

Urgent Field Safety Notice

MAHURKAR™* and Argyle™* Acute Hemodialysis Catheters

May 2019

Medtronic reference: FA866

Dear Physician or Healthcare Professional,

The purpose of this letter is to advise you that Medtronic is issuing a voluntary Urgent Field Safety Notice for its MAHURKAR™* and Argyle™* acute hemodialysis catheters.

Issue Description:

This notice is to clarify that the priming volume values printed on the MAHURKAR™* and Argyle™* acute catheters and Instructions for Use (IFU) are higher than the volumes required to fill each lumen.

NOTE: This Urgent Field Safety Notice is only for the MAHURKAR™* and Argyle™* acute catheters. This Urgent Field Safety Notice does NOT impact the MAHURKAR™* Elite catheters, MAHURKAR™* chronic catheters, Argyle™* peritoneal dialysis or other Medtronic dialysis catheters.

In some instances, priming volumes for the MAHURKAR™* and Argyle™* acute catheters were established using the maximum calculated volume plus an additional volume to ensure the catheter was fully locked. This approach was chosen to ensure that the lumen is always fully primed, minimizing risk of catheter thrombosis. Therefore, the printed priming volumes on current MAHURKAR™* and Argyle™* acute catheters and IFUs exceed the actual locking volume needed to fully fill each lumen. Depending on the catheter size and configuration, a variation from 0.1 mL – 0.5 mL per lumen from the printed priming value (actual locking volume would be lower) could be observed.

Risk to Health

Lack of clarity on the printed priming volume could lead a clinician to administer more heparin than intended. Review of complaints since 2003 identified three complaints (out of approximately five million MAHURKAR™* and Argyle™* acute catheter insertions) regarding catheter priming volumes. In one instance, the patient suffered a hematoma following heparin flush. No patient harm was reported in connection with the other two complaints.

Actions being taken by Medtronic

Medtronic is currently updating the IFU for affected MAHURKAR™* and Argyle™* acute catheters to provide clarity on the currently printed priming volumes.

In addition, to further improve the current labeling, Medtronic is also re-evaluating the priming volume for all configurations and sizes of the MAHURKAR™* and Argyle™* acute catheters and will be working with regulatory agencies globally to subsequently update product and product labeling with these values.

Recommendations

While Medtronic is updating the IFU, we recommend the use of a non-heparinized lock solution, such as 4% sodium citrate or 1000 U/mL heparin to mitigate potential risk associated with unintended administration of additional concentrated heparin.

As per the IFU, Medtronic wants to re-emphasize our recommendations related to heparinization, and appropriate management of each individual patient's unique needs around coagulation. Specifically,

- In all cases, the patient's condition must be considered when choosing a heparin regime. Use less heparin in children and in adults with bleeding disorders.
- Always defer to the physician's experience and judgement or institution protocol.

Medtronic

The Competent Authority of your country has been notified of this action. Please maintain a copy of this notice in your records.

Thank you for your attention to this notification. If you have any questions or concerns, please do not hesitate to contact your Medtronic representative at <XXXX>.

