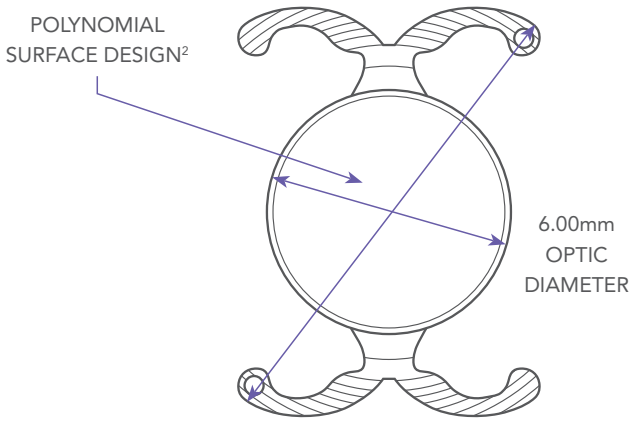
ISOPURE SERENITY

Premium Monofocal Hydrophobic



Description

Model	ISOPURE SERENITY	
Material	GFY Hydrophobic Acrylic[1]	
Overall diameter	11.40mm	
Optic diameter	6.00mm	
Optic	Polynomial Surface Design	
Haptic design	Double C-Loop with Ridgetech® & Posterior Angulated Haptic	
Filtration	UV & Blue Light	
Refractive index	1.53	
Abbe number	42	
Injection system	Medicel Accuject 2.1 / 2.2	
Spherical power[5]	+10D to +30D (0.5D steps) +31D to +35D (1D steps)	
Suggested A constant[3]		**Interferometry**
	Hoffer Q: pACD	5.85
	Holladay 1: Sf	2.06
	Barrett: LF	2.09
	SRK/T: A	119.40
	Haigis[4]: a0; a1; a2	1.70; 0.4; 0.1

[1] The BVI GFY® is patented since 2010.

[2] The ISOFOCAL Polynomial Surface Design has been patented since 2020

[3] Values estimated only: surgeons are recommended to personalize their A-constant based on their surgical techniques and equipment, experience with the lens model and postoperative results.

[4] Not optimized.

[5] Please check the availability of spherical powers with your sales representative.

Note: The ISOPURE SERENITY intraocular lens is not FDA approved.

Contact Information:
www.bvimedical.com/customer-support/

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Product Information

Manufacturer	PhysIOL s.a. - Liège Science Park Allée des Noisetiers 4 B-4031 Belgium +32 4 361 05 49 physiol@bvimedical.com
Certificate information	CE (EU) 2017/745, Annex IX Chapter II : MDR 735732 R000 QMS (EU) 2017/745, Annex IX Chapter I and III : MDR 735719 R000 ISO 13485:2016 & EN ISO 13485:2016 : MD 658518 ISO 13485:2016 : MDSAP 691544
Shelf life	Five (5) years from the manufacturing date
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.
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.
Product Composition	No products of animal or human origin are present in the implant. The intraocular lens is 100% composed of the covalently crosslinked proprietary material of 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.
Sterility	All IOLs from PhysIOL are steam sterilized
Packaging Material	Holder (Polypropylene) Container (Polypropylene) Storage liquid (0.9% NaCl solution) Aluminium lid (Aluminium Gold) Container label (paper) Blister PP (Polypropylene) Tyvek lid
Product Class	Classified as Class IIb implantable long-term surgically invasive medical devices under Rule 8 of Annex VIII of the MDR 2017/745. Not available in the United States

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