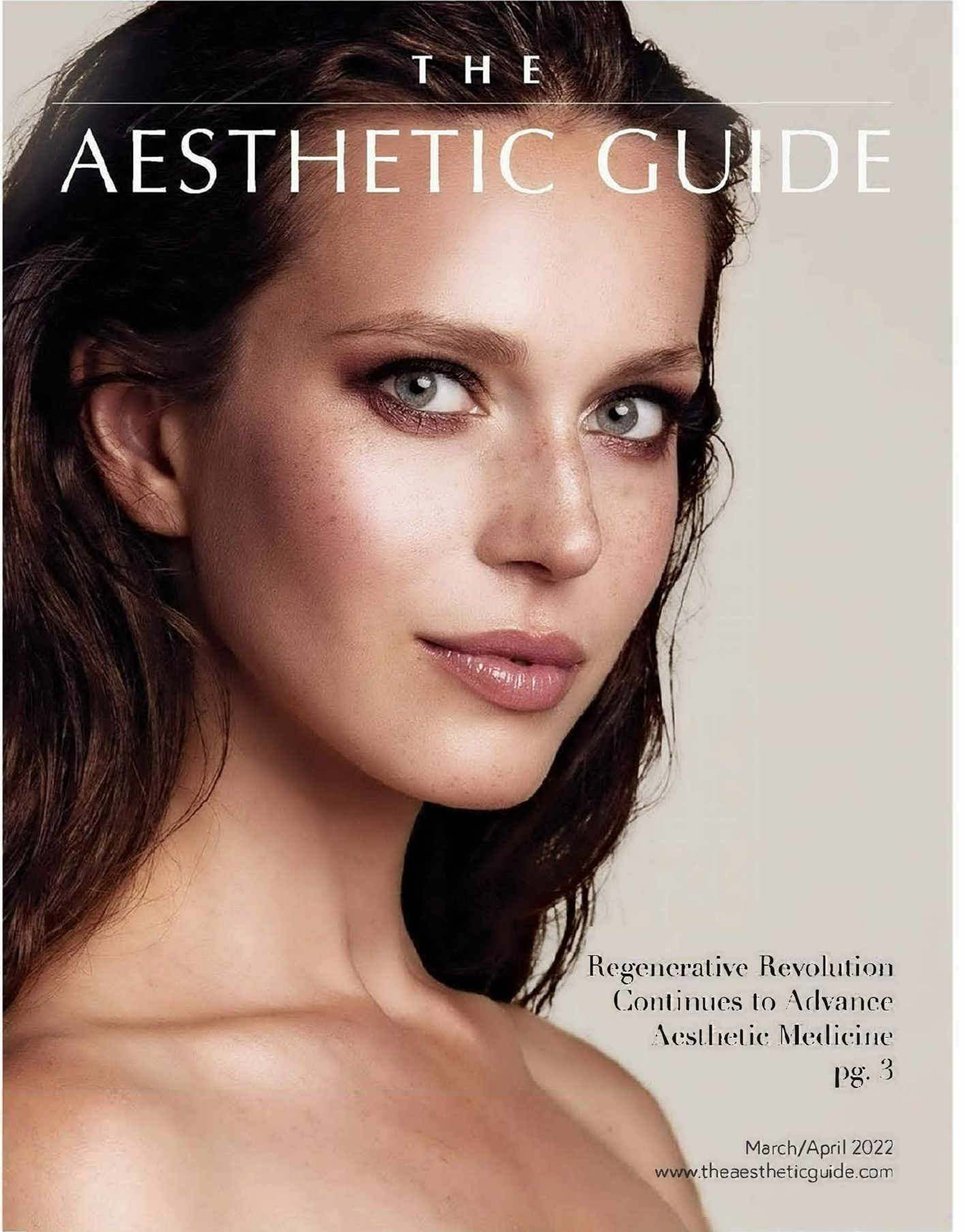




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Continues to Advance
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Leading Regenerative Therapies Creating a Paradigm Shift in Aesthetic Medicine

By Kevin A. Wilson, Contributing Editor

“Safe,” “effective minimally or non-invasive,” “leading-edge technology,” “research-based” and “hassle free” are all descriptors of what patients and practitioners want in aesthetic therapies. Regenerative aesthetics is where all this and more is a daily occurrence, and nowhere else is this more evident than with three key regenerative aesthetic solutions.

