DRAFT TRIFECTA INSTRUCTIONS FOR USE (WORD FORMAT)

ST. JUDE MEDICAL

MORE CONTROL. LESS RISK.

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

ARTEN100039886A

Storage Solution Formaldehyde	Storage Solution – Formaldehyde	RINSE 2 x 500ml x 10 sec	Rinse – 2 x 500ml x 10 sec
Pericardial	Pericardial	AORTIC	Aortic
	Manufacturing Facility	CONTENTS	Contents
	Temperature Indicator: If red, do not use		Do Not Resterilize
	Do Not Reuse		Do Not Use if Package is Damaged
STERILE A	Processed Using Aseptic Technique	STERILE LC	Sterilized by Liquid Chemical Sterilant
	Use By	EC REP	Authorized European Representative
REF	Catalog Number		Consult Instructions for Use
SN	Serial Number		Manufacturer
	Date of Manufacture		Temperature Limitation

Rx only

CAUTION: Federal law restricts this device to sale by or on the order of a physician.

DEVICE DESCRIPTION

The Trifecta™ Valve is a tri-leaflet pericardial valve designed for supra-annular placement in the aortic position. The valve is fabricated using 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 Linx™ anticalcification technology. 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

Model Number	Tissue Annulus Diameter (mm)	Cuff Outer Diameter (mm)	Total Height (mm)	Aortic Protrusion (mm)
TF-19A	19	24	15	12
TF-21A	21	26	16	13
TF-23A	23	28	17	13
TF-25A	25	31	18	14
TF-27A	27	33	19	15
TF-29A	29	35	20	16

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 resterilize the valve by any method.
- 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 Model TF-1000 or 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 flanged portion of the TF-1000 sizer through the annulus when sizing the valve.
- 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 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 the Trifecta Valve is MR conditional. It can be scanned safely under the following conditions:

- Static magnetic field of 3 Tesla or less
- Spatial gradient of 525 Gauss/cm or less
- Maximum whole-body-averaged specific absorption rate (SAR) of 2.0-W/kg for 15 minutes of scanning.

In non-clinical testing, the Trifecta Valve produced a temperature rise of less than or equal to 0.5°C at a maximum whole body averaged specific absorption rate (SAR) of 2.0 W/kg for 15 minutes of MR scanning in a 3-Tesla Signa model (GE) MR scanner. MR image quality may be compromised if the area of interest is the exact same area or relatively close to the position of the bioprosthesis.

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).

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
- leak, transvalvular or perivalvular
- myocardial infarction
- nonstructural dysfunction (entrapment by pannus or suture, inappropriate sizing or positioning, or other)
- prosthesis regurgitation
- stroke
- structural deterioration (calcification, leaflet tear, perforation, or other)
- thromboembolism
- valve thrombosis

It is possible that these complications could lead to:

- reoperation
- explantation
- permanent disability
- death

Table 2 presents the adverse event data collected in the Trifecta Valve clinical investigation.

CLINICAL STUDY

The Trifecta Valve clinical investigation was a prospective, non-randomized, observational study without concurrent or matched controls, designed to evaluate the safety and effectiveness of the Trifecta Valve. Adverse event (AE) rates as compared to a set of Objective Performance Criteria (OPC) and to literature-based control data were used for the design and analysis of this study. New York Heart Association (NYHA) functional classification status and hemodynamic performance of the valve by echocardiography were evaluated. The NYHA functional classification data and hemodynamic data were compared to literature-based control data.

One thousand and twenty-two (1022) subjects were implanted with the Trifecta Valve between June 2007 and November 2009 at 31 investigational sites in the United States (18), Canada (7), and Europe (6). Data are presented on one thousand and fourteen (1014) subjects who met eligibility criteria. Preoperative demographic and baseline data including NYHA functional classification were collected. Postoperative data, including blood and echocardiography data, were collected at discharge, 6 months, one year, and annually thereafter. All echocardiograms were interpreted by the same Echocardiography Core Laboratory. Postoperative NYHA functional classifications were collected at 6 months, one year, and annually thereafter. Adverse Event data (**Table 2**) were collected at the time of occurrence or upon site notification.

The mean age at implant was 72.5 years (standard deviation (SD) 9.0 years, range 32-95 years). Preoperatively, 49.3% of subjects were NYHA functional classification III/IV and 64.1% of subjects were male. The cumulative follow-up 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 the 5°C to 25°C (41°F to 77°F) range.

ACCESSORIES

The following sizer sets and accessories are available for use with the Trifecta Valve.

Sizer Sets

- Trifecta™ Sizer Set Model TF-1000
- 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)

Products may not be available in all locations. Please contact your local St. Jude Medical representative.

DIRECTIONS FOR USE

Use either the Trifecta™ Sizer set Model TF-1000 or TF2000 to determine the correct Trifecta Valve size. See the appropriate Model TF-1000 or TF2000 Trifecta Valve Sizer 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 Model TF-1000 or TF2000 Trifecta Valve Sizer Set for sizing a Trifecta Valve.

Sizing using the Model TF-1000 Sizer Set

The TF-1000 sizer is a double-ended tool with a cylindrical annular sizing end and flanged 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 with moderate resistance through the annulus.

