Dear patient,

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

WHAT IS AN ARTIFICIAL IRIS USED FOR?

The **ARTIFICIAL*IRIS*** is a medical implant used to treat aniridia. Aniridia is marked by partial or complete absence of the eye's natural iris.
An artificial iris restores the natural aperture function to the eye, but the pupil size always remains the same, significantly increasing both visual quality and aesthetic appearance of the iris.

WHICH PATIENTS IS AN ARTIFICIAL IRIS SUITABLE FOR?

An artificial iris can be used in adults and children from 6 years whose natural iris is completely or partially absent. Aniridia can be congenital or caused by an accident or disease. There are no clinical data available for breastfeeding women and immunocompromised persons in connection with the implantation of the device.

ARE THERE ANY ADVERSE EVENTS CAUSED BY THE IMPLANT?

No medical intervention is entirely risk-free, including surgery to treat aniridia and the associated **ARTIFICIAL*IRIS*** 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 ARTIFICIAL IRIS MADE OF?

The HumanOptics artificial iris is made of biocompatible silicone (diphenyl co dimethyl polysiloxane and silicone reinforcing resin) with color pigmentation embedded in the silicone. There are two models of the artificial iris (with/without fiber). The with Fiber model has an embedded polymer fiber meshwork made of polyethylene terephthalate (PET) to increase strength. The with Fiber model is used in special cases where suture fixation is indicated.

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.

HOW LONG CAN THE IMPLANT REMAIN IN MY BODY?

The artificial iris will normally remain in your eye for the rest of your life, provided there is no medical contraindication. The product lifetime of HumanOptics artificial iris is proven for twenty years. Regular ophthalmological check-ups are recommended, in consultation with the treating physician.

IS MY ARTIFICIAL IRIS 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 artificial iris is permanently fixed inside your body once it is implanted.
All artificial iris implants manufactured by HumanOptics are certified as MR conditional. The implant is certified as safe with respect to MRI scans under certain conditions. This means that a patient with an artificial iris implant should only enter the magnetic field of an MRI scanner under certain conditions. Please show your patient card to your doctor before the MRI scan.
For further details, please visit www.humanoptics.com/mri.

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

The following side effects may occur following the iris surgery and normally disappear after a short time:

- Foreign body sensation caused by the incision through which the **ARTIFICIAL*IRIS*** was inserted
- Mild eye redness

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

- Sudden or gradual deterioration in vision/blurred vision, flashes of light or dark running dots (floaters)
- Increased sensitivity to light
- Excessive tearing of the eye
- Severe redness and/or itching of the eye
- Eye pain
- Nausea, vomiting, severe headache

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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