

Operation Manual

PINXEL

Micro Needle Rf & Fractional Rf



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CONVENTIONS Used in this Manual

The following conventions in the form of notes, cautions and warnings are used in this manual:

Note

The content of this *Note* offers general information that is important to keep in mind.

Caution



A *Caution* alerts the user to the possibility of a problem with the device associated with its use or misuse. Such problems include system malfunction, failure, and damage to the system or other

property. The caution statement includes a precautionary action that should be taken to avoid the hazard.



A *Warning* alerts the user to the possibility of injury, death, or serious adverse reactions associated with the use or misuse of the system.

Table of Contents

1. Before Use	
A. Notice	
B. Symbols (Label)	
2. System Features	
3. System Composition	
4. Description of Product	
A. Main Unit	
B. Main Unit (Rear)	
C. Hand-piece	
5. Operating Instruction	
A. Preparations	
B. Safety checking before operation	
C. Operation procedure	
D. Error message	
6. Specification	
A. System classification	
B. Electrical specification	
C. Mechanical specification	
7. General Cautions	

1. Before Use

A. Notice

Before the usage of this equipment, safety precautions and operating procedures should be acknowledged thoroughly.

In general the devices might cause side-effects and accidents in case of improper use.

Please be careful about all potential risks of danger and conduct all necessary precautionary actions according to this manual.

Please also be noted that this equipment should be considered for all repairing works, upgrading and other necessary technical works by our instruction.

B. Symbols (Label)



Warning Alert Label for potential risks in usage of laser devices, will be adhered on Main body.

2. System Features

Pinxel (Fracitonal RF Technology allows effectively treatment of deeper dermis, epidermis, and upper dermis. RF energy is emitted at the end of fractional RF micro-needle; this will treat target area - deeper dermis - without damage of epidermis.

The fractional RF is useful for minimal invasive epidermal rejuvenation.

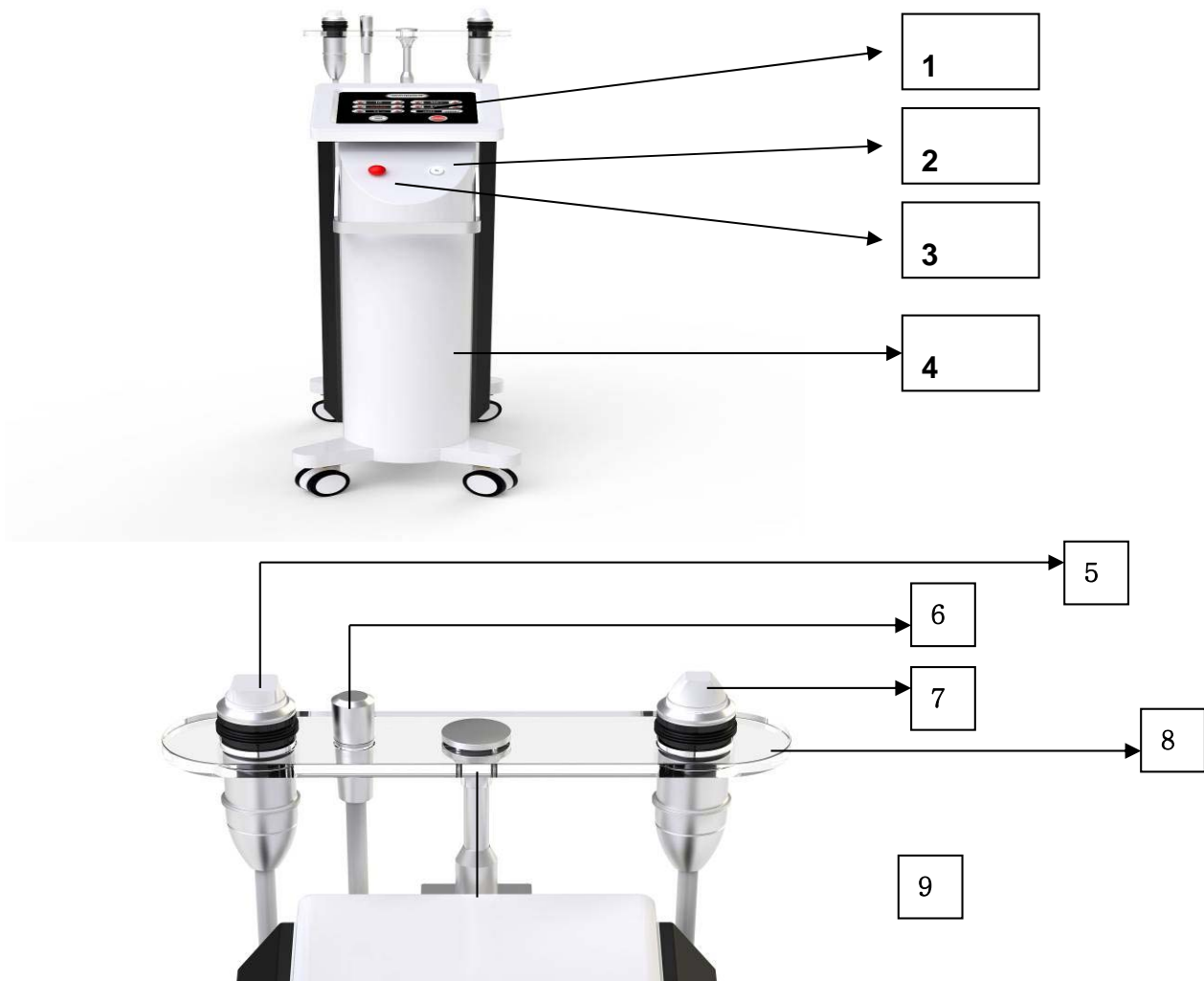
RF energy does not target pigment-making cells in the skin. Pinxel cures and improves wrinkle, scar, skin rejuvenation, and skin tightening safely and efficiently with minimized PIH, using RF energy.

