ST. JUDE MEDICAL
HEART VALVE DIVISION

# Toronto SPV® Valve
# INSTRUCTIONS FOR USE

**Caution: Federal law restricts this device to sale by or on the order of a physician (or properly licensed practitioner).**

## *Table of Contents*

# 1. DEVICE DESCRIPTION

The Toronto SPV® valve is a stentless subcoronary porcine aortic valve preserved in 0.5% glutaraldehyde. It is comprised of only the valve cusps and enough aortic tissue to support the commissures and leaflets. The inflow edge is trimmed to form a flat plane perpendicular to the axis of the valve. The aortic wall tissue on the outflow edge is scalloped, with all three sinuses removed, following the natural contour of the leaflet attachments.

The outer surface is covered with a single layer of polyester fabric. The Toronto SPV® valve is suspended on a holder and tripod assembly within a sealed jar containing a 0.5% glutaraldehyde packing solution. The Toronto SPV® valve is supplied sterile and non-pyrogenic.

The Toronto SPV® valve is available in tissue annulus sizes 21 mm, 23 mm, 25 mm, 27 mm and 29 mm.

Use only St. Jude Medical, Inc. SPA 300 sizers and accessories to size the Toronto SPV® valve.

# 2. INDICATIONS

The Toronto SPV® valve is indicated for the replacement of malfunctioning native or prosthetic aortic valves.

# 3. CONTRAINDICATIONS

The Toronto SPV® valve is contraindicated for use in patients where the diameter of the aortic annulus is larger than the diameter of the sinotubular junction, or where the diameter of the aortic annulus is more than 10% smaller than the sinotubular junction. *Excessive mismatch may cause central incompetence and/or stenosis of the bioprosthesis.*

# 4. WARNINGS

### FOR SINGLE USE ONLY

**DO NOT RESTERILIZE** the valve by any method. Exposure of the valve and container to irradiation, steam, ethylene oxide or other chemical sterilants will render the valve unfit for use.

**Warning:** Accelerated deterioration due to calcific degeneration of bioprostheses may occur in:

- children, adolescents; or young adults;
- patients with altered calcium metabolism (e.g., chronic renal failure, hyperparathyroidism).

# 5. PRECAUTIONS

Implanting physicians must be familiar with the techniques for implanting an unstented bioprosthesis. These techniques are similar to those required for allograft implantation.

In vitro testing of the Toronto SPV® valve has only been performed in a less compliant simulated aorta comparable to the aorta of a middle aged or older patient. Data from clinical or in vitro testing are not available from a more compliant aorta comparable to the aorta of a younger patient.

### Precautions Prior to Use

Do not use the Toronto SPV® valve:

- if the tamper- evident seal is broken;
- if the glutaraldehyde storage solution does not completely cover the valve;
- if the valve has been exposed to freezing or has had prolonged exposure to heat as indicated by the temperature indicators provided in the packaging (see section 10 How Supplied);
- if the valve is damaged.

## 5. PRECAUTIONS *(continued)*

### Precautions During Use

- Do not expose the valve to solutions other than the storage 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 allow the valve tissue to dry. Continuous submersion or irrigation is required (see section 11 Directions for Use).
- Do not add antibiotics to either the storage or the rinse solution. Do not apply antibiotics to the valve.
- Do not lacerate the valve tissue. If a valve is damaged, the valve must be explanted and replaced.
- Do not evert the valve. Eversion will damage valve tissue.
- Passage of a catheter through any bioprosthesis may damage the valve and is, therefore, not recommended.

## 6. ADVERSE EVENTS

A total of 577 Toronto SPV® valves were implanted in the subcoronary position in 577 patients at 12 centers. All 577 patients were included in the adverse event evaluation. The cumulative follow-up was 1325 years with a median follow-up of 2.1 years (range 0 to 6.0 years).

