



Non-Invasive Cancer Treatment

HIFU for Prostate Cancer

*High Intensity
Focused Ultrasound*



Patient Guide to Prostate Cancer and Non-Invasive HIFU Treatment

*HIFU: The prostate cancer treatment
focused on a higher quality of life*



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INTRODUCTION

If you are reading this, chances are high that you or a loved one has recently been diagnosed with prostate cancer. Chances are also high that you have been inundated with information about treatment options and have lots of questions and concerns.

The good news is having prostate cancer doesn't mean you have to stop enjoying life.

New technology is being developed quickly to improve targeted treatment for prostate cancer that minimize side effects related to traditional treatments such as surgery and radiation.

You can eliminate prostate cancer and preserve your quality of life.

HIFU, which is short for, High Intensity Focused Ultrasound is a non-invasive treatment for prostate cancer that can eliminate cancer while maintaining continence and sexual function.

This patient guide is designed to help men and their loves ones navigate easy-to-understand information about prostate cancer, treatment options and specifically about non-invasive HIFU for localized prostate cancer.



Learn more about HIFU by calling
1.877.884.HIFU(4438)
to speak with a HIFU nurse.

Or visit HIFUProstateServices.com

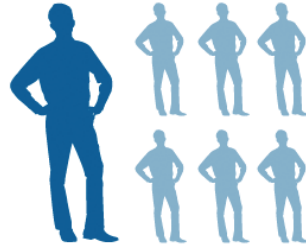


What is prostate cancer?

Prostate cancer is a disease in which normal cells in a man's prostate gland change and grow uncontrollably, forming a mass called a tumor.

As men get older, it becomes more and more important for them to keep a close eye on their prostate health. Studies show is that most men over the age of 50 will be faced with some problem related to their prostate and 1 in 7 men will be diagnosed with prostate cancer in their lifetime.

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It is estimated that approximately 200,000 new cases will be diagnosed each year. It is the most common non-skin cancer among men and more than 2 million men in the U.S. count themselves as prostate cancer survivors.

Aside from non-melanoma skin cancer, prostate cancer is the most common cancer among men in the United States. It is also one of the leading causes of cancer death among men of all races.

What Are The Symptoms Of Prostate Cancer?

Men with prostate cancer may not experience any symptoms at all, so it is very important for men to see their physician regularly and have an annual prostate cancer screening.

If there are any symptoms, the most common ones are:

Difficult urination	Inability to urinate	Weak urine stream
Frequent urination	Burning feeling or pain during urination	Pain in the lower back, hips or upper thighs

Men should talk to their doctor about screening options for prostate cancer and be prepared to ask questions about different types of screenings and how often they should be tested.



PROSTATE CANCER TREATMENTS

Your doctor probably talked to you about a couple different types of treatment options for prostate cancer. The truth is that there are a lot of effective treatments for prostate cancer, but the same ones aren't always right for everyone. Every man should talk to his doctor about what treatment is right for him based on his diagnosis and overall health.

Aggressiveness Scale

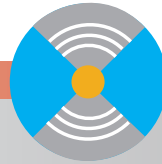
It may help to think of prostate cancer treatment options as a spectrum. Some treatments are geared toward monitoring the disease and only intervening if necessary, which minimizes side effects, but the cancer may still grow or spread. Other treatments are very aggressive, removing the cancer most effectively, but also lead to a higher risk of complications.



ACTIVE SURVEILLANCE

Men regularly visit their doctor and monitor the disease closely with frequent tests which include biopsies as needed.

This is the **least aggressive** treatment option for men who are diagnosed early and cancer is expected to grow slowly.



HIFU

High Intensity Focused Ultrasound is a non-invasive, outpatient procedure that uses focused sound waves to heat and destroy prostatic tissue. HIFU is a one-time treatment that takes 1-4 hours (depending on the size of the prostate gland) with no radiation or blood loss.

