Sultanate of Oman
Ministry of Health
Directorate General of Pharmaceutical Affairs and Drug Control
Muscat

سلطنة عُمان
وزارة الصحة
المديرية العامة للصيدلة والرقابة الدوائية
مسقط

To:
THE DIRECTOR GENERAL OF HEALTH SERVICES IN ALL GOVERNORATES
Commanding Officer, Armed Forces Hospital (Al Khoudh & Salalah)
Director General of Engineering Affairs, MOH
Director General of Royal Hospital
Director General of Khoula Hospital
Director General of Medical Supplies (MOH)
Director General of Pvt. Health Est. Affairs (to kindly arrange distribution to all Pvt. Hospitals)
Hospital Director (Al Nahda Hospital)
Hospital Director (Al Massara Hospital)
The Head of Medical Services in SQU Hospital
The Head of Medical Services in Royal Oman Police
The Head of Medical Services in Ministry of Defence
The Head of Medical Services in The Diwan
The Head of Medical Services in The Sultan's Special Force
The Head of Medical Services in Internal Security Services
The Head of Medical Services in Petroleum Development of Oman
The Head of Medical Services in LNG Oman
ALL PRIVATE PHARMACIES & DRUG STORES

After Compliments,

Please find attached our Circular No 145 **dated** 18/7/23 **Regarding NCMDR Recall of Catheter from (mfr: Medtronic SA).**

Copy to:

- **Director, Office of H.E. The Undersecretary for Health Affairs**
- **Director of Medical Device Control, DGPA&DC**
- **Director of Pharmacovigilance & Drug Information Dept, DGPA&DC**
- **Director of Drug Control Department, DGPA&DC**
- **Director of Pharmaceutical Licensing Department, DGPA&DC**
- **Director of Central Quality Control Lab., DGPA&DC**
- **Supdt. of Central Drug Information**

PADC
المديرية العامة للصيدلة والرقابة الدوائية
Directorate General of Pharmaceutical Affairs & Drug Control

ص.ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩
P.O. Box: 393 Muscat - Postal Code: 100 - Tel: 22357111 - Fax: 22358489
dgpa_dc Email: dg-padc@moh.gov.om

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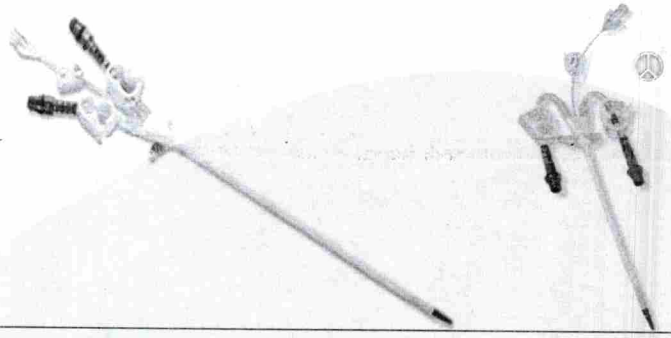
Circular No. 145 / 20223

30-12-1444 H

18-07-2023

Recall of Catheter from Medtronic SA

Source	NCMDR- National Center for Medical Devices Reporting- SFDA https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=19613
Product	Mahurkar Acute Triple Lumen Catheters and Mahurkar Acute High Pressure Triple Lumen Catheters.
Description	Catheter.
Manufacturer	Medtronic SA.
Local agent	Al Zahrawi Medical Supplies LLC.
The affected products	Please refer to list of affected lot numbers in the attachment.
Reason	During manufacturing related testing, the catheter center lumen was found to have an occlusion in the tip of the catheter.
Action	1. Please follow patient recommendation in the attachment. Please return all unused affected product(s) to Medtronic. 2. Contact the local agent for remedial action.
Product image	
comments	Healthcare professionals are encouraged to report any adverse events Suspected to be associated with the above device or any other medical device to Department of Medical Device Control through the E-mail: Med-device@moh.gov.om

Dr. Mohammed Hamdan Al Rubaie

Director General

PADC
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P.O. Box: 393 Muscat - Postal Code: 100 - Tel: 22357111 - Fax: 22358489
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Medtronic

URGENT FIELD SAFETY NOTICE

Mahurkar™ Acute Triple Lumen Catheters and Mahurkar™ Acute High Pressure Triple Lumen Catheters

Recall

June 2023

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 **Mahurkar™ Acute Triple Lumen Catheters** and **Mahurkar™ Acute High Pressure Triple Lumen Catheters**.

Please note: This recall does **not** include any Mahurkar **Elite** Catheters.

You are receiving this letter as Medtronic records indicate your facility may have at least one of the Mahurkar™ Acute Triple Lumen Catheters and/or at least one of the Mahurkar™ Acute High Pressure Triple Lumen Catheters outlined in Attachment B. Medtronic initiated this action to prevent the use of potentially affected product that may impact patients.

