TULSAPROCEDURE[™] Frequently Asked Questions (FAQs)



For Patients

1. How does the TULSA Procedure differ from other prostate therapies?

The TULSA Procedure ablates (destroys) prostate tissue from the 'inside-out'. A device enters the urethra which delivers thermal ultrasound energy (high heat), outwards from the urethra towards the edge of the prostate. This approach avoids the need for surgical incisions to reach the prostate, and it avoids direct thermal contact with the neurovascular bundles surrounding the prostate and with the rectum, which minimizes the risk of side effects like erectile dysfunction and incontinence. A urethral cooling mechanism protects the urethra from thermal damage.

The thermal ultrasound energy is also delivered in a directional pattern allowing it to reach more prostate tissue. This directional beam also moves in a sweeping motion, allowing for efficient ablation of large prostate volumes.

Finally, the TULSA Procedure features real-time temperature maps, enabling the physician to see the temperature of the prostate tissue and surrounding structures every 5-7 seconds during ablation. This visibility allows the physician to actively monitor tissue heating and make changes to the treatment delivery if necessary, making the TULSA Procedure controlled and predictable.

2. Can the TULSA Procedure perform partial and whole gland ablation?

Yes. The physician can customize the procedure to ablate a specific area of the prostate, or the entire prostate, depending on the patients needs and their urinary and sexual preservation goals.

3. What are the side effects?

As with all procedures, there are side effects with the TULSA Procedure but these side effects are minimized since the physician has the ability to avoid important nerve bundles and structures around the prostate. The most common side effects include: pain/discomfort in the ablation area, blood in urine, urinary tract infection, urinary incontinence, and erectile dysfunction. According to the TACT trial*, a whole-gland TULSA Procedure study, 23% of participants had erectile dysfunction, 2.6% had urinary incontinence, 2.6% had urethral stricture, no participants had gastrointestinal toxicity.

*Klotz, et al. "Magnetic Resonance Imaging-Guided Transurethral Ultrasound Ablation of Prostate Cancer." The Journal of Urology (2020)

4. How much does the TULSA Procedure cost? Can I get reimbursed?

The price of the TULSA Procedure varies by center. Some TULSA-PRO Centers are Cash Pay Only, while others accept insurance. The amount that insurance covers varies by center and your insurance policy. To determine if your insurance will cover the TULSA Procedure and how much will be covered, you must first select a TULSA-PRO Provider and TULSA-PRO Center. The TULSA-PRO Center will then work with TULSA-PRO Reimbursement Experts to determine your coverage and out-of-pocket costs.

5. Who qualifies for the TULSA Procedure?

Patients interested in the TULSA Procedure must be screened by a Magnetic Resonance Imaging professional (technologist or radiologist) before entering the MRI suite and assessed by an anesthesiologist before the procedure. Whether a patient qualifies for the TULSA Procedure will be determined by the treating physician.

What is the TULSA Procedure?

The word 'TULSA' stands for Transurethral Ultrasound Ablation. It 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. The physician can see the prostate at all times throughout the procedure. 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.

TULSA Procedure



TULSA Procedure Advantages

Gain Confidence in Your Outcomes

 $\overline{\oslash}$

Using directional thermal ultrasound and MR imaging, you can feel confident knowing that the TULSA-PRO system automatically adjusts the ultrasound output to best 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.

Lage 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.

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.

Customize Your Treatment Plan

No two prostates are the same, and neither should two treatment plans be. The TULSA-PRO system automatically adjusts the ultrasound power to compensate for varying tissue properties and blood flow which are unique to each patient. The TULSA Procedure is not a "one-side-fits-all" treatment - it's a customizable procedure that is personalized based on your unique anatomy and issue.

🖺🕂 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.

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.

Profound Medical Inc. 2400 Skymark Ave. Unit #6 Mississauga, ON L4W 5K5, Canada

www.profoundmedical.com

© Profound Medical Inc., 2021. TULSA-PRO® is approved for commercial sale in the USA, EU, Canada, and select other countries CAUTION: Rx only device. Profound Medical and TULSA-PRO are trademarks of Profound Medical Inc. For more information regarding the regulatory status of the device in other jurisdictions, please contact us at info@profoundmedical.com. 110673A