KAT & CO
AESTHETICS

Informed Consent

Renuvion Skin Tightening

Name :
DOB :

Device Information:

The Renuvion System Generator (owned by Apyx Medical) is intended for delivery of radiofrequency energy and/or helium plasma to cut, coagulate, and ablate soft tissue during open and laparoscopic surgical procedures. 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.

Contraindications:

There are no known contraindications for the use of the Renuvion APR handpiece and compatible electrosurgical generators owned by Apyx medical (RS3, Apyx One Console). However, this device is not recommended for use on patients who are pregnant or have active implantable devices such as AICD, pacemakers, and defibrillators, neurostimulators, or other active implants, as there is a possible hazard due to interference with the device. Patients using anticoagulant medications or substances that could decrease tissue blood flow should consider medical clearance prior to treatment.

Medical History:

Please inform your physician of any prior subdermal or transdermal surgical or aesthetic procedures, including but not limited to liposuction, ultrasound, lasers, cryolipolysis, radiofrequency, injectables, and cosmetic sutures before using this device. Patients with collagen, vascular, and/or autoimmune diseases should not use this device as results may vary. Patients with known impaired wound healing capabilities should be aware that using this device may increase the incidence and severity of scarring and/or delayed healing time. Patients with known hernia should undergo surgical repair prior to using this device.

Risk Factors:

Over treatment of the targeted area or using sequential energy devices may cause unintended burns (deep or superficial), pneumothorax, temporary or permanent nerve injury, ischemia, fibrosis, pain, discomfort, gas buildup resulting in temporary and transient crepitus or pain, bleeding, hematoma, seroma, pigmentation changes, increased healing time, unsatisfactory scarring, asymmetry, and/or unacceptable cosmetic results. Patients should be aware that helium embolism into the surgical site may occur due to inadvertent introduction into the venous or arterial blood supply system.

Expected Side Effects:

Patients should be aware that with a subdermal energy device, expected clinical side effects may include discomfort/pain, edema, erythema, ecchymosis, hypoesthesia, touch sensitivity, itching, temporary weight gain, temporary numbness/tingling, transient migratory firmness, temporary and/or transient crepitus.

Informed Consent:

By signing below, I acknowledge that the physician or designated clinician has fully explained the nature and effects of the procedure, the risks, clinical effects, complications, as well as alternative treatments. I understand the benefits of the proposed procedure, along with the probability of success, have been discussed with me, and I have been given the opportunity to ask questions and have received satisfactory answers. I understand that the practice of medicine and surgery is not an exact science and that results may vary. While there may be some initial improvement, the full clinical results may not be apparent for approximately six to twelve months, and no guarantees of my results have been given to me. I also understand the importance of following the pre/post-procedure instructions given to me by my provider and that failure to comply with all instructions may result in an unsatisfactory result and/or increase my risk of complications.

_____Patient Initials

CONSENT FOR SURGERY / PROCEDURE or TREATMENT

1. I hereby authorize Dr _____ and such assistants as may be selected to perform the following procedure or treatment: Renuvion Skin Tightening

2. I recognize that during the course of the operation and medical treatment or anesthesia, unforeseen conditions may necessitate different procedures than those above. I therefore authorize the above physician and assistants or designees to perform such other procedures that are in the exercise of his or her professional judgment necessary and desirable. The authority granted under this paragraph shall include all conditions that require treatment and are not known to my physician at the time the procedure is begun.

3. I consent to the administration of such anesthetics considered necessary or advisable. I understand that all forms of anesthesia involve risk and the possibility of complications, injury, and sometimes death.

4. I understand what my surgeon can and cannot do, and understand there are no warranties or guarantees, implied or specific about my outcome. I have had the opportunity to explain my goals and understand which desired outcomes are realistic and which are not. All of my questions have been answered, and I understand the inherent (specific) risks to the procedures I seek, as well as those additional risks and complications, benefits, and alternatives. Understanding all of this, I elect to proceed.

5. I consent to be photographed or videoed before, during, and after the operation(s) or procedure(s) to be performed, including appropriate portions of my body, for documentation and use of the photos/videos for medical, scientific, educational or commercial purposes, provided my identity is not revealed by the photos/videos. Separate consent will be sought if your identity cannot be concealed.

6. For purposes of advancing medical education, I consent to the admittance of observers to the operating room.

7. I consent to the disposal of any tissue, medical devices or body parts that may be removed.

8. I consent to the utilization of blood products should they be deemed necessary by my surgeon and/or his/her appointees, and I am aware that there are potential significant risks to my health with their utilization.

9. I understand that the surgeons' fees are separate from the anesthesia and hospital charges, and the fees are agreeable to me. If a secondary procedure is necessary, further expenditure will be required.

10. I realize that not having the operation is an option.

11. IT HAS BEEN EXPLAINED TO ME IN A WAY THAT I UNDERSTAND:
    a. THE ABOVE TREATMENT OR PROCEDURE TO BE UNDERTAKEN
    b. THERE MAY BE ALTERNATIVE PROCEDURES OR METHODS OF TREATMENT
    c. THERE ARE RISKS TO THE PROCEDURE OR TREATMENT PROPOSED

I CONSENT TO THE TREATMENT OR PROCEDURE AND THE ABOVE LISTED ITEMS (1-11). I AM SATISFIED WITH THE EXPLANATION.

_____

Patient or Person Authorized to Sign for Patient

Date _____ Physician Dr Leonardo Fasano

_____Patient Initials