URGENT: MEDICAL DEVICE REMOVAL

ETHICON PHYSIOMESH™ Flexible Composite Mesh
(All Product Codes)

27th May 2016

Please distribute this information to appropriate personnel at your facility.

Dear Sir/Madam,

At Ethicon, Inc. ("Ethicon"), our first priority is to our customers and their patients, and that includes the safe and effective use of our products.

We have initiated a worldwide medical device removal of ETHICON PHYSIOMESH™ Flexible Composite Mesh (for laparoscopic use) ("ETHICON PHYSIOMESH™ Composite Mesh"). We are removing the product following an analysis conducted at the request of the Ethicon Medical Safety Team of unpublished data from two (2) large independent hernia registries (Herniamed German Registry and Danish Hernia Database-DHDB). The recurrence/reoperation rates (respectively) after **laparoscopic** ventral hernia repair using ETHICON PHYSIOMESH™ Composite Mesh were higher than the average rates of the comparator set of meshes among patients in these registries.

Based on the currently available data, we believe the higher rates to be a multifactorial issue (including possible product characteristics, operative and patient factors), but we have not been able to fully characterize these factors. Consequently, we have not been able at this time to issue further instructions to surgeons that might lead to a reduction in the recurrence rate and have decided to remove ETHICON PHYSIOMESH™ Composite Mesh from the global market.

Health care practitioners that have treated patients using ETHICON PHYSIOMESH™ Composite Mesh should continue to follow those patients in the usual manner.

This worldwide medical device removal has been communicated to the U.S. Food and Drug Administration (FDA).

This action involves only the ETHICON PHYSIOMESH™ Composite Mesh product line. It does not include the ETHICON PHYSIOMESH™ Open Flexible Composite Mesh Device, or other hernia mesh or device products manufactured or sold by Ethicon.

The scope of this action includes all product codes of ETHICON PHYSIOMESH™ Composite Mesh.

Johnson & Johnson Medical Singapore
a division of Johnson & Johnson Pte Ltd.
No. 2 International Business Park, #07-01, Tower One, The Strategy, Singapore 609930
Tel: +65 6827 6000 Fax: +65 6720 0750
Business Reg No. 52836279L Company Reg No. 197402104W

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

PRODUCT NAME	PRODUCT CODE	DESCRIPTION/SIZE	PRODUCT LOT
ETHICON PHYSIOMESH™ Composite Mesh	PHY0715R	Rectangle 7.5cm x 15cm	All lots impacted by this removal.
ETHICON PHYSIOMESH™ Composite Mesh	PHY1015V	Oval 10cm x 15cm	All lots impacted by this removal.
ETHICON PHYSIOMESH™ Composite Mesh	PHY1515Q	Square 15cm x 15cm	All lots impacted by this removal.
ETHICON PHYSIOMESH™ Composite Mesh	PHY1520R	Rectangle 15cm x 20cm	All lots impacted by this removal.
ETHICON PHYSIOMESH™ Composite Mesh	PHY1520V	Oval 15cm x 20 cm	All lots impacted by this removal.
ETHICON PHYSIOMESH™ Composite Mesh	PHY2025V	Oval 20cm x 25cm	All lots impacted by this removal.
ETHICON PHYSIOMESH™ Composite Mesh	PHY2030R	Rectangle 20cm x 30cm	All lots impacted by this removal.
ETHICON PHYSIOMESH™ Composite Mesh	PHY2535V	Oval 25cm x 35cm	All lots impacted by this removal.
ETHICON PHYSIOMESH™ Composite Mesh	PHY3035R	Rectangle 30cm x 35cm	All lots impacted by this removal.
ETHICON PHYSIOMESH™ Composite Mesh	PHY3050R	Rectangle 30cm x 50cm	All lots impacted by this removal.

IDENTIFICATION OF PRODUCT SUBJECT TO THIS ACTION:

Product subject to the medical device removal in your inventory can be identified by product code (see product code listing above). All unused ETHICON PHYSIOMESH™ Composite Mesh products are subject to this action and are required to be returned. The product code can be determined by using the Product Identification Tool attached at Attachment 1.

ACTIONS REQUIRED FROM YOU

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

Johnson & Johnson Medical Singapore
a division of Johnson & Johnson Pte Ltd.
No. 2 International Business Park, #07-01, Tower One, The Strategy, Singapore 609930
Tel: +65 6827 6000 Fax: +65 6720 0750
Business Reg No. 52836279L Company Reg No. 197402104W

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. Only unexpired product subjected to this removal is eligible for credit. Expired product that is returned will not be reimbursed.