Factors in Choosing Treatment

While prostate cancer is often very treatable, some treatment options may lead to side effects such as incontinence and erectile dysfunction that significantly impact quality of life. Other considerations include:

Size and location of tumor

Whether or not cancer has spread outside of prostate

Overall health



RADIATION

Targeted radiation energy is used to shrink or stall the growth of a tumor. External Beam Radiation (EBRT) is aimed from outside the body. Brachytherapy, also known as interstitial radiation therapy, uses radioactive seeds that are placed inside the prostate.



SURGERY

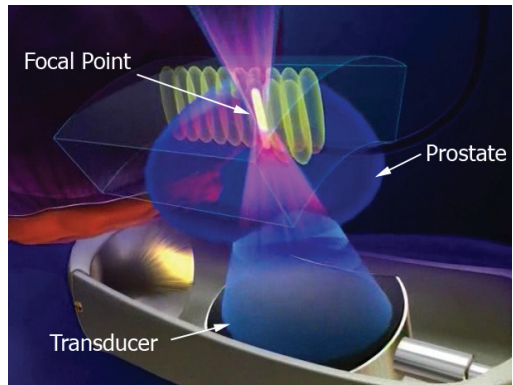
A Radical Prostatectomy completely removes the cancerous tumors, which can also include surrounding tissue. This invasive procedure is one of the **most aggressive** treatment options for prostate cancer.

HIGH INTENSITY FOCUSED ULTRASOUND (HIFU)

Find a balance between eliminating cancer and maintaining quality of life with HIFU

HIFU is a precise and targeted therapy that reduces the risk of complications caused by surgery and radiation. HIFU uses ultrasound energy, or sound waves, to heat and destroy specifically targeted areas of tissue.

During HIFU, the sound waves pass through healthy tissue without causing damage. However, at the focal point of the sound waves the tissue temperature rises rapidly to 90 degrees Celsius destroying the targeted tissue. The same principles are used when light is focused through a magnifying glass.



With HIFU, physicians have the ability to target and treat a small amount of tissue, which minimizes damage done to areas around the prostate. This helps preserve normal urinary function and minimizes risk of erectile dysfunction.

HIFU was cleared by the FDA for prostate tissue ablation in October 2015; however, more than 15,000 men have been treated with Sonablate® HIFU globally. HIFU technology has previously been used successfully since the 1970s to treat other malignancies, including liver, kidney, breast, and pancreatic cancer.

Focal Therapy with HIFU

Focal therapy with Sonablate® HIFU technology creates a small, precise lesion. This targets the tumor within the prostate, leaving the surrounding tissue unharmed.

Experienced physicians use advanced software to merge MRI and real-time images of the prostate to locate the tumor and plan treatment to target that area only.

According to published studies, focal therapy with HIFU for the treatment of non-metastatic prostate cancer has shown low risks of side effects while providing early disease control.

Benefits of HIFU over Traditional Prostate Cancer Treatments

Outpatient, 1-4 hour procedure	No Blood Loss	Radiation Free
Quick Recovery Time	Return to normal lifestyle within a few days	Low risk of erectile dysfunction and incontinence



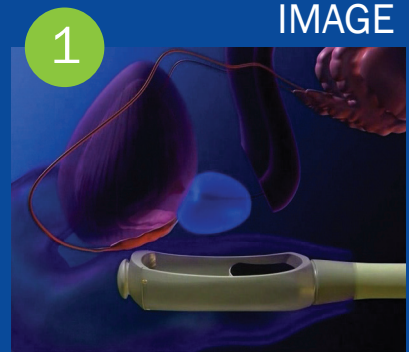
SONABLATE® HIFU

The most advanced and state-of-the-art medical device, that utilizes HIFU to ablate prostate tissue, is the Sonablate®, manufactured by SonaCare Medical. This state-of-the-art technology consists of a console where the physician plans, monitors and adjusts HIFU treatment, a transrectal probe and a chiller, which is a safety device that keeps the rectum cool during treatment.

