

# DUOVISC®

## Viscoelastic System

### VISCOAT® Ophthalmic Viscosurgical Device

### PROVISC® Ophthalmic Viscosurgical Device

**DUOVISC® Viscoelastic System is designed to give two viscoelastic materials with different physicochemical properties that can be used differently and sequentially to perform specific tasks during a cataract procedure. The choice of the viscoelastic is based upon an understanding of the differential ability of each to facilitate performance of the surgical task at hand. DUOVISC® Viscoelastic System consists of VISCOAT® Ophthalmic Viscosurgical Device and PROVISC® Ophthalmic Viscosurgical Device.** The use of **VISCOAT® Ophthalmic Viscosurgical Device** in the initial phases of the anterior segment surgery takes advantage of **VISCOAT® Ophthalmic Viscosurgical Device's** demonstrated tissue protection (1-3) properties. The use of **PROVISC®** during the later phases of the anterior segment surgery takes advantage of the physicochemical properties that make it better suited for the expansion of the capsular bag and facilitation of intraocular lens implantation following the cataract extraction with VISCOAT®.

#### APPLICATIONS:

VISCOAT® Ophthalmic Viscosurgical Device should be carefully introduced using standard sterile techniques (using the 27-gauge cannula provided with the syringe) into the anterior chamber prior to capsulotomy. Instillation of VISCOAT® prior to lens removal will provide additional protection to the corneal endothelium. Instillation of the solution at this point is significant in that a coating of VISCOAT® may protect the corneal endothelium from possible damage arising from surgical instrumentation during the cataract extraction surgery.

Additional VISCOAT® may be instilled intracamerally during anterior segment surgery to fully maintain the anterior chamber or replace any volume 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 sterile irrigating solution.

PROVISC® Ophthalmic Viscosurgical Device also possesses physicochemical properties that make it well suited for tissue manipulation, such as expansion of the capsular bag and facilitation of intraocular lens implantation following cataract extraction with VISCOAT®.

The cannula provided is used to slowly and carefully instill an amount of PROVISC® into the anterior chamber. The instillation may be performed 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 instilled during surgery to replace any PROVISC® lost during surgical manipulation (see PROVISC® **PRECAUTIONS** Section).

#### HOW SUPPLIED:

DUOVISC® Viscoelastic System consists of sterile, non-pyrogenic viscoelastic materials (refer to the separate PROVISC® and VISCOAT® Package Inserts provided). DUOVISC® is supplied in disposable glass syringes delivering 0.35 mL or 0.50 mL of VISCOAT® and 0.4 mL or 0.55 mL of PROVISC®.







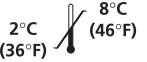

Both VISCOAT® and PROVISC® syringes are aseptically packaged in a single blister pack and terminally sterilized.

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

- Store in refrigerator (2°-8°C, 36°-46°F).
- Protect from freezing.
- Protect from light.

U.S. Patents Nos. 5,273,056; 5,876,379 and 6,051,560.

## Symbols Used On Labeling

Symbol	English
	Attention: See Instructions for Use
	Do not reuse
	Use by (YYYY-MM): Year-Month
	Batch Code
	Sterilized Using Aseptic Processing Techniques
	This Product Contains Dry Natural Rubber ( <i>Provisc</i> )
	Temperature Limitation Store between 2°-8°C (36°-46°F)
	Does Not Contain Dry Natural Rubber or Natural Rubber Latex ( <i>Viscoat</i> )

## Alcon®

**Alcon Laboratories, Inc.**

Fort Worth, Texas 76134 USA

Made in Belgium

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# PROVISC®

## (Sodium Hyaluronate)

Ophthalmic Viscosurgical Device

### DESCRIPTION:

PROVISC® Ophthalmic Viscosurgical Device is a sterile, non-pyrogenic, high molecular weight, non-inflammatory highly purified fraction of sodium hyaluronate, dissolved in physiological sodium chloride phosphate buffer.

Each mL of PROVISC® contains active 10.0 mg sodium hyaluronate; 0.56 mg dibasic sodium phosphate, anhydrous; 0.04 mg monobasic sodium phosphate, monohydrate; 8.4 mg sodium chloride; hydrochloric acid and/or sodium hydroxide to adjust pH and water for injection.

