Tsert SI™
Implantable Telescope Technology

INSTRUCTIONS FOR USE

IMPLANTABLE MINIATURE TELESCOPE (by Dr. Isaac Lipshitz)

MODEL: NG SI IMT 3X

VisionCare™
OPHTHALMIC TECHNOLOGIES

Visioncare Ophthalmic Technologies

These Instructions for Use is copyrighted with all rights reserved. Under copyright laws, these Instructions for Use may not be copied in whole or in part or reproduced in any other media without the express written permission of VisionCare Ophthalmic Technologies Ltd. Permitted copies must carry the same proprietary and copyright notices as were affixed to the original. Under the law, copying includes translation into another language.

Please note that while every effort has been made to ensure that the data given in this document is accurate, the information, figures, illustrations, tables, specifications, and schematics contained herein are subject to change without notice.

VisionCare, the VisionCare logo, Tsert SI™, the Tsert logo, and NG SI IMT 3X are trademarks or registered trademarks of VisionCare Ophthalmic Technologies.

Copyright © 2020, VisionCare Ophthalmic Technologies Ltd.

Version control code: RM01031-02 Rev. 4

Revision Date: Dec 2020

Email: orders@visioncareinc.net

Web Site: https://en.centrasight.com

Use of the Instructions for Use:

BEFORE USING THE DEVICE PLEASE READ THESE INSTRUCTIONS FOR USE CAREFULLY

The Tsert SI™ system, model NG SI IMT 3X is designed to meet international safety and performance standards. Surgeons implanting the device must have a thorough understanding of its proper operation.

These Instructions for Use (IFU) were prepared to aid surgeons to understand and use the device. Do not implant the device before reading this IFU and gaining a clear understanding of its operation. If any part of this IFU is not clear, please contact your VisionCare representative for clarification.

The information provided in this IFU is not intended to replace a mandatory physician training or professional training on the clinical use of the Tsert SI™ system, model NG SI IMT 3X. Such training should include a review of published literature, seminars, workshops, and appropriate preceptorships provided by the manufacturer or their designee. Please contact your VisionCare representative for current information on available training.

VisionCare does not bear any responsibility for improper handling, use not according to the IFU, surgical technique applied, or for any other complications caused by not following the IFU.

The device specifications are subject to change without notice.

These instructions for use are available electronically on our website at http://www.en.centrasight.com or send email to mail@visioncareinc.net.

This product is protected by patents:

US	Europe	Germany
6,569,199 B1	1056416	69920666.9
6,596,026 B1	Application #03010308.9	
6,007,579	1045678	69916238.6
5,876,442	1045679	69917429.5
5,814,103	1045680	69924705.5
5,354,335	0682506	69431428.5

CE

EC REP **Authorized Representative in the European Community:**

Obelis sa

General Wahis 53, 1030 Brussels, Belgium

Tel +32 2 732 59 54

Email: mail@obelis.net

VisionCare Ophthalmic Technologies Ltd.

21 Yegia Kapayim Street

Petah Tikva 4913020, Israel

Phone: +972-3-928-4000

Headquarters:

Samsara Vision Inc.

27 US Highway 202 Suites 8 / 9

Far Hills, NJ 07931, USA

Customer Care: 1-877-997-4448 or 1-408-872-9393

For international orders, please call +1-408-872-9393

TABLE OF CONTENTS

LIST OF FIGURES

INSTRUCTIONS FOR USE CONVENTIONS

Throughout these instructions notes, cautions, and warnings are used to provide critical information needed before the device is used.

	A **Note** is a statement that alerts the operator to particularly important information
	A **Caution** is a statement that alerts the operator to the possibility of a problem with the device associated with its use or misuse. Such problems include device malfunction, device failure, and damage to the device or other property. The caution statement includes the precaution that should be taken to avoid the hazard.
	A **Warning** is a statement that alerts the operator to the possibility of injury, death, or serious adverse reactions associated with the use or misuse of the device.