### *6.1 Observed Adverse Events*

**Table 6.1: Observed Adverse Events**

All patients implanted: N=577,Cumulative Follow-up=1,325 patient-years (pt-yr.)

| | Early Events[1]% (N) | Late Events[2] %/pt-yr. (N) | Actuarial Freedom by Kaplan-Meier [95% CI] 1 Year | 3 Year | 5 Year |
|---|---|---|---|---|---|
| Death (all Causes) | 2.8% (16) | 2.3%/pt-yr (29) | 94% [92%, 96%] | 91% [89%, 94%] | 89% [86%, 93%] |
| Death (related/unexplained) | 0.3% (2) | 0.5%/pt-yr (7) | 99% [98%,99.5%] | 98% [97%, 99%] | 98% [97%, 99%] |
| Thromboembolism | 1.4% (8) | 1.5%/pt-yr (19) | 97% [95%, 98%] | 94% [92%,97%] | 93% [90%, 96%] |
| Permanent Neuro Events | 1.0% (6) | 0.5%/pt-yr (6) | | | |
| Transient Neurological Events | 0.3% (2) | 0.9%/pt-yr (11) | | | |
| Peripheral Arterial Events | 0.0% (0) | 0.2%/pt-yr (2) | | | |
| Valvular Thrombosis | 0.0% (0) | 0.0%/pt-yr (0) | 100% | 100% | 100% |
| Structural Deterioration | 0.0% (0) | 0.0%/pt-yr (0) | 100% | 100% | 100% |
| Nonstructural Dysfunction | 0.0% (0) | 0.0%/pt-yr (0) | 100% | 100% | 100% |
| Anticoag-Related Hemorrhage | 0.0% (0) | 0.3%/pt-yr (4) | 99%[99%,100%] | 99% [98%, 100%] | 99% [98%, 100%] |
| Paravalvular Leak | 1.6% (9) | 0.6%/pt-yr (8) | 97% [96%, 99%] | 97% [95%, 98%] | 97% [95%, 98%] |
| Endocarditis | 0.2% (1) | 0.4%/pt-yr (5) | 99% [98%,99.9%] | 99% [98%,99.8%] | 99% [98%, 99.8%] |
| Hemolysis | 0.0% (0) | 0.0%/pt-yr (0) | 100% | 100% | 100% |
| Reoperation (including Explant) | 0.2% (1) | 0.3%/pt-yr (4) | 99% [99%, 100%] | 99% [98%, 99.9%] | 99% [98%, 99.9%] |
| Explant | 0.2% (1) | 0.3%/pt-yr (4) | 99% [99%,100%] | 99% [98%, 99.9%] | 99% [98%, 99.9%] |

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

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

### *6.2 Potential Adverse Events*

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

- cardiac dysrhythmias;
- death;
- endocarditis;
- hemolysis;
- hemorrhage, anticoagulant/antiplatelet-related;
- leak, transvalvular or paravalvular;
- nonstructural dysfunction (pannus, suture, inappropriate sizing, or other);
- structural deterioration (calcification, leaflet tear, or other);
- thromboembolism;
- valve thrombosis.



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# 7. CLINICAL STUDIES

A prospective, non-randomized, multicenter international study evaluated the Toronto SPV® valve with patient follow-up out to five years.

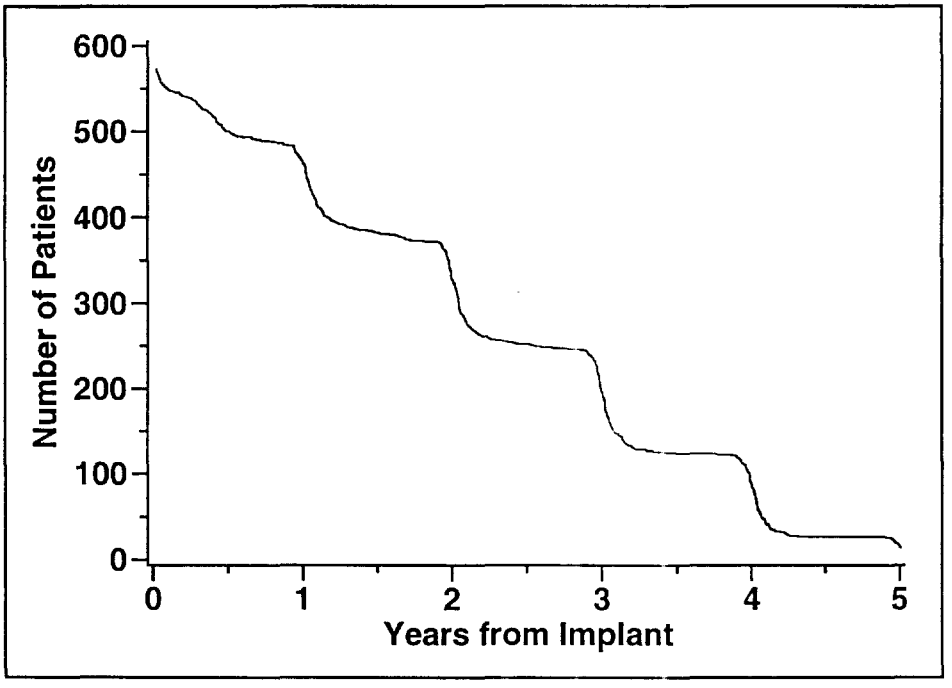
Five hundred and seventy-seven patients were evaluated preoperatively, within 30 days post-operatively, at 3 to 6 months, and annually. Total follow-up was 1325 patient-years (mean 2.0 years, SD 1.4 years, Range 0 to 6.0 years).

