MCL31 Dermablate Training Manual

MCL31 Dermablate

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This training manual is intended as a supplement to the user manual. It was produced with the kind assistance of Dr. Peter Arne Gerber, Dept. of Dermatology, University Hospital Dusseldorf, Germany.

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Basic Anatomy

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The Skin

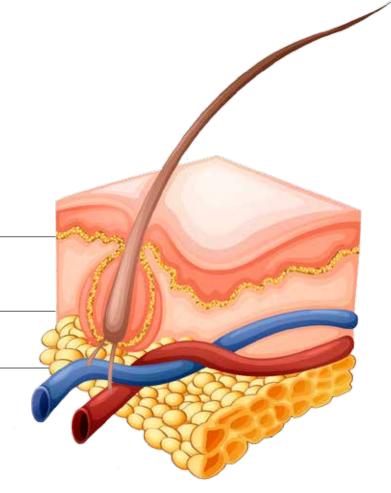
The skin is an organ that covers and protects the body and is made up of various tissues. Skin is defined as healthy when, at any age, its characteristics are normal and its vital processes are all working in harmony. The surface of the skin consists of epithelial tissue, called the **epidermis**, whilst deeper down, below the surface, is connective tissue, called the **dermis**. This is followed by **subcutaneous connective** tissue, which is rich in fat and reaches right up to the fascia covering muscles and bones, depending on the part of the body. The skin also contains a series of **appendages** that completes its structure and function: hairs, nails, and various glands that originate in the epidermis and protrude into the dermis. The skin or cutis, not including the subcutaneous layers, represents a significant proportion of human body weight (about 5 - 6%); its **surface area** is proportional to height and, to a lesser extent, to body weight: in an adult 1.70m tall weighing 70 kg, the surface area of the skin is around 1.8 m^2 . The thickness of the cutis varies for different parts of the human body with the palms of the hands and soles of the feet having an average thickness between 1.5 and 2 mm, whilst the scalp can reach a thickness of 4 mm, and the eyelids a minimum of around 0.5 mm.

The skin is composed of 3 types of tissue: Epidermis, Dermis, Hypodermis

The Epidermis

The Dermis

The Hypodermis



The Epidermis

The epidermis is divided into 5 layers; the cell making up this tissue is keratinocyte, which migrates from the stratum basale to the stratum corneum with the process of keratinization lasting 3-4 weeks and ending with the formation of keratin in direct contact with the exterior 5 layers of the epidermis:

- Stratum corneum
- Stratum lucidum
- Stratum granulosum
- Stratum spinosum
- Stratum basale

It contains no blood or lymphatic vessels. Of the five layers, the stratum corneum and the stratum basale are extremely important in aesthetic treatments.

Stratum corneum

The stratum corneum consists of keratinized cells that have completed their life cycle (25/30 days). The mass of keratinized cells eliminated over 24 hours is 6 to 14 grams. The hydrolipidic film present on the stratum corneum is made from **water**, **lipids**, **and sugars**. It prevents heat dispersion, and has a protective effect against pathogens (pH 4.2/5.6).

Stratum basale

The main function of the stratum basale is the continuous reproduction of keratinocytes by mitosis: each cell periodically splits into two and the new-born cells are forced to migrate upwards. Thanks to contact with the dermis, it draws nutrients and oxygen through the bloodstream. Furthermore, the stratum basale is home to melanocytes, the pigment-producing cells of the skin.



The Dermis

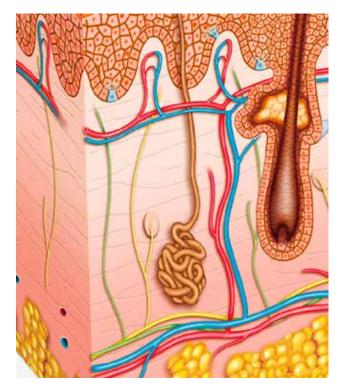
The dermis, the middle layer of the skin, is located beneath the epidermis to which it is closely linked insofar as it sustains it, nourishes it, and provides a home to the epidermal appendages, i.e. glands and hairs.

