IA
INNATE ABILITY

SmartXIDE Tetra

CLINICAL USER'S MANUAL

March 2019

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Innate Ability

INDEX

About this Clinical Manual

The purpose of this manual is to provide a summary of procedures and techniques for using the SmartXide Tetra Laser. The suggestions contained within this guide are based on current clinical use. However, they do not substitute for the clinical judgment of the physician and the individual patient's needs. It is the responsibility of the provider to assess and provide what is best for their patient(s).

Disclaimer

The present material is merely illustrative. The policy described is not of a suggestive nature, it is not intended to be exclusive and/or the best for the treatment of this case and it is not intended to substitute or influence in any way the diligence, prudence and expertise of the operator.

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Consult the Operator's Manual

The SmartXide Tetra laser delivers an array of micro-pulses onto the tissue using internal and/or external probes/handpieces with multiple control parameters.

Please refer to the SmartXide Tetra Operator's Manual code OM118C1-D1 for information on the operation of the SmartXide Tetra laser, its probes/handpiece, scanning unit, scanning patterns and shapes. Operators of the SmartXide Tetra laser must read and understand the operator's manual before using the laser.

Indications / FDA Clearance

The SmartXide Tetra Laser is indicated for incision, excision, ablation, vaporization and coagulation of body soft tissues in medical specialties including aesthetic (dermatology and plastic surgery), podiatry, otolaryngology (ENT), gynecology, neurosurgery, orthopedics, general and thoracic surgery (including open and endoscopic), dental and oral surgery and genitourinary surgery. The use with the scanning unit is indicated for ablative skin resurfacing.

Warnings and Cautions

WARNING: The SmartXide Tetra Laser can cause eye injury. Never use this device without protective eyewear.

CAUTION: Use of controls, adjustments, or performance of procedures other than those specified herein may result in hazardous radiation exposure. To avoid these hazards, the precautions described in the Operator's Manual must be observed when installing, operating, moving or servicing the system.

CAUTION: Laser plume or smoke produced by the laser beam may contain live tissue. Use of a smoke evacuator is advised if plume is present.

CAUTION: Exceeding the Smart Stack recommended maximum setting increases the risk of collateral thermal injury and increases wound healing time.

1 Introduction: CO_2 Laser: Applications in Dermatology

The development of CO_2 laser systems and the new, more sophisticated operating techniques, have led to a considerable increase in potential applications for surgical lasers, which range from resurfacing treatments (ablative and fractional) to high-precision vaporization of many dermatological lesions, even in very delicate areas such as around the eyes, the outer ear, and mucous and pseudo-mucous areas. The introduction of innovative CO_2 laser devices with different powers and pulse management systems offering full and flexible control of ablation depth, while limiting heat diffusion to the surrounding tissues and minimizing the need for local anesthetics, now make it possible to achieve new treatment frontiers.

1.1 Laser Physics

The word LASER (Light Amplification by Stimulated Emission of Radiation) describes a system designed to emit a light beam with special features. The light emitted by a laser device is:

- **Monochromatic.** Radiation at a single wavelength, specific for the target or chromophore. Selectivity is the key factor in laser use in dermatology, since it enables destruction of the target without damaging the surrounding structures.
- **Coherent.** Another feature of the laser beam is that the light waves move in spatial and temporal phases, creating coherence that optimizes beam interaction with the tissues.
- **Collimated.** A laser beam, unlike the light generated by other sources, is unidirectional and does not tend to diverge. As a result, the laser beam emitted by the system can be directed, using lenses with different focal lengths mounted on jointed arms, and concentrated on very small spots.

The CO2 laser is a gas based laser in which the active laser medium is a gaseous mixture containing carbon dioxide, helium, and nitrogen in appropriate proportions, and in which the pumping is obtained via an electromagnetic stimulation. This laser does not make use of electronic transitions; the active laser medium is always in the original energy state; what changes is the vibrational mode.

1.1.1 Laser-tissue Interactions

On the whole, the effects of the laser beam on the tissue depend on the parameters indicated below.

- **Wavelength.** This is the most important parameter. Certain wavelengths are selectively absorbed by specific molecules present in the skin, defined as "targets" or chromophores (water, melanin, hemoglobin). This absorption generates a large amount of heat in the target (by conversion of the radiant energy – light – into thermal energy), which is able to selectively destroy the target molecules (Selective Phototherrmolysis) with minimal damage to the surrounding tissues.

- **Pulse duration.** The destructive capacity of a laser also depends greatly on the duration of the pulse of light it is capable of emitting. After heating, any biological structure takes a certain time to cool, and as it cools it releases heat; thus, selective destruction can be obtained only if the duration of the laser pulse is shorter than the thermal relaxation time (TRT); that is, the time it takes for a biological structure to lose 50% of its heat. Otherwise, the second pulse would cause an additional rise in temperature and due to thermal conduction, carbonize the surrounding tissues with scarring and permanent skin discoloration.
- **Laser output power and beam diameter (energy density).** The effects of a laser beam on the tissue also depend on the concentration of the photons in the light beam (that is, on the relationship between the output power of the device and the beam diameter).

1.1.2 The CO_2 Laser

As water is the main skin component it plays a fundamental role in the laser/tissue interaction. The CO_2 laser emits in the far-infrared spectrum (at a 10,600-nm wavelength) where absorption of the radiation by the water molecules prevails over penetration.

Sufficiently intense irradiation will cause vaporization of the tissue due to evaporation of the water, with tissue penetration limited to about 50 micrometers.

This characteristic, together with appropriate pulse management, allows for operating with extreme precision in vaporizing tissues in successive passes until the clinical end-point is achieved.

The main goal when using a pulsed surgical laser is to obtain ablation while limiting heat damage to a minimum. This can be obtained by vaporizing the tissue for less time than that required for the heat to propagate (namely, a time < TRT).

In order to obtain instantaneous ablation, the energy of the laser beam must exceed the vaporization threshold of the skin, below which, the only effect will be carbonization and necrosis of the tissue. This consideration is fundamental for correct use of surgical lasers: the least heat damage is obtained with high-power, ultra-short pulses.

Depending on the degree and time of tissue exposure, this effect can be divided into three different mechanisms:

- **Hyperthermia,** which involves a moderate rise in temperature (only a few degrees Centigrade) above normal physiological conditions for several minutes (temperatures of between 41°C and 44°C).
- **Coagulation,** which is obtained with exposure to temperatures between 50°C and 90°C for one second at a time, producing desiccation and retraction of the tissue due to denaturation of the tissue proteins, including collagen. The tissues thus treated are removed by the operator (debridement) and the repair process begins. Coagulation is used to destroy tissues and stop bleeding (hemostasis).
- **Vaporization,** which involves an immediate loss of substance in the tissue. The different tissue constituents are eliminated at temperatures higher than 100°C for a relatively short time (a few tenths of a second). If an extremely high temperature can be reached in a very short time, then it will be possible to achieve vaporization of the target with little or no necrosis at the margins of the lesion. This phenomenon, called photoablation, entails minimally explosive photodecomposition.

The thermal relaxation time (TRT) is the essential parameter for correct selection of the CO_2 laser settings. If the duration of the laser pulse is less than the TRT, the laser energy remains "trapped" inside the volume of irradiated tissue. The sharp rise in temperature and relative heat damage will be localized in this region, while the surrounding tissues will undergo very little heating via diffusion. If the laser irradiation time is longer, the heat will then spread inside the tissue, causing undesirable effects and unsightly scarring.

The CO_2 laser was first used in surgery as a tool for vaporizing and removing tissues and it is still the most versatile and widely-used laser system in dermatology.

The acronym WYSIWYG (*What You See Is What You Get*) means that the operator is capable of making a step-by-step visual assessment, using "color indicators," of the level reached (vaporizing only the epidermis or making in-depth use of the heating effect as far as the papillary dermis or reticular dermis) and therefore of correctly evaluating the clinical end point.

The color indicators are as follows:

- Opalescent aspect with formation of micro-bubbles, accompanied by a characteristic crackling and whitening (vaporization of the epidermis);
- Flat, smooth, pink surface (penetration to the papillary dermis);
- Yellowish, hardened tissue, similar in aspect to chamois leather (papillary/reticular dermis)
- Bundles of collagen fibers, appearing macroscopically as "water-soaked cotton threads" (reticular dermis).

