Class 2 Device Recall Echelon Flex Powered Vascular Stapler With Advanced Placement Tip and White Reloads

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See Related Information[23]

Date Posted	May 21, 2015
Recall Status[1]	Open
Recall Number	Z-1641-2015
Recall Event ID	71215[24]
Premarket Notification 510(K) Number	K141952[25]
Product Classification	Staple, Implantable[26] - **Product Code** GDW[27]
Product	ENDOPATH ECHELON" Vascular White Reload for Advanced Placement Tip, Product Usage: The instruments have application in multiple open or minimally invasive general, gynecologic, urologic, thoracic and pediatric surgical procedures.
Code Information	M/N: VASECR35; Product Lot L4FF3W, Expiry Date 2017-11; Product Lot L4FF3X, Expiry Date 2017-11; Product Lot L4FF3Y, Expiry Date 2017-11; Product Lot M4H046, Expiry Date 2017-12; Product Lot M4H105, Expiry Date 2017-12; Product Lot M4H27D, Expiry Date 2017-12; Product Lot M4H30H, Expiry Date 2017-12; Product Lot M4H37J, Expiry Date 2017-12; Product Lot M4H399, Expiry Date 2017-12; Product Lot M4H589, Expiry Date 2018-01; Product Lot M4H54M, Expiry Date 2018-01; Product Lot M4H643, Expiry Date 2018-01 & Product Lot M4H691, Expiry Date 2018-01..
Recalling Firm/ Manufacturer	Ethicon Endo-Surgery Inc 4545 Creek Rd Blue Ash, Ohio 45242-2803
For Additional Information Contact	Mr. Thomas A. Morris 513-337-7000
Manufacturer Reason for Recall	During an internal inspection of the production process the firm discovered an issue which may cause the cartridge to deploy an incomplete staple line.
FDA Determined Cause [2]	OTHER/UNDETERMINED: Under Investigation by the firm
Action	Ethicon sent an Urgent Medical Device Recall letter dated February 27, 2015 to their customers. The letter identified the affected product, problem and actions to be taken. Customers were instructed to examine your inventory immediately to determine if you have recalled product on hand, remove and quarantine the recalled product, communicate the issue to relevant operating room or materials management personnel or anyone else in your facility who needs to be informed, if any product included in this recall has been forwarded to another facility, contact that facility to arrange return, and complete the Business Reply Form (BRF) (Attachment B) confirming receipt of this notice within three (3) business days. The BRF may be sent to Stericycle by fax at 1-800-807-5967or by email at ees8760@stericycle.com. Please return the BRF even if you do not have affected product. For clinical or product support, please contact your local sales representative or call our Customer Support Center at 1-877-ETHICON (1-877-384-4266) (7:30 a.m. 6:30 p.m. EST). If you need additional shipping labels or a communications package, contact Stericycle at 1-877-643-8419 (8:00 a.m. 5:00 p.m. EST) and reference Event 8760.