

LipiFlow treatment Informed consent document

This is a legal document. You need to sign it to give Optical Express written permission to treat you. It is important that you bring this document with you on the day of your treatment. If you do not understand anything in this document, please ask for more information.

Patient's name:

Patient's central ID:

Eye (or eyes) to be treated: Right eye Left eye

Informed consent

Background information

We want to make sure you are fully aware of all the risks, benefits and alternative treatment options to LipiFlow treatment. It is important for you to understand that there are risks with any type of medical treatment.

This informed consent document, along with the information you received at your pre-treatment consultation, is designed to make sure that you can fully consider the risks and benefits of LipiFlow treatment and make an informed decision on whether or not to go ahead with the treatment.

We are giving you all of this information ahead of your treatment so that you have enough time to consider all aspects of LipiFlow treatment.

The information in this document applies to LipiFlow by TearScience.

Please initial each point below to confirm that you understand the information.

Our clinical care team will decide whether or not you are suitable for treatment after carrying out a detailed examination and discussing the treatment with you. The decision will be based on your individual needs.

Please tell your GP that you are considering LipiFlow treatment, as they can give you independent medical advice.

If you have any questions about your treatment, you should ask our clinical care team before you sign this document.

The purpose of this part of the document is to confirm that you have understood all of the information you have received and to keep a record of your decision to go ahead with the treatment.

I have read and understood the points discussed in this section.

Write your initials here:

Before your treatment you must tell your clinical care team if any of the following applies.

- You have any eye problems, including amblyopia (lazy eye), strabismus (muscle imbalance which can cause double vision), herpes infection of the eye or eyelid, severe dry eyes or any recurrent (keeps coming back), residual (an after-effect of another condition) or active eye conditions such as recurrent corneal erosions.
- You have had chronic recurrent eye inflammation within the three months before your treatment.

- You have a problem with your eyelid or eye surface.
- You are a carrier of methicillin-resistant staphylococcus aureus (MRSA) or have been exposed to MRSA.
- You have any general health conditions, including back problems or claustrophobia or other psychological conditions (including a history of anxiety or depression).
- You have any implants, including a cardiac pacemaker, insulin implant or other electronic implanted device.
- You are allergic to any medications or latex.
- You are taking or using any medications, eye drops or supplements, including vitamins or nutritional supplements you have bought 'over the counter' without a prescription.
- You have had an eye injury or eye surgery in the past.
- You are pregnant, breastfeeding or could possibly be pregnant.

It is vital that you have fully and accurately filled in the health and lifestyle questionnaire you received at your pre-treatment consultation before you are scheduled for treatment.

The information you provide in the health and lifestyle questionnaire is extremely important and will help your clinical care team decide whether you are suitable for treatment.

I have read and understood this section and have met all the conditions.

Write your initials here:

General information

The surface of the eye is covered in a lining of tears called the tear film.

The tear film is made up of three layers:

- a lipid (oil) layer which lubricates the eye and aims to prevent tears from evaporating;
- an aqueous (water) layer, which nourishes and protects the eye surface; and
- a mucin layer, which sticks to the eye.

Since the tear film is exposed directly to the air, the protective lipid layer is essential to maintaining a healthy tear film on the eye.

When the protective lipid layer of the tear film is not good enough, the eye surface can become irritated and dry eye symptoms can develop.

Evaporative dry eye is a disease that results from not having enough lipid in the tear film to protect the eye.

Evaporative dry eye is most often caused by a blockage or obstruction of the eyelid glands, called the meibomian glands, which produce the lipid layer of the tear film.

Meibomian gland dysfunction (MGD) is a disease that results from plugs of meibomian material forming inside the meibomian glands, which obstruct the gland openings and limit the amount of lipid produced by the glands into the tears.

I understand the above and all of my questions have been answered.

Write your initials here:

What is the LipiFlow system?

The LipiFlow system is a medical device which eye care specialists use to apply heat and pressure to the eyelids to allow the lipids from the blocked eyelid glands to flow into the tear film.

