

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

EPIC. BY DESIGN.

Engineered to deliver excellent durability, along with smooth implantability and outstanding performance.



EPIC IMPLANTABILITY

The excellent implantability features of the Epic[™] Mitral valve enable surgeons to customize their implantation strategy based upon patient needs, helping minimize implant related complications.

THE LOWEST PROTRUSION FOR OPTIMAL IMPLANTABILITY.

Epic Mitral has the lowest overall ventricular protrusion in all valve sizes, making it an exceptional valve for the mitral position. A symmetrical, low profile design:

- Reduces the risk of LV outflow tract obstruction¹
- Eliminates the need for a specific orientation during implantation
- Makes the valve easier to implant in minimally invasive surgery (MIS)

VENTRICULAR PROTRUSION^{*}



THE INNOVATIVE FLEXFITTM SYSTEM FOR A CUSTOMIZABLE IMPLANTATION.

Symmetrical Triple Composite Design

Eliminates septal muscle bar leaflet and need for orientation

Flexible Polymer Stent

Facilitates placing knots and maneuverability in implantation

Rinse Time of 2 x 10 Seconds

Allows for abbreviated procedure prep time

Soft Sewing Cuff

Provides limited suture drag and parachuting forces

Unique Pericardial Shield

Provides a tissue-to-tissue interface to help prevent the risk of abrasion

Ratcheting Holder

Mitigates potential for suture looping

EPIC PERFORMANCE

The Epic[™] Mitral valve achieves minimal valvular regurgitation by providing excellent paravalvular cuff sealing and impressive central leaflet coaptation, both crucial in the mitral position.

DESIGNED FOR THE CHALLENGES OF THE MITRAL POSITION.

- Innovative Triple Composite Design uses three separate porcine leaflets to optimize leaflet coaptation, reduce stress, and mitigate regurgitation
- The easily conforming sewing cuff minimizes regurgitation in high risk anatomies, such as mitral annular calcification







*From standalone Mitral valve replacement.







EPIC DURABILITY

The Epic[™] valve is identical in design to the Biocor[™] valve, which has proven 20-year durability and more than 35 years of clinical experience.^{8-11*}

PROVEN DESIGN FOR LONG-TERM DURABILITY



BUILDING ON BIOCOR'S SUCCESS.

In animal studies, the Linx AC treatment^{**} has demonstrated resistance to calcification in four ways:



EXTRACTS LIPIDS¹² REDUCES FREE ALDEHYDES^{13,14} MINIMIZES CHOLESTEROL UPTAKE¹⁵ **STABILIZES LEAFLET COLLAGEN¹⁵**

EXCEPTIONAL DURABILITY.

Freedom from Structural Valve Deterioration (SVD)¹⁰:



At 10 years; all patient ages

AT ALL AGES.

Actuarial Freedom from Reoperation Due to SVD^{8-9, 11}*:



*Results from different clinical trials are not directly comparable. Information provided for educational purposes only **Interpolated from Borger data, Figure 5

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At 15 Years

EPIC[™] MITRAL VALVE SYSTEM

Model Number	Valve Size (mm)	Tissue Annulus Diameter (mm)	Internal Diameter (Stent ID mm)	Ventricular Protrusion (mm)	Total Height (mm)
E100-25M-00	25	25	23	9	16
E100-27M-00	27	27	25	9	17
E100-29M-00	29	29	27	10	19
E100-31M-00	31	31	29	10	20
E100-33M-00	33	33	31	11	20

Valve Storage Information

Recommendations

Storage Temperature: 5°–25° C (41°–77° F)

Storage Solution: 0.5% formaldehyde solution

Resterilization: Epic 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

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

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