



FIXcell

## Medical Non-ablative Fractional Laser Systems

### Clinical Manual



FIXcell 1550nm nonablative Er-glass Laser systems base on Fractional photothermolysis (FP) , which is a popular treatment option , has produced significant improvement in photodamage,rhytides,skin texture and scarring ,meanwhile addresses shortcomings of ablative skin resurfacing . Previous studies have demonstrated that FP using the 1550nm wavelength has led to improvement of ultrastructural changes and clinical effects associated with photodamaged skin in the deeper dermal structures. The wavelength produce precise microscopic treatment zones (MTZs) in the skin. The depth of treatment will be to subcutaneous 450 um.

## Indications

The Medical Non-ablative Fractional Laser Systems is intended for use in dermatological procedures requiring fractional skin resurfacing and coagulation of soft tissue , even the treatment of acne, acne-induced depressed scar skin diseases.

In medical institutions, it is used by trained professionals or doctors.

## Contraindications

- Pacemaker or internal defibrillator.
- Superficial metal or other implants in the treatment area.
- Current or history of skin cancer, as well as any other type of cancer, or pre-malignant moles.
- Severe concurrent conditions, such as cardiac disorders. Avoid treating the thyroid area in case of any thyroid pathology.
- Pregnancy and nursing as well 3-6 months post-childbirth or the normal hormonal balance regained.
- Impaired immune system due to immunosuppressive diseases such as AIDS and HIV, or use of immunosuppressive medications.
- Diseases which may be stimulated by laser at the wavelength 1550nm used.
- Patients with a history of diseases stimulated by heat, such as recurrent Herpes Simplex in the treatment area, may be treated only following prophylactic regimen.

- Poorly controlled endocrine disorders, such as diabetes.
- Any active condition in the treatment area such as sores, psoriasis, eczema and rash.
- History of skin disorders, keloids, abnormal wound healing, as well as very dry and fragile skin.
- History of bleeding coagulopathies, or use of anticoagulants.
- Use of medication and herbs known to induce photosensitivity to light exposure at the wavelengths used, such as Isotretinoin (Accutane) within the last 6 months, tetracyclines, or St. John's Wort within the last 2 weeks.
- Facial laser resurfacing and deep chemical peeling within the last 3 months, if face is treated.
- Any surgical procedure in the treatment area within the last 3 months or before complete healing.
- Excessively tanned skin from sun, tanning-beds or tanning creams within the last 2 weeks.
- As per the practitioner's discretion, refrain from treating any condition which might make it unsafe for the patient.

**Note!**

- In case of uncertainty regarding potential side effects, have the patient consult his/her physician and bring a written consent for treatment.
- Additionally, a small area should be treated and assessed a few days later to determine if the patient will tolerate the treatment without developing adverse effects.

## Possible Side Effects

Certain side effects may be experienced during treatment or shortly afterwards, usually as a result of improper use of the system. Although these side effects are rare and temporary, they should be reported immediately to a physician for proper treatment.

These are the side effects that may appear in the treatment area:

Pain

Excessive skin redness (Erythema)

Damage to natural skin texture (scratching, crusting, blister, burn)

## Typical application

This guide introduces FIXcell™ 's main clinical applications.

### Acne Scar

Acne is one of the most frequent inflammatory chronic dermatoses of the pilo-sebaceous unit, requiring a large amount of care and treatment. Acne vulgaris affects approximately 85% of adolescents. Facial scarring occurs to some degree in 90% to 95% of patients, with both sexes affected equally.

### Morphology and classification

Different degrees of the different wound healing processes triggered by active acne lead to a huge amount of different clinical frameworks. There are two basic types of scars depending on whether there is a net loss or gain of collagen (atrophic and hypertrophic scars). Eighty to ninety percent of people with acne scars have scars associated with a loss of collagen (atrophic scars) compared to a minority who show hypertrophic scars and keloids .

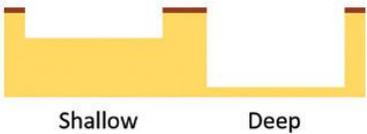
#### **Hypertrophic scars and keloids**

Hypertrophic scars and keloids are associated with an excessive collagen deposition and decreased collagenase activity. Hypertrophic scars are typically pink, raised, and firm, with thick hyalinized collagen bundles that remain within the borders of the original site of injury. The histology of hypertrophic scars is similar to that of other dermal scars. In contrast, keloids form as reddish-purple papules and nodules that proliferate beyond the borders of the original wound; histologically, they are characterized by thick bundles of hyalinized acellular collagen arranged in whorls. Hypertrophic scars and keloids are more common in darker-skinned individuals and occur predominantly on the trunk.

#### **Atrophic scars**

Atrophic acne scars are much more common than keloids and hypertrophic scars with a ratio of 3 to 1. They have been sub-classified into ice pick, boxcar (shallow and deep), and rolling scars (Table 1). With atrophic scars, the ice pick type represents 60%–70% of total scars, the boxcar 20%–30%, and rolling scars 15%–25% .

**Table 1 – Classification of acne scars as their morphology adapted from**

Acne Scars Subtype	Clinical Features
<p><b>Ice pick</b></p> 	<p>Pick scars are narrow (&lt;2 mm), deep, sharply marginated epithelial tracts that extend vertically to the deep dermis or subcutaneous tissue.</p>
<p><b>Boxcar</b></p> 	<p>Boxcar scars are round and oval depressions with sharply demarcated vertical edges, similar to varicella scars. They are clinically wider at the surface than ice pick scars and do not taper to a point at the base. They may be shallow (0.1–0.5 mm) or deep (<math>\geq 0.5</math> mm) and are most often 1.5 to 4.0 mm in diameter.</p>
<p><b>Rolling</b></p> 	<p>Rolling scars occur from dermal tethering of otherwise relatively normal appearing skin and are usually wider than 4 to 5 mm. Abnormal fibrous anchoring of the dermis to the subcutis leads to superficial shadowing and a rolling or undulating appearance to the overlying skin.</p>

The qualitative scarring grading system proposed by Goodman and Baron is simple and universally applicable (Table 2). According to this classification, four different grades (based on the visibility of the scars at the social distance of 50 cm) can be used to identify different clinical frameworks (Table 2).

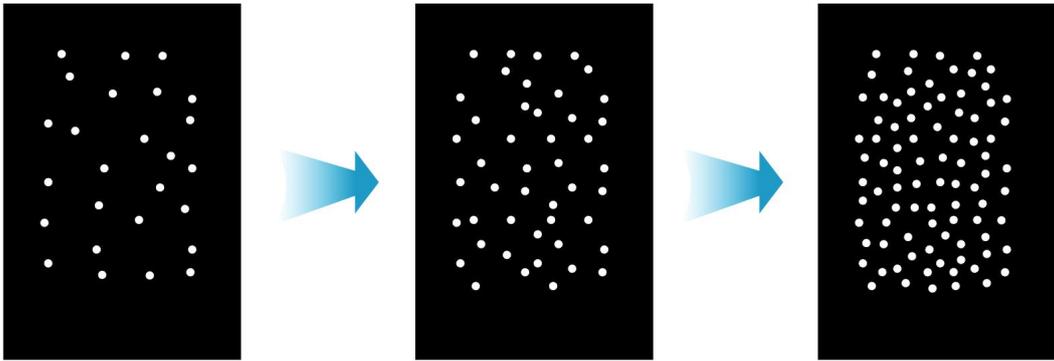
**Table 2 – Goodman and Baron qualitative scar grading**

Grades of Post Acne Scarring	Level of disease	Clinical Features
1	Macular	These scars can be erythematous, hyper- or hypopigmented flat marks. They do not represent a problem of contour like other scar grades but of color.
2	Mild	Mild atrophy or hypertrophy scars that may not be obvious at social distances of 50cm or greater and may be covered adequately by makeup or the normal shadow of shaved beard hair in men or normal body hair if extra facial.
3	Moderate	Moderate atrophic or hypertrophic scarring that is obvious at social distances of 50cm or greater and is not covered easily by makeup or the normal shadow of shaved beard hair in men or body hair if extra facial, but is still able to be flattened by manual stretching of the skin (if atrophic).
4	Severe	Severe atrophic or hypertrophic scarring that is evident at social distances greater than 50cm and is not covered easily by makeup or the

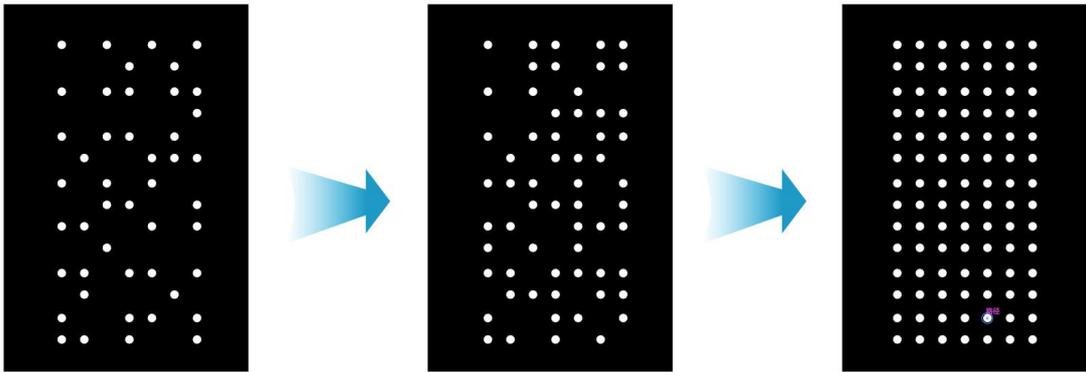
		normal shadow of shaved beard hair in men or body hair if extra facial and is not able to be flattened by manual stretching of the skin.
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In this section, focus will be brought on the treatment approach for atrophic acne scars. FIXcell is a 1550 nm non-ablative fractional device delivering microbeams of some 110µm of diameter with an energy up to 70 mJ. Three main features of the FIXcell **Fraction Mode** : Shape and dimension of the scan can be modified, number of microbeams per cm<sup>2</sup> can be increased from 100 up to 500, and the microbeams are delivered in two different non-sequential scan-controlled modalities ( Scrambled and Random), in addition to continuous non-contact air cooling (Croyshot™.optional).

**Scrambled Mode:** The laser microbeams are delivered in a pre-set area irregularly by random shots method. There is never be a laser microbeam of repetition even if the laser is re-triggered at the same position .



**Random Mode :** The laser microbeams are delivered in a pre-set area regularly by random shots method. If the laser is re-triggered at the same position, all laser microbeams are repeated again.



**Procedure**

**1 PrePre-treatment :** The patient in a sitting position, all scars are marked with a surgical pen and then a potent topical anesthetic is applied for a duration as per manufacturer’ s guidelines (typically

one hour). Just before treatment, anesthetic should be removed, skin should be cleansed and dried. According to the mark area on the skin ,choose the correct treatment tips for the treatment: FP1 or FP3 .

## **2 Treatment**

a. A first pass is performed using the smallest circular pattern, only on the base of each scar using 300-350 microbeams/cm<sup>2</sup> and energy of 20-30 mJ. The aim of this first pass is to stimulate collagen production at the base of the scar to obtain its elevation.

b. A second pass is done with the doughnut pattern (adjusting the size according to the diameter of each scar), using a lower number of microbeams/cm<sup>2</sup> (150) and a higher energy (40-50 mJ) over each scar. The aim of this second pass is to obtain a collagen remodeling of the tissue surrounding the scar.

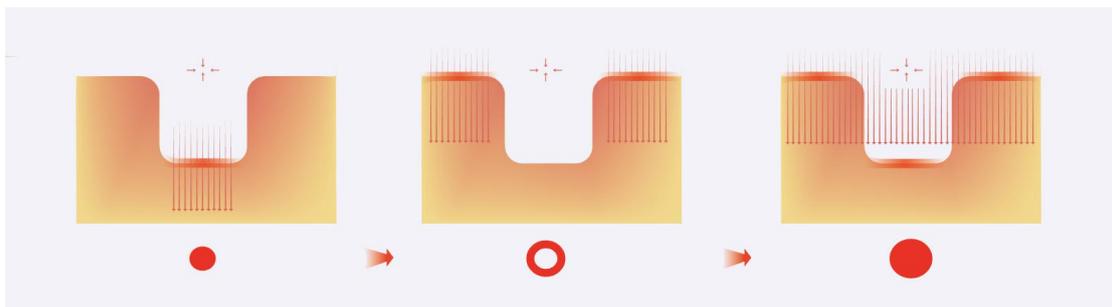
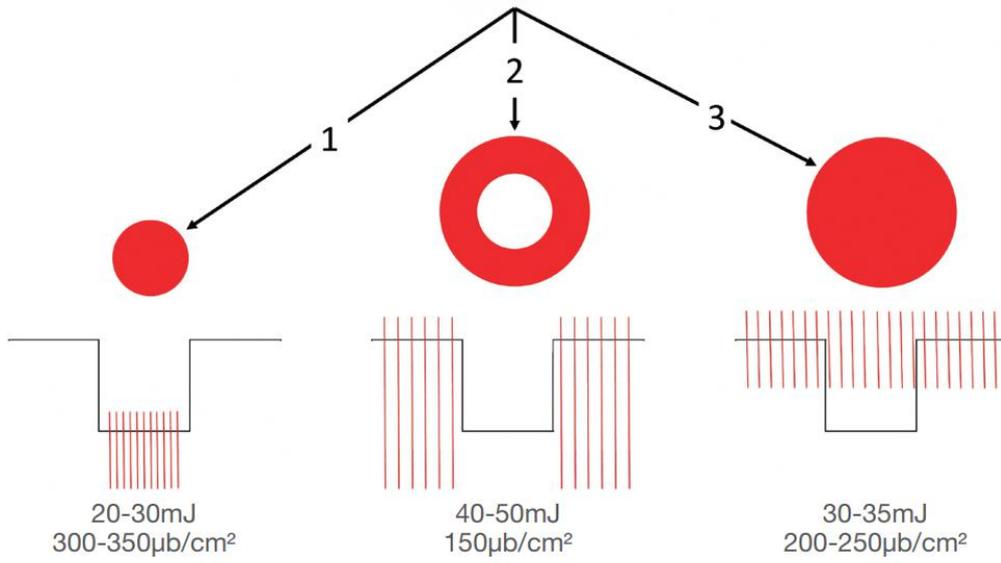
c. A final and third pass is performed over the entire affected area using the largest circular or hexagonal pattern, 30-35 mJ of energy and 200-250 microbeams/cm<sup>2</sup>. Non-affected areas (such as forehead) will now treated with very low settings of energy and density to avoid visual difference between treated and non-treated areas.

## **3Post treatment**

FIXcell treatment does not require specific post-op care. Patients are requested to apply a moisturizer several times a day till the microcrusting flakes off. It is better to use EVO **Mesoskin** to import HA noninvasively every 5 days. Direct sun exposure is to be avoided, and SPF 50 + needs to be applied till the next procedure.

Dark skin patients should be treated using lower energy and density of microbeams (about 30 to 40% less than for fair skin) to reduce the risk of PIH. A complete treatment is composed by at least 4 procedures performed 4-6 weeks apart.

Figure 1 is a schematic explanation of the 3-step procedure



Note:Doughtnut's diameter is a double of the scar's.



*Figure 2: Patient with acne scars Goodman 3B submitted to 4 sessions of FIXcell, 4 weeks apart. 6 months follow-up. Please note that the pigmentation was treated by IPL.*

## Resurfacing

Cutaneous resurfacing encompasses the use of varied technologies to smooth, tighten, even, or otherwise restore epidermal and dermal appearance. Nonablative lasers produce limited thermal damage without causing ablation or vaporization of tissue. The epidermis remains intact during treatment. With the reduced damage, there is typically a reduced efficacy per treatment compared with ablative laser treatment, and most often a need for multiple treatments to achieve optimal results. In addition, while multiple nonablative treatments typically provide large cumulative improvements, results may not reach the same level of improvement as might be seen as ablative treatments. However, side effects are reduced, healing is more rapid, wound care is more convenient, and complications are fewer which make it more popular .

FIXcell has two different tips for skin rejuvenation, OST-7 and OST-15. OST-15 is used for some big area treatment ,such as cheek, forehead. OST-7 is used for some small and bony area treatment ,such as nose, eyes.

In this section, focus will be brought on the treatment approach for photodamage, rhytides, skin texture and tone .

## Procedure

**1 PrePre-treatment :** The patient in a laying position, all skin wounds are marked with a surgical pen and then a potent topical anesthetic is applied for a duration as per manufacturer' s guidelines (typically one hour). Just before treatment, anesthetic should be removed, skin should be cleansed and dried

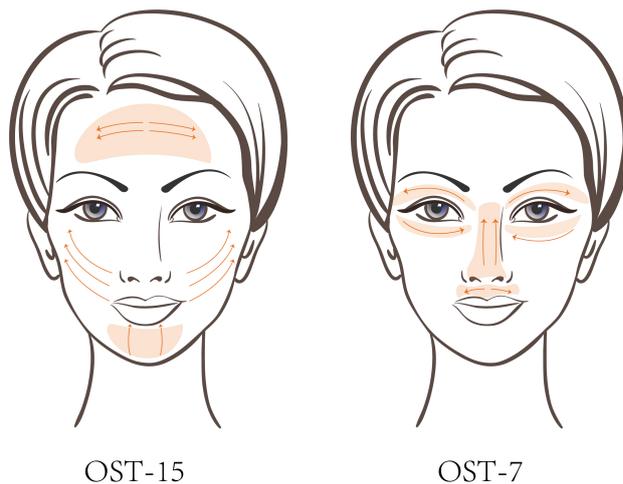
## 2 Treatment

- a. A first pass is performed using the OST-15 , **both way** pattern and energy of 5-8 mJ.
- b. A second pass is OST-15 , both way pattern and energy of 10-20 mJ.
- c. A final and third pass is performed over nose and eyes area using the OST-7 , **Left or right** pattern and energy of 5-8 mJ.

## 3Post treatment

FIXcell treatment does not require specific post-op care. Patients are requested to apply a moisturizer several times a day till the microcrusting flakes off. It is better to use EVO **Mesoskin** to import HA noninvasively every 5 days. Direct sun exposure is to be avoided, and SPF 50 + needs to be applied till the next procedure.

Dark skin patients should be treated using lower energy and density of microbeams (about 30 to 40% less than for fair skin) to reduce the risk of PIH. A complete treatment is composed by at least 6 procedures performed in 4-6 weeks. The interval between each treatment was 2 weeks.

