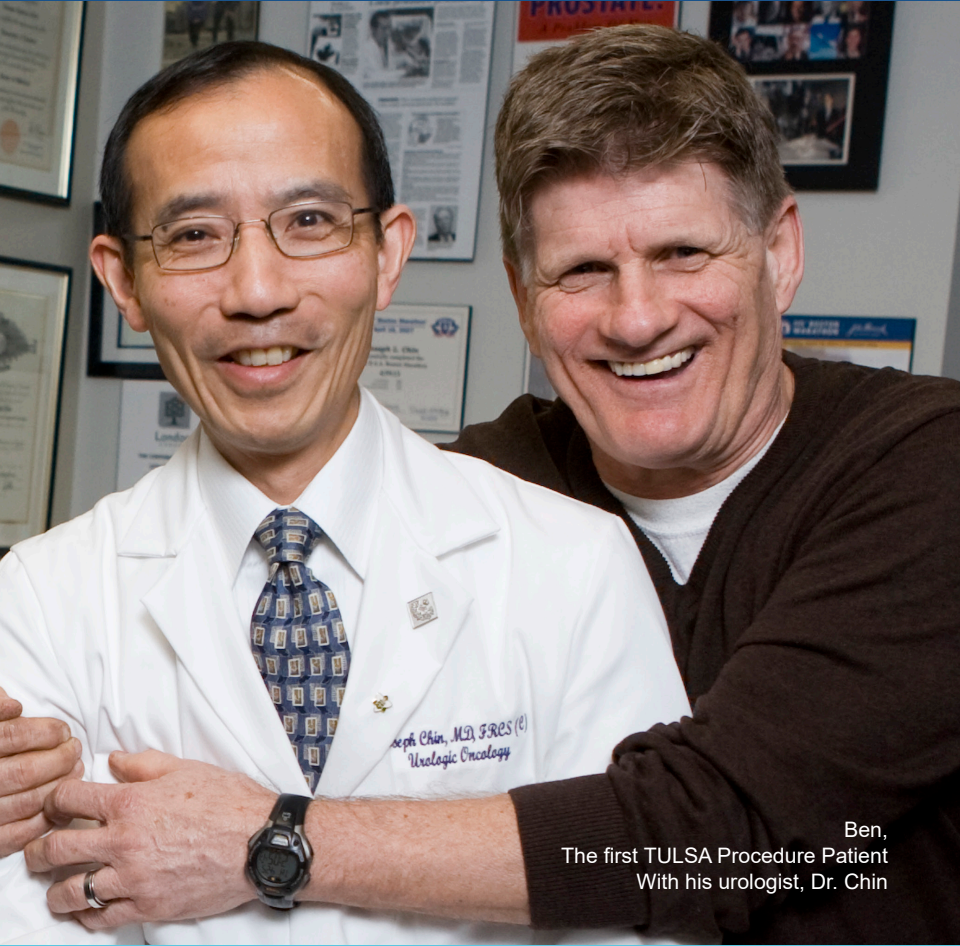


PROFOUND



Ben,  
The first TULSA Procedure Patient  
With his urologist, Dr. Chin

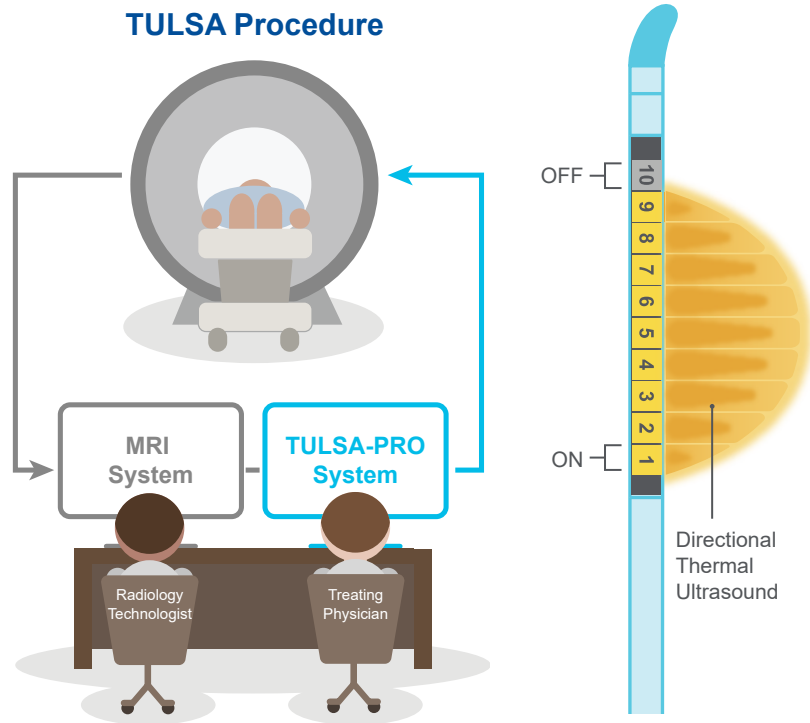
Don't let your prostate disease  
hold you back

