

DUOVISC® Viscoelastic System

DUOVISC® Viscoelastic System is designed to provide two viscoelastic materials with different physicochemical properties which can be used to perform specific tasks in a cataract procedure. The choice of material is based on the different physicochemical properties and the specific surgical task being undertaken.

VISCOAT® Viscoelastic Solution is used in anterior segment surgery to provide protection to the corneal endothelium. VISCOAT should be carefully introduced (using the 27-gauge cannula provided with the syringe) into the anterior chamber prior to capsulotomy. Additional VISCOAT Viscoelastic Solution may be instilled during anterior segment surgery to fully maintain the anterior chamber or replace any solution lost during the surgical procedure.

PROVISC® Viscoelastic Solution is used during anterior segment surgery; the physicochemical properties of PROVISC make it suitable for tissue manipulation, such as expansion of the capsular bag, and facilitate intraocular lens implantation following cataract extraction. The cannula provided is used to slowly and carefully inject an amount of PROVISC into the anterior chamber prior to intraocular lens implantation. PROVISC may also be used to coat surgical instruments and the intraocular lens prior to implantation. Additional PROVISC can be injected during surgery to replace any PROVISC lost during surgical manipulation.

Refer to the separate Product Information of VISCOAT Viscoelastic Solution and PROVISC Viscoelastic Solution provided.

HOW SUPPLIED:

DUOVISC Viscoelastic Solution consists of sterile, non-pyrogenic viscoelastic material. DUOVISC is supplied in single-use glass syringes delivering:

- VISCOAT (sodium hyaluronate 30 mg/mL and sodium chondroitin sulfate 40 mg/mL) Viscoelastic Solution, 0.35 mL; and
 - PROVISC (sodium hyaluronate 10 mg/mL) Viscoelastic Solution, 0.4 mL.
- or
- VISCOAT (sodium hyaluronate 30 mg/mL and sodium chondroitin sulfate 40 mg/mL) Viscoelastic Solution, 0.5 mL; and
 - PROVISC (sodium hyaluronate 10 mg/mL) Viscoelastic Solution, 0.55 mL.

Both VISCOAT and PROVISC syringes are aseptically packaged in a single blister pack with two 27-gauge cannulae and one cannula locking ring for VISCOAT Viscoelastic Solution.

The VISCOAT and PROVISC delivery systems are coded to help distinguish one from the other. The VISCOAT delivery system includes a yellow end cap on the syringe and a yellow cannula cartridge cap. The PROVISC delivery system features a colourless syringe and a colourless cannula cartridge cap.

Refrigerated VISCOAT and PROVISC should be allowed to attain room temperature prior to use (approximately 20 - 40 minutes).

- Store in refrigerator (2°C - 8°C).
- Protect from freezing.
- Protect from light.

Made in Belgium

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® Registered trademark
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VISCOAT® (sodium hyaluronate and sodium chondroitin sulfate) Viscoelastic Solution

DESCRIPTION:

VISCOAT® is a sterile, non-pyrogenic, viscoelastic solution of a highly purified, non-inflammatory medium molecular weight fraction of sodium chondroitin sulfate and sodium hyaluronate.

Each 1 mL of VISCOAT Viscoelastic Solution contains 40 mg sodium chondroitin sulfate, 30 mg sodium hyaluronate, 0.45 mg sodium phosphate - monobasic monohydrate, 2.0 mg sodium phosphate - dibasic anhydrous, 4.3 mg sodium chloride, hydrochloric acid and/or sodium hydroxide (to adjust pH) with Water for Injections, q.s.

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 Viscoelastic Solution 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 moieties of these two compounds occur as repeating disaccharide subunits consisting of glucuronic acid in $\beta 1 \rightarrow 3$ linkage with N-acetylgalactosamine for sodium chondroitin sulfate and N-acetyl glucosamine for sodium hyaluronate. The subunits are then combined by $\beta 1 \rightarrow 4$ linkage of the amino sugar residue to the glucuronic residue of the next subunit to form large polymers. The two compounds differ in that the sodium chondroitin sulfate possesses a sulfate group and a double, rather than a single, negative charge (as in the case of sodium hyaluronate) per repeating disaccharide subunit.

