

**SODIUM CHLORIDE FOR IRRIGATION- sodium chloride for irrigation solution
B. Braun Medical Inc.**

0.9% Sodium Chloride Irrigation USP

Isotonic Solution for Irrigation.

For Irrigation Only.

Not for Injection.

DESCRIPTION

Each 100 mL contains:

Sodium Chloride USP 0.9 g; Water for Injection USP qs

pH adjusted with Hydrochloric Acid NF

pH: 5.75 (4.50-7.00)

Calculated Osmolarity: 308 mOsmol/liter

Concentration of Electrolytes (mEq/liter): Sodium 154; Chloride 154

0.9% Sodium Chloride Irrigation USP is sterile, nonpyrogenic, isotonic and contains no bacteriostatic or antimicrobial agents.

The formula of the active ingredient is:

Ingredient	Molecular Formula	Molecular Weight
Sodium Chloride USP	NaCl	58.44

The plastic container is made from a multilayered film specifically developed for parenteral drugs. It contains no plasticizers and exhibits virtually no leachables. The solution contact layer is a rubberized copolymer of ethylene and propylene. The container is nontoxic and biologically inert. The container-solution unit is a closed system and is not dependent upon entry of external air during administration. The container is overwrapped to provide protection from the physical environment and to provide an additional moisture barrier when necessary.

Not made with natural rubber latex, PVC or DEHP.

CLINICAL PHARMACOLOGY

0.9% Sodium Chloride Irrigation USP is utilized for a variety of clinical indications such as sterile irrigation of body cavities, tissues or wounds, indwelling urethral catheters, surgical drainage tubes, and for washing, rinsing or soaking surgical dressings, instruments and laboratory specimens. It also serves as a diluent or vehicle for drugs used for irrigation or other pharmaceutical preparations.

0.9% Sodium Chloride Irrigation USP provides an isotonic saline irrigation identical in composition with 0.9% Sodium Chloride Injection USP (normal saline).

Physiological irrigation solutions are considered generally compatible with living tissues and organs.

Sodium, the major cation of the extracellular fluid, functions primarily in the control of water distribution, fluid balance, and osmotic pressure of body fluids. Sodium is also associated with chloride and bicarbonate in the regulation of the acid-base equilibrium of body fluid.

Chloride, the major extracellular anion, closely follows the metabolism of sodium, and changes in the acid-base balance of the body are reflected by changes in the chloride concentration.

INDICATIONS AND USAGE

0.9% Sodium Chloride Irrigation USP is indicated for all general irrigation, washing, rinsing and dilution purposes which permit use of a sterile, nonpyrogenic electrolyte solution.

CONTRAINDICATIONS

0.9% Sodium Chloride Irrigation USP is not for injection by usual parenteral routes.

An electrolyte solution should not be used for irrigation during electrosurgical procedures.

WARNINGS

FOR IRRIGATION ONLY. NOT FOR INJECTION.

Irrigating fluids have been demonstrated to enter the systemic circulation in relatively large volumes; thus, irrigation solutions must be regarded as systemic drugs. Absorption of large amounts can cause fluid and/or solute overload resulting in dilution of serum electrolyte concentrations, overhydration, congested states or pulmonary edema.

The risk of dilutional states is inversely proportional to the electrolyte concentrations of the administered parenteral solutions. The risk of solute overload causing congested states with peripheral and pulmonary edema is directly proportional to the electrolyte concentration.

Do not warm above 150°F (66°C).

After opening container, its contents should be used promptly to minimize the possibility of bacterial growth or pyrogen formation.

Discard unused portion of irrigating solution since it contains no preservatives.

PRECAUTIONS

General

Use aseptic technique when preparing and administering sterile irrigation solutions.

Use only if solution is clear and container and seal are intact.

Do not use for irrigation that may result in absorption of large amounts of fluid into the blood.

Caution should be observed when the solution is used for continuous irrigation or allowed to “dwell” inside body cavities because of possible absorption into the blood stream and the production of circulatory overload.

When used for irrigation via appropriate irrigation equipment, the administration set should be attached promptly. Unused portions should be discarded and a fresh container of appropriate size used for the start up of each cycle or repeat procedure. For repeated irrigations of urethral catheters, a separate container should be used for each patient.

