ATHENA

TREATMENT GUIDELINES

etherea MX

ETHEREA-MX®
DUALMODE®
ATHENA®

VERSION 1.2 - NOVEMBER 2017

vydence medical | An Adavium Medical company

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IMPORTANT WARNINGS

- The practical training provided by the company is vital to the understanding of the device and technique. On the other hand, this does not replace any other medical qualifications necessary for its correct use.

- Before handling and/or operating the device, it is required to read the respective operating instructions.

- The ETHEREA® device and its respective DUALMODE® ATHENA® handpiece must be operated only by qualified professionals. The qualifications of the user, as well as the installation requirements and support for the procedures, vary from country to country, therefore, it is the professionals responsibility to gather information from the local regulatory agencies.

- This document does not intend to be a complete and absolute guide for the use of the techniques incorporated in the device and provided in response to the referenced information. It is understood that the operator of the device has appropriate training and proper qualifications for the procedures proposed in this manual.

- The parameters suggested here are not absolute in clinical practice. The operators must understand the interactions of the treatment with the target tissue and be guided by their clinical experience and professional judgment.

- It is recommended to include a detailed and suitable pretreatment questionnaire with guidelines to the patient, stating the effects expected in the pre- and posttreatment, medical history forms, CONSENT FORM regarding the procedure and any other documents that may be considered essential prior to conducting the procedure and in accordance with local laws. VYDENCE MEDICAL provides, for illustrative purposes only, models of these forms along with this manual.

- Always proceed with the photographic documentation for all stages of the treatment. Talk to your patient and explain all the risks involved in the procedure and the potential results as well as its limitations.

- Note, carefully, the recommendations contained in the: PRECAUTIONS, CONTRAINDICATIONS and SIDE EFFECTS section on this manual.

- ETHEREA® DUALMODE® ATHENA® is an electro-medical device that can cause a safety risk for the operator and/or patient under certain circumstances, especially in the case of installation, operation and maintenance inadequacy.

- Always check the integrity and cleanliness of mirrors, applicators and the speculum before performing each procedure. Never use if the lens presents any apparent damage. If it is necessary to perform cleaning, perform the procedure according to the Instruction Manual.

- Safety goggles should be used by all persons in the procedure room, during the procedure. Never wear safety goggles that do not meet the requirements specified by the manufacturer. Also, even when using the appropriate goggles, never look directly into the laser beam.

IMPORTANT WARNINGS

- The Er: Yag LASER should be carefully handled with respect to accidental eye exposure. The potential risk of permanent damage is high. IT IS MANDATORY THAT ALL PERSONS PRESENT IN THE PROCEDURE ROOM WEAR THE PROPER SAFETY GOGGLES.

- Never use the LASER where there are reflective surfaces because of the risk of accidental eye exposure to the beam.

- The Er: Yag LASER 2940 nm is a form of ablative treatment where there is vaporization of the target tissue. Thus, because of the tissue particles suspended in the air, it is imperative to wear a protective mask with a carbon-activated filter and a proper smoke aspirator. The mirrors, applicators and the speculum should always be kept clean. Applicators can be removed and autoclaved.

WHENEVER THE LASER IS NOT IN USE, it is extremely important for the beam output to be properly protected - with the respective nozzle and protective cap. This procedure prevents the entry of solid particles in the LASER cavity, which may result in permanent damage to the product.

1. INSTRUCTIONS FOR USE

DUALMODE® ATHENA® 1. is a procedure indicated for healthy patients, from the ages of 18 to 60 years. The handpiece (applicator) DUALMODE® ATHENA® is indicated for treatments referring to the use of ablative LASERSin the treatment of the female anatomy, particularly for collagen stimulation and an increase in local lubrication. Aimed at treating genitourinary menopause and whitening and skin tightening of the inner and outer vaginal lips.

