

TABLE 1
SENSAR® IOL Model AR40
BEST CORRECTED DISTANCE VISUAL ACUITY AT ONE YEAR
ALL BEST CASE SUBJECTS* (N=274)

AGE DECADE	TOTAL		VISUAL ACUITY 20/40 OR BETTER		FDA GRID	
	N	%	N	%	N	%
<60	2	0.7	2	100.0	2	96.9
60-69	90	33.1	90	100.0	88	93.8
70-79	146	53.7	144	98.6	142	94.9
>80	34	12.5	33	97.1	32	87.9
TOTAL	272	100.0	269	98.9	264	94.0

* Subjects with no pre-operative pathology or macular degeneration at any time during the study.
† Two subjects did not have their best corrected distance visual acuity measured at one year.

TABLE 2
SENSAR® IOL Model AR40
Adverse Events
All Subjects (N=382)

ADVERSE EVENTS	CUMULATIVE		PERSISTENT AT ONE YEAR		FDA GRID	
	N	%	N	%	CUM [†]	PER ^{††}
Subjects with No Adverse Events	376	98.4	335	100.0	-	-
Subjects with Adverse Events*	6	1.6	0	0.0	-	-
- Corneal Edema	-	-	0	0.0	-	0.6
- Iritis	-	-	0	0.0	-	1.0
- Hyphema	0	0.0	-	-	1.0	-
- Macular Edema	3	0.8	0	0.0	3.5	0.8
- Pupilary Block	0	0.0	-	-	0.3	-
- Raised IOP Requiring Treatment	-	-	0	0.0	-	0.5
- Cystitic Membrane	0	0.0	0	0.0	0.0	0.1
- Vitritis	-	-	0	0.0	-	0.1
- Endophthalmitis	1	0.3 [∞]	-	-	<0.1	-
- Anterior Lens Tissue Ongrowth**	33	8.6	17	5.0	-	-
- Retinal Detachment	0	0.0	-	-	0.5	-
- Lens Dislocation	1	0.3	-	-	0.4	-
- Hypopyon	1	0.3	-	-	0.4	-
- Acute Corneal Decompensation	0	0.0	0	0.0	0.2	-
- Intraocular Infection	0	0.0	0	0.0	0.1	-
- Secondary Surgical Intervention (lens removal and replacement)	1	0.3	-	-	2.0	-

* One subject had both endophthalmitis and hypopyon.

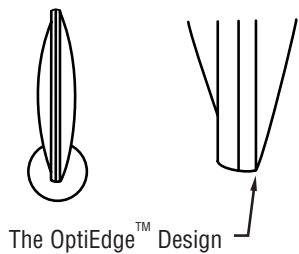
† Cumulative incidence at one year visit.

†† Persistent incidence at one year visit.

∞ Incidence of endophthalmitis was not statistically different from the FDA grid.

** At the conclusion of the three-year clinical study, the cumulative and persistent incidences were 11.3% (43/382) and 7.4% (19/256), respectively; these incidences were not statistically different from the one year levels. Of the 17 cases reported at one year, 8 cases resolved; 10 new cases of ongrowth were seen at the year three visit. Adverse effect on these subjects' vision was not reported by the investigators. Tissue on-growth has been previously reported in the literature on other IOL material types.

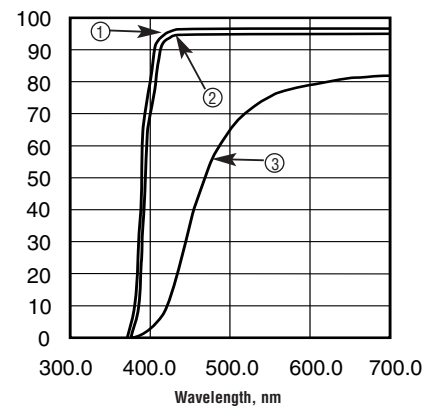
Figure 3



The OptiEdge™ Design

Figure 4

Light Transmittance



LEGEND:

Curve 1: Spectral Transmittance curve of a typical 6 diopter IOL (thinnest), UV cut-off at 10% T is 378 nm.

