

Skin Tightening, Body Contouring, Fractional Skin Resurfacing and Microneedles Skin Remodeling using an innovative 3DEEP[®], FDA approved, Multisource Phase Controlled RF Device



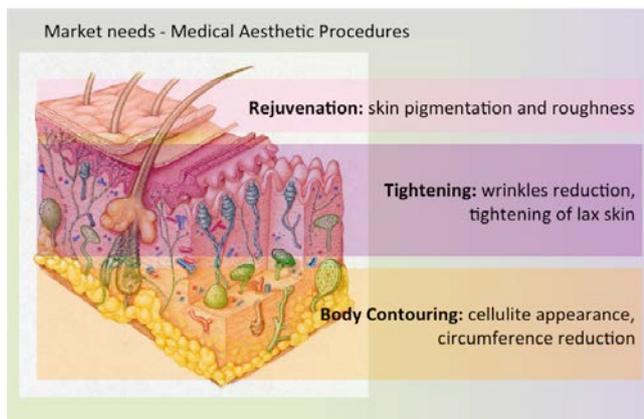
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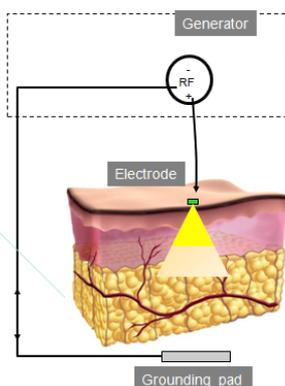
Introduction

Today's aesthetic needs include skin rejuvenation, skin tightening and body contouring. In addition to fat loss and fat reduction. Patient demand for non-surgical, non-invasive and no downtime skin tightening and body contouring treatments has grown dramatically over the past decade as new treatments and technologies have been introduced.

For many years light based system were used for these procedures. Since light (lasers or intense pulsed light) sources have limited ability to penetrate deep in to the tissue, radiofrequency modalities were introduced for the improvement of lax skin, skin tightening and body contouring and skin resurfacing.

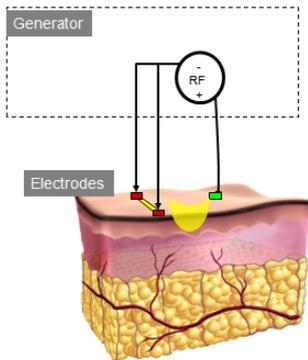
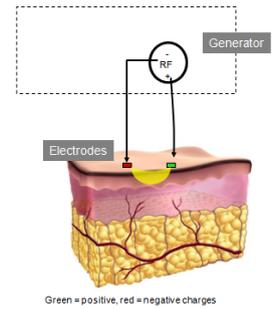


The various radio frequency modalities or techniques used for these needs are mono polar devices, Bipolar devices, multi polar and the new revolutionary technology, the multisource phase controlled RF. Radiofrequency waves penetrate the skin much more efficiently than light and is independent of skin color.



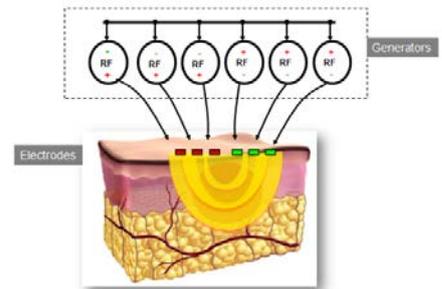
In a mono polar device, the active electrode is placed on the skin surface and the wave passes from the active electrode to the grounding plate in an uncontrolled manner through the tissue. The energy is delivered deep into the tissue. Here there is high energy density at the electrode on the skin surface and there is excessive heating occurring at the active electrode. This can lead to a lot of patient discomfort.

In a bipolar device, the wave of energy passes from the positive to the negative electrode through the tissue. The energy remains superficial and majority of heating of the tissues occur in the upper layers of the skin.



A multipolar device is essentially a bipolar device with multiple positive electrodes and a single negative electrode and a single RF generator. Again, the energy remains superficial and energy delivery occurs superficially.

