Section: SSCP-PB-PT-01	Rev. No.: 03	Date: 29.06.2026

SUMMARY OF SAFETY & CLINICAL PERFORMANCE FOR PATIENTS
OPHTHALMIC FOLDABLE INTRAOCULAR LENS - HYDROPHOBIC (PRELOADED)

This Summary of Safety and Clinical Performance (SSCP) is intended to provide public access to an updated summary of the main aspects of the safety and clinical performance of the device. The information presented below is intended for patients or lay persons. A more extensive summary of its safety and clinical performance prepared for healthcare professionals is found in the first part of this document.

The SSCP is not intended to give general advice on the treatment of a medical condition. Please contact your healthcare professional in case you have questions about your medical condition or about the use of the device in your situation. This SSCP is not intended to replace an Implant card or the Instructions For Use to provide information on the safe use of the device.

The following information is intended for patient.

1.0 Device identification and general information

Device Name : Ophthalmic Foldable Intraocular Lens - Hydrophobic (Preloaded)

Brand / Trade Name(s) : Supraphob, Spheriphob, Supraphob BBY, Maxim IOL, Supraphob Toric, Swiss Phob, Supraphob Infocus & Supraphob Regen.

Manufacturer's Name & Address

Name:	**Appasamy Ocular Devices (P) Ltd.,**
Address:	R.S.No. 9/ 1, 2 & 3, NH-45A Villupuram Main Road, Vadamangalam, Puducherry-605102 India.
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Basic UDI-DI

Sterile Ophthalmic Intra Ocular Lens - Foldable Hydrophobic (Preloaded) - 89041255PHYDROPHOBICMD

Year of first certificate (CE) of the subject device: 27/10/2017

2.0 Intended use of the device

- **Intended Purpose**

IOL can be defined as 'Optical Implants for the replacement of the human crystalline lens in the visual correction of aphakia (cataract)'. Intraocular lens functions as a refracting medium to replace the natural lens in the correction of cataract. The IOL can be placed in Posterior Chamber.

- **Medical Indications**

- Monocular Cataract
- Mature Cataract
- Congenital cataract
- Binocular Cataract
- Refractive lens (exchange) reflex
- Immature cataract
- Traumatic cataract

- **Target Population(s)**

Above age of one year (Male or Female)

- **Intended User**

Ophthalmic surgeon

- **Caution**

  - Chronic Severe Uveitis
  - Epithelial Dystrophy
  - Proliferative Diabetic Retinopathy
  - Choroidal Haemorrhage
  - Microphthalmos
  - Concommitant Severe Eye Disease
  - Non-age related cataract
  - Severe or uncontrolled Glaucoma
  - Rubella associated cataract
  - Massive Vitreous Loss
  - Anirida
  - Sever corneal dystrophy
  - Eyes with fixed dilated pupils or persistent miotic pupils

3.0 Device Description

- **Device description and material/substances in contact with patient tissues**

Foldable Intra Ocular Lens a medical device consisting of optic and haptic components, intended for surgical implantation inside the posterior chamber of the eye. IOL replaces the natural crystalline lens of the eye to rehabilitate the cataract patients. A Single Piece IOL is a device in which the haptic is continuous with the Phobic optic and fabricated from the same material

Materials that come in contact with patient:

The Ophthalmic Foldable Intraocular Lens - Hydrophobic (Preloaded) is made up of Hydrophobic Soft Acrylic (Polymer).

- **Information about medicinal substances in the device, if any**

Ophthalmic Foldable Intraocular Lens - Hydrophobic (Preloaded) does not incorporate medicinal substances. Hence this declaration is not applicable.

- **Description of how the device is achieving its intended mode of action**

Intra Ocular Lens (IOL) functions as a refracting medium to replace the natural lens in the correction of aphakia. The IOL can be placed in Posterior Chamber.

4.0 Risks and warnings

Contact your healthcare professional if you believe that you are experiencing side-effects related to the device or its use or if you are concerned about risks. This document is not intended to replace a consultation with your healthcare professional if needed.

- **How potential risks have been controlled or managed.**

We follow a strong quality management system, as required by ISO 13485:2016, to ensure our lenses are consistently safe and reliable. Throughout the entire manufacturing process, we regularly check and monitor the device to make sure it meets all quality and safety requirements.

To reduce possible risks, several safety measures are built into both the design of the lens and the manufacturing process. These include:

- Designing the lens and the production steps to be as safe as possible
- Adding protective safety measures where needed
- Providing clear safety information for surgeons and users

After these safety steps are applied and checked, the remaining risks (called "residual risks") are very low and are considered acceptable. When these small risks are compared with the benefits of the lens—such as improved vision and better quality of life—the benefits are greater.

As part of the safety review, we compare the expected benefits and the remaining risks using available medical information, published research, and current medical practice standards. This helps confirm that the lens is safe when used as intended.

Any remaining risks are clearly described in the product's labels and Instructions for Use so that patients and healthcare professionals are aware of them.

