



INFORMED CONSENT FORM FOR FORMA V

Patient name: _____ **Treatment Sites:**

I duly authorize A New You Aesthetic Spa to perform the VTONE treatment.

I understand that the VTONE is an EMS (Electrical Muscle Stimulation) device used for intra vaginal treatment providing electrical stimulation and neuromuscular re-education for the purpose of rehabilitation of weak pelvic floor muscles for the treatment of stress, urge, and mixed urinary incontinence in women. It has been explained to me that although EMS treatments has been very effective there is no guarantee that I will benefit from this treatment. I understand the most common side effects and complications from this treatment are the following:

1. Pain: you may experience pain during or after the procedure. If you feel significant discomfort after the treatment, you may use over the counter pain medications after the procedure.
2. Swelling: there may be swelling in the treatment areas after the treatment which can last up to one week in duration.
3. Skin irritation and burns: you may experience a burn which can be mild, moderate or severe to different degrees in the treatment area. Minor burns generally heal without difficulty but more severe burns, though rare, can lead to scarring, sensory or pigmentary changes.
4. Scarring: the risk of this complication is minimal but it can occur whenever the surface of the skin is disrupted. Strict adherence to all post-operative instructions will minimize the possibility of this occurring.
5. Allergic reactions: it is possible to experience an allergic reaction to an anesthetic, topical cream or oral medication.
6. Herpes Eruption: it is possible, even with antiviral prophylaxis, to experience a herpes eruption if you are an HSV carrier. Inform your doctor immediately if you experience pain, skin eruptions or blistering post-treatment so that the proper treatment can be initiated.
7. Infection: this treatment has the potential to cause skin damage, so infection is possible. Infection is unlikely, but can be life-threatening if it does occur and is left untreated; signs and symptoms of infection are: redness, fever, pain, pus and swelling. Should infection occur, you should contact your doctor for immediate evaluation and treatment.

It is important that you tell your doctor if you experience any of these side effects.

I understand that clinical results may vary depending on individual factors, including but limited to medical history, skin type, patient compliance with pre/post treatment instructions, and individual response to treatment.

I certify that I have been fully informed of the nature and purpose of the procedure, expected outcomes and possible complications, and I understand that no guarantee can be given as to the final result obtained. I am fully aware that my condition is of cosmetic concern and that the decision to proceed is based solely on my expressed desire to do so.

I confirm that I have informed the staff regarding any current or past medical condition, disease or medication taken. I confirm that I have had an up-to-date normal PAP test and that I have communicated these results.¹¹

I consent to the taking of photographs and authorize their anonymous use for the purpose of medical audit, education and promotion.

I certify that I have been given the opportunity to ask questions and that I have read and fully understand the contents of this consent form.

Patient Signature _____ Date _____

Witness Signature _____ Date _____



aNewyou
— aesthetic spa —

| | | | |
|-----------------------------|--|---------------|--|
| PERSONAL INFORMATION | | | |
| NAME | | PHONE | |
| ADDRESS | | | |
| CITY | | STATE | |
| ZIP CODE | | DATE OF BIRTH | |
| HOW DID YOU HEAR ABOUT US? | | GENDER | |

| | | | |
|--------------------------------|---------|---------------------------|--|
| GYNECOLOGICAL HISTORY | | | |
| LAST PAP | | PAP RESULTS | |
| LAST MENSTRUAL PERIOD | | | |
| HISTORY OF ABNORMAL PAP SMEARS | YES/ NO | INDICATIONS FOR TREATMENT | |
| ZIP CODE | | DATE OF BIRTH | |
| HOW DID YOU HEAR ABOUT US? | | GENDER | |

| | | | |
|---|--|---|--|
| MEDICAL HISTORY | | | |
| PACEMAKER/DEFIBRILLATOR | | ACTIVE SKIN INFECTION (PSORIASIS, ECZEMA) | |
| METAL IMPLANTS | | SKIN DISORDERS/CONDITIONS(KELOIDS,ABNORMAL WOUND HEALING, VITILIGO) | |
| SKIN CANCER | | BLEEDING DISORDERS | |
| SEVERED MEDICAL CONDITIONS | | MEDICATIONS / HERBS (INDUCED PHOTOSENSITIVITY) | |
| PREGNANCEY/ NURSING | | FACIAL LASER RESURFACING, DEEP CHEMICAL PEEL, LAST 3 MONTHS | |
| IMPAIRED IMMUNE SYSTEM | | NEEDLE EPLIATION, WAXIING OR TWEESING, LAST 6 WEEKS | |
| DISEASSES STIMULATED BY LIGHT | | TATTOO OR PERMANENT MAKEUP | |
| INTRA-DERMAL OR SUPERFICIAL SUBDERMAL INJECTIONS/FILLERS/GRAFTS | | CURENT OR PAST HISTORY OF GOLD THERAPY | |
| DISEASSES STIMULATED BY HEAT | | TANNED SKIN | |
| ENDOCRINE DISORDERS | | SAPHENOUS ISUFFICIENCY/SERVER VARICOSITY | |
| SURGICAL PROCEDURES | | | |
| CURRENT MEDICAITONS | | | |
| LIST ANY ALLERGIES | | | |
| DETAIL ANY MEDICAL CONDITION | | | |
| OTHER CONSIDERATIONS | | | |



