

T H E

AESTHETIC GUIDE

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Evolved HIFEM Plus RF Destroys Fat
and Builds Muscle Simultaneously

Without doubt, the Emsculpt Neo from BTL Aesthetics (Marlborough, Mass.) takes its groundbreaking Emsculpt system to the next level and beyond. Shockingly innovative, the revolutionary non-invasive, no-consumables platform brings together targeted emission of radiofrequency (RF) energy and the firm's signature high intensity focused electromagnetic (HIFEM) in a single applicator. The synergy of these two technologies, delivered simultaneously, creates consistent results even in patients with a BMI as high as 35, replacing the phrase 'fat reduction' with 'fat destruction.'

Emsculpt Neo is a gem that lives up to the hype in an industry rife with hyperbole – especially within the rapidly evolving realm of body contouring, said Bruce Katz, MD, director of JUVA Skin & Laser Center (New York, N.Y.). "This represents a whole different breed of devices. By combining RF and magnetic field energy we get dramatic improvement well beyond what either technology could do by itself. It is a perfect example of synergy." The Emsculpt Neo is intended for non-invasive lipolysis (breakdown of fat) of the abdomen and reduction in circumference of the abdomen with Skin Type I to Skin Type III, as well as for improvement of abdominal tone, strengthening of the abdomen muscles and development of a firmer abdomen, strengthening, toning, firming of buttocks, thighs and calves, and improvement of muscle tone and firmness, for strengthening muscles in arms.

According to Brian M. Kinney, MD, a plastic surgeon located in Beverly Hills, Calif., Emsculpt Neo embodies the 'game-changer' concept. "Few devices get top marks in safety, efficacy, patient comfort, ease of use and overall appeal," he began, "but when you imagine an ideal body sculpting device, what do you envision? Non-invasive, rapid, hassle-free, comfortable no-downtime treatment with a manageable number of sessions in a short time to see results; easy and safe for ancillary staff to perform; and no consumables to inflate the cost of treatment. And what would it do? Build muscle and reduce fat. Who isn't going to want this kind of treatment? Emsculpt Neo is these things and more."

"The original Emsculpt had been demonstrated to induce up to 16% increase in muscle mass with a course of treatment, which itself was impressive," said dermatologist and cosmetic surgeon Suneel Chilukuri, MD, medical director of Refresh Dermatology in Houston, Texas. "This had significant potential benefits to health and wellness in addition to improving the appearance, which is one of the main reasons I offer this treatment. With research showing potential muscle mass increases around 25% with Emsculpt Neo, the potential to positively impact health, wellness and appearance is that much greater."

Moreover, with the growth of truly effective technologies in recent years, the market for body sculpting has never been better and is expected to continue flourishing. According to a March 2020 RealSelf consumer survey, only 26% of men and 12% of women consider their current bodies as 'athletic' or 'toned,' and nine out of ten men are interested in one or both of fat reduction and/or muscle toning solutions.

This bodes well for Emsculpt Neo, to be sure, but additional findings bolster this potential. The survey also found that 96% of men and 99% of women reported being interested in a clinically proven fat reduction and muscle toning treatment providing visible results faster than anything else on the market. About three-quarters of men and women would pay up to \$3000 for a safe and effective treatment backed by extensive clinical research.

"Between the Internet and social media, more information is out there," said dermatologist David J. Goldberg, MD, JD, medical director of Skin & Laser Surgery Specialists, and director of cosmetic dermatology and clinical research for the Schweiger Dermatology Group (with offices in New York City and New Jersey). "Patients should – and will – search it out, and when they do they'll find out how unique, safe and effective Emsculpt Neo is."

The highly touted synergy is seen with simultaneous delivery of HIFEM and what's known as synchronized RF; each mode can also be used individually. Within four minutes of activation, Emsculpt Neo's RF component brings the temperature of subcutaneous fat to a temperature



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The Emsculpt Neo is intended for non-invasive lipolysis of the abdomen and reduction in circumference of the abdomen with Skin Type I to Skin Type III, as well as for improvement of abdominal tone and strengthening of many areas of the body.

sufficient to cause apoptosis, triggering the gradual removal of the free fat and cellular debris by the body. “This is by far the fastest time to target temperature of any RF device seen to date,” stated plastic surgeon Richard M. Goldfarb, MD, owner of The Center for SmartLipo in Langhorne, Pa.