Unique Features of Sonablate® HIFU

The Sonablate® is the **only** HIFU device for prostate cancer that can:

- Locate nerves during HIFU, decreasing the risk of erectile dysfunction caused by nerve damage
- Monitor rectal wall temperatures for patient safety
- Maintain rectum and tissue temperatures by circulating chilled water through the probe during the procedure
- Safely treat different types of prostate tissue by adjusting power levels



Transducer in probe acquires images of the prostate

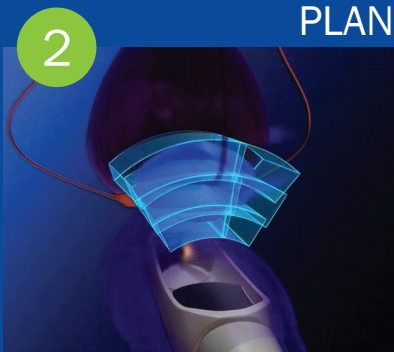
Targeted, Precise and Effective

The Sonablate® obtains real-time ultrasound images of the prostate and surrounding areas. From these images, the doctor precisely defines the treatment zones in order to safely destroy the targeted tissue.

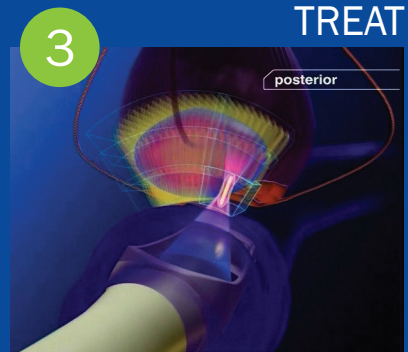
Once a physician has targeted all the areas to be treated, he or she then delivers the HIFU energy, while continually monitoring how the tissue reacts; making adjustments as needed, for safe, effective delivery of HIFU energy.

The control and precision of HIFU means most patients only require one treatment and lower risk of common side effects associated with surgery and radiation.

Unlike radiation, HIFU is non-ionizing so it can be repeated, if necessary, without damaging healthy tissue. This means that HIFU can also be used as a salvage treatment option if there is a recurrence of prostate cancer after a different treatment. Additionally, HIFU does not preclude other treatment options; men who choose HIFU and then need additional therapies still have all their treatment options available.



Physician plans or maps out which tissue to target




Small lesions are created in the prostate at the focal point. This is repeated until all targeted tissue is destroyed.

Features of Sonablate® Software Focused on Patient Safety

- **Neurovascular bundle detection** helps the physician avoid harm to sensitive structures surrounding the prostate, which helps maintain erectile function and preserve a patient's quality of life.
- **Rectal wall monitoring** helps determine the temperature and proximity to the rectal wall, in order to protect rectal wall tissue.
- The **active cooling system** circulates chilled water through the probe during the procedure while monitoring temperature to protect rectal wall tissue.
- **Real-time imaging** allows the physician to view and compare the original image to the real-time image being treated.
- **MRI/Ultrasound fusion integration software** allows the physician to merge MRI images into the Sonablate® planning software in order to determine a more precise ablation plan.
- **TCM or Tissue Change Monitoring** is a color display that gives the physician enhanced feedback about the change in tissue at each point of HIFU delivery.

The Sonablate® is the only HIFU device for prostate cancer that allows for a completely customized HIFU treatment for each patient.

A photograph of an older man and woman sitting on a wooden pier. The man is wearing a light blue and white striped shirt, and the woman is wearing an orange and white patterned dress. They are both smiling and looking towards the right. The background shows a body of water and a clear blue sky with some clouds.

*“After 8 years, my PSA is zero.
Ever since the HIFU surgery,
it has been zero.”*

~Ken H.

THE HIFU TREATMENT

Who is a candidate for HIFU with the Sonablate®?

