State of California—Health and Human Services Agency

California Department of Public Health

Food and Drug Branch – Device Recalls

CALIFORNIA DEVICE RECALL INFORMATION SHEET

Teleflex Recalls Iso-Gard Filter S for Risk of Splitting or Detaching That May Cause Leakage and Insufficient Air Supply to Patients

Recall Date	Product Description	Recalling Firm	Recall Reason
10/14/2022	**Iso-Gard Filter S** Ref: 19212; Microbial medical gas filter, single-use. Bacterial/viral filters for use in breathing system for the protection of patient and equipment.	**TELEFLEX LLC** Morrisville, North Carolina	Incidents of device splitting or detaching during use.

Recall Class	Product Identification	Distribution	Affected Dates
I	19212, UDI: (01)04026704388325(17)251228 (10)KMZ20H0705 - (01)04026704348008(17)270228 (10)KMZ22C0817	Nationwide	August 2022 – October 2022

FOR ADDITIONAL INFORMATION, PLEASE VISIT THE FDA WEBSITE

CDPH Food and Drug Branch
MS 7602 ● P.O. Box 997435 ● Sacramento, CA 95899-7435
(916) 650-6500 ● (916) 650-6650 FAX
Internet Address: www.cdph.ca.gov