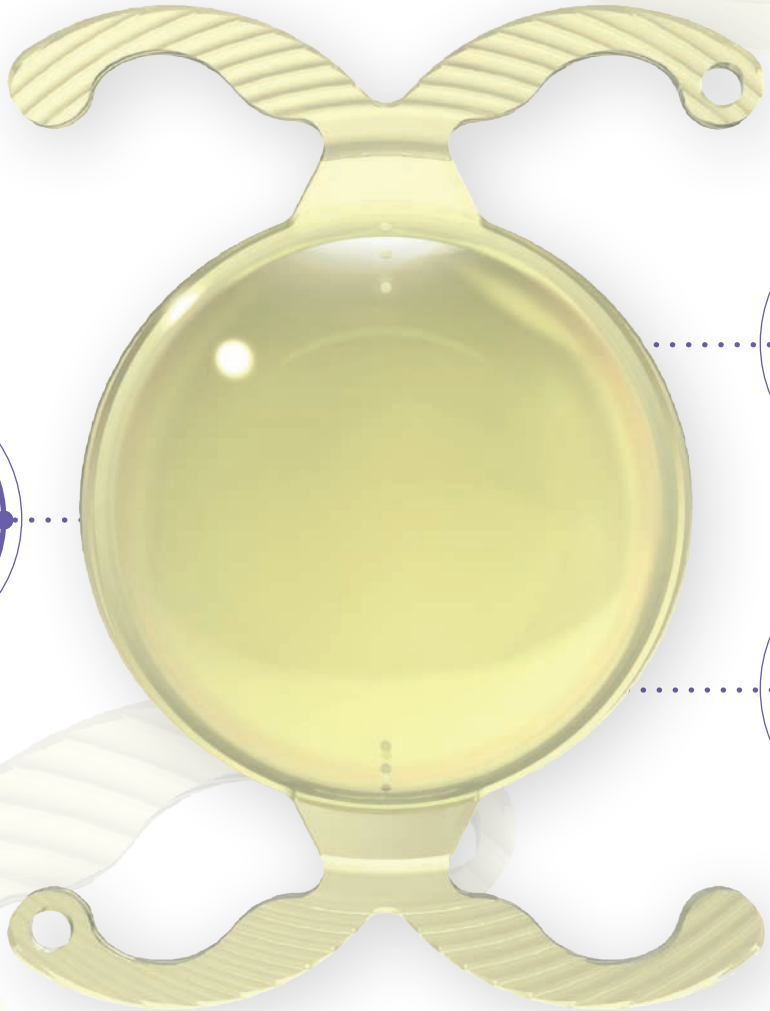
ISOPURE SERENITY & SERENITY TORIC

Premium Monofocal Hydrophobic IOLs



POD Platform

Extended.
Uncompromised.
Simplified

Stability.
Maneuverability.
Accuracy.

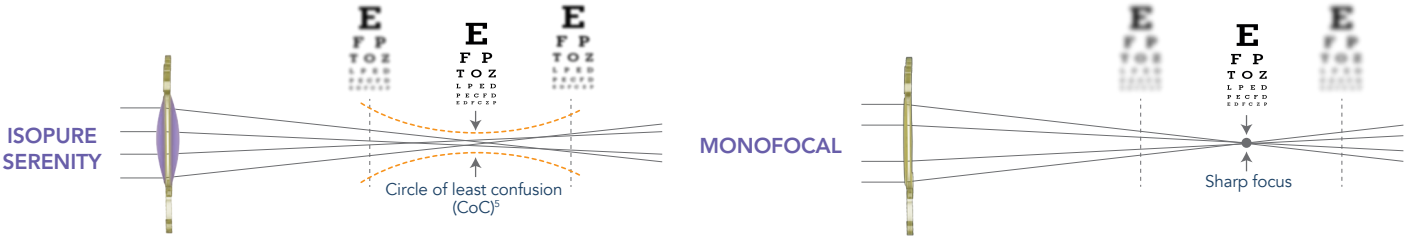
bvimedical.com

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 vision[1] to good intermediate vision[2] in all lighting conditions, **without compromising quality of vision[3] or causing any visual disturbances[3,4]**.