2. CONTRAINDICATIONS

The following are considered general contraindications for LASER and/or light procedures:

- pregnancy or breastfeeding;
- age, on discretion, depending on the procedure indication;
- systemic diseases and immunodeficiency;
- history of acute infections and/or active infectious processes;
- a history of heart problems (pacemaker, arrhythmias, etc.);
- a history of intolerance to anesthesia or derived conditions;
- coagulopathic bleeding a history of;
- poor wound healing history a history of;
- tendency to form keloids;
- hormonal disorders, uncontrolled;
- disease in the area of the treatment (malignant lesions);
- an area with cosmetic fillers not reabsorbed or phagocytosed;
- tanned skin;
- continued use of vitamins A and K;
- photosensitivity and/or allergi to sunlight;
- epilepsy or disorders arising/resulting from;
- use of ASPIRINA® or anticoagulants within two weeks before the procedure;
- use of ibuprofen or alcohol within two weeks prior to the procedure;
- use of photosensitizing medications, such as tretinoin and estrogen;
- diabetes unless under control;

3. SIDE EFFECTS AND ADVERSE EFFECTS

SIDE EFFECTS

Among the side and adverse effects reported in the literature, pain and burning are commonly evident when the treatment is performed in the external area of the genitals. In addition, also subject to incidences are:

swelling, edema or external erythema when treatment is performed in this area;

irritation or hypersensitivity;

burning sensation;

hyper or hypopigmentation;

superficial thrombophlebitis;

incidence of purpura;

mild Auspitz's sign.

It is also emphasized the risk of eye damage by accidental exposure to therapeutic light. For this reason, the safety goggles should remain in use throughout the treatment by both the patient and the operator.

After the treatment of the external area, the majority of patients may experience mild sunburn sensation, which typically disappears without treatment in 2-3 hours. In some patients hyperpigmentation may occur and generally disappears within a specified period (transient effect). In rare cases, however, especially when dealing with absence or reduction of pigment (hypopigmentation), the change in color of the region may be permanent.

In the correct selection of parameters when using the device and the handpieces may result in burns, ulcerations and appearance of scars, which may be permanent.

ADVERSE EFFECTS

As it can occur in most LASER procedures, there is the inherent risk of incidence of mild to severe side effects, especially:

- infections;
- scars or poor wound healing;
- keloid formation;
- tissue ulceration and/or burns;
- tissue necrosis;
- complications related to administration of an anesthetic;

4. PRECAUTIONS

The use of external cooling units before, during and after the treatment is highly recommended. An example of a similar unit is the SIBERIAN® device.

The application of the LASER light must be performed at a perpendicular angle to the area of the treatment (approx. 90º).

After performing the first sequence of shots, wait a few minutes. This procedure is important in order to increase the safety index of the procedure. The result may be a delayed reaction especially in darker skins.

Analyze the area of the treatment, checking if there is no obvious damage on the tissue. Assess the skin type and tanning. In case of wounds not healed yet or even recent intense tanning, postpone treatment.

Direct sunlight should be avoided for at least 4 weeks before the application and throughout the treatment. Previous sun exposure, even when wearing clothes, must take place with care and attention to avoid any complications.

Always remove any make up, dirt, cream or perfume present in the area being treated.

Always talk to the patient before the procedure and explain in detail the type of treatment to be conducted. Try to find out the reason the patient is looking for this kind of procedure. Seek to understand the expecations and ensure the possible results, side effects and adverse effects are clear, as well as the duration of treatment and number of sessions.

When in doubt about the parameter to be used, perform the treatment in a small area for testing, for further evaluation. Choose the least exposed area possible. For PHOTOTYPES I-III, wait from 30 to 60 minutes for evaluation. For PHOTOTYPES III-VI, it is advised to wait, at least, 24 hours. Always start with the recommended minimum parameters.

Make sure that all items relating to the SAFETY of the procedure and use of the device were understood and respected, particularly those concerning the use of safety goggles.

Only use the device after a complete reading and understanding of this APPLICATION PROTOCOL, and taking into account all warnings previously indicated in the section IMPORTANT WARNINGS.

For patients with skin more sensitive to pain, it is possible to use topical anesthetics.

5. APPLICATION PROTOCOL

The parameters suggested here are not an absolute guide in clinical practice. The operator should be guided by his/her own clinical experience and professional judgment to perform all and any procedure proposed in this document.

