HumanOptics

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Instructions for use
ARTIFICIAL*IRIS*

These instructions for use are for the following models and product characteristics:

Models and Design	
ARTIFICIAL*IRIS* with Fiber	ARTIFICIAL*IRIS* Fiber Free
Silicone elastomer with meshwork	Silicone elastomer without meshwork
Color Category	
Individual/Patient-matched ARTIFICIAL*IRIS* CUSTOMFLEX®	
Predefined	

1. Description

The ARTIFICIAL*IRIS* is a foldable iris prosthesis that is used for the treatment of iris defects in eyes which are pseudophakic, aphakic or requiring cataract extraction. The device is manufactured from a commercially available ophthalmic silicone and is delivered sterile (sterilized using steam) in a blister filled with isotonic saline solution.

Colorized silicone paste is applied by hand in a pattern on the front side of the device. For manufacturing of the ARTIFICIAL*IRIS* CUSTOMFLEX®, a photography of the existing iris is used to match the color of the natural iris or, in the case of aniridia, the color of the photography selected by the patient. This custom color-match provides a cosmetically acceptable aesthetic restoration with high patient satisfaction. In addition, the ARTIFICIAL*IRIS* is also manufactured in predefined color variants. The backside of each device is black. Please note, that not all color categories are available for sale in all countries.

The ARTIFICIAL*IRIS* is manufactured as a full 360° iris prosthesis with an overall diameter of 12.80 mm, which can be trephined as needed to custom-fit the device for placement in the posterior chamber (Fiber Free model: ciliary sulcus or capsular bag; with Fiber model: ciliary sulcus). The device has a fixed aperture of 3.35 mm.

The device is available in two different models: with Fiber or Fiber Free. The two models are identical in every respect, except that the with Fiber model has an embedded polyester meshwork layer to provide adequate strength to avoid tearing when suturing. However, the with Fiber model is stiffer and more difficult to fold than the Fiber Free one. Hence, the Fiber Free model is of advantage and recommended when suturing is not indicated.

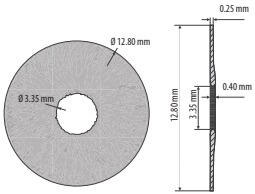

Fig. 1: Anterior view of an ARTIFICIALIRIS and cross section with dimensions of the models with Fiber and Fiber Free

For further information regarding the specification of the ARTIFICIAL*IRIS* please visit www.humanoptics.com.

2. Mode of action / operating principle

The ARTIFICIAL*IRIS* functions as an iris prosthesis. It has a fixed aperture of 3.35 mm, with an opaque perimeter and a black posterior surface to absorb light completely, reducing photic phenomena. The device closely mimics the appearance of the natural iris and at the same time reduces the symptoms associated with aniridia. The small central aperture might increase visual acuity, depth of field, and contrast sensitivity (pinhole effect).

3. Material

The ARTIFICIAL*IRIS* is made of a medical-grade hydrophobic silicone elastomer consisting of diphenyl co dimethyl polysiloxane and silicone reinforcing resin. For colorization inorganic pigments are used. The model with Fiber is additionally reinforced by an embedded polymer fiber meshwork consisting of polyethylene terephthalate (PET).

4. Intended purpose

4a. Indications

The ARTIFICIAL*IRIS* is indicated for the treatment of full or partial aniridia resulting from congenital aniridia, acquired defects, or other conditions associated with full or partial aniridia.

4b. Intended purpose / intended use

The ARTIFICIAL*IRIS* is intended for use as an iris prosthesis for the treatment of iris defects in eyes which are pseudophakic, aphakic or requiring cataract extraction. The device is intended for implantation in the posterior chamber (Fiber Free model: ciliary sulcus or capsular bag; with Fiber model: ciliary sulcus).

4c. Intended patient population

The ARTIFICIAL*IRIS* is indicated for use in adults and children from 6 years for the treatment of full or partial aniridia resulting from congenital aniridia, acquired defects, or other conditions associated with full or partial aniridia. The manufacturer does not hold clinical data relating to breastfeeding women or immunocompromised patient populations.

