PROVISC® Ophthalmic Viscosurgical Device

DESCRIPTION:

PROVISC® (OVD) is a sterile, non-pyrogenic, high molecular weight, non-inflammatory highly purified fraction of sodium hyaluronate, dissolved in physiological sodium chloride phosphate buffer. PROVISC (OVD) is formulated to a viscosity of 50,000 x 10^3 Pa.s at a shear rate of 1 sec^-1 (2°C).

INDICATIONS:

PROVISC (OVD) is indicated for use as an ophthalmic surgical aid in the anterior segment during cataract extraction and microincisional lens implantation.

CONTRAINDICATIONS:

At present there are no known contraindications to the use of PROVISC (OVD) when used as recommended; care should be used in patients with hypersensitivity to any components in this material (see Precautions section).

WARNING: Failure to follow all of the assembly instructions in "Directions for Use" or use of an alternate cannula may result in cannula detachment and the possibility of serious injury.

PRECAUTIONS:

(a) Procedures normally associated with anterior segment surgical procedures should be observed.

(b) 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 occur.

(c) Do not overfill the anterior chamber. It is recommended that PROVISC (OVD) be removed by irrigation and aspiration at the end of surgery. Use of the syringe assembly for this purpose is not advised.

(d) The sodium hyaluronate in PROVISC (OVD) is obtained from bacterial fermentation by a proprietary purification process. Although precautions have been taken to make this device protein-free and it has been tested in animals for allergenic response, this device, used in susceptible persons, may produce allergenic responses.

PROVISC (OVD) possesses physicochemical properties that make it well suited for tissue manipulation, such as expansion of the capsular bag and facilitation of surgical instrumentation during cataract extraction surgery.

Additional VISCOAT (OVD) may be instilled intracamerally during anterior segment surgery to fully maintain the anterior chamber or replace any volume lost during the surgical procedure. At the end of the surgical procedure it is recommended that VISCOAT (OVD) be removed from the eye as completely as practical by thorough irrigation with a sterile irrigating solution and aspiration.

PROVISC (OVD) possesses physicochemical properties that make it well suited for tissue manipulation, such as expansion of the capsular bag and facilitation of intracocular lens implantation following cataract extraction.

The cannula provided is used to slowly and carefully instill PROVISC (OVD) into the anterior chamber. The instillation may be performed prior to intracocular lens implantation.

PROVISC (OVD) may also be used to coat surgical instruments and the intracocular lens prior to implantation. Additional PROVISC (OVD) can be instilled during surgery to replace any PROVISC (OVD) lost during surgical manipulation (see PROVISC (OVD) PRECAUTIONS Section).

HOW SUPPLIED:

DUOVISC® Viscosurgical System consists of sterile, non-pyrogenic viscoelastic materials (refer to the separate PROVISC (OVD) and VISCOAT (OVD) leaflets). DUOVISC® (OVD) is supplied in disposable glass syringes delivering 0.25 mL or 0.50 mL of VISCOAT (OVD) and 0.4 mL or 0.8 mL of PROVISC (OVD). Both VISCOAT and PROVISC (OVD) syringes are aseptically filled and packaged in blister packs. Syringe exteriors are sterilized by ethylene oxide.

Refrigerated VISCOAT (OVD) and PROVISC (OVD) should be allowed to attain room temperature prior to use (approximately 20 - 40 minutes depending on quantity).
PURGE THE REMAINING AIR FROM THE SYSTEM BY HOLDING THE SYRINGE BARREL WITH ONE HAND AND GENTLY DEPRESSING THE PLUNGER ROD WITH THE OTHER UNTIL ProVisc (OVD) APPEARS AT THE CANNULA TIP.
**VISCOAT**

**Ophthalmic Viscosurgical Device**

*(sodium chondroitin sulfate – sodium hyaluronate)*

**DESCRIPTION:**

**VISCOAT** (OV) is a sterile, non-pyrogenic, viscous solution of highly purified, non-inflammatory medium molecular weight sodium chondroitin sulfate and sodium hyaluronate. **VISCOAT** (OV) is formulated to a viscosity of 40,000 to 50,000 cps (at shear rate of 2 sec⁻¹, 25°C).

![VISCOAT Rheology Using Bohlin CS Rheometer at 25°C](image)

Each 1 mL of **VISCOAT** (OV) contains: 40 mg sodium chondroitin sulfate; 30 mg sodium hyaluronate; 0.45 mg monobasic sodium phosphate, monohydrate; 2.0 mg sodium citrate anhydrous; 4.0 mg sodium chloride (with water for injection, USP, q.s.). Sodium hydroxide and/or hydrochloric acid may be used as pH adjusters. The osmolality of **VISCOAT** (OV) is 220 ± 40 mOsm/kg; the pH is 7.0 to 7.4.

Sodium chondroitin sulfate and sodium hyaluronate are quite similar in regard to chemical and physical composition, as each occurs as a large, unbranched chain structure of medium to high molecular weight. The sodium chondroitin sulfate used in the preparation of **VISCOAT** (OV) has a mean molecular weight of approximately 22,500 Daltons, while the sodium hyaluronate exhibits a molecular weight of over 500,000 Daltons.

The sugar residues of these two compounds occur as repeating disaccharide units. The two compounds differ in that sodium chondroitin sulfate possesses a sulfated uronic acid residue, rather than a single, negative charge (as in the case of sodium hyaluronate) per repeating disaccharide unit.

**INDICATIONS:**

**VISCOAT** (OV) is indicated for use as a surgical aid in anterior segment procedures including cataract extraction and intraocular lens implantation. **VISCOAT** (OV) maintains a deep chamber during anterior segment surgery, 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.

