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PRODUCT INFORMATION
Alcon Laboratories, Inc.

ACRYSOF® NATURAL
SINGLE-PIECE IOL

Alcon®
a Novartis company

PRODUCT INFORMATION
Alcon Laboratories, Inc.

ENGLISH

AcrySof® NATURAL SINGLE-PIECE IOL

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

Model Characteristics Chart

Model	Optic Diameter (mm) $Ø_B$	Overall Length (mm) $Ø_T$	Haptic Angle
SN60AT	6.0	13.0	0º

DESCRIPTION

AcrySof® Natural UV and blue light filtering acrylic foldable single-piece posterior chamber lenses are optical implants for the replacement of the human crystalline lens in the visual correction of aphakia in adult patients. AcrySof® Natural with Alcon's proprietary blue light filtering chromophore filters light in a manner that approximates the human crystalline lens in the 400 - 475 nm blue light wavelength range (Boettner and Wolter, 1962). In addition to standard UV-light filtering, the AcrySof® Natural IOL reduces transmittance of blue light wavelengths from 71% at 400 nm to 22% at 475 nm (see Table 1). 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. The lens has a biconvex optic with supporting haptics. The physical properties of the lens are:

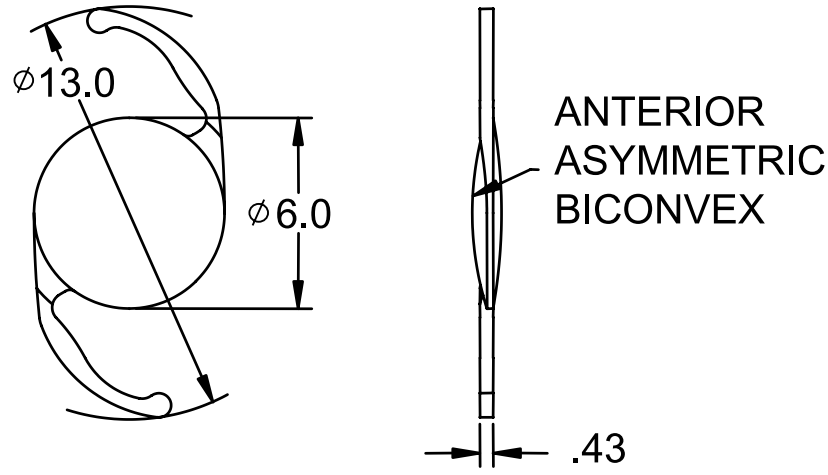
OPTICS

Dimensions:	See Figure 1
Material:	Ultraviolet and blue light absorbing Acrylate/ Methacrylate Copolymer
UV cutoff at 10% T:	See Figure 2
Index of Refraction:	1.55
Configuration:	Anterior Asymmetric Biconvex
Power:	+6.0 through +40.0 diopter

HAPTICS

Dimensions:	See Figure 1
Configuration:	STABLEFORCE® Modified-L
Material:	See Optic Material

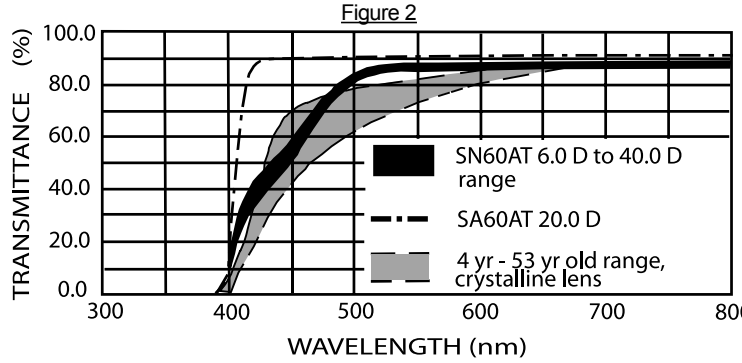
PHYSICAL CHARACTERISTICS
All dimensions in millimeters
Figure 1



SN60AT

SPECTRAL TRANSMITTANCE CURVES

Figure 2



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 and Alcon's proprietary blue light filtering chromophore.
- Measurements were direct transmittance using a 6 mm aperture and a disc of thickness equivalent to the optic center.
- Human lens data from Boettner and Wolter (1962).

