STUDY PARTICIPATION

SCREENING
1 VISIT

Patients that have consented to participate will be screened for eligibility. Screening includes:

- Medical history and medication usage
- Visual acuity assessment
- Microperimetry assessment
- Imaging: OCT, colour fundus (CFP), auto-fluorescence (AF), and fluorescein angiography (FA)
- Anterior and posterior segment

Imaging is reviewed by a third party central reading centre to confirm eligibility.

BASELINE
1 VISIT

Patients that meet initial eligibility will return for baseline assessment which includes visual acuity assessments, colour vision assessment, and microperimetry. If eligibility is confirmed, patients will be booked for their loading treatment sessions.

TREATMENT
INITIAL LOADING: 5 VISITS

On loading day 1, the patient will be randomised to either active or sham therapy, and will be considered 'enrolled'. The participants will then complete 5 consecutive days of treatment (2 sessions per day).

ASSESSMENT
25 VISITS

Participants will return 2 weeks after initial loading treatments for assessments and then return monthly from the 1-month to 24-month timepoint. Assessments will include visual acuities, microperimetry, colour vision, and anterior and posterior exams.

MAINTENANCE

Following completion of assessments, participants will receive a single day (2 sessions each day) of maintenance treatment at months 1, 2, 3 and then every other month through Month 23 timepoint. The assessments and maintenance treatments may be done on separate days.

[PLACEHOLDER FOR RESEARCH SITE LOGO]

For information on the i-Lumen AMD therapy or participating clinical sites please contact i-Lumen at:

1 800 418 675
ANZinfo@i-lumen.com.au

i-SIGHT2 Dry AMD Clinical Study

DRY AMD

Non-invasive, office-based therapeutic to improve or maintain vision in patients with intermediate to advanced nonexudative AMD.

SPONSOR:
i-Lumen Scientific AUS Pty. Ltd. ©2025
Southbank, VIC, Australia
REC 0035, Rev. A

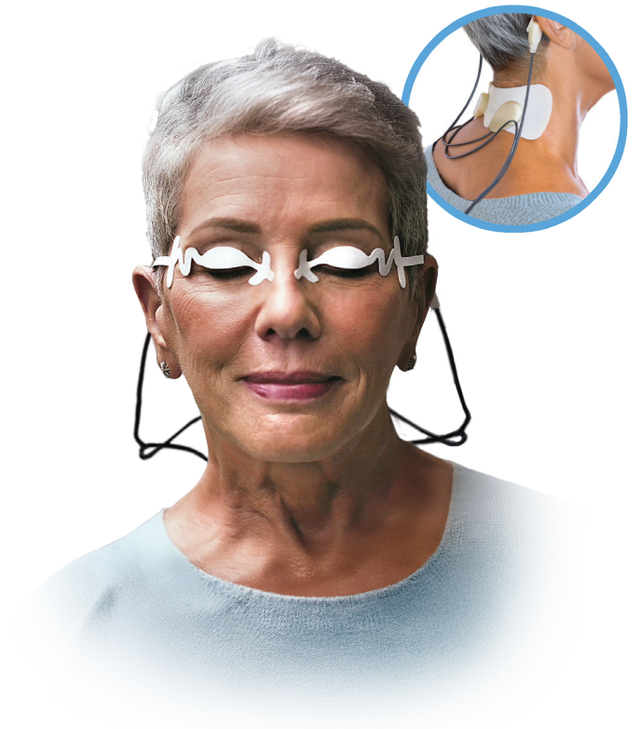
MANUFACTURER:
i-Lumen Scientific, Inc.

For Eye Care Professionals Reference Only.
Not for Patient Distribution.

ABOUT i-LUMEN

i-Lumen Scientific is a U.S. based “bioelectric” medical device manufacturer focused on the use of non-invasive neurostimulation as an ophthalmic therapeutic for the improvement of visual function in patients with vision loss due to Intermediate to Advanced non-exudative AMD.

i-Lumen was founded by U.S. based Optometrist John Jarding. His growing population of AMD patients with no treatment options to offer them led to the development of using microcurrent stimulation as a potential therapy.



i-LUMEN AMD THERAPY

The i-Lumen AMD therapy is an in-office microcurrent therapy using a proprietary combination of waveforms and frequencies (pulses per second), that is delivered transpalpebrally (via the closed eyelid).

The i-Lumen AMD therapy is an initial 5-day treatment regimen, followed by a single day of maintenance treatment administered every other month.

i-SIGHT2 STUDY

The i-SIGHT2 study is currently enrolling eligible participants in Australia, New Zealand and the United Kingdom. i-SIGHT2 is a randomised, sham-controlled study to evaluate the long-term treatment effects of the i-Lumen AMD therapy for patients with vision 6/12 or worse due to Intermediate to Advanced nonexudative AMD.

For the i-SIGHT2 study, eligible randomised participants will complete the initial 5-day treatment sessions and 13 maintenance treatments over a 24-month period. Participants will receive either unilateral or bilateral treatment in the study based on eligibility criteria.

To satisfy regulatory safety evaluation and imaging requirements in support of future marketing clearances or approvals, the study is being conducted in ophthalmology practices and institutions.

STUDY OVERVIEW

120 participants meeting eligibility criteria in at least 1 eye will be enrolled and randomised to active or sham in a 2:1 ratio.

Participants must meet the following key inclusion criteria:

- 60 years of age or older
- Intermediate to Advanced nonexudative AMD
- Presence of at least 1 large druse
- BCVA 6/12 to 6/60

Participants will be excluded if they meet any of the following key exclusion criteria:

- Diabetic retinopathy in either eye
- History of exudative (wet) AMD in both eyes.
- Glaucoma requiring ≥3 medications and/or drops per day, or history of trabeculectomy
- History of any kind of intraocular surgery (excludes cataract IOL surgery)
- High myopia or former high myopia
- Visually significant cataracts or posterior capsular opacification that may require surgery or YAG laser procedure within the next 12 months
- Diagnosis of severe dry eye requiring either artificial tears more than six (6) times a day or prescription drops
- History of amblyopia in the treatment eye
- Any implanted electrical devices (e.g. pacemaker)
- Any implanted metallic device in the head and/or neck
- Current tobacco or tobacco-related product use, or history of heavy smoking (more than ½ pack per day) within the last 5 years.

i-LUMEN SCIENTIFIC™
Advancing Vision Restoration

CAUTION: This is an investigational device.