Sincerely,

Local / BU Manager

Enclosure: Impacted Product Codes

Appendix A: Impacted Product Codes

Item Code	Description	Item Code	Description
8813793009	MAHURKAR™ Acute Dual Lumen Catheter Kit Straight Extensions - 11.5 Fr x 19.5 cm	8830416021	MAHURKAR™ Acute Dual Lumen Catheter Tray Straight Extensions with IC* Safety Components - 11.5 Fr x 16 cm
8813793013	MAHURKAR™ Acute Dual Lumen Catheter Kit Curved Extensions - 11.5 Fr x 19.5 cm	8830416023	MAHURKAR™ Acute Dual Lumen Catheter Tray Curved Extensions with IC* Safety Components - 11.5 Fr x 16 cm
8813794005	MAHURKAR™ Acute Dual Lumen Catheter Straight Extensions with 2 Sealing Caps - 11.5 Fr x 19.5 cm	8831173010	Argyle™ Acute Single Lumen Catheter Kit Straight Extension - 8 Fr x 15 cm
8813794009	MAHURKAR™ Acute Dual Lumen Catheter Curved Extensions with 2 Sealing Caps - 11.5 Fr x 19.5 cm	8831173011	Argyle™ Acute Single Lumen Catheter Kit Straight Extension - 8 Fr x 19.5 cm
8813816005	MAHURKAR™ Acute Dual Lumen Catheter Straight Extensions with 2 Sealing Caps - 11.5 Fr x 13.5 cm	8831173012	Argyle™ Acute Single Lumen Catheter Kit Curved Extension - 8 Fr x 15 cm
8813816009	MAHURKAR™ Acute Dual Lumen Catheter Curved Extensions with 2 Sealing Caps - 11.5 Fr x 13.5 cm	8831661001	MAHURKAR™ Acute Dual Lumen Catheter Kit Straight Extensions - 11.5 Fr x 24 cm
8813817005	MAHURKAR™ Acute Dual Lumen Catheter Kit Straight Extensions - 11.5 Fr x 13.5 cm	8831662001	MAHURKAR™ Acute Dual Lumen Catheter Straight Extensions with 2 Sealing Caps - 11.5 Fr x 24 cm
8813817009	MAHURKAR™ Acute Dual Lumen Catheter Kit Curved Extensions - 11.5 Fr x 13.5 cm	8831663001	MAHURKAR™ Acute Dual Lumen Catheter Tray Straight Extensions with IC* Components - 11.5 Fr x 24 cm
8815668007	MAHURKAR™ Acute Dual Lumen Catheter Tray Straight Extensions with IC* Components - 11.5 Fr x 19.5 cm	8831663002	MAHURKAR™ Acute Dual Lumen Catheter Tray Curved Extensions with IC* Components - 11.5 Fr x 24 cm
8815668011	MAHURKAR™ Acute Dual Lumen Catheter Tray Curved Extensions with IC* Components - 11.5 Fr x 19.5 cm	8831663021	MAHURKAR™ Acute Dual Lumen Catheter Tray Straight Extensions with IC* Safety Components - 11.5 Fr x 24 cm
8815668021	MAHURKAR™ Acute Dual Lumen Catheter Tray Curved Extensions with IC* Safety Components - 11.5 Fr x 19.5 cm	8831663022	MAHURKAR™ Acute Dual Lumen Catheter Tray Curved Extensions with IC* Safety Components - 11.5 Fr x 24 cm
8815668027	MAHURKAR™ Acute Dual Lumen Catheter Tray Straight Extensions with IC* Safety Components - 11.5 Fr x 19.5 cm	8832539001	MAHURKAR™ Acute Dual Lumen Catheter Kit Straight Extensions - 8 Fr x 9 cm
8817142005	MAHURKAR™ Acute Dual Lumen Catheter Straight Extensions with 2 Sealing Caps - 10 Fr x 12 cm	8832539002	MAHURKAR™ Acute Dual Lumen Catheter Kit Straight Extensions - 8 Fr x 12 cm
8817143005	MAHURKAR™ Acute Dual Lumen Catheter Kit Curved Extensions - 10 Fr x 12 cm	8832539003	MAHURKAR™ Acute Dual Lumen Catheter Kit Straight Extensions - 8 Fr x 15 cm