Laboratory Tests

Clinical evaluation and periodic laboratory determinations are necessary to monitor changes in fluid balance, electrolyte concentrations, and acid-base balance after prolonged irrigation, when fluid absorption is suspected, or whenever the condition of the patient warrants such evaluation.

Drug Interactions

Some additives may be incompatible. Consult with pharmacist. When introducing additives, use aseptic technique. Mix thoroughly. Do not store.

Carcinogenesis, Mutagenesis, Impairment of Fertility

Studies with 0.9% Sodium Chloride Irrigation USP have not been performed to evaluate carcinogenic potential, mutagenic potential, or effects on fertility.

Pregnancy

Teratogenic Effects

Animal reproduction studies have not been conducted with 0.9% Sodium Chloride Irrigation USP. It is also not known whether 0.9% Sodium Chloride Irrigation USP can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. 0.9% Sodium Chloride Irrigation USP should be given to a pregnant woman only if clearly needed.

Labor and Delivery

Safety and effectiveness of 0.9% Sodium Chloride Irrigation USP during labor and delivery have not been established. Caution should be exercised, and the fluid balance, glucose and electrolyte concentrations, and acid-base balance, of both mother and fetus should be evaluated periodically or whenever warranted by the condition of the patient or fetus.

Nursing Mothers

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when 0.9% Sodium Chloride Irrigation USP is administered to a nursing woman.

Pediatric Use

The safety and effectiveness of 0.9% Sodium Chloride Irrigation USP in pediatric patients have not been established. Its limited use in pediatric patients has been inadequate to fully define proper dosage and limitations for use.

Geriatric Use

Clinical studies of 0.9% Sodium Chloride Irrigation USP did not include a sufficient number of patients age 65 years and over to determine whether they respond differently from younger subjects. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.

This drug is known to be substantially excreted by the kidney, and the risk of toxic reactions to this drug may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function. Frequent laboratory determinations and clinical evaluations are recommended to monitor changes in blood glucose, electrolyte concentrations, and renal function.

ADVERSE REACTIONS

Possible adverse effects arising from the irrigation of body cavities, tissues, or indwelling catheters and tubes can be minimized when proper procedures are followed. Displaced catheters or drainage tubes can lead to irrigation or infiltration of unintended structures or cavities. Excessive volume or pressure during irrigation of closed cavities may cause undue distension or disruption of tissues. Accidental contamination from careless technique may transmit infection.

If an adverse reaction does occur, discontinue administration of the irrigant, evaluate the patient, institute appropriate therapeutic countermeasures, and save the remainder of the fluid for examination if deemed necessary.

OVERDOSAGE

In the event of overhydration or solute overload, reevaluate the patient's condition, and institute appropriate corrective treatment. Intravascular volume overload may respond to hemodialysis. See **WARNINGS, PRECAUTIONS,** and **ADVERSE REACTIONS.**

DOSAGE AND ADMINISTRATION

As required for irrigation.

When used as a diluent, or vehicle for other drugs, the drug manufacturer's recommendations should be followed.

Some additives may be incompatible. Consult with pharmacist. When introducing additives, use aseptic techniques. Mix thoroughly. Do not store.

Solutions should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permits.

HOW SUPPLIED

0.9% Sodium Chloride Irrigation USP is supplied sterile and nonpyrogenic in single-dose 2000 mL and 3000 mL plastic containers packaged 4 per case.

<u>NDC</u>	<u>REF</u>	<u>SIZE</u>
0264-7388-50	R8205	2000 mL
0264-7388-60	R8206	3000 mL

Exposure of pharmaceutical products to heat should be minimized. Avoid excessive heat. Protect from freezing. It is recommended that the product be stored at room temperature (25°C); however, brief exposure up to 40°C does not adversely affect the product.

Do not warm above 150°F (66°C).

Directions for Use of Plastic Container

Not for injection.