The dermis is composed of:

- Fibers (collagen, elastin, nerves)
- Extracellular matrix (ECM) components (hyaluronan and water)
- Ground substance (sugar and water)
- Fibroblasts
- Vessels (arterial, venous, lymphatic), which also provide nourishment to the epidermis

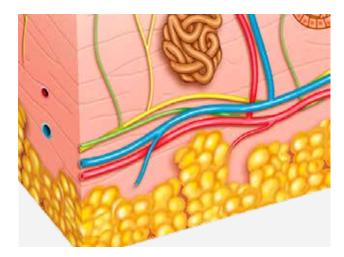
There are:

- Sweat glands: sweat = water + electrolytes
- Sebaceous glands: sebum is part of the hydrolipidic film
- Hair follicles, including hair roots and the bulge region (stem cells): produce hair



The Hypodermis (Subcutis)

The hypodermis is a tissue located beneath the dermis and is predominantly fatty. The function of this tissue is to act as a buffer, as insulation, and as a reserve of calories for periods of fasting. The hypodermis is highly innervated and vascularized. The structure and development of the hypodermis depend on the area of the body, age, gender, race, nutrition, and individual hormonal influences. Its thickness also varies, ranging on average between 0.5 and 2.0 cm. In some locations, such as the nose, eyelids, and pinna, the hypodermis is virtually absent, whilst it is most abundant in other areas, such as the gluteal regions. The subcutaneous adipose tissue can appear more or less rich in fat, but in any case it is a healthy tissue.



Laser Technology

The Laser

A laser is a device capable of emitting a beam of coherent, monochromatic, and unidirectional light concentrated in a straight ray. Furthermore, the intensity of radiation from a laser is very high compared to that of traditional light sources (lamps). These two properties (being coherent and monochromatic) are behind the vast range of applications that laser devices have had and continue to have in a wide range of fields: lasers for cutting, engraving, and welding metals, as well as many medical and aesthetic applications such as hair removal. The interaction between a laser beam and tissue determines the transfer of energy which, transformed into heat, has the effect of destroying the target itself.

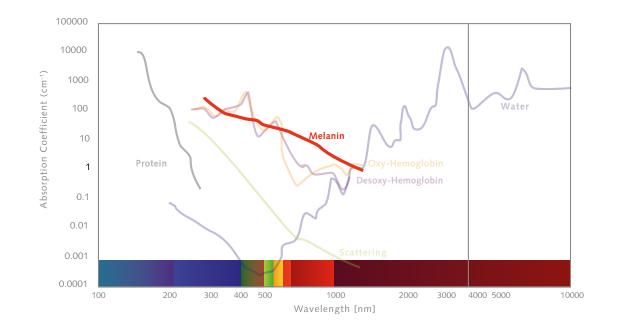
The laser in medicine

There are different types of lasers with effects that vary depending on the wavelength and pulse duration emitted and therefore have different uses; indeed each type of laser is absorbed by a particular component of the skin, and therefore has a different » target «. The main chromophores found in the skin are:

- Haemoglobin (blood vessels)
- Melanin (hair, pigments)
- Water (skin)
- Artificial particles as tattoo inks

Selective photothermolysis

The absorption of light by the target depends on the wavelength. Absorption causes desired heat (target) or undesired heat (side effects). The main aim is to carry out treatment without side effects, with high target absorption, and with no absorption in the surrounding area. For the treatment with an Erbium YAG laser (2,940 nm), the target is water.



