

ISOPURE SERENITY & SERENITY TORIC

Premium Monofocal Hydrophobic IOLs



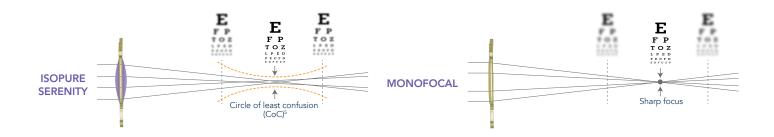
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The Second Generation of IOLs From Our ISOPURE Family

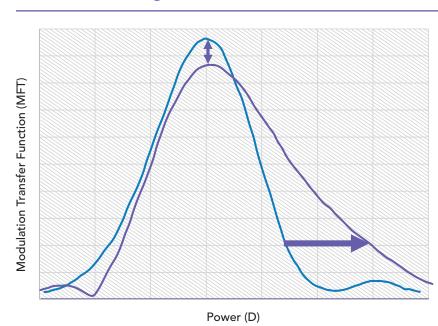
ISOPURE SERENITY and SERENITY Toric Premium Monofocal IOLs are engineered to provide cataract patients with a **consistent** range of vision, from excellent distance vision¹ to good intermediate vision² in all lighting conditions, without compromising quality of vision³ or causing any visual disturbances^{3,4}.

These lenses feature clinically proven, patented **ISOFOCAL technology across the full optic diameter – the only non-diffractive technology that customizes the level of negative spherical aberration according to each dioptric power**.

Additionally, the **unique** double C-loop **POD platform** is specifically designed for the improved stability required by toric IOLs for long-term, accurate astigmatism correction.



EXTENDED. UNCOMPROMISED. SIMPLIFIED.



Extended Range of Vision

Compared to a Monofocal IOL, ISOPURE SERENITY: • Increases depth of focus by approximately **50%**

• With only **12%** decrease in maximum MTF

This is equivalent to approximately 1.0D of extended depth of focus.

PATIENT OUTCOMES

Clinical studies² have repeatedly shown an increased range of vision up to 66cm using ISOPURE optic technology.

- 80% achieve VA 0.1LogMAR at 80cm
- 60% achieve VA 0.1LogMAR at 66cm

Measured in a model eye with ISO 2 cornea = $0.28 \mu m$ SA, at 3.0mm aperture. BVI data held on file

Extended Range of Vision and Customised Spherical Aberration

ISOPURE is the only range of premium monofocal IOLs that utilizes **ISOFOCAL** technology, incorporating spherical aberration across the full optic diameter and on both the anterior and posterior optical surfaces.

- ISOFOCAL technology is unique and patented to BVI.
- ISOPURE are the only lenses to progressively adjust the spherical aberration value across the entire optical surface.

ISOFOCAL technology is designed to **further adjust the value of negative spherical aberration per individual lens power**; therefore, adapting the full optical system to fine tune the patient's extended range of vision.

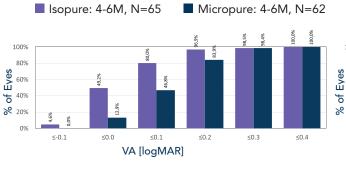


Please note that these drawings are for illustrative purposes only and serve as a general representation of the Intraocular Lens (IOL) design

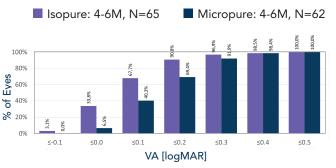
PATIENT OUTCOMES

In this large, prospective, randomized study, ISOFOCAL technology **consistently performed better in unaided intermediate vision** compared to a standard monofocal (80 cm and 66 cm).³

