GMED
GROUPE LNE

ATTESTATION / *CERTIFICATE* **N° 33908 rev. 1**
Délivrée à Paris le 26 novembre 2019
Issued in Paris on November 26th, 2019

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)**

Digitally signed by Pereteatco Alina
Date: 2021.10.08 12:17:32 EEST
Reason: MoldSign Signature
Location: Moldova

GMED SAS GMED SAS

On behalf of the President
Béatrice LYS
Technical Director

GMED_DS-P-V0-01-2016

GMED - 33908 rev. 1
Renouvelle le certificat 33908-0

GMED
GROUPE LNE

Addendum au certificat n° 33908 rev. 1 **page 1/1**
Addendum of the certificate n° 33908 rev. 1
Dossier / *File* N° T000486-1-R

Identification des dispositifs / *Identification of devices*

Description du Dispositif Médical *Medical Device Description*	**Référence Commerciale du Dispositif Médical** *Medical Device Commercial Reference Number*	**Classe du Dispositif Médical** *Medical Device Class*
Injectors for IOL insertion	SoftJect 1.8 and SoftJect 2.4	IIa

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

GMED
GROUPE LNE

ATTESTATION / *CERTIFICATE* N° 34048 rev. 2
Délivrée à Paris le 26 novembre 2019
Issued in Paris on November 26th, 2019

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)**

GMED SAS GMED SAS GMED

On behalf of the President
Béatrice LYS
Technical Director

GMED_Logo-F-V0-07-2018

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

Identification des dispositifs / *Identification of devices*

Nom du dispositif médical *Medical device name*	Dénomination commerciale *Commercial designation*	Classe du DM *MD Class*
Intraocular Lens	OPAB 16	IIb
	OPAB 130	
	BALANCE (ABB3)	
	BAL 15	
	BAL 55	
	BAL 65	
	Biens	
	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	
	Intensity SL	
	Intensity BN	
	Intensity BN EZ	
Intraocular Lens including Kits with Injector SoftJect	Biens 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	
	ClearRing	
Capsule Centering Device	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

CERTIFICAT
CERTIFICATE OF REGISTRATION
N° 34047 Rev. 2

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**

On behalf of the President
Béatrice LYS
Technical Director

cofrac
CERTIFICATION DE SYSTEMES DE MANAGEMENT
Accréditation n°4-0608
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

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

GMED
GROUPE LNE

CERTIFICAT
CERTIFICATE OF REGISTRATION
N° 34047 Rev. 2

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

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Hanita Lenses
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est conforme aux exigences des normes internationales
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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**

GMED

On behalf of the President
Béatrice LYS
Technical Director

cofrac
CERTIFICATION DE SYSTEMES DE MANAGEMENT
Accréditation n°4-0608
Liste des sites accrédités et portée disponible sur www.cofrac.fr

GMED_SQ-F-V0-07-2016

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

ATTESTATION / *CERTIFICATE* **N° 34048 rev. 5**

Délivrée à Paris le 17 mars 2021

Issued in Paris on March 17th, 2021

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)**

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Date: 2021.09.17 22:32:21 EEST

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Beatrice Lys
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On behalf of the President
Béatrice LYS
Technical Director

GMED_b2p3_new2020-V0-04-

GMED - 34048 rev. 5
Modifie le certificat 34048-4

Délivré à Paris le 17/03/2021
Issued in Paris on 03/17/2021

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 dispositlf / Accessories marqués CE *Device designation / EC marked accessories*	**Réf commerciale du dispositif ou code article** *Device commercial reference or article code*	**Classe du DM** *MD Class*
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

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Beatrice Lys
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GMED 0459

GMED - 38190 rev. 0

On behalf of the President
Béatrice LYS
Technical Director

Délivré à Paris le 17/03/2021
Issued in Paris on 03/17/2021

Désignation du dispositif / Accessories marqués CE *Device designation / EC marked accessories*	**Réf commerciale du dispositif ou code article** *Device commercial reference or article code*	**Classe du DM** *MD Class*
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

More than 250,000 implants using ACRYLIC COPOLYMER HEMA/EOEMA, 25% water content have been successfully implanted worldwide.

