1. MANUFACTURER INFORMATION

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2. DEVICE DESCRIPTION

MINIject™ (catalogue number: FG1004) is an integrated system for Minimally Invasive Glaucoma Surgery (MIGS). It consists of **a glaucoma drainage implant,** and **a Delivery System.** The implant is composed of medical-grade silicone which has a precise porous microstructure and is 5.0 mm long with an oblong cross section of 1.1 x 0.6 mm. It has a green marker (0.4 mm wide) on the proximal end of the implant ("coloured ring") that serves as a visual aid to assist with proper implantation depth in the supraciliary space (refer to Section 8.2 - Implantation). The MINIject™ implant is designed to be implanted with its head in the anterior chamber and its body in the supraciliary space as depicted below.

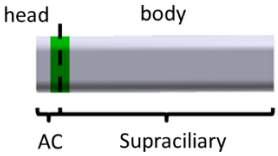

Figure 1: MINIject™ implant

The Delivery System is a disposable, single-use only device. It is composed of 2 components:

- The **MINIject Delivery Tool**, the handheld portion of the system which enables the implant to be released from the Delivery Sheath once it is appropriately positioned within the supraciliary space.

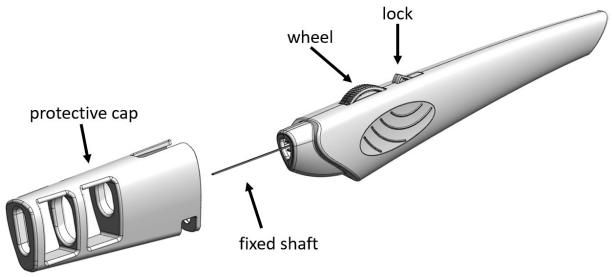

Figure 2: MINIject™ Delivery Tool

- The **Delivery Sheath**, a polyimide tube, curved at its distal extremity, which holds the implant; the Delivery Sheath is introduced into the eye through the corneal incision.

Figure 3: Delivery Sheath with the MINIject™ implant

Each MINIject™ package contains one (1) each of the following:

- Sterile **MINIject** implant preloaded in a **Delivery Sheath**
- Sterile **Delivery Tool**
- Patient Implant Card
- Set of (5) Traceability Labels
- Instructions for Use.

3. INTENDED USE

MINIject™ is intended to be used to reduce intraocular pressure (IOP) by channelling aqueous humour out of the anterior chamber to the supraciliary space, thus enhancing physiological uveoscleral outflow.

4. INDICATIONS FOR USE

MINIject™ is indicated in adult patients diagnosed with open angle glaucoma.

5. CONTRAINDICATIONS

The use of this device is contraindicated if one or more of the following conditions exist:

- eyes with angle closure glaucoma;
- eyes with traumatic, malignant, uveitic or neovascular glaucoma or discernible congenital anomalies of the anterior chamber angle;
- patients with known intolerance or hypersensitivity to silicone.

6. WARNINGS

The MINIject™ implant is intended for long-term use. The physician should monitor the patient postoperatively for proper maintenance of IOP as performance may change over time. If IOP is not adequately maintained, the physician should consider appropriate additional therapy to maintain the target IOP.

7. PRECAUTIONS

- The Delivery System is single-use only and cannot be reused or reloaded.
- The implant should not be removed after placement unless there a positive benefit/risk as assessed by the surgeon.
- The safety and effectiveness of the use of more than a single MINIject™ implant in a single eye has not been established.

The following symbols are used on the product. The related description shall be carefully followed.

Symbol	Description
	Manufacturer
	Date of manufacture
	Caution. Consult instructions for use for warnings and precautions.
	Catalogue number
	Product lot number
	Expiry date (YYYY-MM: Year-Month)
	Sterilized using irradiation
	Sterilized using steam
	Non-pyrogenic
	Read the Instructions for Use carefully before use for operating instructions and important information
	Do not resterilise
	For single-use only. Do not reuse.
	Do not use the product if the packaging has been damaged
	Temperature Limitation (Store at Temperature of 20 +/- 5 °C)

TRAINING REQUIREMENTS
MINIject™ is intended for use by ophthalmic surgeons after receiving training by an authorised trainer.

