NanoKnife

angiodynamics

The NanoKnife System

SYSTEM SPECIFICATIONS

- Maximum pulse amplitude of 3,000 volts
- Maximum current draw of 50 amps
- Touch screen monitor display
- Wheels to transport to and from storage
- Double foot pedal to activate system
- Side pockets for storing cables, accessories, and foot pedal
- Up to 6 electrode probes may be connected
- Electrode probes available in 15 cm and 25 cm lengths.
- 19 gauge with 1cm increment depth markings
- Electrodes are visible under CT and ultrasound
- Adjustable electrode sheath
- 8 ft. cable connection
- Optional electrode spacers used to maintain parallel spacing during electrode placement

ORDERING INFORMATION

SKU	DESCRIPTION
H787204001070	NanoKnife Single Electrode Probe 15 cm
H787204001080	NanoKnife Single Electrode Probe 25 cm
H787204003015	NanoKnife Single Electrode Probe Spacers (Pack of 10)
20300101-US	NanoKnife System v2.2.1

IMPORTANT RISK INFORMATION

INDICATIONS FOR USE: The NanoKnife System has FDA 510(k) clearance for the surgical ablation of soft tissue and has not received clearance for the treatment of any specific disease or condition (per FDA K150089).

CONTRAINDICATIONS: Ablation procedures using the NanoKnife® System are contraindicated in the following cases: Ablation of lesions in the thoracic area in the presence of implanted cardiac pacemakers or defibrillators, Ablation of lesions in the vicinity of implanted electronic devices or implanted devices with metal parts, Ablation of lesions of the eyes, including the eyelids, Patient history of Epilepsy or Cardiac Arrhythmia, and Recent history of Myocardial Infarction.

CLINICAL ISSUES: Including arrhythmias, Hypotension, and Thrombus Risks

- Patients with Q-T intervals greater than 550 ms (milliseconds) are at an increased risk for inappropriate energy delivery and arrhythmia. Verification of proper function of a synchronization device before initiating energy delivery is essential in these patients.
- Asynchronous energy delivery (240 PPM (Pulses Per Minute) or 90 PPM modes) might trigger atrial or ventricular fibrillation, especially in patients with structural heart disease. Ensure that proper interventions (e.g. defibrillator) and appropriately trained personnel are readily available for dealing with potential cardiac arrhythmias (see Section 5.1.3).
- Using QRS synchronization devices whose output is not compatible with the specifications listed in this manual may result in arrhythmias including ventricular fibrillation.
- Adequate precautions should be taken for patients with implantable electrical devices. Note the contraindication in certain patients.
- There are potential risks associated with the location of the ablation: near the pericardium (tachycardia), or near the vagus nerve (bradycardia).
- Additional patients may be at risk with insufficient muscle blockade or anesthetic analgesia (reflex tachycardia and reflex hypertension); patients with abnormal sinus rhythm prior to an ablation (arrhythmia); patients with a history of hypertension (hypertension); or patients with partial portal venous thrombosis, low central venous pressure (CVP), and a prothrombotic condition (venous thrombosis).

POTENTIAL ADVERSE EFFECTS: Adverse effects that may be associated with the use of the NanoKnife system include, but are not limited to the following:

- Arrhythmia including atrial fibrillation or flutter, bigeminy, bradycardia, heart block or atrioventricular block, paroxysmal supraventricular tachycardia, tachycardia (reflex tachycardia and ventricular tachycardia), and ventricular fibrillation.
- Damage to critical anatomical structure (nerve, vessel, and/or duct), fistula formation, hematoma, hemorrhage, hemothorax, infection, muscle contraction, pneumothorax, reflex hypertension, unintended mechanical perforation, vagal stimulation (asystole), and venous thrombosis

Indications, contraindications, warnings and instructions for use can be found in the user manual and instruction for use supplied with each NanoKnife electrode probe and system. Observe all instructions prior to use. Failure to do so may result in patient complications.

CAUTION: Federal (USA) law restricts the sale of this device by or on the order of a physician. This device is sterilized by ethylene oxide. The electrodes are intended for single patient use only.

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