

TECHNICAL SPECIFICATIONS

BIFOCAL HYDROPHOBIC INTRAOCULAR LENS

PRELOADED



Lens type	For implantation in the capsular bag
Optic diameter	6.00 mm (from +10.0D to +25.0D) 5.80 mm (from +25.5D to +35.0D)
Overall diameter	10.79 mm (from +10.0D to +25.0D) 10.50 mm (from +25.5D to +35.0D)
Design	One-piece square edge on 360°
Optic design	Bifocal Aspherical with negative spherical aberration to partly correct corneal spherical aberration Diffractive pattern on the anterior face, biconvex
Angulation	5°
Material	Hydrophobic CBK 1.8 from Cristalens
Dioptric powers	From +10.0D to +35.0D by 0.5D
Additions (at IOL plane)	+2.50D / +3.00D
Estimated A-Constant (SRK-T)	119.3 Ultrasound biometry 119.7 Interference laser biometry
Suggested Anterior Chamber Depth (ACD)	5.77 mm Ultrasound biometry 6.03 mm Interference laser biometry
Refractive index	1.54
Sterilization	Ethylene oxide
Injection system	Preloaded system
Recommended incision size	2.0 mm

ARTIS[®] PL M



- Bifocality
- Superior contrast
- Optimal apodization
- Available in mix&match

PRELOADED



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 **CRISTALENS**

MADE IN **FRANCE**

CE 0459

DIFFRACTIVE TECHNOLOGY

ARTIS PL M benefits from diffraction technology with its 13 rings for addition +3D and 11 rings for addition +2.5D to adapt to pupil dynamics of patients with cataract, notably taking into account that pupil dynamics decrease with age².

The ARTIS PL M's diffractive system light energy distribution was designed for higher visual comfort:

- 60% for distance vision and 40% for near vision for ARTIS PL M add +3D at 3 mm aperture,
- 55% for distance vision and 45% for intermediate vision for ARTIS PL M add +2.5D at 3 mm aperture.

Cristalens has created a unique synergy between its two lenses to optimize distribution of each light energy peak.

SMART APODIZATION

ARTIS PL M is designed with an apodization to fit any pupil which favors distance vision in scotopic conditions.¹ Indeed, Tekin demonstrated on average in elders, a scotopic pupil size of 5.2 mm², mesopic pupil size of 4.2 mm and photopic pupil size of 3.2 mm.

DEPTH OF FOCUS IMPROVEMENT WITH MIX&MATCH

Multifocality is intended to split light energy to achieve vision sharpness at several distances. Depending on the amount of energy chosen for a given focal point, the patient will see a high or low contrast image. For example, trifocal technology allows for 4 times higher contrast for distance vision than for intermediate vision and doubled contrast for near vision compared to intermediate vision.

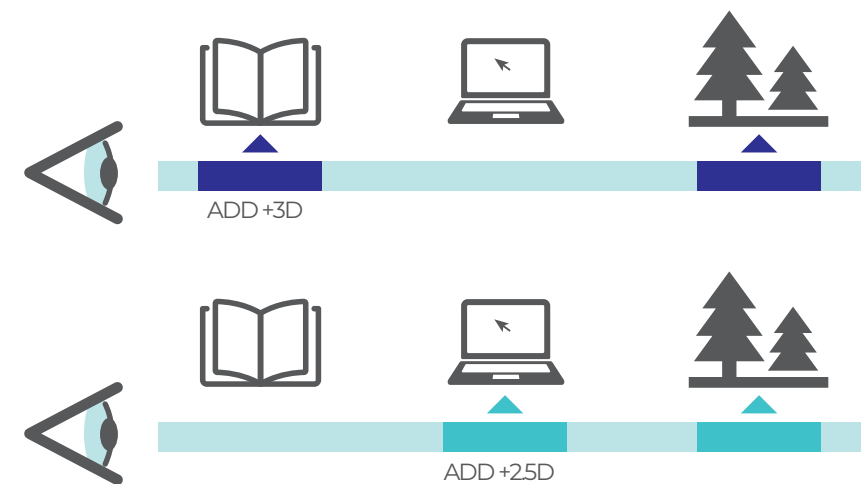
Cristalens Industrie's R&D advises generating intermediate and near vision by combining +2.5D with +3D additions in active patients (for comfortable reading on books, PADs, phones and laptops). This 0.5D difference is chosen to maximize stereopsis in order to achieve continuous contrast from intermediate (60 cm) to near vision (40 cm). The same amount of energy is dedicated to intermediate and to near vision, unlike trifocal intraocular lenses (IOLs).

