

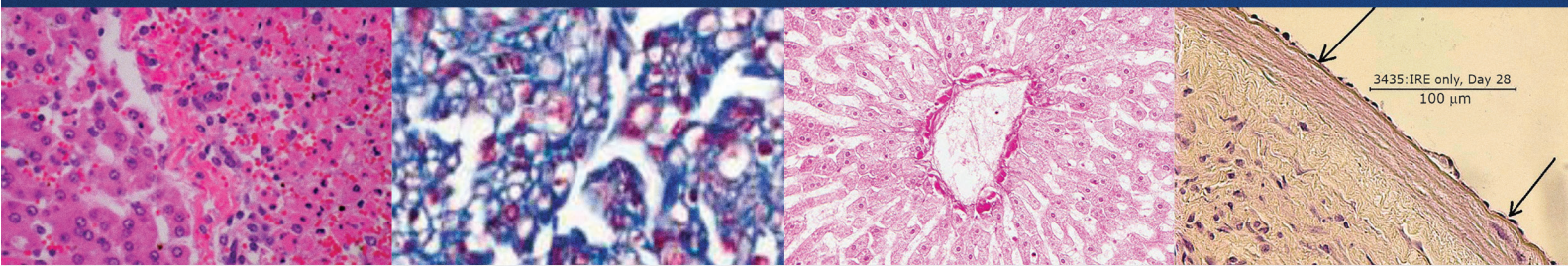
GENERAL BENEFITS OF IRE TREATMENT

Well Demarcated Ablation Zones ¹

Preserved Endoneural Architecture ^{2,3,4}

No Heat Sink Effect ^{6,7}

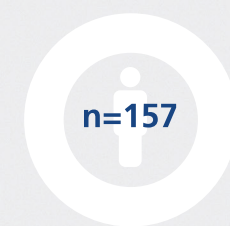
Leaves the Cellular Matrix of Large Blood Vessels Intact ^{5,8,9}



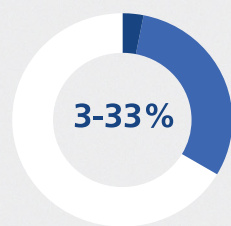
The images show following tissues (from left to right): porcine liver, porcine sciatic nerve, porcine liver & central vein, rat carotid artery

CURRENT STUDY OUTCOMES OF IRE TREATMENT IN PROSTATE CANCER

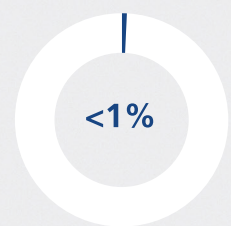
IRE for primary prostate cancer has been performed in a number of trials which demonstrated IRE as a safe and feasible ablation modality for focal therapy in localized prostate cancer. ^{10, 11, 12}



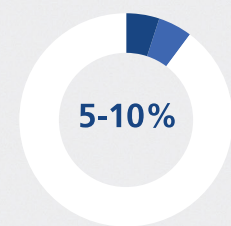
Patients in Studies



Biopsy Positive Oncological Outcome



Incontinence



Erectile Dysfunction

SOURCE: van der Poel HG, et al. Eur Urol, 2018, <https://doi.org/10.1016/j.eururo.2018.01.001>

NOTE: Despite current studies documenting that IRE has a low toxicity profile with encouraging genito-urinary functional outcomes and short-term oncological control is hopeful, Valerio et al. found suspicious residual disease in 38,9% patients (n=6) of which one had a histological verification of failure, long-term data still needs to confirm IRE as an effective focal treatment modality for tumor ablation in prostate cancer. ^{9,13}

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NanoKnife
IRREVERSIBLE ELECTROPORATION

NANOKNIFE SYSTEM

SKU	DESCRIPTION
20300101	NanoKnife System v2.2.0 Includes: Generator, Double Pedal Footswitch, Cardiac Gating Device, and 1-Year Warranty
H787204001030	NanoKnife Single Electrode Probe – Activation - 15 cm
H787204001040	NanoKnife Single Electrode Probe – Standard - 15 cm
H787204001050	NanoKnife Single Electrode Probe – Activation - 25 cm
H787204001060	NanoKnife Single Electrode Probe – Standard - 25 cm
H787204003015	NanoKnife Single Electrode Probe Spacers (Pack of 10)

Please consult your local AngioDynamics representative for country/EU member state specific availability.

INDICATIONS FOR USE:

EU: 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. FDA: The NanoKnife is intended for the surgical ablation of soft tissue in the United States. The FDA has not cleared the NanoKnife System for the treatment of any specific disease state or condition.

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; Pneumothorax; Muscle contraction; Hemorrhage; Unintended mechanical perforation; Infection; Bradycardia; Vagal Stimulation, asystole; and damage to critical anatomical structure (nerve, vessel, and/or duct). Indications, contraindications, warnings, precautions and instructions for use can be found in the Instructions for Use supplied with each device. Observe all instructions prior to use. Failure to do so may result in patient complications.

