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 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.

MODELS MANUFACTURED AT MBI

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

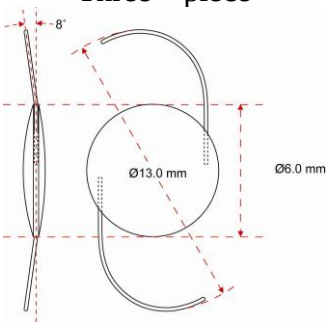
All models are manufactured at the following diopter power range: 0 to +10 D in 1.0 diopter increments, and +10.0 to +30.0 diopters in 0.5 diopter increments, and +30.0 to +34.0 D in 1.0 diopter increments. Refractive index of the material is 1.5.

The Models 300s are three-piece acrylic lenses with square edge, blue PMMA modified-C haptics, with a nominal haptic angle of 8°, a 6.0 mm biconvex optic, and an overall length of 13.0 mm.

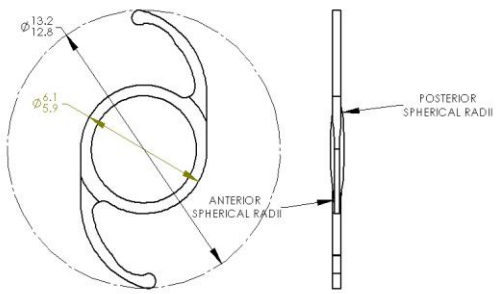
The Models 302s are one-piece acrylic lens with square edge, with plano C-shaped haptics, a 6.0 mm biconvex optic, and an overall length of 13.0 mm.

PHYSICAL CHARACTERISTICS

Three – piece

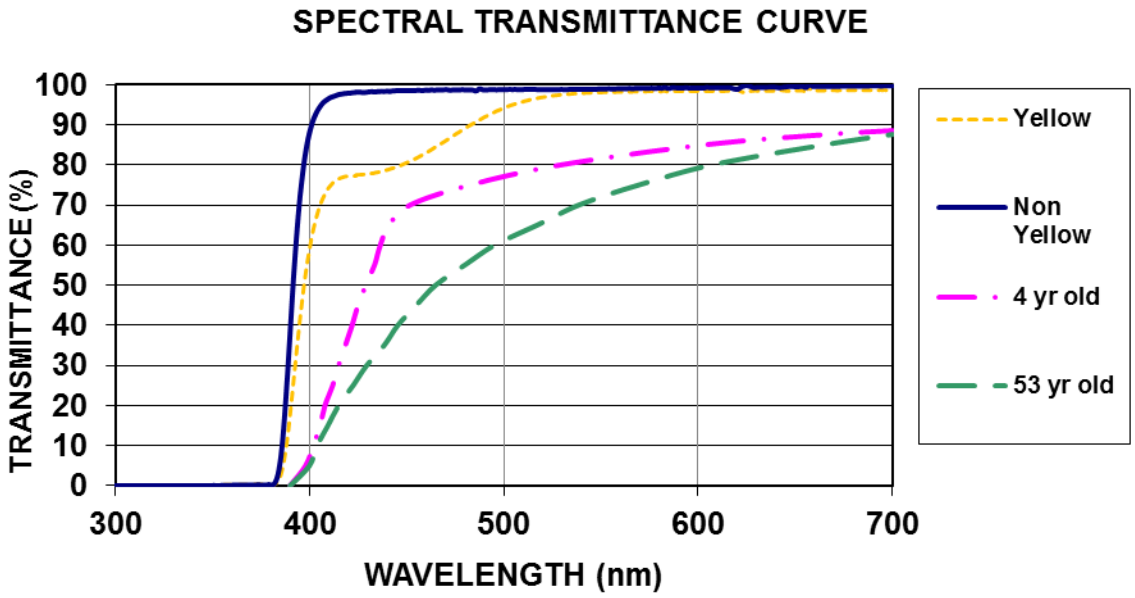


One – piece



TRANSMITTANCE COMPARISON

Material	Characteristics	UV Cutoff at 10% T
Yellow	UV-Absorber + blue light filter	388nm
Non-Yellow (Clear)	UV-Absorber	386 nm



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.

INDICATIONS

The MBI SAL posterior chamber intraocular lenses are indicated for the placement 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.

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 store the lens at a temperature greater than 45ºC (113ºF).
4. Use only sterile intraocular irrigating solutions (such as BSS® or BSS PLUS®) to rinse 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

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.

1. Choroidal hemorrhage
2. Concomitant severe eye disease
3. Excessive vitreous loss
4. Extremely shallow anterior chamber
5. Microphthalmos
6. Non-age-related cataract
7. Posterior capsular rupture (preventing fixation of IOL)
8. Severe corneal dystrophy
9. Severe optic atrophy
10. Uncontrollable positive pressure
11. Zonular separation (Preventing fixation of IOL)
12. Color vision deficiencies
13. Glaucoma
14. Chronic uveitis
15. Diabetic retinopathy
16. Clinically significant macular/RPE changes

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 that 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 under the age of 2 years 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

DIRECTION 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 number and expiration date) is consistent with the information on the outer box.
4. To remove the lens, open the undamaged peel pouch and transfer the case to a sterile environment. Carefully unscrew the case cap to expose the lens. If the lens appears to have damage, particulates or deformation after inspection, use another lens.
5. To minimize the occurrence of marks on the lens due to folding, all instrument should be scrupulously clean and sterile. Any forceps used for lens handling must have round edges and smooth surfaces.
6. When removing the lens from the case, DO NOT grasp the optic area with forceps. Prior to actual folding process, the lens should be handled by the haptic portion only. Handle the lenses carefully to avoid damage to lens surfaces or haptics. DO NOT attempt to reshape haptics in any way.
7. 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.
8. 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 instruction 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 of the lens may damage the lens.
- DO NOT REUSE. This device is for single use only. Re-use of the lens and/or inject or may cause re- or cross-infection leading to ocular infection or lens explanted.

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 outside box. The Soft Hydrophobic Acrylic Intraocular Lens should not be used after the expiration date.

SYMBOLS USED IN LABELLING

SYMBOL	ENGLISH	SYMBOL	ENGLISH
	Manufacturer		Do not reuse
	Authorized representative in the European Community		Consult instructions for use
	Sterilized using ethylene oxide		Do not use if package is damaged
	Use by YYYY-MM		CE-certified
	Temperature limit	SN	Serial number
	Keep away from sunlight		Do not resterilize
	Keep dry	**D (dpt.)**	Diopter (power, spherical)

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EC REP

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