AcrySof® IQ ASPHERIC IOL

with the AcrySert® C delivery system

STERILE UV and Blue Light Filtering Acrylic Foldable Single-Piece Posterior Chamber Lenses with the AcrySert® C Delivery System

CAUTION: Federal (USA) law restricts this device to the 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>SN6CWS</td>
<td>Anterior Asymmetric Biconvex</td>
<td>6.0</td>
<td>13.0</td>
<td>0°</td>
</tr>
</tbody>
</table>

DESCRIPTION

AcrySof® IQ 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 following cataract surgery. AcrySof® IQ IOL 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 (Boethner and Wolter, 1962). In addition to standard
UV-light filtering, the AcrySof® IQ IOL reduces transmittance of blue light wavelengths from 62% at 400 nm to 23% 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 posterior aspheric surface of the AcrySof® IQ Model SN6CWS IOL is designed with negative spherical aberration to compensate for the positive spherical aberration of an average cornea. The image quality of the Model SN6CWS Single-Piece IOL (i.e., modulation transfer function) is illustrated in Figure 4. The AcrySof® IQ Model SN6CWS Single-Piece IOLs are provided in the AcrySert® C Delivery System for a convenient, controlled means to reliably place these lenses into the capsular bag. The physical properties of the lenses are:

**OPTICS**
- Dimensions: See Figure 1
- Material: Ultraviolet and blue light filtering Acrylate/Methacrylate Copolymer
- UV cutoff at 10% T: See Figure 3
- Index of Refraction: 1.55
- Configuration: Anterior Asymmetric Biconvex
- Power: For available power range see Alcon Product Guide

**HAPTICS**
- Configuration: STABLEFORCE® Haptics Modified-L
- Material: See Optic Material

### Table 1
**Transmittance Comparison for 20.0 D IOLs, %**

<table>
<thead>
<tr>
<th>Model</th>
<th>400 nm</th>
<th>425 nm</th>
<th>450 nm</th>
<th>475 nm</th>
</tr>
</thead>
<tbody>
<tr>
<td>SA60AT</td>
<td>21</td>
<td>86</td>
<td>88</td>
<td>88</td>
</tr>
<tr>
<td>SN6CWS</td>
<td>8</td>
<td>34</td>
<td>49</td>
<td>68</td>
</tr>
<tr>
<td>Transmittance Difference (SA60AT–SN6CWS)</td>
<td>13</td>
<td>52</td>
<td>49</td>
<td>68</td>
</tr>
<tr>
<td>Transmittance Reduction with SN6CWS (% of SA60AT)</td>
<td>62</td>
<td>60</td>
<td>44</td>
<td>23</td>
</tr>
</tbody>
</table>

### Figure 3
**SPECTRAL TRANSMITTANCE CURVES**

- SN6CWS 6.0 D to 30.0 D range
- SA60AT 20.0 D
- 4 yr - 53 yr old range, crystalline lens

### Figure 4
**Modulation Transfer Function of Model SN6CWS (20.0 D)**

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.
and normal color vision. The effect on vision of the AcrySof® Natural IOL in subjects with hereditary color vision defects and Studies have shown that color vision discrimination is not adversely affected in individuals with the AcrySof® Natural IOL

16. Clinically significant macular/RPE changes
15. Diabetic retinopathy
14. Chronic uveitis
13. Glaucoma
12. Color vision deficiencies
11. Zonular separation (preventing fixation of IOL)
10. Uncontrollable positive pressure
9. Severe optic atrophy
8. Severe corneal dystrophy
7. Posterior capsular rupture (preventing fixation of IOL)
6. Non-age-related cataract
5. Microphthalmos
4. Extremely shallow anterior chamber
3. Excessive vitreous loss
2. Concomitant severe eye disease
1. Choroidal hemorrhage
decide the benefit/risk ratio before implanting a lens in a patient with one or more of these conditions: Careful preoperative evaluation and sound clinical judgment should be used by the surgeon to
risk to the patient’s eyesight. 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

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, cyclical 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 surgery. Consideration should be given to using an IOL having a larger optic or one that is more stable.
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 decentrations or dislocations. Some clinical cases suggest encapsulation occurs within four weeks.

NOTES:
1.  The image quality of the Model SN6CWS 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.
2.  In addition, the image quality of the Model SN6CWS 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-mm, and 5-mm apertures.

