PODS49P
English

Marketing name	Commercial name	Technical name	Optic	/	Spherical power at IOL plane	/	Overall diameter	Optic diameter	EMDN code
ISOPURE SERENITY	PODS49P	PODS49P	Aspheric enhanced monofocal	/	+10D to +35D Diopter increments: 0.5D increment [from +10.0D to +30.0D]; 1.0D increment [from +31.0D to +35.0D]	/	11.40 mm	6.0 mm	P030102090201 (IOLs, APHAKIC, MONOFOCAL, ASPHERICAL, HYDROPHOBIC ACRYLIC)

1 Manufacturer

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Approved body : (BSI) UKCA 0086

2 Device description

2.1 General :

The subject intraocular lenses (IOL) are precision optical devices made from an acrylic copolymer.
The acrylic lenses are intended for implantation in the capsular bag after opening of the capsule by capsulotomy and should replace the optical function of the cataractous natural crystalline lens.
The enhanced monofocal intraocular lenses are intended to improve distant vision, potentially improve the depth of focus from far to intermediate vision and reduce the spectacle dependence as well.
They have optics with an aspheric refractive polynomial design.

2.2 Raw material

The intraocular lens is 100% composed of the covalently crosslinked medical quality (GFY), which is a (2-hydroxyethylmethacrylate; phenoxy ethylacrylate; polypropylene glycol dimethacrylate) copolymer, including a UV and a blue light-filtering chromophores covalently bound to the material.
The exhaustive chemical studies do not reveal any extractable or leachable substances at concentrations above the threshold of toxicological concern, in terms of protracted exposure, for a device intended for long term implantation.
An intraocular lens of +20.0 diopter transmits < 34% at 400 nm and < 72% at 450 nm
The spectral transmittance of such lens is provided in Figure 1.
The refractive index is 1.53.
The material GFY demonstrated optimal safety in terms of in vitro and in vivo (animal models) physical-chemical, biological and shelf-life stability properties.

The implant presents no specific interactions with surrounding electrical systems, such as Magnetic Resonance Imaging technology.
PhysIOL lenses do not include any of the following:
- Medicinal substances, including a human blood or plasma derivative;
- Tissues or cells or their derivatives, of human origin;
- Tissues or cells or their derivatives, of animal origin.

The lifetime of PODS49P is 20 years.

2.3 Haptic design

The PODS49P device is a foldable intraocular lens with an open Double-C-loop (POD) design.

2.4 Packaging/Sterilization

The device is steam sterilized and supplied in polypropylene container with saline solution.
The container is protected by a polypropylene blister-Tyvek pack as sterile packaging, with an indicator of its sterile state.
Should any part of the packaging be damaged, do not use the device and send it back to the supplier.
The expiration date is indicated on the outside of the lens package.
Do not use the IOL after its expiration date.

2.5 Clinical benefits to be expected

Main safety and performance benefits of PODS49P, as per the clinical evidence collected by the manufacturer, may include:
- Improvement in quantitative visual acuity, including increase in corrected and uncorrected distance visual acuity.
- Restoration of quality of life after cataract removal.
- Predictable refractive outcomes in respect to target refraction
- Useful distance-corrected and uncorrected intermediate visual acuity

2.6 Links to the summary of safety and clinical performance

The summary of safety and clinical performance pertaining to this product is available on EUDAMED
(https://ec.europa.eu/tools/eudamed/#/screen/home)

3 Intended use of the device

3.1 Intended use

The posterior chamber intraocular lens is intended to be placed into the capsular bag with an anterior capsulorhexis for the replacement of the human lens to achieve the visual correction of aphakia in adult patients in whom the cataractous lens has been removed.

3.2 Indication for use

The lens should be used as intended in adult patients, surgically treated for cataract, with possibly associated presbyopia, who desire improved uncorrected far vision, and an extended depth of focus from distance to intermediate, with reduced spectacle dependence.

3.3 Intended users

The lens must be implanted by a skilled health care professional qualified in this type of surgery.
As part of the risk analysis related to the product, the end user is an ophthalmic surgeon, trained and operating according to the current clinical practices.

4 Disclaimer of liability

PhysIOL shall not be liable for any injury or damage suffered by a patient as a result of:
- Improper prescription or model selection,
- Improper device handling,

- Surgical technique applied,
- Any iatrogenic error caused by the implanting surgeon,
- Off-label use of the product,
- Use of expired devices
- Improper compliance to the information contained in this IFU.

PhysIOL makes no expressed or implied warranties in connection with the resale of its intraocular lenses. The user should properly follow those instructions for use as a general recommendation.

