## 1.0 Introduction

The Regulation (EU) 2017/745 on medical devices requires that the manufacturer shall draw up a summary of safety and clinical performance (SSCP) for implantable devices and for class III devices, other than custom-made or investigational devices. The SSCP shall be validated by a notified body (NB) and made available to the public via the European database on medical devices (Eudamed).

The SSCP is intended to provide public access to an updated summary of clinical data and other information about the safety and clinical performance of the medical device. The SSCP will be an important source of information for intended users – both healthcare professionals and if relevant for patients. It is one of several means intended to fulfil the objectives of the Medical Device Regulation (MDR) to enhance transparency and provide adequate access to information.

The SSCP is not intended to:

- Give general advice on the diagnosis or treatment of particular medical conditions, nor
- Replace the instructions for use (IFU) as the main document that will be provided to ensure the safe use of a particular device, nor
- Replace the mandatory information on implant cards or in any other mandatory documents.

The main purpose of this document is to provide guidance on the presentation, content and validation of the SSCP. The word "shall" is used when there is a corresponding "shall" in the MDR, otherwise "should" or "recommended" etc. is used indicating the interpretation of the MDR

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 SSCP is not intended to replace the Instructions for Use as the main document to ensure the safe use of the device, nor is it intended to provide diagnostic or therapeutic suggestions to intended users or patients.

The following information is intended for users/healthcare professionals.

## 2.0 Device identification and general information

### 2.1 Device Brand / Trade Name(s)

| | |
|---|---|
| Product Name: | Ophthalmic Foldable Intraocular Lens - Hydrophobic (Preloaded) |
| | |
| Brand/Proprietary Name: | Supraphob, Spheriphob, Supraphob BBY, Maxim IOL, Supraphob Toric, Swiss Phob, Supraphob Infocus & Supraphob Regen. |

### 2.2 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. |
| Phone: | +91-413- 2666750 & 2660008 |
| Email: | seenivasan.veerasamy@appasamy.com |
| Website: | www.appasamy.com |

## 2.3 Manufacturer's Single Registration Number (SRN)

IN-MF-000019410

## 2.4 Basic UDI-DI

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

## 2.5 Medical Device Nomenclature

**EMDN Code:** P030102090201 - IOLs, Aphakic, Monofocal, Aspheric, Hydrophobic Acrylic.
P030102090301 - IOLs, Aphakic, Monofocal, Toric, Hydrophobic Acrylic.
P030102100201 - IOLs, Aphakic, Multifocal, Aspheric, Hydrophobic Acrylic.

## 2.6 Class of device

| | |
|---|---|
| Duration of Use | Long Term (>30 Days) / Continuous |
| Invasiveness | Surgically invasive device |
| Device Type | Non-active Medical Device & Implantable device |
| Rule Applicable | 08 |
| Classification | IIb |
| Reference | In accordance with Annex VIII of EU Medical Device Regulation 2017/745 |

## 2.7 Year of first certificate (CE) of the subject device

27/10/2017

## 2.8 Authorised Representative

| | |
|---|---|
| Name: | Amstermed B.V |
| Address: | Saturnusstraat 46-62, Unit 032, 2132 HB Hoofddorp, The Netherlands. |
| Phone: | +31 23 5656337 |
| Email: | info@amstermed.nl |
| Website: | www.amstermed.nl |
| SRN: | NL-AR-000001971 |

## 2.9 NB Details

| | |
|---|---|
| Name: | DNV Product Assurance AS |
| Address: | Veritasveien 1, 1363 Høvik, Norway |
| Phone: | +4767579900 |
| Email: | medicalindia@dnv.com |
| Website: | www.dnv.com |
| Notified Body No.: | 2460 |

## 3.0 Intended use of the device

### 3.1 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.

### 3.2 Indications & Target Populations

- **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)

### 3.3 Caution

Apart from general contraindications applicable to any intraocular surgical procedure, implantation of the intraocular lens should be carefully considered in patients presenting with the following conditions.

These conditions are not absolute contraindications; however, they may increase the risk of surgical complications, worsen pre-existing ocular conditions, interfere with diagnosis or treatment, or adversely affect visual outcomes. A thorough preoperative evaluation and a careful benefit–risk assessment by the surgeon are required prior to implantation.

- 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

## 4.0 Device Description

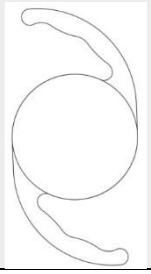
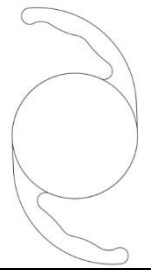
### 4.1 Description of the Device

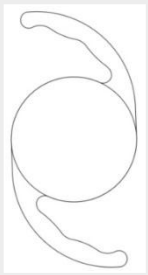
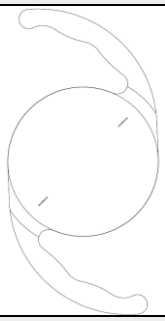
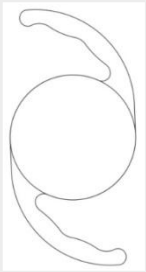
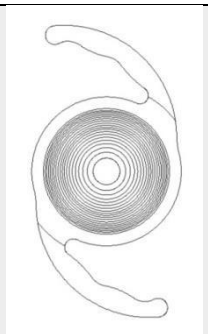
Ophthalmic Foldable Hydrophobic lens a medical device consisting of optic and haptic components, intended for surgical implantation inside the posterior chamber of the eye. IOL replaces the natural crystalline lens of the eye to rehabilitate the cataract patients. A Single Piece IOL is a device in which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

The intraocular lens is supplied in a pre-loaded, ready-to-use pre-loaded intraocular lens system, where the IOL is pre-loaded within the cartridge, and the cartridge is pre-loaded into the injector. This integrated system enables controlled implantation through a small corneal incision while minimizing handling of the lens, thereby reducing the risk of contamination and potential damage during surgical implantation.

The IOL, cartridge, and injector are manufactured by Appasamy Ocular Devices. The cartridge and injector are integral components of the pre-loaded IOL system and are not supplied as separate medical devices. The complete pre-loaded IOL system is covered under the CE certification of the finished medical device; therefore, separate CE certification for the cartridge and injector is not applicable.

#### 4.1.1 Device Drawing

| # | Variant Name | Image |
|---|---|---|
| 1 | Supraphob - SPNT 200, SPNT 300, HPNT 200 & HPNT 300<br>Spheriphob – SPNT 200 |  |
| 2. | Supraphob BBY - SPNT 300-PL, SPNT 200-PL & Supraphob BBY |  |

| # | Variant Name | Image |
|---|---|---|
| 3. | MAXIM IOL - SUPRAPHOB BBY |  |
| 4. | SUPRAPHOB TORIC –<br>SP TORIC (T3-T9) |  |
| 5. | SWISS PHOB - SPH 60130 |  |
| 6. | SUPRAPHOB INFOCUS - SP INFO |  |
| 7. | SUPRAPHOB REGEN – SPMFDY 200 |  |

### 4.1.2 Principle of Operation

Intraocular lenses work much in the same way as a natural lens would. As light rays enter the eye the IOL bends (or refracts) the light rays to help see with accuracy.

### 4.1.3 Mode of Operation

IOL is 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 correction of aphakia.