HIFEM technology is a prime example of treatment specificity, according to Dr. Chilukuri. “With long wavelengths and low energy, non-invasive HIFEM isn’t absorbed by tissue so there’s no thermal effect,” he said. “Secondary currents induced in the surrounding tissue predominantly affect motor neurons, depolarizing them to cause muscle contractions, but the surrounding tissue remains unaffected.”

“Using programmed algorithms designed to thoroughly stimulate target muscle groups, HIFEM causes supramaximal contraction of 100% of muscle fibers in the treatment area, at levels of intensity that could never be achieved through manual exercise,” Dr. Goldberg explained. “Stress-induced muscular adaptation, the natural response of the body to exercise, causes muscle hypertrophy and hyperplasia for average increases in muscle volume of approximately 25%.”

As intuitive as it might seem, merging the two technologies into a single applicator for simultaneous, synchronized action was a supreme challenge, according to Dr. Goldberg. “What’s truly revolutionary is that these two technologies, as they existed previously, were mutually exclusive by nature. RF is a rapidly changing electric current induced using metallic electrodes. HIFEM, on the other hand, is an electromagnetic field that heats up the metal, so when you activated the HIFEM, it destroyed the metallic electrodes.”

“They didn’t have an RF emitter with no metal,” Dr. Kinney pointed out, “so BTL engineers developed a proprietary electrode with 112 mutually-interacting interspaced segments – two separate electrodes with 56 positive and negative poles in each of them – making it relatively transparent to magnetic fields and thus allowing the action of the HIFEM in close proximity.”

“A relative contraindication is treating anyone with Emsculpt who has any metal devices in the body,” Dr. Kinney added. “The presence of metal in the body alters the electromagnetic field and Emsculpt Neo has not been tested with each unique patient who has a metal device to ensure it would remain properly functional.”

According to Dr. Chilukuri, both technologies have been optimized to work together. “Emsculpt Neo isn’t just HIFEM plus RF,” he said. “The RF and HIFEM are synchronized so that pulses are configured to propagate heat uniformly into the treatment area. Emsculpt Neo has dramatically extended the threshold of what’s possible and completely redefined body sculpting.”

“The incredible synergy seen with Emsculpt Neo, and the engineering behind it, are going to change the industry forever,” Dr. Katz also projected. “Companies will be racing to discover the next combination that does things we wouldn’t have thought possible. It is already happening.”

The effect of Emsculpt Neo on muscle is profound. “Studies have shown significant muscular hypertrophy and hyperplasia,” said Yael Halaas, MD, a facial plastic surgeon from New York City, N.Y., “which means we’re seeing an increase in muscle



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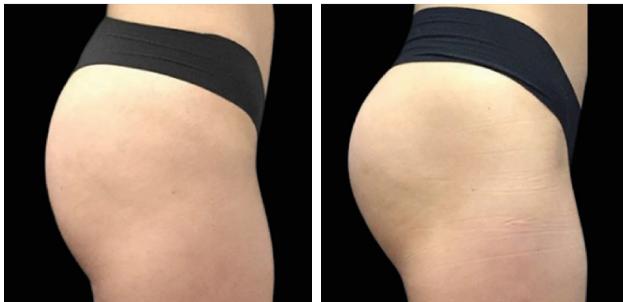
mass with concurrent rise in the number of muscle fibers.”

According to Dr. Katz the difference between the two, as well as the presence of both, is telling. “Muscular hypertrophy can result from increased water uptake by cells, a swelling of the muscle which increases size, can improve performance, but is also temporary. Hyperplasia is more muscle fibers, which means more actual muscle and long-lasting results,” he expressed. “A trial investigating new muscle growth with Emsculpt Neo revealed the strong presence of satellite cells, which are indicators of new muscle growth. The increase in number of satellite cells after treatment was comparable to what one would expect to see after a sixteen-week exercise regimen. Coupled with studies of the original Emsculpt that showed results persisting a year or more, sometimes two years, we have strong evidence of both hypertrophy and hyperplasia that will translate into lasting results with Emsculpt Neo.”



