INSTRUCTIONS FOR USE
Trifecta™ Valve

Sterile components: Trifecta™ Valve, valve collar and holder
Non-sterile components: exterior of valve container, Trifecta™ sizers and holder handles

STORAGE SOLUTION - Consult Instructions for Temperature Limitation

Manufacturer Serial Number

AORTIC Sterilized by Liquid Do Not Use if Package is A

Catalog Number Rinse - 2 x 500 mL x 10 sec

ARTEN100121085A Processed Using Contents Do Not Resterilize

RINSE °C

°F

°C

Table 1: Trifecta™ Valve Model Numbers and Reference Dimensions

<table>
<thead>
<tr>
<th>Model Number</th>
<th>Tissue Annulus Diameter (mm)</th>
<th>Cuff Outer Diameter (mm)</th>
<th>Total Height (mm)</th>
<th>Aortic Protrusion (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>TF-19A</td>
<td>19</td>
<td>24</td>
<td>15</td>
<td>12</td>
</tr>
<tr>
<td>TF-21A</td>
<td>21</td>
<td>26</td>
<td>16</td>
<td>13</td>
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<tr>
<td>TF-23A</td>
<td>23</td>
<td>28</td>
<td>17</td>
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<tr>
<td>TF-25A</td>
<td>25</td>
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<td>TF-27A</td>
<td>27</td>
<td>33</td>
<td>19</td>
<td>15</td>
</tr>
<tr>
<td>TF-29A</td>
<td>29</td>
<td>35</td>
<td>20</td>
<td>16</td>
</tr>
</tbody>
</table>

INDICATIONS FOR USE
The Trifecta Valve is intended as a replacement for a diseased, damaged, or malfunctioning native or prosthetic aortic heart valve.

CONTRAINDICATIONS
None known.

WARNINGS
- For single use only. Do not re-use or re-sterilize. Attempts to re-sterilize the valve may result in valve malfunction, inadequate sterilization, or patient harm.
- Valve size selection is based on the size of the recipient annulus and the anatomy of the sinotubular junction. Implantation of an appropriately large bioprosthesis may result in stent deformation, valvular incompetence, and/or damage to the surrounding tissues. Do not oversize the valve. If the native annulus measurement falls between two Trifecta Valve sizes, use the smaller size Trifecta Valve. Use only the Model TF2000 Trifecta™ Valve Sizer Set for sizing a Trifecta Valve.
- Passage of a catheter or transvenous pacing lead through any bioprosthesis may damage the valve and is therefore not recommended.
- Accelerated deterioration due to calcific degeneration of the Trifecta Valve may occur in:
  - Children, adolescents, or young adults
  - Patients with altered calcium metabolism (e.g., patients with hyperparathyroidism or chronic renal failure)
  - Individuals requiring hemodialysis
- The titanium valve stent is not designed as a flexible stent. Do not bend the titanium valve stent. Deformation of the stent may impair valve function.
- 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.
- The storage solution does not completely cover the valve.

PRECAUTIONS
- The safety and effectiveness of the Trifecta Valve have 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 active endocarditis
  - Patients requiring pulmonic or tricuspid valve replacement
  - Children, adolescents, or young adults
  - Sizers and holder handles are supplied non-sterile, and must be cleaned and sterilized prior to each use. Do not use cracked, crazed, or deformed sizer set components.
- Do not pass the replica end of the TF2000 sizer through the annulus when sizing the valve.
- Position the valve so that the stent posts do not obstruct the coronary ostia.
- 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 solution in which it was shipped, the sterile isotonic saline solution used during the rinsing procedure, or the sterile isotonic saline used to irrigate the valve.
- Do not add antibiotics to either the 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 isotonic sterile saline

DEVELOPMENT DESCRIPTION
The Trifecta™ Valve is a tri-leaflet stented pericardial valve designed for supra-annular placement in the aortic position. The valve is fabricated using a polyester-covered titanium stent. The stent, excluding the sewing cuff, is then covered with porcine pericardial tissue. This covering provides protection from mechanical wear by allowing only tissue-to-tissue contact during valve function. A silicone insert within the polyester sewing cuff is slightly contoured to conform to the shape of the native annulus.

The valve leaflets are fabricated from bovine pericardium. The porcine and bovine pericardium are preserved and crosslinked in glutaraldehyde. Glutaraldehyde, formaldehyde, and ethanol are used in the valve sterilization process. The Trifecta Valve is processed using the Linx™ anticalcification treatment. The Trifecta Valve is supplied sterile and non-pyrogenic.