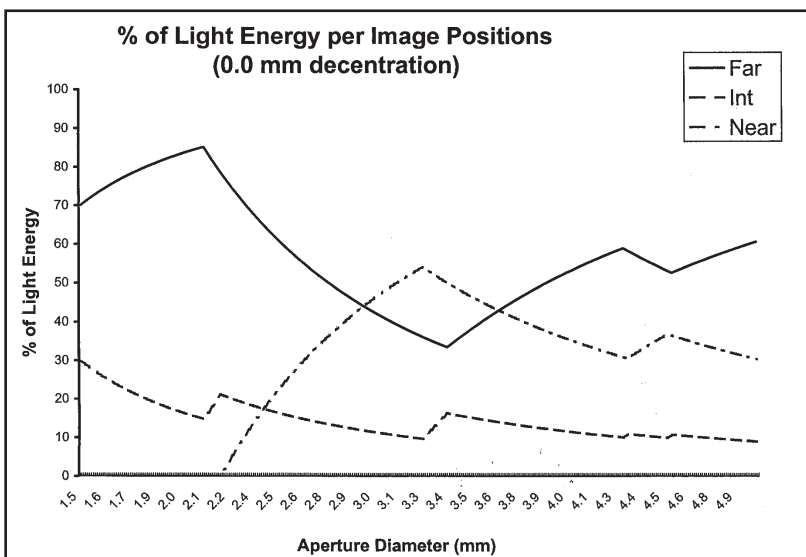
Curve 2: Spectral Transmittance curve of a typical 27 diopter IOL (thickest), UV cut-off at 10% T is 383 nm.

Curve 3: Spectral Transmittance (T) Curve* Corresponding to 53-year-old Phakic Eye.

Note: The cut-off wavelengths and the spectral transmittance curves represent the range of the transmittance values of IOLs (6-30 diopter) made with this material.

* Boettner, E.A., and Wolter J.R. Transmission of the Ocular Media. Investigative Ophthalmology. 1962; 1:776-783.

Figure 5



ReZoom™ Acrylic Multifocal Posterior Chamber Intraocular Lenses

Rx Only - In the U.S., prescription only device

Z310573 Ver. 4.0 706

Description

Advanced Medical Optics, Inc.'s (AMO) ReZoom™ Acrylic Multifocal Posterior Chamber Intraocular Lenses are available as ultraviolet-absorbing biconvex optical lenses, with an anterior multifocal surface, designed to be positioned posterior to the iris where the lens replaces the optical function of the natural crystalline lens in the correction of aphakia. AMO's ReZoom™ Acrylic Multifocal IOLs incorporate the squared OptiEdge™ design (See Fig. 3).

The physical properties of the lenses are:

Detailed Device Description

Lens Optic

- Optic Material: Optically clear soft foldable acrylic with covalently bound UV absorber
- Power +6.0 to +30.0 diopters in 0.5 diopter increments.
- Index of refraction: 1.47 (35°C)
- Light transmittance: UV cut-offs at 10% T for a +6.0 diopter lens (thinnest) and a +27.0 diopter lens (thickest) are shown in Figure 4.
- +3.5 diopters of add power at the IOL plane corresponding to approximately +2.4 D to +2.8 D in the spectacle plane depending on corneal power and anterior chamber depth.
- Refractive zonal-progressive IOL incorporating continuous range of foci (Figure 5).

Haptics

- Material: Blue core polymethylmethacrylate (PMMA) monofilament.
- Three-piece lens.
- Configuration: Modified C.

Model Characteristics

Please refer to outer package.

Mode of Action

The lens is positioned posterior to the iris. This position allows the optical magnification of the intraocular lens to replace the function of the natural crystalline lens. The effectiveness of ultraviolet light absorbing lenses in reducing the incidence of retinal disorders has not been established.

