



# PROFOUND

Customizable, Incision-Free  
Ablation Therapies

Corporate Presentation | November 2020

© 2020 Profound Medical Corp.

NASDAQ: PROF  
TSX: PRN

# Forward-Looking Information

Certain statements in this presentation may contain certain information that is “forward-looking information” or “forward-looking statements” within the meaning of applicable securities laws with respect to Profound Medical Corp. (“Profound” or the “Company”). Such statements include all statements other than statements of historical fact contained in this presentation, such as statements that relate to the Company’s current expectations and views of future events. Often, but not always, forward-looking information can be identified by the use of words such as “may”, “will”, “expect”, “anticipate”, “predict”, “aim”, “estimate”, “intend”, “plan”, “seek”, “believe”, “potential”, “continue”, “is/are likely to”, “is/are projected to” or the negative of these terms, or other similar expressions, as well as future or conditional verbs such as “will”, “should”, “would”, and “could” intended to identify forward-looking statements. These forward-looking statements include, among other things, statements relating to our expectations regarding future clinical trials, expectations regarding regulatory approvals, expectations regarding the safety and efficacy of its products, our expectations regarding commercializing our approved products and our ability to generate revenues and achieve profitability; our expectations regarding the impact of COVID-19 on our business, affairs, operations, financial condition, liquidity, availability of credit and results of operations; our expectations regarding the safety, efficacy and advantages of our products over our competitors and alternative treatment options; our expectations regarding our products fulfilling unmet clinical needs and achieving market acceptance among patients, physicians and clinicians; our expectations regarding reimbursement for our approved products from third-party payers; our expectations regarding our relationship with RadNet; our expectations regarding our relationships with Philips and Siemens, and our ability to achieve compatibility of our systems with MRI scanners produced by other manufacturers; our ability to attract, develop and maintain relationships with other suppliers, manufacturers, distributors and strategic partners; our expectations regarding our pipeline of product development, including expanding the clinical application of our products to cover additional indications; our expectations regarding current and future clinical trials, including the timing and results thereof; our expectations regarding receipt of additional regulatory approvals for our products and future product candidates; our mission and future growth plans; our ability to attract and retain personnel; our expectations regarding maintenance of the current regulatory approvals we have received, including our compliance with the conditions under such approvals; our expectations regarding our competitive position for each of our products in the jurisdictions where they are approved; our ability to raise debt and equity capital to fund future product development, pursue regulatory approvals and commercialize our approved products; and anticipated trends and challenges in our business and the markets in which we currently operate or may in the future operate.

Forward-looking statements involve known and unknown risks, uncertainties and other factors which may cause the actual results, performance or achievements of the Company to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. The results, performance and achievements of the Company will be affected by, among other things, such as risks related to our limited operating history and history of net losses; risks relating to the extent and impact of COVID-19; risks related to our ability to commercialize our approved products, including expanding our sales and marketing capabilities, increasing our manufacturing and distribution capacity, realizing the anticipated benefits of our commercial agreement with RadNet, increasing reimbursement coverage for our approved products and achieving and maintaining market acceptance for our products; risks related to the regulation of our products, including in connection with obtaining regulatory approvals as well as post-marketing regulation; risks related to our successful completion of future clinical trials with respect to our products and future product candidates; risks related to managing growth, including in respect of obtaining additional funding and establishing and maintaining collaborative partnerships, to achieve our goals; risks related to competition that may impact market acceptance of our products and limit our growth; risks relating to fluctuating input prices and currency exchange rates; risks related to the reimbursement models in relevant jurisdictions that may not be advantageous; risks related to reliance on third parties, including our collaborative partners, manufacturers, distributors and suppliers, and increasing the compatibility of our systems with MRI scanners; risks related to intellectual property, including license rights that are key to our business; and risks related to the loss of key personnel, and such other risks detailed from time to time in the other publicly filed disclosure documents of the Company which are available at [www.sedar.com](http://www.sedar.com) and [www.sec.gov](http://www.sec.gov). The Company’s forward-looking statements are made only as of the date of this presentation and, except as required by applicable law, Profound disclaims any obligation to update any forward-looking statements, whether as a result of new information, future events or results or otherwise, unless required by applicable law. There can be no assurance that forward-looking statements will prove to be accurate, as actual results and future events could differ materially from those anticipated in such statements. Accordingly, and because of the above-noted risks, uncertainties and assumptions, readers should not place undue reliance on forward-looking statements due to the inherent uncertainty in them.

TULSA-PRO and SONALLEVE are registered trademarks of Profound Medical Corp.

