# Profound®

Single treatment RF microneedling for facial wrinkles

eBook

CANDELA™

Science. Results. Trust.

AESTHETIC EVERYTHING Awards

Dear reader,

On behalf of Candela Corporation, we would like to say thank you for your interest in the Profound® system, our device to create younger looking skin by creating collagen, elastin and hyaluronic acid. In this eBook, we provide you with the most important information regarding this device, from technology overview to some of the results clinical experts worldwide have achieved with their patients.

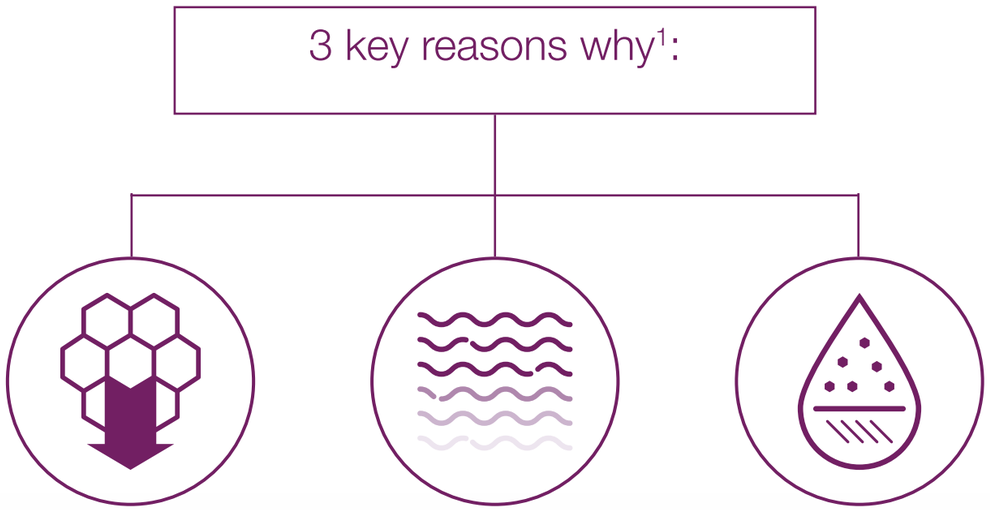
Know that when you decide to work with one or more of our devices, we'll do everything we can to provide you with the highest level of customer service possible.

That's our promise to you.

Candela Marketing Team

# What can you treat?

## As we age, skin loses its elasticity.




Many people notice signs of ageing when skin loses its elasticity and begins to sag around the face, jawline and neck. Intrinsic ageing, also known as the natural ageing process, is a continuous process that normally begins in our mid-20s. Lifestyle, diet, personal habits and sun exposure often act together with the normal ageing process to prematurely age our skin. Other external factors that prematurely age our skin are repetitive facial expressions, gravity, sleeping positions, and smoking.

**1.** Hantash BM, Ubeid AA, Chang H, Kafi R, Renton B. Bipolar fractional radiofrequency treatment induces neoelastogenesis and neocollagenesis. Lasers Surg Med. 2009;41(1):1-9.



Science. Results. Trust. Science.

# Profound treatments: a non-surgical alternative:

The Profound system provides a non-surgical alternative to address ageing skin. Using radiofrequency (RF) injectable energy, it provides lasting facial wrinkle reduction in just one non-surgical treatment.[1-4]

**Non-surgical RF-devices:**

- **Enhance filler results**
- **Are less invasive and painful**
- **Help extend surgical results**
- **Offer an alternative to the use of toxins and fillers**
- **Ensure more manageable downtime**

**1.** Willey A, Kilmer S, Newman J, et al. Elastometry and clinical results after bipolar radiofrequency treatment of skin. Dermatol Surg. 2010;36(6):877-884.
**2.** Profound 510(k) clearance (K161043), September 2016.
**3.** Alexiades-Armenakas M, Newman J, Willey A, et al. Prospective multicenter clinical trial of a minimally invasive temperature-controlled bipolar fractional radiofrequency system for rhytid and laxity treatment. Dermatol Surg. 2013;39(2):263-273.
**4.** Alexiades M, Berube D. Randomized, blinded, 3-arm clinical trial assessing optimal temperature and duration for treatment with minimally invasive fractional radiofrequency. Dermatol Surg. 2015;41(5):623-632.