Hanita Lenses

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Date: 2021.10.07 23:25:31 EEST

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

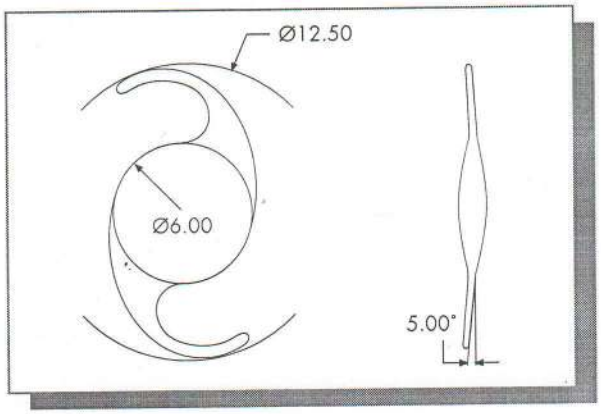
High refractive index
B-Lens High Refractive Index (1,462), optimizes the profile of the lens thus enabling insertion through a 2 ÷ 3.2 mm incision.

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

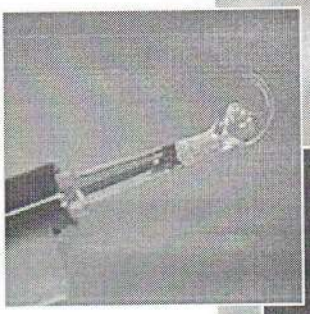
Superior foldability with a gentle and slow unfolding release
B-Lens material has excellent memory properties that ensure a perfect foldability and perfectly slow and gentle unfolding release.

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

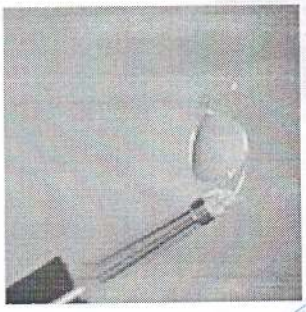
YAG laser compatible
B-Lens is YAG laser compatible



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

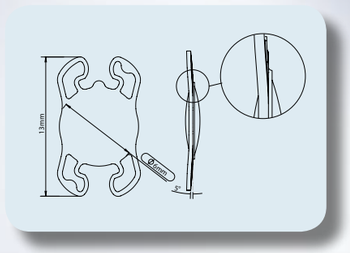
European Authorized Rep. OBELIS S.A., 34, avenue de Tervuren, Bte 44, 1040 Brussels,Belgium.

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.

T1023 01/09

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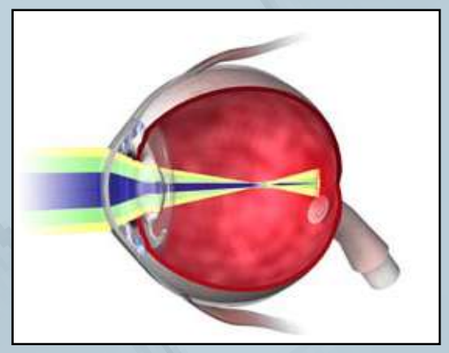
BunnyLens AF

Providing **A**berration **F**ree Vision

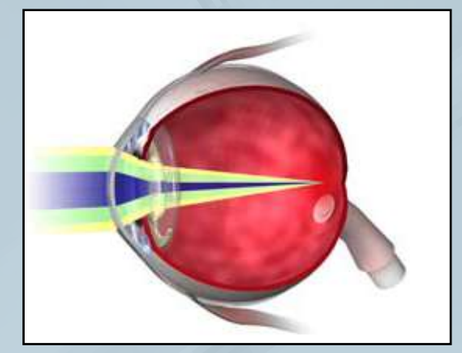
Aspheric IOL Design using mini incision technique

See for yourself

Spheric Lens
Spherical abberation



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

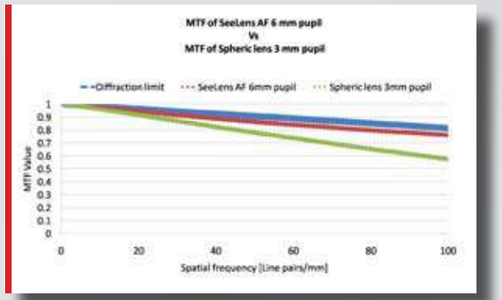
BunnyLens AF, the new Aspheric Intraocular lens from Hanita Lenses, provides the patient with an excellent vision quality at day and night conditions, by using state-of-the-art aberration free aspheric optical design.

