Sonablate® HIFU Overview

Targeted treatment for prostate diseases without cutting, radiation, or hormones.
SonaSurgery

A minimally invasive alternative to the extremes of active surveillance and invasive surgery or radiation.

Case Study: Breast Cancer Treatment

1884
First radical mastectomy is performed and remained standard operation until 20th century.

1937
Radiation therapy is used in addition to surgery to spare breast

1970
Researchers began to develop the lumpectomy

1985
Research shows early-stage breast cancer treated with lumpectomy and radiation have similar survival rates to mastectomy.
Sonablate® HIFU is the next generation of prostate care.

Utilizing focused ultrasound, the Sonablate system is a minimally invasive robotic device that delivers precise and focused ablative energy.

Sonablate® Capabilities

- Real-time Imaging
- Sonafuse (Ultrasound / mpMRI Image Fusion Platform)
- TCM (Tissue Change Monitoring)
- Patient Safety Tools
While the probe remains stationary in the rectum, the transducer moves robotically to follow the physician’s precise ablation plan.

No prostate is the same.

The Sonablate® procedure can be customized for each individual patient’s needs, targeting as much or as little tissue as needed.

**Fully integrated probe with dual imaging and ablation transducers**

While the probe remains stationary in the rectum, the transducer moves robotically to follow the physician’s precise ablation plan.
The Sonablate® Procedure: How it Works

Step 1
The Sonablate® probe is positioned in the patients’ rectum

Step 2
The treating physician will map out a customized ablation plan

Step 3
Physician initiates HIFU delivery creating individual lesions (similar in size to a grain of rice) that together ablate the desired volume
Over 30,000 Patients Treated Worldwide with Sonablate® HIFU

“My decision to use HIFU was researched over a two-year period and confirmed as a good decision by my urologist. It turns out to have been one of the best decisions of my life.”

- Michael, Sonablate® Patient

HIFU Patient Benefits

- 2–4-hour outpatient procedure
- 1-2-hour recovery
- Lower side effects
- Repeatable procedure, if necessary
- Most patients resume normal lifestyle within a few days
Sonablate® A3 Technology

Sonablate® is powered by unique A3 Technology, which allows physicians to:

**AIM** at specific tissue using ultrasound-MR fusion.

**ABLATE** with pinpoint accuracy while sparing untargeted tissue.

**ANALYZE** the delivery of HIFU energy using real-time Tissue Change Monitoring (TCM).
Clinical Application

Sonablate® addresses the need for personalized prostate ablation, using MRI and ultrasound image guidance to create a customizable plan tailored to each patient’s prostate.

This tailored ablation plan allows the user to apply HIFU in a variety of ablation patterns including focal, hemi and whole gland ablation.

Clinical Data

Primary Partial Gland Ablation

<table>
<thead>
<tr>
<th></th>
<th>Sonablate®¹</th>
</tr>
</thead>
<tbody>
<tr>
<td>Median Month Follow-Up</td>
<td>54</td>
</tr>
<tr>
<td>Number of Patients</td>
<td>625</td>
</tr>
<tr>
<td>Intermediate / High Risk</td>
<td>88%</td>
</tr>
<tr>
<td>Negative Biopsy</td>
<td>75%</td>
</tr>
<tr>
<td>Retained Sexual Function</td>
<td>85%</td>
</tr>
<tr>
<td>Maintained Continence</td>
<td>100%</td>
</tr>
<tr>
<td>Absence of Clinically Significant Disease</td>
<td>100%</td>
</tr>
</tbody>
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Clinical Data

*Focal therapy compared to radical prostatectomy for non-metastatic prostate cancer: a propensity score-matched study*

Oncological outcomes over 8 years were similar between focal therapy and radical prostatectomy in patients with non-metastatic low-intermediate prostate cancer

N = 492 patients
246 Radical Prostatectomy
246 Focal Therapy patients (HIFU and Cryotherapy)

1:1 propensity score matched:
- Treatment Year
- Age
- PSA
- Gleason Score
- T-Stage
- Cancer Core Length
- Use of Neoadjuvant Hormones

Failure Free Survival Rate (in %)

- Radical Prostatectomy
- Focal Therapy

Sonafuse

The Sonafuse image fusion platform imports segmented and annotated DICOM Radiology images directly into the Sonablate® system. The fusion software merges these mpMRI scans with live transrectal ultrasound images acquired by the Sonablate®. This real-time fusion of the two imaging techniques further enhances the precision of Sonablate’s targeted HIFU planning, enabling true focal ablation.

- Premier precision
- Enhanced tissue targeting
- Advanced image registration
- Simple interface
- Combines the rich detail of MRI with real-time US
- Optimized HIFU procedure leveraging targeted Bx data

Overview of Components

- Console
- Chiller
- Stepper
- Articulating Arm Probe
Sonablate Corp. is a world leader in minimally invasive high intensity focused ultrasound (HIFU) technologies. SonaCare Medical is committed to developing focused ultrasound related technologies that support precise and innovative procedures for the treatment of a range of medical conditions. Sonablate Corp., with its subsidiary Focus Surgery, Inc., designs and manufactures medical devices, including the following:

Sonablate®, which has 510(K) clearance in the U.S. under a De Novo regulatory classification; Sonablate® 500, which has CE Marking and has obtained regulatory authorization in more than 49 countries outside the U.S.; and Sonatherm™ laparoscopic HIFU surgical ablation system, which has 510(K) clearance in the U.S., has CE Marking and has obtained regulatory authorization in more than 30 countries outside the U.S.