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Patient Authorization for IsoWhite[™] Pterygium Surgery

1. General information

The following information is intended to help you make an informed decision about having IsoWhite[™] pterygium surgery. It is impossible to list ALL of the potential risks and complications associated with the procedure. Risks and complications that are considered to be unforeseeable, remote, or not commonly recognized are not discussed. In addition, because IsoWhite[™] pterygium surgery utilizes recently developed procedures, there may be long-term effects not yet known or anticipated.

2. An Overview of IsoWhite[™] Pterygium Surgery

IsoWhite[™] pterygium surgery is a no-stitch technique developed over many years by Drs. Klein & Scannapiego to remove a pterygium with the goal of having the best possible medical and cosmetic result.

A pterygium is a growth on the eye's surface which involves and destroys the healthy conjunctiva and cornea. During the IsoWhiteTM procedure, the pterygium is surgically excised. Depending on the extent of the defect after pteryigium removal the eye's surface can be repaired with either other conjunctiva from an unaffected portion of the eye or amniotic membrane (used as a type of medical bandage) which helps to encourage healing, or a combination of both. An application of an anti-scarring medication called Mitomycin-C is employed during the surgery to further aide healing and reduce the chances of the problem recurring.

The goal of the IsoWhite[™] pterygium surgery is to make the eye look and feel better; to create a clear, whiter appearance to the eyes. This often results in the eyes looking more youthful and feeling "fresher" with diminished dry eye and irritation.

Therapeutic options: There are different options for treating a pterygium.

1. Medical treatment: At times, artificial tears or a mild steroid eye drop can provide relief, though relief is not permanent and steroid eye drops should not be used for extended periods of time due to the risk of glaucoma and cataracts associated.

2. Standard pterygium surgery: There are many variations of pterygium surgery employed by other surgeons. We have found them not to be as effective as our technique.

3. IsoWhite[™] pterygium surgery: This is the surgical treatment offered by Drs. Klein & Scannapiego.

3. Patient consent

In giving my permission for IsoWhiteTM, I understand the following: The long-term risks and effects of IsoWhiteTM are unknown. I have received no guarantee as to the success of my particular case. I understand the following important points with regard to the procedure:

- 1. I understand that it is crucial to maximally medically treat any underlying medical conditions which predispose my eyes to discoloration before having surgical intervention. The continual treatment of any such medical conditions is important in preventing recurrence of pterygium.
- 2. I understand that it is normal for the eye to be red and irritated as it heals, in most cases, for 3-4 weeks after surgery. In some cases (especially those involving larger surgeries), however, the healing period can persist for several weeks more.
- 3. I understand that typically the vision during recovery is normal but, in some instances, because of medication use or tearing there may be times when the vision is not as good as usual.
- 4. I understand that this procedure is not intended to correct my vision and if I needed glasses before the procedure, I will still require them afterwards.
- 5. I understand that there is a risk of infection after surgery, which could in extremely rare circumstances, threaten the health of the eyes.
- 6. I understand that contact lenses should not be used during the healing period unless specifically stated by Drs. Klein & Scannapiego because they could disrupt the tissue healing or promote infection.
- 7. I understand that having ocular surface surgery can, at times, leave a cosmetic appearance which is not as expected before surgery. This can be for a variety of reasons including the recurrence of the pterygium (less than 1% chance) or, very rarely, the formation of scar tissue or new blood vessels as the surgery heals.
- 8. I understand that in some larger surgeries which involve the eye's limbus (the area where the white of the eye meets the colored part of the eye) the stem cell population which helps the ocular surface renew itself and stay healthy could be diminished. In extremely rare cases, such a stem cell deficiency could be harmful to not only the comfort of the eye but to the clarity of the vision.
- 9. I understand that mitomycin-C (MMC) may be used during my surgery. MMC is an antibiotic that has been used in the medical field for a number of decades. It has been used as an anti-cancer drug because it can stop the proliferation or growth of certain types of cells such as those seen in tumors, and also those cells in the eye which produce scarring or haze. MMC has been used in the eye since the 1980s to prevent scarring after many types of surgical procedures, such as glaucoma filtration and pterygium surgeries. MMC is very potent and potentially toxic, under certain circumstances. Some of the eye-related complications that have been reported following the use of MMC (for other conditions) include, but are not limited to: conjunctival injection (redness of the eye), permanent ocular stem cell deficiency, corneal or scleral thinning or perforation requiring corneal transplantation, corneal decompensation, cataract, and retinal vascular occlusion. The complications have been reported following our IsoWhiteTM technique after thousands of procedures. Our technique uses a low dose (0.02%) of MMC delivered to the ocular surface for a short period of time. This technique minimizes the chance of complications although a small risks is nevertheless present.
- 10. I understand that if I have simultaneous surgery in both eyes that there may be some difficulty with vision, especially in the first 24 hours when swelling is prominent. Some patients are most comfortable with both eyes patched closed the first day after surgery. Patients typically feel significantly better than next day after surgery.
- 11. I understand that there is a natural tendency for the eyelid to droop with age and that manipulation of the eyelid during surgery or post-operative irritation of the eye can accelerate this drooping.
- 12. I do not have a history of elevated eye pressures and I have had this checked by an eye doctor recently.

Patient Name: _____

Patient Signature

Date

I will be having surgery on my:

Right eye only (initials)

Left eye only (initials) _____

Both eyes (initials) _____

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Physician Signature

Date