



July 31, 2023

UPDATE URGENT FIELD SAFETY NOTICE

Trifecta™ Valve and Trifecta™ Valve with Glide Technology
Model: TF-19A, TF-21A, TF23A, TF25A, TF-27A, TF-29A, TFGT-19A,
TFGT-21A, TFGT-23A, TFGT-25A, TFGT-27A, and TFGT-29A

Dear Valued Customer,

The purpose of this letter is to inform you that Abbott has decided to voluntarily recall the Trifecta™ and Trifecta™ with Glide™ Technology (GT) valves.

On 27 February 2023, Abbott communicated the potential for early Structural Valve Deterioration (SVD) and provided patient management considerations for those patients implanted with the Trifecta and Trifecta GT valves. A review of published literature and clinical trial data has shown that the reported rates of SVD for the Trifecta valve do not consistently align with the prospective clinical trial data and demonstrate greater variation across medical centers relative to comparator valves. Abbott's assessment of incidence and risks has not changed since the February communication.

Reasons for the field safety corrective action

Abbott had previously decided to discontinue its Trifecta family of valves to focus on tissue heart valve solutions that maximize possibilities for lifetime management of valvular heart disease and has requested withdrawal of its CE certification. In consultation with the Competent Authority, Abbott is now requesting removal of unused Trifecta and Trifecta GT valves.

Patient Management Considerations

Abbott does not recommend that patients already implanted with the valve undergo a prophylactic device explant. Patient management considerations previously described in our Trifecta family of valves communication from 27 February 2023¹ remain in effect.

Steps Abbott is requesting you to take:


Our records indicate that product was shipped to you.

1. Return any remaining unused product to Abbott. Your Abbott representative can assist you in returning these devices.
2. Complete and return the accompanying Acknowledgment Form to Abbott.

Abbott is informing all applicable regulatory agencies about this matter. Please report any adverse reactions or quality problems experienced with the use of these products to Abbott.

We sincerely apologize for any inconvenience that this may cause. Abbott is committed to providing the highest level of support, and we thank you for assisting with this process. Please contact your local Abbott representative with any questions on this notification.

Sincerely,


Abbott Structural Heart

¹ https://www.structuralheart.abbott/int/fileadmin/pdf/Abbott_Communication_-_Trifecta_Valve_-_Final_Feb_2023_-_International_English_signed_01.pdf



URGENT FIELD SAFETY NOTICE

Important Information Regarding SVD in Trifecta Family of Valves

Trifecta™ Valve and Trifecta™ Valve with Glide Technology

Model: TF-19A, TF-21A, TF23A, TF25A, TF-27A, TF-29A, TFGT-19A, TFGT-21A, TFGT-23A, TFGT-25A, TFGT-27A, and TFGT-29A

February 27, 2023

Attention: Heart Team

Dear Valued Customer,

Abbott is providing information regarding Structural Valve Deterioration (SVD)¹ related to its Trifecta™ family of bioprosthetic heart valves. This communication is intended to raise awareness regarding the potential for early SVD² and provide patient management considerations.

The Trifecta™ Valve and Trifecta™ Valve with Glide™ Technology (GT) constitute the Trifecta family and are tri-leaflet stented bovine pericardial valves designed for supra-annular placement in the aortic position. The valves are fabricated using a covered titanium stent with leaflets mounted externally to maximize valve opening and improve hemodynamic performance.³⁻⁴ The valves are intended as a replacement for a diseased, damaged, or malfunctioning native or prosthetic aortic heart valve.

Incidence and Clinical Outcome:

Abbott monitors product performance through clinical trial data, literature reviews, and complaint reporting. This section addresses all three sources of data and raises awareness of recent literature around SVD.

Clinical Trial Data: As background, Abbott has assessed Trifecta valve performance and durability in two prospective clinical trials (ClinicalTrials.gov Identifier: NCT01593917 and NCT01256710) for the 1st generation Trifecta valve and a third prospective clinical trial (NCT03016169) for the Trifecta GT valve. Hemodynamic performance assessed by an echocardiography core lab demonstrated the absence of a rapid rise in transvalvular gradients through 10 years post-implant in patients implanted with the 1st generation Trifecta valve.⁵ The clinical trial data for the 1st generation Trifecta valve showed that most cases of SVD occurred after 5 years of implant with a peak occurrence at 8 years. **Table 1** provides measures of valve durability for the 1st generation Trifecta valve and Trifecta GT valve relative to a comparator bovine pericardial valve.⁶ At 8 years post-implant, the 1st generation Trifecta valve has a slightly reduced durability relative to the comparator valve.

