

FIVE YEAR FOLLOW-UP OF IMT-002 PATIENTS A LONG-TERM MONITORING STUDY OF IMT-002 PATIENTS

PROTOCOL IMT-002-LTM

∞ STUDY OUTLINE ∞

BACKGROUND	Protocol IMT-002-LTM is intended to provide an additional 36 months of safety data, for a total of 5 years of follow-up on patients participating in the IMT-002 trial, a 24 month pivotal trial conducted to support a marketing application for the IMT (Premarket Application P050034).
OBJECTIVE	The primary objective of IMT-002 LTM is to monitor the long-term safety of the IMT in patients who participated in the IMT-002 trial, a 24-month clinical trial of patients with bilateral moderate to severe central vision impairment due to age-related macular degeneration.
PATIENT POPULATION	Patients who participated in Protocol IMT-002, approved under G000115.
STUDY DESIGN	<p>This is a 5-year study of patients implanted with the IMT under Protocol IMT-002. All patients implanted with the IMT who completed the IMT-002 trial, approximately 178 patients, will be contacted and asked to participate in this study to monitor the long-term safety of the Implantable Miniature Telescope.</p> <p>Patients will undergo examination at six-month intervals to monitor endothelial cell density, posterior capsular opacification, intraocular pressure, visual acuity, device failures, complications and adverse events.</p>
STUDY PARAMETERS	Endothelial cell density, posterior capsular opacification, intraocular pressure, distance visual acuity, device failures, complications and adverse events.
EXAMINATION SCHEDULE	<p>The examination schedule is as following:</p> <ul style="list-style-type: none">• Six-month anniversaries of IMT implantation through 5 years of post-implant follow-up:<ul style="list-style-type: none">Month 30 –34 (Initial Visit)Month 36 (3 years)Month 42Month 48 (4 years)Month 54Month 60 (5 years)

**CLINICAL
PARAMETERS**

The following clinical parameters will be measured at each visit:

1. Intraocular pressure
2. Slit lamp examination
3. Endothelial cell count (implanted and fellow eyes)
4. Best corrected distance visual acuity (implanted and fellow eyes)
5. Complications and adverse events
6. Device failures