Can You See

The Difference?

For the first time in years SHE actually can.
Implantable Telescope Technology:
Different By Design

It Starts With The Technology

The CentraSight treatment program is powered by the Implantable Miniature Telescope (by Dr. Isaac Lipshitz)—the only FDA-approved telescope prosthesis, employing wide-angle micro-optics in a Galilean telescope design. The telescope implant, along with the cornea, enlarges images in front of the eye up to 2.7 times their normal size. This magnification reduces the effect the “blind spot” has on central vision caused by the scotoma associated with a patient’s AMD.

The CentraSight®
Treatment Program

A World Of Difference For End-Stage AMD Patients

CentraSight is a novel treatment program that utilizes a tiny telescope to improve visual acuity and quality of life for patients with End-Stage AMD. But it’s more than just cutting-edge technology—it’s a comprehensive treatment program that supports healthcare professionals and patients from diagnosis and evaluation to surgery and rehabilitation.
Irreversible central vision loss can be a frightening and frustrating event for patients living with macular degeneration. By becoming a CentraSight program provider you can offer patients with End-Stage AMD a way to reconnect with things they love to see and do, improve their quality of life and participate in an ophthalmic first, based on leading-edge Implantable Telescope Technology.

There are several ways to become a CentraSight provider:

**Form Your Own Team**
Join forces with the other eye care specialists needed to build your own CentraSight provider team.

**Join An Existing Team**
Align yourself with an existing CentraSight team—filling a need in their current program or providing an additional resource in your area of expertise.

**Refer Your Patients To An Existing Team**
Identify a trusted, established CentraSight team to which you can refer your End-Stage AMD patients for evaluation.
Rehab

Rehabilitation plays an important role in the CentraSight treatment program. The visual training/rehabilitation program is designed to help patients use their new visual status to achieve functional goals that are important to them. The low vision optometrist and the occupational therapist (OT) work together to help the patient maximize use of their new vision, integrate their new visual status into daily life and progress to their personal goals.

Select

As with any treatment, the telescope implant is not appropriate for every patient with End-Stage AMD. A number of criteria are associated with the indication that must be met before a patient is considered a candidate for the telescope implantation procedure. Determining whether or not a potential candidate meets these criteria involves multiple members of the CentraSight team.

Treat

Telescope implantation candidacy is assessed by the cornea-trained cataract surgeon and potential surgical risks are discussed with the prospective patient. The surgeon receives comprehensive training on the telescope implantation surgical procedure.
Implantation Procedure

Mechanism of Action

The micro-optical telescope is implanted in one eye to magnify and project a high-resolution image onto healthy photoreceptors in areas surrounding the macula. This increases the image size and resolution afforded to the perimacular retina.

Scarred Macula

Central visual field projection (Natural lens/IOL)

Telescope Implant

Central visual field projection

Clinically Validated Efficacy

Clinically significant difference.

Change in Distance BCVA Baseline (N=173)

60% of patients gained ≥ 3 lines of distance BCVA.

2-year Visual Acuity Results¹

Clinically meaningful visual acuity benefit demonstrated through 2-year follow-up. 60% of patients gained ≥3 lines of distance BCVA.

Associated Risks

The most common risks of the telescope implantation surgery include inflammatory deposits or precipitates on the device and increased intraocular pressure. Significant adverse events include corneal edema, corneal decompensation, corneal transplant and decrease in visual acuity. There is a risk that the telescope implantation surgery could worsen vision rather than improve it. Individual results may vary.

Full prescribing information, including indications, contraindications and clinical and safety results can be found in the Professional Use Information booklet at www.CentraSight.com.

The CentraSight treatment program offers new hope and an improved quality of life for patients with End-Stage AMD. Become a part of a CentraSight team and begin making a meaningful difference in the lives of this underserved patient population.

Find out more at www.CentraSight.com or call 877.997.4448
The Implantable Miniature Telescope is referred to as “the IMT (by Dr. Isaac Lipshitz)” or as “the Implantable Miniature Telescope (by Dr. Isaac Lipshitz).” Hereinafter, this device may be referred to as “the product,” “the device,” “the telescope,” “intraocular telescope,” or similar terms which cannot be read as the name of the product. VisionCare’s Implantable Miniature Telescope was invented by company founders Yossi Gross and Dr. Isaac Lipshitz.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.
Helping Patients Navigate the Treatment Process

The CentraSight® Patient Access Program is designed to provide assistance, information, and support to patients and caregivers as they navigate the evaluation process involved in the CentraSight treatment program. Dedicated case managers guide patients through the program by providing candidates preliminary qualification assessment, scheduling appointments, and providing visit reminders throughout the multi-visit evaluation process. With this single point of contact throughout the process, our goal is to provide patients with a seamless, positive experience.