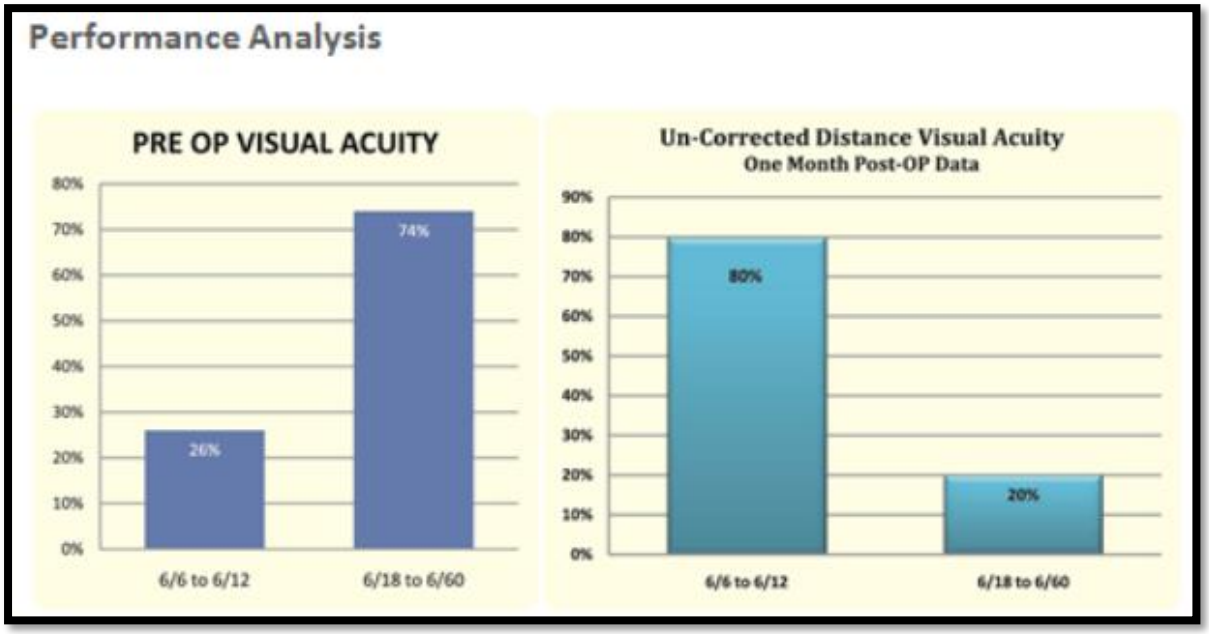
A hydrophobic intraocular lens (IOL) replaces the natural crystalline lens removed during cataract surgery. Its optical design refracts and focuses light onto the retina, thereby restoring visual function and correcting aphakia. By providing a fixed refractive power, the IOL compensates for the loss of the natural lens and enables proper focusing of light on the retina, which improves postoperative visual acuity.

The hydrophobic acrylic material allows the lens to be folded and inserted through a small incision and ensures long-term stability within the capsular bag.

### 4.1.4 Design Characteristics

Hydrophobic is a single piece hydrophobic acrylic lens manufactured from ultra-glistening free proprietary material with excellent compatibility.

- Glistening free -The material is free of microvacuoles and glistening. Glistening's are fluid filled microvacuoles that form within the matrix of the lens when exposed to aqueous environment. High levels of glistening result in scattering of light and reduced contrast sensitivity.
- Natural yellow - Proprietary natural yellow chromophore blocks harmful ultra-violet and blue light which cause
- Foldability and Memory - Handling characteristics and unfolding are optimal for placement inside the capsular bag.
- Aspheric surface - Negative spherical aberration design on anterior surface improves contrast sensitivity and low light visual acuity compared with spherical IOLs.
- Square Edge - 360-degree square edge design reduces the incidence of PCO and YAG capsulotomy rates.
- Stability - Dual muscle haptics design ensures perfect centration and stability inside the capsular bag.
- Ready to Use Preloaded system.



### 4.1.5 Method of Sterilization

Ethylene oxide gas sterilization

### 4.1.6 Device Lifetime/Stability

The Life time of the Ophthalmic Foldable Intraocular Lens - Hydrophobic (Preloaded) is 15 Years after implantation

### 4.1.7 Information about the constituents

*a. Device with Medicinal Product*

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

*b. Device with Human or Animal Origin Tissues*

Ophthalmic Foldable Intraocular Lens - Hydrophobic (Preloaded) does not incorporate any human or animal origin tissues. Hence this declaration is not applicable.

*c. Device with substances absorbed by or locally dispersed in the human body*

Ophthalmic Foldable Intraocular Lens - Hydrophobic (Preloaded) does not incorporate any substances that absorbed by or locally dispersed in human body. Hence this declaration is not applicable.

*d. Device with Carcinogenic, Mutagenic or Toxic to reproduction (CMR) or Endocrine-disrupting substances*

Ophthalmic Foldable Intraocular Lens - Hydrophobic (Preloaded) does not impact any Carcinogenic, Mutagenic or Toxic to reproduction (CMR). Hence this declaration is not applicable.

*e. Materials could result sensitisation or an allergic reaction to patient/user*

Hydrophobic Acrylic Polymer

## 4.2 Reference to previous generation(s) or variants

| Legacy Device Name: | Sterile Ophthalmic Intra Ocular Lens - Foldable Hydrophobic | | |
|---|---|---|---|
| Brand/Proprietary Name: | **Brand Name:** | **Model / Ref:** | **Clear / Yellow** |
| | Supraphob | SPNT 200, SPNT 300, HPNT 200 & HPNT 300 | Clear |
| | Spheriphob | SPNT 200 | Clear |
| | Supraphob BBY | SPNT 300-PL, SPNT 200-PL & Supraphob BBY | Yellow |
| | Maxim IOL | SUPRAPHOB BBY | Yellow |
| | Supraphob Toric | SP TORIC (T3-T9) | Yellow |
| | Swiss Phob | SPH 60130 | Yellow |
| | Supraphob | SP INFO | Yellow |

| | | | |
|---|---|---|---|
| | Infocus | | |
| | Supraphob Regen | SPMFDY 200 | Yellow |
| | | | |
| 93/42/EEC (MDD) Cert. No.: | Certificate# 11657-2017-CE-IND-NA-PS Rev.2.0<br>Expiry Date: 27 May 2024<br><br>Certificate# 10000359965-PA-NA-IND Rev.0.0<br>Expiry Date: 26 May 2024<br><br>**Notified Body Confirmation Letter Reference:** C667176<br>Expiry Date: 31 Dec 2027 | | |
| | | | |
| Notified Body Details: | DNV Product Assurance AS, Veritasveien 1, 1363 Høvik, Norway | | |
| | | | |
| Is any significant difference between Legacy Device & Device Under Evaluation? | There is no significant difference between legacy device and subject device with respect to raw materials used in production, device description, intended purpose, medical indications, target user, target patient population, side-effects, and contraindications. | | |

## 4.4 Combination with other Medical Devices

Ophthalmic Foldable Intraocular Lens - Hydrophobic (Preloaded) is not used with any other medical device. Hence this declaration is not applicable.

