BVI

ISOPURE

Premium Monofocal IOL

UNCOMPROMISED

EXTENDED

SIMPLIFIED

PhysIOL | ISOPURE

bvimedical.com

ISOPURE®

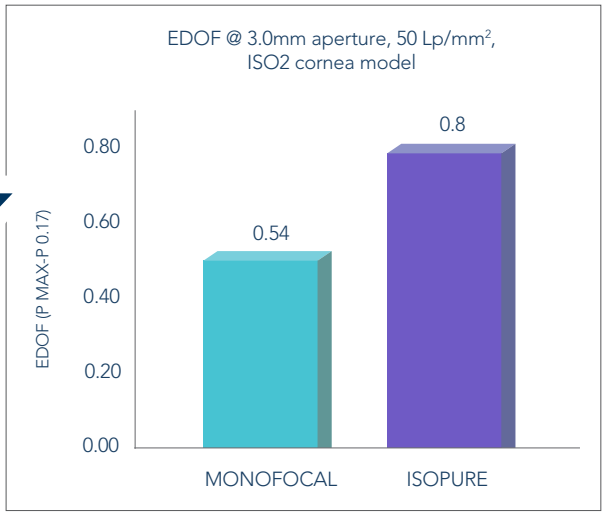
ISOPURE is a premium IOL suitable for cataract patients designed to provide functional intermediate vision, in different conditions, without compromising quality of vision - with the simplicity of a monofocal IOL.

The PhysIOL® ISOPURE Lens

ISOPURE is a non-diffractive aspherical lens based on a unique technology. ISOPURE is designed to provide cataract patients high far vision quality, combined with functional intermediate vision by accentuating the extended depth of focus effect without inducing photic phenomena.

ISOPURE Technology

To achieve extended depth of focus[3] performance, ISOPURE shows a unique design surface due to its unique polynomial[4] technology.



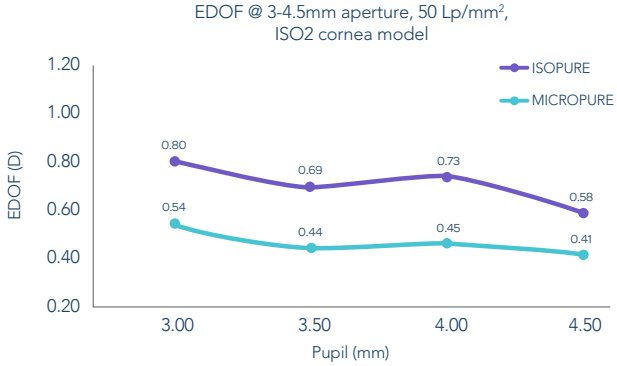
What do the studies say?

On the optical bench[5], the ISOPURE tends to achieve around 1 diopter of depth of focus. This represents an increase of around 50% compared to a standard aspheric monofocal IOL (MICROPURE).

Reference: Data available at PhysIOL.

Pupil Variation

At different conditions, ISOPURE provides a larger depth of focus compared to a monofocal lens.



Data available at PhysIOL.

[1] CoC is used in photography to dermine the depth of focus of an image that is acceptably sharp.

[2] Measurement on optical bench equipped with the ISO2 cornea model which fulfills ISO 11979-2 with 0.28 µm spherical aberrations @ 5.15 mm aperture and IOL plane.

[3] Extended depth of focus is defined as the power add-in diopter from the MTF peak (best focus) to MTF value of 0.17 at 50 Lp/mm (internal PhysIOL criterium).

[4] Patent pending

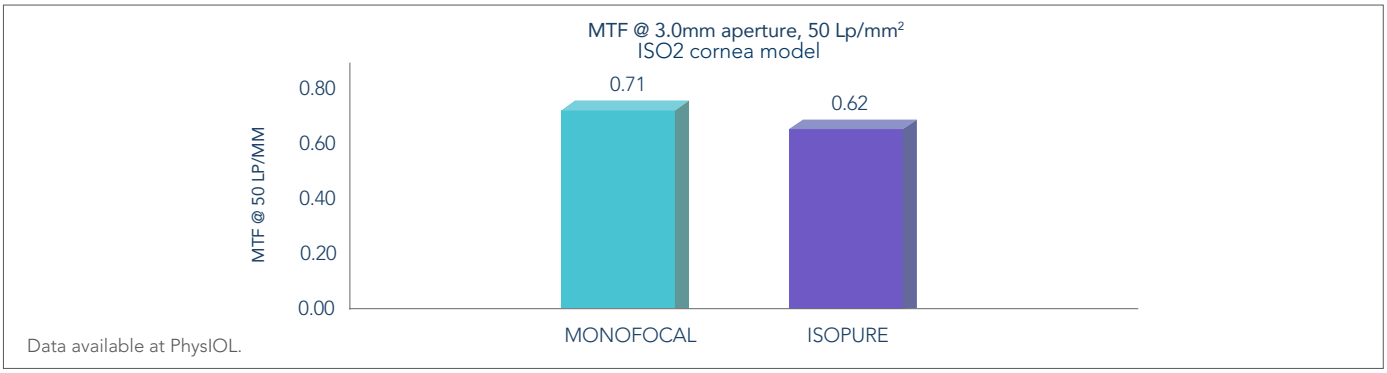
[5] The corneal model to fulfill the ISO 11979-1 guidelines specifications C3 with 0.28mm SA at 5.15mm aperture IOL plane will mimic the average human cornea.

