

URGENT FIELD SAFETY NOTICE **Covidien Parietex™ Composite Parastomal Mesh**

October X, 2018

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 is issuing a voluntary removal for two item codes of its Covidien Parietex™ Composite Parastomal Mesh.

Medtronic is issuing this voluntary removal following receipt of 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 have received a Parietex™ composite parastomal mesh for the treatment of a parastomal hernia should continue to receive ongoing monitoring by their healthcare providers for the recurrence of a parastomal hernia.

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

Item Code	Description	Affected lots
PCOPM15	Parietex™ Composite Parastomal Mesh 15 cm	See lots listed on Attachment A
PCOPM20	Parietex™ Composite Parastomal Mesh 20 cm	

Medtronic requests that you quarantine and return any unused products of the item codes detailed above. Unused products from the affected item codes should be returned as described in the Required Actions section below. If you have distributed Covidien Parietex™ composite parastomal mesh listed above, please promptly forward the information from this letter to those recipients. All unused products from the affected item codes must be returned.

Required Actions:

1. Please quarantine and discontinue use of the affected item codes listed above.
2. Please return affected product as indicated below.
3. Complete the Product Return Form **even if you do not have inventory.**

	Customer inventory with	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 & to the Medtronic contact provided on the verification form.

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 at **XXX-XXX-XXXX**.

Sincerely,

Attachment A

Item Code	Description	Affected Lots				
PCOPM15	Parietex™ Composite Parastomal Mesh 15cm	PNI0064	POJ0880X	PPL0082X	PRA2444X	PRI1409X
		PNJ0989	POK0364X	PQA0483X	PRB1650X	PRJ0480X
		PNK0641	POK0789X	PQC0100X	PRB2015X	PRK0758X
		PNL0039	POL0082X	PQD0395X	PRC0392X	PRK1140X
		POA0469X	PPA0226X	PQE0802X	PRC1062X	PRL0129X
		POB0030X	PPA0508X	PQG1150X	PRD0248X	PRL0528X
		POC0036X	PPB0779X	PQH0608X	PRD0547X	PSA0833X
		POD0036X	PPD0409X	PQJ1246X	PRD1170X	PSA1209X
		POE0262X	PPF0181X	PQJ0971X	PRE0479X	PSB0936X
		POF0295X	PPG0035X	PQK0314X	PRF0408X	PSC0186X
		POG0047X	PPG0723X	PQL0150X	PRG1020X	PSD0420X
		PRG0380X	PPI0630X	PQL0479X	PRH0323X	PSE0906X
		POH0069X	PPI1144X	PRA1193X	PRI0530X	PSF0217X
		POI0260X	PPJ0234X	PRA1655X	PRI1166X	PSG0778X
POI0489X	PPK0523X					
PCOPM20	Parietex™ Composite Parastomal Mesh 20cm	PNI0065	POJ0418X	PPJ0698X	PRB1652X	PRJ0482X
		PNI0402	POK0366X	PPK0524X	PRB2017X	PRK0760X
		PNJ0496	POK0790X	PPL0353X	PRC0394X	PRK1142X
		PNJ0990	PPA0227X	PQC0102X	PRC1064X	PRL0131X
		PNL0037	PPA0509X	PQD0397X	PRD0250X	PRL0530X
		PNL0631	PPB0780X	PQE0187X	PRD0549X	PSA0835X
		POA0963X	PPC0578X	PQG0391X	PRD1172X	PSA1207X
		POB0797X	PPD0410X	PQG1152X	PRE0481X	PSB0938X
		POC0726X	PPE0215X	PQH0610X	PRE1319X	PSC0188X
		POD0033X	PPE0509X	PQJ1248X	PRF0410X	PSD0422X
		POD1016X	PPF0179X	PQJ0973X	PRG0382X	PSE0908X
		POE0149X	PPF0836X	PQK0316X	PRG1022X	PSF0219X
		POE0727X	PPH0355X	PQL0481X	PRH0325X	PSG0780X
		POF0298X	PPI0631X	PRA1195X	PRI0531X	RQA1121X
		POH0070X	PPI1145X	PRA1657X	PRI1168X	
		POI0261X	PPJ0235X	PRA2446X	PRI1411X	

Attachment B

COVIDIEN™

Parietex™

Composite Parastomal Mesh

Monofilament Polyester with Absorbable Collagen Film

15 cm

PCOPM15

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COVIDIEN™ Parietex™ XXXXXXXXXX Use by YYYY-MM-DD	COVIDIEN™ Parietex™ XXXXXXXXXX Use by YYYY-MM-DD	COVIDIEN™ Parietex™ XXXXXXXXXX Use by YYYY-MM-DD	COVIDIEN™ Parietex™ XXXXXXXXXX Use by YYYY-MM-DD
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Item code

Lot number

COVIDIEN™ Parietex™ Composite Parastomal Mesh Monofilament Polyester with Absorbable Collagen Film