40-500-135-002

PRODUCT INFORMATION
Alcon Laboratories, Inc.

STERILE UV and Blue Light Filtering Acrylic Foldable
Apodized Diffractive Aspheric Multifocal Toric Posterior Chamber Intraocular Lens

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

DESCRIPTION

The AcrySof® IQ ReSTOR® +3.0 D add apodized diffractive aspheric multifocal toric posterior chamber intraocular lens (IOL) is an ultraviolet and blue light filtering foldable multifocal intraocular lens. The optical portion consists of a high refractive index material with proprietary blue light filtering chromophore which filters light in a manner that approximates the human crystalline lens in the 400-475 nm blue light wavelength range (Boettner and Wolter, 1962). In addition to standard UV absorption, the blue-light filtering chromophore reduces transmittance of blue light wavelengths (see Table 2). The optical portion is biconvex and consists of a soft acrylic material capable of being folded prior to insertion, allowing placement through an incision smaller than the optic diameter of the lens. The biconvex optic contains an aspheric apodized diffractive structure on the anterior surface. The effects of the aspheric design feature have not been clinically assessed. After surgical insertion into the eye, the lens gently unfolds to restore the optical performance. The anterior surfaces of the AcrySof® IQ ReSTOR® +3.0 D Multifocal Toric IOL is designed with negative spherical aberration to compensate for the positive spherical aberration of the cornea*. The physical properties of these lenses are described in Figure 1 and Tables 1-2.

Figure 1: Physical Characteristics, AcrySof® IQ ReSTOR® +3.0 D Multifocal Toric IOL
(All dimensions in millimeters)

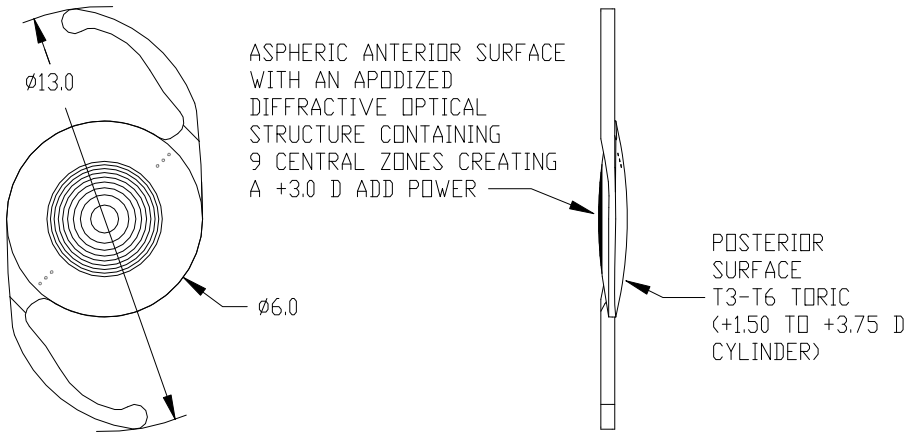
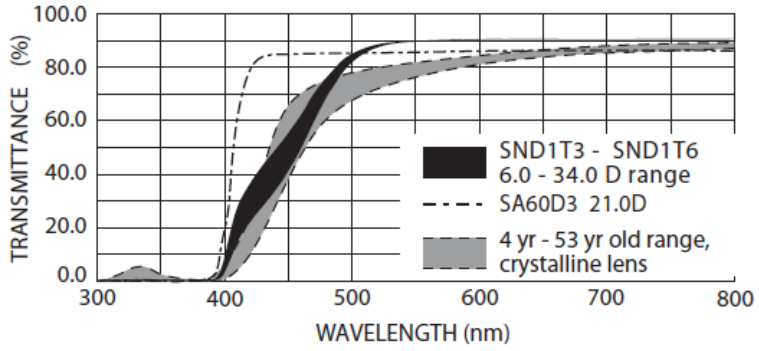


Table 1: Physical Characteristics of AcrySof® IQ ReSTOR® +3.0 D Multifocal Toric IOL

Characteristics	Model			
	SND1T3	SND1T4	SND1T5	SND1T6
Optic Type	Biconvex Apodized Diffractive Aspheric Toric			
Optics/Haptics Material	Ultraviolet and blue light filtering Acrylate/Methacrylate Copolymer			
UV Cutoff at 10% T	401 nm for 21.0 D (See Figure 2)			
Index Of Refraction	1.55			
Optic Powers (spherical equivalent diopters)	+6.0 to +30.0 (0.5 D increments) (+3.0 Diopters of add power for near vision)			
IOL Cylinder Power (Diopters)	1.50	2.25	3.00	3.75
Haptic Configuration	STABLEFORCE® Haptic			
Optics/Haptic Color	Yellow			
Optic Diameter (mm)	6.0			
Overall Length (mm)	13.0			
Haptic Angle	0º			

Figure 2: Spectral Transmittance Curves
(percentage of ultraviolet transmittance)



NOTES:

- The cutoff wavelength and the spectral transmittance curves presented here represent the range of transmittance values for the AcrySof® IQ ReSTOR® +3.0 D Multifocal Toric IOL.
- The mid-power Model SA60D3 IOL spectral transmittance curve is shown for comparison.
- The Model SA60D3 IOL does not contain the blue light filtering chromophore.
- Measurements were direct transmittance using actual lenses in the Diopter powers indicated.
- Human lens data from Boettner and Wolter (1962).

Table 2: Average Transmittance %T Comparison for 21.0 D Single-Piece IOL Designs (%)

Model	400 nm	425 nm	450 nm	475 nm
SA60D3*	23	84	86	86
SND1T3-T6	8	33	48	68
Transmittance Difference (SA60D3- SND1T3-T6)	15	51	38	18
Transmittance Reduction with SND1T3-T6 (% of SA60D3)	65	61	44	21

*The Model SA60D3 IOL does not contain the blue light filtering chromophore.

MODE OF ACTION

AcrySof® IQ ReSTOR® +3.0 D Multifocal Toric IOL is intended to be positioned in the posterior chamber of the eye, replacing the natural crystalline lens. This position allows the lens to function as a refractive medium in the correction of aphakia. These biconvex optic IOLs have an aspheric apodized diffractive structure on the anterior surface. The biconvex aspheric optic reduces spherical aberration as compared to a standard spherical optic in an average eye. Additionally, these IOLs have a toric component on the posterior surface with axis marks to denote the flat meridian (plus cylinder axis). Alignment of the toric axis marks with the post-operative steep corneal meridian allows the lens to correct pre-existing corneal astigmatism. The astigmatic correction at the corneal plane for each AcrySof® IQ ReSTOR® +3.0 D Multifocal Toric IOL model is shown in Table 3.

Table 3: Cylinder Power and Corneal Astigmatism Correction Range

	Cylinder Power		Recommend Corneal Astigmatism Range*	
Lens Model	**IOL Plane**	**Corneal Plane***	**Lower**	**Upper**
SND1T3	1.50	1.03	0.75	1.28
SND1T4	2.25	1.55	1.29	1.80
SND1T5	3.00	2.06	1.81	2.32
SND1T6	3.75	2.57	2.33	2.82

*Based on an average pseudophakic human eye

INDICATIONS

The AcrySof® IQ ReSTOR® +3.0 D Multifocal Toric Intraocular Lens (IOL) is intended for primary implantation in the capsular bag of the eye for the visual correction of aphakia and pre-existing corneal astigmatism secondary to removal of a cataractous lens in adult patients with and without presbyopia, who desire near, intermediate and distance vision, reduction of residual refractive cylinder and increased spectacle independence. The lens is intended to be placed in the capsular bag.

IOL IMPLANTATION

During implantation of the AcrySof® IQ ReSTOR® +3.0 D Multifocal Toric IOL, an Alcon qualified delivery system and viscoelastic combination should be used. The use of an unqualified combination may cause damage to the lens and potential complications during the implantation process. Alcon recommends using the qualified MONARCH IOL Delivery System or any other Alcon qualified combination. For a full list of Alcon qualified viscoelastics, handpieces, and cartridges for this lens, please contact your local Alcon representative.

WARNINGS

1. Some visual effects may be expected due to the superposition of focused and unfocused multiple images. These may include glare, halo and starbursts, as well as other visual symptoms. As with other multifocal IOLs, there is a possibility that visual symptoms may be significant enough that the patient will request explant of the multifocal IOL.
2. A reduction in contrast sensitivity as compared to a monofocal IOL may be experienced by some patients and may be more prevalent in low lighting conditions. Therefore, multifocal patients should exercise caution when driving at night or in poor visibility conditions.
3. The physician should consider the following points that are unique to the use of the AcrySof® IQ ReSTOR® +3.0 D Multifocal Toric IOLs:
   - The surgeon must target emmetropia to achieve optimal visual performance.
   - The surgeon should target the lowest possible residual astigmatism. Patients with significant postoperative astigmatism >1.0 D may not achieve optimal visual outcomes.
   - Care should be taken to achieve IOL centration, as lens decentration may result in a patient experiencing visual disturbances under certain lighting conditions.
   - Patients should be advised that unexpected outcomes could lead to continued spectacle dependence or the need for secondary surgical intervention (e.g., intraocular lens replacement or repositioning).
4. Rotation of the AcrySof® IQ ReSTOR® +3.0 D Multifocal Toric IOLs away from their 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.
5. 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.
6. Carefully remove all viscoelastic from both the anterior and posterior sides of the lens. Residual viscoelastic may cause complications including lens rotation resulting in misalignment of the AcrySof® IQ ReSTOR® +3.0 D Multifocal Toric IOL with the intended axis of placement.

PRECAUTIONS

1. Prior to surgery, prospective patients should be informed of the possible risks and benefits associated with the AcrySof® IQ ReSTOR® +3.0 D Multifocal Toric IOL. A Patient Information Brochure can be found in the label information section at http://www.myalcon.com. Please provide a copy of the Patient Information Brochure to the patient.
2. As with other multifocal IOLs, patients may need glasses when reading small print or looking at small objects.
3. Posterior capsule opacification (PCO) may significantly affect the vision of patients with multifocal IOLs sooner in its progression than patients with monofocal IOLs. This may be due to the reduced contrast sensitivity observed with multifocal IOLs.
4. The safety and effectiveness of the AcrySof® IQ ReSTOR® +3.0 D Multifocal Toric IOL have not been substantiated in patients with the pre-existing conditions and intraoperative complications listed below. 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. Alternative treatment should be considered for patients with one or more pre-existing conditions and intraoperative complications as described below.

   Before Surgery

- Choroidal hemorrhage
- Concomitant severe eye disease
- Irregular corneal astigmatism
- Significant irregular corneal aberration
- Retinal conditions or predisposition to retinal conditions, previous history of, or a predisposition to, retinal detachment or proliferative diabetic retinopathy, in which future treatment may be compromised by implanting this lens.
  - Multifocal IOLs may decrease the level of retinal detail on exam or during treatment slightly, and this could make laser and retinal surgeries and the diagnosis of some conditions more challenging (for example, early diabetic retinopathy when only 1 or 2 microaneurysms are present.)
- Subjects with diagnosed degenerative visual disorders (e.g., macular degeneration or other retinal disorders) that are predicted (by subjective assessment of the retina) to cause future acuity losses to a level worse than 0.2 logMAR
- Amblyopia
- Clinically severe corneal dystrophy (e.g., epithelial, stromal, or endothelial dystrophy), keratitis, keratoconjunctivitis, keratouveitis, keratopathy, or kerectasia
- Any inflammation or edema (swelling) of the cornea
- Rubella, congenital, traumatic or complicated cataracts
- Extremely shallow anterior chamber, not due to swollen cataract
- Recurrent anterior or posterior segment inflammation of unknown etiology, or any disease producing an inflammatory reaction in the eye (e.g. iritis or uveitis).
- Aniridia
- Iris neovascularization
- Glaucoma (uncontrolled or controlled with medication)
- Microphthalmos
- Optic nerve atrophy
- Previous corneal transplant
- Pre-existing ocular conditions which may negatively impact stability of the implant.
- Color vision deficiencies
- Studies have shown that color vision discrimination is not adversely affected in individuals implanted with an AcrySof® Natural IOL and normal color vision. The effect of an AcrySof® Natural IOL in subjects with hereditary color vision defects and acquired color vision defects secondary to ocular disease (e.g. glaucoma, diabetic retinopathy, chronic uveitis, and other retinal or optical nerve diseases) has not been studied.
- Previous retinal detachment
- Diabetic retinopathy
- Previous refractive surgery
- Cervical dystonia or spasmodic torticollis may interfere with the pre-operative surgical plan or IOL axis orientation during surgery. Patients with IOL misalignment may not achieve the visual acuity of patients without such problems and may require IOL repositioning.
- Pregnancy

During Surgery

- Other planned ocular surgery procedures, including but not limited to, LASIK, astigmatic keratotomy, and limbal relaxing incisions
- Excessive iris mobility/Intraoperative Floppy Iris Syndrome
- Mechanical or surgical manipulation required to enlarge the pupil; pupil size must be at least 4.5 mm or larger just prior to IOL implantation;
- Vitreous loss (significant)
- Anterior chamber bleeding (significant)
- Uncontrollable positive intraocular pressure
- Complications in which the IOL stability could be compromised, including, but not limited to:
  - zonular damage, separation, or rupture
  - Capsulotomy by any technique other than a circular tear
  - The presence of radial tears known or suspected at the time of surgery
  - Situations in which the integrity of the circular tear cannot be confirmed by direct visualization
  - Cataract extraction by techniques other than phacoemulsification or liquefaction
  - Situations where the need for a large capsulotomy can be anticipated (e.g., diabetics, retinal detachment in the fellow eye, peripheral retinal pathology, etc.)
  - capsular rupture or capsulorhexis tear
  - Bag-sulcus, sulcus-sulcus or unknown placement of the haptics

5. Patients with preoperative problems such as corneal endothelial disease, abnormal cornea, macular degeneration, retinal degeneration, glaucoma, and chronic drug miosis may not achieve the visual acuity of patients without such problems. The physician must determine the benefits to be derived from lens implantation when such conditions exist.
6. When binocular implantation of the AcrySof® IQ ReSTOR® +3.0 D Multifocal Toric 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.
7. A high level of surgical skill is required for intraocular lens implantation. The surgeon should have observed and/or assisted in numerous implantations and successfully completed one or more courses on intraocular lens implantation before attempting to implant intraocular lenses.

