

SYLFIRM^X

DUAL WAVE RF MICRONEEDLING SYSTEM



SYLFIRM X

ULTIMATE EDITION



**Minimally
Invasive**



**Short
Treatment Time**



**Minimal
Downtime**



**Safe &
Comfortable**



**Immediate
Results**

DUAL WAVE RF MICRO NEEDLING SYSTEM

PULSED WAVE (PW) & CONTINUOUS WAVE (CW)

The world's first & only FDA registered Pulsed Wave (PW) and Continuous Wave (CW) Radio Frequency Micro Needling device featuring 300 Micron depth targeting both skin laxity and pigmentation for ultimate skin rejuvenation. Sylfirm X with its 8 different PW/CW modes has proven its effectiveness and safety through 25+ clinical studies and experiments.

Disclaimer :

SYLFIRM X Ultimate Edition™ is intended for use in dermatology and general surgical procedures for electrocoagulation and hemostasis. (K200185)

BIPOLAR NON-INSULATED ELECTRODE SYSTEM

SYLFIRM X adopted bipolar non-insulated micro needle electrodes to cover all dermal layers with uniform electric field and maximize the treatment result specifically for vascular pigmentation during the Pulsed Wave (PW) modes, and skin revitalization during the Continuous Wave (CW) modes.

300 μ m TREATMENT

SYLFIRM X enables the treatment by targeting the papillary dermis layer by adjusting the needle depth in the range of 0.3 to 4.0 mm. It does not require applying anesthetic cream during the procedure as it is less painful, and it helps patients' quick return to daily life.

As a specialist in researching and developing medical device technologies, Viol, the manufacturer of Sylfirm X, is committing their finest effort to deliver the new solutions in clinical treatment. With Viol's bio-electro technologies and products, we believe our customers can enjoy the beauty of the healthier and richer life.

DESIGN SPECIFICATION

AESTHETIC & INTELLIGENT DESIGN



- **Ergonomic handle**

Comfortable for treatment use

- **Tip base designed to maximize treatment precision**

- **Extended stand length**

Increase ease of use



- **Ease of mobility**



- **Locking wheel mechanism**
- **User-friendly interface**



- **Magnetic foot switch**
- **Signal controller**

SYLFIRM X IS

CLINICALLY PROVEN



The phenomenon as independent electro thermal tissue coagulation around each electrode of bipolar radiofrequency

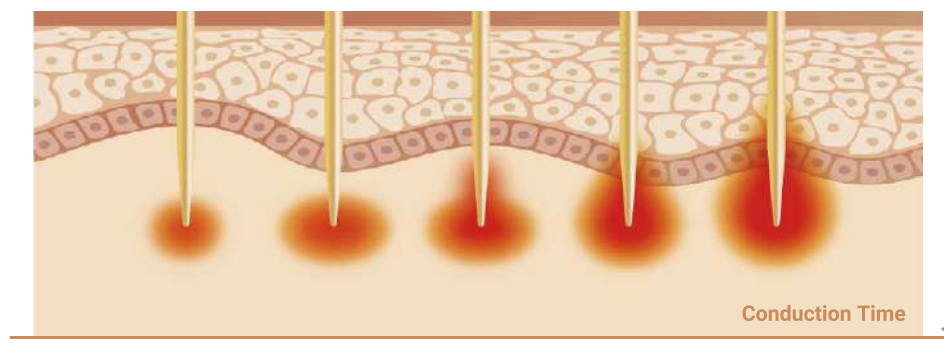


Minimal downtime. Little to no pain.

Na Effect

In 2015, ViOL's founder, Dr. Jung Ju Na, conducted a clinical study to observe the skin response to alternating current bipolar RF energy through non-insulated microneedles.