**Table 7.1: Preoperative Patient Characteristics**
All patients implanted: N = 577

| **Age (mean ± SD), [min., max.], (N)** | **65.6 ± 10.9, [33.3, 93.4], (577)** |
|---|---|
| **Gender (% male/% female)** | **67%/33%** |
| Etiology and pathology (%,n) | |
| – calcification | 70%, 404 |
| – congenital | 30%, 173 |
| – rheumatic fever | 13%, 76 |
| – endocarditis | 2%, 9 |
| – prosthetic failure | 2%, 14 |
| – other | 2%, 13 |
| – unknown | 3%, 16 |

Figure 7.1 Presents the number of patients implanted versus duration of follow-up by valve size.

**Figure 7.1: Number of Patients by Valve Size and Duration of Follow-up**
All patients implanted, N = 577 ,1325 patient-years, median = 2.1 years




| **Valve Size** | **0 years** | **1 years** | **2 years** | **3 years** | **4 years** | **5 years** |
|---|---|---|---|---|---|---|
| **21mm*** | 19 | 15 | 5 | 3 | 3 | 1 |
| **23mm** | 68 | 47 | 34 | 17 | 8 | 3 |
| **25mm** | 136 | 111 | 85 | 53 | 15 | 3 |
| **27mm** | 193 | 157 | 115 | 66 | 30 | 6 |
| **29mm** | 161 | 133 | 91 | 59 | 27 | 5 |
| **Total All Sizes** | **577** | **463** | **330** | **198** | **83** | **18** |

* 21mm includes 20, 21, and 22mm valve sizes



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**Table 7.2: NYHA and Hemodynamic Outcomes**

All patients implanted: N=577, all values reported as: mean ± SD [min., max.] (Number of values)

| Interval | Preoperative | 30 Days[1] | 3-6 Months | 1st Annual |
|---|---|---|---|---|
| **NYHA Classification** | 2.6 ± 0.7, [1,4] (566) | 1.9 ± 0.5, [1,3] (339) | 1.2 ± 0.4, [1,4] (501) | 1.1 ± 0.4, [1,4] (445) |

| Endpoint | 30 Days[1] | 3-6 Months | 1st Annual |
|---|---|---|---|
| **Valvular Regurgitation[2]** | 0.2 ± 0.5 [0+,3+] (519) | 0.2 ± 0.6 [0+,4+] (477) | 0.2 ± 0.6 [0+,4+] (452) |
| **Mean pressure gradient (mmHg)** | | | |
| 21 mm[3] | 12.2 ± 9.7 [2, 42] (17) | 9.7 ± 8.4 [2, 37] (15) | 10.0 ± 9.0 [1, 34] (13) |
| 23 mm | 10.3 ± 6.1 [1, 30] (62) | 8.0 ± 5.2 [0, 29] (57) | 7.3 ± 4.8 [1, 25] (46) |
| 25 mm | 8.3 ± 5.2 [1, 30] (117) | 7.0 ± 4.8 [0, 26] (109) | 6.4 ± 5.1 [0, 32] (111) |
| 27 mm | 8.2 ± 5.5 [0, 43] (173) | 5.3 ± 3.4 [0, 16] (162) | 5.1 ± 3.1 [1, 14] (155) |
| 29 mm | 6.2 ± 3.5 [1, 16] (141) | 4.4 ± 2.7 [0, 14] (140) | 3.8 ± 2.3 [0, 13] (130) |
| **Effective Orifice Area ($cm^2$)** | | | |
| 21 mm[3] | 1.2 ± 0.6 [0.3, 2.5] (17) | 1.3 ± 0.6 [0.5, 2.5] (16) | 1.3 ± 0.7 [0.2, 2.6] (14) |
| 23 mm | 1.4 ± 0.4 [0.4, 2.2] (61) | 1.5 ± 0.5 [0.5, 2.9] (57) | 1.5 ± 0.6 [0.4, 4.1] (46) |
| 25 mm | 1.6 ± 0.6 [0.6, 4.6] (116) | 1.6 ± 0.5 [0.3, 3.2] (108) | 1.7 ± 0.5 [0.6, 3.8] (111) |
| 27 mm | 1.9 ± 0.6 [0.4, 3.5] (171) | 2.0 ± 0.5 [0.9, 3.9] (160) | 2.0 ± 0.6 [0.9, 4.9] (156) |
| 29 mm | 2.2 ± 0.7 [0.9, 5.9] (139) | 2.3 ± 0.7 [1.0, 4.9] (139) | 2.5 ± 0.8 [1.0, 5.9] (129) |

