

November 22, 2024

Subject: Temporary importation of 0.9% Sodium Chloride Injection from South Korea to address drug shortages

Dear Healthcare Professional,

To prevent a shortage of large volume parenteral fluid drug products, Supply Line International Medical (SLI Medical) is coordinating with the U.S. Food and Drug Administration (FDA) to temporarily import 0.9% Sodium Chloride Injection (1,000 mL) from Inno.N’s manufacturing facility in South Korea. FDA has not approved these products manufactured by Inno.N’s South Korea facility.

At this time, no other entity except SLI Medical is authorized by the FDA to import or to distribute this Inno.N product in the United States.

You may be provided with additional letters for other imported products you receive. Please read each letter in its entirety because each letter may contain different product-specific information.

Effective immediately, and during this temporary period, Supply Line International Medical LLC will offer the following imported product from Inno.N’s facility in South Korea:

Product Overview:

Product name and description	Size	Product code	Bags per carton	NDC code of a single bag
0.9% Sodium Chloride Injection	1,000ml	171440	10	84988-1440-01

Approved Lots

Lot Number	Manufacturing date	Expiry date
NS624K4	2024.09.25	2026.03.24
NS624K5	2024.10.02	2026.04.01
NS624H8	2024.08.13	2026.02.12
NS624H9	2024.08.13	2026.02.12
NS624J0	2024.08.21	2026.02.20
NS624J1	2024.08.22	2026.02.21
NS624J2	2024.08.22	2026.02.21
NS624J3	2024.08.29	2026.02.28
NS624J4	2024.08.29	2026.02.28

It is important to note the following:

- The imported products have primary container labels written in both Korean and English. The primary container labels contain the active pharmaceutical ingredient, concentration, volume, and product code in English.
- The imported products’ administration port system is fully compatible with sets marketed in the United States.

- The imported products use a carton box that is taped closed. To avoid damage to the solution container, take care not to use sharp instruments to open the carton.
- The imported products do not contain barcodes on the unit label. Alternative procedures should be followed to ensure that the correct drug product is being used in all systems and processes and administered to individual patients. For example, institutions should consider manually inputting the product into their systems and confirm that barcode systems do not provide incorrect information when the product is scanned.
- 0.9% Sodium Chloride Injection is available only by prescription in the United States. However, the imported products do not have the statement “Rx only” on the labeling.
- USE A NEW BAG IF PARTICULATES ARE VISIBLE OR IF THE IV BAG CONTAINS A LEAK.

Additional key differences in the labeling between the FDA-approved product and the imported products are stated in the product comparison table at the end of this letter as follows:

Table 1. Key differences between FDA-approved and imported 0.9% Sodium Chloride Injection USP
 Table 2. Label images of FDA-approved and imported 0.9% Sodium Chloride Injection USP

Please refer to the FDA-approved prescribing information as follows:

- 0.9% Sodium Chloride Injection, USP [CLICK HERE](#)

Reporting Adverse Events or Product Quality Issues

To report **adverse events** associated with these imported products, please call SLI Medical's Customer Service at 1-844-239-4058. Adverse events or quality problems experienced with the use of these imported products may also 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).

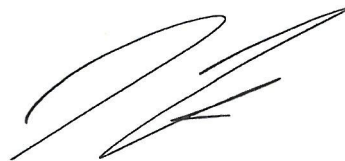
If you have any questions about the information contained in this letter or the use of the imported products, please contact SLI Medical's customer Service at 1-844-239-4058.

To place an order, please contact SLI Medical by calling 1-844-239-4058.

