VISABILITY
NEAR VISION RESTORATION

Patient Information Booklet

Read this entire handbook to best understand the VisAbility™ Micro Insert System Procedure. Discuss all benefits, risks and questions with your eye doctor before proceeding with this surgery.

9155 Sterling Street, Suite 160
Irving, TX 75063
001-949-688-0550

TABLE OF CONTENTS

1. INTRODUCTION

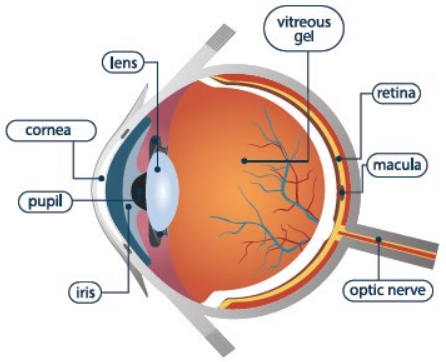
This Handbook provides information to guide you and your Surgeon in deciding whether VisAbility™ Micro Insert System is a good option for treatment of your presbyopia. Please read the handbook and be sure to ask your eye doctor about any additional questions you may have.

2. THE ANATOMY OF THE EYE

The eye is one of the most unique organs in your body. The eye continually sends signals about the world around you to your brain, which translates images into information, enabling you to "see".

Light reflects off objects, then enters the eye through the cornea, a "clear window" that helps your eye focus. The light then enters the pupil (the dark part in the center of the colored part of your eye) and passes through the lens, which shifts to bend the light as needed to focus it on the back of the eye where the retina is found. The retina is composed of 130 million light-sensitive cells that transmit the light from your eye to your brain for translation into an image you "see".

Figure 1: Anatomy of The Eye



3. WHAT IS PRESBYOPIA?

Presbyopia is a normal aging process of the human eye. As you age, the focusing system in your eye is unable to change the shape of the lens in your eye and bend the light that enters. As a result of this aging process, your eye loses its ability to focus on objects that are close to you. This results in blurry near vision that happens naturally over time.

Symptoms of Presbyopia Include:

- Blurred vision at a normal reading distance,
- Holding reading materials at arm's length,
- Eye strain, and
- Headaches when doing close work.

Typically, these symptoms begin in your early to mid-forties and continue to worsen with age. Some people report a sudden onset of symptoms.

4. WHAT OPTIONS ARE AVAILABLE TO TREAT PRESBYOPIA?

Other treatments for your presbyopia beside the VisAbility™ Micro Insert System are available. The options include:

Optical Aids

1. Glasses (bifocals, trifocals, progressives and near vision only readers).
2. Contact lenses,
    - Multifocal – (both near and far vision), or
    - Monovision – (one eye for near and the other for far).

Surgical Treatments

1. Corneal inlays.
2. Intraocular lenses,
    - Multifocal – (both near and far vision).
    - Accommodating – (self-adjusts for near to far vision),
    - Monofocal monovision – (one eye for near and the other for far),
3. Corneal laser therapies (multifocal or monovision).

5. WHAT IS THE VISABILITY™ MICRO INSERT SYSTEM?

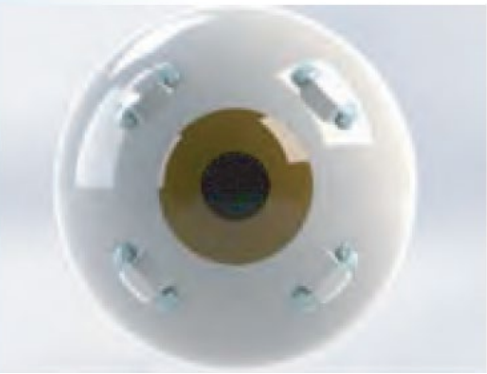
The VisAbility™ Micro Insert System places four small two-piece Micro Inserts into each eye.

Figure 2: Micro Insert individual pieces that are joined during surgery

Figure 3: Comparison of actual size to the euro.

The Micro Inserts are made of the same plastic material as many of the artificial lenses that are used in standard cataract surgery. All four Micro Inserts are individually placed in a small opening beneath the surface of each eye with specialized instruments. All Micro Inserts leave your line of sight unaffected as they are located well away from your cornea and iris (colored part of your eye). See **Figure 4** below. The Micro Inserts are small, normally hidden by your eyelids, and are generally not noticeable after placement.