- **Residual Risks**

- Vision Loss, infection/allergic reaction, severe inflammation
- Toxic anterior segment syndrome, increased IOP, Haptic demolition or crack, Cloudy lens
- Wound Leakage, Corneal Edema, Blurred Vision, develop glare, halos, double vision, decreased vision

- **Potential Hazards**

The relevant hazards and side effects of Intra Ocular Lens are essentially the same as (but not limited to) those of routine cataract extraction. These include the following:

- Intra Ocular Foreign Body debris: *Small particles or debris accidentally left inside the eye during or after surgery*
- Temporary Corneal Edema: *Temporary swelling of the clear front surface of the eye, causing blurred vision.*
- Secondary Cataract Formation: *Clouding that develops behind the implanted lens after cataract surgery, making vision blurry again.*
- Malpositioned lens: *The implanted lens is not sitting in the correct position inside the eye*
- Aphakic Glaucoma: *Increased pressure inside the eye that occurs when the natural lens has been removed and no lens is present*.
- Temporary Flat Anterior Chamber: *The front space of the eye becomes temporarily shallower than normal after surgery.*
- Retinal Detachment: *The light-sensitive layer at the back of the eye separates from its normal position, which can lead to vision loss if untreated*
- Posterior Capsule Opacification: *The thin membrane behind the implanted lens becomes cloudy, causing blurred vision after cataract surgery*
- Cystic Macular Edema: *Swelling in the central part of the retina (macula) due to fluid buildup, causing blurred or distorted vision*

- Iridocyclitis: *Inflammation of the colored part of the eye (iris) and the nearby tissue, causing pain, redness, and blurred vision*
- Iritis: *Inflammation of the iris, leading to eye pain, redness, sensitivity to light, and blurred vision*
- IOL dislocation and subluxation: *The implanted intraocular lens (IOL) moves partly or completely out of its normal position*
- Lens implants loop amputation: *Damage or breakage of one of the supporting arms (loops/haptics) of the implanted lens*
- Endothelial Corneal Dystrophy: *Damage or disease affecting the inner layer of the cornea, leading to swelling and reduced vision*
- Vitreous Herniation into the Anterior Chamber: *The gel inside the back of the eye moves into the front part of the eye through an abnormal opening*
- Infection
- Pupillary Block: *The normal flow of fluid inside the eye is blocked at the pupil, causing increased eye pressure*
- Corneal Dystrophy: *A condition in which the cornea gradually becomes cloudy or damaged, affecting vision*
- Hyalites: *Inflammation of the jelly-like substance (vitreous) inside the eye, which may cause floaters and blurred vision*.
- Endophthalmia and Panophthalmia: *Severe infections inside the eye (endophthalmitis) or involving the entire eye and surrounding tissues (panophthalmitis), which can threaten vision*
- Recurrent anterior or posterior segment inflammation of unknown etiology: *Repeated episodes of inflammation in the front or back part of the eye without a known cause*
- IOL precipitates: *Small deposits that collect on the surface of the implanted lens, which may affect vision if significant*

- **Warnings**

Intra Ocular Lens supplied is void of all warranties expressed or implied, if

- Do Not Resterilise. Resterilisation may compromise device performance, which could cause serious harm to the patient's health and safety.
- Do not store below 5°C or above 40°C to avoid damage to device integrity.
- Lens should not be altered in any manner.
- Lens should not be repackaged by anyone.
- Single use IOLs and single use injectors cannot be reused, as they are not designed to perform as intended after the first and only usage to avoid infection.
- Do not use after the expiry date.
- Non-toothed, polished instruments must be used if handling the IOL.
- Do not allow the IOL to contact substances that are unsterile or ocular-incompatible prior to placement into the eye.
- Do not use unsterile surgical instruments or instruments that may carry a risk of contamination.
- Do not allow the IOL to dehydrate during the procedure.
- Once closed, do not reopen the flaps of the injector.
- Following implantation, irrigate/aspirate to eliminate any viscoelastic residues from the bag, especially between the IOL and posterior capsule.

Summary of any field safety corrective action, (FSCA including FSN) if applicable

There were no identified and/or received reportable events that led to death, a serious deterioration in the state of health of the patient, user, or other person for Ophthalmic Foldable Intraocular Lens - Hydrophobic (Preloaded). Hence FSCA or FSN is not applicable.

5.0 Summary of clinical evaluation and post-market clinical follow-up

- **Clinical background of the device**

A cataract is when the lens of your eye becomes cloudy, which makes your vision blurry. Cataracts usually develop slowly and can affect one or both eyes. They are most common in older people, but sometimes babies can be born with them. Cataracts can make it hard to drive, read, or recognize faces, and poor vision can also increase the risk of falling or feeling depressed. Cataracts are responsible for about half of the blindness cases and a third of vision problems worldwide.

Main causes and risk factors:

- Getting older
- Smoking
- Diabetes
- Being female

With aging populations, cataracts are becoming more common. By 2020, about 30 million people were expected to have age-related cataracts.