Sonablate® HIFU is most effective for men who have early stage, localized prostate cancer that has not spread or metastasized outside the prostate. It is recommended that all men discuss individual medical records and history with a physician in order to confirm whether or not they are a candidate for HIFU.

Sonablate® HIFU is also an effective therapy for recurrent prostate cancer when patients may not have any other treatment options. Many patients who have had radiation therapy experience a rise in PSA and discover that the cancer has returned. These patients may be candidates for the HIFU treatment as well.

The Sonablate® HIFU Procedure

The HIFU procedure typically lasts between 1-4 hours, depending on the size of the prostate, and is either done under general or epidural anesthesia. During the procedure a suprapubic or foley catheter will be put into place to help with urination, and will typically stay in place for 1-3 weeks.

After the HIFU treatment, patients will be in recovery for about 2-4 hours. Once released from the treatment center, patients return home or to a hotel to recover more comfortably.

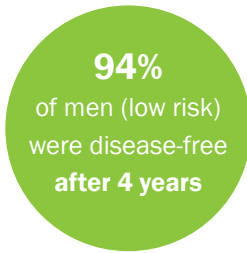
Though, it is recommended that patients take things easy, most patients feel well enough to go out for dinner and maybe even a walk, the day of the procedure.

“For early to intermediate risk cancer, HIFU therapy is equal to radical surgery in terms of cancer control. And it offers a much more favorable side effect profile. Primarily, minimal to no incontinence risks, and a minimal impact on erectile function.”

~Dr. John Jurige

HIFU Outcomes & Effectiveness

Studies show after being treated with HIFU...



Side Effects & Complication Rates

Sonablate® HIFU is *non-invasive* and has the ability to spare the nerves responsible for preserving potency. Additionally, the procedure does not damage muscles that control urinary function. Therefore HIFU patients typically experience much lower rates of side effects than traditional treatments.



What is the history of HIFU and how long has it been around?

HIFU research began as far back as the 1950s at Indiana University. However, the first human prostate cancer study was conducted in 1994 by Dr. Marberger and Dr. Madersbacher at the University of Vienna in Austria using the Sonablate® 200 treating 29 human prostates prior to performing a radical prostatectomy. The goal was to see if the energy delivered was enough to destroy the desired tissue. The study found that treatment could be performed safely and could be repeated.

In 1995, a different study, done at Indiana University showed that the entire prostate could be treated without damaging the prostate capsule or the rectal wall. In 1999, Dr. Toyaki Uchida began treating patients using the Sonablate® in Japan. The device received approval for use in Europe with the CE Mark in 2001 and in 2004, treatment became available at hospitals and treatment centers in Mexico, Costa Rica, South Africa and the Caribbean. Health Canada approved the Sonablate® 500 in June 2005 and the first Sonablate® HIFU procedures were performed in Toronto in March 2006.

Currently, there are approximately 300 physicians using the Sonablate® worldwide and over 15,000 total procedures have been completed. SonaCare Medical is the manufacturer of the Sonablate® and received clearance from the FDA for prostate cancer ablation in October 2015.

Does HIFU only treat the cancerous cells?

Sonablate® HIFU will ablate any tissue that the physician targets with the device during treatment planning. After the physician reviews your diagnosis, he or she will make a recommendation on the best course of treatment. This recommendation, based on your pathology report and imaging, will include how much of the prostate should be treated.

In most cases, the entire prostate will be targeted, which would include the tumor as well as any other tissue in the prostate. Think of it as having the prostate removed, without a single incision. However, some physicians, who work with advanced, MRI- guided imaging for diagnosis, can determine the

exact location of the tumor in the prostate and may use HIFU to only treat the tumor leaving other tissue in the prostate intact; this is referred to as focal therapy.

How does Sonablate® HIFU compare to Ablatherm HIFU?

The Sonablate® device allows for a more precise and customized treatment than the Ablatherm. Sonablate® software allows for smaller treatment zones and adjustable energy delivery, which allow for focal treatments and less risk in damaging important structures such as the urinary sphincter and nerves that are important for erections. Additionally, it is possible to treat larger prostate glands with the Sonablate®.

How do I know if I qualify for HIFU?

While only a physician can determine if you qualify for HIFU or not, typically men with a prostate gland of less than 40 grams with localized prostate cancer (tumor has not spread outside of the prostate gland) may be candidates for HIFU. The other information that physicians usually look at to determine if you qualify for HIFU is a PSA of 20 or less and a Gleason score of 7 or less. It is best to talk with a HIFU nurse or doctor to determine if you might qualify for HIFU.

Can I still be treated if I have a large prostate?

Your physician will need to know the exact dimensions of your prostate to know whether or not you are a candidate for HIFU. If your prostate is too large, there may be ways you can work with your doctor to shrink or reduce the size of the gland prior to scheduling a HIFU procedure.

Should I have total gland HIFU or Focal HIFU?

In order to know if you are a candidate for focal HIFU or whole gland ablation, a physician would need to thoroughly review your pathology report as well as ideally have advanced MRI imaging done to determine the exact size and location of your prostate cancer.

FREQUENTLY ASKED QUESTIONS

Is there a greater chance that the cancer will come back if I choose to have a focal treatment versus full gland treatment?

With focal therapy, the physician only treats the area of the prostate that contains the tumor. This is determined after multiple types of diagnostic imaging as well as biopsy reports to confirm the staging of the disease. The procedure is shorter, recovery time is faster and time wearing a catheter is greatly reduced. This means that if after focal HIFU there is an elevation in PSA and evidence that the cancer has appeared in a different location, the physician can easily go back and deliver HIFU in the new location. Additionally, the patient may choose to have any other type of therapy at that time. This is a much less radical approach to locating the cancer and eliminating it. Prior to having focal HIFU, your physician should thoroughly explain to you the risk of the cancer returning based on your diagnostic reports.

What will I need to do to prepare for the HIFU procedure?

Prior to HIFU, patients usually have lab work (Complete Blood Count (CBC), Complete Medical Panel, Urinary Analysis with culture if indicated by your physician) and an EKG in preparation for undergoing anesthesia. If the patient has any significant medical history, he should see his cardiologist or primary physician. The HIFU procedure itself causes no significant bleeding or swings in blood pressure, etc. A nurse will send detailed information after the procedure has been scheduled regarding diet, medications and any additional lab work or tests that may be required.

How long does the HIFU procedure take?

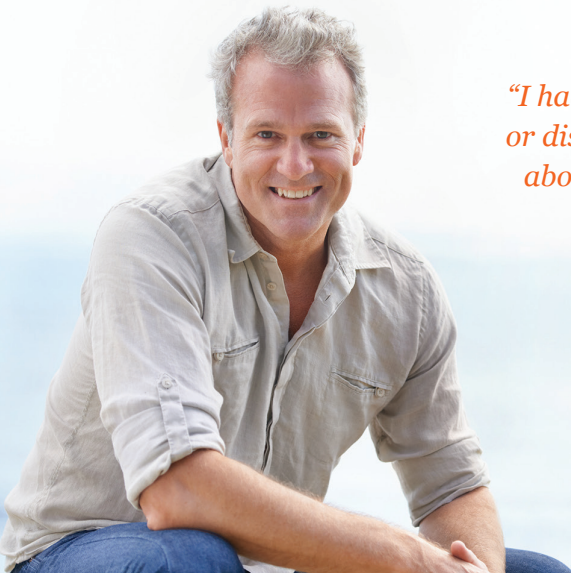
The length of the procedure depends on the size of the prostate gland. Larger glands will take longer to treat completely. A way to estimate time is 1 hour for every 10 grams of tissue to be treated. That works out to an average of 1-4 hours.

What happens to the urethra during HIFU? Since it runs through the center of the prostate, is it destroyed during the procedure?