MODE OF ACTION
AcrySof® IQ 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 aspheric biconvex optic reduces spherical aberration as compared to a standard spherical optic in an average eye. The effectiveness of these lenses in reducing the incidence of retinal disorders has not been established.

INDICATIONS
AcrySof® IQ 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 (see WARNINGS). These lenses are intended for placement in the capsular bag.

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

1. Choroidal hemorrhage
2. Concomitant severe eye disease
3. Excessive vitreous loss
4. Extremely shallow anterior chamber
5. Microphthalamos
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, cyclical 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 decentrations or dislocations. Some clinical cases suggest encapsulation occurs within four weeks.
PRECAUTIONS
1. Do not resterilize these intraocular lenses or the AcrySert® C Delivery System by any method (see RETURNED GOODS POLICY).
2. Do not store intraocular lenses at temperatures over 45° C (113° F).
3. If required, handle lenses carefully to avoid damage to lens surfaces or haptics.
4. Do not attempt to reshape haptics in any way.
5. 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.
6. Contents are sterile unless package is opened or damaged.
7. The AcrySert® C Delivery System is for single-use only. Discard the AcrySert® C device after use.
8. Use the AcrySert® C Delivery System at Operating Room temperatures between 18° C (64° F) and 23° C (73° F).

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:


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.

QUALIFIED ALCON VISCOELASTICS AND ORDER NUMBERS
See supplement included in this package for the qualified Alcon viscoelastic(s) and order number(s).

DIRECTIONS FOR USE
Step 1. Use the AcrySert® C Delivery System at Operating Room temperatures between 18° C (64° F) and 23° C (73° F).
Step 2. Examine the label on the unopened outer box for model, power, proper configuration, and expiration date.
Step 3. After opening the cardboard outer box, inspect the device package for any damage. If damage is observed, use another AcrySof® IQ IOL and AcrySert® C Delivery System. Next, verify that the lens information on the device label (e.g., model, power, and serial number) is consistent with the information on the outer box labeling.
Step 4. To remove the AcrySert® C Delivery System, grip the corner of the plastic tray, peel open the TYVEK™ material lid portion fully, and transfer the device to a sterile environment. If, after inspection, the device nozzle appears to have damage, particulates, or deformation, use another AcrySof® IQ IOL and AcrySert® C Delivery System. If the device is not completely intact, or the plunger appears to have moved during shipping, use another AcrySof® IQ IOL and AcrySert® C Delivery System (see RETURNED GOODS POLICY).

When ready to prepare the lens for delivery, perform Steps 5, 6, and 7 in sequence, with minimal delay between steps.

Step 5. Fully insert the viscoelastic cannula, perpendicular to the device, through the viscoelastic port (cannula guide), located in the lens stop portion of the device as shown in Figure 5. Fill the device until viscoelastic can, at a minimum, be observed flowing past the nozzle “Fill-To” line, and into the nozzle tip. This will require approximately 0.2 mL of viscoelastic. Only use an Alcon viscoelastic qualified for use with the AcrySert® C Delivery System, that has been allowed to come to the operating room temperature. For a list of Alcon qualified viscoelastics, refer to the Supplement included in this package.

![Figure 5](attachment://figure_5.png)
Step 6. Retract the viscoelastic cannula and remove the lens stop by gripping the arrow tab portion and pulling it straight up (Figure 6). Discard the lens stop. Do not attempt to add viscoelastic to the device after the lens stop has been removed or lens damage may result.

Note: If any advancement of the plunger occurs prior to the removal of the lens stop, lens damage may have occurred and it is recommended to use another AcrySof® IQ IOL and AcrySert® C Delivery System.

![Figure 6](image_url)

Figure 6

Step 7. When the lens stop has been removed, gently advance the plunger forward in one smooth, continuous motion until the front edge of the optic aligns with the nozzle “Fill-To” line (Ref. Figures 7a and 7b). This plunger advancement should require at least 7 seconds. It is important not to advance the plunger abruptly as improper folding and lens damage may occur.

![Figures 7a and b](image_url)

“Fill-To” Line

Figures 7a and b

Step 8. After the plunger has been advanced to align the front (leading) edge of the optic with the “Fill-To” line, the lens should be visually inspected to determine the position of the haptics. The plunger should be in contact with the trailing optic edge. No part of the lens should exit the nozzle prior to insertion through the incision (Refer to Figure 8).
Step 9. After confirming the lens is properly positioned and the haptics are folded properly, proceed with lens implantation by inserting the nozzle tip through the incision and positioning the nozzle tip at the anterior capsule opening.

Step 10. Gently advance the plunger in one smooth, continuous motion. Do not advance the plunger too fast or lens damage may occur. It is recommended that delivery of the lens from the visual inspection position should take at least 5 seconds. As the lens begins to exit the nozzle tip, place the leading haptic into the capsular bag and continue to slowly advance the plunger to deliver the lens. As the optic portion of the lens exits the nozzle tip, rotate the device as needed to ensure the lens unfolds anterior side up within the capsular bag, and in a planar fashion parallel to the iris. After the plunger has been fully advanced, pause for a moment before retracting the device to allow the lens to release from the plunger tip.

Step 11. Position the lens within the capsular bag using a suitable positioning instrument.

Step 12. Discard the entire device. Do not re-use the AcrySert® C Delivery System.

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.

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, TX  76134-2099
Call Collect: (817) 551-4445

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.

AcrySof® Foldable Posterior Chamber Lens Clinical Studies

Two randomized, prospective well-controlled clinical studies have been performed on AcrySof® 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 Foldable Single-Piece IOL (with UV and blue light filtering chromophores) with an aspheric optic versus an AcrySof® 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 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 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 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 |
|---|---|---|---|---|---|---|---|---|---|
| Age Category | #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 | % |
| < 60 | 1 | 1 | 100.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 60-69 | 40 | 34 | 85.0 | 6 | 15.0 | 0 | 0.0 | 0 | 0.0 |
| 70-79 | 60 | 47 | 78.3 | 11 | 18.3 | 2 | 3.3 | 0 | 0.0 |
| > =80 | 13 | 9 | 69.2 | 2 | 15.4 | 2 | 15.4 | 0 | 0.0 |
| Total | 114 | 91 | 79.8 | 19 | 16.7 | 4 | 3.5 | 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 |
|---|---|---|---|---|---|---|---|---|---|
| Age Category | #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 | % |
| < 60 | 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 | 0 | 0.0 |
| 70-79 | 42 | 34 | 81.0 | 6 | 14.3 | 1 | 2.4 | 0 | 0.0 |
| > =80 | 12 | 11 | 91.7 | 1 | 8.3 | 0 | 0.0 | 0 | 0.0 |
| Total | 102 | 82 | 80.4 | 16 | 15.7 | 2 | 2.0 | 1 | 1.0 |

**Table 3a**

| Best Corrected Visual Acuity in the Overall Patient Population at a Minimum of One Year Postoperatively, AcrySof® Natural IOL SB30AL |
|---|---|---|---|---|---|---|---|---|---|
| Age Category | #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 | % |
| < 60 | 1 | 1 | 100.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 60-69 | 42 | 36 | 85.7 | 6 | 14.3 | 0 | 0.0 | 0 | 0.0 |
| 70-79 | 72 | 54 | 75.0 | 13 | 18.1 | 3 | 4.2 | 1 | 1.4 |
| > =80 | 20 | 11 | 55.0 | 5 | 25.0 | 4 | 20.0 | 0 | 0.0 |
| Total | 135 | 102 | 75.6 | 24 | 17.8 | 7 | 5.2 | 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

<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>
</tr>
</thead>
<tbody>
<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>100.0</td>
<td>0.0</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>96.5</td>
<td>1.8</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>100.0</td>
<td>0.0</td>
<td>0.0</td>
</tr>
<tr>
<td>Total</td>
<td>127</td>
<td>74.0</td>
<td>16.5</td>
<td>5.5</td>
<td>2.4</td>
<td>98.4</td>
<td>0.8</td>
<td>0.8</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 4
Cumulative Adverse Events at a Minimum of One Year Postoperatively AcrySof® Natural IOL SB30AL and SA30AL control

