4098005

BAUSCH+LOMB

Akreos®

Advanced Optics Aspheric Lens

DEVICE DESCRIPTION

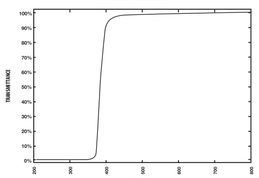
Akreos ultraviolet absorbing posterior chamber intraocular lenses manufactured by Bausch & Lomb Incorporated are one-piece optical implants for the replacement of the human crystalline lens in the visual correction of aphakia.

The Akreos Advanced Optics Aspheric lens (Model AO60) has prolate aspheric surfaces. For information on the clinical study that was conducted to assess the effects of the added aspheric surfaces see CLINICAL EXPERIENCE.

The labeled dioptric power of the lens is in aqueous. The lens has an index of refraction of 1.458 (hydrated) and a transmission of visible light of 90.08% (see **FIG. 1**).

The device packaging includes the Akreos Fold delivery system. The IOL is pre-positioned on the folding device for removal from the vial and folding for implantation using forceps. The Akreos IOL lens is approved for implantation using forceps and with inserters listed-under VALIDATED INSERTERS.

FIG. 1
UV TRANSMITTANCE CURVE



PHYSICAL CHARACTERISTICS

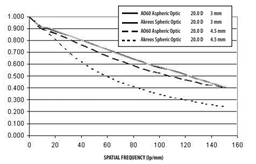
Refractive index of lens when wet at 20°C = 1.459
Refractive index of lens when in the eye at 35°C = 1.458
(V)(362) for +20.0 diopter IOL

LENS POWERS AVAILABLE

Akreos IOLs are available from +0 to +30 diopters (D) by steps of 0.50 or 1D depending on the model and the diopter range.

The Akreos Advanced Optic Aspheric IOL has prolate aspheric surfaces and is designed to be free of spherical aberration. The image quality of the Akreos Advanced Optic Aspheric IOL (i.e. modulation transfer function) is illustrated in **FIG. 2**.

FIG. 2
MODULATION TRANSFER FUNCTION OF 20.0D AKREOS AND AO60 LENSES



NOTE: The image quality of Akreos Advanced Optic Aspheric and Akreos lenses were characterized by measuring modulation transfer function (MTF) in a model eye described in ISO 11979-2:1999 through 3-mm and 4.5mm on the lens apertures.

MODE OF ACTION

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

INDICATIONS

Akreos posterior chamber lenses are indicated for primary implantation for the visual correction of aphakia in adult patients where a cataractous lens has been removed by phacoemulsification. The lens is intended for placement in the capsular bag.

CONTRAINDICATIONS

Implantation is not advisable when the IOL may aggravate an existing condition, interfere with the diagnosis or the treatment of a pathology, or present a risk to the sight of the patient. These conditions are uncontrolled glaucoma, naheotic cataract, retinal detachment, atrophy of the iris, microphthalmia, developing chronic eye infections, endothelial corneal dystrophy, perioperative complications (such as vitreous loss, hemorrhage . . .), foreseeable postoperative complications.