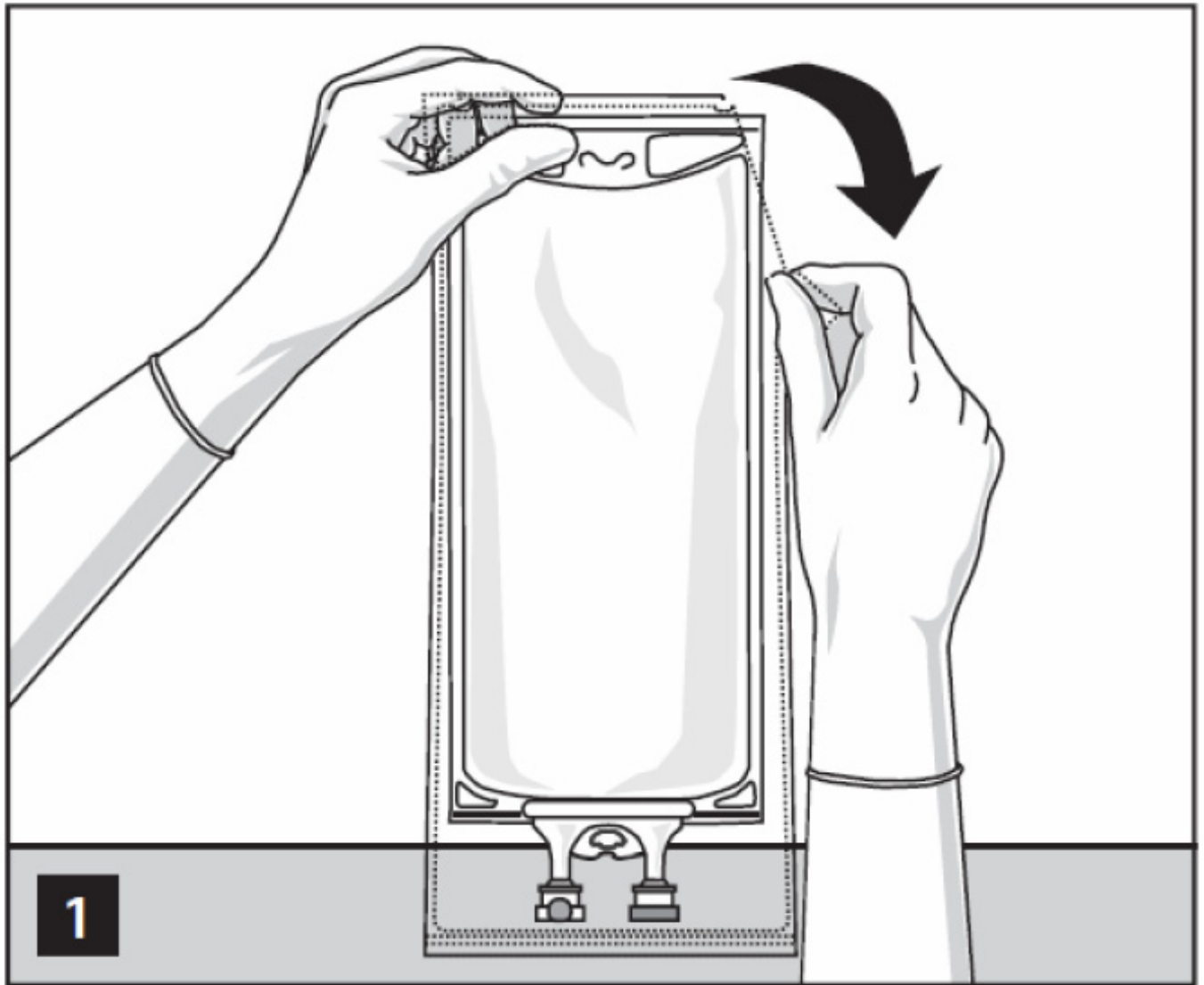
Not for use with pressurized irrigation systems.

Aseptic technique is required.

