

# INDIBA® Vagina Radiofrequency System (RF) Informed Consent

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 14 days 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.

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#### **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 defense 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, which leads to long-lasting results by stimulating the regeneration of these important proteins.

#### Is INDIBA safe

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

### What is the process for the procedure.

The INDIBA vaginal tightening procedure does not require surgery and results in a tighter and more elastic vaginal area. This process will restructure vaginal tissues without the use of numbing creams anesthesia or invasive methods.

INDIBA is a very simple procedure that does not waste time; it can be performed even during your lunch break. According to a survey, most clients do not experience any form of pain or downtime after the procedure. Treatments are typically planned to take place at four to six-week intervals. Almost all customers start noticing positive results after 1 to 3 treatments. Possible side effects include slight bleeding and discomfort. Vaginal dryness and rash which is more likely if the area treated is exposed to heat of friction during the first 72 hours

## Potential side effect but not limited to

**Infection** – Albeit rare, infection is a possibility any time a procedure is performed. I acknowledged and understand that although rare it is possible for an infection to become a blood-borne widespread infection.

**Bruising** – Bruising in the treated area is possible, especially if within the last ten (10) days, I have taken aspirin or aspirin-containing products, or other medications that "thin" the blood.

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**Discomfort** – Minimal discomfort will be experienced during and after the laser treatment. I give my permission for the administration of topical and/or local injection of anesthesia when and if deemed appropriate.

**Poor healing** – The vagina may require more than the usual three days to heal.

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

- Am not pregnant or nursing.
- o Am over 18 years of age.
- o 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.
- o 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 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.
- o 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.
- o Do not have any poorly controlled endocrine disorders, such as diabetes.
- 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.

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Please initial:	
The treatment creates a warm sensation over the skin streatment course is my choice and that I am free to with	•
I was told about the possible side effects of the treatm Hyperpigmentation, local pain, skin redness, swelling, dama (crust, blister, burn), fragile skin and bruising.	<u> </u>
I was told about the possible side effects of the treatm (erythema) and warmth.	ent including: skin redness
Although these effects are rare and expected to be ten should be reported immediately.	nporary, any adverse reaction
I understand that these are usually temporary, but ther permanent reactions.	re is a possibility of long term or
I understand that not everyone is a candidate for this t	reatment and results may vary.
I have had sufficient opportunity to discuss my condition have adequate knowledge upon which to base an informed	
I authorize before, during and after the procedure(s) the measuring of body weight to be part of my patient profile.	ne taking of photographs and
I understand that any treatment provided may or may understand and agree that there is no compensation or refu	
Patient or Person Authorized to Sign for Patient	
Date Witness	

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