Table 1. Catalog Number Descriptions and Reference Dimensions

| Catalog Number | Tissue Annulus Diameter (mm) | Aortic/Ventricular Protrusion (mm) | Total Height(mm) | Cuff Outer Diameter (mm) | Stent Internal Diameter [1] (mm) |
|---|---|---|---|---|---|
| Aortic Heart Valves, Epic™ Plus | | | | | |
| E200-21A | 21 | 9 | 14 | 25 | 18.7 |
| E200-23A | 23 | 9 | 15 | 27 | 20.8 |
| E200-25A | 25 | 10 | 16 | 29 | 22.6 |
| E200-27A | 27 | 11 | 17 | 31 | 24.5 |
| E200-29A | 29 | 12 | 19 | 33 | 26.3 |
| Aortic Heart Valves, Epic™ Plus Supra | | | | | |
| ESP200-19 | 19 | 11 | 14 | 25 | 18.7 |
| ESP200-21 | 21 | 11 | 15 | 28 | 20.8 |
| ESP200-23 | 23 | 13 | 16 | 29 | 22.6 |
| ESP200-25 | 25 | 13 | 17 | 31 | 24.5 |
| ESP200-27 | 27 | 14 | 19 | 33 | 26.3 |
| Mitral Heart Valves, Epic™ Plus | | | | | |
| E200-25M | 25 | 9 | 16 | 33 | 22.6 |
| E200-27M | 27 | 9 | 17 | 35 | 24.5 |
| E200-29M | 29 | 10 | 19 | 37 | 26.3 |
| E200-31M | 31 | 10 | 20 | 39 | 28.4 |
| E200-33M | 33 | 11 | 20 | 41 | 30.3 |

## Indications for Use ข้อบ่งชี้ สรรพคุณ การใช้งาน

The Epic™ Plus valve is indicated for patients requiring replacement of a diseased, damaged, or malfunctioning native aortic and/or mitral heart valve. It may also be used as a replacement for a previously implanted aortic and/or mitral prosthetic heart valve.

The Epic™ Plus Supra valve is indicated for patients requiring replacement of a diseased, damaged, or malfunctioning native aortic heart valve. It may also be used as a replacement for a previously implanted aortic prosthetic heart valve.

## Contraindications

None known.

## Warnings and Precautions

### Warnings

- 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, valve damage, diminished tissue durability, and/or damage to the surrounding tissues. The use of an inappropriately small bioprosthesis may result in suboptimal hemodynamics. Use only the E2000 Epic™ Plus Heart Valve Sizer Set with the Epic™ Plus and Epic™ Plus Supra valves.
- Accelerated deterioration due to calcific degeneration of the Epic Plus and Epic Plus Supra valve may occur in:
  - children, adolescents, or young adults;
  - patients with altered calcium metabolism (e.g., patients with hyperparathyroidism or chronic renal failure); or
  - individuals requiring hemodialysis.
- For single use only. Do not reuse or resterilize. Attempts to resterilize the valve may result in valve malfunction, inadequate sterilization, or patient harm.
- Passage of a catheter or transvenous pacing lead through any bioprosthesis may damage the valve and is therefore not recommended.

Do not use if:

- the valve has been dropped, damaged, or mishandled in any way, or if there is any sign of deterioration;
- the expiration date has elapsed;
- the tamper-evident container seal is damaged, broken, or missing, or if fluid is leaking from the packaging; or
- the storage solution does not completely cover the valve.

[1] Stent Internal Diameter does not account for the tissue/fabric covering the stent which may vary in thickness between approximately 1 to 2 mm.

