Date: 1 May 2024
Reference Number: SG-2405-419-H

قطاع الأجهزة والمستلزمات الطبية
المركز الوطني لبلاغات الأجهزة والمستلزمات الطبية

Medical Devices Sector
National Center for Medical Devices Reporting

الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

رسالة سلامة
Safety Communication

To: Healthcare Provider	**إلى: مقدمي الرعاية الصحية**

Title	Structural Valve Deterioration in Trifecta Family of Valves	**العنوان**
Medical Device Description	Trifecta Valve and Trifecta Valve with Glide Technology	**اسم ووصف الجهاز/المستلزم الطبي**
Manufacturer	St. Jude Medical Inc.	**اسم المصنع**
Authorized Representative	Medical Regulations Gate	**الممثل المعتمد**
Medical Devices Marketing Authorization (MDMA)	MDMA-1-2019-2612	**إذن التسويق**
Potential /Associated risks	Structural Valve Deterioration (SVD) related to Trifecta family of bioprosthetic heart valves. This communication is intended to raise awareness regarding the potential risk for early SVD and provide patient management considerations.	**المخاطر المحتملة/ المرتبطة بالجهاز أو المستلزم الطبي**
Recommendations	• Be aware of the potential risk of early SVD with Trifecta valves and current patient management considerations, as communicated by Abbott. • Monitor patients who have undergone implantation with Trifecta valves for signs and symptoms of potential SVD. • Instruct patients to seek medical attention with new onset of symptoms such as shortness of breath or fatigue. • Ensure lifelong follow-up visits, conducted at least yearly, including transthoracic echocardiogram (TTE) assessment of the valve beginning one-year post-implant. • Report any adverse events or complaints about Trifecta valves to the SFDA. The SFDA will initiate a monitoring plan with healthcare providers for patients who have implanted the Trifecta valve.	**التوصيات**
For Reporting	SFDA 19999 مركز الاتصال الموحد · NCMDR · تيقظ Saudi Vigilance	**للإبلاغ**