In a 3DEEP system there are multiple RF generators. It is the name given to multi source phase controlled RF system. This utilizes multiple RF generators, which can be individually controlled, and the waves formed repel each other resulting in a deeper tissue penetration. The energy density at the electrodes on the skin surface is low since it utilizes multiple electrodes. This reduces the patient discomfort and reduces the need for intense cooling. Thus providing a revolutionary new way to deliver energy into the deeper layers of the skin.



Skin tightening and contouring

Until recently, the options available to treat skin laxity in order to attain a tighter body contour were limited to surgery. Various non-invasive vacuum and massage-based treatments offer only partial and short-term benefits since the improvement was temporary. Devices with various optical heating sources have proved to have limited benefit due to either their inability to penetrate deep enough or due to unwanted side effects.

To treat lax skin and cellulite, the thermal energy must reach the collagen located in the dermis and in the perilobular connective tissue in the sub-dermal layer. The heat penetration achieved by 3DEEP RF technology reaches into the deep dermis and sub-dermal layers to provide effective collagen tightening and remodeling. The effects of dermal heating include an immediate effect on collagen structure via the stimulation of neo-collagenesis. The power and depth of RF energy delivered to the skin can be controlled precisely making it very effective.

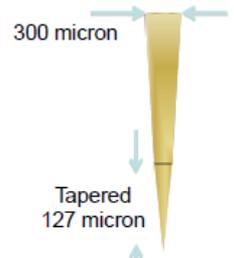
Fractional RF Microneedle Skin Remodelling



The Intensif Handpiece is targeted to treat acne scars, deep wrinkles, dilated pores, stretch marks and other conditions requiring deep dermal coagulation and heating.

Until today, fractional microneedle treatments involved the straightforward mechanical insertion of an array of microneedles or a group of insulated (coated) needles.

Unlike those technologies, the Intensif handpiece uses non-insulated needles, where the RF energy is delivered through the whole needle; enable coagulation at the dermis and epidermis at the same time. For that reason, we can hardly see pin-points bleeding on the face during treatment.



The Intensif Handpiece applies an array of 25 micro-diameter needles, tapered and gold plated, to safely and effectively deliver focused RF energy deep into the dermis, providing a revolutionary collagen remodeling solution, with a minimal discomfort and downtime.



BEFORE

AFTER

The energy is delivered once the needles are inside the skin, and since the conductivity of the epidermis is less the energy gets delivered into the skin rather than on the surface. So, there is no superficial damage to the skin and there is practically no down time.

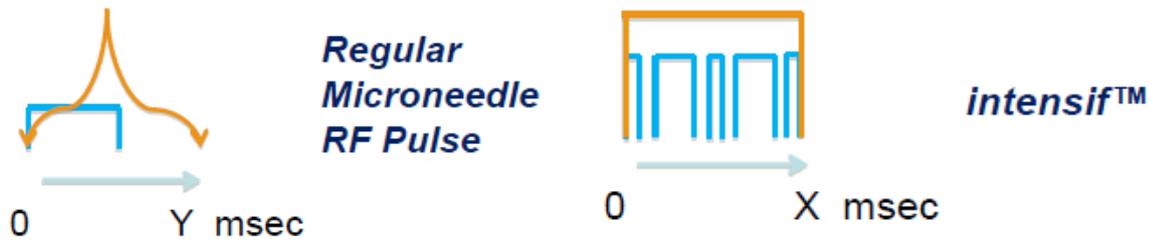
The other advantage of the Intensif is the fractionated power delivery (**Fractionated Pulse Mode, FPM**) i.e., power delivered in small aliquots, and **impedance control energy delivery**, which helps in effectively heating up the surrounding tissues.

EndyMed's proprietary fractionated pulse mode (**FPM™**) uses a **unique algorithm** that was designed to deliver the energy in a micro pattern, enabling a **more uniform distribution of the energy**, resulting in more effective volumetric heating of the skin providing better results.

