Informed Consent Form

Assessment of Clinical and Refractive Outcomes of the Use of a Femtosecond to Treat the Symptoms of Presbyopia in a Patient with Implanted Mono focal IOLs

Protocol number: PL-RIS01
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Sponsor:
Perfect Lens LLC
17785 Sky Park Circle, Suite B
Irvine, CA 92614

INFORMATION SHEET AND CONSENT FORM

TITLE:	Assessment of Clinical and Refractive Outcomes of the Use of a Femtosecond to Treat the Symptoms of Presbyopia in a Patient with Implanted Mono focal IOLs
PROTOCOL NO.:	PL-RIS01
SPONSOR:	Perfect Lens LLC, 17785 Sky Park Circle , Suite B, Irvine , CA 92614
EXAMINING DOCTOR:	MUDr. Pavel Stodůlka, Ph.D., FEBOS-CR
CENTER:	Gemini eye clinic, U Gemini 360, 760 01 Zlín

You have been invited to participate in a clinical study conducted by Gemini Eye Clinic. Approximately 12 patients will participate in this study. The study is initiated, organized and financed by the sponsor Perfect Lens, based in the US. Before you decide to take part in this study, it is important that you understand why this research is being done and what it will involve. Please take the time to read this document carefully. If you want, discuss it with family or loved ones. Ask your doctor about anything that is not clear to you in this document or if you need more information.

WHAT IS THE PURPOSE OF THIS STUDY?

You can participate in this research study because you have an implanted monofocal intraocular lens that provides you with good distance vision. As part of this study, it is possible to modify this type by applying a laser, so that it creates optical properties in the intraocular lens, with the help of which you can see even up close. Similar optical properties are also found in premium so-called multifocal intraocular lenses.

The application to change the intraocular lens inside the eye uses a low-energy femtosecond laser beam to create a focus for near vision while maintaining a focus for distance vision. Exposure of the intraocular lens to the laser beam creates chemical processes that attract water molecules and thereby change the refractive properties of the treated area.

The aim of the study is to verify the safety and effectiveness of this procedure in terms of improving near vision and preserving distance vision.

HOW LONG DOES THE STUDY TAKE?

The expected duration of the study for each patient is 4 months. In addition to the preoperative and operative visit, 3 postoperative visits are planned: after 1 week, after 1 month and after 3 months. Intraocular lens laser treatment can be performed on both eyes on the same day or with a time gap. The schedule of individual visits and their duration are listed below.

WHAT IS EXPECTED OF ME AND WHAT ARE MY RESPONSIBILITIES?

You will be asked to sign this consent form before starting the study. You will be asked a series of questions about your health and the medicines you are taking. You will undergo several tests to determine whether you are eligible to participate in this study. You must be willing and able to follow

study guidelines and procedures as specified by the investigator physician and investigator staff. You will then attend the procedure and three subsequent study visits.

You must not participate in any other drug or medical device studies. You must inform the investigator and the study staff of any side effects or problems you experience during the study.

In addition to the above, the examining physician or staff may tell you other reasons why you may or may not be eligible to participate in this study. It is important that you are honest with the study doctor about your medical history to ensure your safety while participating in this study.

STUDIES VISITS AND PROCEDURES

The following visits and activities are planned during the study. At all visits, you will be given eye drops to dilate the pupils, with which it is possible to examine the fundus of the eye and treat the intraocular lens with a laser. Vision may be blurred after dilation, please arrange for transportation.

Visit 1: screening visit / 60 days to 0 days before treatment (approx. 2–3 h)

After signing the informed consent, the doctor will review your overall health and the medications you are taking. You will undergo a regular ophthalmological examination using a special microscope, examination of visual acuity and refraction, and taking pictures of the eye using specialized cameras, the so-called OCT. You will also be asked to fill in a form assessing the quality of your vision in everyday life. After the administration of eye drops to dilate the pupils, you will have an examination of the fundus.

Visit 2: day of treatment (approx. 2 h)

The doctor will review your medical condition, including the medications you are taking. You will undergo a standard examination before the procedure, as is done with other laser eye procedures.