Types of cataracts:

- Monocular cataract- *A cataract that affects only one eye.*
- Traumatic cataract- *A cataract that develops after an injury to the eye.*
- Refractive Lens Exchange- *A procedure in which the eye's natural lens is replaced with an artificial lens to correct vision problems, even when there is little or no cataract.*
- Mature cataract- *A cataract that has become completely cloudy, causing severe vision loss.*
- Congenital Cataract- *A cataract that is present at birth or develops during infancy.*
- Binocular Cataract- *Cataracts that affect both eyes.*
- Immature Cataract- *A cataract that has started to develop but has not yet become completely cloudy. Vision may be partially affected*

Intraocular lens (IOL):
An IOL is an artificial lens that is put inside the eye to replace a cloudy lens during cataract surgery. The most common type is called a pseudophakic IOL, which helps the eye focus light just like a natural lens does.

- **The clinical evidence for the CE-marking**

The safety and performance of this device have been carefully evaluated using studies and information collected specifically for this device, such as clinical follow-ups and safety checks. The safety and performance of the Ophthalmic Foldable Intraocular Lens - Hydrophobic (Preloaded) have been evaluated through clinical data collected directly on this device. The studies showed:

- significant improvement in vision after implantation
- stable position of the lens inside the eye
- low occurrence of surgery-related complications

No new safety concerns were identified during post-market follow-up of patients who received this lens. The results confirm that the lens performs as intended and provides the expected improvement in vision.

- **Safety**

We have carefully looked at all possible risks of using this device and compared them with the medical benefits it provides. We concluded that the benefits, such as better vision and fewer side effects, outweigh the possible risks. Any remaining risks are considered acceptable when patients follow the instructions provided in the labeling and instruction for use.

Residual Risks	Medical Benefits
1. Vision Loss, infection/allergic reaction, severe inflammation	**Benefits from Subject Device:** 1. Significant improvement after surgery 2. Excellent Visual outcome 3. Satisfactory IOL Position **Benefits from Similar Device:** 4. Good Uveal Biocompatibility 5. IOLs Provide Very Good Optical Clarity **Clinical outcome from Literature:** The foldable hydrophobic acrylic plastic provides efficient light focus and incorporates ultraviolet (UV) radiation and light-normalized spectrum transmission characteristics and the unique hydrophobic chemistry of the surface provides uveal and capsular biocompatibility properties that are different from other IOLs.
2. Toxic anterior segment syndrome, increased IOP, Haptic demolition or crack, Cloudy lens	**Benefits from Subject Device:** 1. Ease of Insertion 2. Reduced Handling Problems 3. Satisfactory IOL Position **Benefits from Similar Device:** 1. Good Mechanical Stability 2. Good Uveal Biocompatibility **Clinical Outcome from Literature:** The unique hydrophobic chemistry of the surface provides uveal and capsular biocompatibility properties that are different from other IOLs and the 3D bulk and square haptic edges of the 0.4 mm-tall haptics, the persistent memory of the material and very low resistance to compression provide predictable immediate and long-term optic positioning within the capsular bag.
3. Wound Leakage, Corneal Edema, Blurred Vision, develop glare, halos, double vision, decreased vision	**Benefits from Subject Device:** 1. Reduced Longer Unfolding Time 2. Significant Improvement after Surgery 3. Excellent Visual Outcome 4. No Post-operation Lens Opacification

Residual Risks	Medical Benefits
	5. Reduced Chances of ACO/PCO **Benefits from Similar Device:** 1. Low Rates of Posterior Capsular Opacification (PCO) 2. Light-normalizing technology, along with its surface and edge characteristics, combine to provide unique advantages for the majority of patients undergoing lens replacement surgery. 3. IOLs provide very good optical clarity **Clinical Outcomes from Literature:** A meta-analysis involving 861 eyes from nine randomized controlled trials demonstrated that hydrophobic acrylic IOLs significantly reduced posterior capsule opacification. In summary, the chemical features including light-normalizing technology, along with its surface and edge characteristics and haptic-capsular bag residential characteristics, combine to provide unique advantages for the majority of patients undergoing lens replacement surgery. The foldable hydrophobic acrylic plastic provides efficient light focus and incorporates ultraviolet (UV) radiation and light-normalized spectrum transmission characteristics.

As part of our safety measures, we continuously monitor the device after it is on the market. This is done through Post-Market Clinical Follow-up (PMCF) studies, which check the safety and performance of the device when used as instructed. These studies are performed every year throughout the device's life cycle, and the results help us update safety information and make improvements if needed. This ensures that the device continues to be safe and effective for patients.

6.0 Possible diagnostic or therapeutic alternatives

When considering alternative treatments, it is recommended to contact your healthcare professional who can take into account your individual situation.

7.0 Suggested training for users

Target Users: Ophthalmic surgeon

Ophthalmic surgeons are responsible for treating problems with the eye as well as diagnosing ailments and prescribing medicine for the eye. An Ophthalmic surgeon also performs surgical procedures on the eye.

There is no special user training is required. However, the device related directions for use information is provided in the Instruction for Use.