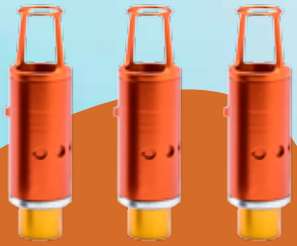
TREATMENT GUIDELINES

etherea MX | ETHEREA-MX®
PRODEEP®



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MADE IN BRAZIL

ETHEREA® PRODEEP®, ITS MODELS AND/OR AVAILABLE ACCESSORIES ARE PRODUCTS MADE IN BRAZIL.

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PRODEEP®

VERSION 1.0 - JULY 2017

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Cryomed Aesthetics

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IMPORTANT WARNINGS

- Practical training offered by the company is critical for understanding the device and the technique. However, this does not supersede any other medical qualification required for its correct use.

- Before handling and/or operating the device, reading the relevant Instructions Manual is required.

- The ETHEREA® device and its respective PRODEEP® handpiece should only be operated by qualified professionals. User qualifications, as well as installation and support requirements to carry out procedures, vary from country to country, so professionals should refer to the relevant local regulating agencies for information.

- This document is not intended to be a complete and absolute guide for using the equipment and are offered as a response to the referenced indications. It is implied that the operator of the device in question has all training and the necessary qualifications to properly perform the procedures proposed herein.

- The parameters suggested here are not absolute in clinical practice. Operators should understand how the treatment interacts with the target tissue and be guided by their own clinical experience and professional judgment.

- It is advisable to have a pre-treatment questionnaire prepared, with instructions for patients, explaining the anticipated effects pre- and post-treatment, medical history, patient consent, and any other documents that may be considered critical and compliant with local laws and regulations. Purely for illustration and exemplification purposes, INDUSTRA® provides templates of these forms along with this manual.

- Always proceed with photographic documentation of all treatment stages. Talk to your patient and explain all risks that the procedure involves, as well as the potential results and their limitations.

- Carefully follow the recommendations provided under PRECAUTIONS, CONTRAINDICATIONS and SIDE EFFECTS.

- ETHEREA® PRODEEP® is electro-medical equipment that can pose a safety hazard to the operator and/or the patient under certain circumstances, especially in cases of improper installation, use, operation and maintenance.

- Always check the integrity and cleanliness of the nozzle lenses before each procedure. Never use the nozzle if the lens has any visible damage. If cleaning is required, perform the procedure according to the product's Instruction Manual.

IMPORTANT WARNINGS

- Goggles should be worn by everyone present in the procedure room during operation. Never wear goggles that do not meet the requirements specified by the manufacturer. Also, even when wearing proper goggles, never look directly at the emitted light beam.
- Considering the risk of accidental eye exposure to the beam, never use the LASER in places with reflective surfaces.

WHENEVER THE LASER IS IN USE, it is extremely important to properly protect the beam's outlet either by using the respective nozzle or the protective cover. This procedure prevents the ingress of solid particles into the LASER cavity, which could lead to permanent damage to the product.

1. USAGE INDICATIONS

ProDeep® is a non-ablative rejuvenation LASER procedure to treat both red and white stretch marks, atrophic scars and recent surgeries, acne scars and melasma. ProDeep® is also indicated as an auxiliary treatment (or off-label therapy) to control and maintain the results in several kinds of alopecia and onychomycosis.

2. CONTRAINDICATIONS

General contraindications for the ProDeep® and/or light procedures are:

- pregnanancy or breastfeeding;
- age group, at the discretion of the medical professional, according to the procedure indication;
- systemic and immunodeficiency disorders;
- a history of acute infections and/or active infectious processes;
- a history of heart problems (pacemaker, arrhythmia, etc.);
- a history of intolerance to anesthesia or related conditions;
- a history of coagulopathic bleeding;
- a history of poor scar formation;
- a tendency of keloid formation;
- uncontrolled hormonal disorders;
- localized disease in the treatment area (malignant lesions);
- an area with filling of phagocyted or non-re-absorbed substances;
- tanned skin;
- ongoing use of vitamins A and K;
- photosensitivity and/or allergic to sunlight;
- epilepsy or derived/related disorders;
- use of ASPIRIN® or anticoagulants within two weeks prior to the procedure;
- use of ibuprofen or alcohol within two weeks prior to the procedure;
- use of photosensitizing medications, such as tretinoin and estrogen;
- diabetes, except if controlled;
- pregnant patients;