8. As with any surgical procedure, there is risk involved. Potential complications accompanying cataract or implant surgery may include, but are not limited to the following: corneal endothelial damage, infection (endophthalmitis), retinal detachment, vitritis, cystoid macular edema, corneal edema, pupillary block, cyclitic membrane, iris prolapse, hypopyon, transient or persistent glaucoma, and secondary surgical intervention. Secondary surgical interventions include, but are not limited to: lens repositioning, lens replacement, vitreous aspiration or iridectomy for pupillary block, wound leak repair, and retinal detachment repair.
9. The clinical study of the AcrySof® IQ ReSTOR® +3.0 D Multifocal Toric IOL was conducted with the lens intended for implantation in the capsular bag only. There are no clinical data to demonstrate its safety and effectiveness for placement in the ciliary sulcus.
10. Anatomic and/or surgical factors may be related to the likelihood that a toric IOL could be placed incorrectly or rotate away from the intended position after placement. Some of these factors can be identified before or during the surgery, but others cannot. If a secondary surgical intervention is necessary to reposition the IOL, explantation should be considered as some subjects may have recurrent or persistent issues related to rotational instability and misalignment.
11. DO NOT resterilize these intraocular lenses by any method.
12. DO NOT store intraocular lenses at temperatures over 45°C (113°F)
13. Use only sterile intraocular irrigating solutions (such as BSS® or BSS PLUS® solution) to rinse and/or soak lenses.
14. Accurate keratometry and biometry in addition to the use of the AcrySof® IQ ReSTOR® +3.0 D Multifocal Toric IOL Calculator (http://www.myalcon-toriccalc.com) are recommended.
15. All preoperative surgical parameters are important when choosing a toric lens for implantation, including preoperative keratometric cylinder (magnitude and axis), incision location, surgeon's estimated surgically induced astigmatism (SIA) and biometry. Variability in any of the preoperative measurements can influence patient outcomes, and the effectiveness of treating eyes with lower amounts of preoperative corneal astigmatism.
16. In the clinical study all corneal incisions were placed temporally and a surgically induced astigmatism (SIA) input value of 0.0 diopters was used in the AcrySof® IQ ReSTOR® +3.0 D Multifocal Toric IOL Calculator (http://www.myalcon-toriccalc.com). The SIA input value of 0.0 diopters was derived from an assumed 0.25 diopter with-the-rule vector SIA from the temporal incision which was assumed to be compensated by an average 0.25 diopter against-the-rule posterior corneal astigmatism in the clinical study. The marketed AcrySof® IQ ReSTOR® +3.0 D Multifocal Toric IOL Calculator allows the surgeon to customize the incision site and SIA based on the surgeon's clinical judgement. Clinical outcomes using incision site or SIA input value different than used in the clinical study have not been evaluated.

CALCULATION OF LENS POWER

Accurate keratometry and biometry is essential for successful visual outcomes. Preoperative calculation of required spherical equivalent lens power for the AcrySof® IQ ReSTOR® +3.0 D Multifocal Toric IOL should be determined by the surgeon's experience and preference. The suggested A-constant listed on the outer label is presented as a starting point for implant power calculations. Lens constants must be "personalized" to compensate for the differences in instrumentation, measurement technique, and IOL power calculation methods that exist between different surgeons. To achieve optimal results with the AcrySof® IQ ReSTOR® +3.0 D Multifocal Toric IOL, it is important to use a personalized lens constant. The provisional A-constant listed on the outer label has been estimated from lens design data. An initial estimate can be obtained by referencing the personalized lens constant for similar lens model (e.g., AcrySof® IQ ReSTOR® IOL Model SN6AD1).

IOL power calculation methods are often included with biometry equipment, and they are also described in the following references:

Hoffer, K.J. The Hoffer Q formula: A comparison of theoretic and regression formulas. *J. Cataract Refract. Surg.* 19:700-712, 1993.

Holladay, J.T. *et al*. Standardizing constants for ultrasonic biometry, keratometry, and IOL power calculations*. J. Cataract Refract. Surg.* 23:1356-1370, 1997.

Olsen, T. Calculation of intraocular lens power: *A review. Acta Ophthalmol Scand.* 85: 472-285, 2007.

Retzlaff, J.A., Sanders, D.R., and Kraff, M. *Lens Implant Power Calculation*, 3rd ed. Slack, Inc., Thorofare, N.J., 1990.

AcrySof® IQ ReSTOR® +3.0 D Multifocal Toric IOLs are labeled with the IOL spherical equivalent power. In order to optimize IOL selection and axis placement, Alcon provides an AcrySof® IQ ReSTOR® +3.0 D Multifocal Toric IOL calculator for the surgeon. Use of the AcrySof® IQ ReSTOR® +3.0 D Multifocal Toric IOL Calculator (http://www.myalcon-toriccalc.com) is recommended to select the cylinder power of the AcrySof® IQ ReSTOR® +3.0 D Multifocal Toric IOL. The astigmatism to be corrected should be determined from keratometry and biometry data rather than refractive data since the presence of lenticular astigmatism in the crystalline lens to be removed may influence results. The size and location of the surgical incision may affect the amount and axis of corneal astigmatism. Pre-operative keratometry and biometry data, incision location (temporal was used in this clinical study), and the surgeon's estimated surgically induced corneal astigmatism are used to determine the appropriate AcrySof® IQ ReSTOR® +3.0 D Multifocal Toric IOL model, spherical equivalent lens power, and axis of placement in the eye.

DIRECTIONS FOR USE

1. Examine the label on the unopened package for model, powers (base, cylinder, and add), proper configuration, and expiration date.
2. After opening the cardboard storage container, verify lens case information (e.g., model, power, and serial number) is consistent with information on outer package labeling.
3. This device is sterile until the inner pouch is opened. Inspect the pouch carefully for tears, cuts, punctures or other signs that the pouch has been opened or damaged. DO NOT implant the IOL if the sterility has been compromised (see RETURNED GOODS POLICY).

4. To remove the lens, open the undamaged pouch and transfer the case to a sterile environment. Carefully open the case to expose the lens.
5. To minimize the occurrence of marks on the lens due to handling, all instrumentation should be scrupulously clean. Any forceps used for lens handling must have round edges and smooth surfaces.
6. When removing the lens from the case, DO NOT grasp the optical area with forceps. The IOL should only be handled by the haptics. Handle 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. Prior to insertion the lens should be carefully examined to ensure that particles have not adhered during handling.
8. Alcon recommends that the AcrySof® IQ ReSTOR® +3.0 D Multifocal Toric IOLs be used with an Alcon approved delivery system.
9. There are various surgical procedures that can be used, and the surgeon should select a procedure that is appropriate for the patient. Current techniques, appropriate instrumentation, and a list of their equivalents for delivery and implantation are available from Alcon. Surgeons should verify that appropriate instrumentation is available prior to surgery.
10. DO NOT reuse this IOL. This device is for single use only.

PLACEMENT OF THE ACRYSOF® IQ RESTOR® +3.0 D MULTIFOCAL 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 AcrySof® IQ ReSTOR® +3.0 D Multifocal Toric IOL optic. These indentations form an imaginary line representing the plus cylinder axis (note: IOL cylinder steep meridian is 90º away). The AcrySof® IQ ReSTOR® +3.0 D Multifocal Toric IOL cylinder axis marks should be aligned with the post-incision steep corneal meridian (intended axis of placement) or as determined by the AcrySof® IQ ReSTOR® +3.0 D Multifocal Toric IOL calculator.

Prior to surgery mark the operative eye with at least two reference points. Alcon recommends one of the following methods for marking the eye: 1) with the patient sitting upright, clearly and precisely mark the two reference positions with a surgical skin marker or a marking pencil, or 2) with the subject sitting upright, use an axis marker to clearly and precisely mark the intended axis of the IOL placement identified by the web-based AcrySof® IQ ReSTOR® +3.0 D Multifocal Toric IOL calculator. Using these marks as reference points, an axis marker can be used immediately prior to or during surgery to mark the axis of lens placement following the use of the AcrySof® IQ ReSTOR® +3.0 D Multifocal Toric IOL calculator to determine the optimal axis of placement.

After the lens is inserted, precisely align the axis marking indentations on the AcrySof® IQ ReSTOR® +3.0 D Multifocal Toric IOL with the marked axis of lens placement. Carefully remove all viscoelastic (Viscoat OVD was used in this clinical study) from both the anterior and posterior sides of the lens. 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 AcrySof® IQ ReSTOR® +3.0 D Multifocal Toric IOL at the intended axis following viscoelastic removal. Residual viscoelastic may allow the lens to rotate causing misalignment of the AcrySof® IQ ReSTOR® +3.0 D Multifocal Toric IOL with the intended axis of placement.

Misalignment of the axis of the lens with the intended axis of placement may compromise its astigmatic correction. Such misalignment can result from inaccurate keratometry or marking of the cornea, inaccurate placement of the AcrySof® IQ ReSTOR® +3.0 D Multifocal Toric IOL axis during surgery, an unanticipated surgically induced change in the cornea, or physical rotation of the AcrySof® IQ ReSTOR® +3.0 D Multifocal 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.

PATIENT REGISTRATION AND REPORTING

The Patient Identification Card included in the package is to be completed and given to the patient, together with instructions to keep the card as a permanent record to be shown to any eye care practitioner the patient consults in the future.

In the United States, each patient should 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 Alcon Laboratories, Inc. long-term patient follow-up program and will assist us in responding to adverse event reports.

Events that reasonably suggest that the lens may have caused or contributed to death or serious injury, including events occurring as a result of failure of a medical device to meet its performance specifications or otherwise perform as intended should be reported to Alcon Laboratories, Inc. This information is being requested from all surgeons in order to document potential long-term effects of intraocular lens implantation. Surgeons in the United States should use the following address and telephone number for reporting adverse events involving these intraocular lenses:

Alcon Laboratories, Inc., Medical Safety
6201 South Freeway, Fort Worth, Texas 76134-2099
Tel.: (800) 757-9780-
Outside the United States, contact local Alcon offices or distributors regarding any reports of adverse events.

CLINICAL STUDIES
The data from a recent clinical study of the AcrySof® IQ ReSTOR® +3.0 D Multifocal Toric IOL Models SND1T3, SND1T4, SND1T5, and SND1T6, and data from two relevant prior studies are included in this section:

1. A clinical study was conducted to assess the safety and effectiveness of the AcrySof® IQ ReSTOR® +3.0 D Multifocal Toric IOL Models SND1T3, SND1T4, SND1T5, and SND1T6.
2. A prior clinical study, including a night driving simulator sub-study, was conducted to demonstrate the safety and effectiveness of the non-blue-light-filtering multi-piece and single-piece AcrySof® ReSTOR® Models MA60D3 and SA60D3. The AcrySof® IQ ReSTOR® +3.0 D Multifocal Toric IOL Models SND1T3, SND1T4, SND1T5, and SND1T6 use an apodized diffractive optic as in Models MA60D3 and SA60D3. The safety data (adverse events and night driving simulation results) provide an expanded description of the safety profile of AcrySof® IQ ReSTOR® +3.0 D Multifocal Toric IOL Models SND1T3, SND1T4, SND1T5, and SND1T6.
3. A prior clinical study, including assessment of color perception, was conducted to demonstrate the safety and effectiveness of the AcrySof® Natural single-piece monofocal IOL Model SB30AL. AcrySof® IQ ReSTOR® +3.0 D Multifocal Toric IOL Models SND1T3, SND1T4, SND1T5, and SND1T6 are also single-piece IOLs using the same material mechanical platform and the same blue light filtering chromophore. This study showed that the blue light filtering chromophore did not have an effect on color perception in subjects with normal color vision prior to surgery. These results provide an expanded description of the safety profile expected of the AcrySof® IQ ReSTOR® +3.0 D Multifocal Toric IOL Models SND1T3, SND1T4, SND1T5, and SND1T6.

