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APPROVAL ORDER

00M-0445

AA V 1

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Barbara A. Niksch
Section Manager, Worldwide Regulatory Affairs
Allergan, Inc.
2525 Dupont Drive
Irvine, CA 92612-9534

FEB 3 2000

Re: P980040

AMO® SENSAR™ Soft Acrylic, UV Light-Absorbing, Posterior Chamber
Intraocular Lens (IOL), Model AR40

Filed: November 13, 1998

Amended: December 7 and 23, 1998; January 4 and 27, March 8 and 23, July 29
(2), October 14, December 14 and 21, 1999; January 13, 2000

Dear Ms. Niksch:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your premarket approval application (PMA) for the AMO® SENSAR™ Soft Acrylic, UV Light-Absorbing, Posterior Chamber Intraocular Lens (IOL), Model AR40. This device is indicated for the visual correction of aphakia in persons 60 years of age or older in whom a cataractous lens has been removed by extracapsular cataract extraction. The lens is intended to be placed in the capsular bag. We are pleased to inform you that the PMA is approved subject to the conditions described below and in the "Conditions of Approval" (enclosed). You may begin commercial distribution of the device upon receipt of this letter.

The sale, distribution, and use of this device are restricted to prescription use in accordance with 21 CFR 801.109 within the meaning of section 520(e) of the Federal Food, Drug, and Cosmetic Act (the act) under the authority of section 515(d)(1)(B)(ii) of the act. FDA has also determined that, to ensure the safe and effective use of the device, the device is further restricted within the meaning of section 520(e) under the authority of section 515(d)(1)(B)(ii) insofar as the sale, distribution, and use must not violate sections 502(q) and (r) of the act.

CDRH approval is subject to full compliance with the conditions described in the enclosure and the following:

1. You should follow all cohort patients for three years. You should provide a post-approval report after the three-year clinical study has been completed. Specifically, the post-approval report should address the following items:

- a) The progression and/or regression of the unresolved tissue ongrowth cases reported in amendment 7 of this PMA.
 - b) Any additional reports of tissue ongrowth.
 - c) Any subjective visual complaints by subjects, who have tissue ongrowth.
 - d) Visual outcomes, including an analysis of visual acuities, for tissue ongrowth subjects.
2. A mechanism to facilitate adverse event reporting to you, such as an 800 telephone number, must be in place.
 3. Advertising and other printed materials prepared by your firm or its distributors may not include indications not included in the FDA-approved labeling for the device.

Expiration dating for this device has been established and approved at twenty-six (26) months. This is to advise you that the protocol you used to establish this expiration dating is considered an approved protocol for the purpose of extending the expiration dating as provided by 21 CFR 814.39(a)(7).]

CDRH will notify the public of its decision to approve your PMA by making available a summary of the safety and effectiveness data upon which the approval is based. The information can be found on the FDA CDRH Internet HomePage located at <http://www.fda.gov/cdrh/pmapage.html>. Written requests for this information can also be made to the Dockets Management Branch, (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. The written request should include the PMA number or docket number. Within 30 days from the date that this information is placed on the Internet, any interested person may seek review of this decision by requesting an opportunity for administrative review, either through a hearing or review by an independent advisory committee, under section 515(g) of the act.

Failure to comply with the conditions of approval invalidates this approval order. Commercial distribution of a device that is not in compliance with these conditions is a violation of the act.

You are reminded that, as soon as possible and before commercial distribution of your device, you must submit an amendment to this PMA submission with copies of all approved labeling in final printed form. As part of our reengineering effort, the Office of Device Evaluation is piloting a new process for review of final printed labeling. The labeling will not routinely be reviewed by FDA staff when PMA applicants include with their submission of the final printed labeling a cover letter stating that the final

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printed labeling is identical to the labeling approved in draft form.