“We are in the midst of a paradigm shift in the aesthetics field and are witnessing and experiencing regenerative therapies doing what we first thought was only possible with invasive procedures, and the results are astounding,” said Chad Deal, MD, owner of Southern Surgical Arts, headquartered in Chattanooga, Tenn., with eight locations and growing. “We are approaching aesthetic medicine from multiple research vectors and redefining what we mean by words like ‘rejuvenation’ and ‘anti-aging.’” At Southern Surgical Arts, this involves our proven regenerative trifecta: latest-generation radiofrequency (RF) microneedling in Sylfirm X Ultimate Edition, the post-treatment powerhouse Exosome Regenerative Complex + powered by ExoSCRT, and the superior MIRACU PDO threads for both face and body. I am excited about these technologies and thrive on teaching and sharing these best-in-class techniques with other practitioners.”

Sylfirm X Ultimate Edition

Invented by JongJu Na, MD, PhD, Sylfirm X Ultimate Edition (manufactured by ViOL, Gyeonggi-do, South Korea) is the first and only dual wave RF microneedle system featuring pulse wave (PW) and continuous wave (CW) RF, penetrating as little as 300 microns into the skin’s surface. This radical approach to RF microneedling features eight different CW and PW bipolar RF delivery modes. Non-insulated bipolar microneedle RF electrodes uniformly treat the entire skin layer, optimizing potential global improvement, with safety and versatility supported by 22 publications.

Originally, Na and colleagues¹ performed *in vivo* treatment of micropig skin and *ex vivo* treatment of bovine liver tissue with microneedle RF, varying insertion depth and conduction time while noting tissue reactions among the settings via histology. Uninsulated needles and appropriate conduction times with minimal surface penetration were found by investigators to produce individual regions of thermal coagulation around each pointed needle tip, converging with nearby coagulation zones. This rapidly produced a pronounced effect at the surface and reduced treatment time to less than 20 minutes. Damage, but not destruction, of vascular tissue in the treatment area occurred, but the surrounding skin was preserved. This was termed the ‘Na Effect’ after its discoverer.

Sylfirm X’s RF energy can be modulated to penetrate between 300 microns to 4 mm to treat the epidermis, basal membranes and papillary dermis, enabling treatment of superficial blemishes to deeper structures, promoting color correction and collagen remodeling while utilizing a single tip. “Dr. Na is a mastermind, he didn’t just settle for good when developing an RF microneedling device, he designed the only RF microneedling device you will ever need,” claimed Renato Saltz, MD, director of Saltz Plastic Surgery (Park City and Salt Lake City, Utah). “It is a smarter device that works and delivers results. Sylfirm X is simple for staff to use, and one treatment tip covers from head to toe. Ergonomic in design, it features the standard traditional adjustable depths of CW but with a patented PW mode and 300-micron depth, harnessing the ‘Na Effect’ which is what really sets it apart from the pack and highlights why it is a leader.

“This device is a workhorse,” he continued. “The pulse wave mode targets abnormal vascular pigmentation, specifically scars, melasma, rosacea and post-inflammatory (CONTINUED ON PAGE 6)



Chad Deal, MD, FACS
Owner
Southern Surgical Arts
Chattanooga, TN



Renato Saltz, MD, FACS
Director
Saltz Plastic Surgery
Park City & Salt Lake City, UT



Richard Goldfarb, MD
Director
Center for Smart Lipo
Langhorne, PA



Gideon Kwok, DO
Co-Owner & Medical
Director
Skin Perfect
Brea, CA

THE AESTHETIC GUIDE

March/April 2022 • Volume 25 • Number 2

Features

- 34 Body Image Report
- 42 Hot Products in 2022
- 52 Vegas Cosmetic Surgery Preview
- 66 Regenerative Aesthetics Update
- 76 The Aesthetic Show Preview
- 96 AMWC Awards Finalists

Practice Management

- 90 Price Negotiating Strategies

Women in Aesthetics

- 92 Mara Shorr

Talent & Techniques

- 94 Nonsurgical Genioplasty with
Hyaluronic Acid

Directory

- 102 Aesthetic Company Directory

Comparison Charts

- 108 Dermal Fillers
- 109 Physician-Dispensed Topicals
- 110 Microneedling
- 112 Skin Rejuvenation
- 116 Fractional Technologies
- 118 Acne Tx Devices
- 120 Hair Removal
- 122 Vascular Technologies
- 124 Emerging Technologies
- 126 Body Shaping Technologies



