



SING IMT™

TECHNICAL DATA SHEET

INTENDED USE:

The SING IMT (model: NG SI IMT 3X) is an ocular implant intended to improve vision in patients with end-stage Age-related Macular Degeneration (AMD).

MODE OF ACTION:

The SING IMT is surgically implanted in the capsular bag of the eye after removal of the crystalline lens and is held in position by silicone haptics. Once positioned, the SING IMT renders enlarged retinal images of objects in the patient's central visual field.

Product Information

NAME OF THE PRODUCT	GENERAL DEVICE DESCRIPTION	QTY/BX	SKU#
Implantable Miniature Telescope Commercial name : SING IMT™ Model : NG SI IMT 3X	Visual prosthetic implantable miniature telescope. A single-use, sterile, disposable pre-loaded telescope delivery system for inserting the implant into the eye.	1	PRO0118-00

SING IMT Delivery System

All primary components of the SING IMT Delivery System are produced using medical grade materials:

- The single-use cartridge is composed of the medical grade polycarbonate and medical grade silicone.
- The Injector Tip nozzle is made of medical grade perfluoroalkoxy alkanes (PFA). The Injector Tip also contains polycarbonate, silicone, and stainless steel, which all are of medical grade.
- The Injector syringe is made using following medical grade materials: glass, polycarbonate, polypropylene, polytetrafluoroethylene, and stainless steel.

The SING IMT delivery system is sterilized by ethylene oxide.



SING IMT™

IMPLANTABLE MINIATURE TELESCOPE

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Product Class Class IIb rule 8	Intended use The SING IMT is intended to improve vision in patients with end-stage Age-related Macular Degeneration (AMD).
Certification Information CE Mark: Yes EC Certification: D1027100016/18 (under EU MDR Extension, D1027100020) Notified Body: 0483 (MDC medical device certification GmbH) EN ISO 13485: 2016 Certificate (Valid until 2027-06-11)	Shelf Life Two (2) years from manufacturing date
Composition of the implantable portion Quartz glass optics, medical grade silicone carrier, stainless steel. The optical component is fixed into the carrier using medical grade silicone glue. All materials are biocompatible for long-term ocular implantation per ISO 10993/ EN ISO 10993.	Absence of Latex/Phthalates/Animal origin components
Packaging <ul style="list-style-type: none"> 1 device, pre-loaded into a single-use cartridge, and 1 injector per box, both sterile, packed into a sterilized blister wrapped in a Tyvek® pouch 1 Instructions for Use, 1 Patient implant Card 	Package materials <ul style="list-style-type: none"> Primary package: Blister pouch + Tyvek® Seal Protective packaging layer: carton box
Sterility Sterilized by ethylene oxide	Weight <ul style="list-style-type: none"> Weight in air: 121 mg ± 10% Weight in aqueous medium: 63 mg ± 10%
Transportation Room temperature for transportation: -13°C to 55°C or 8.6°F to 131°F	Storage Room temperature for storage: 15°C to 31°C or 59°F to 88°F

SING IMT™ is the brand name for the model NG SI IMT 3X. The Implantable Miniature Telescope is referred to as “the SING IMT” or as the “Implantable Miniature Telescope” (by Dr. Isaac Lipshitz). Samsara Vision and all other trademarks (unless noted otherwise) are property of Samsara Vision. ©2025 Samsara Vision, Inc. All Rights Reserved

Technical Specifications

Attribute	Specifications
Implantation technique	<ul style="list-style-type: none"> • Designated for implantation in the capsular bag after crystalline lens removal in a procedure similar to intraocular lens (IOL) implantation. The SING IMT is injected inside the capsular bag using a proprietary injection system. • Incision size (limbal): 6.5–7.5 mm • Haptic orientation: 12: 4: 8
Configuration	The SING IMT is composed of an optical portion (glass telescope) which contains two micro lenses, embedded in a silicone haptic carrier.
Magnification in the emmetropic eye	2.7 X \pm 10%
Best Focusing Plane	3 m
Patient optical compatibility (pre-op)	– 6 to + 4 diopter
Depth of field	1.5m to 10m
Field of View	<ul style="list-style-type: none"> • Full field: 20° (Nominal); (54° on the retina) • Center (high resolution): 6°; (16.2° on the retina)
Clear aperture	3.2 mm
Optical transmission (in the visible spectral band)	<ul style="list-style-type: none"> • T > 80% (in the eye) • T > 70% (in air)
Spectral band compatibility	Photopic
Sterility	Sterilized by ethylene oxide
Ethylene oxide residues	<p>The ethylene oxide residue does not exceed:</p> <ol style="list-style-type: none"> 1. Implantable lens – 0.5 μg/lens (IMT)/day and does not exceed 1.25 μg per lens 2. IMT delivery system (Limited < 24) – does not exceed 4 mg/samples and ethylene chlorohydrin does not exceed 9 mg/samples
LAL residues	> 0.2 EU/implant
Biocompatibility	Implant materials are biocompatible
Optical capsule impermeability	Optical capsule is hermetically sealed
Fragility	Fragile glass components – the optical portion

Attribute	Specifications
Impact endurance	The loaded Injector can endure impact of free fall from max. 12.5 cm with no consequent effect on the device safety, efficacy or quality. If the loaded Injector fell from less than 12.5 cm, the Injector Tip rim should be checked using a surgical microscope for the presence of any damage; if any damage is detected, the product is not suitable for clinical use.
Optic capsule	Fused silica
Haptic (carrier)	Silicon – NuSil MED 1 4850-2 (black)
Silicone Adhesive	MED-2000
Optic diameter ϕ_B	3.6 mm
Sagittal distance	4.4 mm
Overall diameter ϕ_T	10.8 mm
Weight in air	121mg \pm 10%
Weight in aqueous medium	63mg \pm 10%
Injector Tip outer diameter	5.05 mm
Injector Tip length	19.5 mm
Sterile barrier system (primary package)	Blister pouch + Tyvek [®] Seal
Protective packaging layer	Protective package (carton box)

Material Characteristics

SING IMT Implant

The SING IMT implant is composed of two primary components; quartz glass optics, and a medical grade silicone carrier. The optical component is fixed into the carrier using medical grade silicone glue. All materials are biocompatible for long-term ocular implantation per ISO 10993/ EN ISO 10993.



One of the internal components (not in contact with body fluids or tissue) of the SING IMT is made of stainless steel, which may interfere with the safe use of Magnetic Resonance Imaging (MRI). Non-clinical testing demonstrated the SING IMT is MR conditional.

The SING IMT is manufactured, assembled, and packaged in a controlled cleanroom environment.

The SING IMT is sterilized by ethylene oxide.



CONDITIONS FOR USE

Indications for Use

The SING IMT is indicated for bilateral central scotomas due to end-stage age-related macular degeneration in patients 55 years of age or older with stable moderate to profound vision impairment.

Patients must:

- 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 (6/24 metric, 0.25 decimal, 0.60 LogMAR) and no worse than 20/800 (6/240 metric, 0.025 decimal, 1.60 LogMAR) 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 SING IMT.

Contraindications

Implantation of the SING IMT is contraindicated in patients who have any one of the following conditions:

- Evidence of active choroidal neovascularization (CNV) on Angio OCT or with 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
- 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 SING IMT 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 corneal 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