## 5.0 Risks and warnings

### 5.1 Residual risks and undesirable side effects

**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**

- Intra Ocular Foreign Body debris
- Temporary Corneal Edema
- Secondary Cataract Formation
- Malpositioned lens
- Aphakic Glaucoma
- Temporary Flat Anterior Chamber
- Retinal Detachment
- Posterior Capsule Opacification
- Cystic Macular Edema
- Iridocyclitis
- Iritis
- IOL dislocation and subluxation
- Lens implants loop amputation
- Endothelial Corneal Dystrophy
- Vitreous Herniation into the Anterior Chamber
- Infection
- Pupillary Block
- Corneal Dystrophy
- Hyalites
- Endophthalmia and Panophthalmia
- Recurrent anterior or posterior segment inflammation of unknown etiology
- IOL precipitates

### 5.2 Warnings

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

- Do Not Resterilise. Resterilization 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.

## 5.3 Other relevant aspects of safety

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.

## 6.0 Summary of clinical evaluation and post-market clinical follow-up (PMCF)

### 6.1 Summary of clinical data related to equivalent device, if applicable

No equivalent device has been identified. The clinical evaluation of the Ophthalmic Foldable Intraocular Lens - Hydrophobic (Preloaded) is based on the available clinical data collected for the device itself, including preclinical testing, bench performance data, and clinical experience. The safety and performance profile of the device has been assessed in accordance with relevant standards and guidelines, demonstrating that the device meets its intended purpose and performs as intended.

### 6.2 Summary of clinical data from conducted investigations of the device before the CE-marking, if applicable

Not Applicable

### 6.3 Summary of clinical data from other sources, if applicable

- **Literature evidence - Pertinent Literatures for Appraisal**

| # | ID# | Source Link | Literature Title |
|---|---|---|---|
| 1. | L1 | https://pubmed.ncbi.nlm.nih.gov/26100954/ | Glistenings 9 years after phacoemulsification in hydrophobic and hydrophilic acrylic intraocular lenses |
| 2. | L2 | https://pubmed.ncbi.nlm.nih.gov/27521667/ | Brown discoloration of acrylic hydrophobic intraocular lens |
| 3. | L4 | https://pubmed.ncbi.nlm.nih.gov/27445063/ | Posterior capsule opacification 9 years after phacoemulsification with a hydrophobic and a hydrophilic intraocular lens |
| 4. | L6 | https://pubmed.ncbi.nlm.nih.gov/29934027/ | Posterior capsule opacification, glistenings and visual outcomes: 3 years after implantation of a new hydrophobic IOL |
| 5. | L7 | https://pubmed.ncbi.nlm.nih.gov/31436185/ | A comparison of posterior capsular opacification after implantation of three different hydrophobic square edge intraocular lenses |
| 6. | L8 | https://pubmed.ncbi.nlm.nih.gov/22727297/ | Assessment of new-generation glistening-free hydrophobic acrylic intraocular lens material |
| 7. | L9 | https://pubmed.ncbi.nlm.nih.gov/26067189/ | The effect of single-piece hydrophobic acrylic intraocular lenses on the development of posterior capsule opacification |
| 8. | L10 | https://pubmed.ncbi.nlm.nih.gov/20610089/ | Three-year stability of an angle-supported foldable hydrophobic acrylic phakic intraocular lens evaluated by Scheimpflug photography |
| 9. | L11 | https://pubmed.ncbi.nlm.nih.gov/24223736/ | Effect of hydrophobic acrylic versus hydrophilic acrylic intraocular lens on posterior capsule opacification: meta-analysis |
| 10. | L12 | https://pubmed.ncbi.nlm.nih.gov/28366371/ | Intraindividual comparison of capsule |

| # | ID# | Source Link | Literature Title |
|---|---|---|---|
| | | | behavior of 2 hydrophobic acrylic intraocular lenses during a 5- year follow-up |
| 11. | L13 | https://pubmed.ncbi.nlm.nih.gov/38155684/ | Extended depth of focus intraocular lens versus a new monofocal intraocular lens: A prospective comparative and interventional study |
| 12. | L14 | https://pubmed.ncbi.nlm.nih.gov/23471324/ | Effect of aspherical and yellow tinted intraocular lens on blue-on-yellow perimetry |
| 13. | L15 | https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3937253/ | Clinical properties of a novel, glistening-free, single-piece, hydrophobic acrylic IOL |
| 14. | L16 | https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4559235/ | A pilot study to determine if intraocular lens choice at the time of cataract surgery has an impact on patient-reported driving habits |
| 15. | L17 | https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3843900/ | Patient-Reported Difference following Implantation of a Blue Light-Filtering Aspheric Intraocular Lens and a UV-Filtering Aspheric Intraocular Lens |
| 16. | L20 | https://pubmed.ncbi.nlm.nih.gov/20665986/ | Clinical study of Acrysof IQ aspheric intraocular lenses. |
| 17. | L21 | https://pubmed.ncbi.nlm.nih.gov/29736282/ | Biomaterial Influence on Intraocular Lens Performance: An Overview |
| 18. | L22 | https://pubmed.ncbi.nlm.nih.gov/22287168/ | Contrast sensitivity and color perception with orange and yellow intraocular lenses |
| 19. | L24 | https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6188169/ | Long-term effectiveness and safety of a three-piece acrylic hydrophobic intraocular lens modified with hydroxyethyl-methacrylate: an open-label, 3-year follow-up study |
| 20. | L25 | https://link.springer.com/chapter/10.1007/3-540-26678-X_4 | Foldable Intraocular Lenses |
| 21. | L26 | https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5142717/ | Evaluating the Biostability of Yellow and Clear Intraocular Lenses with a System Simulating Natural Intraocular Environment |
| 22. | L27 | https://pubmed.ncbi.nlm.nih.gov/23677137/ | Posterior Capsule Opacification with the iMics1 NY-60 and AcrySof SN60WF 1-Piece Hydrophobic Acrylic Intraocular Lenses: 3-Year Results of a Randomized Trial |
| 23. | L28 | https://pubmed.ncbi.nlm.nih.gov/31564314/ | Blue light–filtering and violet light–filtering hydrophobic acrylic foldable intraocular lenses: Intraindividual comparison |
| 24. | L29 | https://pubmed.ncbi.nlm.nih.gov/24729678/ | Safety and effectiveness of a single-piece hydrophobic acrylic intraocular lens (enVista®) – results of a European and Asian-Pacific study |
| 25. | L30 | https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3614664/ | Post-Operative Capsular Opacification: A Review |
| 26. | L32 | https://pubmed.ncbi.nlm.nih.gov/22094397/ | Measurements of transmission spectrums and estimation of retinal blue-light irradiance values of currently available |

| # | ID# | Source Link | Literature Title |
|---|---|---|---|
| | | | clear and yellow-tinted intraocular lenses |
| 27. | L33 | https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6432853/ | A comparison of the contrast sensitivity function between age-matched phakic emmetropes and pseudophakic individuals with aspheric intraocular lenses |
| 28. | L34 | https://pubmed.ncbi.nlm.nih.gov/32971619/ | Visual outcomes of binocular implantation of a new extended depth of focus intraocular lens |
| 29. | L35 | https://www.touchophthalmology.com/wp-content/uploads/sites/16/2015/07/davison.pdf | Achieving Best Visual Outcomes with a Monofocal Intraocular Lens |
| 30. | L36 | https://10.1097/ICU.0000000000001095 | How do intraocular lens materials influence the outcome of cataract surgery? |
| 31. | L37 | https://doi.org/10.1155/joph/2662730 | Visual Outcomes of a New Hydrophobic Trifocal Intraocular Lens in Cataract Treatment: A Prospective Clinical Study |
| 32. | L38 | https://doi.org/10.2147/OPTH.S544933 | Intraocular Pressure Spikes Following Cataract Extraction: Hydrophobic vs Hydrophilic Acrylic Lenses |
| 33. | L39 | https://doi.org/10.1016/j.ajo.2026.01.041 | Three-Year Outcomes of Toric vs Nontoric Monofocal Intraocular Lens Implantation in Children Aged 3–8 Years With Congenital Cataract |
| 34. | L40 | https://link.springer.com/article/10.1007/s40135-025-00347-4 | IOL Calculations & Selection in Pediatric Cataract Surgery |

Refer Section 4.4 of CER (CER-PB-01) for the detailed literature summary and literature appraisal.

