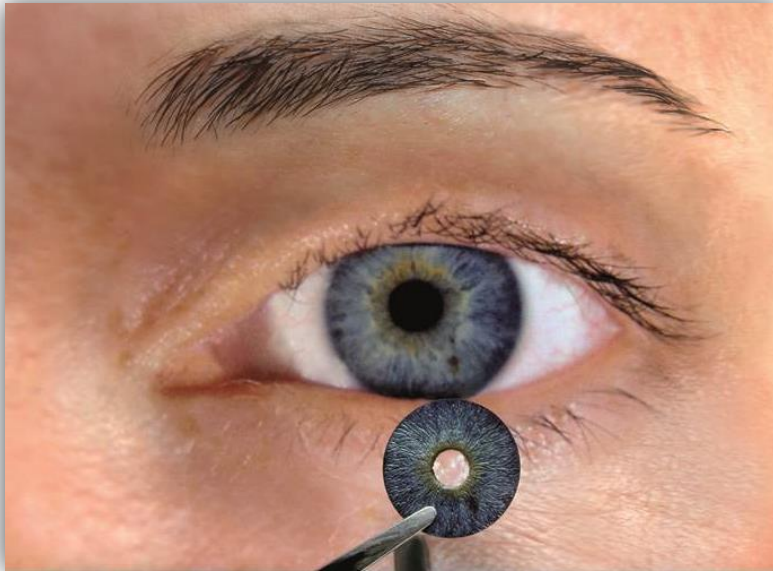




# HUMANOPTICS AG

## Artificial *Iris* – Foldable Iris Prosthesis

# Artificial Iris – Foldable Iris Prosthesis Content



Product presentation

Order Process

Order Form

Taking Pictures

Implantation

Sizing

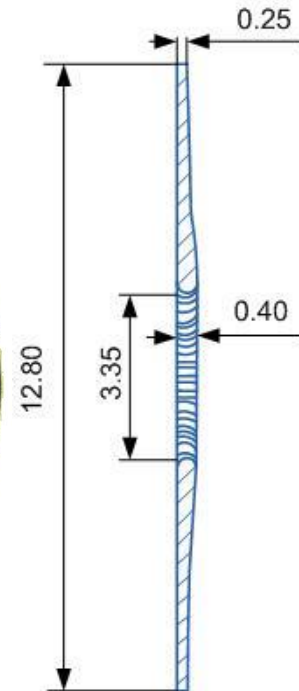
Implantation Preparation

# Product Presentation



# Artificial Iris – Foldable Iris Prosthesis Product Presentation

- Material: foldable, highly biocompatible Silicon
- The anterior surface **mimics** the **natural** iris **appearance** by its:
  - color composition (embedded non-toxic pigments)
  - iris structure (from makrolon mold)
- Black posterior surface prevents light transmission
- Designed **without an optic** to allow the surgeon to select the **IOL** or optic **most appropriate** for the patient



# Artificial Iris – Foldable Iris Prosthesis Product Presentation

## Main indication:

- Congenital Aniridia
- Trauma related defects
  - Traumatic Iris Lesions
  - Traumatic Mydriasis
- Larger coloboma
- Iatrogenic Iris Defects (e.g. after tumor excision or phako emulsification)
- Status post IFIS (Intraoperative Floppy Iris Syndrome)
- ICE-Syndrome (Iridocorneal Endothelial Syndrome)
- Translucent Iris (e.g. due to Albinism)



# Order Process



# Artificial Iris – Foldable Iris Prosthesis Order Process

**HUMANOPTICS**  
DR. SCHMIDT HIGH DEFINITION IMPLANTS

## ARTIFICIAL IRIS ORDER FORM

**FROM**

Surgeon's name: \_\_\_\_\_  
Clinic address: \_\_\_\_\_

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

**TO**

HumanOptics AG  
Spardorfer Str. 150  
91054 Erlangen  
Germany

I, the undersigned, hereby order a custom-made Artificial Iris as follows:

Surgeon certificate no: \_\_\_\_\_  
(if available)

Patient ID: \_\_\_\_\_

Eye to be treated:  RE  LE

Aniridia type:  congenital  acquired

Model selection:

Artificial Iris with Fiber (with polymer fiber meshwork)  
for cases where suturing is indicated (initially or at a later time)

Artificial Iris Fiber Free (no polymer fiber meshwork)  
for cases where suturing is not indicated

Standby selection:  with one standby  with two standbys  
Please return the standby(s) or justify their use promptly after surgery. If not, you will be charged for the full value of the implant(s) and an invoice will automatically be sent to you after 6 months.

