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PRODUCT INFORMATION

Alcon Laboratories, Inc.

ACRYSof® IOL

STERILE UV-Absorbing Acrylic Foldable Multipiece Posterior Chamber Lenses

Alcon®
a Novartis company

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ENGLISH

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STERILE UV-Absorbing Acrylic Foldable Multipiece Posterior Chamber Lenses

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

Model Characteristics Chart

Model	Optic Type	Optic Diameter (mm) $Ø_B$	Overall Length (mm) $Ø_T$	Haptic Angle
MA30AC	A	5.5	12.5	5º
MA30BA	B	5.5	12.5	5º
MA50BM	B	6.5	13.0	10º
MA60AC	A	6.0	13.0	10º
MA60BM	B	6.0	13.0	10º
MA60MA	M	6.0	13.0	5º

DESCRIPTION

AcrySof® UV-absorbing acrylic foldable multipiece posterior chamber lenses are optical implants for the replacement of the human crystalline lens in the visual correction of aphakia in adult patients following cataract surgery. The optical portion consists of a high refractive index soft acrylic material. This material is capable of being folded prior to insertion. The lens gently unfolds to a full-size lens body following implantation. These lenses have biconvex, anterior asymmetric biconvex or meniscus optics with supporting haptics. The physical properties of these lenses are:

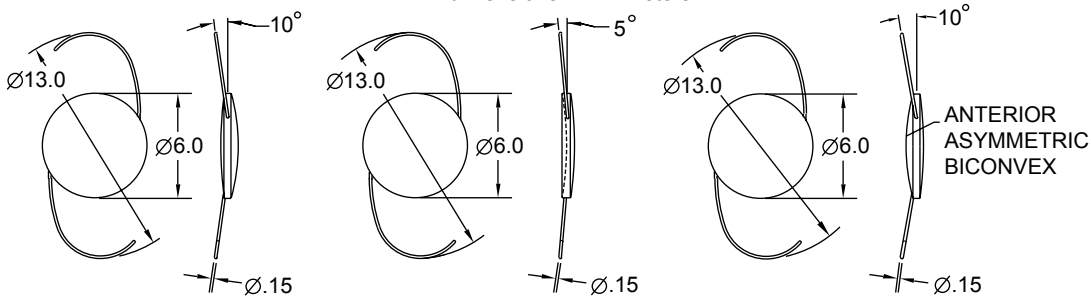
OPTICS

Material: Ultraviolet-absorbing Acrylate/ Methacrylate Copolymer
UV cutoff at 10% T: 395 nm (-5.0 diopter lens)
400 nm (+30.0 diopter lens)
Index of Refraction: 1.55
Configuration: Biconvex, anterior asymmetric biconvex or meniscus
Power: MA30AC/MA30BA (+10.0 through +30.0 diopter)
MA50BM/MA60AC/MA60BM (+6.0 through +30.0 diopter)
MA60MA (-5.0 through +5.0 diopter)

HAPTICS

Configuration: Modified-C
Material: PMMA (Monoflex™*)
Color: Blue

Figure 1
PHYSICAL CHARACTERISTICS
All dimensions in millimeters

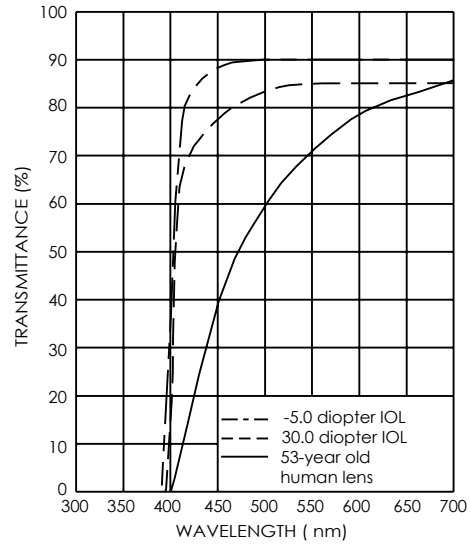


MA60BM MA60MA MA60AC

*Reg. U.S. Pat & TM Off.

