Abbott

LIVING WITH YOUR NEW HEART VALVE

An Educational Booklet for Recipients of the Abbott Trifecta™ GT Valve

See Important Safety Information referenced within.

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.

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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 1).

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.

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

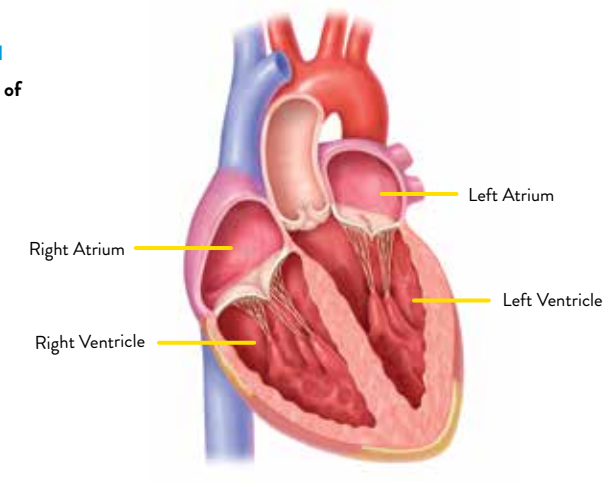
Valves also separate the ventricles and the large blood vessels that carry blood away from the heart. Blood flows through the pulmonic valve between the right ventricle and pulmonary artery and lungs. On the left side of the heart, blood flows through the left ventricle into the aorta through the aortic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

ABOUT VALVULAR HEART DISEASE

Heart valves may become defective for a variety of reasons. Some people are born with heart valve defects, while others suffer valve damage from infection or other diseases.

▶ **FIGURE 1**

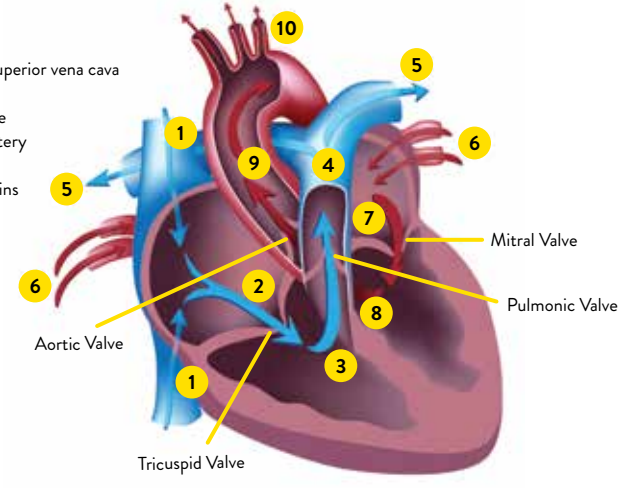
Chambers of the Heart



▶ **FIGURE 2**

Heart Valves

1 Inferior and superior vena cava
2 Right atrium
3 Right ventricle
4 Pulmonary artery
5 Lungs
6 Pulmonary veins
7 Left atrium
8 Left ventricle
9 Aorta
10 Body



The results are either a rigid valve that does not open properly and limits forward blood flow or a valve that does not close properly and permits improper backflow.

Either condition reduces 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 BENEFITS

Heart valve repair surgery can offer several important 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, manmade 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. Mechanical heart valves are implanted using open heart surgery.

Patients with mechanical replacement heart valves must take daily blood thinner (also knowns as anticoagulation) medication to minimize the risk of complications from blood clots.

Bioprosthetic heart valves are made with tissue from pig or cow heart tissue (or a combination of the two). These tissue replacement heart valves are designed to function similar to human heart valves. Bioprosthetic heart valves may be implanted with either open heart surgery or through a small incision in your groin where the tissue valve is inserted through a catheter into your heart. 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 Abbott valve is very durable and may last beyond 30 years.[1-2] However, complications unrelated to valve deterioration may impair valve function, necessitating valve replacement.

Tissue valve durability is dependent on a multitude of factors. Aortic valves tend to last longer than mitral valves in clinical 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.

BACKGROUND & PRODUCT DESCRIPTION — TRIFECTA™ GT VALVE

The Trifecta valve was first introduced into human use during a premarket study conducted between 2007 and 2009. Based on the results of this study the Trifecta valve was approved for use in the United States in 2011. In 2016 a second-generation Trifecta GT (Glide™ Technology) valve was approved for use.

The Trifecta GT valve is a stented bioprosthetic valve made partly with tissue from porcine (pig) or bovine (cow) hearts, which function similarly to human heart valves (Figure 3). The animal tissue has been treated to preserve it and prevent adverse reactions once it is implanted. The Trifecta GT valve has three leaflets made of bovine tissue that are mounted on the outside of a titanium frame (also called a stent) to maximize valve opening.

The Trifecta valve has the benefit of having a large opening area (Figure 4) which decreases the workload of your heart particularly during physical activity.[3]

The Trifecta GT valve is implanted using open heart surgery. The sewing cuff is shaped to enable the surgeon to sew the valve securely into place in the heart (Figure 5).

