Summary of Safety and Clinical Performance

SING IMT™, Model -NG SI IMT 3X

Date Effective: 20 Jan 2026 (Actual date is in Arena System)

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APPROVAL:

Approval		
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Vladimir Belousov	VP R&D	**By electronic signature in Arena PLM**
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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 SING IMT™ 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 document is presented in two sections:

- Part One is information intended for users/healthcare professionals
- Part Two is intended for patients

Contents

1 INFORMATION FOR HEALTHCARE PROFESSIONALS

1.1 The identification of the device and the manufacturer

Device trade name	SING IMT™ (Small Incision New Generation Implantable Miniature Telescope) **Model – NG SI IMT 3X**
Manufacturer's name and address	Samsara Vision Ltd. 21 Yegia Kapayim Street, Petah Tikva 4913020, Israel
Manufacturer's SRN	IL-MF-000018630
Basic UDI-DI	7290018786NGSI00118C8
Medical device nomenclature description	**Device nomenclature code** : PR00118-00 **GMDN code** : 58434, "Optical Implantable device, Non-active" **UMDNS code** : 16071, "Lenses, Intraocular, Posterior Chamber" **NBOG code** : MD 0204, "Non-active soft tissue implants"; MDS 7006, "Medical devices in sterile condition" **EMDN/CND code**: Q0299, OPHTHALMIC DEVICES - OTHERS
Class of device	**Class IIb** Implantable Rule 8 (Annex VIII) Implantable, long-term, surgically invasive
Year when the first certificate (CE) was issued covering the device	24 April, 2020

Authorized representative	Obelis s.a., Bd. Général Wahis 53, B-1030 Brussels, Belgium Phone: +32.2.732.59.54, E-mail: mail@obelis.net SRN -IL-MF-000018630
NB's name	mdc medical device certification GmbH Kriegerstrasse 6, 70191 Stuttgart, Germany Notified Body single identification number: 0483

1.2 Intended use of the device

Intended purpose	The telescope is intended to improve vision in patients with late-stage age-related macular degeneration (AMD).
Indication and target population	The device is indicated for bilateral central scotomas due to late-stage age-related macular degeneration in patients 55 years of age or older with stable moderate to profound vision impairment. Target population: • Be 55 years of age or older. • Have retinal findings of geographic atrophy or disciform scar with foveal involvement as determined by Angio OCT or by fluorescein angiography. • Have evidence of cataract. • Have best-corrected distance visual acuity (BCDVA) no better than 20/80 and no worse than 20/800 in both eyes. • Have adequate peripheral vision in the eye not scheduled for surgery.

	• Achieve at least a five-letter improvement on the ETDRS chart in the eye scheduled for surgery when using Samsara Vision's 3X external telescope simulator (ETS, supplied separately). • Have an anterior chamber depth of at least 2.5 mm in the eye scheduled for surgery. • Be willing to participate in a post-operative training program for the use of the device.

Contraindications and/or limitations	Implantation of the device is contraindicated in patients who have any one of the following conditions:
	• Evidence of active choroidal neovascularization (CNV) on Angio OCT or fluorescein angiography or were treated for CNV within the past six months.
	• Any ophthalmic pathology that compromises the patient's peripheral vision in the fellow eye.
	• A history of steroid-responsive rise in intraocular pressure (IOP), uncontrolled glaucoma, or preoperative IOP>22 mm Hg.
	• Corneal guttata.
	• Known sensitivity to post-operative medications.
	• Significant communication impairment or severe neurological disorders.
	• Have undergone previous intraocular or corneal surgery of any kind in the operative eye, including any type of surgery for either refractive or therapeutic purposes.
	• An ocular condition that predisposes the patient to eye rubbing.
	• Prior or expected ophthalmic-related surgery within 30 days preceding the NG SI IMT 3X implant surgery.
	• Patients for whom the planned operative eye has:
	  ○ Myopia > 6.0 D
	  ○ Hyperopia > 4.0 D
	  ○ Axial length < 21 mm
	  ○ Endothelial cell density < 1600 cells per square mm
	  ○ Narrow angle, i.e., < Schaffer grade 2.
	• Inflammatory ocular disease.
	• Cornea stromal or endothelial dystrophies, including guttata.

- Zonular weakness/instability of crystalline lens, or pseudoexfoliation.
- Diabetic retinopathy.
- Untreated retinal tears.
- Retinal vascular disease.
- Optic nerve disease.
- A history of retinal detachment.
- Retinitis pigmentosa.
- Intraocular tumor.

1.3 Device description

1.3.1 Description of the device

The SING IMT™ (model NG SI IMT 3X) is a visual prosthetic implantable device, which, when combined with the optics of the cornea, constitutes a telephoto system for improvement of visual acuity in patients with bilateral, end-stage macular degeneration.

The NG SI IMT 3X implant comprises a glass telescope and a haptic carrier (**Figure 1**). The telescope's optical component, which contains two micro lenses, is designed to reduce the effective size of the patient's scotoma, magnifying objects in the central visual field and projecting them onto the retina, and allowing the patient to recognize and identify objects that could not otherwise be seen at both near and far distances.

The optical component (glass telescope) is embedded in a silicon carrier, which, after removal of the ocular crystalline lens, allows injection of the device into the capsular bag of the eye in a conventional surgical procedure. The telescope is held in position in the ocular capsular bag by silicon haptic wings.

Figure 1. SING IMT™ device (model NG SI IMT 3X)

The device is optimized for intermediate vision (3 to 10 meters). Distance and near vision corrections are accomplished with conventional glasses.

The device allows scanning of reading materials and other images using natural eye movements, rather than head movements. The device provides sufficient image resolution for different tasks such as reading, face recognition and TV watching at graded visual fields of up to maximum of 12° (36.0° on the retina). Since there is no relative movement between the eye and the telescope, there are no optical aberrations and a wider visual field (nominal field of view of 20° projected onto approximately 54° on the retina) is achieved. The placement of the telescope entirely inside the eye eliminates increased speed of motion and vestibular conflict.

1.3.2 Previous generations

Previous generations of the NG SI IMT 3X exist, these models include WA 2.2X, WA 2.7X, WA 3X and NG IMT.

Models WA 2.7X and WA 3X are the same devices for different markets and therefore bear different labels. They have the same magnification of 2.7x, while model WA 2.2X has magnification of 2.2x. NG SI IMT 3X has an identical optical element to that of the NG IMT and the WA 3X.

Models WA 2.2X and WA 2.7X are FDA approved and have been marketed in the US since 2010. Models WA 2.2X, WA 3X and NG IMT are CE marked.

The previous generations also differ in their haptic, a parameter that affects incision size when implanting the device and in the delivery system on the implant. The WA 2.2X, the WA 2.7X, and the

WA 3X have rigid Poly (methyl methacrylate) (PMMA) haptics which require a 12.0 mm incision and manual insertion of the IMT into the capsular bag. In the NG IMT and in the NG SI IMT 3X, the PMMA haptic was replaced by flexible silicon haptics, which allow the device to be injected into the eye utilizing a smaller incision of 6.5 to 7.5 mm incision.

1.3.3 Description of the IMT delivery system

The SING IMTTM delivery system is intended to support easy and safe implantation of the NG SI IMT 3X implant into the eye of the patients. The telescope delivery system consists of a single-use, sterile, disposable cartridge and Injector. The SING IMTTM cartridge is supplied preloaded with the NG SI IMT 3X implant and Injector Tip in the ready for loading position (Figure 2).

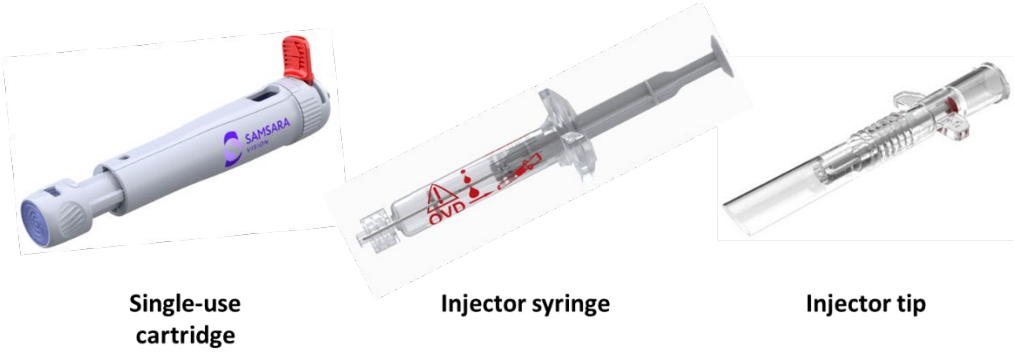

Figure 2. Different pieces of delivery system

This preloaded SING IMTTM cartridge is intended for:

- Storing and protecting the NG SI IMT 3X implant and Injector Tip during sterilization, storage, and transportation.
- Lubricating and loading the NG SI IMT 3X implant into the Injector.

The injector is comprised of the Injector syringe connected to the loaded Injector Tip.

1.4 Risks and warnings

1.4.1 Residual risks and undesirable effects .

The risk management process identifies potential product related hazards. The risk assessment is performed for each of the identified hazards, hazardous situations, and the associated risks by a Risk management team using the risk acceptability criteria that define acceptable and unacceptable risks. For all identified hazards and corresponding risks, including usability risks, appropriate risk control measures were implemented. The risk control measures were applied according to the predefined priority and were verified for effectiveness. No risks, which might have potentially arisen from

applied risk control measures, were identified. Analysis of the residual risks remaining after risk control measures have been taken has shown the following:

- There are no risks remained with “Frequent” (5% < P) and “Probable” (1% < P ≤ 5%) occurrence rankings. Most of risks were reduced to “Remote” (0.04% < P ≤ 0.2%) and “Improbable” (P ≤ 0.04%.
- Risk which fallen into the red category and representing unacceptable risk were transferred to EMRB for making decision whether the medical benefits outweigh the overall residual risk or to return the product to the design phase..

Table 1: Risk assessment

Hazard category	Risks number	Probability of Occurrence of Harm	Consideration	Judgment
Functional hazards	**1**	0.04% < P ≤ 0.2%	Product design addresses the hazardous situation. No AE / SAE related to the hazardous situation was identified in clinical follow-up. Clinical expert judged probability of occurrence of the hazardous situation and harm as negligible.	Considering that the product is intended for use by highly qualified and trained medical professionals, product design and clinical expert judgment, it may be concluded that benefits to the patient outweigh the residual risk.
Usability-related hazards	**2** **1**	0.04% < P ≤ 0.2% 0.2% < P ≤ 1%	Training materials shall be updated to emphasize information necessary to reduce probability of occurrence of hazardous situation. Some engineering changes addressing risk by design were implemented.	Considering that the corrective actions are implemented and that the product used as intended, usability risks constitute acceptable risks

				when weighed against the benefits to the patient.
Iatrogenic hazards	**4**	0.2% < P ≤ 1%	A high level of surgical skill is required for the SING IMT implantation. Only surgeons who have received a formal mandatory training in the clinical use of the SING IMT™ may perform the implantation. A training program for the surgeons and visual rehabilitation specialists was established and verified for effectiveness by clinical use. The post-op rehabilitation process was established.	Considering the users are qualified and trained as required and patients participate in post-operative visual rehabilitation program benefits to the patient outweigh the residual risk.

1.4.2 Warnings

⚠ Implantation of the NG SI IMT 3X implant carries a risk for **ocular complications directly related to the surgical procedure** occurring in the operative or immediate postoperative period, including aborted surgery, choroidal detachment, corneal edema ≤ 30 days, increased IOP requiring treatment ≤ 7 days, iris atrophy ≤ 7 days, iris prolapse, iris transillumination defects ≤ 21 days, phthisis, posterior capsular bag rupture, vitreous in the anterior chamber ≤ 7 days, and vitreous loss.

⚠ Additional risks **associated with anterior chamber surgery and** NG SI IMT 3X implant include: endophthalmitis, hypopyon, retinal detachment and retinal tears.

As with any surgical procedure, there is risk involved with the **surgical procedure itself**. Potential complications accompanying cataract extraction or NG SI IMT 3X implant implantation surgery may include, but are not limited to, the following: corneal endothelial damage, infection, retinal detachment, vitreous loss, ptosis, pupillary block, secondary glaucoma, iris prolapse, posterior capsular rupture, cystoid macular edema, intraocular inflammation, microbial infection, recurrent severe anterior or posterior segment posterior inflammation, and uveitis.

The **long-term effects** of the NG SI IMT 3X implant, including the long-term effects on corneal endothelial cells, have not been established; therefore, physicians should continue to monitor patients postoperatively on a regular basis.

The risk of acute corneal endothelial cell loss during implantation is higher than with conventional anterior segment procedures and, consequently, total endothelial cell loss over time may be higher than for intraocular lenses implanted in the capsular bag.

Risk of complications **occurring during the immediate NG SI IMT 3X implant postoperative period** include: corneal edema, corneal decompensation, corneal transplant, decrease in visual acuity, device failure, diplopia, distorted pupil, gutatae, increased IOP requiring treatment, iris transillumination defects, posterior synechiae, precipitates or inflammatory deposit on the telescope, device dislocation, device removal, vitreous hemorrhage, and vitreous in anterior chamber.

1.4.3 Precautions

The NG SI IMT 3X implant limits the peripheral vision in the implanted eye in a fixed gaze; the functional field of view will be generally limited to that of the non-implanted fellow eye.

NG SI IMT 3X implant implantation restricts the patient's peripheral visual field; driving a car postoperatively is not recommended.

Patients must avoid rubbing the implanted eye; patients who are persistent eye rubbers are contraindicated.

If the patient is unable to participate or does not participate in Samsara Vision training / rehabilitation program before and after the surgery, the potential benefits of the device may be reduced.

Do not use the NG SI IMT 3X implant and IMT Delivery System before reading this IFU.


Do not use the NG SI IMT 3X implant or IMT Delivery System after the expiration date indicated on the package.


Do not resterilize or reuse any part of the system.


Do not use the NG SI IMT 3X implant or IMT Delivery System if the sterile barrier system packaging (Blister sealed by TyVek® Lid) has been opened or damaged, as the sterility of the NG SI IMT 3X implant or IMT Delivery System may be compromised.


Do not use the NG SI IMT 3X implant or IMT Delivery System if the Tyvek lid material was torn during opening of the Sterile barrier system packaging (Blister sealed by TyVek® Lid), as the sterility of the NG SI IMT 3X implant or IMT Delivery System may be compromised.


The NG SI IMT 3X implant should not be implanted after the indicated sterility expiration date.


The NG SI IMT 3X implant and IMT Delivery System are intended for single use only. Discard the IMT Delivery System after use. Reuse of the NG SI IMT 3X implant and IMT Delivery System is prohibited and could pose a risk of infection or nonconformance of the NG SI IMT 3X implant and IMT Delivery System with its specifications.


Use the NG SI IMT 3X implant and IMT Delivery System only for the purpose described in the IFU.


Do not attempt to disassemble, modify, or alter the NG SI IMT 3X implant or IMT Delivery System or any of their components, as this can significantly affect the function and/or structural integrity of the NG SI IMT 3X implant and IMT Delivery System.


Warranty shall not apply to any defects, failure or damage caused by improper use and/or care.


Do not soak or rinse the NG SI IMT 3X implant or IMT Delivery System with any solution.


Do not place heavy objects on the package


Use the NG SI IMT 3X implant and IMT Delivery System at standard operating room temperatures.


Do not use if the NG SI IMT 3X implant or IMT Delivery System were dropped or if any part was struck after it was removed from the shipping case.


A high level of surgical skill is required for NG SI IMT 3X implant implantation. The surgeon should have performed several anterior chamber IOL implantations and successfully completed one or more training courses on intraocular lens implantation as well as training on the clinical use of the SING IMT™ system before implanting the NG SI IMT 3X device.


Thermal lasers should be used with extreme caution around the NG SI IMT 3X implant, and never through the glass optical portion. When applying laser energy around the NG SI IMT 3X implant be aware NOT to focus the laser beam on the carrier/haptic surface.

⚠ Do not use the device if the device or package labeling (serial #, expiration date, etc.) is corrupted or unreadable.

⚠ In cases of labeling damaged to extent that prevents clear identification of print the device is not suitable for clinical use and should be returned to the manufacturer immediately.

