# Novel Radiofrequency (RF) Device for Cellulite & Body Reshaping Therapy

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**ABSTRACT**

Cellulite is among the most disturbing and challenging skin disorder known in the aesthetic market. Despite multi-disciplinary physical, mechanical, pharmacological agents, exercise and diet regimens, cellulite signs and symptoms remain, in most cases, unaffected. In the past decade, cellulite management has inspired new generation of innovative medical devices promising correction of cellulite signs and symptoms. It is now evident that the weaken connective tissue and diminished microcirculation play a key role in the pathophysiology of cellulite and therefore, long term correction of cellulite is possible through modification of the weakened connective tissue and improvement of microcirculation function. The **Accent** (Fig. 1; Alma Lasers, Ltd, Caesarea, Israel) is a novel radiofrequency (RF) device to treat cellulite by employing volumetric thermotherapy. The Accent RF Unipolar handpiece (patent pending) improves cellulite symptoms through three mechanisms: (1) Deep dermal heating/tightening - up-regulation of collagen expression (neocollagenesis and remodeling); (2) Enhancement of stagnant blood microcirculation (hyperemia by vasodilatation) and lymphatic drainage of trapped fatty deposits and toxins and; (3) fat cell disintegration and thermally-induced fat cell apoptosis.

**INTRODUCTION**

There are two clinically reported mechanisms that have demonstrated the ability to thermally modify the skin's connective tissue: optical energy (Laser) and radiofrequency (RF). Although RF devices and lasers differ fundamentally in the way they generate heat within the tissue, both classes of devices are capable of producing temperatures within the critical temperature range (65-75) for connective tissue shrinkage and remodeling.

Light and RF can be controlled through adjustments in:

- Power (Watts or Joules)
- Exposure time (msec, sec)
- Electrode configuration (geometry)
- (RF) Resistance (tissue impedance - ohms)
- (Light) Endogenous chromophore

Recent developments have made it possible to use RF for non-invasive aesthetic applications. With controlled delivery of RF to the dermis, deep dermis and (when applicable) subdermal layers, RF has demonstrated the ability to stimulate collagen production resulting in a softening of wrinkles (i.e. periorbital rhytides and improvement to nasolbial folds, jowls, and Marionette lines). Cooling is an important ingredient when using aesthetic RF to help control epidermal heating (and potential for injury) as well as provide additional patient comfort.

**NEW TECHNOLOGY**

The Accent Unipolar handpiece (patent pending) provides RF energy waves through the emitter without the need or potential hazards of a ground or "return electrode" and is the first aesthetic medical system to provide the Unipolar handpiece for skin tightening, cellulite reduction and for submental fat reduction. The Accent includes a Bipolar handpiece to provide heating to the forehead and neck where the dermis is thin and for the induction of tissue tightening.

Figure 1: The Accent

Traditionally invasive medicine has utilized RF through one of two configurations: Monopolar and Bipolar. Both configurations utilize a two electrode system: one for emission of the RF energy and the other to serve as a return electrode. The mechanism responsible for traditional RF heating of biological tissue is through the resistance of conductive current flow (tissue dependent).. For lypolysis, the monopolar configuration for deep tissue (volumetric) heating is less predictable because it will seek a path of least resistance (through blood and lymphatic vessels) where fat cells would not be directly

affected. The Accent employs two mechanisms of RF-heating of biological tissues: (1) rotational movement of water (dipole) molecules in the alternating electromagnetic fields and corresponding electromagnetic wave (Unipolar) and; (2) tissue resistance to conductive current (Bipolar).

