E-Eye

# CONSENT FORM

Patient information


ESW Vision

PREMIER FABRICANT FRANÇAIS DE HAUTES TECHNOLOGIES DE LUMIÈRE

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Dear patient,

You are about to enjoy the benefits of an innovative treatment for meibomian blepharitis (dry-eye disease) using an exceptional device: E-EYE.

This brochure contains information which is intended:

- To inform you of the technique applied for the stimulation of the meibomian glands using flash lamp technology.

- To confirm the absence of any contraindication associated with the application of this technique.

If all the conditions are fulfilled, and subject to your informed consent, your practitioner will be able to administer this treatment in complete safety and with optimum effectiveness.

I trust that you will be completely satisfied with your treatment and that you will share your experience with your relatives.

With best regards,

Yves Vincent Brottier
Inventor of E-EYE and founder of ESW Vision.

# THE PATHOLOGY

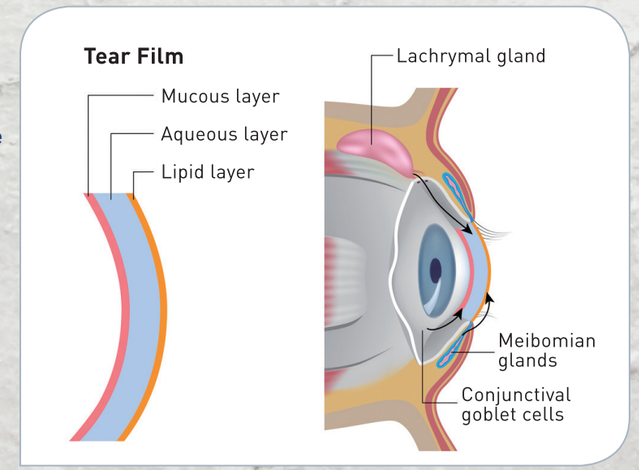
Dry-Eye syndrome is a common pathology affecting between 5 and 15% of the population (up to 30% of certain population groups), with a prevalence which is linked to age and modern living conditions.

In general, ocular dryness is associated with an impairment of the lachrymal film, either in the form of the insufficient production of tears or the excessive evaporation of the latter (evaporative form). The evaporative form of this pathology accounts for 80% of patients affected by ocular dryness. In this case, the condition is mainly attributable to a deficiency in the outer lipid layer of the lachrymal film, which is secreted by the meibomian glands, resulting in the excessive evaporation of tears, instability of the lachrymal film and an inflammatory response in the conjunctiva.

The results is an increasing in vision disorders, with burning sensations or the feeling of a foreign body in the eye.
If the process accelerates, the discomfort becomes permanent, resulting in the paradoxical secretion of tears.
Anatomical changes may occur, including atrophy of the meibomian glands orifices, punctuated by episodes of infection: sties, meibomian cysts, secondary conjunctival infections and, in the most severe cases, micro-ulceration of the corneal epithelium.

**The lacrymal film, necessary to the eye function, is made of 3 layers:**

- The mucous layer, in contact with the ocular globe, secreted by the conjunctival mucous cells.
- The aqueous layer, secreted by lacrymal glands.
- The lidip layer, secreted by meibomian glands.







# AN INNOVATIVE AND SAFE TREATMENT

E•Eye, designed and manufactured in France by E-Swin company, France's leading manufacturer of high-tech light equipment, has been medically certified by an independent international organization.

E•Eye is a dedicated device for the treatment of ocular dryness in its evaporative form. Accordingly, it will be effective in 80% of patients affected by dry-eye disease.

E•Eye device generates polychromatic pulsed light using a new technology: IRPL®(Intense Regulated Pulsed Light). It is capable of generating sequences of uniform and perfectly calibrated light pulses.

E•Eye emits "cold light", which stimulates the meibomian glands in complete safety. In response to this stimulation, the glands resume secretion. The normal structure of the lachrymal film is restored, and symptoms associated with ocular dryness will disappear.

This treatment is non-invasive, entirely painless and completely harmless to the eyeball.