3. SIDE EFFECTS AND ADVERSE EFFECTS

SIDE EFFECTS

Among the side effects and adverse effects reported in literature, pain and ecchymosis are commonly evidenced. Aside from these, others should also be considered, such as:

swelling, edema or erythema;

irritation or hypersensitivity;

hot/burning sensation;

hyper- or hypopigmentation;

superficial thrombophlebitis;

purpura;

ulcers or burns;

hypertrophic scars and keloids;

We also stress the risk of eye damage due to accidental therapeutic light exposure. For this reason, both the patient and the operator must wear goggles during the entire treatment.

After treatment, most patients will experience a slight sunburn sensation, which typically disappears without treatment within 2-3 hours. In some patients, hyperpigmentation occurs even where there is sun protection, which usually disappears within a certain period of time (transient effect). In rare cases, however, especially when treating absent or reduced pigmentation (hypopigmentation), the coloration change in the area may be permanent.

Incorrect parameterization and/or improper use of the device and handpieces may lead to burns, ulcerations and scarring, which can be permanent.

ADVERSE EFFECTS

As with most LASER procedures, there is an intrinsic risk of mild to severe side effects, especially:

- infections;
- scars or healing difficulties;
- keloid formation;
- tissue ulceration and/or burns;
- tissue necrosis;
- complications related to anesthetic administration;

4. PRECAUTIONS

Analyze the treatment area, checking whether there is any obvious damage to the tissue. Assess the skin type and tanning. If unhealed wounds or recent intense tanning are found, postpone the treatment.

Direct exposure to sunlight should be avoided for at least 4 weeks before the application and throughout the entire treatment. Even with clothing, care and attention should be used before exposure to the sun in order to prevent any resulting complications.

Always remove any traces of makeup, impurities, cream or perfume in the area to be treated.

Always talk to the patient before the procedure and explain the type of treatment to be performed in detail. Try to find out the reason for seeking this kind of procedure. Make an effort to understand the expectations and communicate the real result possibilities, side effects and adverse effects, as well as the treatment duration and number of sessions.

When in doubt about the parameter to be used, treat a small test area for subsequent evaluation. Choose the least exposed area. For PHOTOTYPES I-III, wait 30-60 minutes to evaluate. For PHOTOTYPES III-VI, it is advisable to wait at least 24 hours. Always start with the minimum recommended parameters.

Always fire shots perpendicular to the application area. Always fire with the patient's skin touching the delimiters. Never shoot the LASER away from the skin.

Make sure all items related to the procedure's SAFETY and equipment use are understood and considered, especially those regarding the use of goggles.

BE EXTREMELY CAREFUL when using the LASER to treat areas around the eyes. Avoid radiation emitted by the LASER. Proper eye protection should be worn by the patient being treated. The LASER light beam should always be directed at the skin outside the orbital area (use intraocular protection).

Only use the equipment after reading and fully understanding this APPLICATION PROTOCOL, taking into consideration all warnings indicated previously under IMPORTANT WARNINGS.

5. APPLICATION PROTOCOL

The parameters proposed here are not an absolute guide for clinical practice. The operator should use his/her own clinical experience and professional judgment to perform any treatment proposed herein.

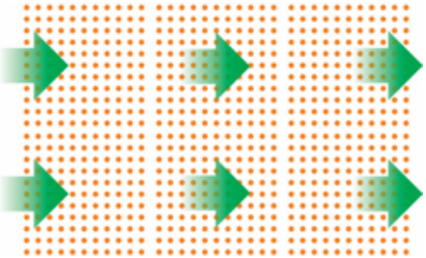
GENERAL ORIENTATION

LASER APPLICATION TECHNIQUE

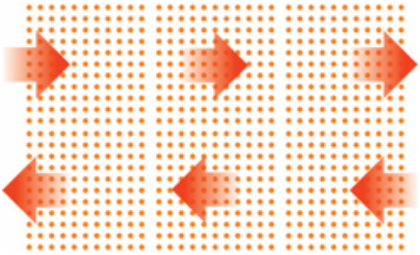
To avoid adverse effects such as burns, following the application technique is critical. Given that this wavelength has high penetration and low water affinity, subdermal heating is more intense. To avoid what literature refers to as "bulking", which is a subdermal hot-spot that may be excessive, shots should follow lines, always starting from the same side, as shown in the figures below.

