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Publication: Groundbreaking Minimally Invasive Helium Plasma/RF Device Contracts
Tissue

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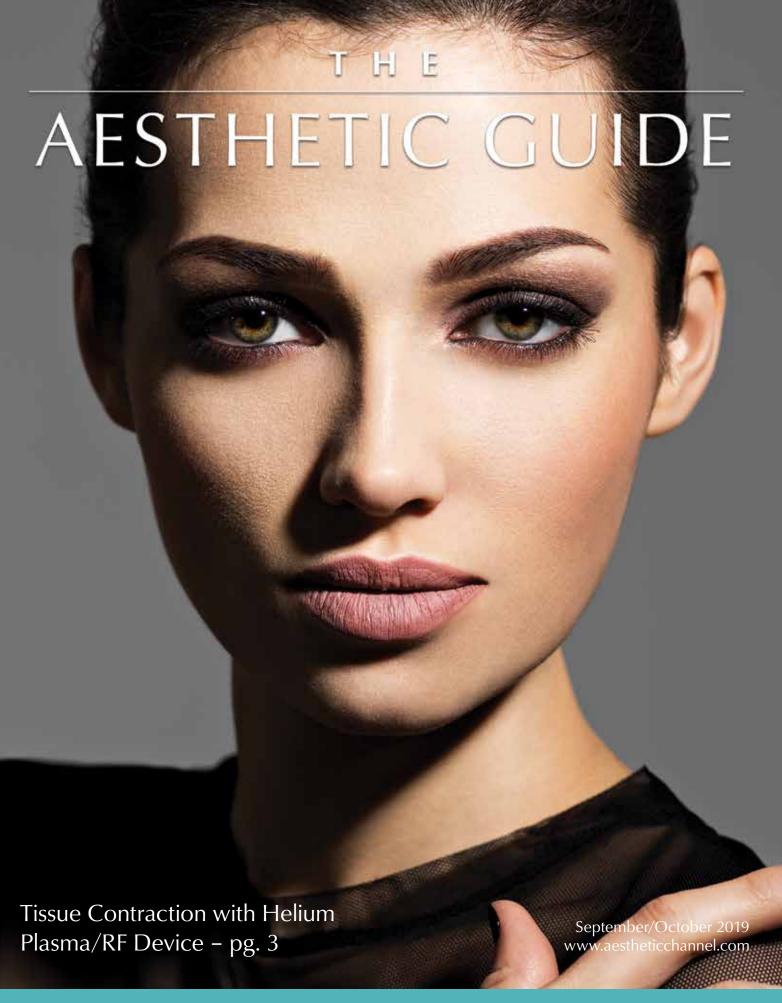
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Images in this article are examples of the Renuvion device used as a tool for coagulation¹ resulting in tissue contraction². As with any procedure, individual results may vary.



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Groundbreaking Minimally Invasive Helium Plasma/RF Device Contracts Tissue

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Renuvion cosmetic technology from Apyx Medical (Clearwater, Fla.) stands out as a truly unique modality in a sea of supposed novelties. While it harnesses heat to contract tissue, Renuvion delivers helium plasma and a proprietary form of radiofrequency (RF) energy subcutaneously. This minimally invasive technology provides heating in two ways: direct contact between the plasma and tissue, and the RF current flowing through the plasma to cause additional heating via the Joule heating effect. Experts say the results of Renuvion are unlike those achieved by any other device.

According to Diane I. Duncan, MD, a plastic surgeon in Fort Collins, Colo., who has considerable experience with Renuvion, and has written extensively on the subject, the helium gas is converted into plasma at the end of the handpiece. The device is FDA cleared for cutting, coagulation and ablation of soft tissue. During use, the plasma couples with the tissue and delivers its energy, also serving as a conduit though which the proprietary RF energy flows and provides additional heating of the tissue.

"The combined plasma and RF energy is selectively taken up by lax, low impedance collagen," Dr. Duncan explained. "Nearby fibrous septae are rapidly heated to 85° C in about 0.044 seconds. When heated, these fibro-septal structures coagulate and contract to become a high impedance structure, causing the plasma beam to seek new low-impedance structures. Rapid cooling follows.

"Instant collagen fiber contractions of about 50% occur at each location," Dr. Duncan continued. "In a larger treatment area, the collection of spot-treated areas creates an overall soft tissue contraction effect. This is essentially a selective instant tissue heating device, as opposed to traditional bulk heating devices, which heat all tissue in the cannula location. This means that the heat goes exactly where it is supposed to, and the effect is specific."

