

“Laser Sight Centres Sydney have used Cytosol Ophthalmics BSS for over two years and have found the company and the product able to meet our high standards. We have never experienced an adverse reaction. Cytosol products are without a doubt, safe and effective, economical and environmentally compatible.”

Louise Rasmus
Director of Nursing
Laser Sight Centres
Sydney, Australia

- Proven history – Manufactured for over 18 years with no adverse reactions reported
- Economical
- Multiple sizes to fit every need – 18ml, 200, 250, 500
- Polypropylene plastic – non-pvc is a safe alternative to glass
- Terminally steam sterilized – insures a sterile product with no EtO residuals
- Latex free – no adverse reactions



**CYTOSOL
OPHTHALMICS™**

Balanced Salt Solution
(STERILE IRRIGATING SOLUTION)



**CYTOSOL
OPHTHALMICS™**

The next generation of surgical ophthalmic products.



- REF 8100** A. 500 mL Glass Bottle 12 Bottles/Case Weight 11.3 kgs (25 lbs.) Cube .27 m³ (.95 ft³)
- REF 8120** B. 200 mL Glass Bottle 12 Bottles/Case Weight 5 kgs (11 lbs.) Cube .011 m³ (.4 ft³)
- REF 8110** C. 500 mL Plastic Bottle 6 Bottles/Case Weight 3.6 kgs (8 lbs.) Cube .008 m³ (.28 ft³)
- REF 8125** D. 250 mL Plastic Bottle 12 Bottles/Case Weight 4.1 kgs (9 lbs.) Cube .008 m³ (.28 ft³)
- REF 8118** E. 18 mL Plastic Bottle 30 Overwrapped Bottles/Case Weight 1.3 kgs (2.8 lbs.) Cube .008 m³ (.28 ft³)

Technical Information

DESCRIPTION:

Cytosol Ophthalmics™ Balanced Salt Solution (Sterile Irrigating Solution) is a sterile, low particulate, physiologic solution which is isotonic to ocular tissue and contains electrolytes required for normal cellular metabolic functions. Each 1.0 mL contains Calcium Chloride Dihydrate (CaCl₂ • 2H₂O), USP .48 mg, Magnesium Chloride Hexahydrate (MgCl₂ • 6H₂O), USP .30 mg, Potassium Chloride (KCl), USP .75 mg, Sodium Acetate Trihydrate (C₂H₃NaO₂ • 3H₂O), USP 3.90 mg, Sodium Chloride (NaCl), USP 6.40 mg, Sodium Citrate Dihydrate (Na₃C₆H₅O₇ • 2H₂O), USP 1.70 mg, and Water for Injection, USP q.s. Hydrochloric Acid and or Sodium Hydroxide added to adjust pH.

CLINICAL PHARMACOLOGY:

A physiological irrigating solution.

INDICATION AND USAGE:

For irrigation of eyes, ears, nose and or throat during a variety of surgical procedures.

WARNINGS:

DO NOT ADMINISTER BALANCED SALT SOLUTION INTRAVENOUSLY. NOT FOR INJECTION.

PRECAUTIONS:

This solution does not contain a preservative and should be discarded after a single use. Do not use this solution unless it is clear and vacuum is present. Do not use if seal assembly or bottle is damaged. The addition of any medication to Balanced Salt Solution may result in damage to intraocular tissue. Studies suggest that intraocular irrigating solutions which are iso-osmotic with normal aqueous fluids should be used with caution in diabetic patients undergoing vitrectomy since intraoperative lens changes have been observed.^{1,2} There have been reports of corneal clouding or edema following ocular surgery in which Balanced Salt Solution was used as an irrigating fluid. As in all surgical procedures appropriate measures should be taken to minimize trauma to the cornea and other ocular tissues.

A DIVERSE REACTIONS:

Bullous keratopathy may result when abnormal corneal endothelium is irrigated or subjected to any other trauma. Should any adverse reaction occur, discontinue use of this product, institute appropriate care, and save the remaining fluid for analysis.