[1] Post-operative evaluation conducted at 30-days post-implantation or hospital discharge.
[2] Average level of regurgitation (0+ = none, 1+ = trivial, 2+ = mild, 3+ = moderate, 4+ = severe)
[3] Data pooled from valve sizes 20 mm, 21 mm, and 22 mm

# 8. INDIVIDUALIZATION OF TREATMENT

### *8.1 Anticoagulant and/or Antiplatelet Therapy*

Long term anticoagulant and/or antiplatelet therapy should be considered in patients with dilated left atrium, a history of thrombotic events, or a cardiac rhythm of atrial fibrillation or flutter.

### *8.2 Specific Patient Populations*

Safety and effectiveness of the Toronto SPV® valve have not been established for the following specific populations:

- patients in whom the Toronto SPV® valve has been implanted for longer than 4 years (see section 7. Clinical Studies);
- 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.

# 9. PATIENT COUNSELING INFORMATION

Patients may require anticoagulant and/or antiplatelet therapy for an indefinite period based on the patient's condition.

Patients with bioprosthetic valves who undergo dental or other potentially bacteremic procedures must be considered for prophylactic antibiotic therapy.

# 10. HOW SUPPLIED

The Toronto SPV® valve is available in tissue annulus sizes 21mm to 29mm.

**Table 10.1: Valve Specifications**

| Model Number | Valve Diameter |
|---|---|
| SPA-101-21 | 21 |
| SPA-101-23 | 23 |
| SPA-101-25 | 25 |
| SPA-101-27 | 27 |
| SPA-101-29 | 29 |

### *10.1 Packaging*

All valves are supplied STERILE in a buffered 0.5% glutaraldehyde storage solution. Sterility may be compromised if the package is opened and/or damaged.

As delivered, the valve is attached to a valve holder and to a tripod. The tripod protects the valve from damage during shipping or storage. The valve holder facilitates handling and manipulation of the valve during removal from the container, rinsing and implantation.

### *10.2 Storage*

The Toronto SPV® valve must be stored between 5° and 25°C (41° and 77°F). Refrigeration is not required, and freezing may damage the valve. Room temperature storage (up to 25°C or 77°F) is satisfactory, provided the bioprosthesis is not exposed to sunlight or other ultraviolet light sources or placed where significant temperature fluctuations may occur.

The storage life of the Toronto SPV® valve is 4 years from date of sterilization. Appropriate inventory control should be maintained so that bioprostheses with earlier expiration dates are preferentially implanted and expiration is avoided.

# 11. DIRECTIONS FOR USE

### *11. 1 Physician Training*

The function of a stentless bioprosthetic valve is sensitive to surgical implantation technique. Implanting physicians must be familiar with the techniques for implanting an unstented bioprosthesis. These techniques are similar to those required for allograft implantation.

### *11.2 Device Features*

The Toronto SPV® valve is a stentless bioprosthesis supplied (prepared) for subcoronary replacement of the native or prosthetic aortic valve. The prosthesis is covered with a thin polyester layer on the external surface, facilitating suturing and handling and promoting tissue ingrowth. The inflow edge is marked with three green sutures at the commissures for orientation during prosthetic valve implantation. The prosthesis is cross-linked at low pressure in 0.5% glutaraldehyde.

### *11.3 Sizing and Handling*

The Toronto SPV® valve with attached holder is packaged in a polypropylene container with a screw-top closure and seal. The container is filled with 0.5% glutaraldehyde solution. The contents of the container are sterile, and must be handled aseptically.

