



LABEL SPECIFICATION

DOCUMENT NO: Z310570
 CURRENT LCR: 20040857
 VERSION: 3.0
 ISSUE DATE: 9/28/04
 HISTORY LCR: 20040396

TITLE: DFU, REZOOM™ ACRYLIC MULTIFOCAL POSTERIOR CHAMBER IOLS (CE MARK, MULTILINGUAL EXPORT ONLY)

SPECIFICATION:

1. **DIMENSIONS:**
 - a. Horizontal: 22" ± 1/32"
 - b. Vertical: 19" ± 1/32"

Flat: 19" x 22" (Tolerance: ± 1/32")

Folded: 3 7/8" X 5 1/2" (Tolerance: ± 1/8")

 - a. Accordion fold to 5 1/2" x 19"
 - b. Right angle fold to 5 1/2" x 11 5/8"
 - c. Right angle fold in thirds to 5 1/2" x 3 7/8"
2. **STOCK:** 40 lb. Offset or 16 lb. Bond, Smooth Opaque Finish. (Minimum Thickness: 0.0020")
3. **STYLE:** One sheet, title facing out, English facing out, two column text layout, printed both sides.
4. **COLOR OF COPY:** Black permanent pigmented ink on white paper.
5. Printing to be clear and legible with no ink smears.
6. Insert to clean. No visible damage, loose or attached particles (fibers) are permitted.
7. Vendor to package product following guidelines according to AMOS #3110.
8. Refer to attached artwork layout.
9. **POINT OF USE:** Puerto Rico
10. The data sheet contains a panel translated from English to each of the following languages –Dutch, Spanish, French, German, and Italian.

11. MULTILINGUAL DATA SHEET LAYOUT:

Front Side:	Graphs	Graphs	Dutch	English
Back Side	French	German	Italian	Spanish

Approved By: _____ Deborah Gasparro _____ Date: _____ 9/28/04 _____

CHANGE SUMMARY

APPROVAL DATE	LCR #	VER.	DESCRIPTION OF CHANGE
6/17/04	20040396	2.0	Create new DFU
9/28/04	20040857	3.0	Change from "Emerald Series Implantation System" to "EMERALDT Implantation System"



ReZoom™ Acrylic Multifocal Posterior Chamber Intraocular Lenses

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

Z310570 Ver. 3.0 904

Description

Advanced Medical Optics, Inc. (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 Model NXG1 IOLs incorporate the squared OptiEdge™ design (See Fig. 1).

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 2.
+3.5 diopters of add power at the IOL plane corresponding to approximately +2.4 D to +2.8 D in the spectacle plane. (see Clinical Results)
Refractive zonal-progressive IOL incorporating continuous range of foci (Figure 3).

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 persons 60 years of age or older in whom a cataractous lens has been removed and who may benefit from useful near vision without reading add and increased spectacle independence across a range of distances. These devices are intended to be placed in the capsular bag.

AMO ReZoom™ Multifocal Intraocular Lenses are indicated for correction of aphakia following refractive lensectomy in presbyopic adults who may benefit from useful near vision without spectacle or contact lens reading add and increased spectacle independence across a range of distances. These devices are intended to be placed in the capsular bag.

Warnings

- Some visual effects may be expected because of the simultaneous focus of multiple images. These include some perception of "ghost" images under certain lighting conditions, or some loss of contrast at near or far. These have also been reported with diffractive bifocal lenses. Some of the effects may be mitigated in patients in which they occur, upon adaptation to the multifocal optic.
Under low contrast conditions, visual acuity is reduced with a multifocal lens when compared to a monofocal lens. Therefore, multifocal patients should exercise caution when driving at night or in poor visibility conditions.
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 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.

Precautions

- Autorefractors may not provide optimal postoperative refraction of multifocal patients. Manual refraction is strongly recommended.
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.
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.
Do not sterilize the lens by any means. Most sterilizers are not equipped to sterilize the soft acrylic material without producing undesirable side effects.
Do not store the lens in direct sunlight or at a temperature greater than 113°F (45°C).
Do not soak or rinse the intraocular lens with any solution other than sterile balanced salt solution or sterile normal saline.
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.
When The UNFOLDER™ EMERALDT 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™ EMERALDT Implantation System.
Special consideration should be given to the dimensions of lenses at the extreme ends of the power range in relation to the anatomical clearances in the patient's eye. The potential impact of factors such as optic central thickness, optic edge thickness, and overall lens size on the patient's long-term clinical outcome should be carefully weighed against the potential benefit associated with the implantation of an intraocular lens.