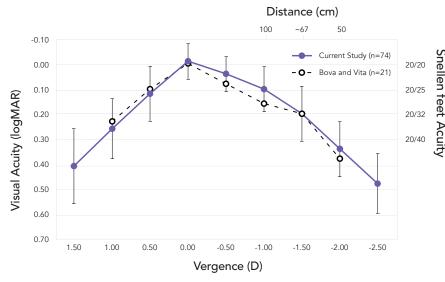
CUMULATIVE BINOCULAR DCIVA @ 80 CM



CUMULATIVE BINOCULAR DCIVA @ 66 CM



CLINICAL EVIDENCE: ISOFOCAL DEFOCUS CURVE



Mean photopic binocular logMAR visual acuity with best correction for distance as a function of the chart vergence from 1.50 to -2.50 diopters (D). Error bars represent standard deviation. The right y-axis shows Snellen feet acuity, and the upper x-axis shows distance values (cm)². Values from Bova and Vita study are depicted for comparative purposes. CUALITY OF VISION EXTENDED RANGE OF VISION THE RIGHT BALANCE

Effect of Spherical Aberration

Uncompromised Quality of Vision

CONTRAST SENSITIVITY

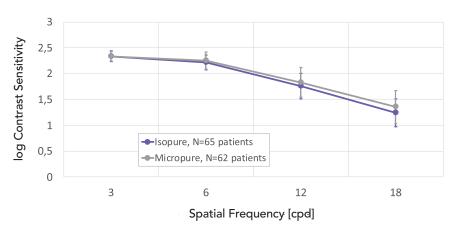
Like a monofocal IOL, the ISOPURE SERENITY optic uses all the available light energy to extend the range of focus. It does not lose light energy through diffraction like multifocal IOLs, and through this design it **maintains contrast sensitivity comparable to a monofocal.**³

PHOTIC PHENOMENA

The ISOPURE SERENITY optic features a smooth surface resembling that of a standard monofocal IOL. Additionally, it has been proven in a comparative clinical study to **exhibit photic phenomena comparable to that of a standard monofocal IOL**.³

CONTRAST SENSITIVITY, BINOCULAR, 4-6M, PHOTOPIC

UNCOMPROMISED



Simplified for the Surgeon

SIMPLIFIED PATIENT MANAGEMENT.

The ISOPURE SERENITY optic features a non-diffractive design, simplifying the discussions for patients who are not candidates for diffractive technology but still desire an extended range of vision and reduced dependence on spectacles for intermediate vision.



SIMPLIFIED LIKE A MONOFOCAL

The ISOPURE SERENITY optic is technologically advanced compared to any optic in this IOL category, yet for the cataract surgeon it is prepared for implantation just like a monofocal IOL.

PATIENT OUTCOMES

According to a PRSIQ questionnaire, 90.9% of ISOPURE patients did not need glasses for distance or intermediate vision.⁶

The Winning Combination for Your Astigmatic Patients

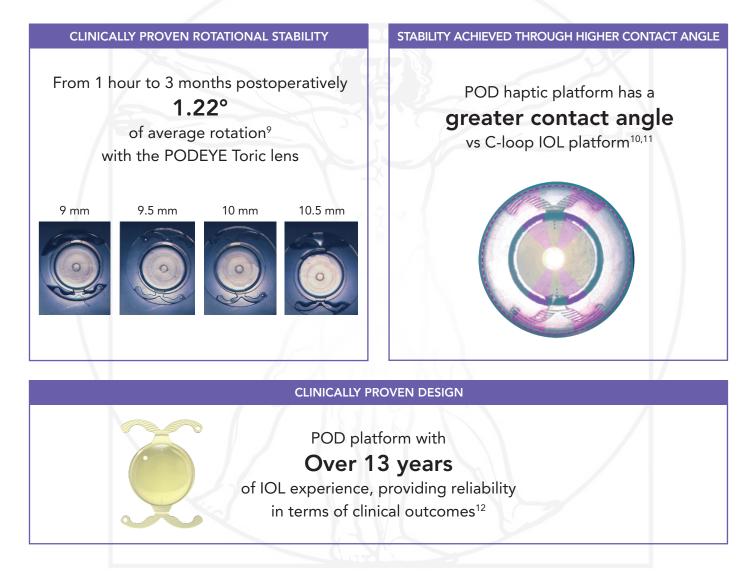
STABILITY. MANEUVERABILITY. ACCURACY.

Stability for Long-term, Accurate Astigmatism Correction

With its **unique double C-loop haptic** configuration for excellent fixation within the capsular bag, **the POD platform** was specifically created for toric IOL correction.