The Trifecta Valve is designed for implantation in the supra-annular position. The flanged portion of the sizer mimics placement of the sewing cuff on top of the annulus, **Figure 3**.

CAUTION: Do not pass the flanged portion of the TF-1000 sizer through the annulus when sizing the 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 4**. 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 5**.

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 UT2000 Holder Handle from the sizer set tray.
2. With the circulating nurse holding the container, connect the UT2000 Holder Handle by pressing the holder handle into the valve holder to ensure a secure connection, as shown in **Figure 6**.
3. Remove the valve from the jar.

NOTE: The leaflets only coapt upon closure during the cardiac cycle. **Figure 9** 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.

CAUTION: Never handle the leaflet tissue.

4. Using a gloved hand or protected forceps, grasp the plastic retaining collar and slide it off the valve holder (see **Figure 7**).
5. Inspect the valve for damage. Do not implant the valve if there is any sign of damage or deterioration.

Rinse Procedure

CAUTION: Do not implant the Trifecta 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 in each basin.
2. Holding the valve by the handle, fully immerse 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 ten seconds, using a gentle back-and-forth motion.
4. Repeat Steps 2 and 3 in the remaining basin.
5. After rinsing, leave the valve immersed in the basin until required by the surgeon for implantation.

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

Surgical Guidelines

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

When implanting supra-annular valves, non-everting mattress sutures are recommended.

Ensure the suture tails do not contact the leaflet tissue.

WARNING: 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.

CAUTION: Use caution when tying knots to avoid bending the stent posts.

Precautions

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

VALVE 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.

   Ensure the suture tails 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 8**, 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 8.

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.

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 neither 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 generally describe the device at the time of manufacture and do not constitute any express warranties.

Table 2: Observed Adverse Event Rates

All subjects analyzed: N=1014 Cumulative follow-up: 924.18 patient-years

Adverse Event	Early Events[1] %[2] (n)	Late Events[3] %/pt-yr[4] (n) [One-Sided Upper 95% CL]	Freedom From Event 1 Year[5] % [95% CI]	Freedom From Event 2 Year[5] % [95% CI]
Thromboembolism	2.7% (27)	1.90% (16) [2.88%]	96.2% [94.7%,97.2%]	92.9% [88.5%,95.6%]
Valve Thrombosis	0.0% (0)	0.00% (0) [0.35%]	100.0% [100.0%,100.0%]	100.0% [100.0%,100.0%]
Major Bleed	8.0% (81)	2.61% (22) [3.72%]	90.4% [88.3%,92.2%]	86.0% [81.0%,89.8%]
Anticoagulant and/or Antiplatelet	1.4% (14)	1.90% (16) [2.88%]	96.8% [95.4%,97.8%]	93.7% [88.7%,96.5%]
Nonstructural Dysfunction	0.3% (3)	0.12% (1) [0.56%]	99.6% [98.9%,99.8%]	99.6% [98.9%,99.8%]
All Perivalvular Leak	0.1% (1)	0.00% (0) [0.35%]	99.9% [99.3%,100.0%]	99.9% [99.3%,100.0%]
Major Perivalvular Leak	0.0% (0)	0.00% (0) [0.35%]	100.0% [100.0%,100.0%]	100.0% [100.0%,100.0%]
Endocarditis	0.0% (0)	1.07% (9) [1.86%]	99.1% [98.1%,99.5%]	98.6% [97.1%,99.4%]
Clinically Significant Hemolysis	0.0% (0)	0.00% (0) [0.35%]	100.0% [100.0%,100.0%]	100.0% [100.0%,100.0%]
Structural Deterioration	0.0% (0)	0.12% (1) [0.56%]	99.9% [99.3%,100.0%]	99.9% [99.3%,100.0%]
Reoperation	0.1% (1)	0.59% (5) [1.25%]	99.4% [98.6%,99.7%]	99.4% [98.6%,99.7%]
Explant	0.1% (1)	0.59% (5) [1.25%]	99.4% [98.6%,99.7%]	99.4% [98.6%,99.7%]
Valve-Related Mortality	0.2% (2)	0.36% (3) [0.92%]	99.4% [98.6%,99.8%]	99.4% [98.6%,99.8%]

[1]Early events are those occurring on or before 30 days post-implant

[2]The early adverse event rate (%) is calculated as the number of early adverse events divided by the total number of subjects, times 100

[3]Late events are those occurring 31 days post-implant or thereafter

[4]Late 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.

[5]Freedom 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

All subjects included in data analysis, N=1014

Implant Duration	Number of subjects	Total Patient-years	Mean	SD	Minimum	Maximum
Cumulative Patient-years	1014	924.18	0.91	0.49	0.00	2.38
Late Patient-years*	955	844.31	0.88	0.45	0.01	2.30

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

Table 4: Preoperative Subject Demographics

All subjects included in data analysis, N=1014

Variable	N=1014
Age at Implant (years)	72.5 ± 9.0 (32,95)
Subject Gender (male)	64.1% (650)
Preoperative NYHA	
Class I	6.6% (67)
Class II	44.1% (447)
Class III	43.9% (445)
Class IV	5.4% (55)

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

Subjects with both preoperative and 1 year NYHA measurements, N=606; n_1=number per subgroup