# Market & Industry Data

Market data and industry forecasts contained in this presentation have been obtained from industry publications, various publicly available third-party sources and subscription-based reports as well as from management's good faith estimates, which are derived from management's knowledge of the industry and independent sources that management believes to be reliable. Industry publications, surveys and forecasts generally state that the information contained therein has been obtained from sources believed to be reliable. Although Profound believes it to be reliable, the Company has not independently verified any of the information from third-party sources nor has it ascertained the validity or accuracy of the underlying economic assumptions relied upon therein. We disclaim responsibility or liability in respect of any third-party sources of market and industry data or information, to the extent permitted by law.

# Use of Projections

This presentation may contain financial forecasts with respect to our estimated future performance. Our independent auditors have not audited, reviewed, compiled or performed any procedures with respect to the projections for the purpose of their inclusion in this presentation and, accordingly, neither of them expressed an opinion or provided any other form of assurance with respect thereto for the purpose of this presentation. These projections should not be relied upon as being necessarily indicative of future results.

In this presentation certain of the above-mentioned projected financial information has been included for purposes of providing comparisons with historical data. The assumptions and estimates underlying the prospective financial information are inherently uncertain and are subject to a wide variety of significant business, economic and competitive risks and uncertainties that could cause actual results to differ materially from those contained in the prospective financial information. Accordingly, there can be no assurance that the prospective results are indicative of our future performance or that actual results will not differ materially from those presented in the prospective financial information. Inclusion of the prospective financial information in this presentation should not be regarded as a representation by any person that the results contained in the prospective financial information will be achieved.

# COVID-19

The COVID-19 outbreak has been declared a pandemic by the World Health Organization. It is too soon to gauge the impacts of the current outbreak, given the many unknowns related to COVID-19 including the duration and severity of the outbreak. COVID-19 is altering business and consumer activity in affected areas and beyond. The global response to the COVID-19 outbreak has resulted in, among other things, border closures, severe travel restrictions, the temporary shut-down of non-essential services and extreme fluctuations in financial and commodity markets. Additional measures may be implemented by one or more governments in jurisdictions where the Company operates. These measures have caused material disruption to businesses globally, resulting in an economic slowdown. The extent to which COVID-19 and any other pandemic or public health crisis impacts the Company's business, affairs, operations, financial condition, liquidity, availability of credit and results of operations will depend on future developments that are highly uncertain and cannot be predicted with any meaningful precision, including new information which may emerge concerning the severity of the COVID-19 virus and the actions required to contain the COVID-19 virus or remedy its impact, among others.

The actual and threatened spread of COVID-19 globally could also have a material adverse effect on the regional economies in which the Company operates, could continue to negatively impact stock markets, including the trading price of Profound's Common Shares, could adversely impact the Company's ability to raise capital, and could cause continued interest rate volatility and movements that could make obtaining financing more challenging or more expensive.

Further, from an operational perspective, the Company's employees, direct sales and marketing teams and distribution partners, as well as the workforce of vendors, services providers and counterparties with which the Company does business, may also be adversely affected by the COVID-19 pandemic or efforts to mitigate the pandemic, including government-mandated shutdowns, requests or orders for employees to work remotely, and other physical distancing measures, which could result in an adverse impact on the Company's ability to conduct its businesses, including its ability to cultivate adoption of the TULSA-PRO technology, support clinical customers with the TULSA-PRO procedures and increase the utilization of the systems and disposable components.

“My life should not  
have to change”