WARNINGS

1. Physicians considering lens implantation under any of the following circumstances should weigh the potential risk/benefit ratio:
   A. Recurrent severe anterior or posterior segment inflammation or uveitis.
   B. Patients in whom the intraocular lens may affect the ability to observe, diagnose, or treat posterior segment diseases.
   C. Surgical difficulties at the time of cataract extraction that might increase the potential for complications (e.g., persistent bleeding, significant iris damage, uncontrolled positive pressure, or significant vitreous prolapse or loss).
   D. A distorted eye due to previous trauma or developmental defect in which appropriate support of the IOL is not possible.
   E. Circumstances that would result in damage to the endothelium during implantation.
   F. Suspected microbial infection.
   G. Children under the age of two (2) years are not suitable candidates for intraocular lenses.
   H. Patients in whom neither the posterior capsule nor zonules are intact enough to provide support.
2. Since the clinical study for the Akreos intraocular lens 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.
3. YAG laser posterior capsulotomies should be delayed until at least 12 weeks after the implant surgery. The posterior capsulotomy opening should be kept as small as possible. There is an increased risk of lens dislocation and/or secondary surgical reintervention with early or large capsulotomies.
4. Improper handling or folding techniques may cause damage to the haptic or optic portions of Akreos foldable lenses. If lenses are not folded according to directions, optic tears may result (see **DIRECTIONS FOR USE**). Physicians should not attempt to implant lenses that have radial optic tears or separations at the optic/haptic interface.
5. Use of folding instruments other than those validated and recommended in the labeling might result in IOL damage (optic tears, haptic damage) that might require IOL explantation.
6. To avoid the creation of permanent forceps marks in the central optic zone, exercise care during handling and insertion of the lens. Read and follow the folding and insertion instructions carefully.

PRECAUTIONS

1. Do not attempt to resterilize these lenses as this can produce undesirable side effects.
2. Do not store the IOL package in direct sunlight or at temperatures below freezing (<0°C). Store at room temperature. Avoid high temperatures (>45°C).
3. Do not implant the IOL if the outer pouch or vial is opened or damaged.
4. Do not re-use the IOL. It is intended for permanent implantation. If explanted, sterility and proper function cannot be assured.
5. Do not soak or rinse lenses in solutions other than balanced salt solution or equivalent.
6. 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 should have completed one or more courses on intraocular lens implantation before attempting to implant intraocular lenses.
7. As with any surgical procedure, there is risk involved. Potential adverse events and complications accompanying cataract or implant surgery may include, but are not limited to the following: corneal endothelial damage, infection (endophthalmitis), retinal detachment, vitritis, cystoid macular edema, corneal edema, pupillary block, cyclitic membrane, iris prolapse, hypopyon, transient or persistent glaucoma and secondary surgical intervention. Secondary surgical interventions include, but are not limited to, lens repositioning, lens replacement, vitreous aspirations or iridectomy for pupillary block, wound leak repair, and retinal detachment repair. Amongst those directly related to the IOL are decentering and subluxation, precipitates on the surface of the IOL. Silicone oil, particularly when used in the surgical treatment of detached retina, may stick to the IOL if the posterior capsule of the crystalline lens is not intact.
8. The IOL should be used in the shortest possible time after opening the vial.
9. Do not implant the IOL if the lens is not completely immersed in solution under any vial orientation.
10. Akreos IOLs can absorb substances that they contact (disinfectant, drug . . .). Do not place the lens in contact with surfaces where such contamination can occur.
11. If a YAG laser posterior capsulotomy is performed, assure that the laser beam is focused slightly behind the posterior capsule.

SUGGESTED A-CONSTANT

The suggested A-constant listed on the outer label is presented as a guideline and is a starting point for implant power calculations. It is recommended that you develop your own constant appropriate for you based on clinical experience with the particular lens models, surgical techniques, measuring equipment, and postoperative results.

IN THE UNITED STATES, IF ADDITIONAL INFORMATION ON LENS POWER IS NEEDED, PLEASE CONTACT BAUSCH & LOMB INCORPORATED AT 1-800-338-2020. OUTSIDE OF THE UNITED STATES, CONTACT LOCAL BAUSCH + LOMB OFFICES OR DISTRIBUTORS.

OPENING INSTRUCTIONS

Open the carton and remove the sterilized pouch containing the lens vial. Gradually peel the pouch apart to release the lens vial onto the sterile field. Before opening the lens vial, make a final check of the IOL and its power. (Please refer to the enclosed figures):

FIG. 3: Hold the vial in one hand, with the pull-tab of the foil lid pointing towards you. Your thumb should be pressed against the flattened side of the vial's profile. Grasp the pull-tab of the foil lid and peel the foil lid away from you to expose the holder inside the vial.

FIG. 4: Carefully lift the holder out of the vial.