Before and one month after the third and final treatment of Emsculpt Neo

Photos courtesy of David Kent, MD

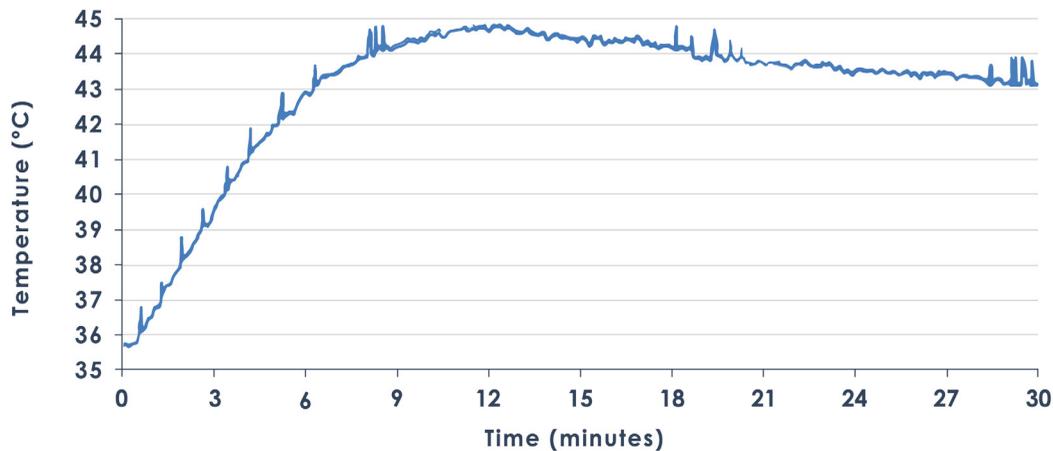


Before and eight weeks after the third and final treatment of Emsculpt Neo

Photos courtesy of Seaside Aesthetics

BTL's reputation for combining technologies has been cemented through devices such as Exilis Ultra (marrying RF and ultrasound) and Emtone (RF plus Targeted Pressure Energy [TPE]). Within a single device, modalities complement each other at the very least, but sometimes the combination results in something more. “Any aesthetic practitioner can tell you that combination therapies, in a single platform or by performing separate modalities with multiple treatment vectors, are the key to unlocking top tier outcomes,” said Dr. Halaas. “It allows you to attack a problem from more than one direction, and when you can do this on the same day it is more convenient for the patient. In addition, sometimes combination treatments have a synergistic effect, especially when you can perform them on the same day or simultaneously. Simultaneous HIFEM and RF has demonstrated greater synergy than anyone could have hoped for.”

In this case, BTL's decades-long research and development of HIFEM technology inspired both Emsculpt and later, Emsella. The unique, controlled delivery of targeted electromagnetic pulses stimulates supramaximal contraction of muscles to work them more thoroughly than manual



Graph demonstrates temperature in fat tissue during Emsculpt Neo treatment. Effective temperature of 42° C was achieved in four minutes and a temperature between 43° and 45° C was maintained throughout most of the therapy. Measurement confirmed lethal thermal damage to adipose tissue.
Source: BTL Aesthetics

exercise ever could, reshaping from the inside-out. The Emsella device targets core musculature to improve incontinence, and in an intuitive move, was incorporated into Emsculpt as an applicator soon after.

Once made feasible via novel engineering, the union of RF and HIFEM became reality. “The end result of marrying RF and HIFEM is a faster, easier treatment to perform that improves the revenue stream of the practice, with no consumables,” said Dr. Goldfarb. “For patients, we have a more comfortable yet powerful therapy yielding up to 30% fat reduction, which is significantly higher than what published studies give for cryolipolysis, which is about 22%. Clinical studies have shown an increase of muscle by up to 25%, which is better than the 16% seen with the original Emsculpt. And you can treat patients with a BMI as high as 35.”

