

Urgent Field Safety Notice
Covidien Parietex™ Hydrophilic Anatomical Mesh
Recall

January 2021

Medtronic Reference: FA954

Dear Customer / Risk Manager,

The purpose of this letter is to advise you that Medtronic is voluntarily recalling one production lot of its **Covidien Parietex™ Hydrophilic Anatomical Mesh**.

Issue Description:

This voluntary recall is being conducted as the incorrect device is contained in the package. While the packaging label indicates that the device is for left side use, the product inside the package is for right side use. Eight complaints were received related to this packaging error. One complaint reported that the procedure was rescheduled as a left side use device was not available at the time of the initial surgery. Use of an opposite side mesh can result in implant failure and hernia recurrence. Patients who received a Parietex™ hydrophilic anatomical mesh, lot SUH0709M, for the treatment of a left side inguinal hernia need no additional follow up or surveillance but should seek surgical evaluation should symptoms of inguinal hernia recur. There is no need for additional visits or imaging in the absence of hernia symptoms.

Packaging process improvements have been implemented to remediate this issue.

This voluntary recall affects only the item code with associated lot number listed below.

Item Code	Description	Affected Lot Number
TECT1510AL	Covidien Parietex™ Hydrophilic Anatomical Mesh 15 cm x 10 cm Polyester left	SUH0709M

Required Actions:

1. Please immediately quarantine and discontinue use of affected item code with associated lot number listed above.
2. Please return affected product as indicated below. All unused products from the affected item code and associated lot number must be returned.
3. If you have distributed the Covidien Parietex™ Hydrophilic Anatomical Mesh listed above, please promptly forward the information from this letter to those recipients.
4. Complete the Return Verification Form even if you do not have inventory.

	Customer with inventory	Customer with zero inventory	Where to send the completed form
Purchased directly from Medtronic	Please complete the attached Returns Verification Form in its entirety. Upon receiving your form, Medtronic Customer Care will contact you to organize the return of your products. You will receive credit for unused device(s) that you return	Complete form and check the box indicating "no inventory"	E-mail or fax the completed form to the Medtronic contact provided on the verification form.
Purchased from a distributor	Complete all fields on the form and contact your distributor directly to arrange for return of product.	Complete form and check the box indicating "no inventory"	E-mail or fax the completed form to your Distributor and to the Medtronic contact provided on the verification form.

Medtronic has notified the Competent Authority of your country of this action.

