

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

October 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 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 & 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.

Sincerely,

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

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

| | | | |
|-----------------------------------------------------------|-----------------------------------------------------------|-----------------------------------------------------------|-----------------------------------------------------------|
| 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 |
|-----------------------------------------------------------|-----------------------------------------------------------|-----------------------------------------------------------|-----------------------------------------------------------|

XXXXXXXXXX Use by YYYY-MM-DD

XXXXXXXXXX
XXXXXXXXXX
XXXXXXXXXX

Item code

Lot number

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