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URGENT FIELD SAFETY NOTICE

Mo.Ma™ Ultra & Ultra Proximal Cerebral Protection Devices

Potential for Incorrect Manifold Sticker

Recall

October 2023

Medtronic Reference: FA1371

EU Manufacturer Single Registration Number (SRN): US-MF-000019977

Dear Healthcare Professional:

The purpose of this letter is to advise you that Medtronic is initiating a recall of specific lots of the **Mo.Ma™ Ultra Proximal Cerebral Protection and Mo.Ma™ Ultra Cerebral Protection Devices** *(CFN: MOM0130069X6, MOM0130068X5).* You are receiving this letter as Medtronic records indicate your facility may have product(s) from at least one of the affected lots of Mo.Ma Ultra Proximal Cerebral Protection and Mo.Ma Ultra Cerebral Protection Devices. Medtronic initiated this action to prevent the use of potentially affected products.

Issue Description:
The Mo.Ma Ultra device manifold is labelled with 2 stickers, an inferior and superior sticker, one on each side of the manifold. These stickers label the common carotid artery (CCA) proximal balloon and external carotid artery (ECA) distal balloon inflation and deflation ports. Both sides of the complaint units' manifold were labelled with the superior label leading to an incorrect identification of the proximal and distal inflation /deflation ports when viewing the devices from the inferior side.

As of 12-Sept-2023, there were three (3) reported complaints potentially related to this issue, equating to an observed rate of 0.077%. Zero (0) serious injuries and zero (0) deaths have been associated with this issue. As this device is used in the carotid space there is the potential for embolism, occlusion/ischemia, and vessel perforation/rupture/blood loss.

The Mo.Ma Ultra device is a single use product and the risk associated with affected units applies solely during the procedure. **No incremental follow up care is needed for patients who have previously had a procedure using the Mo.Ma Ultra device**.

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Product Scope:

Product Names	Manufacturer's Product #	Lot/Serial Number	UDI-DI
Cath MOM0130069X6 PCPD Mo.Ma.Ultra9F 013	MOM0130069X6	See Attachment A for a list of Lot Numbers impacted.	0763000B000050179
Cath MOM0130068X5 PCPD Mo.Ma.Ultra8F 013	MOM0130068X5		

Required Actions:

- Immediately locate and quarantine all unused affected Mo.Ma Ultra Proximal Cerebral Protection and Mo.Ma Ultra Cerebral Protection Devices (CFN: MOM0130069X6, MOM0130068X5) listed in Attachment A – Impacted Lot List.
- Return all unused affected product in your inventory to Medtronic. Your local Medtronic Representative can assist you with the initiation of the return.
- Please share this notice with all those who need to be aware of this issue within your organization or to any organization where the potentially affected devices have been transferred and maintain a copy of this notice in your records.
- Complete and return the Customer Acknowledgment Form enclosed with this letter, acknowledging that you have received this information.

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 any questions regarding this communication, please contact your Medtronic Representative.

Sincerely,
Medtronic (Schweiz) AG

Enclosures:

Attachment A – Impacted Product List
Customer Acknowledgement Form

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Attachment A – Impacted Product List

CFN	Product Description	GTIN	Lot/Serial #
MOM0130069X6	**Cath MOM0130069X6 PCPD Mo.Ma.Ultra9F 013**	08033477090702	226373365, 226388209, 226403314

CFN	Product Description	GTIN	Lot/Serial #
MOM0130068X5	**Cath MOM0130068X5 PCPD Mo.Ma.Ultra8F 013**	08033477090696	226460841

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CUSTOMER ACKNOWLEDGEMENT FORM

Please email this form back to Medtronic (even if you do not have affected inventory): **rs.dusregulatory@medtronic.com**

Urgent Field Safety Notice - Recall

FA1371: Mo.Ma Ultra Incorrect Manifold Sticker

Customer Contact Details			
Company name:			Account number (optional):
Address:	City:		Country:
• I confirm that I have read and understood the Urgent Field Safety Notice. • I agree to pass on the Urgent Field Safety Notice to all those who need to be aware within our organization or to any organization where the potentially affected products have been transferred. • I have reviewed our inventory, identified, and quarantined all unused affected products in our inventory, and I declare the following: ☐ No affected products are located at our facility. ☐ Affected products are located at our facility. See below table for details of affected products to be returned to Medtronic.			
Name (print):	**Job title**:	**Date**:	**Signature**:

Please fill-in the section below only if you have affected stock:

Return Details			
Invoice or Delivery Note *(if available)*	**Item Code**	**Lot # / Serial #**	**Quantity** *(please count units inside of the box)*
☐ If you have more products to return, tick the box. Please create and send separate attachment with same data.			**Total**:
Contact Person at Point of Collection:			
Pick-up address / Department *(please provide location details. Eg: collection/accessible area):*			
City:			Post code:
Pick-up phone number:	Pick-up email:		
When the product will be ready for pick-up? *(Please allow 2 days for handling your request):*			
Opening hours of the pick-up location:			Dimension LxWxH (in cm): … x … x …
# Pallets:	# Parcels:	Number of parcels weighing over 45 KG:	

- Customer Service will contact you directly to organise return of affected products and credit will be given for returned products.
- Please don't send the goods back before having received the return documentation.
- Please package goods according to packaging instructions that will be provided upon confirmation & remove all labels from the inbound shipment.