February 27, 2023
Attention: Heart Team

Dear Valued Customer,

Abbott is providing information regarding Structural Valve Deterioration (SVD) related to its Trifecta™ family of bioprosthetic heart valves. This communication is intended to raise awareness regarding the potential for early SVD 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. 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. 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. At 8 years post-implant, the 1st generation Trifecta valve has a slightly reduced durability relative to the comparator valve.

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 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 (2010 to 2022)**

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 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.
**Important Information Regarding SVD in Trifecta Family of Valves**

**Trifecta™ Valve and Trifecta™ Valve with Glide Technology**


**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 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.

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. Additional information regarding future valve-in-valve considerations can be found in the Trifecta GT valve IFU. 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 working with the FDA on this matter. Report any adverse reactions or quality problems experienced with the use of these products to your local Abbott representative or the customer service department at 1-800-544-1664. Reports may also be sent to the FDA’s MedWatch Adverse Event Reporting program by completing Form FDA 3500 online at www.FDA.gov, calling 1-800-FDA-1088 or faxing to 1-800-FDA-0178.

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 or the customer service department at 1-800-544-1664 (Option 2) with any questions on this notification.

Sincerely,

Christopher Gallivan
Divisional Vice President, Quality
Abbott Structural Heart
Important Information Regarding SVD
in Trifecta Family of Valves

Trifecta™ Valve and Trifecta™ Valve with Glide Technology


References


9. Trifecta GT IFU.

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Appendix A, Literature Review References