

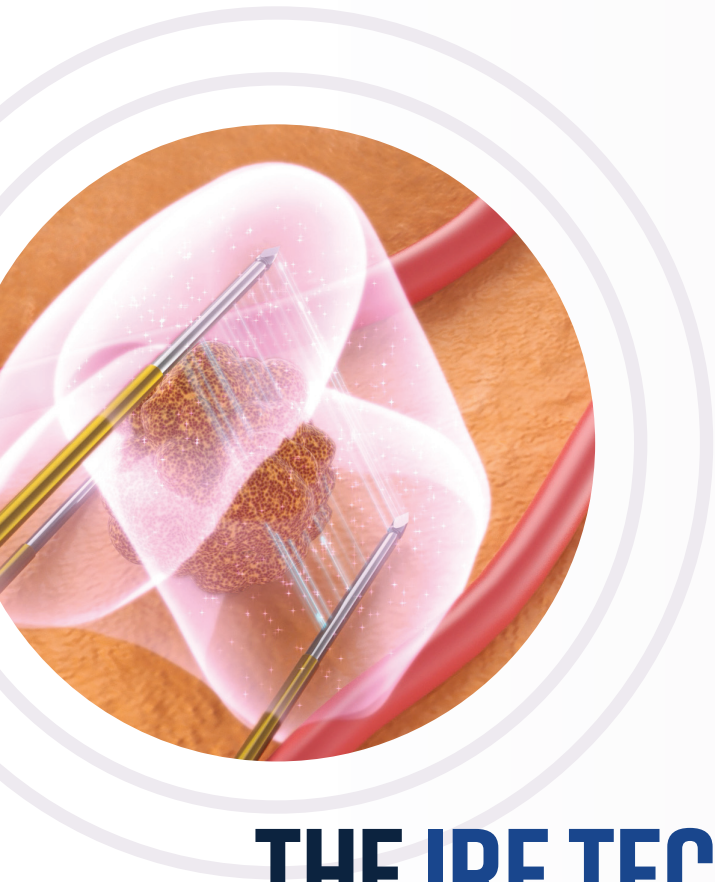


# **EXPANDING THE BOUNDARIES OF ABLATION**



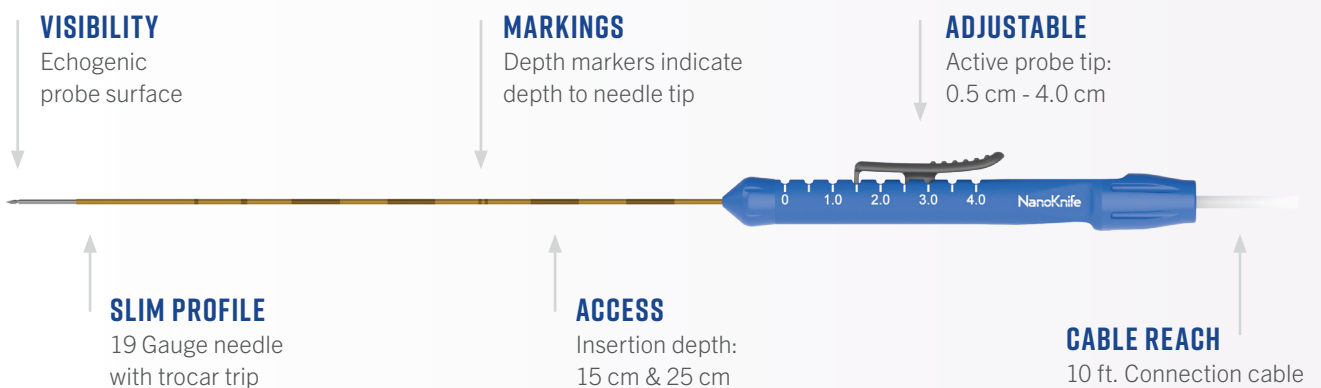
**Nanoknife 3.0**  
Irreversible Electroporation (IRE)





# THE IRE TECHNOLOGY BEHIND THE NANOKNIFE SYSTEM

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.<sup>5</sup>



# THE BENEFITS OF THE NANOKNIFE SYSTEM

## **Critical Structure Sparing** <sup>1, 2, 3, 4</sup>

The NanoKnife System does not rely on heat to achieve cell death. Instead, it induces a more natural method of cell death, while, in turn, destroying only targeted tissue and sparing critical structures, including vessels, nerves, and ducts.

## **No Heat Sink Effect** <sup>1, 2, 3, 4</sup>

Unlike thermal modalities, zones of IRE ablation are not deformed or decreased by proximity to blood vessels.

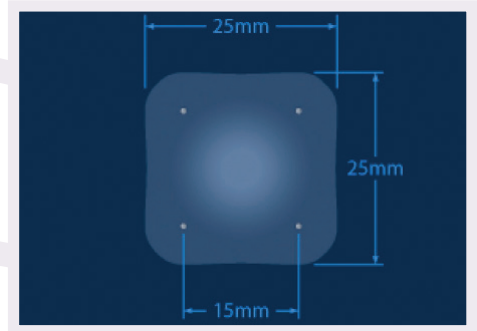
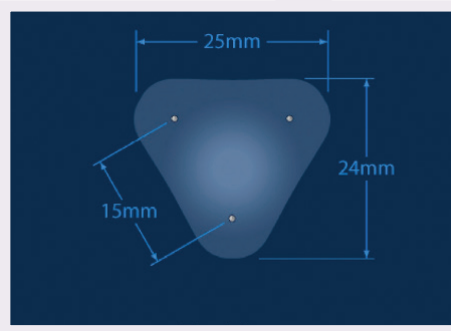
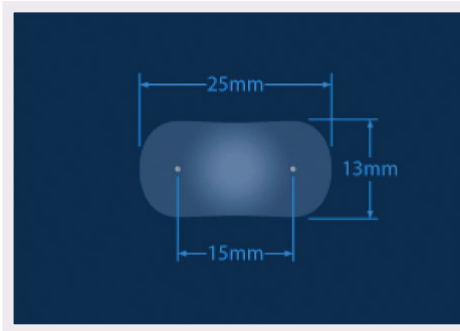


