

# NANOFRACTIONAL RF INFORMED CONSENT BOOKLET

#### INSTRUCTIONS

This Informed Consent Booklet has been prepared by potential benefits, associated risks, and alternatives of the Venus Versa<sup>™</sup> Treatment.

to help inform you about the

During your consultation and medical assessment, will have reviewed with you the potential benefits, associated risks, and alternatives of the Venus Versa<sup>™</sup> that are outlined in this booklet. They will have also provided you with answers to any and all questions you may have had about the procedure.

It is important that you read the information contained in this booklet again carefully and completely. Only when all of your questions and concerns about the procedures have been addressed should you then initial each page, indicating that you have read and fully understood all the items discussed in this booklet. When you reach the end of the booklet, please sign the consent for the procedure as proposed by . If you have any remaining questions or concerns about the potential

benefits, associated risks, or alternatives of the Venus Versa<sup>™</sup>, do not initial any pages or sign the consent without speaking with

# INTRODUCTION

Venus Versa<sup>™</sup> is a non-surgical radio frequency nano-fractional device designed to resurface the skin. The device delivers targeted columns of radio frequency energy to the tissue, designed to damage the existing collagen, stimulating the body's natural healing response. Once the collagen has been damaged, the body begins to repair the collagen by replacing the damaged collagen with new collagen. The radio frequency also stimulates the body to produce new fibroblasts, the "houses" that create collagen, thus increasing the amount of collagen in the tissue. This wound healing response creates a smoother appearance to the skin, plumps up fine lines and wrinkles, treats acne scars, and reduces pigmented lesions and textural irregularities of the skin.

#### POTENTIAL BENEFITS OF THE VENUS VERSA™

The Venus Versa<sup>M</sup> will aid in the improvement of the skin texture and appearance. When discussing the potential benefits the Venus Versa<sup>M</sup> with you, may have shown you a variety of before and after images. It is important to remind you that these images were used as an educational tool to allow you to visualize the general range skin texture improvements that may be achieved with your proposed treatment; the before and after images are <u>not</u> meant to be guarantees of actual or exact outcome.

## RISKS ASSOCIATED WITH THE VENUS VERSA™

Every cosmetic procedure involves a very small degree of risk and, although exceedingly uncommon, it is important that you understand and accept the rare risks involved with the Venus Versa<sup>™</sup>. An individual's informed decision to undergo any cosmetic procedure is based upon a comparison of the risks against the potential benefits, alternatives and costs.

Although the vast majority of Venus Versa<sup>™</sup> patients never experience any of these complications, you should discuss each of them with to ensure you fully understand the alternatives, risks, potential complications, and average outcomes of the Venus Versa<sup>™</sup> treatments.

• Blisters - in rare cases, a blister may occur as a result of the treatment. In this instance,

will recommend

for the treatment of the

blister.

- Hyper- or Hypo- pigmentation in very rare cases a patient may experience changes in their skin colour which may or may not be permanent. In these cases, address the changes in the appearance of the colour of the tissue.
- Swelling edema (or swelling of the skin) is common, and will resolve in a few days. Edema may occur as early as immediately post treatment and as late as a few days post treatment. It is advised to seek a consultation and follow up appointment with should you require medical attention or have concerns.

Client Initials: \_\_\_\_\_

\_\_ Date: \_\_



There are many variable conditions, in addition to risks and potential complications listed above, that may influence the longterm result from the Venus Versa<sup>™</sup>. Even though risks and complications can occur infrequently, the risks cited in this booklet are particularly associated with the Venus Versa<sup>™</sup>. Other complications and risks can occur but are even less common. Should complications occur, additional procedures or treatments may be necessary. The practice of medicine and surgery is not an exact science. Although good results are expected, there is no guarantee or warranty, expressed or implied, as to the results that may be obtained. Infrequently, it may be necessary to perform additional treatment to improve results.

## ALTERNATIVES TO THE VENUS VERSA™

# DRIVING AFTER A VENUS VERSA<sup>™</sup> TREATMENT

Post-treatment discomfort and/or sedation, swelling, anxiety, and altered sensation can possibly limit full mobility of the body and/ or face, or cause you to be distracted or drowsy while driving, and thus may compromise the ability to safely drive a car. It is recommended that all clients undergoing any procedure do not operate a vehicle post-treatment if their vision, concentration, or range of motion is impaired in any way. In these circumstances, all clients should have a companion available to drive them home. It is strongly recommended that you have someone accompany you if you take a taxi or ride service home. If you do not have someone to accompany you, it is recommended that you arrange for a limousine to drive you home; arrangements can be made for you by the staff.

