

## Renuvion Informed Consent Form

**Patient's Name:** \_\_\_\_\_

**Date of Birth:** \_\_\_\_\_

I authorise Dr. Comins to perform the proposed procedure listed below utilising the Renuvion® technology.

**Areas to be treated**

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**By initialling each section, you acknowledge you have read and understand the information provided to you:**

I understand that this device is not to be used without adequate training, product in-servicing, and/or education.

The treatment will use a helium plasma device to deliver radiofrequency energy resulting in heat to the subdermal connective tissues for therapeutic purposes.

I understand this is not recommended for use on patients who are pregnant.

I understand this is not recommended for patients with active implantable devices such as AICD, pacemakers and defibrillators, neurostimulators, or other active implants, as a possible hazard exists because of interference with the device.

I understand this is not recommended for use on patients using anticoagulant medications or substances that could decrease tissue blood flow, consider medical clearance prior to treatment.

I have informed my 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.

I do not have any collagen, vascular and/or an autoimmune disease, as results may vary.

I understand metal objects, such as jewelry and piercings, in the treatment area should be removed or protected prior to the procedure.

I do not have any known impaired wound healing capabilities and I understand these may increase the incidence and severity of scarring and/or delayed healing time.

I understand that the following risks may also be associated with other technologies used in combination therapies: 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 result.

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**As with all energy devices there are inherent risks associated with its use. Experiences and/or risks associated with the use of Renuvion may include:**

Helium embolism into the surgical site due to inadvertent introduction into the venous or arterial blood supply system, unintended burns (deep or superficial), pneumothorax, temporary or permanent nerve injury, ischemia, fibrosis, infection, pain, discomfort, gas buildup resulting in temporary and transient crepitus or pain, bleeding, hematoma, seroma, subcutaneous induration, pigmentation changes, increased healing time, unsatisfactory scarring, asymmetry and/or unacceptable cosmetic result.

I understand that with a subdermal energy device the following are possible 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.

My procedure has been fully explained to me. 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 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.

I am of the opinion that my request for Renuvion treatment is for medical reasons and/or the personal psychological features that are associated with my request. I have expressed my thoughts and feelings to Dr Comins and consent to the treatment for the purpose of restoring and maintaining my health and psychological wellbeing.

I consent to having clinical photographs and/or video taken before, during and after my procedure. I understand that these are an important part of my medical record. In addition, I consent to the use of these photographs and/or videos for clinical and medical educational purposes.

The procedure, risks, ramifications, complications and alternative methods of treatment have fully been explained to me by my provider(s) and I have been given the opportunity to have my questions answered. My signature below acknowledges that I have been fully informed and that I consent to the procedure listed on page one.

Disclaimer: Informed-consent documents are not intended to define or serve as the standard of medical care. Standards of medical care are determined on the basis of all of the facts involved in an individual case and are subject to change as scientific knowledge and technology advance and as practice patterns evolve.

Patient Signature/Date:

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Provider Signature/Date:

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(4.3.22)