THIS ONE-OF-A-KIND PLATFORM IS PROVEN TO:

- Allow for even distribution of the compression forces at the haptic-capsular bag junction⁷
- Maintain low tilt and axial displacement⁷
- Provide excellent centration and rotation stability⁸



Maneuverability for Ease of Use



the optics during and after injection.



Accuracy for More Predictable Results



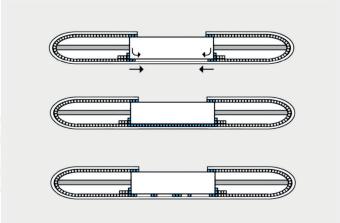
Our toric calculator has been developed to compensate the posterior corneal astigmatism effect by improving the prediction of postoperative astigmatic patient outcomes.18

Go to: https://toric.bvimedical.com/*

GFY Hydrophobic Material for Low PCO¹⁹

The GFY material matches the "No space, no cells" concept.²⁰ This confirms that the perfect bio-adhesiveness of GFY provides a hard tackiness and bond to the capsular bag.

The design of the GFY material integrates **2-Step Technology**, featuring a square edge barrier and posterior haptic angulation. This technology offers a barrier against PCO.





References

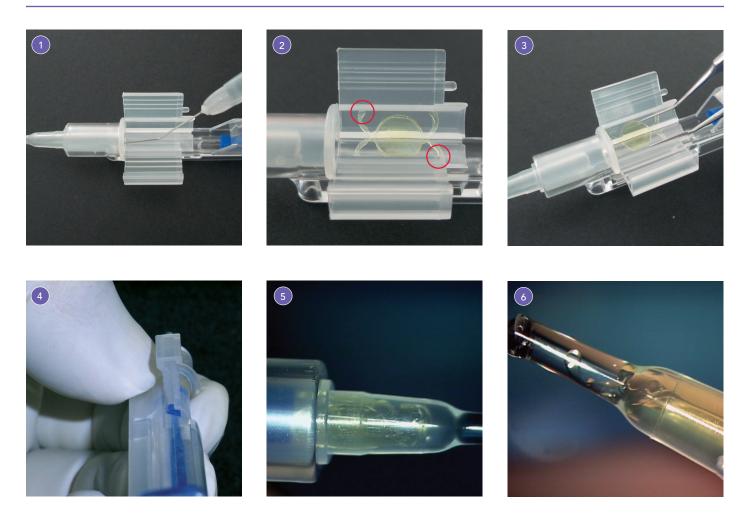
References: 1. Stodulka P, Slovak M. Visual performance of a polynomial extended depth of focus intraocular lens. Open Journal of Ophthalmology 2021;11:214-228. | 2. Bernabeu-Arias G, Beckers S, Rincón-Rosales JL, Tañá-Rivero P, Bilbao-Calabuig R. Visual Performance at Different Distances After Implantation of an Isofocal Optic Design Intraocular Lens. J Refract Surg. 2023 Mar;39(3):150-157. [3. Ang RET, Stodulka P, Poyales F. Prospective Randomized Single-Masked Study of Bilateral Isofocal Optic-Design or Monofocal Intraocular Lenses. Clinical Ophthalmology. 2023; 14. Tomagova N, Elahi S, Vandekerckhove K. Clinical Outcomes of a New Non-Diffractive Extended Depth-of-Focus Intraocular Lens Targeted for Mini-Monovision. Clin Ophthalmol. 2023 Mar 25; 17:981-990. | 5. CoC is used in photography to determine the depth of focus of an image that is acceptably sharp. | 6. Bilbao-Calabuig R. «ISOPURE, Optical Principles and Clinical Results After 20 Months in Our Practice.» BVI Webinar, May 2021. | 7. Bozukova D, Pagnoulle C, Jérôme C. Biomechanical and optical propeties of 2 new hydrophobic platforms for intraocular lenses. J Catract Refract Surg 2013 Sep;39(9):1404-14. | 8. Draschl P, Hirnschall N. Rotational stability of 2 intraocular lenses with an identical design and different materials. J Catract Refract Surg 2017; 43:234-23. | 9. Ang RET, Tañá-Rivero P, Pastor-Pascual F, Stodulka P, Tetz M, Fischinger I. Visual and Refractive Outcomes After Bilateral Implantation of a Biconvex Aspheric Toric Monofocal Intraocular unit a Double C-Loop Haptic Design. Clinical Ophthalmology 2023:17 2765-2776. | 10. REP_503_1_2022_15.2 PODIGF Mechanical specifications. | 11. Borkenstein AF, Borkenstein EM. Geometry of Acrylic, Hydrophobic IOLs and Changes in Haptic-Capsular Bag Relationship According to Compression and Different Well Diameters: A Bench Study Using Computed Tomography. Ophthalmol Ther (2022) 11:711-727. | 12. Periodic Clinical Evaluation Report. | 13. Ang RET. "PODEYE Toric Clinical Outcomes." Presentatio 2018. | 18. Abulafia A, Koch DD. New regression formula for toric intraocular lens calculations. J Cataract Refract Surg 2016; 42:663–671. | 19. Chassain C, Chass