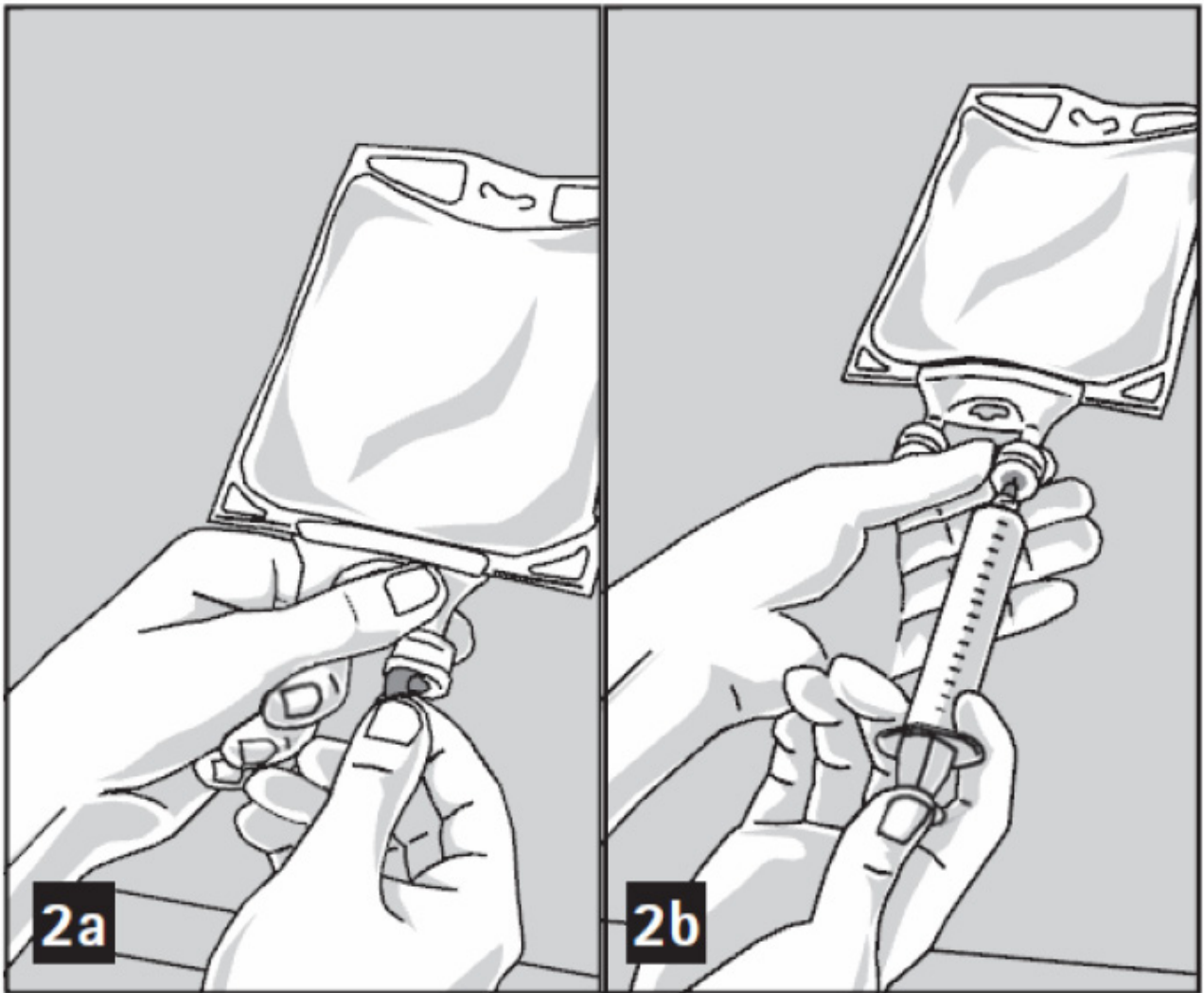
- Inspect irrigation bag: overwrap and primary bag.
- Do not use if overwrap has been damaged.
- Do not use unless solution is clear and closure is intact.