## Precautions

- The safety and effectiveness of the Epic™ Plus and Epic™ Plus Supra valves has not been established for the following specific populations:
  - patients who are pregnant
  - nursing mothers
  - patients with chronic renal failure
  - patients with aneurysmal aortic degenerative conditions (e.g., cystic medial necrosis, Marfan's syndrome)
  - patients with chronic endocarditis
  - patients requiring pulmonic or tricuspid valve replacement
  - children, adolescents, or young adults
- Sizers are supplied non-sterile, and must be cleaned and sterilized prior to each use. Do not use cracked, deformed, or damaged sizer set components.
- Do not pass the flanged portion of the valve replica sizing tool through the annulus.
- Do not place the non-sterile exterior of the valve container in the sterile field.
- Do not expose the valve to solutions other than the formaldehyde valve storage solution in which it was shipped, the sterile isotonic saline solution used during the rinsing procedure, or the sterile isotonic saline solution used to irrigate the valve.
- Do not add antibiotics to either the formaldehyde valve storage solution or the rinse solution.
- Do not apply antibiotics to the valve.
- Do not allow the valve tissue to dry. Place the valve in sterile isotonic saline rinse solution immediately upon removal from the valve storage solution. Once removed from this solution, the valve should be periodically irrigated during implantation.
- Do not use the valve if shipping temperature indicators on the product carton have turned red, or if the valve has been improperly stored in temperature conditions outside of the 5 °C to 25 °C range.
- Do not implant the valve without thoroughly rinsing as directed.
- 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 the mitral valve in a manner to avoid commissure obstruction of the left ventricular outflow tract, and minimize any potential of commissure contact with the ventricular wall.
- Position the aortic valve so that the stent posts do not obstruct the coronary ostia.
- When implanting the Epic™ Plus heart valve, assess the suitability of the selected valve size and stent post position for a potential future valve-in-valve procedure and whether the transcatheter valve-in-valve procedure may result in left ventricular outflow tract or coronary ostia obstruction. For a future valve-in-valve procedure in an Epic Plus valve, refer to the instructions for use supplied with the transcatheter heart valve along with the reference dimensions in Table 1 to determine compatibility. The safety and effectiveness of valve-in-valve procedures in an Epic™ Plus or an Epic™ Plus Supra valve have not been established.
- Avoid prolonged contact with the formaldehyde storage solution. Immediately after contact, thoroughly flush any skin exposed to the solution with water. In case of contact with eyes, flush with water and seek appropriate medical care.

3.6

## MRI Safety Information


Non-clinical testing has demonstrated that Epic™ Plus heart valves are MR Conditional. A patient with one of these devices can be safely scanned in an MR system under the following conditions A patient with one of these devices can be safely scanned in an MR system under the following conditions:

- Static magnetic field of 1.5 Tesla (1.5T) or 3.0-Tesla (3.0T)
- Maximum spatial gradient field of 19 T/m (1900 G/cm)
- Maximum MR system reported, whole-body averaged specific absorption rate (SAR) of 2.0 W/kg (normal operating mode)

Under the scan conditions defined above, the device is expected to produce a maximum temperature rise of less than or equal to 2°C after 15 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by the device extends radially up to 0.6 cm from the device when imaged with a gradient echo pulse sequence in a 1.5T MR system.

## Adverse Events

The clinical investigation of the first generation Epic valve supports the safety and effectiveness of the Epic™ Plus valve and the Epic™ Plus Supra valve. Between January 2003 and March 2006, seven-hundred and sixty-two (762) subjects were implanted with 791 Epic Valve(s) at 19 investigational sites in the United States (U.S.), and three sites in Canada. Five-hundred and fifty-seven (557) subjects received isolated aortic replacement, 176 received isolated mitral replacement, and 29 received replacement of both the aortic and mitral valves. The cumulative follow-up for all subjects was 773.51 patient-years with a mean follow-up of 1.02 patient-years (s.d. = 0.71 patient-years, range 0 – 3.10 patient-years).

## Potential Adverse Events

Adverse events potentially associated with the use of bioprosthetic heart valves (in alphabetical order) include:

- angina
- cardiac arrhythmias
- endocarditis
- heart failure
- hemolysis
- hemolytic anemia
- hemorrhage, anticoagulant/antiplatelet-related
- leak, transvalvular or paravalvular
- myocardial infarction
- nonstructural dysfunction (entrapment by pannus or suture, inappropriate sizing or positioning, or other)
- prosthesis regurgitation
- stroke
- structural deterioration (calcification, leaflet tear, or other)
- thromboembolism
- valve thrombosis

It is possible that these complications could lead to:

- reoperation
- explantation
- permanent disability
- death

## Clinical Studies

The clinical investigation of the first generation Epic valve supports the safety and effectiveness of the Epic Plus valve and the Epic Plus Supra valve.

The first generation Epic valve clinical investigation was a multi-center, multi-country, prospective, non-randomized, observational study, without concurrent or matched controls, conducted under a common protocol. Bayesian methods were used for the design and analysis of this study. This statistical methodology provides a framework for "borrowing" historical data from the SJM Biocor™ Valve PMA data.

