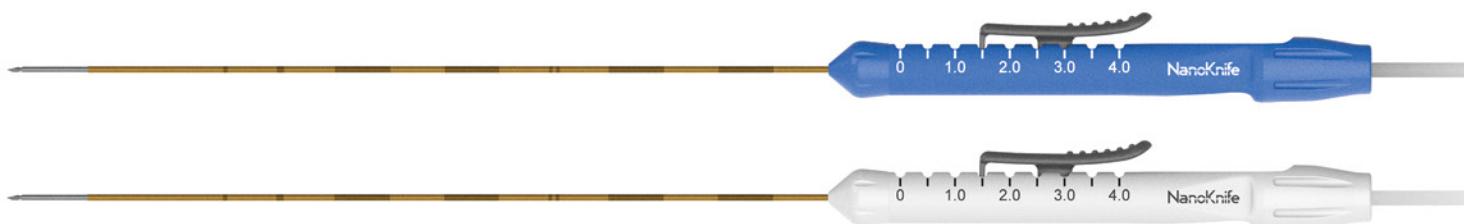




IRREVERSIBLE ELECTROPORATION

A UNIQUE ALTERNATIVE
TO THERMAL ABLATION

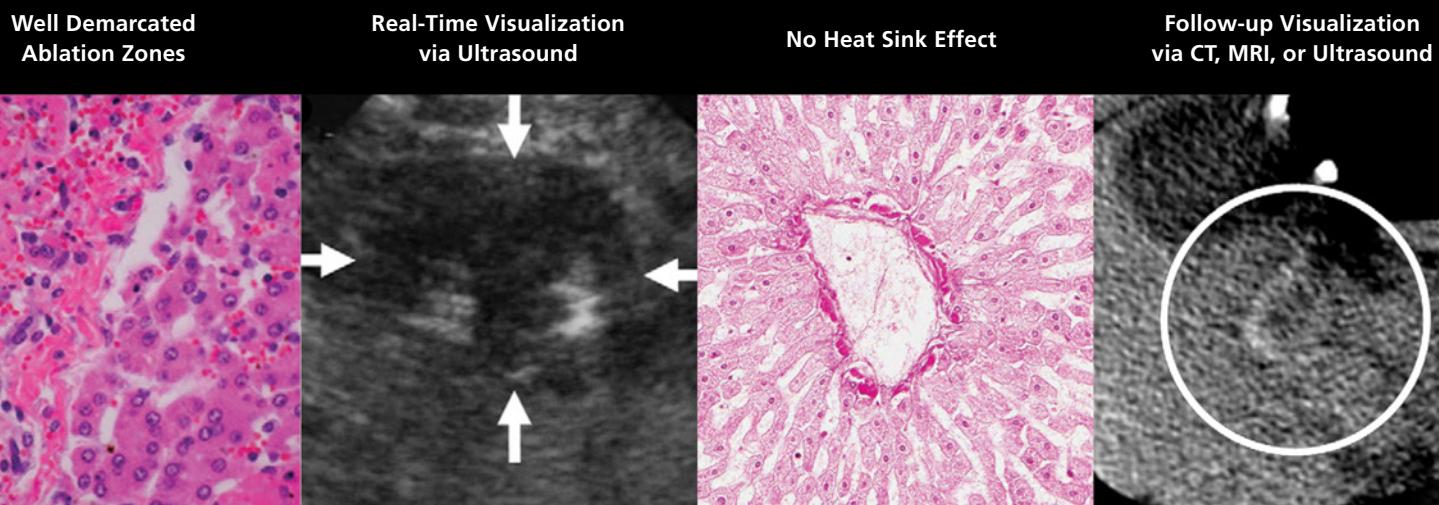


angiodynamics

An ablation procedure that uses low energy electrical pulses to create defects (pores) in cell membranes, resulting in loss of homeostasis and subsequent cell death.

