HUMANOPTICS

INTRAOCULAR
IRIS IMPLANT

CUSTOM*FLEX*® ARTIFICIAL*IRIS*

Instructions for Use

V2.0/2018-05_CF_AI

HumanOptics AG
Spardorfer Str. 150
91054 Erlangern
Germany

Tel.:+49 9131 50665-0
Fax:+49 9131 50665-90
mail@humanoptics.com
www.humanoptics.com

Distributed in U.S.A. by:
VEO Ophthalmics
3308 Jefferson Avenue
Tel: 513-872-1330 Fax: 513-961-2858
Email: info@veo-ophthalmics.com
Website: www.veo-ophthalmics.com

CAUTION: U.S. Federal law restricts this device to sale by or on the order of a physician.

CAUTION: U.S. Federal law restricts this device to practitioners who have been trained and have experience in the surgical management and treatment of aniridia.

Symbols and Explanations:

SN	Serial number
LOT	Batch number
$Ø_{IRIS}$	Total diameter
$Ø_{PUPIL}$	Pupil diameter
STERILE	Sterilized using steam
	Use-by date (year-month)
	Do not re-use
	Do not resterilize
	Do not use if package is damaged
	Keep away from sunlight
	Keep dry
10°C 30°C storage	Temperature limit for storage
	Consult instructions for use
	Manufacturer
	Date of manufacture
MR	MR Unsafe
Rx ONLY	Prescription use only

Instructions for Use
CUSTOM*FLEX*® ARTIFICIAL*IRIS*

en

These instructions for use are for the following models:

MODEL	DESIGN
CUSTOM*FLEX*® ARTIFICIAL*IRIS* With Fiber	Silicone elastomer with meshwork
CUSTOM*FLEX*® ARTIFICIAL*IRIS* Fiber Free	Silicone elastomer without meshwork

Description:
The CUSTOM*FLEX*® ARTIFICIAL*IRIS* device is a foldable iris prosthesis that is custom-made for each individual patient. The CUSTOM*FLEX*® ARTIFICIAL*IRIS* prosthesis is manufactured from a commercially available ophthalmic silicone. Colorized silicone paste is applied by hand in a pattern to match the color of the natural iris using a photograph of the existing iris or, in the case of aniridia, the color of the photograph selected by the patient. This custom color-match provides a cosmetically acceptable aesthetic restoration with high patient satisfaction.

The CUSTOM*FLEX*® ARTIFICIAL*IRIS* device is manufactured as a full 360° iris prosthesis with an overall diameter of 12.8 mm, which can be trephined as needed to custom-fit the device for placement in the ciliary sulcus or capsular bag.

The CUSTOM*FLEX*® ARTIFICIAL*IRIS* With Fiber device is more robust to tighter sutures and is less susceptible to cheese-wiring or tearing under higher suture tensions, although it is stiffer and more difficult to fold. When suturing the CUSTOM*FLEX*® ARTIFICIAL*IRIS* With Fiber model, the suture pass should be at least 1 mm away from the edge in order to guarantee the stability of the device after suturing and minimize the risk of device decentration or dislocation.

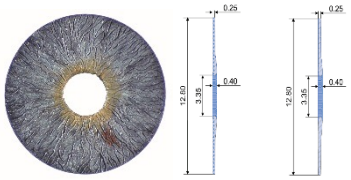

Fig. 1: *Anterior view of a* CUSTOM*FLEX*® ARTIFICIAL*IRIS (left). Cross-sectional dimensioned views of the* CUSTOM*FLEX*® ARTIFICIAL*IRIS With Fiber (middle) and Fiber Free (right) models.*

Material:
Hydrophobic silicone elastomer with embedded color pigments.

The model CUSTOM*FLEX*® ARTIFICIAL*IRIS* With Fiber is additionally reinforced by an embedded polymer fiber meshwork.

Indications:
The CUSTOM*FLEX*® ARTIFICIAL*IRIS* is intended for use as an iris prosthesis for the treatment of iris defects.

The CUSTOM*FLEX*® ARTIFICIAL*IRIS* is indicated for use in children and adults for the treatment of full or partial aniridia resulting from congenital aniridia, acquired defects, or other conditions associated with full or partial aniridia.

