

# FAQs

## Clinical background

### 1. **What is the underlying mechanism behind the improvement in cellulite appearance?**

One of the common reasons for cellulite appearance on the skin is related to fragile collagen fibers and reduction in their amount. When this weakening of collagen structure is added to increased volume of fat cells, the fat cells bulge out and create those famous dimples on the skin surface. Following treatment with (MP)<sup>2</sup>, an improvement in the appearance of cellulite may be achieved due to remodeling of collagen fibers, increase in the number of collagen fibers and reduction in the volume of fat cells.

### 2. **What is the mechanism of action of (MP)<sup>2</sup>?**

(MP)<sup>2</sup> is a synergistic combination of 2 components: radiofrequency (RF) and pulsed magnetic field (PEMF). RF works via a thermal mechanism—it creates a micro-damage in the dermis and triggers the natural healing mechanism of the skin. The result of this process is the synthesis of new collagen and elastic fibers. In addition, the generated heat causes collagen fibers to contract, and increases the reaction rate of lipolysis. PEMF works via a non-thermal mechanism. It induces electrical changes in the dermis that through a complex process of signal transduction, are translated into cellular and molecular processes. The result of this signal transduction is the increase in collagen synthesis by fibroblasts, the proliferation of fibroblasts and the formation of new blood vessels.

### 3. **What is the effect of (MP)<sup>2</sup> on fat cells?**

The fat cells are located in the hypodermis, about 8mm beneath skin surface. The penetration depth of up to 2.75cm of the OctiPolar enables it to reach the fat cells and induce biological activity.

The fat in the fat cells is stored as triglycerides. These triglycerides can undergo enzymatic breakdown into free fatty acids and glycerol—a process that is called lipolysis. During treatment with (MP)<sup>2</sup>, the temperature of the skin is elevated and stress hormones are released into the blood stream. The enzyme that is responsible for lipolysis is hormone sensitive, and the presence of stress hormones increases the reaction rate of this process. As a result, free fatty acids are released into the blood stream and the volume of the fat cell is reduced.

4. **Does (MP)<sup>2</sup> have any effect on the water content of the cell?**

No, the water content is not affected.

5. **How effective is the magnet pulse component of the (MP)<sup>2</sup> and what scientific evidence is there to support it?**

It is well documented that magnetic pulse has a positive effect on wound and bone healing, creation of new small blood vessels (angiogenesis) and collagen production. These clinical effects have been evident in many clinical trials. Furthermore, this non-invasive therapy was approved by the FDA as a safe and effective technology for medical use. The (MP)<sup>2</sup> uses this technology to dramatically improve skin appearance, via inducement of angiogenesis and collagen production.

6. **What is the nature of the synergy between Magnetic Pulse (MP)<sup>2</sup> and Radio Frequency (RF)?**

The (MP)<sup>2</sup> induces the production of collagen via two synergistic mechanisms—the MP component induces the proliferation of fibroblast, who in turn produce collagen, and the RF component creates a controlled thermal damage, and initiates a wound-healing process that involves production of collagen. The result is a significant increase in collagen production.

## **Technology**

1. **What are the advantages of the Multi-Polar RF Matrix compared with other RF systems?**

The Octi-Polar handpiece is equipped with an array of 8 electrodes that emit RF energy and create a matrix. There are several advantages associated with this design:

- this array generates a uniform heat pattern, that enables the operator to reach high temperatures in a short time while avoiding heat spikes
- since there are no heat spikes, the treatment is very pleasant and also very safe and there is no need for a cooling system or anesthesia
- the ability to reach high temperatures contributes to the efficacy of the treatment
- the array covers a large surface area, that translates into shorter treatment time
- the layout of the electrodes is designed to create multiple distances. According to the rule of thumb, the penetration depth of RF into the skin equals half of the distance between the electrodes. Hence the OctiPolar provides several (4) penetration depths

- the presence of 8 electrodes on the handpiece prevent the 'bad coupling' phenomena that is associated with RF treatments

**2. How deep into the skin does (MP)<sup>2</sup> penetrate?**

According to the rule of thumb, the penetration depth of RF equals half the distance between the electrodes. The opposing electrodes on the OctiPolar are 5.5cm apart, so the maximum penetration depth of the RF when using the OctiPolar is 2.75cm (1.1"). The maximum penetration depth of the DiamondPolar is 1.8cm (0.7").

**3. What is the effectiveness of the (MP)<sup>2</sup> compared to a 400 watt system?**

A 400W device uses mono-polar Radio Frequency and necessitates the use of active cooling to avoid skin burns. The system's Octipolar handpiece deploys much less power, since its 8 poles work very efficiently and generate focused and homogeneous heat with no need of cooling aid and no risk of skin burns.

**4. Are any consumables needed for treatment with (MP)<sup>2</sup>?**

No. the only consumable is the glycerin that is used as conductive material.

**5. Is it possible to use ultrasound gel as conductive material, instead of glycerin?**

Ultrasound gel is water-based and tends to evaporate very quickly, as the heat that is generated during the treatment is intense. Glycerin is oil-based and therefore does not evaporate during the treatment. We recommend the use of glycerin.

**6. What regulatory approvals have been granted to (MP)<sup>2</sup>?**

(MP)<sup>2</sup> is approved by the FDA, Health Canada and CE.

