SUBJECT INFORMATION AND CONSENT FORM

Sponsor / Study Title:	**Venus Concept, "Clinical Evaluation of the Safety and Performance of Fractional RF for the Treatment of Surgical Scars Following Breast Augmentation, Abdominoplasty or Face Lift"**
Protocol Number:	**CS0717**
Principal Investigator: (Study Doctor)	**Dr. Kai O. Kaye**
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INTRODUCTION

You are being asked to participate in this research study because you are undergoing treatment for your surgical scars. It is important that you read the following explanation of the proposed study. This form describes the purpose, procedures, benefits, risks, discomforts, and precautions of the study treatments. It also describes the alternative procedures that are available to you and your right to withdraw at any time. A member of the study staff will read through the consent with you and discuss all the information in a private room. When you think you understand the risks, benefits and requirements of the study, you will then be asked if you agree to take part. If you agree, you will be asked to sign and date this consent form. Once you sign and date it, you will be given a signed and dated copy to keep for your records.

You may show this consent form to family, other doctors, and friends before you sign and date it. You may want to discuss it with them to help you decide if you want to be part of this procedure. If you don't know another doctor, but want a second opinion, please ask. The study doctor will give you the name of another doctor who is not participating in the study that you can talk to.

A description of this clinical trial will be available on http://ClinicalTrials.gov. 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.

PURPOSE OF THE RESEARCH

This study is being conducted to evaluate the study treatment effect of radiofrequency (RF) energy on surgical scars following breast augmentation, abdominoplasty or face lift. Radiofrequency treatments have been shown to tighten skin and to treat various skin conditions related to aging such as wrinkles and scars. It is the use of fractional RF energy treatments for treating surgical scars to improve their appearance that is experimental. The radiofrequency energy will be delivered by an applicator attached to the Venus Concept Viva, a medical device approved by health regulatory authorities.

STUDY TREATMENT

You will receive a total of three treatments of radiofrequency energy to one half (left or right side of your face or body) of your surgical scar(s) at one month intervals. This is done to

determine how safe the study treatments are and how well the study treatments work. The other half will not be treated during the study. At the end of the study, you will be offered treatment of your surgical scars on the side that was not treated. This will be offered at no cost to you.

PARTICIPANT SELECTION AND TIME REQUIRED

Up to 50 healthy, adult women who are seeking treatment of their surgical scars following breast augmentation or abdominoplasty and up to 25 male or female subjects requesting treatment of surgical scars following face lift surgery will be asked to take part in this study at one center. The study will consist of a screening visit, three study treatment visits monthly, 3 monthly follow-up visits and one visit 6 months after the final study treatment for a total of up to 11 visits over a period of up to 12 months. The screening visit will take approximately 60 minutes. Each of the three study treatment visits will take approximately 50 minutes. The follow-up visits will take approximately 50 minutes.

YOUR STUDY RESPONSIBILITIES

Taking part in a research study can be an inconvenience to your daily life. Please consider the study time commitments and responsibilities as a research subject when you are deciding to take part. Your responsibilities as a study subject include the following:

- Tell the truth about your medical history and current conditions.
- Tell the study doctor if you have any electrical implant (for instance, a pacemaker or internal defibrillator) or other permanent implants.
- Tell the study doctor if you have any metal material in your teeth or metal implants (for instance, in bone) in/around your surgical scar area.
- Tell the study doctor if you have had any surgical procedure in the study treatment areas within the last 4 weeks.
- Tell the study doctor if you have any tattoos in the treatment area.
- Tell the study doctor about any problems you have during the study.
- The study doctor or study staff will talk to you about any food, medicines or activities (e.g. tanning) that you should not take/do while in this study.

STUDY PROCEDURES

<u>Screening Visit</u>

- The study staff will review the consent form with you and give you the opportunity to ask any questions you may have.
- The study staff will collect information about your medical history, weight and any medications you are currently taking.
- If you are a woman of child-bearing age, a sample of your urine, approximately 2 teaspoons (10ml) will be taken to determine if you are pregnant.
- The study doctor will conduct a physical examination.
- The study staff will perform a test spot in a not so visible area of your surgical scar to determine if you can tolerate the radiofrequency treatment.
- The study doctor will review whether you are eligible to participate in the study.

