

ArtificialIris

Frequently Asked Questions

■ **1 - What material is the ArtificialIris made of?**

Foldable, highly biocompatible, hydrophobic silicone elastomer - exactly the same proven material as in the Dr. Schmidt silicone intraocular lenses, with colour pigmentation and polymer fibre meshwork (optional), fully embedded within the silicone.

■ **2 - Is your ArtificialIris an iris lens?**

No, this device does not integrate an intraocular lens, but is independent of an IOL.

■ **3 - What is the standard size?**

The iris prosthesis comes in one standard diameter of 12.8mm with a standard 3.35mm central aperture, a central circumference thickness of 0.4mm with a final peripheral thickness of 0.25mm.

■ **4 - Can you modify the prosthesis?**

Yes, you can trim and cut-to-size by trephine or scissors both versions when indicated.

■ **5 - Are there different versions to choose from?**

There are two versions available: ArtificialIris – WITH Fibre and ArtificialIris – Fibre Free

■ **6 - What is the difference between the two models?**

Our model ArtificialIris – Fibre Free is not made to hold sutures, is more flexible and can fit through an incision down to 2.5mm. Our model ArtificialIris with polymer fibre meshwork which is embedded in the silicone, is specifically made for suturing and can fit through an incision of about 3.2mm.

■ **7 - How is the ArtificialIris sterilized and delivered?**

It is steam sterilized in a primary container, in sterile saline solution, sealed within a sterile pouch and fully labelled including a picture of the contained ArtificialIris.

■ **8 - What is your standard production and delivery time?**

Delivery time 4 to 8 weeks after receipt of prescription and approved photography.

■ **9 - When and where was the first human implantation of the ArtificialIris?**

The first ArtificialIris implantation was performed successfully by Prof. Hans-Reinhard Koch, the co-inventor, in November 2002 in Bonn, Germany.

■ **10 - Can I use the ArtificialIris for colour change of the eye?**

It is not intended for iris colour change as it is not made for anterior chamber placement.

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■ 11 – What are the stand-by prostheses for and what do I do with them?

The ArtificialIris prosthesis will be delivered with two stand-by implants, as they are hand-crafted each with a slightly different colour composition. The stand-by prostheses are intended for implantation if the primary implant accidentally becomes contaminated. On the other hand they can be utilized for choosing the best aesthetical option in case the colour match of the ArtificialIris prosthesis and remaining natural iris tissue needs to be optimized. The two stand-by prostheses should be returned to the company within 90 days; otherwise they will be invoiced and have to be paid for.

■ 12 - Can I implant the ArtificialIris into the anterior chamber in front of the iris or iris remnant?

No, the iris prosthesis is designed for implantation into the posterior chamber. Because of the danger of damage to the corneal endothelium as well as the danger of severe intraocular pressure increase it must not be implanted into the anterior chamber.

■ 13 - Is it necessary to perform an iridectomy?

A peripheral iridectomy, to be done by the surgeon in the OR, is always recommended (triangular or stamp-edge shaped).

■ 14 – Is it always necessary to reduce the overall diameter of the ArtificialIris with a trephine?

If the ArtificialIris' standard diameter of 12.8 mm is appropriate after measuring the white-to-white diameter plus adding 0.5 mm, we only recommend performing the triangular peripheral iridectomy. Especially in smaller eyes the overall diameter should be reduced for custom fit using a trephine or sharp scissors when indicated.

■ 15 - What is the best overall diameter of the ArtificialIris for the recommended sulcus implantation?

Experienced iris surgeons recommend the “over-the-thumb” rule: The best diameter of the ArtificialIris can be determined by measuring the white-to-white diameter and adding 0.5 mm.

■ 16 - Which incision size should be used for the two ArtificialIris models?

The ArtificialIris without fibre (Fibre Free) may fit through an incision size down to 2.5 mm, while the model ArtificialIris with fibre meshwork can be inserted through an incision of about 3.2 mm.

■ 17 - Which contraindications are known?

The known contraindications include severe chronic uveitis, endothelial corneal dystrophy, microphthalmus, retinal detachment, untreated chronic glaucoma, rubella cataract, rubeosis of the iris and proliferative diabetic retinopathy.

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■ 18 - What kind of complications can occur?

Possible complications are endothelial damage, retinal detachment and cystoid macular edema, increased intraocular pressure and secondary glaucoma.

■ 19 - Can colour dye leach into the eye?

Extensive material testing yielded results showing that no extractable colour pigments are contained. All colour particles are fully embedded inside the silicone material preventing leaching of pigments.

■ 20 - How do I order the ArtificialIris?

For ordering the ArtificialIris please send the completed order form signed by the patient and the surgeon and attach the photo print-out of the patient's eyes. When supplying various print-outs, please make sure to mark the best matching picture

■ 21 - Does the patient have to sign the order form?

Yes, since both the surgeon and the patient share the responsibility for the colour matching of the photo print-out. (Please refer to our form: "directives for photography and print-out").

■ 22 - Can I send digital photos (images) for you to use as target colour for production?

Please do not send the photos (images) digitally 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. We also cannot verify the colour match to the natural iris when we print out the digital photos ourselves.

(Please refer to our form: „directives for photography and print out“).

■ 23 - Is it possible to implant an ArtificialIris in the sulcus with an IOL located in the capsular bag?

Yes, the recommended procedure is ciliary sulcus placement in combination with an IOL in the capsular bag.

■ 24 - Is it always necessary to suture the ArtificialIris in the ciliary sulcus?

No, you can safely implant either version into the ciliary sulcus without sutures. The precondition for the sutureless fixation is a stable and intact ciliary sulcus. Any time suturing is indicated, either for fixation of the full implant behind the iris root or fixation of a segment of the implant to the iris remnant, you will need to order the ArtificialIris with fibre meshwork which is designed to support suturing.

■ 25 - How to suture?

The only model which should be used for suturing is the ArtificialIris with polymer fibre meshwork. The puncture and thread should be at least 1 mm inside of the rim of the device in order to guarantee the stability of the suture in the silicone material. Various suturing techniques using straight or curved needles are possible.