DESCRIPTION

The AcrySof® IQ Toric Posterior Chamber Intraocular Lens (IOL) is a UV-absorbing foldable intraocular lens (IOL). The single-piece design consists of a high refractive index material with proprietary blue light filtering chromophore which 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 blue-light filtering chromophore reduces transmittance of blue light wavelengths (see Table 2). The biconvex toric aspheric optic consists of a high refractive index soft acrylic material capable of being folded prior to insertion, allowing placement through an incision smaller than the optic diameter of the lens. After surgical insertion into the eye, the lens gently unfolds to restore the optical performance. The supporting haptics provide for proper positioning and fixation of the IOL optic within the eye. The anterior surface of the AcrySof® IQ Toric IOL Model SN6AT2 is designed with negative spherical aberration identical to the aspheric AcrySof® IQ IOL Model SN60WF to compensate for the positive spherical aberration of the cornea.

Figure 1: Physical Characteristics of AcrySof® IQ Toric IOL
(All dimensions in millimeters)
Table 1: Physical Characteristics of AcrySof® IQ Toric IOL

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Model</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Optic Type</strong></td>
<td>Biconvex Toric Aspheric Optic</td>
</tr>
<tr>
<td><strong>Optic / Haptic Material</strong></td>
<td>Ultraviolet and blue light filtering Acrylate/Methacrylate Copolymer</td>
</tr>
<tr>
<td></td>
<td>UV cutoff at 10% T: 399 nm (+6.0 diopter lens)</td>
</tr>
<tr>
<td></td>
<td>407 nm (+34.0 diopter lens)</td>
</tr>
<tr>
<td><strong>IOL Powers (spherical equivalent diopters)</strong></td>
<td>See Clinical Protocol</td>
</tr>
<tr>
<td>IOL Cylinder Power (Diopters)</td>
<td>1.00</td>
</tr>
<tr>
<td>Index Of Refraction</td>
<td>1.55</td>
</tr>
<tr>
<td>Haptic Configuration</td>
<td>STABLEFORCE®</td>
</tr>
<tr>
<td>Optic Diameter (mm)</td>
<td>6.0</td>
</tr>
<tr>
<td>Overall Length (mm)</td>
<td>13.0</td>
</tr>
<tr>
<td>Haptic Angle</td>
<td>0°</td>
</tr>
</tbody>
</table>

Figure 2: SPECTRAL TRANSMITTANCE CURVES (PERCENTAGE OF ULTRAVIOLET TRANSMITTANCE)

![Spectral Transmittance Curves]

**NOTE:**

Table 2: Transmittance Comparison for 20.0 D SINGLE-PIECE IOL DESIGNS (%)

<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>SN6AT2</td>
<td>7</td>
<td>33</td>
<td>48</td>
<td>67</td>
</tr>
<tr>
<td>Transmittance Difference (SA60AT –SN6AT2)</td>
<td>14</td>
<td>53</td>
<td>40</td>
<td>21</td>
</tr>
<tr>
<td>Transmittance Reduction with SN6AT2 (% of SA60AT)</td>
<td>67</td>
<td>62</td>
<td>45</td>
<td>24</td>
</tr>
</tbody>
</table>

**MODE OF ACTION**
AcrySof® IQ Toric IOLs 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. These IOLs have a biconvex toric optic with cylinder axis marks to denote the flat meridian (plus cylinder axis). Alignment of the toric IOL axis marks with the post-operative steep corneal meridian allows the lens to correct astigmatism.

The astigmatic correction at the corneal plane for AcrySof® IQ Toric intraocular lenses is shown in Table 3:

Table 3

<table>
<thead>
<tr>
<th>Model</th>
<th>IOL Cylinder Power (diopters)</th>
<th>Cylinder Power at Corneal Plane (diopters*)</th>
</tr>
</thead>
<tbody>
<tr>
<td>SN6AT2</td>
<td>1.00</td>
<td>0.68</td>
</tr>
</tbody>
</table>

*Based on an average pseudophakic human eye
INDICATIONS
The AcrySof® IQ Toric posterior chamber intraocular lenses are intended for primary implantation in the capsular bag of the eye for visual correction of aphakia and pre-existing corneal astigmatism secondary to removal of a cataractous lens in adult patients with or without presbyopia, who desire improved uncorrected distance vision and reduction of residual refractive cylinder.

NOTE: The following warnings and precautions have been preliminarily identified for the AcrySof® IQ Toric IOL Model SN6AT2 and are consistent with those identified as an outcome of the previously conducted clinical investigation of the parent IOL Model SA60T3.

