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INDICATIONS FOR USE & INTENDED USE DISCLOSURES

- The Renuvion[®] Dermal System is an electrosurgical device for dermatological procedures for the treatment of moderate to severe wrinkles and rhytides, limited to patients with Fitzpatrick skin types I, II or III. The treatment is achieved through controlled heating of the outer layers of the skin so that part or all of the epidermis becomes non-viable and there is controlled thermal modification to the underlying dermis.
- Apyx Medical wants to present you with current scientific discourse. Specific usage outside of the cleared indications may not be safe or effective.

RISKS:

 Risks associated with the use of the Renuvion Dermal System include but are not limited to hypertrophic scarring, milia/acne, telangiectasia (spider veins), skin discoloration/ hypopigmentation, dormant infection reactivation, infection, bruising or bleeding. Warning: Application of more than one treatment pass in the perioral area, on the forehead, and along the jawline has been associated with hypertrophic scarring.

As with any procedure, individual results may vary. As with all energy devices there are inherent risks associated with its use, refer to the IFU for further information.

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ADVANCES IN COSMETIC SURGERY

Plasma Energy Skin Rejuvenation

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KEYWORDS

- Cold atmospheric plasma
 Nitrogen plasma skin regeneration
 Helium plasma skin regeneration
- Radiofrequency energy
 Radiofrequency bridge

KEY POINTS

- Energy-based skin rejuvenation has, like other forms of aesthetic treatments, the capability of achieving desirable end results.
- These end results must be balanced with the degree and duration of morbidity, which affects recovery from treatment.
- After the Food and Drug Administration approval process, the settings and protocols for newly released devices are not always at the optimal settings due to lack of clinical experience with a new device.
- In some new technology introductions, the settings may be lower than what eventually will be determined to be more optimal.
- In some new devices, the setting may involve more energy transfer than is necessary for satisfactory treatment.

INTRODUCTION

This article discusses the basic science associated with plasma energy-based resurfacing of the skin and my experience, and that of my colleagues, in the introduction of this exciting technology with a potential new indication. For marketing purposes, the Food and Drug Administration (FDA) restricts claims of rhytid reduction unless approved in specific study. The current status of the Renuvion/J-Plasma (Apyx Medical, Clearwater, Florida) technology lacks a specific indication for wrinkle reduction and a current investigational device exemption study is in progress so that the company can market the device for rhytid reduction.

Plasma skin rejuvenation is a relatively new technology introduced in this millennium and is classified as an energy-based skin rejuvenation technique. Nitrogen plasma skin rejuvenation as well as saline-mediated devices were introduced approximately 10 years to 15 years ago, combining an electrical current initiating the ionization of some substrate (usually a noble gas), which results in the generation of ionized plasma. The degree of

ionization of the substrate (usually a noble gas) distinguishes the plasma as either hot (high ionization) or cold/cool (low ionization). The use of the term, cool heli*um plasma*, is a misnomer because all plasmas have high temperatures, some higher than others, hence the use of the terms, cold/cool versus hot. The newest addition to plasma generators utilizes helium and radiofrequency (RF) energy to activate helium gas delivering thermal energy for skin rejuvenation in a bimodal fashion with direct heating of the skin's surface created by the flow of ionized and un-ionized helium gas as well as current directed or Joule heating of dermal tissue created by the flow of RF current from the treatment tip to the skin/dermis in the flow of ionized helium. The helium plasma generator (RF-HeP) initially developed operated at low level of total Watts, and grounding the patient was unnecessary. The recent generators require patient grounding. The interaction of the RF-HeP is known as coupling and has different characteristics than traditional Joule or resistive heating. This feature is more significant in subdermal applications of RF-HeP.

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