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What's EVO Vision ICL?

Patient Information Leaflet

An Evolution in Visual Freedom™

Also known as the Implantable Collamer Lens, EVO is the new generation in vision correction. Think of it as an implantable lens that works with your natural eye to correct your vision. This procedure creates options for a much wider range of prescriptions that can free you from glasses and contacts. EVO offers benefits, which people suffering from near-sightedness, farsightedness and astigmatism should consider.

Why Choose EVO?

No Dry Eye Syndrome

Only EVO's proprietary lenses are made of biocompatible Collamer. That means the lens material works in harmony with the natural chemistry of your eye and body. The ability to utilise materials your eye accepts while not reshaping your cornea means we can minimise unnatural causes of dry eye syndrome.²

A Removable Option

We describe our implant process as an additive corrective procedure. Our procedure adds a corrective lens to correct near-sightedness, farsightedness and astigmatism. That means that should your prescription update or if other vision needs arise, if you and your doctor decide, your doctor can simply remove our lens.

Quick Procedure & Recovery

The EVO procedure has been refined down to a quick and comfortable process. Most procedures are completed within 20-30 minutes or less. With a minimally invasive procedure, many achieve improved vision nearly immediately.

What's EVO Made Of?

Advanced Collamer Lens Material

Collamer is a proprietary material used exclusively by STAAR Surgical in EVO and other corrective lenses. This material consists of collagen, which naturally occurs in your body. Collamer technology has some unique characteristics that make it an ideal material for a vision correction lens.

Who is a Good Candidate for EVO?

EVO Suitability

- Are between 21 and 60 years old.
- Are near-sighted with mild to severe myopia (-0.5D to -20D).
- Are farsighted with mild to severe hyperopia (+0.5D to +10.0D)
- Have astigmatism between 0.5 and 6.0 D
- Have not had a change in prescription of more than 0.5D in a year.
- Are looking for a procedure that doesn't create dry eye syndrome

What Can I Expect During The Procedure?

Easy 20-30 Minute Procedure

Before the Surgery

Before surgery, your doctor needs to determine your complete medical and eye history and check the health of both your eyes. This exam will determine if your eyes are healthy and if you are a good candidate for ICL surgery. This examination will include a measurement of the inner layer of your cornea (endothelium).

If you wear contact lenses, it is very important that you stop wearing them 2 to 4 weeks before your eye examination and surgery for the doctor to obtain a stable eye measurement. Failure to do this may lead to suboptimal results of your surgery.

Tell your doctor if you take any medications, have any eye conditions, have undergone previous eye surgery, have any medical conditions or have any allergies. Ask your doctor if you should eat or drink right before the surgery. You should also arrange for transportation since you must not drive immediately after surgery. Your doctor will let you know when your vision is good enough to drive again.

Two to Three Weeks before Surgery

Two to three weeks before your Visian ICL surgery, your doctor will make two holes in the extreme outer edge of the colored portion of the eye (peripheral iridotomies) to prepare your eye for implantation of the Visian ICL. This is necessary to make sure that the fluid flows properly from the back chamber to the front chamber of the eye to prevent a buildup of pressure within the eye after Visian ICL surgery. The doctor will usually apply numbing drops to the eye and make tiny openings in the colored portion of the eye (iris) with a laser beam. This can affect your ability to drive home after this procedure but check with your doctor.

After the peripheral iridotomy procedure, you will be prescribed eye drops for you to use. It is important that you follow all medication instructions. Your doctor will instruct you to discontinue the use of these medications before the day of surgery.

The Day of Surgery

On the day of surgery, eye drops will be placed in your eye to

enlarge (dilate) the black part of your eye (pupil). Once your pupil is fully dilated, your doctor will put numbing eye drops in your eye and/or inject a needle with numbing medication into your eye and ask you to lie on your back on the treatment table/chair in the treatment room. Your doctor may discuss alternative anesthetic/sedation options with you before surgery.