1.1.3 Laser: Traditional Resurfacing

The wavelength produced by the CO_2 laser (10,600 nm) is selectively absorbed by the water in the tissue. The latest-generation CO_2 lasers can emit high-energy with a shorter duration than the thermal relaxation time (TRT) of the skin.

This means that the directly-treated tissue can be vaporized with only limited heating of the underlying dermis, thus avoiding necrosis while offering the possibility of achieving good hemostasis.

The effects of the laser beam on the epidermis (where the water is primarily intracellular) vary from the effects on the dermis (where the water is distributed throughout the intercellular space). At the level of the epidermis, a single laser pass causes cell ablation with dermal/epidermal detachment.

In the dermis instead, each successive pass progressively dehydrates the solid component (fibers and cells), with consequent reduction of laser-beam penetration and increased residual heat damage. Thanks to the color indicators (well-known color variations), the modifications induced by heating are clinically detectable.

What can be observed, in fact, is an immediate whitening of the epidermis, followed by the appearance of a fuchsia-pink coloration (papillary dermis) and then a color change from fuchsia pink to yellowish-white (index of vascular coagulation).

Brownish hues indicate excessive thermal damage. Significant clinical effects follow these laser/tissue interactions, with restructuring of the epidermis, shrinking of the residual collagen fibers, and new collagen formation.

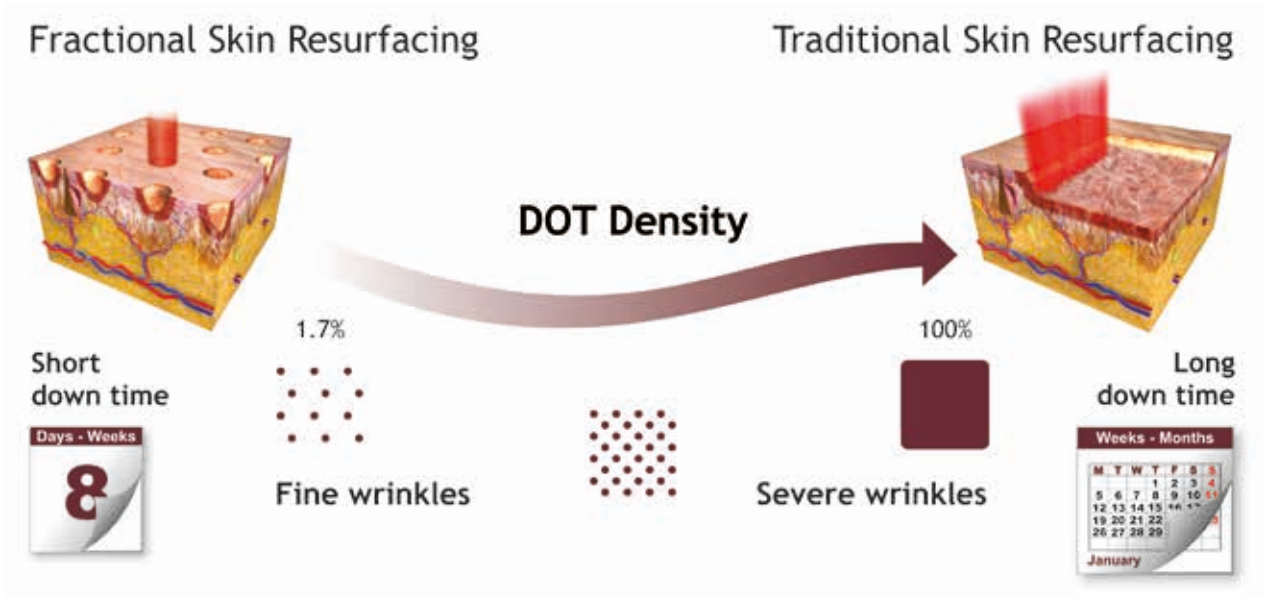
1.1.4 CO_2 Laser: Fractional Resurfacing

While ablative resurfacing with CO_2 lasers via the use of auxiliary scanning systems represents the gold standard in laser surgery, this method is nevertheless associated with long recovery times and persistent erythema.

Fractional ablative resurfacing is therefore the method of election for treating a select group of patients, and it is indicated for a "low" degree of photodamage, in patients requiring short recovery times, with partial restructuring of the epidermis and shrinking of tissue and new collagen formation, but with reduced effects compared to traditional resurfacing. In fact, the use of scanning systems which generate thermal effects in micro-areas (20%) surrounded by healthy tissue, allows for faster recovery with persistent erythema only lasting 3-7 days. The rapid re-epithelization on the second day enables restoration of the epidermal barrier, making it possible for patients to resume their normal social activities.

Fractional resurfacing usually requires several sessions, which are well-tolerated by the patient thanks to the immediate clinical result (shrinkage) and short convalescence after each session (minimal down-time).

When combined with traditional resurfacing, the new fractional resurfacing techniques thus introduce a new working strategy that allows for identifying the most appropriate laser treatment according to the severity of the photodamage, and meets patients' demands for always shorter recovery times.



2
Technical Features

2.1 Pulse shapes

The aim of the system is to generate perfectly-controlled energy pulses, making it the ideal solution for skin resurfacing treatments and skin surgery. The technology eliminates the side effects of constant scanning and is always active, during both the traditional and fractional scanning phases and during the use of handpieces.

With special pulse mode the system can allow two different effect to the tissue:

- **Ablation:** The high power peak of the pulse releases a large quantity of energy in a very short time, for rapid ablation of the epidermis and the first layers of the derma with a lower water content.
- **Thermal effect:** After this rapid vaporization, the energy of the pulse spreads the heat in the water-rich deep derma, generating immediate shrinkage and the production of new collagen. The damage to the epidermis is minimal and recovery times are dramatically reduced.

The new emission modes developed thanks to advanced software and laser source management, such as **S-pulse**, **H-pulse**, and **D-pulse** (available both on fixed and handheld scanners), allow for achieving:

- Different spatial heat distribution patterns;
- Different ablation area shapes;
- Different lateral heat damage distribution;
- Different tissue shrinkage profiles.

Thanks to this technology and the range of available pulse modes, different biological effects can be induced on the tissue stimulating the dermis to produce new collagen, naturally regenerate the tissue structure, and improve skin tightening or softness.

In detail, the **S-pulse** mode acts more selectively on the papillary dermis with a more circular ablation shape, inducing coagulation of the surrounding tissues rather like the effects obtained with the technology of the SmartXide systems.

It has proved effective in treating atrophic scars.

The **D-pulse** mode acts more incisively on the reticular dermis, inducing greater shrinkage of the ablation columns and more circumscribed coagulation; it is therefore particularly indicated in the treatment of flabby skin when used with the scanner.

Confocal laser microscopy assessment and histological studies reveal the special "funnel-shaped" ablative shape achieved in the D-pulse mode, which is different to the one obtained with S-Pulse technology. The former mode allows for greater shrinkage than with the S-Pulse technology. Histological studies of the D-Pulse ablation show a depression of the portion of epidermis not involved in the hardening phenomenon caused by the wave of immediate heat. This can be ascribed to the deeper action exerted

by this mode, which, by also entailing the reticular dermis, induces greater shrinkage in a vertical direction as well.

A third emission mode, called **H-pulse**, is also available for vaporizing skin lesions, especially when used in FreeHand mode.