***WARNING:*** **FOR SINGLE USE ONLY**

**DO NOT RESTERILIZE** the valve by any method. Exposure of the valve and container to irradiation, steam, ethylene oxide or other chemical sterilants will render the valve unfit for use.

**Do not use** the Toronto SPV® valve:

- if the tamper-evident seal is broken;
- if the glutaraldehyde storage solution does not completely cover the valve;
- if the valve has been exposed to freezing or has had prolonged exposure to heat as indicated by the temperature indicators provided in the packaging (see section 10 storage);
- if the valve is damaged.

Notify your St. Jude Medical, Inc. representative if this occurs



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# 11. DIRECTIONS FOR USE *(continued)*

## SURGICAL GUIDELINES

***CAUTION:*** ***Do not*** lacerate the valve tissue. If a valve is damaged, the valve must be explanted and replaced.

***Do not*** attempt repair of valves. Damaged valves must not be used.

***Do not*** evert the valve. Eversion will damage valve tissue.

## AORTOTOMY AND DEBRIDEMENT

A transverse aortotomy should be performed approximately 1 cm above the level of the right coronary artery. The diseased aortic valve must be completely excised. All calcific debris must be carefully removed from the aortic annulus and aortic sinuses.

## SIZING

The diameter of both the aortic annulus and the sinotubular junction immediately above the sinuses must be determined using the Toronto SPV® valve sizers.

The Toronto SPV® valve is contraindicated for use in patients where the diameter of the aortic annulus is larger than the diameter of the sinotubular junction, or where the diameter of the aortic annulus is more than 10% smaller than the diameter of the sinotubular junction. Excessive mismatch my cause central incompetence and/or stenosis of the bioprosthesis.

### Sizing the Sinotubular Junction

Measure the diameter of the sinotubular junction immediately above the aortic sinuses using the Toronto SPV® valve sizers. The appropriate sizer should have a snug, but not tight, fit (see figure 11.1).

### Sizing the Aortic Annulus

Measure the diameter of the aortic annulus using the Toronto SPV® valve sizers. The appropriate sizer should pass through the aortic annulus, and have a snug, but not tight, fit (see figure 11.2).

The diameter of the sinotubular junction determines the size of the Toronto SPV® valve to be used. For example, if the diameter of the sinotubular junction is 27mm, and the aortic annulus is between 25 and 27mm, a 27mm Toronto SPV® valve should be selected.

**Figure 11.1**

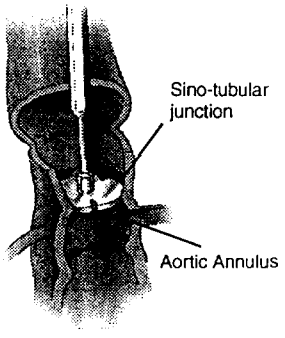



**Figure 11.2**

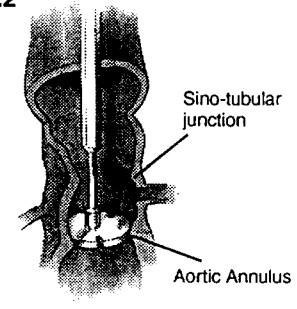



**Table 11.1: Valve Size Recommendations**

| If diameter of the sinotubular junction is: | And diameter of the aortic annulus is: | Use valve size |
|---|---|---|
| 21mm | 19-21mm | 21mm |
| 23mm | 21-23mm | 23mm |
| 25mm | 23-25mm | 25mm |
| 27mm | 25-27mm | 27mm |
| 29mm | 27-29mm | 29mm |

## 11. DIRECTIONS FOR USE *(continued)*

### Removing the valve from the outer package (Circulating Nurse)

***CAUTION:*** ***Do not*** place the non-sterile exterior of the valve container on the sterile field.

***Do not*** expose the valve to solutions other than the storage 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*** allow the valve tissue to dry. Continuous submersion or irrigation is required.

***Do not*** add antibiotics to either the storage or the rinse solution. Do not apply antibiotics to the valve.

Passage of a catheter through any bioprosthesis may damage the valve and is, therefore, not recommended.

1. Within the sterile field, prepare 3 sterile basins containing 500 ml sterile isotonic saline.
2. Choose a valve of the appropriate size.
3. Once the valve container has been removed from the outer packaging, examine the container for evidence of damage, leakage, and broken or missing seals. The valve must not be implanted if the container is damaged, leaking or has broken or missing seals.
4. Verify the valve size on the label.
5. To remove the valve from the container, break the seal and remove the screw-top closure.
6. Firmly hold the container while the scrub nurse or surgeon removes the valve.

