

Class I Medical Device Recall: Stryker Orthopaedics - ShapeMatch Cutting Guide

U.S. Food & Drug Administration

Recall Class: Class I

Date Recall Initiated: April 10, 2013

Product: ShapeMatch Cutting Guides

Manufacturing and Distribution Dates: May 2011 to November 2012

Product Codes and Lot Numbers: All

Use: The ShapeMatch Cutting Guides are single-use, disposable, cutting guides. They are intended to be used as surgical instrumentation to assist in the positioning of total knee replacement (arthroplasty) components intraoperatively and in guiding the marking of bone before cutting. The ShapeMatch Cutting Guides are used with the Triathlon Knee System.

Recalling Firm:

Stryker Howmedica Osteonics Corp.
325 Corporate Drive
Mahwah, NJ 07430

Reason for Recall:

Stryker Orthopaedics has become aware of potential issues associated with internal processes for planning cases and producing ShapeMatch Cutting Guides. The parameters of the manufactured cutting guides did not meet the surgeon's pre-operative planning parameters entered via the web application. When the parameters were manually edited to compensate for a defect in the existing software, the edits resulted in cutting guides ranges that are not cleared by the FDA. Additionally, Stryker Orthopaedics determined that another software defect resulted in the displayed parameters (e.g. depth of resection, angle of cut) not matching the cutting guides produced. This may result in serious adverse health consequences including joint instability, fracture, need for revision surgery and chronic pain and limitations of mobility.

Public Contact: Questions should be directed to Stryker at 1-888-STRYKER (787-9537) Monday through Friday from 8am - 8pm Eastern Time.

FDA District: New Jersey District Office

FDA Comments:

In November 2012, Stryker Orthopaedics e-mailed field locations, registered

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surgeons and imaging centers of the problem and to immediately stop prescribing, planning or performing operative or imaging procedures with the ShapeMatch Cutting Guides until further notice. In January 2013, a Product Notification was issued to all branches, agencies, surgeons and risk managers at affected hospitals informing them of the problem and risk mitigation factors.

On April 10, 2013, Stryker issued an Urgent Medical Device Recall. Stryker is recommending patients who had knee replacement surgery in which ShapeMatch Cutting Guides were used and who are experiencing symptoms to contact their surgeon. If the patient is symptom-free, they should continue to follow-up with surgeon as prescribed. This recall does not affect the Triathlon Knee System or Triathlon standard instrumentation.

The FDA has received a total of 44 reports (41 malfunctions and 3 temporary medically reversible injuries) of incidents related to the ShapeMatch Cutting Guides.

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 the [MedWatch: The FDA Safety Information and Adverse Event Reporting Program](#) [1] either online, by regular mail or by FAX.

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<http://www.mdtmag.com/news/2013/04/class-i-medical-device-recall-stryker-orthopaedics-shapematch-cutting-guide>

Links:

[1] <http://www.fda.gov/Safety/MedWatch/default.htm>