**TULSA-PRO<sup>®</sup>**

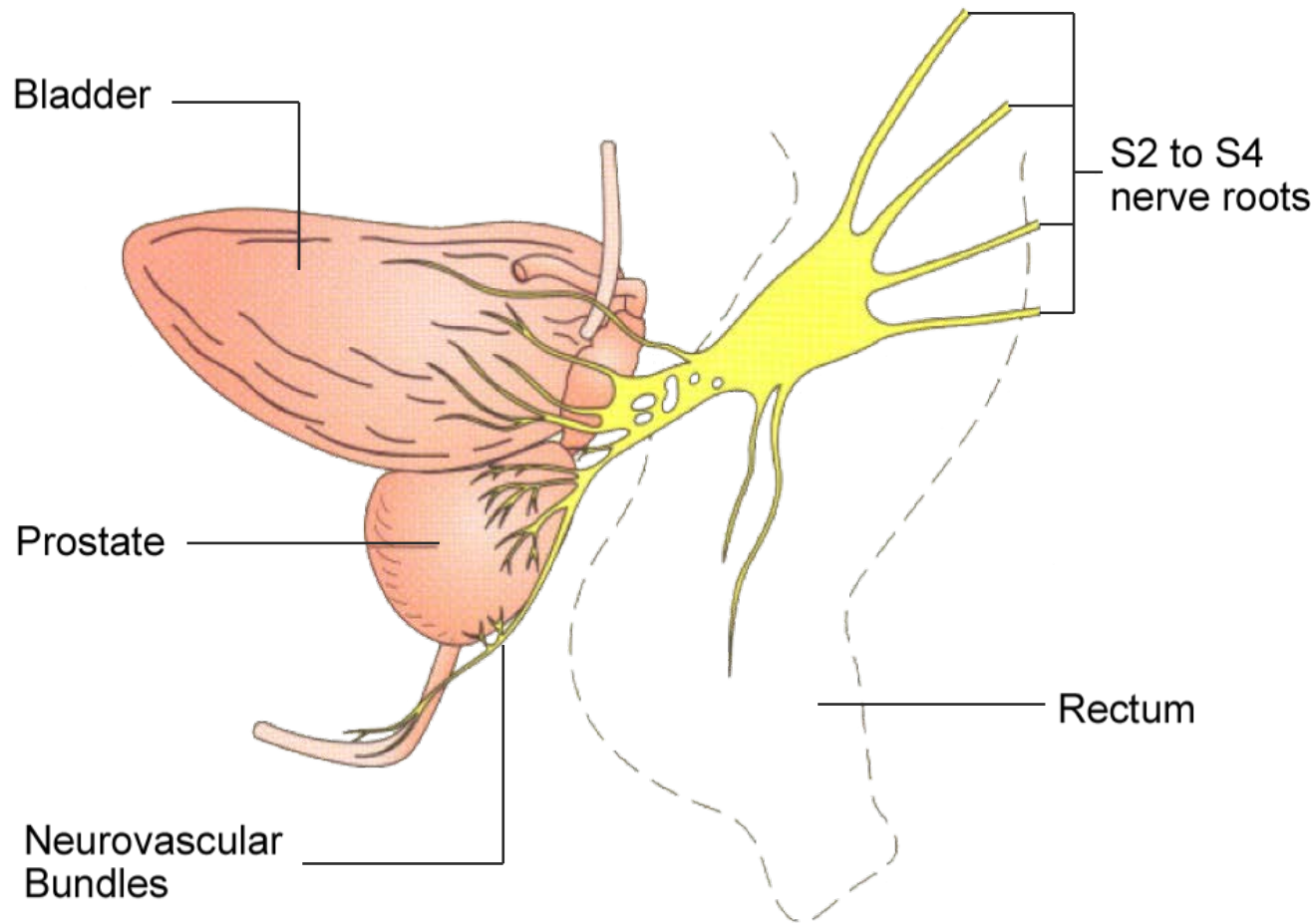
U.S. FDA Cleared, August 2019  
Ablation of Prostate Tissue

PROFOUND



# Prostate Disease

Anatomy & Current Landscape in the United States (“U.S.”)



**~175,000** new prostate cancer cases per year

**60%** are > 65 years

**> 3M** men living with diagnosed prostate cancer

**10M** men living with Benign Prostatic Hyperplasia (“BPH”)<sup>1</sup>

**300,000** BPH surgical procedures per year<sup>1</sup>

## Common treatment options

1. Surgery to remove prostate
2. Radiation to kill it in place

## Common sides effects

1. Urinary and/or rectal incontinence
2. Erectile dysfunction

# TULSA-PRO

Our Solution

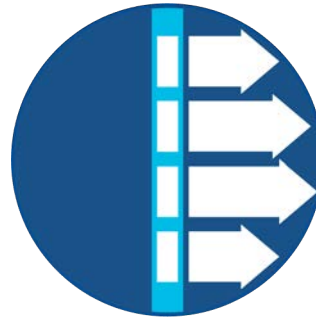
How we  
see & plan



Real-time  
MRI  
Guidance

Ablation using real time  
MRI imaging and  
thermometry

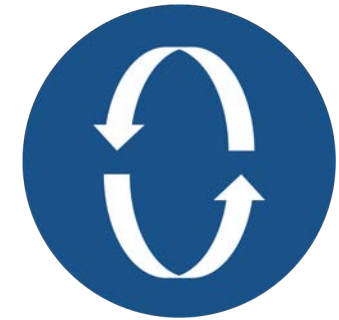
How we  
ablate



Transurethral  
Directional Thermal  
Ultrasound

Transurethral heating of  
the prostate gently to  
55° C without boiling tissue

How we  
control



Closed-loop  
Thermal  
Feedback

Robotic closed loop temperature  
control to enable whole gland  
ablation of any size prostate

