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

Model Characteristics Chart

<table>
<thead>
<tr>
<th>Model</th>
<th>Optic Type</th>
<th>Optic Diameter (mm) $\varnothing_B$</th>
<th>Overall Length (mm) $\varnothing_T$</th>
<th>Haptic Angle</th>
</tr>
</thead>
<tbody>
<tr>
<td>SN60WF</td>
<td>Anterior Asymmetric Biconvex</td>
<td>6.0</td>
<td>13.0</td>
<td>0º</td>
</tr>
</tbody>
</table>

DESCRIPTION

The AcrySof® IQ UV and blue light filtering acrylic foldable single-piece posterior chamber intraocular lens (IOL) is an optical implant for the replacement of the human crystalline lens in the visual correction of aphakia in adult patients following cataract surgery. The AcrySof® IQ lens with Alcon’s proprietary blue light filtering chromophore filters light in a manner that approximates the human crystalline lens in the 400 – 475nm blue light wavelength range (Boettner and Wolter 1962). In addition to standard UV-light filtering, the AcrySof® IQ lens reduces transmittance of blue light wavelengths from 62% at 400nm to 23% at 475nm (see Table 1). The lens consists of a high refractive index soft acrylic material 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 posterior aspheric surface of the AcrySof® IQ Model SN60WF IOL is designed with negative spherical aberration to compensate for the positive spherical aberration of an average cornea. The image quality of the Model SN60WF IOL (i.e., modulation transfer function) is illustrated in Figure 3. The physical properties of the lens are:

OPTICS

Dimensions: See Figure 1
Material: Ultraviolet and blue light filtering Acrylate/Methacrylate Copolymer
UV cutoff at 10% T: See Figure 2
Index of Refraction: 1.55
Configuration: Anterior Asymmetric Biconvex
Power: +6.0 through +30.0 diopter

HAPTICS

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

Figure 1

PHYSICAL CHARACTERISTICS

All dimensions in millimeters
Figure 2
Spectral Transmittance Curves

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 by direct transmittance using a 8mm aperture and a disc of thickness equivalent to the optic center.
• Human lens data is from Boettner and Wolter (1962).

Table 1
Transmittance Comparison for 20.0 D IOLs, %

<table>
<thead>
<tr>
<th>Model</th>
<th>400nm</th>
<th>425nm</th>
<th>450nm</th>
<th>475nm</th>
</tr>
</thead>
<tbody>
<tr>
<td>SA60AT</td>
<td>21</td>
<td>86</td>
<td>88</td>
<td>88</td>
</tr>
<tr>
<td>SN60WF</td>
<td>8</td>
<td>34</td>
<td>49</td>
<td>68</td>
</tr>
<tr>
<td>Transmittance Difference (SA60AT – SN60WF)</td>
<td>13</td>
<td>52</td>
<td>39</td>
<td>20</td>
</tr>
<tr>
<td>Transmittance Reduction with SN60WF (% of SA60AT)</td>
<td>62</td>
<td>60</td>
<td>44</td>
<td>23</td>
</tr>
</tbody>
</table>

Figure 3
Modulation Transfer Function of Model SN60WF (20.0 D)

NOTES:
1. The image quality of the Model SN60WF was characterized by measuring modulation transfer function (MTF) in a model eye described in ISO 11979-2. The ISO 11979-2 requires MTF measurements using only a 3-mm aperture. MTF is a measure of the overall optical quality of an IOL’s design.
2. In addition, the image quality of the Model SN60WF was characterized by measuring MTF in a model eye that utilized a simulated cornea exhibiting typical adult human spherical aberration. Using the modified model eye, MTF measurements were made using both 3 and 5-mm apertures.
MODE OF ACTION
The AcrySof® IQ posterior chamber intraocular lens is 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 aspheric biconvex optic reduces spherical aberration as compared to a standard spherical optic in an average eye. The effectiveness of this lens in reducing the incidence of retinal disorders has not been established.

INDICATIONS
The AcrySof® IQ posterior chamber intraocular lens is indicated for the replacement of the human lens to achieve visual correction of aphakia in adult patients following cataract surgery (see WARNINGS). This lens is intended for placement in the capsular bag.

