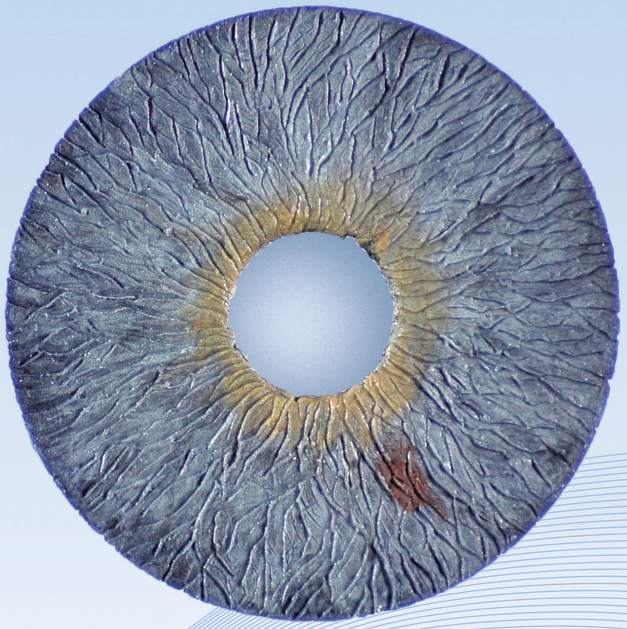
VeoOphthalmics

Introducing the CUSTOM*FLEX*® ARTIFICIAL*IRIS*

FINALLY A SOLUTION FOR PATIENTS WITH ANIRIDIA OR OTHER IRIS DEFECTS



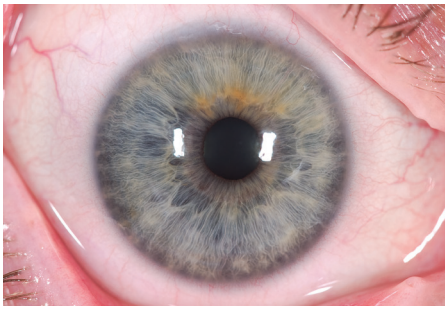
The CUSTOM*FLEX*® ARTIFICIAL*IRIS* is a foldable iris prosthesis custom-made for each individual patient, replicating the natural appearance of the patient's eye. The CUSTOM*FLEX*® ARTIFICIAL*IRIS* is the first and only FDA approved device for treating full or partial aniridia or other iris defects in adults and children.

PROVEN SCIENCE MEETS EXPERT CRAFTSMANSHIP

OVERVIEW

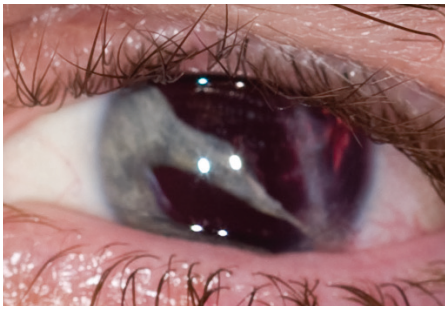
Full or partial iris defects usually lead to many visual symptoms, including decreased visual acuity and light sensitivity. Managing congenital aniridia and acquired iris defects – including, but not limited to, traumatic iris defects and traumatic mydriasis – is often challenging. When iris reconstruction is necessary, the CUSTOM*FLEX*® ARTIFICIAL*IRIS* is a unique device that offers both surgeons and patients important benefits.

TRAUMATIC INJURY

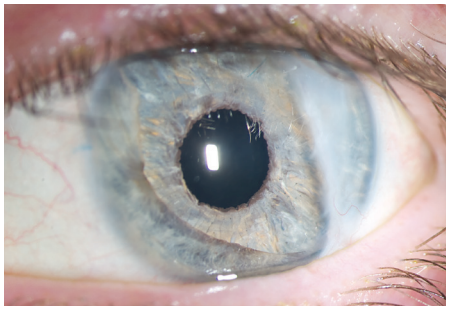


Photos courtesy of Kevin M. Miller, M.D. Jules Stein Eye Institute

Photo of contralateral eye used as template for manufacture of the CUSTOM*FLEX*® ARTIFICIAL*IRIS*

