



## AI OPTICS PRIVATE LIMITED

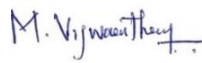
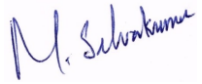

# SUMMARY OF CLINICAL AND SAFETY PERFORMANCE FOR PATIENTS

### Ref. Guidance:


MDCG 2019-9

Summary of safety and clinical performance, A guide for manufacturers and notified bodies

Doc.ID: SSCP-PHI-01A Rev. No.: 04 Issue Date: 21.01.2026

Approvals	Name	Designation	Signature	Date
Prepared By	M.Viswanathan	Regulatory Manager		21.01.2026
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**AI OPTICS PRIVATE LIMITED, CHENNAI-600 098.**

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This Summary of Safety and Clinical Performance (SSCP) is intended to provide public access to an updated summary of the main aspects of the safety and clinical performance of the device.

The SSCP is not intended to replace the Instructions for Use as the main document to ensure the safe use of the device, nor is it intended to provide diagnostic or therapeutic suggestions to intended users or patients.

The following information is intended for users/healthcare professionals.

**1.0 Device identification and general information**

**1.1 Device Brand / Trade Name(s)**

**1.2 Device Name: FOLDABLE HYDROPHILIC INTRAOCULAR LENS- APHAKIC**

**1.3 Brands and Models:**

Brands	Models	Attributes
Acryfold	601, 502, 701, Ultrasmart	Aphakic, Monofocal, Clear
	601Y	Aphakic, Monofocal, Yellow
Naspro	Nas207	Aphakic, Monofocal, Clear
NasproBBY	Nasy207	Aphakic, Monofocal, Yellow
CM-T FLEX	Acryflex T	Aphakic, Monofocal, Clear
Multidiff	MFD605	Aphakic, Multifocal, Clear
	MFDY605	Aphakic, Multifocal, Yellow
Multidiff Trifit	MFDY705	Aphakic, Multifocal, Yellow


**1.4 Manufacturer's Name & Address**

<b>Name:</b>	AI Optics Private Limited
<b>Address:</b>	84/1, Aavin Dairy Road, SIDCO Industrial Estate, Ambattur, Chennai-600098.
<b>Email:</b>	info@appasamy.com
<b>Website:</b>	www.appasamy.com
<b>SRN</b>	IN-MF-000013253

**1.5 Basic UDI-DI**

#	Variant Name	Device Identifier (DI)
1.	ACRYFOLD – 601, 502, 701, ULTRASMART, 601Y	Hydrophilic Aphakic Foldable Intraocular lens 89043129APHAKICNU
2.	NASPRO – NAS207	

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3.	NASPROBBY - NASY207	
4.	CM-T FLEX - Acryflex T	
5.	MULTIDIFF-MFD605, MFDY605	
6.	MULTIDIFF TRIFIT- MFDY705	

**1.6 Medical Device Nomenclature**

EMDN Code	Description
P030102090202	IOLs, APHAKIC, MONOFOCAL, ASPHERICAL, HYDROPHILIC ACRYLIC
P030102100202	IOLs, APHAKIC, MULTIFOCAL, ASPHERICAL, HYDROPHILIC ACRYLIC

**1.7 Class of device**

<b>Duration of Use</b>	Long Term (<30 Days) / Continuous
<b>Invasiveness</b>	Surgically invasive device
<b>Device Type</b>	Non-active Medical Device & Implantable device
<b>Rule Applicable</b>	08
<b>Classification</b>	Iib
<b>Reference</b>	In accordance with Annex VIII of EU Medical Device Regulation 2017/745

**1.8 Year of first certificate (CE) of the subject device**

18 July 2018

**1.9 Authorised Representative**


Name: Amstermed B.V.

<b>Address:</b>	Saturnusstraat 46-62, Unit 032, 2132 HB Hoofddorp, The Neterlands.
<b>Phone:</b>	+31 23 5656337
<b>Email:</b>	<a href="mailto:info@amstermed.nl">info@amstermed.nl</a>
<b>Website:</b>	<a href="http://www.amstermed.nl">www.amstermed.nl</a>
<b>SRN:</b>	NL-AR-000001971

**1.10 NB Details**

<b>Name:</b>	DNV Product Assurance AS
<b>Address:</b>	Veritasveien 1, 1363 Høvik, Norway
<b>Website:</b>	<a href="http://www.dnv.com">www.dnv.com</a>
<b>Notified Body No.:</b>	2460

**1.11 Conformity Assessment Procedure**

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- The device has undergone conformity assessment in accordance with Annex IX of Regulation (EU) 2017/745.
- The conformity assessment was performed by DNV Product Assurance AS (NB2460)
- The ISO13485 Quality Management System Certificate number is 248224-2017-AQ-IND-NA-PS valid until 03 August 2027

## 2.0 Intended use of the device

### 2.1 Intended Purpose

#### FOR MONO FOCAL

##### (ACRYFOD, NASPRO, NASPRO BBY)

It 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.