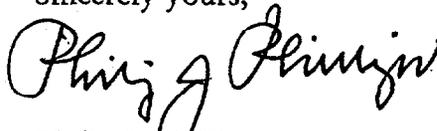
If the final printed labeling is not identical, any changes from the final draft labeling should be highlighted and explained in the amendment. Please see the CDRH Pilot for Review of Final Printed Labeling document at <http://www.fda.gov/cdrh/pmat/pilotpmat.html> for further details.

All required documents should be submitted in triplicate, unless otherwise specified, to the address below and should reference the above PMA number to facilitate processing.

PMA Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Blvd.
Rockville, Maryland 20850

If you have any questions concerning this approval order, please contact Mr. Lawrence J. Romanell at (301) 594-2053.

Sincerely yours,



Philip J. Phillips
Deputy Director for Science and
Regulatory Policy
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Issued: 3-4-98

CONDITIONS OF APPROVAL

APPROVED LABELING. As soon as possible, and before commercial distribution of your device, submit three copies of an amendment to this PMA submission with copies of all approved labeling in final printed form to the PMA Document Mail Center (HFZ-401), Center for Devices and Radiological Health, Food and Drug Administration (FDA), 9200 Corporate Blvd., Rockville, Maryland 20850.

ADVERTISEMENT. No advertisement or other descriptive printed material issued by the applicant or private label distributor with respect to this device shall recommend or imply that the device may be used for any use that is not included in the FDA approved labeling for the device. If the FDA approval order has restricted the sale, distribution and use of the device to prescription use in accordance with 21 CFR 801.109 and specified that this restriction is being imposed in accordance with the provisions of section 520(e) of the act under the authority of section 515(d)(1)(B)(ii) of the act, all advertisements and other descriptive printed material issued by the applicant or distributor with respect to the device shall include a brief statement of the intended uses of the device and relevant warnings, precautions, side effects and contraindications.

PREMARKET APPROVAL APPLICATION (PMA) SUPPLEMENT. Before making any change affecting the safety or effectiveness of the device, submit a PMA supplement for review and approval by FDA unless the change is of a type for which a "Special PMA Supplement-Changes Being Effectuated" is permitted under 21 CFR 814.39(d) or an alternate submission is permitted in accordance with 21 CFR 814.39(e). A PMA supplement or alternate submission shall comply with applicable requirements under 21 CFR 814.39 of the final rule for Premarket Approval of Medical Devices.

All situations which require a PMA supplement cannot be briefly summarized, please consult the PMA regulation for further guidance. The guidance provided below is only for several key instances.

A PMA supplement must be submitted when unanticipated adverse effects, increases in the incidence of anticipated adverse effects, or device failures necessitate a labeling, manufacturing, or device modification.

A PMA supplement must be submitted if the device is to be modified and the modified device should be subjected to animal or laboratory or clinical testing designed to determine if the modified device remains safe and effective.

A "Special PMA Supplement - Changes Being Effectuated" is limited to the labeling, quality control and manufacturing process changes specified under 21 CFR 814.39(d)(2). It allows for the addition of, but not the replacement of previously approved, quality control specifications and test methods. These changes may be implemented before FDA approval upon acknowledgment by FDA that the submission is being processed as a "Special PMA Supplement - Changes Being Effectuated." This acknowledgment is in addition to that issued by the PMA Document Mail Center for all PMA supplements submitted. This procedure is not applicable to changes in device design, composition, specifications, circuitry, software or energy source.

Alternate submissions permitted under 21 CFR 814.39(e) apply to changes that otherwise require approval of a PMA supplement before implementation of the change and include the use of a 30-day PMA supplement or annual postapproval report. FDA must have previously indicated in an advisory opinion to the affected industry or in correspondence with the applicant that the alternate submission is permitted for the change. Before such can occur, FDA and the PMA applicant(s) involved must agree upon any needed testing protocol, test results, reporting format, information to be reported, and the alternate submission to be used.

