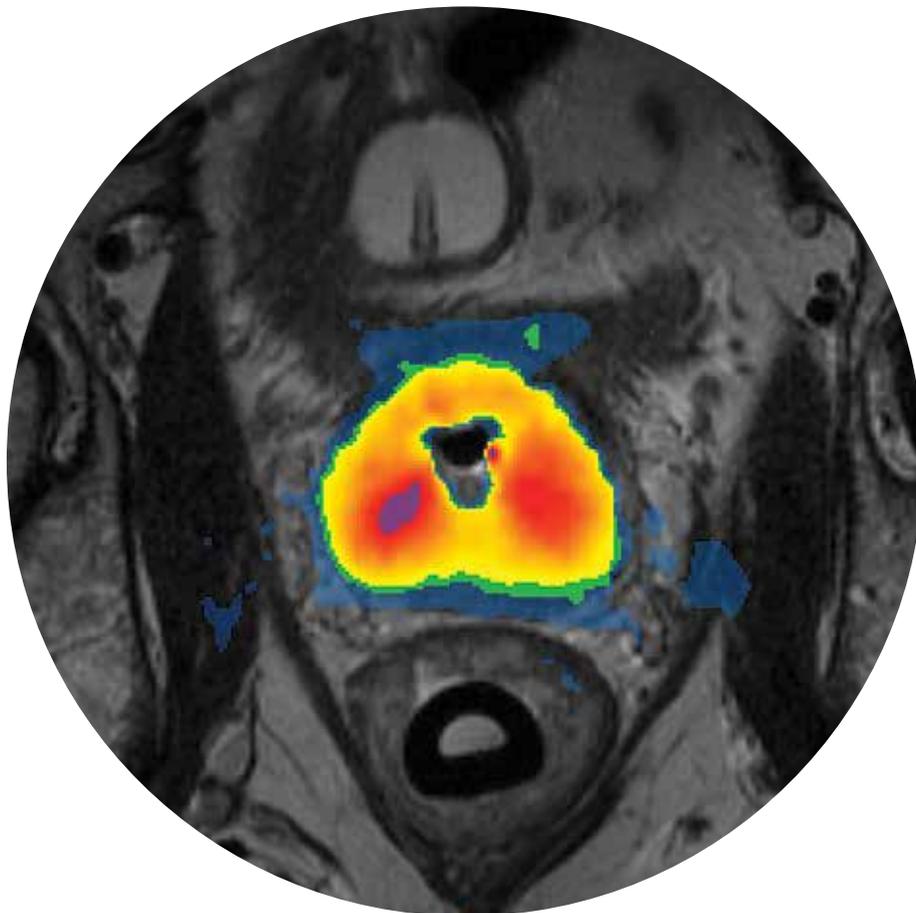


# An Inside Out Approach to Prostate Ablation

TULSA is a transurethral procedure that accurately and effectively ablates targeted prostate tissue.



**PROFOUND**  
MEDICAL Inc.

**TULSA-PRO™**

Profound Medical is a Canadian medical device company that has developed a unique and minimally invasive procedure to ablate targeted prostate tissue.

Profound's novel technology, TULSA, combines real-time MR imaging with transurethral therapeutic ultrasound and closed-loop thermal feedback control. It provides a highly precise treatment tailored to patient-specific anatomy and pathology. This method of prostate ablation offers short treatment times and low morbidity, allowing for fast patient recovery.

12-month results of the TULSA-PRO™ Phase 1 Clinical Trial published in European Urology (<http://bit.ly/1O7LVcv>) demonstrated clinical safety and precision of TULSA-PRO for near whole-gland prostate ablation, with low toxicity and a well-tolerated safety profile. Profound Medical continues to monitor the initial 30 patients for 5 years.

A 110 patient Pivotal Trial is being established in over 10 institutions in Europe (Germany, Spain, The Netherlands), Canada and the United States.



- 1. Ultrasound Applicator
- 2. Positioning System
- 3. Positioning System Interface Box
- 4. System Cart
- 5. System Electronics

# Transurethral Ultrasound Ablation

# Prostate Ablation from the Inside Out

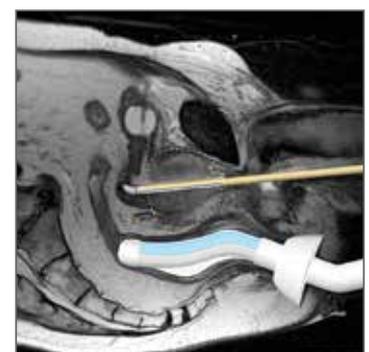
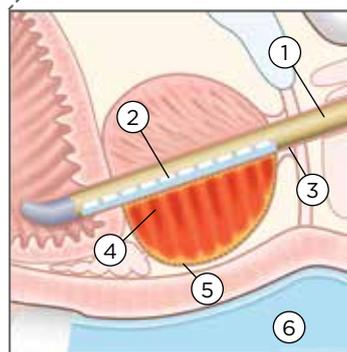
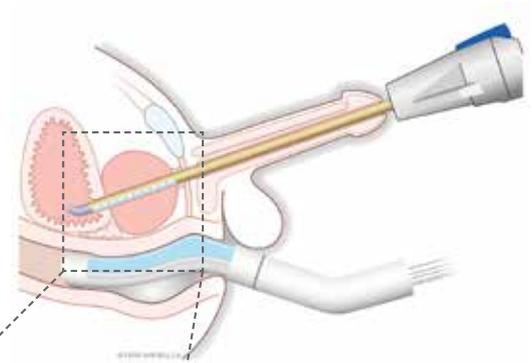
- Safe, fast and accurate
- High resolution MRI treatment planning
- Guided by real-time MR imaging with temperature feedback
- Automated robotic control of the ultrasound beam
- Precisely ablates targeted tissue

