BAUSCH & LOMB Surgical | CHIRON VISION | STORZ

HYDROVIEW® COMPOSITE HYDROGEL FOLDABLE UV- ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENSES

PRODUCT INFORMATION

CAUTION: FEDERAL (USA) LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

Device Description

Hydroview foldable ultraviolet absorbing posterior chamber intraocular lenses manufactured by Bausch & Lomb Surgical, Inc. are optical implants for the replacement of the human crystalline lens in the visual correction of aphakia.

The lenses are lathe cut and polished from a composite material. The foldable optic is cut from the central hydrogel portion which contains a bonded UV absorber. The haptics appear blue and are formed from the outer polymethylmethacrylate (PMMA) portion.

The optical portion is designed for folding prior to insertion. In the preapproval clinical study, 95.9% of Hydroview® lenses were inserted through an incision of 3.3 to 4.6 millimeters (mm).

The labeled dioptric power of the lens is in aqueous. The lens has an index of refraction of 1.474; a specific gravity of 1.19; and a transmission of visible light of 90%.

UV TRANSMISSION

[standard curve to be inserted here]

WAVELENGTH (NANOMETERS)

Human Lens 10 Diopter Lens 30 Diopter Lens

Hydroview intraocular lenses are supplied sterile. The pouch and vial are terminally sterilized and should be opened only under sterile conditions.

Mode of Action

When implanted, the Hydroview intraocular lens functions as a refracting medium to replace the natural lens in the visual correction of aphakia.

Indications

Hydroview posterior chamber lenses are indicated for primary implantation for the visual correction of aphakia in patients 60 years of age or older where a cataractous lens has been removed by extracapsular extraction methods. The lens is designed for implantation in the capsular bag following extracapsular cataract extraction.

Warnings

- Physicians considering lens implantation under any of the following circumstances should weigh the potential risk/benefit ratio:
  1. Recurrent severe anterior or posterior segment inflammation or uveitis.
  2. Patients in whom the intraocular lens may affect the ability to observe, diagnose, or treat posterior segment diseases.
  3. Surgical difficulties at the time of cataract extraction which might increase the potential for complications (e.g., persistent bleeding, significant iris damage, uncontrolled positive pressure, or significant vitreous prolapse or loss).
  4. A distorted eye due to previous trauma or developmental defect in which appropriate support of the IOL is not possible.
  5. Circumstances that would result in damage to the endothelium during implantation.
  6. Suspected microbial infection.
  7. Children under the age of 2 years are not suitable candidates for intraocular lenses.
  8. Patients in whom neither the posterior capsule nor zonules are intact enough to provide support.
- Since the clinical study for Hydroview was conducted with the lens being implanted in the capsular bag only, there are insufficient clinical data to demonstrate its safety and efficacy for placement in the ciliary sulcus.
- Improper handling or folding techniques may cause damage to the haptic or optic portions of Hydroview foldable lenses. If lenses are not folded according to directions, optic tears may result (see "Instructions for Use"). Physicians should not attempt to implant lenses that have radial optic tears or separations at the optic/haptic interface.
- Use of folding instruments other than those validated and recommended in the labeling might result in IOL damage (optic tears, haptic breaks) that might require IOL explantation. In the preapproval clinical studies, haptic breaks (1.6%) and optic tears (1%) occurred using the original packaging

(amber-colored holder). No haptic breaks or optic tears were observed in the clinical study using the Surefold system.

- To avoid the creation of permanent forcep marks in the central optic zone, exercise care during handling and insertion of the lens. In the preapproval clinical study, permanent forcep marks were observed in 3.1% of cases. Read and follow the folding and insertion instructions carefully.

Precautions

1. Do not attempt to resterilize these lenses.
2. Do not store the lens in direct sunlight or at temperatures below freezing.
3. Do not soak or rinse lenses in solutions other than balanced salt solution or equivalent.
4. A surgeon should have observed and/or assisted in numerous surgical implantations and should have completed one or more courses on intraocular lens implantation before attempting to implant intraocular lenses.
5. The physician should have reviewed all instructional materials provided by Bausch & Lomb Surgical, Inc. for proper handling and insertion of Hydroview lenses before attempting to implant these lenses.

Reporting

Adverse reactions and/or potentially sight threatening complications that may reasonably be regarded as lens related and that were not previously expected in nature, severity or degree of incidence should be reported within five (5) days to Bausch & Lomb Surgical, Inc., Clearwater, Florida, at the toll-free number. This information is being requested from all implant surgeons in order to document potential long-term effects of intraocular lens implantation.

