



## Versa Intense Pulsed Light Informed Consent Booklet

### INSTRUCTIONS

This Informed Consent Booklet has been prepared by Silk, A Medical Spa to help inform you about the potential benefits, associated risks and alternatives of the Versa IPL Treatment

During your consultation and medical assessment, Silk, A Medical Spa will have reviewed with you the potential benefits, associated risks and alternatives of the Versa IPL 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 this booklet discusses. 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, associated risks or alternatives of the Versa RF, do not initial any pages or sign the consent without speaking with a qualified Silk representative.

### INTRODUCTION

Versa IPL Treatments are new, proven, high-tech skin care procedures. Published studies indicate that Versa IPL Treatments can significantly improve the appearance of fine lines, wrinkles, pore size, textural irregularities and vascular and pigmentation blemishes in over 80% of cases, with clients reporting a noticeable improvement in the cosmetic appearance of their skin during and at the completion of their program.

Versa IPL treatment consists of directing Intense Pulsed Light (IPL) energy at the skin. The energy passes through the outer surface of the skin, called the epidermis and penetrates into the under carpet of the skin known as the dermis. Once in the dermis, the IPL stimulates a cell called fibroblast to produce your own new collagen. Over several treatments, this new collagen smoothes and softens the appearance of your wrinkles, pore size and textural irregularities. Using special filters to control the wavelength of pulsed light, sun-damaged skin with pigmentation abnormalities, vascular blemishes, such as spider veins and rosacea can be lightened and improved.

Versa IPL treatments are simple office procedures performed by a physician and/or laser nurse and require no needles, medications or surgery. When delivering the laser energy to the skin, it is important to cool that skin to avoid injury. A skin chiller, which blows cool air onto the skin, is one method of protecting the skin during Versa IPL treatments. This skin chiller, used in combination with topical anesthetic cream, makes the Versa IPL treatments very comfortable and there is normally no pain or discomfort associated with the procedure.

Following Versa IPL treatments, there may be a minor degree of redness and puffiness to the skin, with some tingling discomfort that usually disappears within 1 hour to 2 days. You may apply makeup immediately and return to your regular daily activities with no "downtime". A comprehensive Skin care program will be recommended for you to use in conjunction with your Versa IPL treatments. *It is highly recommended you discuss a maintenance program and begin a home skin care program to prevent potential complications, optimize and maintain the cosmetic improvements you obtain with your Versa IPL treatments.*

Before beginning a Versa IPL treatment program you must first attend an Assessment and Information consultation with a Treatment Professional, during which your skin type, facial cosmetic 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 skin type, facial cosmetic concerns, expectations and aesthetic goals. The estimated duration and cost of each session or series of sessions will also be provided to you. If you are a candidate, you may schedule your treatments and test spots at the time of this initial consultation.

Patient Initials: \_\_\_\_\_ Date: \_\_\_\_\_

## **POTENTIAL BENEFITS OF VERSA IPL TREATMENTS**

The most obvious potential benefits are an improvement in the appearance of wrinkles, pore size, textural irregularities, acne scarring, vascular and pigmentation blemishes of aging or sun-damaged skin.

## **RISKS ASSOCIATED WITH VERSA IPL TREATMENTS**

Although the vast majority of Versa IPL treatments clients never experience any of these complications, you should discuss each of them with a Treatment Professional to ensure you fully understand the alternatives, risks, potential complications and average outcomes of Versa IPL treatments.

**Discomfort:** The Versa IPL treatments are very well tolerated office treatments. Client comfort is optimized with the use of a topical anesthetic cream and a skin chiller. With these treatments you may experience a minor and tolerable degree of burning and/or tingling discomfort with each treatment.

**Skin Wound:** It is exceedingly rare for Versa IPL treatments to cause a blister or skin wound. This is more of a risk in darker or tanned skin types. If a blister or skin wound develops it may take 5-10 days to heal, and, in extremely rare instances, may leave a noticeable whitening or darkening of the skin or, even more rarely, a scar. Blisters or skin wounds are much more common if you do not follow the recommended avoidance of sunlight, self tanners, UV light and fluorescent light exposure.

**Scarring:** Occurs less than 0.1%. If you have developed a wound and a scar, the scar may end up being flat and white (hypotrophic), large and red (hypertrophic) or extend beyond the margins of the injury (keloid). Subsequent treatment or surgery may be required to improve the appearance of the scar. The scar may be permanent. Not following pre and post treatment instructions may increase the likelihood of a skin wound or scar.

