

ATTESTATION CE / EC CERTIFICATE

Approbation du Système d'assurance Qualité de la Production / Approval of Production Quality Assurance System

ANNEXE V point 3 Directive 93/42/CEE relative aux dispositifs médicaux

ANNEX V section 3 DIRECTIVE 93/42/EEC concerning medical devices

Pour les dispositifs de classe IIb ou III, un certificat CE de type est requis

For class IIb or III devices, a EC type certificate is required

Fabricant / Manufacturer

HANITA LENSES

Kibbutz Hanita

2288500 ISRAEL

Catégorie du(des) dispositif(s) / Device(s) category

Système de fourniture de lentille intra-oculaire pliable utilisé pendant les interventions ophtalmologiques

Foldable Intra Ocular Lens Delivery System used during ophthalmology procedures

Voir détails sur addendum

See attachment for additional information

GMED atteste qu'à l'examen des résultats figurant dans le rapport référencé T000486-1-R, le système d'assurance qualité - pour la production et le contrôle final - des dispositifs médicaux énumérés ci-dessus est conforme aux exigences de l'annexe V point 3 de la Directive 93/42/CEE.

GMED certifies that, on the basis of the results contained in the file referenced T000486-1-R, the quality system - for manufacturing and final inspection - of medical devices listed here above complies with the requirements of the Directive 93/42/EEC, annex V section 3.

La validité du présent certificat est soumise à une vérification périodique ou imprévue

The validity of the certificate is subject to periodic or unexpected verification

Début de validité / Effective date : November 26th, 2019 (included)

Valable jusqu'au / Expiry date : December 7th, 2022 (included)



On behalf of the President

Béatrice LYS

Technical Director

Identification des dispositifs / Identification of devices

Description du Dispositif Médical <i>Medical Device Description</i>	Référence Commerciale du Dispositif Médical <i>Medical Device Commercial Reference Number</i>	Classe du Dispositif Médical <i>Medical Device Class</i>
Injectors for IOL insertion	SoftJect 1.8 and SoftJect 2.4	Ila

Ce certificat couvre les activités et les sites suivants :

This certificate covers the following activities and sites:

Hanita Lenses
Kibbutz Hanita 2288500 Israel

Fabrication, contrôle final / Manufacturing, final control

GMED 0459



On behalf of the President
Béatrice LYS
Technical Director

ATTESTATION CE / EC CERTIFICATE

Approbation du Système Complet d'assurance Qualité / Approval of full Quality Assurance System

ANNEXE II excluant le point 4 Directive 93/42/CEE relative aux dispositifs médicaux

ANNEX II excluding section 4 Directive 93/42/EEC concerning medical devices

Pour les dispositifs de classe III, un certificat CE de conception est requis

For class III devices, a EC design certificate is required

Fabricant / Manufacturer

HANITA LENSES

Kibbutz Hanita

2288500 ISRAEL

Catégorie du(des) dispositif(s) / Device(s) category

Lentilles Intraoculaires, anneau de tension capsulaire pliable et système de livraison de lentille intraoculaire

Intraocular lenses, capsular tension ring and Foldable Intra Ocular Lens Delivery System

Voir détails sur addendum / See attachment for additional information

GMED atteste qu'à l'examen des résultats figurant dans le rapport référencé T000486-1-R, T000486-2-DOCR, le système d'assurance qualité - pour la conception, la production et le contrôle final - des dispositifs médicaux énumérés ci-dessus est conforme aux exigences de l'annexe II excluant le point 4 de la Directive 93/42/CEE.

GMED certifies that, on the basis of the results contained in the file referenced T000486-1-R, T000486-2-DOCR, the quality system - for design, manufacturing, and final inspection - of medical devices listed here above complies with the requirements of the Directive 93/42/EEC, annex II excluding section 4

La validité du présent certificat est soumise à une vérification périodique ou imprévue

The validity of the certificate is subject to periodic or unexpected verification

Début de validité / Effective date : November 26th, 2019 (included)

Valable jusqu'au / Expiry date : December 7th, 2022 (Included)


On behalf of the President
Béatrice LYS
Technical Director

GMED - 34048 rev. 2
Renouvelle le certificat 34048-1

GMED • Société par Actions Simplifiée au capital de 300 000 € • Organisme Notifié/Notified Body n° 0459
Siège social : 1, rue Gaston Boissier - 75015 Paris • Tél. : 01 40 43 37 00 • gmed.fr

Identification des dispositifs / Identification of devices

Nom du dispositif médical <i>Medical device name</i>	Dénomination commerciale <i>Commercial designation</i>	Classe du DM <i>MD Class</i>
Intraocular Lens	OPAB 16	IIb
	OPAB 130	
	BALANCE (ABB3)	
	BAL 15	
	BAL 55	
	BAL 85	
	Blens	
	SeeLens	
	BunnyLens	
	BunnyLens Easy	
	BunnyLens/4-Lens AF	
	SeeLens AF	
	SeeLens AF EASY	
	BunnyLens AF EASY/4-Lens AF EASY	
	SeeLens MF	
	SeeLens MF EASY	
	BunnyLens MF/4-Lens MF	
	BunnyLens MF EASY / 4-Lens MF EASY	
	SeeLens HP	
	BunnyLens HP/ 4-Lens HP	
	SeeLens HP Easy	
	BunnyLens HP Easy	
	Vistor	
	Vistor EASY	
Intraocular Lens including Kits with Injector SoftJect	Intensity SL	
	Intensity BN	
	Intensity BN EZ	
	Blens KIT	
	SeeLens KIT	
	BunnyLens/4-Lens AF KIT	
	SeeLens AF KIT	
	BunnyLens AF/4-Lens AF KIT	
	SeeLens MF KIT	
	BunnyLens MF/4-Lens MF KIT	
Endo capsular Ring	SeeLens HP KIT	
	BunnyLens HP/4-Lens HP KIT	
Capsule Centering Device	Vistor and Vistor EASY KIT	
	ECR	
	ClearRing	
	AssiAnchor	



GMED 0459

**On behalf of the President
Béatrice LYS
Technical Director**

Ce certificat couvre les activités et les sites suivants :

This certificate covers the following activities and sites:

Hanita Lenses

Kibbutz Hanita 2288500 Israel

Conception, fabrication, contrôle final / Design, manufacturing, final control

GMED 0459



**On behalf of the President
Béatrice LYS
Technical Director**

GMED certifie que le système de management de la qualité développé par
GMED certifies that the quality management system developed by

HANITA LENSES
Kibbutz Hanita
2288500 ISRAEL

pour les activités
for the activities

Conception, fabrication et vente de lentilles de contact souples et dures, lentilles intraoculaires, anneaux de tension capsulaire. Fabrication et vente de système de livraison de lentille intraoculaire pliable