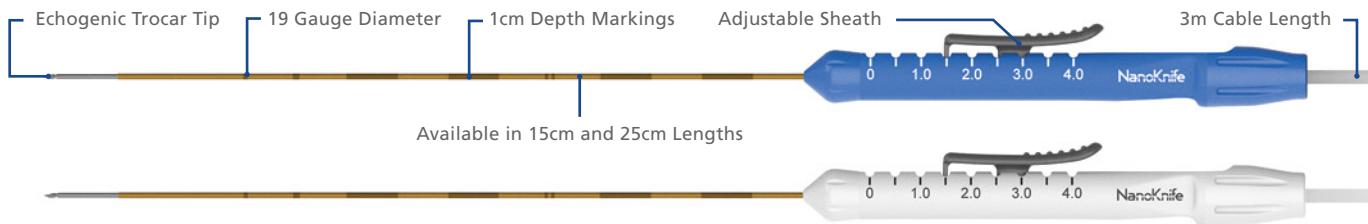
A NanoKnife* procedure is an ablation procedure that involves the delivery of a series of high voltage direct current electrical pulses between two electrodes placed within a target area of tissue. Irreversible electroporation (IRE) is a technique using a non-thermal energy to create permanent nanopores in the cell membrane to disrupt cellular homeostasis. The disruption of cellular homeostasis initiates an apoptotic-like effect which leads to permanent cell death. After delivering a sufficient number of high voltage pulses, the cells within the electrical field will be irreversibly damaged.

The NanoKnife System carries a CE Mark for cell membrane electroporation.



REFERENCES

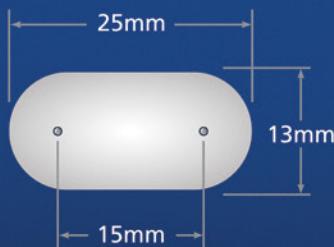
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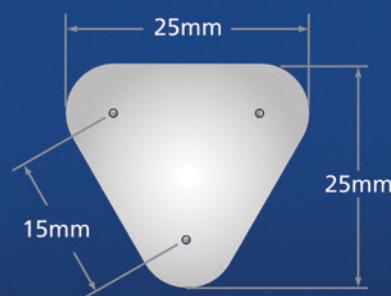
SYSTEM FEATURES:

- Touch screen monitor
- Real-time current, voltage, and resistance monitoring
- USB Port to export procedure data
- Keyboard and trackpad for data entry
- Up to 6 probes, minimum of 2 probes needed
- Side pockets for cables and foot pedal
- Double foot pedal to activate system
- Wheels to transport to and from storage location

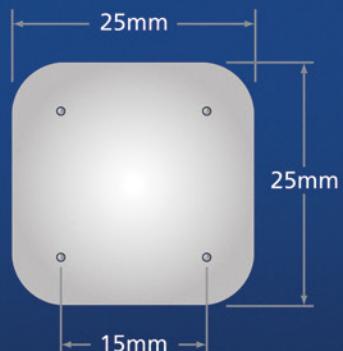
Two Probe Array



Three Probe Array



Four Probe Array



Procedure
Setup



Procedure
Planning



Conductivity
Test



Pulse
Delivery



NANOKNIFE SYSTEM

SKU	DESCRIPTION
20300301	NanoKnife System v3.0 Includes: Generator, Double Pedal Footswitch, Cardiac Gating Device, and 1-Year Warranty
H787204001030	NanoKnife Single Electrode Probe – Activation - 15 cm
H787204001040	NanoKnife Single Electrode Probe – Standard - 15 cm
H787204001050	NanoKnife Single Electrode Probe – Activation - 25 cm
H787204001060	NanoKnife Single Electrode Probe – Standard - 25 cm
H787204003015	NanoKnife Single Electrode Probe Spacers (Pack of 10)

INDICATIONS FOR USE:

EU: The NanoKnife System is a medical device for cell membrane electroporation. Electroporation is a phenomenon that occurs in cell membranes as cells are exposed to an electrical field of sufficiently high intensity. The electric field acts as a physical stimulus, bringing about alterations in cell membranes that result in increased permeability.

FDA: The FDA has not cleared the NanoKnife v3.0.

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; Recent history of Myocardial Infarction.

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; Atrial fibrillation or flutter; Bigeminy; Bradycardia; Heart block or atrioventricular block; Paroxysmal supraventricular tachycardia; Tachycardia; Reflex tachycardia; Ventricular tachycardia; Ventricular fibrillation; Damage to critical anatomical structure (nerve, vessel, and/or duct); Fistula formation; Hematoma; Hemorrhage; Hemothorax; Infection; Pneumothorax; Reflex Hypertension; Unintended mechanical perforation; Vagal Stimulation, asystole; Venous Thrombosis. Indications, contraindications, warnings, precautions and instructions for use can be found in the Instructions for Use supplied with each device. Observe all instructions prior to use. Failure to do so may result in patient complications.

Please refer to the NanoKnife System User Manual and the NanoKnife Single Electrode Probe Directions For Use for complete instructions, warnings and precautions.



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