

Trifecta™ Valve with Glide™ Technology (GT)



TFGT-19A, TFGT-21A, TFGT-23A, TFGT-25A, TFGT-27A, TFGT-29A

INSTRUCTIONS FOR USE

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

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Pat. <http://patents.sjm.com>

EN: English

Sterile components: Trifecta™ valve with Glide™ Technology (GT), valve collar and holder.

Non-sterile components: Exterior of the valve jar, Trifecta™ sizers, and holder handles.

Description

CAUTION: The Trifecta™ Valve with Glide™ Technology (GT) should be used only by physicians who have undergone training on implantation of this device.

The Trifecta™ Valve with Glide™ Technology (GT) (hereafter referred to as "the 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 titanium stent and a titanium band within the sewing cuff provide radiopacity for visualization of the valve.

The stent, excluding the sewing cuff, is covered with porcine pericardial tissue. This covering provides protection from mechanical wear by allowing only tissue-to-tissue contact during valve function. Polyester fabric is rolled/folded within the sewing cuff to contour to the annulus shape. The cuff features three suture markers that may be used to provide reference points during implantation.

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.

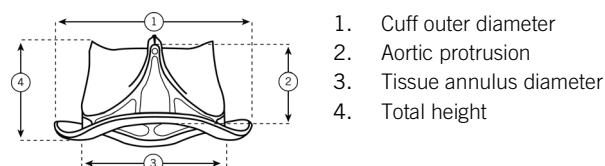
The valve is processed using the Linx™ anticalcification treatment. The valve is supplied sterile and non-pyrogenic.

Table 1. Valve Catalog Numbers and Reference Dimensions

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

*Implanted height differs from total height since the Trifecta GT cuff is compressed when it is sutured into place, as observed through simulated bench testing of all Trifecta GT valve sizes

Figure 1. Trifecta™ Valve with Glide™ Technology (GT)



Indications for Use

The Trifecta™ Valve with Glide™ Technology 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 reuse or resterilize. Attempts to resterilize the valve may result in valve malfunction, inadequate sterilization, or patient harm.
- Do not oversize. Valve size selection is based on the size of the recipient annulus and the anatomy of the sinotubular junction. If the native annulus measurement falls between two valve sizes, use the smaller size valve. Use only the Model TF2000 Trifecta Sizars for sizing the valve. Implantation of an oversized valve may result in stent deformation, valvular incompetence, valve damage, diminished tissue durability, and/or damage to the surrounding tissues.
- Passage of a diagnostic 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 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
- 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 jar seal is damaged, broken, or missing, or if fluid is leaking from the packaging.
 - The storage solution does not completely cover the valve.
- Use only the Trifecta™ Model TF2000 sizers¹ for sizing the valve.
- 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.

Precautions

- Safety and effectiveness of the valve 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
- Sizer sets 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 place the non-sterile exterior of the valve jar in the sterile field.
- 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–25°C (41°F–77°F) range.
- 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 implant the valve without thoroughly rinsing as directed.
- Position the valve so that the stent posts do not obstruct the coronary ostia or come in direct contact with the aortic wall.
- 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.
- 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 use cutting edge needles, unprotected forceps, or sharp instruments, as they may cause structural damage to the valve.
- Do not attempt to repair a valve. Damaged valves must not be used.
- Do not pass the replica end of the TF2000 sizer through the annulus when sizing the valve.
- Use caution when tying knots to avoid bending the stent posts.

Magnetic Resonance (MR) Safety

Non-clinical testing has demonstrated the Trifecta™ Valve with Glide™ Technology (GT) is MR Conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 1.5 tesla (1.5T) or 3.0 tesla (3.0T)
- Maximum spatial field gradient of 3,000 gauss/cm (30 T/m).
- Maximum MR system reported, whole-body averaged specific absorption rate (SAR) of 2.0 W/kg (Normal Operating Mode).

RF Heating

Under the scan conditions defined above, the Trifecta™ Valve with Glide™ Technology (GT) is expected to produce a maximum temperature rise of less than 3°C after 15 minutes of continuous scanning.

