

A SAFER WAY TO TRIFOCALITY*: ELEVATED PHASE SHIFT (EPS)**

7 DIFFRACTIVE RINGS FOR OPTIMAL LIGHT DISTRIBUTION AND
LESS DISTURBANCE

7 DO IT.

- TRIFOCAL PERFORMANCE & GLASS INDEPENDENCY
- UNCOMPROMISED CONTRAST SENSITIVITY
- REFRACTIVE PREDICTABILITY & STABILITY
- OUTSTANDING READING SPEED
- LESS HALOS AND GLARES

MEDICENTUR

Material. Design. Optics.

* 75% of the lens surface is refractive
** patent pending



Elevated Phase Shift*

Diffraction always occurs during the **propagation of light waves**. Each surface of an IOL (either refractive or diffractive) generates a phase shift in light waves. Based on the level of phase shift the diffractive interference can be constructive or destructive in the image plane. MediCentur's proprietary, patented approach to trifocality uses **Elevated Phase Shift* (EPS)** in the central diffractive part of the optic to create constructive interference between the 0th (far) and 1st diffractive (near) order, thus creating a 3rd (intermediate) focal point.

Central Diffractive Elevated Phase Shift* (EPS) Technology

Figure 1: Radial profile with central diffractive phase shift elevated from a destructive level to a constructive interference level

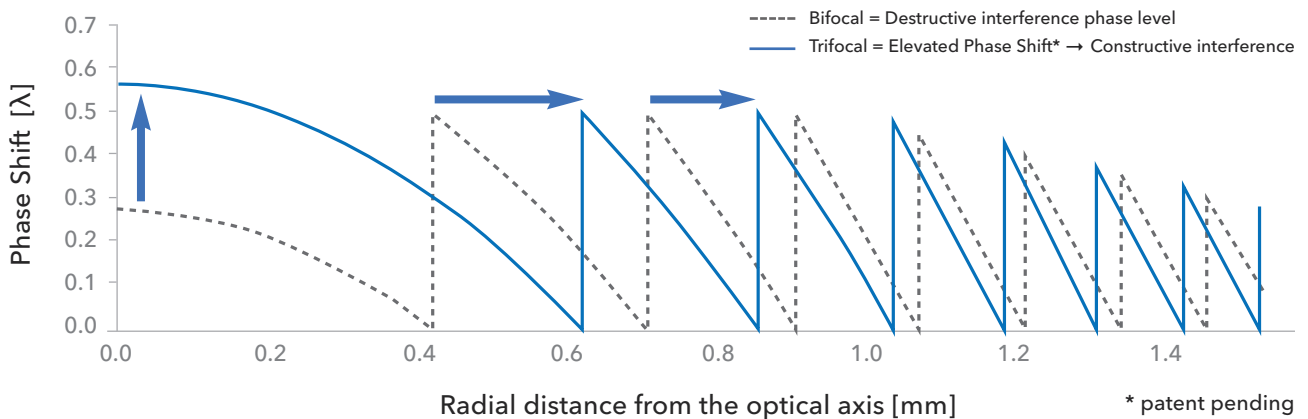
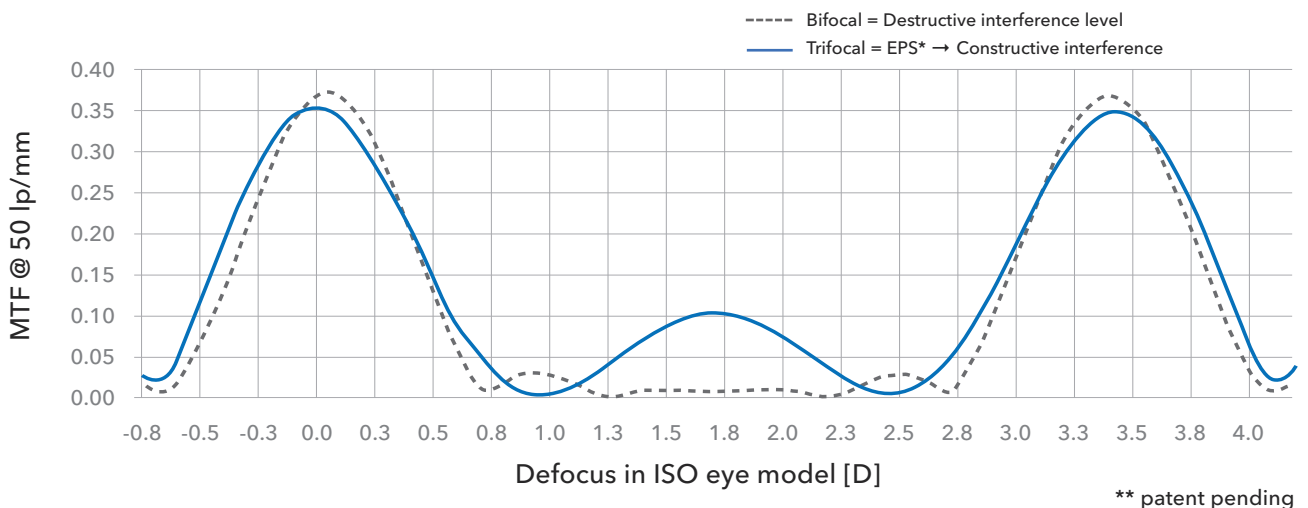


