PRODUCT RECALL ALERT

DRAP ALERT NO. Nº II/S/09-23-37

RECALL ALERT OF TRIFECTA FAMILY OF VALVES

(MANUFACTURED BY M/S ST. JUDE MEDICAL, USA)

Date: 10th October, 2023

Target Audience:

- Healthcare Professionals particularly working in the critical care areas of hospitals including Physicians, Cardiologists, Pharmacists, and Nurses.
- People implanted with affected Trifecta Family Valves.
- Procurement Officers at Hospitals and Healthcare Institutions.
- Pharmacists and Chemists at Distribution, Pharmacies and Medical Stores.

Alert Summary:

Abbot Structural Heart (St.Jude Medical, USA) has initiated a market withdrawal for the Trifecta family of valves (*TrifectaTM Valve and TrifectaTM Valve with Glide Technology see table below*) and will be removing the limited remaining inventory from the field due to potential for early Structural Valve Deterioration (SVD). Accordingly, the manufacturing company is recalling all the defective products from the international market including Pakistan. The Medical Device Board has already suspended the product registration in its 61st Meeting and further course of action for deregistration is in process under the Medical Device Rules 2017.

The detail of the affected Medical device is as under:

Brand Name and description	Model No	GTN/UDI	Manufacturer and Distributor
TrifectaTM Valve 19mm	TF-19A	05414734052016	M/s St. Jude Medical 11 county road b e saint paul, mn USA 55117 **Distributor in Pakistan**: M/s Verizon, 60-D, F.C.C Zahoor Elahi Road, Gulberg-IV, Lahore. **Products registration no**. MDIR -0003639. MDIR -0000233.
TrifectaTM Valve 21mm	TF-21A	05414734052023	
TrifectaTM Valve 23mm	TF-23A	05414734052030	
TrifectaTM Valve 25mm	TF-25A	05414734052047	
TrifectaTM Valve 27mm	TF-27A	05414734052054	
TrifectaTM Valve 29mm	TF-29A	05414734052061	
TrifectaTM Valve with Glide Technology 19mm	TFGT-19A	05415067018205	
TrifectaTM Valve with Glide Technology 21mm	TFGT-21A	05415067018212	
TrifectaTM Valve with Glide Technology 23mm	TFGT-23A	05415067018229	
TrifectaTM Valve with Glide Technology 25mm	TFGT-25A	05415067018236	
TrifectaTM Valve with Glide Technology 27mm	TFGT-27A	05415067018243	
TrifectaTM Valve with Glide Technology 29mm	TFGT-29A	05415067018250	

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Risk Statement:

The valves are intended to maximize valve opening and improve hemodynamic performance. Therefore, defective trifecta family heart valves pose a risk of patient harm which will compromise the hemodynamic performance of the valve and can lead to cardiac arrest, other serious injuries.

Action Initiated: -

The manufacturing company has initiated a withdrawal of the defective devices from the market where it was distributed. All healthcare professionals working in critical care units of hospitals as well as pharmacists and chemists working at distributions and pharmacies should **immediately check** their stocks and stop supplying these models/ GTN/UDI of the product. The remaining stock should be quarantined and returned to the supplier/company. The regulatory field force of all federating units (DRAP and Provincial Health Departments) will also increase surveillance to monitor the recall progress to ensure effective recall.

Advice for Healthcare Professionals: -

DRAP requests to enhance **vigilance** within the supply chains of institutions/pharmacies/healthcare facilities likely to be affected by these defective lots of the Medical Device. Patient using the affected device should immediately contact their doctors for further guidance. Furthermore, Abbott, USA provided patient management considerations for those patients implanted with the Trifecta and Trifecta GT valves. (https://www.structuralheart.abbott/fileadmin/pdf/FINAL_Abbott_Letter_US_Trifecta_Abbott_Website_signed.pdf)

Understanding that clinical decisions are shared between healthcare 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.

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- 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 trans catheter 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.

Adverse reactions or quality problems experienced with the use of this product should be reported to the National Pharmacovigilance Centre (NPC), DRAP using Adverse Event Reporting Form or online through this link. Further information of reporting problems to DRAP is available on this link

Advice for Consumers / General public: -

Consumers should stop using this product bearing the affected Model no and shall contact to their physician or healthcare provider if they have experienced any problems that may be related to using this Medical Device, and report the incident to National Pharmacovigilance Centre of Drug Regulatory Authority of Pakistan, through MedSafety Mobile Application, or online at Med Vigilance E Reporting System.

All therapeutic goods must be obtained from the licensed pharmacies, and other authorized retail outlets. The authenticity and condition of products should be carefully checked. Seek advice from your pharmacists or other healthcare professional in case of any doubt.

Drug Regulatory Authority of Pakistan
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