



PMS

P930014

Memorandum

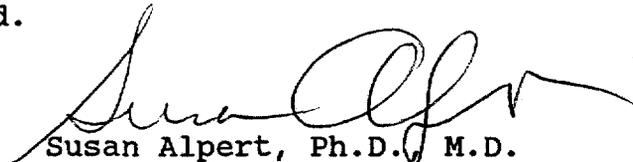
Date DEC 22 1994
From Director, Office of Device Evaluation (HFZ-400)
Center for Devices and Radiological Health (CDRH)
Subject Premarket Approval of Alcon Laboratories'
ACRYSOF® Models MA60BM and MA30BA Ultraviolet-Absorbing Soft
Acrylic Posterior Chamber Intraocular Lenses - ACTION
To The Director, CDRH
ORA _____

ISSUE. Publication of a notice announcing approval of the subject PMA.

FACTS. Tab A contains a FEDERAL REGISTER notice announcing:

- (1) a premarket approval order for the above referenced medical device (Tab B); and
- (2) the availability of a summary of safety and effectiveness data for the device (Tab C).

RECOMMENDATION. I recommend that the notice be signed and published.


Susan Alpert, Ph.D. M.D.

Attachments
Tab A - Notice
Tab B - Order
Tab C - S & E Summary

DECISION

Approved _____ Disapproved _____ Date _____

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

[DOCKET NO. _____]

ALCON LABORATORIES, INC.; PREMARKET APPROVAL OF ACRYSOFT® MODELS MA60BM AND MA30BA ULTRAVIOLET-ABSORBING SOFT ACRYLIC POSTERIOR CHAMBER INTRAOCULAR LENSES

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application by Alcon Laboratories, Inc., Fort Worth, TX, for premarket approval, under section 515 of the Federal Food, Drug, and Cosmetic Act (the act), of the Models MA60BM and MA30BA ultraviolet-absorbing soft acrylic posterior chamber intraocular lenses. After reviewing the recommendation of the Ophthalmic Devices Panel, FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter on December 22, 1994, of the approval of the application.

DATE: Petitions for administrative review by (insert date 30 days after date of publication in the FEDERAL REGISTER).

ADDRESS: Written requests for copies of the summary of safety and effectiveness data and petitions for administrative review to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 1-23, 12420 Parklawn Drive, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Ms. Donna L. Rogers

Center for Devices and Radiological Health (HFZ-460)

Food and Drug Administration

9200 Corporate Blvd.

Rockville, MD 20850

301-594-2053.

SUPPLEMENTARY INFORMATION: On May 28, 1993, Alcon Laboratories, Inc., Fort Worth, TX 76134-2099, submitted to CDRH an application for premarket approval of the Models MA60BM and MA30BA ultraviolet-absorbing soft acrylic posterior chamber intraocular lenses. The devices are posterior chamber intraocular

lenses and are indicated for replacement of the human lens to achieve visual correction of aphakia in patients 60 years of age and older when extracapsular cataract extraction or phacoemulsification are performed. These lenses are intended for placement in the capsular bag.

On May 20, 1994, the Ophthalmic Devices Panel, an FDA advisory panel, reviewed and recommended approval of the application.

On December 22, 1994, CDRH approved the application by a letter to the applicant from the Director of the Office of Device Evaluation, CDRH.

A summary of the safety and effectiveness data on which CDRH based its approval is on file in the Dockets Management Branch (address above) and is available from that office upon written request. Requests should be identified with the name of the device and the docket number found in brackets in the heading of this document.

OPPORTUNITY FOR ADMINISTRATIVE REVIEW

Section 515(d)(3) of the act (21 U.S.C. 360e(d)(3)) authorizes any interested person to petition, under section 515(g) of the act (21 U.S.C. 360e(g)), for administrative review of CDRH's decision to approve this application. A petitioner may request either a formal hearing under part 12 (21 CFR part 12) of FDA's administrative practices and regulations or a review of the application and CDRH's action by an independent advisory committee of experts. A petition is to be in the form of a petition for reconsideration under 10.33(b) (21 CFR 10.33(b)). A petitioner shall identify the form of review requested (hearing or independent advisory committee) and shall submit with the petition supporting data and information showing that there is a genuine and substantial issue of material fact for resolution through administrative review. After reviewing the petition, FDA will decide whether to grant or deny the petition and will publish a notice of its decision in the FEDERAL REGISTER. If FDA grants the petition, the notice will state the issue to be reviewed, the form of the review to be used, the persons who may participate in the review, the time and place where the review will occur, and other details.

Petitioners may, at any time on or before (insert date 30 days after date of publication in the FEDERAL REGISTER), file with the Dockets Management Branch (address above) two copies of each petition and supporting data and information, identified with the name of the device and the docket number found in brackets in the heading of this document. Received petitions may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 515(d), 520(h), and (21 U.S.C. 360e(d), 360j(h)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Devices and Radiological Health (21 CFR 5.53).

Dated: _____.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 22 1993

Mr. Michael E. Pflieger
Associate Director
Regulatory Affairs
Alcon Laboratories, Inc.
6201 South Freeway
Fort Worth, TX 76134-2099

Re: P930014
ACRYSOF® Models MA60BM and MA30BA Ultraviolet-Absorbing Acrylic Foldable
UV-Absorbing Posterior Chamber Intraocular Lenses (IOLs)
Filed: May 28, 1993
Amended: September 14, November 3, and December 27, 1993, and April 5
and 11, May 9, June 8, August 19, September 12 and 22,
October 20, and November 23, 1994

Dear Mr. Pflieger:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your premarket approval application (PMA) for the ACRYSOF® Models MA60BM and MA30BA ultraviolet-absorbing acrylic posterior chamber intraocular lenses (IOLs). These devices are indicated for replacement of the human lens to achieve visual correction of aphakia in patients 60 years of age and older when extracapsular cataract extraction or phacoemulsification are performed. These lenses are intended for placement in the capsular bag. We are pleased to inform you that the PMA is approved subject to the conditions described below and in the "Conditions of Approval" (enclosed). You may begin commercial distribution of the devices upon receipt of this letter.

The sale, distribution, and use of these devices are restricted to prescription use in accordance with 21 CFR 801.109 within the meaning of section 520(e) of the Federal Food, Drug, and Cosmetic Act (the act) under the authority of section 515(d)(1)(B)(ii) of the act.

CDRH approval is subject to full compliance with the conditions described in the enclosure and the following:

1. Registration of all patients receiving the above-referenced intraocular lenses must be continued and the data base shall be maintained indefinitely, or until the applicant is otherwise notified.
2. A way of facilitating adverse reaction reporting, such as an 800 telephone number, must be maintained.
3. FDA notes your agreement that you will continue postoperative follow-up for three years on 500 subjects derived from the core subjects (and modified core, if necessary) to assess further the long-term safety and effectiveness of soft acrylic IOLs. At the completion of the postapproval study, you must submit the clinical data and update your labeling accordingly.
4. Advertising and other printed materials prepared by your firm or its distributors will not include indications or claims not included in the FDA-approved labeling for the devices, e.g., that the use of these lenses (or that small incision surgery) results in more rapid visual

recovery, decreased surgically-induced astigmatism, improved overall quality of vision, or similar claims.

Expiration dating for these devices has been established and approved at 5 years. This is to advise you that the protocol you used to establish this expiration dating is considered an approved protocol for the purpose of extending the expiration dating as provided by 21 CFR 814.39(a)(8).

CDRH will publish a notice of its decision to approve your PMA in the FEDERAL REGISTER. The notice will state that a summary of the safety and effectiveness data upon which the approval is based is available to the public upon request. Within 30 days of publication of the notice of approval in the FEDERAL REGISTER, any interested person may seek review of this decision by requesting an opportunity for administrative review, either through a hearing or review by an independent advisory committee, under section 515(g) of the act.

Failure to comply with the conditions of approval invalidates this approval order. Commercial distribution of a device that is not in compliance with these conditions is a violation of the act.

