SUBJECT INFORMATION AND CONSENT FORM
AND
AUTHORIZATION TO DISCLOSE HEALTH INFORMATION

Sponsor / Study Title:	**Venus Concept Inc. / "Pilot Study for the Clinical Evaluation of Mechanical Coring to Achieve Directional Skin Tightening"**
Protocol Number:	**AI0620**
Principal Investigator: (Study Doctor)	**David Berman, M.D.**
Telephone:	**(650) 325-6000** **(650) 619-0199 (24-Hours)**
Address:	**Berman Skin Institute** **4300 El Camino Real Suite 100** **Los Altos, CA 94022**

What is the purpose of this form?
You are being asked to participate in a research study involving an investigational skin coring device to determine if it can remove small pieces of skin to tighten the skin in that area. 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 do not 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.

You must be honest with the investigator about your health history or you may harm yourself by participating in this study.

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

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.

What is the purpose of this study?
This study is being conducted to evaluate the ability of a micro-coring device (the "coring device") to successfully remove tiny pieces of skin to tighten the skin in the treated area. Medical glue or Tegaderm (a kind of elastic tape) will be used to close the treated area. The goal is that this technique can be used in

the future as a way of reducing wrinkles, scars or removing skin laxity (loose skin) in patients looking for such treatments. We hope to develop a robot to be able to help doctors to do these treatments.

What is the study treatment?
You will be treated a single time with the coring device over 6 areas: one behind each ear (about 1 by 0.5 inch in size) and two on each underarm (about 1 by 3/4 inch in size). The treatment in each area may be slightly different. For example, the size of the needle, the depth and amount of skin removed may be varied slightly. The areas that will be treated will be numbed so you do not feel any pain.

What do you need to know about this study treatment? How long will my participation in the study last?
Up to 40 healthy, adult men and women subjects, 30 to 70 years of age, will be asked to take part in this study at up to 3 clinical centers. The study will consist of a screening visit and study treatment visit that may occur on the same day or within a week of the screening visit. You will then be asked to return for follow up visits 2, 7, 14, 28, 60 and 90 days after the treatment for a follow up visit. Your total participation will be approximately 3 months.

The screening visit will take approximately 60 minutes. The study treatment visit will take approximately 90 minutes. The follow-up visits will take approximately 60 minutes.

What are my 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, current conditions and medications.
- 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 are currently receiving or have received within 1 month before the planned start of study treatment, an investigational drug / investigational medical device.
- Tell the study doctor if you have had any injection of fat, collagen, silicone or other synthetic material behind the ear and/or on your underarms.
- Tell the study doctor if you have had any previous aesthetic (device or surgical) skin treatment behind the ear and/or on your underarms.
- Tell the study doctor if you have any history of keloid (firm, rubbery scar) formation.
- Tell the study doctor if you are an active smoker or have quit in the last 3 months.
- Tell the study doctor if you have any skin piercing in the study treatment areas.
- Tell the study doctor if you have any active, chronic, or recurrent infections.
- Tell the study doctor if you have a compromised immune system and/or healing system (e.g., if you have diabetes).
- Tell the study doctor if you have any allergies to any medications including painkillers.
- Tell the study doctor if you have had any cancer in the last 6 months.
- Tell the study doctor if you are pregnant or breastfeeding or plan to get pregnant in the next 3 months.
- If you are a woman of childbearing age, tell the study doctor if you have been abstaining from sexual intercourse, or have been using an adequate means of birth control for the last 3 months. You will also be required to abstain or use an adequate means of birth control from the day you sign this document until you finish this study.
- You may be required to stop medications or activities while participating in this study.
- Be willing and able to follow the study directions and procedures
- Tell the study staff about any side effects or problems

- Ask questions as you think of them
- Tell the investigator or the study staff if you change your mind about staying in the study

What will happen during the study?

Screening Visit

- 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 demographic information (age, race, etc.) about your medical history, height, weight and any medications you are currently taking.
- If you are a woman of childbearing potential, a sample of your urine, approximately 2 teaspoons (10 ml) will be taken to determine if you are pregnant.
- The study doctor will conduct a physical examination.
- The study doctor will review whether you are eligible to participate in the study.

Study Treatment Visit

- The first study treatment visit may be combined with the screening 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 breathing rate, and blood pressure.
- Temporary tattoo ink will be used to mark the edges of the treatment areas. This tattoo ink will come off on its own with time.
- You will receive a single coring device study treatment on each of the 6 treatment sites.
- Immediately following the treatment, a small dental probe may be inserted into a few of the treatment holes to measure their depth.
- Immediately after the treatment, you will be asked to indicate your discomfort/pain by drawing a line on a visual analog scale. Please note that you will be rating your discomfort/pain related to the study treatment using a 10 cm scale. You will mark how much pain you feel on this scale.
- Photographs of the treatment areas will be taken. By signing this consent form you agree to having your picture taken.
- Ultrasound or Optical Coherence Tomography may be used to take images of your treated skin. These devices allow staff to "see" your skin below the surface.
- The areas that were treated will be closed using Tegaderm or glue to help with the healing. You will be asked not to remove the Tegaderm. This will be done by study staff either at your return visit either 2 or 7 days after the treatment.
- You will be asked about any side effects you may be having.

Follow-Up Visits

- You will be asked to return for follow up visits 2, 7, 14, 28, 60 and 90 days after the treatment.
- The study staff will review your health status, medications you are currently taking and any changes since your last visit.
- Photographs of the treatment areas will be taken.
- If any of your treated areas were covered with Tegaderm, the Tegaderm will be removed at either the Day 2 or Day 7 Follow-Up Visit. If the Tegaderm falls off on its own when you are outside the clinic, the study staff will ask you when this happened and the circumstances/reasons for why it fell off.
- The study doctor or study staff will evaluate how your treatment sites are healing.
- The tattoo marks will be reapplied in the same spots to ensure they are visible at the next visit. This will not be done at the 90 Day visit.
- At the Day 7, 14, 28, 60 and 90 visits, study staff will measure the treatment areas made by the tattoo marks to see if they changed in size.

- Ultrasound or Optical Coherence Tomography may be used to take images of your treated skin. These devices allow staff to "see" your skin below the surface.
- At the Day 28, 60 and/or 90 visits you may be asked to provide skin biopsies (pieces of skin that will be removed using a needle). This will allow us to study your skin under the skin surface using a microscope. Biopsies are optional.
- At each follow up visit you will be asked to fill out a Subject Questionnaire. This questionnaire will ask questions about your recovery from the treatment.
- You will be asked about any side effects you may be having.

What are the potential risks associated with the study procedures using the investigational coring device?
If you do not understand what any of these side effects mean, please ask the investigator or study staff to explain these terms to you.

Because this device is investigational, all of its side effects may not be known. There may be rare and unknown side effects. Some of these may be life threatening.

You must tell the investigator or study staff about all side effects that you have. If you are not honest about your side effects, you may harm yourself by staying in this study.

Skin coring has been done in the past. It is well tolerated by most people. The most common side effects to date are as follows:

- Bruising
- Swelling
- Bleeding
- Tenderness

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

Very rarely, there may be possible:

- Scarring on the treated skin
- Infection
- Nerve damage at the site of treatment
- Hyperpigmentation (skin turns darker)
- Hypopigmentation (skin turns lighter)

What are the additional risks or discomforts?
Biopsy:

If you undergo a biopsy, there may be side effects such as:

- Pain
- Bruising
- Bleeding
- Infection

Birth control, dangers of pregnancy and breastfeeding
If you are a female, you must not get pregnant while in this study. The only certain way to not get pregnant is to not have sex. If you are a female and choose to have sex, you must use a reliable method of birth control for at least 3 months prior to the study. The study investigator will discuss this with you. If you become pregnant during the study, you will be withdrawn from the study.

If you are a man, it is suggested that you use birth control if you choose to have sex with women while in this study.

Even if you use birth control during the study, there is a chance you or your partner could become pregnant. If you or your partner are pregnant or become pregnant during the study, the study device or procedure may involve unforeseeable risks to the unborn baby. A pregnancy test is not always right, especially in the early stages of pregnancy.