Table 1

Prospective Clinical Trials	Freedom from SVD			Freedom from reintervention due to SVD		
	5 years*	8 years	10 years	5 years*	8 years	10 years
Trifecta LTFU Study (NCT01593917) N=710	98.2% N=401	87.6% N=229	67.7% N=96	99.2% N=404	89.8% N=233	75.4% N=105
Trifecta Durability Study (NCT01256710) N=1151	96.7% N=884	87.4% N=594	76.0% N=130	97.5% N=889	91.3% N=609	85.0% N=137
Trifecta GT PMCF Study (NCT03016169) N=362	98.0%* N=152	N/A	N/A	99.2%* N=154	N/A	N/A
Comparator Valve Study (NCT01171625) N=258	99.1% N=202	90.1% N=62	N/A	99.1% N=202	93.6% N=64	N/A

* Data for the Trifecta GT valve are reported at 4 years post-implant; study is still ongoing. All other data shown for the 1st generation Trifecta valve and comparator valve are reported at 5 years post-implant. LTFU = Long-Term Follow-Up; PMCF = Post-Market Clinical Follow-up; N/A = not available.

Recent Literature: An Abbott review of literature published since 2020 identified 21 articles (Appendix A) assessing retrospectively the early (≤ 5 years) and midterm (6 to 10 years) durability of the Trifecta valve. Twelve of these articles compared the durability of the Trifecta valve to other commercially available bovine pericardial valves and four (4) of these articles used propensity matching. **Figure 1** provides measures of valve durability for the Trifecta valve versus comparator valves from the literature review, where each data point (marked with “o” or “x”) represents the results from one publication. Based on the literature review, there appears to be a higher early and midterm cumulative incidence of



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SVD, and a lower freedom from early and midterm reintervention due to SVD for the Trifecta valve. The reported rates of SVD for the Trifecta valve do not consistently align with the prospective clinical trial data and demonstrate greater variation across medical centers relative to the comparator valves.

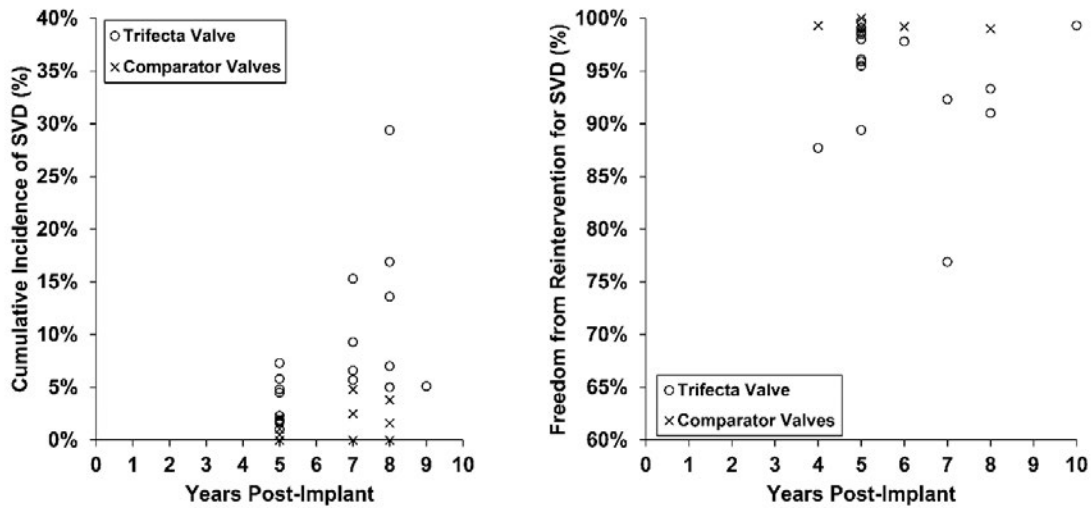


Figure 1: Scatter Diagram of SVD Rates from Literature Review

Complaint Data: Abbott’s complaint analysis has shown that most cases of early SVD which occur within 5 years post-implant are characterized as a non-calcific leaflet tear, while most cases of late SVD which occur beyond 5 years post-implant are characterized as a fibrous-calcific SVD. **Figure 2** shows a histogram of the time to SVD based on all reported complaint data with known implant duration stratified by the various clinical outcomes. While the clinical trial data show a peak time to SVD of 8 years, the complaint data shows a shorter peak time to SVD of 3 to 4 years. There are generally limitations associated with interpreting data collected via passive surveillance through complaint reporting which likely result in under-estimating events due to under-reporting.

