

BSS PLUS®

DESCRIPTION: BSS PLUS® is a sterile intraocular irrigating solution for use during all intraocular surgical procedures, including those requiring a relatively long intraocular perfusion time (e.g., pars plana vitrectomy, phacoemulsification, extracapsular cataract extraction/lens aspiration, 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, hydrochloric acid and/or sodium hydroxide (to adjust pH), 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 have shown BSS PLUS to be an effective irrigation solution for providing corneal detumescence and maintaining corneal endothelial integrity during intraocular perfusion. An *in vivo* study 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, anterior segment reconstruction. No differences have been observed between adults and pediatric patients following use of this drug product.

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. Not for injection or intravenous infusion. Do not use unless product is clear, seal is intact, vacuum is present and container is undamaged. Do not use if product is discolored or contains a precipitate.

PRECAUTIONS: DO NOT USE BSS PLUS UNTIL PART I IS FULLY RECONSTITUTED WITH PART II. Discard unused contents. BSS PLUS does not contain a preservative; therefore, do not use this container for more than one patient. Do not use additives other than BSS PLUS Concentrate Part II (20 mL) with this product. Tissue damage could result if other drugs are added to product. DISCARD ANY UNUSED PORTION 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.

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® Intraocular Irrigating Solution just prior to use in surgery. Follow the same strict aseptic procedures in the reconstitution of BSS PLUS as is used for intravenous additives. Remove the blue flip-off seal 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 outer 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.

Geriatric Use: No overall differences in safety or effectiveness have been observed between elderly and younger patients.

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 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 standard technique 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 the directions for the particular administration set to be used. Insert the spike aseptically into the bottle through the center 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, ensure 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 glass bottle containing 480 mL (Part I) and a 20 mL glass vial (Part II); both using grey butyl stoppers and aluminum seals with polypropylene flip-off caps. See the PRECAUTIONS section regarding reconstitution of the solution.

NDC 0065-0800-50.

Storage: Store Part I and Part II at 2° - 25°C (36° - 77°F). DO NOT FREEZE. Discard prepared solution after six hours.

Rx Only

BSS®

Sterile Irrigating Solution (balanced salt solution)

DESCRIPTION: BSS® Sterile Irrigating Solution is a sterile balanced salt solution, each mL containing sodium chloride (NaCl) 0.64%, potassium chloride (KCl) 0.075%, calcium chloride dihydrate (CaCl₂•2H₂O) 0.048%, magnesium chloride hexahydrate (MgCl₂•6H₂O) 0.03%, sodium acetate trihydrate (C₂H₃NaO₂•3H₂O) 0.39%, sodium citrate dehydrate (C₆H₅Na₃O₇•2H₂O) 0.17%, sodium hydroxide and/or hydrochloric acid (to adjust pH), and water for injection. The pH is approximately 7.5. The osmolality is approximately 300 mOsm/Kg.

CLINICAL PHARMACOLOGY: BSS Sterile Irrigating Solution is an isotonic solution for use in irrigating tissues of the eyes.

INDICATIONS AND USAGE: For use as an extraocular and intraocular irrigating solution during ocular surgical procedure involving perfusion of the eye with an expected maximum duration of less than 60 minutes.

WARNINGS:

- NOT FOR INJECTION OR INTRAVENOUS INFUSION.
- Do not use unless product is clear, seal is intact, vacuum is present and container is undamaged.
- Do not use if product is discolored or contains a precipitate.
- SINGLE patient use only. The contents of this bottle should not be used in more than one patient.
- The use of additives with this solution may cause corneal decompensation.
- This solution contains no preservative, unused contents should be discarded.

PRECAUTIONS: Open under aseptic conditions only.

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.

There have been reports of corneal clouding and edema following ocular surgery in which BSS Sterile Irrigating Solution was used as an irrigating solution.

ADVERSE REACTIONS: Irrigation or any other trauma may result in corneal swelling or bullous keratopathy.

Post-operative inflammatory reactions as well as incidents of corneal edema and corneal decompensation have been reported.

DOSAGE AND ADMINISTRATION: This irrigating solution should be used according to standard format for each surgical procedure. Note: Use an administration set with an air-inlet in the plastic spike since the bottle does not contain a separate airway tube. Follow directions of the particular administration set to be used. Remove the blue flip-off cap. Clean and disinfect the rubber stopper by using a sterile alcohol wipe. Insert the spike aseptically into the bottle through the target area of the rubber stopper. Allow the fluid to flow and remove air from the tubing before irrigation begins.