Special features of Pinxel :

- a) Minimizing downtime
- b) Available to treat both epidermis and dermis layers
- c) It is suitable for all skin types
- d) Lesser risk of PIH and side effects
- e) RF Fractional and RF micro-needle technologies are in one platform.

3. System Composition

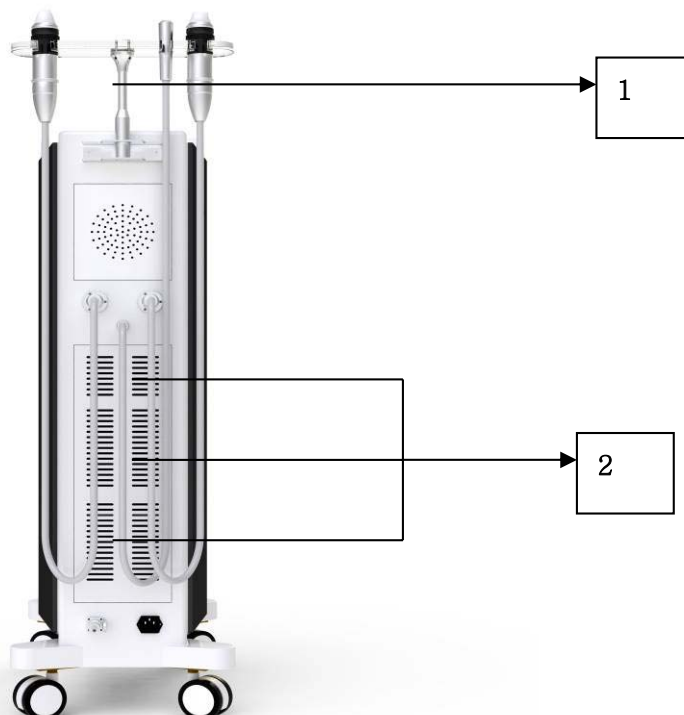
* Front view

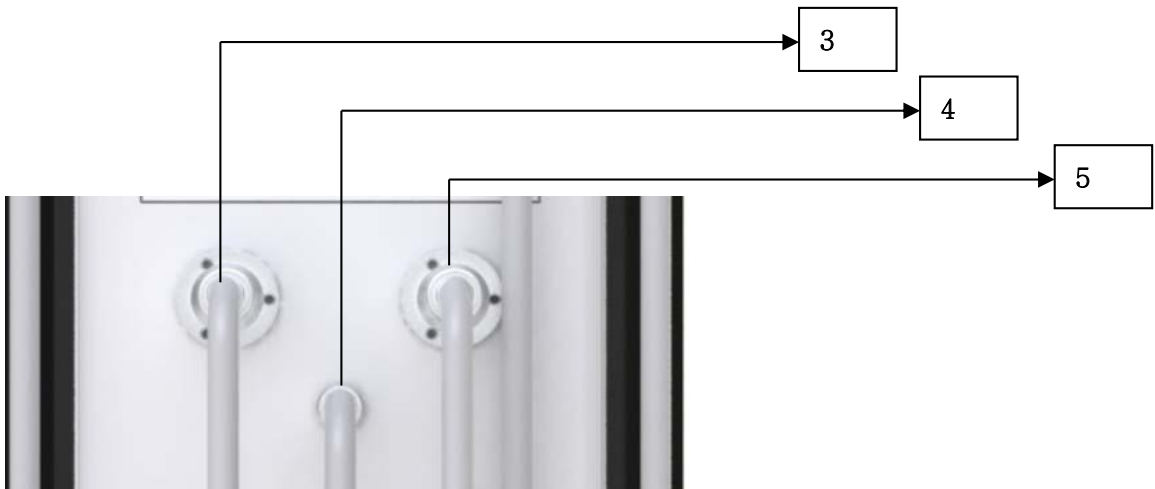


Description

- ① LED Screen
- ② Key Switch
- ③ Emergency off Button
- ④ Main unit
- ⑤ RF fractional hand piece
- ⑥ Earth grounding bar
- ⑦ RF micro-needle hand piece
- ⑧ Holder for hand pieces
- ⑨ Holder screw.

* Back view

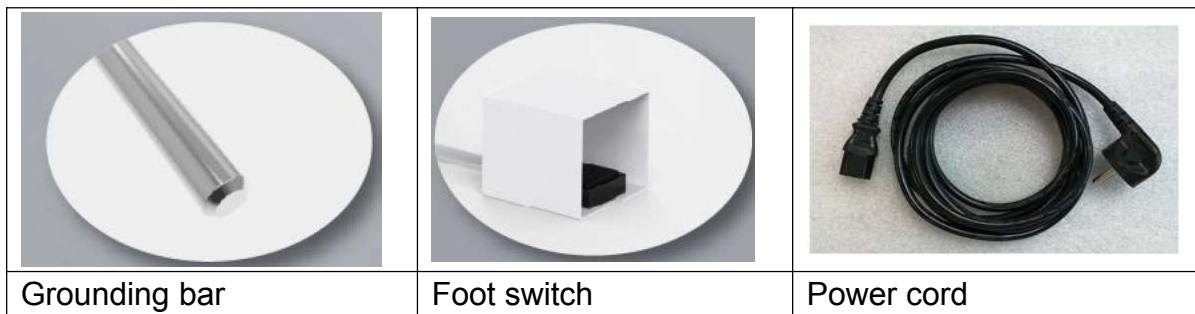
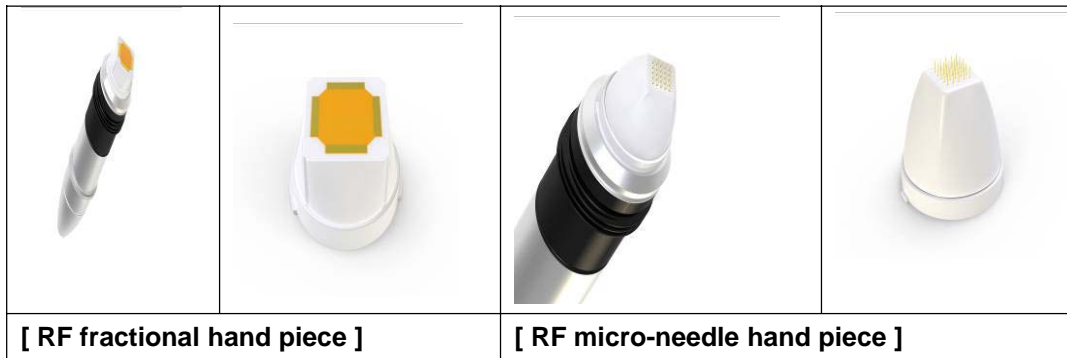




Description

- ① Holder neck
- ② Ventilation windows
- ③ RF Micro needle hand piece connector
- ④ Grounding bar connector.
- ⑤ RF fractional hand piece connector
- ⑥ Power code connector.
- ⑦ Foot switch connector

System Composition



4. Control Panel



Description

- ① Displaying operation status
- ② Key switch: Main power switch. Used for on/off of equipment.
- ③ Emergency stop switch : Switch for operation halt at emergency

5. Operating Instruction

A. Preparation

- 1) Connect power cable into the appropriate socket, Identify safety.
- 2) Make sure air cooling tube is securely connected on main unit.
- 3) Check the using voltage and connect the power cord.
- 4) Check whether the exposure part is polluted and foreign materials exist.