FIG. 5: Position the holder so that the circular hole on top of the protective cover is facing up. Remove the protective cover by grasping the exposed tab, bending it upward, away from the holder and pulling it off.

Remove the lens from the holder by gently grasping the optic along the 6-12 o'clock axis with forceps and pulling upwards. The IOL will be anterior side up in the forceps. Examine the lens closely and rinse with sterile-balanced salt solution. Only insertion instruments that have been validated and approved for use with this lens should be used. **NOTE:** Please refer to the Directions for Use with the insertion instrument for additional information.

LENS ORIENTATION

For the Akreos IOL lens model, the lens is to be implanted with the anterior side of the lens facing up towards the anterior side of the eye. The orientation of the IOL can be verified by visual inspection of the haptics. As illustrated in **FIG. 6**, when the haptic features are top right (**A**) and bottom left (**B**), you are facing the anterior side of the lens.

VALIDATED INSERTERS

LENS	INSERTER	VISCOELASTIC
AO60	AI-28 INJ100 VIS100	OcuCoat® Amvisc® Amvisc® Plus

PATIENT REGISTRATION AND REPORTING

Registration (USA)

Each patient who receives an Akreos intraocular lens must be registered with Bausch & Lomb Incorporated at the time of lens implantation (USA). Registration is accomplished by completing the Lens Accountability Form that is enclosed in the lens box and mailing it to Bausch & Lomb Incorporated. Patient registration is essential for the Bausch & Lomb Incorporated long-term patient follow-up program and will assist Bausch & Lomb Incorporated in responding to Adverse Event Reports and/or potentially sight-threatening complications.

Reporting

Adverse events and/or potentially sight threatening complications that may 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 Incorporated. This information is being requested from all 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 intraocular lens and you wish to report, please call Bausch & Lomb Incorporated at 1-800-338-2020.

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 following references.

Binkhorst, RD., Intraocular Lens Power Calculation Manual. New York; Richard D. Binkhorst, 1978.

Bonzo, PB., et al. "An intraocular lens formula for short, normal and long eyes." CLAO Journal, 1985, 11(2), 95-98.

Gills, J.P. "Minimizing postoperative refractive error." Contact Lens, 1980, 6(1), 56-59.

Hoffer, K.J. "Preoperative evaluation of the cataractous patient." Survey of Ophthalmology, 1984, 29(1), 55-69.

Holladay, J.T., et al. "Improving the predictability of intraocular lens power calculations." Arch. Ophthalmology, 1986, 104, 538-541.

Liang, Y., et al. "Analysis of intraocular lens power calculation." American Intraocular Implant Society Journal, 1985, 11, 268-271.

Retzlaff, J., et al. A Manual of Implant Power Calculation SRK Formula, 1981.

Richards, S.C., et al. "Clinical evaluation of six intraocular lens calculation formulas." 1985, 11, 153-158.

Sanders, D.R., Kraff, M.C. "Improvement of intraocular lens power using empirical data." American Intraocular Implant Society Journal, 1980, 6(2).

Physicians requiring additional information on lens power calculation may contact Bausch & Lomb Incorporated.

CLINICAL EXPERIENCE

The Core clinical trial of the UV-Absorbing, Akreos posterior chamber intraocular lens, Model Akreos, began on November 23, 2004. Patients in the Core clinical trial were implanted exclusively following a circular tear anterior capsulotomy. No Modified Core Patients were enrolled. One year follow-up results from the Core patients indicate that the Akreos Intraocular Lens is a safe and effective device for the visual correction of aphakia when used in accordance with the indications previously listed in this labeling.

PATIENT POPULATION

The population in the clinical trial of the UV-absorbing, Akreos posterior chamber intraocular lens consisted of 356 patients who were enrolled between November 2004 and April 2005. The Core Study Group consisted of 215 females and 141 males; 329 were Caucasian, 13 were Black, 2 were Asian, and 12 were "Other". The mean age for the total population was 71 years. The Core Group was further stratified to identify a "Cohort" group of 329 patients who completed 1-year follow up.

