Hoya Surgical Optics, Inc.
iSpheric™ Intraocular Lens
Model YA-60BB

FINAL Draft Package Insert

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

DEVICE DESCRIPTION
The Hoya iSpheric™ Model YA-60BB Intraocular Lens (IOL) is an ultraviolet absorbing posterior chamber intraocular lens designed to be implanted posterior to the iris where the lens will replace the optical function of the natural crystalline lens. However, accommodation will not be replaced.

INDICATIONS
The Hoya iSpheric™ Model YA-60BB Intraocular Lens is indicated for primary implantation in the capsular bag of the eye for the visual correction of aphakia in adult patients in whom a cataractous lens has been removed.

CONTRAINDICATIONS
No absolute contraindications known.

PRECAUTIONS
Do not attempt to resterilize the lens as this can produce undesirable side effects.

Do not soak or rinse the intraocular lens with any solution other than sterile balanced salt solution or sterile normal saline.

Do not store the lens in direct sunlight or at a temperature greater than 45°C/113°F. Do not autoclave the intraocular lens.

WARNINGS
Physicians considering lens implantation under any of the following circumstances should weigh the potential risk/benefit ratio:

1. Patients in whom the intraocular lens may affect the ability to observe, diagnose, or treat posterior segment diseases.
2. 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).
3. A distorted eye due to previous trauma or developmental defect in which appropriate support of the IOL is not possible.
4. Circumstances that would result in damage to the endothelium during implantation.
5. In patients in whom neither the posterior capsule nor zonules are intact enough to provide support.
6. Suspected microbial infection.
7. Patients under the age of 21.

8. Patients who are pregnant or nursing.
9. Recurrent ocular disease (e.g., uveitis, diabetic retinopathy, glaucoma, corneal Decompensation
10. Macular degeneration.
11. Since the clinical study of the Hoya iSpheric™ Model YA-60BB Intraocular Lens was conducted with the lens being implanted in the capsular bag only, there are insufficient clinical data to demonstrate its safety and effectiveness for placement in the ciliary sulcus. The lens has not been studied in patients in whom the posterior capsule or zonules are not intact enough to support an intraocular lens.

ADVERSE EVENTS

The complications experienced during the clinical trial of the Hoya iSpheric™ Model YA-60BB Intraocular Lens include:

Adverse Event	Model YA-60BB (%)	FDA Grid (%)
Cumulative Hyphema	0.0	2.2
Cumulative Macular Edema	3.9*	3.0
Cumulative Retinal Detachment	0.3	0.3
Cumulative Pupillary Block	0.2*	0.1
Cumulative Lens Dislocation	0.3*	0.1
Cumulative Endophthalmitis	0.3*	0.1
Cumulative Hypopyon	0.2	0.3
Cumulative Surgical Reintervention Lens repositioning Lens removal (any reason)	1.5* 0.3 0.3	0.8 2.0
Persistent Macular Edema	0.8	0.5
Persistent Corneal Edema	0.0	0.3
Persistent Iritis	0.2	0.3
Persistent Raised IOP Requiring Treatment	0.0	0.4

As of November 1, 2007, there were 616 implants and the overall incidence of reported ocular adverse events is 7.0%. Cumulative events were those that were reported at any time during the 3-year clinical study; persistent events were those reported at the 12-month postoperative exam.

*No statistically significant difference compared to FDA Grid rate (Chi-Square Goodness of Fit, α=0.05).

Clinical Trial

Clinical trials of the Hoya iSpheric™ Model YA-60BB Intraocular Lenses were initiated in February, 2004. The results achieved by 616 patients (616 eyes) followed for one year provide the basis for the data which were used to support that this IOL design can be used for the visual correction of aphakia.

