## **Morpheus8 Fractora Informed consent**



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 **MORPHEUS8 FRACTORA**

I \_\_\_\_\_\_ request and authorise \_\_\_\_\_\_ or designated person to perform a procedure on me known as Morpheus8/ Fractora for cosmetic purposes.

### Pre-Treatment questions: Do you have or use any of the following:

Pacemaker or internal defibrillator	🗅 yes 🗅 no
Superficial implants, such as metal plates, screws and metal piercing	🗅 yes 🗅 no
Cochlear implants (stay 1cm away if client does)	🗅 yes 🗅 no
Recent implants, filler, threads or wrinkle relaxer	🗅 yes 🗅 no
Photosensitising medications (such as roaccutane)	🗅 yes 🗅 no
Anticoagulant medication/ fish oil	🗅 yes 🗅 no
Recent UV exposure to the treatment area	🗅 yes 🗅 no
Cold sores (prophylaxis as advised prior to treatment)	🗅 yes 🗅 no
I have followed the prescribed skin prep prior to treatment	🗅 yes 🗅 no

- I \_\_\_\_\_\_ acknowledging the following I hereby agree to follow the recommended post care information:
- I understand mechanical and thermal exposure to the treated area must be avoided.
- Skin cooling after RF treatment is not recommended however sometimes is used during the procedure to assist with comfort
- I agree to avoid actives and follow the details post care instructions provided to me
- Avoid touching the face post Morpheus/Fractora until micro wounds have closed and inflammation has subsided.
- I have followed the prescribed skin prep recommended in my initial consultation

\_\_\_\_\_ I agree to follow the post care information as discussed in my pre treatment consultation and take responsibility to follow the recommended guidelines.

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#### I understand the following: (please initial)

MORPHEUS8/FRACTORA technology utilizes fractional radio frequency (RF) indicated for face and body

\_\_\_\_\_ The MORPHEUS8/FRACTORA treatment induces ablation, thus improving the appearance of rough texture, fine lines, wrinkles, and depressed scars, such as acne scars along with superficial pigments that will be ablated. The treatment also induces skin rejuvenation by heating of the dermis which stimulates collagen generation and replenishment, subdermal remodeling as well as closure of superficial fine blood capillaries.

The treatment in most cases requires anesthesia (topical cream, injections or sedation) \_\_\_\_\_ 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 was told about the possible side effects of the treatment including erythema for 1-3 days edema (swelling) for 1-3 days post treatment, sensitivity for 1-3 days post treatment

\_\_\_\_\_ I may experience initial textural changes to the skin such as MENDS (little dots) and understand this is more common following a superficial treatment and on darker skin Fitzpatrick.

\_\_\_\_ MENDS will dissipate with in 2-4 weeks on the face and 4 - 6 weeks on the body, these are microscopic injury sites and may appear as a slight darkening of the skin

\_\_\_\_\_ complications are rare how ever need to be addresses, if you present with any of the following please contact the clinic for advice.

- damage to the natural skin texture (crust, blister, burn)
- change of skin pigmentation (hyper- or hypopigmentation)
- Although these effects are rare and expected to be temporary, grid patterns and small bumps may last up to 3 weeks, and are part of a normal reaction to the treatment.
- I understand that the treatment involves a few sessions (1-5), a few weeks apart (3-6 weeks), according to treatment parameters and individual response. I understand that I have to comply with treatment schedule, otherwise results may be compromised.
- I recognise that during the course of the procedure unforeseen conditions may necessitate

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 authorise their anonymous use for the purposes of medical audit, education and promotion.  $\Box$  yes  $\Box$  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	