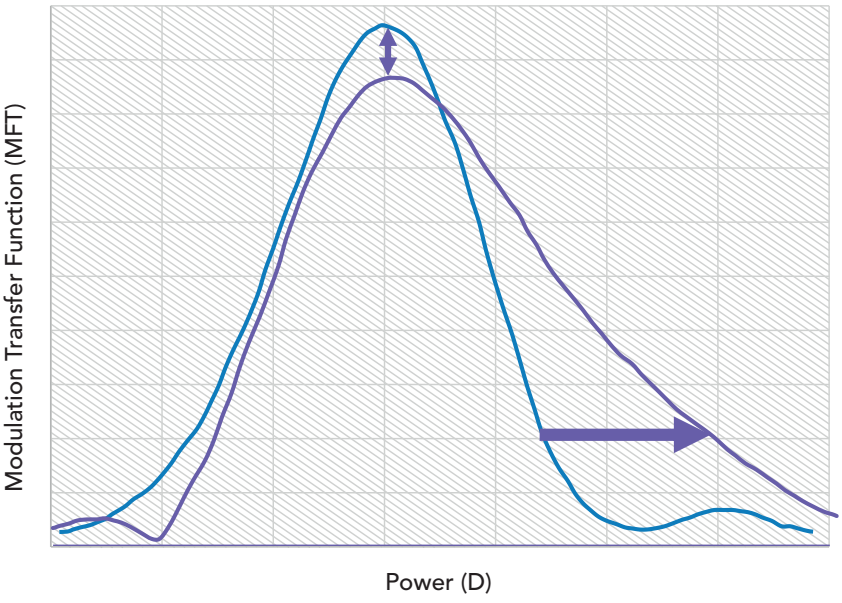
These lenses feature clinically proven, patented **ISOFOCAL technology across the full optic diameter – the only non-diffractive technology that customizes the level of negative spherical aberration according to each dioptric power**.

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



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

Monofocal (MICROPURE) Preminum Monofocal (ISOPURE SERENITY)

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 studies[2] 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

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.

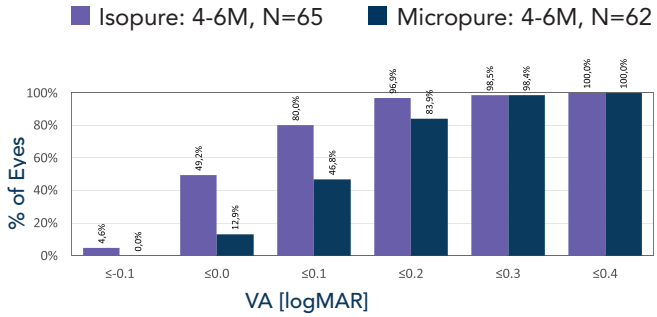
ISOFOCAL technology is designed to **further adjust the value of negative spherical aberration per individual lens power**; therefore, adapting the full optical system to fine tune the patient's extended range of vision.

