MBI
MILLENNIUM
Biomedical Inc.

PreciSAL™

SAL 300A, SAL 300AC
SAL 302A, SAL 302AC

CAUTION: Federal (USA) law restricts this medical device to be sold by prescription or order of a physician only.

MADE IN USA

DEVICE DESCRIPTION

The Millennium Biomedical Soft Hydrophobic Acrylic intraocular lenses (SAL) are foldable posterior chamber, UV absorbing (Clear) or UV+blue-light filtering (Yellow) optical implant lenses used for the replacement of the human crystalline lens in the visual correction of aphakia in adult patients. The yellow SAL also contains MBI's proprietary blue light filtering chromophore that filters light in a manner that approximates a young human crystalline lens in the 400-475 nm blue light wavelength range (see Figure 2).

MODELS MANUFACTURED AT MBI

Model	Three Piece	One Piece	Aspheric	Yellow	Clear
SAL 300A	X		X	X	
SAL 300AC	X		X		X
SAL 302A		X	X	X	
SAL 302AC		X	X		X

All models are manufactured at the following diopter power range: 0 to +10 D in 1.0 diopter increments, and +10.0 to +30.0 diopters in 0.5 diopter increments, and +30.0 to +34.0 D in 1.0 diopter increments. Refractive index of the material is 1.50.

The Models 300s are three-piece acrylic lenses with square edge, blue PMMA modified-C haptics, with a nominal haptic angle of 10°, a 6.0 mm biconvex optic, and an overall length of 13.0 mm (see Figure 1A).

The Models 302s are one-piece acrylic lens with square edge, with planar modified C-shaped acrylic haptics, a 6.0 mm biconvex optic, and an overall length of 13.0 mm (see Figure 1B).

The product is sterilized by ethylene oxide (EO).

The device is supplied sterile and is for single use only. It is intended to be permanently implanted in the patient's eye in the capsular bag using the surgeon's preferred surgical technique via the recommended injector. The materials that will come into contact with the patient during the surgery and implantation are the soft hydrophobic acrylic intraocular lens, viscoelastic material and injector.

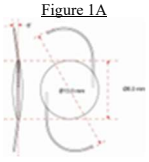
The lifetime of the device in patient's eye is permanent for long term use. The device is intended to be used by a trained ophthalmologist and requires no special training.

The device does not contain or incorporate a medicinal substance, including a human blood or plasma derivative; or tissues or cells, or their derivatives, of human origin; or tissues or cells of animal origin, or their derivatives. No animal tissue or human blood derivatives are used in its manufacture. The device does not contain substances to be absorbed by or dispersed in the human body. In addition, the device does not contain latex.

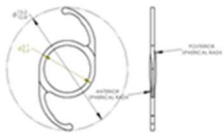
The expected clinical benefit of the device is to achieve visual correction of aphakia in adult patients upon implantation of the PreciSAL intraocular lens.

PHYSICAL CHARACTERISTICS

Three – piece
Figure 1A



One – piece
Figure 1B

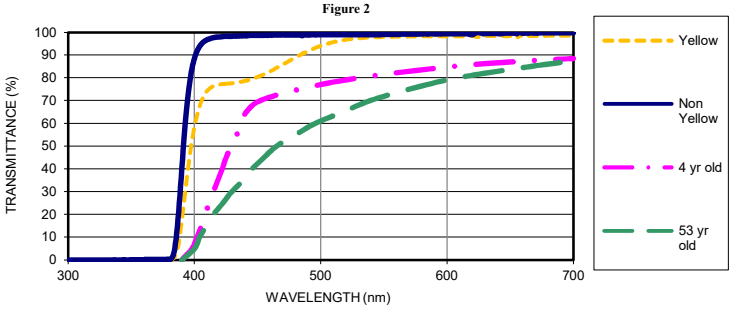


Average Transmittance Comparison for 20.0 D IOL, % (measured in water)

Model	400 nm	425 nm	450 nm	475 nm	UV Cutoff at 10%T
300AC/302AC	87	98	98	98	386 nm
300A/302A	65	82	84	90	388 nm

SPECTRAL TRANSMITTANCE CURVE

Figure 2



NOTE:
• Measurements were direct transmittance using a 6 mm aperture and a disc of thickness equivalent to the optic center of a 20.0 D lens.
• Human lens data from Boettner and Wolter, Transmission of the Ocular Media, Investigative Ophthalmology. 1962; 1:776-783.

MODE OF ACTION

The MBI SAL aspheric posterior chamber intraocular lenses are intended to be positioned in the posterior chamber of the eye, replacing the natural crystalline lens. This position allows the lens to function as a refractive medium in the visual correction of aphakia. The effectiveness of these lenses in reducing the incidence of retinal disorders has not been established.