¹ Maxwell WA, Lane SS, Zhou F. Performance of presbyopia-correcting intraocular lenses in distance optical bench tests. J Cataract Refract Surg. 2009 Jan;35(1):166-71. d

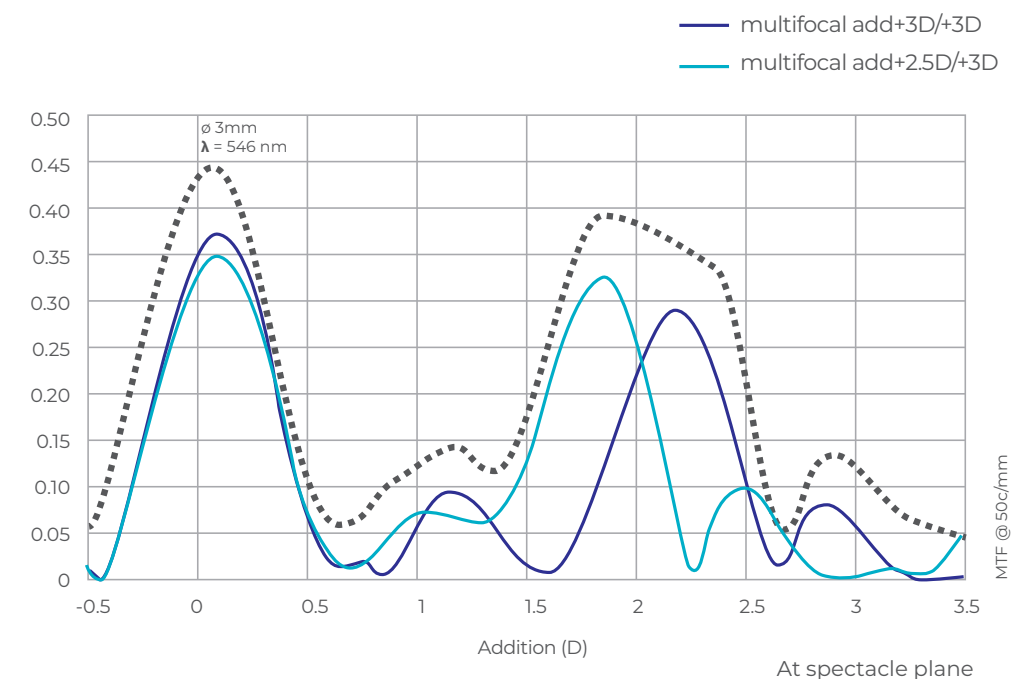
² Tekin K, Sekeroglu MA, Kiziltoprak H, Doguizi S, Inanc M, Yilmazbas P. Static and dynamic pupillometry data of healthy individuals. Clin Exp Optom. 2018 Jan 21.



A Principle of using binocularity to achieve the depth of field presented in schema B



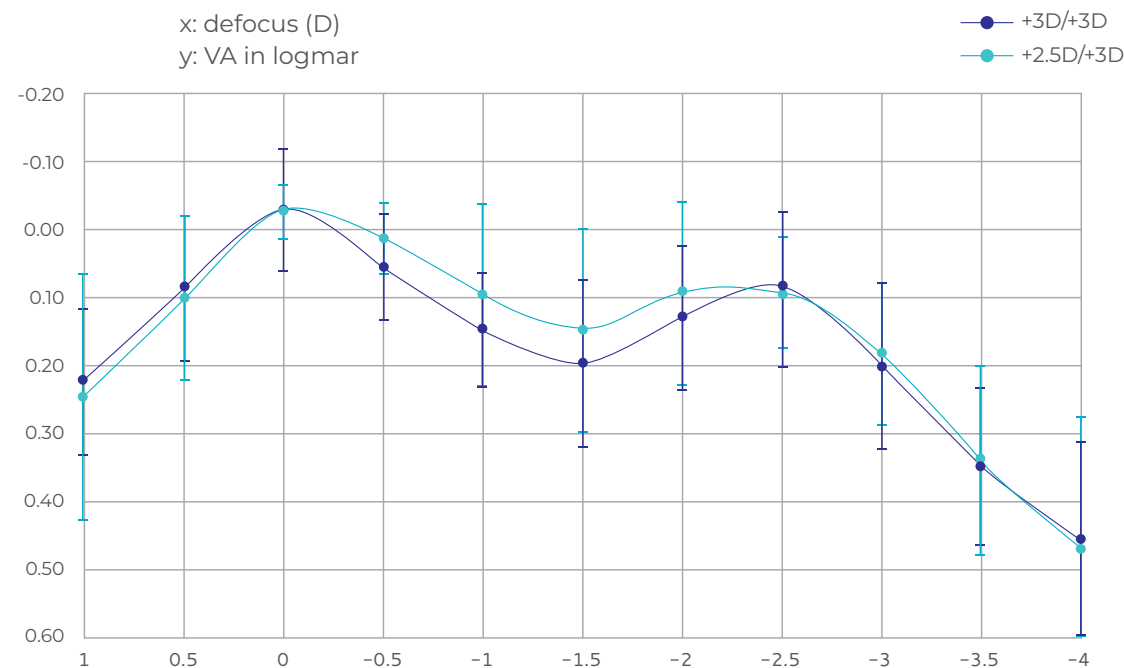
B Modulation transfer function of +3D and +2.5D IOLs according to the defocus at spectacle plane (dotted line, anticipated depth of field)



