State of California—Health and Human Services Agency

California Department of Public Health

Food and Drug Branch – Device Recalls

CALIFORNIA DEVICE RECALL INFORMATION SHEET

Olympus Recalls Pneumoliner Devices due to Manufacturing Error

Recall Date	Product Description	Recalling Firm	Recall Reason
10/26/2021	**ASC PneumoLiner device** Part No. WA90500US (US market only) The Pneumoliner device is intended for use as a multiple instrument port and tissue containment system during minimally invasive gynecologic laparoscopic surgery to enable the isolation and containment of tissue, considered benign, resected during single-port or multi- site laparoscopic surgery during power morcellation and removal.	**Olympus Corporation of the Americas** Center Valley, Pennsylvania	Due to manufacturing error, the Pneumoliner Bag Distal Tab that exits the Introducer shaft is in the wrong orientation. This results in the user deploying the bag upside down, which will make tissue encapsulation and bag closure more difficult, introducing the risk of trapping the small bowel/viscera in the bag at closure resulting in patient injury.

Recall Class	Product Identification	Distribution	Affected Dates
II	**ASC Pneumoliner Device** Lots 647572 and 667060	350 pieces/ 70 boxes nationwide including California	September 2021 and prior

FOR ADDITIONAL INFORMATION, PLEASE VISIT THE FDA WEBSITE

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