8. INSTRUCTIONS FOR USE

8.1. Assembly

Examine the product packaging for any signs of damage or compromise of the contents and verify the expiration date. Prior to implantation (as described in Section 8.2), assemble the MINIject™ in a sterile operating room on a sterile field and follow the steps described below:

- As each package is opened, carefully examine all device components for any signs of damage. Caution: Do not use the device if there is any sign of damage.
- The sterile MINIject™ implant is supplied preloaded in the Delivery Sheath and hydrated in a plastic vial filled with 0.9% buffered saline (Figure 4). Prior to use, open the vial by carefully peeling the aluminium lid completely. This will reveal the adaptor of the Delivery Sheath which is maintained in a vertical position in the vial (shown below). Caution: It is recommended not to pour the saline solution out of the vial nor remove the Delivery Sheath from the vial, to keep the Delivery Sheath hydrated in the sterile saline until you are ready to couple it with the Delivery Tool – this will reduce the risk of implant dehydration, which could potentially impact its drainage properties. However, should the vial tip over on the table, and some saline solution pours out, the use of the device will not be compromised.

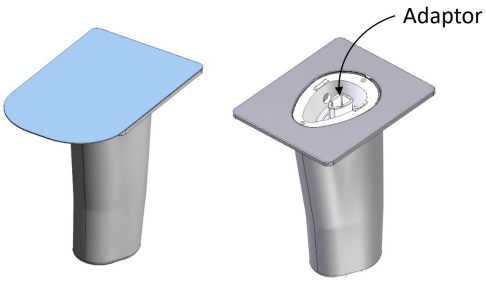

Figure 4: Plastic vial containing the Delivery Sheath preloaded with the MINIject™ implant

- The Delivery Tool is supplied sterile and includes a protective cap that covers the fixed shaft. Keep the protective cap on the Delivery Tool until you are ready to couple it with the Delivery Sheath (see Figure 2).
- The Delivery Tool is equipped with a safety lock. With the protective cap in place, unlock the system by placing the safety lock in the unlocked position (1), completely rotate the wheel forward (2) until the mechanical stop is reached and lock the Delivery Tool by placing the safety lock in the locked position (3) (Figure 5). Verify that the wheel cannot be moved. The device is ready to be coupled with the delivery sheath when the wheel is correctly blocked by the safety lock.

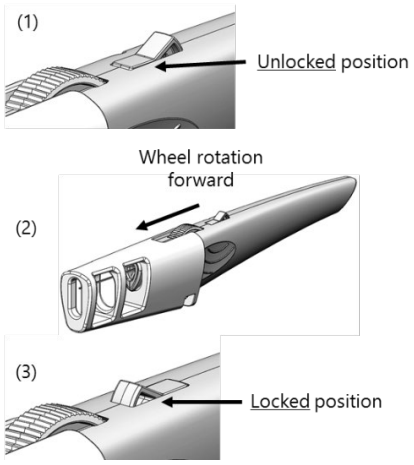

Figure 5: Delivery Tool preparation

- When you are ready to couple the Delivery Tool with the Delivery Sheath, carefully remove the protective cap without damaging the fixed shaft.
- Insert the fixed shaft in the Delivery Sheath still contained in the vial and connect the Delivery Tool by clipping the adaptor portion of the Delivery Sheath (located on the proximal end) onto the Delivery Tool as illustrated in Figure 6. Caution: during this step, use your index finger to roll the wheel in a forward position and keep the fixed shaft as straight as possible when inserting it in the Delivery Sheath.

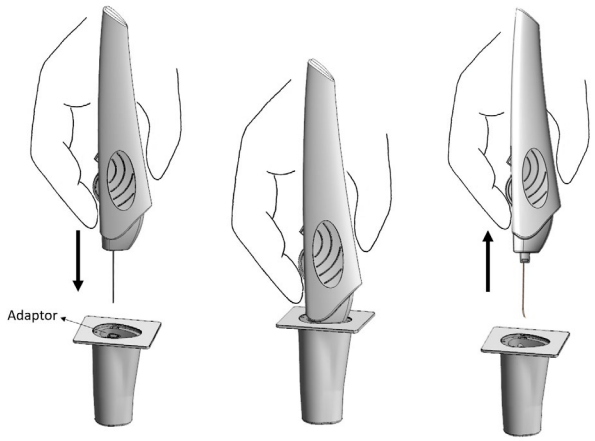

Figure 6: Connection of the Delivery Tool to the Delivery Sheath

- Gently remove the system from the vial by pulling the Delivery Tool with a linear movement. Caution: do not shake the system during retraction. Do not rotate the system in the vial.
- Verify proper assembly of the components by gently pulling the Delivery Sheath away from the Delivery Tool. Caution: During this verification step, manipulate the Delivery Sheath only via the adaptor portion.
- Inspect the Delivery Sheath to verify that the MINIject™ implant is contained entirely inside the Delivery Sheath (Figure 7). This inspection is best performed under a surgical microscope. Caution: If any portion of the implant is visible outside the Delivery Sheath, do not use the system and start with a new device.

