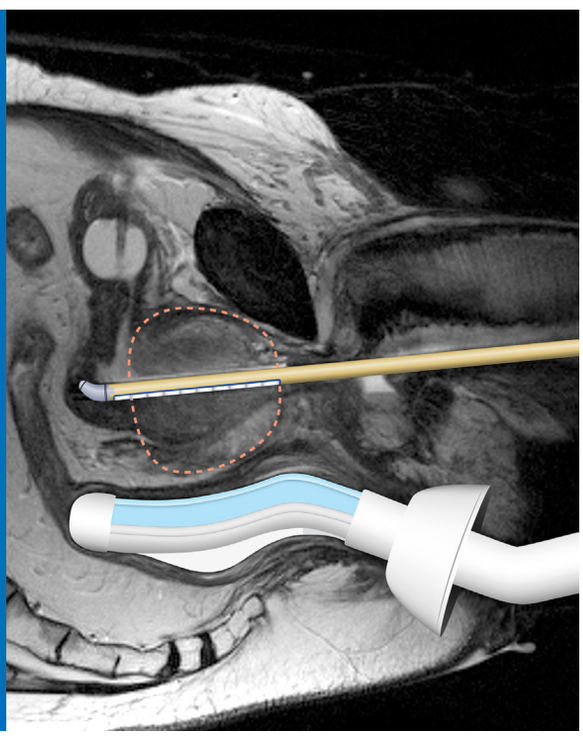
PROFOUND MEDICAL

Transurethral Prostate Ablation
Focal and Whole Gland

TULSA-PRO®

Real-Time MRI Imaging with Thermal Ultrasound

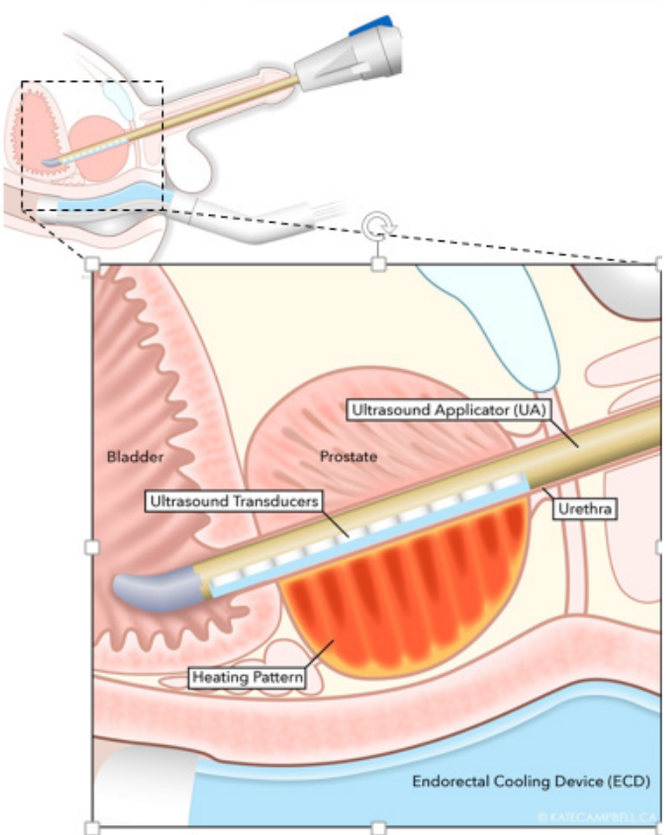
MRI-guided Transurethral Ultrasound Ablation (TULSA) is a minimally-invasive treatment for patients with localized prostate cancer, where the therapeutic endpoint is prostate ablation through thermal coagulation. It combines Magnetic Resonance Imaging (MRI) based planning, monitoring, and treatment control with transurethral delivery of therapeutic ultrasound to ablate prostate tissue from the inside out.



How it works

TULSA-PRO delivers the ultrasound energy via the Ultrasound Applicator. It is inserted into the urethra, making contact with and delivering ultrasound energy directly into the prostate gland.