Design, manufacturing, and sales of soft and hard contact lenses, intraocular lenses, and Capsular Tension Rings. Manufacturing and sales of Foldable Intra Ocular Lens Delivery System

réalisées sur le(s) site(s) de
performed on the location(s) of

Hanita Lenses
Kibbutz Hanita 2288500 ISR

est conforme aux exigences des normes internationales
complies with the requirements of the international standards

NF EN ISO 13485 : 2016

Début de validité / Effective date : November 26th, 2019 (included)

Valable jusqu'au / Expiry date : December 7th, 2022 (Included)

Etabli le / Issued on : November 26th, 2019



CERTIFICATION
DE SYSTEMES
DE MANAGEMENT
Accréditation n°4-0008
Liste des sites accrédités
et portée disponible sur
www.cofrac.fr

GMED N° 34047-2

Ce certificat est délivré selon les règles de certification GMED / This certificate is issued according to the rules of GMED certification

Renouvelle le certificat 34047-1



On behalf of the President
Béatrice LYS
Technical Director

GMED certifie que le système de management de la qualité développé par
GMED certifies that the quality management system developed by

HANITA LENSES
Kibbutz Hanita
2288500 ISRAEL

pour les activités
for the activities

Conception, fabrication et vente de lentilles de contact souples et dures, lentilles intraoculaires, anneaux de tension capsulaire. Fabrication et vente de système de livraison de lentille intraoculaire pliable

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Kibbutz Hanita 2288500 ISR

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Début de validité / Effective date : November 26th, 2019 (included)

Valable jusqu'au / Expiry date : December 7th, 2022 (Included)

Etabli le / Issued on : November 26th, 2019



GMED_34047-10-07-2019
CERTIFICATION
DE SYSTÈMES
DE MANAGEMENT
Accréditation n°4-0008
Liste des sites accrédités
et portée disponible sur
www.cofrac.fr

GMED N° 34047-2

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Renouvelle le certificat 34047-1



On behalf of the President
Béatrice LYS
Technical Director

GMED • Société par Actions Simplifiée au capital de 300 000 € • Organisme Notifié/Notified Body n° 0459
Siège social : 1, rue Gaston Bachelard 75015 Paris • Tél : 01 40 43 37 00 • gmed.fr



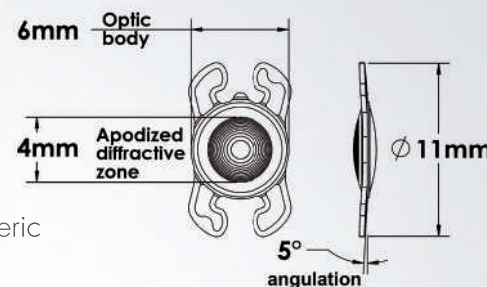
Mini Incision implantation

- Easily and safely injected through an incision as small as 1.8 mm.
- Lower surgically induced astigmatism.
- Fast recovery after surgery, less inflammation.
- Less trauma to the cornea and the eye.
- Less endothelial cell loss.



Technical Specifications

Overall diameter	11.00 mm
Optic diameter	6.00 mm
Power range.....	10.0 to 30.0 (0.5D increments) 31.00 to 35.00 (1.0 D increments)
Optic design	Multifocal Diffractive Apodized Aspheric
Edge design.....	360° Continuous Square Edge
Haptic angulation.....	5°
Material	Hydrophilic Acrylic HEMA/EOEMA copolymer
Filtration.....	UV Blocker and violet light filter
Refractive Index.....	1.46 (hydrated @ 35°C)
Y.A.G laser	Compatible
Estimated A constant	SRK/T IOLMASTER biometry: 118.5* SRK/T US biometry: 118.16*
Placement	Capsular Bag
CE Approved	



* It is recommended that surgeons personalize their A-constant based on their surgical techniques and equipment, experience and post-operative results.
For more information please visit Hanita Lenses web site.

Hanita Lenses

Hanita Lenses is a worldwide trusted manufacturer and provider of intraocular lens solutions for cataract surgery.
With more than 30 years of experience in meeting the varied needs of ophthalmic surgeons, the Hanita Lenses name is synonymous with high quality, reliability and service.



www.hanitalenses.com e.mail: marketing@hanitalenses.com
Hanita Lenses Intraocular & Contact Lenses
Kibutz Hanita 22885 Tel: +972 4 9950700 Fax: +972 4 9950755



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Date: 2021.10.07 23:48:25 EEST



ADD.
+3D

BunnyLens MF
The Premium Multifocal Solution



BunnyLens MF, the new diffractive multifocal aspheric intraocular lens from Hanita Lenses, provides the patient with an excellent depth of focus for the near, intermediate and far visual ranges. The use of BunnyLens MF reduces spectacle dependency for reading, driving or using the computer.

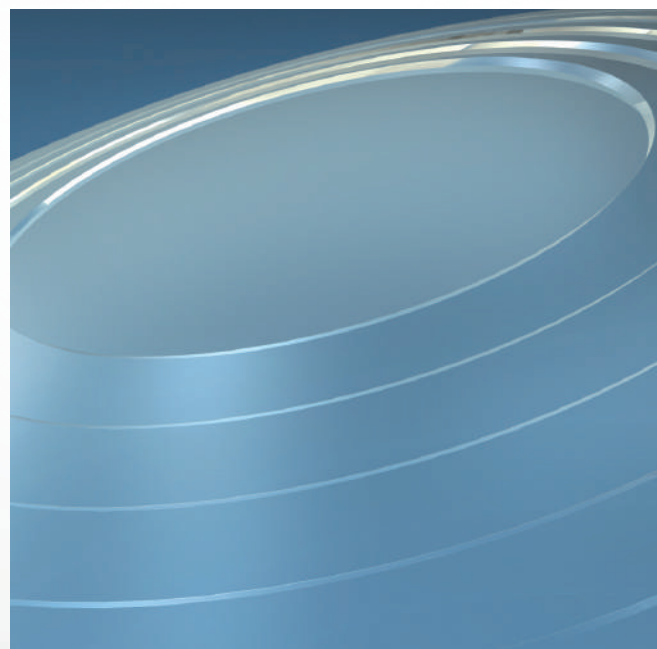


Advanced Optical Design

The BunnyLens MF was designed using the most advanced tools by a professional R&D team of optical and mechanical engineers. The optical diffractive apodized aspheric profile was developed using proprietary algorithms and the Zemax™ software. Calculations were optimized in order to provide optimal energy distribution in different light conditions, minimize spherical aberrations and generate +3.0 D addition power for near vision, equivalent to +2.4D at the spectacle plane.