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

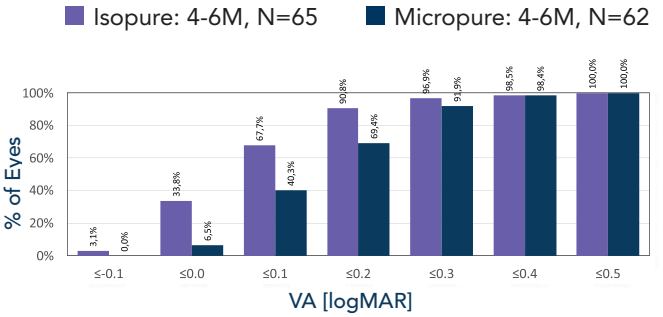
PATIENT OUTCOMES

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

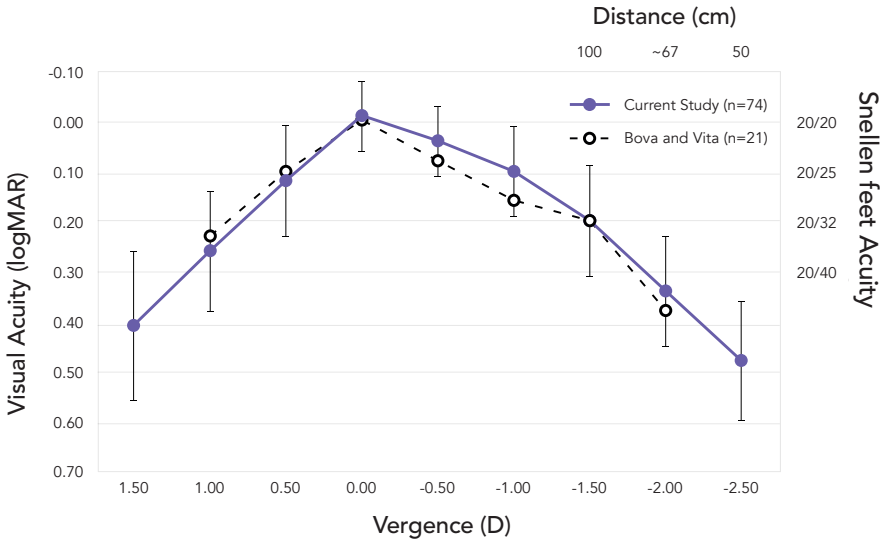
CUMULATIVE BINOCULAR DCIVA @ 80 CM



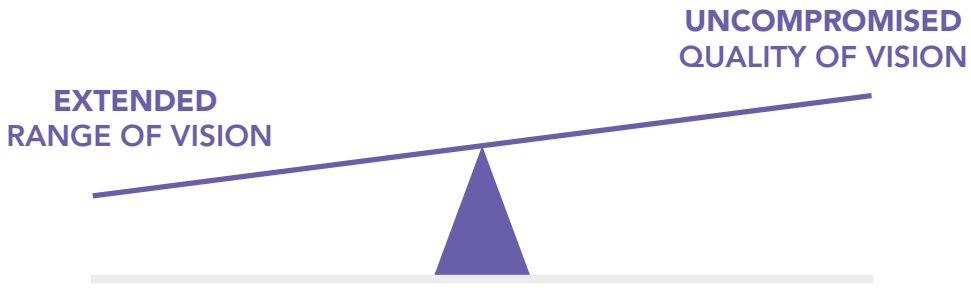
CUMULATIVE BINOCULAR DCIVA @ 66 CM



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.



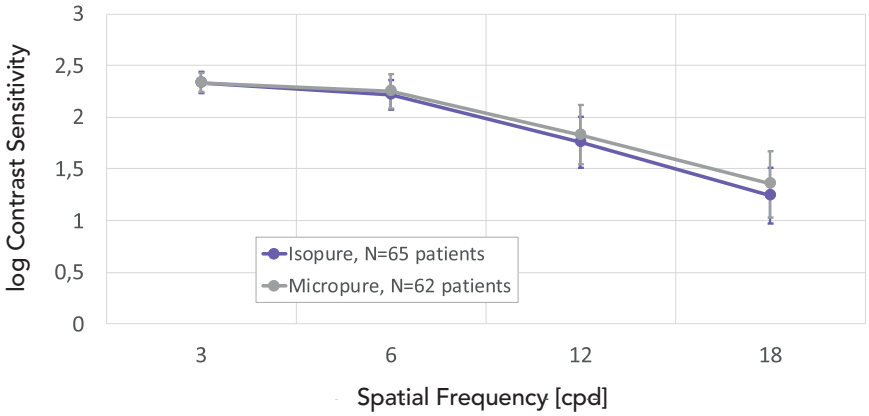
THE RIGHT BALANCE
Effect of Spherical Aberration

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



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 PRISQ questionnaire, 90.9% of ISOPURE patients did not need glasses for distance or intermediate vision.[6]

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:

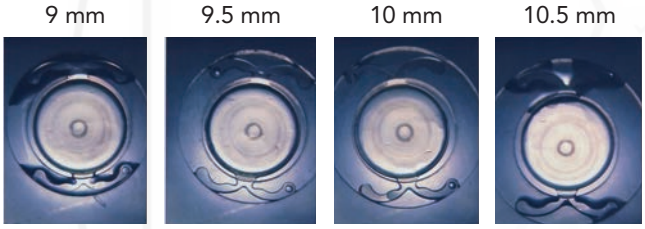
- Allow for even distribution of the compression forces at the haptic-capsular bag junction[7]
- Maintain low tilt and axial displacement[7]
- Provide excellent centration and rotation stability[8]

CLINICALLY PROVEN ROTATIONAL STABILITY

From 1 hour to 3 months postoperatively

1.22°

of average rotation[9]
with the PODEYE Toric lens



STABILITY ACHIEVED THROUGH HIGHER CONTACT ANGLE

POD haptic platform has

70%

greater contact angle
vs C-loop IOL platform[10]

CLINICALLY PROVEN DESIGN

POD platform with

Over 13 years

of IOL experience, providing reliability
in terms of clinical outcomes[11]

Maneuverability for Ease of Use

EASY CONTROL DURING THE PROCEDURE[12]
Rotation to align the IOL cylinder, either clockwise OR counter-clockwise.[13]

Easy placement is
MANEUVERABILITY

Whereas classic C-loop IOLs can only be rotated clockwise and require additional steps in case of misalignment.[13]

Unique *RidgeTech* technology reduces the risk[14] of sticky haptics on the optics during and after injection.