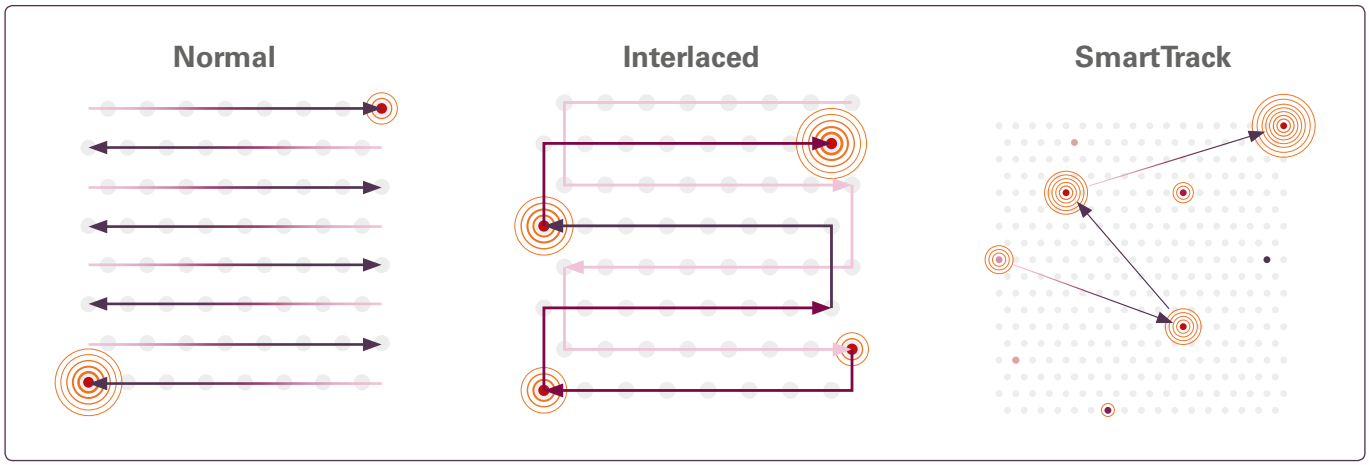
Thanks to its higher emission power than the S-Pulse and D-Pulse modes described above, this mode also makes it possible to obtain two additional effects on the tissues.

It can be used for cold, more delicate ablation thanks to the very low pulse emission times, and for carrying out greater ablation than the other emission modes applied for the same pulse duration.

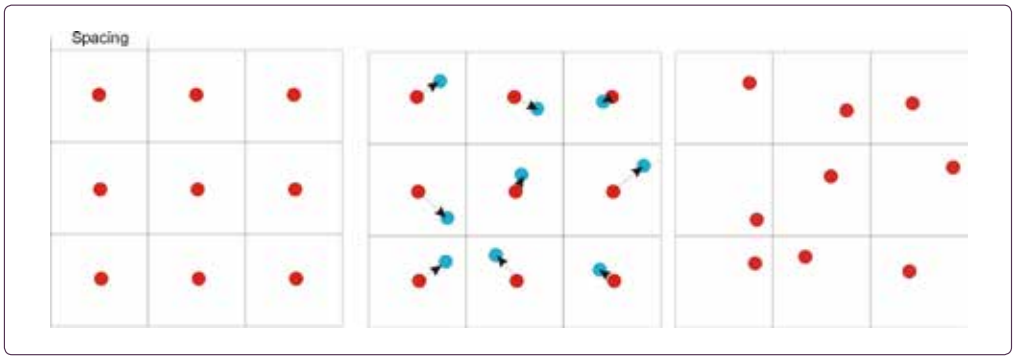
Finally, SmartXide Punto also possesses a considerable energy reserve, which enables the delivery of pulses to larger spots than those possible with the previous SmartXide systems.

2.2 Scanning Modes

In addition to the traditional and interlaced scan methods, SmartXide Punto also features the special SmartTrack algorithm. Developed to enhance post-treatment recovery, SmartTrack optimizes the scanning of the treatment area, minimizing the local increase in temperature.



When Spray mode is active, the dots are spaced in a special random way, avoiding overlapping. With "Spray Mode", the fading out at the borders and the pseudo-random covering of the scanning area provide a more uniform transitions between contiguous areas and more homogeneous DOT textures.



2.3 Stack Theory

Thanks to the possibility of independently selecting three parameters such as "Power", "Pulse dwell time", and "Distance between DOTs", the system can be used on all skin types. The special shapes of the pulses also plays an important role as it ensures superficial ablation of the epidermis while releasing and spreading the heat deeper down in the derma.

This emission mode is the well-known "**spatial**" emission of laser energy in the skin: the DOTs are physically distanced apart and allow for denaturing part of the skin while protecting the surrounding areas that act as tissue repair promoters.

Besides the SmartXide Punto, there are two other groups of fractioned CO_2 lasers available on the world market.

The first and most numerous group consists of CO_2 laser devices which are a direct derivation of the traditional skin-resurfacing technique. These systems emit continuous power (CW) for long periods, from 1 ms to 20 ms. However the lack of peak power (due to working in CW) means that the laser heat has to spread from the epidermis towards the dermis which is extremely difficult since the epidermis contains very little water. Therefore, to obtain results, prevent carbonisation, and limit pain, the pulse dwell time is usually reduced to between 2 and 10 ms.

The other group of systems attempts to vaporise the deeper levels of the derma with very short pulses, high peak powers, and small spot sizes. The laser penetrates in depth, for more than 1 millimetre. In order to obtain such deep vaporisation, the heating of the surrounding spot areas is unavoidable which gives rise to profuse bleeding after treatment.

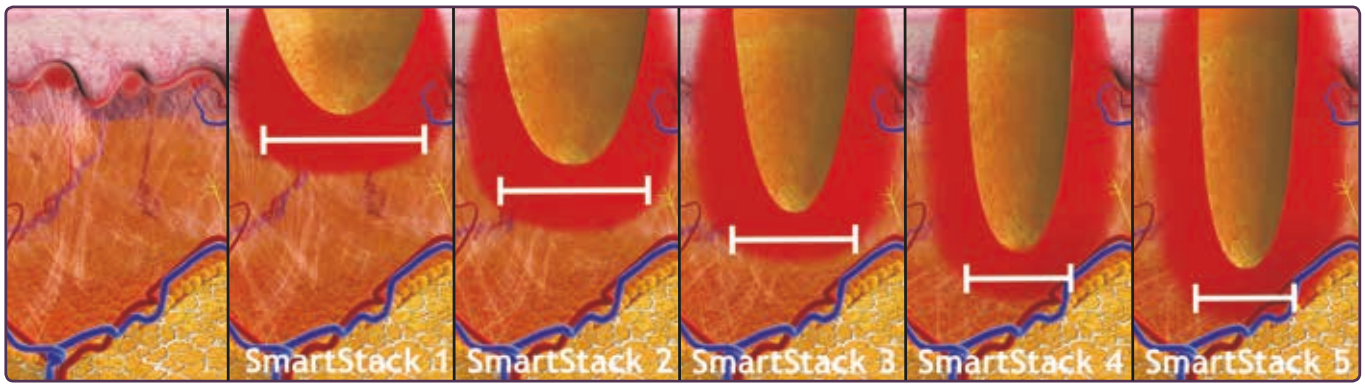
The SmartXide Punto is the only system positioned midway between these groups as it has a pulse consisting of two separate parts: the first with high peak powers capable of creating an opening in the epidermis, and a second which spreads the laser energy all around.

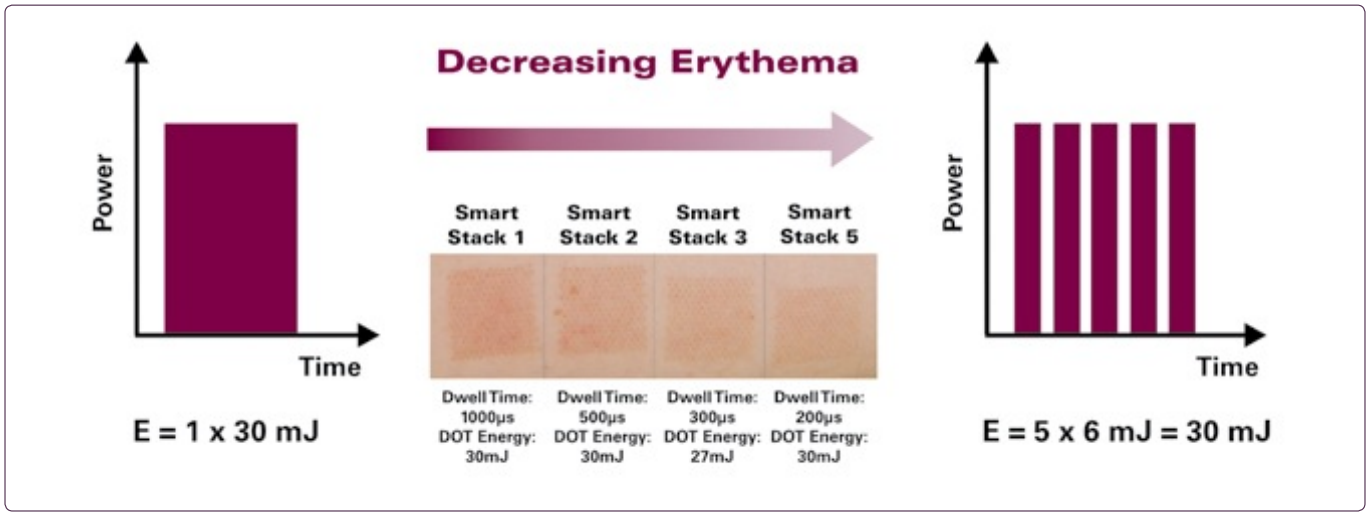
This is the key difference between SmartXide Punto and all the other systems, but not the only one. Another important feature has recently been introduced for ensuring even better results and greater flexibility.

The new addition is the "SmartStack Mode", which repeats the laser pulse in the same DOT for a maximum of 5 times before moving on to the next one. SmartStack can be used in two almost contrasting modes.

The first operating mode uses high powers, producing deep ablation but always with a significant thermal effect around the vaporised area.

The second mode is even more innovative as it introduces a "**temporal**" as well as a spatial fractioning of the energy. Instead of using all the energy in a single pulse it is more beneficial to fraction it over time, while still releasing the same total energy. The sub-pulses fractioned in this way allow the skin to cool down, guaranteeing reduced erythema without compromising the "tightening" effect. The following figure gives a better idea of the temporal fractioning effect produced by the SmartStack system.





As illustrated in the figure, erythema appears less evident with SmartStack=5 compared to 1 single pulse (SmartStack=1) or lower SmartStacks.

The use of fractioned lasers (in spatial mode only) has considerably reduced the side effects produced by the high concentrations of laser energy that overheated the dermis.

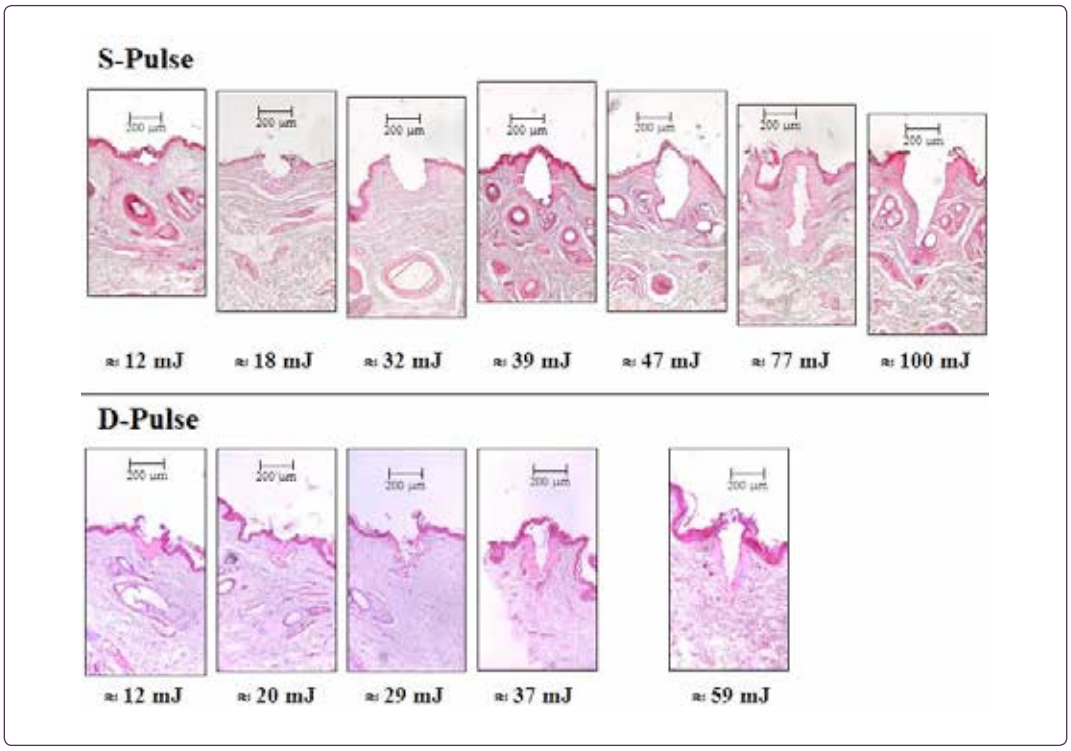
All efforts made so far have focussed on achieving a good "tightening" effect, reducing to a minimum the side effects, the main component of which is erythema.

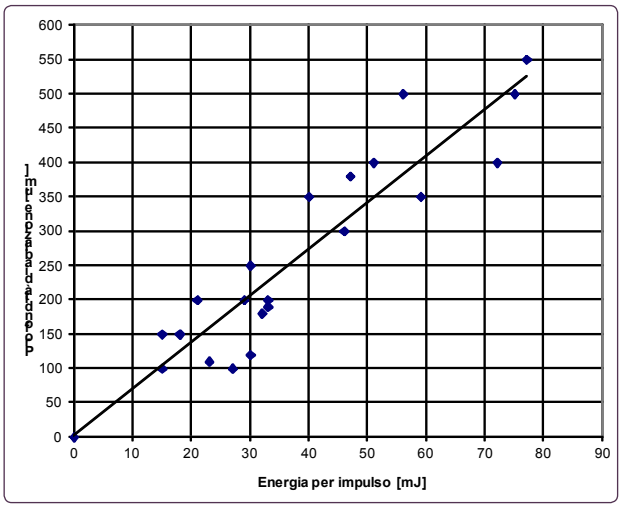
By selecting the parameters available with the SmartXide Punto system (Power, Dwell Time, Spacing and SmartStack level) it is now possible to assess the "degree of erythema" and the "tightening" effect at first glance. By bearing these parameters in mind therefore, it is possible to balance the treatment according to the desired results and downtime.

2.4 Ablation Depths in DOT mode

The depth of ablation is typically correlated to the "Energy per DOT". According to the histological test, a formula could be evaluated. The actual values could vary due to different kind of tissues, but should be used to have an estimation of the intensity of the treatment with a tolerance of 70 µm.

"Ablation depth" [µm] = 6 x "Energy per pulse" [mJ]





3
Clinical Procedure

As with any dermatosurgical modality, the doctor must have a complete understanding of the indication and limitation of a given laser procedure.

3.1 Pre Treatment Care

At the time of the initial visit, the physician should determine the suitability of the laser treatment and inform patients about the treatment.

3.1.1 Patient Examination & Contraindications

There are no known contraindications for the use of the SmartXide Punto system, apart from generalcontraindications of standard surgery.

First of all it is important to proceed with the visit and the anamnesis of the patient. During the initial consultation, the doctor should evaluate the patient's expectation about the treatment. A person's history should be compiled by establishing the following:

- Sun and UV lamp exposure: avoid them before (**at least 1 month**), during and after treatment. Apply SPF50 sunblock before and after the treatment.
- Be careful in case the patient is taking following types of drugs (suspend the administration according to the specific drug so that its effect is expired before the treatment):
  - **Anticoagulants** (as acetylsalicylic acid, heparin, etc),
  - **Retinoids** – these drugs can cause problems in the healing process with possible scar results - (as isotretinoin, etc),
  - **Photo-sensitizers** (as tetracycline [antibiotic], naproxen [NSAD], auranofin [antirheumatic], estrogens and progestins [*oral contraceptive*], cloroquine [*antimalarial*], etc.)
- Recent **exfoliation treatment** (peels, scrubs, retin-A, previous laser resurfacing or dermabrasion) and **surgical treatment** (as lifting, etc.), because the procedure could potentially delay the wound healing response due to the presence of inflammation or fibrosis.
- Past skin disorders and cheloid formation.
- History of herpes virus infection.

In order to ensure a positive outcome with laser treatment, the patient must strictly follow a pre-operative protocol to help prevent the two main possible complications: Post-Inflammatory Hyperpigmentation (PIH) and infection.

3.1.2 PIH prevention

Especially with darker phototypes (III, IV, V and VI) and Asian phototypes, it is recommended to apply a topical cream every day for four weeks before the treatment for inhibiting melanin production. It is possible to use cream containing hydroquinone or, as alternative lighteners, arbutin, azelaic acid, kojic acid or stabilized vitamin C. This procedure is highly recommended with darker and Asian skin types, while for photo type I and II it is just a suggestion.