The CentraSight Patient Access Program is offered at no cost to the patient and is fully sponsored by VisionCare Ophthalmic Technologies for patient education and appointment scheduling purposes. VisionCare has partnered with CliniCalRN®, a provider of nurse-staffed patient services, to develop and manage this important program.

Program Overview

All interested patients are assigned a case manager and provided with a toll-free phone contact number (or they may request a call). Once the patient is in contact with their case manager, they are guided through each step of the process.

Patient Education and Pre-Screening

1. Pre-Screen Patient:
   The CentraSight case manager will conduct a high-level screening to determine if the patient meets the most basic requirements of the program.

2. Educate Patient:
   Information regarding the treatment program is provided over the phone and by mail/e-mail. This information includes:
   
   **How do I know if CentraSight will help me (or my family member)?**
   - General indications, contraindications, benefits and risks of the telescope implant are discussed, as noted in FDA product labeling and its references

   **What is the treatment process?**
   - Explains the steps of the treatment program and discusses the multi-specialty provider roles
   - Explains CentraSight case manager support
   - Provides patient education materials

3. Register Patient:
   Basic patient information is entered into the CentraSight Patient Access System. This tracks patient appointments and allows providers to monitor which visits have been scheduled or completed.
Patient and Provider Treatment Navigation

Once the patient has met the basic program requirements and made the decision to be treated, the CentraSight case manager provides assistance from pre-surgery through surgery.

**Enroll Patient**
Pre-qualified and interested patients complete the enrollment process, which includes information required by the Center’s specialists.

**Schedule Patient Visits**
The patient is scheduled for each appointment.

**Post-Visit Patient Call**
The case manager calls the patient after each appointment to see if they have any questions and to describe what happens next.

**Post-Visit Provider Specialist Call**
The case manager calls the specialist “or their staff” to complete the follow-up checklist and assist in any required information logistics after each appointment.

**Provide Visit Reminders**
The patient’s dedicated case manager calls the patient the day before their visit as a reminder and to provide information on what they can expect at that visit. Patients and centers can also sign up for e-mail or SMS text visit reminders.

**Information/Question Hotline**
The phone number provided to the patient at the very beginning of the process is also the hotline they can call if they have any questions, or for any other reasons. Reasons might include:

- General questions
- Questions regarding upcoming or recent appointments
- Appointment logistics including appointment changes when necessary

This number can also be used by the specialists if there is anything the case manager can do to assist in providing a smooth and pleasant experience for the patient.

Get Started Today!

Once your team is set up in the CentraSight Patient Access Program, you can begin to refer interested patients to the program.

The CentraSight Patient Access Program
Toll-Free: 877.554.6111

Patient Privacy and HIPAA

VisionCare and CliniCallRN take patient privacy and HIPAA seriously. Under no circumstances will VisionCare or CliniCallRN use any information collected from the patient or provided by the specialists for anything other than the treatment program. As a partner in the treatment of the patient, any information provided to CliniCallRN would be considered to be a disclosure for treatment purposes. A disclosure for treatment purposes does not require a specific authorization from the patient, nor does it require a BAA (business associate agreement) between the specialist and CliniCallRN.
Healthcare Common Procedure Coding System (HCPCS) Codes for Insertion of the Ocular Telescope Prosthesis

**Implantable Miniature Telescope** (by Dr. Isaac Lipshitz)

This document provides general reimbursement information for the ocular telescope prosthesis procedure. Additional information on physician and facility coding for the telescope implant, and other reimbursement considerations concerning end-stage AMD patient evaluation and management, are provided by the Corcoran Consulting Group at [http://www.corcoranccg.com/View.aspx/2483/VisionCare-Ophthalmic-Technologies](http://www.corcoranccg.com/View.aspx/2483/VisionCare-Ophthalmic-Technologies).