See Table 1 and Figure 1 for model numbers and reference dimensions.

Table 1: Trifecta™ Valve Model Numbers and Reference Dimensions

- Table 1

- Figure 1

- Diameter

- Annulus

- Cuff Outer

- Height

- Protrusion
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 (41°F to 77°F) range.
- Do not implant the valve without thoroughly rinsing as directed.
- Use caution when placing sutures through the sewing cuff to avoid lacerating the valve tissue. If a valve is damaged, the valve must be 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.
- Use caution when tying knots to avoid bending the stent posts.
- Never handle the leaflet tissue.
- 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.

**MRI Safety Information**

Non-clinical testing has demonstrated that Trifecta™ heart valves are MR Conditional. Patients can be scanned safely immediately after implantation under the following conditions:

- Static magnetic field of 1.5 tesla (1.5T) or 3.0 tesla (3.0T).
- Maximum spatial gradient field less than or equal to 3,000 Gauss/cm (30T/m).
- Normal Operating Mode: Maximum whole-body specific absorption rate (SAR) of:
  - 2.0 W/kg for 15 minutes of scanning in Normal Operating Mode at 1.5T.
  - 2.0 W/kg for 15 minutes of scanning in Normal Operating Mode at 3.0T.

**1.5T RF Heating**

In non-clinical testing with body coil excitation, the valves produced a differential temperature rise of less than or equal to 2.0°C when exposed to a whole-body specific absorption rate (SAR) of 1.4 W/kg for 15 minutes of scanning in a 1.5-tesla MR system (Siemens MAGNETOM Espree™, SYNGO™ MR B17 software, Munich, Germany). Scaling of the SAR and observed heating indicates that SAR of 2.0 W/kg would be expected to yield a localized temperature rise of less than 2.0°C.

**3.0T RF Heating**

In non-clinical testing with body coil excitation, the valves produced a differential temperature rise of less than or equal to 1.0°C when exposed to a whole-body specific absorption rate (SAR) of 3.4 W/kg for 15 minutes of scanning in a 3.0-tesla MR system (Siemens MAGNETOM Trio™, SYNGO™ MR A30 4VA 3OA software, Munich, Germany). Scaling of the SAR and observed heating indicates that SAR of 2.0 W/kg would be expected to yield a localized temperature rise of less than 1.0°C.

CAUTION: The RF heating behavior does not scale with static field strength. Devices that do not exhibit detectable heating at one field strength may exhibit high values of localized heating at another field strength.

**M R Artifacts**

MR image quality may be compromised if the area of interest is the same or relatively close to the position of the device, and it may be necessary to optimize the MR imaging parameters. The shape of the expected artifact follows the approximate contour of the device and extended radially up to 0.3 cm from the implant at 1.5T in gradient echo imaging and 0.2 cm from the implant at 1.5T in gradient echo imaging tests performed in accordance with ASTM F2119-07.

**ADVERSE EVENTS**

The clinical investigation of the Trifecta Valve supports the safety of the Trifecta Valve. Between June 2007 and November 2009, one thousand and twenty-two (1022) subjects were implanted with the Trifecta Valve in the aortic position at 31 investigational sites in the United States (18), Canada (7), and Europe (6). Data are presented on the one thousand and fourteen (1014) subjects who met eligibility criteria. The cumulative follow-up for all subjects was 924.18 patient-years with a mean follow-up of 0.91 years (SD 0.49 years, range 0 - 2.38 years).

Follow-Up

Table 3 presents the number of eligible subjects meeting all inclusion/exclusion criteria, cumulative and late patient-years, and mean follow-up.

Preoperative Subject Demographics

Table 4 presents the preoperative subject demographics.

Effectiveness Outcomes

Quantitative data were collected throughout the study (i.e., NYHA functional classification, echo parameters). Table 5 and Table 6 present subject NYHA classification preoperatively compared to one year follow-up and two years follow-up, respectively. Table 7 presents the hemodynamic follow-up results for the Trifecta Valve replacements.

**PACKAGING AND STORAGE**

As delivered, the valve is attached to a valve holder by three retaining sutures. The valve holder facilitates 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.

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

CAUTION: 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 (41°F to 77°F) range.

