



Medtronic Ireland Limited

T Block 3090-3094
Lake Drive
Citywest Business Campus
Dublin
DN24 XN47
Ireland
Tel: 01 511 1400
Fax: 01 807 7220
www.medtronic.ie

URGENT FIELD SAFETY NOTICE

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

June 2023

Medtronic Reference: FA1333

EU MDR: 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 **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).
2. 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.

3. Return all unused affected product(s) to Medtronic. Your Medtronic Sales Representative can assist in returning any affected product.
4. Please complete the enclosed Customer Acknowledgement Form and email to rs.regulatoryuk-ire@medtronic.com
5. 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 our Representative directly or via Tel No: 01 511 1400.

Sincerely,



Bethany Moxon

Associate Regulatory Affairs Specialist - UK and Ireland

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

COVIDIEN™ REF 8888345611

MAHURKAR™
Acute Triple Lumen Catheter Kit

Curved Extensions
12 Fr/Ch (4.0 mm) x 16 cm
Kit de cathéter d'urgence à triple lumière
Extensions courbées



Kit, drei-lumiger Katheter für die akute Versorgung, Gekrümmte Extensionen
Kit con catetere a triple lume per trattamenti acuti, Prolunghe curve
EQUIPO de cateter de triple lumen para enfermos agudos, Extensiones curvadas
Katheterkit med trippellumen för akutvård, Böjda förlängningslängor
Set med kateter med tredubbel lumen voor acute zorg, Gebogen verlengslangen
Kit de cateter de lumen triple para cuidados intensivos, Extensiones curvas
Akutitilhoiton tarkoitettu, kolmilumainen katetrisarja, Kaarevat laajennusosat
Kathetersatz med tredobbel lumen til akut pleje, Buede forlængerlanger
Kit ušestrujnyh ja trojnnyh lumen, pro akutni peči, Zagnute produževalci dlji
Soupravno katetra s trojným lumen, pro akútne péči, Záhnuté produžovací dlhy
Akut ellátáshoz szolgáló, három lumenű katéterkészlet, ívelt hosszabbítók
Комплект трёхпросветного катетра с трёхпросветного согнутого доступа, Изымные удлинительные трубки
Zestaw cewnika trójkanałowego do krótkotrwałego stosowania, Zakrzywione przewody przedłużające
Akut Bakım Üç Lümenli Kateter Kit, Eğri Uzatmalar
Kathetersatt med tre lumen til akutbehandling, Buede forlængerlanger
Súgrava katitra s trojným lúmenom na krátkodobé starostlivosti, Zakrivené predĺženia
Trudi cateter cu trei lumene pentru îngrijirea pacienților cu boli acute, Extensii curbate
Комплекст катетра с трыох лумена за краткатрайна употреба, Изымне удължителна

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Covidien Ireland Limited, IDA Business & Technology Park, Tullamore.
www.covidien.com
CR8626124-R1

LOT XXXXXXXXXX Use by YYYY-MM-DD

STERILE EO Not made with natural rubber latex Single use Rx ONLY Not made with DEHP Caution, consult accompanying documents

Non-pyrogenic Pyrogenfrei Apyrogeno Apyrogeno Pyrogenfri Niet-pyrogenic

Pyrogenfri Pyrogenfri Apyrogeno Apyrogeno Pyrogenfri Niet-pyrogenic

Projeğin değıdır Pyrogenfri Apyrogeno Apyrogeno Pyrogenfri Niet-pyrogenic

Keep away from sunlight

CE 0123

SEQ #

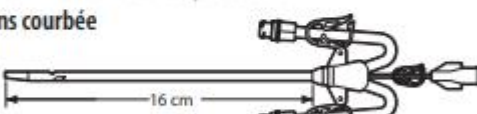
Model Number

Lot Number

COVIDIEN™ REF 8888345611HP

MAHURKAR™
Acute High Pressure Triple Lumen Catheter Kit

Curved Extensions
12 Fr/Ch (4.0 mm) x 16 cm
Kit de cathéter d'hémodialyse aiguë triple lumière haute pression
Extensions courbées



