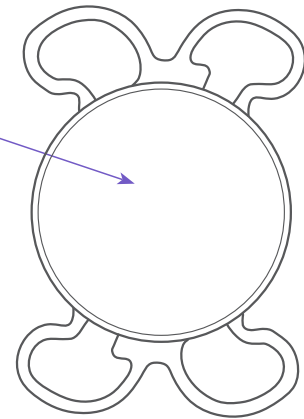


ISOPURE 123

Premium
Monofocal
Hydrophobic
Preloaded

POLYNOMIAL
SURFACE DESIGN⁵



Description

Model	ISOPURE 123	
Material	GFY Hydrophobic Acrylic ¹	
Overall diameter	10D to 24.5D: 11.00mm - 25D to 30D: 10.75mm	
Optic diameter	10D to 24.5D: 6.00mm - 25D to 30D: 5.75mm	
Optic	Polynomial Surface Design	
Haptic design	Micro (4-closed loops) & Posterior Angulated Haptic	
Filtration	UV & Blue Light	
Refractive index	1.53	
Abbe number	42	
Injection system	1.2.3 Premium	
Spherical power	+10D to +30D (0.5D steps) Cartridge with PRS [®] technology ²	
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
	ISOPURE	
Overall diameter	10.75mm	
Optic diameter	5.75mm	
Injection system	Medicel Accuject 2.0 / 2.1 / 2.2mm	
Spherical power	+31D to +35D (1D steps)	

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

² The PRS technology is patent pending.

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 Patent pending.

Note: The ISOPURE 123 intraocular lens is not FDA approved.

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: Certificate N° CE658516 ISO 13485:2016: Certificate N° MD658518 MDSAP: Certificate N° MDSAP 691544
Shelf life	Three (3) years from manufacturing date for IsoPure 123 Five (5) years from manufacturing date for ISOPURE
Intended Use	Intended use (for all IOLs): The posterior chamber intraocular lens which is intended to be placed into the capsular bag 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 by extracapsular cataract extraction.
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, with reduced spectacle dependence.
Product Composition	No products of animal or human origin are present in the implant. The implant is made of the GFY material proprietary to PhysIOL. It is composed of an acrylate copolymer Ethylene Glycol Phenyl Ether Acrylate (2-Phenoxyethyl Acrylate) (EGPEA) and 2 Hydroxyethyl Methacrylate (HEMA) including a UV light filter and a blue light filter
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	MDD Class IIb Sterile, According to European Medical Device Directive 93/42/EEC Not available in the United States

