



# Nanoknife 3.0

Irreversible Electroporation (IRE)

## TODAY, LOCALIZED THERAPY OPTIONS ARE LIMITED

in providing physicians and patients with a customizable and confident treatment. Most options come with substantial trade-offs, dictating your ability to treat effectively.

The NanoKnife System reimagines localized therapy through its unique mechanism of action, improving precision<sup>1</sup>, expanding versatility<sup>2</sup>, and increasing preservation<sup>2,3</sup> - giving you the control to tailor treatments with confidence.<sup>4,5</sup>



Harnesses the power of Irreversible Electroporation (IRE) to effectively destroy targeted cells without the use of thermal energy.<sup>6</sup>



Delivers high-voltage pulses to create permanent nanopores within the cell membrane. This stimulus induces an apoptotic-like cellular death in the targeted tissue, resulting in a complete ablation.<sup>7,8</sup>



Electrodes can be deployed in multiple configurations providing precise and customizable ablation zones.<sup>1</sup>

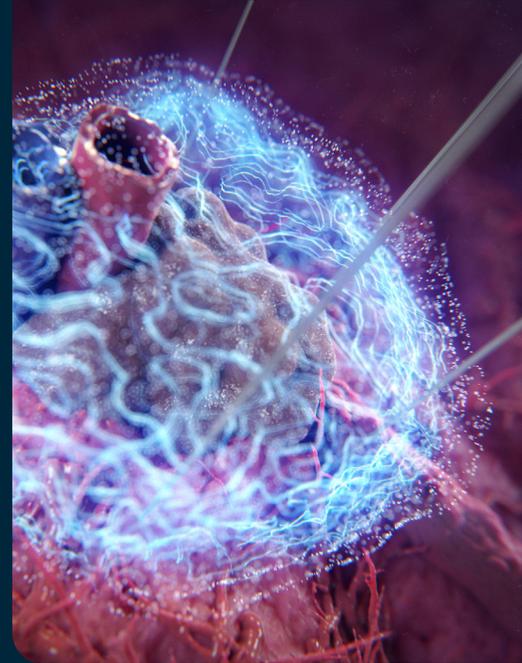


Sharp demarcation of IRE-ablated zone is well-visualized immediately during the procedure using real-time ultrasound imaging.<sup>9</sup>

## PRECISION EMPOWERED.

The NanoKnife System gives you, the physician, the ability to sculpt and control the ablation zone through a variety of electrode configurations.<sup>1</sup>

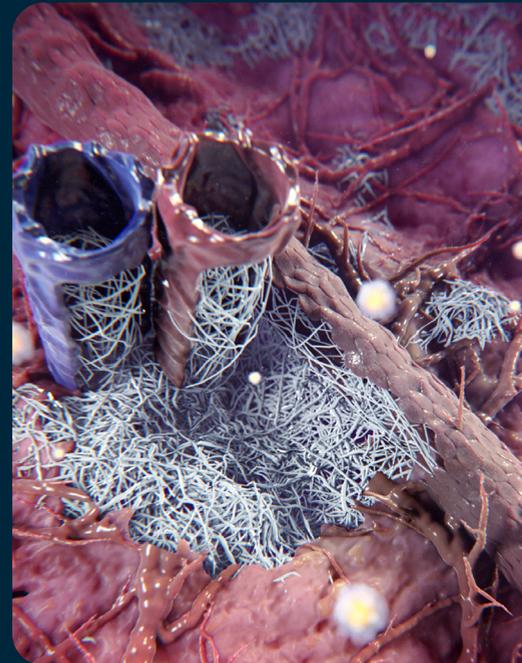
IRE effectively destroys the targeted tissue and gives you precise treatment margins resulting in confident treatment coverage for your procedure.<sup>4,5</sup>



## PRESERVATION REDEFINED.

The procedure spares vital structures by retaining the structural integrity of the targeted tissue.<sup>2,3</sup>