POSTAPPROVAL REPORTS. Continued approval of this PMA is contingent upon the submission of postapproval reports required under 21 CFR 814.84 at intervals of 1 year from the date of approval of the original PMA. Postapproval reports for supplements approved under the original PMA, if applicable, are to be included in the next and subsequent annual reports for the original PMA unless specified otherwise in the approval order for the PMA supplement. Two copies identified as "Annual Report" and bearing the applicable PMA reference number are to be submitted to the PMA Document Mail Center (HFZ-401), Center for Devices and Radiological Health, Food and Drug Administration, 9200 Corporate Blvd., Rockville, Maryland 20850. The postapproval report shall indicate the beginning and ending date of the period covered by the report and shall include the following information required by 21 CFR 814.84:

(1) Identification of changes described in 21 CFR 814.39(a) and changes required to be reported to FDA under 21 CFR 814.39(b).

(2) Bibliography and summary of the following information not previously submitted as part of the PMA and that is known to or reasonably should be known to the applicant:

(a) unpublished reports of data from any clinical investigations or nonclinical laboratory studies involving the device or related devices ("related" devices include devices which are the same or substantially similar to the applicant's device); and

(b) reports in the scientific literature concerning the device.

If, after reviewing the bibliography and summary, FDA concludes that agency review of one or more of the above reports is required, the applicant shall submit two copies of each identified report when so notified by FDA.

ADVERSE REACTION AND DEVICE DEFECT REPORTING. As provided by 21 CFR 814.82(a)(9), FDA has determined that in order to provide continued reasonable assurance of the safety and effectiveness of the device, the applicant shall submit 3 copies of a written report identified, as applicable, as an "Adverse Reaction Report" or "Device Defect Report" to the PMA Document Mail Center (HFZ-401), Center for Devices and Radiological Health, Food and Drug Administration, 9200 Corporate Blvd., Rockville, Maryland 20850 within 10 days after the applicant receives or has knowledge of information concerning:

(1) A mix-up of the device or its labeling with another article.

(2) Any adverse reaction, side effect, injury, toxicity, or sensitivity reaction that is attributable to the device and

(a) has not been addressed by the device's labeling or

(b) has been addressed by the device's labeling, but is occurring with unexpected severity or frequency.

(3) Any significant chemical, physical or other change or deterioration in the device or any failure of the device to meet the specifications established in the approved PMA that could not cause or contribute to death or serious injury but are not correctable by adjustments or other maintenance procedures described in the approved labeling. The report shall include a discussion of the applicant's assessment of the change, deterioration or failure and any proposed or implemented corrective action by the applicant. When such events are correctable by adjustments or other maintenance procedures described in the approved labeling, all such events known to the applicant shall be included in the Annual Report described under "Postapproval Reports" above unless specified otherwise in the conditions of approval to this PMA. This postapproval report shall appropriately categorize these events and include the number of reported and otherwise known instances of each category during the reporting period. Additional information regarding the events discussed above shall be submitted by the applicant when determined by FDA to be necessary to provide continued reasonable assurance of the safety and effectiveness of the device for its intended use.

REPORTING UNDER THE MEDICAL DEVICE REPORTING (MDR) REGULATION. The Medical Device Reporting (MDR) Regulation became effective on December 13, 1984. This regulation was replaced by the reporting requirements of the Safe Medical Devices Act of 1990 which became effective July 31, 1996 and requires that all manufacturers and importers of medical devices, including in vitro diagnostic devices, report to the FDA whenever they receive or otherwise become aware of information, from any source, that reasonably suggests that a device marketed by the manufacturer or importer:

(1) May have caused or contributed to a death or serious injury; or

(2) Has malfunctioned and such device or similar device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

