40-500-231-XXX

PRODUCT INFORMATION
Alcon Laboratories, Inc.

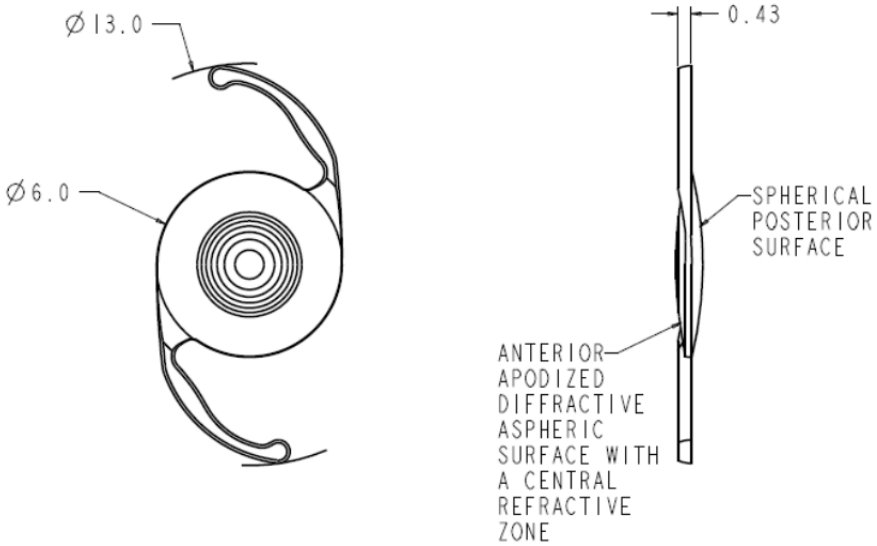
STERILE UV and Blue Light Filtering Foldable
Single-piece Apodized Diffractive Aspheric Multifocal Posterior Chamber Lens

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

DESCRIPTION

The AcrySof® IQ ReSTOR® +2.5 D Apodized Diffractive Aspheric Multifocal Posterior Chamber Intraocular Lens (IOL) is an ultraviolet and blue light filtering foldable multifocal intraocular lens. The optical portion consists of a proprietary high refractive index hydrophobic acrylic material with a 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). 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. After surgical insertion into the eye, the lens gently unfolds to restore the optical performance. The biconvex optic contains an aspheric apodized diffractive structure with a central refractive zone on the anterior surface. The apodized diffractive structure divides incoming light to provide a range of functional vision (defined as visual acuity of 20/40 or better) from distance to near. The anterior surface of the AcrySof® IQ ReSTOR® +2.5 D Multifocal IOL Model SV25T0 is designed with negative spherical aberration to compensate for the positive spherical aberration of the cornea. Compared to other Alcon AcrySof® IQ ReSTOR® Multifocal IOL models (Models SN6AD1, SN6AD3, MN6AD1), this IOL (Model SV25T0) provides an alternate option for clinicians to offer patients with the near add power of +2.5 D, with optimal vision at 53 cm and greater distance dominance in the energy distribution between near and far. The effects of this aspheric design feature have not been clinically assessed. The physical properties of these lenses are described in Figures 1-3 and Table 1.

Figure 1: Physical Characteristics, AcrySof® IQ ReSTOR®
+2.5 D Multifocal IOL Model SV25T0
(All dimensions in millimeters)

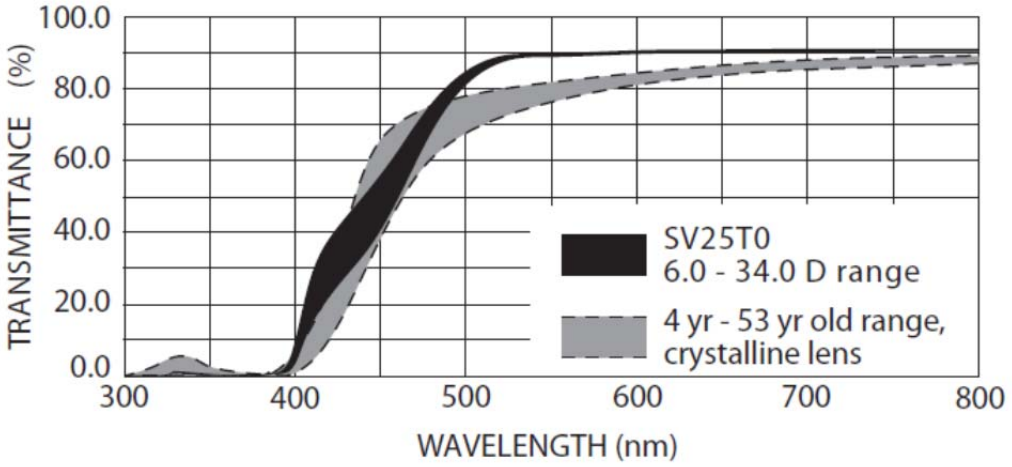


Model SV25T0

Table 1: Physical Characteristics of AcrySof® IQ ReSTOR® +2.5 D Multifocal IOL Model SV25T0

Physical Characteristic	Description
Optic Type	Apodized Diffractive Aspheric Optic With a Central Refractive Zone
Optic Material	Ultraviolet and blue light filtering Acrylate/Methacrylate Copolymer
UV cutoff at 10% T	403 nm for 21 D (See Figure 2)
Index Of Refraction	1.55
Optic Powers	+6.0 - +30.0 (0.5 diopter increments) and +31.0 - +34.0 (1.0 diopter increments) with a +2.5 Diopter add power
Haptic Configuration	STABLEFORCE® Haptic
Haptic Material	Ultraviolet and blue light filtering Acrylate/Methacrylate Copolymer
Haptic Color	Yellow
Optic Diameter (mm)	6.0
Overall Length (mm)	13.0
Haptic Angle	0°