If you are pregnant or breast-feeding, you will not be able to take part in this study. It is not known whether the device can be given to breast fed babies. There may also be risks that are currently unforeseeable.

If you or your partner become pregnant during the study, immediately contact the study doctor. You or your partner will be asked to provide information about the outcome of the pregnancy.

What are the potential benefits of participating in the study?
This study involves normal, healthy subjects. You will receive no medical benefits from participation in this study. Your participation will provide valuable information about the use of skin coring technology. This may benefit the development of treatment for patients with wrinkles, scars, skin laxity and/or other conditions.

What are my alternatives to participating in the study?
Since this research is for research only, the only other choice would be not to be in the study.

Who do you contact in the event of an emergency?
If you experience a side effect 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 the study doctor immediately with any question or concerns you might have.

What happens if you have a study treatment-related injury?
If you become ill or are hurt while you are in the study, get the medical care that you need right away. You should inform the healthcare professional treating you that you are participating in this 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).

To pay these medical expenses, the sponsor will need to know some information about you like your name, date of birth, and social security number or Medicare Health Insurance Claim Number. This is because the sponsor has to check to see if you receive Medicare and if you do, report the payment it makes to Medicare.

Legal Rights
You do not give up any of your legal rights by signing and dating this consent form, nor release the study doctor or sponsors from their legal and professional obligations.

Will it cost you anything to participate in this study?
You will not be charged for the study treatment.

Will you be paid for participating in this study?

For completing this study in its entirety and agreeing to provide skin biopsies, you may be compensated up to a total of $1,000.00. Your full compensation will be given to you at the end of your participation.

If you withdraw or are withdrawn from the study, or do not complete the study in its entirety for any reason, you will be compensated on a **pro-rated** basis (compensation based on study visit completed). You may not be eligible for the entire amount. Please note that you will not be considered a study subject until you are treated.

You may have $50.00 deducted from your compensation amount if you are late for any visits. If you miss a follow up visit, you will have $100.00 deducted from your compensation amount. You may also be removed from the study.

See below for compensation details:

Period Details	Explanation of Compensation
If you attend the Treatment Visit	$200.00
If you agree to provide biopsies (small skin samples) at one or more visits	$100.00
If you complete the study in its entirety without biopsies (Treatment and all 6 Follow-up Visits)	$900.00 ($800.00 for treatment and all follow up visits plus $100.00 study completion amount)
If you complete the study in its entirety with biopsies (Treatment, all 6 Follow-up Visits, and biopsies)	$1000.00 ($800.00 for treatment and all follow up visits plus $100.00 for biopsies plus $100.00 study completion amount)

The study completion amount will only be given to participants who complete the study. If for any reason you are not able to attend all study visits and complete all study procedures, you will not receive the study completion amount. You are not required to provide biopsies to receive the study completion amount.

You may be required to report the payment received for this study to the Internal Revenue Service as taxable income.

Do you have to be in this study?
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 to 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, let the study investigator or study staff know as soon as possible. If you withdraw early, you will be asked to complete the final visit, however, you have the right to refuse. If information generated from this study is published or presented, your identity will not be revealed. If you leave the

study, no more information about you will be collected for this study. However, all of the information you gave us before you left the study will still be used.

The study doctor, Advarra IRB, and/or the sponsor, Venus Concept, Inc., also have the right to terminate your participation in the study if you are unable to tolerate the study treatment, if we find out you should not be in the study, the study is stopped or if you are non-compliant with the study procedures.

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

Who will have access to your study treatment records and/or medical information?
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 you or other 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 an assigned 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 such time as you complete the study or terminate early and withdraw your consent. The information concerning this study may be made available to the U.S. Food and Drug Association (FDA), or other state or federal regulatory agencies of other countries and Advarra IRB. 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, 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 2 years following completion of the study if the coring device is not approved or 2 years after the coring device is approved by the FDA.

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

The Institutional Review Board (Advarra IRB) and accrediting agencies may inspect and copy your records, which may have your name on them. Therefore, total confidentiality cannot be guaranteed. If the study results are presented at meetings or printed in publications, your name will not be used.

