

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 UVE Soft Hydrophobic Acrylic intraocular lenses (UVE-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 UVE-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**

<b>Model</b>	<b>Three Piece</b>	<b>One Piece</b>	<b>Aspheric</b>	<b>Yellow</b>	<b>Non-Yellow</b>
SAL 400A	X		X	X	
SAL 400AC	X		X		X
SAL 402A		X	X	X	
SAL 402AC		X	X		X

All models are manufactured at the following diopter power range: 0 to +10.0 D in 1.0 diopter increments, +10.0 to +30.0 D 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 400s 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 402s are one-piece acrylic lens with square edge, with planar modified C-shaped haptics, a 6.0 mm biconvex optic, and an overall length of 13.0 mm.

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 tip.

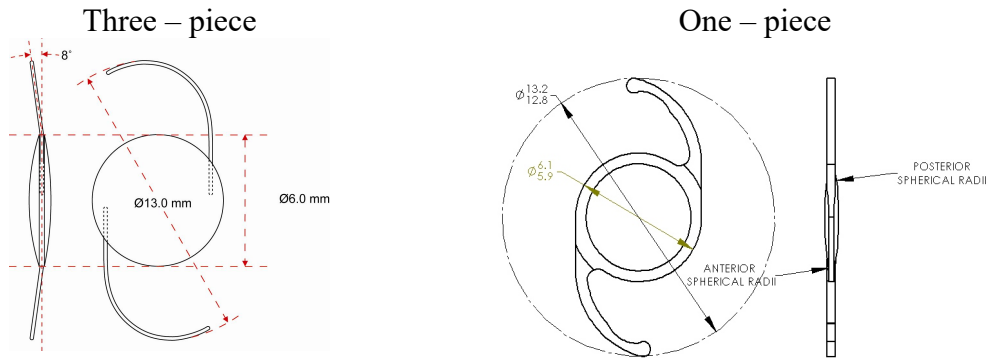
The lifetime of the device in patient's eye is permanent for long term use. The device is intended to be used by a trained ophthalmologist and requires no special training.

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.

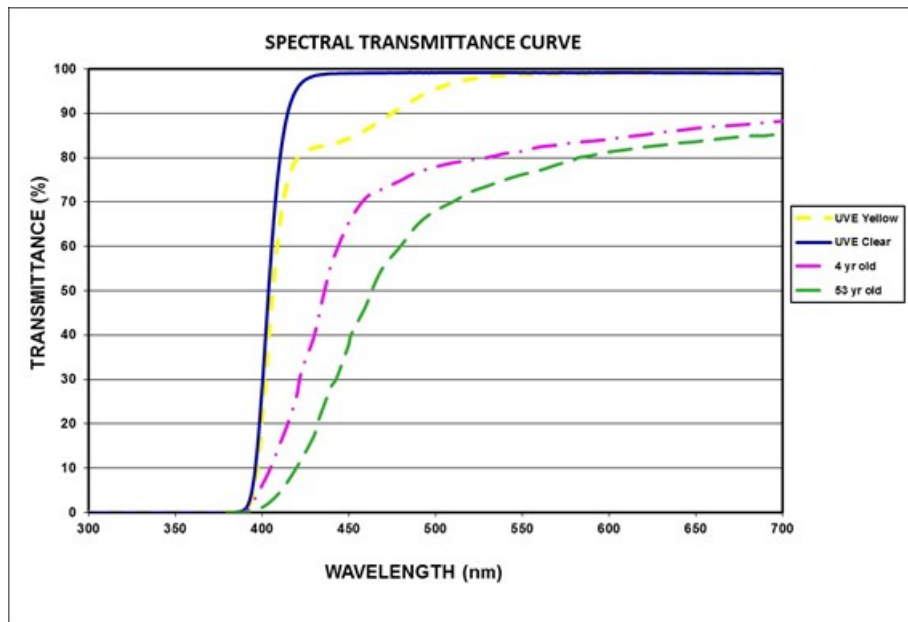
The expected clinical benefit of the device is to achieve visual correction of aphakia in adult patients upon implantation of the PreciSAL UVE intraocular lens.

### PHYSICAL CHARACTERISTICS



**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
400AC/402AC	25	98	98	98	396 nm
400A/402A	20	80	84	90	397 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 UVE-SAL Monofocal 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/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:**

1. Choroidal hemorrhage
2. Concomitant severe eye disease
3. Extremely shallow anterior chamber
4. Microphthalmos
5. Non-age-related cataract
6. Proliferative diabetic retinopathy (severe)
7. Severe corneal dystrophy
8. Severe optic nerve atrophy
9. Irregular corneal astigmatism
10. Medically uncontrolled glaucoma
11. Chronic sever uveitis
12. Diabetic retinopathy

### 13. 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 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 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 pupillary block
  - b) Vitreous aspiration for pupillary block
  - c) Repositioning of lens
  - d) IOL removal for inflammation
  - e) IOL replacement
  - f) Wound leak repair

#### 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](http://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.

#### **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 and serial numbers) 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 402A and 402AC 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:

- There are various surgical procedures which can be utilized, and the surgeon should select a procedure which is appropriate for the patient.
- 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 label and outer box label. 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/ 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		Serial number

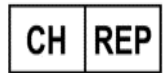
	Keep away from sunlight		Do not resterilize
	Keep dry	<b>D (dpt.)</b>	Diopter (power, spherical)
	Body diameter (optic diameter)		Overall diameter (overall length)
<b>CH REP</b>	Authorized representative in Switzerland	<b>UDI</b>	Unique device identifier
<b>STERILE</b>	Sterile	<b>MD</b>	Medical Device



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