MBI
MILLENNIUM
Biomedical Inc.

PreciSAL™ Preloaded Lens System with Dual Injector

SAL PS302A, SAL PS302AC
SAL PST302A

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

MADE IN USA

DEVICE DESCRIPTION

The Millennium Biomedical PreciSAL™ Preloaded Soft Hydrophobic Acrylic Intraocular Lens System with Accuject™ dual 1.8-BL injector is a fully preloaded lens implantation delivery system at an incision of 2.2 mm with clear (UV filtering) and yellow (UV+blue light filtering) monofocal (302A and 302AC) or toric (T302A) IOL for a safe, reliable and efficient minimal invasive surgery.

The MBI Preloaded Soft Hydrophobic Acrylic intraocular lenses (PSAL) are foldable one-piece posterior chamber, UV or UV+blue light filtering aspheric optical implant lenses with a square edge used for the replacement of the human crystalline lens in the visual correction (monofocal and toric) of aphakia and pre-existing corneal astigmatism (toric only) in adult patients with and without presbyopia. 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.

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 preloaded lens delivery system. 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 the injector tip.

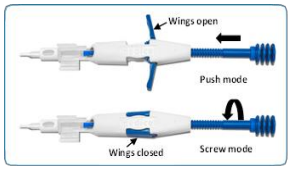
The lifetime of the device in patient's eye is permanent for long term use. The device is intended to be used by a trained ophthalmologist and requires no special training.

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.

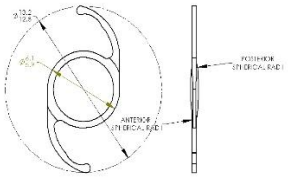
The expected clinical benefit of the device is to achieve visual correction of aphakia in adult patients upon implantation of the PreciSAL intraocular lens. The benefit of visual restoration and correction outweighs the surgical risks.

Physical Characteristics of PreciSAL Lens Delivery Systems with Dual Injector
(all dimensions in mm)

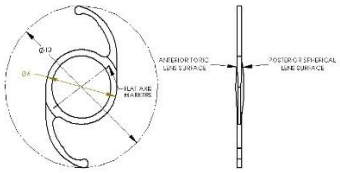
Dual Injector



Monofocal



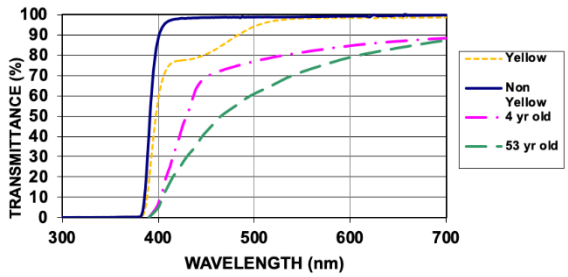
Toric



Physical Characteristics of PreciSAL Preloaded IOL Delivery System

Characteristics	Model		
	SAL PS302A	SAL PS302AC	SAL PST302A
	Preloaded Monofocal IOL		Preloaded Toric IOL
Optic Type	Biconvex Aspheric Optic		Biconvex Toric Aspheric Optic
Optic/Haptic Material	Ultraviolet and blue light filtering Acrylic	Ultraviolet filtering Acrylic	Ultraviolet and blue light filtering Acrylic
IOL Powers (diopter	+0.0 to 34.0		+5.0 to +34.0
IOL Cylinder Power (diopter)	0		+1.0 to +6.0
Index of Refraction	1.50		
Optic Edge	Square		
Optic Diameter (mm)	6.0		
Overall Length (mm)	13.0		
A-Constant	118.7		
Haptic Angle	Planar		
Haptic Configuration	Modified C, integral with optic		
Accuject™ dual Injector	~2.2 mm incision, screw or push mode		

SPECTRAL TRANSMITTANCE CURVE



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.

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
PS302AC	87	98	98	98	386 nm
PS302A	65	82	84	90	388 nm
PST302A	65	82	84	90	388 nm

MODE OF ACTION

The MBI PreciSAL preloaded delivery system provides a sterile, controlled and touch-free method of delivering the lens into the eye. The lens is preloaded and preassembled in the delivery system. This reduces the number of steps required to prepare the IOL for insertion into the eye. The lenses are intended to be delivered in the preloaded injector and 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 (monofocal and toric) and pre-existing corneal astigmatism (toric only) of aphakia in adult patients, with and without presbyopia. The toric IOLs have a biconvex toric aspheric optic with cylinder axis marks to denote the flat meridian (plus cylinder axis). Alignment of the toric IOL cylinder axis marks with the pre-operative steep corneal meridian allows the lens to correct astigmatism.