Asclepions Erbium:YAG laser

Er:YAG

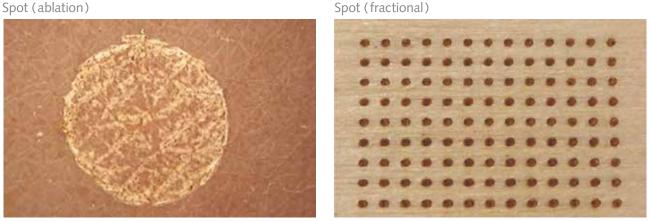
The actual laser consists of a laser head, an optical resonator and a laser bench. The laser head contains an optical reflector that projects multi-spectral light from a pulsed flashbulb into the laser rod. Light is generated by optical excitation of the laser rod. This light is then bundled within the optical resonator. The resonator itself consists of two mirrors, one at each end of the laser head. They are aligned parallel to each other. One mirror provides 100% reflection, with the other mirror reflecting only part of the beam, while allowing the remaining laser energy to pass through as useful laser light. The laser bench provides mechanical support for the laser head and the resonator. It also accommodates further functional components such as an energy measuring head, a pilot laser beam injection module and a mechanical beam shutter. The therapy laser beam, which is coaxially aligned with the pilot laser beam, is directed onto an articulated mirror arm to be passed on to the handpiece.

Handpieces

In order to obtain a homogeneous and uniform spot, the handpieces feature a special developed optics. In the case of the TEAM handpiece, the spot size is changed just by turning the ring. The distance to the skin remains constant. The MicroSpot handpiece contains a micro lens array which divides the beam into hundreds of small laser beams (fractional laser therapy).



Spot (ablation)



Integrated smoke evacuation

Smoke, vapor and tissue particles are produced as by-products of ablative laser treatment. These contaminants are removed by the internal smoke evacuator with three-stage filter system to keep the visual field clean for the operator and exhaust any air pollutants. The patented smoke evacuation system which is integrated into the handpiece allows the therapist to treat without assistance. Due to the fact that the evacuation is automatically activated and finished by the footswitch, the noise is limited to the minimum time.

Modes

The MCL31 Dermablate offers multiple operation modes, allowing different treatments according to the area to be treated and to the experience of the user. You can choose among:

- Standard mode for full skin ablation which allows the users to perform fast and safe treatments on all patients
- Thermal mode for hemostasis during skin ablation
- MicroSpot modes for fractional skin ablation which allows the users to perform a fractional treatment with the lowest risk of side effects.

Modes with different pulse durations and cover rates are available. The different modes can be set just by turning the ring of the MicroSpot handpiece only.

Contra-indications

- Microbiological infections (e.g. impetigo, herpes, pustular acne)
- Heavily tanned skin
- Patients with known unreasonable UV-light exposure
- Tendency to hypertrophic scarring or keloids (perform trial treatment in such cases)
- Pregnancy



Indications

Operating at a wavelength of 2,940 nm, which corresponds with the maximum absorption of water, the MCL 31 Dermablate Er:YAG laser is perfectly suited for precise superficial skin ablation and skin coagulation. Thanks to the MicroSpot handpiece, it is also possible to perform a fractional treatment, which smoothes fine lines, wrinkles and rhytids, blends uneven pigmentation, minimizes the size of pores, clears photo-damaged skin and fills in acne scars.

Fractional laser treatment can also be used to enhance the uptake and bioavailability of externally applied drugs (laser-assisted drug delivery; LADD). An established concept is the combination of fractional laser treatment and consecutive photodynamic therapy (PDT).

Er:YAG ablation indications:



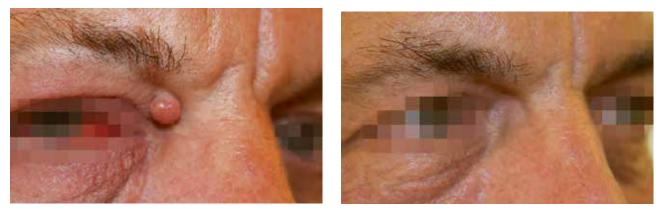
Dermal nevus (Dr. Said Hilton & Heike Heise, Medical Skin Center, Dr. Hilton & Partners, Dusseldorf, Germany)



Viral warts & Verruca seborrhoica (Dr. Peter Arne Gerber, Dept. of Dermatology, University Hospital Dusseldorf, Germany)



Xanthelasma (Dr. Peter Arne Gerber, Dept. of Dermatology, University Hospital Dusseldorf, Germany)