Table 1

Transmittance Comparison for 20.0 D IOLs, %

Model	400 nm	425 nm	450 nm	475 nm
SA60AT	21	86	88	88
SN60AT	6	31	47	69
Transmittance Difference (SA60AT –SN60AT)	15	55	41	19
Transmittance Reduction with SN60AT (% of SA60AT)	71	64	47	22

MODE OF ACTION

AcrySof® Natural 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® Natural posterior chamber intraocular lenses are indicated for the replacement of the human lens to achieve visual correction of aphakia in adult patients 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® Natural Single-Piece 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 SN60AT 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 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. Choroidal hemorrhage
2. Concomitant severe eye disease
3. Excessive vitreous loss
4. Extremely shallow anterior chamber
5. Microphthalmos
6. Non-age-related cataract

7. Posterior capsular rupture (preventing fixation of IOL)
8. Severe corneal dystrophy
9. Severe optic atrophy
10. Uncontrollable positive pressure
11. Zonular separation (preventing fixation of IOL)
12. Color vision deficiencies
13. Glaucoma
14. Chronic uveitis
15. Diabetic retinopathy
16. Clinically significant macular/RPE changes

Studies have shown that color vision discrimination is not adversely affected in individuals with the AcrySof® Natural IOL and normal color vision. The effect on vision of the AcrySof® Natural IOL in subjects with hereditary color vision defects and acquired color vision defects secondary to ocular disease (e.g., glaucoma, diabetic retinopathy, chronic uveitis, and other retinal or optic nerve diseases) has not been studied.

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, 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. These lenses are not intended, nor should they 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).
11. Caution should be used prior to lens encapsulation to avoid lens decentrations or dislocations. Some clinical cases suggest encapsulation occurs within four weeks.
12. The clinical study of the AcrySof® Natural Single-Piece Lens (referenced in Tables 2 through 5) was conducted with the lens intended for implantation in the capsular bag only. There is no clinical data to demonstrate its safety and effectiveness for placement in the ciliary sulcus.

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.

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®**) 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.

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 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®**. 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® style 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. (U.S.)* through your local Alcon office or distributor.

Surgeons wanting direct communication 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, TX 76134-2099, Call Toll free: 1-800-757-9780.

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

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

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.

AcrySof® ACRYLIC FOLDABLE POSTERIOR CHAMBER LENS CLINICAL STUDIES

Three clinical studies have been performed on AcrySof® Acrylic Foldable Posterior Chamber Lenses. The clinical study of the AcrySof® Acrylic Foldable Multipiece Posterior Chamber Lens (Model MA60BM) began in December 1990 and the clinical study of the AcrySof® Acrylic Foldable Single-Piece Posterior Chamber Lens (Model SA30EL) began in January 1997. AcrySof® Acrylic Foldable Single-Piece Posterior Chamber Lens (Single-Piece) is a modification of the parent AcrySof® Acrylic Foldable Multipiece Posterior Chamber Lens (Multipiece). A study was conducted to demonstrate the safety and effectiveness of the AcrySof® Natural Single-Piece Posterior Chamber Lens Model SB30AL (UV and blue light filtering) as the parent lens model. This was a randomized clinical study that included the AcrySof® Model SA30AL (UV-absorbing only) as a control lens. Only data from the first operative eye from those subjects who received either a Model SB30AL or Model SA30AL intraocular lens are included.

AcrySof® Natural SINGLE-PIECE LENS Model SB30AL CLINICAL STUDY

The results achieved by the patients successfully followed for a minimum of one year postoperatively provide reasonable assurance that the AcrySof® Natural Single-Piece lens Model SB30AL is a safe and effective device for the visual correction of aphakia.

AcrySof® Natural SINGLE-PIECE LENS Model SB30AL PATIENT POPULATION

To date, the subject population implanted with a Model SB30AL in at least the first operative eye in this bilateral study consists of 70.6% females and 29.4% males. The subject population implanted with a Model SA30AL (control) intraocular lens consists of 60.5% females and 39.5% males. Stratifying by race for the Model SB30AL population, 95.3% are Caucasian, and 4.7% are Black. The control (SA30AL) subject population were 96.6% Caucasian, 2% Black and 1.4% other. The mean age for the total population receiving the Model SB30AL in at least the first operative eye is 72.9 years. Similarly, the mean age for the total population receiving the Model SA30AL (control) is 71.9 years.