**ACCESSORIES**

The following sizer set and accessories are available for use with the Trifecta Valve:

**Sizer Set**

- Trifecta™ Sizer Set Model TF2000

**Holder Handles**

- Flexible Holder Handle Model UT2000
- Rigid Holder Handle Model UT2000-R (optional)
- Extension Handle Model EX2000-R (optional)
DIRECTIONS FOR USE

Use the Trifecta™ Sizer Set Model TF2000 to determine the correct Trifecta™ Valve size. See the TF2000 Trifecta Valve Sizer Set Instructions for Use for specific instructions on cleaning, sterilization, and handling.

CAUTION: Sizers and holder handles are supplied non-sterile, and must be cleaned and sterilized prior to each use. Do not use cracked, crazed, or deformed sizers.

WARNING: Valve size selection is based on the size of the recipient annulus and the anatomy of the sinotubular junction. Implantation of an inappropriately large bioprosthesis may result in stent deformation, valvular incompetence, and/or damage to the surrounding tissues. Do not oversize the valve. If the native annulus measurement falls between two Trifecta Valve sizes, use the smaller size Trifecta Valve. Use only the TF2000 Trifecta Valve Sizer Set for sizing a Trifecta Valve.

Sizing using the Model TF2000 Sizer Set

The TF2000 sizer is a double-ended tool with a cylindrical annular sizing end and a valve replica end. Figure 2. Use the cylindrical annular sizing end of the sizer to determine the size of the annulus. Select the valve size using the cylindrical annular sizing end that passes readily without resistance through the annulus. The Trifecta Valve is designed for implantation in the supra-annular position. Use the replica end of the sizer to visualize placement of the sewing cuff above the annulus and to confirm placement and fit of the valve in the supra-annular space, Figure 3.

CAUTION: Do not pass the replica end of the TF2000 sizer through the annulus when sizing the valve.

Pre-Implant Handling

The Trifecta Valve is 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.

Warnings

• 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

Precautions

• 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 solution in which it was shipped, the sterile isotonic saline solution used during the rinsing procedure, or the sterile isotonic saline used to irrigate the valve.
• Do not add antibiotics to either the formaldehyde 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.

WARNING: 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.

Removing the Valve from the Storage Container

1. Select the flexible holder handle Model UT2000, or the rigid holder handle Model UT2000-R, for the procedure.
2. With the circulating nurse holding the container, press the holder handle into the valve holder, as shown in Figure 4. Ensure a secure connection.
3. Remove the valve from the jar.

NOTE: The leaflets only coapt upon closure during the cardiac cycle. Figure 7 provides a view of the leaflets prior to implantation.

CAUTION: Do not use cutting edge needles, unprotected forceps, or sharp instruments, as they may cause structural damage to the valve.

VALE IMPLANTATION

To obtain optimum hemodynamic results, the Trifecta Valve should be implanted in the supra-annular position.

1. Based on the sizing instructions, choose a valve of the appropriate size.
2. Ensure the suture tails and knot tying technologies do not contact the leaflet tissue.

CAUTION: Position the valve so that the stent posts do not obstruct the coronary ostia.

2. To remove the holder from the valve, cut the three retaining sutures as shown in Figure 6, and pull the handle and the valve holder away from the valve.

NOTE: To facilitate implantation, the valve holder handle may be removed from the valve holder by depressing the release button on the valve holder, Figure 6.

3. After removing the holder, examine the valve to ensure that there are no holder suture remnants.

INTRA-OPERATIVE ASSESSMENT

The suggested method for assessing competence of the Trifecta Valve is with intra-operative Doppler echocardiography.

PATIENT REGISTRATION

A Medical Device Registration Form and return envelope are included with each device. Complete the identification card attached to the Medical Device Registration Form and provide it to the patient. After implantation, please complete all requested information and return the original form to St. Jude Medical.

Tracking by manufacturers is mandatory in some countries. Please disregard any request for patient information if this contradicts your local legal or regulatory requirements regarding patient privacy.
INDIVIDUALIZATION OF TREATMENT
Anticoagulant and/or Antiplatelet Therapy
It is generally recommended that patients with bioprosthetic valves be maintained on anticoagulant therapy for 12 weeks following implant surgery, unless anticoagulant therapy is contraindicated. 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.

Prophylactic antibiotic treatment should be considered for all patients undergoing dental procedures which are potentially bacteremic.

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

DISPOSAL
This instructions for use is recyclable. Dispose of all packaging materials as appropriate. Dispose of valves and accessories per standard solid biohazard waste procedures.

