

## Simultaneous emission of synchronized radiofrequency and magnetic fields in a single applicator for fat elimination and muscle building

### A unique combination of RF and HIFEM®

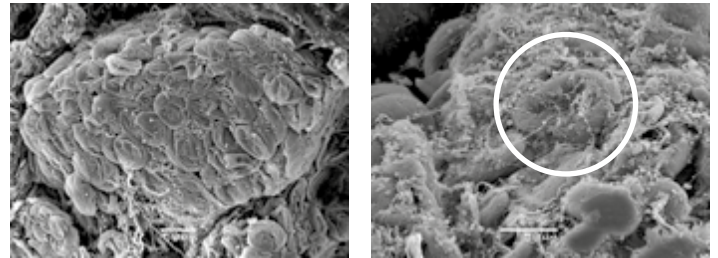
Procedures primarily addressing fat reduction and muscle building non-invasively have been two separate worlds since their inception due to the clinical and technical interferences. EMSCULPT NEO is the first of its kind aesthetic medical device that generates RF and HIFEM energies simultaneously using dual-field applicators.

The RF component delivers different levels of heat to underlying structures; skin, fat, and muscle. HIFEM is a procedure based on high-intensity magnetic fields that elicit external muscle contractions of supra-physiological nature. The unique combination of muscle contractions and heating by EMSCULPT NEO has multiple synergistic effects making the simultaneous treatment more effective than any standalone or consecutive application.

### Effects on adipose tissue

The unique synchronized radiofrequency in EMSCULPT NEO has shown to heat the adipose tissue to 43–45°C uniformly<sup>1,2</sup>. Adipocytes exposed to temperatures in this range begin to lose their cellular viability and enter into the apoptotic process, i.e., natural and permanent deletion<sup>3</sup>. Consequently, the apoptotic cells lose membrane integrity and are digested by immune cells, which clear the degraded cell debris to maintain tissue homeostasis<sup>4</sup>. As a result, the number of fat cells in the treated area is significantly reduced.

The elevated temperature further results in increased blood flow and acceleration of metabolic activity. In response, the lipids stored in the fat cells are broken down into free fatty acids and glycerol, which are subsequently released to the bloodstream<sup>5</sup>. This directly leads to a shrinkage in the size of the remaining fat cells as they lose a large portion of their contents.



SEM evidence of fat cell shrinkage 4 days after treatment (left) and apoptotic fat cell destruction seen 2 weeks after treatment (right). Source: Weiss et al.

Several veterinary and human trials were conducted to investigate the effects of EMSCULPT NEO on subcutaneous fat tissue. Histological and electron microscopy observations of the adipose tissue revealed extensive disruption of fat cells and lipolytic changes<sup>1,2</sup>. Noninvasive MRI and ultrasound evaluation demonstrated that the simultaneous treatments result in an average reduction of 28.3% – 30.8% in the subcutaneous fat layer<sup>6,7</sup>.

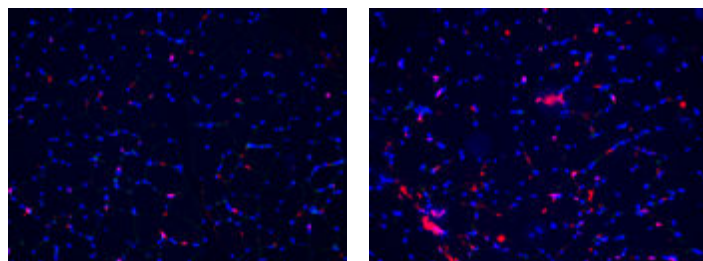
The muscle contractions further contribute to an even heat distribution. Localized heat accumulation is often associated with thermal treatments and the so-called “hot-spots” can lead to various complications. In EMSCULPT NEO, the muscle contractions work as a natural massager distributing the heat homogeneously across the entire treated area.