So what about skin tightening? “RF is known to induce skin tightening,” explained Dr. Katz. “Many companies, including BTL, have successfully employed this modality for that purpose and there is a large body of science behind that application of the technology. Intuitively, delivering RF in the manner of Emsculpt Neo would induce tightening of the skin but it is not yet an indication for the device. BTL has historically been methodical about their research progression so it is no surprise that they would focus their efforts on, and isolate, the specific effects studied to this point. Clinical trials to identify and quantify any level of skin tightening are a next logical step in

this progression. If it is the case, Emsculpt Neo would successfully address all three dimensions of body contouring: reduce fat, build muscle, tighten skin.”

The scientific foundation of Emsculpt Neo, and all BTL devices, for that matter, is marked by transparency and thoroughness. For this device, they assembled an impressive group of cream-of-the-crop physicians, each renowned for their research experience. “These are known experts in their respective fields with reputations and credibility,” said Dr. Katz. Additionally, BTL science is about multiple measures. Previous devices have seen comprehensive evaluation using MRI, CT scan, histology, ultrasound and more; Emsculpt Neo is no different.

“Because of this assembly of top researchers in the field, when making comments for an article like this one, physicians like me are talking in facts, not educated speculation,” Dr. Goldfarb said. “That makes a big difference and readers, among professionals and the public, can tell the difference.”

On top of 30 peer-reviewed studies establishing and supporting the safety, efficacy and mechanism of action of HIFEM, seven new trials led to the launch of Emsculpt Neo, each currently in the pipeline for publication and recently presented at conferences. Drs. Goldberg and Katz were among those featured at the Emsculpt Neo launch event; Dr. Goldberg explained the science, Dr. Katz reviewed information from the seven trials.

The trial Dr. Katz was involved with featured 72 subjects (active group n=49, sham group n=24) undergoing three 30-minute abdominal treatments using an active or deactivated (sham) device, with results assessed using ultrasound imaging. Similar results were noted in a related study by David E. Kent, MD, founder of Dermatologic Surgery Specialists, P.C. (Macon, Ga.), and Carolyn I. Jacob, MD, medical director of Chicago Cosmetic Surgery and Dermatology (Chicago, Ill.), including waist circumference reductions of 5.9 cm and 18.8% reduction in abdominal separation.

Dr. Goldberg's study involved a similar treatment regimen with sham, and a subject group of only four women, but with the goal of gathering histological evidence. "Histology revealed apoptosis and lipolysis of fat cells as well as decreases in the size of adipocytes (up to 33.5%)," he reported. Dr. Goldberg added that his studies also showed further evidence of fat apoptosis, including the presence of pyknotic nuclei; and fat cell disruption, noted in the first ten days after treatment, peaks at around day 20.

Study of porcine tissue (via biopsy) by Dr. Halaas and colleagues showed a 30.2% increase in the levels of myosatellite cells (denoting muscular hyperplasia) a month after treatment. Optimal safe temperature for promoting muscle growth was determined to range between 40° C and 41° C.

Along with solid science, BTL's training and support are also second to none. "In addition to the many events keeping the community informed about developments, BTL goes into offices directly and makes sure users are thoroughly trained," said Dr. Kinney. "The customer support is reliable and top notch, as are their devices, which are robust. The applicator will eventually need an emitter tune-up or replacement service, but it takes quite a while, up to 9,000 minutes, before that becomes an issue."

The lingering COVID-19 crisis has dramatically impacted the way medicine is practiced, and has had a profound economic effect. Almost draconian measures must be taken to prevent the spread of the insidious coronavirus, especially among aesthetic

practices where procedures are inherently elective. Also a factor, aesthetic medicine is most prominent within large population centers where the risk of a spike in the local COVID-19 infection rate is greatest.

Emsculpt Neo is an ideal device for the times, according to Dr. Goldfarb. "By nature, contact with medical professionals during treatment is limited. Rapid treatment minimizes time in the medical office. Patients come in, the applicators are placed, the operator adjusts the settings. Treatment is relatively comfortable; the device has a safety button for the patient if treatment is too intense. And when it is over they go home with manageable staff interaction. This is important in the COVID era."

