Class 2 Device Recall Dermabond "Prineo" System

Date Initiated by Firm: November 27, 2017
Create Date: March 21, 2018
Recall Status: Open, Classified
Recall Number: Z-1147-2018
Recall Event ID: 79356
510(K) Number: K133864
Product Classification: Prosthesis, hip, semi-constrained, polyethylene acetabular bearing surface, cemented or uncemented - Product Code OMO
Product: DERMABOND* PRINEO* Skin Closure System

Product Usage: DERMABOND PRINEO System is intended for topical application only to hold closed easily approximated skin edges of wounds from surgical incisions, including punctures from minimally invasive surgery, and simple, thoroughly cleansed, trauma-induced lacerations. DERMABOND PRINEO System should be used in conjunction with, but not in place of, deep dermal stitches. Additionally, the adjunct wound closure device component maintains temporary skin edge alignment along the length of the wound during application of the liquid adhesive.


Recalling Firm/Manufacturer: Ethicon, Inc
Us Highway 22 West
Somerville NJ 08876

For Additional Information Contact: Tom Morris
908-218-0707

Manufacturer Reason for Recall: Ethicon discovered that specific lots of DERMABOND*PRINEO*System may not dry within the specified time after proper application, and thus may fail off.

FDA Determined Cause: Component change control

Action: Ethicon sent an URGENT MEDICAL DEVICE RECALL REMOVAL letter dated November 2017 to customers titled "DERMABOND*TM PRINEOTM SKIN CLOSURE SYSTEM (22 CM)". The letter identified the affected product, problem and action to be taken. The letter instructed customers to do not use or distribute any product which is subject to recall. Customers are asked to examine inventory, quarantine products that are subject to recall and contact the firm for return of product. Also, post the recall letter in a visible location at facility. If you have additional questions regarding this recall (removal) or to report any customer complaints, please contact Ethicon Customer Support Center at 1-877-ETHICON (1-877-384-4266). The Customer Support Center is open Monday through Friday, 7:30 AM to 6:30 PM ET.

Quantity in Commerce: 20,090 packages (10,545 units)