EXPORT ONLY

# SYLFIRMX

## DUAL WAVE RF MICRONEEDLING SYSTEM

FDA CE

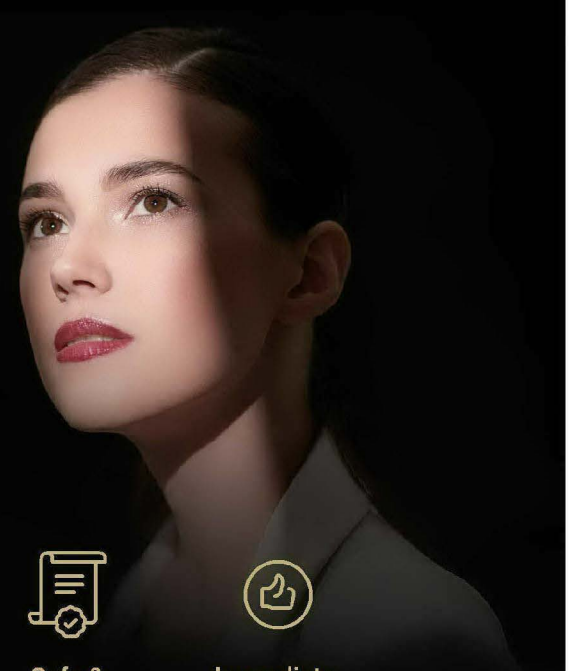




Serendia, LLC
Exhibit 2037
Jeisys v. Serendia
IPR2024-00386
Ex. 2037-001

# SYLFIRM X

ULTIMATE EDITION



**Minimally Invasive** | **Short Treatment Time** | **Minimal Downtime** | **Safe & Comfortable** | **Immediate Results**

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## 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)*

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## 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.

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## 300 µm 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.

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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

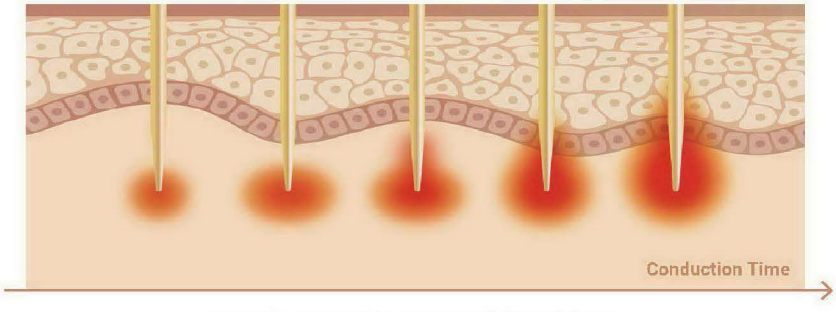
*The phenomenon as independent electro thermal tissue coagulation around each electrode of bipolar radiofrequency*

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.

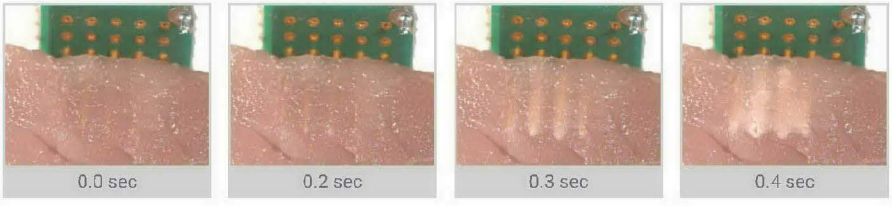
When bipolar RF energy is released through a non-insulated microneedle, tissue coagulation begins at each end of the microneedle electrode, and then forms a droplet or cocoon shape as conduction time increases, showing less thermal effect on the epidermis. This is called the "NA EFFECT".




