Medtronic

URGENT FIELD SAFETY NOTICE
Covidien Parietex™ Composite Parastomal Mesh.

December 2018

Medtronic Reference: FA850

Attention: Risk Management Director, OR Materials Management and ICU Medical Directors

Dear Valued Customer:

The purpose of this letter is to advise you that Medtronic has issued a voluntary removal of two item codes of its Covidien Parietex™ Composite Parastomal Mesh.

Our records indicate that your facility purchased this product more than five years ago and it is beyond its labeled expiration date. While you will not have product to return, Medtronic wants to be sure that you are aware of this action which was taken following receipt of recent reports of Parietex™ composite parastomal mesh failure identified several years following parastomal hernia repair using the modified Sugarbaker repair technique.

In these reports, Parietex™ composite parastomal mesh failure led to hernia recurrence requiring additional surgical treatment. Symptoms of hernia recurrence may include discomfort, localized pain-free or painful bulging, and possible changes in the overlying skin. Medtronic has received, worldwide, a total of ten reports of mesh failure following use of Parietex™ composite parastomal mesh in the last five years. Patients who received a Parietex™ composite parastomal mesh for the treatment of a parastomal hernia need no additional follow up or surveillance but should seek surgical evaluation should symptoms of parastomal hernia recur. There is no need for additional visits or imaging in the absence of hernia symptoms.

This voluntary removal is in relation to all lots of the item code listed below. No other item codes of Parietex™ mesh are affected by this action.

Item Codes	Description	Affected Lots
PCOPM15	Parietex™ Composite Parastomal Mesh 15 cm	All Lots
PCOPM20	Parietex™ Composite Parastomal Mesh 20 cm	

Medtronic's initial communication requested that customers with inventory quarantine and return any unused products of the item codes detailed above. Customers who have distributed Covidien Parietex™ composite parastomal mesh listed above, should promptly forward the information from this letter and the initial letter to those recipients. All unused products from the affected item codes must be returned.

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Required Actions:

1. Complete the attached Acknowledgement Form and return to Medtronic using the email or fax details displayed on the form.
2. Forward the information from this letter to anyone you have distributed the affected devices.

The Competent Authority of your country has been notified of this action. Please maintain a copy of this notice in your records. We request that you contact Medtronic if you experienced quality problems or adverse events.

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 .

Sincerely,

J. Bryan Dannettell
Vice President, Quality Assurance
Surgical Innovations
Minimally Invasive Therapies Group

Medtronic

Acknowledgement and Receipt Form—Response is Required

Covidien Parietex™ Composite Parastomal Mesh

PLEASE COMPLETE THIS FORM

Date: _____

Name of Person Completing this form: _____

Title: _____

Direct Phone#: _____

Email: _____

Account Name: _____

Covidien Account Number: _____

Account Address: _____

City: _____ State: _____ Zip Code: _____

I have read and understand the instructions provided and acknowledge receipt of the URGENT FIELD SAFETY NOTICE regarding the Covidien Parietex™ Composite Parastomal Mesh by signing below.

I also agree to further distribute and communicate this important information within my facility as required.

_____	_____	_____	_____
Name (print)	Signature	Telephone	Date

If you have any questions regarding this URGENT FIELD SAFETY NOTICE, please contact your Medtronic sales representative.