Figure 2
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 from acrylate/methacrylate copolymer with bonded UV-absorber.
- Measurements were direct transmittance using a 6 mm aperture and a disc of thickness equivalent to the optic center.
- UV cutoff at 10% T is 395 nm (-5 diopter lens).
  UV cutoff at 10% T is 400 nm (+30 diopter lens).
- Human lens data from Boettner and Wolter (1962).



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 the replacement of the human lens to achieve visual correction of aphakia in adult patients following cataract surgery when extracapsular cataract extraction or phacoemulsification are performed (see WARNINGS). These lenses are intended for placement in the capsular bag.

IOL IMPLANTATION

During implantation of the AcrySof® IOL, an Alcon qualified delivery system and viscoelastic combination should be used. The use of an unqualified combination may cause damage to the lens and potential complications during the implantation process. Alcon recommends using the qualified MONARCH® IOL Delivery System or any other Alcon qualified combination. For a full list of Alcon qualified viscoelastics, handpieces and cartridges for this lens, please contact your local Alcon representative.

CAUTION

Special consideration should be given to the dimensions of lens Model MA60MA at the extreme ends of the power range in relation to the anatomical clearances in the patient's eye. The potential impact of factors such as optic central thickness, optic edge thickness and overall lens size on a patient's long-term clinical outcome must be carefully weighed against the potential benefit associated with the implantation of an intraocular lens. The patient's clinical progress should be carefully monitored.

Patients with any of the following conditions 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 judgment 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. Choroidal hemorrhage
2. Chronic severe uveitis
3. Concomitant severe eye disease
4. Excessive vitreous loss
5. Extremely shallow anterior chamber
6. Medically uncontrolled glaucoma
7. Microphthalmos
8. Non-age-related cataract
9. Posterior capsular rupture (preventing fixation of IOL)
10. Proliferative diabetic retinopathy (severe)
11. Severe corneal dystrophy
12. Severe optic atrophy
13. Uncontrollable positive pressure
14. Zonular separation (preventing fixation of IOL)

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 iridectomy for pupillary block may be avoided if one or more iridectomies are performed at the time of IOL implantation (Willis, *et al.,* 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.,* 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.
9. Lens Model MA60MA is not intended, nor should it be used, for clear lens exchange.
10. Postoperative distension of the capsular bag with variable amounts of anterior chamber shallowing and induced myopia have been associated with capsulorhexis techniques and implantation of PMMA, silicone and acrylic posterior chamber lenses (Holtz, 1992).

It is recommended that viscoelastic be removed from the eye at the close of surgery with emphasis on the space between the posterior capsule and lens. This may be accomplished by gently depressing the IOL optic posteriorly with the I/A tip and using standard irrigation/aspiration techniques to remove the viscoelastic agent from the eye. This should force any trapped viscoelastic anteriorly where it can be easily aspirated.

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

PRECAUTIONS

1. Do not resterilize these intraocular lenses by any method. (See RETURNED GOODS 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**® solutions) to rinse and/or soak lenses.
4. Handle lenses carefully to avoid damage to lens surfaces or haptics.
5. Do not attempt to reshape haptics in any way.
6. A high level of surgical skill is required for intraocular lens implantation. 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 for these posterior chamber intraocular lenses should be determined by the surgeon's experience, preference, and intended lens placement. Lens power calculation methods are described in the following references:

Hoffer, K.J. The Hoffer Q formula: A comparison of theoretic and regression formulas. *J. Cataract Refract. Surg*. 19:700-712, 1993.

Holladay, J.T. *et al*. A three-part system for refining intraocular lens power calculations. *J. Cataract Refract. Surg.* 14:17-24, 1988.

Holladay, J.T. *et al*. Standardizing constants for ultrasonic biometry, keratometry, and IOL power calculations. *J. Cataract Refract. Surg.* 23:1356-1370, 1997.

Retzlaff, J.A., Sanders, D.R., and Kraff, M. *Lens Implant Power Calculation,* 3rd ed. Slack, Inc., Thorofare, N.J., 1990.

SUGGESTED A-CONSTANT

The 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 calculation is needed, please contact Alcon Laboratories, Inc. at 1-800-TO-ALCON (1-800-862-5266). Outside the United States, contact local Alcon offices or distributors.