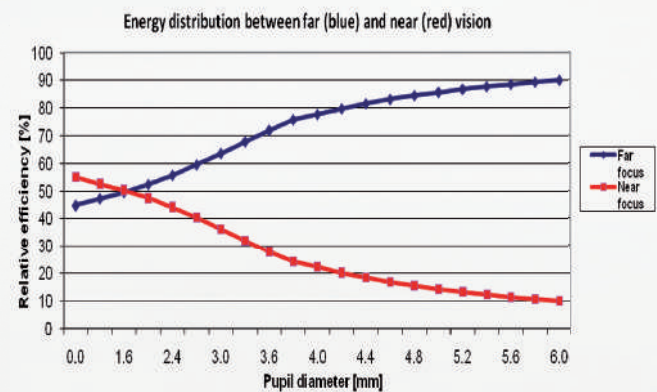
Apodized Diffractive Optics

The aspheric - diffractive profile of the BunnyLens AF has been clinically proven to provide an excellent and aberration free vision, in all conditions and for all distances. The diffractive steps are located in the 4mm central zone, suiting pupil sizes in various lighting conditions. The steps follow an apodization function, meaning they reduce in height according to an algorithm designed so the patient can function comfortably all day long.



The state-of-the-art apodized diffractive surface provides visual functionality throughout the day:

- In photopic conditions, when the pupil is small, the BunnyLens MF distributes 65% of the light for far vision and 35% for near vision, providing light for all daytime activities.
- In mesopic and scotopic conditions, distance vision gets most of the light energy, enabling night vision and driving in the dark, when the pupil is enlarged.

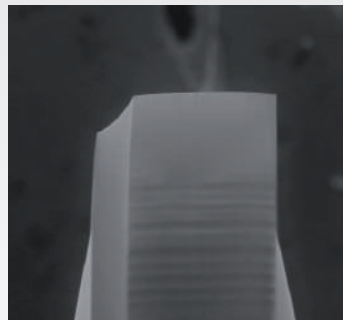


Geometrical Design

- BunnyLens MF ensures excellent stability and centration due to the 4-point haptic design.
- Wide angle of contact with the capsular bag.
- 360° sharp square edge for lowered PCO.



Bunnylens MF provides wide angle of contact with the capsular bag

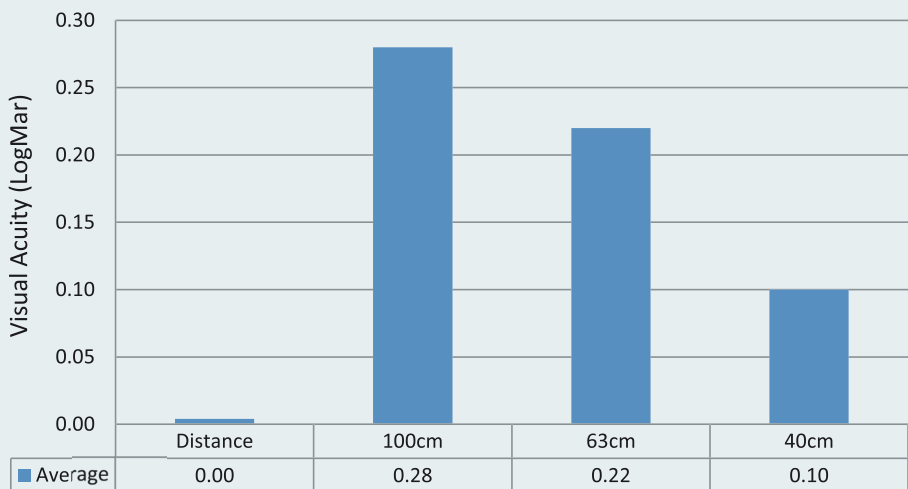


SEM image of Bunnylens MF edge design [1]
[1] Image by Prof. Manfred Tetz, ATK Spreebogen Berlin.

Clinical Evaluation Results*

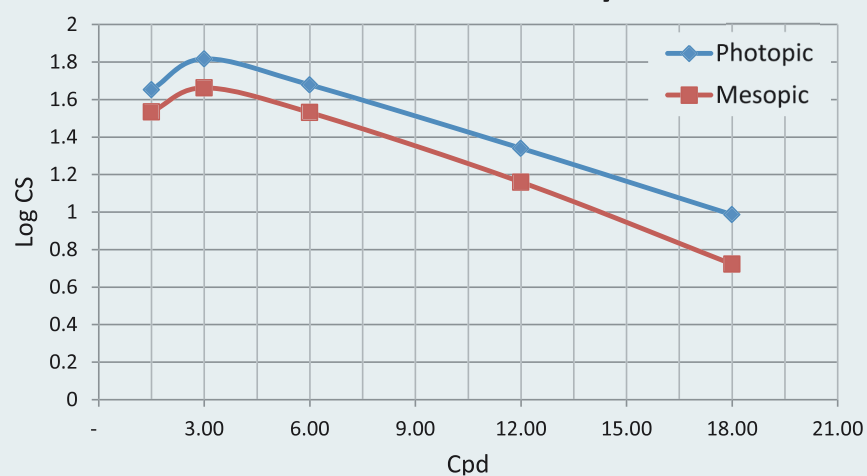
Designed to rejuvenate vision, the BunnyLens MF works in harmony with the pupil to provide a quality depth of vision for all distances.

Visual Acuity for Varied Distance Binocular Vision



Due to its aspheric optical design profile, clinical results of the BunnyLens MF showing superior contrast sensitivity providing sharper vision in all lightning conditions.

Contrast Sensitivity



* Based on the multicenter study of the SeeLens MF lenses by Prof. M. Tetz, Prof. R. Bellucci, Prof. J.L. Aloï

ATTESTATION CE / EC CERTIFICATE

Approbation du Système Complet d'assurance Qualité/ Approval of full Quality Assurance System

ANNEXE II excluant le point 4 Directive 93/42/CEE relative aux dispositifs médicaux

ANNEX II excluding section 4 Directive 93/42/EEC concerning medical devices

Pour les dispositifs de classe III, un certificat CE de conception est requis

For class III devices, a EC design certificate is required

Fabricant / Manufacturer

HANITA LENSES

Kibbutz Hanita

2288500 ISRAEL

Catégorie du(des) dispositif(s) / Device(s) category

Lentilles intraoculaires, anneau de tension capsulaire pliable et système de livraison de lentille intraoculaire

Intraocular lenses, capsular tension ring and Foldable Intra Ocular Lens Delivery System

Voir document complémentaire GMED / See GMED additional document

n° 38190

GMED atteste qu'à l'examen des résultats figurant dans le rapport référencé T001073, le système d'assurance qualité - pour la conception, la production et le contrôle final - des dispositifs médicaux énumérés ci-dessus est conforme aux exigences de l'annexe II excluant le point 4 de la Directive 93/42/CEE.

GMED certifies that, on the basis of the results contained in the file referenced T001073, the quality system - for design, manufacturing, and final inspection - of medical devices listed here above complies with the requirements of the Directive 93/42/EEC, annex II excluding section 4.