Sincerely,



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Josh Kaplan – SLI Medical LLC
 E-mail: info@SLIMedical.com/844-239-4058

Attachments:

Product Comparison Tables 1 and 2

Product Comparison Table

Table 1. Key differences between FDA-approved and imported 0.9% Sodium Chloride Injection USP

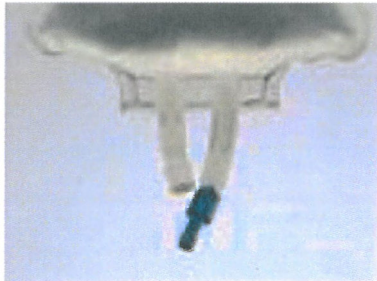
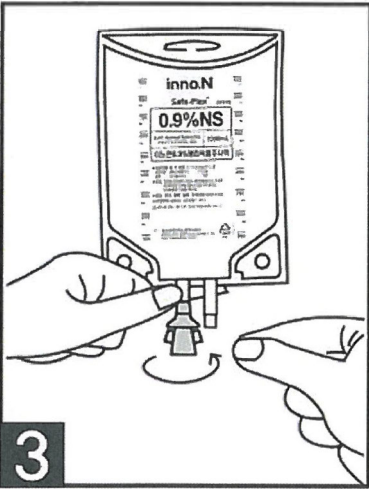

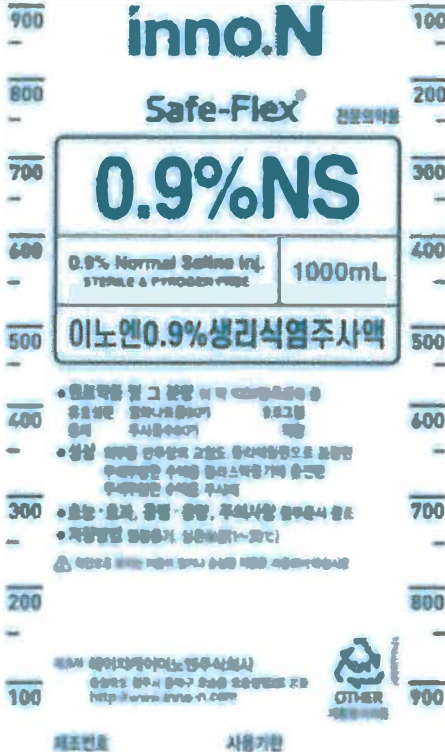
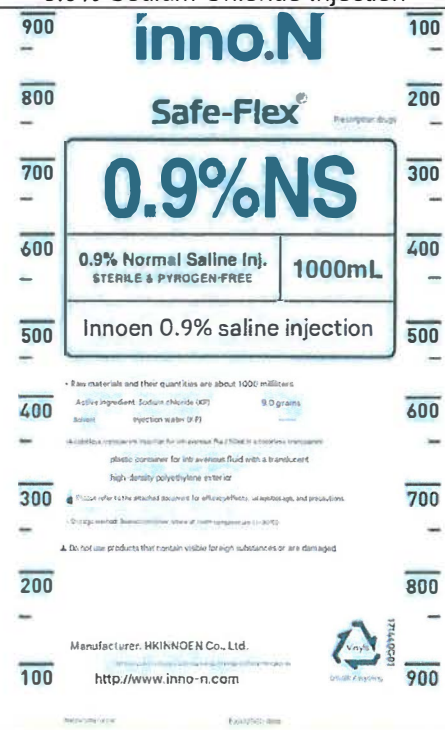
	FDA-approved product	Imported product from South Korea
Product name	0.9% Sodium Chloride Injection USP	0.9% Sodium Chloride Injection
Label volume	1,000 mL	1,000 mL
Language of the Labels	English	Korean/English
Indications	Sodium Chloride Injection, USP is indicated as a source of water and electrolytes. 0.9% Sodium Chloride Injection, USP is also indicated for use as a priming solution in hemodialysis procedures.	Sodium Chloride Injection is indicated as a source of water and electrolytes.
Active ingredients	Each 100 mL contains 900 mg Sodium Chloride, USP	Each 100 mL contains 900 mg Sodium Chloride
Additional information	pH is 5.0 (4.5 to 7.0) Osmolarity 308 mOsm/L (calc)	pH is approximately 5.5 Osmolarity of 308 mOsmol/L (calc)
Storage conditions	Store at room temperature 25°C/77°F.	Store at room temperature 20°C/68°F. to 25°C/77°F.
Container type	VIAFLEX (PVC)	Safe-flex (Non-PVC)
Medication and Administration port closures	Contains medication port and administration port; Pull off port protector (blue color), right side 	Contains medication port and administration port; Twist off shield, left side 