Check each mode works properly before you operate it on patients!!

B. Safety check before operation

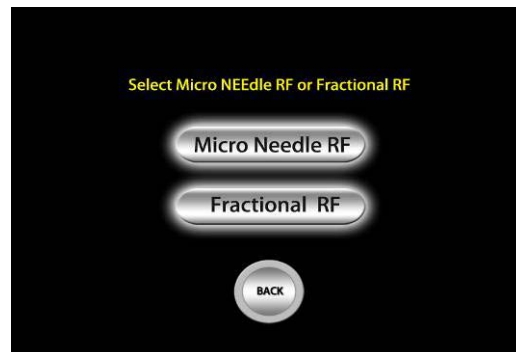
- ① Renew the patient's treatment record.
- ② Check if all operation materials including micro-needle kit are sterilized in normal condition.
- ③ To start operation procedure, we recommend that you check if each modes works properly before you apply it on patient in order to prevent unexpected abnormalities.
- ④ Establish proper parameter considering patient's condition assessment and clinic treatment guideline.
- ⑤ Make patient's skin ready for treatment, such as anesthesia cream, if necessary.
- ⑥ The equipment should stay with STAND BY mode except using period for surgical operation.
- ⑦ All operation procedure status should be monitored on displaying screen.



We recommend starting with low level first then increasing gradually!!

C. Operation procedure

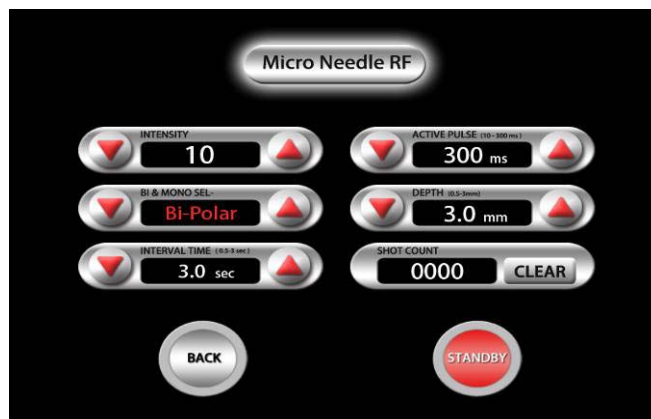
- 1) Make sure power cord is securely connected, and fuse is equipped in right position on main body.
- 2) Turn power 'on' position, then power switch on front side of main unit will be activated.
- 3) Make sure grounding bar and foot switch are properly connected.
- 4) Initial screen will be displayed as following upon key switch on, and stand-by screen will be shown after 2 ~3 seconds.



< Initial Screen >

Micro Needle RF Mode

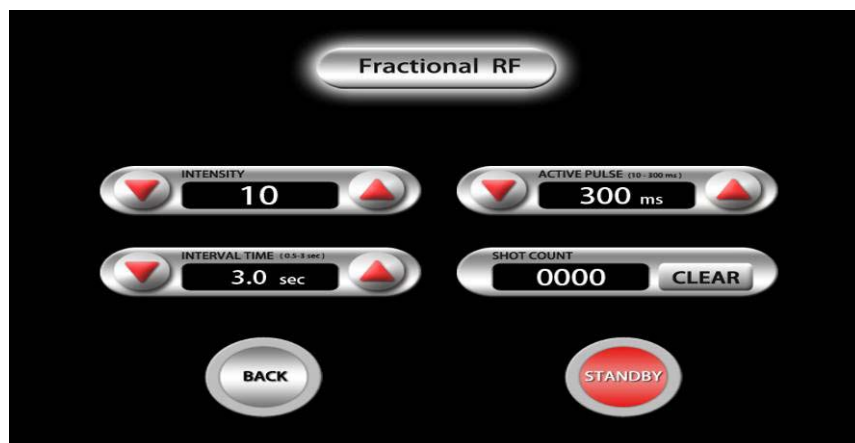
- 5) Select 'micro needle RF mode', and then you can find screen like below picture.



6) Set each parameters in prior to operation in accordance to the following description.

No.	Items	Descriptions
1	intensity	To determine output level (1 ~ 10 level)
2	Polar set	To select Mono-polar or Bio-polar
3	Interval	To set the time between first shot and next shot Single/0.5/1.0/1.5/2.0/2.5/3.0 sec.)
4	Active pulse	To set continuance of output time per each shot (10~300 msec.)
5	Depth	To set the depth of penetration of micro needle (0.5 ~ 3.0mm)
6	Shot count	To count out put on each mode.
7	Back	To return to initial screen
8	Standby (Ready)	To select standby and ready mode.

