



# Patient Guide

to Samsara Vision's Clinical Research Trial  
of the Implantable Miniature Telescope  
(SING IMT™)

## How Common is AMD?

Age-related macular degeneration (AMD) is a leading cause of vision loss for people age 50 and older, and the number 1 cause of blindness in people age 65 years and older. More than 15 million Americans are affected by some form of macular degeneration and approximately 2 million Americans have advanced forms of AMD with associated vision loss. Late-Stage AMD is the most advanced form of age-related macular degeneration (AMD). It results in a loss of central vision, or blind spot, that is uncorrectable by glasses, drugs, injections, or cataract surgery.

## What Causes Age-Related Macular Degeneration?

HISTORY OF HYPERTENSION

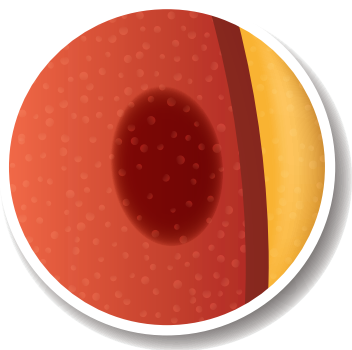
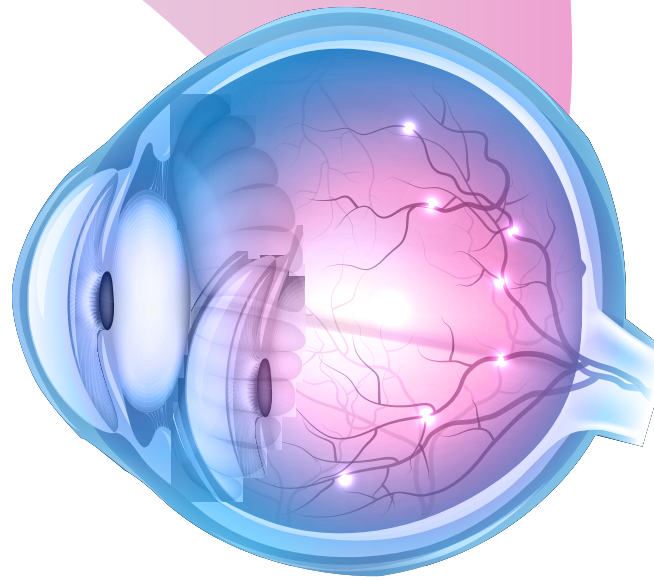
SMOKING OR EXPOSURE TO SECONDHAND SMOKE

AGE: PEOPLE OVER 60 HAVE INCREASED RISK

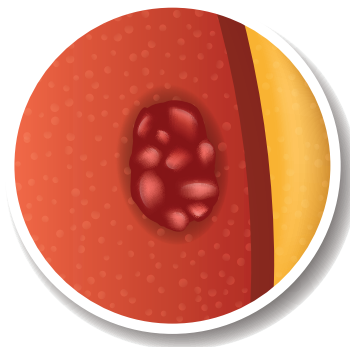
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FAMILY HISTORY

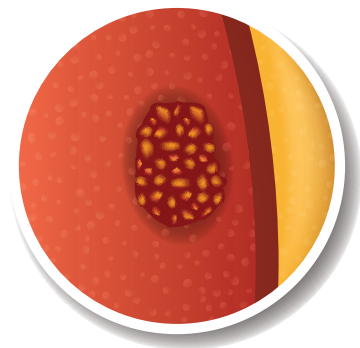
## Are there Different Types of Advanced Macular Degeneration?



HEALTHY EYE



DRY AMD



WET AMD

Yes, there are. Age-related Macular Degeneration is usually described as either “dry” or “wet”. Of these two types “dry” AMD is the most common type. This type of AMD may also be referred to as “non-neovascular”. Small deposits that develop under the retina can expand and cause the cells of the retina to malfunction. The progression of “dry” AMD

is usually slow in progression. “Wet” AMD occurs when very small blood vessels develop below and into the retina. This type of AMD may also be referred to as “neovascular”. These very small blood vessels can burst or leak resulting in damage to the retina and vision loss. Wet AMD usually develops quickly and with greater vision loss than dry AMD.



## How is Late-Stage AMD different from earlier or milder forms of AMD?

In Late-Stage Age-Related Macular Degeneration (AMD), the macula degenerates in both eyes without any healthy macular area left for detailed central vision. For the patient, there is no way to see around the central blind spot in their vision. In earlier or milder forms of AMD, visual symptoms may be minor and not necessarily impact the individual's ability to easily perform daily activities. Also, in less advanced forms of AMD, one eye may still have central vision or, in the case of wet AMD, drug treatments may help stabilize vision or offer some improvement.

## How does AMD impact older adults?

For patients with Late-Stage AMD, the world has literally disappeared before their eyes. They have lost the ability to see and do many of the things they love, like being able to recognize the faces and facial expressions of friends and relatives, watch TV, cook, enjoy hobbies like gardening, cards, or knitting, and read. While treatments exist to try to slow the





## NORMAL VISION



## END-STAGE AMD SIMULATION



progression of age-related macular degeneration and there are assistive devices that can help people with reduced vision see better with magnification or more light, many patients will progress in their disease. Unfortunately, there is no cure for Late-Stage AMD. At this advanced stage of the disease, the macula itself is beyond repair.

