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GUIDE

Unique Technology Transforms RF-Based Microneedling

Of the various energy-based technologies that have permeated the medical aesthetic market in recent years, radiofrequency (RF) has arguably emerged as the most popular due to its flexibility and ability to treat a large number of cosmetic indications. In addition, many manufacturers have embraced RF paired with microneedling to address deep dermal remodeling in the subcutaneous tissues while bypassing the epidermis. In this area, one company has pushed this technology to a new level, demonstrating excellent efficacy and patient satisfaction.

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EndyMed Intensif's Ease of Use and Improved Outcomes Attract Physicians

By Jeffrey Frentzen, Executive Editor

While the thermal effects of monopolar and bi-polar RF-based aesthetic platforms have been shown to improve skin and pigmentary concerns, historically these results tend to be unpredictable. In addition, because of the uncontrolled nature of monopolar or unipolar RF treatments and the superficial nature of energy flow for bi-polar or tri-polar configurations, many first- and even second-generation systems frequently deliver erratic or partial outcomes with patient discomfort and pain, possibly due to the large differences in individual skin impedance.

Pulling ahead of the RF-based microneedling pack is the recently released Intensif™ from EndyMed Medical, Inc. (New York City, N.Y.), which offers advanced energy-based technology and a powerful, yet simple to use microneedling handpiece.

In addition to providing effective dermal skin remodeling and tightening, this device offers efficacious treatment of acne scars, deep wrinkles, stretch marks and other indications that benefit from thermal heating. This minimally invasive procedure presents nominal downtime, no risk and supports all skin types.

The Intensif handpiece works with the firm's EndyMed 3DEEP aesthetic platform, which employs RF-based technology for a variety of handpieces that are adapted for different applications and treatment areas.

Intensif can achieve cylindrical micro zones of coagulation in the papillary and reticular dermis with minimal damage to the epidermis. An array of 25 gold-plated microdiameter needles works in fractional pulse mode, delivering energy in a small pattern and supplying a continuous distribution of power. The needles are inserted into the skin via a specially designed smooth-motion motor that is electronically controlled to minimize patient discomfort.

Depth of needle penetration, energy level and pulse duration may be adjusted on the fly, which gives the practitioner complete control over the treatment. Furthermore, RF emission delivered across the entire dermal portion of the needle allows bulk volumetric heating for effective coagulation, resulting in minimal or no bleeding.

Having several years of experience with the 3DEEP system, Neil Sadick, M.D., F.A.A.D., F.A.A.C.S., F.A.C.P., F.A.C.Ph., a dermatologist and researcher in New York City, N.Y., welcomed this new handpiece. "This technology is advanced for RF-based microneedling. It has non-insulated needles as well as minimal pain and post-operative force. We have found that it is very helpful for the treatment of lines in all skin types, wrinkles, acne scars, stretch marks and pigmentation."

Doris J. Day, M.D., a dermatologist and clinical assistant professor of dermatology at NYU Langone Medical Center in New York City, N.Y., has incorporated both microneedling and RF-based energy devices in her practice. In her experience, this system represents the best combination of both technologies.



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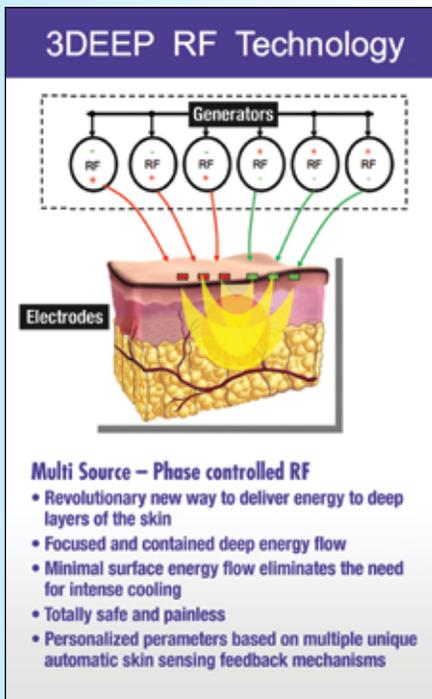
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3DEEP RF technology delivers multi-source phase controlled RF. Image courtesy of EndyMed Medical, Inc.

"Its non-insulated needles with Fractionated Pulse Mode technology safely delivers the RF into the dermis along the full length of the needle, creating an effective thermal zone that allows me to target energy to the depth I choose through the precision guided motorized tip. Since it is coagulating along the length of the needle, there is no bleeding and no downtime," she expressed.

