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INDICATIONS FOR USE & INTENDED USE DISCLOSURES

- The Renuvion Precise, Precise Open, and J-Plasma Handpieces are intended to be used with compatible electrosurgical generators for the delivery of radiofrequency energy and/or helium plasma for cutting, coagulation, and ablation of soft tissue during open surgical procedures.
- Apyx Medical wants to present to you with current scientific discourse. Specific usage outside of the cleared indications may not be safe or effective.

RISKS:

- Risk associated with the use of the device 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, and/or unsatisfactory scarring. There may be additional risks associated with the use of other devices along with Renuvion/J-Plasma 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.

Evolving Technologies for Tissue Cutting

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KEYWORDS

- Ultrasonic surgery • Plasma scalpels • Waterjet surgery
- Rapid evaporative ionization mass spectroscopy (REIMS)

KEY POINTS

- Improved technologies for tissue cutting increase surgical precision, reduce or eliminate thermal injury of adjacent tissues, reduce blood loss, decrease operating time, and may improve outcomes.
- Modern ultrasonic cutting devices reduce the extent of adjacent thermal injury of bone as well as thermal and mechanical injury of surrounding soft tissues compared with traditional rotary instruments or saws.
- Plasma beams used as cutting devices have been shown to cut with equal or more precision compared with conventional blades and generate reduced levels of thermal injury, inflammation, and scarring compared with conventional electrosurgery.
- Waterjet dissection allows for precise dissection and ablation of tissues without generating heat and without causing significant structural injury to nerves and vessels.
- The application of Rapid Ionization Evaporative Mass Spectroscopy of surgical smoke generated by electrocautery is currently undergoing human clinical trials to allow for real-time detection of tumor and assessment of surgical margins.

INTRODUCTION

Surgical manipulation of tissue evolved during the early twentieth century from stainless steel blades and chisels to electric current–powered cauterization, electric handpieces, and saws. Changes resulted from a shift in the type of energy used from human hands to electric current–based power. Manipulation of energy continues to drive advancement in tissue cutting technologies.

The goal of tissue cutting technologies is to divide tissue with precision, limit damage to adjacent tissues, reduce operating time, limit blood loss, and reduce scar tissue. Lasers, ultrasonic devices, plasma beam scalpels, and waterjet scalpels cut tissues with advantages specific to their indications. Bone cutting through ultrasonic methods has increased in popularity, yet rotary and oscillating devices remain the most commonly used modalities. Soft tissue ultrasonic technologies alter tissue through cutting, coaptation, coagulation, or cavitation. Plasma beam scalpels function by adding energy to a gas and demonstrate a high degree of precision and elimination of unintended tissue trauma. Waterjet dissection separates tissues through a focused beam of normal saline instead of burning or fusing.

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