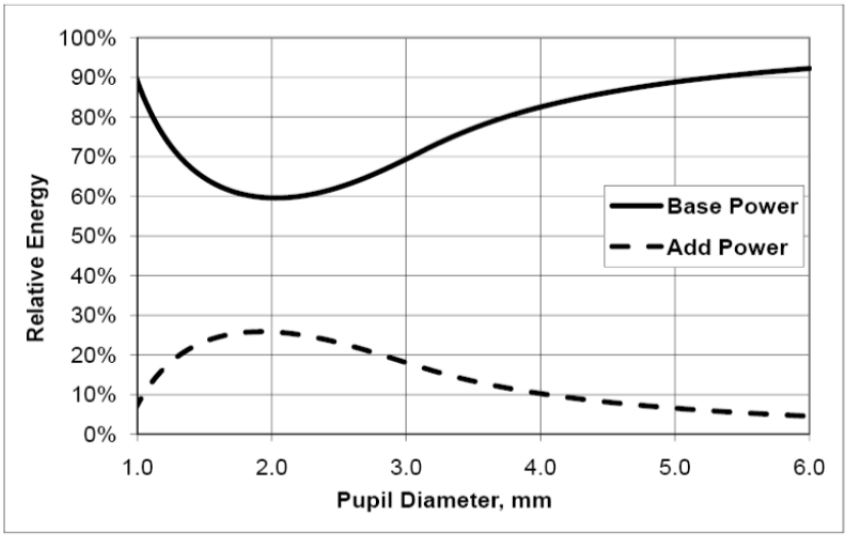
Figure 2: Spectral Transmittance
(measured in air)



NOTE:

- Human crystalline lens data from Boettner and Wolter (1962).

Figure 3: Theoretical Percentage of Light Energy at 550 nm Wavelength



MODE OF ACTION

The AcrySof® IQ ReSTOR® +2.5 D Multifocal 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. This IOL has a biconvex optic containing an aspheric apodized diffractive structure with a central refractive zone on the anterior surface. The apodized diffractive structure divides incoming light to provide a range of functional vision (defined as visual acuity of 20/40 or better) from distance to near. This IOL provides an alternate option for clinicians to offer patients with an add power of +2.5 D designed to provide optimal vision at 53 cm.

INDICATIONS

The AcrySof® IQ ReSTOR® +2.5 D Multifocal IOL is intended for primary implantation in the capsular bag of the eye for the visual correction of aphakia secondary to removal of a cataractous lens in adult patients with and without presbyopia, who desire near, intermediate, and distance vision with increased spectacle independence.

WARNINGS

1. Some visual effects may be expected due to the superposition of focused and unfocused multiple images. These may include some perceptions of halos or radial lines around point sources of light (starbursts) under nighttime conditions, glare, double vision, haziness and blurred vision. 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 AcrySof® IQ ReSTOR® +2.5 D Multifocal IOL:
    - The surgeon must target emmetropia to achieve optimal visual performance.
    - Patients with significant preoperative (determined by keratometry) or expected 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.

PRECAUTIONS

1. Prior to surgery, prospective patients should be informed of the possible risks and benefits associated with the AcrySof® IQ ReSTOR® +2.5 D Multifocal IOL Model SV25T0. A Patient Information Brochure can be found at http://ecatalog.alcon.com/iol_dfu/SV25T0_us_en.pdf. Please provide a copy of the Patient Information Brochure to the patient.
2. As with all multifocal IOLs, spectacle independence rates will vary. 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® +2.5 D Multifocal IOL have not been substantiated in patients with the following pre-existing and intraoperative conditions.

Pre-existing Conditions

- 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

  [This precaution is included because 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)].
- Amblyopia
- Clinically severe corneal dystrophy (eg, 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 (eg, 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 the AcrySof® Natural IOL and normal color vision. The effect of the AcrySof® Natural IOL in subjects with hereditary color vision defects and acquired color vision defects secondary to ocular disease (eg, glaucoma, diabetic retinopathy, chronic uveitis, and other retinal or optic nerve diseases) has not been studied].
- Previous retinal detachment
- Diabetic retinopathy
- Previous refractive surgery
- Pregnancy

Intraoperative Conditions

- Other planned ocular surgery procedures, including but not limited to, LASIK, astigmatic keratotomy, and limbal relaxing incisions
- Excessive iris mobility
- Mechanical or surgical manipulation required to enlarge the pupil
- Dilated pupil size less than 4.5 mm just prior to implantation
- Vitreous loss (significant)
- Anterior chamber bleeding (significant)
- Uncontrolled positive intraocular pressure
- Complications in which the IOL stability could be compromised, including zonular separation

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.

5. The clinical study of the AcrySof® IQ ReSTOR® +2.5 D Multifocal IOL Model SV25T0 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.
6. 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.

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. Care should be taken to remove viscoelastic from the eye at the close of surgery.
10. Do not re-sterilize these intraocular lenses by any method.
11. Do not store intraocular lenses at temperatures over 45° C (113° F).
12. Use only sterile intraocular irrigating solutions (such as BSS® or BSS PLUS® solution) to rinse and/or soak lenses.

CALCULATION OF LENS POWER

Accurate biometry is essential for successful visual outcomes. Preoperative calculation of required lens power for the AcrySof® IQ ReSTOR® +2.5 D Multifocal IOL 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* is listed on the outer label. This reference A-Constant anticipates the use of both corneal power and axial length values from optical biometry equipment with standard settings for a typical patient population and a spectacle far point at 6 meters. IOL power calculation methods are often included with biometry equipment, and they are also described in the references below. In general, lens constants must be "personalized" to compensate for such things as differences in instrumentation, surgical techniques, and IOL power calculation methods that may exist between different clinical sites.

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

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.

http://www.augenklinik.uni-wuerzburg.de/ulib/index.htm

DIRECTIONS FOR USE

1. Examine the label on the unopened package for model, powers (base and add), proper configuration, and expiration date.
2. After opening the cardboard storage container, verify lens case information (eg, model, power, 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® +2.5 D Multifocal 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.

PATIENT REPORTING AND REGISTRATION

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 (AB 2-6)
6201 South Freeway
Fort Worth, TX 76134-2099
Call Collect: (817) 551-4445 in the United States

Outside the United States, contact local Alcon offices or distributors regarding any reports of adverse events.