## 6.4 PMCF Clinical Safety & Performance data

36 subjects each for below mentioned products were considered for the PMCF Study conducted in 2021-2022.

- Supraphob (SPNT300)
- Supraphob BBY (SPNT 300-PL)
- Supraphob (SPNT200)
- Supraphob BBY (Supraphob BBY)
- Supraphob Regen (SPMFDY200)
- Supraphob Toric (SP TORIC)

From the PMCF data collected from 216 patients, visual acuity significantly improved at post-operative when compared to pre-operative values. Visual Acuity (VA) did not display any significant difference between the age groups at pre-operative and 14 days, 60 days, 180 days & 360 days post -operative time. Following benefits were also observed during the study.

- Excellent visual acuity for distance and for near.
- Intermediate vision surprisingly high.
- Contrast sensitivity results equivalent to marketed IOLs.
- Independency of glasses achieved despite small refractive errors.
- Very good safety profile as reflected by a very low rate of postoperative complications at one year.
- The hazards related to user Interface did not arise during this period. The mitigation options are effective and no need for further Improvements require.

## 6.5 An overall summary of the clinical performance and safety

| Residual Risks | Medical Benefits |
|---|---|
| 1. Vision Loss, infection/allergic reaction, severe inflammation | **Benefits from Subject Device:**<br>1. Significant improvement after surgery<br>2. Excellent Visual outcome<br>3. Satisfactory IOL Position<br><br>**Benefits from Similar Device:**<br>4. Good Uveal Biocompatibility<br>5. IOLs Provide Very Good Optical Clarity<br><br>**Clinical outcome from Literature:**<br><br>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:**<br>1. Ease of Insertion<br>2. Reduced Handling Problems<br>3. Satisfactory IOL Position<br><br>**Benefits from Similar Device:**<br>1. Good Mechanical Stability<br>2. Good Uveal Biocompatibility<br><br>**Clinical Outcome from Literature:**<br><br>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:**<br>1. Reduced Longer Unfolding Time<br>2. Significant Improvement after Surgery<br>3. Excellent Visual Outcome<br>4. No Post-operation Lens Opacification<br>5. Reduced Chances of ACO/PCO<br><br>**Benefits from Similar Device:**<br>1. Low Rates of Posterior Capsular Opacification (PCO)<br>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.<br>3. IOLs provide very good optical clarity<br><br>**Clinical Outcomes from Literature:**<br>A meta-analysis involving 861 eyes from nine randomized controlled |

| Residual Risks | Medical Benefits |
|---|---|
| | trials demonstrated that hydrophobic acrylic IOLs significantly reduced posterior capsule opacification.<br><br>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. |

The Ophthalmic Foldable Intraocular Lens - Hydrophobic (Preloaded) complies with all the Safety and Performance requirements with respect to the intended use of the device from the Clinical Evaluation study. The clinical evaluation is complete and conforms to the general safety and performance requirements. The Clinical evidence is demonstrated with the relevant General Safety & Performance Requirements as per Annex I of MDR. Risk Mitigation has been established as per the guidelines of ISO 14971.

## 6.6 Ongoing or planned post-market clinical follow-up

We have planned for a retrospective Post market clinical follow up study for the year 2026-2027.

## 7.0 Possible diagnostic or therapeutic alternatives

- Hydrophilic Acrylic IOL
- Rigid PMMA IOL
- Silicone IOL

## 8.0 Suggested profile and 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.

## 9.0 Reference to any harmonised standards and CS applied

### 9.1 Applicable Harmonized Standards

| # | Standard ID | Current Issue | Tittle |
|---|---|---|---|
| 1. | EN ISO 13485 | 2016/A11:2021 | Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016) |
| 2. | EN ISO 14971 | 2019/A11:2021 | Medical devices – Application of risk management to medical devices (ISO 14971:2019) |
| 3. | EN ISO 11135 | 2014 | Sterilization of health care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices (ISO 11135:2014) |
| 4. | EN ISO 15223-1 | 2021 | Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements (ISO 15223-1:2021) |
| 5. | EN ISO 11607-1 | 2020/A1:2023 | Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems (ISO 11607-1:2019) |
| 6. | EN ISO 11607-2 | 2020/A1:2023 | Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes (ISO 11607-2:2019) |
| 7. | EN ISO 11737-1 | 2018/A1:2021 | Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on products (ISO 11737-1:2018) |
| 8. | EN ISO 11737-2 | 2020 | Sterilization of health care products - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process (ISO 11737-2:2019) |
| 9. | EN ISO 10993-10 | 2023 | Biological evaluation of medical devices – Part 10: Tests for skin sensitisation (ISO 10993-10:2021) |
| 10. | EN ISO 10993-23 | 2021 | Biological evaluation of medical devices - Part 23: Tests for irritation (ISO 10993-23:2021) |

### 9.2 Applicable Non-Harmonized Standards

| # | Standard ID | Current Issue | Tittle |
|---|---|---|---|
| 1. | ISO/TR 24971 | 2020 | Medical devices – Guidance on the application of ISO 14971 |
| 2. | IEC 62366-1 | 2015/AMD 1: 2020 | Medical Devices –Part 1: Application of Usability Engineering to medical devices - Amendment 1 |
| 3. | ISO 10993-1 | 2018 | Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process |
| 4. | ISO 10993-3 | 2014 | Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity |
| 5. | ISO 10993-5 | 2009 | Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity |
| 6. | ISO 10993-6 | 2016 | Biological evaluation of medical devices – Part 6: Tests for local effects after implantation. |
| 7. | ISO 10993-7 | 2008/AMD 1:2019 | Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals - Amendment 1: Applicability of allowable limits for neonates and infants. |