Kit mit Hochdruck-Dreilumen-Katheter für die akute Versorgung, Gebogene Extensionen
Kit con catetere tribune per alta pressione, per trattamenti acuti, Prolunghe curve
Kit de cateter tregușal de triple lumen für altele fluxii, Extensiones curvadas
Högflödeskateter för tredubbel lumen för akutvård, Böjda förlängningar
Kit med högdricka katter med triple lumen voor acute zorg, Gebogen verlengslangen
Kit de cateter de triple-lumen para alta presión en cuidados intensivos, Extensiones curvas
Akutitilhoiton tarkoitettu suuren paineen hoitoon, kolmilumainen katetrisarja, Käydyt jatko-osat
Set med akut dialyskateter til høy flow med triple lumen, Buede forlængerlanger
Kit ušestrujnyh trojn lumen, pro akutni peči, Zagnute produževalci dlji
Soupravno vysokotlakého katetra s trojným lumen, pro akútne péči, Záhnuté produžovací dlhy
Akut ellátáshoz szolgáló nagy nyomású, háromlumenű katéterkészlet, ívelt hosszabbítók
Комплекст катетра високого давления для коротковременного доступа с трыох просветами, Изымные удлинительные трубки

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Covidien Ireland Limited, IDA Business & Technology Park, Tullamore.
www.covidien.com
CR8637149-01

LOT XXXXXXXXXX Use by YYYY-MM-DD

STERILE EO Not made with natural rubber latex Single use Rx ONLY Not made with DEHP Caution, consult accompanying documents

Do not use if package is opened or damaged. Do not utilize se l'emballaggio dell'unità è aperto o danneggiato. No utilizar se la envoltura está abierta o dañada. Använd ej produktens omsättningspackningen är öppnad eller viktad. Niet gebruiken als de verpakking beschadigd of geopend is. Não utilizar se a embalagem que contém a unidade estiver aberta ou danificada. Si asa kütetők, jón pakolás on avartva tal vicedetektum. Må ikke anvendes, hvis emballagen er åbnet eller beskadiget. Μη χρησιμοποιείτε αν η συσκευασία δεν ανοίχτεί ή υφαιστεί ύλα. Produkt nepoužívajte, pokud je balení otevřeno nebo poškozeno. Ties fahuzatási, ha a csomagolás kinyitott vagy megsérült. Не використовуйте виріб, якщо упаковка воєрвана или пошкоджена.

Non-pyrogenic Pyrogenfrei Apyrogeno Apyrogeno Pyrogenfri Niet-pyrogenic

Pyrogenfri Pyrogenfri Apyrogeno Apyrogeno Pyrogenfri Niet-pyrogenic

Projeğin değıdır Pyrogenfri Apyrogeno Apyrogeno Pyrogenfri Niet-pyrogenic

Keep away from sunlight

CE 0123


SEQ #

Model Number

COVIDIEN™ REF 8888345611

MAHURKAR™
Acute Triple Lumen Catheter Kit

Curved Extensions
12 Fr/Ch (4.0 mm) x 16 cm



STERILE EO Not made with natural rubber latex Single use Rx ONLY Not made with DEHP Caution, consult accompanying documents

Non-pyrogenic Pyrogenfrei Apyrogeno Apyrogeno Pyrogenfri Niet-pyrogenic

Pyrogenfri Pyrogenfri Apyrogeno Apyrogeno Pyrogenfri Niet-pyrogenic

Projeğin değıdır Pyrogenfri Apyrogeno Apyrogeno Pyrogenfri Niet-pyrogenic

Keep away from sunlight

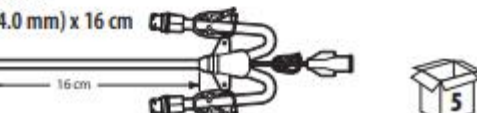
CE 0123

SEQ #

COVIDIEN™ REF 8888345611HP

MAHURKAR™
Acute High Pressure Triple Lumen Catheter Kit

Curved Extensions
12 Fr/Ch (4.0 mm) x 16 cm



STERILE EO Not made with natural rubber latex Single use Rx ONLY Not made with DEHP Caution, consult accompanying documents