ISO 13485
Made by E-Swin

Medical certification

New IRPL® technology


# THE PROTOCOL

The effectiveness of treatment will depend upon the application of a specific protocol. This protocol involves 3 sessions, administered over the following schedule:

**Day 0/day 15/day 45 (day 75 optional)**

Additional sessions may be scheduled for the consolidation and maintenance of clinical benefits achieved.

## BEFORE THE SESSION:

- After having carefully read the document in full 1, complete and sign the present document 2.
- Ensure that you have no cosmetic products on your skin 3.

## DURING THE SESSION:

- Treatment takes just a few minutes.
- You will be comfortably seated in a treatment-chair, preferably of the reclining type.
- Position the Eye mask protective shells on your eyes 4.
- A specific hydrogel is applied to the cheek-bone and right temporal area 5.
- The practitioner administers a series of 5 flashes 6, starting from the inner canthus, up to the temporal area 7.
- The same process is repeated under the other eye 8.
- The practitioner removes the gel and rinses your skin with water 9.

## AFTER THE SESSION:

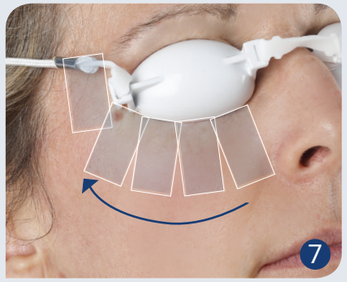
- No other treatment should be applied to the zones which have received flash treatment-throughout the entire cycle of sessions.
- Sunscreen should be applied to the zones which have received flash treatment, in case of exposure to UV.
- Make your appointment for the next session.
- Conventional ocular hygiene procedures may be continued.

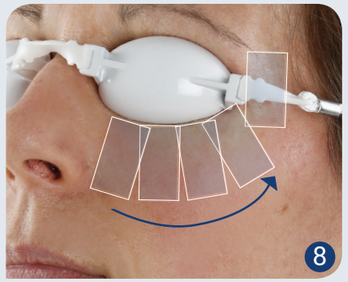










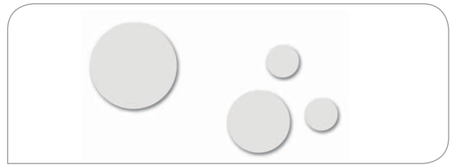

## FOR YOUR SAFETY

Before you receive treatment using E-Eye, the following information should be read carefully:

- Operation of E-Eye is a medical procedure, which must be undertaken by ophthalmological specialists only.
- Your practitioner will provide you a pair of Eye Mask shells. These are designed to protect your eyes during treatment.
- Moles must be concealed beforehand, if they are located within the zone which is to receive flash treatment. They are covered using the self-adhesive Patches.
- It is essential that sunscreen should be applied to zones which have received flash treatment for at least fifteen days, in case of exposure to UV (natural or artificial) following a treatment session.
- Short-term redness may occur after a treatment session.This is a normal occurrence, and should not persist overtime (no more than a few hours).
- In certain cases, more pronounced redness of the type associated with superficial burns may be observed.

### EYE MASK

The eye mask shells must be worn by the patient under treatment. They must be correctly adjusted. These shells protect the eyes of the patient.



### PATCHES

These self-adhesive patches are used to mask small areas which are to be excluded from flash treatment (e.g. moles). They must be positioned before the application of the gel. It will then be possible to apply flash treatment to the entire zone, without worrying about the need to avoid moles. The patches are removed at the end of the session.

### STOP

The plate stop is made from a material that is resistant to flashes. It enables you to cover an area on which the flash must not be used (e.g. tattoo).

# RESULTS

## IMMEDIATE IMPROVEMENT

Stimulation by E-Eye induces the restoration of the normal function of the meibomian glands. The effects achieved appear very rapidly after each session, and their persistence over time increases with the number of sessions conducted.

