

December 10, 2024

IMPORTANT DRUG INFORMATION

Subject: Primary Air Volume (Headspace) Below Specification Limit in Certain Lots and Impact on Container Fluid Level Monitoring of B. Braun Medical Inc.'s FDA-Approved 0.9% Sodium Chloride Injection, USP in the EXCEL® Plus container, 1000 mL and 500 mL.

Dear Healthcare Provider:

The purpose of this letter is to inform you of important information for certain lots of 0.9% Sodium Chloride Injection, USP in the EXCEL® Plus container, 1000 mL and 500 mL. To address the current drug shortage, B. Braun Medical Inc. has coordinated with the U.S. Food and Drug Administration (FDA) to release the twelve lots listed below with primary air volume (headspace) below specification limit which could impact container fluid level monitoring during use. Specifically, the following lots are impacted:

Product Code	NDC	Description	Lot Number	Expiration Date
Q8000	0264-5802-00	0.9% Sodium Chloride USP in the EXCEL® Plus container, 1000 mL	0061903616	2/28/2026
Q8001	0264-5802-10	0.9% Sodium Chloride USP in the EXCEL® Plus container, 500 mL	0061913818	4/30/2026
Q8001	0264-5802-10	0.9% Sodium Chloride USP in the EXCEL® Plus container, 500 mL	0061913823	4/30/2026
Q8001	0264-5802-10	0.9% Sodium Chloride USP in the EXCEL® Plus container, 500 mL	0061913825	4/30/2026
Q8001	0264-5802-10	0.9% Sodium Chloride USP in the EXCEL® Plus container, 500 mL	0061913826	4/30/2026
Q8001	0264-5802-10	0.9% Sodium Chloride USP in the EXCEL® Plus container, 500 mL	0061913829	4/30/2026
Q8001	0264-5802-10	0.9% Sodium Chloride USP in the EXCEL® Plus container, 500 mL	0061913832	4/30/2026
Q8001	0264-5802-10	0.9% Sodium Chloride USP in the EXCEL® Plus container, 500 mL	0061917427	5/31/2026
Q8001	0264-5802-10	0.9% Sodium Chloride USP in the EXCEL® Plus container, 500 mL	0061917428	5/31/2026
Q8001	0264-5802-10	0.9% Sodium Chloride USP in the EXCEL® Plus container, 500 mL	0061918912	4/30/2026
Q8001	0264-5802-10	0.9% Sodium Chloride USP in the EXCEL® Plus container, 500 mL	0061929714	8/31/2026
Q8001	0264-5802-10	0.9% Sodium Chloride USP in the EXCEL® Plus container, 500 mL	0061929744	8/31/2026

Description of the primary air volume (headspace) testing failure:

When EXCEL Plus products are manufactured, a small amount of air is injected into each bag when it is filled with solution to ensure that the solution flows out of each bag evenly and completely during use. This is referred to as the primary air volume, or 'headspace' of the bag. The twelve lots identified within this notice fell below the lower specification limit of 30 cubic centimeters (cc) when tested as finished goods. All twelve of these lots, however, were within the specification when tested in-process.



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When measuring the volume of solution remaining in the bag using the label's graduation marks, there may be a measurement error as great as 30% at nominal headspace volumes; therefore, the label's graduations marks should not be used for dosage determinations. Note that this is typical for products that are within specification and is not unique to these specific batches.

Risks Associated with Use of the Impacted Product

A small amount of primary air volume (headspace) is necessary to ensure that the solution flows out of each bag evenly and completely during use.

Recommended Actions:

While no significant impact to flow rate or delivered volume is expected, if you experience inadequate flow rate or insufficient delivered volume, report a customer complaint to B. Braun by following the instructions below.

Reporting Adverse Events

Health care providers and patients are encouraged to report adverse events in patients receiving 0.9% Sodium Chloride USP in the EXCEL® Plus container, 1000 mL and 500 mL to B. Braun at 1-833-425-1464.

Additionally, adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report Online: www.fda.gov/medwatch/report.htm
- Regular Mail or Fax: Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178 (1-800-332-0178).

You may also contact our Medical Affairs Department at 1-800-854-6851 if you have any questions about the information contained in this letter for the safe and effective use of 0.9% Sodium Chloride USP in the EXCEL® Plus container, 1000 mL and 500 mL.

Sincerely,

Electronically signed by: Jonathan Severino
Reason: For the reason(s) specified in the document.
Date: Dec 10, 2024 14:09 EST

Jonathan Severino
Director, Postmarket Surveillance
B. Braun Medical Inc.

Enclosure: 0.9% Sodium Chloride USP in the EXCEL® Plus container, 1000 mL and 500 mL Full Prescribing Information