Technical Bulletin

Trifecta Valve (Models TF-19A, TF-21A, TF23A, TF25A, TF-27A, and TF-29A) and Trifecta Valve with Glide Technology (Models TFGT-19A, TFGT-21A, TFGT-23A, TFGT-25A, TFGT-27A, and TFGT-29A)

16 July 2020

Dear Clinician,

This Technical Bulletin is intended to summarize the key design changes made to the Trifecta valve from the first-generation Trifecta valve to the second-generation valve reflecting Abbott's commitment to the quality and continuous improvement of our medical devices. In addition, this Technical Bulletin provides a summary of the clinical outcomes achieved at 10 years post-implant for the first-generation Trifecta valve along with information on failure modes. In particular, the Technical Bulletin is intended to raise awareness of the potential for a non-calcific leaflet tear and the importance of implanting the valve in accordance with the Instructions for Use (IFU). A summary of the valve sizing and handling guidelines taken from the IFU, which are important for ensuring optimal valve function and durability, is included in the appendix for reference.

The first-generation Trifecta valve was introduced into clinical use in 2007, designed for supra-annular implantation and excellent hemodynamic performance[1]. The first-generation Trifecta valve has a titanium stent that may be inadvertently deformed in the setting of oversizing and/or a forceful valve insertion, which have the potential to result in valvular incompetence and diminished tissue durability. To ease the implant procedure and provide added handling protection to the stent and leaflets, a second-generation Trifecta valve with Glide Technology (Trifecta GT) was introduced in 2016[2].

The Trifecta GT valve has the following enhancements[2,3].

1) A streamlined holder with legs positioned in front of the leaflets for added protection during valve insertion and knot tying;
2) Internal backstops within the holder to protect the stent posts from deforming during valve insertion;
3) A softer sewing cuff that conforms more easily to the annulus and which minimizes suture drag;
4) An additional titanium band that protects the stent base geometry and provides enhanced fluoroscopic visibility;
5) Revised leaflet suturing process along the stent post to reduce leaflet stress;
6) Implemented an additional collagen fiber alignment technology to control circumferential fiber alignment in an effort to maximize tissue tensile strength and resist fatigue related leaflet tissue degradation.

At the same time the Trifecta GT valve was being developed, an improved version of the first-generation Trifecta valve was produced which included the same manufacturing processes utilized on Trifecta GT to improve the leaflet suturing pattern along the stent post, and the leaflet collagen fiber alignment. These two improvements, which are listed as items #5 and #6 above, were introduced to both Trifecta and Trifecta GT to enhance the durability of the leaflet tissue in attempt to minimize the occurrence of a non-calcific leaflet tear when combined with appropriate valve sizing and handling.

To further ease the implant procedure and improve access to the sewing cuff while suturing, a new holder is now being introduced to the Trifecta GT valve. The new holder has legs with a narrower footprint to permit easier access to the sewing cuff during placement of sutures while retaining the same protective features of the original Trifecta GT holder. The following figures illustrate (1) the evolution of the Trifecta valve timeline; and (2) the specific enhancements introduced with Trifecta GT.