During Whole Gland HIFU, the entire prostate is ablated, including the prostatic urethra. However, the urethra is derived from a different type of tissue (bladder squamous-type epithelium) rather than prostatic tissue (glandular, fibrotic and muscular). While the urethra is an important anatomical structure, the sphincter and bladder neck are more important to maintaining the urinary function. However, during Focal HIFU, the urethra is usually spared (not ablated).

Is there pain with HIFU? What should I expect?

During HIFU, patients are given anesthesia to minimize any movement during the procedure and to make the patient as comfortable as possible. There should be no pain associated with the procedure although patients may experience various levels of discomfort afterwards.



“I had absolutely no pain or discomfort. I just went about my normal life.”

~Barry W.


FREQUENTLY ASKED QUESTIONS

What type of anesthesia is used for the HIFU treatment?

General anesthesia is the preferred anesthesia during HIFU procedures. It is very important that you and your prostate remain still for the duration of the procedure, and general anesthesia assures that this happens.

What is the recovery time and the side effects of Sonablate® HIFU?

Your specific recovery will depend on the stage and location of your disease but in general, recovery involves wearing a catheter; however, most people usually return to most of their normal activities within few days. Immediately following the HIFU procedure, men spend a few hours in recovery at the treatment facility and then are discharged to return home. HIFU patients sometimes experience frequency, urgency, mild discomfort or discharge in urinary stream.



“I came out of the procedure and was doing everything I normally do the next day.”

~David N.

What kind of catheter will I have to wear?

Most patients have a suprapubic catheter after HIFU. This is inserted by a physician after the patient is asleep and before HIFU begins and will be in place after the procedure for 1-3 weeks depending on the size of your gland. The catheter allows for your bladder to empty comfortably while your body heals. It is common to have a catheter for some length of time after prostate cancer procedures. If you are having a focal (partial gland) treatment, you may go home with a foley (urethral) catheter which is typically worn between 5-10 days. The type of catheter you have will be determined by your HIFU physician before your treatment and your HIFU nurse will provide you education on how to care for your catheter.

When can I resume sexual intercourse?

Usually, patients can have sex after their catheter has been removed. You should speak with a physician if you have any questions or concerns about resuming sexual activities.

When can I go back to work/normal activities?

Men may return to office based work and drive the following day. More intense physical activity resumes in 3-5 days, though no activity should be started that dislodges the catheter or stirs up bleeding from the catheter insertion site.

What type of follow up is there after HIFU?

Follow up after HIFU with your physician will be similar to any other treatment for prostate cancer. A HIFU nurse will call you after your procedure to see how you are recovering and ask if you have any questions and concerns. Additionally, you will need to make an appointment several weeks after your procedure to have your catheter removed and then return for visits at 3 months, 6 months, 9 months and 12 months to have your PSA tested.

HIFU Prostate Services was founded to provide men access to a less invasive treatment option for prostate cancer. HIFU has the ability to eliminate cancer and preserve patient quality of life.

We work with experienced doctors through the United States to offer HIFU for prostate cancer at state-of-the-art facilities.

We offer our patients something no one else in the industry can offer, and we call this the HPS Advantage. Our one-of-a-kind, concierge support and our partnerships with the most experienced network of the physicians in the country, enables us to guide you through the best possible HIFU treatment experience available.



**Most
Experienced Staff**

Our entire staff has worked with HIFU over the past 12 years. We have more experience in HIFU than anyone else.



**National
Physician Network**

We can help you find an expert, experienced physician near you or facilitate travel to the physician of your choice.



**Concierge
Medical Services**

Our nurses and staff spent years scheduling and traveling with HIFU patients. They are involved every step of the way.

“At HPS we are experienced, accessible and entirely focused on quality of life.”

Where is HIFU Available?

There are HIFU treatment centers, experienced HIFU proctors, technicians and trained nurses throughout the country.



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Non-Invasive Cancer Treatment