Using Intensif, Dr. Day can treat all skin types without the risks associated with other technologies, such as lasers. "In addition, it has broadened the range of patients that I can treat with issues like perioral / periorbital rhytides, stretch marks and even cellulite," she noted.

Yohei Tanaka, M.D., Ph.D., founder and director of Clinica Tanaka Plastic and Reconstructive Surgery and Anti-Aging Center in Nagano, Japan was looking for new technology that would achieve skin rejuvenation with minimal downtime for patients. "I found the EndyMed Pro 3DEEP technology to be excellent and decided to add the Intensif for new indications. I was easily able to augment my existing EndyMed system," he stated.

Mark B. Taylor, M.D. a cosmetic dermatologist in Salt Lake City, Utah, purchased the 3DEEP system years ago for skin tightening and RF-based resurfacing. "In addition to skin tightening and resurfacing, we use the Intensif for treating scars and addressing large pores. You can also improve skin texture with the Intensif," he said.

The idea of utilizing microneedling with RF-based heat is an advantage, noted Flor A. Mayoral, M.D., a cosmetic dermatologist in Coral Gables, Fla. "If you're looking for a device that is going to create volumetric change, such as tightening and wrinkle reduction, without a lot of downtime or complications, this is where a technology like Intensif falls into place," she indicated. "It has a very easy to use screen interface and we can treat both the face and body. Also, you don't need an additional device to do fractional RF treatments."

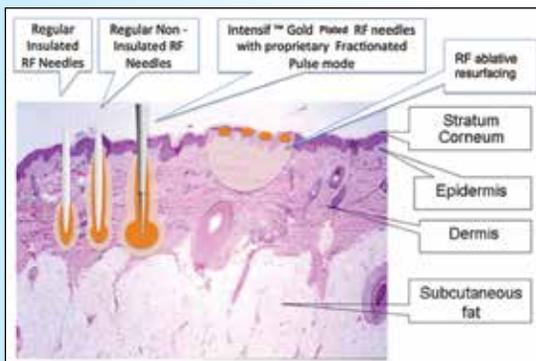


Image demonstrates energy penetration into the dermal layers via insulated, non-insulated and Intensif Gold Plated RF needles. Image courtesy of EndyMed, Medical, Inc.

According to Dr. Taylor, "It is important to pick the right indication for Intensif. For instance, one notoriously difficult issue to treat is skin laxity and aging texture on the neck. However, we've found the Intensif to be quite a good solution in these cases. Another area that has always been very complicated is a patient with extremely oily skin, large pores and pitted scars. This device will help to reduce the population of the sebaceous glands, reduce the oil and alter the appearance of large pores and pitted scars."

David Goldberg, M.D., a cosmetic dermatologist in New York City, N.Y., also employs Intensif for skin tightening, "Specifically in darker skin types, such as Asian, Latino and African American," he reported. "Additionally, it is undoubtedly the treatment of choice for acne scarring. It's somewhat different from other devices because the current is delivered across the entire needle. It is like a 3DEEP Pro system on steroids. These needles penetrate into the skin, therefore with one

application you're going to obtain results similar to what might take four or more treatments with the EndyMed 3DEEP Pro alone."

For Michael H. Gold, M.D., director of the Gold Skin Care Center in Nashville, Tenn., this product is a useful evolution of microneedling that should become quickly accepted among practitioners. "Intensif has been designed exceptionally well, with gold plated needles that are mechanically driven, precise and accurate. They give us exactly the result we are looking for every time," he stated.

Dr. Gold also recognized how well Intensif helps to correct acne scars and traumatic scars. "If you can improve the look of scars then wrinkle reduction is easy," he shared. "If you want to achieve a skin rejuvenation effect, you can get really nice changes in the texture, tone and quality of the face and neck. We recently did a study of Intensif with a couple of other clinics and we found that we achieve a lifting effect with Intensif as well. Not only do we produce the texture changes when we treat, we obtain tightening that is really impressive in a lot of patients."