Summaries of these clinical studies are provided below. Please use caution when comparing these results with results from similar device studies due to potential differences in subject cohorts, test methods, etc.

1. AcrySof® IQ ReSTOR® +3.0 D MULTIFOCAL TORIC INTRAOCULAR LENSES (IOLS)

Summary of Clinical Study
The clinical study was a prospective, nonrandomized, unmasked, parallel-group study was designed for bilateral implantation of a minimum of 510 (maximum of 600 subjects) subjects in total, with a minimum of 340 subjects implanted with the investigational AcrySof® IQ ReSTOR® +3.0 D Multifocal Toric IOL Models SND1T3-SND1T6 (referred to as the ReSTOR® Toric +3.0 D IOL below), and a minimum of 170 subjects implanted with the FDA approved AcrySof® ReSTOR® (+4.0 D Add) Multifocal IOL Model SA60D3 (referred to as the ReSTOR® +4.0 D IOL below), at up to 25 investigational sites in the United States. Assuming a 10% drop-out rate for a 12 month follow-up in the all implanted data set, approximately 459 subjects were intended to be evaluated at the 12 month visit; approximately 306 investigational lens subjects and 153 control lens subjects. The investigational ReSTOR® Toric +3.0 D IOL was designed with a near reading distance of 40 cm and the control ReSTOR® +4.0 D IOL was designed with a near reading distance of 33 cm. The parameters impacted by the near add power difference were intermediate visual acuity and binocular defocus, in favor of the ReSTOR® Toric +3.0 D IOL. No difference was observed in the rate of severe visual disturbances/distortions between the ReSTOR® Toric +3.0 D IOL and the ReSTOR® +4.0 D IOL, although this would be expected to favor the ReSTOR® Toric +3.0 D IOL based on the add power difference.

Inclusion of the ReSTOR® +4.0 D IOL as an active control in the clinical study was necessary to evaluate the safety and the effectiveness of the investigational lens as a new toric multifocal IOL with similar attributes to this established multifocal lens. The trial objective was to demonstrate that the efficacy and safety profile, demonstrated with the control ReSTOR® +4.0 D IOL in non-astigmatic subjects was reasonably retained with the investigational ReSTOR® Toric +3.0 D IOL in subjects with corneal astigmatism.

All of the subjects in the ReSTOR +4.0 D IOL group were required to have ≤ 0.74 D of preoperative keratometric astigmatism in both eyes as measured only by the IOLMaster. Subjects with preoperative astigmatism of ≥ 0.75 D, as measured only by the IOLMaster, in both operative eyes and with 0.75 D to 2.82 D of predicted cross cylinder in both operative eyes, based on the study specific web-based AcrySof® IQ ReSTOR® +3.0 D Multifocal Toric IOL Clinical Calculator, were required to be implanted with one of the ReSTOR Toric +3.0 D IOL Models SND1T3-SND1T6. All corneal incisions were placed temporally and a surgically induced astigmatism (SIA) input value of 0.0 diopters was used in the study specific web based AcrySof® IQ ReSTOR® +3.0 D Multifocal Toric IOL Calculator.

In the investigational ReSTOR Toric +3.0 D IOL group, a minimum of 240 subjects needed to be implanted with Model SND1T3 or SND1T4 in the first operative eye (≤ 2.0 D astigmatism) and a minimum of 100 subjects needed to be implanted with Model SND1T5 or SND1T6 in the first operative eye (>2.0 D astigmatism).

All eyes with successful IOL implantation in at least one eye were considered evaluable for the All Implanted analyses. All eyes successfully implanted that had at least one postoperative visit and had no preoperative ocular pathology or macular degeneration at any time were evaluable for Best Case analyses. The Best Case data set was the primary data set of analysis for the contrast sensitivity and binocular defocus. All eyes with attempted IOL implantation (successful or aborted after contact with the eye) were considered evaluable for the safety analyses.

For subjects with IOL replacement due to visual disturbance, performance testing (including UCDVA, BCDVA, manifest refraction, slit-lamp examination, dilated fundus examination and subject responses to the patient reported outcome questionnaires) results collected prior to the secondary surgical intervention were carried forward to the final analysis.

Clinical Study Results

Subject Population
A total of 574 subjects were bilaterally implanted in this clinical study with 386 subjects receiving the ReSTOR® Toric +3.0 D IOL and 188 subjects receiving the control ReSTOR® +4.0 D IOL.

The study consisted of 65.5% females and 34.5% males. Stratifying by race, there were 93.7% White, 4.5% Black or African American, 0.9% Asian and 0.9% designated "Other". Ethnicity of the study population designated 1.6% as Hispanic. A Best Case cohort (no clinically significant preoperative ocular pathology or postoperative macular degeneration) consisted of 365 ReSTOR® Toric +3.0 D IOL subjects and 175 ReSTOR® +4.0 D IOL control subjects. The mean age for the study population was 67 ± 9 years. The length of subject follow-up was 12 months.

Monocular Visual Acuity
ReSTOR® Toric +3.0 D IOL met the clinical performance target (non-inferiority margin of 0.10 logMAR) for Uncorrected Distance Visual Acuity. There were no clinically relevant differences in the mean Best Corrected Distance Visual Acuity for subjects implanted with either the ReSTOR® Toric +3.0 D IOL compared with subjects implanted with the control ReSTOR® +4.0 D IOL.

The following is a summary of monocular visual acuity (VA) results for subjects who completed the Form 5 (1 year after second eye implantation) visit. The data are presented in Tables 4-5 below.

Table 4: Comparison of Monocular Uncorrected Distance Visual Acuity Using Least Square Estimates All Implanted, 1 Year Postoperative

		ReSTOR® Toric +3.0 D (N=386)	ReSTOR® +4.0 D (N=186)	Difference (95%UCL)
First Implanted Eye	N	373	180	
	Mean	0.126	0.125	0.001 (0.030)
	SE	0.013	0.015	
Second Implanted Eye	N	371	180	
	Mean	0.113	0.102	0.011 (0.038)
	SE	0.011	0.013	

ReSTOR® Toric +3.0 D IOL = AcrySof® IQ ReSTOR® +3.0 D Multifocal Lens Models SND1T3/SND1T4/SND1T5/SND1T6
ReSTOR® +4.0 D IOL = AcrySof® ReSTOR® Multifocal Lens (+4.0 D Add) Model SA60D3
Difference = ReSTOR® Toric +3.0 D IOL – ReSTOR® +4.0 D IOL
Estimates were based on the repeated measure analysis of covariance
UCL = 95% Upper confidence limit; SE = Standard error
"(N=)" in column header is number in the treatment group. Subjects who discontinued before Visit 5 are excluded from this analysis. Numbers with data are indicated in the table body.

ReSTOR® Toric +3.0 D IOL met the clinical performance target (non-inferiority margin of 0.10 logMAR) for Uncorrected Near Visual Acuity at fixed distance. No clinically relevant differences in Distance Corrected Near Visual Acuity at fixed distance for the ReSTOR® Toric +3.0 D IOL and the control ReSTOR® +4.0 D IOL were observed.

Table 5: Comparison of Monocular Uncorrected Near Visual Acuity At Fixed Distance Using Least Square Estimates All Implanted, 1 Year Postoperative

		ReSTOR® Toric +3.0 D (N=386)	ReSTOR® +4.0 D (N=186)	Difference (95%UCL)
First Implanted Eye	**N**	373	180	
	Mean	0.193	0.236	-0.044 (-0.017)
	SE	0.015	0.017	
Second Implanted Eye	**N**	371	180	
	Mean	0.181	0.234	-0.052 (-0.026)
	SE	0.013	0.015	

ReSTOR® Toric +3.0 D IOL = AcrySof® IQ ReSTOR® +3.0 D Multifocal Lens Models SND1T3/SND1T4/SND1T5/SND1T6
ReSTOR® +4.0 D IOL = AcrySof® ReSTOR® Multifocal Lens (+4.0 D Add) Model SA60D3
Difference = ReSTOR® Toric +3.0 D IOL – ReSTOR® +4.0 D IOL
Estimates were based on the repeated measure analysis of covariance
UCL = 95% Upper confidence limit; SE = Standard error
"(N=)" in column header is number in the treatment group. Subjects who discontinued before Visit 5 are excluded from this analysis. Numbers with data are indicated in the table body.

No clinically relevant differences in Uncorrected Near Visual Acuity at best distance were observed for either the ReSTOR® Toric +3.0 D IOL or the control ReSTOR® +4.0 D IOL. Additionally, there were no clinically relevant differences in Distance Corrected Near Visual Acuity at best distance observed for the ReSTOR® Toric +3.0 D IOL or the control ReSTOR® +4.0 D IOLs under photopic or mesopic conditions.

The Best Corrected Near Visual Acuity (BCNVA) for subjects implanted with the ReSTOR® Toric +3.0 D IOL compared favorably to the BCNVA for subjects implanted with the or the control ReSTOR® +4.0 D IOL.

Binocular Visual Acuity
There were no clinically relevant differences in mean Best Corrected Distance Visual Acuity (BCDVA) for subjects implanted with the ReSTOR® Toric +3.0 D IOL compared with subjects implanted with the control ReSTOR® +4.0 D IOL. The observed percentage of subjects achieving a 2 or greater line improvement in BCDVA was similar among the two lens models (ReSTOR® Toric +3.0 D and the control ReSTOR® +4.0 D IOL).

The following is a summary of binocular visual acuity (VA) results for subjects who completed the Form 5 (1 year after second eye implantation) visit. The data are presented in Tables 6-10 below.

Table 6: Overall Comparison of ReSTOR® Toric +3.0 D and ReSTOR® +4.0 D IOLs Mean Binocular Distance-Corrected Visual Acuity (logMAR), All Implanted, 1 Year Postoperative

Model	Near VA @ Best Distance	Intermediate VA @ 50 cm	Intermediate VA @ 60 cm	Intermediate VA @ 70 cm	Distance VA
ReSTOR® +3.0 D Toric	0.08 (20/25)	0.08 (20/25)	0.14 (20/25)	0.20 (20/32)	-0.04 (20/20)
ReSTOR® +4.0 D	0.09 (20/25)	0.28 (20/40)	0.35 (20/50)	0.36 (20/50)	-0.04 (20/20)

ReSTOR® Toric +3.0 D = AcrySof® IQ ReSTOR® +3.0 D Multifocal Toric IOL Models SND1T3/SND1T4/SND1T5/SND1T6
ReSTOR® +4.0 D = AcrySof® ReSTOR® Multifocal IOL (+4.0 D Add) Model SA60D3

Table 7: Cumulative Binocular Photopic Near Visual Acuity of ReSTOR® Toric +3.0 D and ReSTOR® +4.0 D IOLs by Lens Model, All Implanted, 1 Year Postoperative

		N	20/20 (J1) or better %	20/25 (J2) or better %	20/32 (J4) or better %	20/40 (J5) or better %	20/50 (J6) or better %	20/63 (J8) or better %	Worse than 20/63 (J8) %
Uncorrected (Best Distance*)	**ReSTOR® Toric +3.0 D**	371	35.6	69.5	89.5	97.8	98.7	99.5	0.5
	ReSTOR® +4.0 D	180	25.6	67.8	88.9	96.1	98.3	99.4	0.6
Uncorrected (Standard Distance)**	**ReSTOR® Toric +3.0 D**	371	42.3	70.9	89.5	96.2	98.1	99.7	0.3
	ReSTOR® +4.0 D	180	23.9	56.1	84.4	92.2	97.8	98.9	1.1
Distance Corrected (Best Distance*)	**ReSTOR® Toric +3.0 D**	371	37.5	73.9	94.6	97.8	99.2	99.5	0.5
	ReSTOR® +4.0 D	180	35.0	72.2	93.9	95.6	99.4	100.0	0.0
Distance Corrected (Standard Distance)**	**ReSTOR® Toric +3.0 D**	371	44.5	80.6	94.1	98.1	98.9	99.5	0.5
	ReSTOR® +4.0 D	180	31.1	65.6	88.9	97.2	98.3	98.9	1.1
Best Corrected (Standard Distance)**	**ReSTOR® Toric +3.0 D**	371	58.2	86.0	97.3	99.2	99.5	100.0	0.0
	ReSTOR® +4.0 D	180	41.7	81.1	92.8	98.3	99.4	100.0	0.0

ReSTOR® Toric +3.0 D = AcrySof® IQ ReSTOR® +3.0 D Multifocal Toric IOL Models SND1T3/SND1T4/SND1T5/ SND1T6
ReSTOR® +4.0 D = AcrySof® ReSTOR® Multifocal IOL (+4.0 D Add) Model SA60D3
*Best distance: The distance selected by the subject as the distance of best near vision
**Standard distance: 33 cm for the ReSTOR® +4.0 D IOL and 40 cm for ReSTOR® +3.0 D Toric IOL

Table 8: Cumulative Binocular Photopic Distance Visual Acuity of ReSTOR® Toric +3.0 D and ReSTOR® +4.0 D IOLs by Lens Model, All Implanted, 1 Year Postoperative

		N	20/20 or better %	20/25 or better %	20/32 or better %	20/40 or better %	20/50 or better %	20/63 or better %	Worse than 20/63 %
Uncorrected	**ReSTOR® Toric +3.0 D**	371	65.0	88.7	96.0	98.9	99.2	99.5	0.5
	ReSTOR® +4.0 D	180	68.9	91.7	97.8	99.4	99.4	100.0	0.0
Best Corrected	**ReSTOR® Toric +3.0 D**	371	90.3	97.3	99.2	99.7	100.0	100.0	0.0
	ReSTOR® +4.0 D	180	96.1	97.8	99.4	99.4	100.0	100.0	0.0

ReSTOR® Toric +3.0 D = AcrySof® IQ ReSTOR® +3.0 D Multifocal Toric IOL Models SND1T3/SND1T4/SND1T5/ SND1T6
ReSTOR® +4.0 D = AcrySof® ReSTOR® Multifocal IOL (+4.0 D Add) Model SA60D3

Clinically relevant differences favoring the ReSTOR® Toric +3.0 D IOL were observed for mean Uncorrected Intermediate Visual Acuity and for Distance Corrected Intermediate Visual Acuity at all testing distances (50 cm, 60 cm, and 70 cm).