#### HEALTH INSURANCE

Most health insurance companies exclude coverage for cosmetic procedures such as the Venus Versa<sup>™</sup>. Health related complications that may arise from such treatment may not be covered by all insurance plans. Please carefully review your health insurance subscriber-information pamphlet, if you have a private insurance carrier.

#### FINANCIAL RESPONSIBILITIES

Depending on whether the cost of treatment is covered by an insurance plan, you will be responsible for all necessary payments. Additional costs may occur should complications develop from treatment. There are no refunds once a treatment has been performed.

#### DISCLAIMER

Informed Consent Booklets are used to communicate information about the proposed treatment of a condition along with disclosure of risk and alternative treatment(s). The informed consent process attempts to define principles of risk disclosure that should generally meet the needs of most patients in most circumstances.

has discussed with you and has been included in this booklet are the material What feels a reasonable person would want to know. risks both common and uncommon that understand, and consider when making decisions to proceed with the proposed treatment.

However, Informed Consent Booklets should not be considered all-inclusive in defining other methods of care and risk encountered. may provide you with additional or different information based on all the facts in your

particular case and the state of medical knowledge.

Informed consent documents are not intended to define or serve as the standard of medical care. Standards of medical care are determined on the basis of all of the facts involved in an individual case, and are subject to change as scientific knowledge and technology advance, and as practice patterns evolve.

It is important that you read the above information contained on this and all preceding pages carefully and have all of your questions answered by before signing the consent on the last page.

> \_\_ Date: \_\_ Client Initials: \_\_\_



# CONSENT FOR PROCEDURE AND/OR TREATMENT

# I HAVE RECEIVED THE FOLLOWING INFORMATION/INFORMED CONSENT BOOKLET FOR: VENUS VERSA<sup>™</sup> NANOFRACTIONAL RF TREATMENT

- and/or such assistants as may be selected to perform the 1. I hereby authorize following procedure and/or treatment:
- 2. I recognize that during the course of the procedure/treatment unforeseen conditions may necessitate different procedures than those above. I therefore authorize the above physician and/or assistants or designees to perform such other procedures that are in the exercise of his or her professional judgment necessary and desirable. The authority granted under this paragraph shall include all conditions that require treatment and are not known to my physician at the time the procedure is begun.
- 3. I consent to the administration of such topical anesthesia considered necessary or advisable. I understand that all forms of anesthesia involve risk and the possibility of complications, injury, and sometimes death.
- 4. As part of the requirements of the \_\_\_\_ \_\_\_\_\_, my chart may be subject to a peer review for quality control.
- 5. I acknowledge that no guarantee has been given by anyone as to the results that may be obtained.
- 6. I consent to the photographing or televising of the procedure(s) to be performed, including appropriate portions of my body, for medical, scientific or educational purposes, provided they do not reveal my identity. These photographs and videos may be used for medical meetings, advertising, or any promotional or public relations purposes.
- 7. For purposes of advancing medical education, I consent to the admittance of observers to the treatment room.
- 8. I understand that the signature of the witness (if a non-physician) on this document indicates only that the signing of my name has been observed and not that the witness has necessarily provided information regarding the procedure.
- 9. IT HAS BEEN EXPLAINED TO ME BY MY PHYSICIAN AND/OR ASSISTANTS IN A WAY THAT I UNDERSTAND:
  - i. THE ABOVE TREATMENT OR PROCEDURE TO BE UNDERTAKEN
  - ii. THERE MAY BE ALTERNATIVE PROCEDURES OR METHODS OF TREATMENT
  - THERE ARE RISKS TO THE PROCEDURE/TREATMENT PROPOSED iii.
  - ANY QUESTIONS I MAY HAVE ASKED HAVE BEEN ANSWERED TO MY SATISFACTION iv.

#### I CONSENT TO THE PROCEDURE AND/OR TREATMENT AND THE ABOVE LISTED ITEMS (1-9). I AM SATISFIED WITH THE EXPLANATION.

Patient or Person Authorized to Sign for Patient

Please Print Name Here

DATE: WITNESS:

Client Initials: \_\_\_\_\_

\_\_\_\_\_ Date: \_\_