**TULSA PROCEDURE™**

Live a Profound Life

# WHAT IS THE TULSA PROCEDURE?

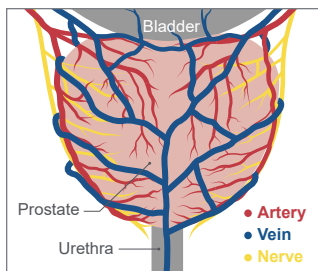
The Transurethral Ultrasound Ablation (TULSA) Procedure is a minimally invasive procedure that uses directional ultrasound to produce very high temperatures to **ablate** (destroy) targeted prostate tissue. The procedure is performed in a Magnetic Resonance Imaging (MRI) suite and uses the TULSA-PRO® 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

## Low Complications

Based on our most recent data, the TULSA Procedure has a relatively low risk of everyday functional decline because your physician has the ability to avoid important nerve bundles and structures around your prostate, decreasing the risk of side effects.

## Rapid Recovery Time

Most patients return to activities quickly and their erectile dysfunction and incontinence return to baseline in about 3 months.

## 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.

## Customizable Treatment Plan

The TULSA Procedure is a customizable procedure that is personalized based on your unique anatomy and disease.

## Precise Targeted Ablation

The TULSA Procedure is precise which allows for local control of clinically significant disease, with significant PSA reduction and low rates of residual cancer on follow-up biopsy.\*

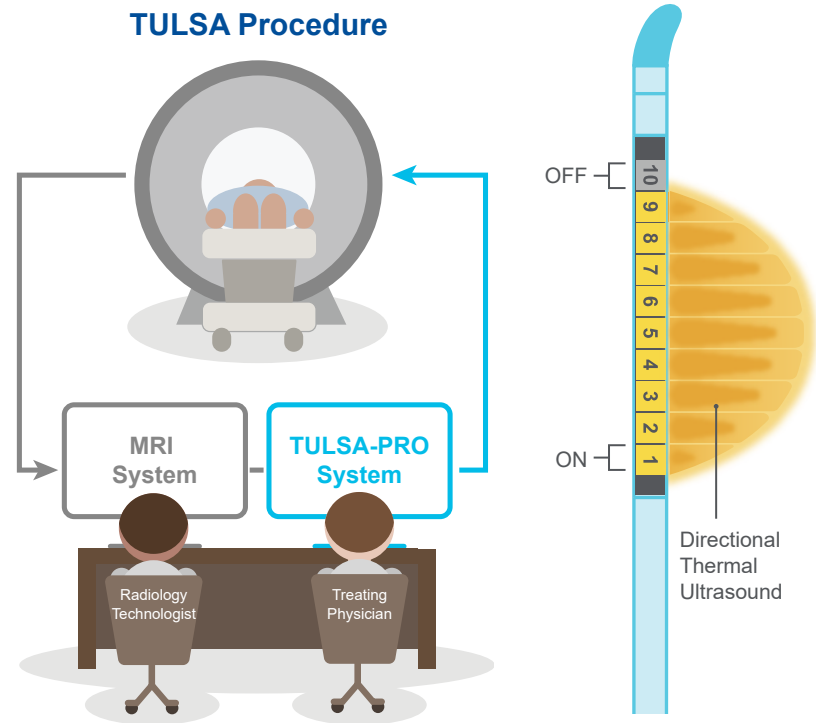
## Keep Your Options Open

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.

\* Klotz, et al. "MP46-03-Pivotal trial of MRI-guided transurethral ultrasound ablation in men with localized prostate cancer: Three-year follow-up". *The Journal of Urology Suppl* (2021)

# WHAT IS THE TULSA PROCEDURE?

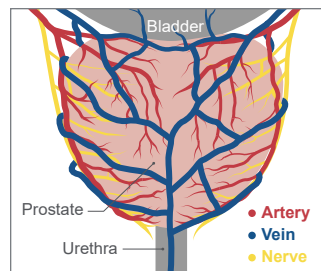
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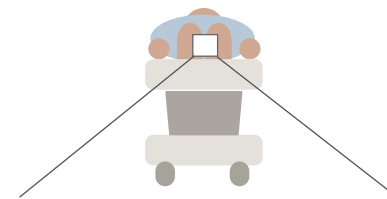
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# HOW DOES IT WORK?