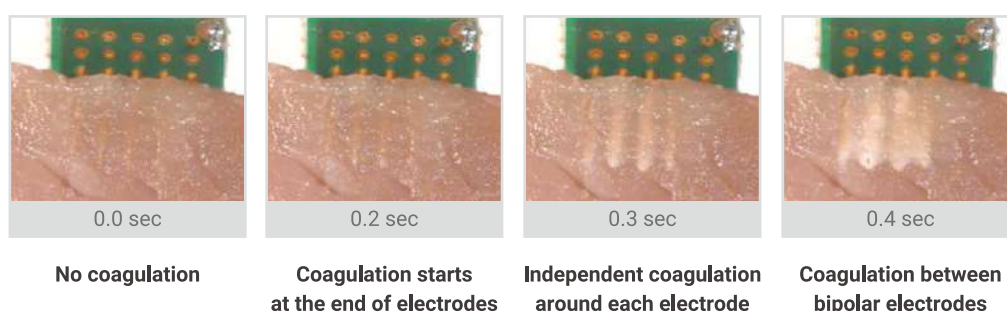
When bipolar RF energy is released through a non-insulated microneedle, tissue coagulation begins at each end of the microneedle electrode, and then forms a droplet or cocoon shape as conduction time increases, showing less thermal effect on the epidermis. This is called the "NA EFFECT".



Complete coagulation in total dermal layer

The primary takeaway of the "Na effect" is that it maximizes the thermal effect on the target with little to no epidermal damage, enabling effective and safe treatment.

< 0.3 sec: Tissue reactions were initiated at the tips of the microneedle electrodes. As the reactions propagated up from the tips of the microneedle electrodes, they expanded to deeper, wider, and higher areas around the microneedle. After a brief delay, the reactions continued to move upward around the body of the microneedle electrode and expand laterally.



Electromagnetic Initiation and Propagation of Bipolar Radiofrequency Tissue Reactions via Invasive Non-Insulated Microneedle Electrodes

Jongju Na, Zhenlong Zheng, Christopher Dannaker, Sang Eun Lee, Jin-Soo Kang & Sung Bin Cho

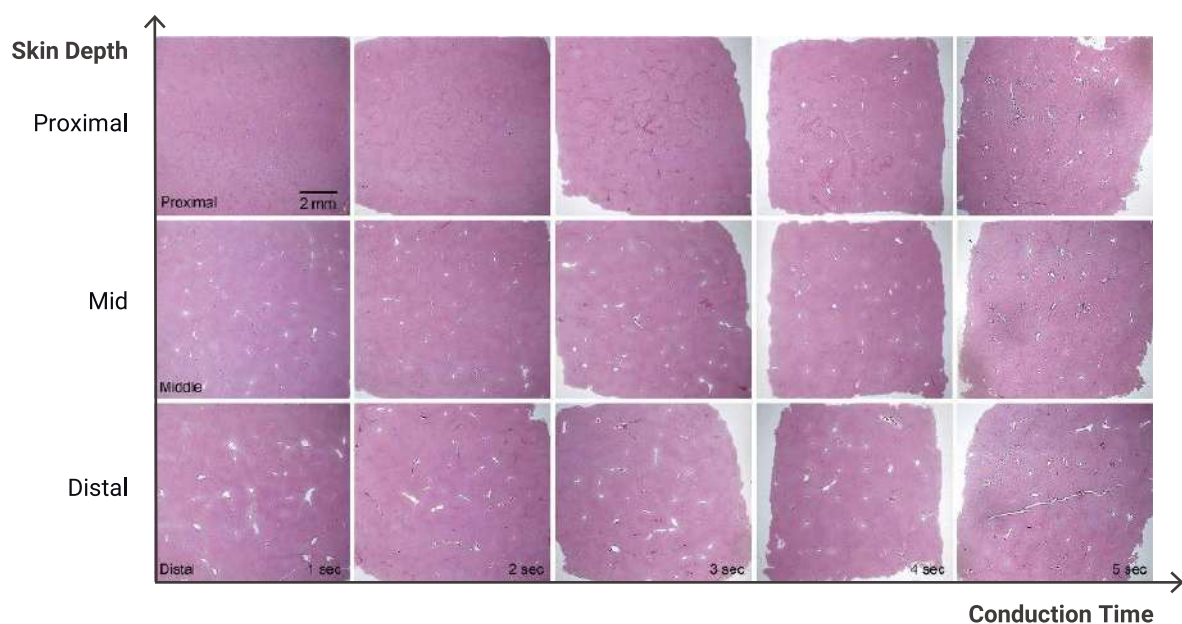
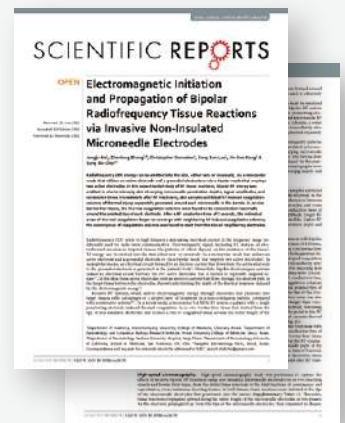
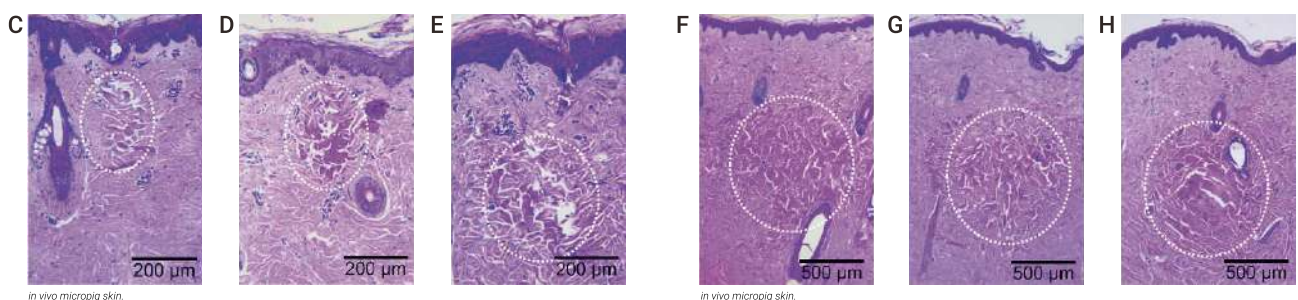