Advertiser Index

Advallight	21
Aesthetic Multispecialty Society	105
The Aesthetic Show	89
Agnes Medical	61
Air-Tite Aesthetics	63
Alastin Skincare	26-27
AMWC Latin America	101
AnteAge	73
ASLMS	111
Benev	2
BTL Aesthetics	11
Candela	79
CAREstream America	51
Certified Aesthetic Practice Program	81
Clearskin Institute of Laser Aesthetics	47
CureVoya	71
Cutera	16-17
DEKA	41
Dp Derm	132
Entrepreneurial Strategy for Aesthetic Physicians	83
Epionce	57
Exocel Bio	131
Hironic	28-29
MTF Biologics	69
Miami Cosmetic Surgery	91
NassifMD	19
PDO MAX	15
Rohrer Aesthetics	55
Scientis U.S.	45
Sofwave	25
Sono Bello	49
Suneva	33
Taylor & Francis	107
Tentech	22-23
TSLMS / Music City Scale	115
Vegas Cosmetic Surgery	65
Viola Threads	75
Zero Gravity Skin	31

Supplemental Inserts:

BTL Aesthetics
 Certified Aesthetic Practice Program /
 Foundations of Advanced Injections
 Entrepreneurial Strategy for Aesthetic Physicians

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"What really separates Sylfirm X from other technologies, besides the PW and CW modes, is being able to see immediate skin tightening while the patient experiences little or no pain. This sold me on Sylfirm X."



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hyperpigmentation (PIH), whereas the continuous mode targets fine lines, wrinkles and skin tightening. This superior functionality gives me both peace of mind in knowing that I can treat all skin types effectively, but it also saves me time and offers my patients little to no pain or downtime. In my practice, I use the Sylfirm X to optimize my surgical results pre- and post-treatments."

Richard Goldfarb, MD, director of the Center for Smart Lipo in Langhorne, Pa. heartily agreed, "My patient demographic is anywhere from 21 to 70 years of age, and the needs of each are different and sometimes unexpected. The versatility of Sylfirm X Ultimate Edition improves my ability to treat a wider range of patients."

"What really separates Sylfirm X from other technologies, besides the PW and CW modes, is being able to see immediate skin tightening while the patient experiences little or no pain. This sold me on Sylfirm X," said Gideon Kwok, DO, co-owner and medical director of eight Skin Perfect medical clinics around southern California – clinics classified within the top 1% in the U.S.

"I needed a device that could allow me to do more, and better control the outcome. I didn't want an ordinary RF device," said Richard Jin, MD, PhD, director of RJ Clinical Institute and Cellum BioMedical (Mission Viejo and Temecula, Calif.). "My problem has been patients that need both pigmentation and skin laxity addressed, and my clinics see all different skin types, so I needed a device that could cater to that. Sylfirm X Ultimate Edition does more by providing me with a 300-micron depth for pain-free, no downtime treatments which encourage patient compliance. My patients are now able to come in consistently, allowing us to give them results in less time. Patients trust me with their treatment and it is my responsibility to offer them the best option available."

Softer, more selective coagulation can be had in the basal membrane and vascular structures

when targeting pigmentation and vascularity because of the device's unique PW mode, which targets abnormal small blood vessels while leaving surrounding tissue virtually unaffected; recovery is rapid. Ten studies have confirmed this efficacy and mechanism of action. "Sylfirm X provides next-level RF microneedling with both CW mode for tissue tightening, and PW mode which shows significant improvements in vascularity and melanin. This is something that I truly have seen the results for myself," said Raminder Saluja, MD, director of Saluja Cosmetic and Laser Center (Huntsville, N.C.).

"This is my go-to device," said Diane Duncan, MD, director of Plastic Surgical Associates (Fort Collins, Colo.). "It has replaced all other microneedling and RF devices in my practice. Patients report feeling no pain and love the fact that treatments don't involve downtime. For what this device does and for what it replaces, the price is a steal."

BENEV Exosome Regenerative Complex + powered by ExoSCRT

Reinvigorating the regenerative aesthetics market for skin and scalp, adipose-derived BENEV Exosome Regenerative Complex + features the same base collection of constituents as its predecessor, with additional peptides and coenzymes, plus twice the volume of exosomes to deliver more powerful results rapidly. They are ideal topical delivery agents because of their natural ability to penetrate the stratum corneum. The patented paraben free, steroid free, and hypoallergenic technologies and ingredients are clinically proven to rejuvenate and regenerate the skin and scalp. "Exosomes are a godsend! We now have something that we can do truly amazing things with. Really, when you dive into it the amount of collagen you can stimulate, the amount of elastin, the decrease in inflammation, it is so quick," Dr. Kwok said.

