

What is HIFU?

HIFU stands for high intensity focused ultrasound, which is a minimally invasive technique for treating diseased tissue with precise, focused ultrasound waves that raise the temperature of the target to nearly 90 degrees Celsius (190 degrees Fahrenheit) in two to three seconds. This rapid-firing heat effectively destroys the targeted tissue, but leaves the surrounding healthy tissue intact.

What is HIFU with the Sonablate® 500?

The Sonablate 500 is a minimally invasive medical device, developed by Focus Surgery, Inc., that uses HIFU to treat localized prostate cancer and benign prostatic hyperplasia (BPH). The Sonablate 500 uses a single transducer to obtain real-time images of the prostate during treatment and provides treatment in one to four treatment zones depending on the size of the prostate. The Sonablate 500 software allows the surgeon to safely ablate the entire gland in one to three hours with a single treatment.

How exactly does Sonablate HIFU treat prostate disease?

The Sonablate directs intersecting, precision-focused ultrasound waves at the diseased tissue only and leaves healthy cells surrounding the prostate untouched. HIFU uses non-ionizing, or clean, energy so the procedure may be repeated if necessary without damaging other tissue, unlike radiation-based therapies.

What are the results of the Sonablate HIFU treatment?

One international study published by Toyaki Uchida, MD out of Japan showed that after four years, 94 percent of patients (low-risk) were disease-free. Additionally, a study from Mark Emberton, MD in England reported that 92 percent of men treated with HIFU had a PSA of .2ng/ML or lower three months after HIFU. The Sonablate is currently in the clinical trial phase in the U.S.

What are the recovery times and side effects of Sonablate HIFU for prostate cancer?

Patients can typically return to their normal lifestyle within a few days after the 1-4hour procedure. Recovery involves wearing a catheter for 2-3 weeks. Some HIFU patients experience urination frequency or urgency or mild discomfort or discharge in the urinary stream. Studies performed outside the U.S. report that potential side effects may also include urinary stricture (18%)², retention (0.6%)¹, incontinence (0.6%)¹, erectile dysfunction (20%)¹ and rectal fistula (1%)¹.

Does HIFU treat only the cancer cells? How?

Sonablate HIFU treats the entire prostate by targeting tissue in the overlapping treatment zones. The tissue is heated rapidly in targets known as lesions until the entire prostate is ablated.

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

Research on HIFU began in the 1950s at Indiana University (IU) in Indianapolis, IN. In 1994, Dr. Michael Marberger and Dr. Stephan Madersbacher performed the first human prostate

¹Toyoaki Uchida, et al. Five years experience of transrectal high-intensity focused ultrasound using the Sonablate® device in the treatment of localized prostate cancer. Dept. of Urology University of Tokai Hachioji Hospital. International Journal of Urology 2006.

cancer study at the University of Vienna in Austria using the Sonablate 200. They treated 29 human prostates in the body before performing a radical prostatectomy in order to see if the energy delivered was enough to destroy the targeted tissue. The study found that treatment could be performed safely and be repeated if necessary.

Other significant dates and milestones include:

- 1995—a study done at IU showed that the whole prostate could be treated without damaging the prostate capsule or rectal wall.
- 1999—Dr. Toyaki Uchida began treating patients using the Sonablate® 200, the first generation of the Sonablate device.
- 2001—The Sonablate 500 received its CE mark (approval for use) in Europe.
- 2004—US HIFU was founded and began placing Sonablate devices in different areas where HIFU was approved. It has put devices in Canada, Mexico, Costa Rica, the Caribbean, India and Argentina
- 2005—Health Canada approved the Sonablate 500.
- 2006—The first Sonablate HIFU procedures were performed in Toronto, Canada.
- 2008—Sonablate HIFU was first performed in India.

Where can I find HIFU data and statistics?

To read and download the latest clinical papers, abstracts and data, visit our clinical data section at www.internationalhifu.com. Click on the “What is HIFU?” tab at the top followed by the “HIFU Results and Clinical Data” tab on the left.

To learn about the benefits of HIFU with the Sonablate 500, visit www.internationalhifu.com. Click on the “What is HIFU?” tab at the top followed by the “Benefits of HIFU with the Sonablate 500” tab on the left.

Where is Sonablate HIFU available now?

The Sonablate 500 is not approved for use in the U.S. It is investigational in this country and being studied for the treatment of prostate cancer in clinical trials in the U.S. The FDA has made no decision as to the safety or efficacy of the Sonablate 500 for the treatment of prostate cancer.

The device is currently available for the treatment of prostate cancer in Europe, Canada, part of Asia, South America, India and the Caribbean. Currently there are nearly 100 Sonablate HIFU centers worldwide on seven continents. There are over 150 physicians using the Sonablate 500 worldwide and more than 7,000 Sonablate procedures have been completed.