FIGURE 3

Trifecta GT Valve

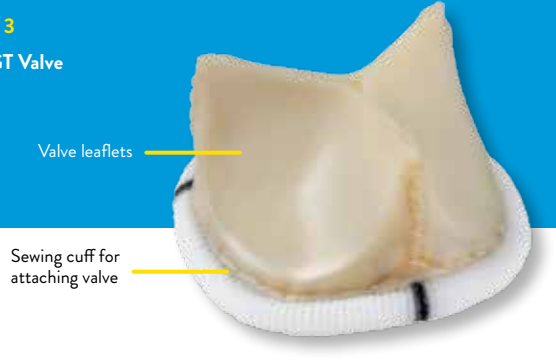


FIGURE 4

Trifecta GT Valve Opening: Expansive, Externally-Mounted Leaflet Design

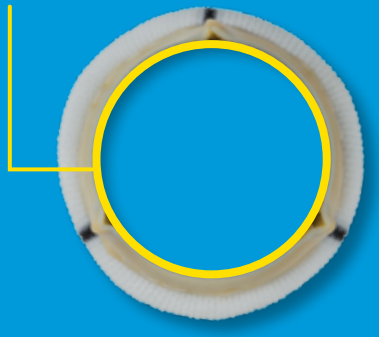
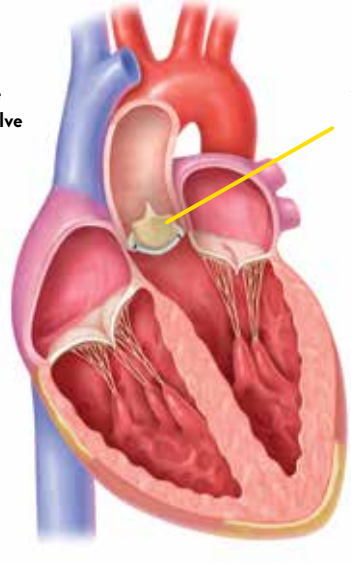


FIGURE 5

Position of the Trifecta GT Valve in the Heart



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.

VALVE REPLACEMENT SURGERY

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 afterward 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 healthcare 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 six to eight 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 blood clots.

When to Call the Doctor

Following your surgery 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 (blood will typically look like tar after it has been exposed to the body's digestive juices)
- Unusual nosebleeds
- Fever
- Numbness or tingling in your arms or legs
- General weakness or loss of energy
- Blurred vision or loss of vision
- Unusual chest sensation

Returning Home

Your involvement in caring for the health of your heart begins now. By understanding the recovery process and lifelong 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 six to eight weeks before you are able to return to your normal routine. You will typically 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 three weeks, you may need to undergo tests such as an electrocardiogram (EKG), ultrasound of your heart (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.

Contact your physician if you develop any health concerns after the procedure or at anytime in the future.

Once you are fully recovered from the surgery, you will need to visit your doctor(s) at least once a year to make sure your artificial valve is working correctly.

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

- 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 imaging), 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. (See page 19 for more information.)

LONG TERM CARE

During your annual follow-up visits your doctor(s) will perform a history and physical examination and monitor your artificial valve for any symptoms or signs of valve deterioration. Your doctor will check your heart and when needed perform an echocardiogram to check the status of your artificial valve.

It is important to remember to keep your annual doctor(s) visits because sometimes your artificial valve may experience *structural valve deterioration* (SVD) or other potential adverse events as listed on page 20 depending on your age and other risk factors.

What is Structural Valve Deterioration:

Structural valve deterioration (SVD) is a known potential adverse event of the valve in which the leaflet tissue is permanently degraded by biological factors and mechanical stress that occurs over the valve's lifetime.

SVD may cause the leaflet tissue to become thicker due to calcification or thinner with loss of tissue fibers. Calcified leaflets may prevent the valve from fully opening and thin leaflets may become torn and result in a leaky valve. Depending on the severity of SVD you may experience symptoms and require treatment.

Accelerated SVD due to leaflet calcification of the Trifecta™ GT 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.

SVD sometimes may also become accelerated whenever the valve size selected for implant is larger than can easily fit into your heart[4-5].

When to Call the Doctor:

Contact your physician(s) if you experience any of the following symptoms which may be related to your artificial valve:

- Shortness of breath
- Difficulty breathing during physical exertion or when lying flat
- General weakness, fatigue, or loss of energy
- Decreased ability to perform physical activities
- Chest, jaw, shoulder, or arm pain
- Unusual chest sensation
- Rapid heart rate
- Dizziness or fainting
- Swelling in your feet or ankles
- Fever, chills, or night sweats

Depending on your symptoms your physician may decide to perform an evaluation which may include an echocardiogram to check the status of your artificial valve.