8817145005	MAHURKAR™ Acute Dual Lumen Catheter Straight Extensions with 2 Sealing Caps - 10 Fr x 15 cm	8832539006	MAHURKAR™ Acute Dual Lumen Catheter Kit Curved Extensions - 8 Fr x 12 cm
8817146001	MAHURKAR™ Acute Dual Lumen Catheter Kit Straight Extensions - 10 Fr x 15 cm	8832539007	MAHURKAR™ Acute Dual Lumen Catheter Kit Curved Extensions - 8 Fr x 15 cm
8817146007	MAHURKAR™ Acute Dual Lumen Catheter Kit Curved Extensions - 10 Fr x 15 cm	8888115132	MAHURKAR™ Acute Dual Lumen Catheter Kit Pre-Curved - 11.5 Fr x 13.5 cm
8817149007	MAHURKAR™ Acute Dual Lumen Catheter Kit Curved Extensions - 10 Fr x 19.5 cm	8888115133	MAHURKAR™ Acute Dual Lumen Catheter Tray Pre-Curved with IC* Components - 11.5 Fr x 13.5 cm
8817232018	Argyle™ Acute Single Lumen Catheter Straight Extensions - 8 Fr x 15 cm	8888115162	MAHURKAR™ Acute Dual Lumen Catheter Kit Pre-Curved - 11.5 Fr x 16 cm
8817232019	Argyle™ Acute Single Lumen Catheter Straight Extension - 8 Fr x 19.5 cm	8888115163	MAHURKAR™ Acute Dual Lumen Catheter Tray Pre-Curved with IC* Components - 11.5 Fr x 16 cm
8817277007	MAHURKAR™ Acute Dual Lumen Catheter Tray Straight Extensions with IC* Components - 11.5 Fr x 13.5 cm	8888115192	MAHURKAR™ Acute Dual Lumen Catheter Kit Pre-Curved - 11.5 Fr x 19.5 cm
8817277011	MAHURKAR™ Acute Dual Lumen Catheter Tray Curved Extensions with IC* Components - 11.5 Fr x 13.5 cm	8888115193	MAHURKAR™ Acute Dual Lumen Catheter Tray Pre-Curved with IC* Components - 11.5 Fr x 19.5 cm
8817277021	MAHURKAR™ Acute Dual Lumen Catheter Tray Curved Extensions with IC* Safety Components - 11.5 Fr x 13.5 cm	8888115242	MAHURKAR™ Acute Dual Lumen Catheter Kit Pre-Curved - 11.5 Fr x 24 cm
8817277027	MAHURKAR™ Acute Dual Lumen Catheter Tray Straight Extensions with IC* Safety Components - 11.5 Fr x 13.5 cm	8888115243	MAHURKAR™ Acute Dual Lumen Catheter Tray Pre-Curved with IC* Components - 11.5 Fr x 24 cm
8830414001	MAHURKAR™ Acute Dual Lumen Catheter Straight Extensions with 2 Sealing Caps - 11.5 Fr x 16 cm	8888135131	MAHURKAR™ Acute Dual Lumen Catheter Kit High Flow Straight Extensions 13.5 Fr x 13.5 cm
8830414002	MAHURKAR™ Acute Dual Lumen Catheter Curved Extensions with 2 Sealing Caps - 11.5 Fr x 16 cm	8888135132	MAHURKAR™ Acute Dual Lumen Catheter Tray High Flow Curved Extensions - 13.5 Fr x 13.5 cm
8830415001	MAHURKAR™ Acute Dual Lumen Catheter Kit Straight Extensions - 11.5 Fr x 16 cm	8888135133	MAHURKAR™ Acute Dual Lumen Catheter Tray High Flow Pre-Curved Shafts - 13.5 Fr x 13.5 cm
8830415003	MAHURKAR™ Acute Dual Lumen Catheter Kit Curved Extensions - 11.5 Fr x 16 cm	8888135134	MAHURKAR™ Acute Dual Lumen Catheter Tray High Flow Straight Extensions 13.5 Fr x 13.5 cm (IC tray)
8830416001	MAHURKAR™ Acute Dual Lumen Catheter Tray Straight Extensions w/ IC* Components - 11.5 Fr x 16 cm	8888135135	MAHURKAR™ Acute Dual Lumen Catheter Tray High Flow Curved Extensions with IC* Components - 13.5 Fr x 13.5 cm
8830416003	MAHURKAR™ Acute Dual Lumen Catheter Tray Curved Extensions with IC* Components - 11.5 Fr x 16 cm	8888135136	MAHURKAR™ Acute Dual Lumen Catheter Tray High Flow Pre-curved with IC* Components - 13.5 Fr x 13.5 cm

