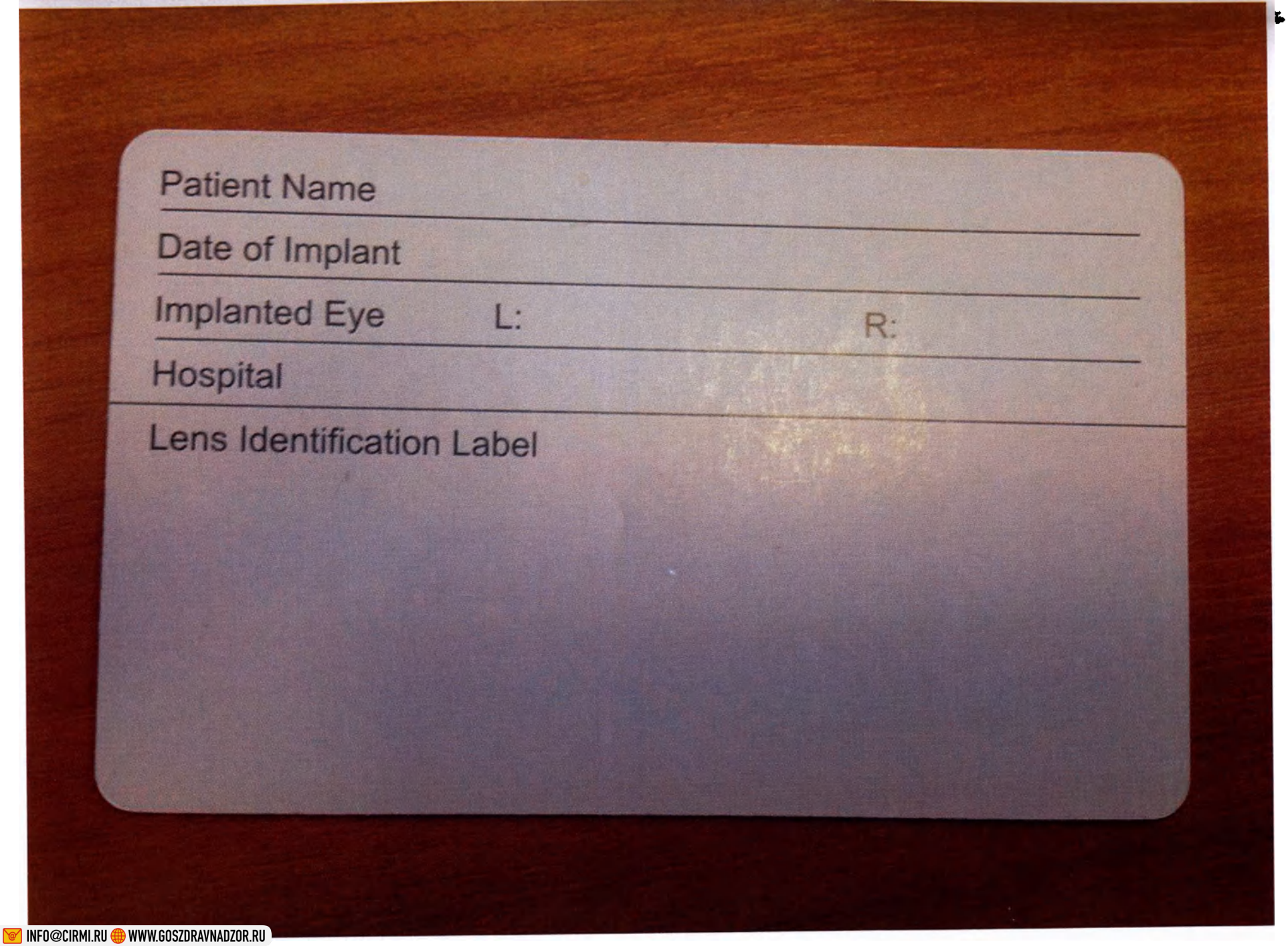
Фотографические изображения медицинского изделия
«Линза гидрофобная асферическая складная монолитная интраокулярная Supra Phob, заправленная в картридже вместе с инжектором»,
производства: «Аппасами Окулар Девайсес (П) Лтд.», Индия («Appasamy Ocular Devices (P) Ltd.», R.S.No. 9/1,2&3, NH-45A, Villupuram Main Road, Vadamangalam, Pondicherry – 605102, India)

1. Линза гидрофобная асферическая складная монолитная интраокулярная монофокальная Supra Phob, заправленная в картридже вместе с инжектором, модель: SPNT-200.

4


OPEN
Supra Phob
Preloaded system
(Contains One(1) Intraocular Lens)
STERILE EO
EO Sterilized
For Single use only
Do not re-sterilize
6.00
13.00
See the Instruction manual
Do not use if the seal is broken
or pack is damaged
Appasamy Ocular Devices (P) Ltd.,
CE 1023
APPASAMY ASSOCIATES
Power : 23.00D
Ref : SPNT200
S/n : 1112319 033
Exp : 12-2016
Size : 6.00X13.00
Supraphob Pre Loaded

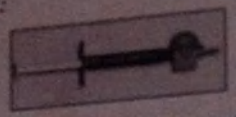


Supra Phob

Preloaded System

Instruction for Use

Step 1:



Peel the blister cover and take the injector carefully.

Step 2:

Slightly move the lens protector Cap forward from the injector.

Step 3:

Check whether the lens placed properly in the cartridge, and to ensure that posterior side of the lens facing downwards.

Step 4:

Apply a thin layer of viscoelastic from the barrel to the tip of the cartridge to serve as a lubricant for the free movement of lens during injections.

Step 5:

Gently remove the lens protector cap and Close the cartridge properly.

Step 6:

Make sure that the lens inside the cartridge should be properly folded or neither the haptic nor optic is caught between the shutters.

Step 7:

Ensure that there is no gap between the shutters, and then gently push the plunger towards the lens.

Step 8:

The lens moves towards the cartridge. The lens will completely come out of the cartridge tip end.

Mfgd. by:

A+D APPASAMY OCULAR DEVICES (P) LTD.

S.F.S.No. 9/1,253, N.H.45-A, Villupuram Main Road, Vedamangalam, Puducherry - 605 102, INDIA.

www.appasamy.com

EC REP **EMERGO EUROPE**
Molenstraat 15,
2513 BH The Hague,
The Netherlands.

