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Medtronic

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Urgent Field Safety Notice

Mahurkar™ Acute Triple Lumen Catheters and

Mahurkar™ Acute High Pressure Triple Lumen Catheters

Recall

June 2023

Medtronic Reference: FA1333

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 TM Acute Triple Lumen Catheters and/or at least one of the Mahurkar TM 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:

MahurkarTM Acute Triple Lumen Catheters and MahurkarTM 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 TM Acute Triple Lumen Catheters and Mahurkar TM 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.dusregulatory@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,

Medtronic GmbH

Enclosures:

Attachment A: Identifying Affected Product

Attachment B: List of Affected Lot Numbers

Customer Confirmation Form

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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.

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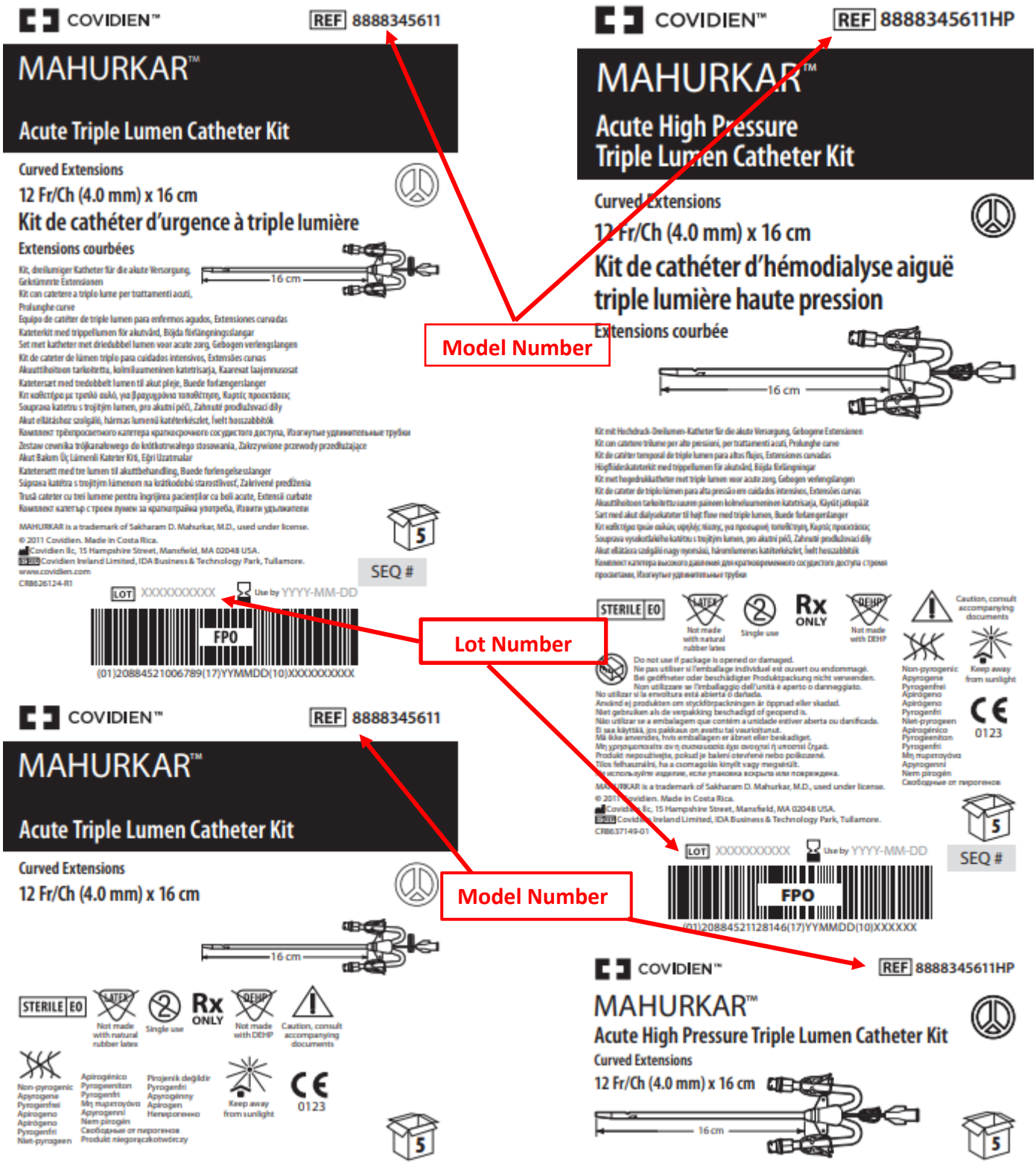
Attachment A: Identifying Affected Product



Model Number

Lot Number

Model Number

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Attachment B: List of Affected Lot Numbers

Product Description	CFN	GTIN	Lot Number			
8888340629 12FR 20CM MAHKA ACUTE 3LCATH	**8888340629**	20884521057019	1921300069			
8888340629HP 12FR 20CM TRIP LUM HP START	**8888340629HP**	20884521128078	1926100313	1926100314	1926100315	1933000064
			2034900046	2102200138	2107700127	2113300296
			2119400212	2123000099	2130800131	2203300174
8888340637HP TRIP LUM HP STRT KIT 24CM	**8888340637HP**	20884521128085	1907700088	2015100039	2019500217	2107700128
			2113300287			
8888345512HP 12FR LUM HP CURV CATH 16CM	**8888345512HP**	20884521128108	2018800014	2023400145	2027200276	2119400215
			2130800064	2201000047		
8888345520HP 12FR LUM HP CURV CATH 20CM	**8888345520HP**	20884521128115	2018800011	2203900129		
8888345603HP 12FR 13CM LUM HP CURV KIT	**8888345603HP**	20884521128139	2028300087	2113300282	2133700046	2227800105
8888345611HP 12FR 16CM LUM HP CURV KIT	**8888345611HP**	10884521128149 20884521128146	1908400297	1908400298	1908400299	1908800136
			1924500090	1926100317	1926100318	1926800467
			2018800044	2018800045	2019500187	2020500079
			2021000109	2021000110	2021000111	2023400151
			2102200137	2104100085	2113000069	2113300288
			2116200130	2119400217	2119400219	2203300166
			2203300169	2203300175	2232700207	
8888345629HP 12FR 20CM LUM HP CURV KIT	**8888345629HP**	20884521128160	1828200086	1925300170	1925300171	2018800013
			2018800024	2019500199	2019500200	2019500222
			2021000106	2021000107	2029600102	2029600103
			2116600083	2131200176	2133700166	2227800108
			2230400250	2234800071		
8888345637HP 12FR 24CM LUM HP CURV KIT	**8888345637HP**	20884521128184	1916500156	2017400085	2028300088	2102600094
			2104600149	2107700145	2113100057	2119400230
			2123000100	2133700164		