A small incision is made into the clear front layer of the eye that lets light enter (cornea) and the Visian ICL is inserted and positioned in its proper position in the eye. The entire procedure will usually take approximately 20 to 30 minutes or less.

After the surgery is complete, your doctor will place some eye drops/ointment in your eye. For your eye protection and comfort, your doctor may apply a patch or shield over your eye. The procedure is painless because of the numbing medication. It is important that you do not drive yourself home and make arrangements before the day of surgery for transportation home.

The First Days after Surgery

Your doctor will need to see you the day after surgery to conduct an eye exam, which will include monitoring the pressure in your eye.

You may be sensitive to light and have a feeling that something is in your eye. Sunglasses may make you more comfortable. Also, your eye may hurt. Your doctor can prescribe pain medication to make you more comfortable during the first few days after the surgery. If you experience severe pain in the eye, please contact your doctor immediately. You will need to use eye drop/ointment

drugs in the first week to treat or prevent infection (antibiotic) and reduce inflammation in the eye (anti-inflammatory) in the first week.

IMPORTANT: Use the eye medications as directed by your eye doctor. (Your results may depend upon your following your doctor's instructions).

DO NOT rub your eyes, especially for the first 3 to 5 days after surgery. If you notice any sudden decrease in your vision, you should contact your doctor immediately.

Long Term Care: In a small number of cases, Visian ICL replacement and/or removal may become necessary. Visian ICL replacement may be performed if your doctor believes a different lens may either fit your eye better or provide you better vision. Visian ICL removal may be necessary if you develop a cataract and your doctor recommends surgery. If you need to have cataract surgery, the intraocular lens used to replace your natural crystalline lens can often correct your nearsightedness.

If your doctor removes the Visian ICL, you will lose the benefit of your nearsightedness correction. This means that your vision may not return to what it was like before the Visian ICL surgery. After Visian ICL surgery it is important that you follow your doctor's recommendations for eye care and follow-up visits.

What Are The Risks?

It's important to consider that the EVO is approved by the local health authority, which means it has been determined to be safe and effective. As with any procedure, there are risks to consider. See Important Safety Information and read more about the risks below. If you have any questions or concerns it's always best to speak with the doctor.

Over or Under Correction

The most common complication with any refractive procedure is overcorrection or under-correction. We take every precaution to take meticulous measurements before your procedure to ensure the right amount of correction is prescribed. Because the EVO lens can be removed, adjustments can be made to reduce any sort of overcorrection or under-correction. The same risks apply to the second surgery.

Halos & Night Glare

In any refractive procedure like Lasik, PRK or EVO there is a possibility of halos and glare around lights at night.

Damage to the Crystalline Lens

Since EVO is placed inside the eye, there is potential risk in touching the eye's natural (crystalline) lens. While occurring in less than 1.5% of patients, any damage to the natural (crystalline) lens may cause an opacity (cataract) of the lens and, in the most serious case, may require removal of the cataractous natural lens

and replacement of the natural (crystalline) lens with a synthetic lens. The surgical risks for IOLs are similar to ICLs.

Increase in Eye Pressure

In some cases, an increase in eye pressure can occur as a result of the procedure. In the event of this occurrence your doctor may quickly correct the problem with additional medication or surgical intervention. If not corrected or left untreated the increased pressure could result in loss of vision. Remember to speak with your doctor about your personal situation and considerations.

Risk of Infection

All surgical or refractive procedures involve some form of invasiveness, which means there is a risk of infection. While uncommon, it's important to realise that an eye infection can have a range of results, from delayed healing to serious eye damage. We try to reduce this risk by starting with sterile products used in a minimally invasive procedure and preventative treatments administered to the affected area.

Loss of Visual Acuity

While extremely rare, all refractive procedures can result in damage to the eye including the loss of visual acuity including in most severe cases loss of functional vision.

Iridotomy Complications (If Iridotomy is required)

During the iridotomy phase of the pre-op treatment a laser is used to make small incisions in the eye. Complications from this incision rarely occur but can cause natural lens or corneal damage, inflammation, increase in intraocular pressure, bleeding and scar formation. Iridotomies are not required for all lens models. Speak with your ophthalmologist to see if your lens model requires this step.