Figure 2: MTF through focus curves with central diffractive phase shifts at a destructive and a constructive interference level

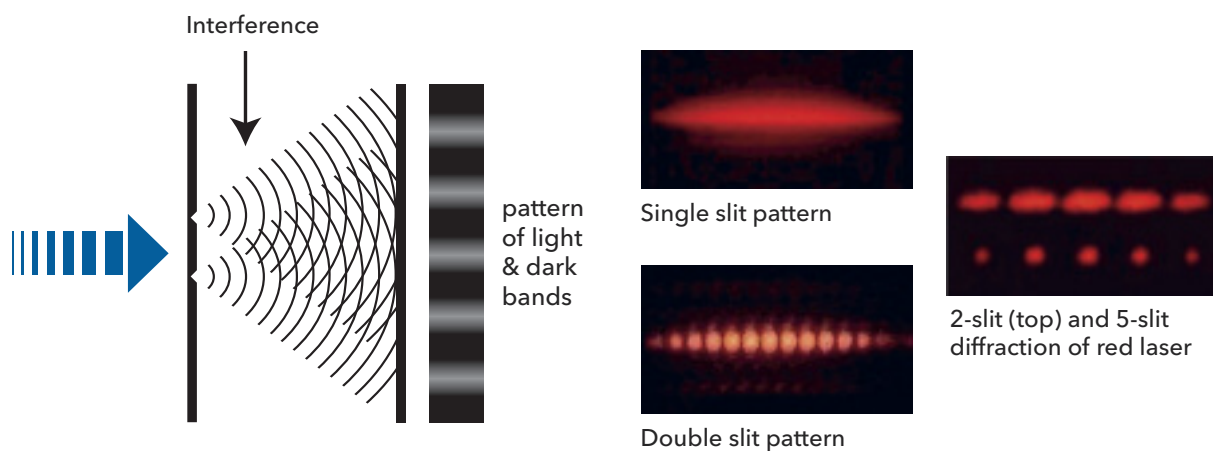


Follow the rules of physics

Diffractive arrays and the loss of light

Each diffractive step inflicts additional energy loss.

The picture demonstrates the difference in energy loss between light rays passing through one or two slits. There is a similar mechanism in the case of diffractive intraocular lenses. The more diffractive arrays there are, the higher the energy loss.



...and what does it mean for your patients?

