CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Study SUN-15-04: The Use of Bellafill® for Atrophic Acne Scar Correction in the Full Facial Area

INVESTIGATOR:	TELEPHONE:

WHAT IS THIS STUDY ABOUT?

You are being asked to participate in a research study designed to evaluate the safety and efficacy of Bellafill injection (a collagen gel polymethymethacrylate (PMMA) microsphere based filler material) for the correction of facial acne scars.

Bellafill has been proven to be safe and effective in improving the appearance of atrophic acne scars by raising the base of the scar so that it is level with the surrounding skin. The FDA approved Bellafill for the correction of acne scars in December 2014.

The study involves up to 50 normal healthy male or female participants, 21 years of age or older who desire correction of their acne scarring with an injectable filler. The study will be sponsored and financed by Suneva Medical, Inc. and conducted at approximately 10 sites in the U.S.

HOW LONG WILL I BE IN THE STUDY?

If you decide to be in this study and the study doctor says you can be in the study, your participation will last approximately 8 months. You will have to come to the study site for 5 visits.

WHAT WILL HAPPEN DURING THIS STUDY?

You will get treatment with Bellafill injection on your face, as well as touch up treatments (if necessary to achieve optimal correction). The Bellafill treatment in this study is provided to you at no charge.

To participate in the study, you must also agree to the following responsibilities:

- You must review and sign this informed consent form and a Health Insurance Portability and Accountability Act (HIPAA) release. You must sign the photography release section on the last page of this informed consent form allowing for the use of your photographs for the research purposes of this study. You have the option to also allow your photographs to be used for publication and promotional purposes. All of your questions should be answered before signing this form. By signing these forms, you agree to follow the study doctor's instructions.
- Prior to attending all study visits, you must refrain from applying facial cosmetics.
- You must not use any cosmetic procedure(s) in the face during the study period including the non-study "filler" treatment(s) during the study period, or you may be discontinued from the study.
- Prior to the use of acne therapies, you must obtain permission from your study doctor (to ensure that they will not interfere with the Bellafill treatment).
- If you are a female who is at age where you could become pregnant, you must use a medically effective contraception and practice such contraceptive method throughout the study.

Visit 1 (Screening Visit, Month -1): This visit lasts about 45 minutes. The study doctor will assess acne scars and determine if you are eligible to participate in this study. Your medical history, current medical conditions, medication use, and previous treatment received will be reviewed. You may be asked to stop using some medications such as aspirin. A urine pregnancy test (UPT) will be performed if you are of childbearing potential. Your face will be photographed and the doctor will rate the severity of your scars. You will receive a "Bellafill Skin Test" where a very small amount of collagen (0.1cc) will be implanted into the skin of your forearm (to confirm that you are not sensitive to the collagen that is part of Bellafill).

Visit 2 (Treatment Visit, Day 0): This visit lasts about 60 minutes. Your Bellafill skin test results will be reviewed and, you will be asked if you have used any new medications/treatments. If applicable, a UPT will be performed. You will complete a short questionnaire, and then you will receive injections of Bellafill to treat your acne scars.

Visit 3 (Month 1): This visit lasts about 60 minutes. You will be asked if you experienced any side effects or used any new medications/treatments since the last visit. If applicable, a UPT will be performed. The study doctor will examine you and determine if touch-up injections of Bellafill are required to obtain optimal treatment effect.

Visit 4 (Month 4): This visit lasts about 30 minutes. You will be asked if you experienced any side effects or used any new medications/treatments since the last visit, and both you and the study doctor will assess the appearance of your acne scars.

Visit 5 (Month 7): This visit lasts about 45 minutes. You will be asked if you experienced any side effects or used any new medications/treatments since the last visit. Your face will be photographed, and both you and the study doctor will assess the appearance of your acne scars. You will also complete a short questionnaire. **You will EXIT the study.**

ARE THERE RISKS TO ME IF I AM IN THE STUDY?

You may experience some pain when the filler is injected under your skin. This injection is permanent, and the filler cannot be removed without surgery. Side effects of Bellafill® implant may include:

- lumpiness at injection area more than one month after injection
- swelling, redness, rash, itching, infection or increased sensitivity at the injection sites
- blurred vision
- flu-like symptoms or allergic reactions
- inflammation or enlargement of the implant
- bruising

When the Bellafill skin test is conducted, you may experience some pain when the filler is injected under your skin. Side effects of the Bellafill skin test may include:

- swelling, redness, rash, itching, bruising, infection or increased sensitivity at the injection sites
- blurred vision
- flu-like symptoms or allergic reactions
- inflammation or enlargement of the implant

As in any research study, the possibility of unknown risks exists. You will be notified if any significant new findings or additional information is discovered during the course of this study, which may affect your willingness to continue participating in this study.

The safety of Bellafill® for use during pregnancy, in breast feeding females, or in patients under 18 years of age has not been established. All women of childbearing potential must have urine pregnancy tests prior to receiving Bellafill treatments (including touch-ups), and must use medically acceptable methods of contraception. Medically acceptable methods of contraception are hormonal methods (contraceptive pill or implant), an intrauterine device (IUD), barrier method such as diaphragm plus spermicide, condom plus spermicide, or vasectomized partner(s). Barrier methods must be in use at least 14 days prior to study drug administration, hormonal methods and IUDs must be in use at least 30 days prior to study administration. Females of childbearing potential who are not sexually active or who have a male partner who has had a vasectomy at least 3 months prior to receive Bellafill treatment (or who has a confirmed '0' sperm count) are not required to use reliable method of contraception.

WHAT ARE THE POTENTIAL BENEFITS?

A potential benefit is that your acne scarring is partially or fully corrected, however this is not guaranteed.

WILL I GET PAYMENT?

You will receive compensation for each visit that you attend., i.e., Visit 1 25.00, Visits 2 thru 4 $50.00 for each visit and $75.00 for Visit 5. The total payment for your participation will depend upon your treatment group assignment and the total number of visits you complete. These payments are for your time, travel expenses, and inconvenience. You will be paid by check at the end of the study only for the visits you attended. If you stop participating before completing the study, you will be paid for visits you completed.

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

If you experience an injury or illness as a result of your study participation you will be provided with free medical care to treat such injury or illness. No financial payments or other form of compensation (such as for lost wages or discomfort) will be offered to you for such injuries; however, you do not give up any legal rights by signing this

form. If you experience an injury, illness or side effect, you should contact: **XXXX 24 hours a day at: (XXX) XXX-XXX**

WHO WILL USE AND SHARE INFORMATION ABOUT MY BEING IN THIS STUDY?

Information in your medical records (including your identity) relating to this study will be kept as confidential as possible under laws and regulations and will not be made publicly available. If the results of the trial are published, you identity will remain confidential. Any information about you that is sent out the clinic will be coded; this means that it will not be identified by name, only by your initials, gender (female/male), birth date and a coded number.

The FDA, Suneva Medical (Study Sponsor, manufacturer of Bellafill), ethica CRO Inc. (the company managing this study), as well as representatives of Veritas IRB may review your medical records related to this study to perform verification without violating your confidentiality. Your coded personal information (including your photographs) may be disclosed to Canfield Scientific (a third party photographic vendor).

The information collected during this study will be kept on file for 2 years after the end of the study. The data from this study will only be used for the research related to this study. Data will be stored in a secured database, and study records will be kept in a locked room at the office of the study doctor.

CLINICAL TRIAL REGISTRY DATABANK: A description of this clinical trial will be available on http://www.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.

WHO CAN I TALK TO ABOUT THE STUDY?

If you have any questions about this study or experience what you feel is a research-related injury or illness, please contact **Dr. XXX at (XXX) XXX-XXXX .**

This study has been reviewed and approved by Veritas Independent Review Board (IRB). If you have any questions about your rights as a research participant or the Investigator's responsibilities, you may contact the Manager of Veritas IRB (Independent Review Board) 24 hours per day and 7 days per week at 514-337-0442 or toll free at 1-866-384-4221. An IRB is a group or scientific and non-scientific individuals who perform the initial and ongoing ethical review of the research study with the subjects' rights and welfare in mind. If you have any study-related comments, complaints or concerns you should first contact the study investigator. Please call the IRB if you need to speak to a person independent from the Investigator and the research staff, and/or if the Investigator and the research staff could not be reached.

The study doctor, the FDA or the IRB may stop your participation at any time with or without your consent.

DO I HAVE TO BE IN THE STUDY?

You do not have to be in the study and can choose not to participate. If you decide to participate in this study, your decision is completely voluntary. Your signature on this form shows your voluntary consent. You may withdraw your consent at any time for any reason and stop your participation. If you choose not to participate or start and later withdraw, you do so without affecting your current or future medical care or benefits to which you are otherwise entitled at this office. If you decide to withdraw during the study, you should contact **Dr. XXX at (XXX) XXX-XXXX .** to arrange for the completion of end-of-study activities, which may include one visit to the study doctor's office for a final exam of the area injected, if possible.

You agree that the study doctor can remove you from this study without your consent for any reason, including, but not limited to:

- There exists a condition or circumstance that may jeopardize your welfare or the integrity of the study.
- Your failure to follow the instructions of the study doctor.
- If the study is stopped by the doctor participating in the study prior to completion**.**

PREGNANCY:

I understand that I should not be enrolled into this study if I am pregnant. If you become pregnant during the study and you choose to continue the pregnancy, you must immediately inform the study doctor. By signing this form, you agree to give **Dr. XXXX** access to your and/or your infant's medical records for the time of pregnancy and for at least 8 weeks following delivery if you become pregnant during the study.

CONTACT WITH YOUR PRIMARY PHYSICIAN

I, the undersigned, confirm that:

☐ **I HAVE A PRIMARY PHYSICIAN AND**

- ☐ *Agree that the investigator contact my primary physician to inform him/her of my participation in the study described in this document.*
- ☐ *Disagree that the investigator contact my primary physician to inform him/her of my participation in the study described in this document.*

☐ **I DO NOT HAVE A PRIMARY PHYSICIAN**

Participant:

_____

Printed Name Signature Date

Person Explaining Consent (e.g. Study Nurse, Investigator):

_____

Printed Name Signature Date

IF YOU WANT TO PARTICIPATE IN THIS STUDY, please read and sign the following pages and the HIPAA (and the California Experimental Subject's Bill of Rights if applicable).

I have read this form, and I have been able to ask questions about this study. The study doctor or study staff has talked with me about this study and they have answered all my questions. I voluntarily agree to be in this study.

I have read this form, and I have been able to ask questions about this study. The study doctor or study staff has talked with me about this study and they have answered all my questions. I voluntarily agree to be in this study. By signing this form I have not given up any of my legal rights as a research participant. I will receive a fully signed copy of this consent form for my records.

_____
Participant's Name (Print)

_____ _____
Participant's Signature Date

I attest that the participant named above had enough time to consider this information, had an opportunity to ask questions, and voluntarily agreed to be in this study.

_____
Name of Person Explaining Consent (Print)

_____ _____
Signature of Person Explaining Consent Date

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

_____
Name of Investigator (Print)

_____ _____
Signature of Investigator Date

PHOTOGRAPHY RELEASE

You confirm voluntarily consenting to the taking, copyright, and use of your picture (your face will be identifiable) and likeness. These photos will be used for the research purposes of the study (eg, determining the severity of your scars by experts other than the study investigators). You will not be able to participate in this study if you do not allow pictures to be taken.

There are other uses for your photographs (eg, publications, promotion of Bellafill, etc.). Please check the "Yes" box for the categories for which you give additional consent for the use of your photographs and the "No" box for the categories for which you do not give additional consent.

YES*	NO	
☐	☐	FOR EDUCATION, PUBLICATIONS, OR INFORMATIONAL PURPOSES*
☐	☐	FOR GENERAL ADVERTISING, PUBLICITY, AND PROMOTIONAL PURPOSES*

** NOTE: You do not have to give consent to either of these two (2) categories to participate in this study.*

By signing this release, you do not forfeit any of your legal rights. It is within your right to revoke this authorization for future uses at anytime.

Participant's name:

_____

Printed Name Signature Date

Investigator:

_____

Printed Name Signature Date