TABLE 1
PATIENT POPULATION
MODEL AKREOS
N = 356

PATIENT POPULATION		DATA
Average Age, Years		70.9
Patients with Pre-existing Macular Degeneration (%)		2.25
Additional Patients with Other Pre-existing Conditions (%)		12.36
Gender (%):	Male	39.61
	Female	60.39
Race (%):	Caucasian	92.42
	Black	3.65
	Asian	0.56
	Other	3.37

VISUAL ACUITY

The following is a summary of final visual acuity postoperatively achieved by Akreos patients (at 12-14 months) who did not have a preoperative ocular pathology or postoperative macular degeneration (Best Case Cohort).

TABLE 2†
BEST CORRECTED VISUAL ACUITY AT ONE YEAR
BEST-CASE PATIENTS
MODEL AKREOS
N=279

AGE GROUP	TOTAL	VISUAL ACUITY															
		20/20 or better		20/21 to 20/25		20/26 to 20/30		20/31 to 20/40		20/40 or better		20/41 to 20/80		20/81 to 20/100		20/101 to 20/200		20/200 or worse	
		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
<60	23	15	65.2	5	21.7	1	4.3	1	4.3	22	95.7	1	4.3	0	0.0	0	0.0	0	0.0
60 to 69	100	52	52.0	13	13.0	9	9.0	5	5.0	79	79.0	11	11.0	0	0.0	0	0.0	0	0.0
70 to 79	117	53	45.3	32	27.4	19	16.2	10	8.5	114	97.4	3	2.6	0	0.0	0	0.0	0	0.0
80 & older	39	12	30.8	13	33.3	8	20.5	3	7.7	36	92.3	3	7.7	0	0.0	0	0.0	0	0.0
Total	279	132	47.3	83	29.7	37	13.3	19	6.8	271	97.1	8	2.9	0	0.0	0	0.0	0	0.0

TABLE 3†††
BEST CORRECTED VISUAL ACUITY AT ONE YEAR
ALL ENROLLED PATIENTS
MODEL AKREOS
N=329

AGE GROUP	TOTAL	VISUAL ACUITY															
		20/20 or better		20/21 to 20/25		20/26 to 20/30		20/31 to 20/40		20/40 or better		20/41 to 20/80		20/81 to 20/100		20/101 to 20/200		20/200 or worse	
		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
<60	25	15	60.0	6	24.0	1	4.0	1	4.0	23	92.0	1	4.0	0	0.0	1	4.0	0	0.0
60 to 69	110	54	49.1	16	14.5	9	8.2	7	6.4	107	97.3	2	1.8	0	0.0	1	0.9	0	0.0
70 to 79	142	61	43.0	39	27.5	27	19.0	11	7.7	138	97.2	4	2.8	0	0.0	0	0.0	0	0.0
80 & older	52	16	30.8	15	28.8	11	21.0	3	5.8	45	94.2	3	5.8	0	0.0	0	0.0	0	0.0
Total	329	146	44.4	96	29.2	51	15.5	24	7.3	317	96.4	11	3.3	0	0.0	1	0.3	0	0.0

†Manifest refractions were performed at 14 feet rather than 20 feet for all patients at one study site (25 patients). After Form 3 (50–60 days post-op), a correction of -0.250 was added to the manifest refraction to ensure that measured BCVA was not impacted by this procedural deviation. BCVA at visits through Form 3 may be lower than actual BCVA achieved.

∞24 patients had YAG capsulotomies, 5 occurring before Form 4 (120-180 days post-op). YAG capsulotomy is expected to produce an improvement in visual outcome compared to the pre-YAG visual acuity.

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 the Akreos intraocular lens, Model Akreos, are listed in **TABLE 4**.