Early adopters can be among the first-to-market, giving them a distinct advantage in the increasingly competitive aesthetic market, especially considering COVID-19. "If the science and the initial reactions from the community are any indication, this technology will become ubiquitous among practices offering body shaping therapies," said Dr. Kinney.

Another way Emsculpt Neo will impact practices is by expanding the potential patient base, according to Dr. Katz. "With the original Emsculpt we would avoid treating larger patients because the effect on the fat is minimal, so you wouldn't see much of a result. Significant fat reduction plus muscle growth increases the range of treatable patients. For doctors, this represents a whole new population for your practice that would not be appropriate for Emsculpt alone, or almost any other non-surgical body shaping treatment. That's a big plus."

Dr. Kinney agreed. "We cannot underestimate the importance of this, because while we discuss non- or minimally invasive body contouring therapies we often lose sight of the reality that we are talking about basically fit, often younger, people. Emsculpt Neo is the real deal when it comes to credibly treating the larger patient, with a BMI up to 35."

While it won't turn an obese man into Brad Pitt, larger patients can expect circumference reduction in treated areas as well as

muscular development. “Obviously, the larger patient population isn’t going to go from fat to ripped,” said Dr. Katz, “but they will get results. We have to be clear with them what to expect, but Emsculpt Neo is a definite, viable body contouring option for larger patients.

“BTL is spending a lot of money to raise public awareness about this device,” Dr. Goldfarb said. The company’s marketing blitz began with the Emsculpt rockstar empowerment bus tour which made appearances around the country, bringing devices to treat patients and generate buzz about the technology in general. While this is winding down, aggressive multimedia campaigning that includes radio advertising and the penning of a pop song, has begun. In six markets, Tesla automobiles have been wrapped with Emsculpt Neo advertising. Major influencers such as Jenny McCarthy Wahlberg, Molly Sims and Carmen Electra are singing the praises of the device. “Emsculpt Neo is so effective and appealing that celebrities and star athletes are stepping up and asking to be a part of this. You don’t see that kind of attention without something tangible to back it up.”

The effect on patients is even more profound. “Patients having undergone treatment with Emsculpt Neo are understandably pleased. They look better in their clothes and have a trimmer silhouette. Where they lacked muscle tone, they have improved muscular definition. They report feeling much better overall, even saying their posture has improved which is a natural result of improved core musculature and function. Overall results can be quite dramatic in some cases,” Dr. Katz said.

The key catchphrase tagged to Emsculpt Neo, ‘More for Less,’ defines what the device is and does, pure and simple, according to Dr. Kinney. “For the patient it means more muscle and less fat, more energy and results for less time and money. For physicians it is more treatments in less time, more customization with less technique dependence and more profit, with less staff and operating expenses. This will be effective because it is true.”



Before and three months after the third and final treatment of Emsculpt Neo

Photos courtesy of Bruce Katz, MD



Before and three months after the third and final treatment of Emsculpt Neo

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EMSCULPT neo[®]

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in Body
Shaping

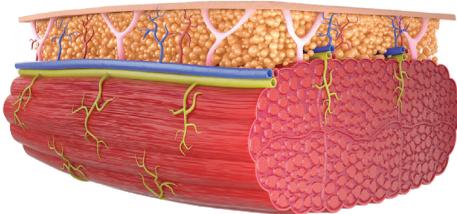
**30-min.
Procedure**



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LESS Fat



Muscle MORE

MORE for LESS

BEFORE



AFTER **EMSCULPT[®]**



3 MONTHS AFTER THE LAST TREATMENT, COURTESY OF: RADINA DENKOVA, M.D.

BEFORE



AFTER **EMSCULPT[®]**



1 MONTH AFTER THE LAST TREATMENT, COURTESY OF: BTL AESTHETICS

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 reduction in circumference of the abdomen with Skin Type I to Skin Type III. 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. ©2020 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. *Data on file.

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