

Safety Communication Form

Safety Communication

رسالة سلامة

To: Healthcare providers	إلى: مقدمي الرعاية الصحية
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Title	SVD 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 its Trifecta™ family of bioprosthetic heart valves. This communication is intended to raise awareness regarding the potential for early SVD and provide patient management considerations	المخاطر المحتملة/ المرتبطة بالجهاز أو المستلزم الطبي
Recommendations	<ul style="list-style-type: none">Patients should be reminded to seek medical attention if they feel symptoms such as shortness of breath or fatigue.An initial post-procedural transthoracic echocardiogram (TTE) study is recommended for patients within the first three months after implant for evaluation of valve hemodynamics and ventricular function.Annual follow-up visit after one year of implant for clinical evaluation (TTE)Please refer to the FSN in the following link: https://ncmdr.sfda.gov.sa/FileDownload.ashx?f=ca&fid=11966	التوصيات:

For Reporting	  	لإبلاغ
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