La validité du présent certificat est soumise à une vérification périodique ou imprévue

The validity of the certificate is subject to periodic or unexpected verification

Début de validité / Effective date : March 17th, 2021 (included)

Valable jusqu'au / Expiry date : May 26th, 2024 (included)

Digitally signed by Pereteatco Alina

Date: 2021.09.17 22:32:21 EEST



DocuSigned by:

Beatrice Lys

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On behalf of the President

Béatrice LYS

Technical Director

Ce document complémentaire GMED n° 38190 rev. 0 atteste de la validité du certificat CE n° 34048 rev. 5 au regard des informations listées ci-dessous.

This GMED additional document N° 38190 rev. 0 attests to the validity of CE certificate n° 34048 rev. 5 with regard to the information listed below.

Fabricant / Manufacturer:

**Hanita Lenses
Kibbutz Hanita
2288500 Israel**

Identification des dispositifs / Identification of devices

Désignation du dispositif / Accessories marqués CE <i>Device designation / EC marked accessories</i>	Réf commerciale du dispositif ou code article <i>Device commercial reference or article code</i>	Classe du DM <i>MD Class</i>
Intraocular Lens	EXTEND SL EXTEND SL EASY EXTEND BN EXTEND BN EASY EXTEND Toric EXTEND Toric EASY OPAB 16 OPAB 130 BALANCE (ABB3) BAL 15 BAL 55 BAL 65 Blens SeeLens BunnyLens BunnyLens Easy BunnyLens/4-Lens AF SeeLens AF SeeLens AF EASY BunnyLens AF EASY/4-Lens AF EASY SeeLens MF SeeLens MF EASY BunnyLens MF/4-Lens MF BunnyLens MF EASY / 4-Lens MF EASY SeeLens HP BunnyLens HP/ 4-Lens HP	IIb

GMED 0459

GMED - 38190 rev. 0



DocuSigned by:

Beatrice Lys

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**On behalf of the President
Béatrice LYS
Technical Director**

Désignation du dispositif / Accessories marqués CE <i>Device designation / EC marked accessories</i>	Réf commerciale du dispositif ou code article <i>Device commercial reference or article code</i>	Classe du DM <i>MD Class</i>
Intraocular Lens	SeeLens HP Easy BunnyLens HP Easy Vistor Vistor EASY Intensity SL Intensity BN Intensity BN EZ Intensity SL HP Intensity BN HP Intensity SL HP EZ Intensity BN HP EZ VisTor MF VisTor MF Easy INTENSITY Toric INTENSITY Toric EZ INTENSITY Toric HP INTENSITY Toric HP EZ	IIb
Intraocular Lens including Kits with Injector SoftJect	Blens KIT SeeLens KIT BunnyLens/4-Lens AF KIT SeeLens AF KIT BunnyLens AF/4-Lens AF KIT SeeLens MF KIT BunnyLens MF/4-Lens MF KIT SeeLens HP KIT BunnyLens HP/4-Lens HP KIT Visitor and Vistor EASY KIT	
Endo capsular Ring	ECR CleaRing	
Capsule Centering Device	AssiAnchor	

Sites couverts et Activités / Locations and Activities

Sites / Locations	Activités / Activities
Hanita Lenses Kibbutz Hanita 2288500 Israel	Conception, fabrication, contrôle final / Design, manufacturing, final control

GMED **0459**

GMED - 38190 rev. 0



DocuSigned by:

Beatrice Lys

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On behalf of the President
Béatrice LYS
Technical Director

Foldable IOL

B-Lens

- Modified C haptic shape
- Square edge design - Optic and Haptic
- High refractive index
- Excellent memory - Superior foldability - Slow and gentle unfolding
- Manufactured from Copolymer HEMA/EOEMA, 25% water content with UV blocker
- Yag laser compatible
- Insertion through a 2mm - 3.2mm

Specifications

Overall length.....	12.50 mm
Optic diameter.....	6.00 mm
Power range.....	+1.00 to +7.00 (1 dpt increments) +8.00 to +30.00 (0.5 dpt increments) +31.00 to +40.00 (1 dpt increments)
Optic design.....	Bi Convex
Finish.....	Square edge
Haptic shape.....	Modified C
Haptic angulation.....	5°
Material.....	Hydrophilic Acrylic UV
Refractive index.....	1.462 (35°C)
Yag laser.....	Compatible
A. constant.....	118.2
Placement.....	Capsular Bag



B-Lens - The excellent optic resolution provides optimum postoperative visual acuity

Improved modified C haptic shape

B-Lens design optimizes the stability of the lens in the capsular bag.

Square edge design

B-Lens square edge design - intended to prevent cell growth under the lens.

Improved posterior capsular tension

B-Lens 5° angulation and haptic shape, improve the posterior capsular tension.

High refractive index

B-Lens High Refractive Index (1,462), optimizes the profile of the lens thus enabling insertion through a 2 ÷ 3.2 mm incision.

Insertion

B-Lens can be implanted with either Forceps or Injector.

Superior foldability with a gentle and slow unfolding release

B-Lens material has excellent memory properties that ensure a perfect foldability and perfectly slow and gentle unfolding release.

UV blocker

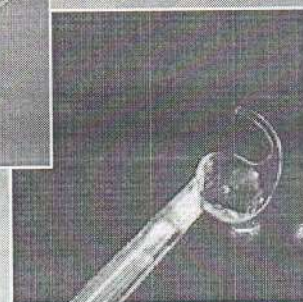
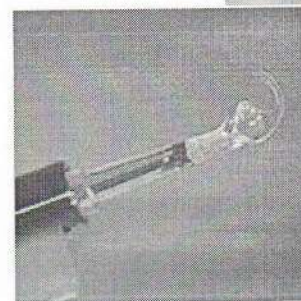
B-Lens material has a built in UV blocker that effectively filters damaging UV radiation.

YAG laser compatible

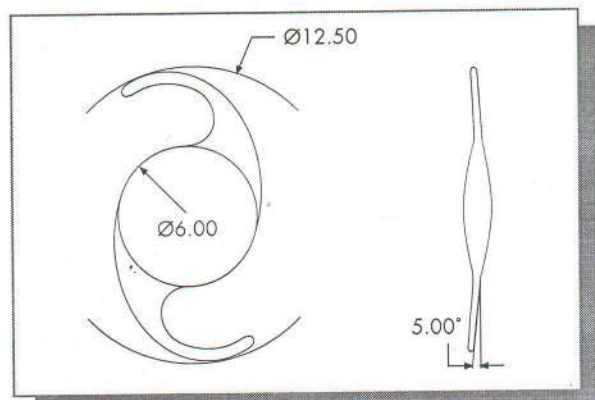
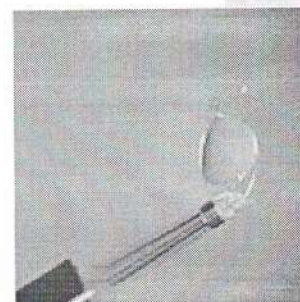
B-Lens is YAG laser compatible



Easy folding with forceps



Gentle unfolding from injector



T1007 08/07

Hanita
Lenses

www.hanitalenses.com • email: marketing@hanitalenses.com

Hanita Lenses • Intraocular & Contact Lenses • Kibbutz Hanita 22885 Israel • Tel. 972 4 9950700 • Fax. 972 4 9950755

European Authorized Rep. OBEUS S.A., 34, avenue de Tervuren, Bte 44, 1040 Brussels, Belgium.