Advanced Optical Design

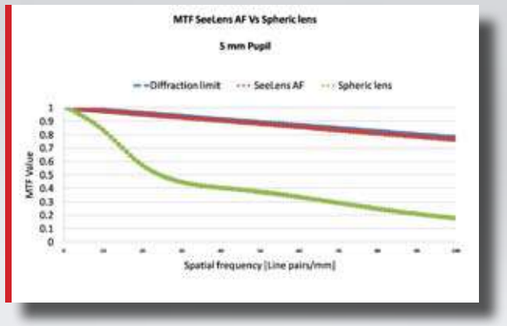
The aspheric BunnyLens AF was designed using the most advanced tools, by a professional R&D team of optical and mechanical engineers.
The optical profile algorithm was calculated using ZEMAX ™ software – a simulating tool for optimized optical design.
Calculations were aimed in order to minimize all 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.



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

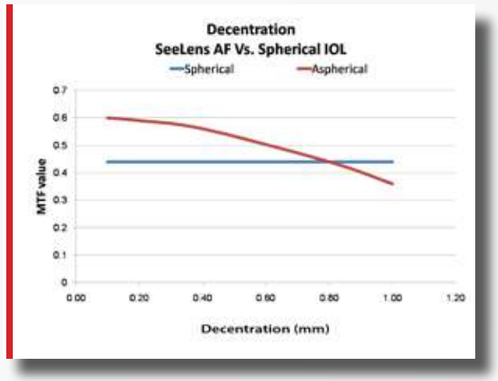
Geometrical Design

Geometrical design

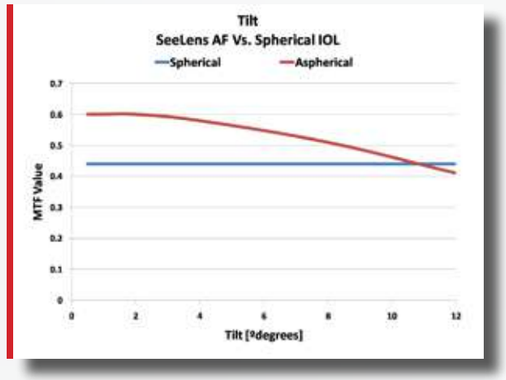
- BunnyLens AF ensures excellent stability and centration due to four- point-fixated mechanical design of the haptics.
- 3600 double square edge in order to minimize PCO
- Excellent memory – slow gentle release, superior foldability

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 spheric lens even if decentered up to 0.8



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

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

Sterile, acrilice, pliabile monobloc

Foldable B-lens

Hanita Lenses
Kibbutz Hanita - 22885 – Israel
Tel: +972(0)4 9950700
Fax: 972 (0)4 9950755
e-mail: marketing@hanitaleneses.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 electronica 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

posterioară a globului ocular reprezintă un implant optic destinat înlocuirii cristalinului ocular uman. Lentilă intraoculară pentru camera posterioară 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 posterioară 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 posterioare 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 s o l u ț i e i d e i r i g a r e s t e r i l e s p e c i a l e, 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 umectată 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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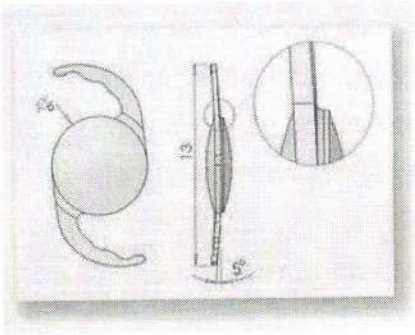
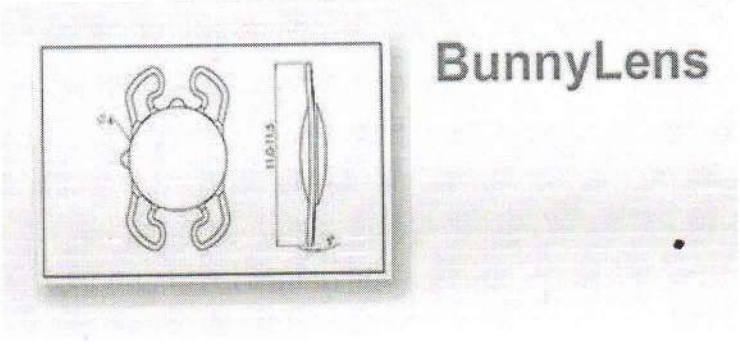
STERILE $0^0C - 45^0C$



Poziția de stânga
See Lens Angularea 5^0



Poziția de stânga
Bunny Lens Angularea 5^0

Poziția de stânga
B-lens Angularea 5^0