For the use of Registered Medical Practitioner, Hospital and Laboratories only

STRUCTURAL HEART

EPIC™ MITRAL VALVE

Implant In-Service

Abbott Tissue Valves- Biocor™/Epic™ Family

BIOCOR

- Stented, triple-composite, porcine tissue valve

EPIC

- Incorporates features of Biocor valve
- Includes anti-calcification technology

BIOCOR VALVE IN CLINICAL USE SINCE 1981

AORTIC

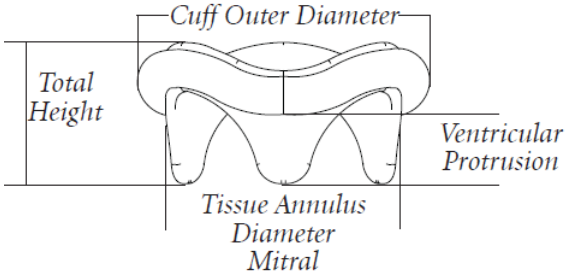
SUPRA

MITRAL

Product Information

Product Information – Available Sizes[1]

Model Number	Valve Size (mm)	Tissue Annulus Diameter (mm)	Internal Diameter (Stent ID mm)[2]	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



Sources: **1.** Epic IFU **2.** Internal Engineering prints. Data on file at Abbott.

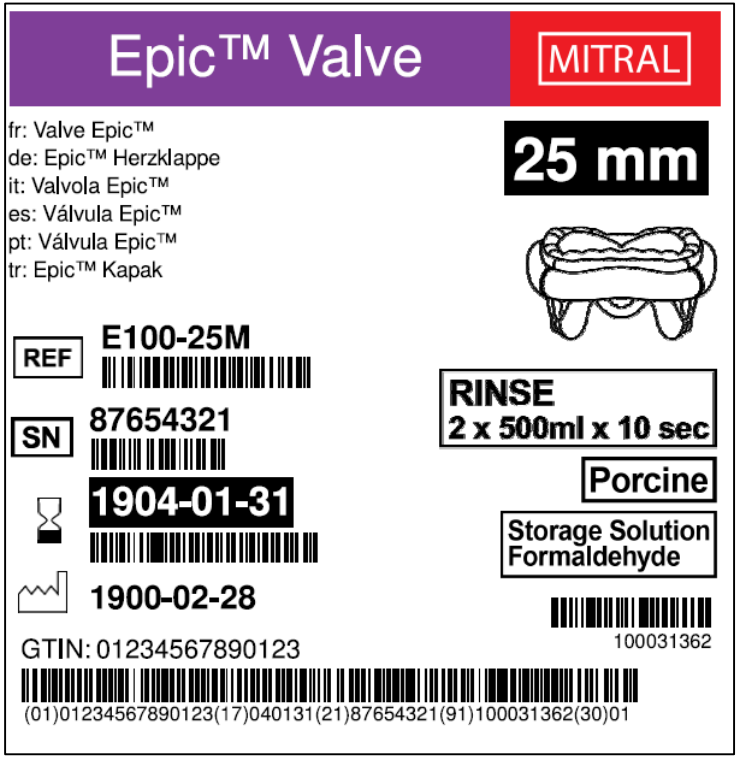
Information contained herein for **DISTRIBUTION outside of the U.S. only**.
Always check the regulatory status of the device in your region.