4d. Intended users

The ARTIFICIAL*IRIS* must be handled by health professionals and implanted by specially trained and certified ophthalmic surgeons (see point 20, Further requirements for usage).

4e. Contraindications

The ARTIFICIAL*IRIS* is not to be used for purely cosmetic reasons.

The device is contraindicated in eyes with any of the following conditions:

- Children who are less than 6 years of age because their eyes are still in a stage of major growth development that would be disrupted by ocular surgery
- Uncontrolled ocular inflammation (e.g. uveitis)
- Severe chronic uveitis
- Microphthalmus
- Untreated retinal detachment
- Untreated chronic glaucoma
- Rubella cataract
- Rubeosis of the iris
- Proliferative diabetic retinopathy
- Stargardt's retinopathy
- Pregnancy
- Intraocular infections

5. Caution

Implantation of the ARTIFICIAL*IRIS* is not recommended in patients with the following conditions and situations:

- Preoperative intraocular pressure (IOP) above 21 mmHg that does not respond to pressure-lowering medication, unless the IOP above 21 mmHg is due to a known underlying condition that is well-controlled with glaucoma treatment, such as ocular hypertension or open-angle glaucoma
- Patients with severe endothelial corneal dystrophy, because the surgical procedure to implant the ARTIFICIAL*IRIS* may damage the cornea sufficiently so that the potential benefits of implantation do not outweigh the risks
- The ARTIFICIAL*IRIS* is not designed for placement in the anterior chamber
- No useful vision or visual potential in the fellow eye, unless the patient has debilitating visual symptoms, so that the potential benefits of ARTIFICIAL*IRIS* implantation clearly outweigh the risks

- Presence of a condition or finding in the fellow eye that would make it unsafe to implant an ARTIFICIAL*IRIS* prosthesis in the eye to be treated
- Allergy to any of the planned postoperative antibiotic or anti-inflammatory medications, unless a suitable alternative medication can be prescribed
- Post-partum women who are nursing or lactating and for whom postoperative medications are contraindicated
- Patients with gastric ulcers or diabetes mellitus in whom high doses of orally administered systemic steroids are required postoperatively
- Any other condition that would interfere with the planned surgical procedure to implant the iris device

6. Warnings

The ARTIFICIAL*IRIS* should be used with caution in the following situations:

- A clear natural crystalline lens – Do not implant the ARTIFICIAL*IRIS* in phakic eyes
- The visual potential of the fellow eye cannot be evaluated preoperatively (e.g., poor visual acuity due to cataract)
- Preoperative IOP > 21 mmHg that is known to be stable and well-controlled with glaucoma treatment (e.g., medication, tubes or shunts)
- Presence of any other medical condition that might be expected to make the patient an unsuitable candidate for ARTIFICIAL*IRIS* implantation
- Anticipated complexity of the planned surgical procedure that might increase the potential for complications
- Implantation in the fellow eye before stabilization of the first implanted eye (typically 1 month or more)

The aperture of the ARTIFICIAL*IRIS* pupil is fixed at 3.35 mm. In the event that a larger pupillary opening is required for posterior segment surgery, the ARTIFICIAL*IRIS* can be explanted and a new ARTIFICIAL*IRIS* may be implanted after completion of the posterior segment surgery. The technique for a secondary implantation would be determined in the same manner as for a primary implantation.

7. Potential complications and undesirable side effects

Below is a list of the potential complications and undesirable side effects associated with the use of the device, surgical procedure, or IOL.

Device-related complications associated with the ARTIFICIAL*IRIS* may include but may not be limited to:

- Elevated intraocular pressure
- Decrease in uncorrected distance visual acuity
- Decrease in best-corrected distance visual acuity
- Worsening of photosensitivity
- Eye inflammation
- Incorrect device positioning, dislocation, and decentration
- Secondary (additional) surgical intervention

Surgical repositioning, replacement or removal of the device may be necessary to correct device dislocations. Device defects can occur if the device is not handled properly.

