

NanoKnife

IRREVERSIBLE ELECTROPORATION



A UNIQUE ALTERNATIVE
TO THERMAL ABLATION

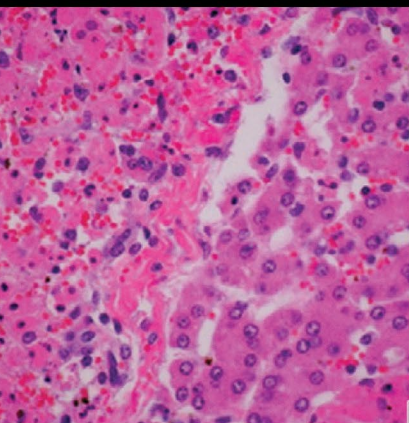


An ablation procedure that uses low energy electrical pulses to create defects (pores) in cell membranes, resulting in loss of homeostasis and subsequent cell death.

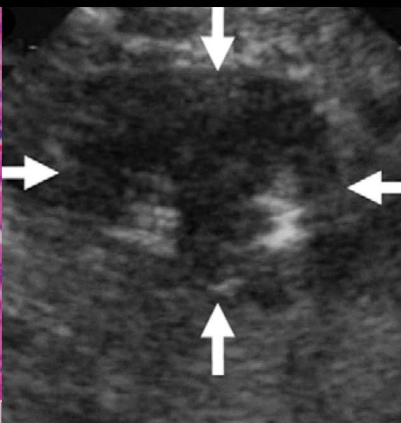
A NanoKnife* procedure is an ablation procedure that involves the delivery of a series of high voltage direct current electrical pulses between two electrodes placed within a target area of tissue. The electrical pulses produce an electric field which induces electroporation on cells within the target area. Electroporation is a technique in which an electrical field is applied to cells in order to increase the permeability of the cell membranes through the formation of nanoscale defects in the lipid bilayer. After delivering a sufficient number of high voltage pulses, the cells surrounding the electrodes will be irreversibly damaged. This mechanism which causes permanent cell damage is referred to as Irreversible Electroporation (IRE).

The NanoKnife System carries a CE Mark for cell membrane electroporation. The NanoKnife System has been cleared by the FDA for the surgical ablation of soft tissue. It has not received clearance for the therapy or treatment of any specific disease or condition.

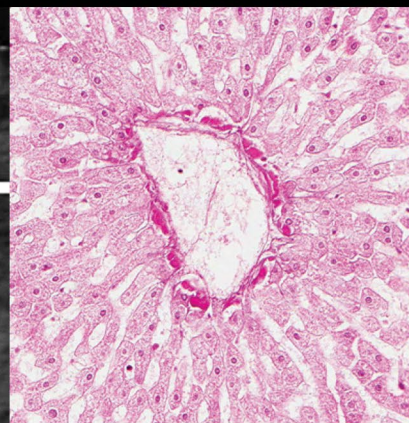
**Well Demarcated
Ablation Zones**



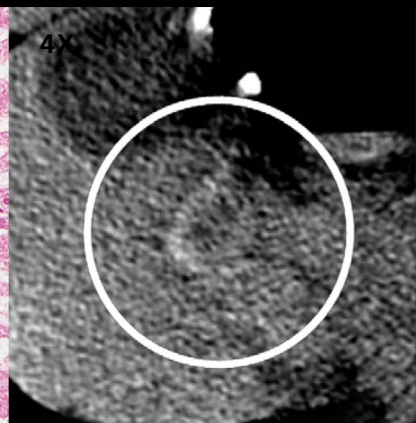
**Real-Time Visualization
via Ultrasound**