Sodium chondroitin sulfate and sodium hyaluronate are biological polymers found in the extracellular matrix of animals and humans. The cornea is the ocular tissue having the greatest concentration of sodium chondroitin sulfate, while the vitreous and aqueous humour contain the greatest concentration of sodium hyaluronate.

VISCOAT is a specific formulation of sodium chondroitin sulfate-sodium hyaluronate that has been developed for use as an aid in ophthalmic surgery.

VISCOAT is completely transparent and exhibits excellent flow properties.

INDICATIONS:

VISCOAT is indicated for use as a surgical aid in anterior segment procedures including cataract extraction and intraocular lens implantation. VISCOAT maintains a deep chamber during anterior segment surgeries, enhances visualisation 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, thus preventing formation of a flat chamber during surgery.

CONTRAINDICATIONS:

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

WARNINGS:

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 the cannula.
- Use only if the material is clear.
- Avoid trapping air bubbles within VISCOAT before injection.

ADVERSE REACTIONS:

VISCOAT 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 effect such a rise if left in the eye after surgery.

CLINICAL APPLICATIONS:

For cataract surgery and intraocular lens implantation, VISCOAT should be carefully introduced using standard aseptic techniques (and using only the 27-gauge cannula provided with the syringe) into the anterior chamber prior to capsulotomy. VISCOAT may be injected into the chamber prior to or during removal of the crystalline lens. Instillation of VISCOAT prior to lens removal will provide additional protection to the corneal endothelium. Instillation of the solution provides a coating of VISCOAT which may protect the corneal endothelium from possible damage from surgical instrumentation during the cataract extraction surgery. VISCOAT may also be used to coat an intraocular lens as well as the tips of surgical instrumentation prior to implantation surgery. Additional VISCOAT may be injected during anterior segment surgery to fully maintain the chamber or replace any solution lost during the surgical procedure. At the end of the surgical procedure, it is recommended that VISCOAT be removed from the eye as completely as practical by thoroughly irrigating and aspirating with a balanced salt solution.

HOW SUPPLIED:

VISCOAT is a sterile, non-pyrogenic, 0.5 mL viscoelastic preparation supplied in a single-use syringe with a threaded luer tip. A sterile 27-gauge, single-use, bent, blunt-tip cannula and cannula locking ring are provided separately. The cannula sheath should be used to firmly attach the cannula to the syringe, followed by attachment of the cannula locking ring.

STORE BETWEEN 2°C - 8°C. REFRIGERATE. DO NOT FREEZE. PROTECT FROM LIGHT.

DIRECTIONS FOR USE:

FOR INTRAOCULAR USE.

BOTH VISCOAT AND CANNULA ARE DESIGNED FOR SINGLE USE ONLY.

The syringe assembly is designed only for the injection of the VISCOAT Viscoelastic Solution it contains. Use of the syringe assembly for aspiration is not advised.

NOTICE:

THIS VISCOAT® DELIVERY SYSTEM IS NOT DESIGNED OR INTENDED TO BE ATTACHED TO REUSABLE (METAL-HUBBED) INSTRUMENTS OR TO SINGLE-USE 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 BALANCED SALT 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 SOLUTION 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 TRAVELLED THE FULL LENGTH OF THE THREADS AND IS FIRMLY SEATED. USE ONLY THE CANNULA PROVIDED.
6. VISUALLY INSPECT THAT THE CANNULA THREADS HAVE TRAVELLED 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.
8. HOLD THE VISCOAT VISCOELASTIC SOLUTION SYRINGE UPRIGHT. SLIP THE CANNULA LOCKING RING OVER THE CANNULA ALLOWING THE DISTAL TIP OF THE CANNULA TO PASS THROUGH THE SMALL HOLE IN THE CANNULA LOCKING RING.
9. SECURE THE CANNULA BY ROTATING THE CANNULA LOCKING RING CLOCKWISE 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 VISCOELASTIC SOLUTION APPEARS AT THE CANNULA TIP.