**Post-procedure**, the dead prostate tissue is slowly resorbed by the body

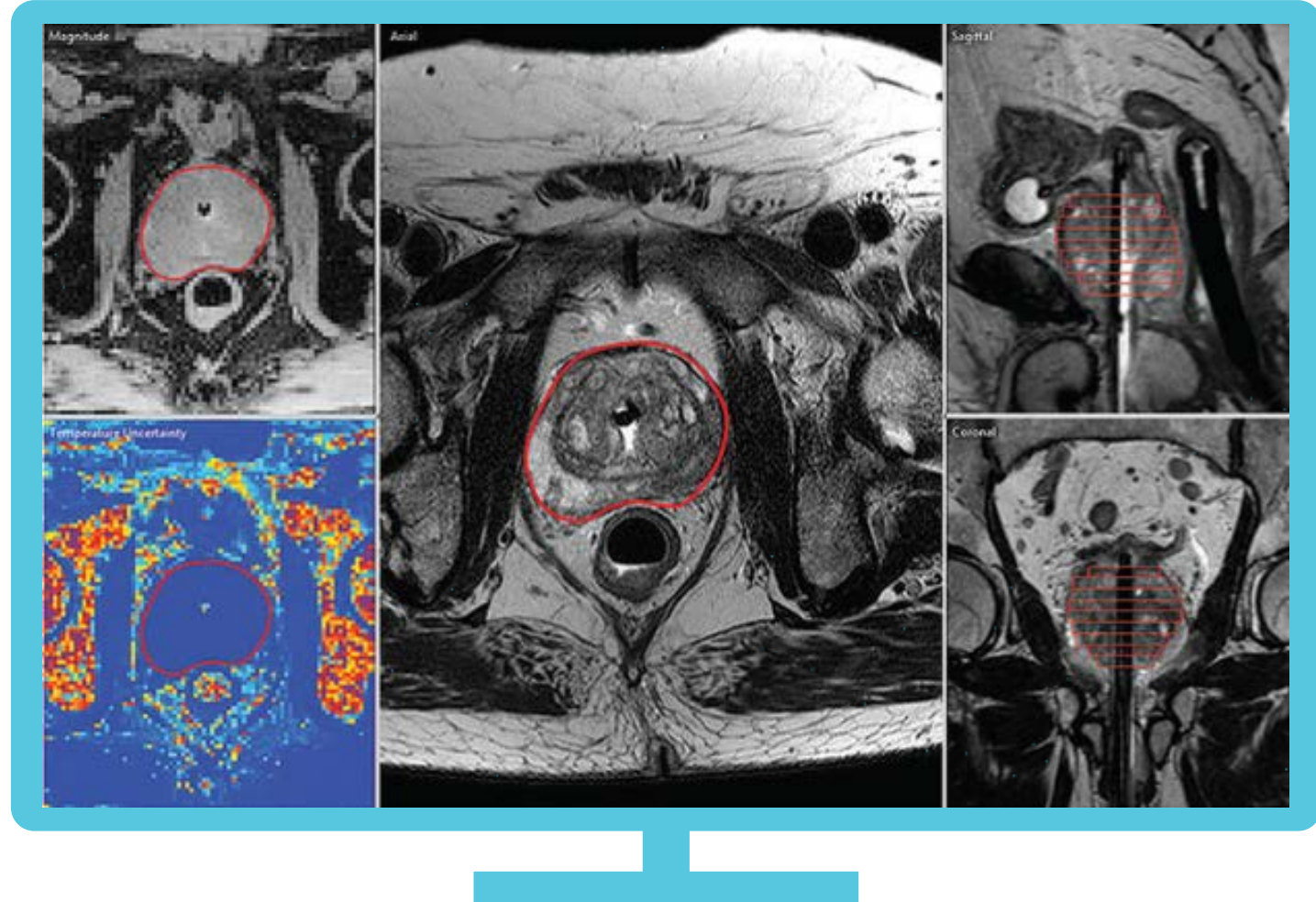
# TULSA-PRO

Patient MRI Bore, Physicians Create 3D Treatment Plan Using Real-Time MRI Visualization

