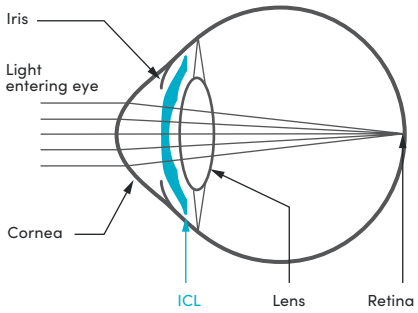
STAARSURGICAL™

Patient Safety Information for STAAR Surgical Implantable Collamer Lenses (ICLs) for Nearsightedness

GENERAL INFORMATION

The STAAR Surgical EVO and EVO+ Implantable Collamer® Lens (ICL) are refractive lenses also known as **phakic intraocular lenses** (IOLs). "Phakic" meaning that the natural lens of the eye is left in place, and "IOL" meaning that an artificial intraocular lens is surgically implanted inside the eye. The ICL lens is intended to correct or reduce **nearsightedness** with or without **astigmatism**. **Nearsightedness** is a focusing error that results in blurred vision of far objects. **Astigmatism** is a focusing error that results in blurred vision of far and/or near objects.

Your eyeglass or contact lens prescription tells your doctor how **nearsighted** you are and how much **astigmatism** you have. The ICL is intended to correct or reduce **nearsightedness** in patients with prescriptions of from -0.5 to -20.0 **diopters** with or without **astigmatism** of up to 6.0 **diopters**. It is intended to be implanted in patients 21 - 45 years of age through a small incision in the **cornea** and placed in the eye, behind the **iris** (the colored part of the eye) and in front of the **natural crystalline lens**. The EVO/EVO+ ICL is a lens made from a soft, biocompatible collagen-based material called Collamer. It is similar to lenses that are placed in the eye (intraocular lenses) to correct vision after **cataract** surgery.



Location of the ICL after surgery

AVAILABLE MODELS

The EVO/EVO + ICL models available in Australia are:

- VICMO
- VTICMO
- VICM5
- VTICM5

See the section at the end of this leaflet on Patient Implant Cards for how to identify the specific model implanted in your eye(s).

DEVICE MATERIAL INFORMATION

STAAR ICLs are made from a material called Collamer®, a polymer proprietary to STAAR Surgical that is made of a similar material to that found in soft contact lenses combined with a small amount of purified porcine collagen. It also contains an ultraviolet light filter. Collamer is biocompatible, which means that it does not cause a reaction inside the eye.

RISKS

Implantation of the ICL is a surgical procedure, and as such, carries potentially serious risks, which should be discussed with your doctor.The following represent potential complications/adverse events:

- under/over correction of vision,
- additional surgeries,
- ICL removal, replacement, or repositioning,
- **cataract** formation,
- temporary or permanent loss of best corrected vision,
- raised pressure inside the eye,
- a loss of cells on the innermost surface of the **cornea**,
- a reddening of the observable, white portion of the eyeball and inner eyelid,
- abnormal fluid build-up/swelling in the **cornea**,
- severe infection or inflammation of the entire eyeball,
- significant **glare** and/or **halos** around lights,
- blood in the eye,
- pus in the eye,
- eye infection,
- ICL dislocation,
- swelling in the area responsible for fine (reading) vision on the back surface of the eye,
- non-reactive pupil,
- the inability of fluid to flow from the back chamber of the eye to the front chamber frequently blocking drainage of fluid out of the eye and raising the pressure in the eye,
- severe inflammation of the eye, inflammation in the front chamber, middle layer of tissue, or other portion of the eye,
- loss of a clear gel-like material from the farthest back chamber of the eye during a surgical procedure,
- separation of the **retina** from its natural position on the back surface of the eyeball, and
- **corneal** transplant.

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

STAAR ICLs are intended to remain in place without maintenance. The long-term effect of the lens has not been determined. After ICL surgery it is important that you follow your doctor's recommendations for eye care and follow-up visits.

All surgical procedures involve some form of invasiveness, which means there is a risk of infection. While uncommon, it is important to realize that an eye infection can have a range of results, from delayed healing to serious eye damage. Surgeons reduce this risk by using sterile products, a minimally invasive procedure, and preventative treatments given to the affected area.

If you notice any sudden decrease in your vision, you should contact your doctor immediately. After ICL surgery it is important that you follow your doctor's recommendations for eye care and follow-up visits. The Patient Implant Card should be used to provide information regarding your implanted ICL to any eye doctor that you visit.

A thin, single layer of cells (**endothelial cells**) on the inner surface of the **cornea** inside of your eye, keeps the **cornea** clear by pumping water out of it. Normally, these cells slowly decrease in number as you age. Additional loss of these cells beyond the normal amount can happen after many kinds of eye surgery. If too many cells are lost, the **cornea** can become cloudy, which can decrease vision. You should see your doctor regularly for **Endothelial Cell Density** (ECD) exams after ICL implantation surgery. This will help your doctor monitor the long-term health of your **cornea**.