¹ TF2000 sizers are included in sizer set models TF2000 and TF2000-2.

MR Artifacts

In non-clinical testing, the image artifact extended radially 0.6 cm from the prosthetic valve when imaged with a gradient echo pulse sequence and a 3.0T System.

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.

Adverse Events

The Trifecta™ Valve with Glide™ Technology is based upon the Trifecta™ Valve design. Therefore, a previous clinical investigation of the Trifecta Valve supports the safety of the Trifecta Valve with Glide Technology. 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 include:

- angina
- cardiac arrhythmias
- endocarditis
- heart failure
- hemolysis
- hemolytic anemia
- hemorrhage
- 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

See the Clinical Study section of these instructions for adverse event data collected in the Trifecta™ Valve clinical investigation.

Clinical Study

The Trifecta™ valve with Glide™ Technology is based upon the Trifecta™ valve design. Therefore, a previous clinical investigation of the Trifecta valve supports the safety and efficacy of the Trifecta valve with Glide Technology. 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 shown in the following table 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).

Table 2. Observed Adverse Event Rates

All subjects analyzed: N=1014

Cumulative follow-up: 924.18 patient-years

Adverse Event	Early Events ² % ³ (n)	Late Events ⁴ % / pt-yr ⁵ (n) [One-Sided Upper 95% CL]	Freedom From Event 1 Year ⁶ % [95% CI]	Freedom From Event 2 Year ⁷ % [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)	0.0% (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%]

Follow-Up

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

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

All subjects included in 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 ⁸	995	844.31	0.88	0.45	0.01	2.30

Preoperative Subject Demographics

The following table presents the preoperative subject demographics.

Table 4. Preoperative Subject Demographics

All subjects included in 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)

² Early events are those occurring on or before 30 days post-implant

³ The early adverse event rate (%) is calculated as the number of early adverse events divided by the total number of subjects, times 100

⁴ Late events are those occurring 31 days post-implant or thereafter

⁵ 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

⁶ 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)

⁷ 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)

⁸ Late patient-years are determined from 31 days post-implant to the last follow-up visit (or contact), or adverse event.

Effectiveness Outcomes

Quantitative data were collected throughout the study (i.e., NYHA functional classification, echo parameters). The following tables present subject NYHA classification preoperatively compared to one year follow-up and two years follow-up, respectively.

Table 5. Effectiveness Outcomes, NYHA Functional Classification: 1 year Follow-up⁹

Subjects with both preoperative and 1 year NYHA measurements, N=606; n₁=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%

Table 6. Effectiveness Outcomes, NYHA Functional Classification: 2 year Follow-up¹⁰

Subjects with both preoperative and 2 year NYHA measurements, N=97; n₁=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%

The following table presents the hemodynamic follow-up results for the Trifecta valve replacements.

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 ¹¹
	N=68 ¹²	N=160	N=198	N=136	N=40	N=15
Mean Gradient ¹³	n=66 ¹⁴	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 ¹⁵	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 ¹⁶	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)

⁹ Subjects with both preoperative and one year NYHA measurements available are included in this table

¹⁰ Subjects with both preoperative and 2 year NYHA measurements available are included in table

¹¹ 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

¹² N= number of subjects with a completed echo per valve size

¹³ Mean Gradient= pressure drop measured across the valve recorded in mmHg

¹⁴ n= number of subjects per valve size with available hemodynamic parameter

¹⁵ EOA= calculated effective orifice area measured in cm²

¹⁶ Aortic Regurgitation presented as 'Percentage (Count)'

-Severe	0.0% (0)	0.0% (0)	1.0% (2)	0.7% (1)	0.0% (0)	0.0% (0)
-Unknown ¹⁷	5.8% (4)	0.6% (1)	1.0% (2)	0.7% (1)	0.0% (0)	0.0% (0)

Packaging and Storage

The valve is packaged in a jar with formaldehyde storage solution. A retaining collar stabilizes the valve within the jar.