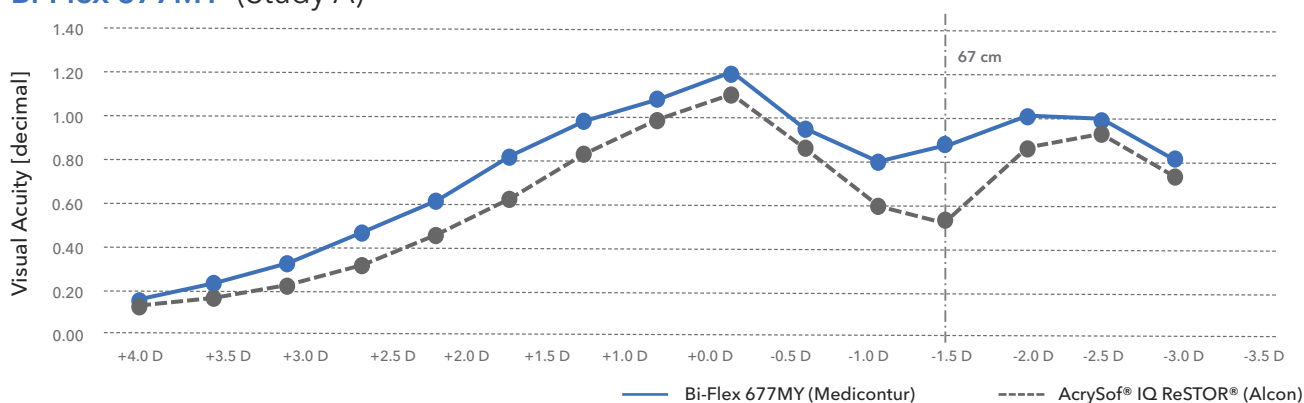
- Each additional diffractive ring means additional loss of energy and lowering the contrast sensitivity. Each additional diffractive ring means higher incidence of halos and glares. This is why Bi-Flex 677MY is limited to seven rings – 7 do it.
- **EPS* technology** offers you a trifocal lens with the lowest number of diffractive rings within a 3 mm diffractive zone with minimal loss of contrast sensitivity.
- **EPS* technology** for optimal light energy distribution and less visual disturbances.

** patent pending

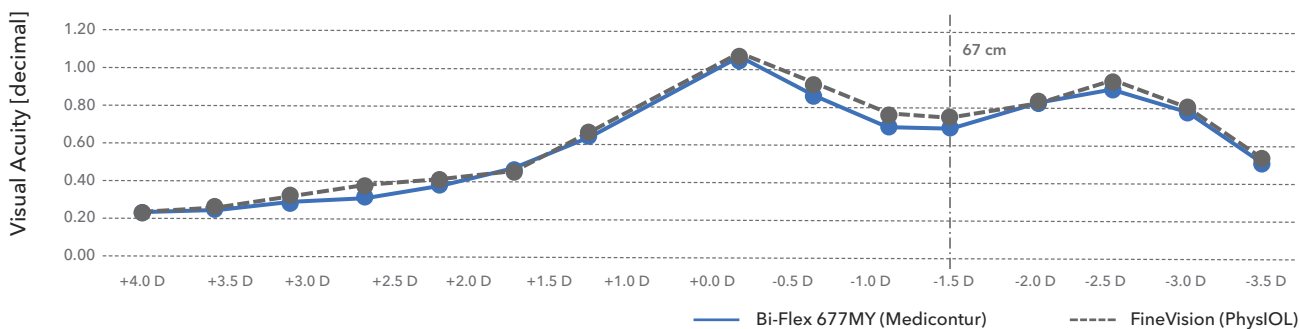


Excellent far & near vision & adequate intermediate vision.
Defocus curves of Bi-Flex 677MY demonstrate trifocal clinical performance.

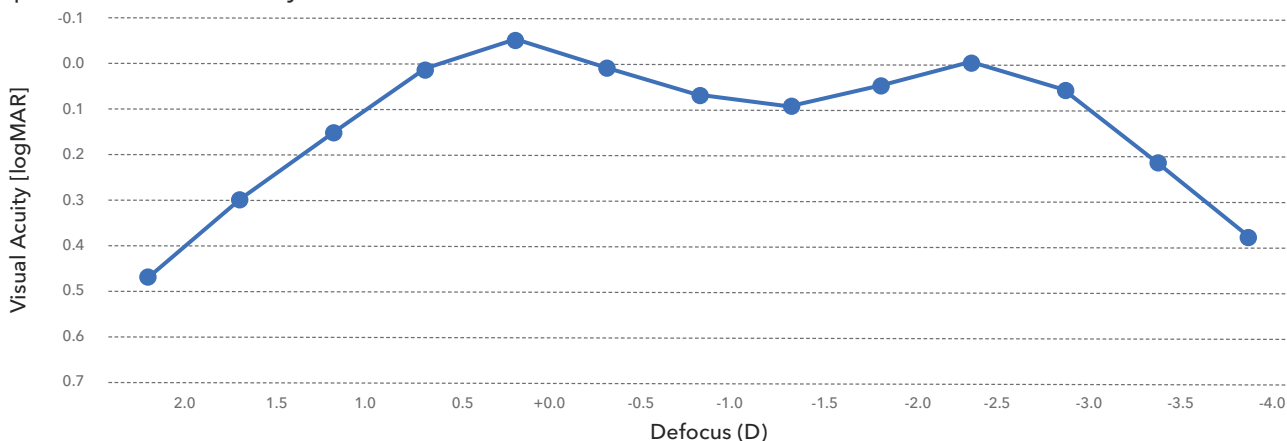
Compared to bifocal AcrySof® IQ ReSTOR® with significant difference **in favor of Bi-Flex 677MY** (Study A)



