**Directions for Use**

XX-XXX-XXX <insert commodity number>

## PRODUCT INFORMATION

Alcon Laboratories, Inc.

## AcrySof™ IQ Vivity™ Extended Vision Intraocular Lenses (IOLs)
## Models: DFT015, DFT315, DFT415, DFT515

### DESCRIPTION

The non-diffractive AcrySof™ IQ Vivity™ Extended Vision Posterior Chamber Intraocular Lenses (IOLs) Model DFT015 and Toric Models DFT315, DFT415, and DFT515 are UV-absorbing and blue light filtering foldable intraocular lenses (IOLs) which, compared to a monofocal IOL, provide an extended range of vision from distance to near while maintaining a low incidence of visual disturbances. The AcrySof™ IQ Vivity™ Toric Extended Vision IOL models also compensate for corneal astigmatism.

The single-piece design consists of a high refractive index hydrophobic acrylic 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. The biconvex 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 its optical performance. The supporting haptics provide proper positioning and fixation of the IOL optic within the eye.

The depth of field extension is achieved through the patented Wavefront-Shaping technology located on the anterior surface of the IOL. The location of the Wavefront-Shaping optic is identical for all lens powers. The anterior surface of the AcrySof™ IQ Vivity™ Extended Vision IOL is designed with negative spherical aberration to compensate for the positive spherical aberration of the cornea. The posterior surface of the Toric lens is biconic creating a toricity to correct the astigmatism on the cornea. The flat meridian of the AcrySof™ IQ Vivity™ Toric IOLs is identified with indentations (dots) on the posterior surface of the optic. The physical characteristics of the Vivity™ IOL are summarized in Figures 1, 2 and 3 and Table 1. The modulation transfer function (MTF) through-focus response of a Vivity IOL in a model eye using polychromatic light (white light) is depicted in Figure 4.

**Figure 1: Physical Characteristics of AcrySof™ IQ Vivity™ IOL**
(All dimensions in millimeters)

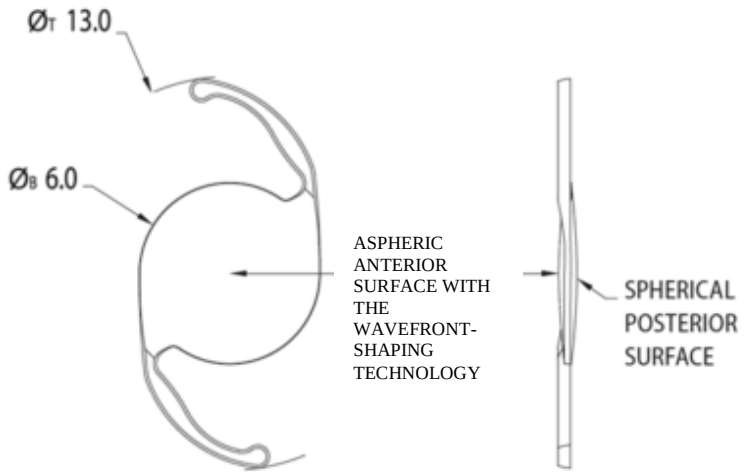



**Figure 2: Physical Characteristics of AcrySof™ IQ Vivity™ Toric IOLs**
(All dimensions in millimeters)

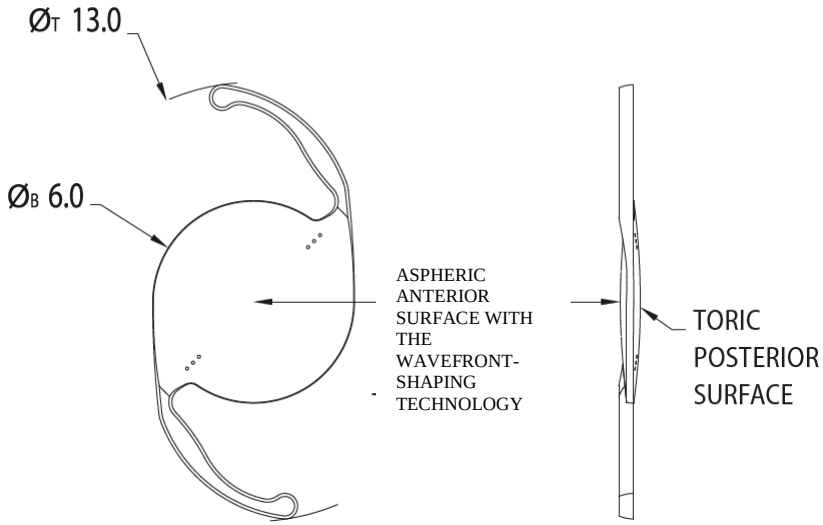


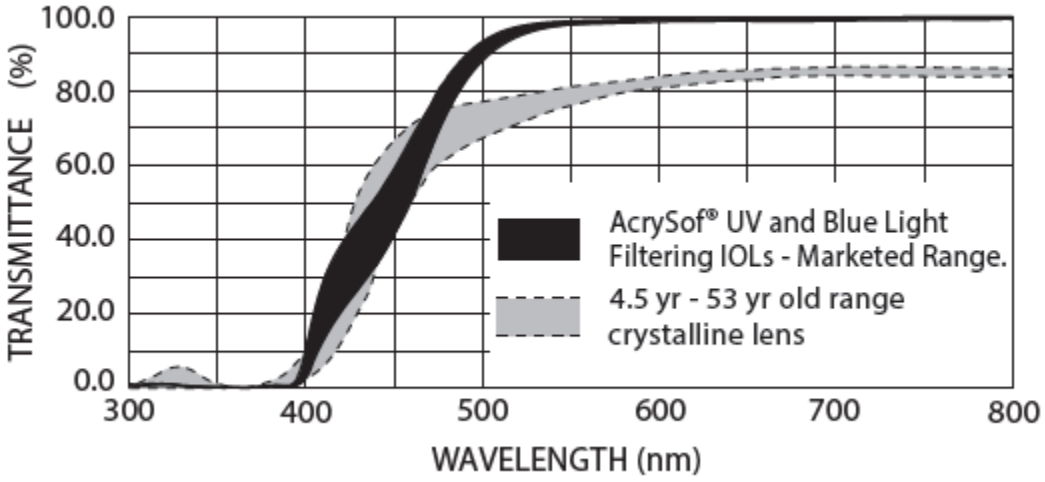

**Table 1: Physical Characteristics of AcrySof™ IQ Vivity™ IOL**

| **Characteristics** | **Model** | | | |
|---|---|---|---|---|
| | DFT015 | DFT315 | DFT415 | DFT515 |
| Optic Type | Biconvex Wavefront-Shaping Optic | Biconvex Toric Wavefront-Shaping Optic | | |
| Optic / Haptic Material | Ultraviolet and blue light filtering hydrophobic Acrylate/Methacrylate Copolymer<br>UV cutoff at 10% T: 401 nm (+20.0 diopter lens) | | | |
| Spherical Powers | +15.0 diopters – +25.0 diopters in 0.5 diopter increments | | | |

| Characteristics | Model | | | |
|---|---|---|---|---|
| | DFT015 | DFT315 | DFT415 | DFT515 |
| IOL Cylinder Powers – IOL Plane (Diopters) | N/A | 1.50 | 2.25 | 3.00 |
| IOL Cylinder Powers – Corneal Plane* (Diopters) | N/A | 1.03 | 1.55 | 2.06 |
| Index Of Refraction | 1.55 | | | |
| Haptic Configuration | STABLEFORCE® Modified-L Haptics | | | |
| Optic Diameter (mm) $Ø_B$ | 6.0 | | | |
| Overall Length (mm) $Ø_T$ | 13.0 | | | |
| Haptic Angle | 0º | | | |

*Based on the average pseudophakic human eye

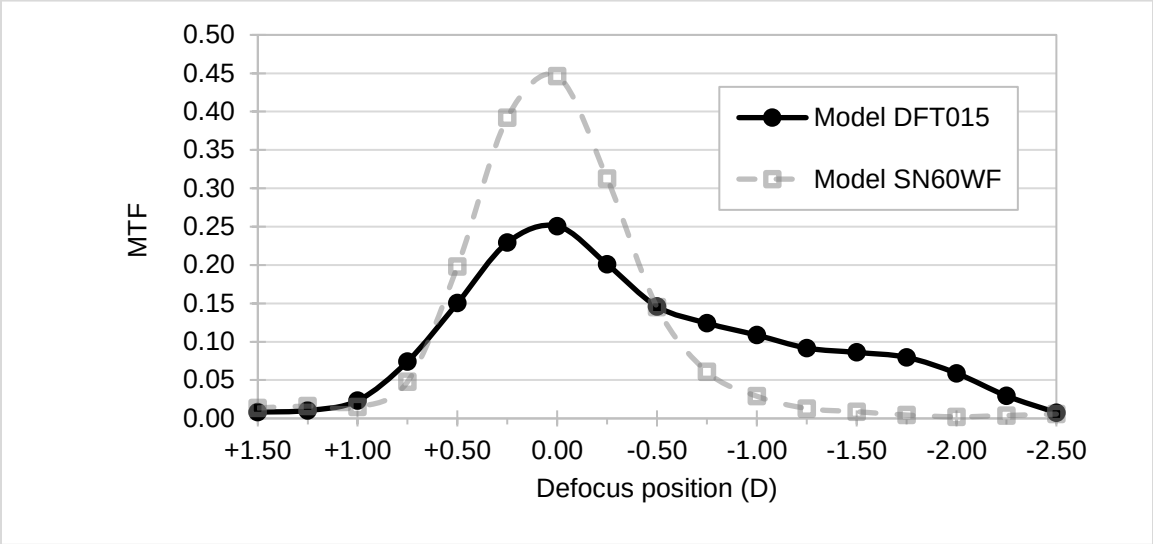
**Figure 3: Spectral Transmittance**




**NOTES:**

1. The cutoff wavelength and the spectral transmittance curves presented here represent the range of transmittance values of IOLs made from hydrophobic acrylate/methacrylate copolymer with bonded UV-absorber and Alcon's proprietary blue light filtering chromophore.
2. Measurements were by direct transmittance using AcrySof® IOLs (UV and blue light filtering IOLs) with center thickness equivalent to the marketed range.
3. Human crystalline lens data is from Boettner and Wolter (1962).

**Figure 4: Modulation Transfer Function (MTF) Through-Focus Response of 20.0 D IOLs in a Model Eye (White Light, 50 lp/mm, 3 mm Aperture)**




## INDICATIONS

The AcrySof™ IQ Vivity™ Extended Vision IOL Model DFT015 is indicated for primary implantation for the visual correction of aphakia in adult patients with < 1.00 D of preoperative corneal astigmatism, in whom a cataractous lens has been removed by extracapsular cataract extraction. The lens mitigates the effects of presbyopia by providing an extended depth of focus. Compared to an aspheric monofocal IOL, the lens provides improved intermediate and near visual acuity, while maintaining comparable distance visual acuity. The AcrySof™ IQ Vivity™ IOL is intended for capsular bag placement only.

The AcrySof™ IQ Vivity™ Toric Extended Vision IOL Models DFT315, DFT415, and DFT515 are indicated for primary implantation for the visual correction of aphakia and for reduction of residual refractive astigmatism in adult patients with pre-existing corneal astigmatism, in whom a cataractous lens has been removed by extracapsular cataract extraction. The lenses mitigate the effects of presbyopia by providing an extended depth of focus. Compared to an aspheric monofocal IOL, the lenses provide improved intermediate and near visual acuity, while maintaining comparable distance visual acuity. The AcrySof™ IQ Vivity™ Toric IOLs are intended for capsular bag placement only.

## IOL IMPLANTATION

During standard cataract surgery and implantation of the AcrySof™ IQ Vivity™ IOL, an Alcon qualified delivery system and viscoelastic combination should be used. The use of an unqualified combination may cause damage to the lens and potential complications during the implantation process. Alcon recommends using the qualified MONARCH® IOL Delivery System or any other Alcon qualified combination. Currently qualified combinations that can be used with these lenses are listed in Table 2; contact Alcon for further information on qualified combinations.

**Table 2: Qualified Combinations of Compatible Products**

| Lens Model | Diopter Range | Cartridge | Handpiece | Ophthalmic Viscosurgical Device (OVD) |
|---|---|---|---|---|
| **DFT015**<br>**DFT315**<br>**DFT415**<br>**DFT515** | +15.0 to +25.0 | MONARCH™ III D (8065977763) | MONARCH™ III (blue) (8065977773) | VISCOAT™ OVD<br>PROVISC™ OVD<br>DISCOVISC™ OVD |

Contact Alcon for any additional Alcon qualified OVDs, handpieces, and cartridges for use with this lens.

See “DIRECTIONS FOR USE” for implantation instructions for the AcrySof™ IQ Vivity™ IOLs, which are similar to those of Alcon’s AcrySof™ IQ monofocal IOLs.

## CALCULATION OF LENS POWER

Accurate biometry is essential for successful visual outcomes. Preoperative calculation of required lens power for the AcrySof™ IQ Vivity™ IOLs should be determined by the surgeon's experience and preference. A reference SRK/T A-Constant value for optical biometry equipment such as IOLMaster** or LenStar** as well as *contact* ultrasound biometry is listed on the outer label. The reference optical A-Constant anticipates the use of both corneal power and axial length values from optical biometry or contact ultrasound equipment with standard settings for a typical patient population and a spectacle far point at 6 meters.

In general, lens constants must be “personalized” to compensate for such things as differences in instrumentation, surgical techniques, and IOL power calculation that may exist between clinical practice. IOL power calculation methods are often included with biometry equipment, and they are also described in the references (Hoffer 1993; Holladay 1997; Olsen 2007; Retzlaff, Sanders & Kraff 1990; Haigis 2014).

**IOLMaster is a trademark of Carl Zeiss; LenStar is a trademark of HAAG-STREIT.

## CONTRAINDICATIONS

There are no known contraindications to the use of the AcrySof IQ Vivity IOLs when used as recommended.

## 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 the AcrySof™ IQ Vivity™ Toric IOL away from its intended axis can reduce the astigmatic correction. Misalignment greater than 30° 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. 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. Residual viscoelastic may allow the lens to rotate causing misalignment of the AcrySof™ IQ Vivity™ Toric IOL with the intended axis of placement.
4. Most patients implanted with the Vivity IOL are likely to experience significant loss of contrast sensitivity as compared to a monofocal IOL. Therefore, it is essential that prospective patients be fully informed of this risk before giving their consent for implantation of the Vivity IOL. In addition, patients should be warned that they will need to exercise caution when engaging in activities that require good vision in dimly lit environments, such as driving at night or in poor visibility conditions, especially in the presence of oncoming traffic.

## PRECAUTIONS

1. Prior to surgery, prospective patients should be informed of the possible risks and benefits of the AcrySof™ IQ Vivity™ IOL Models DFT015, DFT315, DFT415, and DFT515. A patient information brochure can be found in the labeling information section under the link to Products at https://ifu.alcon.com. Please provide a copy of the patient information brochure to the patient.
2. The safety and effectiveness of this IOL have not been studied in patients with certain pre-existing conditions and/or intraoperative conditions (listed in Tables 3 and 4) as these

patients were excluded from the clinical studies. Patients with pre-existing conditions may not achieve the visual acuity of patients without such conditions. As with the implantation of any IOL, 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.

3. 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: lens epithelial cell on-growth, corneal endothelial damage, infection (endophthalmitis), retinal detachment, vitritis, cystoid macular edema, corneal edema, pupillary block, cyclitic membrane, iris prolapse, hypopyon, anterior uveitis, hyphema, pigment dispersion, posterior capsule opacification, transient or persistent glaucoma, residual refractive error resulting in secondary surgical intervention, and other secondary surgical interventions. 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.
4. It is possible to experience very bothersome visual disturbances, significant enough that the patient could request explant of the IOL. In the Vivity clinical study, 1% to 2% of Vivity patients reported very bothersome starbursts, halos, blurred vision, or dark area visual disturbances; however, no explants were reported.
5. Accurate keratometry and biometry in addition to the use of the Toric Calculator for the AcrySof™ IQ Vivity™ Toric IOL models (http://www.myalcon-toriccalc.com) are recommended to achieve optimal visual outcomes.
6. Autorefractors may not provide optimal postoperative refraction of patients with AcrySof™ IQ Vivity™ Toric IOLs. Manual refraction with maximum plus technique is strongly recommended.
7. Clinical data supporting the use of these IOLs were collected with the lens implanted in the capsular bag only. There are no clinical data to demonstrate safety or effectiveness for placement in the ciliary sulcus.
8. Do not re-sterilize these IOLs by any method (see RETURNED GOODS POLICY).
9. Do not store these IOLs at temperatures over 45°C (113°F).
10. Handle lenses carefully to avoid damage to lens surfaces or haptics.
11. Do not attempt to reshape haptics in any way.
12. DO NOT implant the IOL if the sterility has been compromised or if the sterile package has been unintentionally opened before use.

**Table 3: Preexisting Conditions with No Safety and Effectiveness Data**

| | |
|---|---|
| • Clinically severe corneal dystrophy (e.g., epithelial, stromal, or endothelial dystrophy), corneal irregularity (including irregularity due to dry eye syndrome), keratitis, keratoconjunctivitis, keratouveitis, keratopathy, or kerectasia<br>• Irregular corneal astigmatism<br>• Subjects with any ocular disease or pathology, other than cataract that are predicted to cause future acuity losses to a level worse than 0.20 logMAR<br>• Any inflammation or edema of the cornea<br>• Significant irregular corneal aberration<br>• Previous corneal transplant<br>• Aniridia<br>• Iris neovascularization<br>• Uncontrolled glaucoma<br>• Rubella, congenital, traumatic, or complicated cataracts<br>• Extremely shallow anterior chamber, not due to swollen cataract<br>• Choroidal hemorrhage<br>• Previous retinal detachment<br>• Diabetic retinopathy<br>• Optic nerve atrophy<br>• Recurrent anterior or posterior segment inflammation. | • Amblyopia<br>• Pre-existing ocular conditions which may negatively impact stability of the implant (e.g., diagnosis of pseudoexfoliation syndrome)<br>• Color vision deficiencies<br>  ○ Studies have shown that color vision discrimination is not adversely affected in individuals implanted with a blue light filtering IOL who have normal color vision. The effect of the blue light filtering 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.<br>• Microphthalmos<br>• Previous refractive surgery<br>• Current or previous usage of alpha-1-selective adrenoceptor blocking agent or antagonist of alpha 1A adrenoceptor [e.g., Flomax† (tamsulosin HCL), Hytrin†, or Cardura†]<br>• Pregnancy |

**Table 4: Intraoperative Conditions with No Safety and Effectiveness Data**

| | |
|---|---|
| • Other planned ocular surgery procedures, including but not limited to, LASIK, astigmatic keratotomy, and limbal relaxing incisions<br>• Excessive iris mobility or floppy iris syndrome<br>• Mechanical or surgical manipulation required to enlarge the pupil | • Vitreous loss (significant)<br>• Anterior chamber bleeding (significant)<br>• Complications in which the IOL stability could be compromised, including but not limited to zonular dehiscence or capsulorhexis rupture<br>• Uncontrollable IOP |

13. When binocular implantation of the AcrySof™ IQ Vivity™ IOL is planned, both eyes of a subject are not intended to be operated on the same day. Simultaneous binocular implantation has not been studied.
14. A high level of surgical skill is required for any 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.
15. The AcrySof IQ Vivity Toric IOLs have not been evaluated in a clinical study. However, clinical results for the parent Toric IOL (AcrySof Toric) are presented in the clinical study section. As with other premium IOLs, patients with large levels of residual astigmatism may need spectacle correction to achieve satisfactory visual acuity.

**SELECTION OF TORIC IOL**

For selection of the appropriate toric IOL, Alcon provides a web-based tool (www.myalcon-toriccalc.com, Abulafia, Barrett, et al. 2015 and Abulafia, Hill, et al. 2015) that uses pre-operative biometry data, incision location, and surgically induced corneal astigmatism. The astigmatism to be corrected should be determined from 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. Pre-operative keratometry and biometry data, incision location, and the surgeon's estimated surgically induced corneal astigmatism are used to determine the appropriate AcrySof IQ Vivity Toric IOL model, spherical equivalent lens power, and axis of placement in the eye.

## AXIS PLACEMENT OF TORIC IOL

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 toric IOL optic. These indentations form an imaginary line representing the plus cylinder axis (note: IOL cylinder steep meridian is 90º away). The cylinder axis marks should be aligned with the post-incision steep corneal meridian (intended axis of placement) or as determined by the web-based IOL calculator.

Prior to surgery, the lens placement axis should be marked. One way used in clinical practice to mark the eye is as follows: With the patient sitting upright to prevent cyclotorsion, clearly and precisely mark two reference positions with a surgical skin marker or a marking pencil indicated for ophthalmic use. Using these marks as reference points, an axis marker can be used immediately prior to or during surgery to mark the optimal axis of lens placement identified by the web-based IOL calculator (www.myalcon-toriccalc.com).

Precisely align the axis marking indentations on the toric IOL with the marked intended axis of lens placement. Remove all viscoelastic from both the anterior and posterior sides of the lens since residual viscoelastic may allow the lens to rotate causing misalignment of the toric IOL with the intended axis of placement. This may be accomplished by manipulating the IOL optic with the I/A tip and using standard irrigation/aspiration techniques to remove all viscoelastic from the eye. Bimanual techniques may be used, if preferred, to ensure removal of viscoelastic from behind the lens implant. Special care should be taken to ensure proper positioning of the toric IOL at the intended axis following viscoelastic removal.

Misalignment of the axis of the lens versus 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 toric IOL axis during surgery, an unanticipated surgically induced change in the cornea, or physical rotation of the 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.

## DIRECTIONS FOR USE

1. Examine the label on the unopened package for model, optical power, cylinder power (if applicable), proper configuration, and expiration date.
2. After the outer box is open, verify that the lens primary label information (e.g., model, powers, and serial number) is consistent with information on the outer box labeling.
3. Inspect the primary package carefully for tears, cuts, punctures, or other signs that the pouch has been opened or damaged. This device is sterile until the inner primary package is opened. DO NOT implant the IOL if the sterility has been compromised or if the sterile package has been unintentionally opened before use (see RETURNED GOODS POLICY).
4. Open the undamaged primary package and transfer the case to a sterile environment. Carefully open the case to expose the lens.
5. Use instrumentation that is scrupulously clean to minimize the occurrence of marks. Any forceps used for lens handling must have round edges and smooth surfaces.
6. Handle the IOL by the haptics only when removing the lens from the case. DO NOT grasp the optical area with forceps. Handle 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® solution. Examine the IOL carefully prior to insertion to ensure that particles have not adhered during handling.

8. Implant the IOL with the most appropriate surgical procedure for the patient. Surgeons should verify that appropriate instrumentation is available prior to surgery.

## MAGNETIC RESONANCE COMPATIBILITY

The AcrySof™ IQ Vivity™ IOLs are magnetic resonance (MR) Safe. The IOLs consist of acrylate/methacrylate copolymer material, which is a non-conducting, non-metallic, non-magnetic material that poses no known hazards in all magnetic resonance imaging environments.

## PATIENT REGISTRATION

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 that the patient consults in the future.

In the United States, 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. Patient registration is essential for the long-term patient follow-up program and will assist Alcon Laboratories, Inc. in responding to reports of adverse events.

## SERIOUS INCIDENT REPORTING

Any serious incident that may reasonably be regarded as device related should be reported to Alcon Laboratories, Inc.:

By Phone:
In USA - (800) 757-9780
Website:
http://www.alcon.com/contact-us/

Each IOL is identified by a serial number which provides traceability, and this information should be given to Alcon.

## HOW SUPPLIED

The AcrySof™ IQ Vivity™ 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 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 should be shipped via traceable means. A Returned Goods Number is obtained by contacting Alcon Laboratories, Inc. 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.

## CLINICAL STUDIES

Several prospective clinical studies were performed that support the safety and effectiveness of the AcrySof™ IQ Vivity™ IOLs (Models DFT015, DFT315, DFT415, DFT515) and are described in this labeling:

1. Data from the US study of AcrySof™ IQ Vivity™ IOL Model DFT015 are presented to describe the safety and effectiveness of the AcrySof™ IQ Vivity™ IOL optical design.
2. AcrySof™ Toric clinical study data are presented to describe the safety and effectiveness of the toric optical design of AcrySof™ IQ Vivity™ Toric IOL Models DFT315, DFT415, and DFT515.

3. An overview of AcrySof™ single-piece IOL studies is presented for an expanded description of the safety of AcrySof™ single-piece IOLs.

Additionally, a study of the AcrySof™ IQ Vivity™ IOL was conducted outside the United States (OUS). Data collected on the AcrySof™ IQ Vivity™ IOL in the OUS study was consistent with that observed in the US AcrySof™ IQ Vivity™ IOL study, and that of AcrySof™ IOLs generally.

NOTE: The toric element on the posterior side of the AcrySof™ IQ Vivity™ Toric IOLs is identical to that of the clinically studied AcrySof™ Toric IOLs.

### 1. US AcrySof™ IQ Vivity™ Model DFT015 Clinical Study

Clinical study ILI875-C002 was a prospective, randomized, controlled study of bilateral implantation of the AcrySof™ IQ Vivity™ IOL Model DFT015 or the control IOL Model SN60WF. 107 and 113 subjects were implanted with the AcrySof™ IQ Vivity™ IOL Model DFT015 ("Vivity™ IOL") and the FDA-approved monofocal control IOL Model SN60WF, respectively, at 11 investigational sites in the United States. IOL implantation instructions did not change based on randomization assignment.

Primary study effectiveness objectives included demonstrating that the Vivity IOL provides non-inferior monocular best-corrected distance visual acuity (BCDVA), superior monocular distance corrected intermediate visual acuity (DCIVA), and a 0.5 D increase in the monocular negative defocus range at 0.20 logMAR compared to the monofocal control IOL. Secondary study effectiveness objectives included demonstrating superior monocular distance corrected near visual acuity (DCNVA) and superiority for percentage of subjects never needing spectacles overall compared to the monofocal control IOL.

Study safety objectives included a comparison of Vivity IOL adverse event rates to ISO Safety and Performance Endpoint (SPE) targets, description of monocular mesopic contrast sensitivity (with and without glare) and estimation of rates of severe and most bothersome visual disturbances..

The clinical study results achieved at 6 months postoperatively demonstrate that the AcrySof™ IQ Vivity™ IOL is safe and effective for the visual correction of aphakia, provides superior distance-corrected intermediate and near vision, an increased depth of focus, and decreased need for eyeglasses when compared to the monofocal control IOL, while demonstrating distance vision comparable to the monofocal control lens, low rates of visual disturbances (e.g. halos, starbursts, glare, etc.), and acceptably low rates of adverse events.

All eyes with successful IOL implantation were considered evaluable for the All Implanted Set (AAS).

#### Clinical Study Results

#### Subject Population

A total of 220 subjects were implanted in this study, with 107 subjects receiving the AcrySof™ IQ Vivity™ IOL and 113 receiving the aspheric Monofocal Control IOL. At the baseline visit, the study consisted of 55.9% females and 44.1% males. Stratifying by race, 97.7% designated White, 0.9% designated Black or African American, 0.5% designated American Indian or Alaska Native, and 0.9% designated "Other". 1.8% of the study population designated their ethnicity as Hispanic or Latino. The mean (± SD) age for the study population was 68.8 ± 7.22 years. A summary of photopic pupil size for Vivity and Monofocal Control first implanted eyes at baseline is presented in Table 5.

**Table 5:** Baseline Photopic Pupil Size of Vivity and Monofocal Control IOL First Eyes

| | **Vivity IOL First Eyes** N = 107 | **Monofocal Control IOL First Eyes** N = 113 |
|---|---|---|
| n | 107 | 113 |
| Mean (SD) | 4.03 (0.859) | 4.08 (0.981) |
| Median | 4.0 | 4.0 |
| (Min, Max) | (2.4, 6.5) | (2.0, 7.8) |

Data are reported for the 6 Months visit. One of the subjects in the AcrySof™ IQ Vivity™ IOL group was not bilaterally implanted and does not contribute to binocular assessments. Two subjects in the monofocal control group discontinued study prior to 6 months.

**IOL Power Calculation and Postoperative Manifest Refraction**

In this study, surgeons were instructed to select the lens power that targeted emmetropia (closest to 0.0 D) for both the AcrySof™ IQ Vivity™ and the Monofocal Control IOLs prior to randomization. Table 6 summarizes absolute manifest refraction spherical equivalent (MRSE) data for AcrySof™ IQ Vivity™ IOL and Monofocal Control IOL subjects at 6 Months. For first eyes, 91.6% implanted with AcrySof™ IQ Vivity™ IOL and 86.5% implanted with the Monofocal Control IOL achieved MRSE within 0.5 D of emmetropia and mean ± SD MRSE in first eyes at 6 Months was 0.049 ± 0.345 D and 0.081 ± 0.411 D respectively.

**Table 6: Mean Absolute MRSE at 6 Months by Treatment Group**

| | **AcrySof™ IQ Vivity™ IOL** | | **Monofocal Control IOL** | |
|---|---|---|---|---|
| **MRSE Category** | **First Eyes N = 107 n (%)** | **Second Eyes N = 106 n (%)** | **First Eyes N = 113 n (%)** | **Second Eyes N = 113 n (%)** |
| ≤ 0.25 D | 69 (64.5) | 72 (67.9) | 63 (56.8) | 69 (62.2) |
| ≤ 0.5 D | 98 (91.6) | 92 (86.8) | 96 (86.5) | 93 (83.8) |
| ≤ 1.00 D | 107 (100.0) | 106 (100.0) | 108 (97.3) | 110 (99.1) |
| > 1.00 D | 0 (0.0) | 0 (0.0) | 3 (2.7) | 1 (0.9) |
| Total | 107 | 106 | 111 | 111 |

Percentages are calculated as (n/Total)*100

## EFFECTIVENESS

### Visual Acuity

Visual Acuity was assessed under high-contrast, photopic conditions using a computerized test system (CTS, M&S Technologies, Niles, IL). The following subsections present monocular and binocular visual acuity data collected at distance, intermediate (66 cm), and near (40 cm). Primary and secondary study analyses included the following assessments of monocular visual acuity:

- Mean best corrected distance visual acuity (BCDVA) and distance corrected intermediate and near visual acuities (DCIVA and DCNVA) by treatment group
- Monocular defocus curves by treatment group

These analyses are discussed in the following subsections. Monocular visual acuity was also assessed in low-contrast, photopic conditions; results of this testing is presented in the “Safety” section of this document.

Monocular Visual Acuity

Table 7 presents monocular, photopic, best corrected distance (4 m) visual acuity (BCDVA), distance corrected intermediate (66 cm) visual acuity (DCIVA), and distance corrected near (40 cm) visual acuity (DCNVA) data for first eyes treated with the AcrySof™ IQ Vivity™ and monofocal control IOLs at 6 Months.

**Table 7: Comparison of Mean Monocular Photopic (First Eyes) BCDVA, DCIVA, and DCNVA Using Least Square Estimates**
**All Implanted, 6 Months Postoperative**

| Monocular Mean Visual Acuity | AcrySof™ IQ Vivity™ IOL | | | Monofocal Control IOL | | | 95% One-Sided UCL | P-Value |
|---|---|---|---|---|---|---|---|---|
| | Total | Mean logMAR | Standard Error | Total | Mean logMAR | Standard Error | | |
| BCDVA | 107 | 0.016 | 0.0091 | 111 | -0.036 | 0.0089 | 0.073[a] | N/A |
| DCIVA | 107 | 0.148 | 0.0120 | 111 | 0.312 | 0.0118 | N/A | < 0.001[b] |
| DCNVA | 107 | 0.359 | 0.0147 | 111 | 0.515 | 0.0144 | N/A | < 0.001[b] |

[a]Non-inferiority of AcrySof™ IQ Vivity™ IOL to the Monofocal Control IOL is demonstrated by the one-sided 95% Upper Confidence Limit (UCL) for treatment difference < 0.10 logMAR
[b]Superiority of AcrySof™ IQ Vivity™ IOL over the Monofocal Control IOL is demonstrated by the upper bound of two-sided 95% CI for treatment difference is < 0.00 logMAR and p-value is less than alpha = 0.05.

The AcrySof™ IQ Vivity™ IOL met the clinical performance co-primary endpoint for mean photopic BCDVA non-inferior to the monofocal control IOL (non-inferiority margin of 0.10 logMAR). The upper limit of the one sided 95% confidence interval (CI) of the mean difference in BCDVA between IOL groups was less than 0.10 logMAR (less than a line), demonstrating that the AcrySof™ IQ Vivity™ IOL is non-inferior to the control lens in providing BCDVA. Additionally, AcrySof™ IQ Vivity™ IOL first eyes achieved BCDVA of 0.30 logMAR or better at a rate of 99.1% and 100.0% in the AAS and Best-Case Analysis Set (BAS) set, respectively. This exceeded the ISO BCDVA Safety and Performance Endpoint (SPE) rates of 92.5% and 96.7%, respectively.

The AcrySof™ IQ Vivity™ IOL provided mean photopic monocular DCIVA superior to the monofocal control IOL with an increase in 1.6 lines read and met the clinical performance co-primary endpoint with > 50% (72.9%) of first eyes achieving DCIVA of 0.20 logMAR or better at 6 Months. When analyzed by pupil size (< 3 mm, ≥3 - ≤4 mm, and > 4 mm), mean monocular DCIVA in all pupil size subgroups of the Vivity IOL arm remains above 0.20 logMAR, and > 1 line above those of the monofocal control IOL arm.

