



**IMPLANTABLE MINIATURE TELESCOPE  
(IMT™ BY DR. ISAAC LIPSHITZ)  
FOR AGE-RELATED MACULAR DEGENERATION (AMD)**

**PROFESSIONAL USE INFORMATION**

**RESTRICTED DEVICE: U.S. Federal Law restricts this device to sale, distribution, and use by or on the order of a physician or other licensed practitioner. U.S. Federal Law restricts this device to practitioners who have been trained in ophthalmology and who have experience in the surgical management and treatment of central vision impairment.**

**This document provides information concerning the intended clinical use of the VisionCare Ophthalmic Technologies Implantable Miniature Telescope (IMT<sup>by Dr. Isaac Lipshitz</sup>) for improvement of visual acuity in patients with bilateral moderate to profound central vision impairment due to age-related macular degeneration.**

**Carefully read all instructions prior to use. Observe all contraindications, warnings, and precautions noted in these instructions. Failure to do so may result in complications.**

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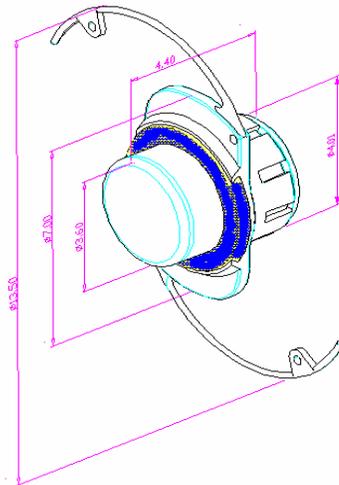
## 1. GENERAL WARNINGS

**Restricted Device:** Federal (U.S.) law restricts these devices to sale by, or on the order of, a physician.

**Carefully read all instructions prior to use. Observe all contraindications, warnings, and precautions.**

## 2. DEVICE DESCRIPTION

VisionCare's Implantable Miniature Telescope, IMT™ by Dr. Isaac Lipshitz (hereafter "AMD implant") is a visual prosthetic device which, when combined with the optics of the cornea, constitutes a telephoto system for improvement of visual acuity in patients with bilateral macular degeneration. The AMD implant is surgically implanted in the posterior chamber of the eye, in the capsular bag after removal of the eye's lens, and is held in position by haptic loops.



**FIGURE 2-1: IMPLANTABLE MINIATURE TELESCOPE** (BY DR. ISAAC LIPSHITZ)

The AMD implant is composed of three primary components; a fused silica capsule that contains optical elements, a clear polymethylmethacrylate (PMMA) carrier, and a blue PMMA light restrictor. The optical component is snap-fitted into the carrier. All materials are biocompatible for long-term ocular implantation per ISO 10993. One of the internal components (not in contact with body fluids or tissue) of the AMD implant contains stainless steel, which may interfere with the safe use of Magnetic Resonance Imaging (MRI). Until MRI compatibility of the AMD implant has been established, the use of MRI is unsafe. The AMD implant is assembled and packaged in a controlled environment and is sterilized by ethylene oxide. Table 2-1 below compares the finished product specifications of the two device models.

Each AMD implant is packaged in a protective polycarbonate case with cap, which assures that the device is held firmly during handling and transportation. The case with AMD implant is placed in a Polyethylene (PETG) blister, which is sealed with a Tyvek® lid. Following ethylene

oxide sterilization, the blister is placed in a unit box with labels and product information. The expiration date appears on the outside of the Tyvek® lid and on the outside of the box (the shelf-life is 2-years from the date of manufacture).

**TABLE 2-1**  
**FINISHED PRODUCT SPECIFICATIONS OF THE IMT™** (by Dr. Isaac Lipshitz)

FEATURE	MODEL WA 2.2X	MODEL WA 3.0X
MAGNIFICATION	x 2.2 ± 10%	x 2.7 ± 10%
DEPTH OF FIELD	1.5 to 10 m	1.5 to 10 m
OPTIMAL FOCUSING DISTANCE	3 m	3 m
FIELD OF VIEW	Full field: 24° (Nominal), 52.8° on the retina Center (High Resolution): 9°, 20° on the retina	Full field: 20° (Nominal), 54° on the retina Center (High Resolution): 6°, 16.2° on the retina
OPTICAL TRANSMISSION (VISIBLE SPECTRUM)	T > 80% in the eye T > 70% in air	T > 80% in the eye T > 70% in air
<b>DIMENSIONS</b>		
Overall Diameter	13.5 mm	13.5 mm
Clear Aperture	3.2 mm	3.2 mm
Telescope Diameter	3.6 mm	3.6 mm
Axial Length	4.4 mm	4.4 mm
Haptic Angulation	12.7°	12.7°
<b>WEIGHT</b>		
Air	115 mg ± 10%	115 mg ± 10%
Aqueous	60 mg ± 10%	60 mg ± 10%

### 3. MODE OF ACTION

The device contains two micro lenses, which enlarge the retinal image of objects in the central visual field, allowing the patient to distinguish and discern images that may have been unrecognizable or difficult to see due to the scotoma associated with their AMD. The AMD implant is available in two models: Wide Angle (WA) 2.2X, and Wide Angle (WA) 3.0X, which provide nominal magnification of ×2.2 and ×2.7, respectively.

Both models are designed predominantly for the restoration of intermediate-far vision (increasing the ability to view objects several meters away from the patient). The addition of conventional spectacles provides correction for near vision activities.

The AMD implant is implanted in one eye only. The implanted eye provides central vision, while the fellow eye continues to be used for peripheral vision.

### **3.1 SELECTING THE MODEL AND EYE FOR IMPLANT**

There are two models of the AMD implant device, which correspond to the magnification of the external telescopes, i.e., 2.2X and 3X. The patient's visual acuity and visual function is to be tested with both 2.2X and 3X external telescopes. The model of telescope selected for implantation should correspond with the external telescope magnification (2.2X or 3X) which provided the best testing results. The eye selected for surgery will depend on the results of visual acuity testing and discussions of preferences between the patient and the physician.

## **4. INDICATIONS**

The AMD implant is indicated for use in adult patients with bilateral, stable moderate to profound central vision impairment due to macular degeneration. Patients selected for implantation should meet the following criteria:

- 55 years of age or older with bilateral, stable central vision disorders resulting from age-related macular degeneration as determined by fluorescein angiography, and evidence of cataract.
- Distance BCVA between 20/80 and 20/800, and adequate peripheral vision in one eye (the non-targeted eye) to allow for orientation and mobility.
- Achieve at least a five-letter improvement on the ETDRS chart in the eye scheduled for surgery using an external telescope.
- Show interest in participating in a postoperative visual rehabilitation program.

## **5. CONTRAINDICATIONS**

Implantation of the AMD implant is contraindicated in patients with:

- Evidence of active CNV on fluorescein angiography or treatment for CNV within the past six months
- Any ophthalmic pathology that compromises the patient's peripheral vision in the fellow eye
- Significant communication impairments or severe neurological disorders
- Previous intraocular or corneal surgery of any kind in the operative eye, including any type of surgery for either refractive or therapeutic purposes.
- Prior or expected ophthalmic related surgery within 30 days preceding AMD implant surgery.
- A history of steroid-responsive rise in intraocular pressure, uncontrolled glaucoma, or preoperative IOP >22 mm Hg.
- Pregnancy or lactation.
- Known sensitivity to post-op medications
- The planned operative eye has:
  - Myopia > 6.0 D
  - Hyperopia > 4.0 D
  - An axial length < 21 mm

- Anterior chamber depth < 2.5mm
- Endothelial cell density < 1600 cells/mm<sup>2</sup>
- A narrow angle, i.e., < Schaffer grade 2
- Cornea stromal or endothelial dystrophies or disorders
- Inflammatory ocular disease
- Zonular weakness/instability of crystalline lens, or pseudoexfoliation
- Diabetic retinopathy
- Untreated retinal tears
- Retinal vascular disease
- Optic nerve disease
- A history of retinal detachment
- Intraocular tumor
- Retinitis pigmentosa
- An ocular condition that predisposes the patient to eye rubbing

## 6. DIRECTIONS FOR USE

**Caution:** Fragile glass components – the telescope (optical portion) is comprised of glass. Do not impose any mechanical forces on the optical portion. Grasp the device by the clear PMMA carrier plate. The device is intended for placement in an intact capsular bag with a 7 mm anterior capsulorhexis after extraction of the crystalline lens. Do not implant if there is zonular instability or inadequate capsular bag integrity.

1. In a sterile environment, peel to open the pouch to present the device case.
2. Twist and remove the screw cap. The anterior aspect of the device is up, as it sits in the case. Do not re-screw cap back on case.
3. Use forceps to grasp carrier plate when removing device from case. Avoid grasping or handling of haptic loops and glass telescope.
4. Examine the implant thoroughly to ensure it is free from debris, and examine the optical surfaces under magnification for other defects.

**Caution:** Do not use the device if the package has been opened or damaged, as the sterility of the device may be compromised.

### 6.1 PATIENT PREPARATION

Induce anesthesia by retrobulbar or peribulbar injection. Administer mydriatic agents to ensure adequate pupil dilatation during surgery. Place a lid speculum on the eye to be implanted, to provide maximum cornea exposure. 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.

## 6.2 DEVICE IMPLANTATION

**Caution:** The AMD device is a large visual prosthetic device; 4.4mm long with large stiff loops (13.5mm) requiring a large incision and capsulorhexis for implantation. The risk of endothelial cell loss is significantly higher than intraocular lens (IOL) implantation procedures. Special care should be taken to minimize the risk of corneal endothelial cell loss including attention to proper patient selection, appropriate surgical techniques, device handling precautions, selection and use of ocular viscoelastic devices (OVD), wound management, appropriate post-procedure medications and patient instructions. Corneal decompensation resulting from operative complications necessitating device removal, IOL implantation, and penetrating keratoplasty has occurred in two patients participating in a pivotal clinical evaluation of the device.

The visual prosthetic device may be implanted in the posterior chamber using a limbal insertion technique. The crystalline lens must be removed before the device can be implanted in the posterior chamber. Lens extraction can be performed using the surgeon's preferred method with phacoemulsification. The following steps have been identified:

1. Maximally dilate the pupil. Create a 12-13 mm conjunctival incision and achieve hemostasis by cautery. Create 12 mm partial thickness limbal groove. Note: Less beveled incision allows advantageous device entry angle into anterior chamber (AC).

**Caution:** do not make smaller incision as it will make device implantation more difficult.

2. Make paracentesis and inject ophthalmic viscosurgical devices (OVD) into the AC, e.g., "softshell technique." Coat endothelium with dispersive OVD and fill the AC with cohesive OVD.
3. After the incisions are made, create a continuous curvilinear capsular incision to achieve a 7.0 mm capsulorhexis.

**Caution:** do not make a smaller capsulorhexis as it makes device implantation more difficult.

4. Phacoemulsification is performed to remove the lens utilizing settings that help preserve endothelial cells. Special care should be taken to remove any cortical remnants and polish the posterior capsular bag.

**Caution:** do not implant the device if capsule integrity is compromised (insert IOL instead).

5. OVD use and incision preparation: Utilize the "Softshell technique" as follows to prepare the anterior segment. First, coat the endothelium with dispersive OVD (e.g., Viscoat); then inject cohesive OVD (e.g., Healon V or other viscoadaptive/cohesive OVD) to fill the AC and capsular bag. Note: lower viscosity OVDs may "burp" out during device insertion. Coat the device with OVD. A dispersive OVD (e.g., Viscoat or equivalent) is used to liberally coat the device (optical portion and leading haptic). Enlarge the incision to 12 mm.

6. Device handling, implantation, and precautions:

**Caution:**

- The device is comprised of a glass optical apparatus. Damage (micro-cracks) can be induced due to trauma to the devices during handling and manipulation.
- Compression of the optical element of the device resulting from improper handling by surgical instruments can induce such a failure.
- The haptics are stiff - use of sharp forceps, when manipulated aggressively, can induce forces sufficient to damage or break the loops of the device.

**Device implantation into capsular bag:**

- a) Grasp the device by the device's carrier plate;
- b) Lift the cornea maximally while avoiding "tenting;"
- c) Avoid contact with the corneal endothelium;
- d) The leading loop inserted into the bag with device at approximately 45 degrees to the horizontal plane;
- e) Both loops must be placed inside the capsular bag. Direct placement using a superior haptic compression technique should be employed.

**Caution:** Dialing the trailing haptic into position should be avoided as the haptics are too stiff. A second instrument through the paracentesis incision may be helpful in holding the device steady during trailing haptic placement.

- f) Loops are bimanually rotated to the 12:6 o'clock position.

**Caution:** Liberally coat the device with dispersive OVD prior to insertion. Avoid corneal touch during the implant procedure. Iris damage increases the risk of endothelial cell loss. Use OVDs appropriately to insure the AC does not flatten.

7. Once device is in place, place several uninterrupted sutures to create water-tight incision and prevent shallowing AC. Constrict the pupil.
8. Irrigate and meticulously aspirate OVD to minimize post-operative IOP spikes. Special care is to be taken to remove OVD between the carrier plate and the capsular bag.
9. A peripheral iridectomy is performed.
10. Additional sutures are placed to close the wound and knots trimmed and buried.
11. Test the incision carefully for leakage.

A sub-Tenon's injection of betamethasone depot (or appropriate substitute) is to be administered at the end of surgery.

**6.3 POSTOPERATIVE TREATMENT**

- Avoid external pressure of the eye. Use a plastic eye-shield for several days.

- Avoid ocular hypotension.
- Administer one drop of a topical ophthalmic antibiotic solution following surgery, and then continue as per product labeling for at least two days.
- Administer one drop of Voltaren Ophthalmic (diclofenac sodium 0.1%, CIBA Vision Ophthalmics) following surgery, and then continue as per product labeling for at least two days.
- Administer prednisolone acetate (1%) administered every 2 waking hours for the first two weeks post-implantation, followed by administration every 4 waking hours for 2-4 weeks.
- Gradually taper prednisolone acetate (1%) over the next 4 to 6 weeks 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.
- Administer homatropine 5% twice daily for 4 to 6 weeks postoperatively. If homatropine is inadequate to maintain cycloplegia, atropine may be used.