Sequences of circular shots are potentially dangerous.

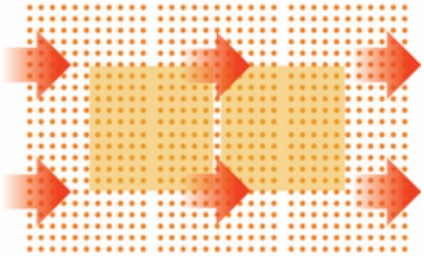
Stacked shots are not recommended with this kind of laser. The risk of adverse effects is significant. Initially, try and use the lowest frequency (shot repetition rate) to get familiar with the tip. We recommend using this feature when high energies are used.



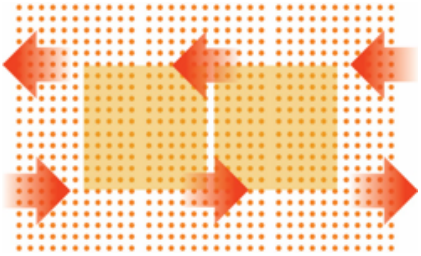
appropriate application technique: linear start and restart, always from the same point to the same direction.



application technique not recommended: alternating back and forth movements may cause overlap and result in undesirable effects.



application technique not recommended: never overlap, not even when back and forth passes start from the same point and end at the same point.



application technique not recommended: alternating back and forth movements increases the possibility of causing shot overlaps and resulting in undesirable effects.

The stipulated levels of erythema and edema are for reference only, provided only as a basis for immediate post-treatment effect. It warrants emphasis that even when using the same parameters, different phototypes and skin thickness may show immediate effects at different levels.

Always start with a test area. Try and fire around 3 (three) sequential shots and wait about 10-15 minutes to assess the erythema and edema resulting from the treatment. Try and perform this test on less exposed areas.

Start the treatment at a low power and, if you deem it necessary, increase the power according to the patient's tolerance and reaction to the treatment. This precaution may extend the number of sessions but, on the other hand, it will minimize the possibility of unwanted adverse effects.

Follow concurrent cooling and application technique information.

If more than one pass is made, always start from the previous pass starting point. Cool the skin down between passes.

Always use intrapalpebral protectors (not included) to treat periorbital areas. Not following this guideline may cause serious risk to the patient.

Clean the skin to remove perfumes, cosmetics and sunscreens. Skin should be dry during application.

Assess skintype! Skintypes above III have a higher risk of hyperpigmentation after treatment.

Using external cooling before and during shots is highly advisable. Aside from providing an epidermal protection, it also significantly reduces the burning sensation for the patient. We recommend using cold air coolers, such as the Siberian Fit appliance (VYDENCE MEDICAL).

TOPICAL ANESTHETICS AND FORMULATION

The use of anesthetics can be prescribed to increase the patient's comfort during the procedure. However, it warrants emphasis that, due to the procedure's inherent nature, there is insufficient data to confirm the real efficacy of analgesia.

Clinical experience shows that combining micro-focused ultra-sound technology with a topical anesthetic may cause an allergic reaction and lead to the formation of papules on some treated areas.

Using a topical anesthetic prior to the treatment is a choice that depends on the physician's clinical criteria. There are several alternatives and formulations available on the market. They include:

a. 7% lidocaine and 7% tetracaine anesthetic gel;
b. 4% lidocaine anesthetic gel;

References to formulations herein are indicative of clinical practice and should not be interpreted, under any circumstances, as an absolute guideline for clinical reference. The physician's judgment will determine the suitability of use. Prior evaluation of the formulation's toxicity, including its usage history, must ALWAYS be considered, especially regarding its use on the patient.