INTENDED PURPOSE

The MBI SAL posterior chamber intraocular lenses are indicated for the replacement of the human lens to achieve visual correction of aphakia in adult patients when extracapsular cataract extraction or phacoemulsification is performed. These lenses are intended for placement in the capsular bag. The device is not applicable for children and pregnant woman until after delivery.

PRECAUTIONS

1. Do not resterilize the lens by any method.
2. Do not reuse the lens. The lens is for single use only. Re-use of the lens may cause re- or cross-infection leading to patient infection or lens explant.
3. Do not transport the lens at a temperature greater than 45°C (113°F). Store the lens at 27°C (81°F) or below.
4. Use only sterile intraocular irrigating solutions (such as BSS® or BSS PLUS®) to rinse or soak lenses.
5. Handle lenses carefully to avoid damage to lens surface or haptics.
6. Do not attempt to reshape haptics in any way.
7. A high level of surgical skill is required for intraocular lens implantation. The surgeon should have observed and/or assisted in numerous implantations and successfully completed one or more courses on intraocular lens implantation before attempting to implant intraocular lens.

CONTRAINDICATIONS

Pregnant women and patients with any of the following conditions may not be suitable candidates for an intraocular lens because the lens may exacerbate an existing condition, may interfere with diagnosis or treatment of a condition, or may pose an unreasonable risk to the patient's eyesight. Careful preoperative evaluation and sound clinical judgment should be used by the surgeon to decide the benefit/risk ration before implanting a lens in a patient with one or more of the following conditions.

Before Surgery:

13. Choroidal hemorrhage
14. Concomitant severe eye disease
15. Extremely shallow anterior chamber
16. Microphthalmos
17. Non-age-related cataract
18. Proliferative diabetic retinopathy (severe)
19. Severe corneal dystrophy
20. Severe optic nerve atrophy
21. Irregular corneal astigmatism
22. Medically uncontrolled glaucoma
23. Chronic severe uveitis
24. Diabetic retinopathy
25. Clinically significant macular/RPE changes

During Surgery:

1. Excessive vitreous loss
2. Capsulotomy by any technique other than a circular tear
3. The presence of radial tears known or suspected at the time of surgery
4. Situation in which the integrity of the circular tear cannot be confirmed by direct visualization
5. Cataract extraction by techniques other than phacoemulsification or liquefaction
6. Situation where the need for a large capsulotomy can be anticipated (e.g., diabetics, retinal detachment in the fellow eye, peripheral retinal pathology, etc.)
7. Posterior capsular rupture (preventing fixation of IOL)
8. Zonular damage (Preventing fixation of IOL)
9. Uncontrollable positive pressure
10. Significant anterior chamber hyphema

WARNINGS

The lens should not be implanted in the following conditions:

1. The posterior capsule is ruptured or if a primary capsulotomy is to be performed.
2. The peel pouch is found to be damaged or opened.
3. Suspected microbial infection.
4. Recurrent severe anterior or posterior segment inflammation or uveitis.
5. Patients in whom the intraocular lens may affect the ability to observe, diagnose, or treat posterior segment disease.
6. Surgical difficulties at the time of cataract extraction might increase the potential for complications (e.g. persistent bleeding, significant iris damage, uncontrolled positive pressure, or significant vitreous prolapse or loss).
7. A distorted eye due to previous trauma or developmental defect in which appropriate support of the IOL is not possible.
8. Circumstances that would result in damage to the endothelium during implantation.
9. Children and pregnant women are not suitable for intraocular lenses.

COMPLICATIONS

The following lists the complications which have been associated with the implantation of intraocular lenses (this list is not intended to be all-inclusive):

Cumulative Adverse Events:

1. Hyphema
2. Hypopyon
3. Lens Dislocation
4. Cystoid Macular Edema
5. Pupillary Block
6. Retinal Detachment
7. Intraocular Infection
8. Secondary surgical intervention (excluding retinal detachment and posterior capsulotomy), including, but not limited to, the following:
   a. Iridectomy for papillary block
   b. Vitreous aspiration for papillary block
   c. Repositioning of lens

d. IOL removal for inflammation
e. IOL replacement

Persistent Adverse Events:
1. Corneal Stroma Edema
2. Cystoid Macular Edema
3. Iritis
4. Raised IOP requiring treatment

NOTE: Customers in the EU shall report any serious incident associated with the device to their national authority, distributor, and the manufacturer.

NOTE: For patient information, please visit www.mbius.com.