HOW SUPPLIED: BSS® Sterile Irrigating Solution is supplied in a glass bottle using a grey butyl stopper and aluminum seal with a blue polypropylene flip-off cap.

250 mL in a 325 mL container: NDC 0065-0795-25.

500 mL in a 635 mL container: NDC 0065-0795-50.

STORAGE: Store at 36° - 77° F (2° - 25°C). DO NOT FREEZE.

Rx Only

DisCoVisc® Ophthalmic Viscosurgical Device (Sodium Chondroitin Sulfate – Sodium Hyaluronate).

Description: DisCoVisc® Ophthalmic Viscosurgical Device has an intermediate cohesive/dispersive index (CDI) and can best be described as the first viscous dispersive viscoelastic and is optimized for the entire surgical procedure.

Indications: DisCoVisc® Ophthalmic Viscosurgical Device is indicated for use during surgery in the anterior segment of the eye. It is designed to create and maintain space, to protect the corneal endothelium and other intraocular tissues and to manipulate tissues during surgery. It may also be used to coat intraocular lenses and instruments during cataract extraction and IOL insertion.

Warnings: Failure to follow assembly instructions or use of an alternate cannula may result in cannula detachment and potential patient injury.

Precautions: Precautions are limited to those normally associated with the surgical procedure being performed. Although sodium hyaluronate and sodium chondroitin sulfate are highly purified biological polymers, the physician should be aware of the potential allergic risks inherent in the use of any biological material.

Adverse Reactions: DisCoVisc® Ophthalmic Viscosurgical Device was very well tolerated in nonclinical and clinical studies. A

transient rise in intraocular pressure in the early postoperative period may be expected due to the presence of sodium hyaluronate, which has been shown to effect such a rise. It is therefore recommended that DisCoVisc be removed from the anterior chamber by thorough irrigation and/or aspiration at the end of surgery to minimize postoperative IOP increases. Do not overfill anterior chamber.

ATTENTION: Reference the Physician Labeling/Directions for Use for a complete listing of indications, warnings and precautions.

CAUTION: FEDERAL (USA) LAW RESTRICTS THIS DEVICE TO THE SALE BY OR ON THE ORDER OF A PHYSICIAN.

U.S. Patent Nos. 5,273,056; 5,876,379 and 6,051,560.

DUOVISC®

DUOVISC® Viscoelastic System is designed to give two viscoelastic materials with different physico-chemical properties that can be used differently and/or sequentially to perform specific tasks during a cataract procedure. **DUOVISC®** Viscoelastic System consists of **VISCOAT®** Ophthalmic Viscosurgical Device and **PROVISC®** Ophthalmic Viscosurgical Device.

CAUTION: Federal law restricts this device to sale by or on the order of a physician.

Viscoat® (Sodium Chondroitin Sulfate – Sodium Hyaluronate) Ophthalmic Viscosurgical Device

Indications: Viscoat is indicated for use as an ophthalmic surgical aid in anterior segment procedures including cataract extraction and intraocular lens (IOL) implantation. Viscoat maintains a deep anterior chamber during anterior segment surgeries, enhances visualization during the surgical procedure, and protects the corneal endothelium and other ocular tissues. The viscoelasticity of the solution maintains the normal position of the vitreous face and prevents formation of a flat chamber during surgery.

Warnings: Failure to follow assembly instructions or use of an alternate cannula may result in cannula detachment and potential patient injury.

Precautions: Precautions are limited to those normally associated with the surgical procedure being performed. Although sodium hyaluronate and sodium chondroitin sulfate are highly purified biological polymers, the physician should be aware of the potential allergic risks inherent in the use of any biological material.

Adverse Reactions: Viscoat has been extremely well tolerated in human and animal studies. A transient rise in intraocular pressure in the early postoperative period may be expected due to the presence of sodium hyaluronate, which has been shown to effect such a rise. It is therefore recommended that Viscoat be removed from the anterior chamber by thorough irrigation and/or aspiration at the end of surgery to minimize postoperative IOP increases. Do not overfill anterior chamber.

ATTENTION: Reference the Physician Labeling/Directions for Use for a complete listing of indications, warnings and precautions.

