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

Abbott

July 31, 2023

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 2023[1] 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,

Christopher Gallivan
Divisional Vice President, Quality
Abbott Structural Heart

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