LIST OF ABBREVIATIONS

AMD	Age-Related Macular Degeneration
BCDVA	Best Corrected Distance Visual Acuity
CNV	Neovascularization
ETDRS	Early Treatment Diabetic Retinopathy Study
ETS	External Telescope Simulator
IFU	Instructions For Use
IMT	Implantable Miniature Telescope
IOL	Intraocular Lens
IOP	Intraocular Pressure
MDD	Medical Device Directive (Council Directive 93/42/EEC Amended By Directive 2007/47/EC)
MRI	Magnetic Resonance Imaging
OVD	Ophthalmic Viscosurgical Device
PCO	Posterior Capsule Opacification
SAR	Specific Absorption Rate

1 SYSTEM OVERVIEW

The Tsert SI™ system, model NG SI IMT 3X is an implantable device and delivery system comprising:

- A visual prosthetic implantable telescope referred to hereafter as the "NG SI IMT 3X implant".
- A single-use, sterile, disposable telescope delivery system for inserting the implant into the eye referred to hereafter as “IMT Delivery System”.

1.1 INTENDED USE

The NG SI IMT 3X implant is intended to improve vision in patients with end-stage age-related macular degeneration (AMD).

(See INDICATIONS FOR USE, Section 2.1, for full details)

1.2 STERILE PACKAGE CONTENT

The NG SI IMT 3X implant is supplied sterile and preloaded in the Tsert SI™ single-use cartridge (Figure 1 - A) and with an Injector (Figure 1 - B) within a sterilized blister with pouch + Tyvek ® Seal (Figure 1). The blister pack is sterilized using ethylene oxide and should only be opened under sterile conditions.

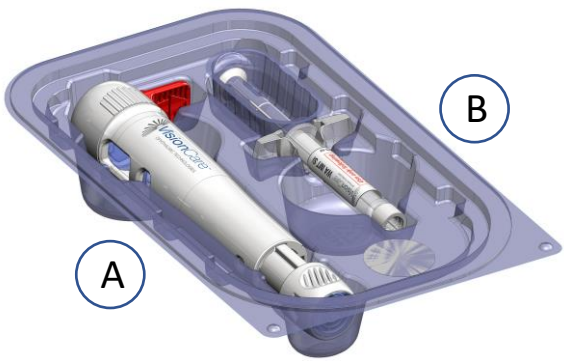


Figure 1

1.3 DEVICE DESCRIPTION

1.3.1 NG SI IMT 3X Implant

The NG SI IMT 3X implant 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 age-related macular degeneration.

The NG SI IMT 3X implant comprises a glass telescope and a haptic carrier (**Figure 2**). 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 outpatient surgical procedure. The telescope is held in position in the ocular capsular bag by silicon haptic wings.

The NG SI IMT 3X implant 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.

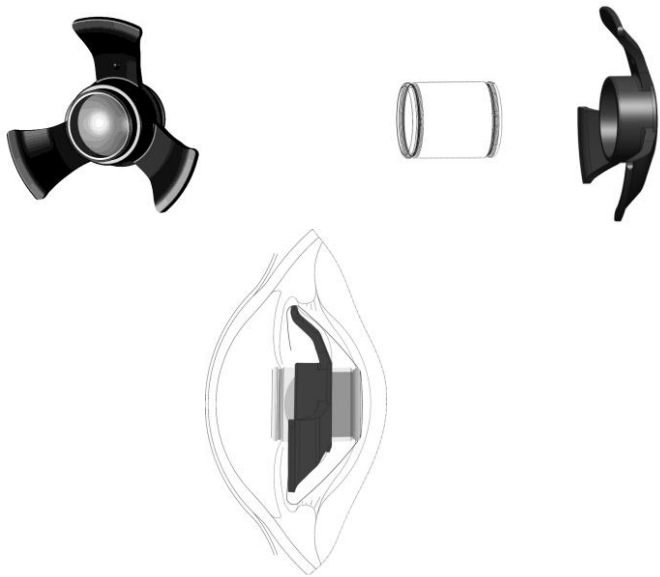


Figure 2

1.3.2 IMT Delivery System

The Tsert SI™ IMT 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 (Figure 3B) and Injector (Figure 3E). The Tsert SI™ cartridge is supplied preloaded with the NG SI IMT 3X implant (Figure 3A) and Injector Tip (Figure 3C) in the ready for loading position.

This preloaded Tsert SI™ 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 (Figure 3E) is comprised of the Injector syringe (Figure 3D) connected to the loaded Injector Tip (Figure 3C).