##### (CM-T FLEX)

It is intended to be positioned in the sulcus in the bed of the sclera pocket and covered with a scleral mat by means of a special anchor with a self-locking system, replacing the natural crystalline lens. This position allows the lens to function as a refractive medium in the correction of aphakia.

It is suitable for aphakic eyes, without a capsular bag. its anchoring to the scleral tissue using special anchors without the need for stitches, which simplifies surgery and greatly reduces its duration. It is not placed in the capsular bag. Instead, it is placed in the sulcus who do not have an intact capsular bag or have a damaged capsular bag.


#### FOR MULTI FOCAL

##### (MULTIDIFF)

It 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. It provides clear vision at both near and far.

##### (MULTIDIFF TRIFIT)

It 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. It provides clear vision for distance, intermediate and near.

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## 2.2 Indications & Target Populations

### Medical Indications:

#### FOR MONO FOCAL

##### (ACRYFOD, NASPRO, NASPRO BBY)

IOL indicated for the replacement of the human lens to achieve visual correction of aphakia following cataract (Monocular cataract or Mature cataract or congenital cataract or Occupational needs or traumatic or senile cataract) surgery. These lenses are intended for placement in the capsular bag.

##### (CM-T FLEX)

The device is indicated for secondary intraocular lens (IOL) implantation to restore emmetropia in adult patients requiring scleral fixation due to:

- Surgical or congenital aphakia.
- Dislocated or subluxated primary IOL.
- Inadequate capsular/zonular support post-complicated cataract surgery.
- Post-traumatic lens absence

#### FOR MULTIFOCAL

##### (MULTIDIFF & MULTIDIFF TRIFIT)

IOL indicated for the replacement of the human lens to achieve visual correction of aphakia following cataract (Monocular cataract or Mature cataract or congenital cataract or Occupational needs or traumatic or senile cataract) surgery. These lenses are intended for placement in the capsular bag.

### Target Population(s):

#### FOR MONO FOCAL

##### (ACRYFOD, NASPRO, NASPRO BBY)


Above age of one year (Male or Female)

##### (CM-T FLEX)

- The device is primarily recommended for adults aged 18 years(Male or Female) and older with stable ocular anatomy.
- **Pediatric Use:** Use in infants or children below 18 years is a clinical decision that must be made by the surgeon based on a dedicated risk-benefit analysis of the individual patient's condition.

#### FOR MULTIFOCAL

##### (MULTIDIFF & MULTIDIFF TRIFIT)

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- The device is primarily recommended for adults aged 18 years(Male or Female) and older with stable ocular anatomy.
- **Pediatric Use:** Use in infants or children below 18 years is a clinical decision that must be made by the surgeon based on a dedicated risk-benefit analysis of the individual patient's condition.

### 2.3 Contraindications and/or Limitations

#### FOR MONO FOCAL

##### (for ACRYFOD, NASPRO, NASPRO BBY)

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

##### (CM-T FLEX)

The CM-T Flex must not be implanted in eyes with:


- **Active Intraocular Infection:** Any sign of active or recent endophthalmitis.
- **Active Inflammation:** Uncontrolled uveitis or severe chronic internal ocular inflammation

#### FOR MULTIFOCAL

##### (MULTIDIFF & MULTIDIFF TRIFIT)

Apart from non-specific contraindications related to any form of ocular surgery, the following non-exhaustive list of specific contraindications must be respected:

- Chronic Severe Uveitis
- Epithelial Dystrophy
- Proliferative Diabetic Retinopathy
- Choroidal Haemorrhage
- Microphthalmos

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- Concomitant Severe Eye Disease
- Glaucoma Problem
- Rubella Cataract
- Massive Vitreous Loss
- Anirida

### 3.0 Device Description

#### 3.1 Description of the Device

##### FOR MONO FOCAL

##### (ACRYFOD, NASPRO, NASPRO BBY)

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).

##### (CM-T FLEX)

Intra Ocular Lenses are optical for the human crystalline lens in the visual correction of aphakia.

CM-T-Flex Intra Ocular Lenses is a single piece, sterile, foldable, hydrophilic acrylic optical device.


##### FOR MULTIFOCAL

##### (MULTIDIFF)

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).

Diffraction is used as a basis for the determination of light distribution in multifocal diffractive IOLs. It splits the light between the far & near vision; The lens provides one optical power for distance vision

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and a separate lens power for near vision. So, it rectifies the Distance and Near Vision in the optical system. Biconvex and special haptic design with slots prevents post-operative complications such as buckling or anteroposterior movement of the lens.