AcrySof™ IQ Vivity™ IOL provided mean photopic monocular DCNVA superior to the monofocal control IOL, with 40.2% (95% CI: 30.8%, 50.1%) of AcrySof™ IQ Vivity™ IOL first eyes achieving DCNVA of 0.30 logMAR or better at 6 Months, at a rate > 25% above that of the monofocal control IOL, and an increase of 1.6 lines read.

**Monocular Defocus Curve**

Monocular defocus curves were obtained at 6 months for the AcrySof™ IQ Vivity™ IOL and the monofocal control IOL reflecting 95% confidence limits and ±1 standard deviation (SD) are depicted in Figures 5 and 6, respectively. Data were obtained from 107 and 111 subjects respectively in each arm using a computerized visual acuity test system (CTS, M&S Technologies, Niles, IL). The Vivity IOL group demonstrated a mean defocus range of 1.53 D compared to 0.99 D for the Monofocal Control IOL, providing an increase of 0.54 D in depth of focus at 0.20 logMAR. Therefore, the AcrySof™ IQ Vivity™ IOL met the clinical performance co-primary endpoint, demonstrating a monocular defocus range of > 0.5 D greater than the monofocal control IOL at 0.20 logMAR at 6 Months.

**Figure 5: Mean Monocular (First Eyes) Defocus Curve with 95% Confidence Limits by Lens Model at 6 Months Postoperative All Implanted**

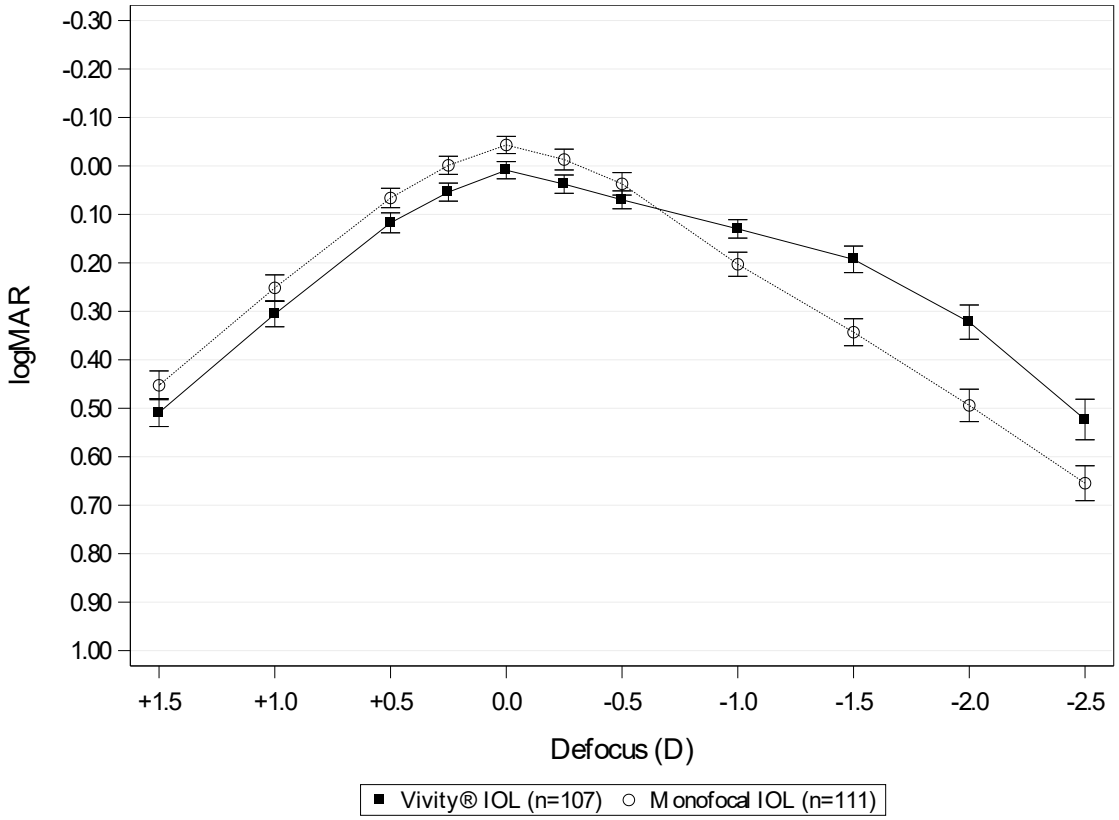
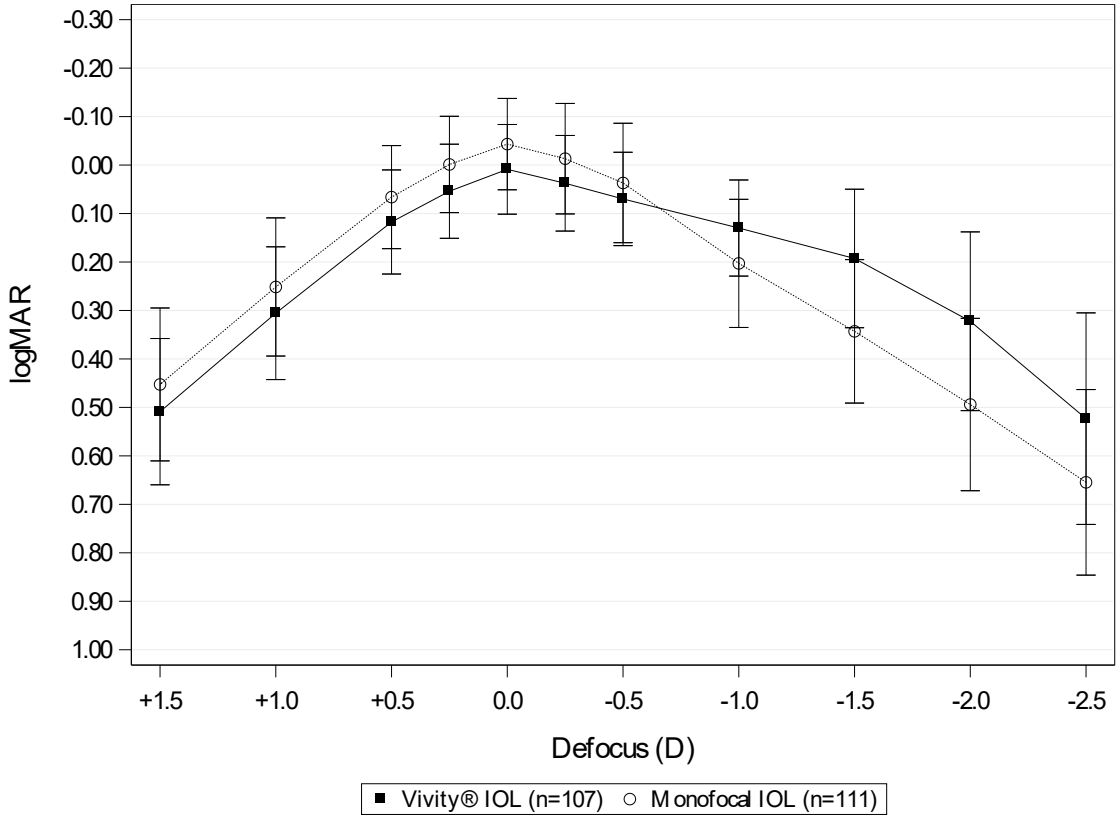


**Figure 6: Mean Monocular (First Eyes) Defocus Curve with ±1 SD by Lens Model at 6 Months Postoperative**
**All Implanted**




Monocular defocus curves stratified by post-operative (Month 6) photopic pupil size in the Vivity and Monofocal IOL groups are presented in Figures 7 and 8, respectively.

**Figure 7: Monocular Mean Defocus Curve by Post-Operative Pupil Size at 6 Months, Vivity IOL Group**

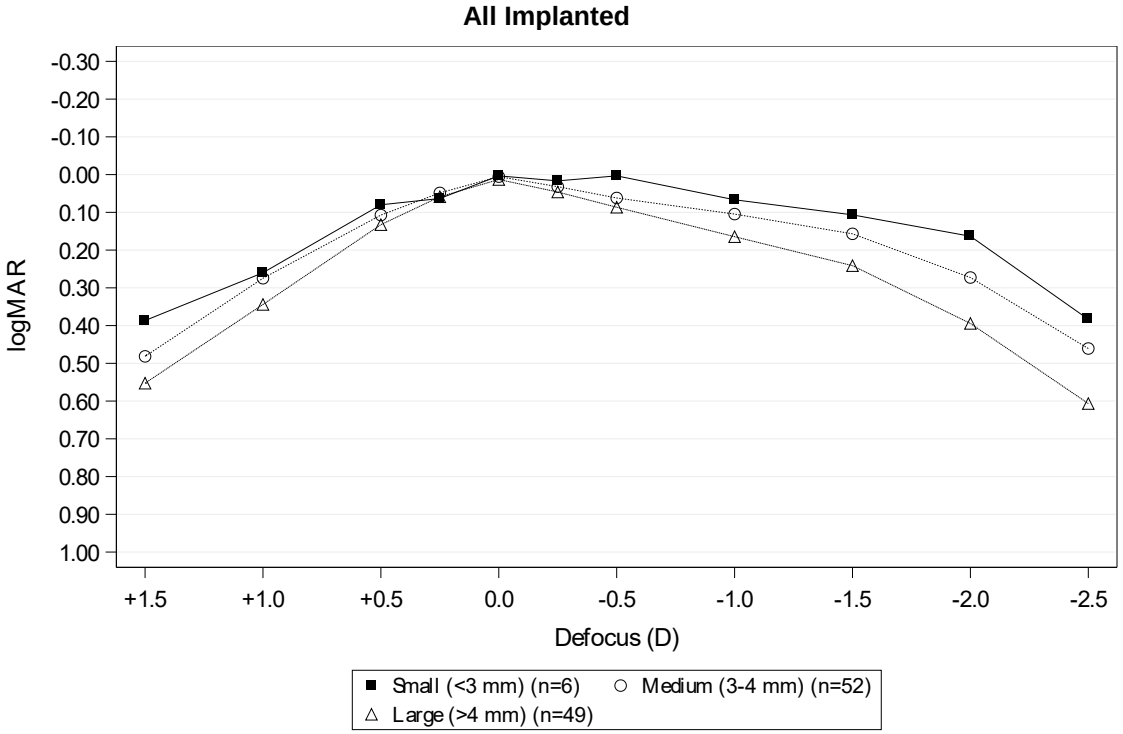
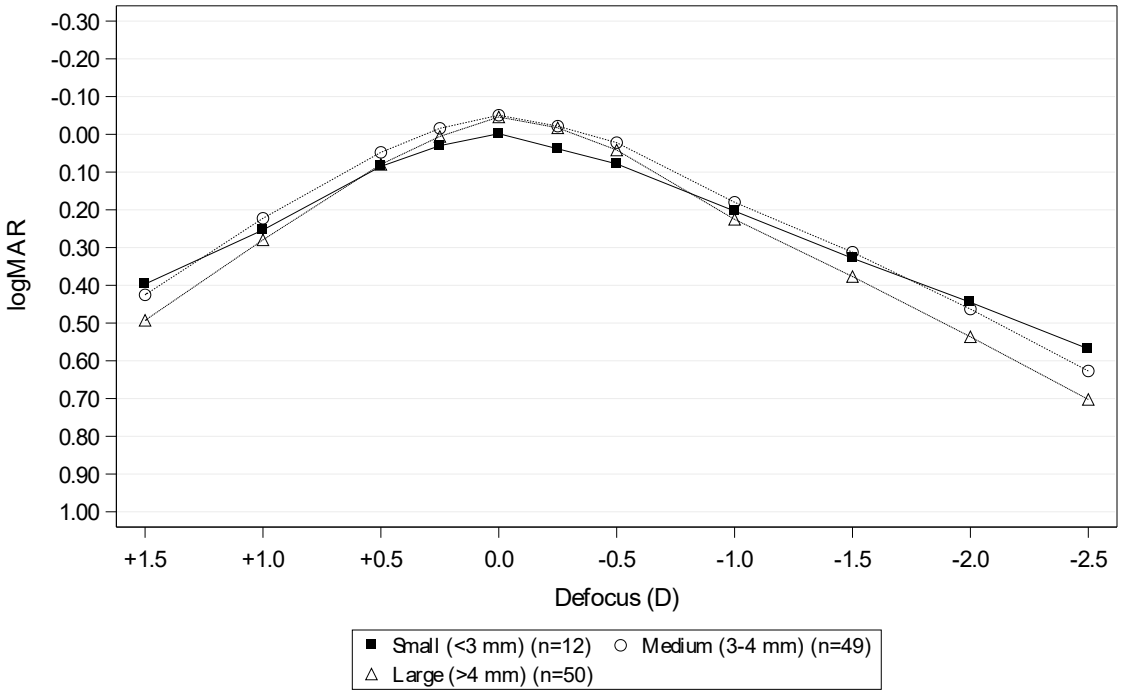



**Figure 8: Monocular Mean Defocus Curve by Post-Operative Pupil Size at 6 Months, Monofocal IOL Group**



Binocular Visual Acuity

Additional descriptive and categorical analyses of binocular uncorrected and best corrected distance visual acuities (UCDVA and BCDVA), uncorrected and distance corrected intermediate visual acuities (UCIVA and DCIVA), and uncorrected and distance corrected near visual acuities (UCNVA and DCNVA), in addition to binocular defocus curves are presented in the following subsections.

### Binocular Mean Visual Acuity

Binocular mean BCDVA, UCDVA, DCIVA, UCIVA, DCNVA, and UCNVA are presented by treatment group in Table 8. Binocular visual acuity data for the AcrySof™ IQ Vivity™ IOL group showed mean BCDVA to be within 2 letters of the Monofocal Control IOL, while differences in mean DCIVA and mean DCNVA were > 1 line. One of the subjects in the AcrySof™ IQ Vivity™ IOL group was not bilaterally implanted and does not contribute to binocular assessments.

**Table 8: Comparison of Binocular Mean Photopic BCDVA, UCDVA, DCIVA, UCIVA, DCNVA, and UCNVA**
**All Implanted, 6 Months Postoperative**

| Binocular Mean Visual Acuity | AcrySof™ IQ Vivity™ IOL N = 106 | | | Monofocal Control IOL N = 113 | | |
|---|---|---|---|---|---|---|
| | n | Mean logMAR | Standard Deviation | n | Mean logMAR | Standard Deviation |
| BCDVA | 106 | -0.028 | 0.084 | 111 | -0.071 | 0.086 |
| UCDVA | 106 | 0.035 | 0.102 | 111 | -0.022 | 0.107 |
| DCIVA | 106 | 0.054 | 0.093 | 111 | 0.196 | 0.113 |
| UCIVA | 106 | 0.058 | 0.083 | 111 | 0.139 | 0.122 |
| DCNVA | 106 | 0.253 | 0.118 | 111 | 0.391 | 0.135 |
| UCNVA | 106 | 0.208 | 0.104 | 111 | 0.339 | 0.149 |

### Binocular Categorical Visual Acuity

Tables 9 and 10 present the percentage of subjects achieving binocular photopic BCDVA and UCDVA by Snellen and logMAR categories, respectively, at 6 Months. The majority of subjects in both the AcrySof™ IQ Vivity™ IOL and the monofocal control IOL groups achieved $20/20^{-2}$ or better.

### Table 9: Binocular Photopic Distance Best Corrected and Uncorrected Visual Acuity (Snellen) All Implanted, 6 Months Postoperative

| Binocular Snellen Visual Acuity | AcrySof™ IQ Vivity™ IOL N = 106 | | Monofocal Control IOL N = 113 | |
|---|---|---|---|---|
| | Uncorrected n (%) | Best Corrected n (%) | Uncorrected n (%) | Best Corrected n (%) |
| 20/20$^{-2}$ or better | 65 (61.3) | 93 (87.7) | 85 (76.6) | 105 (94.6) |
| 20/25$^{-2}$ or better | 94 (88.7) | 103 (97.2) | 105 (94.6) | 109 (98.2) |
| 20/32$^{-2}$ or better | 102 (96.2) | 104 (98.1) | 109 (98.2) | 111 (100.0) |
| 20/40$^{-2}$ or better | 105 (99.1) | 106 (100.0) | 111 (100.0) | 111 (100.0) |
| Worse than 20/40$^{-2}$ | 1 (0.9) | 0 (0.0) | 0 (0.0) | 0 (0.0) |
| Total Responses | 106 | 106 | 111 | 111 |

Snellen VA was converted from logMAR VA. A Snellen notation of 20/20$^{-2}$ or better indicates a logMAR VA of 0.04 or better, which means 3 or more of the 5 ETDRS chart letters in the line were identified correctly.
Percentages are calculated as (n/Total)*100

### Table 10: Binocular Photopic Distance Best Corrected and Uncorrected Visual Acuity (logMAR) All Implanted, 6 Months Postoperative

| Binocular logMAR Visual Acuity | AcrySof™ IQ Vivity™ IOL N = 106 | | Monofocal Control IOL N = 113 | |
|---|---|---|---|---|
| | Uncorrected n (%) | Best Corrected n (%) | Uncorrected n (%) | Best Corrected n (%) |
| 0.00 or better | 47 (44.3) | 78 (73.6) | 77 (69.4) | 99 (89.2) |
| 0.10 or better | 88 (83.0) | 102 (96.2) | 96 (86.5) | 108 (97.3) |
| 0.20 or better | 98 (92.5) | 104 (98.1) | 109 (98.2) | 111 (100.0) |
| 0.30 or better | 105 (99.1) | 106 (100.0) | 111 (100.0) | 111 (100.0) |
| Worse than 0.30 | 1 (0.9) | 0 (0.0) | 0 (0.0) | 0 (0.0) |
| Total Responses | 106 | 106 | 111 | 111 |

Percentages are calculated as (n/Total)*100

Tables 11 and 12 present the percentage of subjects achieving binocular photopic DCIVA and UCIVA by Snellen and logMAR categories, respectively, at 6 Months. The majority of AcrySof™ IQ Vivity™ IOL subjects achieved 20/20$^{-2}$ or better binocular uncorrected and distance corrected intermediate VA, as compared to 27.0% and 10.8% of control subjects, respectively.

**Table 11: Binocular Photopic Intermediate (66 cm) Distance Corrected and Uncorrected Visual Acuity (Snellen)**
**All Implanted, 6 Months Postoperative**

| Binocular Snellen Visual Acuity | AcrySof™ IQ Vivity™ IOL N = 106 | | Monofocal Control IOL N = 113 | |
|---|---|---|---|---|
| | Uncorrected n (%) | Distance Corrected n (%) | Uncorrected n (%) | Distance Corrected n (%) |
| 20/20$^{-2}$ or better | 59 (55.7) | 59 (55.7) | 30 (27.0) | 12 (10.8) |
| 20/25$^{-2}$ or better | 91 (85.8) | 93 (87.7) | 70 (63.1) | 38 (34.2) |
| 20/32$^{-2}$ or better | 105 (99.1) | 103 (97.2) | 92 (82.9) | 82 (73.9) |
| 20/40$^{-2}$ or better | 106 (100.0) | 106 (100.0) | 106 (95.5) | 103 (92.8) |
| Worse than 20/40$^{-2}$ | 0 (0.0) | 0 (0.0) | 5 (4.5) | 8 (7.2) |
| Total Responses | 106 | 106 | 111 | 111 |

Snellen VA was converted from logMAR VA. A Snellen notation of 20/20$^{-2}$ or better indicates a logMAR VA of 0.04 or better, which means 3 or more of the 5 ETDRS chart letters in the line were identified correctly.
Percentages are calculated as (n/Total)*100

**Table 12: Binocular Photopic Intermediate (66 cm) Distance Corrected and Uncorrected Visual Acuity (logMAR)**
**All Implanted, 6 Months Postoperative**

| Binocular logMAR Visual Acuity | AcrySof™ IQ Vivity™ IOL N = 106 | | Monofocal Control IOL N = 113 | |
|---|---|---|---|---|
| | Uncorrected n (%) | Distance Corrected n (%) | Uncorrected n (%) | Distance Corrected n (%) |
| 0.00 or better | 39 (36.8) | 43 (40.6) | 16 (14.4) | 6 (5.4) |
| 0.10 or better | 82 (77.4) | 79 (74.5) | 47 (42.3) | 24 (21.6) |
| 0.20 or better | 100 (94.3) | 99 (93.4) | 87 (78.4) | 66 (59.5) |
| 0.30 or better | 105 (99.1) | 104 (98.1) | 101 (91.0) | 94 (84.7) |
| Worse than 0.30 | 1 (0.9) | 2 (1.9) | 10 (9.0) | 17 (15.3) |
| Total Responses | 106 | 106 | 111 | 111 |

Percentages are calculated as (n/Total)*100

Tables 13 and 14 present the percentage of subjects achieving binocular photopic UCNVA and DCNVA by Snellen and logMAR categories, respectively, at 6 Months. 67.0% and 57.5% of the AcrySof™ IQ Vivity™ IOL subjects achieved 20/32$^{-2}$ or better binocular uncorrected and distance corrected near VA, compared to 28.8% and 16.2% of control subjects, respectively.

**Table 13: Binocular Photopic Near (40 cm) Distance Corrected and Uncorrected Visual Acuity (Snellen) All Implanted, 6 Months Postoperative**

| Binocular Snellen Visual Acuity | AcrySof™ IQ Vivity™ IOL N = 106 | | Monofocal Control IOL N = 113 | |
|---|---|---|---|---|
| | Uncorrected n (%) | Distance Corrected n (%) | Uncorrected n (%) | Distance Corrected n (%) |
| 20/20$^{-2}$ or better | 3 (2.8) | 1 (0.9) | 1 (0.9) | 0 (0.0) |
| 20/25$^{-2}$ or better | 37 (34.9) | 23 (21.7) | 11 (9.9) | 2 (1.8) |
| 20/32$^{-2}$ or better | 71 (67.0) | 61 (57.5) | 32 (28.8) | 18 (16.2) |
| 20/40$^{-2}$ or better | 96 (90.6) | 82 (77.4) | 62 (55.9) | 48 (43.2) |
| Worse than 20/40$^{-2}$ | 10 (9.4) | 24 (22.6) | 49 (44.1) | 63 (56.8) |
| Total Responses | 106 | 106 | 111 | 111 |

Snellen VA was converted from logMAR VA. A Snellen notation of 20/20$^{-2}$ or better indicates a logMAR VA of 0.04 or better, which means 3 or more of the 5 ETDRS chart letters in the line were identified correctly.
Percentages are calculated as (n/Total)*100

**Table 14: Binocular Photopic Near (40 cm) Distance Corrected and Uncorrected Visual Acuity (logMAR) All Implanted, 6 Months Postoperative**

| Binocular logMAR Visual Acuity | AcrySof™ IQ Vivity™ IOL N = 106 | | Monofocal Control IOL N = 113 | |
|---|---|---|---|---|
| | Uncorrected n (%) | Distance Corrected n (%) | Uncorrected n (%) | Distance Corrected n (%) |
| 0.00 or better | 2 (1.9) | 1 (0.9) | 1 (0.9) | 0 (0.0) |
| 0.10 or better | 17 (16.0) | 9 (8.5) | 8 (7.2) | 2 (1.8) |
| 0.20 or better | 60 (56.6) | 46 (43.4) | 27 (24.3) | 8 (7.2) |
| 0.30 or better | 90 (84.9) | 76 (71.7) | 49 (44.1) | 39 (35.1) |
| Worse than 0.30 | 16 (15.1) | 30 (28.3) | 62 (55.9) | 72 (64.9) |
| Total Responses | 106 | 106 | 111 | 111 |

Percentages are calculated as (n/Total)*100

**Defocus Curves**

Binocular defocus curves were obtained at 6 months for the AcrySof™ IQ Vivity™ IOL and the monofocal control IOL and are depicted with 95% confidence interval and ±1 SD error bars in Figures 9 and 10, respectively. Data were obtained from 106 and 111 subjects in each arm using a computerized visual acuity test system (CTS, M&S Technologies, Niles, IL). Consistent with the monocular defocus curve presented in Figures 5 and 6, AcrySof™ IQ Vivity™ IOL subjects demonstrated a > 0.5 D greater defocus range compared to the monofocal control group.

**Figure 9: Binocular Mean Defocus Curve with 95% Confidence Limits by Lens Model at 6 Months Postoperative All Implanted**

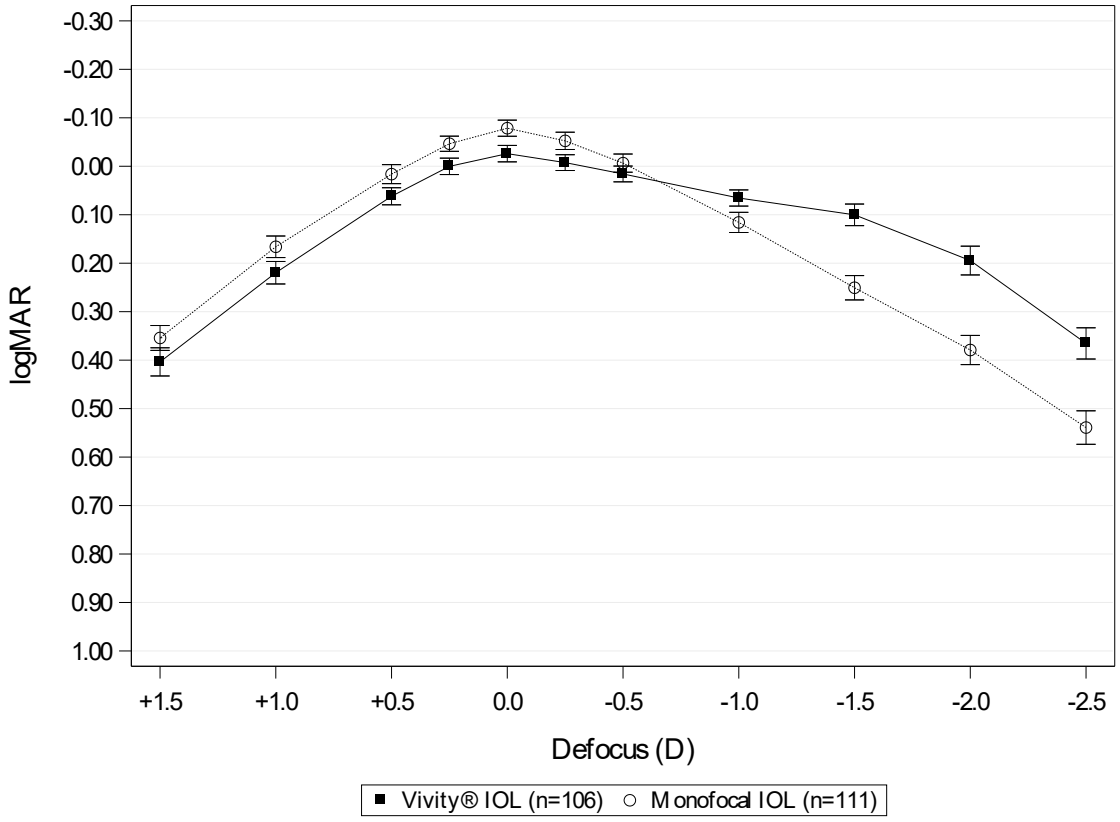
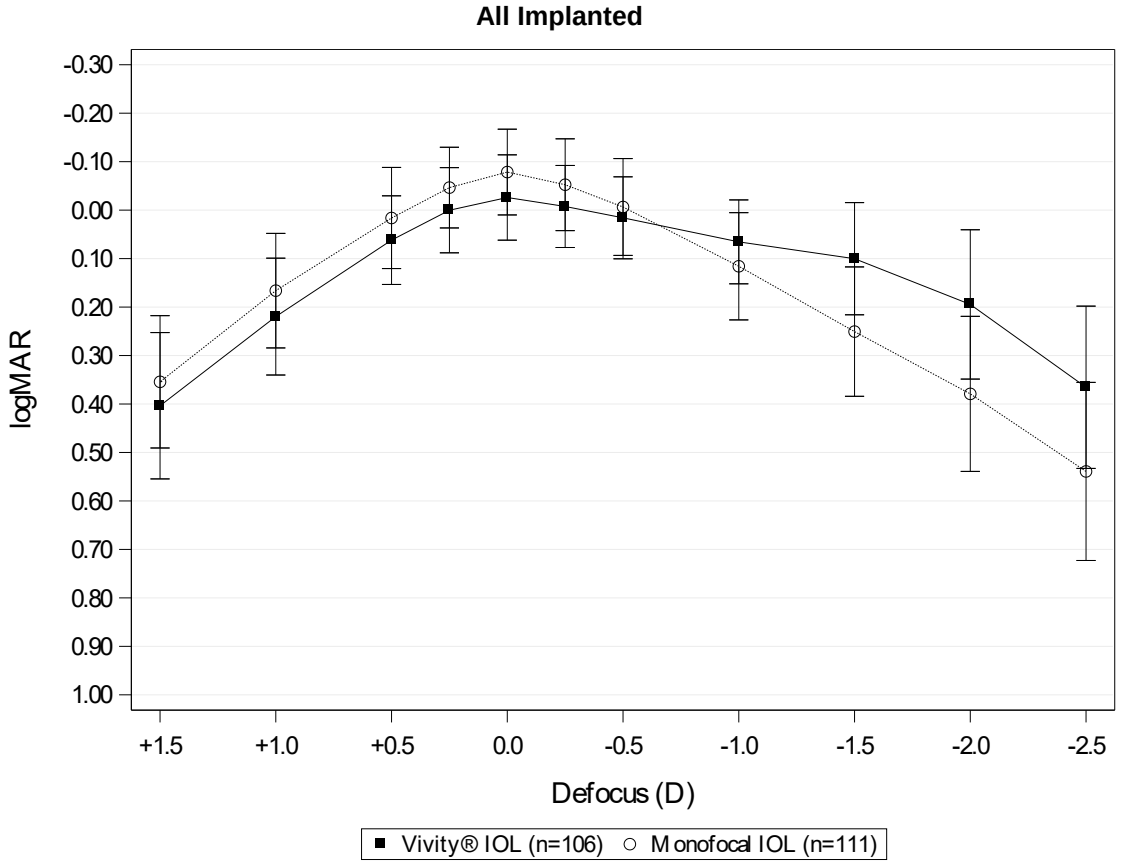


**Figure 10: Binocular Mean Defocus Curve with ±1 SD by Lens Model at 6 Months Postoperative**




**Need for Eyeglasses/Contact Lenses**

A Patient Reported Outcome Measure instrument was developed and validated for use in this clinical study to assess need for eyeglasses/contact lenses following implantation with the IOL. The AcrySof™ IQ Vivity™ IOL (N = 102) showed a greater proportion of subjects reporting never needing to wear eyeglasses or contact lenses at 6 months: 21.6% of subjects versus 3.6% for the Monofocal Control IOL (N = 111); however, a statistical test was not performed.

The questionnaire evaluated subject-reported use of eyeglasses or contact lenses at distance ('far away'), intermediate ('arm's length'), and near ('up close'), in bright and dim lighting conditions. Table 15 summarizes another analysis assessing the proportion of AcrySof™ IQ Vivity™ IOL and Monofocal Control IOL subjects 'never' or 'rarely' needing eyeglasses or contact lenses. Data for this analysis are presented overall and under each lighting and distance condition.

**Table 15: Proportion of Subjects Rarely or Never Needing Eyeglasses or Contact Lenses by Distance and Lighting Condition**

| Condition | | Proportion of Subjects Rarely or Never Needing Eyeglasses or Contact Lenses | | | | | |
|---|---|---|---|---|---|---|---|
| | | AcrySof™ IQ Vivity™ IOL N = 106 | | | Monofocal Control IOL N = 113 | | |
| | | Total Responses | n | % | Total Responses | n | % |
| Overall | | 102 | 46 | 45.1 | 111 | 19 | 17.1 |
| Bright Light | Distance ('Far away') | 102 | 96 | 94.1 | 111 | 102 | 91.9 |
| | Intermediate ('At arm's length') | 102 | 89 | 87.2 | 111 | 64 | 57.6 |
| | Near ('Up close') | 102 | 47 | 46.1 | 111 | 18 | 16.2 |
| Dim Light | Distance ('Far away') | 102 | 95 | 93.2 | 111 | 99 | 89.2 |
| | Intermediate ('At arm's length') | 102 | 86 | 84.3 | 111 | 59 | 53.1 |
| | Near ('Up close') | 102 | 40 | 39.2 | 111 | 12 | 10.8 |

Subjects who reported not using eyeglasses at least some of the time (95.0% and 85.7% in the AcrySof™ IQ Vivity™ IOL and Monofocal Control IOL groups, respectively) were asked to report their quality of vision without eyeglasses, up close, at arm's length, and far away, in dim and bright light. The proportion of subjects reporting 'good' or 'very good' vision without eyeglasses at 6 Months is presented by treatment group in Table 16.

**Table 16: Proportion of Subjects Reporting 'Good' or 'Very Good' Vision Without Eyeglasses by Distance and Lighting Condition**

| Condition | | AcrySof™ IQ Vivity™ IOL N = 106 | | | Monofocal Control IOL N = 113 | | |
|---|---|---|---|---|---|---|---|
| | | Total Responses | n | % | Total Responses | n | % |
| Bright Light | Distance ('Far away') | 96 | 90 | 93.7 | 89 | 82 | 92.2 |
| | Intermediate ('At arm's length') | 96 | 88 | 91.6 | 89 | 56 | 62.9 |
| | Near ('Up close') | 96 | 55 | 57.3 | 89 | 22 | 24.8 |
| Dim Light | Distance ('Far away') | 96 | 84 | 87.5 | 90 | 70 | 77.8 |
| | Intermediate ('At arm's length') | 96 | 80 | 83.4 | 89 | 45 | 50.6 |
| | Near ('Up close') | 96 | 36 | 37.5 | 89 | 7 | 7.8 |

The results of this questionnaire demonstrate a reduced overall spectacle need in subjects implanted with the AcrySof™ IQ Vivity™ IOL compared to the monofocal control IOL. Statistical testing of this endpoint was not performed, as prespecified in the statistical analysis plan, because of the failure to meet the first co-secondary effectiveness endpoint.