NYHA Class	N=606			
	Preoperative		1 Year	
	n_1	% (n_1/N)	n_1	% (n_1/N)
I	34	5.6%	517	85.3%
II	275	45.4%	82	13.5%
III	273	45.0%	7	1.2%
IV	24	4.0%	0	0.0%
All	606	100.0%	606	100.0%

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

Table 6: Effectiveness Outcomes, NYHA Functional Classification: 2 Year Follow-up*

Subjects with both preoperative and 2 year NYHA measurements, N=97; n_1=number per subgroup

NYHA Class	N=97			
	Preoperative		2 Year	
	n_1	% (n_1/N)	n_1	% (n_1/N)
I	8	8.2%	81	83.5%
II	45	46.4%	14	14.4%
III	36	37.1%	2	2.1%
IV	8	8.2%	0	0.0%
All	97	100.0%	97	100.0%

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

Table 7: Effectiveness Outcomes at 1 Year Follow-up Visit, Hemodynamic Results

All subjects included in data analysis, N=1014

Hemodynamic Parameter	19 mm	21 mm	23 mm	25 mm	27 mm	29 mm[1]
	N[2]=68	N=160	N=198	N=136	N=40	N=15
Mean Gradient[4]	n[3]=66	n=160	n=197	n=135	n=40	n=15
Mean ± SD	10.7 ± 4.6	8.1 ± 3.5	7.2 ± 2.8	6.2 ± 2.7	4.8 ± 2.0	4.7 ± 1.6
Min, Max	3.3, 26.4	0.6, 23.7	1.0, 19.5	1.4, 20.3	0.5, 9.8	2.0, 7.1
EOA[5]	n=60	n=151	n=190	n=129	n=38	n=13
Mean ± SD	1.41 ± 0.24	1.63 ± 0.29	1.81 ± 0.30	2.02 ± 0.32	2.20 ± 0.20	2.35 ± 0.22
Min, Max	0.91, 2.19	0.87, 2.58	0.78, 2.77	1.15, 2.76	1.86, 2.82	2.02, 2.73
Regurgitation[6]	n=68	n=160	n=198	n=136	n=40	n=15
None	64.7% (44)	74.3% (119)	73.7% (146)	74.2% (101)	75.0% (30)	80.0% (12)
Trivial	25.0% (17)	22.5% (36)	23.2% (46)	19.1% (26)	22.5% (9)	20.0% (3)
Mild	2.9% (2)	1.8% (3)	0.5% (1)	3.6% (5)	0.0% (0)	0.0% (0)
Moderate	1.4% (1)	0.6% (1)	0.5% (1)	1.4% (2)	2.5% (1)	0.0% (0)
Severe	0.0% (0)	0.0% (0)	1.0% (2)	0.7% (1)	0.0% (0)	0.0% (0)
Unknown[7]	5.8% (4)	0.6% (1)	1.0% (2)	0.7% (1)	0.0% (0)	0.0% (0)

[1] Data for size 29 mm 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 cm^2

[6] Aortic Regurgitation presented as 'Percentage (Count)'

[7] Unknown - Includes echos that did not contain the appropriate images to evaluate aortic regurgitation

Figure 1: Trifecta™ Valve

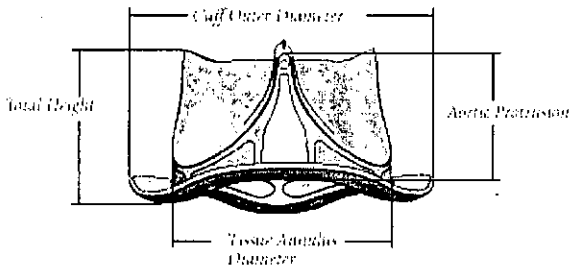
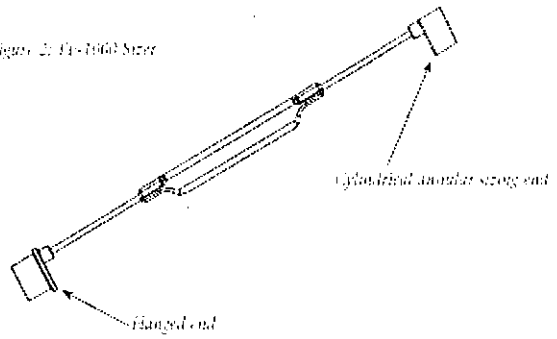


Figure 3: TV-19MS Sizer



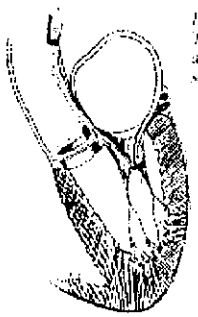


Figure 5: The flanged end of the TV-19MS sizer may be used to approximate the placement of the sewing cuff on the top of the annulus.

