nAspro& nAspro BBY

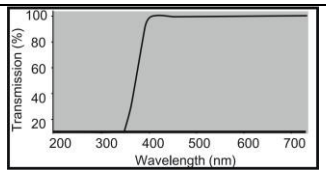
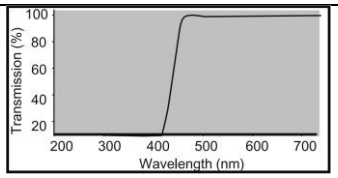
(Nano Aspheric Precision Optics)
Hydrophilic Monofocal Aspheric Intraocular Lens
with Delivery System

DESCRIPTION OF THE DEVICE

IOL can be defined as Optical Implants for the replacement of the human crystalline lens in the visual correction of Aphakia (cataract). Intraocular lens functions as a refracting medium to replace the natural lens in the correction of cataract. The HEMA IOLs are designed to be surgically implanted into the capsular bag of the human eye as a replacement for the crystalline lens Phacoemulsification.

A Single Piece IOL is a device in which the haptic is continuous with the HEMA optic and fabricated from the same material. The IOL are divided in two zones - the central clear optic (which acts as visual zone) and the peripheral haptic (which helps the lens to stay in position).

MATERIAL AND PRODUCT CHARACTERISTICS

Material Characteristics		
Model	**NAS207**	**NASY207**
Colour	Clear	Yellow
Material	Copolymer of Hydroxy Ethyl Methacrylate and Methyl Methacrylate	Copolymer of Hydroxy Ethyl Methacrylate and Methyl Methacrylate
Water content	26%	26%
Refractive Index	1.46	1.46
Minimum Resolution Efficiency	70%	70%
YAG Laser Compatible	Yes	Yes
Light Transmittance		
Product Characteristics		
Optics Design	Bi-Convex/Convex - Concave	Bi-Convex/Convex - Concave
Haptic Design	Dual Haptic	Dual Haptic
Drawing		
Optic Diameter	6.00 mm	6.00 mm
Overall Length	12.50 mm	12.50 mm
Power Range	-10.00 D to +50.00 D (In steps of 0.5D)	-10.00 D to +50.00 D (In steps of 0.5D)

INTENDED USE

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NASPRO& NASPROBBY is intended to be positioned in the posterior chamber of the eye, replacing the natural crystalline lens. This position allows the lens to function as a refractive medium in the correction of aphakia.

SPHERICAL ABERRATION

When parallel rays of incident light pass through an ideal lens they are brought to a common focus. When such rays pass through a spherical lens of positive power, rays near the lens periphery are brought to a focus closer to the posterior lens surface than those rays passing through, or near, the optical centre. This condition is termed positive spherical aberration. In the young eye the naturally occurring positive spherical aberration of the cornea is compensated by the naturally occurring negative aberration of the crystalline lens. As age advances the crystalline lens becomes more positive and does not fully compensate for the spherical aberration of the cornea. The anterior surface of the NASPRO Aspheric IOL is modified to have a negative aspheric surface. This refracts all parallel rays incident on the anterior lens surface in such a way that they are brought to a common focus. NASPRO Aspheric IOLs can therefore improve contrast sensitivity and functional visual activity in the pseudophakic patient in comparison to a standard spherical lens.

INDICATIONS

NASPRO& NASPRO BBY Aspheric IOL Indicated for the replacement of the human lens to achieve visual correction of aphakia following cataract

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

These lenses are intended for placement in the capsular bag.

CONTRAINDICATIONS

- Chronic Severe Uveitis
- Epithelial Dystrophy
- Proliferative Diabetic Retinopathy
- Choroidal Haemorrhage
- Microphthalmos
- Concommitant Severe Eye Disease
- Glaucoma Problem
- Rubella Cataract
- Massive Vitreous Loss
- Anirida

DEVICE INTENDED USER:

Ophthalmic surgeon

PATIENT POPULATION:

Above age of one year (Male or Female)

Link for SSCP:

https://www.appasamy.com/ai-optics

RESIDUAL RISKS

1.Vision Loss
2.Inflammation, Optic Decentration, Posterior Capsule (PC) Rent
3.Wound Leakage, Corneal Edema, Blurred Vision, Toxic anterior segment syndrome.

