

STUDY: Clinical Evaluation of Oté Sensation Multi-Purpose Solution Care System
PROTOCOL NO: «Protocol_No»
STERLING IRB ID: «IRB_ID»
DATE OF IRB REVIEW:

PARTICIPANT INFORMED CONSENT FORM AND AUTHORIZATION TO USE AND DISCLOSE MEDICAL INFORMATION

STUDY TITLE: «Protocol_Title»

PROTOCOL NO: «Protocol_No»

STUDY DOCTOR: «First_Name» «Middle_Name» «Last_Name», «Suffix»

STUDY SITE:
«Company_Name»
«Address»
«City_State_ZIP»

TELEPHONE:
«Telephone»
«Telephone_2_if_applicable»

SPONSOR: «Sponsor»

You are being asked to take part in a research study that involves wearing, daily wear soft contact lenses, along with the use of a multi-purpose solution care system, for approximately one month. Your participation in this research study is strictly voluntary, meaning that you may or may not choose to take part.

This form describes the study in order to help you decide if you want to participate. Before you decide to take part it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully. You should ask the study investigator (doctor) or study staff about anything you do not understand and ask any questions you may have before you decide if you want to be in the study. Do not sign this form unless you are satisfied with the answers to your questions and decide that you want to be part of this study. You may consult with your family, friends or regular eye care doctor (if different) before deciding to participate. You will be given a copy of your signed consent form to take home and keep for your records.

WHAT IS THE PURPOSE OF THIS STUDY?

The purpose of this study is to evaluate the clinical performance of a new contact lens care product in soft contact lens wearers. The test product is investigational which means it has not yet been approved for use in the USA by the Food and Drug Administration (FDA). The test product has been approved for use in Europe.

In this study the test products ability to cleanse, disinfect and use for rinsing and storing of contact lenses will be compared with another widely used soft lens multipurpose solution which will be used as a control product.

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The study will include 200 men and women, aged 18 years or older, who currently use soft contact lenses to correct their eyesight. This is one out of approximately 10 sites where the study will take place. The sites are located in both the U.K. and the U.S.A.

WHO IS PAYING FOR THIS STUDY?

The company sponsoring and paying for the study is, «Sponsor». They will be paying the study doctor.

HOW LONG WILL I BE IN THE STUDY?

Your participation in the study will be for approximately one month. You will need to attend a maximum of four scheduled visits to the clinic over this time. The length of the visits will vary from between 0.5 to 1.0 hours.

HOW DO I KNOW IF I CAN BE IN THE STUDY?

Participants in the study must have healthy eyes, except for their needed eyesight correction. You cannot be included in this study if you are pregnant or breastfeeding.

To be in this study all of the following should apply to you:

- You are a current soft contact lens wearers (you should have regularly worn soft contact lenses for more than 1 month)
- You are greater than or equal to 18 years of age
- You have the required eye correction prescription for the study (the study doctor will review this with you)
- You have normal eyes with no evidence of abnormality or disease (this will be determined by the study doctor)
- You have read and signed this informed consent document
- You are able to conduct proper daily lens care
- You are able to comply with the wear schedule
- You are able to comply with the study visit schedule

You should not be in this study if any of the following apply to you (the study doctor will review these with you):

- You have any systemic (general) disease affecting ocular (eye) health.
- You are diabetic.
- You have a known sensitivity to the study eye care products.
- You are taking any systemic or topical medications that will, in the study doctor's opinion, affect ocular physiology or contact lens performance.
- You have an active corneal (the front part of the eye) infection, injury, inflammation or abnormality
- You have had surgery to the front part of your eye.
- You are currently (to the best of your knowledge) pregnant, planning a pregnancy or lactating.

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- You are participating in another research study

WHAT WILL HAPPEN DURING THIS STUDY?

You will be assigned to wear one type of soft contact lens and to use one type of lens care product for the duration of the study. Your assignment will be randomly selected (like flipping a coin) out of the 6 possible types of contact lenses and two types of lens care products that are being used in the study. Neither you nor the study doctor will know the lens care product you have been assigned. However, the study doctor can find out the lens care product you are using in the event of a medical emergency.

WHAT HAPPENS WHEN I COME FOR STUDY VISITS?

Before you can start the study, the study doctor or study staff will talk to you about the study. Then you have to sign this form before the study doctor or study staff can enroll you into the study.

Visit 1a - Initial Assessments

You will be asked to wear your current contact lenses to this first visit. You will be asked questions about:

- Your eye health
- Your general health
- Medications you use, including any over-the-counter medications (vitamin/herbal supplements)
- Contact lens history, including the name/ and type of lenses/products you currently use.