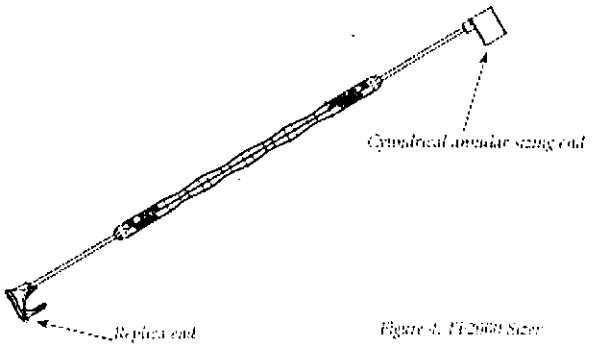


Figure 6: TV-29MS Sizer

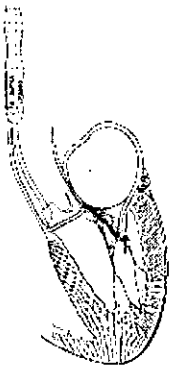


Figure 7: The replica end of the TV-29MS sizer may be used to visualize placement of the sewing cuff above the annulus and to confirm the fit of the valve in the supra-annular space.

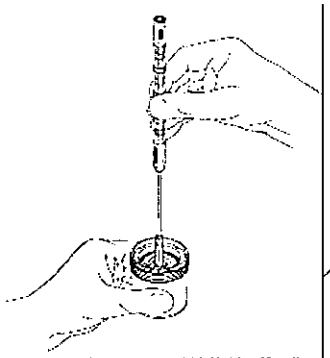


Figure 6: Press the UT3006 Holder Handle into the valve holder to ensure a secure connection.

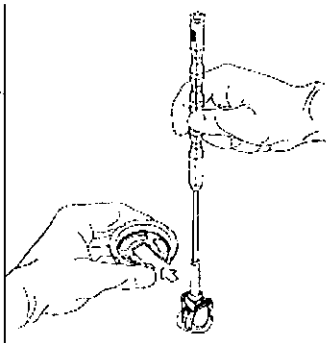


Figure 7: Slide the retaining collar off the valve holder.

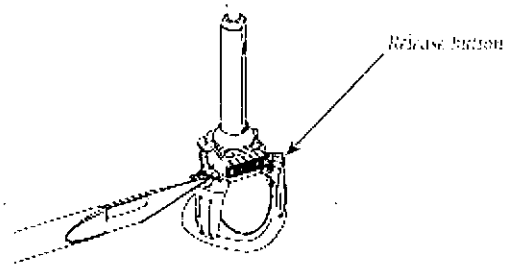


Figure 8: Cut the retaining sutures to remove the holder.

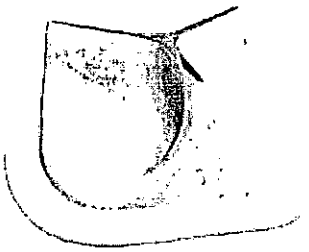


Figure 9: Leaflets - outflow view

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+1 651 490 4410
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Manufacturing Facility:
St. Jude Medical Costa Rica Ltda.
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El Coyol,Alajuela – Costa Rica

Or

St. Jude Medical Brasil Ltda.
Rua da Paisagem, 310B
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Nova Lima – MG
CEP 34.000-000 – Brasil

Or

St. Jude Medical
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St. Paul, Minnesota 55117 USA

Rx only

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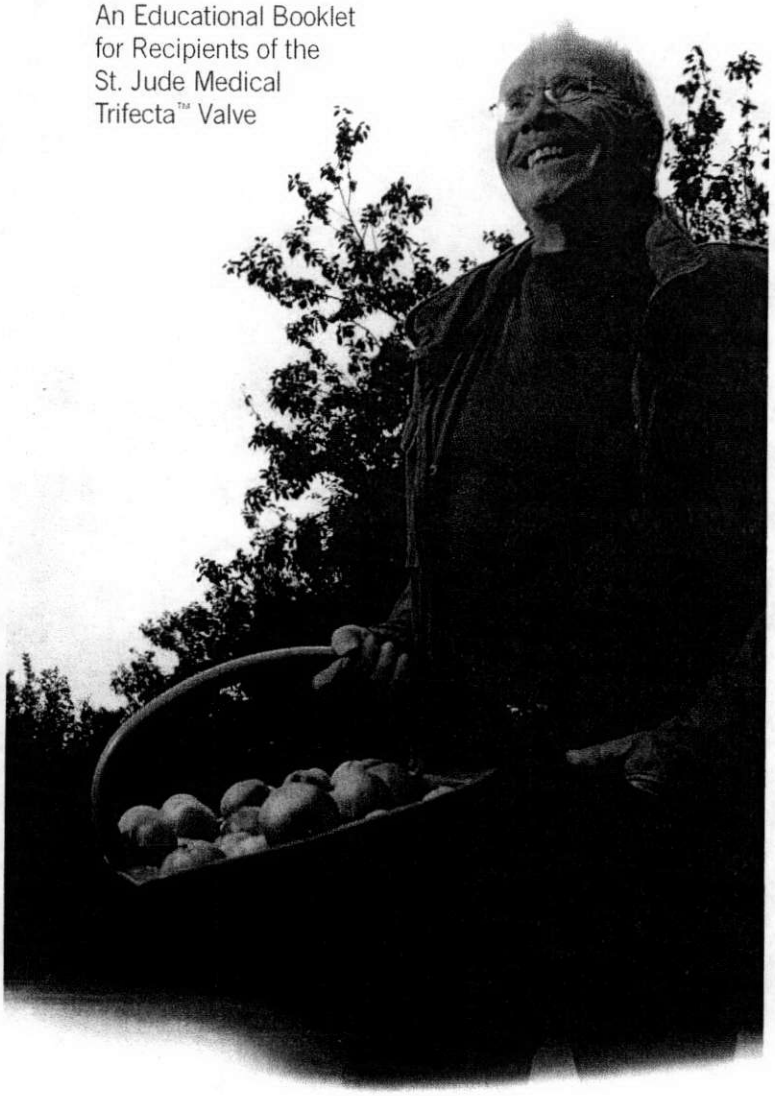
07/2010