TABLE 4

CUMULATIVE ADVERSE EVENT	AKREOS INCIDENCE (%) N=353	FDA GRID (%)
Hyphema	0.0	2.2
Macular Edema	1.4	3.0
Retinal Detachment	0.0	0.3
Pupillary Block	0.0	0.1
Lens Discoloration	0.0	0.1
Endophthalmitis	0.0	0.1
Hypopyon	0.0	0.3
Surgical Reintervention	0.0	0.8

TABLE 5
As of April 2006, there were 356 Akreos study implants and the overall incidence of adverse events is 3.5%.

PERSISTENT ADVERSE EVENT	AKREOS INCIDENCE (%) N=329	FDA GRID (%)
Macular Edema	0.3 (6*)	0.5
Corneal Edema	0.9 (3)	0.3
Iritis	0.3 (1)	0.3
Raised IOP Requiring Treatment	0.6 (2)	0.4

*One patient was counted for both cumulative and persistent Macular Edema.

CLINICAL TRIAL ON AKREOS ASPHERIC MODEL AO60

The Akreos Advanced Optics Aspheric lens (Model AO60) has prolate aspheric surfaces and a clinical study was conducted to assess the effects of the added aspheric surfaces. The primary endpoints were a comparison between the original spherical Akreos and aspheric Model AO60 for low contrast best corrected visual acuity (BCVA) and mean mesopic and photopic contrast sensitivity at 3 months postoperatively. An additional primary endpoint was a comparison between lenses for posterior capsular opacification (PCO) at one and two years postoperatively. Secondary endpoints examined included a comparison between IOLs for spherical aberration and total high order aberrations at 1 and 3 months postoperatively and high contrast UCVA and BCVA at 24 months.

The following outcomes were observed for the primary endpoints:

- Mean low contrast logMAR BCVA for the aspheric IOL population was 0.22 ±0.10 and for the spherical IOL population was 0.24 ±0.13 at 3-months postoperatively. There was no statistically significant difference between groups.
- Photopic and mesopic contrast sensitivity at 3-months postoperatively were not clinically or statistically significantly different between the aspheric and the spherical IOL populations.
- PCO results were inconclusive due to missing data.

The following outcomes were observed for secondary endpoints:

- The outcomes related to spherical aberration and total higher-order aberrations were not interpretable due to large amounts of missing data.
- Mean high contrast logMAR UCVA for the aspheric population was 0.64 +0.26 and for the spherical IOL population was 0.64 +0.25 before cataract surgery and improved to 0.22 +0.18 and 0.27 +0.23 respectively at 24-months postoperatively. Mean high contrast logMAR BCVA for the aspheric population was 0.37 +0.20 and for the spherical IOL population was 0.39 +0.21 before cataract surgery and improved to 0.11 +0.14 and 0.15 +0.19 respectively at 24-months postoperatively.