Surgery-related adverse events may include, but may not be limited to:

- Cystoid macular edema
- Hypopyon
- Endophthalmitis
- Device migration
- Pupillary block
- Retinal detachment
- Secondary surgical intervention (unplanned)
- Corneal edema, persistent at 3 months or later
- Chronic iritis/anterior segment inflammation persistent at 3 months or later

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If lens replacement is performed during the same surgical procedure as the iris implant surgical procedure, IOL-related complications may include, but may not be limited to:

- Anisometropia
- Glare/halos
- Diplopia
- IOL removal or replacement due to lens power calculation error

8. Clinical benefits

The ARTIFICIAL*IRIS* implant has the potential to improve the quality of life by reducing visual symptoms and improving the cosmetic appearance of the eye.

9. Safety and clinical performance

For products registered under Regulation (EU) 2017/745, the summary of safety and clinical performance (SSCP) will be published in EUDAMED, the European Database on Medical Devices, under the URL [https://ec.europa.eu/tools/eudamed]. The SSCP of the ARTIFICIAL*IRIS* is linked to the Basic UDI-DI 04049154_AI_M1_H1_01_X7. Until EUDAMED will be fully functional, the SSCP is available at www.humanoptics.com.

Find HumanOptics Holding under the SRN DE-MF-000017892 on EUDAMED. The SSCP is reviewed at least annually and updated if needed to ensure that any contained clinical and/or safety information remains correct and complete.

10. Handling

- Store the ARTIFICIAL*IRIS* between 10°C/50°F and 30°C/86°F, protected from light and under dry conditions.
- Do not re-use the implant or any parts of the packaging.
- Before use, check the package for the correct model and the expiration date. The implant should not be implanted after the indicated expiration date.
- Before use, check the integrity of the sterile barrier system. The device is sterile only if the sterile pouch is undamaged. The implant container may only be opened under sterile conditions. Only implant a sterile ARTIFICIAL*IRIS*.
- To remove the ARTIFICIAL*IRIS*, hold the flap of the sealed foil lid of the container and pull it off, then remove the protective cover. After removing the implant from the container, ensure that the device surface is free of any adhering particles or any other defects.

Please note that the color of the ARTIFICIAL*IRIS* in air versus in saline solution differs. The actual color of the device in aqueous humor may vary due to the cornea.

Note: The actual device color may vary from the image shown on front of carton.

In the event of a malfunction of the device or a change in its performance, please return the affected product including all available documentation (e.g. labels, packaging) to your local distributor or the manufacturer. Please make sure to clearly mark contaminated material when returning it to the manufacturer.

Contact to the manufacturer via email: complaint@humanoptics.com.

11. Surgical use instructions

11a. Model selection and preparation

ARTIFICIAL*IRIS* is available in two models: with Fiber or Fiber Free. The two models are identical in every respect, except that the with Fiber model has an embedded polyester meshwork layer to provide adequate strength to avoid tearing when suturing. The selection of the surgical technique should be dictated by the preoperative iris and anterior segment anatomy and pathology. The with Fiber model is generally used when suture fixation is planned, whereas the Fiber Free model is designed for sutureless implantation techniques. For placement in the capsular bag, only the Fiber Free version should be used. See section "General Surgical Procedure" for further considerations and a description of implantation techniques.

Important considerations for preparing the device:

- **Capsular Bag Trephining:** When implantation in the capsular bag is planned, the ARTIFICIAL*IRIS* should be trephined to an appropriate size. For an adult eye with an average-sized natural lens, the appropriate diameter is typically 10.00 mm, though it can vary from patient to patient. The capsular bag diameter should be estimated based on the size of the evacuated capsular bag once a capsular tension ring has been placed, especially in smaller eyes, pediatric eyes, larger myopic eyes, or megalo-ophthalmic eyes.

