

*"I have used all the various Sodium Hyaluronate products and after having used Shellgel™ viscoelastic, there is no reason to use any of the others! Shellgel performs as well or better than any. I appreciate the .8mL volume of the syringe, which enables me to complete all cases without resorting to a 2nd syringe. I also find Shellgel to be a superior value."*

—Kevin Kovach, M.D.,  
Elmhurst Outpatient Surgery  
Center, Elmhurst, IL.



# Shellgel™

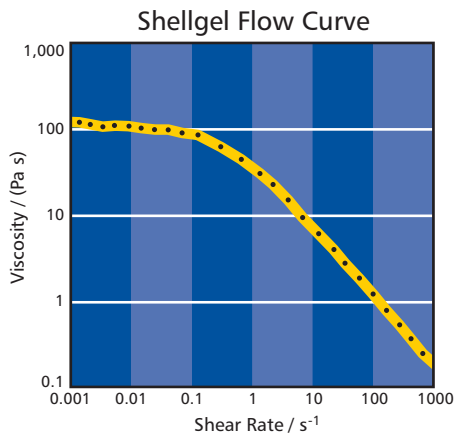
SODIUM HYALURONATE



- Surgically efficient: Easy to use and remove, optically clear
- Efficacy: Excellent chamber maintenance, endothelial protection
- Sodium Hyaluronate – Highest quality industry standard
- Quality: 100% final visual inspection
- Economical
- Latex Free



The next generation of surgical ophthalmic products.



Distributed by:

**PRODUCT INFORMATION**

**DESCRIPTION** SHELLGEL is a sterile nonpyrogenic, transparent viscoelastic solution of highly purified sodium hyaluronate. SHELLGEL contains 12 mg/mL of high molecular weight (greater than 1 million daltons) sodium hyaluronate dissolved in physiological saline. In the limit of zero shear rate, the viscosity is 105,000 cps (105 Pa s) at 25°C, and the osmolality is approximately 320 milliosmols (1).

Sodium hyaluronate is a naturally occurring polysaccharide composed of sodium glucuronate and N-acetylglucosamine found throughout the tissues of both man and animals. SHELLGEL is prepared from the dermis of rooster combs (2).

**INDICATIONS**

SHELLGEL is intended for use during surgery in the anterior (3) and posterior (4) segments of the human eye. Procedures include:

- Cataract extraction
- Corneal transplantation surgery
- Surgical procedures to reattach the retina
- Intraocular lens (IOL) implantation
- Glaucoma filtering surgery

SHELLGEL is designed to create and maintain anterior chamber depth and visibility, protect corneal endothelial cells and other intraocular tissues, minimize interaction between tissues during surgical manipulation, and act as a vitreous substitute during retinal reattachment surgery (5). SHELLGEL also preserves tissue integrity and good visibility when used to fill the anterior and posterior segments of the eye following open sky procedures.

**CONTRAINDICATIONS**

At the present time there are no contraindications for the use of SHELLGEL when used as recommended.

**PRECAUTIONS**

Those precautions normally considered during anterior segment and retinal attachment procedures are recommended. Transient increases in intraocular pressure may occur following surgery because of preexisting glaucoma or due to the surgery itself (6). For these reasons, the following precautions should be considered:

- An excess quantity of SHELLGEL should not be used.
- SHELLGEL should be thoroughly removed from the anterior chamber after surgery to prevent or minimize post-operative intraocular pressure increases (spikes).
- If the post-operative intraocular pressure increases above expected values, appropriate therapy should be initiated.
- SHELLGEL is prepared from a biological source and the physician should be aware of the possible effects of using any biological material.
- A single use disposable cannula, such as the one provided in this package, should be used when administering SHELLGEL. Reuse of cannula should be avoided. The repeated use of a cannula could release particulate matter as SHELLGEL is injected.
- There have been isolated reports of diffuse particulates or haziness appearing after injection of products similar to SHELLGEL into the eye. While such reports are infrequent and seldom associated with any effects on ocular tissues, the physician should be aware of the occurrence. If observed, the particulate matter should be removed by irrigation and or aspiration.

**APPLICATIONS**

**Cataract surgery and IOL implantation**

The required amount of SHELLGEL is slowly infused through a needle or cannula into the anterior chamber. The protective effect of SHELLGEL as a surgical aid is optimized when the injection is performed prior to cataract extraction and insertion of the IOL, and is effective for both intra- and extracapsular cataract procedures. SHELLGEL may be applied to the IOL prior to insertion.

**Corneal transplant surgery**

The corneal button is removed and the anterior chamber filled with SHELLGEL, until it is level with the surface of the cornea. The donor graft is then placed on top of the SHELLGEL and sutured into place.

**Glaucoma filtration surgery**

SHELLGEL is injected through a corneal paracentesis to restore and maintain anterior chamber volume during the performance of the trabeculectomy

**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 SHELLGEL injected through a needle (22 to 30 gauge) passed via the pars plana epithelium. The volume of SHELLGEL injected (2-4mL) will vary with the volume of the subretinal fluid released and the space occupied by the buckle.

**HOW SUPPLIED**

SHELLGEL is a sterile viscoelastic preparation supplied in a disposable glass syringe delivering 0.8 mL of sodium hyaluronate dissolved in physiological saline. Each mL contains 12 mg of sodium hyaluronate, 9 mg of sodium chloride and q.s. sterile water for injection USP Sodium hydroxide and or hydrochloric acid are used to adjust pH (if necessary). SHELLGEL is sterile filtered and aseptically transferred to syringes. The filled syringes are sealed and the final packaging is sterilized by irradiation. Contents are sterile and nonpyrogenic in unopened and undamaged pouches. Do not use if package is opened or damaged.

**STORAGE AND HANDLING**

Store at 2 to 8 °C. Protect from freezing. Refrigerated SHELLGEL should be allowed to reach room temperature (approximately 20 to 45 minutes) prior to use.

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

**REFERENCES**

1. Arshinoff, Steve A., MD; "Dispersive and Cohesive Viscoelastic Materials in Phacoemulsification," Ophthalmic Practice; 13:3, 1995.
2. Swann DA. Studies of Hyaluronic Acid. I. The preparation and properties of rooster comb hyaluronic acid. Biochim Biophys Acta 1968; 156:17.
3. Pape LG, Balazs EA. The use of sodium hyaluronate (Healon®) in human anterior segment surgery. Ophthalmol 1980; 87:699.
4. Pruet RC, Schepens CL, Swann DA. Hyaluronic acid vitreous substitute. A six year clinical evaluation. Arch Ophthalmol 1979; 97:2325.
5. Miller D, Stegmann R. Use of Na-hyaluronate in anterior segment eye surgery. AM Intra-Ocular Implant Soc J 1980; 6:13.
6. Miller D, Stegmann R. The use of Healon® in intraocular lens implantation. Int Ophthalmol Clinics 1982; 22:177.

Manufactured by:  
 Anika Therapeutics, Inc.  
 Woburn, MA 01801 USA

Healon is a registered trademark of Pharmacia Corp.  
 SHELLGEL is a trademark of Cytosol Ophthalmics, Inc.  
 ©Copyright 2001 Anika Therapeutics, Inc. All Rights Reserved.