State of California—Health and Human Services Agency

California Department of Public Health

Food and Drug Branch – Device Recalls

CALIFORNIA DEVICE RECALL INFORMATION SHEET

GORE recalls Cardioform Septal Occluders due to Incorrect Expiration Date

Recall Date	Product Description	Recalling Firm	Recall Reason
11/3/2021	**GORE CARDIOFORM SEPTAL OCCLUDER 30 mm Diameter** REF/Cat no GSX0030A, Catheter Working Length 75 cm, Delivery Profile 10 Fr, STERILE EO, Rx Only, UDI: 00733132631032	**W L Gore & Associates, Inc.** Flagstaff, Arizona	Product is labeled with a 3 yr. expiration date instead of 2 yrs.
11/3/2021	**GORE CARDIOFORM SEPTAL OCCLUDER 20 mm Diameter** REF/Cat no GSX0020A, Catheter Working Length 75 cm, Delivery Profile 10 Fr, STERILE EO, Rx Only, UDI: 00733132631018	**W L Gore & Associates, Inc.** Flagstaff, Arizona	Product is labeled with a 3 yr. expiration date instead of 2 yrs.
11/3/2021	**GORE CARDIOFORM SEPTAL OCCLUDER 25 mm Diameter** REF/Cat no GSX0025A, Catheter Working Length 75 cm, Delivery Profile 10 Fr, STERILE EO, Rx Only, UDI: 00733132631025	**W L Gore & Associates, Inc.** Flagstaff, Arizona	Product is labeled with a 3 yr. expiration date instead of 2 yrs.

Recall Class	Product Identification	Distribution	Affected Dates
II	**GORE CARDIOFORM SEPTAL OCCLUDER 30 mm Diameter** Serial # 22689696-23569078	165 Devices in California	September 2021 and prior
II	**GORE CARDIOFORM SEPTAL OCCLUDER 20 mm Diameter** Serial # 22689696-23569078	10 Devices in California	September 2021 and prior

II	**GORE CARDIOFORM SEPTAL OCCLUDER 25 mm Diameter** Serial # 22689696-23569078	108 Devices in California	September 2021 and prior

FOR ADDITIONAL INFORMATION, PLEASE VISIT THE FDA WEBSITE

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