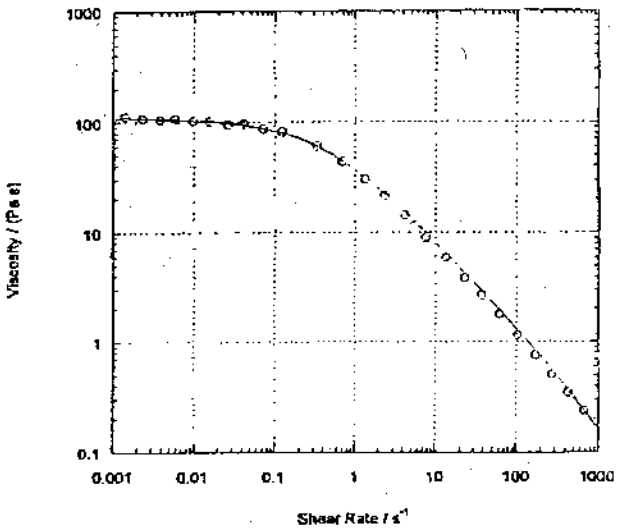
STAARVISC™ II
Sodium Hyaluronate

PRODUCT INFORMATION

DESCRIPTION
STAARVISC™ II is a sterile nonpyrogenic, transparent viscoelastic solution of highly purified sodium hyaluronate. **STAARVISC II** 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 milliosmoles (1).

STAARVISC™ II Flow Curve



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

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

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

STAARVISC II 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). **STAARVISC II** 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 to the use of **STAARVISC II** 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 **STAARVISC II** should not be used.
- **STAARVISC II** should be thoroughly removed from the anterior chamber after surgery to prevent or minimize post-operative intraocular pressure increases (spikes).

- If the postoperative intraocular pressure increases above expected values, appropriate therapy should be initiated.
- **STAARVISC II** 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 **STAARVISC II**. Reuse of cannula should be avoided. The repeated use of a cannula could release particulate matter as **STAARVISC II** is injected.
- There have been isolated reports of diffuse particulates or haziness appearing after injection of products similar to **STAARVISC II** 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 **STAARVISC II** is slowly infused through a needle or cannula into the anterior chamber. The protective effect of **STAARVISC II** 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. **STAARVISC II** may be applied to the IOL prior to insertion.

Corneal transplant surgery
The corneal button is removed and the anterior chamber filled with **STAARVISC II** until it is level with the surface of the cornea. The donor graft is then placed on top of the **STAARVISC II** and sutured into place.

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

HOW SUPPLIED

STAARVISC II 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). **STAARVISC II** 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 the package is opened or damaged.

STORAGE AND HANDLING

Store at 2 to 8°C. Protect from freezing. Refrigerated **STAARVISC II** 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.