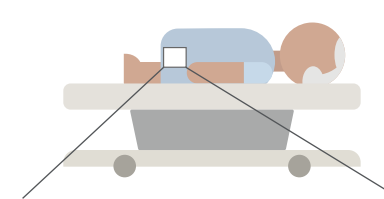
## 1. DEVICE INSERTION

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.

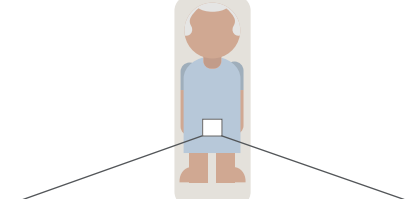
### Axial View



### Sagittal View



### Coronal View

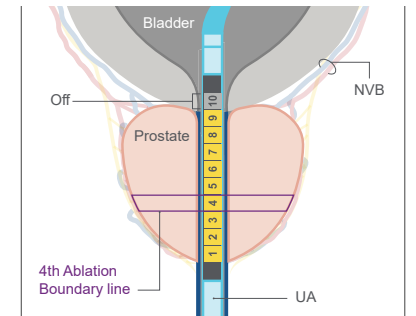
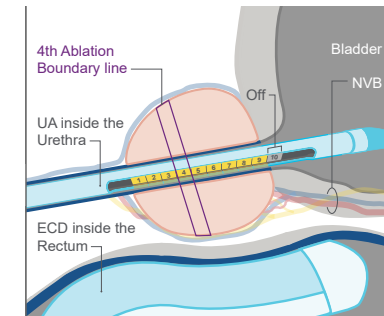
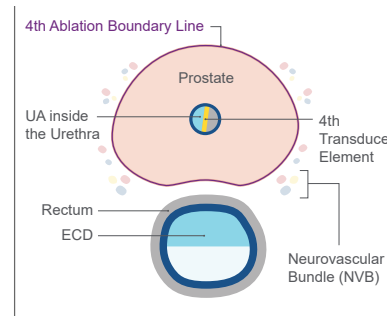


## 2. CLEAR MRI VIEWS

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

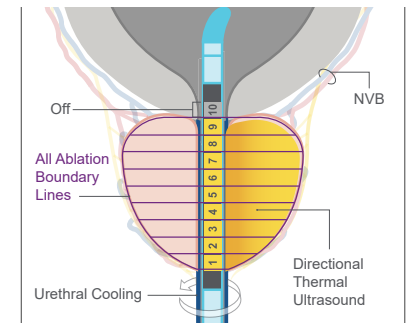
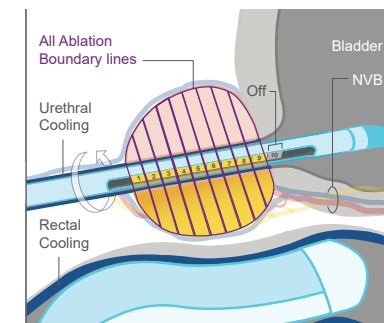
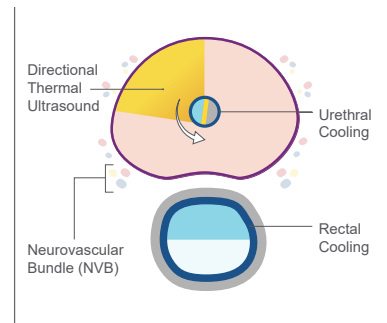
## 3. BOUNDARY LINES

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.



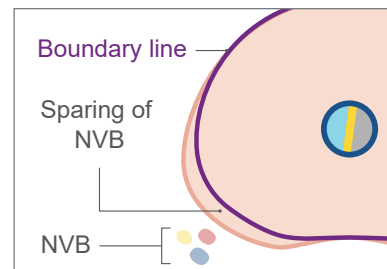
## 4. PROSTATE ABLATION

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.



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

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

# 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**.

Visit our Website at  
[www.tulsaprocedure.com](http://www.tulsaprocedure.com)



SCAN ME

## Focal Outcomes

98%

of men reported **preservation of continence** and were **pad-free** at median 16 months follow-up<sup>1</sup>

98%

of men reported preservation of erections sufficient for penetration at median 16 months follow-up<sup>1</sup>

## Whole-gland Outcomes

76%

of men reported **maintenance or recovery of erectile function** at interim 3 year follow-up<sup>2</sup>

100%

of men **remained continent** at interim 3 year follow-up<sup>2</sup>

1. Lumiani, et al. "Single center retrospective analysis of fifty-two prostate cancer patients with customized MR-guided transurethral ultrasound ablation (TULSA)" *Urologic Oncology* (2021)

2. Klotz, et al. "MP46-03-Pivotal trial of MRI-guided transurethral ultrasound ablation in men with localized prostate cancer: Three-year follow-up". *The Journal of Urology Suppl* (2021)



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**PROFOUND**

**TULSA-PRO**<sup>®</sup>

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