As delivered, the valve is attached to a valve holder by retaining sutures. The valve holder facilitates handling and manipulation of the valve during removal from the jar, rinsing, and implantation.

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 the 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 - 25°C (41°F - 77°F range).

Accessories

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

Sizer Set

Trifecta™ Valve Series Sizer Set Model TF2000-2 (includes TF2000 sizers, Rigid Holder Handle Models T2002-R and UT2000-R).

UT2000-R is not compatible with the valve.

Optional Handles

- Flexible Holder Handle Model T2002
- Rigid Extension Handle Model EX2000-R
- Flexible Extension Handle Model EX-05

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

Directions for Use

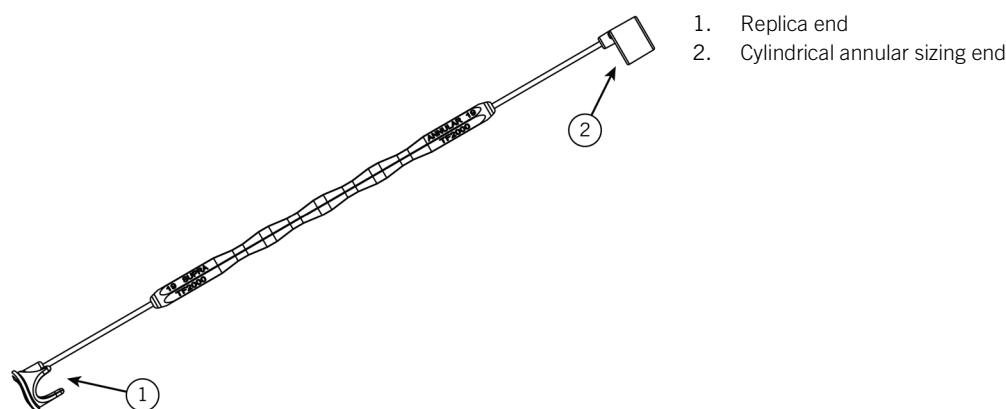
Sizing the Valve

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

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

Use only Model TF2000 sizers to size the valve. The TF2000 sizer is a double-ended tool with a cylindrical annular sizing end and a valve replica end. Use the cylindrical annular sizing end of the sizer to determine the annulus size. Select the valve size using the cylindrical annular sizing end that passes readily without resistance through the annulus. See the sizer instructions for use for specific instructions on cleaning, sterilization, and handling.

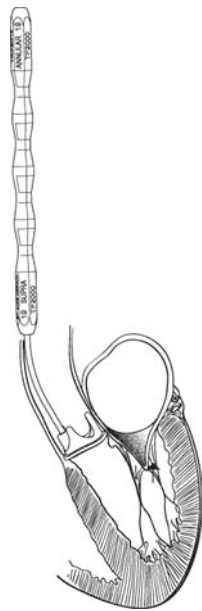
Figure 2. TF2000 Sizer



¹⁷ Unknown - Includes echoes that did not contain the appropriate images to evaluate aortic regurgitation

The 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. Sizing the valve



The replica end of the TF2000 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.

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

Pre-Implant Handling

The valve is supplied in a storage jar with a screw-cap closure and tamper-evident seal. The contents of the jar 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 Package

PRECAUTIONS:

- Do not place the non-sterile exterior of the valve jar 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. Select the appropriate valve size, as determined from the sizing procedure.
2. Once the valve jar has been removed from the outer packaging, examine the jar for evidence of damage.

WARNING: The valve must not be implanted if the tamper-evident jar 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 jar, 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 Jar

1. Select the Rigid Holder Handle Model T2002-R, or the Flexible Holder Handle Model T2002, for the procedure.

NOTE: The valve must be removed from the jar using a threaded screw-in holder handle. The click-in Model UT2000-R holder handle provided with the Model TF2000-2 sizer set is not compatible with the valve.

2. With the circulating nurse holding the jar, screw the holder handle into the valve holder by rotating the handle in the clockwise direction, as shown (page 8). Ensure a secure connection.

