



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 the treatment procedure, local specific regulatory requirements and language.

INMODE SAMPLE INFORMED CONSENT
For Volunteer patients, In service-training
EVOKE

FACE SUBMENTAL

I _____ request and authorise _____ or designated person to perform a procedure on me known as Body /Mini FXs for cosmetic purposes.

Pre-Treatment questions:

- | | |
|--|--|
| I have updated medical history and medications? | <input type="checkbox"/> yes <input type="checkbox"/> no |
| I do not have a pacemaker or internal defibrillator | <input type="checkbox"/> yes <input type="checkbox"/> no |
| I do not have Superficial implants, such as metal plates, screws and metal piercing | <input type="checkbox"/> yes <input type="checkbox"/> no |
| I have ceased use of photosensitising medications | <input type="checkbox"/> yes <input type="checkbox"/> no |
| I have avoided taking anticoagulants for 7-10 days (if suitable to do so) | <input type="checkbox"/> yes <input type="checkbox"/> no |
| I not undertaken any major or minor surgical procedures in the past 3 month | <input type="checkbox"/> yes <input type="checkbox"/> no |
| I have not had Dermal filler, threads or facial implants in the past 2 months | <input type="checkbox"/> yes <input type="checkbox"/> no |
| I suffer from poorly controlled endocrine disorders | <input type="checkbox"/> yes <input type="checkbox"/> no |
| I suffer from active conditions in the treatment area (sores/psoriasis/eczema/rash) | <input type="checkbox"/> yes <input type="checkbox"/> no |
| I have a history of keloids, abnormal wound healing, dry fragile skin | <input type="checkbox"/> yes <input type="checkbox"/> no |
| I have removed excessive facial hair in the treatment area (if previously discussed) | <input type="checkbox"/> yes <input type="checkbox"/> no |

Post care information:

I understand the following to the best of my ability and agree to the following post care recommendations explained to me by my provider. (please initial)

___ Avoid very hot water and direct heat exposure for 24 – 48 hours post treatment

___ avoid scrubbing and scratching the treatment area for 24-48 hours

___ Moisturise can be applied to the skin surface

I understand that the device being used for skin improvement which I am consenting to be a patient receiving _____ treatment (specify procedure).

___ 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.



INMODE

EVOKE is the first and only all in one hands free facial remodeling device, cleared by the FDA. Evoke delivers three-dimensional subdermal remodeling. EVOKE uses bipolar radiofrequency to the cheeks, jowls, submental area and jawline. By directly targeting these areas Evoke remodels skin and subdermal tissue to deliver more defined facial characteristics. The treatment is suitable for patients with some fat deposits and loose skin looking to improve appearance.

____ I understand that taking the treatment course is my choice and that I am free to withdraw at any time, without giving any reason.

____ I am aware of the post care instructions provided

____ I understand that side effects such as erythema (redness), edema (swelling) are expected and temporary

____ Complications are rare and in the event of an adverse response the clinic/practice will address the situation accordingly

please contact the clinic for advice. (these are rare, in most cases temporary)

- Discomfort or pain, excessive redness and or swelling, scarring or blisters
- Damage to natural skin texture, change of pigmentation (hyper or hypopigmentation)

____ I understand that the treatment involves approx. 3-6 weekly sessions (or as directed)

____ I understand the results are according to treatment parameters and individual response. I understand that I have to comply with treatment schedule, otherwise results may be compromised.

____ I understand that not everyone is a candidate for this treatment and results may vary, therefore there is no guarantee as to the result that may be obtained

____ I understand that treatment with this system involves a series of treatments, I understand maintenance treatments may be required to maintain results

____ The call button purpose has been explained to me and I agree to use it if I experience discomfort or excessive heat through out the procedure.

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 authorise their anonymous use for the purposes of medical audit, education and promotion. yes no

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 _____