<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></td>
<td>N%</td>
<td>N%</td>
<td></td>
</tr>
<tr>
<td>Hypopyon</td>
<td>0</td>
<td>0</td>
<td>NA</td>
</tr>
<tr>
<td>Intraocular Infection / Endophthalmitis</td>
<td>0</td>
<td>0</td>
<td>NA</td>
</tr>
<tr>
<td>Macular Edema</td>
<td>4</td>
<td>2.6</td>
<td>0.6847</td>
</tr>
<tr>
<td>Pupillary Block</td>
<td>0</td>
<td>0</td>
<td>NA</td>
</tr>
<tr>
<td>Retinal Detachment or Retinal Detachment Repair</td>
<td>0</td>
<td>0</td>
<td>NA</td>
</tr>
<tr>
<td>Lens Dislocation</td>
<td>1</td>
<td>0.7</td>
<td>NA</td>
</tr>
<tr>
<td>Secondary Surgical Reintervention</td>
<td>5</td>
<td>3.3</td>
<td>0.4482</td>
</tr>
<tr>
<td>Removal of Residual Cortex</td>
<td>1</td>
<td>0.7</td>
<td>0.0</td>
</tr>
<tr>
<td>Explant (dislocation due to capsular rupture)</td>
<td>1</td>
<td>0.7</td>
<td>0.0</td>
</tr>
<tr>
<td>Cryotherapy to Repair Retinal Tear</td>
<td>1</td>
<td>0.7</td>
<td>0.0</td>
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<td>Paracentesis to Lower IOP</td>
<td>1</td>
<td>0.7</td>
<td>0.0</td>
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<td>Focal Laser Treatment</td>
<td>1</td>
<td>0.7</td>
<td>0.0</td>
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<tr>
<td>Photodynamic Therapy</td>
<td>0</td>
<td>0</td>
<td>0.7</td>
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<tr>
<td>Explant Due to Biometry Error</td>
<td>0</td>
<td>0</td>
<td>0.7</td>
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<tr>
<td>Hyphema</td>
<td>0</td>
<td>0</td>
<td>NA</td>
</tr>
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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 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

<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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<tbody>
<tr>
<td></td>
<td>N</td>
<td>%</td>
<td>N</td>
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<tr>
<td>Persistent Corneal Edema</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Iritis</td>
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<td>0</td>
<td>0</td>
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<td>Macular Edema</td>
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<td>1.4</td>
<td>1</td>
</tr>
<tr>
<td>Vitritis</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Raised IOP Requiring Treatment</td>
<td>0</td>
<td>0</td>
<td>0</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 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 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 eyes was approximately 0.1 micrometers. Figure 9 represents the statistically significant reduction in spherical and total higher order aberrations observed in favor of the AcrySof® IQ lens. Figure 10 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 eyes was independent of age.

Figure 9
Spherical and Total Higher Order RMS
90-120 Days after 2nd Eye Implant

* Differences favor AcrySof® IQ IOL overall and at each visit (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 11 and 12.

Figure 11
LogMAR BCVA
- AcrySof® IQ IOL (N=77)
- Control (N=75)

* Denotes statistical significance between lenses (p<0.0001)

Figure 12
LogMAR UCVA
- AcrySof® IQ IOL (N=77)
- Control (N=75)

Differences are not statistically significant
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 13 and 14 depict the mesopic contrast sensitivity results at all spatial frequencies tested for both the AcrySof® IQ lens and control lens.

![Figure 13](image1)

**Figure 13**
Mesopic Contrast Sensitivity (CSV-1000)
90-120 Days after 2nd Eye Implant

![Figure 14](image2)

**Figure 14**
Mesopic Contrast Sensitivity (FACT) Substudy
Minimum of 90 days after 2nd Eye Implant

AcrySof® IQ Lens – Night Driving Simulation

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 15 through 18 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.

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.
**HOW SUPPLIED**
These posterior chamber intraocular lenses are supplied dry, in the AcrySert® C Delivery System, within a primary sterilization package, and terminally sterilized with ethylene oxide. The primary sterilization package must be opened only under aseptic conditions (see DIRECTIONS FOR USE).

**EXPIRATION DATE**
Sterility is guaranteed unless the primary sterilization package is damaged or opened. The expiration date is clearly indicated on the outer box label of the AcrySert® C Delivery System. 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 the applicable returned goods policy.
REFERENCES

SYMBOLS USED ON LABELING

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<th>SYMBOL</th>
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<td></td>
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</table>

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U.S. Pat. Nos. 5,470,932, 5,716,403, 7,156,854 and 7,350,916
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