



URGENT FIELD SAFETY NOTICE

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

June 2023

<For use in countries that follow 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).
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 rs.ranordic@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,

[Local / OU Manager](#)

Enclosures:

Attachment A: Identifying Affected Product

Attachment B: List of Affected Lot Numbers

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, Gebogenne Extensions
Kit con catetere a triple lume per trattamento acuto, Prolunghe curve
Equipo de cateter de triple lumen para enfermos agudos, Extensiones curvadas
Katheterkit med trippellumen för akutvård, Böjda förlängningslängor
Set met katheter med trieddubbel lumen voor acute zorg, Gebogen verlengslangen
Kit de cateter de lumen triple para cuidados intensivos, Extensões curvas
Akutthörselön tarkoitettu kolmilumainen katetrisarja, Kaarevat laajennusosat
Katheterset med tredobbel lumen til akut pleje, Buede forlængerslanger
Kit katétrója je trojitérná, je závažného zraněného, Kardi; nemocného, Souprava katétru s trojitým lumen, pro akutní péči, Zahradní produkovácí díly
Akut ellátáshoz szolgáló, három lumenű katéterkészlet, ívelt hosszabbítók
Комплект трёхпросветного катетера критического сосудистого доступа, Изогнутые удлинительные трубки
Zestaw szwenika trójkanalowego do kłótkatowego stosowania, Zakrzywione przedłużacze
Akut Bakım İçin Lümenli Kateter Kit, Eğri Uzatmalar
Kathetersett med tre lumen til akuttbehandling, Buede forlængerlanger
Súprava katétru s trojitým lúmenom na kritickodobí stavovsteví, Zahrievné predĺženia
Trojč cateter cu trei lumene pentru îngrijirea pacienților cu boli acute, Extensii curbate
Комплект катетра с тремя лумена за критическая употреба, Изагнати удължители

MAHURKAR is a trademark of Saktharam D. Mahurkar, M.D., used under license.
© 2011 Covidien. Made in Costa Rica.
Covidien Inc., 15 Hampshire Street, Mansfield, MA 02048 USA.
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 Apirógeno Pirógenfrei Apyrógeni Nem pirógin Pyrogenfrei Не пірогенні Produkt nieogrzęzkawczy

Pyrogenfrei Pyrogenfrei Apirógeno Pirógenfrei Apyrógeni Nem pirógin Pyrogenfrei Не пірогенні Produkt nieogrzęzkawczy

Keep away from sunlight

CE 0123

SEQ #

Model Number

Lot 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 Apirógeno Pirógenfrei Apyrógeni Nem pirógin Pyrogenfrei Не пірогенні Produkt nieogrzęzkawczy

Pyrogenfrei Pyrogenfrei Apirógeno Pirógenfrei Apyrógeni Nem pirógin Pyrogenfrei Не пірогенні Produkt nieogrzęzkawczy

Keep away from sunlight

CE 0123

SEQ #

Model 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 courbée

Kit mit Hochdruck-Dreilumen-Katheter für die akute Versorgung, Gebogene Extensions
Kit con catetere trilume per alta presión, per trattamento acuto, Prolunghe curve
Kit de cateter temporal de triple lumen para alta presión, Extensiones curvadas
Högflödeskateterkit med trippellumen för akutvård, Böjda förlängningar
Kit de cateter de triple lumen para alta presión em cuidados intensivos, Extensões curvas
Akutthörselön tarkoitettu suuren paineen kolmilumainen katetrisarja, Käytilä jatkaajit
Set met akut dialyskateter til højt flow med triple lumen, Buede forlængerlanger
Kit katétrója je trojitérná, je závažného zraněného, Kardi; nemocného, Souprava vysokotlakého katétru s trojitým lumen, pro akutní péči, Zahradní produkovácí díly
Akut ellátáshoz szolgáló, három lumenű katéterkészlet, ívelt hosszabbítók
Комплект катетера высокой давления для критического сосудистого доступа с тремя просветами, Изогнутые удлинительные трубки

MAHURKAR is a trademark of Saktharam D. Mahurkar, M.D., used under license.
© 2011 Covidien. Made in Costa Rica.
Covidien Inc., 15 Hampshire Street, Mansfield, MA 02048 USA.
Covidien Ireland Limited, IDA Business & Technology Park, Tullamore.
www.covidien.com
CR8637148-01

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. Nie pas użyciar si i emballage individual est ouvert ou endommagé. Ist geöffneter oder beschädigter Produktpackung nicht verwenden. No utilizar si la emballaje individual está abierto o dañado. Använd ej produkten om styckförpackningen är öppen eller skadad. Nie górnikiem albo de verpakking beschadigd of geopend is. Não utilizar se a embalagem que contém a unidade estiver aberta ou danificada. Di saa käyttää, jos pakkaus on avattu tai vaurioitunut. Må ikke anvendes, hvis emballagen er åbret eller beskadiget. My yppinrajoitettua on vaurioituneita lääkintötarvikkeita. Produkt nieporozużywać, jeżeli jest uszkodzony lub uszkodzony. Не використовувати апарат, якщо упаковка відкрита або пошкоджена.

Non-pyrogenic Pyrogenfrei Apirógeno Pirógenfrei Apyrógeni Nem pirógin Pyrogenfrei Не пірогенні Produkt nieogrzęzkawczy

Pyrogenfrei Pyrogenfrei Apirógeno Pirógenfrei Apyrógeni Nem pirógin Pyrogenfrei Не пірогенні Produkt nieogrzęzkawczy

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 Apirógeno Pirógenfrei Apyrógeni Nem pirógin Pyrogenfrei Не пірогенні Produkt nieogrzęzkawczy

Pyrogenfrei Pyrogenfrei Apirógeno Pirógenfrei Apyrógeni Nem pirógin Pyrogenfrei Не пірогенні Produkt nieogrzęzkawczy

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

Product Description	CFN	GTIN	Lot Number				
			1916500157	2002100115	2009400127	2131200161	2232700203
			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				