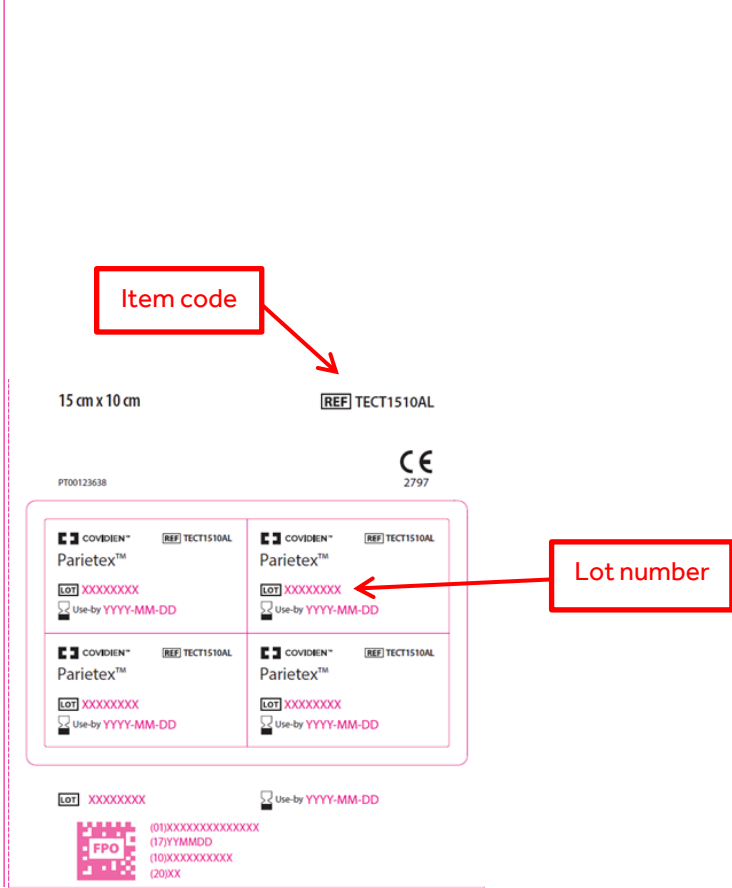
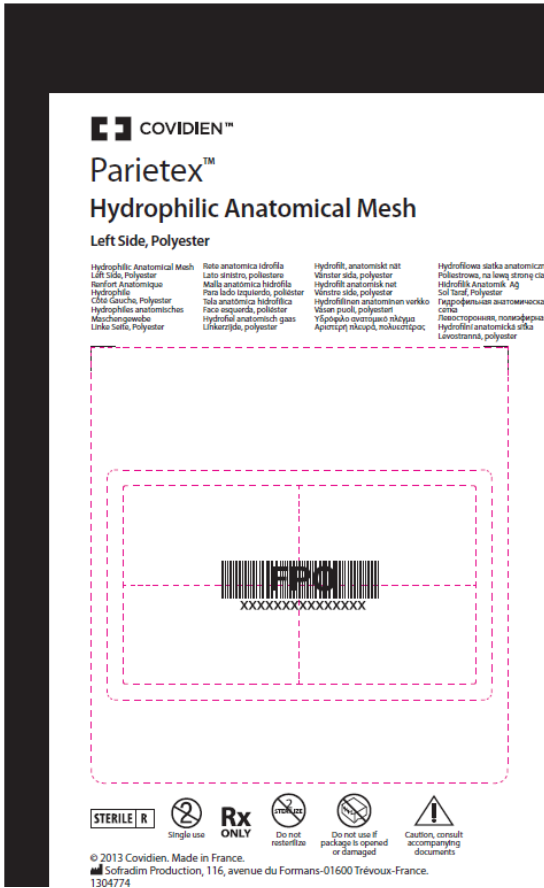
We regret any inconvenience this may cause. We are committed to patient safety and appreciate your prompt attention to this matter. If you have any questions regarding this communication, please contact your Medtronic representative at

<XXXX>.

Sincerely,



Identifying Affected Product



RETURN VERIFICATION FORM

FA954: Covidien Parietex™ Hydrophilic Anatomical Mesh

Please complete this form and return it to Medtronic even if you do not have affected inventory

[Please insert date the form was sent]

Customer Contact Details	Medtronic Contact Details
Hospital Name: Covidien/Medtronic Account Number:	To: [please insert name]
Account Address: Street: Postal Code: City: Department: Contact Person at Point of Collection: Opening Hours: Name of person completing this form:	Address: [please insert Medtronic address]
Telephone:	Telephone: [please insert Medtronic telephone number]
Fax:	Fax: [please insert Medtronic fax number]
E-mail:	E-mail: [please insert contact e-mail address]

Please list the quantity of affected product at your facility, if you have **no** inventory, please tick the box below.

No Inventory (Please tick):

Item Code	Invoice or Despatch Note (if available)	Lot number	Quantity (Eaches or Cases) Please specify

Information for the courier:

Number of parcels to collect: _____

Number of these parcels that weigh more than 45 KG: _____

By signing this form, I confirm that I have read and understand the communication from Medtronic regarding the Covidien Parietex™ Hydrophilic Anatomical Mesh dated January 2021.

I also agree to further distribute and communicate this important information from this letter to those whom I have distributed any of the Covidien Parietex™ Hydrophilic Anatomical Mesh noted in this letter.

Name: (print)

Signature:

Date:

- Please fax or email this form back to Medtronic within 10 days using the contact details referenced at the top of this form.
- Customer Service will contact you directly to organise return of affected products and credit will be given for returned products.
- Please don't send the goods back before having received the return documentation