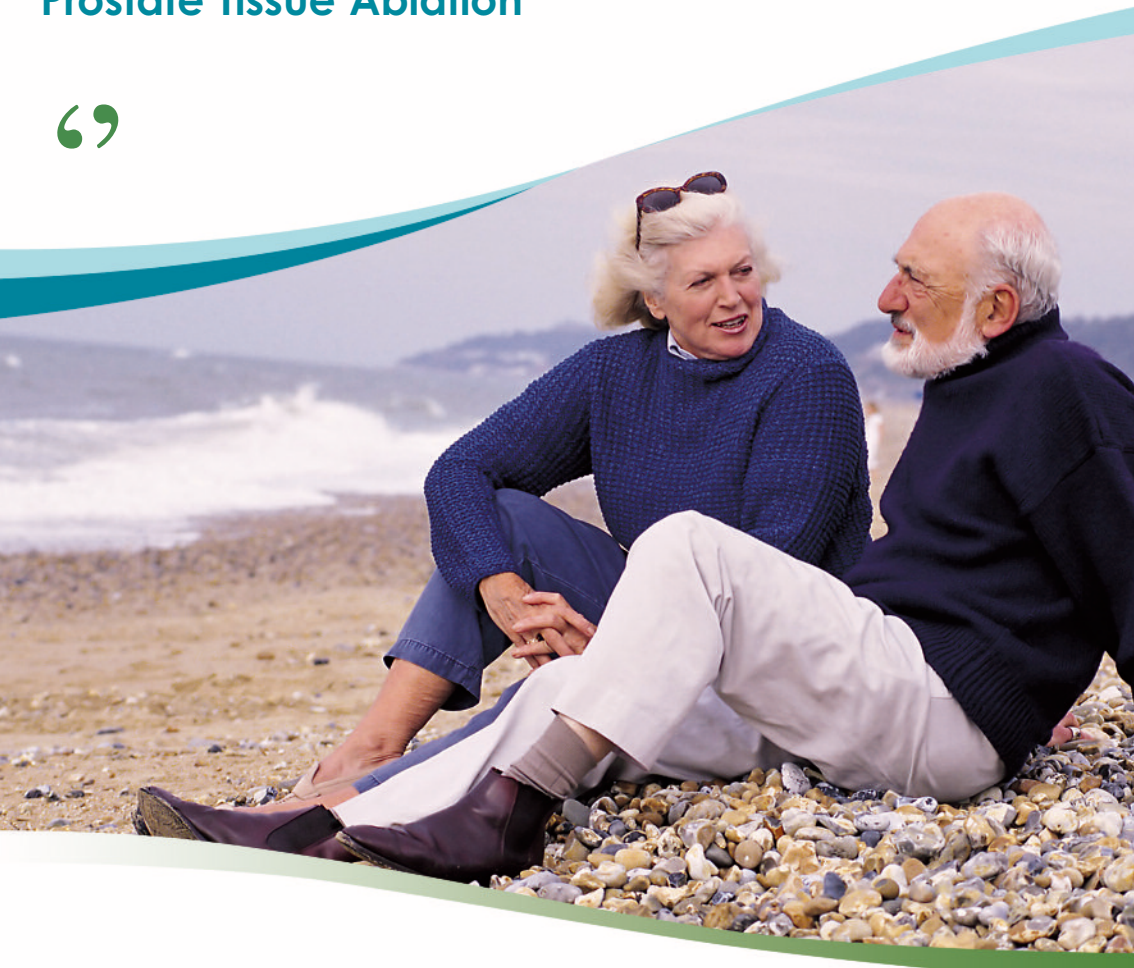




High Intensity Focused Ultrasound for  
**Prostate Tissue Ablation**



## Patient Information



**CAUTION:** Federal law restricts this device to sell by or on the order of a physician

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## CONTENT

Introduction.....	3
The prostate.....	4
What is cancer?.....	5
Prostate cancer.....	5
Assessment and diagnosis.....	6
Classification.....	7
Treatments of localized prostate cancer.....	7
About Ablatherm HIFU procedure.....	8
Ablatherm HIFU procedure step by step.....	12
The benefits.....	14

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# Introduction



You have been diagnosed with prostate cancer and your urologist has suggested an ablation using High Intensity Focused Ultrasound.

You probably have many questions concerning your disease, treatment options and their possible effects.

This brochure contains information on prostate cancer, its diagnosis and the various treatment options available, including High Intensity Focused Ultrasound (HIFU) ablation. It will help you understand why your urologist has recommended this particular approach.