<u>Study Treatment Visits</u>

- The second and third study treatments will be scheduled monthly after your first study treatment.
- You will need to shave the skin in the treatment area before every treatment at home, using a foam or gel to minimize skin irritation.
- You will be asked to complete a short questionnaire to describe your scar before your first treatment visit only.
- The study staff will review your health status, medications you are currently taking and any changes since your last visit.

- The study staff will collect your weight, temperature, heart and respiratory rate, and blood pressure.
- The study staff will take non-identifying photographs of the treatment area before the first treatment only.
- You will receive the radiofrequency (RF) energy treatment to one half of the surgical scar (treatment area).
- The treatment area will be checked by the Study Doctor immediately and 30 minutes after the treatment, to see if there is any change in the area (redness, irritation or any other changes).
- At the end of each study treatment, you will be asked to indicate your discomfort/pain by drawing a line on a visual analog scale.

Follow-Up Visits after Each Treatment Visit

- Two days after each study treatment, you will have a follow-up visit.
- The study staff will review your health status, medications you are currently taking and any changes since your last visit.
- The study staff will collect your weight, temperature, heart and respiratory rate, and blood pressure.

Follow-Up Visits

- Your first follow-up visit will be scheduled one month after your last study treatment.
- The second and third follow-up visits will be scheduled monthly after your first follow-up visit.
- You will be asked to complete a short questionnaire to describe your scar and your overall satisfaction with the study treatment before your third follow-up visit only.
- The study staff will review your health status, medications you are currently taking and any changes since your last visit.
- The study staff will collect your weight, temperature, heart and respiratory rate, and blood pressure.
- The study staff will take non-identifying photographs of the treatment area.

Final Visit

- Seven months after the third follow-up visit, you will have a final follow-up visit.
- You will be asked to complete a short questionnaire to describe your scar and your overall satisfaction with the study treatment before your third follow-up visit only.
- The study staff will review your health status, medications you are currently taking and any changes since your last visit.
- The study staff will collect your weight, temperature, heart and respiratory rate, and blood pressure.
- The study staff will take non-identifying photographs of the treatment area.

RISKS AND DISCOMFORTS

To date, there have been no reports of any serious risks involving this study treatment. This study treatment has already been approved by health regulatory authorities for use to improve the appearance of patients with facial wrinkles. It has also been reported to be well tolerated. The most common side effects to date are as follows:

- Possibility of temporary minor skin irritation in the treated area
- Redness or swelling in the treated area which may last from a few minutes to a few hours
- Mild swelling in the treated area for up to a week
- Slight heat discomfort during the study treatment

Most of these side effects are temporary and resolve with time.

Very rarely, there may be possible:

- Bruising
- Burns
- Hyperpigmentation (skin turns darker)
- Hypopigmentation (skin turns lighter)

If you are pregnant or breast-feeding, you will not be able to take part in this study. Also, women who are able to become pregnant will be required to use an approved method of birth control while on the study. There may also be risks that are currently unforeseeable.

BENEFITS OF THE RESEARCH AND BENEFITS TO YOU
Your scar may improve with the study treatment, stay the same, or worsen. Your participation will provide valuable information about the study treatment of surgical scar tissue. This may benefit other patients with surgical scars. However, there is no guarantee that your scar appearance will improve.

EMERGENCY INFORMATION
If you experience an adverse reaction or a study treatment-related injury after the study treatment, you should immediately contact the study doctor at the number listed on the first page of this form.

If you seek emergency care, or if you are hospitalized, please alert the doctor who is treating you that you are participating in a clinical study being conducted by the study doctor listed on the first page of this form. Tell the study doctor about any changes in your medical condition.

You are instructed to call immediately with any question or concerns you might have.

MEDICAL CARE FOR INJURY RELATED TO THE STUDY
If you suffer a physical injury as a result of your participation during this study, you will receive appropriate medical care to treat the injury. The clinic will pay for any treatment-related injury that occurs during this study not covered by your government health plan (if applicable) or private insurance (if any). You may receive medical care in the same way as you would normally. No funds have been set aside for payments or other forms of compensation (such as for lost wages, lost time, or discomfort). The sponsor of this study also has insurance to cover the expenses associated with appropriate medical care required to treat study-related injury.

However, you do not give up any of your legal rights by signing this consent form, nor release the study doctor or sponsors form their legal and professional obligations.

COSTS
You will not be charged for the study treatment.

PAYMENT FOR PARTICIPATION

Options – depending upon site:

You will not be paid for participating in study.

Parking and travel expenses for study visits will be reimbursed up to €25 per visit. You will be paid at the end of your participation in the study. If you do not finish the study, you will only be reimbursed for completed visits.

The study doctor is being paid by the sponsor to cover the costs of conducting the research.

VOLUNTARY PARTICIPATION

Your participation in this study is voluntary. Your refusal to participate or your withdrawal from it, will involve no penalty or loss of benefits to which you are entitled and alternative treatment will not be withheld from you. You may stop your participation at any stage. If you choose not to participate or to withdraw early, you will be offered standard alternative treatment according the study doctor's normal standard of medical care. If you withdraw early, you will be asked to complete the final visit, however, you have the right to refuse.

The study doctor and/or the sponsor, Venus Concept, also have the right to terminate your participation in the study if you are unable to tolerate the study treatment or if you are non-compliant with the study procedures.

Any significant findings during the course of the study that is relevant to your continued participation in the study will be communicated to you.

CONFIDENTIALITY AND SHARING THE RESULTS

As part of this research, the study doctor will collect the results of your study-related tests and procedures and may also access your personal medical records for health information such as past medical history and test results. Records of your participation in this study will be held confidential so far as permitted by law. The results of the testing that relate to your participation will be pooled with the results of other subjects. The pooled results will not identify individuals but may be presented at scientific meetings or published in scientific journals.

As part of the study, your study doctor and his/her study team will report study-related information about you to the sponsor and/or their agents and representatives, but you will only be identified by your initials and an assigned a unique code. Information about the code will be kept in a secure location and access limited to the research study personnel. Information about you will continue to be collected until you complete the study or terminate early and withdraw your consent. The information concerning this study may be made available to European Medicines Evaluation Agency (EMEA), Health Canada (HC), the U.S. Food and Drug Association (FDA), or regulatory agencies of other countries. Your study data may be analyzed in any country worldwide. Information sent from the study site will not contain your name or any identifying information. These organizations will treat such information with a policy of strict confidentiality and your privacy will be protected.

You have the right to check your study records and request changes if the information is not correct. While every effort will be made to protect the privacy of your information accordingly to Ley Orgánica 15/1999, de 13 de diciembre, de Protección de Datos de Carácter Personal and Ley 14/2007, de 3 de julio, de Investigación Biomédica, absolute confidentiality cannot be guaranteed. This does not limit the duty of the researchers and others to protect your privacy.

Your study doctor will maintain all records related to the study, in a secure location, for a period of 5 years following completion of the study.

By signing this consent, I give my consent to the collection, use and disclosure of my health information as described above.

QUESTIONS ABOUT THE RESEARCH
You can ask questions about this consent form or the study (before you decide to start the study or at any time during the study). Questions may include:

- Who to contact in the case of a research-related injury or illness.
- Any payment for being in the study.
- Your rights and your responsibilities as a study subject.
- Other questions.

Contact the study doctor or study staff <u>listed on the first page of this form</u> with any questions, concerns or complaints.

This study has been reviewed by a Research Ethics Board (REB)/Institutional Review Board (IRB). This Committee reviewed this study to help ensure that your rights and welfare are protected and that this study is carried out in an ethical manner.

NEW INFORMATION
You will be told about any new information found during the study that may affect whether you want to continue to take part.

USE OF PHOTOGRAPHS FOR RESEARCH PURPOSES

I agree that all non-identifying photographs taken during my participation in the study, of the procedure area, may be used for scientific research purposes and governing regulatory bodies for review and is a requirement for participation in this study.

YES _____ NO _____
Initials Initials

USE OF PHOTOGRAPHS FOR MARKETING PURPOSES

I agree that all non-identifying photographs taken during my participation in the study, of the procedure area, may be used for marketing purposes.

YES _____ NO _____
Initials Initials

SUBJECT STATEMENT:

I have been given a chance to ask questions about this study. These questions have been answered to my satisfaction. If I have any more questions about taking part in this study, I may contact the study doctor at the number listed on the first page of this form. I understand that my participation in this research project is voluntary. I know that I may quit this study at any stage without affecting my present or future medical care to which I might be entitled. I also understand that the study doctor or the study sponsor in charge of this study may decide at any time that I should no longer participate.

By signing and dating this form, I have not waived any of my legal rights.

I have read and understand the above information. I agree to participate in this study. **I understand that I will be given a copy of this signed and dated form for my own records.**

Subject (signature)	Date
Print Subject Name	
Study Staff (signature)	Date
Print Study Staff Name	