This dual action complex is absorbed quickly by skin, delivering the concentrated power of stem-cell-derived lyophilized exosomes,



Before and after treatment with Exosome Regenerative Complex +
Photos courtesy of Lauren Olson, PA-C

potent growth factors, peptides, coenzymes, minerals, hyaluronic acid, amino acids and vitamins. The exosome-based product was designed and co-developed by BENEV Company Inc., a U.S. FDA-registered manufacturing facility based in Southern California, and ExoCoBio (Seoul, South Korea), the fourth largest exosome research company and largest exosome GMP manufacturer in the world.*

The patented purification method separating and refining 0.1% pure exosomes from stem cell conditioned media, known as ExoSCRT, also lyophilizes it to maximize stability before freeze drying. Reconstitution is thus easy and predictable for a more stable, cost-effective post-treatment solution. "What most people don't understand is that it is highly cost prohibitive for most companies to lyophilize exosomes, thus the reason most companies sell exosomes that require

cryogenic freezing," explained Dr. Goldfarb. "Not all exosomes are created equal; you need to know where they come from, how they were purified including what they were tested for, and what studies have been done on them, along with the type of registration the products have. I use BENEV Exosomes for this reason. I know the quality and trust the product, which is registered with the FDA as a topical cosmetic solution and has both INCI and PCPC registration, not to mention the crucial

factor of cost. I have never seen this quality of an exosome product at the price they offer, it is unheard of."

Exosomes play a key role in the regenerative cascade, well beyond that seen with platelet-rich plasma (PRP) or growth factor concentrates, because they are responsible for cell-to-cell communication, according to Randy Miller, MD, medical director of Miller Plastic Surgery in Miami, Fla. "Exosomes are definitely the future of aesthetic and general medicine," he said. "Exosomes derived from stem cells activate the mechanisms we are looking to harness, and adipose tissue is the richest source available. With BENEV Exosome Regenerative Complex we see greater fibroblast production by 180% and neocollagenesis by around 300%, significantly beyond what one could achieve using something like PRP."



Before and after treatment with Exosome Regenerative Complex +
Photos courtesy of Lauren Olson, PA-C



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Medical Director
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TJ Tsay, MD, FACS
Director
Ageless MD
Tustin, CA



Suneel Chilukuri, MD, FACS
Director
Refresh Dermatology
Houston, TX

Thus, is it an easy-to-use post-treatment enhancer to decrease inflammation and treatment discomfort, reduce downtime and optimize outcomes. “We are excited to use the BENEV Exosomes for topical application after RF microneedling, not only for the ease of use, but also because of the adjunctive benefits to standard PRP that they bring along,” said Anna Petropoulos, MD, director of The New England Facial Cosmetic Surgery Center and Center for Classic Beauty (Boston, Mass.).

“BENEV Exosome Regenerative Complex + delivers a variety of more than 50 active components, including growth factors directly to cells in the treatment area using the very mechanisms of natural intercellular communication,” explained Dr. Jin. “This makes BENEV Exosome Regenerative Complex + the ultimate addition to the regenerative aesthetics armamentarium by itself, or supplementing any therapy. The potential applications across the entire field of medicine are staggering.”

BENEV Exosome Regenerative Complex is also uniquely stable enough for reconstitution at the time of use, according to J.D. McCoy, ND, medical director of Contour Medical (Gilbert, Ariz), making it a mainstay of his hair restoration protocol. “The product is powerful and aggressive, but still natural with clinically proven safety and efficacy. Its utility is impressive. You can use it as a stand-alone therapy, but it excels when added to your existing treatment protocols to improve healing, reduce recovery time and maximize onset of results. Anyone who doesn’t adopt this is missing out.”

MIRACU PDO Threads

MIRACU PDO Threads, manufactured by DongBang Medical Co. Ltd. (Sunghnam, Korea) – the largest PDO and cannula manufacturer in the world – are distributed exclusively by BENEV in North America. They are FDA-cleared for soft tissue approximation where an absorbable suture is appropriate. These threads offer tensile strength ten to twenty times greater than others, with sterile individual packaging. According to Dr. Duncan, “They received FDA approval for both their threads and insertion cannulas before launch, which appealed to me considerably as it reflects the care and extensive research and development that went into MIRACU PDO Threads.” As minimally invasive lifting modalities, these polydioxanone (PDO) absorbable threads uniquely induce a regenerative reaction in the



Before and one month after treatment with MIRACU PDO Threads
Photos courtesy of Michael Schreiber, DO

body, as well as simultaneously providing a sort of biodegradable scaffold.