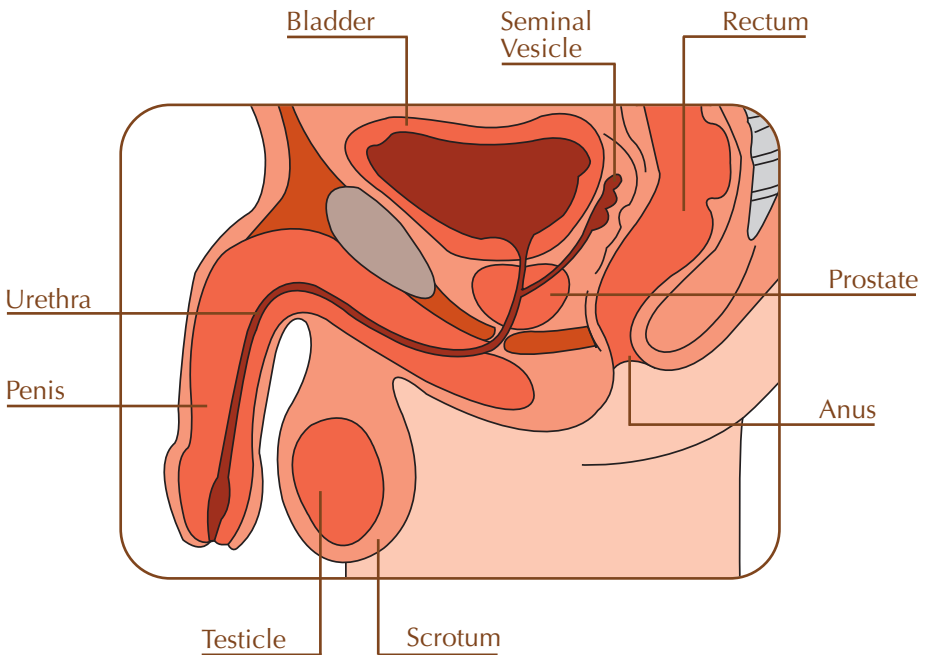


# The prostate

**The prostate is a part of the male reproductive system.**

The prostate is not involved in sexual intercourse directly. Its function is to add nutrients and fluid to sperm.

Normally the size of a walnut, the prostate tends to grow with age. It is located in front of the rectum and just below the bladder. It surrounds the urethra, the tube that carries urine and semen through the penis.



# What is cancer?

**All body organs are composed of cells that are specialized to the type of job that they do. Our cells are dying and being replaced constantly and this process occurs by cell division.**

Cancer is caused by a defect during the division of normal cells which turns them into malignant (cancerous) cells. Malignant cells grow much faster than healthy ones and can spread into surrounding tissue.

Typically malignant cells will grow and multiply forming a mass of tissue known as a tumor. First located in one organ, a tumor may grow into surrounding tissue and also spread throughout the body.

When tumor cells are transported through the blood and lymph systems to reach remote organs, we use the term metastases (from the Greek word meaning displacement).

# Prostate Cancer

**Prostate cancer is the most common cancer in men; responsible for one in three of all male cancers. There are more cases of prostate cancer every year than lung and colon cancer.**

The aggressiveness of prostate cancer can vary; some cancers develop very slowly and have no symptoms, whereas others spread quickly, invading surrounding tissue and forming metastases.

The risk of prostate cancer increases with age. Prostate cancer is diagnosed in about 1 of every 7 men during their lifetime but only 1 in 38 will die of the disease. There are generally no signs or symptoms during the early stages of the disease, and these appear depending on where the cancer is located in the prostate and whether it has spread.

# Assessment & diagnosis

**If diagnosed early the chance of recovery from prostate cancer is very high.**

Prostate cancer can be detected in routine screening. A doctor will perform a digital rectal examination of the prostate to feel for any abnormalities such as hardness or increased size. A doctor may also carry out a blood test to record levels of prostate specific antigen (PSA). PSA is a protein produced by both normal and cancerous prostate cells and high levels of PSA can be a sign of cancer. The PSA test helps identify tumors that cannot be detected by digital rectal examination (about

30% of cases of all prostate cancers). Some cancers are detected during treatment of benign prostate hypertrophy.

Tests to check for cancer include:

## **1. Biopsy**

A sample of prostate tissue is removed with a fine needle for examination.

## **2. MRI or CT scan**

Imaging of all body organs to detect for possible cancer in the lymph nodes, liver or other organs.

## **3. Bone scan**

Imaging of all bones to check for any cancer in the bones.