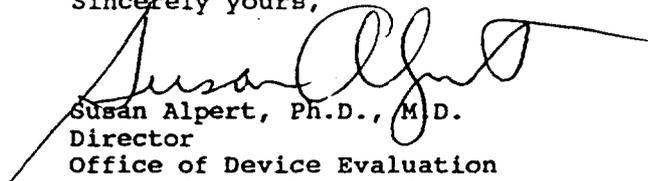
You are reminded that as soon as possible, and before commercial distribution of your devices, that you must submit an amendment to this PMA submission with copies of all approved labeling in final printed form.

All required documents should be submitted in triplicate, unless otherwise specified, to the address below and should reference the above PMA number to facilitate processing.

PMA Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Blvd.
Rockville, Maryland 20850

If you have any questions concerning this approval order, please contact Ms. Susanna W. Jones at (301) 594-2053.

Sincerely yours,


Susan Alpert, Ph.D., M.D.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SUMMARY OF SAFETY AND EFFECTIVENESS DATA

I. GENERAL INFORMATION

- A. Premarket Approval Application (PMA) Number: P930014
Date Filed: May 28, 1993
Date Approved: DEC 22 1994
- B. Generic Name of Device: Posterior Chamber Intraocular Lenses
- C. Trade Names of Device: ACRYSOF® Models MA60BM and MA30BA
Acrylic Foldable UV-Absorbing Posterior Chamber Intraocular Lenses (IOLs)
- D. Applicant's Name and Address:
Alcon Laboratories, Inc.
6201 South Freeway
Fort Worth, TX 76134-2099
- E. Good Manufacturing Practice (GMP) Inspection Dates:
Date of Inspection (Huntington, WV Facility): June 15, 1994
Conclusion: The manufacturing site was found to be in compliance with device GMP requirements.
- F. Ophthalmic Devices Panel (Panel):
Date Reviewed: May 20, 1994
Recommendation: Approval

II. INDICATIONS

Alcon Laboratories, Inc.'s ACRYSOF® Models MA60BM and MA30BA Soft Acrylic Posterior Chamber Intraocular Lenses (IOLs) are indicated for replacement of the human lens to achieve visual correction of aphakia in patients 60 years of age and older when extracapsular cataract extraction or phacoemulsification are performed. These lenses are intended for placement in the capsular bag.

III. SUMMARY

The applicant has performed nonclinical and clinical testing on this device in accordance with the FDA guidance document for testing intraocular lenses

dated June 9, 1980. Nonclinical testing demonstrates the safety and effectiveness of this device from microbiology, toxicology, engineering, and manufacturing perspectives. Data on 590 patients followed postoperatively for 12-14 months were clinically and statistically evaluated against historical controls. The population at risk for developing visually-disabling cataracts and needing cataract surgery is typically elderly; the elderly population has a slightly higher proportion of females to males. The average age of the cohort subjects was 73.3 years at the time of surgery; 62.7% of the cohort subjects were female and 37.3% were male. The inclusion/exclusion criteria did not exclude patients on the basis of gender or gender-related pathology. The study population is 94.9% Caucasian, 3.2% African-American, and 1.9% other. In this study, which began in 1990, all patients who met the inclusion criteria were included in the study.

Based on the analysis of the detailed data presented in the PMA, it was determined that the clinical performance of this device, i.e., complications and adverse reactions and visual acuity results, compares favorably with FDA's 1983 grid of historical data (refer to Section IV.B. Safety and Effectiveness Data). In the case of cumulative hyphema and cumulative endophthalmitis, the incidence of these complications exceeded the grid values but was not statistically significant; in addition, close analysis did not reveal a lens-related etiology. While patients who experience these complications are less likely to achieve a final visual acuity of 20/40 or better, the detailed data presented in the PMA demonstrate that the benefits outweigh the risks when the device is implanted in accordance with the indications described above in Section II and in the approved labeling. There were no statistically significant differences between male and female eyes with respect to preoperative pathologies. Postoperative sight-threatening complication and adverse reaction rates were likewise not significantly different when compared by gender. The overall and best-case visual acuity rates are within FDA grid values for both genders.

IV. SAFETY AND EFFECTIVENESS DATA

A. Nonclinical Studies

The applicant conducted a battery of in-vivo and in-vitro acute and chronic toxicity tests that establish the biocompatibility of the lens materials. These studies, combined with data from chemistry and engineering analyses, demonstrate the suitability of the material and overall device design for use in an intraocular lens. The adequacy of the manufacturing processes, including sterilization, was established

through review of the manufacturing information in the PMA as well as through on-site inspections.

B. Clinical Studies

	P930014	Grid
<u>Overall Visual Acuity (20/40 or better, Cohort = 590)</u>		
Age < 60 Years	100.0% [15/15]	93.7%
Age 60-69 Years	98.3% [173/176]	90.8%
Age 70-79 Years	97.4% [260/267]	88.6%
Age > 80 Years	93.2% [123/132]	75.2%
All Ages Combined	96.8% [571/590]	88.0%
Best Case*, All Ages Combined	99.5% [409/411]	94.0%
<u>Adverse Reactions (Core = 826)</u>		
Hypopyon	0.2% [2]	0.4%
Intraocular Infection	0.2% [2]	0.1%
Acute Corneal Decompensation	0.0% [0]	0.2%
Surgical Reintervention	1.2% [10]	2.0%
<u>Postoperative Complications (Cohort = 590)</u>		
Cumulative Hyphema	1.7% [10]	1.0%
Cumulative Macular Edema	1.4% [8]	3.5%
Persistent Macular Edema	0.2% [1]	0.8%
Cumulative Pupillary Block	0.3% [2]	0.3%
Persistent Secondary Glaucoma	0.2% [1]	0.5%
Persistent Cyclitic Membrane	0.0% [0]	<0.1%
Persistent Vitritis	0.0% [0]	0.1%
Cumulative Retinal Detachment	0.3% [2]	0.5%
Cumulative Endophthalmitis	0.2% [1]	<0.1%
Persistent Corneal Edema	0.0% [0]	0.6%
Persistent Iritis	0.0% [0]	1.0%
Cumulative Lens Dislocation	0.0% [0]	0.4%

* Best Case: Excludes patients with preoperative ocular pathology or macular degeneration at any time.

V. CONCLUSION

The Center for Devices and Radiological Health (CDRH) and the Panel reviewed the PMA and concluded that the PMA contained sufficient valid scientific evidence to provide reasonable assurance of the safety and effectiveness of the device under the prescribed indications for use. CDRH approved this PMA in a letter to the PMA applicant dated ~~DEC 22 1994~~ and signed by the Director, Office of Device Evaluation.

PRODUCT INFORMATION

M-04

Alcon Laboratories, Inc.

ACRYSOF®

Acrylic Foldable

UV-Absorbing Multipiece
Posterior Chamber Lenses

MODEL CHARACTERISTICS

Model	Optic Style/ Diameter (mm)	Overall Length (mm)	Haptic Angle	Configuration R/L Handed
MA30BA	Biconvex/5.5	12.5	5°	Right
MA60BM	Biconvex/6.0	13.0	10°	Right

DESCRIPTION

ACRYSOF® UV-absorbing posterior chamber multipiece lenses are optical implants for replacement of the human crystalline lens in patients sixty years of age and older. These lenses are designed to be implanted into the capsular bag following extracapsular cataract extraction or phacoemulsification. The optical portion consists of a high refractive index soft acrylic material. This material is capable of being folded prior to insertion, allowing placement through an incision of approximately 3.5mm. The lens gently unfolds to a full-size lens body following implantation. The physical properties of these lenses are:

OPTICS

Material: UV-absorbing Acrylate/Methacrylate Copolymer
UV cutoff at 10% T: 398 nm (10.0 diopter lens)
400 nm (30.0 diopter lens)
Index of Refraction: 1.55 (35° C)
Configuration: Biconvex
Power: +10.0 through +30.0 diopter

HAPTICS

Configuration: Modified-C
Material: PMMA (MONOFLEX®)
Color: Blue

ACRYSOF®, MONOFLEX®, BSS® and BSS PLUS® are registered trademarks of Alcon Laboratories, Inc.