LIVING WITH YOUR NEW HEART VALVE

An Educational Booklet
for Recipients of the
St. Jude Medical
Trifecta™ Valve



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Your role in the management of your health is very important. This information is not intended to replace the medical advice of your physician. All medical treatment decisions should be made in consultation with and under the direction of your physician. If the information you receive from your physician differs from this brochure, always follow your physician's instructions.

Table of Contents

Glossary

Angina	Chest pain
Anticoagulation Medicine	Medication prescribed to prevent blood clot formation
Aorta	Primary artery that carries oxygenated blood to the body
Aortic Valve	Valve located between left ventricle and aorta
Arrhythmia	Abnormal heart rhythm
Atria	Atria is the plural for atrium. The atrium refers to a chamber in which blood enters the heart, as opposed to the ventricle, where the blood is pushed out.
Atrial Fibrillation	Atrial fibrillation is an irregular and often rapid heart rate that commonly causes poor blood flow to the body. During atrial fibrillation, the heart's two upper chambers (the atria) beat chaotically and irregularly — out of coordination with the two lower chambers (the ventricles) of the heart. Atrial fibrillation symptoms include heart palpitations, shortness of breath and weakness.
Atrial Flutter	A regular heart rhythm in which many impulses begin and spread through the atria. The resulting rhythm is organized, but so rapid that the atria are not able to fully empty their contents into the ventricles.
Bioprosthetic Valve	Replacement heart valve that is made from animal tissue
Bovine	Of cow origin
Dilated	Enlarged
Dysrhythmia	Abnormal heart rhythm
Endocarditis	Infection of the heart's inner lining or valves
Explantation	Surgical removal of medical device
Hemolysis	Change or destruction of red blood cells
Hemolytic anemia	Anemia caused by excessive destruction of red blood cells
Hemorrhage	Excessive bleeding
Incompetent Valve	Valve unable to close completely, thus allowing blood to flow backward through the valve
Left Ventricle	The left ventricle is one of four chambers (two atria and two ventricles) in the human heart. The ventricle pushes the blood out of the heart.
Native Valve	Original valve
Paravalvular Leak	Leak near the valve
Polyester Cloth	Man-made material used to create the sewing cuff that is used to secure the implanted valve to the tissue
Pericardial	Made of tissue from the pericardium - the protective sack that surrounds the heart
Porcine	Of pig origin
Prosthetic	Device used to replace some part of the body
Pumping Efficiency	Ability of the heart to force blood into the body
Regurgitant Valve	Valve unable to close completely, thus allowing blood to flow backward through the valve
Stenotic Valve	Narrowed or hardened valve that no longer opens completely
Stent	Mounting frame to provide structural support
Thromboembolism	Blood clot that travels through the bloodstream, eventually blocking a vessel

Thrombosis	Formation of a blood clot in the body
Valve	Structure that regulates flow
Valvular Pannus	Abnormally thick tissue around the valve

Product Description – Trifecta™ Valve

The Trifecta valve is a tissue valve (Figure 1). Tissue valves are made with real tissue from porcine (pig) or bovine (cow) heart tissue because they function like human heart valves. Once the animal tissue is removed, it is treated to preserve it and prevent adverse reactions once it is placed.The Trifecta valve is stented, which provides support for the tissue inside the valve.

The sewing cuff is shaped to enable the surgeon to sew the valve securely into place in the heart (Figure 2).