Mini Incision implantation

- Easy to fold and inject safely through an incision of 1.8 mm

Technical Specifications

Overall length 11 mm (9.5D and above); 11.5mm for lower D

Optic diameter 6.00 mm

Power range -10.00D – 8.00D (1.0D increments)

8.00 11.00 – 30.00 (0.5D increments)

30.00 – 35.00(1.0D increments)

Optic design Aspheric Bi convex design

Finish. Double Square Edge

Haptic angulations 5°

Material Hydrophilic Acrylic HEMA/EOEMA copolymer

with a UV and Violet Light Filter

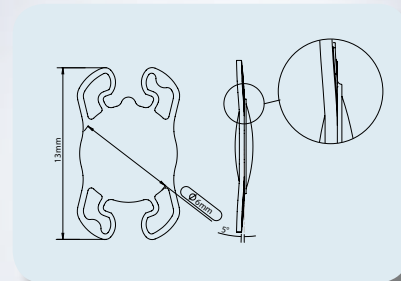
Refractive Index 1.46 (hydrated @ 35°C)

Y.A.G laser Compatible

A constant 118.9 Carl Zeiss IOL MASTER

118.56 US Biometry

Placement Capsular Bag or Sulcus



Hanita Lenses

Hanita Lenses is an Intraocular Lens and contact lenses manufacturer which is active in the Israeli domestic market and the global market since 1981.

Hanita Lenses' strategy focuses on technology and innovative R&D, in order to keep the company as a dynamic leading player in the Medical Device Ophthalmic market.

The company holds high-end technologies and vast knowledge in the refractive and cataract surgery field.

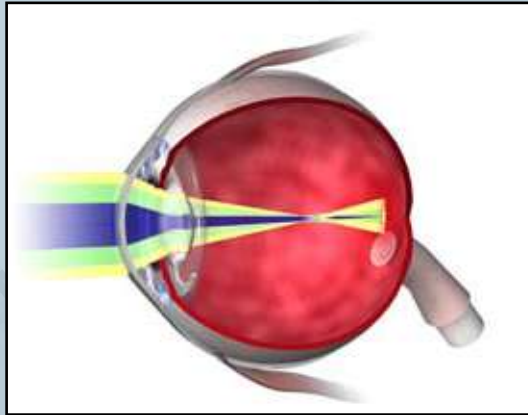
BunnyLens AF

Providing Aberration Free Vision

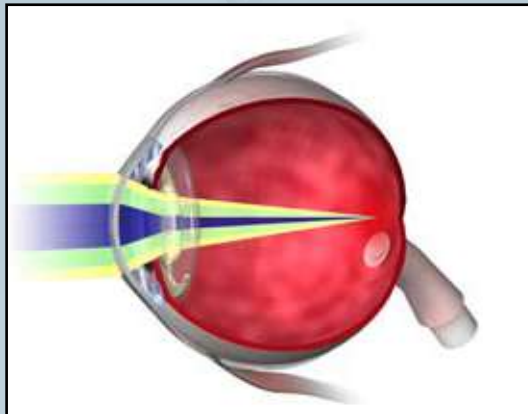
Aspheric IOL Design using mini incision technique

See for yourself

Spheric Lens
Spherical aberration



SeeLens AF
Abberation free



- **BunnyLens AF** reduces spherical aberration to minimum.
- **BunnyLens AF** improves functional vision
- **BunnyLens AF** improves night vision
- **BunnyLens AF** designed with the most advanced optical tools

BunnyLens AF, the new Aspheric Intraocular lens from Hanita Lenses, provides the patient with an excellent vision quality at day and night conditions, by using state-of-the-art aberration free aspheric optical design.

Advanced Optical Design

The aspheric BunnyLens AF was designed using the most advanced tools, by a professional R&D team of optical and mechanical engineers.

The optical profile algorithm was calculated using ZEMAX™ software – a simulating tool for optimized optical design.

Calculations were aimed in order to minimize all aberrations, including the spherical aberration of the cornea, and to optimize the MTF (Modulated Transfer Function) of the IOL.

The BunnyLens AF is thinner than ever, being easily injectable through 1.8mm incisions at even high diopters when the IOL is usually too thick.

Eye Model

Optical design was performed using Arizona eye model. This advanced model is most suitable for IOL design, since it represents the eye anatomy with relation to age.

Hanita Lenses designed an aspheric surface IOL optimized for the aged patient. Thus, the result is an advantageous accurate simulation of the visual performance of the lens in a post-operative average eye.

Geometrical Design

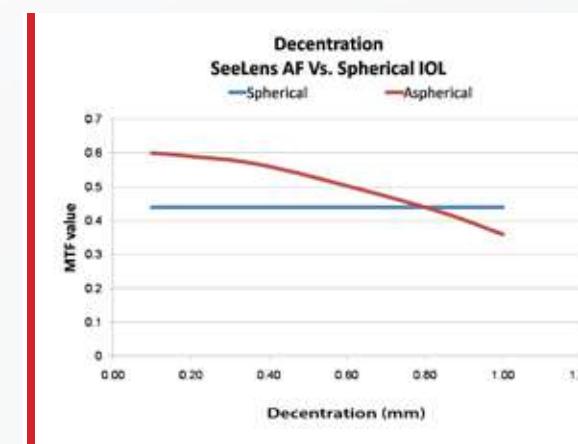
Geometrical design

- BunnyLens AF ensures excellent stability and centration due to four- point-fixated mechanical design of the haptics.
- 3600 double square edge in order to minimize PCO
- Excellent memory – slow gentle release, superior foldability

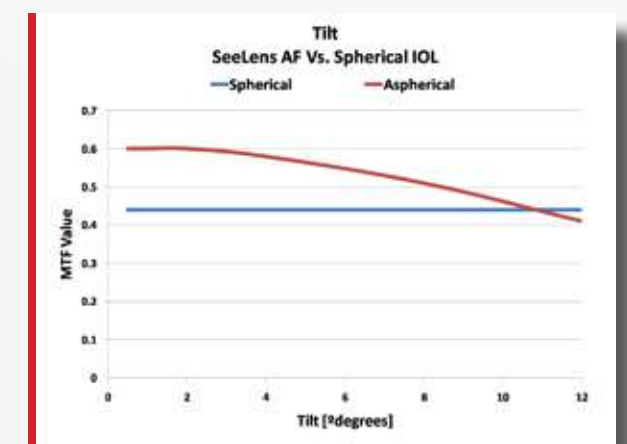
Image of the SeeLens AF square edge using SEM (X400) in a wet cell