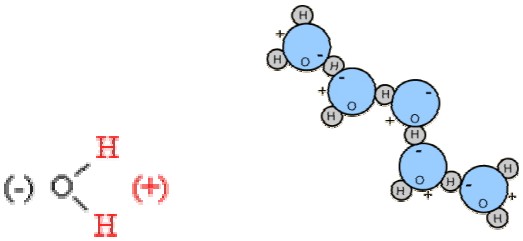


Figure 2. Water (dipole) molecule

The dipolar interaction between water molecules represents a large amount of internal energy and is a factor in water's large specific heat. The dipole moment of water provides a "handle" for interaction with RF electric fields (Fig. 2). RF electromagnetic waves to a specific tissue inducing heat through water molecule rotation bypasses the need for a return electrode and is unique to the Accent system, The Unipolar probe applies an electric field that produces heat in the area adjacent to the probe with a predictable depth of penetration. The polarity of the applied RF-field is then rapidly changed. The inherent resistance to the movement of ions and the water molecules rotation in tissue causes friction (heat). The resistance and level of heat produced depends on several factors including the impedance of the treated tissue, the amount of target tissue and the cooling applied.

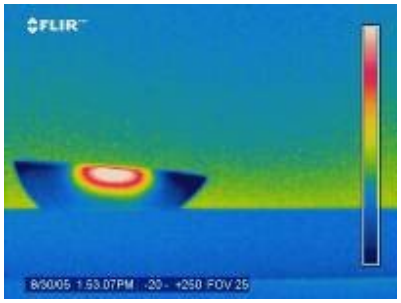


Fig. 3. Thermogram of Accent Unipolar RF emission field.

**DEVICE OVERVIEW**

The Accent has 2 attached handpiece applicators and an RF-generator that operates at a frequency of 40.68 MHz. Both handpieces (Fig. 4) are used in constant motion (cris-cross) while in contact with the skin. The Unipolar RF energy penetrates to a depth of up to 20 mm, heating the skin tissue and subcutaneous tissue without damage to the tissue surface. The applied RF-power is 100-200 Watts dependent on the application.

Fig. 4. The Unipolar and Bipolar Handpieces

The Accent Unipolar handpiece consists of an RF-resonant system with includes a thermo-electric coupling (TEC) cooler and pushbutton activation. There is a green LED (visible to the operator) that illuminates when the handpiece is activated. The application technique begins with the drawing of rectangular grids on the skin (20-60 square centimeter area) with a skin marker. The system is adjusted to appropriate settings of energy (watts) and time (seconds) for the desired application. The skin temperature is monitored using a laser thermometer and recorded in the patients treatment form. The application technique is always a contact sweeping motion beginning with horizontal strokes followed by vertical strokes – alternating until the time expires. To prevent friction on the surface of the skin a light coating of oil (baby oil or aromatic oil only – no ultrasound gel is used) is applied just prior to treatment. Following treatment of each grid the temperature is recorded and the operator then moves on to the next treatment grid. Both operator and patient are pleased with the technique as it is relatively fast, painless and does not interrupt the patients' routine as the treatment does not require lifestyle changes and is without down time for the patient.

**CELLULITE AND FAT**

Cellulite is no different from an accumulation of white fat cells found in any other part of the body. Adipose tissue consists of small vesicles or "fat cells" lodged within a matrix of Areolar connective tissue. These fat cells are contained in discrete clusters in the Areolar of fine connective tissue. Areolar tissue is a form of

connective tissue in which the investing connective tissue matrix is separated into areolae (or spaces) which open into one another and are easily permeated by fluids. Areolar tissue binds different parts of the body together. Areolar connective tissue is found beneath the skin in a continuous layer all over the body, connecting the skin (dermis) to subjacent tissues. In many parts of the body, the areolae are occupied by fat cells. The matrix and fat cells constituting adipose tissue are referred to as "depot fat".

In cellulite, fat is stored in fat cells which lie between the skin and muscle tissue. Fat cells are grouped together into large collections which are separated by fibrous strands (fibrous septae). These fibrous strands run between the muscle and the skin and function to hold the fat in place (in small compartments). The skin is tethered down by string-like tissues that pull it inward, toward the interior of the body. As fat cells expand (with weight gain), the gap between the muscle tissue and skin expands. The fibrous strands cannot stretch and can not support the skin. The tension of these septae pulls sections of fat in along with them, causing the fat cells in the subcutaneous layer to increase and stick together within the connective tissue fibers which results in the dimpling (also described as “mattress” or “cottage cheese”) (Fig. 5).

