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FDA Approves Samsara Vision's Telescope Implant for Macular Degeneration in Patients 65 Years and Older

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Samsara Vision Ophthalmic Technologies, Inc. a developer of advanced visual prosthetic devices for the treatment of age-related macular degeneration (AMD), today announced the U.S. Food and Drug Administration approved the [Implantable Miniature Telescope](#) (by Dr. Isaac Lipshitz) for use in patients living with bilateral end-stage age-related macular degeneration who are age 65 or older. The telescope implant is the only FDA approved surgical device for end-stage AMD and is Medicare eligible.

The telescope implant is the integral component of Samsara Vision's comprehensive treatment program called [CentraSight®](#), which helps patients follow the steps necessary for proper diagnosis, surgical evaluation, implantation and postoperative care. The telescope implant improves visual acuity and quality of life for suitable patients with AMD whose sight is permanently obstructed by a blind spot in their central vision, making it difficult or impossible to see faces, read, and perform everyday activities such as watching TV, preparing meals, and self-care.ⁱ End-stage AMD is uncorrectable by any other treatment including glasses, vitamins, drugs or cataract surgery and is associated with increased stress and depression as vision diminishes.ⁱⁱ

"Despite all the great pharmacotherapy advances in AMD treatment, some patients will unfortunately progress to end stage AMD where their straight ahead, central vision is permanently blocked," said Dr. David Boyer, of Retina Vitreous Associates Medical Group, Beverly Hills, CA. "Once end-stage AMD patients have lost their central vision, cataract surgery will not provide them with as much benefit to their quality of life as the telescope implant."

AMD is the leading cause of vision loss in Americans aged 60 and older, affecting an estimated 15 million people.ⁱ Of those, 2 million Americans are living with end-stage AMDⁱⁱⁱ and that number will increase as the Baby Boomer cohort ages.ⁱ

"We are pleased and excited about this important FDA decision," said Allen W. Hill, President and Chief Executive Officer, Samsara Vision Ophthalmic Technologies. "We developed the telescope implant to help older adults who've missed seeing moments in their life and lost much of their independence. Now, younger individuals, those age 65 to 74, will also have access to this important therapy for treating end-stage AMD."

The telescope implant is not a cure for End-stage AMD. As with any medical intervention, potential risks and complications exist with the telescope implant. Possible side effects include decreased vision or vision impairing corneal swelling. The risks and benefits associated with the telescope implant are discussed at www.CentraSight.com.

About CentraSight and the Telescope Implant

The telescope implant was previously approved by the FDA for patients greater than or equal to 75 years of age. FDA approval to expand access to those age 65 and older was based on clinical data provided by the pivotal safety and efficacy study, IMT-002, and long-term studies IMT-002-LTM and IMT-002-LTME, which followed patients to 5 and 8 years, respectively.

The Implantable Miniature Telescope (by Dr. Isaac Lipshitz) is indicated for monocular implantation to improve vision in patients greater than or equal to 65 years of age with stable severe to profound vision impairment (best-corrected distance visual acuity 20/160 to 20/800) caused by bilateral central scotomas (blind areas) associated with end-stage AMD. This level of visual impairment constitutes statutory (legal) blindness. Smaller than a pea, the telescope is implanted in one eye in an outpatient surgical procedure. In the implanted eye, the device renders enlarged central vision images over a wide area of the retina to improve central vision, while the non-operated eye provides peripheral vision for mobility and orientation.

Patients and physicians can learn more about the telescope implant by visiting www.CentraSight.com or calling 1-877-99-SIGHT.

About Samsara Vision Ophthalmic Technologies

Samsara Vision Ophthalmic Technologies, Inc., headquartered in Saratoga, CA, is a privately-held company. The Company and its ISO 13485 certified and FDA registered manufacturing and R&D facility are focused on development, manufacturing, and marketing of implantable ophthalmic devices and technologies that are intended to improve vision and quality of life for individuals with end-stage age-related macular degeneration. Samsara Vision's Implantable Miniature Telescope was invented by company founders Yossi Gross and Isaac Lipshitz.

i What is AMD? Macular Degeneration Partnership. Accessed on September 19, 2014 at <http://www.amd.org/what-is-macular-degeneration/>

ii Bennion, AE, Shaw, RL, Gibson, JM "What do we know about the experience of age related macular degeneration? A systematic review and meta-synthesis of qualitative research?" Social Science & Medicine. 75 (2012) 976-985.

iii Vision Problems in the United States. Prevent Blindness America. Accessed on September 19, 2014 at <http://www.visionproblemsus.org/amd/amd-map.html>

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