Issue Description:

During manufacturing related testing, the catheter center lumen was found to have an occlusion in the tip of the catheter. Investigation identified the source of the occlusion as excessive MDX, a silicone-based lubricant which coats the catheter tip. As of 10 June 2023, there have been zero (0) confirmed complaints. Additionally, there have been zero (0) reported adverse events and there have been zero (0) reported deaths.

Risk to Health:

An incorrect application of MDX to catheters may result in the hazardous situation whereby the catheter is occluded, partially or fully, and/or uncured or excessive MDX may dislodge from the catheter. An occurrence of the hazardous situation may lead to potential harms identified as full catheter obstruction resulting in delay to treatment and partial obstruction resulting in reduced flow or particulate dislodgement that may result in delay to treatment, hemolysis, embolism/embolus or thrombosis/thrombus.

Patient Recommendation:

Mahurkar™ Acute Triple Lumen Catheters and Mahurkar™ Acute High Pressure Triple Lumen Catheters are intended for short term use of up to 29 days. For patients with affected lot(s) currently in place, a replacement procedure is recommended. If a patient is found to have a catheter from an affected lot, the patient's medical team should assess the overall patient risk when considering the timing of a replacement. Clinicians should

continue to follow current product Instructions For Use (IFU) along with facility specific policies and procedures for routine assessment of the hemodialysis access device for patency, function, and efficacy.

Required Actions:

1. Immediately quarantine and discontinue use of all unused Mahurkar™ Acute Triple Lumen Catheters and Mahurkar™ Acute High Pressure Triple Lumen Catheters referenced in Attachment B - List of affected Lot numbers (see Attachment A for guidance to identify impacted product).
   To help you identify if you have affected product, please visit our website www.Medtronic.com/Mahurkar-Triple-Lumen-Catheter-Recall. Here you will find a tool to help you determine if the product you have is affected by this recall.
   Please note: This recall does **not** include any Mahurkar **Elite** Catheters.
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 and email to nahar.s.alsurayi@medtronic.com
4. This notice should be passed on to all those who need to be aware within your organization or to any organization including but not limited to Nephrologists, Intensivists, 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 any questions regarding this communication, please contact your Medtronic Representative .

Sincerely,

Sameh Allam
Operating Unit Manager

Enclosures:

Attachment A: Identifying Affected Product

Attachment B: List of Affected Lot Numbers

Customer Confirmation Form

Attachment A: Identifying Affected Product

The **MAHURKAR™* Triple Lumen Catheter** is a radiopaque, polyurethane tube with two clear silicone catheter extensions and three internal lumina distinguished by color-coded adapters on the extensions:

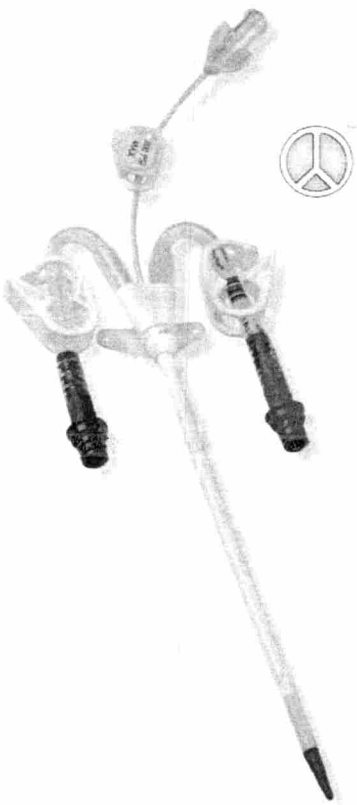
- Red adapter (arterial)
- Blue adapter (venous)
- Clear adapter (medial)

The 12 Fr/Ch catheter is available in various implantable lengths as shown on the box and device labels. The **MAHURKAR™* Triple Lumen Catheter** is intended for short term central venous access for hemodialysis, apheresis, and infusion.