Please refer to the NanoKnife System User Manual and the NanoKnife Single Electrode Probe Directions For Use for complete instructions, warnings and precautions.

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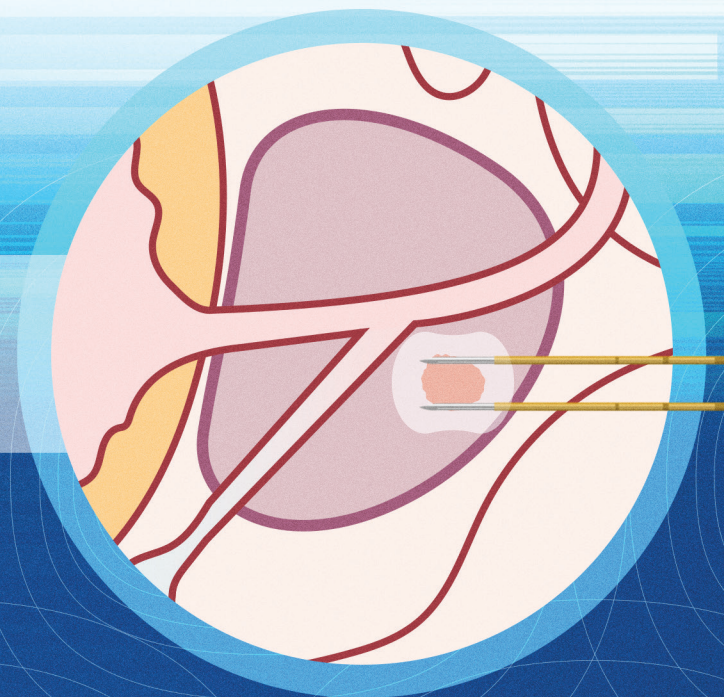
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NanoKnife
IRREVERSIBLE ELECTROPORATION

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PROSTATE CANCER



A UNIQUE ALTERNATIVE TO THERMAL ABLATION



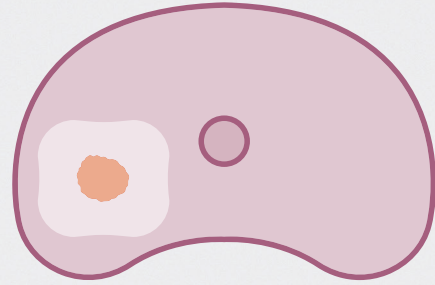
angiodynamics

The role of focal therapy as an emerging treatment option for localised prostate cancer

Focal therapy targets tumor lesions with the goal to spare adjacent anatomical structures that are of importance for urinary, bowel, and sexual function.¹

RELEVANCE

The European Association of Urology states that “radical treatment of localised prostate cancer is recognised to be an unnecessary intervention or overtreatment in many men. Consequently, there has been a rapid uptake in the use of focal ablative therapies. [...] Focal therapy is still considered to be an investigational modality, and encourage prospective recording of outcomes and recruitment of suitable patients.”²



PATIENT SELECTION

An international consensus project agreed on the following patient selection criteria:

- Multiparametric magnetic resonance imaging (mpMRI), including histological confirmation.
- Systematic biopsy to assess mpMRI-negative areas
- D’Amico low-/intermediate-risk cancer including Gleason 4+3
- Gleason 3+4 cancer, where localized, discrete and of favourable size represents the ideal case for focal therapy.
- Tumor foci <1.5 ml on mpMRI or <20% of the prostate are suitable for FT, or up to 3 ml or 25% if localised to one hemi-gland.
- Gleason 3+3 at one core 1mm is acceptable in the untreated area.³

FOCAL TREATMENT OPTIONS

Following table shows focal therapy options for primary prostate cancer management.²

TECHNIQUE	ABLATION	IMAGE GUIDANCE	NUMBER OF STUDIES (PATIENTS)	FU RANGE	ONCOLOGICAL OUTCOME	INCONTINENCE	URINARY RETENTION	ED
1 Cryotherapy	Freeze–thaw cycles	TRUS, mpMRI	12 (n=2118)	6–58 mo	4–25% biopsy positive	<1%	5% (6 mo)	0–31%
2 HIFU	Heat	TRUS, mpMRI	5 (n=171)	6–24 mo	0–21% biopsy positive	<1%	<5%	0–25%
3 IRE	Electroporation	mpMRI	5 (n=157)	6–12 mo	3–33% biopsy positive	<1%	<3%	5–10%
4 Laser	Heat	mpMRI	6 (n=85)	3 wk - 12 mo	4–64% biopsy positive	<1%	<1%	<5%
5 Photodynamic therapy	Vascular targeting	TRUS	3 (n=313)	6-24 mo	26–51% biopsy positive	<5%	7%	<2%
6 Brachytherapy	Radiation	TRUS, MRI dosimetry	7 (n=541)	24-60 mo	0–17% biopsy positive	<5%	NR	NR

ED = erectile dysfunction, as defined and reported by the studies; FU = follow-up; HIFU = high-intensity focused ultrasound; IRE = irreversible electroporation; mpMRI = multiparametric magnetic resonance imaging; MRI = magnetic resonance imaging; NR = not reported; TRUS = transrectal ultrasound.

Patients are encouraged to discuss their options with their oncologist.

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2. van der Poel HG, et al. Eur Urol, 2018, <https://doi.org/10.1016/j.eururo.2018.01.001>
3. Tay KJ, et al., 2017, 1–6, doi:10.1038/pcan.2017.8

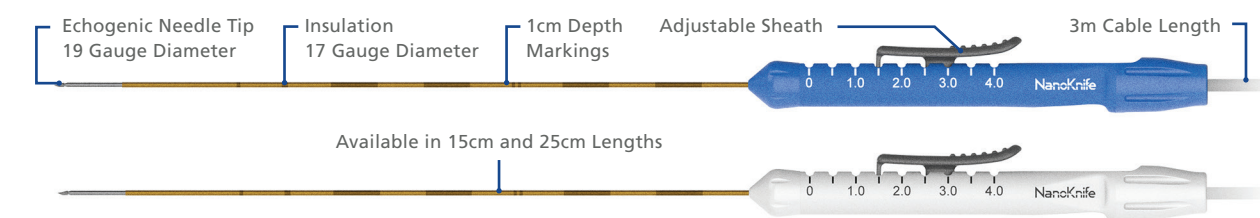
NanoKnife

IRREVERSIBLE ELECTROPORATION

An ablation procedure that uses low energy electrical pulses to create defects (pores) in cell membranes, resulting in loss of homeostasis and subsequent cell death.

A NanoKnife* procedure is an ablation procedure that involves the delivery of a series of high voltage direct current electrical pulses between two electrodes placed within a target area of tissue. The electrical pulses produce an electric field which induces electroporation on cells within the target area. Electroporation is a technique in which an electrical field is applied to cells in order to increase the permeability of the cell membranes through the formation of nanoscale defects in the lipid bilayer. After delivering a sufficient number of high voltage pulses, the cells surrounding the electrodes will be irreversibly damaged. This mechanism which causes permanent cell damage is referred to as Irreversible Electroporation (IRE).

The NanoKnife System carries a CE Mark for cell membrane electroporation.

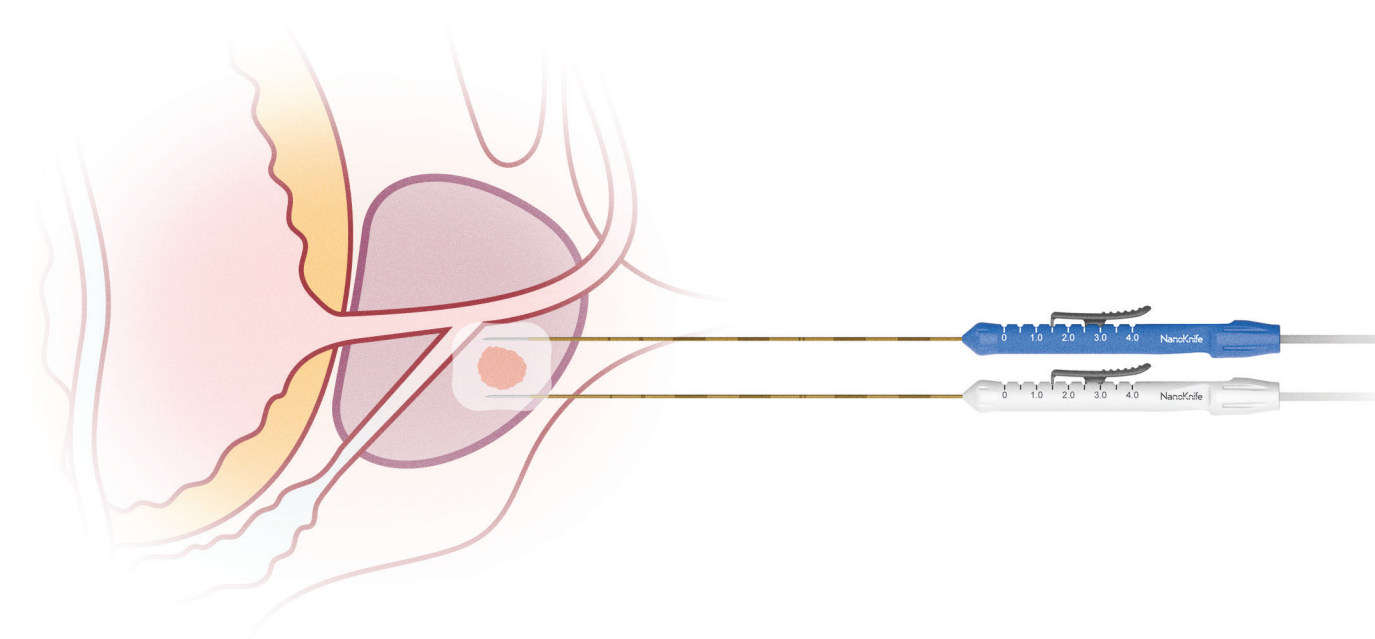


SYSTEM COMPONENTS

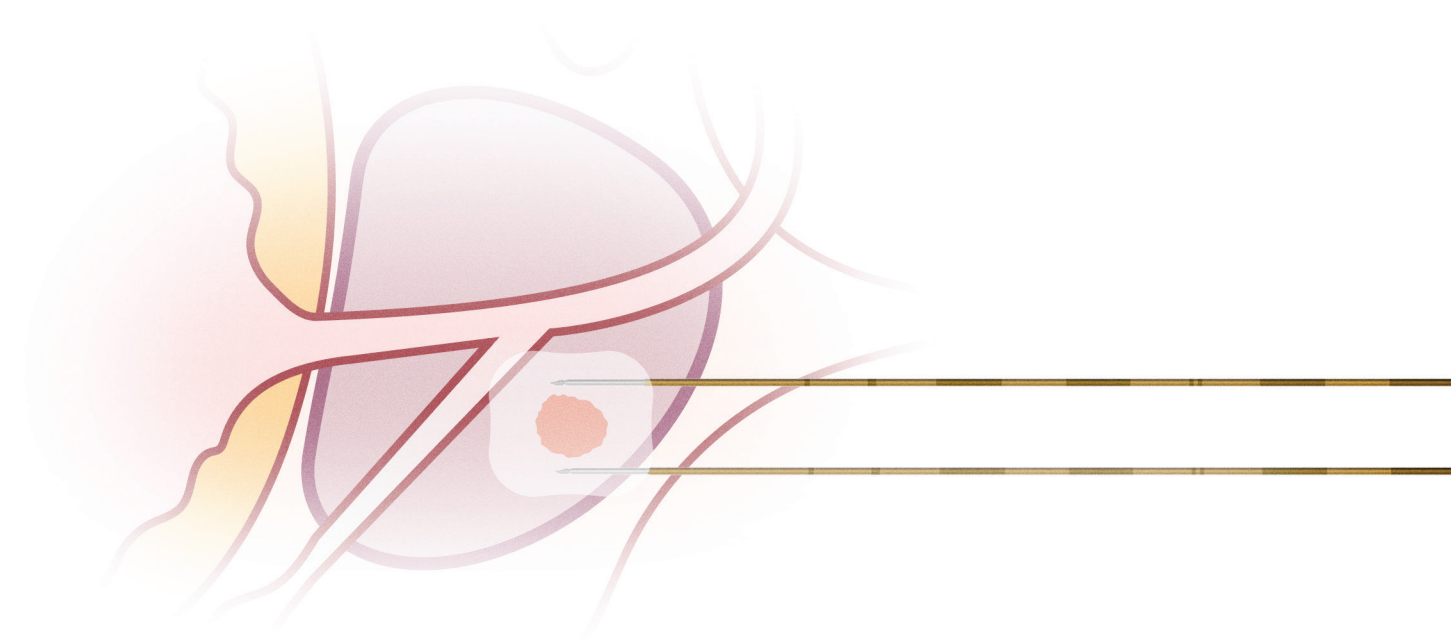
- Touch screen monitor
- USB Port to export procedure data
- Keyboard and trackpad for data entry
- Up to 6 probes, minimum of 2 probes needed
- Side pockets for cables and foot pedal
- Double foot pedal to activate system
- Wheels to transport to and from storage location

EXCERPT OF NANOKNIFE PROCEDURE STEPS

CAUTION: This page only shows a very short excerpt of the full NanoKnife ablation procedure. Please refer to the NanoKnife System User Manual and the NanoKnife Single Electrode Probe Directions For Use for complete instructions, warnings and precautions.



1) Under transrectal ultrasound guidance up to 6 NanoKnife probes are placed in the target zone. The use of a transperineal grid can facilitate this step.



2) Follow the steps displayed on the NanoKnife generator, make sure patient is under anaesthesia care with full muscle paralysis before delivering any pulses.

INFO: To prevent cardiac arrhythmias the pulses are synchronized with an electrocardiogram synchronizer.

