



Food and Drug Branch – Device Recalls

CALIFORNIA DEVICE RECALL INFORMATION SHEET

Covidien Recalls Mahurkar Series Dialysis Catheters for Leaking Resulting in Unanticipated Fluid Return

Recall Date	Product Description	Recalling Firm	Recall Reason
1/18/2023	MAHURKAR 13.5Fr High Flow Dual Lumen Acute Dialysis Catheter Sterile, Single Use, Rx Only: 13.5cm, Straight Extensions, Kit - Model No. 8888135131-8888135243	Covidien LP Mansfield, Massachusetts	There is a potential leaking condition within the hub of affected devices, due to an inter-lumen void in the hub component, which may result in unanticipated fluid return during use.

Recall Class	Product Identification	Distribution	Affected Dates
I	Model no. 8888135131, UDI-DI (GTIN) 20884521006208, Serial Numbers/Lots 1812900083 - 2113300229 - Model no. 8888135132 UDI-DI (GTIN) 20884521006215 Serial numbers/Lots 1807900113 - 2201800062 - Model No. 8888135133 UDI/DI (GTIN) 20884521006253 Serial Numbers/Lots 1801000105 - 2201800060 - Model No. 8888135134 UDI/DI (GTIN) 20884521006284 Serial Number/Lot 2128000086 - Model no. 8888135161 UDI-DI (GTIN) 20884521006352 Serial Numbers/Lots 1800300109 - 2201800085 - Model No. 8888135162 UDI/DI (GTIN) 20884521006376 Serial Numbers/Lots 1804500112 -	Nationwide	December 2022 and prior

	<p>2201700095 - Model No. 8888135164 UDI/DI (GTIN) 20884521006406 Serial number/lot 2200400119 - Model No. 8888135191 UDI/DI (GTIN) 20884521006444 Serial numbers/lots 1800300110 - 2203300086 - Model No. 8888135192 UDI/DI (GTIN) 20884521006475 Serial numbers/lots 1810200112 - 2201800076 - Model no. 8888135193 UDI/DI (GTIN) 20884521006499 Serial numbers/lots 1810000111 - 2035000078 - Model No. 8888135194 UDI/DI (GTIN) 20884521006505 Serial numbers/lots 2128000083 - Model No. 8888135198 UDI/DI (GTIN) 10884521057364 Serial numbers/lots 2123000182 - Model No. 8888135241 UDI/DI (GTIN) 20884521006536 Serial Numbers/lots 1812200143 - 2203300075 - Model No. 8888135242 UDI/DI (GTIN) 20884521006543 Serial numbers/lots 1802300089 - 2113300219 - Model No. 8888135243 UDI/DI (GTIN) 20884521006550 Serial numbers/lots 1820500153 1824700198 2106900052</p>		
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FOR ADDITIONAL INFORMATION, PLEASE VISIT THE [FDA WEBSITE](#)

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