***CAUTION:*** ***Do not*** breathe the glutaraldehyde storage solution vapor. Avoid prolonged contact with the 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.

### Placing the valve in the sterile field

1. With the circulating nurse firmly holding the container, a member of the operating team uses slight pressure to insert the sterilized handle into the center of the holder (see figure 11.3).
2. Remove the valve from the container using the handle (see figure 11 4).
3. Separate the valve from the tripod used for packaging by cutting the suture that holds the tripod closed (see figure 11.5).
4. Inspect the valve for damage.

**Figure 11.3**

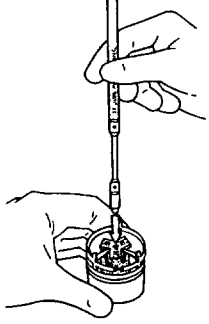


**Figure 11.4**

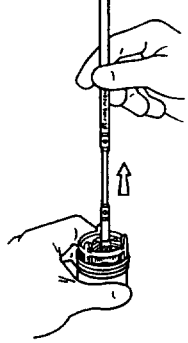
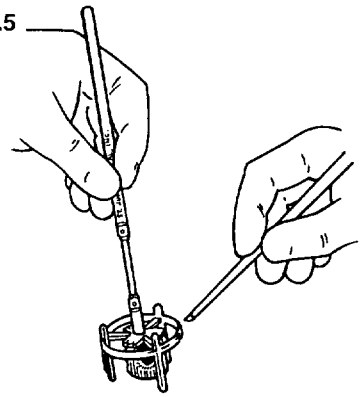


**Figure 11.5**



### Rinse procedure (Scrub Nurse)

1. Holding the valve by the handle, fully immerse the valve in sterile isotonic saline in the first basin.
2. Continually rinse the valve for three minutes, using a gentle back-and-forth motion.
3. Repeat this procedure in the remaining two basins of saline.
4. After rinsing, the valve must remain immersed in the third basin of saline until used.

***CAUTION:*** ***Do not*** allow the valve tissue to dry. Continuously irrigate the valve with sterile isotonic saline solution from the time it is removed from the container through implantation.

### *11.4 Device Implantation*

**SUTURING GUIDELINES**

While suturing techniques for individual patients should be selected by the implanting surgeon, the following procedures provide guidelines based upon existing clinical experience.

#### Inflow Tract Suture Placement

***CAUTION:*** ***Place sutures*** below the suture line running circumferentially around the base of the inflow edge of the valve. This will reduce the risk of damaging a valve leaflet.

The Toronto SPV® valve sizer also aids in valve orientation. Insert the selected valve sizer intra-annularly to determine the plane in which the inflow edge of the Toronto SPV® valve should lie. Sutures should be placed in a plane perpendicular to the lowest point of two of the three aortic sinuses. In a situation with one low-lying sinus, it may be necessary to orient the valve so that part of the inflow edge is supra-annular and part is intra-annular.

***CAUTION:*** Aortic insufficiency may result from **misalignment of the valve commissures** or failure to place the inflow edge of the valve in a plane perpendicular to the longitudinal axis of the ascending aorta.

The sizer has three evenly spaced notches at 0°, 120° and 240° to provide guidance for suture placement. The notches correspond approximately to the commissures of the prosthetic valve. With the sizer in the annulus, use the notches to orient the prosthetic valve's commissures with respect to the coronary ostia. The height of the valve commissures and sinuses and the shape of the aortic root must also be considered. In a normal tricuspid aortic valve, with normal location of the ostia, the sizer notches would align with the native valve commissures.

Use double-armed 4-0 braided polyester sutures. Once the correct plane for the inflow edge of the valve has been determined, place three sutures through the native aortic annulus (inflow side to outflow side) corresponding to the notches on the sizer. Tag these sutures which will correspond to the prosthetic valve commissures (see figure 11.6).

Place simple interrupted sutures approximately 3 mm apart in equal numbers between the three marked sutures.

The Toronto SPV® valve has three green sutures at the base of the inflow edge which approximately identify the location of the valve commissures. Place each of the three tagged sutures at an appropriate green marker below the circumferential line on the prosthesis. This assures correct orientation of the valve in the annulus. Place the remaining sutures in a similar manner.