Fibroma (Dr. Said Hilton & Heike Heise, Medical Skin Center, Dr. Hilton & Partners, Dusseldorf, Germany)



Fibroma (Dr. Said Hilton & Heike Heise, Medical Skin Center, Dr. Hilton & Partners, Dusseldorf, Germany)





Lentigo senilis (Dr. Said Hilton & Heike Heise, Medical Skin Center, Dr. Hilton & Partners, Dusseldorf, Germany)



Fibrous papule of the nose (Dr. Said Hilton & Heike Heise, Medical Skin Center, Dr. Hilton & Partners, Dusseldorf, Germany)



Freckles (D. Fleming, M.D., Brisbane, Australia)

Er:YAG fractional indications:



Acne scars (Dr. Feller-Heppt, University Clinic Mannheim, Germany)



Acne scars (Prof. Kabir Sardana, Delhi, India)



Acne scars (Prof. Kabir Sardana, Delhi, India)







Acne scars (Prof. Kabir Sardana, Delhi, India)



Skin rejuvenation (Dr. Daniel Cassuto, Milan, Italy)





Fractional skin resurfacing (Dr. Said Hilton & Heike Heise, Medical Skin Center, Dr. Hilton & Partners, Dusseldorf, Germany)

Before you start the treatment

Please note!

- Please read the user manual first and observe all warnings and informations carefully.
- As a general rule, the skin should be preserved.
- For the first application, always use the lowest parameters suggested (low frequency, low fluence).
- The information contained in this manual should be considered as a suggested use of the device. It may not be considered an exhaustive and comprehensive guide for the use of a laser device and should not in any way substitute for the training course that each laser operator should attend before using the device.
- Please always be aware that following instructions is no substitute for operator experience and observation.
- Each individual is different, and therefore results can vary; expectations concerning the achievable results should be adjusted according to individual differences.
- All persons in the treatment room must wear safety goggles or eye protection.
- In case of extreme pain or redness, treatment should be discontinued immediately.
- Doctors and assisting personnel should wear surgical masks. If ablative treatment of viral lesions (e.g. verruca vulgaris, condylomata acuminata) is performed, these masks should provide the highest level of protection (FFP3).
- If you have any doubts, please ask a specialist before you proceed. (you can also send an email to expert@asclepion.com)

What you (and your patient) should expect from the treatment

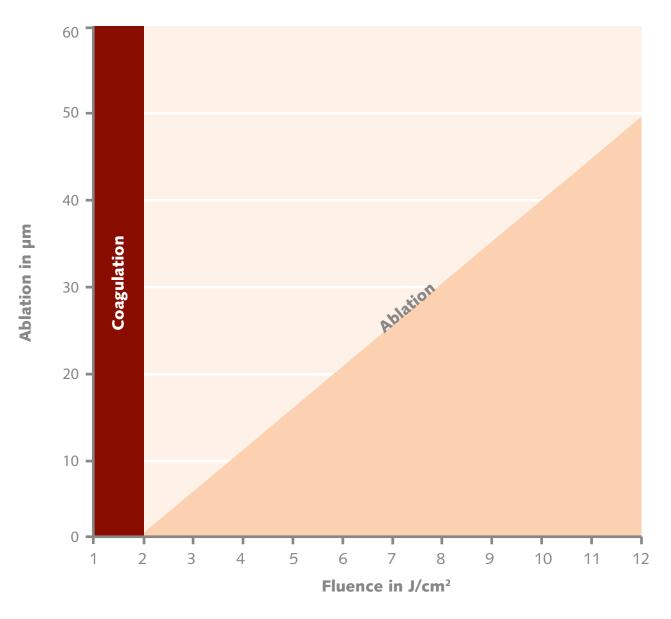
Er:YAG lasers accomplish superficial ablation with a minimum thermal in-depth effect. The physician can precisely track how deep a therapy penetrates. Because of its excellent visual results, this method is reliable and safe. For this reason, the top criterion for suitable laser settings should be the user's visual self-check.

Before starting a laser treatment, it is important to correctly identify possible variables which could compromise the effectiveness of the treatment. An accurate anamnesis together with a diagnosis is therefore vital. The patients should then be informed about the results that they can expect from the treatment according to their individual characteristics.



General guidelines

The fluence determines the depth of ablation. Er:YAG lasers work with a directly proportional relationship, i.e. ablation depth will increase in a linear relationship with increasing fluence. This applies both when a single laser pulse is used and when several laser pulses are applied to the same location. The following picture illustrates this relationship. The pulse duration determines the level of thermal effects. Short pulses (100 μ s) generate minimal levels of thermal damage and are ideal for "cold" ablation (less pain & higher risk of bleeding). Long pulses generate maximal levels of thermal damage and are ideal for achieving heat effects (skin tightening & lower risk of bleeding).



Treatment Protocols

How to prepare the treatment

The area to be treated must be carefully cleaned.

Depending on the size and/or depth of the lesion to be dealt with, it must be decided if anesthesia is required and what type of anesthesia is appropriate. Some types of anesthesia increase the water content of the skin and make it more difficult to ablate precisely.

Therapeutic treatment performed with an Er:YAG laser causes a consistent amount of fume formation resulting from photo ablation. Released particles and aerosols are extracted by the handpiece close to their point of origin during laser operation. A built-in smoke evacuator contains special filters that are capable of retaining particles and releasing the air in a cleaned state. If there is no exhaust facility to support the process, the optical performance of the handpiece will quickly deteriorate as a consequence of particle sedimentation which, in turn, may result in burn effects and damage.

The handpiece has to be cleaned (as do the optics!) and disinfected before starting the treatment; if necessary, the distance holder sterilized.

Preparation of patient:

- Careful removal of cosmetics
- Skin disinfection
- Local anesthesia where necessary
- Wear laser safety goggles

Please note!

Before treating a patient for the first time, a test treatment should always be performed on the area to be treated. The patient's individual skin reaction and pain sensitivity can vary. The application technique used for the test treatment should also be used for the later real treatment.

Treatment techniques (ablation)

Planar skin disorder (age spots, etc.) can be ablated by applying a uniform series of continuously overlapping laser spots. The degree of overlapping that appears to be the best match to the beam profile ranges from 10% to 20% of the beam's spot diameter. Although it is possible to work with a greater overlap, you should consider that energy densities will add up in the areas where overlapping occurs. Fluence settings must be reduced in such cases! An overlap degree below 10% is not advisable, because ablation will not occur with uniform depth in this case. Skin unevenness (wrinkles, flat acne scars, etc.) can be effectively smoothed out. For example, following an area-related ablation, single treatment steps are performed for individual lesion pockets, i.e. moving along the shoulders of a wrinkle or similar irregular patterns. Deep acne scars (ice-pick scars) have to be removed before laser treatment, e.g. by punch biopsy. Point lesions (syringomas, etc.) can be treated using single-shot technique. This should be done with frequency setting (repetition rate) as low as possible, in order to prevent overheating of the lesion. For small lesions, the goal should be to be ready with ablation before discomfort starts and blood appears.

Please note!

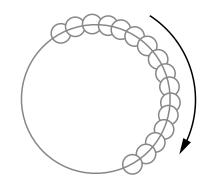
We advise performing a histopathological analysis of any lesion of uncertain dignity prior to any ablative laser treatment!

Trial treatment:

One trial treatment session (1-2 cm²) appears reasonable in all cases to be able to gauge the final result of therapeutic procedures (after 6 to 10 weeks).

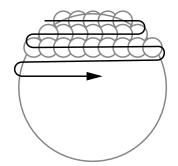
Circular

- Planarize the rim of a lesion (e.g. acne scar) using overlap technique
- Remove debris
- Continue treatment until desired ablation effect is achieved
- Stop capillary bleeding if necessary



Paintbrush

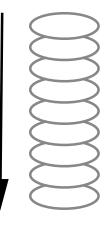
- Paintbrushing can be used to handle with extended lesions (e.g. lentigines)
- Important: clear debris away from time to time for better visual tracking of results
- Continue treatment until desired ablation effect is achieved. Stop capillary bleeding if necessary.