How we  
see & plan



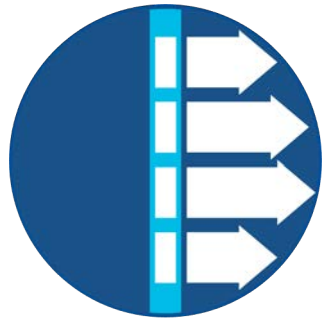
Real-time  
MRI  
Guidance



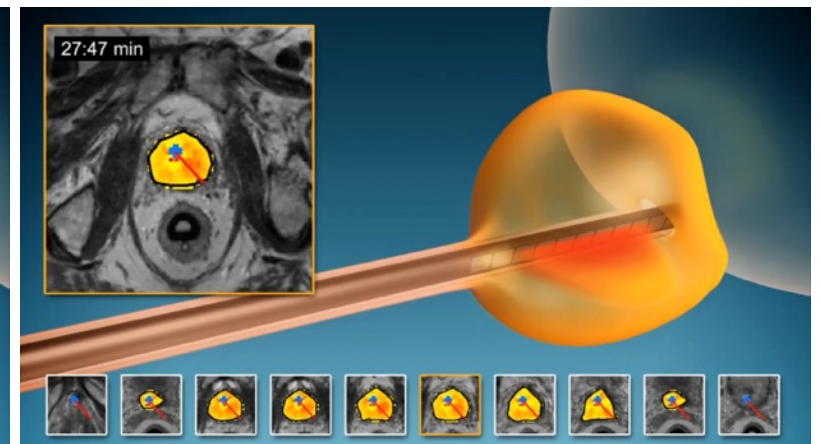
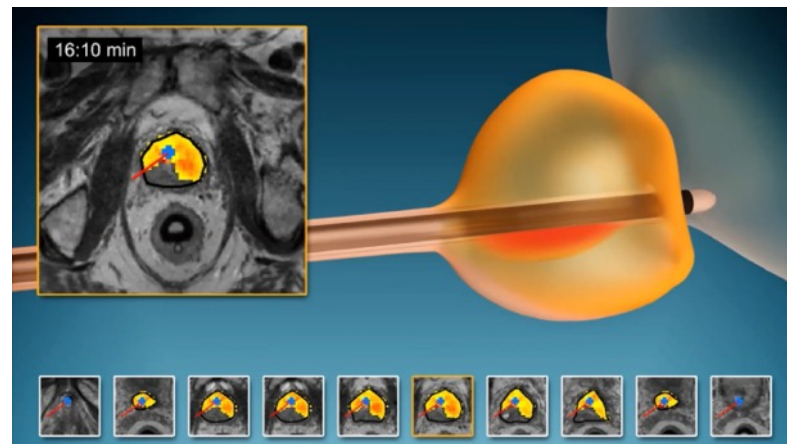
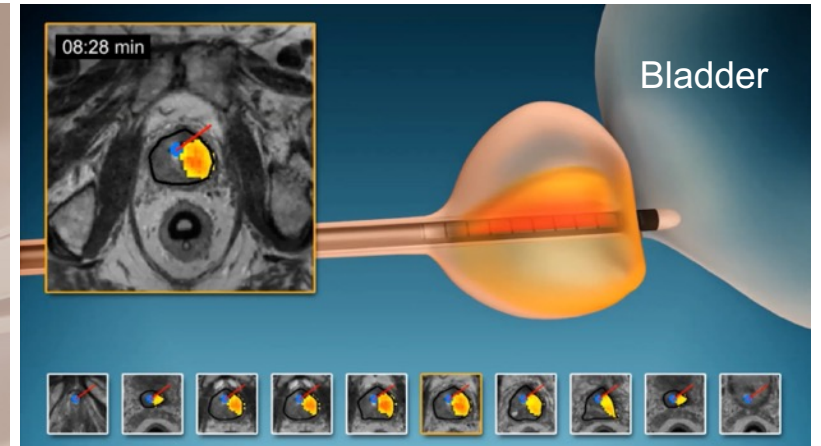
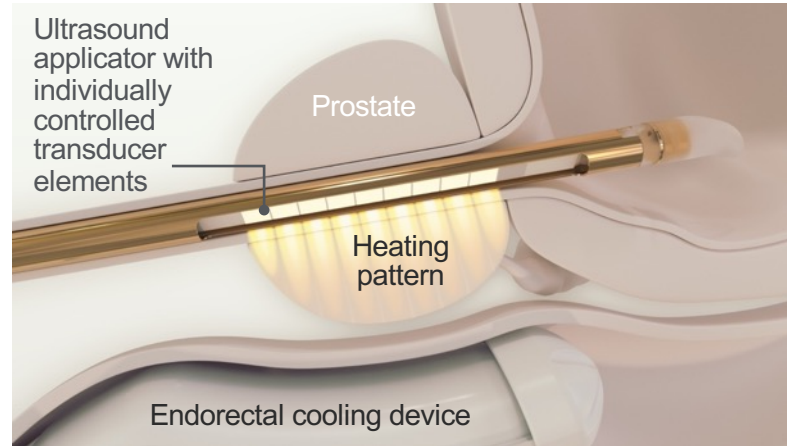
# TULSA-PRO