You will then undergo an examination of your eyes. These assessments will be no different than those that would be conducted at a normal contact lens check-up visit. They will include vision and lens fitting assessments and also include the use of Fluorescein drops, which is a dye used to help show-up any problems with your cornea.

If your eyes are confirmed to be healthy the study doctor will then assign you to the type of lens and lens care product you will use for the study.

Visit 1b – Lens Fitting and Dispensing

This visit may or may not take place immediately following Visit 1a.

- If the site has your lens prescription in stock you will be dispensed your study lenses and undergo additional assessments to ensure the lens fit and that your comfort and vision are acceptable with these lenses on your eyes.
- If your lenses need to be ordered you will be scheduled to return for the lens fit assessments on another day.

Visit 2 – 1-week Follow-up

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This visit will occur after 1-week of wearing the lenses and using the lens care product.

You should come to the visit wearing the lenses having inserted the lenses not less than 1 hour or more than 3 hours beforehand.

You will be asked questions regarding your wear time and experience with the study lenses/products, and undergo assessments to ensure your eye health and vision remain acceptable.

Visit 3 – 1-month Follow-up and Study Exit

This visit will occur approximately 3 weeks after Visit 2, for a total of one month of study lens wear.

You should come to the visit wearing the lenses, and bring with you any remaining study lenses and leftover care products.

You will be asked similar questions and undergo similar assessments to Visit 2. You will not be given study contact lenses when you leave this final visit. You will leave wearing your own contact lenses or eyeglasses.

The study assessments are important in order to collect the data about the study materials and to ensure your continued ocular health.

WHAT WILL HAPPEN WHEN THE STUDY IS OVER?

You should talk to the study doctor about your options for correcting your eyesight and eyecare options after the study is over so they can advise you how to best continue with your eyecare.

The study assessments should not take the place of your regular periodic eye examinations.

IS THERE ANYTHING I NEED TO DO WHILE I AM IN THE STUDY?

As a participant, your responsibilities include to:

- Follow the instructions you are given
- Keep your study visit appointments. If it is necessary to miss an appointment, please contact the study staff to reschedule as soon as you know you will miss the appointment
- Tell the study doctor or study staff about side effects or any changes in your health
- Tell the study doctor or study staff if you believe you might be pregnant
- Keep the study contact lenses and care products in a safe place out of reach of children and for your use only
- Tell the study doctor or study staff if you want to stop being in the study at any time
- Bring your own eye glasses to each visit

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Unscheduled visits will be made available to you at your request, or if the study doctor thinks it is in your best interests. At the end of your participation in the study, it is required that all unused study products that have been issued to you are returned to the study doctor.

POSSIBLE RISKS OR DISCOMFORTS RELATED TO THE STUDY

What can happen if I use the study products?

As you are already a successful contact lens wearer, and due to the nature and duration of the study the risks of participating are low.

The study contact lenses and control lens care product are approved for sale and use in Europe (CE-marked) and the USA (FDA approved). At this time the test lens care product is only approved in the European Union.

All contact lens wear or lens care products, however, can carry a risk of serious injury to the eye. You should take particular care to follow the instructions given to you by the doctor, especially if the study involves a different lens care regime to your normal one.

Complications of contact lens wear and/or lens care products can include light sensitivity, swelling of the cornea (the front part of the eye), red eye, corneal vascularisation (small blood vessels growing into the cornea) and, in extreme cases, corneal infection. Smoking increases the risk of corneal infection. Corneal infection may rarely cause a permanent reduction, or even loss, of vision. If a complication should occur during the study your eye may be photographed, a longer appointment may be necessary; you may be referred for medical treatment and/or what has occurred may be reported to the sponsor company. You may be required to wear eye glasses for a period of time.

If you have any problems using the study contact lenses and/or care solutions, or have any problems with your eyes during the study, you should stop using the contact lenses and care solutions immediately and contact the site or other eye care professional. In the case of an emergency you should attend your nearest Emergency department and inform them you are participating in a research study.

Are there any side effects from the study procedures?

The study procedures involve assessments and tests that are routinely done to evaluate eye health and contact lens fitting. The fluorescein dye used to examine the front part of your eye may be used during a routine eye examination. Allergic reaction to the dye is rare. Allergic reactions to the dye may appear as a rash or itching of your skin.

COULD I HAVE ANY OTHER PROBLEMS WITH MY HEALTH IF I DO THIS RESEARCH STUDY?