Figure 3. Horizontal sections of the ex vivo bovine liver tissue.

Disposable tips used by the bipolar RF device comprise 25 invasive non-insulated electrodes arranged in a 5 X 5 pattern. (c) Tissue sections of bovine liver were obtained after RF treatment with a penetration depth of 3.0mm a signal amplitude of 36.6V. Remarkable carbonization is observed along the distal ends of penetrating electrodes after 1 second of RF conduction. Along the middle of the electrodes, tissue coagulation is visible at the conduction time of 1 second, and remarkable carbonization seems to develop after 3 seconds. At the proximal ends of the electrodes, distinguishable congestion of vascular structures is observed on the specimens treated over RF conduction times of 2 and 3 seconds. Coagulation along superficial portions of the ex vivo bone liver tissue is found after RF treatment with a conduction time of 4 seconds, while remarkable carbonization appears after the conduction time of 5 seconds. H&E stain.



The longer RF conduction time created a larger area of coagulation in the dermis at the same penetration depth and amplitude of the RF signal; (c)120ms, (d)200ms, (e)300ms.

Higher energy generated more degrees of tissue destruction at the same microneedle penetration depth and RF conduction time; (f)29.5V, (g)32.6V, (h)35.6V.

PW MODE

Pulsed Wave Mode

Vascular Pigmentation

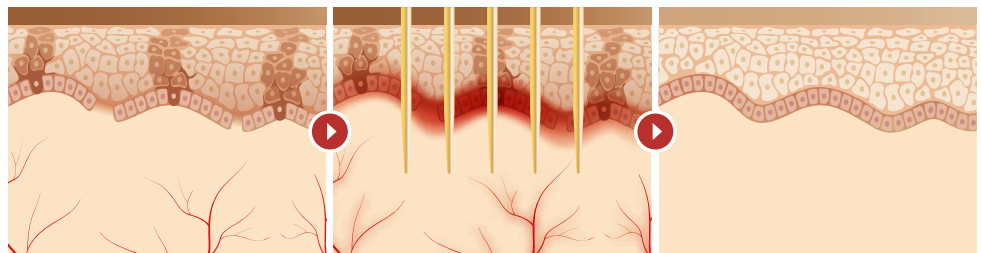


Selective Thermal Effect for Basement Membrane & Blood Vessel

- Pulsed wave irradiates RF energy in the form of multiple pulses.
- It's selectively affected highly conductive tissues such as microvascular components, small blood vessels, or basement membrane with no noticeable effect on surrounding tissue