NOTE: To prevent cross-threading, keep the holder handle perpendicular to the valve holder during attachment.

3. Remove the valve from the jar.

NOTE: The leaflets only coapt upon closure during the cardiac cycle. See leaflet outflow view illustration (page 8).

CAUTION: Do not handle the valve with unprotected forceps. Do not use cutting edge needles or sharp instruments. Never handle the leaflet tissue.

4. Using gloved hands, grasp the plastic retaining collar with one hand and the holder handle with the other hand. Lift up on the holder handle, then slide the holder handle out of the slot in the retainer collar, as shown (page 9).
5. Inspect the valve for damage. Do not implant the valve if there is any sign of damage or deterioration.

Figure 4. Use the holder handle to remove the valve from the jar

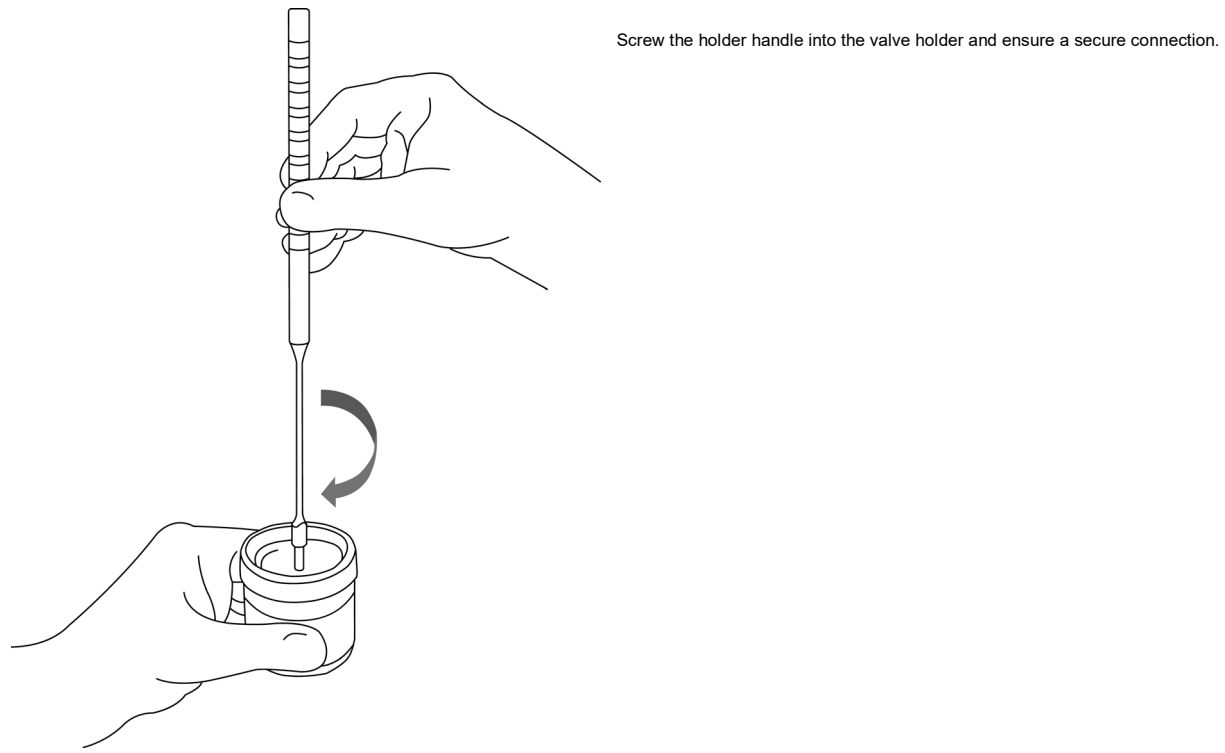


Figure 5. Leaflet outflow view

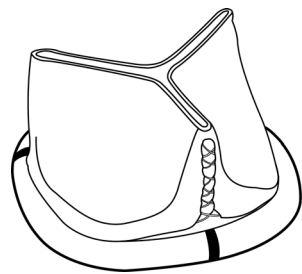
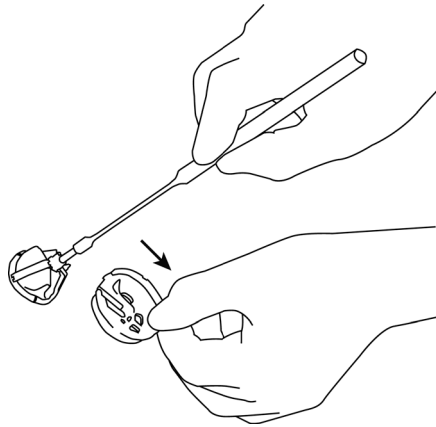


Figure 6. Slide the retaining collar off the valve holder



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 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.

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 and knot tying technologies 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.

PRECAUTIONS:

- Use caution when tying knots to avoid bending the stent posts.
- 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.
- 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, implant the valve in the supra-annular position.

1. Based on the sizing instructions, choose a valve of the appropriate size.

CAUTION: Position the valve so that the stent posts do not obstruct the coronary ostia or come in direct contact with the aortic wall.

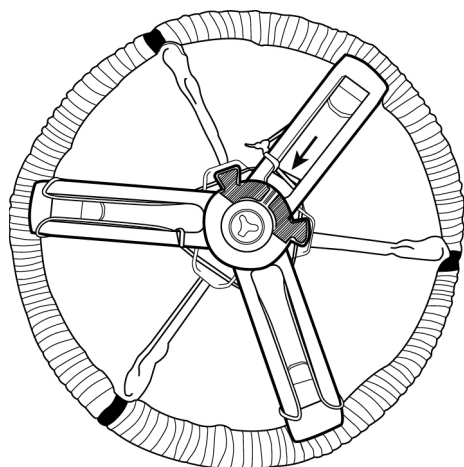
2. Ensure the suture tails do not contact the leaflet tissue.
3. To remove the holder from the valve, make a single cut to the retaining sutures as shown (page 10), and pull the handle and the valve holder away from the valve.

WARNING: To minimize contact with leaflet tissue, gently pull the valve holder straight up through the opening between the leaflets.

