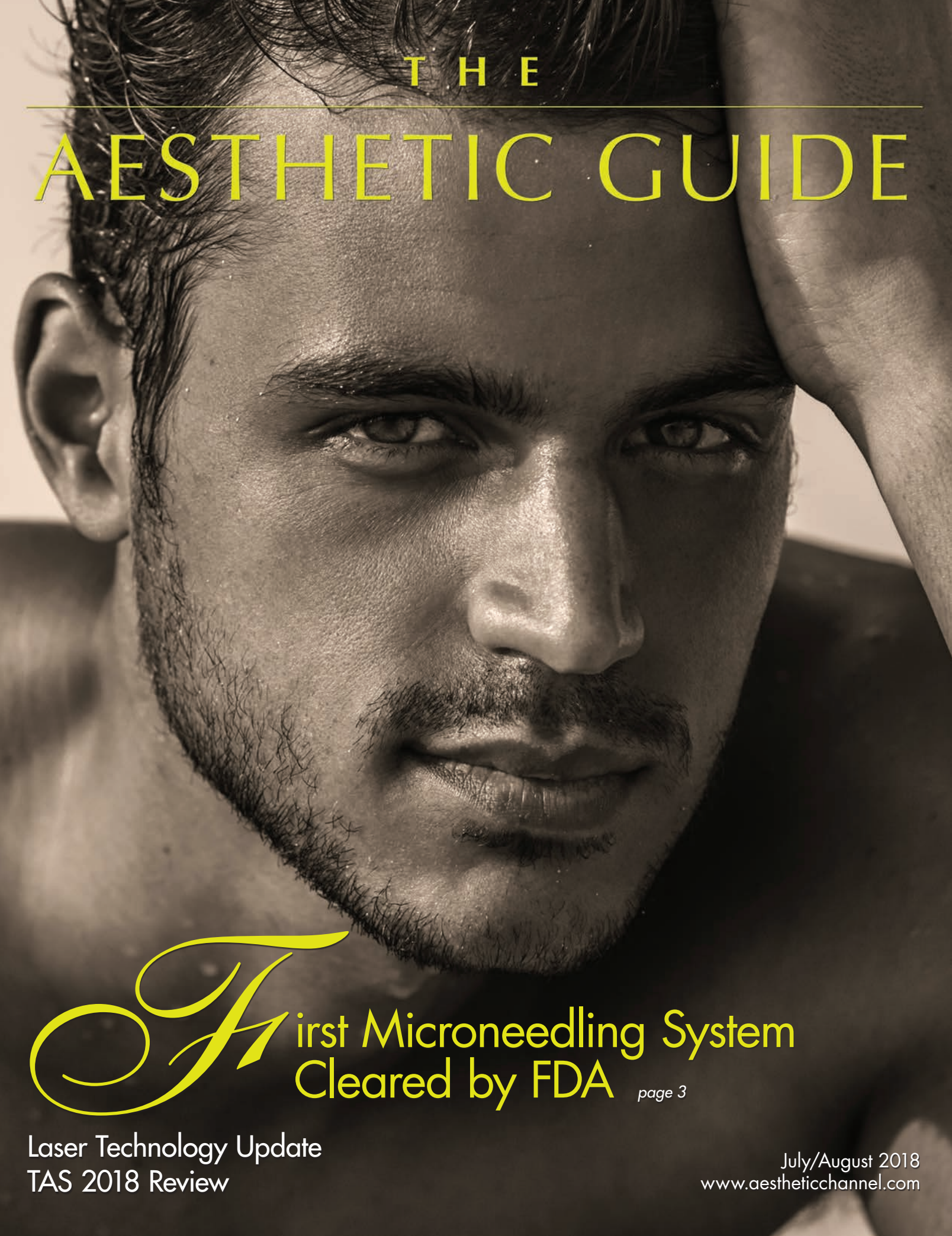

THE AESTHETIC GUIDE

First Microneedling System Cleared by FDA

page 3

Laser Technology Update
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FDA Clearance Puts SkinPen on Top

By Jeffrey Frentzen, Executive Editor

Microneedling has come of age in the medical aesthetic arena as SkinPen® from Bellus Medical (Addison, Texas) recently announced that it is the first and only microneedling system to receive a De Novo clearance as a Class II medical device by The Food and Drug Administration (FDA). This designation grants the company clearance and marketing authorization for the device, which is intended to improve the appearance of facial acne scars in adults aged 22 years or older. This clearance was based on the FDA's recently codified language regarding aesthetic uses of microneedling.

