



## 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](http://www.Medtronic.com/MahurkarQplusRecall)

**Required Actions:**

1. To help you identify if you have affected product, please visit our website [www.Medtronic.com/MahurkarQplusRecall](http://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:**

	<b>Customer with inventory</b>	<b>Customer with zero inventory</b>	<b>Where to send the completed form</b>
Purchased <b>directly</b> from Medtronic	Please complete the attached Returns Verification Form in its entirety.  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 <b>distributor</b>	Complete <b>all</b> 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

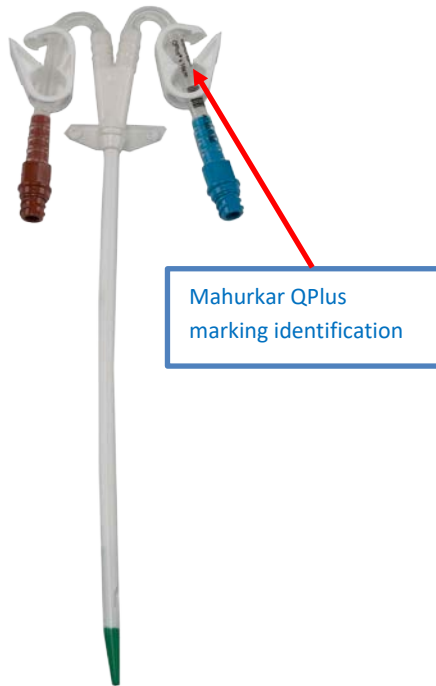
## Attachment A:

### 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)


REF 8888135193

## MAHURKAR™

Acute Dual Lumen Catheter Kit

**High Flow Pre-Curved**  
13.5 Fr/Ch (4.5 mm) x 19.5 cm

**Kit de cathéter d'urgence à double lumière**  
Précourbé pour débit élevé

**Kit, zweilumiger Katheter für die akute Versorgung,**  
Vorgebogen für hohen Durchfluss

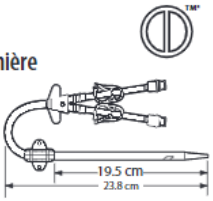
**Kit con catetere a doppio lume per trattamenti acuti,**  
Per flusso elevato, Pre-curvato

**Equipo de catéter de doble lumen para enfermos agudos,**  
Precurvada de alto flujo




**Kateterkit med dubbellumen för akutvård, Förböjd, för högt flöde**  
Set met katheter met dubbel lumen voor acute zorg, Hoge flow, vorgebogen






**Kit de cateter de lumen duplo para cuidados intensivos, Pré-curvo de caudal elevado**

Catheter, 18 G (1.27 mm) x 7 cm Introducer Needle; 0.038" (0.965 mm) x 70 cm J/Straight Stainless Steel Guidewire; 10 Fr/Ch (3.3 mm) Dilator; 14 Fr/Ch (4.7 mm) Dilator; (2) Wound Dressings; Removable Suture Wing; (2) Sealing Caps  
Catheter; Aiguille d'introduction de 18 G (1.27 mm) x 7 cm; Guide en J/droit en acier inoxydable de 0,965 mm (0,038 pou.) x 70 cm; Dilatateur de 10 Fr/Ch (3,3 mm); Dilatateur de 14 Fr/Ch (4,7 mm); (2) pansements; ailettes de suture amovibles; (2) bouchons obturateurs  
Katheter; 18 G (1,27 mm) x 7 cm Einführungsnadel; 0,965 mm (0,038 Zoll) x 70 cm Edelstahlführungsdraht mit J-Formiger und gerader Spitze; Dilator, 10 Fr/Ch (3,3 mm); Dilator, 14 Fr/Ch (4,7 mm); (2) Verbände; entfernbare Fixierflügel; (2) Abdeckklappen  
Catetere; Ago introdutora da 18 G (1,27 mm) x 7 cm; Fio guida a J/dritto di acciaio inossidabile da 0,965 mm (0,038 pol.) x 70 cm; Dilatatore de 10 Fr/Ch (3,3 mm); Dilatatore de 14 Fr/Ch (4,7 mm); (2) vendas para heridas; aleta de sutura separabile; (2) tapas de sellado  
Kateter; 18 G (1,27 mm) x 7 cm infiringsnål; 0,965 mm (0,038 tum) x 70 cm J-formad/rak ledare i rostfritt stål; 10 Fr/Ch (3,3 mm) dilator; 14 Fr/Ch (4,7 mm) dilator; (2) förband; löstagbar suturving; (2) iv-proppar  
Katheter; 18 G (1,27 mm) x 7 cm introducerenaald; 0,965 mm (0,038 inch) x 70 cm roestvrijstalen voorraad met J-vormige/rechte tip; 10 Fr/Ch (3,3 mm) dilator; 14 Fr/Ch (4,7 mm) dilator; (2) wondverbanden; verwijderbare hechtvleugel; (2) afsluitdoppen  
Cateter; Aghula introdutora 18 G (1,27 mm) x 7 cm; Fio-guia em aço inoxidável em "J"recto com 0,965 mm (0,038 pol.) x 70 cm; Dilatador de 10 Fr/Ch (3,3 mm); Dilatador de 14 Fr/Ch (4,7 mm); (2) pensos; aleta de sutura amovível; (2) tampas vedantes



