



Consent Form

Patient Information
Dry Eye Treatment

Dry Eye Management
One step ahead.



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 Consent form



Dear patient,

You are about to enjoy the benefits of an innovative treatment for meibomian blepharitis (dry-eye disease) using the highly effective intense regulated pulsed light technology (IRPL®) by 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.

We trust that you will be completely satisfied with your treatment and that you will share your experience with your family and friends.

With best regards,

Your
E•EYE Customer Service

Follow us on Social Media (Facebook, LinkedIn, Instagram) and discover more on www.esw-vision.com.

Pathology of Dry Eye

Dry Eye Disease 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 lacrimal film, either in the form of insufficient tear production or excessive tear evaporation (evaporative form). The evaporative form of this pathology accounts for 80% of patients affected by ocular dryness. In this case, the condition is mainly attributed to a deficiency in the outer lipid layer of the tear film, which is secreted by the meibomian glands. This in turn results in the excessive evaporation of tears, instability of the tear film

and an inflammatory response in the outermost layer of the eye surface.

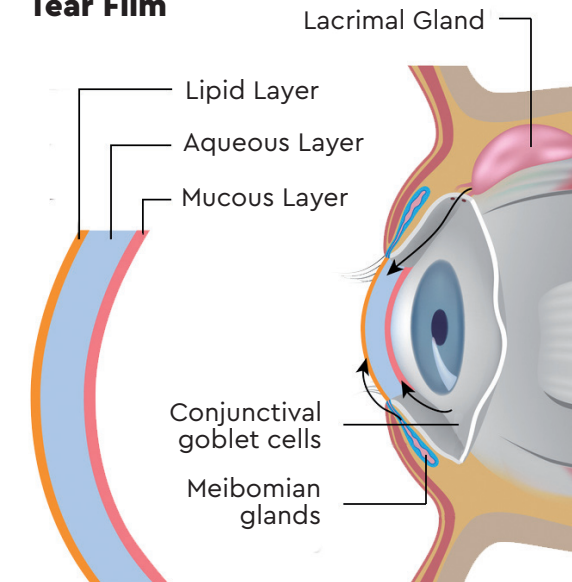
The results are increased vision disorders, with burning sensations or the feeling of a foreign body in the eye. If the process accelerates, the discomfort becomes permanent, resulting in excessive tearing. As such people with Dry Eye Disease can paradoxically have over-production of tears.

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 **tear film**, necessary for eye function, is made of 3 layers:

- The mucous layer, in contact with the globe of the eye, secreted by the conjunctival mucous cells.
- The aqueous layer, secreted by the lacrimal glands.
- The lipid layer, secreted by the meibomian glands.

Tear Film





Innovative and safe technology

E•Eye, designed and manufactured in France by E-SWIN, a leading manufacturer of high-tech medical equipment, has been specially certified for the treatment of Meibomian gland dysfunction (Dry Eye Disease).

E•Eye is a device dedicated for the treatment of eye dryness in its evaporative form. 80% of Dry Eye cases are known to be evaporative.

E•Eye 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 of the tear film. The normal structure of the tear film is restored, and symptoms associated with ocular dryness will disappear.

This technology is non-invasive, entirely painless and completely harmless to the eye.



Made by E-SWIN



Medical certification



Patented technology

Treatment 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 the skin area below the eye (flash zone). ③

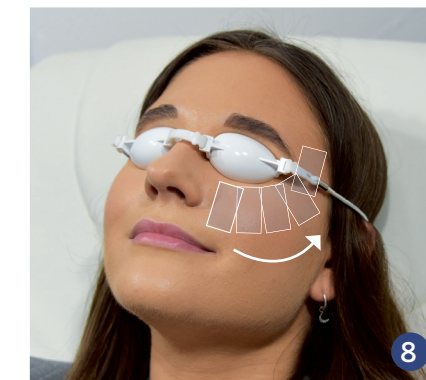
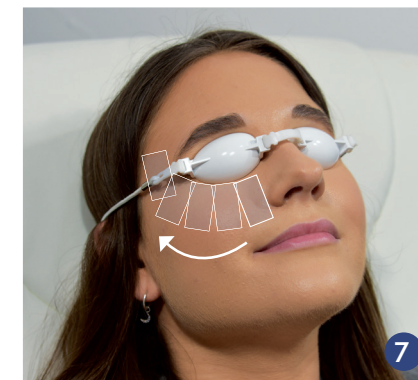
During the session

- The session takes just five minutes.
- You will be comfortably seated in a treatment chair, preferably of the reclining types.
- Position the **eye mask** protective shells on your eyes. ④

- A specific hydrogel is applied to the cheekbone and right temporal area. ⑤
- The practitioner administers a series of 5 flashes per eye 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 circle of sessions.
- The treated zone should be covered with sunglasses and sunscreen should be applied to the area flashed, in case of exposure to UV.
- Make your appointment for the next session.
- Conventional ocular hygiene procedures can be continued.



For your safety

Before you receive your **E•Eye** treatment, the following information should be read carefully:

- Operation of **E•Eye** is a medical procedure, which must be undertaken by eye specialists only.
- Your practitioner will provide you with a pair of **eye mask** shells. These are designed to protect your eyes during treatment.
- Moles must be covered before treatment, if they are in the area to be treated. They are covered using the self-adhesive **patches**.

- It is essential that sunscreen is applied to zones which have received flash treatment for at least fifteen days, in case of exposure to UV (natural or artificial) following a 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 obvious redness associated with superficial burns may be observed.