#### **6.4 POSTERIOR CAPSULE OPACIFICATION**

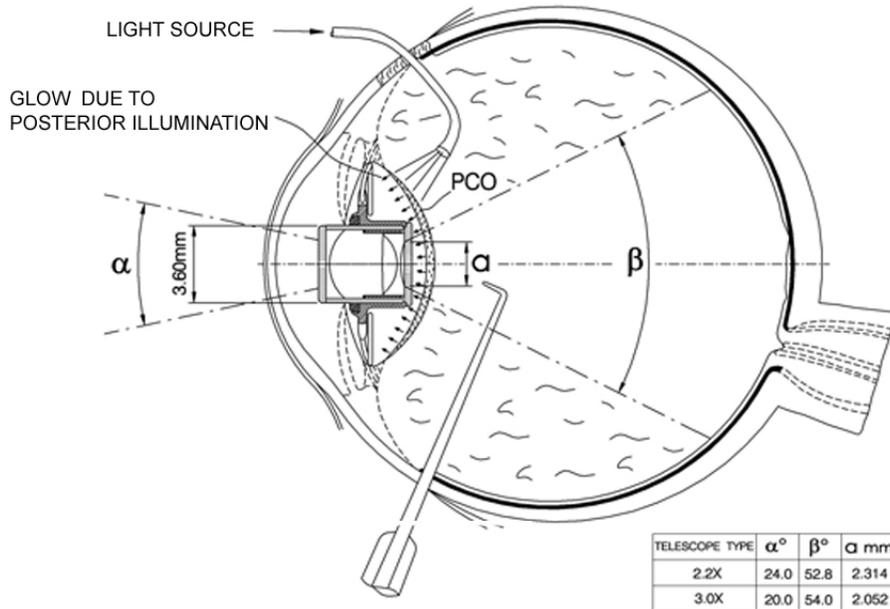
In the event visually significant posterior capsule opacification (PCO) occurs, YAG laser capsulotomy can be performed. In addition or in conjunction with YAG capsulotomy, needling may be utilized to remove the secondary cataract.

Instructions for use of Nd:YAG laser for PCO in patient implanted with an IMT are as follows:

- Maximally dilate the iris
- Insure there are no adhesions between the pupillary margin of the iris and the telescope apparatus. If adhesions are present, carefully dissect the adhesions with the laser.
- Aim the laser at the posterior capsule and fire the laser around the periphery of the telescope.
- Avoid contact between the laser and optical glass elements of the telescope. Contact with the glass optical element may damage the telescope.
- Do not aim and fire the laser through the optical telescope member of the device. Firing the laser through the telescope may damage the device.
- The laser can be aimed through and fired through the clear PMMA carrier plate and haptics.
- Needling may be required to complete dislodgement of the membrane from the posterior aspect of the IMT. If needling is utilized, special care should be taken to minimize any force and to avoid scratching or damaging the posterior window of the device.

As an alternative to the use of a YAG laser, a standard needling procedure may be used to treat PCO in patients implanted with the AMD device along with cleaning of the PCO by rupturing a rhexis on the posterior wall of the capsular bag.

Two patients implanted with the IMT successfully underwent treatment for PCO with needling; one of these cases employed a pars plana approach as illustrated below:



## 7. PRECAUTIONS

- Do not re-sterilize the device.
- Do not hold the device by or apply any mechanical forces on the glass telescope (optical portion).
- Do not re-screw the top of the device case when the telescope implant is seated in the holding well.
- Do not soak or rinse the device with any solution other than sterile balanced salt solution or sterile normal saline.
- Do not store the device in direct sunlight or at a temperature higher than 43°C. Do not autoclave the device.
- Do not expose the device to a pressure above 1.5 atm (absolute).
- Do not use the device if it has been dropped onto a hard surface during surgical handling.

## 8. WARNINGS

Physicians considering implanting the AMD device should weigh the potential risk/benefit ratio:

- As with any surgical procedure, risk is involved. Potential complications accompanying cataract extraction and AMD implant surgery may include, but are not limited to: (acute) corneal decompensation, choroidal detachment, choroidal hemorrhage, corneal edema, microbial infection, retinal detachment, vitreous loss, posterior capsular rupture, intraocular inflammation, uveitis etc.
- Surgical difficulties at the time of cataract extraction that might increase the potential for complications (e.g., persistent bleeding, significant iris damage, uncontrolled positive pressure, or significant vitreous prolapse or loss).
- The AMD device is large and requires a 12mm corneal incision and 7mm capsulorhexis for implant. The risk of corneal endothelial cell loss during implantation is higher than conventional anterior segment procedures and endothelial cell loss over time may be higher than IOLs over time.
- Some adverse events that have been associated with implantation of intraocular lenses include: hypopyon, intraocular infection, acute corneal decompensation, and secondary surgical intervention.
- Secondary surgical intervention includes: implant repositioning, implant removal, corneal transplant, and implant replacement.
- A very small percentage of patients (< 2% in the U.S. Clinical Study) may be dissatisfied to the point that they have the device explanted.
- Thermal lasers should be used with extreme caution around the device and never through the glass optical portion.
- The long-term effects of the AMD implant have not been established, including loss of patterned input to portions of the sensory retina occluded by the device. Physicians should continue to monitor implant patients postoperatively on a regular basis.
- Patients must be informed that participation in visual rehabilitation is necessary to maximize the benefit of the change in visual status. The inability or failure to participate in visual rehabilitation may significantly diminish the potential benefits of the procedure.
- The patient must be informed that eye rubbing should be avoided as much as possible.
- The AMD implant restricts the patient's peripheral field. The functional field of view will be generally limited to that of the non-implanted eye.
- Note the Miniature Telescope (IMT™ by Dr. Isaac Lipshitz) is **MR unsafe – poses hazards in all MR environments.**

## 9. ENVIRONMENTAL HAZARDS

If any of the following occurs, the specific product will be disqualified for clinical use and should be returned to the manufacturer immediately:

- Damage to labeling that prevents clear identification or print.
- Damaged Tyvek seal.
- Seriously crushed/deformed package.
- Package exposed to temperatures higher than 54<sup>0</sup>C and/or lower than -23<sup>0</sup>C for a period of more than 2 hours.

- Package exposed to pressure higher than 1.5 atm (abs.) and/or lower than 0.5 atm (abs.).
- Package fell from higher than 1.2 m.
- The device fell from higher than 12.5 cm onto a rigid surface.

## 10. U.S. CLINICAL STUDY RESULTS

The data for this report were gathered from a prospective, multicenter clinical evaluation of the use of the AMD implant in subjects with bilateral, stable moderate to profound central vision impairment due to age-related macular degeneration.

The objective of this study was to demonstrate the safety and effectiveness of the AMD implant for the improvement of visual acuity in patients with bilateral moderate to severe central vision impairment due to age-related macular degeneration.

The primary efficacy variable for this study was an improvement of 2 lines or greater in either near or distance best corrected acuity in 50% of the implanted eyes at 12 months post implantation. Quality of Life questionnaires were used as secondary measurements of procedure success. Safety outcomes included preservation of best corrected visual acuity (i.e., no more than 10% of implanted eyes were to experience a loss of either near (8” and 16”) or distance BCVA without a corresponding improvement or with a loss in the other measure of acuity.

A total of 206 eyes were successfully implanted at 28 US clinical sites. Of the 206 eyes, 115 were implanted with the 2.2X WA AMD implant and 91 were implanted with the 3.0X WA AMD implant. As anticipated, this is an elderly study population (mean age at surgery was 75.4 years [S.D. 7.2, range 55 – 93 years]). The cohort consisted primarily of Caucasians.