The same events subject to reporting under the MDR Regulation may also be subject to the above "Adverse Reaction and Device Defect Reporting" requirements in the "Conditions of Approval" for this PMA. FDA has determined that such duplicative reporting is unnecessary. Whenever an event involving a device is subject to reporting under both the MDR Regulation and the "Conditions of Approval" for a PMA, the manufacturer shall submit the appropriate reports required by the MDR Regulation within the time frames as identified in 21 CFR 803.10(c) using FDA Form 3500A, i.e., 30 days after becoming aware of a reportable death, serious injury, or malfunction as described in 21 CFR 803.50 and 21 CFR 803.52 and 5 days after becoming aware that a reportable MDR event requires remedial action to prevent an unreasonable risk of substantial harm to the public health. The manufacturer is responsible for submitting a baseline report on FDA Form 3417 for a device when the device model is first reported under 21 CFR 803.50. This baseline report is to include the PMA reference number. Any written report and its envelope is to be specifically identified, e.g., "Manufacturer Report," "5-Day Report," "Baseline Report," etc.

Any written report is to be submitted to:

Food and Drug Administration
Center for Devices and Radiological Health
Medical Device Reporting
PO Box 3002
Rockville, Maryland 20847-3002

Copies of the MDR Regulation (FOD # 336&1336) and FDA publications entitled "An Overview of the Medical Device Reporting Regulation" (FOD # 509) and "Medical Device Reporting for Manufacturers" (FOD #987) are available on the CDRH WWW Home Page. They are also available through CDRH's Fact-On-Demand (F-O-D) at 800-899-0381. Written requests for information can be made by sending a facsimile to CDRH's Division of Small Manufacturers Assistance (DSMA) at 301-443-8818.

SUMMARY OF SAFETY AND
EFFECTIVENESS DATA (SSED)



SUMMARY OF SAFETY AND EFFECTIVENESS DATA

I. GENERAL INFORMATION

- A. Premarket Approval Application (PMA) Number: P980040
Date Filed: October 1, 1998
Date Approved: FEB - 3 2000
- B. Generic Name of Device: Monofocal Posterior Chamber Intraocular Lens (IOL)
- C. Trade Name of Device: SENSAR™ Soft Acrylic UV Light-Absorbing Posterior Chamber Intraocular Lens, Model AR40
- D. Applicant's Name and Address: Allergan, Inc.
2525 Dupont Drive
Irvine, CA 92623
- E. Good Manufacturing Practice (GMP) Inspection Date: September 24, 1999
Conclusion: The manufacturing site was found to be in compliance with device GMP requirements.
- F. Ophthalmic Devices Panel (Panel): N/A

II. INDICATIONS

Allergan, Inc, SENSAR™ Soft Acrylic UV Light-Absorbing Posterior Chamber Intraocular Lens, Model AR40, is indicated for the visual correction of aphakia in persons 60 years of age or older in whom a cataractous lens has been removed by extracapsular cataract extraction. The lens is intended to be placed in the capsular bag.

III. SUMMARY

The applicant has performed nonclinical and clinical testing on the device, following the recommendations in the draft FDA guidance testing for intraocular lenses dated October 10, 1997. Data on 335 patients followed postoperatively for 12 months were evaluated against historical controls (Stark WJ, et al 1983. The FDA Report on Intraocular Lenses. Ophthalmology 90(4): 311-317).

The population at risk for developing visually disabling cataracts and needing cataract surgery is typically elderly; the elderly population has a slightly higher proportion of females to males. For the cohort subjects at the time of surgery, 30.4 % of subjects were 60-69 years old; 54% of the subjects were 70-79 years old; and 14.6 % were at least 80 years old. Approximately 60% of the 335 cohort subjects were female and approximately 40% were male. The inclusion/exclusion criteria did not exclude patients on the basis of gender or gender-related pathology. The cohort study

population of 335 patients was 97.6% Caucasian, 2.1% Black and 0.3% Asian. This study, which began in 1996, included all patients who met the inclusion criteria.

