

VII. PRODUCT INFORMATION

BSS® PLUS Sterile Intraocular Irrigating Solution

(Balanced Salt Solution Enriched with Bicarbonate, Dextrose and Glutathione)

Description: BSS® PLUS is a sterile intraocular irrigating solution for use during all intraocular surgical procedures, even those requiring a relatively long intraocular perfusion time (e.g., pars plana vitrectomy, phacoemulsification, extracapsular cataract extraction/lens aspiration, and anterior segment reconstruction, etc.). The solution does not contain a preservative and should be prepared just prior to use in surgery.

Part I: Part I is a sterile 480 mL solution in a 500 mL single-dose bottle to which the Part II concentrate is added. Each mL of Part I contains: Sodium Chloride 7.44 mg, Potassium Chloride 0.395 mg, Dibasic Sodium Phosphate 0.433 mg, Sodium Bicarbonate 2.19 mg, Hydrochloric Acid and/or Sodium Hydroxide (to adjust pH), in Water for Injection.

Part II: Part II is a sterile concentrate in a 20 mL single-dose vial for addition to Part I. Each mL of Part II contains: Calcium Chloride Dihydrate 3.85 mg, Magnesium Chloride Hexahydrate 5 mg, Dextrose 23 mg, Glutathione Disulfide (Oxidized Glutathione) 4.6 mg, in Water for Injection.

After addition of BSS PLUS Part II to the Part I bottle, each mL of the reconstituted product contains: Sodium Chloride 7.14 mg, Potassium Chloride 0.38 mg, Calcium Chloride Dihydrate 0.154 mg, Magnesium Chloride Hexahydrate 0.2 mg, Dibasic Sodium Phosphate 0.42 mg, Sodium Bicarbonate 2.1 mg, Dextrose 0.92 mg, Glutathione Disulfide (Oxidized Glutathione) 0.184 mg, in Water for Injection.

The reconstituted product has a pH of approximately 7.4. Osmolality is approximately 305 mOsm.

Clinical Pharmacology: None of the components of BSS PLUS are foreign to the eye, and BSS PLUS has no pharmacological action. Human perfused cornea studies^{1,4,5} have shown BSS PLUS to be an effective irrigating solution for providing corneal detumescence and maintaining corneal endothelial integrity during intraocular perfusion. An *in vivo* study² in rabbits has shown that BSS PLUS is more suitable than normal saline or Balanced Salt Solution for intravitreal irrigation because BSS PLUS contains the appropriate bicarbonate, pH, and ionic composition necessary for the maintenance of normal retinal electrical activity. Human *in vivo* studies have demonstrated BSS PLUS to be safe and effective when used during surgical procedures such as pars plana vitrectomy, phacoemulsification, cataract extraction/lens aspiration and anterior segment reconstruction.

Indications and Usage: BSS PLUS is indicated for use as an intraocular irrigating solution during intraocular surgical procedures involving perfusion of the eye.

Contraindications: There are no specific contraindications to the use of BSS PLUS; however, contraindications for the surgical procedure during which BSS PLUS is to be used should be strictly adhered to.

Warnings: For IRRIGATION during ophthalmic surgery only. BSS PLUS is NOT for injection or intravenous infusion.

Precautions: DO NOT USE BSS PLUS UNTIL RECONSTITUTED. Do not use Part I if it does not contain a vacuum. Do not use additives other than Part II. Do not use if the reconstituted solution is discolored or contains a precipitate. SINCE BSS PLUS IS INTENDED FOR INTRAOCULAR IRRIGATION, IT DOES NOT CONTAIN A PRESERVATIVE AND, THEREFORE, SHOULD NOT BE USED FOR MORE THAN ONE PATIENT. DISCARD ANY UNUSED SOLUTION SIX HOURS AFTER PREPARATION. Studies suggest that intraocular irrigating solutions which are iso-osmotic with normal aqueous fluids should be used with caution in diabetic patients undergoing vitrectomy since intraoperative lens changes have been observed.^{3,6}

There have been reports of corneal clouding or edema following ocular surgery in which BSS PLUS was used as an irrigating solution. As in all surgical procedures appropriate measures should be taken to minimize trauma to the cornea and other ocular tissues.

Preparation: Reconstitute BSS PLUS just prior to use in surgery. Follow the same strict aseptic procedures in the reconstitution of BSS PLUS as are used for intravenous additives. Pull the tab to remove the outer aluminum ring and dust cover from the BSS PLUS Part I (480 mL) bottle. Remove the blue flip-off seal from the BSS PLUS Part II (20 mL) vial. Clean and disinfect the rubber stoppers on both containers by using sterile alcohol wipes. Transfer the contents of the Part II vial to the Part I bottle using a BSS PLUS Vacuum Transfer Device (provided). An alternative method of solution transfer may be accomplished by using a 20 mL syringe to remove the Part II solution from the vial and transferring exactly 20 mL to the Part I container through the target area of the rubber stopper. An excess volume of Part II is provided in each vial. Gently agitate the contents to mix the solution. Place a sterile cap on the bottle. Remove the tear-off portion of the label. Record the time and date of reconstitution and the patient's name on the bottle label.

Adverse Reactions: Postoperative inflammatory reactions as well as incidents of corneal edema and corneal decompensation have been reported. Their relationship to the use of BSS PLUS has not been established.

Overdosage: The solution has no pharmacological action and thus has no potential for overdosage. However, as with any intraocular surgical procedure, the duration of intraocular manipulation should be kept to a minimum.

Dosage and Administration: The solution should be used according to the technique standardly employed by the operating surgeon. Use an administration set with an air inlet in the plastic spike since the bottle does not contain a separate airway tube. Follow directions for the particular administration set to be used. Insert the spike aseptically into the bottle through the target area of the rubber stopper. Allow the fluid to flow to remove air from the tubing before intraocular irrigation begins. If a second bottle is necessary to complete the surgical procedure, insure that the vacuum is vented from the second bottle BEFORE attachment to the administration set.

How Supplied: BSS PLUS is supplied in two packages for reconstitution prior to use: a 500 mL bottle containing 480 mL (Part I) and a 20 mL vial (Part II). See the **Precautions** and **Preparation** sections for information concerning reconstitution of the solution.

Storage: Store Part I and Part II at 46°-80°F (8°-27°C). Discard prepared solution after six hours.

References:

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2. Moorhead, L.C., Redburn, D.A., Merritt, J., and Garcia, C. The Effects of Intravitreal Irrigation During Vitrectomy on the Electroretinogram. *Am. J. Ophthalmol.*, 88: 239-245, 1979.
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4. Edelhauser, H.F., Van Horn, D.L., Hyndluk, R.A., and Schultz, R.O. Intraocular Irrigating Solutions: Their Effect on the Corneal Endothelium. *Arch. Ophthalmol.*, 93: 648-657, 1975.
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6. Faulborn, J., Conway, B.P., Machemer, R. Surgical Complications of Pars Plana Vitreous Surgery. *Ophthalmology*, 85: 116-125, 1978.