GENERAL ORIENTATION

TOPICAL ANESTHETICS AND FORMULATION

The use of anesthetics can be indicated to increase the feeling of comfort for the patient during the procedure, mainly for external treatment. However, it is worth noting that, due to the procedure's inherent nature, there is not enough clinical data available to prove the real effectiveness of the sense of analgesia.

Clinical experience indicates that the combination of laser technology with topical anesthetic use may cause an allergic reaction and result in papule formations located in some areas of the treatment.

The use of topical anesthetics prior to treatment is solely at the discretion of the medical profesional performing the treatment. There are several possibilities and formulations available in the market. Among them, it is possible to mention:

a. anesthetic gel, with 7% of lidocaine and tetracaine (ex.: PLIAGLIS®);
b. anesthetic gel, with 4% of lidocaine (ex.: DERMOMAX®);

References to the formulations provided herein are only indicative of clinical practice and should not be treated, under any circumstances, as an absolute guide of clinical reference. It is up to the medical professional to make the proper use judgment. The preliminary evaluation of the toxicity of the formulation, including its history of uses, should ALWAYS be considered, especially in relation to its use for the patient

It is essential to ALWAYS FOLLOW THE INSTRUCTIONS OF THE SUPPLIER OF THE MEDICATION, in relation to handling and care required for safety (before, during and after treatment) and efficacy of desired effects. Check, especially, the risks of adverse effects and how to act in case they occur. The size of the area and time of application and duration of anesthesia vary according to the manufacturer and/or supplier.

Be careful when using the anesthetic in the area of the mucous membranes.

NEVER PROVIDE OR PRESCRIBE ANESTHETICS FOR DOMESTIC USE.

FRACTIONAL RESURFACING

ATHENA 360º is an intravaginal treatment that allows rejuvenation, restoration, hydration and stimulates collagen contained in the vaginal walls.

This treatment is contraindicated for pregnant women, those who have sexually transmitted diseases a presence of cytology changes in the last Pap test, inflammation of the vulva or diseases related to blood clotting.

If the patient has a history of genital herpes, prophylactic treatment should be performed before and after the treatment.

Make sure that the chosen ATHENA applicator is properly attached to the DUALMODE® handpiece with the platform already in operation.

Check the need for anesthesia or not.

Perform careful asepsis of the external genitalia.

The duration of the session is approximately 15 minutes.

If the patient has no contraindication, topical estrogen use is indicated for one month before starting the treatment to improve lubrication or other genital moisturizer.

Important: perform 4 consecutive shots on the same area, passing each applicator 3 times.

Start each treatment with the ATHENA 90º.

For the application of ATHENA 90º, consider the following guideline:

The first application at 12pm, the next at 1pm and another at 11am, as instructed below:

Two or three sessions are required at monthly intervals; Most women do not report any discomfort after the procedure, however a slight local discomfort after the treatment and several days after the session may occur;

Sexual intercourse should be avoided for one week post-treatment;

During the healing period, it is recommended to avoid heavy lifting or other activities, such as hot bathing or physical exercise.

ATHENA LASER FOR WOMEN'S INTIMATE REJUVENATION				
HANDPIECE	MODE	FLUENCE	RATE OF RETREATING (mm/SHOT)	COMMENTS
ATHENA 360º	COLLIMATED	1,5 – 2,5 J/cm^2	4-5	Circular beam, 3.5 mm width
ATHENA 90º	FRACTIONAL	30 – 40 mJ/mtz	8-9	SPOT 8 mm
ATHENA 90º	COLLIMATED	3 – 4 J/cm^2	8-9	SPOT 8 mm

For sagging skin treatments and lip hyperpigmentation, protocol adjustments may be necessary, as described below.

GENITOURINARY SYNDROME OF MENOPAUSE

The ATHENA 90º applicator is best for the treatment of urinary incontinence with or without menopause, but for a better response, the ideal is the combined use of the two applicators.

