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
❑BODY TITE ❑ FACETITE

I _____ request and authorise _____ or designated person to perform a procedure on me known as Subdermal Skin tightening and sculpting utilizing temperature controlled Radio Frequency technology. This procedure is being used to treat my condition/ medical diagnosis of Laxity and/or Adiposity.

Pre-Treatment questions:

I have updated medical history and medications?	❑ yes ❑ no
I do not have a pacemaker or internal defibrillator	❑ yes ❑ no
I do not have Superficial implants, such as metal plates, screws and metal piercing	❑ yes ❑ no
I do not have cochlear implants (stay 1cm away if client does)	❑ yes ❑ no
I do not have recent implants, filler, threads or wrinkle relaxer	❑ yes ❑ no
I have ceased use of photosensitising medications	❑ yes ❑ no
I have avoided taking anticoagulants for 7-10 days (if suitable to do so)	❑ yes ❑ no
I have NOT had recent UV exposure to the treatment area	❑ yes ❑ no
I suffer from cold sores and have started taking medication for prophylaxis as advised	❑ yes ❑ no
I have removed dense hairs from the treatment area if required (clean razor)	❑ yes ❑ no

Please initial each item:

_____The areas for treatment have been reviewed with me today and I am in agreement. I have been thoroughly and completely advised regarding the objectives of the procedure. I understand that the practice of medicine and surgery is not an exact science and although these procedures are effective in most cases, no results have been guaranteed.
I acknowledge that imperfections might ensue and that the operative result may not live up to my expectations. I understand that skin tightening may not be fully apparent for 6-12 months after this procedure, that tissue tightening varies from individual to individual and results are age-dependent.

_____ The treatment will involve applying heat to the adipose (fat) tissue and dermis using radiofrequency for therapeutic purposes and may be combined with Liposuction.

_____ I am aware of the following possible experiences and/or risks associated with the procedure:

- I consent to the administration of local and tumescent anesthesia. I understand that all forms of anesthesia involve risks and the possibility of complications, injury, or death.
- Discomfort may be experienced during and/or after the treatment.
- Some bruising and/or swelling may occur following the procedure. However, it should resolve in days, weeks, or months.
- Temporary redness (erythema) and swelling of the treated area can occur.
- Nerve Injury:
  Facial and body nerve branch injury – weakness of affected areas
  Hyperactivity – temporary change in smile or any facial expression
  Temporary numbness/tingling in the area treated.
- Scarring is rare, but is a possibility if the skin surface is disrupted.
- Although uncommon, burns can occur.
- Infection is rare, but should it occur, treatment with antibiotics and/or surgical intervention may be required. Infection can further increase the risk of scarring. Proper wound care is important in the prevention of infection. If signs of infection such as pain, heat, blisters, or surrounding redness develop, call the office immediately.
- I understand the importance of the pre and post treatment instructions and that the failure to comply with these instructions may increase the possibility of complications.

_____ I understand that lipoaspiration may be used in conjunction with the Subdermal Skin Tightening and Sculpting treatment, if _____ determines it is necessary to do so. I understand that skin irregularities may occur with any lipoaspiration treatment.

_____ I consent to having clinical photographs taken before, during and after my procedure. I understand that these photographs are an important part of my medical record. In addition, I consent to the use of these photographs, without my identity being revealed, for the education of future patients, professional clinical presentations and medical journals.

_____ The nature and effects of the procedure, the risks, the ramifications, complications, as well as alternative methods of treatment have been fully explained to me by the physician or designated person and I understand them. I am aware that this device is FDA cleared for soft tissue coagulation. The benefits of the proposed procedure, along with the probability of success have also been discussed with me. I have been given the opportunity to ask questions and have received satisfactory answers. I certify that I have read the above authorization and that I fully understand it.

DISCLAIMER

Informed Surgical Consent Forms are used to communicate information about the proposed treatment of a condition along with disclosure of risk and alternative treatment(s). The informed consent process attempts to define principles of risk disclosure that should generally meet the needs of most patients in most circumstances.

What the surgical and office staff have discussed with you and has been included in this consent are the material risks both common and uncommon that the doctor feels a reasonable person would want to know, understand and consider in deciding if the proposed treatment of a condition is something they would like to proceed with.

However, Informed Surgical Consent should not be considered all-inclusive in defining other methods of care and risk encountered. The staff may provide you with additional or different information that

is based on all the facts in your particular case and the state of medical knowledge. Informed-consent documents are not intended to define or serve as the standard of medical care. Standards of medical care are determined on the basis of the facts involved in an individual case and are subject to change as scientific knowledge and technology advance and as practice patterns evolve. It is important that you read the above information contained on this and all preceding pages carefully and have all of your questions answered by the doctor before signing the consent on the last page.

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.

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_____