EyeKon Medical, Inc.
2451 Enterprise Road,
Clearwater, Florida 33763

HYDROPHOBIC INTRAOCULAR LENSES

Intended Use
The ultra-violet absorbing intraocular lenses manufactured by EyeKon Medical, Inc. are optical implants for the replacement of the human lens in the visual correction of aphakia.
The posterior chamber intraocular lenses are intended to be positioned in the posterior chamber of the eye, replacing the natural crystalline lens. This position allows the lens to function as a refractive medium in the correction of aphakia.

How the Device is Supplied
Hydrophobic intraocular lenses are ethylene oxide sterilized in a lens tray contained within a sealed pouch. The contents of the pouch are STERILE unless the package is damaged or opened. The lens box contains peelable labels which display the lens serial number, model name and model number. These labels are for convenience in maintaining and reporting records of implants. They are designed to be affixed to the patient's hospital chart, the physician's chart and the implant notification card. One of these labels should be affixed to the patient identification card contained in this package and given to the patient as a permanent record of the implant.

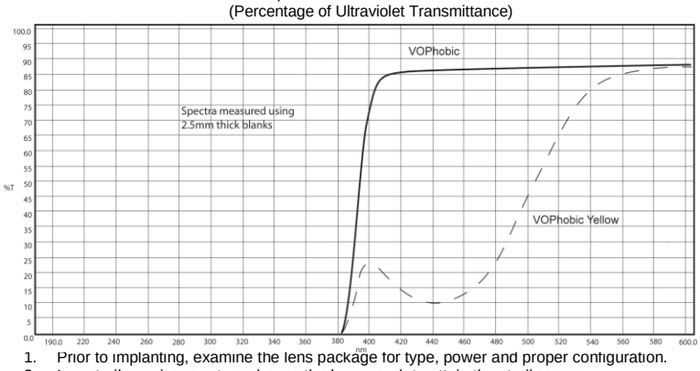
Physicians should not attempt to implant lenses that have broken haptics. A variety of surgical techniques may be employed during the implantation of an intraocular lens. Therefore, the surgeon is best advised to use the method which his training and judgment dictate to be best for the patient.

Indications
The intraocular lens is designed to be used for visual correction of aphakia for primary implantations following extra capsular cataract extractions in adult patients. It is intended for fixation in the capsular bag.

Implantation of posterior chamber intraocular lenses should not be performed in patients under age 18.

Spectral Transmission Curve
The cutoff wavelength and the spectral transmittance curves presented here represent the range of transmittance values of IOLs manufactured with VOPhobic material.

Spectral Transmission Curves
(Percentage of Ultraviolet Transmittance)



1. Prior to implanting, examine the lens package for type, power and proper configuration.
2. In a sterile environment, peel open the lens pouch to attain the sterile case.
3. Care must be taken to remove the lens without bending the haptic into an unnatural state. Prior to the actual folding process, the lens should be handled by the haptic portion only.
4. Haptic breakage should be eliminated by lifting the optic or haptic straight outward out of the case until the lens clears the post. You may also release the lens by inverting the case and allowing the lens to fall gently onto a sterile surface.
5. Rinse the lens with balanced salt solution prior to implantation into the eye.
6. There are various surgical procedures which can be utilized, and the surgeon should select a procedure which is appropriate for the patient.
7. To minimize the occurrence of marks on the lens due to folding, all instrumentation should be scrupulously clean.
8. If using a lens injector, follow manufacturer's instructions.
9. Store at +15˚ C to + 30˚ C.

Implantation Technique
1. Coat lens with Viscoelastic and rotate the forceps counterclockwise 90°.
2. Insert inferior haptic and the optic through the incision with the haptic supported by the optic edge. Place the inferior haptic into capsular bag.
3. Rotate the forceps clockwise 90° so optic is vertical. Confirm the rotation of the superior haptic outside of wound.
4. When the optic is centered in the capsular bag, slowly release the lens. Withdraw forceps. Tuck or dial superior haptic into capsular bag. An instrument may be used through a side port to aid lens release.

Cautions
Physicians should not attempt to implant lenses that have broken haptics.

