



Can You **See** The Difference?

Functional

Functionally
Blind

For the first time in years
SHE actually can.

CentraSight®
By VisionCare Ophthalmic Technologies

The CentraSight® Treatment Program



Implantable Telescope Technology: Different By Design



A World Of Difference For End-Stage AMD Patients

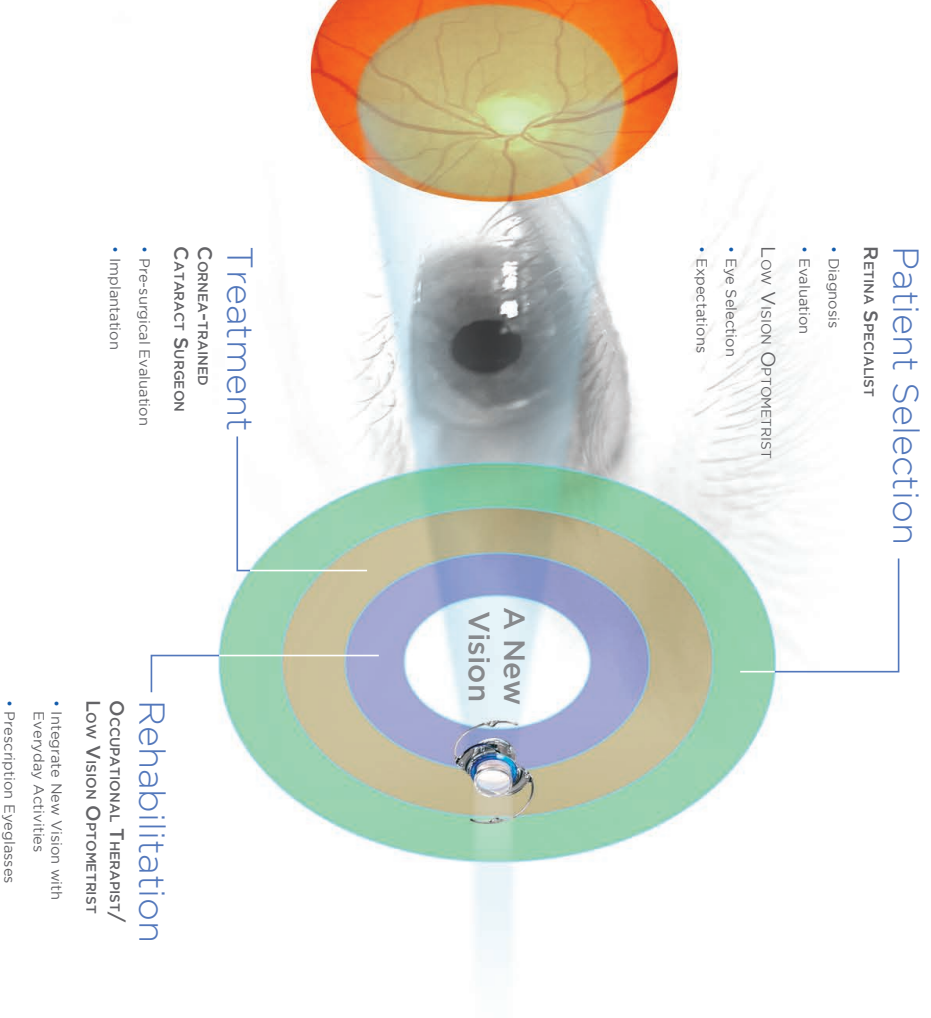
CentraSight is a novel treatment program that utilizes a tiny telescope to improve visual acuity and quality of life for patients with End-Stage AMD. But it's more than just cutting-edge technology—it's a comprehensive treatment program that supports healthcare professionals and patients from diagnosis and evaluation to surgery and rehabilitation.

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.

Select. Treat. Rehab.

A COMPREHENSIVE TREATMENT MODEL.