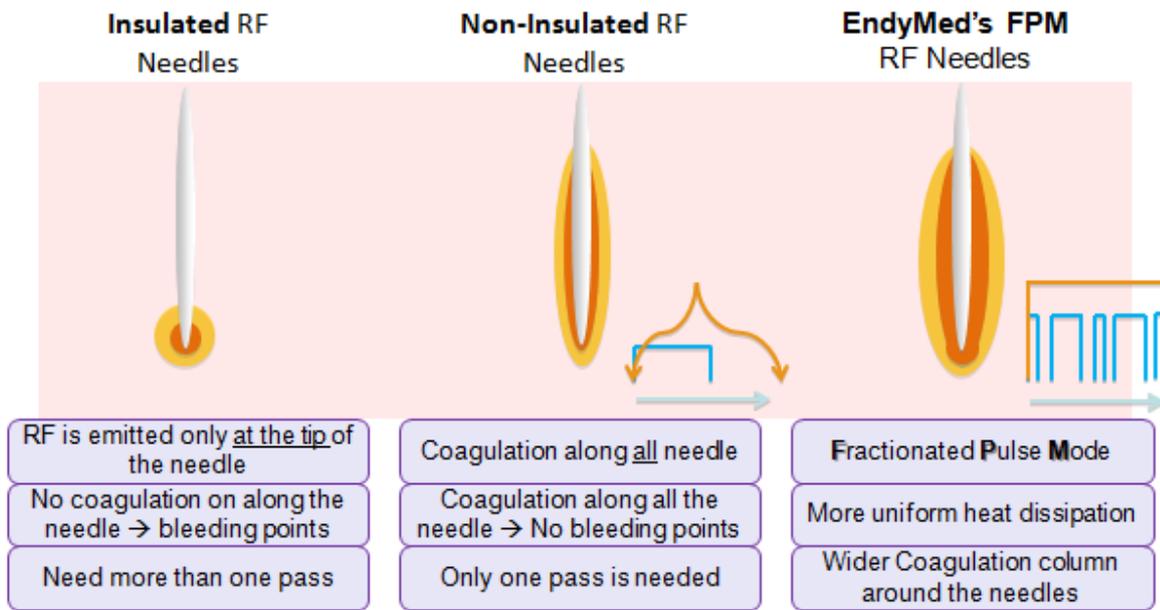


BEFORE

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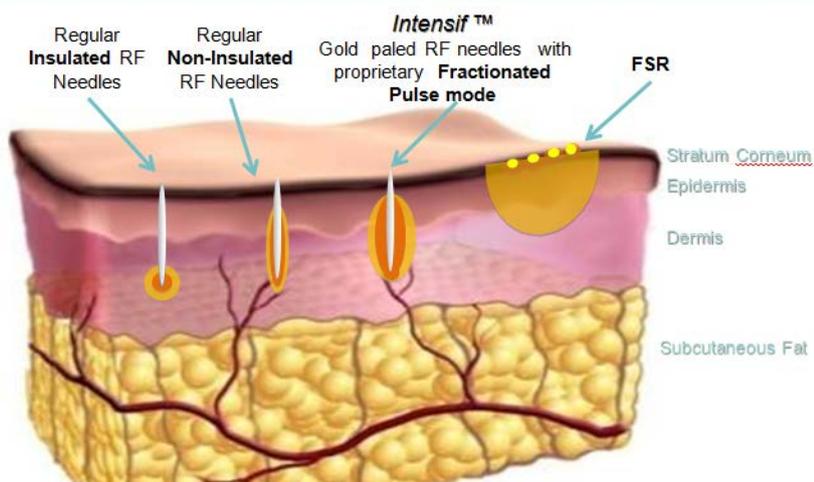
Two main RF emitting methods



The depth of penetration of the needles can be controlled unlike with that of Fractional Carbon dioxide lasers where the depth is dependent on the power. But, an increase in power means more collateral damage.