### 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 alternately beta 1-3 and beta 1-4 glycosidic bonds. The 1% viscous and transparent material, 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® Ophthalmic Viscosurgical Device is indicated for use as an ophthalmic surgical aid in the anterior segment during cataract extraction and intraocular lens (IOL) implantation.

Ophthalmic viscoelastics serve to maintain a deep anterior chamber during anterior segment surgery allowing reduced trauma to the corneal endothelium and surrounding ocular tissues. They help to push back the vitreous face and prevent formation of a flat chamber during surgery.

### CONTRAINDICATIONS:

At present there are no known contraindications to the use of PROVISC® Ophthalmic Viscosurgical Device when used as recommended; care should be used in patients with hypersensitivity to any components in this material (**see Precautions section**).

### PRECAUTIONS:

- Precautions normally associated with anterior segment surgical procedures should be observed.
- Postoperative increases in intraocular pressure have been reported with sodium hyaluronate products. The IOP should be carefully monitored and appropriate therapy instituted if significant increases occur.
- It is recommended that PROVISC® Ophthalmic Viscosurgical Device be removed by irrigation and/or aspiration at the close of surgery. Do not overfill the anterior chamber.**
- PROVISC® is obtained from microbial fermentation by a purified proprietary process. Although precautions have been taken to make this device protein-free and it has been tested in animals for allergenic response, this device, used in susceptible persons, may produce allergenic responses.

### DIRECTIONS FOR USE:

#### FOR INTRAOCULAR USE. FOR SINGLE USE ONLY.

The syringe assembly is designed only for the injection of the PROVISC® Ophthalmic Viscosurgical Device it contains. Use of the syringe assembly for aspiration is not advised.

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

**NOTICE: THIS PROVISC® DELIVERY SYSTEM IS NOT DESIGNED OR INTENDED TO BE ATTACHED TO REUSABLE (METAL-HUBBED) INSTRUMENTS OR TO DISPOSABLE INSTRUMENTS OTHER THAN THE ONE PROVIDED WITH THE PRODUCT. FAILURE TO FOLLOW THESE ASSEMBLY INSTRUCTIONS MAY RESULT IN CANNULA DETACHMENT.**

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

- Do not reuse cannulas.
- Use only if material is clear.
- Avoid trapping air bubbles.
- Use only if the container is undamaged.

(f) **This Product Contains Dry Natural Rubber**

### ADVERSE REACTIONS:

- PROVISC® Ophthalmic Viscosurgical Device is tolerated after injection into human eyes during ophthalmic surgical procedures. As with most viscoelastics, a transient rise in intraocular pressure has been reported in some cases.
- Postoperative inflammatory reactions such as hypopyon and iritis have been reported with the use of ophthalmic viscoelastics, as well as incidents of corneal edema 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 and carefully inject a sufficient amount of PROVISC® Ophthalmic Viscosurgical Device into the anterior chamber. The injection may be performed before or after removal of the crystalline lens.

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 (**see Precautions section**).

### HOW SUPPLIED:

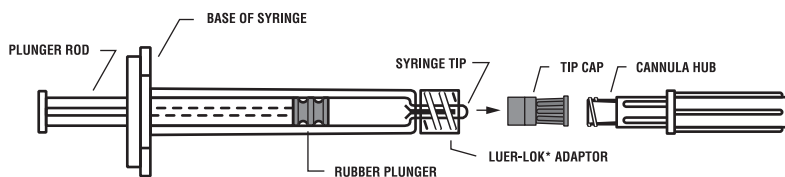
PROVISC® is a sterile **STERILE**, non-pyrogenic, single use ophthalmic viscosurgical device (sodium hyaluronate, 10 mg/mL, dissolved in physiological sodium chloride phosphate buffer) supplied in disposable glass syringes delivering 0.4 mL, 0.55 mL or 0.85 mL.