| # | Standard ID | Current Issue | Tittle |
|---|---|---|---|
| 8. | ISO 10993-11 | 2017 | Biological evaluation of medical devices - Part 11: Tests for systemic toxicity |
| 9. | ISO 20417 | 2021 | Medical Devices - Information to be supplied by the manufacturer. |
| 10. | ISO 11140-1 | 2014 | Sterilization of health care products - Chemical indicators - Part 1: General requirements |
| 11. | ISO 11138-2 | 2017 | Sterilization of health care products - Biological indicators - Part 2: Biological indicators for ethylene oxide sterilization processes |
| 12. | ISO 14644-1 | 2015 | Cleanrooms and associated controlled environments – Part 1: Classification of air cleanliness by particle concentration |
| 13. | ISO 14644-2 | 2015 | Cleanrooms and associated controlled environments — Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration |
| 14. | ISO 14644-3 | 2019 | Cleanrooms and associated controlled environments – Part 3: Test methods |
| 15. | ISO 14644-4 | 2022 | Cleanrooms and associated controlled environments – Part 4: Design, construction and start-up |
| 16. | ISO 14644-5 | 2004 | Cleanrooms and associated controlled environments – Part 5: Operations |
| 17. | ISO 14644-7 | 2004 | Cleanrooms and associated controlled environments – Part 7: Seperative devices (clean air hoods, glove boxes, isolators and mini-environments) |
| 18. | ISO 14644-8 | 2022 | Cleanrooms and associated controlled environments – Part 8: Assessment of air cleanliness by Chemical Concentration (ACC) |
| 19. | ISO 14644-9 | 2022 | Cleanrooms and associated controlled environments – Part 9: Assessment of surface cleanliness for particle concentration |
| 20. | ISO 14644-10 | 2022 | Cleanrooms and associated controlled environments – Part 10: Assessment of surface cleanliness for chemical contamination |
| 21. | ISO 14698-1 | 2003 | Cleanrooms and associated controlled environments – Bio contamination control – Part 1: General principles and methods |
| 22. | ISO 14698-2 | 2003/Cor 1:2004 | Cleanrooms and associated controlled environments – Bio contamination control – Part 2: Evaluation and interpretation of Bio contamination data |
| 23. | ISO 11979-1 | 2018 | Ophthalmic Implants – Intraocular Lenses – Part 1 : Vocabulary |
| 24. | ISO 11979-2 | 2024 | Ophthalmic Implants – Intraocular Lenses–Part 2: Optical properties and test methods |
| 25. | ISO 11979-3 | 2012 | Ophthalmic Implants – Intraocular Lenses – Part 3: Mechanical Properties and test Methods |
| 26. | ISO 11979-4 | 2008/Amd 1 :2012 | Ophthalmic Implants – Intraocular Lenses –Part 4 : Labeling and Information - Amendment 1 |
| 27. | ISO 11979-5 | 2020 | Ophthalmic implants-Intraocular lenses- Part5: Biocompatibility |
| 28. | ISO 11979-6 | 2014 | Ophthalmic Implants – Intraocular lenses – Part 6 : Shelf life and transport stability testing |
| 29. | ISO 11979-7 | 2024 | Ophthalmic Implants – Intraocular Lenses – Part 7: Clinical |

| # | Standard ID | Current Issue | Tittle |
|---|---|---|---|
| | | | Investigations of intraocular lenses for the correction of aphakia |
| 30. | ISO 11979-8 | 2017 | Ophthalmic Implants – Intraocular Lenses – Part 8: Fundamental Requirements |
| 31. | ISO/TR 20416 | 2020 | Medical devices – Post market surveillance for manufacturers |
| 32. | USP 37 – NF 32 | 2014 | United States of Pharmacopeia/ National Formulary official, December 1, 2014 to April 30, 2015 |

## 9.3 Applicable Guidelines

| # | Guideline | Current Issue | Tittle |
|---|---|---|---|
| 1. | MEDDEV 2.7.1 Rev. 4 | June 2016 | Clinical Evaluation |
| 2. | MEDDEV 2.5/5 Rev. 3 | February 1998 | Translation Procedure |
| 3. | MEDDEV 2.12-1 Rev. 8 | January 2013 | Vigilance Control |
| 4. | MEDDEV 2.12/2 Rev. 2 | January 2012 | Post market Clinical Follow-up |
| 5. | NB-MED 2.12/Rec. 1 | July 2019 | Post Market surveillance |
| 6. | MDCG 2020-5 | 2020 | Clinical Evaluation – Equivalence A guide for manufacturers and notified bodies. |
| 7. | MDCG 2020-6 | 2020 | Clinical evidence needed for medical devices previously CE marked under Directives 93/42/EEC. |
| 8. | MDCG 2018-1 Rev.4 | April 2021 | Guidance on BASIC UDI-DI and changes to UDI-DI |
| 9. | MDCG 2020-7 | April 2020 | Post-market clinical follow-up (PMCF) Plan Template - A guide for manufacturers and notified bodies |
| 10. | MDCG 2020-8 | April 2020 | Post-market clinical follow-up (PMCF) Evaluation Report Template - A guide for manufacturers and notified bodies |

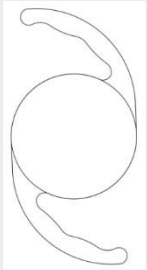
## 9.4 Regulations

| S. No. | Standard | Description |
|---|---|---|
| 1. | EU MDR 2017 / 745 | EU Medical device Regulation |

## 9.5 Product Technical specifications

### 9.5.1 Variant/Model – SUPRAPHOB and SPHERIPHOB – SPNT 200, SPNT 300, HPNT 200 & HPNT 300 and SPNT 200

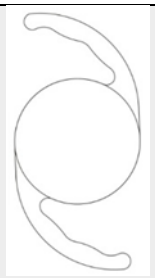
| Parameter | Specification |
|---|---|
| Optic Type | Monofocal |
| Optic Material | Hydrophobic Soft Acrylic – Clear (Polymer) or Hydrophobic Soft Acrylic– Clear (Co-polymer of Phenyl ethyl Acrylate (PEA) and Phenyl ethyl Methacrylate (PEMA)). |
| Spectra Transmission (Imaging Quality) | Above 85% |
| Refractive Index | 1.5050 |
| Optic Design | Biconvex |
| Haptic Material | Hydrophobic Soft Acrylic (Polymer) |
| Optic Diameter | 5.75 to 6.50mm(with 0.25 increments) |

| Parameter | Specification |
|---|---|
| Overall Length | 12.50 to 13.50mm(with 0.25 increments) |
| Haptic Angle | 0° |
| "A" Constant | 118.8 |
| Square Edge | 360° |
| Diopter Range | -10.00D to +50.00D in steps of 0.50D |
| Diopter Increment | 0.50D |
| Compatible Lens delivery system | Cartridge 2.2 & 2.8 |
| Sterilization | EO Gas |
| Intended Use | 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. |
| Attributes | Aphakic, Monofocal, Aspheric |
| Design (one per line)<br>- Single piece or<br>- Three piece or<br>- multi piece | Single piece |
| Design (One per line)<br>- Plate haptic<br>- Loop haptic: C loop, J loop<br>- Plate loop haptic<br>- Other design |  <br>C Loop Closed Haptic |
| Location (One per line)<br>- Capsular bag<br>- Anterior chamber or Posterior chamber<br>- Scleral or Iris or Sulcus Fixated | Capsular bag in posterior chamber |
| Device Intended User | Ophthalmic surgeon |
| Patient Population | Above age of one year (Male or Female) |
| Indications | - Monocular cataract<br>- Mature cataract<br>- Congenital cataract<br>- Binocular Cataract<br>- Refractive lens (exchange) reflex<br>- Immature cataract<br>- Traumatic cataract |
| Caution | Apart from general contraindications applicable to any intraocular surgical procedure, implantation of the intraocular lens should be carefully considered in patients presenting with the following conditions.<br>These conditions are not absolute contraindications; however, they may increase the risk of surgical complications, worsen pre-existing ocular conditions, interfere with diagnosis or treatment, or adversely affect visual outcomes. A thorough preoperative evaluation and a careful benefit–risk assessment by the surgeon are required prior to implantation.<br><br>- Chronic Severe Uveitis<br>- Epithelial Dystrophy |

| Parameter | Specification |
|---|---|
| | - Proliferative Diabetic Retinopathy<br>- Choroidal Haemorrhage<br>- Microphthalmos<br>- Concommitant Severe Eye Disease<br>- Non-age related cataract<br>- Severe or uncontrolled Glaucoma<br>- Rubella associated cataract<br>- Massive Vitreous Loss<br>- Anirida<br>- Sever corneal dystrophy<br>- Eyes with fixed dilated pupils or persistent miotic pupils<br>- |
| Shelf Life | 5 Years |
| Packing Contains | • One (1) Sterile Preloaded IOL with Blister pack<br>• One (1) Preloaded Delivery System Includes (One Cartridge & one soft Tipped Injector)<br>• Instruction for use<br>• Patient ID card<br>• Labels |