MR CONDITIONAL
Non-clinical testing demonstrated that the NG SI IMT 3X implant is MR conditional. Thus, a patient implanted with the NG SI IMT 3X implant can be safely scanned with MR under the following conditions:

- Static magnetic field of 1.5 Tesla or 3 Tesla.
- Maximum spatial gradient magnetic field of 1000 Gauss/cm (10 Tesla/m).
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2 W/kg for 15 minutes of scanning (i.e., per pulse sequence in the normal operating mode of operation for the MR system. Under the scan conditions defined, the NG SI IMT 3X implant is expected to produce a maximum temperature rise of 1.6°C after 15-minutes of continuous scanning (i.e., per pulse sequence).

In non-clinical testing, the image artifact caused by the NG SI IMT 3X implant extends approximately 5 mm from the NG SI IMT 3X implant when imaged using a gradient echo pulse sequence and a 3-Tesla MR system.

1.4.4 Other relevant aspects of safety, including summary of any field safety corrective action, (FSCA including FSN) if applicable

FSCA-0001

A limited number of SING IMT™ devices have been identified with an inaccurate marking on the injector. This issue is temporary, has been corrected, and only impacts devices currently in stock. No patient safety concerns have been reported in relation to this issue.

The UP markings on the wings of the tip, are placed there to be used as an aid to confirm the correct orientation of the injector prior to use. When an injector is properly assembled, the UP marking aligns with the longer end of the bevel of the injector tip. During the surgery, proper insertion of the injector through the limbal incision starts with the longer end of the tip facing upwards and is followed by the shorter end which is facing downwards.

There have been three reported instances of incorrect orientation of the UP markings on the injector, all reports originating from within the United States and all three identical to the issue described above (the UP-mark points down relative to the bevel and the implant). The first two reported cases were from the same lot, leading to the initial supposition that the issue was isolated to that one specific lot. The third case involved a different lot.

Examination of the expiring devices that Samsara Vision had in stock in the US at the time of the third case showed:

- That some, not all, had the same incorrect orientation of the marking.
- Although the marking is incorrect, the implant is correctly positioned within the injector and thus is properly oriented relative to the bevel of the injector tip.

History of surgeries with incorrect UP mark:

All SING IMT cases in the US are carried out as part of the SING IMT Clinical Trial, G210239.

Three SING IMT surgeries with the incorrect UP mark reported took place in the United States. All three surgeries with the incorrect UP proceeded to completion without incident. This outcome is a result of the surgical training program, which emphasizes that the correct orientation of the injector during implantation is not solely based on the UP marking, but is also assessed by visualizing the direction of the bevel.

Following the three cases, each of the surgeons were asked if they had any concerns or noted adverse events that could be related to the UP orientation, and no concerns or events were described.

To date, none of these three subjects have exhibited any unusual or unanticipated adverse events. The issue with the injector has been recorded in these subjects' CRF and monitoring of these cases will proceed per the approved SING IMT monitoring plan.

Samsara Visions Quality Assurance department initiated a CAPA Process; the Corrective and Preventive Actions are described below.

Corrective and Preventive Actions:

A CAPA process was initiated: CAR-000105.

An investigation into the incorrect marking has revealed that, errors occurred during the tip beveling process. Additionally, the QC Checklist did not include a specific quality control check to verify the orientation of the "UP" mark in relation to the bevel on the tip.

The Corrective Actions that have been implemented are:

- Revise the Tip Base Work Instructions to include additional detail regarding the correct orientation of the "UP" mark upon insertion into the jig to create the bevel.

- Revise the Work Instructions for the 'QC Procedures for Assemblies of Syringe, Tip and Pre-loaded cartridge' of the SING IMT to ensure that the QC Checks for this assembly include verification of the orientation of the UP marking.
    - Updated the associated QC Inspection Form to ensure that inspection results are recorded.
- Trained Production and Quality Departments personnel on the updated QC Work Instructions and forms.

<u>The Preventative Actions are the following two actions at the manufacturing site:</u>

- All newly assembled devices will be manufactured with the updated WI and QC checks for the Assemblies of Syringe, Tip and Pre-loaded cartridge of SING IMT.
- Newly assembled devices will be provided for the US clinical study as early as December 2025.

<u>Field safety actions implemented for Europe:</u>

Additionally to the corrective and preventive measures listed above, Samsara is providing updated implanting instructions in two forms to the users:

1. A field safety notice sent directly to implanting sites with reception acknowledged by return signature.
2. A box notice included with every device shipped to the sites. The notice is placed on the outside of the box on the opening flap and needs to be removed to access the device.

The timeline from incident awareness to conclusion of the FSCA is as follow:

- May 4, 2025: Samsara Manufacturing facility received two identical customer complaints, identified as CMPLT-000029 and CMPLT-000030. Both complaints originated from two clinical study sites in the United States. Both were from the same Lot: 11831.
- May 2025: Re-train the Production personnel on the accurate process for orientation of the UP marking on injector during the manufacturing of the injector.
- 30 June 2025: Update SOP 100072090 from Rev 7 to Rev 8: "QC Procedures for Assemblies of Syringe, Tip and Pre-loaded cartridge of QA SI NG SI IMT 3X" and QC Checklist forms.
- 30 June 2025: Update Work Instruction 100070176 from Rev 3 to Rev 4: "Assembly Instructions for WA SI / NG SI Tip Assembly"
- June 2025: Examine the remainder of Lot 11831 that is in stock to determine if those device have the incorrect marking
- 23 July 2025: receive a third complaint from the US Clinical Trial of the same incorrect marking. This device was from Lot 11935. Determine that this is not a isolated issue.
- 22 August 2025: Submit to Obelis, Samsara Visions Authorized Representative, a notification of a Field Safety Corrective Action for the SING IMT. Also sent to Obelis a Field Safety Notice to the EU Users describing temporary changes to instructions for use.
- 12 September 2025: Obelis sent the FSCA to the Competent Authorities.

- September 2025: Samsara Field Employees/Proctors and Surgeon Users were trained on the FSN.
- September 2025: Samsara Employees were trained on the Box Notice.
- Q4 2025 send FSN to all implant sites
- 2026 File the final FSCA report once all affected devices will no longer be in stock

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

1.5.1 Summary of clinical data related to equivalent device

1.5.1.1 Clinical data related to the equivalent model NG IMT

Table 2: Data reported in the literature related to the equivalent model NG IMT

Ref.	Performance outcomes	Safety outcomes
(Alió et al. 2004)	Mean uncorrected distance visual acuity (UCDVA) in the operated eye improved from 0.9 logMAR (0.125± 0.01, range 0.1 to 0.3 in decimal values) preoperatively to 0.6 logMAR (0.25± 0.14, range 0.1 to 0.5 in decimal values). Mean uncorrected near visual acuity (UCNVA) in the operated eye improved from 0.8 logMAR (0.16 0.13, range 0.1 to 0.5 in decimal values) preoperatively to 0.4 logMAR (0.4 0.26, range 0.1 to 1.0 in decimal values) at 1 year postoperatively.	7 eyes (17.5%) developed persistent complications in the form of PCO (4 eyes, 10%), synechias (2 eyes, 5%), and fibrin deposition on the pupil (1 eye, 2.5%). Major complications including corneal decompensation, glaucoma, iris atrophy, vitreous hemorrhage, retinal detachment, posterior dislocation of the telescope and IMT malpositioning did not occur. The mean endothelium cell loss was 14.5% at 3 months, 30.8% at 6 months, and 34.5% at 12 months.
(Lane et al. 2004)	At 12 months, 77% of patients gained 2 more lines of either distance or near BCVA, and 62% of patients gained 3 or more lines in either distance or near BCVA.	Late intraocular inflammation observed postoperatively, with varying clinical signs: anterior chamber cells, fibrin, conjunctival injection, iritis and anterior uveitis. Two non-ocular events were reported: the death of one study patient 10 months after implantation of the IMT and surgical removal of a kidney stone after 30 days of implantation. Mean ECD decreased by 13%.
(Chun, Heier & Raizman 2005)	At 6 months, nearly 90% of patients gained two or more lines of BCVA.	Transient elevated IOP and corneal edema in the 1st month postoperatively. Distorted pupil (2.5%), inflammatory deposits (8.9%) and posterior synechiae (3.5%) at 6 months postoperatively. Mean ECD stabilized through 2 years, with 2.4% mean cell loss occurring from one to two years.
(Hudson et al. 2006)	At 1 year, 67% of implanted eyes achieved a 3-line or more improvement in BCDVA versus 13% of fellow eye controls. 53% of implanted eyes achieved a 3-line or more improvement in both BCDVA and BCNVA versus 10% of fellow eyes.	Ocular adverse events include inflammatory and pigment deposits on device, guttae and posterior synechiae. Mean ECD loss was 25% at 1-year postoperative, and stabilized from 1 through 2 years, with 2.4% mean cell loss occurring in that period.
(Lane & Kuppermann 2006)	At 6 months, 89% of eyes achieved a 2-line or more improvement in mean distance or near BCVA. A total of 68% and 56% achieved a 2-line and 3-line or more improvement in both distance and near BCVA, respectively.	ECD reduction was correlated with postoperative day 1 edema that was +2 or greater in severity, indicating that the cell loss was due to trauma sustained at the time of surgery. At 6 months, there were no significant retinal complications. ECD was reduced by 20% at 3 months and 25% at 1 year.

(Hudson et al. 2008)	At two years, 59.5% of telescope-implanted eyes gained three lines or more (doubling of visual angle) of BCVA compared with 10.3% of 174 fellow control eyes.	The most common complication was inflammatory deposits. Mean ECD stabilized through two years, with 2.4% mean cell loss occurring from one to two years.
(Boyer et al. 2015)	Overall, patients experienced a mean improvement in BCDVA of 3.2 lines at 24 months and 2.4 lines at 60 months.	The most common complication was inflammatory deposits. The procedure is very safe and has very few anterior segment complications in long term follow-up. Mean ECD loss was 25% at 1-year postoperative and stabilized from 1 through 2 years, with 2.4% mean cell loss occurring in that period.

1.5.1.2 Clinical Studies Evaluating the WA 3X

The WA 3X was evaluated by prospective, multi-center clinical trials: IMT-002 - a pivotal study, and IMT-002-LTM, a long-term safety study in which patients implanted under the IMT-002 study were followed for 5 years (**Table 3**). These studies are described in the sections below.

Note: The original PMA submission to the FDA referred to two magnifications: 2.2X and 2.7X. While the FDA assessed the PMA submission, the same 2.7X device was submitted for CE mark in Europe and was approved under a new name 3X. At this stage the product has already been approved for use in Europe under the name WA 3X. To comply with the FDA requirement, it was decided to change the product name in the US to WA 2.7X. Therefore, the WA 3X is the same device as the WA 2.7X.

Table 3: List of clinical studies evaluating the WA 3X

Study name	Document No.	Study design	Objective	Number of sites	Number of subjects
Protocol IMT-002 Pivotal	IMT-002 report Aug 5, 2005 (Attachment 12)	Prospective, single-arm, open, multi-center trial; use of WA 2.2X and 2.7X	To evaluate the safety & effectiveness of the intraocular telescope	28	217 enrolled 206 implanted
Protocol IMT-002-LTM Long-Term Monitoring	100035025R Rev. 03 Summary of clinical study - LTM report (Attachment 13)	Prospective single-arm, open, multicenter trial, use of WA 2.2X and 2.7X	To conduct long-term safety monitoring of a cohort of patients enrolled in IMT-002	25	129 enrolled
Protocol the IMT-002-LTME (Long-Term Monitoring Extension)	IMT-002-LTME study report (Attachment 14)	Prospective, observational, cohort, open label, single group assignment safety study .use of WA 2.2X and 2.7X	Pivotal study of the intraocular telescope to 8 years post-surgery	19	Enrolled 51

IMT-002 Pivotal Study and IMT-002-LTM Long-Term Monitoring Study

The objective of the 2-year, prospective, 28-center IMT-002 pivotal study (n=217) was to evaluate the safety and effectiveness of the intraocular telescope (either 2.2X or 2.7X model were used) for the improvement of VA and vision-related quality of life in patients with bilateral moderate to profound central vision impairment due to untreatable, end-stage AMD.

The study population was 55 years or older, with BCDVA no better than 20/80 (0.6 LogMAR), ECD at least 1,600 cell/mm^2 and ACD ≥2.5mm. Patients with guttata were not excluded. Fellow eyes were not implanted to provide peripheral vision and served as controls.

The IMT-002 protocol was submitted to the FDA on 12 July 2002. The first patient had surgery on 20 December 2002 and the last on 17 November 2003. The database for the study was locked on July 18, 2005 for the purpose of data analysis and preparation of the clinical study report. At the time of database lock, 194 eyes had reached the 12-month follow-up, 180 eyes had reached the 18-month follow-up examination and 148 eyes had reached the 24-month follow-up. The timing of this analysis was related to submission of PMA to the FDA. The timing of the PMA submission was discussed with the FDA to determine whether the PMA for the IMT could be submitted with complete 18-month data and at least 50% of the 24-month data. Based on statistical modelling (generalized estimating equation and regression methods), a determination was made by FDA that the PMA could be submitted at this time. This was particularly important given the age of the study population and the associated increasing numbers of hospitalizations and deaths that have occurred during the second year of patient follow-up.

Patient disposition: Of 218 patients enrolled at 28 clinical sites in the IMT-002 study, 207 patients were eligible to participate in the study, but one patient withdrew prior to surgery; therefore 206 patients (eyes) underwent surgery for WA IMT implantation. Of these 206 subjects, 108 (52.4%) were male and 98 (47.6%) were female. The mean age was 75.4 years (S.D. 7.2, range 55 – 93 years). Of the 206 implanted eyes, 115 eyes were implanted with the WA 2.2X IMT and 91 eyes were implanted with the WA 2.7X. In five patients surgery was aborted due to choroidal detachment (2 patients) and posterior capsular rupture (3 patients). Six patients had to undergo intraoperative IMT explantation due to posterior capsular rupture (4 patients), choroidal hemorrhage (one patient) and zonular dehiscence (one patient). A standard IOL was placed in these eyes.

Of the patients enrolled in the IMT-002 study, a cohort of 129 patients (63% of patients enrolled in the IMT-002 study) enrolled in the IMT-002-LTM study, which was designed to assess the long-term safety of the IMT. These patients were included in an additional 36-month follow-up, summing up to a total of 60 months' follow-up. At the 60-month visit 84 patients (65%) were examined. At this point 12 patients had died; 24 were lost to follow-up or discontinued and 9 patients did not attend the scheduled 60-month visit.

Efficacy: By 3 and 6 months postoperative, nearly 90% of all study eyes had gained at least 1 line of BCDVA, over 75% had gained 2 or more lines, and approximately 60% of eyes had gained 3 or more

lines of BCDVA. At the 9-months follow-up this trend continued with 46/56 (82.1%) of eyes gaining at least 2 lines in BCDVA and 40/56 (71.4%) eyes with a gain of at least 3 lines in BCDVA at 6 months. Visual outcomes were generally better in eyes implanted with the WA 2.7X than in eyes with the WA 2.2X, however, the improvements in BCDVA for the WA 2.2X were well within the efficacy target established in the study protocol.

Similar gains in best corrected visual acuity were observed for measurements made at near. A gain of > 2 lines in BCNVA at 8 inches was reported for almost 63% of all implanted eyes at 3 months and this proportion increased to 67% at 6 months and more than 69% at 9 months; the proportions for WA 2.2X implanted eyes and for WA 3X implanted eyes at 3 and 6 months were similar.

Improvement of 2 or more lines of BCNVA measured at 16 inches was observed in approximately 63% of implanted eyes at 3 months, in 68% at 6 months and in 75% at 9 months. Furthermore, a substantial proportion of eyes gained > 3 lines in BCDVA as well as a gain of > 3 lines BCNVA at 8 inches *or* 16 inches, respectively: 44.6% at 3-months to 50.8% at 6-months, and 55.4% at 9-months. Visual outcomes regarding BCNVA at 16 inches were better in eyes implanted with the WA 3X than in eyes with the WA 2.2X.

The proportion of eyes assessed at 9 months with a > 2 line improvement in visual acuity (either distance or near) was 94.6% (53/56). Of the 3 eyes without at least 2 lines improvement in either BCNVA at 8 inches or 16 inches, or BCDVA, one eye had a 1.6 line improvement in BCDVA and one eye had a 1.4 line improvement in BCDVA at 9 months. The third eye also lost more than 2 lines in BCDVA.

At 12 months, 90% of telescope-implanted eyes achieved at least a 2-line or greater gain in either distance or near BCDVA, exceeding the 50% criterion specified for the primary endpoint. This improvement was maintained at 24 months.

These findings exceeded the primary effectiveness outcome defined in the protocol, which specified that the IMT procedure is to be considered successful if more than 50% of the implanted eyes have an improvement of 2 lines or greater in either near or distance acuity at 12 months follow-up post-IMT implantation.