4. Examine the valve to ensure that there are no holder suture remnants.

NOTE: To facilitate implantation, the valve holder handle may be removed from the valve holder.

Figure 7. Cut the retaining sutures to remove the holder



Intra-Operative Assessment

The suggested method for assessing competence of the 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

Anticoagulation/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

Prophylactic antibiotic treatment should be considered for all patients undergoing dental procedures.

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.

Future Valve-in-Valve Considerations

A transcatheter heart valve implanted in a surgical aortic tissue valve (ViV) is emerging as a reasonable treatment option for severely symptomatic patients with a failed surgical valve who are judged by the heart team to be at high or prohibitive risk of surgical reoperation, and in whom improvement in hemodynamics is anticipated. The information in this section is intended to be helpful for future ViV procedures in Trifecta™ Valves with Glide™ Technology (GT).

CAUTION: When performing a ViV procedure, the instructions for use of the transcatheter heart valve must be followed. The safety and efficacy of ViV procedures in a Trifecta™ Valve with Glide™ Technology (GT) have not been established.

Surgical Valve Implantation

When implanting the Trifecta™ Valve with Glide™ Technology (GT), it is important to:

- Ensure that there is adequate clearance of the coronary artery openings and that there is no direct contact between the stent posts and the aortic wall
- Assess the suitability of the implanted surgical valve and anatomy for a future ViV intervention

The replica end of the sizer accurately represents the valve and should be used to assess the position of the valve relative to the encountered anatomy and thereby ensure proper coronary opening clearance and assess suitability of the valve for a future ViV intervention.

Trifecta™ Valve with Glide™ Technology (GT) Radiographic Dimensions

The following table provides detailed dimensional information that may aid in transcatheter heart valve size selection.