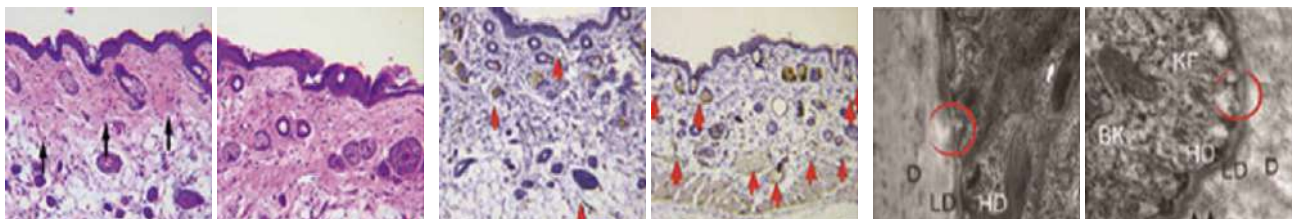
Multiple Short Pulses



Melasma/redness occur due to weakening of basement membrane & increase of abnormal blood vessels

Selectively generate heat to the weakened basement membrane & abnormal blood vessels

By curing the underlying cause, treat melasma/redness as well as improve skin tone



Reference 1 Efficacy of Pulsed Wave Needle RF on Skin

Mode	PW1	PW2	PW3	PW4
Wave Form				
Pulse Duration	30 msec	40 msec	50 msec	60 msec
Application	Melasma, Diffuse redness (Sensitive)	Melasma, Diffuse redness	Telangiectasia	Acne Vulgaris

Reference

- [a] Senescent Fibroblasts Drive Aging Pigmentation: A Potential Therapeutic Target for Senile Lentigo. *Theranostics* 2018, Vol. 8, Issue 17
- [b] Senescent Fibroblasts in Melasma Pathophysiology. *Experimental Dermatology*. 2018;1-4.



CW^{MODE}

Continuous Wave Mode

Skin Rejuvenation

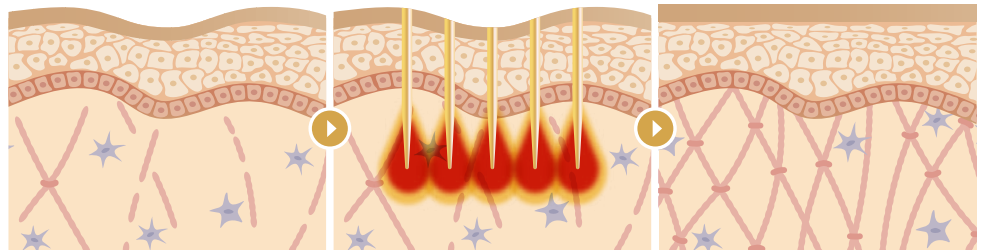


Thermal Coagulation, 'Na effect' for Total Dermal Layer

- CW mode creates wide, independent coagulation around each electrode.
- The coagulation area continues from deeper dermis to upper dermis with one penetration.
- Promising optimal skin rejuvenation, for a firmer, more youthful looking appearance.