"Due to this rapid heating and near instantaneous cooling effect, you can create specific areas of high temperature exactly

where it is needed," said Brian Kinney, MD, a plastic surgeon in Beverly Hills, Calif. "However, nearby tissue remains cool and if you touch the overlying skin, it also remains cool. This increases the margin of safety significantly."

Renuvion fills the niche between excisional tightening of skin and less aggressive non- or minimally invasive modalities such as lasers, which tighten only surface skin," said Paul Ruff, MD, a plastic surgeon in Washington, D.C., who has treated nearly 400 patients with Renuvion.

"Risk, recovery and healing from surgery is significant and some people don't want that, but surface skin tightening isn't enough for those with more severe laxity," Dr. Ruff pointed out. "We don't get the full results seen with excisional surgery. However, the downside of surgery is that the reduction in laxity comes with the baggage of additional risk and downtime, the difficult balance of tension versus blood supply to achieve the best endpoint possible, and the excision scar.

"The tissue contraction effect of Renuvion is unlike anything else out there, combining two interesting ways to treat underlying collagen," Dr. Ruff continued. "The lower face and neck, arms, inner thighs and abdomen seem to respond extremely well. We get great results – maybe 50% to 70% of what excisional surgery will provide, but we don't disrupt blood supply, the underlying architecture remains intact, an anatomically pleasing appearance is maintained, and there are only a few small puncture wounds which heal beautifully."

Physicians are really impressed by what is possible with Renuvion. "What we're seeing is tissue contraction at multiple levels," said Edward M. Zimmerman, MD, director of Aesthetic Revolution Las Vegas (Las Vegas, Nev.).

"We achieve contraction of the fascia covering of the muscle, the fibrous septal network and just below the dermis, for a global contraction, versus the bipolar RF technology that goes just under and then on top of the skin," Dr. Zimmerman expressed. "That treatment tightens the skin, but it will only tighten so much and will become lax within a year. Conversely, Renuvion achieves lasting contraction you just can't get with superficial skin tightening. So, having a technology like Renuvion, where we get contraction of the underlying tissue without cutting, is amazing."

The safety profile is very favorable. "We get tissue contraction and improvements in collagen structure over time. Results are even better one year out, and there's minimal chance of burning or scarring," Dr. Duncan stated.

In addition, Dr. Duncan pointed out that it is important to understand that the RF energy effect from various devices can be different. "It is not just about power, but waveform," she elaborated. "Renuvion's current is an order of magnitude lower than





This 40-year-old mother received ultrasonic liposuction to remove 150 cc of fat from her abdominal area followed by subdermal Renuvion treatment to her entire abdomen. Patient is shown 31 weeks after ultrasonic liposuction and Renuvion procedures.

Photos courtesy of Vaishali Doolabh, MD





After undergoing Bariatric surgery this 32-year-old female received liposuction to remove 600 cc of fat from her arms followed by subdermal Renuvion treatment to the anterior and posterior arms. Patient is shown six weeks after liposuction and Renuvion procedures.

Photos courtesy of David Melniczek, MD

that of regular monopolar and bipolar RF devices so it doesn't penetrate as deeply. Treatment of tissue raises its impedance, so the beam no longer prefers that region and it seeks untreated tissue. This automatic selectivity renders overtreatment unlikely."

One may, however, treat with additional passes at different depths, Dr. Duncan added. "I like to treat deeply first, just above the fascial layer, and then move toward the surface. I always try to stay at least 5 mm below skin in the fatty layer so you don't damage the youthful look of the skin. You don't want to scrape the underside of the dermis, as this may create weak areas or superficial depressions."

A minor challenge is the clinical endpoint. For example, typical endpoints such as erythema or tissue warmth do not occur with Renuvion. "The speed of the application, number of passes in a region and the power settings, are the factors that determine optimal treatment," Dr. Duncan noted. "The speed of application should always be at 1 cm/sec and the general guidance is to use between 60% and 80% power, 1.5 – 3 L/min of helium flow and between three to six passes per treatment area."

The onset of contraction is rapid. "You literally see visible contraction the next day," Dr. Duncan reported. "You just don't see that with other devices; that kind of outcome is rare in this business." And, compared with surgery, the downtime is also minimal – days vs. weeks.

"Another key to great outcomes is the use of compression garments." Dr. Duncan stated. "We firmly believe that compression garments help to properly mold the tissue post-procedure. We recommend patients wear their garment for six weeks, but many patients choose to wear it longer."