**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.

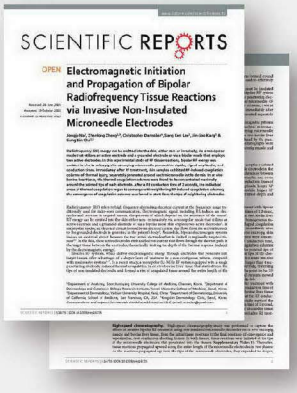



**No coagulation** | **Coagulation starts at the end of electrodes** | **Independent coagulation around each electrode** | **Coagulation between bipolar electrodes**

SCIENTIFIC REPORTS

# 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



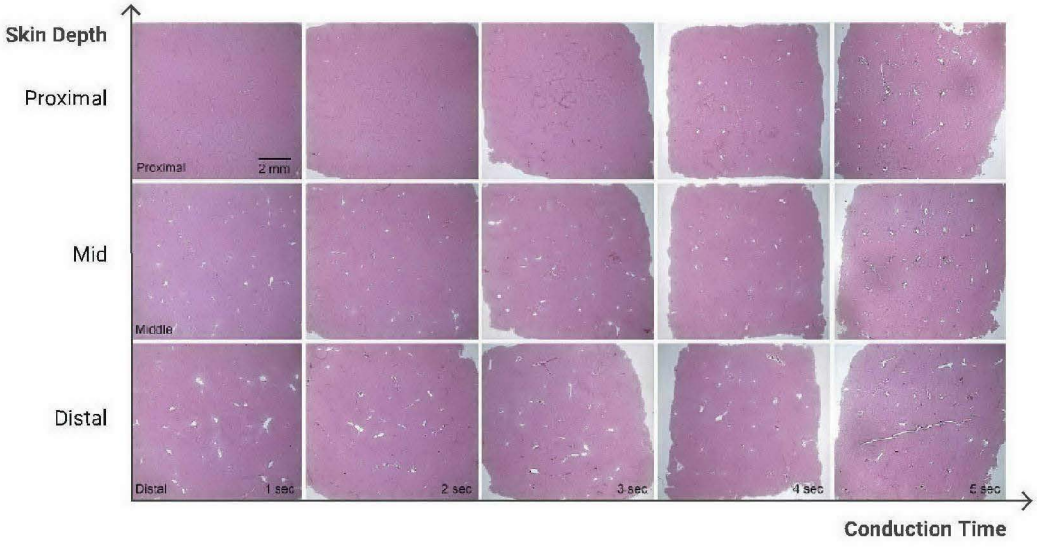
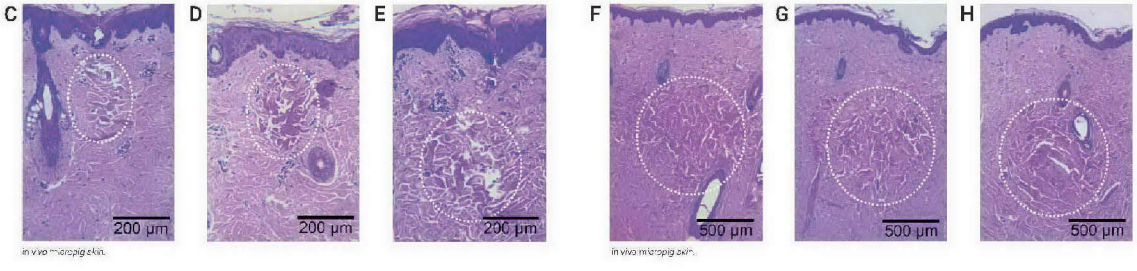
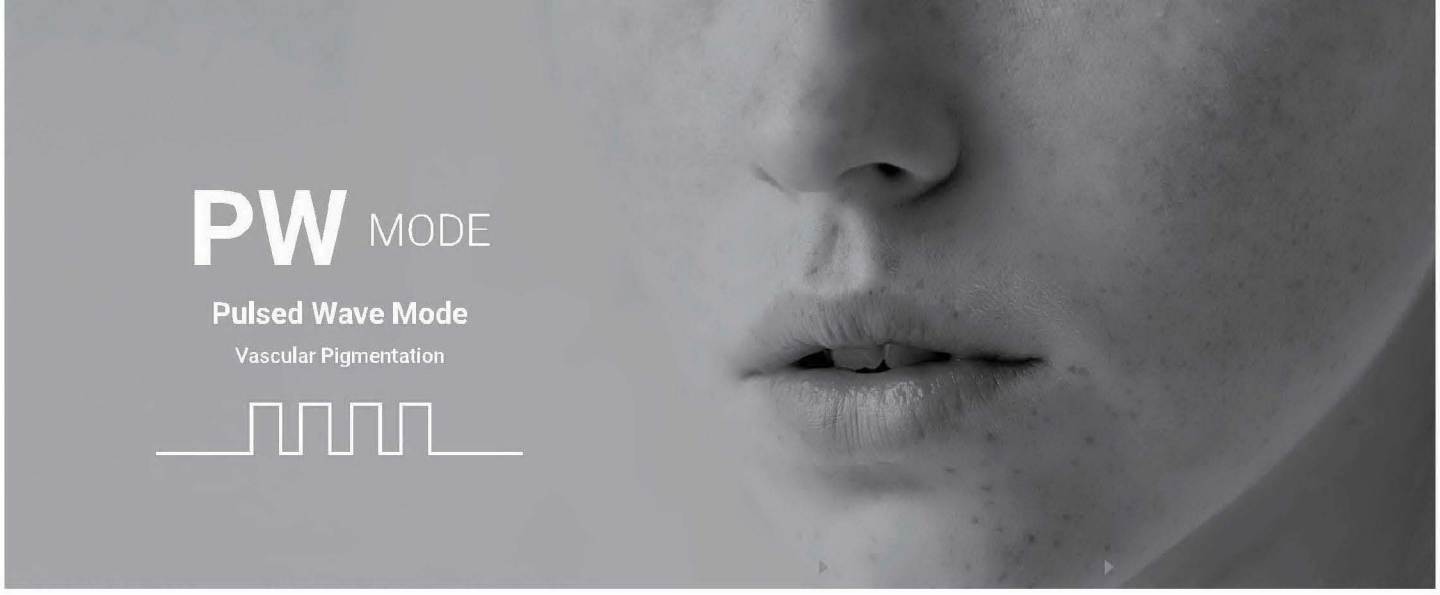



