

# Using Ablatherm® HIFU to help patients with prostate cancer



The Ablatherm® HIFU system treats 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. It is no longer considered an experimental procedure and its effectiveness has been demonstrated.

The Ablatherm® HIFU is recognized by the orders of urology specialists in several countries, which regularly issue official recommendations relating to its use.

The Ablatherm® HIFU offers a real alternative to surgery and radiotherapy that should be considered and discussed with every patient.



## Which patients can be treated with the Ablatherm® HIFU?

### Patients who have not yet received any treatment for prostate cancer

- The Ablatherm® 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

The Ablatherm® 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

The Ablatherm® 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.

### Ablatherm® 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)

The Ablatherm® HIFU has been developed and is distributed by EDAP TMS (Lyon, France, [www.edap-tms.com](http://www.edap-tms.com)) in conjunction with the French national institute for health and medical research, Inserm.

The Ablatherm® HIFU bears the 'CE' mark since 2000. EDAP TMS has more than 30 years' experience as a major force for medical innovation in the area of non-invasive treatments for urological pathologies such as calculi and prostate cancer.

## Patient benefits offered by the Ablatherm® HIFU

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

Ablatherm® 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 Ablatherm® 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 Ablatherm® 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 Ablatherm® HIFU 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 Ablatherm® HIFU treatment do?

### Ablatherm® HIFU - a safe and effective non-invasive treatment

Ablatherm® HIFU treatment is performed under local or regional anesthetic. A typical session lasts between 90 minutes and 2 hours. The patient lies on the Ablatherm® HIFU table 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 Ablatherm® 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. Each ultrasound «shot» treats an area approximately 25 mm long and 2 mm in diameter. Treating a complete prostate therefore requires between 400 and 600 shots.

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

## Clinical effectiveness of the Ablatherm® HIFU in figures

The medical teams pioneering the Ablatherm® HIFU have reported very encouraging clinical results, with data histories of up to 10 years in certain studies.

### Disease control

A literature review relating to the use of Ablatherm® HIFU for first-line therapy conducted by the Association Française d'Urologie<sup>(1)</sup> revealed that the disease was brought under control in up to 93% of patients (64-93%). A European study revealed an average negative biopsy rate of 87%<sup>(2)</sup>.

When treating failed radiotherapy cases with the Ablatherm® HIFU, 10-year checkup biopsy results were negative for 73% of patients.

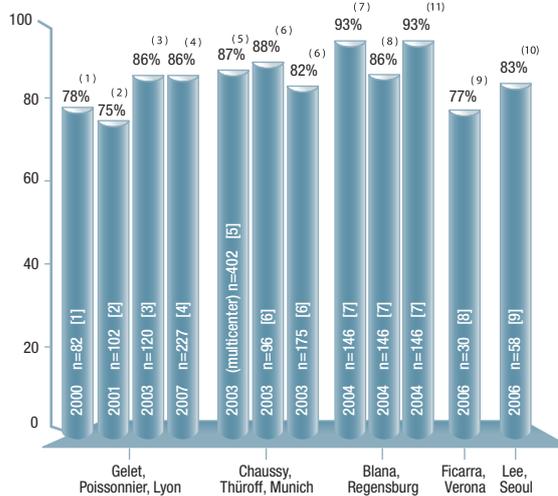
### Side effects

Incontinence and erectile dysfunction are the two most common side effects associated with prostate cancer treatments. They have a severe impact on the patient's quality of life.

With the Ablatherm® HIFU, almost all patients (98%) remain continent after treatment<sup>(3)</sup>.

In addition, 87% of patients treated with the Ablatherm® HIFU did not suffer attributable sexual impotence, due to the strategy of preserving the erector nerves<sup>(4)</sup>.

### Negative biopsy rate



1. Gelet et al. J Endourol. 2000;14(6):519-28; 2. Gelet et al. Eur Urol. 2001;40(2):124-9; 3. Poissonnier et al. Prog Urol. 2003;13(1):60-72; 4. Poissonnier et al. Eur Urol. 2007;51(2):381-7; 5. Thüroff et al. J Endourol. 2003;17(8):673-7; 6. Chaussy et al. Curr Urol Rep. 2003;4(3):248-52; 7. Blana et al. Urology. 2004;63(2):297-300; 8. Blana et al. European Urol. 2008; 53:1194-1203; 9. Ficarra et al. BJU Int. 2006;98(6):1193-8; 10. Lee et al. Prostate Cancer Prostatic Dis. 2006;9(4):439-43; 11. Blana et al. Urology. 2008;72:1329-33

## More information on Ablatherm® HIFU : [www.hifu-planet.com](http://www.hifu-planet.com)

- Go and see a treatment video
- Find an Ablatherm® HIFU treatment site
- Order and receive a brochure for free
- Read the patients' experiences
- A certified HONcode website



<sup>(1)</sup>High-intensity focused ultrasound in prostate cancer; a systematic literature review of the French Association of Urology; Xavier Rebillard et al; BJU International 2008 1464-410X.2008.07504.x.  
<sup>(2)</sup>High-Intensity Focused Ultrasound and Localized Prostate Cancer: Efficacy Results from the European Multicentric Study; S.Thüroff et al; Journal of Endourology, Volume 17, Number 8, October 2003.  
<sup>(3)</sup>The Status of High-Intensity Focused Ultrasound in the Treatment of Localized Prostate Cancer and the Impact of a Combined Resection; C. Chaussy, S.Thüroff; Munich-Harlaching University, Germany, Current Urology Reports, Volume 4, Issue 3, 2003; 248  
<sup>(4)</sup>High-Intensity Focused Ultrasound and Localized Prostate Cancer: Efficacy Results from the European Multicentric Study; S.Thüroff et al; Journal of Endourology, Volume 17, Number 8, October 2003.