The bottom line for aesthetic practices: SkinPen is the first and only microneedling system to receive this type of clearance.

SkinPen has also set a new technological and safety standard for microneedling, offering minimally invasive, non-ablative options utilizing state-of-the-art skin rejuvenating technology. Employing straight needles that penetrate at a 90° angle, SkinPen creates hundreds of vertical microscopic channels in the dermis to trigger skin remodeling without causing scar tissue formation.

FDA Clearance Wins Physician Support

According to Mary Lupo, M.D., a dermatologic surgeon in New Orleans, La., "It is significant that SkinPen is the only microneedling product on the market that is cleared for use in both the U.S. and Europe. I was attracted to SkinPen because I know that the procedure has been scientifically proven for safety and efficacy. I appreciate the expense of such a process and the commitment to safe results."

As noted by Steven Dayan, M.D., a plastic and cosmetic surgeon in Chicago, Ill., "We had heard about SkinPen's development and were holding out for the FDA clearance. When it came, that gave us a boost and created a new initiative to get started with SkinPen."

Dr. Dayan added, "We do a lot of training and there has been a lot of interest from physicians about microneedling, mainly its efficacy and safety. With SkinPen and its FDA clearance, we were able to teach more about this type of approach. The device gets a ton of use in my practice between me and my aestheticians, medical assistants and PAs. They love it."

As reported by Joe Proctor, president & CEO of Bellus Medical, "The procedure has virtually no downtime and a very good adverse event profile. In fact, in our clinical study we had zero adverse events tied to the actual device. In addition, SkinPen is safe on all skin types."

As many aesthetic physicians have expressed interest in adopting microneedling, Mr. Proctor considers SkinPen to be a gateway product

Mary Lupo, M.D.
Dermatologist
New Orleans, LA

Steven Dayan, M.D.
Plastic Surgeon
Chicago, IL

Joe Proctor
President & CEO
Bellus Medical
Addison, TX

Thomas Hitchcock, Ph.D.
Acting Chief Science Officer
Bellus Medical
Addison, TX

SkinPen microneedling device

Skinfuse post-microneedling protocol

that would bring in new patients. "This is for the patient that comes into a clinic and asks, 'Can I get an aesthetic procedure that achieves real results and improves the look of my skin?' SkinPen is available by prescription only and is a Class II medical device. Both of these aspects protect the practice," he stated.

Dr. Dayan and his staff employ SkinPen on a daily basis. "We use it to treat facial acne scars much in the same way we have used dermabrasion in the past," he said. "SkinPen's mechanism of action is superior and the hardware is very well designed. In addition, the procedure is helped greatly by the topical hydrogel."

Skinfuse® Lift HG hydrogel, which is used to lubricate the skin as the pen is guided across the face, was integral to SkinPen's regulatory clearance, according to Thomas Hitchcock, Ph.D., acting chief science officer at Bellus Medical, who is also a geneticist and tissue engineer.

"The FDA cleared the hydrogel literally as part of the device," he stated. "Not only is the device cleared, but also the cartridge, the charging base, the plastic disposable sheath and the lubricant. All are confirmed as safe and effective parts of the SkinPen Precision System."

It was important to the FDA that Bellus Medical offered a device that would not cause foreign body reactions in patients, Dr. Hitchcock reported. "With other microneedling pens and devices, practitioners have tended to just pull various products off the shelves, such as cosmeceuticals and serums, thinking they could deliver these formulations into the skin and use them as a lubricant," he said. "The FDA is wary about this practice because these serums, etc., come with preservatives or synthetic molecules that are not intended for use on broken skin."