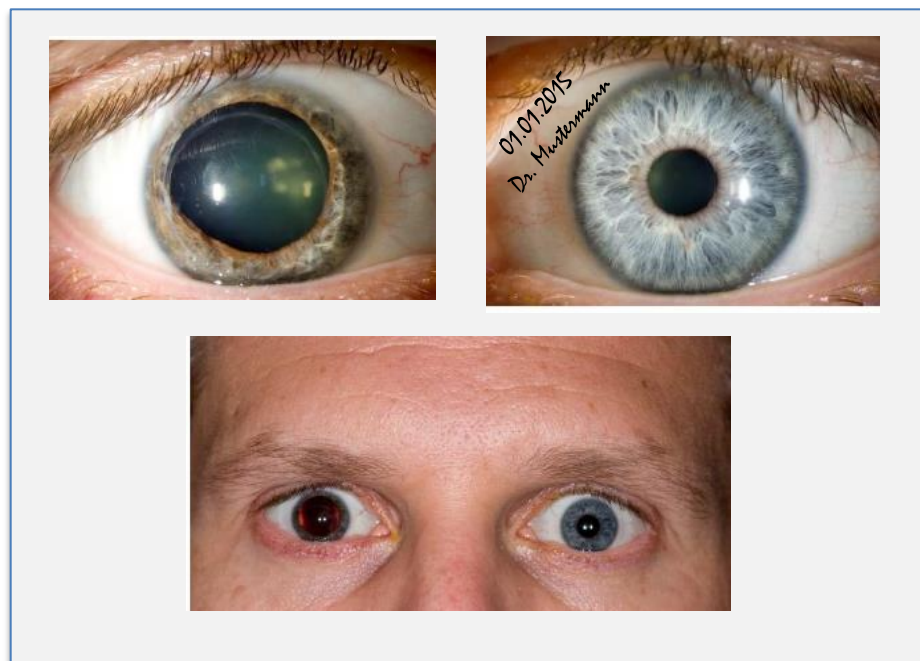
Surgeon (and patient) approve the labelled photo from the enclosed printouts as the target color/color distribution for the customized production of the Artificial Iris implant.  
The manufacturer is not liable for a postoperative difference in color between the natural iris tissue and the iris implant.

CHECK-LIST:

- 1) photo printouts of the right eye, the left eye and both eyes together (bridge)
- 2) one printout signed and dated by the surgeon for production
- 3) completed and signed order form

Date \_\_\_\_\_ Surgeon Signature (mandatory) \_\_\_\_\_ Patient Signature (optional) \_\_\_\_\_

In case of cancellation of this custom-made medical device after the production process has been initiated, a refund or credit is not possible.



# Artificial Iris – Foldable Iris Prosthesis Order Process

## Online Certification Course:

- Developed in collaboration with iris experts
- Provides comprehensive knowledge about Artificial Iris handling
- Individual certificate number enables physician to order the implant.

**HUMANOPTICS**  
DR. SCHMIDT HIGH DEFINITION IMPLANTS

### ARTIFICIAL IRIS ORDER FORM

**FROM**

Surgeon's name: \_\_\_\_\_  
Clinic address: \_\_\_\_\_

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



**TO**

HumanOptics AG  
Spardorfer Str. 150  
91054 Erlangen  
Germany

I, the undersigned, hereby order a custom-made Artificial Iris as follows:

Surgeon certificate no: \_\_\_\_\_  
(If available)

Patient ID: \_\_\_\_\_

Eye to be treated:  RE   LE 

Aniridia type:  congenital  acquired



# Artificial/Iris – Foldable Iris Prosthesis Order Process

Model selection:

**Artificial/Iris with Fiber** (with polymer fiber meshwork)  
for cases where suturing **is** indicated (initially or at a later time)

**Artificial/Iris Fiber Free** (no polymer fiber meshwork)  
for cases where suturing **is not** indicated

## Artificial/Iris with Fiber



- Polymer fiber meshwork layer increases mechanical implant stability (tensile strength)
- For cases where suturing is indicated (initially or at a later time)
- Can be used for sector implantation

## Artificial/Iris Fiber Free



- Without fiber meshwork for easier handling and more pliability
- For cases where suturing is not indicated
- Not for sector implantation

# Artificial Iris – Foldable Iris Prosthesis Order Process

Standby selection:

 with **one** standby

 with **two** standbys

Please return the standby(s) or justify their use promptly after surgery. If not, you will be charged for the full value of the implant(s) and an invoice will automatically be sent to you after 6 months.



