Medical Device Recalls

New Search

Class 2 Recall
Ethicon Stratofix Symmetric PDS
Plus Knotless Tissue Control Device

Date Posted: December 06, 2013
Recall Status: Open
Recall Number: Z-0458-2014

Product Classification: Suture, Surgical, Absorbable, Poliglecaprone 25, Product Code: NEW

Product: Ethicon Stratofix Symmetric PDS Plus Knotless Tissue Control Device Ethicon LLC
Guaynabo, Puerto Rico 00989. Intended for general soft tissue approximation where use of an absorbable suture is appropriate.

Code Information: K113004 D153642 All product codes beginning with SXPP1A.

Recalling Firm/Manufacturer: Ethicon, Inc.
US Highway 22 West
Somerville, New Jersey 08876

Manufacturer Reason for Recall: Ethicon Stratofix Symmetric PDS Plus Knotless Tissue Control Device has a small number of tab failures and fascial dehiscences in lower abdominal incisions.

Action: Ethicon Inc. sent recall noticifications/business reply forms on 9/25/2013 via UPS next day certified mail.

Quantity in Commerce: 37,164 eaches

Distribution: Worldwide Distribution: USA and the Caribbean, Chile, Singapore and Malaysia.

Total Product Life Cycle: TPLC Device Report

For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 802.30.

Links on this page:
4. http://www.fda.gov/MedicalDevices/default.htm
6. /scripts/cdrh/devicesatfda/index.cfm
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12/23/2013