PhysIOL | ISOPURE 123

Premium
Monofocal
Hydrophobic
Preloaded

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.

Contact Information:
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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: 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

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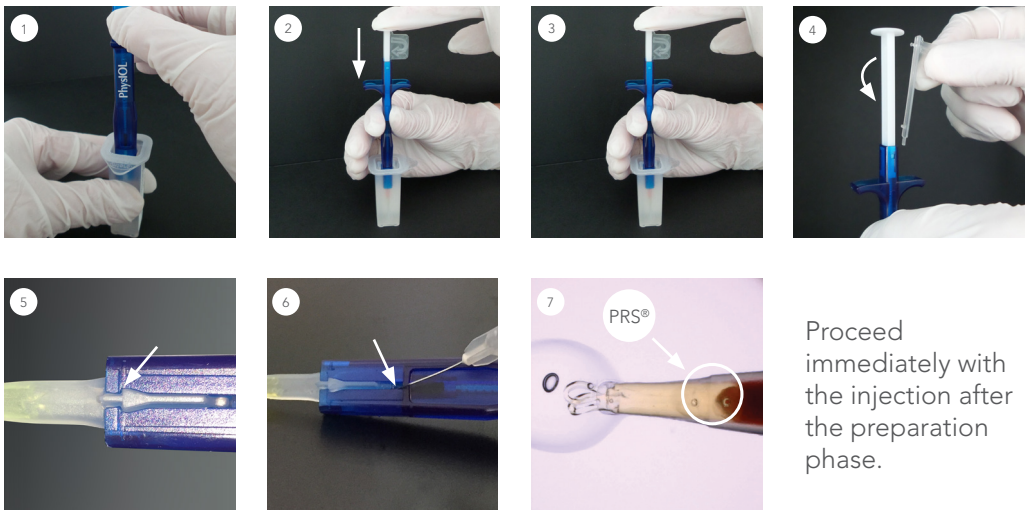
Single-Use Injector 1.2.3. Premium

For 2.2-2.4 mm Incisions with PRS® (Pressure Release System) Technology

The ISOPURE 123 lens is delivered preloaded in a cartridge, which is simply clipped to the Single-Use Injector 1.2.3. Premium.

The Single-Use Injector 1.2.3. Premium requires no lens handling which ensures perfect control of asepsis and makes lens injection comfortable and reproducible. Additionally the unique PRS® technology offers an extremely smooth injection in combination with a significant decrease of pressure on the incision.



Proceed immediately with the injection after the preparation phase.

Injection Guidelines

1. Connect the injector vertically onto the preloaded cartridge until you hear the "clip" indicating that both elements have been firmly and adequately locked. If you do not hear the "clip", there is a possibility that the connection of both elements could not be secured. In the event you do not hear the "clip", first remove the assembled device from the container. Secondly, vertically place the assembled device into the container and proceed once again to the "clipping".
2. Push the plunger completely down towards the safety catch and...
3. ... keep the plunger in this position for 3 seconds. This ensures the lens is securely loaded in the cartridge. Then, gently release the plunger.
4. Remove the safety catch by a twist motion.
5. Remove the assembled system from the container and check that the cartridge is properly locked onto the injector. The non-return safety clip of the cartridge should be located just behind both lateral marks of the injector body, as illustrated in the above picture.
6. Rinse the IOL with Balanced Salt Solution (BSS) by introducing the cannula of the Balanced Salt Solution (BSS) syringe into the small hole on the body of the injector, and then inject a generous amount of ophthalmic viscoelastic device (OVD)[1] into the same hole.
7. Push the plunger for injection. When the first two haptics are out of the cartridge, release the plunger a few millimeters to free both posterior haptics, then push again until the implantation.

[1] Take the ophthalmic viscoelastic device (OVD) solution out of the refrigerator at least one hour before use.

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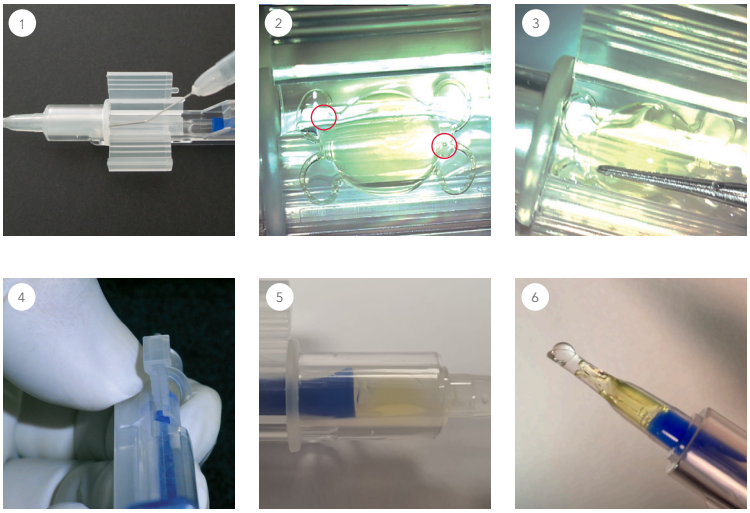
ISOPURE (non-preloaded) Injection System

The Medicel Accuject 2.0 / 2.1 / 2.2 injection systems are recommended for implanting the ISOPURE (non-preloaded) lenses.

These fully single-use systems represent total reliability for safe and effective lens injections.

Their compact design with integrated cartridge enables a simple, predictable loading and positioning of the lens.



1. Apply ophthalmic viscoelastic device (OVD) into the tip and the loading chamber of the injector cartridge.
2. Remove the lens from the lens holder. Position the lens into the cartridge in such way that the two haptics with the notches are pointing at 1 and 7 o'clock.
3. Exert slight pressure onto the lens optic and make sure that all haptics are inside before further closing the cartridge. Close the cartridge and check the position of the lens.
4. Once the "click-lock" mechanism engages, the lens is securely loaded and ready for injection.
5. Press the injector plunger forward and push the lens into the conical tip of the cartridge.
6. Pull the plunger back a few millimeters and then inject the lens in one continuous motion. For gentle implantation, it is not necessary to fully push the plunger to the bottom of the cartridge.

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