LIMITED WARRANTY
St. Jude Medical (SJM) warrants that reasonable care has been used in the manufacturing of this device. THIS WARRANTY IS IN LIEU OF AND EXCLUDES ALL OTHER WARRANTIES NOT EXPRESSLY SET FORTH HEREIN, WHETHER EXPRESS OR IMPLIED BY OPERATION OF LAW OR OTHERWISE INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, since handling, storage, cleaning, and sterilization of this device as well as factors relating to the patient, diagnosis, treatment, surgical procedures, and other matters beyond SJM’s control directly affect this device and the results obtained from its use. SJM SHALL NOT BE LIABLE FOR ANY INCIDENTAL OR CONSEQUENTIAL LOSS, DAMAGE, OR EXPENSE directly or indirectly arising from the use of this device other than the replacement of all or part of it. SJM further assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this device.

Some states in the United States do not allow limitations on how long an implied warranty lasts, so the above limitations may not apply to you. This limited warranty gives you specific legal rights, and you may have other rights which vary from jurisdiction to jurisdiction.

Descriptions of specifications, appearing in SJM literature, are meant solely to help you understand the device at the time of manufacture and do not constitute any express warranties.

### Table 2: Observed Adverse Event Rates

<table>
<thead>
<tr>
<th>Adverse Event</th>
<th>Early Events² [%] (n)</th>
<th>Late Events³ [% / pt-yr] (n) [One-Sided Upper 95% CL]</th>
<th>Freedom From Event 1 Year⁴ [% (95% CI)]</th>
<th>Freedom From Event 2 Year⁵ [% (95% CI)]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Thromboembolism</td>
<td>2.7% (27)</td>
<td>1.90% (16) [2.88%]</td>
<td>96.2% (94.7%, 97.2%)</td>
<td>92.9% (88.5%, 95.6%)</td>
</tr>
<tr>
<td>Valve Thrombosis</td>
<td>0.0% (0)</td>
<td>0.00% (0) [0.35%]</td>
<td>100.0% (100.0%, 100.0%)</td>
<td>100.0% (100.0%, 100.0%)</td>
</tr>
<tr>
<td>Major Bleed</td>
<td>8.0% (81)</td>
<td>2.61% (22) [3.72%]</td>
<td>90.4% (88.3%, 92.2%)</td>
<td>86.0% (81.0%, 89.8%)</td>
</tr>
<tr>
<td>-Anticoagulant and/or Antiplatelet</td>
<td>1.4% (14)</td>
<td>1.90% (16) [2.88%]</td>
<td>96.6% (95.4%, 97.8%)</td>
<td>93.7% (88.7%, 96.5%)</td>
</tr>
<tr>
<td>Nonstructural Dysfunction</td>
<td>0.3% (3)</td>
<td>0.12% (1) [0.56%]</td>
<td>99.6% (98.9%, 99.8%)</td>
<td>99.6% (98.9%, 99.9%)</td>
</tr>
<tr>
<td>All Perivalvular Leak</td>
<td>0.1% (1)</td>
<td>0.00% (0) [0.35%]</td>
<td>99.9% (99.3%, 100.0%)</td>
<td>99.9% (99.3%, 100.0%)</td>
</tr>
<tr>
<td>-Major Perivalvular Leak</td>
<td>0.0% (0)</td>
<td>0.00% (0) [0.35%]</td>
<td>100.0% (100.0%, 100.0%)</td>
<td>100.0% (100.0%, 100.0%)</td>
</tr>
<tr>
<td>Endocarditis</td>
<td>0.0% (0)</td>
<td>1.07% (9) [1.86%]</td>
<td>99.1% (98.1%, 99.5%)</td>
<td>98.6% (97.1%, 99.4%)</td>
</tr>
<tr>
<td>Clinically Significant Hemolysis</td>
<td>0.0% (0)</td>
<td>0.0% (0) [0.35%]</td>
<td>100.0% (100.0%, 100.0%)</td>
<td>100.0% (100.0%, 100.0%)</td>
</tr>
<tr>
<td>Structural Deterioration</td>
<td>0.0% (0)</td>
<td>0.12% (1) [0.56%]</td>
<td>99.9% (99.3%, 100.0%)</td>
<td>99.9% (99.3%, 100.0%)</td>
</tr>
<tr>
<td>Reoperation</td>
<td>0.1% (1)</td>
<td>0.59% (5) [1.25%]</td>
<td>99.4% (98.6%, 99.7%)</td>
<td>99.4% (98.6%, 99.7%)</td>
</tr>
<tr>
<td>- Explant</td>
<td>0.1% (1)</td>
<td>0.59% (5) [1.25%]</td>
<td>99.4% (98.6%, 99.7%)</td>
<td>99.4% (98.6%, 99.7%)</td>
</tr>
<tr>
<td>Valve-Related Mortality</td>
<td>0.2% (2)</td>
<td>0.36% (3) [0.92%]</td>
<td>99.4% (98.6%, 99.8%)</td>
<td>99.4% (98.6%, 99.8%)</td>
</tr>
</tbody>
</table>