The following are relative circumstances where the physician should consider whether implanting an intraocular lens does not create undue risk. Physicians should explore the use of alternative methods of aphakic correction and consider less implantation only if alternatives are deemed unsatisfactory to meet the needs of the patient.
- Congenital bilateral cataracts.
- Cataracts in eyes with recurrent anterior or posterior segment inflammation.
- Surgical difficulty at the time of cataract extraction which might increase the potential for complications (vitreous loss, bleeding, etc.).
- Abnormality of the iris which would preclude adequate fixation of the lens, such as aniridia, hemi-iridectomy or severe atrophy.
- Uncontrolled glaucoma.
- Microphthalmos.
- Cataract in eyes where the ability to observe, diagnose or treat anterior or posterior segment disease might be reduced.

As with any surgical procedure, there is potential risk involved. Potential complications accompanying intraocular lens implantation may include, but are not limited to the following: Vitreous Loss, Cystoid Macular Edema, Secondary Glaucoma, Iris Prolapse, Vitreous Wick Syndrome, Pupillary membrane, Lens Dislocation , Corneal Endothelial Damage, Infection, Pupillary Block, Non-pigment Precipitates, Retinal Detachment

Warning
The safety and effectiveness of this lens if placed in the anterior chamber has not been established. Implantation of posterior chamber lenses in the anterior chamber has been shown to be unsafe in some cases. Such implantation should take place only under an investigational protocol approved by the FDA.
Long-term effects of intraocular lens implantation have not been determined. Therefore, physicians should continue to monitor implants on a regular basis. The effectiveness of this ultra-violet absorbing lens in reducing the incidence of retinal disorders has not been established. The need for secondary iridectomy for pupillary block may be prevented by one or more iridectomies at the time of IOL implantation.
Patients with ocular pathology may not achieve the visual acuity and/or may have increased complications compared to patients without such pathology. Physicians should explore the use of alternative methods of aphakic correction in these patients, and should consider lens implantation only if alternative treatments are deemed unsatisfactory to meet the needs of the patient.
Secondary glaucoma has been reported occasionally in patients with pre-existing glaucoma who have received lens implants. The intraocular pressure of implant patients with glaucoma should be carefully monitored postoperatively. Hyphema, secondary glaucoma, pupillary block, cyclitic membrane formation and vitritis have been reported at increased rates in patients who have surgical complications associated with the cataract extraction procedure. Patients who have operative complications should be carefully monitored postoperatively for the occurrence of these complications.

Precautions
- Do not resterilize the lens.
- Lenses requiring resterilization should be returned to the manufacturer. EyeKon cannot assure the sterility of the lens if not sterilized by EyeKon.
- Do not soak the intraocular lens with any solution other than a sterile balanced salt solution or a sterile normal saline as other solutions may damage the lens.
- Do not use the intraocular lens after the expiration date shown on the outside of the package as sterility cannot be assured after the expiration date.
- Handle the lens carefully. Rough or excessive handling may damage the lens.

A high level of surgical skill is required for intraocular lens implantation. A surgeon should have observed and/or assisted in numerous surgical implantations and successfully completed one or more courses on intraocular lenses prior to attempting to implant intraocular lenses.

Adverse Reactions
The following adverse reactions have been reported following cataract extraction and implantation of an intraocular lens:
Hypophyon, Intraocular Infection, Corneal Decompensation, Lens Removal, Pupillary Block and Lens Dislocation and/or Replacement.

Calculation of Lens Power
Preoperative calculation of lens power of these posterior chamber intraocular lenses should be determined by the surgeon's experience, preference and lens placement. Lens power calculation methods are described in the following references:
- Holladay, J.E., et al, A Three part System for Refining Intraocular lens Power Calculation: J. Cataract Refract. Surg., 14:17-24, 1988;
- Olsen, Thomas O., M.D., et al, Prediction of Pseudophakic Anterior Chamber Depth With Newer IOL Lens Calculation Formulas, I. Cataract Refract. Surg. 18:280-285, 1992;
- Retzlaff, J.A., Sanders, D.R. and Kraft, M.S., Development of the SRK/T Intraocular Lens Implant Power Calculations Formula, I - Cataract Refract. Surg., 16:333-340,1990;

If additional information on Lens Power Calculation is needed, please contact EyeKon Medical, Inc.

Return of Goods and Resterilization Policy
Unopened lenses will be exchanged for a comparable dollar value provided they have not exceeded their expiration date. The returned lens must be in its original, unopened, and undamaged packaging to be eligible for replacement or credit. A reprocessing fee may be assessed for the unopened lenses. Prior to returning the lenses the customer must obtain a Return Authorization number, and provide serial number, power, and reason for return. It is EyeKon's policy not to issue credit or cash refunds for returned lenses.
DO NOT ATTEMPT TO RESTERILIZE THE 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 to EyeKon Medical, Inc., 2451 Enterprise Road, Clearwater, Florida 33763. This information is being requested from all implant surgeons.
• 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 an EyeKon intraocular lens and you wish to report, please call EyeKon Medical, Inc. (800) 633-9248 Local: (727) 793-0170 Fax: (727) 799-2212.

