

# Sample Informed Consent for FormaV

BELOW IS A **SAMPLE** INFORMED CONSENT FORM 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 CONSENT FORMS ACCORDING TO TREATMENT PROCEDURE, LOCAL SPECIFIC REQUIREMENTS AND LANGUAGE.

Patient name: \_\_\_\_\_

Treatment Sites: \_\_\_\_\_

I duly authorize \_\_\_\_\_ to perform the FormaV treatment.

I understand that the FormaV is an RF device used for remodeling of the tissue. It has been explained to me that although RF 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. **Bruising:** you may experience temporary bruising in the treated area which will subside with healing.
4. **Ecchymosis & Purpura:** you may experience some temporary bruising or purple discoloration in the treatment area which will subside with healing.
5. **Blistering / Bullae:** you may experience some temporary blistering / bullae in the treatment area which will subside with healing.
6. **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.
7. **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).
8. **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.
9. **Allergic reactions:** it is possible to experience an allergic reaction to an anesthetic, topical cream or oral medication.
10. **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.

11. **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 you 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

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