DIRECTIONS FOR USE

1. Examine the label on the unopened package for model, power, proper configuration, and expiration date.
2. After opening the cardboard storage container, verify lens case information (*e.g.,* model, power, and serial number) is consistent with information on outer package labeling.
3. This device is sterile until the inner pouch is opened. Inspect the pouch carefully for tears, cuts, punctures or other signs that the pouch has been opened or damaged. DO NOT implant the IOL if the sterility has been compromised (see RETURNED GOODS POLICY).
4. To remove the lens, open the pouch and transfer the case to a sterile environment. Carefully open the case to expose the lens. When removing the lens from the case, DO NOT grasp the optical area with forceps. Prior to the actual folding process, the lens should be handled by the haptic portion only. Rinse the lens thoroughly using sterile intraocular irrigating solution such as **BSS**® or **BSS PLUS**® solution. DO NOT rinse the lens in solutions other than sterile intraocular irrigating solution.
5. There are various surgical procedures which can be utilized, and the surgeon should select a procedure which is appropriate for the patient.
6. To minimize the occurrence of marks on the lens due to folding, all instrumentation should be scrupulously clean.
7. Alcon recommends using an ALCON® folding system or equivalent forceps with round edges and smooth surfaces.
8. Current techniques, appropriate instrumentation, and a list of their equivalents for folding and implantation are available from Alcon. Surgeons should verify that appropriate instrumentation is available prior to surgery.

NOTE: Prior to insertion, the lens should be carefully examined to ensure that particles have not adhered during handling.

PATIENT REGISTRATION AND REPORTING

Each patient must be registered with Alcon Laboratories, Inc. immediately following implantation of one of these lenses.

Registration is accomplished by completing the Implant Registration Card that is enclosed in the lens box and mailing it to Alcon Laboratories, Inc. using the postage paid envelope provided.

Patient registration is essential for Alcon Laboratories, Inc. long-term patient follow-up program and will assist us in responding to adverse event reports.

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.

Adverse events 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 surgeons in order to document potential long-term effects of intraocular lens implantation.

Surgeons should use the following address and telephone number for reporting adverse events involving these intraocular lenses: Alcon Laboratories, Inc. Medical Safety (AB 2-6), 6201 South Freeway, Fort Worth, Texas 76134-2099. Call Toll Free: 1-800-757-9780.

Outside the United States, contact local Alcon offices or distributors regarding reports of adverse events.

CLINICAL STUDIES

The clinical studies of the AcrySof® Model MA60BM posterior chamber lens began in December 1990. The results achieved by the patients successfully followed for three years provide reasonable assurance that the AcrySof® Model MA60BM posterior chamber lens is a safe and effective device for the visual correction of aphakia.

Since the clinical study of the AcrySof® 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.

PATIENT POPULATION

The patient population in the clinical studies consisted of 61.1% females and 38.9% males. Stratifying by race, 94.5% were Caucasian, 3.2% were Black, and 2.1% were Other. The mean age for the total population was 66 years.

VISUAL ACUITY

The following is a summary of visual acuity achieved at one year and three years (Tables 1 and 1A) postoperatively by subjects who did not have preoperative ocular pathology, abnormal corneas, or postoperative macular degeneration (Best Case) and visual acuity achieved by overall subject population and by method of cataract extraction as shown in Tables 2, 2A, 3 and 3A.

Table 1

Visual Acuity in Best Case Patient Population at One Year

	20/40 or better		20/41 - 20/80		Worse than 20/80		Total Reported
Age	N	%	N	%	N	%	N
<60	30	100.0	0	0.0	0	0.0	30
60-69	218	99.5	0	0.0	1	0.5	219
70-79	307	99.4	2	0.6	0	0.0	309
>79	118	100.0	0	0.0	0	0.0	118
Total	673	99.6	2	0.3	1	0.1	676

Table 1A

Visual Acuity in Best Case Patient Population at Three Years

	20/40 or better		20/41 - 20/80		Worse than 20/80		Total Reported
Age	N	%	N	%	N	%	N
<60	16	100.0	0	0.0	0	0.0	16
60-69	110	98.2	2	1.8	0	0.0	112
70-79	144	99.3	1	0.7	0	0.0	145
>79	51	98.1	1	1.9	0	0.0	52
Total	321	98.8	4	1.2	0	0.0	325