- Minimally-invasive, transurethral approach
- Millimeter accuracy of ablation to targeted prostate tissue
- Spares nearby critical anatomy
- Continuous ablation, no cold spots
- Cooled applicator protects urethra



TREATMENT PLANNING

## PROCEDURE



UA AND ECD POSITIONING

1. Ultrasound Applicator (UA)
2. Ultrasound Transducers
3. Urethra
4. Heating Pattern
5. Thermal Ablation Boundary
6. Endorectal Cooling Device (ECD)

## Favourable Patient Outcomes\*

- Approximately 30 – 40 minute treatment time
- Low morbidity profile
- Rapid recovery



### Single-Use Disposables:

#### Transurethral Ultrasound Applicator (UA)

Houses a high-power piezo-ceramic ultrasound transducer that emits high intensity ultrasound energy into the prostate during treatment.



#### Endorectal Cooling Device (ECD)

Inserted into the patient's rectum, water is circulated through the device to protect rectal tissue from thermal damage during treatment



#### Positioning System (PS)

The PS supports the UA once it is inserted into the patient. It provides motor-controlled translation of the UA for positioning the ultrasound elements precisely in the prostate.



#### System Cart (SC)/ System Electronics (SE)

The SC is a transportable cart that houses two main system components, the Fluid Circuit (FC) hardware and the System Electronics (SE). The SE provides power and electrical signals to all system components.



\*Chin JL, et al. Magnetic Resonance Imaging-Guided Transurethral Ultrasound Ablation of Prostate Tissue in Patients with Localized Prostate Cancer: A Prospective Phase 1 Clinical Trial. Eur Urol (2016).

**ULTRASOUND APPLICATOR**

Profound Medical proprietary design trans-urethral single use sterile device

Construction	Rigid tube with soft coude tip, diameter 7.5 mm (22 Fr), 260 mm maximum insertion length, passage for guide wire	
Ultrasound Transducer	Linear array of 10 planar rectangular ultrasound transducer elements with individually controlled frequency and power	
Dual Frequency	Low Frequency Range: 4 to 4.8 MHz	High Frequency Range: 13.4 to 14.4 MHz
Acoustic Power per Element	Low Frequency Range: 4 W max	High Frequency Range: 2 W max
Heating Method	Rotation of high intensity directional (not focused) ultrasound produces controlled heating of swept volume	
Treatable Volume	Max Length: 5 cm along urethra	Max Radius: 3 cm from urethra

**POSITIONING SYSTEM**

2-axis controlled and 3-axis manual adjustment

Rotation (Controlled)	Accuracy: $\pm 1^\circ$	Max Speed: 120°/min	Range: 2.5 rotations
Linear (Controlled)	Accuracy: $\pm 0.1$ mm	Max Speed: 30 mm/min	Range: 60 mm
Y-axis (Manual)	Vertical linear with range: 205 mm		
Z-axis (Manual)	Horizontal linear along axis of bore with range: 240 mm		
Tilt (Manual)	Rotation about X axis $+30^\circ$ to $-5^\circ$		

**TEMPERATURE CONTROL**

Real-time MRI measured temperature for automatic control of ultrasound power and rotation rate

MRI Thermometry Sequence	EPI temperature sensitive proton resonance frequency shift induced phase difference 12 slice axial 4 to 5 mm thickness, in-plane resolution of 2 mm (approx.)		
Thermal Image Maps	Refresh Rate: 5 to 7 sec	Accuracy: $\leq 1^\circ\text{C}$	Precision: $\leq 2^\circ\text{C}$

**TREATMENT DELIVERY CONSOLE**

Computer and software for treatment planning, temperature mapping, ablation feedback control, therapy guidance and communication with MR scanner

Computer	Intel Core i7-4790S, 8Gb RAM, 1TB HD, mains Power: 100-240Vac, 50/60Hz, 300W
Monitor	22" LED display, 1920x1080 resolution, mains Power: 100-240Vac, 50/60Hz, 20W
MRI Compatibility	Compatible with select Siemens and Philips 3T models. Contact Profound for a complete list of supported scanners and coils.

**GENERAL**

Environment	Temperature: 18°C to 30°C	Humidity: 40% to 80% non-condensing
System Cart	System Electronics, fluid pumps and sensors Mains Power: 100-240Vac, 50/60Hz, 1000W	



**Dr. Joseph L. Chin**  
Chief of Surgical Oncology  
Western University,  
London Health  
Sciences Centre

“This is an exciting time in the treatment of localized prostate cancer. TULSA-PRO is a unique therapy that is showing to be effective and accurate. It appears to be well-tolerated by patients and has to date shown to have low side effects, with minor or no impact to erectile and urinary function. This helps patients quickly get back to their normal quality of life, which is a critical outcome when evaluating their treatment options. Although the precise role of TULSA-PRO in the management of localized prostate cancer still needs to be confirmed by larger and more extensive studies, the results from our first trial are very encouraging.”

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Regulatory Authorization is  
pending for all other jurisdictions.

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