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It is possible that problems and side effects of the study contact lenses and lens care products which have not been seen before could occur. If the study doctor learns of any new safety related information about the study products while you are participating in the study you will be told.

ARE THERE RISKS TO ME IF I AM PREGNANT DURING THE STUDY?

Wearing contact lenses and the use of lens care products during pregnancy does not pose any health risks to either the mother or fetus. Pregnancy, however, can change the nature of tears and affect contact lens comfort. Therefore, if you are pregnant or are lactating, you will not be allowed to take part in the study.

WILL BEING IN THIS STUDY HELP ME?

The study contact lenses might help correct your eyesight while you are wearing them, but there is no assurance that this study will help you. Your eyesight might not be corrected by the study contact lenses or might get worse while you are in this study. Information from this study may help researchers come up with new products to help others in the future.

WILL IT COST ANYTHING TO BE IN THIS STUDY?

No. You do not have to pay for the contact lenses, care products, study visits, or tests that are part of the study.

While you are participating in the study you will still have to cover the costs of your regular eye care that are not a part of this study.

WILL I GET PAID?

You will be compensated for your time and participation. Upon completion of the study you will receive up to a total of \$90.00. If you do not complete the entire study you will be reimbursed for the visits that you did complete at \$30.00 per visit.

DO I HAVE TO BE IN THIS STUDY?

No, you do not have to be in the study. Your participation in this study is voluntary; it is your decision whether you would like to participate or not.

You can change your mind at any time. There will be no penalty to you. Your eye care at this practise will not change if you decide to say “no”. If you say “yes”, you are agreeing to the sponsor being able to use your data.

The study doctor or sponsor can withdraw you from the study at any time, even if you want to continue to be in the study. This could happen if:

- The study doctor believes it is best for you to stop being in the study.
- You are unable to follow the study instructions.

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- The sponsor stops the study for any reason.

If you want to stop being in the study, tell the study doctor or a member of the study staff and return any unused study products. The study doctor/staff may ask you some questions about being in the study. They may also ask you to have some more tests to ensure your withdrawal from the study happens safely.

IS THERE ANYTHING ELSE I CAN DO FOR MY EYESIGHT?

You do not have to be in this study to get help for your eyesight. Some other things you can do are:

- Wear eyeglasses
- Use FDA-approved soft or hard contact lenses
- Get laser or other refractive surgery

You can talk to your primary eye care provider about your options, including their risks and benefits, before you participate in the study.

You should continue to go to your regular doctor even if you join this study.

CAN I TALK TO OTHERS ABOUT THE STUDY PRODUCTS?

By agreeing to participate in this study, you agree not to share information about the study products with anyone outside of the study without first obtaining written permission from the study sponsor. To ask questions about this, talk to the study doctor or study staff.

WHAT IF I GET HURT OR SICK WHILE I AM IN THE STUDY?

If you get hurt or sick while you are in this study, and the study doctor and the study sponsor reasonably determine your illness or injury to be a direct result of the study, medical treatment will be provided free of charge by the sponsor. If you have not followed the study doctor's instructions about the study, the sponsor may not pay these expenses.

The sponsor has made arrangements for insurance and/or indemnity to meet the potential legal liability of the sponsor arising from the study. You will not lose any legal rights by participating in this study.

To ask questions about this, talk to the study doctor or study staff.

WHO CAN I TALK TO ABOUT THE STUDY?

If you have any questions about the study please contact Dr. «Last_Name» or the study staff at «Telephone» or «Telephone_2_if_applicable».

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This study was reviewed by Sterling Institutional Review Board (IRB). An institutional review board (IRB) is a group of people who review the risks and benefits of a study. If you have questions regarding your rights as a research participant, or if you have questions, concerns, complaints about the research, would like information, or would like to offer input, you may contact the Sterling Institutional Review Board Regulatory Department, 6300 Powers Ferry Road, Suite 600-351, Atlanta, Georgia 30339 (mailing address) at telephone number 1-888-636-1062 (toll free).

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

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CONSENT FORM

Please **initial** box

1. I confirm that I have read all 11 pages of this Participant Informed Consent Form and have had the opportunity to ask questions. Any questions I had were answered to my satisfaction.
2. I acknowledge that my participation is voluntary and that I am free to withdraw at any time, without giving any reason and without my future care or legal rights being affected.
3. I agree that photographs and/or videos that do not identify me may be taken of my eyes, if needed. I am aware that these may be necessary to document my ocular health and, aside from my right to withdraw consent from the study entirely, are not optional.
4. I give permission for my ophthalmic records (eye clinic notes) and research data to be looked at by responsible individuals from the sponsor company, Visioncare Research or from regulatory authorities where it is relevant to my taking part in this research.
5. I acknowledge that I am able to obtain a summarized copy of the final study results if I wish and can obtain these by contacting the study doctor at the end of the study.
6. I voluntarily agree to take part in this study.