Seven-hundred and sixty-two (762) subjects were implanted with 791 Epic Valve(s) between January 2003 and March 2006 at 19 investigational sites in the United States (U.S.), and three sites in Canada. Five-hundred and fifty-seven (557) subjects received isolated aortic replacement, 176 received isolated mitral replacement, and 29 received replacement of both the aortic and mitral valves. Demographic and baseline data were collected preoperatively. Postoperative data, including blood and echocardiography data were collected at discharge, 6 months, one year, and annually thereafter. All echoes were sent to the Echo Core Lab for interpretation. Adverse event data (Table 2) was collected at the time of occurrence or site notification using definitions from Edmunds et al., 1996 [2].

The mean age at implant for all subjects was 73.9 years (s.d. = 9.2 years, range 24-93 years). Preoperatively, 57.4 % of all subjects were NYHA classification III/IV. The cumulative follow-up for all subjects was 773.51 patient-years with a mean follow-up of 1.02 years (s.d. = 0.71 years, range 0 – 3.10 years).

Table 2. Observed Adverse Event Rates

All subjects entered into study: N=762, cumulative follow-up=717.4 late Patient-years

| Adverse Event | Early Events[1] n (%) | Late Events[2] n (% / pt-yr) | Bayesian Posterior mean rate[3] | Freedom From Event 1 Year % [95% CI] |
|---|---|---|---|---|
| Hemolysis | 2 ( 0.3) | 1 ( 0.1) | 0.104 | 99.6% [ 98.6%, 99.9%] |
| Structural Deterioration | 0 ( 0.0) | 2 ( 0.3) | 0.324 | 100.0% [100.0%,100.0%] |
| Paravalvular Leak | 2 ( 0.3) | 11 ( 1.5) | 1.363 | 98.2% [ 96.7%, 99.0%] |
| Embolism | 20 ( 2.6) | 18 ( 2.5) | 2.136 | 94.8% [ 92.8%, 96.3%] |
| Valve Thrombosis | 1 ( 0.1) | 0 ( 0.0) | 0.014 | 99.8% [ 98.9%,100.0%] |
| Major Bleeding Events – Anticoagulant and/or Antiplatelet Related Hemorrhage | 38 ( 5.0) | 13 ( 1.8) | 1.357 | 93.2% [ 91.0%, 94.9%] |
| – Anticoagulant Related Hemorrhage[4] | 27(3.5) | 7 ( 0.98) | 0.88 | 95.2% [ 93.2%, 96.6%] |
| Endocarditis | 1 ( 0.1) | 9 ( 1.3) | 0.845 | 98.5% [ 97.1%, 99.2%] |
| Reoperation | 1 ( 0.1) | 11 ( 1.5) | 1.456 | 98.3% [ 96.8%, 99.1%] |
| Mortality - Valve Related | 2 ( 0.3) | 5 ( 0.7) | 0.804 | 99.2% [ 98.1%, 99.7%] |

[2] Edmunds LH, Clark RE, Cohn LH, Grunkemeier GL, Miller CM, Weisel RD. Guidelines for Reporting Morbidity and Mortality after Cardiac Valvular Operations. Ann Thorac Surg 1996;62:932-5

1. Early events are those occurring on or before 30 days post-implant. The early adverse event rate (%) is calculated as the number of early adverse events divided by the total number of subjects implanted, times 100.
2. Late events are those occurring 31 days post-implant or thereafter.
3. Bayesian posterior mean are the event rates modeled from a Bayesian hierarchical model.
4. Excludes subjects receiving only antiplatelet therapy.

## Follow-up

Table 3 presents the number of patients implanted, cumulative follow-up, and late follow-up for each implant position.

