



CentraSight® Frequently Asked Questions

What is CentraSight?

CentraSight (www.CentraSight.com) is a revolutionary new treatment program using a tiny telescope that is implanted inside the eye to improve vision and quality of life for patients with the most advanced form of macular degeneration: end-stage AMD. The program is designed to help patients see the things that are important to them, regain independence, and re-engage in everyday activities. The program utilizes a multispecialty provider team approach and has been created to help patients follow the necessary steps for proper diagnosis, surgical evaluation, and postoperative care.

What is the telescope implant?

The telescope implant is the first medical device to be implanted *inside* the eye for patients missing their central vision due to end-stage AMD.

How does it work?

Smaller than a pea, the telescope implant functions like a telephoto lens of a camera. It magnifies images so patients can see them better. The images are projected onto the healthy area of the retina not affected by AMD. The telescope implant allows patients to use natural eye movements to see things that are close and far, such as read the newspaper or watch TV.

How does it benefit patients?

Patients with end-stage AMD have a central blind spot or missing area in their vision. This vision loss makes it difficult or impossible to see faces, read, and perform everyday activities such as watching TV, preparing meals, and self-care. In general, patients in the FDA clinical trial were able to see 3 to 4 lines better on the eye test chart and demonstrate improved quality of life, including:

- The ability to complete daily tasks such as:
 - Reading activities (e.g., newspaper, recipes, street signs, grocery shopping)
 - Leisure activities (e.g., watching TV, plays, sporting events)
 - Everyday essentials (e.g., self-care, cooking, paying bills)
- Regain independence and re-engage in social activities:
 - Recognizing people's faces (e.g., family members, friends)
 - Returning to favorite hobbies (e.g., playing bingo, card games)
 - Being more confident going to and from unfamiliar and even familiar places

Who is it for?

The telescope implant is intended for patients with end-stage AMD, the most debilitating form of macular degeneration where central blindness affects both eyes. This disease is the leading cause of irreversible vision loss and legal blindness in the US. As this is a progressive disease, it typically affects older Americans. End-stage AMD results in a loss of central vision, or blind spot, and is uncorrectable by glasses, drugs or cataract surgery.

How many people have AMD?

Approximately 2 million Americans have advanced forms of AMD with associated vision loss. Over a half million of these individuals have end-stage AMD and may be candidates for the telescope implant. Despite the availability of new drug treatments that slow the progression of AMD, the number of people with end-stage AMD is expected to double by the year 2050.

What can prospective patients expect?

The CentraSight treatment program involves 4 steps:

- 1) Medical diagnosis
- 2) Candidate evaluation
- 3) Surgical procedure
- 4) Rehabilitation: Learning to use the new vision

How long does the surgery take?

The telescope implantation is performed by a specially trained ophthalmic surgeon as an outpatient procedure that generally lasts a little over an hour. Follow-up care includes patient visits with their eye surgeon and vision rehabilitation specialists to help them adapt their new vision for everyday activities that are important to them.

Patients will perform eye exercises with their new implant for 6 to 12 weeks after the surgery, such as tracking objects with their telescope eye, watching TV shows, practicing reading large print, and following moving objects outdoors (e.g., pedestrians on sidewalk).

Who will provide the treatment?

The CentraSight treatment program is generally coordinated by retina specialists who treat macular degeneration and other back-of-the-eye disorders. The treatment program focuses on comprehensive patient care, requiring prospective patients to undergo medical and visual evaluation to determine whether they may be a good candidate. A unique aspect of the evaluation is the ability to simulate, prior to surgery, what a person may expect to see once the telescope is implanted to determine if the improvement possible will meet the patient's expectations. Once the telescope has been implanted into the eye by an eye surgeon in an outpatient procedure, the patient will need to work with vision rehabilitation specialists for approximately 6 to 12 weeks to learn how to use their new vision in their everyday activities.

Where can patients get treatment?

CentraSight treatment centers are opening weekly across the nation. Patients can call 1-877-99-SIGHT to find the treatment center in their area.

Is the telescope implant FDA approved?

Yes, the telescope implant is approved by the FDA.

Is it covered by Medicare?

Yes, the cost for the telescope implant and visits associated with the treatment program are Medicare eligible in all 50 states.

Who is a candidate for the telescope implant?

To be considered a potential candidate for the telescope implant, an ophthalmologist must confirm that the patient:

- Has irreversible, end-stage AMD resulting from either dry or wet AMD
- Is no longer a candidate for drug treatment of their AMD
- Has not had cataract surgery in the eye in which the telescope will be implanted
- Meets age, vision and cornea health requirements

Some people with end-stage AMD may not be a candidate for a telescope implant. Patients and their physicians will assess if the benefits of the procedure outweigh the potential risks to decide if this treatment option is right for them.

How effective is the telescope implant?

Although the telescope implant is not a cure for AMD, studies showed that in general patients were able to see 3 to 4 lines better on the eye test chart and demonstrated improved quality of life on the National Eye Institute Visual Functioning Questionnaire. Two multi-year clinical studies involving 28 leading ophthalmic centers across the U.S. enrolled over 225 patients to evaluate the safety and efficacy of the telescope implant used in the CentraSight treatment program. The results have been published in top-tier scientific journals.

What are the risks associated with the telescope implant?

Risks include all those associated with cataract surgery, such as postoperative inflammation, raised intraocular pressure, corneal swelling, and the potential for compromised corneal health.

Why should patients consider CentraSight?

Because of the impact it has on patients' lives. In the FDA study, patients reported they are less dependent on others, less worried or frustrated about their vision, less limited in their activities related to vision, more able to visit with others, and better able to recognize faces and see the facial expressions of family and friends. As with many surgical procedures there are tradeoffs. It is important that the patient understands that after implantation the fellow eye becomes the dominant eye for peripheral vision and the telescope eye is used for central vision.

The patient population is old, what if they suffer from dementia or Alzheimer's after they have the surgery and forget the training?

CentraSight employs an extensive pre-screening process to select the most appropriate patients.

Full prescribing information can be found at www.CentraSight.com or downloaded here at http://www.centrasight.com/important_safety_information