ETHICON

URGENT: FIELD SAFETY NOTICE

ETHICON PHYSIOMESH™ Flexible Composite Mesh
(All Product Codes)

25 May 2016

Dear Operating Room Supervisors, Materials Management Personnel, and Chief of Surgery:

PLEASE DISTRIBUTE THIS INFORMATION TO ALL STAFF WITHIN YOUR FACILITY WHO USE ETHICON PHYSIOMESH™ FLEXIBLE COMPOSITE MESH

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

Ethicon has initiated a voluntary product recall of ETHICON PHYSIOMESH™ Flexible Composite Mesh (for laparoscopic use) ("ETHICON PHYSIOMESH™ Composite Mesh"). Ethicon is recalling the product following an analysis conducted at the request of the Ethicon Medical Safety Team of unpublished data from two (2) large independent hernia registries (Herniamed German Registry and Danish Hernia Database-DHDB).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, Ethicon believes the higher rates to be a multifactorial issue (including possible product characteristics, operative and patient factors), but has not been able to fully characterize these factors. Consequently, Ethicon 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 recall 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 voluntary recall has been communicated to the U.S. Food and Drug Administration (FDA) and the European Competent Authorities.

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 unexpired product codes of ETHICON PHYSIOMESH™ Composite Mesh and all unexpired Procedure Packs containing this product.

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ETHICON PHYSIOMESH™ Flexible Composite Mesh
(All Product Codes)

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

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

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ETHICON PHYSIOMESH™ Flexible Composite Mesh
(All Product Codes)

EFFECTIVE IMMEDIATELY – DO NOT USE OR DISTRIBUTE ANY OF THE FOLLOWING PROCEDURE PACKS:

PRODUCT NAME	PROCEDURE PACK PRODUCT CODE	ETHICON PHYSIOMESH MESH PRODUCT CODE	PRODUCT LOT
Laparoscopic Hernia Pack	ELH5	PHY1515Q	All unexpired lots impacted by this voluntary product recall.
Laparoscopic Hernia Pack	ELH10	PHY1515Q	All unexpired lots impacted by this voluntary product recall.

IDENTIFICATION OF PRODUCT SUBJECT TO THIS ACTION:

Product subject to the voluntary product recall in your inventory can be identified by product code (see product code listing above). All unexpired, 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 Tools attached at Attachment 1 (individual product codes) and Attachment 2 (Procedure Packs).

ACTION REQUIRED:

1. Examine your inventory immediately to determine if you have product subject to this action on hand and quarantine such product(s).

2. Remove the product subject to this voluntary product recall 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 product subject to this action has been forwarded to another facility, contact that facility to arrange return.

4. Complete the Business Reply Form (BRF) (Attachment 3) confirming receipt of this notice and provide a copy to [INSERT LOCAL AFFILIATE OR SALES REPRESENTATIVE, EMAIL ADDRESS, FAX NUMBER] within three (3) business days. Please return the BRF **even if you do not have product subject to this action**.

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

6. Customers are required to return all unexpired ETHICON PHYSIOMESH™ Composite Mesh products that are in their inventory immediately. Only unexpired product subject to this recall returned by September 16, 2016 will be credited to your account. Expired product that is returned **after that date** will not be reimbursed.

7. To return product subject to this action, photocopy the completed BRF, place it in the box with the product, and return the product to your Sales Representative.

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

Ethicon recognizes the voluntary product recall of the ETHICON PHYSIOMESH™ Composite Mesh may be disruptive to your facility and apologizes 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

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 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 your Sales Representative, directly to Ethicon, or to your National Health Authority.

If you have any further questions related to this notice or if you require additional information, please contact your Sales Representative.

Attachments:
Attachment 1: Product Identification Tool
Attachment 2: Procedure Pack Identification Tool
Attachment 3: Business Reply Form

URGENT: FIELD SAFETY NOTICE

ETHICON PHYSIOMESH™ Flexible Composite Mesh
(All Product Codes)

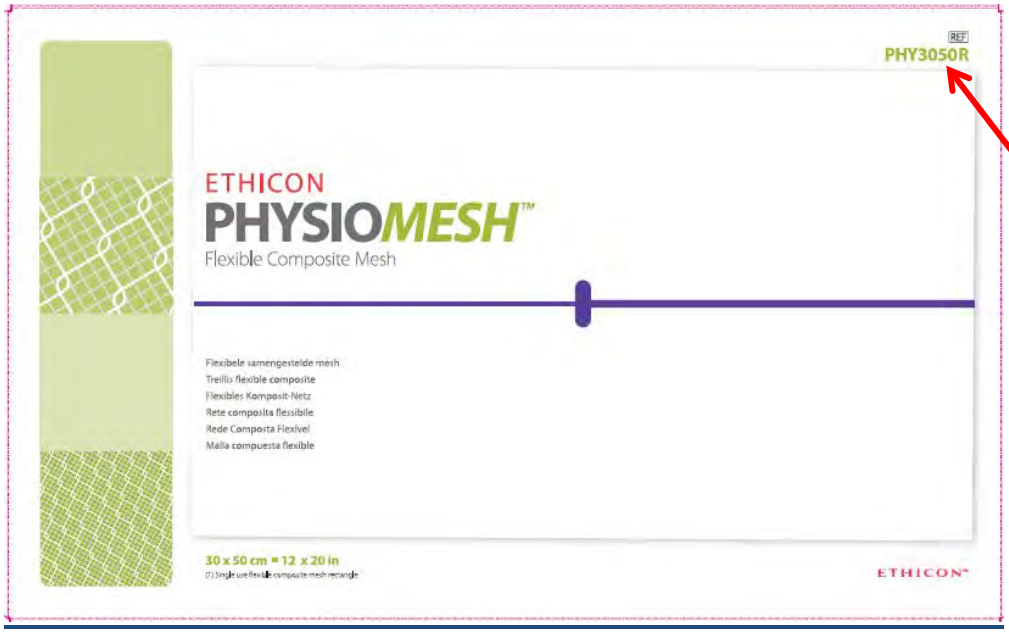
ATTACHMENT 1: Product Identification Tool for ETHICON PHYSIOMESH™ Flexible Composite Mesh (All Product Codes)

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 Field Safety Notice.

Product Code PHY3050R is used as an example.

TYVEK® ENVELOPE (containing 1 mesh)

Front of Envelope



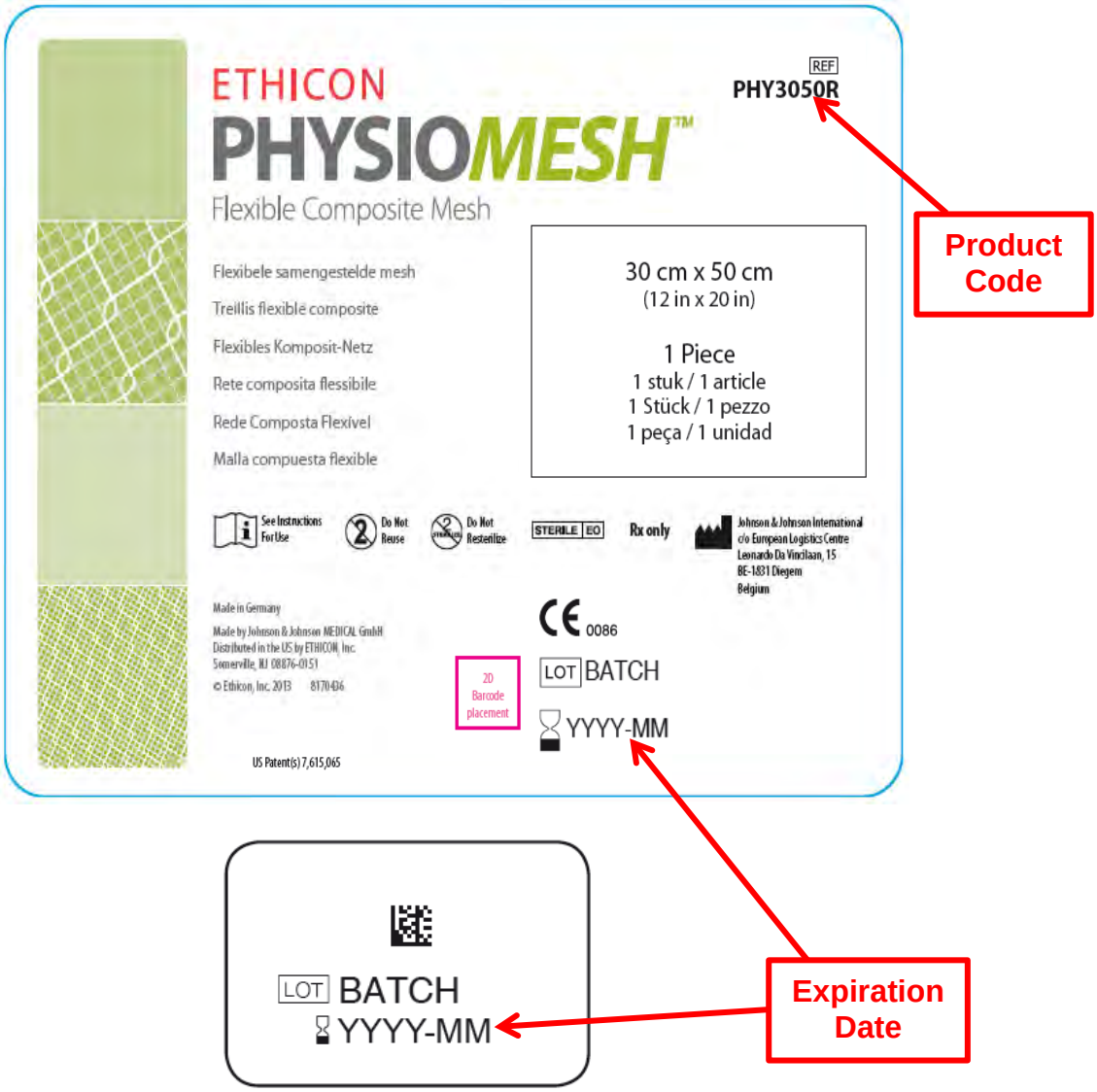
Back of Envelope

URGENT: FIELD SAFETY NOTICE

ETHICON PHYSIOMESH™ Flexible Composite Mesh
(All Product Codes)

FOIL POUCH (containing 1 mesh)

Front of Pouch



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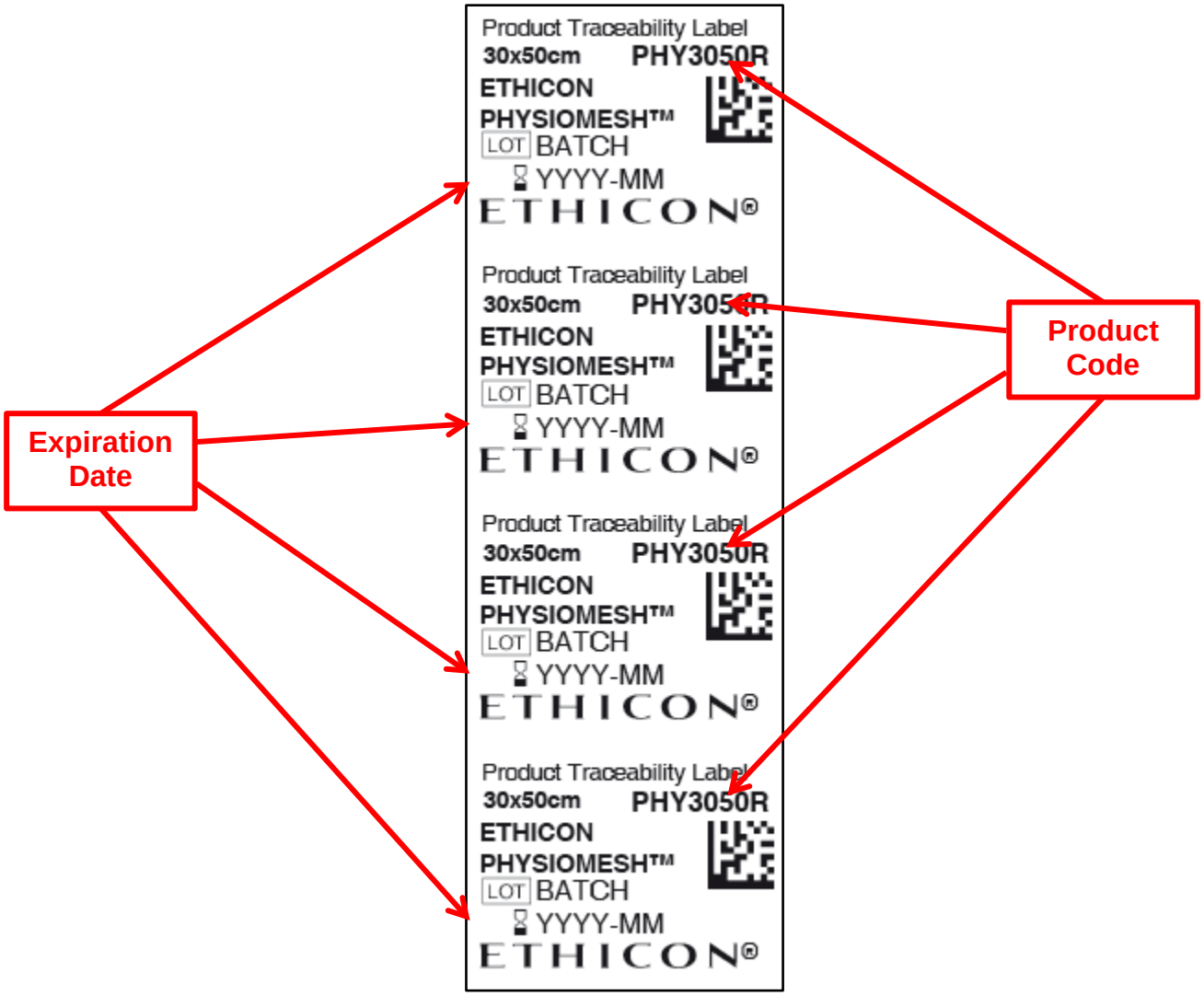
ETHICON PHYSIOMESH™ Flexible Composite Mesh
(All Product Codes)

Back of Pouch



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ETHICON PHYSIOMESH™ Flexible Composite Mesh
(All Product Codes)

ATTACHMENT 2: Product Identification Tool for Procedure Packs Containing ETHICON PHYSIOMESH™ Flexible Composite Mesh (Product Codes: ELH5 and ELH10)

This tool will help customers identify the Procedure Packs containing product subject to this action by using the package labels. This document applies to the labeling on Procedure Pack Product Codes ELH5 and ELH10 as identified on page 2 of the Field Safety Notice.

Product Code ELH5 is used as an example.

Procedure Pack Top Label

Procedure Pack Product Code

ELH5 — Laparoscopic Hernia Pack

Qty	Product Code		Product Description (Consult Instructions For Use)
1	2B12LT CE 0123		**ENDOPATH® XCEL™ with OPTIVIEW™ Technology Bladeless Trocar with Stability Sleeve - 12 mm Diameter, 100 mm Shaft Length** ENDOPATH® XCEL™ avec technologie OPTIVIEW™ Trocart sans lame avec chemise striée - 12 mm de diamètre, tige de 100 mm de long ENDOPATH® XCEL™ mit OPTIVIEW™ Technologie Bladeless Trokar ohne Klinge mit profilierter Hülse - Durchmesser 12 mm, Schaftlänge von 100 mm Trocar senza lama ENDOPATH® XCEL™ con tecnologia OPTIVIEW™ con cannula di stabilità - diametro 12 mm, lunghezza stelo di 100 mm Trocarte sem Lâmina com Cânula de Estabilização ENDOPATH® XCEL™ com tecnologia OPTIVIEW™ - diâmetro de 12 mm, haste de 100 mm de comprimento Trócar sin hoja con cánula de estabilidad ENDOPATH® XCEL™ con tecnología OPTIVIEW™, - 12 mm de diámetro, eje de 100 mm de longitud ENDOPATH® XCEL™ met OPTIVIEW™ Technologie Lemmetloze trocar met stabiliteitshuls, - 12 mm diameter, Schachtlengte van 100 mm
1	B5LT CE 0123		**ENDOPATH® XCEL™ Bladeless Trocar with Stability Sleeve, 5 mm diameter - 100 mm length** Trocart sans lame ENDOPATH® XCEL™ avec chemise de stabilité, 5 mm de diamètre - 100 mm de long ENDOPATH® XCEL™ Bladeless Trokar ohne Klinge mit profilierter Hülse, 5 mm Durchmesser - 100 mm Länge ENDOPATH® XCEL™ Trocar senza lama con cannula di stabilità, diametro 5 mm - lunghezza 100 mm ENDOPATH® XCEL™ Trocarte sem Lâmina com Cânula de Estabilização, 5 mm de diâmetro - 100 mm de comprimento ENDOPATH® XCEL™ Trócar sin hoja con cánula de estabilidad, 5 mm de diámetro - 100 mm de longitud ENDOPATH® XCEL™ Lemmetloze trocar met stabiliteitshuls, 5 mm diameter - 100 mm lengte
1	CB5LT CE 0123		**ENDOPATH® XCEL™ Universal Trocar Stability Sleeve - 5 mm Diameter, 100 mm Length** Chemise striée universelle pour trocart ENDOPATH® XCEL™ - 5 mm de diamètre, 100 mm de long ENDOPATH® XCEL™ profilierte Universal-Trokarhülse - 5 mm Durchmesser, 100 mm Länge Cannula di stabilità universale per trocar ENDOPATH® XCEL™ - diametro 5 mm, lunghezza 100 mm Cânula universal de estabilização do trocarte ENDOPATH® XCEL™ - 5 mm de diâmetro, 100 mm de comprimento Cánula universal de estabilización del trócar ENDOPATH® XCEL™ - 5 mm de diámetro, 100 mm de longitud ENDOPATH® XCEL™ Universele Trocar-stabiliteitshuis - diameter 5 mm, lengte 100 mm
1	STRAP25R CE 0086		**ETHICON SECURESTRAP™ Absorbable Strap Fixation Device** Dispositif de fixation Strap résorbable de ETHICON SECURESTRAP™ ETHICON SECURESTRAP™ Fixierungsinstrument für resorbierbare Straps Dispositivo di fissaggio di graffe assorbibili da ETHICON SECURESTRAP™ Dispositivo de fixação STRAP absorvível de ETHICON SECURESTRAP™ Dispositivo de fijación de anclaje absorbible de ETHICON SECURESTRAP™ ETHICON SECURESTRAP™ Instrument met brede resorbeerbare fixatiebandjes
1	PHY1515Q CE 0086		**ETHICON PHYSIOMESH™ Flexible Composite Mesh 15x15 cm** ETHICON PHYSIOMESH™ Treillis flexible composite 15x15 cm ETHICON PHYSIOMESH™ Flexibles Komposit-Netz 15x15 cm ETHICON PHYSIOMESH™ Rete composita flessibile 15x15 cm ETHICON PHYSIOMESH™ Rede Composta Flexível 15x15 cm ETHICON PHYSIOMESH™ Malla compuesta flexible 15x15 cm ETHICON PHYSIOMESH™ Flexibele samengestelde mesh 15x15 cm

PHYSIOMESH™ Product Code

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ETHICON PHYSIOMESH™ Flexible Composite Mesh
(All Product Codes)

Procedure Pack Side Label

Procedure Pack Product Code

ELH5	Laparoscopic Hernia Pack

Qty	Product Code		Product Description (Consult Instructions For Use)
1	2B12LT CE 0123		ENDOPATH® XCEL™ with OPTIVIEW™ Technology Bladeless Trocar with Stability Sleeve - 12 mm Diameter, 100 mm Shaft Length
1	B5LT CE 0123		ENDOPATH® XCEL™ Bladeless Trocar with Stability Sleeve, 5 mm diameter - 100 mm length
1	CB5LT CE 0123		ENDOPATH® XCEL™ Universal Trocar Stability Sleeve - 5 mm Diameter, 100 mm Length
1	STRAP25R CE 0086		ETHICON SECURESTRAP™ Absorbable Strap Fixation Device
1	PHY1515Q CE 0086		ETHICON PHYSIOMESH™ Flexible Composite Mesh 15x15 cm

ETHICON

PHYSIOMESH™ Product Code

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ETHICON PHYSIOMESH™ Flexible Composite Mesh
(All Product Codes)

ATTACHMENT 3: Business Reply Form (BRF)

Your timely response to this customer notification is requested. Please complete and fax/email this form to [INSERT LOCAL AFFILIATE NAME, EMAIL ADDRESS, FAX NUMBER] **within 3 business days, even if you do not have product subject to this voluntary product recall to return.**

If you have product subject to this recall to return, please make a photocopy of your completed Business Reply Form and enclose with your return. Thank you for your cooperation.

Product Inventory – *please check TWO*

- ☐ **We have no ETHICON PHYSIOMESH™ Flexible Composite Mesh subject to this action.**
- ☐ **We have no Procedure Packs subject to this action.**
- ☐ **We have Procedure Packs subject to this action and are returning the following devices:**
- ☐ **We have ETHICON PHYSIOMESH™ Flexible Composite Mesh subject to this action and are returning the following devices:**

Device Name	Product Code	Quantity Returning (in "Eaches")	Product Code	Quantity Returning (in "Eaches")
ETHICON PHYSIOMESH™ Flexible Composite Mesh	PHY0715R		PHY2025V	
	PHY1015V		PHY2030R	
	PHY1515Q		PHY2535V	
	PHY1520R		PHY3035R	
	PHY1520V		PHY3050R	

Procedure Pack Name	Procedure Pack Product Code	Device Product Code	Quantity Returning (in "Eaches")
Laparoscopic Hernia Pack	ELH5	PHY1515Q	
	ELH10	PHY1515Q	

Facility Name:	Street Address:	City, Country, Postal Code:

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(All Product Codes)

Print Name of Person Completing Business Reply Form:	Telephone Number:
Account Number: (number used to order J&J product)	Date:
Signed*: **Your signature provides confirmation that you have received and understood this notification*	
Your comments are welcome.	