

## **FDA Classifies Synthes' Voluntary Medical Device Recall of Synex II Central Body Components as a Class I Recall**

*West Chester (PA), USA, November 4, 2009*

Synthes (SWX: SYST.VX) announced today that the U.S. Food and Drug Administration (FDA) has classified a recall of Synthes Synex II Central Body components as Class I. This means that the product could impose an imminent hazard to health in patients.

The notification relates to a global voluntary recall of Synex II Central Body components on September 14, 2009, which was initiated after receiving six adverse event reports. These reports included moderate to severe loss of vertebral body replacement height (caused by failure of the central body component) in situ at six to fifteen months post implantation. Potential adverse health issues that could be associated with this issue include neural injury, increased pain, spinal kyphosis if unrecognized, failure of supplementary fixation, and/or need for reoperation/revision surgery.

Synthes advises that surgeons and hospitals in possession of the subject devices must stop implanting them immediately. Physicians should contact Synthes for return instructions. Synthes further recommends annual monitoring of implanted patients by their physicians through radiographs and pain assessment. Radiographic changes and/or an increase in pain or other symptoms may be indicators of loss of device height and device failure. If patients have an increase in pain or other symptoms, they should contact their surgeons. This monitoring may or may not fall within Synex II surgeon users' routine postoperative care plan, and more frequent monitoring may be indicated depending on the patient's clinical profile.

The recall involves part numbers 04.808.001-011, Synex II Central Body, Titanium (all lots).

Synthes notified hospitals and sales consultants of this recall through mail. The notification included identification of recalled product, description of the issue, and the potential adverse health ramifications that could occur. Instructions for return of product were enclosed in the mailing. Synthes will also provide additional notification and instruction to physicians and to patients (via their physicians).

Physicians with questions related to this medical device recall should contact Synthes at 1 (800) 620-7025, ext. 5375. Any adverse reactions/events experienced with use of the Synex II Central Body devices should be reported to Synthes at:

- Phone: 1 (800) 752-0128, or
- E-mail: [ComplaintUnit@synthes.com](mailto:ComplaintUnit@synthes.com)

Patients with questions are encouraged to speak with their surgeon.

Adverse reactions or quality problems experienced with these products may also be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax at:

- Online: <http://www.fda.gov/medwatch/report.htm>
- Regular Mail: use postage-paid FDA form 3500 available at [www.fda.gov/MedWatch/getforms.htm](http://www.fda.gov/MedWatch/getforms.htm).  
Mail to MedWatch 5600 Fishers Lane, Rockville, MD 20852-9787
- Fax: 1 (800) FDA-0178

**Synthes: A leading medical device company**

Synthes is a leading global medical device company. We develop, produce and market instruments, implants and biomaterials for the surgical fixation, correction and regeneration of the human skeleton and its soft tissues.

**For further information please contact**

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