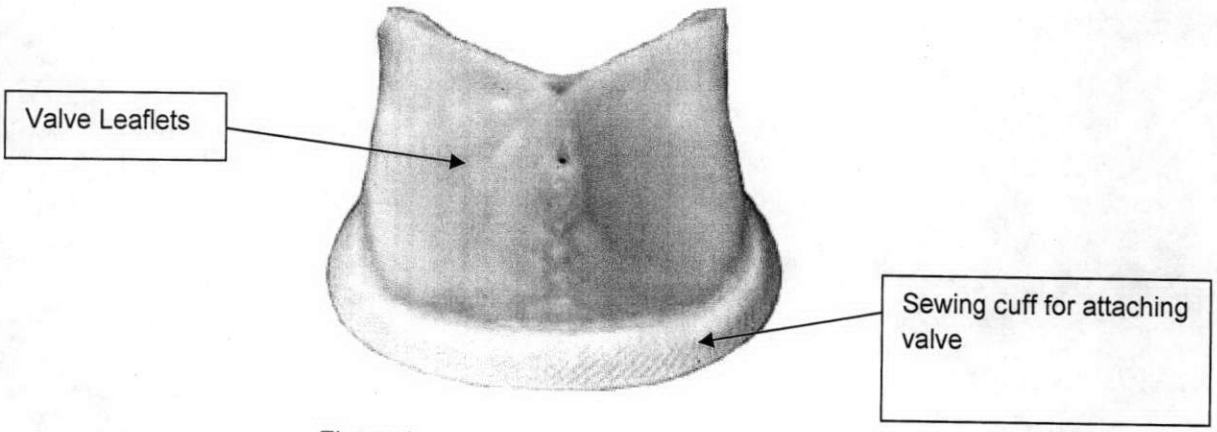

Figure 1

Trifecta™ Valve

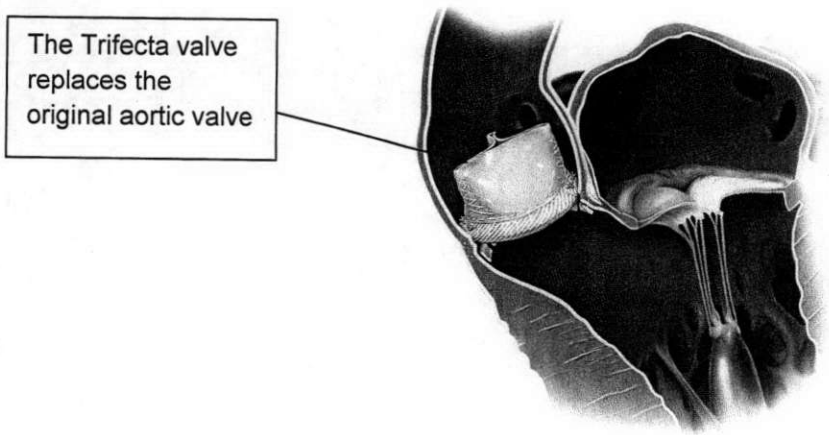

Figure 2
Position of Trifecta valve in the heart

Indications for Use

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

Warnings

Precaution: It is very important you consider the following advice.

Contact your physician(s) if you develop any of these symptoms:

- Redness or drainage of your incision
- Shortness of breath
- Swelling of your feet or ankles
- Chest, jaw, shoulder or arm pain
- Bruising
- Excessive bleeding
- Blood in your urine
- Bloody or black tarry (blood will typically look like tar after it has been exposed to the body's digestive juices) bowel movements
- Unusual nosebleeds
- Fever
- Numbness or tingling in your arms or legs
- General weakness or loss of energy
- Blurred or loss of vision
- Unusual chest sensation

Remember you are an important member of your healthcare team. The following will help you maintain a healthy heart.

- Report any signs of fluid retention to your doctor.
- It is very important to tell your dentist or physician you have an artificial heart valve because you will need to take antibiotics prior to any dental work or surgery to prevent infection of your heart valve.

- Follow an exercise program as outlined by your physician.
- If you are told you need to have an MRI (magnetic resonance image), tell the doctor you have an artificial heart valve, and show him/her your patient identification card. It contains important information about how to perform an MRI safely with your valve.

Your doctor will monitor the deterioration of your valve. 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

Valvular Heart Disease

Heart valves may become defective for a variety of reasons. Some people are born with heart valve defects while others acquire valve damage from infection or other diseases. The results are the same: either a rigid valve that limits forward blood flow or a valve that does not close properly and permits improper backflow

The end result of valvular heart disease is the reduction in the heart's pumping ability. The heart tries to compensate for ineffective valve function by working harder to deliver oxygen-rich blood to other organs and tissues. The overworked heart may begin to fail, causing shortness of breath, dizziness, chest pains, fatigue, and fluid retention. After physical examination and further tests, physicians may recommend valve replacement.

Valve Replacement Risks and Benefits

Risks

There are risks with any heart valve replacement. These may include, but are not limited to, blood cell damage (hemolysis); low red blood cell count (hemolytic anemia); bleeding (hemorrhage); infection (endocarditis), clotting in or on the valve (thrombus formation); tissue on the valve (valvular pannus); loose clots in the bloodstream that may block an artery in your arms; legs or brain (thromboembolism); valve failure (which may include structural damage); leakage around the edge of the valve (paravalvular leak); abnormal heartbeat (arrhythmia); stroke; angina; heart failure; heart attack; the need for reoperation or explantation; and death.

Benefits

Heart valve repair surgery can offer several key benefits. The procedure is designed to help your heart pump blood more effectively, which means you may begin to feel better immediately. Others may feel better gradually, regaining energy and strength over the first few weeks following the surgery. Be sure to talk to your doctor about your progress and get advice on the exercises and activities you can do to regain your strength.

The first clinical replacement heart valve surgery took place in 1952. Today, several replacement valve options are available within two broad categories of valve types, mechanical heart valves and bioprosthetic or tissue heart valves.

Mechanical heart valves are constructed with strong, man-made materials and designs. The most important benefit of mechanical valves is that they are the most durable of the valve types and are designed to last the lifetime of the patient. Patients with mechanical replacement

heart valves must take daily blood anticoagulation medication to minimize the risk of complications from blood clots.

Bioprosthetic heart valves are made with tissue from porcine (pig) heart valves or bovine (cow) heart tissue (or a combination of the two). These tissue replacement heart valves are designed to function like human heart valves. The most important benefit of this valve type is that the valve is very compatible with the bloodstream. Patients with tissue valves are not always dependent on daily medication to minimize complications from blood clots.

Your physician can help you make the decision between a mechanical heart valve and a bioprosthetic heart valve. The decision may be based on your age, lifestyle, medication requirements, and other factors.

How Long Valves Last

Mechanical heart valves are made of graphite and coated with pyrolytic carbon. Studies have shown that the St. Jude Medical valve will not wear out during a person's lifetime.[1] However, if there are problems with blood clot formation, the valve may need to be replaced.

Various clinical studies indicate that tissue heart valves may last from 8 to 20 years depending on their position. Aortic valves have tended to last longer than mitral valves in these studies. The exact timing depends on the type of tissue valve, your age, lifestyle, medication requirements and other factors. The symptoms of valve failure may be the same symptoms you experienced before surgery, such as shortness of breath, dizziness, chest pain, fatigue, and fluid retention. If one or more of these symptoms occur, notify your doctor.

1. Elizondo DR, Boland ED, Amburs JR, et al. Mechanical cardiac valve prostheses: wear characteristics and magnitudes in three bileaflet valves. *J Heart Valve Dis.* 1996;5(Suppl.I): S115-S123

Before the Procedure

A nurse, patient advocate or your doctor will discuss the procedure with you on the day you are scheduled to receive your new valve. The length of the procedure varies for each patient.

During the Procedure

During the procedure a general anesthetic will be administered that will put you to sleep so you do not feel any pain during the surgery.

Your surgeon will make an incision in your chest to reach your heart. Your heart will be stopped temporarily so the valve can be implanted and you will be placed on a heart-lung machine. First the surgeon will remove the diseased valve and determine the correct replacement valve size. Next, the new valve will be positioned in the original valve location and firmly sewn into place. The surgeon then closes the incision, restarts your heart and closes all the other incisions. The heart-lung machine is then removed and your natural heart rhythm is returned.

After the Procedure

After your heart valve surgery, you will be placed in the intensive care unit (ICU) where you can be monitored continuously. You will have help

breathing during surgery and for a while afterwards, from a tube that has been placed down your throat and positioned in your lungs.
You will probably wake up with this tube still in position. It will be removed as soon as you are stable and awake enough to breathe on your own. You will not be able to talk while this tube is in. Other tubes will come from your chest near the heart to drain extra blood and fluid from the surgical area.

Intravenous lines will give you fluid, blood and medications as needed, and you will have a bladder catheter to drain urine. You will be hooked up to a monitor that shows your heart rate, heart rhythm, blood pressure and other measurements that the nursing staff will use to assess your recovery status. You will receive medications to ease your pain and anxiety as needed.

The typical length of stay in the ICU is one or two days. It is important to remember that every patient recovers at a different rate. The nursing staff will monitor your recovery and remove the tubes as appropriate. From the ICU you will be moved to a cardiac medical-surgical floor where your heart will continue to be monitored, but there you may be more independent and active. The health care team will continue to support and instruct you in recovery care, rehabilitation, medications, nutrition and other needs.

Keep in mind that every patient recovers at a different rate. Once you leave the hospital, it will typically be 6 to 8 weeks before you are able to return to your normal routine.

Your doctor will advise you whether you should take:

- A low dose of aspirin
- Anticoagulant therapy, which is recommended for all patients with bioprosthetic valves who have risk factors for thromboembolism.

When to Call the Doctor

Contact your physician(s) if you develop any of these symptoms:

- Redness or drainage of your incision
- Shortness of breath
- Swelling of your feet or ankles
- Chest, jaw, shoulder or arm pain
- Bruising
- Excessive bleeding
- Blood in your urine
- Bloody or black tarry (blood will typically look like tar after it has been exposed to the body's digestive juices) bowel movements
- Unusual nosebleeds
- Fever
- Numbness or tingling in your arms or legs
- General weakness or loss of energy
- Blurred or loss of vision
- Unusual chest sensation

Returning Home

Remember to:

- Take medication as prescribed.
- Follow-up with blood tests as directed by your physician.
- Enjoy a heart-healthy diet.

Valve replacement does not mean a sedentary lifestyle. Many people who receive valves are able to lead a more active and fulfilling life than before surgery. Ask your doctor what kinds of activities and sports you should avoid. Report any falls, blows to the body or head, or other injuries, to your doctor right away.

Your involvement in caring for the health of your heart begins now. By understanding the recovery process and life-long management necessary for your valve, you can make better heart-healthy decisions. Long-term management of your health requires your active participation. With your physician, you can work toward a healthy recovery.

When you return home, you must take special care of yourself until you are fully recovered. It may be about 6 to 8 weeks before you are able return to your normal routine. You will feel better each day; however, it is normal to experience some ups and downs. You will need to allow time to rest regularly; this will help speed your recovery.

At your follow-up visit to your doctor around 3 weeks, you may need to undergo tests such as an electrocardiogram, echocardiogram or chest x-ray to evaluate how your new valve is working. Your doctor may also perform blood work to assess your medication levels.

Travel

After you've recovered, you should be able to enjoy traveling. Talk with your doctor if you're planning a trip to an exotic or tropical destination as certain destinations may harbor bacteria and other microbes that could be dangerous for your heart.

Airport Metal Detectors

The amount of metal used in mechanical heart valves and heart valve rings is very small. It is usually not enough to set off the metal detectors; however, if it does, simply show security personnel your patient identification card. Passing through a metal detector will not affect your heart valve.

