

# ArtificialIris

## Indication

- Full or partial aniridia may be caused by congenital as well as acquired defects, like trauma and diseases.
- The iris not only gives our eyes their colour and thus our personal appearance, it also plays an important role within the optical system.
- Full or partial aniridias not only reduce visual quality due to photophobia, aberration disorders, glare effects and loss in depth of focus, but also cause severe aesthetical limitations.

## Solution

- The ArtificialIris, with its fully customized, hand-made colour composition for each patient and its surface structure closely matching the appearance of the natural iris, gives individual aesthetical restoration leading to potentially very high patient satisfaction.
- Made of foldable, highly biocompatible silicone material that has been tested and proven with intraocular lenses for many years.
- Available in two versions – with polymer fibre meshwork for fixation with sutures and without polymer fibre meshwork – Fibre Free – for sutureless fixation. The ArtificialIris will fit through an incision of about 3.2mm.
- Delivered as a 360° iris, the standard 12.8mm overall diameter can be trimmed with a trephine or sharp scissors to custom-fit the device for the treatment of full aniridia. In case of partial aniridia the ArtificialIris can easily be cut in a suitable segment for suturing to the iris remnant and transscleral suture support.

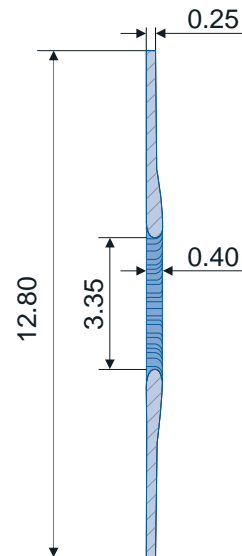


## Application Procedure

- Please fill in the enclosed order form.
- Please proceed according to the enclosed directives for photography and evaluation for the required print-outs (hard copies).
- Please add the required photo print-out of each eye to the signed order form and mail them together to Dr. Schmidt Intraocularlinsen GmbH.
- The hand-crafted ArtificialIris prosthesis will be delivered with two stand-by implants with a slightly different colour composition. The colour match should be obtained by viewing the prosthesis while immersed in the sterile saline solution before removing it from the sterile container during surgery.
- Please note that it is recommended to combine the procedure in phakic eyes with lens removal and IOL implantation, even if no cataract is apparent.

# Artificial Iris

## Drawing



## Technical Information



Model	Artificial Iris	Artificial Iris - Fibre Free
Application	Treatment of Full or Partial Aniridia, Fixation by Scleral Sutures	Treatment of Full Aniridia for Sutureless Implantation
Material	Pigmented Silicone Elastomer <b>with</b> Polymer Fibre Meshwork	Pigmented Silicone Elastomer <b>without</b> Polymer Fibre Meshwork
Design	Design Based on the Photo Print-Out (Hard Copy) of the Patient's Eye Serving as Colour Target for the Individual Production with Structure and Topography Resembling the Natural Iris.	
Availability	Delivery Time 4 to 8 Weeks after Receipt of Prescription and Approved Photography.	

## Dr. Schmidt Intraocularlinsen GmbH, Germany

Westerwaldstr. 11-13  
53757 Sankt Augustin

Phone: +49 (0) 2241 / 25 787-0  
Fax: +49 (0) 2241 / 25 787-88

mail@dr-schmidt-iol.de  
www.dr-schmidt-iol.de

From (surgeon`s name and address)

Name: \_\_\_\_\_  
 Address: \_\_\_\_\_  
 Phone/Fax: \_\_\_\_\_  
 E-Mail: \_\_\_\_\_

Please fill in with capital letters.

to

Dr. Schmidt Intraocularlinsen GmbH  
 Westerwaldstr. 11-13  
 53757 Sankt Augustin / Germany  
 Fax: +49 (0) 2241 - 25 787-88

## Order form for ArtificialIris



I herewith prescribe with my signature at the bottom of this form a custom-made ArtificialIris for the following patient:

→ Patient Name: \_\_\_\_\_

→ Eye to be treated:



RE



LE

- Model Selection:
- with** polymer fibre meshwork for treatment of partial aniridia **with suture fixation**
  - with** polymer fibre meshwork for treatment of full aniridia **suitable for scleral suturing** (if ciliary sulcus is insufficient or nonexistent)
  - without** polymer fibre meshwork - Fibre Free - for treatment of full aniridia and **sutureless implantation** (only if ciliary sulcus is intact)

→ Colour Template: A photo print-out (hard copy) is needed as colour template for the production of the ArtificialIris. Please submit your photo of each eye and label the one that shall serve as template for production.