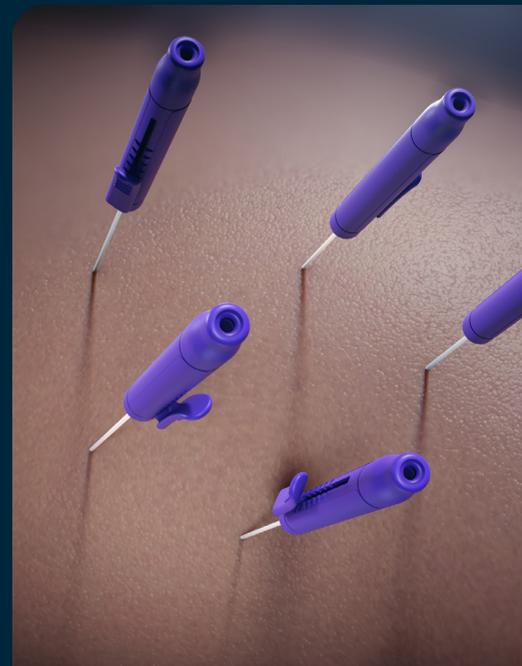
The delivery of non-thermal energy allows for the preservation of the extra-cellular matrix, facilitating post-ablation, histological and functional tissue regeneration.<sup>2,3</sup>



## VERSATILITY PERFECTED.

Multiple electrode configurations, coupled with a unique mechanism of action, allow the device to be used in all segments of an organ to optimize treatment delivery.<sup>2</sup>

Electrodes can be confidently placed near vital structures, maximizing your ability to personalize treatment to your patient's anatomy.<sup>4,5</sup>



YOUR  
TREATMENT  
REIMAGINED.

# 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> Blazevski A, Amin A, Scheltema MJ, Balakrishnan A, Haynes AM, Barreto D, Cusick T, Thompson J, Stricker PD. Focal ablation of apical prostate cancer lesions with irreversible electroporation (IRE). *World J Urol.* 2020 Jun 2. doi: 10.1007/s00345-020-03275-z. Epub ahead of print. PMID: 32488359.
- <sup>2</sup> Scheltema MJ, Chang JI, van den Bos W, Gielchinsky I, Nguyen TV, Reijke TM, Siriwardana AR, Böhm M, de la Rosette JJ, Stricker PD. Impact on genitourinary function and quality of life following focal irreversible electroporation of different prostate segments. *Diagn Interv Radiol.* 2018 Sep;24(5):268-275. doi: 10.5152/dir.2018.17374. PMID: 30211680; PMCID: PMC6135060.
- <sup>3</sup> Li W, Fan Q, Ji Z, Qiu X, Li Z. The effects of irreversible electroporation (IRE) on nerves. *PLoS One.* 2011 Apr 14;6(4):e18831. doi: 10.1371/journal.pone.0018831. PMID: 21533143; PMCID: PMC3077412.
- <sup>4</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
- <sup>5</sup> Guidance for Selection of NanoKnife Probe Array Configuration and Ablation parameters for the Treatment of Stage III Pancreatic Cancer.
- <sup>6</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>7</sup> Bower M, Sherwood L, Li Y, Martin R. Irreversible electroporation of the pancreas: definitive local therapy without systemic effects. *J Surg Oncol.* 2011 Jul 1;104(1):22-8. doi: 10.1002/jso.21899. Epub 2011 Feb 28. PMID: 21360714.
- <sup>8</sup> Van Den Bos W, de Bruin DM, Jurhill RR, Savci-Heijink CD, Muller BG, Varkarakis IM, Skolarikos A, Zondervan PJ, Laguna-Pes MP, Wijkstra H, de Reijke TM, de la Rosette JJ. The correlation between the electrode configuration and histopathology of irreversible electroporation ablations in prostate cancer patients. *World J Urol.* 2016 May;34(5):657-64. doi: 10.1007/s00345-015-1661-x. Epub 2015 Aug 22. PMID: 26296371; PMCID: PMC4841841.
- <sup>9</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.

## 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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