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.

CLINICAL STUDIES

The data from a recent clinical study of the AcrySof® IQ ReSTOR® +2.5 D Multifocal IOL Model SV25T0, and data from two relevant prior clinical studies are included in this section:

1. A clinical study was conducted to assess the safety and effectiveness of the AcrySof® IQ ReSTOR® +2.5 D Multifocal IOL Model SV25T0.
2. 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. The AcrySof® IQ ReSTOR® +2.5 D Multifocal IOL Model SV25T0 is also a single-piece IOL using the same material mechanical platform and the same blue filtering chromophore, as the Model SB30AL. The data showed the blue 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® +2.5 D Multifocal IOL Model SV25T0.
3. A prior clinical study, including a night driving simulator sub-study, was conducted to demonstrate the safety and effectiveness of the non-blue-filtering multi-piece and single-piece AcrySof® ReSTOR® Models MA60D3 and SA60D3. The AcrySof® IQ ReSTOR® +2.5 D Multifocal IOL Model SV25T0 uses an apodized diffractive optic as in Models MA60D3 and SA60D3. The safety data (adverse events and night driving simulation results) from this study provide an expanded description of the safety profile expected of the AcrySof® IQ ReSTOR® +2.5 D Multifocal IOL Model SV25T0.

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 patient cohorts, test methods, etc.

1. AcrySof® IQ ReSTOR® +2.5 D MULTIFOCAL INTRAOCULAR LENS (IOL) (Model SV25T0)

The AcrySof® IQ ReSTOR® +2.5 D Multifocal Intraocular Lens (IOL) study was a prospective, multicenter, randomized, masked (to subjects and vision examiners), controlled clinical investigation designed to assess the safety and effectiveness of the AcrySof® IQ ReSTOR® +2.5 D Multifocal Intraocular Lens Model SV25T0 in adult subjects secondary to removal of a cataractous lens with and without presbyopia. A total of 320 subjects were implanted in this clinical study, with 155 subjects receiving IOL Model SV25T0 and 165 subjects receiving the monofocal control lens Model SN60WF. In the data tables in this section, “+2.5 D Multifocal“ refers to Model SV25T0 and “Monofocal” refers to Model SN60WF.

The study population consisted of 60.3% females and 39.7% males. Subjects were 91.3% White, 6.6% Black or African American, 0.9% Asian, 0.6% American Indian or Alaska Native, 0.3% multi-race, and 0.3% designated “Other.” Five percent (5%) of the study population designated ethnicity as Hispanic. A Best Case cohort (subjects with no preoperative ocular pathology or postoperative macular degeneration and no major protocol deviations)

consisted of 145 AcrySof® IQ ReSTOR® +2.5 D Multifocal IOL Model SV25T0 subjects and 149 Monofocal Control subjects. The mean age for the study population was 69.0 ± 9.0 years. The length of subject follow-up was 6 months.

Mean Visual Acuity

Monocular visual acuity results are presented for first implanted eyes. AcrySof® IQ ReSTOR® +2.5 D Multifocal IOL subjects experienced a significant increase in distance corrected photopic monocular near vision (at 40 cm) as compared to monofocal control subjects. The mean photopic monocular distance corrected visual acuity at 40 cm for subjects implanted with the AcrySof® IQ ReSTOR® +2.5 D Multifocal IOL was 0.206 logMAR (~2 lines on an ETDRS visual acuity chart) better than those implanted with the monofocal lens ($p < 0.001$).

AcrySof® IQ ReSTOR® +2.5 D Multifocal IOL subjects also experienced a significant increase in distance corrected photopic monocular intermediate vision (at 53 cm) as compared to the monofocal control subjects. The mean photopic monocular distance corrected visual acuity at the 53 cm test distance for subjects implanted with the AcrySof® IQ ReSTOR® +2.5 D Multifocal IOL was 0.190 logMAR better (~2 lines) than for those implanted with the monofocal lens ($p < 0.0001$).

Descriptive statistics for monocular (first eye implanted) and binocular mean distance corrected near (33 cm and 40 cm), intermediate (53 cm and 60 cm), and distance (4 m) visual acuity (VA) are shown in Table 2. AcrySof® IQ ReSTOR® +2.5 D Multifocal IOL subjects achieved uncorrected and best corrected mean distance visual acuities similar to those of the monofocal control subjects.

Table 2: Distance Corrected Visual Acuity (logMAR) at 6 Months Postoperative, All Implanted

		+2.5 D Multifocal (N=155)			Monofocal (N=165)		
		n	Mean	SD	n	Mean	SD
VA @ 4 m	Monocular - First Eye	153	0.02	0.122	160	0.00	0.107
	Binocular	153	-0.04	0.100	159	-0.06	0.102
VA @ 60 cm	Monocular - First Eye	153	0.33	0.174	160	0.43	0.169
	Binocular	153	0.23	0.143	159	0.34	0.162
VA @ 53 cm	Monocular - First Eye	153	0.32	0.172	159	0.52	0.182
	Binocular	153	0.24	0.145	158	0.40	0.161
VA @ 40 cm	Monocular - First Eye	153	0.43	0.170	160	0.64	0.184
	Binocular	153	0.34	0.151	159	0.52	0.182
VA @ 33 cm	Monocular - First Eye	153	0.56	0.175	160	0.70	0.189
	Binocular	153	0.47	0.168	159	0.60	0.190

Categorical Binocular Visual Acuity

Categorical binocular visual acuity (VA) results for subjects at 6 months postoperative are summarized in Tables 3-4 below. Each column shows the proportion of subjects achieving the indicated visual acuity for each test condition. Table 3 provides binocular photopic visual acuity at 40 cm, 53 cm, 60 cm, and at best distance. The best distance is the near distance at which each subject held the near visual acuity chart to obtain his or her best visual outcome. Table 4 provides binocular photopic visual acuity at distance (4 m). The percentage of subjects achieving 20/20 visual acuity at distance (4 m) was similar between the two IOLs.