Silicone ARRAY® Clinical Trial

The ARRAY® Model SSM26NB multifocal silicone posterior chamber intraocular lens was evaluated in a prospective, nonrandomized study of 456 patients followed for one year.

The postoperative results demonstrated that the ARRAY® Multifocal IOL provides distance vision comparable to a monofocal IOL, intermediate vision, and increased near vision. 82.6% of patients achieved both 20/40 or better and J3 or better uncorrected vision. The distance and near acuities achieved by the best case cohort patients (those with no preoperative pathology or postoperative macular degeneration) are described in Tables 1 and 2.

Adverse Events

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

Secondary Surgical Interventions are reported in Table 3.

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 pupillary block, iridectomy for pupillary 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.

Other complications: 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) (0.9 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.

Contrast Acuity: Mean differences between eyes for the Monofocal Fellow Eye Control Subset where significant, were generally within 1 to 1.5 lines. The frequency of patients 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 patients for halos, glare/flare, and blurred far vision. Patients 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%).

Soft Acrylic SENSAR® 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 4 and 5. 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.
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™ EMERALDT Implantation System designed for use with the AMO Soft Acrylic Multifocal Posterior Chamber IOL, should be used to insert the lens in the folded state. Refer to specific instructions provided with The UNFOLDER™ EMERALDT 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™ EMERALDT 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 SRKT 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 rate of occurrence 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.

How Supplied

AMO's 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.

Patient Information

It is recommended that each patient receive information regarding intraocular lenses in a manner that is suitable to the patient. This information should be provided prior to the decision to implant an intraocular lens. Postoperative information should also be provided by the physician.

ReZoom, and The UNFOLDER are trademarks, and the multifocal design is a servicemark of Advanced Medical Optics, Inc.

AMO®, the AMO logo, ARRAY®, and SENSAR® are registered trademarks of Advanced Medical Optics, Inc.

OptiEdge™ is a trademark of Ocular Sciences Inc.

SENSAR® is produced and/or sold under at least one of the following U.S. Letters: 4,573,998; 4,898,461; 5,166,711; 5,166,712; 5,225,858; 5,270,744; 5,521,856; RE 36,150; 6,162,249; 5,657,108; 5,877,839; 6,186,625; 6,409,304; 6,210,005; 6,468,306. Likewise patents pending and foreign equivalents available upon request.

ReZoom is produced and/or sold under at least one of the following U.S. Letters: 6,210,005; 6,435,681; and 6,557,998.

OptiEdge™ is produced and/or sold under at least one of the following U.S. Letters: 6,162,249, and 6,468,306.

Symbols on Sterile Packaging

Table with 2 columns: SYMBOL and ENGLISH. Symbols include a box with 'STERILE EO', a crossed-out trash can, and a warning triangle.

MANUFACTURED IN THE USA: Advanced Medical Optics, Inc. Santa Ana, CA 92705 USA (800) 366-6554

Distributed in the UK by: AMO United Kingdom Limited Jupiter House Mercury Park Woodburn Green High Wycombe Buckinghamshire HP10 0HH UK

www.amo-inc.com



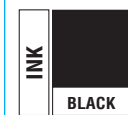
AMO Ireland Sweepstakes Centre Ballsbridge Dublin 4 Ireland

AMO WORLDWIDE SPECIFICATIONS

DRAWING NUMBER: N/A (refer to label spec.)

- ARTWORK IS ACTUAL SIZE
- ALL COPY PRINTS BLACK UNLESS OTHERWISE SPECIFIED
- DROP COLOR CALLOUTS AND KEYLINES BEFORE PROCESSING
- COPY IS SHOWN NOT TO SCALE

PLATFORM: MAC - QUARK XPRESS 4.0



Worldwide Specifications Labeling and Packaging

ARTWORK SPECIFICATIONS

PART #: Z310570 Ver.3.0 DRAWING #: N/A

Table with 3 columns: WorldWide Specifications Labeling/Packaging, Regulatory Affairs Labeling Compliance, LCR Requestor. Includes handwritten signatures and dates.

YOUR SIGNATURE IS REQUIRED.

If signatures are NOT present, this document is NOT valid.