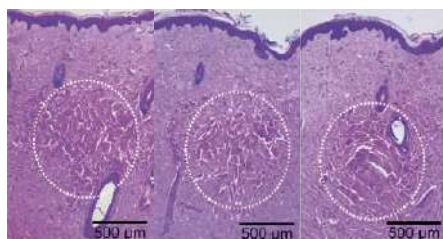
Single Long Pulse



Wrinkled and sagging skin due to aging

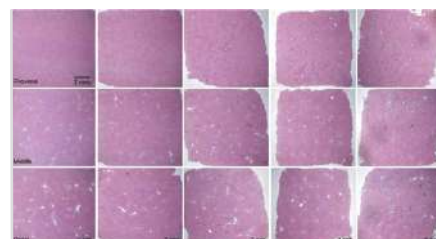
Promotes collagen regeneration by forming hot spots in the skin

Improves skin elasticity by increasing collagen in the skin



Reference 2

Thermal coagulation at the target depth



Reference 2

Safety of non-insulated needle

Mode	CW1	CW2	CW3	CW4
Wave Form				
Pulse Duration	120 msec	160 msec	200 msec	300 msec
Application	Scalp	Face	Body	Scar

Reference

2. [a] Electromagnetic Initiation and Propagation of Bipolar Radio frequency Tissue Reactions via Invasive Non-Insulated. [b] Micro needle Electrodes. Sci Rep. 2015; 5; 16735. [c] Clinical Study of Facial Wrinkle Treatment with Fractional Micro needle Radio Frequency System. Med Laser 2014;3(2):59-64

INDICATIONS

PW MODE

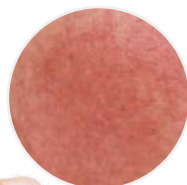
Pulsed Wave Mode

Vascular Pigmentation



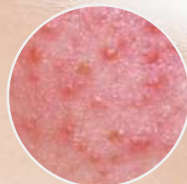
Pigmented Lesions

Melanogenesis factors in 300µm
papillary dermis
Melasma
Post-inflammatory Hyperpigmentation



Vascular Lesions

Diffuse Redness
Rosacea
Telangiectasia



Acne

Before



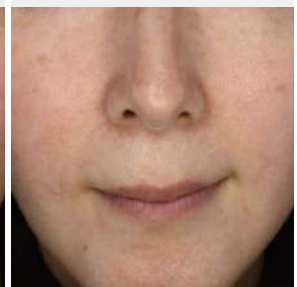
After



Before



After



Before



After



Before



After

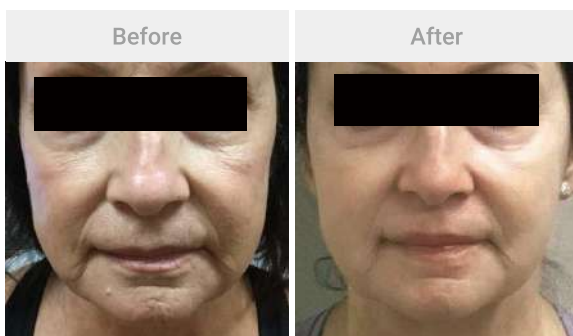
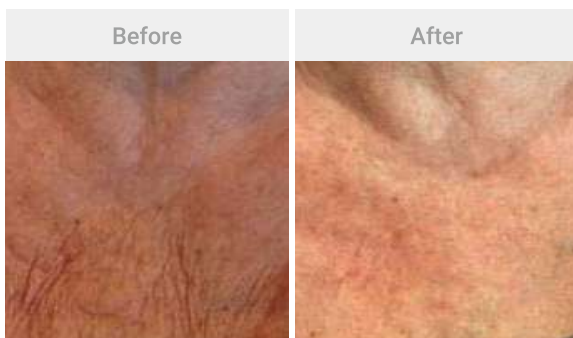


BEFORE & AFTER

CW MODE

Continuous Wave Mode

Skin Rejuvenation



Facial Rejuvenation

Collagen Remodeling in 300 μ m

Papillary Dermis

Enlarged Pores

Wrinkles, Fine Line

Rhytides, Skin Laxity



Scars

Acne Scars

Atrophic Scars

Hypertrophic Scars

Stretch Marks



Body Rejuvenation

Turkey Neck

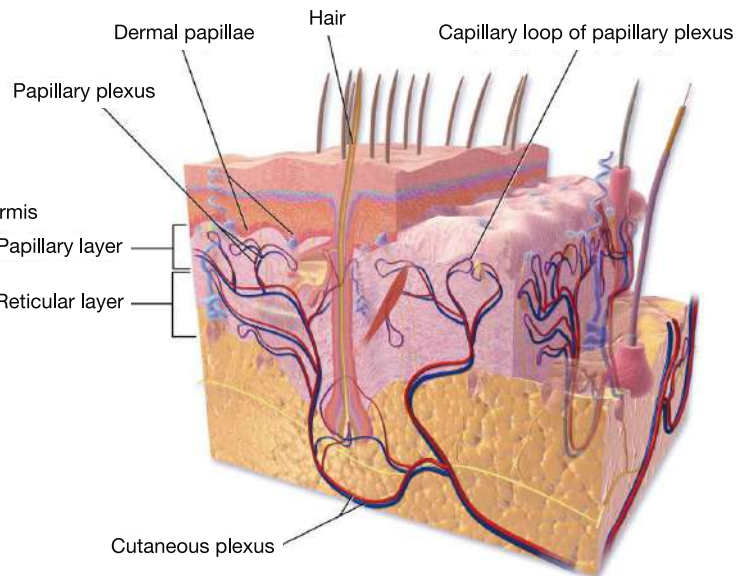
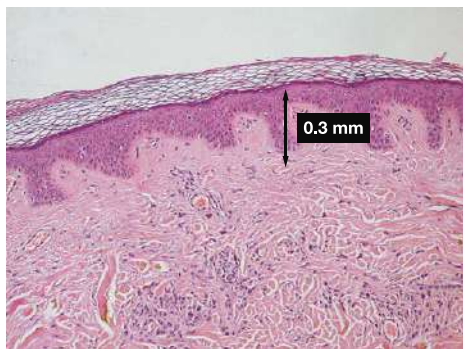
Double Chin

Décolletage

At 300 μ m, Papillary Dermis

Papillary dermis is located just below the basement membrane at a skin depth 300 μ m. It contains factors associated with pigmented lesions, vascular lesions and skin rejuvenation such as senescent fibroblasts, capillaries and blood vessels, and type III collagen. The 300 μ m targeted treatment can effectively treat melasma, diffuse redness, rosacea, uneven skin tone and texture, with less pain and less downtime. [a]

Skin Layer [b]



Reference

[a] Sorrell, J. M. & Caplan, A. I. (2004). Fibroblast heterogeneity: more than skin deep. *Journal of Cell Science*, 117-667-675.

[b] Illustration of Dermal Circulation and Layers by Wikipedia

300 μ m Targeted Treatment With SYLFIRM X

Little to no pain and anesthesia-free treatment

Optimal Skin Rejuvenating Depth

Papillary Dermis contains collagen factors, especially Type III collagen. Compared with older adults, the distribution of Type III collagen in the fetus's skin is higher than that of Type I. Also Type III collagen is present more in papillary dermis than reticular dermis. The density of type III collagen increased after 300 μ m targeted treatment with Sylfirm X.

