PreciSAL Intraocular Lens – Patient Information Leaflet

The Information in this document is provided to the patient receiving the implanted PreciSAL intraocular lens (IOL) manufactured by Millennium Biomedical, Inc. (California, USA). This document is designed to assist in understanding what the device is so that patients can ask relevant clinical questions from their healthcare team. It also helps to direct them in case where any device -related serious incidents need to be reported.

This leaflet relates to the list of PreciSAL IOLs in the Appendix attached.

Intended Purpose:

The PreciSAL IOL is indicated for the placement 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 lens is intended for placement in the capsular bag.

Intended Performance:

The IOL is designed to focus light entering your eye so that you may see clearly. The PreciSAL IOL is surgically positioned in the lens capsular bag within your eye. It replaces the function of the natural crystalline lens, which is removed prior to implanting the PreciSAL IOL. The expected lifetime of the device is permanent in patient's eye.

Device Description:

The PreciSAL IOLs are foldable posterior chamber, Clear (UV absorbing) or Yellow (UV+blue light filtering) soft hydrophobic acrylic optical lenses used for the replacement of the human crystalline lens in the visual correction of aphakia in adult patients. The device contains no animal tissue or human blood derivatives and no animal tissue or human blood derivatives are used in its manufacture. The device does not contain latex, medicinal substance or non-viable materials of animal origin. All IOLs are supplied sterile.

Undesirable Side Effects:

As a result of the surgery or associated anesthesia, it is possible that your vision could be made worse. After your eye heals, you may need to wear glasses in order to see clearly at different distances. It is possible that the capsular bag that holds the IOL may develop haze. You may need to have an additional laser treatment performed to treat this haze. It is also possible that the desired results of the surgery may not be obtained or may not last.

Potential risk during or following cataract surgery with implantation of an IOL may include but are not limited to:

- Persistent corneal stromal oedema- persistent build up of fluid in the cornea
- IOL dislocation
- Cystoid macular oedema - accumulation of 'cys-like' sacs of fluid in the macula, the centre of the retina
- Pupillary block – blockage of normal flow of fluid in the eye
- Hyphema – blood collecting inside the front of the eye
- Endophthalmitits (Inflammation of two or more adjacent coats of the eye)/Intraocular infection
- Hypopyon – A medical condition involving inflammatory cells in the eye
- Retinal detachment/tear
- Persistent inflammation of the iris
- Persistent raised intraocular pressure requiring treatment
- Acute corneal decompensation – temporary functional deterioration of the cornea
- Secondary intraocular surgical intervention – including implant repositioning, removal, replacement, Anterior chamber Tap (controlled drainage of fluid from the eye), performed later than one week after cataract surgery, or other surgical procedure
- Any other adverse incident that leads to permanent visual impairment or requires surgical or medical intervention to prevent permanent visual impairment

Warnings and Precautions:

1. Before the surgery, if you wear contact lenses, your healthcare team may ask you to stop wearing them before being tested for the IOL.
2. Before the surgery, inform your healthcare team if you have any health conditions that may affect your surgery or vision. Examples include high blood pressure, diabetes, and heart disease.
3. After the surgery, you may begin to see better within 1 to 2 days. Some are stable at 10 to 14 says. Some may take 4 to 6 weeks to recover from surgery. Improvements in vision are different for each person.
4. Please follow the directions from your healthcare team following implantation, in order to minimize the likelihood of IOL movement and infection.
5. You may experience unwanted visual symptoms such as glare and rings around lights at night. Image quality such as contrast may also vary between IOL models. Caution should be taken when driving at night or in poor visibility conditions.
6. Call your healthcare team immediately if you experience any itching, pain, flashing lights, "floaters", redness, severe headache, nausea/vomiting, light sensitivity, or watery eyes afer suregery.

Recommended Monitoring:

1. You will return home after the surgery. Your healthcare team will give you antibiotic eye drops and medicines to speed up healing and to prevent infection. Take all prescribed medicines and apply eye drops as instructed by your healthcare team.
2. You will be given a date and time for a follow-up visit. It is typically the next day. Your healthcare team will examine you several more times following your suregery. It may take you some time to get used to your new IOL.
3. Your IOL is designed to last your entire lifetime without the need for replacement. However, if you notice any pain, redness, discomfort, or if your vision deteriorates over time, you should contact your healthcare team to see how they can assist.

Reporting of Serious Incidents:

Any serious incident that occurred in relation to the device should be reported to Millennium Biomedical Customer Service by calling 1-909-621-7646 or via email to cs@mbius.com. It should also be reported to the Therapeutic Goods Administration. Their website is https://www.tga.gov.au/.

Australia Sponsor:
IQ Medical

Legal Manufacturer:
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Appendix: List of IOLs

IOL Model Number	IOL Material and Characteristics
SAL 300A	Soft acrylic with yellow dye and UV absorber IOL with blue PMMA haptics (Three-piece)
SAL 300AC	Soft acrylic with UV absorber IOL with blue PMMA haptics (Three-piece)
SAL 302A	Soft acrylic with yellow dye and UV absorber one-piece IOL
SAL 302AC	Soft acrylic with UV absorber one-piece IOL
SAL P302A	Soft acrylic with yellow dye and UV absorber preloaded monofocal IOL in Accuject™ Pro 2.2-1p Injector (≈2.4 mm incision)
SAL P302AC	Soft acrylic with UV absorber preloaded monofocal IOL in Accuject™ Pro 2.2-1p Injector (≈2.4 mm incision)
SAL PT302A	Soft acrylic with yellow dye and UV absorber preloaded toric IOL in Accuject™ Pro 2.2-1p Injector (≈2.4 mm incision)
SAL PS302A	Soft acrylic with yellow dye and UV absorber preloaded monofocal IOL in Accuject™ Dual 1.8-BL Injector (≈2.2 mm incision)
SAL PS302AC	Soft acrylic with UV absorber preloaded monofocal IOL in Accuject™ Dual 1.8-BL Injector (≈2.2 mm incision)
SAL PST302A	Soft acrylic with yellow dye and UV absorber preloaded toric IOL in Accuject™ Dual 1.8-BL Injector (≈2.2 mm incision)