**SAFETY**

The incidences of cumulative and persistent adverse events (AEs) including 1-sided 95% lower confidence limits for the AcrySof™ IQ Vivity™ IOL and Monofocal Control IOL as compared to the ISO 11979-7:2014 historical grid rates are provided in Tables 17 (first implanted eyes in each IOL group), 18 (second implanted eyes in each IOL group), and 19 (all implanted eyes in each IOL

group). If the same event occurred multiple times in an eye, only the first occurrence is counted in the tables below. The safety and performance endpoint (SPE) rate is considered not exceeded if the 1-sided 95% lower CL for an AE is less than the SPE%. No cumulative adverse events exceeded the established rates according to ISO 11979-7:2014.

No persistent adverse events (adverse events in the ISO grid that are observed at the 6 month postoperative visit) were observed for 107 subjects implanted with AcrySof™ IQ Vivity™ IOL.

**Table 17: Cumulative and Persistent Serious Adverse Events in First Eyes and SPE Rates for AcrySof™ IQ Vivity™ and Monofocal IOL Group (Safety Analysis Set)**

| | AcrySof IQ Vivity IOL First Implanted Eyes N = 107 | | Monofocal Control IOL First Implanted Eyes N = 113 | | |
|---|---|---|---|---|---|
| **Cumulative Serious Adverse Events** | **n(%)** | **1-sided 95% Lower CL** | **n (%)** | **1-sided 95% Lower CL** | **SPE %** |
| Cystoid macular oedema | 1 (0.9) | 0.05 | 1 (0.9) | 0.05 | 3.0 |
| Hypopyon | 0 (0.0) | 0.00 | 0 (0.0) | 0.00 | 0.3 |
| Endophthalmitis | 0 (0.0) | 0.00 | 0 (0.0) | 0.00 | 0.1 |
| Lens dislocated from posterior chamber | 0 (0.0) | 0.00 | 0 (0.0) | 0.00 | 0.1 |
| Pupillary block | 0 (0.0) | 0.00 | 0 (0.0) | 0.00 | 0.1 |
| Retinal detachment | 0 (0.0) | 0.00 | 1 (0.9) | 0.05 | 0.3 |
| Secondary surgical intervention | 0 (0.0) | 0.00 | 2 (1.8)* | 0.32 | 0.8 |
| Other | | | | | |
| Hyphaema | 1 (0.9) | 0.05 | 0 (0.0) | 0.00 | N/A |
| Transient ischaemic attack | 1 (0.9) | 0.05 | 0 (0.0) | 0.00 | N/A |
| Photopsia | 0 (0.0) | 0.00 | 1 (0.9) | 0.05 | N/A |
| **Persistent Serious Adverse Events** | | | | | |
| Corneal stroma oedema | 0 (0.0) | 0.00 | 0 (0.0) | 0.00 | 0.3 |
| Cystoid macular oedema | 0 (0.0) | 0.00 | 0 (0.0) | 0.00 | 0.5 |
| Iritis | 0 (0.0) | 0.00 | 0 (0.0) | 0.00 | 0.3 |
| Raised IOP requiring treatment | 0 (0.0) | 0.00 | 0 (0.0) | 0.00 | 0.4 |

Percentages are calculated as (n/N)*100
*One SSI was a pars plana vitrectomy and one SSI was an IOL explant

## Table 18: Cumulative and Persistent Serious Adverse Events in Second Eyes and SPE Rates for AcrySof™ IQ Vivity™ and Monofocal IOL Group (Safety Analysis Set)

| | AcrySof IQ Vivity IOL Second Implanted Eyes N = 106 | | Monofocal Control IOL Second Implanted Eyes N = 113 | | |
|---|---|---|---|---|---|
| **Cumulative Serious Adverse Events** | **n(%)** | **1-sided 95% Lower CL** | **n (%)** | **1-sided 95% Lower CL** | **SPE %** |
| Cystoid macular oedema | 0 (0.0) | 0.00 | 1 (0.9) | 0.05 | 3.0 |
| Hypopyon | 0 (0.0) | 0.00 | 0 (0.0) | 0.00 | 0.3 |
| Endophthalmitis | 0 (0.0) | 0.00 | 0 (0.0) | 0.00 | 0.1 |
| Lens dislocated from posterior chamber | 0 (0.0) | 0.00 | 0 (0.0) | 0.00 | 0.1 |
| Pupillary block | 0 (0.0) | 0.00 | 0 (0.0) | 0.00 | 0.1 |
| Retinal detachment | 0 (0.0) | 0.00 | 0 (0.0) | 0.00 | 0.3 |
| Secondary surgical intervention | 2 (1.9)* | 0.34 | 0 (0.0) | 0.00 | 0.8 |
| Other | | | | | |
| Cataract operation complication** | 2 (1.9) | 0.34 | 0 (0.0) | 0.00 | N/A |
| **Persistent Serious Adverse Events** | | | | | |
| Corneal stroma oedema | 0 (0.0) | 0.00 | 0 (0.0) | 0.00 | 0.3 |
| Cystoid macular oedema | 0 (0.0) | 0.00 | 0 (0.0) | 0.00 | 0.5 |
| Iritis | 0 (0.0) | 0.00 | 0 (0.0) | 0.00 | 0.3 |
| Raised IOP requiring treatment | 0 (0.0) | 0.00 | 0 (0.0) | 0.00 | 0.4 |

Percentages are calculated as (n/N)*100
*****Both SSIs were unrelated to the IOL and were performed to remove retained cataract material from the eye.
**Both events were due to retained cataract material in the eye

## Table 19: Cumulative and Persistent Serious Adverse Events in All Eyes and SPE Rates for AcrySof™ IQ Vivity™ and Monofocal IOL Group (Safety Analysis Set)

| | AcrySof IQ Vivity IOL All Implanted Eyes N = 213 | | Monofocal Control IOL All Implanted Eyes N = 226 | | |
|---|---|---|---|---|---|
| **Cumulative Serious Adverse Events** | **n(%)** | **1-sided 95% Lower CL** | **n (%)** | **1-sided 95% Lower CL** | **SPE %** |
| Cystoid macular oedema | 1 (0.5) | 0.02 | 2 (0.9) | 0.16 | 3.0 |
| Hypopyon | 0 (0.0) | 0.00 | 0 (0.0) | 0.00 | 0.3 |
| Endophthalmitis | 0 (0.0) | 0.00 | 0 (0.0) | 0.00 | 0.1 |
| Lens dislocated from posterior chamber | 0 (0.0) | 0.00 | 0 (0.0) | 0.00 | 0.1 |
| Pupillary block | 0 (0.0) | 0.00 | 0 (0.0) | 0.00 | 0.1 |
| Retinal detachment | 0 (0.0) | 0.00 | 1 (0.4) | 0.02 | 0.3 |
| Secondary surgical intervention* | 2 (0.9)* | 0.17 | 2 (0.9)*** | 0.16 | 0.8 |
| Other | | | | | |
| Cataract operation complication** | 2 (0.9) | 0.17 | 0 (0.0) | 0.00 | N/A |
| Hyphaema | 1 (0.5) | 0.02 | 0 (0.0) | 0.00 | N/A |
| Transient ischaemic attack | 1 (0.5) | 0.02 | 0 (0.0) | 0.00 | N/A |
| Photopsia | 0 (0.0) | 0.00 | 1 (0.4) | 0.02 | N/A |
| **Persistent Serious Adverse Events** | | | | | |
| Corneal stroma oedema | 0 (0.0) | 0.00 | 0 (0.0) | 0.00 | 0.3 |
| Cystoid macular oedema | 0 (0.0) | 0.00 | 0 (0.0) | 0.00 | 0.5 |
| Iritis | 0 (0.0) | 0.00 | 0 (0.0) | 0.00 | 0.3 |
| Raised IOP requiring treatment | 0 (0.0) | 0.00 | 0 (0.0) | 0.00 | 0.4 |

Percentages are calculated as (n/N)*100
*****Both SSIs in the Vivity IOL group were unrelated to the IOL and were performed to remove retained cataract material from the eye.
**Both events were due to retained cataract material in the eye
*******One SSI with the Monofocal Control IOL was a pars plana vitrectomy and the other was an IOL explant.

The results of adverse events analyses based on the consensus definitions as set forth by the American Academy of Ophthalmology's Task Force (Masket et al. Ophthalmology 2017) are shown in Tables 20 and 21 for first and second implanted eyes, respectively.

**Table 20: Supportive Characterization of Ocular Adverse Events in First Eyes based on a Modified Version of AAO Consensus (Masket et al., 2017) for AcrySof™ IQ Vivity™ and Monofocal IOL Groups (Safety Analysis Set)**

| | AcrySof IQ Vivity IOL First Implanted Eyes N = 107 | | | Monofocal IOL First Implanted Eyes N = 113 | | |
|---|---|---|---|---|---|---|
| **Adverse Event** | **n (%)** | **2-sided 95% CI** | **E** | **n (%)** | **2-sided 95% CI** | **E** |
| Chronic anterior uveitis | 0 (0.0) | (0.00, 3.39) | 0 | 0 (0.0) | (0.00, 3.21) | 0 |
| Clinically significant cystoid macular edema | 0 (0.0) | (0.00, 3.39) | 0 | 1 (0.9) | (0.02, 4.83) | 1 |
| Visually significant corneal edema | 0 (0.0) | (0.00, 3.39) | 0 | 0 (0.0) | (0.00, 3.21) | 0 |
| Endophthalmitis | 0 (0.0) | (0.00, 3.39) | 0 | 0 (0.0) | (0.00, 3.21) | 0 |
| Mechanical pupillary block | 0 (0.0) | (0.00, 3.39) | 0 | 0 (0.0) | (0.00, 3.21) | 0 |
| Increased IOP | 2 (1.9) | (0.23, 6.59) | 2 | 3 (2.7) | (0.55, 7.56) | 3 |
| Rhegmatogenous RD | 0 (0.0) | (0.00, 3.39) | 0 | 1 (0.9) | (0.02, 4.83) | 1 |
| Toxic anterior segment syndrome | 0 (0.0) | (0.00, 3.39) | 0 | 0 (0.0) | (0.00, 3.21) | 0 |
| Secondary IOL intervention – Exchange | 0 (0.0) | (0.00, 3.39) | 0 | 0 (0.0) | (0.00, 3.21) | 0 |
| Secondary IOL intervention – Removal | 0 (0.0) | (0.00, 3.39) | 0 | 1 (0.9) | (0.02, 4.83) | 1 |
| Secondary IOL intervention – Reposition | 0 (0.0) | (0.00, 3.39) | 0 | 0 (0.0) | (0.00, 3.21) | 0 |

Percentages are calculated as (n/N)*100

**Table 21: Supportive Characterization of Ocular Adverse Events in Second Eyes based on a Modified Version of AAO Consensus (Masket et al., 2017) for AcrySof™ IQ Vivity™ and Monofocal IOL Groups (Safety Analysis Set)**

| | AcrySof IQ Vivity IOL Second Implanted Eyes N = 106 | | | Monofocal IOL Second Implanted Eyes N = 113 | | |
|---|---|---|---|---|---|---|
| **Adverse Event** | **n (%)** | **2-sided 95% CI** | **E** | **n (%)** | **2-sided 95% CI** | **E** |
| Chronic anterior uveitis | 0 (0.0) | (0.00, 3.42) | 0 | 0 (0.0) | (0.00, 3.21) | 0 |
| Clinically significant cystoid macular edema | 0 (0.0) | (0.00, 3.42) | 0 | 0 (0.0) | (0.00, 3.21) | 0 |
| Visually significant corneal edema | 0 (0.0) | (0.00, 3.42) | 0 | 0 (0.0) | (0.00, 3.21) | 0 |
| Endophthalmitis | 0 (0.0) | (0.00, 3.42) | 0 | 0 (0.0) | (0.00, 3.21) | 0 |
| Mechanical pupillary block | 0 (0.0) | (0.00, 3.42) | 0 | 0 (0.0) | (0.00, 3.21) | 0 |
| Increased IOP | 2 (1.9) | (0.23, 6.65) | 2 | 2 (1.8) | (0.22, 6.25) | 2 |
| Rhegmatogenous RD | 0 (0.0) | (0.00, 3.42) | 0 | 0 (0.0) | (0.00, 3.21) | 0 |
| Toxic anterior segment syndrome | 0 (0.0) | (0.00, 3.42) | 0 | 0 (0.0) | (0.00, 3.21) | 0 |
| Secondary IOL intervention – Exchange | 0 (0.0) | (0.00, 3.42) | 0 | 0 (0.0) | (0.00, 3.21) | 0 |
| Secondary IOL intervention – Removal | 0 (0.0) | (0.00, 3.42) | 0 | 0 (0.0) | (0.00, 3.21) | 0 |
| Secondary IOL intervention – Reposition | 0 (0.0) | (0.00, 3.42) | 0 | 0 (0.0) | (0.00, 3.21) | 0 |

Percentages are calculated as (n/N)*100

### Device-Related Adverse Events

Two eyes (both from 1 subject) out of 213 eyes implanted with the Vivity IOL experienced non-serious AEs of photophobia. One eye out of 226 eyes implanted with the Monofocal IOL experienced a serious AE of photopsia, as well as the subsequent SSI of IOL explant.

### Intraoperative Problems

One intraoperative problem was reported during the study: an event of iris damage during second eye implantation with the Vivity IOL. The IOL was successfully implanted and the subject completed the study. Iris Transillumination was noted during the slit-lamp exam for this eye at the 1 Day, 1 Month, and 6 Month visits. However, no other adverse sequelae associated with the iris damage during surgery were reported during the study.

### Contrast Sensitivity

Monocular mesopic contrast sensitivity (with and without glare) was assessed at 6 months for the AcrySof™ IQ Vivity™ IOL and the Monofocal Control IOL. Data were obtained from 107 and 111 subjects in the Vivity and Monofocal Control IOL groups, respectively, using a backlit sine wave grating chart system (CSV1000-HGT, VectorVision, Greenville, OH).

A summary of median contrast sensitivity data is depicted in Table 22. The AcrySof IQ Vivity IOL was associated with a reduction in monocular mesopic contrast sensitivity with and without glare compared to the Monofocal Control IOL, as evidenced by reductions in the median log contrast with increasing spatial frequency test condition (Table 22). Additionally, more patients were unable to see the reference pattern at higher spatial frequencies with the AcrySof IQ Vivity IOL as compared to the Monofocal Control IOL (17.8% vs. 3.6% without glare and 18.7% vs. 4.5% with glare at 6 cpd; and 43.0% vs. 20.7% without glare and 52.3% vs. 25.2% with glare at 12 cpd). For more information, see Warning 4.

**Table 22: Monocular Mesopic Contrast Sensitivity at 6 Months**

| | | | Mesopic Without Glare | | | Mesopic With Glare | | |
|---|---|---|---|---|---|---|---|---|
| | | | | Eyes that did not see the reference pattern[a] | | | Eyes that did not see the reference pattern[a] | |
| Spatial Frequency | IOL Group | N | Median (log units) | n | % | Median (log units) | n | % |
| 1.5 Cycles Per Degree (CPD) | Vivity | 107 | 1.52 | 0 | 0.0 | 1.52 | 0 | 0.0 |
| | Monofocal | 111 | 1.52 | 0 | 0.0 | 1.37 | 1 | 0.9 |
| 3 Cycles Per Degree (CPD) | Vivity | 107 | 1.34 | 0 | 0.0 | 1.34 | 1 | 0.9 |
| | Monofocal | 111 | 1.49 | 1 | 0.9 | 1.49 | 1 | 0.9 |
| 6 Cycles Per Degree (CPD) | Vivity | 107 | 1.38 | 19 | 17.8 | 1.38 | 20 | 18.7 |
| | Monofocal | 111 | 1.55 | 4 | 3.6 | 1.55 | 5 | 4.5 |
| 12 Cycles Per Degree (CPD) | Vivity | 107 | 0.61 | 46 | 43.0 | < 0.61 | 56 | 52.3 |
| | Monofocal | 111 | 0.91 | 23 | 20.7 | 0.91 | 28 | 25.2 |

[a]Number of eyes unable to see a targeted spatial frequency at any available contrast

### Low Contrast Visual Acuity

Monocular (first implanted eye) low contrast visual acuity assessments were performed using 10% and 25% low contrast visual acuity computerized logMAR charts. Best corrected visual acuity at distance (4 m) and distance corrected visual acuity at Intermediate (66 cm) and Near (40 cm) were tested under photopic conditions, with results depicted in Table 23. Differences in mean best corrected distance visual acuity between the 2 groups for both contrast levels were approximately 1 line or less and within the test-retest variability of low contrast visual acuity (Cho 2004). Greater than 1 line improvements in intermediate visual acuity (improvement of 0.132 logMAR and 0.141 logMAR at 10% and 25% contrast respectively) and near visual acuity (improvement of 0.118 logMAR and 0.137 logMAR) were observed for the Vivity IOL over the Monofocal Control IOL at both contrast levels.

**Table 23: Summary of Monocular, Photopic, Low Contrast Distance, Intermediate, and Near VAs by Test Condition and IOL Group**

| Test Condition | IOL Group | Monocular, Photopic, Low Contrast VA (Mean logMAR, Approximate Snellen Line Equivalent) | | |
|---|---|---|---|---|
| | | Distance | Intermediate (66 cm) | Near (40 cm) |
| 10% Contrast | Vivity IOL | 0.393, 20/50 | 0.534, 20/63 | 0.764, 20/125 |
| | Monofocal Control IOL | 0.281, 20/40 | 0.666, 20/100 | 0.882, 20/160 |
| 25% Contrast | Vivity IOL | 0.223, 20/32 | 0.372, 20/50 | 0.593, 20/80 |
| | Monofocal Control IOL | 0.137, 20/25 | 0.513, 20/63 | 0.730, 20/100 |

## Visual Disturbances

A Patient Reported Outcome Measure instrument was developed and validated for use in this clinical study to assess visual disturbances. Subjects who reported experiencing a particular visual disturbance (glare, halos, starbursts, hazy vision, blurred vision, double vision in one or both eyes, color distortion, or peripheral dark area) were asked to rate the severity, frequency, and bothersomeness of the disturbance. A subject may report multiple symptoms. As demonstrated in Tables 24 and 25, rates of reports of severe or very bothersome visual disturbances/distortions were low (< 4%) for the AcrySof™ IQ Vivity™ IOL and the monofocal control IOL (< 3%) groups at 6 months.

**Table 24: Comparison of Visual Disturbance Bothersomeness for AcrySof™ IQ Vivity™ IOL and Monofocal Control IOL 6 months Postoperative (following second eye implantation)**

| | **AcrySof™ IQ Vivity™ IOL N = 106** | | | | | | **Monofocal Control IOL N = 113** | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Visual Disturbance** | **Total** | **Not at all bothered[a] n (%[b])** | **A Little bit n (%[b])** | **Somewhat n (%[b])** | **Quite a bit n (%[b])** | **Very much n (%[b])** | **Total** | **Not at all bothered[a] n (%[b])** | **A Little bit n (%[b])** | **Somewhat n (%[b])** | **Quite a bit n (%[b])** | **Very much n (%[b])** |
| Starbursts | 106 | 78 (73.6) | 15 (14.2) | 10 (9.4) | 1 (0.9) | 2 (1.9) | 110 | 79 (71.8) | 16 (14.5) | 12 (10.9) | 2 (1.8) | 1 (0.9) |
| Halos | 106 | 88 (83.0) | 13 (12.3) | 3 (2.8) | 1 (0.9) | 1 (0.9) | 110 | 98 (89.1) | 6 (5.5) | 5 (4.5) | 1 (0.9) | 0 (0.0) |
| Glare | 105 | 82 (78.1) | 12 (11.4) | 7 (6.7) | 4 (3.8) | 0 (0.0) | 111 | 84 (75.7) | 11 (9.9) | 13 (11.7) | 3 (2.7) | 0 (0.0) |
| Hazy Vision | 105 | 94 (89.5) | 5 (4.8) | 3 (2.9) | 3 (2.9) | 0 (0.0) | 111 | 98 (88.3) | 4 (3.6) | 7 (6.3) | 2 (1.8) | 0 (0.0) |
| Blurred Vision | 106 | 97 (91.5) | 0 (0.0) | 5 (4.7) | 3 (2.8) | 1 (0.9) | 111 | 89 (80.2) | 10 (9.0) | 8 (7.2) | 2 (1.8) | 2 (1.8) |
| Double Vision | 106 | 104 (98.1) | 1 (0.9) | 1 (0.9) | 0 (0.0) | 0 (0.0) | 111 | 110 (99.1) | 0 (0.0) | 1 (0.9) | 0 (0.0) | 0 (0.0) |
| Dark Area *Negative Dysphotopsia* | 106 | 98 (92.5) | 6 (5.7) | 0 (0.0) | 1 (0.9) | 1 (0.9) | 111 | 100 (90.1) | 6 (5.4) | 3 (2.7) | 1 (0.9) | 1 (0.9) |

[a] Includes patients who did not experience the disturbance and those reporting being not at all bothered
[b] Percentages calculated as (n / Total) * 100

**Table 25: Comparison of Visual Disturbance Severity for AcrySof™ IQ Vivity™ IOL and Monofocal Control IOL 6 months Postoperative (following second eye implantation)**

| | AcrySof™ IQ Vivity™ IOL N = 106 | | | | | | Monofocal Control IOL N = 113 | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Visual Disturbance** | **Total** | **None[a] n (%[b])** | **A Little n (%[b])** | **Mild n (%[b])** | **Moderate n (%[b])** | **Severe n (%[b])** | **Total** | **None[a] n (%[b])** | **A Little n (%[b])** | **Mild n (%[b])** | **Moderate n (%[b])** | **Severe n (%[b])** |
| Starbursts | 106 | 70 (66.0) | 3 (2.8) | 15 (14.2) | 14 (13.2) | 4 (3.8) | 110 | 68 (61.8) | 8 (7.3) | 18 (16.4) | 13 (11.8) | 3 (2.7) |
| Halos | 106 | 78 (73.6) | 6 (5.7) | 12 (11.3) | 9 (8.5) | 1 (0.9) | 110 | 91 (82.7) | 5 (4.5) | 9 (8.2) | 4 (3.6) | 1 (0.9) |
| Glare | 105 | 81 (77.1) | 0 (0.0) | 15 (14.3) | 9 (8.6) | 0 (0.0) | 111 | 81 (73.0) | 8 (7.2) | 11 (9.9) | 11 (9.9) | 0 (0.0) |
| Hazy Vision | 105 | 93 (88.6) | 2 (1.9) | 5 (4.8) | 5 (4.8) | 0 (0.0) | 111 | 96 (86.5) | 3 (2.7) | 3 (2.7) | 9 (8.1) | 0 (0.0) |
| Blurred Vision | 106 | 96 (90.6) | 1 (0.9) | 8 (7.5) | 1 (0.9) | 0 (0.0) | 111 | 89 (80.2) | 9 (8.1) | 10 (9.0) | 3 (2.7) | 0 (0.0) |
| Double Vision | 106 | 104 (98.1) | 1 (0.9) | 1 (0.9) | 0 (0.0) | 0 (0.0) | 111 | 110 (99.1) | 0 (0.0) | 1 (0.9) | 0 (0.0) | 0 (0.0) |
| Dark Area *Negative Dysphotopsia* | 106 | 96 (90.6) | 5 (4.7) | 3 (2.8) | 1 (0.9) | 1 (0.9) | 111 | 96 (86.5) | 6 (5.4) | 7 (6.3) | 1 (0.9) | 1 (0.9) |

[a] Includes patients who did not experience the disturbance and those reporting severity of "none"
[b] Percentages calculated as (n / Total) * 100

## 2. AcrySof™ TORIC INTRAOCULAR LENS CLINICAL STUDY OVERVIEW

A multicenter, subject-masked, randomized, prospective clinical study was performed in the United States to evaluate the safety and effectiveness of AcrySof™ Toric IOL (Models SA60T3-SA60T5) when implanted into the capsular bag following phacoemulsification. In this study, the results achieved by the subjects successfully followed for 6 months postoperatively (defined as 120 to 180 days postoperative after the second eye implant) provide reasonable assurance that the AcrySof™ Toric IOL is a safe and effective device for the visual correction of aphakia and pre-existing corneal astigmatism following cataract surgery. The clinical study results (shown below) illustrate excellent rotational stability leading to significant reduction or elimination of residual refractive cylinder and significantly improved uncorrected distance visual acuity, which results in increased distance spectacle independence.

This clinical study was conducted to demonstrate the safety and effectiveness of the AcrySof™ Toric Posterior Chamber IOL Model SA60TT (which is a collective way to refer to Models SA60T3, SA60T4, and SA60T5). This was a randomized clinical study that included the AcrySof™ IOL Model SA60AT as a control lens. Only data from the first operative eye from those subjects who received either a Model SA60TT or Model SA60AT intraocular lens are included. Three different lens models of varying cylinder correction were evaluated in this clinical study. The three different models evaluated and their applicable cylinder powers are listed in Table 26.

**Table 26: IOL Models and Cylinder Power in Clinical Study**

| IOL Model[**] | Cylinder Power | | Recommended Corneal Astigmatism Correction Ranges |
|---|---|---|---|
| | at IOL plane | at corneal plane | |
| SA60T3 | 1.50 | 1.03 | 0.75 - 1.50 D |
| SA60T4 | 2.25 | 1.55 | 1.50 - 2.00 D |
| SA60T5 | 3.00 | 2.06 | 2.00 D & up |

[**]These IOL models are collectively referred to as SA60TT in the text that follows.

The recommended corneal astigmatism correction ranges are based on 1) the preoperative corneal astigmatism and 2) the predicted effect of 0.5 diopter surgically induced astigmatism for a standardized temporal incision. The combination of these two parameters is used in Alcon provided software to select the appropriate Toric IOL model and recommended axis of placement. As such,

the recommended range of corneal astigmatism to be corrected while not identical, is directly related to, the preoperative keratometric cylinder.

## AcrySof™ TORIC INTRAOCULAR LENS CLINICAL STUDY SUBJECT POPULATION

Specific requirements for study participation included (1) ≥0.75 D of preoperative With-the-Rule or preoperative oblique regular corneal astigmatism and (2) ≥1.00 D of preoperative Against-the-Rule regular corneal astigmatism. The subject population implanted with a Model SA60TT in the first operative eye consists of 53.3% females and 46.7% males. The subject population implanted with the Model SA60AT (control) intraocular lens consists of 57.2% females and 42.8% males. Stratifying by race for the Model SA60TT population, 97.6% are Caucasian, 2.0% are Black, and 0.4% are other. The control (SA60AT) population is 95.6% Caucasian, 1.6% Black, 1.2% Asian and 1.6% other. The mean age for the population receiving the Model SA60TT and SA60AT were 70.0 and 72.4, respectively.

## AcrySof™ TORIC INTRAOCULAR LENS UNCORRECTED DISTANCE VISUAL ACUITY (UCDVA)

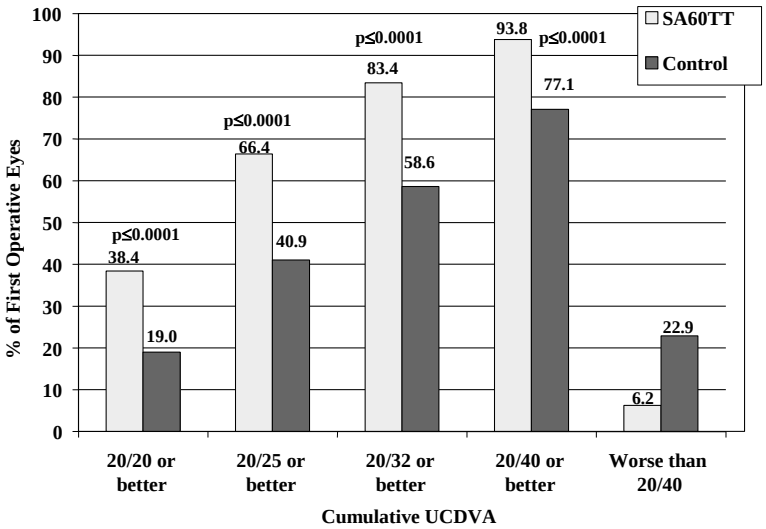
A summary of uncorrected distance visual acuity achieved for Models SA60TT and SA60AT at six months postoperatively (Form 5 visit) is presented in Table 27.

**Table 27: Uncorrected Distance Visual Acuity, Status at Form 5**
**Lens Models SA60TT and SA60AT, All Implanted**

| | Sample size | Acuity | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | 20/20 or better | | 20/25 | | 20/32 | | 20/40 | | Worse than 20/40 | | 20/40 or better | |
| | N | n | % | n | % | n | % | n | % | n | % | n | % |
| Total (SA60TT) | 211 | 81 | 38.4 | 59 | 28.0 | 36 | 17.1 | 22 | 10.4 | 13 | 6.2 | 198 | 93.8 |
| Total (SA60AT) | 210 | 40 | 19.0 | 46 | 21.9 | 37 | 17.6 | 39 | 18.6 | 48 | 22.9 | 162 | 77.1 |

At six months postoperatively (Form 5 visit), shown in Figure 11, 93.8% of Model SA60TT subjects achieved 20/40 or better UCDVA (first operative eye of the All Implanted data set) compared to 77.1% of the subjects implanted with the control Model SA60AT. The difference in UCDVA between Models SA60TT and SA60AT was statistically significant (all p-values ≤0.0001) in favor of Model SA60TT.

**Figure 11: Cumulative UCDVA, Status at Form 5, Model SA60TT vs. Control**



Similar results were noted when data was analyzed by cylinder range (data provided in the Physician Labeling for SN6AT3-SN6AT5):

- The difference in cumulative UCDVA between Models SA60T3 and SA60AT was statistically significant (all p-values ≤0.0115) for each visual acuity category (20/20 or better, 20/25 or better, 20/32 or better and 20/40 or better) in favor of Model SA60T3.
- The difference in cumulative UCDVA between Models SA60T4 and SA60AT was statistically significant (all p-values ≤0.0082) for each visual acuity category (20/25 or better, 20/32 or better and 20/40 or better) in favor of Model SA60T4, with the exception of the 20/20 or better category.
- The difference in cumulative UCDVA between Models SA60T5 and SA60AT was statistically significant (all p-values ≤0.0171) for each visual acuity category (20/20 or better, 20/25 or better, 20/32 or better and 20/40 or better) in favor of Model SA60T5.

**AcrySof™ TORIC IOL BEST SPECTACLE DISTANCE CORRECTED VISUAL ACUITY (BSCDVA)**

A summary of best spectacle corrected distance visual acuity (BSCDVA) achieved at six months postoperatively (Form 5 visit) among subjects who did not have any visually significant preoperative pathology or macular degeneration at any time (Best Case) is presented in Table 28. Visual acuity achieved by the overall subject population is shown in Table 30. Control data are found for the same data sets in Tables 29 and 31, respectively.

Of the first operative eyes implanted with a Model SA60TT and examined at six months postoperatively (Form 5 visit), 100.0% achieved a BSCDVA of 20/40 or better in the Best Case dataset. These rates exceed the FDA grid rates of 96.7%.

**Table 28: BSCDVA by Age Category, Status at Form 5 - Lens Model SA60TT, Best Case**

| Age | Sample size | Acuity | | | | | | | | | | 20/40 or better | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | 20/20 or better | | 20/25 | | 20/32 | | 20/40 | | Worse than 20/40 | | | |
| Category | N | n | % | n | % | n | % | n | % | n | % | n | % |
| <60 | 29 | 27 | 93.1 | 1 | 3.4 | 1 | 3.4 | 0 | 0 | 0 | 0 | 29 | 100.0 |
| 60-69 | 51 | 42 | 82.4 | 7 | 13.7 | 2 | 3.9 | 0 | 0 | 0 | 0 | 51 | 100.0 |
| 70-79 | 73 | 57 | 78.1 | 13 | 17.8 | 3 | 4.1 | 0 | 0 | 0 | 0 | 73 | 100.0 |
| ≥80 | 20 | 14 | 70.0 | 4 | 20.0 | 1 | 5.0 | 1 | 5.0 | 0 | 0 | 20 | 100.0 |
| Total | 173 | 140 | 80.9 | 25 | 14.5 | 7 | 4.0 | 1 | 0.6 | 0 | 0 | 173 | 100.0 |

**Table 29: BSCDVA by Age Category, Status at Form 5 - Lens Model SA60AT, Best Case**

| Age | Sample size | Acuity | | | | | | | | | | 20/40 or better | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | 20/20 or better | | 20/25 | | 20/32 | | 20/40 | | Worse than 20/40 | | | |
| Category | N | n | % | n | % | n | % | n | % | n | % | n | % |
| <60 | 15 | 13 | 86.7 | 1 | 6.7 | 1 | 6.7 | 0 | 0 | 0 | 0 | 15 | 100.0 |
| 60-69 | 49 | 38 | 77.6 | 11 | 22.4 | 0 | 0 | 0 | 0 | 0 | 0 | 49 | 100.0 |
| 70-79 | 75 | 48 | 64.0 | 21 | 28.0 | 6 | 8.0 | 0 | 0 | 0 | 0 | 75 | 100.0 |
| ≥80 | 32 | 19 | 59.4 | 8 | 25.0 | 2 | 6.3 | 3 | 9.4 | 0 | 0 | 32 | 100.0 |
| Total | 171 | 118 | 69.0 | 41 | 24.0 | 9 | 5.3 | 3 | 1.8 | 0 | 0 | 171 | 100.0 |

Of the first operative eyes implanted with a Model SA60TT and examined at six months postoperatively (Form 5 visit), 100.0% achieved a BSCDVA of 20/40 or better in the All Implanted dataset. These rates exceed the FDA grid rates of 92.5%.