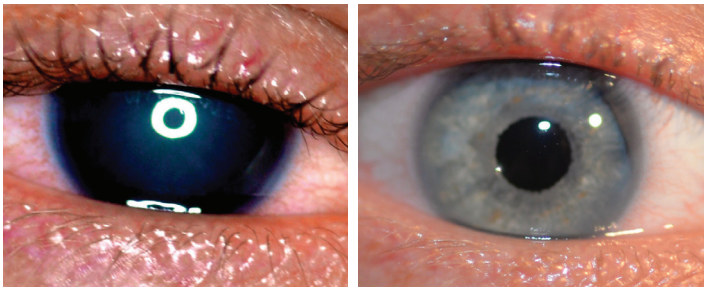


Before implantation of the CUSTOM*FLEX*® ARTIFICIAL*IRIS*



After implantation of the CUSTOM*FLEX*® ARTIFICIAL*IRIS*

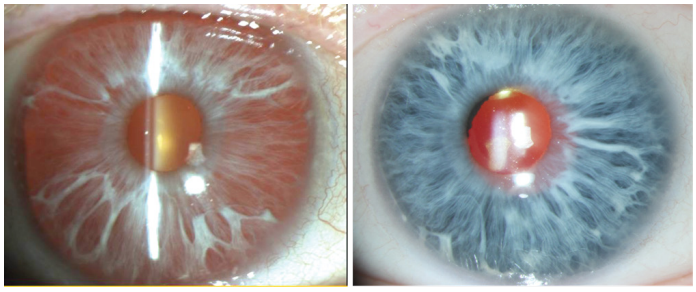
CONGENITAL ANIRIDIA



Photos courtesy of Brandon Ayres, M.D. Opthalmic Partners of Pennsylvania

Before and after implantation of the CUSTOM*FLEX*® ARTIFICIAL*IRIS*

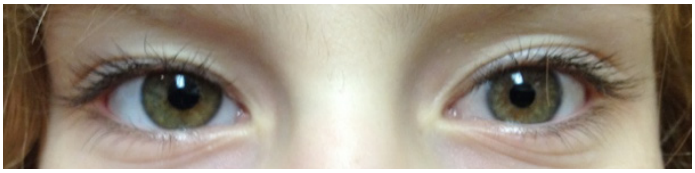
OCULOCUTANEOUS ALBINISM



Photos courtesy of Michael Snyder, M.D. Cincinnati Eye Institute

Before and after implantation of the CUSTOM*FLEX*® ARTIFICIAL*IRIS*

CUSTOM COLOR MATCH



Photos courtesy of Michael Snyder, M.D. Cincinnati Eye Institute

Left eye had the CUSTOM*FLEX*® ARTIFICIAL*IRIS* implanted after traumatic injury. Each CUSTOM*FLEX*® ARTIFICIAL*IRIS* is custom made to closely match a patient's natural iris.

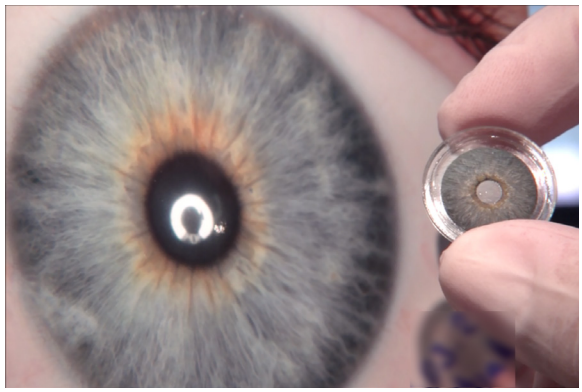
BENEFITS

Biocompatibility: Long, safe history of highly biocompatible medical-grade silicone

Flexibility: Flexible material that can be folded for insertion through small incisions using forceps or an auto injector

Versatility:

- Sutureless and Sutured Surgical Procedures
  - Capsular bag placement
  - Passive sulcus fixation with or without sutures
  - Suture fixation to the scleral wall
  - PCIOL Sutured Ex vivo to the CUSTOM*FLEX*® ARTIFICIAL*IRIS*
- Can be easily sized for each patient's needs
- Can be implanted with most intraocular lenses

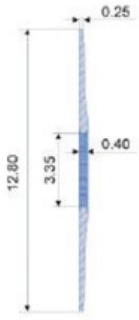


Limits Light Transmission: Reduces photosensitivity symptoms and can be used to treat transillumination defects with a fixed aperture of 3.35mm and opaque black posterior surface to absorb light

Customized: Every CUSTOM*FLEX*® ARTIFICIAL*IRIS* is custom-made to match the patient's natural iris tissue, addressing both symptomatic and cosmetic aspects of iris defects.

PRODUCT SPECIFICATIONS

- Overall Diameter: 12.8 mm
- Pupil Size: 3.35 mm
- Injectable
- For further information, please visit **www.veo-ophthalmics.com/product-info**



ARTIFICIAL*IRIS*
WITH FIBER

For sutured implant techniques

ARTIFICIAL*IRIS*
FIBER FREE

For sutureless implant techniques or can be sutured

CLINICAL SCIENCE

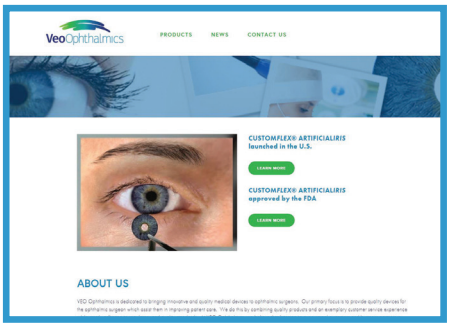
The safety and efficacy of the CUSTOM*FLEX*® ARTIFICIAL*IRIS* was demonstrated in a non-randomized clinical trial of 447 eyes of 389 adult and pediatric patients with aniridia or other iris defects. There was an overall significant improvement in photosensitivity symptoms, quality of life, and vision in pediatric and adult subjects. At study conclusion, 63% of eyes reported no or mild daytime light sensitivity and 79% reported no or mild nighttime light sensitivity, while more than 70% of eyes reported no or mild glare during the day or at night. 94% of subjects were satisfied with the CUSTOM*FLEX*® ARTIFICIAL*IRIS* appearance.

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.

HOW TO GET STARTED

VEO Ophthalmics is proud to offer comprehensive online training and Dry Lab modules for surgeons interested in implanting the CUSTOM*FLEX*® ARTIFICIAL*IRIS.*

To learn more about the CUSTOM*FLEX*® ARTIFICAL*IRIS*, please visit www.veo-ophthalmics.com. For Training and Certification, please contact us at 513-872-1330 or info@veo-ophthalmics.com.



ON OUR WEBSITE, WE OFFER:

- Product Information
- Photo Directives
- Surgical Videos
- Publication Lists
- Physician Use Information
- Patient Information

Contraindications: CUSTOM*FLEX*® ARTIFICIAL*IRIS* is contraindicated for patients with certain eye conditions, such as uncontrolled inflammation, severe chronic uveitis, microphthalmus, untreated retinal detachment, untreated chronic glaucoma, rubella cataract, rubeosis of the iris, proliferative diabetic retinopathy, Stargardt's retinopathy, or intraocular infections, or in pregnant women.

Warning: Implantation of the CUSTOM*FLEX*® ARTIFICIAL*IRIS* is not recommended in 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.

Refer to the Instructions for Use and Physician's Information Brochure for other warnings, precautions, and instructions for the use of the device.

The CUSTOM*FLEX*® ARTIFICIAL*IRIS* was developed, and is manufactured by, HumanOptics AG (Dr. Schmidt Intraocularlinsen) in collaboration with Professor H.R. Koch (Bonn, Germany).

The clinical trial is posted on clinicaltrials.gov.
https://www.clinicaltrials.gov/ct2/show/NCT01860612?term=NCT01860612&rank=1

Veo Ophthalmics

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