Each mL of PROVISC® contains active 10.0 mg sodium hyaluronate; 0.56 mg dibasic sodium phosphate, anhydrous; 0.04 mg monobasic sodium phosphate, monohydrate; 8.4 mg sodium chloride; hydrochloric acid and/or sodium hydroxide to adjust pH and QS water for injection. PROVISC® syringes are aseptically packaged in blister packs and terminally sterilized. Refrigerated PROVISC® should be allowed to attain room temperature prior to use (approximately 20-40 minutes depending on quantity).

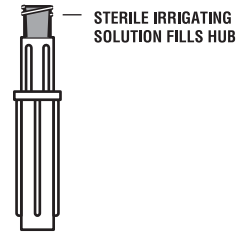
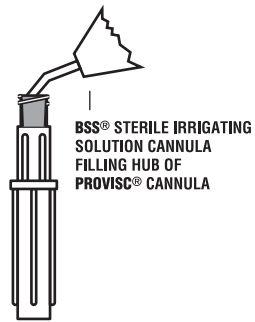
- Store in refrigerator (2°-8°C, 36°-46°F).
- Protect from freezing.
- Protect from light.

### CAUTION:

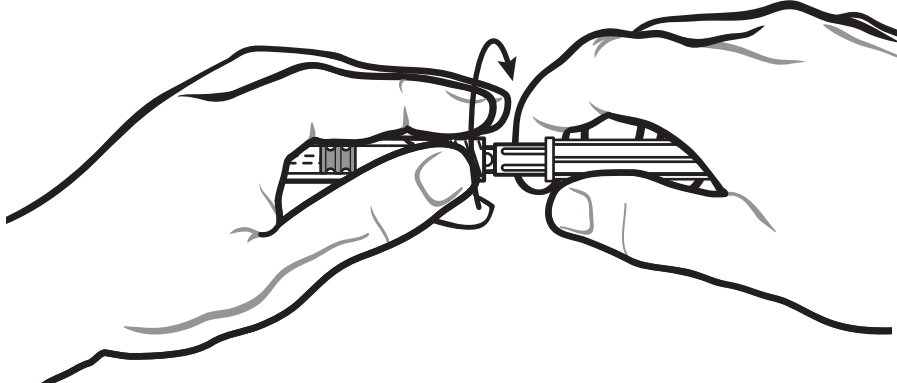
Federal (USA) law restricts this device to sale by or on the order of a physician.



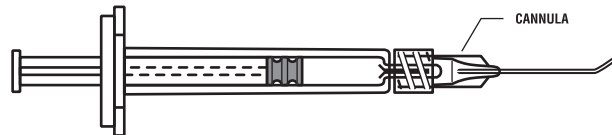
- PEEL LID FROM BLISTER PACK UNDER ASEPTIC CONDITIONS.
- REMOVE RUBBER TIP CAP FROM SYRINGE TIP (CAP IS ON TIGHTLY).



3. INJECT STERILE IRRIGATING 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 ONTO THE OUTSIDE OF THE SYRINGE TIP.
- 



5. THREAD THE CANNULA ONTO THE SYRINGE BY GRASPING THE SYRINGE AND LUER-LOK® ADAPTOR WITH ONE HAND WHILE TWISTING THE CANNULA IN A CONTINUOUS MOTION USING THE CARTRIDGE AS A WRENCH WITH THE OTHER HAND. TWIST UNTIL THE CANNULA HUB HAS TRAVELED THE FULL LENGTH OF THE THREADS AND IS FIRMLY SEATED. USE ONLY THE CANNULA PROVIDED.
  6. VISUALLY INSPECT THAT THE CANNULA HUB HAS TRAVELED THE FULL LENGTH OF THE LUER-LOK® ADAPTOR.
  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. 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 PROVISC® APPEARS AT THE CANNULA TIP.
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# VISCOAT®

(Sodium Chondroitin Sulfate - Sodium Hyaluronate)  
OPHTHALMIC VISCOSURGICAL DEVICE

## DESCRIPTION:

VISCOAT® Ophthalmic Viscosurgical Device is a sterile, non-pyrogenic, viscoelastic solution of highly purified, non-inflammatory medium molecular weight sodium chondroitin sulfate and sodium hyaluronate. VISCOAT® is formulated to a viscosity of  $40,000 \pm 20,000$  cps (at shear rate of  $2 \text{ sec}^{-1}$ ,  $25^\circ\text{C}$ ).