A. NG SI IMT 3X implant

B. Single-use Cartridge

C. Injector Tip

D. Injector syringe

E. Injector

Figure 3

1.4 TECHNICAL SPECIFICATIONS

Attribute	Specifications
Implantation technique	• Designated for implantation in the capsular bag after cortex removal in a procedure similar to intraocular lens (IOL) implantation. The NG SI IMT 3X implant 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 NG SI IMT 3X implant 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 ± 10%
Best Focusing Plane	3 m
Patient optical compatibility (pre-op)	- 6 to + 4 diopter
Depth of field	1.5 to 10 m
Field of View	• Full field: 20º (Nominal); (54º on the retina) • Center (high resolution): 6º; (16.2º on the retina)
Clear aperture	3.2 mm
Optical transmission (in the visible spectral band)	• T > 80% (in the eye) • T >70% (in air)
Spectral band compatibility	Photopic
Sterility	Sterilized by ethylene oxide
Ethylene oxide residues	The ethylene oxide residue does not exceed: 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

Attribute	Specifications
Biocompatibility	Implant materials are biocompatible
Optical capsule impermeability	Optical capsule is hermetically sealed
Fragility	Fragile glass components – the optical portion
Impact endurance	The NG SI cartridge or 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 $Ø_B$	3.6 mm
Sagittal distance	4.4 mm
Overall diameter $Ø_T$	10.8 mm
Weight in air	121mg ± 10%
Weight in aqueous medium	63mg ± 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)

1.5 MATERIAL CHARACTERISTICS

1.5.1 NG SI IMT 3X Implant

The NG SI IMT 3X 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 NG SI IMT 3X implant is made of stainless steel, which may interfere with the safe use of Magnetic Resonance Imaging (MRI). Non-clinical testing demonstrated the NG SI IMT 3X implant is MR conditional.

The NG SI IMT 3X implant is manufactured, assembled, and packaged in a controlled cleanroom environment.

The NG SI IMT 3X implant is sterilized by ethylene oxide.

1.5.2 IMT Delivery System

All primary components of the 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 IMT delivery system is sterilized by ethylene oxide.

1.6 MODE OF ACTION

The NG SI IMT 3X implant 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 NG SI IMT 3X implant renders enlarged retinal images of objects in the patient's central visual field.

2 CONDITIONS FOR USE

2.1 INDICATIONS FOR USE

The NG SI IMT 3X implant 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 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 VisionCare'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 NG SI IMT 3X implant.

2.2 CONTRAINDICATIONS

Implantation of the NG SI IMT 3X implant is contraindicated in patients who have any one of the following conditions:

- Evidence of active choroidal neovascularization (CNV) on 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.

2.3 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 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 VisionCare 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 Tsert SI™ 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 HAZARDS

In the following cases, the Tsert SI™ system is not suitable for clinical use and should be returned to the manufacturer immediately:

- If the NG SI IMT 3X protective package fell from a height greater than 38 cm the system is not suitable for clinical use and should be returned to the manufacturer immediately.
- If the cartridge or loaded Injector falls from a height greater than 12.5 cm onto a rigid surface the Tsert SI system is not suitable for clinical use and should be returned to the manufacturer immediately.
- Damage to labeling to an extent that prevents clear identification of print.
- A damaged Tyvek seal.
- A crushed or deformed package.
- Failure of the loading process.
- Wet package.

3 DEVICE TRACEABILITY AND PATIENT INFORMATION

3.1 DEVICE TRACEABILITY

Device traceability is essential for VisionCare for responding to potential field safety corrective actions. Set of implant identification stickers is supplied in the device package. These stickers contain necessary information for assuring device traceability in case of need: device information, unique device identifier and manufacturer contact details. The stickers should be placed in the patient's medical file, where applicable.

3.2 PATIENT INFORMATION

Each patient should receive information regarding the NG SI IMT 3X implant. It is recommended for the patient to receive this information in a manner suitable for the patient. This information should be provided prior to decision of implantation and should include:

- An external telescope visual acuity test and simulation.
- Explanation of the surgical procedure, possible symptoms of discomfort, postoperative treatment, and precautions
- Explanation of the need to participate in postoperative visual training/rehabilitation sessions to help utilize the new postoperative visual status in activities of daily living.
- An implant card is included in the pack to record all implant information. It shall be given to the patient, with the instruction to keep this card. The card should be shown to any eye care professional the patient visits in future.

4 REPORTING

Please report to VisionCare without delay:

Any malfunction or deterioration in the characteristics and/or performance of an NG SI IMT 3X implant or IMT Delivery System, as well as any customer complaints including quality complaints, adverse events and other medical device related observations.