## MEASURABLE EFFECTIVENESS

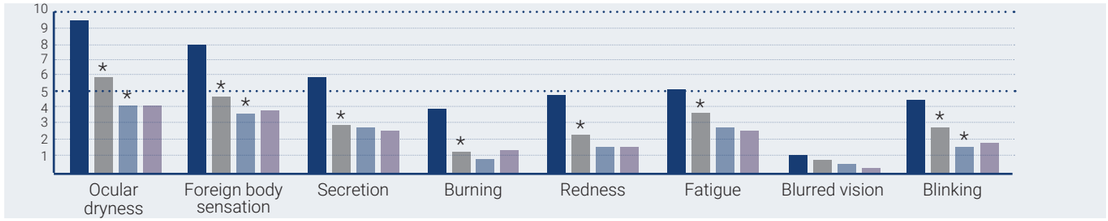
Clinical studies have been conducted in France, New Zealand and China. These studies have shown:

- A considerable improvement in the symptoms perceived by patients.
- A correlation between this perception and clinical measurements executed.

## CLINICAL STUDIES

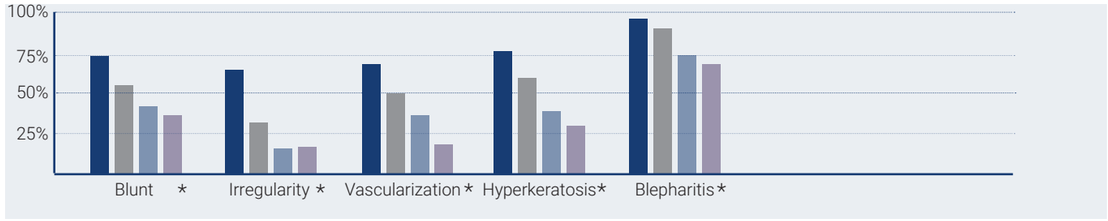
***Perceptions of patients, rated from 1 to 10.***

* Significant margin of improvement.




***Clinical percentage measurements.***

* Significant margin of improvement.



# SPECIFIC CASES

A near-consistent level of effectiveness is achieved for all forms of dysfunction of the meibomian glands. Conversely, given the inherent nature of this treatment, this level of effectiveness will not be achieved in forms of the condition associated with an isolated impairment of the aqueous phase or mucous phase, or in the presence of an associated secondary infection which will require treatment beforehand.

Patients suffering from a more severe pathology, classified as grade 3 or 4, will need to receive simultaneous treatment on the lower and upper eyelids, in which case the eyeball will be protected by a opaque shell which is in contact with the cornea.  Here again, improvements by one or two grades may be achieved.

Detachable part to be completed by the patient before each session.

E-Eye

# CONSENT FORM

Having read the previous document, I hereby give my consent to the administration of sessions for the stimulation of the meibomian glands by pulsed light (flash lamp) technology using E-Eye device.

**Name:**

**Last name:**

**Date of birth:**

**Date and signature**
(signature of at least one parent, for children of minority age)

# COMPATIBILITY CHECKLIST

E-Eye must not be used on persons who are unsuitable for pulsed light treatment.
Any doubt concerning a pathology and/or a treatment in progress should be indicated prior to the session.
If your state of health changes between two sessions, please inform your practitioner.

Please complete the following questionnaire:

| | Session 1 Date: | | Session 2 Date: | | Session 3 Date: | | Session 4 (optional) Date: | |
|---|---|---|---|---|---|---|---|---|
| | yes | no | yes | no | yes | no | yes | no |
| Are you pregnant? | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| Do you have history of allergic reaction to sunlight? | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| Have you undergone high-pressure UV treatement within the last ten days? | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| Have you suffered facial sunburn which has healed within the last month? | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| Do you have a history of facial dermatological pathologies? | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| Do you have any infections in the area which is to receive flash treatment? | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| Are you receiving any photo-sensitizing medical treatment? | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| Do you have any tattoos or permanent make-up in the area which is to receive flash treatment? | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| Are you taking any food supplements which promote tanning? | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| Are you using any self-tanning product at present? | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| Do you have dark skin (phototype VI)? | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| Are you diabetic? | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| Are you epileptic? | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| Do you wear a pacemaker? | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |

ESW Vision

Ref. M029GB001C08A

# E-Eye: a French innovation


*Your E-Eye practitioner:*

www.esw-vision.com

ESW Vision

Ref. . M029GB001C08A

E-EYE, designed and manufactured by E-Swin (France), is a class IIb regulated health care device carrying the CE mark (issued by the organization CE 0197). This device is used for the treatment of meibomian blepharitis. Conditions for use described in these instructions must be observed.