

About International HIFU

- International HIFU is committed to creating a new standard for the treatment of prostate cancer and prostate disease with high intensity focused ultrasound (HIFU) therapy through the distribution and use of Sonablate® 500 medical devices and HIFU therapy where it is approved, authorized, or otherwise permitted for such uses outside the U.S.
- International HIFU is a subsidiary of the company US HIFU, LLC, a privately held healthcare company focused on treating primary and recurrent prostate cancer using HIFU, a minimally invasive outpatient procedure which significantly improves patients' quality of life.
- International HIFU currently has treatment centers in India, Toronto, Niagara Falls, Montreal and Winnipeg, Canada; Puerto Vallarta and Cancun, Mexico; Nassau, Bahamas; Santo Domingo, Dominican Republic; and in Buenos Aires, Argentina.

About HIFU—the energy

- HIFU, or high intensity focused ultrasound, is a minimally invasive therapy that destroys unhealthy tissue with rapid heat elevation.
- Ultrasound energy, or sound waves, is focused at a specific location in the body. At that location, or focal point, the temperature rapidly rises to almost 90 degrees Celsius (195 degrees Fahrenheit). Any tissue at the focal point is destroyed, but any tissue outside of the focal point is unharmed.
- Unlike radiation, HIFU uses clean (also known as non-ionizing) energy, so the procedure can be repeated, if necessary, without damaging healthy tissue.
- HIFU is being studied around the world to treat all types of cancer and soft tissue diseases.

About HIFU with the Sonablate® 500

- The Sonablate 500 is a minimally invasive medical device developed by Focus Surgery, Inc., a subsidiary of USHIFU located in Indianapolis, IN., that uses HIFU to treat localized prostate cancer and benign prostatic hyperplasia (BPH) in countries where it is approved.
- The Sonablate 500 obtains real-time ultrasound images of the prostate and surrounding areas. From these images, the doctor plans where the ultrasound energy will be delivered. The Sonablate software allows the physician to precisely define the treatment zones in order to destroy the entire gland.
- The Sonablate 500 is the only HIFU device for prostate cancer that does not require a transurethral resection of the prostate—known as TURP, an invasive, surgical procedure—prior to treatment in order to achieve effective results when the prostate is enlarged. Sonablate HIFU can treat large prostates up to 40 grams.
- The Sonablate incorporates three-dimensional imaging so the treating physician can achieve better visuals of the prostate, especially any irregularities, and, as a result, create the most effective treatment plan possible.
- Current numbers:
 - There are more than 250 trained Sonablate users worldwide.
 - More than 7,000 patients have undergone Sonablate HIFU outside the U.S.
 - There are currently more than 100 HIFU centers outside the U.S.
 - All these numbers continue to grow.
- The Sonablate® 500 is not approved for use in the U.S. The Sonablate® 500 remains investigational in the U.S. and is being studied for the treatment of prostate cancer in clinical trials in the U.S. FDA has made no decision as to the safety or efficacy of the Sonablate® 500 for the treatment of prostate cancer.