**Figure 3. Horizontal sections of the ex vivo bovine liver tissue.**
Disposable tips used by the bipolar RF device comprise 25 invasive non-insulated electrodes arranged in a 5 X 5 pattern. (c) Tissue sections of bovine liver were obtained after RF treatment with a penetration depth of 3.0mm a signal 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.



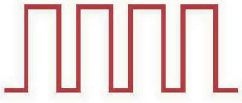

The longer RF conduction time created a larger area of coagulation in the dermis at the same penetration depth and amplitude of the RF signal, (c)120ms, (d)200ms, (e)300ms.

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.

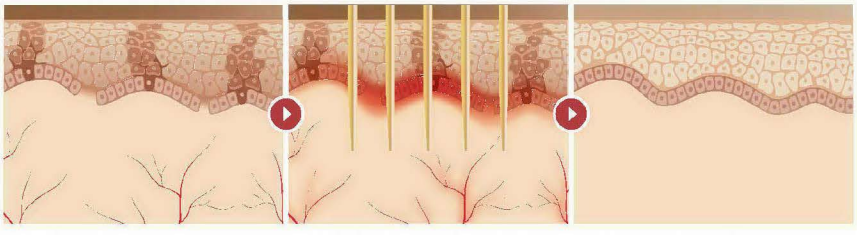



## Selective Thermal Effect for Basement Membrane & Blood Vessel

- 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 surroundig tissue



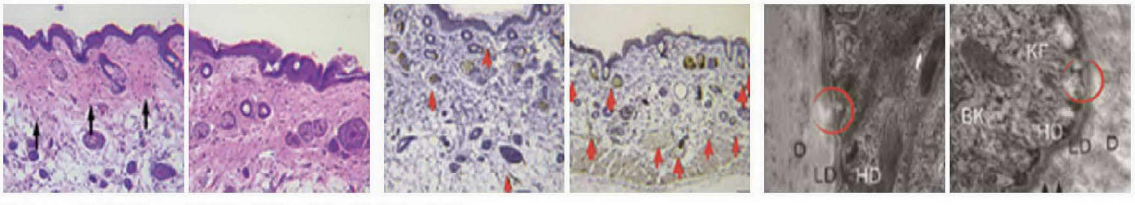
**Multiple Short Pulses**



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**

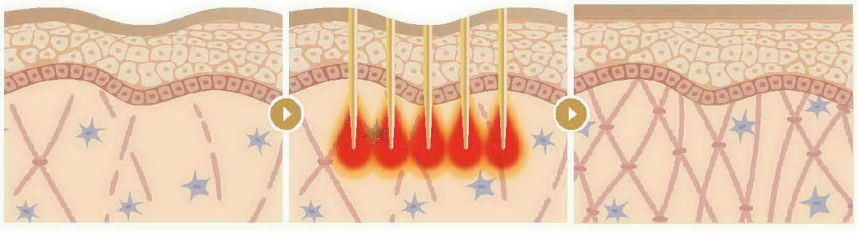
| Mode | PW1 | PW2 | PW3 | PW4 |
|---|---|---|---|---|
| Wave Form | | | | |
| Pulse Duration | 30 msec | 40 msec | 50 msec | 60 msec |
| Application | Melasma, Diffuse redness (Sensitive) | Melasma, Diffuse redness | Telangiectasia | Acne Vulgaris |