CE 1023


REF. : SPNT200
POWER : 23.0D
Ø B : 6.00mm
Ø T : 13.00mm
B. No. : 3716
: 12-2016
S. No. : 1112319 033
Supra Phob
CE 1023
8 904125 562554
1112319 033
REF. : SPNT200
POWER : 23.0D
Ø B : 6.00mm
Ø T : 13.00mm
B. No. : 3716
: 12-2016
S. No. : 1112319 033
Supra Phob
CE 1023
8 904125 562554
1112319 033
REF. : SPNT200
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Ø B : 6.00mm
Ø T : 13.00mm
B. No. : 3716
: 12-2016
S. No. : 1112319 033
Supra Phob
CE 1023
8 904125 562554
1112319 033

PRODUCT INFORMATION

Supra Phob

Hydrophobic Foldable intraocular lens with Aspheric Optics

DESCRIPTION OF THE DEVICE

Intra Ocular Lenses are optical implants for the human crystaline lens in the visual correction of aphakia. The lens optic is lathe cut from HYDROPHOBIC ACRYLIC BLANKS with UV blocking properties.

MODE OF ACTION

Intra Ocular Lens (IOL) functions as a refracting medium to replace the natural lens in the correction of aphakia. The IOL can be placed in Posterior chamber. The following indications and contra indications are based on research of medical literature and are to be used only as guides. The list is indicative and not be viewed as complete or comprehensive.

INDICATIONS

- Monocular Cataract
- Mature Cataract
- Congenital Cataract
- Occupational Needs
- Traumatic Cataract

CONTRAINDICATIONS

- Chronic Severe Uveitis
- Epithelial Dystrophy
- Proliferative Diabetic Retinopathy
- Choroidal Hemorrhage
- Microphthalmos
- Aninida
- Concommitant Severe Eye Disease
- Glaucoma Problem
- Rubella Cataract
- Massive Vitreous Loss
- In Cataracts Present in Children

POTENTIAL HAZARDS

The relevant hazards and side effects of Intra Ocular lens essentially the same as (but not limited to) those of routine cataract extraction. These include the following :-

- Intra Ocular Foreign Body Debris
- Temporary Corneal Edema
- Secondary Cataract Formation
- Malpositioned Lens
- Aphakic Glaucoma
- Temporary Flat Anterior Chamber
- Retinal Detachment
- Lens Implants loop Amputation
- Endothelial Corneal Dystrophy
- Vitreous Herniation into the Anterior Chamber
- Infection
- Pupillary Block
- Corneal Dystrophy

'A' CONSTANT

'A' Constant value is to be located on the Box Cover Label. This number is given only as a guideline and not based on any clinical data. It is advised that the surgeon calculates his own value for each style and specifications of Intra Ocular Lens.

PACKAGE

The Lens is supplied in a Sterile Package. Validity of sterilization applies as long as the sealed inner peel-pouch is not disturbed or damaged. Any damage to the peel-pouch or any accidental opening of the peel-pouch is to be declared as "NOT STERILE"

DIRECTIONS FOR USE

PLEASE examine the peel-pouch prior to opening to assure sterility. Any Damage to the peel-pouch should be viewed very seriously and the IOL inside might not be sterile. After proper examination, peel the pouch and remove the Lens case. Hold and lift the lens using smooth edged forceps. Use BSS (or) Balanra to clear off the static charges that might have developed on the lens surface. Do not touch the central optic portion of the lens with forceps, it will leave permanent forceps marks on the visual axis. Do not use rubber gloves dusted with talc powder, it may cause irritation.

REPORTING

Adverse reactions and potentially sight threatening complications that may reasonably be regarded as lens related and that were not previously expected in nature severity or degree of incidence should be reported to Appasamy Ocular Devices (P) Ltd. This information is requested from the all implanting surgeons in order to document potentially long term effects of IOL implants.

PATIENT IDENTITY CARD

The packaging contains product identification stickers for maintaining a record of the IOL implantation. Surgeons are requested to give the "Patient ID Card" to the patient after implantation and advise them to carry the card at all times.

RETURN GOODS POLICY

Appasamy Ocular Devices (P) Ltd., accepts returned lenses for exchanges only. No cash refunds will be issued. To return lenses, you must first obtain a return authorization number from customer services department. No returned goods will be accepted without proper authorization number. Returned lenses should be shipped by traceable method. No credit will be given to lost or damaged lenses in shipment. Lenses will be replaced as long as they are returned within six months of their original invoice date.

WARNING

Intra Ocular Lens supplied is void of all warranties expressed or implied, if

1. The lens is re sterilized.
2. Lens is altered in any manner.
3. Lens is repackaged by any one other than Appasamy Ocular Devices (P) Ltd.

DISPOSING OF NON STERILE OR CONTAMINATED MEDICAL DEVICES

There are not specific guidelines for disposing of Non sterile or contaminated medical devices. Follow standard procedures for discarding outdated or contaminated products.

PRECAUTIONS

- Do not re sterilize the IOLs
- Do not Re-use the product
- [T° < 40°C / 104°F] Do not store above 45°C (Fragile, avoid shocks)
- Use only sterile BSS irrigating solution for rinsing / soaking
- Do not use if the pouch is opened
- Handle gently to avoid lens surface and haptic damage
- Use as soon as the IOL is out of lens case.

Mfgd by
A•D APPASAMY OCULAR DEVICES (P) LTD.
R.S. No. 9 /1,2 & 3, N.H.45-A, Villupuram Main Road, Vadamangalam, Puducherry - 605 102, INDIA.

CE 1023

RENSEIGNEMENTS SUR LE PRODUIT

Supra Phob

Hydrophobe pliable lentille intraoculaire avec les éléments optiques asphériques

DESCRIPTION DU DISPOSITIF

Lentilles intra oculaires sont les implants optiques pour la lentille cristalline de l'homme dans la correction visuelle d'une aphakie. L'optique de l'objectif est tour à couper à partir d'ébauches HYDROPHOBES Acrylic With bloquer les rayons UV propriétés.

MODE D'ACTION

Lentille intra oculaire (LIO) fonctionne comme un milieu réfringent à remplacer le cristallin naturel dans la correction d'une aphakie. La LIO peut être placé dans la chambre postérieure. Les indications ci-après et contre-indications sont fondées sur la recherche de la littérature médicale et doivent être utilisés uniquement comme guides. Cette liste est indicative et non pas être considérée comme complète ou exhaustive.