Your eye care specialist will decide if the LipiFlow system is an appropriate treatment for you based on a detailed examination of your eye health, including checking for blocked glands and associated dry eye symptoms.

I understand the above and all of my questions have been answered.

Write your initials here:

The LipiFlow system is used to apply localised heat and pressure therapy in adult patients with chronic cystic conditions of the eyelids, including meibomian gland dysfunction (MGD), also known as evaporative dry eye or lipid deficiency dry eye.

I understand the above and all of my questions have been answered.

Write your initials here:

There is a significant amount of medical evidence which shows that LipiFlow treatment is safe and effective.

However, it is not possible to absolutely guarantee that LipiFlow treatment will improve your condition or that you will not need other types of treatment to improve your condition.

I understand the above and all of my questions have been answered.

Write your initials here:

LipiFlow is a continual treatment and most people need further treatment every 12 to 18 months.

I understand that further treatment is necessary and all my questions have been answered.

Write your initials here:

After having LipiFlow treatment, it is possible that you may develop eye conditions that are unrelated to, and not caused by or prevented by LipiFlow treatment, such as vitreous opacities, cataracts, glaucoma, age-related macular degeneration and other conditions of the retina.

I may need more surgery to treat these conditions.

I understand that LipiFlow treatment does not increase or reduce my chance of developing these eye conditions in the future, or other conditions where there is no known cause.

Write your initials here:

Precautions regarding LipiFlow treatment

The disposable eyepiece used for treatment may not fit all eyes, such as eyes with small eyelids.

LipiFlow treatment is not recommended in patients with the following conditions. Ask your doctor if you have any of the following conditions.

- Moderate to severe allergy in the eye.
- Severe eyelid inflammation. If you have severe eyelid inflammation you should have medical treatment to treat the inflammation before having LipiFlow treatment.

LipiFlow may not be as effective as usual if you have one of these conditions because they may cause eye symptoms which are not related to the meibomian glands. The safety and effectiveness of the device have not been studied in patients with these conditions.

The treatment may also loosen any punctal plugs you have had inserted into your tear ducts to prevent drainage. This may make your dry eye symptoms worse.

I understand the above and all of my questions have been answered.

Write your initials here:

Possible risks and complications of LipiFlow treatment

There is no guarantee that you will receive any medical benefit as a result of the LipiFlow treatment.

It is possible that your dry eye symptoms and blocked eyelid glands will improve as a result of treatment. It is also possible that your condition will remain the same or worsen after treatment.

Certain diseases and general health medications can contribute to symptoms of dry eye.

Possible negative effects that may develop as a result of the procedure include:

- eyelid or eye pain, which may mean you have to discontinue the treatment;
- irritation or inflammation of the eyelid (for example, eyelid swelling, itching or a sty);
- irritation or inflammation of the eye surface (for example, scratch on the eye surface, swelling of the eye surface or eye redness); and
- eye symptoms (for example, burning, stinging, tearing, itching, discharge, redness, the feeling of something in the eye, visual disturbance, sensitivity to light).

Possible serious negative effects may include:

- heat-related injury to the eyelid or eye;
- physical injury to the eyelid caused

by the pressure applied; and

- infection of the eye surface.

The LipiFlow treatment may also involve risks that cannot be predicted.

There is always the possibility that you may have a negative effect or problem that is currently unknown and unexpected.

You should discuss with your clinical care team any questions or concerns you might have. If you experience any problems during the treatment, it is important that you tell your clinical care team immediately.

It is extremely important to take any medications you are given and follow any aftercare advice after your treatment.

I understand the above and all of my questions have been answered.

Write your initials here:

Other complications

It is impossible to list every possible complication.

We have not told you about risks and complications that are considered to be unforeseeable or extremely rare, or which have not previously been reported.

Also, there may be long-term effects that we do not yet know about or cannot expect at the current time.

I understand all of the information provided about risks and complications.

All of my questions have been answered.

Write your initials here:

To achieve the best result and reduce the risks, I agree to follow the aftercare routine described in the information documents.