**Pigment Change:** With the IPL energy used in Versa IPL treatments, there is a small risk of <1% 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 very rare and may occur in less than 1% of cases. The majority of Versa IPL clients will receive skin care products. The medical skin care products are important to obtain optimal results.

**Tanning:** It is essential that you not tan your skin or use tanning creams prior to Versa IPL treatments as the pigment in your skin will absorb some of the IPL energy and this will increase your risk of pigment change or skin wound. You should not have Versa IPL treatments if you have tanned skin until the tan has faded appreciably (at least 6 weeks) and avoiding tanning for 2 weeks afterwards. If you are using artificial tanning creams, allow these to fade (for 2-3 weeks) prior to beginning treatment.

**Bruising:** It is exceedingly uncommon to have any skin bruising following treatment. If bruising occurs, it can be camouflaged immediately and will usually resolve in 8-10 days. As the bruising fades, there may be a rust-brown discoloration of the skin (hyper pigmentation) that may take special creams to fade away.

**Infection:** Because Versa IPL 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 1-2 hours and is easily camouflaged with make-up. This may persist, in rare instances, for 1-2 days. A mild steroid cream (0.5% hydrocortisone available at the clinic) or ice application, will usually settle this. Versa IPL treatments will leave your skin photosensitized for 48 hours after each treatment and you must avoid light. Failure to do so will result in significant redness and swelling that may be quite disfiguring and may increase the rare risk of complication, such as blisters, scarring and pigmentation changes.

**Fragile Skin:** The skin overlying the treatment area may become quite fragile. Although uncommon, the fragile skin can become reddened and the outer layer may peel off, much like a blister. This usually settles in 8-10 days. Fragile skin or blisters may be more common after IPL if IPL post-care instructions are not followed. If you are subject to cold sores, please notify your Treatment professional, as cold sore eruptions can be common with Versa IPL treatments, you may need to go on an anti-viral medication during your treatment.

**Accutane** – An acne medication that must be stopped 3 months prior to treatments.

Patient Initials: \_\_\_\_\_ Date: \_\_\_\_\_

**Additional Treatment** - In most instances, it is recommended that you have a Versa IPL session every 3 month (once a season) after completion of the initial course.

**Lack of Satisfaction** - No facial wrinkles, blemishes and skin types respond the same to Versa IPL treatments. Your response may be subject to variation, but on average, almost 100% of clients who have undergone treatment report a noticeable improvement of between 40-70% in the appearance, quality and youthful vitality of their skin. However, there is a risk that you may not see an appreciable improvement in the quality and appearance of your skin.

**Pregnancy** - Although no known adverse reactions upon a fetus are known to result we do not recommend proceeding with treatment if you are known to be pregnant.

There are many variable conditions in addition to risks and potential complications listed above that may influence the long-term result from Versa IPL treatments. Even though risks and complications can occur infrequently, the risks cited in this booklet are particular for Versa IPL treatments. Other complications and risks can occur but are even less common. Should complications occur, additional surgery or treatment may be necessary. The practice of medicine and surgery is not an exact science. Although good results are expected, there is not a guarantee or warranty expressed or implied as to the results that may be obtained. Infrequently, it is necessary to perform additional treatment to improve your results.

## **HEALTH INSURANCE**

Facial wrinkles, pores, textural irregularity, vascular and pigment blemishes are cosmetic concerns and pose no medical or health care threat. Most health insurance companies, including OHIP, exclude coverage for these treatments.

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

## **FINANCIAL RESPONSIBILITES**

Depending on whether the cost of treatment is covered by an insurance plan, you will be responsible for 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.

What Silk, A Medical Spa has discussed with you and has been included in this booklet are the material risks both common and uncommon that we feel a reasonable person would want to know, understand and consider in trying to decide if the proposed treatment of a condition is something they would like to proceed with.

However, Informed Consent Booklets should not be considered all-inclusive in defining other methods of care and risk 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 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 a qualified Silk representative before signing the consent on the last page.

Patient Initials: \_\_\_\_\_ Date: \_\_\_\_\_

# Consent for Procedure and/or Treatment

I have received the following information/informed consent booklet for:

## VERSA INTENSE PULSED LIGHT

1. I hereby authorize Silk, A Medical Spa and/or such assistants as may be selected 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 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. 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 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
  - 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 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

Patient Initials: \_\_\_\_\_ Date: \_\_\_\_\_