



**CALIFORNIA DEVICE RECALL INFORMATION SHEET**

**Covidien Recalls Mahurkar Triple Lumen Acute Dialysis Catheter For Occlusion In Tip Of Center Lumen**

Recall Date	Product Description	Recalling Firm	Recall Reason
8/23/2023	<p><b>Mahurkar 12 Fr High Pressure Triple Lumen Acute Dialysis Catheter</b></p> <p>13 cm, Curved Extensions, IC Tray REF:8888101001HP            16 cm, Curved Extensions, IC Tray REF: 8888101002HP            20 cm, Curved Extensions, IC Tray REF: 8888101003HP            24 cm, Curved Extensions, IC Tray REF: 8888101004HP            20 cm, Straight Extensions, IC Tray REF: 8888102003HP            24 cm, Straight Extensions, IC Tray REF: 8888102004HP            13 cm, Curved Extensions, PASS Tray REF: 8888103001HP            20 cm, Curved Extensions, PASS Tray REF: 8888103002HP            24 cm, Curved Extensions, PASS Tray REF: 8888103004HP            20 cm, Straight Extensions, PASS Tray REF: 8888104003HP            24 cm, Straight Extensions, PASS Tray REF: 8888104004HP            20 cm, Straight Extensions, Kit REF: 8888340629HP            24 cm, Straight Extensions, Kit REF: 8888340637HP            16 cm, Curved Extensions REF: 8888345512HP            20 cm, Curved Extensions</p>	<p><b>COVIDIEN LP</b>            Mansfield,            Massachusetts</p>	<p>Catheter center lumen was found to have an occlusion in the tip of the catheter; the source of the occlusion an excessive MDX, a silicone-based lubricant which coats the catheter tip. An occluded, partially or fully, and/or uncured or excessive MDX may dislodge from the catheter lead to 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</p>

	REF: 8888345520HP 13 cm, Curved Extensions, Kit REF: 8888345603HP 16 cm, Curved Extensions, Kit REF: 8888345611HP 20 cm, Curved Extensions, Kit REF: 8888345629HP 24 cm, Curved Extensions, Kit REF: 8888345637HP		
8/23/2023	<b>Mahurkar 12 Fr Triple Lumen Acute Dialysis Catheter</b> 20 cm, Straight Extensions, Kit REF: 8888340629 24 cm, Straight Extensions, Kit REF: 8888340637 13 cm, Curved Extensions, Kit" REF: 8888345603 16 cm, Curved Extensions, Kit" REF: 8888345611 20 cm, Curved Extensions, Kit" REF: 8888345629 24 cm, Curved Extensions, Kit REF: 8888345637	<b>COVIDIEN LP</b> Mansfield, Massachusetts	Catheter tip occlusion

Recall Class	Product Identification	Distribution	Affected Dates
I	<b>Mahurkar 12 Fr High Pressure Triple Lumen Acute Dialysis Catheter</b> GTIN:20884521127897, 20884521127965, 20884521127972, 20884521127989, 20884521127996, 20884521128009, 0884521128010, 20884521128023, 20884521128047, 20884521128054, 20884521128061, 10884521128071, 20884521128078, 10884521128088, 20884521128085, 20884521128108, 20884521128115, 20884521128139, 10884521128149 /	85327 Units Nationwide	Must include first affected date

	20884521128146, 0884521128163/ 20884521128160, 10884521128187 / 20884521128184		
I	<b>Mahurkar 12 Fr Triple Lumen Acute Dialysis Catheter</b> 20884521057019, 20884521057026, 10884521006768/ 20884521006765, 10884521006782 / 20884521006789, 10884521006799, 10884521006829/ 20884521006826	124893 Units Nationwide	Must include first affected date

FOR ADDITIONAL INFORMATION, PLEASE VISIT THE [FDA WEBSITE](#)

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