URGENT: FIELD SAFETY NOTICE

GYNECARE THERMACHOICE™ III Thermal Balloon Ablation Silicone Catheter
(Product Codes TC033 and TC043)

3rd December 2015

Please distribute this information to appropriate personnel at your facility.

Dear Sir/Madam,

Ethicon, Inc. ("ETHICON") has initiated a voluntary recall of the GYNECARE THERMACHOICE™ III Thermal Balloon Ablation Silicone Catheter ("THERMACHOICE™ Catheter"). We are removing this product from the market because stability data does not substantiate the labelled two-year shelf life of affected product.

The voluntary recall involves only the THERMACHOICE® Catheter component of the GYNECARE THERMACHOICE™ III Uterine Balloon Therapy System and does not include other components of the system (controller, umbilical cable etc.).

EFFECTIVE IMMEDIATELY – DO NOT USE ANY OF THE FOLLOWING PRODUCT CODES:

PRODUCT NAME	PRODUCT CODE	PRODUCT LOT
GYNECARE THERMACHOICE® III Thermal Balloon Ablation Silicone Catheter	TC033	All unexpired lots*
GYNECARE THERMACHOICE® III Thermal Balloon Ablation Silicone Catheter	TC043	All unexpired lots*

*From 31 October 2013 due to 2 year expiration

Please see Attachment 1 for a Product Identification Tool to assist in identifying the impacted lots of affected product using package labels.

Customers are required to return all unexpired, unused THERMACHOICE™ Catheters (Product Code TC033 and TC043) that are components of the GYNECARE THERMACHOICE™ III Uterine Balloon Therapy System in their inventory immediately. Affected products returned by February 26, 2016 will be reimbursed.

ETHICON will not accept returns for other components of the GYNECARE THERMACHOICE™ III Uterine Balloon Therapy System (such as the cable or controller).

At ETHICON, our first priority is to our customers and their patients, and that includes the safe and effective use of our products.

There is no significant safety issue with the device, nor does the data suggest any impact to the outcome of a procedure. Healthcare practitioners that have treated patients using

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the THERMACHOICE™ Catheter should continue to follow their patients in the usual manner.

We recognize the voluntary recall of the affected product may disrupt you or your facility and we apologize for any inconvenience this may cause. At this time, we do not have further information regarding a market return for the THERMACHOICE™ Catheter, and we do not currently have a direct replacement for this product within our portfolio.

We advise you to identify potential alternative products and/or procedures to help treat women with menorrhagia.

This voluntary recall has been communicated to the U.S. Food and Drug Administration (FDA) and the European Competent Authorities in the countries affected by this voluntary product recall.

ACTIONS REQUIRED FROM YOU

1. Examine your inventory immediately to determine if you have affected product on hand.

2. **Remove and quarantine** the affected product and communicate the issue to relevant operating room or materials management personnel, or anyone else in your facility who needs to be informed.

3. If any affected product has been forwarded to another facility, contact that facility to arrange return.

4. Complete the Customer Acknowledgement Form confirming receipt of this notice within two (2) business days and return the Customer Acknowledgement Form to your Ethicon sales representative or fax it to 67200750. Please return the Customer Acknowledgement Form **even if you do not have affected product.**

5. Keep this notice visibly posted for awareness until all affected product has been returned to Ethicon. While processing your returns, please maintain a copy of this notice with the affected product and keep a copy for your records.

6. Credit is available for customers who return affected product.

    - All affected product must be returned immediately. Any affected product returned after February 26, 2016 will not be eligible for credit.

    - To return affected product, photocopy the completed customer acknowledgement form, place it in the box with the affected product, and return the product to your Sales Representative.

If you need clinical or product support, please contact your local Sales Representative or ETHICON.

As with any medical device, adverse reactions or quality problems experienced with the use of this product should be reported your Sales Representative, directly to ETHICON, or the National Health Authority.

If you have any further question related to this notice or if you need an additional communications letter, please contact your Sales Representative.

Thank you for your attention and cooperation.

Yours sincerely,

Lee Ching Hwee

Senior Regulatory Affairs Executive

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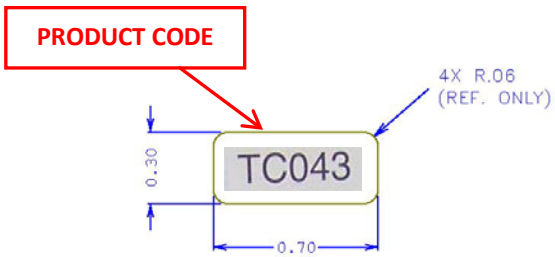
ATTACHMENT 1: Product Identification Tool for GYNECARE THERMACHOICE™ III Thermal Balloon Ablation Silicone Catheter (TC033 and TC043)

This tool will help customers identify the affected product using package labels. This document applies to the sales unit carton, sales unit side label, Tyvek® packaging and shipper unit label for product codes TC033 and TC043. Product Code TC043 is used as an example.

