

Site No.: Patient Initials:

Investigator No.: Patient No.:

Protocol: IMT- 002 - LTM

Date of Exam: M D Y Operative Eye: OD OS

ALL ITEMS MUST BE COMPLETED. MISSING OR INCORRECTLY COMPLETED ITEMS WILL REQUIRE ADDITIONAL FOLLOW-UP.

EXIT FORM

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1. Date of Subject Exit: M D Y

2. Outcome: (mark one) Completed Terminated Discontinued

Termination: Subject's participation in the study ended for reasons related to the IMT.

Discontinuation: Subject's participation in the study ended for reasons unrelated to the IMT (e.g., non-compliance, voluntary withdrawal, etc.).

3. Reason for Termination/Discontinuation: (check one)

Explain as Needed:

1 Due to non-study-related medical reasons
(other than Adverse Events)

2 Voluntary withdrawals

3 Due to inability to continue
(e.g., moved, personal, etc.)

4 Due to improper entry of subject
(e.g., did not meet entry criteria)

5 Adverse Event (AE); please specify:

Date of AE onset: D M Y

6 Lost to follow-up

7 Death

8 Other _____

4. Who Terminated/Discontinued subject: (check one)

Patient

Investigator

Sponsor

5. Were any secondary surgical interventions performed on the subject's study eye due to an adverse event?

No Yes If Yes, specify:

Procedure:

Date Performed:

Investigator's Signature: _____

Date: _____

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POSTOPERATIVE REPORT

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30 Months (+/-3 MO) 36 Months (+/-3 MO) 42 Months (+/-3 MO) 48 Months (+/-3 MO)

54 Months (+/-3 MO) 60 Months (+/-3 MO) Interim, reason: _____

Check if patient is unavailable for this scheduled examination but continuing in study. Submit form and mark (not available) NAV. Reason: _____

1. Manifest Refraction: (indicate + or - sphere and - cylinder)

OD			OS		
+/- <input type="text"/> <input type="text"/> . <input type="text"/> <input type="text"/>	- <input type="text"/> . <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>	+/- <input type="text"/> <input type="text"/> . <input type="text"/> <input type="text"/>	- <input type="text"/> . <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>
<i>Sphere</i>	<i>Cylinder</i>	<i>Axis</i>	<i>Sphere</i>	<i>Cylinder</i>	<i>Axis</i>

2. Distance Best Corrected Visual Acuity* (ETDRS):

	OD		OS	
Distance chart used: (check 1)	<input type="checkbox"/> 1m	<input type="checkbox"/> 2m	<input type="checkbox"/> 1m	<input type="checkbox"/> 2m
Logmar:	<input type="text"/> . <input type="text"/> <input type="text"/>			

3. Slit Lamp Examination:

Cornea:

- 1 Normal
- 2 1 + Edema
- 3 2 + Edema
- 4 3 + Edema
- 5 4 + Edema

Endothelium:

- 1 Normal
- 2 1 + Folds
- 3 2 + Folds
- 4 3 + Folds
- 5 Keratic precipitates
- 6 Guttata

Anterior Chamber:

Cells

- 1 Normal
- 2 Trace (0-5 cells)
- 3 6-10 cells
- 4 11-20 cells
- 5 21-50 cells
- 6 >50 cells

Flare

- 1 None
- 2 Trace
- 3 Moderate
- 4 Marked
- 5 Severe
- 6 Other (specify): _____

Iris:

- 1 Normal
- 2 Fibrin deposits
- 3 Other (specify)

4. Intraocular Pressure: OD mmHg OS

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5. Posterior Capsular Opacification: (check one)

- None Minimal Opacity Moderate Opacity Dense Opacity

6. IMT Positioning: (check each that applies)

- Centered
 Tilted
 Malpositioned (specify) _____

7. Endothelial Cell Count:

OD	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	Cells/mm ²	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	Cells/mm ²	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	Cells/mm ²
OS	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	Cells/mm ²	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	Cells/mm ²	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	Cells/mm ²