DEAR SURGERY TEAM, DEAR DISTRIBUTOR TEAM,

For certain primary implants a back-up implant (standby) is supplied on demand for your surgery, as a part of our professional service. Standbys are included free of charge, but remain the property of HumanOptics AG and therefore should be returned to us within **six months** from the date of invoice of the primary implant.

Should the surgeon use the standby units during surgery or if the need for keeping the standby units for a longer period than six months arises, please inform us accordingly by using the **report form** below. We can then extend the return period.

In case neither the standby nor the report form are returned by the end of the six months, the standby will be invoiced automatically at the price of the primary implant.

Please note that it is not permitted to use sterile standbys for training purposes; these will be also invoiced at the price of the primary implant.


Please do not return standbys that became non-sterile. Use the report form below to advise us accordingly.

Thank you,  
Your HumanOptics-Team

**RETURN ADDRESS -**  
For standbys and report form

Please return the standbys to our local distribution partner or directly to us:

**HumanOptics AG** [customerservice@humanoptics.com](mailto:customerservice@humanoptics.com)  
Spardorfer Str. 150  
91054 Erlangen Phone: +49 (0) 9131 50665-0  
Germany Fax: +49 (0) 9131 50665-90

 **REPORT FORM** to HumanOptics or local distribution partner

Please report the serial number (SN) of the standby in question and mark the reason why it cannot be returned (on time).

Surgeon's name \_\_\_\_\_  
Customer ID \_\_\_\_\_  
Hospital \_\_\_\_\_  
Address \_\_\_\_\_  
ZIP code/City \_\_\_\_\_  
Country \_\_\_\_\_  
Date, Surgeon's signature \_\_\_\_\_

**THE STANDBY IMPLANT BECAME NON-STERILE**  
SN of primary implant: \_\_\_\_\_  
SN of non-sterile standby: \_\_\_\_\_  
Reason: \_\_\_\_\_

**THE SURGERY HAS NOT TAKEN PLACE**  
SN of primary implant: \_\_\_\_\_  
Reason: \_\_\_\_\_

**OTHER**  
Reason: \_\_\_\_\_  
SN of primary implant: \_\_\_\_\_

V1-03/2014



**REPORT FORM** to HumanOptics or local distribution partner

Please report the serial number (SN) of the standby in question and mark the reason why it cannot be returned (on time).

Surgeon's name \_\_\_\_\_  
Customer ID \_\_\_\_\_  
Hospital \_\_\_\_\_  
Address \_\_\_\_\_  
ZIP code/City \_\_\_\_\_  
Country \_\_\_\_\_  
Date, Surgeon's signature \_\_\_\_\_

**THE STANDBY IMPLANT BECAME NON-STERILE**

SN of primary implant: \_\_\_\_\_

SN of non-sterile standby: \_\_\_\_\_

Reason: \_\_\_\_\_

**THE SURGERY HAS NOT TAKEN PLACE**

SN of primary implant: \_\_\_\_\_

Reason: \_\_\_\_\_

**OTHER**

Reason: \_\_\_\_\_

SN of primary implant: \_\_\_\_\_

V1-03/2014

# Artificial/Iris – Foldable Iris Prosthesis Order Process



Surgeon (and patient) approve the labelled photo from the enclosed printouts as the target color/color distribution for the customized production of the Artificial/Iris implant.

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

## CHECK-LIST:

- 1) photo printouts of the **right** eye, the **left** eye and **both** eyes together (bridge)
- 2) **one** printout **signed and dated** by the surgeon for production
- 3) completed and signed **order form**

-----  
Date

-----  
Surgeon Signature (mandatory)

-----  
Patient Signature (optional)

In case of cancellation of this custom-made medical device after the production process has been initiated, a refund or credit is not possible.