TABLE 1 TABLEAU 1 TABELLE 1	
ARRAY® Model SSM26NB Distance Visual Acuity Best Case Cohort Population (N = 392)	
Uncorrected	With best correction
20/20 or better	71.2%
20/40 or better	98.5%
20/41 - 20/80	1.0%
Worse than 20/80	0.5%

TABLE 2 TABLEAU 2 TABELLE 2		
ARRAY® Model SSM26NB Near Visual Acuity Best Case Cohort Population (N = 392)		
Uncorrected	With distance correction	With additional add
J1 or better	48.0%	95.8%
J3 or better	87.9%	99.5%
Worse than J3	12.1%	0.5%

TABLE 3 TABLEAU 3 TABELLE 3		
ARRAY® Model SSM26NB Secondary Surgical Interventions All Core Subjects (N = 456)		
Uncorrected	With distance correction	With additional add
J1 or better	48.0%	95.8%
J3 or better	87.9%	99.5%
Worse than J3	12.1%	0.5%

TABLE 4 TABLEAU 4 TABELLE 4				
ARRAY® Model SSM26NB 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/Vitreotomy	1	0.2	0	0.0
- Argon Laser Retinopathy	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 patients experiencing Secondary Surgical Interventions after the final study visit as of May 10, 1996.
† Nine (9) patients exhibited ten (10) interventions. One patient had two secondary surgical procedures, vitrectomy and IOL replacement.
†† This patient also underwent a scleral buckle procedure for the fellow eye implanted with an otherwise similar monofocal IOL.

TABLE 5 TABLEAU 5 TABELLE 5					
SENSAR® Model AR40 Adverse Events All Subjects (N=382)					
ADVERSE EVENTS	CUMULATIVE	PERSISTENT AT ONE YEAR	CUMI*	FDA GRID	PER**
	N	%	N	%	%
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
- Pupillary 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
- 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.

TABLE 6 TABLEAU 6 TABELLE 6					
SENSAR® 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		
<60	2	0.7	2	100.0	96.9
60-69	90	33.1	90	100.0	93.8
70-79	146	53.7	144	98.6	94.9
>80	34	12.5	33	97.1	87.9
TOTAL	272	100.0	269	98.9	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.



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SENSAR® Model AR40 Adverse Events All Subjects (N=382)					
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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
- Pupillary 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
- 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
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* 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.



ReZoom™ acryl multifocale intraoculaire lenzen voor de achterste oogkamer
Alleen op voorschrift - In de VS alleen op voorschrift verkrijgbaar

Beschrijving
Advanced Medical Optics, Inc. (AMO) ReZoom™ acryl multifocale intraoculaire lenzen voor de achterste oogkamer zijn verkrijgbaar als ultraviolet absorberende biconvexe optische lenzen, met een anterior multifocaal oppervlak, die ontwikkeld zijn voor plaatsing achter de iris waar de lens de optische functie van de natuurlijke kristallijne ooglenzen vervangt voor de correctie van dikke, 50%, 50%, 25% en 11% en C.A.T. (contrast acuity) test kaarten voor dichtbij zien bij een contrast van 100%, 50%, 25% en 12.5%.

Geïndiceerde beschrijving
Optiek van de lens
• Optisch materiaal: Optisch helder zacht vouwbaar acryl met covalent gebonden UV-absorber
• Sterkte +6.0 tot +30.0 dioptrieën in stappen van 0.5 dioptrie.
• Refractie-index: 1.47 (55°C)
• Lichtvoerdichtheid: UV cut-off waarden bij 10% T voor een +6.0 dioptrie lens (dünste) en een +27.0 dioptrie lens (dikste) worden getoond in afbeelding 2.
• +3.5 dioptrieën toegevoegde sterkte op het intraoculaire lensvak correspondeert met ongeveer +2.4 D tot +2.8 D in het buitenvak. (zie klinische resultaten)

Haptiek
• Materiaal: Blauwe kern polymethylmethacrylaat (PMMA) monofilaan.
• De chirurg dient te controleren op **emmetropie** aangezien deze lens ontwikkeld is voor optimale visuele prestatie bij emmetropie.

Modelmerken
Zie buitenkant verpakking.

Werking
De lens wordt achter de iris geplaatst. In deze positie kan de optische vergroting van de intraoculaire lens de functie van de natuurlijke kristallijne ooglenzen vervangen. De werkzaamheid van lenzen die ultraviolet licht absorberen bij het verlagen van de incidentie van retinale aandoeningen is niet vastgesteld.

