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**Informed Consent – Fact Sheet - Annular Keratopigmentation
- FLAAK –**

Dear Madam, Sir,

You have a healthy eye and want to change its appearance by changing its color. Your ophthalmologist offers a **FLAAK surgery** (Annular Aesthetic Keratopigmentation **with** Femtosecond Laser) with the use of pigment.

Very important preamble:

The natural color of the eye is given by the iris. Surgeries to change the color of the iris have known risks of potentially serious complications.

The change in eye color is just a formulation.

In reality it is only possible to change the color of a natural iris by photodisruption with a special **Laser**, but it has been learned over time that the risk of complications with this technique is so high that it is refused in France, moreover the only possible color is a bluish gray.

The exchange of the iris by an artificial iris is indeed possible but is only for very severely traumatized eyes in which a total reconstruction of the anterior segment is necessary (cornea, lens, iris). Indeed in a normal eye there is not enough space to introduce the artificial iris. A series of French patients operated on in Tunisia and Latin America could be analyzed in different French centers and published in 2020: out of 87 cases 80% of serious complications were noted leading to the removal of artificial irises, some eyes lost their vision.

The proposed solution is totally different, it is an artistic corneal tattooing process that allows you to modify the appearance of your look according to a range of colors from azure blue to dark brown through shades of green.

FLAAK, is a technique developed in collaboration with NEWCOLOR. The principle consists of a hydro-injection of biocompatible pigments (meeting the requirements of the French and European health authorities) into a tunnel created with a Femtosecond Laser inside the cornea. Thanks to the FLAAK technique, the distribution of the pigment throughout the tunnel is done in a few minutes, where the classic technique of manual keratopigmentation required a long dissection before distributing the pigment (or "painting" the inside of the tunnel). The effect obtained has analogies with that of widely used skin tattoos.

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With this FLAAK technique, the change in appearance is therefore created by masking the natural color of the iris.

**BEWARE OF THE REACTIONS OF YOUR ENTOURAGE, KERATOPIGMENTATION
IS MORE SURPRISING THAN CHANGING COLOR OR HAIRCUT**

**This sheet details the information concerning the operation that is proposed to you,
its results and risks.**

Why operate with annular keratopigmentation surgery?

The technique of annular keratopigmentation with a FEMTOSECOND LASER (FLAAK) has an excellent tolerance and a priori presents very little risk of serious complications. The technique uses the same surgical equipment and FEMTOSECOND LASER as the conventional myopia surgery commonly performed in the world (LASIK/SMILE).

The equipment necessary for laser annular keratopigmentation:

The laser: this is a **Femtosecond laser** commonly used in corneal surgeries.

Pigment: the pigments used are biocompatible and meet the requirements of the health authorities for intra-corneal use. No cases of intolerance or allergic reaction have been reported so far but this cannot be ruled out.

The annular keratopigmentation operation with a FEMTOSECOND LASER:

The procedure is performed while the patient is installed on his back in a surgical environment.

Hospitalization: the operation does not require hospitalization, it is performed on an outpatient basis.

Anesthesia: the operation is performed under local (topical) anesthesia by eye drops instillation.

Operative technique: it takes place in two stages:

1. Realization with a FEMTOSECOND LASER of a tunnel in the thickness of the cornea

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The femtosecond laser cuts a tunnel into the thickness of the cornea. It is then finalized and adjusted manually by the surgeon.

2. Instillation and distribution of the pigment in the tunnel

The surgeon injects the pigment necessary for the coloration of the cornea into the tunnel. The pigment is distributed in the most harmonious way possible by getting as close as possible to the simulation carried out preoperatively. The proposal is not contractual, it is not possible to achieve exactly the same rendering as the proposal but an approaching result.

On the periphery, a darker limbic crown is left without pigment, which has the effect of improving the aesthetic rendering.

Intraoperative incidents or difficulties:

They are rare and unpredictable.

The cutting of the corneal tunnel may be imperfect, altering the shape and/or transparency of the cornea as well as the distribution of the pigment.

The shape of the pupil may be slightly altered. The positioning of the laser can cause a shift in the position of the tunnel and give the impression of an offset or asymmetrical pupil.

The distribution of the pigment can give a different look to each eye.

In the event of a LASER failure, the intervention may be interrupted. This is most often an inconsequential inconvenience that will not prohibit a reprogramming of the surgery immediately or later.

The usual postoperative course:

In the vast majority of cases, the operated eye is little or no pain. The visual recovery is very fast and the result is immediately appreciable.

Local care is reduced to the instillation of eye drops.

After any eye surgery, wearing ultraviolet filtering lenses is recommended for about two months in case of sun exposure.

Regulations concerning the visual abilities of professions are continually being amended. It is therefore essential that you check yourself with the administrations concerned if a laser

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keratopigmentation intervention is accepted (army, police, gendarmerie, navy, firefighters, SNCF, air or road transport, etc ...).

Laser annular keratopigmentation leads to a change in physical appearance, so it is also mandatory to have your identity documents modified.

The limits of FEMTOSECOND LASER ANNULAR KERATOPIGMENTATION (FLAAK):

The results of this surgery are not necessarily definitive.

Indeed, pigmentation can sometimes diminish over time and lose its shine, hue or intensity.

In case of imperfect result, it may sometimes be necessary to perform a second intervention on the operated eye in order to obtain the desired appearance. This second intervention is called "reprocessing or retouching".

This technique is not completely reversible. It is possible to remove most of the pigment but not in its entirety. The use of a pigment similar to the initial hue of the eye may be necessary to get closer to the preoperative state.