DOSAGE AND ADMINISTRATION:

Balanced Salt Solution should be in conjunction with established practices for each surgical procedure. For 500mL, 250mL, and 200mL bottles, an administration set equipped with an air inlet device in the plastic spike end should be used since the container does not have an airway tube: 1. Flip off plastic cap from the aluminum seal assembly; 2. Using a septic technique, it is recommended to insert the spike through the larger circular, indented area of the rubber plug; 3. Prior to irrigating, invert the bottle and allow solution to flow entire length of tubing so air is purged from the tubing. For 18mL plastic bottles, the Luer-Lok® adapter is designed to accept a needle or other device with reciprocal fitting. For external irrigation, attachment of any device may not be necessary. To use the container in an aseptic field: 1. Remove the backing material to expose the container of Balanced Salt Solution, 2. Aseptically transfer the container out of the plastic tray and remove the protective cap with a brisk twist to reveal the adapter; 3. Attach needle or appropriate attachment by pushing it firmly onto the adapter and twisting into place; 4. Prior to use, test the assembly to ensure proper function.

HOW SUPPLIED:

REF 8100 500mL Glass Bottle NDC 61534-8100-5 (box of 12)
REF 8110 500mL Plastic Bottle NDC 61534-8100-1 (box of 6)
REF 8118 18mL Plastic Bottle NDC 61534-8100-8 (box of 30)
REF 8120 200mL Glass Bottle NDC 61534-8100-2 (box of 12)
REF 8125 250mL Plastic Bottle NDC 61534-8100-3 (box of 12)

STORAGE:

Store under normal room conditions at temperature ranges from 46 °F to 75 °F (85°C -24°C). Avoid exposure to excessive heat and do not allow to freeze.

REFERENCES:

1. Faulborn, J., Conway, B.P., Macherer, R., Surgical Complications of Pars Plana Vitreous Surgery. Ophthalmology 85:116-125, 1978.
2. Haimann, M.H. and Abrams, G.W., Prevention of Lens Opacification During Diabetic Vitrectomy Ophthalmology 91: 116-121, 1984.

Authorized European Representative: MDSS GmbH, Burckhardtstr. 1, D-30163 Hannover, Germany

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"We have been using Cytosol products for over 14 years in thousands of cataract cases. I find that Cytosol provides an excellent quality product with superior customer service... every time!"

—Vickey Shoemaker, R.N.,
Cabarrus Eye Center,
Concord, NC.



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Our full array of precision-etched metal blades are available in full-handle or blade and tip format. Designed for unparalleled surgical precision, the blades are acid-etched, producing an edge technically superior to one mechanically ground. The consistent edge, immune to the human errors inherent in mechanical grinding, eliminates tearing or burrs and allows for precise self-sealing wound closure.

Our Product Line Includes:



0001

Stab Knives -15°, 22.5°, 30°, or 45° with available restricted depth blade.

0002

Crescent Knives - Designed for creating a perfect scleral shelf and self-sealing wound.

0003

Slit Knives - Consistent phaco width incisions. Available in bevel up, double bevel, or parallel sides.

0004

Implant Knives - Precise lens insertion width, available with pilot tip to perfectly follow the slit blade incision.

0005

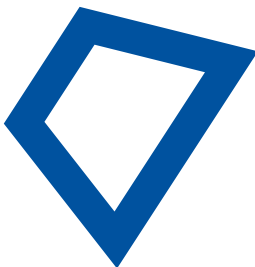
Clear Cornea Knives - Available from 2.65mm to 3.2mm widths, angled or straight, standard or parallel sides, with depth markings at 1.5mm, 1.75mm, and 2.0mm.

0006

Trapezoid Knives - Economical all-in-one clear cornea and implant knife. Sizes from 2.75mm - 3.00mm to 3.2mm - 3.75mm. Creates oarlock effect during phaco, reducing wound stretching.

0007

Vitrectomy Knives - Precise access incisions for all your posterior segment instruments.



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"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.