INDICATIONS

- Monoculaire de la cataracte
- D'âge mûr de la cataracte
- Cataracte congénitale
- Professionnelles doit
- Traumatiques de la cataracte

CONTRE-INDICATIONS

- L'uvéite chronique sévère
- Épithéliales Dystrophie
- La rétinopathie diabétique Proliférante
- Hémorragie choroïdienne
- Microphtalmie
- Aninda
- Concommitant sévère sur les maladies oculaires
- Problème glaucome
- Rubéole Cataracte
- Les pertes massives Vitreous
- En Cataractes présente chez les enfants

DANGERS POTENTIELS

Les dangers pertinents et les effets secondaires de lentilles intra-oculaires essentiellement les mêmes que (mais non exclusivement) ceux de l'extraction de la cataracte de routine. En voici la liste: –

- Intra oculaire Foreign Body débris
- Temporaire œdème cornéen
- La formation de cataractes secondaires
- Malposition Lens
- Aphaques Glaucome
- Indemné forfaitaire Temporaire d'ombre antérieure
- Lens Implants boucle Amputation
- Dystrophie endothéliale cornéenne
- Vitreous hernie dans la chambre antérieure
- Infection
- Pupillaire Block
- Dystrophie cornéenne
- Décollement de la rétine

'A' CONSTANT

'A' Valeur constante A 'doit être situé sur l'étiquette Cover Box. Ce numéro n'est donné qu'à titre indicatif et ne repose sur aucune donnée clinique. Il est conseillé que le chirurgien calcule sa propre valeur pour chaque style et les spécifications des lentilles intra oculaire.

FORFAIT

La lentille est fourni dans un emballage stérile. Validité de la stérilisation s'applique tant que la peau intérieure scellée pochette ne soit pas perturbé ou endommagé. Tout dommage à la peau-poche ou toute ouverture accidentelle de la peau-poche est à déclarer comme "non stérile"

MODE D'EMPLOI

S'IL VOUS PLAÎT examiner les Pael-pochette avant l'ouverture pour assurer la stérilité. Tout dommage à la peau-poche devrait être pris très au sérieux et la LIO à l'intérieur pourrait ne pas être stériles. Après l'examen proprement dit, peler et retirer le sachet étui. Hold et lever l'objectif en utilisant une pince lisse tranchant. Utilisez BSS (ou) Salaire de déguerpir les changements statique qui aurait pu se développer sur la surface de la lentille. Ne touchez pas la partie optique centrale de la lentille, avec des pincet, elle va laisser des marques permanentes pince sur l'axe visuel. Ne pas utiliser de gants en caoutchouc saupoudrés de poudre de talc. Elle mai provoquer une irritation.

RAPPORTS

Les réactions indésirables et potentiellement menacer le pronostic visuel complications mai raisonnablement être considérés comme Lens et qui n'étaient pas précédemment attendue en nature ou le degré de gravité de l'incidence devrait être signalé à Appasamy Ocular Devices (P) Ltd. Cette information est demandée à l'implantation de tous les chirurgiens afin de documenter les effets à long terme potentiellement des implants IOL.

CARTE D'IDENTITÉ DU PATIENT

L'emballage contient des étiquettes d'identification de produit pour maintenir un registre des implantation IOL. Les chirurgiens sont priés de donner les «Patient ID Card" pour le patient après l'implantation et leur conseille de porter la carte à tout moment.

RETOUR DE MARCHANDISES POLITIQUE

Appasamy Ocular Devices (P) Ltd.accepte vernes retournés pour échange seulement. Aucun remboursement ne sera émis. Pour revenir lentilles, vous devez d'abord obtenir un numéro d'autorisation de retour de service clientèle. Aucune marchandise retournée sera accepté sans numéro d'autorisation adéquate. Lentilles retournées doivent être expédiées par la méthode de traçabilité. Aucun crédit ne sera donnée aux objets perdus ou endommagés lentilles dans l'expédition. Lentilles sera remplacé dans la mesure où ils sont retournés dans les six mois à compter de leur date de facture originale.

AVERTISSEMENT

Intra oculaire objectif fourni est vide de toute garantie expresse ou implicite, si

1. La lentille est restérilisé
2. Lens est modifié de quelque façon
3. Lens reconditionnement est effectué par une personne autre que Appasamy Ocular Devices (P) Ltd.

ÉLIMINATION DE NON STÉRILES OU CONTAMINÉS DISPOSITIFS MÉDICAUX

Il n'y a pas de directives spécifiques pour l'élimination des dispositifs non stériles ou contaminés médicaux. Suivre les procédures standard pour les rejets produits périmés ou contaminés.

PRÉCAUTIONS

- Ne pas stériliser la LIO
- Ne pas ré-utiliser le produit
- [T° < 40°C / 104°F] Ne pas stocker au dessus 45°C (Fragile, d'éviter les chocs)
- Utilisez uniquement BSS stériles solution d'irrigation pour le rinçage / trempage
- Ne pas utiliser si le sachet est ouvert
- Manipuler délicatement pour éviter de surface de la lentille et haptiques dommages
- Utiliser dès que la LIO est hors de l'étui.

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R.S. No. 9 /1,2 & 3, N.H.45-A, Villupuram Main Road, Vadamangalam, Puducherry - 605 102, INDIA.

CE 1023

PRODUKTINFORMATION

Supra Phob

Hydrophobe Faltbare Intraokularlinse mit Asphärische Optik

BESCHREIBUNG DER EINRICHTUNG

Intra Ocular sind optische Linsen-Implantaten für den menschlichen Linse in kristallklarem die visuelle Korrektur der Aphakie. Die optische Linse ist geschnitten Drehmaschine aus hydrophoben Acryl-Platinen mit UV-Blocking-Eigenschaften.

Wirkungsweise

Intraokularlinse (IOL) dient als brechenden Medium, um die natürliche Linse bei der Korrektur von Aphakie ersetzen. Die IOL kann im hinteren Raum platziert werden. Die folgenden Indikationen und Gegenanzeigen sind auf die Forschung der medizinischen Literatur und sind nur als Führer verwendet werden. Die Liste ist indikativ und nicht als vollständig oder umfassend betrachtet werden.