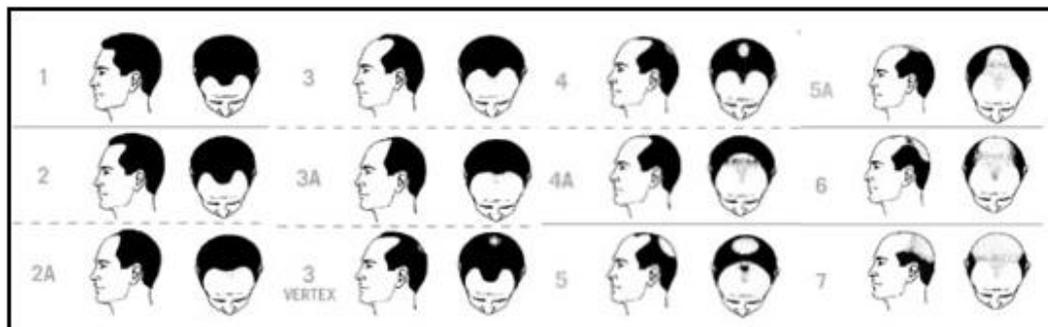


# Androgenic alopecia

Androgenic alopecia is a progressive hair density reduction, the specific performance is gradually thinner, shorter, lighter color, can not effectively cover the scalp, is the most common clinical alopecia, and genetic androgen related. It can occur in both men and women, but is more common in men, with an average incidence of about 20% in men. Androgen alopecia occurs in 50% of men at age 50, rising to 70% with age.

## Morphology and classification

In 1975, Norwood, dermatologist and hair transplant doctor, proposed a more detailed classification method of **Norwood Classification**, based on the detailed study of the previous hair loss classification and grade classification, combined with his own long-term observation and research. This method has been in use until now and is the most widely used classification method in the world.



In this section, focus will be brought on the treatment approach for Androgenic alopecia .

The RenuvaTMTM has 3 fractional tips for scalp treatment: FP1,FP2,FP3.

## Procedure

**1 Pre-treatment** : The patient in a sitting position, all treatment area should be clarified between clients and doctors. According to the **Norwood Classification** ,choose the correct treatment tips. Clean all the treatment areas by bromogeramine or 75% alcohol 2 times.

Norwood Classification	Recomented tips	Gender	Recomented tips
2\2A\3	FP1	Male	FP1 and FP3
3A\3 VERTEX	FP1 and FP2	Female	FP2
4\4A\5	TP2 and FP3		
5A\6\7	FP3		

**Notes:**

The **Scalp Mode** indicator on the operation interface will help doctors to mark treatment area. If possible, please use FIXcell™ system **Fast parameters setting** to help mark all parameters of every treatment.

**2 Treatment**

The treatment principle is **low energy high density** method. 5mj to 8mj and 100-300 shots/cm2 is the recommended parameters. Laser output mode should be **Random or Scrambled**.

a. Patch test first, choose the best energy from 5mj to 8mj and suitable ponits density from 100 to 300 shots/cm2. The standard is the largest energy and ponits density that the patient can bear. More energy and more shots will cause more pain.

b. Deliver the laser energy to the scalp carefully only one pass, make sure there is no beam overlaps and no omissions.

**3 Post treatment**

FIXcell treatment does not require specific post-op care. Patients are requested to apply a moisturizer or calming and smoothing products several times. Don't wash hair in 2 days. There may be itching of the scalp after treatment, do not scratch.

A complete treatment is composed by 5 procedures, performed 2 weeks apart.



Male ,38 years old, Hair growth before and after, 2 sessions of 1550nm non-ablitive laser treatment .



Female ,48 years old, Hair growth before and after, 5 sessions of 1550nm non-ablitive laser treatment .

## **EVO words**

**Non-ablative laser is mainly used for reconstruction of skin and the collagen regeneration, with its unique noninvasive, fast recovery, no significant complications etc are recognized by more and more doctors, but also in the drug import, gravid grain removal, and other fields have to try, achieved significant effect, to welcome you in the process of using, the valuable experience to share with EVO,we will continue to upgrade the product, also for a wider range of applications.**