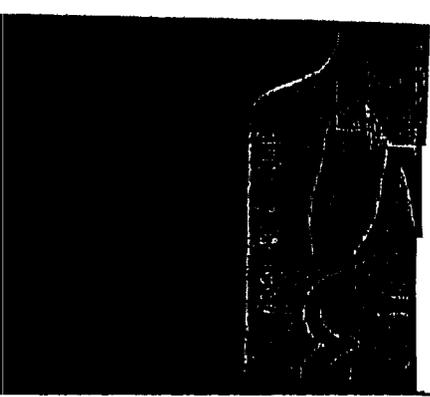
contacting Alcon's Cu
this number does not
products. For detailed
please contact your
Representative.

CAUTION: FEDERAL
SALE BY OR ON THE

REFERENCES

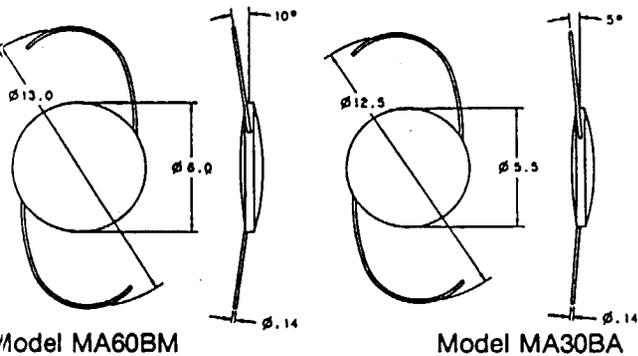
1. Brint, S.F., Small Inc and logel Hydrogel and Intraocular Len Inc., Thorofare, USA
2. Bruckner, H., *Implar Acrylens. Phacoe Implantation*, edited 1992, pp. 133-142.
3. Girard, L.J., et al., *C Phacoprosthesis in t April 1983.*
4. Gould, H.L., *Extrac plantation. Cataract 1978*, pp. 522-534.
5. Jaffe, N.S., *Major C and Its Complication 123.*
6. Jaffe, N.S., *Aphakic Complications. The 1978*, pp. 177-180.
7. Jaffe, N.S. et al., *Pse 1978*, pp. 177-180.
8. Steen, W.H., *Implan Memory Lens. Ph Implantation*, edited 1992, pp. 161-179.
9. Willis, D.A., et al., *Chamber Lenses. Oj*

10-500-088



PHYSICAL CHARACTERISTICS

All dimensions in millimeters



Model MA60BM

Model MA30BA

SPECTRAL TRANSMITTANCE CURVES

(PERCENTAGE OF ULTRAVIOLET TRANSMITTANCE)

NOTES:

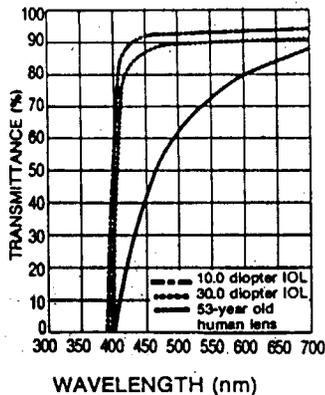
The cutoff wavelength and the spectral transmittance curves presented here represent the range of transmittance values of IOLs made with acrylate/methacrylate copolymer with bonded UV-absorber.

IOL measurements were of direct transmittance using a 6 mm aperture on a disc of thickness equivalent to the central optic portion of a given lens.

UV cutoff at 10% T for 10 diopter lens is 398 nm.

UV cutoff at 10% T for 30 diopter lens is 400 nm.

Human lens data from Boettner, E.A. and Wolter, J.R. 1962. Transmission of the Ocular Media, *Invest. Ophthalmol.* 1:776-783.



MODE OF ACTION

ACRYSOF® 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. The effectiveness of these lenses in reducing the incidence of retinal disorders has not been established.

INDICATIONS

ACRYSOF® posterior chamber intraocular lenses are indicated for replacement of the human lens to achieve visual correction of aphakia in patients sixty years of age and older when extracapsular cataract extraction or phacoemulsification are performed (see WARNINGS). These lenses are intended for placement in the capsular bag.

CAUTION

Patients with any of the conditions listed below may not be suitable candidates for an intraocular lens because the lens may exacerbate an existing condition, may interfere with diagnosis or treatment of a condition, or may pose an unreasonable risk to the patient's eyesight. Careful preoperative evaluation and sound clinical judgement should be used by the surgeon to decide the benefit/risk ratio before implanting a lens in a patient with one or more of these conditions:

1. Congenital bilateral cataracts.
2. Recurrent severe anterior or posterior segment inflammation of unknown etiology.
3. Patients in whom the intraocular lens may interfere with the ability to observe, diagnose, or treat posterior segment diseases.
4. Surgical difficulties at the time of cataract surgery which might increase the potential for complications, (e.g., persistent bleeding, uncontrollable positive pressure, significant vitreous loss).
5. Patients having only one eye with potentially good vision.
6. Medically uncontrollable glaucoma.
7. Severe corneal dystrophy.
8. Proliferative diabetic retinopathy.
9. Corneal Plana.
10. Microphthalmos.
11. Severe optic atrophy.
12. Rubella cataract.
13. Extremely shallow anterior chamber, not due to swollen cataract.

WARNINGS

1. As with any surgical procedure, there is risk involved. Postoperative complications accompanying cataract or implant surgery 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, and traumatic persistent glaucoma.
2. The safety and effectiveness of intraocular lens implantation has not been substantiated in patients with preexisting conditions (chronic drug miosis, glaucoma, amblyopia, diabetic retinopathy, previous corneal transplant, retinal detachment, and/or iritis, etc.). Physicians considering lens implantation in such patients should explore the alternative methods of aphakic correction and consider lens implantation only if alternatives are deemed unsatisfactory, meeting the needs of the patient.
3. The long-term effects of intraocular lens implantation have not been determined. Therefore, physicians should continue to monitor patients postoperatively on a regular basis.
4. Patients with preoperative problems such as endothelial disease, abnormal cornea, macular degeneration, retinal degeneration, glaucoma, and chronic drug miosis may not achieve the visual acuity of patients without such conditions. The physician must determine the benefits to be derived from lens implantation when such conditions exist.
5. A secondary iridotomy for pupillary block may be avoided if one or more iridectomies are performed at the time of lens implantation (Willis, et al, *Ophthalmic Surgery*, Vol. 14, Feb. 1985).
6. The safety and effectiveness of a posterior chamber lens placed in the anterior chamber, has not been established. Implantation of posterior chamber lenses in the anterior chamber has been shown in some cases to be unsafe (Willis, et al, *Ophthalmic Surgery*, Vol. 14, No. 4, Apr. 1983).
7. Some adverse reactions which have been associated with the implantation of intraocular lenses are: hypopyon, infection, acute corneal decompensation and secondary glaucoma. Surgical intervention. Secondary surgical intervention but are not limited to: lens repositioning, lens removal, vitreous aspiration or iridectomy for pupillary block, vitreous repair and retinal detachment repair.



chamber Intraocular lenses are intended to be placed in the anterior chamber of the eye, replacing the natural lens. This position allows the lens to function as if it were the natural lens for the correction of aphakia. The effectiveness of these lenses in reducing the incidence of retinal disorders has been demonstrated.

Posterior chamber intraocular lenses are indicated for use in human eyes to achieve visual correction of nearsightedness in young years of age and older when extracapsular cataract extraction and phacoemulsification are performed (see instructions for use). These lenses are intended for placement in the posterior chamber of the eye.