ProVisc® (Sodium Hyaluronate) Ophthalmic Viscosurgical Device

Indications: ProVisc is indicated for use as an ophthalmic surgical aid in the anterior segment during cataract extraction and intraocular lens (IOL) implantation. Ophthalmic viscoelastics serve to maintain a deep anterior chamber during anterior segment surgery allowing reduced trauma to the corneal endothelium and surrounding ocular tissues. They help push back the vitreous face and prevent formation of a flat chamber during surgery.

Precautions: Postoperative increases in intraocular pressure have been reported with sodium hyaluronate products. The IOP should be carefully monitored and appropriate therapy instituted if significant increases should occur. It is recommended that **ProVisc®** be removed by irrigation and/or aspiration at the close of surgery. Do not overfill anterior chamber. Although sodium hyaluronate is a highly purified biological polymer, the physician should be aware of the potential allergic risks inherent in the use of any biological

material; care should be used in patients with hypersensitivity to any components in this material. Cannula assembly instructions should be followed to prevent patient injury.

Adverse Reactions: Postoperative inflammatory reactions such as hypopyon and iritis have been reported with the use of ophthalmic viscoelastics, as well as incidents of corneal edema, corneal decompensation, and a transient rise in intraocular pressure.

ATTENTION: Reference the Physician Labeling/Directions for Use for a complete listing of indications, warnings and precautions.

IOL Brief Statements

DESCRIPTION: Alcon® UV-absorbing Single Piece PMMA and Monoflex™ PMMA posterior chamber lenses and Single Piece PMMA anterior chamber lenses are optical implants for the replacement of the human crystalline lens in the visual correction of aphakia in adult patients following cataract removal. These lenses have biconvex, convexoplano, convexoplano with Hoffer™* ridge modification, or meniscus optics with supporting haptics.

AcrySof® Posterior Chamber Intraocular Lenses are indicated for the replacement of the human lens to achieve visual correction of aphakia in adult patients following cataract removal. These lenses are intended for placement in the capsular bag.

CAUTION: Federal law restricts this device to sale by or on the order of a physician.

WARNINGS: Careful preoperative evaluation and sound clinical judgment should be used by the surgeon to decide the risk/benefit ratio before implanting a lens in a patient with any of the conditions described in the Directions For Use labeling. Some adverse reactions that have been associated with the implantation of intraocular lenses are: hypopyon, intraocular infection, acute corneal decompensation, and secondary surgical intervention.

PRECAUTIONS: Do not resterilize; do not store over 45°C; use only sterile irrigating solutions such as BSS® or BSS PLUS®.

ATTENTION: Reference the Product Insert for a complete listing of warnings & precautions as they may vary by lens.

ACRY SOF® RESTOR® SN6AD3/SN60D3/MN60D3/SA60D3/ MA60D3

CAUTION: Federal law restricts this device to sale by or on the order of a physician.

INDICATIONS: The AcrySof® ReSTOR® Apodized Diffractive Optic Posterior Chamber Intraocular Lens (IOL) is intended for primary implantation for the visual correction of aphakia secondary to removal of a cataractous lens in adult patients with or without presbyopia, who desire near, intermediate and distance vision with increased spectacle independence. The lens is intended to be placed in the capsular bag.

WARNINGS: Careful preoperative evaluation and sound clinical judgment should be used by the surgeon to decide the risk/benefit ratio before implanting a lens in a patient with any of the conditions described in the Directions for Use labeling. Some adverse reactions that have been associated with the implantation of intraocular lenses are: hypopyon, intraocular infection, acute corneal decompensation, macular edema, pupillary block, retinal detachment, and secondary surgical intervention (including but not limited to lens repositioning, biometry error, visual disturbances or patient dissatisfaction). As a result of the multifocality, some visual effects (halos or radial lines around point sources of light at night) may also be expected due to the superposition of focused and unfocused multiple images. A reduction in contrast sensitivity may also be experienced by some patients, especially in low lighting conditions such as driving at night. In order to achieve optimal visual performance with this lens, emmetropia must be targeted. Patients with significant preoperative or expected postoperative astigmatism >1.0D may not achieve optimal visual outcomes. Care should be taken to achieve IOL centration, as lens decentration may result in a patient experiencing visual disturbances under certain lighting conditions.