INDIKATIONEN

- Monokulare Cataract
- Ältere Cataract
- Angeborene Katarakt
- Beruflichen Erfordernisse
- Traumatische Katarakt

CONTRAINDICATIONS

- Schweren chronischen Uveitis
- Epitheliale Dystrophy
- Proliferative diabetische Retinopathie
- Choroidale Blutung
- Mikrophthalmie
- Aninda
- Begleitemscheinung Severe Eye Disease
- Glaukom Problem
- Röteln-Katarakt
- Massive Glaskörperverluttes
- In Gegenwart Grauer Star bei Kindern

MÖGLICHE GEFAHREN

Die relevanten Risiken und Nebenwirkungen der Intraokularlinse im Wesentlichen das gleiche wie (aber nicht beschränkt auf) die Routine der Katarakt-Extraktion. Dazu gehören die folgenden: -

- Intra Ocular Fremdkörpergranulom Debris
- Temporäre Hornhautödem
- Sekundäre Entstehung von grauem Star
- Glaskörper Herniation in die vordere Kammer
- Infektion
- Pupillarblock
- Hornhautdystrophie
- Linsenimplantate Schleife Amputation
- Endothelial Hornhautdystrophie
- Zahnfehlstellungen Lens
- Aphakischen Glaukom
- Temporäre Flache Vorderkammer
- Netzhautablösung

'A' CONSTANT

'A' Konstanter Wert ist auf der Box Cover Label dargestellt werden. Diese Zahl wird nur als Richtlinie gelten und nicht auf der Grundlage klinischer Daten. Es wird empfohlen, dass der Chirurg seinen eigenen Wert für jeden Stil und Spezifikationen der Intraokularlinse berechnet.

PACKAGE

Das Objektiv ist in einer sterilen Verpackung geliefert. Gültigkeit der Sterilisation gilt so lange, wie die innere verschlossene Peel-Beutel ist nicht gestört oder beschädigt werden. Schäden an der Schale-Beutel oder unbeabsichtigtes Öffnen der Peel-Beutel wird als "nicht steril" deklariert werden.

GEBRAUCHSANWEISUNG

Überprüfen Sie bitte die Peel-Beutel vor dem Öffnen zu Sterilität zu gewährleisten. Jede Beschädigung des Peel-Beutel ist sehr ernst und die IOL in möglicherweise nicht steril angesehen. Nach einer sorgfältigen Prüfung, ziehen Sie die Tasche und nehmen Sie die Linse Fall. Halten und heben Sie die Linse mit glatten

2. Линза гидрофобная асферическая складная монолитная интраокулярная монофокальная желтая Supra Phob BBY, заправленная в картридже вместе с инжектором, модель: SPNT-200Y.

Supra Phob-bby

Blue Blocking Yellow

Preloaded System

- Attention, see instructions for use
- Achtung, Gebrauchsanweisung einsehen
- Atención, ver instrucciones de uso
- Attention, voir mode d'emploi
- Attenzione, vedere le istruzioni per l'uso

STERILE EO | Do not resterilize | Do not reuse

Store away from sunlight | Store in dry place

T° < 40°C / 104° F | Do not use if package damaged

Contains : One (1) Hydrophobic Single Piece Biconvex Foldable Lens One (1) STERILE EO Delivery System

REF. :SupraPhob BBY POWER : 20.00D

Ø B : 6.00mm Ø T : 13.00mm

S. No. : P1310121 091

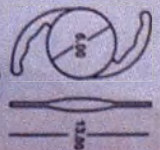
B. No. : 4587

:09-2018

A. CONSTANT : 118.0

Supra Phob - BBY

CE 1023




S/n P1310121 091
Optic 6.00 mm Power 20.00 D
Length 13.00 mm
Exp 9-2018 Ref SUPRAPHOB BBY

Patient Lens Implant
Identification Card

EU Representative :
EMERGO EUROPE
Molenstraat 15,
2513 BH The Hague,
The Netherlands

