Dr. Michael Cedars, Dr. Tomi Wall, and Lasering USA.

INFORMED CONSENT

Research Study Title: **THE EFFECTS OF THE MIXTO SX FRACTIONAL CO2 LASER ON PHOTOAGING CHANGES**

ABIRB Protocol # S08-01-02

_____ _____

Participant's Initials Study Patient Identification Number

INTRODUCTION:

You are being asked to participate in a research study. Before volunteering to participate, you agree to carefully read this Informed Consent document. It describes the purpose, procedures, risks, and possible benefits of the study. It also explains the alternative treatments available to you and states your right to withdraw from the study at any time. If you decide not to participate in this study, this will not influence your present or future medical care in any way.

DESCRIPTION OF RESEARCH:

This study will assess the safety and efficacy of a new laser device to treat aging of the skin (wrinkling and brown spots). This study is being conducted by Dr. Michael Cedars, Dr. Tomi Wall, and Lasering USA (the company that distributes the laser device in the US). You are being asked to participate in this study because your doctor has determined that you are eligible to undergo laser treatment for aging skin

PURPOSE AND BACKGROUND:

Treatment of aging skin with lasers has been available since the 1980s. The first type of laser used for this purpose was the carbon dioxide laser. Although the treatment was effective, there was a prolonged period of healing and many side effects, including discoloration, scarring, and infection. Newer "nonablative" or "fractional" lasers were available in the 1990s. These lasers had very few adverse effects and very rapid healing times, but the results were not as impressive.

This study will examine the effects of a new laser device, a modified carbon dioxide laser, to treat aging changes of the skin. The new device is called the “MiXto SX” laser. This laser is FDA-approved and has been used in Italy to treat 160 patients with few adverse effects. Based on its use so far, this new laser device appears to combine the effectiveness of the carbon dioxide lasers with the shorter healing time of the nonablative lasers. The reason for this study is to gather more information about the safety and effectiveness of the device. During the study, the laser will be used in accordance with standard of care.

PROCEDURES:

Your entire face, except for the ears, will be treated with a new laser device called the MiXto SX on two separate days, spaced one month apart. The laser projects a series of bright light flashes that convert to heat within the skin. Each flash produces a microscopic-sized hole in the skin, and one treatment session, over 15-20 minutes, treats about 25 % of the skin in the region treated, with fairly uniformly spaced holes. There is a sensation of heat during the treatment. After the two treatments, you will be asked to return at specific time intervals so that we can monitor your progress. The follow-ups will be at one day after the first treatment, one week after the first treatment, and 3 months after the last treatment (4 months after the first treatment), for a total of 5 visits. Photographs will be taken and you will be examined by a physician at each follow-up visit. We will ask you to complete a very short questionnaire at several of the visits.

RISKS AND PRECAUTIONS:

The MiXto SX laser is a micro-fractional carbon dioxide laser. In addition to the following potential risks, there may be risks that are unknown at this time. If new information concerning risks becomes available, you will be informed as soon as possible.

Common

Common side effects from treatment with the MiXto SX laser include these:

Redness lasting for a few hours to a few days
Swelling lasting for a few hours to a few days
Tenderness during the treatment and immediately after
Flaking of skin
Activation of oral herpes (cold sores)

Less Common

Swelling lasting over one week
Redness lasting over one week
Hyperpigmentation (darker discoloration), temporary or permanent
Hypopigmentation (lighter discoloration), temporary or permanent

Rare but Serious

Blistering
Scarring

POTENTIAL BENEFITS:

Potential benefits include removal of brown spots, decrease in wrinkling, improved skin texture, new collagen production, and mild tightening of the skin. However, it is possible that you may not benefit at all from participating in this study. The researchers hope that the knowledge gained from the study will help improve treatments in the future.

ALTERNATIVE TREATMENTS:

Acceptable alternative procedures to the MiXto SX laser include, but are not limited to: no treatment, deep chemical peels, other laser treatments, Botox, and injectable fillers.

REPRODUCTION:

Caution is necessary with all procedures during pregnancy because long-term effects are unknown. Women of reproductive potential must use an effective method of contraception because of the use of medicines at the time of laser treatment. You must notify Dr. Cedars or Dr. Wall if there is any possibility that you are pregnant prior to any treatment.

COMPENSATION:
At the time of your final (4-month) visit, you will receive partial compensation for parking for all of your visits. In addition, we will provide you at no charge a re-usable cold facial mask and sunscreen to be used after treatment.

COSTS:
Insurance companies generally do not cover the costs of laser treatment for cosmetic purposes. You will be responsible for the costs of this treatment.

RESEARCH-RELATED INJURY:

If you experience a research-related injury, medical treatment will be made available. In the event an illness or injury is directly attributable to the use of the research laser, Dr. Cedars and Dr. Wall will provide care for the problem at no charge. However, care by other health care providers or care at hospitals will not be reimbursed by these physicians, and these costs will be billed to your insurance. If your insurance does not pay, you will be responsible for these costs. Dr. Cedars and Dr. Wall and Alta Bates Summit Medical Center are not financially responsible for the treatment of side effects or injuries caused by participation in this study. Financial compensation for such things as lost wages, disability or discomfort due to injury, transportation costs, etc., is not available.

THE RIGHT TO WITHDRAW:
You may withdraw from this study at any time without prejudice to Dr. Michael Cedars, Dr. Tomi Wall, or future medical care. Your course of treatment may be terminated by your physician without your consent if she/he deems it necessary in the best interests of your health. The sponsor may also stop your participation at any time.