Identical performance without any significant difference Bi-Flex 677MY vs FineVision (Study B)

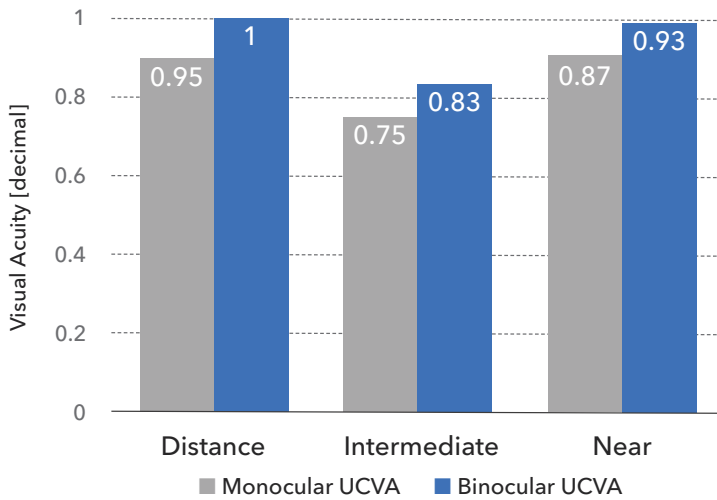


Defocus curve Bi-Flex 677MY: Mean values from 100 eyes clearly proved trifocal clinical performance (Study C)



Mean visual acuity outcomes with Bi-Flex 677MY confirm excellent far & near, adequate intermediate vision

(Study A, B, C, F)



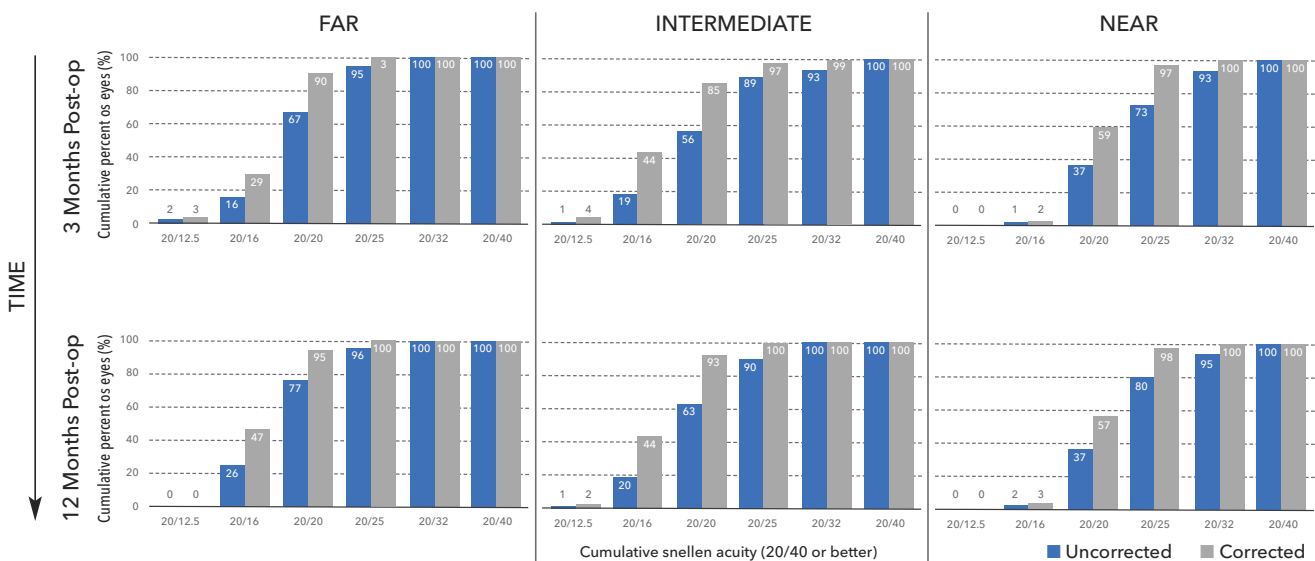
Predictability:

mean spherical equivalent residual error of -0.15 ± 0.33 D and 88% of eyes in ± 0.50 D

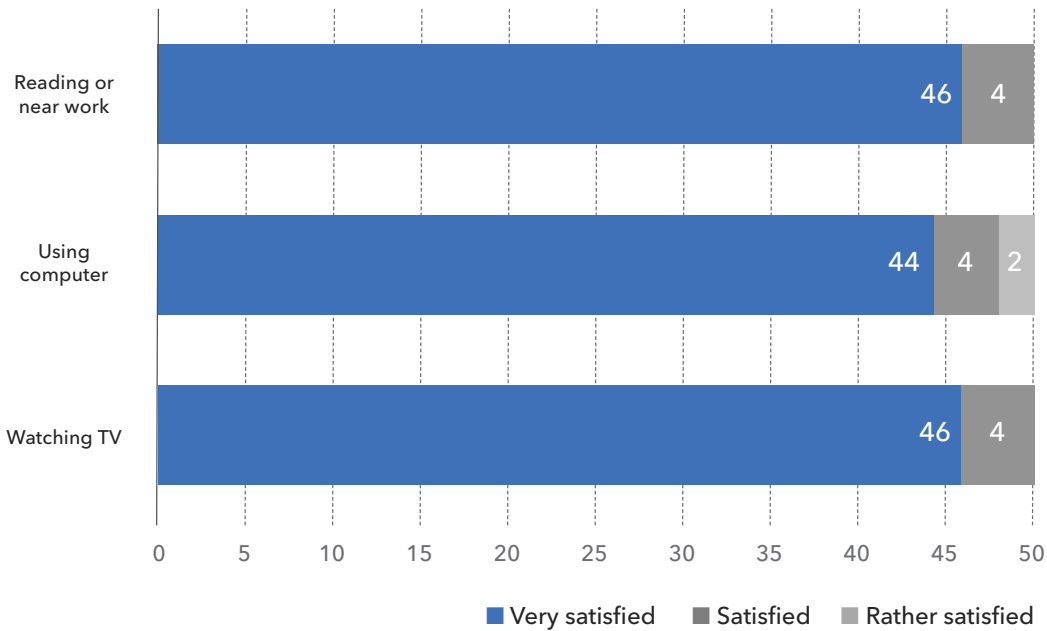
Based on studies: A, B, C, D

Refractive stability of visual outcome with Bi-Flex 677MY across follow-up periods in all three measured distances

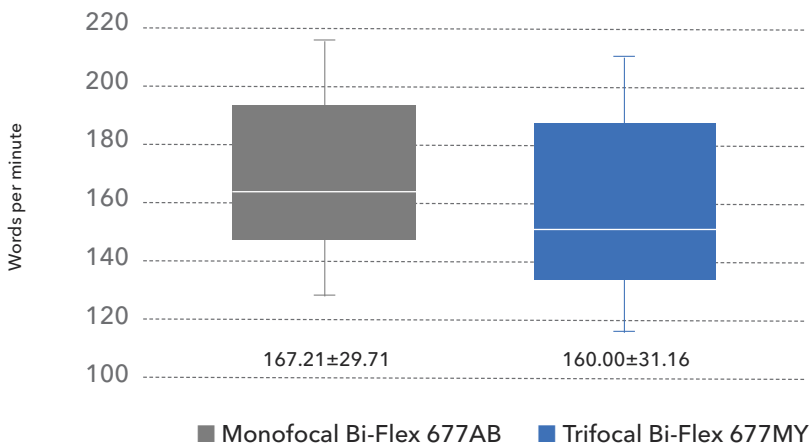
(Study C)