Conversely, SkinPen's water-based gel provides the glide needed to safely and securely perform a microneedling procedure without blocking the cartridge. Used to prevent the skin from drying out during and after treatment, Skinfuse Lift HG hydrogel is part of an effective protocol that is also non-cytotoxic, meaning that the gel is free of harmful ingredients that could affect cellular components.

Improved Outcomes with Skinfuse Post-Procedure Protocol

Bellus Medical's entire Skinfuse Post-Procedure Protocol is well-integrated into the SkinPen Precision System. This protocol introduces essential nutrients into skin cells following treatment, for optimization of the microneedling results for 90 days and longer. Importantly, Skinfuse contains no ingredients that could potentially hinder the skin's remodeling process, further enhancing outcomes.

The protocol consists of Skinfuse Purify Cleansing Complex, a pre- and post-microneedling skin cleaner; Skinfuse Rescue

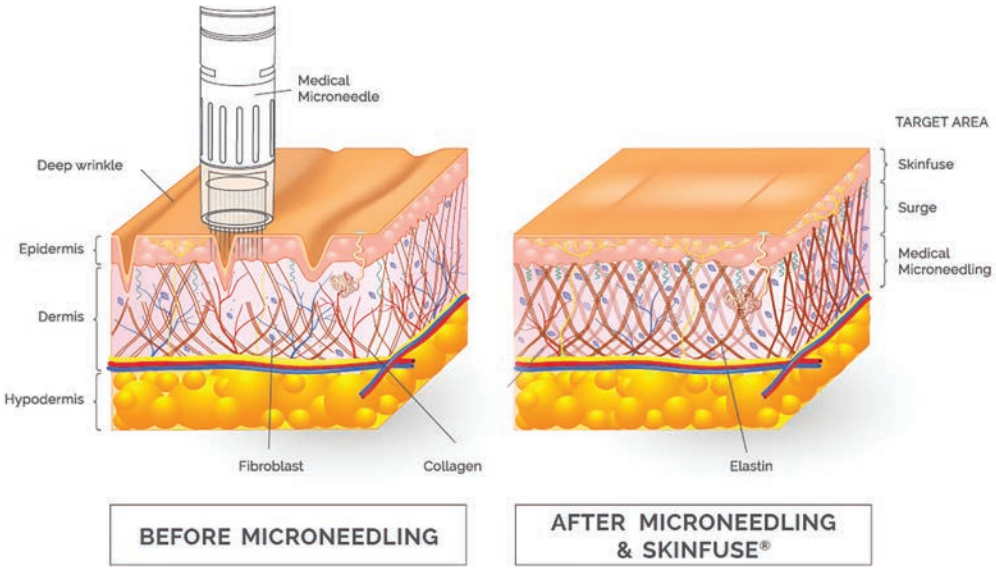
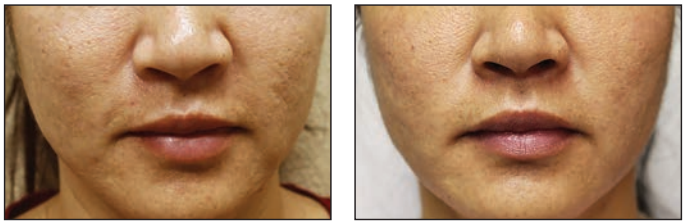
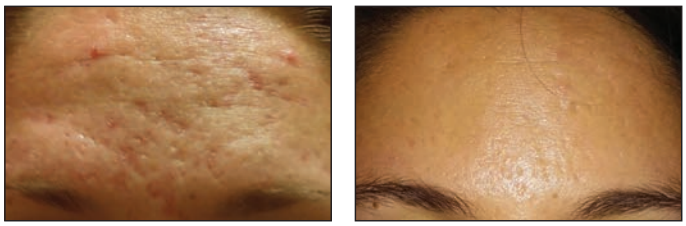


Image courtesy of Bellus Medical



Before and after three SkinPen procedures.
Courtesy of Christy Bunyan, L.A.