WARNINGS
1. This lens should not be implanted if the posterior capsule is ruptured, if the zonules are damaged, or if a primary posterior capsulotomy is planned.
2. Rotation of AcrySof® IQ Toric IOL away from their intended axis can reduce their astigmatic correction. Misalignment greater than 30º may increase postoperative refractive cylinder. If necessary, lens repositioning should occur as early as possible prior to lens encapsulation. Some clinical cases suggest encapsulation is complete within four weeks of implantation.
3. Carefully remove all viscoelastic from both the anterior and posterior sides of the lens. Residual viscoelastic may allow the lens to rotate causing misalignment of the AcrySof® IQ Toric IOL with the intended axis of placement.
4. Please refer to the Investigator’s Brochure for a comprehensive explanation of the risks and benefits of this lens and for a detailed list of the subject inclusion and exclusion criteria for this clinical evaluation.

PRECAUTIONS
1. 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.
2. As with any surgical procedure, there is risk involved. Potential complications accompanying cataract or implant surgery may include, but are not limited to the following: corneal endothelial damage, infection (endophthalmitis), retinal detachment, vitritis, cystoid macular edema, corneal edema, pupillary block, cyclitic membrane, iris prolapse, hypopyon, transient or persistent glaucoma and secondary surgical intervention. Secondary surgical interventions include, but are not limited to: lens repositioning, lens replacement, vitreous aspirations or iridectomy for pupillary block, wound leak repair, and retinal detachment repair.
3. The safety and effectiveness of the IQ Toric intraocular lens has not been substantiated in patients with the following preexisting ocular conditions and intraoperative complications (see below). Careful preoperative evaluation and sound clinical judgment should be used by the surgeon to decide the benefit/risk ratio before implanting a lens in a patient with one or more of these conditions.
   Before Surgery
   • Choroidal hemorrhage
   • Chronic severe uveitis
   • Concomitant severe eye disease
   • Extremely shallow anterior chamber
   • Medically uncontrolled glaucoma
   • Microphthalmos
   • Non-age-related cataract
   • Proliferative diabetic retinopathy (severe)
   • Severe corneal dystrophy
   • Severe optic nerve atrophy
   • Irregular corneal astigmatism
   • Color vision deficiencies

Studies have shown that color vision discrimination is not adversely affected in individuals with the AcrySof® Natural IOL and normal color vision. The effect 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 optical nerve diseases) has not been studied.

During Surgery
• Excessive vitreous loss
• Capsulotomy by any technique other than a circular tear
• The presence of radial tears known or suspected at the time of surgery
• Situations in which the integrity of the circular tear cannot be confirmed by direct visualization
• Cataract extraction by techniques other than phacoemulsification or liquefaction
• Situations where the need for a large capsulotomy can be anticipated (e.g., diabetics, retinal detachment in the fellow eye, peripheral retinal pathology, etc.)
• Capsular rupture
• Significant anterior chamber hyphema
• Uncontrollable positive intraocular pressure
• Zonular damage
4. 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.

5. 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.

6. DO NOT store the IOL at temperatures over 45° C (113° F).

7. DO NOT reuse the IOL. This IOL is for single use only.

8. DO NOT resterilize the IOL by any method.

9. Use only sterile intraocular irrigating solutions such as BSS® or BSS PLUS® to rinse and/or soak lenses.

10. Accurate keratometry and biometry in addition to the use of the IQ Toric Calculator (reference Clinical Protocol) are recommended to achieve optimal visual outcomes.

11. Please refer to the Investigator’s Brochure for a comprehensive explanation of the risks and benefits of this lens and for a detailed list of the subject inclusion and exclusion criteria for this clinical evaluation.

**CALCULATION OF LENS POWER**

Please consult the Clinical Study Protocol for the specific instructions related to the calculation of lens power to be followed in this clinical study.

**DIRECTIONS FOR USE**

1. Examine the label on the unopened package for model, power (spherical equivalent and cylinder), and expiration date.

2. After opening the cardboard storage container verify lens case information (model, power, and serial number) is consistent with information on outer packaging.

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 undamaged pouch and transfer the case to a sterile environment. Carefully open the case to expose the lens.

5. To minimize the occurrence of marks on the lens due to handling, all instrumentation should be scrupulously clean. Any forceps used for lens handling must have round edges and smooth surfaces.

6. When removing the lens from the case, DO NOT grasp the optical area with forceps. The IOL should only be handled by the haptics. Handle the lenses carefully to avoid damage to lens surfaces or haptics. DO NOT attempt to reshape haptics in any way.

7. Rinse the lens thoroughly using sterile intraocular irrigating solution such as BSS® or BSS PLUS®. DO NOT rinse the IOL in solutions other than sterile intraocular irrigating solution. Prior to insertion, the IOL should be carefully examined to ensure that particles have not adhered during handling.