# Artificial *Iris* – Foldable Iris Prosthesis

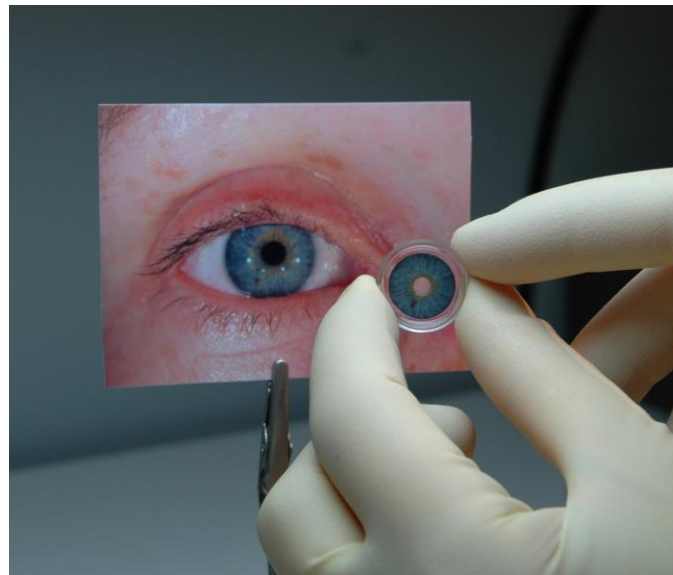
## Order Process – Taking Pictures

### Taking pictures for production

#### Purpose:

Since the manufacturer cannot see the patient's natural iris himself, he needs to rely on the pictures he gets.

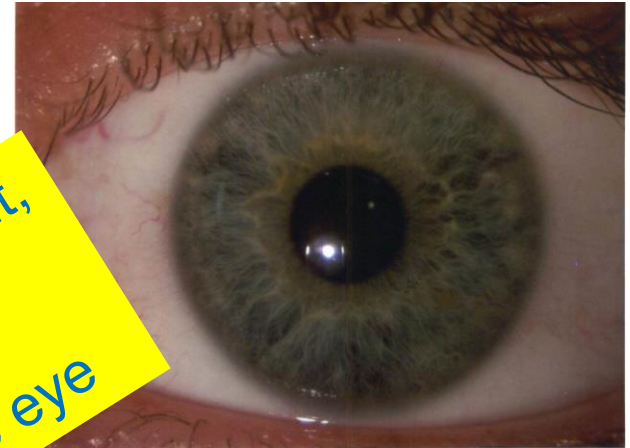
The color of every computer screen and printer shows different results of a photo. That is the reason why evaluated hardcopies of the pictures are still necessary.



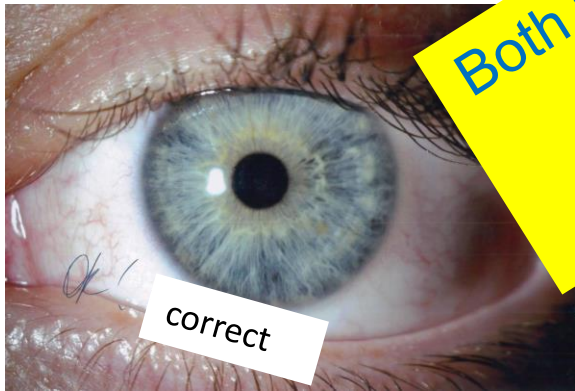
# Artificial Iris – Foldable Iris Prosthesis

## Order Process – Taking Pictures

- Conjunctiva has a reddish color
- Iris color is greenish
- Picture seems underexposed



Both times same patient,  
Difference:  
Illumination of the eye



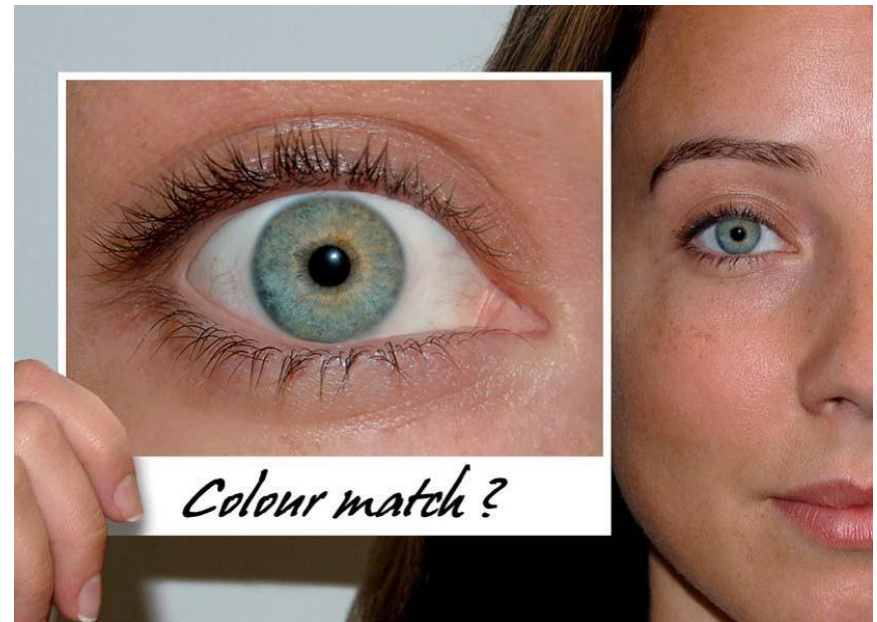
- Conjunctiva is white
- Iris color is bluish

# Artificial/Iris – Foldable Iris Prosthesis

## Order Process – Taking Pictures

### Compare the printout with the natural iris

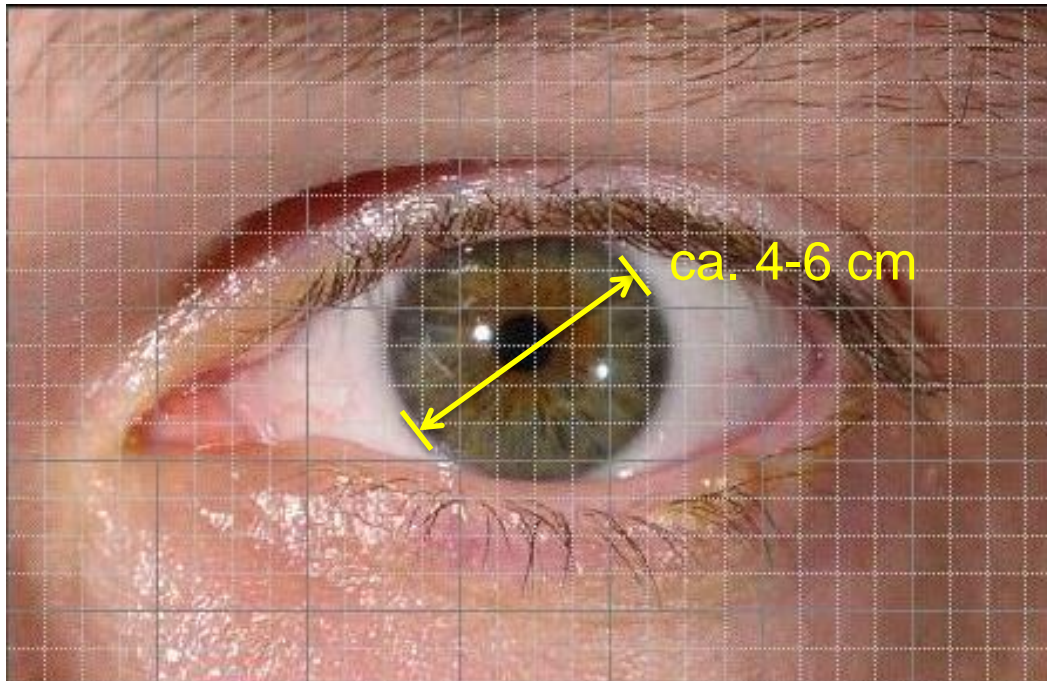
- Take care that natural iris and printout are compared under the same light conditions.
- Hold the printout right next to the patient's eye.
- Compare if the conjunctiva is white on the printout.
- Do the color patterns of the natural iris match the printout's color composition?



➔ Surgeon initials and signs the picture we should use for production.