CLINICAL PERFORMANCES

• VISUAL ACUITY

Early outcomes shows continuous sharp vision from 40 to 60 cm as shown below:

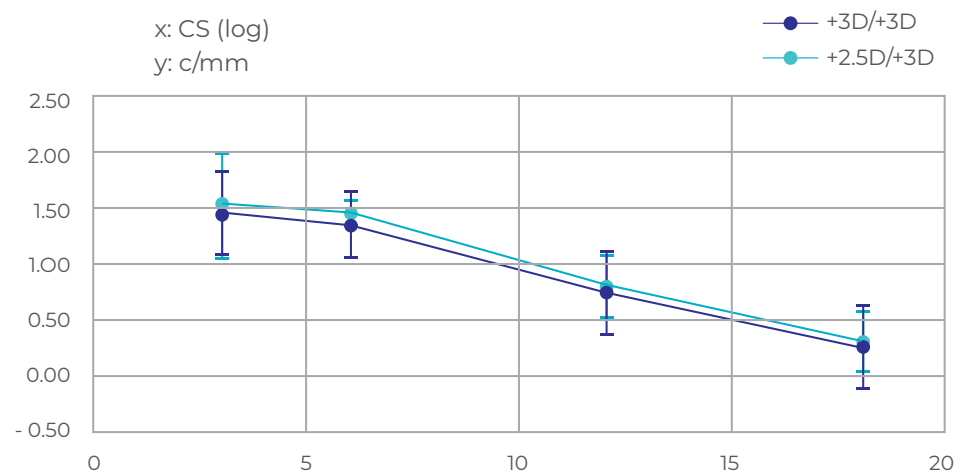


Binocular defocus curve (with the best distance correction) in photopic conditions for a +3D/+3D group (dark blue) and a +2.5D/+3D group (light blue).

Groups were aged (69.6±9.9 years for the +3D/+3D group and 72.7±7.1 for the +3D/+2.5D group)
(Interim outcomes of a multicentric study conducted in France, Promotor Cristalens Industrie).