### Effect on muscles

Due to the RF, the muscle is heated to 40–41°C<sup>8</sup>, which causes increased blood flow into the active tissue and thus a significant increase in the oxygen and nutrient delivery to the strained muscle fibers<sup>9</sup>. Increased oxygenation and nutrient supplementation promotes the anabolic processes that take place in an organism and are necessary for faster muscle fiber regeneration and growth.<sup>10</sup>

The HIFEM-induced supramaximal muscle contractions produce a strong response that triggers muscle tissue hypertrophy<sup>11</sup>. During the treatment, muscle fibers are stretched and relaxed with high frequency and intensity, leading to micro-ruptures in the muscle fibers<sup>12,13</sup>. In turn, signaling molecules (heat shock proteins - HSP) are released to activate regenerative and muscle growth processes to strengthen the muscle.<sup>13</sup> Satellite cells (SC), the muscle-derived stem cells responsible for **myofiber development, and renewal**<sup>14</sup> are activated at the same time. When activated the SC's may differentiate to support existing muscle fibers, or to generate new muscle fibers.<sup>15</sup>

Both HSP and SC can be activated by intense muscle exercise, but also by heat. Several studies have documented the ability of muscle heating to alter the levels of HSP as well as SC<sup>16</sup>. Moreover, the simultaneous application of heat and mechanical stress showed the highest levels in the expression of **HSPs** when compared to either heat or mechanical stress alone<sup>17</sup>.



Immunofluorescence images. The levels of satellite cells (red) are increased significantly at 2 weeks post-treatment (right) when compared to baseline (left). Adopted from Halaas et al.

Multiple IRB studies have investigated the synergy, and their results have shown a muscle thickening effect of 24-26%<sup>6,7</sup>. On the other hand, the studies investigating the use of HIFEM without RF heating reported growth in muscle thickness by 16%<sup>18</sup>. This comparison clearly shows that the heat plays an important role in achieving superior clinical efficacy.

## Concluding comments

EMSCULPT NEO represents the first technology in the aesthetic field allowing the application of RF heating and HIFEM energies to the same body area simultaneously. This represents a breakthrough approach to non-surgical body shaping that clinically allows combining RF-induced fat elimination and HIFEM-induced muscle building in a wide range of patients, varying from athletes to high-BMI individuals. This new approach addresses

the two biggest patient concerns in a single treatment while unlocking the various synergistic benefits that can only be seen when the energies are emitted at the same time. Multiple clinical studies investigating the synergistic effect of dual emission documented an efficacy superior to any other standalone or consecutive treatment available in aesthetic medicine today.



MRI images taken at baseline (left) and 3 months post-treatment (right). Adopted from Jacob et al.