Table 10-1 presents the effectiveness and safety endpoints in visual acuity for all implanted eyes. Per protocol, effectiveness was defined as an improvement of 2 lines or greater in either near or distance best corrected acuity in 50% of the implanted eyes at 12 months post-implantation. This overall success rate was achieved by 89.1% of eyes at 6 months, by 89.7% at 9 months, 90.1% at 12 months and remained stable at 87.2% at 18 months and 85.7% at 24 months. These results significantly surpassed the effectiveness endpoint defined in the protocol. The proportion of eyes that showed a gain of at least 2 lines in both BCDVA **and** BCNVA underscore the effectiveness of the AMD implant with approximately 70% of eyes achieving an improvement of 2 or more lines in both near and distance acuity. The proportion of eyes with >2 lines loss in BCDVA and no gain in BCNVA, or >2 lines loss in BCNVA and no gain in BCDVA was 4.5% at 6 months, 4.6% at 9 months, 5.2% at 12 months, 4.5% at 18 months, and 6.1% at 24 months.

**TABLE 10-1**  
**SUMMARY OF EFFECTIVENESS AND SAFETY ENDPOINTS IN VISUAL ACUITY**  
**ALL EYES IMPLANTED WITH IMT™** (BY DR. ISAAC LIPSHITZ)

BCVA Endpoints	6 Months n (%) % CI	9 Months n (%) % CI	12 Months n (%) % CI	18 Months n (%) % CI	24 Months n (%) % CI
<b>Effectiveness (N=)</b>	201	195	192	179	147
<b>Overall Effectiveness Endpoint (Success Rate)</b>	<b>179</b>	<b>175</b>	<b>173</b>	<b>156</b>	<b>126</b>
<i>(Success Rate)</i>	<i>(89.1%)</i>	<i>(89.7%)</i>	<i>(90.1%)</i>	<i>(87.2%)</i>	<i>(85.7%)</i>
<b>≥2 lines gain of BCDVA or BCNVA*</b>	<b>84.7%, 92.5%</b>	<b>85.4%, 93.1%</b>	<b>85.8%, 93.4%</b>	<b>82.3%, 91.1%</b>	<b>80.1%, 90.2%</b>
<b>Binomial exact p-value for Ha: success rate &gt; 50%</b>	<b>&lt;.0001</b>	<b>&lt;.0001</b>	<b>&lt;.0001</b>	<b>&lt;.0001</b>	<b>&lt;.0001</b>
<b>≥2 lines gain of BCDVA and BCNVA*</b>	138 (68.7%) 62.8%, 74.1%	134 (68.7%) 62.8%, 74.2%	141 (73.4%) 67.7%, 78.6%	127 (70.9%) 64.9%, 76.5%	99 (67.3%) 60.4%, 73.7%
Not reported/IMT removal	1	1	2	1	1
Total	202	196	194	180	148
<b>Safety (N=)</b>	201	195	193	179	147
<b>Overall Safety Rate</b>					
<b>&gt;2 lines loss of BCDVA and no change/loss of BCNVA or &gt;2 lines loss of BCNVA and no change/loss of BCDVA†</b>	<b>9 (4.5%) 2.4%, 7.7%</b>	<b>9 (4.6%) 2.4%, 7.9%</b>	<b>10 (5.2%) 2.8%, 8.6%</b>	<b>8 (4.5%) 2.2%, 7.9%</b>	<b>9 (6.1%) 3.2%, 10.4%</b>
<b>Binomial exact p-value for Ha: safety rate &lt; 10%</b>	<b>0.0033</b>	<b>0.0048</b>	<b>0.0120</b>	<b>0.0055</b>	<b>0.0696</b>
<b>&gt;2 lines loss of BCDVA and BCNVA‡</b>	2 (1.0%) 0.2%, 3.1%	4 (2.1%) 0.7%, 4.6%	2 (1.0%) 0.2%, 3.2%	2 (1.1%) 0.2%, 3.5%	2 (1.4%) 0.2%, 4.2%
<b>&gt;2 lines loss of BCDVA and no change in BCNVA§</b>	1 (0.5%) 0.0%, 2.3%	2 (1.0%) 0.2%, 3.2%	1 (0.5%) 0.0%, 2.4%	1 (0.6%) 0.0%, 2.6%	0 (0.0%) 0.0%, 2.0%
<b>&gt;2 lines loss of BCNVA and no change of BCDVA§</b>	6 (3.0%) 1.3%, 5.8%	3 (1.5%) 0.4%, 3.9%	7 (3.6%) 1.7%, 6.7%	5 (2.8%) 1.1%, 5.8%	7 (4.8%) 2.3%, 8.8%
Not reported/IMT removal	1	1	1	1	1
Total	202	196	194	180	148

For effectiveness, N = number of records with non-missing BCDVA and BCNVA changes from preop. The records with BCDVA gain ≥2 lines and BCNVA missing and the records with BCNVA gain ≥2 lines and BCDVA missing were counted as successful events.

For safety, N = number of records with non-missing BCDVA and BCNVA changes from preop. The records with BCDVA loss > 2 lines and BCNVA missing and the records with BCNVA loss > 2 lines and BCDVA missing were counted as safety events.

Not reported = number of records with missing BCDVA and/or BCNVA changes from preop.

IMT removal = number of treated eyes with IMT removal at the visit. Records after IMT removal were excluded and reported separately.

Total = number of treated eyes that returned for the visit.

% = n ÷ N × 100. %CI = **90%** confidence interval for %. It was calculated based on Clopper Pearson method.

\* BCNVA gain ≥2 lines means that either BCNVA at 8" or BCNVA at 16" gained ≥2 lines.

† No gain in BCNVA means that both BCNVA at 8" and BCNVA at 16" did not gain ≥2 lines. No gain in BCDVA means that BCDVA did not gain ≥2 lines.

‡ >2 lines loss in BCNVA means that one BCNVA (8" or 16" lost > 2 lines without the other BCNVA (8" or 16") gaining ≥2 lines.

§ No change = within a loss of 2 lines to a gain of <2 lines. For BCNVA, it means that both BCNVA at 8" and BCNVA at 16" are within a loss of 2 lines to a gain of <2 lines.

The substantial improvements in BCDVA and BCNVA were reflected in quality of life measurements. Table 10-2 shows the change in Vision Function Questionnaire (VFQ) score

from baseline for all eyes implanted with AMD implant. The VFQ-25 is a validated version of the National Eye Institute VFQ which measures vision-targeted health related quality of life for persons with chronic eye diseases including macular degeneration. A five (5) point difference in subscale and/or composite scores may be interpreted as clinically significant. VFQ-25 subscales of general vision, near activities, and distance activities improved by clinically meaningful levels of 14.0 points, 11.2 points, and 7.9 points in patients implanted with the AMD implant. Additionally clinically significant improvements across all vision specific subscales (social functioning, mental health, role difficulties, and dependency) were noted. In subscales where no improvement, non-applicability, or a decline in performance was expected (color vision, driving and peripheral vision), performance was stable or declined.