Single-spot

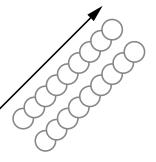
- Single-spot technique is intended for ablation of very small lesions (e.g. fibromata)
- Important: remove debris from time to time until desired amount of ablation is achieved
- Stop capillary bleeding if necessary

Note: In case the lesion is smaller than the spot to be used, proceed as follows: put a drop of ultrasound gel on the lesion including the surrounding skin. Remove the gel above the lesion using a spatula. Start with ablation of the lesion and surrounding gel until the lesion is removed.



Overlap

- Use overlap technique to smooth the rims of a lesion (e.g. wrinkles)
- Remove debris from time to time
- Continue treatment until desired result is achieved
- Stop capillary bleeding if necessary





Treatment procedure (ablation)



Verruca seborrhoica - prior to laser treatment.

Procedure

- 1. Skin disinfection
- MCL31 laser ablation (Paintbrush technique): spot 2 mm, pulse duration 100 µs (»cold« ablation), fluence 18 J/cm²
- 3. The treatment can be tolerated without any anesthesia!



Verruca seborrhoica – appearance of the lesion immediately after laser ablation (minimal bleeding).



Verruca seborrhoica – 3 weeks after laser ablation (Dr. Peter Arne Gerber, Dept. of Dermatology, University Hospital Dusseldorf, Germany).

Treatment techniques (MicroSpot)

As an alternative to the planar tissue removal, the MicroSpot handpiece allows you to apply a series of micrometer-sized spots arranged according to a specific pattern of mutual distances. Because these spots are surrounded by untreated tissue, the method is less harmful and the healing progress distinctly more rapid. Secondly, since untreated tissue is involved in the process of healing, extended skin areas are induced to renewal. Main applications of this method are the removal of wrinkles and the improvement of skin texture.

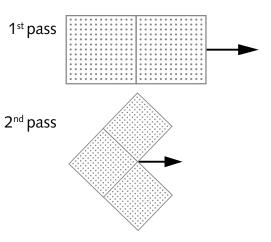
Trial treatment:

One trial treatment session appears reasonable in all cases to be able to gauge the final result of therapeutic procedures (after 6 to 10 weeks).

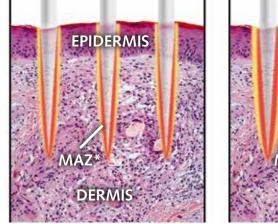
EPIDERMIS

Spot by spot

- Treatment should be performed for entire aesthetic areas
- 1st pass: pattern to be set without gaps and overlap
- 2nd pass: turn the handpiece about 45° and then follow the same procedure
- 3th and 4th pass, if necessary (e.g. scars)
- fade out at random to avoid limit lines



*MAZ = Microscopic Ablation Zone



(Dr. Bettina A. Buhren & Dr. Peter Arne Gerber, Dept. of Dermatology, University Hospital Dusseldorf, Germany)

»**Cold**« **Mode** (pulse duration: 100 µs) »Normal« Mode (pulse duration: 300µs) »Warm« Mode (pulse duration: 1,000 µs)

DER

EPIDER



Treatment procedure (MicroSpot)

Fractional skin resurfacing (Dr. Said Hilton & Heike Heise, Medical Skin Center, Dr. Hilton & Partners, Dusseldorf, Germany)

