VISION CARE IMT-PAS-01

A PROSPECTIVE, MULTICENTER POST-APPROVAL STUDY (PAS) OF THE IMPLANTABLE MINIATURE TELESCOPE (BY DR. ISAAC LIPSHITZ) IN PATIENTS WITH BILATERAL SEVERE TO PROFOUND CENTRAL VISION IMPAIRMENT ASSOCIATED WITH END-STAGE AGE-RELATED MACULAR DEGENERATION PROTOCOL IMT-PAS-01

Y	N	INCLUSION	
		1. Have retinal findings of geographic atrophy or disciform scar with foveal involvement, as determined by **fluorescein angiography**.	
		2. Have evidence of visually significant cataract **(> Grade 2)**	
		3. Agree to undergo pre-surgery training assessment (typically 2 to 4 sessions) with low vision specialists (optometrist or occupational therapist) in the use of an external telescope sufficient for the patient for the patient assessment and for the patient to make an informed decision.	
		4. Achieve at least a **5- letter improvement on the ETDRS chart with an external telescope.**	
		5. Have adequate peripheral vision in the eye not scheduled for surgery.	
		6. Agree to participate in postoperative visual training with low vision specialist.	
		7. Have BCDVA between (**20/160 to 20/800)** on the ETDRS chart.	

8. Age 65 or older.

Y	N	EXCLUSION	
		1. Has stargardt's macular dystrophy	
		2. Has **central anterior chamber depth (ACD) less than 3.0 mm**; measurement of the ACD should be taken from the posterior surface of the cornea (endothelium) to the anterior surface of the crystalline lens.	
		3. Has presence of corneal guttata.	
		4. Does not meet minimum age and endothelial density requirements shown in the table. **BASELINE ENDOTHELIAL CELL DENSITY** Age Range | 65 to < 70 | 70 to <75 | 75 or Greater Minimum Cell Density | 2300 | 2000 | 1800	
		5. Has cognitive impairment that would interfere with the ability to understand and complete the Acceptance of Risk and Informed Decision Agreement or prevent proper training/rehabilitation with the device.	

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		6. Has had evidence of active CNV on fluorescein angiography or treatment for CNV within the last 6 months.	
		7. Has any **ophthalmic pathology** that compromises the patients peripheral vision in the fellow eye	
		8. Has had any **previous intraocular or cornea surgery of an kind in the operative eye**, including any type of surgery for either refractive or therapeutic purposes	
		9. Has had **prior or expected ophthalmic related surgery within 30 days preceding intraocular telescope surgery.**	
		10. Has a history of steroid-responsive rise in intraocular pressure, **uncontrolled glaucoma,** or preoperative IOP **greater than 22mm Hg**, while on maximum medication	
		11. Has known sensitivity to post-operative medications	
		12. Have history of **eye rubbing** or an ocular condition that predisposes them to eye rubbing	
		13. If the operative eye has, **Myopia ≥ 6.0** **Hyperopia ≥ 4.0** **An axial length ≤21mm** **A narrow angle, i.e.,≤ schaffer grade 2** **Cornea stromal or endothelial dystrophies, including guttata 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**	