INFORMED CONSENT REPORT

for

CAPACITIVE/RESISTIVE 448 kHz MONOPOLAR RADIOFREQUENCY TREATMENT: INDIBA® DEEP CARE

1. HEALTHCARE PROFESSIONAL

That the Physician ☐ / Physiotherapist ☐ / Nurse ☐

Dr / Mr /Ms ……

has explained to me, (Mr / Ms) ……

aged …… years, with National ID (DNI) No. …… and address at

…… Postcode ……

Town/city …… Phone number …….

E-mail ……..

the treatment that I will undergo in a manner that is clear and easy to understand.

2. INTRODUCTION

Radiofrequency applied for medical purposes is a common technology that is widely used in Cosmetic Medicine. It is applied by means of various devices that are available on the market, which are characterised and differ from each other in terms of the frequency at which they operate.

The purpose of this document is to enable the patient to give his/her informed consent with regard to the technology known as **448 kHz Capacitive/Resistive Monopolar Radiofrequency**, known commercially as **INDIBA® Deep Care**, which is indicated for pre- and post-surgery treatment, skin firming, body contouring, cellulite reduction and vaginal rejuvenation.

The technology on which INDIBA® DEEP CARE is based was introduced, developed, researched and patented by INDIBA, S.A. more than thirty-five years ago and is now sold in many countries throughout Europe, Asia and America.

3. BASIC DESCRIPTION OF THE TECHNIQUE AND BIOLOGICAL EFFECTS

This method consists in applying a current to the patient that circulates through the tissue being treated via two electrodes that are placed on the surface and/or cavities of their body (vagina or rectum), usually on opposite sides of the body (mainly the back/face, back/abdomen, back/chest, and abdomen/buttocks). The effect of this is a localised increase in temperature (hyperthermia), which explains some of the effects achieved.

Thanks to this technique, it is possible to improve the condition and appearance of the tissues that are treated. In particular, it:

1. Improves the appearance of the skin
2. Combats flaccidity, firms tissues and helps to redefine face and body contour and to rejuvenate the external genitalia
3. Reduces cellulite
4. Favours elimination of the waste products of cellular metabolism
5. Prepares tissues for surgery and, in post-surgical treatments, improves recovery from the intervention thanks to its tissue regenerating activity
6. At the internal vaginal level, it reduces tissue laxity and dryness, thus improving hydration and increasing the trophism of the mucosa

4. CONTRAINDICATIONS, WARNINGS AND SIDE EFFECTS

4.1 Contraindications:

This treatment is contraindicated in the following situations:

- Use of pacemakers or other electronic implants
- Pregnancy
- Broken skin (open wounds or recent burns)
- Thrombophlebitis
- People suffering from lack of sensitivity (congenital insensitivity to pain, nerve damage, paraplegia or patients exposed to pharmacological treatments that reduce sensitivity to pain or heat)
- Known allergy to nickel or chrome

4.2 Precautions:

- These treatments are intended for adults
- The patient should not come into contact with conductive parts or earthing elements, which could generate unwanted channels for the circulation of radiofrequency currents
- People with low blood pressure who undergo treatment may suffer from a drop in blood pressure. Should this occur, treatment must be stopped to re-establish normal blood pressure levels
- In facial treatments in resistive mode, removable dentures should be taken out before the treatment, as they can hamper the circulation of the current
- The patient must remove any rings, earrings, body piercings and other metal items he/she is wearing
- Patients being treated with oral anticoagulants must consult their doctor before beginning treatment with INDIBA®
- INDIBA® is only indicated for treatment in adults
- In elderly patients, who are more likely to present skin disorders, the treatment must be performed with extra care to avoid causing skin lesions or burns
- It is important to mention beforehand if you have experienced any skin allergies to cosmetic products
- In intracavitary applications (vaginal and/or rectal), treatments shall always be carried out using unipersonal electrodes and applying at all times the measures proposed by INDIBA S.A. to ensure cleanliness and disinfection

4.3 Side effects:

After applying the treatment, it is normal for the patient to notice a sensation of increased heat in the area that has been treated.

The treatment tends to produce erythema (reddening of the skin), the intensity and extent of which will depend on the area of application, the size of the electrode used, the distance between the active and neutral electrodes, the body mass index, the patient's age, the skin type and colour, and the patient's sensitivity to the increase in heat, among other factors. This redness is harmless and generally disappears after a few hours.

The increase in temperature is not harmful; it is part of the mechanism of action and contributes to the therapeutic effects, disappearing several hours after the treatment ends.

