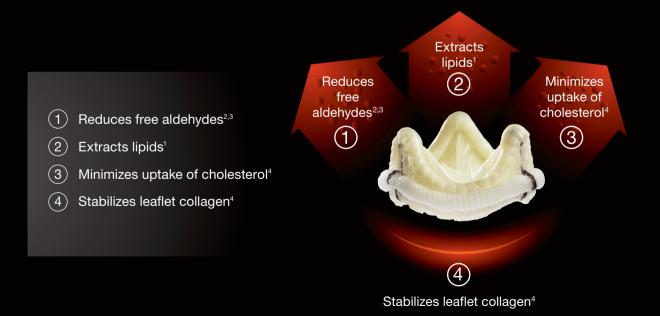
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The Epic[™] Valve offers Linx[™] AC Technology with the design of the Biocor[™] Valve. The Biocor[™] Valve is supported by 17-year published durability data, and 25 years of clinical experience.

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.¹



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 Dimensions¹³ International Model Numbers ONLY

Valve Size

(mm)

21

25

27

29

31

SUPRA					
Model Number	Valve Size (mm)	Tissue Annulus Diameter (mm)	Internal Diameter (Stent ID mm)	Aortic Protrusion (mm)	Total Heig (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

Tissue Annulus

Diameter (mm)

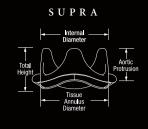
21

25

27

29

31



aht

Total Height

(mm)

16

Aortic Protrusion

(mm)

9

10

12

12

AORTIC Internal Tissue Annulu

MITRAI

AORTIC

Model Number

E100-21A

E100-23A

E100-25A

E100-27A

E100-29A

EL-31A*

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

MITRAL Internal Diameter

* 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
В1000-Н	Replacement Handle One (1) click-in holder handle

Internal Diameter (Stent ID mm)

19

23

29

REFERENCES

Vvavahare N, Hirsch D, Lerner E, Baskin JZ, Schoen FJ, Bianco R, Kruth HS, Zand R, Levv RJ, Prevention of Bioprosthetic Heart Valve Calcification by Ethanol Preincubation. Circulation 1997;95:479-488.

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- St. Jude Medical, Inc. Engineering Report 05-04-01. Mosaic Marketing Materials, UC200103933b EN (2002). Hancock II Marketing Materials, UC200001201 EN (1999)

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- for Heart Valve Disease, 2005. 12. 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. 13. ST. Jude Medical Instructions for Use Stented Porcine Tissue Valves Epic™ Epic™ Supra, 681935-001 or 68193. 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.

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