# Artificial Iris – Foldable Iris Prosthesis

## Order Process – Taking Pictures



Standardized picture

- Size of photo 9 x 13 cm (3.5 x 5“)
- Size of iris approx. 4 – 6 cm (1.5 – 2.5“)

# Artificial Iris – Foldable Iris Prosthesis Order Process

**HUMANOPTICS**  
DR. SCHMIDT HIGH DEFINITION IMPLANTS

## ARTIFICIAL IRIS ORDER FORM

**FROM**

Surgeon's name: \_\_\_\_\_  
Clinic address: \_\_\_\_\_

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

**TO**

HumanOptics AG  
Spardorfer Str. 150  
91054 Erlangen  
Germany

I, the undersigned, hereby order a custom-made Artificial Iris as follows:

Surgeon certificate no: \_\_\_\_\_  
(if available)

Patient ID: \_\_\_\_\_

Eye to be treated:  RE  LE

Aniridia type:  congenital  acquired

Model selection:

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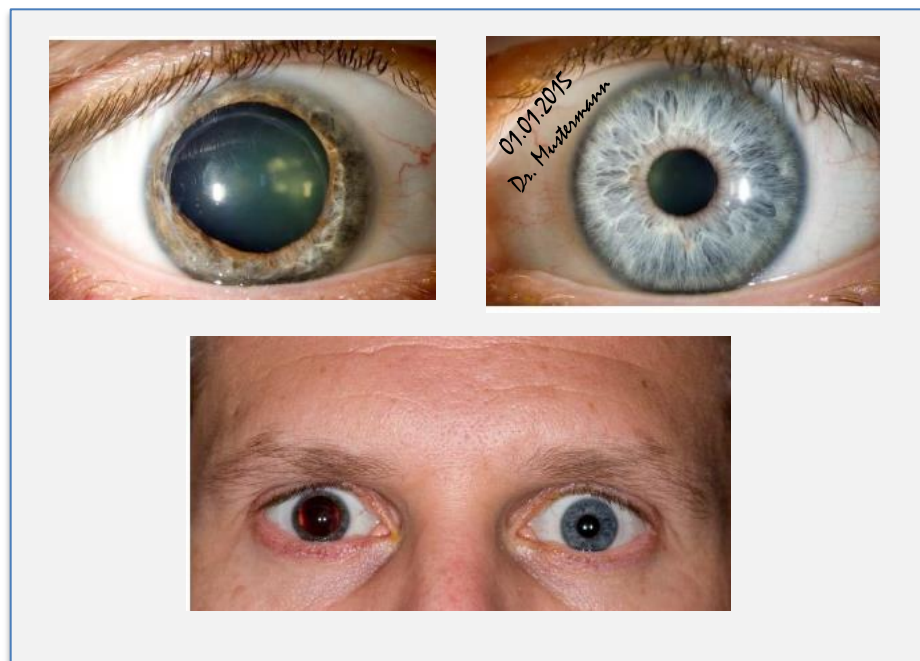
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Date \_\_\_\_\_ Surgeon Signature (mandatory) \_\_\_\_\_ Patient Signature (optional) \_\_\_\_\_

In case of cancellation of this custom-made medical device after the production process has been initiated, a refund or credit is not possible.





# Implantation Preparation



# Artificial *Iris* – Foldable Iris Prosthesis Implantation Preparation

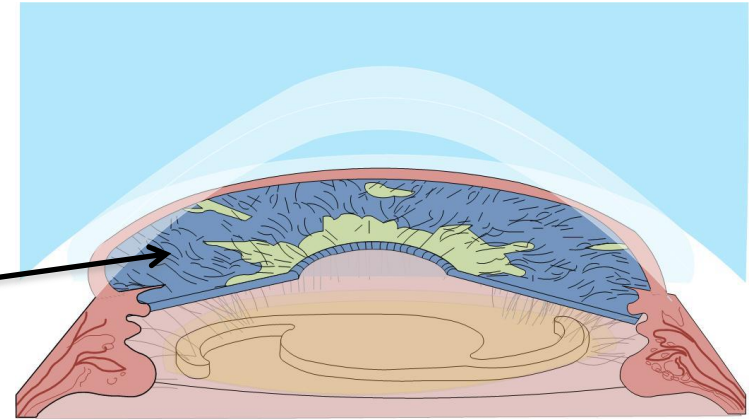
## General principles:

### Implantation ...

- ... only in pseudophakic or aphakic eyes
- ... always in the posterior chamber (sulcus or bag)
- ... behind iris remnants when present
- ... of a sector (only model **with Fiber**) when applicable
- ... with forceps or injector

✓ Always have a second *Artificial Iris* available as a back-up (standby).

Artificial *Iris*



# Artificial Iris – Foldable Iris Prosthesis Implantation – Sizing

## Sizing:

Various possibilities to estimate or measure the diameter of the ciliary sulcus, e.g.:

- ultrasound biomicroscopy (UBM),
- optical coherence tomography (OCT),
- direct intraoperative measurement,
- white-to-white caliper measurement



# Artificial Iris – Foldable Iris Prosthesis Implantation – Sizing

## Rule of thumb:

For horizontal white-to-white (caliper) measurement **add a value of +0.5 mm** (Prof. Dr. H.-R. Koch).

**Round** the resulting number **down** to the next  $\frac{1}{2}$  mm step to obtain the suggested trephine diameter.

Example:

w-t-w:	11.7 mm
+ 0.5 mm :	12.2 mm
round down:	12.0 mm

→ therefore: suggested trephine: 12.0 mm

## Routine trephine sizes for ...

- sulcus implantation: 12.0 mm, 11.5 mm, 11.0 mm
- in-the-bag implantation: 10.0 mm, 9.5 mm, 9.0 mm

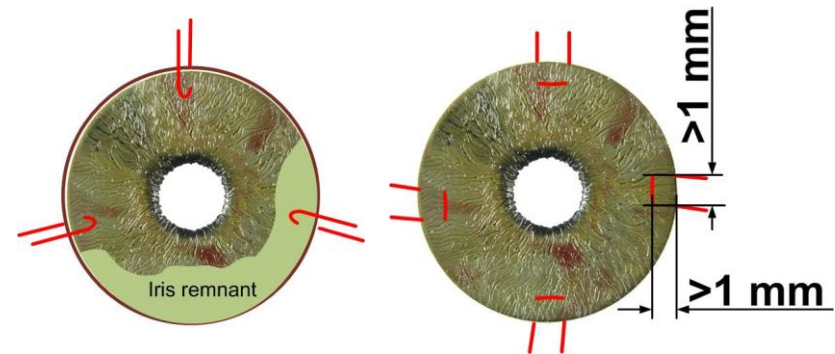
# Artificial Iris – Foldable Iris Prosthesis Implantation Preparation

## Implantation preparation:

- Indications for transscleral suturing:
  - Absence of capsular or insufficient zonular support and/or
  - Lack of iris remnantsto guarantee the stability of the implant in the eye.

### Most used suturing material:

- 10-0 or 9-0 Prolene
- 10-0 Polyester
- Gore Tex CV-8
- Needle according to preference

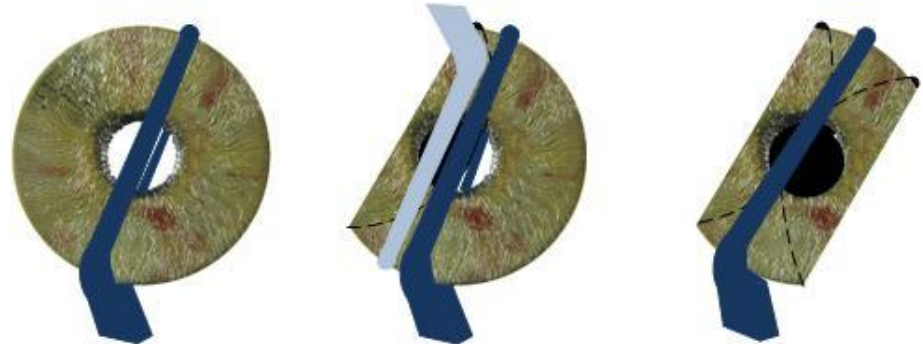


# Artificial Iris – Foldable Iris Prosthesis Implantation Preparation

- Implantation with injector or forceps possible
- In case of planned suturing place sutures to the implant prior to inserting the device with forceps
- Perform at least a triangular iridectomy to decrease IOP risk



→ One possibility is to fold the Artificial Iris in three parts using two forceps



## Outstanding features in summary:

- **Foldable** - small incision
- **Versatile** - placement in the sulcus or in the bag
  - Fiber Free for full device implantation and with Fiber for full or partial device suture fixation
- **Flexible** - individual sizing
- **Distinct** - realistic appearance mimicking the natural iris
- **Suturable** - with fiber meshwork for segment use and as full implant
- **One Piece** - not various components
- **Independent** - from the IOL: model, diopter, material and location

# Artificial Iris – Foldable Iris Prosthesis

Courtesy of Kevin Miller, MD (UCLA, USA)



pre-op



post-op

For further information about the *Artificial Iris*, e.g. publication list, photo directives and implantation videos, please go to [www.artificial-iris.com](http://www.artificial-iris.com) .