

Patient Information Sheet
Visian ICL™ (Implantable Collamer Lens) for
Nearsightedness (Myopia)

IMPORTANT:

The following basic information about the Visian Implantable Collamer Lens (ICL) is provided for you by STAAR Surgical Company.

If you are interested in the Visian ICL, please see a licensed eye care professional. Based on your individual needs, your eye care professional will determine if the Visian ICL is right for you. The Visian ICL is implanted by an ophthalmic surgeon and therefore you will need to make arrangements to meet with an ophthalmic surgeon experienced with the Visian ICL.

What is the Visian ICL for Nearsightedness?

The Implantable Collamer Lens for Nearsightedness 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 Visian ICL is a posterior chamber implant that is situated through a small incision in the eye behind the iris (the colored part of the eye), and in front of the natural crystalline lens in order to improve your nearsightedness.

What are Visian ICL’s 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 Visian ICL intended for?

The Visian ICL is designed for the correction of moderate to high nearsightedness (-3.0 to -15.0 diopters (D)), and the reduction of nearsightedness in patients with up to -20 diopters (D) of nearsightedness. It is indicated for patients who are at least 21 years of age. In order to be sure that your surgeon will use an Visian ICL with the most adequate power for your eye, your nearsightedness should be stable for at least a year before undergoing eye surgery.

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

The Visian ICL is not intended to correct any astigmatism you may have.

Who should not have Visian ICL surgery?

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 Visian ICL 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 Visian ICL.

What is the key potential benefit of the Visian ICL?

The key benefit of Visian ICL surgery is the permanent correction or reduction of your nearsightedness allowing you to see clearly at long distances 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 are the potential risks of the Visian ICL for Nearsightedness?

Early complications reported the first week after Visian ICL surgery include: Visian ICL removal and reinsertion at the time of initial surgery, shallowness of the front chamber of the eye that can create an increase of the pressure into your eye and may necessitate a peripheral iridectomy (a procedure where a small hole is placed in iris (colored part of eye) using a laser called “YAG laser), temporary corneal swelling (edema) and transient inflammation in the eye or iritis.

Complications after 1 week include: increase in astigmatism, loss of best corrected vision, clouding of the Crystalline lens (cataract), loss of cells from the back surface of the cornea responsible for the cornea remaining clear (endothelial cell loss), increase in eye pressure, iris prolapse, cloudy areas on the crystalline lens that may or

may not cause visual symptoms (crystalline lens opacities), macular hemorrhage, subretinal hemorrhage, retinal detachment, secondary Visian ICL related surgeries (replacements, repositionings, removals, removals with cataract extraction), too much or too little nearsightedness correction, and additional YAG iridotomy necessary.

What are risks of Refractive Eye Surgery in general?

Potential complications for refractive surgery in general include: irritation of the conjunctiva (white part of eye), corneal swelling (outer layer of eye), eye infection, significant glare and/or halos around lights, blood/pus in the eye, lens dislocation, macular edema, (swelling in back of the eye), non-reactive pupil, pupillary block glaucoma resulting in raised eye pressure, irritation of the iris (colored part of the eye), severe inflammation of the eye and loss of the vitreous (gel in back of eye).

You should carefully review all benefits and risks of Visian ICL surgery with your eye care professional before making a decision about the Visian ICL.

What is involved in the Visian ICL procedure?

The Visian ICL surgery is performed on an outpatient basis which means that the patient has surgery and leaves the same day. The patient will need someone to drive them home on surgery day. A light, topical or local anesthetic 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.

Can the Visian ICL be felt once it is in place?

The Visian ICL 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.

Can the Visian ICL be removed?

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

What are the key points to remember?

Follow all of your eye care professional's instructions before and after implantation of the Visian ICL. Take any prescribed medication and schedule all recommended follow-up visits with your eye care professional, usually on an annual basis after the healing of the Visian ICL surgery. Contact your eye care professional immediately if you should experience a problem.

What if I have more questions regarding the Visian ICL for Nearsightedness?

It is crucial you visit your eye care professional about your eye health and to obtain complete information concerning the Visian ICL procedure. Please discuss all your questions with your eye care professional.

If you want to read more about the Visian ICL for Nearsightedness, ask your eye care professional for the patient education booklet available from STAAR Surgical or the package insert written for the eye care professional.

For more information call (800) 352-7842 or visit our website at www.staar.com.

The Visian ICL is:

Distributed by:

**STAAR Surgical Company
1911 Walker Avenue
Monrovia, CA 91016 USA
Tel: (800) 352-7842
Fax: (800) 952-4923**

Manufactured by:

**STAAR Surgical AG
Hauptstrasse 104
CH2560 Nidau, Switzerland
Tel: +(41) 32 332 8888
Fax: +(41) 32 332 8899**