VISUAL ACUITY

	<60 years (N=51)	60-69 years (N=144)	70-79 years (N=198)	≥80 years (N=53)	All Patients (N=445)
BCVA					
20/15	7 (13.73%)	15 (10.4%)	7 (3.6%)	0 (0.0%)	29 (6.5%)
20/20	31 (60.8%)	84 (58.3%)	94 (47.7%)	26 (49.1%)	235 (52.8%)
20/25	8 (15.7%)	31 (21.5%)	55 (27.9%)	16 (30.2%)	110 (24.7%)
20/30	2 (3.9%)	11 (7.6%)	27 (13.7%)	7 (13.2%)	47 (10.6%)
20/40	1 (2.03%)	1 (0.7%)	13 (6.6%)	3 (5.7%)	18 (4.0%)
Total 20/40 or better	49 (96.1%)	142 (98.6%)	196 (99.5%)	52 (98.1%)	439 (98.7%)
Total worse than 20/40	2 (3.9%)	2 (1.4%)	1 (0.5%)	1 (1.9%)	6 (1.3%)
Total	51	144	197*	53	445
FDA Grid	**98.5%**	**96.5%**	**97.5%**	**94.8%**	**96.7%**

* BCVA not reported for one subject

Only six patient eyes enrolled in the study failed to achieve Best Corrected Visual Acuity of 20/40 or better at 12-14 months postoperative. All of those eyes were Best Case patients (i.e., patients with no preoperative ocular pathologies or macular degeneration at any time during the study).

Detailed Device Description

Configuration:	Modified c-loop, bonded single-piece construction
Overall Diameter:	12.5 mm
Optic Shape:	Biconvex
Optic Diameter:	6.0 mm
Index of Refraction:	1.516 AT 35°C
Visible Light Transmission	> 90% (>500 nm)
UV-Light Transmission	< 10% @375 nm
Optic material:	Foldable, hydrophobic acrylic w/yellow tint
Haptic Material:	PMMA, blue
Available Powers:	6.0 to 30.0 dioptres in 0.5 D increments

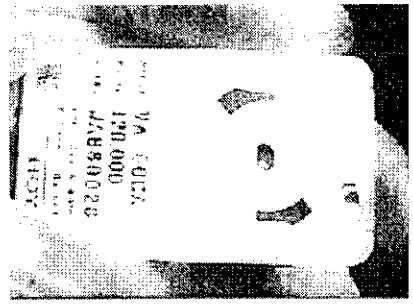
Directions for Use

1. Prior to implanting, examine the lens package for type, power, and proper configuration.
2. Open the peel pouch and remove the lens in a sterile environment.
3. Examine the lens thoroughly to ensure particles have not become attached to it, and examine the lens optical surfaces for other defects.
4. The lens may be soaked in sterile balanced salt solution until ready for implantation.

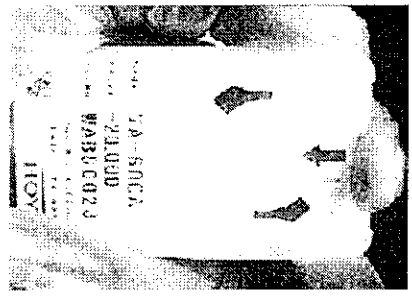
Caution: Do not use lens if the package has been damaged. The sterility of the lens may have been compromised.

The lens should be folded aseptically using the lens case in which the lens is packed inside the sterile pouch, and then placed inside the eye with forceps. This may be done at room temperature, without warming the IOL.

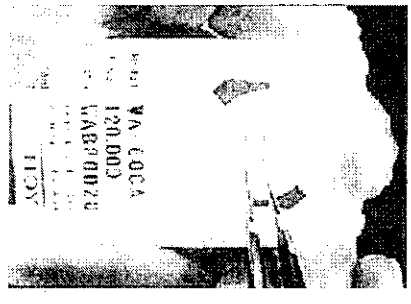
1. Turn the cap of the lens case to the left to remove it.



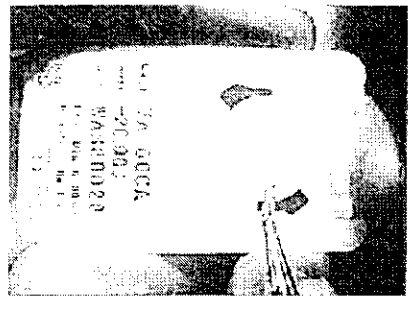
2. Push the tab in the direction of the arrow to fold the lens.