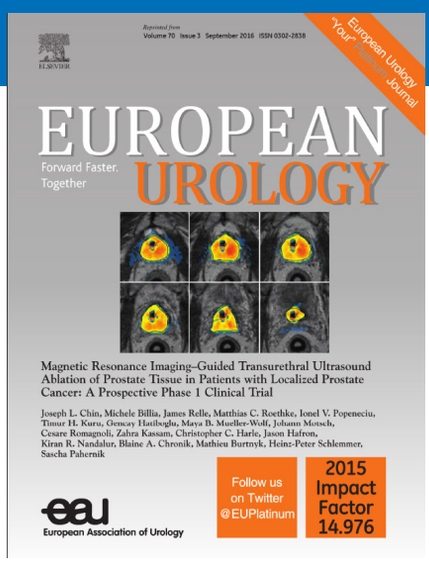
A linear array of 10 independent ultrasound transducer elements emits directional (but unfocused) high-intensity ultrasound energy directly into the adjacent prostate, quickly raising tissue temperatures to thermal coagulation and subsequent cell death. The configuration of the ultrasound beams enables treatment of a large volume of prostate tissue, resulting in treatment times of typically 40-60 minutes. Fluid is circulated through the UA, providing 1-2 mm of urethral tissue protection. A separate circuit flows water through the Endorectal Cooling Device to provide thermal protection of rectal tissue during ultrasound ablation delivery.



Precise Ablation With Millimeter Accuracy:
Flexibility to design ablation zone: targeted to whole gland

Real-time MR Guidance & Robotic Applicator:
Intelligent software drives coordination of MR scanner, robotic applicator and ultrasound delivery to deliver millimeter precision

Ablate Prostate from Inside-Out:
Inherently safer than outside-in.
Actively protects urethra and rectum via cooling.



Clinical Evidence

TULSA-PRO is the culmination of decades of pre-clinical and clinical research.
Key outcomes of Phase I Clinical Trial are summarized below.
It is important to note that a 3 mm safety margin representing approximately 10% of the prostate volume was maintained in this clinical trial.

TACT Pivotal Trial is a multicenter, prospective FDA-registered clinical trial, TACT, which is designed to further demonstrate the safety and effectiveness of TULSA-PRO. TACT is expected to support Profound's application to the FDA for approval to market TULSA-PRO in the United States.

OBJECTIVE	**Determine safety and feasibility of MRI-TULSA for whole-gland prostate ablatio in a primary treatment setting of localized prostate cancer**
SUBJECTS	30 Patients (Inclusion criteria: Men ≥ 65 yr, organ confined PCa, PSA ≤ 10 ng/ml, Gleason score 3+3 or 3+4)
OUTCOMES	• 30 patients treated with at least 12 month follow-up • No intraoperative complications, no rectal injury or fistula • Erectile dysfunction rate of 8% (IIEF item 2 ≥ 2) • At 12 months, only 1 patient (3%) with Grade 1 urinary incontinence (no pads) • Functional quality-of-life outcomes back to baseline levels • Accuracy of thermal ablation +/- 1.3 mm

TACT is being conducted at the below sites in Germany, Netherlands, Spain, USA and Canada.

1. **Western University, London Health Sciences Centre**
2. **Sunnybrook Health Sciences Centre**
3. **William Beaumont Hospital**
4. **Johns Hopkins Hospital**
5. **Vanderbilt University Medical Center**
6. **University of Chicago Medical Center**
7. **Indiana University Hospital**
8. **University of Texas Southwestern Medical Center**
9. **UCLA Health**
10. **Heidelberg University/ German Cancer Research Institute (DKFZ)**
11. **University of Cologne**
12. **Radboud University Medical Center**
13. **ResoFus Alomar**

CE

TULSA-PRO® has CE Marking. Regulatory Authorization is pending for all other jurisdictions.