**TABLE 10-2**  
**CHANGE IN VFQ-25 SCORE FROM BASELINE,**  
**ALL EYES IMPLANTED WITH IMT™** (BY DR. ISAAC LIPSHITZ)

<b>Change in VFQ-25</b>	<b>3 Months</b>	<b>6 Months</b>	<b>9 Months</b>	<b>12 Months</b>
<b>General Vision</b>	<b>N = 199</b>	<b>N = 200</b>	<b>N = 196</b>	<b>N = 193</b>
Mean (SD)	17.99 (20.60)	16.90 (21.23)	15.10 (20.47)	14.09 (21.99)
95% confidence interval for mean*	15.11, 20.87	13.94, 19.86	12.22, 17.99	10.97, 17.22
Median	20.00	20.00	20.00	20.00
Range	-40.00, 60.00	-40.00, 80.00	-20.00, 60.00	-40.00, 60.00
<b>Near Activities</b>	<b>N = 199</b>	<b>N = 200</b>	<b>N = 196</b>	<b>N = 193</b>
Mean (SD)	12.63 (17.91)	12.10 (19.35)	11.93 (18.68)	11.16 (19.28)
95% confidence interval for mean*	10.12, 15.13	9.41, 14.80	9.30, 14.56	8.42, 13.90
Median	8.34	8.34	8.34	8.34
Range	-33.33, 58.34	-33.34, 58.34	-33.33, 75.00	-25.00, 100.00
<b>Distance Activities</b>	<b>N = 199</b>	<b>N = 200</b>	<b>N = 196</b>	<b>N = 193</b>
Mean (SD)	11.56 (22.09)	11.04 (22.44)	9.99 (23.58)	7.90 (24.68)
95% confidence interval for mean*	8.47, 14.65	7.91, 14.17	6.67, 13.31	4.40, 11.41
Median	8.34	8.34	8.33	8.33
Range	-41.67, 75.00	-50.00, 75.00	-37.50, 83.34	-50.00, 83.34
<b>Social Functioning</b>	<b>N = 199</b>	<b>N = 200</b>	<b>N = 196</b>	<b>N = 193</b>
Mean (SD)	11.68 (27.90)	11.13 (25.64)	8.86 (27.42)	8.61 (26.63)
95% confidence interval for mean*	7.78, 15.58	7.55, 14.70	5.00, 12.73	4.83, 12.39
Median	12.50	12.50	12.50	0.00
Range	-75.00, 100.00	-62.50, 87.50	-87.50, 75.00	-75.00, 75.00
<b>Mental Health</b>	<b>N = 199</b>	<b>N = 200</b>	<b>N = 196</b>	<b>N = 193</b>
Mean (SD)	9.83 (23.24)	9.81 (22.81)	9.15 (22.83)	9.29 (22.54)
95% confidence interval for mean*	6.58, 13.08	6.63, 12.99	5.94, 12.37	6.09, 12.49
Median	6.25	6.25	6.25	6.25
Range	-50.00, 87.50	-50.00, 87.50	-62.50, 81.25	-50.00, 81.25
<b>Role Difficulties</b>	<b>N = 199</b>	<b>N = 200</b>	<b>N = 196</b>	<b>N = 193</b>
Mean (SD)	9.30 (24.52)	7.88 (26.62)	9.25 (29.41)	7.25 (26.13)
95% confidence interval for mean*	5.87, 12.72	4.16, 11.59	5.10, 13.39	3.54, 10.96
Median	12.50	0.00	0.00	0.00
Range	-75.00, 75.00	-75.00, 87.50	-62.50, 87.50	-62.50, 87.50
<b>Dependency</b>	<b>N = 199</b>	<b>N = 200</b>	<b>N = 196</b>	<b>N = 193</b>
Mean (SD)	10.64 (27.99)	9.83 (26.81)	9.40 (26.87)	10.02 (27.53)
95% confidence interval for mean*	6.72, 14.55	6.10, 13.57	5.61, 13.18	6.11, 13.93
Median	8.33	8.33	8.33	8.33
Range	-66.67, 83.33	-58.33, 100.00	-41.67, 91.67	-66.67, 100.00

N = number of treated eyes returned for the visit with a non-missing change in VFQ-25 assessment. Records after IMT removal were excluded.

Per protocol, VFQ-25 was performed at baseline, and the 1, 3, 6, 9, and 12 months follow-up visits.

\* Normal distribution approach was used for mean. CI for % was calculated based on Clopper Pearson method.

**TABLE 10-2 (CONTINUED)**  
**CHANGE IN VFQ-25 SCORE FROM BASELINE**  
**ALL EYES IMPLANTED WITH IMT™ (BY DR. ISAAC LIPSHITZ)**

<b>Change in VFQ-25</b>	<b>3 Months</b>	<b>6 Months</b>	<b>9 Months</b>	<b>12 Months</b>
<b>Driving</b>	<b>N = 187</b>	<b>N = 185</b>	<b>N = 184</b>	<b>N = 179</b>
Mean (SD)	-0.82 (7.49)	0.12 (6.69)	-0.29 (6.29)	-0.52 (7.00)
95% confidence interval for mean*	-1.90, 0.26	-0.85, 1.09	-1.21, 0.63	-1.55, 0.51
Median	0.00	0.00	0.00	0.00
Range	-60.00, 35.00	-45.00, 35.00	-45.00, 35.00	-45.00, 40.00
<b>Peripheral Vision</b>	<b>N = 197</b>	<b>N = 197</b>	<b>N = 194</b>	<b>N = 190</b>
Mean (SD)	-1.90 (30.82)	-2.66 (33.06)	-1.42 (31.81)	-5.92 (30.99)
95% confidence interval for mean*	-6.23, 2.43	-7.31, 1.98	-5.92, 3.09	-10.36, -1.49
Median	0.00	0.00	0.00	0.00
Range	-75.00, 100.00	-100.0, 100.00	-75.00, 100.00	-75.00, 100.00
<b>Color Vision</b>	<b>N = 190</b>	<b>N = 190</b>	<b>N = 189</b>	<b>N = 185</b>
Mean (SD)	8.95 (26.83)	6.71 (27.78)	6.48 (27.43)	3.38 (24.56)
95% confidence interval for mean*	5.11, 12.79	2.74, 10.69	2.55, 10.42	-0.18, 6.94
Median	0.00	0.00	0.00	0.00
Range	-75.00, 100.00	-75.00, 100.00	-75.00, 100.00	-75.00, 75.00
<b>Ocular Pain</b>	<b>N = 199</b>	<b>N = 200</b>	<b>N = 196</b>	<b>N = 193</b>
Mean (SD)	2.83 (16.78)	-0.44 (18.56)	1.08 (17.39)	0.58 (18.85)
95% confidence interval for mean*	0.48, 5.17	-3.03, 2.15	-1.37, 3.53	-2.09, 3.26
Median	0.00	0.00	0.00	0.00
Range	-50.00, 75.00	-50.00, 62.50	-62.50, 50.00	-75.00, 62.50
<b>Overall Composite</b>	<b>N = 199</b>	<b>N = 200</b>	<b>N = 196</b>	<b>N = 193</b>
Mean (SD)	8.38 (13.42)	7.43 (13.90)	7.23 (14.16)	6.03 (14.41)
95% confidence interval for mean*	6.50, 10.25	5.49, 9.37	5.24, 9.23	3.98, 8.07
Median	6.56	5.89	4.57	5.34
Range	-20.46, 50.15	-19.73, 50.15	-19.43, 51.85	-31.29, 58.29
n & % of eyes with increase ≥5 points	107 ( 53.8%)	103 ( 51.5%)	94 ( 48.0%)	100 ( 51.8%)
95% confidence interval for %*	46.6%, 60.8%	44.3%, 58.6%	40.8%, 55.2%	44.5%, 59.0%
<b>General Health</b>	<b>N = 199</b>	<b>N = 200</b>	<b>N = 196</b>	<b>N = 193</b>
Mean (SD)	-2.89 (20.75)	-3.38 (22.09)	-5.10 (21.32)	-5.05 (21.73)
95% confidence interval for mean*	-5.79, 0.01	-6.46, -0.29	-8.11, -2.10	-8.14, -1.97
Median	0.00	0.00	0.00	0.00
Range	-50.00, 50.00	-100.0, 75.00	-75.00, 50.00	-75.00, 50.00

N = number of treated eyes returned for the visit with a non-missing change in VFQ-25 assessment. Records after IMT removal were excluded.