* https://toric.bvimedical.com/ is a forwarding URL for www.physioltoric.eu

Medicel Accuject Injector Guidelines* With POD Platform

This fully single-use system represents reliable and effective lens injections with POD platform. The compact design with integrated cartridge enables predictable loading and positioning of the lens.

Guidelines Steps With Accuject



- 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 a 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.

ISOPURE SERENITY



Description

Model	ISOPURE SERENITY									
Material	GFY Hydrophobic Acrylic ²¹									
Overall diameter	11.40mm									
Optic diameter	6.00mm									
Optic	Polynomial Surface Design									
Haptic design	Double C-Loop with Ridgetech & Posterior Angulated Haptic									
Filtration	UV & Blue Light									
Refractive index	1.53									
Abbe number	42									
Injection system	Medicel Accuject 2.1 / 2.2									
Spherical power ²³	+10D to +30D (0.5D steps) +31D to +35D (1D steps)									
Suggested A constant ²²	Interferometry									
	Hoffer Q: pACD				5.85					
	Holladay 1: Sf				2.06					
	Barrett: LF				2.09					
	SRK/T: A				119.40					
	Haigis: a0; a1; a2				1.70; 0.4; 0.1					
Model	ISOPURE SERENITY TORIC									
Material	GFY Hydrophobic Acrylic ²¹									
Overall diameter	11.40mm									
Optic diameter	6.00mm									
Optic	Polynomial Surface Design									
Haptic design	Double C-loop with Ridgetech & Posterior Angulated Haptic									
Filtration	UV & Blue Light									
Refractive index	1.53									
Abbe number	42									
Injection system	Medicel Accuject 2.1 / 2.2									
Spherical power ²³	+10D to +30D (0.5D steps) + 31D to +35D (1D steps)									
Cylinder power (IOL plane) ²³	1.00 - 1.50 - 2.25 - 3.00 - 3.75 - 4.50 - 5.25 - 6.00D									
Suggested A constant ²²					Interferometry					
	Hoffer Q: pACD				5.85					
	Holladay 1: Sf				2.06					
	Barrett: LF				2.09					
	SRK/T: A				119.40					
	Haigis: a0; a1; a2			,	1.70; 0.4; 0.1					
	SERENITY TORIC 1.0	SERENITY TORIC 1.5	SERENIT TORIC 2.		SERENITY TORIC 3.0	SERENITY TORIC 3.75	SERENITY TORIC 4.5	SERENITY TORIC 5.25	SERENITY TORIC 6.0	
Cylinder power at IOL plane	1.00D	1.50D	2.25D)	3.00D	3.75D	4.50D	5.25D	6.00D	
Cylinder power at corneal plane ²⁴	0.68D	1.03D	1.55D)	2.06D	2.57D	3.08D	3.60D	4.11D	

21. The BVI GFY® is patented since 2010. | 22. 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. | 23. Please check the availability of spherical and cylinder powers with your sales representative. | 24. Savini G., J Cataract Refract Surg 2013; 39:1900–1903.

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