Procedure

1. Skin disinfection



Before



Immediately after



2. MCL31 fractional ablation: spot 13 x 13 mm, pulse

3. The treatment was tolerated without any anesthesia!

duration 300 µs, fluence 40 J/cm²

Day 2



Day 4



After several weeks

Parameters for skin ablation

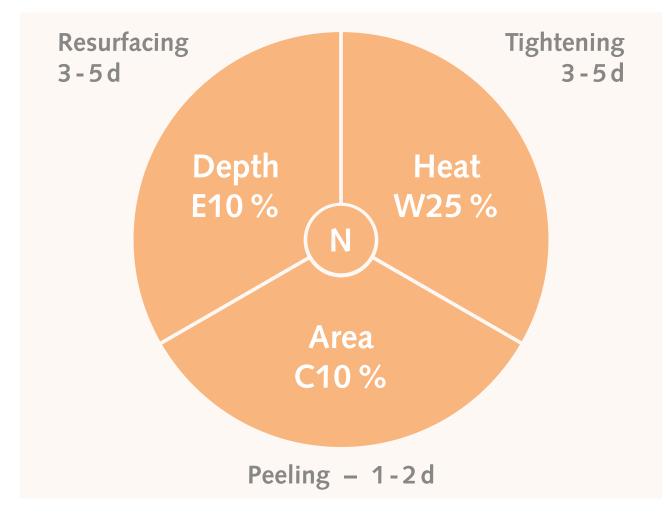
| | Spot size | Recommended fluence |
|---------------------|-----------|----------------------------|
| Ablation of lesions | 1-6mm | 4 - 10 J / cm ² |
| Fade out of rims | | 2-3J/cm ² |

Parameters for fractional laser therapy

| | | E 10% | N 10% | N 25% | C 10% | W 25% |
|--------------------------|-------------------|------------------|--------|--------|-------|-------|
| Mode | | Expert Energy | Normal | Normal | Cold | Warm |
| Spot number | Ν | 169 | 169 | 169 | 169 | 169 |
| Spot diameter | mm | 0.35 | 0.35 | 0.56 | 0.35 | 0.6 |
| Energy per pulse | J | 1.6 | 0.8 | 2.0 | 0.6 | 2.0 |
| Fluence per pulse | J/cm ² | 10 | 5 | 5 | 4 | 4 |
| Coverage | % | 10 | 10 | 25 | 10 | 25 |
| Pulse duration | μs | 300 | 300 | 300 | 100 | 1000 |
| Recommended pulse number | | 2-3 | 3 - 4 | 3 - 4 | 4 | 2 |



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Er:YAG fractional parameter effects

With the MicroSpot handpiece, you can be very flexible regarding the 3 parameters: depth, heat and area. The following treatments can be performed:

- C10 (»cold«): Peeling with a downtime from 1 to 2 days
- E10 (»expert«): Skin resurfacing with a downtime from 3 to 5 days
- W25 (»warm«): Skin tightening with a downtime from 3 to 5 days
- N (»normal«): This option allows you to combine the effects of peeling, resurfacing and tightening

Multimodal treatment concepts

The MCL31 microspot handpiece is ideal for performing ablative fractional laser treatments (AFXL). The generated microscopic ablations zones (MAZ) provide a temporary opening of the epidermal barrier (TOR) which can be used to enhance the uptake and bioavailability of externally applied drugs (laser-assisted drug delivery ; LADD). An established concept is the combination of AFXL and photodynamic therapy (PDT).

Treatment procedure (Laser-assisted PDT):

- 1. Skin disinfection
- MCL31 microspot treatment: C10 % or E10%, fluence 40J/cm², 1 pass
- 3. Remove debris
- 4. Apply photosensitizer and cover up with lightproof dressing
- 5. Continue with standard PDT protocol

Please note!

Laser-assisted PDT has been demonstrated to be significantly more effective as compared to conventional PDT. However, laser-assisted PDT is also more painful and will result in a more severe PDT-reaction (side-effects) as compared to conventional PDT.



Aftercare

- Please clean and disinfect handpiece; if necessary sterilize distance holder.
- Please change the bandage until treated area has fully healed. Do not expose the treated area to sunlight or sunlamps for at least 10/15 days prior to treatment. In summertime and in general when treating areas exposed to sunlight (e.g. the face), the use of sunscreen is recommended. Accordingly, the ideal time for facial treatments is the wintertime.

| Notes | |
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