Class I Medical Device Recall: Zimmer Spine, Inc. - PEEK Ardis Inserter

U.S. Food & Drug Administration

Recall Class: Class I

Date Recall Initiated: December 21, 2012

Product: PEEK *Ardis* Inserter

Manufacturing and Distribution Dates: June 2008 – December 201

The affected models and lot numbers: Affected lots and part numbers are available on the FDA's website [1].

Use: The PEEK *Ardis* Inserter is a surgical instrument used during spinal surgery to implant the PEEK *Ardis* Interbody Spacer.

Recalling Firm:
Zimmer Spine, Inc
7375 Bush Lake Road
Minneapolis, Minnesota 55439

Reason for Recall: Zimmer Spine has received reports of the PEEK *Ardis* Interbody Spacer breaking into fragments when too much lateral force is applied to the *Ardis* Inserter. If the PEEK *Ardis* Interbody Spacer breaks during implantation, surgical delays of up to 60 minutes could occur and health risks may include a tear in the thin covering of the spinal cord (dural tear), cerebrospinal fluid leakage, significant blood loss and nerve injury. Long-term health risks may include disability, dysfunction, or death.

Public Contact: Questions should be directed to Zimmer Spine at 1-866-774-6368, Monday through Friday from 8 am to 5 pm Central Time.

FDA District: Detroit

FDA Comments: Initially, in November 2012, Zimmer Spine issued a Medical Device Correction memo to inform surgeons and hospitals of the problem and to provide updated precautions and surgical technique guidance to decrease the risk of implant breakage. In this memo, Zimmer Spine also indicated that on or about May 2013, a redesigned inserter would be available for use when implanting the PEEK *Ardis* Interbody Spacer.

On Dec. 20, 2012, Zimmer Spine modified their Medical Device Correction memo and initiated a voluntary recall of all 315 units of the PEEK *Ardis* Inserter. Surgeons

and hospitals were instructed to immediately stop using the *Ardis* Inserter and to return them to Zimmer Spine. Surgeons and hospitals should be aware that surgery using the PEEK *Ardis* Interbody Spacer cannot be performed as intended without the use of the *Ardis* Inserter. Therefore the PEEK *Ardis* Implant System will be unavailable for use until a redesigned inserter is cleared by the FDA.

Class I recalls are the most serious type of recall and involve situations in which there is a reasonable probability that use of these products will cause serious adverse health consequences or death.

Health care professionals and consumers may report adverse reactions or quality problems they experienced using these products to MedWatch: The FDA Safety Information and Adverse Event Reporting Program [2] either online, by regular mail or by FAX.

Useful Links:

1. Firm Press Release [1]
2. Firm Recall Webpage [3] [4]

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http://www.mdtmag.com/news/2012/12/class-i-medical-device-recall-zimmer-spine-inc-peek-ardis-inserter?qt-video_of_the_day=0

Links:
[1] http://www.fda.gov/Safety/Recalls/ucm333093.htm
[2] http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm
[3] http://www.zimmer.com/en-US/hcp/news/zimmer-news-02-12-2012.jspx
[4] http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm