Medtronic

Sofradim Production
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URGENT MEDICAL DEVICE RECALL (Europe only)

Covidien Parietex™ Plug and Patch System and ProGrip™ Self-Gripping Polyester Mesh

22 September 2016

Attention: Risk Management Director and O.R. Materials Management

Dear Valued Customer:

The purpose of this letter is to advise you that Medtronic is voluntarily recalling specific item codes and production lots of Covidien Parietex™ Plug and Patch System and Covidien ProGrip™ Self-Gripping Polyester Mesh. This voluntary recall is being conducted as the devices contain the incorrect mesh material. The affected devices were manufactured with a polypropylene-based textile instead of a polyester-based textile. There have been no complaints reported associated with this issue

Both polypropylene and polyester are approved non-biodegradable materials used in implantable mesh. Both materials exhibit similar performance characteristics. As such, no adverse consequences to patients would be expected unless a patient has a specific allergy to polypropylene. The literature supports only rare reports of allergic reaction to polypropylene. No further action is recommended for patients without a polypropylene allergy who received the mesh. If a patient with the affected mesh has a documented polypropylene allergy, continued monitoring is recommended.

Medtronic requests that you quarantine and return any unused products of the items codes and lot numbers detailed below. Unused products from the affected item codes and lot numbers should be returned as described in the Required Actions section below. If you have distributed the sterile Parietex™ Plug and Patch System and Covidien ProGrip™ Self-Gripping Polyester Mesh products listed below, please promptly forward the information from this letter to those recipients. All unused products from the affected item codes and lots must be returned.

This voluntary recall affects only the item codes and lot numbers listed below. No other lot numbers are affected.

Item	Description	Lot Number
PNP8X3	Parietex™ Plug and Patch System	SQD0439X
TEM1208GL	ProGrip™ Self-Gripping Polyester Mesh	SQD0721X
TEM1208GR	ProGrip™ Self-Gripping Polyester Mesh	SQD0435X
TEM1409GR	ProGrip™ Self-Gripping Polyester Mesh	SQD0427X

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This action is being taken with the knowledge of regulatory authorities. We request that you contact Medtronic if you experienced quality problems or adverse events.

- Email Medtronic Post Market Vigilance at: Quality.Assurance@Covidien.com

Required Actions:

1. Please quarantine and discontinue use of the affected item codes and lots listed above.

2. Please return affected product as follows:

	Customer with inventory	Customer with zero inventory	Where to send the completed form
Purchased **DIRECTLY** from Medtronic	Ship affected product with RGA# provided by Customer Service to: **Medtronic** ***< MITG warehouse>***	Complete form and check the box indicating "no inventory".	Fax form to XXX-XXX-XXXX or email it to <local Customer Service mailbox Exception: Customers with Zero inventory, Fax or email to <local RA Mailbox>
Purchased from a **Distributor**	Complete **ALL** fields on the form and contact your Distributor directly to arrange for product return.	Complete form and check the box indicating "no inventory".	Fax or email to <local RA Mailbox>

We apologize for this inconvenience. If you have any questions or concerns, please do not hesitate to contact your Medtronic representative or Customer Service.

Sincerely,

Christophe Cosson
Director, Quality Assurance
Surgical Innovations
Medtronic

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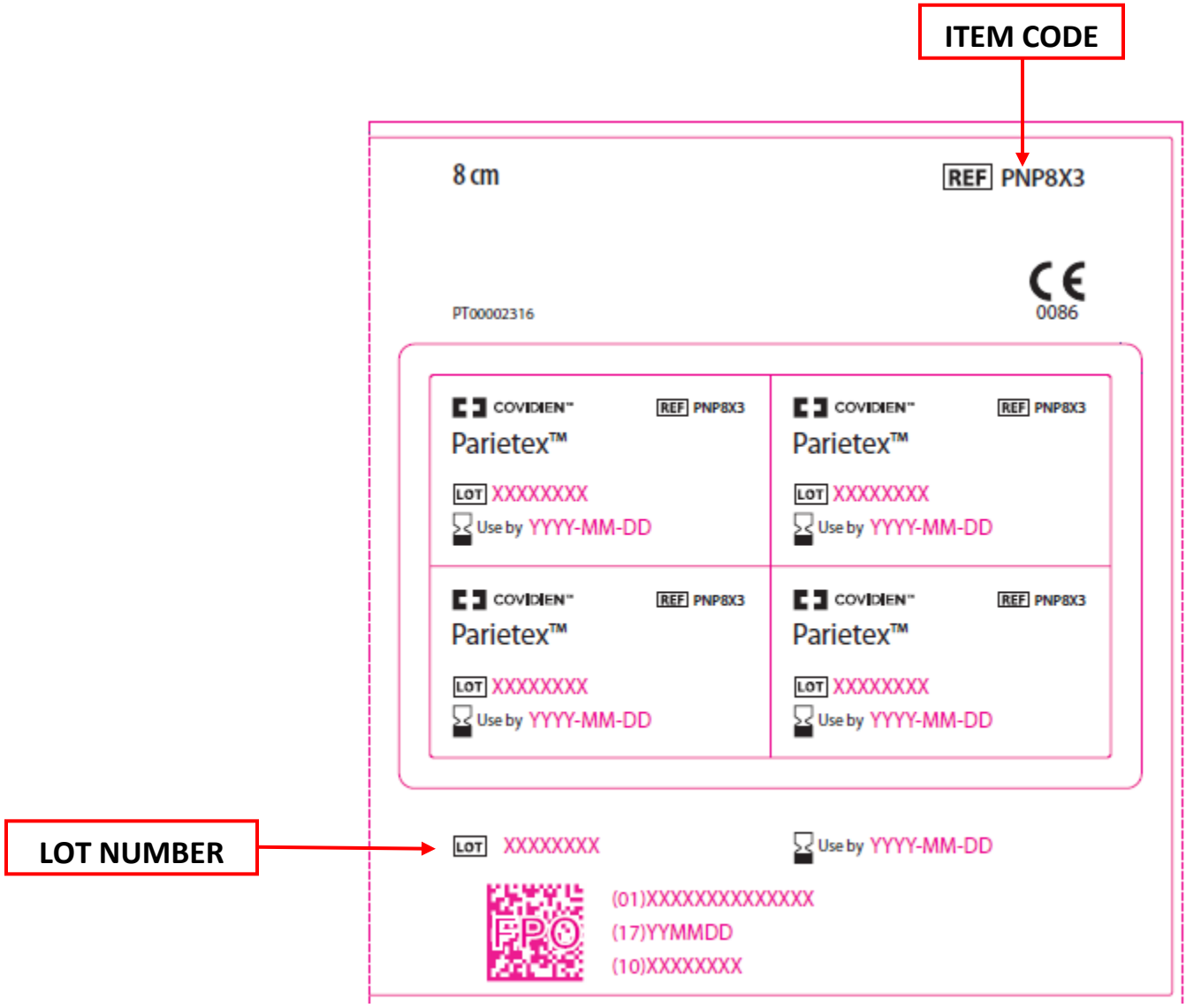
Attachment B

Distinguish affected product by Item Code and Lot Number.



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RECALLED PRODUCT RETURN FORM

Covidien Parietex™ Plug and Patch System and ProGrip™ Self-Gripping Polyester Mesh

PLEASE COMPLETE THIS FORM

Date:

Name of Person Completing this Form Title:

Direct Phone # Email

How did the account purchase this product? (Please complete **ONLY** A or B)

Direct from Medtronic (Complete A): **From a Distributor (Complete B):**

A. Direct Customers:

Account Name:

Primary Account #:

Account Address:

City:

State: Zip Code

B. From a Distributor:

Distributor

Customer Information:

Customer Name:

Address

City:

State: Zip:

RETURN INVENTORY TO: Medtronic, Attn: Field Returns Dept. 195 McDermott Road North Haven, CT 06473 USA

Return Goods Authorization (RGA) #: _____ (please include once received from Customer Service)

No Inventory (Please check):

Item Code	Lot Number	Qty	Case or Each

I acknowledge receipt of the Covidien Parietex™ Plug and Patch System and ProGrip™ Self-Gripping Polyester Mesh recall notification dated 22 September 2016, and understand the recall instructions provided.

(Signature Required)

PLEASE EMAIL OR FAX THIS ACKNOWLEDGEMENT TO:

Medtronic

Product purchased directly from Medtronic:
Product purchased through distributor: