

SURGICAL PROCEDURE FOR ARTISAN APHAKIA IOL IMPLANTATION

This surgical procedure is described for both anterior and posterior chamber iris fixation. Unless indicated otherwise, the steps are applicable for both implantation methods.

Note:

Use a different a-constant for the lens power calculation in case of posterior chamber (retropupillary) implantation. An approximate a-constant can be found on the company website and is also provided on the label on the outer package. The a-constant is a theoretical value and should be personalized by the physician.

1. Prior to implantation, carefully examine all packaging to verify that the correct lens power has been chosen, the expiration date is respected, and the contents have not been damaged. Using a sterile technique, open the blister pack and deliver the lens tray with the lens to the sterile prep tray.
2. Make a main incision of 5.5 mm. The incision should be at 90° from the intended enclavation axis.
3. **For anterior chamber iris fixation:** Inject a miotic agent into the anterior chamber to constrict the pupil. The pupil has to be constricted to facilitate enclavation in the mid-periphery of the iris.
For posterior chamber iris fixation: Do NOT inject a miotic agent. Leave the pupil at a minimum size of approximately 3 mm to allow the lens to reach the retropupillary position. Constriction of the pupil will impede the movement of the intraocular lens (IOL) through the pupil and might result in damage to the iris tissue.
4. Inject a sufficient amount of viscoelastic to maintain anterior chamber depth (**for anterior chamber iris fixation**) or anterior chamber and posterior chamber depth (**for posterior chamber iris fixation**), but do not overfill. Only use high-viscosity sodium hyaluronate viscoelastic.
5. **For anterior chamber iris fixation:** Make a 1.2 mm (enclavation needle) or 1.5 mm (Vacufix) paracentesis on either side of the main incision site. The paracenteses must be approximately 9.0 mm apart, oriented towards the enclavation sites, and pointing slightly downwards. In case the enclavation forceps are used, make two paracenteses of 2.0-2.5 mm at 3 and 9 o'clock directed to the pupil. Test whether the enclavation instruments can properly enter the paracenteses.
For posterior chamber iris fixation: Make a paracentesis of 1.2 mm on either side of the intended main incision site. The paracenteses must be in line with the haptics and pointing slightly downwards.
6. The IOL can become electrostatically charged and stick to the lid of the lens tray. Carefully tap on the lid before opening the lens container. Open the lens tray and examine the IOL carefully for damage or debris.
7. The IOL may be rinsed with a sterile balanced salt solution to remove the electrostatic charge and coated with a viscoelastic prior to implantation to facilitate easy passing through the main incision.
8. **For posterior chamber iris fixation only:** Invert the IOL before insertion into the eye.
9. Introduce the IOL into the anterior chamber through the main incision in a vertical orientation using the implantation forceps or Artifix holding forceps. Retract the forceps. Avoid contact with the corneal endothelium.
10. Rotate the IOL 90°, and align it with the enclavation axis using the lens manipulator. Centre the lens over the pupil.
11. Bring the appropriate implantation forceps through the main incision and firmly grasp the IOL at the edge of the optic.
12. **For posterior chamber iris fixation only:** Carefully move the IOL through the non-constricted pupil. Move the IOL upwards against the iris to facilitate enclavation.
13. Choose a side of the lens to enclavate.

14. For **anterior chamber iris fixation**: Insert the enclavation needle through one of the paracenteses. Hold the optic securely with the implantation or holding forceps and use the enclavation needle to create a small knuckle of mid-peripheral iris tissue that is virtually immobile. Make a snow ploughing movement at the desired enclavation site. Gently lift the iris tissue through the slot at the inferior claw of the haptics.

Sufficient iris tissue must be placed through the haptic slot to ensure adequate lens stability. As a rule of thumb, an iris bridge or knuckle with a width approximately the same as the widest part of a haptic claw should be enclavated.

If case the enclavation forceps is used, take up a fold of iris tissue below the claw slot, while securely holding the optic. Press down the IOL over the iris fold with the implantation forceps while holding the enclavation forceps at the original level.

The enclavation procedure may also be performed using the Vacufix enclavation system; procedure as described in the instructions for use of the Vacufix.

For **posterior chamber iris fixation**: Insert a cannula through one of the paracenteses to fixate the lens to the iris. Hold the optic securely with the implantation forceps and use a cannula to carefully push sufficient mid-peripheral iris tissue, which is virtually immobile, through the slot of the haptics. Sufficient iris tissue must be placed through the haptic slot to ensure adequate lens stability.

15. Repeat step 14 on the other side of the IOL. Make sure the IOL is well centered over the pupil and verify the amount of iris tissue which is enclavated.
16. Perform an iridotomy or iridectomy outside the periphery of the IOL, preferably in the part of the iris that the upper eyelid will cover. A single small iridotomy is preferred to prevent light-related complaints. The iridotomy is sufficient in size as soon as a red light reflex can be observed.

Alternatively, an iridotomy may be performed at least one week prior to the IOL implantation using a neodymium-doped yttrium aluminum garnet (Nd:YAG) laser.
17. Remove all viscoelastic from the eye by flushing with saline using a syringe with cannula. Make a semi-circular movement during flushing from opposite the main incision. Also, flush out viscoelastic from underneath the IOL. Make sure no viscoelastic remains in the eye as this may cause high intraocular pressure postoperatively.
18. Close the main incision to prevent wound leakage. Watertight wound closure is of paramount importance to prevent a shallow anterior chamber in the immediate postoperative period. Do not suture too tight to avoid surgically induced astigmatism. When sutures are made, corneal sphericity can be checked with a Placido disk under the microscope, and adjustments to sutures can be made, if necessary.
19. Administer and prescribe postoperative medication (e.g. antibiotics and corticosteroids).
20. Place a protective patch over the eye after surgery.
21. Patients must be instructed not to rub the eye, to avoid physical impact or direct pressure to the eye, and to avoid activities that increase the risk for ocular trauma (e.g. certain martial arts sports) or to wear safety glasses during such activities.
22. Patients must be informed that, besides a postoperative follow-up after six months, yearly examinations, are required to assess the long-term safety of the IOL. Those examinations must include intraocular pressure, endothelial cell counts, and anterior chamber measurements.

The physician must ensure traceability of the IOL and provide the patient with a patient card.

SURGICAL PROCEDURE FOR RE-ENCLAVATION

Re-enclavation may be required in case of decentration or (partial) luxation. Warning: do not re-enclavate when the IOL haptics appear damaged.

1. Make a 2.0 mm incision at 90° from the intended enclavation axis.
2. Follow step 3 of the surgical procedure for implantation.
3. Follow step 4 of the surgical procedure for implantation.
4. Make a paracentesis of 1.2 mm (enclavation needle), 1.5 mm (Vacufix) or 2.0-2.5 mm (enclavation forceps) at the side of luxation or the side causing the decentration. The paracentesis must be oriented towards the enclavation site and pointing slightly downwards.
5. If required, de-enclavate haptics:
For anterior chamber iris fixation: by carefully holding one haptic and gently pushing down on the iris bridge to release the iris fold or knuckle.
For posterior chamber iris fixation: by carefully holding the optic and gently moving the iris tissue beneath the claw slot upwards with for instance an iris spatula to release the fold or knuckle.
6. Re-align the IOL with the implantation axis and centre over the pupil while holding the IOL at the edge of the optic.
7. Re-enclavate the luxated haptic according to step 14 of the surgical procedure for implantation.
8. Remove all viscoelastic from the eye, close the incision, administer and prescribe postoperative medications (steps 17-19 of the surgical procedure for implantation).
9. Place a protective patch over the eye of the patient and instruct patient on postoperative behavior and follow-up examinations.

SURGICAL PROCEDURE FOR EXPLANTATION

In some cases explantation may be required. The decision to explant is up to the judgment of the treating physician.

1. Make a main incision of 5.5 mm at 90° from the intended enclavation axis.
2. Follow steps 3-5 of the surgical procedure for implantation.
3. De-enclavate haptics by carefully holding one haptic and gently pushing down on the iris bridge to release the iris fold or knuckle.
4. Extract the lens through the main incision.
5. Remove all viscoelastic from the eye, close the main incision, administer and prescribe postoperative medications (steps 17-19 of the surgical procedure for implantation).
6. Place a protective patch over the eye of the patient and instruct patient on postoperative behavior and follow-up examinations.

More information can be obtained by contacting:

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