Table 9: Intermediate Photopic Visual Acuity for ReSTOR® +3.0 D Toric and ReSTOR® +4.0 D IOLs by Lens Model, All Implanted, 1 Year Postoperative

			Percent 20/40 or better		
		N	50 cm	60 cm	70 cm
Uncorrected	**ReSTOR® Toric +3.0 D**	371	93.3	86.3	79.8
	ReSTOR® +4.0 D	180	63.3	47.2	50.6
Distance Corrected	**ReSTOR® Toric +3.0 D**	371	96.5	88.4	79.0
	ReSTOR® +4.0 D	180	66.7	37.8	38.9

ReSTOR® Toric +3.0 D = AcrySof® IQ ReSTOR® +3.0 D Multifocal Toric IOL Models SND1T3/SND1T4/SND1T5/SND1T6
ReSTOR® +4.0 D = AcrySof® ReSTOR® Multifocal IOL (+4.0 D Add) Model SA60D3

Table 10: Mean LogMAR Binocular Distance Corrected Intermediate Visual Acuity, for ReSTOR® Toric +3.0 D and ReSTOR® +4.0 D IOLs, All Implanted, 1 Year Postoperative

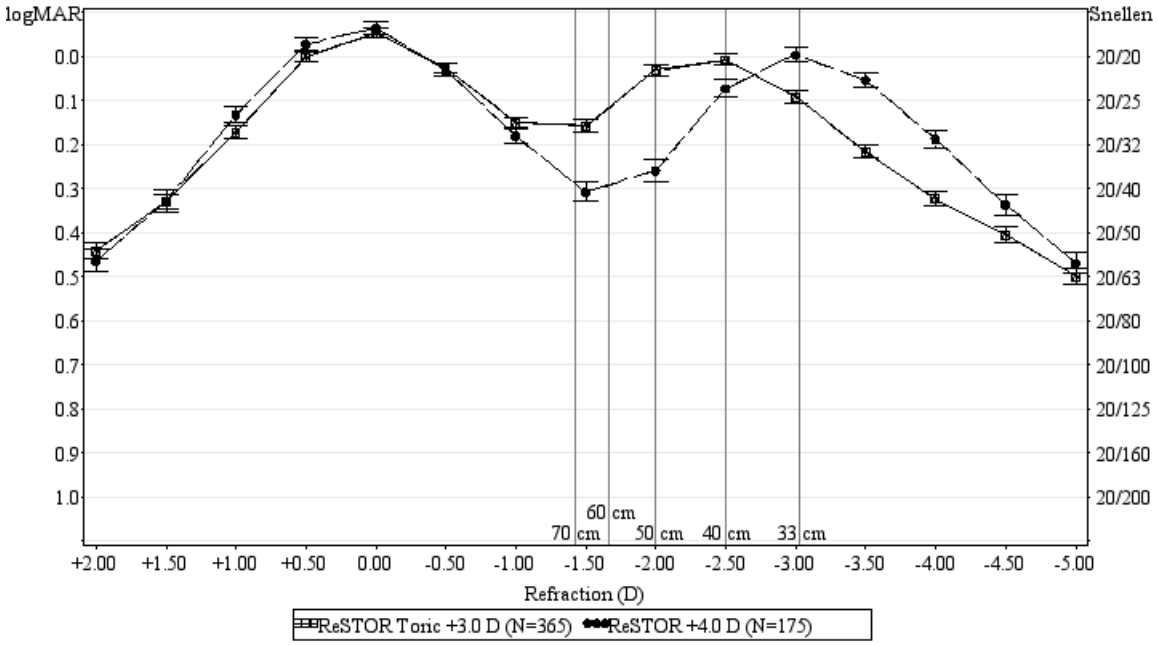
Intermediate VA	ReSTOR® Toric +3.0 D	ReSTOR® +4.0 D
50 cm	0.08	0.28
60 cm	0.14	0.35
70 cm	0.20	0.36

ReSTOR® Toric +3.0 D = AcrySof® IQ ReSTOR® +3.0 D Multifocal Toric IOL Models SND1T3/SND1T4/SND1T5/SND1T6
ReSTOR® +4.0 D = AcrySof® ReSTOR® Multifocal IOL (+4.0 D Add) Model SA60D3

Binocular Defocus Curves

The mean binocular defocus curves obtained at 6 months for the ReSTOR® Toric +3.0 D IOL and the ReSTOR® +4.0 D IOL display two peaks that demonstrate their multifocal performance, one at the zero baseline position, which corresponds to optical infinity, and one near; at –2.5 D for the ReSTOR® Toric +3.0 D IOL corresponding to the 40 cm near focal point, and at -3.0 D for the ReSTOR® +4.0 D IOL corresponding to the 33 cm near focal point of the lens (Figure 3). The ReSTOR® Toric +3.0 D IOL provided mean range of 20/40 or better vision (depth of focus) from approximately -3.75 D to 0.00 D, corresponding to a range of distances from approximately 26 cm to infinity.

Figure 3: Mean Defocus Curves with 95% Confidence Limits by Lens Model at 6 Months Postoperative Overall (Best Case Population)



ReSTOR Toric +3.0 D= ACRYSOF IQ ReSTOR (+3.0 D) Multifocal Toric Lens Models SND1T3/SND1T4/SND1T5/SND1T6
ReSTOR +4.0 D= ACRYSOF ReSTOR Multifocal Lens (+4.0 D Add) Model SA60D3

Contrast Sensitivity

Binocular best corrected distance contrast sensitivity was performed using a sine wave grating acuity chart (VectorVision CSV1000E) at the 4-6 month exam under four conditions: photopic without glare, photopic with glare, mesopic without glare, and mesopic with glare.

Descriptive statistics including mean contrast scores and standard deviations (SD) are provided for the ReSTOR® Toric +3.0 D IOL and for the ReSTOR® +4.0 D IOL groups under each photopic lighting condition and spatial frequency (Table 11) and each mesopic lighting condition and spatial frequency (Table 12). The number and percent of subjects unable to see at least one grating are shown in the table in the “Number Scoring (-1)” rows. As per ISO 11979-9:2006, these analyses were performed using data from the best case data set (defined as all eyes successfully implanted that had at least 1 postoperative visit and had no preoperative ocular pathology or macular degeneration at any time).

Table 11: Descriptive Statistics for Binocular Photopic Contrast Sensitivity at 6 Months Postoperative (Best Case Population)

		Photopic without glare		Photopic with glare	
		ReSTOR® Toric +3.0 D	ReSTOR® +4.0 D	ReSTOR® Toric +3.0 D	ReSTOR® +4.0 D
3.0 CPD	**n**	360	173	360	173
	Number scoring (-1)	0 (0.0%)	0 (0.0%)	2 (0.6%)	1 (0.6%)
	Mean (SD)	1.68 (0.22)	1.71 (0.23)	1.59 (0.27)	1.62 (0.28)
	(Min, Max)	(1.18, 2.08)	(0.70, 2.08)	(0.40, 2.08)	(0.40, 2.08)
	95% CI	(1.65, 1.70)	(1.67, 1.74)	(1.56, 1.61)	(1.58, 1.66)
6.0 CPD	**n**	360	173	360	173
	Number scoring (-1)	1 (0.3%)	0 (0.0%)	24 (6.7%)	6 (3.5%)
	Mean (SD)	1.78 (0.24)	1.81 (0.23)	1.61 (0.39)	1.66 (0.36)
	(Min, Max)	(0.61, 2.29)	(0.90, 2.29)	(0.61, 2.29)	(0.61, 2.29)
	95% CI	(1.76, 1.81)	(1.78, 1.85)	(1.57, 1.65)	(1.61, 1.71)
12.0 CPD	**n**	360	173	360	173
	Number scoring (-1)	5 (1.4%)	3 (1.7%)	18 (5.0%)	7 (4.0%)
	Mean (SD)	1.38 (0.35)	1.37 (0.32)	1.25 (0.41)	1.24 (0.38)
	(Min, Max)	(0.31, 2.00)	(0.31, 2.00)	(0.31, 2.00)	(0.31, 2.00)
	95% CI	(1.34, 1.42)	(1.32, 1.42)	(1.21, 1.29)	(1.18, 1.30)
18.0 CPD	**n**	360	173	360	173
	Number scoring (-1)	4 (1.1%)	1 (0.6%)	8 (2.2%)	2 (1.2%)
	Mean (SD)	0.87 (0.31)	0.88 (0.30)	0.84 (0.33)	0.81 (0.32)
	(Min, Max)	(-0.13, 1.56)	(-0.13, 1.56)	(-0.13, 1.56)	(-0.13, 1.56)
	95% CI	(0.84, 0.90)	(0.83, 0.92)	(0.80, 0.87)	(0.77, 0.86)

ReSTOR® Toric +3.0 D = AcrySof® IQ ReSTOR® +3.0 D Multifocal Toric IOL Models SND1T3/SND1T4/ SND1T5/SND1T6
ReSTOR® +4.0 D = AcrySof® ReSTOR® Multifocal IOL (+4.0 D Add) Model SA60D3

Table 12: Descriptive Statistics for Binocular Mesopic Contrast Sensitivity at 6 Months Postoperative (Best Case Population)

		Mesopic without glare		Mesopic with glare	
		ReSTOR® Toric +3.0 D	ReSTOR® +4.0 D	ReSTOR® Toric +3.0 D	ReSTOR® +4.0 D
1.5 CPD	**n**	359	172	359	172
	Number scoring (-1)	5 (1.4%)	2 (1.2%)	7 (1.9%)	3 (1.7%)
	Mean (SD)	1.57 (0.26)	1.55 (0.25)	1.51 (0.29)	1.50 (0.28)
	(Min, Max)	(0.30, 1.97)	(0.30, 1.97)	(0.30, 1.97)	(0.30, 1.97)
	95% CI	(1.54, 1.59)	(1.51, 1.59)	(1.48, 1.54)	(1.46, 1.55)
3.0 CPD	**n**	360	172	360	172
	Number scoring (-1)	0 (0.0%)	0 (0.0%)	3 (0.8%)	0 (0.0%)
	Mean (SD)	1.57 (0.25)	1.57 (0.24)	1.55 (0.28)	1.55 (0.26)
	(Min, Max)	(0.70, 2.08)	(0.85, 2.00)	(0.40, 2.08)	(0.70, 2.08)
	95% CI	(1.54, 1.59)	(1.53, 1.61)	(1.52, 1.58)	(1.52, 1.59)
6.0 CPD	**n**	360	172	360	172
	Number scoring (-1)	9 (2.5%)	5 (2.9%)	41 (11.4%)	19 (11.0%)
	Mean (SD)	1.51 (0.31)	1.50 (0.31)	1.41 (0.37)	1.40 (0.37)
	(Min, Max)	(0.61, 2.29)	(0.61, 2.29)	(0.61, 2.29)	(0.61, 2.21)
	95% CI	(1.47, 1.54)	(1.46, 1.55)	(1.37, 1.45)	(1.35, 1.46)
12.0 CPD	**n**	360	172	360	172
	Number scoring (-1)	52 (14.4%)	31 (18.0%)	94 (26.1%)	50 (29.1%)
	Mean (SD)	0.92 (0.39)	0.89 (0.40)	0.81 (0.40)	0.80 (0.41)
	(Min, Max)	(0.31, 2.00)	(0.31, 2.00)	(0.31, 2.00)	(0.31, 2.00)
	95% CI	(0.88, 0.96)	(0.83, 0.95)	(0.76, 0.85)	(0.74, 0.87)

ReSTOR® Toric +3.0 D = AcrySof® IQ ReSTOR® +3.0 D Multifocal Toric IOL Models SND1T3/SND1T4/ SND1T5/SND1T6
ReSTOR® +4.0 D = AcrySof® ReSTOR® Multifocal IOL (+4.0 D Add) Model SA60D3

Orientation of Lens Axis

Lens axis misalignment, the orientation of the lens axis at the operative visit compared to the intended lens axis orientation (calculated using preoperative biometry measurements and the study specific web-based Alcon AcrySof® IQ ReSTOR® +3.0 D Multifocal Toric IOL Clinical Calculator) was assessed and accuracy of lens placement was demonstrated with the mean absolute difference between intended axis orientation and achieved axis orientation at surgery being 5.0º (S.D. 6.1) for the ReSTOR® Toric +3.0 D IOLs in the first operative eyes (Table 13). Nine subjects (seven first eyes and two second eyes) had actual misalignments of 20 degrees or more on the day of surgery, of whom three had SSIs (repositioning surgeries) as a result of incorrect axis placement due to anatomical and/or surgical factors (refer to Precautions 4 and 10).