It is critical to ALWAYS FOLLOW THE DRUG SUPPLIER'S ORIENTATIONS regarding handling and required safety precautions (before, during and after treatment) and the efficacy of desired effects. More importantly, make sure to understand the risks of adverse effects and how to proceed if they occur. The size of the area, application time and duration of anesthesia varies by manufacturer and/or supplier;

Be careful when using the anesthetic on mucosa (lips, nostrils and especially the eyes);

NEVER PROVIDE OR PRESCRIBE ANESTHETICS FOR HOME USE.

ANALGESICS AND ANTI-INFLAMMATORY DRUGS

Administration of oral or sublingual analgesic or anti-inflammatory drugs is a clinical consensus commonly associated with the procedure above. This may increase comfort during the procedure, although there is a certain variability due to the patient's physiology.

FRACTIONAL REJUVENATION

In recent years, self-esteem and self-image concerns have been considerably increasing, leading to the search for new non-invasive treatment options that restore a youthful and renewed appearance to the skin.

LASER fractional rejuvenation is a non-ablative procedure indicated to treat wrinkles, fine lines and expression marks. Initially considered as a therapeutic alternative to traditional ablative LASERs, fractional photo-rejuvenation has gained its own space over the years, and today new technologies are being developed and used in combination to significantly improve the results.

MILD TO MODERATE WRINKLES

The number of sessions usually ranges from 3 to 5. The interval is usually around 30 days, depending on the aggressiveness of the treatment.

MILD TO MODERATE WRINKLES				
SPOT SIZE	POWER	PULSE TIME	PASSES	EDEMA AND ERYTHEMA
8 mm & 100 mtz/cm^2	70-90 mJ/mtz	3-5 ms	1-2	moderate
8 mm & 100 mtz/cm^2	90-120 mJ/mtz	3-5 ms	1	moderate
8 mm & 100 mtz/cm^2	120-140 mJ/mtz	3-10 ms	1	severe

*If cooling is not used, limit the power to 100 mJ/mtz and the frequency to 1.5 Hz;

PHOTODAMAGE AND PIGMENTATION

The number of sessions usually ranges from 3 to 5. The interval is usually around 30 days, depending on the aggressiveness of the treatment.

PHOTODAMAGE AND PIGMENTATION				
SPOT SIZE	POWER	PULSE TIME	PASSES	EDEMA AND ERYTHEMA
10 mm & 400 mtz/cm^2	10-16 mJ/mtz	3-5 ms	2-3	mild
10 mm & 400 mtz/cm^2	14-20 mJ/mtz	3-5 ms	2	mild
10 mm & 400 mtz/cm^2	10-14 mJ/mtz	3-10 ms	1-3	moderate

*If cooling is not used, limit the power to 100 mJ/mtz and the frequency to 1.5 Hz;

SCARS

Scars are the result of a skin injury, usually resulting from accidents, surgical incisions or, in some cases, even an adverse effect after treating active acne. Proper management of scars is critical to the patients' recovery and well-being, given that results that are not aesthetically pleasing may affect social life and self-esteem. Today, with new technologies such as the fractional LASER, new solutions have been incorporated to permanently eliminate or minimize issues caused by scar tissue formation.

The number of sessions usually ranges from 3 to 7. The interval is usually around 30 days, depending on the aggressiveness of the treatment.

SCARS				
SPOT SIZE	POWER	PULSE TIME	PASSES	EDEMA AND ERYTHEMA
8 mm & 100 mtz/cm^2	10-16 mJ/mtz	3 ms	2	moderate
8 mm & 100 mtz/cm^2	120-150 mJ/mtz	3-5 ms	1	severe

*if cooling is not used, limit the power to 100 mJ/mtz and the frequency to 1.5 Hz;
**more recent atrophic scars have better therapeutic indication;

STRETCH MARKS

Stretch marks are characterized by the rupture of elastic fibers that support the dermis, mainly made of collagen and elastin and responsible for the tissue tone and elasticity. Stretch marks affect men, women and children of many ages, with different triggering factors, such as rapid growth, constantly gaining and losing weight, hormonal imbalance, excessive physical activity, pregnancy, and even the continuous skin dryness. Stretch marks are most common on the breast, hips, inner and outer thighs and buttocks.