Table 3. Patient Numbers, and Cumulative and Late Patient Follow-Up

All subjects entered into study, N=762
Mean, SD, Minimum, and Maximum are represented in "Patient-years"

| Implant Position | Number of Subjects | Total Patient-years | Mean | SD | Minimum | Maximum |
|---|---|---|---|---|---|---|
| Cumulative Patient-years | | | | | | |
| Isolated Aortic | 557 | 582.13 | 1.05 | 0.70 | 0.00 | 3.08 |
| Isolated Mitral | 176 | 168.96 | 0.96 | 0.73 | 0.00 | 3.10 |
| Double | 29 | 22.43 | 0.77 | 0.66 | 0.02 | 2.01 |
| All Implants | 762 | 773.51 | 1.02 | 0.71 | 0.00 | 3.10 |
| Late Patient-years* | | | | | | |
| Isolated Aortic | 474 | 540.93 | 1.14 | 0.61 | 0.00 | 3.00 |
| Isolated Mitral | 147 | 156.12 | 1.06 | 0.65 | 0.02 | 3.001 |
| Double | 23 | 20.34 | 0.88 | 0.60 | 0.02 | 1.93 |
| All Implants | 644 | 717.40 | 1.11 | 0.62 | 0.00 | 3.01 |

* Late patient-years at risk are determined from 31 days post implant to the censoring event.

## Preoperative Patient Demographics

Table 4 presents the preoperative patient demographics.

Table 4. Preoperative Patient Demographics

All subjects entered into study: N=762

| Variable | Isolated Aortic (N=557) | Isolated Mitral (N=176) | Double (N= 29) | All (N=762) |
|---|---|---|---|---|
| Age | 74.4 ± 9.3 ( 24, 93) | 72.1 ± 8.9 ( 44, 91) | 75.9 ± 8.3 ( 55, 92) | 73.9 ± 9.2 ( 24, 93) |
| Gender (Male) | 61.0% | 44.3% | 34.5% | 56.2% |
| Preoperative NYHA | | | | |
| I | 9.2% | 8.0% | 0.0% | 8.5% |
| II | 34.6% | 30.1% | 34.5% | 33.6% |
| III | 43.1% | 43.2% | 34.5% | 42.8% |
| IV | 12.6% | 18.2% | 31.0% | 14.6% |
| Unknown | 0.5% | 0.6% | 0.0% | 0.5% |

## Effectiveness Outcomes

Quantitative data were collected throughout the study (i.e., NYHA functional classification, echo parameters). Table 5 presents patient NYHA classification at one year follow-up. Tables 6 and 7 present the hemodynamic follow-up results for the first generation Epic aortic and mitral valve replacements.

Table 8 presents the hemodynamic follow-up results for the 25mm first generation mitral Epic valve size augmented with data collected from Brazil for the Biocor™ 25 mm valve.

Table 5. Effectiveness Outcomes, NYHA Functional Classification: 1-year Follow-up*

Subjects with both preoperative and 1 year NYHA measurements, N=460; n1=number per subgroup

| NYHA Class | Isolated Aortic n=353 | | | | Isolated Mitral n=93 | | | | Double n=14 | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Preoperative | | 1 Year | | Preoperative | | 1 Year | | Preoperative | | 1 Year | |
| | $n_1$ | % ($n_1$/n) | $n_1$ | % ($n_1$/n) | $n_1$ | % ($n_1$/n) | $n_1$ | % ($n_1$/n) | $n_1$ | % ($n_1$/n) | $n_1$ | % ($n_1$/n) |
| I | 35 | 9.9 | 244 | 69.1 | 6 | 6.5 | 66 | 71.0 | 0 | 0 | 12 | 85.7 |
| II | 131 | 37.4 | 98 | 27.8 | 30 | 32.3 | 22 | 23.7 | 6 | 42.9 | 1 | 7.1 |
| III | 146 | 41.1 | 11 | 3.1 | 40 | 43.0 | 43 | 5.4 | 4 | 28.6 | 1 | 7.1 |
| IV | 39 | 11.0 | 0 | 0 | 17 | 18.3 | 18.3 | 0 | 4 | 28.6 | 0 | 0 |
| All | 353 | 100.0 | 353 | 100.0 | 93 | 100.0 | 93 | 100.0 | 14 | 100.0 | 14 | 100.0 |

*Subjects with both preoperative and one year NYHA measurements available are included in this table.