Based on the analysis of the detailed data presented in the PMA, it was determined that the clinical performance of this device, i.e., adverse events and visual acuity results, compares favorably with FDA's 1983 grid of historical data.

Most SENSAR™ patients achieved a visual acuity of 20/40 or better. The rates for best-case visual acuity for both genders exceeded FDA grid values.

IV. SAFETY AND EFFECTIVENESS DATA

A. Nonclinical Studies

The applicant conducted a battery of in-vivo and in-vitro acute and chronic toxicity tests that establish the biocompatibility of the lens materials. These studies, combined with data from chemistry and engineering analyses, demonstrate the suitability of the material for use in intraocular lenses. The adequacy of the manufacturing processes, including sterilization, was established through a review of the manufacturing information in the PMA as well as thorough on-site inspections. Non-clinical testing demonstrates the safety and effectiveness of this device from microbiology, toxicology, engineering, and manufacturing perspectives.

B. Clinical Studies

<u>Visual Acuity (% 20/40 or better)</u>	<u>Model AR40</u>		<u>Grid</u>
Age			
≤ 59	100.0%	[2/2]	93.7%
60-69	100.0%	[102/102]	90.8%
70-79	98.4%	[179/182]	88.6%
≥80	95.7%	[45/47]	75.2%
All Cases, All Ages	98.5%	[328/333*]	88.0%
Best Case, All Ages	98.9%	[269/272*]	94.0%

* - Two subjects did not have their best corrected distance visual acuity measured at 1 year.

Cumulative Adverse Events

Endophthalmitis*	0.3%	1	<0.1%
Hyphema	0.0%	0	1.0%
Hypopyon	0.3%	1	0.4%
Lens Dislocation	0.3%	1	0.4%
Macular Edema	0.8%	3	3.5%
Pupillary Block	0.0%	0	0.3%
Retinal Detachment	0.0%	0	0.5%
Lens Epithelial Ongrowth (Anterior Surface)**	9.2%	35	
Secondary Surgical Intervention	0.3%	1	2.0%
• Iridectomy for Pupillary Block	0.0%	0	
• Vitreous Aspiration for Pupillary Block	0.0%	0	
• Repositioning of Lens	0.0%	0	
• IOL Removal For Inflammation	0.0%	0	
• IOL Replacement	0.3%	1	

* - Incidence is not statistically different from grid rate

Persistent Adverse Events

Corneal Edema	0.0%	0	0.6%
Hyphema	0.0%	0	1.0%
Iritis	0.0%	0	1.0%
Macular Edema	0.0%	0	0.8%
Secondary Glaucoma	0.0%	0	0.5%
Vitritis	0.0%	0	0.1%
Lens Epithelial Ongrowth (Anterior Surface)**	5.0%	14	

** - Includes 2 and 3 year reports of tissue ongrowth on the anterior lens surface through July 15, 1999. Adverse effect on these subjects' vision was not reported by the investigators. Tissue ongrowth has been previously reported in the literature on other IOL material types.

V. CONCLUSION

The Center for Devices and Radiological Health (CDRH) reviewed the PMA and concluded that the PMA contained sufficient valid scientific evidence to provide reasonable assurance of the safety and effectiveness of the device under the prescribed indications for use. In accordance with the provisions of section 515 (c)(2) of the Federal Food, Drug and Cosmetic Act as amended by the Safe Medical Devices Act of 1990, this PMA was not referred to the Ophthalmic Devices Panel for review and recommendation because the information in the PMA substantially duplicates the information previously reviewed by this panel. CDRH approved this PMA in a letter to the PMA applicant dated FEB - 3 2000 and signed by the Deputy Director for Science and Regulatory Policy, Office of Device Evaluation.

LABELING

SENSAR™ Posterior Chamber Lenses

Soft Acrylic Ultraviolet Light Absorbing Posterior Chamber Intraocular Lens

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

Device Description

Allergan's SENSAR™ Posterior Chamber Lenses are ultraviolet-absorbing posterior chamber intraocular lenses. They are designed to be positioned posterior to the iris where the lens should replace the optical function of the natural crystalline lens.