### Table 30: BSCDVA by Age Category, Status at Form 5 - Lens Model SA60TT, All Implanted

| Age | Sample size | Acuity | | | | | | | | | | 20/40 or better | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | 20/20 or better | | 20/25 | | 20/32 | | 20/40 | | Worse than 20/40 | | | |
| Category | N | n | % | n | % | n | % | n | % | n | % | n | % |
| <60 | 33 | 30 | 90.9 | 2 | 6.1 | 1 | 3.0 | 0 | 0 | 0 | 0 | 33 | 100.0 |
| 60-69 | 56 | 47 | 83.9 | 7 | 12.5 | 2 | 3.6 | 0 | 0 | 0 | 0 | 56 | 100.0 |
| 70-79 | 90 | 72 | 80.0 | 15 | 16.7 | 3 | 3.3 | 0 | 0 | 0 | 0 | 90 | 100.0 |
| ≥80 | 32 | 22 | 68.8 | 5 | 15.6 | 4 | 12.5 | 1 | 3.1 | 0 | 0 | 32 | 100.0 |
| Total | 211 | 171 | 81.0 | 29 | 13.7 | 10 | 4.7 | 1 | 0.5 | 0 | 0 | 211 | 100.0 |

### Table 31: BSCDVA by Age Category, Status at Form 5 - Lens Model SA60AT, All Implanted

| Age | Sample size | Acuity | | | | | | | | | | 20/40 or better | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | 20/20 or better | | 20/25 | | 20/32 | | 20/40 | | Worse than 20/40 | | | |
| Category | N | n | % | n | % | n | % | n | % | n | % | n | % |
| <60 | 15 | 13 | 86.7 | 1 | 6.7 | 1 | 6.7 | 0 | 0 | 0 | 0 | 15 | 100.0 |
| 60-69 | 54 | 41 | 75.9 | 12 | 22.2 | 1 | 1.9 | 0 | 0 | 0 | 0 | 54 | 100.0 |
| 70-79 | 91 | 59 | 64.8 | 22 | 24.2 | 10 | 11.0 | 0 | 0 | 0 | 0 | 91 | 100.0 |
| ≥80 | 49 | 28 | 57.1 | 13 | 26.5 | 2 | 4.1 | 3 | 6.1 | 3 | 6.1 | 46 | 93.9 |
| Total | 209 | 141 | 67.5 | 48 | 23.0 | 14 | 6.7 | 3 | 1.4 | 3 | 1.4 | 206 | 98.6 |

Figures 12-14 show a summary of cumulative best corrected visual acuities for each Toric model compared to the control subjects in the same cylinder range for the All Implanted dataset.

### Figure 12: Cumulative BSCDVA, Model SA60T3 vs. Control, Form 5, All Implanted

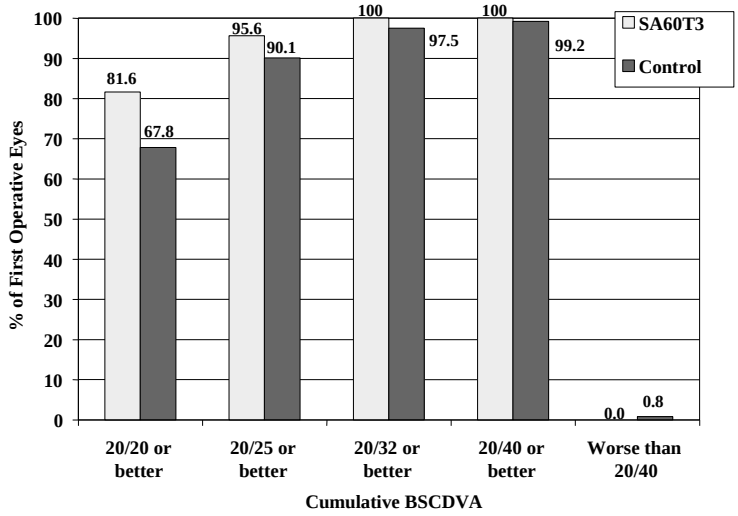


**Figure 13: Cumulative BSCDVA, Model SA60T4 vs. Control, Form 5, All Implanted**

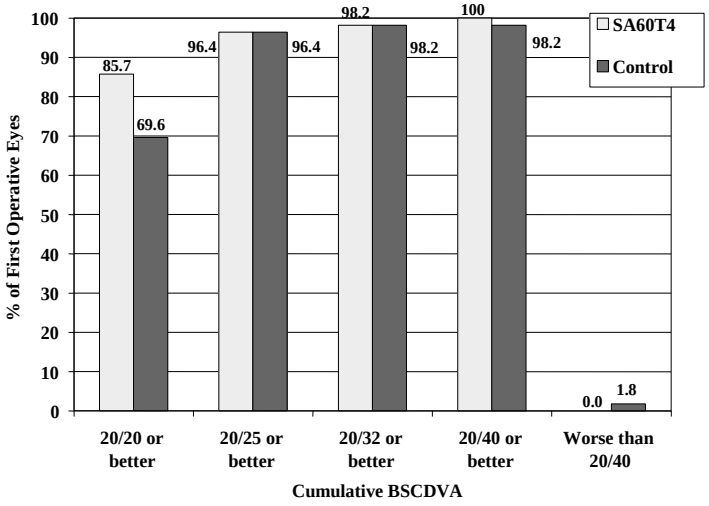
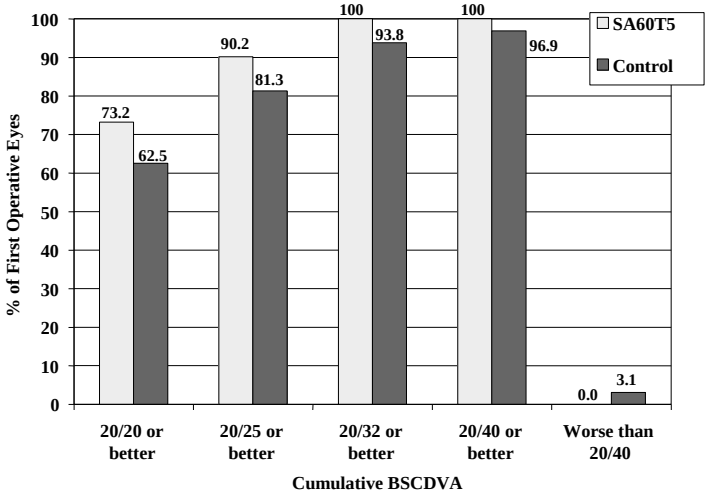



**Figure 14: Cumulative BSCDVA, Model SA60T5 vs. Control, Form 5, All Implanted**




## AcrySof™ TORIC INTRAOCULAR LENS ABSOLUTE RESIDUAL REFRACTIVE CYLINDER

Figures 15-17 demonstrate that residual refractive cylinder values were statistically significantly lower among those subjects implanted with an AcrySof™ Toric IOL Model SA60T3, SA60T4 or SA60T5 when compared to the corresponding subjects implanted with the control Model SA60AT. Subjects implanted with an AcrySof™ Toric Model SA60T3 showed a 62.4% mean reduction in refractive cylinder from the preoperative visit (keratometric cylinder) as compared to the 10.8% mean reduction for subjects implanted with the concurrent control Model SA60AT. Subjects implanted with an AcrySof™ Toric IOL Model SA60T4 or SA60T5 showed similar results with a mean reduction in refractive cylinder of 54.8 % and 67.8%, respectively, as compared to subjects implanted with the concurrent control model who had a mean reduction in refractive cylinder of 22.1% and 27.7%, respectively. Each of the AcrySof™ Toric Lens Models SA60T3, SA60T4 and SA60T5 had at least a 3-fold increase in the likelihood of achieving residual refractive cylinder of 0.5 D or less as compared to the corresponding control model.

**Figure 15: Absolute Residual Refractive Cylinder, Model SA60T3 vs. Control, Form 5, All Implanted**

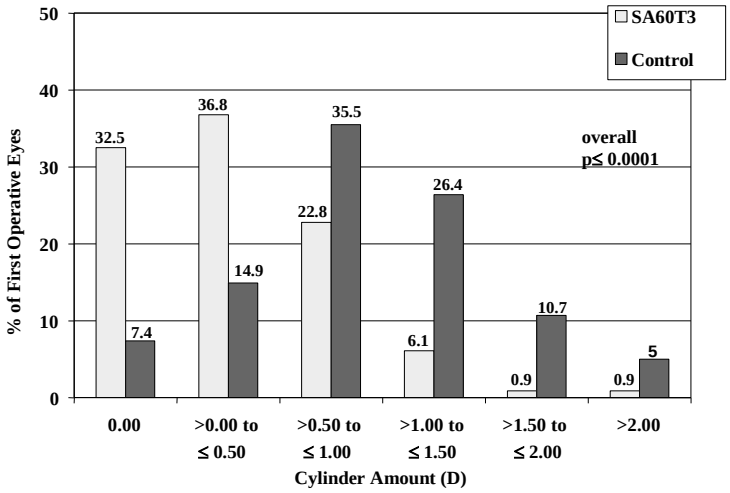



**Figure 16: Absolute Residual Refractive Cylinder, Model SA60T4 vs. Control, Form 5, All Implanted**

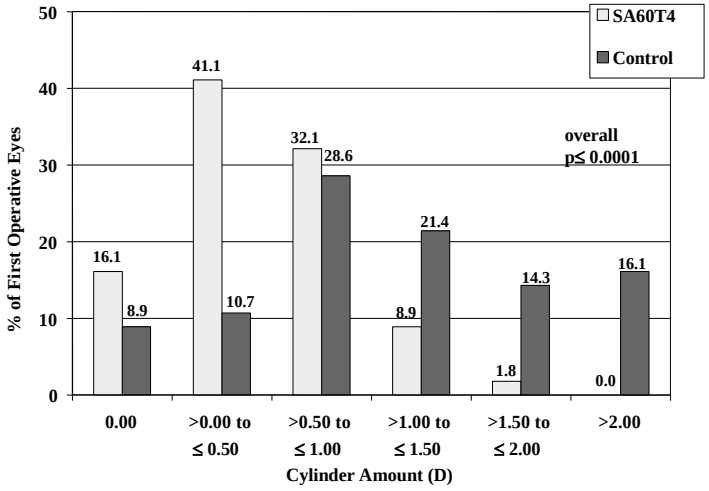
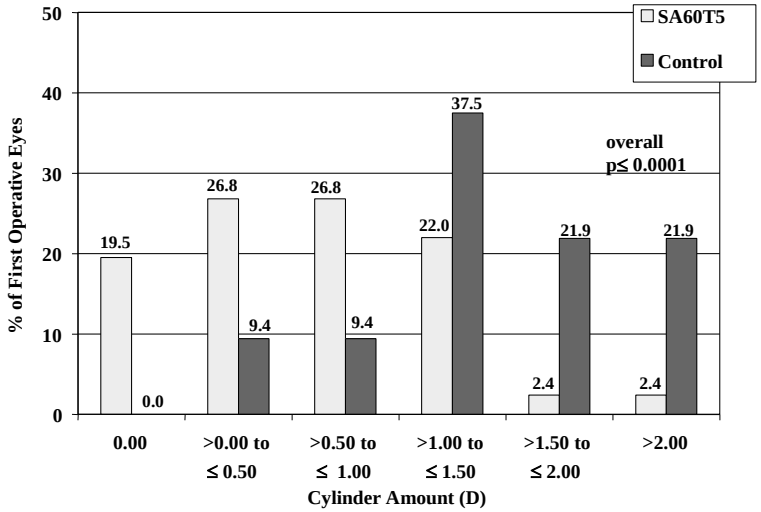


**Figure 17: Absolute Residual Refractive Cylinder, Model SA60T5 vs. Control, Form 5, All Implanted**




## AcrySof™ TORIC INTRAOCULAR LENS STABILITY OF CYLINDER

Subjects implanted with lens Model SA60TT exhibited stability of cylinder at Form 4 (3 months) with greater than 90% of all subjects changing less than or equal to 1.00 diopter at consecutive visits between Form 3 (one month) and Form 6 (twelve months) as described in Tables 32-35.

**Table 32: AcrySof™ Toric IOL: Stability of Cylinder**
**(Eyes that had 2 consecutive exams, but not necessarily every follow-up exam)**

| Recommended Corneal Astigmatism Correction Ranges | Toric IOL Model | Magnitude of Vector Change in Cylinder | 1 and 3 Months n/N,% | 3 and 6 Months n/N,% | 6 and 12 Months n/N,% |
|---|---|---|---|---|---|
| < 1.5 D | SA60T3 | ≤ 1.00 D | 106/107,99.07% | 101/105,96.19% | 55/55,100.00% |
| | | Mean Change | 0.28 | 0.29 | 0.20 |
| | | SD | 0.32 | 0.33 | 0.25 |
| ≥ 1.5 - < 2.0 D | SA60T4 | ≤ 1.00 D | 54/56,96.43% | 53/54,98.15% | 25/27,92.59% |
| | | Mean Change | 0.40 | 0.27 | 0.46 |
| | | SD | 0.35 | 0.22 | 0.45 |
| ≥ 2.0 D | SA60T5 | ≤ 1.00 D | 40/45,88.89% | 35/40,87.50% | 27/30,90.00% |
| | | Mean Change | 0.43 | 0.42 | 0.41 |
| | | SD | 0.44 | 0.45 | 0.38 |
| Combined | SA60TT | ≤ 1.00 D | 200/208,96.15% (93.54,98.77) | 189/199,94.97% (91.94,98.01) | 107/112,95.54% (91.71,99.36) |
| | | Mean Change | 0.35 | 0.31 | 0.32 |
| | | SD | 0.36 | 0.34 | 0.36 |
| | | 95% CI | 0.30,0.39 | 0.26,0.36 | 0.25,0.39 |
| n/N,%,(%CI) are for percent with change between ± 1.00D | | | | | |

## Table 33: AcrySof™ Toric IOL: Stability of Cylinder (Eyes that had every follow-up exam up to Form 6, 12 months)

| Recommended Corneal Astigmatism Correction Ranges | Toric IOL Model | Magnitude of Vector Change in Cylinder | 1 and 3 Months n/N,% | 3 and 6 Months n/N,% | 6 and 12 Months n/N,% |
|---|---|---|---|---|---|
| < 1.5 D | SA60T3 | ≤ 1.00 D | 34/34,100.00% | 34/34,100.00% | 34/34,100.00% |
| | | Mean Change | 0.25 | 0.24 | 0.21 |
| | | SD | 0.23 | 0.22 | 0.24 |
| ≥ 1.5 - < 2.0 D | SA60T4 | ≤ 1.00 D | 17/17,100.00% | 16/17,94.12% | 16/17,94.12% |
| | | Mean Change | 0.27 | 0.25 | 0.35 |
| | | SD | 0.25 | 0.26 | 0.33 |
| ≥ 2.0 D | SA60T5 | ≤ 1.00 D | 17/19,89.47% | 15/19,78.95% | 16/19,84.21% |
| | | Mean Change | 0.44 | 0.56 | 0.52 |
| | | SD | 0.47 | 0.50 | 0.43 |
| Combined | SA60TT | ≤ 1.00 D | 68/70,97.14% (93.23,100.00) | 65/70,92.86% (86.82,98.90) | 66/70,94.29% (88.84,99.73) |
| | | Mean Change | 0.31 | 0.33 | 0.33 |
| | | SD | 0.32 | 0.35 | 0.34 |
| | | 95% CI | 0.23,0.38 | 0.24,0.41 | 0.25,0.41 |
| n/N,%,(%CI) are for percent with change between ± 1.00D | | | | | |

## Table 34: AcrySof™ Toric IOL: Stability of Absolute Cylinder (Eyes that had 2 consecutive exams, but not necessarily every follow-up exam)

| Recommended Corneal Astigmatism Correction Ranges | Toric IOL Model | Magnitude of Change in Absolute Cylinder | 1 and 3 Months n/N,% | 3 and 6 Months n/N,% | 6 and 12 Months n/N,% |
|---|---|---|---|---|---|
| < 1.5 D | SA60T3 | ≤ 1.00 D | 107/107,100.00% | 104/105,99.05% | 55/55,100.00% |
| | | Mean Change | 0.04 | 0.02 | 0.05 |
| | | SD | 0.32 | 0.38 | 0.29 |
| ≥ 1.5 - < 2.0 D | SA60T4 | ≤ 1.00 D | 54/56,96.43% | 54/54,100.00% | 27/27,100.00% |
| | | Mean Change | 0.18 | 0.05 | -0.12 |
| | | SD | 0.42 | 0.27 | 0.41 |
| ≥ 2.0 D | SA60T5 | ≤ 1.00 D | 44/45,97.78% | 37/40,92.50% | 29/30,96.67% |
| | | Mean Change | 0.09 | 0.06 | 0.00 |
| | | SD | 0.38 | 0.49 | 0.45 |
| Combined | SA60TT | ≤ 1.00 D | 205/208,98.56% (96.93,100.00) | 195/199,97.99% (96.04,99.94) | 111/112,99.11% (97.36,100.00) |
| | | Mean Change | 0.09 | 0.03 | -0.01 |
| | | SD | 0.37 | 0.38 | 0.37 |
| | | 95% CI | 0.04,0.14 | -0.02,0.09 | -0.08,0.06 |
| n/N,%,(%CI) are for percent with change between ± 1.00D | | | | | |

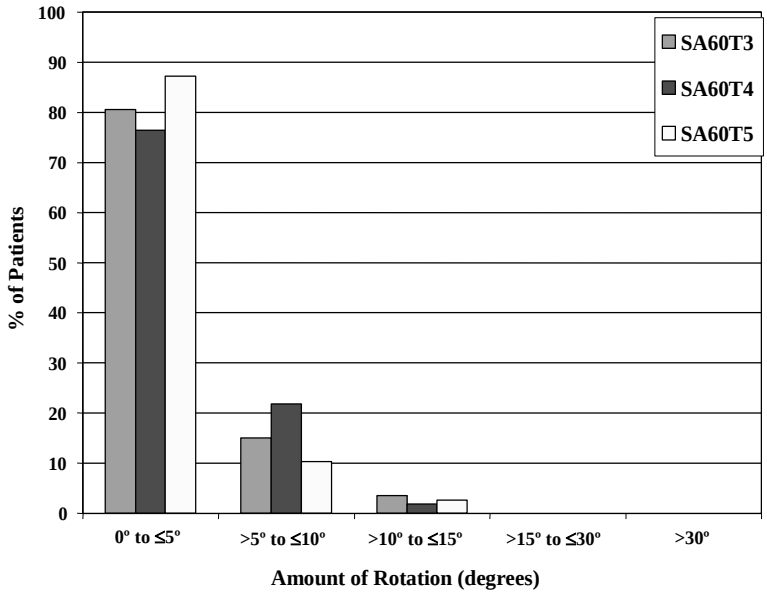
**Table 35: AcrySof™ Toric IOL: Stability of Absolute Cylinder (Eyes that had every follow-up exam up to Form 6, 12 months)**

| Recommended Corneal Astigmatism Correction Ranges | Toric IOL Model | Magnitude of Change in Absolute Cylinder | 1 and 3 Months n/N,% | 3 and 6 Months n/N,% | 6 and 12 Months n/N,% |
|---|---|---|---|---|---|
| < 1.5 D | SA60T3 | ≤ 1.00 D | 34/34,100.00% | 34/34,100.00% | 34/34,100.00% |
| | | Mean Change | 0.01 | -0.01 | 0.07 |
| | | SD | 0.28 | 0.31 | 0.28 |
| ≥ 1.5 - < 2.0 D | SA60T4 | ≤ 1.00 D | 17/17,100.00% | 17/17,100.00% | 17/17,100.00% |
| | | Mean Change | 0.06 | 0.19 | -0.04 |
| | | SD | 0.30 | 0.21 | 0.42 |
| ≥ 2.0 D | SA60T5 | ≤ 1.00 D | 18/19,94.74% | 17/19,89.47% | 18/19,94.74% |
| | | Mean Change | 0.17 | 0.05 | 0.01 |
| | | SD | 0.45 | 0.54 | 0.55 |
| Combined | SA60TT | ≤ 1.00 D | 69/70,98.57% (95.78,100.00) | 68/70,97.14% (93.23,100.00) | 69/70,98.57% (95.78,100.00) |
| | | Mean Change | 0.07 | 0.05 | 0.03 |
| | | SD | 0.34 | 0.38 | 0.40 |
| | | 95% CI | -0.01,0.15 | -0.04,0.14 | -0.07,0.12 |
| n/N,%,(%CI) are for percent with change between ± 1.00D | | | | | |

## AcrySof™ TORIC INTRAOCULAR LENS ROTATIONAL STABILITY

A summary of the change in axis orientation (rotation) from the operative visit to the Form 5 visit (120-180 days postoperative) is presented in Figure 18. The rotational stability of the AcrySof™ Toric Model SA60TT is established with the majority of the lenses rotating ≤ 5°. In addition, the amount of rotation seen in each AcrySof™ Toric IOL model is independent of the amount of cylinder power present on the lens.

**Figure 18: Change in Axis Orientation from Operative Visit to Form 5, All Implanted**



## AcrySof™ TORIC INTRAOCULAR LENS ADVERSE EVENTS

The incidence of cumulative adverse events for the Model SA60TT compared favorably to the FDA historical grid rates. Only the rates for retinal detachment/repair and surgical reintervention exceeded the FDA historical grid (Table 36). However, neither of these rates were statistically significant (p=0.5196 and p=0.1336, respectively). No occurrences of persistent adverse events were observed in any subjects implanted with the AcrySof™ Toric IOL.

**Table 36: Adverse Events Incidence Rates, First Eye – Safety**

| | Model SA60TT N=244 | | FDA Grid Rate |
|---|---|---|---|
| **Cumulative Adverse Events** | **N** | **%** | **%** |
| Retinal Detachment/Repair | 1 | 0.4 | 0.3 |
| Surgical Reintervention | 4** | 1.6 | 0.8 |
| IOL Reposition Due to Rotation | 1 | 0.4 | NA |
| IOL Replacement Due to Rotation | 1 | 0.4 | NA |
| Laser Treatment | 2 | 0.8 | NA |
| Paracentesis | 1 | 0.4 | NA |

The incidence rates in this table are based upon the number of eyes with an event divided by the number of eyes implanted.
Cumulative adverse events are those events that have occurred at any time during the clinical study.
FDA Grid Rate = FDA Grid of Adverse Events with Posterior Chamber Intraocular Lens Historical Controls, FDA Intraocular Lens Guidance Document, Annex B (October 14, 1999)
**There were 5 occurrences of surgical reintervention in 4 eyes for Model SA60TT first eye

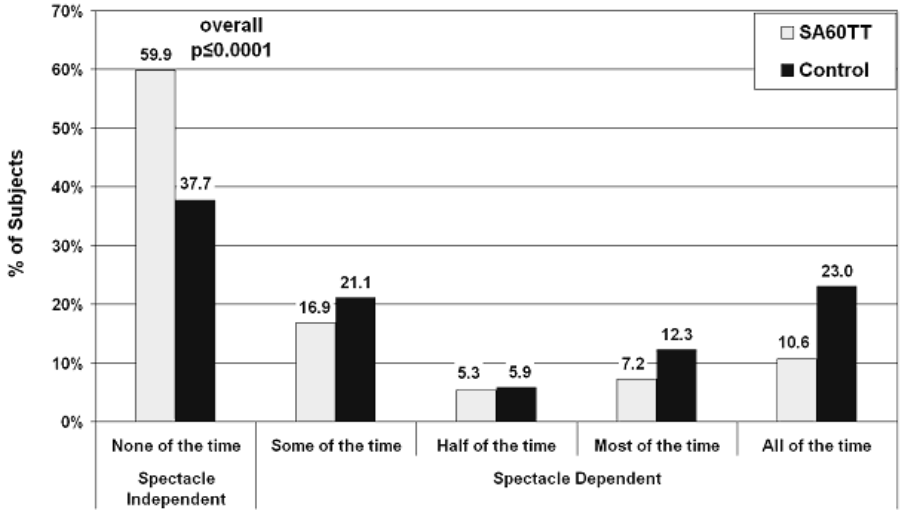
The incidence of cumulative adverse events for the Model SA60TT also compared favorably to the concurrent control.

## AcrySof™ TORIC INTRAOCULAR LENS DISTANCE-VISION SPECTACLE INDEPENDENCE

Spectacle independence was assessed in the study by direct subject responses obtained from a self-reported, binocular subject questionnaire. Since the AcrySof™ Toric IOL study was completed in 2005, the questionnaire utilized was not developed using the US FDA guidance document "*Patient-Reported Outcomes Measures: Use in Medical Product Development to Support Labeling Claims"* dated December 2009.

Statistically significantly more Model SA60TT subjects reported postoperative distance-vision spectacle independence compared to Model SA60AT subjects (59.9% versus 37.7%, respectively) when unilaterally implanted. Distance-vision spectacle independence was defined as the percentage of subjects who selected the "none of the time" response for distance-vision frequency-of-spectacle-wear. Spectacle dependence was defined as subjects indicating any reliance on glasses for distance-vision and represents the summation of the "some of the time", "half of the time", "most of the time" and "all of the time" frequency-of-spectacle-wear responses. Consequently, fewer Model SA60TT subjects were spectacle dependent at 40.1% compared to 62.3% of the Model SA60AT subjects. Figure 19 illustrates the distance-vision frequency-of-spectacle-wear distributions between Model SA60TT and Model SA60AT groups. Implantation of an AcrySof™ Toric Intraocular lens in astigmatic subjects provides significantly improved distance-vision spectacle independence relative to a conventional monofocal IOL.

**Figure 19: Distance-Vision Spectacle Independence: Frequency of Spectacle Wear, Form 5, All Implanted**




## 3. OVERVIEW OF AcrySof™ SINGLE-PIECE LENS STUDIES

### CLINICAL STUDY WITH AcrySof™ Natural SINGLE-PIECE IOL MODEL SB30AL

A clinical study was conducted on subjects receiving the AcrySof™ Natural Single Piece IOL (Model SB30AL) as compared to the AcrySof™ UV Single Piece IOL (Model SA30AL) as a control lens. The results achieved by the subjects successfully followed for a minimum of one year postoperatively provided reasonable assurance of safety and effectiveness for the visual correction of aphakia. For information pertaining to the comprehensive results obtained in this clinical study, please reference the Physician Labeling for any AcrySof™ Natural monofocal IOL.

### 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 an AcrySof™ 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 an AcrySof™ 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 AcrySof™ Model SB30AL and AcrySof™ 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 subjects with normal color vision.

### REFERENCES

Abulafia A, Barrett GD, Kleinmann G, Ofir S, Levy A, Marcovich AL, *et al*. Prediction of refractive outcome with toric intraocular lens implantation. *J Cataract Refractive Surgery*. 2015; 41:936–944.

Abulafia A, Hill WE, Franchina M, Barrett GD. Comparison of methods to predict residual astigmatism after intraocular lens implantation. *J Refractive Surgery*. 2015b; 31(10):699-706.

Boettner, E.A. and Wolter, J.R. Transmission of the ocular media. Invest. Ophthalmol. 1962;1:776-83.

Cho P, Woo GC. Opthalmic Physiol Opt. 2004; 24(5): 427-35.

Hoffer KJ. The Hoffer Q formula: a comparison of theoretic and regression formulas. J Cataract Refract Surg. 1993;19(6):700-12.

Holladay JT. Standardizing constants for ultrasonic biometry, keratometry, and intraocular lens power calculations. J Cataract Refract Surg. 1997;23(9):1356-70.

Olsen T. Calculation of intraocular lens power: a review. Acta Ophthalmol Scand. 2007;85(5):472-85.

Retzlaff JA, Sanders DR, Kraff M. Lens Implant Power Calculation. 3rd ed. Thorofare (NJ): Slack, Inc.; 1990.

Haigis W. ULIB - User group for Laser Interference Biometry. Updated 2014 Jul 17; cited 2015 Mar 13. Available at: http://ocusoft.de/ulib/.

## STAND ALONE SYMBOLS FROM ISO 7000/ ISO 7001‡ USED ON LABELING
## (ISO 7000/IEC 60417 Title: Graphical Symbols for Use on Equipment)
## (‡ISO 7001 Title: Graphical symbols – Public information symbols)

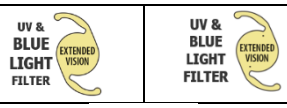
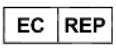
| Symbol | Reference Number from ISO 7000 / IEC 60417* / ISO 7001* | Symbol Title / Explanatory Text |
|---|---|---|
|  | 1051 | Do not re-use |
|  | 2608 | Do not resterilize |
|  | 2607 | Use-by date |
|   | 2501 | Sterilized using ethylene oxide |
|   | 2498 | Serial number |
|   | 2493 | Catalogue number |
|  | 0434A | Caution |
|  | 3082 | Manufacturer |
|   | 0632 | Temperature Limit |
|  | 1641 | Consult instructions for use |
|  | 2606 | Do not use if package has been damaged |
|  | 2497 | Date of Manufacture |
|  | 3079 | Open Here |
|   | 3010 | RFID tag, general |
|   | 6050* | Model number |
|   | 6049* | Country of manufacture |
|   | 5662* | Date |
|  | 5664* | Patient identification |
|  | PI PF 044‡ | Health care centre or doctor |
|  | PI PF 002‡ | Hospital |

‡This symbol is from ISO 7001.
*This symbol is from IEC 60417.

## STAND ALONE SYMBOL FROM ASTM F2503-13 USED ON LABELING
## (Title: Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment)

| Symbol | Reference Number from ASTM F2503-13 | Symbol Title / Explanatory Text |
|---|---|---|
|  | N/A | MR (magnetic resonance) safe |

## ABBREVIATIONS or SYMBOLS USED ON LABELING

| Symbol | Symbol Title / Explanatory Text |
|---|---|
| IOL | Intraocular lens |
|  | Single sterile barrier system |
|  | Medical device |
|  | Unique device identifier |
|  | Patient information website |
|  | UV and Blue Light Filter with Wavefront-Shaping technology (i.e. Extended Vision) |
|  | Posterior chamber |
| UV | Ultraviolet |
| D | Diopter |
| CYL | Cylinder power |
| $Ø_B$ | Body diameter (Optic diameter) |
| $Ø_T$ | Overall diameter (Overall length) |
| L | Left |
| R | Right |
| PWR | Spherical equivalent power |
|  | D-size nozzle for MONARCH® Delivery System cartridge |
|  | Not made with natural rubber latex |
|  | Does not contain PHT (phthalates) |
|  | MR Safe |
|  | Caution: Federal (USA) Law restricts this device to sale by or on the order of a physician |
|  | Authorized Representative in the European Community |

Manufacturer:
Alcon Laboratories, Inc.
6201 South Freeway
Fort Worth, Texas 76134-2099 USA



Alcon

**Directions for Use**

XX-XXX-XXX <insert commodity number>

## PRODUCT INFORMATION

Alcon Laboratories, Inc.

## AcrySof™ IQ Vivity™ Extended Vision UV Absorbing Intraocular Lenses (IOLs)
## Models: DAT015, DAT315, DAT415, DAT515

### DESCRIPTION

The non-diffractive AcrySof™ IQ Vivity™ Extended Vision **UV Absorbing** Posterior Chamber Intraocular Lenses (IOLs) Model DAT015 and Toric Models DAT315, DAT415, and DAT515 are UV-absorbing foldable intraocular lenses (IOLs) which, compared to a monofocal IOL, provide an extended range of vision from distance to near while maintaining a low incidence of visual disturbances. The AcrySof™ IQ Vivity™ Toric Extended Vision **UV Absorbing** IOL models also compensate for corneal astigmatism.

The biconvex 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 its optical performance. The supporting haptics provide proper positioning and fixation of the IOL optic within the eye.

The depth of field extension is achieved through the patented Wavefront-Shaping technology located on the anterior surface of the IOL. The location of the Wavefront-Shaping optic is identical for all lens powers. The anterior surface of the AcrySof™ IQ Vivity™ Extended Vision **UV Absorbing** IOL is designed with negative spherical aberration to compensate for the positive spherical aberration of the cornea. The posterior surface of the Toric lens is biconic creating a toricity to correct the astigmatism on the cornea. The flat meridian of the AcrySof™ IQ Vivity™ Toric **UV Absorbing** IOLs is identified with indentations (dots) on the posterior surface of the optic. The physical characteristics of the Vivity™ IOL are summarized in Figures 1, 2 and 3 and Table 1. The modulation transfer function (MTF) through-focus response of a Vivity IOL in a model eye using polychromatic light (white light) is depicted in Figure 4.