Appendix A: Impacted Product Codes (continued)

Item Code	Description	Item Code	Description
8888135137	MAHURKAR™ Acute Dual Lumen Catheter Tray High Flow Straight Extensions with IC* Components -13.5Fr x 13.5cm(PASS)	8888340637	MAHURKAR™ Acute Triple Lumen Catheter Kit Straight Extensions - 12 Fr x 24 cm
8888135138	MAHURKAR™ Acute Dual Lumen Catheter Tray High Flow Curved Extensions with IC* Components - 13.5 Fr x 13.5 cm	8888345504	MAHURKAR™ Acute Triple Lumen Catheter with Curved Extensions-12FR x 13cm
8888135139	MAHURKAR™ Acute Dual Lumen Catheter Kit High Flow Pre-Curved with IC* Safety Components -13.5 X 13.5CM (PASS Tray)	8888345512	MAHURKAR™ Acute Triple Lumen Catheter with Curved Extensions-12 Fr x 16 cm
8888135140	MAHURKAR™ Acute Dual Lumen Catheter Kit High Flow Pre-Curved with IC* Safety Components -13.5X16CM (PASS Tray)	8888345520	MAHURKAR™ Acute Triple Lumen Catheter with Curved Extensions- 12 FR x 20 cm
8888135141	MAHURKAR™ Acute Dual Lumen Catheter Kit High Flow Pre-Curved with IC* Safety Components -13.5 X 19CM (PASS Tray)	8888345538	MAHURKAR™ Acute Triple Lumen Catheter with Curved Extensions- 12 Fr x 24 cm
8888135142	MAHURKAR™ Acute Dual Lumen Catheter Kit High Flow Pre-Curved with IC* Safety Components 13.5 X 24CM (PASS Tray)	8888345603	MAHURKAR™ Acute Triple Lumen Catheter Kit Curved Extensions - 12 Fr x 13 cm
8888135161	MAHURKAR™ Acute Dual Lumen Catheter Kit High Flow Straight Extensions -13.5 Fr x 16 cm	8888345611	MAHURKAR™ Acute Triple Lumen Catheter Kit Curved Extensions - 12 Fr x 16 cm
8888135162	MAHURKAR™ Acute Dual Lumen Catheter Kit High Flow Curved Extensions - 13.5 Fr x 16 cm	8888345629	MAHURKAR™ Acute Triple Lumen Catheter Kit Curved Extensions - 12 Fr x 20 cm
8888135163	MAHURKAR™ Acute Dual Lumen Catheter Kit High Flow Pre-Curved - 13.5 Fr x 16 cm	8888345637	MAHURKAR™ Acute Triple Lumen Catheter Kit Curved Extensions - 12 Fr x 24 cm
8888135164	MAHURKAR™ Acute Dual Lumen Catheter Tray High Flow Straight Extensions with IC* Components-13.5 Fr x 16 cm(IC Tray)	8888101001HP	MAHURKAR™ Acute High Pressure Triple Lumen Catheter Tray Curved Extensions with IC* Safety Components -12 Fr x 13 cm (IC
8888135165	MAHURKAR™ Acute Dual Lumen Catheter Tray High Flow Curved Extensions with IC* Components- 13.5 Fr x 16 cm (IC Tray)	8888101002HP	MAHURKAR™ Acute High Pressure Triple Lumen Catheter Tray Curved Extensions with IC* Components - 12 Fr x 16 cm
8888135166	MAHURKAR™ Acute Dual Lumen Catheter Tray High Flow Pre-Curved with IC* Components-13.5 Fr x 16 cm	8888101003HP	MAHURKAR™ Acute High Pressure Triple Lumen Catheter Tray Curved Extensions with IC* Components - 12 Fr x 20 cm
8888135167	MAHURKAR™ Acute Dual Lumen Catheter Tray High Flow Straight Extensions with IC* Components- 13.5 Fr x 16 cm(PASS	8888101004HP	MAHURKAR™ Acute High Pressure Triple Lumen Catheter Tray Curved Extensions with IC* Components - 12 Fr x 24 cm
8888135168	MAHURKAR™ Acute Dual Lumen Catheter Tray High Flow Curved Extensions with IC* Components-13.5Fr x 16cm (PASS Tray)	8888102003HP	MAHURKAR™ Acute High Pressure Triple Lumen Catheter Tray Straight Extensions with IC* Components - 12 Fr x 20 cm
8888135191	MAHURKAR™ Acute Dual Lumen Catheter Kit High Flow Straight Extensions - 13.5 Fr x 19.5 cm	8888102004HP	MAHURKAR™ Acute High Pressure Triple Lumen Catheter Tray Straight Extensions with IC* Components - 12 Fr x 24 cm