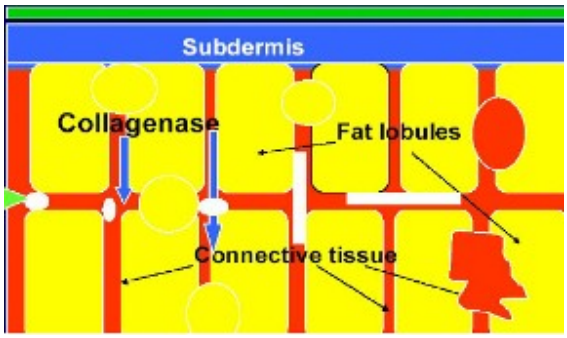

Fig. 5. The subdermal reorganization of cellulite

The Accent provides controlled radiofrequency energy to depths of up to 2 cm generating heat within the dermis and sub-dermis.

In vitro and in vivo studies have demonstrated that women (when compared to men) had a diffuse pattern of irregular and discontinuous connective tissue immediately below the dermis. It is believed that decreased integrity of the dermis or an increase in the compression of adipose tissue by radially oriented connective tissue septa could account for the outpouching of subcutaneous adipose tissue into the reticular dermal layer. If the connective tissue separating the dermal and adipose tissue layers is inherently weaker in affected individuals, then adipose tissue would have a tendency to extrude outward into the dermis.

The result of the controlled thermal injury may result in tissue shrinkage (molecular contraction) followed by an inflammatory response accompanied by the migration of fibroblasts into the area creating new collagen tissue and a tightening of the skin (cellular contraction). There is also a tightening of the fibrous layer of tissue at the interface between the dermis and the subcutaneous tissue which will also serve to reduce future cellulite symptoms.

**ACTION MECHANISM**

The Accent RF Unipolar handpiece alleviates cellulite symptoms by means of three major mechanisms: (1) Dermal tightening of the fibrous septae due to thermal injury affecting the vasculature, which in turn initiates a cascade of inflammatory events, including fibroblastic proliferation and apparent up-regulation of collagen expression (neocollagenesis/remodeling); (2) Enhancement of local blood circulation (vasodilatation and hyperemia) and drainage of fatty deposits to the lymphatic system; and (3) Fat cell disintegration and thermal-induced fat cell apoptosis.

The skin and the underlying collagen-containing tissue are heated without substantially modifying the melanocytes and other epithelial cells in the epidermis. The result is a contraction of the collagen tissue and a tightening of the skin. Tightening the fibrous layer of tissue at the interface between the dermis and the subcutaneous tissue reduces cellulite symptoms. Controlled thermal injury may result in tissue shrinkage followed by an inflammatory response accompanied by the migration of fibroblasts into the area. The intentional and directed infiltration of fibroblasts to the thin layer of tissue, including the interface, may be used to reinforce its structural integrity, resulting in amelioration or elimination of the subdermal fat protrusion that causes skin bulging. The area is reinforced with additional connective tissue deposits as part of the tissue repair and healing phase. This phase is followed by a period of maturation of the newly deposited connective tissue, thereby resulting in contracture and tightening of the injured tissues and the tissue overlying the dermis-epidermis interface. This newly deposited connective tissue matrix may be used to strengthen the natural fibrous layer between the dermis and subcutaneous tissue.

The thermal trauma to the fat cells (disintegration of the cell membrane) may cause the release of triglycerides from the fat cells. These triglycerides are likely broken down into free fatty acids and glycerol by the enzyme lipoprotein lipase (LPL). The free fatty acids (water insoluble) bind to albumin and are slowly transported to

the liver. Glycerol (water soluble) is transported to the liver via the interstitial fluid compartments – tissue fluids and blood fluid. In addition, it has been shown that adipocyte apoptosis plays an important role in adipose tissue homeostasis and can be altered under a variety of physiological and pathological conditions such as hyperthermia.

