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Important Medical Device Information

Updates on Instructions for Use (IFU) regarding Erosion
for the AMPLATZER™ Septal Occluder (ASO)

Affected products	AMPLATZER™ Septal Occluder (ASO) Model # ASD-004 to 040
Adverse Event **Specifically erosion**	Erosion, though rare, is a potentially serious life threatening event with symptomatic signals including chest pain, shortness of breath, fainting, and difficulty breathing. If erosion occurs, emergency surgery may be required for a successful outcome.
Risk of erosion	The risk for potential erosion has remained stable over time. The world-wide estimated incidence rate for erosion is between 0.1% and 0.3%.

Revision of ASO Instructions for Use	The primary revisions to the IFU are pertaining to additional information for physicians regarding the risks and symptoms of erosion. The IFU has been updated and clarified as follows:
	• The contraindication for defect margins less that 5 mm has been updated to include the inferior vena cava rim
	• Warnings have been updated or modified to include:
	  ○ patients with a retro-aortic rim of less than 5 mm in any echocardiographic plane or patients in whom the device impinges on the aortic root may be at increased risk of erosion
	  ○ placement of the ASD occluder may impact future cardiac interventions, for example transseptal puncture and mitral valve repair
	  ○ do not release the device from the delivery cable if the device does not conform to its original configuration or if the device position is unstable or if the device interferes with any adjacent cardiac structure, such as superior vena cava (SVC) pulmonic valve (PV), mitral valve (MV), coronary sinus (CS) or aorta (AO). Recapture the device and redeploy. If still unsatisfactory, recapture the device and replace with a new device (italicized and underlined text shows modified warning)
	• The adverse events were updated to include more detail on the rare event of erosion, including the rate of tissue erosion of 1-3 per 1000 patients
	• The following additional changes were also made to the IFU to align the US and international IFUs and add to the effective use of the device:
	  ○ Clinical follow-up recommendations have been updated. Specifically, follow-up with a cardiologist and echocardiograms are recommended at implant, 1 day post-implant, pre-discharge, and again at 1 week, 1 month, 6 months, and 12 months post-implant. Clinical follow-up with a cardiologist annually thereafter is also recommended
	  ○ Patient awareness has been emphasized. Specifically, patients should be educated to seek immediate medical attention that includes an echocardiogram, if they develop signs or symptoms of hemodynamic instability such as chest pain, arrhythmia, fainting, or shortness of breath.
	  ○ Patients should be instructed to avoid strenuous activity for a minimum 1 month postdevice implant or as directed by their physician. Strenuous activities may lead to the increased risk of adverse events including erosion. Patients should be reminded that if they experience any symptoms of shortness of breath or chest pain at any time and especially after strenuous activity,

	they should seek medical care immediately
Availability of Revised Instructions For Use	The revised Instructions For Use will be added to our packaging as soon as regulatory approval is obtained.
Patient education	Patients should be informed of the potential warning signs of erosion, including direction to seek immediate medical assistance in the event they experience any of the symptoms or warning signs.
Incident reporting	If erosion is suspected in one of your patients, please immediately report this event to your St. Jude Medical representative. Additionally, please ensure that all necessary records (including, but not limited to implant and event images, surgical records, catheterization reports, etc.) are provided to facilitate a complete assessment of the event.
More information	Please do not hesitate to contact your local St. Jude Medical representative should you need more information.

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22 November 2013

Dear Customer,

This letter is to inform you about important information concerning updates to the Instructions for Use (IFU) for the AMPLATZER Septal Occluder (ASO). After many years of experience with the ASO used in clinical practice, St. Jude Medical is updating the IFU for the ASO to reflect most recent knowledge and clinical experience. These changes are intended to provide guidance to physicians regarding the use of the ASO and to mitigate the incidence of erosion; a rare but serious adverse event. Analysis of confirmed and suspected erosion events has allowed us to update contraindications and warnings as well as provide additional guidance regarding echo imaging and follow-up recommendations in the IFU. This letter is to inform you about those changes.

St. Jude Medical is dedicated to continuous improvement and actively seeks out data to enhance our understanding of erosion etiology and its potentiating factors in order to reduce patient risk and provide education and guidance to physicians to reduce the occurrence of erosion. The potential risk for erosion has remained stable over time with a world-wide estimated incidence rate between 0.1% and 0.3%. The overall known safety profile of the device has not changed since marketing approval; however, the awareness of the full spectrum of adverse events and outcomes has become clearer. Although erosion remains a very low incidence event, this well known risk which may be very serious for the patient.

New products will be packaged with the updated IFU upon regulatory approval. If you need any further information, please do not hesitate to contact your local St. Jude Medical Representative.

Patient safety is very important to St. Jude Medical and we hope the update of our IFU will help you to better manage your patients.

Sincerely,

Roland Gerard
Vice President Regulatory and Quality Affairs
International Division