

### **URGENT FIELD SAFETY NOTICE**

#### **Palindrome™ Chronic Catheter, Palindrome™ Precision Chronic Catheter,**

October xx, 2015

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

**Please forward this communication to all surgeons, surgical personnel, and any other potential users of the product.**

Dear Valued Customer:

The purpose of this letter is to advise you that Medtronic is recalling specific item codes and production lots of Covidien Palindrome™ catheters. This Field Safety Corrective Action (FSCA) is being conducted due to a manufacturing issue causing catheters to be packaged with a bend at the distal tip of the device. No complaints for this issue have been reported from customers. The use of products with this condition may result in a potentially increased risk for reduced or no patient therapy and/or damage to the central vein. No patient injuries have been reported related to this bent catheter tip issue.

Medtronic is requesting that you quarantine any remaining inventory of the items/lots detailed below. Unused products from the affected item codes and lots should be returned as described in the Required Actions section below. If you have distributed Palindrome™ catheters to other persons or facilities, please promptly forward the information from this letter to those recipients.

This FSCA is NOT related to the Palindrome™ catheter recall dated May 2015 and is limited to the item codes and lots below and does NOT affect any other item codes of Medtronic devices.

Item Code	Product Description	Lot Numbers
8888145042	Palindrome™ Chronic Catheter Kit Symmetrical Tip, Tal VenaTrac™ Stylet 14.5 Fr/Ch (4.8mm) X 33 cm	1503500094 1431900098 1435800009
8888145017P	Palindrome™ Precision Chronic Catheter Kit Symmetrical Tip 14.5 Fr/Ch (4.8mm) X 33 cm	1500600182 1423000104
8888145042P	Palindrome™ Precision Chronic Catheter Kit Symmetrical Tip, Tal VenaTrac™ Stylet 14.5 Fr/Ch (4.8mm) X 33 cm	1504700102
8888145046C	Palindrome™ Precision H Chronic Catheter Kit Symmetrical Tip, Heparin Coating and Tal VenaTrac™ Stylet 14.5 Fr/Ch (4.8mm) X 33 cm	1506100125

**Required Actions:**

1. Please quarantine and discontinue use of the affected item codes listed above.
2. Please return affected product as follows:

	Customer with inventory:	Customer with Zero Inventory	Where to send the completed form
Purchased <b>DIRECTLY</b> from Medtronic	<p>1. Please complete the attached Returns Verification Form in its entirety and e-mail it to &lt;local RA Mailbox&gt; or fax to XXX.</p> <p>Upon receiving your form, Customer Service will contact you to organize the return of your products. You will receive credit for unused device(s) that you return.</p>	Complete form & indicate that you have no inventory to return.	E-mail or fax the completed form to the Medtronic contact provided on the verification form
Purchased from a <b>Distributor</b>	Complete <b>ALL</b> fields on the form & contact your Distributor directly to arrange for return of product.	Complete form & indicate that you have no inventory to return.	E-mail or fax the completed form to the Medtronic contact provided on the verification form

This action is being taken with the knowledge of the (Insert Local Competent Authority Name).

If you are aware of any incidents related to this issue, please contact your local Medtronic Representative using the contact information stated above to provide information regarding those events so regulatory reporting obligations can be fulfilled.

We apologize for this inconvenience. If you have any questions or concerns, please do not hesitate to contact your Medtronic representative at (xxx-xxx-xxx).

Sincerely,





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