Currently, there are several treatment options for stretch marks, such as LASER fractional rejuvenation which, combining different principles, acts on the tissue to stimulate the production of new collagen and elastin fibers.

The number of sessions usually ranges from 3 to 7. The interval is usually around 30 days, depending on the aggressiveness of the treatment.

STRETCH MARKS				
SPOT SIZE	POWER	PULSE TIME	PASSES	EDEMA AND ERYTHEMA
8 mm & 100 mtz/cm^2	90-120 mJ/mtz	3 ms	2	moderate
8 mm & 100 mtz/cm^2	120-150 mJ/mtz	3-5 ms	1	severe

*if cooling is not used, limit the power to 100 mJ/mtz and the frequency to 1.5 Hz;
**more recent red stretch marks have better therapeutic indication;

MELASMA

Melasma is a very common dermatosis, distinguished by dark patches, especially on the face, causing severe social impact in the people it afflicts. Several treatment methods and alternatives are currently available, with the LASER representing a new, highly successful technique that is becoming a common option either alone or combined with other known therapies. In mid-2009, the FDA approved melasma treatments using a low-fluence LASER.

The number of sessions usually ranges from 1 to 4. The interval is usually around 15 to 30 days, depending on the aggressiveness of the treatment.

MELASMA				
SPOT SIZE	POWER	PULSE TIME	PASSES	EDEMA AND ERYTHEMA
10 mm & 400 mtz/cm^2	10-16 mJ/mtz	10 ms	2	mild
10 mm & 400 mtz/cm^2	5-10 mJ/mtz	10 ms	2	mild

*whitening formulations may be combined during immediate post-treatment to boost the results;

ALOPECIA

LASER capillary therapy has been used with great efficacy in recent years. Using photo--bio-stimulation, the LASER power acts directly on the pilous bulge, a structure rich in stem cells, and induces an increase in local cellular activity, thus promoting thickening of existing hair. Usually, this is a gold standard indication for people with a family history of baldness or little hair, especially those who have been noticing a pronounced increase in hair loss, either related to stress or various clinical conditions.

The number of sessions usually ranges from 4 to 6. The interval is usually around 15 to 30 days, depending on the aggressiveness of the treatment.

ALOPECIA				
SPOT SIZE	POWER	PULSE TIME	PASSES	EDEMA AND ERYTHEMA
10 mm & 400 mtz/cm^2	10-16 mJ/mtz	10 ms	2	mild

*drug infiltration or topical substances may be combined (drug delivery) during immediate post-treatment to boost the results;

POST-TREATMENT

Using an SPF 50 sunscreen is recommended throughout the treatment and for at least 30 days before the first session. T he patient should always use sunscreen on treated areas before, during and after the treatment.

Using waxes or shaving creams, tweezers or tanning creams is not recommended during the 2 weeks before and after the treatment.

Using a soothing lotion, applied in circular movements, as well as cool compresses, may help to minimize the burning feeling post-treatment. After the application and the procedure, the treated area should be washed gently for up to 3 days, avoiding intense rubbing.

Using LED and topical and/or oral corticosteroids is always recommended to soothe the skin immediately after each session.

Pre-/post-treatment clinical action is key to the therapy's success, as well as for preventing unwanted and adverse effects.

Patients should also be instructed to immediately contact the doctor if any signs of infection (such as pus, pruritus, draining or fever), significant pain or complications and side effects emerge.

Patients should be advised to immediately seek a medical profesional for urgent care in the event of severe or abnormal side effects after the treatment.

Patients should return for medical follow-up as prescribed. The time to return is usually 24-72 hours after the procedure;

6. BIBLIOGRAPHY

Costa MLM, Azevedo LCM, Stock FS, Grohs LMH, Wanczinski MI, Cunha PR, Campos VB. ESTUDO COMPARATIVO DA EFICÁCIA DO USO DE LASER 2940-NM, 1340-NM E LIP NO REJUVENESCIMENTO GLOBAL DAS MÃOS. Trabalho apresentado no V Simpósio de Cosmiatria e LASER da SBD, São Paulo, SP. 2013

