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 N	CUMULATIVE %	PERSISTENT AT ONE YEAR N	PERSISTENT AT ONE YEAR %	FDA GRID CUM† %	FDA GRID 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

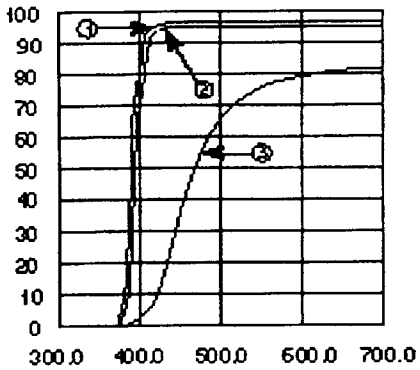
BEST CORRECTED DISTANCE VISUAL ACUITY AT ONE YEAR
ALL BEST CASE SUBJECTS* (N=274†)

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

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