Figure 4: Location of Micro Inserts



6. WHAT ARE THE POTENTIAL BENEFITS OF THE PROCEDURE?

Results of the clinical study showed that study participants implanted with the VisAbility™ Micro Insert showed improvement in their near vision. This means that if you currently use glasses or magnifiers to read small print close up, you may decrease your dependence on them or no longer need them to see clearly at near after the procedure. You should be able to read your cell phone more easily. Also, you should be able to adjust your computer or tablet view settings to a smaller font to be able to see more information on your screen.

The VisAbility™ Micro Insert System improved near vision in the study participants without compromising distance vision.

7. WHAT ARE THE POTENTIAL RISKS OF THE PROCEDURE?

As with any eye procedure, your vision may be worse after surgery or you may need to wear reading glasses for some near vision activities.

Other risks include the following:

Decreased Blood Flow to Your Iris (the colored part of your eye)

A decrease in blood flow to your iris may cause a temporary decrease in vision, cloudy vision and/or eye pain. There could be a permanent change in the shape of your iris opening (pupil) and/or a decrease in your pupil response. Your pupil response will be monitored on the day of surgery and if a decrease in response is found, removal of the implants will be considered.

Scleral Perforation

A hole in the white tissue of the eye which might lead to retinal complications or increase the risk of infection, and may be repaired with glue or sutures.

Dry Eye

You may develop new dry eye symptoms or have worsening of pre-existing dry eye symptoms after the procedure. Symptoms of dry eye include watery, burning, itchy, red and/or uncomfortable eyes. You may have brief episodes of blurred vision. If you experience dry eyes, you may be treated with artificial tears, prescription medications, punctal plugs, sleep masks or other treatments targeting your symptoms. If the dryness is related to the VisAbility™ Micro Insert, and cannot be alleviated by the aforementioned treatments, your eye surgeon may discuss removing it.

Increased Eye Pressure

The eye drops used after the procedure to control inflammation may increase your eye pressure. If this occurs, your doctor will either adjust your medication or add a medication to lower the eye pressure.

Conjunctival Cyst

You may develop a fluid filled cyst in the conjunctiva (outer most tissue of your eye). The cyst could go away by itself. It may also remain small and unnoticeable. If the cyst persists and bothers you, it can be removed by your eye surgeon.

Contact Lens Intolerance

If you currently wear contact lenses successfully, you may be unable to wear contact lenses after the procedure if the edge of the contact lens rubs against the tissue over the VisAbility™ Micro Insert. Removal of the Micro Insert or changing the contact lens brand will likely eliminate symptoms.

Other Risks

Other risks include droopy and/or swollen eyelids; thinning of the clear covering of the eye; prolonged redness of the eye; and broken blood vessels on the surface of the eye. Additionally, it may be necessary to remove one or more of the Micro Insert segments; this requires a minor surgical procedure.

8. WHO SHOULD NOT HAVE THE VISABILITY™ PROCEDURE?

You should not have the VisAbility™ procedure if:

- You have inflammation in either eye that occurs often or is constant.
- You have an eye disease(s) that affects the whole body and that can cause inflammation of the eye.
- You have had previous eye surgery (e.g., corneal transplant, glaucoma filtering procedure, vitrectomy, retinal detachment repair, cataract surgery).
- You have had surgery of the muscles of the eye.
- You have a crossed eye, an imbalance of the muscles of the eye or use glasses with prism correction.

- Your sclera (white part of your eye) is too thin. (This can be measured)
- You have chronic eye disease.
- You have an active eye infection or inflammation in either eye (e.g., conjunctivitis, blepharitis, chalazion, corneal abrasion or keratitis).
- You have a chronic illness that may affect your eye.
- You have an uncontrolled disease of either the eye or the body that could compromise your recovery.
- You use a blood thinning medication and your primary care doctor cannot allow you to stop this medication for at least 10 days before the surgery. Examples include coumadin, aspirin, or a nonsteroidal anti-inflammatory medication.
- You have severe dry eye.
- You are currently pregnant or lactating.

9. WARNINGS AND PRECAUTIONS

WARNINGS

- Contact your eye doctor immediately if you have any concerning symptoms after surgery (e.g., pain, cloudy vision, or decreased vision).
- There are risks involved with any surgical procedure. These risks may include infection, retinal detachment, or an increase in eye pressure.
- Contact your doctor immediately if you experience pain and/or decreased vision.