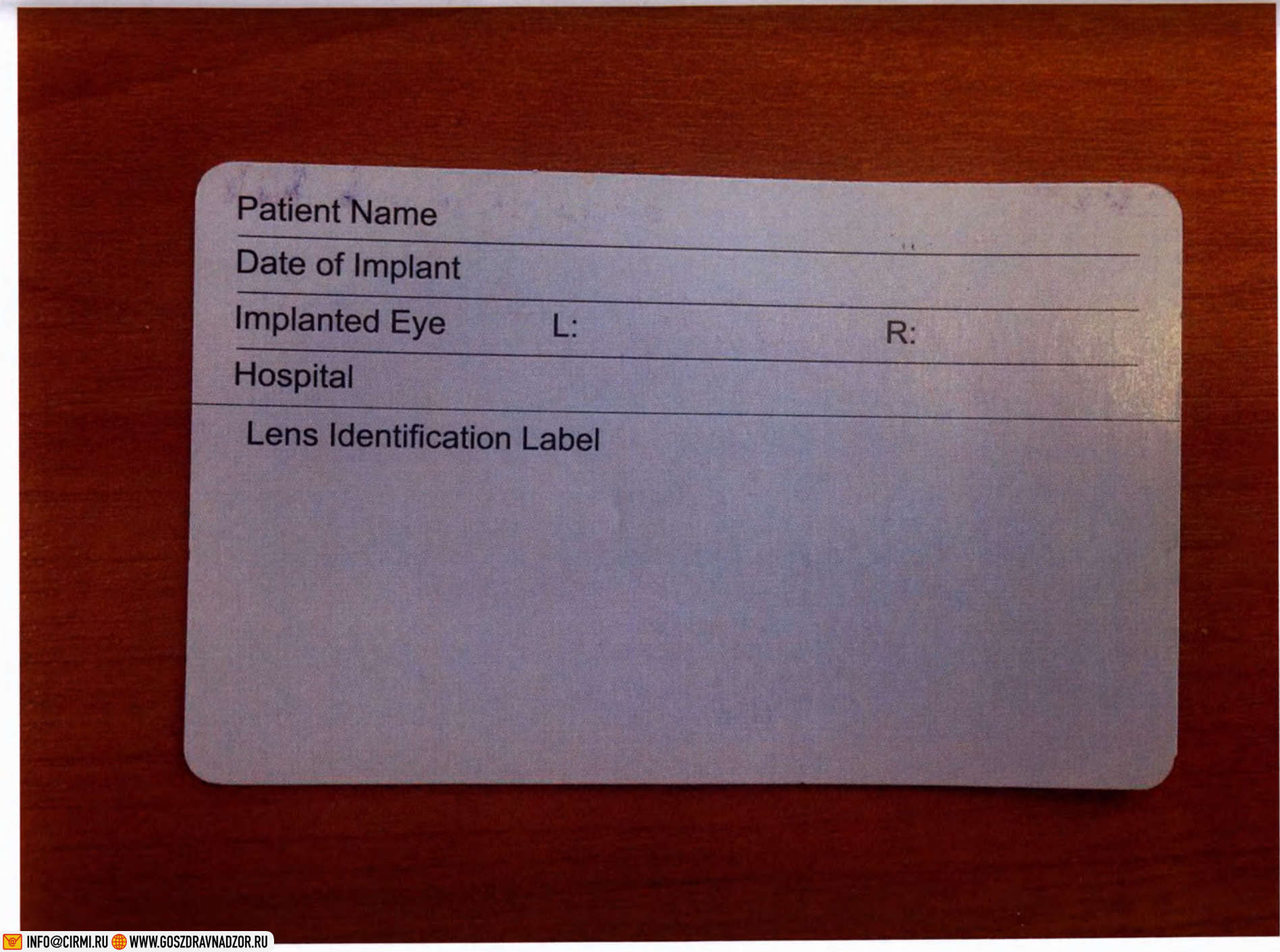
Supra Phob-bby

Blue Blocking Yellow

Preloaded System

Hydrophobic Foldable Intraocular Lens
with
Aspheric Optics

CE 1023




REF. : SupraPhob BBY
Ø B : 6.00mm
B. No.: 4587
S. No.: P1310121 091
Supra Phob - BBY
POWER: 20.00D
Ø T : 13.00mm
: 09-2018
CE 1023
8 904125 564923

Supra Phob

Preloaded System

Instruction for Use

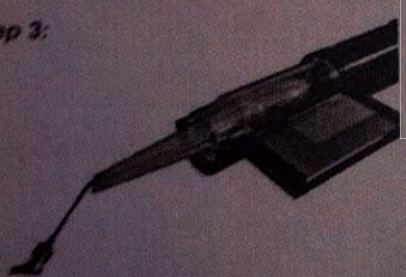
Step 1:

Peel the blister cover and take the injector carefully.

Step 2:

Close the cartridge by pressing the wings of the cartridge. The Lens protecting cover will automatically come out. Click sound indicates the proper closure of cartridge.

Step 3:



Apply the cisco elastic from the front barrel of the cartridge upto the pusher in the injector before implantation of the IOL

Step 4:

Then gently push the plunger towards the lens.

Step 5:

The lens moves towards the cartridge. The lens will completely come out of the cartridge tip end.

Mfgd. by:

APPASAMY OCULAR DEVICES (P) LTD.
R.S.No. 9/1,2&3, N.H.45-A, Villupuram Main Road,
Vadamangalam, Puducherry - 605 102. INDIA

EC REP **EMERGO EUROPE**
Molenstraat 15,
2513 BH The Hague,
The Netherlands.

CE 1023

PRODUCT INFORMATION

Supra Phob-bby

Blue Blocking Yellow
Preloaded System

Hydrophobic Foldable Intraocular lens with Aspheric Optics

DESCRIPTION OF THE DEVICE

Intra Ocular Lenses are optical implants for the human crystaline lens in the visual correction of aphakia. The lens optic is lathe cut from HYDROPHOBIC ACRYLIC BLANKS with UV blocking properties.

MODE OF ACTION

Intra Ocular Lens (IOL) functions as a refracting medium to replace the natural lens in the correction of aphakia. The IOL can be placed in Posterior chamber. The following indications and contra indications are based on research of medical literature and are to be used only as guides. The list is indicative and not be viewed as complete or comprehensive.

YELLOW LENSES

Throughout life, the crystalline lens protects the retina from hazardous UV light. Cataract extraction removes this protective barrier and may accelerate retinal photo toxicity to control the amount of radiation transmitted to the retina after cataract surgery, IOLs were created with the capability of blocking UV radiation. All IOLs today block short wavelength UV radiation up to 400nm.

Blue-absorbing chromophores added to IOL material to expand protection and decrease the amount of UV-blue energy (400- to 500-nm range) reaching the retina. It is thought that adding a blue-blocking chromophore increased protection from photic retinopathy, because it simulated the properties of the natural crystalline lens.

Yellow IOLs approximate the UV and blue-light attenuating properties of the human crystalline lens. This IOL contains a covalently bound chromophore, that providing increased protection against harmful UV light while allowing optimal blue light transmission, improving contrast sensitivity in low light conditions especially in eyes at risk of age-related macular degeneration.

INDICATIONS

- Monocular Cataract
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- Occupational Needs
- Traumatic Cataract

CONTRAINDICATIONS

- Chronic Severe Uveitis
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- Microphthalmos
- Aniridia
- Concommitant Severe Eye Disease
- Glaucoma Problem
- Rubella Cataract
- Massive Vitreous Loss
- In Cataracts Present in Children

POTENTIAL HAZARDS

The relevant hazards and side effects of Intra Ocular lens essentially the same as (but not limited to) those of routine cataract extraction. These include the following :-

- Intra Ocular Foreign Body Debris
- Temporary Corneal Edema
- Secondary Cataract Formation
- Malpositioned Lens
- Aphakic Glaucoma
- Temporary Flat Anterior Chamber
- Retinal Detachment
- Lens Implants loop Amputation
- Encothelial Corneal Dystrophy
- Vitreous Herniation into the Anterior Chamber
- Infection
- Pupillary Block
- Corneal Dystrophy

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In Collaboration with

GANTEC CORPORATION U.S.A
2354 Hassell Road, Suite D,
Hoffman Estates, IL 60195

PACKAGE

The Lens is supplied in a Sterile Package. Validity of sterilization applies as long as the sealed Inner peel-pouch is not disturbed or damaged. Any damage to the peel-pouch or any accidental opening of the peel-pouch is to be declared as "NOT STERILE"

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Adverse reactions and potentially sight threatening complications that may reasonably be regarded as lens related and that were not previously expected in nature severity or degree of incidence should be reported to Appasamy Ocular Devices (P) Ltd. This information is requested from the all implanting surgeons in order to document potentially long term effects of IOL implants.

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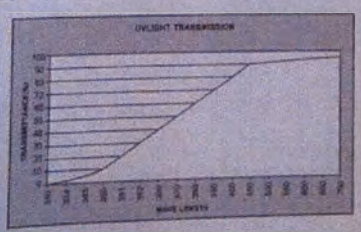
- Do not Re-use the product
- T° < 40°C / 104°F Do not store above 45°C (Fragile, avoid shocks)
- Use only sterile BSS irrigating solution for rinsing / soaking
- Do not use if the pouch is opened
- Handle gently to avoid lens surface and haptic damage
- Use as soon as the IOL is out of lens case.



