State of California—Health and Human Services Agency

California Department of Public Health

Food and Drug Branch – Device Recalls

California Device Recall Information Sheet

Johnson & Johnson Surgical Vision Inc. Recalls VISION reusable LAMINAR high flow irrigation sleeve and test chamber due to manufacturing variation of the irrigation sleeves

Recall Date	Product Description	Recalling Firm	Recall Reason
5/8/2024	**VISION Reusable LAMINAR High Flow Irrigation Sleeve and Test Chamber** The irrigation sleeve is a device intended to direct irrigation solution across the shaft of a phacoemulsification tip, allowing the solution to enter the eye during ocular surgery.	**JOHNSON & JOHNSON SURGICAL VISION, INC.** Irvine, California	This device is being recalled due to manufacturing variation of the irrigation sleeves which could result in a missing port hole. This non-conformity could lead to insufficient flow to cool the ultrasonic phaco tip, potentially leading to an unstable anterior chamber which could cause possible harms.

Recall Class	Product Identification	Distribution	Affected Dates
II	**VISION Reusable LAMINAR High Flow Irrigation Sleeve And Test Chamber** Part Number: OPOHF21L UDI-DI/GTIN code: 05050474573376 Lot Numbers: 60477723 60479361 60505085 60508179 60508923	376 Units in California California	May, 2024 and prior

For additional information, please visit the FDA website

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