# Mechanism of Action

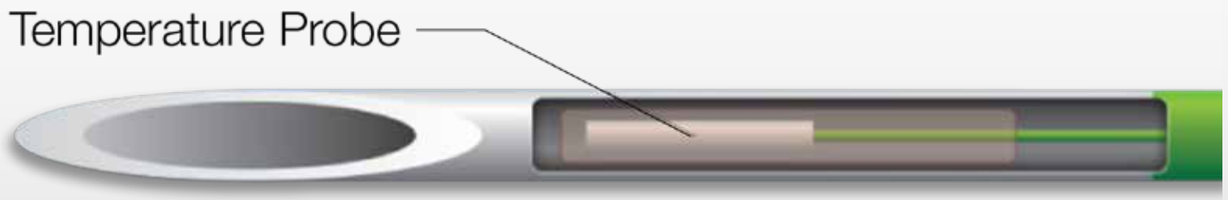
**ONE** treatment **only**

**100%** response rate[1]

Elastin, collagen and hyaluronic acid[3, 4]

The technology implemented in the Profound device has been carefully selected and designed to consistently and predictably meet the procedural endpoint – creating fractional injuries within the optimal narrow time temperature window, to produce partially denatured collagen, essential for creating profound neoelastogenesis. This engineering achievement has resulted in a device, which delivers unprecedented, consistent and predictable clinical success following a single treatment. Physicians can, therefore, predict positive results with high confidence during patient consultations in their practices.

The Profound system is the first device with temperature controlled radiofrequency clinically and scientifically proven to deliver energy directly to the deep dermis to stimulate neo-elastogenesis, neocollagenesis and hyaluronic acid deposition. The Profound device delivers fractional RF energy to the subcutaneous layer enabling treatment of both adipose tissue and the septae as well. The Profound treatment is a fully comprehensive treatment addressing both the Dermal & SubQ layers. Confidently expand your practice offerings with this single treatment procedure with a 100% response rate for facial wrinkles[1,2].




Science. Results. Trust. Science.

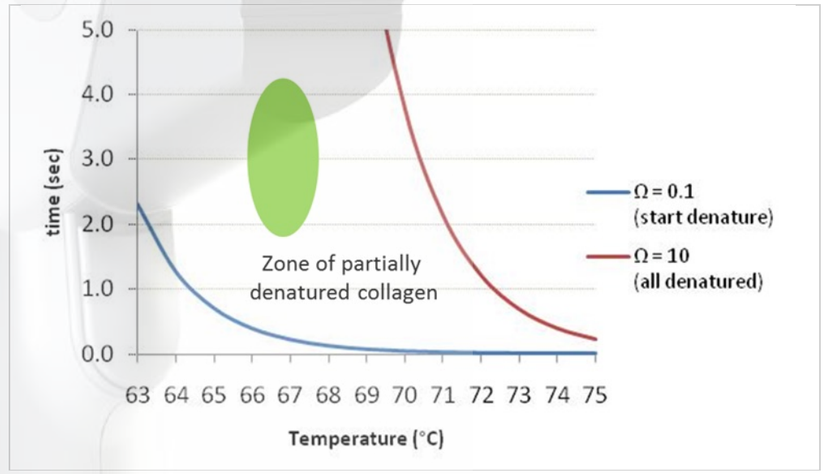
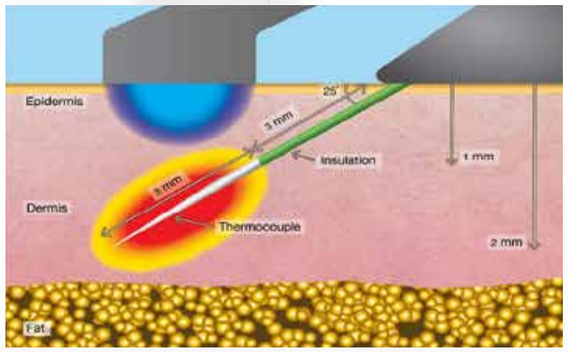
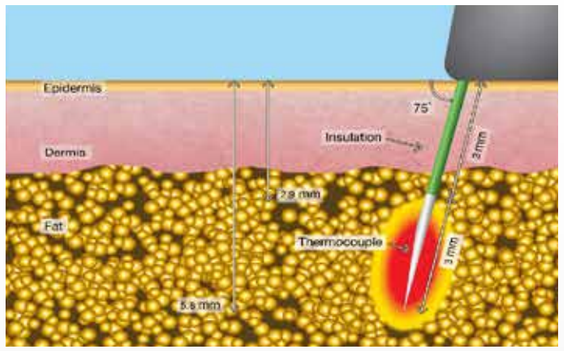



