

U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

Abbott Vascular Recalls MitraClip Clip Delivery System Due to Issue with Delivery System Deployment Process

The FDA has identified this as a Class I recall, the most serious type of recall. Use of this device may cause serious injuries or death.

Recalled Product:

- MitraClip Clip Delivery System Lot Numbers:
- 50811U1, 50811U2, 50812U1, 50813U1, 50814U1, 50826U1, 50826U2, 50827U1, 50908U1, 50908U2, 50909U1, 50910U1, 50910U2, 50911U1, 50924U1, 50925U1, 50928U1, 50929U1, 51010U1, 51012U1, 51012U2, 51013U1, 51014U1, 51014U2, 51026U1, 51027U3, 51028U1, 51028U2, 51029U1, 51030U1, 51105U1, 51106U1, 51109U1, 51109U2, 51110U1, 51110U2, 51117U1, 51203U1, 51204U1, 51205U1, 51207U1
- Manufactured from: July 14, 2015 to August 11, 2015
- Distributed from: August 28, 2015 to February 3, 2016
- Devices Recalled in the U.S.: 3,534 units nationwide, including Puerto Rico

Device Use



Photo of MitraClip Clip Delivery System®

The Abbott Vascular MitraClip Delivery System is intended to treat patients with degenerative mitral regurgitation (DMR) a condition involving a dysfunction of the heart's mitral valve. The MitraClip Clip Delivery System is indicated for use in patients who have been determined to be at prohibitive risk for mitral valve surgery.

The delivery system has three parts: a delivery catheter; a steerable sleeve; and an implantable clip. The implantable clip is introduced into the left atrium of the heart through the steerable sleeve and the delivery catheter. The implantable clip is then positioned and closed between the leaflets that separate the left atrium and the left ventricle to reduce the reversed blood flow.

Reason for Recall

Abbott Vascular has received reports of cases where the Clip Delivery System could not be detached from the Clip due to a malfunction of the device. These cases resulted in open heart surgery to retrieve the delivery system. Abbott Vascular is therefore recalling the MitraClip Delivery System to provide updated instructions and training for health care providers who use the device.

The use of affected products may cause serious adverse health consequences, including serious patient injury or death. Currently there are 3,534 devices on the market, with nine reports of this malfunction. There has been 1 death.

Who May be Affected

- Health care providers implanting the MitraClip Clip Delivery System

- All patients undergoing a mitral regurgitation procedure using the MitraClip Clip Delivery System

What to Do

On February 4, 2016, Abbott Vascular issued a safety notice to all physicians using the device instructing them to:

- Carefully read the revised deployment sequence instructions
- Participate in training with an Abbott Vascular representative
- Share the information with other pertinent staff

Contact Information:

Customers can contact Abbott Vascular Customer Support at 1-800-227-9902.

Date Recall Initiated:

February 4, 2016

Additional Resources:

- [Abbott Press Release](#)
- [FDA MedWatch Safety Alert for This Recall](#)

How do I report a problem?

Health care professionals and consumers may report adverse reactions or quality problems they experienced using these devices to [MedWatch: The FDA Safety Information and Adverse Event Reporting Program](#) online, by regular mail or by FAX.

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