



NANOKNIFE SYSTEM PATIENT GUIDE

WHAT IS ABLATION?

Ablation is typically a minimally invasive technique used to destroy a targeted area of tissue. It commonly uses thermal energy, either cold or hot, to bring cells to a cytotoxic level (less than -40°C or more than 60°C) resulting in cell death.¹



THERMAL ABLATION

Utilizing Heat
more than 60°C



THERMAL ABLATION

Utilizing Cold
less than -40°C



NON-THERMAL ABLATION

Not relying on heat/cold to
damage the targeted cells

WHY DID MY DOCTOR CHOOSE THE NANOKNIFE SYSTEM?

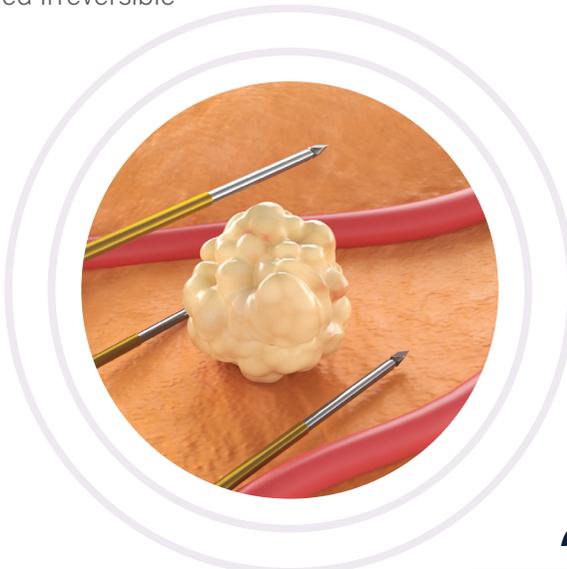
The NanoKnife System is an ablative technology used to destroy a targeted area of tissue. However, unlike other ablative technologies, the NanoKnife System does not rely on thermal energy to achieve cell death. Instead, it uses a technique called Irreversible Electroporation or IRE.

WHAT IS IRE TECHNOLOGY?

Irreversible Electroporation, also known as IRE, is a technique in which electrical pulses are applied to targeted cells. This results in the creation of small holes in the cells' membranes.

After enough pulses are delivered to the cells, the cells initiate a process that mimics apoptosis, or cell death, which leads to permanent cell death. Thus, destroying the cells.²

Because the NanoKnife System does not use thermal energy to destroy the tissue, it has the ability to spare critical structures, like major blood vessels, nerves and ducts, during the ablation.^{3,4,5,6}



HOW DOES THE NANOKNIFE SYSTEM WORK?

The NanoKnife System has two main components - the generator and the probes.

THE GENERATOR

controls the energy output of the device and has a computer to calculate and monitor the procedure

THE PROBES

connect to the generator and are placed inside the patient to bracket around the targeted tissue for treatment



WHAT TO EXPECT DURING THE PROCEDURE



The procedure is performed percutaneously* or open, depending on the preference of your physician. The patient receiving treatment will be sedated during the procedure.



During the procedure, your physician will place the probes to bracket around the targeted tissue. The number of probes used can range from 2 to 6, which is determined by your physician before treatment.



Once the probes are placed, your physician will initiate a series of electrical pulses between the probes. The voltage used and time of the procedure is determined by your physician before treatment.



After your physician has delivered a sufficient amount of pulses, the procedure is complete, and the probes are removed.

*For a percutaneous procedure, the probe(s) are placed through the skin and the body does not have to be surgically opened.

NanoKnife

Irreversible Electroporation (IRE)

References

- ¹ Knavel E, Brace C. Tumor Ablation: Common Modalities and General Practices. *Tech Vasc Interv Radiol.* (2013);16(4):192-200. doi:10.1053/j.tvir.2013.08.002
- ² 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
- ³ Maor E. et al., The effect of irreversible electroporation on blood vessels, *Technol. Cancer Res. Treat.* (2007);6(4):307–312. doi:10.1177/153303460700600407
- ⁴ Rubinsky, B., Onik, G., and Mikus, P., Irreversible electroporation: a new ablation modality—clinical implications. *Technol. Cancer Res. Treat.* (2007);6:37–48. doi: 10.1177/153303460700600106
- ⁵ Onik G., Mikus P., and Rubinsky B., Irreversible electroporation: implications for prostate ablation, *Technol. Cancer Res. Treat.* (2007);6(4): 295–300. doi:10.1177/153303460700600405
- ⁶ Lee EW, Chen C, Prieto VE, Dry SM, Loh CT, Kee ST., Advanced hepatic ablation technique for creating complete cell death: irreversible electroporation. *Radiology* (2010);255:426–433. doi:10.1148/radiol.10090337

Important Risk Information

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.

Refer to Directions for Use and/or User Manual provided with the product for complete Instructions, Warnings, Precautions, Possible Adverse Effects, and Contraindications. **CAUTION:** Federal Law (USA) restricts this device to sale by or on the order of a physician.

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