HIGH PATIENT SATISFACTION: 9.5/10



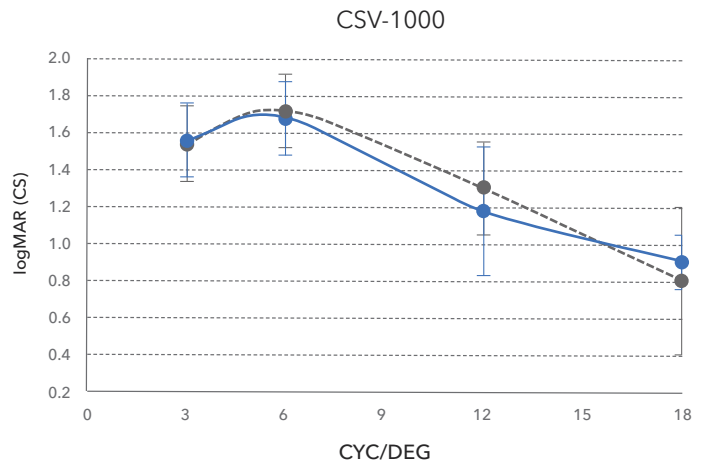
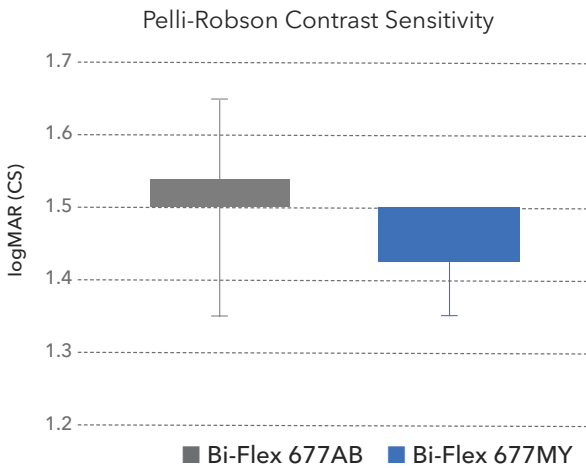
- **Glass independency 100%** (Studies A, B, C, F)
- **Minimal reports of dysphotopsia** (All studies)



• Outstanding reading speed

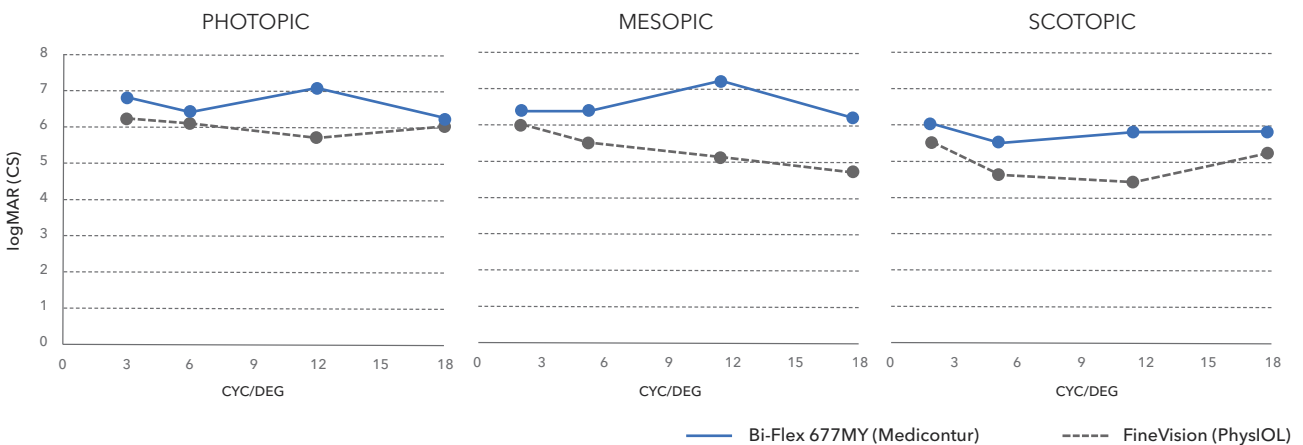
No significant difference was found between monofocal and multifocal IOL groups (Bi-Flex 677AB & Bi-Flex 677MY) in maximal reading speed. (Study E)