Be A Part Of The Difference

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

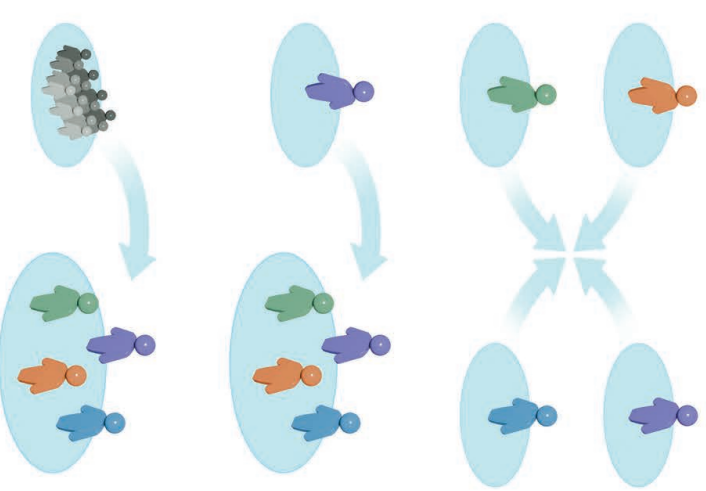
Join forces with the other eye care specialists needed to build your own CentraSight provider team.

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.





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.

Retina Specialist Cornea-Trained Cataract Surgeon

Low Vision Optometrist

Low Vision Occupational Therapist

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.



Implanted eye, 6 week post-op

Retina Specialist

Cornea-Trained Cataract Surgeon

Low Vision Optometrist

Low Vision Occupational Therapist



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.

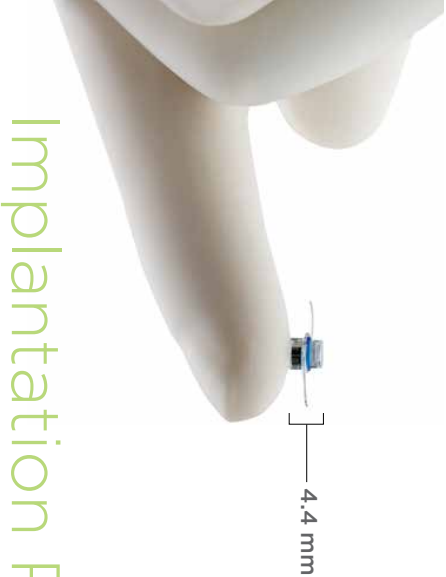
Retina Specialist

Cornea-Trained Cataract Surgeon

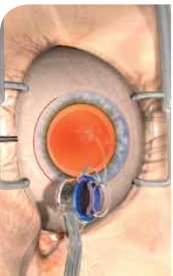
Low Vision Optometrist

Low Vision Occupational Therapist

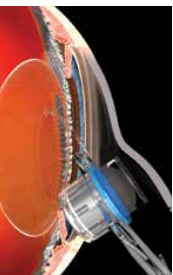




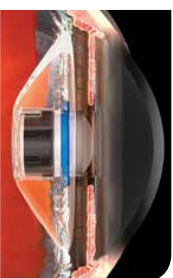
Implantation Procedure



12 mm limbal incision,
7 mm capsulorhexis



Implantation technique



Secured in capsular bag
for centration

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



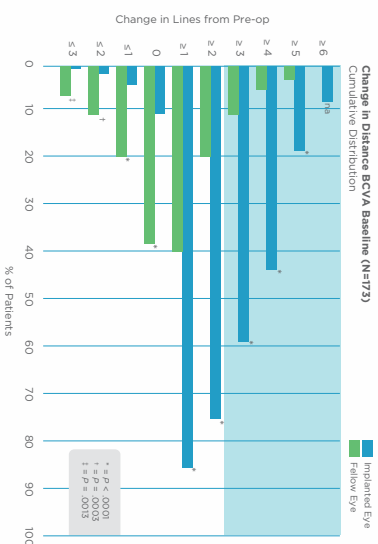
Central visual field projection

H Z C K O N C K H D Z H G S R S Z R D N K C N O R O C D N

Clinically Validated Efficacy

Clinically significant difference.

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, vision-impairing corneal edema, 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.