Figure 7: Side view of MINIject™ implant inside the Delivery Sheath

- Immediately prior to entry in the anterior chamber, carefully unlock the Delivery Tool safety lock and use your index finger to maintain the wheel in the forward position.
- Once the safety lock has been unlocked, minimise manipulation of the Delivery Tool. Keep the wheel in this forward position to avoid unwanted or premature implant release.

8.2. Implantation

MINIject™ is intended to be used in a standalone procedure (i.e., not performed in conjunction with cataract surgery). The device is implanted in the supraciliary space using local (topical, peribulbar, or retrobulbar) anaesthesia. Implant the MINIject™ in a sterile operating room using sterile procedures and following the surgical technique described below:

1. Position the microscope above the patient's head. During the entire surgical procedure, ensure the patient's head position and microscope tilt angle allow sufficient gonioscopic visualisation of the iridocorneal angle.
2. Use the microscope and a gonioscopy lens (Volk Vold VVG Surgical Lens®, or similar, recommended, or other choices acceptable at surgeon's discretion or when orbit too small) to assess the iridocorneal angle anatomy and the desired quadrant for implantation. Although the supranasal quadrant is considered more ergonomically convenient, implantation in any of the other quadrants is also possible, avoiding areas of prior incisional glaucoma surgery. Complete stabilization of the eye during the entire procedure is important.
3. Confirm the iridocorneal angle is open.
4. Create a peripheral clear corneal incision (incision width between 2.0-2.2 mm recommended), 1 - 1.5 mm anterior to the limbus.
5. Fill the AC with ophthalmic viscoelastic device (OVD, Healon GV® recommended) and use additional OVD as necessary to maintain a deep, stable AC during the implantation process.
6. Intraoperative miotics (e.g., Miochol, Miostat) may be administered as customary for the surgeon; however, intraoperative administration of antifibrotics/antimetabolites (e.g., mitomycin C, 5-FU) are not required.
7. Immediately prior to entry in the anterior chamber, carefully unlock the Delivery Tool safety lock and use your index finger to maintain the wheel in the forward position. Minimize manipulation of the Delivery Tool. Keep the wheel in this forward position until you reach the desired implant location. This will avoid unwanted or premature implant release.
8. Gently insert the distal end of the Delivery Sheath through the peripheral corneal incision and guide the Delivery Sheath through the anterior chamber towards the iridocorneal angle.
9. Use a gonioprism and an appropriately positioned surgical microscope to magnify visualisation of the iridocorneal angle, increasing microscope magnification and fine focus as needed. At the iris root, gently advance the Delivery Sheath tip between the scleral spur and the ciliary body, then in the supraciliary and suprachoroidal spaces. Exert gentle pressure towards the sclera with the Delivery Sheath to avoid ciliary body penetration. **WARNING: Do not exert pressure on the ciliary body while advancing the Delivery Sheath, so as to minimize the cleft size**.
10. Advance the Delivery Sheath within the sub scleral space until the coloured ring on the implant is aligned with the scleral spur, as shown in Figure 8.

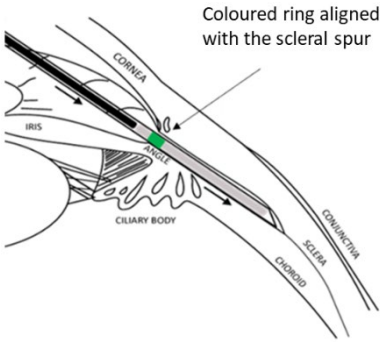

Figure 8: Insertion of the Delivery Sheath

11. To release the implant, use your index finger to gently and slowly roll the wheel backwards (towards you) until you reach a mechanical stop. This step retracts the Delivery Sheath over the fixed shaft (see Figure 9) and releases the implant. The fixed shaft will be visible under the microscope, extending out of the Delivery Sheath, indicating implant delivery is complete.
12. After full retraction of the Delivery Sheath, keep holding the fixed shaft against the implant for about five seconds.
13. Carefully remove the Delivery Tool from the eye.

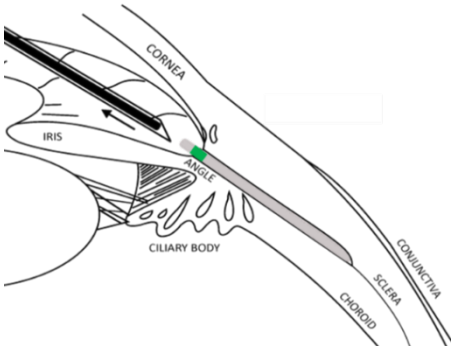

Figure 9: Removal of the Delivery System from the eye

14. Confirm that the patient's head position and microscope angle allow sufficient gonioscopic visualization of the angle, increasing microscope magnification and fine focus as needed. Additional viscoelastic tamponade may be needed to assure haemostasis and maintain visibility during implantation.
15. Verify the correct implantation depth (see Figure 10) by gonioscopic examination of the MINIject™ implant. The green coloured ring should be visible. No white portion of the implant posterior to the green ring should be visible in the anterior chamber. The surgical endpoint has been reached when the tip of the implant is at the junction of the pigmented and non-pigmented trabecular meshwork.
16. If proper implant placement cannot be achieved (malpositioning), implant removal should be considered. The MINIject™ implant can be immediately retrieved from the eye using 23 gauge serrated micro-holding forceps (see section 8.3).
17. Irrigate and aspirate viscoelastic from the anterior chamber, preferably using an automated aspirator for complete removal of viscoelastic. Caution: retained viscoelastic can lead to elevated IOP in the early postoperative period.
18. Seal the corneal incision in accordance with standard protocol.

If there is any problem with the device (implant or delivery system), please retain the entire device (if possible) and the original packaging, and contact iSTAR Medical immediately to make arrangements to return the device to iSTAR Medical for evaluation.

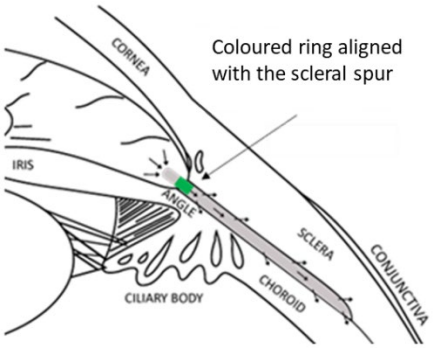

Figure 10: Correct implantation depth

8.3. Intraoperative Implant Repositioning or Retrieval

Intraoperatively, the fixed shaft of the Delivery Tool can be used to make minor adjustments to optimize implant position. If additional repositioning is needed once the fixed shaft has been removed from the eye, micro-adjustments to the implant position can be made intraoperatively utilising a gonioprism for visualisation. A 23-gauge serrated micro-holding forceps can be inserted through the existing corneal incision to reposition the MINIject™ implant, being careful to avoid damaging the implant and surrounding ocular structures. If proper placement cannot be achieved, implant removal should be considered.

If the MINIject™ implant needs to be removed during the implantation procedure, it can be retrieved by inserting a 23-gauge serrated micro-holding forceps through the existing corneal incision. Use the forceps to grasp the implant head and gently withdraw the device backwards, being careful to avoid damaging surrounding ocular structures.

8.4. Postoperative Implant Repositioning or Removal

In the event that MINIject™ needs to be explanted postoperatively to address a safety concern, the ophthalmic surgeon must consider the relative risks and benefits and use their best medical judgment to consider the patient's safety. Any secondary surgical intervention carries with it some additional risk (e.g., infection, bleeding, damage to surrounding ocular structures, alterations in aqueous flow, IOP fluctuation, etc.). It is also highly recommended that iSTAR Medical be contacted prior to device removal. If explantation is medically indicated (e.g., the expected benefits of device removal outweigh the potential risks), the MINIject™ can be explanted ab-interno through an incision under direct gonioscopy and anterior chamber viscoelastic stabilization. Use of 23 gauge serrated micro-holding forceps is encouraged for optimal surgical control and access. The MINIject™ can be repositioned or removed as follows:

- Perform a peripheral clear corneal incision (incision width between 2.0-2.2 mm is recommended) and instill ophthalmic viscoelastic device (OVD, Healon GV® recommended) into the anterior chamber.
- Using a gonioprism for visualisation, carefully grasp the MINIject™ with 23-gauge serrated micro-holding forceps and gently remove the device from its position, being careful to avoid damaging surrounding ocular structures.
- Remove the remaining OVD from the anterior chamber and adjust the tension in the eye by injecting and/or allowing egress of Buffered Saline Solution (BSS).
- Seal the incision.
- Retain the explanted MINIject™ and contact iSTAR Medical immediately to make arrangements to return the device to iSTAR Medical for evaluation.
- Warning: Following post-operative explantation, do not implant another MINIject™.

8.5. Postoperative Instructions

After surgery, patients should be monitored for IOP changes that may occur as possible sequelae following intraocular surgery. Gonioscopy should be performed to assess the implant position postoperatively.

9. DISPOSAL AFTER USE

After the implantation is completed, the Delivery System is considered biohazardous waste and should be disposed according to the biohazard disposal practices of the healthcare facility.

10. EXPECTED CLINICAL BENEFITS

The primary benefit of MINIject™ is a ≥20% reduction in IOP when used in a standalone setting. There are a number of other benefits supported with clinical data from existing iSTAR Medical clinical studies (STAR-I, STAR-II and STAR-III). The data available from these clinical studies indicate that MINIject™ meets the performance criterion of >20% reduction in IOP at 6 months. In addition, MINIject™ is implanted in the supraciliary space, thereby preserving the conjunctiva and trabecular meshwork for future incisional procedures.

In the STAR-I, STAR-II and STAR-III studies, the mean reduction in diurnal IOP was 39.1%, 40.2% and 39.0% respectively for the patients attending the 6-month follow-up visit, with 87.5%, 55.2% and 35.0% of them being free from IOP-lowering medications, respectively. Mean diurnal IOP was reduced to 14.2 mmHg, 14.7 mmHg and 14.4 mmHg respectively, representing a mean absolute reduction of 9.0 mmHg, 9.9 mmHg and 9.4 mmHg from the baseline value (23.2 mmHg, 24.6 mmHg, 23.6 mmHg) respectively. Maintained performance continued to be observed through 24 months of follow-up post-implantation in the STAR-I study with mean diurnal IOP reduced to 13.8 mmHg, representing a mean absolute reduction of 9.55 mmHg and a relative reduction of 40.7% from baseline. This was achieved with 47.6% of patients at the visit being free from IOP-lowering medications. In the 3 studies and up to 24-month follow-up for STAR-I, 6-month follow-up for STAR-II and 12-month follow-up for STAR-III the percentage of patients that had a mean IOP ≤ 18.0 mmHg ranged from 70.8% to 95.2%. In the 3 studies, at 6 months, 95.8%, 82.8% and 85.0%, respectively, of the patients had an IOP reduction ≥20% from baseline, whereas 100% of the patients present at the 24-month visit in STAR-I achieved this criterion. There was a large decrease in the amount of IOP-lowering therapy in the study eye in the 3 studies up to 24-month follow-up compared to baseline, reflecting a reduced need for IOP-lowering medication therapy after implantation of the MINIject™ implant. Specifically, means of 2.0, 2.9 and 2.2 ingredients IOP-lowering medication per patient was used at baseline in STAR-I, STAR-II and STAR-III, respectively, which was substantially reduced to a mean of 0.3, 1.0 and 1.4 ingredients at 6 months, and in STAR-I to 1.0 ingredient at 24 months. In STAR-I and STAR-III, these performance results were achieved without the need for additional glaucoma surgery, and in STAR-II, additional glaucoma surgery was only required in 3 patients. No significant untoward safety issue after implantation was identified. MINIject™ was considered safe and well-tolerated.