## ACCENT APPLICATION IN CELLULITE

After checking a patient's medical history and contraindications, the practitioner and the patient should discuss the treatment plan, expectations and desired results. The practitioner should screen the patient for skin laxity, skin quality, tone conditions and cellulite severity (Table 1). All jewelry or pendants, including necklaces, bracelets, watches, should be removed. High quality pre- and post-treatment photographs are an important step in documenting the degree of efficacy achieved during treatment. Weight (lbs or kg), thigh circumference (inches or cm), and hip-to-waist ratio should be measured using a scale and a tape measure, respectively. The intended treatment area should be marked with grids of ~ 5 x 6 cm (15 seconds exposure time) or 10 x 6 cm (30 seconds exposure time) using a surgical pen. Just before the applicator is applied to the skin, the treatment area should be lubricated with a thin layer of baby oil or aromatic oil to eliminate friction from the movement of the handpiece against the skin. Occasionally, it is advisable to inspect the entire handpiece, especially the tip, to identify any damage or debris. The initial treatment parameters should be set (power - watts and time of exposure - seconds) according to the recommended parameters. For moisturized skin or sensitive skin types, power should be reduced by 10-20 watts. For oily skin, acne, sagging skin or aging skin, the power should be raised by 10 watts.

Table 1. Cellulite Grading

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| **Grade I** | Symptomatic with no superficial changes, but microscopic evaluation may reveal increased thickness of the areolar layer and increased capillary permeability. |
| **Grade II** | After skin compression or muscle contraction, the skin is pale, with decreased temperature and decreased permeability. |
| **Grade III** | Padded and/or orange peel appearance of the skin is evident at rest |
| **Grade IV** | More palpable, visible and painful nodules, adherence to deep dermal levels and obvious wavy appearance of the skin surface. |

The cooling mode should always be set to "ON" (touch the applicator head to insure the cooling is activated). During treatment, the patient should be monitored for heat sensation by employing a scale from 0 (no heat; no pain) to 5 (burning; extremely painful). If discomfort is indicated, the parameters should be modified (reduce energy level by 10%). The applicator must be in contact with the lubricated skin and in motion before the handpiece's red knob is triggered. The practitioner should always apply a rubbing technique by randomly moving the applicator away from the area just exposed. It is good practice to conform to the grid borders. Epidermal temperature should be checked with a laser thermometer immediately before and after each pass. It is recommended to touch and feel the patient's skin following each pass. After reaching therapeutic threshold of ~41°C (Up-slope; Phase I), multiple passes (3-4) should be applied on the treatment area (Maintenance; Phase II). In the maintenance phase the energy level and the time of exposure should be down-titrated (10-15%). During Phase I and II, homogenous erythema (hyperemia) should be visible. Erythema may persist 15-30 minutes post treatment.

Fig 6. Endpoints: hyperemia and erythema

The patient may experience a heating sensation or pain (rare) during or just following the treatment; however, such pain should be mild and is expected to be resolved within a few minutes. There is a possibility of extended side effects which may include persistent erythema which will resolve normally after 24 hours or more important, a skin burn (may occur if the operator did not follow instructions, i.e., used an energy level that was too high energy or kept the handpiece on the same spot for too long). The post-treatment procedure is enhanced by having the patient cool down for 10 minutes in the office. No other post-treatment actions are needed (application of aloe vera is optional). The recommended treatment regimen includes (up to) six treatments spaced by 2 weeks interval.

## PRECLINICAL AND CLINICAL STUDIES

Ongoing preclinical and clinical studies of the Accent Unipolar handpiece have exhibited a high safety and efficacy profile. In a clinical study (unpublished data) using the Accent Unipolar handpiece, 18 women (ranging in age from 25- 46 years, with a cellulite

severity of grade II-IV, and Fitzpatrick skin type II-V) were treated in the buttock-thigh areas twice a week for four consecutive weeks. Before and after images were taken routinely. Patients reported no change in daily activities or dietary habits. No adverse side effects or down time was noted or documented. All patients demonstrated improvement in cellulite symptoms, as seen clinically and through images taken before and after treatment. All patients reported a high satisfaction rate.

Before

After 2 Tx

**Courtesy of David Freidman, M.D**

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