Remember to speak with your doctor about your personal situation and considerations.

FAQ

- What is EVO?

EVO is a refractive lens also known as a phakic IOL. “Phakic” meaning that the natural lens of the eye is in place, and “IOL” meaning intraocular lens, or a lens inside the eye. The EVO is a posterior chamber implant that is situated through a small incision in the eye behind the iris (the coloured part of the eye), and in front of the natural crystalline lens in order to improve your near-sightedness, farsightedness or astigmatism.

- What and who is EVO intended for?

EVO surgery is intended to safely and effectively correct near-sightedness (-0.5 to -18.0 dioptres (D)), the reduction of near-sightedness in patients with up to -20 dioptres (D) of near-sightedness, treatment of astigmatism from +0.5D to +6D and and correction of farsightedness from 0.5 to 10.0D. It is indicated for patients who are at least 21 years of age.

In order to be sure that your surgeon will use an EVO lens with the most adequate power for your eye, your near-sightedness should be stable for at least a year before undergoing eye surgery.

The EVO represents an alternative to other refractive surgeries including laser assisted in situ keratomileusis (LASIK), photorefractive keratectomy (PRK), other laser vision correction procedures, incisional surgeries or other means to correct myopia such as contact lenses and eye glasses.

- Who should not have the EVO procedure?

Patients who are pregnant and nursing and patients with a narrow angle in the front chamber of their eye, because in this case the space for the EVO lens would be too small. The patient education booklet provides an additional list of conditions that should be

taken into consideration when making a decision about the EVO procedure.

- What is the key potential benefit of EVO?

The key benefit of EVO surgery is the permanent correction or reduction of your near-sightedness, farsightedness or astigmatism allowing you to see clearly without eyeglasses or contact lenses or reduce your dependence upon them. In addition to the improvement of your uncorrected vision (vision without eyeglasses or contact lenses), your best-corrected vision (best vision with contact lenses/eye glasses) may be improved.

- What is EVO made of?

The material is called Collamer® , a collagen co-polymer that contains a small amount of purified collagen which is proprietary to STAAR Surgical; the remainder is made of a similar material to that found in soft contact lenses. It is very biocompatible (does not cause a reaction inside the eye) and stable. It also contains an ultraviolet light filter.

- What is the history of EVO?

Prior to being placed on the market, EVO & Visian ICL was subject to extensive research and development. Today, more than 900,000 lenses in the EVO family have been implanted worldwide. In a US clinical study, over 99 percent of patients were

satisfied with their implant. The EVO has a track record of excellent clinical outcomes. Additionally, the lens has been available internationally for over 15 years.

- Can EVO be removed from my eye?

EVO is intended to remain in place without maintenance. The lens can be removed by your eye care professional if needed in the future. If your physician removes the lens, you will lose the benefit of your vision correction.

- Is the EVO lens visible to others?

No. EVO is positioned behind the iris (the coloured part of the eye), where it is invisible to both you and others. Only your eye care practitioner will be able to tell that vision correction has taken place.

- Will I be able to feel the EVO lens once it's in place?

EVO is not typically noticeable after it is implanted. It does not attach to any structures within the eye and does not move around once in place.

- What is involved in the EVO procedure?

The EVO surgery is performed on an outpatient basis, which means that the patient has surgery and leaves the same day. The

procedure itself usually takes 20-30 minutes or less. The patient will need someone to drive them home on surgery day. A light, topical or local anaesthetic is administered. There is very little discomfort during or after surgery. Some eye drops or medication may be prescribed and a visit with your eye care professional is usually scheduled the day after surgery.

- What are the key points to remember?

Follow all of your eye care professional's instructions before and after implantation of the EVO lens. Take any prescribed medication and schedule all recommended follow-up visits with your eye care professional. Contact your eye care professional immediately if you should experience a problem.