- Physicians are encouraged to report these events in order to aid in identifying emerging or potential problems with intraocular lenses. These problems may be related to a specific lot of lenses or may be indicative of long-term effects associated with these lenses or with IOLs in general.
- If the patient has a Bausch & Lomb Surgical intraocular lens and you wish to report, please call:

Bausch & Lomb Surgical, Inc.
1-(800) 252-7890
Local (727) 724-6600

Calculation of Lens Power

The physician should determine preoperatively the power of the intraocular lens to be implanted. Lens power calculation methods are described in the references listed in the bibliography at the end of this insert. Alternately, physicians requiring additional information on lens power calculation may contact Bausch & Lomb Surgical, Inc., Clearwater, Florida.

How Supplied

Hydroview foldable intraocular lenses are supplied STERILE in a hydrated state, in a glass vial which is enclosed in a sterile autoclaved pouch, and should be opened only under sterile conditions (see section "Directions For Use").

Expiration Date

The expiration date on the lens package is the sterility expiration date. Any lens held after this date should be returned to Bausch & Lomb Surgical, Inc., Clearwater, Florida 33759.

Warranty

Bausch & Lomb Surgical, Inc. warrants that its IOL products conform to all applicable laws and that they will perform as represented.

BAUSCH & LOMB SURGICAL, INC. DISCLAIMS ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED, INCUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OTHER THAN THOSE EXPRESSLY SET FOR THE IN THE PRODUCT LABELING. IN NO EVENT WILL BAUSCH & LOMB SURGICAL, INC. BE LIABLE FOR ANY INCIDENTAL, INDIRECT OR CONSEQUENTIAL DAMAGE IN CONNECTION WITH THE PURCHASE OR USE OF ITS PRODUCTS.

Return Goods and Resterilization Policy

All lenses being returned must be accompanied by an authorization number issued by Bausch & Lomb Surgical Customer Service. Opened or unopened lenses will be exchanged for a comparable dollar value, provided they have not exceeded their expiration date. A reprocessing charge may be assessed for lenses which have exceeded their expiration date. This applies to opened or unopened lenses. It is not Bausch & Lomb Surgical policy to issue credit or cash refunds for returned lenses.

Instructions for Use

Note: To avoid dehydration, leave lens immersed in vial until ready to fold and implant. The lens should be folded within 3 minutes after removal from vial.

Note: In the preapproval clinical study, 95.9% of Hydroview® lenses were inserted through an incision of 3.3 to 4.6 millimeters (mm).

1. In a sterile environment, peel open the pouch to present the sterile vial.
2. Twist and remove screw cap. Remove folding mechanism from vial. The lens is contained within the mechanism.
3. Remove the lens retainer by gently rotating the retainer counterclockwise until it stops (about a 25 degree turn), and then lifting (Reference Fig. 1 and 2). Do not squeeze the folder while removing the retainer.
4. Figure 3 shows an unfolded lens seated in the folder.
5. Fold lens by squeezing two halves of the holder between the thumb and fore-finger (Reference Fig. 4).

6. Grasp the folded optic as close as possible to the folder with smooth-edged insertion forceps. The forceps should be completely clean and free of all particulate matter. Release the pressure on the folder. **The superior haptic should be between the smooth-edged forceps' prongs** (Reference Fig. 5 and 6).
7. Thoroughly rinse lens with BSS solution.
8. During insertion, the haptic tip should point to the surgeon's left and should enter the incision first in the orientation shown (Reference Fig. 6). The inferior haptic should first be placed beneath the anterior capsular rim. The forceps should be rotated clockwise and opened slowly. The superior haptic will rotate outside of the eye. Once the lens has unfolded, introduce the superior haptic into the capsular bag in a fashion similar to a conventional lens.
   Note: To avoid damage, do not expand the haptics, flex the haptics out of the plane of the lens, or twist or torque the lens. Possible damage includes tearing the optic, damaging the optic/haptic interface or breaking the haptic.

Alternative Folding Techniques

Note: To avoid scratching the lens, alternate folding techniques should not be used for lenses higher than 27 diopters in power.
Note: All folding instruments should be completely clean and free of all particulate matter.

- Osher-Seibel Folding instrument (E2976) - After removing the lens from the holder, place the lens in a petri dish with BSS solution. The anterior side of the lens should be facing up. Grasp the lens at the 3 and 9 o'clock positions with the Osher-Seibel folder (Reference Fig. 7). Fold the lens by squeezing the forceps while keeping the lens against the bottom of the petri dish. Continue with step 6 above.

