

Cook Medical Inc. Recalls Zenith Alpha Thoracic Endovascular Graft for the treatment of Blunt Traumatic Aortic Injury (BTAI) Due to the Potential Formation of Thrombus Inside the Device After Implantation

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

Recalled Product:

- Zenith Alpha Thoracic Endovascular Graft
- Lot or serial numbers: **All lots**
(<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=154969>)
- Manufacturing dates: April 10, 2015 to January 3, 2017
- Distribution dates: October 29, 2015 to March 10, 2017
- Devices recalled in the U.S.: Approximately 4,500 devices will be relabeled and 500 devices (18 to 22 mm) will be removed.

Device Use

The Zenith Alpha Thoracic Endovascular Graft is intended to treat isolated lesions (not including dissections) in a patient's main blood vessel that carries blood from the heart down through the chest (descending thoracic aorta) into the abdomen. The device is used in patients who have a suitable vascular anatomy for endovascular repair.



Cook Zenith Alpha Thoracic Endovascular Graft

Reason For Recall

Cook Medical Inc. is recalling the Zenith Alpha Thoracic Endovascular Graft when used for the treatment of BTAI because blood clots (thrombus) may form inside the device after implantation. Cook Medical is also aware of reported cases where the graft became blocked or closed (occlusion) when used to treat BTAI. Thrombosis or occlusion may lead to serious adverse health consequences, including death.

Who May Be Affected

- Physicians using the Cook Zenith Alpha Thoracic Endovascular Graft
- Patients with BTAI receiving treatment with this device

What To Do

On March 22, 2017, Cook Medical Inc. sent an "Urgent: Medical Device Correction and Removal" notification to all affected customers. This recall notification included a description of the problem and reason for the recall, list of affected products and customer actions to be taken in response to the recall notification.

On June 22, 2017, Cook Medical Inc. sent an updated "Urgent: Medical Device Correction and Removal" notification to all affected customers. This recall notification informed customers the Instructions for Use (IFU) for this device were updated to remove the indication for use in BTAI. As a result, it is necessary to remove specific sizes of this device (<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=154969>) (grafts with a proximal or distal diameter of 18-22mm) that would likely be used only for the treatment of BTAI.

Cook Medical Inc. recommends that patients already treated with the Zenith Thoracic Endovascular Graft for the BTAI indication should be followed according the current IFU and with considerations outlined in Cook Medical's March 22, 2017 "Medical Device Correction and Removal" notification.

A Cook Medical Sales Representative will follow-up with all affected customers and provide a

corrected IFU.

Contact Information

Customers with questions about this recall may contact Cook Medical Customer Relations at 800-457-4500 or 812-339-2235.

Date Recall Initiated

March 22, 2017

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** (<https://www.accessdata.fda.gov/scripts/medwatch/index.cfm>) either online, by regular mail or by FAX to 1-800-FDA-0178.

More in Medical Device Recalls
(</MedicalDevices/Safety/ListofRecalls/default.htm>)

2017 Medical Device Recalls (</MedicalDevices/Safety/ListofRecalls/ucm535289.htm>)

2016 Medical Device Recalls (</MedicalDevices/Safety/ListofRecalls/ucm480134.htm>)