Reference
1. [a] Senescent Fibroblasts Drive Aging Pigmentation: A Potential Therapeutic Target for Senile Lentigo. Theranostics 2018, Vol. 8, Issue 7
[b] Senescent Fibroblasts in Melasma Pathophysiology. Experimental Dermatology. 2018; –4.

## 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.

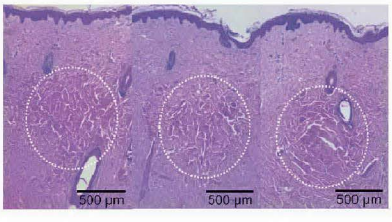
Single Long Pulse



Wrinkled and sagging skin due to aging

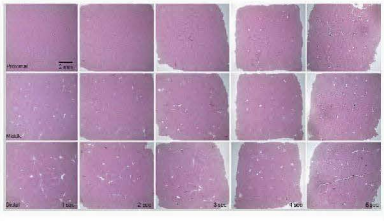
Promotes collagen regeneration by forming hot spots in the skin

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

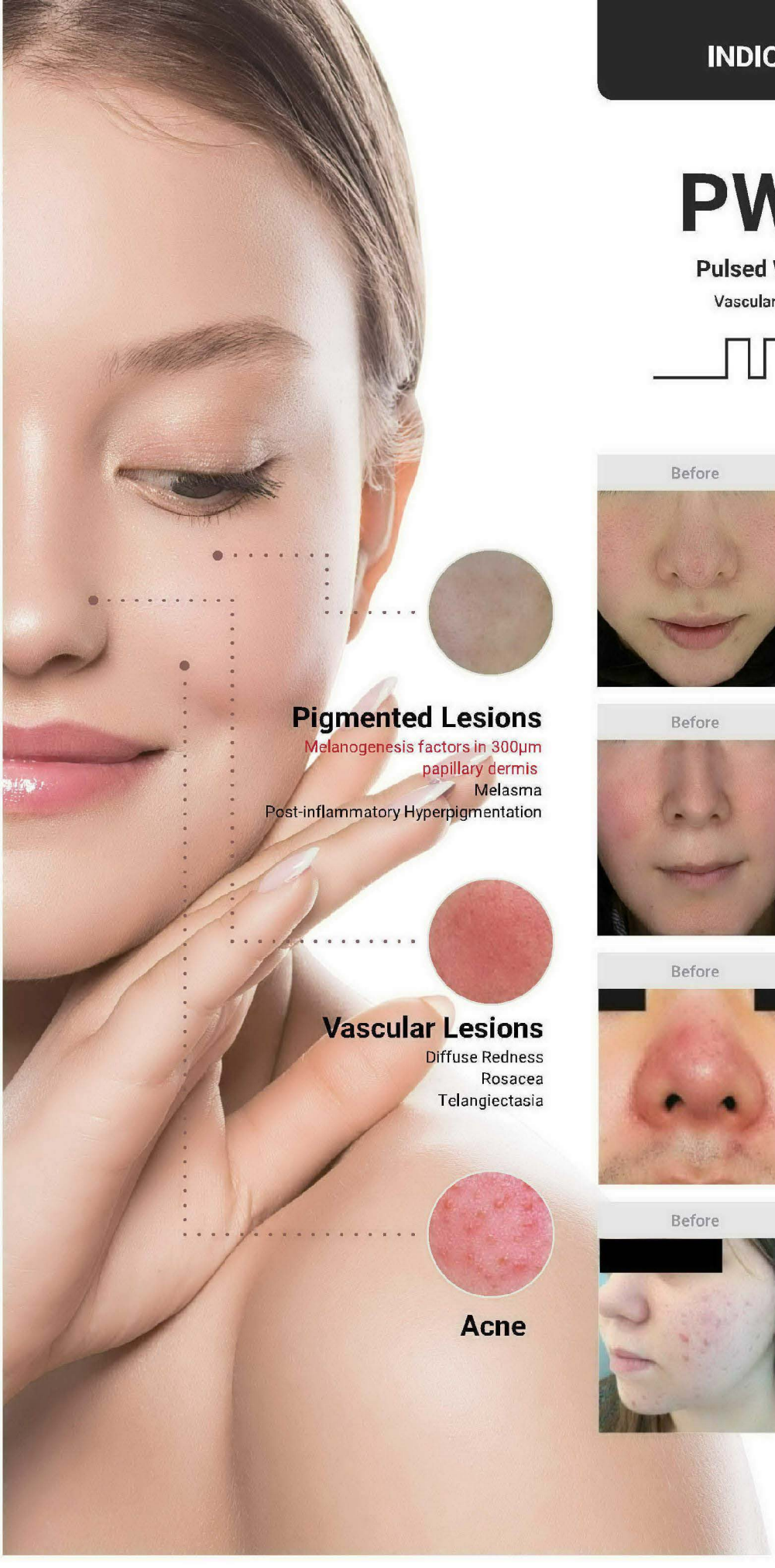
2. [a] Electromagnetic Initiation and Propagation of Bipolar Radio frequency Tissue Reactions via Invasive Non-Insulated. [b] Micro needle Electrodes. Sci Rep. 2015; 5; 16735. [c] Clinical Study of Facial Wrinkle Treatment with Fractional Micro needle Radio Frequency System. Med Laser 2014;3(2):59-64