The change in BCDVA from baseline is shown in **Table 4**. At 12 months, 66.3% of patients had a gain of ≥3 lines of BCDVA, and 45.1% had a gain of ≥4 lines. At 60 months, 61.8% of patients had a gain of ≥2 lines of BCDVA, and 47.4% had a gain of ≥3 lines.

Comparison of the implanted eye with the fellow eye (which served as control) at the 12-month follow up showed that 67% of implanted eyes achieved a 3-line or more improvement in BCDVA versus 13% of fellow eyes; 53% of implanted eyes achieved a 3-line or more improvement in both BCDVA and BCNVA versus 10% of fellow eyes. Furthermore, mean BCDVA and mean BCNVA improved by 3.5 lines

and 3.2 lines, respectively, in the implanted eyes versus 0.8 lines and 1.8 lines, respectively, in the fellow eyes. The change in visual acuity was not related to lesion type.

Table 4: IMT-002 and IMT-002-LTM studies: BCDVA change from baseline and mean change in all IMT-implanted eyes

Time from implantation (months)	**1**	**3**	**6**	**9**	**12**	**24**	**36**	**48**	**60**
	N=203	**N=201**	**N=130**	**N=193**	**N=56**	**N=173**	**N=74**	**N=96**	**N=76**
BCDVA change from baseline	**n (%)**	**n (%)**	**n (%)**	**n (%)**	**n (%)**	**n (%)**	**n (%)**	**n (%)**	**n (%)**
Gain ≥ 6 lines	-	-	-	-	21 (10.9%)	16 (9.2%)	2 (2.7%)	7 (7.3%)	5 (6.6%)
Gain ≥ 5 lines	-	-	-	-	49 (25.4%)	33 (19.1%)	11 (14.9%)	9 (9.4%)	9 (11.8%)
Gain ≥ 4 lines	-	-	-	-	87 (45.1%)	74 (42.8%)	26 (35.1%)	27 (28.1%)	21 (27.6%)
Gain ≥ 3 lines	78 (38.3%)	118 (58.7%)	81 (62.3%)	40 (71.4%)	128 (66.3%)	103 (59.5%)	39 (52.7%)	46 (47.9%)	36 (47.4%)
Gain ≥ 2 lines	48 (23.6%)	33 (16.4%)	18 (13.8%)	6 (10.7%)	155 (80.3%)	129 (74.6%)	51 (68.9%)	65 (67.7%)	47 (61.8%)
Gain ≥ 1 line	30 (14.8%)	27 (13.4%)	17 (13.1%)	5 (8.9%)	170 (88.1%)	146 (84.4%)	63 (85.1%)	75 (78.1%)	56 (73.7%)
No change	26 (12.8%)	18 (9.0%)	10 (7.7%)	4 (7.1%)	19 (9.8%)	24 (13.9%)	9 (12.2%)	17 (17.7%)	16 (21.1%)
Lost ≥1 line but <2 lines	13 (6.4%)	2 (1.0%)	2 (1.5%)	0	-	-	-	-	-
Lost 2 lines	2 (1.0%)	1 (0.5%)	0	0	-	-	-	-	-
Loss > 2 lines	2 (1.0%)	0	0	0	4 (2.1%)	3 (1.7%)	2 (2.7%)	4 (4.2%)	4 (5.3%)
Loss > 3 lines	4 (2.0%)	2 (1.0%)	2 (1.5%)	1 (1.8%)	3 (1.6%)	1 (0.6%)	2 (2.7%)	4 (4.2%)	3 (3.9%)
Loss > 4 lines	-	-	-	-	2 (1.0%)	1 (0.6%)	1 (1.4%)	4 (4.2%)	2 (2.6%)
Loss > 5 lines	-	-	-	-	2 (1.0%)	1 (0.6%)	0 (0.0%)	2 (2.1%)	0 (0.0%)
Loss > 6 lines	-	-	-	-	1 (0.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Mean Change (SD)					3.43 lines (SD 2.31)	3.15 lines (SD 2.19)	2.74 lines (SD 2.17)	2.48 lines (SD 2.60)	2.41 lines

N = number of non-missing BCDVA change from baseline, SD = standard deviation

Mean BCDVA improved from 20/312 at baseline to 20/141 at 12 months and to 20/149 at 24 months. Mean BCNVA at 8 inches improved from 20/315 at baseline to 20/181 at 12 months and to 20/190 at 24 months. Mean BCNVA at 16 inches improved from 20/262 at baseline to 20/149 at 12 months and to 20/157 at 24 months. Long-term follow-up data demonstrated that mean BCDVA improvements were generally retained over time in IMT-implanted eyes. There was a slight decline in BCDVA at 48 months (Table 5).

Table 5: IMT-002 and IMT-002-LTM studies: BCDVA in IMT-implanted eyes during the study

	Baseline		12 months		24 months		36 months		48 months		60 months	
	N	Mean (95% CI)	N	Mean (95% CI)	N	Mean (95% CI)	N	Mean (95% CI)	N	Mean (95% CI)	N	Mean (95% CI)
BCDVA	206	**20/312** (20/334, 20/291)	193	**20/141** (20/152, 20/131)	173	**20/149** (20/161, 20/138)	**74**	**20/156** (20/175, 20/139)	**96**	**20/171** (20/191, 20/152)	**76**	**20/169** (20/193, 20/148)
BCNVA at 8"	206	**20/315** (20/341, 20/291)	192	**20/181** (20/196, 20/167)	173	**20/190** (20/207, 20/174)						
BCNVA at 16"	206	**20/262** (20/282, 20/244)	192	**20/149** (20/161, 20/138)	173	**20/157** (20/170, 20/145)						

BCDVA = best-corrected distance visual acuity, BCNVA = best-corrected distance visual acuity; CI = confidence interval.

Fellow eyes were not implanted to provide peripheral vision and served as controls.

Quality of life: Quality of life, a secondary outcome measure, was assessed by the National Eye Institute's Visual Function Questionnaire-25 (VFQ-25). A 5 point difference in subscale and/or composite scores is considered clinically significant. Implantation with the IMT improved quality of life in the study population. The percentage improvement in ADL score was 66.5% (S.D. 107.7%) at 3 months, 65.4% (S.D. 98.3%) at 6 months, and 66.0% (S.D. 131.9%) at 9 months. The percentage improvement in overall VFQ score was 26.7% (S.D. 44.6%) at the 3-month visit, 28.1% (S.D. 50.9%) at the 6-month visit, and 25.0% (S.D. 47.5%) at the 9 months visit.

At 12 months, the mean VFQ-25 composite score increased by 6 points. Overall, seven of the VFQ-25 subscales improved by clinically significant levels (general vision, near activities, distance activities, social functioning, mental health, role difficulties, and dependency). In subscales where no improvement or a decline in performance was expected (color vision, driving, and peripheral vision), performance was stable or declined. Also, the mean score of the general health subscale declined by 5 points, likely reflecting the impact of other health-related events on the non-vision related general health of the elderly study population.

Safety: Preservation of visual acuity was to be assessed in terms of whether not more than 10% of telescope-implanted eyes lost >2 lines of either BCDVA or BCNVA without a corresponding improvement in the other. Loss of lines of best corrected acuity, both distance and near, was very limited in the study cohort. This target has been achieved. A total of 8 eyes lost more than 2 lines in BCDVA, and the majority (7 of the 8 eyes) occurred in WA 2.2X implanted eyes. The majority of these eyes (6/8 or 75%) had only a transient loss of more than 2 lines in BCDVA and regained BCDVA at subsequent visits., since only one eye (0.8%) lost > 2 lines in BCDVA and in BCNVA at 8 inches, and one eye (0.8%) lost > 2 lines in BCDVA and BCNVA at 16 inches at 6 months. Similar to the 6-months results, only one eye lost >2 lines in BCDVA and BCNVA at 8 inches, and one eye lost >2 lines in BCDVA and BCNVA at 16 inches at 9 months. At 12 months, only 2.1% of eyes incurred such losses, and at 60 months, only 5.3% of eyes incurred such losses.

ECD was stratified by several parameters: ACD, incision type, severity of acute corneal edema, increasing surgeon experience. The endpoint for ECD loss in the IMT-002 study was specified to not exceed 17% one year after implantation. ECD decreased by 20% at 3 months and by 25% at 1 year, exceeding the 17% target. The most significant loss of corneal endothelial cells occurred from baseline to 3 months and from baseline to 6 months. The decrease in ECD was correlated with postsurgical edema, and there was no evidence that endothelial cell loss is accelerated by ongoing endothelial trauma after implantation. From 6 and 12 months through 48 months, the observed annual rate of endothelial cell loss in the study population was approximately 3%. Therefore, a systemic decline of ECD loss from baseline to all study examination points can be observed throughout the study.

Complications and adverse events (AEs): Ocular complications were defined as events directly related to the surgical procedure for telescope implantation, whether successful or not, occurring in the operative and immediate postoperative period. Events occurring after the immediate postoperative period were classified as AEs. The incidence of complications and ocular adverse events reported in more than 4% of the study population in the IMT-002 study is shown in Table 6 and

Table 7, respectively.

The most common complication was increased IOP requiring treatment ≤7 days (27.7% of patients) and the most common AE was inflammatory deposits on IMT (26.6%) The majority of AEs and nearly all complications were reported early in the postoperative period. Analysis of AEs and complications by time after the implantation has indicated a low frequency of AEs at 6- and 9-months post WA IMT implantation. With the exception of foreign body sensation inflammatory deposits and pigment deposits on WA IMT (overall incidence, 1.9%, 3.9% and 4.4%, respectively), the incidence of other AEs at 6 and 9 months was low, suggesting that most AEs resolved over time.

Table 6: **IMT-002 and IMT-002-LTM studies: ocular complications in ≥3% of patients**

	Operated Eyes (N=217)	
Events	**n**	**(%)**
Increased IOP requiring treatment ≤7 days	57	(27.7%)
Corneal edema ≤30 days	14	(6.8%)
Corneal abrasion	11	(5.3%)
Iris prolapse	12	(5.5%)
Posterior capsular rupture	10	(4.6%)
Hyphema	9	(4.4%)
Iris damage	9	(4.1%)
Iris transillumination ≤21 days after surgery	8	(3.7%)
Vitreous loss – vitrectomy required	7	(3.2%)
% = n/N ×100		

Table 7: **IMT-002 and IMT-002-LTM studies: ocular adverse events in ≥3% of patients**

	Operated Eyes (N=217)	
Adverse Events	**n**	**%**
Inflammatory deposits on IMT	26	(12.6%)
Decrease in BCDVA	15	(6.9%)
Corneal edema >30 days after surgery *	14	(6.5%)
Iritis >30 days after surgery	12	(5.5%)
Telescope removal	12	(5.5%)
Posterior synechiae	11	(5.3%)
Persistent unresolved corneal edema (subset of corneal edema) >30 days after surgery	10	(4.6%)
Iris transillumination defects	10	(4.9%)
Iris atrophy >7 days after surgery	9	(4.1%)
Pigment deposits on IMT	9	(4.1%)
Guttata	8	(3.6%)
Persistent vision-impairing corneal edema (subset of persistent unresolved corneal edema)	8	(3.6%)
% = n/N ×100		

The cumulative probability of developing irreversible vision-impairing corneal edema in the telescope implanted eye over 5 years was 6.9%. For corneal transplant, a subset of vision-impairing corneal edema, the cumulative probability of corneal edema leading to corneal transplant over 5 years was 4.1%.

Five study eyes underwent corneal transplantation in the IMT-002 and IMT-002-LTM studies. All 5 cases involved surgical complications at the time of intraocular telescope implantation. In 2 of the 5 cases, the telescope was removed during the corneal transplantation procedure and replaced with an IOL. Visual acuity returned to baseline levels in these 2 patients. The telescope was left in place in the other 3 cases of corneal transplantation.

Four device failures were reported in the IMT-002 study. Two of the telescope failures occurred during surgery and involved a broken haptic; one occurred before implantation and the device was not used, and one occurred during implantation, necessitating intraoperative replacement. The other 2 telescope failures involved condensation in the telescope portion of the device resulting from trauma to the devices at or before device implant and occurring one month postoperatively, resulting in device removal.

No further device failures were reported over the course of follow-up through 5 years. Postoperatively, the intraocular telescope was removed from 12 eyes. Eight patients requested removal of the telescope because they were dissatisfied with the device. As noted above, the telescope was also removed from 2 eyes due to device failures and in 2 eyes that underwent corneal transplantation.

Seven secondary surgical interventions not involving telescope removal were performed during the clinical studies. These procedures consisted of one YAG laser treatment of the anterior surface of the telescope to eliminate pigment deposits, 4 YAG laser peripheral iridotomies, one surgical repair of a distorted pupil; and 1 removal of a cortical fragment resulting from inadequate cataract removal.

In summary: the proportion of eyes experiencing a gain of 2 or more lines of best corrected visual acuity, at both distance or near, exceeded the study protocol target for effectiveness. The incidence of AEs was relatively low and preservation of best corrected visual acuity was well established in the study cohort.

IMT-002-LTME Study

The purpose of the IMT-002-LTME study (IMT-002-LTME Study Report, Attachment 18) was to provide additional long-term safety information for patients who participated in the IMT-002 and IMT-002-LTM studies. Patients who enrolled in the IMT-002 trial, including those who enrolled in the IMT-002-LTM trial, whether the telescope was successfully implanted or not, were contacted and invited to participate in this LTME study. The LTME study objective was to calculate the incidence of

ocular adverse events associated with IMT implant surgery to 8 years post-surgery. Pre-specified events of interest were vision-impairing corneal edema (corneal edema leading to persistent loss of BCDVA >2 lines from pre-surgery baseline level), corneal transplantation, retinal detachment, device explant, and device malfunction.

Patient disposition: A total of 51 subjects were enrolled in the LTME study: 49 of them were implanted with the intraocular telescope, while 2 enrolled subjects had surgical complications and were not implanted with the intraocular telescope. Three patients withdrew from the study before the 96-month visit (one patient died, one patient had a stroke, and one patient experienced a non-ocular adverse event); therefore 46 subjects completed the 96-month visit.

Note: The information about the distribution of patients in the context of size magnification (i.e. how many participants were implanted with the WA 2.2x device and how many with the 2.7x device) was not required at the time for LTM and LTME studies and therefore no such data are available.

Performance outcomes: Eight years after IMT implantation, 22/46 patients (47.8%) participating in the study had clinically significant ≥2-line improvement in BCDVA, 17/46 (37.0%) had ≥3-line improvement in BCDVA and 9/46 (19.6%) had ≥4-line improvement (Table 8).

Table 8: IMT-002-LTME study: BCDVA change from baseline in IMT-implanted eyes

	Baseline N=49 n (%)	LTME Enrollment N=11 n (%)	84 Months N=6 n (%)	96 Months N=46 n (%)
IMT-Implanted eyes				
Gain ≥ 5 lines	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (4.3%)
Gain ≥ 4 lines	0 (0.0%)	0 (0.0%)	0 (0.0%)	9 (19.6%)
Gain ≥ 3 lines	0 (0.0%)	2 (18.2%)	0 (0.0%)	17 (37.0%)
Gain ≥ 2 lines	0 (0.0%)	4 (36.4%)	0 (0.0%)	22 (47.8%)
Gain ≥ 1 line	0 (0.0%)	5 (45.5%)	3 (50.0%)	28 (60.9%)
No change	49 (100.0%)	5 (45.5%)	1 (16.7%)	12 (26.1%)
Loss of >2 lines	0 (0.0%)	1 (9.1%)	2 (33.3%)	6 (13.0%)
Fellow eyes				
N	49	11	6	46
Gain ≥ 5 lines	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Gain ≥ 4 lines	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (4.3%)
Gain ≥ 3 lines	0 (0.0%)	2 (18.2%)	0 (0.0%)	3 (6.5%)
Gain ≥ 2 lines	0 (0.0%)	2 (18.2%)	1 (16.7%)	5 (10.9%)
Gain ≥ 1 line	0 (0.0%)	3 (27.3%)	2 (33.3%)	16 (34.8%)
No change	49 (100.0%)	6 (54.5%)	3 (50.0%)	17 (37.0%)
Loss of >2 lines	0 (0.0%)	2 (18.2%)	1 (16.7%)	13 (28.3%)

N = number of non-missing BCDVA change from baseline regardless of postoperative telescope removal for the telescope-implanted eyes.

Source: IMT-002-LTME study report

Safety outcomes: No new cases of persistent vision-impairing corneal edema, corneal transplantation, retinal detachment, device explant or device malfunction were reported during the LTME study. During the study one patient died, one patient had a stroke, and one patient experienced a non-ocular adverse event (fungus). None of these events were related to the device.

Seven cases (14% of LTME participants) of BCDVA loss greater than 2 lines compared to the IMT-002 pre-surgery baseline. The decrease in BCDVA was reported as device related in 3 subjects (6%), unlikely to be related in 3 subjects (6%) and not related in 1 subject (2%). There were 14 reports (29%) of BCDVA loss >2 lines in non-implanted fellow eyes compared to IMT-002 baseline, twice the number and percent of telescope-implanted eyes. Other adverse events included ocular hypertension in one case (2.0%) and trauma to the eye in one case (2.2%).

Study conclusions: The results of the IMT-002-LTME confirmed that there are no specific clinical concerns or potential hazards that have newly emerged and need to be addressed. Therefore, residual risks and uncertainties regarding medium- and long-term performance were addressed and the safety and performance of the WA-IMT were confirmed.

1.5.2 Summary of clinical data from conducted investigations of the device

Table 9: Clinical data reported in the literature related to the NG SI IMT 3X

Ref.	Performance outcomes	Safety outcomes
(Savastano et al. 2024)	BCVA for distance and for near improved from baseline to 3 months follow up (23.91 ± 9.418 ETDRS letters and 59.09 ± 11.58 ETDRS letters respectively ($p < 0.001$).	Only two late complications occurred during the follow-up period and they were briefly and successfully resolved. One patient developed an episode of anterior uveitis solved by topical corticosteroid therapy at three weeks follow up and one patient developed an acute angle closure with pupillary block solved performing a Nd:YAG laser iridotomy. The rate of cell density reduction was around 8.3% (baseline versus 3 months).
(Toro et al. 2023)	At 3 months, mean CDVA and CDNVA improved by +14.9±7.1 letters and +7.7±3.2 Jaeger levels, respectively. 70.83% of patients gained ≥ 2 lines, 58.33% ≥ 3 lines and 25.00% ≥ 4 lines of CDVA.	The most common complication was corneal edema within 30 days after surgery. Other complications such as iris incarceration, atrophy, damage and prolapse were relatively uncommon. SING IMT™ delivers lower ECD loss than the first-generation IMT.
(Mastropasqua et al. 2024)	At final follow-up, in the study eyes, mean BCDVA improved by + 10.0 letters (6.25; 13.8) letters and mean BCNVA improved by −0.30 logMAR (−0.55; − 0.20). Compared to	No intraoperative complications have been reported. In post-operative time, common reported adverse events were corneal edema, which occurred in 2 patients, but persisted beyond 1 month after surgery in only one, despite topical steroid therapy. One patient reported postoperative

		the baseline, ECD loss at 6 months follow-up was 12.6 %.	diplopia. 3 patients required YAG laser iridotomy treatment for postoperative IOP management and 2 of them underwent prolonged topical glaucoma therapy. Finally, one patient was scheduled for surgical removal of the IMT™, due to poor IOP control consequent to the formation of irido-device synechiae for 360°.
	(Savastano et al. 2024)	Postoperative outcomes demonstrated improvements in visual acuity for most patients with an average gain in CDVA and CNVA of 16,8 ± 10,2 and 13,8 ± 7,4 ETDRS letters, respectively.	Only a few complications have been observed. In one case, the device dislocated into the vitreous chamber. This was resolved through vitrectomy and scleral fixation of the SING IMT using a Gore-Tex suture.
	(Sasso et al. 2024)	From baseline to the last follow-up visit, 82% of patients (n = 9) achieved an improvement of ten letters, 54.5% (n = 6) an improvement of 15 letters, and one patient an improvement of 25 letters. At 24 weeks after SING IMT implantation, mean BCDVA was 28.5 ± 7.4 letter score which was significantly higher than baseline BCDVA ($p < 0.0001$). Moreover, BCDVA was found to be significantly improved between the first and the last rehabilitation sessions ($p = 0.0125$).	NR
	(Landini et al. 2024)	All four treated patients showed an increase in both BCDVA and BCNVA at the 6-month follow-up.	No intraoperative, aborted surgeries or postoperative complications were observed in any patient, and none required IOP-lowering medications post-surgery.
	(Toro et al. 2025)	At 6 months post-surgery, the mean ± standard deviation (SD) change in BCDVA from baseline was − 0.29 ± 0.142, and at least 1-, 2-, and 3-line gains in BCDVA were achieved in 97.1 %, 68.6 % and 51.4 %, of operated eyes, respectively. The percentage of patients able to read at near distance increased from 28.6 % at baseline to 97.1 % at 6 months post-surgery with	The most frequent adverse event was corneal edema, and all cases were resolved with topical medications.

	a mean improvement of −0.57 ± 0.206. The mean (SD) change from baseline in ECD at 6 months in operated eyes was − 280.7 (315.9) cells/mm^2 (− 11.4 %).	
(Adamo et al. 2025)	After surgery, CDVA significantly improved (from 17.00 ± 9.74 to 26.00 ± 8.53) letters (P = 0.008). Significant improvement of CNVA was also observed (from 12.27 ± 4.36 to 8 ± 2.61 Jaeger levels; P = 0.004). Mean ECL was 4.8 ± 5.5% at 3 months.	No intraoperative complications were observed, while postoperative complications included iris incarceration (9.1%), pigment deposition on the device (9.1%), and transient corneal oedema (27.3%). Nevertheless, 10 of 11 patients (90.9%) began to complain of blurred or hazy vision within 3 months of surgery. The device was ultimately explanted in 3 patients (27.3%) because of this symptom.

1.5.3 Overall summary of the clinical performance and safety

Safety and performance of the NG SI IMT 3X as well as the previous models considered as equivalent devices (NG IMT, WA-DE 3X, WA 3X and WA 2.2X models) have been evaluated in several trials. Best-corrected distance visual acuity (BCDVA) has been systematically assessed in all conducted trials and distance-corrected near visual distance (DCNVA) in some of these trials. These outcomes were measured to assess the performance of the device to improve visual acuities at different follow-up timepoints following the device implantation. The rate of adverse events including endothelial cell loss (ECL) was also assessed to determine the safety profile. All these data allowed us to determine the benefit/risk ratio.

In all conducted studies, the implantation of the device (both NG SI IMT 3X and previous models) resulted in significant BCDVA and BCNVA improvement and of at least 2 lines for most of the patients and for up to 60 months.

For the previous model IMT, complications reported in the studies included anterior chamber cells, fibrin, conjunctival injection, iritis, anterior uveitis, transient elevated IOP, corneal edema, distorted pupil, inflammatory deposits and posterior synechiae, inflammatory and pigment deposits on device and guttae. Some of these complications were present up to 6 months after device implantation. Moreover, an ECL of 2.4% to 40% were reported according to the study and the follow-up time.

The rates of adverse events and especially the high ECL reported in the studies led to the development of the last model NG SI IMT 3X, SING IMT™ which has the same magnification, optics diameter, and axial height; however, unlike its predecessor, it has a smaller overall diameter, requires fewer sutures, and has greater postoperative corneal clearance.

Safety outcomes for NG SI IMT 3X showed a significant reduction in surgical trauma and induced astigmatism, which permits more rapid initiation of rehabilitation and a significant reduction in ECL (~7%) compared to IMT model.
The results of a user survey revealed that most patients implanted with NG SI IMT 3X were satisfied with their vision at 4 weeks follow-up and with the rehabilitation program, and most patients met their expectations in terms of visual acuity. Users highlighted that patient selection is key to promoting post-operative satisfaction outcomes. Overall, this survey confirmed that the NG SI IMT 3X allows patients with late AMD to regain visual acuity and reading ability.

Overall, sufficient clinical evidence is available to demonstrate clinical safety and performance according to the MDR GSPR1, 6.

1.5.4 Ongoing or planned post-market clinical follow-up

According to the requirements of post-market data collection under MDR9, the manufacturer has put in place the following clinical activities:

1. **Screening of scientific literature and other sources of clinical data**
2. **Post-market clinical study**
   The study is an interventional, prospective, multicenter, open label, single group assignment post-market clinical follow-up study. The study is ongoing at 13 clinical sites across Europe. The primary objective of the study is to demonstrate the safety of the SING IMTTM System, model NG SI IMT 3X, including its delivery system, when used as intended for the improvement of visual acuity in patients with central vision impairment associated with AMD.
3. **Collection of information from various safety databases**
4. **Collection of information from ophthalmological congresses**
5. **Collection of publicly available information regarding similar devices**
6. **Collection of clinical evidence from Investigator Initiated Research outcomes**
7. **Survey from users, patients and distributors**
8. **Collection of information from medical experts**

Table 10 Overview of Samsara Vision sponsored research studies

Device name	Type of activity	Description of activity	No of eyes	Target population/ medical condition	Aim of activity	Rationale and appropriateness of the chosen method	Rationale of methods appropriateness	Status, timelines of the activity
SING IMT™	Case report	Dr. Nicole Eter (Germany). A case report to describe the surgical technique for scleral fixation of the SING-IMT.	1	Patient with with bilateral geographic atrophy and bilateral cataract	Scleral fixation of the SING IMT			Published
SING IMT™	Case report	Dr. Alfonso Savastano (Italy). A case report to describe a surgical technique for scleral fixation of the SING-IMT.	1	Patient with SING IMT dislocation	Scleral fixation of the SING IMT	Scleral fixation of SING-IMT haptics might be useful in eyes with dislocated or not stable SING IMT. The Gore-Tex suture could assure firm fixation of the SING IMT and could reduce the risk of recurrent dislocations.		Published
SING IMT™	Case report	Dr. Kirk A J Stephenson (Ireland). Retinal examination and imaging through the IMT.	1	Patient with moderate lens opacity and end-stage dry AMD	To evaluate the visual outcomes and safety of the SING IMT™ telescope. Follow-up at 6 and 24 months.	Clinical examination and imaging of the macula are possible through the IMT, enabling monitoring for progression and treatment of reactivated neovascular AMD.		Published
SING IMT™	Case report	Dr. Alfonso Savastano (Italy). SING IMT in pseudophakic eyes: Results of the first experiences	5	Pseudophakic patients with stable dry AMD	To evaluate the feasibility and outcomes of implanting the SING IMT in pseudophakic patients affected by late-stage dry AMD.	Surgical procedures were performed with careful IOL removal and SING IMT implantation. Postoperative follow-up was conducted regularly to monitor visual acuity, device positioning and complications.	In accordance with the Declaration of Helsinki and approved from the Ethics Committee of Catholic University.	Published
SING IMT™	Case report	Dr. Alfonso Savastano (Italy). SING-IMT Removal for Unsatisfied Patients: Step-by-Step Surgery for a Safe Explant.	3	Patients with stable dry AMD previously implanted with SING-IMT who failed to adapt to the device and request its explantation.	To report three cases of SING-IMG explantation and three-piece acrylic intraocular lens (IOL) implantation in patients affected by late-stage dry AMD.	Surgical procedures were performed with careful removal of the SING IMT and implantation of a three-piece acrylic IOL. Patients were followed postoperatively for at least 6 months, with particular attention to IOL stability and posterior capsule integrity.	In accordance with the Declaration of Helsinki and approved from the Ethics Committee of Catholic University.	Published
SING IMT™	Retrospective cohort study	Dr. Luca Landini (Italy). Multifocal Electroretinography changes in patients with late-stage AMD after SING IMT.	4	Phakic patients with late-stage AMD	To report changes in multifocal electroretinography (mfERG) 6 months post–SING IMT implantation.	Retrospective study evaluating a cohort of phakic patients with late-stage AMD who underwent SING IMT implantation and describing mfERG changes following SING IMT implantation.	In accordance with Good Clinical Practice (GCP), the principles of the Declaration of Helsinki, the institutional standards and international guidelines for ethical research practices. The study was notified to the Ethics Committee.	Published
SING IMT™	Retrospective cohort study	Dr. Mario Damiano Toro (Italy). To evaluate the intermediate-term visual and safety outcomes of the SING IMT in patients with late-stage AMD at 6 months post-surgery.	35	Patients with central vision impairment due to late-stage AMD	To evaluate the visual outcomes and safety of the SING IMT™ telescope. 6 months follow-up.	Retrospective study assessing the performance and safety outcomes after SING IMT implantation in two different centers in Italy.	In accordance with the Declaration of Helsinki and approved by the Ethics Committee of the University of Naples Federico II and the Policlinico Gemelli hospital (protocol n◦ EC-19/2022 & protocol n◦ 4634, respectively).	Published

Device name	Type of activity	Description of activity	No of eyes	Target population/ medical condition	Aim of activity	Rationale and appropriateness of the chosen method	Rationale of methods appropriateness	Status, timelines of the activity
SING IMT™	Retrospective interventional case series	Dr. Ginevra Giovanna Adamo (Italy). Anatomical and functional results of patients with late-stage AMD 6 months after SING IMT™ implantation.	11	Patients with bilateral advanced AMD	To evaluate anatomical and functional outcomes of the SING IMT™ in patients with bilateral advanced AMD.	Non-comparative retrospective single-surgeon interventional case series included patients with bilateral late-stage AMD who underwent cataract surgery and SING IMT™ implantation.	In accordance with the Declaration of Helsinki	Published
SING IMT™	Prospective case series study	Dr. Rodolfo Mastropasqua (Italy). To report the short-term (6 months) effects on visual functionality and safety of femto-laser assisted SING IMT™.	6	Patients with central vision impairment due to late-stage AMD	To evaluate the visual outcomes and safety of the SING IMT™ telescope. 6 months follow-up.	Prospective multicentric observational case series study to report the short-term (6 months) effects on visual functionality and safety of femto-laser assisted SING IMT™) implanting	Approved by the Institutional Review Board, following the principles of the Declaration of Helsinki	Published
SING IMT™	Post market clinical data collection	Dr. Mario Damiano Toro (Italy). Non-comparative retrospective study to evaluate the short-term (3 months) safety and efficacy of the device in patients with bilateral visual acuity loss due to disciform scars or geographic atrophy at baseline.	24	Patients with central vision impairment due to late-stage AMD	To evaluate the visual outcomes and safety of the SING IMT™ telescope. 3 months follow-up.	Collecting real world clinical evidence for the confirmation of product safety and performance	In accordance with Declaration of Helsinki and approved by the Ethics Committee of the University of Naples Federico II (n_ EC-19/2022), ISO 14155:2020	Published
SING IMT™	Post market clinical data collection	Dr. Alfonso Savastano (Italy). Retrospective study to report the 3 months follow up clinical outcomes of cataract surgery with SING IMT™ implantation followed by rehabilitation training in patients with central visual loss due to late-stage AMD.	11	Patients with central vision impairment due to late-stage AMD	To report the clinical outcomes of cataract surgery with SING IMT™ implantation followed by rehabilitation training. 3 months follow-up.	Collecting real world clinical evidence for the confirmation of product safety and performance	According to the guidelines of Declaration of Helsinki and approved by the Ethics Committee of Policlinico Gemelli hospital (approval code: 4634),ISO 14155:2020	Published
SING IMT™	Post market clinical data collection	Dr. Paola Sasso (Italy). Retrospective study to report the functional outcomes of cataract surgery with SING IMT™ implantation followed by rehabilitation training in patients with central visual loss due to late-stage AMD.	11	Patients with central vision impairment due to late-stage AMD	To report the functional outcomes of cataract surgery with SING IMT™ implantation followed by rehabilitation training. 6 months follow-up.	Collecting real world clinical evidence for the confirmation of product safety and performance	According to the guidelines of Declaration of Helsinki and approved by the Ethics Committee of Policlinico Gemelli hospital (approval code: 4634), ISO 14155:2020	Accepted to publish
SING IMT™	Prospective study	Prof. David Keegan (Ireland). Prospective study to demonstrate the safety and effectiveness of the SING IMT™ System, including its delivery system.	9	Patients with central vision impairment due to late-stage AMD	To evaluate the visual outcomes and safety of the SING IMT™ telescope.	Collecting real world clinical evidence for the confirmation of product safety and performance	According to the guidelines of Declaration of Helsinki and approved by the Ethics Committee Mater hospital ISO 14155:2020	Study completed and Manuscript in preparation
SING IMT™	Post market clinical data collection	Prof. Leonardo Mastropasqua (Italy). Retrospective study to report the 3 months follow up clinical outcomes of cataract surgery with SING IMT™ implantation usinf FACS technology.	10	Patients with central vision impairment due to late-stage AMD	To evaluate the visual outcomes and safety of the SING IMT™ telescope.	Collecting real world clinical evidence for the confirmation of product safety and performance	According to the guidelines of Declaration of Helsinki and approved by the Ethics Committee of University hospital of Chieti ISO 14155:2020	Study completed and Manuscript Submitted

Device name	Type of activity	Description of activity	No of eyes	Target population/ medical condition	Aim of activity	Rationale and appropriateness of the chosen method	Rationale of methods appropriateness	Status, timelines of the activity
SING IMT™	Post market clinical data collection	Dr. Salvatore Parrulli (Italy). OCT visualization after SING IMT device implantation	1	Patients with central vision impairment due to late-stage AMD	To evaluate the visual outcomes and safety of the SING IMT™ telescope.	Collecting real world clinical evidence for the confirmation of product safety and performance	ISO 14155:2020	Published
SING IMT™	Post market clinical data collection	Dr. Alfonso Savastano (Italy). Description of the surgical experience in managing a smaller incision, improving visual acuity and life quality of patients with late-stage AMD using SING IMT telescope implant.	3	Patients with central vision impairment due to late-stage AMD	To improve visual acuity and the quality of life for patients with late-stage AMD	Collecting real world clinical evidence for the confirmation of product safety and performance	In adherence with the tenets of the Declaration of Helsinki, ISO 14155:2020	Published
SING IMT™	Post market clinical data collection	Prof Marco Mura (Italy). Description of surgical experience in managing a smaller incision, improving visual acuity and life quality of patients with late-stage AMD using SING IMT telescope implant.	1	Patients with central vision impairment due to late-stage AMD	To improve visual acuity and the quality of life for patients with late-stage AMD	Collecting real world clinical evidence for the confirmation of product safety and performance in a scleral suture technique	In adherence with the tenets of the Declaration of Helsinki, ISO 14155:2020	Published
SING IMT™	Post market lab data collection	Dr. Irene Nepita (Italy) . Bench Study to anlazye the Optical-Quality Assessment of a Miniaturized Intraocular Telescope	0	No patients involved	To test optical characteristics of the device in different set ups.	Collecting bench data about the device performance	ISO 14155:2020	Published
SING IMT™	Post market lab data collection	Dr. Maximiliam Hammer (Germany) . Capsule Dynamics,Implantation, and Explantation of the SINGIMT: a Miyake–Apple Study	0	No patients involved	To test device behaviours in different potential surgical postion inside cadaver eyes.	Collecting bench data about the device performance	ISO 14155:2020	Published
SING IMT™	PMCF Prospective post-marketing study	10 sites in UK, ES, IT, DE, IRE, BE recruiting for Post-marketing clinical investigation of the SING IMT™ System, model NG SI IMT 3X	95	Patients with central vision impairment due to late-stage AMD	To evaluate the visual outcomes and safety of the SING IMT™ telescope.	Propsective post marketing study to collect evidence for product safety and performance	According to the guidelines of Declaration of Helsinki and approved by the Ethics Committee ISO 14155:2020	Study ongoing with 33 enrolled patients
SING IMT™	Post-approval study	An interventional, prospective, multicenter (4 active sites in the US: Dr. Shahzad Mian, Dr. Marc Levy, Dr. Michael Rauser and Dr. Victor H. Gonzalez), open label, single-group assignment, post-approval safety study of Samsara Vision, Inc's IMT in patients with bilateral severe to profound central vision impairment associated with end-stage AMD.	36	Patients with central vision impairment due to end-stage AMD	To improve visual acuity and the quality of life for patients with late-stage AMD	Collecting real world clinical evidence for the confirmation of product safety and performance	Approved by the FDA (PMA approval)	Study ongoing with 36 patients recruited

Clinicaltrials.gov registers have been used to monitor post-market studies on Samsara Vision products, and 9 clinical trials have been identified (Table 11). Two studies regarding the NG IMT device were withdrawn. There are two ongoing studies on the SING-IMT, one in the US and one in Europe, with a third starting in Europe in late 2025. These studies have, respectively, estimated completion dates of 2027, 2026 and 2028.

Table 11: Overview of ClinicalTrials.gov ongoing activities on Samsara Vision

ClinicalTrials.gov Identifier:	Title, aim	Location	Number of patients/eyes	Primary goals	Study Start Date	Estimated completion	Study status
NCT00976235	Five Year Follow up of IMT-002 Patients; A Long-Term Monitoring Study of IMT-002 Patients	28 study sites in US: Arizona, California, Colorado, Florida, Georgia, Illinois, Kentucky, Maryland, Massachusetts, Michigan, Minnesota, Missouri, New York, North Carolina, Ohio, Oklahoma, Oregon, Pennsylvania, Tennessee, Texas and Wisconsin	129 participants	Long term safety	June 2006	May 2011	Completed
NCT00555165	A Prospective Multicenter Clinical Study of the Implantable Miniature Telescope* in Patients with Central Vision Impairment Associated with AMD: IMT-UK Protocol (*IMT by Dr. Isaac Lipshitz)	4 study sites in UK: Frimley Park Hospital NHS Trust, Frimley, Surrey, UK Royal Hospitals, Belfast Health & Social Care Trust, Belfast, UK Moorfields Eye Hospital NHS Trust, London, UK King's College Hospital NHS Trust, London, UK	18 participants	BCVA	November 2007	May 2011	Completed
NCT01757132	Post-approval Study of VisionCare's Implantable Miniature Telescope (by Dr. Isaac Lipshitz) in Patients with Bilateral Severe to Profound Central Vision Impairment Assoc. with End-stage Age-related Macular Degeneration	17 study sites in US: Arizona, California, Colorado, Florida, Georgia, Michigan, Missouri, New York, Oregon and Texas	257 participants	Long term safety study of IMT	August 2010	June 2045	Enrolling
NCT01361256	Pilot Study of WA-NG Telescope Prosthesis in Patients with Central Vision Impairment Associated with	1 study site in Israel: Sheba Medical Center, Tel Hasomer, Israel	No participants	Safety study of WA-NG telescope	May 2011	May 2016	Withdrawn

	End-stage Age-related Macular Degeneration						
NCT01731964	Pilot Study of WA-NG Telescope Prosthesis in Patients with Central Vision Impairment Associated with End-stage Age-related Macular Degeneration	1 study site in Israel: Assaf Harofeh Medical Center, Zerifin, Israel	No participants	Safety study of WA-NG telescope	November 2012	December 2015	Withdrawn
NCT04468373	Study of the WA-NG (NG-IMT) Telescope Prosthesis in Patients with Central Vision Impairment Associated with End-Stage Age Related Macular Degeneration	2 study sites: Mater Private Hospital, Dublin, Ireland VISSUM Ophthalmological Corporation, Alicante, Spain	9 participants	Positional stability and adverse events	May 2015	July 2020	Terminated
NCT03011554	A Prospective, Multicenter Clinical Trial of the Implantable Miniature Telescope in Pseudophakic Eyes with Central Vision Impairment Associated with End-Stage Macular Degeneration.	14 study sites in US: Arizona, California, Florida, Michigan, Minnesota, Missouri, New Mexico, Tennessee and Texas	75 participants	Adverse events	March 22, 2017	December 31, 2022	Completed
NCT05438732	A Prospective, Multicenter Clinical Study of the Implantable Miniature Telescope, Model SING in Patients with Central Vision Impairment Associated with End-stage Age-related Macular Degeneration (AMD)	10 study sites in US: California, Florida, Massachusetts, New Jersey, North Carolina, Pennsylvania, Texas and Wisconsin	125 participants	Primary Effectiveness Outcome	June 16, 2022	June 2024	Recruiting
NCT04796545	A Prospective, Multicenter Post-marketing Clinical Investigation of the SING IMT™ System, Model NG SI IMT 3X in Patients with Central Vision Impairment Associated with End-stage Age-related Macular Degeneration	Seven sites in Ireland, UK, Germany, Spain and Italy	76 participants	Safety	May 2021	May 2025	Recruiting

1.6 Possible alternative treatments

The age-related changes that cause choroidal neovascularization (CNV) are not completely understood. Therapy for dry AMD has primarily focused on slowing or arresting vision impairment related to late AMD associated with CNV (Hooper et al. 2008).

Several therapies, including laser photocoagulation, photodynamic therapy, and intravitreal anti-vascular endothelial growth factor (anti-VEGF) injections (ranibizumab, becacizumab) are commercially available for the treatment of CNV. Ranibizumab has been shown to improve visual acuity by three lines in 30%–40% of patients with monthly dosing. Bevacizumab has been shown to be equivalent to ranibizumab with monthly dosing; however, despite treatment some patients still progress, especially those with geographic atrophy (Singer et al. 2011). Atorvastatin, lampalizumab and fenretinide were also suggested as potential treatments (Waugh et al. 2018). Currently, there are no commercially available therapies for geographic atrophy.

For dry AMD patients with bilateral moderate to profound vision impairment caused by central scotomas associated with end-stage AMD therapeutic options are very limited. Even low vision rehabilitation does not provide uniformly improved quality of life in this patient population (Hooper et al. 2008).

- Low-Vision Magnifiers

The main method for helping patients with end-stage AMD has been visual rehabilitation with low vision magnifiers such as hand/stand magnifiers, spectacles, handheld telescopes, closed circuit televisions, and high-plus spectacles in conjunction with high-minus contact lenses to create a telescopic effect. Although these tools may be effective for correcting overall visual functioning, they are cumbersome to use and cosmetically burdensome (Grzybowski et al. 2017).

- Implantable Magnifying Devices for AMD Treatment

A variety of implantable magnifying devices have been developed to improve visual acuity in patients with AMD by creating a magnified retinal image without the need for a hand-held magnifier. These include magnifying intraocular lenses (IOLs) and implantable miniature telescopes (IMTs). The method and amount of magnification and resultant visual field produced by these prosthetic devices varies considerably, but in general the magnified retinal image provides patients with improved visual acuity at the expense of some peripheral field loss and depth perception (Dunbar & Dhawahir-Scala 2018).

There are various types of implantable magnifying devices. These include Galilean-type telescopes, Cassegrain-type IOLs, and various single- or double-IOLs designed for near- or far-distance magnification according to their optical characteristics.

The Galilean-type telescope consists of two optical elements with high positive and negative power that are used in combination with the cornea. These include the IMT, the IOL-VIP System, and IOL-AMD. Other devices provide partial solutions, such as Scharioth Macula Lens (SML), that enable reading from a short distance, or prismatic lens that has effect of shifting the image to the PRL (Preferred Retinal Location).

The **IOL-AMD** technology (Sharpview Ophthalmology GmBH, Bamberg, Germany) (Table 12), includes two injectable, hydrophobic acrylic IOLs. In the iolAMD procedure, the IOLs are bilaterally implanted through a 3 mm incision. The IOLs work together like a Galilean telescope to magnify the image about 1.3 times (x1.3) and direct it to a healthier part of the retina.

Visual Acuity: Results from 18 eyes of 12 patients (Qureshi et al. 2015) indicated an improvement in mean decimal corrected distance visual acuity (CDVA) from 0.12 preoperatively to 0.20 at 4 months. The mean change in spherical equivalent was 1.5 diopters (D) with 0.5 D of induced astigmatism. Microperimetric testing in a subset of three patients indicated a magnification effect and a deviation of the retinal image by up to 5 degrees, with improved fixation stability (Qureshi et al. 2015).

Endothelial cell density: The mean endothelial cell density was reduced by 18% at 4 months (2119 ± 502 cells/mm^2 versus 1729 ± 508 cells/mm^2) (Qureshi et al. 2015)

Adverse events: IOP elevation and anterior vaulting of the IOL in the capsular bag in one patient, which resulted in a decrease in visual quality.

Complications: There were no significant intra- or postoperative complications (Qureshi et al. 2015).

Limitations: One of the limitations of this technology is the magnification which extends only to x1.3. Moreover, further progression of AMD may require additional surgery due to the associated change in PRL. The normal range of daily activities typically requires multiple PRLs, and limiting the PRL to one area could cause further visual dysfunction (Borkenstein, Borkenstein & Augustin 2023). In addition, this technology is limited to eyes with an axial length of 21 to 23 mm with a resulting power of 21 D because there are no power ranges available; therefore the IOL power cannot currently be adapted perfectly to patient anatomy (Dunbar & Dhawahir-Scala 2018, Grzybowski et al. 2017).

The **IOL-VIP System** (Soleko, Ponecorvo, Italy) (Table 12) is a dual IOL system which includes a biconcave high-minus-power IOL in the capsular bag and a biconvex high-plus-power IOL in the anterior chamber, creating, with the cornea, a Galilean telescope system that enlarges images 1.3 times (x1.3). Insertion of the IOL-VIP System is preceded by a standard phacoemulsification. In recent years the system has been changed (IOL-VIP Revolution) from the placement of two separate lenses to a singular combined lens system implanted in the capsular bag of one or both eyes. Two case studies (retrospective) appear to be available from 2007 (Orzalesi et al. 2007) and 2008 (Amselem et

al. 2008) with the original device and provides positive BCVA gains in a group of 40 eyes of 35 patients. It is unclear if CE mark was ever achieved using the system in Europe, and it does not appear to have US FDA commercial approval. In both case series, both eyes gained in mean visual acuity even if only one eye was implanted and it is unclear whether preoperative visual acuity was measured before or after preoperative PRL training and the effect of the preoperative training alone was not described. In one review of 40 eyes implanted (Orzalesi et al. 2007), endothelial cell density was evaluated in 38 of 40 patients at the end of a mean follow-up of 20 months (range, 7– 35). The patient with the lowest preoperative count (1783 cells/mm^2) showed a 10% loss (1603 cells/mm^2) 7 months after surgery, and the count in the case with the longest follow-up went from 2035 to 1896 cells/mm2 (–7%) after 35 months (Orzalesi et al. 2007). Results from the other study with 13 procedures/eyes in 10 patients show a mean endothelial cell loss of 11.1% from preoperatively to 12 months postoperatively and 5.2% from 12 to 18 months postoperatively (Amselem et al. 2008).

Adverse events: Transient elevations in intraocular pressure (IOP), corneal edema, ocular pain, posterior capsule opacification, pupillary block, and anterior capsule fibrosis.

Limitations: This technology has limitations that include the need for a large corneal incision for insertion (a capsulorrhexis with a diameter of at least 6 mm, with the enlargement of the temporal corneal incision up to 7 mm) due to the thickness of the IOLs. The large incision may result in induced astigmatism and challenges with wound healing in the postoperative period. Other potential risks for this system include a possible crowding effect with two lenses, particularly with one IOL in the anterior chamber that may increase the risk for glaucoma or angle closure, especially in patients with hyperopia. Furthermore, the magnification is limited to ×1.3, and long periods of pre- and postoperative adaptation are required for the IOL-VIP, which may not be acceptable for some patients (Borkenstein, Borkenstein & Augustin 2023).

The **Scharioth Macula Lens** (Medicontur, Törökbálint, Hungary) (Table 12) is a one-piece foldable intraocular hydrophilic acrylic lens with a central magnifying portion implanted in the ciliary sulcus of pseudophakic eyes, which improves near vision in patients with AMD. The overall diameter of the IOL is 13.0 mm with four symmetric haptics. It has a central portion of 1.5 mm diameter with an addition of +10.0 D and neutral remaining optical zone.

SML has numerous benefits including the improvement of near vision with reduced reading distance and maximum magnification, without affecting peripheral vision. It can be implanted simultaneously during uncomplicated standard phacoemulsification with in-the-bag posterior chamber IOL implantation or years after cataract surgery. Another feature of this device is the small incision required for implantation (2.2 mm).

Visual Acuity: Results from a prospective multicenter study (Srinivasan et al. 2019) that included 50 eyes of 50 pseudophakic patients with either dry or previously treated wet AMD that was stable for ≥ 6 months showed a mean CNVA improvement from 0.23 preoperatively to 0.57 at 1 year postoperatively. The mean preoperative CDVA was 0.19, which did not change postoperatively.

Complications: There were no intraoperative complications (Srinivasan et al. 2019).

Adverse events: One patient had the lens explanted 3 months postoperatively due to glare/halos.

Limitations: This lens is contraindicated in patients with other eye conditions including chronic uveitis, zonular weakness, secondary cataracts and central corneal opacities (Borkenstein, Borkenstein & Augustin 2023).

The Lipshitz Macular Implant (LMI) (Table 12) is based on a Cassegrain configuration, which uses mirrors instead of lenses. The overall diameter of the IOL is 13.0 mm, and the optic is 6.5 mm. The anterior central mirror is 1.4 mm. The posterior mirror, which is doughnut shaped and 2.8 mm in diameter, has a central clear area of 1.4 mm in diameter. The peripheral zone of the optic is similar to that of a normal IOL in order to provide undisturbed peripheral vision. The reflecting surfaces of the LMI are coated with multiple layers of titanium oxide and silicon dioxide (dielectric coatings), which creates a mirror effect. The mirrors are 1 to 2 mm thick. The entire IOL is coated with poly-para-xylylenes (Parylene C) to enhance biocompatibility.