    - All affected product must be returned immediately. Any affected product returned after September 16, 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 require any assistance with returning product, please contact your local Sales Representative or ETHICON.

Ethicon will not return the ETHICON PHYSIOMESH™ Composite Mesh product to the market worldwide.

We recognize the removal of the ETHICON PHYSIOMESH™ Composite Mesh may be disruptive to your facility and we apologize for any inconvenience this may cause.

Ethicon offers the following products to consider for ventral hernia repair and other fascial deficiencies.

For intraperitoneal/intra-abdominal mesh placement:
- PROCEED™ Surgical Mesh
- ETHICON PHYSIOMESH™ Open

Johnson & Johnson Medical Singapore
a division of Johnson & Johnson Pte Ltd.
No. 2 International Business Park, #07-01, Tower One, The Strategy, Singapore 609930
Tel: +65 6827 6000 Fax: +65 6720 0750
Business Reg No. 52836279L Company Reg No. 197402104W

For extraperitoneal mesh placement, Ethicon manufactures several flat meshes for use in extraperitoneal ventral hernia repair:

- PROLENE™ Mesh
- PROLENE™ Soft Mesh
- ULTRAPRO™ Mesh
- ULTRAPRO™ Advanced Mesh

Please read the full Instructions For Use for the above named products for more detailed information on proper use, indications, contraindications, warnings, precautions and adverse events. Please also consider alternative products from other manufacturers and alternative procedures to treat patients with hernias.

If you have additional questions regarding this action or to report any customer complaints, or require assistance with alternative options for hernia repair, please contact your sales representative.

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

Thank you for your attention and cooperation.

Yours sincerely,

[redacted]

Lee Ching Hwee

Associate Manager Regulatory Affairs

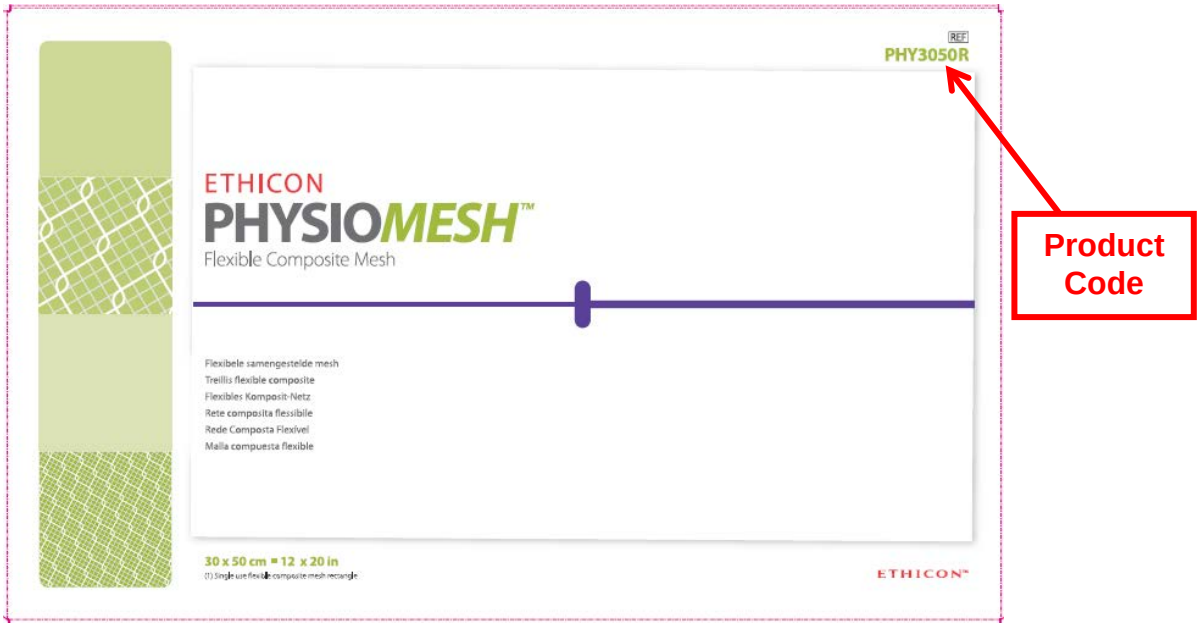
Johnson & Johnson Medical Singapore
a division of Johnson & Johnson Pte Ltd.
No. 2 International Business Park, #07-01, Tower One, The Strategy, Singapore 609930
Tel: +65 6827 6000 Fax: +65 6720 0750
Business Reg No. 52836279L Company Reg No. 197402104W

ATTACHMENT 1: Product Identification Tool for ETHICON PHYSIOMESH™ Flexible Composite Mesh (All Product Codes)

This tool will help customers identify the lots of product subject to this action by using the package labels. This document applies to the Tyvek® envelope and foil pouch for the product codes identified on page 2 of the notification letter.