5 Use of the device

5.1 IOL power calculation

The power of the implanted IOL for each patient can be calculated from the corneal radius, the axial length of the eye, and the A-constant specified for the lens according to formulas in the literature.
Users (surgeons) may further optimise their own A-constant to adapt it to their own surgical technique.
The labelled indicative Interferometry SRK/T A-constant value is given on the outer box.

5.2 Handling

Examine the unopened box for proper model, power and expiration date.
Check if the information on the carton box label is consistent with the information present on the secondary blister and self-adhesive labels (e.g. model, power and serial number).
Remove the sterilized secondary blister containing the IOL container, peel the secondary blister, open and place the IOL container to a sterile environment.
Check to ensure there are no leaks.
Open the container and take the holder with the IOL out of the sterile storage solution.
Always keep the lens holder horizontal, to prevent the IOL from falling.
Handle with care and do not use excessive force when taking the IOL out of the holder.
All manipulations required for implantation must be performed using non-toothed forceps and polished instruments, especially when the IOL is folded prior to insertion.
The lens must be rinsed with balanced salt solution (BSS) before implantation.
After implantation, carefully eliminate any viscoelastic residues from the bag by aspiration, especially between the IOL and the posterior capsule.

5.3 Injection system and viscoelastic solution (accessories not included within but required to be used in combination with the intraocular lens during cataract surgery)

The Medicel Accuject injection systems are recommended for implanting the ISOPURE lenses
The Medicel Accuject 2.0 should be used for lenses up to +24.5D and Medicel Accuject 2.1 / 2.2 is to be used for the full range.
Instruction for use regarding the hereabove items are provided together with the injection system.
The incision size depends on the surgical technique and is the decision of the surgeon.
Basic instruction for connecting the device to the insertion system:
(1) Apply viscoelastic into the tip and the loading chamber of the injector cartridge.
(2) Position the lens into the cartridge in such way that both haptics with the notches are pointing at 1 and 7 o'clock (see Figure 2).
(3) Exert slight pressure onto the lens optic and make sure that all haptics are inside before further closing the cartridge.
(4) Close the cartridge and check the position of the lens. Once the "click-lock" mechanism engages, the lens is securely loaded.
(5) Engage the injector plunger in the cartridge chamber.
(6) Press the injector plunger forward and push the lens into the conical tip of the cartridge.
Pull the plunger back a few millimetres to verify if the haptics are captured and then inject the lens in one continuous slow motion.
Before withdrawing the injector tip from the incision, gently release the plunger in order to retract the silicone cushion back into the cartridge.
Best surgical practices should be considered for loading the lens, depositing the viscoelastic solution, handling the connection system and injecting the lens.
NOTES:
- Check compatibility indicated on information supplied with the injector of choice prior to use.
PhysIOL makes no warranty regarding the use of other products not mentioned in this IFU.
- The viscoelastic solution used should be based on sodium hyaluronate.

5.4 Safe disposal of the device, its accessories and the consumables

Accessories, consumables and device packaging related to the surgery should be discarded according to regional requirements or hospital recommendations for biohazardous waste.

6 Precautions, warnings and recommendations

6.1 Precautions for storage and handling conditions

- Do not store at a temperature over 45°C or below 2°C.
- The device is SINGLE-USE ONLY: DO NOT RE-USE.
To avoid any risk of cross contamination this device must only be used for one single patient.
- DO NOT RESTERILIZE.
- Devices should not be used past the expiration date.
- Do not use an implant from a damaged package.
- After opening of the sterile package the lens needs to be used in a short time.
- To minimize the occurrence of marks on the implant due to folding, all instrumentation should be scrupulously clean.
-The lens may absorb substances with which it comes in contact (disinfectant, medicine, conservative agents).
Always rinse the implant in a sterile physiologic solution prior to use.

If the implant is prepared for implanting but is not finally used or if the package is damaged, send the lens back to your supplier.
Return the lens in a humid environment in its original package, indicating the serial number, the power and your reference.
- The lens is to be implanted with the anterior side of the lens facing up towards the anterior side of the eye.
The orientation of the IOL can be verified by visual inspection of the haptics.
As illustrated (figure 2), when the orientation haptic features are top right B and bottom left A, you are looking at the anterior side of the lens.
- No data is available for the combined use of any type of supplementary lens in patients already implanted with PhysIOL's posterior chamber intraocular lens.
- No clinical safety and performance data is available for the device implanted in patients with congenital bilateral cataracts or with only one eye with potentially good vision, or in pregnant or breast-feeding women, or in paediatric patients.
Therefore, the use of the device was not evaluated in these populations.
The device is not intended for use in these patient populations.