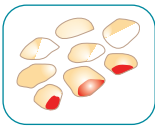


# Classification

Cancers are diagnosed at different stages of development and progression and are classified into:

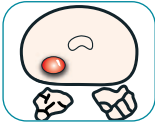
## ■ Localized prostate cancer (stages T1 or T2).

The tumor is confined to the prostate itself (intracapsular).



### Stage T1

Only a few cells have turned cancerous and so cancer can only be detected via blood tests or a biopsy. The cancer is not revealed by a rectal examination.



### Stage T2

The cancer is a little bigger and makes the prostate gland harder. A doctor can now detect the cancer during a rectal examination.

## ■ Locally advanced prostate cancer (stages T3 and T4)

The tumor spreads into surrounding organs

### Stage T3



The prostate cancer has spread to the shell of the prostate gland.

### Stage T4



The prostate cancer has spread outside the prostate and possibly to other organs.

# Treatments for localized prostate cancer

## ■ Treatments for prostate cancer include:

### Surgery (radical prostatectomy)

The whole prostate is removed with the seminal vesicles (which produce semen), the connected canals (which carry the sperm), part of the neck of the bladder and

the surrounding lymph nodes. Surgery requires a general anesthesia and lasts about three to four hours.

### External radiotherapy

This treatment involves the use of radiation (very high energy rays) directed at the prostate gland to

kill cancerous cells. Most healthy cells have a special repair mechanism if affected by this type of radiation but cancer cells do not so are killed. Radiotherapy does not require anesthesia and treatment is generally given during regular visits over several weeks.

### **Brachytherapy**

This treatment is performed under general anesthesia most of the

time and involves the implantation of tiny radioactive seeds directly into the prostate gland to irradiate and destroy the cancer cells.

### **Cryotherapy**

Guided by ultrasound, the prostate gland is frozen solid killing the cancerous cells. The procedure is done under general or spinal anesthesia.

## About **Ablatherm<sup>®</sup>** HIFU procedure

### ■ **High Intensity Focused Ultrasound**

High Intensity Focused Ultrasound (**HIFU**) is a minimally-invasive ablation which can be used for cases of localized (contained) prostate cancer. Ultrasound waves are focused with extreme precision instantly and effectively destroying the targeted cells within the prostate.

The ultrasound waves are delivered via a probe which is inserted into the rectum. The procedure lasts one to three hours and can be performed under general or spinal anesthesia.

### ■ **About Ablatherm HIFU**

**Ablatherm HIFU is a minimally-invasive medical device which uses HIFU (High Intensity Focused Ultrasound) to ablate prostate tissue.**

The procedure requires only a short hospital stay and has a low complication rate. The prostate tissue will be destroyed by the thermal effect of **HIFU** (temperature rising to 85°C), therefore there is no radiation involved.

### ■ **Who should undergo HIFU?**

Your urologist may recommend **Ablatherm HIFU** if you require treatment for localized prostate cancer for the first time and wait a minimally invasive treatment.



■ **Are there reasons why or circumstances in which HIFU procedure is not a possible option?**

Almost none – this type of procedure is not the most appropriate for men with very large prostates but if is the case a TURP (Transurethral Resection of the Prostate) or hormone treatment can be given to reduce the size of the gland so that the **Ablatherm HIFU** procedure is made possible. In some cases **Ablatherm HIFU** is not recommended for men who have experienced hardening of the rectal wall due to previous cancer treatments.

■ **Is HIFU FDA approved?**

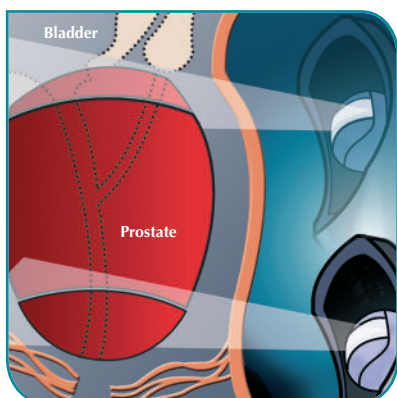
The first treatment was performed in 1993 and the latest generation of **Ablatherm HIFU** device was given market approval for Europe (CE) in 2005 and for the USA (FDA) in 2015.