19.5 cm  
23.8 cm

 <p><b>MAHURKAR™</b> Acute Dual Lumen Catheter 13.5 Fr/Ch (4.5 mm) x 19.5 cm, A-1.6 mL, V-1.7 mL</p>	REF 8888135193 LOT XXXXXXXXXXXX <small>MAHURKAR™ is a trademark of Saksharam D. Mahurkar, M.D., used under license. cc - ml</small>
 <p><b>MAHURKAR™</b> Acute Dual Lumen Catheter 13.5 Fr/Ch (4.5 mm) x 19.5 cm, A-1.6 mL, V-1.7 mL</p>	REF 8888135193 LOT XXXXXXXXXXXX <small>MAHURKAR™ is a trademark of Saksharam D. Mahurkar, M.D., used under license. cc - ml</small>
 <p><b>MAHURKAR™</b> Acute Dual Lumen Catheter 13.5 Fr/Ch (4.5 mm) x 19.5 cm, A-1.6 mL, V-1.7 mL</p>	REF 8888135193 LOT XXXXXXXXXXXX <small>MAHURKAR™ is a trademark of Saksharam D. Mahurkar, M.D., used under license. cc - ml</small>

**STERILE EO**  Not made with natural rubber latex  Single use **Rx ONLY**  Not made with DEHP  Caution, consult accompanying documents  Keep away from sunlight

Do not use if package is opened or damaged.  
Ne pas utiliser si l'emballage individuel est ouvert ou endommagé.  
Für proffiner oder beschädigter Produktpackung nicht verwenden.  
Non utilizzare se l'imballaggio dell'unità è aperto o danneggiato.  
No utilizar si la envoltura está abierta o dañada.  
Använd ej produktén om späckförpackningen är öppnad eller skadad.  
Niet gebruiken als de verpakking beschadigd of geopend is.  
Não utilizar se a embalagem que contém a unidade estiver aberta ou danificada.


Non-pyrogenic Apirogeno  
Apyrogenic Pirogenético  
Pyrogenfrei Niet-pyrogen  
Apirogeno Apirogénico

COVIDEN, COVIDEN with logo, and Covidien logo and Positive Results for Life are U.S. and internationally registered trademarks of Covidien AG. \* brands are trademarks of their respective owner. MAHURKAR™, Double-D™, and the Double-D design are U.S. registered trademarks of Saksharam D. Mahurkar, used under license. All other brands are trademarks of a Covidien company.  
May be covered by U.S. patents: www.covidien.com/patents  
© 2011 Covidien, Made in Costa Rica.  
Covidien Inc., 15 Hampshire Street, Mansfield, MA 02048 USA.  
PT00102437

LOT XXXXXXXXXXXX

Use by YYYY-MM-DD

SEQ #



FPO - GTIN/EXP/LOT

(01)10884521006492(17)YYMMDD(10)XXXXXXXXXX

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
		1823900126	2016000062	2035000075
		1826800101	2016300043	2035000076
		1830300163		

# Medtronic

## CUSTOMER ACKNOWLEDGEMENT FORM

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

[rs.ranordic@medtronic.com](mailto: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:
<ul style="list-style-type: none"><li>I confirm that I have read and understood the Urgent Field Safety Notice.</li><li>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.</li><li>I have reviewed our inventory, identified, and quarantined all unused affected products in our inventory, and I declare the following: <input type="checkbox"/> No affected products are located at our facility. <input type="checkbox"/> Affected products are located at our facility. See below table for details of affected products to be returned to Medtronic.</li></ul>			
<b>Name (print):</b>	<b>Job title:</b>	<b>Date:</b>	<b>Signature:</b>

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)
<input type="checkbox"/> If you have more products to return, tick the box. Please create and send separate attachment with same data.			<b>Total:</b>
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.