Indications

AMO ReZoom™ Acrylic Multifocal Posterior Chamber Intraocular Lenses are indicated for the visual correction of aphakia in adult patients with and without presbyopia in whom a cataractous lens has been removed and who desire near, intermediate, and distance vision without reading add and increased spectacle dependence. These devices are intended to be placed in the capsular bag.

Warnings

1. Some visual effects may be expected because of the superposition of focused and unfocused multiple images. These include some perception of halos or radial lines around point sources of light under nighttime conditions. It is expected that, in a small percentage of patients, the observation of such phenomena will be annoying and may be perceived as a hindrance, particularly in low illumination conditions. A very small percentage of patients (<1% in the U.S. Clinical Study) may be dissatisfied to the point that they request explanation of the multifocal lens.
2. Under low contrast conditions, visual acuity is reduced with a multifocal lens when compared to a monofocal lens. Therefore, multifocal subjects should exercise caution when driving at night or in poor visibility conditions.
3. For Model NXG1, under low light conditions, reduced near visual acuity may be experienced for large pupils (5mm).
4. Patients with any of the following conditions may not be suitable candidates for an intraocular lens because the lens may exacerbate an existing condition or interfere with diagnosis or treatment of a condition or may pose an unreasonable risk to the patient's eyesight:
 - a. Patients in whom the intraocular lens may affect the ability to observe, diagnose, or treat posterior segment diseases.
 - b. Surgical difficulties at the time of cataract extraction and/or intraocular lens implantation that might increase the potential for complications (e.g., persistent bleeding, significant iris damage, uncontrolled positive pressure, or significant vitreous prolapse or loss).
 - c. A distorted eye due to previous trauma or developmental defect in which appropriate support of the IOL is not possible.
 - d. Circumstance that would result in damage to the endothelium during implantation.
 - e. Suspected microbial infection.
 - f. Patients in whom neither the posterior capsule nor zonules are intact enough to provide support.
 - g. Congenital bilateral cataracts.
 - h. Recurrent severe anterior or posterior segment inflammation of unknown etiology, or any disease producing an inflammatory reaction in the eye.
 - i. Previous history of, or a predisposition to, retinal detachment.
 - j. Patients with only one eye and potentially good sight.
 - k. Medically uncontrollable glaucoma.
 - l. Corneal endothelial dystrophy.
 - m. Proliferative diabetic retinopathy.
 - n. Although rarely observed during the clinical trial, the imaging quality and depth of field through this lens may potentially impact vitreoretinal surgery.
 - o. The safety and effectiveness of this lens if placed in the anterior chamber have not been established. Implantation of posterior chamber lenses in the anterior chamber has been shown in some cases to be unsafe. Such implantation should take place only under an investigational protocol approved by FDA.

Precautions

1. Prior to surgery, the surgeon must provide prospective patients with a copy of the patient information brochure for this product and inform these patients of the possible risks and benefits associated with the use of this device.
2. Autorefractors may not provide optimal postoperative refraction of multifocal patients. Manual refraction is strongly recommended.
3. The long-term effects of intraocular lens implantation have not been determined. Therefore, physicians should continue to monitor implant patients postoperatively on a regular basis.
4. Secondary glaucoma has been reported occasionally in patients with controlled glaucoma who received lens implants. The intraocular pressure of implant patients with glaucoma should be carefully monitored postoperatively.
5. Do not resterilize the lens by any means. Most sterilizers are not equipped to sterilize the soft acrylic material without producing undesirable side effects.
6. Do not store the lens in direct sunlight or at a temperature greater than 113°F (45°C).
7. Do not soak or rinse the intraocular lens with any solution other than sterile balanced salt solution or sterile normal saline.
8. Please refer to the specific instructions for use provided with The UNFOLDER® Implantation System for the amount of time the IOL can remain in the cartridge before the IOL must be discarded.
9. When The UNFOLDER® Emerald Series Implantation System is used improperly, the haptics of the soft acrylic multifocal lens may become crimped or broken. Please refer to the specific instructions for use provided with The UNFOLDER® Emerald Series Implantation System.
10. The effectiveness of ultraviolet light absorbing lenses in reducing the incidence of retinal disorders has not been established.