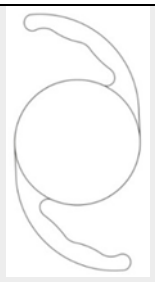
### 9.5.2 Variant/Model – SUPRAPHOB BBY - SPNT 300-PL, SPNT 200-PL & SUPRAPHOB BBY

| Parameter | Specification |
|---|---|
| Optic Type | Monofocal |
| Optic Material | Hydrophobic Soft Acrylic – Yellow (Polymer) or Hydrophobic Soft Acrylic – Yellow (Co-polymer of Phenyl ethyl Acrylate (PEA) and Phenyl ethyl Methacrylate (PEMA)). |
| Spectra Transmission (Imaging Quality) | Above 85% |
| Refractive Index | 1.5050 |
| Optic Design | Biconvex |
| Haptic Material | Hydrophobic Soft Acrylic (Polymer) |
| Optic Diameter | 5.75 to 6.50mm(with 0.25 increments) |
| Overall Length | 12.50 to 13.50mm(with 0.25 increments) |
| Haptic Angle | 0° |
| "A" Constant | 118.8 |
| Square Edge | 360° |
| Diopter Range | -10.00D to +50.00D in steps of 0.50D |
| Diopter Increment | 0.50D |
| Compatible Lens delivery system | Cartridge 2.2 & 2.8 |
| Sterilization | EO Gas |
| Intended Use | 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. |
| Attributes | Aphakic, Monofocal, Aspheric |
| Design (one per line)<br>- Single piece or<br>- Three piece or | Single piece |

| Parameter | Specification |
|---|---|
| - multi piece | |
| Design (One per line)<br>- Plate haptic<br>- Loop haptic: C loop, J loop<br>- Plate loop haptic<br>- Other design |  <br>C Loop Closed Haptic |
| Location (One per line)<br>- Capsular bag<br>- Anterior chamber or Posterior chamber<br>- Scleral or Iris or Sulcus Fixated | Capsular bag in posterior chamber |
| Device Intended User | Ophthalmic surgeon |
| Patient Population | Above age of one year (Male or Female) |
| Indications | - Monocular cataract<br>- Mature cataract<br>- Congenital cataract<br>- Binocular Cataract<br>- Refractive lens (exchange) reflex<br>- Immature cataract<br>- Traumatic cataract |
| Caution | Apart from general contraindications applicable to any intraocular surgical procedure, implantation of the intraocular lens should be carefully considered in patients presenting with the following conditions.<br><br>These conditions are not absolute contraindications; however, they may increase the risk of surgical complications, worsen pre-existing ocular conditions, interfere with diagnosis or treatment, or adversely affect visual outcomes. A thorough preoperative evaluation and a careful benefit–risk assessment by the surgeon are required prior to implantation.<br><br>- Chronic Severe Uveitis<br>- Epithelial Dystrophy<br>- Proliferative Diabetic Retinopathy<br>- Choroidal Haemorrhage<br>- Microphthalmos<br>- Concommitant Severe Eye Disease<br>- Non-age related cataract<br>- Severe or uncontrolled Glaucoma<br>- Rubella associated cataract<br>- Massive Vitreous Loss<br>- Anirida<br>- Sever corneal dystrophy<br>- Eyes with fixed dilated pupils or persistent miotic pupils |
| Shelf Life | 5 Years |
| Packing Contains | • One (1) Sterile Preloaded IOL with Blister pack<br>• One (1) Preloaded Delivery System Includes (One Cartridge & one soft Tipped Injector) |

| Parameter | Specification |
|---|---|
| | • Instruction for use<br>• Patient ID card<br>• Labels |

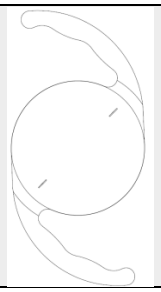
### 9.5.3 Variant/Model – MAXIM IOL - SUPRAPHOB BBY

| Parameter | Specification |
|---|---|
| Optic Type | Monofocal |
| Optic Material | Hydrophobic Soft Acrylic – Yellow (Polymer) or Hydrophobic Soft Acrylic – Yellow (Co-polymer of Phenyl ethyl Acrylate (PEA) and Phenyl ethyl Methacrylate (PEMA)). |
| Spectra Transmission (Imaging Quality) | Above 85% |
| Refractive Index | 1.5050 |
| Optic Design | Biconvex |
| Haptic Material | Hydrophobic Soft Acrylic (Polymer) |
| Optic Diameter | 5.75 to 6.50mm(with 0.25 increments) |
| Overall Length | 12.50 to 13.50mm(with 0.25 increments) |
| Haptic Angle | 0° |
| "A" Constant | 118.8 |
| Square Edge | 360° |
| Diopter Range | -10.00D to +50.00D in steps of 0.50D |
| Diopter Increment | 0.50D |
| Compatible Lens delivery system | Cartridge 2.2 & 2.8 |
| Sterilization | EO Gas |
| Intended Use | 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. |
| Attributes | Aphakic, Monofocal, Aspheric |
| Design (one per line)<br>- Single piece or<br>- Three piece or<br>- multi piece | Single piece |
| Design (One per line)<br>- Plate haptic<br>- Loop haptic: C loop, J loop<br>- Plate loop haptic<br>- Other design |  <br>C Loop Closed Haptic |
| Location (One per line)<br>- Capsular bag<br>- Anterior chamber or Posterior chamber<br>- Scleral or Iris or Sulcus Fixated | Capsular bag in posterior chamber |
| Device Intended User | Ophthalmic surgeon |
| Patient Population | Above age of one year (Male or Female) |
| Indications | - Monocular cataract |

| Parameter | Specification |
|---|---|
| | - Mature cataract<br>- Congenital cataract<br>- Binocular Cataract<br>- Refractive lens (exchange) reflex<br>- Immature cataract<br>- Traumatic cataract |
| Caution | Apart from general contraindications applicable to any intraocular surgical procedure, implantation of the intraocular lens should be carefully considered in patients presenting with the following conditions.<br><br>These conditions are not absolute contraindications; however, they may increase the risk of surgical complications, worsen pre-existing ocular conditions, interfere with diagnosis or treatment, or adversely affect visual outcomes. A thorough preoperative evaluation and a careful benefit–risk assessment by the surgeon are required prior to implantation.<br><br>- Chronic Severe Uveitis<br>- Epithelial Dystrophy<br>- Proliferative Diabetic Retinopathy<br>- Choroidal Haemorrhage<br>- Microphthalmos<br>- Concommitant Severe Eye Disease<br>- Non-age related cataract<br>- Severe or uncontrolled Glaucoma<br>- Rubella associated cataract<br>- Massive Vitreous Loss<br>- Anirida<br>- Sever corneal dystrophy<br>- Eyes with fixed dilated pupils or persistent miotic pupils |
| Shelf Life | 5 Years |
| Packing Contains | • One (1) Sterile Preloaded IOL with Blister pack<br>• One (1) Preloaded Delivery System Includes (One Cartridge & one soft Tipped Injector)<br>• Instruction for use<br>• Patient ID card<br>• Labels |