**Figure 1: Physical Characteristics of AcrySof™ IQ Vivity™ UV Absorbing IOL**
(All dimensions in millimeters)

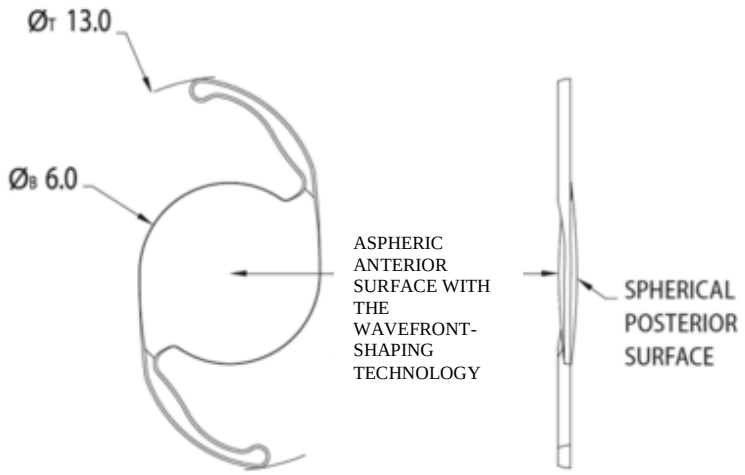



**Figure 2: Physical Characteristics of AcrySof™ IQ Vivity™ Toric UV Absorbing IOLs**
(All dimensions in millimeters)

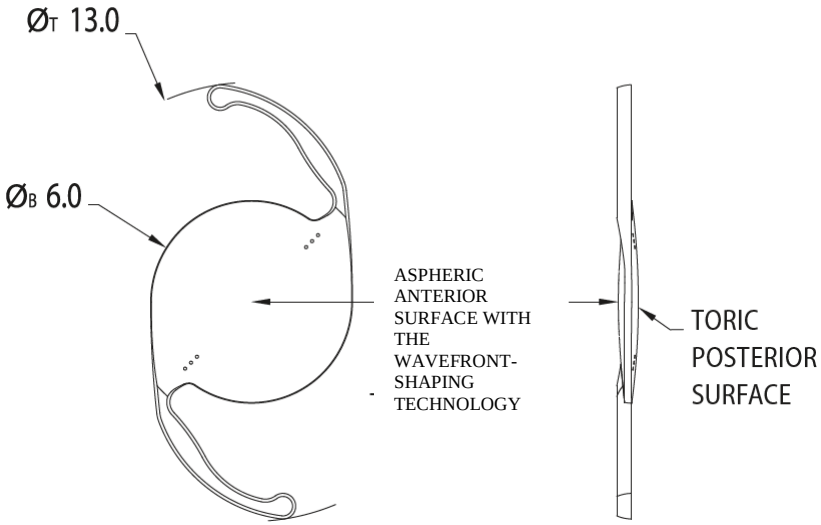
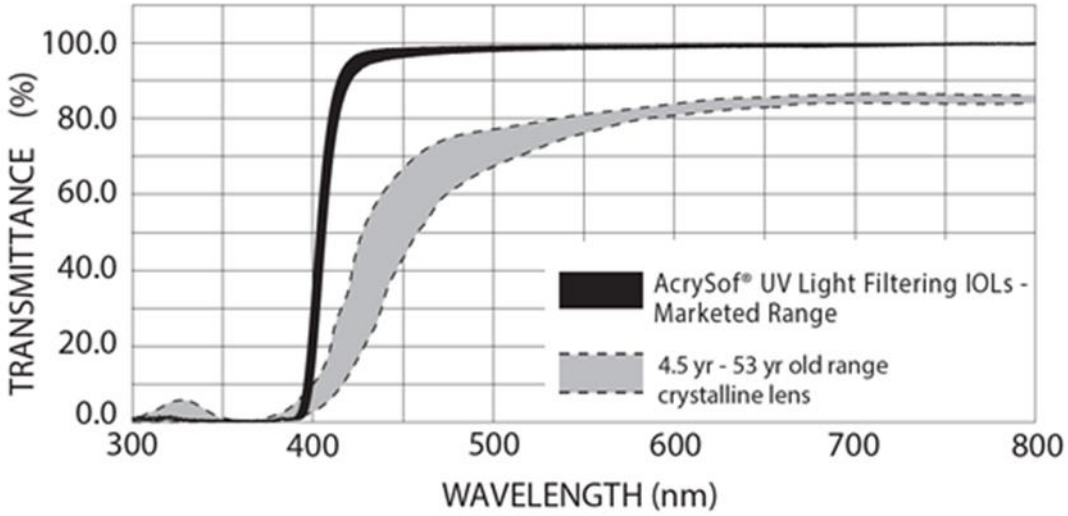


**Table 1: Physical Characteristics of AcrySof™ IQ Vivity™ UV Absorbing IOL**

| Characteristics | Model | | | |
|---|---|---|---|---|
| | DAT015 | DAT315 | DAT415 | DAT515 |
| Optic Type | Biconvex Wavefront-Shaping Optic | Biconvex Toric Wavefront-Shaping Optic | | |
| Optic / Haptic Material | Ultraviolet filtering hydrophobic Acrylate/Methacrylate Copolymer<br>UV cutoff at 10% T: 396 nm (+20.0 diopter lens) | | | |
| Spherical Powers | +15.0 diopters – +25.0 diopters in 0.5 diopter increments | | | |
| IOL Cylinder Powers – IOL Plane (Diopters) | N/A | 1.50 | 2.25 | 3.00 |
| IOL Cylinder Powers – Corneal Plane* (Diopters) | N/A | 1.03 | 1.55 | 2.06 |
| Index Of Refraction | 1.55 | | | |
| Haptic Configuration | STABLEFORCE® Modified-L Haptics | | | |
| Optic Diameter (mm) $Ø_B$ | 6.0 | | | |
| Overall Length (mm) $Ø_T$ | 13.0 | | | |
| Haptic Angle | 0º | | | |

*Based on the average pseudophakic human eye

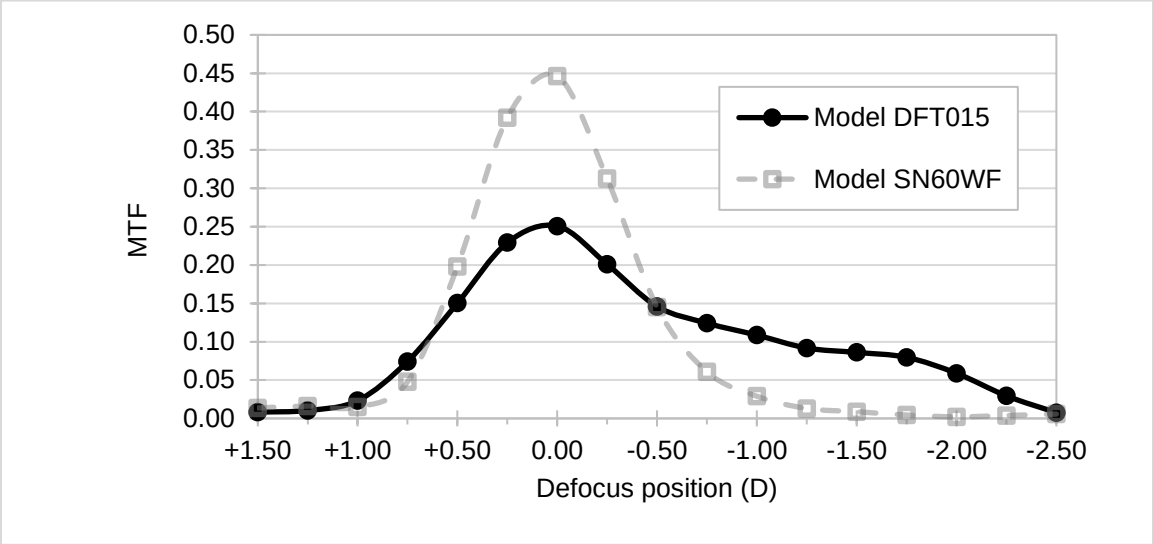
**Figure 3: Spectral Transmittance**




**NOTES:**

1. The cutoff wavelength and the spectral transmittance curves presented here represent the range of transmittance values of IOLs made from hydrophobic acrylate/methacrylate copolymer with bonded UV-absorber.
2. Measurements were by direct transmittance using AcrySof™ IOLs (UV light filtering IOLs) with center thickness equivalent to the marketed range.
3. Human crystalline lens data is from Boettner and Wolter (1962).

**Figure 4: Modulation Transfer Function (MTF) Through-Focus Response of 20.0 D IOLs in a Model Eye (White Light, 50 lp/mm, 3 mm Aperture)**




## INDICATIONS

The AcrySof™ IQ Vivity™ Extended Vision UV Absorbing IOL Model DAT015 is indicated for primary implantation for the visual correction of aphakia in adult patients with < 1.00 D of preoperative corneal astigmatism, in whom a cataractous lens has been removed by extracapsular cataract extraction. The lens mitigates the effects of presbyopia by providing an extended depth of focus. Compared to an aspheric monofocal IOL, the lens provides improved intermediate and near visual acuity, while maintaining comparable distance visual acuity. The AcrySof™ IQ Vivity™ UV Absorbing IOL is intended for capsular bag placement only.

The AcrySof™ IQ Vivity™ Toric Extended Vision UV Absorbing IOL Models DAT315, DAT415, and DAT515 are indicated for primary implantation for the visual correction of aphakia and for reduction of residual refractive astigmatism in adult patients with pre-existing corneal astigmatism, in whom a cataractous lens has been removed by extracapsular cataract extraction. The lenses mitigate the effects of presbyopia by providing an extended depth of focus. Compared to an aspheric monofocal IOL, the lenses provide improved intermediate and near visual acuity, while maintaining comparable distance visual acuity. The AcrySof™ IQ Vivity™ Toric UV Absorbing IOLs are intended for capsular bag placement only.

## IOL IMPLANTATION

During standard cataract surgery and implantation of the AcrySof™ IQ Vivity™ UV Absorbing IOL, an Alcon qualified delivery system and viscoelastic combination should be used. The use of an unqualified combination may cause damage to the lens and potential complications during the implantation process. Alcon recommends using the qualified MONARCH® IOL Delivery System or any other Alcon qualified combination. Currently qualified combinations that can be used with these lenses are listed in Table 2; contact Alcon for further information on qualified combinations.

**Table 2: Qualified Combinations of Compatible Products**

| Lens Model | Diopter Range | Cartridge | Handpiece | Ophthalmic Viscosurgical Device (OVD) |
|---|---|---|---|---|
| **DAT015**<br>**DAT315**<br>**DAT415**<br>**DAT515** | +15.0 to +25.0 | MONARCH™ III D (8065977763) | MONARCH™ III (blue) (8065977773) | VISCOAT™ OVD |
| | | | | PROVISC™ OVD |
| | | | | DISCOVISC™ OVD |

Contact Alcon for any additional Alcon qualified OVDs, handpieces, and cartridges for use with this lens.

See “DIRECTIONS FOR USE” for implantation instructions for the AcrySof™ IQ Vivity™ UV Absorbing IOLs, which are similar to those of Alcon’s AcrySof™ IQ monofocal IOLs.

## CALCULATION OF LENS POWER

Accurate biometry is essential for successful visual outcomes. Preoperative calculation of required lens power for the AcrySof™ IQ Vivity™ UV Absorbing IOLs should be determined by the surgeon's experience and preference. A reference SRK/T A-Constant value for optical biometry equipment such as IOLMaster** or LenStar** as well as *contact* ultrasound biometry is listed on the outer label. The reference optical A-Constant anticipates the use of both corneal power and axial length values from optical biometry or contact ultrasound equipment with standard settings for a typical patient population and a spectacle far point at 6 meters.

In general, lens constants must be “personalized” to compensate for such things as differences in instrumentation, surgical techniques, and IOL power calculation that may exist between clinical practice. IOL power calculation methods are often included with biometry equipment, and they are also described in the references (Hoffer 1993; Holladay 1997; Olsen 2007; Retzlaff, Sanders & Kraff 1990; Haigis 2014).

**IOLMaster is a trademark of Carl Zeiss; LenStar is a trademark of HAAG-STREIT.

## CONTRAINDICATIONS

There are no known contraindications to the use of the AcrySof IQ Vivity IOLs when used as recommended.

## 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 the AcrySof™ IQ Vivity™ Toric UV Absorbing IOL away from its intended axis can reduce the astigmatic correction. Misalignment greater than 30° 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. 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. Residual viscoelastic may allow the lens to rotate causing misalignment of the AcrySof™ IQ Vivity™ Toric UV Absorbing IOL with the intended axis of placement.
4. Most patients implanted with the Vivity IOL are likely to experience significant loss of contrast sensitivity as compared to a monofocal IOL. Therefore, it is essential that prospective patients be fully informed of this risk before giving their consent for implantation of the Vivity IOL. In addition, patients should be warned that they will need to exercise caution when engaging in activities that require good vision in dimly lit environments, such as driving at night or in poor visibility conditions, especially in the presence of oncoming traffic.

## PRECAUTIONS

1. Prior to surgery, prospective patients should be informed of the possible risks and benefits of the AcrySof™ IQ Vivity™ UV Absorbing IOL Models DAT015, DAT315, DAT415, and DAT515. A patient information brochure can be found in the labeling information section under the link to Products at https://ifu.alcon.com. Please provide a copy of the patient information brochure to the patient.
2. The safety and effectiveness of this IOL have not been studied in patients with certain pre-existing conditions and/or intraoperative conditions (listed in Tables 3 and 4) as these

patients were excluded from the clinical studies. Patients with pre-existing conditions may not achieve the visual acuity of patients without such conditions. As with the implantation of any IOL, 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.

3. 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: lens epithelial cell on-growth, corneal endothelial damage, infection (endophthalmitis), retinal detachment, vitritis, cystoid macular edema, corneal edema, pupillary block, cyclitic membrane, iris prolapse, hypopyon, anterior uveitis, hyphema, pigment dispersion, posterior capsule opacification, transient or persistent glaucoma, residual refractive error resulting in secondary surgical intervention, and other secondary surgical interventions. 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.
4. It is possible to experience very bothersome visual disturbances, significant enough that the patient could request explant of the IOL. In the Vivity clinical study, 1% to 2% of Vivity patients reported very bothersome starbursts, halos, blurred vision, or dark area visual disturbances; however, no explants were reported.
5. Accurate keratometry and biometry in addition to the use of the Toric Calculator for the AcrySof™ IQ Vivity™ Toric UV Absorbing IOL models (http://www.myalcon-toriccalc.com) are recommended to achieve optimal visual outcomes.
6. Autorefractors may not provide optimal postoperative refraction of patients with AcrySof™ IQ Vivity™ Toric UV Absorbing IOLs. Manual refraction with maximum plus technique is strongly recommended.
7. Clinical data supporting the use of these IOLs were collected with the lens implanted in the capsular bag only. There are no clinical data to demonstrate safety or effectiveness for placement in the ciliary sulcus.
8. Do not re-sterilize these IOLs by any method (see RETURNED GOODS POLICY).
9. Do not store these IOLs at temperatures over 45°C (113°F).
10. Handle lenses carefully to avoid damage to lens surfaces or haptics.
11. Do not attempt to reshape haptics in any way.
12. DO NOT implant the IOL if the sterility has been compromised or if the sterile package has been unintentionally opened before use.

**Table 3: Preexisting Conditions with No Safety and Effectiveness Data**

| | |
|---|---|
| • Clinically severe corneal dystrophy (e.g., epithelial, stromal, or endothelial dystrophy), corneal irregularity (including irregularity due to dry eye syndrome), keratitis, keratoconjunctivitis, keratouveitis, keratopathy, or kerectasia<br>• Irregular corneal astigmatism<br>• Subjects with any ocular disease or pathology, other than cataract, that are predicted to cause future acuity losses to a level worse than 0.20 logMAR<br>• Any inflammation or edema of the cornea<br>• Significant irregular corneal aberration<br>• Previous corneal transplant<br>• Aniridia<br>• Iris neovascularization<br>• Uncontrolled glaucoma<br>• Rubella, congenital, traumatic, or complicated cataracts | • Amblyopia<br>• Pre-existing ocular conditions which may negatively impact stability of the implant (e.g., diagnosis of pseudoexfoliation syndrome)<br>• Color vision deficiencies<br>• Microphthalmos<br>• Previous refractive surgery<br>• Current or previous usage of alpha-1-selective adrenoceptor blocking agent or antagonist of alpha 1A adrenoceptor [e.g., Flomax† (tamsulosin HCL), Hytrin†, or Cardura†]<br>• Pregnancy |

| | |
|---|---|
| • Extremely shallow anterior chamber, not due to swollen cataract<br>• Choroidal hemorrhage<br>• Previous retinal detachment<br>• Diabetic retinopathy<br>• Optic nerve atrophy<br>• Recurrent anterior or posterior segment inflammation. | |

**Table 4: Intraoperative Conditions with No Safety and Effectiveness Data**

| | |
|---|---|
| • Other planned ocular surgery procedures, including but not limited to, LASIK, astigmatic keratotomy, and limbal relaxing incisions<br>• Excessive iris mobility or floppy iris syndrome<br>• Mechanical or surgical manipulation required to enlarge the pupil | • Vitreous loss (significant)<br>• Anterior chamber bleeding (significant)<br>• Complications in which the IOL stability could be compromised, including but not limited to zonular dehiscence or capsulorhexis rupture<br>• Uncontrollable IOP |

13. When binocular implantation of the AcrySof™ IQ Vivity™ UV Absorbing IOL is planned, both eyes of a subject are not intended to be operated on the same day. Simultaneous binocular implantation has not been studied.
14. A high level of surgical skill is required for any 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.
15. The AcrySof IQ Vivity Toric IOLs have not been evaluated in a clinical study. However, clinical results for the parent Toric IOL (AcrySof IQ Toric) are presented in the clinical study section. As with other premium IOLs, patients with large levels of residual astigmatism may need spectacle correction to achieve satisfactory visual acuity.

**SELECTION OF TORIC IOL**

For selection of the appropriate toric IOL, Alcon provides a web-based tool (www.myalcon-toriccalc.com, Abulafia, Barrett, et al. 2015 and Abulafia, Hill, et al. 2015) that uses pre-operative biometry data, incision location, and surgically induced corneal astigmatism. The astigmatism to be corrected should be determined from 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. Pre-operative keratometry and biometry data, incision location, and the surgeon's estimated surgically induced corneal astigmatism are used to determine the appropriate AcrySof IQ Vivity Toric IOL model, spherical equivalent lens power, and axis of placement in the eye.

**AXIS PLACEMENT OF TORIC IOL**

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 toric IOL optic. These indentations form an imaginary line representing the plus cylinder axis (note: IOL cylinder steep meridian is 90º away). The cylinder axis marks should be aligned with the post-incision steep corneal meridian (intended axis of placement) or as determined by the web-based IOL calculator.

Prior to surgery, the lens placement axis should be marked. One way used in clinical practice to mark the eye is as follows: With the patient sitting upright to prevent cyclotorsion, clearly and precisely mark two reference positions with a surgical skin marker or a marking pencil indicated for ophthalmic use. Using these marks as reference points, an axis marker can be used immediately

prior to or during surgery to mark the optimal axis of lens placement identified by the web-based IOL calculator (www.myalcon-toriccalc.com).

Precisely align the axis marking indentations on the toric IOL with the marked intended axis of lens placement. Remove all viscoelastic from both the anterior and posterior sides of the lens since residual viscoelastic may allow the lens to rotate causing misalignment of the toric IOL with the intended axis of placement. This may be accomplished by manipulating the IOL optic with the I/A tip and using standard irrigation/aspiration techniques to remove all viscoelastic from the eye. Bimanual techniques may be used, if preferred, to ensure removal of viscoelastic from behind the lens implant. Special care should be taken to ensure proper positioning of the toric IOL at the intended axis following viscoelastic removal.

Misalignment of the axis of the lens versus 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 toric IOL axis during surgery, an unanticipated surgically induced change in the cornea, or physical rotation of the 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.

## DIRECTIONS FOR USE

1. Examine the label on the unopened package for model, optical power, cylinder power (if applicable), proper configuration, and expiration date.
2. After the outer box is open, verify that the lens primary label information (e.g., model, powers, and serial number) is consistent with information on the outer box labeling.
3. Inspect the primary package carefully for tears, cuts, punctures, or other signs that the pouch has been opened or damaged. This device is sterile until the inner primary package is opened. DO NOT implant the IOL if the sterility has been compromised or if the sterile package has been unintentionally opened before use (see RETURNED GOODS POLICY).
4. Open the undamaged primary package and transfer the case to a sterile environment. Carefully open the case to expose the lens.
5. Use instrumentation that is scrupulously clean to minimize the occurrence of marks. Any forceps used for lens handling must have round edges and smooth surfaces.
6. Handle the IOL by the haptics only when removing the lens from the case. DO NOT grasp the optical area with forceps. Handle 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® solution. Examine the IOL carefully prior to insertion to ensure that particles have not adhered during handling.
8. Implant the IOL with the most appropriate surgical procedure for the patient. Surgeons should verify that appropriate instrumentation is available prior to surgery.

## MAGNETIC RESONANCE COMPATIBILITY

The AcrySof™ IQ Vivity™ UV Absorbing IOLs are magnetic resonance (MR) Safe. The IOLs consist of acrylate/methacrylate copolymer material, which is a non-conducting, non-metallic, non-magnetic material that poses no known hazards in all magnetic resonance imaging environments.

## PATIENT REGISTRATION

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 that the patient consults in the future.

In the United States, 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. Patient registration is essential for the long-term patient follow-up program and will assist Alcon Laboratories, Inc. in responding to reports of adverse events.

## SERIOUS INCIDENT REPORTING

Any serious incident that may reasonably be regarded as device related should be reported to Alcon Laboratories, Inc.:

By Phone:
In USA - (800) 757-9780
Website:
http://www.alcon.com/contact-us/

Each IOL is identified by a serial number which provides traceability, and this information should be given to Alcon.

## HOW SUPPLIED

The AcrySof™ IQ Vivity™ UV Absorbing 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 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 should be shipped via traceable means. A Returned Goods Number is obtained by contacting Alcon Laboratories, Inc. 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.

## CLINICAL STUDIES

Several prospective clinical studies were performed that support the safety and effectiveness of the AcrySof™ IQ Vivity™ UV Absorbing IOLs (Models DAT015, DAT315, DAT415, DAT515) and are described in this labeling:

1. Data from the US study of AcrySof™ IQ Vivity™ IOL Model DFT015 are presented to describe the safety and effectiveness of the AcrySof™ IQ Vivity™ UV Absorbing IOL optical design.
2. AcrySof™ Toric clinical study data are presented to describe the safety and effectiveness of the toric optical design of AcrySof™ IQ Vivity™ Toric UV Absorbing IOL Models DAT315, DAT415, and DAT515.
3. AcrySof Single-Piece IOL Model SA30EL data are presented to provide additional information regarding the safety and effectiveness of the AcrySof Single-Piece IOL design.

Additionally, a study of the AcrySof™ IQ Vivity™ IOL was conducted outside the United States (OUS). The performance and safety profile of the AcrySof™ IQ Vivity™ IOL in the OUS study was consistent with that demonstrated in the US AcrySof™ IQ Vivity™ IOL study, and that of AcrySof™ IOLs generally.

NOTE: The toric element on the posterior side of the AcrySof™ IQ Vivity™ Toric UV Absorbing IOLs is identical to that of the clinically studied AcrySof™ Toric IOLs.

### 1. US AcrySof™ IQ Vivity™ Model DFT015 Clinical Study

Clinical study ILI875-C002 was a prospective, randomized, controlled study of bilateral implantation of the AcrySof™ IQ Vivity™ IOL Model DFT015 or the control IOL Model SN60WF. 107 and 113 subjects were implanted with the AcrySof™ IQ Vivity™ IOL Model DFT015 (“Vivity™ IOL”) and the FDA-approved monofocal control IOL Model SN60WF, respectively, at 11 investigational sites

in the United States. IOL implantation instructions did not change based on randomization assignment.

Primary study effectiveness objectives included demonstrating that the Vivity IOL provides non-inferior monocular best-corrected distance visual acuity (BCDVA), superior monocular distance corrected intermediate visual acuity (DCIVA), and a 0.5 D increase in the monocular negative defocus range at 0.20 logMAR compared to the monofocal control IOL. Secondary study effectiveness objectives included demonstrating superior monocular distance corrected near visual acuity (DCNVA) and superiority for percentage of subjects never needing spectacles overall compared to the monofocal control IOL.

Study safety objectives included a comparison of Vivity IOL adverse event rates to ISO Safety and Performance Endpoint (SPE) targets, description of monocular mesopic contrast sensitivity (with and without glare) and estimation of rates of severe and most bothersome visual disturbances..

The clinical study results achieved at 6 months postoperatively demonstrate that the AcrySof™ IQ Vivity™ IOL is safe and effective for the visual correction of aphakia, provides superior distance-corrected intermediate and near vision, an increased depth of focus, and decreased need for eyeglasses when compared to the monofocal control IOL, while demonstrating distance vision comparable to the monofocal control lens, low rates of visual disturbances (e.g. halos, starbursts, glare, etc.) and acceptably low rates of adverse events.

All eyes with successful IOL implantation were considered evaluable for the All Implanted Set (AAS).

**Clinical Study Results**

**Subject Population**

A total of 220 subjects were implanted in this study, with 107 subjects receiving the AcrySof™ IQ Vivity™ IOL and 113 receiving the aspheric Monofocal Control IOL. At the baseline visit, the study consisted of 55.9% females and 44.1% males. Stratifying by race, 97.7% designated White, 0.9% designated Black or African American, 0.5% designated American Indian or Alaska Native, and 0.9% designated “Other”. 1.8% of the study population designated their ethnicity as Hispanic or Latino. The mean (± SD) age for the study population was 68.8 ± 7.22 years. A summary of photopic pupil size for Vivity and Monofocal Control first implanted eyes at baseline is presented in Table 5.

**Table 5:** Baseline Photopic Pupil Size of Vivity and Monofocal Control IOL First Eyes

| | **Vivity IOL First Eyes** N = 107 | **Monofocal Control IOL First Eyes** N = 113 |
|---|---|---|
| n | 107 | 113 |
| Mean (SD) | 4.03 (0.859) | 4.08 (0.981) |
| Median | 4.0 | 4.0 |
| (Min, Max) | (2.4, 6.5) | (2.0, 7.8) |

Data are reported for the 6 Months visit. One of the subjects in the AcrySof™ IQ Vivity™ IOL group was not bilaterally implanted and does not contribute to binocular assessments. Two subjects in the monofocal control group discontinued study prior to 6 months.

**IOL Power Calculation and Postoperative Manifest Refraction**
In this study, surgeons were instructed to select the lens power that targeted emmetropia (closest to 0.0 D) for both the AcrySof™ IQ Vivity™ and the Monofocal Control IOLs prior to randomization. Table 6 summarizes absolute manifest refraction spherical equivalent (MRSE) data for AcrySof™

IQ Vivity™ IOL and Monofocal Control IOL subjects at 6 Months. For first eyes, 91.6% implanted with AcrySof™ IQ Vivity™ IOL and 86.5% implanted with the Monofocal Control IOL achieved MRSE within 0.5 D of emmetropia and mean ± SD MRSE in first eyes at 6 Months was 0.049 ± 0.345 D and 0.081 ± 0.411 D respectively.

**Table 6: Mean Absolute MRSE at 6 Months by Treatment Group**

| | AcrySof™ IQ Vivity™ IOL | | Monofocal Control IOL | |
|---|---|---|---|---|
| MRSE Category | First Eyes N = 107 n (%) | Second Eyes N = 106 n (%) | First Eyes N = 113 n (%) | Second Eyes N = 113 n (%) |
| ≤ 0.25 D | 69 (64.5) | 72 (67.9) | 63 (56.8) | 69 (62.2) |
| ≤ 0.5 D | 98 (91.6) | 92 (86.8) | 96 (86.5) | 93 (83.8) |
| ≤ 1.00 D | 107 (100.0) | 106 (100.0) | 108 (97.3) | 110 (99.1) |
| > 1.00 D | 0 (0.0) | 0 (0.0) | 3 (2.7) | 1 (0.9) |
| Total | 107 | 106 | 111 | 111 |

Percentages are calculated as (n/Total)*100

## EFFECTIVENESS

### Visual Acuity

Visual Acuity was assessed under high-contrast, photopic conditions using a computerized test system (CTS, M&S Technologies, Niles, IL). The following subsections present monocular and binocular visual acuity data collected at distance, intermediate (66 cm), and near (40 cm). Primary and secondary study analyses included the following assessments of monocular visual acuity:

- Mean best corrected distance visual acuity (BCDVA) and distance corrected intermediate and near visual acuities (DCIVA and DCNVA) by treatment group
- Monocular defocus curves by treatment group

These analyses are discussed in the following subsections. Monocular visual acuity was also assessed in low-contrast, photopic conditions; results of this testing is presented in the “Safety” section of this document.

Monocular Visual Acuity

Table 7 presents monocular, photopic, best corrected distance (4 m) visual acuity (BCDVA), distance corrected intermediate (66 cm) visual acuity (DCIVA), and distance corrected near (40 cm) visual acuity (DCNVA) data for first eyes treated with the AcrySof™ IQ Vivity™ and monofocal control IOLs at 6 Months.

**Table 7: Comparison of Mean Monocular Photopic (First Eyes) BCDVA, DCIVA, and DCNVA Using Least Square Estimates**
**All Implanted, 6 Months Postoperative**

| Monocular Mean Visual Acuity | AcrySof™ IQ Vivity™ IOL | | | Monofocal Control IOL | | | 95% One-Sided UCL | P-Value |
|---|---|---|---|---|---|---|---|---|
| | Total | Mean logMAR | Standard Error | Total | Mean logMAR | Standard Error | | |
| BCDVA | 107 | 0.016 | 0.0091 | 111 | -0.036 | 0.0089 | 0.073[a] | N/A |
| DCIVA | 107 | 0.148 | 0.0120 | 111 | 0.312 | 0.0118 | N/A | < 0.001[b] |
| DCNVA | 107 | 0.359 | 0.0147 | 111 | 0.515 | 0.0144 | N/A | < 0.001[b] |

[a]Non-inferiority of AcrySof™ IQ Vivity™ IOL to the Monofocal Control IOL is demonstrated by the one-sided 95% Upper Confidence Limit (UCL) for treatment difference < 0.10 logMAR
[b]Superiority of AcrySof™ IQ Vivity™ IOL over the Monofocal Control IOL is demonstrated by the upper bound of two-sided 95% CI for treatment difference is < 0.0 logMAR and p-value is less than alpha = 0.05.

The AcrySof™ IQ Vivity™ IOL met the clinical performance co-primary endpoint for mean photopic BCDVA non-inferior to the monofocal control IOL (non-inferiority margin of 0.10 logMAR). The upper limit of the one sided 95% confidence interval (CI) of the mean difference in BCDVA between IOL groups was less than 0.10 logMAR (less than a line), demonstrating that the AcrySof™ IQ Vivity™ IOL is non-inferior to the control lens in providing BCDVA. Additionally, AcrySof™ IQ Vivity™ IOL first eyes achieved BCDVA of 0.30 logMAR or better at a rate of 99.1% and 100.0% in the AAS and Best-Case Analysis Set (BAS) set, respectively. This exceeded the ISO BCDVA Safety and Performance Endpoint (SPE) rates of 92.5% and 96.7%, respectively.

The AcrySof™ IQ Vivity™ IOL provided mean photopic monocular DCIVA superior to the monofocal control IOL with an increase in 1.6 lines read and met the clinical performance co-primary endpoint with > 50% (72.9%) of first eyes achieving DCIVA of 0.20 logMAR or better at 6 Months. When analyzed by pupil size (< 3 mm, ≥3 - ≤4 mm, and > 4 mm), mean monocular DCIVA in all pupil size subgroups of the Vivity IOL arm remains above 0.20 logMAR, and > 1 line above those of the monofocal control IOL arm.

AcrySof™ IQ Vivity™ IOL provided mean photopic monocular DCNVA superior to the monofocal control IOL, with 40.2% (95% CI: 30.8%, 50.1%) of AcrySof™ IQ Vivity™ IOL first eyes achieving DCNVA of 0.30 logMAR or better at 6 Months, at a rate > 25% above that of the monofocal control IOL, and an increase of 1.6 lines read.

**Monocular Defocus Curve**

Monocular defocus curves were obtained at 6 months for the AcrySof™ IQ Vivity™ IOL and the monofocal control IOL reflecting 95% confidence limits and ±1 standard deviation (SD) are depicted in Figures 5 and 6, respectively. Data were obtained from 107 and 111 subjects respectively in each arm using a computerized visual acuity test system (CTS, M&S Technologies, Niles, IL). The Vivity IOL group demonstrated a mean defocus range of 1.53 D compared to 0.99 D for the Monofocal Control IOL, providing an increase of 0.54 D in depth of focus at 0.20 logMAR. Therefore, the AcrySof™ IQ Vivity™ IOL met the clinical performance co-primary endpoint, demonstrating a monocular defocus range of > 0.5 D greater than the monofocal control IOL at 0.2 logMAR at 6 Months.

