State of California—Health and Human Services Agency

California Department of Public Health

Food and Drug Branch – Device Recalls

CALIFORNIA DEVICE RECALL INFORMATION SHEET

Alcon Research Recalls Custom Pak Surgical Procedure Pack for Drape Adhesive Liner Removal Difficulty and Skin Injury

Recall Date	Product Description	Recalling Firm	Recall Reason
12/07/2022	**Alcon Custom Pak Surgical Procedure Pack**	**Alcon Research, LLC** Houston, Texas	Due to difficulty removing the liner on the adhesive components of the affected drapes and as a result may render the product unusable. In addition, the manufacturer of the drapes has observed an increase in reported adhesive related skin injuries for these affected lots.

Recall Class	Product Identification	Distribution	Affected Dates
II	UDI Codes for: UDI for Latex Free Custom Pak: H5301ALCON1CPAK10B UDI for Latex Free Custom Pak: H5302ALCON2CPAK20E Custom Pak # / Lot #: Custom Pak # Lot # 100007214 14ACYR - 100104358 JZ5123496	34,437 Packs in California	October 2022 and prior

FOR ADDITIONAL INFORMATION, PLEASE VISIT THE FDA WEBSITE

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