

### Post-operative treatment

The procedure enables the healthy tissue in the treatment area to completely regenerate after a short time, whilst the cancerous tissue is completely destroyed. In this way, important functions of the prostate are maintained.

Depending on the location of the prostate tumour, it is possible to protect the potency nerves so that impotence can be avoided.

Following treatment, many patients feel a fleeting muscle ache as the electrical impulses have activated the leg and pelvis muscles. In most cases, the catheter can be removed just a few days after treatment and the patient can leave the clinic after just one night's stay under medical supervision.

As with all tumours, close monitoring is also required after therapy in the case of prostatic carcinomas. It is not only a way of monitoring the success of the treatment, but also allows early recognition of possible complications which in most cases can be successfully resolved.

Possible temporary impotence or incontinence is rare, but cannot be ruled out 100 percent. However, these symptoms usually disappear after a few weeks - if they occur at all.

A follow-up examination is carried out after one month and then every three to six months during the first year following treatment.

The urologists control the field strength and impulse length via the generator.



The NanoKnife System has received FDA (US Food and Drug Administration) clearance for the surgical ablation of soft tissue. It has not received clearance for the therapy or treatment of any specific disease or condition. [510(k) Number: K080376].

The Clinic for Prostate Therapy is the only clinic in Germany where the urologists use the procedure as a standard therapy for prostate cancer.

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All informations  
about modern  
prostate therapy



## Gentle prostate therapy with NanoKnife/irreversible electroporation (IRE)



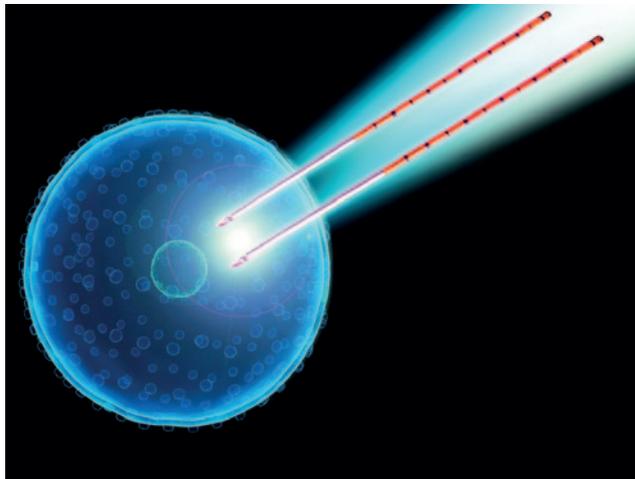
## Gentle and minimally invasive

There are alternatives to a radical prostatectomy (complete surgical removal of the prostate), which are very gentle and minimally invasive:

- Firstly, the **HIFU** treatment concept. High intensity focused ultrasound waves produce heated areas which destroy the tumour cells in a targeted manner. However, tumours cannot always be treated using this method. For instance, if the prostate is too large or partially calcified. Or if the carcinoma is located outside the range of the ultrasonic waves due to its position or anatomical variations in the prostate. Here, the IRE procedure provides a possible treatment option:

- **The irreversible electroporation (IRE) procedure**

The NanoKnife IRE procedure used in the Heidelberg Clinic for Prostate Therapy was developed by the American company AngioDynamics (New York, USA) and is being used by the Heidelberg urologists for the very first time in Germany as a standardised procedure for the treatment of prostate cancer.

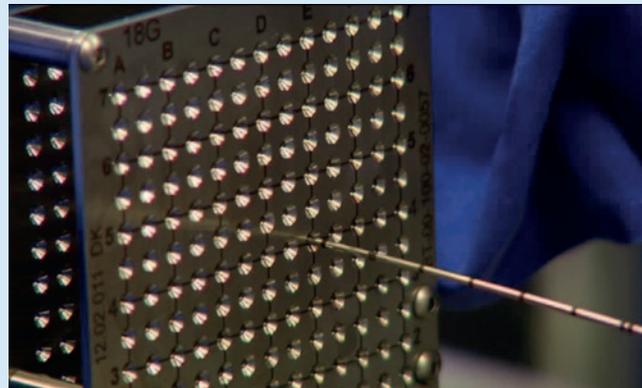


In IRE therapy, a pulsed electrical field is created around the needle-like probes and this opens the cell membranes in the treatment area, thereby destroying the cells. As no heat is generated in this procedure, the healthy tissue can recover, whilst the cancer cells die.

## The principle of irreversible electroporation (IRE)

The procedure uses short electrical pulses to effectively destroy cancer cells – a physical effect that has been known for decades. The impulses which have differing strengths and last for only a few microseconds, open pores in the cells in the treatment area and this causes the cells to die. This is also where the term “NanoKnife” originates from – a kind of “electronic scalpel” that opens the cell membrane.

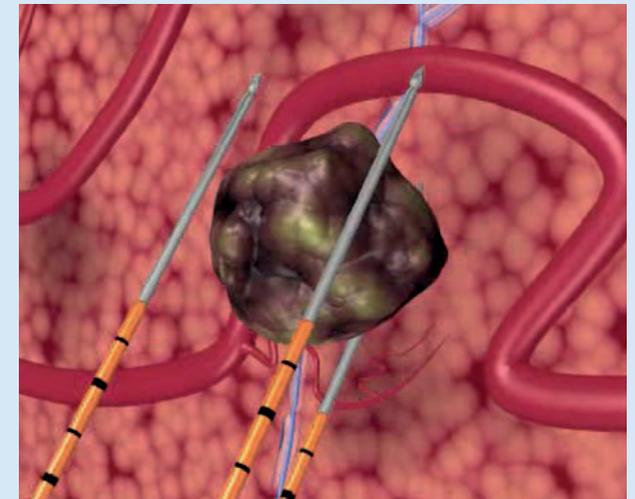
What is special about this method of treatment is that the pulses are extremely short and it does not generate heat. This means that the cell matrix of the healthy tissue in the area of treatment remains preserved and is able to regenerate itself: the healthy tissue grows again without any problem and the healthy areas of the prostate such as blood vessels and other ducts are preserved to the greatest possible extent. The dead cancer cells are replaced by healthy cells as part of the body’s natural growth process.



The metal template is similar to the template used in the MRI-guided biopsy. It has a coordinate system which enables the IRE probes to be positioned in the prostate or around the tumour with millimetre precision.

Depending on the size of the tumour, between two and six needles are required. Larger tumours can also be treated. When the needles are positioned around the tumour, high-voltage impulses of 70 microseconds ( $\mu$ s) in length are emitted, which are repeated every 100 to 1,000 milliseconds (ms). They create short currents of around 50 amperes. The electrical impulses open the cell membranes by creating tiny holes, known as nanopores. The cell then dies.

The field strength and impulse length are set so that no heat is generated - therefore the cells are not destroyed by heat, but by the electrical field of the NanoKnife which opens the cell membrane.



The diagram shows the insertion of three IRE probes, which are positioned around the tumour. The quantity of probes used depends on the size and position of the tumour.