QUESTIONS:
If you have any further questions about the study or if you have a research-related injury, you should call Dr. Michael Cedars at (510) 763-2662 or Dr. Tomi Wall at (773) 882-4421. If you have any questions or comments about participation in this study, you should first talk with the investigators. If you have additional questions

about your rights as a participant in a research project, you may contact the Summit Institutional Review Board at (510) 204-1414.

CONFIDENTIALITY:

All personal information will be held confidential and will not be released without your written permission, to the extent permitted by law. However, it is expected that the results of the study will be published. Your records and results will not be identified in any publication resulting from these studies as pertaining to you specifically. By signing this consent form, you give permission for the release of your clinical records (information gathered from your participation in the study) to Lasering USA, for review by the Summit IRB, for possible submission to the FDA, and also for possible publication by the doctor and/or her/his colleagues. Your pertinent medical records may be reviewed by federal or state officials.

Photos taken of your face before and after the laser treatment may be published in medical journals. You will not be identified by name, but the photos may include images of your entire face.

CONSENT:

You have been given copies of this consent form and the Experimental Subject's Bill of Rights to keep.

PARTICIPATION IN RESEARCH IS VOLUNTARY. I have the right to decline to participate or to withdraw at any point in the study without jeopardy to my medical care. If I wish to participate, I should sign below.

With full knowledge of the above information, I consent to participate in this research study.

Note: Must have both printed names and signatures in this section.

_____ _____

Signature of Patient Date

_____

Printed Name of Patient

_____ _____

Signature of Person Obtaining Consent Date

_____

Printed Name of Person Obtaining Consent

Alta Bates Summit Institutional Review Board
Alta Bates Summit Medical Center
Experimental Subject's Bill of Rights

The rights listed below are the rights of every person who is asked to be in a research study. As an experimental subject, I have the following rights:

1. To be told what the study is trying to find out,

2. To be told what will happen to me and whether any of the procedures, drugs, or devices are different from what would be used in standard practice,

3. To be told about the frequent and/or important risks, side effects, or discomforts of the things that will happen to me for research purposes,

4. To be told if I can expect any benefit from participating, and if so, what the benefit might be,

5. To be told the other choices I have and how they may be better or worse than being in the study,

6. To be allowed to ask any questions concerning the study both before agreeing to be involved and during the course of the study,

7. To be told what sort of medical treatment is available if any complications arise,

8. To refuse to participate at all or to change my mind about participation after the study is started. This decision will not affect my rights to receive the care I would receive if I were not in the study,

9. To receive a copy of the signed and dated consent form,

10. To be free of pressure when considering whether I wish to agree to be in the study.

If I have other questions, I should ask the researchers or the research assistant. In addition, I may contact the Summit IRB (which is concerned with protection of volunteers in research projects). I may reach the IRB's office by calling: 510-204-1414 or by writing to the Alta Bates Summit Institutional Review Board, IRB Office, Alta Bates Summit Medical Center, 2450 Ashby Avenue, Berkeley, CA 94705.

_____ _____
Patient Signature Date

_____ _____
Signature of Person Obtaining the Consent Date

Alta Bates Summit Medical Center
____ Alta Bates /Herrick Campus _____Summit Campus

Patient Authorization for the Use and Disclosure of Protected Health Information for Research Purposes

Participant Name _____

Principal Investigator: Michael G. Cedars, M.D. Phone: 510 763-2662__

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Protected Health Information (PHI) is any health information including medical records, mental health records, billing records, survey data, and demographic data that is identified to you. By signing below, you are authorizing the Principal Investigator and the research team to collect, store, use and disclose the PHI described below. You are also authorizing the Principal Investigator and research team to request copies of your medical and/or billing records from the providers listed.

Your authorization is required for participation in the Research Study. You may revoke your authorization at any time by sending a written notification to the Principal Investigator at the address listed above. We will discontinue collecting, using or disclosing your information except as required to maintain the integrity of the Research Study or as required by law. For example, we may need to use your information to document why you have withdrawn from the study, for compliance reporting purposes, or to report adverse events.

During the Research Study, your Research team will look at the following information:

[ ] Billing records for healthcare services
[X] Medical records
[ ] Lab, pathology and/or radiology results
[ ] Mental Health records
[ ] Previous Research records
[X] Questionnaires and interviews
[ ] Other (specify)

During the Research Study, your Research team may disclose your PHI to the following individuals or organizations:

[X] Summit Institutional Review Board for oversight purposes
[X] Study sponsor --Lasering USA
[X] Office for Human Subjects Research or the Food and Drug Administration (FDA) for safety, efficacy, and compliance reports
[X] Statistician for data analysis
[ ] Outside lab for specimen processing
[ ] Others (list all that apply)_____

During the Research Study, we may request copies of your PHI from the following sources (list all that apply):

Name_____ Name_____
Address_____ Address_____

[ ] _____ If this boxed is checked and initialed, I authorize the Principal Investigator named above to obtain copies of any of my medical records needed for purposes of the research study during my enrollment.

[ ] _____ If this box is checked and initialed, I acknowledge that my right to access my health information pertaining to the Research study will be suspended until the study is concluded.

Alta Bates Summit Medical Center is required by State and Federal laws to protect your information. California law prohibits the recipient from making further disclosure of your health information unless the recipient obtains another authorization from you or unless the disclosure is required or permitted by law. This protection does not extend to recipients outside the state of California. There is always the possibility that your information could be disclosed to a party that is not required to protect its confidentiality. Your identity will not be revealed in any publication that may result from this study.

I hereby authorize the Principal Investigator listed above and the research team to use and disclose my protected health information as described above for research purposes.

Signature_____ Date_____

Name_____ Authorization expiration_____