Dear Sir or Madame,

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

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, you can perform this session in complete safety and with optimum effectiveness.

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

With best regards,

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

Dry-Eye syndrome is a common condition 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 lacrimal film, either in the form of the insufficient production of tears or the excessive evaporation of the latter (evaporative form). The evaporative form accounts 80% people affected by ocular dryness. It is due to an insufficiency of the lipid layer of the tear film, secreted by the Meibomian glands. Excessive evaporation of the tears; instability of the tear film and inflammation of the conjunctiva are observed.

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 lacrimal 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 lacrimal glands.
- The lipid layer, secreted by meibomian glands.

Dry-Eye is a dedicated to the management of ocular dryness in its evaporative form. Accordingly, it will be effective in 80% of affected people. 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 lacrimal film is restored, and symptoms associated with ocular dryness will disappear. This technology is non-invasive, entirely painless and completely harmless to the eyeball.

AN INNOVATIVE AND SAFE TECHNOLOGY
THE PROTOCOL

The effectiveness of the session 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:
• The session just takes five 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 cheekbone and right temporal area 5.
• A series of five flashes will be administered 6, starting from the inner canthus, up to the temporal area 7.
• The same process is repeated under the other eye 8.
• The gel will be removed and your skin will be rinsed with water 9.

AFTER THE SESSION:
• No other procedure should be implemented to the areas that have been flashed throughout the entire circle 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.
RESULTS

IMMEDIATE IMPROVEMENT

Stimulation by $\text{E-Ey}$ 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.

FOR YOUR SAFETY

Before your $\text{E-Ey}$ session, the following information should be read carefully:

- The use of $\text{E-Ey}$ must be practiced by authorized persons only.
- A pair of $\text{Ey Mask}$ shells that are designed to protect your eyes will be provided.
- Mole must be concealed beforehand, if they are located within flash zone. They are covered using the self-adhesive patches.
- It is essential that sunscreen should be applied to zones for at least fifteen days, in case of exposure to UV (natural or artificial) following a session.
- Short-term redness may occur after a 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.

The $\text{Ey Mask}$ shells must be worn during the session. They must be correctly adjusted. The shells protect the eyes.

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

The plate $\text{Stop}$ 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).
A near-consistent level of effectiveness is achieved for all forms of dysfunction of the meibomian glands. Conversely, given the inherent nature of this procedure, 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.

Patients suffering from a more severe form, classified as grade 3 or 4, will sometimes require a complementary intervention on the lower and upper eyelids. Here again, improvements by one or two grades may be achieved.
If your answer is “yes” to one of the following criteria, you are entitled to ask your doctor, if an session is possible for you.

<table>
<thead>
<tr>
<th>Session 1</th>
<th>Session 2</th>
<th>Session 3</th>
<th>Session 4 (optional)</th>
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<tr>
<td>yes</td>
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Unusual-looking skin lesions

You are receiving any photo-sensitizing medical treatment

COMPATIBILITY CHECKLIST

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

Please complete the following questionnaire before each session:

If your answer is “yes” to one of the following criteria, you cannot undergo an E•Eye session.

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Pregnant women

Injured, burned or infected skin

Sunburned skin which has healed within the last month

Skin that has been exposed to high-pressure UV within the last ten days

Use of self-tanning products (creams, dietary supplements) within the last two weeks

Epilepsy

Porphyria cutanea tarda

Wearing a pacemaker or cardiac defibrillator

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History of allergic reaction to sunlight

Unusual-looking skin lesions

You are receiving any photo-sensitizing medical treatment

Ref. M529GB001C08A
E•Eye: a French innovation

Your Dry Eye Center:

www.esw-vision.com

Ref. M529GB001C08A

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.