### 9.5.4 Variant/Model – SUPRAPHOB TORIC – SP TORIC (T3-T9)

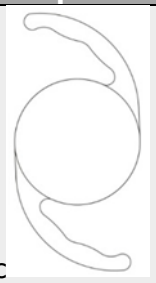
| Parameter | Specification |
|---|---|
| Optic Type | Monofocal |
| Optic Material | Hydrophobic Soft Acrylic – Yellow (Polymer) or Hydrophobic Soft Acrylic – Yellow (Co-polymer of Phenyl ethyl Acrylate (PEA) and Phenyl ethyl Methacrylate (PEMA)). |
| Spectra Transmission (Imaging Quality) | Above 85% |
| Refractive Index | 1.5050 |
| Optic Design | Biconvex |
| Haptic Material | Hydrophobic Soft Acrylic (Polymer) |
| Optic Diameter | 5.75 to 6.50mm(with 0.25 increments) |

| Parameter | Specification |
|---|---|
| Overall Length | 12.50 to 13.50mm(with 0.25 increments) |
| Haptic Angle | 0° |
| "A" Constant | 118.8 |
| Square Edge | 360° |
| Diopter Range | -10.00D to +50.00D in steps of 0.50D |
| Diopter Increment | 0.50D |
| Compatible Lens delivery system | Cartridge 2.8 |
| Sterilization | EO Gas |
| Intended Use | 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. |
| Attributes | Aphakic, Monofocal, Toric |
| Design (one per line)<br>- Single piece or<br>- Three piece or<br>- multi piece | Single piece |
| Design (One per line)<br>- Plate haptic<br>- Loop haptic: C loop, J loop<br>- Plate loop haptic<br>- Other design | C Loop Closed Haptic  |
| Location (One per line)<br>- Capsular bag<br>- Anterior chamber or Posterior chamber<br>- Scleral or Iris or Sulcus Fixated | Capsular bag in posterior chamber |
| Device Intended User | Ophthalmic surgeon |
| Patient Population | Above age of one year (Male or Female) |
| Indications | - Monocular cataract<br>- Mature cataract<br>- Congenital cataract<br>- Binocular Cataract<br>- Refractive lens (exchange) reflex<br>- Immature cataract<br>- Traumatic cataract |
| Caution | Apart from general contraindications applicable to any intraocular surgical procedure, implantation of the intraocular lens should be carefully considered in patients presenting with the following conditions.<br><br>These conditions are not absolute contraindications; however, they may increase the risk of surgical complications, worsen pre-existing ocular conditions, interfere with diagnosis or treatment, or adversely affect visual outcomes. A thorough preoperative evaluation and a careful benefit–risk assessment by the surgeon are required prior to implantation.<br><br>- Chronic Severe Uveitis |

| Parameter | Specification |
|---|---|
| | - Epithelial Dystrophy<br>- Proliferative Diabetic Retinopathy<br>- Choroidal Haemorrhage<br>- Microphthalmos<br>- Concommitant Severe Eye Disease<br>- Non-age related cataract<br>- Severe or uncontrolled Glaucoma<br>- Rubella associated cataract<br>- Massive Vitreous Loss<br>- Anirida<br>- Sever corneal dystrophy<br>- Eyes with fixed dilated pupils or persistent miotic pupils |
| Shelf Life | 5 Years |
| Packing Contains | • One (1) Sterile Preloaded IOL with Blister pack<br>• One (1) Preloaded Delivery System Includes (One Cartridge & one soft Tipped Injector)<br>• Instruction for use<br>• Patient ID card<br>• Labels |

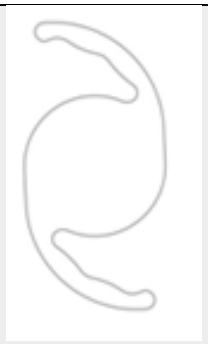
### 9.5.5 Variant/Model – SWISSPHOB - SPH 60130

| Parameter | Specification |
|---|---|
| Optic Type | Monofocal |
| Optic Material | Hydrophobic Soft Acrylic – Yellow (Polymer) or Hydrophobic Soft Acrylic – Yellow (Co-polymer of Phenyl ethyl Acrylate (PEA) and Phenyl ethyl Methacrylate (PEMA)). |
| Spectra Transmission (Imaging Quality) | Above 85% |
| Refractive Index | 1.5050 |
| Optic Design | Biconvex |
| Haptic Material | Hydrophobic Soft Acrylic (Polymer) |
| Optic Diameter | 5.75 to 6.50mm(with 0.25 increments) |
| Overall Length | 12.50 to 13.50mm(with 0.25 increments) |
| Haptic Angle | 0° |
| "A" Constant | 118.8 |
| Square Edge | 360° |
| Diopter Range | -10.00D to +50.00D in steps of 0.50D |
| Diopter Increment | 0.50D |
| Compatible Lens delivery system | Cartridge 2.2 & 2.8 |
| Sterilization | EO Gas |
| Intended Use | 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. |
| Attributes | Aphakic, Monofocal, Aspheric |
| Design (one per line)<br>- Single piece or<br>- Three piece or<br>- multi piece | Single piece |

| Parameter | Specification |
|---|---|
| Design (One per line)<br>- Plate haptic<br>- Loop haptic: C loop, J loop<br>- Plate loop haptic<br>- Other design |  <br>C Loop Closed Haptic |
| Location (One per line)<br>- Capsular bag<br>- Anterior chamber or Posterior chamber<br>- Scleral or Iris or Sulcus Fixated | Capsular bag in posterior chamber |
| Device Intended User | Ophthalmic surgeon |
| Patient Population | Above age of one year (Male or Female) |
| Indications | - Monocular cataract<br>- Mature cataract<br>- Congenital cataract<br>- Binocular Cataract<br>- Refractive lens (exchange) reflex<br>- Immature cataract<br>- Traumatic cataract |
| Caution | Apart from general contraindications applicable to any intraocular surgical procedure, implantation of the intraocular lens should be carefully considered in patients presenting with the following conditions.<br><br>These conditions are not absolute contraindications; however, they may increase the risk of surgical complications, worsen pre-existing ocular conditions, interfere with diagnosis or treatment, or adversely affect visual outcomes. A thorough preoperative evaluation and a careful benefit–risk assessment by the surgeon are required prior to implantation.<br><br>- Chronic Severe Uveitis<br>- Epithelial Dystrophy<br>- Proliferative Diabetic Retinopathy<br>- Choroidal Haemorrhage<br>- Microphthalmos<br>- Concommitant Severe Eye Disease<br>- Non-age related cataract<br>- Severe or uncontrolled Glaucoma<br>- Rubella associated cataract<br>- Massive Vitreous Loss<br>- Anirida<br>- Sever corneal dystrophy<br>- Eyes with fixed dilated pupils or persistent miotic pupils |
| Shelf Life | 5 Years |
| Packing Contains | • One (1) Sterile Preloaded IOL with Blister pack<br>• One (1) Preloaded Delivery System Includes (One Cartridge & one soft Tipped Injector)<br>• Instruction for use |