The benefit of the LMI is that it provides 2.5 magnification, which means that the central image on the retina is magnified 2.5 times. The patient thus sees a magnified central image through the mirror telescope and a normal non-magnified image through the periphery of the IOL. This provides magnified central vision while maintaining spatial orientation due to normal peripheral vision (Agarwal et al. 2008).Visual Acuity: Results from 6 eyes of 6 patients (Agarwal et al. 2008) (4 with AMD and 1 each with myopic macular degeneration or macular dystrophy) indicated a mean gain in distance acuity of 3.66 lines and a mean increase in the Early Treatment Diabetic Retinopathy Study (ETDRS) score for near acuity of 50.83 logMAR. The best corrected distance acuity and near acuity improved significantly although a very small sample size for comparison (both P = 0.014) (Agarwal et al. 2008).

Endothelial cell density: The mean change in endothelial count in the operated eye was –5.79% ± –4.07% cells/mm^2 (Agarwal et al. 2008), which is comparable to values in other studies of phacoemulsification (Dick, Kohnen & Jacobi 1995, Walkow, Anders & Klebe 2000).

Complications: There were no intraoperative complications (Agarwal et al. 2008).

Adverse events: All patients implanted with this lens experienced glare postoperatively, and two patients complained of shadowing which resolved by 3 months (Borkenstein, Borkenstein & Augustin 2023).

Limitations: Although LMI can provide high magnification, its sophistication probably requires higher manufacturing costs, especially compared to a simple silicon or acrylic IOL. The use of small mirrors might generate the risk of glare effects, due to diffraction and ghost reflections. Another limitation of this IOL is that it requires large incisions (6.5 mm) (Grzybowski et al. 2017).

The **EyeMax Mono** (Sharpview Ophthalmology, Bamberg, Germany) (Table 12), is similar to a standard monofocal IOL. It may be implanted in one or both eyes, and surgeons can select a hypermetropic refractive target in severe AMD cases to generate 10% to 20% magnification with the aid of spectacle correction (Borkenstein & Borkenstein 2019).

Benefits: EyeMax Mono improves image quality across the entire macula, increasing the breadth of focus and reducing blur. The optics of this lens are optimized with the aim of providing improved image quality for an area extending about 10 degrees from the center of the fovea, where photoreceptor cell densities may still afford visual acuities of 6/30 Snellen or better. It permits patients with single or multiple PRLs to gain optimum benefit from the most functional areas of their macula and provides magnification from ×1.1 to ×1.2. The lens is also designed to minimize chromatic aberration, further optimizing image quality delivered to the macula.

Results from a consecutive case series of 244 eyes (Qureshi et al. 2018) with dry or stable wet AMD and logMAR visual acuity ≥ 0.3 indicated a mean CDVA (logMAR) improvement from 1.06 preoperatively to 0.71 postoperatively. Mean preoperative CNVA (logMAR) increased from 1.36 to 0.88.

Endothelial cell density: Mean of differences between preoperative and postoperative endothelial cell counts was -143 (95% confidence interval [CI] -219.1 to -66.24; $p<0.001$) (Qureshi et al. 2018).

Adverse events: One patient experienced an anterior capsular tear during surgery with implantation of the IOL in the capsular bag and no sequelae; 4 patients had intraoperative floppy iris syndrome managed successfully with intracameral phenylephrine; 3 patients required iris hooks for management of small pupils. One patient developed postoperative subretinal fluid at 1 month that resolved spontaneously; another patient required a YAG laser posterior capsulotomy at 10 months. Two subjects experienced steroid-induced ocular hypertension, with IOP of 30 mm Hg and 34 mm Hg, respectively, at 4 weeks postoperatively, that was controlled on topical ocular hypotensive treatment and resolved on cessation of topical steroid therapy (Qureshi et al. 2018).

Complications associated with the implantation of the EyeMax Mono included anterior capsular tear, postoperative subretinal fluid and elevated IOP (Borkenstein, Borkenstein & Augustin 2023).

1.6.1 Implantable Miniature Telescope (WA-IMT)

Samsara Vision's implantable miniature telescope (IMT) (Table 12) is a fixed-focus telescopic system comprising an ultraprecision quartz glass wide-angle micro-optics, creating a Galilean telescopic effect. The device produces a telephoto effect, in conjunction with the cornea, which enlarges the visual objects in a patient's central visual field. This design is intended to allow the individual to distinguish and discern more visual information in the central field for improved function. Because a 20°–24° forward field of view is projected onto approximately 55° of the retina, the peripheral field in the treated eye is reduced. The device is implanted in one eye only, leaving the fellow eye to compensate for peripheral vision.

The IMT optics and configuration are designed for a standard eye. Once implanted, the IMT together with the cornea, functions as a telephoto system, producing an image on the retina that is three times larger than the image normally projected by the cornea and crystalline lens. Postoperatively, standard prescription spectacle lenses are dispensed for distance and near vision, fine-tuning the focus of the enlarged retinal image. The optical design of the device provides a large depth of field, much larger than the normal eye with an intraocular lens. The optic is also made to produce an image on the spherical retina so that curvature of field is minimized. The IMT is designed for monocular use in patients with central field loss and intact peripheral vision. The implanted eye provides central vision, while the fellow eye provides peripheral vision for orientation and mobility tasks.

The primary performance advantage of the IMT telescope over alternative treatments for visual impairment is that the device allows scanning of reading materials and other images using natural eye movements, rather than head movements. Since there is no relative movement between the eye and the telescope, there are no optical aberrations and a wider visual field is achieved (nominal field of view of 20º projected onto approximately 54º on the retina).

IMT lenses can achieve higher magnification than the IOL-VIP System and IOL-AMD because the positive and negative lenses are embedded in air. This configuration increases the dioptric power in each of the lenses in an order of magnitude that cannot be achieved with lenses embedded in an aqueous medium. However, the IMT requires the implantation of a long tube through a larger corneal incision (Grzybowski et al. 2017).

A functional advantage of the IMT is avoidance of patient symptoms precipitated by vestibular ocular reflex conflict, which can occur with head-mounted image-enlargement devices.

The capability afforded by the device of scanning distant or near images using natural eye scanning movements, rather than head scanning movements, can provide comfortable, functional use in daily visual activities. Cosmetically, natural appearance is maintained.

The IMT is the only telescope system which has long-term clinical results and is approved for treatment of AMD in the USA as well as in the EU.

The National Institute for Clinical Excellence (NICE) in the UK published an Interventional Procedure Guidance for miniature lens system implantation for advanced age-related macular degeneration, which examined evidence from the IMT, IOL-VIP and the LMI and acknowledged that most evidence is based on the IMT device. The guidance noted that devices can improve visual acuity and quality of life in the short term (Srebniak et al. 2016). The report stressed the importance of assessing the patient's ability to cope with the change in visual status prior to surgery.

Samsara Vision's IMT models include the WA 2.2X, which enlarges images 2.2 times and the WA 2.7X, the WA 3X IMTs, the NG IMT and the NG SI IMT 3X, which enlarge images 2.7 times. The NG SI IMT 3X implant has an identical optical element to that of the NG IMT and the WA 3X IMT. The WA IMT 2.2X and the WA IMT 3X and the NG IMT are CE marked. The WA IMT 2.2X and the WA IMT 2.7X are FDA approved.

The development of the SING IMT™ Implantable Telescope, model NG SI IMT 3X was based on the device's predecessor models.

The WA 2.2X, the WA 2.7X, and the WA 3X IMTs have rigid Poly (methyl methacrylate) (PMMA) haptics which require a 12.0 mm incision and manual insertion of the IMT into the capsular bag. In the NG IMT and in the NG SI IMT 3X, the PMMA haptic was replaced by flexible silicon haptics, which allow the device to be injected into the eye utilizing a smaller incision of 6.5 to 7.5 mm incision. The NG IMT was implanted using an off-the-shelf syringe with a modified tip. The delivery of the NG SI IMT 3X implant is done by the SING IMT™ Delivery System, a delivery system that was specifically developed for inserting the NG SI IMT 3X implant into the ocular bag. The NG SI IMT 3X implant has an identical optical element to that of the NG IMT and the WA 3X IMT.

Table 12: Summary of technologies used for AMD treatment (Borkenstein, Borkenstein & Augustin 2023)

Device	IOL-AMD	IOL-VIP	SML	LMI	EyeMax Mono	IMT
Reference	(Qureshi et al. 2015)	(Orzalesi et al. 2007)	(Scharioth 2015)	(Agarwal et al. 2008)	(Qureshi et al. 2018)	(Hudson et al. 2006)
Technology used	Double Intraocular lens	Double Intraocular lens	IOL	Cassegrain Lens	IOL	Galilean Telescope
Magnification	x1.3	x1.3 (distance)	x2.0	x2.5	x1.1-x1.2	x2.2 and x2.7
Lens status	Phakic/Pseudophakic	Phakic/Pseudophakic	Phakic/Pseudophakic	Phakic	Phakic/Pseudophakic	Phakic
Incision size (mm)	2.8	7	2.2	6.5	2.2	10-11
Monocular /binocular	Binocular	Binocular	Monocular	Binocular	Binocular	Monocular
Rehab required	Yes	Yes	No	Yes	No	Yes
PRL selection required	Yes	Yes	No	No	No	No
Number of patients enrolled	12	35	8	6	244	217
Mean age	77	73	NR	NR	80	75.6

Gender	NR	19 (54.3%) female 16 (45.7%) male	NR	1 (16.67%) female 5 (83.33%) male	146 (59.8%) female 98 (40.2%) male	103 (47.5%) female 114 (52.5%) male
Baseline BCDVA (logMAR) mean	0.92	1.29	0.62	1.47	1.06	1.20
BCDVA improvement (logMAR) mean	-0.22 (p = UNK)	-0.52 (p = UNK)	NS	-0.37 (p = 0.14)	-0.35 (p < 0.0001)	-0.35 (p < 0.0001)
Baseline BCNVA (logMAR) mean	0.85	NR	0.75 at 40 cm 0.52 at 15 cm	1.22	1.36	1.10
BCNVA improvement (logMAR) mean	-0.18 (p = UNK)	NR	−0.21 to −0.44 at 15 cm (p = UNK)	-1.02 (p = 0.14)	-0.48 (p < 0.0001)	-0.32 (p < 0.0001)
Endothelial cell loss	18%	7-10%	NR	6%	≈7%	25-40%
Effect on QoL	NR	NR	NR	NS	Improved	Improved

				(p = 0.14)		
VA test method	CDVA was measured with a Snellen chart. CNVA was measured with N-point at 40 cm	BCVA was evaluated by the ETDRS chart	Radner chart in German was used to test reading vision	BCDVA was measured with a Snellen chart. BCNVA was measured using the ETDRS near vision chart at 20 cm	Full subjective refraction BCVA was measured. Near acuity was measured with N-point at 40 cm	BCDVA was Measured by ETDRS. BCNVA was measured at 20 and 40 cm with the New ETDRS chart 1, using M-unit equivalents for each line of acuity measured. The better of the two BCNVA was reported

Ocular complications	No intraoperative or immediate postoperative complications	No intraoperative or postoperative complications	No intraoperative complications	No intraoperative complications	Anterior capsular tear, postoperative subretinal fluid and elevated IOP	Increased IOP within 7 days requiring treatment, corneal edema within 30 days, iris prolapse and corneal abrasion
Adverse events	IOP elevation and anterior vaulting of the IOL in the capsular bag in one patient, resulting in a decrease in visual quality	Transient elevations in IOP, corneal edema, ocular pain, posterior capsule opacification, pupillary block, and anterior capsule fibrosis	One patient had the lens explanted 3 months postoperatively due to glare/halos	All patients implanted with this lens experienced glare postoperatively, and two patient complained of shadowing which resolved by 3 months	One patient experienced an anterior capsular tear during surgery with implantation of the IOL in the capsular bag and no sequelae; 4 patients had intraoperative floppy iris syndrome managed successfully with intracameral phenylephrine; 3 patients required iris hooks for management of small pupils. One patient developed postoperative subretinal fluid at 1 month that resolved spontaneously; another patient required a YAG laser posterior capsulotomy at 10 months.	Inflammatory /pigment deposits on device, Guttae, and posterior synechiae

CDVA corrected distance visual acuity, CNVA corrected near visual acuity, BCNVA best-corrected near vision acuity, BCDVA best-corrected distance vision acuity, ETDRS Early Treatment Diabetic Retinopathy Study, logMAR Logarithm of the Minimum Angle of Resolution, NR not reported, NS not significant, PRL preferred lens focus, UNK unknown.

1.7 Suggested profile or training for users

The NG SI IMT 3X surgery is always performed by a healthcare professional (Ophthalmologist) who has specialized in the diagnosis and surgical treatment of eye diseases. They are required by law to continue their professional training throughout their active profession. Samsara sales and Marketing team perform annual training with surgeons to keep them updated with new and existing Samsara technology.

In addition, specialists should perform the Post-Telescope Implant Visual Rehabilitation Program. This program provides rehabilitation specialists with the knowledge, tools, and skills necessary for effective partnering with patients as they seek to maximize their visual functioning and accomplish specific activities of daily living goals to improve their quality of life. To provide comprehensive visual rehabilitation, a rehabilitation specialist will need to incorporate other compensatory strategies used in visual rehabilitation, such as increasing lighting, increasing contrast, and decreasing glare during functional tasks. (Further details are provided in the attachment to this document: Post-Telescope Implant Visual Rehabilitation Guidance MT01-0036 Rev. 1.)

1.8 Reference to any harmonised standards and CS applied

Assessment of compliance to all relevant applicable standards can be addressed within “General Safety and Performance Requirements” document, MDR-GSPR-600 Issue 1.

Samsara concluded to be fully compliant to the below standards. No standards have been implemented with amendments.

- General Safety and Performance Requirements – (EU) 2017/745
- Essential Requirements – [93/42/EEC]
- Essential Principle (Australia TGA) – [SR 2002 No. 236]
- Regulation (Canada MDR) – [SOR 98-282]

Table 13: List of standards applied in part or in full during the manufacture of Samsara IMTs.