## INDICATIONS

# PW MODE

**Pulsed Wave Mode**

Vascular Pigmentation



### Pigmented Lesions

Melanogenesis factors in 300μm papillary dermis

Melasma

Post-inflammatory Hyperpigmentation

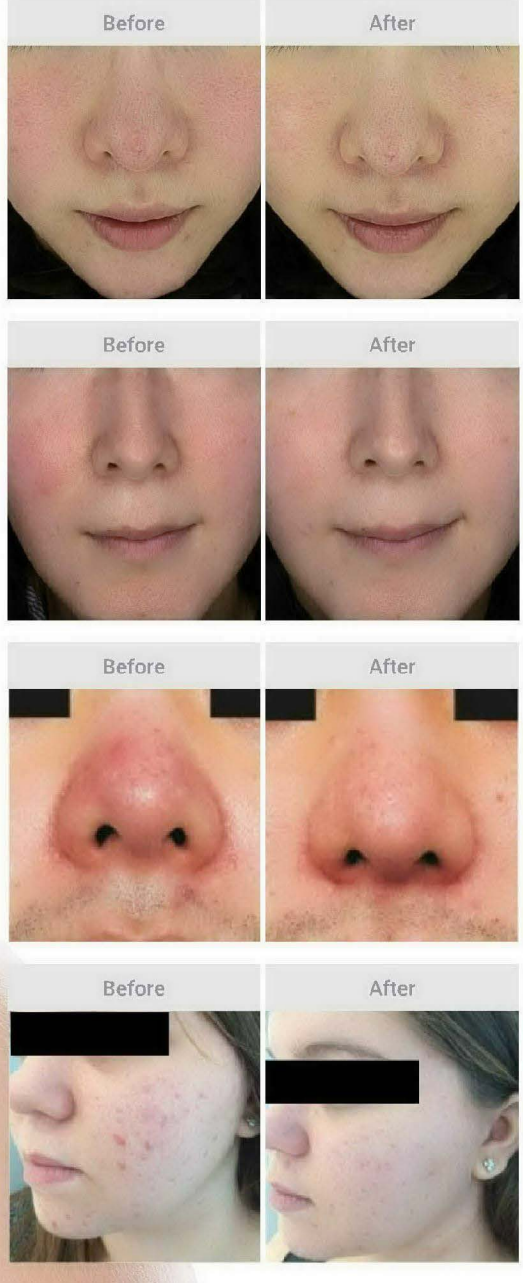
### Vascular Lesions

Diffuse Redness

Rosacea

Telangiectasia

### Acne



## BEFORE & AFTER

# CW MODE

**Continuous Wave Mode**

Skin Rejuvenation

### Facial Rejuvenation

Collagen Remodeling in 300μm
Papillary Dermis
Enlarged Pores
Wrinkles, Fine Line
Rhytides, Skin Laxity

### Scars

Acne Scars
Atrophic Scars
Hypertrophic Scars
Stretch Marks

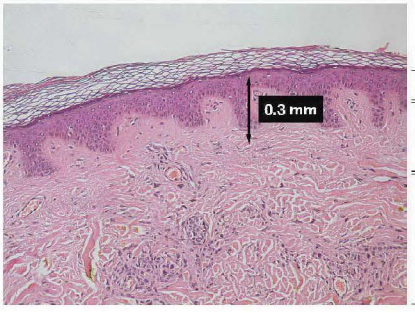
### Body Rejuvenation

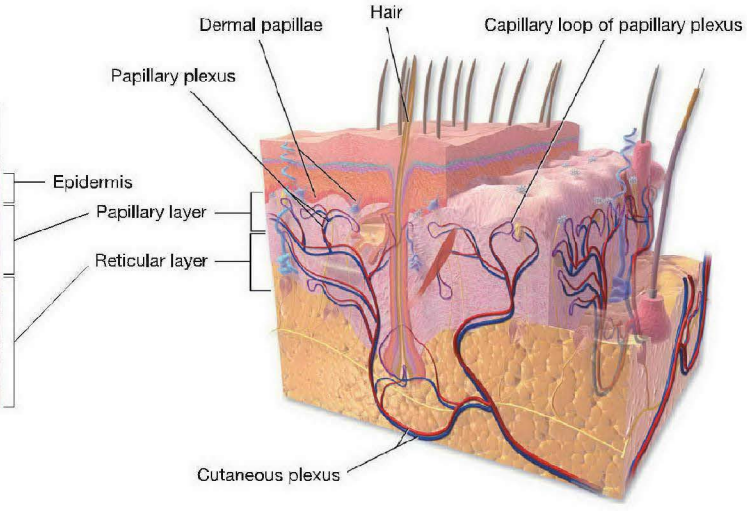
Turkey Neck
Double Chin
Décolletage

## At 300 μm, Papillary Dermis

Papillary dermis is located just below the basement membrane at a skin depth 300 μm. 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 μm targeted treatment can effectively treat melasma, diffuse redness, rosacea, uneven skin t one 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 μm Targeted Treatment With SYLFIRM X

Little to no pain and anesthesia-free treatment

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### 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 incresed after 300μm targeted treatment with Sylfirm X.

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### 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 μm targeted treatment helps to repair senescent fibroblasts, which promote melanin production, and strengthens the basement membrane to improve melasma.

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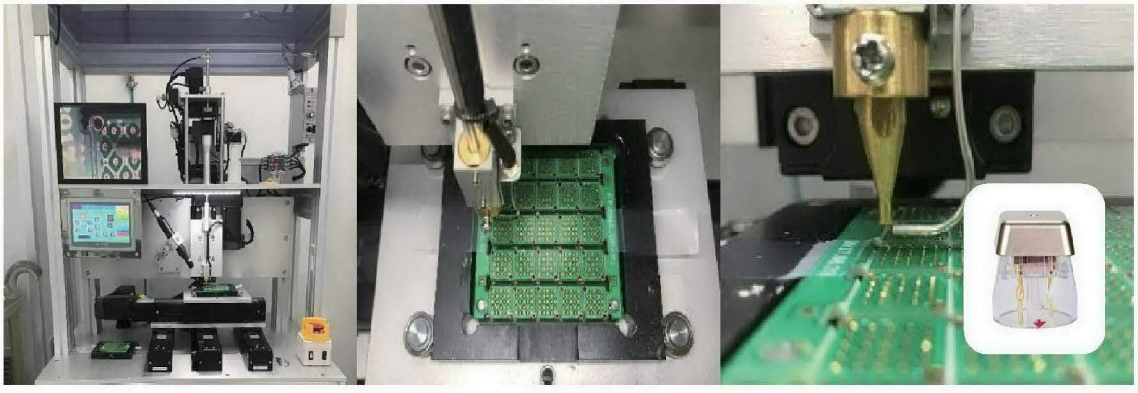
### Anesthesia-Free Treatment

