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New Search

Class 2 Device Recall Lactosorb RapidFlap

Date Initiated by Firm
Create Date
Recall Status
Recall Number
Recall Event ID
510(K) Number
Product Classification
Product

The RapidFlap LS Cranial Fixation System is indicated for use in pediatric cranotomy flap fixation.

Code Information

Lots

Lactosorb RapidFlap, bone plate. Model No. 915-0020

Recalling Firm / Manufacturer

Zimmer Biomet, Inc.
56 E Bell Dr
Warsaw IN 46582-6889

For Additional Information Contact

411 Technical Services
574-371-3071

Manufacturer Reason for Recall

The recalling firm has confirmed that the outer plate component exhibits an excessive chamfer on the threading after deburring operations. This excessive chamfer results in non-conforming product where the threads of the outer plate component have limited to no engagement with the post component.

FDA Determined Cause

Process control

Action

Zimmer Biomet sent an Urgent Medical Device Recall letter dated April 5, 2018, to Distributors, Sales Representatives, and Distribution Managers. A separate recall letter was sent to Risk Managers on the same date. Consignees were informed of the product issue and risk of non-functioning device and delays in surgery. All parties were instructed to review the notice, locate and quarantine affected product in inventory, return all affected product with a completed return form and mark “RECALL” on the outside of returned cartons, and return the completed customer response form.

If you have further questions or concerns regarding this recall, please call (904)741-4400 extension 9133 between 8:00 am and 5:00 pm EST. Monday through Friday. Calls received outside of operating hours will receive a voicemail prompt. For further questions, please call (574) 371-3071.

Quantity in Commerce

13175

Distribution

worldwide Distribution - US Distribution to the states of CA, FL, MO, NC, SC, TX, and Wl, and to the countries of...