PRECAUTIONS: Do not resterilize. Do not store over 45° C. Use only sterile irrigating solutions such as BSS® or BSS PLUS® Sterile Intraocular Irrigating Solution. Clinical studies with the AcrySof® ReSTOR® IOL indicated that posterior capsule opacification (PCO), when present, developed earlier into clinically significant PCO. Studies have shown that color vision discrimination is not adversely affected in individuals with the AcrySof® Natural IOL and normal color vision. The effect on vision of the AcrySof® Natural IOL in subjects with hereditary color vision defects and acquired color vision defects secondary to ocular disease (e.g., glaucoma, diabetic retinopathy, chronic uveitis, and other retinal or optic nerve diseases) has not been studied. The long-term effects of filtering blue light and the clinical efficacy of that filtering on the retina have not been conclusively established.

ATTENTION: Reference the Physician Labeling/Directions for Use for a complete listing of indications, warnings and precautions.

ACRY SOF® Toric IOL Models SN60T3, SN60T4, and SN60T5

CAUTION: Federal law restricts this device to sale by or on the order of a physician.

INDICATIONS: AcrySof® Toric IOL Models SN60T3, SN60T4, and SN60T5 Posterior Chamber Intraocular lenses are intended for primary implantation in the capsular bag of the eye for the visual correction of aphakia and pre-existing corneal astigmatism secondary to the removal of a cataractous lens in adult patients with or without presbyopia, who desire improved uncorrected distance vision, reduction of residual refractive cylinder and increased spectacle independence for distance vision.

WARNINGS: Careful preoperative evaluation and sound clinical judgment should be used by the surgeon to decide the risk/benefit ratio before implanting a lens in a patient with any of the conditions described in the Directions for Use labeling. Toric IOLs should not be implanted if the posterior capsule is ruptured, if the zonules are damaged, or if a primary posterior capsulotomy is planned. Rotation can reduce astigmatic correction, if necessary lens repositioning should occur as early as possible prior to lens encapsulation. All viscoelastics should be removed from both the anterior and posterior sides of the lens; residual viscoelastics may allow the lens to rotate.

PRECAUTIONS: Studies have shown that color vision discrimination is not adversely affected in individuals with the AcrySof® Natural IOL and normal color vision. The effect on vision of the AcrySof® Natural IOL in subjects with hereditary color vision defects and acquired color vision defects secondary to ocular disease (e.g., glaucoma, diabetic retinopathy, chronic uveitis, and other retinal or optic nerve diseases) has not been studied. The long-term effects of filtering blue light and the clinical efficacy of that filtering on the retina have not been conclusively established. Do not resterilize; do not store over 45° C; use only sterile irrigating solutions such as BSS® or BSS PLUS® Sterile Intraocular Irrigating Solutions.

ATTENTION: Reference the Directions for Use labeling for a complete listing of indications, warnings and precautions.

The ACRY SOF® IQ Aspheric Natural & ACRY SOF® Natural IOLs

CAUTION: Federal law restricts this device to sale by or on the order of a physician.

INDICATIONS: AcrySof® IQ Aspheric Natural Intraocular lenses and the AcrySof® Natural Posterior Chamber Intraocular Lenses (IOLs) are indicated for the replacement of the human lens to achieve visual correction of aphakia in adult patients following cataract surgery. These lenses are intended for placement in the capsular bag.

WARNINGS: Careful preoperative evaluation and sound clinical judgment should be used by the surgeon to decide the risk/benefit ratio before implanting a lens in a patient with any of the conditions described in the Directions for Use labeling. Some adverse reactions that have been associated with the implantation of intraocular lenses are: hypopyon, intraocular infection, acute corneal decompensation and secondary surgical intervention. Caution should be used prior to lens encapsulation to avoid lens decentrations or dislocations.

PRECAUTIONS: Studies have shown that color vision discrimination is not adversely affected in individuals with the AcrySof® Natural IOL and normal color vision. The effect on vision of the AcrySof® Natural IOL in subjects with hereditary color vision defects and acquired color vision defects secondary to ocular disease (e.g., glaucoma, diabetic retinopathy, chronic uveitis, and other retinal or optic nerve diseases) has not been studied. The long-term effects of filtering blue light and the clinical efficacy of that filtering on the retina have not been conclusively established. Do not resterilize; do not store over 45° C; use only sterile irrigating solutions such as BSS® or BSS PLUS® Sterile Intraocular Irrigating Solutions.

ATTENTION: Reference the Physician Labeling/Directions for Use for a complete listing of indications, warnings and precautions. The long-term effects of filtering blue light and the clinical efficacy of that filtering on the retina have not been conclusively established.