Table 13: Absolute Difference Between Intended Axis of Placement and Achieved Axis Placement (Degrees) at the Operative Visit (All Implanted Set)

	First Implanted Eye	Second Implanted Eye
	(n = 363)	**(n = 366)**
Mean (SD)	5.0 (6.1)	4.7 (4.0)
(Min, Max)	(0, 87)	(0, 36)
95% CI	(4.3, 5.6)	(4.2, 5.1)

The results for lens axis orientation at all postoperative visits were compared to those at surgery to determine lens axis rotation. The difference between the achieved lens axis orientation at month 12 and the achieved axis placement at surgery was 2.7º ± 5.8 in the first operative eyes and 2.2º ± 2.7 in the second operative eyes (Table 14). Lens axis rotation ranged from 1.4 to 2.7 degrees at all postoperative visits. Eight subjects had lens axis rotation of twenty degrees or more at month 12 month, two of whom had incorrect lens axis orientation measurements and three of whom underwent lens repositioning and have improved outcomes with the lens implanted (post repositioning rotation was less than 6 degrees). All eight subjects had improved visual performance at month 12.

Table 14: Descriptive Statistics for the Absolute Difference Between Lens Axis Orientation at the Post-operative Visit and Achieved Axis Placement (Degrees) at the Operative Visit (All Implanted Set)

		Absolute Rotation	
		First Implanted Eye	Second Implanted Eye
Day 1	**n**	376	375
	Mean (SD)	1.4 (1.8)	1.5 (1.7)
	(Min, Max)	(0, 18)	(0, 14)
	95% CI	(1.2, 1.6)	(1.3, 1.6)
1 week	**n**	375	366
	Mean (SD)	1.8 (2.3)	2.0 (2.7)
	(Min, Max)	(0, 23)	(0, 30)
	95% CI	(1.6, 2.0)	(1.7, 2.2)
1 month	**n**	367	368
	Mean (SD)	2.2 (5.1)	2.1 (2.7)
	(Min, Max)	(0, 85)	(0, 24)
	95% CI	(1.6, 2.7)	(1.8, 2.4)
6 months	**n**	363	364
	Mean (SD)	2.3 (5.2)	2.3 (3.0)
	(Min, Max)	(0, 85)	(0, 27)
	95% CI	(1.7, 2.8)	(2.0, 2.6)
12 months	**n**	356	357
	Mean (SD)	2.7 (5.8)	2.2 (2.7)
	(Min, Max)	(0, 84)	(0, 24)
	95% CI	(2.1, 3.3)	(1.9, 2.5)

For subjects with missing Operative Visit axis placement data, Day 1 (Visit 1) data were used as baseline

Furthermore, the rotational stability of the ReSTOR® Toric +3.0 D IOL was maintained between 2 consecutive visits at least 3 months apart (between 1 month and 6 months). As recommended by the 2010 ANSI standard for toric intraocular lenses, the data demonstrate that at least 90% of ReSTOR® Toric +3.0 D IOL subjects achieved a rotational stability of 5 degrees or less between 2 consecutive visits, at least 3 months apart (Table 15).

Table 15: Number and Percentage of Subjects by Lens Axis Rotation Between 1 Month and 6 Months (All Implanted)

		ReSTOR® Toric +3.0 D	
		n	(%)
First Implanted Eye	**Total**	**359**	
	Lens Movement ≤ 5 degrees	338	(94.2)
	Lens Movement >5 degrees	21	(5.8)
Second Implanted Eye	**Total**	**361**	
	Lens Movement ≤ 5 degrees	339	(93.9)
	Lens Movement >5 degrees	22	(6.1)

ReSTOR® Toric +3.0 D = AcrySof® IQ ReSTOR® +3.0 D Multifocal Toric IOL Models SND1T3/SND1T4/SND1T5/SND1T6
Subjects with missing observations at either 1 month or 6 months were excluded

REDUCTION OF CYLINDER

The ReSTOR® Toric +3.0 D IOLs are effective in the reduction of corneal astigmatism in the range of 0.75 D to 2.82 D. As demonstrated in Table 16, the percent reduction in cylinder with respect to target cylinder was calculated and descriptive statistics were computed at each postoperative visit. Target cylinder was defined as the amount of anticipated residual astigmatism as calculated by the AcrySof® IQ ReSTOR® +3.0 D Multifocal Toric IOL Clinical Calculator.

Table 16: Number and Percentage of Subjects With Reduction of Cylinder Within the Target Cylinder at 1 year for ReSTOR® Toric +3.0 D (All Implanted)

	First Implanted Eye (N = 373)		Second Implanted Eye (N = 371)	
	n	(%)	n	(%)
Within 0.5D	278	(74.5)	295	(79.5)
Within 1.0D	351	(94.1)	362	(97.6)
> 1.0D	22	(5.9)	9	(2.4)

SAFETY

The incidences of cumulative adverse events for the ReSTOR® Toric +3.0 D IOL and the control ReSTOR® 4.0 D IOL as compared to the FDA historical grid rates are provided in Table 17. If the same event occurred multiple times in an eye, only the first occurrence is counted in the table below. The rate of secondary surgical interventions (SSIs) exceeded the FDA grid rate in the ReSTOR® Toric +3.0 D IOL group for the first and second eyes. The rate of secondary surgical interventions exceeded the FDA grid rate for the control ReSTOR® +4.0 D IOL group in the second eyes only. However, as shown in Table 18, a majority of the secondary surgical interventions were unrelated to the IOL and were due to other ocular pathology. Table 17 includes the number of eyes that underwent a SSI while Table 18 is the number of actual SSIs (i.e., a single eye could have had more than 1 SSI) that occurred during the study. Details of the discrepancies in numbers are discussed in the footnotes of Table 18. There was a single occurrence of a persistent adverse event (adverse events in the FDA grid that are observed at the 12 month postoperative visit) observed in one subject implanted with the ReSTOR® Toric +3.0 D IOL. The observed persistent adverse event rates in each eye did not exceed the Safety and Performance Endpoints (SPE) rates.

Table 17: Serious and Persistent Adverse Events and SPE Rates (Safety)

	First implanted eye						Second implanted eye					
	ReSTOR® Toric +3.0 D (N = 386)			ReSTOR® +4.0 D (N = 188)			ReSTOR® Toric +3.0 D (N = 383)			ReSTOR® +4.0 D (N = 188)		
	N	%	SPE %	N	%	SPE %	N	%	SPE %	N	%	SPE %
Serious Adverse Events												
Cystoid macular edema	1	(0.3)	3.0	0	(0.0)	3.0	3	(0.8)	3.0	1	(0.5)	3.0
Endophthalmitis	0	(0.0)	0.1	0	(0.0)	0.1	0	(0.0)	0.1	0	(0.0)	0.1
Hypopyon	0	(0.0)	0.3	0	(0.0)	0.3	0	(0.0)	0.3	0	(0.0)	0.3
Lens dislocated from posterior chamber	0	(0.0)	0.1	0	(0.0)	0.1	0	(0.0)	0.1	0	(0.0)	0.1
Pupillary block	0	(0.0)	0.1	0	(0.0)	0.1	0	(0.0)	0.1	0	(0.0)	0.1
Retinal detachment	1	(0.3)	0.3	0	(0.0)	0.3	2	(0.5)	0.3	1	(0.5)	0.3
Secondary surgical intervention	12	(3.1)	0.8	4	(2.1)	0.8	11	(2.9)	0.8	6	(3.2)	0.8
Persistent Serious Adverse Events												
Corneal edema	0	(0.0)	0.3	0	(0.0)	0.3	0	(0.0)	0.3	0	(0.0)	0.3
Cystoid macular edema	1	(0.3)	0.5	0	(0.0)	0.5	1	(0.3)	0.5	0	(0.0)	0.5
Iritis	0	(0.0)	0.3	0	(0.0)	0.3	0	(0.0)	0.3	0	(0.0)	0.3
Raised IOP requiring treatment	0	(0.0)	0.4	0	(0.0)	0.4	0	(0.0)	0.4	0	(0.0)	0.4

ReSTOR® Toric +3.0 D = AcrySof® IQ ReSTOR® +3.0 D Multifocal Toric IOL Models SND1T3/SND1T4/SND1T5/SND1T6
ReSTOR® +4.0 D = AcrySof® ReSTOR® Multifocal IOL (+4.0 D Add) Model SA60D3

Table 18: Secondary Surgical Interventions - First and Second Eyes

	First Eye		Second Eye	
	ReSTOR® Toric +3.0 D (N=386)	ReSTOR® +4.0 D (N=188)	ReSTOR® Toric +3.0 D (N=383)	ReSTOR® +4.0 D (N=188)
Secondary Surgical Intervention	**15**	**5**	**13**	**6**
IOL repositioning due to IOL misalignment	1[a]	0	0	0
IOL repositioning due to inaccurate IOL placement	4[b,c]	0	0	0
IOL repositioning due to haptic outside of the bag	1	0	0	0
IOL replacement due to visual disturbances	0	2	0	2
LASIK to correct residual refractive error	1	0	1	0
Astigmatic keratotomy to correct residual refractive error (astigmatism)	1	0	0	0
Limbal relaxing incision to correct surgically induced astigmatism	1	0	1	0
Limbal relaxing incision to correct pre-existing astigmatism	0	1	0	1
Macular hole repair	0	0	1	0
YAG laser capsulotomy for wrinkles, folds or strands in capsule	1[b]	0	3	0
Intraocular injection for wet age related macular degeneration	0	2[d]	0	0
Retinal detachment repair and prophylactic retinopexy	2	0	5[e]	1
Retained lens removal	2	0	1	1
Corneal wound leak repair	0	0	1	1
Anterior vitrectomy	1	0	0	0

[a] One subject required an IOL repositioning surgery at the 6 month visit. The Investigator considered the event related to the patient's eye anatomy and the IOL rotation was assumed to have occurred within the first 24 hours following surgery.
[b] One subject experienced floppy iris during surgery and required two repositioning procedures. The same subject also experienced a YAG laser capsulotomy for wrinkled capsule in the first eye.
[c] The IOL was implanted at the incorrect axis in two subjects.
[d] One subject was administered two intraocular injections for wet age related macular degeneration in the first eye.
[e] One subject had one prophylactic retinopexy procedure performed in the first eye and three retinopexy procedures performed in the second eye.
ReSTOR® Toric +3.0 D = AcrySof® IQ ReSTOR® +3.0 D Multifocal Toric IOL Models SND1T3/SND1T4/SND1T5/SND1T6
ReSTOR® +4.0 D = AcrySof® ReSTOR® Multifocal IOL (+4.0 D Add) Model SA60D3

Visual Disturbances
A Patient Reported Outcomes instrument was developed and used in this clinical study to assess visual disturbances and distortions. The questionnaire administered was not validated according to FDA's guidance document entitled "Patient-reported outcome measures: use in medical product development to support labeling claims", dated December 2009. As demonstrated in Table 19, reports of visual disturbances/distortions were similar between the ReSTOR® Toric +3.0 D IOL and the control ReSTOR® +4.0 D IOL groups at 1 year. The highest rate of "severe" reports of visual disturbances/distortions at 1 year was for halos at 7.5% for ReSTOR® Toric +3.0 D IOL and 11.0% for the control ReSTOR® +4.0 D IOL.