The conditions listed below may not be met in all patients. The presence of an intraocular lens because the lens may be in the anterior chamber, may interfere with diagnosis or treatment, or may pose an unreasonable risk to the patient. A careful preoperative evaluation and sound judgment should be used by the surgeon to decide the advisability of implanting a lens in a patient with one or more of the following conditions:

1. Active anterior or posterior segment inflammation of the eye.

2. The presence of an intraocular lens may interfere with the ability to diagnose, or treat posterior segment disease.

3. The presence of an intraocular lens at the time of cataract surgery which might result in complications, (e.g., persistent elevated intraocular pressure, significant vitreous loss, or vitreous hemorrhage).

4. The presence of an intraocular lens in one eye with potentially good vision.

5. The presence of an intraocular lens in a patient with glaucoma.

6. The presence of an intraocular lens in a patient with retinal disease.

7. The presence of an intraocular lens in a patient with retinal detachment.

8. The presence of an intraocular lens in a patient with a history of ocular trauma.

9. The presence of an intraocular lens in a patient with a swollen anterior chamber, not due to swollen cornea.

WARNINGS

1. As with any surgical procedure, there is risk involved. Potential 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, and transient or persistent glaucoma.
2. The safety and effectiveness of intraocular lens implants have not been substantiated in patients with preexisting ocular conditions (chronic drug miosis, glaucoma, amblyopia, diabetic retinopathy, previous corneal transplant, previous retinal detachment, and/or iritis, etc.). Physicians considering lens implantation in such patients should explore the use of alternative methods of aphakic correction and consider lens implantation only if alternatives are deemed unsatisfactory in meeting the needs of the patient.
3. The long-term effects of intraocular lens implantation have not been determined. Therefore, physicians should continue to monitor patients postoperatively on a regular basis.
4. Patients with preoperative problems such as corneal endothelial disease, abnormal cornea, macular degeneration, retinal degeneration, glaucoma, and chronic drug miosis may not achieve the visual acuity of patients without such problems. The physician must determine the benefits to be derived from lens implantation when such conditions exist.
5. A secondary iridotomy for pupillary block may be avoided if one or more iridectomies are performed at the time of IOL implantation (Willis, et al, *Ophthalmic Surgery*, Vol. 16, No. 2, Feb. 1985).
6. The safety and effectiveness of a posterior chamber lens, if placed in the anterior chamber, has not been established. Implantation of posterior chamber lenses in the anterior chamber has been shown in some cases to be unsafe (Girard, et al, *Ophthalmic Surgery*, Vol. 14, No. 4, Apr. 1983).
7. Some adverse reactions which have been associated with the implantation of intraocular lenses are: hypopyon, intraocular infection, acute corneal decompensation and secondary surgical intervention. Secondary surgical interventions include, but are not limited to: lens repositioning, lens replacement, vitreous aspiration or iridectomy for pupillary block, wound leak repair and retinal detachment repair.

8. Small amounts of lens decentration, occurring with an IOL having a narrow or small optic, may result in a patient experiencing glare or other visual disturbances under certain lighting conditions. Surgeons should consider this potential before implanting an IOL having a narrow or small optic. When implanting a narrow or small optic lens, it is recommended that capsulorhexis be performed.

NOTE: Implantation of intraocular lenses should not be performed in patients under 18 years of age.

PRECAUTIONS

1. Do not resterilize these ACRYSOFT® lenses or ACRYPAK™ folders by any method. (See RETURN LENS POLICY).
2. Do not store intraocular lenses at temperatures over 45°C (113°F).
3. Use only sterile intraocular irrigating solutions (such as BSS® or BSS PLUS®) to rinse and/or soak lenses.
4. Handle lenses carefully to avoid damage to lens surfaces or support structures.
5. Do not attempt to reshape supporting elements in any way.
6. A high level of surgical skill is required to implant intraocular lenses. The surgeon should have observed and/or assisted in numerous implantations and successfully completed one or more courses on intraocular lens implantation before attempting to implant intraocular lenses.

CALCULATION OF LENS POWER

Preoperative calculation of required lens power of these lenses should be determined by the surgeon's experience, preference, and intended lens placement. Lens power calculation methods are described in the following references:

Binkhorst, R.D.: *Intraocular Lens Power Calculation Manual*, New York, Richard D. Binkhorst; 1978.

Holladay, J.T.: A Three-Part System for Refining Intraocular Lens Power Calculations, *J. Cataract Refract Surgery*, Vol. 14: January 1988.

Retzlaff, J., Sanders, D., and Kraff, M.: *A Manual of Implant Power Calculation - Including SRK II Formula*. Chicago: Authors 1988.

SUGGESTED A-CONSTANT AND EFFECTIVE LENS POSITION

The numbers listed here are presented as guidelines and are starting points for implant power calculations. It is recommended that you develop your own A-constant and effective lens position based on your experience with particular lens models, surgical techniques, measuring equipments, and postoperative results.

CALCULATIONS OF LENS POWER BY MODEL

Model	A-Constant	Effective Lens Position
MA30BA	118.8 D	5.22mm
MA60BM	118.9 D	5.25mm

Effective Lens Position (ELP) is defined as the distance from the anterior vertex of the cornea to the principal plane of the lens.

If additional information on lens power calculation is needed, please contact Alcon® Surgical at 1-800-TO-ALCON.

DIRECTIONS FOR USE

1. Examine the lens and label on the unopened package for model, power, proper configuration, and expiration date.
2. After opening package, verify lens cassette information (i.e., model, power and serial number) is consistent with information on outer package labeling.
3. To remove the lens, open the outer bag and remove the cassette into a sterile environment. Carefully open the cassette to expose the lens. When removing the lens from the cassette, DO NOT grasp the optical area with forceps (see ACRYSOF® FOLDING AND IMPLANTATION GUIDE). Prior to the actual folding process, the lens should be handled by the haptic portion only. Rinse the lens thoroughly using sterile balanced salt solution such as BSS® or BSS PLUS®. DO NOT rinse the lens in solutions other than sterile balanced salt solution.
4. There are various surgical procedures which can be utilized, and the surgeon should select a procedure which is appropriate for the patient.
5. To minimize the occurrence of marks on the lens due to folding, all instrumentation should be scrupulously clean.
6. Alcon® recommends using a Western Medical style folding system, or equivalent forceps with non-serrated jaws, based on the surgeon's own preference and experience.

NOTE: Because the lens and the packaging materials are plastic, the lens may pick up an electrostatic charge upon opening the package. The lens should be carefully examined to ensure that particles have not been attracted to it.

- 6 -

ACRYSOF® FOLDING AND IMPLANTATION GUIDE

INSTRUMENTATION

The following folding instruments or their equivalents are preferred for use with the ACRYSOF® lens.

Implantation Instrumentation

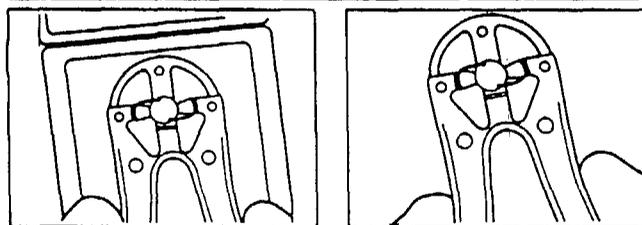
Alcon® ACRYSOF® Implantation Forceps 8065977730
 Katena Model #K5-8225 Livemols-McDonald
 Katena Model #K5-8228 Ernest-McDonald
 Western Medical Model M1 or equivalent

Holding Instrumentation

Alcon® ACRYSOF® Holding Forceps 8065977710
 Western Medical Model MH1

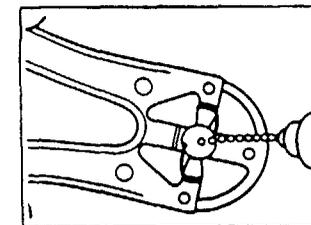
NOTE: Clean and sterilize all folding and holding instruments according to manufacturer's recommendations prior to using with the ACRYSOF® lens. All instruments should be inspected prior to use for rough or sharp surfaces which may damage lens.