3.1.3 Infection prevention

Both bacterial and viral infections are potential side effects if proper clinical precautions are not observed. Complications, though rare, can occur and should be discussed and understood. The patient must understand the importance of pretreatment and post-treatment instructions, and that failure to comply with these instructions may increase the probability of complications. Subjects with a history of Herpes may be prescribed prophylactic drugs one week prior to laser treatment.

The drugs used fall into two main categories:

- **Antiviral drugs** (aciclovir, valaciclovir, etc). It is suggested to start the antiviral prophylaxis 6 days before the treatment in subjects with a positive anamnesis of herpes virus infections history. The antiviral treatment can start 2 days before the treatment in subjects without previous experience of herpes infections. It is recommended to continue the antiviral drugs at routine doses for 5-15 days after the intervention.
- **Antibiotic drugs** (macrolides, cephalosporins, etc). The doctor may consider prescribing antibiotic drugs for 7-8 days after the procedure. Remark: It is not necessary to prescribe antibiotic drugs in all cases. It is often enough the application of a topical antibiotic cream or ointment (like gentamicin) after the procedure.

3.1.4 Cleaning the Skin

Before treatment clean the relevant area, removing all impurities that could interact with the light radiation (make-up, lotions, deodorants, ointments etc.). Use a mild soap and rinse well with water. As a precaution the patient should be advised not to use cosmetics for 48 hours prior to treatment.

3.1.5 Classification of the Phototypes

Before starting treatment it will be necessary to evaluate the patient's phototype.

Type	Hair colour	Skin colour	Eye colour	Reaction to the Sun
I	Red	Fair	Blue-grey	Goes red, does not tan
II	Blonde	Fair	Blue	Goes red, does not tan
III	Brown	Medium	Brown	Goes red, then tans
IV	Dark brown	Light brown	Dark brown	Tans
V	Black	Dark brown	Black	Tans
VI	Black	Black	Black	Tans

3.1.6 Photographic Monitoring

Taking pictures that document the patient during the various treatment phases helps to monitor the effectiveness of the treatment. For ensuring the best photographic quality it is necessary to standardise the shots in order to reproduce the same position of the patient and the same lighting conditions.

3.1.7 Anaesthesia Indications

Dermal treatments with laser may give rise to a painful sensation described as similar to an elastic band being pinged against the skin, or the pain caused by burns.

The anaesthetic protection for CO_2 laser skin therapies becomes necessary in specific cases, such as:

- Traditional CO_2 laser skin resurfacing;
- The treatment of extensive skin areas;
- The treatment of deep lesions;
- Patients with a low pain threshold;
- Non-compliant patients;
- Paediatric patients.

Irrespective of the anaesthetic method used (such as transdermal and infiltrative anaesthesia or peripheral and locoregional blocks), several indispensable precautions are necessary. A careful clinical assessment (if an anaesthetist is necessary this will be their exclusive responsibility), with particular attention to cardiovascular, pulmonary, and neurological pathologies, hypertension, diabetes, allergic phenomena and/or any idiosyncratic reactions to the medicinal products to be administered;

Detailed indications regarding the administration, modification or discontinuation of therapies in progress (in the current condition and in relation to the type of intervention/treatment, the assessment will mainly concern the anticoagulant therapy).

In case of fractional resurfacing with SmartXide Punto it is usually enough to apply a topical anaesthetic 1 hour before the treatment. In case of quite superficial action, to use the SmartCryo skin cooling system during the treatment can be a possible alternative to the topical anaesthetic.

The use of anaesthetic protection could influence the correct perception of the pain during the treatment and the adverse effect.

3.1.8 Skin Surgery – Free Hand

The following setting are developed by the use of the **7" Handpiece**. The suggested value should be fit with the dimension a depth of the lesion. The operator must be skilled in determining the best level of power to be used that will vary during the ablative treatment.

The higher level represents the higher ablation rate. We suggest to start with the lower indicated level

to be used as starting point for being able to increase the work power in order to achieve the requested ablation and greater benefits, while monitoring the side effects, tolerability and depth of the lesion.

Consider that usually, after the detection of the best starting value, the procedure starts setting with high level value (which corresponds to a deeper skin ablation effect) for the "rough-shape" phase. At the end of the procedure the level value is reduced to perform more precise "final touches". In particular we suggest to start with a SP mode, that represent the typical CO_2 ablation, and finally use the HP mode to obtain a more precise finishing of the lesion with a "cold Er:YAG laser like" effect.

Treatments	Emission Mode	Power (W)	Frequency (Hz)	Handipiece	Distance to the tissue*
Sebaceous adenoma	SP	0,5/1	10/20	7"	Focalised or slightly defocused
Seborrheic keratosis d <0,5 cm	HP	0,1/0,8	5/10	7"	Focalised or slightly defocused
Seborrheic keratosis d >0,5 cm	DP	0,1/2	10/20	7"	Focalised or slightly defocused
	CW	7 W		7"	Defocused
Actinic keratosis	SP	0,1/1	10/20	7"	Slightly defocused
Actinic cheilitis	SP	0,1/1.5	10/20	7"	Focalised or slightly defocused
Acne scars	HP	0,1/0,5	5/10	7"	Focalised or slightly defocused
Condyloma Acuminatum	SP	0,5/2	10/20	7"	Focalised or slightly defocused
	CW	4/10W		7"	Defocused
Chondrodermatitis nodularis helicis	SP	0,1/1	10/20	7"	Slightly defocused
Molluscum fibroma	HP	0,1/0,4	5/10	7"	Focalised
Apocrine hidrocystoma	SP	0,1/0,7	10	7"	Focalised or slightly defocused
Hirsuties papillaris genitalis	SP	0,1/0,5	10/20	7"	Focalised or slightly defocused
Superficial Dyschromias	HP	0,1/0,3	5/20	7"	Slightly defocused
Leukoplakia (with biopsy)	SP	0,1/1,5	10/20	7"	Focalised or slightly defocused

Treatments	Emission Mode	Power (W)	Frequency (Hz)	Handipiece	Distance to the tissue*
Favre-Racouchot's disease	SP	0,1/0,7	10/20	7"	Focalised or slightly defocused
Milium	HP	0,1/0,3	5/10	7"	Focalised
Pringle Bourneville's disease	HP	0,3/0,9	5/10	7"	Slightly defocused
Sebaceous Nevus	SP	0,3/0,7	10	7"	Slightly defocused
Neurofibroma	HP	0,1/1	5/10	7"	Focalised or slightly defocused
Dermal Nevus (with biopsy)	SP	0,1/1,5	10/20	7"	Focalised or slightly defocused
Epidermal Nevus	SP	0,1/1	10/20	7"	Focalised or slightly defocused
Otophyma	SP	0,3/1,5	10/20	7"	Focalised or slightly defocused
Oral papilloma	SP	1/1,5	20	7"	Focalised or slightly defocused
Glandular rhinophyma	SP	0,9/3	10/20	7"	Focalised or slightly defocused
	CW	5/8W		7"	Defocused
Syringoma	HP	0,1/1	5/10	7"	Focalised or slightly defocused
Trichoepithelioma	SP	0,1/1,5	10/20	7"	Focalised or slightly defocused
Common wart	SP	0,3/2	10/20	7"	Focalised or slightly defocused
	CW	3/4 W		7"	Defocused
Flat wart	HP	0,1/0,7	5/10	7"	Focalised or slightly defocused
Filiform wart	HP	0,1/0,7	5/10	7"	Focalised or slightly defocused
Plantar wart	CW	3/5 W		7"	Defocused
Xanthelasma	HP	0,1/1	5/10	7"	Defocused

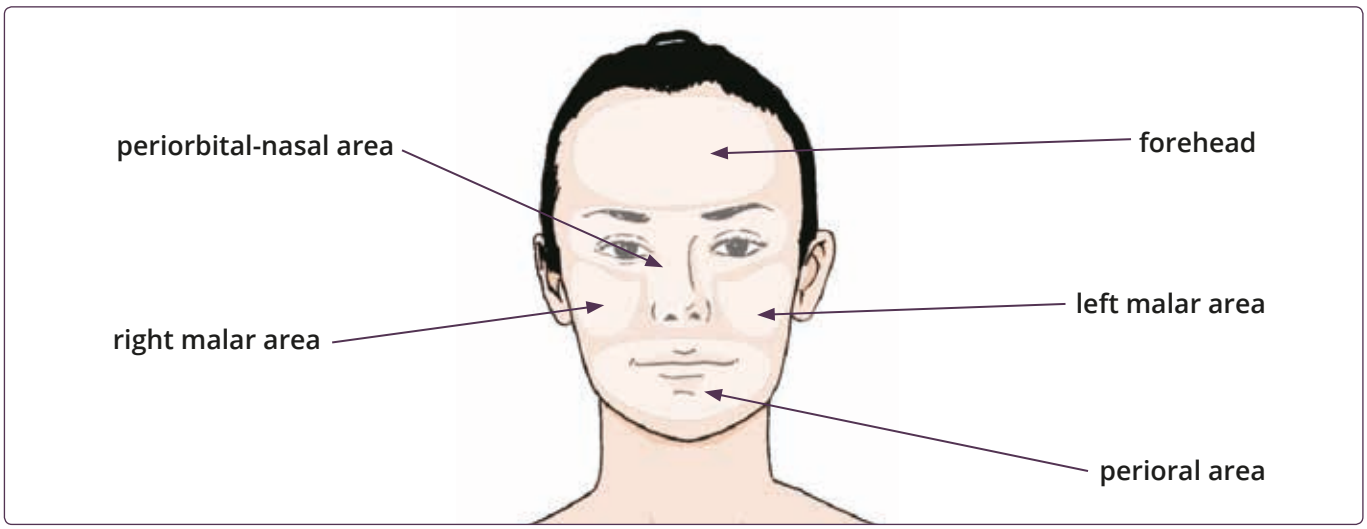
*** The following setting are developed by the use of the 7" Handpiece. All other free hand handpieces must be used in a defocused manner, slightly distancing them from the skin.**

The following setting are developed by the use of the **1.5", 2" and 4" Handpiece** 1.5", 2" and 4" free hand handpieces must be used for vaporization in a defocused manner, slightly distancing them from the skin.

Treatments	Emission Mode	Power (W)	Frequency (Hz)	Handipiece	Distance to the tissue
Sebaceous adenoma	SP	0,5/1	10/20	1.5", 2", 4"	Slightly defocused
Seborrheic keratosis d <0,5 cm	HP	0,1/0,8	5/10	1.5", 2", 4"	Slightly defocused
Seborrheic keratosis d >0,5 cm	DP	0,1/2	10/20	1.5", 2", 4"	Slightly defocused
	CW	7 W		1.5", 2", 4"	Defocused
Actinic keratosis	SP	0,1/1	10/20	1.5", 2", 4"	Slightly defocused
Actinic cheilitis	SP	0,1/1.5	10/20	1.5", 2", 4"	Slightly defocused
Acne scars	HP	0,1/0,5	5/10	1.5", 2", 4"	Slightly defocused
Condyloma Acuminatum	SP	0,5/2	10/20	1.5", 2", 4"	Slightly defocused
	CW	4/10W		1.5", 2", 4"	Defocused
Chondrodermatitis nodularis helicis	SP	0,1/1	10/20	1.5", 2", 4"	Slightly defocused
Molluscum fibroma	HP	0,1/0,4	5/10	1.5", 2", 4"	Slightly defocused
Apocrine hidrocystoma	SP	0,1/0,7	10	1.5", 2", 4"	Slightly defocused
Hirsuties papillaris genitalis	SP	0,1/0,5	10/20	1.5", 2", 4"	Slightly defocused
Superficial Dyschromias	HP	0,1/0,3	5/20	1.5", 2", 4"	Slightly defocused
Leukoplakia (with biopsy)	SP	0,1/1,5	10/20	1.5", 2", 4"	Slightly defocused
Favre-Racouchot's disease	SP	0,1/0,7	10/20	1.5", 2", 4"	Slightly defocused
Milium	HP	0,1/0,3	5/10	1.5", 2", 4"	Slightly defocused
Pringle Bourneville's disease	HP	0,3/0,9	5/10	1.5", 2", 4"	Slightly defocused
Sebaceous Nevus	SP	0,3/0,7	10	1.5", 2", 4"	Slightly defocused
Neurofibroma	HP	0,1/1	5/10	1.5", 2", 4"	Slightly defocused
Dermal Nevus (with biopsy)	SP	0,1/1,5	10/20	1.5", 2", 4"	Slightly defocused
Epidermal	SP	0,1/1	10/20	1.5", 2", 4"	Slightly defocused

Treatments	Emission Mode	Power (W)	Frequency (Hz)	Handipiece	Distance to the tissue
Nevus Otophyma	SP	0,3/1,5	10/20	1.5", 2", 4"	Slightly defocused
Oral papilloma	SP	1/1,5	20	1.5", 2", 4"	Slightly defocused
Glandular rhinophyma	SP	0,9/3	10/20	1.5", 2", 4"	Slightly defocused
	CW	5/8W		1.5", 2", 4"	Defocused
Syringoma	HP	0,1/1	5/10	1.5", 2", 4"	Slightly defocused
Trichoepithelioma	SP	0,1/1,5	10/20	1.5", 2", 4"	Slightly defocused
Common wart	SP	0,3/2	10/20	1.5", 2", 4"	Slightly defocused
	CW	3/4 W		1.5", 2", 4"	Defocused
Flat wart	HP	0,1/0,7	5/10	1.5", 2", 4"	Slightly defocused
Filiform wart	HP	0,1/0,7	5/10	1.5", 2", 4"	Slightly defocused
Plantar wart	CW	3/5 W	1.5", 2", 4"	Defocused	Slightly defocused
Xanthelasma	HP	0,1/1	5/10	1.5", 2", 4"	Defocused

3.2 Treatment Procedure for HiScanDOT



The face is divided into five aesthetic units: right malar, perioral, left malar, forehead and periorbital-nasal areas. In case of laser skin resurfacing (both fractional and traditional) full face treatment is performed on each aesthetic unit sequentially, with care being taken to avoid overlapping.

3.2.1 Fractional Mode

Topical anaesthetic has to be removed just before the treatment.

Set the SmartXide Punto system in DOT mode according to patient phototype, the area to be treated and the application. Usually we recommend performing a full-face and single passage treatment to obtain a better colour and texture uniformity.

SmartXide Punto offers the possibility to adapt the procedure according to the expectation of the patient: more or less aggressive treatment corresponds to longer or shorter down time after every session.

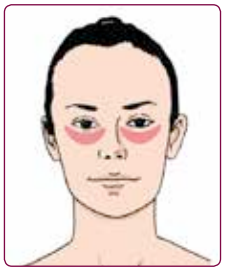
The "Energy per Pulse (in mJ)" and the "Fluence" (density of energy measured in J/cm^2) delivered with the scanner is correlated with the effect provoked on the skin. The following formula allows to calculate the fluence level delivered in DOT mode:

Fluence (J/cm^2) = [**Power** (W) ***** **Dwell Time** (ms) ***** 105] / [**Spacing (µm)** + SPOT]2 ***** **Stack**

As a simple result of the formula above, reducing the Power and/or the Dwell Time and/or increasing the Spacing, it is possible to reduce the fluence and to control the thermal effect on the skin.

The **Energy per Pulse** represents the total amount of mJ delivered over the same DOT, in witch the effect of the Stack is already included in the calculation.

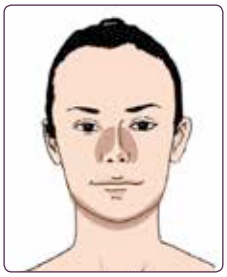
3.2.1.1 Special Care: Periocular Area



This area is very delicate. A common side effect is to have swelling and oedema. It is strongly suggested to follow the specific protocol for Upper and Lower Eyelids with the setting of SmartStack level equal to 1. It is recommended to decrease the fluence **30% less** in comparison to the "mild skin ageing" protocol.

➔ Dwell Time ↓ ➔ Energy per Pulse ↓ ➔ Fluence ↓

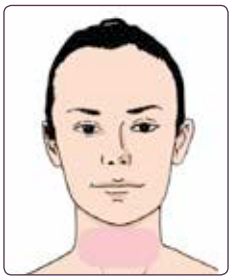
3.2.1.2 Special Care: Perinasal & Perimandibular Areas



In the perinasal area and in the submandibular area the risk of post treatment scars is high. It is recommended to decrease the fluence **20% less** in comparison to the "mild skin ageing protocol".