Package Labeling – Epic™ Mitral

Purple Color Bar →

Valve Model →

Valve Expiration →



← Valve Position

← Valve Size

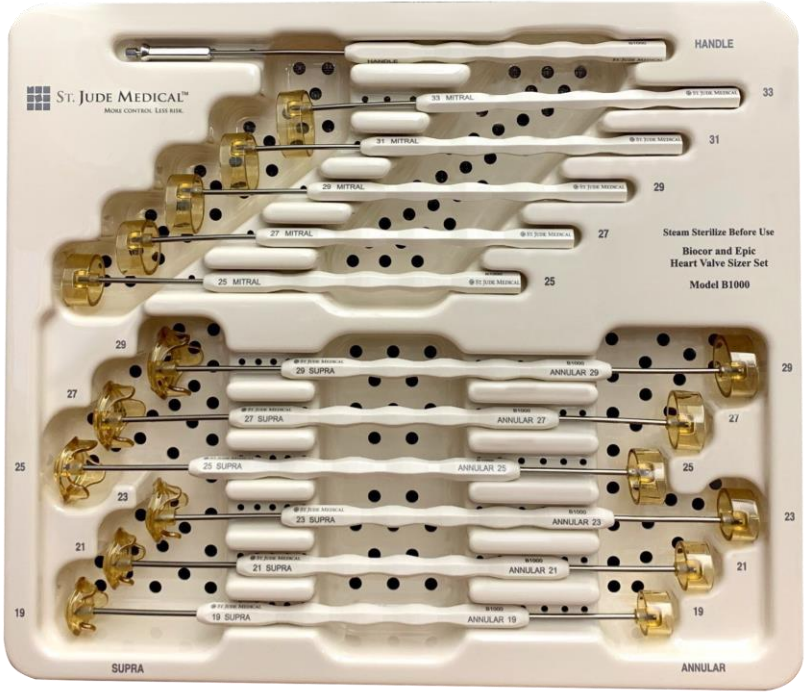
← Line Art

Biocor™/Epic™ B1000 Sizer Set

SET INCLUDES

- One (1) click-in holder handle
- Six (6) double ended aortic/Supra sizers
  - 19, 21, 23, 25, 27, 29 mm
- Five (5) mitral sizers
  - 25, 27, 29, 31, 33 mm
- One (1) autoclavable tray for storage of components
- One (1) autoclavable tray cover

INSTRUCTIONS FOR USE INCLUDED



Biocor™ /Epic™ B1000 Mitral Sizer

- The B1000 sizer is a tool with a cylindrical annular sizing end.
- Do not bend the sizer handle beyond a 90-degree angle.

Biocor™ /Epic™ Holder Handles

CLICK-IN HANDLE – B1000

- Made to click into all Biocor/Epic Holders

RIGID EXTENSION HANDLE – EX2000-R

- Made of stainless steel (with a screw-in end) to provide additional length when used with a holder handle. Ordered separately.

FLEXIBLE EXTENSION HANDLE – EX-05 (NOT PICTURED)

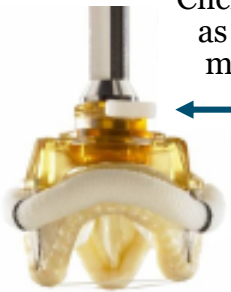
- Flexible extension handle option available to provide additional length when used with a holder handle. Ordered separately.

Valve Pre-Implant Handling Instructions

FlexFit™ Click-in Handle

VALVE PREPARATION

- Press the handle into the valve holder and remove valve from jar
- The handle can be disengaged from the valve holder by depressing the white button on the valve holder



Click-in handle, as shown on mitral valve

White Release Button

Please refer to the IFU for more complete information on the use of this device.

FlexFit™ 20 Second Rinse

VALVE PREPARATION

- Prepare 2 sterile basins with 500 mL of sterile isotonic saline solution in each
- Holding the valve by the handle, fully immerse the valve in the first basin, with “touchless” valve support, moving back and forth for 10 seconds
- Repeat in the second basin
- Leave valve immersed until required for implantation

Please refer to the IFU for more complete information on the use of this device.

Removal of Valve Support

VALVE PREPARATION

- Prior to implantation, remove “touchless” valve support by depressing the three tabs below the level of the valve support ring

Please refer to the IFU for more complete information on the use of this device.

FlexFit™ Mitral Ratcheting System

VALVE PREPARATION

- Ratcheting system exists to mitigate suture looping risk
- With handle and valve holder engaged, turn the handle clockwise to deflect the valve stent posts
  - The valve is protected from over-ratcheting

Mitral Valve	25mm	27mm	29mm	31mm	33mm
# Clicks	2	2	2	3	3

A few turns of the handle and the valve is fully ratcheted

- The stent posts will remain constricted until the valve holder has been removed
  - Put another way, handle removal after ratcheting will not un-constrict the posts