Once all the inflow sutures have been placed, carefully remove the valve from the holder by cutting the three retaining sutures at the scalpel guides on the valve holder. Carefully pulling on all sutures, gently "parachute" the valve into the annulus. Check for proper suture alignment and tie down all sutures. The suture knots should lie between the Toronto SPV® valve and the aortic wall.

***CAUTION:*** ***Cut interrupted*** sutures close to the knots so that the suture tails will not come in contact with, and thus potentially damage, cusp tissue.

#### Outflow Tract Suture Placement

***CAUTION:*** ***Inspect the*** Toronto SPV® valve often during suturing to assure proper leaflet coaptation. Either insufficient or excessive tension supporting the commissures may result in valvular incompetence. If necessary, reposition one or more commissural stitches and realign both circumferentially and vertically until normal coaptation of the leaflet(s) is observed.

***Extreme care*** must be exercised during outflow suturing to avoid damage to the leaflets of the valve.

Double-armed 4-0 polypropylene sutures are used for the outflow tract. Beginning with the commissure between the left and right cusps at the outflow orifice, secure the valve above the commissure to the host aortic wall with an inside-to-outside horizontal mattress suture technique. While carefully maintaining the shape of the Toronto SPV® valve, use a running technique to start a suture line from the base of the sinus, or top of the commissure (see figure11.7).

Carefully align a second commissure so that the leaflet assumes a natural, cupped shape. The polyester fabric on the valve should not appear wrinkled, as this indicates incorrect alignment. If it does, realign the second commissure. Secure the second commissure to the aortic wall with a horizontal mattress suture. Complete the first running suture line to the second commissure. Tie off the suture outside the aorta.

Repeat this suturing procedure until all three commissures are secured to the aortic wall and the running sutures are completed around the entire outflow edge of the valve.

**Figure11.6**

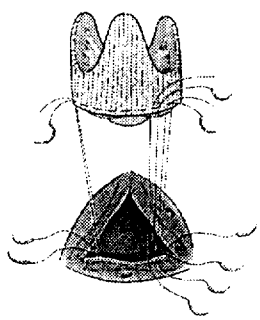
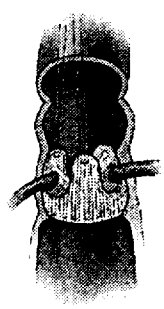


**Figure 11.7**



Align and Tag Commissures

## 11. DIRECTIONS FOR USE *(continued)*

**INTRA-OPERATIVE ASSESSMENT**

The suggested method for assessing competence of the Toronto SPV® valve is with Doppler echocardiography.

### *11.5 Accessories*

**NOTE:** Use only St. Jude Medical, Inc. SPA 300 sizers and accessories to size the Toronto SPV® valve.

## 12. POSTOPERATIVE INFORMATION

### *12.1 Catheterization*

Passage of a catheter through any bioprosthesis may damage the valve and is, therefore, not recommended.

### *12.2 Return of Explanted Bioprosthetic Valves*

St. Jude Medical, Inc. is extremely interested in obtaining recovered clinical specimens of the Toronto SPV® valve. Specific pathological studies of the explant will be determined by the SJM Field Experience Review Board under the direction of the consulting pathologist. A written report summarizing our findings will be returned to you. Please contact St. Jude Medical, Inc. to obtain a Product Return Kit and Return Material Authorization Number (RMA#), protocol, and explant pathology information form. The explanted valve should be placed, completely submersed in 10% formalin, immediately after excision unless otherwise directed by your SJM representative.

## 13. PATIENT INFORMATION

### *13.1 Registration Information*

A patient registration form is included in each valve package. After implantation, please complete all requested information. Return the original form to the address indicated on the patient registration form. To maintain traceability records, Federal law (USA) requires that all patient registration forms be completed at the time of implant and returned to St. Jude Medical, Inc. Upon receipt of the registration, the company will send the patient a wallet-size information card.

An Implanted Device Identification Card is provided to the patient. The card contains the name and telephone number of the patient's physician, as well as, information that medical personnel would require in the event of an emergency.

The circulating nurse is responsible for completing all requested information.

### *13.2 Description of the Patient's Manual*

Prior to hospital discharge, the patient should receive the Toronto SPV® Valve Patient Educational Booklet. This booklet provides the patient with information on heart valve disease and on managing their long term health with the Toronto SPV® valve. Nursing personnel should fill out necessary clinical information at the back of the booklet.

## 14. REFERENCES


1 David TE, Feindel CM, Bos J, Sun Z, Scully HE, Rakowski H. Aortic valve replacement with a stentless porcine aortic valve. J Thorac and Cardiovasc Surg 1994;108;6:1030-6.

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3 Jin XY, Zhang Z, Gibson DG, Yacoub MH, Pepper JR. Effects of valve substitute on changes in left ventricular function and hypertrophy after aortic valve replacement. Ann Thorac Surg 1996;62:683-90.

4 Walther T, Falk V, Autschbach R, Scheidt A, Baryalei M, Schindewolf K, Dalichau H, Mohr FW. Hemodynamic assessment of the stentless Toronto SPV bioprosthesis by echocardiography. J Heart Valve Dis 1994;3:6:657-65.

5 David TE. Implantation Technique for the Toronto SPV™ Bioprosthesis. In *Surgery For Acquired Aortic Valve Disease*, Ed. A. Piwnica and S. Westaby., pp.102-109. Oxford: Isis Medical Media, Ltd., 1997.




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## CLINICAL INFORMATION

*Have your nurse complete the information on this page.*

CLINICAL CENTER

CARDIAC SURGEON

Address

Phone

Next Appointment

CARDIOLOGIST

Address

Next Appointment

## NOTES:

ST. JUDE MEDICAL
HEART VALVE DIVISION

*Visit our Website at http://www.sjm.com*

CAUTION: FEDERAL LAW RESTRICTS THIS DEVICE TO SALE, DISTRIBUTION AND USE BY OR ON THE ORDER OF A PHYSICIAN.
Refer to the physician's manual provided with each device for detailed instructions for use, warnings, precautions and possible adverse device effects.

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# THE TORONTO SPV© VALVE PATIENT EDUCATIONAL BOOKLET

ST. JUDE MEDICAL
HEART VALVE DIVISION

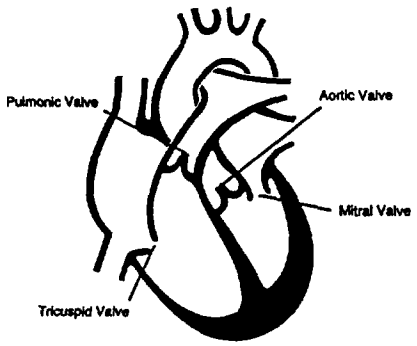
*Your role in the management of your health is very important. We hope you find this booklet interesting and helpful when making these clinical decisions. This information is not intended to replace the medical advice of your physician. If the information you receive from your physician differs from this brochure, always follow your physicians' instructions.*

**How Your Heart Works**

The main job of the heart is to pump oxygen-rich blood through your body. It does this by pumping an average of 60-90 times a minute.

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

There are four valves in the heart. Two of these valves are between the upper and lower chambers of the heart. The other valves are between the lower chambers and the large vessels that leave your heart. The valves that most frequently need replacement are the aortic and mitral valves. The St. Jude Medical Toronto SPV® valve is only intended for aortic valve replacement.




**Valvular Heart Disease**

Heart valves may fail to function properly for a variety of reasons. Rheumatic fever, the most common cause, causes a valve to stiffen over time. This limits the ability of the valve to open and close properly. Some people are born with heart valve defects while others acquire valve damage from infection or other diseases. The results are the same: a rigid valve limiting forward blood flow (called a stenotic valve) or a valve which does not close properly permitting back flow (called an incompetent or regurgitant valve).

The result of valve disease is a decrease in the heart's pumping ability. This contributes to the shortness of breath, dizziness, chest pain or a tired feeling you may have experienced.

**Toronto SPV Valve**

The Toronto SPV® valve was first implanted in patients in 1991.

The Toronto SPV® valve is a heart valve developed from a pig (porcine)valve. The valve has been chemically treated and prepared for human implantation.

Conventional tissue valves have a stent, or plastic frame, supporting the valve. The Toronto SPV® valve is a stentless design. Instead of a plastic frame supporting the valve, the native aortic wall supports the valve. Eliminating the stent allows a larger valve to be implanted, thus providing more area for blood to flow across.

**Returning Home**

Long-term management of your health requires your active participation. With your physician, you can work toward a healthy recovery. 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 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

Follow the guidelines your physician has given you regarding diet, exercise and medications and keep all scheduled appointments.

Consult your physician about any concerns or questions you have about your health. Together with your physician, you can work toward a healthy recovery.