3. Apply forceps to the optic parallel to the folding area, then push down to fold lens.



4. Remove the folded lens from the case and insert into eye.



NOTE: The lens is packaged in the case so that it may be folded lengthwise. If the lens is to be folded diagonally, remove the lens from the case and fold with forceps. The lens is oriented in the case so that it curved (anterior) surface faces up. To ensure that the lens will be oriented in the eye so that the 5^0 angulation of the haptics will cause the lens to vault posteriorly, follow the 4-step folding procedure outlined above using the lens case and then ensure the lens is not turned upside down when grasping it with forceps and inserting it into eye. The lens should only be folded using ASICO AE-4276 or equivalent forceps. An incision size of 3.5 mm or larger should be used for inserting this lens.

Once the lens is properly positioned in the posterior chamber, gently release the forceps to allow the lens to slowly unfold. Verify that both haptics are completely within the capsular bag and adjust the position

of the IOL, as needed to ensure that the entire lens is within the capsular bag and behind the anterior capsule. Following this, the residual viscoelastic should be removed and the procedure completed according to the surgeon's standard technique.

Lens Power Calculations

The physician should determine preoperatively the power of the lens to be implanted. Lens power calculation methods are described in the following references:

1. Hoffer, K.J., "The Hoffer Q formula: a comparison of theoretic and regression formulas," Journal of Cataract and Refractive Surgery, Vol. 19, pp. 700-712, 1993; ERRATA, Vol. 20, pp. 677, 1994.
2. Holladay, J.T., Musgrove, K.H., Prager, T.C., Lewis, J.W., Chandler, T.Y., and Ruiz, S., "A three-part system for refining intraocular lens power calculations," Journal of Cataract and Refractive Surgery, Vol. 14, pp. 17-24, 1988.
3. Holladay, J.T., "Standardizing Constants for Ultrasonic Biometery, Keratometry and Intraocular Lens Power Calculations"; Journal of Cataract and Refractive Surgery, Vol. 23, pp. 1356-1370, 1997.
4. Norrby, N.E.S., "Unfortunate Discrepancies," Letter to the Editor and Reply by Holladay, J.T., Journal of Cataract and Refractive Surgery, Vol. 24, pp. 433-434, 1998.
5. Olsen, T., Olesen, H., Thim, K., and Corydon, L., "Prediction of pseudophakic anterior chamber depth with the newer IOL calculation formulas," Journal of Cataract and Refractive Surgery, Vol. 18, pp. 280-285, 1992.
6. Retzlaff, J.A., Sanders, D.R., and Kraff, M.C., "Development of the SRK/T intraocular lens implant power calculation formula," Journal of Cataract and Refractive Surgery , Vol. 16, pp. 333-340, 1990; ERRATA, Vol. 16, pp. 528, 1990.

Physicians requiring additional information on lens power calculation may contact:

Hoya Surgical Optics, Inc.
14768 Pipeline Avenue
Chino Hills, CA 91709 (USA)
Telephone: 866-750-5870

Patient Registration Section

The lens package contains product identification labels for maintaining a record of lens usage and patient registration. At the time of surgery, the postage-paid implant registration card (Lens Accountability Form) included in the package is to be completed and returned to Hoya Surgical Optics, Inc. where a record of all implants is maintained in order to monitor long-term effects of implantation of these lenses. FDA REQUIRES THAT REGISTRATION BE COMPLETED FOR ALL PATIENTS.

The Patient Identification Card included in the package is to be completed and given to the patient, together with instructions, to keep the card as a permanent record to be shown to any eye care practitioner the patient consults in the future.

Reporting

Adverse events 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 Hoya Surgical Optics, Inc. at 866-750-5870. This information is being requested from all implant surgeons in order to document potential long-term effects of intraocular lens implantation.

How Supplied

The Hoya iSpheric™ Model YA-60BB Intraocular Lens is supplied sterile in a tyvek package. The package is sterilized with ethylene oxide and should be opened only under sterile conditions.