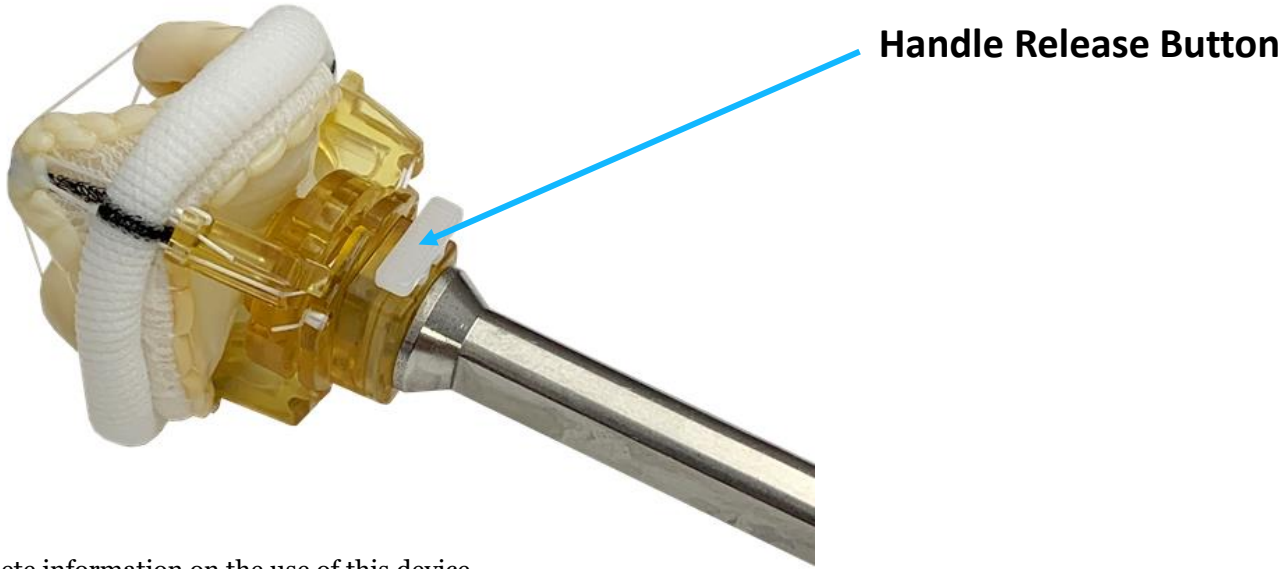
Please refer to the IFU for more complete information on the use of this device.

Valve Implantation

Removing Handle from Holder

VALVE PREPARATION

- To remove the handle from the holder, depress the white button on the holder shown below
- With the button depressed, pull the valve handle away from the holder/valve assembly

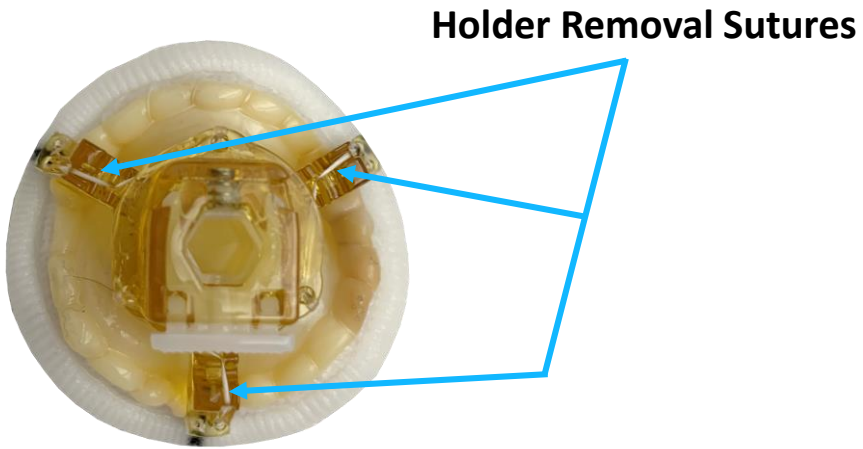


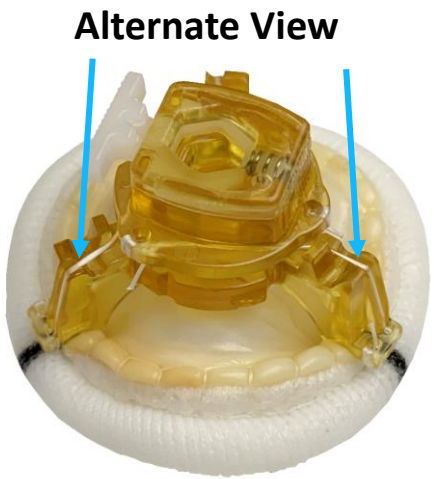
Please refer to the IFU for more complete information on the use of this device.

Removing Valve from Holder

VALVE PREPARATION

- To remove the holder from the valve, make three cuts as shown and pull the handle and the valve holder away from the valve
- Pull the valve holder away from the valve
- After removing the holder, examine the valve to ensure that there are no holder suture remnants

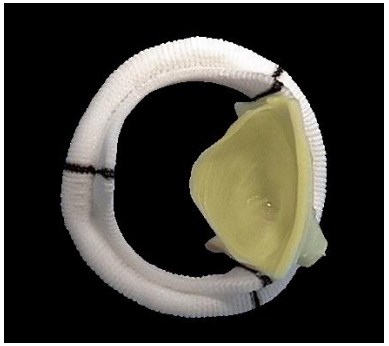




Please refer to the IFU for more complete information on the use of this device.