Indications

SENSAR™ Posterior Chamber 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 by extracapsular cataract extraction. The lens is intended to be placed in the capsular bag.

Precautions

Do not resterilize the lens. Most sterilizers are not equipped to sterilize the soft acrylic material without producing undesirable side effects.

Do not soak or rinse the intraocular lens with any solution other than sterile balanced salt solution or sterile normal saline.

Do not store the lens in direct sunlight or at a temperature greater than 113°F (45°C). Do not autoclave the intraocular lens.

The lens should be discarded if it remains folded for longer than 5 minutes in The UNFOLDER™ Sapphire Series cartridge, or longer than 1 minute in insertion forceps.

When The UNFOLDER™ Sapphire Series System is used improperly, the haptics of the AR40 lens may become crimped or broken. Please refer to the specific instructions for use provided with The UNFOLDER™ Sapphire Series System.

Warnings

Physicians considering lens implantation under any of the following circumstances should weigh the potential risk/benefit ratio:

1. Recurrent severe anterior or posterior segment inflammation or uveitis.
2. Patients in whom the intraocular lens may affect the ability to observe,

- diagnose, or treat posterior segment diseases.
3. Surgical difficulties at the time of cataract extraction that might increase the potential for complications (e.g., persistent bleeding, significant iris damage, uncontrolled positive pressure, or significant vitreous prolapse or loss).
 4. A distorted eye due to previous trauma or developmental defect in which appropriate support of the IOL is not possible.
 5. Circumstances that would result in damage to the endothelium during implantation.
 6. Suspected microbial infection.
 7. Children under the age of 2 years are not suitable candidates for intraocular lenses.
 8. Patients in whom neither the posterior capsule nor zonules are intact enough to provide support.

Since the clinical study of the Model AR40 was conducted with the lens being primarily implanted in the capsular bag only, there are insufficient clinical data to demonstrate its safety and efficacy for placement in the ciliary sulcus.

Adverse Events

The incidence of complications experienced during the clinical trial of Model AR40 were all comparable to or less than those of the historic control ("FDA grid") population (see Table 1). As of May 27, 1998, there were 382 implants and the overall incidence of reported adverse events is 1.6%.

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 provide the basis for the data that were used to support that this IOL design can be used for the visual correction of aphakia. The visual acuity results obtained for all subjects in this clinical trial are presented in Table 2.

Detailed Device Description

Lens Optic

- Optic Material: Optically clear, soft foldable acrylic with a covalently bound UV absorber.

- Power: +10.0 to +27.0 diopter powers in +0.5 diopter increments. +27.0 to +30.0 diopter powers in +1.0 diopter increments.
- Index of Refraction: 1.47 at 35°C
- Light transmittance: UV cut-offs at 10% T for a + 10 diopter lens (thinnest) and a +27.0 diopter lens (thickest) are shown in Figure 1.

Haptics

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

Directions for Use

1. Prior to implanting, examine the lens package for IOL type, power, proper configuration and expiration date.
2. Open the peel pouch and remove the lens in a sterile environment.
3. Examine the lens thoroughly to ensure particles have not become attached to it, and examine the lens optical surfaces for other defects.
4. If desired, the lens may be soaked or rinsed in sterile balanced salt solution until ready for implantation.
5. The UNFOLDER™ Sapphire Series Implantation System, designed exclusively for use with the SENSAR™ IOL, should be used to insert the SENSAR™ Posterior Chamber Lens in the folded state. Refer to the specific instructions provided with The UNFOLDER™ Sapphire 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.
6. 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.
7. The IOL should not be kept in the folded condition for longer than 5 minutes in The UNFOLDER™ Sapphire Series cartridge, or for longer than 1 minute in insertion forceps.
8. Average unfolding times for the SENSAR™ Posterior Chamber Lens are 3-5 seconds at 35°C and 16-24 seconds at 30°C.