Indicaties
AMO ReZoom™ acryl multifocale intraoculaire lenzen voor de achterste oogkamer zijn geïndiceerd voor de visuele correctie van ataxie bij personen van 60 jaar of ouder bij wie een lens met cataract verwijderd is en die er baat bij kunnen hebben om dichtbij te zien zonder lenzerl of minder afhankelijk van een bril te zijn over een groter afstandsbereik. Deze lenzen zijn bedoeld om in het kapszakje geplaatst te worden.
AMO ReZoom™ multifocale intraoculaire lenzen voor de achterste oogkamer zijn geïndiceerd voor de correctie van ataxie na refractieve laserstralende bij volwassenen die er baat bij kunnen hebben om dichtbij te kunnen zien zonder lenzerl of contactlenzen en minder afhankelijk van een bril te zijn over een groter afstandsbereik. Deze lenzen zijn bedoeld om in het kapszakje geplaatst te worden.

Waarschuwingen
1. Enkele visuele effecten kunnen verwacht worden doordat meerdere beelden tegelijkertijd scherpe afbeeldingen moeten worden. Hiertoe behoren onder bepaalde lichtomstandigheden de waarneming van "spook"beelden of enig contrastverlies dichtbij of veraf. Deze effecten zijn ook geassocieerd met diffractieve bifocale lenzen. Sommige van deze effecten kunnen na adaptatie aan de multifocale optiek afnemen bij patiënten die te laat van hebben.
2. Onder condities met laag contrast wordt de gezichtsscherpte met een multifocale lens in vergelijking met een monofocale lens vermindert. Multifocale patiënten dienen dertalve voorzichtig te zijn wanneer ze 's nachts of onder omstandigheden met slecht zicht autorijden.
3. Patiënten met een van de volgende aandoeningen zijn misschien geen geschikte kandidaat voor een intraoculaire lens omdat de lens de bestaande aandoening kan verergeren of de diagnose of behandeling van een aandoening kan bemoeilijken of een onreëel risico kan vormen voor het gezichtsvermogen van de patiënt.
a. Patiënten bij wie de intraoculaire lens het vermogen om aandoeningen van het achterste segment waar te nemen, te diagnosticeren of te behandelen kan beïnvloeden.
b. Chirurgische problemen ten tijde van de cataractextractie of de implantatie van de intraoculaire lens die de lens of complicaties (bijv. aanhoudend bloederigheids, aanzienlijke beschadiging van de iris, ongecontroleerde positieve druk of aanzienlijke prolaps of verlies van vocht) kunnen veroorzaken.
c. Een vermindert oog door eerder letsel of een ontwikkelingsstoornis waardoor juiste ondersteuning van de IOL niet mogelijk is.
d. Enkele omstandigheden die tijdens implantatie tot beschadiging van het endothelium kan leiden.
e. Vermoeden van een bacteriologische infectie.
f. Patiënten bij wie noch het achterste knipkaspeel noch de zonulair veezels voldoende intact zijn om ondersteuning te bieden.
g. Congenitale bilaterale cataracten.
h. Terugnede ontwikkeling van het voornet of achterste segment met onbekende etiologie, of een ziekte die een ontstekingsreactie aan het oog veroorzaakt.
i. Voorgeschiedenis van of aanleg voor netvliesloslating.
j. Patiënten met slechts één oog en mogelijk geringe gezichtsvermogen.
k. Medisch oncontroleerbaar glaucoom.
l. Dystrofie van het hoornvliesendothelium.
m. Proliferatieve diabetische retinopathie.

Voorspansaanpak
1. Autorfactie levert misschien niet de meest optimale postoperatieve refractie bij multifocale patiënten op. Handmatige refractie wordt sterk aanbevolen.
2. De lange-termijn effecten van intraoculaire lensimplantatie zijn nog niet bepaald. De arts dient derhalve patiënten met een implantaat postoperatief regelmatig te blijven controleren.
3. Er is sporadisch melding gemaakt van een secundair glaucoom bij patiënten met een gecontroleerd glaucoom die aan lensimplantatie hebben gekregen. De intraoculaire druk bij glaucoompatiënten met een implantaat dient postoperatief zorgvuldig gecontroleerd te worden.
4. De lens niet op enige wijze optisch stabiliseren. De meeste stabilisatoren zijn niet uitgerust om het zachte acryl te stabiliseren zonder ongewenste bijwerkingen.
5. De lens niet in direct zonlicht of bij een temperatuur van meer dan 45°C bewaren.
6. De intraoculaire lens alleen waken of spoelen in een steriele gebalanceerde zuutoplossing of een steriele fysiologische zuutoplossing.
7. Raadpleeg de specifieke gebruiksaanwijzing bij het UNFOLDER™ implantaatsysteem om te zien hoe lang de IOL in de cartridge kan blijven voor de IOL weggegooid moet worden.
8. Als The UNFOLDER™ EMERALD™ implantaatsysteem incorrect gebruikt wordt, kan de haptiek van de zachte acryl multifocale lens getrimpt of gebroken worden. Raadpleeg de specifieke gebruiksaanwijzing bij het UNFOLDER™ EMERALD™ implantaatsysteem.
9. Speciale aandacht dient gegeven te worden aan de afmetingen van de lenzen aan de uiterste waarden van het sterktebereik in verhouding tot de beschikbare ruimte in de oogkamer van de patiënt. De overvulde invloed van factoren, zoals de dikte van het midden van de lens, de dikte van de rand van de lens en de algehele vorm van de lens, op het lange-termijn klinische resultaat voor de patiënt, dient zorgvuldig afgewogen te worden tegen het mogelijke voordeel dat aan de implantatie van een intraoculaire lens is verbonden.

