



UPDATE: IMPORTANT INFORMATION REGARDING 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 global retirement and discontinuation of the Trifecta family of valves (see Table 1 below).

On February 27, 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. The assessment of incidence and risk associated with early SVD and the overall benefit risk profile has not changed since the February communication. Abbott will continue its post-market surveillance activities associated with the device.

Abbott has 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.

Patient Management Considerations

The patient management considerations previously provided in the February 2023 communication remain in effect (https://www.structuralheart.abbott/int/fileadmin/pdf/Abbott_Communication_-_Trifecta_Valve_-_Final_Feb_2023_-_International_English_signed_01.pdf).

Steps Abbott Is Taking

Abbott will take the appropriate steps for your consigned inventory to expedite its discontinuation plan in accordance with your regulatory framework.

Please continue to report any adverse reactions or quality problems experienced with the use of these products to Abbott and contact your local Abbott representative with any questions.

Sincerely,

A handwritten signature in black ink that reads 'C. Gallivan'.

Christopher Gallivan
Divisional Vice President, Quality
Abbott Structural Heart



UPDATE: IMPORTANT INFORMATION REGARDING 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

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 |