Regulation of Hyperactive Melanocytes

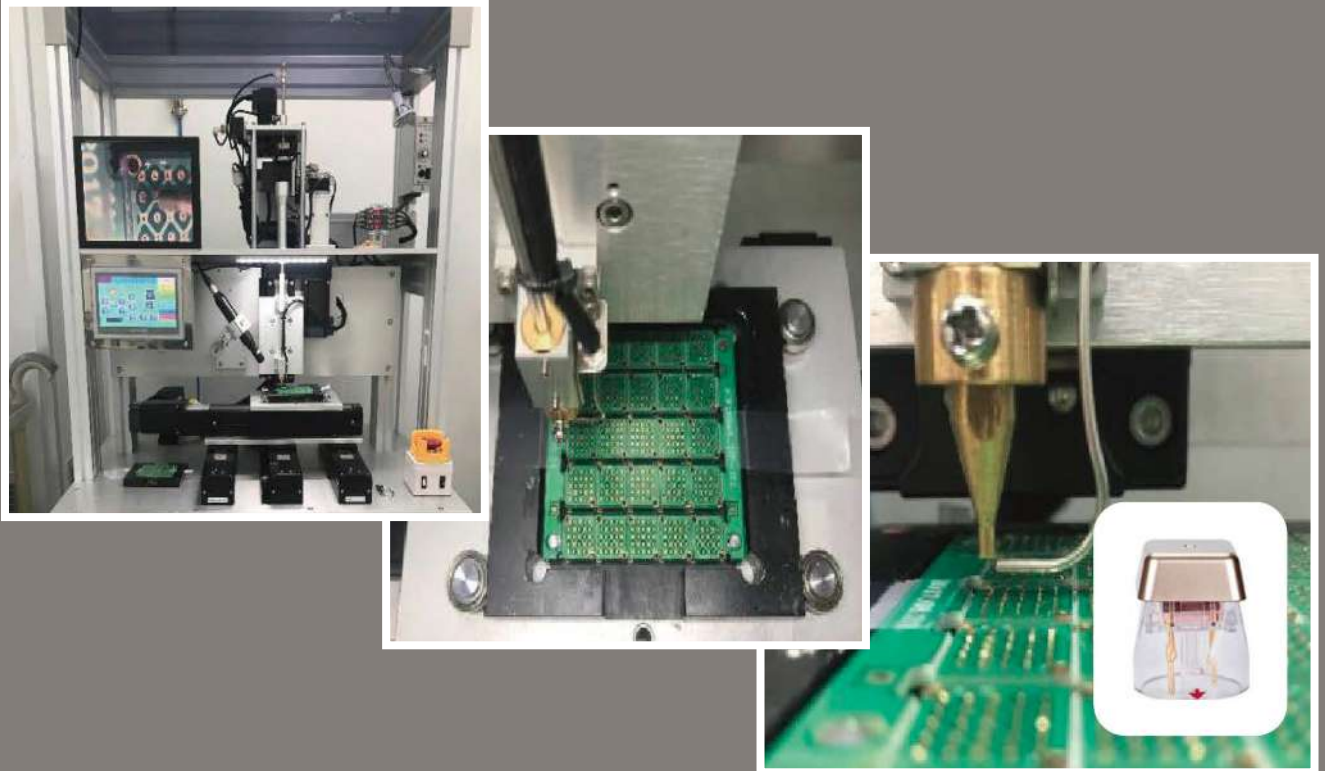
The senescent fibroblasts, which stimulate melanogenesis, are more distributed in the melasma lesion than in the perilesional area, and more in the papillary dermis than in the reticular dermis. 300 μ m targeted treatment helps to repair senescent fibroblasts, which promote melanin production, and strengthens the basement membrane to improve melasma.

Anesthesia-Free Treatment

- 300 μ m targeted treatment minimizes nerve contact to reduce pain and it enables the treatment without anesthetic cream
- 10 minutes of treatment time (takes 30-40 minutes if applying anesthetic cream)
- Allow patients' quick return to daily life with its short downtime

Elaborately Manufactured Needle Tip

The micro needles are precisely produced by the robotic system, which brings evenly-leveled electrodes to penetrate an accurate target depth during the treatment.



SYLFIRM X Consumable Tip

- New tips provide increased visibility and tip-to-skin contact during treatment.
- Non-insulated electrodes with 'Na Effect' deliver maximum effect with less pain and downtime.



THE #1 MOST REQUESTED TREATMENT TO DATE

SYLFIRM^X



Improves Vascular
Pigmentation



Improves Skin
Texture & Tone



Minimizes
Appearance of Scars



Improves
Skin Laxity



Improves
Skin Rejuvenation

FAQs

How does the microneedling treatment work?

The treatment uses microneedling bipolar RF technology to coagulate dermal collagen and elastin fiber in skin. Electrocoagulation helps to rejuvenate existing dermal fibers and produce new collagen and elastin fibers, which improves skin tightening and texture of skin.

What is Na effect?