FORMA V PRE-TREATMENT INSTRUCTIONS

- Have an up-to-date normal PAP test and recent normal vaginal exam to ensure that there are no active infections.
- Have a consultation visit with the physician before scheduling a treatment plan.
- Please notify the physician if you have a history of HERPES SIMPLEX VIRUS. Prophylactic medications may be needed prior to the procedure.
- Hair should be SHAVED in the treatment area 24-48 hours prior to procedure. The hair should not be waxed or chemically removed.
- A vaginal exam will be performed immediately prior to procedure to visualize the area that will be treated. • EMPTY BLADDER immediately prior to treatment.
- No NSAIDs 7 days prior to treatment.
- Avoid anticoagulants, such as aspirin, throughout the treatment regimen. Anticoagulants can increase your risk of bleeding and bruising.
- Shower the day of procedure.
- Have all informed consent paperwork signed.
- Please notify our office if your menstruation has started. FORMA V is not recommended while you are menstruating. We will need to reschedule your appointment.



POST-TREATMENT INSTRUCTIONS

- Emollient cream or healing ointment will be applied to the external treatment area. Vaniply, Vaseline, antibiotic ointment or Aquaphor may be used.
- EMPTY BLADDER immediately after treatment.
- ANTIBIOTICS may be prescribed after treatment if infection is suspected. Patient is to contact the physician if there is any indication of infection, excessive swelling, redness, undue pain, or any other unusual or untoward symptoms.
- No NSAIDs for 7 days following treatment.
- If MORPHEUS8 was used, TINY SCABS may appear 1-3 days afterward and stay for several days following the treatment. The scabs should not be touched or scratched, even if they itch, and should be allowed to flake off naturally.
- During the first 2 days following FORMA V treatment, any mechanical or thermal damage to the area must be avoided. You may resume intercourse on the same day if you feel comfortable.
- If Morpheus8 is used in conjunction with FORMA V, no intercourse or anything in the vagina is recommended for 2-7 days following treatment.
- In case of vaginal discharge, a panty liner may be worn for the first day after treatment. You may experience a large amount of gel coming out after the procedure.
- Notify the physician of any abnormal discharge or odor.



Forma V POSSIBLE SIDE EFFECTS MAY INCLUDE

Pain: you may experience pain during or after the procedure. If you feel significant discomfort after the treatment, you may use over the counter pain medications after the procedure.

Swelling: there may be swelling in the treatment areas after the treatment, which can last up to one week in duration.

Bruising: you may experience temporary bruising in the treated area which will subside with healing.

Ecchymosis & Purpura: you may experience some temporary bruising or purple discoloration in the treatment area which will subside with healing.

Blistering/Bullae: you may experience some temporary blistering/bullae in the treatment area which will subside with healing.

Burn: you may experience a burn which can be mild, moderate or severe to different degrees in the treatment area. Minor burns generally heal without difficulty but more severe burns, though rare, can lead to scarring, sensory or pigmentary changes.

Pigmentary changes: you may experience lightening of the skin which may be temporary or permanent (hypopigmentation). You may experience temporary or permanent darkening of the skin (hyperpigmentation).

Scarring: the risk of this complication is minimal but it can occur whenever the surface of the skin is disrupted. Strict adherence to all post-operative instructions will minimize the possibility of this occurring.

Allergic reactions: it is possible to experience an allergic reaction to an anesthetic, topical cream or oral medication.

Herpes Eruption: it is possible, even with antiviral prophylaxis, to experience herpes eruption if you are an HSV carrier. Inform your doctor immediately if you experience pain, skin eruptions or blistering posttreatment so that the proper treatment can be initiated.

Infection: this treatment has the potential to cause skin damage, so infection is possible, including urinary tract infection. Infection is unlikely but can be life-threatening if it does occur and is left untreated; signs and symptoms of infection are: redness, fever, pain, pus and swelling. Should infection occur, you should contact your doctor for immediate evaluation and treatment.