Class 2 Device Recall Gynecare Thermachoice III

See Related Information 22

Date Posted	January 06, 2016
Recall Status[1]	Open
Recall Number	Z-0602-2016
Recall Event ID	72840[23]
PMA Number	P970021[24]
Product Classification	Catheter, balloon, dilation of cervical canal[25] - **Product Code** PFJ[26]
Product	Gynecare Thermachoice III Uterine Balloon Therapy System Ethicon, Inc. The GYNECARE THERMACHOICE¿ III Uterine Balloon Therapy (UBT) System is a thermal balloon ablation device intended to ablate the endometrial lining of the uterus in pre-menopausal women with menorrhagia (excessive uterine bleeding) due to benign causes for whom childbearing is complete.
Code Information	TC003 (US Only) TC013 (US Only) TC033 (OUS Only) TC043 (OUS Only). Code, Batch: TC04320, GMMG07; TC00320, GMMG08; TC00320, GMMG09; TC00320, GMMG10; TC04320, GMMG11; TC03320, GPMG01; TC04320, GPMG02; TC00320, GPMG03; TC00320, GPMG04; TC00320, GPMG05; TC01320, GPMG06; TC04320, GPMG07; TC03320, GPMG08; TC04320, GPMG09; TC00320, GPMG10; TC00320, GPMG11; TC00320, HAMG01; TC00320, HAMG02; TC03320, HAMG03; TC04320, HAMG04; TC00320, HAMG05; TC00320, HAMG06; TC00320, HAMG07; TC00320, HAMG08; TC01320, HAMG09; TC03320, HAMG10; TC04320, HAMG11; TC04320, HAMG12; TC00320, HAMG13; TC00320, HAMG14; TC00320, HBMG01; TC00320, HBMG02; TC04320, HBMG03; TC04320, HBMG04; TC03320, HBMG05; TC00320, HBMG06; TC00320, HBMG07; TC04320, HBMG08; TC03320, HBMG09; TC00320, HBMG10; TC00320, HCMG01; TC00320, HCMG02; TC00320, HCMG03; TC00320, HCMG04; TC04320, HCMG05; TC04320, HCMG06; TC03320, HDMG01; TC00320, HDMG02; TC00320, HDMG03; TC00320, HDMG04; TC00320, HDMG05; TC03320, HEMG01; TC04320, HEMG02; TC01320, HEMG03; TC00320, HEMG05; TC00320, HEMG06; TC00320, HEMG07; TC00320, HEMG08; TC04320, HEMG09; TC04320, HGMG01; TC03320, HGMG02; TC00320, HGMG03; TC00320, HGMG04; TC00320, HGMG05; TC00320, HGMG06; TC00320, HGMG07; TC04320, HGMG08; TC04320, HGMG09; TC04320, HGMG10; TC00320, HHMG01; TC00320, HHMG02; TC00320, HHMG03; TC00320, HHMG04; TC03320, HHMG05; TC04320, HHMG06; TC00320, HHMG08; TC00320, HHMG09; TC00320, HHMG10; TC04320, HHMG07; TC00320, HHMG11; TC00320, HHMG12; TC00320, HJMG02; TC00320, HJMG03; TC00320, HJMG04; TC00320, HJMG05; TC00320, HJMG06; TC01320, HJMG07; TC03320, HJMG08; TC04320, HJMG09; TC04320, HJMG10; TC00320, HJMG11; TC00320, HJMG12; TC00320, HJMG13; TC04320, HKMG01; TC00320, HJMG14; TC04320, HKMG02; TC03320, HKMG03; TC00320, HKMG04; TC00320, HKMG05; TC00320, HKMG06; TC04320, HKMG07; TC03320, HKMG08; TC00320, HKMG10; TC00320, HKMG09; TC00320, HKMG11; TC00320, HLMG01; TC00320, HLMG02; TC00320, HLMG03; TC01320, HLMG04; TC04320, HLMG05; TC03320, HLMG06; TC00320, HLMG07; TC00320, HLMG08; TC00320, HLMG09; TC04320, HLMG10; TC03320, HMMG01; TC04320, HMMG02; TC00320, HMMG03; TC00320, HMMG04; TC04320, HMMG05; TC00320, HMMG06; TC00320, HMMG07; TC00320, HPMG01; TC00320, HPMG02; TC04320, HPMG04; TC03320,

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Recalling Firm/ Manufacturer	Ethicon, Inc. US Highway 22 West Somerville NJ 08876 908-218-0707
For Additional Information Contact	Customer Service 877-384-4266
Manufacturer Reason for Recall	Stability data does not substantiate the labeled two-year shelf life of affected product.
FDA Determined Cause [2]	Device Design
Action	Ethicon, Inc. sent "Urgent: Medical Device Recall (REMOVAL)" notifications and Business Reply Forms dated 12/3/2015 on same date via UPS Next Day Mail to its customers. The notification informed the customers of the issue with the product; how to identify affected product and action required. The customers were instructed to examine their inventory immediately to determine if they have affected product on hand and quarantine the affected product(s); remove the affected product and communicate the issue to relevant operating room or materials management personnel, or anyone else in their facility who needs to be informed; if any affected product has been forwarded to another facility, contact that facility to arrange return; complete and return the enclosed Business Reply Form (BRF) confirming receipt of this notice within three (3) business days to Stericycle by fax at 1-866-792-5453 or by email at Ethicon7427@stericycle.com, return BRF even if you do not have affected product. Stericycle is handling returns. If the customer requires any assistance with returning product or have any questions, they were instructed to contact the Customer Support Center at 1-877-ETHICON (1-877-384-4266). Ethicon, Inc. issued an update to their 12/3/2015 letter in a notification dated 12/23/2015. The 12/23/2015 notification clarified the lots of the product subject to their recall previously communicated in their 12/3/2015 letter. There are three (3) lots of product subject to the recall that were inadvertently omitted from the original lot listing. The notification stated that "All THERMACHOICE¿ Catheter lots with an expiration date prior to December 10, 2017 are subject to this recall and are required to be returned. The lot number listing of all product subject to the recall is contained in Attachment 1. The expiration date and lot number can be determined by using the Product Identification Tool attached hereto at Attachment 2." The attachments included the updated pr
Quantity in Commerce	96,124 units
Distribution	Worldwide Distribution: US (nationwide) including Puerto Rico and countries of: India, Belgium, Argentina, Mexico, Brazil, Canada, Colombia, Ecuador, Singapore, Aruba and Venezuela.
Total Product Life Cycle	TPLC Device Report[27]

[1] For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 §7.55[28]