- Bausch & Lomb Surgical Hydrofolder (2-778) - After removing the lens from the holder and rinsing with BSS solution, insert the lens into the holder by sliding it above the two support plates and into the grooves located on the inside arms of the folder. Insert the lens until the leading haptic reaches the notch located on the instrument arm (Reference Fig. 8). Squeeze the folding instrument until the haptics are in the vertical position. Continue with step 6 above.

Note: The recommended folding technique is to fold the lens along the 6 to 12 o'clock axis, with a maximum deviation of 10 degrees counterclockwise (Reference Fig. 9). Do not fold Hydroview® lenses along the 3 to 9 o'clock axis. Folding along any other axis may cause damage to the optic or haptics.

Patient Registration Instructions

Bausch & Lomb Surgical has a patient registration system in order to contact physicians or patients if unrecognized long-term effects of the lenses are discovered. The lens package contains product identification stickers for maintaining a record of lens usage and patient registration. At the time of surgery, the prepaid implant registration card included in the package is to be completed and returned to Bausch & Lomb Surgical, Inc., Clearwater, Florida. It is critical that all patients be registered.

An implant identification card to be supplied to the patient is also included in the package. Patients should be instructed to keep the card as a permanent record of their implant, and should also be instructed to show the card to any eye practitioner consulted in the future.

Clinical Experience

Clinical trials of the Hydroview® Model H60M posterior chamber lens began in January 1995. The data presented for the Hydroview® clinical trial represents the experience of 387 patients successfully followed throughout one year of postoperative study. The results achieved indicate that Hydroview® (H60M) posterior chamber intraocular lenses with UV absorber are safe and effective for the visual correction of aphakia. The patient population in the clinical trials consisted of 63.3% females and 36.7% males. Of this population, 96.4% were Caucasian, 2.3% were black, 1.3% other. The mean age for the total population was 74.2 years.

Visual Acuity

The following is a summary of visual acuity reported at 12-14 month postoperatively by subjects who did not have preoperative ocular pathology, abnormal corneas or postoperative macular degeneration (Best Case). The table compares the results with the historical control, the Stark grid (Stark, W.J., et al, 1983).

Table 1
Visual Acuity in Best Case Population (N =272)

Age	Cases N (%)	Visual Acuity 20/ 0-20 n (%)	21-30 n (%)	31-40 n (%)	>40 n (%)	Stark Grid Results 20/40 or better
<59	7 (2.6)	6 (85.7)	1 (14.3)	0 (0.0)	0 (0.0)	93.7%
60-69	82 (30.1)	56 (68.3)	25 (30.5)	0 (0.0)	1 (1.2)	90.8%
70-79	124(45.6)	67 (54.0)	48 (38.7)	9 (7.3)	0 (0.0)	88.6%
80+	59 (21.7)	30 (50.8)	26 (44.1)	2 (3.4)	1 (1.7)	75.2%
TOTAL	272 (100.0)	159(58.5)	100(36.8)	11 (4.0)	2 (0.7)	

Adverse Events

Cumulative adverse events include the total number of adverse events that have occurred at any time during the first postoperative year. The cumulative adverse events experienced during the clinical trial of Model H60M are listed in Table 2.

Table 2

Cumulative Adverse Event	H60M Incidence (%)	Stark Grid
	N = 387	
Macular Edema	2.6%	3.5%
Hyphema	0.3%	1.0%
Secondary Surgical Intervention TOTAL	0.3%	2.0%
• Iridectomy for Pupillary Block	0.0%	N/A
• Vitreous Aspiration for Pupillary Block	0.0%	N/A
• Repositioning of Lens	0.0%	N/A
• IOL Removal for Inflammation	0.0%	N/A
• IOL Replacement	0.0%	N/A
• Other (Per investigator, not lens related)	0.3%	N/A
Endophthalmitis	0.0%	<0.1%
Hypopyon	0.0%	0.4%
Lens Dislocation	0.0%	0.4%
Pupillary Block	0.0%	0.3%
Retinal Detachment	0.0%	0.3%
Lens Epithelial Ongrowth (anterior surface)	1.0%	NA

Persistent adverse events are those present at the one-year postoperative visit. The persistent adverse events experienced during the clinical trial of Model H60M are listed in Table 3.).

Table 3

Persistent Adverse Event	H60M Incidence (%)	Stark Grid
	N = 332	
Iritis	0.3%	1.0%
Hyphema	0.0%	1.0%
Corneal Edema	0.0%	0.6%
Macular Edema	0.0%	0.8%
Secondary Glaucoma	0.0%	0.5%
Vitritis	0.0%	0.1%
Lens Ephithelial Ongrowth (anterior surface)	0.6%	NA

As of January, 1999, there were 782 H60M study implants and the overall incidence of adverse events is 2.7%.

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