8888135192	MAHURKAR™ Acute Dual Lumen Catheter Kit High Flow Curved Extensions -13.5 Fr x 19.5 cm	8888103001HP	MAHURKAR™ Acute High Pressure Triple Lumen Catheter Tray Curved Extensions with IC* Safety Components -12 Fr x 13 cm
8888135193	MAHURKAR™ Acute Dual Lumen Catheter Kit High Flow Pre-Curved- 13.5 Fr x 19.5 cm	8888103002HP	MAHURKAR™ Acute High Pressure Triple Lumen Catheter Tray Curved Extensions with IC* Safety Components - 12 Fr x 16 cm
8888135194	MAHURKAR™ Acute Dual Lumen Catheter Tray High Flow Straight Extensions with IC* Components-13.5Fr x 19.5cm(IC Tray)	8888103003HP	MAHURKAR™ Acute High Pressure Triple Lumen Catheter Tray Curved Extensions with IC* Safety Components - 12 Fr x 20 cm
8888135195	MAHURKAR™ Acute Dual Lumen Catheter Tray High Flow Curved Extensions with IC* Components- 13.5 Fr x 19.5 cm	8888103004HP	MAHURKAR™ Acute High Pressure Triple Lumen Catheter Tray Curved Extensions with IC* Safety Components - 12 Fr x 24 cm
8888135196	MAHURKAR™ Acute Dual Lumen Catheter Tray High Flow Pre-Curved with IC* Components - 13.5 Fr x 19.5 cm	8888104003HP	MAHURKAR™ Acute High Pressure Triple Lumen Catheter Tray Straight Extensions with IC* Safety Components - 12 Fr x 20 cm
8888135197	MAHURKAR™ Acute Dual Lumen Catheter Tray High Flow Straight Extensions with IC* Components - 13.5 Fr x 19.5 cm	8888104004HP	MAHURKAR™ Acute High Pressure Triple Lumen Catheter Tray Straight Extensions with IC* Safety Components 12 Fr x 24 cm
8888135198	MAHURKAR™ Acute Dual Lumen Catheter Tray High Flow Curved Extensions - 13.5 Fr x 19.5 cm	8888340629HP	MAHURKAR™ Acute High Pressure Triple Lumen Catheter Kit Straight Extensions - 12 Fr x 20 cm
8888135241	MAHURKAR™ Acute Dual Lumen Catheter Kit High Flow Straight Extensions- 13.5 Fr x 24 cm	8888340637HP	MAHURKAR™ Acute High Pressure Triple Lumen Catheter Kit Straight Extensions - 12 Fr x 24 cm
8888135242	MAHURKAR™ Acute Dual Lumen Catheter Kit Tray High Flow Curved Extensions -13.5 Fr x 24 cm	8888345504HP	MAHURKAR™ Acute High Pressure Triple Lumen Catheter Curved Extensions - 12 Fr x 13 cm
8888135243	MAHURKAR™ Acute Dual Lumen Catheter Kit High Flow Pre-Curved -13.5 Fr x 24	8888345512HP	MAHURKAR™ Acute High Pressure Triple Lumen Catheter Curved Extensions - 12 Fr x 16 cm
8888135244	MAHURKAR™ Acute Dual Lumen Catheter Tray High Flow Straight Extensions with IC* Components-13.5 Fr x 24 cm (IC Tray)	8888345520HP	MAHURKAR™ Acute High Pressure Triple Lumen Catheter Curved Extensions - 12 Fr x 20 cm
8888135245	MAHURKAR™ Acute Dual Lumen Catheter Tray High Flow Curved Extensions with IC* Components -13.5 Fr x 24 cm (IC Tray)	8888345538HP	MAHURKAR™ Acute High Pressure Triple Lumen Catheter Curved Extensions - 12 Fr x 24 cm
8888135246	MAHURKAR™ Acute Dual Lumen Catheter Tray High Flow Pre-Curved with IC* Components-13.5 Fr x 24 cm	8888345603HP	MAHURKAR™ Acute High Pressure Triple Lumen Catheter Kit Curved Extensions - 12 Fr x 13 cm
8888135247	MAHURKAR™ Acute Dual Lumen Catheter Tray High Flow Straight Extensions with IC* Components-13.5 Fr x 24 cm (PASS	8888345611HP	MAHURKAR™ Acute High Pressure Triple Lumen Catheter Kit Curved Extensions - 12 Fr x 16 cm
8888135248	MAHURKAR™ Acute Dual Lumen Catheter Tray High Flow Curved Extensions with IC* Components-13.5Fr x 24cm(PASS Tray)	8888345629HP	MAHURKAR™ Acute High Pressure Triple Lumen Catheter Kit Curved Extensions - 12 Fr x 20 cm
8888340629	MAHURKAR™ Acute Triple Lumen Catheter Kit Straight Extensions - 12 Fr x 20 cm	8888345637HP	MAHURKAR™ Acute High Pressure Triple Lumen Catheter Kit Curved Extensions - 12 Fr x 24 cm