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URGENT FIELD SAFETY NOTICE

Palindrome™ Chronic Catheter Kit - 14.5 Fr/Ch (4.8 mm) x 23 cm (8888145015)

Incorrect Catheter Length in Package - Four (4) lots affected

Recall

August 2023

Medtronic Reference: FA1355
EU Manufacturer Single Registration Number (SRN): US-MF-000028763

Dear Risk Manager/Healthcare Professional:
The purpose of this letter is to advise you that Medtronic is initiating a recall of four (4) specific lots of **Palindrome™ 14.5 Fr/Ch (4.8 mm) x 23 cm Chronic Catheter Kits**. You are receiving this letter as Medtronic records indicate your facility may have at least one of the affected lots of **Palindrome™ 14.5 Fr/Ch (4.8 mm) x 23 cm Chronic Catheter Kits.** Medtronic initiated this action to prevent the use of potentially affected products which may impact patients.

Please note: This recall does **not** include Palindrome **Precision** Catheter Kits.

Issue Description:
Post-market analysis identified incorrect labeling of some catheter kits contained within four (4) specific lots of **Palindrome™ 14.5 Fr/Ch (4.8 mm) x 23 cm Chronic Catheter Kits**. Some catheter kits labeled as 23 cm implant length incorrectly included catheters of 28 cm implant length; the actual catheter implant length is identifiable based upon the correct labeling on the catheter body. As of 08-Aug-2023, there were six (6) reported complaints: five (5) complaints from China and one (1) from the United States. No serious injuries or deaths have been reported.

Below is a list of catheter kits with the incorrectly labeled product within the scope of this recall:

Product Name	Manufacturer's Product #	GTIN / UPN / Material #	Lot #
Palindrome™ Catheter Kit - 14.5 Fr/Ch (4.8 mm) x 23 cm	8888145015	10884521013162 20884521013169	2221700131
		10884521013162	2224200233
		10884521013162 20884521013169	2230400271
		10884521013162	2230400272

Risk to Health:
In the event that an impacted catheter is not identified prior to placement, implanting a catheter of an incorrect longer length may result in the potential harms of arrhythmia, perforation of vessels, cardiac perforation, hemorrhaging/bleeding, or delay to treatment. These harms are also consistent with known procedural complications associated with central venous catheter placement. Successful catheter insertion and appropriate tip positioning should always be confirmed with image guidance via fluoroscopy or portable chest x-ray as outlined in the product's instructions for use.

Patient Recommendation:
Palindrome™ 14.5 Fr/Ch (4.8 mm) x 23 cm Chronic Catheter Kits are intended for hemodialysis, apheresis, and infusion. Catheters may be inserted either percutaneously or by cutdown. For patients with implanted catheters from affected lots, a replacement procedure may not be necessary. Clinicians should continue to follow facility-specific policies and procedures for routine assessment of the hemodialysis access device for patency, function, efficacy, and catheter tip placement, as well as for monitoring the patient's clinical status.

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Required Actions:

1. Immediately quarantine and discontinue use of all unused affected lots of the **Palindrome™ 14.5 Fr/Ch (4.8 mm) x 23 cm Chronic Catheter Kits**. Please note**:** This recall does **not** include Palindrome **Precision** Catheter Kits.
2. Return all unused affected product(s) to Medtronic. Your Medtronic Sales Representative can assist in returning any affected product.
3. Please complete the enclosed Customer Acknowledgement Form.
4. If purchased from a distributor, contact your distributor directly to arrange for the return of the product back to your distributor.
5. This notice should be passed on to those who need to be aware within your organization or to any organization including, but not limited to, nephrologists, intensivists, implanting and managing physicians, renal nurses, critical care nurses, or other dialysis staff where the potentially affected devices have been transferred. Please maintain a copy of this notice in your records.

Additional Information:
Medtronic has notified the Competent Authority of your country of this action.

We regret any inconvenience this may cause. We are committed to patient safety and appreciate your prompt attention to this matter. If you have questions regarding this communication, please contact your local representative

Sincerely,
Medtronic GmbH