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Publication Information

Abstract Title: Optimizing Tissue Interaction with Helium Driven Plasma plus Radiofrequency using a Porcine Model

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Author: Diane I. Duncan, MD

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FINANCIAL DISCLOSURES

Diane Duncan is a Medical Advisory Board member, consultant, and grant recipient with Apyx Medical and receives compensation in the form of Apyx stock and hourly compensation.

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- Apyx Medical wants to present you with current scientific discourse. Specific usage outside of the general cleared indication may not be safe or effective. Renuvion/J-Plasma has received a general clearance and has not been determined to be safe or effective for use in any specific indication or anatomical location including skin tightening indication referenced in this article.
- Apyx Medical manufactures and owns the Renuvion/J-Plasma technology discussed in this article.

RISKS: Risk associated with the use of the Renuvion technology may include unintended burns (deep or superficial), pneumothorax, scars, temporary or permanent nerve injury, pain, discomfort, gas buildup resulting in temporary and transient crepitus or pain, infection, hematoma, seroma; asymmetry and/or unacceptable cosmetic result. There may be additional risks associated with the use of other devices along with Renuvion and there may be an increased risk for patients who have undergone prior surgical or aesthetic procedures in the treatment area. 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.

INTENDED USE DISCLOSURE: The Renuvion®/J-Plasma® Precise Open Handpiece is intended to be used with compatible J-Plasma electrosurgical generators for the delivery of radiofrequency energy and/or helium plasma for cutting, coagulation and ablation of soft tissue during open surgical procedures. The Renuvion®/J-Plasma® Precise & Precise Open® Handpieces are compatible with electrosurgical Generators BVX-200H, and BVX-200P. Refer to the Instructions for Use for the currently approved or cleared indications.

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Location: 2019 American Society for Laser Medicine and Surgery Annual Conference

Date: 30 Mar 2019

Presenter: Diane Duncan, MD

Abstract:

Background: A study of a helium plasma radiofrequency energy device for the coagulation of subdermal tissue was conducted in a live porcine model. The purpose of the study was to determine the impact of multiple treatment variables on internal and external tissue temperatures with the intent of establishing a range of optimal device settings.

Study Design/Materials and Methods: Various combinations of device power settings (40%, 60%, and 80%), helium flow rates (1 LPM, 2 LPM, and 4LPM), and number of passes with the device (3 and 6) were evaluated in a live porcine model (female domestic cross pig). To mimic clinical conditions, a simulated liposuction procedure, including infiltration with Klein solution, was performed prior to treatment with the helium plasma device. Following the simulated liposuction procedure, the helium plasma device was used to treat 18 separate areas. Visualization windows were created to allow for capture of temperature using a high-resolution Forward Looking Infrared (FLIR) camera (FLIR A615). Internal and external tissue temperatures were measured during tissue treatment.

Results: Device power settings ranging from 60% to 80% provide optimal internal temperatures for soft tissue coagulation and collagen contraction. There was no significant trend between helium flow rate and temperatures. The maximum change in external tissue temperature after 6 passes was less than 4°C, meaning that skin temperature would not go beyond 41°C assuming a starting temperature of 37°C (body temperature).

Conclusion: Based on the results of this study, device power settings ranging from 60% to 80% power and a helium flow rate setting of 2LPM was determined to be appropriate due to clinical performance and ease of gas management at these settings.