11. COMPLICATIONS/ADVERSE EVENTS

Implantation of the device may induce the following complications:

- Additional surgery to remove the implant or to repair damage to the eye.
- Bleeding inside the eye, e.g., pre- or post-operative intraocular haemorrhage, transient or persistent hyphaema, choroidal haemorrhage, conjunctival haemorrhage, conjunctival hyperaemia, subjunctival haemorrhage, vitreous haemorrhage.
- Change in eye geometry or eye mobility leading to change in vision and/or loss of visual acuity, e.g. myopia, strabismus, astigmatism, atrophy/phthisis (loss of function/shrinking of eye), angle closure glaucoma, limited ocular mobility, blindness with/without loss of the eye.
- Device dislocation, extrusion, misplacement, fracture, clogging, or implantation failure.
- Damage to the cornea or corneal complications, e.g. corneal endothelial pigment, corneal gutatta, corneal opacification or decompensation, corneal touch abrasion, corneal endothelial cell loss, vital dye staining cornea, corneal injury or trauma, Descemet's membrane (corneal) fold, dry eye or increased tear production.
- Damage to the iris e.g. iridodialysis, iris hypopigmentation, irididocele, iris adhesions, iris atrophy, iris hypopigmentation, iris incarceration, iridocorneal touch, synechia, Pupil disorders e.g. abnormal reaction of the pupil to stimuli, mydriasis, blown pupil, pigment dispersion syndrome.
- Damage to other internal or external parts of the eye (e.g. capsular bag tear/rupture, detached Descemet's membrane, iris injury or trauma, retinal tear, retinal detachment, scleral perforation, angle recession, oversized cyclodialysis cleft, zonular dialysis, retinopathy, retinal degeneration, wound dehiscence, maculopathy, macular membrane (puckering).
- Damage to the natural lens/IOL, e.g. lens/IOL dislocation, lens touch or abrasion, lenticular pigmentation, formation or worsening of cataract in eyes with a natural lens. lenticular opacities.
- Eyelid complications e.g. Ptosis (drooping of the upper eyelid), ectropion.
- Fluid retention or swelling inside the eye or e.g. choroidal effusion, conjunctival oedema, corneal oedema, macular oedema, cystoid macular oedema, papilloedema, (cystoid) macular oedema.
- Foreign body sensation or adverse reaction (inflammation) or eye pain.
- Inflammation or infection in other internal parts of the eye (e.g. anterior chamber inflammation, anterior chamber cells and flare, conjunctivitis, endophthalmitis, eye pruritus, iridocyclitis, iritis, blepharitis, local infection, irritation, punctate keratitis, conjunctivochalasis).
- Impaired flow of fluid inside your eye e.g. vitreous prolapse/loss, eye pressure that is too high (transient or persistent elevated IOP), eye pressure that is too low (transient or persistent hypotony, chorioretinal folds, choroidal wrinkles/folds) and conditions resulting from that, e.g., hypotony maculopathy.
- Visual disturbances such as blurred vision, halos, glare, vitreous floaters, metamorphopsia, photophobia, visual field defects.

There may be additional risks that are unknown.

Certain complications have been observed during iSTAR Medical-sponsored clinical trials. The observed frequencies for a period of up to two years are provided below. The majority of AEs occurred less than 3 months after the MINIject™ implantation.

Observed Complications	Reported frequency (range)
Angle closure glaucoma	0 – 3.2%
Anterior chamber cell*	0 – 3.8%
Anterior chamber disorder*	0 – 7.7%
Anterior chamber flare	0 – 3.2%
Anterior chamber inflammation*	3.2 – 44.0%
Cataract*	0 – 20.0%
Cataract subcapsular*	0 – 3.8%
Chalazion	0 – 3.8%
Chorioretinal folds*	0 – 6.5%
Choroidal detachment	0 – 3.8%
Choroditis	0 – 3.2%
Conjuctival haemorrhage*	4.0 – 9.7%
Conjuctival hyperaemia*	0 – 9.7%
Conjuctival oedema*	0 – 7.7%
Conjuctivitis*	0 – 6.5%
Conjunctivitis allergic	0 – 3.8%
Conjunctivitis bacterial*	0 – 8.0%
Conjunctivochalasis*	0 – 6.5%
Corneal abrasion	0 – 3.8%
Corneal disorder	0 – 3.8%
Corneal epithelium defect*	0 – 4.0%
Corneal erosion*	0 –3.2%
Corneal oedema*	3.8 – 1.5%
Cystoid macular oedema*	0 – 3.8%
Detached Descemet's membrane*	0 – 4.0%
Diabetic retinopathy*	0 – 4.0%
Dry eye	0 – 19.4%
Erythema	0 – 3.2%