No significant difference between monofocal and trifocal IOL groups (Bi-Flex 677AB & Bi-Flex 677MY) (Study E)



Superior contrast sensitivity of Bi-Flex 677MY in different light conditions compared to FineVision (PhysIOL)

(Study B, C)





Bi-Flex 677MY TECHNICAL SPECIFICATION

Type	Single-piece hydrophilic intraocular lens for implantation into the capsular bag
Material	25% water content with UV absorber + blue light filter Refractive Index 1.46 - ABBE number 58
Optic design	Biconvex, aspheric, diffractive-refractive, apodized
Powers available*	0.0 D → +35.0 D · (increment: 0.5 D)
Diffractive zone	EPS technology**, anterior surface, Ø 3.0 mm
Addition	+3.5 D (near); 1.75 D (intermediate)
A-constant***	118.9 (SRK/T)
Dimensions	Overall length 13.0 mm; optic Ø 6.0 mm
Haptic angulation	0° - asymmetrical design with posterior vaulting
Sterilization	Steam (shelf life 5 years after sterilization)
Storage conditions	at +15°C - +35°C (15% - 50% humidity)

*Other powers upon request **Patent pending ***It is recommended that surgeons personalize the constants they use. Please find more information about IOL constants on ULIB. <http://www.ocusoft.de/ulib/c1.htm>

References

Number of eyes

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A	A. F. Dunai, K. Kranitz, E. Juhasz, G. Sandor, T. Filkorn, Z.Zs. Nagy (Hungary): Comparison of two multifocal IOL Types (50 Bi-Flex 667MY & 50 Acrysof ReSTORE IQ) - long term visual outcome. ESCRS 2016, 2017	50
B	E. Van Acker (Belgium): Comparison of clinical outcomes and patient satisfaction after implantation of two different types of diffractive apodized IOLs: 40 Bi-Flex 677MY & 40 FineVision trifocal diffractive IOL. Prospective, randomized, observational study. ESCRS 2017	40
C	J. Györy (Hungary): Long term functional and morphological outcomes and patient satisfaction after cataract surgery with 100 Bi-Flex 677MY implantation with/without posterior central circular capsulorhexis (PCCC) ESCRS 2016, 2017	100
D	Fernández J, Rodríguez-Vallejo M, Tauste A, Martínez J, Piñero DP, (Spain): Visual performance of patients implanted with Bi-Flex 677MY analyzed by the Qvision iPad Multifocal LensAnalyzer. ESCRS 2017	50
E	E. Law, P. Buckhurst, H. Buckhurst, R. Aggarwal and H. Kasaby (UK): Randomised clinical trial of the Bi-Flex 677MY multifocal intraocular lens. ESCRS 2017	100
F	A. Dextl (Austria), J. Pasta (Czech R.), I. Nemcova (Czech R.) Visual Outcome, Patient Satisfaction and Spectacle Independency after Implantation of 100 eyes with trifocal Bi-Flex 677MY. Final Result of a Multicentric Trial with 50 Consecutive Patients. ESCRS 2015	100
G	C. Naval (Philippines): Evolution of multifocal practice. ESCRS 2014	82
H	N. Mejjide (Argentina): Visual Outcomes After Bilateral Implantation of an Apodized Diffractive Trifocal IOL. Clinical outcome ASCRS 2018 ID 42517	30
I	J. García-Bella, N.Ventura-Abreu, L. Morales-Fernandez, P. Talavero-Gonzales, J. Carballo-Alvarez, J. C. Sanz-Fernandez, J. M. Vazquez-Molini, J. M. Martinez-de-la-Casa (Spain): Visual outcomes after progressive apodized diffractive intraocular lens implantation. Eur J Ophthalmol 11.09.2017	50
J	M. Assouline (France): Comparative Outcome of Four Multifocal Intraocular Lenses. ESCRS 2015	100

TOTAL: 702