Non-pyrogenic Pyrogenfrei Apyrogeno Apyrogeno Pyrogenfri Niet-pyrogenic

Pyrogenfri Pyrogenfri Apyrogeno Apyrogeno Pyrogenfri Niet-pyrogenic

Projeğin değıdır Pyrogenfri Apyrogeno Apyrogeno Pyrogenfri Niet-pyrogenic

Keep away from sunlight

CE 0123

SEQ #

Attachment B: List of Affected Lot Numbers

| Product Description | CFN | GTIN | Lot Number | | | | |
|--|--------------|----------------------------------|------------|------------|------------|------------|------------|
| 8888101001HP 12FR X 13CM HPTLC MAH TRAY | 8888101001HP | 20884521127897 | 2133600127 | 2133700049 | 2200400180 | | |
| 8888101002HP 12FR X 16CM HPTLC MAH TRAY | 8888101002HP | 20884521127965 | 2133600171 | 2133700060 | 2230400213 | | |
| | | | 2133600172 | 2200400110 | 2230400214 | | |
| | | | 2133700047 | 2204000236 | 2233400068 | | |
| | | | 2133700048 | | | | |
| 8888101003HP 12FR X 20CM HPTLC MAH TRAY | 8888101003HP | 20884521127972 | 2130900104 | 2226500171 | 2227800104 | | |
| | | | 2133600083 | 2226500173 | 2227800109 | | |
| | | | 2133600160 | 2227800101 | 2230400208 | | |
| | | | 2133600165 | | | | |
| 8888101004HP 12FR X 24CM HPTLC MAH TRAY | 8888101004HP | 20884521127989 | 2130900107 | 2133700059 | | | |
| 8888102003HP 20CM 12FR MAH HPTLC TY W SE | 8888102003HP | 20884521127996 | 2204000239 | 2227800110 | | | |
| 8888102004HP 24CM 12FR MAH HPTLC TY W SE | 8888102004HP | 20884521128009 | 2200400154 | | | | |
| 8888103001HP MAH HPTLC CDC-CETRAY12FX13 | 8888103001HP | 40884521128010 | 2133700228 | | | | |
| 8888103002HP MAH HPTLC CDC-CETRAY12FX16 | 8888103002HP | 20884521128023 | 2133700232 | 2133700247 | 2133700248 | | |
| 8888103004HP MAH HPTLC CDC-CETRAY12FX24 | 8888103004HP | 20884521128047 | 2133700227 | | | | |
| 8888104003HP MAH HPTLC CDC-SETRAY12FX20 | 8888104003HP | 20884521128054 | 2131200173 | 2200400273 | 2200400290 | | |
| | | | 2133700237 | | | | |
| 8888104004HP MAH HPTLC CDC-SETRAY12FX24 | 8888104004HP | 20884521128061 | 2200400292 | | | | |
| 8888340629 12FR 20CM MAHKA ACUTE 3LCATH | 8888340629 | 20884521057019 | 1921300069 | 2227800100 | | | |
| 8888340629HP 12FR 20CM TRIP LUM HP START | 8888340629HP | 10884521128071 20884521128078 | 1926100313 | 2102200138 | 2123000099 | | |
| | | | 1926100314 | 2107700127 | 2130800131 | | |
| | | | 1926100315 | 2113300296 | 2203300174 | | |
| | | | 1933000064 | 2119400212 | 2230400227 | | |
| | | | 2034900046 | | | | |
| 8888340637 12FR 24CMMAHURKAR ACUTE3LCATH | 8888340637 | 20884521057026 | 2119400209 | 2122900117 | 2124600187 | | |
| 8888340637HP TRIP LUM HP STRT KIT 24CM | 8888340637HP | 10884521128088 | 1907700088 | 2019500217 | 2113300287 | | |
| | | 20884521128085 | 2015100039 | 2107700128 | | | |
| 8888345512HP 12FR LUM HP CURV CATH 16CM | 8888345512HP | 20884521128108 | 2018800014 | 2027200276 | 2130800064 | | |
| | | | 2023400145 | 2119400215 | 2201000047 | | |
| 8888345520HP 12FR LUM HP CURV CATH 20CM | 8888345520HP | 20884521128115 | 2018800011 | 2203900129 | | | |
| 8888345603 12FR 13CM MAHURKAR 3LCATHKIT | 8888345603 | 10884521006768 20884521006765 | 1907700093 | 1921100199 | 2002900099 | 2010800201 | 2131200162 |
| | | | 1908400296 | 1921100201 | 2002900103 | 2010800203 | 2131200163 |
| | | | 1914400157 | 1921300056 | 2002900104 | 2010800204 | 2227800106 |
| | | | 1914400158 | 1921300057 | 2005700211 | 2010800206 | 2227800111 |
| | | | 1914800241 | 1928700083 | 2005700212 | 2010800207 | 2227800112 |
| | | | 1914800242 | 1932300211 | 2007800069 | 2015100040 | 2227800114 |
| | | | 1914800243 | 2000700063 | 2007800070 | 2015100043 | 2227800115 |
| | | | 1915800144 | 2000700064 | 2007800088 | 2017400082 | 2230400303 |
| | | | 1915800145 | 2001400084 | 2009000047 | 2019500192 | 2230400304 |
| 1916500157 | 2002100115 | 2009400127 | 2131200161 | 2232700203 | | | |