No Heat Sink Effect

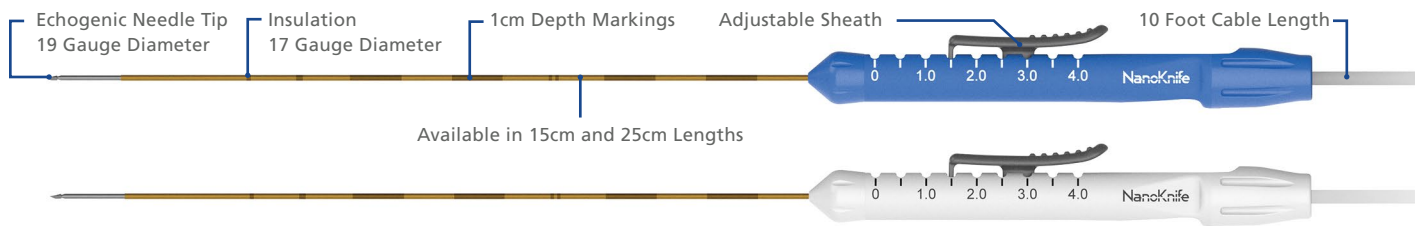


**Follow-up Visualization
via CT, MRI, or Ultrasound**



REFERENCES

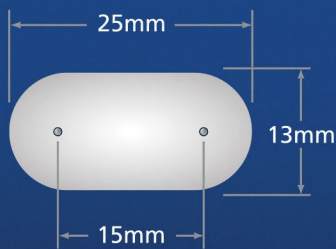
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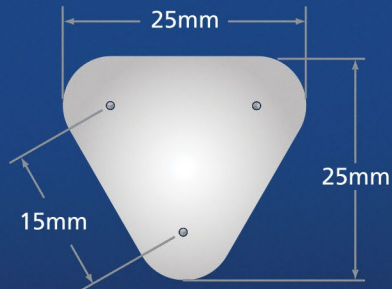
SYSTEM COMPONENTS

- Touch screen monitor
- 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

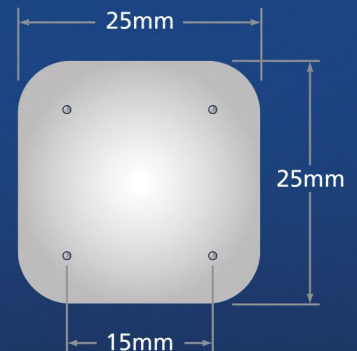
Two Probe Array



Three Probe Array



Four Probe Array



Procedure
Information



Probe
Selection



Probe
Placement



Pulse
Generation

Information

Patient Information
Patient ID: _____
Name: _____
Age: _____

Clinical data
Clinical indication: _____

Case Information
Procedure date: 7/11/2012 12:00 PM
Physician name: _____
Case notes: _____

Institution
Angelo Hospital
401 Chalmers Ave.
Chattanooga, TN 37405
Tel: 423.246.7722
Fax: 423.246.7725

Lesion zone (cm) Target zone (cm)
Length: 1.0 Length: 3.0
Width: 1.0 Width: 3.0
Depth: 1.0 Depth: 3.0
Margin: 1.0

NO PPM NO PPM ECG synchronization

NanoKnife

Probe Selection

Probe type
☐ Bipolar probe
☐ Two probe array
☐ Three probe array
☐ Four probe array
☐ Five probe array
☐ Six probe array
☐ Six probe array 10mm
☐ Six probe array 15mm

Probe Connection Status
☒ Connected
☐ Disconnected
☐ Not Connected
☐ Not Connected
☐ Not Connected
☐ Not Connected

Diagrams shown for examples only

Side view Top view

25mm 15mm 25mm 25mm

Probe Placement Process

Probe #	Probe	Probe Length	Probe Width	Probe Depth
1	2	150	15	15
2	2	150	15	15
3	2	150	15	15

Adjust Dial

Default Setting: Volume Locking
1500 3 Volume 1 Volume 1 Volume

Probe Dock And/Or ePort
☐ Dock Probes
☐ Undock Probes

Hint:
Lay out all probes and add additional rows to the spreadsheet if necessary

Save Settings Cancel Settings

Pulse Generation

Probe #	Probe	Initial Voltage	Voltage	Probe Length	Start Pulse	Total Pulse	Status
1	2	2400	2400	15	75	75	Completed
2	2	2400	2400	15	75	75	Completed
3	2	2400	2400	15	75	75	Completed

Plan section
☒ Deliver text (pulse)
☒ ECG synchronized

Click Deliver temperature to start

Charge section
☐ 20V
☐ Charge

NANOKNIFE SYSTEM

SKU	DESCRIPTION
20300101	NanoKnife System v2.2.0 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
H787204001060	NanoKnife Single Electrode Probe Spacers (Pack of 10)

Please consult your local AngioDynamics representative for country/EU member state specific availability.

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 NanoKnife is intended for the surgical ablation of soft tissue in the United States. The FDA has not cleared the NanoKnife System for the treatment of any specific disease state or condition.

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; Pneumothorax; Muscle contraction; Hemorrhage; Unintended mechanical perforation; Infection; Bradycardia; Vagal Stimulation, asystole; and damage to critical anatomical structure (nerve, vessel, and/or duct). 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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www.angiodynamics.com

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