



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



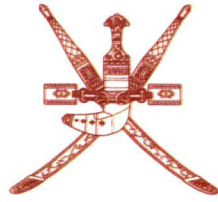
PADC
المديرية العامة للصيدلة والرقابة الدوائية
Directorate General of Pharmaceutical
Affairs & Drug Control



ص.ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩

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

Twitter: dgpa_dc Email: dg-pad@mo.gov.om



Circular No. 246/ 2022

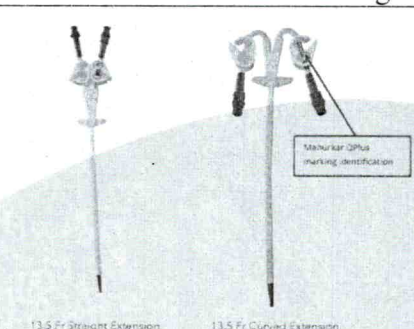
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29 -12-2022

ننقد بثقة
Moving Forward
with Confidence

رؤية عمان
2040
Vision
2040

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
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

Twitter: dgpa_dc Email: dg-padcc@moh.gov.om



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

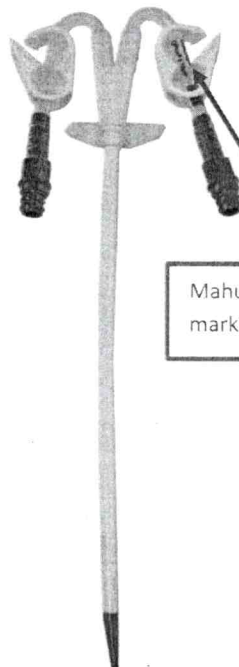
Attachment A:

IDENTIFYING AFFECTED PRODUCT

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



13.5 Fr Straight Extension



Mahurkar QPlus
marking identification

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)

COVIDIEN™

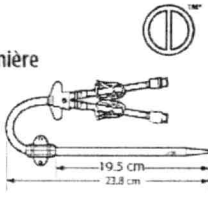
MAHURKAR™

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

RtL, zweilumiger Katheter für die akute Versorgung.
Vorgebogen für hohen Durchfluss.
RtL con catetere a doppio lume per trattamenti acuti.
Per flusso elevato, Pre-curvato.
Equipo de catéter de doble lumen para enfermos agudos.
Precurvado de alto flujo.
Katheterkit med dubbellumen för akutvård. Förhöjd, för högt flöde.
Set met catheter 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 1/8" 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 1/8" en acier inoxydable de 0.965 mm
(0.038 po.) x 70 cm; Dilateur de 10 Fr/Ch (3.3 mm); Dilateur de 14 Fr/Ch (4.7 mm); (2) pansements; ailette de
suture amovible; (2) bouchons obturateurs
Katheter: 18 G (1.27 mm) x 7 cm Einführnadel; 0.965 mm (0.038 Zoll) x 70 cm Edelstahlführungsdraht mit
1/8"-Formiger und gerader Spitze; Dilator, 10 Fr/Ch (3.3 mm); Dilator, 14 Fr/Ch (4.7 mm); (2) Verbande;
entfernbarer Fadenflügel; (2) Abdeckklappen
Catetere: Ago introdutória de 18 G (1.27 mm) x 7 cm; Fio-guia de aço inoxidável de 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) vendagens per incisão;
alética sutura removível; (2) tappers auto-selantes
Catheter: Aguja introductora de 18 G (1.27 mm) x 7 cm; Guía metálica de acero inoxidable recta y 1/8" de 0.965 mm
(0.038 pulg.) x 70 cm; Dilatador de 10 Fr/Ch (3.3 mm); Dilatador de 14 Fr/Ch (4.7 mm); (2) vendajes para heridas;
alética sutura separable; (2) tapas de sellado
Katheter: 18 G (1.27 mm) x 7 cm anföringsnål; 0.965 mm (0.038 tum) x 70 cm 1/8"-formig/ak ledare i rostfritt stål;
10 Fr/Ch (3.3 mm) dilatator; 14 Fr/Ch (4.7 mm) dilatator; (2) förband; löstgjutbar suturvinge; (2) sv propäpar
Katheter: 18 G (1.27 mm) x 7 cm introduccional; 0.965 mm (0.038 inch) x 70 cm roestvrijstalen voorraad met
1/8"-vormige/rechte tip; 10 Fr/Ch (3.3 mm) dilatator; 14 Fr/Ch (4.7 mm) dilatator; (2) wondverbanden; verwijderbare
hechtheuvel; (2) afdekklappen
Cateter: Aiguila introdutora 18 G (1.27 mm) x 7 cm; Fio-guia em aço inoxidável em 1/8" 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; alética de sutura
amovível; (2) tampas vedantes

REF 8888135193

Model Number

COVIDIEN™

MAHURKAR™

Acute Dual Lumen Catheter

13.5 Fr/Ch (4.5 mm) x 19.5 cm, A-1.6 ml, V-1.7 ml

REF 8888135193

LOT XXXXXXXXXX

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© - ml

Model Number

Lot Number

COVIDIEN™

MAHURKAR™

Acute Dual Lumen Catheter

13.5 Fr/Ch (4.5 mm) x 19.5 cm, A-1.6 ml, V-1.7 ml

REF 8888135193

LOT XXXXXXXXXX

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© - ml

Model Number

Lot Number

COVIDIEN™

MAHURKAR™

Acute Dual Lumen Catheter

13.5 Fr/Ch (4.5 mm) x 19.5 cm, A-1.6 ml, V-1.7 ml

REF 8888135193

LOT XXXXXXXXXX

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© - ml

Model Number

Lot Number

STERILE EO

Not made with natural rubber latex

Rx ONLY

Single use

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.
Bei geöffnetem oder beschädigtem 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 produkt om styckpackningen är öppnad eller skadad.
Niet gebruiken als de verpakking beschadigd of open is.
Não utilizar se a embalagem que contém a unidade estiver aberta ou danificada.

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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.
P100102427

SEQ #

LOT XXXXXXXXXX

Use by YYYY-MM-DD

FPO - GTIN/EXP/LOT

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

Expiration Date

Lot Number

Expiration Date

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