Medtronic

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URGENT: Medical Device Voluntary Removal
Covidien Parietex™ Composite Parastomal Mesh

15 October 2018

Attention: Risk Management Director and O.R. Materials Management
CC: The Chairman Medical Board and relevant Head of Departments

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 code 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 and lots listed.

2. Please complete the attached Recalled Product Return Form in its entirety. If you do not have any units from the affected lots in your inventory, simply tick “No affected inventory to be returned” and revert back to your local Medtronic Representative.

3. Please return affected product as follows:

- **CUSTOMERS WHO PURCHASED PRODUCT DIRECTLY FROM MEDTRONIC**

  Please complete the **Covidien Parietex™ Composite Parastomal Mesh** Recalled Return Form (attached) and return to your local Medtronic representative together with affected units if any.

- **CUSTOMERS WHO PURCHASED PRODUCT FROM A DISTRIBUTOR**

  Please complete the **Covidien Parietex™ Composite Parastomal Mesh** Recalled Return Form (attached) and contact your Distributor directly. All affected product and Recalled Product Return Form must be returned through the Distributor.

This notification is being issued or will be notified to relevant regulatory bodies according to applicable regulations. Please communicate this important information within your facility and or other facilities as required. We request that you contact Medtronic if you experienced quality problems or adverse events.

If you have any questions or concerns regarding this recall, please do not hesitate to contact your local Medtronic representative.

We appreciate your attention to this matter and apologize for any inconvenience this issue may have caused.

Sincerely,

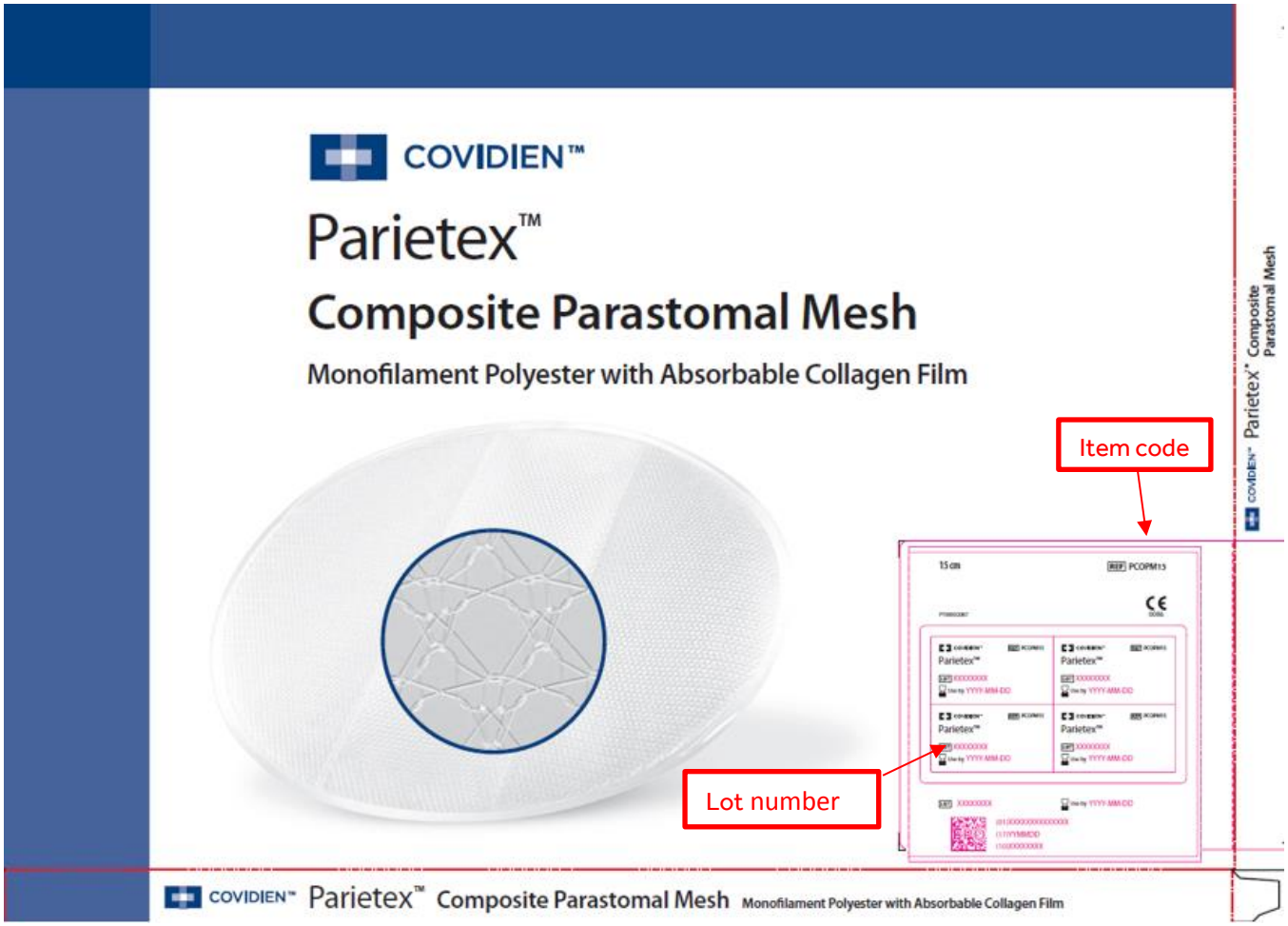
[redacted]

Diana Teo
Quality Management System Manager
Medtronic

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	PQI1246X	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	PQI1248X	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



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RECALLED PRODUCT RETURN FORM
Covidien Parietex™ Composite Parastomal Mesh

ALL CUSTOMERS PLEASE COMPLETE THE FORM IN ITS ENTIRETY

Customer Contact Details	Medtronic Contact Details
Hospital / HCP:	**By E-mail:**
Address:	**By Post:**
Telephone no:	
Fax no:	**Telephone:**
E-mail:	

Even if you have no affected stock to returned, please complete this form and table; return to your local Medtronic contacts stated above

Please tick (either one) only:

☐ No, no affected inventory to be returned.

☐ Yes, affected inventory to be returned (Please fill up the below table if chosen)

Item code	Product Description	Lot number	QTY (Each)

I acknowledge receipt of the Covidien Parietex™ composite parastomal mesh removal notification dated 15 October 2018, and understand the instructions provided.

Name: _____ (print) Signature: _____ Stamp: _____ Date:_____