URGENT FIELD SAFETY NOTIFICATION

Palindrome™ Precision SI Chronic Catheter, Palindrome™ SI Chronic Catheter, Palindrome™ Precision HSI Chronic Catheter, and Palindrome™ HSI Chronic Catheter

May 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 sixteen (16) item codes of former Covidien Palindrome™ SI Chronic Catheter, Palindrome™ Precision SI Chronic Catheter, Palindrome™ Precision HSI Chronic Catheter, and Palindrome™ HSI Chronic Catheter with the expiry date of February 2018 and earlier.

Medtronic is conducting this Field Safety Corrective Action (FSCA) as recent internal testing suggests that the affected products may not meet the minimum silver release specification for the entire 30-day period. Silver eluted by the sleeve is intended to reduce microbial colonization on the catheter's surface and in the subcutaneous tunnel tract. Test results show that silver release initially meets specification; however, after day nine, silver release continues, but at a reduced level. Patients currently implanted with this device face no additional risk due to this condition.

We have not received any reports of adverse effects related to this issue. This FSCA is being conducted as a precautionary measure.

This FSCA is limited to the item codes identified with an expiry date of February 2018 and earlier and does ***NOT*** affect any other item codes of Medtronic devices.

Item Code	Item Description
8888145048	Palindrome HSI Chronic Catheter Kit w/VenaTrac Stylet 14.5 Fr x 23cm
8888145048C	Palindrome HSI Chronic Catheter Kit w/VenaTrac Stylet 14.5 Fr x 23cm
8888145048CP	Palindrome Precision HSI Chronic Catheter Kit w/VenaTrac Stylet 14.5 Fr x 23cm
8888145049	Palindrome HSI Chronic Catheter Kit w/VenaTrac Stylet 14.5 Fr x 28cm
8888145049C	Palindrome HSI Chronic Catheter Kit w/VenaTrac Stylet 14.5 Fr x 28cm
8888145049CP	Palindrome Precision HSI Chronic Catheter Kit w/VenaTrac Stylet 14.5 Fr x 28cm
8888145050	Palindrome HSI Chronic Catheter Kit w/VenaTrac Stylet 14.5 Fr x 33cm
8888145050C	Palindrome HSI Chronic Catheter Kit w/VenaTrac Stylet 14.5 Fr x 33cm
8888145050CP	Palindrome Precision HSI Chronic Catheter Kit w/VenaTrac Stylet 14.5 Fr x 33cm
8888145057	Palindrome HSI Chronic Catheter Kit w/VenaTrac Stylet 14.5 Fr x 19cm
8888145057C	Palindrome HSI Chronic Catheter Kit w/VenaTrac Stylet 14.5 Fr x 19cm
8888145057CP	Palindrome Precision HSI Chronic Catheter Kit w/VenaTrac Stylet 14.5 Fr x 19cm

8888145062	Palindrome SI Chronic Catheter Kit w/VenaTrac Stylet 14.5 Fr x 19cm
8888145063	Palindrome SI Chronic Catheter Kit w/VenaTrac Stylet 14.5 Fr x 23cm
8888145066	Palindrome SI Chronic Catheter Kit 14.5 Fr x 55cm
8888145066C	Palindrome SI Chronic Catheter Kit 14.5 Fr x 55cm

REQUIRED ACTIONS:

1. Please quarantine and discontinue use of the affected devices.

2. Please return affected product as follows:

• CUSTOMERS WHO PURCHASED PRODUCT DIRECTLY FROM MEDTRONIC
Please complete the Palindrome™ Precision SI Chronic Catheter, Palindrome™ Precision HSI Chronic Catheter, and Palindrome™ HSI Chronic Catheter Returns Verification Form and fax it to xxx-xxxxx for the attention of [Insert Local RA contacts name].or email it to INSERT LOCAL EMAIL ADDRESS. If you do not have any units to return, simply return the form indicting you have zero (0) units.
Upon receiving your form, Customer Service will contact you to organize the return of your products. You will receive credit for unused and unexpired device(s) that you return. Please contact your local Covidien representative for details on alternative product options.

• CUSTOMERS WHO PURCHASED PRODUCT FROM A DISTRIBUTOR
Please complete the Returns Verification Form (attached) and contact your Distributor directly for direction on returning product. The completed form should be emailed to the following address: LOCAL CONTACT EMAIL ADDRESS or faxed to (XXX)-XXX-XXXX. All affected product must be returned through the Distributor with a copy of the completed form.

• ALL CUSTOMERS
We ask that all customers reply to Medtronic **WHETHER OR NOT** you have affected product at your site. Your response is vital to our monitoring of the effectiveness of this FSCA. Please complete the Returns Verification form and return to Medtronic via the instructions provided.

Thank you for your business and continued support. This action is being taken with the knowledge of the (INSERT LOCAL REGULATORY 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 and thank you for your business and continued support. If you have any questions or concerns, please do not hesitate to contact your Medtronic representative at (XXX)-XXX-XXXX.

Sincerely,

Lisa Newcombe-Dierl
Vice President Manufacturing Quality, Patient Monitoring & Recovery
Medtronic

FIGURE 1: Identification of Lot and Reorder Code on Label