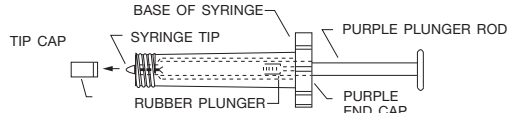
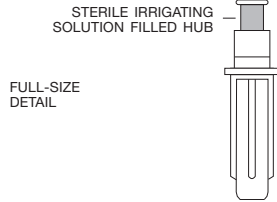
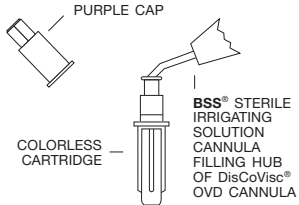


DIRECTIONS FOR USE

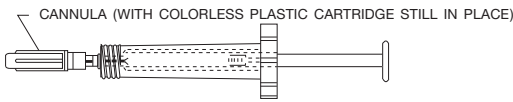
DisCoVisc® Ophthalmic Viscosurgical Device (OVD) should be carefully injected into the anterior chamber using standard aseptic technique (see steps below). DisCoVisc® OVD may be injected into the chamber prior to or following removal of the crystalline lens. Instillation of DisCoVisc® OVD prior to lens removal will provide additional protection to the corneal endothelium. Instillation of the solution at this point is significant, in that a coating of DisCoVisc® OVD may protect the corneal endothelium from possible damage arising from surgical instrumentation during the cataract extraction surgery. DisCoVisc® OVD may also be used to coat the tips of surgical instruments and/or an intraocular lens prior to implantation. Additional DisCoVisc® OVD 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 DisCoVisc® OVD be removed from the eyes as completely as practical by thoroughly irrigating and aspirating with a sterile irrigating solution.



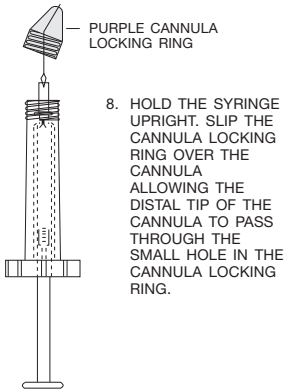
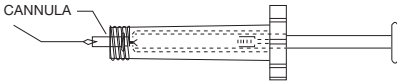
1. PEEL LID FROM BLISTER PACK UNDER ASEPTIC CONDITIONS.
2. REMOVE RUBBER CAP FROM SYRINGE TIP (CAP IS ON TIGHTLY).



3. INJECT STERILE IRRIGATING SOLUTION INTO THE CANNULA HUB AND FILL IT TO THE TOP.
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 VISCOSURGICAL DEVICE INTO THE OUTSIDE OF THE SYRINGE TIP.

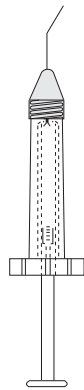


5. THREAD THE CANNULA ONTO THE SYRINGE SLEEVE IN A CONTINUOUS MOTION BY USING THE CARTRIDGE AS A WRENCH. TWIST UNTIL THE CANNULA HUB HAS TRAVELED THE FULL LENGTH OF THE THREADS AND IS FIRMLY SEATED. USE ONLY THE CANNULA PROVIDED.
6. VISUALLY INSPECT THAT THE CANNULA THREADS HAVE TRAVELED THE FULL LENGTH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

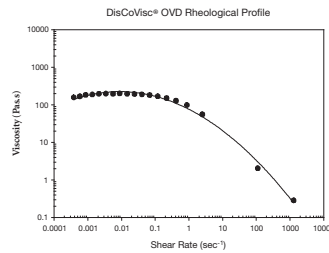
Ophthalmic Viscosurgical Device
DisCoVisc®

(sodium chondroitin sulfate – sodium hyaluronate)

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

DESCRIPTION

DisCoVisc® Ophthalmic Viscosurgical Device (OVD) is a sterile, nonpyrogenic, viscoelastic solution of highly purified, noninflammatory sodium chondroitin sulfate and sodium hyaluronate. DisCoVisc® OVD is formulated to a viscosity of 75,000 ± 35,000 mPa.s (at shear rate of 1 sec⁻¹, 25°C).



INDICATIONS

DisCoVisc® OVD is indicated for use during surgery in the anterior segment of the eye. It is designed to create and maintain space, to protect the corneal endothelium and other intraocular tissues and to manipulate tissues during surgery. It may also be used to coat intraocular lenses and instruments during cataract extraction and IOL insertion.

CONTRAINDICATIONS

At present, there are no known contraindications to the use of DisCoVisc® OVD.

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. 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 glass container is undamaged.

ADVERSE REACTIONS

DisCoVisc® Ophthalmic Viscosurgical Device was very well tolerated in nonclinical and clinical 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.