Accuracy for More Predictable Results

Toric IOL selection with built in

Abulafia-Koch (AK) Formula

Toric Calculator[15] with AK formula delivers

94%

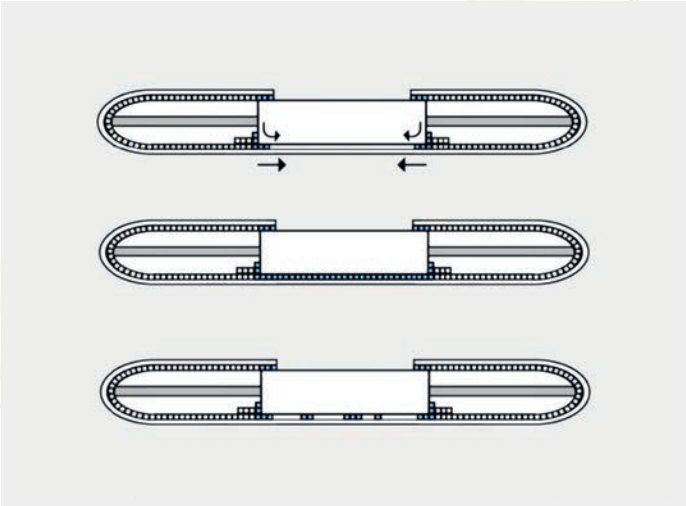
of eyes with **less than 0.75D** of **absolute predicted residual astigmatism[16]**

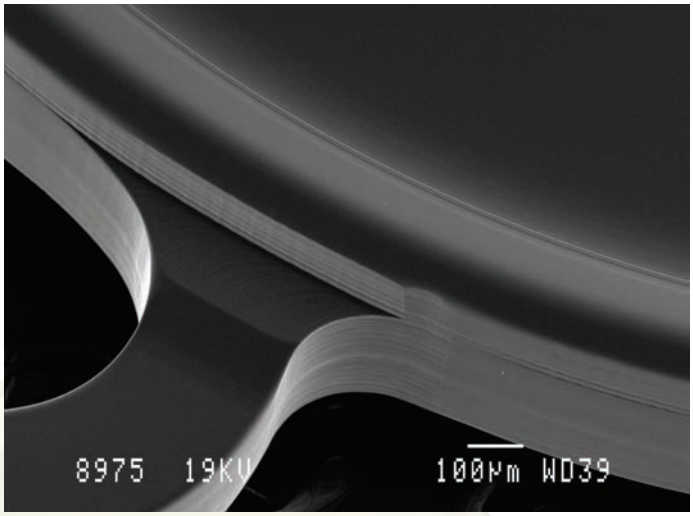
Our toric calculator has been developed to compensate the posterior corneal astigmatism effect by **improving the prediction of postoperative astigmatic patient outcomes.**[17]

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

GFY Hydrophobic Material for Low PCO[18]

The GFY material matches the **"No space, no cells" concept.**[19] 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.