Silicone ARRAY® IOL

Clinical Trial.

Adverse Effects
A total of 456 Core subjects were evaluated in clinical trials to determine the safety of the ARRAY® IOL Model SSM26NB Multifocal Silicone Posterior Chamber Intraocular Lens.

Secondary Surgical Interventions were reported as follows:

Secondary Surgical Interventions
All Core Subjects (N=456)

	Within One Year		After One Year*	
	n	%	n	%
TOTAL SECONDARY SURGICAL INTERVENTIONS	10†	2.2	4	0.9
- Repositioning of Lens	1	0.2	0	0.0
- IOL Replacement for Improper Power Calculation	2	0.4	0	0.0
- IOL Replacement for Optical/Visual Symptoms	1	0.2	2	0.4
- IOL Replacement for Other Surgical Procedures (Enhanced Retinal Visualization)	1†	0.2	0	0.0
- Vitrectomy/Vitreolysis	3†	0.6	0	0.0
- Repair of Macular Hole/Vitrectomy	1	0.2	0	0.0
- Argon Laser Retinopexy	1	0.2	0	0.0
- Scleral Buckle Procedure	0	0.0	1	0.2
- Cryotherapy to repair retinal tear	0	0.0	1††	0.2

* Includes subjects experiencing Secondary Surgical Interventions after the final study visit as of May 10, 1996.

† Nine (9) subjects exhibited ten (10) interventions. One subject had two secondary surgical procedures, vitrectomy and IOL replacement.

†† This subject was a participant in the Monofocal Fellow Eye Control Substudy (see Clinical Study Results) and also underwent a scleral buckle procedure for the fellow eye implanted with an otherwise similar monofocal IOL.

Difficulty in maintaining stereopsis and fusion while performing an epiretinal membrane peel procedure was reported in a single case. Additional effort to maintain fine focus was reported in a second epiretinal membrane peel. No other difficulty was reported for the other posterior segment procedures performed.

Potential secondary surgical interventions that have been associated with intraocular lenses, but did not occur in this clinical trial include: lens removal due to corneal touch, lens removal due to inflammation, corneal transplant, vitreous aspiration for pupilary block, iridectomy for pupilary block. Other adverse events which have been associated with intraocular lenses, but did not occur in this clinical trial include: hypopyon, intraocular infection, acute corneal decompensation.

Contrast Acuity: Mean differences between eyes for the Monofocal Fellow Eye Control Subset (see Clinical Study Results), where significant, were generally within 1 to 1.5 lines. The frequency of subjects with paired-eye differences of >2 lines increased with decreased contrast and with glare to a maximum of 26.4% at 11% contrast with the B.A.T. set at low. (Testing was conducted using Regan acuity charts at 96%, 50%, 25% and 11% contrast at distance and C.A.T. charts at 100%, 50%, 25% and 12.5% contrast at near.)

Visual Symptoms: Statistically significant differences were observed at one year for the mean degree of difficulty reported by subjects for **halos, glare/flare, and blurred far vision**. Subjects reported "severe" difficulty with these symptoms at the following rates (multifocal vs. monofocal eyes):

- halos (15.3 vs. 6.1%)
- glare/flare (10.5% vs. 1.1%)
- blurred far vision (4.2 vs. 1.0%)

Differences in mean difficulty scores at one year were not significant for the following symptoms (incidence of "severe" reports, multifocal vs. monofocal eyes): distorted near (4.0% vs. 2.0%) or far (3.1% vs. 0.0%) vision, difficulty with night vision (8.4% vs. 4.2%), blurred near vision (8.2% vs. 3.1%), monocular (2.0% vs. 1.0%) or binocular (1.0% vs. 1.0%) diplopia, depth perception (1.0% vs. 1.0%), and color perception (0.0% vs. 0.0%).

Other complications: No incidence of hypopyon, intraocular infection or acute corneal decompensation was reported during the clinical study.