CLINICAL STUDIES

DisCoVisc® OVD was compared to Healon† in a randomized, observer masked, multi-center clinical trial during cataract extraction and IOL implantation. Two hundred forty-nine (249) patients (128 DisCoVisc® OVD and 121 Healon†) were evaluated for safety and effectiveness.

Viscoelastic Name	CDI
Healon GV†	72
ProVisc®	50
Healon†	40
DisCoVisc® OVD	12
VISCOAT®	3.4

† HEALON is a registered trademark of Advanced Medical Optics, Inc.

^ AMVISC is a registered trademark of Bausch & Lomb, Inc.

U.S. Patent Nos. 5,876,379; 6,051,560 and 7,820,194.

Manufacturer:
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6201 South Freeway
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USA 76134 - 2099
(817) 293-0450
1-800-757-9195
MedInfo@AlconLabs.com

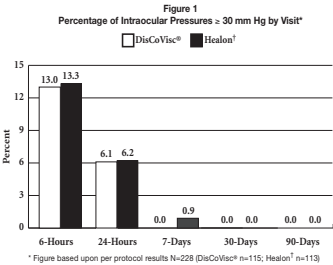
Produced by:
SA Alcon-Couvreur NV
Rijksweg 14
B-2870 Puurs
Belgium

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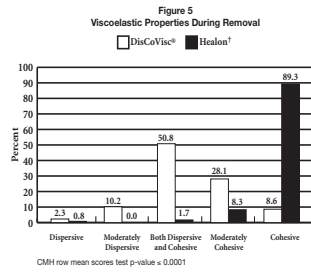


SAFETY

DisCoVisc® Ophthalmic Viscosurgical Device (OVD) was clinically comparable to Healon[†] in the incidence of IOP's greater than or equal to 30 mm Hg (in the absence of IOP lowering medications) at all post-operative exams including one at six hours (Figure 1). No specialized removal technique was required. DisCoVisc® OVD was safe and well tolerated when administered in patients undergoing cataract extraction and intraocular lens implantation, based on a review of adverse events and an assessment of ocular parameters.

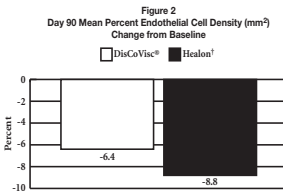


In contrast, during removal DisCoVisc® Ophthalmic Viscosurgical Device (OVD) was characterized as having cohesive properties in over 87% of cases (Figure 5).

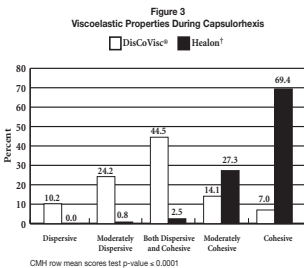


EFFECTIVENESS

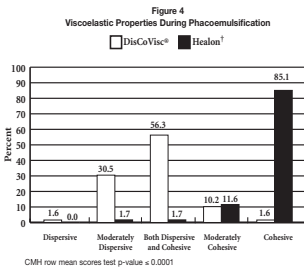
In a well controlled clinical study, DisCoVisc® OVD demonstrated superior results during virtually all phases of the cataract procedure. DisCoVisc® OVD was clinically comparable to Healon[†] in the protection of endothelial cells (Figure 2).



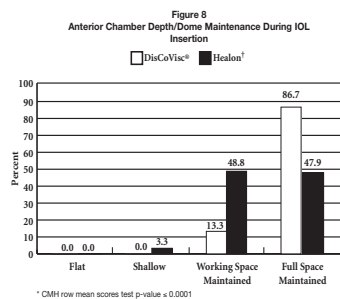
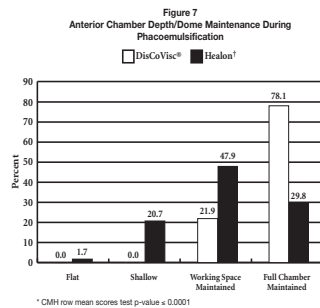
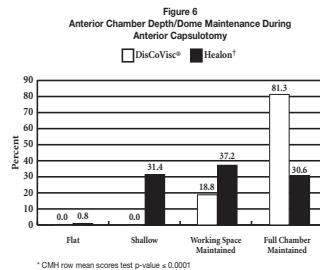
DisCoVisc® OVD exhibited both dispersive and cohesive properties during capsulorhexis, phacoemulsification, and removal (Figures 3, 4 and 5). During capsulorhexis, DisCoVisc® OVD was characterized as having dispersive properties in over 78% of cases (Figure 3).



During phacoemulsification, DisCoVisc® OVD was characterized as having dispersive properties in over 88% of cases (Figure 4).