For your comfort, numbing eye drops and pupil dilation drops will be applied to your eye. After the eye drops have taken effect, you will lie down on a couch, and to keep your eye open for the entire duration of the treatment, a spacer will be inserted into your eye. The doctor will then place a rubber attachment on the eye, which will hold your eye in place during the laser treatment. You will be asked to lie still during the treatment, which will last about 2 minutes. After the application is finished, the attachment is removed and the doctor will check your eye. After the treatment, you stay at the clinic for a short time for examination and then you go home.

You may be prescribed antibiotic and anti-inflammatory (steroid) eye drops as well as eye drops or pain relievers. It is important that you take these medications as prescribed. You can also use artificial tears, according to your need. Your examining physician will provide you with information regarding additional risks associated with any medications he may prescribe.

Visits 3 and 4: 1st week and 1st month (approx. 1–2 h)

The doctor will examine your state of health, you will undergo a routine ophthalmological examination using a special microscope, refraction and visual acuity examination. For the examination, you will again receive drops to dilate the pupils. At the visit in the 1st month, an examination will also be performed using a specialized OCT camera.

Visit 5: 3rd month (approx. 2–3 h)

At this visit, you will undergo the same examinations as at previous visits. In addition, you will be asked to fill out a form evaluating the quality of your vision and images of your eyes will be taken using specialized cameras to evaluate the effectiveness of the procedure.

RISKS AND DISCOMFORT

Participating in any study may involve certain risks, discomforts and side effects. You must also keep in mind that treatment with any medication poses potential risks.

Eye drops to numb the eyes and dilate the pupils or pain drops can cause discomfort in your eyes, such as redness, tearing or stinging, blurred vision, eye pain, dry eyes. Less common reactions include feeling faint, dizziness, headache and allergic reactions.

Treatment within the study

There may not be an improvement in the quality of your vision, but it is also possible that participation in this study will, on the contrary, lead to a significant improvement. Should there be any deterioration, the examining physician will suggest further procedures and appropriate treatment. Your health and comfort are our priority and every step of the study will be carefully monitored to ensure the best results and minimize any risk.

Possible side effects of treatment include damage or swelling of the cornea, increased intraocular pressure, decreased visual acuity, presence of inflammation in the anterior chamber requiring the initiation of corticosteroid treatment, swelling or a retinal problem.

There may be side effects of the medical procedure that are not currently known. Please inform the investigator physician or the trial staff if you experience any of the adverse effects. Please also tell them if you have any other problems with your health or how you feel during the study, whether you think they are related to the study or not.

NEW INFORMATION

You will be informed of any news that could change your decision to participate in this study. In this case, you may be asked to sign a new consent.

ADVANTAGES

We assume that after the intraocular lens treatment you will be provided with near vision and will therefore not need glasses, however this cannot be promised. The results of this study may help people and researchers further develop this treatment in the future.

COSTS AND PAYMENT FOR PARTICIPATION

You will not incur any costs in connection with treatment as part of the study, examinations and tests. The sponsor of the study, Perfect Lens, bears the cost of all procedures and visits related to the study and research.

If you participate in this study, you will receive 500 CZK for each visit as compensation for travel expenses.

ALTERNATIVE TREATMENT

Improvement of near vision after implantation of monofocal intraocular lenses is possible with the help of spectacle correction or contact lenses. Alternative procedures, but very rarely used, may also include replacing monofocal intraocular lenses with multifocal or laser refractive surgery. The examining doctor will discuss them with you, including their important potential benefits and risks.

INSURANCE

If you become injured or become ill as a result of participating in this study, contact the investigator's physician immediately. The examining physician will provide emergency medical treatment. If your injury or illness is a direct result of participating in this study, the sponsor of the study will submit a claim to your insurance company for reimbursement of medical expenses.

If your injury or illness is not a direct result of participating in this study, you, your health insurance company, or another payer (responsible for payment) will be billed for these medical expenses.

For the purposes of the study, insurance was taken out with XXXX to cover all costs of damages associated with the study with a maximum limit of insurance coverage for each patient of €250,000.