Na effect was first published in Scientific Reports, a journal of the Nature Publishing Group by Dr. Jongju Na. He named this discovery the “Na effect” . Na effect is the key method for the safest and most effective RF treatment. The distinguishing factor of this phenomenon is the achievement of independent tissue coagulation around each micro-needle electrode. The proven science behind the Na effect is what allows the Sylfirm X to deliver state-of-the-art care and healing for people of all skin types and issues.

How many treatments are required?

The treatment delivers results in a single treatment for most patients with little to no downtime. The treatment is very comfortable and attractive to patients. More treatments give more results. We recommend 3~6 treatments during a year to maximize skin rejuvenation.

How long does a treatment take?

The treatment takes about 20 minutes for the face and 10 minutes for the neck. The time needed for a body treatment depends on the size and condition of the area to be treated. The treatment is both time-efficient and revolutionarily effective.

Is there any special preparation or follow-up regimen?

No. The treatment doesn't need any special preparation or follow-up regimen. Basic skin care and sunscreen is enough for aftercare. Since the procedure has little to no downtime, most patients return to their regular activities immediately following treatment. Rosacea patients exhibit a temporary redness or minor swelling after treatment, but this usually goes away within 24 to 72 hours. Microneedle treatment is the safest treatment in the field of RF systems, with little to no down time and no side effects. Clients are good to go immediately after treatment; there is no bleeding or sensitivity as experienced with other microneedle treatments.



THE #1 MOST REQUESTED TREATMENT TO DATE

FEATURED ON

BUSINESS INSIDER

THE AESTHETIC GUIDE

YAHOO! FINANCE



How is the microneedling treatment for different skin types?

Unlike LASER treatments, microneedling treatment is safe and works on all skin types: I, II, III, IV, V and VI. The treatment coagulates total dermal layers to rejuvenate total skin without any pigmentation (P.I.H.). Our technology is based on electric signals, which doesn't affect skin color.

What does microneedling treatment treat?

Microneedling treatment targets scalp skin tightening, face skin tightening and lifting, double chin, neck and body skin tightening. Recently, Short pulse Radio Frequency technology of the treatment was clinically proven to improve rosacea, acne, vulgaris, melasma, and mottled telangiectasia. It is very safe and no rebounded with lower recurrence. And needless to say, the treatment improves common issues such as skin texture, pores, photo-aging, scars, and striae.

How does the treatment deliver energy into the skin?

The treatment uses minimally invasive microneedle electrode technology, which coagulates the dermis directly with precisely controlled RF energy and varying treatment depth. Treatment depth, power, and mode are adjustable by the user. This procedure delivers the most direct and accurate energy into the skin without any thermal damage on the skin surface.

More information is on <http://www.nature.com/articles/srep16735>.

When do the results appear, and how long do they last?

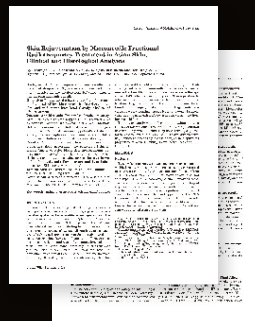
Visible tightening results come immediately, and the results of dermal remodeling appear over time in the course of new collagen, elastin fibers regeneration and vascular rejuvenation. For most patients, measurable results appear gradually in 2 to 3 months. The results can last 6 months to a year following a single treatment, depending on your skin condition and aging process.

How does it feel?

Most patients report experiencing little to no pain. For example, the Sylfirm X delivers energy to the skin in a time interval of less than 300 milliseconds (0.3 sec). It is the shortest heating time among all RF devices. The microneedle electrodes are extremely thin and work with gentle pressure and slow speed technology, developed through numerous clinical trials. Microneedling treatment presents patients with maximum results and maximum comfort.

PROVEN BY

25+ CLINICAL PAPERS



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info@scarletrf.com / www.viol.co.kr



SYLFIRM^X

ULTIMATE EDITION

Amico Yasna Pars (Pr.J.S.Co)



Tel: +9821-71137000

Fax: +9821-71137300

2nd Floor, No. 1698, Shariati Ave., Tehran, Iran Postal Code:1914744755

www.aypmedical.com info@aypmedical.com