PRECAUTIONS

- Tell your eye doctor about any health condition that may affect your surgery or vision.
- Avoid all activities that could harm your eye while you are recovering from surgery.
- Take all prescribed medications.
- Apply eye drops as instructed.
- Wear the provided eye shield while sleeping for at least 1 week after the surgery.

10. AM I A GOOD CANDIDATE FOR THIS PROCEDURE?

You may be a good candidate for this procedure if:

- You are between 45 and 60 years old.
- You have not had cataract surgery.
- You only need glasses or contact lenses to see clearly at near distances.
- Your distance vision in each eye is clear without wearing glasses or contact lenses.

11. WHAT TO EXPECT BEFORE, DURING AND AFTER THE VISABILITY™ PROCEDURE?

It is important to follow your doctor's recommendations and care regimen before and after the surgery.

Before Surgery

If you are interested in the VisAbility™ Micro Insert System, your eye doctor will conduct a thorough examination that includes an evaluation of:

- Your overall health,
- Your medical history,
- Your current medications,
- The health of both of your eyes to ensure you can qualify for the Micro Insert Procedure,
- Pupil measurement and function,
- The white of the eye to ensure adequate thickness to safely place the Micro Inserts.

If you and your doctor agree that you are qualified for and choose to undergo the VisAbility™ procedure, your doctor will recommend medication(s) to be taken before and after surgery. These may include prescription and non-prescription therapies, such as antibiotics that prevent infection, anti-inflammatory medications that reduce swelling and/or pain medications. Your doctor will also recommend artificial tears to help make your eyes more comfortable after surgery.

During Surgery

Prior to the Micro Insert procedure, eye drops will be administered to the surface of your eye to eliminate pain. Additionally, you may be given other prescription medications (either by mouth or through a vein in your arm) before, during, or after the surgery to prevent infection, treat pain, relieve discomfort, or target other side effects of the surgery. It is possible that you may receive general anesthesia before the procedure; your doctor will discuss this with you if he thinks it will be helpful to you during the procedure.

Your doctor may place very small sutures in your eye during the procedure. These sutures will be absorbed or removed by your doctor within 1-2 weeks.

Your doctor may place very small temporary plugs in the tear ducts of your eyelid. These plugs prevent tears from draining off the surface of your eye. This may increase the moisture on the surface of your eye and should make you more comfortable after surgery.

After Surgery

Following surgery, you will be closely monitored until you have fully recovered from the medications given to you before and during surgery. Your pupil will be evaluated in a dark room to ensure adequate blood flow to your eye. You will be discharged once your doctor confirms that your pupil has full functionality.

You cannot drive for the remainder of the day. Someone must drive you home once you are discharged.

It is best if you rest and keep your eyes closed until the next day. Your doctor will likely examine you the next day. Your eye doctor will likely provide you with eye shields to wear while sleeping during the first week after surgery.

You will use medications for a few weeks to prevent infection, reduce swelling, and discomfort. Occasionally, you may be given a drop or a pill to control the pressure in your eye, and/or you may be given an oral pain medication.

You should not rub your eyes while you are recovering from surgery. You should also avoid getting ocean, lake, hot tub, or shower water in your eyes for at least 1 week after surgery.

As soon as possible, start using your near vision without readers or bifocals in the weeks following surgery. Allow more time and consider increased light to read.

It is important to follow your doctor's recommendations and care regimen before and after the surgery.

12. CLINICAL STUDY FINDINGS

A clinical study was conducted to evaluate the safety and effectiveness of the VisAbility™ Micro Insert for improvement in near vision. A total of 708 eyes of 360 patients between 45 and 60 years of age were treated at 13 U.S. clinical sites. Sixty (60) percent of the patients treated with the VisAbility™ Micro Insert were male and 40% were female. The average age of the study patients was 51 years, and the majority of the study patients were Caucasian (85%).

Effectiveness Outcomes

Results of the VisAbility™ clinical study show improved near vision in eyes implanted with the VisAbility™ Micro Insert System without a permanent decrease in distance vision.

Before the surgery, only 6% of the patients were able to read the 20/32 line on a near vision chart without any glasses using both eyes. The 20/32 letter size is similar to the size of letters in a small print paperback novel or the size of letters in a typical footnote. By 3 months after the surgery, 85% of the subjects were able to read the 20/32 line, and at 12 months, 88% were able to read it. At 24 months, 89% of the patients were able to read the 20/32 line using both eyes without glasses.

