



**Implantable Miniature Telescope (by Dr. Isaac Lipshitz)
for End-Stage Macular Degeneration**

Indication for Use (CE Marked Device)

Implantable Miniature Telescope (by Dr. Isaac Lipshitz)

INDICATION FOR USE (EU member states):

The IMT (by Dr. Isaac Lipshitz) is indicated for improvement of visual acuity in patients with bilateral moderate to profound central vision impairment due to age-related macular degeneration. Patients selected for implantation should meet the following criteria:

Patients must:

- Patients 55 years of age or older with bilateral, stable, untreatable central vision disorders resulting from age related macular degeneration as determined by fluorescein angiography, and cataract
- Patients with distance BCVA between 20/80 and 20/800 (6/24 to 6/240), and adequate peripheral vision in one eye (the non-implanted eye) to allow navigation
- Patients who achieve at least a five-letter improvement on the ETDRS chart in the eye scheduled for surgery when using an external telescope
- The planned operative eye must have an anterior chamber depth of 2.5mm
- Patient shows interest in participating in postoperative visual rehabilitation sessions



IMT™ (by Dr. Isaac Lipshitz)

Actual Size of Device



CONTRAINDICATIONS:

Exclude patients with any of the following conditions:

- Evidence of active CNV on fluorescein angiography or treatment for CNV within the past six months,
- 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., $< \text{Schaefer grade } 2$
 - Inflammatory ocular disease
 - Zonular weakness/instability of crystalline lens; pseudoexfoliation
 - Diabetic retinopathy
 - Untreated retinal tears
 - Retinal vascular disease
 - Optic nerve disease
 - History of retinal detachment
 - Retinitis pigmentosa
 - Any intraocular tumor and medical or ophthalmic condition that renders the subject unsuitable for participation in the study
 - Any ophthalmic pathology that compromises the patient's peripheral vision in the fellow eye
 - An ocular condition that predisposes the patient to eye rubbing
- Patients with significant communication impairment or severe neurological disorders
- Patients who 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
- Patients who have a history of steroid-responsive rise in intraocular pressure, uncontrolled glaucoma, or preoperative IOP > 22 mm Hg

Full prescribing information can be found at
www.CentraSight.com.



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The Implantable Miniature Telescope is referred to as "the IMT (by Dr. Isaac Lipshitz)" or as "the Implantable Miniature Telescope (by Dr. Isaac Lipshitz)." This device may be referred to "the product", "the device", "the telescope", "intraocular telescope", or similar terms which cannot be read as the name of the product. VisionCare's Implantable Miniature Telescope was invented by company founders Yossi Gross and Dr. Isaac Lipshitz.

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