Figure 1: The evolution of the Trifecta valve timeline

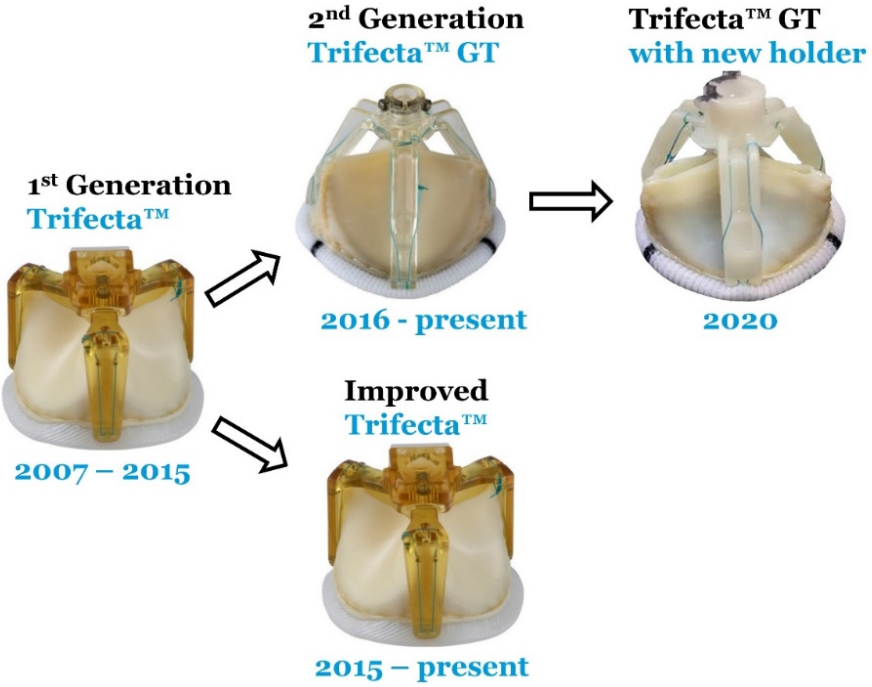
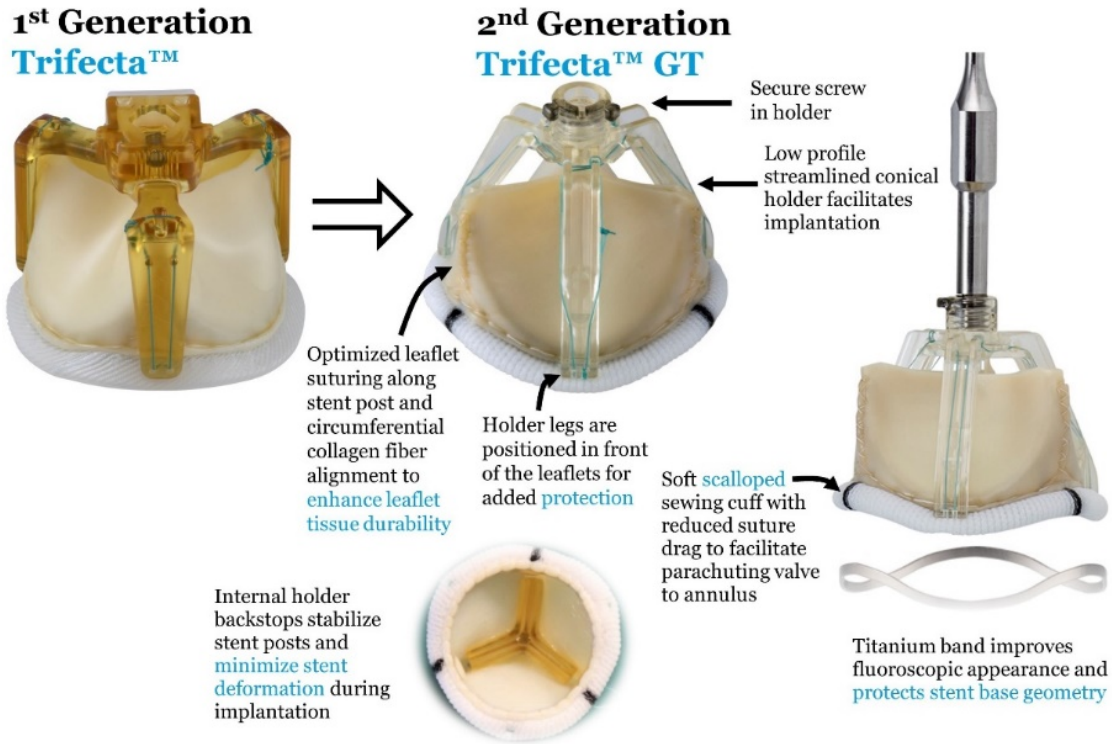


Figure 2: The specific enhancements introduced with Trifecta GT



Bioprosthetic heart valves have a potential for developing either non-structural valve dysfunction (NSVD[4]) or structural valve deterioration (SVD[4]) over the lifetime of the valve. NSVD is characterized as any abnormality not intrinsic to the valve itself (such as entrapment by pannus, tissue, or suture; paravalvular leak; and inappropriate sizing or positioning) that may result in stenosis or regurgitation of the operated valve or hemolysis. SVD is characterized as changes intrinsic to the valve itself (such as calcification, leaflet fibrosis, leaflet tear, or flail leaflet) that may result in stenosis or regurgitation due to irreversible valve degeneration. Two known modes of SVD observed with tissue heart valves are fibrous-calcific structural valve deterioration (FCSVD) and a non-calcific leaflet tear (NCLT).

- FCSVD is characterized by fibrous thickening of the leaflet tissue and/or infiltration of the leaflet tissue with calcium deposits resulting in decreased leaflet mobility (aortic stenosis). Echocardiography demonstrates an elevated transvalvular gradient but may sometimes also show aortic insufficiency secondary to incomplete leaflet coaptation due to leaflet stiffening.
- NCLT is characterized by thinning of the leaflet tissue with loss and disruption of collagen fibers at the tear site with absence of leaflet fibrosis and calcification. Echocardiography demonstrates aortic insufficiency without an elevated transvalvular gradient.

