



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 Packs for Sterility Issues

Recall Date	Product Description	Recalling Firm	Recall Reason
4/05/2023	Alcon Custom Pak Surgical Procedure Pack 1035 packs	Alcon Research, LLC Houston, Texas	Sterile surgical procedure packs contain incomplete seals

Recall Class	Product Identification	Distribution	Affected Dates
II	Lot #-Pack #-Expiry Date - UDI: 158JNA 17533-04 9/30/2024 00380655132814; 158L18 18704-03 12/31/2024 00380651672833; 158JNN 18382-03 10/31/2024 00380655117132; 158L27 8685-21 09/30/2024 00380655142486; 158L24 19451-02 09/30/2024 00380655143995; 158L44 19136-03 12/31/2024 00380655129975; 158HU3 18401-03 04/30/2024 00380651651487; 158MH8 16032-05 12/31/2024 00380653369250; 158L5X 17570-05 10/31/2024 00380655129227; 158NEX 19002-02 10/31/2024 00380655120231; 158MJ3 10560-14 12/31/2024 00380655136317; 158NE8 16877-11 12/31/2024 00380655116579; 158NDK 19061-02 08/31/2024 00380655118504; 158NEM 18911-02 04/30/2024 00380651691940; 158PCP	424 Paks distributed in California	March 2023 and prior

	17469-02 08/31/2024 00380653377156; 158PCD 18917-01 09/30/2024 00380651677333; 158P8K 17115-06 07/31/2024 00380651698079; 158NDC 17780-04 12/31/2024 00380651682719; 158N9Y 2452-58 12/31/2024 00380653403589; 158MFC 19096-01 10/31/2024 00380651696235; 158MHL 18023-04 10/31/2024 00380651661189; 158P7W 17039-13 08/31/2024 00380651701229; 158P97 5300-61 10/31/2024 00380651672659;		
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FOR ADDITIONAL INFORMATION, PLEASE VISIT THE [FDA WEBSITE](#)

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