

# Versa Hair Removal Informed Consent Booklet

#### **INSTRUCTIONS**

This Informed Consent Booklet has been prepared by Silk, A Medical Spa to help to inform you about the potential benefits and associated risks of, as well as the alternatives to, Venus Versa™ Intense Pulsed Light (IPL) hair removal treatments. During your consultation and medical assessment, Silk, A Medical Spa will have reviewed with you the potential benefits and associated risks of, as well as the alternatives to, the Venus Versa™ IPL hair removal treatments that are outlined in this booklet. They will have also provided you with answers to any questions you may have had about your procedure. It is important that you carefully read the information contained in this booklet. Only when all of your questions and concerns about the procedures have been addressed should you then initial each page, indicating that you have fully read and 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 Silk, A Medical Spa. If you have any remaining questions or concerns about the potential benefits and associated risks of, or the alternatives to, the Venus Versa™ IPL hair removal treatments outlined in this book, do not initial any pages or sign the consent without first speaking with Silk, A Medical Spa.

### INTRODUCTION

Venus Versa™ IPL hair removal treatments are proven, high-tech hair removal procedures. Published studies indicate that IPL treatments can significantly reduce the appearance of unwanted hair with very little maintenance. Venus Versa™ IPL hair removal treatments direct intense pulsed light energy at the skin to disable the growth center of the hair, called the hair follicle. This is possible through a process of "selective photothermolysis," or "radiophotothermolysis," whereby the energy is absorbed by and injures only those tissues around the target. At the base of the hair follicle and hair shaft are pigment cells. The light emitted from the Venus Versa™ IPL device applicator has a specific energy level that lasts a specific duration such that its absorption by the pigment in the hair follicle is maximized. When the energy is absorbed, the heat released is sufficient to disable the hair follicle, which interrupts its ability to produce a hair shaft (a process called "selective photothermolysis"). While delivering the energy to the hair follicle, it is important to cool the skin to avoid injury. A cooling crystal is integrated in the Venus Versa™ IPL applicator to assist with patient comfort and safety. Following Venus Versa™ IPL hair removal treatments, there may be a minor degree of redness and puffiness to the skin, with some tingling or discomfort. These effects usually disappear within 1 hour or up to 2 days. You may apply makeup, body lotion, and sunscreen immediately following treatment and can return to your regular daily activities with no downtime. It is highly recommended you discuss a maintenance program to maintain the cosmetic improvements you obtain with your Venus Versa™ IPL hair removal treatments. Before beginning a Venus Versa™ IPL hair removal treatment program, you must first attend an assessment and information

consultation with a treatment professional, during which your skin type, hair concerns, expectations, and goals will be assessed and discussed. The treatment professional will work with you to select the best treatment or combination of treatments for your unwanted hair concerns, expectations, and aesthetic goals. The estimated duration and cost of each session or series of sessions will also be provided to you during this time. If you are a candidate for Venus Versa™ IPL hair removal treatments, you may schedule your treatments and test spots at the time of this initial consultation.

### POTENTIAL BENEFITS OF VENUS VERSA™ IPL HAIR REMOVAL TREATMENTS

The most obvious potential benefit of Venus Versa™ IPL hair removal treatments is the long-term reduction of unwanted hair.

### RISKS ASSOCIATED WITH VENUS VERSA™ IPL HAIR REMOVAL TREATMENTS

Although the vast majority of Venus Versa™ IPL hair removal treatment patients never experience any complications after treatment, you should still discuss each of these items with your treatment provider to ensure you fully understand the alternatives, risks, and average outcomes of Venus Versa™ IPL hair removal treatments, and the different circumstances that may affect your results.

Venus Versa™ IPL hair removal treatments will leave your skin photosensitized for 48 hours after each treatment. You must avoid sunlight. Failure to do so will result in significant redness and swelling, and may increase the rare risk of disfiguring, and complications like blisters, scarring, or pigment changes.

### Discomfort:

Venus Versa<sup>™</sup> IPL hair removal treatments are very widely well-tolerated. Patient comfort is optimized with the cooling crystal that is integrated in the Venus Versa<sup>™</sup> IPL applicator to assist with patient comfort. Topical anesthetic cream may also be used. You may experience a minor and tolerable degree of burning and/or tingling sensation with each treatment.

## Skin Wound:

It is exceedingly rare for Venus Versa™ IPL hair removal treatments to cause a burn, blister, or skin wound. This is more of a risk for darker or tanned skin types. If a burn, blister, or skin wound develops, it may take 5 to 10 days to heal. In extremely rare instances, it may lead to a noticeable whitening or darkening of the skin, or—even more rarely—a scar. The risk of burns, blisters, or skin wounds is much higher if patients do not follow the recommended use of sunscreen and avoid sunlight, self-tanners, UV light, and fluorescent light exposure.

#### Scarring:

Scarring occurs in less than 0.1% of patients. If you have developed a wound and a scar, the scar may become flat and white (hypotrophic) or large and red (hypertrophic), or it may extend beyond the margins of the original injury (keloid). Subsequent treatment or surgery may be required to improve the appearance of the scar. In some cases, the scar may be permanent. Not following pre- and post-treatment care instructions may increase the likelihood of a skin wound or scar.

### Pigment Change:

With the IPL energy used in Venus Versa™ IPL hair removal treatments, there is a very small risk of temporary hyperpigmentation (increased pigment or brown discoloration) or hypopigmentation (whitening of the skin). Usually

these pigment effects are temporary and resolve over several weeks or months. Permanent hyperpigmentation or hypopigmentation is extraordinarily rare, and may occur in less than one per cent of cases.