Table 6. Effectiveness Outcomes at One Year Follow-Up Visit, Hemodynamic Results - All Epic™ Aortic Valves

All aortic subjects entered into study: N=586

| Hemodynamic Parameter | 21 mm | 23 mm | 25 mm | 27 mm | 29 mm* |
|---|---|---|---|---|---|
| Mean Gradient (mmHg) | n= 49 | n=120 | n=121 | n= 36 | n= 10 |
| ~ Mean ± SD | 19.1 ± 8.2 | 13.9 ± 6.0 | 12.1 ± 5.1 | 11.4 ± 4.1 | 7.5 ± 3.3 |
| ~ Min, Max | 3.1, 43.5 | 1.7, 35.0 | 3.7, 34.3 | 6.5, 26.3 | 2.7, 12.7 |
| EOA ($cm^2$) | n= 46 | n=118 | n=121 | n= 35 | n= 10 |
| ~ Mean ± SD | 1.0 ± 0.3 | 1.4 ± 0.5 | 1.5 ± 0.5 | 1.6 ± 0.4 | 2.4 ± 1.1 |
| ~ Min, Max | 0.5, 2.3 | 0.5, 3.5 | 0.2, 3.3 | 0.8, 2.7 | 1.2, 4.6 |
| Regurgitation (n, %) | n= 56 | n=130 | n=128 | n= 38 | n= 10 |
| ~ None | 47 ( 84%) | 103 ( 79%) | 92 ( 72%) | 28 ( 74%) | 9 ( 90%) |
| ~ Trivial | 7 ( 13%) | 21 ( 16%) | 29 ( 23%) | 9 ( 24%) | 1 ( 10%) |
| ~ Mild | 2 ( 4%) | 6 ( 5%) | 6 ( 5%) | 1 ( 3%) | 0 ( 0%) |
| ~ Moderate | 0 ( 0%) | 0 ( 0%) | 1 ( 1%) | 0 ( 0%) | 0 ( 0%) |
| ~ Severe | 0 ( 0%) | 0 ( 0%) | 0 ( 0%) | 0 ( 0%) | 0 ( 0%) |
| ~ Unknown | 0 ( 0%) | 0 ( 0%) | 0 ( 0%) | 0 ( 0%) | 0 ( 0%) |

*Includes 2 subjects at greater than one year visit

n= number of subjects evaluated

Table 7. Effectiveness Outcomes at One Year Follow-Up Visit, Hemodynamic Results - All Epic™ Mitral Valves

All mitral subjects entered into study: N=205

| Hemodynamic Parameter | 27 mm* | 29 mm | 31 mm | 33 mm* |
|---|---|---|---|---|
| Mean Gradient (mmHg) | n= 30 | n= 41 | n= 26 | n= 24 |
| ~ Mean ± SD | 6.1 ± 2.9 | 5.5 ± 1.7 | 4.8 ± 1.4 | 4.1 ± 1.6 |
| ~ Min, Max | 2.7, 14.0 | 2.9, 10.0 | 2.6, 8.3 | 1.5, 7.9 |
| EOA ($cm^2$) | n= 16 | n= 26 | n= 15 | n= 22 |
| ~ Mean ± SD | 1.4 ± 0.7 | 1.5 ± 0.5 | 1.6 ± 0.3 | 1.5 ± 0.3 |
| ~ Min, Max | 0.6, 3.1 | 0.6, 2.8 | 1.1, 2.4 | 1.1, 2.2 |
| Regurgitation (n, %) | n= 30 | n= 45 | n= 28 | n= 25 |
| ~ None | 30 (100%) | 41 ( 91%) | 23 ( 82%) | 23 ( 92%) |
| ~ Trivial | 0 ( 0%) | 1 ( 2%) | 0 ( 0%) | 1 ( 4%) |
| ~ Mild | 0 ( 0%) | 3 ( 7%) | 5 ( 18%) | 0 ( 0%) |
| ~ Moderate | 0 ( 0%) | 0 ( 0%) | 0 ( 0%) | 1 ( 4%) |

Table 7. Effectiveness Outcomes at One Year Follow-Up Visit, Hemodynamic Results - All Epic™ Mitral Valves

All mitral subjects entered into study: N=205

| Hemodynamic Parameter | 27 mm* | 29 mm | 31 mm | 33 mm* |
|---|---|---|---|---|
| ~ Severe | 0 ( 0%) | 0 ( 0%) | 0 ( 0%) | 0 ( 0%) |
| ~ Unknown | 0 ( 0%) | 0 ( 0%) | 0 ( 0%) | 0 ( 0%) |

*Includes 4 (27 mm) and 6 (33 mm) subjects at greater than one year visit.

n= number of subjects evaluated

Table 8. Biocor™/Epic™ Effectiveness Outcomes, 25mm Mitral Hemodynamic results ( ≥ 11 months)