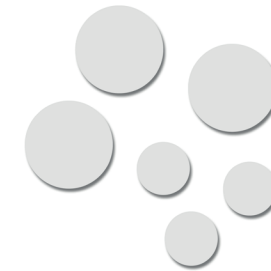
eye mask

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



stop

The plate **stop** is made from a flash-resistant material. It is used to mask an area where flash treatment must not be applied (e.g. tattoos) and protect beard or eye brows.



patches

These self-adhesive **patches** are used to mask small areas where flash treatment should not be applied (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 zone, regardless of the presence of beauty spots. The **patches** are removed at the end of the session.

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 Europe, New Zealand and China. These studies have shown:

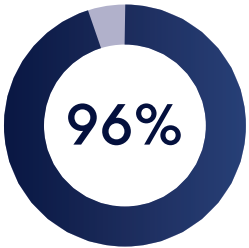
- A considerable improvement in the symptoms perceived by patients.
- A correlation between this perception and clinical measurements executed.



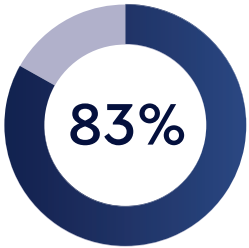
Long-lasting Results

The treatment with **E•Eye** provides long-lasting results with significant improvement of Dry Eye symptoms for minimum six months. In 60% of cases the effect last more than

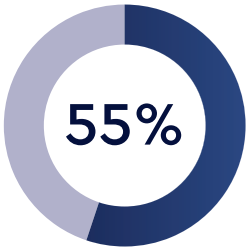
one year up to three years. A regular single maintenance session is recommended in case of need, usually once a year.



recommend the treatment



confirm improvements of symptoms



stop using eye-drops after the treatment

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 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.



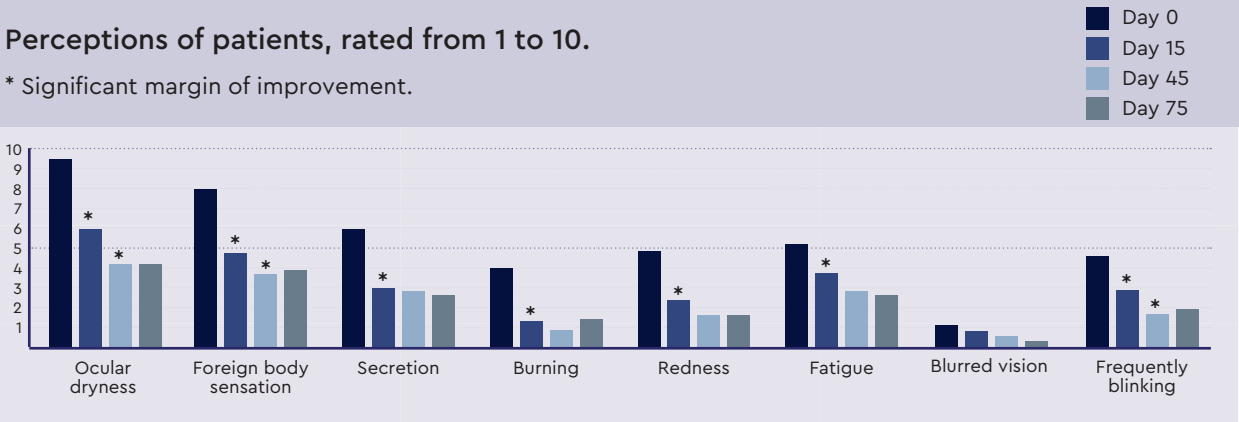
Patients suffering from a more severe pathology, classified as grade 3 or 4, will need to receive simultaneous treatment on the lower and upper eyelid.

In this case the eyeball will be protected by an opaque shell which is in contact with the cornea. Here again, improvements by one or two grades may be achieved.

Clinical studies

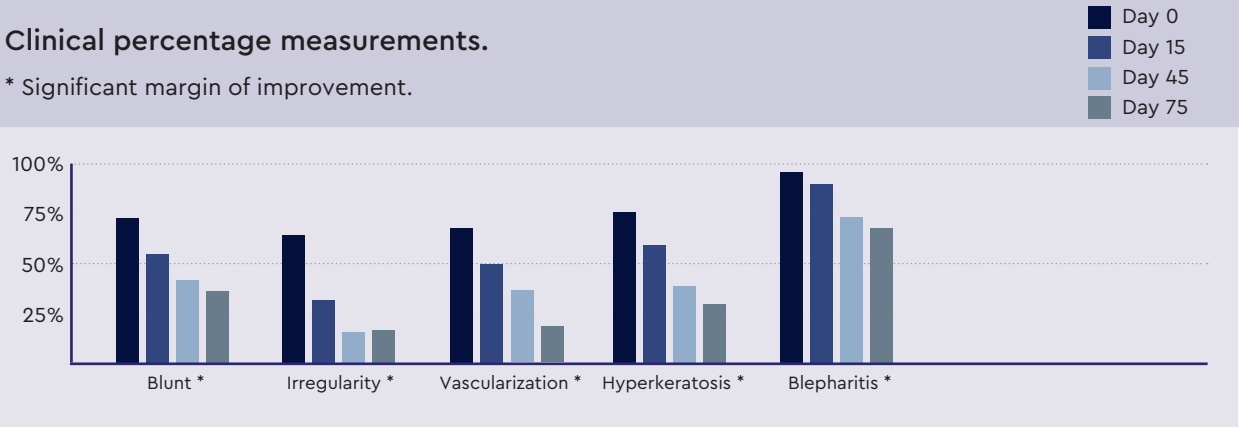
Perceptions of patients, rated from 1 to 10.

* Significant margin of improvement.



Clinical percentage measurements.

* Significant margin of improvement.



Source: Clinical Study. Peking Third University Hospital (2016). www.esw-vision.com/press-studies



Dry Eye Treatment



Your **E-EYE** specialist:

www.esw-vision.com

ESW vision
part of group E-SWIN