The VisAbility™ clinical study also measured each patient's preferred reading distance, which is the distance where the patient judged the letters of a near vision chart to be the clearest. Before the surgery, patients reported the letters being clearest at an average distance of 59cm which would correspond to trying to hold a newspaper a full arms-length away to read. Forty centimeters represents the typical non-presbyopic reading distance where one is comfortable reading with a bent elbow. This is why a common presbyopic complaint is that "my arms are not long enough" to read clearly. At just 3 months after the VisAbility™ surgery, the patients reported that they were able to see clearest an average of 16.6cm closer than they were before surgery. At 24 months, the average was 18.9cm closer. This means that most no

longer needed to fully extend their arms to read and could now read comfortably with a bent elbow instead.

The official clinical study benchmark was the percentage of patients who were able to achieve functional near vision (20/40) in their first surgically implanted eye along with at least 2 lines of improvement from their vision prior to surgery. Real life examples of 20/40 size print would be the print in a telephone directory or want ads. At 12 months, 81% of the patients' first implanted eyes achieved this combined goal and by 24 months, 86% of the patients' first implanted eyes achieved this combined goal.

Safety Outcomes

Distance Vision

The best distance vision when corrected with glasses was 20/20 or better in 99% of all eyes in the study and 20/40 in all eyes at the 12, 18 and 24 month visits. There were no instances of permanent loss of distance vision. There were temporary decreases in distance vision in 10 eyes of 9 subjects which returned to normal by the next study visit. Two of these eyes in two patients had decreased distance vision due to developing cataracts and required cataract surgery to return to normal.

Ocular Adverse Events

Ocular Adverse Events are described below. The majority of adverse events were not serious and resolved without intervention.

The most common adverse events involved the surface of the eye and were events such as:

- Dry eye – 12% of patients were treated for dry eyes with prescription medication after 6 months from the surgery. Many were treated only because they said the eye felt dry and they didn't show any signs of dryness when examined by the doctor.
- Lash debris or clogged eyelid glands – 9% of patients had these findings after 3 months from the surgery. This is a common finding in people of this study age group, and is often treated with lid scrubs and more than 25% of these study eyes had some of these signs before the surgery.
- Conjunctival injection – 6% of patients had red or injected eyes at 3 months or later after the surgery. This condition is usually treated with artificial tears. Over half of these patients' cases resolved within 3 months.

Resuturing

- 15 or 4.4% of patients had additional sutures placed between day 1 and 1 week.
- There were no complications associated with these cases.

Scleral Perforation

- 8 or 2.2% of patients developed a small hole in the white tissue of the eye (sclera) during the surgical procedure.
- No loss of vision

- No infections
- 1 eye had a temporary leak of fluid and a cataract which resulted in cataract surgery.

Implant Removal

- 8 or 2.2% of patients
- 2 patients – Explant recommended by the doctor for delayed pupil recovery.
- Explants requested by the patient for the following reasons:
    - 2 patients – felt like something was in the eye
    - 2 patients – eye redness around the implant
    - 1 patient – felt like there was no effect
    - 1 patient – blurry distance vision without glasses
- There were no complications or loss of vision as a result of the implant removals.

Changes to Pupil Response

- 5 or 1.4% of patients experienced a temporary change in the pupil response of one eye that was possibly related to a decrease in blood flow to the iris.
- All of the pupil responses and shapes eventually returned to normal.
- None of the eyes had any permanent loss of vision.
- 2 eyes had the implants removed on the day of surgery.
- 1 eye developed a lighter colored area of the iris.

13. WHERE CAN I GO FOR ADDITIONAL INFORMATION?

Primary Eye Care Professional

Name: _____

Address: _____

Telephone number: _____

Eye Surgeon

Name: _____

Address: _____

Telephone number: _____

Surgical Center

Name: _____

Address: _____

Telephone number: _____

Manufacturer and Customer Service

9155 Sterling Street, Suite 160
Irving, TX 75063
001-949-688-0550
www.refocus-group.com

CE 2797

EC REP

EMERGO EUROPE
Prinsessegracht 20
2514 AP The Hague
The Netherlands

NOTES

BL001 v1 Released 25June21