Table 3: Categorical Binocular Photopic Visual Acuity (60, 53, and 40 cm, and Best Distance) by Lens Model, All Implanted, 6 Months Postoperative

	Lens Model	Sample Size	20/20	20/25	20/32	20/40	20/50	20/63	Worse than 20/63
		N	%	%	%	%	%	%	%
Distance Corrected at 60 cm	+2.5 D Multifocal	153	11.1	22.2	28.8	20.3	11.8	4.6	1.3
	Monofocal	159	4.4	8.8	22.0	16.4	28.9	12.6	6.9
Uncorrected at 60 cm	+2.5 D Multifocal	153	9.2	19.0	26.8	24.2	12.4	7.2	1.3
	Monofocal	159	6.3	20.1	22.6	18.9	14.5	8.8	8.8
Distance Corrected at 53 cm	+2.5 D Multifocal	153	9.2	22.2	24.2	19.6	15.7	7.2	2.0
	Monofocal	158	1.3	3.8	14.6	15.8	27.2	22.8	14.6
Uncorrected at 53 cm	+2.5 D Multifocal	153	9.2	15.7	25.5	22.2	17.6	7.8	2.0
	Monofocal	158	3.2	7.0	21.5	24.7	17.7	14.6	11.4
Best Corrected at 40 cm	+2.5 D Multifocal	153	29.4	29.4	20.9	12.4	7.2	0.0	0.7
	Monofocal	159	52.2	20.1	15.1	9.4	1.3	1.3	0.6
Distance Corrected at 40 cm	+2.5 D Multifocal	153	1.3	7.2	22.2	26.8	23.5	9.8	9.2
	Monofocal	159	0.0	1.9	3.8	13.8	19.5	20.8	40.3
Uncorrected at 40 cm	+2.5 D Multifocal	153	2.0	13.1	15.7	24.8	20.9	14.4	9.2
	Monofocal	159	0.0	3.1	13.2	15.1	18.9	17.0	32.7
Distance Corrected at best distance	+2.5 D Multifocal	153	7.8	15.0	20.3	20.9	13.7	15.0	7.2
	Monofocal	159	0.6	5.0	10.7	18.9	11.9	21.4	31.4
Uncorrected at best distance	+2.5 D Multifocal	153	4.6	13.1	19.0	25.5	18.3	8.5	11.1
	Monofocal	159	4.4	7.5	13.8	17.0	15.1	20.1	22.0

Table 4: Categorical Binocular Photopic Distance Visual Acuity (4 m) by Lens Model, All Implanted, 6 Months Postoperative

	Lens Model	Sample Size	20/20	20/25	20/32	20/40	20/50	20/63	Worse than 20/63
		N	%	%	%	%	%	%	%
Best Corrected	+2.5 D Multifocal	153	88.2	9.2	1.3	1.3	0.0	0.0	0.0
	Monofocal	159	90.6	6.9	1.3	0.6	0.0	0.6	0.0
Uncorrected	+2.5 D Multifocal	153	75.8	19.0	0.7	2.6	1.3	0.0	0.7
	Monofocal	159	77.4	15.1	6.3	1.3	0.0	0.0	0.0

Categorical Monocular Visual Acuity

The following is a summary of categorical monocular visual acuity (VA) results for the first eyes implanted with the AcrySof® IQ ReSTOR® +2.5 D Multifocal IOL Model SV25T0 and monofocal control IOL Model SN60WF at 6 months postoperative. The data are summarized in Tables 5-6 below. Each column shows the categorical proportion of subjects achieving the indicated visual acuity for each test condition. Table 5 provides categorical monocular photopic visual acuity at 40 cm, 53 cm, and at best distance. The best distance is the near distance at which each subject held the near visual acuity chart to obtain his or her best visual outcome. Mean monocular distance corrected VA for the +2.5 D multifocal IOL was approximately 2 lines better than the monofocal control IOL at 53 cm and 40 cm. Table 6 provides categorical monocular photopic visual acuity at distance (4 m). The percentage of subjects achieving 20/20 visual acuity at distance (4 m) was fairly similar between the +2.5 D Multifocal and Monofocal IOLs.

Table 5: Categorical Monocular Photopic Visual Acuity (53 cm, 40 cm, and Best Distance) by Lens Model, Primary Eye, All Implanted, 6 Months Postoperative

	Lens Model	Sample Size	20/20	20/25	20/32	20/40	20/50	20/63	Worse than 20/63
		N	%	%	%	%	%	%	%
Distance Corrected at 53 cm	+2.5 D Multifocal	153	2.0	14.4	19.0	27.5	13.7	16.3	7.2
	Monofocal	159	0.0	1.3	6.3	11.3	15.7	25.8	39.6
Uncorrected at 53 cm	+2.5 D Multifocal	153	2.6	5.2	15.0	26.1	24.8	11.8	14.4
	Monofocal	159	0.0	5.0	9.4	16.4	18.2	19.5	31.4
Best Corrected at 40 cm	+2.5 D Multifocal	153	18.3	28.1	20.9	17.0	9.8	2.6	3.3
	Monofocal	160	30.6	33.1	16.9	8.1	6.3	2.5	2.5
Distance Corrected at 40 cm	+2.5 D Multifocal	153	1.3	3.9	10.5	18.3	27.5	18.3	20.3
	Monofocal	160	0.0	0.0	2.5	3.8	10.0	14.4	69.4
Uncorrected at 40 cm	+2.5 D Multifocal	153	0.7	4.6	11.1	11.8	24.8	22.9	24.2
	Monofocal	160	0.0	0.0	6.3	6.3	16.3	14.4	56.9
Distance Corrected at best distance	+2.5 D Multifocal	153	3.3	7.8	17.0	16.3	21.6	13.1	20.9
	Monofocal	160	0.0	1.3	4.4	9.4	16.3	21.9	46.9
Uncorrected at best distance	+2.5 D Multifocal	153	2.0	6.5	10.5	24.2	17.0	17.6	22.2
	Monofocal	160	0.6	5.0	8.8	11.3	13.1	18.8	42.5