Before and after six SkinPen procedures
Courtesy of Cathy A. Presnick, L.A.

Calming Complex, a post-procedure gel that soothes the skin; Skinfuse Reclaim Hydrating Support, a nutrient-rich moisturizer formulation; Skinfuse Forfity Vita C Serum antioxidant; and the Skinfuse Shield Zinc Oxide 21% sunscreen.

In Dr. Lupo's experience, this integrated protocol provides what she characterizes as a consistent continuity between the system's modules. "There is high value in using the Skinfuse line as an adjunct to SkinPen therapy. Knowing these products have been specifically designed for use with this particular device further enhances my confidence in safe results," she said.

"My staff uses Skinfuse products quite a bit with SkinPen," Dr. Dayan stated. "However, I don't utilize Skinfuse as much because I tend to use SkinPen more aggressively."

Most aesthetic microneedling devices (including SkinPen) are electric-powered units that come with a series of piercing needles that are precision-set for causing micro-injuries in the skin up to certain depths. In the case of SkinPen, these needles create strategic dermal wounds that address facial acne scars.

The usual method of action for any microneedling device involves the operator "gliding" the needles across the skin, which pierce the skin at a prescribed depth. As a result, platelets release cytokines and growth factors that send signals to the body's immune system. Neutrophils (a type of white cell), and macrophages are sent in to disinfect the wounds, clear the debris, perform angiogenesis and kick off the granulation process, or the creation of new cellular and extracellular materials.

While many existing microneedling devices offer similar features, SkinPen was stringently evaluated as part of the clinical trials that led to FDA clearance.

Only System Validated for Safety

SkinPen rises above the competition not only with its FDA clearance, but also due to its advanced technology. "A lot of people don't realize that just because a device might function similarly doesn't make it equal," noted Dr. Hitchcock. "There is a lot of validation that goes into an FDA clearance, in which we basically had to show that we had taken the steps to ensure that all the different components of the device would be manufactured in a way that completely maintains safety, and there is a consistency of quality from batch to batch."

Technologically, SkinPen is notable for its Advanced Microneedle Cartridge. This single-use cartridge includes a proprietary safety feature that allows practitioners to perform a treatment knowing that fluids, serums and blood generated during the procedure do not penetrate the cartridge or enter the body of the device. This innovation significantly reduces the risk of cross contamination.

In addition, the system's motor shaft prevents suction and reduces the risk of broken capillaries. SkinPen's 14 sterile, 32-Gauge medical grade steel needles minimize epidermal damage while still properly initiating the tissue repair cascade.

"We have done validation studies to show that there are several mechanisms in place to mitigate against cross contamination," noted Dr. Hitchcock.

"Unfortunately, to save on costs, a lot of other devices don't go through any kind of validation. They just assume that people won't know the difference. That is not to say that other devices don't have their own mechanisms in place to guard against cross contamination. The difference between SkinPen and the others is that SkinPen has been cleared by the FDA; therefore, the safety features have been validated. It's an important distinction."

The clinical trials for SkinPen revealed no surprises in terms of safety, efficacy and usability. "It's not as though microneedling

has not been clinically assessed before," Dr. Hitchcock pointed out. "When we did the studies we pretty much saw what we expected to see in terms of outcomes, safety and so forth. The results were not outside the realm of the known, and were on par with what was expected."