Figure 1 -Thermal dose for collagen. The blue curve indicates the dose necessary to start collagen denaturation, while the red curve indicates when the denaturation precess is fully completed.



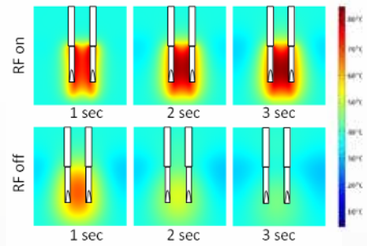

**1.** Alexiades-Armenakas M, Newman J, Willey A, et al. Prospective multicenter clinical trial of a minimally invasive temperature-controlled bipolar fractional radiofrequency system for rhytid and laxity treatment. Dermatol Surg. 2013;39(2):263-273.
**2.** Data on file. Individual results may vary.
**3.** Hantash BM, Ubeid AA, Chang H, Kafi R, Renton B. Bipolar fractional radiofrequency treatment induces neoelastogenesis and neocollagenesis. Lasers Surg Med. 2009;41(1):1-9.
**4.** Profound 510(k) clearance (K161043), September 2016.

## THE PROFOUND SYSTEM TREATS

- Both dermal & adipose tissues
- Wrinkles

## ADVANTAGES OF THE PROFOUND SYSTEM

- Just one non-surgical treatment required to achieve lasting results[2,4,5,6]
- Ergonomic, single-button handpieces to treat multiple locations
- 100% response rate for facial wrinkles[5,7]
- The only real-time, temperature-controlled, fractional RF microneedling device[4]
- Proven in 8 comprehensive clinical studies[10]




**1.** Hantash BM, Ubeid AA, Chang H, Kafi R, Renton B. Bipolar fractional radiofrequency treatment induces neoelastogenesis and neocollagenesis. Lasers Surg Med. 2009;41(1):1-9.
**2.** Willey A, Kilmer S, Newman J, et al. Elastometry and clinical results after bipolar radiofrequency treatment of skin. Dermatol Surg. 2010;36(6):877-884.
**3.** Howard D. Structural changes associated with ageing skin. The International Dermal Institute website. Available at: http://www.dermalinstitute.com/us/library/11_article_ Structural_Changes_AssociatAs_with_Ageing_Skin.html.
**4.** Profound 510(k) clearance (K161043), September 2016.
**5.** Alexiades-Armenakas M, Newman J, Willey A, et al. Prospective multicenter clinical trial of a minimally invasive temperature-controlled bipolar fractional radiofrequency system for rhytid and laxity treatment. Dermatol Surg. 2013;39(2):263-273.
**6.** Alexiades M, Berube D. Randomized, blinded, 3-arm clinical trial assessing optimal temperature and duration for treatment with minimally invasive fractional radiofrequency. Dermatol Surg. 2015;41(5):623-632.
**7.** Data on file. Individual results may vary.
**8.** Rate for independent thigh assessment. Patients with Fitzpatrick skin types I-III were assessed for improvement in dimples and undulation irregularities. The mean pain level reported was 3.74 on a 10-point scale. Anticipated treatment responses such as erythema and edema were reported and were completely resolved without medical intervention.4
**9.** Alexiades M, Munavalli G, Goldberg D, Berube D. Prospective multicenter clinical trial of a temperature-controlled subcutaneous microneedle fractional bipolar radiofrequency system for the treatment of cellulite. Dermatol Surg. 2018;1-10. doi: 10.1097. Candela, data on file.
**10.** Berube D. How Profound effectively treats cellulite via collagenesis and elastogenesis. 2016. Candela, data on file.



Science. Results. Trust.

Results.

# Results | Wrinkle Reduction

Baseline | After 2 months / 1 treatment

Photos courtesy of Stephen Eubanks, M.D.

Photos are unretouched. Non-study patient treated with the Profound system; individual results may vary.

Baseline | After 3 months / 1 treatment

Photos courtesy of Ben Talei, M.D.

Photos are unretouched. Non-study patient treated with the Profound system; individual results may vary.

Baseline | After 3 months

Photos courtesy of Suzanne Kilmer, MD; Andrea Willey, M.D.

Photos are unretouched. Non-study patient treated with the Profound system; individual results may vary.

# Results | Wrinkle Reduction

Baseline

5 months post treatment

Photos courtesy of David de Jongh, M.D.

Photos are unretouched. Non-study patient treated with the Profound system; individual results may vary.

Baseline

After 3 months / 1 treatment

Photos courtesy of Ben Talei, M.D.

Photos are unretouched. Non-study patient treated with the Profound system; individual results may vary.

Baseline

After 5 months

Photos courtesy of Stefan Eubanks, M.D.

Photos are unretouched. Non-study patient treated with the Profound system; individual results may vary.





# Results | Skin Improvement

Baseline

After 1 treatment

Photos courtesy of Virginia Beniítez Roig, M.D.

Photos are unretouched. Non-study patient treated with the Profound system; individual results may vary.

Baseline

3 months post treatment

Photos courtesy of Peter Capizzi, M.D.

Photos are unretouched. Non-study patient treated with the Profound system; individual results may vary.

Baseline

After 5 months

Photos courtesy of Kevin Keller, M.D. Upstate Plastic Surgery

Photos are unretouched. Non-study patient treated with the Profound system; individual results may vary.

# Results | Skin Improvement

Baseline

After 1 treatment

Photos courtesy of Ben Talei, M.D.

Photos are unretouched. Non-study patient treated with the Profound system; individual results may vary.

Baseline

After 1 month / 1 treatment

Photos courtesy of Julene Samuels, M.D.

Photos are unretouched. Non-study patient treated with the Profound system; individual results may vary.

Baseline

After 6 months / 1 treatment

Photos courtesy of Macrene Alexiadies, M.D.

Photos are unretouched. Non-study patient treated with the Profound system; individual results may vary.





# Don't take our word. Take it from our customers.

"The Profound system takes us to the next level. We deliver the RF energy directly to the reticular dermis, which is the target. We also have real-time feedback of target tissue temperature and delivered energy, so we can control how much energy we deliver, as well as achieve and maintain a therapeutic temperature level exactly where the energy is supposed to go."

**Macrene Alexiades-Armenakas, MD, Ph.D**
*New Haven, CT, USA*

"In my practice, the Profound system is our preferred and most successful treatment for skin volumizing and lifting of the face. An additional benefit of the Profound treatment is the overall improvement in skin quality, and a noticeably greater elasticity of the skin."