ACRYPAK™ FOLDING TECHNIQUE

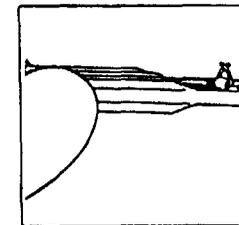


1. Remove ACRYPAK™ folder containing the lens from case. Folding results are improved at 68° F (20° C) or above.
2. Gently grasp the ACRYPAK™ folder arms. Do not compress at this time.

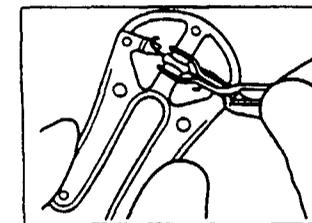
- 7 -



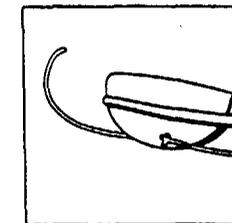
3. Wet lens thoroughly by irrigating or immersing in BSS® Sterile Irrigating Solution.



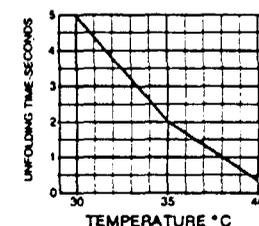
4. Using gentle pressure compress ACRYPAK™ until lens is completely DO NOT release pressure until lens is removed.



5. Center opened implantation forceps over lens. Position the forceps squarely on the ACRYPAK™ surface.



6. Close forceps on folder. Remove lens from AC folder, and release AC folder arms.



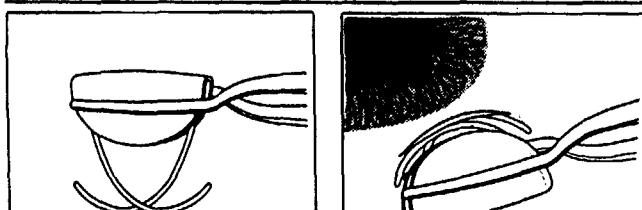
Time/Temperature Chart
 Unfolding time as a function of temperature.

- 8 -

IMPLANTATION TECHNIQUE



ALTERNATIVE IMPLANTATION TECHNIQUE



PATIENT REGISTRATION AND REPORTING

Each patient who receives an ACRYSOF® lens must be registered with Alcon Laboratories, Inc. immediately following implantation.

Registration is accomplished by completing the prepaid Registration Card enclosed in the lens box, then mailing it to Alcon Laboratories, Inc.

Patient registration is essential for Alcon Laboratories' long-term patient follow-up program and will assist in resolution of adverse reaction reports and/or potentially sight-threatening complications.

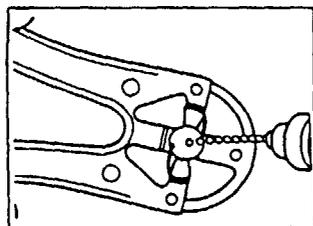
LOADING AND UNLOADING GUIDE

Implantation instruments or their equivalents are used to implant ACRYSOF® lens.

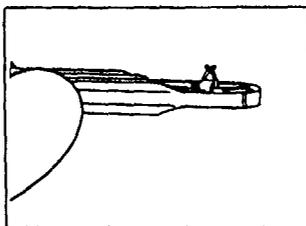
Implantation
 Implantation Forceps 8065977730
 Illinois-McDonald
 Ernest-McDonald
 M1 or equivalent

Implantation Forceps 8065977710
 MH1

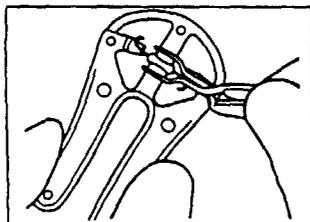
Use all folding and holding instruments in accordance with the manufacturer's recommendations prior to using with ACRYSOF® lens. Instruments should be inspected prior to use to ensure that surfaces which may damage lens are smooth and free of debris.



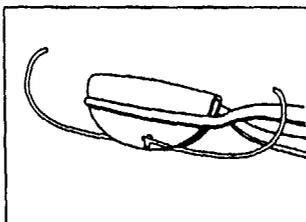
3. Wet lens thoroughly by irrigating or immersing in BSS® Sterile Irrigating Solution.



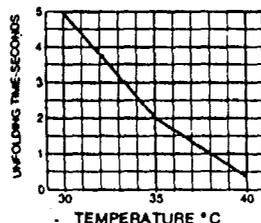
4. Using gentle pressure, slowly compress ACRYPAK™ arms until lens is completely folded. DO NOT release pressure on arms until lens is removed.



5. Center opened implantation forceps over lens. Position the forceps squarely on the ACRYPAK™ surface.



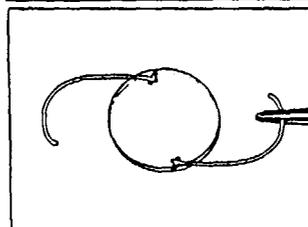
6. Close forceps on folded lens. Remove lens from ACRYPAK™ folder, and release ACRYPAK™ folder arms.



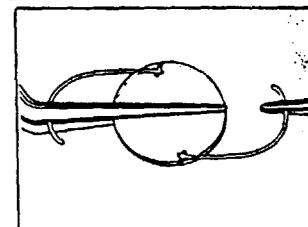
Time/Temperature Chart

Unfolding time as a function of temperature.

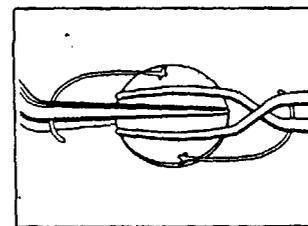
FOLDING FORCEPS TECHNIQUE



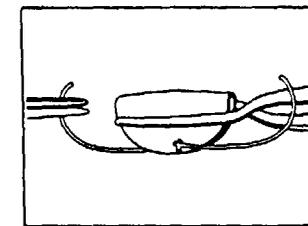
1. Using holding forceps to remove lens from case by nudging optic and then lifting lens by haptic. Wet lens thoroughly by irrigating or immersing in BSS® Sterile Irrigating Solution.



2. Using the holding forceps, grasp the lens parallel with the haptics across the optic. Folding results are improved at 68° F (20°C) or above.

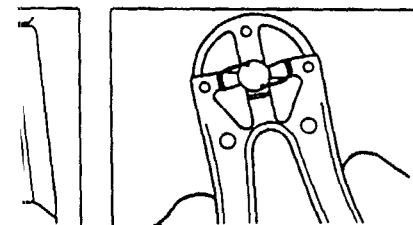


3. Open folding forceps and place over holding forceps as shown. Gentle downward pressure on the optic will allow the lens to fold gradually and in a controlled manner.



4. Prior to lens folding completely, release and retract the holding forceps and then close the folding forceps. Lens should be held just above center line.

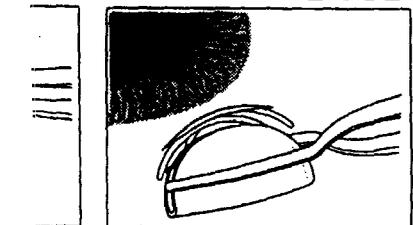
IMPLANTATION TECHNIQUE



1. Gently grasp the ACRYPAK™ folder arms. Do not compress at this time.

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IMPLANTATION TECHNIQUE



2. Compress the lens haptics against the incision and rotate the optic into the incision.

3.4.

PATIENT REGISTRATION AND REPORTING

Each patient who receives an ACRYSOF® lens must be registered with Alcon Laboratories, Inc. immediately following lens implantation.

Registration is accomplished by completing the prepaid Implant Registration Card enclosed in the lens box, then mailing it to Alcon Laboratories, Inc.

Patient registration is essential for Alcon Laboratories, Inc.'s long-term patient follow-up program and will assist in responding to adverse reaction reports and/or potentially sight-threatening complications.