- **Ciliary Sulcus Trephining:** For placement into an anatomically suitable ciliary sulcus, the sulcus diameter should be measured preoperatively by ultrasound or intraoperatively by direct measurement of the pressurized globe. For passive sulcus placement, the iris device should be trephined to the estimated smallest diameter of the ciliary sulcus. For suture fixation to the scleral wall, the iris device should be trephined to at least 1 mm less than the estimated sulcus size.
- Always use sharp, sterile instruments for cutting or trephining the ARTIFICIAL*IRIS*.
  The ARTIFICIAL*IRIS* can be folded and implanted via forceps. Only the Fiber Free model can also be implanted using commercially available injector systems. Injectors tested in this context are the Medicel ViscoJect™ 2.2-1P BIO (Medicel AG, Switzerland) and the Lenstec Metal screw-type Injector I-9012FS with Cartridge CART 45S (Lenstec Inc. USA). Please contact customerservice@humanoptics.com for more information.
  Note: Implantation of a with Fiber model through an injection system can lead to permanent deformation and defects of the implant.
- When suturing the ARTIFICIAL*IRIS* with Fiber model, the suture pass should be at least 1.00 mm away from the edge in order to guarantee the stability of the device after suturing and thereby minimizing the risk of device decentration or dislocation.

12. General surgical procedure

12a. Anterior segment preparation

The anterior segment should be appropriately prepared by cataract removal and IOL placement, and/or vitrectomy, as dictated by the preoperative anterior segment anatomy and pathology, in preparation for implanting the device by one of the surgical methods described below. The limbal-corneal wound should be of adequate size for the selected delivery method. Typically, a 2.75 mm wound is required to insert the device, and at least a 4.00 mm wound is required if forceps will be used to insert the device.

12b. Capsular bag placement

The Fiber Free model should be used for placement of the iris device within the capsular bag. The anterior segment should be appropriately prepared, as described in the "Anterior Segment Preparation" section above. The anterior capsule should be stained with trypan blue or indocyanine green at the beginning of the surgical procedure. A capsular tension ring is inserted into the capsular bag to prevent post-operative retraction of the capsule with subsequent tilt and decentration of the artificial iris device. The iris device should be trephined as described in section 11a.

The selected IOL is then implanted in the capsular bag. The limbal-corneal wound should be enlarged, if necessary, for implantation of the iris device. During the procedure, the anterior chamber should be deepened as much as possible by a cohesive ophthalmic viscosurgical device (OVD) to allow adequate space for the iris device to unfold, minimizing contact with other intraocular structures. If the initial dye has faded, additional trypan blue or indocyanine green may be applied or instilled along the anterior capsule margin just prior to iris device implantation.

The iris device is either folded for implantation with forceps or rolled and placed in the injection cartridge with the colored side facing outwards. The leading edge of the folded device should be placed under the distal capsule margin, visualized by noting the trypan blue or indocyanine green over the iris device, before the iris device is unfolded. It should be allowed to unfold with the edges of the implant oriented posteriorly (curled with the colored side facing outwards), so that contact with the corneal endothelium is minimized. A spatula can guide the unfolding or injecting process. Once the iris device is unfolded, the edges can be completely tucked into the capsular bag, with care being taken to avoid undue pressure on the bag margins, especially in patients with congenital aniridia. The iris device can be manipulated either by hooks or micrograsping forceps to facilitate positioning. If the iris device does not go into the bag easily, grasping it with intraocular microforceps at the pseudopupil margin and folding it can facilitate implantation. Once the IOL and iris device are centered and stability is confirmed, the OVD can be removed. If the chamber shallows, the iris device may escape from the capsular bag and require repositioning. Removal of the OVD using a bimanual approach may help to maintain a deep chamber and avoid dislocation of the artificial iris. The incision should be sealed and secured according to surgeon's preference. Instillation of intraocular carbachol is recommended to reduce the risk of post-operative pressure elevation.

12c. Passive sulcus placement

Either the with Fiber or Fiber Free model of the iris device can be used for implantation in the ciliary sulcus without suture fixation. If suture fixation is necessary, please refer to section 12d. The anterior

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segment should be appropriately prepared, as described in the "Anterior Segment Preparation" section above. The iris device should be trephined as described in section 11a. The limbal-corneal incision should be of adequate size. The anterior chamber should be deepened as much as possible with a cohesive OVD to allow adequate space for the iris device to unfold, minimizing contact with intraocular structures.