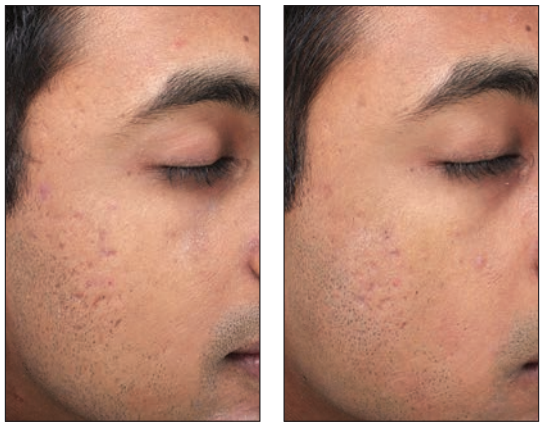
Prior to SkinPen's development, Mr. Proctor noted, "We quickly recognized that in the microneedling space there was a very real and significant opportunity for improvement in the basic technology. We saw cross contamination risks and the ways fluid, blood or serums could get into a device. There were unsafe protocols that needed to be improved greatly, and problems with companies promoting microneedling products that were not meant to be used on broken skin. That is why we did not just do a device and cartridge study for the FDA."

According to Mr. Proctor, when it became clear the company had met its development goals, the question arose; "Do we take that long path to get to FDA clearance? The answer was an easy yes. We were already raising the bar with manufacturing our technology for safety purposes. We conducted usability studies and looked at all the risks associated with this type of technology. We put mitigation strategies in place for all the safety risks. And then we validated that our mitigation strategies actually alleviated the risk," he expressed.

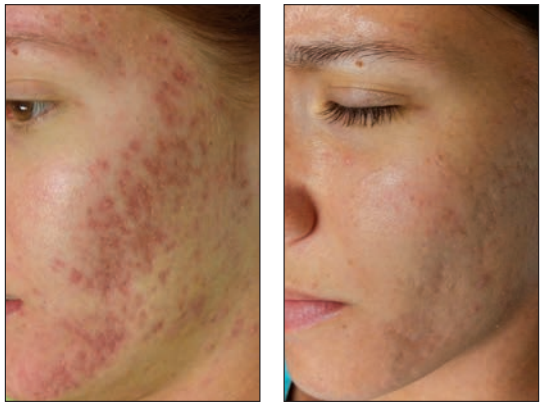
As luck would have it, the FDA released its new microneedling requirements when SkinPen's development was nearing completion. "It wasn't until after our development had already started that the FDA came out with their opinion on microneedling technologies," Mr. Proctor expressed. "Prior to SkinPen, there was no microneedling device that was legally on the market. We reached out to the FDA and told them what we were already doing, and asked, 'How does that line up with how you think about these technologies?' Through that interaction with the FDA, we filed for a review and continued to work through the development process."

Practices that employ SkinPen on a daily basis reap the benefits of this validation. "Patient satisfaction has been through the roof," said Dr. Dayan. "A 95% patient satisfaction rate is actually quite realistic, and that is what is really great about SkinPen."

Although a single treatment shows results, a series of treatments is typically recommended. "We use the FDA-cleared 'Bellus glide' approach and do three passes, typically in three directions," Dr. Lupo shared. "It is safe for all skin colors and all ages. It is also a very nice procedure for the budget conscious that don't mind doing a series of treatments."



27-year-old male before and after two SkinPen treatments
Courtesy of Linda Bui, L.A.



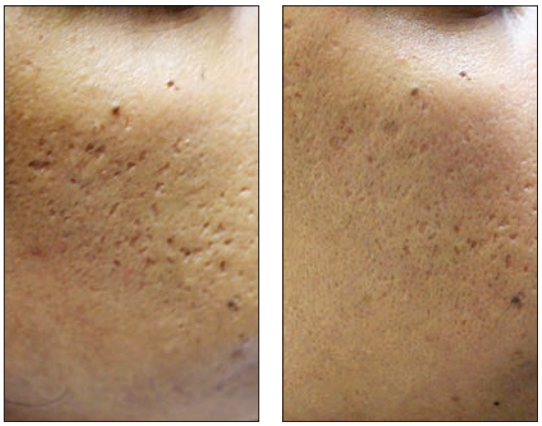
26-year-old female before and after six SkinPen procedures
Courtesy of Cathy A. Presnick, L.A.

