



Food and Drug Branch – Device Recalls

CALIFORNIA DEVICE RECALL INFORMATION SHEET

Mallinckrodt Manufacturing LLC Recalls Mallinckrodt One-Way Valve For Reduce Flow Of Ventilated Air Or Oxygen

Recall Date	Product Description	Recalling Firm	Recall Reason
9/20/2023	Mallinckrodt Manufacturing Mallinckrodt One-Way Valve, 22F x 22M, a) Part #91346 (1 piece) and b) Part #50412 (pack of 5) Used with ventilators.	Mallinckrodt Manufacturing Madison, Wisconsin	The One-Way Valve, 22F x 22M may stick and prevent or reduce the flow of ventilated air or oxygen.

Recall Class	Product Identification	Distribution	Affected Dates
I	Mallinckrodt One-Way Valve A) UDI/DI 10810055283460, Lot Codes: 74L2001714, 74L2001715, 74L2001716, 74M2001125, 74B2100237; b) UDI/DI 10810055283467, Lot Codes: 74L2001714, 74L2001715, 74L2001716, 74M2001125, 74B2100237	13,602 Units Nationwide	August 2023 and prior

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