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
- Vitreous Herniation into the formation
- Malpositioned Lens
- Aphakic Glaucoma
- Temporary Flat Anterior Chamber
- Retinal Detachment
- Lens Implants Loop Amputation
- Endothelial Corneal Dystrophy Anterior Chamber Infection
- Pupillary Block
- Corneal Dystrophy
- Posterior capsular opacification

If product is used for Cataract in patients below age of 18 years the following complications may occur:

- Amblyopia
- Risk of glare and halos
- Visual axis opacities due to inflammation or tissue growth
- Reading acuity
- Squint

The manufacturer has pursued the clinical literatures and risk management activities and finally came out with a risk-benefit analysis for the clinical decision making.

Hence the final clinical decision for the infants/children below 18 shall be made by the ophthalmologist based on risk based benefit analysis based on the clinical conditions.

WARNINGS

1.Do Not Resterilize. Resterilization may compromise the device performance, which could cause

serious harm to the patient's health and safety.
2.Do not store below 5°C and above 40°C to avoid shocks & fragile.
3.Lens should not be altered in any manner.
4.Lens should not be repackaged by anyone.
5.Single use IOLs and single use injectors cannot be reused, as they are not designed to perform as intended after the first and only usage to avoid infection.
6.Do not use after the expiry date.
7.Non-toothed, polished instruments must be used if handling the IOL.
8.Do not allow the IOL to contact substances that are unsterile or ocular-incompatible prior to placement into the eye.
9.Do not use unsterile surgical instruments or instruments that may carry a risk of contamination.
10.Do not allow the IOL to dehydrate during the procedure.
11.Once closed, do not reopen the flaps of the injector.
12.Following implantation, irrigate/aspirate to eliminate any viscoelastic residues from the bag, especially between the IOL and posterior capsule.

CALCULATION OF LENS POWER

Accurate Keratometry and biometry is essential to successful visual outcomes. Preoperative calculation of the required lens power for these posterior chamber intraocular lenses should be determined by the surgeon's experience, preference, and intended lens placement. The A-constant listed on the outer label is presented as a guideline and is a starting point for implant power calculations. This provisional A- constant has been theoretically derived. Lens constants must be "Personalized" to compensate for the differences in instrumentation, measurement technique, and IOL power calculation methods. A convenient initial estimate can be obtained by referencing to the personalized lens constant for a similar lens model.

DISCLAIMER OF LIABILITY

AI Optics Private Limited accepts no liability for improper model selection by the physician, for improper handling, use, surgical technique applied or for any other iatrogenic error caused by the implanting surgeon. AI Optics Private Limited makes no expressed or implied warranties in connection with sale of the IOL.

'A'CONSTANT

'A' Constant Value is to be provided 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.

STERILIZATION

Sterilization is done By Moist Heat Sterilization Method. Validity of sterilization applies as long as the sealed 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".

DIRECTION 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 PP Cup carefully. Hold the PP Cup and peel the aluminum seal in a sterile field Lift the PP Cup seal up to expose the IOL. Please NEVER soak or rinse the IOL in solutions. 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 AI Optics Private Limited . 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 (labels) to paste on the patient record & patient ID card for maintaining the record of the IOL implantation. for maintaining the 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

AI Optics Private Limited accepts returned lenses for exchanges only. NO cash refunds will be issued. To return lenses, you must 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 the original invoice date.

CAUTION

Federal (USA) law restricts this device to sale by or on the order of a physician.

DISPOSAL OF IOL

The intended disposal of an intraocular lens should be safe and effective way. The IOL at an end of life or explants of faculty; defective or opened in unsterile environment or due to mishandling or any other reason the product is not possible to implant should be discarded into the waste and comply with the local health & safety requirements.