INTENDED PURPOSE

The PreciSAL preloaded monofocal and toric posterior chamber intraocular lenses are indicated for the replacement of the human lens to achieve visual correction (monofocal and toric) and pre-existing corneal astigmatism (toric) of aphakia in adult patients when extracapsular cataract extraction or phacoemulsification is performed. The PreciSAL preloaded toric lenses provide patients with improved uncorrected distance vision, reduction of residual refractive cylinder, and increased spectacle independence for distance vision following removal of a cataractous lens. These lenses are intended for placement in the capsular bag. The device is not applicable for children and pregnant women until after delivery.

WARNINGS

Physicians considering lens implantation should weigh the potential risk/benefit ratio for any circumstances that could increase complications or impact patient outcomes.
This lens should not be implanted under the following conditions:

1. If the posterior capsule is ruptured, if the zonules are damaged, or if a primary posterior capsulotomy is planned.
2. The Tyvek cover of the blister pack 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 development 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.

PRECAUTIONS

1. Do not resterilize the lens by any method.
2. Do not transport the lens at a temperature greater than 45°C (113°F). Store the lens at 27°C (81°F) or below.
3. Do not re-use the device. The device is for single use only. Re-use of the lens and/or injector may cause re- or cross-infection leading to patient infection or lens explanted.
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.
8. For PreciSAL Preloaded Toric Lenses:
   a. Accurate keratometry and biometry in addition to the use of the MBI's Toric Calculator (www.mbius.com) are recommended to achieve optimal visual outcome.
   b. Rotation of PreciSAL Toric IOLs away from their intended axis can reduce their astigmatic correction. Misalignment greater than 30° may increase postoperative refractive cylinder. If necessary, the lens repositioning should occur as early as possible prior to lens encapsulation. Some clinical cases suggest encapsulation is complete within four weeks of implantation.
   c. Carefully remove all viscoelastic from both the anterior and posterior sides of the lens. Residual viscoelastic may allow the lens to rotate causing misalignment of the PreciSAL Toric IOL with the intended axis of placement.
9. Use the Preloaded Delivery System at Operating Room temperatures between 18°C (64°F) and 23°C (73°F).

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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 severe 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

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. Corneal endothelial damage
2. Infection (endophthalmitis)
3. Hyphema
4. Hypopyon
5. Lens Dislocation
6. Cystoid macular edema
7. Corneal edema
8. Pupillary block
9. Cyclitic membrane
10. Iris prolapse
11. Retinal detachment
12. Vitritis
13. Transient or persistent glaucoma
14. Secondary surgical intervention (excluding retinal detachment and posterior capsulotomy), include, 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
    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.

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.

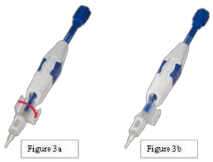
DIRECTION FOR USE

1. Examine the label on the unopened outer box for proper lens model, diopter power and expiration date. Verify the diopter power matches that of the patient.
2. Open the outer box to remove the sealed blister pack containing the intraocular lens in the preloaded lens injector loading chamber and verify that the label information on the blister pack (e.g. power, model, serial number, and expiration date) is consistent with the information on the outer box.
3. Ensure that the blister pack is not damaged and the seal is not broken.
4. Grip the corner of blister pack, carefully peel open the Tyvek cover fully and transfer the device to a sterile environment. If the device appears to have damage, particulates or deformation after inspection, use another preloaded lens injectable system.
   NOTE: The preloaded lens delivery system with the dual injector is packaged with both wings or finger flanges in closed position. It is ready to inject the lens by screw-mode at this position.
5. Apply a small amount of the OVD only under the lens by placing the OVD cannula alongside the plunger under the loading chamber cover under the lens. (Figure 1). High viscosity or high concentration of OVD (Healon GV, Provisc, Viscoat, or similar OVD) is not recommended.
6. Apply a moderate amount of Balanced Salt Solution (BSS) through the cartridge tip until the BSS reaches behind the lens in the folding chamber (Figure 2) while holding the injector horizontally to avoid generation of air bubbles.
7. Insert Viscoelastic cannula into the cartridge tip filled with BSS and slowly inject viscoelastic in the tip (Figure 2). DO NOT close the mechanism until the surgeon is ready to inject the lens