The report should include the details of the complaint/event, the applied therapy, the product type/model, and the Lot/serial number of the device used.

5 INSTRUCTIONS FOR USE

5.1 PATIENT PREPARATION

1. To determine if candidates meet the minimum requirements for implantation of the **NG SI IMT 3X** implant, diagnostic testing, including corneal endothelial cell density and anterior chamber depth measurements, should be performed prior to surgery.
2. Induce anesthesia by retrobulbar or peribulbar injection.
3. Administer mydriatic agents to ensure adequate pupil dilation during surgery.
4. Place a lid speculum on the eye to be implanted, to provide maximum ocular cornea exposure.
5. Position the operating microscope over or in front of the eye to be treated. Illumination from the operating microscope provides adequate visualization during the procedure.

5.2 SURGICAL PROCEDURE

Use of a proper surgical technique is the responsibility of the individual surgeon. The surgeon must determine the suitability of any particular procedure based upon his or her medical training and experience.

1. Following iris dilation, create a 6.5-7.0 mm groove and a 5.5 mm capsulorhexis in the lens capsule.
2. Remove the lens by phacoemulsification or by extra-capsular lens cataract extraction.
3. Enlarge the corneal limbal opening to 6.5-7.5 mm.
4. Coat the endothelium with dispersive ophthalmic viscosurgical device (OVD) then inject a cohesive OVD to fill the anterior chamber and capsular bag.

5.3 PREPARATION OF THE DEVICE

The NG SI IMT 3X implant is supplied sterile and preloaded in the IMT Delivery System's single-use cartridge within a sterilized blister pack.

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 or IMT Delivery System.

Use the system at standard operating room temperatures.

1. Examine the label on the unopened outer box for the model and expiration date. Make sure that the appropriate, unexpired, sterile preloaded IMT Delivery System and NG SI IMT 3X is available.

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

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

2. After opening the cardboard outer box, inspect the sterile barrier for any damage. If damage is observed, use another Tsert SI™ system.

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.

3. Verify that the model and serial number on the Sterile barrier system label are consistent with the information on the outer box labeling.
4. In a sterile environment open the Tyvek and remove the blister lid.

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 device may be compromised.

5. The Cartridge and the Injector should be removed from the blister in an aseptic way making sure that there is no contact with any unsterile areas during the transfer.

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.

6. Leave the Unintended-Injection-Blocker fixed on the Injector (Figure 4). If any signs of damage or degradation are visible, use another device and return the damaged device to the manufacturer.

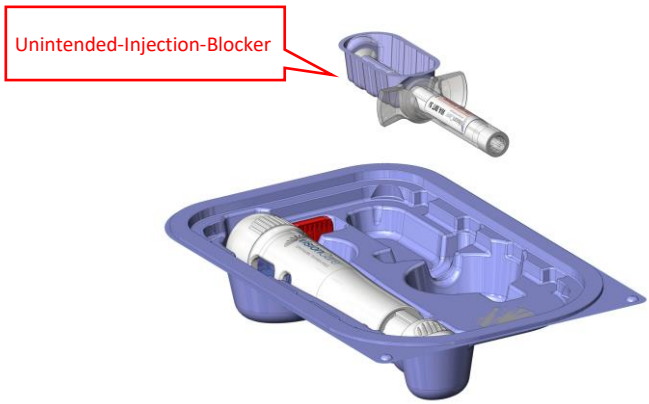


Figure 4

Do not resterilize or reuse any part of the NG SI IMT 3X implant or IMT Delivery System.

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.

When ready for implantation, perform the steps below in sequence, with minimal delay between each step.

Once started, the NG SI IMT 3X implant loading procedure cannot be reversed and shall be completed with minimal delay between steps.

The device loading movement should be smooth in order to avoid any damage to the fragile device.

1. Hold the single-use Cartridge vertically and connect the OVD syringe to the luer port (Figure 5).

Figure 5

2. Inject at least 0.75 mL of the OVD syringe contents into the Cartridge (Figure 6).
3. Remove the OVD Syringe.

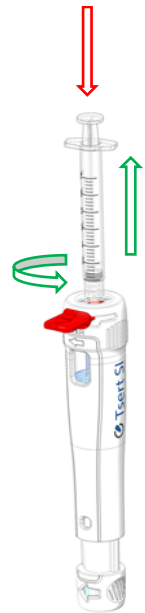
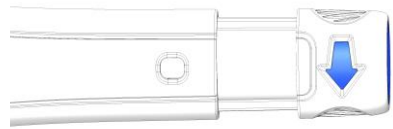


Figure 6

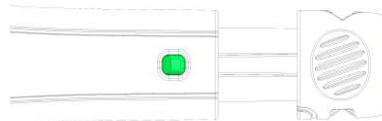
4. Replace the OVD syringe with the Injector (Figure 7).

