

CLINICAL FOLLOW-UP

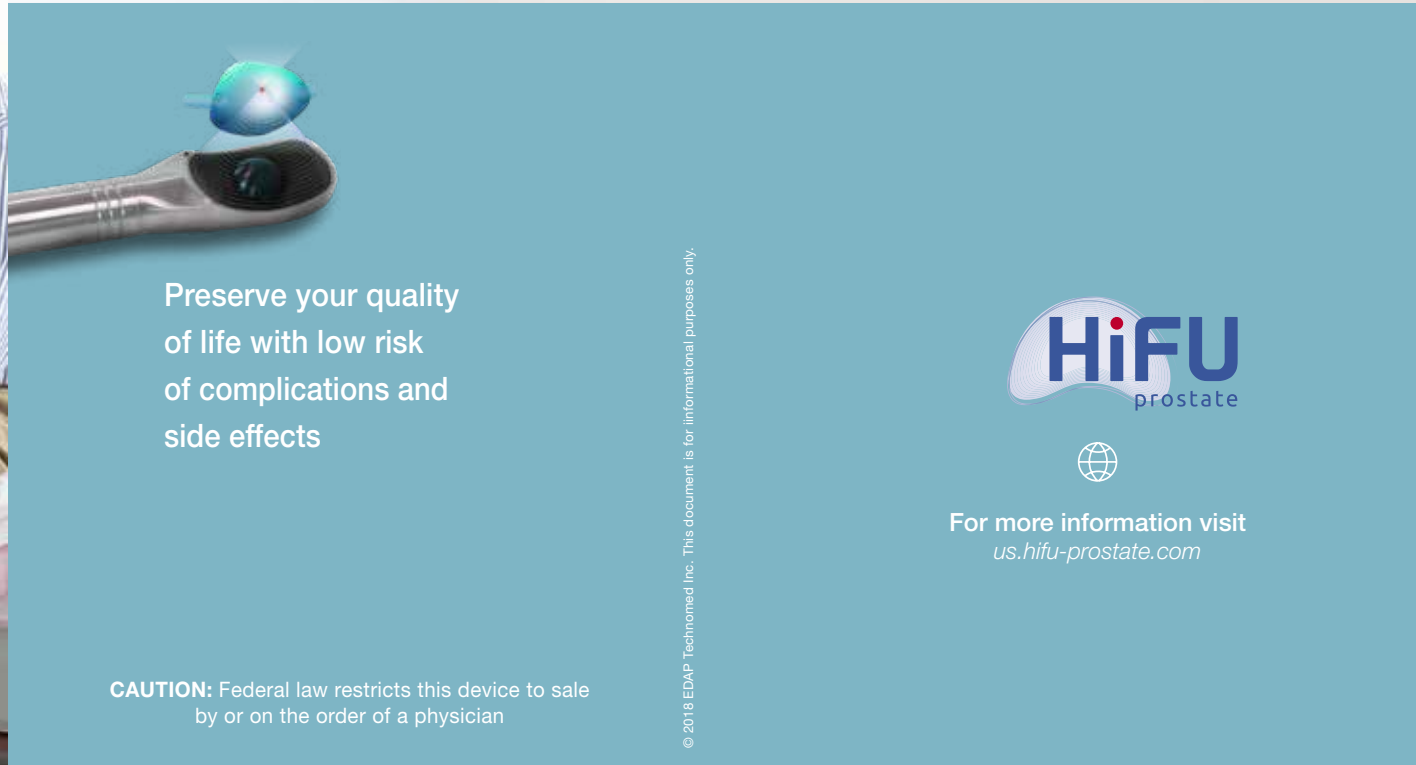
At the end of the procedure, a temporary urinary catheter will be placed in order to limit the risk of urinary retention due to the temporary swelling. This catheter can be removed at the first follow-up visit.

Typical follow-up will include PSA testing at three months, six months, and one year, to evaluate the result. This follow-up can be performed by the treating urologist, or, if you traveled from a remote location, your local urologist.