HOW SUPPLIED

AI Optics Private Limited IOLs are supplied with Delivery system depends on customer requirement.

The Package Contains

One Sterile Intra Ocular Lens, One sterile Lens Delivery system, Patient ID Card, Labels and Information for use (IFU).

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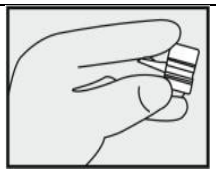
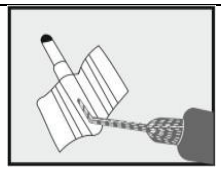
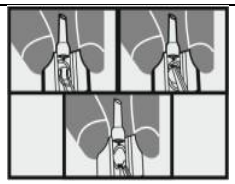
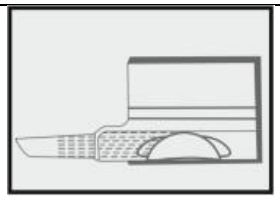
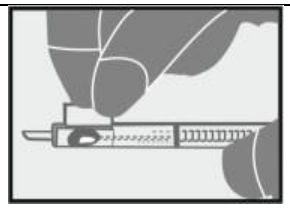
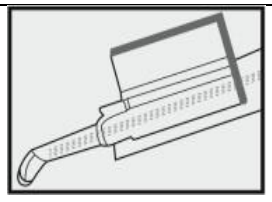
AI Optics Private Limited recommends using IOL Delivery System provided with our IOL for patient's safety. The use of other Delivery system may cause damage to the lens and potential complications during the implantation process.

If using AI Optics Private Limited Lens Delivery system provided with our IOL, please follow the "Instruction for Use of Delivery System."

NOTE: To avoid dehydration, leave the lens as immersed in saline until ready to fold and implant. The lens should be folded and implanted within 3 minutes after removal from the saline.

INSTRUCTION FOR USE OF DELIVERY SYSTEM

	**STEP:1** Open the cartridge using thumb and index finger. It is most convenient to load the lens.
	**STEP:2** Apply a thin layer of viscoelastic in the lens loading chamber and in the barrel to serve as a lubricant for the free movement of lens through the cartridge during injection. Since the lens has square edge on its posterior side, place the lens in the loading chamber of the cartridge to ensure that posterior side of the lens face downwards.
	**STEP:3** Use flat forceps to gently press the lens and at the same time, partially close the cartridge. Then gently push the leading and trailing haptic over the optic and close cartridge.
	**STEP:4** If it is not possible to lock the cartridge, then open the cartridge, remove the lens and reload the lens following steps 2, 3 and 4. Make sure neither the haptic nor optic is caught between the shutters.
	**STEP:5** Ensure that there is no gap between the shutters before loading the cartridge into the injector. Load the cartridge into the injector through the groove provided.
	**STEP:6** Gently push the plunger until the lens moves towards the cartridge tip. The lens will completely come out of the cartridge.

SYMBOLS USED ON LABELING

D	Diopter(Spherical equivalent)
IOL	Intraocular lens
STERILE	Sterilized using steam or dry heat
	Do not re-use
	Do not resterilize
SN	Serial number
	Do not use if package is damaged
	Store between 5°C to 40°C
	Instructions for use
	Keep away from sunlight
	Keep dry
STERILE EO	Sterilized using Ethylene oxide
	Manufacture
	Date of Manufacture
	Expiry
LOT	LOT Number
REF	Reference (Model) Number
$Ø_B$	Optic Diameter
$Ø_T$	Overall Length
	Single sterile barrier system
	Double sterile barrier system
	Caution, Consult
MD	Medical Device
CE ####	CE conformity Marketing and the Notified body number
EC REP	Authorized Representative in the European Community/European Union

EC REP **Amstermed B.V,**

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Phone: +31 23 5656337
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CE 2460

Manufacturing License No. MFG/MD/2025/000107
Manufacturer by*:*

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