### **(MULTIDIFF TRIFIT)**

The Multidiff Trifit sterile UV-absorbing Hydrophilic foldable single piece posterior chamber lens is an optical implant for the replacement of human crystalline lens in the visual correction of aphakia. Multidiff Trifit is available in variable diopters ranging from 0 to 35 diopters with the increment of 0.5 D which are inspected by higher end laser interferometers. These lenses have four point supporting haptics for easy centration and aspherical surface on posterior side and Refractive-Diffractive surface on anterior surface. This feature helps to the patient for reading without spectacle. Multidiff Trifit provides clear vision for distance, intermediate and near. The add power for near vision is +3.5D and for the intermediate vision it is +1.65D.

**The lens is supplied with and without Disposable Injector System.**



The lens delivery system is sterile Single Use Disposable Injector System. The lens delivery system consists of an Injector with silicon cushion and a cartridge. Lens Delivery system is a medical device used to implant a **FOLDABLE HYDROPHILIC INTRAOCULAR LENS-APHAKIC** in a patient's eye.


### **Materials that come in contact with patient:**

The Hydrophilic Aphakic Foldable Intraocular Lens is made up of HEMA – Hydroxyethyl methacrylate.

### **Information about medicinal substances in the device, if any:**

Hydrophilic Aphakic Foldable Intraocular Lens does not incorporate medicinal substances. Hence this declaration is not applicable.

### **Description of how the device is achieving its intended mode of action:**

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Hydrophilic Aphakic Intra Ocular Lens (IOL) functions as a refracting medium to replace the natural lens in the correction of aphakia. The IOL can be placed either in Posterior Chamber or in Anterior Chamber.

#### **Description of accessories, if any:**

The lens is supplied with or without lens delivery system.

#### **Lens Delivery System/Injector:**



#### **4.0 Risks and warnings**

Contact your healthcare professional if you believe that you are experiencing side-effects related to the device or its use or if you are concerned about risks. This document is not intended to replace a consultation with your healthcare professional if needed.


#### **How potential risks have been controlled or managed:**

We have established and maintaining a strong quality management system and continuous process monitoring controls as per ISO 13485:2016 requirements. We have implemented all necessary risk control measures for each hazard that are appropriate for reducing the risks to an acceptable level in a reasonably practicable way. As per the risk management plan, we have identified the risk control options as mentioned below.

- Making the medical device design and the manufacturing process inherently safe.
- Taking protective measures in the medical device or in the manufacturing processes.
- Information for safety.

After all risk control measures implementation and verification, the overall residual risks are acceptable as per the defined risk acceptability criteria. The risk associated with the indented use is acceptable when weighed against benefit to the patient. As part of “Hydrophilic Aphakic Foldable Intraocular Lens” risk assessment, the identified residual risks are analysed through benefit-risk analysis.

The Hydrophilic Aphakic Foldable Intraocular Lens medical benefits and residual risks are compared based on medical condition, literature data certainty, similar device data (benefits & residual risks) from the market, acknowledged state of the art. The defined residual risks are outweighed by the expected

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medical benefits when used as per the defined intended purpose of Hydrophilic Aphakic Foldable Intraocular Lens.

However, the residual risks are accepted as per the benefit-risk analysis with proper literature evidence and also by providing necessary information on safety to the end user's awareness in the form of "Label" and "Instructions for Use".

#### **Residual Risks:**

- Vision Loss
- Wound Leakage, Corneal Edema, Blurred Vision, Toxic anterior segment syndrome.
- Inflammation, Optic Decentration, Posterior Capsule Rent, TASS (Toxic anterior segment syndrome)


#### **Precautions:**

As with any surgical procedure, there is risk involved. Potential complications accompanying cataract or implant surgery may include, but are not limited to the following:

- Temporary Corneal Edema,
- Secondary Cataract Formation,
- Vitreous Herniation into the Formation,
- Mal-positioned Lens,
- Aphakic Glaucoma,
- Temporary Flat Anterior Chamber,
- Retinal Detachment,
- Lens Implants Loop Amputation,
- Endothelial Corneal Dystrophy Anterior Chamber,
- Ocular Infection,
- Pupillary Block,
- Corneal Dystrophy and
- IOL opacification.