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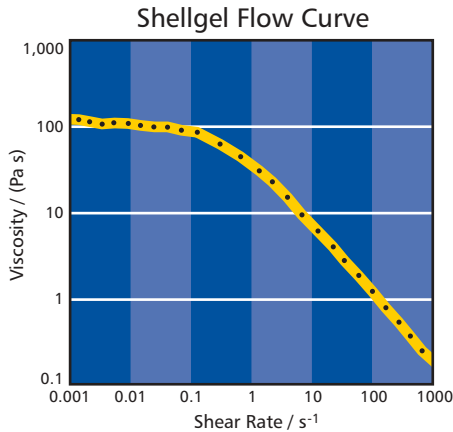
SODIUM HYALURONATE



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- Efficacy: Excellent Chamber maintenance, good endothelial protection
- Sodium Hyaluronate – Highest quality industry standard
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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. USR 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

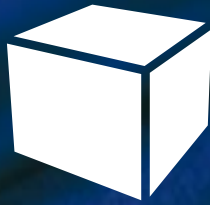
1. Arshinoff, Steve A., MD; "Dispersive and Cohesive Viscoelastic Materials in Phacoemulsification," Ophthalmic Practice; 13:3, 1995.
2. Swann DA. Studies of Hyaluronic Acid. I. The preparation and properties of rooster comb hyaluronic acid. Biochim Biophys Acta 1968; 156:17.
3. Pape LG, Balazs EA. The 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.
Waltham, MA 01801 USA

P/N 495-003 rev. 6/01
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"We are delighted with the exceptional service given by Cytosol Ophthalmics. The products are very competitively priced and the quality control is unfaulted."

—Eye Clinic,
Footscray,
Victoria, Australia.



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ExactPack™ custom surgical kits are ideal for your specific surgical supply needs. All the components needed for a particular procedure are prepackaged and prepared in a single kit, rather than having to assemble all the components from various packages and quantities. ExactPack custom surgical kits will save you time and money. Possible component sets could include the following:



**EYES001: Lasik
ExactPack # 1**

Designed for Bi-Lateral Procedures Includes: 2 - 3cc L/S Syringe; 1 - .22 Micron Fluid Filter; 4 - 4x4 4-Ply Gauze; 1 - Tray, 10x10x2; 1 - Skin Marker with ruler; 1 - Blue O.R. Towel; 1 - 18ml BSS; 1 - PVP Swabstick; 2 - Eye Shield; 1 - Utility Drape w/ tape; 1 - Drape, Bilateral Ophthalmic 54 x 44; 1 - Nevyas Drape Retractor; 2 - Eye Spears 10/pk; 2 - 1oz Medicine Cup; 1 - CSR Wrap

**EYES002: Lasik
ExactPack # 2**

For use with Microkeratome Instruments Includes: 2 - 3cc L/S Syringe; 1 - .22 Micron Fluid Filter; 4 - 4x4 4-Ply Gauze; 1 - Tray, 10x10x2; 1 - Skin Marker with ruler; 2 - Eye Shield; 1 - Utility Drape w/ tape; 1 - 18ml BSS; 2 - Eye Spears 10/pk; 1 - White O.R. Towel; 1 - 15x15 Aperture Drape; 1 - CSR Wrap

**EYES003: Lasik
ExactPack # 3**

Includes: 2 - 3cc L/S Syringe; 4 - 4x4 4-Ply Gauze; 1 - Tray, 10x10x2; 1 - Skin Marker with ruler; 1 - 18ml BSS; 1 - PVP Swabstick; 2 - Eye Shield; 1 - Utility Drape w/ tape; 1 - White O.R. Towel; 1 - Steri-Strip w/ Iodophor 5x4 6'pk; 2 - Eye Spears 10/pk; 1 - CSR Wrap

**EYES004: Lasik
ExactPack # 4**

Designed for Maximum Fluid Control Includes: 1 - .22 Micron Fluid Filter; 4 - 4x4 4-Ply Gauze; 1 - Tray, 10x10x2; 1 - Steri-Strip w/ Iodophor 5x4 6'pk; 1 - Skin Marker with ruler; 1 - 18ml BSS; 1 - PVP Swabstick; 2 - Eye Shield; 1 - Utility Drape w/ tape; 1 - White O.R. Towel;