EC REP
EMERGO EUROPE
Molenstraat 15, 2513, BH The Hague,
The Netherlands.
Tel: (31) (0) 70 345-8570,
Fax: (31) (0) 70 346-7299
E mail: europe@emergogroup.com
Website: www.emergogroup.com

CE 1023

QSP - 0810 / 02

3. Линза гидрофобная асферическая складная монолитная интраокулярная торическая Supra Phob Toric, заправленная в картридже вместе с инжектором, модели: SP TORIC T3, SP TORIC T4, SP TORIC T5, SP TORIC T6, SP TORIC T7, SP TORIC T8.


SN AT1405847 001
Ref SP-TORIC T3 Power 20.00 Cyl 1.50 D
Optic 6.00 mm Length 13.00 mm
Exp 04-2019
SUPRAPHOB TORIC


REF. : SP-TORIC T3
POWER : 20.00D
Adi.Cyl 1.5D
Ø B : 6.00mm
Ø T : 13.00mm
S/N : AT1405847 001
: 4-2019
Supra Phob Toric
: 5-2014
8 904125 671041

Supra Phob Toric

Foldable Hydrophobic Acrylic Intraocular Lens

Preloaded System

DESCRIPTION:
Intraocular lenses are optical implants for the human crystalline lens in the visual correction of aphakia. The lens optic is lathe cut from Hydrophobic Acrylic Blanks with UV blocking property with more than 90% light transmittance. The lens has a good memory and preloaded in an injecting system for easy delivery.
After surgical insertion into the eye, the lens perfectly unfolds to restore the original shape. The dual haptics provide for proper positioning and fixation of the IOL optic within the Capsular bag.

MODE OF ACTION
Supraphob Toric IOLs are intended to be positioned in the posterior chamber of the eye. Replacing the natural crystalline lens and which allows the lens to function as a refractive medium in the correction of aphakia. These IOL's have a biconvex-Anterior Toric optic with cylinder axis marks to denote the flat meridian (plus cylinder axis). Alignment of the toric IOL axis marks with the post –operative steep corneal meridian allows the lens to correct astigmatism.

INDICATIONS
The Supraphob Toric Posterior chamber intraocular lenses are intended for primary implantation in the capsular bag of the eye for visual correction of aphakia and pre-existing corneal astigmatism secondary to removal of a cataractous lens in audit patients with or without presbyopia, who desire improved uncorrected distance vision, reduction of residual refractive cylinder and increased spectacle independence for distance vision.

'A' CONSTANT
'A' constant value is printed on the secondary packing. This number is given only as a guideline and not based on any clinical data. It is advised that the surgeon calculates his own value for each style and specifications of Intra Ocular Lens.

PACKAGE
The lens is supplied in a Pre loaded Blister Sterile Package. Validation of Sterilization applies as long as the sealed inner Blister pack is not disturbed or damaged. Any damage to the Blister pack or any accidental opening of the Blister pack is to be declared as **"NOT STERILE"**

DIRECTIONS FOR USE

1.Examine the label on the unopened package for model, power (spherical equivalent and cylinder) and expiration date.

2.After opening the secondary package, verify the lens information (model, power, Spherical power, Cylinder power and serial number) is consistent with information on outer package labeling.

3.This device is sterile until the primary blister is obtained. Inspect the blister carefully for tears, cuts, punctures or other signs that the blister has been opened or damaged.

4.Apply the Viscoelastic tip of the cartridge for a smooth delivery of the lens as well back side of the lens. Refer the Illustration.

5.Apply a gentle pressure to the Injector to deliver the lens comfortably.

REPORTING
Adverse reactions and potentially sight threatening complications that may reasonably be regarded as lens related and that were not previously expected in nature severity or degree of incidence should be reported to Appasamy Ocular Devices (P) Ltd, PONDY. This information is requested from all implanting surgeons in order to document potentially long-term effects of IOL implants

PATIENT IDENTITY CARD
The packing contains product identification stickers for maintaining a record of the IOL implantation and identification. Surgeons are requested to give the "Patient ID Card" to the patients after implantation and advise them to carry the card at all times.

RETURN GOODS POLICY
Appasamy Ocular Devices (P) Ltd accepts returned lenses for exchanges only. No cash refunds will be issued. To return lens, you must first obtain a return authorization number from customer services department. No returned goods will be accepted without proper authorization number, Returned lenses should be shipped by traceable method. No credit will be given to lost or damaged lenses in shipment. Lenses will be replaced as long as they are returned within six months of their original invoice date.