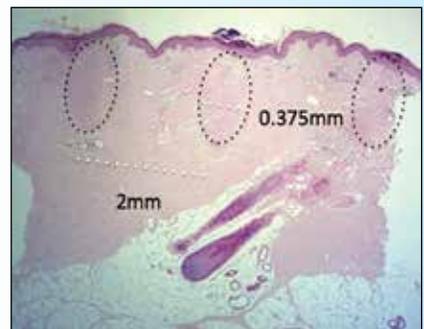
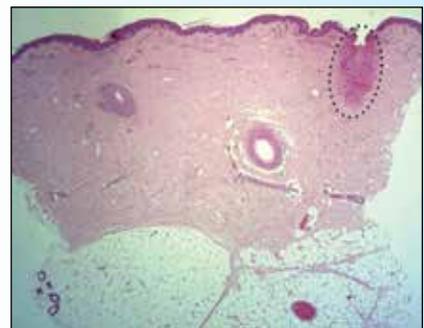
In the area of acne scarring, there's no question that RF-based systems are better than lasers for these indications, stated Amy Forman Taub, M.D., a dermatologist and associate professor of clinical dermatology at Northwestern University's Medical School (Chicago, Ill.). "With the microneedles you can break up scars and treat them more effectively than in the past," she pointed out. "That is really where the Intensif device shines. When approaching darker skin types you don't have to worry as much about post-inflammatory pigmentation. This is because you are really bypassing the epidermis during the procedure."

For Harold Lancer, M.D., F.A.A.D., a dermatologist in Beverly Hills, Calif., Intensif is a popular treatment for submental tightening of the neck skin. "We use it for post-surgical periumbilical tightening of tissue," he began. "It is useful for tightening some of the laxity that is created in the liposculpting world and is also often used to correct flaws that are either natural or created by other procedures." According to Dr. Lancer, Intensif excels because of the strong RF component it adds to the EndyMed platform.

For physicians looking to avoid using lasers, but wanting to achieve similar results, Intensif is as good, but does not involve the patient pain and downtime usually linked with those modalities, according to users.

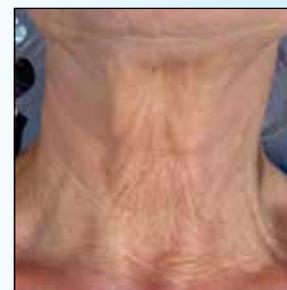
"When I would do CO₂-based resurfacing I'd hear patients say they'd never do that again," expressed Glynis Ablon, M.D., F.A.A.D., a dermatologist in Manhattan Beach, Calif. "More downtime and recovery time was involved, and more hand holding. Now, I'm just so pleased and excited that we are seeing such dramatic results from this level of less invasive technology."

Invasive or ablative procedures, such as face-lifts and laser resurfacing are very effective for skin tightening, but do come with potentially adverse effects, Dr. Tanaka agreed. "In addition, while many alternative microneedling

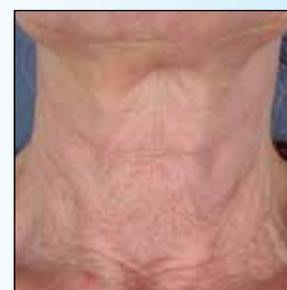


Histologies show effects immediately after Intensif Tx (top) and full epidermal recovery with excretion of coagulated debris through the epidermis and matrix recovery in the dermis four days post Tx (bottom).

Images courtesy of EndyMed Medical, Inc.



72 year old patient before Tx



Four months after one Intensif Tx
Photos courtesy of Isabelle Rousseaux, M.D.



Before Tx



After three Intensif treatments
Photos courtesy of Gregory S. Keller, M.D.



27 year old female with stretch marks before Tx



Five months after Intensif Tx
Photos courtesy of Daniel Barolet, M.D.

technologies may also be effective for treatment of dilated pores, acne and acne scars they are associated with prolonged recovery time, bleeding, oozing and the risk of post treatment hyper- or hypopigmentation. Intensif microneedling technology produces excellent results, low risk and patients like the lack of downtime."

Indeed, Intensif's implementation of RF-based microneedling is different from other, similar devices Dr. Goldberg concurred. "It does not have a one-generator system that determines the power, but instead uses six generators, which means that this technology can treat both superficially and deeply. Of all the fractional RF microneedling devices, this is the only one that is an add-on to an underlying RF-based aesthetic system," he emphasized.

Intensif takes advantage of the EndyMed 3DEEP's motor system, "Which allows uniform insertion of delivered energy," Dr. Goldberg added. "You're not traumatizing the skin, which in turn means the amount of swelling and redness is truly minimized. You can also control needle depth, anywhere from .5 mm to 3.5 mm depending upon what you are trying to accomplish."

The ability to adjust the depth of the needles makes a big difference, Dr. Taylor maintained. "For instance, you can do one pass at 3 mm or 3.5 mm to tighten the deeper tissues, and then move to a more superficial depth for surface improvements. You don't have to change the tip when you want to perform this kind of multi-level approach."

