

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 customise the consent forms according to the treatment procedure, local specific regulatory requirements and language.

INMODE SAMPLE INFORMED CONSENT
 For Volunteer patients, In service-training
 VOTIVA AVIVA FORMA V

PATIENT NAME _____
 TREATMENT SITES _____
 I DULY AUTHORISE _____ TO PERSON _____
 TREATMENT.

I understand that the Votiva 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.

Pre-Treatment questions:

- I have updated medical history and medications? yes no
- I have avoided taking anticoagulants for 7-10 days (if suitable to do so) yes no
- I suffer from recurrent Herpes simplex in the treatment area and have commenced medication for prophylaxis as advised yes no
- I have removed dense hairs from the treatment area if required (clean razor) yes no
- I am not currently pregnant or menstruating yes no
- I do not have any permanent implants in the area to be treated yes no
- I have not had vaginal or pelvic surgery with in the past 12 months yes no
- I do not have history of skin cancer, genital area cancer or any other type of cancer yes no
- I do not have an impaired immune system due to immunosuppressive diseases such as AIDS and HIV or the use of medications yes no
- Isotretinoin (Accutane) with in last 6 months
- Any active condition in the treatment area, such as sores, Psoriasis, eczema, and rash, open lacerations, abrasions or lesions yes no
- Infection in the area to be treated, current urinary tract infection or pelvic infection, uterine prolapse, cystocele, rectocele. yes no
- Any surgical procedure in the treatment area within the last 12 months or before complete healing. yes no

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. yes no

I understand the most common side effects and complications from this treatment are the following:

___ you may experience discomfort 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. (aviva)

___ Ecchymosis & Purpura: you may experience some temporary bruising or purple discoloration 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 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.

___ 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.

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.

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. 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 N M O D E

Demo/Training
Votiva
Treatment SAMPLE

I consent to the taking of photographs and authorise their anonymous use for the purposes of medical audit, education and promotion yes no

Patient Signature _____

Date _____

Witness _____