PROFOUND



Don't let your prostate disease hold you back

TULSA PROCEDURE

Live a Profound Life

WHAT IS THE TULSA PROCEDURE?

The Transurethral Ultrasound Ablation (TULSA) Procedure is a minimally invasive procedure that uses directional ultrasound to produce very high temperatures to **ablate** (destroy) targeted prostate tissue. The procedure is performed in a Magnetic Resonance Imaging (MRI) suite and uses the TULSA-PRO® system to ablate prostate tissue from the 'inside-out'. The procedure combines real-time MRI with robotically-driven, directional thermal ultrasound to deliver predictable, physician-prescribed ablation of whole gland or partial prostate tissue.



Figure 1. The TULSA-PRO system works together with the MRI system to deliver the TULSA Procedure.

Figure 2. Ultrasound Applicator (UA) with 10 individually controlled transducer elements.

WHY INSIDE-OUT ABLATION?



Figure 3. Neurovascular bundles (arteries, veins and nerves) wrap around the prostate gland.

The neurovascular bundles (NVBs) surrounding the prostate, control reproductive and urinary functions. Damage to these NVBs can result in erectile dysfunction or incontinence. The TULSA Procedure ablates the prostate from the 'inside-out' (from inside the urethra heating outwards to the edge of the prostate) avoiding direct contact with the NVBs, helping to preserve men's functional abilities.

TULSA PROCEDURE ADVANTAGES

Gain Confidence in Your Outcomes

Using directional thermal ultrasound and MR imaging, you can feel confident knowing that the TULSA-PRO system automatically adjusts the ultrasound output to precisely ablate the treatment plan, and that your physician actively monitors tissue heating throughout the prostate and nearby critical structures in real-time, for best safety and efficacy outcomes.

▲ Minimize Risk of Side Effects

The TULSA Procedure is precise. Without making any incisions or using radiation, your physician has the ability to avoid important nerve bundles and structures around your prostate, decreasing the risk of side effects.

Same-Day Outpatient Procedure

The TULSA Procedure is a "one-and-done" procedure, performed in a single session that takes a few hours. There is no need for repeat procedure visits, meaning you can take less time off work, spend less time in the hospital, and spend more time living.

Sustomize Your Treatment Plan

No two prostates are the same, so no two treatment plans are the same. The TULSA-PRO system automatically adjusts the ultrasound power and depth to compensate for varying tissue properties and blood flow which are unique to each patient. The TULSA Procedure is not a "one-size-fits-all" treatment - it's a customizable procedure that is personalized based on your unique anatomy and disease.

Lead Engage in Shared Decision Making

Before your TULSA Procedure, you will decide with your physician on a treatment plan - together. You will decide exactly what areas of your prostate you want to ablate, and what areas you want to avoid. The TULSA Procedure helps you take back control over your life and play an active role in your treatment decisions.

Keep Your Options Open

If you are in need of future prostate care, you may either have a repeat TULSA Procedure, or choose any other type of prostate therapy to address your prostate needs.

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HOW DOES IT WORK?

1. DEVICE INSERTION

A device called the ultrasound applicator (UA) is inserted into the urethra, which delivers the ultrasound energy towards the prostate using 10 individually controlled transducer elements.

2. CLEAR MRI VIEWS

Using high-precision MR imaging, the physician can clearly see the prostate in the coronal, sagittal and axial view.

3. BOUNDARY LINES

Using these images, the treating physician draws the boundary lines around the prostate section that corresponds to each transducer element. For example, to the left, a specific boundary line is drawn for transducer element 4.

4. PROSTATE ABLATION

The physician continues to draw separate boundary lines for the rest of the transducer elements until the entire targeted prostate tissue region is selected and ready for ablation. The example to left shows a whole-gland ablation.

CUSTOMIZED ABLATION

The physician can customize the boundary lines depending on the size of the prostate, area intended to be treated, and location of critical structures to be spared, such as the NVBs.

By customizing the boundary line, the physician can preserve the function of the patient's critical structures yet still deliver effective treatment.



Figure 4. Sparing of the neurovascular bundles (NVBs) using customized physician prescribed boundary line.

COOLING MECHANISM

The UA has a cooling mechanism that protects the urethra from the ultrasound energy. An endorectal cooling device (ECD) is also inserted into the rectum protecting the rectal tissue, helping to preserve the patient's natural functions.











ABLATION ADVANTAGES

The UA rotates within the urethra so that the directional ultrasound can reach more of the prostate tissue and creates a continuous, **sweeping** heating pattern, **reducing** the risk of missed spots.

The TULSA-PRO system **automatically** carries out the ablation instructions, ablating only within the prescribed boundary lines, **minimizing** the risk of human error.

The physician uses MR imaging to **monitor** the tissue heating within and surrounding the prostate, in real-time. The physician can make adjustments to the plan if necessary, enabling the procedure to be very **controlled** and **predictable**.



Prostate

Transduce

Flement

Veurovascula

Bundle (NVB)

Cooling

UA Inside

the Urethr

Rectum

ECD

Bundle (NVB)

Visit our Website at www.tulsaprocedure.com



- of men reported proper erectile function at 1 75% year, with continued recovery of erection firmness sufficient for penetration*
- of men maintained urinary continence and 93% were pad-free at 1 year*
- of men reported NO rectal injury and NO rectal fistula*

*Results are based on TACT: TULSA-PRO® Ablation Clinical Trial Klotz, et al. "Magnetic Resonance Imaging-Guided Transurethral Ultrasound Ablation of Prostate Cancer." The Journal of Urology (2020)

Did you receive the **TULSA Procedure?** Share your Story!





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