Table 2. Label images of FDA-approved and imported 0.9% Sodium Chloride Injection

FDA-approved product	Imported product from South Korea
0.9% Sodium Chloride Injection USP	0.9% Sodium Chloride Injection
Label Color: Black. Barcode not shown. 1,000 mL shown as representative label.	Label Color: Blue. No Barcode.
<div style="text-align: center;">  </div> <h2 style="text-align: center;">0.9% Sodium Chloride Injection USP</h2> <p style="text-align: center;">1000 mL</p> <p>Each 100 mL contains 900 mg Sodium Chloride USP pH 5.0 (4.5 to 7.0) mEq/L Sodium 154 Chloride 154 Osmolality 308 mOsm/L (CALC) STERILE NONPYROGENIC SINGLE DOSE CONTAINER ADDITIVES MAY BE INCOMPATIBLE CONSULT WITH PHARMACIST IF AVAILABLE WHEN INTRODUCING ADDITIVES USE ASEPTIC TECHNIQUE MIX THOROUGHLY DO NOT STORE DOSEAGE INTRAVENOUSLY AS DIRECTED BY A PHYSICIAN SEE DIRECTIONS CAUTIONS SQUEEZE AND INSPECT SIPPER BAG WHICH MAINTAINS PRODUCT STERILITY DISCARD IF LEAKS ARE FOUND MUST NOT BE USED IN SERIES CONNECTIONS DO NOT USE UNLESS SOLUTION IS CLEAR Rx ONLY STORE UNIT IN MOISTURE BARRIER OVERWRAP AT ROOM TEMPERATURE (25°C/77°F) UNTIL READY TO USE AVOID EXCESSIVE HEAT SEE INSERT</p> <p>VIAFLEX CONTAINER PL 146 PLASTIC BAXTER VIAFLEX AND PL 146 ARE TRADEMARKS OF BAXTER INTERNATIONAL INC FOR PRODUCT INFORMATION 1-800-933-0303</p> <p>Baxter BAXTER HEALTHCARE CORPORATION DEERFIELD IL 60015 USA MADE IN USA</p>	 <p>이노엔 0.9% 생리식염주사액</p> <ul style="list-style-type: none"> • 원료약품 및 그 분량 외 약 성분(보조제) 중 용출성분 염화나트륨(NaCl) 9.0그램 용액 주사용수(0.9%) • 성상 투명한 무색의 고압도 용액(투명)으로 보편적인 투여방법 수액용 용액(투명)을 가해 용액(투명) 투여가능한 수액(투명) 주사액 • 용용·용액, 용액·용액, 주사사용 용액(투명) 용액 • 저장방법 병뚜껑을 닫고 15~25°C <p>제조번호 사용기한</p>
	English-Translated Product Label
	0.9% Sodium Chloride Injection
	 <p>Innoen 0.9% saline injection</p> <ul style="list-style-type: none"> • Raw materials and their quantities are about 1000 milliliters Active ingredient: Sodium chloride (NaCl) 9.0 grams Excipient: Injection water (0.9%) • A sterile, pyrogen-free, clear, colorless, isotonic, plastic container for intravenous fluid with a translucent high-density polyethylene exterior • Please refer to the attached document for efficacy, safety, and production. • Do not use products that contain visible foreign substances or are damaged <p>Manufacturer: HIKINNOEN Co., Ltd. http://www.inno-n.com</p>