

Rare Serious Erosion Events Associated with St. Jude Amplatzer Atrial Septal Occluder (ASO)

U.S. Food & Drug Administration

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Audience: Pediatric and Adult Interventional Cardiologists; Cardiothoracic Surgeons; Non-Invasive Cardiologists; Referring and follow-up physicians including Pediatricians; and Patients implanted with the device

Medical Specialty: Pediatric and Adult Interventional Cardiology and Cardiothoracic Surgery; and Non-Invasive Cardiology

Device: The St. Jude Amplatzer Atrial Septal Occluder (ASO) is a cardiac implant device used in children and adults to treat an abnormal hole between the upper left and right chambers (atria) of the heart, known as an atrial septal defect (ASD). The metal device is put into place through a thin tube (catheter) inserted into a vein. This is considered a minimally invasive method for ASD closure, and is an alternative to open heart surgery.

Purpose: The Food and Drug Administration (FDA) is alerting health care providers and patients that in very rare instances, tissue surrounding the Amplatzer ASO can break down (erode) and result in life-threatening emergencies that require immediate surgery. According to published estimates, these events occur in approximately 1 to 3 of every 1,000 patients implanted with the Amplatzer ASO. As of March 31, 2013, there have been 234,103 Amplatzer ASO devices sold worldwide.

Summary of Problem and Scope: Tissue erosion caused by the Amplatzer ASO is rare, but can be life-threatening. Between 2002 and 2011, the FDA received more than 100 reports of erosions associated with the St. Jude Amplatzer ASO. During the same period, several medical journals contained articles reporting tissue erosion among patients implanted with this device.

The device rubbing against the wall of the heart can erode the tissue and create a hole. It can also lead to further scraping or erosion through tissue in the upper chambers (atria) of the heart, primarily in the top of the atria near the aorta. This scraping may also cause separate or simultaneous holes in the aortic root, potentially leading to blood building up in the sac surrounding the heart (cardiac tamponade). If too much blood builds up in this sac, the heart will not be able to work properly.

Immediate open heart surgery may then be necessary to remove the device, close the holes or other defects caused by erosion, and close the original defect the device was meant to treat less invasively. Tissue erosion can also cause fistulas -

abnormal scar tissue that connects parts of the heart that were not previously connected. Fistulas are not life-threatening, but do require surgery for treatment and could result in congestive heart failure.

The FDA has not yet identified risk factors related to the occurrence of erosion. Articles in professional medical journals have discussed the possibility that patients with a lack of tissue in the retro-aortic rim might be at higher risk of erosion events; however, this relationship has not been determined. This type of device failure has not been seen in similar devices used to treat this condition.

Recommendations for Physicians:

- Review the updated [Instructions For Use](#) [1]  [2] (IFU) for the Amplatzer ASO before implanting the device.
- Consider the potential for erosion when talking to patients about long- and short-term benefits and risks of treatment options, including implantation with the Amplatzer ASO.
- Inform patients that most people implanted with the Amplatzer ASO experience good outcomes and that erosion is a very rare event.
- Educate patients implanted with the Amplatzer ASO to seek immediate medical attention if they develop symptoms such as chest pain, numbness, sudden weakness, dizziness, fainting, shortness of breath, or rapid heartbeat.
- The FDA does **NOT** recommend device removal for patients who have the Amplatzer ASO unless physicians determine it is appropriate for their particular patient(s). The risks associated with device removal surgery may be equal to or greater than the risk of erosion.
- If erosion is suspected in one of your patients, immediately report this event to St. Jude Medical and the FDA via the established [adverse event reporting](#) [3] process in your facilities. Please provide all necessary records, including implant and event images, surgical records, and catheterization reports, so that the FDA has the most complete assessment of the event.

Recommendations for Patients:

- Talk to your doctor about the long- and short-term benefits and risks of treatment options, including implantation with the Amplatzer ASO, to determine which treatment option is best for you.
- If you have an ASD occluder implant and experience ANY symptoms of erosion you should **immediately** contact your doctor and go to the emergency room for an echocardiogram (ultrasound of the heart). Symptoms of erosion may include chest pain, numbness, sudden weakness, dizziness, fainting, shortness of breath, or rapid heartbeat.
- Current recommendations for follow-up with a cardiologist after Amplatzer ASO implantation include the following:
 - You should have an ultrasound of your heart (echocardiogram) at the following timeframes:

- implantation,
- one day after implantation,
- before hospital discharge, and
- one week after implantation.
- You should follow-up with your cardiologist at the following timeframes after implantation:
 - one month,
 - six months, and
 - one year.
- After the first 12 months, you should follow up with your cardiologist once each year (unless you have symptoms or concerns).

FDA Activities: To better understand how erosion impacts the performance of the Amplatzer ASO and assess potential risk factors related to the occurrence of erosion, the FDA is requiring St. Jude to conduct a study of patients who have been recently implanted with the device. The study is designed to estimate the incidence of erosion events within seven days, one month, six months, and 12 months after the implantation of the Amplatzer ASO. The study will also compare patients who experience an erosion event to those who do not, and will identify differences in demographic, clinical, and device characteristics.

The FDA, medical device industry and echocardiography societies are collaborating to develop standardized echocardiographic imaging techniques and guidelines for ASD procedures. These techniques and guidelines will provide needed information toward understanding pre-, peri-, and post-procedural anatomical characteristics of patients with atrial septal defects and the operation of the device in use.

Reporting Problems to the FDA: Prompt reporting of adverse events can help the FDA identify and better understand the risks associated with medical devices. If you suspect a problem with an atrial septal defect occluder, we encourage you to file a voluntary report through [MedWatch, the FDA Safety Information and Adverse Event Reporting Program](#) [4]. Health care personnel employed by facilities that are subject to [FDA's user facility reporting requirements](#) [5] should follow the reporting procedures established by their facilities.

To help the FDA learn as much as possible about the adverse events associated with atrial septal occluders, please include the following information in your reports, if available:

- Manufacturer's Name
- Device Name (Brand Name)
- Date Device was Manufactured
- Implant Duration by providing Date of Implant, Date of Event and/or Date of Explant
- Distributor's Name
- Details of Adverse Event and Medical and/or Surgical Interventions (if required)

Contact Information:

If you have questions about this communication, please contact the Division of Small Manufacturers, International and Consumer Assistance (DSMICA) at, industry.devices@fda.hhs.gov [6], 1-800-638-2041, or 301-796-7100.

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<http://www.mdtmag.com/news/2013/10/rare-serious-erosion-events-associated-st-jude-amplatzer-atrial-septal-occluder-aso>

Links:

[1] <http://www.sjmprofessional.com/Resources/instructions-for-use/amplatzer-septal-occluder-us.aspx>

[2] <http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm>

[3] <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/ucm2005291.htm>

[4] <http://www.fda.gov/Safety/MedWatch/HowToReport/ucm2007306.htm>

[5] <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/ucm2005737.htm>

[6] [http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/mailto:industry.devices@fda.hhs.gov](mailto:industry.devices@fda.hhs.gov)