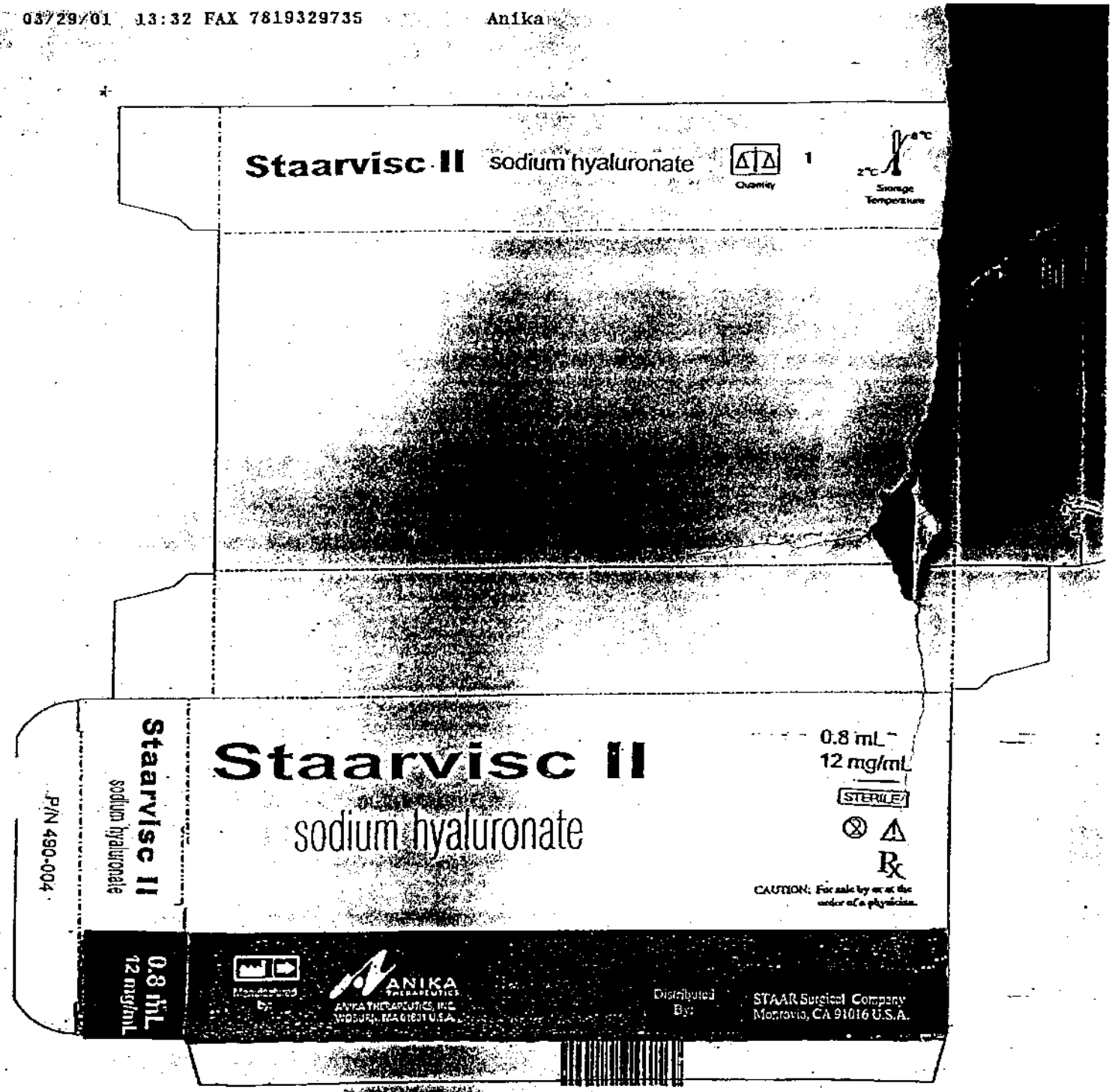
REFERENCES

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. Pruett RC, Schepens CL, Swann DA. Hyaluronic acid vitreous substitute. A six year clinical evaluation. Arch Opthalmol 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

Distributed by:
STAAR Surgical Company
Monrovia, CA 91016 USA
(626) 303-7902

P/N 490-003 rev 03/01


Staarvisc II sodium hyaluronate
1
Quantity
2°C 8°C
Storage Temperature
Staarvisc II
sodium hyaluronate
P/N 490-004
0.8 mL
12 mg/mL
Staarvisc II
sodium hyaluronate
0.8 mL
12 mg/mL
STERILE
Rx
CAUTION: For sale by or at the order of a physician.
Manufactured by:
ANIKA THERAPEUTICS
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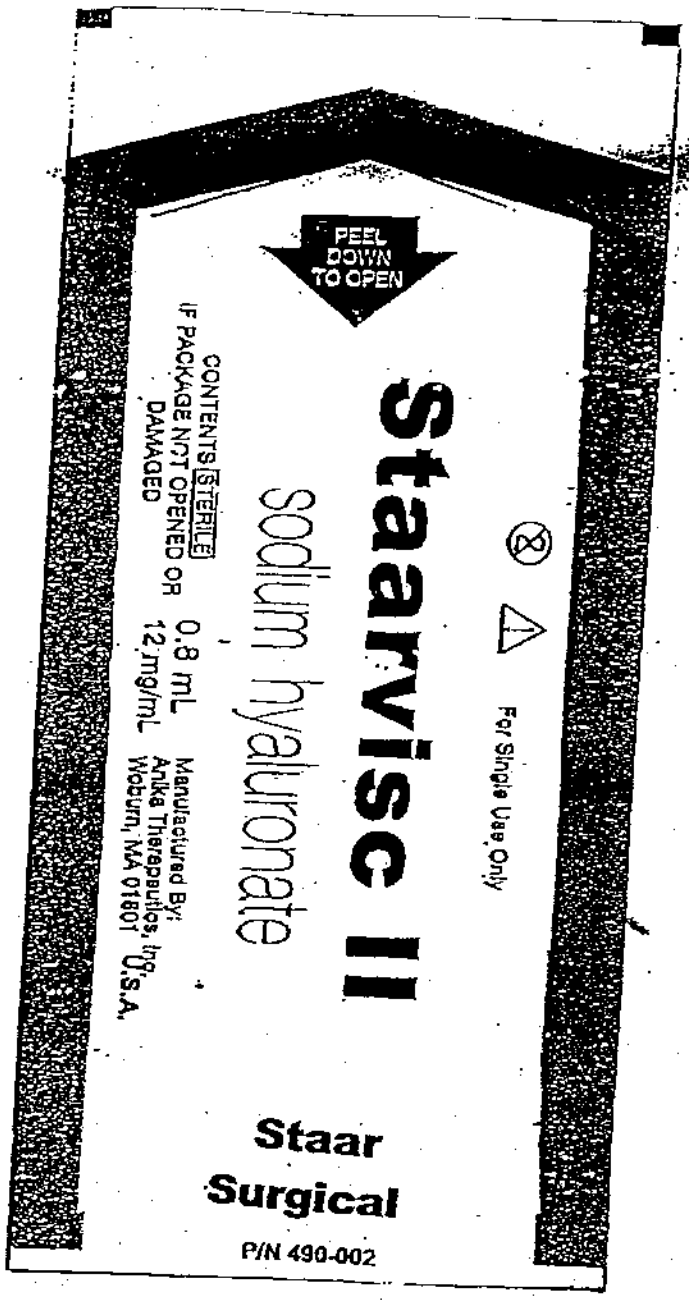
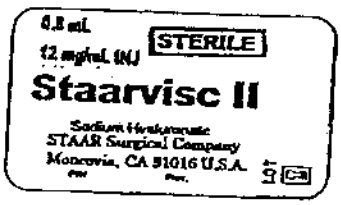

PEEL DOWN TO OPEN
Staarvisc II
sodium hyaluronate
For Single Use Only
CONTENTS STERILE IF PACKAGE NOT OPENED OR DAMAGED
0.8 mL
12 mg/mL
Manufactured By:
Anika Therapeutics, Inc.
Woburn, MA 01801 U.S.A.
Staar Surgical
P/N 490-002


0.8 mL
12 mg/mL (IN)
STERILE
Staarvisc II
Sodium Hyaluronate
STAAR Surgical Company
Monrovia, CA 91016 U.S.A.

(1) 27GA
Anterior Chamber Cannula

Contents sterile if pouch
is not opened or damaged.
Do not resterilize.

SINGLE USE ONLY

STERILE R

LOT

Manufactured For:

Anika Therapeutics, Inc.
Woburn, MA 01801 USA

P/N 300-019