Recall Date: March 03, 2016
Recall Status: Open
Recall Number: Z-1043-2016
Recall Event ID: 7285323
510(K)Number: K08377224
Product: Columbus Revision Knee System, EnduRo Knee System
Product Usage:
The Columbus Revision Knee System and EnduRo Knee System are indicated for use in reconstruction of the diseased knee joint.

Code Information: All codes
Recalling Firm/Manufacturer: Aesculap, Inc.
3773 Corporate Pkwy
Center Valley PA 18034-8217
For Additional Information Contact: 800-258-1946 Ext. 5067
Manufacturer Reason for Recall: Aesculap Inc. US has initiated a recall on Tibial and Femur extension sterile pressfit stem implant packaging that are used for Columbus Revision/Enduro Knee Implants because it is labeled as Cementless. US product is indicated in the US for use with Bone Cement only.

FDA Determined Cause: Packaging change control
Action: Aesculap sent an Urgent Medical Device Correction letter to Distributors and Sales Rep. The letter identified the affected product, problem and actions to be taken. Customers were notified to add the over label to product packaging. Telephone conferences with Distributors and Sales Rep reiterated need for representative to inform Surgical Handler of the label when providing product for review. Customers were instructed to complete the attached Product Correction Acknowledgement Form and return to Aesculap Quality Assurance department by faxing the form to 610-791-6882 or e-mail to val.strawn@aesculap.com, two (2) weeks of receipt, even if the total inventory in your possession is zero (0).
Quantity In Commerce: 1232
Distribution: US Nationwide Distribution
Total Product Life Cycle: TPLC Device Report27

http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=142358
3/21/2016