There is a part of the eye that fluid flows through when draining from the inside of the eye. After ICL surgery, this drainage area may narrow and should be monitored by your doctor. In some cases, an increase in eye pressure can occur because of the procedure. If this occurs, your doctor may quickly correct the problem with medication or a surgical intervention. If not corrected or left untreated the increased pressure could result in loss of vision. It is important that you return to the doctor after surgery, according to the schedule that s/he provides.

In a small number of cases, ICL removal and/or replacement may become necessary. ICL replacement may be performed if your doctor believes a different lens may either fit your eye better or provide you with better vision. 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 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 ICL surgery. After ICL surgery it is important that you follow your doctor's recommendations for eye care and follow-up visits.

In any vision correction procedure like ICL there is a possibility of **halos** and **glare** around lights at night.

While extremely rare, all vision correction procedures can result in damage to the eye including the loss of sharpness of vision, including loss of functional vision in severe cases.

Toric Models VTICMO and VTICM5 only - ICL repositioning may be performed if your doctor finds the Toric ICL is not properly aligned for the correction of **astigmatism**.

REPORTING

Any serious incident that occurs in relation to the ICL should be reported to the manufacturer and the Therapeutic Goods Administration (TGA).

Manufacturer contact information

STAAR Surgical AG
Hauptstrasse 104 CH-2560, Nidau
Switzerland
www.staar.com
+41 32 332 8888

TGA contact information

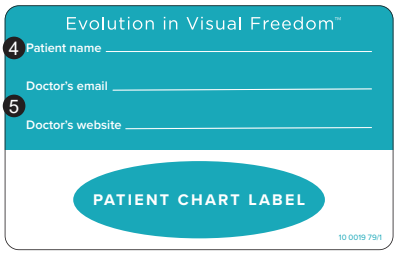
https://www.tga.gov.au

GLOSSARY

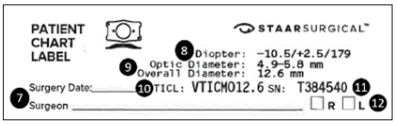
- **Astigmatism** - A focusing error that results in blurred distant and/or near vision. The *cornea* is more curved in some directions than others, and causes light rays to focus at different points inside the eye. Parts of objects appear clearer than other parts.
- **Cataract** - Opacity, or clouding, of the *crystalline lens* inside the eye that can blur vision.
- **Cornea** - The clear front layer of the eye.
- **Crystalline Lens** - A structure inside the eye that helps to focus light onto the back surface (*retina*) of the eye.
- **Diopter** - A unit of focusing power, used to describe the amount of *nearsightedness* and *astigmatism* of an eye. Abbreviated as "D".
- **Endothelium** - A thin, single layer of cells on the innermost surface of the *cornea*, responsible for keeping the *cornea* clear. These cells do not reproduce and decrease in number with age.
- **Glare** - A harsh or uncomfortable bright light. *Glare* symptoms are usually caused by a distortion of light that would otherwise be tolerable without the distortion.
- **Halos** - Circular flares or rings of light that may appear around a headlight or other lighted object. This symptom may occur after surgery.
- **Iris** - Colored part of the eye which controls the amount of light entering the eye.
- **Nearsighted/Nearsightedness** - A focusing error that results in blurrier vision at distance than near.
- **Phakic Intraocular Lens** - A thin man-made lens that is placed in an eye that still has its natural *crystalline lens*.
- **Retina** - The layer of nerve tissue at the back of the eye that captures images, similar to film in a camera, and sends information about these images to the brain. Light must be focused correctly on the *retina* to form clear images.

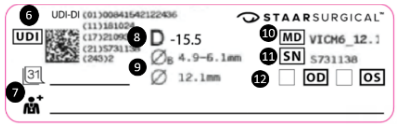
PATIENT IMPLANT CARD

The implant card provided to you by your surgeon contains information specific to the individual STAAR ICL that was implanted.



The chart label on the card will be one of the following styles





1. The type of device implanted.
2. The website to find important safety information about the ICL.
3. The name, address, and website of the ICL manufacturer.
4. Your name.
5. You doctor's email and website.
6. The unique device identification (UDI) number and barcode. This number is specific to the model, size, and power that was implanted. This will not be present on all labels.
7. The date of surgery and name of the surgeon.
8. The power of the ICL that was implanted.
9. Size of the optic and the overall size of the ICL that was implanted.
10. Model of ICL that was implanted and lens length.
11. Serial number of the ICL that was implanted.
12. Eye that was implanted. R/OD = right eye and L/OS = left eye.