California Device Recall Information Sheet

Food and Drug Branch – Device Recalls

Channel Medsystems, Inc. Cerene Cryotherapy Device Thermal Ablation, Endometrial

Recall Date	Product Description	Recalling Firm	Recall Reason
04/16/2025	Brand Name: Cerene Cryotherapy Device Product Name: Device, Thermal Ablation, Endometrial Model/Catalog Number: FGS-7000 Product Description: The Cerene Cryotherapy Device is an endometrial ablation device that uses nitrous oxide (N2O) to freeze and ablate the endometrium to reduce future menstrual bleeding. The device is intended for use by healthcare professionals who have received appropriate training and are familiar with the principles, clinical applications, complications, side effects, and hazards commonly associated with endometrial ablation. The Cerene Device is single use, disposable, and provided sterile. The average procedure time is 7 minutes, with 2.5 minutes of active cryoablation. Ablation is achieved throughout the uterine cavity through the	Channel Medsystems, Inc.	Due to evaporator gasket not sealing which can cause liquid nitrous oxide to drip/leak from the bottom of the device handle during treatment or after treatment during venting of the device

	use of cryothermic energy. The cryothermic energy is provided by a liquid-to-gas phase change of N2O. During the 2.5-minute treatment cycle, liquid N2O (originating from a small Cylinder located in the device handle) flows through a delivery line and into an inflow line with multiple jets. This liquid N2O is infused into an ultra-thin polyurethane Liner, where it converts into gas. The gaseous N2O is exhausted through the Exhaust Hose exiting the bottom of the handle. Component: N/A		

Recall Class	Product Identification	Distribution	Affected Dates
II	Model No: FGS-7000 UDI-DI: 00850008595035 Lot Numbers: 108638953, 108645585, 108645586, 108645587, 108866674, 108866675, 109493291, 109493292 and 109895874	46 units in California	March and prior

For additional information, please visit the FDA Website.