The normal functioning of the iris is not changed, the central diameter of the tunnel being fixed, it is possible in case of high brightness that part of the iris is visible in the center. In low-light conditions, the fixed diameter of the colored ring can impair night vision.

This surgery can cause a change in vision, regardless of the initial visual defect. Laser refractive surgery can possibly be performed at least 4 months after FLAAK surgery.

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Complications of FEMTOSECOND LASER ANNULAR KERATOPIGMENTATION :

The desired result can never be perfectly guaranteed because it depends on the healing phenomena. Reprocessing is sometimes necessary a few months after surgery.

This operation is no exception to the general rule that there is no risk-free surgery. Severe complications are very rare but they may however require re-intervention and lead to a reduction in visual acuity even with correction, or even in the most extreme cases to the loss of the vision or the eye. This possibility is so exceptional that its frequency is impossible to assess.

These can include the following complications :

1. **Infection:** any surgical procedure presents an infectious risk even if it is extremely rare. Intensive antibiotic treatment accompanied by hospital monitoring is therefore essential
2. **Inflammation:** This is an inflammatory reaction of the cornea. This phenomenon is rare and can delay visual recovery. Treatment is usually based on the instillation of steroid-antibiotic eye drops but may exceptionally require surgical washing of the inflammatory zone.
3. **abnormal** scarring that can lead to clouding of the cornea: this phenomenon is rare and can delay visual recovery. The treatment will require eye drops instillations but may exceptionally require a new intervention.
4. **deformation of the cornea** (ectasia): this is a deformation of the cornea following the intervention. This complication is extremely rare (1 case in 700,000*) because it can be avoided thanks to a mandatory topographic analysis of the morphology of the cornea preoperatively. In the case of ectasia, a visual defect gradually worsening disturbs vision. Therapeutic management by surgical treatment may be considered.
5. **reduction of visual acuity:** very rare cases have already been noted, these are the possible consequences of another complication.

Other less severe consequences may occur, including:

subconjunctival hemorrhage: very banal, benign and disappearing without treatment in a few days;

perception of luminous halos: quite frequent during the first weeks but not very disturbing, these halos around bright lights fade little by little. Sometimes the perception of halos can be definitive and make driving at night uncomfortable.

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dry eye can be seen in 23% of cases in laser corneal surgery while moderate or severe dryness accounts for only 3% each. Several treatment axes are possible depending on the type of drought. Most often the use of wetting eye drops is sufficient. This is usually transient. In more severe forms, it is possible to use ointments, meatus obturators or restimulation treatments of the eyelids (Meibomian glands). In rare cases, visual recovery may be delayed by several months.

a tendency to **glare**: a high sensitivity to light is common during the first hours after the procedure but disappears quickly. Some patients may experience this sensitivity for several days.

impaired night vision: In low light conditions, the fixed diameter of the tunnel may slightly impair night vision.

split vision or distortion of images: rare and very transient. Split perception is most often related to postoperative dry eye.

lowering of the upper eyelid,

reduction in uncorrected visual acuity: in rare cases, a slight change in the initial visual defect was noted.

fluctuating vision: frequent during the first days, this fluctuation gradually decreases at the same time as dry eye.

following local anesthesia of the eye , a decrease in eye sensitivity is theoretically possible but has never been identified.

These transient or permanent complications may sometimes require medical or surgical treatment.

FEMTOSECOND LASER ANNULAR KERATOPIGMENTATION and refractive surgery

For patients who also wish to benefit from refractive surgery, it is **IMPERATIVE** to inform the surgeon **BEFORE** keratopigmentation surgery. Depending on the visual defect, refractive surgery is not necessarily feasible, it is only a few months after keratopigmentation surgery that the surgeon will validate its feasibility. It is best to perform refractive surgery at least 4 months **AFTER** keratopigmentation.

For patients who have already undergone refractive surgery, it is **IMPERATIVE** to inform the surgeon **BEFORE** the surgery. A keratopigmentation operation is generally possible but it is only during the procedure that the surgeon will validate the feasibility, depending on the progress of the laser bag creation step. If at the end of this step the surgeon judges that keratopigmentation is not possible, the intervention will be stopped.

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Cataract and treatment of retinal conditions

Due to the pupillary area reduced to 5 mm, the technique has been criticized for making cataract surgery or access to the fundus difficult. It is true that these gestures are a little more complicated than usual, but you should also know that modern techniques today make it possible to perform these gestures without major difficulties in specialized centers.

I am at your disposal to answer any supplementary questions you may have. (email : iris@dr-georges-baikoff.com)

The regulations require the physician to prove that he or she has provided the information to the patient. You are therefore asked to sign this document, a copy of which will be kept by your doctor and the Clinic where you will be operated.

I, the undersigned, "....." acknowledge that the nature of the intervention, as well as its risks, were explained to me in terms that I understood, and that all the questions I asked were satisfactorily answered.

I received information about the costs of surgery.

I had sufficient time to reflect and: (cross out any unnecessary mentions)

I give my consent

- | | | |
|--|---------------------|----|
| ✓ for the realization of the act proposed to me: | YES | NO |
| ✓ to operate both eyes at the same time: | YES | NO |
| ✓ for the anonymous use of photos of your eyes : | YES | NO |
| ✓ for surgical retouching if necessary | YES | NO |
| ✓ for color | (to be specified) | |

Date and Signature preceded by the mention: "I understood the benefits and risks of this surgery, they were explained to me orally by the surgeon in terms that I understood and the questions I asked were satisfactorily answered."

*Made in triplicate in NICE on
signature*

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