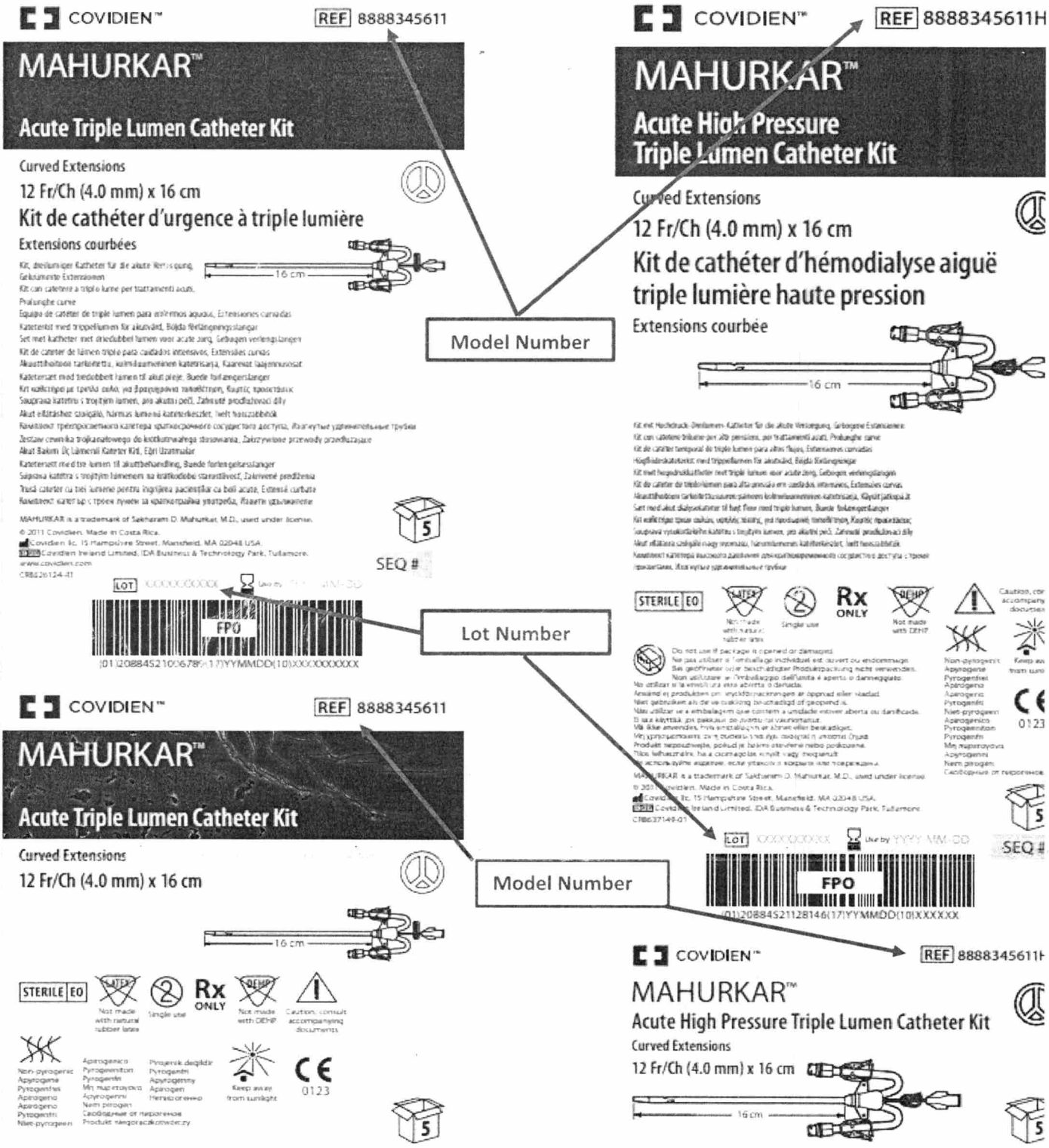
The **MAHURKAR™* Acute High Pressure Triple Lumen Catheter** is a radiopaque, polyurethane tube with two clear silicone catheter extensions and one clear polyurethane Infusion lumen. The three internal lumina can be distinguished by the color-coded luer-lock adapters on the silicone rubber extensions:

- Red adapter (arterial)
- Blue adapter (venous)
- Clear adapter (medial)

The proximal lumen provides "arterial" outflow from the patient; the distal lumen provides "venous" return; the medial lumen is for infusion of fluid, blood products, medications, blood sampling, pressure injection of contrast media and central venous pressure monitoring.



Attachment A: Identifying Affected Product



Attachment B: List of Affected Lot Numbers

Product Description	CFN	GTIN	Lot Number	
8888340629HP 12FR 20CM TRIP LUM HP START	8888340629HP	10884521128071 20884521128078	2107700127	
8888345611HP 12FR 16CM LUM HP CURV KIT	8888345611HP	10884521128149 20884521128146	1926800467	2104100085
			1908400298	2113000069
			1908400299	2018800044
			2119400217	2018800045
			1920500260	2018800046
			1924500090	2019500187
			1926100317	
8888345629HP 12FR 20CM LUM HP CURV KIT	8888345629HP	10884521128163 20884521128160	1828200086	2019500199
			1925300170	2019500222
			1925300171	2018800013
8888345637HP 12FR 24CM LUM HP CURV KIT	8888345637HP	10884521128187 20884521128184	1916500156	