The NanoKnife® 3.0 System

<table>
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<tr>
<th>US Part Numbers</th>
<th>International Part Numbers</th>
<th>Description</th>
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</tbody>
</table>

References
5. Guidance for Selection of NanoKnife Probe Array Configuration and Ablation parameters for the Treatment of Stage III Pancreatic Cancer.

Indication For Use
10. The NanoKnife System can be used in conjunction with standard surgical or endoscopic procedures in the following conditions:

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:
• Arrhythmia
• Atrial fibrillation or flutter
• Bigeminy
• Bradycardia
• Heart block or atrioventricular block
• Paroxysmal supraventricular tachycardia
• Tachycardia
• Reflex tachycardia
• 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

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NanoKnife.com

YOUR TREATMENT REIMAGINED.
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, expanding versatility, and increasing preservation—giving you the control to tailor treatments with confidence.

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.

Electrodes can be deployed in multiple configurations providing precise and customizable ablation zones.

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

Harnesses the power of Irreversible Electroporation (IRE) to effectively destroy targeted cells without the use of thermal energy.

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

IRE effectively destroys the targeted tissue and gives you precise treatment margins resulting in confident treatment coverage for your procedure.

The procedure spares vital structures by retaining the structural integrity of the targeted tissue.

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

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.

Electrodes can be confidently placed near vital structures, maximizing your ability to personalize treatment to your patient’s anatomy.

PRECISION EMPOWERED.

PRESERVATION REDEFINED.

VERSATILITY PERFECTED.
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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.

Electrodes can be confidently placed near vital structures, maximizing your ability to personalize treatment to your patient’s anatomy.

PRECISION EMPOWERED.

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

IRE effectively destroys the targeted tissue and gives you precise treatment margins resulting in confident treatment coverage for your procedure.

PRESERVATION REDEFINED.

The delivery of non-thermal energy allows for the preservation of the extra-cellular matrix, facilitating post-ablation, histological and functional tissue regeneration.
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, expanding versatility, and increasing preservation—giving you the control to tailor treatments with confidence.

**Precision Empowered.**

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

IRE effectively destroys the targeted tissue and gives you precise treatment margins resulting in confident treatment coverage for your procedure.

**Preservation Redefined.**

The procedure spares vital structures by retaining the structural integrity of the targeted tissue.

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

**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.

Electrodes can be confidently placed near vital structures, maximizing your ability to personalize treatment to your patient’s anatomy.

Harnesses the power of Irreversible Electroporation (IRE) to effectively destroy targeted cells without the use of thermal energy.

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.

Electrodes can be deployed in multiple configurations providing precise and customizable ablation zones.

Sharp demarcation of IRE-ablated zone is well-visualized immediately during the procedure using real-time ultrasound imaging.
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## Indication For Use

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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
- Reflex tachycardia
- Ventricular tachycardia
- Ventricular fibrillation
- Damage to critical anatomical structure (nerve, vessel, and/or duct)
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- Hemothorax
- Infection
- Pneumothorax
- Reflex Hypertension
- Unintended mechanical perforation
- Vagal Stimulation, asystole
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**YOUR TREATMENT REIMAGINED.**
### THE NanoKnife 3.0 SYSTEM

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---|---|---
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H787204001090 | H7872040010300 | NanoKnife Single Electrode Activation Probe 15 cm
H787204001100 | H7872040010500 | NanoKnife Single Electrode Activation Probe 25 cm
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