Simplified: Photic Phenomena

Due to the combination of its non-diffractive design and the unique polynomial technology, the ISOPURE optic has been designed to provide a low incidence of halos, glares or starbursts and comparable to a monofocal lens.

Uncompromised: Quality of Vision

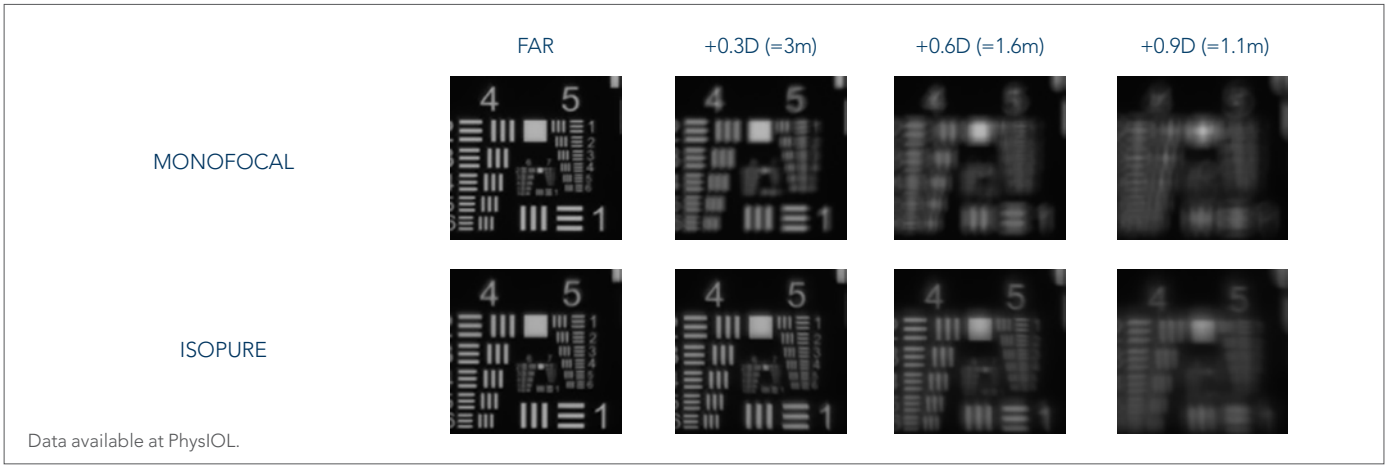
ISOPURE benefits from a unique aspheric design on the anterior and posterior surface. Optical bench demonstrates comparable contrast sensitivity to a monofocal lens (ISO2 cornea model).



Data available at PhysIOL.

Extended: USAF Resolution Target

A model eye bench simulator viewing USAF 1951 target charts demonstrates below the optimal image quality for ISOPURE at far distance to an intermediate vision compared with monofocal aspheric lens.



Data available at PhysIOL.

10 years proven technology

- G-free® (GFY) is the glistening-free hydrophobic material by PhysIOL patented since 2010.
- Proven micro platform stability and long-term safety.
- Preloaded injection system PhysIOL 1.2.3

PhysIOL | ISOPURE

Technical Specifications

Commercial name	ISOPURE 123		
Material	PhysIOL G-free® (GFY) (hydrophobic acrylic glistening-free[1])		
Overall diameter	10D to 24.5D: 11.00 mm - 25D to 30D: 10.75 mm		
Optic diameter	10D to 24.5D: 6.00 mm - 25D to 30D: 5.75 mm		
Optic	Polynomial surface design		
Filtration	UV & blue light		
Refractive index	1.52		
Abbe number	42		
Injection system	PhysIOL 1.2.3		
Incision size	≥ 2.2 mm		
Spherical power	10D to 30D (0.5D steps) Cartridge with PRS® technology[2]		
Square edge	360°		
Nominal manufacturer A constant	119.40		
Suggested A constant[3]		**Interferometry**	**Ultrasound**
	Hoffer Q: pACD	5.85	5.59
	Holladay 1: Sf	2.06	1.80
	Barrett: LF	2.09	-
	SRK/T: A	119.40	119.05
	Haigis[4]: a0; a1; a2	1.70; 0.4; 0.1	1.214; 0.4; 0.1
	ISOPURE (non-preloaded)		
Overall diameter	10.75 mm		
Optic diameter	5.75 mm		
Injection system	Medicel Accuject 2.0/2.1/2.2		
Spherical power	31D to 35D (1D steps)		

[1] The PhysIOL G-free® (GFY) is patented since 2010. Chassain C, *J Fr Ophthalmol* 2018, 41(6):513-520. [2] The PRS® technology is patent pending. [3] Estimates only: surgeons are recommended to use their own values based upon their personal experience. Refer to our website for updates. [4] Not optimized.

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 - ISO 9001:2015: Certificate N° FM 658519
Shelf life	Five (5) years from manufacturing date for ISOPURE (non-preloaded) Three (3) years from manufacturing date for ISOPURE 123
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

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

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