Per protocol, VFQ-25 was performed at baseline, and the 1, 3, 6, 9, and 12 months follow-up visits.

\* Normal distribution approach was used for mean. CI for % was calculated based on Clopper Pearson method.

Table 10-3 shows the change in Activities of Daily Living (ADL) score from baseline for all eyes implanted with AMD implant. The ADL questionnaire is a modified version of the Activities of Daily Vision Scale to more appropriately address challenges facing individuals with end-stage macular degeneration. ADL subscales of navigation, distance activities and near activities improved significantly.

**TABLE 10-3**  
**CHANGE IN ADL SCORE FROM BASELINE**  
**ALL EYE IMPLANTED WITH IMT™**<sub>(BY DR. ISAAC LIPSHITZ)</sub>

Change in ADL	3 Months	6 Months	9 Months	12 Months
<b>Mobility</b>	<b>N = 199</b>	<b>N = 200</b>	<b>N = 196</b>	<b>N = 193</b>
Mean (SD)	15.82 (20.82)	14.00 (22.49)	12.90 (22.46)	11.97 (22.80)
95% confidence interval for mean*	12.91, 18.73	10.87, 17.14	9.73, 16.06	8.74, 15.21
Median	14.50	12.50	12.50	10.50
Range	-35.50, 75.00	-56.25, 81.25	-56.25, 87.50	-56.25, 100.00
<b>Distance Activities</b>	<b>N = 199</b>	<b>N = 200</b>	<b>N = 196</b>	<b>N = 193</b>
Mean (SD)	17.37 (19.60)	15.29 (20.10)	15.29 (20.68)	13.36 (20.97)
95% confidence interval for mean*	14.63, 20.11	12.48, 18.09	12.38, 18.20	10.38, 16.34
Median	16.50	13.75	12.50	12.50
Range	-21.00, 87.50	-33.50, 66.75	-33.50, 71.00	-33.50, 100.00
<b>Near Activities</b>	<b>N = 199</b>	<b>N = 200</b>	<b>N = 196</b>	<b>N = 193</b>
Mean (SD)	21.75 (21.55)	20.92 (22.22)	18.30 (23.10)	17.01 (22.27)
95% confidence interval for mean*	18.74, 24.76	17.82, 24.02	15.05, 21.55	13.85, 20.17
Median	20.75	20.75	20.00	16.50
Range	-40.00, 85.75	-35.00, 81.75	-54.25, 80.75	-46.00, 91.50
<b>Total</b>	<b>N = 199</b>	<b>N = 200</b>	<b>N = 196</b>	<b>N = 193</b>
Mean (SD)	18.49 (18.40)	16.99 (19.10)	15.82 (19.77)	14.15 (19.63)
95% confidence interval for mean*	15.91, 21.06	14.32, 19.65	13.04, 18.61	11.37, 16.94
Median	18.75	16.88	14.88	12.50
Range	-25.00, 76.75	-35.50, 68.75	-35.50, 69.75	-34.75, 81.25
n & % of eyes with increase ≥10 points	134 ( 67.3%)	128 ( 64.0%)	113 ( 57.7%)	110 ( 57.0%)
95% confidence interval for %*	60.3%, 73.8%	56.9%, 70.6%	50.4%, 64.7%	49.7%, 64.1%

N = number of treated eyes returned for the visit with a non-missing change in ADL assessment. Records after IMT removal were excluded.

Per protocol, ADL was performed at baseline, and the 1, 3, 6, 9, and 12 months follow-up visits.

\* Normal distribution approach was used for mean. CI for % was calculated based on Clopper Pearson method.

Statistical analyses revealed a statistically significant relationship between change in VFQ-25 composite score and change in ADL total score at each postoperative examination (p < 0.0001 at 3, 6, 9 and 12 month).

Ocular adverse events reported for all eyes implanted with an AMD implant are shown in Table 10-4 for all regularly scheduled visits, including subject visits following AMD implant removal, and for all unscheduled interim visits. The cumulative incidence of each adverse event is displayed in Table 10-4 as well. The AMD implant was removed from eight eyes postoperatively after the initial implantation procedure. Four subjects requested removal of the AMD implant since they were dissatisfied with the device. The AMD implant was also removed from two eyes due to condensation of the telescope portion of the AMD implant, and in two eyes that underwent corneal transplantation as a result of corneal decompensation.

A total of four device failures have been reported in this 24-month study. Two failures involved a broken haptic, one case occurred prior to implantation and one occurred during implantation, requiring intraoperative AMD implant replacement. The two other device failures consisted of condensation in the telescope portion of the AMD implant, and resulted in postoperative AMD implant removal (see previous paragraph).

