References


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.
What is Localized Therapy?

Localized therapy is a treatment that is directed to a specific organ or targeted area of the body. This type of therapy is focused on treating one focused area, rather than a whole section of the body. The NanoKnife System is a localized therapy that uses a technology called Irreversible Electroporation (IRE) to ablate, or destroy, a targeted area of tissue.

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A patient’s guide to the NanoKnife System
The NanoKnife System is a localized therapy option providing many benefits due to its unique IRE technology.

The technology allows the device to be extremely versatile in its use, giving your physician the ability to deliver targeted and effective treatment.

The NanoKnife System is able to destroy targeted tissue without relying on thermal energy. This means the device can be used in areas of the body located near vital structures without causing permanent damage. Vital structures can include major blood vessels, nerves and bile ducts.

The NanoKnife System uses Irreversible Electroporation or IRE. This is a technology in which electrical pulses are applied to a targeted area of cells. The pulses create small holes in the cells’ membranes.

After enough pulses are delivered, the cells initiate a process that mimics apoptosis or natural cell death. The body responds to the apoptotic-like cell death by initiating the removal of cellular debris.

The procedure is performed percutaneously* or open, depending on the preference of your physician. Before the procedure begins, you will be sedated and remain sedated until the procedure is complete.

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

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

After your physician has delivered a sufficient number of pulses to the targeted area, the procedure is complete, and the electrodes are removed. Post-procedure recovery can be discussed with your physician.

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