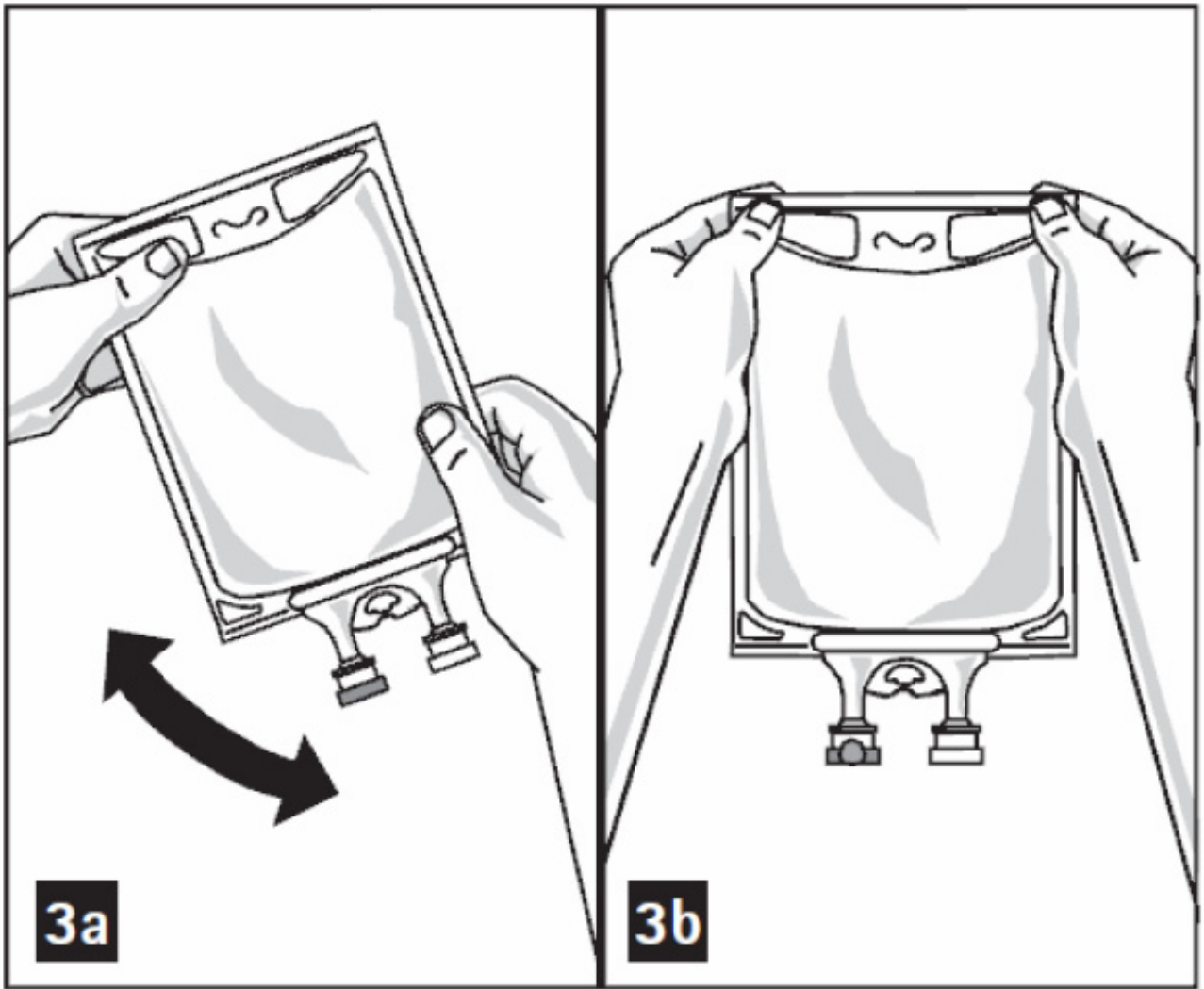
1. To open: Tear overwrap starting from the tear notches. (Figure 1)