Dr. Taub added, "The needles can go very deep – up to 3.5 mm. When treating acne, we definitely need to reach that depth. If you're talking about wrinkle reduction or tightening, you probably don't need to be deeper than 1.5 mm on the face. It depends on gender, too. Men have much thicker skin so you might want to go a little bit deeper. It is very easy to adjust the unit."

As well, Intensif's overall design is clearly an advancement for microneedling devices, stated Dr. Ablon. "Many microneedling products utilize a single press down and that's it, which does not provide the range we find with Intensif. The idea is that you also have the polarity, which allows these multiple passes and multiple RF generators to work at the same time, providing that deep penetration that I like."

"The microneedling handpiece has an advantage over other solutions in that it is smoother," Dr. Lancer advised. Some of the other products have more of an unpleasant sensation. The smoother needle penetration of the Intensif is more desirable. Treatments can be more time consuming because the Intensif does not operate on a repetition mode. It is on a single pulse mode. The needles penetrate to deliver the energy and then retract inward. While it is a slower technique, I'm a fan of the technology and it works."

Although Dr. Ablon was skeptical at first because of the traditionally inconsistent results provided by other microneedling products, she says, Intensif takes

microneedling to a whole new level. "You can deliver energy deeper into the dermal tissue and attain some decent tightening. Notably, the needles are not insulated, which made me pause at the beginning because I had heard insulated needles provide a better overall result, but I'm seeing some really remarkable results with Intensif."

"There is a debate in the field about whether or not you want insulated needles, with which energy is delivered just at the tip, versus non-insulated needles where the energy is distributed across the course of the needle," Dr. Gold joined in. "There are pros and cons to this, but I believe that the non-insulated needles allow improved coagulation and provide a better injury pattern into the skin, which allows us to use only a single pass 99% of the time. With other microneedling systems you have to do multiple passes and you have the potential for pain and bleeding. Therefore, the Intensif procedure is much cleaner for my patients."

Another debate among practitioners is on the question of employing heat – as in RF-based energy – in microneedling procedures. "The 'purists' out there still think you don't need heat and that heat is a negative," stated Dr. Taub. "The idea, however, is that you are creating what is called a scarless wound. You activate a different biologic pathway for healing and then you use topical therapies, such as high doses of vitamin C and A to encourage the healing. However, without the heating that you have with Intensif you simply won't see as much tightening or wrinkle reduction. In practice, you can use the Intensif without the heat if you want. I've done that in a couple of patients and they love it. In those cases, there is actually no pain whatsoever."

Heat or no heat, the bottom line is that Intensif delivers high patient satisfaction. "Most of my patients are very pleased with the outcomes," stated Dr. Tanaka. "If any patients may have been dissatisfied with the initial results, they are usually happy after an additional Intensif treatment."

In Dr. Mayoral's practice, "Patients are always ready to do the next treatment. Even after the first session, many of them are so surprised at how much better their skin feels and looks."

Overall patient response has been very exciting in Dr. Ablon's clinic. "I have not had a patient come back from a treatment that did not say, when's my next one?" she said. "We have seen impressive results from a single session, as well. Usually, I tell my patients to expect three to five applications and they come back after one and say they've observed good results. In addition, the downtime is very tolerable."

Satisfaction among physicians is also high, not only because of Intensif's consistently good outcomes, but also owing to its overall ease of use and delegation. As reported by Dr. Sadick, "The unit is very simple to operate. I will do some treatments and I delegate others. All of the physicians in our practice use the technology."



52 year old female before Tx



One month after two Intensif treatments
Photos courtesy of Kenneth Rothaus, M.D.



Telangiectasia and rosacea before Tx



One week after one Intensif Tx
Photos courtesy of Yoram Harth, M.D.



Before Tx



After three Intensif treatments
Photos courtesy of Gregory S. Keller, M.D.



60 year old female before Tx



One month after one Intensif Tx
Photos courtesy of Mark B. Taylor, M.D.

Dr. Taylor determines the settings based on skin type and what levels he wants – the pulse width and so on. “Once I get the settings I want I delegate these treatments to my nurse and physician assistant,” he stated. “We use local anesthesia for these procedures, in order to make the patient more comfortable. Any of my medical assistants that can legally inject local anesthetic can also do the Intensif procedure.”

In addition, the unit includes sophisticated built-in safeguards. “The handpiece comes with contact, temperature and motion sensors,” said Dr. Goldberg. “If you are not in good contact with the skin, not at the temperature you want, or if you’re not moving it constantly, then the device will not operate. It is incredibly safe to use.”

However, as Dr. Goldberg also urged, “Even though RF-based technologies are pretty safe, since many physicians like to delegate treatments to different calibers of providers you always want to make sure patient safety is paramount.”