1Late adverse event rate (% / pt-yr) is calculated as the number of late adverse events divided by the total number of patients, times 100
²Early events are those occurring on or before 30 days post-implant
³Late events are those occurring 31 days post-implant or thereafter
⁴Late adverse event rate (% / pt-yr) is calculated as the number of late events divided by the total late patient-years, times 100. The late adverse event rates were calculated based on 844.31 late patient-years.
⁵Freedom from event estimates at 1 year and at 2 years from Kaplan-Meier analysis are calculated based on 12 months and 24 months, respectively (where 30.4 days = 1 month).

### Table 3: Eligible Subjects, Cumulative and Late Patient-Years, and Mean Follow-up

<table>
<thead>
<tr>
<th>Implant Duration</th>
<th>Number of subjects</th>
<th>Total Patient-years</th>
<th>Mean</th>
<th>SD</th>
<th>Minimum</th>
<th>Maximum</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cumulative Patient-years</td>
<td>1014</td>
<td>924.18</td>
<td>0.91</td>
<td>0.49</td>
<td>0.00</td>
<td>2.38</td>
</tr>
<tr>
<td>Late Patient-years*</td>
<td>995</td>
<td>844.31</td>
<td>0.88</td>
<td>0.45</td>
<td>0.01</td>
<td>2.30</td>
</tr>
</tbody>
</table>

*Late patient-years are determined from 31 days post-implant to the last follow-up visit (or contact), or adverse event.

### Table 4: Preoperative Subject Demographics

<table>
<thead>
<tr>
<th>Variable</th>
<th>N=1014</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age at Implant (years)</td>
<td>72.5 ± 9.0 (32.95)</td>
</tr>
<tr>
<td>Subject Gender (Male)</td>
<td>64.1% (650)</td>
</tr>
<tr>
<td>Preoperative NYHA</td>
<td></td>
</tr>
<tr>
<td>Class I</td>
<td>6.6% (67)</td>
</tr>
<tr>
<td>Class II</td>
<td>44.1% (447)</td>
</tr>
<tr>
<td>Class III</td>
<td>43.9% (445)</td>
</tr>
<tr>
<td>Class IV</td>
<td>5.4% (55)</td>
</tr>
</tbody>
</table>

All subjects included in analysis: N=1014
Table 5: Effectiveness Outcomes, NYHA Functional Classification: 1 year Follow-up*
Subjects with both preoperative and 1 year NYHA measurements, N=606; n1=number per subgroup

<table>
<thead>
<tr>
<th>NYHA Class</th>
<th>Preoperative</th>
<th>1 Year</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n1</td>
<td>% (n1/N)</td>
</tr>
<tr>
<td>I</td>
<td>34</td>
<td>5.6%</td>
</tr>
<tr>
<td>II</td>
<td>275</td>
<td>45.4%</td>
</tr>
<tr>
<td>III</td>
<td>273</td>
<td>45.0%</td>
</tr>
<tr>
<td>IV</td>
<td>24</td>
<td>4.0%</td>
</tr>
<tr>
<td>All</td>
<td>606</td>
<td>100.0%</td>
</tr>
</tbody>
</table>

*Subjects with both preoperative and 1 year NYHA measurements available are included in this table

Table 6: Effectiveness Outcomes, NYHA Functional Classification: 2 year Follow-up*
Subjects with both preoperative and 2 year NYHA measurements, N=97; n1=number per subgroup

<table>
<thead>
<tr>
<th>NYHA Class</th>
<th>Preoperative</th>
<th>2 Year</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n1</td>
<td>% (n1/N)</td>
</tr>
<tr>
<td>I</td>
<td>8</td>
<td>8.2%</td>
</tr>
<tr>
<td>II</td>
<td>45</td>
<td>46.4%</td>
</tr>
<tr>
<td>III</td>
<td>36</td>
<td>37.1%</td>
</tr>
<tr>
<td>IV</td>
<td>8</td>
<td>8.2%</td>
</tr>
<tr>
<td>All</td>
<td>97</td>
<td>100.0%</td>
</tr>
</tbody>
</table>