Figure 1


Figure 2

8. IMPORTANT: **ONL when the surgeon is ready to inject the lens**, close the preloading chamber flap (the IOL automatically folds in chamber, Figure 3a) until the click-lock mechanism engages. (Figure 3b).



9. Immediately after closing the loading chamber flap push the plunger smoothly until middle of the barrel (Figure 4). Pass the injector to the surgeon.

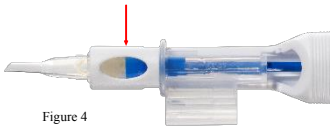


Figure 4

10. For screw style injection (with both wings or finger flange closed into the injector body), push the plunger until it stops to engage the screw mechanism. Rotate the injector clockwise 90° (Figure 5a). Insert the cartridge tip in the incision. Proceed to advance the plunger by turning screws clockwise **smoothly but continuously** until the lens is properly placed in the capsular bag.
    NOTE: Should the leading haptic start to rotate upon injection in the eye, rotate the injector slightly in the opposite direction to ensure correct lens placement in the capsular bag.
11. For push style injection, open both wings or finger flange from the injector body. Rotate the injector clockwise 90° (Figure 5b). Insert the cartridge tip in the incision. Proceed to push the plunger forward **smoothly but continuously** until the lens is properly placed in the capsular bag.
    NOTE: Should the leading haptic start to rotate upon injection in the eye, rotate the injector slightly in the opposite direction to ensure correct lens placement in the capsular bag.

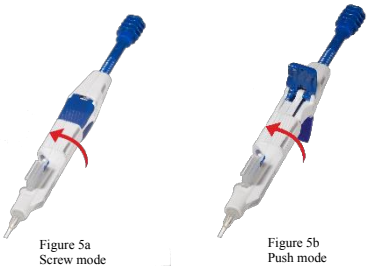


Figure 5a
Screw mode

Figure 5b
Push mode

12. Do not pause the plunger at the end of the cartridge tip position. The lens could be stuck inside the tip.

13. Observe the progress of the blue plunger **inject only until the distal end of the plunger reaches the proximal end of the bevel.** If the lens trailing haptic does not release from the tip, pull back the plunger slightly (~1 mm) then push forward to release the lens. DO NOT inject further to avoid the blue plunger squeezing out of the tip and expanding.

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Additional Notes:

- 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 delivery system may damage the lens.
- DO NOT REUSE this preloaded IOL lens delivery system. This device is for single use only. Re-use of the lens and/or injector may cause re- or cross-infection leading to patient 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 as biohazard material 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 MBI Preloaded Soft Hydrophobic Acrylic Intraocular Lenses are supplied dry, fully preloaded in an injector packaged in a blister pack sealed with a Tyvek peel cover and terminally sterilized by ethylene oxide. The preloaded lens system must be opened only under aseptic conditions (See DIRECTIONS FOR USE above).

EXPIRATION DATE

The packaged PreciSAL preloaded Soft Hydrophobic Acrylic Intraocular Lens is sterile unless the Tyvek cover seal is damaged or opened. There is a sterility expiration date clearly indicated on the blister pack and the outside box label. The Preloaded 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
EC REP	Authorized representative in the European Community		Consult instructions for use or consult electronic instructions for use
STERILE EO	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	CE-certified
40°C (113°F)	Upper limit of temperature for transportation	SN	Serial number
	Keep away from sunlight	2	Do not resterilize
	Keep dry	**D (dpt.)**	Diopter (power, soherical)
$Ø_B$	Body diameter (optic diameter)	$Ø_T$	Overall diameter (overall length)
CH REP	Authorized representative in Switzerland	UDI	Unique device identifier
STERILE	Sterile	CYL	Cylinder
	Dual injector		IOL
	Toric IOL	MD	Medical device

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