IOL IMPLANTATION
During implantation of the AcrySof® IQ posterior chamber intraocular lens, 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
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. 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).

10. Caution should be used prior to lens encapsulation to avoid lens decenterations or dislocations. Some clinical cases suggest encapsulation occurs within four weeks.

11. 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® solution) 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® 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 the 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 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:


**AcrySof® ACRYLIC FOLDABLE POSTERIOR CHAMBER LENS CLINICAL STUDIES**

Two randomized, prospective well-controlled clinical studies have been performed on AcrySof® Acrylic Single-Piece Foldable Posterior Chamber Lenses. The first 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. A second randomized clinical study of the AcrySof® IQ Acrylic Foldable Single-Piece IOL (with UV and blue light filtering chromophores) with an aspheric optic versus an AcrySof® Acrylic Foldable Single-Piece control lens was conducted to assess the clinical/functional benefits over a traditional spherical design.

**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**

The subject population implanted with a Model SB30AL in at least the first operative eye in this bilateral study consisted of 70.6% females and 29.4% males. The subject population implanted with a Model SA30AL (control) intraocular lens consisted of 60.5% females and 39.5% males. Stratifying by race for the Model SB30AL population, 95.3% were Caucasian, and 4.7% were Black. The control (SA30AL) subject population was 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 was 72.9 years. Similarly, the mean age for the total population receiving the Model SA30AL (control) was 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>
<thead>
<tr>
<th>Age Category</th>
<th>#Per</th>
<th>20/20 or Better</th>
<th>20/25</th>
<th>20/30</th>
<th>20/40</th>
<th>20/40 or Better</th>
<th>&gt;20/40 to &lt;20/80</th>
<th>&gt;20/80</th>
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<tbody>
<tr>
<td>&lt;60</td>
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<td>0.00</td>
<td>0.0</td>
<td>0.0</td>
<td>0.0</td>
<td>1.00</td>
<td>0.0</td>
<td>0.0</td>
</tr>
<tr>
<td>60-69</td>
<td>40</td>
<td>85.0</td>
<td>6</td>
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<td>0.0</td>
<td>0.0</td>
<td>40.0</td>
<td>0.0</td>
</tr>
<tr>
<td>70-79</td>
<td>60</td>
<td>47.3</td>
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<td>3.3</td>
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<td>60.0</td>
</tr>
<tr>
<td>&gt;=80</td>
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<td>9</td>
<td>2</td>
<td>15.4</td>
<td>2</td>
<td>15.4</td>
<td>0.0</td>
<td>13.0</td>
</tr>
<tr>
<td>Total</td>
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<td>91.8</td>
<td>19</td>
<td>16.7</td>
<td>4</td>
<td>3.5</td>
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</tbody>
</table>
### Table 2b
**Best Corrected Visual Acuity in the Best Case Patient Population**
**at a Minimum of One Year Postoperatively, AcrySof® Lens SA30AL control**

<table>
<thead>
<tr>
<th>Age Category</th>
<th>#Per</th>
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<th>20/25</th>
<th>20/30</th>
<th>20/40</th>
<th>20/40 or Better</th>
<th>&gt;20/40 to &lt;20/80</th>
<th>&gt; 20/80</th>
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<td></td>
<td>N</td>
<td>N %</td>
<td>N %</td>
<td>N %</td>
<td>N %</td>
<td>N %</td>
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<tr>
<td>&lt;60</td>
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<td>0.0</td>
<td>0.0</td>
<td>0.0</td>
<td>0.0</td>
<td>0.0</td>
<td>0.0</td>
<td>0.0</td>
</tr>
<tr>
<td>60-69</td>
<td>48</td>
<td>37.7</td>
<td>9.8</td>
<td>2.1</td>
<td>1.2</td>
<td>48.0</td>
<td>100.0</td>
<td>0.0</td>
</tr>
<tr>
<td>70-79</td>
<td>42</td>
<td>34.1</td>
<td>14.3</td>
<td>2.4</td>
<td>0.0</td>
<td>41.7</td>
<td>97.6</td>
<td>2.4</td>
</tr>
<tr>
<td>&gt;=80</td>
<td>12</td>
<td>11.2</td>
<td>8.3</td>
<td>0.0</td>
<td>0.0</td>
<td>12.5</td>
<td>100.0</td>
<td>0.0</td>
</tr>
<tr>
<td>Total</td>
<td>102</td>
<td>82.0</td>
<td>16.1</td>
<td>2.0</td>
<td>1.0</td>
<td>101.0</td>
<td>99.0</td>
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</table>