The iris device should be folded for implantation with forceps or rolled and placed in the injection cartridge with the colored side facing outwards. The injection with injector is only possible with the model Fiber Free. The leading edge of the folded device should be placed in the ciliary sulcus and allowed to unfold with the edges of the implant oriented posteriorly, so that contact with the corneal endothelium is minimized. The iris device can be manipulated either with hooks or with a micro-grasping small-gauge intraocular forceps to facilitate the positioning. A snug fit should be confirmed. If the iris device appears to buckle or fits too tightly, it should be removed, trephined to a smaller size, and then reinserted. If the iris device is freely mobile in the sulcus due to the device being trephined too small, it can be removed and replaced with the standby device after it is trephined to a larger diameter. Alternatively, gently placed and carefully tightened suspension sutures can be placed through the scleral wall at the ciliary sulcus to prevent movement of the device. The sutures should be tied with only enough tension to prevent movement and achieve centration. Overtightening the sutures can tear the device if a Fiber Free device is utilized. Once acceptable centration and stability are confirmed, the OVD can be removed. Removal of the OVD using a bimanual approach may help to maintain a deep chamber and avoid dislocation of the artificial iris. The incision should be sealed and secured according to surgeon preference. Instillation of intraocular carbachol is advised to reduce the risk of postoperative pressure elevation. Patch graft material can be placed over fixation sutures, as deemed necessary by the operating surgeon.

12d. Sulcus placement with suture fixation to the scleral wall

The with Fiber model should be used for fixation in the ciliary sulcus with sutures. The Fiber Free model is also an option with appropriate technique.

If an IOL has not been implanted yet, refer to section 12e for appropriate sulcus placement. The anterior segment should be appropriately prepared, as described in the "Anterior Segment Preparation" section above. The iris device should be trephined as described in section 11a.

The limbal-corneal incision should be of adequate size. The anterior chamber should be deepened as much as possible by a cohesive OVD to allow adequate space for the iris device to unfold, minimizing contact with intraocular structures.

After the preparation ex-vivo of the sutures for the fixation to the scleral wall, the iris device should be folded for implantation with forceps with the colored side facing outwards. The leading edge of the folded device should be placed in the ciliary sulcus and allowed to unfold with the edges of the implant oriented posteriorly, so that contact with the corneal endothelium is minimized. The iris device can be manipulated either with hooks or with a micro-grasping small-gauge intraocular forceps to facilitate the positioning. The iris device should be placed within the ciliary sulcus, and an adequately snug fit should be confirmed. If the iris device appears to buckle or fits too tightly, it should be removed, trephined to a smaller size, and then reinserted. If the iris device is freely mobile, then the sutures should be passed and tightened to achieve good centration of the device. Overtightening of the sutures could lead to ovalization of the pupil, distortion of the device. Once acceptable centration and stability are confirmed, the OVD can be removed. Removal of the OVD using a bimanual approach may help to maintain a deep chamber and avoid dislocation of the artificial iris. The incision should be sealed and secured according to surgeon preference. Instillation of intraocular carbachol is advised to reduce the risk of postoperative pressure elevation. Patch graft material can be placed over fixation sutures, as deemed necessary by the operating surgeon.

12e. Sulcus placement of the iris device and posterior-chamber IOL (PCIOL) with suture fixation to the scleral wall

The suture fixation of both a PCIOL and iris device can be achieved using one of three methods:

1) Fixation of the iris device to the PCIOL *ex vivo* on the surgical field, then the PCIOL-iris device complex is affixed by using non-absorbable sutures passing through the scleral wall with these sutures affixed to the IOL portion of the complex; only the "with Fiber" model can be used;
2) Fixation of the iris device to the PCIOL *ex vivo* on the surgical field, then the PCIOL-iris device complex is affixed by using non-absorbable sutures passing through the scleral wall with these sutures affixed to the iris device portion of the complex; only the "with Fiber" model can be used;

3) The PCIOL and iris device can be independently fixated to the scleral wall using nonabsorbable sutures, either placed through same scleral wall openings or separate scleral wall openings; the "with Fiber" model should be primarily used; the "Fiber Free" model is also an option with appropriate technique.

Note: Gluing the ARTIFICIAL*IRIS* to the IOL is not a recommended method to achieve fixation.