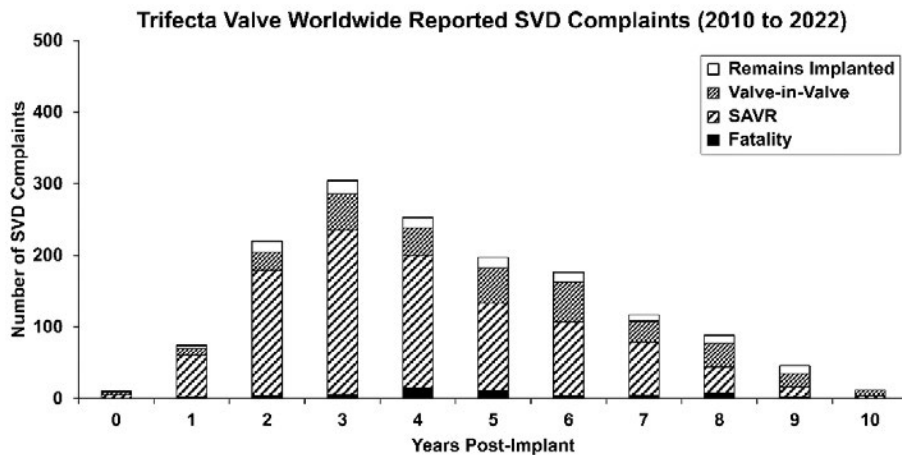


Figure 2: Histogram of Time to SVD based on Worldwide Reported Complaints

SAVR = Surgical Aortic Valve Replacement; Valve-in-Valve = Transcatheter valve-in-valve intervention

In summary, a recent literature review of the Trifecta valve indicates a higher early and midterm cumulative incidence of SVD relative to comparator bovine pericardial valves. While the data primarily reflects the 1st generation Trifecta valve, the 4-year clinical trial data for the Trifecta GT valve suggests that its performance



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and durability is comparable to the 1st generation Trifecta valve, such that the following patient management considerations apply to the entire Trifecta family of valves.

Patient Management Considerations: Clinically significant early SVD will compromise the hemodynamic performance of the valve; therefore, in choosing a Trifecta valve, the potential for early SVD should be balanced against its hemodynamic benefits^{3-5,7-8} and discussed with the patient.

When implanting the Trifecta GT valve, it is important to implant the valve in accordance with the IFU sizing and handling guidelines.^{9-10, 29}

Understanding that clinical decisions are shared between health care providers and patients, please consider the following post-implant:

- Patients should be reminded to seek medical attention with new onset of symptoms such as shortness of breath or fatigue.
- An initial post-procedural transthoracic echocardiogram (TTE) study is recommended for all patients within 1 to 3 months after the implant procedure to evaluate valve hemodynamics and ventricular function.
- Schedule annual follow-up visits beginning 1-year post-implant for clinical evaluation, including TTE to assess transvalvular gradients and valvular regurgitation grade.
- Patients presenting with changes in symptoms (e.g., shortness of breath or fatigue on exertion) or signs (e.g., murmur) indicative of potential SVD should undergo a TTE.
- Patients with evidence of hemodynamically significant SVD should be considered, in consultation with a heart team, for a possible valve intervention with either surgical aortic valve replacement (SAVR) or a transcatheter valve-in-valve intervention depending on individual patient risks and benefits.
- Patients being considered for a valve-in-valve intervention should undergo pre-procedure planning with imaging studies to ensure all potential procedure-related risks such as coronary obstruction are minimized. Please note that the titanium frame of the Trifecta GT valve cannot be fractured using a balloon.


Actions Abbott is Asking You to Take:

- Please consider this information in your practice and share with relevant health care professionals (e.g., cardiac surgeons, cardiologists, primary care physicians) involved in the care of patients implanted with the Trifecta family of valves in your institution.
- Complete and return the provided Acknowledgement Form.
- Report any product incidents, regardless of procedure or patient outcome, to Abbott.

Abbott is informing all applicable regulatory agencies about this matter. Please report any adverse reactions or quality problems experienced with the use of these products to your local Abbott representative.

Thank you for your attention to this matter. Abbott is committed to providing high-quality products and partnering with you to ensure the safety of each patient. Please contact your local Abbott representative with any questions on this notification.

Sincerely,


Abbott Structural Heart



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