The complications experienced during the clinical trial of the ARRAY® Multifocal Silicone Posterior Chamber Lenses include (in order of frequency): (clinical study rate vs. "FDA grid" rate): macular edema (persistent) (0.8 vs. 0.8%), iritis (persistent) (0.3 vs. 1.0%), corneal edema (persistent) (0.0% vs. 0.6%), pupillary block (cumulative) (0.3% vs. 0.3%), secondary glaucoma (cumulative) (1.5% vs. N/A), and vitritis (cumulative) (0.5% vs. N/A). Incidences of these complications were all comparable to or lower than those of the historic control ("FDA grid") population.

Potential complications which did not occur in this clinical trial, but which may accompany cataract or implant surgery include, but are not limited to, the following: corneal endothelial damage, non-pigment precipitates, infection, retinal detachment, vitreous loss, iris prolapse, vitreous wick syndrome, uveitis and pupillary membrane.

Clinical Study Results

The ARRAY® IOL Model SSM26NB multifocal silicone posterior chamber intraocular lens was evaluated in a prospective, nonrandomized study of 456 subjects followed for one year. Both historic and prospective controls were used, depending on substudy. The ReZoom™ IOL Model NXG1 has not been clinically evaluated and may not perform identically to the SA40N or SSM26NB ARRAY® IOLs.

The 400 subject Cohort population in the clinical trial consisted of 63.3% females (253/400) and 36.8% males (147/400) 98.7% were Caucasian, 1.0% were Black and 0.3% were Asian. The mean age was 72.2 years. A total of 392 Cohort subjects did not have preoperative ocular pathology or postoperative macular degeneration (Best Case Cohort). Inclusion criteria required visual potential to be 20/30 or better in the operative eye.

The postoperative results demonstrated that the ARRAY® Multifocal IOL provides distance and intermediate vision comparable to a monofocal IOL, with increased near vision. The distance and near acuities achieved by the best case cohort subjects (those with no preoperative pathology or postoperative macular degeneration) are described in the following tables:

Distance Visual Acuity Best Case Cohort Population (N = 392)		
	Uncorrected	With best correction
20/20 or better	39.8%	71.2%
20/40 or better	92.1%	98.5%
20/41 - 20/80	7.4%	1.0%
Worse than 20/80	0.5%	0.5%

Near Visual Acuity Best Case Cohort Population (N = 392)			
	Uncorrected	With distance correction	With additional add
J1 or better	48.0%	43.6%	95.8%
J3 or better	87.9%	87.3%	99.5%
Worse than J3	12.1%	12.7%	0.5%

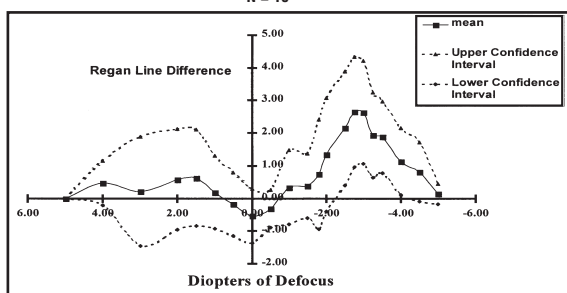
Combined Distance and Near Visual Acuities Best Case Cohort Population (N = 392)			
	Uncorrected	With distance correction	With additional add
20/40 or better/distance and J3 or better/near	82.6%	87.1%	98.4%
Worse than 20/40 /distance and J3 or better/near	5.4%	0.3%	1.0%
20/40 or better/distance and worse than J3/near	9.5%	11.4%	0.0%
Worse than 20/40/distance and worse than J3/near	2.6%	1.3%	0.5%

Test Results for Clinical Substudies: The Monofocal Fellow Eye Control Subset was comprised of 102 Cohort subjects with an otherwise comparable monofocal IOL in the contralateral eye.

The **Visual Field Substudy** showed comparable visual field performance between multifocal and monofocal eyes.

