

## Important Product Information for PROVISC® OVD

**CAUTION:** Federal (USA) law restricts this device to sale by, or on the order of, a physician.

**INDICATION:** PROVISC® (Sodium Hyaluronate) Ophthalmic Viscoelastic Device (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 EVENTS:**

- 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 intraocular pressure.

**ATTENTION:** Reference the directions for use for a complete listing of indications, warnings and precautions.