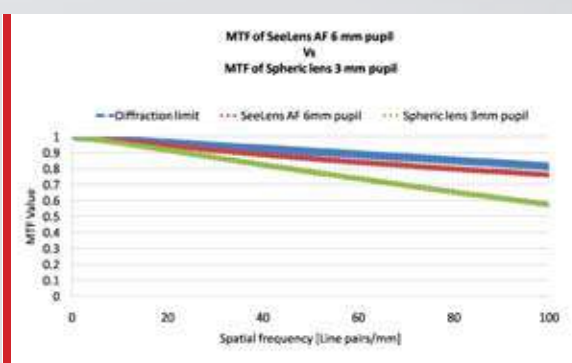
Stability and Centration



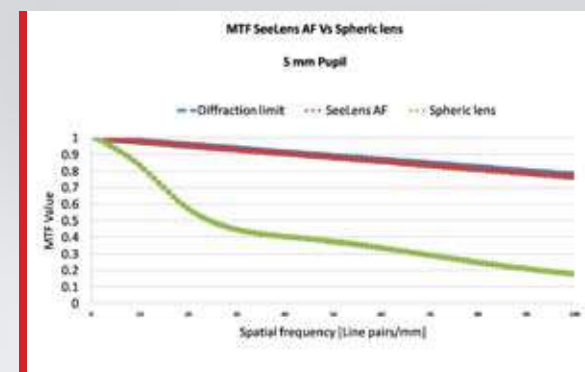
The BunnyLens AF design provides a visual advantage for patients over spherical lens even if decentered up to 0.8



The BunnyLens AF design provides a visual advantage for patients over spherical lens even if tilted up to 10 degrees



The BunnyLens AF provides excellent night vision, even better than daylight vision with a standard spherical IOL



The BunnyLens AF design provides excellent optical quality at night conditions, near the theoretical limit

Material

- The BunnyLens AF is made from hydrophilic acrylic HEMA/ EOEMA copolymer material with a UV and Violet Light Filter, having a proven excellent reputation and many years of clinical experience
- The BunnyLens AF is characterized by excellent biocompatibility and mechanical quality.



Lentile intraoculară de cameră posterioară

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Date: 2021.09.17 22:53:53 EEST

Foldable B-lens

Sterile, acrilice, pliabile monobloc



Hanita Lenses

Kibbutz Hanita - 22885 - Israel

Tel: +972(0)4 9950700

Fax: 972 (0)4 9950755

e-mail: marketing@hanitalenses.com

OBELIS S.A.

Boulevard General Wahis 53

1030 Brussels - Belgium

Tel. +32(0) 2 732 5954

Fax: +32(0) 2 732 6003

Instrucțiune de exploatare

Informații suplimentare privind produsele oftalmologice de calitate înaltă se pot obține adresând la numărul de telefon, fax sau prin poșta electronică solicitarea catalogului de publicitate complet al lentilelor (intra)oculare ale Companiei „Hanita”.

După implantare, eliminate minuțios și complet resturile de material elastic-vâscos din cavitatea sacului capsular al ochiului (globului ocular) prin spălarea acestei cavități/aspirația lichidului din această cavitate, în special, din spațiul dintre lentila oculară și camera posterioară a sacului capsular al ochiului.

Responsabilitatea Companiei

Responsabilitatea Companiei cuprinde în exclusivitate construcția și calitatea confecționării lentilei intraoculare. Compania nu poartă vreo responsabilitate pentru orice accidente legate de utilizarea acestui produs. Cu scopul asigurării calității înalte a produsului finit, lentilele intraoculare se supun unei verificări riguroase și controlului calității în procesul fabricării acestora. În cazul în care se constată vreo defecțiune (deformare) a articolului sau dacă apar dubii în privința calității acestuia, lentila urmează să fie utilizată.

Descriere:

Lentilă intraoculară acrilică cu monobloc pentru camera posterioară a globului ocular, confecționată de compania „Hanita Lenses”. Lentilă intraoculară pentru camera



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posterioară a globului ocular reprezintă un implant optic destinat înlocuirii cristalinului ocular uman. Lentilă intraoculară pentru camera posteroară a globului ocular (IOL) este un dispozitiv optic acrilic hidrofil intraocular, confecționat din copolimer de tipul HidraxiEtil-Metil-Acrilat cu absorbant de raze ultraviolete, fixat prin metoda sudării cu laser. Lentilele se confecționează în diferite variante constructive, prezentate mai sus în Fig.1.

Caracteristica materialului:

- Conținut de apă: 25%
- Indice de refracție 1,452 (la 25...C)
- Lentila este compatibilă cu radiația laser pe granatul de itriu - aluminiu.

Lentila se sterilizează cu abur.

INDICAȚII:

Lentilele intraoculare pentru camera posteroară a globului ocular (IOL) de la Compania „Hanita” sunt indicate în tratamentul chirurgical al cataractei senile, congenitale sau traumatice. Lentilele intraoculare de tipul IOL sunt destinate plasării în sacul capsular al ochiului.

CONTRAINDICAȚII:

Până în prezent, contraindicații absolute pentru implantarea lentilei intraoculare nu s-au depistat.

Contraindicațiile indirecte pot avea legătură cu unele forme de maladii oftalmologice, enumerate mai jos:

- Uveită cronică (inflamația tunicii vasculare a globului ocular) în fază activă.
- Afecțiuni ale retinei, dacă implantul poate împiedica efectuarea intervenției chirurgicale pe retina oculară.

COMPLICAȚII POSIBILE:

Tratamentul chirurgical al cataractei, atât în cazul implantării lentilei, cât și fără implantarea acesteia poate fi asociat cu manifestările de mai jos:

- Inflamația sclerei
- Hemoragie
- Hipertensiune oculară
- Infecții postoperatorii
- Desprinderea de retină
- Edem eritematos (tumefiere)
- Edem cornean
- Opacitatea camerei posteroare a sacului capsular (globului ocular)

Complicațiile legate direct de implantarea lentilei intraoculare:

- Ruptura capsulei oculare



- Pierderea corpului vitros
- Deplasarea centrului lentilei
- Calculul incorect al puterii dioptrice a lentilei
- Deteriorarea lentilei în procesul implantării acesteia.