## References:

- Weiss RA, Bernardy J, Tichy F. Simultaneous Application of High-Intensity Focused Electromagnetic and Synchronized Radiofrequency for Fat Disruption: Histological and Electron Microscopy Porcine Model Study. *Dermatol Surg.* 2021;47(8):1059-1064. doi:10.1097/DSS.0000000000003091.
- Goldberg DJ. Deletion of adipocytes induced by a novel device simultaneously delivering synchronized radiofrequency and hifem: Human histological study. *J Cosmet Dermatol.* 2021;20(4):1104-1109. doi:10.1111/jocd.13970.
- Weiss R, Weiss M, Beasley K, Vrba J, Bernardy J. Operator Independent Focused High Frequency ISM Band for Fat Reduction: Porcine Model: FOCUSED FIELD RF FOR FAT REDUCTION. *Lasers in Surgery and Medicine.* 2013;45(4):235-239.
- Nikoletopoulou V, Markaki M, Palikaras K, Tavernarakis N. Crosstalk between apoptosis, necrosis and autophagy. *Biochimica et Biophysica Acta (BBA) - Molecular Cell Research.* 2013;1833(12):3448-3459.
- Adatto MA, Adatto-Neilson RM, Morren G. Reduction in adipose tissue volume using a new high-power radiofrequency technology combined with infrared light and mechanical manipulation for body contouring. *Lasers in Medical Science.* 2014;29(5):1627-1631.
- Jacob C, Kent D, Ibrahim O. Efficacy and Safety of Simultaneous Application of HIFEM and Synchronized Radiofrequency for Abdominal Fat Reduction and Muscle Toning: A Multicenter Magnetic Resonance Imaging Evaluation Study. *Dermatol Surg.* 2021;47(7):969-973. doi:10.1097/DSS.0000000000003086.
- Samuels JB, Weiss RA, Katz B. Radiofrequency Heating and HIFEM Delivered Simultaneously: The First Sham-Controlled Randomized Trial. *Plast Reconstr Surg.* In press.
- Halaas Y, Duncan D, Bernardy J, Ondrackova P, Dinev I. Activation of Skeletal Muscle Satellite Cells by a Device Simultaneously Applying High-Intensity Focused Electromagnetic Technology and Novel RF Technology: Fluorescent Microscopy Facilitated Detection of NCAM/CD56. *Aesthet Surg J.* 2021;41(7):NP939-NP947. doi:10.1093/asj/sjab002.
- Giombini A, Giovannini V, Cesare AD, et al. Hyperthermia induced by microwave diathermy in the management of muscle and tendon injuries. *Br Med Bull.* 2007;83(1):379-396.
- Racinais S, Cocking S, Périard JD. Sports and environmental temperature: From warming-up to heating-up. *Temperature (Austin).* 2017;4(3):227-257.
- Duncan D, Dinev I. Noninvasive Induction of Muscle Fiber Hypertrophy and Hyperplasia: Effects of High-Intensity Focused Electromagnetic Field Evaluated in an In-Vivo Porcine Model: A Pilot Study. *Aesthetic Surgery Journal.* Published online October 26, 2019;sjz244.
- Brown SJ, Child RB, Day SH, Donnelly AE. Exercise-induced skeletal muscle damage and adaptation following repeated bouts of eccentric muscle contractions. *Journal of Sports Sciences.* 1997;15(2):215-222.
- Ebbeling CB, Clarkson PM. Exercise-induced muscle damage and adaptation. *Sports Med.* 1989;7(4):207-234.
- Mauro A. Satellite Cells of Skeletal Muscle Fibers. *The Journal of Cell Biology.* 1961;9(2):493-495.
- Schultz E, McCormick KM. Skeletal muscle satellite cells. *Rev Physiol Biochem Pharmacol.* 1994;123:213-257.
- Kakigi R, Naito H, Ogura Y, et al. Heat stress enhances mTOR signaling after resistance exercise in human skeletal muscle. *J Physiol Sci.* 2011;61(2):131-140.
- Goto K, Okuyama R, Sugiyama H, et al. Effects of heat stress and mechanical stretch on protein expression in cultured skeletal muscle cells. *Pflügers Archiv European Journal of Physiology.* 2003;447(2):247-253.
- Katz BE. An overview of HIFEM technology in body contouring. *Dermatol Rev.* 2020;1(3):91-96. doi:10.1002/der.2.24.

**Results and patient experience may vary.** As with any medical procedure, ask your doctor if the EMSCULPT NEO® procedure is right for you. EMSCULPT NEO® is intended for non-invasive lipolysis (breakdown of fat) of the abdomen and thighs and reduction in circumference of the abdomen and thighs with Skin Type I to Skin Type VI. EMSCULPT NEO® is also cleared for improvement of abdominal tone, strengthening of the abdominal muscles and development of firmer abdomen. Strengthening, toning, firming of buttocks, thighs, and calves. Improvement of muscle tone and firmness, for strengthening muscles in arms. ©2021 BTL Group of Companies. All rights reserved. BTL, EMSCULPT NEO® and EMSCULPT® are registered trademarks in the United States of America, the European Union, or other countries. The products, the methods of manufacture or the use may be subject to one or more U.S. or foreign patents or pending applications. Trademarks EMSCULPT®, EMSCULPT NEO®, Emsella®, Emtone®, Embody®, and HIFEM® are parts of EM™ Family of products.

