

BELOW ARE **SAMPLES** OF INFORMED CONSENT FORM AND TREATMENT FORMS FOR REGULAR PATIENTS OR FOR VOLUNTEER PATIENTS FOR TRAINING. INMODE PROVIDES THESE FORMS FOR DEMONSTRATION ONLY AND DOES NOT ACCEPT ANY LIABILITY FOR THEIR CONTENTS. IT IS ESSENTIAL THAT EACH CLINIC CUSTOMIZE THE CONSENT FORMS ACCORDING TO TREATMENT PROCEDURE, LOCAL SPECIFIC REGULATORY REQUIREMENTS AND LANGUAGE.

Sample Informed Consent for VTONE

Patient name: _____

Treatment Sites: _____

I duly authorize _____ 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 give as to the final result obtained. I am fully aware that my condition is of cosmetic concern and that the decision to procced 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.

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

I agree to waive, release, discharge, and covenant not to sue Invasix, Inc. d/b/a InMode ("InMode") and its employees, agents, and representatives, from any liability, loss, cost, damage, expense, claim or lawsuit whatsoever for any and all injury, loss, illness, harm, cost, expense, or damage related to the treatment, including any negligent acts or conduct by InMode and its agents, employees, and/or representatives (collectively, "Claims").

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