ATENȚIONĂRI:

- Nu folosiți lentila intraoculară, dacă aceasta are ambalajul exterior deteriorat sau există scurgere din containerul acesteia, sau dacă apar orice dubii.
- În cazul în care este necesară sterilizarea repetată a lentilei, aceasta urmează să fie returnată obligatoriu Companiei „Hanita Lenses” pentru efectuarea acestei sterilizări.
- Lentila intraoculară cu termenul de valabilitate expirat nu poate fi utilizată în continuare. În niciun caz nu sterilizați lentila intraoculară cu forțe proprii, folosind orice metode de sterilizare.
- Nu păstrați lentila intraoculară la o temperatură de peste 45°C (113° F).
- Păstrarea lentilei intraoculare la o temperatură mai mică de 18°C poate avea ca efect aburirea acesteia, care dispare complet în 2-3 ore atât în organismul viu, cât și în condiții de laborator, la temperaturi ridicate ale mediului ambiant.
- Nu expuneți lentila intraoculară acțiunii vreunui lichid decât a soluției de irigare sterile speciale, destinate umezirii acesteia în timpul păstrării.
- Dat fiind faptul că lentila intraoculară de tipul IOL se usucă în mediul aerian, aceasta nu poate fi păstrată în stare neumezită. Pentru a evita deteriorarea lentilei intraoculare de tipul IOL, aceasta trebuie umețată cu o soluție echilibrată sau o soluție analogică chiar înaintea implantării, cât și atunci când ea trebuie păstrată un timp.

AMBALAJ

Lentile intraoculare de tipul IOL de la Compania „Hanita” într-un flacon înfășurat în pachet steril. Sterilitatea ambalajului este garantată numai dacă nu a fost afectată integritatea pachetului de ambalat.

INSTRUCȚIUNI DE UTILIZARE

Există diferite metodologii chirurgicale de introducere a lentilei intraoculare. Chirurgul urmează să aleagă metoda cea mai potrivită și optimă pentru fiecare pacient:

- Să verifice prezența inscripției pe eticheta cutiei de ambalaj și să se asigure că lentila este exact de modelul, puterea dioptrică necesară și că termenul acesteia nu a expirat.



- Să deschidă ambalajul și să se asigure de corespunderea informației interioare privind lentila cu informația de pe eticheta exterioară a cutiei.
- Să extragă pachetul steril cu lentila, să deschidă pachetul steril, să introducă flaconul într-un mediu steril, să deschidă capacul și să extragă lentila din flacon.
- Să spele lentila minuțios în soluție fiziologică sterilă.
- Metode și instrumente moderne de manipulare (depozitare) a lentilei.
- Notă: Capetele sclerale ale lentilei au o angulare (orientare unghiulară) specifică, de aceea lentila va fi introdusă în ochi astfel încât capătul scleral din față să fie orientat spre stânga pentru lentilele de tipul B-Lens, SeeLens sau HeliLens, în conformitate cu elementele proeminente indicative de pe lentila de tipul BunnyLens. Rotirea lentilei în ochi se va efectua în sensul acelor ceasornicului.

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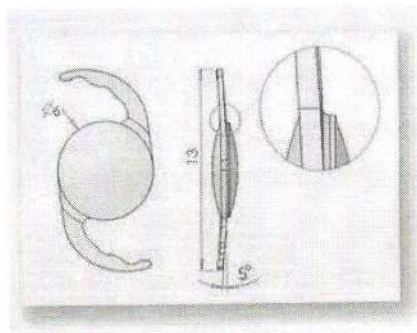
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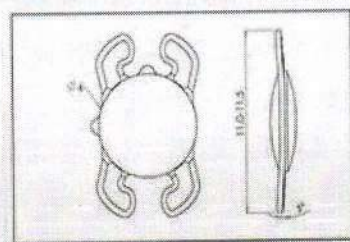
STERILE



0°C – 45°C

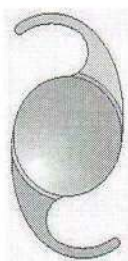


Poziția de stânga
See Lens Angularea 5°



BunnyLens

Poziția de stânga
Bunny Lens Angularea 5°



Poziția de stânga
B-lens Angularea 5°



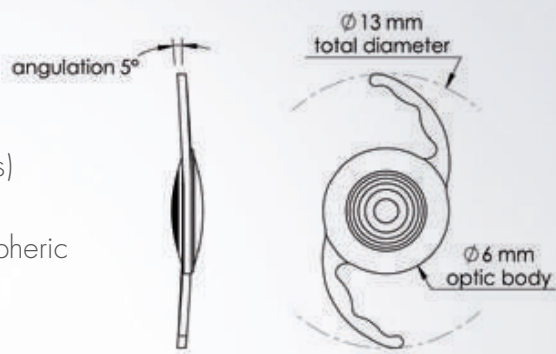
Mini Incision implantation

- Easily and safely injected through an incision as small as 1.8 mm.
- Lower surgically induced astigmatism.
- Fast recovery after surgery, less inflammation.
- Less trauma to the cornea and the eye.
- Less endothelial cell loss.



Technical Specifications

Overall diameter	13.0 mm
Optic diameter	6.0 mm
Power range*	+10.0 to +30.0 (0.5 D increments) +31.0 to +35.0 (1 D increments)
Optic design	Multifocal Diffractive Apodized Aspheric
Edge design	360° Continuous Square Edge
Haptic angulation.	5°
Material	Hydrophilic Acrylic with UV Blocker and violet light filter
Refractive Index	1.46 (hydrated @ 35°C)
Nd-YAG laser	Compatible
Estimated A constant	SRK/T IOIMASTER biometry: 118.6** SRK/T US biometry: 118.27**
Placement	Capsular Bag
CE Approved	



* Additional power range can be provided by special order
** It is recommended that surgeons personalize their A-constant based on their surgical techniques and equipment, experience and post-operative results. For more information please visit Hanita Lenses web site.

Hanita Lenses

Hanita Lenses is a worldwide trusted manufacturer and provider of intraocular lens solutions for cataract surgery. With more than 30 years of experience in meeting the varied needs of ophthalmic surgeons, the Hanita Lenses name is synonymous with high quality, reliability and service.

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ADD.
+2.25D +3D

SeeLens MF

The Premium Multifocal Solution



www.hanitalenses.com e-mail: marketing@hanitalenses.com
Hanita Lenses Intraocular & Contact Lenses
Kibbutz Hanita 2288500 Tel: +972 4 9950700 Fax: +972 4 9950755

SeeLens MF, the diffractive multifocal aspheric intraocular lens from Hanita Lenses, provides the patient with an excellent depth of focus for the near, intermediate and far visual ranges. The use of SeeLens MF reduces spectacle dependency for reading, driving and using the computer.



