# Class 2 Device Recall B. Braun AM Aesculap



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See Related Information[22]

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|---|---|
| **Recall Date** | March 03, 2016 |
| **Recall Status[1]** | Open |
| **Recall Number** | Z-1043-2016 |
| **Recall Event ID** | 72853[23] |
| **510(K)Number** | K083772[24] |
| **Product Classification** | Prosthesis, knee, patellofemorotibial, semi-constrained, cemented, polymer/metal/polymer[25] - **Product Code** JWH[26] |
| **Product** | Columbus Revision Knee System, EnduRo Knee System<br><br>Product Usage:<br>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.<br>3773 Corporate Pkwy<br>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 [2]** | 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 Report[27] |