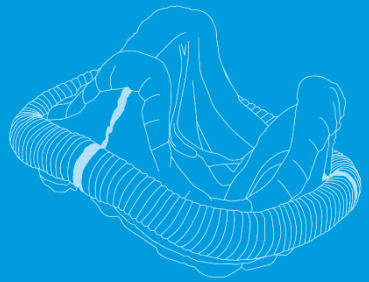
STRUCTURAL HEART

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

EPIC™ SUPRA VALVE AORTIC

Implant In-Service



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Abbott Stented Tissue Valves

BIOCOR / EPIC PORTFOLIO

BIOCOR

- Stented, triple-composite, porcine tissue valve
- FDA approved in 2007
- In clinical use since 1981

Aortic Stented Tissue Valve

EPIC

- Incorporates features of Biocor valve
- Includes anti-calcification technology
- FDA approved in 2007

Epic™ Supra
Aortic Stented Tissue Valve

Epic™ Mitral
Stented Tissue Valve

EPIC™ SUPRA VALVE AORTIC

Key Features & Design

Epic™ Supra Valve Aortic

Silicone-filled cuff allows for supra-annular implantation

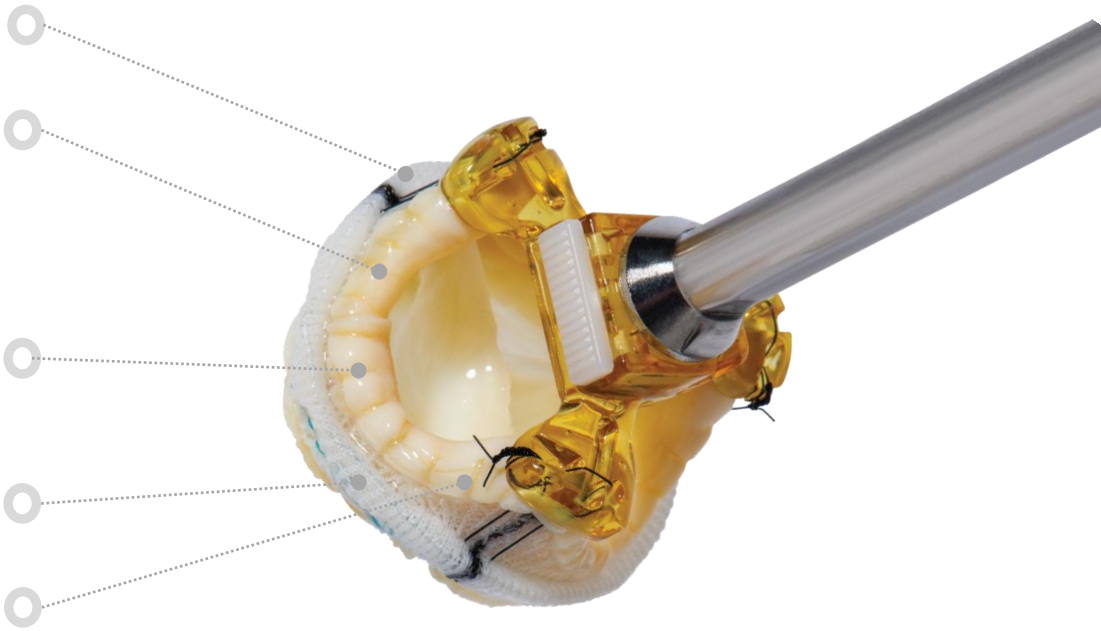
FlexFit™ polymer stent

- Withstands up to approximately 8 atm pressure during balloon valvuloplasty procesures[1]
- Eases implant
- Accommodates MIS procedures

Unique pericardial shield provides a tissue-to-tissue interface to help prevent the risk of abrasion

Flexible cuff mitigates PVL and easily fits patient anatomy

Low stent post height mitigates risk of coronary obstruction



Source: 1. Allen KB, Chhatriwalla A, Cohen DJ, et al. Bioprosthetic valve fracture to facilitate transcatheter valve-in-valve implantation. Ann Thorac Surg. 2017;104:1501-1508.

Resists Calcification with 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

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

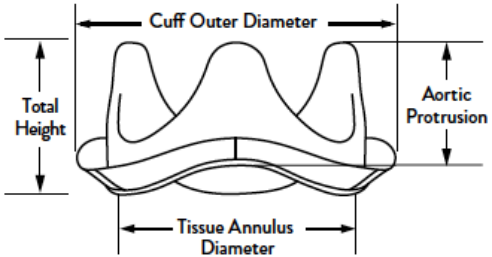
Sources: **1.** Frater RWM, Seifter E., Liao K,j Wasserman F. Advances in Anticalcific and Antidegenerative Treatment of Heart Valve Bioprostheses. Edited by Gabbay S. and Wheatley D. First Edition, Silent partner, Inc. 1997;8:105-113. **2.** Kelly SJ, Ogle MF,Carlyle WC, Mirsch MW, Biocompatibility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