**TABLE 10-4**  
**REPORTED OCULAR ADVERSE EVENTS**  
**ALL EYES IMPLANTED WITH IMT™ (BY DR. ISAAC LIPSHITZ)**

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Adverse Events	Operative N = 206	Day 1 N = 206	Day 7 N = 205	1 Month N = 206	3 Months N = 201	6 Months N = 202	9 Months N = 196	12 Months N = 194	18 Months N = 180	24 Months N = 148	Interim N = 109	Cumulative N = 206
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Anterior chamber inflammation > 30 days	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	3 ( 1.5%)	2 ( 1.0%)	2 ( 1.0%)	2 ( 1.0%)	3 ( 1.7%)	0 ( 0.0%)	3 ( 2.8%)	6 ( 2.9%)
Anterior ischemic optic neuropathy	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 0.5%)	1 ( 0.5%)	1 ( 0.5%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 0.9%)	1 ( 0.5%)
Choroidal neovascularization	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 0.5%)	1 ( 0.5%)	1 ( 0.5%)	1 ( 0.6%)	2 ( 1.4%)	0 ( 0.0%)	3 ( 1.5%)
Conjunctivitis	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 0.5%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	3 ( 2.8%)	4 ( 1.9%)
Corneal decompensation > 7 days	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2 ( 1.0%)	2 ( 1.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2 ( 1.0%)
Corneal edema > 30 days	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 0.5%)	1 ( 0.5%)	1 ( 0.5%)	0 ( 0.0%)	0 ( 0.0%)	3 ( 2.0%)	2 ( 1.8%)	6 ( 2.9%)
Cyclitic membrane > 7 days	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 0.5%)	1 ( 0.5%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 0.5%)
Cystoid macular edema	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 0.5%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 0.5%)
Decrease in visual acuity	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 0.5%)	2 ( 1.0%)	2 ( 1.0%)	2 ( 1.0%)	2 ( 1.0%)	2 ( 1.1%)	3 ( 2.0%)	2 ( 1.8%)	4 ( 1.9%)
Device failure	1 ( 0.5%)	2 ( 1.0%)	2 ( 1.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2 ( 1.0%)
Diplopia	0 ( 0.0%)	1 ( 0.5%)	1 ( 0.5%)	1 ( 0.5%)	2 ( 1.0%)	2 ( 1.0%)	2 ( 1.0%)	2 ( 1.0%)	1 ( 0.6%)	1 ( 0.7%)	2 ( 1.8%)	3 ( 1.5%)
Distorted pupil	0 ( 0.0%)	1 ( 0.5%)	3 ( 1.5%)	3 ( 1.5%)	3 ( 1.5%)	5 ( 2.5%)	4 ( 2.0%)	4 ( 2.1%)	4 ( 2.2%)	2 ( 1.4%)	3 ( 2.8%)	7 ( 3.4%)
Dry eye	0 ( 0.0%)	0 ( 0.0%)	1 ( 0.5%)	1 ( 0.5%)	2 ( 1.0%)	2 ( 1.0%)	6 ( 3.1%)	4 ( 2.1%)	3 ( 1.7%)	1 ( 0.7%)	4 ( 3.7%)	10 ( 4.9%)
Entropion	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 0.5%)	1 ( 0.5%)	1 ( 0.5%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 0.9%)	2 ( 1.0%)
Exposed suture	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	3 ( 2.8%)	3 ( 1.5%)
Eye pain	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2 ( 1.0%)	2 ( 1.0%)	1 ( 0.6%)	1 ( 0.7%)	3 ( 2.8%)	3 ( 1.5%)
Flat anterior chamber > 21 days	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 0.5%)	1 ( 0.5%)	1 ( 0.6%)	1 ( 0.7%)	0 ( 0.0%)	1 ( 0.5%)
Floaters	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 0.5%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 0.5%)	1 ( 0.6%)	1 ( 0.7%)	1 ( 0.9%)	2 ( 1.0%)
Focal striae	0 ( 0.0%)	1 ( 0.5%)	1 ( 0.5%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 0.5%)
Foreign body sensation	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 0.5%)	2 ( 1.0%)	4 ( 2.0%)	4 ( 2.0%)	4 ( 2.1%)	4 ( 2.2%)	1 ( 0.7%)	7 ( 6.4%)	9 ( 4.4%)
Guttae	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 0.5%)	7 ( 3.5%)	8 ( 4.1%)	13 ( 6.7%)	11 ( 6.1%)	9 ( 6.1%)	3 ( 2.8%)	16 ( 7.8%)
IMT dislocation	0 ( 0.0%)	0 ( 0.0%)	2 ( 1.0%)	2 ( 1.0%)	1 ( 0.5%)	1 ( 0.5%)	1 ( 0.5%)	1 ( 0.5%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 0.9%)	2 ( 1.0%)
IMT removal	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	8 ( 7.3%)	8 ( 3.9%)
IMT replacement	1 ( 0.5%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 0.9%)	1 ( 0.5%)
Increased IOP requiring treatment > 7 days	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	5 ( 2.4%)	2 ( 1.0%)	1 ( 0.5%)	1 ( 0.5%)	1 ( 0.5%)	1 ( 0.6%)	2 ( 1.4%)	3 ( 2.8%)	7 ( 3.4%)

% = n/N × 100.

The same adverse event could have been reported for a subject at multiple visits.

**TABLE 10-4 (CONTINUED)**

**REPORTED OCULAR ADVERSE EVENTS**  
**ALL EYES IMPLANTED WITH IMT™** (BY DR. ISAAC LIPSHITZ)

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Adverse Events	Operative N = 206	Day 1 N = 206	Day 7 N = 205	1 Month N = 206	3 Months N = 201	6 Months N = 202	9 Months N = 196	12 Months N = 194	18 Months N = 180	24 Months N = 148	Interim N = 109	Cumulative N = 206
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Inflammatory deposits on IMT	0 ( 0.0%)	2 ( 1.0%)	9 ( 4.4%)	2 ( 1.0%)	5 ( 2.5%)	18 ( 8.9%)	21 ( 10.7%)	25 ( 12.9%)	24 ( 13.3%)	10 ( 6.8%)	6 ( 5.5%)	51 ( 24.8%)
Inflammatory membrane	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 0.5%)	1 ( 0.5%)	0 ( 0.0%)	1 ( 0.5%)	1 ( 0.6%)	1 ( 0.7%)	1 ( 0.9%)	1 ( 0.5%)
Iridotomy > 7 days	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 0.5%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 0.6%)	0 ( 0.0%)	1 ( 0.9%)	3 ( 1.5%)
Iris atrophy > 7 days	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	4 ( 1.9%)	4 ( 2.0%)	4 ( 2.0%)	3 ( 1.5%)	6 ( 3.1%)	7 ( 3.9%)	7 ( 4.7%)	2 ( 1.8%)	7 ( 3.4%)
Iris transillumination defects > 21 days	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	5 ( 2.4%)	9 ( 4.5%)	9 ( 4.5%)	9 ( 4.6%)	8 ( 4.1%)	8 ( 4.4%)	6 ( 4.1%)	2 ( 1.8%)	11 ( 5.3%)
Iritis > 30 days	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	3 ( 1.5%)	2 ( 1.0%)	1 ( 0.5%)	0 ( 0.0%)	4 ( 2.2%)	1 ( 0.7%)	7 ( 6.4%)	12 ( 5.8%)
Keratic precipitates on IMT > 30 days	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 0.7%)	1 ( 0.9%)	2 ( 1.0%)
Obstructed iridectomy	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 0.5%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 0.5%)
Ocular allergy	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 0.9%)	1 ( 0.5%)
Pigment deposits on IMT	0 ( 0.0%)	1 ( 0.5%)	2 ( 1.0%)	1 ( 0.5%)	3 ( 1.5%)	4 ( 2.0%)	12 ( 6.1%)	12 ( 6.2%)	13 ( 7.2%)	7 ( 4.7%)	4 ( 3.7%)	23 ( 11.2%)
Pigment epithelium around the peripheral iridectomy > 30 days	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 0.5%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 0.5%)
Posterior synechiae	0 ( 0.0%)	0 ( 0.0%)	4 ( 2.0%)	4 ( 1.9%)	7 ( 3.5%)	9 ( 4.5%)	8 ( 4.1%)	8 ( 4.1%)	7 ( 3.9%)	4 ( 2.7%)	4 ( 3.7%)	15 ( 7.3%)
Ptosis	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 0.5%)	1 ( 0.5%)	1 ( 0.5%)	1 ( 0.5%)	1 ( 0.6%)	0 ( 0.0%)	1 ( 0.9%)	2 ( 1.0%)
Secondary glaucoma	0 ( 0.0%)	0 ( 0.0%)	2 ( 1.0%)	1 ( 0.5%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2 ( 1.0%)
Subconjunctival hemorrhage	0 ( 0.0%)	1 ( 0.5%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 0.5%)	1 ( 0.5%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	6 ( 5.5%)	9 ( 4.4%)
Subretinal hemorrhage	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 0.6%)	1 ( 0.7%)	0 ( 0.0%)	2 ( 1.0%)
Synechiae	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 0.5%)	1 ( 0.5%)	1 ( 0.5%)	1 ( 0.5%)	1 ( 0.6%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 0.5%)
Tearing	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 0.9%)	1 ( 0.5%)
Visual disturbance	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 0.5%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 0.9%)	1 ( 0.5%)
Vitreous flare	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 0.5%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 0.5%)
Vitreous hemorrhage > 7 days	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 0.5%)	1 ( 0.5%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	2 ( 1.8%)	3 ( 1.5%)
Vitreous in anterior chamber > 7 days	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	3 ( 1.5%)	1 ( 0.5%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	0 ( 0.0%)	1 ( 0.9%)	4 ( 1.9%)

% = n/N × 100.