| Parameter | Specification |
|---|---|
| | • Patient ID card<br>• Labels |

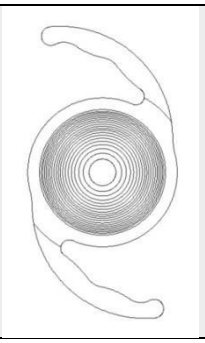
### 9.5.6 Variant/Model – SUPRAPHOB INFOCUS – SP INFO

| Parameter | Specification |
|---|---|
| Optic Type | Multifocal |
| Optic Material | Hydrophobic Soft Acrylic – Yellow (Polymer) or Hydrophobic Soft Acrylic – Yellow (Co-polymer of Phenyl ethyl Acrylate (PEA) and Phenyl ethyl Methacrylate (PEMA)). |
| Spectra Transmission (Imaging Quality) | Above 85% |
| Refractive Index | 1.5050 |
| Optic Design | Biconvex |
| Haptic Material | Hydrophobic Soft Acrylic (Polymer) |
| Optic Diameter | 5.75 to 6.50mm(with 0.25 increments) |
| Overall Length | 12.50 to 13.50mm(with 0.25 increments) |
| Haptic Angle | 0° |
| "A" Constant | 118.8 |
| Square Edge | 360° |
| Diopter Range | -10.00D to +50.00D in steps of 0.50D |
| Diopter Increment | 0.50D |
| Compatible Lens delivery system | Cartridge 2.2 & 2.8 |
| Sterilization | EO Gas |
| Intended Use | 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. |
| Attributes | Aphakic, Multifocal, Aspheric |
| Design (one per line)<br>- Single piece or<br>- Three piece or<br>- multi piece | Single piece |
| Design (One per line)<br>- Plate haptic<br>- Loop haptic: C loop, J loop<br>- Plate loop haptic<br>- Other design |  <br>C Loop Closed Haptic |
| Location (One per line)<br>- Capsular bag<br>- Anterior chamber or Posterior chamber<br>- Scleral or Iris or Sulcus Fixated | Capsular bag in posterior chamber |
| Device Intended User | Ophthalmic surgeon |
| Patient Population | Above age of one year (Male or Female) |
| Indications | - Monocular cataract<br>- Mature cataract |

| Parameter | Specification |
|---|---|
| | - Congenital cataract<br>- Binocular Cataract<br>- Refractive lens (exchange) reflex<br>- Immature cataract<br>- Traumatic cataract |
| Caution | Apart from general contraindications applicable to any intraocular surgical procedure, implantation of the intraocular lens should be carefully considered in patients presenting with the following conditions.<br><br>These conditions are not absolute contraindications; however, they may increase the risk of surgical complications, worsen pre-existing ocular conditions, interfere with diagnosis or treatment, or adversely affect visual outcomes. A thorough preoperative evaluation and a careful benefit–risk assessment by the surgeon are required prior to implantation.<br><br>- Chronic Severe Uveitis<br>- Epithelial Dystrophy<br>- Proliferative Diabetic Retinopathy<br>- Choroidal Haemorrhage<br>- Microphthalmos<br>- Concommitant Severe Eye Disease<br>- Non-age related cataract<br>- Severe or uncontrolled Glaucoma<br>- Rubella associated cataract<br>- Massive Vitreous Loss<br>- Anirida<br>- Sever corneal dystrophy<br>- Eyes with fixed dilated pupils or persistent miotic pupils |
| Shelf Life | 5 Years |
| Packing Contains | • One (1) Sterile Preloaded IOL with Blister pack<br>• One (1) Preloaded Delivery System Includes (One Cartridge & one soft Tipped Injector)<br>• Instruction for use<br>• Patient ID card<br>• Labels |

### 9.5.7 Variant/Model – SUPRAPHOB REGEN – SPMFDY 200

| Parameter | Specification |
|---|---|
| Optic Type | Multifocal |
| Optic Material | Hydrophobic Soft Acrylic – Yellow (Polymer) or Hydrophobic Soft Acrylic – Yellow (Co-polymer of Phenyl ethyl Acrylate (PEA) and Phenyl ethyl Methacrylate (PEMA)). |
| Spectra Transmission (Imaging Quality) | Above 85% |
| Refractive Index | 1.5050 |
| Optic Design | Biconvex |
| Haptic Material | Hydrophobic Soft Acrylic (Polymer) |
| Optic Diameter | 5.75 to 6.50mm(with 0.25 increments) |
| Overall Length | 12.50 to 13.50mm(with 0.25 increments) |

| Parameter | Specification |
|---|---|
| Haptic Angle | 0° |
| "A" Constant | 118.8 |
| Square Edge | 360° |
| Diopter Range | 0.00 D to 35.00 D in steps of 0.50D Additional Power 3.50D |
| Diopter Increment | 0.50D |
| Compatible Lens delivery system | Cartridge 2.8 |
| Sterilization | EO Gas |
| Intended Use | 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. |
| Attributes | Aphakic, Multifocal, Aspheric |
| Design (one per line)<br>- Single piece or<br>- Three piece or<br>- multi piece | Single piece |
| Design (One per line)<br>- Plate haptic<br>- Loop haptic: C loop, J loop<br>- Plate loop haptic<br>- Other design | C Loop Closed Haptic  |
| Location (One per line)<br>- Capsular bag<br>- Anterior chamber or Posterior chamber<br>- Scleral or Iris or Sulcus Fixated | Capsular bag in posterior chamber |
| Device Intended User | Ophthalmic surgeon |
| Patient Population | Above age of one year (Male or Female) |
| Indications | - Monocular cataract<br>- Mature cataract<br>- Congenital cataract<br>- Binocular Cataract<br>- Refractive lens (exchange) reflex<br>- Immature cataract<br>- Traumatic cataract |
| Caution | Apart from general contraindications applicable to any intraocular surgical procedure, implantation of the intraocular lens should be carefully considered in patients presenting with the following conditions.<br><br>These conditions are not absolute contraindications; however, they may increase the risk of surgical complications, worsen pre-existing ocular conditions, interfere with diagnosis or treatment, or adversely affect visual outcomes. A thorough preoperative evaluation and a careful benefit–risk assessment by the surgeon are required prior to implantation. |

| Parameter | Specification |
|---|---|
| | - Chronic Severe Uveitis<br>- Epithelial Dystrophy<br>- Proliferative Diabetic Retinopathy<br>- Choroidal Haemorrhage<br>- Microphthalmos<br>- Concommitant Severe Eye Disease<br>- Non-age related cataract<br>- Severe or uncontrolled Glaucoma<br>- Rubella associated cataract<br>- Massive Vitreous Loss<br>- Anirida<br>- Sever corneal dystrophy<br>- Eyes with fixed dilated pupils or persistent miotic pupils |
| Shelf Life | 5 Years |
| Packing Contains | • One (1) Sterile Preloaded IOL with Blister pack<br>• One (1) Preloaded Delivery System Includes (One Cartridge & one soft Tipped Injector)<br>• Instruction for use<br>• Patient ID card<br>• Labels |

## 10.0 Revision history

| SSCP Rev. No. | Date Issued | Change description | Rev. Validated by the NB |
|---|---|---|---|
| **01** | 03.03.2025 | Initial Release | ☐ Yes<br>Validation language: English<br>☐ No |
| **02** | 03.04.2026 | New Brand "Spheriphob" Included | ☐ Yes<br>Validation language: English<br>☐ No |
| **03** | 29.06.2026 | Updated section 3.2, 3.3, 4.1.3, 7, 9.5 | ☐ Yes<br>Validation language: English<br>☐ No |