Table 8. Trifecta™ Valve with Glide™ Technology (GT) Radiographic Dimensions

Model	Labeled Size (mm)	Radiographic ID* (mm)	Radiographic Height* (mm)
TFGT-19	19	17.2	11.6
TFGT-21	21	19.2	12.7
TFGT-23	23	21.2	13.6
TFGT-25	25	23.2	14.8
TFGT-27	27	25.1	15.8
TFGT-29	29	27.1	16.9

* Radiographic ID and height are based on stent dimension, which provides a reliable post-implant imaging measurement

Three-dimensional CT imaging is the recommended measurement method to assess a failed surgical valve dimensions when selecting the appropriate transcatheter heart valve size during a ViV procedure. The reference dimensions above do not account for valve tissue thickening, calcium burden/distribution, or other factors that vary by patient and are important when selecting a transcatheter heart valve size.

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.

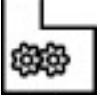
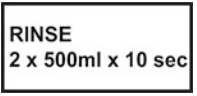
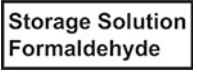
Descriptions of specifications, appearing in SJM literature, are meant solely to generally describe the device at the time of manufacture and do not constitute any express warranties.

This limited warranty is available during the warranty period stated below if the St. Jude Medical ("SJM") device fails to perform consistent with its labeling due to a material defect at the time of manufacturing. This warranty shall continue for a period of one year from delivery of the device to you, and is in lieu of, AND SJM HEREBY DISCLAIMS AND EXCLUDES, ALL OTHER WARRANTIES, REPRESENTATIONS, OR CONDITIONS, WHETHER EXPRESS OR IMPLIED BY OPERATION OF LAW OR OTHERWISE, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTIES OF MERCHANTABILITY, NON-INFRINGEMENT, COURSE OF DEALING, QUIET ENJOYMENT, OR FITNESS FOR A PARTICULAR PURPOSE. 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 result obtained from its use, and SJM IS NOT RESPONSIBLE FOR THE FOREGOING OR ANY USE OF THE DEVICE INCONSISTENT WITH OR CONTRARY TO THE ABOVE INSTRUCTIONS FOR USE ("IFU"). SJM SHALL NOT BE LIABLE FOR ANY INCIDENTAL, INDIRECT, SPECIAL, COVER, PUNITIVE, OR CONSEQUENTIAL LOSS, DAMAGE, OR EXPENSE DIRECTLY OR INDIRECTLY ARISING FROM THE USE OF OR RELATED TO THIS DEVICE. SJM'S SOLE LIABILITY, AND YOUR SOLE REMEDY, RELATED TO THE DEVICE IS THE REPAIR OR REPLACEMENT OF ALL OR PART OF IT, OR REFUND OF THE DEVICE PURCHASE PRICE IF REPAIR OR REPLACEMENT IS NOT FEASIBLE AS DETERMINED BY SJM. IN NO EVENT SHALL SJM BE LIABLE TO YOU OR ANY THIRD PARTY FOR ANY CLAIM OR DAMAGES, HOWEVER ARISING, IN AN AMOUNT THAT EXCEEDS THE DEVICE PURCHASE PRICE. SJM neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this device.

Symbols

The following symbols are used on the valve labels.

Symbol	Description
	Catalog Number

Symbol	Description
	Sterilized by liquid chemical sterilant
	Date of Manufacture
	Temperature Indicator: If red, do not use
	Do not reuse
	Serial number
	Use by
	Temperature limitations
	Manufacturing facility
	Authorized EC Representative in the European Community
	Consult instructions for use
	Rinse - 2 x 500 mL x 10 seconds
	Aortic
	Storage solution - formaldehyde
	Sterilized using aseptic processing techniques
	MR Conditional
	Follow instructions for use on this website
	Manufacturer
	Quantity, package contents
	Do not use if package is damaged
	Do not resterilize
	Pericardial
	CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

Symbol	Description
	Conformite Europeenne (European Conformity). Affixed in accordance with European Council Directive 93/42/EEC. Hereby, St. Jude Medical declares that this device is in compliance with the essential requirements and other relevant provisions of this directive.

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