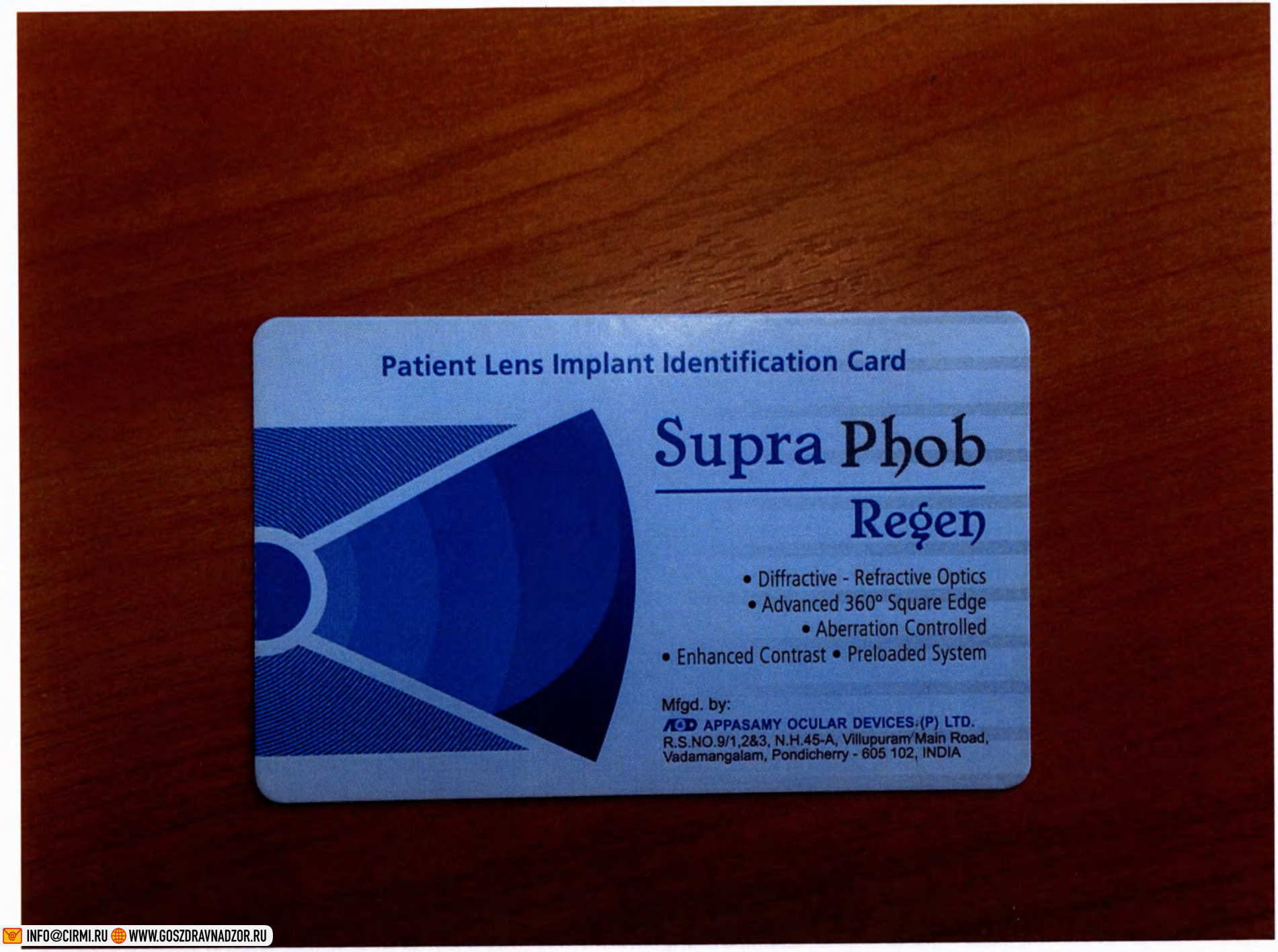
SELECTION PLACEMENT OF THE Supraphob TORIC IOL
The astigmatism to be corrected should be determined from keratometry and biometry. The size and location of the surgical incision may affect the amount and axis of corneal astigmatism. In order to optimize IOL selection and axis placement. We provide a web-based tool (www.appasamy.com) for the surgeon. Pre-operative keratometry and biometry data, incision location, and the surgeon's estimated surgically induced corneal astigmatism are used to determine the appropriate Supraphob Toric IOL model spherical equivalent lens power, and axis of placement in the eye.
For optimum results, the surgeon must ensure the correct placement and orientation of the lens within the capsular bag. The Anterior surface of the IOL is marked with a thin line at the haptic/optic junction that identity the flat meridian of the Supraphob Toric optic. This identification from an imaginary line representing the plus cylinder axis. The Supraphob Toric IOL cylinder axis marks should be aligned with the post-incision steep control meridian (indented axis of placement).

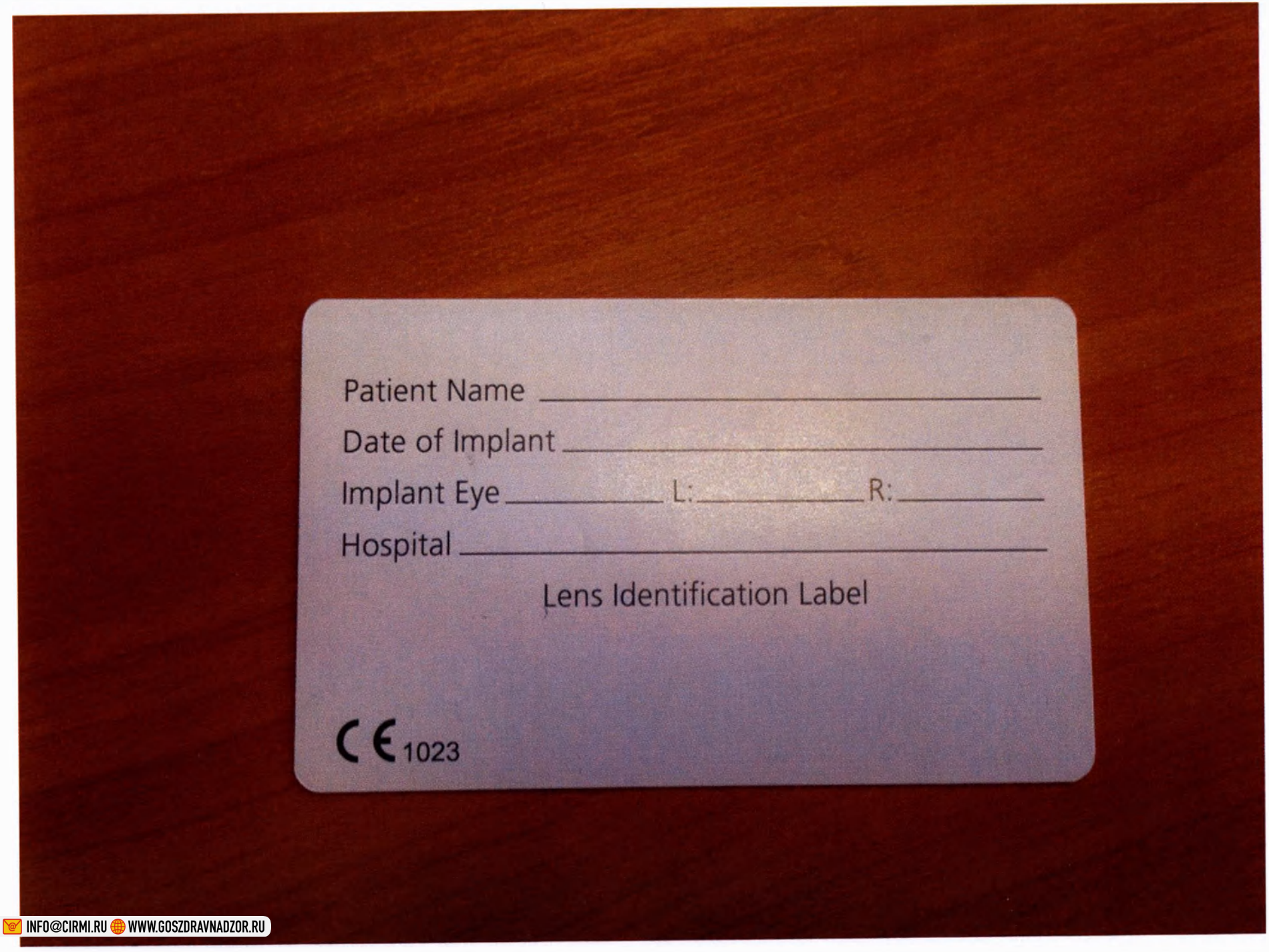
WARNINGS

1. This lens should not be implanted if the posterior capsule is ruptured OR the zonules are damaged OR a primary posterior capsulotomy is planned.