**Figure 5: Mean Monocular (First Eyes) Defocus Curve with 95% Confidence Limits by Lens Model at 6 Months Postoperative**
**All Implanted**

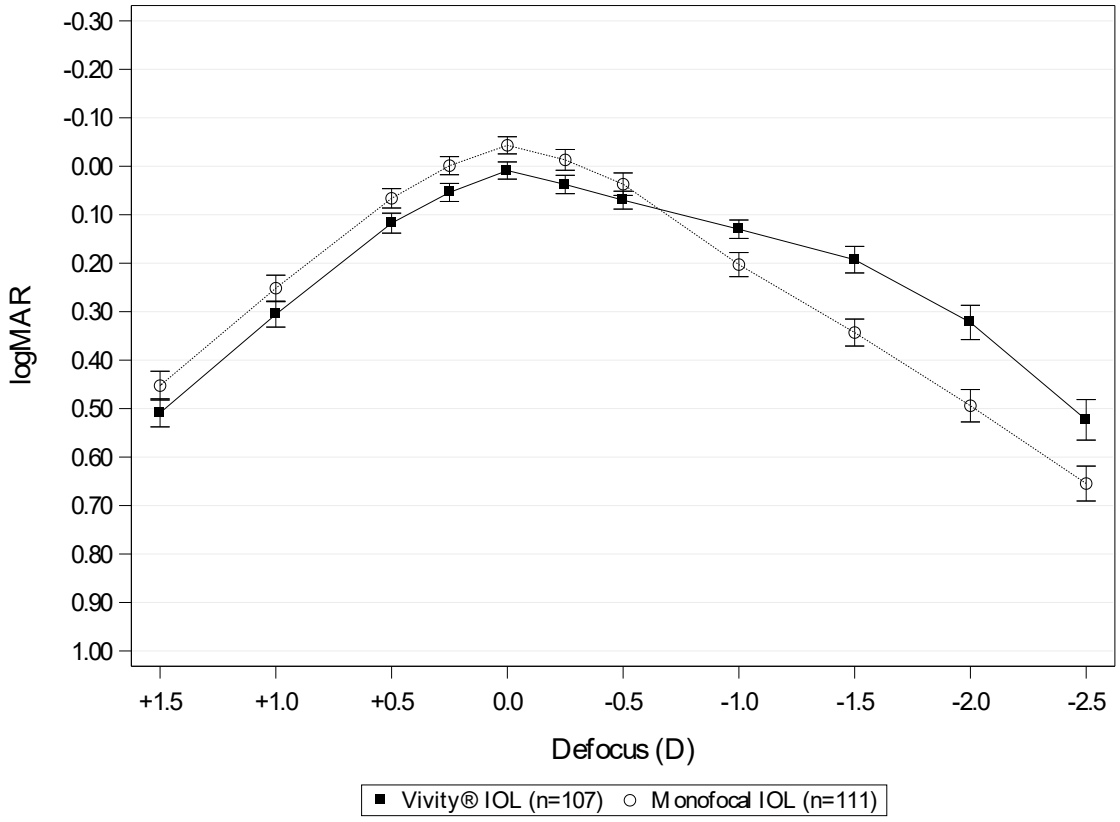
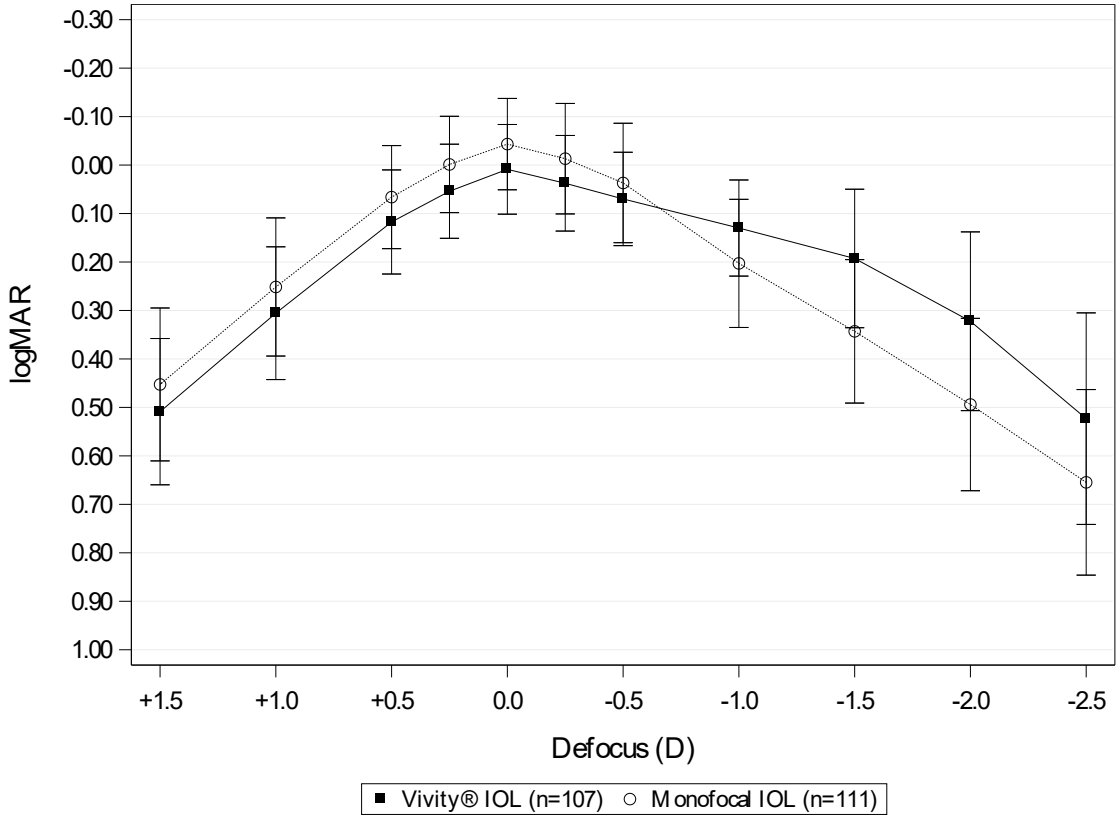


**Figure 6: Mean Monocular (First Eyes) Defocus Curve with ±1 SD by Lens Model at 6 Months Postoperative**
**All Implanted**




Monocular defocus curves stratified by post-operative (Month 6) photopic pupil size in the Vivity and Monofocal IOL groups are presented in Figures 7 and 8, respectively.

**Figure 7: Monocular Mean Defocus Curve by Post-Operative Pupil Size at 6 Months, Vivity IOL Group**

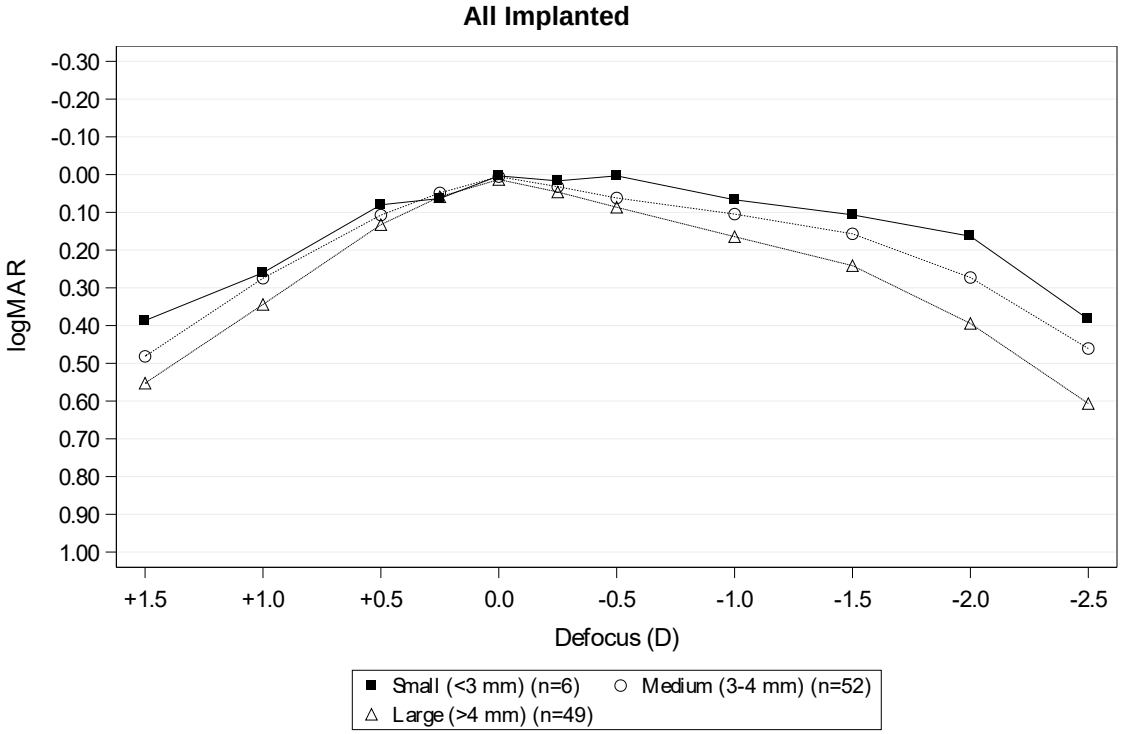
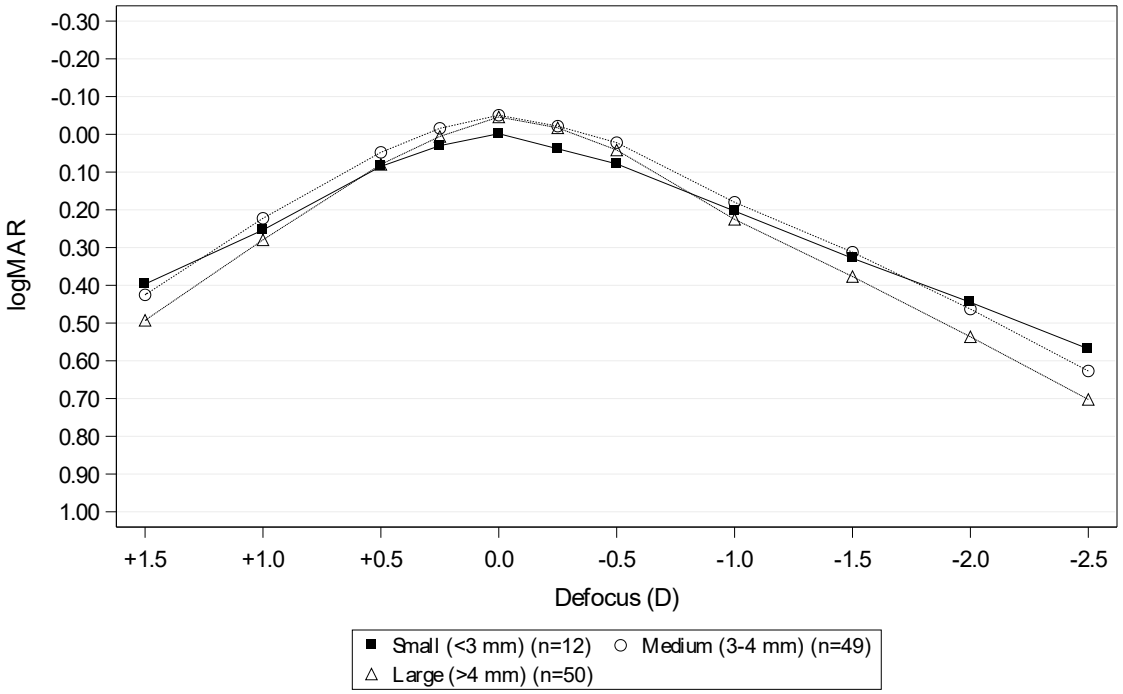



**Figure 8: Monocular Mean Defocus Curve by Post-Operative Pupil Size at 6 Months, Monofocal IOL Group**



Binocular Visual Acuity

Additional descriptive and categorical analyses of binocular uncorrected and best corrected distance visual acuities (UCDVA and BCDVA), uncorrected and distance corrected intermediate visual acuities (UCIVA and DCIVA), and uncorrected and distance corrected near visual acuities (UCNVA and DCNVA), in addition to binocular defocus curves are presented in the following subsections.

**Binocular Mean Visual Acuity**

Binocular mean BCDVA, UCDVA, DCIVA, UCIVA, DCNVA, and UCNVA are presented by treatment group in Table 8. Binocular visual acuity data for the AcrySof™ IQ Vivity™ IOL group showed mean BCDVA to be within 2 letters of the Monofocal Control IOL, while differences in mean DCIVA and mean DCNVA were > 1 line. One of the subjects in the AcrySof™ IQ Vivity™ IOL group was not bilaterally implanted and does not contribute to binocular assessments.

**Table 8: Comparison of Binocular Mean Photopic BCDVA, UCDVA, DCIVA, UCIVA, DCNVA, and UCNVA**
**All Implanted, 6 Months Postoperative**

| | AcrySof™ IQ Vivity™ IOL N = 106 | | | Monofocal Control IOL N = 113 | | |
|---|---|---|---|---|---|---|
| **Binocular Mean Visual Acuity** | **n** | **Mean logMAR** | **Standard Deviation** | **n** | **Mean logMAR** | **Standard Deviation** |
| BCDVA | 106 | -0.028 | 0.084 | 111 | -0.071 | 0.086 |
| UCDVA | 106 | 0.035 | 0.102 | 111 | -0.022 | 0.107 |
| DCIVA | 106 | 0.054 | 0.093 | 111 | 0.196 | 0.113 |
| UCIVA | 106 | 0.058 | 0.083 | 111 | 0.139 | 0.122 |
| DCNVA | 106 | 0.253 | 0.118 | 111 | 0.391 | 0.135 |
| UCNVA | 106 | 0.208 | 0.104 | 111 | 0.339 | 0.149 |

**Binocular Categorical Visual Acuity**

Tables 9 and 10 present the percentage of subjects achieving binocular photopic BCDVA and UCDVA by Snellen and logMAR categories, respectively, at 6 Months. The majority of subjects in both the AcrySof™ IQ Vivity™ IOL and the monofocal control IOL groups achieved 20/20$^{-2}$ or better.

### Table 9: Binocular Photopic Distance Best Corrected and Uncorrected Visual Acuity (Snellen) All Implanted, 6 Months Postoperative

| Binocular Snellen Visual Acuity | AcrySof™ IQ Vivity™ IOL N = 106 | | Monofocal Control IOL N = 113 | |
|---|---|---|---|---|
| | Uncorrected n (%) | Best Corrected n (%) | Uncorrected n (%) | Best Corrected n (%) |
| 20/20$^{-2}$ or better | 65 (61.3) | 93 (87.7) | 85 (76.6) | 105 (94.6) |
| 20/25$^{-2}$ or better | 94 (88.7) | 103 (97.2) | 105 (94.6) | 109 (98.2) |
| 20/32$^{-2}$ or better | 102 (96.2) | 104 (98.1) | 109 (98.2) | 111 (100.0) |
| 20/40$^{-2}$ or better | 105 (99.1) | 106 (100.0) | 111 (100.0) | 111 (100.0) |
| Worse than 20/40$^{-2}$ | 1 (0.9) | 0 (0.0) | 0 (0.0) | 0 (0.0) |
| Total Responses | 106 | 106 | 111 | 111 |

Snellen VA was converted from logMAR VA. A Snellen notation of 20/20$^{-2}$ or better indicates a logMAR VA of 0.04 or better, which means 3 or more of the 5 ETDRS chart letters in the line were identified correctly.
Percentages are calculated as (n/Total)*100

### Table 10: Binocular Photopic Distance Best Corrected and Uncorrected Visual Acuity (logMAR) All Implanted, 6 Months Postoperative

| Binocular logMAR Visual Acuity | AcrySof™ IQ Vivity™ IOL N = 106 | | Monofocal Control IOL N = 113 | |
|---|---|---|---|---|
| | Uncorrected n (%) | Best Corrected n (%) | Uncorrected n (%) | Best Corrected n (%) |
| 0.00 or better | 47 (44.3) | 78 (73.6) | 77 (69.4) | 99 (89.2) |
| 0.10 or better | 88 (83.0) | 102 (96.2) | 96 (86.5) | 108 (97.3) |
| 0.20 or better | 98 (92.5) | 104 (98.1) | 109 (98.2) | 111 (100.0) |
| 0.30 or better | 105 (99.1) | 106 (100.0) | 111 (100.0) | 111 (100.0) |
| Worse than 0.30 | 1 (0.9) | 0 (0.0) | 0 (0.0) | 0 (0.0) |
| Total Responses | 106 | 106 | 111 | 111 |

Percentages are calculated as (n/Total)*100

Tables 11 and 12 present the percentage of subjects achieving binocular photopic DCIVA and UCIVA by Snellen and logMAR categories, respectively, at 6 Months. The majority of AcrySof™ IQ Vivity™ IOL subjects achieved 20/20$^{-2}$ or better binocular uncorrected and distance corrected intermediate VA, as compared to 27.0% and 10.8% of control subjects, respectively.

**Table 11: Binocular Photopic Intermediate (66 cm) Distance Corrected and Uncorrected Visual Acuity (Snellen)**
**All Implanted, 6 Months Postoperative**

| Binocular Snellen Visual Acuity | AcrySof™ IQ Vivity™ IOL N = 106 | | Monofocal Control IOL N = 113 | |
|---|---|---|---|---|
| | Uncorrected n (%) | Distance Corrected n (%) | Uncorrected n (%) | Distance Corrected n (%) |
| 20/20$^{-2}$ or better | 59 (55.7) | 59 (55.7) | 30 (27.0) | 12 (10.8) |
| 20/25$^{-2}$ or better | 91 (85.8) | 93 (87.7) | 70 (63.1) | 38 (34.2) |
| 20/32$^{-2}$ or better | 105 (99.1) | 103 (97.2) | 92 (82.9) | 82 (73.9) |
| 20/40$^{-2}$ or better | 106 (100.0) | 106 (100.0) | 106 (95.5) | 103 (92.8) |
| Worse than 20/40$^{-2}$ | 0 (0.0) | 0 (0.0) | 5 (4.5) | 8 (7.2) |
| Total Responses | 106 | 106 | 111 | 111 |

Snellen VA was converted from logMAR VA. A Snellen notation of 20/20$^{-2}$ or better indicates a logMAR VA of 0.04 or better, which means 3 or more of the 5 ETDRS chart letters in the line were identified correctly.
Percentages are calculated as (n/Total)*100

**Table 12: Binocular Photopic Intermediate (66 cm) Distance Corrected and Uncorrected Visual Acuity (logMAR)**
**All Implanted, 6 Months Postoperative**

| Binocular logMAR Visual Acuity | AcrySof™ IQ Vivity™ IOL N = 106 | | Monofocal Control IOL N = 113 | |
|---|---|---|---|---|
| | Uncorrected n (%) | Distance Corrected n (%) | Uncorrected n (%) | Distance Corrected n (%) |
| 0.00 or better | 39 (36.8) | 43 (40.6) | 16 (14.4) | 6 (5.4) |
| 0.10 or better | 82 (77.4) | 79 (74.5) | 47 (42.3) | 24 (21.6) |
| 0.20 or better | 100 (94.3) | 99 (93.4) | 87 (78.4) | 66 (59.5) |
| 0.30 or better | 105 (99.1) | 104 (98.1) | 101 (91.0) | 94 (84.7) |
| Worse than 0.30 | 1 (0.9) | 2 (1.9) | 10 (9.0) | 17 (15.3) |
| Total Responses | 106 | 106 | 111 | 111 |

Percentages are calculated as (n/Total)*100

Tables 13 and 14 present the percentage of subjects achieving binocular photopic UCNVA and DCNVA by Snellen and logMAR categories, respectively, at 6 Months. 67.0% and 57.5% of the AcrySof™ IQ Vivity™ IOL subjects achieved 20/32 or better binocular uncorrected and distance corrected near VA, compared to 28.8% and 16.2% of control subjects, respectively.

**Table 13: Binocular Photopic Near (40 cm) Distance Corrected and Uncorrected Visual Acuity (Snellen) All Implanted, 6 Months Postoperative**

| Binocular Snellen Visual Acuity | AcrySof™ IQ Vivity™ IOL N = 106 | | Monofocal Control IOL N = 113 | |
|---|---|---|---|---|
| | Uncorrected n (%) | Distance Corrected n (%) | Uncorrected n (%) | Distance Corrected n (%) |
| 20/20$^{-2}$ or better | 3 (2.8) | 1 (0.9) | 1 (0.9) | 0 (0.0) |
| 20/25$^{-2}$ or better | 37 (34.9) | 23 (21.7) | 11 (9.9) | 2 (1.8) |
| 20/32$^{-2}$ or better | 71 (67.0) | 61 (57.5) | 32 (28.8) | 18 (16.2) |
| 20/40$^{-2}$ or better | 96 (90.6) | 82 (77.4) | 62 (55.9) | 48 (43.2) |
| Worse than 20/40$^{-2}$ | 10 (9.4) | 24 (22.6) | 49 (44.1) | 63 (56.8) |
| Total Responses | 106 | 106 | 111 | 111 |

Snellen VA was converted from logMAR VA. A Snellen notation of 20/20$^{-2}$ or better indicates a logMAR VA of 0.04 or better, which means 3 or more of the 5 ETDRS chart letters in the line were identified correctly.
Percentages are calculated as (n/Total)*100

**Table 14: Binocular Photopic Near (40 cm) Distance Corrected and Uncorrected Visual Acuity (logMAR) All Implanted, 6 Months Postoperative**

| Binocular logMAR Visual Acuity | AcrySof™ IQ Vivity™ IOL N = 106 | | Monofocal Control IOL N = 113 | |
|---|---|---|---|---|
| | Uncorrected n (%) | Distance Corrected n (%) | Uncorrected n (%) | Distance Corrected n (%) |
| 0.00 or better | 2 (1.9) | 1 (0.9) | 1 (0.9) | 0 (0.0) |
| 0.10 or better | 17 (16.0) | 9 (8.5) | 8 (7.2) | 2 (1.8) |
| 0.20 or better | 60 (56.6) | 46 (43.4) | 27 (24.3) | 8 (7.2) |
| 0.30 or better | 90 (84.9) | 76 (71.7) | 49 (44.1) | 39 (35.1) |
| Worse than 0.30 | 16 (15.1) | 30 (28.3) | 62 (55.9) | 72 (64.9) |
| Total Responses | 106 | 106 | 111 | 111 |

Percentages are calculated as (n/Total)*100

**Defocus Curves**

Binocular defocus curves were obtained at 6 months for the AcrySof™ IQ Vivity™ IOL and the monofocal control IOL and are depicted with 95% confidence interval and ±1 SD error bars in Figures 9 and 10, respectively. Data were obtained from 106 and 111 subjects in each arm using a computerized visual acuity test system (CTS, M&S Technologies, Niles, IL). Consistent with the monocular defocus curve presented in Figures 5 and 6, AcrySof™ IQ Vivity™ IOL subjects demonstrated a > 0.5 D greater defocus range compared to the monofocal control group.

**Figure 9: Binocular Mean Defocus Curve with 95% Confidence Limits by Lens Model at 6 Months Postoperative All Implanted**

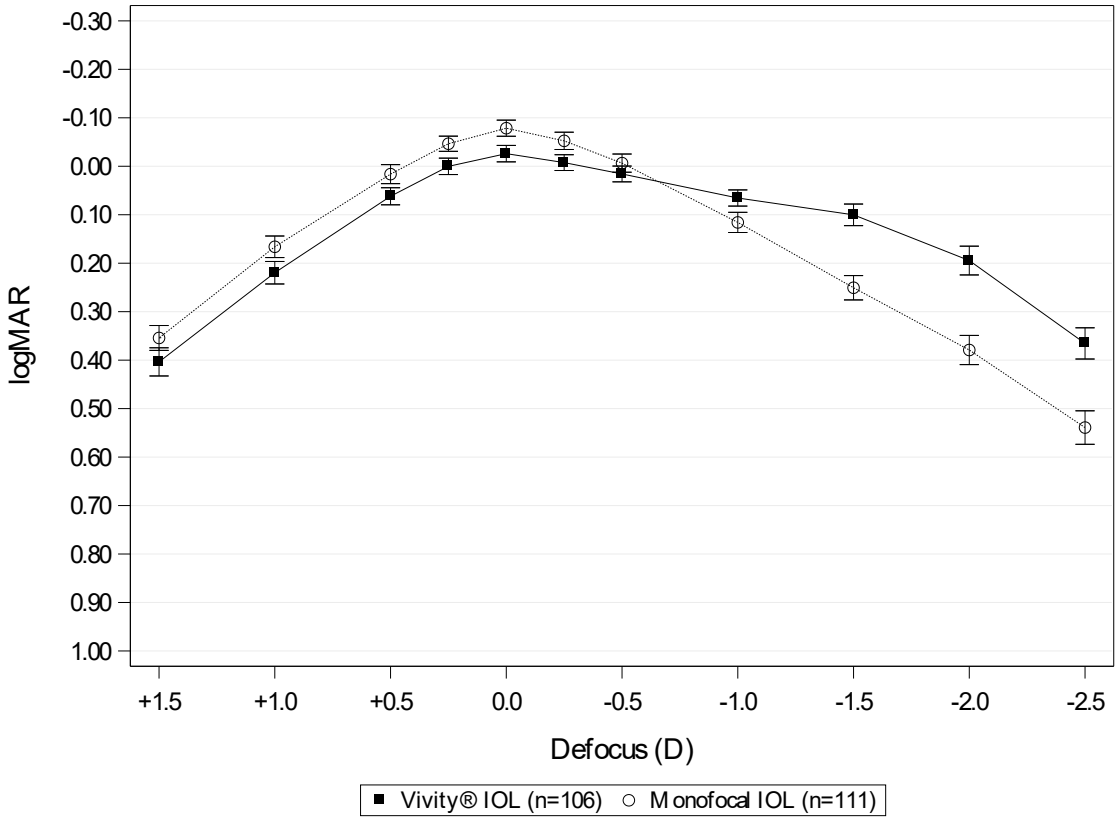
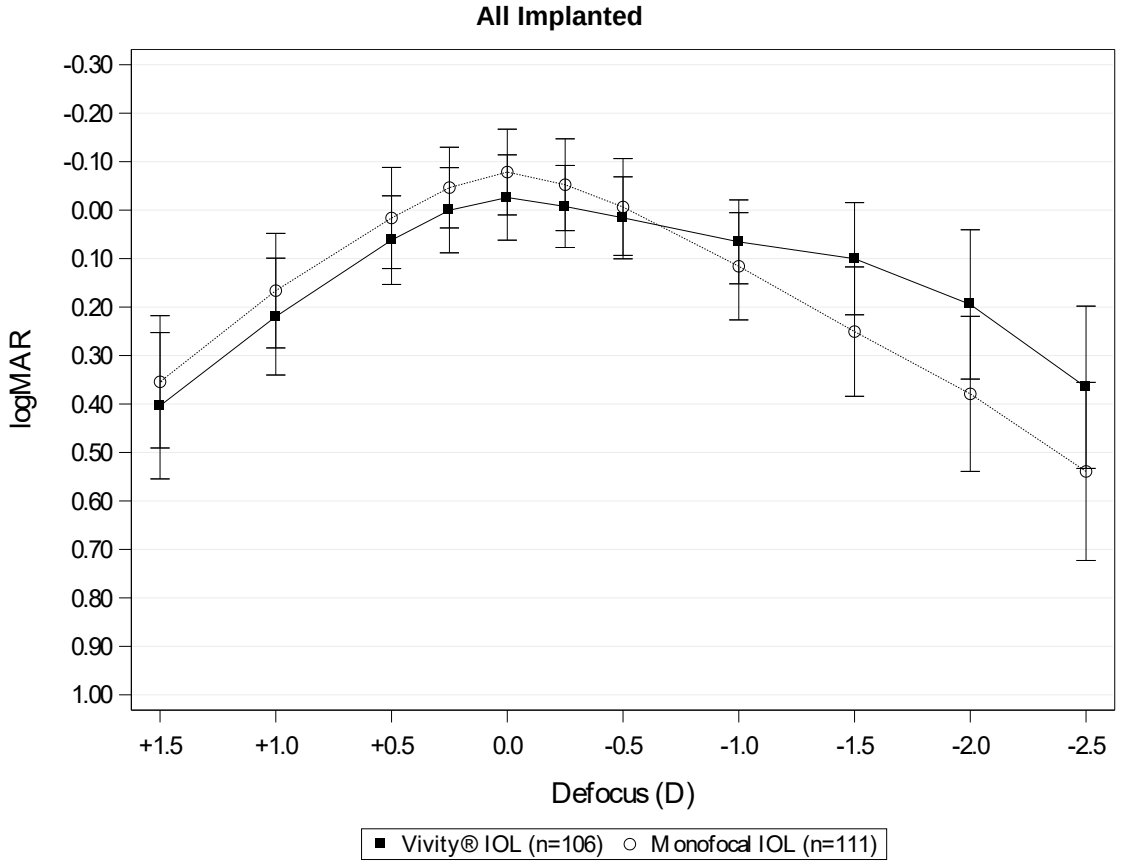


**Figure 10: Binocular Mean Defocus Curve with ±1 SD by Lens Model at 6 Months Postoperative**




**Need for Eyeglasses/Contact Lenses**

A Patient Reported Outcome Measure instrument was developed and validated for use in this clinical study to assess need for eyeglasses/contact lenses following implantation with the IOL. The AcrySof™ IQ Vivity™ IOL (N = 102) showed a greater proportion of subjects reporting never needing to wear eyeglasses or contact lenses at 6 months: 21.6% of subjects versus 3.6% for the Monofocal Control IOL (N = 111); however, a statistical test was not performed.

The questionnaire evaluated subject-reported use of eyeglasses or contact lenses at distance ('far away'), intermediate ('arm's length'), and near ('up close'), in bright and dim lighting conditions. Table 15 summarizes another analysis assessing the proportion of AcrySof™ IQ Vivity™ IOL and Monofocal Control IOL subjects 'never' or 'rarely' needing eyeglasses or contact lenses. Data for this analysis are presented overall and under each lighting and distance condition.

**Table 15: Proportion of Subjects Rarely or Never Needing Eyeglasses or Contact Lenses by Distance and Lighting Condition**

| Condition | | Proportion of Subjects Rarely or Never Needing Eyeglasses or Contact Lenses | | | | | |
|---|---|---|---|---|---|---|---|
| | | AcrySof™ IQ Vivity™ IOL N = 106 | | | Monofocal Control IOL N = 113 | | |
| | | Total Responses | n | % | Total Responses | n | % |
| Overall | | 102 | 46 | 45.1 | 111 | 19 | 17.1 |
| Bright Light | Distance ('Far away') | 102 | 96 | 94.1 | 111 | 102 | 91.9 |
| | Intermediate ('At arm's length') | 102 | 89 | 87.2 | 111 | 64 | 57.6 |
| | Near ('Up close') | 102 | 47 | 46.1 | 111 | 18 | 16.2 |
| Dim Light | Distance ('Far away') | 102 | 95 | 93.2 | 111 | 99 | 89.2 |
| | Intermediate ('At arm's length') | 102 | 86 | 84.3 | 111 | 59 | 53.1 |
| | Near ('Up close') | 102 | 40 | 39.2 | 111 | 12 | 10.8 |

Subjects who reported not using eyeglasses at least some of the time (95.0% and 85.7% in the AcrySof™ IQ Vivity™ IOL and Monofocal Control IOL groups, respectively) were asked to report their quality of vision without eyeglasses, up close, at arm's length, and far away, in dim and bright light. The proportion of subjects reporting 'good' or 'very good' vision without eyeglasses at 6 Months is presented by treatment group in Table 16.

**Table 16: Proportion of Subjects Reporting 'Good' or 'Very Good' Vision Without Eyeglasses by Distance and Lighting Condition**

| Condition | | AcrySof™ IQ Vivity™ IOL N = 106 | | | Monofocal Control IOL N = 113 | | |
|---|---|---|---|---|---|---|---|
| | | Total Responses | n | % | Total Responses | n | % |
| Bright Light | Distance ('Far away') | 96 | 90 | 93.7 | 89 | 82 | 92.2 |
| | Intermediate ('At arm's length') | 96 | 88 | 91.6 | 89 | 56 | 62.9 |
| | Near ('Up close') | 96 | 55 | 57.3 | 89 | 22 | 24.8 |
| Dim Light | Distance ('Far away') | 96 | 84 | 87.5 | 90 | 70 | 77.8 |
| | Intermediate ('At arm's length') | 96 | 80 | 83.4 | 89 | 45 | 50.6 |
| | Near ('Up close') | 96 | 36 | 37.5 | 89 | 7 | 7.8 |

The results of this questionnaire demonstrate a reduced overall spectacle need in subjects implanted with the AcrySof™ IQ Vivity™ IOL compared to the monofocal control IOL. Statistical testing of this endpoint was not performed, as prespecified in the statistical analysis plan, because of the failure to meet the first co-secondary effectiveness endpoint.

## SAFETY

The incidences of cumulative and persistent adverse events (AEs) including 1-sided 95% lower confidence limits for the AcrySof™ IQ Vivity™ IOL and Monofocal Control IOL as compared to the ISO 11979-7:2014 historical grid rates are provided in Tables 17 (first implanted eyes in each IOL group), 18 (second implanted eyes in each IOL group), and 19 (all implanted eyes in each IOL group). If the same event occurred multiple times in an eye, only the first occurrence is counted in the tables below. The safety and performance endpoint (SPE) rate is considered not exceeded if the 1-sided 95% lower CL for an AE is less than the SPE%. No cumulative adverse events exceeded the established rates according to ISO 11979-7:2014.

No persistent adverse events (adverse events in the ISO grid that are observed at the 6 month postoperative visit) were observed for 107 subjects implanted with AcrySof™ IQ Vivity™ IOL.