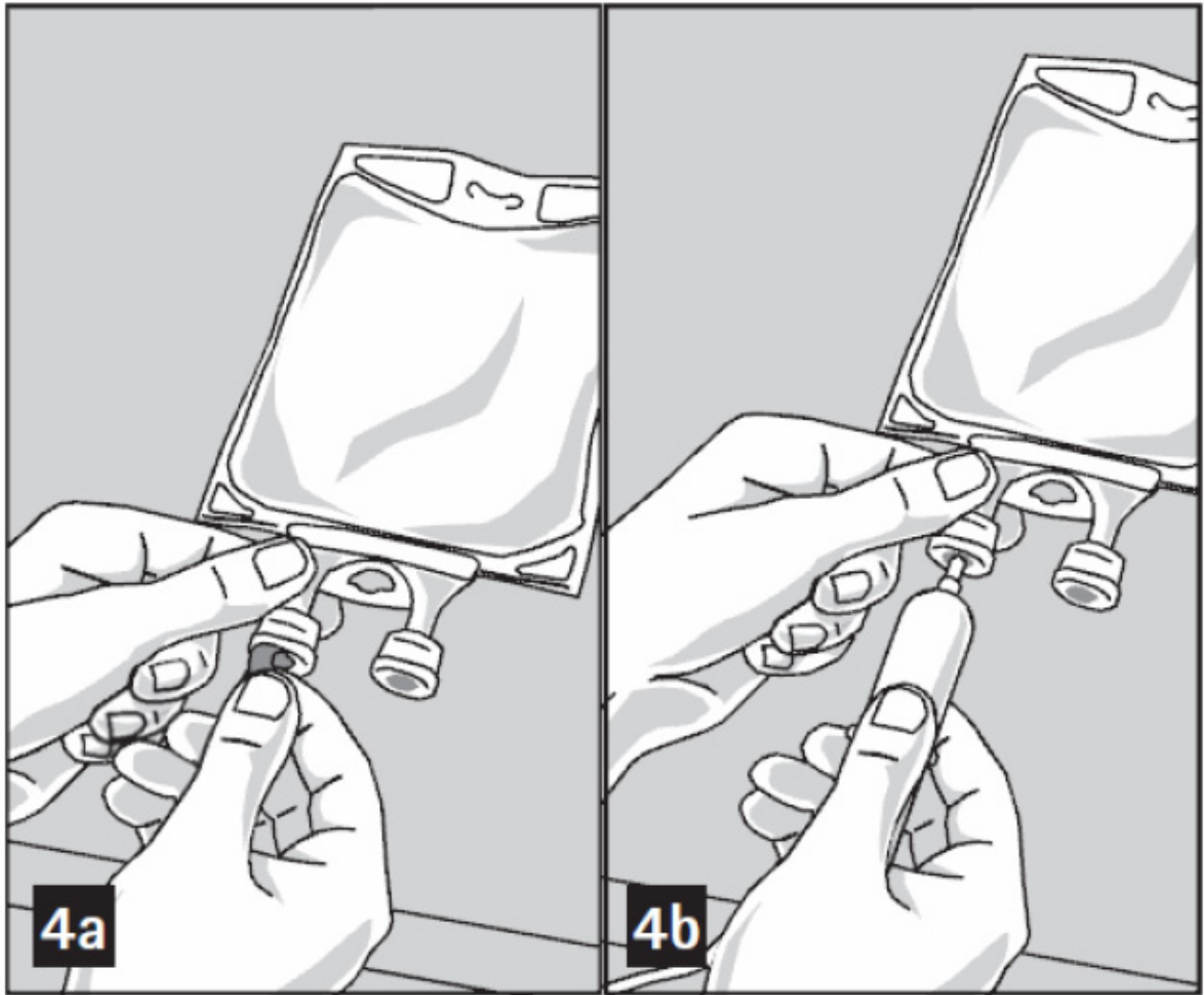
2. Prepare medication port by removal of aluminum foil. (Figure 2a)
 - Puncture resealable medication port by using 19 - 22 gauge needle and inject additive(s). (Figure 2b)