ATHENA LASER FOR WOMEN'S INTIMATE REJUVENATION				
HANDPIECE	MODE	FLUENCE	RATE OF RETREATING (mm/SHOT)	COMMENTS
ATHENA 90º	FRACTIONAL	30 – 40 mJ/mtz	8-9	SPOT 8 mm
ATHENA 90º	COLLIMATED	3 – 4 J/cm^2	8-9	SPOT 8 mm

This treatment is contraindicated for pregnant women, who have sexually transmitted diseases or presented cytology changes in the last Pap test, inflammation of the vulva or diseases related to blood clotting.

If the patient presents a genital herpes history, prophylactic treatment should be performed before and after the treatment.

Make sure that the chosen ATHENA applicator is properly attached to the DUALMODE® handpiece, with the platform already in operation.

Check the need for anesthesia or not.

Perform careful asepsis of the external genitalia.

The duration of the session is approximately 15 minutes.

If the patient has no contraindication, topical estrogen use is indicated.

Two or three sessions with monthly intervals are required.

Most women report mild discomfort in the area after the treatment and several days after the session.

Sexual intercourse should be avoided for a week.

During the healing period, it is recommended to avoid heavy lifting or other activities, such as taking hot bath or exercise

LOCAL WHITENING AND SKIN TIGHTENING

Suitable for treatment of inner and outer vaginal lips.

The use of topical anesthetic may be necessary as it provides more comfort for the patient. Remove it before the procedure.

Important: for these treatments, the entire area should be free of hair.

In the immediate post-treatment, a soothing cream is recommended.

The Athena can also be indicated in conjunction with genital chemical peeling during the immediate post-treatment, to improve pigmentation.

For skin tightening:

INLIFT LASER LIFTING			
MODE	ENERGY	NUMBER OF SHOTS	FITZPATRICK
FRACTIONAL INLIFT	30-40 mJ/mtz	30-80 per side	I-VI

For whitening outer lips and groin:

ENERGY	PULSE TIME	SPOT SIZE	APPLICATION	SHOT FREQUENCY
2-3 mJ/mtz	µ	8/400 mtz	1	1-3Hz

POST - TREATMENT

Treatment with DUALMODE® ATHENA® is usually well tolerated and there is no need for extreme care after the procedure.

Sexual abstinence of 7 days is advised.

An antifungal for local application can be indicated in cases of higher sensitivity.

Edema and erythema are expected effects in the post-treatment of the external area and usually, disappear completely in 7 days following the procedure, depending on the aggressiveness of the treatment performed. In some cases, they may persist for up to 3 weeks.

The microlesions arising from the application of the fractional laser beam on the external area will commonly disappear within 24-48 hours after the treatment. Initially, the lesions will have a diffuse erythema appearance and, later, with the healing process having started, the appearance is similar to tanning. The appearance of lesions and also the overall appearance of the area in the post-treatment vary according to the intensity and agressiveness of the treatment. Usually, they may last from 3 to 7 days.

A soothing lotion applied in circular movements, as well as the application of cold compresses can help alleviate the burning sensation in post-treatment. After the application and completion of the procedure, the area treated should always be gently washed for up to 3 days avoiding intense friction.

In the immediate post-treatment, the reported use of occlusive aqueous cream is highly recommended in many publications. Dexpanthenol based solutions (ex.: BEPANTOL®), for example, may be used in 4 day segments. The application of other topical agents in a derived oily solution (vaseline) can induce allergic conditions (ex.: Contact dermatitis).

The clinical care for pre/post-treatment is critical to the success of the therapy and the prevention of unwanted adverse effects.

Patients should also be instructed to contact the doctor immediately if any signs of infection appear (for example, puss, itching, drainage or fever), significant pain or complications and consequent side effects.

Patients should be advised not to delay in seeking medical professional help, immediately, in the case of severe side effects or abnormal occurrences during the post-treatment.

The patient should return for a medical follow up as prescribed. This period is usually from 24 to 72 hours after the procedure.

The total number of sessions varies from case to case and treatment indication. It is usually required from 1 to 3 treatment sessions. The interval between sessions is about 30 days and may increase depending on the area of application and aggressiveness of the treatment.

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