



CUSTOMFLEX[®] ARTIFICIALIRIS
PREMIUM RESULTS FOR PATIENTS WITH ANIRIDIA

CUSTOMFLEX® ARTIFICIAL IRIS

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CUSTOMFLEX® ARTIFICIALIRIS

THE SOLUTION FOR YOUR PATIENTS WITH ANIRIDIA

The CUSTOMFLEX® ARTIFICIALIRIS represents an ideal treatment option for patients with complete and partial aniridia. The foldable iris implant provides both medical and aesthetic rehabilitation.

AETIOLOGY

Complete or partial aniridia can be congenital or acquired by trauma or diseases.

IMPAIRMENT CAUSED BY ANIRIDIA

- Loss of vision
- Increased sensitivity to glare
- Loss of depth of focus
- Negative impact on the quality of life



Patient with complete aniridia in the right eye*



Same patient after implantation of the CUSTOMFLEX® ARTIFICIALIRIS*

FOR MEDICAL AND AESTHETIC REHABILITATION

* Pictures by courtesy of Kevin M. Miller, MD, Jules Stein Institute, University of California, Los Angeles, USA

CLINICALLY EFFECTIVE REGULATED LIGHT TRANSMISSION

THE CUSTOMFLEX® ARTIFICIAL IRIS

- Reduces photic phenomena
- Enhances contrast sensitivity
- Eliminates transillumination defects

PRINCIPLE OF ACTION

- Fixed aperture of 3.35 mm
- Opaque black posterior surface to absorb light completely



The clinical effectiveness of CUSTOMFLEX® ARTIFICIAL IRIS is confirmed by studies. The implant is accredited by CE marking and FDA (U.S. Food and Drug Administration) approval.

70% OF PATIENTS
REPORTED
SIGNIFICANT
**DECREASES
IN LIGHT
SENSITIVITY
AND GLARE¹**



"The artificial iris prosthesis sets a new standard in the reconstruction of complex anterior segment pathologies with partial or complete aniridia. Our patients benefit from improved visual function, reduced glare and a satisfactory cosmetic appearance. The latter is important and legitimate, considering that trauma patients are mostly young and long for a cosmetically acceptable outcome."

Peter Szurman, MD,
Augenklinik Sulzbach, Knappschaftsklinikum Saar, Germany²

EVERY EYE IS UNIQUE THE CUSTOMFLEX® ARTIFICIALIRIS TOO

The CUSTOMFLEX® ARTIFICIALIRIS is a unique treatment option of its kind for patients with aniridia. The aesthetic rehabilitation with the custom-made iris implant leads to a very high patient satisfaction and contributes significantly to the improvement of the quality of life of aniridia patients.¹

- Custom-made
- Based on the natural structure of the iris
- Personal colouring of the patient's original iris
- Impressively realistic results

*„HumanOptics made my iris and since these my life has drastically changed.
I am now able to drive. My vision has improved greatly.
But the biggest thing for me is that I now feel normal.“*

Patient statement after implantation of CUSTOMFLEX® ARTIFICIALIRIS



„A patient [...] called to tell me that receiving the artificial iris was one of the best things that had ever happened to her She still calls or sends a note periodically just to remind me and my team of her happy result.“

*Michael E. Snyder, MD,
Cincinnati Eye Institute, USA ³*

94% OF PATIENTS
WERE
SATISFIED
OR VERY SATISFIED WITH THEIR
POSTOPERATIVE
APPEARANCE¹



AS VERSATILE AS YOUR PATIENTS

INJECTABLE

The CUSTOMFLEX® ARTIFICIAL/IRIS is made of highly biocompatible flexible silicone that is clinical proven for two decades. It can be folded and rolled for insertion through small incisions.



CUSTOMIZABLE

The CUSTOMFLEX® ARTIFICIAL/IRIS has an overall diameter of 12.8 mm and can be customized in shape and size to the respective iris defect by using trephines.

Also see our selected range of trephines:

Diameter 9.0-12.5 mm, steps 0.5 mm

Further models available on request



"Until now, iris reconstruction was a challenging surgical procedure requiring large sclerocorneal incisions and often resulting in poor cosmetic outcomes. With the ARTIFICIALIRIS, small self-sealing incisions are possible, enabling fast visual recovery and excellent cosmetic outcomes. The device may be used for complete or partial iris reconstruction."

*Stephan Kaminski, MD,
Augenlinik Zürich West, Switzerland & Auge und Laser Wien, Austria⁴*

TWO MODELS FOR MAXIMUM FLEXIBILITY

The CUSTOMFLEX® ARTIFICIALIRIS allows a maximum of patient-specific care. In addition to the appearance, the application options can also be flexibly adjusted to the anatomy and initial situation of the affected eye.

THE STANDARD CARE

Developed for cases without suture fixation.
Suture fixation possible with appropriate technique.

ARTIFICIALIRIS Fiber free



FOR SPECIAL INDICATIONS

For cases where suturing is indicated.

ARTIFICIALIRIS with Fiber



IMPORTANT NOTE

The CUSTOMFLEX® ARTIFICIALIRIS is not intended for cosmetic color change.

The device is designed for placement in the posterior chamber, not in the anterior chamber.