Contraindications:
The CUSTOM*FLEX*® ARTIFICIAL*IRIS* device is contraindicated in eyes with any of the following conditions:

- 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 in women
- Intraocular infections

Warnings:

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

- Children who are less than 3 years of age because their eyes are still in a stage of major growth development that would be disrupted by ocular surgery

- Preoperative intraocular pressure (IOP) above 21 mm Hg that does not respond to pressure-lowering medication, unless the IOP above 21 mm Hg 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 surgery to implant the CUSTOM*FLEX*® ARTIFICIAL*IRIS* may damage the cornea sufficiently such that the potential benefits of implantation do not outweigh the risks
- No useful vision or visual potential in the fellow eye, unless the patient has debilitating visual symptoms so that the potential benefits of CUSTOM*FLEX*® ARTIFICIAL*IRIS* implantation clearly outweigh the risks
- Presence of a condition or finding in the contralateral eye that would make it unsafe to implant a CUSTOM*FLEX*® 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
- Implantation for cosmetic color changes of the irisPost-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

- **Precautions:**

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

- A clear natural crystalline lens
- The visual potential of the fellow eye cannot be evaluated preoperatively (e.g., poor visual acuity due to cataract)
- Preoperative IOP > 21 mm Hg 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 CUSTOM*FLEX*® ARTIFICIALIRIS 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)

Safety and effectiveness of intraocular lenses (IOLs) have not been established in pediatric patients in the U.S.

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

Adverse Events:
Below is a list of the probable adverse events or complications associated with the use of the device, surgical procedure, or IOL.

Device-Related complications associated with the CUSTOM*FLEX*® ARTIFICIAL*IRIS* may include but may not be limited to:

- Worsening of photosensitivity and vision
- Elevated intraocular pressure
- Decrease in uncorrected distance visual acuity
- Decrease in best-corrected distance visual acuity
- Eye infection/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

If IOL 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

For Clinical Data:
U.S. users, see the CUSTOM*FLEX*® ARTIFICIAL*IRIS* Professional Use Information. All other users, see www.humanoptics.com.

Handling:
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.

To remove the CUSTOM*FLEX*® ARTIFICIAL*IRIS*, hold the flap of the sealed foil lid of the container and pull it off. 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 appearance and color of the CUSTOM*FLEX*® ARTIFICIAL*IRIS* may be different in air than it is after implantation in the eye. The actual color of the device in aqueous humor may vary due to the cornea.

CUSTOM*FLEX*® ARTIFICIAL*IRIS*

Surgical Use Instructions

CUSTOM*FLEX*® ARTIFICIAL*IRIS*

Model Selection and Preparation:

The CUSTOM*FLEX*® ARTIFICIAL*IRIS* is a foldable device that is custom-made for each individual patient. The CUSTOM*FLEX*® 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 a polyester meshwork layer embedded in it to provide adequate strength to avoid tearing when suturing. The Fiber Free model is suitable for sutureless implant techniques or can be sutured. The selection of the surgical technique should be dictated by the preoperative iris and anterior segment anatomy and pathology. The Fiber Free model can be implanted as a full diaphragm either within the ciliary sulcus or within the capsular bag. The With Fiber model is generally used when suture fixation is planned. Important considerations for preparing the device:

- **Capsular Bag Trephining:** When implantation in the capsular bag is planned, the CUSTOMFLEX® ARTIFICIAL*IRIS* should be trephined to an appropriate size. For an adult eye with an average-sized natural lens, the appropriate diameter is typically 10.0 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 passive placement into an anatomically suitable ciliary sulcus, the iris device should be trephined to the estimated smallest diameter of the ciliary sulcus.
- Always use sharp, sterile instruments for cutting or trephining the CUSTOM*FLEX*® ARTIFICIAL*IRIS*.
- The CUSTOM*FLEX*® ARTIFICIAL*IRIS* can be delivered via forceps or the AMO Silver Series IOL Injector and PSCST cartridge. The mechanical effects of folding and passage of the CUSTOM*FLEX*® ARTIFICIAL*IRIS* through an injector have only been validated with this injector system.