**EYES005: Basic
Cataract ExactPack**

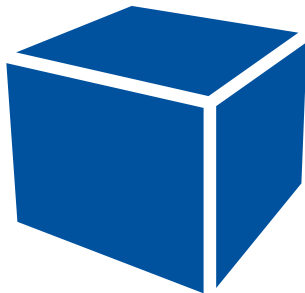
Includes: 1 - 250cc Bowl; 1 - Opth. Incise Drape 51x51; 1pr - Gloves, Surgeons 7.5; 1 - 1cc L/S Syringe; 1 - 25G x 5/8" Needle; 1 - Gown, Lg Non-Reinf.; 1 - Eye Spears 10/pk; 1 - Instrument Wipe; 1 - Gown, XL Non-Reinf.; 1 - Utility Drape w/ tape; 2 - 2oz Medicine Cup; 1pr - Gloves, Derma 7.5 latex free; 1 - 5cc L/L Syringe; 3 - Absorbent Towel; 1 - 1oz PVP Iodine Prep; 2 - 3" Cotton Tip Applicator; 1 - Mayo Cover; 1 - Table Cover 50x90; 1 - Bedside Bag; 1 - 25G x 5/8" Needle; 1 - 4x4 4-Ply Gauze

**EYES006: Advanced
Cataract ExactPack**

Includes: 1 - 3cc L/L Syringe; 1 - .22 Micron Fluid Filter; 30 - 4x4 4-ply Gauze; 2 - 1oz Medicine Cup; 1 - Tray, 2 compartment; 1 - 250cc Bowl; 1 - Mayo Cover; 1pr - Gloves, Surgeons sz 7.5; 1 - Gown, Lg Non-Reinf.; 1 - 1cc L/S Syringe; 1 - 25G x 5/8" Needle; 1 - Eye Spears 10/pk; 1 - Instrument Wipe; 1 - Gown, XL Non-Reinf.; 1 - Utility Drape w/ tape; 1 - 18G Bi-Polar Cautery Pencil; 2 - 2oz Medicine Cup; 1 - Mayo Tray, 14 x 10 x 1; 1 - Emesis Basin; 1 - Ant. Chamb. Cannula, 30G; 1 - 27G Capsule Polisher; 1 - Opth. Incise Drape, 51x51; 1 - Medium Drape; 1 - Ophthalmic Drape; 1 - EENT Split Drape; 1 - Utility Drape w/ tape; 1pr - Gloves, Derma sz 7.5 latex free; 1 - 5cc L/S Syringe LOR; 1 - 10cc L/L Syringe; 1 - 2oz Ear/Ulcer Syringe; 1 - Utility Drape w/ tape; 1 - Rubberband; 1 - Steri-Strips, 1/4x3 3/pk; 1 - 4oz PVP Scrub; 4 - 3" Cotton Tip Applicator; 12 - 6" Cotton Tip Applicator; 1 - Lt Corneal Shield; 1 - Drain, Eye Wick 80cc; 1 - .2 Micron Filter; 1 - Ocular Occluder; 2 - Eye Shield; 1 - Table Cover, 50x90; 1 - Bedside Bag; 1 - 12ft Bi-polar Cord; 1 - 35oz Bowl; 1 - Mayo Cover; 1 - 25G x 5/8" Needle

**EYES007: General
Refractive ExactPack**

Includes: 1 - 15x15 Aperture Drape; 1 - Visimark Dome; 1 - Instrument Wipe; 1 - Eye Spears 5/pk; 1pr - Gloves, Surgeons sz 7.5; 1pr - Gloves, Exam; 1 - Plastic Drape, 18x26; 8 - 4x4 12ply Gauze; 1 - Absorbent Towel



If the components included in these ExactPacks do not fit your needs, please call 1-800-234-5166 and we will create a custom ExactPack to your specifications.

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