8. Adverse Events: Yes No

If yes, Complete Adverse Event Form

- | | |
|--|--|
| <input type="checkbox"/> Anterior chamber inflammation | <input type="checkbox"/> Iridotomy |
| <input type="checkbox"/> Choroidal detachment | <input type="checkbox"/> Iris atrophy |
| <input type="checkbox"/> Choroidal hemorrhage | <input type="checkbox"/> Iris damage |
| <input type="checkbox"/> Choroidal neovascularization | <input type="checkbox"/> Iris prolapse |
| <input type="checkbox"/> Corneal decompensation | <input type="checkbox"/> Iritis |
| <input type="checkbox"/> Corneal edema | <input type="checkbox"/> Iris transillumination defect |
| <input type="checkbox"/> Corneal transplant | <input type="checkbox"/> Optic atrophy |
| <input type="checkbox"/> Cyclitic membrane | <input type="checkbox"/> Precipitates or deposits on IMT |
| <input type="checkbox"/> Diplopia | <input type="checkbox"/> Pupillary block |
| <input type="checkbox"/> Distorted pupil | <input type="checkbox"/> Retinal detachment |
| <input type="checkbox"/> Endophthalmitis | <input type="checkbox"/> Retinal vascular occlusion |
| <input type="checkbox"/> Flat anterior chamber | <input type="checkbox"/> Subretinal hemorrhage |
| <input type="checkbox"/> Hyphema | <input type="checkbox"/> Synchia <input type="text"/> AS <input type="text"/> PS <input type="text"/> of Clock hours |
| <input type="checkbox"/> Hypotony | <input type="checkbox"/> Treatment of PCO (Nd:YAG, Needling) |
| <input type="checkbox"/> Hypopyon | <input type="checkbox"/> Uveitis/Vitritis |
| <input type="checkbox"/> IMT dislocation | <input type="checkbox"/> Vitrectomy/vitreous aspiration |
| <input type="checkbox"/> IMT repositioning | <input type="checkbox"/> Vitreous hemorrhage |
| <input type="checkbox"/> IMT removal | <input type="checkbox"/> Vitreous in anterior chamber |
| <input type="checkbox"/> Increased IOP requiring treatment | <input type="checkbox"/> Zonular dehiscence |
| <input type="checkbox"/> Secondary Surgical Intervention | <input type="checkbox"/> Other 1: Specify _____ |
| <input type="checkbox"/> Other 2: Specify _____ | <input type="checkbox"/> Other 3: Specify _____ |

Investigator's Signature: _____ Date: _____

Patient Initials: _____

Patient ID#: _____

Date: _____

IMT STUDY-DISTANCE VISUAL ACUITY WORK SHEET

Instruction for 2 meter acuity test: 1.circle each letter the patient identifies correctly, 2.write total correct for each row in the place provided, 3.compute the total correct for all rows.

CHART 1 Preop w/o telescope

CHART 2

w telescope WA2.2X WA3X

OD 1MO 3MO 6MO 9Mo 12 MO 18MO 24 MO Interim **OS**

	# correct	(Acuity equivalence for reference only)		# correct
N C K Z O		20/400	D S R K N	
R H S D K		20/320	C K Z O H	
D O V H R		20/250	O N R K D	
C Z R H S		20/200	K Z V D C	
O N H R C		20/160	V S H Z O	
D K S N V		20/126	H D K C R	
Z S O K N		20/100	C S R H N	
C K D N R		20/80	S V Z D K	
S R Z K D		20/64	N C V O Z	
H Z O V C		20/50	R H S D V	
N V D O K		20/40	S N R O H	
V H C N O		20/32	O D H K R	
S V H C Z		20/25	Z K C S N	
O Z D V K		20/20	C R H D V	

Total # of correct letters at 2 meter: OD _____

OS _____

Instructions for 1 meter acuity test: If the total # correct @ 2 meters is less than 20: 1.position the patient 1 meter from the chart, 2. add +0.50D sphere to the distance correction in the trial frame, 3.test VA using only the first 3 rows of the test letters, 4. fill in row totals and grand total above.

	# correct	(Acuity equivalence for reference only)		# correct
N C K Z O		20/800	D S R K N	
R H S D K		20/640	C K Z O H	
D O V H R		20/500	O N R K D	

Total number correct at 1 meter: _____

Total number correct at 1 meter: _____

Visual Acuity Score:

Visual Acuity Score:

Total at 2 meters _____

Total at 2 meters _____

If ≥ 20 enter 15, if not, enter 0 _____

If ≥ 20 enter 15, if not, enter 0 _____

Total correct at 1 meter _____

Total correct at 1 meter _____

Visual Acuity Score (sum of 3 numbers) _____

Visual Acuity Score (sum of 3 numbers) _____

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- Preoperative Report (**DAY -45 TO 0**) 3 Months (*6-18 weeks*) 6 Months (*18-32 weeks*)
- 9 Months (*32-44 weeks*) 12 Months (*44-56 weeks*) 18 Months (*56-86 weeks*)
- 24 Months (*86-104 weeks*) Interim, reason: _____

Check if patient is unavailable for this scheduled examination but continuing in study. Submit form and mark (not available) NAV. Reason: _____

Instructions: I'm going to read you some statements about problems, which involve your vision, or feelings that you have about your vision condition. After each question I will read you a list of possible answers. Please choose the response that describes your situation. Please answer all the questions as if you were wearing your glasses or contact lenses (if any). Please take as much time as you need to answer each question. All your answers are confidential. In order for this survey to improve our knowledge about vision problems and how they affect your quality of life, your answers must be as accurate as possible. Remember, if you wear glasses or contact lenses for a particular activity, please answer all of the following questions as though you were wearing them. **Part 1 –**

General Health and Vision

1. **In general**, would you say your overall **health** is*: (*check one*) **READ CATEGORIES**
 1 Excellent 2 Very Good 3 Good 4 Fair 5 Poor
2. At the present time, would you say your eyesight using both eyes (with glasses or contact lenses, if you wear them) is **excellent, good, fair, poor**, or **very poor** or are you **completely blind**? (*check one*) **READ CATEGORIES**
 1 Excellent 2 Good 3 Fair 4 Poor 5 Very Poor 6 Completely blind
3. How much of the time do you **worry** about your eyesight? (*check one*) **READ CATEGORIES**
 1 None of the time 2 A little of the time 3 Some of the time 4 Most of the time 5 All of the time
4. How much **pain or discomfort** have you had **in and around your eyes** (for example, burning, itching, or aching)? Would you say it is: (*check one*) **READ CATEGORIES**
 1 None 2 Mild 3 Moderate 4 Severe, or 5 Very severe

Part 2 – Difficulty with Activities

The next questions are about how much difficulty, if any, you have doing certain activities wearing your glasses or contact lenses if you use them for that activity.

5. How much difficulty do you have **reading ordinary print in newspapers**? Would you say you have: (*check one*) **READ CATEGORIES AS NEEDED**
 1 No difficulty at all 2 A little difficulty 3 Moderate difficulty 4 Extreme difficulty
 5 Stopped doing this because of your eyesight 6 Stopped doing this for other reasons or not interested in doing this
6. How much difficulty do you have doing work or hobbies that require you to **see well up close**, such as cooking, sewing, fixing things around the house, or using hand tools? Would you say: (*check one*) **READ CATEGORIES AS NEEDED**
 1 No difficulty at all 2 A little difficulty 3 Moderate difficulty 4 Extreme difficulty
 5 Stopped doing this because of your eyesight 6 Stopped doing this for other reasons or not interested in doing this



Site No.: [] [] []

Investigator No: [] [] []

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Protocol: IMT - 002

Date of Exam: M [] [] D [] [] Y [] []

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VISUAL FUNCTIONING QUESTIONNAIRE - 25

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Part 2 - Difficulty with Activities continued

- 7. Because of your eyesight, how much difficulty do you have finding something on a crowded shelf? (check one) READ CATEGORIES AS NEEDED
8. How much difficulty do you have reading street signs or the names of stores? (check one) READ CATEGORIES AS NEEDED
9. Because of your eyesight, how much difficulty do you have going down steps, stairs, or curbs in dim light or at night? (check one) READ CATEGORIES AS NEEDED
10. Because of your eyesight, how much difficulty do you have noticing objects off to the side while you are walking along? (check one) READ CATEGORIES AS NEEDED
11. Because of your eyesight, how much difficulty do you have seeing how people react to things you say? (check one) READ CATEGORIES AS NEEDED
12. Because of your eyesight, how much difficulty do you have picking out and matching your own clothes? (check one) READ CATEGORIES AS NEEDED
13. Because of your eyesight, how much difficulty do you have visiting with people in their homes, at parties, or in restaurants? (check one) READ CATEGORIES AS NEEDED
14. Because of your eyesight, how much difficulty do you have going out to see movies, plays, or sports events? (check one) READ CATEGORIES AS NEEDED

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-
- 5 Stopped doing this because of your eyesight
-
- 6 Stopped doing this for other reasons or not interested in doing this

VISUAL FUNCTIONING QUESTIONNAIRE – 25

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Part 2 – Difficulty with Activities *continued*15. Now, I'd like to ask about **driving a car**. Are you **currently driving**, at least once in a while? (*check one*)

-
- 1 Yes (
- skip to Q 15c*
-)
-
- 2 No

15a. IF NO, ASK: Have you **never** driven a car or have you **given up driving**? (*check one*)

-
- 1 Never drove (
- skip to Part 3, Q 17*
-)
-
- 2 Gave up

15b. IF GAVE UP DRIVING: Was that **mainly because of your eyesight, mainly for some other reason**, or because of **both your eyesight and other reasons**? (*check one*)

-
- 1 Mainly eyesight (
- skip to Part 3, Q 17*
-)
-
- 2 Mainly other reasons (
- skip to Part 3, Q 17*
-)
-
-
- 3 Both eyesight and other reasons (
- skip to Part 3, Q 17*
-)

15c. IF CURRENTLY DRIVING: How much difficulty do you have **driving during the daytime in familiar places**? Would you say you have: (*check one*)

-
- 1 No difficulty at all
-
- 2 A little difficulty
-
- 3 Moderate difficulty
-
- 4 Extreme difficulty

16. How much difficulty do you have **driving at night**? Would you say you have: (*check one*) **READ CATEGORIES AS NEEDED**

-
- 1 No difficulty at all
-
- 2 A little difficulty
-
- 3 Moderate difficulty
-
- 4 Extreme difficulty
-
-
- 5 Stopped doing this because of your eyesight
-
- 6 Stopped doing this for other reasons or not interested in doing this

16a. How much difficulty do you have **driving in difficult conditions, such as in bad weather, during rush hour, on the freeway, or in city traffic**? Would you say you have: (*check one*) **READ CATEGORIES AS NEEDED**

-
- 1 No difficulty at all
-
- 2 A little difficulty
-
- 3 Moderate difficulty
-
- 4 Extreme difficulty
-
-
- 5 Stopped doing this because of your eyesight
-
- 6 Stopped doing this for other reasons or not interested in doing this

Part 3 – Responses to Vision ProblemsThe next questions are about how things you do may be affected by your vision. For each one, I'd like you to tell me if this is true for you **all, most, some, a little**, or **none** of the time.17. **Do you accomplish less** than you would like because of your vision? (*check one*) **READ CATEGORIES**

-
- 1 All of the time
-
- 2 Most of the time
-
- 3 Some of the time
-
- 4 A little of the time
-
- 5 None of the time

18. **Are you limited** in how long you can work or do other activities because of your vision? (*check one*) **READ CATEGORIES**

-
- 1 All of the time
-
- 2 Most of the time
-
- 3 Some of the time
-
- 4 A little of the time
-
- 5 None of the time

19. How much does pain or discomfort **in or around your eyes**, for example, burning, itching, or aching, keep you from doing what you'd like to be doing? Would you say: (*check one*) **READ CATEGORIES**

-
- 1 All of the time
-
- 2 Most of the time
-
- 3 Some of the time
-
- 4 A little of the time
-
- 5 None of the time

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VISUAL FUNCTIONING QUESTIONNAIRE – 25

Part 3 – Responses to Vision Problems *continued*

For each of the following statements, please tell me if it is **definitely true**, **mostly true**, **mostly false**, or **definitely false** for you or you are **not sure**.

20. I **stay home most of the time** because of my eyesight. (*check one*)

- 1 Definitely true 2 Mostly true 3 Not sure 4 Mostly false 5 Definitely false

21. I feel **frustrated** a lot of the time because of my eyesight. (*check one*)

- 1 Definitely true 2 Mostly true 3 Not sure 4 Mostly false 5 Definitely false

22. I have **much less control** over what I do, because of my eyesight. (*check one*)

- 1 Definitely true 2 Mostly true 3 Not sure 4 Mostly false 5 Definitely false

23. Because of my eyesight, I have to **rely too much on what other people tell me**. (*check one*)

- 1 Definitely true 2 Mostly true 3 Not sure 4 Mostly false 5 Definitely false

24. I **need a lot of help** from others because of my eyesight. (*check one*)

- 1 Definitely true 2 Mostly true 3 Not sure 4 Mostly false 5 Definitely false

25. I worry about **doing things that will embarrass myself or others**, because of my eyesight. (*check one*)

- 1 Definitely true 2 Mostly true 3 Not sure 4 Mostly false 5 Definitely false

That's the end of the interview. Thank you very much for your time and your help.

Interviewer's Signature: _____

Date: _____