Figure 7

5. Unlock the plunger by rotating it 90 degrees in the direction of the blue arrow (Figure 8) until green color appears in the lower small window indicating that the plunger is ready for the next step.



*Position A: Plunger **Locked***



*Position B: Plunger **Unlocked***

Figure 8

6. Push the plunger all the way in, and confirm visually through the upper window that the device was loaded (Figure 9).

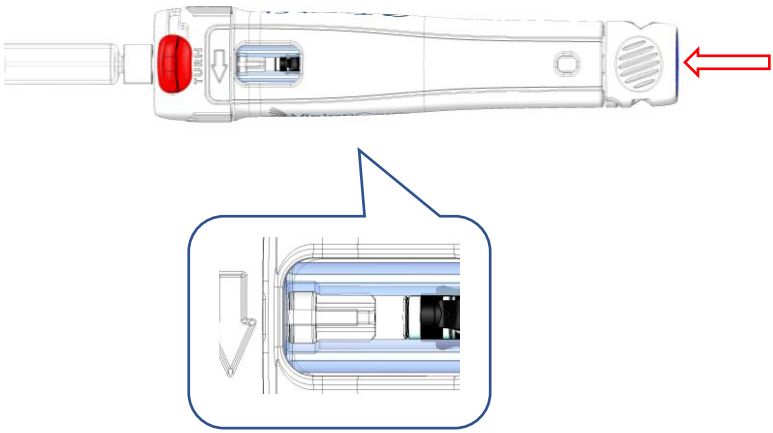


Figure 9

7. Rotate the cap all the way as indicated by arrow (Figure 10, A) and then remove the safety pin (Figure 10, B).

Figure 10

8. Carefully detach the loaded Injector (Figure 11) and confirm by visual observation that the NG SI IMT 3X implant does not protrude from the Injector Tip.

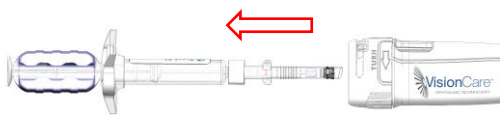


Figure 11

9. **Remove the Unintended-Injection-Blocker** from the syringe plunger (Figure 12)

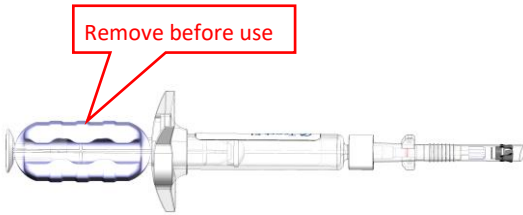
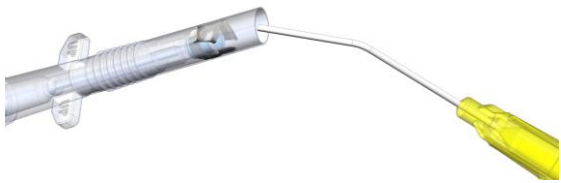


Figure 12

10. **Important:** Before injecting the implant, fill the empty space of the Injector Tip with OVD (Figure 13):

Figure 13



Avoid direct contact of the OVD cannula with the Injector Tip.

Do not press the syringe plunger until ready to implant the NG SI IMT 3X implant.

The NG SI IMT 3X implant should be implanted within 8 minutes after loading, as OVD may lose its lubricating properties when exposed to air for a long period of time.

5.4 IMPLANTATION PROCEDURE

1. Insert the Injector Tip through the limbal incision. The angle between the Injector and the iris plane should be maintained at about 45° to 70° (Figure 14).

   It is critical to ensure the correct orientation of the Injector Tip prior to inserting the Injector into the incision:

   The Injector wings should be positioned horizontally with the UP sign on the Injector wings facing up (Figure 14).

2. Bring the Injector Tip to the capsulorhexis plane. Verify the position by gently altering the syringe tilt until you are sure that the angulated edge of the Injector Tip is completely inside the bag (Figure 14).

