Class 2 Device Recall

LATARJET EXPERIENCE Combo Screw Driver

Date Initiated by Firm
May 12, 2017

Create Date
June 20, 2017

Recall Status
Open, Classified

Recall Number
Z-2615-2017

Recall Event ID
772522

510(K) Number
K110763 K091694 K083096

Product Classification
Screw, fixation, bone - Product Code HWC

Product
DePuy Mitek LATARJET EXPERIENCE-Combo Screw Driver
Product Code: 288211

Product Usage:
The Latarjet Cortical Screw set is intended to treat recurrent shoulder instability by supporting the anteroinferior glenoid with a bony graft.

Code Information
GTN: 0110886705026890, Lot codes: 16D02, 16E01, 16J01, 17A01, 17B01, 17B02

Recalling Firm/Manufacturer
DePuy Mitek, Inc., a Johnson & Johnson Co.
325 Paramount Dr
Raynham MA 02767-5199

For Additional Information Contact
SAME
508-880-8100

Manufacturer Reason for Recall
Combo Screw Driver (Product Code 288211) tip has the increased potential to break intraoperatively when being used at an angle off-axis to screw

FDA Determined Cause
Component design/selection

Action
DePuy Mitek issued recall letter dated May 12, 2017 advising of the problem and requesting return of the product. A Response Form is to be completed and returned. Questions: contact your DePuy Synthes Mitek Sales Consultant or Carolyn Somerville, DePuy Mitek, Inc. (via telephone: 508.828.3647 Fax: 508.828.3762 or via email: DPYUS-MitekFieldActions@its.jnj.com).

Quantity in Commerce
173 units

Distribution
US: AZ, CA, CO, GA, MA, MI, OH, WA Foreign: Austria, Australia, Belgium, France, Germany, Spain, Switzerland, Netherlands, Poland, UK

Total Product Life Cycle
TPLC Device Report

1 A record in this database is created when a firm initiates a correction or removal action. The record is updated if the FDA identifies a violation and classifies the action as a recall, and it is updated for a final time when the recall is terminated. Learn more about medical device recalls.

2 Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=155555

6/28/2017