All mitral 25 mm subjects: N= 15

Brazil Biocor™ Valve Study(n=12)

Epic™ Valve IDE (n=3)

| Hemodynamic Parameter | 25 mm |
|---|---|
| Mean Gradient (mmHg) | n= 15 |
| ~ Mean ± SD | 6.8 ± 2.5 |
| ~ Min, Max | 3.7, 13.7 |
| EOA ($cm^2$) | n=15 |
| ~ Mean ± SD | 1.2 ± 0.3 |
| ~ Min, Max | 0.5, 1.7 |
| Regurgitation (n, %) | n= 15 |
| ~ None | 11 (73.3%) |
| ~ Trivial | 0 (0.0%) |
| ~ Mild | 4 (26.7%) |
| ~Moderate | 0 (0.0%) |
| ~Severe | 0 (0.0%) |
| ~ Unknown | 0 (0.0) |

n= number of subjects evaluated

## Individualization of Treatment

Anticoagulant and/or Antiplatelet Therapy

Long-term, low-dose aspirin, unless contraindicated, is recommended for all patients with bioprosthetic valves. Long-term anticoagulant therapy, unless contraindicated, is recommended for all patients with bioprosthetic valves who have risk factors for thromboembolism.

## Patient Counseling Information

Long-term, low-dose aspirin, unless contraindicated, is recommended for all patients with bioprosthetic valves. Long-term anticoagulant therapy, unless contraindicated, is recommended for all patients with bioprosthetic valves who have risk factors for thromboembolism.

Patients with bioprostheses who undergo dental or other procedures that are potentially bacteremic should receive endocarditis prophylactic antibiotic therapy.

Abbott Medical publishes a patient brochure. Copies of this booklet are available through your Abbott sales representative.

## 3.5 Packaging and Storage

As delivered, the valve is attached to a valve holder by three retaining sutures. A flexible plastic support surrounds the valve. The valve holder and support facilitate handling and manipulation of the valve during removal from the container, rinsing, and implantation.

The valve is packaged in a formaldehyde storage solution.

Store the valve in the upright position.

The valve should be stored in temperatures from 5° C to 25° C (41° F to 77° F). Do not store the valve where significant temperature fluctuations may occur.

CAUTION:

- Do not implant the valve without thoroughly rinsing as directed.
- Do not use the valve if shipping temperature indicators on the product carton have turned red, or if the valve has been improperly stored in temperature conditions outside the 5° C to 25° C (41° F to 77° F) range.

# Directions for Use

## Pre-Implant Handling

The Epic™ Plus and the Epic™ Plus Supra valves are supplied in a storage container with a screw-cap closure and tamper-evident seal. The contents of the container are sterile, and must be handled aseptically to prevent contamination.

WARNING:

- Do not use the valve if the expiration date has elapsed.
- Do not use the valve if fluid is leaking from the packaging.
- Do not resterilize the valve by any method.

## Removing the Valve from the Outer Packaging

PRECAUTION:

- Do not place the non-sterile exterior of the valve container in the sterile field.
- Do not expose the valve to solutions other than the formaldehyde valve storage solution in which it was shipped, the sterile isotonic saline solution used during the rinsing procedure, or the sterile isotonic saline solution used to irrigate the valve.
- Do not add antibiotics to either the formaldehyde valve storage solution or the rinse solution.
- Do not apply antibiotics to the valve.

1. After sizing, choose a valve of the appropriate size.
2. Once the valve container has been removed from the outer packaging, examine the container for evidence of damage.

   WARNING:

   - The valve must not be implanted if the tamper-evident container seal is damaged, broken, or missing; or if fluid is leaking from the packaging.
   - The valve must not be implanted if the storage solution does not completely cover the valve.
3. Verify the valve size and expiration date on the label.
4. To remove the valve from the container, break the seal and remove the screw-top closure.

   CAUTION: Avoid prolonged contact with the formaldehyde storage solution. Immediately after contact, thoroughly flush any skin exposed to the solution with water. In case of contact with eyes, flush with water and seek appropriate medical care.
5. Complete the medical device registration form and return it to Abbott Medical. Place one of the pull-off labels with the designated model and serial number in the patient's chart.