**As of 2015, over 45,000 patients have benefited from Ablatherm HIFU in 250 centers across the world.**



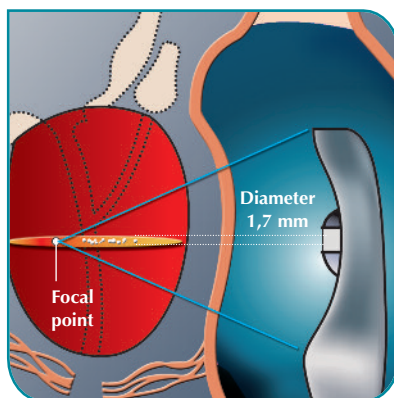
## ■ How does Ablatherm HIFU work?

The doctor uses the **Ablatherm HIFU** device to ablate prostate tissue. The doctor inserts a probe into the rectum. This probe includes an imaging component which allows the doctor to view the treatment area on a computer screen. The probe also includes a transducer which emits the focused ultrasound waves.



*The targeted prostatic volume is localized with a transrectal ultrasound imaging probe.*

The doctor inputs a treatment plan into the computer which then controls and aims the ultrasound waves. These are focused with extreme precision onto the targeted cancerous cells in the prostate, causing a very brief rise in temperature (around 85° C). The targeted tissue is then instantly and effectively destroyed, while the surrounding tissue is preserved.

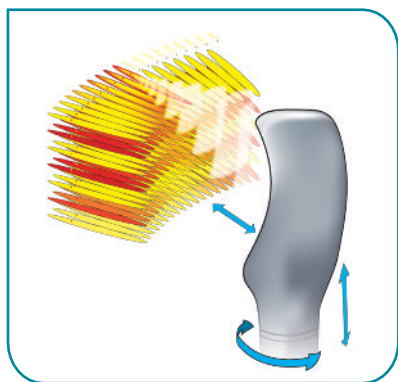


*At the focal point of the ultrasound beam, a sharp temperature rise destroys the cancer cells.*

The **Ablatherm HIFU** machine has numerous safety checks which are constantly monitored throughout the procedure to ensure patient safety. This means that the treatment is always delivered to the same high standard and quality.

## ■ Procedure

You will be asked to come into hospital the night before your treatment. You will be given a digestive preparation (enema) to prepare the rectum. The procedure is generally performed under local (epidural) or general anesthesia to ensure you remain completely still. You will lie on your right-hand side and the doctor will place a gel-coated probe into your rectum. The doctor locates your prostate and the area to be treated. The **HIFU** procedure can then start - 400 to 600 shots of High Intensity Focused Ultrasound



The **Ablatherm HIFU** probe is controlled by a computer to generate the ultrasound waves.

waves are generally given. The procedure can last between one and three hours.

### ■ Why is catheterization needed?

The prostate swells after treatment and presses on the urethra (canal which discharges urine from the bladder) so catheterization to remove urine is necessary until the swelling subsides.

To reduce the need for catheterization after treatment, a transurethral resection of the prostate (TURP) can be performed before the procedure. TURP involves removing the part of the prostate which presses on the urethra by passing a thin tube up the urethra via the penis.

### ■ Is the Ablatherm HIFU procedure painful?

The procedure itself is not painful as it is carried out under spinal anesthetic (epidural) or general

anesthetic. Pain at the end of the treatment is rare, although most patients feel a slight discomfort which disappears after a few days. The procedure is minimally invasive so there are no wounds and patients do not experience the burning sensation often associated with radiotherapy.

### ■ What happens after treatment?

Most patients can go back to eating normal food the evening after treatment and are discharged from hospital the next day. The urinary catheter is generally removed three or four days later. Medication may be prescribed after HIFU to prevent any infection of the urethra or bladder. In the period after treatment you may experience some discomfort including mild bleeding at the start of urination, frequent and sometimes urgent urination, urine leakage during physical exertion or coughing and sometimes the elimination of dead cancer cells in the urine. Infections with fever are rare but possible and require antibiotics. These side effects disappear in the weeks following the treatment.

### ■ What long-term follow up is required?

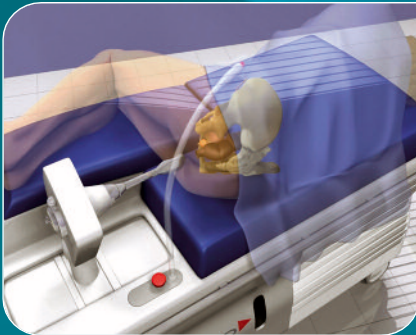
Usually PSA levels are checked every three months and a biopsy is undertaken six months after treatment.