Another tip for success, according to Dr. Zimmerman, is proper management of the helium gas. "Always ensure you have multiple incision sites and that the tissue is well dissected between these sites. This will ensure the excess gas can easily escape the subcutaneous area. Sometimes you have a small subcutaneous gas pocket that takes a week or two to subside. These usually resolve without issue, but we make patients aware of this possibility and always take steps after the procedure to ensure we remove as much of the gas as possible, such as massaging the gas toward the incision sites and even drawing out the gas."

Contraindications for Renuvion are the same as standard RF devices, according to Dr. Ruff. "For example, we avoid treating

patients with implanted electronic devices such as pacemakers. In addition, patients with collagen or autoimmune diseases, whose inflammatory response isn't normal, won't benefit as much because some of the result is dependent on that inflammatory response, so proceed with caution. Those with extreme laxity due to weight loss would not be ideal candidates, nor would people with unrealistic expectations, which is the case with any procedure."

Dr. Duncan first explored Renuvion as an alternative to competing monopolar or bipolar RF technologies, which work, but can be tiresome to use. "When you have a run of 6'4" men wanting their torso treated in one day, it is time consuming and tiring," she shared.

"Conversely, Renuvion doesn't need to raise the temperature of the entire area to a certain level and maintain it for X minutes to achieve endpoint erythema and temperature," Dr. Duncan pointed out. "Instead, you make several passes using a few small ports in the skin and Renuvion's unique mechanism of action does the work for you. It is also much faster, about two-thirds the time versus traditional RF heating devices. As a business owner, you save time, and when time is money, reducing things like patient time under anesthesia or staff overtime is tremendous. Plus, you're not exhausted at the end of the day."

In Dr. Kinney's opinion, Renuvion is an excellent tool unlike any other, with specific obvious applications. "Renuvion is great as a stand-alone procedure, but it is often used in conjunction with an open procedure or liposuction, because it is a nice adjunct to those," Dr. Kinney highlighted.

"After liposuction, Renuvion can provide additional contraction with natural improvement of the contour. While liposuction provides some skin contraction, Renuvion helps us achieve a better balance between natural surface contraction and subsurface tissue contraction," Dr. Ruff said. "However, the primary effect of Renuvion is contracting the subcutaneous collagen, which responds quickly to this device, thus Renuvion can provide an excellent effect by itself."

Dr. Ruff, who initially began using the device as an adjunct to liposuction, has used it more extensively as a stand-alone treatment over the last year.

"The patient experience will be different depending on their case. If it is part of a surgical procedure the patient will experience the same recovery and downtime, but with a better overall outcome because of the addition of Renuvion," he noted.

"Renuvion's unique mechanism of action does the work for you. It is also much faster, about two-thirds the time versus traditional RF heating devices."



This 69-year-old female received liposuction to remove 150 cc of fat from her arms followed by subdermal Renuvion treatment to her arms. Patient is shown four weeks after liposuction and Renuvion procedures.

Photos courtesy of Terry Restivo, DO





This 53-year-old female received liposuction to remove 1,100 cc of fat from her legs followed by subdermal Renuvion treatment to the anterior and posterior thighs. Patient is shown five weeks after liposuction and Renuvion procedures.

Photos courtesy of Melinda Lacerna, MD

"It sets you apart from competitors because of the unique tissue contraction result from either standalone treatment, or as a complement to any of the minimally invasive, invasive or non-invasive procedures that you may perform."





This 54-year-old female received ultrasonic liposuction followed by subdermal Renuvion treatment on her jowls and neck. Patient is shown two weeks after ultrasonic liposuction and Renuvion procedures.

Photos courtesy of Paul G. Ruff, MD





This 51-year-old male received vaser liposuction to remove 100 mL of fat from his neck followed by subdermal Renuvion treatment on his jowls and neck. Patient is shown four weeks after Vaser liposuction and Renuvion procedures.

Photos courtesy of Grant Hamlet, MD

"Recently I treated a fit, healthy woman in her 50s with just Renuvion. She experienced the procedure completely awake under local anesthesia via small incision points with pre-tunneling; the procedure was trouble free," Dr. Ruff recounted. "She went home, was a little fatigued later, and needed only some acetaminophen the next day for soreness. This is pretty typical. We do like our patients to use compression garments for two to six weeks, and they can return to exercise or activity within three to five days."

