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 246 **dated** 29/12/2022 **Regarding NCMDR recall of Dental products - dental material from (mfr: Ivoclar Vivadent AG).**

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
ISO 9001:2015 CERTIFIED

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

Sultanate of Oman
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سلطنة عُمان
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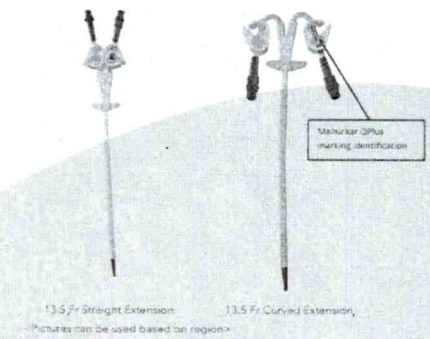
Circular No. 246/ 2022

05 -06-1444 H

29 -12-2022

Recall of Mahurkar Acute Dual Lumen High Flow (13.5 French) Hemodialysis Catheters (Mahurkar QPlus from Covidien LLC

Source	NCMDR- National Center for Medical Devices Reporting- SFDA https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=18370
Product	Mahurkar Acute Dual Lumen High Flow (13.5 French) Hemodialysis Catheters (Mahurkar QPlus)
Description	Hemodialysis Catheters.
Manufacturer	Covidien LLC
The affected products	Product Name: MAHURKAR™* 13.5 Fr High Flow Dual Lumen Acute Dialysis Catheter, 16 cm, Curved Extensions, Kit Models: 8888135162, GTIN: 20884521006376, Lot Numbers: 1822600141
Reason	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.
Action	1. Refer to "Patient Recommendation" in the attached FSN 2. Immediately quarantine and discontinue use of all unused affected items. 3. Return all unused affected items.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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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

Medtronic

Urgent Field Safety Notice

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

Recall

December 2022

Medtronic Reference: FA1295

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. 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,

Sameh Allam

Operating Unit Manager

Enclosures:

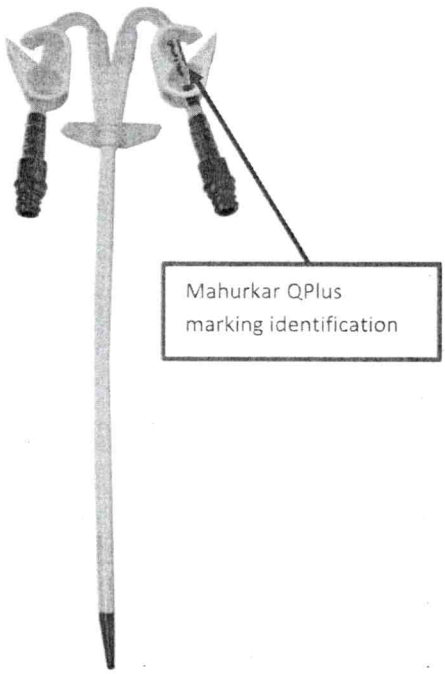
Attachment A: IDENTIFYING AFFECTED PRODUCT

Attachment A:

IDENTIFYING AFFECTED PRODUCT

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

13.5 Fr Straight Extension



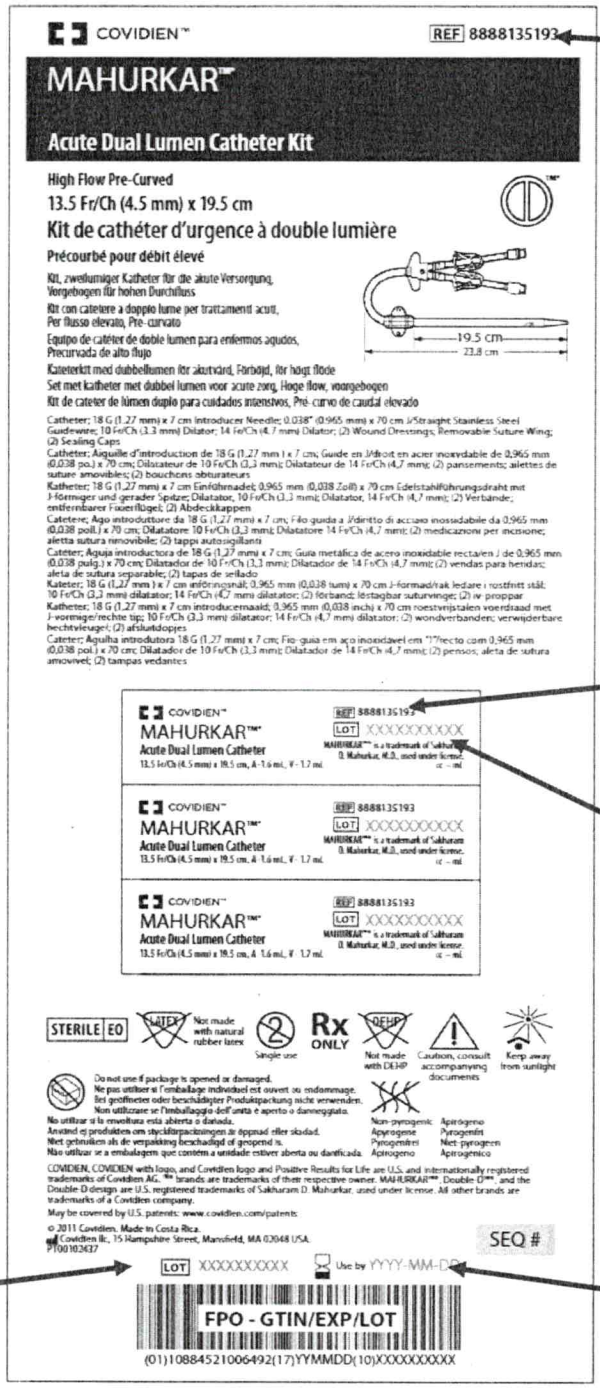
13.5 Fr Curved Extension

<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)



Product Name	Models	GTIN	Lot Numbers
MAHURKAR™* 13.5 Fr High Flow Dual Lumen Acute Dialysis Catheter, 16 cm, Curved Extensions, Kit	8888135162	20884521006376	1822600141