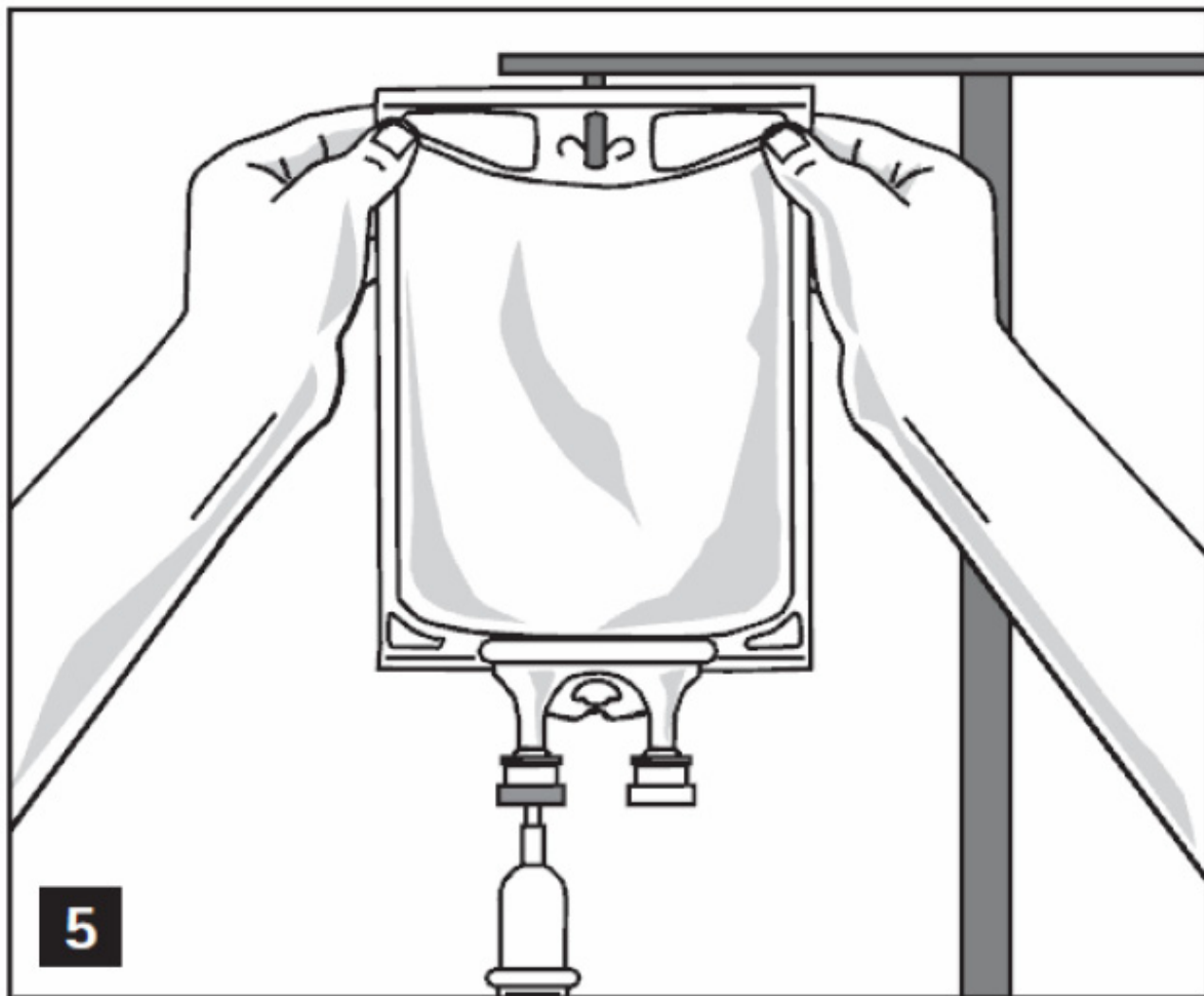
- Mix solution and medication thoroughly. (Figure 3a)
- Medication port must be swabbed with disinfection agent (e.g. iso-propanol or chlorhexidine) before re-puncturing.
- Check admixture visually for particulate matter. (Figure 3b)



3. Remove aluminum foil from outlet/set port at the bottom of container (Figure 4a) and attach administration set (Figure 4b): use non-vented infusion set or close air vent on a vented set. Refer to directions for use accompanying the administration set.



4. Hang bag on IV Pole. (Figure 5)



Y36-002-963 LD-398-4

Package Insert

Rx only

Revised: June 2018

B. Braun Medical Inc.

Bethlehem, PA 18018-3524 USA

1-800-227-2862

PRINCIPAL DISPLAY PANEL - 2000 mL Container Label

0.9% SODIUM CHLORIDE IRRIGATION USP

ISOTONIC SOLUTION FOR IRRIGATION

REF R8205

NDC 0264-7388-50

LOT

EXP.

2000 mL

Each 100 mL contains
Sodium Chloride USP 0.9 g
Water for Injection USP qs

pH adjusted with
Hydrochloric Acid NF

pH: 5.75 (4.50-7.00)
Calc. Osmolarity: 308 mOsmol/liter

Electrolytes (mEq/liter): Sodium 154 Chloride 154

Sterile, nonpyrogenic. Single unit container.
Discard unused portion.

Not for Injection. Use only if solution is clear and
container and seal are intact.

Warning: Do not warm above 150°F (66°C).

Recommended Storage: Room temperature (25°C).
Avoid excessive heat. Protect from freezing.

See Package Insert.

Not made with natural
rubber latex, PVC or DEHP.

Rx only



Y38-000-060 LD-253-7

B. Braun Medical Inc.
Bethlehem, PA 18018-3524 USA
1-800-227-2862

SET



0.9% SODIUM CHLORIDE IRRIGATION USP

ISOTONIC SOLUTION FOR IRRIGATION

— **REF** R8205 | **2000 mL**
NDC 0264-7388-50
LOT
1500 **EXP.**

Each 100 mL contains
Sodium Chloride USP 0.9 g
Water for Injection USP qs

pH adjusted with
Hydrochloric Acid NF



1000 pH: 5.75 (4.50-7.00)
Calc. Osmolarity: 308 mOsmol/liter

Electrolytes (mEq/liter):
Sodium 154 Chloride 154

Sterile, nonpyrogenic. Single unit container.
Discard unused portion.