SkinPen can also be the ideal adjunct to other aesthetic procedures, Dr. Dayan added. "In one notable case, I had performed a rhinoplasty on a woman who had acne scars on her nostrils. She got an alar base reduction to fix the size of the nostrils, which were disproportionally enlarged relative to the nasal tip and the position of the eyes. We then used SkinPen on those scars and it was incredible how much better her face looked after a single treatment. You can obtain really good results after a single treatment, but I like to do additional treatments if I can, just to be thorough."

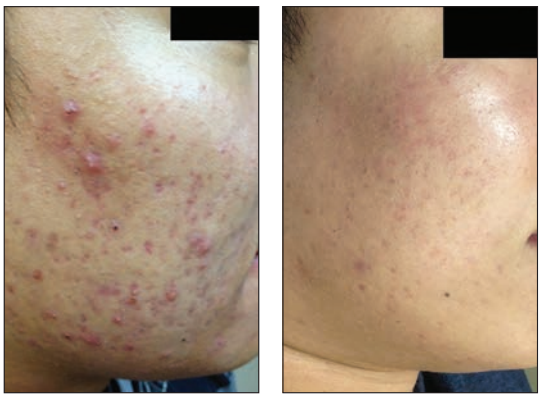
Award-Winning Innovation

Dr. Lupo, who employs SkinPen on acne scars in patients with skin of color, agreed that patient satisfaction has been good. "They like the ease of doing the treatment, the short recovery and the results," she said. "In addition, the return on investment (ROI) is very high since the cost is so much lower than most energy-based devices and the disposables are kept to a reasonable cost."

Likewise, Dr. Dayan has tracked good ROI for SkinPen. "This is because using SkinPen doesn't cost me a lot of money. For instance, the consumable costs are very low, which is a great benefit. I can't really say that about most devices, such as lasers, where the capital equipment costs are high," he said.



38-year-old female before and after five SkinPen procedures
Courtesy of Christy Matter, M.D.



26-year-old male before and after three SkinPen procedures
Courtesy of Elizabeth Steigner, M.A.

Mr. Proctor describes adopting SkinPen in a modern practice as a "Win-win-win. Regarding ROI, rarely do you have a deal where the manufacturing company can make money, the practice can make money, and patients feel like it is a really good value."

Bellus Medical not only sells and supports SkinPen, it actively gets involved in helping the practice grow. "That's the only way the collaborative business model works," Mr. Proctor indicated.

"We help promote our customers' practices and put tools in place that allow them to grow, as well as implement business strategies to help them scale," he explained. "For instance, SkinPen is a gateway product that can bring new patients to the practice. We also help practices manage their reputation and become recognized as experts in this space, as well as help them convert patients. We offer solutions for those business partnerships," he said.

"Our goals are to enhance the patient experience by providing innovation in technology, followed by excellent customer service and high ROI for the practice," Mr. Proctor continued. "With the SkinPen procedure, a practice is able to make a significant profit margin. When you line up the results with other procedures and devices in the space, figure in the downtime and safety profile, as well as the economics of implementing SkinPen, both the patient and the practice get an incredible value."

In fact, the company's strong push for FDA clearance, commitment to technological advancement and collaborative business model, all contributed to Mr. Proctor winning the TAG! You're IT! Award for non-physician innovator of the year at The Aesthetic Show in July 2018.

Physicians agree that SkinPen and its developer have brought a lot to the table in an extremely competitive marketplace. "I'm impressed with this very professional company, its high-grade disposables and support team," said Dr. Lupo.

"Bellus Medical is a great company to work with, no doubt about that," stated Dr. Dayan. "As a physician, you want to work with a firm that has put in the time, energy and effort to work with the FDA. It says a lot." ■

For more information about SkinPen's FDA clearance, please see: https://www.federalregister.gov/documents/2018/06/08/2018-12335/medical-devices-general-and-plastic-surgery-devices-classification-of-the-microneedling-device-for.