EndyMed's Intensif Microneedle

Handpiece Receives FDA Clearance

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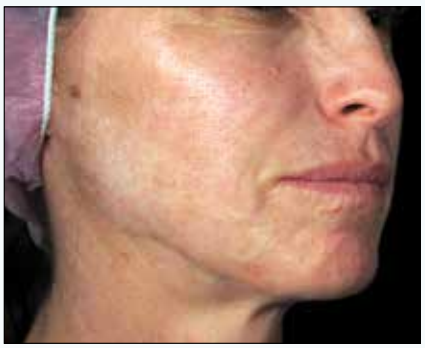
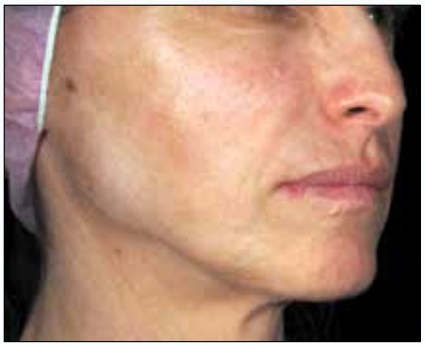


Before Tx



After one Intensif Tx

Photos courtesy of EndyMed Medical, Ltd.

By Kevin A. Wilson, Contributing Editor

With its recent FDA clearance, the new Intensif microneedle RF applicator for the EndyMed PRO platform from EndyMed Medical, Ltd. (Caesarea, Israel) will change the increasingly intense arena of aesthetic fractional microneedling in the U.S. Intensif is safe for all skin types with a very minimal amount of downtime or bleeding, and is approved for general use in dermatology as well as electrocoagulation of tissue and hemostasis.

At present, fractional microneedle treatments involve the straightforward mechanical insertion of an array of microneedles, or groups of insulated microneedle-like electrodes which, upon insertion, deliver RF energy for thermal coagulation of dermal tissue around the tip. Every Intensif single-use disposable tip features an array of 25 uninsulated, ultra-sharp, tapered gold-plated microneedles, each measuring 300 µm in diameter, through which a short RF pulse is delivered.

"Successful employment of uninsulated microneedles is what makes Intensif stand out," said dermatologist Yoram Harth, M.D., medical director of EndyMed. "The device only delivers RF energy at the precise moment of maximum insertion depth for that treatment, which is electronically user controlled. In addition, we harness differences in skin impedance between the dermis and epidermis to prevent epidermal damage and maximize dermal effect. These important features allow us to heat three times the dermal volume compared to insulated RF needles of the same length, with full hemostasis and minimal to no damage to the epidermis."

Depth of insertion with Intensif can be adjusted between 0 mm and 3.5 mm in increments of 0.1 mm. Power is modulated between 0 W and 25 W in increments of 1 W, with pulse duration adjustable in 30 ms increments. "Whether treating acne scars, deep wrinkles, striae or other conditions, the ability to fine tune treatment parameters with Intensif is of particular value, not only for tailoring treatment based on indication or body area, but to allow us further latitude as we explore and expand the capabilities of this modality," said Dr. Harth. "It also provides a gap-filling treatment between ablative and non-ablative fractional laser devices, which in the former case may be overly traumatic and in the latter case are exceedingly shallow."

Additionally, proprietary technology maintains tight control over a specially designed smooth needle insertion motor to ensure smooth and almost painless insertion which, when coupled with the hemostatic nature of the treatment, makes the mechanism behind the no-hassle nature of Intensif microneedling obvious. "RF is also naturally safe for all skin types because risk of PIH is minimal, which is another advantage over lasers," Dr. Harth added.

Dr. Harth is also lead author of a recent article in the *Journal of Drugs in Dermatology*[1] detailing the results of an *in vivo* study of Intensif microneedle treatment. This trial involved the treatment of a female pig using various energy levels and insertion depths with subsequent histological examination to demonstrate efficacy and rapid healing, confirm predictability and further elucidate the thermal profile.

The Intensif applicator enhances the capabilities of the already versatile EndyMed PRO multisource RF platform, providing a color-blind treatment for skin tightening, body contouring and overall skin improvement.

Reference:

1. Harth Y, Frank I. *In vivo* histological evaluation of non-insulated microneedle radiofrequency applicator with novel fractionated pulse mode. *J Drugs Dermatol* 2013 Dec;12(12):1430-3.