Number	Full Title of the Standard
GENERAL	
MDD 93/43/EEC	Council Directive 93/42/EEC of 14th June 1993 concerning medical devices (MDD)
EU (MDR) 2017/745	European Medical Device Regulation (EU MDR)
EU 2023-607	Regulation EU 2023-607 of the European Parliament and of the Council
ISO 13485:2016	Medical Devices-Quality Management systems-requirements of regulatory purposes
EN ISO 13485:2016 CEN EN ISO 13485:2016/A11:2021	Medical Devices-Quality Management systems-requirements of regulatory purposes
ISO 14971:2019	Medical devices-Application of risk management to medical devices
EN ISO 14971:2019	Medical devices-Application of risk management to medical devices
ISO / TR24971 :2020	Medical devices - Guidance on the application of ISO 14971
IEC 62366-1:2015+AMD1:2020	Medical devices – Part 1: Application of usability engineering to medical devices

Number	Full Title of the Standard
IEC TR 62366-2:2016+ AMD1:2020	Medical devices – Part 2: Guidance on the application of usability engineering to medical devices
ISO 14698-1:2003	Cleanrooms and associated controlled environments - Biocontamination control - Part 1- General principles and methods
ISO 14698-2:2003/Cor 1:2004	Cleanrooms and associated controlled environments - Biocontamination control - Part 2 - Evaluation and interpretation of biocontamination data
ISO 14644-1:2015	Cleanrooms and associated controlled environments Part 1: Classification of air cleanliness by particle concentration
ISO 14644-2:2015	Cleanrooms and associated controlled environments— Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration
ISO 14155:2020	Clinical investigation of medical devices for human subjects -- Good clinical practice
EN ISO 14155:2020	Clinical investigation of medical devices for human subjects -- Good clinical practice
MEDDEV 2.7/1 Rev 4, Jun 2016	Clinical Evaluation: a guide for Manufacturers and Notified Bodies Under Directives 93/42/EEC and 90/385/EEC
MEDDEV 2.7/4, Dec 2010	Guidelines on Clinical Investigation: A Guide for Manufacturers and Notified Bodies
MEDDEV 2.12-1 Rev 8, Jan 2013	Guidelines on a Medical Devices Vigilance System

Number	Full Title of the Standard
MEDDEV 2.12/2 Rev 2, Jan 2012	Post Marketing Clinical Follow-up Studies, A Guide for Manufacturers and Notified Bodies
SOR/98-282, Nov 28, 2022	Canadian Medical Devices Regulations
UK MDR 2002	Medical Devices Regulations 2002
Therapeutic Goods Administration (TGA)	Therapeutic Goods Medical Devices Regulations 2002
South Korea Ministry of Food and Drug Safety (MFDS)	Korean quality system regulations for medical devices: Korea Good Manufacturing Practices (KGMP)
PACKAGING	
ISO 11607-1:2019/Amd 1:2023	Packing for terminally sterilized medical devices- Part: 1 Requirements for materials, sterile barrier systems and packaging systems
EN ISO 11607-1:2020/Amd 1:2023	Packing for terminally sterilized medical devices- Part: 1 Requirements for materials, sterile barrier systems and packaging systems
ISO 11607-2:2019/Amd 1:2023	Packaging for terminally sterilized medical devices -- Part 2: Validation requirements for forming, sealing and assembly processes
ISO 11607-2:2019/Amd 1:2023	Packaging for terminally sterilized medical devices -- Part 2: Validation requirements for forming, sealing and assembly processes

Number	Full Title of the Standard
ASTM D4169-22	Standard Practice for Performance Testing of Shipping Containers and Systems
ASTM D3078-02(2021)E1	Standard Test Method for Determination of Leaks in Flexible Packaging by Bubble Emission
ASTM F88/F88M-23	Standard Test Method for Seal Strength of Flexible Barrier Materials
ASTM F1140/F1140M-13(2020)E1	Standard Test Methods for Internal Pressurization Failure Resistance of Unrestrained Packages
ASTM F1929-15 1.10.2015	Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
ASTM F1886/F1886M-16	Standard Test Method for: Determining Integrity of Seals for Medical Packaging by Visual Inspection
ASTM F2338 - 09(2020)	Standard Test Method for Nondestructive Detection of Leaks in Packages by Vacuum Decay Method
ASTM F2096-11(2019)	Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test)
LABELING	

Number	Full Title of the Standard
EN ISO 1523-1:2021 ISO 15223-1:2021	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements
ISO 11979-4:2008, Amd1:2012	Ophthalmic implants - Intraocular Lenses-Part 4: Labelling and information
ASTM F2503-23e1	Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment
ISO 20417: 2021	Medical devices — Information to be supplied by the manufacturer
STERILIZATION	
EN 556-1:2001 CEN EN 556-1:2001/AC:2006	Sterilization of medical devices - Requirements for medical devices to be designated "STERILE" - Part 1: Requirements for terminally sterilized medical devices
ISO 11135:2014 Amendment 1:2018	Sterilization of health care products - Ethylene oxide; Requirements for development, validation and routine control of a sterilization process for medical device
EN ISO 11135:2014 Amendment 1:2018	Sterilization of health care products - Ethylene oxide; Requirements for development, validation and routine control of a sterilization process for medical device

Number	Full Title of the Standard
ISO 11737-1:2018/Amd 1:2021	Sterilization of health care products -- Microbiological methods -- Part 1: Determination of a population of microorganisms on products
EN ISO 11737-1:2018/Amd 1:2021	Sterilization of medical devices - Microbiological methods - Part 1: Determination of a population of microorganisms on products (ISO 11737-1:2006)
ISO 11737-2:2019	Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
EN ISO 11737-2:2020	Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process (ISO 11737-2:2009)
FDA Guidance Aug 2015	FDA Guidance - Endotoxin Testing Recommendations for Single-Use Intraocular Ophthalmic Devices
BIOCOMPATIBILITY	
ISO 10993-1:2018	Biological evaluation of medical devices —Part 1: Evaluation and testing within a risk management process
EN ISO 10993-1:2020	Biological evaluation of medical devices —Part 1: Evaluation and testing within a risk management process

Number	Full Title of the Standard
EN ISO 11979-5:2020	Ophthalmic implants-Intraocular Lenses - Part 5: Biocompatibility
ISO 10993-3:2014	Biological evaluation of medical devices Part 3. Test for genotoxicity, carcinogenicity and reproductive toxicity
EN ISO 10993-3:2014	Biological evaluation of medical devices Part 3. Test for genotoxicity, carcinogenicity and reproductive toxicity
ISO 10993-5: 2009	Biological evaluation of medical devices Part 5. Tests for cytotoxicity: In vitro methods
EN ISO 10993-5:2009	Biological evaluation of medical devices Part 5. Tests for cytotoxicity: In vitro methods
ISO 10993-6:2016	Biological evaluation of medical devices Part 6. Tests for local effects after implantation
EN ISO 10993-6:2016	Biological evaluation of medical devices Part 6. Tests for local effects after implantation
ISO 10993-10:2021	Biological evaluation of medical devices Part 10. Tests for irritation and sensitization
EN ISO 10993-10:2023	Biological evaluation of medical devices Part 10. Tests for irritation and sensitization
ISO 10993-11:2017	Biological evaluation of medical devices Part 11. Tests for systemic toxicity

Number	Full Title of the Standard
EN ISO 10993-11:2018	Biological evaluation of medical devices Part 11. Tests for systemic toxicity
ISO 10993-17:2023	Biological evaluation of medical devices — Part 17: Establishment of allowable limits for leachable substances
EN ISO 10993-17:2009	Biological evaluation of medical devices — Part 17: Establishment of allowable limits for leachable substances
ISO 10993-18:2020	Biological evaluation of medical devices— Part 18 Chemical characterization of materials
EN ISO 10993-18:2020	Biological evaluation of medical devices— Part 18 Chemical characterization of materials
MECHANICS AND MANUFACTURE	
ISO 11979-2:2014	Ophthalmic Implants-Intraocular lenses-Part 2: Optical properties and test methods
ISO 11979-3:2012	Ophthalmic implants-Intraocular Lenses-Part 3: Mechanical properties and test methods
ISO 11979-6:2014	Ophthalmic implants-Intraocular Lenses-Part 6: Shelf-life and transport stability
MRI	

Number	Full Title of the Standard
ASTM F2052-21	Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment
ASTM F2119-07 (2013)	Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants
ASTM F2182-11a, ASTM F2182-19e2	Standard Test Method for Measurement of Radio Frequency Induced Heating on or Near Passive Implants During Magnetic Resonance Imaging
ASTM F2213-17	Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment

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1.10 Revision history

Date changed	Change approval reference	The change from previous revision	Revision level	Revision validated by the Notified Body
03 Sep 2023	DCO-003486	First revision	0	Yes
14 Dec 2023	DCO-003517	1.General updates to whole document: 2.new brand name SING IMT instead Tsert 3.update Residual risks and undesirable effects sec 1.4.1 4.update Summary of clinical evaluation and post-market clinical follow-up (PMCF), sec 1.5 5.add/update Clinical data 6.update Reference to any harmonised standards and CS applied, sec 1.8	1	Yes
31 July 2024	DCO-003568	• Added data for WA 3x. • Adjusted references in Table in 1.5.1.1/1.5.2 and added general bibliography section for the document • Added information from the PMCF plan as well as ongoing and planned PMCF studies	2	☒Yes Validation language: English ☐No

		• Add description of benefit risk of treatment alternatives • Added revision history table according to MDCG 2019-9 • Added justification for not performing a clinical investigation in section 2.5 • Added risk/benefit acceptability statement in section 2.5.1 • Added indication to contact doctor in section 2.6 • Added brief description of treatment alternatives in section 2.6 • Added reference to training material (attachment to the SSCP)		
27 Aug 2025 28 Oct 2025	DCO-003656, DCO-003676	• Added clinical data in section 1.5.2 • Updated Ongoing or planned post-market clinical follow-up (section 1.5.4) from the PMCF report • Updated possible alternative treatments in section 1.6 from the CER • Updated section 1.8 “Reference to any harmonised standards and CS applied” • Updated section 1.9 “List of references” • Typos correction	3	☐Yes Validation language: English ☒No
14 Jan 2026	DCO-003694	• Updated section 2.8 “Suggested training for users” following MDC request.	4	☐Yes Validation language: English ☒No

A summary of the safety and clinical performance of the device, intended for patients, is given below.

2 INFORMATION FOR PATIENTS

2.1 Device identification and general information

Device trade name	SING IMT™ (Small Incision New Generation Implantable Miniature Telescope) **Model – NG SI IMT 3X**
Manufacturer's name and address	Samsara Vision Ltd. 21 Yegia Kapayim Street, Petah Tikva 4913020, Israel
Basic UDI-DI	7290018786NGSI00118C8
Year when the first certificate (CE) was issued covering the device	24 April, 2020

2.2 Intended use of the device

Intended purpose	The telescope is intended to improve vision in patients with late-stage age-related macular degeneration (AMD).
Indication and target population	The device is indicated for central blind spots in both eyes due to late-stage age-related macular degeneration in patients 55 years of age or older with stable moderate to profound vision impairment. Target population: • Be 55 years of age or older. • Central blind spots • Have evidence of cataract.

	• Have vision no better than 20/80 and no worse than 20/800 in both eyes. • Have adequate peripheral vision in the eye not scheduled for surgery. • Achieve some vision improvement when using Samsara Vision's 3X external telescope simulator. • Have an anterior chamber depth of at least 2.5 mm in the eye scheduled for surgery. • Be willing to participate in a visual rehabilitation program for the use of the device after surgery.
Contraindications and/or limitations	Implantation of the device is contraindicated in patients who have any one of the following conditions: • Evidence of new blood vessels in the choroid layer (called choroidal neovascularization or CNV) or were treated for CNV within the past six months. • Any eye pathology that compromises the patient's peripheral vision in the fellow eye. • A history of intraocular pressure (IOP) increasing in case of use of steroid medications, uncontrolled glaucoma, or IOP before surgery superior to 22 mm Hg. • Corneal guttata (appearance of droplet shaped bulges on the cornea) • Known sensitivity to medications prescribed after surgery. • Significant communication impairment or severe neurological disorders. • Have undergone previous intraocular or corneal surgery of any kind in the operative eye, including any type of surgery for either refractive or therapeutic purposes. • An ocular condition that predisposes the patient to eye rubbing. • Prior or expected surgery in the eye within 30 days preceding the SING IMT™ surgery. • Patients for whom the planned operative eye has:

- Myopia > 6.0 D
- Hyperopia > 4.0 D
- Axial length < 21 mm
- Corneal endothelial cell density < 1600 cells per square mm
- Narrow angle, i.e., < Schaffer grade 2.

- Inflammatory ocular disease.
- Cornea stromal or endothelial disorders
- If cataract tends to push forward and push the back of the iris toward the front of the eye or any instability of crystalline lens, or if tiny flakes of dandruff-like material build up in the eye (called pseudoexfoliation).
- Diabetic retinopathy.
- Untreated retinal tears.
- Retinal vascular disease.
- Optic nerve disease.
- A history of retinal detachment.
- Retinitis pigmentosa.
- Intraocular tumor.

2.3 Device description

SING IMT™ stands for **S**maller-**I**ncision **N**ew **G**eneration **I**mplantable **M**iniature **T**elescope. This device is a Galilean telescope implant designed to improve visual acuity and quality of life for patients with late-stage AMD.

SING IMT™ is intended to be implanted inside the eye after removal of the crystalline lens. composed of optical components made of glass surrounding by 3 black wings made of silicone. These wings aim to stabilize the device inside the eye.

*Figure 3. SING IMT™**(model NG SI IMT 3X)***

Once implanted inside the eye, the NG SI IMT 3X projects images in the field of view onto healthy areas of your central retina outside of the degenerated macula. The image is enlarged, reducing the effect the blind spot has on central vision. Normally the healthy areas outside of the macula are used for peripheral or "side vision." The magnification provided by the telescope implant (2.7X) makes it possible to see or discern the central vision object of interest.

SING IMT™ telescope device is inserted into the eye with a delivery system.

The SING IMT™ device magnifies what a person with late-stage, age-related macular degeneration (AMD) sees in "straight-ahead" central vision.

The implant consists of two lenses within a small glass tube. Once inside the eye, it works like a fixed telephoto lens, working with the cornea to project a magnified image of whatever the wearer is viewing onto the undamaged part of the retina. This enables a person to recognize and identify previously unseen or difficult to see objects. Patients may be able to recognize the faces of friends and family and enjoy leisure activities like watching TV or reading.

Because only the central parts of the retina are damaged in the disease, magnifying the image onto a broader part of the retina beyond the damaged area allows detection of objects. The peripheral or healthier parts of the retina normally generate low-resolution visual information for the brain, compared to the macula, but magnifying or enlarging the image enables viewing with this lower resolution retina.

2.4 Risks and warning

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.

2.4.1 How potential risks have been controlled or managed

There is a process for identifying the risks associated with use of the device and then a process for initiating efforts to eliminate the potential for the risk to occur and reducing the severity of the event if it should happen.

Section 2.4.2 describes the remaining risks. To manage these risks, there is a requirement to collect events that occur during use of the product. This is done using a customer complaint process that includes monitoring for adverse events and safety issues. If needed, Regulatory

Action can include updating the remaining risks and undesirable effects listed below or other action. No risks, which might have potentially arisen from applied risk control measures, were identified

2.4.2 Remaining risks and undesirable effects

The most common risks of the NG SI IMT 3X surgery include inflammatory deposits or precipitates on the device and increased intraocular pressure. Significant adverse events include corneal edema, vision-impairing corneal edema, corneal transplant, and decrease in visual acuity. There is a risk that having the telescope implantation surgery could worsen your vision rather than improve it. Individual results may vary.

Some Other Risks of Intraocular Telescope Surgery:

- double vision
- inability or difficulty controlling when to switch from using one eye to the other
- decreased peripheral vision in the eye with the intraocular telescope
- bleeding in the eye due to surgery
- infection inside the eye
- decrease in contrast sensitivity
- the need to surgically remove the intraocular telescope if it breaks inside your eye
- medical or visual complications
- dizziness or a queasy feeling
- changes in depth perception
- difficulty seeing in dim light
- difficulty seeing in bright light
- cloudy or blurred vision that makes it hard to see
- difference in speed of motion of the images in the two eyes, when the eyes are moved together.

2.4.3 Warnings

⚠ Implantation of the NG SI IMT 3X implant carries a risk for **ocular complications directly related to the surgical procedure** occurring in the operative or immediate postoperative period, including aborted surgery, choroidal detachment, corneal edema ≤ 30 days, increased IOP requiring treatment ≤ 7 days, iris atrophy ≤ 7 days, iris prolapse, iris transillumination defects ≤ 21 days, phthisis, posterior capsular bag rupture, vitreous in the anterior chamber ≤ 7 days, and vitreous loss.

Additional risks **associated with anterior chamber surgery and** NG SI IMT 3X implant include: endophthalmitis, hypopyon, retinal detachment and retinal tears.

As with any surgical procedure, there is risk involved with the **surgical procedure itself**. Potential complications accompanying cataract extraction or NG SI IMT 3X implant implantation surgery may include, but are not limited to, the following: corneal endothelial damage, infection, retinal detachment, vitreous loss, ptosis, pupillary block, secondary glaucoma, iris prolapse, posterior capsular rupture, cystoid macular edema, intraocular inflammation, microbial infection, recurrent severe anterior or posterior segment posterior inflammation, and uveitis.

The **long-term effects** of the NG SI IMT 3X implant, including the long-term effects on corneal endothelial cells, have not been established; therefore, physicians should continue to monitor patients postoperatively on a regular basis.

The risk of acute corneal endothelial cell loss during implantation is higher than with conventional anterior segment procedures and, consequently, total endothelial cell loss over time may be higher than for intraocular lenses implanted in the capsular bag.

Risk of complications **occurring during the immediate NG SI IMT 3X implant postoperative period** include: corneal edema, corneal decompensation, corneal transplant, decrease in visual acuity, device failure, diplopia, distorted pupil, gutatae, increased IOP requiring treatment, iris transillumination defects, posterior synechiae, precipitates or inflammatory deposit on the telescope, device dislocation, device removal, vitreous hemorrhage, and vitreous in anterior chamber.

2.4.4 Precautions

The NG SI IMT 3X implant limits the peripheral vision in the implanted eye in a fixed gaze; the functional field of view will be generally limited to that of the non-implanted fellow eye.

NG SI IMT 3X implant implantation restricts the patient's peripheral visual field; driving a car postoperatively is not recommended.

Patients must avoid rubbing the implanted eye; patients who are persistent eye rubbers are contraindicated.


