URGENT FIELD SAFETY NOTICE

Covidien Emprint™ Percutaneous Antenna with Thermosphere™ Technology

August 2017

Attention: Risk Management Director and O.R. Materials Management

Medtronic Reference: FA781

Dear Valued Customer:

The purpose of this letter is to advise you that Medtronic is voluntarily recalling all Covidien Emprint™ Percutaneous Antennas with Thermosphere™ Technology.

Issue Description:

This Field Safety Corrective Action (FSCA) is being conducted following six (6) customer reports of the ceramic trocar tip of the Emprint™ ablation antenna disengaging from the needle shaft post-ablation. Tip disengagement can result in the ceramic trocar tip remaining in the patient presenting a risk of latent migration and potential damage to adjacent tissue. Four of the complaint reports indicate that the trocar tip was not retrieved.

This FSCA affects only the item code and lots listed below.

<table>
<thead>
<tr>
<th>Item Code</th>
<th>Product Description</th>
<th>Item Code</th>
<th>Product Description</th>
<th>Lots beginning with</th>
<th>Expiration Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>CA15L1</td>
<td>Emprint™ Percutaneous Antenna with Thermosphere™ Technology, Short (15 cm)</td>
<td>CA15L2</td>
<td>Emprint™ Percutaneous Antenna with Thermosphere™ Technology – Reinforced Antenna, Short (15 cm)</td>
<td>S5L through S7G</td>
<td>November 2017 through July 2019</td>
</tr>
<tr>
<td>CA20L1</td>
<td>Emprint™ Percutaneous Antenna with Thermosphere™ Technology, Standard (20 cm)</td>
<td>CA20L2</td>
<td>Emprint™ Percutaneous Antenna with Thermosphere™ Technology – Reinforced Antenna, Standard (20 cm)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CA30L1</td>
<td>Emprint™ Percutaneous Antenna with Thermosphere™ Technology, Long (30 cm)</td>
<td>CA30L2</td>
<td>Emprint™ Percutaneous Antenna with Thermosphere™ Technology – Reinforced Antenna, Long (30 cm)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Medtronic is requesting that you quarantine any remaining inventory 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 the Covidien Emprint™ Percutaneous Antenna devices affected by this recall to other persons or facilities, please promptly forward the information from this letter to those recipients. All units must be returned.
Required Actions:

1. Please quarantine and discontinue use of the affected item codes and lots listed on page one.
2. Please return affected product as indicated below.

<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><strong>Purchased directly from Medtronic</strong></td>
<td>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.</td>
<td>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.</td>
</tr>
<tr>
<td><strong>Purchased from a distributor</strong></td>
<td>Complete all fields on the form and contact your distributor directly to arrange for return of product</td>
<td>Complete form and check the box indicating “no inventory”. E-mail or fax the completed form to your Distributor &amp; to the Medtronic contact provided on the verification form.</td>
</tr>
</tbody>
</table>

This action is being taken with the knowledge of the Saudi Food and Drug Authority. Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. We request that you contact Medtronic if you experienced quality problems or adverse events.

We apologize for this inconvenience. If you have any questions or concerns, please do not hesitate to contact your Medtronic representative at mohamed.el-ghor@medtronic.com.
Emprint™

Short Percutaneous Microwave Antenna

Large Spherical Ablation Zone
15 cm
Antenne micro-ondes percutanée courte
Large zone d’ablation

Item #

Lot

Lot