1. Hudson HL, Stulting RD, Heier JS, et al. Implantable telescope for end-stage age-related macular degeneration: long-term visual acuity and safety outcomes. *Am J Ophthalmol*. 2008;146:64-673.

Small Wonder.
Meaningful Difference.



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



Painting by a CentraSight patient.

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.



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MM01-0011 Rev 2 02/16

CentraSight® Patient Access Program

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 CliniCallRN™, 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



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.



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

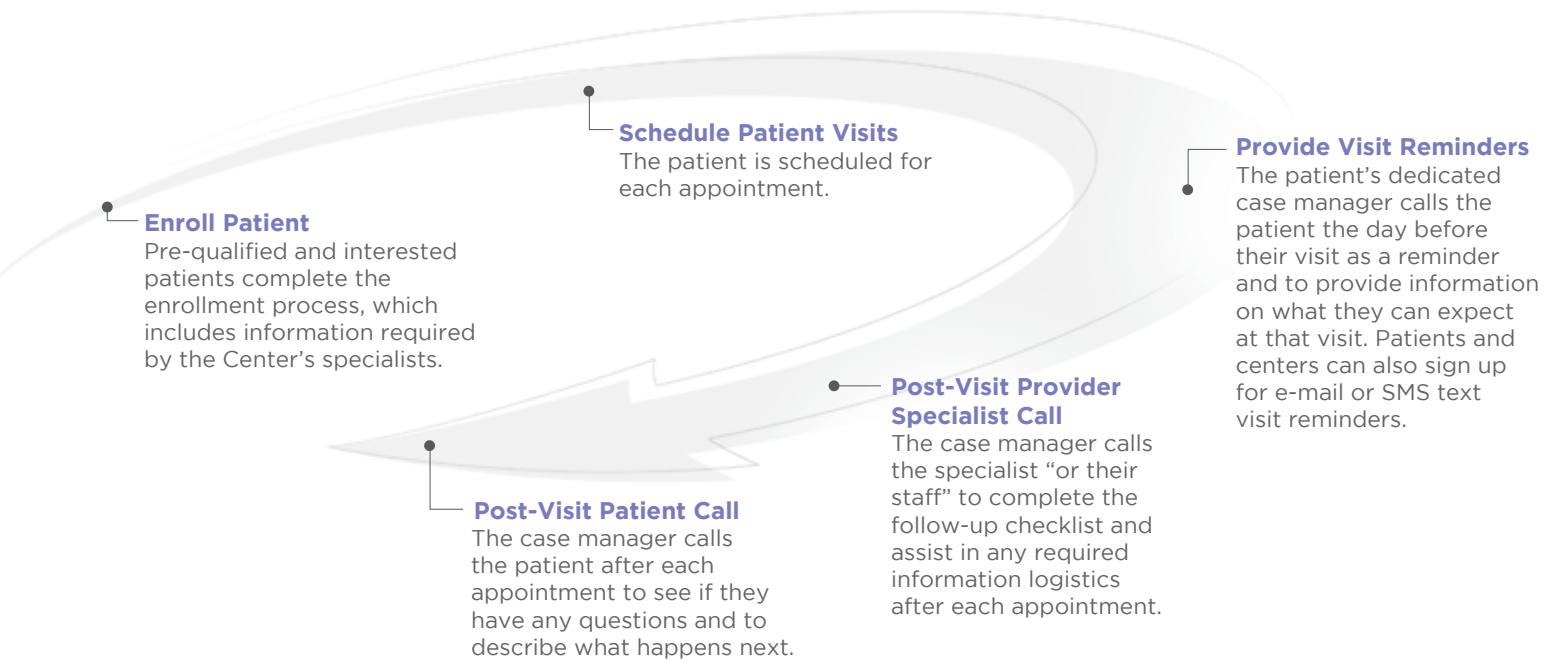


Register Patient:

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.



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 CliniCallIRN take patient privacy and HIPAA seriously. Under no circumstances will VisionCare or CliniCallIRN 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 CliniCallIRN 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 CliniCallIRN.