# Ablatherm HIFU

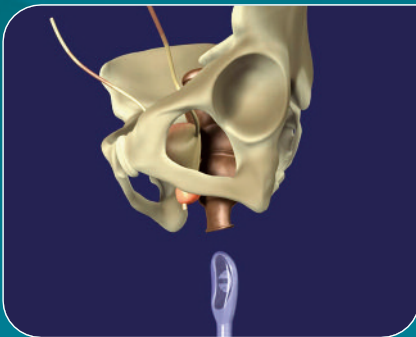
## Treatment step by step



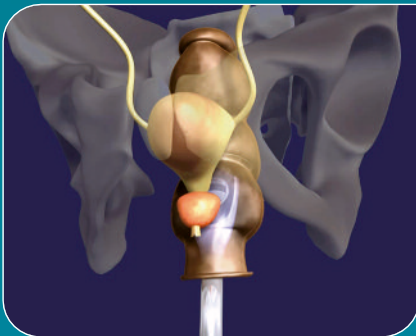
- 1 The patient lies down on his right hand side and stays in this position throughout the treatment.



- 2 This picture illustrates the position of the probe in relation to the rectum and the prostate (here in orange colour).

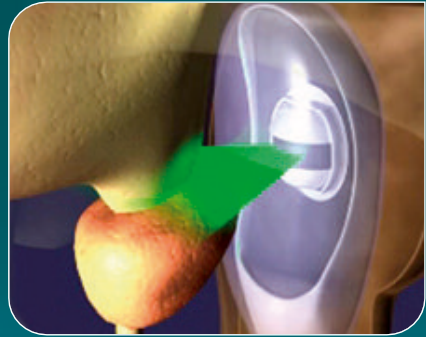


- 3 Due to the closeness of the prostate to the rectal wall, the treatment is performed optimally using the transrectal approach.

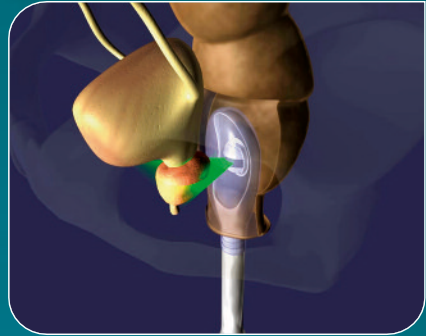


- 4 The probe is lubricated and then inserted into the rectum via the anus. The prostate is then accessible for ultrasound ablation.

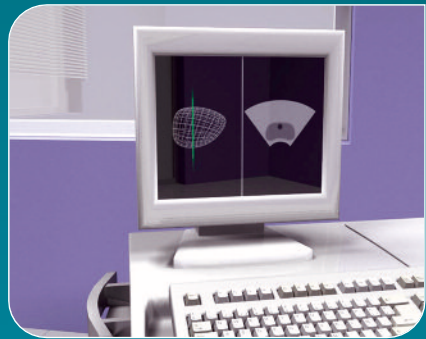
- 5 The imaging transducer in the middle of the probe allows a very precise three-dimensional reconstruction of the area to be treated and to be seen on a monitor.



- 6 The whole prostate is scanned and visible on the computer screen.



- 7 On the screen, the surgeon plans each step of the treatment with a microscope precision.




- 8 Finally, the machine produces High Intensity Focused Ultrasound waves which destroy the cancer cells.



# The benefits



The ablation of prostate tissue with High Intensity Focused Ultrasound is an option with many advantages:

- **Non-invasive procedure**
  - **Destruction of the cancerous tissue with minimal effect to the surrounding organs**
  - **Does not use radiation**
  - **Can be performed under spinal anesthesia**
  - **Can be performed in one session**
  - **Requires only a short stay in hospital**
  - **Other therapeutic alternatives can be considered if results are unsatisfactory**
- 



## James C. Lin, M.D.

### EDUCATION

B.S., Rensselaer Polytechnic Institute  
M.D., Albany Medical College, Albany NY  
Residency - Wayne State University/Detroit Medical  
Center General Surgery Residency and Urology Residency

### SPECIALITIES

HIFU  
MRI Fusion Guided Prostate Biopsy (URONAV)  
Men's Health  
Prostate Cancer

### BIOGRAPHY

After finishing his training at Albany Medical College, Dr. Lin has been practicing urology in the Boston area since 2002. He co-founded the robotics urology program at Beth Israel Deaconess Hospital in Milton in 2008. The program eventually was expanded to the downtown medical center.

Dr. Lin is trained and certified in 3D MRI fusion biopsy, a diagnostic procedure with higher accuracy than biopsy guided by ultrasound alone. Additionally, in 2016, Dr. Lin was one of two physicians to perform the first Ablatherm® HIFU surgery in the state of Massachusetts.

### HOSPITAL AFFILIATIONS

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