Class 2 Device Recall Weck EFx Classic Fascial Closure System

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See Related Information[22]

Recall Date	August 15, 2016
Recall Status[1]	Open
Recall Number	Z-2538-2016
Recall Event ID	74683[23]
Product Classification	Instrument, ligature passing and knot tying[24] - **Product Code** HCF[25]
Product	Weck EFx Classic Fascial Closure System, Rx Only, Sterile, The product is intended to facilitate placement and withdrawal of suture loops to repair port side defects following laparoscopic surgery
Code Information	Product Code EFXCT1 - Lot/Batch Nos. ML-000342, ML-000343, ML-000344, ML-000348, ML-000349; Product Code EFXSP1 - Lot/Batch Nos. ML-000345, ML-000347
Recalling Firm/ Manufacturer	Teleflex Medical 2917 Weck Dr Research Triangle Park NC 27709-0186
For Additional Information Contact	Alice Harper 610-378-0131
Manufacturer Reason for Recall	Incorrect expiration date was printed on the product label.
FDA Determined Cause [2]	Unknown/Undetermined by firm
Action	Teleflex sent an Urgent Medical Device Recall Notification letter dated March 24, 2016, to all affected consignees. The letter requested that consignees check their stock, immediately discontinue use and quarantine any products. To return affected product consignees were instructed to complete the enclosed Recall Acknowledgement Form and fax it to 1-855-419-8507, ATTN: Customer Service or email to recalls@teleflex.com. Customers with questions were instructed to contact their local sales representative or Customer Service at 1-866-246-6990. For questions regarding this recall call 610-378-0131.
Quantity in Commerce	45
Distribution	Nationwide Distribution to CA, CO, IA, KS, MD, MI, NY, NC, PA
Total Product Life Cycle	TPLC Device Report[26]

[1] For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 §7.55[27]
[2] Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.

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