**CONTRAINDICATIONS:**

At the present time, there are no known contraindications to the use of **VISCOAT** (OV) when used as recommended.

**WARNING:**

Failure to follow all of the assembly instructions in "Directions for Use" or use of an alternate cannula may result in cannula detachment and the possibility of serious 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.

In addition to the above, the following precautions should be observed:

- Do not reuse cannulas.
- Use only if material is clear.
- Avoid trapping air bubbles.
- Do not reuse cannulas.

**ADVERSE REACTIONS:**

**VISCOAT** (OV) has been extremely well tolerated in human and animal studies. A transient rise in intraocular pressure may be expected due to the presence of sodium hyaluronate, which has been shown to affect such a rise (10% to 25 mm Hg during 1–3 days after surgery in human clinical trials).

**CLINICAL APPLICATIONS:**

For cataract surgery and intraocular lens implantation, **VISCOAT** (OV) should be carefully injected using standard aseptic techniques (and using only the cannula provided) into the anterior chamber. **VISCOAT** (OV) may be injected into the chamber prior to or following removal of the crystalline lens. Instillation of **VISCOAT** (OV) prior to lens removal will provide additional protection to the corneal endothelium. Instillation of the solution at this point is significant, in that a coating of **VISCOAT** (OV) may protect the corneal endothelium from possible damage arising from surgical instrumentation during the cataract extraction surgery. **VISCOAT** (OV) may also be used to coat an intraocular lens, as well as the tips of surgical instruments, prior to implantation. Additional **VISCOAT** (OV) may be injected during anterior segment surgery to fully maintain the chamber or replace any volume lost during the surgical procedure. At the end of the surgical procedure it is recommended that **VISCOAT** (OV) be removed from the eye as completely as practical by through irrigation (with sterile irrigating solution) and aspiration.

**HOW SUPPLIED:**

**VISCOAT** (OV) is a sterile, non-pyrogenic, single-use, ophthalmic viscosurgical device supplied in a disposable syringe delivering 0.35 mL or 0.50 mL, packaged with a sterile, 27-gauge, disposable, blunt-tip cannula and cannula locking ring. **VISCOAT** (OV) syringes are aseptically filled and packaged in blister packs. Syringe stoppers are sterilized by ethylene oxide.

**STERILE US**

**STORE UNDER REFRIGERATION BETWEEN 2°C – 8°C (36°F – 46°F), PROTECT FROM FREEZING AND LIGHT.**

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

U.S. Pat. No. 6,051,560; 5,876,379

**REFERENCES**

2. OLCO, Inc. Study “Practical evaluation of the protective efficacy of OVD PLUS on rabbit corneal buttons” (1993).
DIRECTIONS FOR USE:

FOR INTRAOCULAR USE: VISCOAT® (OVD) CANNULA AND CANNULA LOCKING RING ARE FOR SINGLE USE ONLY.

The syringe assembly is designed only for the injection of the VISCOAT® (OVD) it contains. Use of the syringe assembly for aspiration is not advised. Refrigerated VISCOAT® (OVD) should be allowed to attain room temperature prior to use (approximately 20 - 40 minutes depending on quantity).

NOTE: THIS VISCOAT® (OVD) DELIVERY SYSTEM IS NOT DESIGNED OR INTENDED TO BE ATTACHED TO REUSABLE (METAL-HUBBED) INSTRUMENTS OR TO DISPOSABLE INSTRUMENTS OTHER THAN THE ONE PROVIDED WITH THE PRODUCT. FAILURE TO FOLLOW THESE ASSEMBLY INSTRUCTIONS MAY RESULT IN CANNULA DETACHMENT.

1. PEEL LID FROM BLISTER PACK UNDER ASEPTIC CONDITIONS.
2. REMOVE RUBBER CAP FROM SYRINGE TIP (CAP IS ON TIGHTLY).
3. INJECT STERILE IRRIGATING SOLUTION INTO THE CANNULA HUB AND FILL IT TO THE TOP.
4. EXPRESS THE AIR FROM THE TIP OF THE SYRINGE BY HOLDING THE SYRINGE BARREL WITH ONE HAND WHILE GENTLY DEPRESSING THE PLUNGER ROD WITH THE OTHER. BE CAREFUL NOT TO EXPRESS VISCOELASTIC ONTO THE OUTSIDE OF THE SYRINGE TIP.
5. THREAD THE CANNULA ONTO THE SYRINGE SLEEVE IN A CONTINUOUS MOTION BY USING THE CARTRIDGE AS A WRENCH. TWIST UNTIL THE CANNULA HUB HAS TRAVELED THE FULL LENGTH OF THE THREADS AND IS FIRMLY SEATED. USE ONLY THE CANNULA PROVIDED.
6. VISUALLY INSPECT THAT THE CANNULA THREADS HAVE TRAVELED THE FULL LENGTH OF THE SYRINGE SLEEVE THREADS.
7. REMOVE PLASTIC CARTRIDGE FROM THE CANNULA IN A STRAIGHT MOTION, BEING SURE NOT TO TWIST OR UNSCREW THE CANNULA WHILE REMOVING THE CARTRIDGE.
9. SECURE THE CANNULA BY ROTATING THE CANNULA LOCKING RING COUNTERCLOCKWISE UNTIL IT STOPS AGAINST THE CANNULA HUB.
10. PURGE THE REMAINING AIR FROM THE SYSTEM BY HOLDING THE SYRINGE BARREL WITH ONE HAND AND GENTLY DEPRESSING THE PLUNGER ROD WITH THE OTHER UNTIL VISCOAT Ophthalmic Viscosurgical Device appears at the cannula tip.

STORE UPRIGHT