

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.

Sincerely,

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-13.5FrX13.5cm(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-13.5FrX16cm (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-13.5FrX19.5cm(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-13.5FrX24cm(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 |