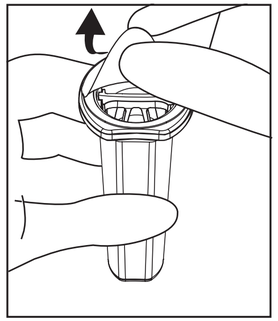


FIG. 3

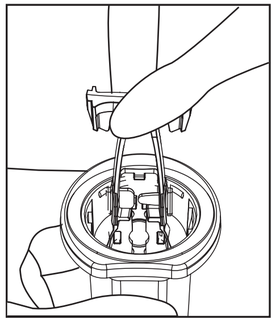


FIG. 4

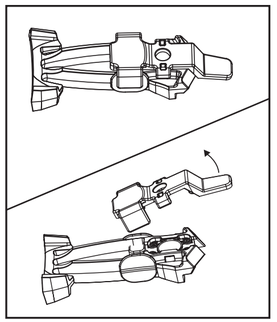


FIG. 5

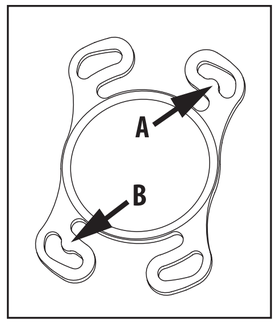


FIG. 6

HOW SUPPLIED

Akreos intraocular lenses are supplied sterile and are individually packaged in a vial and a pouch. The pouch and vial are steam sterilized and should be opened only under sterile conditions. Akreos IOLs are presented in a fixture that holds the implant. A patient card and self-adhesive labels identifying the implant ensure the medical follow-up of the patient and provide traceability of the IOL. These are supplied in the carton containing instructions for use (diagram and characteristics of the IOL, serial number, expiration date . . .). Akreos IOLs are steam sterilized. The IOL model, its power and expiration date should be verified before opening the protective packaging and before opening the individual sterile pouch. Sterility of the IOL is guaranteed only if the individual sterile pouch has not been opened or damaged. Do not use the IOL if the carton or carton seal are opened or damaged.

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. Any lens held after this date should be returned to Bausch & Lomb Incorporated.

WARRANTY

Bausch & Lomb Incorporated warrants that the intraocular lens, when delivered, will conform to all applicable laws and the manufacturer's then current version of the published specifications for such intraocular lens in all material respects and will be free from defects in material and workmanship.

BAUSCH & LOMB INCORPORATED DISCLAIMS ALL OTHER WARRANTIES, EXPRESS, IMPLIED OR BY OPERATION OF LAW, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. BAUSCH & LOMB INCORPORATED SHALL NOT BE LIABLE FOR ANY INCIDENTAL, CONSEQUENTIAL, INDIRECT OR EXEMPLARY DAMAGES OF ANY KIND, DIRECTLY OR INDIRECTLY ARISING FROM THE PURCHASE OR USE OF THIS PRODUCT EVEN IF BAUSCH & LOMB INCORPORATED HAD BEEN ADVISED OF THE POSSIBILITY OF SUCH LOSS, DAMAGE OR EXPENSE.

RETURN GOODS POLICY

All lenses being returned must be accompanied by an authorization number issued by Bausch + Lomb 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 that have exceeded their expiration date. This applies to opened or unopened lenses. It is not Bausch + Lomb policy to issue credit or cash refunds for returned lenses.

BIBLIOGRAPHY

1. Barnett GD. A new hydrogel intraocular lens design. J Cataract Refract Surg. 1994; 20: 18-25
2. Dick HB. Capsular bag diameter: effect on IOL designs. Symposium on cataract, IOL and refractive surgery. April-May 2001, abstract 604.
3. Hayashi H, Hayashi K, Nakao F, Hayashi F. Quantitative comparison of posterior capsule opacification after polymethylmethacrylate, silicone and soft acrylic intraocular lens implantation. Arch Ophthalmol. 1998; 116 : 1579-82
4. Lim JS. Analysis of zonular-free zone and lens size in relation to axial length of eye with age. J Cataract Refract Surg. 1998 ; 24 : 390-6
5. Oshika T, Suzuki Y, Hirofumi K, Yaguchi S. Two year clinical study of a soft acrylic intraocular lens. J Cataract Refract Surg. 1996 Jan/Feb ; 22 : 104-9

MANUFACTURER
Bausch & Lomb Incorporated
1400 North Goodman Street
Rochester, NY 14609 USA

EC REP
Bausch & Lomb GmbH
Brunsbüttler Damm 165-173
13581 Berlin, Germany

AUTHORIZED REPRESENTATIVE IN THE EUROPEAN COMMUNITY

CE 0197

Manufactured by:
Bausch & Lomb Incorporated
21 Park Place Blvd. North
Clearwater, FL 33759 USA

℞ ONLY — PRESCRIPTION ONLY (USA)
STERILE — STERILIZED USING STEAM
DO NOT RE-USE
MEETS EU PACKAGING DIRECTIVE
DO NOT RESTERILIZE
0°C 32°F / 45°C 113°F — TEMPERATURE LIMIT

Rev. 2018-08