Read this package insert completely before use and comply with the instructions for use.

ViscAid® Ophthalmic Viscoelastic

GRAPHICAL SYMBOLS			
	Single use only	REF	Catalog Number
	Read instructions before use	LOT	Lot Number
STERILE A	Sterilization using aseptic	2°C 8°C	Store at 2~8°C
	Do not re-sterilize		Keep away from sunlight
	Use by expiry date		Do not use if package is damaged
	Manufacturer		Recycling

Description

ViscAid® is a sterile, non-pyrogenic, ophthalmic viscosurgical device prepared of the non-inflammatory, high molecular weight fraction of sodium hyaluronate. This high molecular weight polymer is made up of repeating disaccharide units of N-acetylglucosamine and sodium glucuronate linked by ß 1-3 and ß 1-4 glycosidic bonds. Each pre-filled syringe contains 15 mg/mL of highly purified sodium hyaluronate dissolved in physiological saline solution. The viscoelastic solution has a molecular weight of 1,300,000 ~ 2,000,000 Dalton, a pH of 6.8 ~ 7.5, and an osmolality of approximately 290 mOsm/kg.

Indications

ViscAid® is indicated for use as surgical aids in ophthalmic anterior and posterior segment surgeries including intra-/extra- cataract extraction with or without implantation of an intraocular lens (IOL), intraocular lens implantation, keratoplasty / corneal transplantation surgery, glaucoma filtering surgery, and surgical procedures to reattach the retina. ViscAid® has also been used successfully as a vitreum replacement after vitrectomy and retinal detachment surgery. Due to its lubricating, transparent and viscoelastic properties, ViscAid® aids in maintaining a deep chamber and visibility during anterior segment surgeries, while allowing for more efficient manipulation and implantation with less trauma to the corneal endothelium and other surrounding ocular tissues. ViscAid® may also be used to coat an intraocular lens as well as the tips of surgical instruments prior to implantation surgery. The corneal endothelial cells and surrounding tissues are protected from possible damage arising from surgical instrumentation during ophthalmic surgeries. ViscAid® also preserves the tissue integrity and good visibility when used to fill the anterior or posterior segments of the eye following open sky procedures.

Contraindications

At present there are no contraindications to the use of ViscAid® when used as recommended as an intraocular implant.

General Information

Sodium hyaluronate is a high molecular weight polysaccharide composed of sodium glucuronate and N-acetylglucosamine. It is a physiological substance widely distributed in the extracellular matrix of connective tissues in both animals and human. Tissues with high concentrations of sodium hyaluronate include vitreous and aqueous humor of the eye, the synovial fluid, the skin, the umbilical cord and the dermis of rooster combs. Sodium hyaluronate functions as a tissue lubricant and it is thought to play an important role in modulating the interactions between adjacent tissues. Sodium hyaluronate prepared from different tissues may have different molecular weights but base on the same chemical structure.

ViscAid® is a specific high molecular weight fraction of sodium hyaluronate reported to be non-antigenic, non-pyrogenic and does not cause inflammatory or foreign body reactions. ViscAid® is well tolerated in human eyes and does not interfere with normal wound healing processes.

Precaution

- Those precautions normally considered during the surgical procedure should be observed.
- ViscAid® viscoelastics are prepared from a biological source. It is a highly purified fraction but may still contain minute amounts of proteins. The physician should be aware of potential risks that can be occurred with the injection of any biological materials.
- The intraocular pressure of patient receiving ViscAid® should be carefully monitored, especially during the immediate postoperative period. There may be an elevated postoperative intraocular pressure due to pre-existing glaucoma, compromised outflow or by the operative procedures itself. If the postoperative intraocular pressure increases above expected values, appropriate correcting therapy should be administered.
- An excess quantity of ViscAid® should not be used. All ViscAid® should be removed from the anterior chamber by irrigation or aspiration at the end of surgery.
- On infrequent occasions, reports have shown that ViscAid® may become cloudy or form diffuse precipitates or haziness following instillation into the eye. While such reports are seldom associated with any effects on ocular tissues, the physician should be aware of this occurrence. If it is observed, the precipitated matter should be removed by irrigation and/or aspiration. In vitro, laboratory studies have shown opalescence of sodium hyaluronate when mixed with solutions containing quarternary ammonium compounds. Hence, sodium hyaluronate should not be injected through a cannula used in conjunction with such solutions.
- Reuse of cannula should be avoided. Even after cleaning and rinsing, resterilized cannula could be denatured and release particulate matter as ViscAid® is injected. It is recommended that disposable cannula, such as the one provided in this package, should be used when administering ViscAid®.
- Do not use ViscAid® if package is opened or damaged.

Adverse Reaction

Sodium hyaluronate is a natural component in the tissues of the body and is extremely well tolerated in human eyes. Transient postoperative inflammatory reactions have been reported and oral or topical steroid preparation were administered. Animal study has confirmed the fact that sodium hyaluronate are non-inflammatory, hence any phlogistic response is considered to be consequences of the surgical procedures. The best index of the degree of inflammatory response is the postoperative clarity of the vitreous cavity. A transient postoperative increase in intraocular pressure has been observed following the use of sodium hyaluronate in anterior segment surgery. On rare occasions, postoperative reactions including inflammation, corneal edema and corneal decompensation have been reported. The relationship to the use of ViscAid® has not been established.

Administration

1. Cataract surgery and IOL implantation

The sufficient amount of ViscAid® is slowly infused through a needle or cannula into the anterior chamber to replace the aqueous humor before any instrument is introduced into the eye. Filling the anterior chamber and the capsular bag facilitates in-the-bag implantation. The protective effect of ViscAid® as an aid is optimized when the injection is performed prior to cataract extraction and insertion of IOL and is effective for both intra- and extra-capsular cataract procedures. ViscAid® may be applied to the IOL prior to insertion. Additional ViscAid® can be injected as required during surgery to replace any loss to facilitate surgical manipulation (see precautions).

2. Corneal transplantation surgery

The corneal button is removed and the anterior chamber filled with ViscAid® until it is level with the surface of the cornea. The donor graft is then placed on top of the ViscAid® and sutured into place. Additional ViscAid® can be used as required to aid in the surgical procedures (see precautions).

3. Glaucoma filtration surgery

ViscAid® is injected slowly and carefully through a corneal paracentesis to restore and maintain the anterior chamber volume during the performance of the trabeculectomy. Additional ViscAid® can be injected until it extruded into the subconjunctival filtration site through and around the sutured outer scleral flap (see precautions).

4. Intraocular injection with scleral buckling procedures for retina reattachment

After release of subretinal fluid and development of buckling by tying the mattress sutures, air is injected into the vitreous cavity and then exchanged with ViscAid® injected through a needle (22 to 30 gauge) passed via the pars plana epithelium. The volume of ViscAid® injected (2-4 mL) will vary with the volume of the subretinal fluid released and the space occupied by the buckle.

5. Trauma

A sufficient amount of ViscAid® can be used in the management of various kinds of penetrating eye trauma. It is injected to reform the anterior chamber, to maneuver, protect and support ocular tissues and to create space for surgical instruments during reconstructive surgery.

Storage Conditions and Shelf Life

Shelf life is 3 years if stored in original unopened package at the correct temperature.
Store at 2-8°C. Protect against light, heat and frost. DO NOT FREEZE.
KEEP OUT OF THE REACH OF CHILDREN.

How Supplied

ViscAid® is a sterile viscoelastic preparation of sodium hyaluronate in physiological buffered saline solution, supplied in a sterile disposable syringe. Each pre-filled syringe contains of 15 mg/mL (1.5%) sodium hyaluronate. The syringe is supplie with one sterile 27G cannula. ViscAid® syringe is terminally sterilized and aseptically packaged. Refrigerated ViscAid® should be allowed to reach room temperature prior to use.

Each mL contains:
Sodium hyaluronate 15.0 mg
Sodium chloride13.5mg
Sterile water for injection q.s.
Sodium hydroxide and/or hydrochloric acid for pH adjustment (if necessary)

Catalogue No.	Product spectrum
VA-2040	0.40cc 1.5% Sodium Hyaluronate
VA-2055	0.55cc 1.5% Sodium Hyaluronate
VA-2080	0.80cc 1.5% Sodium Hyaluronate
VA-2100	1.00cc 1.5% Sodium Hyaluronate

Warnings

- Reading expiration date before use. Do not use if expiration date gas been exceeded.
- Do not concomitantly use disinfectants containing quaternary ammonium salts because hyaluronate can be precipitated in their presence.
- Anaphylactic and allergic reactions have been reported with this product.
- STERILE CONTENTS. The syringe is intended for single use only. Discard any unused ViscAid®.
- ViscAid should be used in a clean surgery room.
- ViscAid can not be reuse, the patient may expose the risk of disease and have possibility od cross-infection may lead to death.

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