Reimbursement Codes

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>

Telescope Implant Procedure Coding Effective January 1, 2016

CPT Procedure Code
0308T – Insertion of ocular telescope prosthesis including removal of crystalline lens or intraocular lens prosthesis. <i>Do not report 0308T in conjunction with 65800 through 65815, 66020, 66030, 66600 through 66635, 66761, 66825, 66982 through 66986 and 69990.</i>

Device Code Effective January 1, 2011

HCPCS Code
C1840 – Lens, intraocular (telescopic) only recognized by Medicare on hospital outpatient department claims.

Fee-For-Service Medicare Reimbursement

Provider Type	HCPCS Codes	Medicare Payment System	Ambulatory Payment Classification (APC)	Status/Payment Indicator	Medicare Payment Resources
Physician (Place of Service Code 11)	0308T	Physician Fee Schedule	n/a	C (Contractor priced-local fee schedule applies)	Carriers price the code. Carriers will establish RVUs and payment amounts for these services.
Ambulatory Surgery Center (Place of Service Code 24)	0308T	ASC Fee Schedule	Device bundled with payment for procedure	J8 (Device Intensive Procedure)	ASC Addenda
Hospital Outpatient Department (Place of Service Code 22)	0308T	Outpatient Prospective Payment System	Intraocular Procedures	J1 (Comprehensive APC)	Hospital Outpatient Addenda
	C1840*		Bundled with payment for procedure	N (Payment is packaged into payment for other services, no separate APC payment.)	

* While Medicare does not make separate payment for most devices described by C codes, procedures that require the implantation of a device that are assigned to a device-intensive APC will require a device code on the claim.

Possible International Classification of Diseases (ICD) Diagnosis Codes – Age-Related Macular Degeneration

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

For claims on or after October 1, 2015

ICD-10-CM H35.31 – Nonexudative age-related macular degeneration
• Atrophic age-related macular degeneration

Possible Applicable Revenue Codes

278 – Medical Device and Implants

Contact



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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 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 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 and physicians should use independent judgment when selecting codes that most appropriately describe the services provided to a patient. Hospitals and physicians are solely responsible for compliance with Medicare and other payors' laws, rules, and requirements, and should confirm the accuracy of any coding or billing practice with these payors prior to submitting claims.

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Patient Criteria

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 65 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 (\geq 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

Additional Patient Criteria (Indications and Contraindications)

Retina Specialist

Patients must:

- Have retinal findings of geographic atrophy or disciform scar with foveal involvement, as determined by fluorescein angiography
- Have adequate peripheral vision in the eye not scheduled for surgery

Contraindications:

Implantation of the intraocular telescope is contraindicated in patients:

- With Stargardt's macular dystrophy
- Who have evidence of active CNV on fluorescein angiography or treatment for CNV within the past 6 months
- With any ophthalmic pathology that compromises the patient's peripheral vision in the fellow eye
- In whom the planned operative eye has:
 - Diabetic retinopathy, untreated retinal tears, retinal vascular disease, history of retinal detachment, retinitis pigmentosa
 - Intraocular tumor
 - Optic nerve disease

Cornea-Trained Cataract Surgeon

Contraindications:

Implantation of the intraocular telescope is contraindicated in patients:

- With central anterior chamber depth (ACD) < 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
- With the presence of corneal guttata
- Who do not meet the minimum age and endothelial cell density requirements (age 65 to < 70 min. cell density ≥ 2300 cells/mm²; age 70 to < 75 min. cell density ≥ 2000 cells/mm²; age 75 or greater min. cell density ≥ 1800 cells/mm²)
- Who have prior or expected ophthalmic related surgery within 30 days preceding intraocular telescope implantation
- With known sensitivity to post-operative medications
- Who have a history of eye rubbing or an ocular condition that predisposes them to eye rubbing
- In whom the planned operative eye has:
 - Myopia > 6.0 D, Hyperopia > 4.0 D
 - Axial length < 21 mm
 - A narrow angle, i.e., < Schaffer grade 2
 - Cornea stromal or endothelial dystrophies, including guttata
 - Zonular weakness/instability of crystalline lens, or pseudoexfoliation
- 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.

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