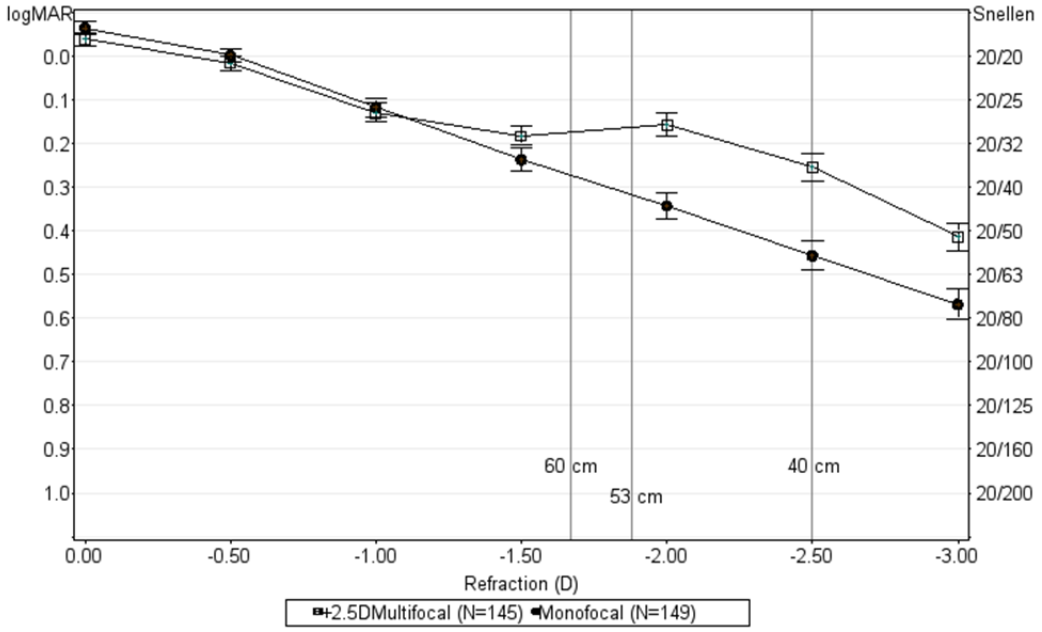
Table 6: Categorical Monocular Photopic Distance Visual Acuity (4 m) by Lens Model, Primary Eye, All Implanted, 6 Months Postoperative

	Lens Model	Sample Size	20/20	20/25	20/32	20/40	20/50	20/63	Worse than 20/63
		N	%	%	%	%	%	%	%
Best Corrected	+2.5 D Multifocal	153	71.9	17.0	7.2	2.6	0.7	0.0	0.7
	Monofocal	160	75.0	16.3	7.5	0.6	0.6	0.0	0.0
Uncorrected	+2.5 D Multifocal	153	39.2	35.3	13.7	5.9	4.6	0.7	0.7
	Monofocal	160	46.9	25.0	16.9	8.1	2.5	0.0	0.6

Binocular Defocus Curves

A binocular refraction defocus curve shows two peaks, with one at the zero baseline position, which corresponds to the distance corrected binocular visual acuity obtained at the distance focal point of the lens, and one near the –2.0 D position, which corresponds to the distance corrected binocular visual acuity obtained at the intermediate focal point of the lens (53 cm). The distance peak of this curve demonstrates that AcrySof® IQ ReSTOR® IOL subjects achieved a mean distance visual acuity of 20/20 or better with an additional increased depth of focus from +2.0 D to -2.75 D, as compared to monofocal control subjects. This additional increased depth of focus translates to a mean intermediate visual acuity of 20/32 or better at the intermediate distances, most pronounced around 53 cm, with almost a two line visual acuity improvement for subjects implanted with a AcrySof® IQ ReSTOR® +2.5 D Multifocal IOL versus the monofocal control (Figure 4).

Figure 4: Mean Defocus Curves by Lens Model, Binocular, Best Case, 1 Month Postoperative



Contrast Sensitivity

Binocular best corrected distance contrast sensitivity was performed using a sine wave grating 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 and median contrast scores, standard deviations (SD), ranges (Min, Max), and two-sided 90%confidence intervals are provided for the AcrySof® IQ ReSTOR® +2.5 D Multifocal IOL Model SV25T0 group and for the Model SN60WF monofocal IOL group under each photopic lighting condition and spatial frequency (Table 7) and each mesopic lighting condition and spatial frequency (Table 8). For some measurement conditions, one or more patients could not see any contrast gratings for a specific spatial frequency, therefore the values shown with"<" are overestimates and the standard deviations shown with ">" are underestimates. The number and percent of subjects unable to see any gratings for each specific measurement condition/spatial frequency are shown in the table in the "Number Scoring (-1)" rows. The percentage of subjects who could not see any gratings ranged from 0.8% (3 cpd, photopic without glare) to 31.6% (12 cpd, mesopic with glare) in the AcrySof® IQ ReSTOR® +2.5 D Multifocal IOL Model SV25T0 group and from 0% (3 and 6 cpd, photopic without glare) to 20.4% (12 cpd, mesopic with glare) in the Model SN60WF monofocal IOL group.