### Table 3a
**Best Corrected Visual Acuity in the Overall Patient Population**
**at a Minimum of One Year Postoperatively, AcrySof® Natural Lens SB30AL**

<table>
<thead>
<tr>
<th>Age Category</th>
<th>#Per</th>
<th>20/20 or Better</th>
<th>20/25</th>
<th>20/30</th>
<th>20/40</th>
<th>20/40 or Better</th>
<th>&gt;20/40 to &lt;20/80</th>
<th>&gt; 20/80</th>
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<td>N %</td>
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<tr>
<td>&lt;60</td>
<td>1</td>
<td>100.0</td>
<td>0.0</td>
<td>0.0</td>
<td>0.0</td>
<td>0.0</td>
<td>1.0</td>
<td>0.0</td>
</tr>
<tr>
<td>60-69</td>
<td>42</td>
<td>85.7</td>
<td>14.3</td>
<td>0.0</td>
<td>0.0</td>
<td>42.0</td>
<td>100.0</td>
<td>0.0</td>
</tr>
<tr>
<td>70-79</td>
<td>72</td>
<td>75.0</td>
<td>18.1</td>
<td>4.2</td>
<td>1.4</td>
<td>71.0</td>
<td>96.6</td>
<td>1.4</td>
</tr>
<tr>
<td>&gt;=80</td>
<td>20</td>
<td>55.0</td>
<td>25.0</td>
<td>20.0</td>
<td>0.0</td>
<td>20.0</td>
<td>100.0</td>
<td>0.0</td>
</tr>
<tr>
<td>Total</td>
<td>135</td>
<td>75.6</td>
<td>17.8</td>
<td>5.2</td>
<td>1.7</td>
<td>134.0</td>
<td>99.3</td>
<td>0.7</td>
</tr>
</tbody>
</table>

### Table 3b
**Best Corrected Visual Acuity in the Overall Patient Population**
**at a Minimum of One Year Postoperatively, AcrySof® Lens SA30AL control**