Not for Injection. Use only if solution is clear and
container and seal are intact.

Warning: Do not warm above 150°F (66°C).

500 Recommended Storage: Room temperature (25°C).
Avoid excessive heat. Protect from freezing.

See Package Insert.

Not made with natural
rubber latex, PVC or DEHP.

Rx only



Y38-000-060 LD-253-7

BARCODE



B | BRAUN

B. Braun Medical Inc.
Bethlehem, PA 18018-3524 USA
1-800-227-2862

0.9% Sodium Chloride Irrigation 2L Container Label

PRINCIPAL DISPLAY PANEL - 3000 mL Container Label

0.9% SODIUM CHLORIDE IRRIGATION USP

ISOTONIC SOLUTION FOR IRRIGATION

REF R8206

NDC 0264-7388-60

LOT

EXP.

3000 mL

Each 100 mL contains
Sodium Chloride USP 0.9 g
Water for Injection USP qs

pH adjusted with
Hydrochloric Acid NF

pH: 5.75 (4.50-7.00)

Calc. Osmolarity:
308 mOsmol/liter

Electrolytes (mEq/liter):

Sodium 154 Chloride 154

Sterile, nonpyrogenic. Single unit container. Discard unused portion.

Not for Injection. Use only if solution is clear and container and seal are intact.

Warning: Do not warm above 150°F (66°C).

Recommended Storage: Room temperature (25°C). Avoid excessive heat. Protect from freezing.

See Package Insert.

Not made with natural rubber latex, PVC or DEHP.

Rx only



Y38-000-061 LD-254-6

B. Braun Medical Inc.

Bethlehem, PA 18018-3524 USA

1-800-227-2862

SET



**0.9% SODIUM CHLORIDE
IRRIGATION USP**
ISOTONIC SOLUTION FOR IRRIGATION

2500

REF R8206 | **3000 mL**
NDC 0264-7388-60
LOT
2000 **g** EXP.

Each 100 mL contains
Sodium Chloride USP 0.9 g
Water for Injection USP qs

pH adjusted with
Hydrochloric Acid NF

1500 pH: 5.75 (4.50-7.00)
Calc. Osmolarity:
308 mOsmol/liter



Electrolytes (mEq/liter):
Sodium 154 Chloride 154

Sterile, nonpyrogenic. Single unit container.
Discard unused portion.

1000 **Not for Injection.** Use only if solution is clear
and container and seal are intact.

Warning: Do not warm above 150°F (66°C).

Recommended Storage: Room temperature
(25°C). Avoid excessive heat. Protect from
freezing.

See Package Insert.

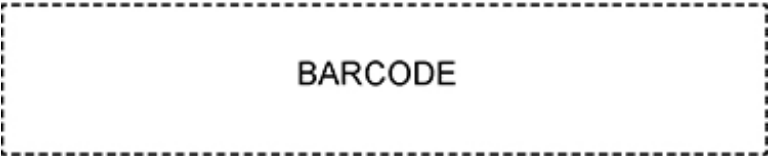
Rx only



Not made with natural
rubber latex, PVC or DEHP.

Y38-000-061 LD-254-6

500



BARCODE



B | BRAUN

B. Braun Medical Inc.
Bethlehem, PA 18018-3524 USA
1-800-227-2862

SODIUM CHLORIDE FOR IRRIGATION

sodium chloride for irrigation solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0264-7388
Route of Administration	IRRIGATION		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM CHLORIDE (UNII: 451W47IQ8X) (SODIUM CATION - UNII:LYR4M0NH37, CHLORIDE ION - UNII:Q32ZN48698)	SODIUM CHLORIDE	0.9 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0264-7388-50	4 in 1 CASE	04/19/2013	
1		2000 mL in 1 CONTAINER; Type 0: Not a Combination Product		
2	NDC:0264-7388-60	4 in 1 CASE	04/19/2013	
2		3000 mL in 1 CONTAINER; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA016733	04/19/2013	

Labeler - B. Braun Medical Inc. (002397347)

Establishment

Name	Address	ID/FEI	Business Operations
B. Braun Medical Inc.		037425308	label(0264-7388) , manufacture(0264-7388) , pack(0264-7388)