If you do not receive your permanent, plastic ID card within 90 days of your surgery, or if you need a replacement card, contact St. Jude Medical to request a card:

St. Jude Medical Customer Service

Toll-free Phone #: 800.544.1664

E-mail: heartvalves@sjm.com

MRI Testing

If you are told you need to have an MRI (magnetic resonance imaging), tell the doctor that you have an artificial heart valve and show your ID card, which contains important information about how to perform an MRI safely with your valve.

Your doctor or MRI technician may request the following information:

Non-clinical testing has demonstrated that St. Jude Medical heart valves and repair devices are MR conditional. They can be scanned safely under the following conditions:

- Static magnetic field of 3 Tesla or less
- Spatial gradient of 525 Gauss/cm or less
- Maximum whole-body-averaged specific absorption rate (SAR) of 2.0-W/kg for 15 minutes of scanning

If you have questions or concerns about this and other diagnostic tests and your heart valve, please talk to your doctor.

It is wise to provide your doctor with the information outlined above about MRI testing and your heart valve.

Potential Adverse Effects of a New Device on Your Health

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
- leak, transvalvular or perivalvular
- myocardial infarction
- nonstructural dysfunction (entrapment by pannus or suture, inappropriate sizing or positioning, or other)
- prosthesis regurgitation
- stroke
- structural deterioration (calcification, leaflet tear, perforation, or other)
- thromboembolism
- valve thrombosis

It is possible that these complications could lead to:

- reoperation
- explantation
- permanent disability
- death

User Assistance

If you have questions about your medical condition, please contact your doctor. St. Jude Medical, as a manufacturer of medical devices, does not provide medical advice

St. Jude Medical Customer Service

Toll-free Phone #: 800.544.1664

E-mail: heartvalves@sjm.com

Your Heart

The heart consists of four chambers. The upper, receiving chambers are called the atria (each chamber is called an atrium) and the lower, pumping chambers are the ventricles (Figure 3). Because of their pumping function, the ventricles are larger than the atria.

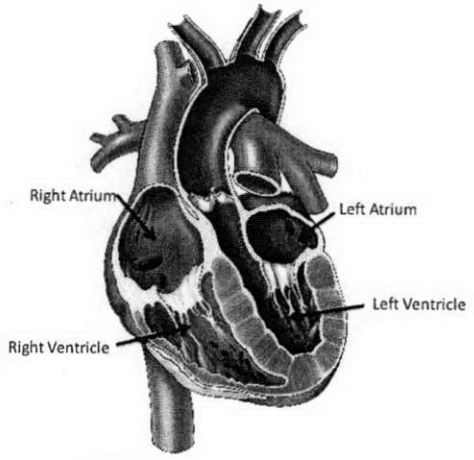

Figure 3
Chambers of the Heart

The main job of the heart is to pump oxygen-rich blood through your body. It does this by contracting an average of 70 times per minute for a total of more than 36 million heart beats per year.

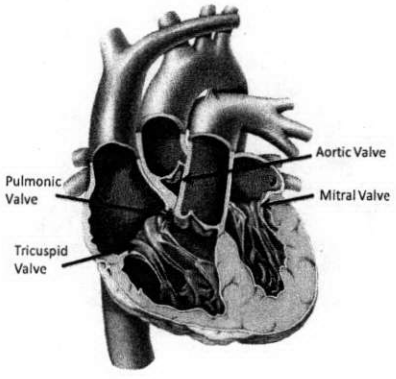

Figure 4
Heart Valves

Heart valves direct blood flow between the chambers of the heart. These valves act like one-way doors, allowing blood to flow forward into the next chamber. The valves close to prevent backflow.

Figure 4 shows the heart valves. On the right side of the heart, the blood flows through the tricuspid valve which lies between the atrium and the ventricle. On the left side of the heart, blood flows between the left atrium and the left ventricle through the mitral valve.

Valves also separate the ventricles and the large blood vessels that carry blood away from the heart. Blood flows through the pulmonic valve between the right ventricle and pulmonary artery and lungs. On the left side of the heart, blood flows through the left ventricle into the aorta through the aortic valve.

St. Jude Medical Customer Service

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Brief Summary: Please review the Instructions for Use prior to using these devices for a complete listing of indications, contraindications, warnings, precautions, potential adverse events and directions for use.

Indications: St. Jude Medical Stented Tissue Valves are indicated for use as a replacement for malfunctioning native or prosthetic aortic and/or mitral valves. Adverse events potentially associated with the use of bioprosthetic heart valves include: angina, cardiac arrhythmia, endocarditis, heart failure, hemolysis, hemolytic anemia, hemorrhage (anticoagulant/antiplatelet-related), leak (transvalvular or paravalvular), myocardial infarction, nonstructural dysfunction (e.g., pannus, suture, inappropriate sizing or other), prosthesis regurgitation, stroke, structural deterioration (e.g., calcification, leaflet tear or other), thromboembolism and valve thrombosis. It is possible that these complications could lead to reoperation, explantation, permanent disability or death. 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. Please see the Instructions for Use (IFU) for a full description of indications, contraindications, side effects, precautions, warnings and Instructions for Use.