But for people living with Late-Stage AMD, the Smaller-Incision New-Generation Implantable Miniature Telescope (SING IMT™) is a treatment option that may help to improve their vision and quality of life. Samsara Vision provides physician and patient support as patients work with a team of health care professionals, including a retina specialist, corneal surgeon, and low vision specialist, to determine if they are candidates for the device, which may improve vision and quality of life by varying levels in the majority of qualified patients who have Late-Stage AMD.



## Can you have AMD and Cataracts?

Cataracts are common in patients over sixty and also affect vision. Though cataracts can develop from other causes, the majority are part of the aging process. Cataracts occur when the natural lens in the eye becomes progressively cloudy as patients age. When cataract progress enough they are usually removed. Most cataract removal surgery involves its removal and the implantation of an intraocular lens, IOL.

Many Age-Related Macular Degeneration patients have developed cataracts as well. Cataract removal surgery is common and may help patients with AMD. However, the removal of cataracts will not address the blank spot in the patient's visual field.



END-STAGE AMD



CATARACT



There is no order for either AMD or cataracts in development. Many patients will develop cataracts and later be diagnosed with AMD. Some patients will first experience issues with AMD followed by issues with cataracts. Patients with age-related macular degeneration may retain some limited peripheral vision or side vision but will not have the vision in the central portion of their eye or eyes. These central cells of the retina are damaged and cannot process the light images to the brain. In advanced or Late-Stage AMD, this vision loss is irreversible.

Late-Stage AMD is the most advanced form of age-related macular degeneration. Some degeneration of the macula, which is part of the retina, is normal during aging. In early, less advanced AMD, visual symptoms are generally mild (blurred vision and/or seeing straight lines as crooked) and may or may not impact vision-related

activities. While treatments exist to try to slow the progression of age-related macular degeneration and there are assistive devices that can help people with reduced vision see better with magnification or more light, some patients will progress to Late-Stage AMD and have a significant blind spot in both eyes. With Late-Stage AMD (caused either by wet or dry AMD), the macula reaches a point where central vision is lost in both eyes, making it difficult to perform everyday tasks.

This blind spot is different than the visual disturbances experienced with cataracts (clouding of the eye's lens) and is not correctable by drugs, vitamins, injections, cataract surgery or eyeglasses. Peripheral vision, is not affected by AMD but is too low resolution to make up for lost central vision.

## What about the other eye?

Late-Stage Age-Related Macular Degeneration (AMD) affects detailed central vision in both eyes. It does not affect peripheral vision. Peripheral vision is low resolution (blurry). You cannot use it to read, but you can use it to detect objects and movement. A patient who receives the SING IMT™ will use the eye with the telescopic implant for detailed central vision (such as reading “WALK” signs at a crosswalk). The other eye is used for peripheral vision (such as checking to see if cars are coming from the side).

## How do I use the device once it is implanted?

The telescopic implant does not limit your natural eye movements and does not require you to move your entire head, as you have to do with external magnifying appliances. You can use natural eye movements to see things that are close and far away from you, such as reading printed materials or watching television. As a tradeoff to improving central vision, the peripheral (side) vision will be restricted in the eye with the telescope implant. However, your peripheral vision will stay the same as before the surgery in your non-implanted eye.





The brain is highly adaptable even at older ages. As a patient, you will work with low vision specialists to develop the skills you need to use your new vision. One of the skills you need to learn is how to switch your viewing back and forth between the eye with the telescope implant and the eye without the implant. You will also need to wear eyeglasses and may need to sometimes use a hand-held magnifier with the telescope-implanted eye to read or see fine details clearly. However, in general, less magnification will be needed after your surgery.

The telescope is virtually unnoticeable to others because it is implanted totally inside the eye, and mostly covered by the colored portion of the eye (iris).

**Is the device difficult to use?**

**What does the device look like in the eye? Can others see it?**





## What is the recovery time from surgery?

The recovery from surgery is relatively rapid. Any discomfort from the surgical procedure generally subsides within several days.





# If I decide to be in the study, what must I do after the procedure?



## Follow-up Visits:

You will be under the care of the ophthalmologist from the research trial. Your vision will be checked, and various tests will be performed both prior to and after the telescope implant procedure. You will need to return to your investigational center for examination at each of the required visits.



## Medications:

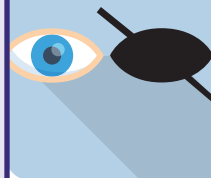
You will have to use eye drops as recommended by your doctor before and after the procedure. You will be provided detailed instructions on what eye drops must be used and how frequently by your doctor.



## Vision Training:

Training is needed to help adapt to the IMT. This starts

the second week after the procedure and continues approximately every other week for the first three months. During this time, you will be taught the basic vision skills necessary to adjust to and maximize the use your new vision so you can perform your daily tasks.



**Eye Patch:** You may experience double vision or unequal vision as a result of

the two different images being received by the brain. The operated eye with the IMT will have magnified central vision, while the other eye will retain the peripheral vision. In most cases, this state of unequal vision is transient and simply requires temporary patching of one eye.

# For More information

Samsara Vision  
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CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

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