**Leyda Bowes, MD**
*Dermatologist, Miami, Florida*

The Profound system causes very precise dermal injuries that arouse an anabolic wound healing response which stimulates the growth of collagen and elastin in a way that we've not seen before. We are consistently able to create younger, more elastic skin.

**Andrea Willey, MD**
*Laser and Skin Surgery Center of Northern California, Sacramento*

We all know that the key to maximising results is the ability to maximise the delivery of adequate treatment energy to achieve the desired effect. It's easy for us to tell how much energy we're using, but how do we know if it is being delivered to the target, and if it is enough to help us achieve the desired result? The Profound system answers these questions, so users can rely on more than reasonable expectations.

**James Newman, MD**
*Facial Plastic Surgeon, Medical Director,*
*Premier Plastic Surgery Palo Alto and San Mateo, California*

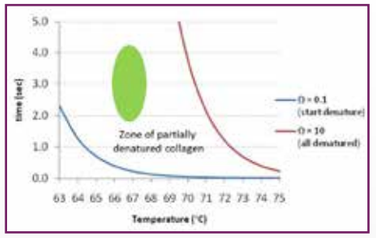




# Peer-reviewed Articles

Prospective Multicenter Clinical Trial of a Minimally Invasive Temperature-Controlled Bipolar Fractional Radiofrequency System for Rhytid and Laxity Treatment.

*- Alexiades-Armenakas M, et al. Dermatol Surg. 2013;39(2):263-73.*




100%

Response rate with average of 26% improvement in wrinkles (Fitzpatrick Wrinkle Scale).

Randomized, blinded, 3-arm clinical trial assessing optimal temperature and duration for treatment with minimally invasive fractional radiofrequency.

*- Alexiades M, Berube D. Dermatol Surg. 2015 May;41(5):623-32.*

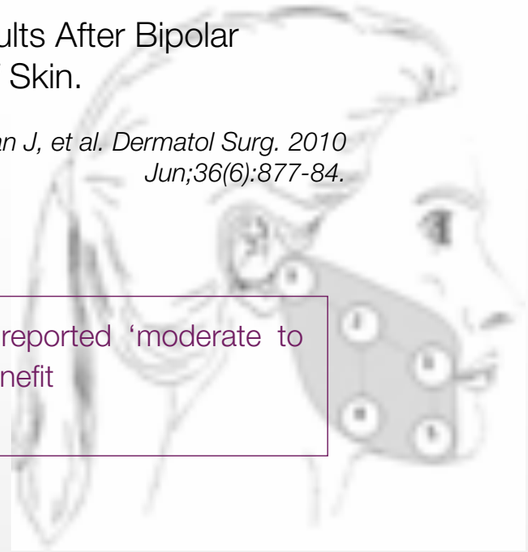
**TABLE 1. Treatment Settings**

| | Target Temperature (°C) | Duration (sec) |
|---|---|---|
| Arm 1 | 52–57 | 3 |
| Arm 2 | 62 | 3 |
| Arm 3 | 67 | 3 |

"Improvement along neckline/jawline."

Elastometry and Clinical Results After Bipolar Radiofrequency Treatment of Skin.

*- Willey A, Kilmer S, Newman J, et al. Dermatol Surg. 2010 Jun;36(6):877-84.*



96% Of patients reported ‘moderate to dramatic’ benefit

Bipolar fractional radiofrequency treatment induces neoelastogenesis and neocollagenesis.

*- Hantash BM, et al. Lasers Surg Med. 2009;41(1):1-9.*

“Reticular dermal volume, cellularity, hyaluronic acid, and elastin content increased.”

Blinded, Randomized, Quantitative Grading Comparison of Minimally Invasive, Fractional Radiofrequency and Surgical Face-lift to Treat Skin Laxity.