EPIC™ SUPRA VALVE AORTIC

Product Information

Available Sizes

Model Number	Valve Size (mm)	Tissue Annulus Diameter (mm)	Internal Diameter (mm)	Aortic Protrusion	Total Height (mm)	Cuff Outer Diameter (mm)
ESP100-19	19	19	19	11	14	25
ESP100-21	21	21	21	11	15	28
ESP100-23	23	23	23	13	16	29
ESP100-25	25	25	25	13	17	31
ESP100-27	27	27	27	14	19	33



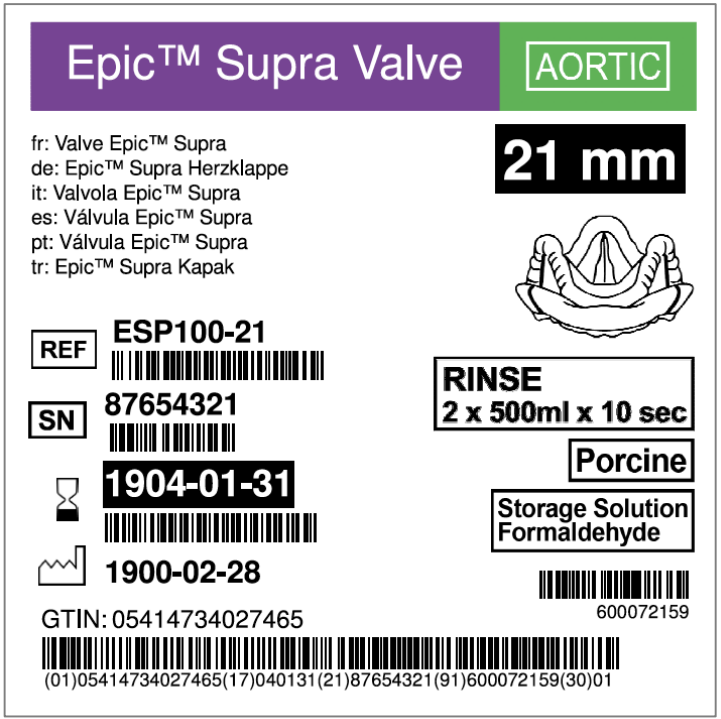
Supra Aortic Valve

Package Labeling

Purple Color Bar

Valve Model

Valve Expiration



Valve Position

Valve Size

Line Art

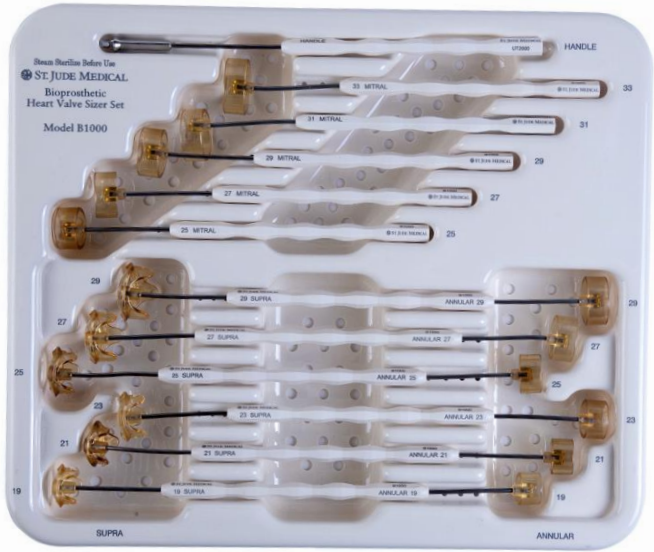
Biocor / Epic B1000 Sizer Set

To determine the correct valve size, use the Model B1000 aortic sizers

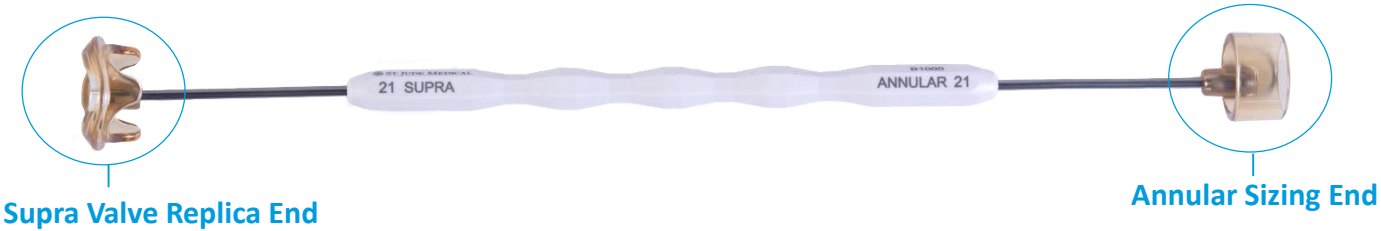
SET INCLUDES:

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

Instructions for Use included.