• CONTRAST

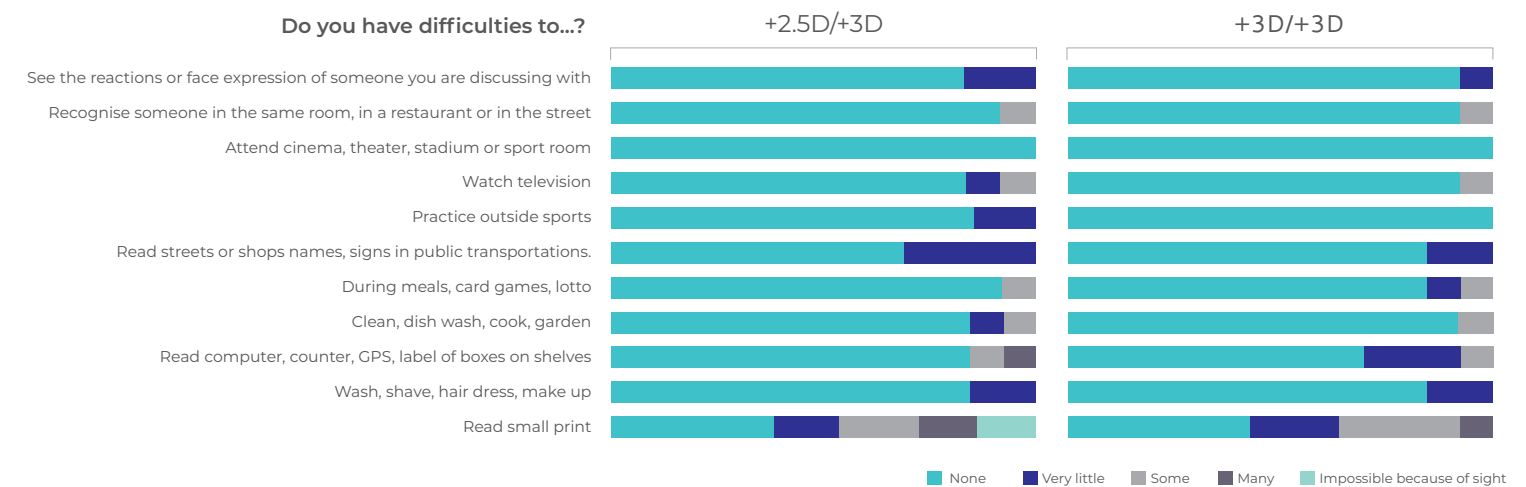
Your patient can benefit from a continuous contrasted vision for a modern life style: he will be able to perform all outdoors activities and use phone, pad, laptop, digital book, newspaper without glasses.



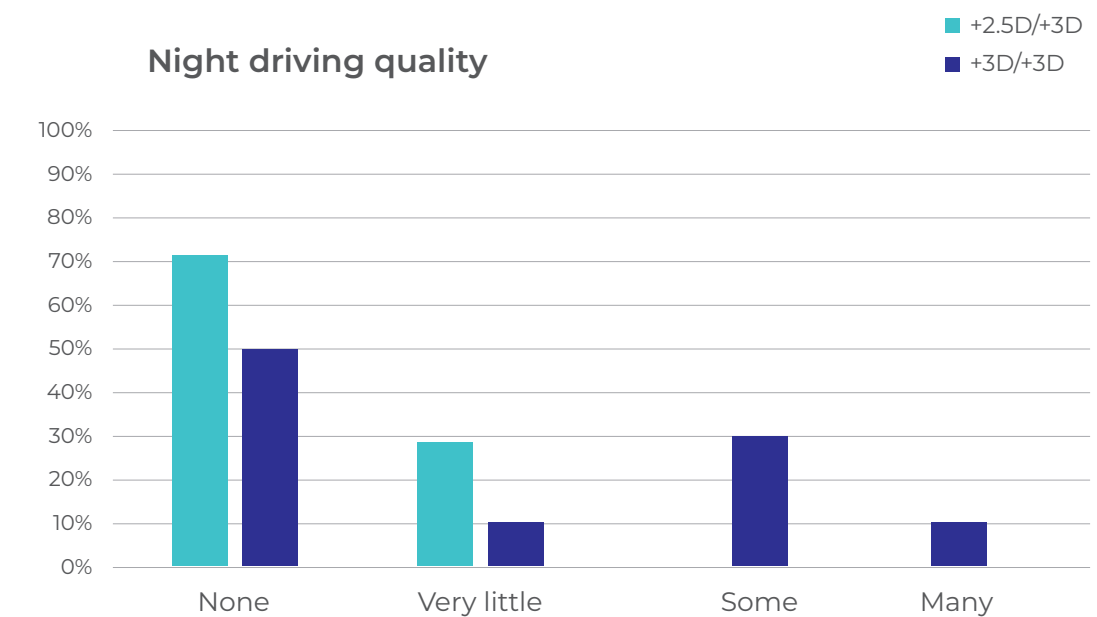
Contrast sensitivity in distance-corrected binocular vision under photopic conditions after implantation of ARTIS PL M (Interim outcomes of a multicentric study conducted in France, Promotor Cristalens Industrie).

• EVERYDAY TASKS PERFORMANCES

The interim outcomes showed that more than 90% of the patients could easily perform most of everyday tasks.



