California Device Recall Information Sheet

Food and Drug Branch – Device Recalls

Stryker Corporation Nasopore, Otopore Cylinder, and Hemopore Dressings

Recall Date	Product Description	Recalling Firm	Recall Reason
03/28/2025	Otopore Cylinder Standard outer ear dressings Catalog Numbers: 5400-010-000 and 5400-010-000ITL Nasopore Standard 4cm fragmentable nasal dressing Catalog Numbers: 5400-010-004, 5400-010-004ITL Nasopore Standard 8cm fragmentable nasal dressing Catalog Numbers: 5400-010-008, 5400-010-008ITL Otopore Cylinder outer ear wound dressing Firm Catalog Number: 5400-020-000 Forte Catalog Number: 5400-020-000TL Nasopore 8cm fragmentable nasal dressing Firm Catalog Number: 5400-020-008 Forte Catalog Number: 5400-020-008ITL Nasopore 4cm fragmentable nasal dressing Firm Catalog Number:	Stryker Corporation	There is a potential for blister seals on the product to present a bubble on the seal area of the packaging. This seal acts as a sterile barrier and, in this event, indicates that the sterility seal has been breached.

	5400-020-004 Forte Catalog Number: 5400-020-004ITL Otopore Square outer ear wound dressing Firm Catalog Number: 5400-020-100 Forte Catalog Number: 5400-020-100ITL Nasopore FD fragmentable nasal dressing Catalog Numbers 5400-020-108, 5400-020-108ITL Hemopore 8cm nasal/sinus temporary wound dressing Catalog Numbers: 5400-020-208, 5400-020-208ITL (OUS) Nasopore Ex Firm 8cm fragmentable nasal dressing Catalog Number: 5400-030-008 Nasopore Forte plus 8cm Catalog Number: 5400-030-008ITL Nasopore 4cm Standard 2PK fragmentable nasal dressing Catalog Number: 5400-212-004S Nasopore 4cm Firm 2PK Catalog Number: 5400-222-004S Nasopore 4cm Standard 2PK fragmentable nasal dressing Catalog Number: 5400-212-004S Nasopore 4cm Firm 2PK Catalog Number: 5400-222-004S		

	Hemopore 2PK nasal/sinus temporary wound dressing Catalog Number: 5400-222-208S		

Recall Class	Product Identification	Distribution	Affected Dates
II	5400-010-000 UDI-DI: 07613327301663 Lot Numbers: 2023011112 - 2024032615 5400-010-000ITL UDI-DI: 07613327359510 Lot Numbers: 2023022132 - 2024032013 5400-010-004 UDI-DI: 07613154340798 Lot Numbers: 2022101814 - 2024082216 5400-010-004ITL UDI-DI: 07613327359435 Lot Numbers: 2022111414 - 2024082216 5400-010-008I UDI-DI: 07613154340804 Lot Numbers: 2022100514 - 2024082014 5400-010-008ITL UDI-DI: 07613327359503 Lot Numbers: 2022092712 - 2023050415 5400-020-000 UDI-DI: 07613327301670 Lot Numbers: 2022101214 - 2024050814	2,048 units in California	February and prior

	5400-020-000ITL UDI-DI: 07613327359466 Lot Numbers: 2022101912 - 2024091034 5400-020-008 UDI-DI: 07613154340828 Lot Numbers: 2022101214 - 2024050814 5400-020-008ITL UDI-DI: 07613327359428 Lot Numbers: 2022101912 - 2024091034 5400-020-004 UDI-DI: 07613154340811 Lot Numbers: 2022100314 - 2024073012 5400-020-004ITL UDI-DI: 07613327359459 Lot Numbers: 2022102012 - 2024061114 5400-020-100 UDI-DI: 07613327301656 Lot Numbers: 2022101016 - 2024022114 5400-020-100ITL UDI-DI: 07613327359497 Lot Numbers: 2023021715 - 2024081415 5400-020-108 UDI-DI: 07613327117226 Lot Numbers: 2023011317 - 2024080717 5400-020-108ITL UDI-DI: 07613327117226 Lot Numbers: 2023012017 - 2024011217		

	5400-020-208 UDI-DI: 07613327117233 Lot Numbers: 2022093020 - 2024052332 5400-030-008 UDI-DI: 07613154340842 Lot Numbers: 2023012515 - 2024040212 5400-030-008ITL UDI-DI: 07613327359473 Lot Numbers: 2022092714 - 2024062814 5400-212-004S UDI-DI: 07613154340842 Lot Numbers: 2024011914 5400-222-004S UDI-DI: 07613327359473 Lot Numbers: 2024021212, 2024052813 5400-222-208S UDI-DI: 07613327500486 Lot Numbers: 2024020221 - 2024082321		

For additional information, please visit: FDA Website (1), FDA Website (2), FDA Website (3), FDA Website (4), FDA Website (5), FDA Website (6), FDA Website (7), FDA Website (8), FDA Website (9), FDA Website (10), FDA Website (11), FDA Website (12), FDA Website (13), and FDA Website (14).