SUGGESTED A-CONSTANT

The suggested A-constant listed on the outer box label is presented as a guideline and is a starting point for implant power calculations. It is recommended that you develop your own constant appropriate for you based on clinical experience with the particular lens models, surgical techniques, measuring equipment, and postoperative results. If additional information on lens power calculation is needed, please contact your local distributors.

DIRECTIONS FOR USE

1. Examine the label on the lens box for proper lens model, diopter power and expiration date.
2. Verify that the diopter power of the lens matches that on the patient chart or record.
3. Open the lens box to remove the pouched lens and verify the lens case information (e.g. power, model, serial numbers and expiration date) is consistent with the information on the outer box.
4. Ensure that the Tyvek pouch is not damaged, and the seal is not broken.
5. To remove the lens, open the undamaged peel pouch and transfer the case to a sterile environment. Carefully open the case to expose the lens. When removing the lens from the case, DO NOT grasp the optic area with forceps. Prior to the actual folding process, the lens should be handled by the haptic portion only.
6. To minimize the occurrence of marks on the lens due to folding, all instruments should be scrupulously clean. Any forceps used for lens handling must have round edges and smooth surfaces.
7. Handle the lenses carefully to avoid damage to lens surfaces or haptics. DO NOT attempt to reshape haptics in any way.
8. There are various surgical procedures which can be utilized, and the surgeon should select a procedure which is appropriate for the patient. Surgeons should verify that appropriate instrumentation is available prior to surgery.
9. MBI recommends using an Accuject™ 2.2-BL dual injector set, item code ADB2200 (Medicel AG, Switzerland) for delivery of SAL 302A and 302AC in the capsular bag. Follow the instructions for use provided with the injector. The injector is supplied sterile and for single use only, which can be purchased from Medicel AG.

Additional Note:
- DO NOT RESTERILIZE. Re-sterilize the lens may damage the lens.
- DO NOT REUSE. This device is for single use only. Re-use of the lens and/or inject may cause re- or cross-infection leading to ocular infection or lens explanted.
- DISPOSAL. The surgical device may be contaminated after use with potentially infectious agents of human origin. Due to this fact, proper disposal must be ensured.

CALCULATION OF LENS POWER

Preoperative calculation of required lens power for these posterior chamber intraocular lenses should be determined by the surgeon's experience, preference, and intended lens placement. Lens power calculation methods are described in the following references:

Hoffer, K.J. The Hoffer Q formula: A comparison of theoretic and regression formulas. J. Cataract Refract. Surg. 19:700-712, 1993.
Holladay, J.T., et al. A three-part system for refining intraocular lens power calculations. J. Cataract Refract. Surg. 14:17-24, 1988.
Holladay, J.T., et al. Standardizing constants for ultrasonic biometry, keratometry, and IOL power calculations. J. Cataract Refract.Surg. 23:1356-1370, 1997.
Retzlaff, J.A., Sanders, D.R., and Kraff, M. Lens Implant Power Calculation, 3rd ed. Slack, Inc., Thorofare, N.J., 1990

REPORTING

All side effects, regardless of their severity and whether or not they can be attributed to the implant or not, should be reported to MBI. To do so, contact your local distributors. Any potentially fatal incident or serious adverse events must be reported immediately to MBI (no later than 48 hours), by telephone or by contacting your local distributors.

HOW SUPPLIED

The Soft Hydrophobic Acrylic Intraocular Lenses are supplied dry, in a lens case, packaged in a Tyvek peel pouch and terminally sterilized by ethylene oxide. The Lenses must be opened only under aseptic conditions (See DIRECTIONS FOR USE above).

EXPIRATION DATE

The packaged Soft Hydrophobic Acrylic Intraocular Lens is sterile unless the peel pouch is damaged or opened. There is a sterility expiration date clearly indicated on the lens case and outer box label. The Soft Hydrophobic Acrylic Intraocular Lens should not be used after the expiration date.

SYMBOLS USED IN LABELING

SYMBOL	ENGLISH	SYMBOL	ENGLISH
	Manufacturer		Do not reuse
	Authorized representative in the European Community/ European Union		Consult instructions for use or consult electronic instructions for use
	Sterilized using ethylene oxide in single sterile barrier system		Do not use if package is damaged and consult instructions for use
	Use-by date YYYY-MM		CE-certified
	Upper limit of temperature for transportation	SN	Serial number
	Keep away from sunlight		Do not resterilize
	Keep dry	D (dpt.)	Diopter (power, spherical)
$Ø_B$	Body diameter (optic diameter)	$Ø_T$	Overall diameter (overall length)
CH REP	Authorized representative in Switzerland	UDI	Unique device identifier
STERILE	Sterile		Single sterile barrier system

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