### Tanning:

It is essential that you do not tan your skin or use tanning creams prior to your Venus Versa™ IPL hair removal treatments, as the pigment in your skin will absorb some of the IPL energy, increasing your risk of pigment changes or skin wounds. If you have tanned skin, you should not have Venus Versa™ IPL hair removal treatments until the tan has faded appreciably (at least 6 weeks). You should avoid tanning for 2 weeks post-treatment. If you are using artificial tanning creams, allow these to fade for 2 to 3 weeks prior to beginning treatment.

### Bruising:

It is exceedingly uncommon to have any skin bruising following Venus Versa™ IPL hair removal treatments. If bruising occurs, it can

be camouflaged immediately using makeup and will usually resolve in 8 to 10 days. As the bruising fades, there may be a rust-brown

discoloration of the skin (hyperpigmentation) that may require a special cream to fade.

### Infection:

Venus Versa™ IPL hair removal treatments involve no actual cutting, surgery, or skin penetration. Infection is exceedingly rare.

### Excessive Redness and Swelling:

Rarely, a minor degree of redness and/or puffiness of the skin may follow treatment and usually lasts 1 to 2 hours. In rare instances, this redness and swelling may persist for one to two days. Silk, A Medical Spa will assess and prescribe the appropriate treatment.

### Fragile Facial Skin (for Hair Removal on the Face):

The skin overlying the treatment area may become quite fragile. Although uncommon, this fragile skin can become reddened and the outer layer may peel off, much like a blister. This usually settles in 8 to 10 days. Fragile skin or blisters may be more common if post care instructions are not followed.

### Viral Susceptibility:

If you are susceptible to cold sores, please notify your treatment provider, as cold sore eruptions can be common with IPL hair removal treatments. You may need to go on an anti-viral medication during your treatment to control cold sore eruptions.

### Isotretinoin:

If you are currently taking Isotretinoin, an acne medication (e.g. Roaccutane), you must stop taking it at least 3 months prior to your IPL hair removal treatments.

### Additional Treatments:

In most instances, it is recommended that you book a Venus Versa™ IPL hair removal treatment maintenance session every 3 to 6 months after completion of the initial course of treatments to maintain your results.

### Lack of Satisfaction:

Your body's response to IPL hair removal treatments is subject to variation as not all patients or hair will respond the same. However, the overwhelming majority of patients who have undergone Venus Versa™ IPL hair removal treatments report a noticeable reduction in unwanted hair growth beginning after the first treatment. There is a risk

that you may not see an appreciable reduction in the area of unwanted hair.

### Pregnancy:

Although Venus Versa™ IPL hair removal treatments have no known adverse reactions upon a fetus, we do not recommend proceeding with treatments if you are known to be pregnant.

There are many variable conditions in addition to the risks and potential complications listed above that may influence your long-term results from Venus Versa™ IPL hair removal treatments. Even though risks and complications can occur infrequently, the risks cited in this booklet are specific to Venus Versa™ IPL hair removal treatments. Other complications and risks can occur but are even less common. Should complications occur, additional surgery or treatment(s) may be necessary. The practice of medicine 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 is necessary to perform additional treatment(s) to improve your results.

#### **HEALTH INSURANCE**

Unwanted hair is a cosmetic concern that poses no medical or healthcare threat. Most health insurance companies exclude coverage for these treatments.

Complications that may occur from such treatments are usually considered a healthcare concern and may be covered. Please carefully review the health insurance subscriber-information pamphlet specific to your plan if you have a private insurance carrier.

#### FINANCIAL RESPONSIBILITIES

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 the disclosure of risk(s) 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.

The contents of this booklet and any discussions with Silk, A Medical Spa are the material risks, both common and uncommon, that Silk, A Medical Spa feels a reasonable person would want to know, understand, and consider when deciding how and if they wish to proceed with the proposed treatment of their condition. However, Informed Consent Booklets should not be considered all-inclusive in defining other methods of care and risks encountered.

Silk, A Medical Spa may provide you with additional or different information that is based on all the facts in your particular case and 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 carefully read the above information contained on this and all preceding pages and have all of your questions answered by Silk, A Medical Spa before signing the consent on the last page of this booklet.

HAVE RECEIVED THE FOLLOWING INFORMATION/INFORMED CONSENT BOOKLET FOR: VENUS VERSA™ IPL HAIR REMOVAL TREATMENTS

- 1. I hereby authorize Silk, A Medical Spa to perform the 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 Silk, A Medical Spa 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. As part of the requirements of the, my chart may be subject to a peer review for quality control.
- 4. I acknowledge that no guarantee has been given by anyone as to the results that may be obtained.
- 5. 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.
- 6. For purposes of advancing medical education, I consent to the admittance of observers to the treatment room.
- 7. 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.
- 8. IT HAS BEEN EXPLAINED TO ME BY SILK, A MEDICAL SPA 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
- iii. THERE ARE RISKS TO THE PROCEDURE/TREATMENT PROPOSED
- iv. ANY QUESTIONS I MAY HAVE ASKED HAVE BEEN ANSWERED TO MY SATISFACTION

I CONSENT TO THE PROCEDURE AND/OR TREATMENT.

I AM SATISFIED WITH THE EXPLANATION.

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