Expiration Date

The expiration date on the lens package is the sterility expiration date. This lens should not be implanted after the indicated sterility expiration date.

Return/Exchange Policy

Contact Hoya Surgical Optics, Inc. at 866-750-5870 for return policy and return authorization. Returned lens should be marked as biohazard.

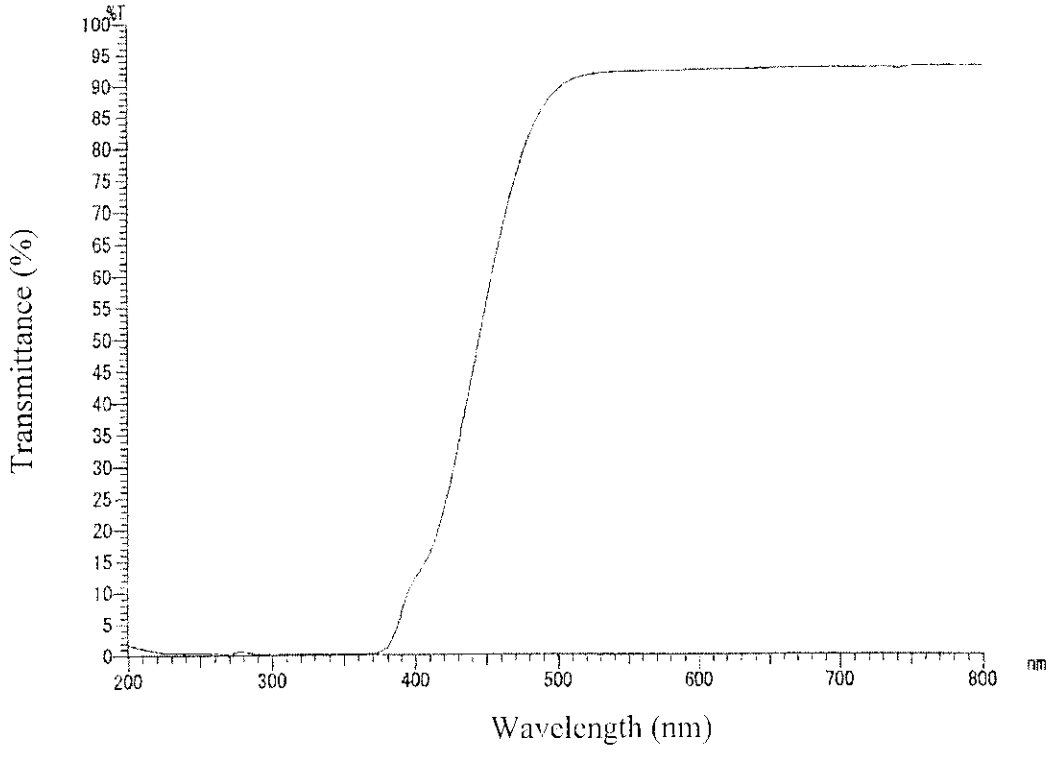
Bibliography

1. Hayashi K, Hayashi H. Visual function in patients with yellow-tinted intraocular lenses compared with vision in patients with nontinted intraocular lenses. Br J Ophthalmol. 2006 Apr 5.
2. Okajima Y, Saika S, Sawa M.Effect of surface coating an acrylic intraocular lens with poly(2-methacryloyloxyethyl phosphorylcholine) polymer on lens epithelial cell line behavior. J Cataract Refract Surg. 2006 Apr;32(4):666-71.

UV-Visible Light Transmittance

The lens allows transmission of over 95% of visible light at approximately 500 nm and approximately 10% transmission at 375 nm.

Light Transmittance – Model YA-60BB



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Symbol	English
<<add symbol>>	Date of Manufacture
<<add symbol>>	Do not Reuse
<<add symbol>>	Sterility Expiration date (MM-YY: month-year)
<<add symbol>>	See Instructions for Use
<<add symbol>>	Sterilized by ethylene oxide gas