UPDATE TO IMPORTANT INFORMATION REGARDING SVD IN TRIFECTA FAMILY OF VALVES

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

July 31, 2023

Dear Valued Customer,

The purpose of this letter is to inform you that Abbott is initiating a US Market Withdrawal for the Trifecta family of valves (see Table 1 below) and will be removing the limited remaining inventory from the field.

On February 27, 2023, Abbott and the US FDA 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. The assessment of incidence and risk associated with early SVD has not changed since the February communication. Abbott continues to work closely with the FDA on post-market surveillance associated with prior implants.

Abbott 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. Abbott is initiating inventory-related activities world-wide in accordance with respective regulatory frameworks.

Patient Management Considerations
The patient management considerations previously provided in the February 2023 communication remain in effect (https://www.structuralheart.abbott/fileadmin/pdf/FINAL_Abbott_Letter_US_Trifecta_Abbott_Website_signed.pdf).

Steps Abbott is Requesting You to Take
Abbott will collect its unused consigned inventory and will assist you with returning any customer-owned inventory. We request that you acknowledge this communication with the accompanying form.

In addition, please continue to report any adverse reactions or quality problems experienced with the use of these products to Abbott. 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.

Please contact your local Abbott representative with any questions.

Sincerely,

Christopher Gallivan
Divisional Vice President, Quality
Abbott Structural Heart

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Table 1: Trifecta Family in Scope of Update

Model Number	Product Description	GTN/UDI
TF-19A	Trifecta™ Valve 19mm	05414734052016
TF-21A	Trifecta™ Valve 21mm	05414734052023
TF-23A	Trifecta™ Valve 23mm	05414734052030
TF-25A	Trifecta™ Valve 25mm	05414734052047
TF-27A	Trifecta™ Valve 27mm	05414734052054
TF-29A	Trifecta™ Valve 29mm	05414734052061
TFGT-19A	Trifecta™ Valve with Glide Technology 19mm	05415067018205
TFGT-21A	Trifecta™ Valve with Glide Technology 21mm	05415067018212
TFGT-23A	Trifecta™ Valve with Glide Technology 23mm	05415067018229
TFGT-25A	Trifecta™ Valve with Glide Technology 25mm	05415067018236
TFGT-27A	Trifecta™ Valve with Glide Technology 27mm	05415067018243
TFGT-29A	Trifecta™ Valve with Glide Technology 29mm	05415067018250