It is strongly recommended that the CUSTOMFLEX® ARTIFICIALIRIS be implanted after natural lens removal and IOL implantation.

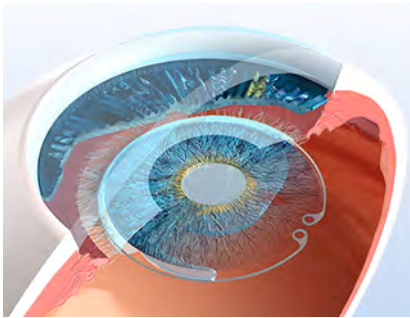
IMPLANTATION METHODS

VARIOUS POSSIBILITIES

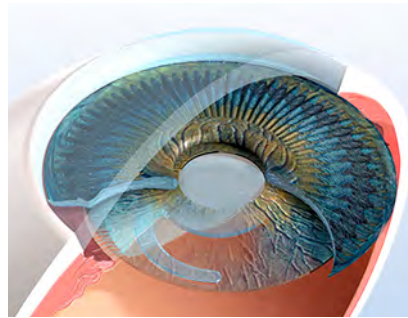
The CUSTOMFLEX® ARTIFICIALIRIS allows a variety of implantation methods, adapted to the specific conditions of the affected eye.

Remain flexible – even during the procedure.

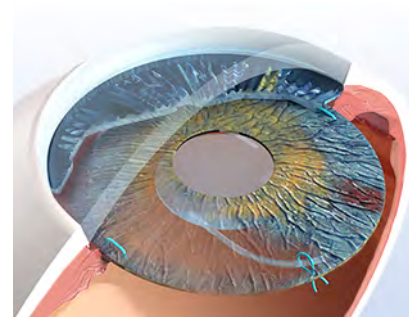
The iris implant can be combined with almost all IOL models.



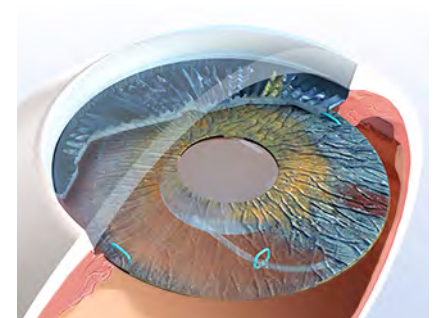
CUSTOMFLEX® ARTIFICIALIRIS,
IOL and capsular tension ring
placed in capsular bag



CUSTOMFLEX® ARTIFICIALIRIS
placed in sulcus,
IOL placed in the capsular bag



CUSTOMFLEX® ARTIFICIALIRIS
and IOL separately fixed
in the sulcus



IOL fixed to
CUSTOMFLEX® ARTIFICIALIRIS,
implantation in the sulcus



"ARTIFICIALIRIS is a device designed to correct the subjective symptoms of aniridia, including photophobia and glare, and to provide an excellent cosmetic result [...]. It is a highly versatile tool in anterior segment reconstruction as it can be folded and injected into the capsular bag or sutured to the sclera."

Ike Ahmed, MD,
University of Toronto, Canada⁵

STEP BY STEP ONLINE CERTIFICATION COURSE

In collaboration with an international group of iris experts, the OCC was developed for highest training standards.

THE PLATFORM PROVIDES

- Basic knowledge about the CUSTOMFLEX® ARTIFICIAL/IRIS
- Application techniques
- Surgery videos

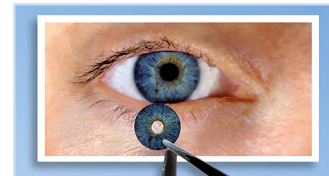
After completion of the OCC, each participant will receive a certificate number, which is required to proceed with the order.



PHOTO PRINTOUTS

As a basis for the individual manufacturing of the CUSTOMFLEX® ARTIFICIAL/IRIS, we require high quality photo printouts:

- The quality of the photo printouts is crucial for a natural postoperative appearance
- Please refer to our photo directives for creating high-quality photos and printouts under www.artificial-iris.com



SUBMIT THE ORDER

When ordering the CUSTOMFLEX® ARTIFICIAL/IRIS, we kindly ask you to note the following:

- The production time is 4 to 8 weeks
- The order form can be downloaded from **www.artificial-iris.com**
- To place your order the certificate number from the OCC is necessary

Please forward the order form including the photo printouts to the distributor in your country or directly to:

HumanOptics Holding AG
Spardorfer Str. 150, 91054 Erlangen

REFERENCES

- ¹ Data on file: www.clinicaltrials.gov/ct2/show/NCT01860612?term=NCT01860612&
(Access: 24.06.2020).

- ² Personal statement, 2019.

- ³ Doran M, contributing writer interviewing Miller K, Rosenthal K, Sikder S, Snyder M. Anterior segment iris implants advance – but face continuing challenges. American Academy of Ophthalmology, EyeNet, 2013; Issue February: 29–31.

- ⁴ Kaminski S. Iatrogenic coloboma, aniridia, and aphakia. J Cataract Refract Surg Today Europe 2012; July/August: 52–54.

- ⁵ Gooi P, Teichman J, Ahmed I. Sutureless intrascleral fixation of a custom-tailored iris prosthesis with an intraocular lens. J Cataract Refract Surg 2014; 40:1759–63.