## Removing the Valve from the Storage Container

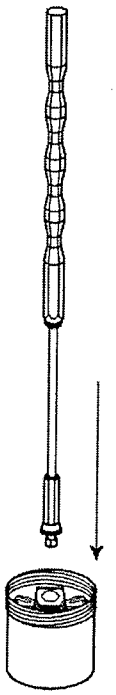
The Epic Plus valves are available in the aortic and mitral sizes indicated in Table 1. Epic Plus standard valves are designed to allow intra-annular placement of the inflow edge of the valve with supra-annular placement of the sewing cuff.

Epic Plus Supra valves are available in the aortic sizes indicated in Table 1. Epic Plus Supra valves are designed for supra-annular implantation of both the valve and the sewing cuff. The sewing cuff is the only difference between the Epic Plus valve and the Epic Plus Supra valve.

The Epic Plus and Epic Plus Supra valves are processed using the Linx™ anticalcification treatment.

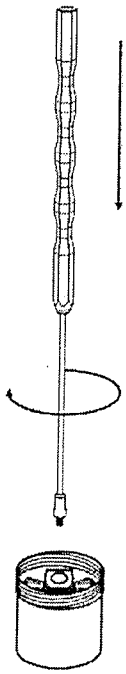
1. Select the appropriate valve holder handle.
   - For aortic valves, select the aortic holder handle (model E2000-HA).
   - For mitral valves, select the mitral holder handle (model E2000-HM).
2. With the circulating nurse holding the container, press the valve holder handle into the valve holder as shown in Figure 3, and remove the valve from the container.
   - For aortic valves, connect the aortic valve holder handle to the valve holder by pressing the aortic holder handle into the holder as shown in Figure 3.

Figure 3. Press the aortic valve holder handle into the valve holder



- For mitral valves, connect the mitral valve holder handle to the valve holder by threading the mitral holder handle clockwise into the valve holder as shown in Figure 4.

Figure 4. Thread the mitral valve holder handle clockwise into the valve holder



CAUTION: 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.

3. Inspect the valve for damage.

   WARNING: Do not implant the valve if it has been dropped, damaged, or mishandled in any way, or if there is any sign of deterioration.

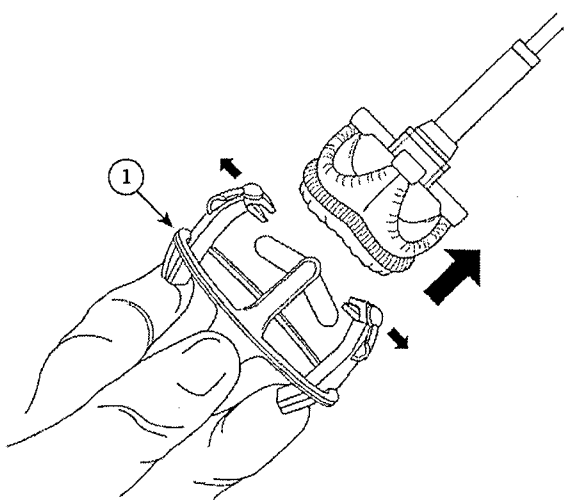
## Rinse Procedure

CAUTION: Do not implant the valve without thoroughly rinsing as directed.

1. Within the sterile field, prepare two sterile basins with a minimum of 500 mL of sterile isotonic saline solution in each basin.
2. Holding the valve by the handle, fully immerse the valve support, the valve, the valve holder, and the portion of the holder handle that was submerged in the valve storage solution, in the sterile isotonic saline solution in the first basin.
3. Continually rinse the valve for 10 seconds, using a gentle back-and-forth motion.
4. Repeat steps two and three in the second basin.
5. After rinsing, leave the valve immersed in the basin until required by the surgeon for implantation.
6. Prior to implantation, remove the valve support by depressing the three tabs below the level of the valve support ring, as indicated in Figure 5.

   CAUTION: Do not allow the valve tissue to dry. Place the valve in sterile isotonic saline rinse solution immediately upon removal from the valve storage solution.

