

## PROSTATE CANCER PHASE 1 CLINICAL TRIALS USING HIGH INTENSITY FOCUSED ULTRASOUND (HIFU)

Under the approved protocols by the Food and Drug Administration (FDA), Focus Surgery, Inc. is treating prostate cancer with its Sonablate<sup>®</sup> 500 device. The Sonablate<sup>®</sup> 500 is a minimally invasive ultrasound device that combines diagnostic ultrasound imaging of the prostate, treatment planning and treatment of cancer tissue using High Intensity Focused Ultrasound (HIFU). As shown in Figure 1, the device treats the whole prostate gland by placing HIFU focal zones under computerized 3D image-based treatment planning. Figure 2 shows the wide angle view and treatment zones possible with the Sonablate<sup>®</sup> 500 for prostate cancer. In addition, real time monitoring of treatment provides safe and effective therapy.

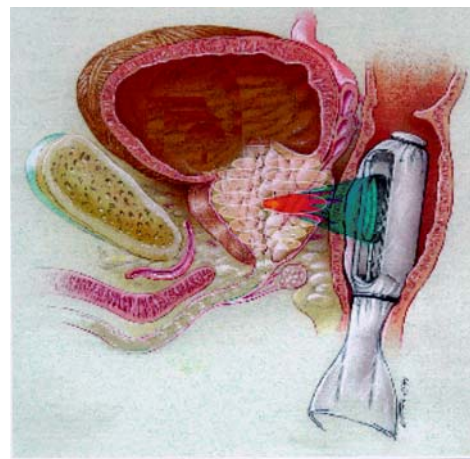


Figure 1

### The advantages of HIFU treatments are:

1. HIFU can elevate tissue temperature in the focal zone up to 70° to 90° very quickly (1-4 seconds) to ablate selected cancer tissue while leaving the surrounding tissue untreated.
2. HIFU can be applied externally and contact free to targeted cancer tissue.
3. HIFU can produce sharp and predictable lesions.
4. HIFU energy is non-ionizing and can be applied repeatedly.



Figure 2

The approved clinical studies are being conducted at Indiana University School of Medicine, Indianapolis, Indiana and Case Western Reserve University, Cleveland, Ohio. Initially, patients who have prostate cancer confined within the prostatic gland (T1/T2 NoMo) or have recurrent prostate cancer will be treated under these protocols. Please contact: **Focus Surgery, Inc.** at 317/541-1580 or visit our website at [www.focus-surgery.com](http://www.focus-surgery.com) for more detailed information about these studies.

# HIFU TREATMENT PROTOCOL FOR PROSTATE CANCER USING THE SONABLATE® SYSTEM (A Novel Non-Invasive Approach)

**Introduction:**

Two feasibility studies will be conducted in the USA to study the safety and effectiveness of this modality in treating two categories of subjects.

- i) T<sub>1</sub> T<sub>2</sub> N<sub>0</sub> M<sub>0</sub> Prostate Cancer (organ confined)
- ii) Locally recurrent prostate cancer (post external beam radiation or post radical prostatectomy) with no documentary evidence of local or distant spread.

**Subject Selection Criteria:**

Male subjects between the ages of 40 and 80 and in good physical health with positive biopsy for prostate cancer, PSA ≤ 10 and a Gleason Score ≤ 7 will be selected for the study. Bone scan done within the past three months is mandatory to reduce chances of underscoring.

**Treatment & Treatment Planning:**

Each study has been limited to two sites and twenty subjects by the FDA. The treatment is conducted under anesthesia. An elective suprapubic cystostomy will be performed to avoid any subject discomfort due to urinary obstruction. One to two day hospital stay may be needed. Treatment planning is done on the display monitor. Figure 1 shows the treatment-planning scheme. During treatment cool degassed water is circulated in the probe tip to prevent rectal wall injury.

**Follow Up:**

The subjects will be followed at 48 hours, 14, 30, 90 and 180 days post treatment. Total PSA will be monitored. Prostate biopsy will be performed on 90 and 180 day follow-up visits. In case of rising PSA (PSA velocity) and positive biopsy retreatment with HIFU will be offered to the subject unless contraindicated.

**Expected Results:**

- PSA < 0.5 ng/ml (90-180 days)
- Negative prostate biopsy
- Decrease in prostate size (Figure 2) of a subject who received HIFU treatment for Prostate Cancer.

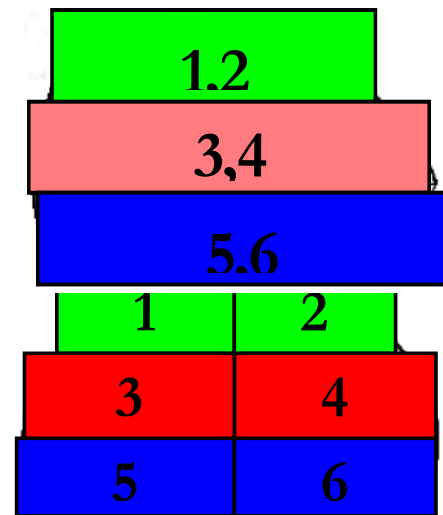


Figure 1

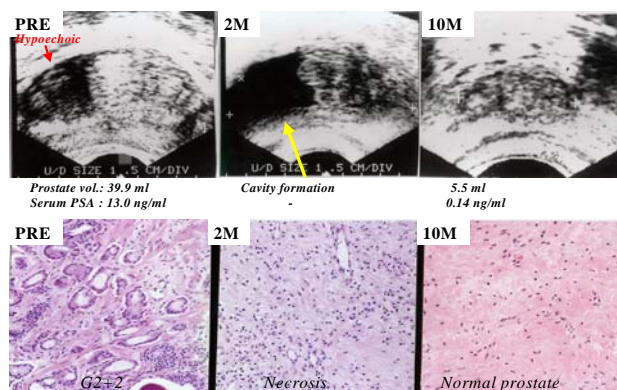


Figure 2

Diagrams and slides printed with permission from Dr. Toyoaki Uchida, Dept. of Urology, Kitasato University