Surgeon and patient approve the enclosed and labelled photo print-out as the targeted colour / colour distribution for the customized production of the ArtificialIris implant.

*Attachment: photos print-outs of both eyes, one print-out labelled*

\_\_\_\_\_ → \_\_\_\_\_ → \_\_\_\_\_  
 Date Surgeon / Prescriber Signature Patient Signature



## Directives for the photography and evaluation of the print-out

Since the colour composition of the ArtificialIris is custom-made on the basis of a photo print-out utmost care should be taken to receive the highest quality photographs and print-outs (hard copies) for each eye.

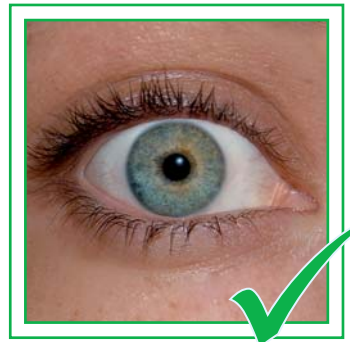
### Please notice the following details:

- Light the patient's eye evenly, without shadows to the iris.  
To avoid glares adjust the light sources from two sides on the object.
- Before taking the photo, a white balance of the camera is necessary (see instruction manual of the digital camera). Therefore, instead of the patient's eye a white paper or a grey chart may be used. Please do not displace the adjusted lighting.
- After that place the patient in the same position and take a photo of each eye.  
**Do not use a video camera for photography.**

Examples:



too far away



low lid, too blurry

- **Use** a photo printer with special photo paper to print-out your digital images.



If you are not set up for high quality photography and photo print-outs we recommend to **send the patient to a professional photographer** of their choice to provide the patient and doctor with the high quality photo and print-out of each eye needed for their approval as the target colour for production.



Evaluate your photo print-out (**HARD COPY**):

- Check the colour of the conjunctiva on the print. If it isn't white the picture has a colour deviation.
- Compare the colour of the photo with the natural iris (both, photo and natural iris, under the same illumination).



*Only you and your patient on location can evaluate and select the photo print-out most closely matching his/her natural iris.*

- ➔ Please **DO NOT** send the photos **DIGITALLY** via email only because we cannot make sure that the appearance of the digital image on our screen is identical to the colour composition of the patient's natural iris, and we also cannot verify the colour match to the natural iris when we print out the digital photos ourselves.
- ➔ Please let your patient sign the order form agreeing with the photo selection you make before sending us the labelled pictures together with the appropriately filled-in order form by **mail** to:

Dr. Schmidt Intraocularlinsen GmbH  
Westerwaldstr.11-13, 53757 St. Augustin, Germany

## Publications and Presentations

Koch H-R.

Irisprothetik: Ein Überblick, Neuentwicklungen einer flexiblen Kunstiris  
DGII 2003, Presentation R27, <http://www.dgii.org/tagung/tagung2003.html>

Koch H-R.

Personalised prosthesis comes a shade closer to the ideal coloured iris solution  
Euro Times. June 2003, 36

Koch H-R.

Irisplastik, Irisprothetik, Kapselspannringe, Knickringe  
AAD Düsseldorf 2004

Koch H-R.

The Artificial Iris  
ESCRS Paris Sept 2004

Schmitz K, Behrens-Baumann W.

Operative Rekonstruktion von Iris- und Pupillendefekten Teil 2: Iris-Prothetik-Implantate  
Ophthalmo-Chirurgie 18, 2006, 80-85

Bleckmann H.

Implantation von synthetischen Irisprothesen bei partieller bzw. kompletter Aniridie  
Klinische Monatsblätter für Augenheilkunde 2006, 223

Szurman P.

Das Irisdiaphragma in der rekonstruktiven Chirurgie  
Baltic Congress Nov 2007

Winkler von Mohrenfels C.

Implantation of artificial iris implant for aniridia after corneal transplant  
EEBA Munich Jan 2008

Winkler von Mohrenfels C.

Artificial iris implant provides good surgical results  
Ophthalmology Times July 2008

Koch H-R.

A New Foldable Artificial Iris. Indications, Surgical Techniques and First Results  
WOC 2008

Menapace R. M.

Cataract Surgical Problem  
Journal of Cataract and Refractive Surgery Vol. 34 August 2008