Safe usage of any microneedling device extends to all topicals or drugs that might be applied to the affected skin following a procedure, added Dr. Taub. “When you create a hole in the skin, granted it is probably only open for about 15 minutes, during that time you must be careful about what you put in there,” she stressed. “I only use sterile hyaluronic acid immediately after treatment. If you put anything in there that has a particle in it or even something that is meant to sit on the epidermis, then you could cause a reaction. If you put an acid right on the wound, even vitamin C, it could sting. However, within 24 hours you can apply whatever you want.”

Interestingly, Dr. Goldberg applies platelet-rich plasma (PRP) shortly after an Intensif session. “You are penetrating the skin and creating a wound that leads to new collagen formation, and PRP just adds to that,” he stated. “The holes made with the needles remain open for a little while, which allows us to avoid having to inject the PRP, which generally with PRP you have to inject it in many different locations. With Intensif you don’t have to. It just soaks right through. It’s a realistic application of PRP.”

As in the PRP example, physicians have found that Intensif can be a valuable adjunct to other modalities when trying to achieve specific results. It is an ideal platform when employing combination approaches, noted Dr. Taylor. “For instance, Intensif can be used with IPL, non-ablative resurfacing, or a variety of modalities. This approach can yield a multi-level improvement in the patient’s skin appearance and color, tightness and texture. If you combine IPL with bulk heating to tighten the skin and add in Intensif to improve texture then you get a triple whammy.”

“Combination approaches are very important in my clinic, as every technology and modality accomplishes something different,” Dr. Ablon stated. “However, the timing of when to perform combination therapies is important. I’m not a big

fan of same day treatment of Intensif and other modalities. When you try to do too many things on the same day you are asking for more complications."

Dr. Lancer has settled on this tactic, as well. "We don't combine Intensif with anything during the same session," he confirmed. "Sometimes we will alternate it with ultrasound treatments, such as Ultherapy from Merz Aesthetics (Raleigh, N.C.), and sometimes we'll combine it with Halo BBL treatments from Sciton (Palo Alto, Calif.)."

In Dr. Mayoral's experience, "Combining the Intensif with dermal fillers and neurotoxins can give patients the best results possible in a short amount of time. Acne patients that have scars and enlarged pores are the happiest with their results."

Dr. Sadick relayed, "In order to treat stretch marks we will sometimes combine the Intensif with Retin-A. For melasma and chemical peels, we use it in combination with hydroquinone derivatives. For the treatment of acne scars we use it in combination with Bellafil from Suneva Medical (San Diego, Calif.)."

In addition, one can employ other tissue tightening devices with Intensif to achieve certain results, Dr. Taub insisted. "You can get a bigger volumetric response. Intensif is all about compacting tissue, in a way, in a smaller volume. If your patient has neck laxity or is overweight then you might add in 3DEEP technology or something similar. Then you will also be able to move more tissue in bulk. For those patients you might want to add a foundational treatment, in which you're talking about deeper and bigger bulk heating. It's something you might achieve using Ultherapy or Thermage from Solta Medical, a division of Valeant Pharmaceuticals (Hayward, Calif.). Do that first and then follow with Intensif. If you see epidermal changes then you would turn to an IPL."

With the seemingly ever-expanding list of indications and approaches that utilize Intensif, physicians tout a solid return on investment. "EndyMed's 3DEEP technology does not require any consumables and the Intensif is a premium treatment with a low cost of use," stated Dr. Tanaka. "I believe the whole EndyMed platform is attractive due to higher efficacy, reduced patient discomfort and low-cost procedure delivery. It's an investment that quickly pays for itself."

Dr. Taylor remarked that he has also seen a good return. "Intensif has been a good, profitable addition to our portfolio of aesthetic devices," he said. "The tip is a consumable, but it is reasonably affordable and quite generous in that it includes 1,000 pulses on each tip. That's usually more than enough to achieve the outcome you want for your patient."

Ultimately, the pay-off comes in the form of offering patients the best outcomes. "Everything we do needs to be based on one thing: Can we really get the results that we are promising our patients?" expressed Dr. Ablon. "Intensif really does provide consistently good outcomes for them. I'm pleased with the technology and that we have the ability to treat all skin types, use it for a variety of indications and end up with very happy patients." ■



66 year old patient before Tx



Four months after one Intensif Tx

Photos courtesy of Isabelle Rousseaux, M.D.



Before Tx



Four days after Intensif Tx

Photos courtesy of Amy Patdu, M.D.