Figure 5. Remove the valve support from the valve cuff




1. Support ring

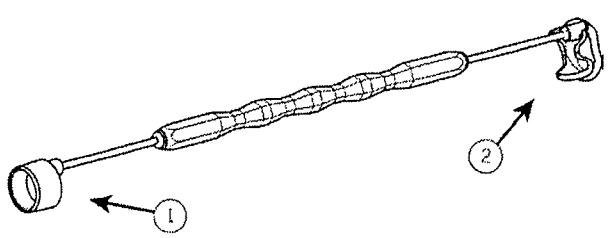
## Sizing Epic™ Plus Standard Aortic Valves

Epic Plus standard aortic valves are designed for intra-annular stent placement and supra-annular cuff placement.

To determine the correct standard aortic valve size, use the Model E2000 aortic sizers. The Model E2000 aortic sizer is a double-ended tool, with a supra valve replica end and an annular sizing end (Figure 6).

NOTE: Use only the annular sizing end of the E2000 sizer to size standard aortic valves.

Figure 6. Aortic sizer




1. Annular sizing end
2. Supra valve replica end

Identify the sizer that fits snugly in the annulus and select the corresponding valve size.

WARNING: Standard aortic valve size selection is based on the size of the recipient annulus. Implantation of an inappropriately large bioprosthesis may result in stent deformation, valvular incompetence, valve damage, diminished tissue

durability, and/or damage to the surrounding tissues. The use of an inappropriately small bioprosthesis may result in suboptimal hemodynamics. Use only the Epic™ Plus Heart Valve Sizer Model E2000 to size Epic Plus standard aortic valves.

CAUTION: Sizers are supplied non-sterile, and must be cleaned and sterilized prior to each use. Do not use cracked, deformed, or damaged sizer set components.

## Sizing Epic™ Plus Supra Aortic Valves

Epic™ Plus Supra valves are designed for supra-annular aortic placement.

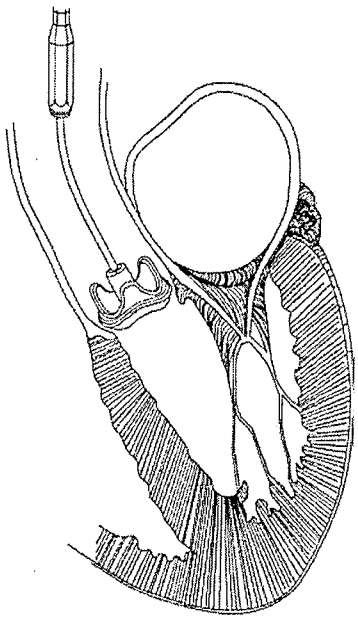
To determine the correct supra aortic valve size, use the Model E2000 aortic sizers. The aortic sizer is a double-ended tool, with a supra valve replica end and an annular sizing end. Use the annular sizing end to determine the size of the annulus. Insert the corresponding supra valve replica end in the supra-annular space to confirm placement and fit of the valve (Figure 7).

WARNING: Supra-annular aortic valve size selection is based on the size of the recipient annulus and the anatomy of the sinotubular space. Implantation of an inappropriately large bioprosthesis may result in stent deformation, valvular incompetence, valve damage, diminished tissue durability, and/or damage to the surrounding tissues. The use of an inappropriately small bioprosthesis may result in suboptimal hemodynamics. Use only the E2000 Epic™ Plus Heart Valve Sizer Set to size Epic Plus Supra valves.

CAUTION:

- Sizers are supplied non-sterile, and must be cleaned and sterilized prior to each use. Do not use cracked, deformed, or damaged sizer set components.
- Do not pass the flanged portion of the supra valve replica sizing tool through the annulus.

Figure 7. Place the supra valve replica end in the supra-annular space



## Sizing Epic™ Plus Mitral Valves

Epic™ Plus mitral valves are designed for intra-annular stent placement and supra-annular cuff placement.

To determine the correct standard mitral valve size, use the Model E2000 mitral sizers (Figure 8). Identify the sizer that fits snugly in the annulus and select the corresponding valve size.

WARNING: Mitral valve size selection is based on the size of the recipient annulus. Implantation of an inappropriately large bioprosthesis may result in stent deformation, valvular incompetence, valve damage, diminished tissue durability, and/or damage to the surrounding tissues. The use of an inappropriately small bioprosthesis may result in suboptimal hemodynamics. Use only the E2000 Epic™ Plus Heart Valve Sizer Set to size Epic Plus mitral valves.

CAUTION: Sizers are supplied non-sterile, and must be cleaned and sterilized prior to each use. Do not use cracked, deformed, or damaged sizer set components.