Write your initials here:

Alternatives to LipiFlow treatment

Possible alternative treatments for MGD and evaporative dry eye include:

- your doctor applying pressure to the eyelid glands by hand;
- warm compress therapy and eyelid hygiene using scrubs or massage;
- prescription medications such as eyedrops;
- over-the-counter tear replacements and lubricants for dry eye;
- punctal plugs made of silicone or collagen inserted in the tear ducts; and
- cauterization (sealing) of the opening of the tear duct in the eye.

You have received this document because we have recommended LipiFlow treatment as the best procedure to meet the goals you have identified during your pre-treatment consultation.

If you would like more information about other treatment options, please ask us.

I understand that there are alternatives to LipiFlow treatment.

I understand that LipiFlow treatment is an elective procedure and I have chosen to go ahead with this procedure.

Write your initials here:

Patient consent

Your clinical team will help you with the choices in this section.

I give my fully informed consent to having the following treatment. (Tick the appropriate box.)

I choose to have the following treatment:

LipiFlow system treatment
Right eye Left eye

Write your initials here:

Use of medical information

I give permission for you to use information relating to my treatment to help you provide my treatment, review my treatment, give me advice about additional treatment, carry out any additional treatment, and manage your business properly, for example to allow you to keep accurate records and for quality-control purposes.

Write your initials here:

I give permission for you to use information relating to my treatment for research purposes, for statistical analysis, in connection with academic and scientific papers, presentations and other publications, and for marketing purposes.

I understand that the information relating to my treatment will not reveal my identity.

Write your initials here:

Patient declaration

We advise you to take enough time to carefully and thoroughly read and understand the information in this document, and the other information you receive during your pre-treatment consultation.

If you have not read or understood all of this information, please let us know and do not go ahead with the treatment.

At my consultation my optometrist discussed the risks, benefits and alternatives to LipiFlow treatment with me.

Write your initials here:

I received my LipiFlow treatment terms and conditions and informed consent documents at the time of my consultation.

Write your initials here:

I received my LipiFlow treatment terms and

conditions and informed consent documents at least 24 hours before my treatment.

Write your initials here:

I confirm that I have taken enough time to carefully and thoroughly read and understand the information in this document and the other information I received during my pre-treatment consultation.

Write your initials here:

I confirm that I have not been placed under any pressure and I do not feel obliged to have the treatment.

I understand that the decision whether to go ahead with treatment is mine alone, and should be based on the information I have received in this document and during my pre-treatment consultation.

Write your initials here:

I confirm that all my questions have been answered, and I am satisfied with the answers.

Write your initials here:

I understand that LipiFlow treatment is an elective procedure (which means that I can choose whether or not to have this procedure).

I understand that there are other ways to treat my condition.

The risks and benefits of treatment have been thoroughly explained to me.

Write your initials here:

I give my consent to go ahead with treatment.

Write your initials here:

Confirmation of declaration

Please confirm you want to go ahead with the treatment by writing the following statement in the box below.

‘Having considered the information I received at my pre-treatment consultation and the information in this document, and discussed the risks, side effects, possible outcomes and benefits of treatment with my clinical care team, I am happy to go ahead with the treatment. I understand that I am under no obligation to do so.’

Your signature:

Your full name (print):

Your date of birth:

Date of your pre-treatment consultation:

Date of your signature:

Witness declaration

Witness's signature:

Witness's full name (print):

Witness's date of birth:

Date of witness's signature:

Clinician declaration

I have discussed the risks, benefits and alternatives to LipiFlow treatment with the patient, and asked the patient whether they feel pressured or obliged to have the treatment for any reason.

I am satisfied that the patient understands the meaning of the technical terms in this document, the nature and purpose of the treatment and the risks and possible complications that are described in this document, and that they accept these risks and are voluntarily (and without feeling pressure or obligation) choosing to have LipiFlow treatment.

I agree to accept this patient on the above terms and provide the treatment as set out in this document.

Clinician's signature:

Clinician's full name (print):

Date of clinician's signature:

Clinician's status (please tick as appropriate):

Employee of Optical Express Independent practitioner

Date of clinician's signature: