

**Health Canada Endorsed Important Safety Information on  
Amplatzer Septal Occluder**



04/09/2014

Dear Health Care Professional

**Subject: Risk of Erosion associated with the Amplatzer Septal Occluder (ASO)**

St. Jude Medical Inc., in collaboration with Health Canada, is informing you about the risk of erosion associated with the AMPLATZER Septal Occluder (ASO). The ASO is a medical device implant that is used in adults and children to close an atrial septal defect (ASD). Erosion is a rare but serious life threatening event defined as abrasion of the tissue of the atrium and/or adjacent aorta.

Analysis of confirmed and suspected erosion events has led St. Jude Medical to update the contraindications and warnings sections of device's Instructions For Use (IFU).

- Erosion is a rare but serious life threatening event which has been associated with the ASO. If it occurs, erosion can result in pericardial effusion. Immediate surgery may be required.
- Physicians and other health professionals should review and be familiar with the updated ASO IFU for additional guidance regarding echocardiographic imaging and follow-up recommendations with patients to further mitigate the risk of erosion.
- Patients with an ASO should be educated to seek immediate medical attention, if they develop signs or symptoms of possible erosion, which include shortness of breath, chest pain, fainting, and/or a rapid or irregular heart beat.

The potential risk for erosion has remained stable over time with a world-wide estimated incidence rate between 0.1% and 0.3%. Almost 90% of erosions occur within one year of being implanted, but some may occur several years after implant. The overall known safety profile of the device has not changed since marketing approval. Although the rate of erosion events remains very low, this is a well known risk which may be very serious for the patient.

Physicians should provide current and future patients with information about the risks and benefits of transcatheter closure with the ASO device. The St. Jude Medical website has a link with additional resources and information for patients implanted with or considering ASO devices. Please make your patients aware of this site:  
[www.atrialseptaldefectanswers.com](http://www.atrialseptaldefectanswers.com).

## Reporting Adverse Incidents

Managing marketed health product-related adverse incidents depends on health care professionals and consumers reporting them. Any case of erosion or other serious or unexpected adverse incidents associated with an ASO should be reported to St. Jude Medical or Health Canada at the following addresses:

St. Jude Medical Canada, Inc.  
2100 Derry Rd. West, Suite 400  
Mississauga, ON L5N 0B3  
Telephone: 1-888-276-4170  
Fax: 1-877-800-7562

**To correct your mailing address or fax number, contact St. Jude Medical Canada, Inc.**

**Any suspected adverse incident can also be reported to:**

Health Products and Food Branch Inspectorate  
Health Canada  
Address Locator: 2003D  
Ottawa, Ontario K1A 0K9  
Telephone: 1-800-267-9675

The [Medical Devices Problem Report Form and Guidelines](http://www.hc-sc.gc.ca/dhp-mps/compli-conform/info-prod/md-im/index-eng.php) (<http://www.hc-sc.gc.ca/dhp-mps/compli-conform/info-prod/md-im/index-eng.php>) can be found on the Health Canada Web site.

For other medical device inquiries related to this communication, contact Health Canada at:  
Marketed Health Products Directorate  
E-mail: [mhpd\\_dpssc.public@hc-sc.gc.ca](mailto:mhpd_dpssc.public@hc-sc.gc.ca)  
Telephone: 613-954-6522  
Fax: 613-952-7738

The updated ASO IFU may be accessed from the St. Jude Medical *Healthcare Professionals* website at <http://professional-intl.sjm.com/resources/ifu/sh/asd-closure>. In addition, all newly manufactured products will be packaged with the updated instructions. If you need any further information, please contact your local St. Jude Medical Representative or call St. Jude Medical Customer Service at (905) 812-9758 or toll-free 1 (800) 276-4170.



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