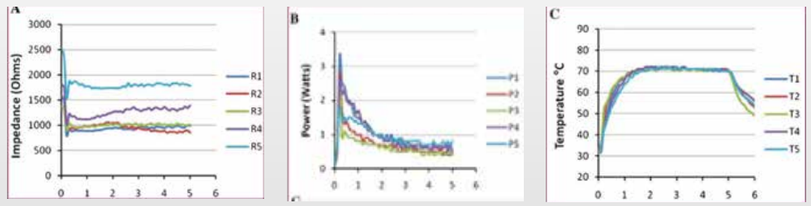
*- Alexiades-Armenakas M, et al. Arch Dermatol. 2010 Apr;146(4):396-405.*

“Average laxity improvement was 37% of surgical face-lift.”

96% of the power was deposited in the dermis without spreading to nearby skin layers.

A predictive model of minimally invasive bipolar fractional radiofrequency skin treatment.

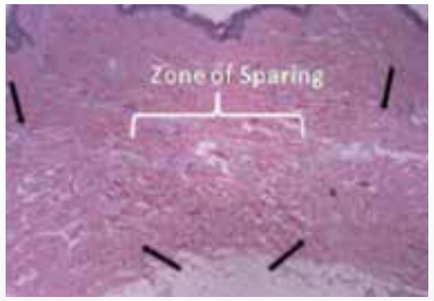
*Berube D, Renton B, Hantash BM. Lasers Surg Med. 2009;41(7):473-8.*



Pilot clinical study of a novel minimally invasive bipolar microneedle radiofrequency device.

*- Hantash BM, et al. Lasers Surg Med. 2009;41(2):87-95.*

| Study-No.: | 2 |
|---|---|
| Number of subjects | 15 |
| Treated areas | 3x preauricular 12x abdomen |
| Treatment temperature | 60-80°C. |
| Treatment time | 1-25 seconds |
| Histolog. Examination after | 10 weeks |




"Histology showed zones of denatured collagen within the reticular dermis with sparing of adnexal structures and adipose tissue."





# Main conclusions from peer-reviews:

- Real-time temperature-controlled FRF (fractional radiofrequency) is a highly reproducible treatment with 100% response rate
- Treatment results in formation of elastic fibers (neoelastogenesis) & collagen fibers (neocollagenesis)
- Reliable, non-surgical treatment option for facial wrinkles
- High satisfaction rate
- Minimal & transient side effects

# AWARDS

**“2019 Aesthetic Everything Awards”**

**“Top Medical Device Company”**

**“Top Aesthetics Company”**

**“Top Aesthetics RF & Skin Care Company”**

by Aesthetic Awards





# System Specifications

| | |
|---|---|
| Bi-polar Radio Frequency | 5 ± 460 kHz |
| Maximum Output Voltage | 84 VRMS; 5W per channel |
| Dermal Handpiece | 5 independent pairs of bi-polar micro-needles |
| SubQ Handpiece | 7 independent pairs of bi-polar micro-needles |
| Mode | PID temperature control |
| Target Temperature Range | 65-75°C (149 – 167°F) ± 1°C |
| Treatment Duration | 3-5 seconds, 0.2 second increments |
| User Interface | GUI – color touch screen |
| System Dimensions | 125 x 46.5 x 44.5 centimeters<br>29.5 x 18.5 x 17.5 inches |
| System Weight | 23 kg / 55 lbs |
| Electrical Requirements | 100 – 240 VAC; 2.5 A; 50-60 Hz; single phase |

CANDELA™

Science. Results. Trust.

www.candelamedical.com

**Disclaimer:** All contents of this material are for informational purposes only and provided by Candela without warranties of any kind. Healthcare professionals are solely responsible for making their own independent evaluation as to the suitability of any product for any particular purpose and in accordance with country specific regulations. The availability of products and the indications mentioned in this material is subject to the regulatory requirements and product registration status in each country. Refer to the User Manual for country specific indications. Products and technical specifications may change without notice. Please contact Candela for more details.



CE 0344