## Transurethral Gentle Heating of Prostate to 55° C

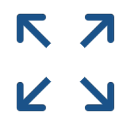
How we  
ablate




Transurethral  
Directional Thermal  
Ultrasound



 Sweeping ultrasound,  
continuous rotation

 Capable of treating both large  
and small prostate volumes

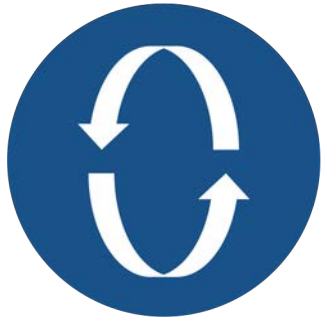
 Thermal protection of  
important anatomy



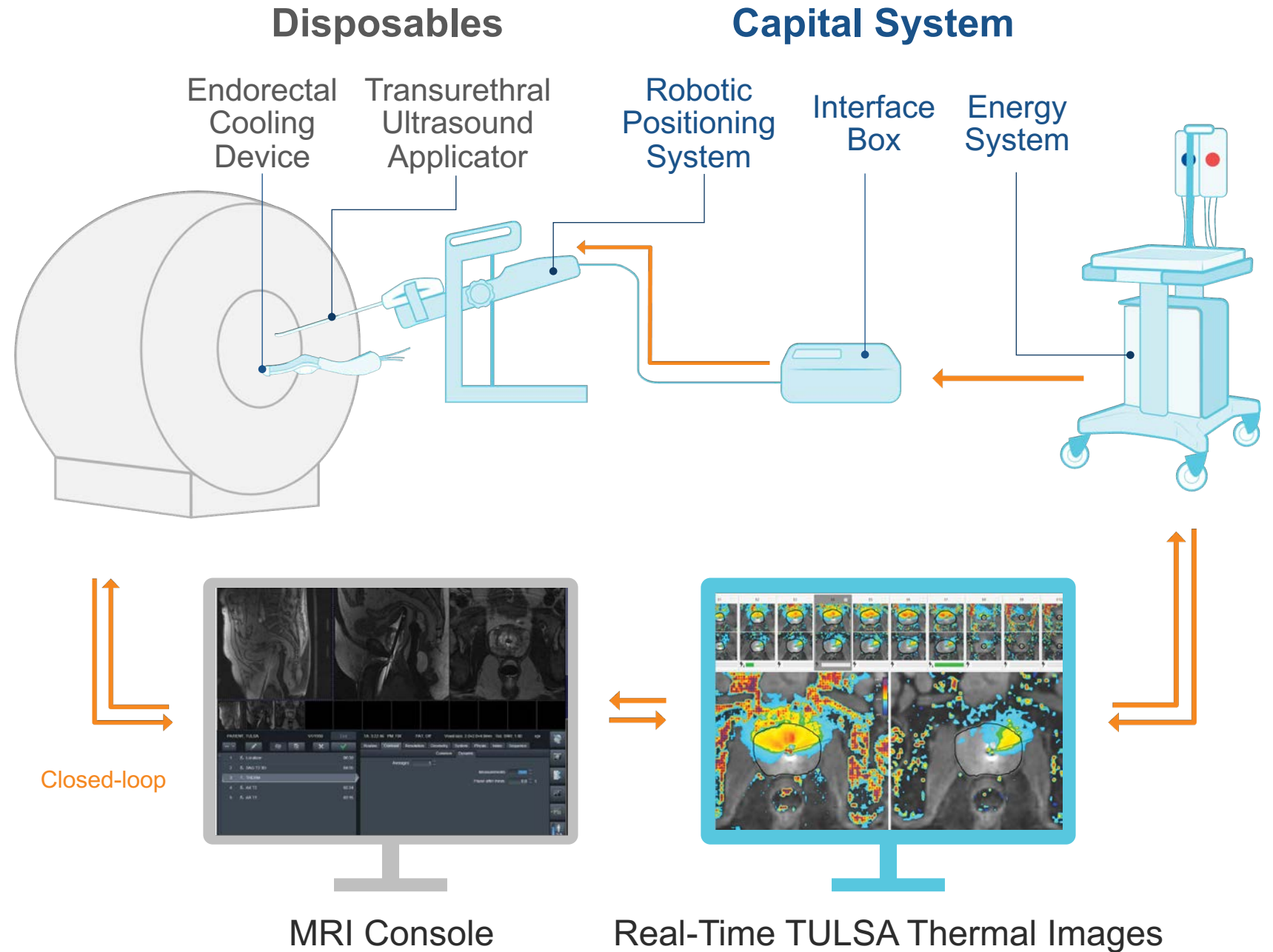
# TULSA-PRO

System Components

How we control



Closed-loop Thermal Feedback



# TACT Clinical Trial

## Pivotal Study of Whole-Gland Ablation in a Clinically-Significant Patient Population

**n=115**

**13** clinical sites

**5** countries

**45-80** years old

**Prostate Cancer Risk** Intermediate (67%)  
Low (33%)

### PSA primary efficacy endpoint resolutely met:

- Median PSA reduction was **95%**, stable to 2 years

Pre-Treatment	Nadir	1 year	2 years
6.3 ng/ml	0.34 ng/ml	0.53 ng/ml	0.63 ng/ml

**80%**  
of men

**Extensive biopsy sampling demonstrated a histological benefit for nearly 80% of men**

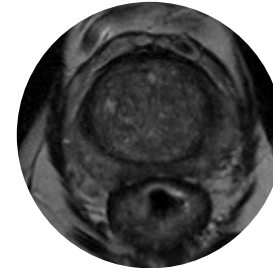
**7%**  
of men

**Underwent additional intervention for their prostate cancer by 2 years, comparable to accepted rates of relapse after standard prostate cancer treatments**

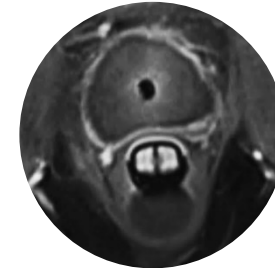
### Prostate volume significantly reduced:

