Medtronic

# Urgent Field Safety Notice

## Mahurkar™* Acute Dual Lumen High Flow (13.5 French) Hemodialysis Catheters (Mahurkar QPlus)

Recall

December 2022

Medtronic Reference: FA1295

*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 voluntarily initiating a recall for specific lots of the Mahurkar™* Acute Dual Lumen High Flow (13.5 French) Hemodialysis Catheters. This product is also known as the Mahurkar QPlus**.**

**Please note:** This recall does **not** include the Mahurkar **Elite** High-Flow (13.5 French) Catheters.

You are receiving this letter as Medtronic records indicate your facility may have at least one of the Mahurkar Acute Dual Lumen High Flow (13.5 French) Hemodialysis Catheters outlined in Attachment A. Medtronic initiated this action to prevent the use of potentially affected product that may impact patients.

**Issue Description:**

During the production process, a potential internal leaking condition within the hub of specific Mahurkar Acute Dual Lumen High Flow (13.5 French) Hemodialysis Catheter was identified as a result of a void in the catheter hub. During dialysis, this observed adverse internal leaking condition could translate into cross communication of the blood circuit. Globally, there have been seven complaints as of October 14th,2022, one of which has confirmed evidence of interlumen communication. There have been two reports of adverse events including one for thrombosis and one for insufficient flow.. There are no deaths reported.

**Risk to Health:**

Utilization of a product with this manufacturing defect could introduce the potential for patient harm(s) including inadequate treatment, unintended radiation exposure, hemolysis, thrombus formation, embolism, delay to treatment, and potential infection.

**Patient Recommendation:**

For patients with affected lots of Mahurkar Acute Dual Lumen High Flow (13.5 French) Hemodialysis Catheters currently in place, a replacement procedure may not be necessary. Screening of catheters in production indicated that a majority of catheters (e.g., >99%) within the scope of the recall function as intended and do not exhibit the internal leaking condition within the catheter's hub component. Clinicians should continue to follow facility specific policies and procedures for routine assessment of the hemodialysis access device for patency, function, and efficacy. If an interlumen void in the catheter hub is present, a 'communication' or movement of catheter contents between the venous and arterial lumens within the catheter may be visible; however, it would not present as an external leak or defect. If detected, the patient's medical team should use their clinical judgement in determining the necessity and timing of a replacement catheter in accordance to the product Instructions For Use and facility specific policies and procedures.

Additional information is available on the Medtronic website: www.Medtronic.com/MahurkarQplusRecall

**Required Actions:**

1. To help you identify if you have affected product, please visit our website www.Medtronic.com/MahurkarQplusRecall. Here you will find a tool to help you determine if the product you have is affected by this recall.
   **Note:** The affected device is located within a catheter kit. Please reference Attachment A to help identify affected product.
2. Immediately quarantine and discontinue use of all unused Mahurkar Acute Dual Lumen High Flow (13.5 French) Hemodialysis Catheters of the affected lots (see Attachment A).
3. Please complete the Customer Acknowledgment Form even if you **do not** have unused inventory.
4. Return all unused affected Mahurkar Acute Dual Lumen High Flow (13.5 French) Hemodialysis Catheters from your inventory to Medtronic as indicated in the **Shipping and Return Instructions** below.
5. If you have distributed any of the affected lots of Mahurkar Acute Dual Lumen High Flow (13.5 French) Hemodialysis Catheters listed in Attachment A, you are required to promptly provide this recall information to those recipients.
6. Share this notice with those who need to be aware within your organization, including but not limited to Nephrologists, physicians, renal nurses, or other dialysis staff.
7. Retain this notification for your records.

**Shipping and Return Instructions:**

| | Customer with inventory | Customer with zero inventory | Where to send the completed form |
|---|---|---|---|
| Purchased **directly** from Medtronic | Please complete the attached Returns Verification Form in its entirety.<br><br>Upon receiving your form, Medtronic Customer Care will contact you to organize the return of your products. You will receive credit for unused device(s) that you return | Complete form and check the box indicating "no inventory" | E-mail or fax the completed form to the Medtronic contact provided on the verification form. |
| Purchased from a **distributor** | Complete **all** fields on the form and contact your distributor directly to arrange for return of product. | Complete form and check the box indicating "no inventory" | E-mail or fax the completed form to your Distributor and to the Medtronic contact provided on the verification form. |

**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,

Local / BU Manager

**Enclosures:**

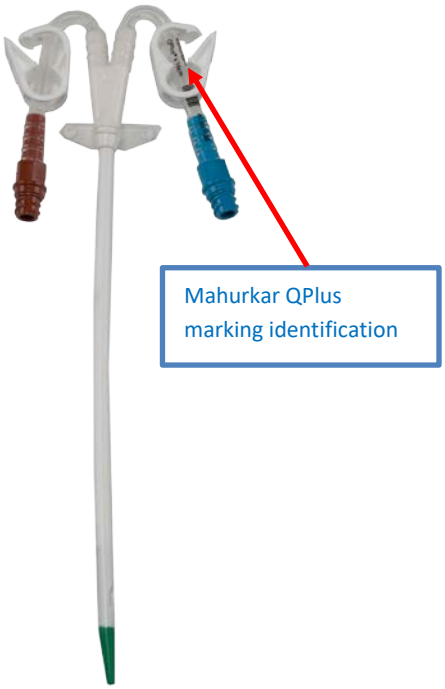
Attachment A: IDENTIFYING AFFECTED PRODUCT

**Attachment A:**

## IDENTIFYING AFFECTED PRODUCT

**Mahurkar™* Acute Dual Lumen High Flow (13.5 French) Hemodialysis Catheters (Mahurkar QPlus)**

13.5 Fr Straight Extension



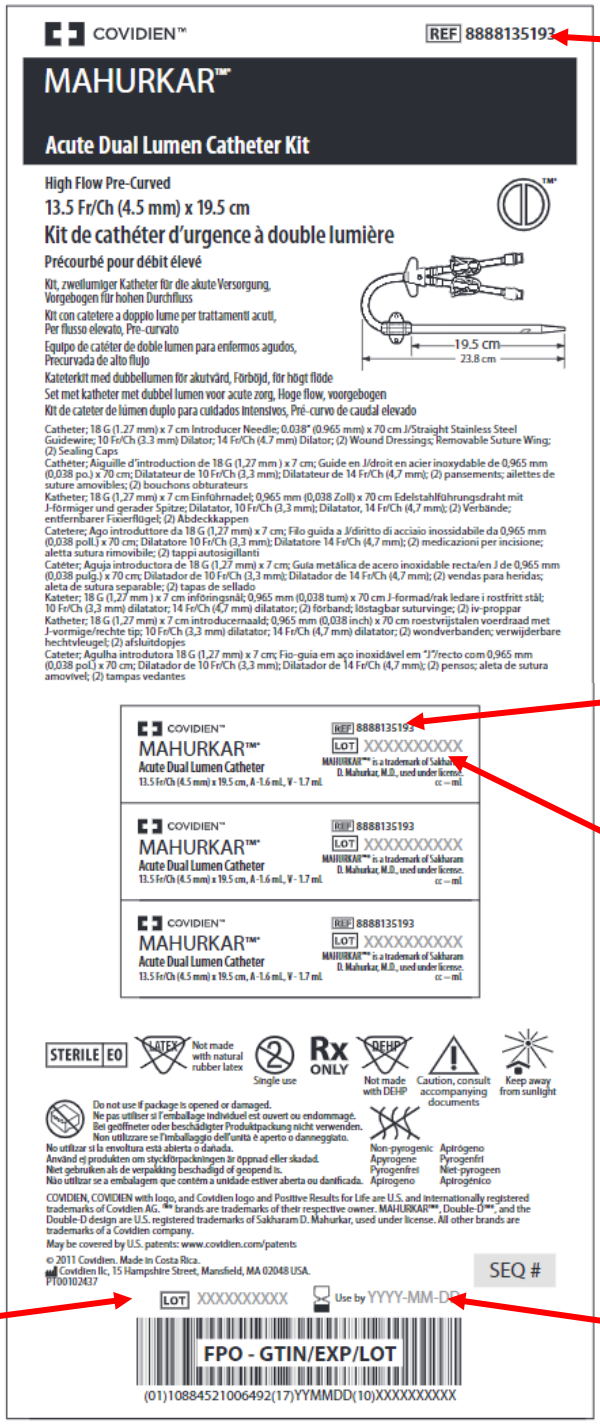

13.5 Fr Curved Extension

<Pictures can be used based on region>

**Attachment A:**

## IDENTIFYING AFFECTED PRODUCT

## Mahurkar™* Acute Dual Lumen High Flow (13.5 French) Hemodialysis Catheters (Mahurkar QPlus)




Model Number

Model Number

Lot Number

Lot Number

Expiration Date

| Product Name | Models | Lot Numbers |
|---|---|---|
| MAHURKAR™* 13.5 Fr High Flow Dual Lumen Acute Dialysis Catheter, 19.5 cm, Curved Extensions, Kit | 8888135192 | 1822000070 1924000217 2019500176<br>1823900126 2016000062 2035000075<br>1826800101 2016300043 2035000076<br>1830300163 |

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**CUSTOMER ACKNOWLEDGEMENT FORM**

Please email or fax this form back to Medtronic (even if you do not have affected inventory):

rs.ranordic@medtronic.com or Fax:

Denmark +45 3248 1801; Finland +358 (0) 20 728 1201; Norway +47 6710 3210 ; Sweden +46 (0) 8 568 585 01

## Urgent Field Safety Notice - Recall

### FA1295: Mahurkar Catheter Hub Void Inter-lumen leakage

| **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.