<table>
<thead>
<tr>
<th>Age Category</th>
<th>#Per</th>
<th>20/20 or Better</th>
<th>20/25</th>
<th>20/30</th>
<th>20/40</th>
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<th>&gt;20/40 to &lt;20/80</th>
<th>&gt; 20/80</th>
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<tr>
<td></td>
<td>N</td>
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<td>N %</td>
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<tr>
<td>&lt;60</td>
<td>0</td>
<td>0.0</td>
<td>0.0</td>
<td>0.0</td>
<td>0.0</td>
<td>0.0</td>
<td>0.0</td>
<td>0.0</td>
</tr>
<tr>
<td>60-69</td>
<td>52</td>
<td>78.8</td>
<td>17.3</td>
<td>1.9</td>
<td>1.9</td>
<td>52.0</td>
<td>100.0</td>
<td>0.0</td>
</tr>
<tr>
<td>70-79</td>
<td>57</td>
<td>71.9</td>
<td>15.8</td>
<td>7.0</td>
<td>1.8</td>
<td>55.0</td>
<td>96.5</td>
<td>1.8</td>
</tr>
<tr>
<td>&gt;=80</td>
<td>18</td>
<td>66.7</td>
<td>16.7</td>
<td>11.1</td>
<td>5.6</td>
<td>18.0</td>
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</tr>
<tr>
<td>Total</td>
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<td>74.0</td>
<td>21.6</td>
<td>7.5</td>
<td>2.4</td>
<td>125.0</td>
<td>98.4</td>
<td>1.0</td>
</tr>
</tbody>
</table>
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>
<thead>
<tr>
<th>Type of Adverse Event</th>
<th>SB30AL (N = 153)</th>
<th>SA30AL (N = 147)</th>
<th>p-value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cumulative Hypopyon</td>
<td>0 0.0</td>
<td>0 0.0</td>
<td>NA</td>
</tr>
<tr>
<td>Intraocular Infection / Endophthalmitis</td>
<td>0 0.0</td>
<td>0 0.0</td>
<td>NA</td>
</tr>
<tr>
<td>Macular Edema</td>
<td>4 2.6</td>
<td>2 1.4</td>
<td>0.6847</td>
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<tr>
<td>Pupillary Block</td>
<td>0 0.0</td>
<td>0 0.0</td>
<td>NA</td>
</tr>
<tr>
<td>Retinal Detachment or Retinal Detachment Repair</td>
<td>0 0.0</td>
<td>0 0.0</td>
<td>NA</td>
</tr>
<tr>
<td>Lens Dislocation</td>
<td>1 0.7</td>
<td>0 0.0</td>
<td>1.0000</td>
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<tr>
<td>Secondary Surgical Reintervention</td>
<td>5 3.3</td>
<td>2 1.4</td>
<td>0.4482</td>
</tr>
<tr>
<td>Removal of Residual Cortex</td>
<td>1 0.7</td>
<td>0 0.0</td>
<td>0.00</td>
</tr>
<tr>
<td>Explant (dislocation due to capsular rupture)</td>
<td>1 0.7</td>
<td>0 0.0</td>
<td>0.00</td>
</tr>
<tr>
<td>Cryotherapy to Repair Retinal Tear</td>
<td>1 0.7</td>
<td>0 0.0</td>
<td>0.00</td>
</tr>
<tr>
<td>Paracentesis to Lower IOP</td>
<td>1 0.7</td>
<td>0 0.0</td>
<td>0.00</td>
</tr>
<tr>
<td>Focal Laser Treatment</td>
<td>1 0.7</td>
<td>0 0.0</td>
<td>0.00</td>
</tr>
<tr>
<td>Photodynamic Therapy</td>
<td>0 0.0</td>
<td>1 0.7</td>
<td>0.70</td>
</tr>
<tr>
<td>Explant Due to Biometry Error</td>
<td>0 0.0</td>
<td>1 0.7</td>
<td>0.70</td>
</tr>
<tr>
<td>Hyphema</td>
<td>0 0.0</td>
<td>0 0.0</td>
<td>NA</td>
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</table>

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

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

The rates of these adverse events persisting 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>
<thead>
<tr>
<th>Type of Adverse Event</th>
<th>SB30AL (N = 138)</th>
<th>SA30AL (N = 127)</th>
<th>p-value*</th>
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<tr>
<td>Persistent Corneal Edema</td>
<td>0 0.0</td>
<td>1 0.8</td>
<td>0.4792</td>
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<tr>
<td>Iritis</td>
<td>0 0.0</td>
<td>0 0.0</td>
<td>NA</td>
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<tr>
<td>Macular Edema</td>
<td>2 1.4</td>
<td>1 0.8</td>
<td>1.0000</td>
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<tr>
<td>Vitritis</td>
<td>0 0.0</td>
<td>0 0.0</td>
<td>NA</td>
</tr>
<tr>
<td>Raised IOP Requiring Treatment</td>
<td>0 0.0</td>
<td>0 0.0</td>
<td>NA</td>
</tr>
</tbody>
</table>

* 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.

AcrySof® IQ LENS CLINICAL STUDY
Consistent with the design of similar previously conducted IOL studies, adult subjects in good general ocular health (e.g. no prior ocular surgery, degenerative visual disorder which would significantly impact visual acuity, or severe acute or chronic condition that may increase patient risk) having bilateral cataracts were enrolled in a controlled, randomized, double-masked, multi-center, contralateral implant clinical investigation of the AcrySof® IQ lens versus a spherical control lens. Ocular spherical aberrations were statistically significantly less with the AcrySof® IQ lens than the control lens. Contrast sensitivity results demonstrated a statistically significant postoperative (at 3 months) improvement in favor of AcrySof® IQ lens implanted eyes. Eyes implanted with the AcrySof® IQ lens also experienced statistically and clinically significant improvements in a functional vision measurement, simulated night driving, under several conditions tested - especially glare and fog. These results reflect that the AcrySof® IQ IOL (an aspheric optic on a material platform containing a blue-light filtering chromophore) provides beneficial clinical performance as compared to the monofocal AcrySof® IOL (without an aspheric optic and blue-light filtering chromophore).

AcrySof® IQ LENS – SPHERICAL AND TOTAL HIGHER ORDER ABERRATIONS
The mean ocular spherical aberration of the AcrySof® IQ IOL eyes was approximately 0.1 micrometers. Figure 4 represents the statistically significant reduction in spherical and total higher order aberrations observed in favor of the AcrySof® IQ lens. Figure 5 provides the mean spherical aberration measurements of all eyes with wavefront aberrometer measurements by lens and age group. As depicted in this chart, the reduction in spherical aberration of the AcrySof® IQ IOL eyes was independent of age.

![Figure 4: Spherical and Total Higher Order RMS 90-120 Days after 2nd Eye Implant](image)

* Differences favor AcrySof® IQ IOL overall and at each visit (p<0.0001)
Figure 5
Mean Spherical Aberration Overall and by Age Group
90-120 Days after 2nd Eye Implant

- AcrySof® IQ IOL
- Control

<table>
<thead>
<tr>
<th>Age Group (Years)</th>
<th>N</th>
</tr>
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<tbody>
<tr>
<td>Total</td>
<td>73</td>
</tr>
<tr>
<td>&lt; 60</td>
<td>6</td>
</tr>
<tr>
<td>60 - 69</td>
<td>19</td>
</tr>
<tr>
<td>&gt;70</td>
<td>48</td>
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* Denotes statistical significance between lenses (p<0.0001)

AcrySof® IQ LENS – DISTANCE VISUAL ACUITY
The AcrySof® IQ lens and the control lens provided clinically similar postoperative visual acuity. Monocular visual acuity results are presented in Figures 6 and 7.

Figure 6
LogMAR BCVA

- AcrySof® IQ IOL (N=77)
- Control (N=75)

Days Postoperative
- Quantitative Lens Model Main Effect (p=0.0214)
AcrySof® IQ LENS - CONTRAST SENSITIVITY

The primary objective of the clinical investigation was to demonstrate superiority of the AcrySof® IQ lens over the control lens via mean contrast sensitivity measured postoperatively under mesopic conditions with or without glare at either of two spatial frequencies (3 or 6 cycles per degree) using the Vector Vision CSV-1000 (with chart luminance of 3 cd/m²). In a subset of patients, the Functional Acuity Contrast Test (FACT) was also performed (with chart luminance of 3 cd/m²). In this clinical investigation, superiority of the AcrySof® IQ lens over the control lens under mesopic conditions was demonstrated at 6 cycles per degree both with and without glare (CSV-1000) and at 3 and 6 cycles per degree without glare (FACT). Figures 8 and 9 depict the mesopic contrast sensitivity results at all spatial frequencies tested for both the AcrySof® IQ lens and control lens.
A subset of patients underwent testing in a validated night driving simulator. Patients were tested monocularly under conditions which simulate city and rural settings under normal, glare and fog conditions.

The nighttime city driving scene employs a variety of street lights, car lights, store lights and signs to recreate the high level of ambient lighting typical under these conditions. The nighttime rural driving scene uses a minimal amount of ambient lighting. Simulated driving speeds of approximately 35 mph and 55 mph were used for the city and rural scenes, respectively.

Patients were asked to detect and identify a series of targets in each scene, including white-green highway information signs, black-yellow warning signs and pedestrians. Patients were asked to respond when they saw the first target, allowing a detection distance to be recorded. Patients were then asked to respond when they could distinguish the target (e.g., what the sign says, which direction the pedestrian was walking, etc.) so that an identification distance could be recorded.

Figures 10 through 13 present the average differences between the AcrySof® IQ lens and control lens in city and rural driving scenes for both detection and identification distances (e.g., the mean of the intra-individual differences).

The AcrySof® IQ lens performed functionally better than the control in 34 of the 36 conditions tested, reflecting improvement in both detection and identification distances in both city and rural driving scenes under the various driving conditions tested (normal, glare, fog). Furthermore, the AcrySof® IQ lens performed statistically significantly better than the control in 12 of these conditions, with the most significant impact and greatest advantage observed in detection and identification of city pedestrians (under glare and fog conditions) and rural warning signs (under glare and fog conditions). Under reduced visibility conditions (glare, fog) in the city scene, the increased visibility distance at 35 mph provides the AcrySof® IQ lens greater than 0.5 second additional time to respond to a pedestrian target, a hazard more commonly encountered in city settings. This 0.5 second increase is functionally significant in allowing for greater time to take appropriate actions such as stopping, avoidance, etc. (Green, 2000; McBride and Matson, 2004). Under all conditions in the rural scene, the increased visibility distance at 55 mph provides the AcrySof® IQ lens more than 1 second additional time to identify warning signs, a situation frequently encountered in rural areas. A 0.5 second increase is functionally significant in allowing for greater time to take appropriate action while driving, which becomes critical at night in unfamiliar rural areas where ambient lighting is often absent. There were 6 patients in the substudy who postoperatively experienced macular degeneration or PCO. When these patients were removed from the driving analysis, the difference between IOls for detection and identification of pedestrian targets under glare conditions in the city location fell short of the 0.5-second threshold for clinical relevance. When the original analyses were adjusted for multiplicity, the difference between IOls was no longer statistically significant for city detection of text under glare (Hommel’s p-value = 0.0539) or for rural detection of pedestrian under glare (Hommel’s p-value = 0.0507).

These results demonstrate improved functional vision and likely meaningful safety benefits to elderly drivers with the AcrySof® IQ lens and to other drivers and pedestrians with whom they share the road. The results of this test demonstrate that the AcrySof® IQ lens improves functional vision, which in turn may improve patient safety for other life situations under low visibility conditions.
Figure 10
Night Driving Simulator
Mean Intra-individual Differences in Detection Sight Distances, City
Minimum of 90 days Postoperatively
AcrySof® IQ IOL – Control (n=44)

Differences for both lens groups were normalized.
* Denotes statistical significance (p<0.05) in favor of AcrySof® IQ IOL.

Figure 11
Night Driving Simulator
Mean Intra-individual Differences in Identification Sight Distances, City
Minimum of 90 days Postoperatively
AcrySof® IQ IOL – Control (n=44)

Differences for both lens groups were normalized.
* Denotes statistical significance (p<0.05) in favor of AcrySof® IQ IOL.
Figure 12
Night Driving Simulator
Mean Intra-individual Differences in Detection Sight Distances, Rural
Minimum of 90 days Postoperatively
AcrySof® IQ IOL – Control (n=44)

Differences (feet)  --  Distance difference equivalent to 0.5 seconds

Fog  Pedestrian  Warning  Text  Pedestrian  Warning  Text  Pedestrian  Warning

Differences (feet)  --  Distance difference equivalent to 0.5 seconds

Distances for both lens groups were normalized.
* Denotes statistical significance (p<0.05) in favor of AcrySof® IQ IOL.

Figure 13
Night Driving Simulator
Mean Intra-individual Differences in Identification Sight Distances, Rural
Minimum of 90 days Postoperatively
AcrySof® IQ IOL – Control (n=44)

Differences (feet)  --  Distance difference equivalent to 1 second

Fog  Pedestrian  Warning  Text  Pedestrian  Warning  Text  Pedestrian  Warning

Distances for both lens groups were normalized.
* Denotes statistical significance (p<0.05) in favor of AcrySof® IQ IOL.

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


SYMBOLS USED ON LABELING

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<thead>
<tr>
<th>SYMBOL</th>
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<tr>
<td>IOL</td>
<td>Intraocular lens</td>
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<tr>
<td>PC</td>
<td>Posterior chamber</td>
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<tr>
<td>PCL</td>
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<tr>
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<td>Ultraviolet</td>
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<tr>
<td>D</td>
<td>Diopter</td>
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<td>Body diameter (Optic diameter)</td>
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<tr>
<td>Ø_T</td>
<td>Overall diameter (Overall length)</td>
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<td>[Y]</td>
<td>Use by</td>
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<td>☢️</td>
<td>Authorized Representative in the European Community</td>
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<td>🌫️ 45 °C</td>
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U.S. Pat. No's. 5,470,932, 5,716,403 and 7,350,916.

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Fort Worth, Texas 76134-2099 USA