California Device Recall Information Sheet

Food and Drug Branch – Device Recalls

Integra LifeSciences Recalls MicroMyst Applicators

Recall Date	Product Description	Recalling Firm	Recall Reason
06/25/2025	MicroMyst Applicator, Box of 5. Consisting of a multilumen applicator and filtered line for use with the Integra Flow Source for the controlled application of two liquids.	Integra LifeSciences	Integra LifeSciences is recalling MicroMyst Applicators due to incomplete bioburden assessments and incomplete sterilization location transfer documentation, both of which help ensure the products were effectively sterilized. The use of affected product may cause serious adverse health consequences, including inflammation, infection, and death. Integra LifeSciences has not reported any serious injuries or deaths associated with this issue.

Recall Class	Product Identification	Distribution	Affected Dates
I	Model/Catalog Number: 205000DS; UDI No. 10381780000112; All lots.	Worldwide Dist., US Nationwide and countries Taiwan (Province China), Viet Nam, Brazil, Trinidad	May 2025 and prior.

		Tobago, El Salvador, South Korea, Peru, Canada, Australia, New Zealand, Belgium, France, Germany, Ireland, Israel, Italy, Kenya, Slovenia, South Africa, Spain, Sweden, Switzerland and United Kingdom.	

For additional information, please visit the FDA Website.

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