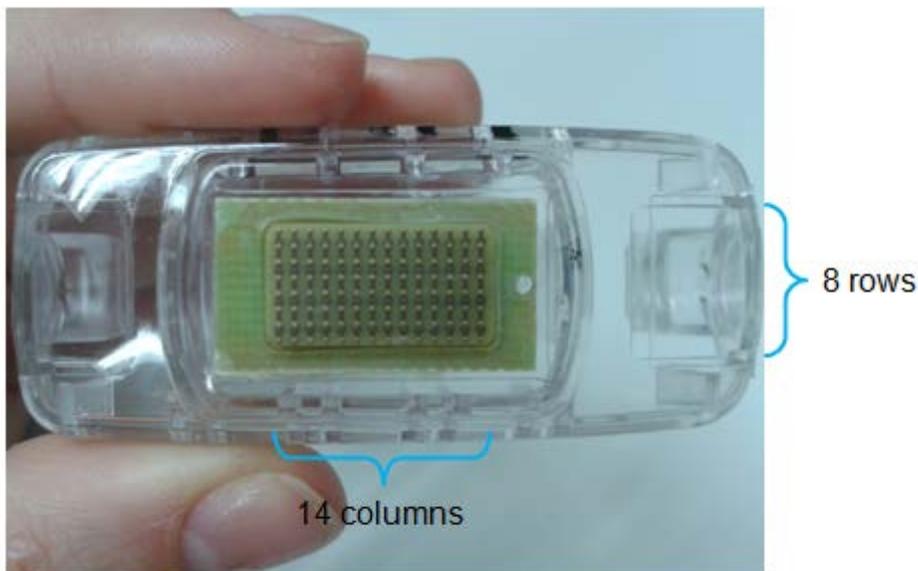
Comparison with other Fractional Technologies



Fractional Skin Resurfacing

For many people today, their major skin appearance concern is that of aging skin. There are a variety of ways to treat aging skin with medical procedures from full laser resurfacing to non-ablative treatments to deep peeling. One treatment that is growing in popularity is fractional skin resurfacing which treats a fraction of the skin's surface so that there are reservoirs of healing tissue left to promote rapid healing and reduce downtime.

The FSR handpiece is used for correction of fine wrinkles and scars, improvement in skin laxity, skin texture correction and pigmentary abnormalities of the skin. The FSR applicator utilizes multisource phase-controlled energy for simultaneous fractional RF microablation & deep dermal heating. The electrode has 112 dots (14 by 8), fractional spots of 300 microns. The technique used is stationary treatment or stamping. Advanced user control of the ratio between microablation on skin surface and deep dermal heating for antiwrinkle effect is possible with the device in a single pulse.



14 columns, 8 rows

The upper skin layers (stratum corneum and epidermis) are best treated with ablation, allowing removal of damaged skin cells for the reduction of skin roughness and hyperpigmentation. The use of fractional ablation to accomplish this effect allows fast recovery with minimal downtime.

FSR vs. Competition on gelatin - top view

Maximum settings for both machines:

FSR : 6W 60msec

Competition : 62 mJ/pin

FSR

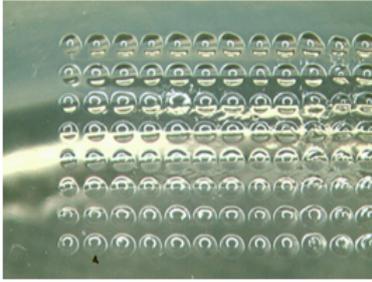


Image taken using microscope, showing 12 out of 14 columns

Gelatin has melted evenly => all electrodes are conducting the same power.

Competition

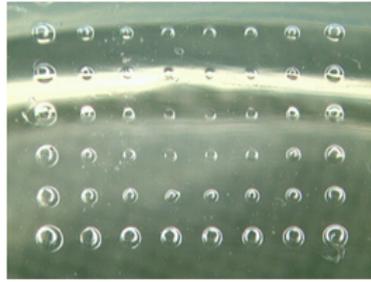


Image taken using microscope, showing bottom 6 out of 8 rows

Gelatin has melted more on the periphery of the tip => more power is conducted on the outside.



In contrast, the deeper skin layer (dermis) is best treated with non ablative deep dermal heating, which leads to collagen remodeling and the reduction of scars and wrinkles. EndyMed's FSR (fractional skin resurfacing) simultaneously performs micro-fractional ablation on the epidermal layer and deep dermal volumetric heating in one pulse.

This results in brighter skin, reduction of epidermal hyper pigmentation, improvement of skin texture, smoothing of wrinkles and treatment of scars. This procedure is minimally invasive with minimal discomfort and minimal downtime.