TYVEK® ENVELOPE (containing 1 mesh)

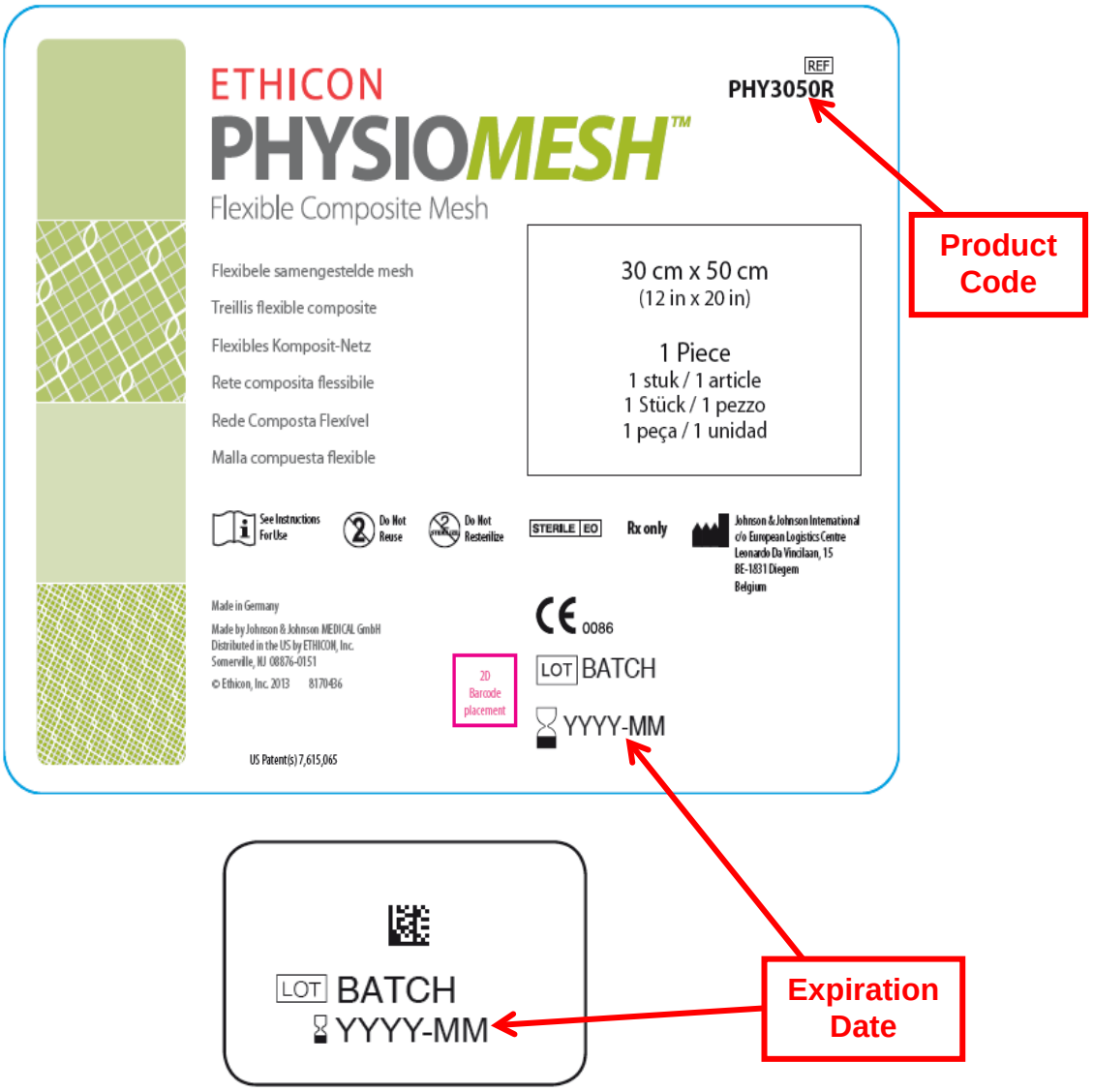
Front of Envelope



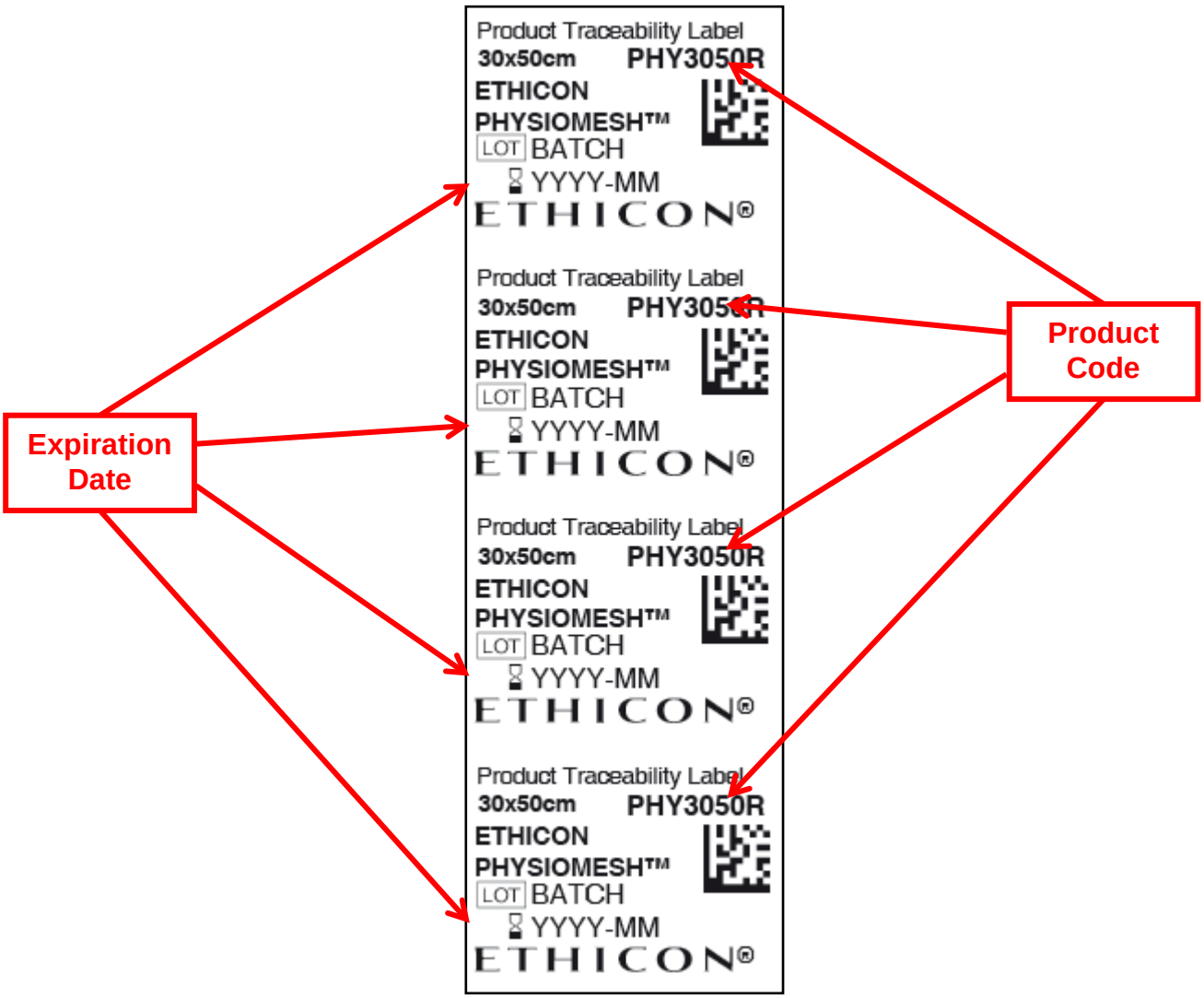
Back of Envelope

FOIL POUCH (containing 1 mesh)

Front of Pouch



Back of Pouch



Johnson & Johnson Medical Singapore
a division of Johnson & Johnson Pte Ltd.
No. 2 International Business Park, #07-01, Tower One, The Strategy, Singapore 609930
Tel: +65 6827 6000 Fax: +65 6720 0750
Business Reg No. 52836279L Company Reg No. 197402104W