CUTTING EDGE TECHNOLOGY

The NanoKnife® System is designed for the ablation of soft tissue and represents the next generation in focal ablation. The NanoKnife System carries a CE Mark for cell membrane electroporation. The NanoKnife System has also received FDA 510(k) clearance for the surgical ablation of soft tissue and has not been approved for the treatment of any specific disease or condition. The NanoKnife System is the first ablation system to use low energy electrical pulses which are believed to permanently open pores in cell membranes, which leads to cell death in the target tissue.

HOW THE NANO KNIFE SYSTEM WORKS

The NanoKnife System uses a rapid series of high voltage, but low energy, direct current (LED) to create defects (pores) in cell membranes, resulting in loss of homeostasis and subsequent cell death. The process with which LEDC ablates soft tissue is known as electroporation or [in the case of NanoKnife] irreversible electroporation (IRE). The electrical pulses are delivered through several needle-like probes placed into or around the target tissue under CT or ultrasound guidance. Since the NanoKnife System uses low energy direct current (LED), it does not rely on heat to ablate tissue. The procedure is done under general anesthesia and requires muscle blockade.

DOES NOT RELY ON HEAT

The NanoKnife System is a generation apart from other ablation modalities that use extreme heat or cold, such as microwave energy, radiofrequency ablation and cryoablation. Unlike these ablative modalities, the NanoKnife System does not utilize extreme heat or cold and poses no heat sink issues.

WELL DEMARCATED POST ABLATION ZONES

Physicians have experienced challenges with other ablative modalities, such as cryoablation or microwave ablation, because these modalities are unable to provide well demarcated post ablation zones. In contrast, the NanoKnife System procedure creates well demarcated post ablation zones (see Figure 1) by confirming needle placement under real-time CT or ultrasound guidance prior to energy delivery (see Figure 2).

Cells within the ablated area are irreversibly porated resulting in loss of homeostasis and subsequent cell death.
NanoKnife System Benefits

Because it does not rely on heat to create the ablation, NanoKnife may expand options for patients in whom the ablation of soft tissue may be difficult using other modalities.

- Uses high voltage, low energy electrical pulses to achieve tissue effect
- Poses no heat sink issues
- Well demarcated post ablation zones
- Allows real-time CT/ultrasound imaging of ablation zones
- Does not rely on heat to ablate tissue

Figure 1: Well defined post ablation zone can be viewed on hypoechoic ultrasound imaging which correlates to the gross pathology. (Images based on pre-clinical research in healthy porcine liver.)

Figure 2: Real-time CT/ultrasound imaging of probe placement.


IMPORTANT RISK INFORMATION

INDICATION FOR USE: The NanoKnife System with six outputs is indicated for surgical ablation of soft tissue. The system includes an energy generator, footswitch and single-use disposable electrode.

CONTRAINDICATIONS: Procedures based on high voltage pulses are not recommended in the following cases: Treatment of lesions in the thoracic area in the presence of implanted cardiac pacemakers or defibrillators; treatment of lesions in the vicinity of implanted electronic devices or implanted devices with metal parts, treatment of lesions of the eyes, including the eyelids; or patients with a history of epilepsy, cardiac arrhythmia, or recent history of myocardial infarction. The effects of NanoKnife System use on a fetus are not known. Procedure on pregnant women should be contemplated only after ensuring that the procedure benefits outweigh the risks.

WARNINGS AND PRECAUTIONS: The electrodes are sterilized by ethylene oxide and intended for single patient use. Sterile unless the package is opened or damaged. Do not re-sterilize or use if the device’s insulation is damaged. Avoid short-circuiting the electrodes when delivering pulses. The device is intended for use with an AngioDynamics generator only. Nanoflare Generator: Caution – Electrostatic Hazard! The Generator internally produces voltages that are dangerous and may be fatal. Do not use the Generator in the presence of flammable or explosive gas mixtures. Do not use the Generator if a malfunction is suspected. The physician MUST read the User Manual thoroughly before operating the NanoKnife System.

POTENTIAL COMPLICATIONS: Dissection, perforation, hematoma, arrhythmia (atrial fibrillation or flutter, heart block or atrioventricular block, paroxysmal supraventricular tachycardia, ventricular fibrillation, ventricular tachycardia, bradycardia, presyncope, muscle contraction, hemorrhage, unintended mechanical perforation, infection, vagal stimulation (myasthenia), fistula formation, venous thrombosis, or damage to critical anatomical structure (nerve, vessel, and/or duct). Indications, contraindications, warnings and instructions for use can be found in the user manual and instruction for use supplied with each NanoKnife electrode probe and system. Observe all instructions prior to use. Failure to do so may result in patient complications.

CAUTION: Federal (USA) law restricts the sale of this device by or on the order of a physician.