ONE YEAR DATA

Table 2

N = 18

Visual Acuity By Extraction Method at One Year

Planned Extracapsular Cataract Extraction

	20/40 or better		20/41 - 20/80		Worse than 20/80		Total Reported
Age	N	%	N	%	N	%	N
<60	0	0.0	0	0.0	0	0.0	0
60-69	4	100.0	0	0.0	0	0.0	4
70-79	9	75.0	3	25.0	0	0.0	12
>79	2	100.0	0	0.0	0	0.0	2
Total	15	83.3	3	16.7	0	0.0	18

Table 2A

N = 1020

Visual Acuity By Extraction Method at One Year

Phacoemulsification Cataract Extraction

	20/40 or better		20/41 - 20/80		Worse than 20/80		Total
Age	N	%	N	%	N	%	N
<60	38	100.0	0	0.0	0	0.0	38
60-69	277	98.6	3	1.1	1	0.4	281
70-79	436	95.6	12	2.6	8	1.8	456
>79	202	93.1	10	4.6	5	2.3	217
Age Not Reported	16	100.0	0	0.0	0	0.0	16
Total	969	96.1	25	2.5	14	1.4	1008
VA Not Reported	NA	NA	NA	NA	NA	NA	12
Grand Total	NA	NA	NA	NA	NA	NA	1020

THREE YEAR DATA

Table 3

Visual Acuity By Extraction Method at Three Years

Planned Extracapsular Cataract Extraction

	20/40 or better		20/41 - 20/80		Worse than 20/80		Total Reported
Age	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	1	100.0	0	0.0	0	0.0	1
Overall ECCE	6	100.0	0	0.0	0	0.0	6

Table 3A

Visual Acuity By Extraction Method at Three Years

Phacoemulsification Cataract Extraction

	20/40 or better		20/41 - 20/80		Worse than 20/80		Total Reported
Age	N	%	N	%	N	%	N
<60	20	100.0	0	0.0	0	0.0	20
60-69	154	97.5	3	1.9	1	0.6	158
70-79	221	96.5	4	1.7	4	1.7	229
>79	87	91.6	3	3.2	5	5.3	95
Overall Phaco	482	96.0	10	2.0	10	2.0	502

Total Three Year Visual Acuity Data N = 508

COMPLICATIONS

The United States 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 (present at the one year visit) rates of these complications during the first and third postoperative years for the Model MA60BM patients stratified by cataract extraction method is shown in Tables 4, 4A, 5 and 5A. Complication rates include all enrolled subjects for whom a case report form was received.

Table 4

Cumulative Postoperative Complications at One Year

	ECCE N = 24		PHACO N = 1203		OVERALL N = 1227	
	N	%	N	%	N	%
Corneal Edema	NA	-	NA	-	NA	-
Iritis	NA	-	NA	-	NA	-
Hyphema	1	4.2	17	1.4	18	1.5
Macular Edema	3	12.5	20	1.7	23	1.9
Pupillary Block	0	0.0	3	0.2	3	0.2
Secondary Glaucoma	NA	-	NA	-	NA	-
Cyclitic Membrane	0	0.0	1	<0.1	1	<0.1
Vitritis	NA	-	NA	-	NA	-
Endophthalmitis	0	0.0	3	0.2	3	0.2
Retinal Detachment	0	0.0	3	0.2	3	0.2
Lens Dislocation	0	0.0	0	0.0	0	0.0

Table 4A

Persistent Postoperative Complications at One Year

	ECCE N = 24		PHACO N = 1203		OVERALL N = 1227	
	N	%	N	%	N	%
Corneal Edema	0	0.0	0	0.0	0	0.0
Iritis	0	0.0	1	0.1	1	0.1
Hyphema	0	0.0	0	0.0	0	0.0
Macular Edema	0	0.0	2	0.2	2	0.2
Pupillary Block	0	0.0	0	0.0	0	0.0
Secondary Glaucoma	0	0.0	0	0.0	0	0.0
Cyclitic Membrane	0	0.0	0	0.0	0	0.0
Vitritis	0	0.0	0	0.0	0	0.0
Endophthalmitis	0	0.0	0	0.0	0	0.0
Retinal Detachment	0	0.0	1	0.1	1	0.1
Lens Dislocation	0	0.0	0	0.0	0	0.0