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

Lens Power Calculations

The physician should determine preoperatively the power of the lens to be implanted. Lens power calculation methods are described in the following references:

1. Hoffer, K.J. The Hoffer Q formula: a comparison of theoretic and regression formulas. **Journal of Cataract and Refractive Surgery**. 1993; 19:700-712; *ERRATA*. 1994; 20:677.
2. Holladay, J.T., Musgrove K.H., Prager, T.C., Lewis, J.W., Chandler, T.Y., and Ruiz, R.S. A three-part system for refining intraocular lens power calculations. **Journal of Cataract and Refractive Surgery**. 1988; 14:17-24.
3. Retzlaff, J.A., Sanders, D.R., and Kraff, M.C. Development of the SRK/T intraocular lens implant power calculation formula. **Journal of Cataract and Refractive Surgery**. 1990; 16:333-340; *ERRATA*. 1990; 16:528.

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

Patient Registration Section

Each patient who receives a SENSAR™ Posterior Chamber Lens must be registered with Allergan at the time of lens implantation.

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

An Implant Identification 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 events 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 should be reported to Allergan at (800) 366-6554 (U.S.A). This information is being requested from all implant surgeons in order to document potential long-term effects of intraocular lens implantation.

How Supplied

SENSAR™ Posterior Chamber Lenses are supplied sterile in a lens case within a double aseptic transfer peel pouch. The double aseptic transfer peel pouch is sterilized with ethylene oxide and should be opened only under sterile conditions. The pouch and product labels are enclosed in a shelf pack. The external surfaces of the outer pouch are not sterile.

Expiration Date

The expiration date on the lens package is the sterility expiration date. This lens should not be implanted after the indicated sterility expiration date.

Return/Exchange Policy

Please contact your local Allergan office regarding lens return or exchange.

Bibliography

Alzner E. Mistlberger, and Grabner G. One year results following implantation of soft acrylic lenses (IOPTEx ACR360). *Spectrum der Augen*. 1996; 10:164-166.

Sanchez E., Artaria L. Evaluation of the first 50 ACR360 acrylic intraocular lens implantation. *J Cataract Refract Surg*. 1996; 22: 1373-1378.

TABLE 1
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
- Pupillary Block	0	0.0	-	-	0.3	-
- Raised IOP Requiring Treatment	-	-	0	0.0	-	0.5
- Cyclitic 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**	35	9.2%	14	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 (IOL Replacement)	1	0.3	-	-	2.0	-

* One subject had both endophthalmitis and hypopyon

† Cumulative

†† Persistent

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

** Includes 2 and 3 year reports of tissue ongrowth on the anterior lens surface through July 15, 1999. Adverse effect on these subject's vision was not reported by the investigator. Tissue ongrowth has been previously reported in the literature on other IOL material types.

TABLE 2

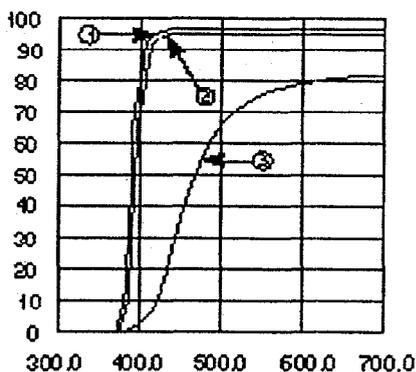
BEST CORRECTED DISTANCE VISUAL ACUITY AT ONE YEAR
ALL BEST CASE SUBJECTS* (N=274)

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.

Figure 1
Light Transmittance



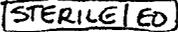
LEGEND:

- Curve 1: Spectral Transmittance curve of a typical 10 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 (10-30 diopter) made with this material.

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

Symbol/Explanation:

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

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