According to Scott Callahan, PA-C, director of Dolce Vida (Trumbull, Conn.), MIRACU PDO Threads offer the most extensive and innovative threads portfolio in the industry. “Their Elastic Line and Elastic Meshfill threads put them light years ahead. With innovative designs and multiple sizes and gauges, you can create custom treatments to meet individual patient needs,” he expressed. “MIRACU includes 23 types of Barb threads, eight types of Volumizing Threads, 11 types of Smooth Threads, six types of Meso Needles, and 20 types of microcannulas.

“This means more options, better results and fewer insertions requiring less overall product with reduced treatment time and cost,” Mr. Callahan continued. “As leaders and pioneers in the PDO realm, who perform anywhere from 100 to 200 treatments per week, as well as teach such as I do during my Dolce Vida Symposiums, it is easy to see why MIRACU PDO threads stand at the forefront of this field. They have shifted what I am able to do in my practice and have provided me with another tool to create better outcomes.”

Elastic Line threads are manufactured via unique methods to provide a high polymer double coating, with an exclusive FCV cannula tip carefully positioned to reduce resistance from the fixing anchor during insertion to minimize scarring. The anchor itself maximizes fixation to the muscle to optimize lifting. For

Jason Emer, MD, director of Jason Emer MD (Beverly Hills, Calif.), this feature provides the best correction without ‘pushing’ skin tissue. “The shape of each deep cog hook is also designed for strong fixation and powerful lifting. Traditional molded cogs have shallower hooks and comparatively weak fixation,” he noted. “By far this is my favorite MIRACU thread, it is unlike any other thread on the market, giving the most lifting, tightening and collagen production that I have seen in any thread.”



Before and one month after treatment with MIRACU PDO Threads
Photos courtesy of Michael Schreiber, DO

Well-suited for volumization and rejuvenation, Elasty Meshfill threads feature a 16-line weave of mono threads creating, in effect, a hollow cylindrical mesh. This means a stronger, softer thread with greater elasticity than alternative mesh threads. This enhances the scaffolding function of the threads, according to Dr. Jin. “After insertion between the submuscular aponeurotic system (SMAS) and the dermis, it takes about two weeks for soft tissue to fill in the gaps created by the scaffold provided by Elasty Meshfill threads.”

Dr. Duncan uses Elasty Meshfill with autologous fat and fillers to occupy a particular niche in her armamentarium, and also uses Elasty Line threads. “I was searching for some kind of injectable implant for a few years before I found MIRACU PDO Threads. They offer outstanding, customizable correction when used for treatments on the face and body. I specifically use the Elasty Line and Forte threads when performing my signature Perky

Thread Lift for the breast area, as it provides the lift my patients are looking for without the downtime.”

In Dr. Goldfarb’s experience, the 16-line mono mesh thread, once implanted, reduces diffusion and migration when filler material is injected along the insertion vector for better results using less filler – a synergistic effect with fillers. “This is classic regenerative aesthetics,” he said. “The PDO threads stimulate collagen production in addition to any filler-related correction so when using this kind of protocol, we use less filler product but get up to 40% improvement in longevity of the outcomes. It reduces costs because we use less filler product and get a better, longer lasting result. You can augment the treatment further by adding PRP, and it is also a standout alternative to implanting larger volumes of filler in hard-to-treat locations.”

According to TJ Tsay, MD, director of Ageless MD (Tustin, Calif.), who is known for his creative use of MIRACU PDO Threads to achieve the natural yet filler-like outcomes, “MIRACU threads go well with other treatment modalities including fillers, toxins and energy-based devices. You can mix and match different threads and even use them when patients have had other threads previously.”

The BENEV name is becoming almost synonymous with regenerative aesthetics. “With three leading-edge products and continued development, BENEV is paving the way for others in the field of regenerative aesthetics,” said Suneel Chilukuri, MD, director of Refresh Dermatology (Houston, Texas). “It is our responsibility to offer patients nothing but the best. We need to work continuously and actively to gain the knowledge and skills needed to be the best, while becoming aware of new and emerging technologies that are reshaping aesthetics and integrate them into our practice. In doing so we will continue to raise the bar of excellence and continue to push companies such as BENEV to innovate and propel us into the future of aesthetics.”

Reference:

1. Na, J; Zheng, Z; Dannaker, C; et al. *Electromagnetic initiation and propagation of bipolar radiofrequency tissue reactions via invasive non-insulated microneedle electrodes. Sci Rep* 2015;5:16735.

*ExoCoBio is an equity investor of BENEV Company Inc.