6.2 Recommendations

- It is recommended emmetropia be targeted for optimum visual performance.
- Care should be taken to achieve lens centration, as lens decentration may result in a patient experiencing decrease of visual quality under certain lighting conditions.
- Prior to surgery, the surgeon must inform prospective patients of the possible risks and benefits associated with the use of this device and provide a copy of the patient information brochure to the patient.

Operative Recommendations:
- When the lens is injected in the capsular bag, remove all viscoelastic material behind and in front of the lens using I/A cannula.
- With a syringe filled with BSS solution, test the watertight self-sealing of the incisions and ensure that the normal intraocular pressure is recovered.
- Gently push the lens towards the posterior capsule with the micromanipulator.
- Check again that the incision is watertight.
- Carefully remove the eyelid speculum.

Specific warning
Care in patient selection should be made in the choice of the polynomial technology (enhanced monofocal).
Previous corneal intervention underwent by the patient and possibly causing corneal aberrations could impair the final optical outcomes of the IOL.
NOTE: Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority.

7 Contraindications

1. Pre-existing pathology or physiology which may be aggravated by the implant or where the implant may interfere with the possibility of examining or treating disease:
- Chronic uveitis
- Progressive eye disease (diabetic retinopathy, uncontrolled glaucoma)
- Corneal endothelial dystrophy
- Recurrent anterior or posterior segment inflammation of unknown etiology
- Extremely shallow anterior chamber.
- Patients in whom the intraocular lens may interfere with the ability to observe, diagnose or treat posterior segment diseases
- A compromised eye due to previous trauma or developmental defects in which appropriate support of the IOL is not possible
- Suspected microbial infection
- Patients in whom neither the posterior capsule nor zonules are intact enough to provide support for the IOL
- Previous history of, or a predisposition to, retinal detachment

2. Severe complications during surgery:
- Significant vitreous loss
- Persistent bleeding
- Insufficient capsular support
- Significant iris damage
- Uncontrolled positive intraocular pressure
- Circumstance that would result in damage to the endothelium during implantation
3. Patients with significant preoperative (determined by keratometry) or expected post-operative astigmatism >1.0D may not achieve optimal visual outcomes.

8 Anticipated Side Effects

8.1 General

As with any surgical procedure, potential side effect accompanying cataract or implant surgery
may include but are not limited to the following:
- Ocular infection (endophtalmitis, microbial keratitis)
- Inflammatory reaction (e.g. uveitis, Toxic Anterior Segment Syndrome (TASS), hypopyon)
- Anterior Capsular Contraction Syndrome (ACCS, Phimosis)
- Corneal edema
- Corneal endothelial damage
- Cystoid Macular Edema (CME)
- Secondary surgical intervention (include, but are not limited to: lens repositioning, lens replacement, vitreous aspiration, iridectomy for pupillary block, wound leak repair, and retinal detachment repair)
- IOL Dislocation, Tilt, decentration, luxation, rotation
- Elevated intraocular pressure
- Pupillary block
- Posterior capsular opacification (PCO)
- Chromatic aberrations
- Dysphotopsia
- Loss of visual acuity
- Deviation from target refraction
- Hyphema
- Retinal detachment
- Iris or pupil damage
- Posterior capsular rupture
- Vitreous loss
- Wound leak (positive Seidel)

9 Patient information

The information relative to possible side effects should be reported to the patient.
Also, a patient international implant card is included in the package and must be completed as it is intended to be kept by the patient.
The patient must be made aware of (1) the adequate instructions to keep this card as a permanent record of the implant and (2) the need to show this card to any eye care professional seen in future.
This card provides the link to the manufacturing website on which the patient can find information regarding any warnings, precautions, contra- indications, measures to be taken and limitations of use.

10 Symbols and abbreviations used on packaging

Intraocular lens

Hydrophobic Acrylic Material with UV and Blue Light Filter (GFY)


Manufacturer


Date of manufacture

Country of Manufacture: Belgium


Use-by date

Batch code

Serial number

Sterilized using steam


Do not resterilize


Do not use if package is damaged


Keep away from sunlight

Temperature limit


Do not re-use


Consult electronic instructions for use
https://ifu.bvimedical.com


Caution

Medical Device

PODS49P
English

UDI	Unique Device Identifier
	Double sterile barriers
∅B	Optic body diameter
∅T	Total lens diameter
CE 2797	CE mark
UK CA 0086	UKCA mark
	Keep dry
	Capsular fixation

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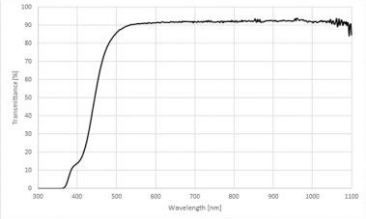
Figures

Spectral transmittance Curve – Figure 1



Orientation of the double-C-loop (POD) haptics – Figure 2