The Patient Identification Card included in the package is to be completed and given to the patient. The patient should be instructed to keep the card as a permanent record and to show it to any eye care practitioner consulted in the future.

Adverse reaction and/or sight-threatening complications that may reasonably be regarded as lens-related, and that were not previously expected in nature, severity, or degree of incidence

- 8 -

PATIENT POPULATION

The patient population in the core clinical trials consisted of 62.1% females and 37.9% males. 94.9% were caucasian, 2.9% were black, 2.2% were other. The mean age for the total population was 73.3 years.

VISUAL ACUITY

The following is a summary of visual acuity achieved at 12 to 14 months postoperatively by cohort subjects who did not have preoperative ocular pathology, abnormal corneas, or postoperative macular degeneration (Best Case Cohort).

Table 1
Visual Acuity in Best Case Patient Population
at 12 to 14 months N=410

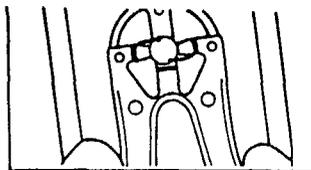
20/40 or better 20/41- Worse than 20/40

- 9 -

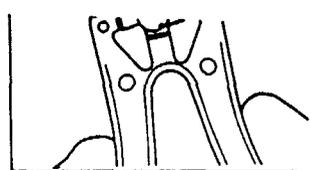
lens in solutions other than sterile balanced salt solution.
 4. There are various surgical procedures which can be utilized, and the surgeon should select a procedure which is appropriate for the patient.

5. To minimize the occurrence of marks on the lens due to folding, all instrumentation should be scrupulously clean.
 6. Alcon® recommends using a Western Medical style folding system, or equivalent forceps with non-serrated jaws, based on the surgeon's own preference and experience.

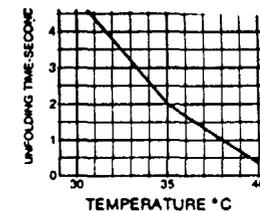
NOTE: Because the lens and the packaging materials are plastic, the lens may pick up an electrostatic charge upon opening the package. The lens should be carefully examined to ensure that particles have not been attracted to it.



1. Remove ACRYPAK™ folder containing the lens from case. Folding results are improved at 68° F (20° C) or above.

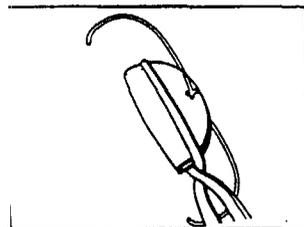


2. Gently grasp the ACRYPAK™ folder arms. Do not compress at this time.

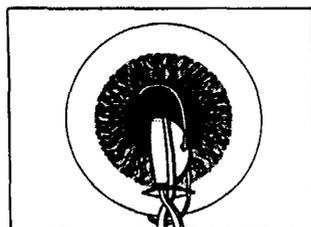


Time/Temperature Chart
 Unfolding time as a function of temperature.

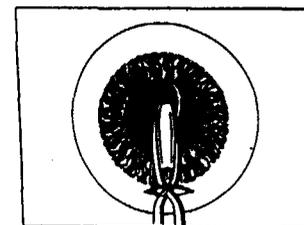
IMPLANTATION TECHNIQUE



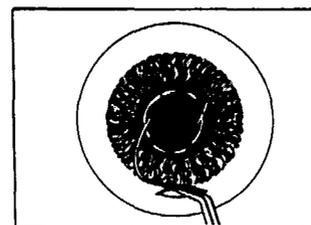
1. Coat lens with viscoelastic (VISCOAT® or PROVISC™), rotate forceps counterclockwise 90°.



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.

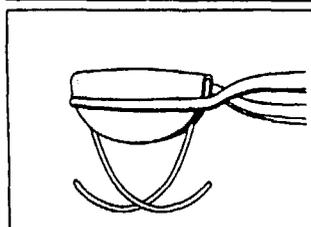


3. Rotate the forceps clockwise 90° so optic is vertical. Confirm rotation of the superior haptic outside of wound.

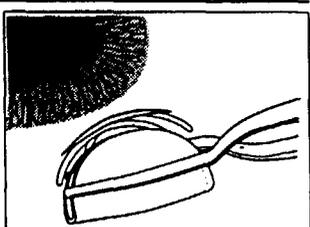


4. When the optic is centered in the capsular bag, slowly release the lens. Withdraw forceps. Tuck or dial superior haptic into capsular bag. An instrument may be used through a side port to aid lens release.

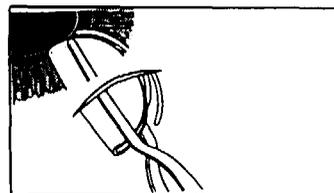
ALTERNATIVE IMPLANTATION TECHNIQUE



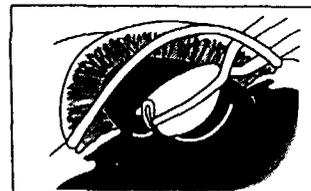
1. Hold the lens obliquely (4:00 and 10:00) and fold as described in Forceps Folding Technique, steps 1 through 4.



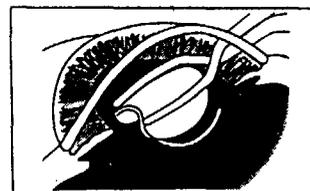
2. Compress the lens haptics against the incision and rotate the optic into the incision.



3. Insert the lens through the incision, keeping both haptics compressed.



4. After lens is fully inserted, rotate the forceps clockwise 90° so optic is vertical. Position haptics and optic in the capsular bag.



5. Open the forceps and release both haptics into capsular bag.

PATIENT REGISTRATION AND REPORTING

Each patient who receives an ACRYSOFTM lens must be registered with Alcon Laboratories, Inc. immediately following implantation.

Registration is accomplished by completing the prepaid Registration Card enclosed in the lens box, then mailing it to Alcon Laboratories, Inc.

Patient registration is essential for Alcon Laboratories long-term patient follow-up program and will assist in response to adverse reaction reports and/or potentially sight-threatening complications.

The Patient Identification Card included in the package completed and given to the patient. The patient should be instructed to keep the card as a permanent record and to show it to any eye care practitioner consulted in the future.

Adverse reaction and/or sight-threatening complications may reasonably be regarded as lens-related, and that any such complication previously expected in nature, severity, or degree of it should be reported to Alcon Laboratories, Inc.

This information is being requested from all implant surgeons in order to document potential long-term effects of intraocular implantation.

Surgeons should use the following address and phone for reporting adverse reactions or potentially sight-threatening complications involving these lenses:

Alcon Laboratories, Inc.
 Technical Consumer Affairs (Q-122)
 6201 South Freeway
 Fort Worth, Texas 76134
 Call Collect: (817) 551-4445

CLINICAL STUDIES

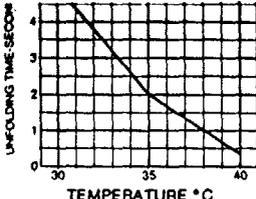
The core clinical trials of the ACRYSOFTM Model MA60BM posterior chamber lens began in December 1990. They have indicated that the ACRYSOFTM Model MA60BM posterior chamber lens is a safe and effective device for the visual correction of cataract-induced myopia.

Since the clinical study of the ACRYSOFTM lens was completed, there is insufficient clinical data to demonstrate its efficacy for placement in the ciliary sulcus.



ACRYPAK™ folder arms from case. The lens is improved at this time.

2. Gently grasp the ACRYPAK™ folder arms. Do not compress at this time.



Time/Temperature Chart
Unfolding time as a function of temperature.