Based on VISCOAT/PI-#6

PROVISC® (sodium hyaluronate) Viscoelastic Solution

DESCRIPTION:

PROVISC® Viscoelastic Solution is a sterile, non-pyrogenic, high molecular weight, noninflammatory highly purified fraction of sodium hyaluronate, dissolved in a physiological sodium chloride/phosphate buffer.

Each mL of sodium hyaluronate contains 10.0 mg sodium hyaluronate, 2.0 mg dibasic sodium phosphate, anhydrous; 0.45 mg monobasic sodium phosphate; 7.5 mg sodium chloride; hydrochloric acid and/or sodium hydroxide to adjust pH and Water for Injections to 1 mL.

CHARACTERISTICS:

Sodium hyaluronate is a high molecular weight polysaccharide, composed of sodium glucuronate and N-acetyl-glucosamine which forms a repeating disaccharide unit by linking alternate $\beta 1 \rightarrow 3$ and $\beta 1 \rightarrow 4$ glycosidic bonds. The 1% viscous and transparent solution, PROVISC, is a specific fraction of sodium hyaluronate, developed as an aid in ophthalmic surgery. It acts as a space-occupying fluid that replaces the body's natural fluids.

INDICATIONS:

PROVISC Viscoelastic Solution is indicated for use as an ophthalmic surgical aid in the anterior segment during cataract extraction and intraocular lens (IOL) implantation.

Ophthalmic viscoelastic solutions serve to maintain a deep anterior chamber during anterior segment surgery, thereby reducing trauma to the corneal endothelium and surrounding ocular tissues. They help to push back the vitreous face and prevent formation of a flat chamber postoperatively.

CONTRAINDICATIONS:

At present there are no known contraindications to the use of PROVISC Viscoelastic Solution when used as recommended; care should be used in patients with hypersensitivity to any components in this solution (see **PRECAUTIONS**).

PRECAUTIONS:

a) Precautions 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 monitored and appropriate therapy instituted if significant increases occur.

c) PROVISC should be removed by irrigation and/or aspiration at the close of surgery. Do not overfill the anterior chamber.

d) PROVISC Solution is obtained from microbial fermentation by a proprietary purification process. Although precautions have been taken to limit protein levels in this device, and it has been tested

in animals for allergic response, this device, used in susceptible persons, may produce allergic responses.

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

- * Do not reuse cannula.
- * Use only if solution is clear.
- * Avoid trapping air bubbles.

ADVERSE REACTIONS:

a) PROVISC Solution is tolerated after injection into human eyes during ophthalmic surgical procedures. As with most viscoelastic solutions, a transient rise in intraocular pressure has been reported in some cases.

b) Postoperative inflammatory reactions such as hypopyon and iritis have been reported with the use of ophthalmic viscoelastic solutions, as well as incidents of corneal oedema and corneal decompensation. Their relationship to the use of sodium hyaluronate (PROVISC) has not been established.

APPLICATIONS:

Cataract Surgery - IOL Implantation

A cannula or needle is used to slowly inject a sufficient amount of PROVISC solution into the anterior chamber. The injection may be performed before or after removal of the crystalline lens.

PROVISC Viscoelastic Solution may also be used to coat surgical instruments and the intraocular lens prior to implantation.

PROVISC Viscoelastic Solution can be injected during surgery to replace any PROVISC Viscoelastic Solution lost during surgical manipulation (see **PRECAUTIONS**).

DIRECTIONS FOR USE:

Refrigerated PROVISC should be allowed to attain room temperature prior to use (approximately 20 - 40 minutes).

- Store in refrigerator (2°C- 8°C).
- Protect from freezing.
- Protect from light.