CUSTOM*FLEX*® ARTIFICIAL*IRIS*

General Surgical Procedure

Anterior Segment Preparation:
The anterior segment should be appropriately prepared by cataract removal and IOL placement, synechiolysis, 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 to accommodate the selected delivery method. Typically a 2.75 mm wound is required to inject the device, and at least a 4 mm wound is required if forceps will be used to insert the device.

Capsular Bag Placement:
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 should be inserted into the capsular bag if the capsular bag and capsulorhexis remain intact. The IOL should then be implanted in the capsular bag. The limbal-corneal wound should be enlarged, if necessary, for implantation of the iris device. 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 can be painted or instilled along the anterior capsule margin just prior to iris device implantation.

The iris device should be folded for implantation with forceps or rolled and placed in the injection cartridge with the colored side outward. 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 outward), so that contact with the corneal endothelium is minimized. A spatula or second hand instrument 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 congenital aniridics. The iris device can be manipulated either by hooks or micro-grasping small-gauge intraocular forceps. 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 repeat positioning. Removal of the OVD using a bimanual approach may help to maintain a deep chamber and avoid dislocation of the artificial iris. The wound should be sealed and secured according to surgeon preference. Instillation of intraocular carbachol is advised to reduce the risk of post-operative pressure elevation.

Passive Sulcus Fixation:
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, the With Fiber model should be used. The anterior segment should be appropriately prepared, as described in the "Anterior Segment Preparation" section above. The iris device should be trephined to the estimated sulcus size, as measured preoperatively by ultrasound or intraoperatively by direct measurement of the pressurized globe. The limbal-corneal wound 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.

The iris device should be folded for implantation with forceps or rolled and placed in the injection cartridge with the colored side outward. 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 aid in positioning. A snug fit should be confirmed. If the iris device appears to buckle or fits too tightly, it should be removed. Devices that fit too tightly 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 wound should be sealed and secured according to surgeon preference. Instillation of intraocular carbachol is advised to reduce the risk of post-operative pressure elevation. Patch graft material can be placed over fixation sutures, as deemed necessary by the operating surgeon.

Suture Fixation to the Scleral Wall:
The With Fiber model should be used for fixation in the ciliary sulcus with sutures. The anterior segment should be appropriately prepared, as described in the "Anterior Segment Preparation" section above. The iris device should be trephined to at least 1 mm less than the estimated sulcus size, as measured preoperatively by ultrasound or intraoperatively by direct measurement of the pressurized globe.

The limbal-corneal wound 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 intraocular structures.

The iris device should be folded for implantation with forceps or rolled and placed in the injection cartridge with the colored side outward. 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 aid in positioning. If suture fixation is necessary, sutures should be fixated to the device, and the device should be implanted with forceps. 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. Devices that fit too tightly 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 result in ovalization of the pupil, distortion of the device, or cheese-wiring through 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 wound should be sealed and secured according to surgeon preference. Instillation of intraocular carbachol is advised to reduce the risk of post-operative pressure elevation. Patch graft material can be placed over fixation sutures, as deemed necessary by the operating surgeon.

Placement of a Device with PCIOL Sutured Ex Vivo to the CUSTOM*FLEX*® ARTIFICIAL*IRIS*
Only the CUSTOM*FLEX*® ARTIFICIAL*IRIS* With Fiber model can be used for this surgical technique.

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; 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; or, 3) The PCIOL and iris device can be independently fixated to the scleral wall using non-absorbable sutures, either placed through the same scleral wall openings or separate scleral wall openings.

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

MRI SAFETY INFORMATION:
The CUSTOM*FLEX*® ARTIFICIAL*IRIS* implant is MR Unsafe.

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

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 CUSTOM*FLEX*® ARTIFICIAL*IRIS* in relation to the patient or his/her condition.

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

Caution:
Use of the CUSTOM*FLEX*®ARTIFICIAL*IRIS* may cause serious adverse events or complications that must be reported to HUMANOPTICS AG. Any device defects must also be reported to HUMANOPTICS AG.

U.S. Federal law restricts this device to sale by or on the order of a physician.

U.S. Federal law restricts this device to practitioners who have been trained and have experience in the surgical management and treatment of aniridia.

EU law restricts this device to practitioners who have been trained and have experience in the surgical management and treatment of aniridia.