➔ Dwell Time ↓ ➔ Energy per Pulse ↓ ➔ Fluence ↓

3.2.1.3 Special Care: Neck Area & Décolletage



This area is very delicate. A common side effect is to have swelling and oedema. It is strongly suggested to follow the specific protocol for Neck with the setting of SmartStack level equal to 1. It is recommended to decrease the fluence **30% less** in comparison to the "mild skin ageing protocol".

➔ Dwell Time ↓ ➔ Energy per Pulse ↓ ➔ Fluence ↓

3.2.2 Atrophic Scars – "D-Pulse & SmartPulse" Protocols

Mild Atrophic Scars - Forehead and Cheeks: *CO_2 Only*

Power (W)	Dwell Time (µs)	Spacing (µm)	Stack (n°)
8	700	500	2
Scan mode	Pulse Mode	Pulse Energy (mJ)	
Normal / SmartTrack	SmartPulse	31.8	

Severe Atrophic Scars - Forehead and Cheeks: *CO_2 Only*

Power (W)	Dwell Time (µs)	Spacing (µm)	Stack (n°)
10	700	500	2
Scan mode	Pulse Mode	Pulse Energy (mJ)	
Normal / SmartTrack	DP	42.8	

3.2.3 Atrophic & Hypertrophic Scars – "H-Pulse" Protocols

Mild Atrophic Scars - Forehead and Cheeks: *CO_2 Only*

Power (W)	Dwell Time (µs)	Spacing (µm)	Stack (n°)
8	---	400	2
Scan mode	Pulse Mode	Pulse Energy (mJ)	
Normal / SmartTrack	HP	35.2	

Severe Atrophic Scars - Forehead and Cheeks: *CO_2 Only*

Power (W)	Dwell Time (µs)	Spacing (µm)	Stack (n°)
8	---	400	3
Scan mode	Pulse Mode	Pulse Energy (mJ)	
Normal / SmartTrack	HP	52.9	

Mild Hypertrophic Scars - Cheeks: *CO_2 Only*

Power (W)	Dwell Time (µs)	Spacing (µm)	Stack (n°)
15	---	500	1
Scan mode	Pulse Mode	Pulse Energy (mJ)	
SmartTrack	HP	33.0	

Severe Hypertrophic Scars - Cheeks: *CO_2 Only*

Power (W)	Dwell Time (µs)	Spacing (µm)	Stack (n°)
15	---	600	2
Scan mode	Pulse Mode	Pulse Energy (mJ)	
SmartTrack	HP	66.1	

Mild Hypertrophic Scars - Forehead: *CO_2 Only*

Power (W)	Dwell Time (µs)	Spacing (µm)	Stack (n°)
15	---	700	1
Scan mode	Pulse Mode	Pulse Energy (mJ)	
SmartTrack	HP	33.0	

Severe Hypertrophic Scars - Forehead: *CO_2 Only*

Power (W)	Dwell Time (µs)	Spacing (µm)	Stack (n°)
15	---	700	2
Scan mode	Pulse Mode	Pulse Energy (mJ)	
SmartTrack	HP	66.1	

3.2.4 Post Burn Scars – "H-Pulse" Protocols

Post Burn scars: *CO_2 Only*

Power (W)	Dwell Time (µs)	Spacing (µm)	Stack (n°)
10	---	500	2
Scan mode	Pulse Mode	Pulse Energy (mJ)	
Smart Track	HP	22.0	

3.2.5 Skin Ageing - "D-Pulse & SmartPulse" Protocols

Mild Skin Ageing - Cheek and Forehead: *CO_2 Only*

Power (W)	Dwell Time (µs)	Spacing (µm)	Stack (n°)
8	800	500	2
Scan mode	Pulse Mode	Pulse Energy (mJ)	
Normal / SmartTrack	SmartPulse	34.9	

Severe Skin Ageing - Cheek and Forehead: *CO_2 Only*

Power (W)	Dwell Time (µs)	Spacing (µm)	Stack (n°)
8	1000	500	2
Scan mode	Pulse Mode	Pulse Energy (mJ)	
Normal / SmartTrack	DP	45.0	

Skin Ageing - Perioral: *CO_2 Only*

Power (W)	Dwell Time (µs)	Spacing (µm)	Stack (n°)
8	500	400	2
Scan mode	Pulse Mode	Pulse Energy (mJ)	
Normal / SmartTrack	DP	37	

Skin Ageing - Periocular: *CO_2 Only*

Power (W)	Dwell Time (µs)	Spacing (µm)	Stack (n°)
10	500	400	2
Scan mode	Pulse Mode	Pulse Energy (mJ)	
Normal / SmartTrack	DP	38.8	

Skin Ageing - Neck: *CO_2 Only*

Power (W)	Dwell Time (µs)	Spacing (µm)	Stack (n°)
8	600	500	1
Scan mode	Pulse Mode	Pulse Energy (mJ)	
Normal / SmartTrack	DP	19.3	

3.2.6 Skin Ageing - "H-Pulse" Protocols

Mild Skin Ageing - Cheek and Forehead: *CO_2 Only*

Power (W)	Dwell Time (µs)	Spacing (µm)	Stack (n°)
8	---	500	2
Scan mode	Pulse Mode	Pulse Energy (mJ)	
Normal / SmartTrack	HP	35.2	

Severe Skin Ageing - Cheek and Forehead: *CO_2 Only*

Power (W)	Dwell Time (µs)	Spacing (µm)	Stack (n°)
12	---	500	2
Scan mode	Pulse Mode	Pulse Energy (mJ)	
Normal / SmartTrack	HP	52.9	

Skin Ageing - Perioral: *CO_2 Only*

Power (W)	Dwell Time (µs)	Spacing (µm)	Stack (n°)
10	---	400	2
Scan mode	Pulse Mode	Pulse Energy (mJ)	
Normal / SmartTrack	HP	44.1	

Skin Ageing - Periocular: *CO_2 Only*

Power (W)	Dwell Time (µs)	Spacing (µm)	Stack (n°)
10	---	400	1
Scan mode	Pulse Mode	Pulse Energy (mJ)	
Normal / SmartTrack	HP	22.0	

Skin Ageing - Neck: *CO_2 Only*

Power (W)	Dwell Time (µs)	Spacing (µm)	Stack (n°)
10	---	500	1
Scan mode	Pulse Mode	Pulse Energy (mJ)	
Normal / SmartTrack	HP	22.0	