Whom To Contact About This Study
During the study, if you experience any medical problems, suffer a research-related injury, or have questions, concerns or complaints about the study, please contact the study doctor at the telephone number listed on the first page of this consent document. If you seek emergency care, or hospitalization is required, alert the treating physician that you are participating in this research study.

An institutional review board (IRB) is an independent committee established to help protect the rights of research subjects. If you have any questions about your rights as a research subject, and/or concerns or complaints regarding this research study, contact:

- By mail:
  Study Subject Adviser
  Advarra IRB
  6100 Merriweather Dr., Suite 600
  Columbia, MD 21044
- or call **toll free**: 877-992-4724
- or by **email**: adviser@advarra.com

Please reference the following number when contacting the Study Subject Adviser: Pro00051616.

REQUIRED FOR CALIFORNIA SITES ONLY:
Subject's Bill Of Rights
You will be given a separate copy of the California Experimental Research Subject's Bill of Rights. If you have not received a copy of this document, please notify study staff.

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.**

Check one of the two options below:

☐ I AGREE for biopsies (small tissue samples) to be collected from the sites of treatment during the study. I know that I may change my mind at any stage without affecting my present or future medical care.

☐ I DO NOT AGREE for biopsies (small tissue samples) to be collected from the sites of treatment during the study.

_____ _____

Subject (signature) Date

_____

Print Subject Name

STATEMENT OF PERSON EXPLAINING CONSENT

I have carefully explained to the subject the nature and purpose of the above study. There has been an opportunity for the subject to ask questions about this research study. I have been available to answer any questions that the subject has about this study.

_____ _____

Study Staff (signature) Date

_____

Print Study Staff Name

HIPAA Authorization Agreement
Permission to Review, Use and Release Information about You

If you decide to be in this study, the study doctor and research team will use and share health data about you to conduct the study. Health data may include:

- Your name.
- Address.
- Phone number.
- Date of birth.
- Medical history and information contained in your medical records.
- Information from your study visits, including all test results.

Health data may come from your study records or from existing records kept by your doctor or other health care workers.

For this study, the research team may share health data about you with authorized users. Authorized users may include:

- Representatives of Venus Concept Inc.
- Representatives of Advarra IRB (an Institutional Review Board that reviews this study).
- The Food and Drug Administration (FDA) and other US governmental agencies.
- Government agencies to whom certain diseases (like HIV, hepatitis, and STDs) must be reported.
- Governmental agencies of other countries.
- Labs working with the sponsor on this study.
- Other authorized users such as staff working at the study doctor's clinic.

The sponsor and those working for the sponsor may use the health data sent to them:

- To see if the study device works and is safe.
- To compare the study device to other devices.
- For other research activities related to the study device.
- To seek marketing approval of the study device or other new products.
- To comply with applicable laws.
- To develop future research studies.

Once your health data has been shared with authorized users, it may no longer be protected by federal privacy law and may be re-shared by the authorized users.

Your permission to use and share health data about you will not end unless required by state law. If state law applies, your permission to use and share health data about you will end on December 31, 2070.

You may take back your permission to use and share health data about you at any time by writing the study doctor at the address listed below:

If you do this, you will not be able to stay in this study. No new health data that identifies you will be gathered after your written request is received. However, health data about you that has already been gathered may still be used and given to others as described in this form.

Your right to access your health data in the study records will be suspended during the study to keep from changing the study results. When the study is over, you can access your study health data.

If you decide not to sign and date this form, you will not be able to take part in the study.

STATEMENT OF AUTHORIZATION

I have read this form and its contents were explained. My questions have been answered. I voluntarily agree to allow study staff to collect, use and share my health data as specified in this form. I will receive a signed and dated copy of this form for my records. I am not giving up any of my legal rights by signing and dating this form.

_____ ____/____/____

Signature of Research Subject Date

_____

Printed Name of Research Subject

STATEMENT OF PERSON EXPLAINING AUTHORIZATION

I have carefully explained to the subject the nature and purpose of this form.
I have been available to answer any questions that the subject has about this form.

_____ ____/____/____
Signature of Person Explaining Authorization Date

_____
Printed Name of Person Explaining Authorization