Using HIFU

to help patients with prostate cancer

Ablatherm® HIFU and Focal One® treat prostate cancer by focusing high-intensity ultrasound waves on the affected area, creating a localized heating effect that destroys the cells in the gland without damaging the surrounding tissue. This non-invasive treatment has been used in humans since 1993 and has since demonstrated its therapeutic efficacy. HIFU treatment is recognized by the urogical associations or organizations in several countries, which regularly issue official recommendations relating to its use. HIFU offers a real alternative to surgery and radiotherapy that should be considered and discussed with every patient.

Which patients can be treated with HIFU?

Patients who have not yet received any treatment for prostate cancer

HIFU is particularly recommended for radical treatment with patients who have:

- A localized stage t1 or t2 cancer
- A Gleason score of 7 or less
- A desire to maintain maximum quality of life after treatment

Patients seeking an innovative approach: Focal treatment

HIFU is the ideal treatment tool in cases where the decision has been made to treat just the diseased part of the prostate in order to maintain maximum quality of life by limiting the impact of treatment on the surrounding tissue (including sphincters, erector nerves, the bladder and the rectum). The aim of this therapeutic approach is to control the disease by closely monitoring the patient and repeating the treatment if and when necessary. This innovative care strategy is currently being investigated.

Patients who have relapsed after radiotherapy

HIFU offers an unprecedented curative option for patients suffering from localized relapse following radiotherapy. Survival rates are low when this situation is treated with surgery, and hormone therapy serves only a palliative purpose.

HIFU contraindications

- Anal or rectal surgery that prevents insertion of the probe
- Artificial sphincter, penile implants and intra-prostatic implants
- Latex allergy (due to the composition of the balloon surrounding the treatment probe)

HIFU (Ablatherm® HIFU and Focal One® devices) has been developed and is distributed by EDAP TMS (Lyon, France, www.edap-tms.com) in conjunction with the French national institute for health and medical research, Inserm. Ablatherm® HIFU bears the CE mark since 2000 and is approved by FDA in the United states from 2015. Focal One® is CE marked from 2013 and its FDA approval is pending. EDAP TMS has more than 37 years' experience as a major force for medical innovation in the area of non-invasive treatments for urological pathologies such as urinary stones and prostate cancer.

Patient benefits offered by HIFU

Non-invasive (incisionless) treatment allowing speedy resumption of normal life

HIFU is a non-invasive treatment performed via the rectum, which limits the need for post-operative care, shortens hospital stays and allows patients to resume their normal lives very quickly.

Repeatable radiation-free treatment

As the treatment principle is to generate high-intensity focused ultrasound waves that cause a sudden temperature increase (90°C) in the treated area, the concept of a maximum dose is not relevant.

Customized "radical" or "focal" treatment

With the HIFU, the urologist is able to perform a personalized treatment, taking into account the anatomy of the prostate, the patient's preferences and any other treatments already received. The urologist may decide to treat only the diseased part of the prostate (in a «focal» strategy, as opposed to a «radical» approach) in order to maintain maximum quality of life by limiting the impact on the surrounding tissue.

Robotized treatment for maximum precision and safety

The urologist plans the HIFU treatment and the machine then executes the instructions to the letter, with movements that are accurate to within a millimeter, which is not possible when working by hand. The HIFU device is equipped with many automatic safety features and the treatment parameters can be monitored in real time for maximum safety and effectiveness.

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What does HIFU treatment do?

HIFU - a safe and effective non-invasive treatment

HIFU treatment is performed under local or general anesthesia. A typical session lasts between 90 minutes and 2 hours. The patient lies in the lateral decubitus right position. The treatment probe is inserted into the patient's rectum, allowing the physician to view the prostate using the built-in ultrasound scanner and treat the patient.

The operating principle enables selective treatment that spares the surrounding tissue

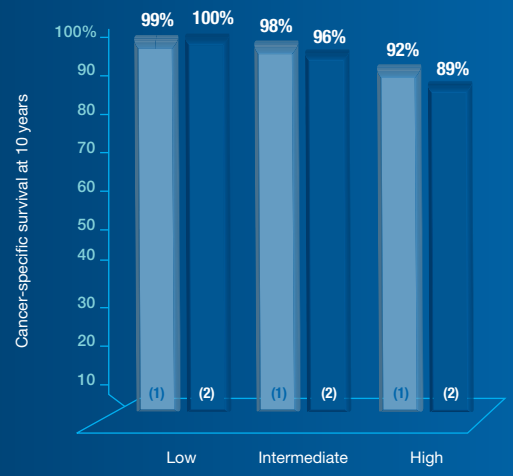
The HIFU machine emits computer-controlled, high-intensity focused ultrasound (HIFU) pulses directed at a very small area of the prostate (accurate to within 1 mm), instantly and permanently destroying the targeted tissue, without damaging the surrounding tissue. Prostate tissue is destroyed by coagulative necrosis. This effect is achieved by raising the temperature above 85°C.

HIFU also spares the erector nerves, thereby minimizing impotence, which is a common side effect of prostate cancer treatments.

HIFU Clinical Evidence

10 year follow-up data

- High Intensity Focused Ultrasound for Prostate Cancer is backed-up with more than 80 articles reviewed for urologist specialists showing long-therm, large number or quantity of treatment results.



Proven oncological efficacy at 10 years for primary treatment

[1] Crouzet S et al. Eur Urol. 2014 May;65(5):907-14 - [2] Ganzer R et al. BJU Int. 2013 Aug; 112(3):322-9

Focal HIFU

Hemiablation strategy results

- French multicentric (10 centers) study on half gland ablation by HIFU promoted by French Association of Urology.*

111	Patients treated by Hemi-HIFU – mean follow-up of 30.4 months
95%	Absence of Clinically Significant Cancer (CSC: Gleason score ≥7 or cancer core length >3mm regardless of grade or >2 positive cores)
89%	Radical Treatment Free Survival (RTFS) at 2 years
97%	Continence preservation
78%	Erectile Function preservation

* Rischmann et al.; European Urology, October 2016; S0302-2838(16)30679-0