Table 7: Descriptive Statistics for Binocular Photopic Contrast Sensitivity at Visit 4A (4-6 months postoperative, Best Case Population)

		Without Glare		With Glare	
Frequency		+2.5 D Multifocal (N=133)	Monofocal (N=137)	+2.5 D Multifocal (N=133)	Monofocal (N=137)
3 CPD	Not Assessed	1 (0.8%)	4 (2.9%)	1 (0.8%)	4 (2.9%)
	Number Assessed	132 (99.2%)	133 (97.1%)	132 (99.2%)	133 (97.1%)
	Number Scoring (-1)	1 (0.8%)	0 (0.0%)	2 (1.5%)	2 (1.5%)
	Number with Data for Analysis	131 (98.5%)	133 (97.1%)	130 (97.7%)	131 (95.6%)
	Mean	<1.676	1.743	<1.608	<1.692
	Median	<1.633	1.785	<1.633	<1.785
	SD	>0.259	0.203	>0.307	>0.274
	(Min, Max)	(<0.70, 2.08)	(1.18, 2.08)	(<0.70, 2.08)	(<0.70, 2.08)
	CI	(<1.639, 1.714)	(1.714, 1.773)	(<1.563, 1.653)	(<1.652, 1.732)
6 CPD	Not Assessed	1 (0.8%)	4 (2.9%)	1 (0.8%)	4 (2.9%)
	Number Assessed	132 (99.2%)	133 (97.1%)	132 (99.2%)	133 (97.1%)
	Number Scoring (-1)	2 (1.5%)	0 (0.0%)	15 (11.3%)	8 (5.8%)
	Number with Data for Analysis	130 (97.7%)	133 (97.1%)	117 (88.0%)	125 (91.2%)
	Mean	<1.816	1.938	<1.684	<1.844
	Median	<1.845	1.996	<1.699	<1.845
	SD	>0.256	0.251	>0.316	>0.309
	(Min, Max)	(<0.90, 2.29)	(1.20, 2.29)	(<0.90, 2.29)	(<0.90, 2.29)
	CI	(<1.778, 1.853)	(1.902, 1.974)	(<1.636, 1.733)	(<1.798, 1.889)
12 CPD	Not Assessed	1 (0.8%)	4 (2.9%)	1 (0.8%)	4 (2.9%)
	Number Assessed	132 (99.2%)	133 (97.1%)	132 (99.2%)	133 (97.1%)
	Number Scoring (-1)	3 (2.3%)	1 (0.7%)	15 (11.3%)	6 (4.4%)
	Number with Data for Analysis	129 (97.0%)	132 (96.4%)	117 (88.0%)	127 (92.7%)
	Mean	<1.460	<1.555	<1.334	<1.475
	Median	<1.544	<1.544	<1.398	<1.544
	SD	>0.312	>0.312	>0.321	>0.336
	(Min, Max)	(<0.60, 2.00)	(<0.60, 2.00)	(<0.60, 2.00)	(<0.60, 2.00)
	CI	(<1.414, 1.505)	(<1.510, 1.599)	(<1.285, 1.383)	(<1.426, 1.524)
18 CPD	Not Assessed	1 (0.8%)	4 (2.9%)	1 (0.8%)	4 (2.9%)
	Number Assessed	132 (99.2%)	133 (97.1%)	132 (99.2%)	133 (97.1%)
	Number Scoring (-1)	2 (1.5%)	2 (1.5%)	13 (9.8%)	5 (3.6%)
	Number with Data for Analysis	130 (97.7%)	131 (95.6%)	119 (89.5%)	128 (93.4%)
	Mean	<0.970	<1.109	<0.914	<1.043
	Median	<0.978	<1.114	<0.978	<1.114
	SD	>0.348	>0.325	>0.333	>0.361
	(Min, Max)	(<0.18, 1.56)	(<0.18, 1.56)	(<0.18, 1.56)	(<0.18, 1.56)
	CI	(<0.919, 1.021)	(<1.062, 1.156)	(<0.863, 0.964)	(<0.990, 1.096)

SD = Standard Deviation
CI = Two-sided 90% Confidence Interval
CPD = Cycles Per Degree
The score was set to (-1) when a subject could not complete a sensitivity measurement.
For mean and variability estimations, scores of (-1) were excluded from the calculations. Hence the corresponding mean and median measures are overestimated and variability measures are underestimated.
Column header is number of subjects in the best case population
Number assessed is number in the best case population minus number not assessed.
Number with data for analysis is number assessed minus number scoring (-1).

Table 8: Descriptive Statistics for Binocular Mesopic Contrast Sensitivity at Visit 4A (4-6 months postoperative, Best Case Population)

Frequency		Without Glare		With Glare	
		+2.5 D Multifocal (N=133)	Monofocal (N=137)	+2.5 D Multifocal (N=133)	Monofocal (N=137)
1.5 CPD	Not Assessed	1 (0.8%)	4 (2.9%)	1 (0.8%)	4 (2.9%)
	Number Assessed	132 (99.2%)	133 (97.1%)	132 (99.2%)	133 (97.1%)
	Number Scoring (-1)	4 (3.0%)	2 (1.5%)	5 (3.8%)	4 (2.9%)
	Number with Data for Analysis	128 (96.2%)	131 (95.6%)	127 (95.5%)	129 (94.2%)
	Mean	<1.594	<1.622	<1.536	<1.596
	Median	<1.595	<1.595	<1.520	<1.670
	SD	>0.224	>0.204	>0.237	>0.238
	(Min, Max)	(<0.83, 1.97)	(<1.07, 1.97)	(<0.90, 1.97)	(<0.98, 1.97)
	CI	(<1.562, 1.627)	(<1.593, 1.652)	(<1.501, 1.570)	(<1.561, 1.631)
3 CPD	Not Assessed	1 (0.8%)	4 (2.9%)	1 (0.8%)	4 (2.9%)
	Number Assessed	132 (99.2%)	133 (97.1%)	132 (99.2%)	133 (97.1%)
	Number Scoring (-1)	1 (0.8%)	1 (0.7%)	4 (3.0%)	3 (2.2%)
	Number with Data for Analysis	131 (98.5%)	132 (96.4%)	128 (96.2%)	130 (94.9%)
	Mean	<1.563	<1.618	<1.542	<1.600
	Median	<1.564	<1.633	<1.562	<1.599
	SD	>0.267	>0.226	>0.292	>0.296
	(Min, Max)	(<0.70, 2.08)	(<1.00, 2.08)	(<0.70, 2.08)	(<-0.35, 2.08)
	CI	(<1.525, 1.602)	(<1.586, 1.651)	(<1.499, 1.585)	(<1.557, 1.643)
6 CPD	Not Assessed	1 (0.8%)	4 (2.9%)	1 (0.8%)	4 (2.9%)
	Number Assessed	132 (99.2%)	133 (97.1%)	132 (99.2%)	133 (97.1%)
	Number Scoring (-1)	10 (7.5%)	3 (2.2%)	18 (13.5%)	7 (5.1%)
	Number with Data for Analysis	122 (91.7%)	130 (94.9%)	114 (85.7%)	126 (92.0%)
	Mean	<1.581	<1.673	<1.543	<1.617
	Median	<1.628	<1.663	<1.556	<1.620
	SD	>0.296	>0.275	>0.329	>0.277
	(Min, Max)	(<0.90, 2.29)	(<0.90, 2.29)	(<0.90, 2.29)	(<0.90, 2.29)
	CI	(<1.537, 1.625)	(<1.633, 1.713)	(<1.492, 1.594)	(<1.577, 1.658)
12 CPD	Not Assessed	1 (0.8%)	4 (2.9%)	1 (0.8%)	4 (2.9%)
	Number Assessed	132 (99.2%)	133 (97.1%)	132 (99.2%)	133 (97.1%)
	Number Scoring (-1)	30 (22.6%)	21 (15.3%)	42 (31.6%)	28 (20.4%)
	Number with Data for Analysis	102 (76.7%)	112 (81.8%)	90 (67.7%)	105 (76.6%)
	Mean	<1.077	<1.208	<1.043	<1.153
	Median	<1.079	<1.167	<0.929	<1.079
	SD	>0.363	>0.345	>0.385	>0.375
	(Min, Max)	(<0.60, 2.00)	(<0.60, 2.00)	(<0.60, 2.00)	(<0.60, 2.00)
	CI	(<1.017, 1.136)	(<1.154, 1.262)	(<0.975, 1.110)	(<1.092, 1.214)