Jordão J, Campos V, Santos T, Pinto C, Trevisan F, Pitassi L. FRACTIONAL ABLATIVE LASER VERSUS FRACTIONAL ABLATIVE AND COAGULATIVE LASER FOR THE TREATMENT OF PHOTODAMAGED SKIN IN ARMS AND FOREARMS. Poster originally presented at ASLMS Annual Conference, 2011

CR Antonio, JR Antonio, GB de Oliveira, LA Trídico, MP Borim. USO DO LASER FRACIONADO NÃO ABLATIVO NDYAP 1.340NM NO TRATAMENTO DA ACNE NÓDULO CÍSTICA RESISTENTE À ISOTRETINOÍNA. Surg Cosmet Dermatol 2013;5(4):3104.

CR Antonio, GB de Oliveira, MGG Coura, LA Trídico, LR Pereira, SCGP D'Ávila. TRATAMENTO DE HIDROSADENITE COM LASER ND:YAP 1340 NM. Surg Cosmet Dermatol 2015;7(1):46-9.

V Campos, J Jordão. EFFICACY AND PATIENT SATISFACTION OF A NEW NON ABLATIVE FRACTIONAL ND:YAP LASER 1340 NM FOR FACIAL REJUVENATION IN BRAZILIAN PATIENTS. Poster originally presented at ASLMS Annual Conference, 2011.

CR Antonio. O USO DO ND:YAP 1.340 nm PARA O TRATAMENTO DA FOLICULITE DISSECANTE DO COURO CABELUDO: RELATO DE CASO. Trabalho apresentado no XXVI Congresso Brasileiro de Cirurgia Dermatológica, 2014.

Geraghty NL, Biesman B. CLINICAL EVALUATION OF A SINGLE-WAVELENGTH FRACTIONAL LASER AND A NOVEL MULTI-WAVELEGHT FRACTIONAL LASER IN THE TREATMENT OF PHOTODAMAGED SKIN Med. 41:408–416, 2009. 2009 Wiley-Liss, Inc.

Angelis F, Kolesnikova L. FRACTIONAL, NON-ABLATIVE LASER THERAPY FOR THE TREATMENT OF STRIAE DISTENSAE

Vasily DB, Cerino M. Fractional, NON-ABLATIVE LASER THERAPY FOR THE TREATMENT OF SURGICAL AND TRAUMA SCARS Aesthetica Cosmetic and LASER Surgery Center, Bethlehem, PA 18018

Kim WS, Lee HI, Lee JW, Lim YY, Lee JS, Kim JB, Kim NM, Song KY, Park SW. FRACTIONAL PHOTOTHERMOLUSIS LASER TREATMENT OF MALE PATTERN HAIR LOSS © 2010 by the American Society for Dermatologic Surgery, inc • Dermatol srg 2011;37;41-51 • DOI: 10.1111/j.1524-4725.2010.01833.x

Manstein D, Herron SG,Sink K,Tanner H, Anderson R. FRACTIONAL PHOTOTHERMOLYSIS: A NEW CONCEPT FOR CUTANEOUS REMODELING USING MICROSCOPIC PATTERNS OF THERMAL INJURY LASERs in Surgery and Medicine 34:426–438 (2004)

Geronemus GR. FRACTIONAL PHOTOTHERMOLYSIS: CURRENT AND FUTURE APPLICATIONS. LASERs in Surgery and Medicine 38:169–176 (2006)

Goldberg JD, Alexander L. Berlin LA, Phelps R. HISTOLOGIC AND ULTRASTRUCTURAL ANALYSIS OF MELASMA After Fractional Resurfacing. LASERs in Surgery and Medicine 40:134–138 (2008)

Bas S. Wind SB, Kroon WM, Meesters AA, Beek FJ, J.P. Wietze van der Veen, Nieuweboer-Krobotova L, Jan D. Bos DJ, Wolkerstorfer A. NON-ABLATIVE 1,550 NM FRACTIONAL LASER THERAPY VERSUSTRIPLE TOPICAL THERAPY FOR THE TREATMENT OF MELASMA:A RANDOMIZED CONTROLLED SPLIT-FACE STUDY. LASERs in Surgery and Medicine 42:607–612 (2010)

7. NOTES

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