SALES UNIT CARTON (Secondary Label)

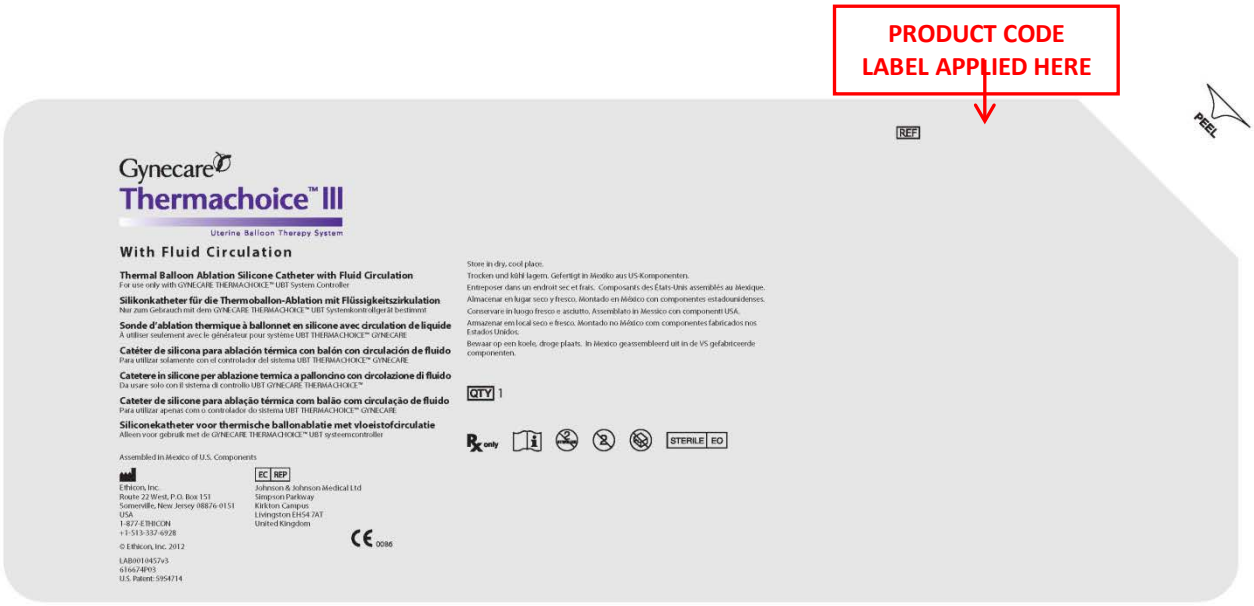
FRONT and DISPENSER PANELS

PRODUCT CODE LABEL

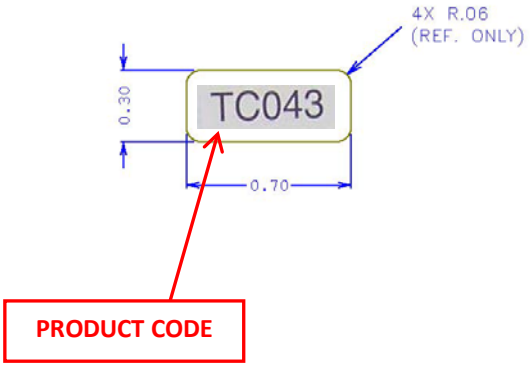


SALES UNIT LABEL

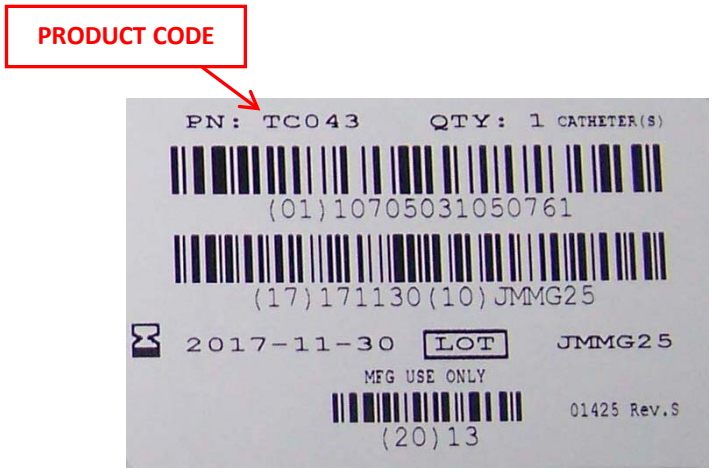
TYVEK® SINGLE UNIT



PRODUCT CODE LABEL

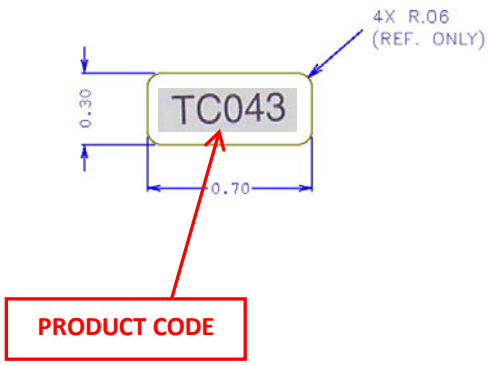


SINGLE UNIT LABEL



SHIPPER UNIT LABEL

PRODUCT CODE LABEL



SHIPPER UNIT LABEL