

**Public Communication -  
Health Canada Endorsed Important Safety Information on  
Amplatzer Septal Occluder**



04/14/2014

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

St. Jude Medical Inc., in collaboration with Health Canada, has issued a Health Professional Communication regarding a rare but serious 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 opening (hole) in the wall (also known as septum) of the heart.

St. Jude Medical has updated the label for the ASO with respect to the adverse event of erosion.

- Erosion is a rare but potential life threatening event which may be caused by the ASO rubbing against the wall of the heart or surrounding structures.
- Symptoms of possible erosion may include shortness of breath, chest pain, fainting, and/or rapid or irregular heart beat.
- Any patient with an ASO who experiences any of the symptoms of erosion should immediately call his or her heart specialist, or go to the nearest emergency room.

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 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

**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\\_dpsc.public@hc-sc.gc.ca](mailto:mhpd_dpsc.public@hc-sc.gc.ca)  
Telephone: 613-954-6522  
Fax: 613-952-7738

A copy of this communication is available at <http://professional-intl.sjm.com/resources/product-performance/amplatz-septal-occluder-performance/canadian-updates> and on the Health Canada Website at [www.healthycanadians.gc.ca/index-eng.php](http://www.healthycanadians.gc.ca/index-eng.php). Information for patients can also be found at [www.atrialseptaldefectanswers.com](http://www.atrialseptaldefectanswers.com).

Patients should address any health-related concerns directly with their physician. Patients with an ASO who have health-related concerns regarding their implanted device should address their concerns directly with their heart specialist. For other questions, please contact St. Jude Medical Canada Inc. at the address or telephone number listed above.



Frank Shannon  
Director, Regulatory Affairs and Quality Systems  
St. Jude Medical Canada, Inc.