AcrySof® Natural SINGLE-PIECE LENS Model SB30AL VISUAL ACUITY

A summary of visual acuity achieved at a minimum of one year postoperatively among subjects who did not have preoperative ocular pathology, abnormal corneas, or macular degeneration at any time (Best Case) is presented in Table 2a, and visual acuity achieved by overall subject population is shown in Table 3a. Control data are found for the same data sets in Tables 2b and 3b, respectively. There was no statistically significant difference in visual acuity between Model SB30AL and the control lens, Model SA30AL, in either the best case or overall data sets.

Table 2a

Best Corrected Visual Acuity in the Best Case Patient Population at a Minimum of One Year Postoperatively, AcrySof® Natural IOL SB30AL

	Acuity														
	#Per	20/20 or Better		20/25		20/30		20/40		20/40 or Better		>20/40 to <20/80		> 20/80	
	N	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Age Category															
<60	1	1	100.0	0	0.0	0	0.0	0	0.0	1	100.0	0	0.0	0	0.0
60-69	40	34	85.0	6	15.0	0	0.0	0	0.0	40	100.0	0	0.0	0	0.0
70-79	60	47	78.3	11	18.3	2	3.3	0	0.0	60	100.0	0	0.0	0	0.0
>=80	13	9	69.2	2	15.4	2	15.4	0	0.0	13	100.0	0	0.0	0	0.0
Total	114	91	79.8	19	16.7	4	3.5	0	0.0	114	100.0	0	0.0	0	0.0

Table 2b

Best Corrected Visual Acuity in the Best Case Patient Population at a Minimum of One Year Postoperatively, AcrySof® IOL SA30AL control

	Acuity														
	#Per	20/20 or Better		20/25		20/30		20/40		20/40 or Better		>20/40 to <20/80		> 20/80	
	N	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Age Category															
<60	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
60-69	48	37	77.1	9	18.8	1	2.1	1	2.1	48	100.0	0	0.0	0	0.0
70-79	42	34	81.0	6	14.3	1	2.4	0	0.0	41	97.6	1	2.4	0	0.0
>=80	12	11	91.7	1	8.3	0	0.0	0	0.0	12	100.0	0	0.0	0	0.0
Total	102	82	80.4	16	15.7	2	2.0	1	1.0	101	99.0	1	1.0	0	0.0

Table 3a

Best Corrected Visual Acuity in the Overall Patient Population at a Minimum of One Year Postoperatively, AcrySof® Natural IOL SB30AL

	Acuity														
	#Per	20/20 or Better		20/25		20/30		20/40		20/40 or Better		>20/40 to <20/80		> 20/80	
	N	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Age Category															
<60	1	1	100.0	0	0.0	0	0.0	0	0.0	1	100.0	0	0.0	0	0.0
60-69	42	36	85.7	6	14.3	0	0.0	0	0.0	42	100.0	0	0.0	0	0.0
70-79	72	54	75.0	13	18.1	3	4.2	1	1.4	71	98.6	0	0.0	1	1.4
>=80	20	11	55.0	5	25.0	4	20.0	0	0.0	20	100.0	0	0.0	0	0.0
Total	135	102	75.6	24	17.8	7	5.2	1	0.7	134	99.3	0	0.0	1	0.7

Table 3b

Best Corrected Visual Acuity in the Overall Patient Population at a Minimum of One Year Postoperatively, AcrySof® IOL SA30AL control

	Acuity														
	#Per	20/20 or Better		20/25		20/30		20/40		20/40 or Better		>20/40 to <20/80		> 20/80	
	N	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Age Category															
<60	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
60-69	52	41	78.8	9	17.3	1	1.9	1	1.9	52	100.0	0	0.0	0	0.0
70-79	57	41	71.9	9	15.8	4	7.0	1	1.8	55	96.5	1	1.8	1	1.8
>=80	18	12	66.7	3	16.7	2	11.1	1	5.6	18	100.0	0	0.0	0	0.0
Total	127	94	74.0	21	16.5	7	5.5	3	2.4	125	98.4	1	0.8	1	0.8

AcrySof® Natural SINGLE-PIECE LENS Model SB30AL CUMULATIVE ADVERSE EVENTS

The cumulative rates of these adverse events up to and including a minimum of a one year postoperative period for the AcrySof® Natural Single-Piece Lens Model SB30AL and the Model SA30AL patients are shown in Table 4. There were no statistically significant differences between the Model SB30AL and the Model SA30AL for the proportion of subjects experiencing any of the cumulative adverse events.