3.2.7 Superficial Benign Pigmented Lesion – "H-Pulse" Protocols

Diffuse pigmentary resurfacing: *CO_2 Only*

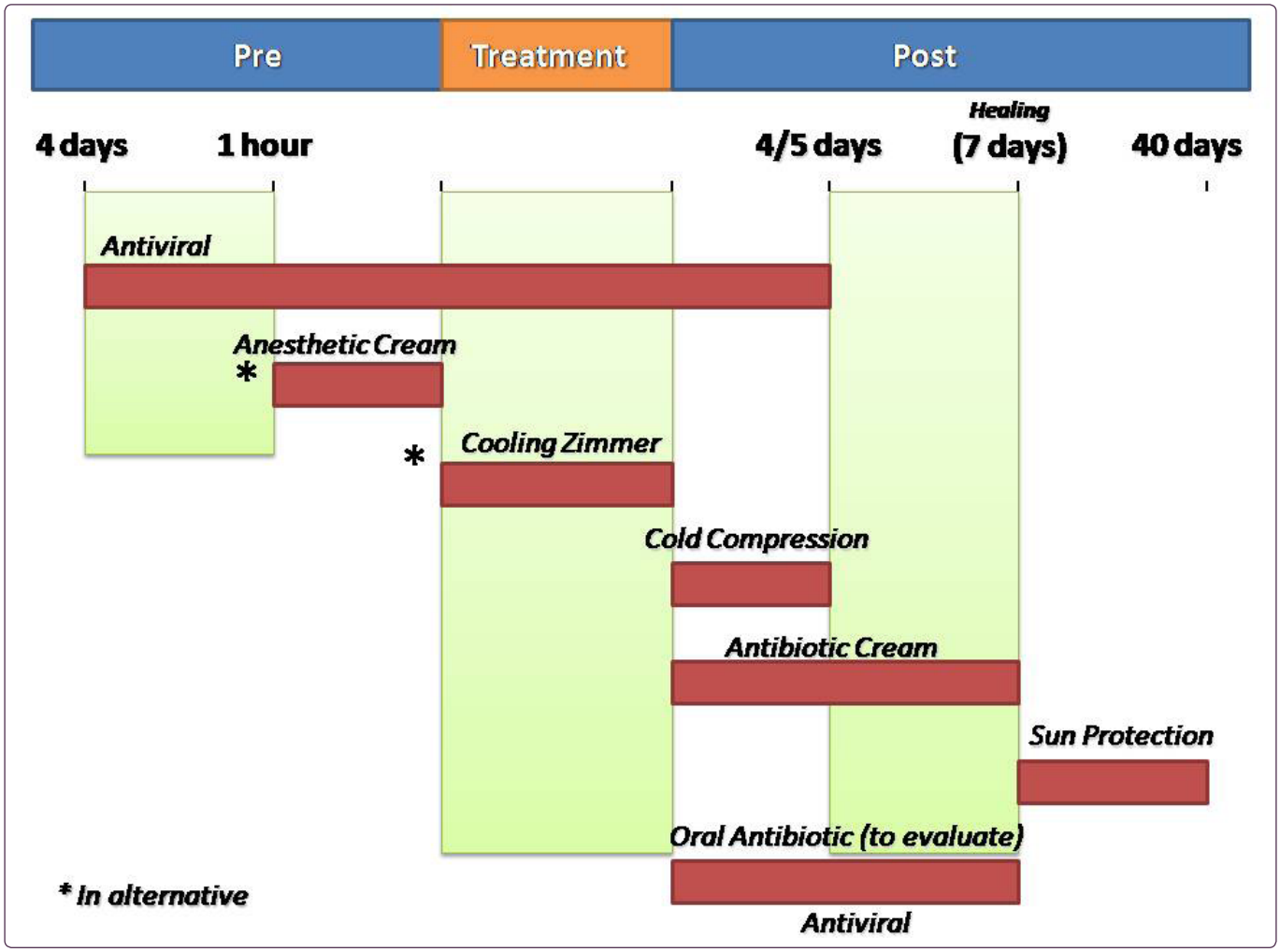
Power (W)	Dwell Time (µs)	Spacing (µm)	Stack (n°)
10	---	400	1
Scan mode	Pulse Mode	Pulse Energy (mJ)	
SmartTrack	HP	22.0	

3.2.8 Superficial Benign Pigmented Lesion - "D-Pulse & SmartPulse" Protocols

Diffuse pigmentary resurfacing: *CO_2 Only*

Power (W)	Dwell Time (µs)	Spacing (µm)	Stack (n°)
30	100	500	1
Scan mode	Pulse Mode	Pulse Energy (mJ)	
SmartTrack	DP	16,2	

3.2.9 Fractional Treatment - Summary Table



3.3 Coolpeel Skin Resurfacing

CoolPeel is the newest lunch time treatment that helps remove a thin layer of damaged skin to improve texture and provide a youthful appearance with full control of both depth of ablation and treatment downtime.

CoolPeel works by delivering a randomly scanned array of laser beams over the treatment area to remove the damaged superficial cells that are giving the skin an aged and tired appearance. As the skin re-epithelializes, new cells resurface in the treated area. A healthier and younger looking skin results from this fast procedure. Downtime is controlled from 0-2 days depending on the selection of a mild, moderate or aggressive treatment.

The depth is controlled by a unique technology, PSD – Pulse Shape Design Technology, available only in the SmartXide Tetra Fractional C02 Laser. PSD provides a specific pulse shape (HP – High Pulse) which is able to adjust the depth of penetration (20-70um) which is directly related to clinical downtime (0-2 days). The result is a pleasant and efficient treatment whilst minimizing the probability of PIH and offering a treatment outcome tailored to a patient's specific skin conditions. The procedure is performed in the physician's office. There is no topical numbing needed for this procedure. Some may use cooled air, if available, for added comfort.

3.3.1 Coolpeel Skin Resurfacing: Clinical Protocol

CoolPeel is carried out over the face, neck, décolletage, hands, etc. by applying the scanner terminals in contact with the skin. Each part has to be treated in its entirety, avoiding overlap. The "SPRAY" mode allows for consecutive scans to be delivered very quickly and with random borders, so as to reduce emphasis on skipped or overlapped areas. Choose the appropriate protocol and size of the scanning area to manage the expected downtime and treatment area. Select one of the three power levels (3W, 4W or 5W) and use spacing of 600um. Please remember, darker skin types (ST IV, V, and VI) and Asian patients should be treated with the recommended power setting of 3W.

Moist saline-soaked gauzes may be used to remove debris during the procedure and provide better aesthetic outcomes, but is not required. This may be done gently, in a blotting fashion, to minimize additional tissue trauma. Debris removal is sometimes necessary to avoid a 'heat-sink' phenomenon, which results in more thermal irritation of tissues and anesthetic spot deposition over the treated areas.

The outlined protocol includes one pass and there is no need for additional passes. The interval between treatment sessions is 30-45 days. The interval is such that adequate time is allotted for new tissues to regenerate in the treated area(s).

The endpoint of the treatment displays mild redness which subsides in a few minutes to a few hours.

3.3.2 Neck & Decolleté

Contrary to traditional skin resurfacing and chemical peels, neck and décolletage can be treated with CoolPeel because of the gentle delivery and controlled depth. However, to reduce the probability of a demarcation line, the "SPRAY" mode should always be used.

3.3.3 Perioral Area

In the perioral area, CoolPeel may be used up to the vermillion border. Please make sure the laser beam never makes direct contact with the teeth. During treatment around the mouth, many surgeons use a protective mouth-piece or wet gauze inside the mouth, covering the teeth.

3.3.4 Forehead

When treating the forehead, the hair may be moistened and/or protected with a hair band or blocked with a wooden tongue depressor. A wooden tongue depressor may also be used to protect the eyebrows. Metal shields or moist towels are used to protect the patients eyes.

3.3.5 Periorbital Area

Because the eyelid tissue is so delicate, eye protection must be adopted (patient shields or glass / metal intraocular shields, if appropriate). If treating the eyelids, CoolPeel is used no closer than 3 to 5mm from ciliary margin to minimize probability of edema and/or possible thermal irritation to the meibomian glands in the eyelid area. For the upper eyelid, treatment is carried down to the superior tarsal fold.

3.4 Laser procedures Post Treatment care

After each treatment session, physicians should advise their patients on proper care of the treated area. Discomfort may be relieved by ice packs. In order to reduce the swelling and the inflammation that may occur after the procedure of fractional skin resurfacing, we recommend applying on the skin, just after the treatment, cool compression or wet gauzes cooled using the Cryo6 air jet. A mild serous (watery) discharge could be seen, which subsides spontaneously after 2/3 days. As post-treatment care, execute a medication with accurate gentle skin cleansing, cold packs compression which must always be carried out with sterile gauze and physiological solution. Patient must re-applies every time emollient and/or antibiotic and enzymatic ointments, especially after cleaning and showers. This procedure has to be performed 3-4 times per day until the clinical healing is observed (4-7 days typically). After this time, apply a normal skin-care moisturizer and a sunblock protection (for 2-5 months according to the skin photo type and the environmental conditions). It is suggested to wait for 1 day before having a shower (avoid hot water on the treated area until healing is complete). Avoid sun exposure for at least 2-4 weeks. The use of moisturizing and emollient lotions is suggested without time limitation: it helps in maintaining the uniform and compact aspect of the new skin.

N.B.: The patient must immediately call the physician in the event of any side effects such as excessive reddening, infections or blistering. The physician will judge whether it is necessary to use antibiotic creams.

3.5 Repeating the fractional treatments

The majority of patients observe increased skin tone and texture after the first fractional treatment. The results will be visible immediately after the first session, but continue to develop for 3-6 months.The doctors should evaluate a plan of fractional sessions at varying intervals depending on the area to be treated and to the severity (Fluence and energy per pulse) of the treatment.In general it's suggested to repeat the fractional treatment after 2-3 months. The following treatment can be carried out if the tissue has completely healed.

DEKA
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