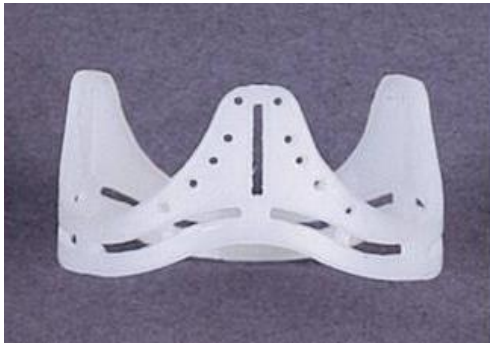
Key Features

Valve Construction



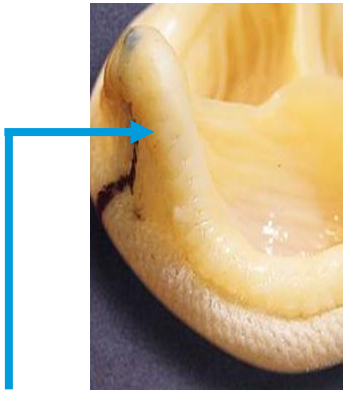
TRIPLE COMPOSITE DESIGN

- Three separate leaflets matched to provide symmetrical stress distribution
- Optimal leaflet coaptation to aid durability



FLEXFIT™ STENT

- Polymer stent provides easier implantation in calcified annulus
- Stent deflection eases securing knots
- Stent and posts return to original shape after deflection
- Aids durability by minimizing stress on the leaflets
- Identical post lengths do not necessitate specific orientation



PERICARDIAL TISSUE SHIELD

- Helps prevent risk of abrasion between leaflets and stent fabric cover by providing a tissue-to-tissue interface
- Mitigating abrasion risk may increase durability

Linx™ AC Technology

Linx™ AC Technology is a patented, proprietary valve treatment that in animal studies has been demonstrated to resist calcification in four ways:

1. Reduces free aldehydes
2. Extracts lipids
3. Minimizes uptake of cholesterol
4. Stabilizes leaflet collagen

Sources: **1.** Frater RWM, Seifter E., Liao K,j Wasserman F. Advances in Anticalcific and Antidegenerative Treatment of Heart Valve Bioprostheses. Edited by Gabbay S. and Wheatley D. First Edition, Silent partner, Inc. 1997;8:105-113. **2.** Kelly SJ, Ogle MF,Carlyle WC, Mirsch MW, Biocompatibility and Calcification of Bioprosthetic Heart Valves. Soiewty of Biomaterials, Sixth WorldbiomaterialsCongress Trasaction, 2000;1353 **3.** 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 **4.** 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.

IFU Warnings and Precautions- Valve Size Selection

- Valve size selection is based on the size of the recipient annulus, and for supra-annular aortic placement, the anatomy of the sinotubular space. Implantation of an inappropriately large bioprosthesis may result in stent deformation, valvular incompetence, and/or damage to the surrounding tissues. The use of an inappropriately small bioprosthesis may result in suboptimal hemodynamics. Use only the appropriate St. Jude Medical™ Model B803 or B1000 sizer set with St. Jude Medical stented porcine tissue valves.

- **Do not** pass the flanged portion of the valve replica sizing tool through the annulus.

IFU Warnings and Precautions- Valve Handling

- **Do not** lacerate the valve tissue. If a valve is damaged, the valve must be explanted and replaced.
- **Do not** attempt to repair a valve. Damaged valves must not be used.
- **Do not** use cutting edge needles, unprotected forceps, or sharp instruments, as they may cause structural damage to the valve.
- Never handle the leaflet tissue.
- Position mitral valves in a manner to avoid commissure obstruction of the left ventricular outflow tract and minimize any potential of commissure contact with the ventricle wall.

CAUTION: This product is intended for use by or under the direction of a physician. Prior to use, reference the Instructions for Use, inside the product carton (when available) or at eifu.abbottvascular.com or at medical. Abbott/manuals for more detailed information on Indications, Contraindications, Warnings, Precautions and Adverse Events.

Photos on file at Abbott. Illustrations are artist's representations only and should not be considered as engineering drawings or photographs.

Abbott St. Jude Medical India Pvt Ltd
No. 1-11 250/A. Matarani Sensation, Begumpet. Hyderabad, India 500016.
(St. Jude Medical is now Abbott)

www.structuralheartsolutions.com

Information contained herein for **DISTRIBUTION outside of the U.S. only**.
Always check the regulatory status of the device in your region.


Abbott