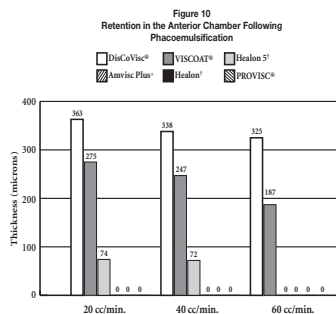
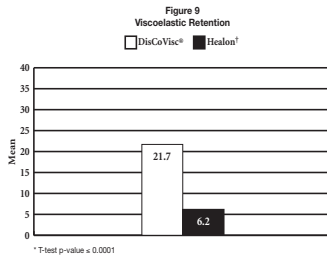


For space maintenance, DisCoVisc® OVD was statistically superior to Healon[†] during capsulorhexis, phacoemulsification, and IOL insertion (Figures 6, 7 and 8).

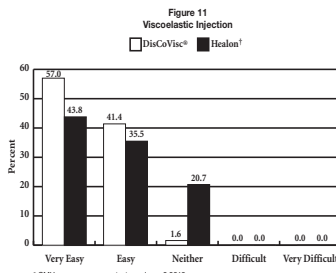


In the area of protection, DisCoVisc® Ophthalmic Viscosurgical Device (OVD) was statistically superior to Healon[†] in the amount of viscoelastic retained in the anterior chamber following phacoemulsification (Figure 9).

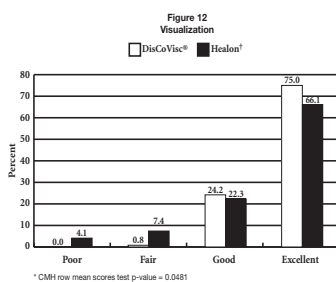
The finding in Figure 9 was confirmed by nonclinical work conducted by Lane et al. (ASCRS Annual Meeting, Abstract No. 714, April 2004) which indicated that DisCoVisc® OVD exhibited superior retention at various flow rates (Figure 10).



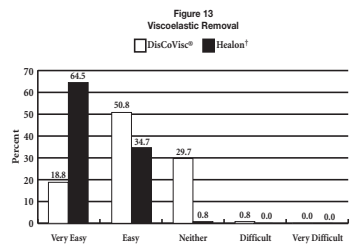
DisCoVisc® OVD was easy to inject in over 98% of the cases (Figure 11).



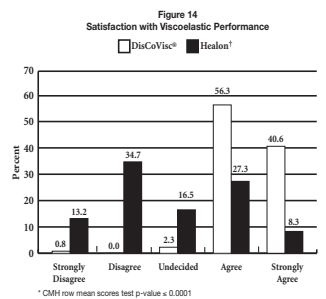
DisCoVisc® OVD was statistically superior to Healon[†] for visualization during the surgical procedure (Figure 12).



DisCoVisc® Ophthalmic Viscosurgical Device (OVD) was easy to remove at the end of the procedure (Figure 13).



Regardless of viscoelastic preference (cohesive or dispersive), surgeons were satisfied with the performance of DisCoVisc® OVD in over 96% of cases (Figure 14).



In overall performance, DisCoVisc® OVD was superior to Healon[†]. DisCoVisc® OVD is the first viscoelastic optimized for the entire surgical procedure.

HOW SUPPLIED

DisCoVisc® OVD is a sterile, nonpyrogenic, single-use, ophthalmic viscosurgical device, supplied in a disposable syringe delivering 0.5 mL or 1.0 mL with a 27-gauge cannula and cannula locking ring, packaged in a blister tray. The product (viscosurgical device solution) is aseptically processed and the syringe exterior is sterilized by ethylene oxide.

FOR INTRAOCULAR USE. DisCoVisc® OVD, CANNULA AND CANNULA LOCKING RING ARE FOR SINGLE-USE ONLY.

DisCoVisc® OVD MUST BE STORED IN A REFRIGERATOR BETWEEN 2° - 8° C (36° - 46° F). PROTECT FROM FREEZING AND LIGHT.

REFRIGERATED DisCoVisc® OVD SHOULD BE ALLOWED TO ATTAIN ROOM TEMPERATURE PRIOR TO USE (APPROXIMATELY 20 - 40 MINUTES).

SYMBOLS USED ON LABELING

Symbol	English
	Attention: See Instructions for Use
	Do not reuse
	Use By (YYYY-MM): Year-Month
	Batch Code
	Product Syringe Contents Sterilized Using Aseptic Processing Techniques
	Primary Container Syringe Exterior Sterilized by Ethylene Oxide
	Temperature limitation. Store between 2° - 8° C (36° - 46° F).
	Does not contain dry natural rubber or natural rubber latex
	Manufacturer