4.4 Other risks:

Application under the following conditions:

- By unqualified people
- Following protocols (power and/or application times, placement of the return electrode, position, pressure or speed of movement of the electrodes) other than those approved by INDIBA®
- Using damaged capacitive electrodes (perforated or with visible signs of cracks in their polyamide coating)
- Handling the capacitive electrodes directly (not using the electrode holder) during treatment
- With conductive creams other than those indicated by INDIBA®
- Using an insufficient amount of cream or not reapplying it during the treatment
- Applying INDIBA® together with other cosmetic products or formulations
- A history of hypersensitivity to other topical products or their ingredients

may increase the risk of localised burning in the area in which the electrodes (active and/or return) come into contact with the skin and/or the mucous membranes.

Should any burning occur, it will be localised and limited only to the area in direct contact with the electrodes. If this happens, the treatment will be stopped and conservative medical treatment will be applied.

Facial treatments or the treatment of under-eye bags may cause mild discomfort (congestion, a heavy sensation, swelling of the eyelids and/or eyes, watering eyes) due to conductive cream accidentally coming into contact with the ocular mucosa. If the conductive cream does come into contact with the ocular mucosa, the usual remedy is to wash the area continuously with a gentle stream of running water. Should you experience these problems, they are temporary and do not require corrective measures.

5. PATIENT DECLARATION

I have understood the explanations I have been given in clear, simple language.

The professional who has discussed it with me has allowed me to make all the necessary comments and has answered all my questions.

I understand that I can revoke the consent I am giving now at any time by signing this document and without having to give explanations.

I therefore declare that I am satisfied with the information received and that I understand the scope and risks of the treatment.

I hereby exempt the person applying the treatment, the clinic or centre where the treatment is applied and the manufacturer of the product from liability for any consequences deriving from any untrue information given in this Declaration, or from not having informed them of reasons that might contraindicate or prevent the treatment.

I CONSENT

To undergo treatment with INDIBA® Deep Care (tick box):

- ☐ pre-surgery
- ☐ post-surgery
- ☐ skin firming
- ☐ body contouring
- ☐ cellulite reduction
- ☐ vaginal rejuvenation
- ☐ training (_____)

……[place]……..,……[day]……[month]……[year]……

Signature and seal of the Centre
Signed: The patient

REVOCATION

Patient: Mr /Ms ……..

aged …… years, with National ID (DNI) No. …… and address at ……

……..

I REVOKE my consent given on ……(date)…… and do not wish to continue with the treatment, which I hereby consider completed.

Signature and seal of the Centre

Signed: The patient

In accordance with Article 13 et seq of the General Data Protection Regulation (GDPR) 2016/679 and of the LOPDPGDD 3/2018, ……. (the title holder), the Data Controller, informs you that the data you have provided to us or, as the case may be, you may provide to us during the course of the performance of a ……. shall be processed for the exclusive purpose of managing such data.
The personal data that will be processed will be those that can be included in any of the following categories: identifying data (name, surname, National ID (DNI) No.), data of a personal nature (family details, nationality, sex, date of birth, etc.), and will be processed with the utmost confidentiality and with the required duty of secrecy.

Your consent, the legal basis for the processing, will be maintained until the end of the ..... and your data will not be transferred to third parties, other than the competent health organisations and/or third parties authorised by INDIBA for statistical purposes. Withdrawal of consent shall not affect the legality of the processing based on consent prior to withdrawal.
You may exercise your rights of access, rectification, erasure, portability, restriction and opposition by sending a written communication, attaching a photocopy of your National Identity (DNI) Card or equivalent identification document, to..... (title owner), in .... (address), or to the e-mail address ..... (e-mail). If your rights are not respected, you can appeal to the AEPD (Spanish Data Protection Agency).
Name and surname(s);
National ID (DNI) No.:

By signing this document, you authorise INDIBA, S.A. to process your personal data in the terms indicated.
In proof of CONFORMITY, I hereby sign this document.

_____[place]_____, ___[day]_____ _____[month]_____ 20____

Signature:

'INDIBA, S.A. LIABILITY DISCLAIMER'

This document is the property of INDIBA, S.A.

The Informed Consent form is an indicative proposal, a guidance document. Under no circumstances does it imply that consent has been given to INDIBA. Nor does INDIBA assume any responsibility for the use, modification or alteration of the wording of this document by the client.
In deference to its clients, INDIBA, S.A. has also drawn up the Data Protection clause as a model clause; the clients are responsible for ensuring the correct application of the data protection regulations they collect in their activity and taking the appropriate security measures.
The use of this clause by clients of INDIBA, S.A. in no way implies that INDIBA, S.A. is the depository of the data that may be collected with this form and, consequently, INDIBA, S.A. shall not be the Data Controller nor the party responsible for the processing thereof.
In addition, INDIBA, S.A. is exonerated from any liability in relation to the updating of the clause, or its use with respect to such variations as may occur at any time in the legislation in force, as well as from any modification that the user may make to this document'.