**7. What products by Venus Concept have trade mark?**

We have a trade marks for Venus Freeze™, Venus Swan™, Venus (MP)<sup>2</sup>™, Octipolar™ and Diamondpolar™.

**8. Is (MP)<sup>2</sup> a patented technology?**

Yes. The synergy between PEMF and RF (or any other heat source) is registered as a patent.

## **Clinical results**

### **1. What clinical conditions can be treated with (MP)<sup>2</sup>?**

All conditions related to aging skin and body contouring may be treated with (MP)<sup>2</sup>:

- Wrinkles and rhytides
- Loose skin
- Cellulite
- Localized fat deposits
- Decreased skin elasticity
- Xerosis (skin dryness)

### **2. What clinical results can (MP)<sup>2</sup> deliver?**

The results following treatment with (MP)<sup>2</sup> are generally divided into 2 types:

- Immediate results: collagen fibers in the dermis contract as a result of the exposure to heat, and create an immediate effect of skin tightening and firming. Improvement in wrinkles and skin texture will follow shortly after the treatment.
- Long-term results: synthesis of collagen and elastic fibers, formation of new blood vessels, proliferation of fibroblasts and lipolysis, will have a long-term positive effect on skin texture and elasticity, cellulite and body contour.

### **3. Can (MP)<sup>2</sup> reduce laugh-line wrinkles?**

Since (MP)<sup>2</sup> enhances the elasticity of the skin and improves skin tone, laugh-line wrinkles are also expected to be positively affected.

### **4. Is it possible to predict the exact effect of (MP)<sup>2</sup> treatment on wrinkle reduction and/or circumference reduction?**

Since the effect of such treatment depends on many variables such as age, life style, tolerance to heat during the treatment, etc., it is not possible to provide such prediction.

### **5. Who is likely to get optimal results following (MP)<sup>2</sup> treatments?**

Generally speaking, patients with the following profile can expect optimal results:

- non-obese
- age 30-60yrs
- good physical and mental health
- healthy and balanced diet
- active lifestyle

**6. Is it possible to treat the décolleté area?**

Yes. The skin in this area tends to become loose over time, due to the effects of aging and gravity. Treatments with (MP)<sup>2</sup> can improve skin tone, elasticity and texture.

**Treatment protocol**

**1. What areas of the body can be treated with (MP)<sup>2</sup>?**

(MP)<sup>2</sup> treatments may be performed on the face (excluding the eyelids), neck, arms, thighs, knees and lower legs, buttocks, abdomen and décolleté.

**2. What does treatment with (MP)<sup>2</sup> feel like?**

Heat is generated during the treatment, and the patient will feel a heating sensation. The treatment is not painful, but rather pleasant and soothing.

**3. How many treatments are needed to get good clinical results?**

A series of facial treatments will include 6-8 treatments, and a series of body treatments will include 8-10 treatments.

**4. At what frequency should treatments be performed?**

Treatments should be performed once a week.

**5. Are maintenance treatments recommended? If yes, for how long?**

Yes, it is recommended to perform maintenance treatments once every 2-3 months. There is no limit on the number of maintenance treatments. These treatments help prevent additional skin-aging damages that might appear with time.

**6. What is the duration of a single treatment with (MP)<sup>2</sup>?**

The duration of the treatment depends on the treatment area. Face treatments take about 30 minutes, and body treatments take between 15-40 minutes.

**7. Is there any limit on the number of treatments a patient can undergo? Is it possible to continue with treatments immediately after the completion of a treatment series?**

There is no limit on the number of treatments a patient can undergo. If a patient wishes to, they can undergo additional treatments.

**8. How can the operator tell that the treatment is performed properly and effectively?**

The best indication is the temperature on the skin surface during the treatment. The operator should reach the end point temperature, which is the therapeutic temperature ( $\geq 39^{\circ}\text{C}$  for the face,  $\geq 41^{\circ}\text{C}$  for the body), and maintain it for the entire treatment duration. As long as the therapeutic temperature is maintained, the treatment is effective.

**9. Does treatment with (MP)<sup>2</sup> have any side effects?**

The only side effects associated with the treatment are slight erythema and edema on the treated area. In addition, the skin will keep radiating heat for a while. All of these effects will diminish within several hours and will not interfere with the daily activities.

**10. Is there any downtime following treatment with (MP)<sup>2</sup>?**

No, there is no downtime following the treatment. The patient may resume their daily routine immediately.

**11. How long after completion of Roaccutane treatment is it possible to receive treatment with (MP)<sup>2</sup>?**

6 months.

**12. If a patient has an Intra-Uterine device installed, can they still receive (MP)<sup>2</sup> treatments?**

Yes. This device is located deeper than the maximum penetration depth of the (MP)<sup>2</sup>, and therefore it is not affected by the treatment.

**13. How long after completion of treatment series with IPL or laser is it possible to receive treatment with (MP)<sup>2</sup>?**

Once the skin has healed completely, it is possible to start a treatment series with (MP)<sup>2</sup>. If in doubt, consult a physician.

**14. Is it permitted to treat a patient that suffers from Eczema?**

No. Eczema is a comprehensive definition of chronic inflammatory condition of the skin, and it is considered a contra-indication.

**15. If a patient has dental braces installed, can they undergo facial treatment with (MP)<sup>2</sup>?**

Provided that the braces are insulated (by a plastic cover), it is permitted to treat the patient.