PROSTATE

NON-INVASIVE ABLATION *WITH*
FOCAL ONE® ROBOTIC HIFU



Preserve your quality
of life with low risk
of complications and
side effects



For more information visit
us.hifu-prostate.com

CAUTION: Federal law restricts this device to sale
by or on the order of a physician

WHAT IS HIFU?

High Intensity Focused Ultrasound



Quality of life preservation



Low risk of side effects such as incontinence and erectile dysfunction



Less time away from work and leisure activities

High Intensity Focused Ultrasound (HIFU) is a non-invasive and effective option for prostate ablation with a low occurrence of side effects.

HIFU uses an ultrasound probe to scan the prostate and deliver high-intensity sound waves directed at the target area—similar to how a magnifying glass can focus light rays to burn a leaf. The probe is inserted into the rectum and does not require any incision.

The magnitude of ultrasound energy delivered rapidly raises the temperature at the focal point, causing coagulation necrosis (cell damage and death), without damaging healthy tissue and structures outside the targeted area.



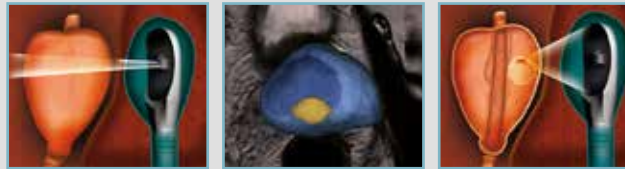
In the past 20 years, over 50,000 patients have benefited from HIFU in 300+ centers worldwide.

HIFU is FDA cleared in the U.S. for prostate tissue ablation since 2015.

NO BLADE, NO SCAR, NO RADIATION

Non-invasive robotic HIFU: How it works

Focal One® is a state-of-the-art device. It uses a high performance, high intensity focused ultrasound (HIFU) technology that allows the ablation of prostate tissue with minimal morbidity. This unique technology makes it possible to target and destroy a part of the prostate, sparing the rest of the organ and therefore minimizing side effects.



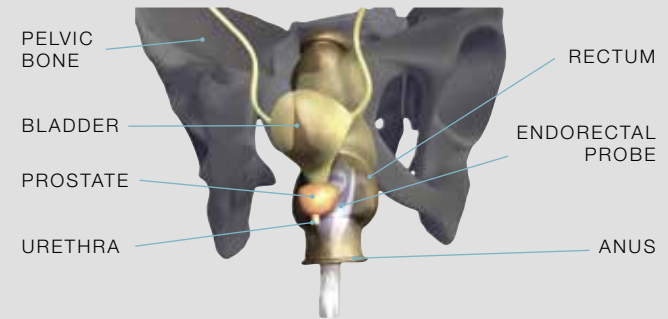
Imaging

Planning

Treatment

Focal One® precisely destroys targeted tissue while sparing healthy surrounding structures.

Instead of using radiation, high intensity sound waves are used to heat up and burn the targeted tissue, choking off the blood supply and causing cell death. This procedure is in no way a therapy roadblock, as it is repeatable and can be followed, like for a prostatectomy, by external radiotherapy. It preserves the erectile nerves and urinary sphincter thanks to the precise targeting of lesions.



THE FOCAL ONE® PROCEDURE: STEP-BY-STEP

- 1 The patient arrives the morning of the procedure. The patient will have completed a bowel prep the night before or the morning of the procedure.
- 2 The patient is positioned on his side, under general or spinal anesthesia.
- 3 An ultrasound scan with a 3D reconstruction of the prostate is performed at the beginning of the treatment.
- 4 The urologist chooses the most appropriate treatment strategy based on the clinical situation and plans the procedure millimeter by millimeter.
- 5 The Focal One® robot executes the treatment plan ablating only the targeted tissue. The real-time ultrasound image provides constant monitoring of the procedure.
- 6 The patient is typically discharged shortly after the procedure. It is necessary for someone to accompany the patient for ambulatory treatments.