**Physician Coding** Effective July 1, 2012

<table>
<thead>
<tr>
<th>CPT Procedure Codes</th>
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</thead>
<tbody>
<tr>
<td><strong>0308T</strong> – Insertion of ocular telescope prosthesis including removal of crystalline lens</td>
</tr>
</tbody>
</table>

*Note: Medicare does not assign RVUs to Category III CPT Codes. Instead, payers typically determine reimbursement based on individual review. A copy of the procedure report is usually required.*

**Facility Coding – Medicare Outpatient Prospective Payment System (OPPS)** Effective July 1, 2012

<table>
<thead>
<tr>
<th>HCPCS Code</th>
<th>APC Code/ (Status Indicator)</th>
<th>Required Code†</th>
<th>2013 Rate National Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Procedure Code</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>0308T</strong> – Insertion of ocular telescope prosthesis including removal of crystalline lens</td>
<td>0234 (T)*</td>
<td>C1840</td>
<td>$1,644</td>
</tr>
<tr>
<td>Device Pass-Through Code</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>C1840</strong> – Lens, Intraocular, Telescopic</td>
<td>Pass-Through (H)†</td>
<td>0308T</td>
<td>Pass-through with device offset (see explanation below)</td>
</tr>
</tbody>
</table>

* Status Indicator T: Significant procedure subject to multiple-procedure discounts.
† Status Indicator H: Separate cost-based pass-through payment. Not subject to coinsurance. Note: Payment is based on hospital charges reduced to cost (see explanation below).

**Possible ICD-9 Diagnosis Codes – Age-Related Macular Degeneration**

Provider and hospital are responsible for reviewing any applicable coverage policy and must verify coding with their local Medicare Administrative Contractor or other payer.

362.51 – Nonexudative senile macular degeneration of retina

**Possible Applicable Revenue Codes**

278 – Medical device and implants
276

Additionally, hospitals can write-in on cost reports “Implantable medical devices charged to patients.”
Important Considerations for Hospitals Using C-Code C1840

- Correct Coding: Use of correct codes helps to ensure appropriate payment.
- Hospitals will need to establish charges for C1840 and 0308T on their chargemasters. An explanation of how pass-through payments are calculated by CMS is provided below.
- Complete and accurate coding is necessary for appropriate reimbursement. Future APC payments for C1840 and 0308T will be based on hospital charges reduced to costs. Careful review of charges for these codes now is critical to the development of future payment rates. Please share this document with others at the hospital who may find this information beneficial.

Pass-Through Payment Considerations

Device Offset: CMS is required to deduct from pass-through payments for devices an offset amount that reflects the portion of the applicable APC payment that could reasonably be attributed to the cost of the device that is eligible for pass-through payment. For 2012, CMS determined this offset amount for APC 0234 to be $104.72. This amount is subtracted from the pass-through payment for the telescope. (2012 Offset Amounts by Ambulatory Payment Classification [APC]. See APC-234, https://www.cms.gov/hospitaloutpatientPPS/04_passthrough_payment.asp.)

Cost-to-Charge Ratio: When a hospital implants a device that is eligible for pass-through payment, Medicare pays for the item on the basis of that hospital's billed charges reduced by a cost-to-charge ratio (CCR). Therefore, it is important for the hospital to carefully review its charges for the device and establish a charge for the device on their chargemaster. Below is a worksheet that hospitals can use to calculate possible payments from Medicare for the implantable telescope. Please insert the applicable numbers for each item. Note: For pass-through device payment, the hospital’s overall outpatient CCR applies.

Calculate the Hospital Charge: Hospital Acquisition Cost x Mark Up = Hospital Charge
Calculate the Medicare Payment: (Hospital Charge x Applicable CCR) – $104.72 (Device Offset) = Medicare Payment

Contact

Chet Kumar  |  Vice President, Business & Market Development
408.329.9133  |  chet@visioncareinc.net

FDA INDICATION FOR USE: VisionCare’s Implantable Miniature Telescope (by Dr. Isaac Lipshitz) (intraocular telescope) is indicated for monocular implantation to improve vision in patients greater than or equal to 75 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 associated with end-stage age-related macular degeneration.

Full prescribing information can be found at www.CentraSight.com.

DISCLAIMER: This document is for informational purposes only and is not legal advice. It is not intended to increase or maximize reimbursement by any payer. VisionCare does not guarantee that the use of this information will result in coverage or payment for the service or the implantable telescope. Hospitals are solely responsible for compliance with Medicare and other payers’ laws, rules, and requirements, and should confirm the accuracy of any coding or billing practices with these payers prior to submitting claims.

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Implantable Miniature Telescope (by Dr. Isaac Lipshitz) for End-Stage Macular Degeneration

Indication for Use/Contraindications

Indication For Use (USA): The intraocular telescope is indicated for monocular implantation to improve vision in patients 75 years of age or older with stable severe to profound vision impairment (best-corrected distance visual acuity 20/160 to 20/800) caused by bilateral central scotomas associated with end-stage age-related macular degeneration.