- 300μm 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

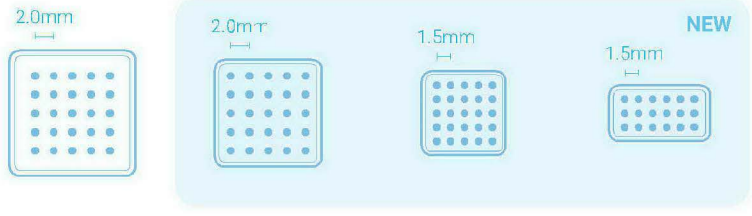
## Elaborately Manufactured Needle Tip

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 Tips

- 4 different tip options to choose from for specific treatment.
- 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.




| X-25 TIP | XE-25 TIP | XA-25 TIP | XW-18 TIP |
|---|---|---|---|
| 5*5(25pin) | 5*5(25pin) | 5*5(25pin) | 3*6(18pin) |

| Full Face | Full Face<br>Peri-orbital<br>Philtrum | Acne Vulgaris<br>Acne Scar<br>Scar<br>Syringoma | Stretch Mark<br>Deep Wrinkle<br>Deep Scar<br>Eye Bag |
|---|---|---|---|

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.

1 TREATMENT

## 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?**

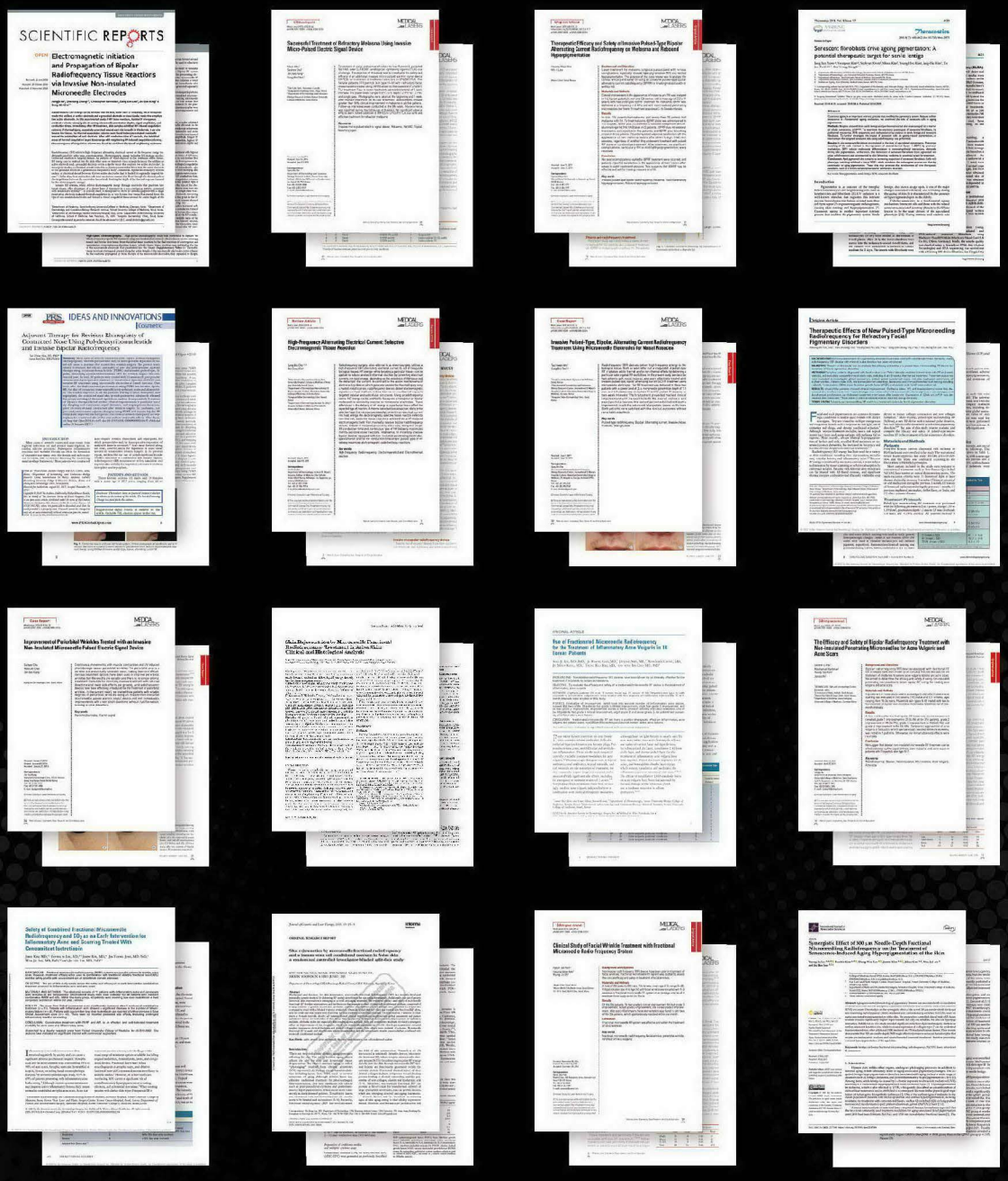
Visible tightening results come immediately, and the results of dermal remodeling appear over time in the course of new collagen, elastin fibers regenesis and vascular rejuvenation. For most patients, measurable results appear gradually in 2 to 3 months. The results can last 6 months to a year following 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



