

TRIBELLA (3 in 1) INFORMED CONSENT BOOKLET VENUS VERSA

Patient Name:	
INTRODUCTION:	
Tri-modality; total facial therapy. Three modalities, one powerful treatment.	

Step1: IPL (Intense Pulsed Light)

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, outsized pores, and textural irregularities. The treatment utilizes special filters to control the wavelength of the IPL energy to improve the appearance of rosacea, sundamaged skin with pigmentation abnormalities, and vascular blemishes such as spider veins.

Step 2: (MP)2 (radiofrequency) skin tightening

Venus Versa (MP)2 treatments use a non-surgical radio frequency, pulsed electromagnetic device designed to tighten the skin, reduce circumference, and soften wrinkles. The device delivers radiofrequency and pulsed electromagnetic energy targeted at the tissue, designed to damage the existing collagen, stimulating the body's healing response. Once the collagen has been damaged, the body begins to repair the skin by replacing the damaged tissue with new collagen. The radiofrequency 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, and treats acne. Pulsed electromagnetic fields increase the vascularity of the skin and create new pathways for the blood to flow. This increase in blood will provide more oxygen to the skin and bring more nutrients to the tissue. A fresher, more youthful glow is common after treatments.

Step 3: Nano-Fractional (Viva) skin resurfacing

Venus Versa nano-fractional applicator designed to resurface the skin through ablation and coagulation. It delivers targeted columns of radiofrequency 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 radiofrequency also stimulates the body to produce new fibroblast, 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.

Following each Venus Versa TriBella treatment, there may be a minor degree of redness and puffiness to the skin, with some tingling or discomfort. Use Vaseline or CeraVe healing ointment for the first 24 or more hours.

POTENTIAL BENEFITS OF VENUS VERSA TRIBELLA TREATMENTS:

The primary potential benefits are an improvement in the appearance of wrinkles, pore size, textural irregularities, acne scarring, vascular and pigmentation blemishes as a result of aging or sun-damaged skin, as well as improvement in overall skin appearance. While discussing the potential benefits of this treatment 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 improvements that may be achieved with your proposed treatment; the before and after images are not meant to be guarantees of actual or exact outcome.

RISKS ASSOCIATED WITH VENUS VERSA TRIBELLA TREATMENTS:

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 TriBella treatment. 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 TriBella 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 TriBella treatments.

Venus Versa TriBella treatments will leave your <u>skin photosensitized for 48 hours after each treatment</u>. You must avoid <u>SUNLIGHT</u>. 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 TriBella 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 during the photofacial portion of the treatment. Topical anesthetic cream may also be used. You may experience a minor and a tolerable degree of burning and/or a tingling sensation with each treatment.

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. If severe or worsening it is advised to seek a consultation and follow up appointment with your provider if you should require medical attention or have concerns.

Blisters:

In rare cases, a blister may occur as a result of the treatment. In this instance, the provider will recommend Vaseline and bandaging for the treatment of the blister.

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 TriBella treatments, there is a small risk (less than one percent) 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 rare and may occur in less than one percent of cases.

Tanning:

It is essential that you do not tan your skin or use tanning creams prior to your Venus Versa TriBella 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 TriBella treatments until the tan has faded appreciably (at least 6 weeks). Sun exposure, tanning beds, and artificial tanning lotions are not allowed in the treated areas during the course of the treatment and healing. If you are using artificial tanning creams, allow these to fade for six weeks prior to beginning treatment.

Bruising:

It is uncommon to have any skin bruising following Venus Versa TriBella treatments. As the bruising fades, there will be a change from purple/dark blue to green to yellow discoloration of the skin. Be very gentle to this skin as it heals over 1-2 weeks.

Excessive Redness and Swelling:

A moderate degree of redness and/or puffiness of the skin may follow treatment. This may be easily camouflaged with makeup 24 hours after treatment. In some instances, this redness and swelling may persist for 3 to 4 days. **AVOID** heat from saunas/hot tubs/hot bathes for 2-3 days.

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. <u>Fragile skin or blisters may be more common after TriBella treatments if post-treatment care instructions are not followed.</u>

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 TriBella treatments. You may need to go on an anti-viral medications during your treatment to control cold sore eruptions.

Isotretinoin:

If you are currently taking Isotretinoin, an acne medication (e.g. Accutane), you must stop taking it at <u>least 3 months</u> prior to your TriBella treatments.

Additional Treatments:

In most instances, it is recommended that you book a Venus Versa TriBella maintenance session every 6-12 months 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 TriBella treatments. Your skin's response may be subject to variation. However, the overwhelming majority of patients who have undergone Venus Versa TriBella 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:

Patients must not be pregnant, nor wish to become pregnant, for the duration of the treatment program. A reliable method of birth control is required, such as the birth control pill, diaphragm, condom, IUD, and/or abstinence. The effects on a pregnant patient or fetus undergoing this procedure have not been studied.

There are many variable conditions in addition to the risk and potential complications listed above that may influence your long-term results from Venus Versa TriBella treatments. Even though risks and complications can occur infrequently, the risk cited in this booklet are specific to Venus Versa TriBella 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 TRIBELLA: No treatment.

FRAXEL, other laser; or Thermage treatments, (at another practice); Botox, fillers, or topical prescription creams.

HEALTH INSURANCE

Facial wrinkles, pores, textural irregularities, and vascular and pigment blemishes are cosmetic concerns that pose <u>no</u> <u>medical or healthcare threat</u>. All health insurances 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

The cost of treatment is not covered by any 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.

Patient Name:	
Patient Signature: _	
Date:	



CONSENT FOR PROCEDURE AND/OR TREATMENT

I HAVE RECEIVED THE FOLLOWING INFORMATION/INFORMED CONSENT BOOKLET FOR: VENUS VERSA TRIBELLA TREATMENTS.

- 1. I hereby authorized (provider) and/or such assistants as may be selected to perform the following procedure and/or treatment: Venus Versa <u>TriBella</u>.
- 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 judgement 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 acknowledge that no guarantee has been given by anyone as to the results that may be obtained.
- 4. 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.

5. 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 (1-5)
I AM SATISFIED WITH THE EXPLANATION.

Patient Name:		
Patient Signature:		
Date:	Witness	

Jason G. Whalen, MD I Katie O'Brien, MPAS, PA-C, Rachel A. Limpert, CRNP | Rachel A. Weyant, MPAS, PA-C