Patients must:

- Have evidence of visually significant cataract (≥ Grade 2)
- Agree to undergo pre-surgery training and assessment (typically 2 to 4 sessions) with low vision specialists (optometrist or occupational therapist) in the use of an external telescope sufficient for patient assessment and for the patient to make an informed decision
- Achieve at least a 5-letter improvement on the ETDRS chart with an external telescope
- Agree to participate in postoperative visual training with a low vision specialist

Contraindications:

Implantation of the intraocular telescope is contraindicated in patients:

- With cognitive impairment that would interfere with the ability to understand and complete the Acceptance of Risk and Informed Decision Agreement or prevent proper visual training/rehabilitation with the device
- With previous intraocular or cornea surgery of any kind in the operative eye, including any type of surgery for either refractive or therapeutic purposes
- With a history of steroid-responsive rise in intraocular pressure, uncontrolled glaucoma, or preoperative IOP >22 mm Hg, while on maximum medication
- In whom the planned operative eye has inflammatory ocular disease

Full prescribing information can be found at [www.CentraSight.com](http://www.CentraSight.com)
Additional Patient Criteria (Indications and Contraindications)

<table>
<thead>
<tr>
<th>Retina Specialist</th>
<th>Cornea-Trained Cataract Surgeon</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Patients must:</strong></td>
<td><strong>Contraindications:</strong></td>
</tr>
<tr>
<td>• Have retinal findings of geographic atrophy or disciform scar with foveal involvement, as determined by fluorescein angiography</td>
<td>Implantation of the intraocular telescope is contraindicated in patients:</td>
</tr>
<tr>
<td>• Have adequate peripheral vision in the eye not scheduled for surgery</td>
<td>• With central anterior chamber depth (ACD) &lt; 3.0 mm; measurement of the ACD should be taken from the posterior surface of the cornea (endothelium) to the anterior surface of the crystalline lens</td>
</tr>
<tr>
<td><strong>Contraindications:</strong></td>
<td>• With the presence of corneal guttata</td>
</tr>
<tr>
<td>Implantation of the intraocular telescope is contraindicated in patients:</td>
<td>• Who do not meet the minimum age and endothelial cell density requirements (age 75–84 years, &lt; 2000 cells/mm²; age 85 years and up, &lt; 1800 cells/mm²)</td>
</tr>
<tr>
<td>• With Stargardt’s macular dystrophy</td>
<td>• Who have prior or expected ophthalmic related surgery within 30 days preceding intraocular telescope implantation</td>
</tr>
<tr>
<td>• Who have evidence of active CNV on fluorescein angiography or treatment for CNV within the past 6 months</td>
<td>• With known sensitivity to post-operative medications</td>
</tr>
<tr>
<td>• With any ophthalmic pathology that compromises the patient’s peripheral vision in the fellow eye</td>
<td>• Who have a history of eye rubbing or an ocular condition that predisposes them to eye rubbing</td>
</tr>
<tr>
<td>• In whom the planned operative eye has:</td>
<td>• In whom the planned operative eye has:</td>
</tr>
<tr>
<td>○ Diabetic retinopathy, untreated retinal tears, retinal vascular disease, history of retinal detachment, retinitis pigmentosa</td>
<td>○ Myopia &gt; 6.0 D, Hyperopia &gt; 4.0 D</td>
</tr>
<tr>
<td>○ Intraocular tumor</td>
<td>○ Axial length &lt; 21 mm</td>
</tr>
<tr>
<td>○ Optic nerve disease</td>
<td>○ A narrow angle, i.e., &lt; Schaffer grade 2</td>
</tr>
<tr>
<td></td>
<td>○ Cornea stromal or endothelial dystrophies, including guttata</td>
</tr>
<tr>
<td></td>
<td>○ Zonular weakness/instability of crystalline lens, or pseudoexfoliation</td>
</tr>
<tr>
<td></td>
<td>• In eyes in which both haptics cannot be placed within the capsular bag during surgery, the intraocular telescope should be removed and replaced with a conventional intraocular lens (IOL); sulcus fixation of either one or both haptics increases the risk of severe endothelial cell loss and corneal transplant.</td>
</tr>
</tbody>
</table>

Full prescribing information can be found at www.centrasight.com/HCP_Important_Safety_Information