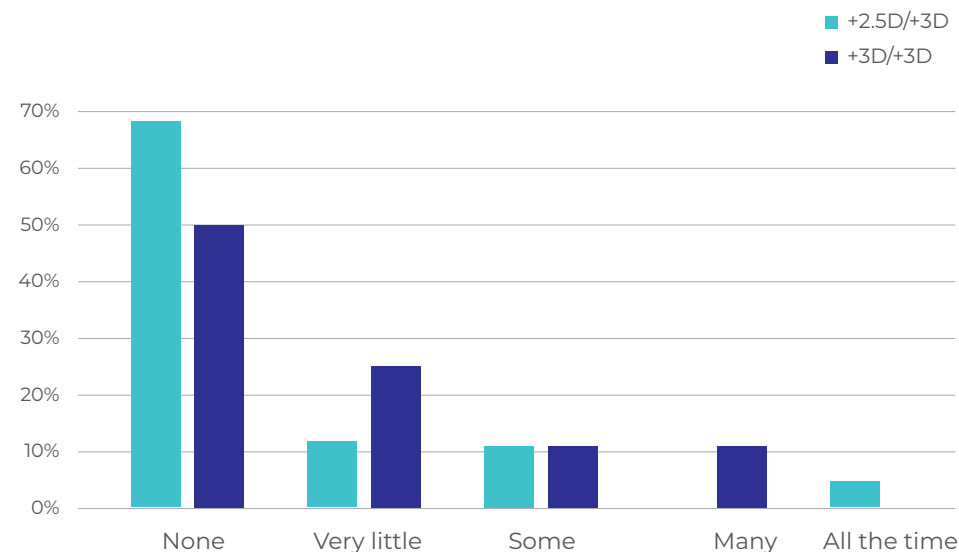
Stack histogram of patients' subjective scoring of their everyday life activities after bilateral implantation of ARTIS PL M (Interim outcomes of a multicentric study conducted in France, Promotor Cristalens Industrie)



100% of the +2.5D/+3D group and 60% of the +3D/+3D group experienced no or very little difficulties for night driving.
(Interim outcomes of a multicentric study conducted in France, Promotor Cristalens Industrie)

HALOS

Bifocal intraocular lenses give rise to halos observed by patients under conditions of dim lighting. In both groups, the halo perception complies with previous studies. Scores in the halometry showed a direct relationship between the halo size and addition power.³ As with trifocal IOLs, this interim study reported fewer patient complaints about halos when two ARTIS PL M IOLs were implanted with one addition +2.5D and one addition +3D.



Subjective quotation of halos after bilateral implantation of ARTIS PL M
(Interim outcomes of a multicentric study conducted in France, Promotor Cristalens Industrie).

ASPHERICITY CORRECTION

ARTIS PL M has the advantage of IOL asphericity correction no matter the lens' dioptric power.

³ Alba-Bueno F, Garzón N, Vega F, Poyales F, Millán MS. Patient-Perceived and Laboratory-Measured Halos Associated with Diffractive Bifocal and Trifocal Intraocular Lenses. Curr Eye Res. 2018 Jan;43(1):35-42

CLEAR IOL FOR HAPPY PATIENTS

Implanting a clear, UV-blocking, but not blue light-blocking IOL during cataract surgery has the potential for improving circadian rhythm and systemic health parameters.⁴ Clear IOLs are providing a protection from depression in elderly patients.⁵

OPTIMIZED PRELOADED SYSTEM

Preloaded system personalized for Cristalens Industrie's hydrophobic IOLs:
2.2 mm incision size.

Preloaded IOLs tend to reduce endophthalmitis⁶ due to the absence of manipulation of the intraocular lens.

Remove the lens holder, hydrate for 1 minute, protect your IOL with viscoelastic product, clip the cartridge and everything is ready for injection:

- IOL inspection possible before injection,
- Easy to use,
- No need for help,
- IOL stays hydrated,
- One of your hands is free (unlike a screw loading system).



⁴ Ayaki M, Negishi K, Tsubota K. Rejuvenation effects of cataract surgery with ultraviolet blocking intra-ocular lens on circadian rhythm and gait speed. Rejuvenation Res.2014 Aug;17(4):359-65

⁵ Mendoza-Mendieta ME, Lorenzo-Mejía AA. Associated depression in pseudophakic patients with intraocular lens with and without chromophore. Clin Ophthalmol. 2016 Mar 31;10:577-81.

⁶ K Weston, R Nicholson, C Bunce... An 8-year retrospective study of cataract surgery and post-operative endophthalmitis: injectable intraocular lenses may reduce the incidence of postoperative endophthalmitis. Br J Ophthalmol. 2015 Oct;99(10):1377-80.