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

Posterior Chamber Lenses
Introduction
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.

1 piece - The lens is manufactured from medical grade polymethylmethacrylate (PMMA) Index refraction is 1.49.

No substances of animal origin are used in the manufacture of EyeKon products. Contains no phthalates.

To allow the surgeon flexibility in meeting individual patient requirements, several distinct types of lenses are available.

How The Device Is Used
Indications
The intraocular lens is designed to be used for visual correction of aphakia for primary implantations following extracapsular cataract extractions in adult patients. It is intended for fixation in either the ciliary sulcus or capsular bag.

Implantation of posterior chamber intraocular lenses should not be performed in patients under age 18.
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: Small amounts of lens decentration occurring with intraocular lenses having narrow or small optics may result in the patient experiencing glare or other visual disturbances under certain lighting conditions. Surgeons should consider this potential before implanting an intraocular lens with a small or narrow optics.

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 has 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.

Warnings
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.

Clinical Investigation
The clinical data from the Model PC-10 J-Loop posterior chamber lens is being provided in this package insert. The clinical study on the PC-10 posterior chamber lens began in October 1978. The results achieved by five hundred two (502) patients who were followed for one year provided the basis for the data which were used to determine that this style lens was a safe and effective device for the visual correction of aphakia in patients 60 years of age or older.

The clinical study population had an average age of 74 years. 8.17% of the population had pre-existing macular degeneration and an additional 5.4% had other pre-existing conditions such as glaucoma, previous glaucoma, filtering surgery, chronic drug miosis, amblyopia, diabetic retinopathy, and retinal detachment. There were 40.44% females in the cohort and 59.56% males. Of the 502 patients, 91.83% were Caucasian, 1.99% were Black and 4.78% were other.

Clinical Experience with the Posterior Chamber Intraocular Lenses Containing Ultraviolet Absorber
Five hundred and seven (507) patients (cohort) each implanted with one of four models of posterior chamber intraocular lens containing ultraviolet absorber and presented.
The summary of the clinical experience represents the combined populations of four models which were determined by the Sponsor to be equivalent in design, use and function to allow the clinical data to be combined for the evaluation of their safety and effectiveness.

Visual Acuity
In patients over 80 years old with pre-existing ocular problems, the poorest postoperative visual acuity results were achieved.

Patients who experienced surgical problems at the time of cataract surgery may achieve a poorer visual outcome. 7.4% (2) of those patients who had surgical problems had worse than 20/200 at the final visit whereas only 1.3% (6) patients without surgical problems had the same result.

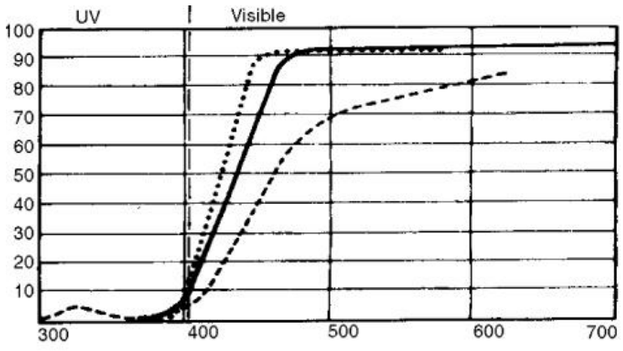
For posterior chamber lenses with ultraviolet absorber, visual acuity of 20/40 or better was achieved by 94.2% of those patients who presented without pre-existing ocular pathologies (best case cohort), compared to 91.9% reporting of the parent Model PC-10. The incidence of sight-threatening complications is also equivalent to that of the PC-10. Modified J-Loop lens. Low incidence of adverse reactions were also found in the analysis of 42.876 adjunct study patients which was equivalent to similar findings with the Model PC-10 lens.

Complications
Twelve (12) complications following cataract extraction and/or intraocular lens implantation have been identified by the Food and Drug Administration as potentially sight-threatening.

Fourteen (14) patients experienced one or more of these complications; however, these complications occurred early in the postoperative time frame and appear to be associated with the cataract extraction procedure. Only two (2) patients (0.4%) were reported to have these complications 12-14 months after surgery.

Spectral Transmission Curves

Human lens data from Boettner, E.A. ad Wolter, J.R., 1962 Transmission of the Ocular Media, Invest. Ophthal. 1:776.
CUT-OFF WAVELENGTH
10% transmittance of light occurs at 405 nanometers for both thinnest and thickest lenses.



NOTE: The cuff-off wavelengths and spectral transmittance curves presented above represent the range of values of IOL's manufactured from PMMA CQ-UV.

How Supplied
The intraocular lens is 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.

Directions for Use
Peel open the pouch and remove the lens. The lens should be inspected for debris or damage. Care must be taken to remove the lens without bending the haptic into an unnatural state. 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.

Rinse the lens with balanced salt solution prior to implantation into the eye.

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

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 implanted. 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.

In the occurrence a lens needs to be destroyed, proper disposal is as follows:

1. Defacing identifying labels (vial, packaging) by permanent marking.
2. Cutting lens in half before disposal.

Surgical Technique
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. Only tools and equipment intended for use in cataract surgery should be used to implant the intraocular lens. Below are standard techniques that may be followed:

1. Perform standard phacoemulsification technique.
2. If an injector delivery system is used, proceed as directed in the respective injection system's IFU.
3. If using viscoelastic, proceed as directed in the respective viscoelastic IFU.
4. Irrigate out the viscoelastic from the anterior chamber and from behind the IOL.
5. Hydrate the edges of the section to seal it. No sutures are normally required but if the section appears leaky or the chamber remains shallow, a suture may be advisable.

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.

Return of Goods and Resterilization Policy
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 the unopened lenses. It is EyeKon's policy not to issue credit or cash refunds for returned lenses.

Bibliography

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

Symbol	Description
⚠	Attention: See instructions for use
⊘	Do not reuse
LOT	Batch Code
STERILE EO	Sterilization by EO
⌛	Use until

Manufactured By:

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