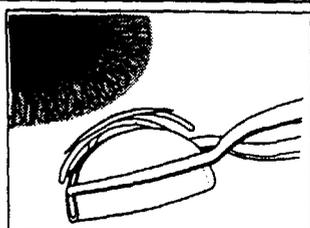
- 7 -

- 8 -

IMPLANTATION TECHNIQUE



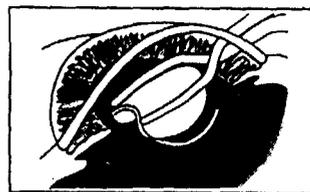
liquely (4:00 o'clock as depicted). Folding through 4.



2. Compress the lens haptics against the incision and rotate the optic into the incision.



Insert the lens through the incision, keeping both haptics compressed.



5. Open the forceps and release both haptics into capsular bag.



4. Inserted, clockwise. Position in the ciliary sulcus.

PATIENT REGISTRATION AND REPORTING

Each patient who receives an ACRYSOFTM lens must be registered with Alcon Laboratories, Inc. immediately following lens implantation.

Registration is accomplished by completing the prepaid Implant Registration Card enclosed in the lens box, then mailing it to Alcon Laboratories, Inc.

Patient registration is essential for Alcon Laboratories, Inc.'s long-term patient follow-up program and will assist in responding to adverse reaction reports and/or potentially sight-threatening complications.

The Patient Identification Card included in the package is to be completed and given to the patient. The patient should be instructed to keep the card as a permanent record and to show it to any eye care practitioner consulted in the future.

Adverse reaction and/or 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 Alcon Laboratories, Inc.

This information is being requested from all implant surgeons in order to document potential long-term effects of intraocular lens implantation.

Surgeons should use the following address and phone number for reporting adverse reactions or potentially sight-threatening complications involving these lenses:

Alcon Laboratories, Inc.
Technical Consumer Affairs (Q-122)
6201 South Freeway
Fort Worth, Texas 76134
Call Collect: (817) 551-4445

CLINICAL STUDIES

The core clinical trials of the ACRYSOFTM Model MA60BM posterior chamber lens began in December 1990. The results achieved by the core patients successfully followed for one year, indicate that the ACRYSOFTM Model MA60BM posterior chamber lens is a safe and effective device for the visual correction of aphakia.

Since the clinical study of the ACRYSOFTM lens was conducted with the lens being intended for implantation in the capsular bag, there is insufficient clinical data to demonstrate its safety and efficacy for placement in the ciliary sulcus.

place over holding forceps as shown. Gentle downward pressure on the optic will allow the lens to fold gradually and in a controlled manner.

precisely, release and retract the holding forceps and then close the folding forceps. Lens should be held just above center line.

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PATIENT POPULATION

The patient population in the core clinical trials consisted of 62.1% females and 37.9% males. 94.9% were caucasian, 2.9% were black, 2.2% were other. The mean age for the total population was 73.3 years.

VISUAL ACUITY

The following is a summary of visual acuity achieved at 12 to 14 months postoperatively by cohort subjects who did not have preoperative ocular pathology, abnormal corneas, or postoperative macular degeneration (Best Case Cohort).

Table 1
Visual Acuity in Best Case Patient Population at 12 to 14 months N=410

AGE	20/40 or Better		20/41-20/80		Worse than 20/80		Total Reported
	N	%	N	%	N	%	N
< 60	13	100.0	0	0.0	0	0.0	13
60-69	134	100.0	0	0.0	0	0.0	134
70-79	185	100.0	0	0.0	0	0.0	185
> 79	77	98.7	1	1.3	0	0.0	78
Total	409	99.8	1	0.2	0	0.0	410

Table 2A
Visual Acuity By Extraction Method
Planned Extracapsular Cataract Extraction N=5

AGE	20/40 or Better		20/41-20/80		Worse than 20/80		Total Reported
	N	%	N	%	N	%	N
< 60	0	0.0	0	0.0	0	0.0	0
60-69	1	100.0	0	0.0	0	0.0	1
70-79	4	100.0	0	0.0	0	0.0	4
> 79	0	0.0	0	0.0	0	0.0	0
Overall ECCE	5	100.0	0	0.0	0	0.0	5

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- 12 -

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M-04

1. Brint, S.F., Small Incision Technique for Implantation of Acrysol and Intraocular Lens Implantation, edited by Yalon, M. Slack, and Intraocular Lens Implantation, Phacoemulsification and Intraocular Lenses, Phacoemulsification and Intraocular Lens Implantation, edited by Yalon, M. Slack, 1977-1978.

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

contacting Alcon's Customer Support Department, issuance of this number does not constitute final acceptance of the returned products. For detailed policy guidelines including exchange, please contact your Account Manager or Customer Support Representative.

Table 2B
Visual Acuity By Extraction Method
Phacoemulsification Cataract Extraction N=583

AGE	20/40 or Better		20/41 20/80		20/81-20/100		20/101-20/200		Worse than 20/200		Total Reported
	N	%	N	%	N	%	N	%	N	%	
<60	15	100.0	0	0.0	0	0.0	0	0.0	0	0.0	15
60-69	172	98.9	2	1.1	0	0.0	0	0.0	0	0.0	174
70-79	256	97.3	5	1.9	1	0.4	0	0.0	1	0.4	263
>79	123	93.9	5	3.8	1	0.8	2	1.5	0	0.0	131
Overall	Phaco 566	97.1	12	2.1	2	0.3	2	0.3	1	0.2	583

COMPLICATIONS

The Food and Drug Administration has identified eleven (11) potentially sight-threatening complications which may occur following cataract extraction and/or intraocular lens implantation. The cumulative and persistent rates of these complications during the first postoperative year for the Model MA60BM cohort patients stratified by cataract extraction method is shown in Table 3.

Table 3

	ECCE N=5				PHACO N=585				OVERALL N=590			
	Cum	%	Per	%	Cum	%	Per	%	Cum	%	Per	%
Corneal Edema	NA	-	0	0.0	NA	-	0	0.0	NA	-	0	0.0
Iritis	NA	-	0	0.0	NA	-	0	0.0	NA	-	0	0.0
Hypohemia	0	0.0	0	0.0	10	1.7	0	0.0	10	1.7	0	0.0
Macular Edema	0	0.0	0	0.0	8	1.4	1	0.2	8	1.4	1	0.2
Pupillary Block	0	0.0	0	0.0	2	0.3	0	0.0	2	0.3	0	0.0
Secondary												
Glaucoma	NA	-	0	0.0	NA	-	1	0.2	NA	-	1	0.2
Oblitic Membrane	0	0.0	0	0.0	1	0.2	0	0.0	1	0.2	0	0.0
Vitis	NA	-	0	0.0	NA	-	0	0.0	NA	-	0	0.0
Endophthalmitis	0	0.0	0	0.0	1	0.2	0	0.0	1	0.2	0	0.0
Retinal Detachment	0	0.0	0	0.0	2	0.3	0	0.0	2	0.3	0	0.0
Lens Dislocation	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

Twenty-four (4.1%) cohort patients receiving the ACRYSOFF Model MA60BM posterior chamber lens experienced one or more of the above complications, however, the majority of these complications occurred early in the postoperative time frame and appeared to be associated with the cataract extraction. Two patients (0.3%) were reported to have these complications 12-14 months after surgery.

NOTE: Persistent indicates a complication was reported at Form 6.

ADVERSE REACTIONS

Adverse reactions were reported at the following rate for ACRYSOFF Model MA60BM posterior chamber intraocular lens core implant patients:

Table 4

	ECCE N=21		PHACO N=805		OVERALL N=826	
	N	%	N	%	N	%
Hypopyon	0	0.0	2	0.2	2	0.2
Intraocular Infection	0	0.0	2	0.2	2	0.2
Acute Corneal Decompensation	0	0.0	0	0.0	0	0.0
Secondary Surgical Intervention:	1	4.8	9	1.1	10	1.2
a) Lens Replacement/Removal	0	0.0	2	0.2	2	0.2
b) Retinal Detachment Repair	0	0.0	1	0.1	1	0.1
c) Repositioning of Lens	1	4.8	2	0.2	3	0.4
d) Vitrectomy	0	0.0	1	0.1	1	0.1
e) Iridectomy for Pupillary Block	0	0.0	1	0.1	1	0.1
f) Retinal Detachment Repair	0	0.0	1	0.1	1	0.1
g) Wound Repair Leak	0	0.0	1	0.1	1	0.1

HOW SUPPLIED

These posterior chamber intraocular lenses are supplied dry, in a package terminally sterilized with ethylene oxide, and must be opened only under aseptic conditions. (See DIRECTIONS FOR USE).