Fractional RF Mode



No.	Items	Descriptions
1	Intensity	To determine output level (1 ~ 10 level)

2	Interval	To set the time between first shot and next shot (Single/0.5/1.0/1.5/2.0/2.5/3.0 sec.)
3	Active pulse	To set continuance of output time per each shot (10~300 msec.)
4	Shot count	To count out put on each mode.
5	Back	To return to initial screen
6	Standby (Ready)	To select standby and ready mode.



When you stop operation please return to initial screen and off the system.



Please be noted that it is not completely power 'off' during stand-by status. It will be completely power off by pressing main power switch in rear side of main unit.

6. Specification

A. System Classification

- 1) Electric shock protection: Class I equipment,
- 2) Electrical device class by IEC: Class IIa
- 3) Protection against ingress of liquids: Ordinary equipment
- 4) Mode of operation: Stand-by and Continuous in timer

B. Electrical Specification

- 1) Input rating : 100 ~ 240VAC \pm 10% , 50/60Hz
- 2) Power consumption : 300 VA in max.
- 3) System
 - ① Main frequency :2 MHz \pm 10%

- ② Output (micro needle mode) : max. 30 watt, 250 V_{p-p}, 200Ω
- ③ Output (Fractional RF mode) : max. 20 watt, 300 V_{p-p}, 200Ω
- ④ Mode : Micro needle RF (mono or bi polar) / Fractional RF
- ⑤ Grounding bar : Ø20 x 110mm, SUS-303

4) Display : LED Screen

C. Mechanical Specification

- 1) Dimension : W280mm x L505mm x H1,100mm
- 2) Weight : approximately 20kg
- 3) Standard acc'y: 2 handpieces / ground bar / foot switch / power cord

7. General Cautions

A. Environment and Restrictions for use

- 1) Environment: Do not use where humidity is high (example: bathroom)
 - [1] Operating Temperature : 10°C ~ 40°C (With enclosure)
 - [2] Operating Humidity : 10% ~ 80%, Non-condensing
 - [3] Storage Temperature : 10°C ~ 60°C (With enclosure)
 - [4] Storage Humidity : 10 - 90%, Non-condensing
 - [5] Pressure : 500 ~ 1060 hPa

B. Cautions before use

- 1) Check operation procedure preliminary.
- 2) Check buttons to make sure they work normally.
- 3) Do not modify without our consent.
- 4) Check all codes connections to make sure they are not separated.
- 5) Check the others except the previous articles when using the equipment after a long halt in

the operation. Check whether the other instruments are normal and work safely.

- 6) A bunch of cords can be a cause of overheating. Do not use cables in a state of that.
- 7) Do not step on plugs or give strong impact on them.
- 8) Do not use inflammables or fire.

C. Cautions during use



- 1) Stop using the equipment and power off immediately when its malfunction is found.
- 2) Power off immediately when power is failed. And return operation handles, switches etc. to the original position.
- 3) This equipment should not be used in contiguity of patient monitor equipments.
- 4) Only persons who had special training are allowed to use.
- 5) The equipment should be used after consulting with a medical specialist.
- 6) Pay attention to following cautions during use.
 - ① Check whether there are abnormal conditions in the equipment or patient.
 - ② If any abnormal condition in the equipment or patient is found, take care of patient first.
 - ③ Then, stop using the equipment. Start reusing after checking patient and the equipment.
 - ④ Not qualified persons, including patient, are not allowed to contact the equipment.
 - ⑤ Do not use the equipment where chemicals are kept or gas is generated.

D. Cautions after use

- 1) Power off after returning operation handles, switches etc. to the original position according to the procedure when operation is finished.
- 2) Don't do unreasonable actions (example: holding cord) to cord connection part when removing cord.

E. Maintenance

- 1) Do not repair at discretion when out of order. Ask the store or maker.
- 2) Do not open the case of the equipment or controller.

8, Packing List

Component	Quantity
Main Body	1
RF fractional hand piece	1
RF Needle hand piece	1
Ground Bar	1
Key	2
Fuse	2
Foot switch	1
Protective goggle	1
Power cord	1
Holder for hand piece	1
Holder screw	1
RF fractional treatment tips	10
RF Needle treatment tips	20

9, Treatment Procedure

A, Cautions before operating patients

- Cleanse always the medical treatment area before the operation to remove the foreign substance like cosmetics.
- The patient must wear the protective goggles.
- Begin the energy for treatment from low power to prevent any side effect, and lower the patient's treatment expectancy level, and it will be better to perform the operation with frequent treatments.