Observed Complications	Reported frequency (range)
Eye allergy	0 – 3.2%
Eye haemorrhage*	0 – 3.2%
Eye infection*	0 – 3.2%
Eye pain*	3.8 – 15.4%
Eyelid ptosis	0 – 3.8%
Flat anterior chamber of eye*	0 – 8.0%
Foreign body in the eye	0 –3.8%
Foreign body sensation in eyes*	0 – 15.4%
Glare*	3.2 – 7.7%
Halo Vision*	0 – 12%
Hypersensitivity	0 – 3.2%
Hyphaema*	0 – 22.6%
Hypotony of the eye*	0 – 11.5%
IOP decreased*	0 – 12.0%
IOP increased*	3.8 – 48.4%
Iridocyclitis*	0 – 12.0%
Iridocele*	0 – 7.7%
Iris adhesions	0 – 3.2%
Iris atrophy*	0 – 3.8%
Iris disorder*	0 – 3.8%
Iris hypopigmentation*	0 – 3.2%
Iris incarceration*	0 – 3.2%
Iris injury*	0 – 7.7%
Lacrimation increased*	0 – 3.8%
Lenticular opacities	0 – 19.2%
Lenticular pigmentation	0 – 3.2%
Macular fibrosis*	0 – 4.0%
Macular oedema*	0 – 7.7%
Maculopathy*	0 – 4%
Medical device site haemorrhage*	0 – 3.2%
Metamorphopsia*	0 – 3.2%
Mydriasis*	0 – 3.8%
Toxic anterior segment syndrome*	0 – 3.8%
Ocular discomfort*	0 – 6.5%
Ocular hyperaemia*	0 – 3.8%
Papilloedema*	0 – 4.0%
Photophobia*	0 – 9.7%
Pigment dispersion syndrome*	0 – 3.2%
Posterior capsule opacification	0 – 3.8%
Posterior capsule rupture*	0 – 3.8%
Post-procedural haemorrhage*	0 – 6.5%
Pruritus	0 – 7.7%
Punctate keratitits*	0 – 3.8%
Pupillary deformity*	0 – 12.9%
Retinal degeneration*	0 – 3.2%
Retinal tear*	0 – 3.8%
Retinal vein occlusion*	0 –3.8%
Vision blurred*	0 –23.1%
Visual acuity reduced*	0 – 44.0%
Visual field defect*	3.8 – 26.9%
Vital dye staining cornea present*	0 – 9.7%
Vitreous haemorrhage*	0 – 4.0%
Vitreous prolapse*	0 – 3.8%

* Complications with onset observed mostly within 3 months after MINIject™ implantation.

Adverse events and/or complications that may reasonably be regarded as related to MINIject™ and not previously expected in nature, severity or incidence must be reported to iSTAR Medical at:

Phone: +32 (0)10 771 654
Email: incidents@istarmed.com

12. SUMMARY OF SAFETY AND CLINICAL PERFORMANCE
The summary of safety and clinical performance can be found by using the keyword "542503325-MINIJECT-627-7B" at the EUDAMED Database: ec.europa.eu/tools/eudamed

13. HOW SUPPLIED
Each MINIject™ contains one MINIject™ implant, supplied in a hydrated state in a physiological solution and preloaded in the Delivery Sheath, and one Delivery Tool. The implant and Delivery Sheath are supplied STERILE (steam) and the Delivery Tool is supplied STERILE (gamma irradiation).

IF THE STERILE PACKAGING IS DAMAGED OR UNINTENTIONALLY OPENED BEFORE USE, DO NOT USE THE DEVICE.

Each device is supplied with a Patient Implant Card, an Implant Card Leaflet with instructions on how to complete the card, these instructions for use, and a set of five (5) traceability labels. The Patient Implant Card and traceability labels identify the device name and lot number.

The Patient Implant Card included in the package is to be completed and given to the patient, together with instructions to keep the card as a permanent record to be shown to any health care practitioner that the patient consults in the future.

MINIject™ is FOR SINGLE-USE ONLY.
Do not re-use the implant or the Delivery System, as this may result in infection and/or intraocular inflammation, as well as occurrence of potential adverse events/complications as described in Section 10.

14. STORAGE REQUIREMENTS
MINIject™ should be stored at room temperature in the range of 15° to 25° C.

15. EXPIRATION DATE
The sterility expiration date is clearly labelled on the unit box. Sterility is assured until the expiration date, as long as the packaging is not damaged. MINIject™ should not be used after the date indicated. If a device is expired, contact your local iSTAR Medical customer service representative for instructions.