SD = Standard Deviation
CI = Two-sided 90% Confidence Interval
CPD = Cycles Per Degree
The score was set to (-1) when a subject could not complete a sensitivity measurement.
For mean and variability estimations, scores of (-1) were excluded from the calculations. Hence the corresponding mean and median measures are overestimated and variability measures are underestimated.
Column header is number of subjects in the best case population
Number assessed is number in the best case population minus number not assessed.
Number with data for analysis is number assessed minus number scoring (-1).
Mesopic contrast tests were conducted twice and the official sensitivity was defined as the mean of the two individual measures. The mean score was (-1) if either or both of the individual scores were (-1).

Adverse Events

The safety of the AcrySof® IQ ReSTOR® +2.5 D Multifocal IOL Model SV25T0 is based in part on the safety demonstrated by its parent Model MA60D3 and Model SA60D3.

No unanticipated serious adverse device effects were observed in any subjects implanted with Models SV25T0 or SN60WF. There were no reports of explants during this clinical study. Adverse events shown in Table 9 were reported as unrelated to the IOL.

Table 9: Cumulative and Persistent Adverse Events and SPE Rates, Safety, 6 Months Postoperative

	First implanted eye								Second implanted eye							
	+2.5 D Multifocal				Monofocal				+2.5 D Multifocal				Monofocal			
	(N = 155)				(N = 165)				(N = 155)				(N = 163)			
	n	%	SPE %	p-value[a]	n	%	SPE %	p-value[a]	n	%	SPE %	p-value[a]	n	%	SPE %	p-value[a]
Cumulative Adverse Events																
Cystoid macular oedema	2	1.3	3.0	0.9484	0	0.0	3.0	1.0000	2	1.3	3.0	0.9484	0	0.0	3.0	1.0000
Endophthalmitis	0	0.0	0.1	1.0000	0	0.0	0.1	1.0000	0	0.0	0.1	1.0000	0	0.0	0.1	1.0000
Hypopyon	0	0.0	0.3	1.0000	0	0.0	0.3	1.0000	0	0.0	0.3	1.0000	0	0.0	0.3	1.0000
Lens dislocated from posterior chamber	0	0.0	0.1	1.0000	0	0.0	0.1	1.0000	0	0.0	0.1	1.0000	0	0.0	0.1	1.0000
Pupillary block	0	0.0	0.1	1.0000	0	0.0	0.1	1.0000	0	0.0	0.1	1.0000	0	0.0	0.1	1.0000
Retinal detachment	0	0.0	0.3	1.0000	0	0.0	0.3	1.0000	0	0.0	0.3	1.0000	0	0.0	0.3	1.0000
Secondary surgical intervention	0	0.0	0.8	1.0000	0	0.0	0.8	1.0000	0	0.0	0.8	1.0000	3	1.8	0.8	0.1432
Persistent Adverse Events																
Corneal stroma oedema	0	0.0	0.3	1.0000	0	0.0	0.3	1.0000	0	0.0	0.3	1.0000	0	0.0	0.3	1.0000
Cystoid macular oedema	1	0.6	0.5	0.5402	0	0.0	0.5	1.0000	1	0.6	0.5	0.5402	0	0.0	0.5	1.0000
Iritis	1	0.6	0.3	0.3723	0	0.0	0.3	1.0000	1	0.6	0.3	0.3723	0	0.0	0.3	1.0000
Raised IOP requiring treatment	0	0.0	0.4	1.0000	1	0.6	0.4	0.4838	0	0.0	0.4	1.0000	1	0.6	0.4	0.4797

SPE = Safety and Performance Endpoints
[a] One-sided exact binomial test (alpha = .05)

Visual Disturbances

A new Patient Reported Outcomes instrument (Assessment of Photic Phenomena & Lens EffectS, abbreviated APPLES) was developed and used in this clinical study. The instrument 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. Patient reported rates of visual disturbances are presented in Table 10 stratified by rating (None, Mild, Moderate, and Severe).

At Visit 4A (6 months), there were more reports of severe halos and starbursts in the AcrySof® IQ ReSTOR® +2.5 D Multifocal IOL group while other categories of reports of severe visual disturbance were the same or lower compared to the monofocal IOL group.