Table 4

Cumulative Adverse Events at a Minimum of One Year Postoperatively
AcrySof® Natural SB30AL and SA30AL control

		SB30AL (N= 153)		SA30AL (N= 147)		p-value*
		N	%	N	%	
Type of Adverse Event						
Cumulative	Hypopyon	0	0.0	0	0.0	NA
	Intraocular Infection / Endophthalmitis	0	0.0	0	0.0	NA
	Macular Edema	4	2.6	2	1.4	0.6847
	Pupillary Block	0	0.0	0	0.0	NA
	Retinal Detachment or Retinal Detachment Repair	0	0.0	0	0.0	NA
	Lens Dislocation	1	0.7	0	0.0	1.0000
	Secondary Surgical Reintervention	5	3.3	2	1.4	0.4482
	Removal of Residual Cortex	1	0.7	0	0.0	
	Explant (dislocation due to capsular rupture)	1	0.7	0	0.0	
	Cryotherapy to Repair Retinal Tear	1	0.7	0	0.0	
	Paracentesis to Lower IOP	1	0.7	0	0.0	
	Focal Laser Treatment	1	0.7	0	0.0	
	Photodynamic Therapy	0	0.0	1	0.7	
	Explant Due to Biometry Error	0	0.0	1	0.7	
	Hyphema	0	0.0	0	0.0	NA

*p-values from Fisher's Exact Test comparing Model SB30AL to Model SA30AL.

AcrySof® Natural SINGLE-PIECE LENS Model SB30AL PERSISTENT ADVERSE EVENTS

The persistent rates of these adverse events at a minimum of a one year postoperative period for the AcrySof® Natural Single-Piece Lens Model SB30AL patients and the Control Model SA30AL are shown in Table 5. There were no statistically significant differences between the Model SB30AL and the Model SA30AL for the proportion of subjects experiencing any of the persistent adverse events.

Table 5

Persistent Adverse Events at a Minimum of One Year Postoperatively
AcrySof® Natural IOL SB30AL and SA30AL control

		SB30AL (N= 138)		SA30AL (N= 127)		p-value*
		N	%	N	%	
Type of Adverse Event						
Persistent	Corneal Edema	0	0	1	0.8	0.4792
	Iritis	0	0	0	0.0	NA
	Macular Edema	2	1.4	1	0.8	1.0000
	Vitritis	0	0	0	0.0	NA
	Raised IOP Requiring Treatment	0	0	0	0.0	NA

*p-values from Fisher's Exact Test comparing Model SB30AL to Model SA30AL.

AcrySof® Natural SINGLE-PIECE LENS Model SB30AL COLOR PERCEPTION

Color perception testing using the Farnsworth D-15 Panel Test was conducted at the 120 to 180 day postoperative period. Of the 109 subjects with normal color vision implanted with a Model SB30AL in the first operative eye and examined at the 120 to 180 day postoperative visit, 107 (98.2%) passed the color perception test. Of the 102 subjects with normal color vision implanted with a Model SA30AL in the first operative eye and examined at the 120 to 180 day postoperative visit, 97 (95.1%) passed the color perception test. There were no statistically significant differences between Model SB30AL and Model SA30AL for the percent of subjects that passed the color perception test at the 120 to 180 day postoperative visit. Therefore, the addition of the proprietary chromophore does not negatively affect color vision in patients with normal color vision.

AcrySof® Natural SINGLE-PIECE LENS Model SB30AL Nd:YAG RATES

With a mean follow-up of 21.6 months, three (3) of the 135 subjects (2.2%) implanted with SB30AL experienced a Nd:YAG posterior capsulotomy. With a mean follow-up of 21.9 months, two (2) of the 127 subjects (1.6%) implanted with SA30AL experienced a Nd:YAG posterior capsulotomy.

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.

REFERENCES

Boettner, E.A. and Wolter, J.R. Transmission of the ocular media. *Invest. Ophthalmol.* 1:776-783, 1962.

Girard, L.J., et al. Complications of the Simcoe Flexible Loop Phacoprosthesis in the anterior chamber. *Ophthalmic Surg.* 14(4):332-335, 1983.

Holtz, S.J. Postoperative capsular bag distension. *J. Cataract Refract. Surg.* 16(5):310-317, 1992.

Willis, D.A., et al. Pupillary block associated with posterior chamber lenses. *Ophthalmic Surg.* 16(2):108-109, 1985.

SYMBOLS USED ON LABELING

SYMBOL	ENGLISH
IOL	Intraocular lens
PC	Posterior chamber
PCL	Posterior chamber lens
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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EC REP

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