

INTENSE PULSED LIGHT INFORMED CONSENT BOOKLET

INSTRUCTIONS

This Informed Consent Booklet has been prepared by _____ 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) treatments.

During your consultation and medical assessment, _____ will have reviewed with you the potential benefits and associated risks of, as well as the alternatives to, the Venus Versa™ IPL treatments that are outlined in this booklet. They will have also provided you with answers to any questions you may have had about the 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 _____. If you have any remaining questions or concerns about the potential benefits and associated risks of, or alternatives to, Venus Versa™ IPL treatments, do not initial any pages or sign the consent without first speaking with _____.

INTRODUCTION

Venus Versa™ IPL treatments are proven, advanced skin care procedures. Published studies indicate that Venus 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; clients report a noticeable improvement in the cosmetic appearance of their skin during and at the completion of their treatment program.

Venus Versa™ IPL treatments direct IPL energy to the skin in targeted treatment areas. This energy passes through the outer surface of the skin, called the epidermis, and penetrates into the lower layer of the skin, called the dermis. Once in the dermis, the IPL energy stimulates a cell called a fibroblast to produce new collagen. Over several treatments, this new collagen smoothens and softens the appearance of wrinkles, oversized pores, and textural irregularities. The treatment utilizes special filters to control the wavelength of the IPL energy to improve the appearance of rosacea, sun-damaged skin with pigmentation abnormalities, and vascular blemishes such as spider veins.

Venus Versa™ IPL treatments are simple office procedures performed by a physician and/or a trained clinical treatment provider. They require no needles, medications, or surgery. When delivering the IPL energy to the skin, 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 each Venus Versa™ IPL treatment, there may be a minor degree of redness and puffiness to the skin, with some tingling or discomfort that usually disappears in as little as 1 hour or up to 2 days. You may apply makeup immediately following treatment and can 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 Venus Versa™ IPL treatments. It is highly recommended you discuss a maintenance program with _____ and begin a home skin care program to prevent potential complications and to optimize and maintain the cosmetic improvements you obtain through your Venus Versa™ IPL treatments.

Before beginning a Venus 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 during this time. If you are a qualified candidate, you may schedule your Venus Versa™ IPL treatments and test spots at the time of this initial consultation.

POTENTIAL BENEFITS OF VENUS VERSA™ IPL TREATMENTS

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

Client Initials: _____ Date: _____

RISKS ASSOCIATED WITH VENUS VERSA™ IPL TREATMENTS

Although the vast majority of Venus Versa™ IPL treatment clients never experience any complications, you should discuss each of them with your treatment provider to ensure you fully understand the alternatives, risks, and average outcomes of Venus Versa™ IPL treatments.

Venus Versa™ IPL 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™ IPL treatments are very well-tolerated office treatments. Patient comfort is optimized with the cooling crystal that is integrated in the Venus Versa™ 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 a tingling sensation with each treatment.

Skin Wound:

It is exceedingly rare for Venus Versa™ IPL treatments to cause a blister or skin wound. However, this is more of a risk in darker or tanned skin types. If a blister or skin wound develops, it may take 5 to 10 days to heal and, in extremely rare instances, may lead to 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 exposure, and fluorescent light exposure post-treatment.

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 injury (keloid). Subsequent treatment or surgery may be required to improve the appearance of the scar. In some cases, the scar may be permanent. Failure to follow 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 treatments, there is a small risk (less than one per cent) 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 one per cent of cases. The majority of Venus Versa™ IPL patients will receive skin care products. The use of these medical skin care products is important to obtain optimal results.

Tanning:

It is essential that you do not tan your skin or use tanning creams prior to your Venus Versa™ IPL 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 treatments until the tan has faded appreciably (at least 6 weeks). 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 treatments. If bruising occurs, it can be camouflaged immediately using makeup and will usually resolve in eight to ten days. As the bruising fades, there may be a rust-brown discoloration of the skin (hyperpigmentation) that may require a medical cream or ointment to fully address—consult your treatment provider.

Infection:

Because Venus 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, usually lasting one to two hours. This may be easily camouflaged with makeup. In rare instances, this redness and swelling may persist for 1 to 2 days. _____ will assess and prescribe the appropriate treatment.

Client Initials: _____ **Date:** _____

Fragile Skin:

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 after IPL treatments if post-treatment care instructions are not followed.

Viral Susceptibility:

If you are susceptible to cold sores, please notify your treatment provider prior to treatment, as cold sore eruptions can be common with Venus Versa™ IPL 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 treatments.

Additional Treatments:

In most instances, it is recommended that you book a Venus Versa™ IPL maintenance session every 3 months (once per season) after completion of the initial course of treatments.

Lack of Satisfaction:

Not all facial wrinkles, blemishes, and skin types respond the same to Venus Versa™ IPL treatments. Your skin's response may be subject to variation. However, the overwhelming majority of clients who have undergone Venus Versa™ IPL treatments report a noticeable improvement in the appearance of skin quality and youthful vitality, by 40 - 70%. There is a risk that you may not see an appreciable improvement in the quality and appearance of your skin.

Pregnancy:

Although Venus Versa™ IPL 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 treatments. Even though risks and complications can occur infrequently, the risks cited in this booklet are specific to Venus Versa™ IPL 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 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 is necessary to perform additional treatment(s) to improve your results.

ALTERNATIVES TO THE VENUS VERSA™

HEALTH INSURANCE

Facial wrinkles, pores, textural irregularities, and vascular and pigment blemishes are cosmetic concerns that pose 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

Depending on whether the cost of treatment is covered by an insurance plan, you may 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.

Client Initials: _____ **Date:** _____

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 _____ are the material risks, both common and uncommon, that _____ 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. _____ 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 _____ before signing the consent on the last page of this booklet.

Client Initials: _____ **Date:** _____

CONSENT FOR PROCEDURE AND/OR TREATMENT

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

1. I hereby authorize _____ 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. 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 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 (1-8).
I AM SATISFIED WITH THE EXPLANATION.**

Patient or Person Authorized to Sign for Patient

Please Print Name Here

DATE: _____ WITNESS: _____

Client Initials: _____ Date: _____