8. The AcrySof® IQ Toric IOL is qualified for use with MONARCH® II and III handpieces. The following cartridges should be used: MONARCH® II B cartridge (6.0-34.0 diopters), MONARCH® II/III C cartridge (6.0-30.0 diopters), or MONARCH® II D cartridge (6.0-25.0 diopters) using Viscoat® Ophthalmic Viscosurgical Device viscoelastic.

9. Please consult the Clinical Study Protocol for the specific instructions related to the surgical procedures that should be utilized in this clinical study.

10. Surgeons should verify that appropriate instrumentation is available prior to surgery.

**Selection and Placement of the AcrySof® IQ Toric IOL**

The astigmatism to be corrected should be determined from keratometry and biometry data rather than refractive data since the presence of lenticular astigmatism in the crystalline lens to be removed may influence results. The size and location of the surgical incision may affect the amount and axis of corneal astigmatism. In order to optimize IOL selection and axis placement, Alcon provides an AcrySof® IQ Toric IOL study specific calculator for the surgeon (see Clinical Study Protocol). Pre-operative keratometry and biometry data, incision location, and estimated surgically induced corneal astigmatism are used to determine the appropriate AcrySof® IQ Toric IOL model, spherical equivalent lens power, and axis of placement in the eye.

For optimal results, the surgeon must ensure the correct placement and orientation of the lens within the capsular bag. The posterior surface of the IOL is marked with indentations (three at each end) at the haptic/optic junction that identify the flat meridian of the AcrySof® IQ Toric optic. These indentations form an imaginary line representing the plus cylinder axis (note: IOL cylinder steep meridian is 90° away). The AcrySof® IQ Toric IOL cylinder axis marks should be aligned with the post-incision steep corneal meridian (intended axis of placement).

Misalignment of the axis of the lens with the intended axis of placement may compromise its astigmatic correction. Such misalignment can result from inaccurate keratometry or marking of the cornea, inaccurate placement of the AcrySof® IQ Toric IOL axis during surgery, an unanticipated surgically induced change in the cornea, or physical rotation of the AcrySof® IQ Toric IOL after implantation. In order to minimize this effect, the surgeon should be careful to ensure that preoperative keratometry and biometry is accurate and that the IOL is properly oriented prior to the end of surgery.

**NOTE:** Please refer to the Clinical Study Protocol for the specific instructions related to the surgical procedures that should be utilized in this clinical study.
PATIENT REGISTRATION AND REPORTING

Please follow protocol instructions regarding completion of the Implant Registration Card that is enclosed in the lens box. 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 at the time stated in the protocol, 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. The adhesive lens identification labels provided should be placed in the patients’ hospital record and in the surgeons’ office records following any special instructions in the protocol. These labels are also for use on any report as permitted by the protocol.

ADVERSE EVENT/DEVICE EFFECTS REPORTING

See Clinical Study Protocol for instructions.

HOW SUPPLIED

The AcrySof® IQ Toric IOL is 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

The Investigator should examine the lens preoperatively and immediately following implantation to observe any visible damage to the optic or haptics of the lens. Any damage to an implanted lens should be noted and recorded on the Operative Case Report Form. If the lens is not implanted, it should be returned to the address below. See Clinical Study Protocol for additional information.

REFERENCE


SYMBOLS USED ON LABELING

<table>
<thead>
<tr>
<th>SYMBOL</th>
<th>ENGLISH</th>
</tr>
</thead>
<tbody>
<tr>
<td>IOL</td>
<td>Intraocular lens</td>
</tr>
<tr>
<td>PC</td>
<td>Posterior chamber</td>
</tr>
<tr>
<td>UV</td>
<td>Ultraviolet</td>
</tr>
<tr>
<td>D</td>
<td>Diopter (Spherical Equivalent)</td>
</tr>
<tr>
<td>CYL</td>
<td>Cylinder Power</td>
</tr>
<tr>
<td>ØB</td>
<td>Body diameter (Optic diameter)</td>
</tr>
<tr>
<td>ØT</td>
<td>Overall diameter (Overall length)</td>
</tr>
<tr>
<td>!</td>
<td>Do not reuse</td>
</tr>
<tr>
<td>or</td>
<td>Use by (YYYY-MM: year-month)</td>
</tr>
<tr>
<td>SN or</td>
<td>Sterilized by ethylene oxide</td>
</tr>
<tr>
<td>SN</td>
<td>Serial number</td>
</tr>
<tr>
<td>!</td>
<td>Attention: See instructions for use</td>
</tr>
<tr>
<td></td>
<td>Manufacturer</td>
</tr>
</tbody>
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