VAT: IE9513488W

Registered in Ireland No. 275799

| Product Description | CFN | GTIN | Lot Number | | | | |
|---|--------------|----------------------------------|------------|------------|------------|------------|------------|
| | | | | | | | |
| | | | 1920700126 | | | | |
| | | | 1921100198 | | | | |
| 8888345603HP 12FR 13CM LUM HP CURV KIT | 8888345603HP | 20884521128139 | 2017400081 | 2113300282 | 2227800105 | | |
| | | | 2028300087 | 2133700046 | | | |
| 8888345611 12FR 16CM MAHURKAR 3LCATHKIT | 8888345611 | 10884521006782 20884521006789 | 1907700087 | 1935100073 | 2007800071 | 2019500198 | 2123000115 |
| | | | 1915800147 | 1935100074 | 2007800072 | 2029700145 | 2124600186 |
| | | | 1915800149 | 1935100085 | 2007800073 | 2032300067 | 2124600190 |
| | | | 1924500084 | 1935100086 | 2009200094 | 2032800039 | 2127300095 |
| | | | 1924500085 | 1935100087 | 2009300094 | 2032800040 | 2131200168 |
| | | | 1924500087 | 1935100088 | 2009300095 | 2033100068 | 2131200172 |
| | | | 1924500088 | 2000700065 | 2009300096 | 2033100069 | 2131200175 |
| | | | 1933000070 | 2000700066 | 2010800205 | 2104100115 | 2131200178 |
| | | | 1933000071 | 2002100112 | 2011300096 | 2122900118 | 2131200179 |
| | | | 1933000073 | 2002100114 | 2011300098 | 2122900159 | 2133700137 |
| | | | 1934300131 | 2002900106 | 2011300099 | 2122900161 | 2133700138 |
| | | | 1934300134 | 2003900122 | 2017400084 | 2122900195 | 2133700140 |
| | | | 1934300135 | 2003900123 | 2018800018 | 2122900217 | 2230400265 |
| | | | 1934300136 | 2005500062 | 2018800021 | 2122900276 | 2230400277 |
| | | | 1934400128 | 2005500064 | 2018800023 | 2122900277 | 2230400278 |
| | | | 1934400174 | 2006500075 | 2019500195 | 2123000092 | 2234800082 |
| 8888345611HP 12FR 16CM LUM HP CURV KIT | 8888345611HP | 10884521128149 20884521128146 | 1908400297 | 1926800467 | 2021000110 | 2116200130 | 2203300170 |
| | | | 1908400298 | 2018800025 | 2021000111 | 2116500175 | 2203300173 |
| | | | 1908400299 | 2018800044 | 2023400151 | 2119400217 | 2203300175 |
| | | | 1908800136 | 2018800045 | 2102200137 | 2119400219 | 2232700163 |
| | | | 1920500260 | 2018800046 | 2102600093 | 2131200183 | 2232700197 |
| | | | 1924500090 | 2019500187 | 2104100085 | 2203300166 | 2232700207 |
| | | | 1926100317 | 2020500079 | 2113000069 | 2203300169 | 2234800070 |
| | | | 1926100318 | 2021000109 | 2113300288 | | |
| 8888345629 12FR 20CM MAHU 3LCATH KIT | 8888345629 | 10884521006799 20884521006796 | 2009400128 | 2119400221 | 2122900216 | | |
| | | | 2113300290 | 2119400227 | 2122900231 | | |
| | | | 2116500142 | 2122900119 | 2127300111 | | |
| | | | 2116500176 | 2122900127 | 2127300113 | | |
| 8888345629HP 12FR 20CM LUM HP CURV KIT | 8888345629HP | 10884521128163 20884521128160 | 1828200086 | 2018800043 | 2021000107 | 2133700166 | |
| | | | 1925300170 | 2019500199 | 2029600102 | 2227800108 | |
| | | | 1925300171 | 2019500200 | 2029600103 | 2230400250 | |
| | | | 2018800013 | 2019500222 | 2116600083 | 2230400251 | |
| | | | 2018800024 | 2021000106 | 2131200176 | 2234800071 | |
| 8888345637 12FR 24CM MAHURKAR 3LCATHKIT | 8888345637 | 10884521006829 20884521006826 | 2124600191 | 2127300121 | | | |
| 8888345637HP 12FR 24CM LUM HP CURV KIT | 8888345637HP | 10884521128187 20884521128184 | 1916500156 | 2104600149 | 2119400230 | | |
| | | | 2017400085 | 2107700145 | 2123000100 | | |
| | | | 2028300088 | 2113100057 | 2133700164 | | |
| | | | 2102600094 | | | | |

