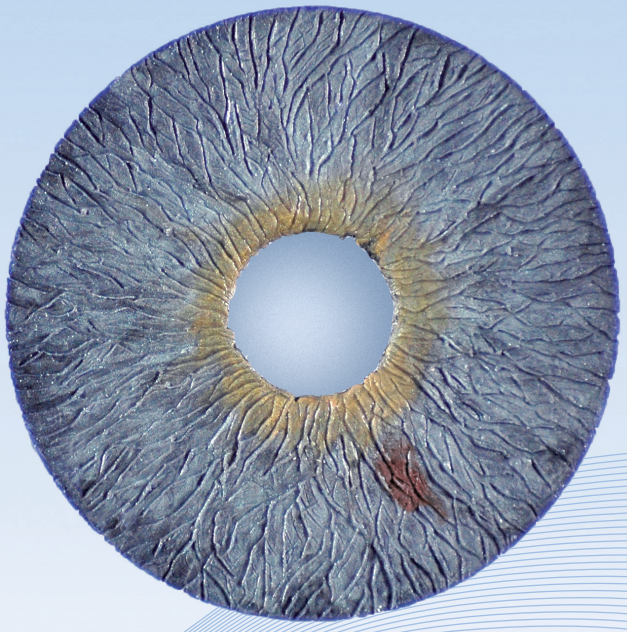
VeoOphthalmics

Introducing the CUSTOM*FLEX*® ARTIFICIAL*IRIS*

A CUSTOM-MADE IMPLANT TO TREAT 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

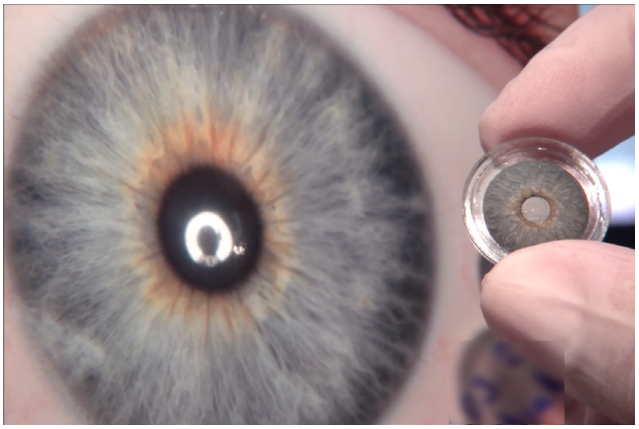
The CUSTOM*FLEX*® ARTIFICIAL*IRIS* is intended for use as an iris prosthesis for the treatment of iris defects. The CUSTOM*FLEX*® ARTIFICIAL*IRIS* is indicated for use in children and adults for the treatment of full or partial aniridia resulting from congenital aniridia, acquired defects, or other conditions associated with full or partial aniridia. When implanted, the CUSTOM*FLEX*® ARTIFICIAL*IRIS* mimics the natural iris and produces an improvement in the visual symptoms associated with aniridia that most affect the patient's quality of life.

These symptoms include:

- Light sensitivity day and night
- Reading difficulty
- Difficulty night driving
- Starbursts
- Glare and halos day and night

CUSTOM-COLOR MATCH

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.



