PATIENT INFORMATION LEAFLET FOR INTRAOCULAR LENSES

Dear patient,

You recently received an artificial lens implant (also known as an intraocular lens or IOL) manufactured by HumanOptics. This Patient Information Leaflet is designed to provide answers to the questions most frequently asked about intraocular lenses. Please consult your ophthalmologist if you would like any further information.

WHAT IS AN INTRAOCULAR LENS USED FOR?

During your surgery, your eye's natural clouded lens was removed and replaced with an intraocular lens. This normally significantly improves visual quality.

WHICH PATIENTS IS AN INTRAOCULAR LENS SUITABLE FOR?

An intraocular lens is used in adult patients whose natural lens is no longer present. The absence of the lens may be either congenital, due to an accident or, as in the majority of cases, caused by removal during cataract surgery. There are no clinical data available for children, pregnant or breastfeeding women, and immunocompromised persons in connection with the implantation of intraocular lenses from HumanOptics.

ARE THERE ANY ADVERSE EVENTS CAUSED BY THE IMPLANT?

No medical intervention is entirely risk-free, including cataract surgery and the associated IOL implantation. However, there are no known adverse events caused by the implant itself.

HOW CAN YOU FIND OUT WHICH PRODUCT YOU HAVE BEEN IMPLANTED WITH?

After the surgery, you were given a patient card with the manufacturer's contact details. As well as your name, the date of the surgery, and the contact details of the ophthalmologist carrying out the surgery and the ophthalmology center, the patient card provides detailed information about the implant used in your case. Your implant is identified by its unique serial number (SN).

WHAT MATERIAL IS THE INTRAOCULAR LENS MADE OF?

Artificial lenses produced by HumanOptics are made of a biocompatible plastic. This is an optically clear, biocompatible, flexible, hydrophilic acrylic copolymer consisting of a polyacrylate (74%) and saline solution (26%), with a refractive index of 1.46 and an Abbe number of 56. This material is compatible with any laser treatment (Nd:YAG laser) that may subsequently be required.

The polyacrylate consists of the main components 2-hydroxyethyl methacrylate (HEMA, approx. 80%) and methyl methacrylate (MMA, approx. 20%) with a UV absorber (<1%).
Models with the trailing “Y” also contain a blue light filter (<0.05%) to protect against high-energy blue components of visible light, which can lead to possible damage to the retina in the long term.
No harmful quantities of substances are released from the IOL material.

WHAT DO I NEED TO DO AFTER THE SURGERY?

To ensure the best treatment outcome, it is important that you follow your ophthalmologist’s instructions and attend the follow-up appointments as agreed with your ophthalmologist.
Unless you have agreed otherwise with your ophthalmologist you should avoid any manipulation on the operated eye, such as pressing or rubbing, in the first two weeks after the surgery. Please also ensure that your eye does not come into contact with water or soap when you are showering or washing. You should also avoid physical exertion, swimming, diving, cycling, or visits to the sauna during the initial period. Activities involving a great deal of dust and dirt should also be avoided.
In the first few days after the surgery, we recommend wearing sunglasses, as you may experience increased sensitivity to glare.

If necessary, you can have new eyeglasses prescribed, normally four to six weeks after the cataract surgery. There is no point in doing this earlier, as the eye needs to become accustomed to the new lens first. In the case of multifocal IOLs, the acclimatization period can be up to 6 months. If you have surgery on the second eye scheduled shortly, we recommend that you do not have your new eyeglasses prescribed until both eyes have been operated on. Please tell your optician about the intraocular lens that has been fitted and any additional features (toric= correction of corneal astigmatism/ multifocal= correction of presbyopia).

HOW LONG CAN THE IMPLANT REMAIN IN MY BODY?

The artificial lens will normally remain in your eye for the rest of your life, provided there is no medical contraindication. The product lifetime of HumanOptics IOLs is proven for twenty years. Regular ophthalmological check-ups are recommended, as for patients with natural lenses.

IS MY INTRAOCULAR LENS MRI SAFE (COMPATIBLE)?

You’ll find information on the Magnetic Resonance Imaging (MRI) safety (compatibility) of your implant on your patient card. This provides important information on the implant with respect to magnetic radiation during MRI scans, as the intraocular lens is permanently fixed inside your body once it is implanted.
All HumanOptics intraocular lenses are MR safe, which means there are no additional restrictions when the IOL enters the magnetic field of an MRI scanner. For further details, please visit www.humanoptics.com/mri.

WHAT SIDE EFFECTS/SYMPTOMS MAY OCCUR THAT ARE ASSOCIATED WITH THE IOL IMPLANTATION OR MAY INDICATE A DEFECT?

The following side effects may occur following the lens implantation and normally disappear after a short time:

- Foreign body sensation caused by the small incision through which the lens was inserted
- Halos, which can form around sources of light, particularly at dusk or in darkness (they may occur more frequently with multifocal IOLs)
- You may experience increased sensitivity to light in the first few weeks after the surgery

The following symptoms may indicate complications associated with an artificial lens implantation. If these occur you should consult your doctor:

- Sudden or gradual deterioration in vision/blurred vision
- Severe redness of the eye
- Eye pain

These symptoms can occur very rarely, even if all precautions are taken. If you experience any of the symptoms listed above, or any unexpected problems with the healing process, please contact your ophthalmologist. If a severe adverse event occurs, the doctor must report it to the manufacturer and to the relevant public health authority. You can find the relevant public health authority in your country listed at www.humanoptics.com/patient-information under “Authorities”.

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