*Subjects with both preoperative and 2 year NYHA measurements available are included in this table

Table 7: Effectiveness Outcomes at 1 Year Follow-up Visit, Hemodynamic Results
All subjects included in data analysis: N=1014

<table>
<thead>
<tr>
<th>Hemodynamic Parameter</th>
<th>19mm</th>
<th>21mm</th>
<th>23mm</th>
<th>25mm</th>
<th>27mm</th>
<th>29mm1</th>
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<tbody>
<tr>
<td>Mean Gradient4</td>
<td></td>
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</tr>
<tr>
<td>n=66</td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean ± SD</td>
<td>10.7 ± 4.6</td>
<td>8.1 ± 3.5</td>
<td>7.2 ± 2.6</td>
<td>6.2 ± 2.7</td>
<td>4.8 ± 2.0</td>
<td>4.7 ± 1.6</td>
</tr>
<tr>
<td>Min, Max</td>
<td>3.3, 21.9</td>
<td>0.6, 23.7</td>
<td>1.0, 19.5</td>
<td>1.4, 20.3</td>
<td>0.5, 9.8</td>
<td>2.0, 7.1</td>
</tr>
<tr>
<td>EOA5</td>
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<tr>
<td>n=60</td>
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</tr>
<tr>
<td>Mean ± SD</td>
<td>1.41 ± 0.24</td>
<td>1.63 ± 0.29</td>
<td>1.81 ± 0.30</td>
<td>2.02 ± 0.32</td>
<td>2.20 ± 0.20</td>
<td>2.35 ± 0.22</td>
</tr>
<tr>
<td>Min, Max</td>
<td>0.91, 2.19</td>
<td>0.87, 2.58</td>
<td>0.78, 2.77</td>
<td>1.15, 2.76</td>
<td>1.86, 2.82</td>
<td>2.02, 2.73</td>
</tr>
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<td>Regurgitation6</td>
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<tr>
<td>n=68</td>
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</tr>
<tr>
<td>None</td>
<td>64.7% (44)</td>
<td>74.3% (119)</td>
<td>73.7% (146)</td>
<td>74.2% (101)</td>
<td>75.0% (30)</td>
<td>80.0% (12)</td>
</tr>
<tr>
<td>Trivial</td>
<td>25.0% (17)</td>
<td>22.5% (36)</td>
<td>23.2% (46)</td>
<td>19.1% (26)</td>
<td>22.5% (9)</td>
<td>20.0% (3)</td>
</tr>
<tr>
<td>Mild</td>
<td>2.9% (2)</td>
<td>1.8% (3)</td>
<td>0.5% (1)</td>
<td>3.6% (5)</td>
<td>0.0% (0)</td>
<td>0.0% (0)</td>
</tr>
<tr>
<td>Moderate</td>
<td>1.4% (1)</td>
<td>0.6% (1)</td>
<td>0.5% (1)</td>
<td>1.4% (2)</td>
<td>2.5% (1)</td>
<td>0.0% (0)</td>
</tr>
<tr>
<td>Severe</td>
<td>0.0% (0)</td>
<td>0.0% (0)</td>
<td>1.0% (2)</td>
<td>0.7% (1)</td>
<td>0.0% (0)</td>
<td>0.0% (0)</td>
</tr>
<tr>
<td>Unknown7</td>
<td>5.8% (4)</td>
<td>0.6% (1)</td>
<td>1.0% (2)</td>
<td>0.7% (1)</td>
<td>0.0% (0)</td>
<td>0.0% (0)</td>
</tr>
</tbody>
</table>

1 Data for size 29mm are based on follow-up cutoff date of 10/26/2010. All other data in table are based on follow-up cutoff date of 3/25/2010
2 N = number of subjects with a completed echo per valve size
3 n = number of subjects per valve size with available hemodynamic parameter
4 Mean Gradient= pressure drop measured across the valve recorded in mmHg
5 EOA = calculated effective orifice area measured in cm²
6 Aortic Regurgitation presented as Percentage (Count)
7 Unknown - Includes echoes that did not contain the appropriate images to evaluate aortic regurgitation
Figure 5: Slide the retaining collar off the valve holder.

Figure 6: Cut the retaining sutures to remove the holder.

Figure 7: Leaflets - outflow view