**Table 17: Cumulative and Persistent Serious Adverse Events in First Eyes and SPE Rates for AcrySof™ IQ Vivity™ and Monofocal IOL Group (Safety Analysis Set)**

| | AcrySof IQ Vivity IOL First Implanted Eyes N = 107 | | Monofocal Control IOL First Implanted Eyes N = 113 | | |
|---|---|---|---|---|---|
| **Cumulative Serious Adverse Events** | **n(%)** | **1-sided 95% Lower CL** | **n (%)** | **1-sided 95% Lower CL** | **SPE %** |
| Cystoid macular oedema | 1 (0.9) | 0.05 | 1 (0.9) | 0.05 | 3.0 |
| Hypopyon | 0 (0.0) | 0.00 | 0 (0.0) | 0.00 | 0.3 |
| Endophthalmitis | 0 (0.0) | 0.00 | 0 (0.0) | 0.00 | 0.1 |
| Lens dislocated from posterior chamber | 0 (0.0) | 0.00 | 0 (0.0) | 0.00 | 0.1 |
| Pupillary block | 0 (0.0) | 0.00 | 0 (0.0) | 0.00 | 0.1 |
| Retinal detachment | 0 (0.0) | 0.00 | 1 (0.9) | 0.05 | 0.3 |
| Secondary surgical intervention | 0 (0.0) | 0.00 | 2 (1.8)* | 0.32 | 0.8 |
| Other | | | | | |
| Hyphaema | 1 (0.9) | 0.05 | 0 (0.0) | 0.00 | N/A |
| Transient ischaemic attack | 1 (0.9) | 0.05 | 0 (0.0) | 0.00 | N/A |
| Photopsia | 0 (0.0) | 0.00 | 1 (0.9) | 0.05 | N/A |
| **Persistent Serious Adverse Events** | | | | | |
| Corneal stroma oedema | 0 (0.0) | 0.00 | 0 (0.0) | 0.00 | 0.3 |
| Cystoid macular oedema | 0 (0.0) | 0.00 | 0 (0.0) | 0.00 | 0.5 |
| Iritis | 0 (0.0) | 0.00 | 0 (0.0) | 0.00 | 0.3 |
| Raised IOP requiring treatment | 0 (0.0) | 0.00 | 0 (0.0) | 0.00 | 0.4 |

Percentages are calculated as (n/N)*100

*****One SSI was a pars plana vitrectomy and one SSI was an IOL explant

## Table 18: Cumulative and Persistent Serious Adverse Events in Second Eyes and SPE Rates for AcrySof™ IQ Vivity™ and Monofocal IOL Group (Safety Analysis Set)

| | AcrySof IQ Vivity IOL Second Implanted Eyes N = 106 | | Monofocal Control IOL Second Implanted Eyes N = 113 | | |
|---|---|---|---|---|---|
| **Cumulative Serious Adverse Events** | **n(%)** | **1-sided 95% Lower CL** | **n (%)** | **1-sided 95% Lower CL** | **SPE %** |
| Cystoid macular oedema | 0 (0.0) | 0.00 | 1 (0.9) | 0.05 | 3.0 |
| Hypopyon | 0 (0.0) | 0.00 | 0 (0.0) | 0.00 | 0.3 |
| Endophthalmitis | 0 (0.0) | 0.00 | 0 (0.0) | 0.00 | 0.1 |
| Lens dislocated from posterior chamber | 0 (0.0) | 0.00 | 0 (0.0) | 0.00 | 0.1 |
| Pupillary block | 0 (0.0) | 0.00 | 0 (0.0) | 0.00 | 0.1 |
| Retinal detachment | 0 (0.0) | 0.00 | 0 (0.0) | 0.00 | 0.3 |
| Secondary surgical intervention | 2 (1.9)* | 0.34 | 0 (0.0) | 0.00 | 0.8 |
| Other | | | | | |
| Cataract operation complication** | 2 (1.9) | 0.34 | 0 (0.0) | 0.00 | N/A |
| **Persistent Serious Adverse Events** | | | | | |
| Corneal stroma oedema | 0 (0.0) | 0.00 | 0 (0.0) | 0.00 | 0.3 |
| Cystoid macular oedema | 0 (0.0) | 0.00 | 0 (0.0) | 0.00 | 0.5 |
| Iritis | 0 (0.0) | 0.00 | 0 (0.0) | 0.00 | 0.3 |
| Raised IOP requiring treatment | 0 (0.0) | 0.00 | 0 (0.0) | 0.00 | 0.4 |

Percentages are calculated as (n/N)*100
*****Both SSIs were unrelated to the IOL and were performed to remove retained cataract material from the eye.
**Both events were due to retained cataract material in the eye

## Table 19: Cumulative and Persistent Serious Adverse Events in All Eyes and SPE Rates for AcrySof™ IQ Vivity™ and Monofocal IOL Group (Safety Analysis Set)

| | AcrySof IQ Vivity IOL All Implanted Eyes N = 213 | | Monofocal Control IOL All Implanted Eyes N = 226 | | |
|---|---|---|---|---|---|
| **Cumulative Serious Adverse Events** | **n(%)** | **1-sided 95% Lower CL** | **n (%)** | **1-sided 95% Lower CL** | **SPE %** |
| Cystoid macular oedema | 1 (0.5) | 0.02 | 2 (0.9) | 0.16 | 3.0 |
| Hypopyon | 0 (0.0) | 0.00 | 0 (0.0) | 0.00 | 0.3 |
| Endophthalmitis | 0 (0.0) | 0.00 | 0 (0.0) | 0.00 | 0.1 |
| Lens dislocated from posterior chamber | 0 (0.0) | 0.00 | 0 (0.0) | 0.00 | 0.1 |
| Pupillary block | 0 (0.0) | 0.00 | 0 (0.0) | 0.00 | 0.1 |
| Retinal detachment | 0 (0.0) | 0.00 | 1 (0.4) | 0.02 | 0.3 |
| Secondary surgical intervention* | 2 (0.9)* | 0.17 | 2 (0.9)*** | 0.16 | 0.8 |
| Other | | | | | |
| Cataract operation complication** | 2 (0.9) | 0.17 | 0 (0.0) | 0.00 | N/A |
| Hyphaema | 1 (0.5) | 0.02 | 0 (0.0) | 0.00 | N/A |
| Transient ischaemic attack | 1 (0.5) | 0.02 | 0 (0.0) | 0.00 | N/A |
| Photopsia | 0 (0.0) | 0.00 | 1 (0.4) | 0.02 | N/A |
| **Persistent Serious Adverse Events** | | | | | |
| Corneal stroma oedema | 0 (0.0) | 0.00 | 0 (0.0) | 0.00 | 0.3 |
| Cystoid macular oedema | 0 (0.0) | 0.00 | 0 (0.0) | 0.00 | 0.5 |
| Iritis | 0 (0.0) | 0.00 | 0 (0.0) | 0.00 | 0.3 |
| Raised IOP requiring treatment | 0 (0.0) | 0.00 | 0 (0.0) | 0.00 | 0.4 |

Percentages are calculated as (n/N)*100
*****Both SSIs in the Vivity IOL group were unrelated to the IOL and were performed to remove retained cataract material from the eye.
**Both events were due to retained cataract material in the eye
*******One SSI with the Monofocal Control IOL was a pars plana vitrectomy and the other was an IOL explant.

The results of adverse events analyses based on the consensus definitions as set forth by the American Academy of Ophthalmology's Task Force (Masket et al. Ophthalmology 2017) are shown in Tables 20 and 21 for first and second implanted eyes, respectively.

**Table 20: Supportive Characterization of Ocular Adverse Events in First Eyes based on a Modified Version of AAO Consensus (Masket et al., 2017) for AcrySof™ IQ Vivity™ and Monofocal IOL Groups (Safety Analysis Set)**

| | AcrySof IQ Vivity IOL First Implanted Eyes N = 107 | | | Monofocal IOL First Implanted Eyes N = 113 | | |
|---|---|---|---|---|---|---|
| **Adverse Event** | **n (%)** | **2-sided 95% CI** | **E** | **n (%)** | **2-sided 95% CI** | **E** |
| Chronic anterior uveitis | 0 (0.0) | (0.00, 3.39) | 0 | 0 (0.0) | (0.00, 3.21) | 0 |
| Clinically significant cystoid macular edema | 0 (0.0) | (0.00, 3.39) | 0 | 1 (0.9) | (0.02, 4.83) | 1 |
| Visually significant corneal edema | 0 (0.0) | (0.00, 3.39) | 0 | 0 (0.0) | (0.00, 3.21) | 0 |
| Endophthalmitis | 0 (0.0) | (0.00, 3.39) | 0 | 0 (0.0) | (0.00, 3.21) | 0 |
| Mechanical pupillary block | 0 (0.0) | (0.00, 3.39) | 0 | 0 (0.0) | (0.00, 3.21) | 0 |
| Increased IOP | 2 (1.9) | (0.23, 6.59) | 2 | 3 (2.7) | (0.55, 7.56) | 3 |
| Rhegmatogenous RD | 0 (0.0) | (0.00, 3.39) | 0 | 1 (0.9) | (0.02, 4.83) | 1 |
| Toxic anterior segment syndrome | 0 (0.0) | (0.00, 3.39) | 0 | 0 (0.0) | (0.00, 3.21) | 0 |
| Secondary IOL intervention – Exchange | 0 (0.0) | (0.00, 3.39) | 0 | 0 (0.0) | (0.00, 3.21) | 0 |
| Secondary IOL intervention – Removal | 0 (0.0) | (0.00, 3.39) | 0 | 1 (0.9) | (0.02, 4.83) | 1 |
| Secondary IOL intervention – Reposition | 0 (0.0) | (0.00, 3.39) | 0 | 0 (0.0) | (0.00, 3.21) | 0 |

Percentages are calculated as (n/N)*100

**Table 21: Supportive Characterization of Ocular Adverse Events in Second Eyes based on a Modified Version of AAO Consensus (Masket et al., 2017) for AcrySof™ IQ Vivity™ and Monofocal IOL Groups (Safety Analysis Set)**

| | AcrySof IQ Vivity IOL Second Implanted Eyes N = 106 | | | Monofocal IOL Second Implanted Eyes N = 113 | | |
|---|---|---|---|---|---|---|
| **Adverse Event** | **n (%)** | **2-sided 95% CI** | **E** | **n (%)** | **2-sided 95% CI** | **E** |
| Chronic anterior uveitis | 0 (0.0) | (0.00, 3.42) | 0 | 0 (0.0) | (0.00, 3.21) | 0 |
| Clinically significant cystoid macular edema | 0 (0.0) | (0.00, 3.42) | 0 | 0 (0.0) | (0.00, 3.21) | 0 |
| Visually significant corneal edema | 0 (0.0) | (0.00, 3.42) | 0 | 0 (0.0) | (0.00, 3.21) | 0 |
| Endophthalmitis | 0 (0.0) | (0.00, 3.42) | 0 | 0 (0.0) | (0.00, 3.21) | 0 |
| Mechanical pupillary block | 0 (0.0) | (0.00, 3.42) | 0 | 0 (0.0) | (0.00, 3.21) | 0 |
| Increased IOP | 2 (1.9) | (0.23, 6.65) | 2 | 2 (1.8) | (0.22, 6.25) | 2 |
| Rhegmatogenous RD | 0 (0.0) | (0.00, 3.42) | 0 | 0 (0.0) | (0.00, 3.21) | 0 |
| Toxic anterior segment syndrome | 0 (0.0) | (0.00, 3.42) | 0 | 0 (0.0) | (0.00, 3.21) | 0 |
| Secondary IOL intervention – Exchange | 0 (0.0) | (0.00, 3.42) | 0 | 0 (0.0) | (0.00, 3.21) | 0 |
| Secondary IOL intervention – Removal | 0 (0.0) | (0.00, 3.42) | 0 | 0 (0.0) | (0.00, 3.21) | 0 |
| Secondary IOL intervention – Reposition | 0 (0.0) | (0.00, 3.42) | 0 | 0 (0.0) | (0.00, 3.21) | 0 |

Percentages are calculated as (n/N)*100

### Device-Related Adverse Events

Two eyes (both from 1 subject) out of 213 eyes implanted with the Vivity IOL experienced non-serious AEs of photophobia. One eye out of 226 eyes implanted with the Monofocal IOL experienced a serious AE of photopsia, as well as the subsequent SSI of IOL explant.

### Intraoperative Problems

One intraoperative problem was reported during the study: an event of iris damage during second eye implantation with the Vivity IOL. The IOL was successfully implanted and the subject completed the study. Iris Transillumination was noted during the slit-lamp exam for this eye at the 1 Day, 1 Month, and 6 Month visits. However, no other adverse sequelae associated with the iris damage during surgery were reported during the study.

### Contrast Sensitivity

Monocular mesopic contrast sensitivity (with and without glare) was assessed at 6 months for the AcrySof™ IQ Vivity™ IOL and the Monofocal Control IOL. Data were obtained from 107 and 111 subjects in the Vivity and Monofocal Control IOL groups, respectively, using a backlit sine wave grating chart system (CSV1000-HGT, VectorVision, Greenville, OH).

A summary of median contrast sensitivity data is depicted in Table 22. The AcrySof IQ Vivity IOL was associated with a reduction in monocular mesopic contrast sensitivity with and without glare compared to the Monofocal Control IOL, as evidenced by reductions in the median log contrast with increasing spatial frequency test condition (Table 22). Additionally, more patients were unable to see the reference pattern at higher spatial frequencies with the AcrySof IQ Vivity IOL as compared to the Monofocal Control IOL (17.8% vs. 3.6% without glare and 18.7% vs. 4.5% with glare at 6 cpd; and 43.0% vs. 20.7% without glare and 52.3% vs. 25.2% with glare at 12 cpd). For more information, see Warning 4.

**Table 22: Monocular Mesopic Contrast Sensitivity at 6 Months**

| | | | Mesopic Without Glare | | | Mesopic With Glare | | |
|---|---|---|---|---|---|---|---|---|
| | | | | Eyes that did not see the reference pattern[a] | | | Eyes that did not see the reference pattern[a] | |
| **Spatial Frequency** | **IOL Group** | **N** | **Median (log units)** | **n** | **%** | **Median (log units)** | **n** | **%** |
| **1.5 Cycles Per Degree (CPD)** | **Vivity** | 107 | 1.52 | 0 | 0.0 | 1.52 | 0 | 0.0 |
| | **Monofocal** | 111 | 1.52 | 0 | 0.0 | 1.37 | 1 | 0.9 |
| **3 Cycles Per Degree (CPD)** | **Vivity** | 107 | 1.34 | 0 | 0.0 | 1.34 | 1 | 0.9 |
| | **Monofocal** | 111 | 1.49 | 1 | 0.9 | 1.49 | 1 | 0.9 |
| **6 Cycles Per Degree (CPD)** | **Vivity** | 107 | 1.38 | 19 | 17.8 | 1.38 | 20 | 18.7 |
| | **Monofocal** | 111 | 1.55 | 4 | 3.6 | 1.55 | 5 | 4.5 |
| **12 Cycles Per Degree (CPD)** | **Vivity** | 107 | 0.61 | 46 | 43.0 | < 0.61 | 56 | 52.3 |
| | **Monofocal** | 111 | 0.91 | 23 | 20.7 | 0.91 | 28 | 25.2 |

[a]Number of eyes unable to see a targeted spatial frequency at any available contrast

### Low Contrast Visual Acuity

Monocular (first implanted eye) low contrast visual acuity assessments were performed using 10% and 25% low contrast visual acuity computerized logMAR charts. Best corrected visual acuity at distance (4 m) and distance corrected visual acuity at Intermediate (66 cm) and Near (40 cm) were tested under photopic conditions, with results depicted in Table 23. Differences in mean best corrected distance visual acuity between the 2 groups for both contrast levels were approximately 1 line or less and within the test-retest variability of low contrast visual acuity (Cho 2004). Greater than 1 line improvements in intermediate visual acuity (improvement of 0.132 logMAR and 0.141 logMAR at 10% and 25% contrast respectively) and near visual acuity (improvement of 0.118 logMAR and 0.137 logMAR) were observed for the Vivity IOL over the Monofocal Control IOL at both contrast levels.

**Table 23:** Summary of Monocular, Photopic, Low Contrast Distance, Intermediate, and Near VAs by Test Condition and IOL Group

| Test Condition | IOL Group | Monocular, Photopic, Low Contrast VA (Mean logMAR, Approximate Snellen Line Equivalent) | | |
|---|---|---|---|---|
| | | Distance | Intermediate (66 cm) | Near (40 cm) |
| 10% Contrast | Vivity IOL | 0.393, 20/50 | 0.534, 20/63 | 0.764, 20/125 |
| | Monofocal Control IOL | 0.281, 20/40 | 0.666, 20/100 | 0.882, 20/160 |
| 25% Contrast | Vivity IOL | 0.223, 20/32 | 0.372, 20/50 | 0.593, 20/80 |
| | Monofocal Control IOL | 0.137, 20/25 | 0.513, 20/63 | 0.730, 20/100 |

## Visual Disturbances

A Patient Reported Outcome Measure instrument was developed and validated for use in this clinical study to assess visual disturbances. Subjects who reported experiencing a particular visual disturbance (glare, halos, starbursts, hazy vision, blurred vision, double vision in one or both eyes, color distortion, or peripheral dark area) were asked to rate the severity, frequency, and bothersomeness of the disturbance. A subject may report multiple symptoms. As demonstrated in Tables 24 and 25, rates of reports of severe or very bothersome visual disturbances/distortions were low (< 4%) for the AcrySof™ IQ Vivity™ IOL and the monofocal control IOL (< 3%) groups at 6 months.

**Table 24: Comparison of Visual Disturbance Bothersomeness for AcrySof™ IQ Vivity™ IOL and Monofocal Control IOL 6 months Postoperative (following second eye implantation)**

| | **AcrySof™ IQ Vivity™ IOL N = 106** | | | | | | **Monofocal Control IOL N = 113** | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Visual Disturbance** | **Total** | **Not at all Bothered[a] n (%[b])** | **A Little bit n (%[b])** | **Somewhat n (%[b])** | **Quite a bit n (%[b])** | **Very much n (%[b])** | **Total** | **Not at all bothered[a] n (%[b])** | **A Little bit n (%[b])** | **Somewhat n (%[b])** | **Quite a bit n (%[b])** | **Very much n (%[b])** |
| Starbursts | 106 | 78 (73.6) | 15 (14.2) | 10 (9.4) | 1 (0.9) | 2 (1.9) | 110 | 79 (71.8) | 16 (14.5) | 12 (10.9) | 2 (1.8) | 1 (0.9) |
| Halos | 106 | 88 (83.0) | 13 (12.3) | 3 (2.8) | 1 (0.9) | 1 (0.9) | 110 | 98 (89.1) | 6 (5.5) | 5 (4.5) | 1 (0.9) | 0 (0.0) |
| Glare | 105 | 82 (78.1) | 12 (11.4) | 7 (6.7) | 4 (3.8) | 0 (0.0) | 111 | 84 (75.7) | 11 (9.9) | 13 (11.7) | 3 (2.7) | 0 (0.0) |
| Hazy Vision | 105 | 94 (89.5) | 5 (4.8) | 3 (2.9) | 3 (2.9) | 0 (0.0) | 111 | 98 (88.3) | 4 (3.6) | 7 (6.3) | 2 (1.8) | 0 (0.0) |
| Blurred Vision | 106 | 97 (91.5) | 0 (0.0) | 5 (4.7) | 3 (2.8) | 1 (0.9) | 111 | 89 (80.2) | 10 (9.0) | 8 (7.2) | 2 (1.8) | 2 (1.8) |
| Double Vision | 106 | 104 (98.1) | 1 (0.9) | 1 (0.9) | 0 (0.0) | 0 (0.0) | 111 | 110 (99.1) | 0 (0.0) | 1 (0.9) | 0 (0.0) | 0 (0.0) |
| Dark Area *Negative Dysphotopsia* | 106 | 98 (92.5) | 6 (5.7) | 0 (0.0) | 1 (0.9) | 1 (0.9) | 111 | 100 (90.1) | 6 (5.4) | 3 (2.7) | 1 (0.9) | 1 (0.9) |

[a] Includes patients who did not experience the disturbance and those reporting being not at all bothered
[b] Percentages calculated as (n / Total) * 100

**Table 25: Comparison of Visual Disturbance Severity for AcrySof™ IQ Vivity™ IOL and Monofocal Control IOL 6 months Postoperative (following second eye implantation)**

| | AcrySof™ IQ Vivity™ IOL N = 106 | | | | | | Monofocal Control IOL N = 113 | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Visual Disturbance** | **Total** | **None[a] n (%[b])** | **A Little n (%[b])** | **Mild n (%[b])** | **Moderate n (%[b])** | **Severe n (%[b])** | **Total** | **None[a] n (%[b])** | **A Little n (%[b])** | **Mild n (%[b])** | **Moderate n (%[b])** | **Severe n (%[b])** |
| Starbursts | 106 | 70 (66.0) | 3 (2.8) | 15 (14.2) | 14 (13.2) | 4 (3.8) | 110 | 68 (61.8) | 8 (7.3) | 18 (16.4) | 13 (11.8) | 3 (2.7) |
| Halos | 106 | 78 (73.6) | 6 (5.7) | 12 (11.3) | 9 (8.5) | 1 (0.9) | 110 | 91 (82.7) | 5 (4.5) | 9 (8.2) | 4 (3.6) | 1 (0.9) |
| Glare | 105 | 81 (77.1) | 0 (0.0) | 15 (14.3) | 9 (8.6) | 0 (0.0) | 111 | 81 (73.0) | 8 (7.2) | 11 (9.9) | 11 (9.9) | 0 (0.0) |
| Hazy Vision | 105 | 93 (88.6) | 2 (1.9) | 5 (4.8) | 5 (4.8) | 0 (0.0) | 111 | 96 (86.5) | 3 (2.7) | 3 (2.7) | 9 (8.1) | 0 (0.0) |
| Blurred Vision | 106 | 96 (90.6) | 1 (0.9) | 8 (7.5) | 1 (0.9) | 0 (0.0) | 111 | 89 (80.2) | 9 (8.1) | 10 (9.0) | 3 (2.7) | 0 (0.0) |
| Double Vision | 106 | 104 (98.1) | 1 (0.9) | 1 (0.9) | 0 (0.0) | 0 (0.0) | 111 | 110 (99.1) | 0 (0.0) | 1 (0.9) | 0 (0.0) | 0 (0.0) |
| Dark Area *Negative Dysphotopsia* | 106 | 96 (90.6) | 5 (4.7) | 3 (2.8) | 1 (0.9) | 1 (0.9) | 111 | 96 (86.5) | 6 (5.4) | 7 (6.3) | 1 (0.9) | 1 (0.9) |

[a] Includes patients who did not experience the disturbance and those reporting severity of "none"
[b] Percentages calculated as (n / Total) * 100

## 2. AcrySof™ TORIC INTRAOCULAR LENS CLINICAL STUDY OVERVIEW

A multicenter, subject-masked, randomized, prospective clinical study was performed in the United States to evaluate the safety and effectiveness of AcrySof™ Toric IOL (Models SA60T3-SA60T5) when implanted into the capsular bag following phacoemulsification. In this study, the results achieved by the subjects successfully followed for 6 months postoperatively (defined as 120 to 180 days postoperative after the second eye implant) provide reasonable assurance that the AcrySof™ Toric IOL is a safe and effective device for the visual correction of aphakia and pre-existing corneal astigmatism following cataract surgery. The clinical study results (shown below) illustrate excellent rotational stability leading to significant reduction or elimination of residual refractive cylinder and significantly improved uncorrected distance visual acuity, which results in increased distance spectacle independence.

This clinical study was conducted to demonstrate the safety and effectiveness of the AcrySof™ Toric Posterior Chamber IOL Model SA60TT (which is a collective way to refer to Models SA60T3, SA60T4, and SA60T5). This was a randomized clinical study that included the AcrySof™ IOL Model SA60AT as a control lens. Only data from the first operative eye from those subjects who received either a Model SA60TT or Model SA60AT intraocular lens are included. Three different lens models of varying cylinder correction were evaluated in this clinical study. The three different models evaluated and their applicable cylinder powers are listed in Table 26.

**Table 26: IOL Models and Cylinder Power in Clinical Study**

| IOL Model[**] | Cylinder Power | | Recommended Corneal Astigmatism Correction Ranges |
|---|---|---|---|
| | at IOL plane | at corneal plane | |
| SA60T3 | 1.50 | 1.03 | 0.75 - 1.50 D |
| SA60T4 | 2.25 | 1.55 | 1.50 - 2.00 D |
| SA60T5 | 3.00 | 2.06 | 2.00 D & up |

[**]These IOL models are collectively referred to as SA60TT in the text that follows.

The recommended corneal astigmatism correction ranges are based on 1) the preoperative corneal astigmatism and 2) the predicted effect of 0.5 diopter surgically induced astigmatism for a standardized temporal incision. The combination of these two parameters is used in Alcon provided software to select the appropriate Toric IOL model and recommended axis of placement. As such,

the recommended range of corneal astigmatism to be corrected while not identical, is directly related to, the preoperative keratometric cylinder.

**AcrySof™ TORIC INTRAOCULAR LENS CLINICAL STUDY SUBJECT POPULATION**

Specific requirements for study participation included (1) ≥0.75 D of preoperative With-the-Rule or preoperative oblique regular corneal astigmatism and (2) ≥1.00 D of preoperative Against-the-Rule regular corneal astigmatism. The subject population implanted with a Model SA60TT in the first operative eye consists of 53.3% females and 46.7% males. The subject population implanted with the Model SA60AT (control) intraocular lens consists of 57.2% females and 42.8% males. Stratifying by race for the Model SA60TT population, 97.6% are Caucasian, 2.0% are Black, and 0.4% are other. The control (SA60AT) population is 95.6% Caucasian, 1.6% Black, 1.2% Asian and 1.6% other. The mean age for the population receiving the Model SA60TT and SA60AT were 70.0 and 72.4, respectively.

**AcrySof™ TORIC INTRAOCULAR LENS UNCORRECTED DISTANCE VISUAL ACUITY (UCDVA)**

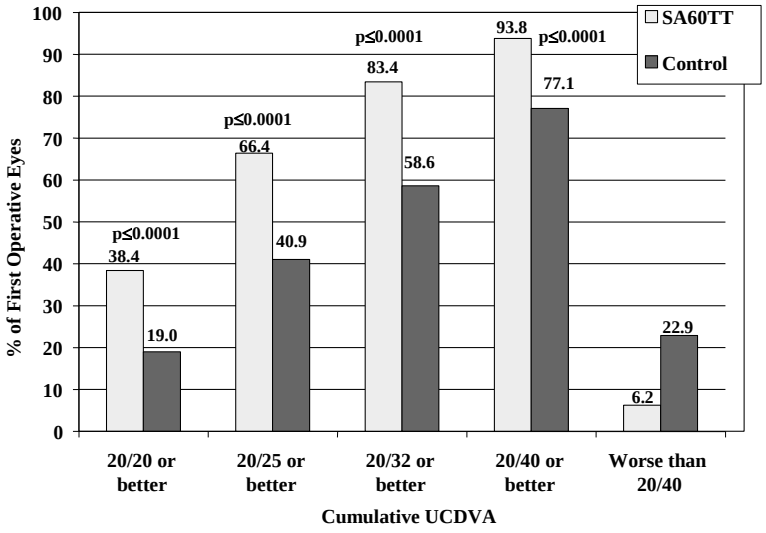
A summary of uncorrected distance visual acuity achieved for Models SA60TT and SA60AT at six months postoperatively (Form 5 visit) is presented in Table 27.

**Table 27**: **Uncorrected Distance Visual Acuity, Status at Form 5**
**Lens Models SA60TT and SA60AT, All Implanted**

| | Sample size | Acuity | | | | | | | | | | 20/40 or better | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | 20/20 or better | | 20/25 | | 20/32 | | 20/40 | | Worse than 20/40 | | | |
| | N | n | % | n | % | n | % | n | % | n | % | n | % |
| Total (SA60TT) | 211 | 81 | 38.4 | 59 | 28.0 | 36 | 17.1 | 22 | 10.4 | 13 | 6.2 | 198 | 93.8 |
| Total (SA60AT) | 210 | 40 | 19.0 | 46 | 21.9 | 37 | 17.6 | 39 | 18.6 | 48 | 22.9 | 162 | 77.1 |

At six months postoperatively (Form 5 visit), shown in Figure 11, 93.8% of Model SA60TT subjects achieved 20/40 or better UCDVA (first operative eye of the All Implanted data set) compared to 77.1% of the subjects implanted with the control Model SA60AT. The difference in UCDVA between Models SA60TT and SA60AT was statistically significant (all p-values ≤0.0001) in favor of Model SA60TT.

**Figure 11: Cumulative UCDVA, Status at Form 5, Model SA60TT vs. Control**




Similar results were noted when data was analyzed by cylinder range (data provided in the Physician Labeling for SN6AT3-SN6AT5):

- The difference in cumulative UCDVA between Models SA60T3 and SA60AT was statistically significant (all p-values ≤0.0115) for each visual acuity category (20/20 or better, 20/25 or better, 20/32 or better and 20/40 or better) in favor of Model SA60T3.
- The difference in cumulative UCDVA between Models SA60T4 and SA60AT was statistically significant (all p-values ≤0.0082) for each visual acuity category (20/25 or better, 20/32 or better and 20/40 or better) in favor of Model SA60T4, with the exception of the 20/20 or better category.
- The difference in cumulative UCDVA between Models SA60T5 and SA60AT was statistically significant (all p-values ≤0.0171) for each visual acuity category (20/20 or better, 20/25 or better, 20/32 or better and 20/40 or better) in favor of Model SA60T5.

**AcrySof™ TORIC IOL BEST SPECTACLE DISTANCE CORRECTED VISUAL ACUITY (BSCDVA)**

A summary of best spectacle corrected distance visual acuity (BSCDVA) achieved at six months postoperatively (Form 5 visit) among subjects who did not have any visually significant preoperative pathology or macular degeneration at any time (Best Case) is presented in Table 28. Visual acuity achieved by the overall subject population is shown in Table 30. Control data are found for the same data sets in Tables 29 and 31, respectively.

Of the first operative eyes implanted with a Model SA60TT and examined at six months postoperatively (Form 5 visit), 100.0% achieved a BSCDVA of 20/40 or better in the Best Case dataset. These rates exceed the FDA grid rates of 96.7%.

**Table 28: BSCDVA by Age Category, Status at Form 5 - Lens Model SA60TT, Best Case**

| Age | Sample size | Acuity | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | 20/20 or better | | 20/25 | | 20/32 | | 20/40 | | Worse than 20/40 | | 20/40 or better | |
| Category | N | n | % | n | % | n | % | n | % | n | % | n | % |
| <60 | 29 | 27 | 93.1 | 1 | 3.4 | 1 | 3.4 | 0 | 0 | 0 | 0 | 29 | 100.0 |
| 60-69 | 51 | 42 | 82.4 | 7 | 13.7 | 2 | 3.9 | 0 | 0 | 0 | 0 | 51 | 100.0 |
| 70-79 | 73 | 57 | 78.1 | 13 | 17.8 | 3 | 4.1 | 0 | 0 | 0 | 0 | 73 | 100.0 |
| ≥80 | 20 | 14 | 70.0 | 4 | 20.0 | 1 | 5.0 | 1 | 5.0 | 0 | 0 | 20 | 100.0 |
| Total | 173 | 140 | 80.9 | 25 | 14.5 | 7 | 4.0 | 1 | 0.6 | 0 | 0 | 173 | 100.0 |

**Table 29: BSCDVA by Age Category, Status at Form 5 - Lens Model SA60AT, Best Case**

| Age | Sample size | Acuity | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | 20/20 or better | | 20/25 | | 20/32 | | 20/40 | | Worse than 20/40 | | 20/40 or better | |
| Category | N | n | % | n | % | n | % | n | % | n | % | n | % |
| <60 | 15 | 13 | 86.7 | 1 | 6.7 | 1 | 6.7 | 0 | 0 | 0 | 0 | 15 | 100.0 |
| 60-69 | 49 | 38 | 77.6 | 11 | 22.4 | 0 | 0 | 0 | 0 | 0 | 0 | 49 | 100.0 |
| 70-79 | 75 | 48 | 64.0 | 21 | 28.0 | 6 | 8.0 | 0 | 0 | 0 | 0 | 75 | 100.0 |
| ≥80 | 32 | 19 | 59.4 | 8 | 25.0 | 2 | 6.3 | 3 | 9.4 | 0 | 0 | 32 | 100.0 |
| Total | 171 | 118 | 69.0 | 41 | 24.0 | 9 | 5.3 | 3 | 1.8 | 0 | 0 | 171 | 100.0 |

Of the first operative eyes implanted with a Model SA60TT and examined at six months postoperatively (Form 5 visit), 100.0% achieved a BSCDVA of 20/40 or better in the All Implanted dataset. These rates exceed the FDA grid rates of 92.5%.

**Table 30: BSCDVA by Age Category, Status at Form 5 - Lens Model SA60TT, All Implanted**

| Age | Sample size | Acuity | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | 20/20 or better | | 20/25 | | 20/32 | | 20/40 | | Worse than 20/40 | | 20/40 or better | |
| Category | N | n | % | n | % | n | % | n | % | n | % | n | % |
| <60 | 33 | 30 | 90.9 | 2 | 6.1 | 1 | 3.0 | 0 | 0 | 0 | 0 | 33 | 100.0 |
| 60-69 | 56 | 47 | 83.9 | 7 | 12.5 | 2 | 3.6 | 0 | 0 | 0 | 0 | 56 | 100.0 |
| 70-79 | 90 | 72 | 80.0 | 15 | 16.7 | 3 | 3.3 | 0 | 0 | 0 | 0 | 90 | 100.0 |
| ≥80 | 32 | 22 | 68.8 | 5 | 15.6 | 4 | 12.5 | 1 | 3.1 | 0 | 0 | 32 | 100.0 |
| Total | 211 | 171 | 81.0 | 29 | 13.7 | 10 | 4.7 | 1 | 0.5 | 0 | 0 | 211 | 100.0 |

**Table 31: BSCDVA by Age Category, Status at Form 5 - Lens Model SA60AT, All Implanted**

| Age | Sample size | Acuity | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | 20/20 or better | | 20/25 | | 20/32 | | 20/40 | | Worse than 20/40 | | 20/40 or better | |
| Category | N | n | % | n | % | n | % | n | % | n | % | n | % |
| <60 | 15 | 13 | 86.7 | 1 | 6.7 | 1 | 6.7 | 0 | 0 | 0 | 0 | 15 | 100.0 |
| 60-69 | 54 | 41 | 75.9 | 12 | 22.2 | 1 | 1.9 | 0 | 0 | 0 | 0 | 54 | 100.0 |
| 70-79 | 91 | 59 | 64.8 | 22 | 24.2 | 10 | 11.0 | 0 | 0 | 0 | 0 | 91 | 100.0 |
| ≥80 | 49 | 28 | 57.1 | 13 | 26.5 | 2 | 4.1 | 3 | 6.1 | 3 | 6.1 | 46 | 93.9 |
| Total | 209 | 141 | 67.5 | 48 | 23.0 | 14 | 6.7 | 3 | 1.4 | 3 | 1.4 | 206 | 98.6 |

Figures 12-14 show a summary of cumulative best corrected visual acuities for each Toric model compared to the control subjects in the same cylinder range for the All Implanted dataset.