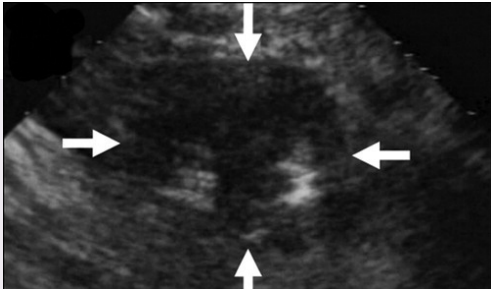


## Enhanced User Experience

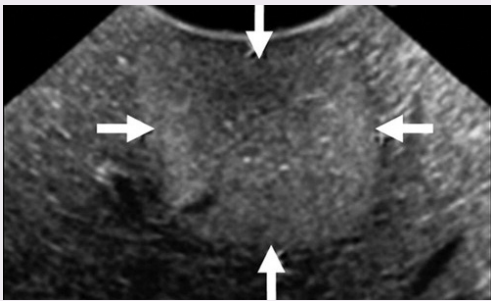
Intuitive software interface that streamlines procedure set-up and delivers real-time visual feedback, allowing for customization at every step of the ablation.

## Probe Placement





**FIGURE 1A**



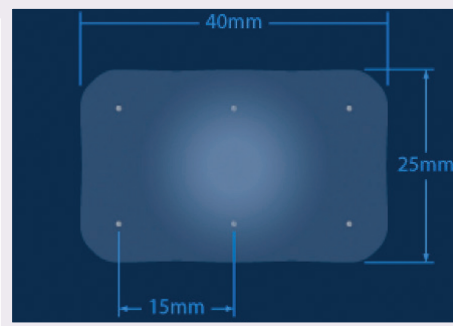
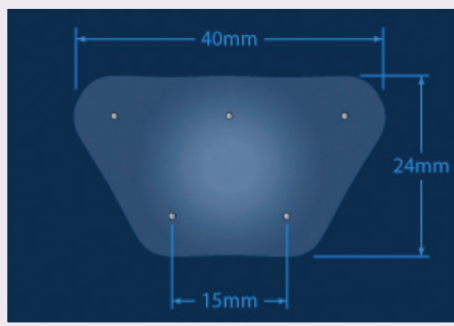
**FIGURE 1B**

## Real-Time Visualization <sup>4</sup>

Figure 1a & 1b: Real-time ultrasound imaging obtained during IRE shows hypoechoic areas of ablation in close proximity to the probes.

Sharp demarcation of IRE-ablated zone is well-visualized immediately during the procedure (arrows).

Note: Results shown in figures 1a & 1b were performed in swine liver.



## THE NANOKNIFE 3.0 SYSTEM

US Part Numbers	International Part Numbers	Description
H78720300301US0	H787203003010	NanoKnife 3.0 Generator
H787204001090	H787204001030	NanoKnife Single Electrode Activation Probe 15 cm
H787204001100	H787204001050	NanoKnife Single Electrode Activation Probe 25 cm
H787204003015	H787204003015	NanoKnife Single Electrode Probe Spacer (Pack of 10)

### References

- <sup>1</sup>Maor E. et al., The effect of irreversible electroporation on blood vessels, Technol. Cancer Res. Treat. 6(4), 307–312 (2007).10.1177/153303460700600407.
- <sup>2</sup>Rubinsky, B., Onik, G., and Mikus, P., Irreversible electroporation: a new ablation modality—clinical implications. Technol. Cancer Res. Treat. 6, 37–48. (2007). doi: 10.1177/153303460700600106.
- <sup>3</sup>Onik G., Mikus P., and Rubinsky B., Irreversible electroporation: implications for prostate ablation, Technol. Cancer Res. Treat. 6(4), 295–300 (2007).10.1177/153303460700600405.
- <sup>4</sup>Lee EW, Chen C, Prieto VE, Dry SM, Loh CT, Kee ST., Advanced hepatic ablation technique for creating complete cell death: irreversible electroporation. Radiology 255:426–433. (2010). doi: 10.1148/radiol.10090337.
- <sup>5</sup>Lee EW, Thai S, Kee ST. Irreversible electroporation: a novel image-guided cancer therapy. Gut Liver. (2010);4(SUPPL. 1):99–104. doi: 10.5009/gnl.2010.4.S1.S99.

### Indication For Use

US: The NanoKnife System with six outputs is indicated for surgical ablation of soft tissue.

CE: 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.

### 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 o Reflex tachycardia
- o 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

Refer to Directions for Use and/or User Manual provided with the product for complete Instructions, Warnings, Precautions, Possible Adverse Effects and Contraindications. Observe all instructions for use prior to use. Failure to do so may result in patient complications. CAUTION: Federal Law (USA) restricts this device to sale by or on the order of a physician.

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