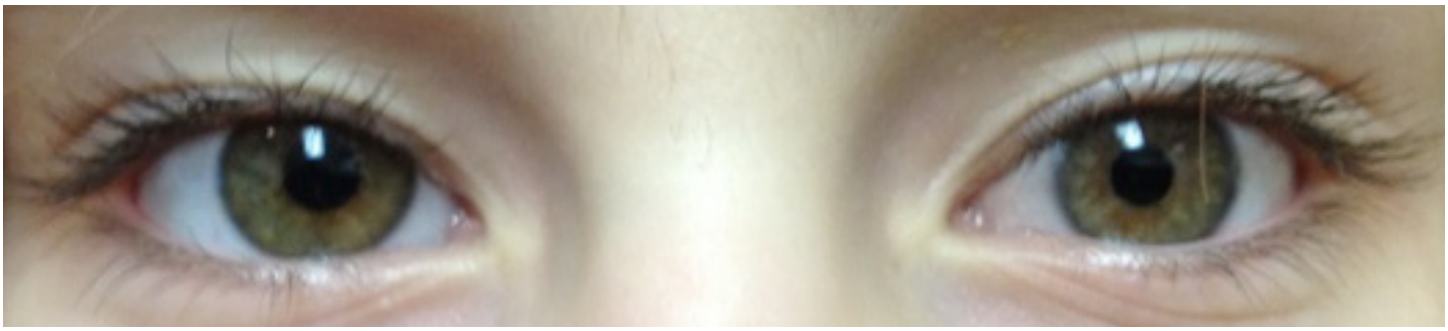


Photo courtesy of Michael Snyder, M.D.
Cincinnati Eye Institute

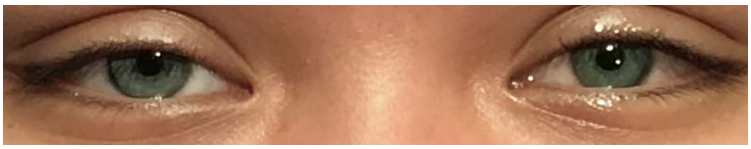
Left eye had the CUSTOM*FLEX*® ARTIFICIAL*IRIS* implanted after traumatic injury.

INDICATIONS

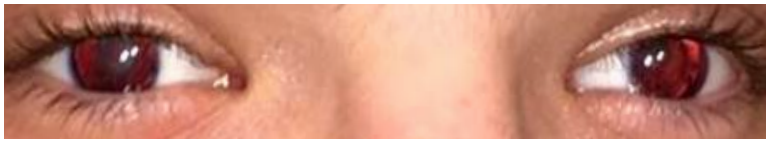
CONGENITAL ANIRIDIA

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

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



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



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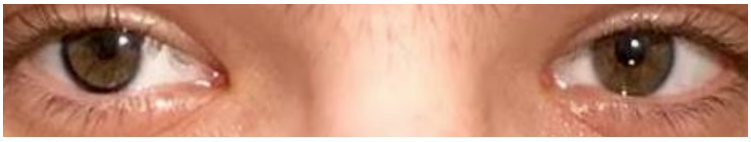
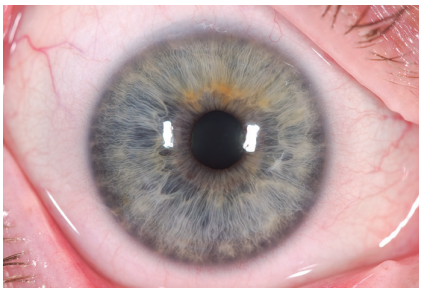


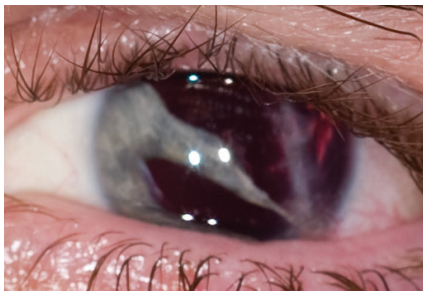
After implantation of the CUSTOM*FLEX*® ARTIFICIAL*IRIS*