**Figure 12: Cumulative BSCDVA, Model SA60T3 vs. Control, Form 5, All Implanted**

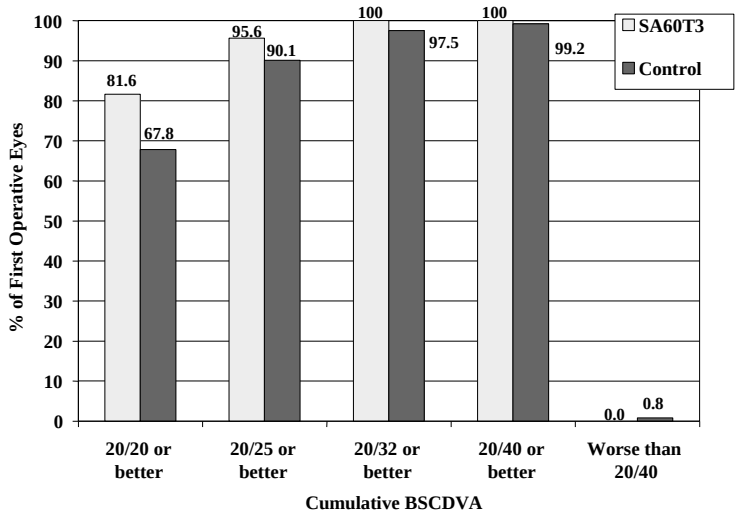



**Figure 13: Cumulative BSCDVA, Model SA60T4 vs. Control, Form 5, All Implanted**

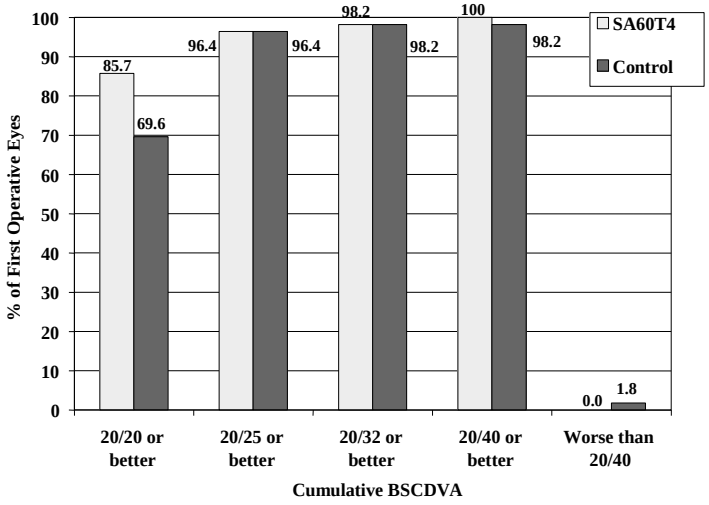
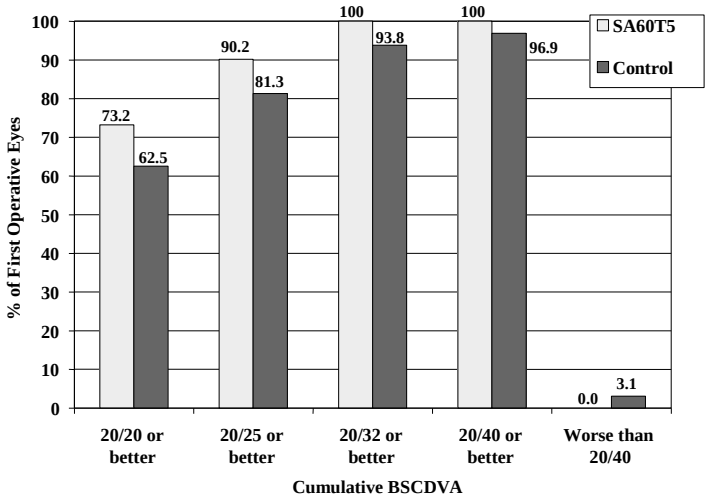


**Figure 14: Cumulative BSCDVA, Model SA60T5 vs. Control, Form 5, All Implanted**




**AcrySof™ TORIC INTRAOCULAR LENS ABSOLUTE RESIDUAL REFRACTIVE CYLINDER**

Figures 15-17 demonstrate that residual refractive cylinder values were statistically significantly lower among those subjects implanted with an AcrySof™ Toric IOL Model SA60T3, SA60T4 or SA60T5 when compared to the corresponding subjects implanted with the control Model SA60AT. Subjects implanted with an AcrySof™ Toric Model SA60T3 showed a 62.4% mean reduction in refractive cylinder from the preoperative visit (keratometric cylinder) as compared to the 10.8% mean reduction for subjects implanted with the concurrent control Model SA60AT. Subjects implanted with an AcrySof™ Toric IOL Model SA60T4 or SA60T5 showed similar results with a mean reduction in refractive cylinder of 54.8 % and 67.8%, respectively, as compared to subjects implanted with the concurrent control model who had a mean reduction in refractive cylinder of 22.1% and 27.7%, respectively. Each of the AcrySof™ Toric Lens Models SA60T3, SA60T4 and SA60T5 had at least a 3-fold increase in the likelihood of achieving residual refractive cylinder of 0.5 D or less as compared to the corresponding control model.

**Figure 15: Absolute Residual Refractive Cylinder, Model SA60T3 vs. Control, Form 5, All Implanted**

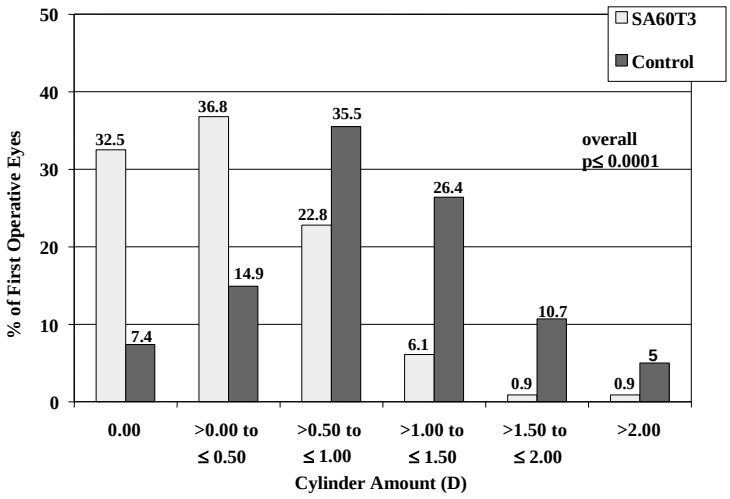


**Figure 16: Absolute Residual Refractive Cylinder, Model SA60T4 vs. Control, Form 5, All Implanted**

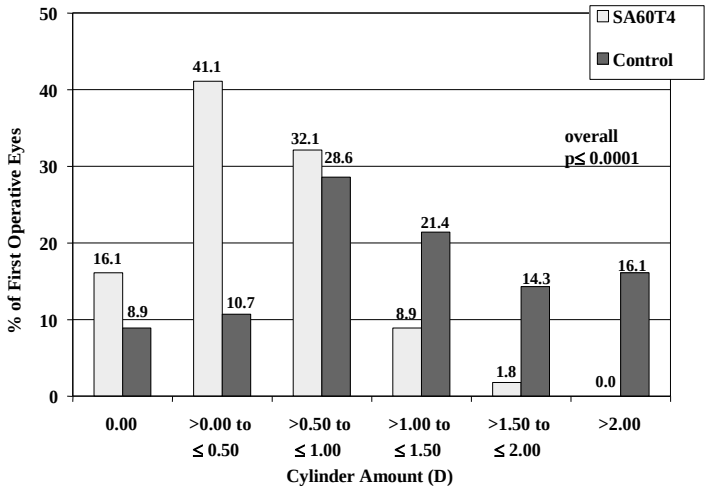
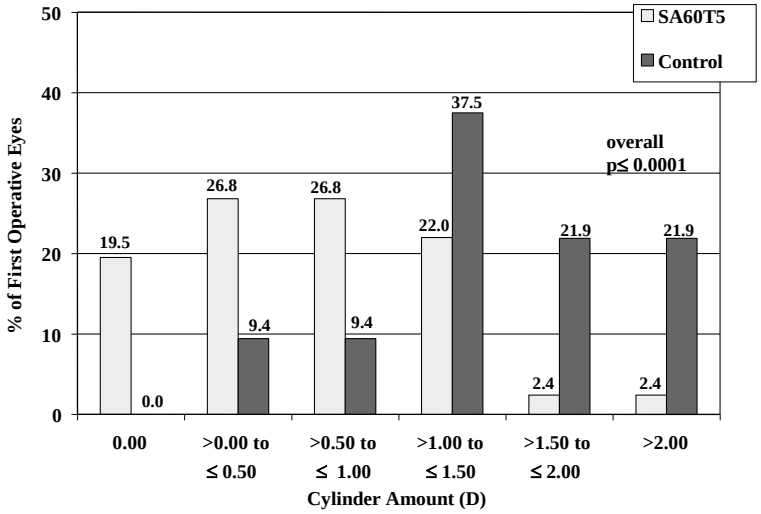



**Figure 17: Absolute Residual Refractive Cylinder, Model SA60T5 vs. Control, Form 5, All Implanted**




## AcrySof™ TORIC INTRAOCULAR LENS STABILITY OF CYLINDER

Subjects implanted with lens Model SA60TT exhibited stability of cylinder at Form 4 (3 months) with greater than 90% of all subjects changing less than or equal to 1.00 diopter at consecutive visits between Form 3 (one month) and Form 6 (twelve months) as described in Tables 32-35.

## Table 32: AcrySof™ Toric IOL: Stability of Cylinder (Eyes that had 2 consecutive exams, but not necessarily every follow-up exam)

| Recommended Corneal Astigmatism Correction Ranges | Toric IOL Model | Magnitude of Vector Change in Cylinder | 1 and 3 Months n/N,% | 3 and 6 Months n/N,% | 6 and 12 Months n/N,% |
|---|---|---|---|---|---|
| < 1.5 D | SA60T3 | ≤ 1.00 D | 106/107,99.07% | 101/105,96.19% | 55/55,100.00% |
| | | Mean Change | 0.28 | 0.29 | 0.20 |
| | | SD | 0.32 | 0.33 | 0.25 |
| ≥ 1.5 - < 2.0 D | SA60T4 | ≤ 1.00 D | 54/56,96.43% | 53/54,98.15% | 25/27,92.59% |
| | | Mean Change | 0.40 | 0.27 | 0.46 |
| | | SD | 0.35 | 0.22 | 0.45 |
| ≥ 2.0 D | SA60T5 | ≤ 1.00 D | 40/45,88.89% | 35/40,87.50% | 27/30,90.00% |
| | | Mean Change | 0.43 | 0.42 | 0.41 |
| | | SD | 0.44 | 0.45 | 0.38 |
| Combined | SA60TT | ≤ 1.00 D | 200/208,96.15% (93.54,98.77) | 189/199,94.97% (91.94,98.01) | 107/112,95.54% (91.71,99.36) |
| | | Mean Change | 0.35 | 0.31 | 0.32 |
| | | SD | 0.36 | 0.34 | 0.36 |
| | | 95% CI | 0.30,0.39 | 0.26,0.36 | 0.25,0.39 |
| n/N,%,(%CI) are for percent with change between ± 1.00D | | | | | |

## Table 33: AcrySof™ Toric IOL: Stability of Cylinder (Eyes that had every follow-up exam up to Form 6, 12 months)

| Recommended Corneal Astigmatism Correction Ranges | Toric IOL Model | Magnitude of Vector Change in Cylinder | 1 and 3 Months n/N,% | 3 and 6 Months n/N,% | 6 and 12 Months n/N,% |
|---|---|---|---|---|---|
| < 1.5 D | SA60T3 | ≤ 1.00 D | 34/34,100.00% | 34/34,100.00% | 34/34,100.00% |
| | | Mean Change | 0.25 | 0.24 | 0.21 |
| | | SD | 0.23 | 0.22 | 0.24 |
| ≥ 1.5 - < 2.0 D | SA60T4 | ≤ 1.00 D | 17/17,100.00% | 16/17,94.12% | 16/17,94.12% |
| | | Mean Change | 0.27 | 0.25 | 0.35 |
| | | SD | 0.25 | 0.26 | 0.33 |
| ≥ 2.0 D | SA60T5 | ≤ 1.00 D | 17/19,89.47% | 15/19,78.95% | 16/19,84.21% |
| | | Mean Change | 0.44 | 0.56 | 0.52 |
| | | SD | 0.47 | 0.50 | 0.43 |
| Combined | SA60TT | ≤ 1.00 D | 68/70,97.14% (93.23,100.00) | 65/70,92.86% (86.82,98.90) | 66/70,94.29% (88.84,99.73) |
| | | Mean Change | 0.31 | 0.33 | 0.33 |
| | | SD | 0.32 | 0.35 | 0.34 |
| | | 95% CI | 0.23,0.38 | 0.24,0.41 | 0.25,0.41 |
| n/N,%,(%CI) are for percent with change between ± 1.00D | | | | | |

**Table 34: AcrySof™ Toric IOL: Stability of Absolute Cylinder**
**(Eyes that had 2 consecutive exams, but not necessarily every follow-up exam)**

| Recommended Corneal Astigmatism Correction Ranges | Toric IOL Model | Magnitude of Change in Absolute Cylinder | 1 and 3 Months n/N,% | 3 and 6 Months n/N,% | 6 and 12 Months n/N,% |
|---|---|---|---|---|---|
| < 1.5 D | SA60T3 | ≤ 1.00 D | 107/107,100.00% | 104/105,99.05% | 55/55,100.00% |
| | | Mean Change | 0.04 | 0.02 | 0.05 |
| | | SD | 0.32 | 0.38 | 0.29 |
| ≥ 1.5 - < 2.0 D | SA60T4 | ≤ 1.00 D | 54/56,96.43% | 54/54,100.00% | 27/27,100.00% |
| | | Mean Change | 0.18 | 0.05 | -0.12 |
| | | SD | 0.42 | 0.27 | 0.41 |
| ≥ 2.0 D | SA60T5 | ≤ 1.00 D | 44/45,97.78% | 37/40,92.50% | 29/30,96.67% |
| | | Mean Change | 0.09 | 0.06 | 0.00 |
| | | SD | 0.38 | 0.49 | 0.45 |
| Combined | SA60TT | ≤ 1.00 D | 205/208,98.56% (96.93,100.00) | 195/199,97.99% (96.04,99.94) | 111/112,99.11% (97.36,100.00) |
| | | Mean Change | 0.09 | 0.03 | -0.01 |
| | | SD | 0.37 | 0.38 | 0.37 |
| | | 95% CI | 0.04,0.14 | -0.02,0.09 | -0.08,0.06 |
| n/N,%,(%CI) are for percent with change between ± 1.00D | | | | | |

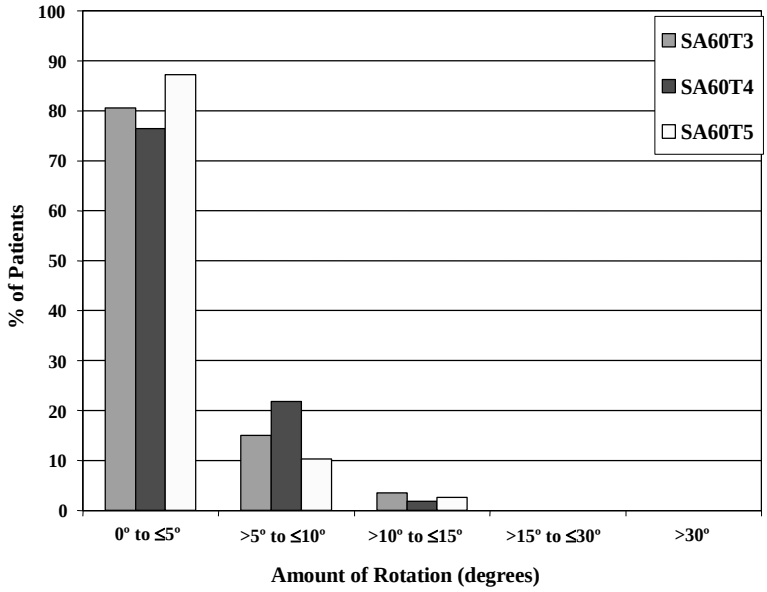
**Table 35: AcrySof™ Toric IOL: Stability of Absolute Cylinder**
**(Eyes that had every follow-up exam up to Form 6, 12 months)**

| Recommended Corneal Astigmatism Correction Ranges | Toric IOL Model | Magnitude of Change in Absolute Cylinder | 1 and 3 Months n/N,% | 3 and 6 Months n/N,% | 6 and 12 Months n/N,% |
|---|---|---|---|---|---|
| < 1.5 D | SA60T3 | ≤ 1.00 D | 34/34,100.00% | 34/34,100.00% | 34/34,100.00% |
| | | Mean Change | 0.01 | -0.01 | 0.07 |
| | | SD | 0.28 | 0.31 | 0.28 |
| ≥ 1.5 - < 2.0 D | SA60T4 | ≤ 1.00 D | 17/17,100.00% | 17/17,100.00% | 17/17,100.00% |
| | | Mean Change | 0.06 | 0.19 | -0.04 |
| | | SD | 0.30 | 0.21 | 0.42 |
| ≥ 2.0 D | SA60T5 | ≤ 1.00 D | 18/19,94.74% | 17/19,89.47% | 18/19,94.74% |
| | | Mean Change | 0.17 | 0.05 | 0.01 |
| | | SD | 0.45 | 0.54 | 0.55 |
| Combined | SA60TT | ≤ 1.00 D | 69/70,98.57% (95.78,100.00) | 68/70,97.14% (93.23,100.00) | 69/70,98.57% (95.78,100.00) |
| | | Mean Change | 0.07 | 0.05 | 0.03 |
| | | SD | 0.34 | 0.38 | 0.40 |
| | | 95% CI | -0.01,0.15 | -0.04,0.14 | -0.07,0.12 |
| n/N,%,(%CI) are for percent with change between ± 1.00D | | | | | |

**AcrySof™ TORIC INTRAOCULAR LENS ROTATIONAL STABILITY**

A summary of the change in axis orientation (rotation) from the operative visit to the Form 5 visit (120-180 days postoperative) is presented in Figure 18. The rotational stability of the AcrySof™ Toric Model SA60TT is established with the majority of the lenses rotating ≤ 5°. In addition, the amount of rotation seen in each AcrySof™ Toric IOL model is independent of the amount of cylinder power present on the lens.

**Figure 18: Change in Axis Orientation from Operative Visit to Form 5, All Implanted**




## AcrySof™ TORIC INTRAOCULAR LENS ADVERSE EVENTS

The incidence of cumulative adverse events for the Model SA60TT compared favorably to the FDA historical grid rates. Only the rates for retinal detachment/repair and surgical reintervention exceeded the FDA historical grid (Table 36). However, neither of these rates were statistically significant (p=0.5196 and p=0.1336, respectively). No occurrences of persistent adverse events were observed in any subjects implanted with the AcrySof™ Toric IOL.

**Table 36: Adverse Events Incidence Rates, First Eye – Safety**

| | Model SA60TT N=244 | | FDA Grid Rate |
|---|---|---|---|
| **Cumulative Adverse Events** | **N** | **%** | **%** |
| Retinal Detachment/Repair | 1 | 0.4 | 0.3 |
| Surgical Reintervention | 4** | 1.6 | 0.8 |
| IOL Reposition Due to Rotation | 1 | 0.4 | NA |
| IOL Replacement Due to Rotation | 1 | 0.4 | NA |
| Laser Treatment | 2 | 0.8 | NA |
| Paracentesis | 1 | 0.4 | NA |

The incidence rates in this table are based upon the number of eyes with an event divided by the number of eyes implanted.
Cumulative adverse events are those events that have occurred at any time during the clinical study.
FDA Grid Rate = FDA Grid of Adverse Events with Posterior Chamber Intraocular Lens Historical Controls, FDA Intraocular Lens Guidance Document, Annex B (October 14, 1999)
**There were 5 occurrences of surgical reintervention in 4 eyes for Model SA60TT first eye

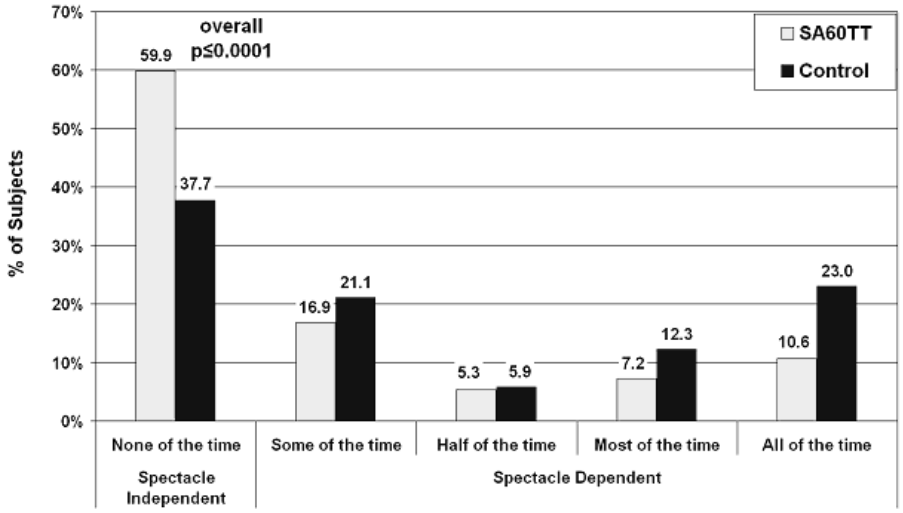
The incidence of cumulative adverse events for the Model SA60TT also compared favorably to the concurrent control.

**AcrySof™ TORIC INTRAOCULAR LENS DISTANCE-VISION SPECTACLE INDEPENDENCE**

Spectacle independence was assessed in the study by direct subject responses obtained from a self-reported, binocular subject questionnaire. Since the AcrySof™ Toric IOL study was completed in 2005, the questionnaire utilized was not developed using the US FDA guidance document "*Patient-Reported Outcomes Measures: Use in Medical Product Development to Support Labeling Claims"* dated December 2009.

Statistically significantly more Model SA60TT subjects reported postoperative distance-vision spectacle independence compared to Model SA60AT subjects (59.9% versus 37.7%, respectively) when unilaterally implanted. Distance-vision spectacle independence was defined as the percentage of subjects who selected the "none of the time" response for distance-vision frequency-of-spectacle-wear. Spectacle dependence was defined as subjects indicating any reliance on glasses for distance-vision and represents the summation of the "some of the time", "half of the time", "most of the time" and "all of the time" frequency-of-spectacle-wear responses. Consequently, fewer Model SA60TT subjects were spectacle dependent at 40.1% compared to 62.3% of the Model SA60AT subjects. Figure 19 illustrates the distance-vision frequency-of-spectacle-wear distributions between Model SA60TT and Model SA60AT groups. Implantation of an AcrySof™ Toric Intraocular lens in astigmatic subjects provides significantly improved distance-vision spectacle independence relative to a conventional monofocal IOL.

**Figure 19: Distance-Vision Spectacle Independence: Frequency of Spectacle Wear, Form 5, All Implanted**




## 3. OVERVIEW OF AcrySof ACRYLIC FOLDABLE POSTERIOR CHAMBER LENS CLINICAL STUDIES

Two clinical studies have been performed on AcrySof Acrylic Foldable Posterior Chamber Lenses. The clinical study of the AcrySof Acrylic Foldable Multipiece Posterior Chamber Lens (Model MA60BM) began in December 1990 and the clinical study of the AcrySof Acrylic Foldable Single-Piece Posterior Chamber Lens (Model SA30EL) began in January 1997. AcrySof Acrylic Foldable Single-Piece Posterior Chamber Lens (Single-Piece) is a modification of the parent AcrySof Acrylic Foldable Multipiece Posterior Chamber Lens (Multipiece) and therefore data from the Multipiece clinical study are applicable to Single-Piece lens models. However, only data from the Single-Piece clinical study are included for reference in this labeling.

### AcrySof ACRYLIC FOLDABLE SINGLE-PIECE LENS CLINICAL STUDY

The results achieved by the patients successfully followed for 330 to 420 days postoperatively provide reasonable assurance that the AcrySof Single-Piece lens is a safe and effective device for the visual correction of aphakia. Since the clinical study of the AcrySof Single-Piece lens was conducted with the lens intended for implantation in the capsular bag, there is insufficient clinical data to demonstrate its safety and efficacy for placement in the ciliary sulcus.

### AcrySof ACRYLIC FOLDABLE SINGLE-PIECE LENS PATIENT POPULATION

The subject population in the clinical studies consisted of 62.8% females and 37.2% males. Stratifying by race, 91.9% were Caucasian, 6.8% were Black, and 1.3% were Other. The mean age for the total population was 70 years.

### AcrySof ACRYLIC FOLDABLE SINGLE-PIECE LENS VISUAL ACUITY

A summary of visual acuity achieved at 330 to 420 days postoperatively by subjects who did not have preoperative ocular pathology, abnormal corneas, or macular degeneration at any time (Best Case) are presented in Table 37 and visual acuity achieved by overall subject population is shown in Table 38.

**Table 37**
**N = 86**
**Best Corrected Visual Acuity in Best Case Patient Population at 330 to 420 Days**

| | 20/40 or better | | 20/41 - 20/80 | | Worse than 20/80 | | Total Reported |
|---|---|---|---|---|---|---|---|
| Age | N | % | N | % | N | % | N |
| <60 | 3 | 100.0 | 0 | 0.0 | 0 | 0.0 | 3 |
| 60-69 | 23 | 100.0 | 0 | 0.0 | 0 | 0.0 | 23 |
| 70-79 | 40 | 97.6 | 1 | 2.4 | 0 | 0.0 | 41 |
| >79 | 19 | 100.0 | 0 | 0.0 | 0 | 0.0 | 19 |
| Total | 85 | 98.8 | 1 | 1.1 | 0 | 0.0 | 86 |

**Table 38**
**N = 129**
**Best Corrected Visual Acuity in Overall Patient Population at 330 - 420 Days**

| | 20/40 or better | | 20/41 - 20/80 | | Worse than 20/80 | | Total |
|---|---|---|---|---|---|---|---|
| Age | N | % | N | % | N | % | N |
| <60 | 3 | 100.0 | 0 | 0.0 | 0 | 0.0 | 3 |
| 60-69 | 31 | 100.0 | 0 | 0.0 | 0 | 0.0 | 31 |
| 70-79 | 61 | 96.8 | 2 | 3.2 | 0 | 0.0 | 63 |
| >79 | 30 | 93.8 | 2 | 6.3 | 0 | 0.0 | 32 |
| Grand Total | 125 | 96.9 | 4 | 3.1 | 0 | 0.0 | 129 |

**AcrySof ACRYLIC FOLDABLE SINGLE-PIECE LENS ADVERSE EVENTS**

The cumulative and persistent (present at one-year postoperatively) rates of these adverse events up to and including the 330 to 420 day postoperative period for the AcrySof Single-Piece Lens patients are shown in Tables 39 and 40, respectively.

**Table 39**
**Cumulative Postoperative Adverse Events at 330 to 420 Days**

| | Events N = 148† | |
|---|---|---|
| Type of Adverse Event | N | % |
| Endophthalmitis | 0 | 0.0 |
| Hypopyon | 0 | 0.0 |
| Lens Dislocation | 0 | 0.0 |
| Macular Edema | 1 | 0.7 |
| Pupillary Block | 0 | 0.0 |
| Retinal Detachment | 0 | 0.0 |
| Surgical Reintervention | 1 | 0.7 |

The N = 148 represents the total number of patients implanted with AcrySof* Single-Piece Lenses during the clinical study.

**Table 40**
**Persistent Postoperative Adverse Events at 330 to 420 Days**

| | Cumulative Incidence N = 129† | |
|---|---|---|
| Type of Adverse Event | N | % |
| Corneal Stromal Edema | 0 | 0.0 |
| Iritis | 0 | 0.0 |
| Raised IOP Requiring Treatment | 0 | 0.0 |
| Cystoid Macular Edema | 0 | 0.0 |
| Hyphema | 0 | 0.0 |
| Vitritis | 0 | 0.0 |
| Other | 0 | 0.0 |

†The N = 129 represents the total number of patients implanted with AcrySof* Single-Piece Lenses that completed a 330 to 420 day postoperative examination.

In addition to the above safety and effectiveness parameters assessed during this clinical study, the number of Nd:YAG posterior capsulotomies were reported as 4 (2.7%) within 12 months postoperatively, 6 (4.0%) between 12 and 18 months; and, 1 (0.7%) after 18 months.

**REFERENCES**

Abulafia A, Barrett GD, Kleinmann G, Ofir S, Levy A, Marcovich AL, *et al*. Prediction of refractive outcome with toric intraocular lens implantation. *J Cataract Refractive Surgery*. 2015; 41:936–944.

Abulafia A, Hill WE, Franchina M, Barrett GD. Comparison of methods to predict residual astigmatism after intraocular lens implantation. *J Refractive Surgery*. 2015b; 31(10):699-706.

Boettner, E.A. and Wolter, J.R. Transmission of the ocular media. Invest. Ophthalmol. 1962;1:776-83.

Cho P, Woo GC. Opthalmic Physiol Opt. 2004; 24(5): 427-35.

Hoffer KJ. The Hoffer Q formula: a comparison of theoretic and regression formulas. J Cataract Refract Surg. 1993;19(6):700-12.

Holladay JT. Standardizing constants for ultrasonic biometry, keratometry, and intraocular lens power calculations. J Cataract Refract Surg. 1997;23(9):1356-70.

Olsen T. Calculation of intraocular lens power: a review. Acta Ophthalmol Scand. 2007;85(5):472-85.

Retzlaff JA, Sanders DR, Kraff M. Lens Implant Power Calculation. 3rd ed. Thorofare (NJ): Slack, Inc.; 1990.

Haigis W. ULIB - User group for Laser Interference Biometry. Updated 2014 Jul 17; cited 2015 Mar 13. Available at: http://ocusoft.de/ulib/.

**STAND ALONE SYMBOLS FROM ISO 7000/ ISO 7001‡ USED ON LABELING**
**(ISO 7000/IEC 60417 Title: Graphical Symbols for Use on Equipment)**
**(‡ISO 7001 Title: Graphical symbols – Public information symbols)**

| Symbol | Reference Number from ISO 7000 / IEC 60417* / ISO 7001* | Symbol Title / Explanatory Text |
|---|---|---|
|  | 1051 | Do not re-use |
|  | 2608 | Do not resterilize |

| | | |
|---|---|---|
|  | 2607 | Use-by date |
|  | 2501 | Sterilized using ethylene oxide |
|  | 2498 | Serial number |
|  | 2493 | Catalogue number |
|  | 0434A | Caution |
|  | 3082 | Manufacturer |
|  | 0632 | Temperature Limit |
|  | 1641 | Consult instructions for use |
|  | 2606 | Do not use if package has been damaged |
|  | 2497 | Date of Manufacture |
|  | 3079 | Open Here |
|  | 3010 | RFID tag, general |
|  | 6050* | Model number |
|  | 6049* | Country of manufacture |
|  | 5662* | Date |
|  | 5664* | Patient identification |
|  | PI PF 044‡ | Health care centre or doctor |
|  | PI PF 002‡ | Hospital |

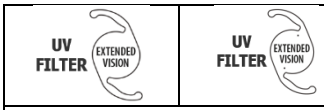
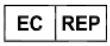
‡This symbol is from ISO 7001.
*This symbol is from IEC 60417.

**STAND ALONE SYMBOL FROM ASTM F2503-13 USED ON LABELING**
**(Title: Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment)**

| Symbol | Reference Number from ASTM F2503-13 | Symbol Title / Explanatory Text |
|---|---|---|
|  | N/A | MR (magnetic resonance) safe |

**ABBREVIATIONS or SYMBOLS USED ON LABELING**

| Symbol | Symbol Title / Explanatory Text |
|---|---|
| IOL | Intraocular lens |
|  | Single sterile barrier system |
|  | Medical device |
|  | Unique device identifier |
|  | Patient information website |

| | |
|---|---|
|   | UV Filter with Wavefront-Shaping technology (i.e. Extended Vision) |
|   | Posterior chamber |
|  | Eye |
| OVD | Ophthalmic viscosurgical device |
| UV | Ultraviolet |
| D | Diopter |
| CYL | Cylinder power |
| $Ø_B$ | Body diameter (Optic diameter) |
| $Ø_T$ | Overall diameter (Overall length) |
| L | Left |
| R | Right |
| PWR | Spherical equivalent power |
|   | D-size nozzle for MONARCH® Delivery System cartridge |
|  | Not made with natural rubber latex |
|   | Does not contain PHT (phthalates) |
|   | MR Safe |
|   | Caution: Federal (USA) Law restricts this device to sale by or on the order of a physician |
|   | Authorized Representative in the European Community |

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Alcon