In Dr. Kinney's experience, Renuvion is excellent for use with other procedures because of the niche it fills. "The plasma component brings a new level of technology to the cosmetic market. By nature of the physics of Renuvion, the energy seeks and contracts the target tissue. This makes it an obvious adjunct to liposuction of any kind, but it also works well with other minimally invasive modalities," he said. "The holy grail is a device that gives the dermatologist, or other specialist, a great minimally invasive result, while providing the plastic surgeon with an alternative option, one that works well by itself or with more aggressive or invasive options. Renuvion is awfully close to this holy grail device."

According to Leif Rogers, MD, a plastic surgeon in Beverly Hills, Renuvion is a great practice builder and friendly to new users. "It is solid state equipment, has a very reasonable startup time and the device is very easy to use," he commented. "Most importantly, it sets you apart from competitors because of the unique tissue contraction result from either stand-alone treatment, or as a complement to any of the minimally invasive, invasive or non-invasive procedures that you may perform."

Dr. Rogers uses the device most often to maximize liposuction results. "Renuvion does a great job of taking up post-liposuction laxity and improving overall contraction because it contracts the fibrous septae, which contributes greatly to the overall appearance of laxity. Also, you can use the same ports for the Renuvion device that you used for the liposuction so you're not having to do extra work or create additional incisions unless you're doing a very large area where the distance greatly exceeds the length of the Renuvion cannula."

"The fact that you can treat multiple areas is a big plus," Dr. Zimmerman expressed. "Instead of treating a single area, you contract tissue all around and it gives you that reduction you can actually see, especially in the problem area. And, it is fairly





This 38-year-old female received liposuction to remove 25 cc of fat from her neck followed by subdermal Renuvion treatment on her neck and jowls. Patient is shown six months after liposuction and Renuvion procedures.

Photos courtesy of Justin Yovino, MD

easy. With other technologies it would take a lot of time and energy to get anywhere near the kind of result I see with Renuvion because you don't usually treat—and patients don't want to pay for—the non-problem areas." The relatively long cannula makes this possible. "To treat so much with lasers or superficial RF would take hours, especially for larger areas."

According to Dr. Zimmerman the ideal patient has youthful tissue with good thickness and some elastin, but it could also be an early senior who doesn't want surgery and who, depending on their tissue quality, can expect at least 30% improvement. "The result with Renuvion will look natural without scarring. I can artfully hide the small incisions knowing that it will take several months to see the full result. The imperceptibly natural look of the result is a big part of the outcome, and you won't always get that natural look with surgery, especially to a trained eye."

"I use Renuvion for a lot of body areas, but it is great for necks," said Dr. Duncan. "Not many modalities do a consistently great job on the neck. If you have a younger patient who is a little overweight, or has genetic double chin, they might get injection lipolysis elsewhere, but a little local liposuction and Renuvion is so much better and less painful. You get eradication of the double chin plus get a more distinct jawline. Downtime is minimal at most. We have such minor bruising and swelling that you can go back to work the next day, although I do not recommend it."

"I also like Renuvion for bra rolls and flanks," she remarked. "In the case of one patient, her husband didn't want her to spend the money for the procedure, which then creates an inherent demand for a perfect outcome. The patient had a flawless result in the bra roll area. You could surgically address a challenging

area like that, but nobody wants the scar. The Renuvion device gives us a new approach to a lot of similar cases where we can avoid excisional surgery."

According to Dr. Zimmerman, the DocMatter website (www.docmatter.com), where doctors post questions and information about their treatment, has been helping to push the technology forward rapidly. "While the service is independent of Apyx Medical, the technology is definitely benefitting from this interaction. When you post a question or case information, dozens of practitioners can respond with tips, data, etc.," he stated. "In this way, we are all helping each other with the best settings, as well as pre-op and post-op care."

And, as Apyx Medical works closely with its physician partners to refine and improve their product lines, new developments are in the works for Renuvion. "There is a lot of potential for Renuvion and the current improvements being developed will greatly enhance the technology," said Dr. Zimmerman. "That is all I can say about it."

"I suspect this will be adopted widely as we continue to get the word out there. It provides a unique result by itself or as an adjunctive procedure, with an excellent safety profile," Dr. Rogers said.

"We still don't understand the energy enough to achieve 100% of a surgical result with just this technology, but I believe the distance to that, from where we are right now, may be surprisingly short," Dr. Ruff asserted.

Editor's note: Renuvion has received a general clearance from FDA, but is not cleared for any specific anatomical location, and as with any electrosurgical device, there are inherent risks (see product instructions for details).