State of California—Health and Human Services Agency

California Department of Public Health

Food and Drug Branch – Device Recalls

CALIFORNIA DEVICE RECALL INFORMATION SHEET

Galt Medical Corporation Tearaway Introducer Kit for Cracks or Dislodging of Luer Connection

Recall Date	Product Description	Recalling Firm	Recall Reason
6/21/2023	**Tearaway Introducer Kit** REF: KIT-010-12, KIT-010-17, KIT-900-16	**Galt Medical Corporation** Garland, TX	Sheath introducer assemblies could potentially, due to improper storage conditions, have a luer connection portion of the dilator hub that cracks or dislodges during use, which renders the dilator component unusable, and can require the use of a replacement device.

Recall Class	Product Identification	Distribution	Affected Dates
II	**Tearaway Introducer Kit** REF/UDI-DI/LOT (Expiration): KIT-010-12/00841268105195/S23104607(2/05/2027), S22356870(1/11/2027); KIT-010-17/00841268105249/S23083725(2/05/2027), S22231321(9/08/2026), S22328872(1/18/2027); KIT-900-16/S22308637(1/04/2027)	5 Units in California	Must include first affected date

FOR ADDITIONAL INFORMATION, PLEASE VISIT THE FDA WEBSITE

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