There are multiple factors that have the potential to influence the occurrence of NSVD and SVD. NSVD may commonly be attributed to technical factors encountered at the time of valve implant[1,2], while SVD may commonly be attributed to biological factors and mechanical stress which develop over a longer implant duration[3]. Specific factors with a potential to influence the occurrence of NCLT[3] include:

- Implant-related technical factors such as oversizing and mishandling of the valve that may result in stent deformation with localized increases in leaflet stress and/or interaction of the stent post with the aortic wall; and
- Biological factors and mechanical stress occurring over the lifetime of the valve which may result in pannus formation with uneven leaflet stress distribution and degeneration of the collagen fibers with thinning and diminished durability of the leaflet tissue.

The enhancements introduced with the Trifecta GT valve (Figure 2) were implemented to ease the implant procedure, provide added handling protection to the stent and leaflets, and enhance the durability of the leaflet tissue when combined with appropriate valve sizing and handling[1-3]. As of March 31st, 2020, the overall estimated global incidence of NCLT determined for each iteration of the Trifecta valve (# reported events/# units distributed) is 0.30% for the 1st generation Trifecta valve, 0.18% for the Improved Trifecta valve, and 0.05% for the Trifecta GT valve[5]. The overall incidence of NCLT in the USA for the various iterations of the Trifecta valve is 0.18% for the 1st generation Trifecta valve, 0.12% for the Improved Trifecta valve, and 0.02% for the Trifecta GT valve[5]. Each patient implanted with the 1st generation Trifecta valve should continue to receive appropriate follow-up per established local standards of care and institutional practices, while balancing the risks associated with the COVID-19 pandemic.

To assess the long-term clinical outcomes of the first-generation Trifecta valve, Abbott conducted a Long-Term Follow-Study (ClinicalTrials.gov NCT01593917)[5]. The 10-year follow-up from this study was recently completed and demonstrated excellent hemodynamic performance at 10 years (mean transvalvular gradient of 15.6 mmHg). At 10 years post implant, the freedom from all-cause mortality was 70%, the freedom from surgical explant due to SVD was 87%, and the freedom from any reintervention (surgical explant or transcatheter valve-in-valve intervention) due to SVD was 75%. The freedom from any reintervention and all-cause mortality at 10 years post-implant was 51%, which is consistent with the rate reported for other bioprosthetic aortic valves[6,7]. Additionally, the freedom from any reintervention at 8 years post-implant was 88.3%, which is comparable with the rate reported from a prospective contemporary study for a competitor valve (89.8%)[8]. In choosing a bioprosthetic aortic valve, the potential for SVD should be balanced against the potential hemodynamic and survival benefits of the Trifecta valve. In comparison to the first-generation Trifecta valve, the Trifecta GT valve has additional features that make the valve easier to implant and potentially reduce the occurrence of NSVD and SVD over the lifetime of the valve.

In summary, the Trifecta and Trifecta GT valves have been designed and continuously improved with the aim to optimize performance by easing valve implantation and minimizing leaflet tissue damage. These design characteristics, in combination with proper valve sizing and handling in accordance with the IFU (see Appendix for further details), minimize the potential for developing NSVD and SVD, leading to the best clinical outcomes.

With the launch of the Trifecta GT valve with the new holder, physician training will be provided for new and existing users to reinforce best practices when implanting the Trifecta valve and raise awareness of NCLT. If you have any questions about this communication or become aware of any adverse events associated with the Trifecta or Trifecta GT valves, please contact and report the information to Abbott Customer Service at 1-800-544-1664 or to your local Abbott representative.

Sincerely,

Kara Carter
Divisional Vice President, Quality
Structural Heart

References

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Appendix

The Trifecta and Trifecta GT valves should be implanted in accordance with the Instructions for Use (IFU) to ensure appropriate valve sizing and handling to optimize valve performance and durability. Recommended implant best practices promote adherence to the following sizing and handling guidelines as described in the IFU (for a complete copy of the IFUs, refer to manuals.sjm.com).

Sizing Guidelines

The Trifecta and Trifecta GT valves are designed for implantation in the supra-annular position. Valve sizing is to be performed using only the Model TF2000 sizers. 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.

Use the replica end of the TF2000 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.

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

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.

Handling Guidelines

The actual choice of surgical technique, modified in accordance with the instructions for use (IFU), is left to the discretion of the individual surgeon. Select the appropriate valve size, as determined from the sizing procedure.

WARNING: The titanium valve stent is not designed as a flexible stent. Do not bend the titanium valve stent. Deformation of the stent may impair valve function.

CAUTION: Do not handle the valve with unprotected forceps, or use cutting edge needles or sharp instruments as they may cause structural damage to the valve. Never handle the leaflet tissue. Position the valve so that the stent posts do not obstruct the coronary ostia or come in direct contact with the aortic wall.

PRECAUTIONS:

- Use caution when tying knots to avoid bending the stent posts.
- 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.
- Ensure the suture tails and knot tying technologies do not contact the leaflet tissue.