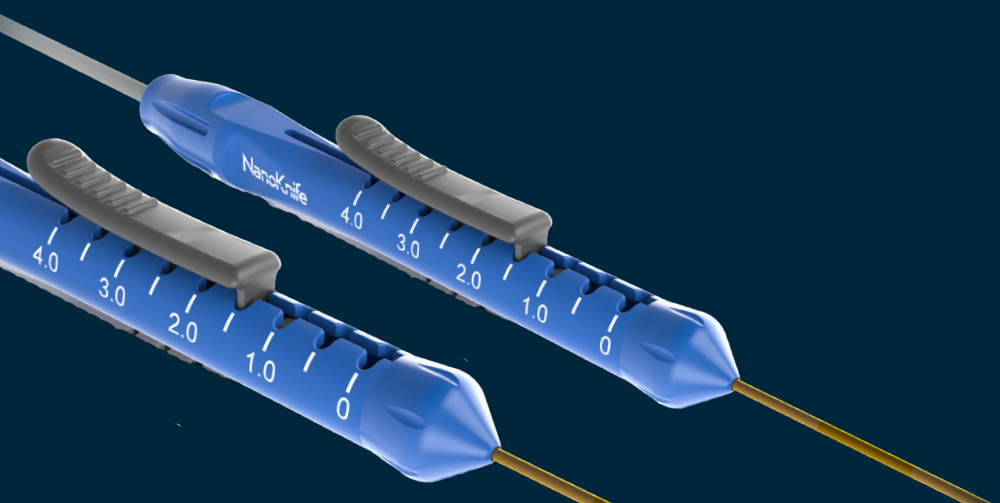
NanoKnife
Irreversible Electroporation (IRE)

NANOKNIFE SYSTEM FACT SHEET

- The NanoKnife System utilizes Irreversible Electroporation, or IRE, technology to destroy a targeted area of diseased cells.
- The device consists of a generator and multiple electrodes that deliver the energy. The system can use up to 6 electrodes, with a minimum of 2 required for treatment.
- The NanoKnife Electrodes are placed around a targeted area of tissue and send electrical pulses that create permanent holes in the cells' membranes. This causes an apoptotic-like effect, or natural cell death, which leads to death of the targeted tissue.[1,2]
- The NanoKnife System does not rely on heat to achieve cell death, and in turn, destroys only targeted tissue while preserving the functional anatomy of vital structures - including blood vessels, nerves, and bile ducts.[3]
- Multiple electrode configurations, coupled with the unique IRE Technology, allow the device to be used in all segments of an organ to optimize treatment delivery and provide precise ablation zones.[4]
- The NanoKnife 3.0 System has an enhanced user interface that streamlines procedure set-up and delivers real-time visual feedback, allowing for customization at every step of the ablation.
- 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.
- Learn more at NanoKnife.com



NanoKnife
Irreversible Electroporation (IRE)

REFERENCES

[1] 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.

[2] 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.

[3] Maor E. et al., The effect of irreversible electroporation on blood vessels, Technol. Cancer Res. Treat. 6(4), 307–312 (2007).10.1177/153303460700600407.

[4] 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.

IMPORTANT RISK INFORMATION

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

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.

angiodynamics