



CALIFORNIA DEVICE RECALL INFORMATION SHEET

Edwards Lifesciences Issues Voluntary Worldwide Recall on Fogarty Arterial Embolectomy Catheters Due to an Increase of Confirmed Latex Deterioration

Recall Date	Product Description	Recalling Firm	Recall Reason
11/09/2022	Fogarty Arterial Embolectomy Catheters and Fogarty Arterial Embolectomy Catheter with Stylet 715,620 units Model Numbers: 120602FP 120403FP 120803FP 120404FP 120804FP 120805FP 120806FP 120807FP 120403FSP 120803FSP	Edwards Lifesciences, LLC Irvine, California	Due to an increase of confirmed latex deterioration complaints for arterial embolectomy catheters packaged in pouches.
11/09/2022	Fogarty Biliary Balloon Probes 26,560 units Model Number: 410235FP 410405FP 410236FP	Edwards Lifesciences, LLC Irvine, California	Due to an increase of confirmed latex deterioration complaints for arterial embolectomy catheters packaged in pouches.

Recall Class	Product Identification	Distribution	Affected Dates
II	Fogarty Arterial 120403FP Embolectomy Catheters Model/UDI-DI Code: 120602FP / 00690103205206 Lot # 63325817 to 64354939 Model/UDI-DI Code: 120403FP / 00690103205084 Lot # 63281594 to 64180561 Model/UDI-DI Code: 120803FP / 00690103205091 Lot # 63281615 to 64332512 Model/UDI-DI Code: 120404FP / 00690103205107 Lot # 63316243 to 64457671	Worldwide distribution including California	September 2021 and prior

	<p>Model/UDI-DI Code: 120804FP / 00690103205213 Lot # 63349774 to 64405978 Model/UDI-DI Code: 120805FP / 00690103205220 Lot # 63325740 to 64344580 Model/UDI-DI Code: 120806FP / 00690103205237 Lot # 63357594 to 64320997 Model/UDI-DI Code: 120807FP / 00690103201789 Lot # 63358177 to 64344678 Fogarty Arterial Embolectomy Catheter with Stylet Model/UDI-DI Code: 120403FSP / 00690103205190 Lot # 63281613 to 64220845 Model/UDI-DI Code: 120803FSP / 00690103205244 Lot # 63292306 to 63990056</p>		
II	<p>Fogarty Biliary Balloon Probes Model/UDI-DI Code: 410235FP / 00690103205114 Lot # 63292039 to 64393877 Model/UDI-DI Code: 410405FP / 00690103205138 Lot # 63226302 to 64383520 Model/UDI-DI Code: 410236FP / 00690103205121 Lot # 63292038 to 64383519</p>	Worldwide distribution including California	September 2021 and prior

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