- Median prostate volume decreased **91%** from 37 cc to 3 cc

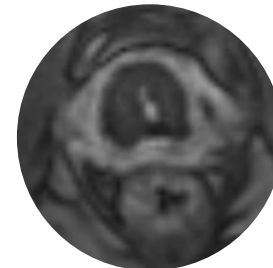
**Screening: 58 cc**  
PSA 5.5 ng/ml



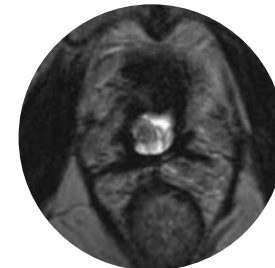
**Immediate Post**  
PSA 6.0 ng/ml



**3-months Post**  
PSA < 0.1 ng/ml

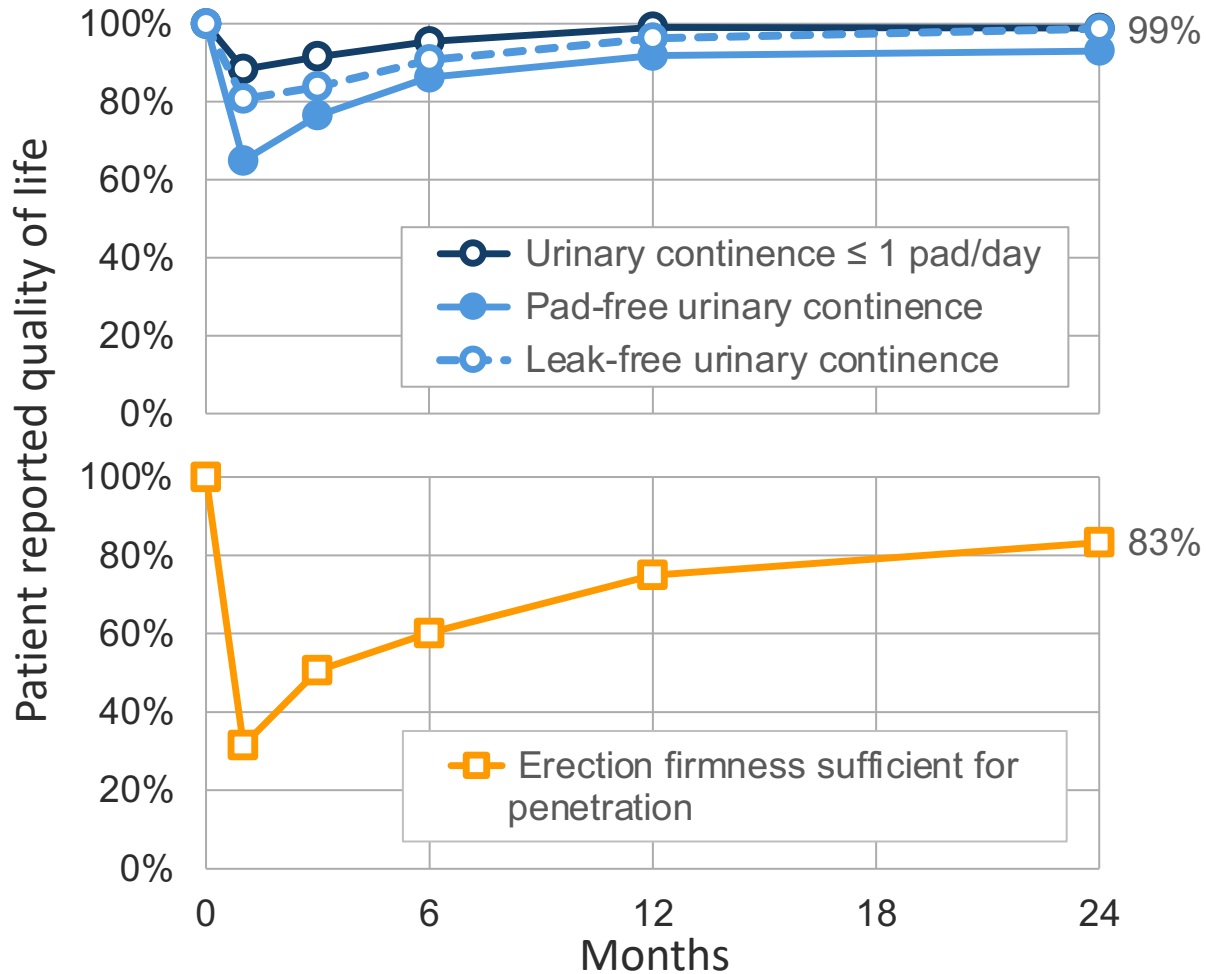


**12-months Post: 0.5 cc**  
PSA < 0.1 ng/ml



# TACT

## Safety & Patient Quality of Life



### Adverse Events

- No grade  $\geq 4$  adverse events
- No intraoperative complications
- No rectal injury, no rectal fistula
- 7% of men experienced a serious adverse event, all resolved by 1 year

### Urinary Incontinence

- No new onset between 1 and 2 years
- 1% patients reported one or more leak per day, 7% wear a pad for security

### Erectile Dysfunction

- One new onset between 1 and 2 years
- 0% severe ED (medication not helpful)