If the patient is unable to participate, or does not participate in Samsara Vision training / rehabilitation program before and after the surgery, the potential benefits of the device may be reduced.


Do not use the NG SI IMT 3X implant and IMT Delivery System before reading this IFU.


Do not use the NG SI IMT 3X implant or IMT Delivery System after the expiration date indicated on the package.


Do not resterilize or reuse any part of the system.


Do not use the NG SI IMT 3X implant or IMT Delivery System if the sterile barrier system packaging (Blister sealed by TyVek® Lid) has been opened or damaged, as the sterility of the NG SI IMT 3X implant or IMT Delivery System may be compromised.


Do not use the NG SI IMT 3X implant or IMT Delivery System if the Tyvek lid material was torn during opening of the Sterile barrier system packaging (Blister sealed by TyVek® Lid), as the sterility of the NG SI IMT 3X implant or IMT Delivery System may be compromised.


The NG SI IMT 3X implant should not be implanted after the indicated sterility expiration date.


The NG SI IMT 3X implant and IMT Delivery System are intended for single use only. Discard the IMT Delivery System after use. Reuse of the NG SI IMT 3X implant and IMT Delivery System is prohibited and could pose a risk of infection or nonconformance of the NG SI IMT 3X implant and IMT Delivery System with its specifications.


Use the NG SI IMT 3X implant and IMT Delivery System only for the purpose described in the IFU.


Do not attempt to disassemble, modify, or alter the NG SI IMT 3X implant or IMT Delivery System or any of their components, as this can significantly affect the function and/or structural integrity of the NG SI IMT 3X implant and IMT Delivery System.


Warranty shall not apply to any defects, failure or damage caused by improper use and/or care.


Do not soak or rinse the NG SI IMT 3X implant or IMT Delivery System with any solution.


Do not place heavy objects on the package

⚠ Use the NG SI IMT 3X implant and IMT Delivery System at standard operating room temperatures.

⚠ Do not use if the NG SI IMT 3X implant or IMT Delivery System were dropped or if any part was struck after it was removed from the shipping case.

⚠ A high level of surgical skill is required for NG SI IMT 3X implant implantation. The surgeon should have performed several anterior chamber IOL implantations and successfully completed one or more training courses on intraocular lens implantation as well as training on the clinical use of the SING IMT™ system before implanting the NG SI IMT 3X device.

⚠ Thermal lasers should be used with extreme caution around the NG SI IMT 3X implant, and never through the glass optical portion. When applying laser energy around the NG SI IMT 3X implant be aware NOT to focus the laser beam on the carrier/haptic surface.

⚠ Do not use the device if the device or package labeling (serial #, expire date, etc.) is corrupted or unreadable.

⚠ In the cases of labeling damaged to extent that prevents clear identification of print the device is not suitable for clinical use and should be returned to the manufacturer immediately.

MR CONDITIONAL

Non-clinical testing demonstrated that the NG SI IMT 3X implant is MR conditional. Thus, a patient implanted with the NG SI IMT 3X implant can be safely scanned with MR under the following conditions:

- Static magnetic field of 1.5 Tesla or 3 Tesla.
- Maximum spatial gradient magnetic field of 1000 Gauss/cm (10 Tesla/m).
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2 W/kg for 15 minutes of scanning (i.e., per pulse sequence in the normal operating mode of operation for the MR system. Under the scan conditions defined, the NG SI IMT 3X implant is expected to produce a maximum temperature rise of 1.6°C after 15-minutes of continuous scanning (i.e., per pulse sequence).

In non-clinical testing, the image artifact caused by the NG SI IMT 3X implant extends approximately 5 mm from the NG SI IMT 3X implant when imaged using a gradient echo pulse sequence and a 3-Tesla MR system.

2.5 Summary of clinical evaluation and post-market clinical follow-up

The optical element of the NG SI IMT 3X is equivalent to the optical element of NG IMT and WA 3X; therefore the evaluation of the clinical performance of the NG SI IMT 3X was based entirely

on clinical data used to support the performance claims of the NG IMT and WA 3X, including a comprehensive literature search of published articles, unpublished clinical data from the manufacturer (Samsara Vision), safety reports and adverse event reports. It was shown in all the studies conducted that the implantation of the device (both NG SI IMT 3X and previous models) resulted in an improved vision at distance and near of at least 2 lines for most of the patients and for up to 60 months.

For the previous models, complications reported in the studies included anterior chamber cells, fibrin, conjunctival injection, iritis, anterior uveitis, transient elevated IOP, corneal edema, distorted pupil, inflammatory deposits and posterior synechiae, inflammatory and pigment deposits on device and guttae. Some of these complications were present up to 6 months after device implantation. Moreover, a corneal endothelial cell loss (ECL) of 2.4% to 40% were reported according to the study and the follow-up time.

The rates of adverse events and especially the high ECL reported in the studies led to the development of the last model NG SI IMT 3X, SING IMT™ which has the same magnification, optics diameter, and axial height; however, unlike its predecessor, it has a smaller overall diameter, requires fewer sutures, and has greater postoperative corneal clearance.

Safety outcomes for NG SI IMT 3X showed a significant reduction in surgical trauma and induced astigmatism, which permits more rapid initiation of rehabilitation and a significant reduction in ECL (~7%) compared to IMT model.

The results of a user survey conducted as a post-market follow-up activity revealed that most patients implanted with NG SI IMT 3X were satisfied with their vision at 4 weeks follow-up and with the rehabilitation program, and most of patients met their expectations in terms of visual acuity. Users highlighted that patient selection is key to promoting post-operative satisfaction outcomes. Overall, this survey confirmed that the NG SI IMT 3X allows patients with late AMD to regain visual acuity and reading ability.

2.5.1 Benefit-risk ratio for the patient

As part of the clinical evaluation all clinical risks associated with Samsara Vision NG SI IMT 3X have been reviewed, as has all labelling, including the IFU, in order to confirm that the documents altogether contain correct information to reduce the risk of use error, information on adverse events and their management (e.g. handling instructions, description of hazards, warnings, precautions, contraindications, instructions for managing foreseeable unwanted situations) and that all of the user's responsibilities are covered.

The overall residual risk of the product was assessed and weighed against clinical benefits associated with the intended use of the product:

- The NG SI IMT 3X implant is intended to improve vision in patients with end-stage age-related macular degeneration (AMD).
- Clinical benefits as a result of NG SI IMT 3X implant may include, but not limited to the following:
  - Improved ability to perform essential daily tasks.
  - Improved vision contributes to overall well-being and independence for people.
  - Improved visual abilities.
  - Improvement of visual acuity and vision-related quality of life.

All residuals risks were mitigated as far as possible after safeguard implementation. Following the risk mitigation, 89 residual risks were considered acceptable. Two “non-acceptable” residual risks, ranked with “Critical” severity, which probability of occurrence is rated as “Remote”, were transferred for review by the EMRB decision-making forum. The EMRB has reviewed the overall residual risk/benefit assessment and ensured that the overall residual risk can be judged acceptable when weighed against the benefits of the device.

All safety issues were addressed and no new risks were identified during the preclinical and bench testing of the NG SI IMT 3X implant and delivery system.

Implantation with the NG SI IMT 3X equivalent device, the NG IMT, in patients with bilateral, end-stage AMD resulted in limited ECD loss during the 12 months post-implantation and was not involved with any unexpected ocular adverse events. Moreover, potential side effects and the rate of ECD loss are similar to those reported for IOLs. The improved vision has a positive effect on quality of life.

It can be concluded that any risks associated with the use of the NG SI IMT 3X implant are acceptable when weighed against the benefits to the patient.

2.6 Possible AMD treatment alternatives

Contact your healthcare professional if wish to discuss any possible treatment options. This document is not intended to replace a consultation with your healthcare professional if needed.

The age-related changes that cause choroidal neovascularization (CNV) are not completely understood. Therapy for dry AMD has primarily focused on slowing or arresting vision impairment related to late AMD associated with CNV (Hooper et al. 2008).

Several therapies, including laser photocoagulation, photodynamic therapy, and intravitreal anti-vascular endothelial growth factor (anti-VEGF) injections (ranibizumab, becacizumab) are commercially available for the treatment of CNV. Ranibizumab has been shown to improve visual acuity by three lines in 30%–40% of patients with monthly dosing. Bevacizumab has been shown to be equivalent to ranibizumab with monthly dosing; however, despite treatment some patients still progress, especially those with geographic atrophy (Singer et al. 2011). Atorvastatin, lampalizumab and fenretinide were also suggested as potential treatments (Waugh et al. 2018). Currently, there are no commercially available therapies for geographic atrophy.

For dry AMD patients with bilateral moderate to profound vision impairment caused by central scotomas associated with end-stage AMD therapeutic options are very limited. Even low vision rehabilitation does not provide uniformly improved quality of life in this patient population (Hooper et al. 2008).

- Low-Vision Magnifiers

The main method for helping patients with end-stage AMD has been visual rehabilitation with low vision magnifiers such as hand/stand magnifiers, spectacles, hand held telescopes, closed circuit televisions, and high-plus spectacles in conjunction with high-minus contact lenses to create a telescopic effect. Although these tools maybe effective for correcting overall visual functioning, they are cumbersome to use and cosmetically burdensome (Grzybowski et al. 2017).

- Implantable Magnifying Devices for AMD Treatment

A variety of implantable magnifying devices have been developed to improve visual acuity in patients with AMD by creating a magnified retinal image without the need for a hand-held magnifier. These include magnifying intraocular lenses (IOLs) and implantable miniature telescopes (IMTs). The method and amount of magnification and resultant visual field produced by these prosthetic devices varies considerably, but in general the magnified retinal image provides patients with improved visual acuity at the expense of some peripheral field loss and depth perception (Dunbar & Dhawahir-Scala 2018).

There are various types of implantable magnifying devices. These include Galilean-type telescopes, Cassegrain-type IOLs, and various single- or double-IOLs designed for near- or far-distance magnification according to their optical characteristics.

The Galilean-type telescope consists of two optical elements with high positive and negative power that are used in combination with the cornea. These include the IMT, the IOL-VIP System, and IOL-AMD. Other devices provide partial solutions, such as Scharioth Macula Lens (SML), that enable reading from a short distance, or prismatic lens that has effect of shifting the image to the PRL (Preferred Retinal Location).

The **IOL-VIP System** (Soleko, Ponecorvo, Italy) is a dual IOL system which includes a biconcave high-minus-power IOL in the capsular bag and a biconvex high-plus-power IOL in the anterior chamber, creating, with the cornea, a Galilean telescope system that enlarges images 1.3 times (x1.3). Insertion of the IOL-VIP System is preceded by a standard phacoemulsification.

This technology has limitations that include the need for a large corneal incision for insertion (a capsulorrhexis with a diameter of at least 6 mm, with the enlargement of the temporal corneal incision up to 7 mm) due to the thickness of the IOLs. The large incision may result in induced astigmatism and challenges with wound healing in the postoperative period. Other potential risks for this system include a possible crowding effect with two lenses, particularly with one IOL in the anterior chamber that may increase the risk for glaucoma or angle closure, especially in patients with hyperopia. Furthermore, the magnification is limited to ×1.3, and long periods of pre- and postoperative adaptation are required for the IOL-VIP, which may not be acceptable for some patients (Borkenstein, Borkenstein & Augustin 2023).

The **Scharioth Macula Lens** (Medicontur, Törökbálint, Hungary) is a one-piece foldable intraocular hydrophilic acrylic lens with a central magnifying portion implanted in the ciliary sulcus of pseudophakic eyes, which improves near vision in patients with AMD. The overall diameter of the IOL is 13.0 mm with four symmetric haptics. It has a central portion of 1.5 mm diameter with an addition of +10.0 D and neutral remaining optical zone.

SML has numerous benefits including the improvement of near vision with reduced reading distance and maximum magnification, without affecting peripheral vision. It can be implanted simultaneously during uncomplicated standard phacoemulsification with in-the-bag posterior chamber IOL implantation or years after cataract surgery. Another feature of this device is the small incision required for implantation (2.2 mm).

Limitations: This lens is contraindicated in patients with other eye conditions including chronic uveitis, zonular weakness, secondary cataracts and central corneal opacities (Borkenstein, Borkenstein & Augustin 2023).

The Lipshitz Macular Implant (LMI) is based on a Cassegrain configuration, which uses mirrors instead of lenses. The overall diameter of the IOL is 13.0 mm, and the optic is 6.5 mm. The anterior central mirror is 1.4 mm. The posterior mirror, which is doughnut shaped and 2.8 mm in diameter, has a central clear area of 1.4 mm in diameter. The peripheral zone of the optic is similar to that of a normal IOL in order to provide undisturbed peripheral vision. The reflecting surfaces of the LMI are coated with multiple layers of titanium oxide and silicon dioxide (dielectric coatings), which creates a mirror effect. The mirrors are 1 to 2 mm thick. The entire IOL is coated with poly-para-xylylenes (Parylene C) to enhance biocompatibility.

The benefits of the LMI include provision of ×2.5 magnification and the fact that a newer version of this device can be directly implanted in the sulcus (LMI-SI).

Limitations: Although LMI can provide high magnification, its sophistication probably requires higher manufacturing costs, especially compared to a simple silicon or acrylic IOL. The use of small mirrors might generate the risk of glare effects, due to diffraction and ghost reflections. Another limitation of this IOL is that it requires large incisions (6.5 mm) (Grzybowski et al. 2017).

The **EyeMax Mono** (Sharpview Ophthalmology, Bamberg, Germany) is similar to a standard monofocal IOL. It may be implanted in one or both eyes, and surgeons can select a hypermetropic refractive target in severe AMD cases to generate 10% to 20% magnification with the aid of spectacle correction (Borkenstein & Borkenstein 2019).

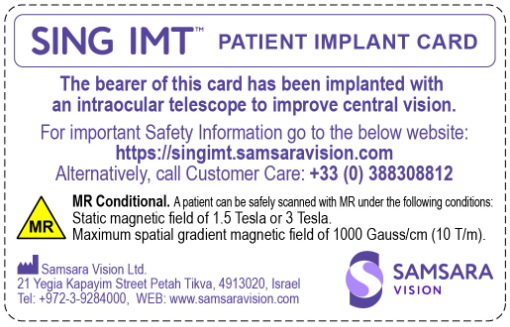
Benefits: EyeMax Mono improves image quality across the entire macula, increasing the breadth of focus and reducing blur. The optics of this lens are optimized with the aim of providing improved image quality for an area extending about 10 degrees from the center of the fovea, where photoreceptor cell densities may still afford visual acuities of 6/30 Snellen or better. It permits patients with single or multiple PRLs to gain optimum benefit from the most functional areas of their macula and provides magnification from ×1.1 to ×1.2. The lens is also designed to minimize chromatic aberration, further optimizing image quality delivered to the macula.

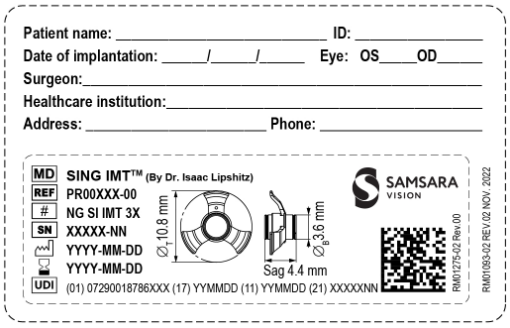
Complications associated with the implantation of the EyeMax Mono included anterior capsular tear, postoperative subretinal fluid and elevated IOP (Borkenstein, Borkenstein & Augustin 2023).

2.7 Patient information card

Following surgery, you will receive a Patient Implant Card with full details of the MR environment and specified conditions.

Patient Implant Card for NG SI IMT 3X





Patients can ask the surgeon any questions you may have regarding magnetic resonance (MR) imaging and the risks of MR imaging after implantation of the intraocular telescope. Patients can refer to the MRI information at: https://singimt.samsaravision.com/en

2.8 Suggested training for users

The user of NG SI IMT 3X is a trained ophthalmic surgeon.

Mandatory professional training for ophthalmic surgeons is provided by Samsara's clinical and professional education teams to ensure proper surgical technique and familiarity with the IMT technology.

All handling, implantation, adjustments, and clinical decision-making related to the device are performed exclusively by qualified ophthalmic surgeons

The rehabilitation process that follows the implantation surgery is considered standard post-operative care for Implantable Miniature Telescope patients.

2.8.1 Post-implantation rehabilitation training

Following implantation, **patients undergo visual rehabilitation** always performed by trained low-vision specialists.
This rehabilitation supports patient adaptation to the new monocular visual system and includes fixation training, functional vision exercises, mobility and safety assurance, and daily-activity adaptation.