CONFIDENTIALITY

During the clinical evaluation, medical and personal data will be collected from you and will be recorded in your personal file. The data are first stored at the study site and then forwarded to the study sponsor in pseudonymized form for evaluation. The data will only be published in an anonymized form.

Pseudonymized means that no name, address, date of birth or initials information is used, but only a number and/or letter code. Anonymized means that the data can no longer be attributed to specific individuals. The data is secured against unauthorized access. Only the examining team at the medical facility has the key to your identity. Decryption is only carried out under the conditions prescribed by law or if it is necessary for your health.

Your identity will remain confidential and, except for the information described above, will not be shared with others unless such disclosure is required by law.

You have the right to see and copy your study-related health information. If the results of this study are published in a medical journal or presented at scientific or medical meetings, your identity will not be revealed.

VOLUNTARY PARTICIPATION AND WITHDRAWAL

Participation in this study is completely voluntary. You can choose not to participate in the study or leave it at any time. There will be no disadvantages for your current or future treatment. If you agree to participate, you will be asked to sign a consent form.

The examining physician or study sponsor may terminate your participation in this study at any time without your consent for any of the following reasons:

- if it is in your best interest,
- if you experience a serious adverse side effect,
- unless you later agree to any future changes that may be made to the study plan,
- if you move and cannot make the remaining follow-up visits,

- or for any other reason that the examining physician determines that it is not in your best interests to continue with the study.

If you decide to withdraw from the study, you must inform the examining physician. If you leave the study before the scheduled final visit, the examining physician may ask you to undergo some of the end-of-study procedures to ensure that you can leave the study safely without serious consequences to your health. After that, no further data will be collected. The data collected up to this point will be evaluated for study purposes. After completing the study, discuss further treatment with your doctor.

QUESTIONS

Contact the examining physician listed on page 1 of the consent form for any of the following reasons:

- if you have any questions about this study or your participation in it,
- if you feel you have suffered a research-related injury or adverse reaction to an investigational product/procedure, or
- if you have questions, concerns or complaints about the research.

CONTACT INFORMATION

You can contact the examining physician or members of the study team at +420 577 202 202.

- with questions, concerns or complaints regarding this tracking,
- with questions regarding your rights as a patient and participant in this monitoring,
- to report a tracking-related injury, or
- with information on monitoring procedures.

You can contact the study team or the staff of the Office for Personal Data Protection (ÚOOÚ) with questions about data security. With questions regarding your rights as a patient participating in clinical monitoring, you can contact the ethics committee that approved the clinical monitoring:

Ethics Committee of the Gemini Eye Clinic, U Gemini 360, 760 01 Zlín
Tel.: (+420) 734 853 615,
E-mail: eticka.komise@gemini.cz

We'd love to hear about any issues you encounter so we can resolve them as soon as possible. It can be problems with the date of the visit, health problems, or experiences from the stay at the eye clinic. If you have any concerns about any aspect of this study, please discuss them with your doctor.

INFORMED CONSENT

TITLE: Evaluation of clinical and refractive outcomes of using a femtosecond laser to treat presbyopic symptoms in a patient with monofocal intraocular lenses

PROTOCOL NO.: **XXXXXX**

I have read this consent form in its entirety and understand its contents.

My examining physician informed me of the risks, long-term effects, and potential benefits of participating in this clinical trial.

I was also informed about other available treatment options.

I had the opportunity to discuss the clinical trial procedure with the investigator and ask questions. I understand and accept the patient information and all answers I received from the doctor in response to my questions.

I have had enough time to decide whether I want to participate in this clinical follow-up and I am aware that participation in this clinical trial is voluntary.

I am aware that I can revoke this consent at any time (verbally or in writing) without giving a reason, without this having any negative impact on the subsequent care provided by my doctor.

I hereby agree to my voluntary participation in the aforementioned clinical trial. I have received a copy of the patient information and patient consent form. One homologue remains at the center of a clinical trial.

SIGNATURE OF CONSENT:

……..
Name and surname of the patient, in block letters

…… ……..……
Signature Date

…….
The name of the physician conducting the informed consent discussion, in block letters

…… ……..……
Signature Date