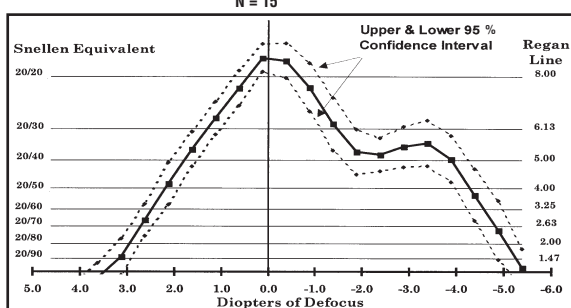
The **Defocus Curve Substudy** showed that multifocal eyes demonstrated a significantly increased depth of focus at 20/40 visual acuity level compared to monofocal eyes within the medium pupil size range (p=0.008), with a mean depth of focus increase of 0.94 D. In this analysis, depth of focus was defined as the total range of defocus between distance and near where the visual acuity was 20/40 or better. The mean paired-eye, Regan line acuity difference, and the 95% confidence intervals, is provided in **Figure 1**. This figure demonstrates that the effect of the additional depth of focus is most pronounced at near, with approximately a three line visual acuity increase. The mean depth of focus curve for all subjects in the Supplemental Defocus Curve Substudy is provided in **Figure 2**. Performance of subjects with pupil sizes in the >2.5 and <4.0 mm group and the ≥4.0 mm group were generally similar. Insufficient data were available to evaluate the performance of subjects with pupil sizes <2.5 mm.

Figure 1
Depth of Focus
Mean Multifocal minus Monofocal Eye Acuity Line Difference
Pupil Size > 2.5 mm and < 4.00 mm
N = 10



(See text for explanation)

Figure 2
Mean Depth-of-Focus Curve
N = 15



(See text for explanation)

The **Fundus Photography Substudy** showed some differences in the quality of the photos for multifocal and monofocal subjects. The photographic quality varied from slightly worse to slightly better in comparing the multifocal and monofocal fundus photographs, however the results indicated that excellent photographs of the fundus can be achieved through the ARRAY® multifocal optic.

The **Driving Simulation Substudy** was conducted to determine if the presence of the ARRAY® Multifocal intraocular lens impacts driving performance and driving safety using a validated simulation of three different low contrast, visually challenging, environmental conditions: nighttime in clear weather, nighttime with glare from an oncoming headlight, and fog.

Sign recognition (rates and distances for 15 signs) and hazard detection and avoidance (rates, distances and avoidance scores for 4 objects) were evaluated for 33 bilateral multifocal subjects vs. 33 bilateral monofocal subjects.

A total of 30 measures of performance were evaluated. No significant difference in driving performance was found between groups for 26 of the measures; monofocal subjects had significantly better performance for 4 measures. There was a trend toward better performance by the monofocal subjects when an analysis was performed of those trials where one subject group had a greater detection rate and a greater detection distance.

Drivers with monofocal IOLs correctly identified warning signs at a significantly higher rate under one of nine conditions tested, clear nighttime. Of those subjects who correctly identified the signs, no corresponding difference in *sign recognition distances* was found between the two lens groups for this condition. In simulated fog conditions, drivers with multifocal IOLs generally had shorter guide and warning sign recognition distances (up to 26% shorter). **Under fog conditions, at average driving speeds, 7.7% more multifocal than monofocal patients were less than 2.25 seconds from the sign when it was identified. The minimum recommended time to recognize a sign is about 2.25 seconds.** However, the mean recognition distances of drivers with multifocal IOLs remained within safety guidelines (American Association of State Highway and Transportation Officials).

Among subjects who were under 75 years old, drivers with monofocal IOLs detected certain roadway hazards at a significantly greater distance than those with multifocal IOLs. There was no such difference for these hazards in drivers greater than 75 years old. **For the most challenging simulated object under nighttime conditions (one of nine trials), 21.7% more multifocal subjects did not detect the hazard until closer than 100 feet. The distance of 100 feet is significant because at speeds of 30 mph or greater, a driver would not usually be able to stop safely within 100 feet.** In the simulation, however, drivers could maneuver around hazards, and there was no significant difference in hazard avoidance (e.g., collisions) between drivers with multifocal vs. monofocal IOLs.

The Driving Simulation Substudy results indicate that multifocal subjects should exercise caution when driving at night or in poor visibility conditions.

Spectacle independence was reported for a range of distances from near through far, for ARRAY® silicone posterior chamber intraocular lens Cohort subjects as shown below. The bilateral multifocal subjects were significantly more spectacle independent than the other two groups at near only.

Percentage of Subjects Able to Function Comfortably Without Glasses at One Year (Directed Response*)

	All Cohort Subjects (N=400)		
	BILATERAL MULTIFOCAL N = 123	MULTIFOCAL/MONOFOCAL N = 177	MULTIFOCAL/OTHER† N = 100
	%	%	%
NEAR	81.4	56.4	57.7
INTERMEDIATE	92.6	85.8	79.2
DISTANCE	93.4	85.6	77.4

* Subject responses to prompted-choice questions from general subject questionnaire.

† Cataractous or non-cataractous phakic or aphakic fellow eye.

Frequency of spectacle wear was significantly different between bilateral multifocal and bilateral monofocal subjects (p < 0.001).

Percentage of Subjects Who Always, Occasionally, or Never Wear Spectacles

	Quality of Life Substudy	
	BILATERAL MULTIFOCAL N = 100	BILATERAL MONOFOCAL N = 103
	%	%
ALWAYS	8.0	34.0
OCCASIONALLY	51.0	54.4
NEVER	41.0	11.7

Intermediate Visual Acuity Study: In a prospective, randomized, and masked study, the intermediate visual acuities of 60 bilateral multifocal Model SA40N subjects and 54 bilateral monofocal Model SI40NB[®]IOL subjects were measured using high contrast images under two conditions: direct measurement at a distance of 70 cm and defocused to simulate a distance of 67 cm.

Using the defocus method, the mean binocular distance-corrected intermediate visual acuity for the multifocal group was statistically significantly better than the mean of the monofocal group (0.8 Regan lines or 0.08 logMAR units difference). Using direct measurement, however, the mean binocular distance-corrected intermediate acuities were not statistically significantly different. The mean monocular distance-corrected intermediate visual acuity was statistically significantly better for the multifocal group as measured by both direct measurement (0.6 C.A.T. lines or 0.06 logMAR units difference) and the defocus method (0.7 Regan lines or 0.07 logMAR units difference).

Soft Acrylic SENSAR® IOL

Clinical Trial

The U.S. clinical trial of Model AR40 was initiated on July 24, 1996. The results achieved by 335 patients followed for one year are presented in Tables 1 and 2. Incidence of complications was comparable to or less than those of historic control population.

Directions for Use

Caution: Do not use the lens if the package has been damaged. The sterility of the lens may have been compromised.

- The physician should consider the following:
 - The surgeon should target **emmetropia** as this lens is designed for optimum visual performance when emmetropia is achieved.
 - Patient selection and operative technique should be managed to ensure that the total postoperative corneal **astigmatism** does not exceed 1.5 diopters as effects of greater astigmatism on multifocal function are unknown.
 - Care should be exercised to achieve **centration** of this IOL.
 - Patients with **pupil sizes** less than 2.5 mm may not have any near benefit.
- Prior to implanting, examine the lens package for IOL type, dioptic power, proper configuration and expiration date.
- Open the peel pouch and remove the lens in a sterile environment.
- Examine the lens thoroughly to ensure particles have not become attached to it, and examine the lens optical surfaces for other defects.
- If desired, the lens may be soaked or rinsed in sterile balanced salt solution until ready for implantation.
- Handle the lens by the haptic portion. Do not grasp the optical area with forceps.
- Transfer the lens, using sterile technique, to an appropriate loading device.
- Various surgical procedures can be utilized. The surgeon should select a procedure which is appropriate for the patient.
- The UNFOLDER® Emerald Series Implantation System designed for use with the AMO Soft Acrylic Multifocal Posterior Chamber IOLs, should be used to insert the lens in the folded state. Refer to specific instructions provided with The UNFOLDER® Emerald Series Implantation System. If forceps are used to implant the lens, viscoelastic should be applied to both sides of the IOL optic, before folding, and the compressive force on the lens should be minimized to reduce the potential for the lens to adhere to itself or to instruments.
- As an alternative to The UNFOLDER® Emerald Series Implantation System, forceps may be used for lens insertion. If forceps are used during implantation of the lens, care should be taken by the surgeon to avoid contacting the central portion of the lens optic, as permanent forceps marks can be induced in the visual axis.
- The IOL should not be kept in the folded condition for longer than 5 minutes in The UNFOLDER® Emerald Series Cartridge, or for longer than 1 minute in insertion forceps, otherwise the lens should be discarded.

Calculation of Lens Power

The physician should determine preoperatively the power of the lens to be implanted. **Emmetropia** should be targeted. The estimated A-constant for this lens is provided on the lens box. Lens power calculation methods are described in the following references:

- Hoffer, K.J., The Hoffer Q formula, A comparison of theoretical and regression formulas, *J. Cataract Refract Surg*, Vol 19, November 1993.
- Retzlaff, J.A., et al. Development of the SRK/T intraocular lens implant power calculation formula, *J. Cataract Refract Surg*, Vol 16, May 1990.
- Holladay J.T., et al. A Three Part System for Refining Intraocular Lens Power Calculations, *J. Cataract Refract Surg*, Vol 14, January 1988.

Physicians requiring additional information on lens power calculation may contact AMO.

Patient Registration Instructions and Reporting

Registration

Where required, each patient who receives an AMO® Posterior Chamber Lens should be registered with AMO at the time of lens implantation.

Registration is accomplished by completing the Implant Registration Card that is enclosed in the lens box and mailing it to AMO. Patient registration is essential for AMO's long-term patient follow-up program and will assist AMO in responding to Adverse Reaction Reports and/or potentially sight-threatening complications.

An Implant Notification Card is supplied in the lens package. This card should be given to the patient with instructions to keep it as a permanent record of the implant and to show the card to any eye care practitioner seen in the future.

Reporting

Adverse reactions and/or potentially sight-threatening complications that may reasonably be regarded as lens related and that were not previously expected in nature, severity or degree of incidence must be reported to AMO. This information is being requested from all surgeons in order to document potential long-term effects of intraocular lens implantation, especially in younger patients.

Purpose: Physicians are required to report these events in order to aid in identifying emerging or potential problems with the Posterior Chamber Lenses. These problems may be related to a specific lot of lenses or may be indicative of long-term problems associated with these lenses or with IOLs in general.

Physicians should use the following toll-free number when reporting adverse reactions or potentially sight threatening complications involving AMO® intraocular lenses. **National:** (800) 366-6554.

How Supplied

AMO® Posterior Chamber IOLs are supplied as individual sterile units. Each sterile lens is enclosed in its own case within a double aseptic transfer peel pouch, the contents of which are sterile unless the packages are damaged or opened. *The external surfaces of the double aseptic transfer peel pouch are not sterile.*

Expiration Date

Sterility is guaranteed unless the *double aseptic transfer peel pouch* is damaged or opened. In addition, there is a sterility expiration date that is clearly indicated on the outside of the shelf-pack. The lens should not be used after the indicated date.

Return/Exchange Policy

Please contact your local AMO Office regarding lens return or exchange.

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Advanced Medical Optics, Inc.

OptiEdge is a trademark of Ocular Sciences, Inc.

Symbols on Sterile Packaging

SYMBOL	ENGLISH
	Sterilized by ethylene oxide
	DO NOT REUSE
	USE BY (YYYY-MM: year-month)
	SEE INSTRUCTIONS FOR USE

MANUFACTURED IN THE USA:
Advanced Medical Optics, Inc.
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