Table 5

Cumulative Postoperative Complications at Three Years

	ECCE N = 24		PHACO N = 1203		OVERALL N = 1227	
	N	%	N	%	N	%
Corneal Edema	NA	-	NA	-	NA	-
Iritis	NA	-	NA	-	NA	-
Hyphema	1	4.2	17	1.4	18	1.5
Macular Edema	3	12.5	23	1.9	26	2.1
Pupillary Block	0	0.0	3	0.2	3	0.2
Secondary Glaucoma	NA	-	NA	-	NA	-
Cyclitic Membrane	0	0.0	1	<0.1	1	<0.1
Vitritis	NA	-	NA	-	NA	-
Endophthalmitis	0	0.0	3	0.2	3	0.2
Retinal Detachment	0	0.0	3	0.2	3	0.2
Lens Dislocation	0	0.0	0	0.0	0	0.0

Table 5A
Persistent Postoperative Complications at Three Years

	ECCE N = 24		PHACO N = 1203		OVERALL N = 1227	
	N	%	N	%	N	%
Corneal Edema	0	0.0	0	0.0	0	0.0
Iritis	0	0.0	1	0.1	1	0.1
Hyphema	0	0.0	0	0.0	0	0.0
Macular Edema	0	0.0	2	0.2	2	0.2
Pupillary Block	0	0.0	0	0.0	0	0.0
Secondary Glaucoma	0	0.0	0	0.0	0	0.0
Cyclitic Membrane	0	0.0	0	0.0	0	0.0
Vitritis	0	0.0	0	0.0	0	0.0
Endophthalmitis	0	0.0	0	0.0	0	0.0
Retinal Detachment	0	0.0	1	0.1	1	0.1
Lens Dislocation	0	0.0	0	0.0	0	0.0

Fifty-four (4.4%) patients receiving the AcrySof® Model MA60BM posterior chamber lens experienced one or more of the complications listed in the previous tables. However, the majority of these complications occurred early in the postoperative time frame and appeared to be associated with the cataract extraction.
NOTE: Cumulative refers to any complication reported at any time during the clinical study. Persistent refers to any complication reported at 12-14 months.

ADVERSE REACTIONS

Adverse reactions were reported at the following rates for AcrySof® Model MA60BM posterior chamber intraocular lens implant patients at one and three years postoperatively (Tables 6 and 6A) and includes all enrolled subjects for whom a case report form was received.

Table 6
Adverse Reactions at One Year Postoperatively

	ECCE N = 24		PHACO N = 1203		OVERALL N = 1227	
	N	%	N	%	N	%
Hypopyon	0	0.0	4	0.3	4	0.3
Intraocular Infection	0	0.0	4	0.3	4	0.3
Acute Corneal Decompensation	0	0.0	0	0.0	0	0.0
Secondary Surgical Intervention:	3	12.5	20	1.7	23	1.9
a) Lens Replacement/ Removal	1	4.2	2	0.2	3	0.2
b) Retinal Detachment Repair	0	0.0	5	0.4	5	0.4
c) Repositioning of Lens	1	4.2	2	0.2	3	0.2
d) Vitrectomy	0	0.0	3	0.2	3	0.2
e) Iridectomy	1	4.2	1	0.1	2	0.2
f) Wound Repair Leak	0	0.0	1	0.1	1	0.1
g) Photocoagulation	0	0.0	1	0.1	1	0.1
h) Removal of Residual Cortex Material	0	0.0	1	0.1	1	0.1
i) Anterior Capsulotomy	0	0.0	4	0.3	4	0.3

Table 6A
Adverse Reactions at Three Years Postoperatively

	ECCE N = 24		PHACO N = 1203		OVERALL N = 1227	
	N	%	N	%	N	%
Hypopyon	0	0.0	4	0.3	4	0.3
Intraocular Infection	0	0.0	4	0.3	4	0.3
Acute Corneal Decompensation	0	0.0	0	0.0	0	0.0
Secondary Surgical Intervention:	3	12.5	26	2.2	29	2.4
a) Lens Replacement/Removal	1	4.2	2	0.2	3	0.2
b) Retinal Detachment Repair	0	0.0	9	0.7	9	0.7
c) Repositioning of Lens	1	4.2	3	0.2	4	0.3
d) Vitrectomy	0	0.0	3	0.2	3	0.2
e) Iridectomy	1	4.2	1	0.1	2	0.2
f) Wound Repair Leak	0	0.0	1	0.1	1	0.1
g) Photocoagulation	0	0.0	2	0.2	2	0.2
h) Removal of Residual Cortex Material	0	0.0	1	0.1	1	0.1
i) Anterior Capsulotomy	0	0.0	4	0.3	4	0.3

