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.

<table>
<thead>
<tr>
<th>Item Code</th>
<th>Description</th>
<th>Affected lots</th>
</tr>
</thead>
<tbody>
<tr>
<td>PCOPM15</td>
<td>Parietex™ Composite Parastomal Mesh 15 cm</td>
<td>See lots listed on Attachment A</td>
</tr>
<tr>
<td>PCOPM20</td>
<td>Parietex™ Composite Parastomal Mesh 20 cm</td>
<td></td>
</tr>
</tbody>
</table>

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 donot have inventory.
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.

### Table: Where to send the completed form

<table>
<thead>
<tr>
<th>Customer with inventory</th>
<th>Customer with zero inventory</th>
<th>Where to send the completed form</th>
</tr>
</thead>
<tbody>
<tr>
<td>Purchased directly from Medtronic</td>
<td>Complete all fields on the form and contact your distributor directly to arrange for return of product</td>
<td>E-mail or fax the completed form to your Distributor &amp; to the Medtronic contact provided on the verification form.</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Item Code</th>
<th>Description</th>
<th>Affected Lots</th>
</tr>
</thead>
<tbody>
<tr>
<td>PCOPM15</td>
<td>Parietex™ Composite Parastomal Mesh 15cm</td>
<td>PNI0064 POI0880X PPL0082X PRA2444X PRI1409X PNI0989 POK0364X PQA0483X PRB1650X PRI0480X PK0641 POJ0789X PQC0100X PRB2015X PRK0758X PN0089 POL0082X PQC0395X PRC0392X PKR1140X POA0469X POA0226X POE0820X PRC1062X L0129X POB0030X PPA0508X PQC1150X PRD0248X PRL0528X POC0036X PBB0779X PQC0608X PRD0547X PSC0833X POD0036X PPD0409X PQI1246X PRD1170X PSC1209X POE0262X PPF0181X PQI0971X PDE0479X PSB0936X POFO25X PPG0035X PQK0314X PRF0408X PS0186X POG0047X PPG0723X PQL0150X PRG1020X PSD0420X PRG0380X PPI0630X PQL0479X PRH0323X PSE0906X POH0069X PPI1144X PRA1193X PRI0530X PFS0217X POI026X PPI0234X PRA1655X PRI1166X PS00778X POI0489X PPK0523X</td>
</tr>
</tbody>
</table>
Attachment B

Covidien™

Parietex™
Composite Parastomal Mesh
Monofilament Polyester with Absorbable Collagen Film

Item code

Lot number