Patients who experience a leaflet tear may develop symptoms rapidly over several days, while patients who experience leaflet calcification are more likely to develop symptoms gradually over several months to years.

Treatment options for SVD:

In the event your are found to have mild SVD with minimal symptoms your physician may recommend waiting before doing any treatment and to keep monitoring your valve during follow-up visits.

In the event you are found to have significant symptoms related to severe SVD your physician may recommend treatment to fix your artificial valve.

One treatment option is to undergo a minimally invasive procedure where a second valve is inserted into your artificial valve (also called valve-in-valve) using a catheter that is placed from your groin. A second treatment option is to undergo repeat surgery to replace your artificial valve similar to the surgery performed the first time the valve was implanted. Your physician will discuss with you and recommend which treatment option is best depending on your condition and preferences.

Under rare circumstances, if you do not seek medical attention in a timely manner and a decision is made not to treat severe SVD, you may not survive long-term.

REMINDERS

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.

Remember to:

- Take medication as prescribed.
- Follow-up with blood tests as directed by your physician.
- Enjoy a heart-healthy diet.
- Call your doctor if you experience any symptoms or signs of SVD or if you have any concerns regarding your health.

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 and tissue heart valves and heart valve rings is very small. It is usually not enough to set off the metal detectors, but 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 Abbott to request a card:

Abbott Patient Device Tracking Customer Service

Toll-free Phone Number: 1-800-550-1648

Email: SY_PDTA@abbott.com

MRI TESTING

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 or MRI technician may request the following information:

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

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

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 include the following. See Glossary on page 21 for any unfamiliar terms.

- 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. Abbott, as a manufacturer of medical devices, does not provide medical advice.

Abbott Customer Service

Toll-free Phone Number: 800-328-3873

Email: sjm-customerservice@abbott.com

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 the left ventricle and the 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
Echocardiogram	Ultrasound imaging of your heart that can be used to assess the function of your artificial valve.
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
Pericardial	Made of tissue from the pericardium — the protective sack that surrounds the heart
Perivalvular Leak	Leak near the valve
Polyester Cloth	Manmade material used to create the sewing cuff that is used to secure the implanted valve to the tissue
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
Valve-in-Valve	A minimally invasive procedure in which a new tissue valve is implanted inside a previously implanted tissue valve using a catheter that is inserted from the groin.
Valvular Pannus	Abnormally thick tissue around the valve

1. Saito, Satoshi, Hiroyuki Tsukui, Shizuko Iwasa, Nobuhiro Umehara, Hideyuki Tomioka, Shigeyuki Aomi, and Kenji Yamazaki. "Bileaflet mechanical valve replacement: an assessment of outcomes with 30 years of follow-up." *Interactive CardioVascular and Thoracic Surgery* 23, no. 4 (2016): 599-607. **2.** Johnson, Scott, Martha R. Stroud, John M. Kratz, Scott M. Bradley, Fred A. Crawford Jr, and John S. Ikonomidis. "Thirty-year experience with a bileaflet mechanical valve prosthesis." *The Journal of Thoracic and Cardiovascular Surgery* 157, no. 1 (2019): 213-222. **3.** Stock, Sina, Inga Lohmann, Thorsten Hanke, Ulrich Stierle, Doreen Richardt, Stanislav Tsvelodub, and Hans-Hinrich Sievers. "Rest and exercise haemodynamics in patients with one of two stented bioprostheses and in healthy controls with small aortic annuli." *Interactive CardioVascular and Thoracic Surgery* 26, no. 3 (2018): 425-430. **4.** Goldman, Scott. "Bigger valve size is not always better." *The Journal of Thoracic and Cardiovascular Surgery* 154, no. 3 (2017): 820-821. **5.** Escalera, Alain, Isaac Pascual, Daniel Hernandez-Vaquero, Francesco Formica, Julio Casares, Rocio Diaz, Ruben Alvarez et al. "Association of the Surgical Technique With the Structural Valve Deterioration of a Bioprosthesis: A Prospective Cohort Study." *In Seminars in Thoracic and Cardiovascular Surgery*. WB Saunders, 2022.

IMPORTANT SAFETY INFORMATION

℞ ONLY TRIFECTA™ VALVE WITH GLIDE™ TECHNOLOGY (GT)

INDICATION 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 the 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.
- 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 sizers[1] 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

IMPORTANT SAFETY INFORMATION (CONTINUED)

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.

POTENTIAL 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.

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

CAUTION: This product is intended for use by or under the direction of a physician. Prior to use, reference the Instructions for Use, inside the product carton (when available) or at eifu.abbottvascular.com or at medical.abbott/manuals for more detailed information on Indications, Contraindications, Warnings, Precautions and Adverse Events.

Illustrations are artist's representations only and should not be considered as engineering drawings or photographs.

Photos on file at Abbott.

Abbott
3200 Lakeside Dr., Santa Clara, CA 95054 USA, Tel: 1 800 227 9902
www.structuralheart.abbott

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