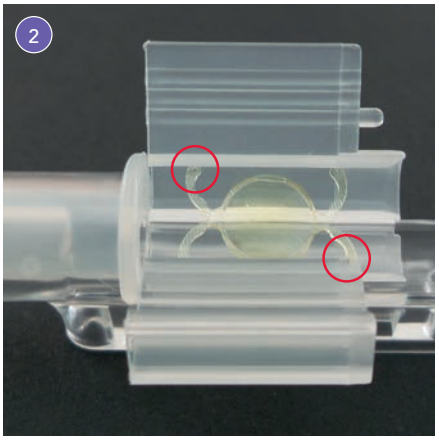
References:
1. Stodulka P, Slovak M. Visual performance of a polynomial extended depth of focus intraocular lens. Open Journal of Ophthalmology 2021;11:214-228. | 2. Bernabeu-Arias G, Beckers S, Rincón-Rosales JL, Tañá-Rivero P, Bilbao-Calabuig R. Visual Performance at Different Distances After Implantation 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. | 4. 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. Dimitriya Bozukova, Christophe Pagnoulle, Christine Jérôme. Biomechanical and optical propeties of 2 new hydrophobic platforms for intraocular lenses. J Cataract Refract Surg 2013 Sep;39(9):1404-14. | 8. Petra Draschl, MD, Nino Hirnschall, MD, PhD. Rotational stability of 2 intraocular lenses with an identical design and different materials. J Cataract Refract Surg 2017; 43:234–23. | 9. Robert Edward T Ang, Pedro Tañá-Rivero, Francisco Pastor-Pascual, Pavel Stodulka, Manfred Tetz, Isaak Fischinger. Visual and Refractive Outcomes After Bilateral Implantation of a Biconvex Aspheric Toric Monofocal Intraocular with a Double C-Loop Haptic Design. Clinical Ophthalmology 2023:17 2765–2776. | 10. Mechanical properties according to 11979-3 of Double C Loop (ID: 99B8EB20-C5D6-418E-A4DA-348E1114C396). | 11. Periodic Clinical Evaluation Report. | 12. Ang RET. "PODEYE Toric Clinical Outcomes." Presentation, BVI Advisory Board meeting, Boston 2024 | 13. Torio et al. Comparison of the Rotational Stability of Different Toric Intraocular Lens Implants. Philipp J Ophthalmol 2014;39:67-72 | 14. Physiol Report 002, 9 nov 2012. | 15. https://toric.bvimedical.com/ | 16. Insert CRSToday Europe, January 2018. | 17. Abulafia A, Koch DD, J Cataract Refract Surg 2016, 42(5):663-671. | 18. Chassain C, Chamard C. Posterior capsule opacification, glistenings and visual outcomes: 3 years after implantation of a new hydrophobic. Journal Français d'Ophtalmologie 2018; 513-520. | 19. Linnola RJ. Sandwich theory: Bioactivity–based explanation for PCO. JCRS 1997;23:1539-42.

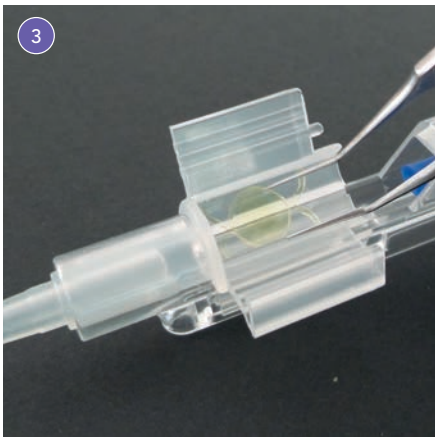
* https://toric.bvimedical.com/ is a forwarding URL for www.physioltoric.eu.

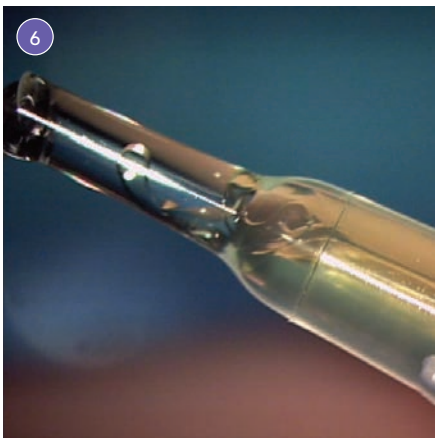
Medicel Accuject Injector Guidelines* With POD Platform

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.

*Please note that these are guidelines only. Surgeons are recommended to refer to the official Medicel Injector IFU supplied with the device.

ISOPURE SERENITY

Description

Model	ISOPURE SERENITY							
Material	GFY Hydrophobic Acrylic[20]							
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[21]		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[20]							
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[25]	+10D to +30D (0.5D steps) + 31D to +35D (1D steps)							
Cylinder power (IOL plane)[22]	1.00 - 1.50 - 2.25 - 3.00 - 3.75 - 4.50 - 5.25 - 6.00D							
Suggested A constant[21]		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	SERENITY TORIC 2.25	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

20. The BVI GFY® is patented since 2010. | 21. 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. | 22. Not optimized. | 23. Please check the availability of spherical powers with your sales representative. | 24. Savini G., J Cataract Refract Surg 2013; 39:1900–1903. | 25. Please check the availability of spherical and cylinder powers with your sales representative.

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

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