The same adverse event could have been reported for a subject at multiple visits.

Table 10-5 shows endothelial cell density (ECD) for all IMT implanted eyes and Table 10-6 shows the percentage change in ECD from baseline for all device implanted eyes.

**TABLE 10-5**  
**ENDOTHELIAL CELL DENSITY (ECD)**  
**ALL EYES IMPLANTED WITH IMT™** (BY DR. ISAAC LIPSHITZ)

ECD	Preop	3 Months	6 Months	9 Months	12 Months	18 Months	24 Months
N	206	192	198	190	186	180	144
Mean	2496.13	1996.87	1936.83	1890.82	1871.29	1878.11	1786.36
Standard Deviation	354.33	585.92	579.73	572.29	592.09	618.22	602.61
Median	2510.0	2026.3	2017.8	1938.8	1929.5	1977.5	1860.0
Range	1695.0, 3356.0	432.3, 3125.7	385.3, 2935.7	309.0, 3008.0	310.7, 2959.0	351.0, 2900.0	385.7, 2930.0

N = number of successful IMT implanted eyes returned for the visit with non-missing ECD.  
 % =  $n \div N \times 100$

**TABLE 10-6**  
**PERCENTAGE CHANGE IN ENDOTHELIAL CELL DENSITY (ECD) FROM BASELINE**  
**ALL EYES IMPLANTED WITH IMT™** (BY DR. ISAAC LIPSHITZ)

ECD % Change from Baseline	3 Months	6 Months	9 Months	12 Months	18 Months	24 Months
N	192	198	190	186	180	144
Mean	-20.0%	-22.4%	-24.4%	-25.3%	-25.2%	-28.2%
Standard Deviation	21.1%	20.9%	20.5%	21.3%	22.2%	22.5%
90% confidence interval for mean	-22.5%, -17.5%	-24.8%, -19.9%	-26.9%, -22.0%	-27.9%, -22.7%	-28.0%, -22.5%	-31.3%, -25.1%
Median	-13.0%	-17.0%	-19.2%	-20.9%	-21.3%	-24.2%
Range	-85.1%, 18.0%	-84.4%, 30.9%	-87.5%, 13.5%	-87.6%, 12.7%	-87.9%, 25.1%	-80.9%, 28.1%

N = number of successful IMT implanted eyes returned for the visit with non-missing ECD change from baseline.  
 Percentage change in ECD from baseline =  $(\text{postop} - \text{baseline}) \div \text{baseline} \times 100$ .  
 % =  $n \div N \times 100$

Extensive statistical analyses showed that the most significant loss in ECD was observed from baseline to 3 months in the study cohort, with ECD loss tapering off after 3 months and stabilizing at the 9 month visit.

Since the most significant loss in ECD occurred at 3 months, factors that may have contributed to early cell loss were evaluated. The final model identified that Day 1 corneal edema and surgeon specialty are the two factors that appear to affect the mean change in ECD from baseline to 3 months.

In addition, the annual ECD percentage change was calculated for the 188 device implanted eyes with at least one postoperative ECD percentage change at 9 months or later, the mean annual percent change in ECD from 9 months to 24 months is -0.5% (S.D. 28.6%; 90% CI -4.0% to 2.9%). The annual ECD percentage change for the 24-month consistent cohort, which consists of 130 device implanted eyes, was -3.0% (S.D. 15.0%).

In order to compare the change in ECD after 3 months in the study cohort to a clinically relevant control group, the percentage change in ECD in pseudophakic fellow eyes was calculated. As would be anticipated, the change in ECD between visits in the pseudophakic fellow eyes was similar to that observed in the AMD implanted eyes, and greater than the change in ECD between visits than the cohort of all fellow eyes.

In summary, in this elderly, central vision impaired population suffering from permanent moderate to profound vision loss associated with macular degeneration, results of this clinical trial clearly establish the benefit of visual acuity improvements and quality of life benefits following IMT<sub>(by Dr. Isaac Lipshitz)</sub> implantation. The magnitude of improvement in vision achieved by the study population supports an acceptable overall risk-to-benefit ratio for the AMD implant.

## **11. PHYSICIAN TRAINING PROGRAM**

A surgeon training program has been developed to focus on the unique aspects of the AMD device surgical procedure that differ from other intraocular implants. As outlined below, there are seven components of the training program. Two components, i.e., the AMD device Physician-Led Training Session and In-service Program, are required prior to implantation of the first AMD device. The other components are optional and will be provided at the physician's request.

The training program consists of the following components:

- *AMD device Physician-Led Training Session:* A physician-led training session is required for anterior segment surgeons wanting to be approved to implant the AMD device.
- *In-service Program:* An in-service training, conducted by a VisionCare representative, is required for surgical staff prior to the first AMD device implantation procedure.
- *Online Education Forum:* An online training is available for anterior segment surgeons wanting to review and reference information for the utilization of the AMD device.
- *Surgical Technique Video:* A video demonstrating the recommended surgical procedure for the AMD device implantation is available to participating anterior segment surgeons.
- *Hands-on Simulation:* A hands-on simulation experience is provided to assist the anterior segment surgeon with the required instrumentation for the proper handling and insertion of the AMD device.
- *Medical Monitor Surgical Review:* A review and recommendations for technique adjustment, based on the anterior segment surgeon's video-recorded initial surgical cases, is provided by a Medical Monitor.

- *AMD Device Professional Education:* Continuing education courses are offered at key ophthalmic medical meetings.

## **12. ADVERSE EVENT REPORTING**

Adverse events and/or potentially sight-threatening complications that may reasonably be regarded as device-related should be reported to VisionCare. This information is being requested from all implanting surgeons in order to document potential long-term effects of device implantation.

*Purpose:* Physicians are required to report these events in order to aid in identifying emerging or potential problems with the AMD device implant. These problems may be related to a specific lot of devices or may be indicative of long-term problems associated with the AMD device implant. Physicians should use the following number when reporting adverse events involving the AMD device implant: (408) 872-9393.

## **13. HOW SUPPLIED**

The product is supplied sterile in three stiff package layers. The device in its immediate packaging is EtO sterilized and should be opened only under sterile conditions. An implant identification sticker is supplied in the device package. This label should be placed in the patient's medical file.

## **14. RECOMMENDED STORAGE AND TRANSPORTATION CONDITIONS**

- Ambient temperature - 0<sup>0</sup> C to 43<sup>0</sup> C (32<sup>0</sup> F to 109<sup>0</sup> F)
- Relative humidity – 20% to 95%
- Barometric pressure – 0.5 atm to 1.2 atm (abs.)
- Illumination – Not specified

Products not meeting the storage conditions specified in this document or damaged product packaging should not be used for clinical applications.

## **15. EXPIRATION DATE**

The expiration date on the product package is the sterility expiration date. The device should not be implanted after the indicated sterility expiration date.

## **16. INFORMATION FOR PATIENTS**

It is recommended that each patient receive information regarding the device in a manner that is 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 surgery technique, possible symptoms or discomfort, postoperative treatment, precautions, and the need to participate in postoperative visual rehabilitation sessions to help in performance of activities of daily living.

#### **17. RETURN/EXCHANGE POLICY**

Please contact VisionCare regarding device return or exchange. Due to device fragility, it is recommended to keep one spare implant in house.

*U.S. patents: 6,569,199 B1, 5,928,283, 5,391,202, 5,354,335, 6,596,026 B1*