

Abbott Trifecta Valves: Potential Risk of Early Structural Valve Deterioration- Letter to Health Care Providers

February 27, 2023

The U.S. Food and Drug Administration (FDA) is informing health care providers about the potential risk of early structural valve deterioration (SVD) with Abbott Trifecta valves, including the Trifecta Valve and the Trifecta Valve with Glide Technology (Trifecta GT), which feature leaflets externally mounted to the valve frame.

Information from published literature suggests a higher cumulative incidence of early (five years or less) SVD for Trifecta valves compared to other commercially available surgical bioprosthetic valves. The FDA is working with the manufacturer to evaluate information from all available sources on this issue.

The FDA is encouraging you to report adverse events related to Trifecta valves to the FDA. Prompt reporting of adverse events can help the FDA identify and better understand the risks associated with medical devices.

Recommendations

The FDA recommends that health care providers:

- Be aware of the potential risk of early SVD with Trifecta valves, and current patient management considerations, as communicated by [Abbott](#).
- Discuss the risks and benefits of all available aortic valve treatment options with your patients and their caregivers as part of shared clinical decision-making prior to surgery.
- Read and carefully follow the Instructions for Use (IFU) when implanting a Trifecta GT valve.
- Monitor patients who have undergone implantation with Trifecta valves for signs and symptoms of potential SVD.
 - Instruct patients to seek medical attention with new onset of symptoms such as shortness of breath or fatigue.
 - Ensure lifelong follow-up visits, conducted at least yearly, including transthoracic echocardiogram (TTE) assessment of the valve beginning one-year post-implant.
- Report any adverse events with Trifecta valves to the FDA. Refer to the [Reporting Problems to the FDA](#) section below.

Background

The Trifecta and Trifecta GT valves are heart valve replacement devices intended to treat diseased, damaged, or malfunctioning native or prosthetic aortic heart valves. The first-generation Trifecta valve was first approved in 2011 and is no longer marketed in the U.S. The Trifecta GT valve was approved in 2016.

The FDA routinely evaluates adverse event reports and published literature to monitor the safety and effectiveness of medical devices. The published literature includes a comparison of durability for Trifecta valves to other commercially available bovine pericardial valves across different timepoints post-implant. Outcomes from these studies suggest a higher cumulative incidence of early SVD and lower freedom from reintervention due to SVD associated with Trifecta valves. The published literature includes results combined for the Trifecta and Trifecta GT valves, and the patient management considerations provided by [Abbott](#) apply to both Trifecta valve models.

The FDA has also received medical device reports (MDRs) that describe early SVD with Trifecta valves, with reports showing a peak time to SVD of three to four years post-implant. Reported outcomes include surgical valve explant/replacement, transcatheter valve-in-valve intervention, and in some cases death. The FDA recognizes the limitations of MDR data, including that incidence cannot be determined from the passive surveillance reporting system. Reports submitted to the FDA are just one source of information that the FDA uses to monitor the safety of medical devices.

FDA Actions

The FDA is working with the manufacturer to further evaluate the issue and develop additional patient management strategies, if needed.

The FDA will continue to monitor the literature and reports of adverse events related to the issue.

The FDA will inform the public if any significant, new information or recommendations become available.

Reporting Problems to the FDA

The FDA encourages health care providers to report any adverse events or suspected adverse events experienced with Abbott Trifecta valves.

- Voluntary reports can be submitted through [MedWatch, the FDA Safety Inf](#) (</safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda>),ormation and Adverse Event Reporting program.
- Device manufacturers and user facilities must comply with the applicable [Medical Device Reporting \(MDR\) regulations](#) (</medical-devices/postmarket-requirements-devices/mandatory-reporting-requirements-manufacturers-importers-and-device-user-facilities>).
- Health care personnel employed by facilities that are subject to the [FDA's user facility reporting requirements](#) (</safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda>) should follow the reporting procedures established by their facilities.

Prompt reporting of adverse events can help the FDA identify and better understand the risks associated with medical devices.

Additional Resources

- From Abbott: [Important Information Regarding SVD in Trifecta Family of Valves](#) (https://www.structuralheart.abbott/fileadmin/pdf/FINAL_Abbott_Letter_US_Trifecta_Abbott_Website_signed.pdf) [↗](http://www.fda.gov/about-fda/website-policies/website-disclaimer) (<http://www.fda.gov/about-fda/website-policies/website-disclaimer>)

Contact Information

If you have questions about this letter, [contact the Division of Industry and Consumer Education](#) (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice>) (DICE).