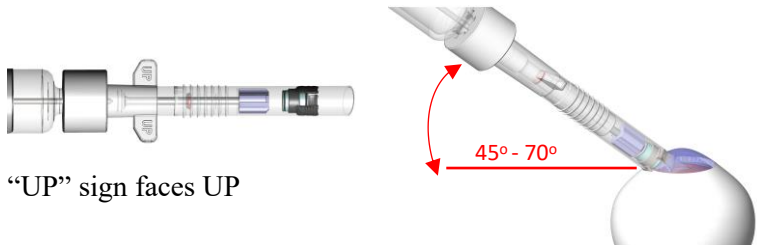


Figure 14

Inject the NG SI IMT 3X implant only when the Injector Tip is COMPLETELY inside the bag.

3. Gently advance the plunger forward in one smooth, continuous motion while keeping the Injector Tip completely inside the bag. Hold the Injector stably in place throughout the injection.

   The NG SI IMT 3X implant advancement should be made no faster than 1mm per 2 seconds

   When pushing the plunger avoid any retraction of the syringe body!

4. The NG SI IMT 3X implant should be placed entirely in the capsular bag. Do not place the implant in the ciliary sulcus.

5. When the NG SI IMT 3X implant is injected, gently release the Injector body out of the eye by short rotating movements in both directions.

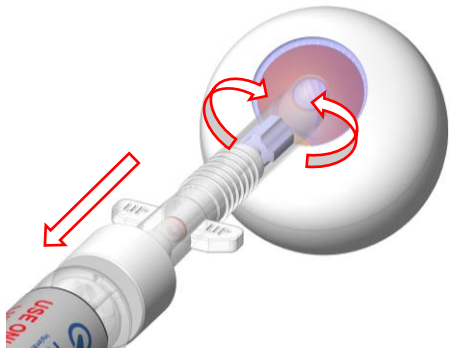


Figure 15

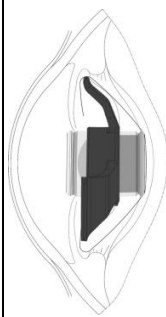
6. The NG SI IMT 3X implant should be well centered and have no visible tilt with the haptics stretched inside the bag and edges located in the equator of the capsule. If, after a few seconds, the NG SI IMT 3X implant does not stabilize in the centered position, the surgeon may gently nudge the telescope using a surgical hook.
7. Iridectomy should be performed.

Iridectomy should be performed.

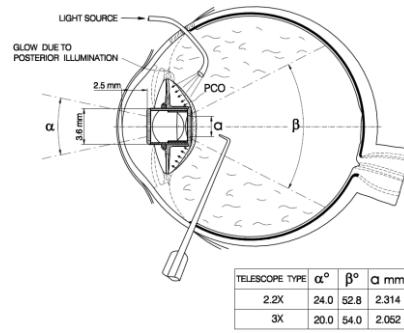
8. Suture the eye (with a distance of approximately 1.5-2.0 mm between sutures) and ensure sealing of the incision.

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 or IMT Delivery System is prohibited and could pose a risk of infection or nonconformance of the device with its specifications.

5.5 TROUBLESHOOTING

Condition	Possible Cause	Recommended Action
NG SI IMT 3X implant loading failure	Mechanical failure of the single-use loading Cartridge.	Use a spare Tsert SI™ system.
One or more haptic wings are outside the bag after device injection.	The NG SI IMT 3X implant was injected when the Injector Tip was not completely inside the bag.	Use a surgical hook to return it into the bag by applying hook pressure to the root area of the haptic and folding it into the bag. If required,  smoothly dial the NG SI IMT 3X implant to its designated position at the bag equator. Be especially careful not to turn the implant over by these manipulations and be sure the device orientation remains as shown in the picture.
Not all 3 haptic wings are fully opened.	One (or more) of the haptic wings is not completely stretched inside the bag.	Employ the following technique: Administer OVD behind the folded wing. Gently open the folded wing by using a surgical hook.
Iris adhered to the NG SI IMT 3X implant.	Iris tissue is in physical contact with the NG SI IMT 3X implant	As a preventive action, it is highly recommended to administer mydriatics to the implanted eye for at least 15 days after surgery to ensure pupil dilation.
Abortion of the surgery due to complication or adverse event	NG SI IMT 3X implantation procedure cannot be successfully	The pre-calculated IOL should be implanted following the extraction of the NG SI IMT 3X implant from the eye. During NG SI IMT 3X

