

What is HIFU?

High Intensity Focused Ultrasound (*HIFU*) is a procedure used for the treatment of prostate cancer. It works by using precision-focused ultrasound waves to rapidly heat and destroy cancerous prostate tissue without affecting healthy surrounding tissue. This minimally invasive treatment is relatively new in the field of prostate cancer and is performed as a day case procedure under a general anesthetic.

HIFU – How does it work?

Using intersecting precision focused ultrasound waves, the device destroys diseased tissue within the prostate and leaves healthy cells around the outside of the prostate capsule untouched. In addition to being minimally invasive, HIFU energy is non-ionizing ‘clean energy’ that can be applied repeatedly without damaging other tissue, unlike radiation based therapies. HIFU energy works like a magnifying glass and sunlight. Using a magnifying glass you can focus energy of the sun and concentrate it over a focal point while allowing safe and harmless energy transfer over the entire course of that beam up until it reaches the point of concentration. Cancer cells are fortunately more sensitive to higher temperatures; precision focused ultrasound waves raise the temperature of the target tissue to more than 80-90 degrees Celsius in two to three seconds, effectively destroying the targeted cancerous tissues.

HIFU is being used around the world to treat all types of cancer and soft tissue diseases. HIFU has been approved by the National Institute of Clinical Excellence (NICE) for use in the UK in the treatment of prostate cancer. The technique is relatively new in the field of prostate cancer treatments and so there is very little long-term data to verify its clinical effectiveness but the early results are very promising.

What equipment is used?

The HIFU treatment is performed using a Sonablate® 500 which is manufactured by Misonix Inc. (NASDAQ: MSON) of Farmingdale, New York.

The Sonablate® 500 is approved in many countries outside the U.S. as an image-guided acoustic ablation device developed by Focus Surgery to treat prostate disease. The technology behind the device originated at the Indiana University School of Medicine in Indianapolis in the 1970s. It was further developed in leading research centres across the world.

The Sonablate® 500 allows a trained urologist to visualize the prostate and plan and monitor the treatment in real time, ensuring maximum precision, flexibility, safety and control.

What are the results so far?

Real time imaging and treatment of the prostate with HIFU offers the possibility of very low rates of erectile dysfunction and negligible rates of incontinence. Neurovascular structures responsible for erectile function and continence can be imaged, and the treatment can be designed to avoid treatment of these sensitive areas. The precise results of clinical studies depend on the surgical protocol adopted by the researchers, but an overall average assessment is that less than 20% of men will have erectile dysfunction

Studies in Japan have shown that in 90 percent of the patients studied, HIFU technology produced PSA measurements below 1.0 within one year following treatment, with only 20% of men suffered erectile dysfunction and less than 1% suffering urinary incontinence. More recently, researchers at University College Hospital, London, have presented a research study to fellow surgeons and oncologists at the British Prostate Group with 83% of men treated to a PSA nadir of 0.2ng/ml or less. This very low level of PSA is used by more established techniques such as radiotherapy to predict cancer cure rates at 10 years. The PSA level can be reached after just 3 months with HIFU treatment, giving men the early peace of mind that they have been successfully treated.

Treatment may also be repeated as necessary and HIFU can be used following treatment with other therapies such as radiotherapy. Recently the Journal of Urology published an article authored by Dr Wieland and Dr Blanna from the University of Regensburg (Germany). The study, conducted using a prostate HIFU device from EDAP Technomed, included patients with a five-year follow-up and showed 93.4% constant negative biopsies in the patient population and with only two patients having a PSA level that rose to greater than four. Publications by Dr Toyooki Uchida, M.D., from Tokai University Hospital and John C. Rewcastle, PhD from the Department of Radiology, University of Calgary in Canada reported very similar positive findings.

Who can be treated?

- Men who have been diagnosed with T1 or T2 (organ confined) carcinoma of the prostate
- Men with a life expectancy of five or more years
- Men with a Gleason score of ≤ 7
- Men with a serum PSA less than 20 ng/ml
- Men with a prostate volume less than 40 cc or have had their prostate reduced in size to 40cc with hormone therapy

Who cannot be treated?

- Men with evidence of metastatic disease
- Men with an inability to tolerate a transrectal ultrasound
- Men with latex allergies
- Men with any active urinary tract infection
- Men with very high volume prostates