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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.

The following document may only be disseminated with this disclaimer cover page attached.

The Ultralift

Ultrasound and Energy-Based Facelifting



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KEYWORDS

- Facelift • Energy-based devices • Deep cervicoplasty • Vaser • Facelite • Renuvion • Skin tightening
- Lipolysis

KEY POINTS

- Tesla Facelifting is the process of utilizing energy devices as surgical tools during rhytidectomy and neck lifting.
- Devices used for Tesla Face and Neck lifting include fiberlasers, Radiofrequency devices, High frequency Ultrasound and Plasma energy devices.
- Advantage of Tesla face and neck lifting include better visualization for surgical intervention due to reduced bleeding, better access to hard to access facial and neck locations, and long term skin tightening form the subdermal energy treatment.

AGING DEMOGRAPHICS AND FACIAL REJUVENATION PROCEDURES

Aging baby boomers are a formidable demographic force in the United States, with a person turning 60 years old every 10 seconds. Age demographic data in 2017 note that between 30% and 40% of the of the total US population is older than 50 years of age [1]. This represents more than 115 million potential patients with skin and laxity of the face and neck. Excisional facial surgery, such as a rhytidectomy, has long been considered the gold standard of facial rejuvenation, but recent years have seen the introduction of new technologies and energy-based devices (EBD) for subdermal skin tightening whether used as a stand-alone treatment paradigm or used concurrently with rhytidectomy. These technologies and applications are presented and critiqued in this article and concentrate on current technologies being used concurrently with rhytidectomy.

INTRODUCTION TO TESLA RHYTIDECTOMY

For the purposes of this discussion, TESLA rhytidectomy (TR) is the use of EBD subdermally in a manner that complements the rhytidectomy whether it is being used for hemostasis or for subdermal skin tightening. TR also refers to EBD use in stand-alone procedures (device only) or when used concurrently with surgical techniques, including nonexcisional and full-excisional rhytidectomy (hybrid procedures). Thermal FibroLipoSculpting (TFLS) during the process of TR is referred to as “sculpturing” and is the result of the thermal effects of these devices on adipose and collagen in the subdermal or interstitial space. TFLS or “sculpturing” capabilities when combined with surgery specifically established rhytidectomy techniques, either full or limited, are synergistic in effecting long-term results. The term ThermoPlastic (now TESLA) was initially used in plastic surgery and aesthetic dermatology to describe the beneficial effects of lasers and light being

The Renuvion® APR Handpiece is intended for the delivery of radiofrequency energy and/or helium plasma where coagulation/contraction of soft tissue is needed. Soft tissue includes subcutaneous tissue.

The Renuvion APR Handpiece is intended for the coagulation of subcutaneous soft tissues following liposuction for aesthetic body contouring.

The Renuvion APR Handpiece is indicated for use in subcutaneous dermatological and aesthetic procedures to improve the appearance of lax (loose) skin in the neck and submental region.

The Renuvion APR Handpiece is intended for the delivery of radiofrequency energy and/or helium plasma for cutting, coagulation and ablation of soft tissue during open surgical procedures.

The Renuvion APR Handpiece is intended to be used with compatible electro-surgical generators owned by Apyx Medical.

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