13. MRI safety status

The ARTIFICIAL*IRIS* devices containing the maximal amount of magnetic pigments were tested according to ASTM Standards F2052-15:2015, F2119-07:2013, F2182-11a:2011 and F2213-17:2017.

Non-clinical testing has demonstrated the ARTIFICIAL*IRIS* is MR Conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 1.5 Tesla, 3 Tesla and 7 Tesla
- Maximum spatial field gradient of 200 G/cm (2 T/m)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2 W/kg (normal Operating Mode)

Care has to be taken when moving the patient inside and outside the imaging area, because spatial field gradients for almost all scanners are higher than the limits defined here. However, these higher spatial field gradients could affect the patient only for a very short period of time (a few seconds) and for a very short distance (within a few centimeters).

Under the scan conditions defined above, the ARTIFICIAL*IRIS* device is expected to produce a maximum temperature rise of less than 2.00°C/35.60°F after 15 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by the device extends approximately 24.20 mm from the ARTIFICIAL*IRIS* when imaged with a gradient echo pulse sequence and a 7 Tesla MR system.

If the MRI scan can only be performed under different conditions than the above-mentioned ones, it is recommended that the patient sees the treating ophthalmologist after the examination.

This information is also available on the website www.humanoptics.com/mri.

14. Reprocessing

The ARTIFICIAL*IRIS* is for single-use only. Reprocessing or re-sterilization of the ARTIFICIAL*IRIS* is strictly prohibited, and may compromise device performance, which could cause serious harm to the patient's health and safety.

15. Disposal in accordance with national and local regulations

Discarded ARTIFICIAL*IRIS* devices (used or unused) are classified as medical or clinical waste due to their potentially infectious nature and must be disposed of accordingly in accordance with national and local regulations.

16. Patient information

A patient card is included in the package of every product. Enter the patient data on the patient card and apply the self-adhesive label containing the product identification to the designated space on the card. Instruct the patient to keep this card as a permanent record and to show it to any eye care professional consulted in the future. For further patient information please visit www.humanoptics.com/patient-information.

17. Lifetime of the ARTIFICIAL*IRIS*

The ARTIFICIAL*IRIS* devices are intended to remain permanently in the patient's eye. Simulated aging tests on the material confirm the stability of the ARTIFICIAL*IRIS* devices over a product lifetime of twenty years. Due to the properties of the material, the devices are expected to be stable indefinitely from the implantation date over the lifetime of the patient. Regular ophthalmological check-ups are recommended, in consultation with the treating physician.

18. Reporting

Serious incidents should be reported to HumanOptics and to the relevant competent authorities.

19. Disclaimer

The manufacturer is not liable either for the implantation method or the operative technique used by the physician performing the procedure or for the selection of the ARTIFICIAL*IRIS* in relation to the patient or his/her condition.

Furthermore, the manufacturer is not liable for a postoperative difference in color between the natural iris tissue and the iris implant.

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20. Further requirements for usage

A high level of surgical skill and experience in the field of anterior segment surgery is required for ARTIFICIAL*IRIS* implantation. Before the first implantation, the surgeon must have successfully completed the OCC (Online Certification Course). Each participant receives a certificate number, which is required to proceed with the product order.

The ARTIFICIAL*IRIS* is restricted to sale by or on the order of a physician or any other health entity.

21. Symbols and Explanations

SN	Serial number		Manufacturer
REF	Reference number	DE	Date of Manufacture and Country of Manufacture (DE)
$\varnothing_{Iris}$	Total diameter	Rx ONLY	Prescription use only
$\varnothing_{Pupil}$	Pupil diameter	MD	Medical device
STERILE	Sterilized using steam	MR	MR Conditional
	Use-by date (YYYY-MM-DD)	UDI	Unique Device Identifier
	Do not re-use		Single sterile barrier system with protective packaging inside
	Do not resterilize		Patient name or patient ID
	Do not use if package is damaged	31	Date of implantation
	Keep away from sunlight		Name and address of the implanting healthcare institution/provider
	Keep dry		Information website for patients
10°C 30°C storage	Temperature limit for storage	OD	Right eye
eIFU indicator	Consult instructions for use	OS	Left eye

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