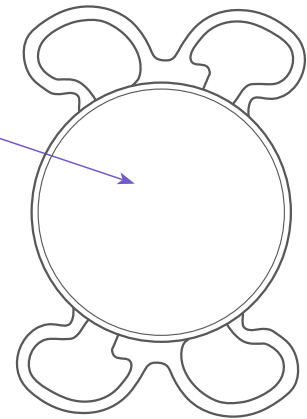


# ISOPURE

Premium  
Monofocal  
Hydrophobic

POLYNOMIAL  
SURFACE DESIGN<sup>4</sup>



## Description

Model	ISOPURE	
Material	GFY Hydrophobic Acrylic <sup>1</sup>	
Overall diameter	10D to 24.5D: 11.00mm - 25D to 35D: 10.75mm	
Optic diameter	10D to 24.5D: 6.00mm - 25D to 35D: 5.75mm	
Optic	Polynomial Surface Design	
Haptic design	MICRO (closed loop quadripode) & Posterior Angulated Haptic	
Filtration	UV & Blue Light	
Refractive index	1.53	
Abbe number	42	
Injection system	Medicel Accuject 1.8 up to 24.5D Medicel Accuject 2.0/2.1/2.2 up to 35D	
Spherical power	+10D to +30D (0.5D steps) +31D to +35D (1D steps)	
Suggested A constant <sup>2</sup>		<b>Interferometry</b>
	Hoffer Q: pACD	5.85
	Holladay 1: Sf	2.06
	Barrett: LF	2.09
	SRK/T: A	119.40
	Haigis <sup>3</sup> : a0; a1; a2	1.70; 0.4; 0.1

<sup>1</sup> The PhysIOL GFY<sup>®</sup> is patented since 2010.

<sup>2</sup> 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.

<sup>3</sup> Not optimized.

<sup>4</sup> Patent pending.

Note: The ISOPURE intraocular lens is not FDA approved.

## Product Information

<b>Manufacturer</b>	PhysIOL s.a. - Liège Science Park Allée des Noisetiers 4 B-4031 Belgium +32 4 361 05 49 physiol@bvimedical.com
<b>Certificate information</b>	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
<b>Shelf life</b>	Five (5) years from manufacturing date for ISOPURE
<b>Intended Use</b>	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.
<b>Indication for use</b>	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.
<b>Product Composition</b>	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.
<b>Sterility</b>	All IOLs from PhysIOL are steam sterilized
<b>Packaging Material</b>	Holder (Polypropylene) Container (Polypropylene) Storage liquid (0.9% NaCl solution) Aluminium lid (Aluminium Gold) Container label (paper) Blister PP (Polypropylene) Tyvek lid
<b>Product Class</b>	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

