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

See Related Information[21]

Date Posted	December 06, 2013
Recall Status[1]	Open
Recall Number	Z-0458-2014
Product Classification	Suture, Surgical, Absorbable, Polydioxanone[22] - **Product Code** NEW[23]
Product	Ethicon Stratafix Symmetric PDS Plus Knotless Tissue Control Device Ethicon LLC Guaynabo, Puerto Rico 00969. Intended for general soft tissue approximation where use of an absorbable suture is appropriate.
Code Information	K113004 D183642 All product codes beginning with SXPP1A.
Recalling Firm/ Manufacturer	Ethicon, Inc. US Highway 22 West Somerville, New Jersey 08876
Manufacturer Reason for Recall	Ethicon Stratafix 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 notifications/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[24]

[1] For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 §7.55[25]

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