Biocor / Epic B1000 Aortic Sizer



- The B1000 aortic sizer is a double-ended tool with a supra valve replica end and an annular sizing end
- Use the annular sizing end to determine the size of the annulus
- Insert the corresponding supra valve replica end in the supra-annular space to confirm placement and fit of the valve
- Do not bend the sizer handle beyond a 90-degree angle

Biocor /Epic Holder Handles

CLICK IN HANDLE: B1000-H

- Made to click into all Biocor/Epic Holders

RIGID EXTENSION HANDLE: EX2000-R

- Made of stainless steel (with 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.

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EPIC™ SUPRA AORTIC STENTED TISSUE VALVE

Surgical Guidelines & Precautions

Refer to the Instructions for Use for additional information.

Surgical Guidelines

The actual choice of surgical technique, modified in accordance with the instructions in the Instructions for Use, is left to the discretion of the individual surgeon.

- When implanting supra-annular valves, non-everting mattress sutures are recommended
- Avoid any contact between the implantation sutures or knot tying technologies and the leaflets

Precautions

- Do not allow the valve tissue to dry. Place the valve in isotonic sterile saline rinse solutions immediately upon removal from the valve storage solution. Once removed from the solution, the valve should be periodically irrigated during implantation.
- 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
- 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.

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EPIC™ SUPRA VALVE AORTIC

Valve Pre-Implant Handling Instructions

Refer to the Instructions for Use for additional information.

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

Pre-Implant Handling

EXPIRATION DATE

- Verify the valve size and expiration date on the label

TEMPERATURE INDICATOR

- Review temperature indicator on the valve packaging to ensure that the product has remained within the required parameters
- If the temperature indicator is red, do not use the valve

Refer to the Instructions for Use for additional information.

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FlexFit™ Click-in Handle

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STERILE HANDLING

1. Press the valve holder handle into the valve holder
2. Remove the valve from the jar and leave the valve in the valve support
   - The handle can be disengaged from the valve holder by depressing the white button on the valve holder
3. Inspect the valve for damage. Do not implant the valve if it is mishandled or there is any sign of damage or deterioration

Refer to the Instructions for Use for additional information.

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FlexFit™ 20 Second Rinse

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VALVE RINSING

1. Prepare two sterile basins each with 500 ml of sterile isotonic saline solution
2. 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
3. Repeat step 2 in the second basin

4. Leave the valve fully immersed in the second basin until required for implantation. Do not allow the tissue to dry. Once removed from this solution, the valve should be periodically irrigated during implantation

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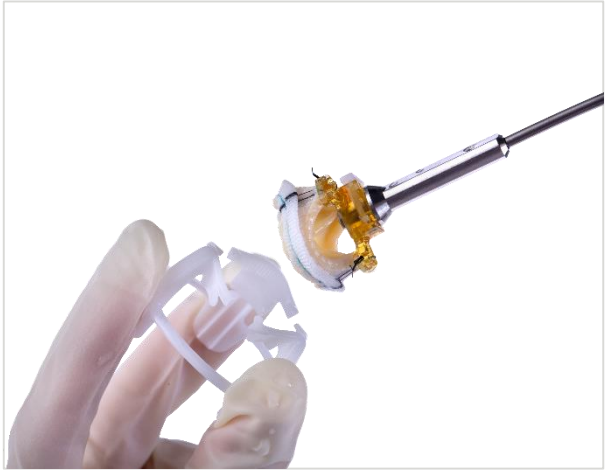
Removal of Valve Support

VALVE PREPARATION

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



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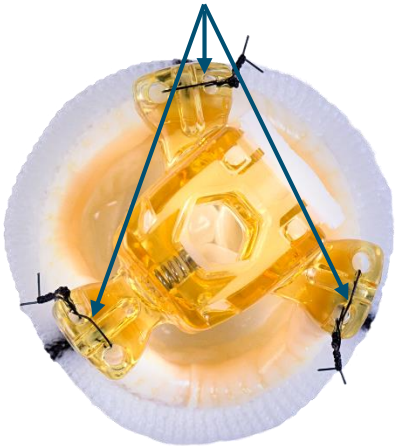
Valve Implantation

Refer to the Instructions for Use for additional information.

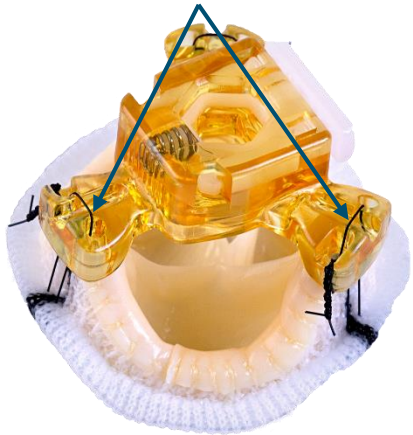
Removal of Valve from Aortic Holder

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

Holder Removal Sutures



Alternate View



Refer to the Instructions for Use for additional information.

Caution: These products are 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 medical.abbott/manuals for more detailed information on Indications, Contraindications, Warnings, Precautions and Adverse Events.

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

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Begumpet. Hyderabad, India 500016.
(St. Jude Medical is now Abbott)


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