

# INDIBA® Radiofrequency System (RF) Informed Consent

Area(s) to be treated: \_\_\_\_\_\_

The purpose of this Informed Consent to INDIBA® Radiofrequency System (RF) is to obtain your consent to the INDIBA® RF services offered by Siam Clinic Co.,Ltd ., the medical corporation providing the services under the Siam Clinic Phuket brand. It is intended to document that you have been informed about the benefits and risks of INDIBA® RF Therapy, and that you voluntarily consent to the treatment.

INDIBA® RF services are provided by therapist of Siam Clinic Co.,Ltd. who are under the supervision of Dr. Phimphakarn Tantithummawong, MD.

I hereby authorize Dr.Phimphakarn Tantithummawong/or therapist, to treat me using the INDIBA® Radiofrequency System (RF). INDIBA® RF is a multi-purpose radio-frequency device for the treatment of wrinkles, skin tightening and body contouring.

INDIBA® RF delivers precise Radio-frequency of 448 kHz (kilohertz) to achieve biostimulation and thermal effects. The electric current function of the INDIBA® system delivers its results by stimulating cellular activity to the dermis and subcutaneous tissue. Radio-frequency uses electrical pulses to target and penetrate the under layer of skin using heat to stimulate collagen.

I understand the results may vary from person-to-person and that at least 4 - 6 treatments, spaced 24 hours apart, are necessary to observe results. Because all individuals are different, it is not possible to completely predict results. Some patients will have dramatic results, some will have moderate results. Due to the nature of this treatment, an exact result cannot be predicted and I acknowledge that no guarantees have been made as to the results that may be obtained.

# How does INDIBA work

INDIBA is an electromagnetic current which is delivered to the body via electrodes at a radiofrequency of 448kHz. This current gradually increases the treated tissue temperature. The temperature rise triggers the body's natural regeneration, repair and defence responses. For the current frequency of 448 kHz other effects can also be obtained without heating the body's tissues, demonstrated via molecular research; bio-stimulation.

# Is INDIBA safe

INDIBA is approved by specific country's regulatory bodies, it is CE marked and FDA approved.

### What happen during an INDIBA treatment

Your therapist will discuss why INDIBA treatment may be of benefit. During the treatment the therapist will use conductive media on the skin to conduct the current. It is completely painless, they use either a coated electrode called a capacitive which generates more superficial warmth or resistive which is a metal electrode, developing a deeper heat and targeting tissue deeper in the body.

I understand that I will be undergoing INDIBA® treatment and certify that I:

- Am not pregnant or nursing.
- Am over 18 years of age.
- Do not have a pacemaker, internal defibrillator or metal implants in the treatment area.
- Do not have current or a history of cancer, especially skin cancer, or pre-malignant moles in the area of treatment.
- Do not have an impaired immune system due to immunosuppressive diseases such as AIDS and HIV, or use of immunosuppressive medications.
- Do not have any severe concurrent conditions such as cardiac disorders.
- Do not have a history of diseases stimulated by heat, such as recurrent Herpes Simplex in the treatment area. If so, I agree to use prophylactic antiviral therapy.
- Do not have any active condition in the treatment area, such as sores, psoriasis, eczema and rash as well as excessively/freshly tanned skin.
- Do not have a history of skin disorders such as keloid scarring, abnormal wound healing, as well as very dry and fragile skin.
- Am not taking medications such as blood thinners.
- Have no condition which could be adversely affected by heat.
- Have not had any surgical, invasive, ablative procedure in the treatment area before treatment.

- Do not have any medical condition that might impair skin healing.
- Do not have any permanent implant in the treated area such as metal plates and screws, silicone implants or an injected chemical substance.
- Do not have any poorly controlled endocrine disorders, such as diabetes.
- Have not used Isotretinoin (Accutane®) within 6 months prior to treatment.
- Understand that this treatment is not guaranteed to achieve the results that I want and there is no way to predict the response that I will get.
- Understand that it will take 6-12 months to see maximal benefits and that any benefits will be reduced or eliminated with weight fluctuations, and normal aging.

### Please initial:

\_\_\_\_\_ The treatment creates a warm sensation over the skin surface. I understand that taking the treatment course is my choice and that I am free to withdraw at any time.

\_\_\_\_\_ I was told about the possible side effects of the treatment including: Hyperpigmentation, local pain, skin redness, swelling, damage to the natural skin texture (crust, blister, burn), fragile skin and bruising.

\_\_\_\_\_ I was told about the possible side effects of the treatment including: skin redness (erythema) and warmth.

\_\_\_\_\_ Although these effects are rare and expected to be temporary, any adverse reaction should be reported immediately.

\_\_\_\_\_ I understand that these are usually temporary, but there is a possibility of long term or permanent reactions.

\_\_\_\_\_ I understand that not everyone is a candidate for this treatment and results may vary.

\_\_\_\_\_ I have had sufficient opportunity to discuss my condition and treatment. I believe I have adequate knowledge upon which to base an informed consent.

\_\_\_\_\_ I authorize before, during and after the procedure(s) the taking of photographs and measuring of body weight to be part of my patient profile.

\_\_\_\_\_ I understand that any treatment provided may or may not meet my expectations. I understand and agree that there is no compensation or refund of monies paid in any event

Patient or Person Authorized to Sign for Patient

Date

Witness

Initials.....Date.....