SURGICAL PROCEDURE FOR ARTIPLUS PHAKIC IOL IMPLANTATION

1. Prior to implantation, all packaging should be carefully examined to verify that the correct lens power has been chosen, the expiration date is respected and that 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 3.2 mm main incision. The main incision should be at 90 degrees from the intended enclavation axis.
3. 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 and to protect the natural lens during the procedure.
4. Inject a sufficient amount of high viscosity viscoelastic to maintain anterior chamber depth, but do not overfill. Injecting viscoelastics for this procedure differs from the technique for cataract surgery. The viscoelastic must be injected slowly from the periphery toward the pupil, but never directly into the pupillary area. Only use high viscosity sodium hyaluronate.
5. Make a paracentesis of 1.2 mm on either side of the main incision site. The paracenteses must be approximately 9 mm apart, oriented towards the enclavation sites and pointing slightly downwards. Test whether the Enclavation Needle can properly enter the paracenteses.
6. Prior to implantation, verify that the correct product and lens power has been selected for the correct eye. Open the lens tray and examine the lens carefully for damage or debris. Remove the IOL from the tray by grasping the IOL at the haptic. Do not hold the lens at the optic as this may damage the lens.
7. Load the dry lens on the Insertion Spatula: bring the tip of the spatula through the leading haptic and then slightly bend the spatula away from the lens so that the trailing haptic enters below the lower lid of the spatula. Slowly bring the spatula back to its straight position, allowing the lower lid of the spatula to snap into the opposite haptic of the PIOL.
8. The IOL may be rinsed with sterile balanced salt solution and coated with a viscoelastic prior to implantation to facilitate easy passing through the main incision.
9. Introduce the lens into the anterior chamber through the main incision in a vertical orientation using the insertion spatula. Retract the spatula through the main incision while preventing withdrawal of the IOL with a forceps. Care must be taken to avoid contact of the spatula with the crystalline lens or the corneal endothelium.
10. Add a small amount of viscoelastics on top of the IOL to prevent corneal touch.
11. Rotate the lens 90 degrees and align with the enclavation axis using the ARTIFLEX Lens Manipulator. Centre the lens over the pupil.
12. Choose a side of the lens to enclavate. Bring the appropriate implantation forceps through the main incision and stably hold the superior haptic at the appropriate side of the lens. Do not hold the lens at the optic as this may damage the lens.
13. Insert the iris enclavation needle through one of the paracenteses to fixate the lens to the iris. Perform the first enclavation with the non-dominant hand. Perform the first enclavation with the non-dominant hand. While securely holding the optic with the implantation forceps, 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 haptic. Do not attempt to lift the enclavation needle from under the haptic which is held with the forceps as this may deform the haptic and result in lens luxation. 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.

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The enclavation procedure may also be performed using the VacuFix Enclavation System (procedure as described in the Instructions for use of the VacuFix).

14. Repeat step 13 at the opposite side of the lens. Make sure the lens is well centred over the pupil and that the haptics are in a horizontal plane after the enclavation of the IOL. Furthermore, verify the amount of iris tissue which is enclavated.
15. Perform an iridotomy or iridectomy outside the periphery of the IOL, preferably in the part of the iris that will be covered by the upper eyelid. To prevent light complaints, a single small iridotomy is preferred. For all iris types, the iridotomy is sufficient in size as soon as a red light reflex can be observed. Alternatively, iridotomy may be performed at least one week prior to the IOL implantation using a neodymium-doped yttrium aluminium garnet (Nd:YAG) laser.
16. Remove all viscoelastic from the eye by flushing with saline using a syringe with cannula. During flushing make a semi-circular movement 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.
17. Close the main incision by stromal hydration to prevent wound leakage. Watertight wound closure is of paramount importance to prevent a shallow anterior chamber in the immediate postoperative period. When sutures are made, do not suture too tight to avoid surgically induced astigmatism. Corneal sphericity can be checked with placido disk under the microscope and, if necessary, adjustments to sutures can be made.
18. Administer and prescribe postoperative medication (e.g. antibiotics and corticosteroids).
19. A protective patch should be placed over the eye following surgery.
20. 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 of ocular trauma (e.g. certain ball or martial arts sports) or to wear safety glasses during such activities.
21. Patients must be informed that besides a postoperative follow-up after six months, yearly examinations, including intraocular pressure, endothelial cell counts and anterior chamber measurements, are required to assess the long-term safety of the IOL

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 main incision. The main incision should be at 90 degrees from the intended enclavation axis.
2. Follow step 3 and 4 of the surgical procedure for implantation.
3. Make a paracentesis of 1.2 mm at the side of luxation or the side causing the decentration. The paracentesis must be oriented towards the enclavation site and pointing slightly downwards.
4. If required, de-enclavate the haptic by carefully holding one haptic and gently pushing down on the iris bridge to release the iris fold or knuckle.
5. Re-align the IOL with the implantation axis and centre over the pupil.
6. Re-enclavate the luxated haptic (step 13 of the implantation procedure).
7. Remove all viscoelastic from the eye, close the main incision, administer and prescribe postoperative medications (steps 16-18).
8. Place a protective patch over the eye of the patient and instruct patient on postoperative behaviour 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 3.2 mm main incision. The main incision should be at 90 degrees from the intended enclavation axis.

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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. To facilitate removal, the IOL may be cut in half through the optic using scissors.
5. Remove all viscoelastic from the eye, close the main incision, administer and prescribe postoperative medications (steps 16-18).
6. Place a protective patch over the eye of the patient and instruct patient on postoperative behaviour and follow-up examinations.

More information can be obtained by contacting:


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