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Covidien is joining Medtronic

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URGENT MEDICAL DEVICE RECALL

Palindrome™ Precision SI Chronic Catheter
Palindrome™ SI Chronic Catheter
Palindrome™ Precision HSI Chronic Catheter
Palindrome™ HSI Chronic Catheter

29 April, 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 PRODUCTS

Dear Valued Customer,

The purpose of this letter is to advise you that Medtronic is voluntarily recalling 62 item codes of Palindrome™ Precision SI Chronic Catheter, Palindrome™ SI Chronic Catheter, Palindrome™ Precision HSI Chronic Catheter, and Palindrome™ HSI Chronic Catheter manufactured by Covidien, with expiry dates of February 2018 or earlier.

You may be aware that Medtronic completed its acquisition of Covidien in January 2015.

Medtronic is conducting this voluntary recall 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 9, 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 voluntary recall is being conducted as a precautionary measure.

This voluntary recall 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 these devices.

Kindly refer to **ATTACHMENT 1: Affected Item Codes**

REQUIRED ACTIONS

1. Please quarantine and discontinue use of the affected devices.
2. Please complete the attached Verification Form in its entirety. If you do not have any units from the affected lots in your inventory, simply tick "No affected inventory to be returned" and revert back to your local Medtronic Representative.

3. Please return affected product as follows:

- **CUSTOMERS WHO PURCHASED PRODUCT DIRECTLY FROM COVIDIEN**
Please complete the Palindrome Catheter Urgent Medical Device Recall – Verification Form (attached) and return to your local Medtronic representative together with affected units if any.
- **CUSTOMERS WHO PURCHASED PRODUCT FROM A DISTRIBUTOR**
Please complete the Palindrome Catheter Urgent Medical Device Recall – Verification Form (attached) and contact your Distributor directly. All affected product and Verification Form must be returned through the Distributor.

This notification is being issued or will be notified to relevant regulatory bodies according to applicable regulations. Please communicate this important information within your facility and or other facilities as required.

If you have any questions or concerns regarding this recall, please do not hesitate to contact your local Medtronic representative.

We appreciate your attention to this matter and apologize for any inconvenience this issue may have caused.

Yours sincerely



Alec Chow
Director, Post Market Vigilance, Asia
Medtronic

ATTACHMENT 1: Affected Item Codes

Item Code	Item Description
8888245062	Palindrome SI Chronic Catheter Kit 14.5 Fr x 19cm
8888245063	Palindrome SI Chronic Catheter Kit 14.5 Fr x 23cm
8888245064	Palindrome SI Chronic Catheter Kit 14.5 Fr x 28cm
8888245065	Palindrome SI Chronic Catheter Kit 14.5 Fr x 33cm
8888219368	Palindrome SI Chronic Catheter Sport Pack 14.5 Fr x 19cm
8888223408	Palindrome SI Chronic Catheter Sport Pack 14.5 Fr x 23cm
8888228458	Palindrome SI Chronic Catheter Sport Pack 14.5 Fr x 28cm
8888233508	Palindrome SI Chronic Catheter Sport Pack 14.5 Fr x 33cm
8888145062	Palindrome SI Chronic Catheter Kit w/VenaTrac Stylet 14.5 Fr x 19cm
8888145062C	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
8888145063C	Palindrome SI Chronic Catheter Kit w/VenaTrac Stylet 14.5 Fr x 23cm

Item Code	Item Description
8888145064	Palindrome SI Chronic Catheter Kit w/VenaTrac Stylet 14.5 Fr x 28cm
8888145064C	Palindrome SI Chronic Catheter Kit w/VenaTrac Stylet 14.5 Fr x 28cm
8888145065	Palindrome SI Chronic Catheter Kit w/VenaTrac Stylet 14.5 Fr x 33cm
8888145065C	Palindrome SI Chronic Catheter Kit w/VenaTrac Stylet 14.5 Fr x 33cm
8888145066	Palindrome SI Chronic Catheter Kit 14.5 Fr x 55cm
8888145066C	Palindrome SI Chronic Catheter Kit 14.5 Fr x 55cm
8888145062P	Palindrome Precision SI Chronic Catheter Kit w/VenaTrac Stylet 14.5 Fr x 19cm
8888145062CP	Palindrome Precision SI Chronic Catheter Kit w/VenaTrac Stylet 14.5 Fr x 19cm
8888145063P	Palindrome Precision SI Chronic Catheter Kit w/VenaTrac Stylet 14.5 Fr x 23cm
8888145063CP	Palindrome Precision SI Chronic Catheter Kit w/VenaTrac Stylet 14.5 Fr x 23cm
8888145064P	Palindrome Precision SI Chronic Catheter Kit w/VenaTrac Stylet 14.5 Fr x 28cm
8888145064CP	Palindrome Precision SI Chronic Catheter Kit w/VenaTrac Stylet 14.5 Fr x 28cm
8888145065P	Palindrome Precision SI Chronic Catheter Kit w/VenaTrac Stylet 14.5 Fr x 33cm
8888145065CP	Palindrome Precision SI Chronic Catheter Kit w/VenaTrac Stylet 14.5 Fr x 33cm
8888146144P	Palindrome Precision SI Chronic Catheter Kit 14.5 Fr x 44cm
8888146144CP	Palindrome Precision SI Chronic Catheter Kit 14.5 Fr x 44cm
8888145066P	Palindrome Precision SI Chronic Catheter Kit 14.5 Fr x 55cm
8888145066CP	Palindrome Precision SI Chronic Catheter Kit 14.5 Fr x 55cm

Item Code	Item Description
8888119368	Palindrome SI Chronic Catheter Sport Pack w/VenaTrac Stylet 14.5 Fr x 19cm
8888123408	Palindrome SI Chronic Catheter Sport Pack w/VenaTrac Stylet 14.5 Fr x 23cm
8888128458	Palindrome SI Chronic Catheter Sport Pack w/VenaTrac Stylet 14.5 Fr x 28cm
8888133508	Palindrome SI Chronic Catheter Sport Pack w/VenaTrac Stylet 14.5 Fr x 33cm
8888119368P	Palindrome Precision SI Chronic Catheter Sport Pack w/VenaTrac Stylet 14.5 Fr x 19cm
8888123408P	Palindrome Precision SI Chronic Catheter Sport Pack w/VenaTrac Stylet 14.5 Fr x 23cm
8888128458P	Palindrome Precision SI Chronic Catheter Sport Pack w/VenaTrac Stylet 14.5 Fr x 28cm
8888133508P	Palindrome Precision SI Chronic Catheter Sport Pack 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
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
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
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

Item Code	Item Description
8888145057P	Palindrome Precision 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
8888145048P	Palindrome Precision 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
8888145049P	Palindrome Precision 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
8888145050P	Palindrome Precision 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
8888119369	Palindrome HSI Chronic Catheter Sport Pack w/VenaTrac Stylet 14.5 Fr x 19cm
8888123409	Palindrome HSI Chronic Catheter Sport Pack w/VenaTrac Stylet 14.5 Fr x 23cm
8888128459	Palindrome HSI Chronic Catheter Sport Pack w/VenaTrac Stylet 14.5 Fr x 28cm
8888133509	Palindrome HSI Chronic Catheter Sport Pack w/VenaTrac Stylet 14.5 Fr x 33cm
8888119369P	Palindrome Precision HSI Chronic Catheter Sport Pack w/VenaTrac Stylet 14.5 Fr x 19cm

URGENT MEDICAL DEVICE RECALL – VERIFICATION FORM

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

ALL CUSTOMERS PLEASE COMPLETE THE FORM IN ITS ENTIRETY

Customer Contact Details	Covidien Contact Details
Hospital / HCP:	By E-mail:
Address:	By Post:
Telephone no:	
Fax no:	
E-mail:	

To identify location of expiration date, you may refer - **FIGURE 1: Identification of Lot and Reorder Code on Label**

Please tick (either one) only:

- No, no affected inventory to be returned.
- Yes, affected inventory to be returned (Please fill up the below table if chosen)

Item code	Product Description	Lot number	Expiry Date	QTY (Each)

I have read and understand the instructions provided and acknowledge receipt of the Recall regarding Palindrome Catheter by signing below

Name: _____ (print) Signature: _____ Date: _____

Even if you have no affected stock, please complete this form and return to your local Medtronic contacts stated above