TRAUMATIC INJURY

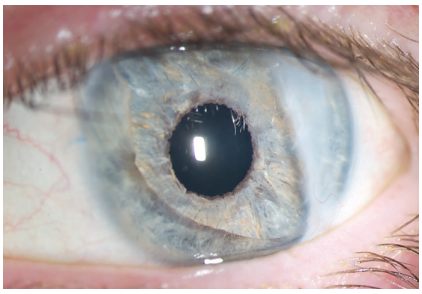


Photos courtesy of Kevin M. Miller, M.D.
Jules Stein Eye Institute

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

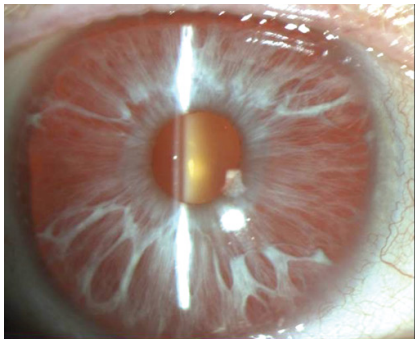


Before implantation of the CUSTOM*FLEX*® ARTIFICIAL*IRIS*



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

OCULOCUTANEOUS ALBINISM



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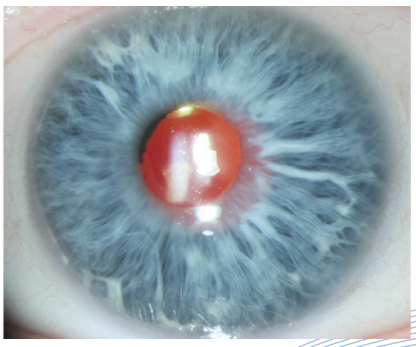

After implantation of the CUSTOM*FLEX*® ARTIFICIAL*IRIS*

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.

BENEFITS:

- There was a decrease in the severity of day-time symptoms of light sensitivity, glare and halos
- There was a decrease in the severity of night-time symptoms of light sensitivity, glare, halos and starbursts
- Reading was improved
- Difficulty driving at night was improved
- There was a three-fold improvement in the patients' ability to complete normal vision-related activities of daily living, as measured by a standardized health related quality of life questionnaire.
- Satisfaction with the cosmetic appearance was high, with 93.8% of patients rating their appearance as improved to very much improved after implantation of the CUSTOM*FLEX*® ARTIFICIAL*IRIS*.
- Although the CUSTOM*FLEX*® ARTIFICIAL*IRIS* is not designed to improve vision, 67.2% of the eyes had better uncorrected visual acuity (vision without glasses or contact lenses) after the artificial iris surgery; and, 27.7% of the eyes had uncorrected vision that was unchanged.

RISKS:

- None of the eyes had a clinically significant loss of more than 2 lines on the eye chart of best corrected vision at 12 months postoperatively that was caused by the CUSTOM*FLEX*® ARTIFICIAL*IRIS*.
- Increases in intraocular pressure greater than 30 mm Hg were the most common adverse event reported in the study.
- The CUSTOM*FLEX*® ARTIFICIAL*IRIS* implant remained in its intended position in the majority of eyes throughout the 12 month study; secondary surgeries could be performed when needed to reposition the device.
- Inflammation occurring at one month or later after surgery was related to the CUSTOM*FLEX*® ARTIFICIAL*IRIS* device in 0.7% of the eyes.

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 Patient Information Brochure for complete study results, other warnings, precautions, and instructions for the use of the device. **www.veo-ophthalmics.com**

LEARN MORE ABOUT THE CUSTOM*FLEX*®ARTIFICIAL*IRIS*

To learn more about the CUSTOM*FLEX*® ARTIFICAL*IRIS*, please visit **www.veo-ophthalmics.com**. Please contact us at 513-872-1330 or info@veo-ophthalmics.com to find a certified surgeon in your area.

ON OUR WEBSITE, WE OFFER:

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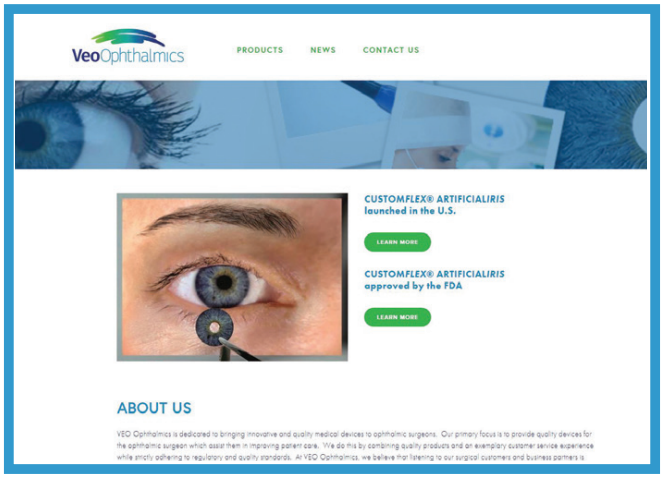

The CUSTOM*FLEX*® ARTIFICIAL*IRIS* was developed, and is manufactured by, HumanOptics AG (Dr. Schmidt Intraocularlinsen) in collaboration with Professor H.R. Koch (Bonn, Germany).

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

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