المملكة العربية السعودية
الهيئة العامة للغذاء والدواء
Kingdom of Saudi Arabia
Saudi Food & Drug Authority

Medical Device Sector
Surveillance & Biometrics Executive Department

قطاع الأجهزة والمنتجات الطبية
الإدارة التنفيذية للرقابة والقياسات الحيوية

**Safety Communication** رسالة سلامة

# Cases of structural valve deterioration insufficiency and early revision.

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| **Device/ Product Description:** | Bio-prosthetic aortic heart valves |
| **Brand:** | Trifecta / Trifecta GT |
| **Affected product:** | **Models**: TF-19A, TF-21A, TF23A, TF25A, TF-27A, TF-29A<br>**Models** TFGT19A, TFGT-21A, TFGT-23A, TFGT-25A, TFGT-27A, TFGT-29A |
| **Manufacturer:** | Abbott |
| **Problem:** | Adverse incident reports relate to revision (explant or valve-in-valve repair) due to some form of structural valve deterioration (SVD). The most common reported problems were leaflet damage and/or valvular insufficiency along with a range of other associated concerns. Time to failure ranged from perioperative to 8 years, with approximately half occurring between 2 to 3 years post implant. |
| **Recommendation /Actions:** | • Make sure that this notice is reached to the end-users.<br>• Read Abbott's Technical Bulletin, dated 13 January 2020, on the Trifecta/Trifecta GT bioprosthetic surgical aortic heart valve.<br>• Note precautions regarding proper valve sizing and handling in accordance with the instructions for use (IFU):<br>  ○ Implantation of an inappropriately large bioprosthesis may result in stent deformation, valvular incompetence, and/or damage to the surrounding tissue<br>  ○ Do not oversize the valve<br>  ○ Do not bend the titanium valve stent. The titanium valve stent is not designed as a flexible stent.<br>• Identify those patients implanted with a 1st generation Trifecta valve and consider implementing enhanced follow-up. |

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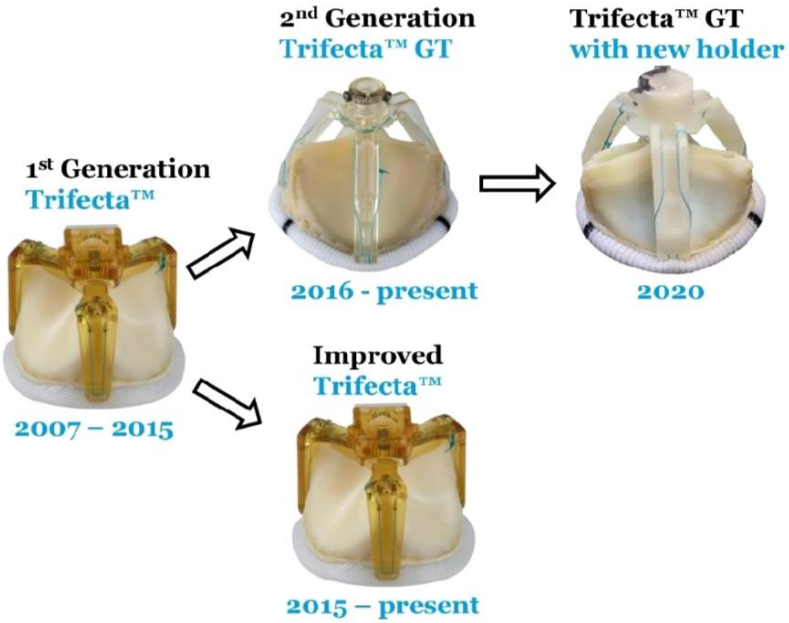
| | For more information, Please click here.<br><br>If you think you had a problem with your device or a device your patient uses, please report the problem to SFDA through:<br>NCMDR<br>Vigilance system<br>19999 unified call center |
| **Devices/Products photo:** |  |

| **Authorized Representative Details** | | |
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