

TONE Sample Informed Consent Form

BELOW IS **SAMPLE** OF 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 THE CONSENT FORMS ACCORDING TO TREATMENT PROCEDURE, LOCAL SPECIFIC REGULATORY REQUIREMENTS AND LANGUAGE.

TONE SAMPLE INFORMED CONSENT

PATIENT NAME _____

TREATMENT SITES _____

I DULY AUTHORIZE _____ TO PERFORM TONE TREATMENT.

I understand that the device being used for muscle tone improvement of which I am consenting to be a patient receiving TONE treatment.

I understand that clinical results may vary depending on individual factors, including but not limited to medical history, skin type, patient compliance with pre- and post-treatment instructions, and individual response to treatment.

I understand that there is a possibility of short-term effects such as reddening, mild burning, pain, swelling, muscles spasm, and temporary discoloration of the skin, as well as the possibility of rare side effects such as treatment area infection, scarring and permanent discoloration. These effects have been fully explained to me _____ (patient's initials).

I understand that treatment with this system involves a series of treatments and the fee structure has been fully explained to me _____ (patient's initials).

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 consent to the taking of photographs and authorize their anonymous use for the purposes 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 _____

CONTRAINDICATIONS CHECKLIST:

- Surgery in the treatment within the last 12 months.
- Implants in the treatment area
- History of herpes. Patients with history of diseases stimulated by heat, such as recurrent Herpes Simplex in the treatment area, may be treated only following a prophylactic regimen.
- UTI
- Current or history of skin cancer and genital area cancer, or current condition of any other type of cancer, or pre-malignant moles.
- Significant illness such as diabetes, cardiac disease, autoimmune disease
- History of epidermal or dermal disorders involving collagen or microvasculature
- Active electrical implant in any region of the body
- Pregnancy and nursing
- Diseases of the immune system such as HIV, AIDS or immunosuppressive med
- Use of anticoagulants or history of bleeding disorders
- Any active condition in the treatment area, such as open lacerations, infection, abrasions or lesions, psoriasis, eczema or rashes
- History of skin disorders, keloids, abnormal wound healing
- Tattoo in the treatment area
- History of Accutane use in the previous 6 months
- Having received treatment with light, laser, RF, or other devices in the treated area within 2-3 weeks for non-ablative procedures, and 6-12 weeks for ablative fractional laser resurfacing (according to treatment severity) prior to treatment, except special recommendations.
- Use of non-steroidal anti-inflammatory drugs (NSAIDS, e.g., ibuprofen-containing agents) one week before and after each treatment session, as per the practitioner's discretion.
- Excessively tanned skin in the treatment area from sun, sun-beds or tanning creams