Each 1 mL of VISCOAT® contains not more than 40 mg sodium chondroitin sulfate, 30 mg sodium hyaluronate, 0.45 mg monobasic sodium phosphate, monohydrate; 2.00 mg dibasic sodium phosphate anhydrous, 4.3 mg sodium chloride (with water for injection, USP, q.s.). The osmolarity of VISCOAT® is  $325\text{mOsm} \pm 40\text{mOsm}$ ; the pH is  $7.2 \pm 0.2$ .

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® 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-acetylglucosamine 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 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 humor 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 anterior segment surgery.

VISCOAT® is completely transparent and exhibits excellent flow properties.

## INDICATIONS:

VISCOAT® Ophthalmic Viscosurgical Device 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 visualization 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 and prevents formation of a flat chamber during surgery.

## CONTRAINDICATIONS:

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

## WARNING:

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.

## DIRECTIONS FOR USE:

**FOR INTRAOCULAR USE. BOTH VISCOAT® (Ophthalmic Viscosurgical Device) CANNULA AND CANNULA LOCKING RING ARE FOR SINGLE USE ONLY.**

The syringe assembly is designed only for the injection of the VISCOAT® Ophthalmic Viscosurgical Device it contains. Use of the syringe assembly for aspiration is not advised.

Refrigerated VISCOAT® should be allowed to attain room temperature prior to use (approximately 20-40 minutes depending on quantity).

**NOTICE: THIS VISCOAT® DELIVERY SYSTEM IS NOT DESIGNED OR INTENDED TO BE ATTACHED TO REUSABLE (METAL-HUBBED) INSTRUMENTS OR TO DISPOSABLE INSTRUMENTS OTHER THAN THE ONE PROVIDED WITH THE PRODUCT. FAILURE TO FOLLOW THESE ASSEMBLY INSTRUCTIONS MAY RESULT IN CANNULA DETACHMENT.**

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

- Do not reuse cannulas.
- Use only if material is clear.
- Avoid trapping air bubbles.
- Use only if the container is undamaged.

## ADVERSE REACTIONS:

VISCOAT® Ophthalmic Viscosurgical Device 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 ( $9.8\% > 25\text{mmHg}$  during 1-3 days after surgery in human clinical trials).

## CLINICAL APPLICATIONS:

For cataract surgery and intraocular lens implantation, VISCOAT® Ophthalmic Viscosurgical Device should be carefully injected using standard aseptic technique (and using only the cannula provided, see "Directions for Use" below) into the anterior chamber. VISCOAT® may be injected into the chamber prior to or following removal of the crystalline lens. Instillation of VISCOAT® prior to lens removal will provide additional protection to the corneal endothelium. Instillation of the solution at this point is significant in that a coating of VISCOAT® may protect the corneal endothelium from possible damage arising 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 instruments prior to implantation. Additional VISCOAT® may be injected during anterior segment surgery to fully maintain the chamber or replace any volume 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 sterile irrigating solution.

## HOW SUPPLIED:

VISCOAT® is a sterile **STERILE**, non-pyrogenic, single-use ophthalmic viscosurgical device, supplied in a disposable syringe delivering 0.50 mL or 0.75 mL, packaged with a sterile 27-gauge, disposable, blunt tip cannula and cannula locking ring.

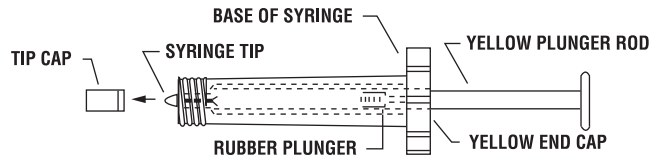
STORE IN A REFRIGERATOR BETWEEN  $2^\circ\text{-}8^\circ\text{C}$  ( $36^\circ\text{-}46^\circ\text{F}$ ). PROTECT FROM FREEZING AND LIGHT.

**CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.**

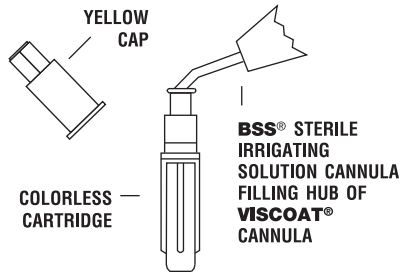
U.S. Patent Nos. 5,876,379; 6,051,560.

## REFERENCES:

1. CILCO, Inc. Study "Preclinical evaluation of CDS-PLUS: Measurement of intraocular pressure variation after instillation into artificial eyes" (1983).
2. CILCO, Inc. Study "Preclinical evaluation of the protective efficacy of CDS-PLUS on rabbit corneal buttons" (1983).
3. CILCO, Inc. Study "Evaluation of CDS for induction of anaphylaxis in guinea pigs" (1981).
4. Richter, W., Ryde, M. and Zetterstrom, O. Nonimmunogenicity of purified sodium hyaluronate preparation in man, *Int Arch Allergy Appl Immunol* 59:45-48, (1979).
5. Richter, W. Nonimmunogenicity of purified hyaluronic acid preparations tested by passive cutaneous anaphylaxis. *Int Arch Allergy Appl Immunol* 47:211-217, (1974).
6. CILCO, Inc. Study "Evaluation of CDS for induction of antibodies in rabbits" (1982).
7. Balazs, E.A. Ultrapure hyaluronic acid and the use thereof, U.S. patent 4,141,973 (1979).
8. CILCO, Inc. Summary of Safety and Efficacy for VISCOAT (1984).



1. PEEL LID FROM BLISTER PACK UNDER ASEPTIC CONDITIONS.
2. REMOVE RUBBER CAP FROM SYRINGE TIP (CAP IS ON TIGHTLY).

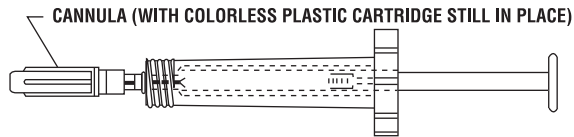


3. INJECT STERILE IRRIGATING SOLUTION INTO THE CANNULA HUB AND FILL IT TO THE TOP.

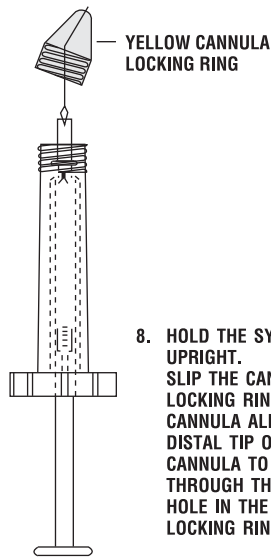
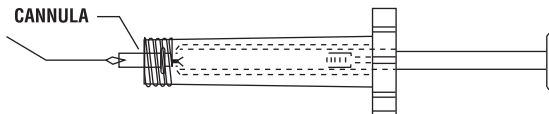
STERILE IRRIGATING SOLUTION FILLS HUB



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 ONTO THE OUTSIDE OF THE SYRINGE TIP.

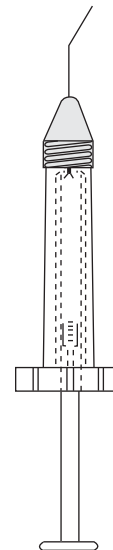


5. THREAD THE CANNULA ONTO THE SYRINGE SLEEVE IN A CONTINUOUS MOTION BY USING THE CARTRIDGE AS A WRENCH. TWIST UNTIL THE CANNULA HUB HAS TRAVELED THE FULL LENGTH OF THE THREADS AND IS FIRMLY SEATED. USE ONLY THE CANNULA PROVIDED.
6. VISUALLY INSPECT THAT THE CANNULA THREADS HAVE TRAVELED THE FULL LENGTH OF THE SYRINGE 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 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 VISCOAT® OPHTHALMIC VISCOSURGICAL DEVICE APPEARS AT THE CANNULA TIP.