#### **Warnings:**

- Do Not Resterilize. Resterilization may compromise device performance, which could cause serious harm to the patient's health and safety.
- Do not store intraocular lenses at temperatures below 5 °C and above 40°C to avoid shocks and fragile.
- Lens should not alter in any manner
- Lens should not be repackaged by anyone

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- 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.
- Do not use after the expiry date
- Non-toothed, polished instruments must be used if handling the IOL
- Do not allow the IOL to contact substances that are unsterile or ocular-incompatible prior to placement into the eye
- Do not use unsterile surgical instruments or instruments that may carry a risk of contamination
- Do not allow the IOL to dehydrate during the procedure
- Once closed, do not reopen the flaps of the injector
- Following implantation, irrigate/aspirate to eliminate any viscoelastic residues from the bag, especially between the IOL and posterior capsule

**Summary of any field safety corrective action, (FSCA including FSN) if applicable:**

There were no identified and/or received reportable events that led to death, a serious deterioration in the state of health of the patient, user, or other person for Hydrophilic Aphakic Foldable Intraocular Lens. Hence FSCA or FSN is not applicable.


**5.0 Summary of clinical evaluation and post-market clinical follow-up (PMCF)**

**PMCF Clinical Safety & Performance data**

Overall, **244** populations were considered for this PMCF study. We clinically investigated all the cases and thoroughly reviewed Clinical Study data. As per the PMCF study, the **FOLDABLE HYDROPHILIC INTRAOCULAR LENS-APHAKIC** have met the primary and secondary objectives.

The **FOLDABLE HYDROPHILIC INTRAOCULAR LENS-APHAKIC** – Acryfold, Naspro CM-T Flex, Multidiff & Multidiff Trifit from AI OPTICS (P) LIMITED has reached all the safety and performance requirements with respect to the intended use of the device from the Post Market Follow up Clinical study. The clinical evidence is demonstrated with the relevant Essential Requirements. The Performance and Safety of the device as we claimed it have been established in the Technical File and Instruction for Use/Operator Manual (IFU). There were no new risks identified from the PMCF study for the product hence there is no addition to the residual risks which we have already identified in the Risk Management Report and that is been mitigated and are acceptable when weighed against the benefits to the patient.

**The clinical evidence for the CE-marking:**

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The safety and performance of this device have been carefully evaluated using studies and information collected specifically for this device, such as clinical follow-ups and safety checks. The safety and performance of the Ophthalmic Foldable Hydrophilic Lens have been evaluated through clinical data collected directly on this device. The studies showed:

- significant improvement in vision after implantation
- stable position of the lens inside the eye
- low occurrence of surgery-related complications

No new safety concerns were identified during post-market follow-up of patients who received this lens.

The results confirm that the lens performs as intended and provides the expected improvement in vision.

• **Safety**

We have carefully looked at all possible risks of using this device and compared them with the medical benefits it provides. We concluded that the benefits, such as better vision and fewer side effects, outweigh the possible risks. Any remaining risks are considered acceptable when patients follow the instructions provided in the labeling and instruction for use.


Residual Risks	Medical Benefits
1. Vision loss 2. Inflammation, Optic Decentration, Posterior Capsule (PC) Rent 3. Wound Leakage, Corneal Edema, Blurred Vision, Toxic anterior segment syndrome	1. Increased Visual effect for distance objects 2. Decreased side effects 3. Decreased Post-operative effects 4. Less dysphotopsia 5. Good biocompatibility 6. Good optical clarity 7. Resistance to damage during insertion 8. Less susceptibility to bio contamination

**6.0 Possible diagnostic or therapeutic alternatives**

When considering alternative treatments, it is recommended to contact your healthcare professional who can take into account your individual situation.

**General description of therapeutic alternatives:**

The only treatment for Cataract is Cataract Surgery, which is a procedure to remove the lens of your eye and, in most cases, replace it with an artificial lens. Hence there is no medical alternative.

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**7.0 Suggested profile and training for users**

**Target Users:** Ophthalmic surgeon

Ophthalmic surgeons are responsible for treating problems with the eye as well as diagnosing ailments and prescribing medicine for the eye. An Ophthalmic surgeon also performs surgical procedures on the eye.

There is no special user training is required. However, the device related directions for use information are provided in the Instruction for Use.

**8.0 Revision history**

SCP Rev. No.	Date Issued	Change description	Rev. Validated by the NB
01	01.11.2023	Initial release- EU MDR 2017/745 regulations update	<input type="checkbox"/> Yes Validation language: English <input checked="" type="checkbox"/> No
02	01.11.2024	As per annual review update 2023-24	<input type="checkbox"/> Yes Validation language: English <input checked="" type="checkbox"/> No
03	10.11.2025	The two models given in the QRF is added in the TD File- Monofocal (CM-T FLEX) & multifocal (MFDY705) as per Initial Assessment-Technical Dated 17.10.2025 & Annual review update 2024-25	<input type="checkbox"/> Yes Validation language: English <input type="checkbox"/> No
<b>04.</b>	21.01.2026	The document has been updated based on the inputs and comments received in the Initial Assessment of technical file (TD-PHI-01) clinical part Dated 19.01.2026	<input type="checkbox"/> Yes Validation language: English <input type="checkbox"/> No