Siliconen ARRAY® Klinisch onderzoek
De ARRAY® Model SSM26NB multifocale siliconen intraoculaire lens voor de achterste oogkamer werd in een prospectief, niet-gerandomiseerd onderzoek met 456 patiënten, die gedurende een jaar gevolgd werden, geëvalueerd.
De postoperatieve resultaten laten zien dat de ARRAY® multifocale IOL een zicht voor afstand oplevert die vergelijkbaar is met een monofocale IOL, middelmataandiscen en verbeterd dichtbij zien. 82,6% van de patiënten behaalde zowol 20/40 of beter en een score van J-3 op de Jaegerkaart of beter met ongecorrigeerd gezichtsvermogen. De scherpheid van het ver zicht dichtbij zien dat door het cohort met de beste patiënten bereikt werd (patiënten zonder preoperatieve pathologie of postoperatieve maculaire degeneratie) wordt beschreven in tabel 1 en 2.

Bijwerkingen
In totaal werden 456 patiënten in klinisch onderzoek naar de veiligheid van de ARRAY® Model SSM26NB multifocale siliconen intraoculaire lens voor de achterste oogkamer geëvalueerd.
Secundaire chirurgische ingrepen worden vermeld in tabel 3.
Er werd melding gemaakt van één patiënt die problemen had bij het behoud van stereoscopisch zien en de fusie van de beelden tijdens een epineurale weefselverwijderingsprocedure. Extra inspanning om gezichtsscherpte te behouden werd gemeld tijdens een tweede epineurale weefselverwijderingsprocedure. Voor de overige procedures die op het achterste segment werden uitgevoerd werden geen problemen gemeld.
Tot eventuele secundaire chirurgische ingrepen die met intraoculaire lenzen in verband gebracht zijn, maar zich niet voordeden tijdens dit klinische onderzoek, behoren: verwijdering van de lens vanwege contact met het hoornvlies, verwijdering van de lens ten gevolge van een ontsteking, hoornvliestransplantatie, aspiratie van het glaucoom vanwege pupilliek, indometacine vanwege pupilliek. Andere bijwerkingen die met intraoculaire lenzen in verband gebracht zijn, maar zich niet voordeden tijdens dit klinische onderzoek, zijn: hypopyon, intraoculaire infectie en acute decompensatie van het hoornvlies.
Andere complicaties: De complicaties die zich tijdens het klinische onderzoek voordeden, omvatten (in volgorde van frequentie): frequente klinisch onderzoek vs. frequente "FDA-tabel"; maculair oedeem (persisterend) 0,8 vs. 0,8%, iritis (persisterend) 0,2 vs. 1,0%, cornea-oedeem (persisterend) 0,0 vs. 0,6%, pupilliek (cumulatief) 0,3 vs. 0,3%, secundair glaucoom (cumulatief) 11,5 vs. n.v.t.), en vitritis (cumulatief) 0,5 vs. n.v.t.). De incidentie van deze complicaties was vergelijkbaar met of lager dan de incidentie van de historische controlepopulatie ("FDA-tabel"). Mogelijke complicaties die zich niet voordeden tijdens dit klinische onderzoek, maar die met cataractoperaties of implantaties gepaard kunnen gaan, zijn, en beperken zich niet tot de volgende: beschadiging van het hoornvliesendothelium, niet-gepigmenteerde precipitaten, infectie, netvliesloslating, verlies van glavoest, prolaps van de iris, weegleken van glavoest, weefsel onocclusie/pupilliek.

Contraïndicaties: Het gemiddelde verschil tussen de ogen in de monofocale controle-afleveringsgroep bestaande uit de

