Important Product Information for DUOVISC ® OVD

Description: DUOVISC® Viscoelastic System is designed to provide 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 (USA) law restricts this device to sale by, or on the order of, a physician.

Description: VISCOAT® (Sodium Chondroitin Sulfate – Sodium Hyaluronate) Ophthalmic Viscosurgical Device

Indications: VISCOAT® OVD is indicated for use as an ophthalmic surgical aid in anterior segment procedures including cataract extraction and intraocular lens (IOL) implantation. VISCOAT® OVD 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/Precautions: Failure to follow assembly instructions or use of an alternate cannula may result in cannula detachment and potential patient injury. 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® OVD 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 affect such a rise. It is therefore recommended that VISCOAT® OVD 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: Please refer to the Directions for Use for a complete listing of indications, warnings and precautions.

Description: PROVISC® (Sodium Hyaluronate) Ophthalmic Viscosurgical Device

Indications: PROVISC® OVD 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.

Warnings/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® OVD 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: Please refer to the directions for use for a complete listing of indications, warnings and precautions.