Condition	Possible Cause	Recommended Action
	accomplished due to surgical complications (posterior capsular rupture, or other), NG SI IMT 3X implant or IMT Delivery System failure or other adverse event	explant assure protection of the endothelium cell layer with a sufficient amount of the dispersive OVD: • Coat the endothelium with dispersive OVD • Enlarge the corneal limbal opening to 10-12mm. • Cut two (2) of device haptic (wings) using the surgical micro scissors. • Coat the endothelium and device with dispersive OVD • Extract cut wings and the device itself from the eye • Implant the pre-calculated IOL Note: Irrespective of the surgical technique utilized, a sub-Tenon's injection of betamethasone depot (or appropriate substitute) should be administered at the end of surgery.
Visually significant posterior capsule opacification		In the event visually significant posterior capsule opacification (PCO) occurs, a posterior capsulotomy procedure may be used to open the central portion of the posterior capsule in patients implanted with the intraocular telescope. Two patients implanted with the intraocular telescope successfully underwent treatment for PCO without the use of a YAG laser; one of these cases employed a pars plana approach using a 25-gauge vitrector to engage the posterior

Condition	Possible Cause	Recommended Action
		capsule (capsulotomy performed using a combination of peeling and direct vitrectomy), as shown below, and the other manually with a cystatome.  TELESCOPE TYPE | α° | β° | α mm 2.2X | 24.0 | 52.8 | 2.314 3X | 20.0 | 54.0 | 2.052 *Pars Plana Posterior*

5.6 POSTOPERATIVE TREATMENT

Avoid external pressure on the eye. Use a plastic eye shield for several days, as directed by the surgeon.

Avoid ocular hypotension.

1. Following surgery, administer one drop of a topical ophthalmic antibiotic solution and then continue as per product labeling for two days.
2. Following surgery, administer one drop of diclofenac sodium 0.1% and then continue as per product labeling for two days.
3. Administer prednisolone acetate (1%) every 2 hours for the first two weeks post-implantation, followed by administration every 4 hours for 2-4 weeks.
4. Over the next 4-6 weeks, taper prednisolone acetate (1%) for a total duration of postoperative steroid treatment of approximately 3 months. Tapering may be performed over a shorter period of time, if deemed appropriate by the prescribing physician.
5. Administer homatropine 5% twice daily for 4-6 weeks postoperatively. If homatropine is inadequate to maintain cyclopegia, atropine may be used.

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.

Device 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, or does not participate, in the VisionCare training/rehabilitation program before and after the surgery, the potential benefits of the device may be reduced.

6 TRANSPORTATION AND STORAGE

6.1 TRANSPORTATION

Ambient temperature for transportation: -13° to 55°C (8.6°F to 131°F).

Relative humidity for transportation: 5% to 70%.

Barometric pressure for transport: 0.5 atmospheres to 1.2 atmospheres (abs.).

No limitation on any type of light to heavy vehicle or commercial pressurized airborne carrier.

6.2 STORAGE

Ambient temperature for storage: 15° to 31°C (59°F to 88°F)

Relative humidity for storage: 30% to 70%

Barometric pressure for storage: 0.5 atmospheres to 1.2 atmospheres (abs.)

Illumination: Keep away from direct sunlight

7 DEVICE DISPOSAL

The device should be disposed of in accordance with local regulations.

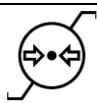
Discard used NG SI IMT injector as biohazardous waste in accordance with local regulations.

8 RETURN POLICY

Closed sterile packages that are received with packing or device damage should be returned to VisionCare immediately for replacement. If possible, return the medical device and/or its original container and/or any part of the packaging to your local distributor. Due to device fragility it is recommended to keep one spare Tsert SI™ System in inventory. Before returning a product, please contact Customer Service for Return Material Authorization (RMA) number.

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

9 SYMBOLS

Symbol	Meaning
	Serial number
	Use before
	Storage temperature
	Storage humidity
	Atmospheric Pressure range
	Keep away from sunlight
	Do not reuse
	Do not resterilize
	Do not use if package is damaged
	Consult instructions for use
	Ethylene oxide sterilization
	Manufacturer
	Date of manufacture
	CE Mark

	Authorized representative in the European Community
	Catalogue number
	Batch code
	MR Conditional
	Warning
	Caution, consult accompanying documents