Advanced Optical Design

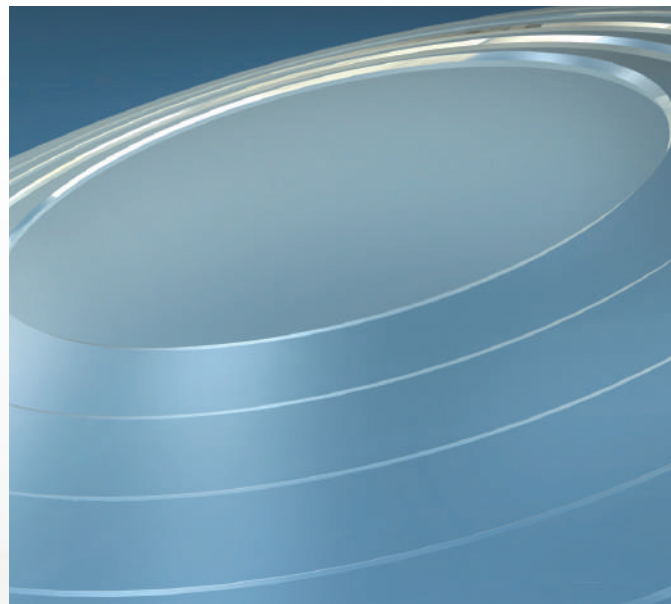
The SeeLens MF was designed using the most advanced tools by a professional R&D team of optical and mechanical engineers.

The optical diffractive apodized aspheric profile was developed using proprietary algorithms and the Zemax™ software. Calculations were optimized to provide optimal energy distribution in different light conditions and minimize spherical aberrations. The available addition powers of +2.25 or +3.0 diopters in IOL plane allow the surgeon to select a treatment option with either a longer or shorter focal distance, depending on patient lifestyle and personal preference.

Apodized Diffractive Optics

The aspheric - diffractive profile of the SeeLens MF has been clinically proven to provide an excellent and reduced spherical aberration, in all conditions and for all distances. The diffractive steps are located in the 4mm central zone, suiting pupil sizes in various lighting conditions.

The steps follow an apodization function, meaning they reduce in height according to an algorithm designed so the patient can function comfortably all day long.

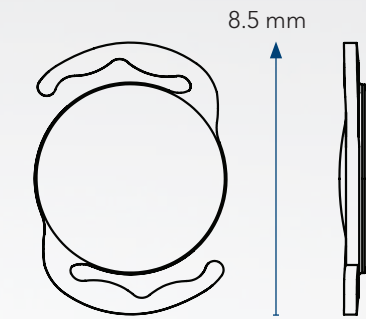


The state-of-the-art apodized diffractive surface provides visual functionality throughout the day:

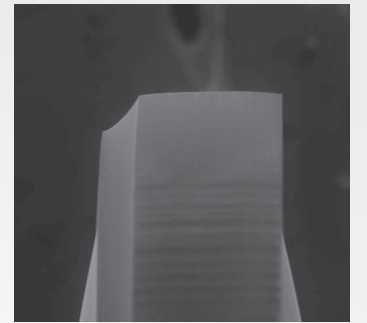
- In photopic conditions, when the pupil is small, the SeeLens MF distributes 60% of the light for far vision and 40% for near vision, providing light for all daytime activities.
- In mesopic and scotopic conditions, distance vision gets most of the light energy, enabling night vision and driving in the dark, when the pupil is enlarged.

Geometrical Design

- Excellent stability and centration due to the unique haptic design
- Fixed position of IOL along the visual axis allowing for highly predictable refractive outcome
- 360° continuous square edge in order to reduce PCO



SeeLens MF provides stable position of the optic even in exceptionally small capsules

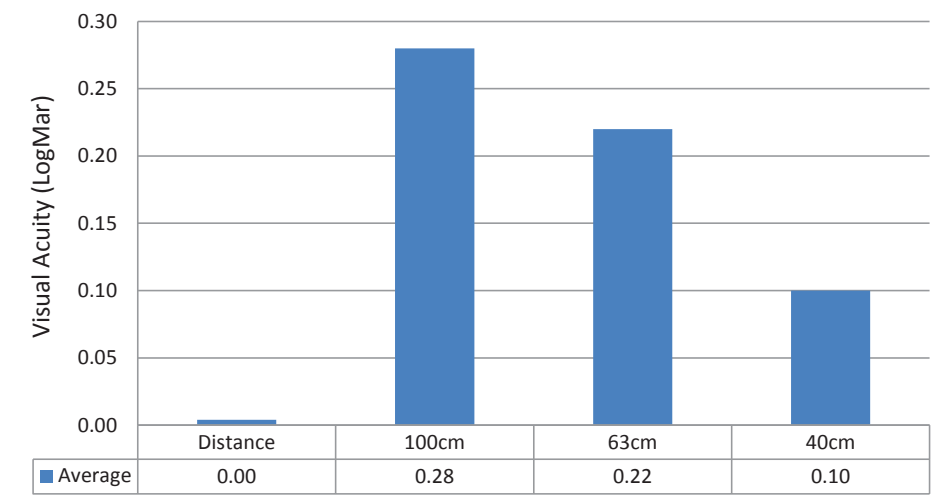


SEM image of SeeLens MF edge design[1]
[1] Image by Prof. Manfred Tetz, ATK Spreebogen Berlin.

Clinical Evaluation Results*

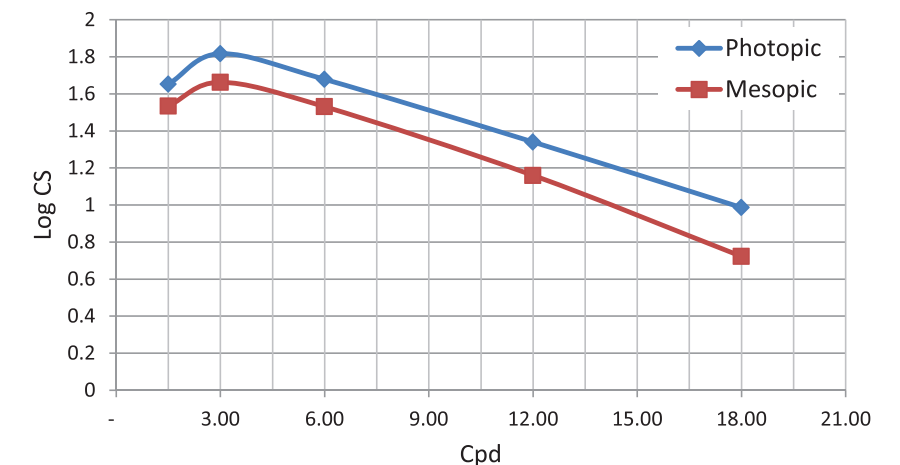
Designed to rejuvenate vision, the SeeLens MF works in harmony with the pupil to provide a quality depth of vision for all distances.

**Visual Acuity for Varied Distance
Binocular Vision (Add+3)**



Due to its aspheric optical design profile, clinical results of the SeeLens MF show superior contrast sensitivity providing sharper vision in all lighting conditions.

Contrast Sensitivity (Add+3)



*Based on Clinical results of the SeeLens MF Multi-center study by Prof. M. Tetz, Prof. R. Bellucci, Prof. J.L. Alio