SUPPLEMENTAL PUBLISHED DATA

A prospective, well-controlled and randomized study (Ursell *et al*, 1998; Hollick *et al*. #1. 1998) with AcrySof® lenses utilizing a uniquely-developed coaxial illumination method linked to a novel computerized digital imaging system (Pande *et al*, 1998) was conducted with a total of 90 eyes (30 AcrySof®, 30 PMMA and 30 silicone), with all lenses implanted unfolded using a planned ECCE procedure with continuous curvilinear capsulorhexis (CCC). There were no statistical differences in best corrected visual acuity and contrast sensitivity established between AcrySof® and the PMMA and silicone lenses studied.

This study demonstrated a statistically significant reduction in the area of lens epithelial cells computed at 6 months and 1, 2 and 3 years postoperative in comparison with specific models of silicone and PMMA lenses of similar design (Table 7). Lens epithelial cells, or LECs, are believed to be the major contributor to posterior capsule opacification, or PCO.

Table 7
Percentage of Area Opacified†
Median and Range

Follow-up	6 months	1 year	2 years	3 years
AcrySof®				
Median	8.2	10.7	11.8	10.2
Range	4.1 - 34.7	1.1 - 34.4	2.6 - 52	3.4 - 53.7
N	21	25	16	18
SILICONE				
Median	20.1	22.2	33.5	39.9
Range	7.7 - 59.4	5.8 - 61.2	4.7 - 75.6	5.5 - 74.3
N	24	23	21	21
PMMA				
Median	19.9	26.1	43.7	56.1
Range	1.3 - 66	9.5 - 54.1	3.9 - 67	4.8 - 94.2
N	25	21	24	21
P value	0.0003	0.0001	0.0001	0.0001

† Area of opacification is defined as the boundary of the posterior lens capsule within the border of the anterior capsulorhexis exhibiting a relative difference in brightness in forward light scatter

A statistically significant difference in Nd:YAG capsulotomy rate was observed between AcrySof® and a similarly designed PMMA lens (p=0.02), but not between AcrySof® and a silicone lens (p=0.23) at 3 years postoperative (Table 8).

Table 8
Posterior (Nd:YAG) Capsulotomy Rates

IOL Material @ 3 years			
	AcrySof®	Silicone	PMMA
N	0/19	3/22	6/23
%	0%	14%	26%
P value	NA	0.23	0.02

In addition, the reduced area of LECs observed in this study was associated with decreased lens epithelial cell proliferation (Hollick *et al*, #2. 1998) and anterior capsule movement (Ursell *et al*, 1997) for AcrySof® lenses as compared to the models of similarly designed silicone and PMMA lenses.

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

In the United States, returned lenses will only be accepted in exchange for other products, not credit. All returns must be accompanied by an Alcon Laboratories, Inc. Returned Goods Number and be shipped via traceable means. A Returned Goods Number is obtained by contacting Alcon's Customer Service Department. Issuance of this number does not constitute final acceptance of the returned products. For detailed policy guidelines including exchange, please contact your Sales or Customer Service Representative. Outside the United States, contact local Alcon offices or distributors regarding returned goods policy.

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SYMBOLS USED ON LABELING

SYMBOL	ENGLISH
PMMA	Polymethylmethacrylate
IOL	Intraocular lens
PC	Posterior chamber
PCL	Posterior chamber lens
A	Anterior Asymmetric Biconvex
B	Biconvex
M	Meniscus
UV	Ultraviolet
D	Diopter
$Ø_B$	Body diameter (Optic diameter)
$Ø_T$	Overall diameter (Overall length)
	Do not reuse
	Use by
STERILE EO	Sterilized by ethylene oxide
SN	Serial number
	Attention: See instructions for use
	Manufacturer
EC REP	Authorized Representative in the European Community
	Upper Limit of Temperature

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