Disclaimer of Liability
EyeKon will not be liable for any injury suffered to a patient as a result of: Any implantation method or technique used by a physician to implant the lens. Any prescription selection and use of the lens for any individual patient or patient's condition. EyeKon makes no expressed or implied warranties in connection with the sale of this intraocular lens and specifically disclaims any warranty liability of the marketability or fitness for use.

REFERENCES

1. Bruckner, H., Implantation of a New Foldable Acrylic IOL: The Acrylens. Phacoemulsification and Intraocular Lens implantation, edited by Yalon, M. Slack, Inc., Thorofare, USA, 1992,.pp. 133-142.
2. Girard, L.J., et al., Complications of the Simcoe Flexible Loop Phacoprosthesis in the Anterior Chamber, Ophthal. Surg. 14(4): April 1983.
3. Gould, H.L., Extracapsular Cataract Surgery and Lens Implantation. Cataract Surgery. The C.V. Mosby Co., St. Louis, 1978, pp. 522-534.
4. Jaffe, N.S., Major Operative Complications. Cataract Surgery and Its Complications. The C.V. Mosby Co., St. Louis, 1972, p. 123.
5. Jaffe, N.S. Aphakic Pupillary Block, Cataract Surgery and Its Complications. The C.V. Mosby Co., St. Louis, 1972, p. 169.
6. Jaffe, N.S. et al., Pseudophakos. The C.V. Mosby Co., St. Louis, 1979, pp. 177-180.
7. Jaffe, N.S. "Current concepts in posterior chamber lens technology." American Intraocular Implant Society Journal, 1985, 11, 456-460.
8. Steen, W.H., Implantation of Foldable Thermoplastic 10L: The Memory Lens. Phacoemulsification and Intraocular Lens Implantation, edited by Yalon, M. Slack, Inc., Thorofare, USA, 1992, pp. 161-179.
. Willis. DA.. et al., Pupillary Block Associated with Posterior Chamber Lebses. Ophthal. Surg. 16(2): February 1985.
9. Apple, D.J. et al. "Loop fixation of posterior chamber intraocular lenses." Cataract, 1984, 7-10.

CAUTION
Federal U.S. law restricts this device to sale by or on the order of a physician.

Symbol	Description
	Warning/Caution
	Do not reuse
	Batch Code
	Reference Number
	Sterilization by Ethylene Oxide
	Use until
	See the instructions before use
	Don't use when packing damaged
	Manufacturer
	EC Representative
	Keep from Sunlight
	Keep dry
	Do not re-sterilize
ISO 15523-1	Symbol Reference Standard

Manufactured ByM
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EC REP

EyeKon Medical, Ltd.
1 Friary Temple Quay Bristol, BS1 6EA United Kingdom

It is EyeKon Medical's intent to supply the highest quality hydrophobic intraocular lenses available. We would like your feedback to help us achieve this goal. We request that you answer the following questions. You can then fax your answers to 727-799-2212, or e-mail the completed form to info@eyekonmedical.com. Alternatively, you may go to www.eyekonmedical.com and follow the link for "Feedback". Thank you for your assistance.

Lens Serial Number: _____ Model: _____

Date of Implant: _____/_____/_____ Dr. Name: _____
mm dd yyyy

Contact information for doctor: Address: _____

_____

_____

Telephone: _____

Fax: _____

e-mail: _____

On a scale of 1 – 5, with 1 being the lowest and 5 being the highest, please evaluate the following:

	Circle One				
1. Packaging / presentation:	**1**	**2**	**3**	**4**	**5**
2. Information included on and in the box:	**1**	**2**	**3**	**4**	**5**
3. Ease of opening the lens case and removing the lens:	**1**	**2**	**3**	**4**	**5**
4. Quality of the lens:	**1**	**2**	**3**	**4**	**5**
5. Ease of implant:	**1**	**2**	**3**	**4**	**5**
6. Patient's satisfaction with lens:	**1**	**2**	**3**	**4**	**5**
7. Doctor's satisfaction with lens:	**1**	**2**	**3**	**4**	**5**

If an injector was used, what type and model: _____

Any problems encountered: _____

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Additional comments: _____

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Thank you for your participation.