Table 10: Visual Disturbances, Safety, 6 Months Postoperative

	+2.5 D Multifocal					Monofocal				
	N	None	Mild	Mod	Severe	N	None	Mild	Mod	Severe
		%	%	%	%		%	%	%	%
Glare	153	39.9	35.9	20.9	3.3	160	49.4	33.8	13.1	3.8
Halos	153	37.3	30.1	22.2	10.5	160	61.9	26.9	7.5	3.8
Starbursts	153	55.6	24.8	11.8	7.8	160	61.9	26.9	7.5	3.8
Hazy vision	153	66.0	26.8	6.5	0.7	160	66.9	24.4	7.5	1.3
Blurred vision	153	73.9	19.6	6.5	0.0	160	71.9	23.1	5.0	0.0
Distortion where straight lines look tilted	153	90.8	7.2	2.0	0.0	160	93.1	5.6	0.0	1.3
Distortion where flat lines look curved	153	95.4	2.6	2.0	0.0	160	95.0	3.1	0.6	1.3
Double vision	153	92.8	4.6	2.0	0.7	160	95.6	2.5	0.6	1.3
Color distortion	153	94.1	5.2	0.7	0.0	160	93.8	5.6	0.6	0.0

	+2.5 D Multifocal					Monofocal				
	N	None	Mild	Mod	Severe	N	None	Mild	Mod	Severe
		%	%	%	%		%	%	%	%
Feeling sick due to distortion	153	95.4	3.9	0.7	0.0	160	91.9	6.3	1.9	0.0

Glistenings

AcrySof® IOLs had a low rate of reported glistenings: 95.5% of all 624 implanted lenses demonstrated no glistenings at 6 months. For the 4.5% that reported glistenings, none were reported to be clinically significant by the implanting surgeon.

2. AcrySof® NATURAL SINGLE-PIECE IOL CLINICAL STUDY (Model SB30AL)

A clinical study was conducted on subjects receiving the monofocal AcrySof® Natural Single Piece IOL Model SB30AL compared to the monofocal AcrySof® UV Single Piece IOL Model SA30AL. Subjects were followed for a minimum of one year postoperatively and the results provided reasonable assurance of the safety and effectiveness of AcrySof® Natural Single Piece IOL Model SB30AL for the visual correction of aphakia.

Color Perception

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 a AcrySof® Natural IOL Model SB30AL in the first operative eye and examined at the 120 to 180 day postoperative visit, 107 (98.2%) passed the color perception test. Of the 102 subjects with normal color vision implanted with a AcrySof® UV IOL 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® 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 did not negatively affect color vision in patients with normal color vision.

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

Multicenter clinical studies were conducted in the United States and Europe to establish the safety and effectiveness of the multifocal AcrySof® ReSTOR® Apodized Diffractive Optic IOL (Models MA60D3 and SA60D3). An All Implanted cohort consisted of a total of 566 first-eye implanted ReSTOR® IOL (440 MA60D3 and 126 SA60D3) subjects and 194 AcrySof® Model MA60BM monofocal IOL subjects. 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.

Summary of Driving Sub-study

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). Night driving performance was 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 subjects implanted with ReSTOR® IOL Models MA60D3 and SA60D3 to detect and identify road signs and hazards at night was similar to that of subjects implanted with the monofocal control Model MA60BM under normal visibility driving conditions.

Sign Identification

Rural Driving Conditions
The mean visibility distances, standard deviations, and percentage differences between monofocal (Model MA60BM) subjects and ReSTOR® IOL (Model MA60D3) subjects for sign identification under normal, fog, and glare conditions in the rural scene are shown in Table 11.

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

Table 11: Mean (± SD) Sign Identification Distances in Rural Scene

Identification Distance (feet)		Lens		Difference	% Loss over Control
		Monofocal Control IOL Model MA60BM	ReSTOR® IOL Model MA60D3		
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 deviations, and percentage differences between monofocal (Model MA60BM) subjects and ReSTOR® IOL (Model MA60D3) subjects for sign identification under normal, fog, and glare conditions in the city scene are shown in Table 12.

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

Table 12: Sign Identification Distances in City Scene

Identification Distance (feet)		Lens		Difference	% Loss Over Control
		Monofocal Control IOL Model MA60BM	ReSTOR® IOL Model MA60D3		
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 deviations, and percentage differences between 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 13. In rural conditions, all differences for detecting hazards were less than 20%.

Table 13: Hazard Detection Distances in Rural Scene

Detection Distance (feet)	Lens		Difference	% Loss Over Control
	Monofocal Control IOL Model MA60BM	ReSTOR® IOL Model MA60D3		
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 deviations, 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 14. For city conditions, in all instances the mean differences were less than 15%.

Table 14: Hazard Detection Distances in City Scene

Detection Distance (feet)	Lens		Difference	% Loss Over Control
	Monofocal Control IOL Model MA60BM	ReSTOR® IOL Model MA60D3		
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).

Adverse Events
The incidences of cumulative adverse events for the ReSTOR® IOL as compared to the FDA historical grid rates are provided in Table 15. 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 15: 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 16). 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 16: 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

HOW SUPPLIED
These apodized diffractive optic posterior chamber intraocular lenses are supplied dry, in a package terminally sterilized with ethylene oxide. They must be opened only under aseptic conditions (see DIRECTIONS FOR USE section).

EXPIRATION DATE
Sterility is guaranteed until 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 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 Laboratories, Inc., office or distributors regarding the Returned Goods Policy.

REFERENCE
Boettner EA. Wolter JR. Transmission of the ocular media. Invest Ophthalmol Vis Sci. 1962;1(6):776-83.

SYMBOLS USED ON LABELING

SYMBOL	ENGLISH
IOL	Intraocular lens
PC	Posterior chamber
PCL	Posterior chamber lens
UV	Ultraviolet
D	Diopter
$Ø_B$	Body diameter (Optic diameter)
$Ø_T$	Overall diameter (Overall length)
	Do not reuse
	Use by (YYYY-MM: year-month)
	Sterilized by ethylene oxide
	Serial Number
	Attention: See instructions for use
	Manufacturer
	Upper Limit of Temperature

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