You will be given a copy of this signed Participant Informed Consent Form to keep.

Name of Participant Date Signature

I attest that I discussed this study with the above-named participant. This person had enough time to consider this information, had an opportunity to ask questions, and voluntarily agreed to participate in this study.

Name of person taking consent Date Signature

Name of Investigator Date Signature
 waive, if the person obtaining consent is the Principal Investigator or Sub-Investigator

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AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION

During your participation in this research study, the study doctor and study staff will collect or create personal health information about you (for example, medical histories, photographs, and results of any tests, examinations or procedures you undergo while in the study) and record it on study forms. The study doctor will keep this personal health information in your study-related records (that we will refer to as "your study records"). In addition, the study doctor may obtain, and include in your study records, information regarding your past, present, and/or future physical or mental health and/or condition. Your study doctor may ask you to sign a separate authorization to obtain some or all of your medical records from your doctor. Your study records may include other personal information (such as social Security Number, medical record numbers, date of birth, etc.), which could be used to identify you. Health information that could identify you is called "Protected Health Information" (or "PHI").

Under federal law (the "Privacy Rule"), your PHI that is created or obtained during this research study cannot be "used" to conduct the research or "disclosed" (given to anyone) for research purposes without your permission. This permission is called an "Authorization". Therefore, you may not participate in this study unless you give your permission to use and disclose your PHI by signing this Authorization. By signing, you are agreeing to allow the study doctor and staff to use your PHI to conduct this study.

By signing this Authorization, you also are agreeing to allow the study doctor to disclose PHI as described below:

- The sponsor of this study and anyone working on behalf of the sponsor to conduct this study (referred to as "the sponsor"). The sponsor will analyze and evaluate the PHI and may use it to develop new tests, procedures, and commercial products. The study staff will assign a code number and/or letters to your records, which means you will not ordinarily be identified in the records sent to the sponsor. The sponsor may, however, look at your complete study records that identify you. In addition, the sponsor may visit the study site to oversee the way the study is being conducted and may review your PHI during these visits to make sure the information is correct.
- Sterling Institutional Review Board ("IRB") may have access to your PHI in relation to its responsibilities as an Institutional Review Board.
- The study doctor or sponsor may disclose your PHI to the United States Food and Drug Administration ("FDA") or similar regulatory agencies in the United States and/or foreign countries.

These disclosures also help ensure that the information related to the research is available to all parties who may need it for research purposes.

After your encoded Protected Health Information is disclosed to the study sponsor, the results of the study may be re-analyzed at a later date and may be combined with the results of other studies. The study sponsor and people who work with the study sponsor may use the results of this study for other research purposes, including:

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- Reviewing the safety or effectiveness of the study contact lenses and other products or therapies
- Evaluating other products or therapies for patients
- Developing a better understanding of disease
- Improving the design of future clinical research studies

Except for the disclosures described above, your PHI will not be shared with others unless required by law. If your PHI is given to the parties listed above and/or to others who are not required to comply with the federal law, your PHI will no longer be protected by this law and could possibly be used or disclosed in ways other than those listed here.

The results of the study may be published in a medical book or journal or presented at meetings for educational purposes. Neither your name nor any other personal health information that specifically identifies you will be used in those materials or presentations.

You have a right to see and make copies of your PHI. You are agreeing, however, by signing this form, not to see or copy some or all of your PHI until the sponsor has completed all work related to this study. At that time, you may ask to see your records.

This Authorization will expire 50 years from the date you sign it unless you revoke (cancel or withdraw) it sooner.

You have a right to revoke your Authorization at any time. If you revoke it, your PHI will no longer be used for this study, except to the extent the parties to the research have already taken action based upon your Authorization or need the information to complete analysis and reports for this research. To revoke your Authorization, you must write to the study doctor, stating that you are revoking your Authorization to Use or Disclose Protected Health Information. If you revoke this Authorization, you will not be allowed to continue to be in this study.

You will receive a copy of this Authorization after you have signed it.

Printed Name of Participant

Signature of Participant

Date of Signature

Printed Name of the Person Obtaining the Authorization

Signature of the Person Obtaining the Authorization:

Date of Signature