Table 19: Comparison of Visual Disturbances for ReSTOR® Toric +3.0 D and ReSTOR® +4.0 D 1 Year Postoperative (following second eye implantation)

		ReSTOR® Toric +3.0 D					ReSTOR® +4.0 D			
Visual Disturbance	**N**	**None %**	**Mild %**	**Mod[a] %**	**Severe %**	**N**	**None %**	**Mild %**	**Mod[a] %**	**Severe %**
Glare	372	40.6	36.3	19.6	3.5	182	35.2	36.8	25.3	2.7
Halos	372	22.6	38.4	31.5	7.5	182	20.9	40.7	27.5	11.0
Starbursts	372	37.4	39.0	19.4	4.3	182	34.6	37.4	19.2	8.8
Hazy vision	372	55.1	33.1	10.5	1.3	182	51.6	30.8	17.0	0.5
Blurred vision	372	70.7	19.1	9.4	0.8	182	69.2	23.6	7.1	0.0
Distortion where straight lines look tilted	372	96.8	2.2	1.1	0.0	182	92.9	4.9	2.2	0.0
Distortion where flat lines look curved	372	96.5	3.2	0.3	0.0	182	94.0	4.9	1.1	0.0
Double vision	372	89.8	7.5	1.9	0.8	182	91.2	6.6	2.2	0.0
Color distortion	371	94.3	5.1	0.5	0.0	182	95.1	3.8	1.1	0.0
Feeling sick due to visual distortion	371	98.4	1.3	0.3	0.0	182	97.8	1.6	0.0	0.5

[a] Mod = Moderate
ReSTOR® Toric +3.0 D = AcrySof® IQ ReSTOR® +3.0 D Multifocal Toric IOL Models SND1T3/SND1T4/SND1T5/SND1T6
ReSTOR® +4.0 D = AcrySof® ReSTOR® Multifocal IOL (+4.0 D Add) Model SA60D3

Spectacle Independence
A subjective questionnaire consisting of sponsor-developed questions was used in the study to assess spectacle independence following implantation with the IOL. However, the questionnaire was not determined to be a psychometrically valid assessment of "spectacle independence". Responses to items on this questionnaire were not meaningfully different between the two groups.

Glistenings
95.7 % of ReSTOR Toric and 97.3% of ReSTOR subjects had no observation of glistenings in the first implanted eye and 96.0% of ReSTOR Toric and 97.3% of ReSTOR subjects had no observation of glistenings in the second implanted eye. None of the observed glistenings were reported as clinically significant by the implanting surgeons.

Prior Clinical Studies:

2. AcrySof® ReSTOR® APODIZED DIFFRACTIVE OPTIC POSTERIOR CHAMBER MULTIFOCAL IOL CLINICAL STUDIES

Multicenter clinical studies were conducted in the United States and Europe to establish the safety and effectiveness of the AcrySof® ReSTOR® Apodized Diffractive Optic IOL (+4.0 D Add) (Models MA60D3 and SA60D3). A total of 566 first-eye implanted ReSTOR® IOL (440 Model MA60D3 and 126 Model SA60D3) and 194 AcrySof® Monofocal IOL Model MA60BM Control subjects comprise the All Implanted cohort. A Best Case cohort (subjects with no clinically significant preoperative ocular pathology or postoperative macular degeneration) consisted of 391 Model MA60D3 and 109 Model SA60D3 ReSTOR® IOL subjects and 172 Model MA60BM monofocal IOL subjects. Demographically, these studies consisted of 65.3% female and 34.7% male subjects. Stratified by race, subjects were 93.9% Caucasian, 2.6% Black, 0.9% Asian, and 2.5% designated "Other." The mean age for the total study population was 68.8 years.

Visual Acuity
ReSTOR® IOL subjects experienced a significant increase (≥ 2 lines) in uncorrected photopic and distance corrected photopic near vision as compared to monofocal control patients. The improvement in distance corrected near vision was greater under photopic than mesopic conditions. Mean spherical add power needed to achieve best corrected near visual acuity was higher under mesopic conditions (mean value of 2.5 D) than photopic conditions (range of mean values: 0.09 to 0.16 D). The average distance of best focus for near vision was approximately 2 cm closer than the predicted distance of 33 cm.

Results from a controlled clinical study revealed that maximum visual performance is achieved when implanted bilaterally. Binocularly implanted ReSTOR® IOL subjects achieved uncorrected and best corrected distance visual acuities similar to monofocal control subjects. When implanted monocularly, a statistically significant decrease (≤ 2 letters) in mean uncorrected and best corrected distance visual acuity was observed in subjects with ReSTOR® IOLs as compared to the monofocal

controls. Older subjects implanted with the ReSTOR® lens (e.g., ≥ 80 years old), demonstrated a trend for poorer uncorrected distance visual acuity than the monofocal control patients.

Binocular Visual Acuity

The following is a summary of binocular visual acuity (VA) results for patients who completed the Form 4A (120-180 days after second eye implantation).

Figure 4: Combined 20/40 or Better Distance & Near Photopic Visual Acuity Binocular, Best Case 6 Months Postoperative

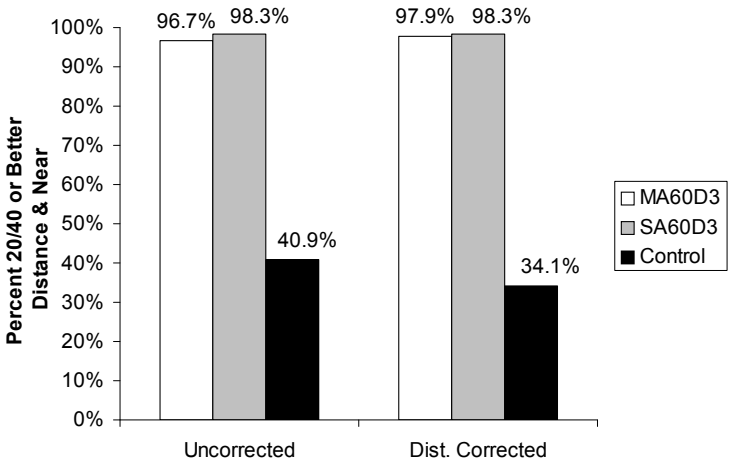


Figure 5: Combined 20/25 or Better Distance & 20/32 or Better Near Photopic Visual Acuity Binocular, Best Case 6 Months Postoperative

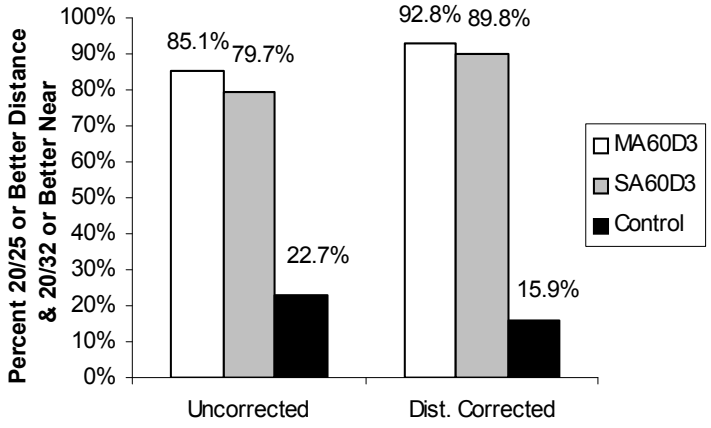


Table 20: Cumulative Binocular Photopic Near Visual Acuity by Lens Model, All Implanted, 6 Months Postoperative

		Sample size	20/20 (J1) or better	20/25 (J2) or better	20/32 (J4) or better	20/40 (J5) or better	Worse than 20/40 (J5)
		N	%	%	%	%	%
Uncorrected (Best Distance)	MA60D3	388	38.9	74.5	90.5	96.4	3.6
	SA60D3	69	46.4	69.6	87.0	98.6	1.4
	Monofocal	157	3.2	14.0	23.6	40.8	59.2
Uncorrected (Standard Distance)	MA60D3	388	36.9	69.1	87.9	95.9	4.1
	SA60D3	69	42.0	69.6	87.0	98.6	1.4
	Monofocal	157	0.6	2.5	8.9	26.1	73.9
Distance Corrected (Best Distance)	MA60D3	387	45.5	76.2	92.5	97.9	2.1
	SA60D3	69	43.5	76.8	88.4	97.1	2.9
	Monofocal	157	1.9	5.7	15.9	33.8	66.2
Distance Corrected (Standard Distance)	MA60D3	387	47.5	77.5	93.8	97.9	2.1
	SA60D3	69	44.9	76.8	89.9	98.6	1.4
	Monofocal	157	0.6	3.8	8.3	21.0	79.0
Best Corrected (Standard Distance)	MA60D3	387	54.3	85.0	96.4	98.4	1.6
	SA60D3	68	58.8	85.3	95.6	98.5	1.5
	Monofocal	157	52.9	79.6	94.3	96.8	3.2

Table 21: Cumulative Binocular Photopic Distance Visual Acuity by Lens Model, All Implanted, 6 Months Postoperative

		Sample size	20/20 or better	20/25 or better	20/32 or better	20/40 or better	Worse than 20/40
		N	%	%	%	%	%
Uncorrected	MA60D3	388	64.2	88.1	95.1	99.2	0.8
	SA60D3	69	58.0	88.4	95.7	100.0	0.0
	Monofocal	157	70.7	91.7	94.9	97.5	2.5
Best Corrected	MA60D3	387	89.4	97.9	100.0	100.0	0.0
	SA60D3	69	88.4	100.0	100.0	100.0	0.0
	Monofocal	157	93.0	97.5	98.7	100.0	0.0

Monocular Visual Acuity

The following is a summary of monocular visual acuity (VA) results for patients who completed the Form 4 (120-180 days after first eye implantation), and Form 5 (330-420 days after first eye implantation) exams.

Table 22: Cumulative Monocular Photopic Near Vision by Lens Model, All Implanted, 6 Months Postoperative

		Sample size	20/20 (J1) or better	20/25 (J2) or better	20/32 (J4) or better	20/40 (J5) or better	Worse than 20/40 (J5)
		N	%	%	%	%	%
Uncorrected (Best Distance)	MA60D3	407	27.3	51.8	74.9	86.2	13.8
	SA60D3	110	28.2	53.6	79.1	90.0	10.0
	Monofocal	176	1.1	5.7	12.5	26.1	73.9
Uncorrected (Standard Distance)	MA60D3	407	19.2	42.5	67.6	84.5	15.5
	SA60D3	110	19.1	41.8	67.3	85.5	14.5
	Monofocal	176	0.0	0.6	6.8	11.9	88.1
Distance Corrected (Best Distance)	MA60D3	407	30.2	58.2	83.0	92.1	7.9
	SA60D3	110	30.9	63.6	86.4	94.5	5.5
	Monofocal	176	0.6	2.3	9.1	21.6	78.4
Distance Corrected (Standard Distance)	MA60D3	407	26.8	59.0	81.1	92.9	7.1
	SA60D3	110	30.0	64.5	80.9	96.4	3.6
	Monofocal	176	0.6	1.1	3.4	11.4	88.6
Best Corrected (Standard Distance)	MA60D3	406	35.5	70.7	88.4	95.6	4.4
	SA60D3	110	36.4	77.3	90.0	97.3	2.7
	Monofocal	176	34.7	67.0	85.2	94.9	5.1

Table 23: Cumulative Monocular Photopic Distance Vision by Lens Model, All Implanted, 6 Months Postoperative

		Sample size	20/20 or better	20/25 or better	20/32 or better	20/40 or better	Worse than 20/40
		N	%	%	%	%	%
Uncorrected	MA60D3	407	33.2	59.2*	77.1*	90.2	9.8
	SA60D3	110	29.1	53.6*	80.0*	92.7	7.3
	Monofocal	176	42.0	71.6	85.8	94.9	5.1
Best Corrected	MA60D3	407	73.5*	92.6	97.1	99.3	0.7
	SA60D3	110	77.3*	92.7	98.2	100.0	0.0
	Monofocal	176	84.7	96.0	98.3	99.4	0.6

*Statistically significant difference versus monofocal control

Table 24: Cumulative Monocular Photopic Near Vision by Lens Model, All Implanted, 1 Year Postoperative

		Sample size	20/20 (J1) or better	20/25 (J2) or better	20/32 (J4) or better	20/40 (J5) or better	Worse than 20/40 (J5)
		N	%	%	%	%	%
Uncorrected (Best Distance)	MA60D3	319	21.0	53.6	74.9	85.6	14.4
	Monofocal	89	3.4	4.5	11.2	19.1	80.9
Uncorrected (Standard Distance)	MA60D3	319	17.9	43.6	69.6	79.6	20.4
	Monofocal	89	0.0	0.0	2.2	12.4	87.6
Distance Corrected (Best Distance)	MA60D3	318	30.5	62.9	82.1	90.9	9.1
	Monofocal	89	0.0	1.1	3.4	14.6	85.4
Distance Corrected (Standard Distance)	MA60D3	319	29.5	60.5	80.6	90.3	9.7
	Monofocal	89	0.0	1.1	2.2	9.0	91.0
Best Corrected (Standard Distance)	MA60D3	319	36.4	70.2	89.3	94.7	5.3
	Monofocal	89	50.6	79.8	94.4	95.5	4.5

Table 25: Cumulative Monocular Photopic Distance Vision by Lens Model, All Implanted, 1 Year Postoperative

		Sample size	20/20 or better	20/25 or better	20/32 or better	20/40 or better	Worse than 20/40
		N	%	%	%	%	%
Uncorrected	MA60D3	319	30.1	58.9*	76.8*	90.0	10.0
	Monofocal	89	42.7	78.7	89.9	95.5	4.5
Best corrected	MA60D3	319	74.6*	93.4	97.8	99.1	0.9
	Monofocal	89	87.6	94.4	98.9	100.0	0.0

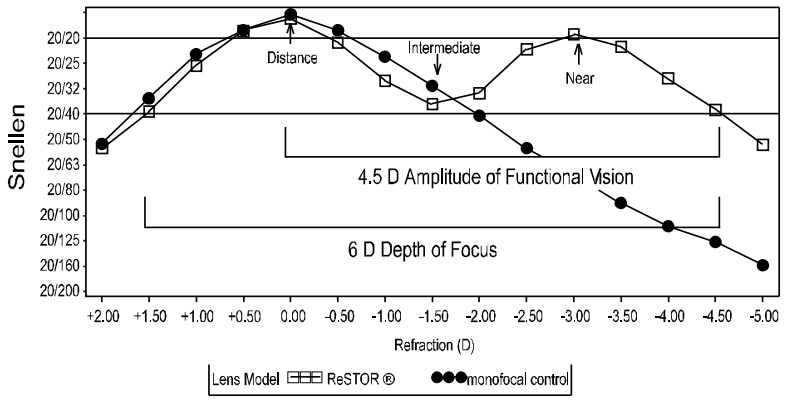
*Statistically significant difference versus monofocal control

Clinical Sub-studies

Defocus

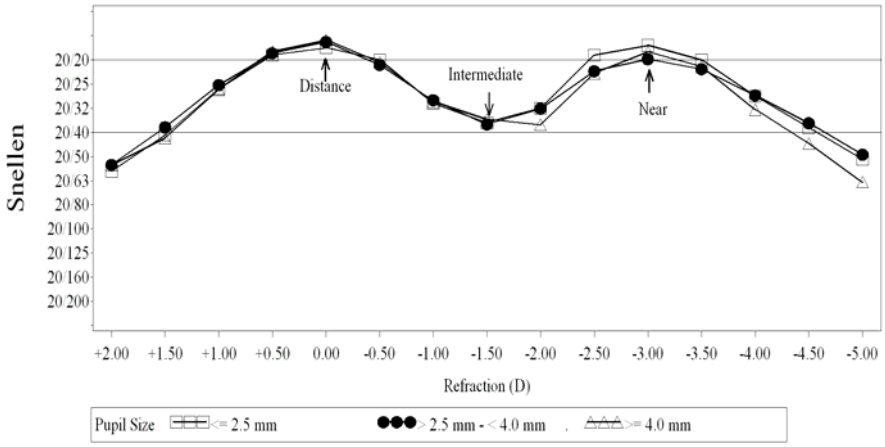
A binocular refraction defocus curve from the United States Intermediate Vision Study (34 AcrySof® ReSTOR® IOL MA60D3 All Implanted patients) displays two peaks, with one at the zero baseline corresponding to the distance focal point of the lens and one near the -3.0 D of correction, which corresponds to the near focal point of the lens. The distance peak of this curve demonstrates that ReSTOR® IOL patients achieved a mean distance visual acuity of 20/20 or better, with an additional increased depth of focus from -2.0 D to -4.5 D as compared to monofocal control patients (N=27). This additional increased depth of focus translates to a mean intermediate visual acuity of 20/40 or better and is most pronounced at near, with up to a five-line visual acuity improvement for patients implanted with a ReSTOR® IOL versus the monofocal control (Figure 6).

**Figure 6: Mean Defocus Curves by Lens Model,
Binocular, All Implanted**



These data demonstrate that the ReSTOR® IOL provides a 4.5 diopter amplitude of functional (20/40 or better) vision (from optical infinity to approximately 22 cm). Binocular performance of the ReSTOR® IOL was approximately 0.5 lines better for near vision and 1.5 lines better for intermediate vision than the monocular performance of the ReSTOR® IOL. Additionally, the defocus curves were within 1 line among groups when stratified by pupil size (Figure 7).

**Figure 7: Mean Defocus Curves by Pupil Size
Binocular, All Implanted (N=34)**



Intermediate Vision

In addition to the clinical studies supporting the safety and effectiveness of AcrySof® ReSTOR® IOL Models MA60D3 and SA60D3, a parallel group (N=34), non-randomized, multi-center supplemental study was conducted in the U.S. to evaluate the performance of the AcrySof® ReSTOR® IOL Model MA60D3 for intermediate vision compared to the monofocal control, AcrySof IOL Model MA60BM. At a distance of 70 cm, the percentage of eyes achieving 20/20 or better uncorrected vision and 20/25 or better distance corrected vision was significantly worse for the ReSTOR® IOL as compared to the monofocal control. No statistical differences were observed between the ReSTOR® IOL and the monofocal control lens for uncorrected and distance corrected vision 20/32 or better when tested at 50, 60 or 70 cm.

Table 26: Intermediate Photopic Visual Acuity, Binocular, All Implanted

		Total Sample Size	Percent 20/40 or better		
			50 cm	60 cm	70 cm
Uncorrected	**ReSTOR®**	34	82.4*	85.3	67.6
	Control	27	59.3	66.7	63.0
Distance Corrected	**ReSTOR®**	34	64.7	70.6	52.9
	Control	27	59.3	66.7	77.8

*=Statistically different from control at 0.05 level

Low Contrast Visual Acuity and Contrast Sensitivity

Contrast sensitivity and low contrast acuity under various lighting conditions was clinically equivalent between ReSTOR® IOL and monofocal control patients. While there was a tendency for reduced contrast sensitivity and low contrast acuity in ReSTOR® IOL patients in low lighting (mesopic) conditions when exposed to a glare source, no differences in contrast sensitivity from the monofocal control exceeded more than 0.3 log units, and no difference in low contrast acuity exceeded more than 2 Snellen lines.

Low contrast acuity results were comparable between ReSTOR® IOL and monofocal control groups measured with Regan contrast charts at all light sources and gray scales (100%, 25% and 9%). Functional vision (20/40 or better) was maintained under photopic conditions at all gray scales with and without glare and under mesopic conditions at 100% and 25% with and without glare.

A Vector Vision (CSV1000) contrast sensitivity chart that employs a full range of sine wave gratings at 9 contrast levels and 4 spatial frequencies (3, 6, 12, and 18 cpd) was used to assess contrast sensitivity under photopic (85 cd/m^2) and mesopic (2-5 cd/m^2) conditions, with and without a glare source. Statistical and descriptive comparisons of contrast sensitivity of the AcrySof® ReSTOR® IOL versus the monofocal control indicate that, while there are measurable differences between the two groups at higher spatial frequencies when tested under the same photopic and mesopic conditions with and without glare, none of these differences exceeded 0.3 log units. At certain spatial frequencies, the AcrySof® ReSTOR® IOL Model SA60D3 performed statistically significantly better than the AcrySof® ReSTOR® IOL Model MA60D3 by at least 0.128 log units under monocular mesopic with and without glare conditions and by 0.143 log units under binocular mesopic with glare conditions. Additionally, for monocular contrast sensitivity testing, there was no difference in the percentage of ReSTOR® IOL and monofocal IOL control patients who were not able to see any of the gratings. For binocular contrast sensitivity testing at least 85% of patients in both the ReSTOR® IOL and monofocal IOL control groups were able to see at least one grating, with the exception of mesopic with glare testing at 12 and 18 cycles per degree. At these spatial frequencies, the percentage of ReSTOR® IOL patients able to see at least one grating ranged from 85.9% - 75.0% as compared to 95.8% - 90.6% of monofocal control patients.

Table 27: Mean Log Decrease in Contrast Sensitivity ReSTOR® IOL Compared to Monofocal Control Under Photopic, Mesopic and Glare Conditions, Monocular, All Implanted, 6 Months Postoperative

		Spatial Frequency (c/d)			
Light Source (↓)	**Model**	**A(3)**	**B(6)**	**C(12)**	**D(18)**
Photopic w/o Glare	**MA60D3**	-0.02	-0.04	-0.09	-0.05
	SA60D3	0.01	-0.03	-0.12	-0.09
Photopic w/ Glare	**MA60D3**	-0.06	-0.15	-0.15	-0.15
	SA60D3	-0.05	-0.14	-0.18	-0.16
Mesopic w/o Glare	**MA60D3**	0.00	-0.12	-0.13	-0.09
	SA60D3	0.00	-0.02	0.00	-0.04
Mesopic w/ Glare	**MA60D3**	-0.08	-0.11	-0.12	-0.12
	SA60D3	-0.01	-0.04	-0.02	-0.06

Table 28: Mean Log Decrease in Contrast Sensitivity ReSTOR® IOL Compared to Monofocal Control Under Photopic, Mesopic and Glare Conditions, Binocular, All Implanted, 6 Months Postoperative

		Spatial Frequency (c/d)			
Light Source (↓)	**Model**	**A(3)**	**B(6)**	**C(12)**	**D(18)**
Photopic w/o Glare	MA60D3	-0.03	-0.11	-0.17	-0.12
	SA60D3	-0.06	-0.15	-0.21	-0.16
Photopic w/ Glare	MA60D3	-0.07	-0.23	-0.22	-0.17
	SA60D3	-0.10	-0.24	-0.23	-0.24
Mesopic w/o Glare	MA60D3	-0.06	-0.12	-0.26	-0.18
	SA60D3	-0.07	-0.17	-0.23	-0.19
Mesopic w/ Glare	MA60D3	-0.15	-0.24	-0.25	-0.19
	SA60D3	-0.07	-0.24	-0.23	-0.21

Summary of Driving Sub-study (Models MA60D3 and SA60D3)
Night driving performance was tested using the NDS (Night Driving Simulator) developed and validated by Vision Sciences Research, Corp. in bilaterally implanted subjects (23 subjects implanted with ReSTOR® IOL Model MA60D3 and 25 subjects implanted with monofocal control Model MA60BM) were tested to determine visibility distances for the detection and identification of road warning signs, message signs and road hazards under various conditions (clear [normal], inclement weather [fog] and glare conditions). The simulated driving scenes using the NDS (Night Driving Simulator) were a city street at night with streetlights and a rural highway with low beam headlights.

It is important to realize that there are no absolute detection and identification distances for all targets to determine safety and efficacy. Actual visibility distances, excluding individual differences, will depend upon the target size, contrast (sign age, clean or dirty sign), background clutter (oncoming vehicle headlights, street and store lights) and vehicle headlight condition (low or high beams, clean or dirty lens). The NDS was designed to provide similar visibility distances to that of similar targets reported in the literature. One could use other targets in the real world and obtain other visibility distances; however, those distances would be relevant only for the conditions noted above, such as age and condition of the target, and would change over time. Therefore, safety and efficacy analysis can only be based on relative differences between the lenses, not absolute values. Visibility distance values could be biased to allow a very large difference between lenses to satisfy stopping distance requirements by making the simulator targets visible at very large distances or, conversely, visibility distance values could be biased to allow a very small difference between lenses to satisfy stopping distance requirements by making the simulator targets visible at very small distances. With this in mind, further analysis uses the actual target visibility distance examples first reported in the validation study literature for the NDS.

The ability of ReSTOR® IOL (Models MA60D3 and SA60D3) subjects to detect and identify road signs and hazards at night was similar to the monofocal control Model MA60BM under normal visibility driving conditions.

Sign Identification

Rural Driving Conditions
The mean visibility distances, standard deviation and percentage difference of monofocal (Model MA60BM) and ReSTOR® IOL (Model MA60D3) subjects for sign identification under normal, fog and glare conditions in the rural scene are shown in Table 29.

Both fog and glare are seen to cause larger differences between the monofocal and ReSTOR® IOL Model MA60D3 subject performance than the clear night condition. However, in all instances the mean differences were less than 15%.

Table 29: Mean (± SD) Sign Identification Distances in Rural Scene

Identification Distance (feet)		**Lens**		**Difference**	**% Loss over Control**
		Control	**ReSTOR®**		
Visibility Condition	**Targets**				
Normal	Text	249 ± 57	230 ± 41	19	7.5 %
	Warning	523 ± 68	476 ± 81	47	8.9 %
Fog	Text	248 ± 42	215 ± 50	33	13.4 %
	Warning	512 ± 89	453 ± 88	60	11.6 %
Glare	Text	228 ± 56	195 ± 52	33	14.1 %
	Warning	512 ± 89	448 ± 83	64	12.5 %

City Driving Conditions
The mean visibility distances, standard deviation and percentage difference of monofocal (Model MA60BM) and ReSTOR® IOL Model MA60D3 subjects for sign identification under normal, fog and glare conditions in the city scene are shown in Table 30.

Under glare conditions, the ability of the ReSTOR® IOL Model MA60D3 subjects to identify the text sign is reduced on average by 28%, however there was only a small difference under these conditions for the warning sign.

Table 30: Sign Identification Distances in City Scene

Identification Distance (feet)		Lens		Difference	% Loss Over Control
		Control	ReSTOR®		
Visibility Condition	**Targets**				
Normal	Text	160 ± 30	143 ± 31	17	10.8 %
	Warning	211 ± 26	201 ± 25	10	4.7 %
Fog	Text	159 ± 24	138 ± 34	21	13.2 %
	Warning	208 ± 23	184 ± 31	24	11.7 %
Glare	Text	142 ± 33	102 ± 46	40	28 %
	Warning	194 ± 26	170 ± 28	24	12.5 %

Detecting Hazards

Rural Conditions
The mean visibility distances, standard deviation and percentage difference of monofocal (Model MA60BM) subjects and ReSTOR® IOL (Model MA60D3) subjects for hazard detection under normal, fog and glare conditions in the rural scene are shown in Table 31. In rural conditions, all differences for detecting hazards were less than 20%.

Table 31: Hazard Detection Distances in Rural Scene

Detection Distance (feet)	Lens		Difference	% Loss Over Control
	Control	ReSTOR®		
Visibility Condition				
Normal	511 ± 80	474 ± 87	37	7.2 %
Fog	507 ± 92	465 ± 101	42	8.5 %
Glare	480 ± 98	386 ± 150	94	19.7 %

City Conditions
The mean hazard detection, standard deviation and percentage differences for control (Model MA60BM) subjects and ReSTOR® IOL (Model MA60D3) subjects for hazard detection under normal, fog and glare conditions in the city scene are shown in Table 32. For city conditions, in all instances the mean differences were less than 15%.

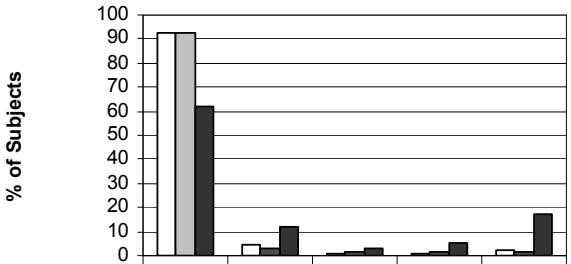
Table 32: Hazard Detection Distances in City Scene

Detection Distance (feet)	Lens		Difference	% Loss Over Control
	Control	ReSTOR		
Visibility Condition				
Normal	200 ± 52	183 ± 38	17	8.5 %
Fog	229 ± 66	211 ± 65	18	7.9 %
Glare	190 ± 67	166 ± 48	24	12.6 %

Retinal Detail
No difficulties in retinal treatment were encountered by any investigator in the study. However, one investigator had 20 reports of loss of retinal detail (i.e., the fundus appeared more anterior).

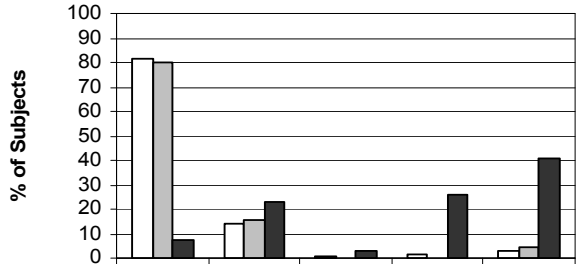
Quality of Life/Spectacle Independence
Patient reported spectacle independence was determined using the Cataract TyPE Specification instrument (Javitt, 1997). ReSTOR® IOL spectacle independence rates were statistically better ($p<0.0001$) than the control rates.

Figure 8: Frequency of Spectacle Wear
Distance Vision, Bilateral Comparison



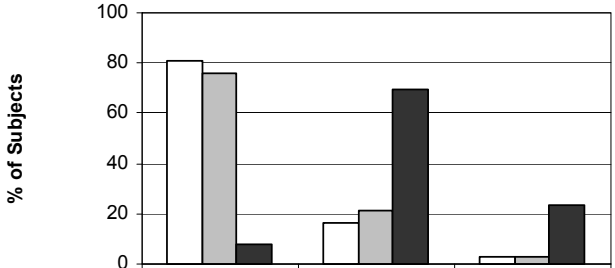
	None of the time	Some of the time	Half of the time	Most of the time	All of the time
MA60D3	92.5	4.5	0.4	0.8	1.9
SA60D3	92.9	2.9	1.4	1.4	1.4
Control	62.2	12.2	3.2	5.1	17.3

Figure 9: Frequency of Spectacle Wear
Near Vision, Bilateral Comparison



	None of the time	Some of the time	Half of the time	Most of the time	All of the time
MA60D3	81.2	13.9	0.4	1.5	3
SA60D3	80	15.7	0	0	4.3
Control	7.7	23.2	2.6	25.8	40.6

Figure 10: Overall Frequency of Spectacle Wear, Bilateral Comparison



	Never	Sometimes	Always
MA60D3	81	16	3
SA60D3	75.7	21.4	2.9
Control	7.7	69.2	23.1

Table 33: Patient Satisfaction with Vision (without glasses)

		MA60D3	SA60D3	Control
Overall	**Baseline**	0.6 (N=311)	0.5 (N=126)	0.6 (N=193)
	Unilateral	2.6* (N=309)	2.5 (N=124)	2.4 (N=184)
	Bilateral	3.5** (N=268)	3.4** (N=69)	3.0 (N=155)
Day Vision	**Baseline**	0.9 (N=311)	0.7 (N=126)	0.8 (N=194)
	Unilateral	2.7* (N=309)	2.6 (N=123)	2.5 (N=185)
	Bilateral	3.5** (N=269)	3.4** (N=68)	3.0 (N=156)
Night Vision	**Baseline**	0.6 (N=311)	0.5 (N=126)	0.6 (N=193)
	Unilateral	2.4 (N=309)	2.5 (N=124)	2.4 (N=185)
	Bilateral	3.3** (N=269)	3.2* (N=69)	2.9 (N=156)

Satisfaction Scale (0-4): 0=not at all satisfied, 4=completely satisfied.
*=Significantly different from control at 0.05 level
**=Significantly different from control at 0.01 level

Table 34: Self Rating of Vision (without glasses)

	MA60D3	SA60D3	Control
Baseline	4.2 (N=313)	4.1 (N=125)	4.1 (N=194)
Unilateral	7.1 (N=307)	7.1 (N=123)	6.9 (N=185)
Bilateral	8.7* (N=266)	8.9* (N=70)	7.9 (N=155)

Rating Scale (0-10): 0=worst possible vision, 10=best possible vision
*=Significantly different from control at 0.01 level

Adverse Events
The incidences of cumulative adverse events for the ReSTOR® IOL as compared to the FDA historical grid rates are provided in Table 35. A single occurrence of retinal detachment/repair, single occurrence of pupillary block, and surgical reinterventions exceeded the FDA Grid rate. No occurrences of persistent adverse events (adverse events in the FDA grid that are observed at the 12 month postoperative visit) were observed in any patients implanted with the ReSTOR® IOL.

Table 35: ReSTOR® IOL versus FDA Historical Grid, First Eye – Safety

	ReSTOR® MA60D3 (N=440)		ReSTOR® SA60D3 (N=126)		FDA Grid rate*
	N	%	N	%	%
Cumulative Adverse Events					
Endophthalmitis	0	0.0	0	0.0	0.1
Macular Edema	12	2.7	1	0.8	3.0
Retinal Detachment/Repair	0	0.0	1	0.8	0.3
Hyphema	0	0.0	0	0.0	2.2
Pupillary block	1	0.2	0	0.0	0.1
Lens Dislocation	0	0.0	0	0.0	0.1
Surgical reintervention	10	2.3	2	1.6	0.8
IOL replacement for biometry error	2	0.5	0	0.0	NA
IOL replacement for incorrect power/operating room error	2	0.5	0	0.0	NA
IOL replacement for visual disturbance	1	0.2	0	0.0	NA
IOL replacement for decentered IOL due to trauma	1	0.2	0	0.0	NA
IOL replacement due to patient dissatisfaction	0	0.0	1	0.8	NA
Laser treatment	3	0.7	1	0.8	NA
Fibrin removal	1	0.2	0	0.0	NA
Persistent Adverse Events:					
Macular Edema	0	0.0	0	0.0	0.5
Raised IOP Requiring Treatment	0	0.0	0	0.0	0.4
Corneal Edema	0	0.0	0	0.0	0.3
Iritis	0	0.0	0	0.0	0.3

*FDA draft guidance on Monofocal Intraocular Lenses, Annex B (October 14, 1999)

Visual Disturbances
With the exception of blurred near vision and problems with color perception, the monofocal control patients had a lower rate of severe observations than the ReSTOR® IOL patients (Table 36). Of the 440 subjects implanted with ReSTOR® IOL Model MA60D3 and 126 subjects implanted with Model SA60D3, one subject implanted with ReSTOR® IOL Model MA60D3 required lens explantation due to visual disturbances.

Table 36: Visual Disturbances, 6 Months Postoperative (Following second eye implantation)

Visual Disturbance	ReSTOR® Model MA60D3		ReSTOR® Model SA60D3		Monofocal Control	
	% Moderate	% Severe	% Moderate	% Severe	% Moderate	% Severe
Glare/Flare	20.1	4.9	23.2	4.3	7.1	1.9
Problems with Night Vision	8.5	4.1	10.1	2.9	3.8	1.9
Halos	18.0	4.4	23.2	7.2	1.9	1.3
Distorted Near Vision	0.8	0.8	0.0	0.0	0.6	0.0
Distorted Far Vision	1.0	0.3	0.0	0.0	0.6	0.0
Blurred Near Vision	5.9	0.8	7.2	0.0	12.8	3.8
Blurred Far Vision	5.9	1.0	5.8	0.0	3.2	0.6
Double Vision in both eyes	1.5	0.8	1.4	0.0	1.3	0.0
Problems with Color Perception	0.5	0.0	0.0	0.0	0.0	0.0

3. AcrySof NATURAL SINGLE-PIECE IOL CLINICAL STUDY (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. The results achieved by the subjects successfully followed for a minimum of one year postoperatively provided reasonable assurance of safety and effectiveness of the AcrySof Natural Single Piece IOL Model SB30AL for the visual correction of aphakia.

Summary of Color Perception Study
Color perception testing using the Farnsworth D-15 Panel Test was conducted on all subjects at the 120 to 180 day postoperative period. Of the 109 subjects with normal color vision implanted with the AcrySof Natural IOL Model SB30AL in the first operative eye and examined at the 120-180 day postoperative visit, 107 (98.2%) passed the color perception test. Of the 102 subjects with normal color vision implanted with a AcrySof UV IOL Model SA30AL in the first operative eye and examined at the 120-180 day postoperative visit, 97 (95.1%) passed the color perception test. There were no statistically significant differences between AcrySof Natural IOL Model SB30AL and AcrySof UV IOL 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.

HOW SUPPLIED
The AcrySof IQ® ReSTOR® +3.0 D Multifocal Toric IOL Models SND1T3, SND1T4, SND1T5 and SND1T6 are supplied dry, in a package terminally sterilized with ethylene oxide, and must be opened only under aseptic conditions (see DIRECTIONS FOR USE).

EXPIRATION DATE
Sterility is guaranteed unless the pouch is damaged or opened. The expiration date is clearly indicated on the outside of the lens package. Any lens held after the expiration date should be returned to Alcon Laboratories, Inc. (see RETURNED GOODS POLICY).

RETURNED GOODS POLICY
In the United States, returned lenses will only be accepted in exchange for other products, not credit. All returns must be accompanied by an Alcon Laboratories, Inc. Returned Goods Number and 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.

Outside the United States, contact your local Alcon office or distributors regarding the Returned Goods Policy.

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

Symbols Used on Labeling

SYMBOL	ENGLISH
IOL	Intraocular lens
PC	Posterior chamber
PCL	Posterior chamber lens
UV	Ultraviolet
D	Diopter (Spherical Equivalent)
CYL	Cylinder Power
$Ø_B$	Body diameter (Optic diameter)
$Ø_T$	Overall diameter (Overall length
	Do not reuse
	Use by date
	Sterilized using ethylene oxide
	Serial Number
	Caution
	Manufacturer
	Upper Limit of Temperature

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

U.S. Pat. No's. 5,699,142; 5,470,932; 5,716,403; 7,879,089; and 8,167,940.

Alcon
a Novartis company