B, Treatment procedure

1, wear anesthesia cream on the treatment area (Anesthesia is suitable for about 45-55 minute)

After clean up anesthesia cream from face.

2, Perform an operation with the Pinxel (Refer to basic protocol for the energy setting)

3, The treatment as the sequence of the followings:

- ① Forehead
- ② Around eyes
- ③ Nose

- ④ Under eyes
- ⑤ cheek
- ⑥ Around lips
- ⑦ Chin and under chin
- ⑧ Jaw lines

4, After operation, strong cooling is essential for about 20 minutes.

5, Then perform the cooling and moisturizing care.

C, Cautions when and after performing operations

- Every treatment should be done as one passing of full face according to basic protocol.
- And you can do 2~3 passing additionally according to the lesions.
- Strong cooling after performing an operation is essential, and cooling and moisturizing care are needed to enhance the treatment effect and to prevent any side effect.
- To enhance the cooling effect, after you treated the half of face, please cool down the parts with roller which you already treated while you treat the other half of face also it is very important that all the patients should cooling the face completely after treatment. (We recommend you to use cooling up to 40 to 60 minute continuously by roller or Ice pack...etc)
- Cooling is very important to prevent any side effect and when patient face still feel hot after cooling , then please cooling their face by using fan or air conditioner blow cooling air to the face.
- After treatment, there appear Edema and Erythema. Edema goes for 1-2 days and Erythema goes for 1-2 weeks.

D, Basic protocol

Indication	Level	Needle Tip (mm)	ON time	Pass	sessions	Delay weeks
Large pore	3-5	1.0-1.5mm	100-150ms	2-3	3-4	4-5
Acne/Acne scar	3-5	1.0-1.5mm	150-200ms	2-3	3-4	4-5
Skin rejuvenation	3-5	0.5-1.0mm	50-100ms	1-2	3-4	4-5
Skin resurfacing	3-5	0.5-1.0mm	50-100ms	2-3	3-4	4-5
Skin tightening	3-5	1-1.5mm	50-100ms	1-2	3-4	4-5
Body tightening (Abdominal)	5-8	2.0-3.0mm	100-150ms	2-3	3-4	4-5

Stretch marks	5-8	2.0-3.0mm	100-200ms	2-3	3-4	4-5
Neck	3-5	0.5-1.0mm	50-100ms	1-2	3-4	4-5
Wrinkle/Fine line	3-5	1-1.5mm	150-200ms	2-3	3-4	4-5

10, Question and Answer

1, What is the difference of Fractional RF and Fractional Co2 laser?

Fraction RF is better than Fractional Co2 laser, Since Fractional laser is single wavelength, the indications is small range, and only have limitation on skin color. The absorbed energy is different with different pigment color. But the result of Fractional RF is not effected by the pigment and suitable for all kind of skin color. Obviously result can be seen after each treatment.

2, How about the safety of Fractional RF?

Fractional RF treatment has passed the FDA and CE certification, the safety has been proved according to clinical report.

3, What kind of skin problem that the Fractional RF can treat?

Fractional RF could treat wrinkles, skin loose, Acne scar, large pores. In some treatment, the pigment and vascular has been treated in some degree. This is a multiple treatment and it can improve the skin property all round.

4, Is it suitable for sensitive skin?

The sensitive skin is suitable for the Fractional RF treatment, it could change the sensitivity in some degree.

5, Is it suitable for the dark color skin?

It is suitable for the dark color skin, since there is not light power only RF energy. The dark skin could use the treatment.

6, Does the skin become thinner after the treatment?

The Fractional RF treatment will not make the skin thinner. Oppositely, it could active the growth of collagen in skin to make the skin healthier.

7, What will happen on skin after the treatment?

At the treatment, the redness and slight swelling will happen, but the customer could totally accept. After 24 hours, the treatment area will show some needle shape escharotics. The customer could use make up to cover the treatment area, and not effect normal life and work.

8, Is it necessary for long time treatments? How long time to do another treatment?

Obviously result will happen even after one treatment. But as the time pass by, the skin will become loose. So we suggest do another treatment after 6 weeks interval. Each course could do 3-5 treatment.

9, How long time the result can be kept?

According to different skin property, single treatment could keep 2-6 month. 3-10 years can kept after one whole course.

9, Contact Details

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