EXPIRATION DATE

Sterility is guaranteed unless the pouch is damaged or opened. The expiration date is clearly indicated on the outside of the lens package. Any lens held after the expiration date should be returned to Alcon Laboratories, Inc. (See RETURNED GOODS POLICY).

RETURNED GOODS POLICY

Returned lenses will only be accepted in exchange for other products, not credit. All returns must be accompanied by an Alcon Laboratories, Inc.'s Returned Goods Number and be shipped via traceable means. A Returned Goods Number is obtained by

contacting Alcon's Customer Support [this number does not constitute final ac products. For detailed policy guidelin please contact your Account Manage Representative.

CAUTION: FEDERAL (USA) LAW REST SALE BY OR ON THE ORDER OF A LIC

REFERENCES

1. Brint, S.F., Small Incision Technique for and logel Hydrogel Intraocular Lens: and Intraocular Lens Implantation, ex Inc., Thorofare, USA, 1992, pp. 107-110
2. Bruckner, H., Implantation of a New F Acrylens. Phacoemulsification and Implantation, edited by Yalon, M. Slack, 1992, pp. 133-142.
3. Girard, L.J., et al., Complications of the Phacoprosthesis in the Anterior Chamber. April 1983.
4. Gould, H.L., Extracapsular Cataract Implantation. Cataract Surgery. The C.V. Mosby Co., 1978, pp. 522-534.
5. Jaffe, N.S., Major Operative Complications and Its Complications. The C.V. Mosby Co., 1978, pp. 123.
6. Jaffe, N.S., Aphakic Pupillary Block, Complications. The C.V. Mosby Co., 1978, pp. 177-180.
7. Jaffe, N.S. et al., Pseudophakos. The C.V. Mosby Co., 1978, pp. 177-180.
8. Steen, W.H., Implantation of Foldable Memory Lens. Phacoemulsification and Implantation, edited by Yalon, M. Slack, 1992, pp. 161-179.
9. Willis, D.A., et al., Pupillary Block in the Chamber Lenses. Ophthal. Surg. 16(1)

M-04

1. Brint, S.F., Small Incision Technique for Implantation of Acrysof
REFERENCES
CAUTION: FEDERAL (USA) LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A LICENSED PHYSICIAN.
 Representative.
 please contact your Account Manager or Customer Support Department for detailed policy guidelines. For detailed policy guidelines, please contact your Account Manager or Customer Support Department. This number does not constitute final acceptance of the product. For detailed policy guidelines, please contact your Account Manager or Customer Support Department.



ADVERSE REACTIONS

Adverse reactions were reported at the following rate for ACRYSOF® Model MA60BM posterior chamber intraocular lens core implant patients:

Table 4

	ECCE		PHACO		OVERALL	
	N=21		N=805		N=826	
	N	%	N	%	N	%
Hypopyon	0	0.0	2	0.2	2	0.2
Intraocular Infection	0	0.0	2	0.2	2	0.2
Acute Corneal Decompensation	0	0.0	0	0.0	0	0.0
Secondary Surgical Intervention:	1	4.8	9	1.1	10	1.2
a) Lens Replacement/Removal	0	0.0	2	0.2	2	0.2
b) Retinal Detachment Repair	0	0.0	1	0.1	1	0.1
c) Repositioning of Lens	1	4.8	2	0.2	3	0.4
d) Vitrectomy	0	0.0	1	0.1	1	0.1
e) Iridectomy for Pupillary Block	0	0.0	1	0.1	1	0.1
f) Retinal Detachment Repair	0	0.0	1	0.1	1	0.1
g) Wound Repair Leak	0	0.0	1	0.1	1	0.1

HOW SUPPLIED

These posterior chamber intraocular lenses are supplied dry, in a package terminally sterilized with ethylene oxide, and must be opened only under aseptic conditions. (See DIRECTIONS FOR USE).

EXPIRATION DATE

Sterility is guaranteed unless the pouch is damaged or opened. The expiration date is clearly indicated on the outside of the lens package. Any lens held after the expiration date should be returned to Alcon Laboratories, Inc. (See RETURNED GOODS POLICY).

RETURNED GOODS POLICY

Returned lenses will only be accepted in exchange for other products, not credit. All returns must be accompanied by an Alcon Laboratories, Inc.'s Returned Goods Number and be shipped via traceable means. A Returned Goods Number is obtained by

contacting Alcon's Customer Support Department. Issuance of this number does not constitute final acceptance of the returned products. For detailed policy guidelines including exchange, please contact your Account Manager or Customer Support Representative.

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

REFERENCES

- Brint, S.F., Small Incision Technique for Implantation of Acrysof and logel Hydrogel Intraocular Lenses. *Phacoemulsification and Intraocular Lens Implantation*, edited by Yalon, M. Slack, Inc., Thorofare, USA, 1992, pp. 107-132.
- 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.
- Girard, L.J., et al., Complications of the Simcoe Flexible Loop Phacoprosthesis in the Anterior Chamber. *Ophthalm. Surg.* 14(4): April 1983.
- Gould, H.L., Extracapsular Cataract Surgery and Lens Implantation. *Cataract Surgery*. The C.V. Mosby Co., St. Louis, 1978, pp. 522-534.
- Jaffe, N.S., Major Operative Complications. *Cataract Surgery and Its Complications*. The C.V. Mosby Co., St. Louis, 1972, p. 123.
- Jaffe, N.S., Aphakic Pupillary Block. *Cataract Surgery and Its Complications*. The C.V. Mosby Co., St. Louis, 1972, p. 169.
- Jaffe, N.S. et al., *Pseudophakos*. The C.V. Mosby Co., St. Louis, 1978, pp. 177-180.
- Steen, W.H., Implantation of Foldable Thermoplastic IOL: The Memory Lens. *Phacoemulsification and Intraocular Lens Implantation*, edited by Yalon, M. Slack, Inc., Thorofare, USA, 1992, pp. 161-179.
- Willis, D.A., et al., Pupillary Block Associated with Posterior Chamber Lenses. *Ophthalm. Surg.* 16(2): February 1985.

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PRODUCT INFORMATION

Alcon Laboratories, Inc.

ACRYSOF®

Acrylic Foldable

UV-Absorbing Multi-piece

Posterior Chamber Lenses

MODEL CHARACTERISTICS

Model	Optic Style/ Diameter (mm)	Overall Length (mm)	Haptic Angle	Configu- R/L Hand
MA30BA	Biconvex/5.5	12.5	5°	Right
MA60BM	Biconvex/6.0	13.0	10°	Right

DESCRIPTION

ACRYSOF® UV-absorbing posterior chamber multi-piece are optical implants for replacement of the human crystallin in patients sixty years of age and older. These lenses are designed to be implanted into the capsular bag following extracapsular cataract extraction or phacoemulsification. The optical part consists of a high refractive index soft acrylic material which is capable of being folded prior to insertion, and gently unfolds to a full-size lens body following implantation. The physical properties of these lenses are:

OPTICS

Material: UV-absorbing Acrylate/Methacrylate Copolymer
 UV cutoff at 10% T: 398 nm (10.0 diopter lens)
 400 nm (30.0 diopter lens)
 Index of Refraction: 1.55 (35° C)
 Configuration: Biconvex
 Power: +10.0 through +30.0 diopter

HAPTICS

Configuration: Modified-C
 Material: PMMA (MONOFLEX®)
 Color: Blue

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