4. Линза гидрофобная асферическая складная монолитная интраокулярная мультифокальная Supra Phob Regen, заправленная в картридже вместе с инжектором, модель SPNT-200MF.


SN RN1305003 033
Ref SPNT200MF Power21.00 Adl 3.50 D
Optic 6.00 mm Length 13.00 mm
Exp 04-2018
SUPRAPHOB REGEN






REF. : SPNT200MF
POWER : 21.00D
Add 3.50
Ø B : 6.00mm
Ø T : 13.00mm
S/N : RN1305003 033
: 4-2018
Supra Phob
Reşeo
8 904125 571181

Генеральный директор
ЗАО «Вартамана Интернэшнл Тредерс»

_____ Виджаякумар Г.С.

Прошито и пронумеровано 35 лист об

VARTHAMANA INTERNATIONAL TRADERS
15,ST KOSIGINA,FLOOR-7,OFFICE-726,MOSCOW, RUSSIA-117334 TEL:(495) 933-00-49 TEL/FAX: (495) 775-01-32
S.-PETERSBURG, TEL/FAX(812) 716-73-29 www.varthamana.com E-Mail: varthamana@inbox.ru

«Линза гидрофобная асферическая складная монолитная интраокулярная Supra Phob, заправленная в картридже вместе с инжектором»

Макет упаковки на вариант исполнения Линза гидрофобная асферическая складная монолитная интраокулярная монофокальная Supra Phob, заправленная в картридже вместе с инжектором, модель: SPNT-200

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S.-PETERSBURG, TEL/FAX(812) 716-73-29 www.varthamana.com E-Mail: varthamana@inbox.ru

Макет упаковки на вариант исполнения Линза гидрофобная асферическая складная монолитная интраокулярная мультифокальная Supra Phob Regen, заправленная в картридже вместе с инжектором, модель SPNT-200MF

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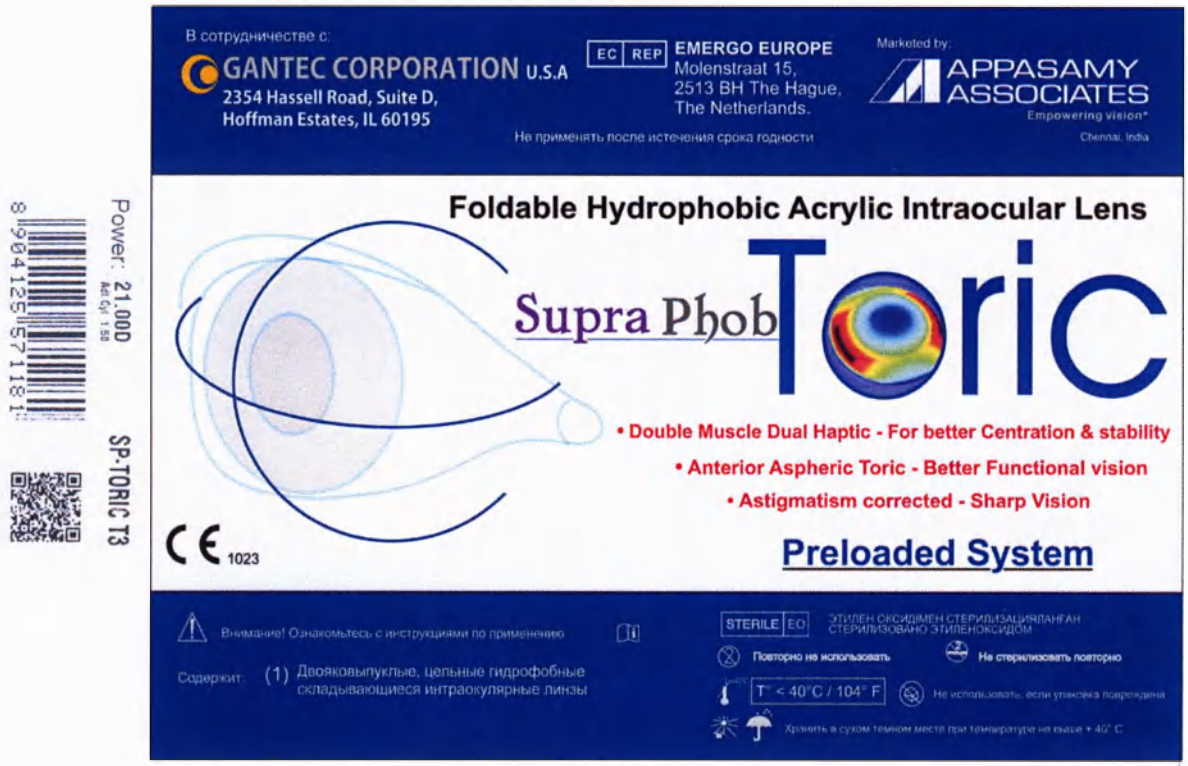
Макет упаковки на вариант исполнения Линза гидрофобная асферическая складная монолитная интраокулярная торическая Supra Phob Toric, заправленная в картридже вместе с инжектором, модели: SP TORIC T3, SP TORIC T4, SP TORIC T5, SP TORIC T6, SP TORIC T7, SP TORIC T8.



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S.-PETERSBURG, TEL/FAX(812) 716-73-29 www.varthamana.com E-Mail: varthamana@inbox.ru

Макет упаковки на вариант исполнения Линза гидрофобная асферическая складная монолитная интраокулярная монофокальная желтая Supra Phob BBY, заправленная в картридже вместе с инжектором, модель: SPNT-200Y

Генеральный директор
ЗАО «Вартамана Интернэшнл Тредерс»

_____ Виджаякумар Г.С.

Прошито и пронумеровано 4 листа