

PhysIOL | PODEYE TORIC

Monofocal Toric Hydrophobic



Technical Specifications

Commercial name	PODEYE TORIC									
Material	1 2 2 2 1 2 1 1 1 1 1 1 1 1 1 1 1 1 1 1									
Overall diameter	PhysIOL G-free® (GFY) (hydrophobic acrylic glistening-free)¹									
	11.40 mm									
Optic diameter	6.00 mm									
Optic	Biconvex aspheric aberration-correcting (-0.11μ SA)									
Haptic design	Double C-loop & RidgeTech®									
Filtration	UV & blue light									
Refractive index	1.52									
Abbe number	42									
Angulation	5°									
Injection system	Medicel Accuject 2.1 / 2.2									
Incision size	> 2.0 mm									
Spherical power	6D to 30D (0.5D steps) ⁴									
Cylinder power (IOL plane)	1.00 - 1.50 - 2.25 - 3.00 - 3.75 - 4.50 - 5.25 - 6.00D ⁴									
Square edge	360°									
Nominal manufacturer A constant	119.40									
Suggested A constant ²	Interferometry Ultrasound							d		
	Hoffer Q: pACD				5.85			5.59		
	Holladay 1: Sf Barrett: LF SRK/T: A			2.06			1.80			
				2.09			-			
				119.40			119.05			
		Haigis³: a0; a1; a2			1.70; 0.4; 0.1			1.214; 0.4; 0.1		
	PODEYE TORIC 1.0	PODEYE TORIC 1.5	PODE TORIC	. —	PODEYE TORIC 3.0	PODEYE TORIC 3.75	PODE TORIC	-	PODEYE TORIC 5.25	PODEYE TORIC 6.0
Cylinder power at IOL plane	1.00D	1.50D	2.25[)	3.00D	3.75D	4.50[)	5.25D	6.00D
Cylinder power at corneal plane ⁵	0.68D	1.03D	1.55D		2.06D	2.57D	3.081)	3.60D	4.11D
Recommended corneal astigmatism correction range	0.50D - 0.89D	0.90D - 1.28D	1.29D - 1.80D		1.81D - 2.32D	2.33D - 2.82D	2.83D - 3.33D		3.34D - 3.85D	3.86D - 4.36D

¹ The PhysIOL G-free® (GFY) is patented by PhysIOL SA/NV since 2010. Chassain C, J Fr Ophthalmol 2018, 41(6):513-520.

² Estimates only: surgeons are recommended to use their own values based upon their personal experience. Refer to our website for updates.

⁴ Please check the availability of spherical and cylinder powers with your sales representative.

 $^{^{\}rm 5}$ Savini G., J Cataract Refract Surg 2013; 39:1900–1903.

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			
Intended Use	Intended use (for all IOLs): The posterior chamber intraocular lens which is intended to be placed int the capsular bag for the replacement of the human lens to achieve the visual correction of aphakia ir 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, with pre-existing astigmatism, 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			



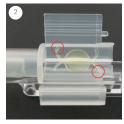
Injection Guidelines

The Medicel Accuject injection system is recommended for implanting the PODEYE TORIC lenses.

This fully single-use system represents total reliability for safe and effective lens injections.

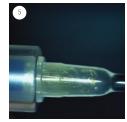
Its compact design with integrated cartridge enables a simple, predictable loading and positioning of the lens.













- 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 holes 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.

Surgical Guidelines

Preoperative:

- 1. Use the PhysIOL Toric Calculator www.physioltoric.eu which will recommend you the cylindrical lens powers and the optimal axis alignment of the IOL.
- 2. Mark the eye with the patient sitting upright in order to avoid cyclotorsion effect.

Peroperative:

- 1. When the PODEYE TORIC lens is injected in the capsular bag, remove all ophthalmic viscoelastic device (OVD) behind and in front of the lens using I/A canula.
- 2. With a syringe filled with Balanced Salt Solution (BSS) solution, test the watertight self-sealing of the incisions and ensure that the normal intraocular pressure is recovered.
- 3. If necessary, reposition the lens in the axis of the IOL marks using a micromanipulator.
- 4. Gently push the lens towards the posterior capsule with the micromanipulator.
- 5. Check again that the incision is watertight.
- 6. Carefully remove the eyelid speculum.

Do not over-inflate the capsular bag at the end of the surgery.