If you would like to have further information on the above published articles of Sylfirm X, please contact via email or visit our website presented.

**scarletsales@scarletrf.com / www.violmedical.com**

## Clinical articles based on Viol's RF microneedling technology

- Na Effect_2015_Electromagnetic Initiation and Propagation of Bipolar Radiofrequency Tissue Reactions via Invasive Non-Insulated Microneedle Electrodes
- PW_Pigmented Lesion_2015_Successful Treatment of Refractory Melasma Using Invasive Micro-Pulsed Electric Signal Device.
- PW_Pigmented Lesion_2017_Periorbital melamsa - Hierarchical cluster analysis of clinical features in Asian patients
- PW_Pigmented Lesion_2017_Therapeutic Efficacy and Safety of Invasice Pulsed-Type Bipolar Alternating Current Radiofrequency on Melasma and Rebound Hyperpigmentation
- PW_Pigmented Lesion_2018_Senescent fibroblasts drive ageing pigmentation A potential therapeutic target for senile lentigo
- PW_Pigmented Lesion_2018_Senescent fibroblasts in melasma pathophysiology
- PW_Pigmented Lesion_2022_Therapeutic effects of new pulsed-type microneedling radiofrequency for refractory facial pigmentary disorders
- PW_Rejuvenation_2016_Improvement of Periorbital Wrinkles Treated with an Invasive
- PW_Scar_2018_Adjuvant Therapy for Revision Rhinoplasty of Contracted Nose Using Polydeoxyribonucleotide and Invasive Bipolar Radiofrequency
- PW_Skin Reaction_2016_High-Frequency Alternating Electrical Current Selective
- PW_Skin Reaction_2018_In vivo skin reactions from pulsed-type, bipolar, alternating current radiofrequency treatment using invasive noninsulated electroces.
- PW_Vascular Lesion_2021_Therapeutic effects of a new invasive pulsed type bipolar radiofrequency for facial erythema associated with acne vulgaris and rosacea
- PW_Vascular_Lesion_2017_Invasive Pulsed-Type, Bipolar, Alternating Current Radiofrequency Treatment Using Microneedle Electrodes for Nasal Rosacea
- 300 Micron_2021_Synergistic effect of 300um needle-depth fractional microneedling radiofrequency on the treatment of senescence-induced aging hyperpigmentation of the skin
- CW_Acne_2012_Use of Fractionated Microneedle Radiofrequency for the Treatment of Inflammatory Acne Vulgaris in 18 Korean Patients
- CW_Acne_2015_The Efficacy and Safety of Bipolar Radiofrequency Treatment with Non-Insulated Penetrating Microneedles For Acne Vulgaris And Acne Scars
- CW_Acne_2020_Safety of Combined Fractional Microneedle Radiofrequency and CO2 as an Early Intervention for Inflammatory Acne and Scarring Treated with Concomitant Isotretinoin
- CW_Rejuvenation_2012_Skin Rejuvenation by Microneedle Fractional Radiofrequency Treatment in Asian Skin - Clinical and Histological Analysis
- CW_Rejuvenation_2013_Skin rejuvenation by micronnedle fractional radiofrequency and a human stem cell conditioned medium in Asian skin
- CW_Rejuvenation_2014_Clinical Study of Facial Wrinkle Treatment with Fractional Microneedle Radio Frequency System

WEBSITE

FACEBOOK

INSTAGRAM

# SYLFIRM X

ULTIMATE EDITION

Victory of Life
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