- Continued recovery of erectile function at 2 years, 17% previously potent patients reported erection firmness insufficient for penetration

# Clinical Applications of TULSA-PRO

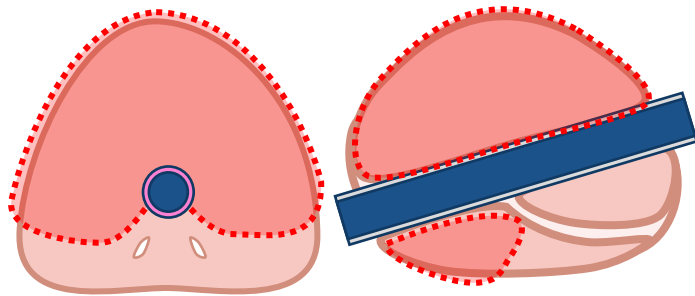
Ongoing Investigator-initiated Clinical Trials

Benign	Organ Confined Prostate Cancer			Salvage / Palliative
	Low Risk	Intermediate Risk	High Risk	

## Large prostate BPH <sup>1,2</sup>

NCT03350529 to-date (n=10):

- IPSS 18.4 → 4.6 @ 6m
- IPSS QOL 4.1 → 0.6 @ 6m



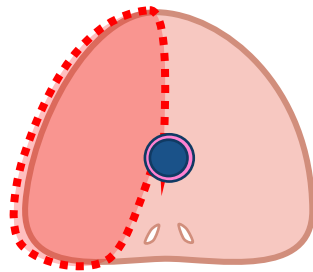
Ablation of benign prostate tissue

## Customized ablation <sup>3-8</sup>

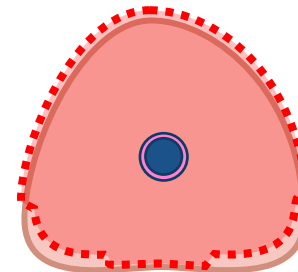
NCT02766543 (n=115 + 35), TACT

NCT03814252 (n=30), ongoing single-arm

NCT03668652 (n=250), ongoing RCT vs. RP



Targeted ablation of diseased prostate tissue



Whole gland ablation with bilateral nerve sparing

## Recurrence after radiation <sup>9</sup>

NCT03350529 to-date (n=11):

- 10/11 neg. in-field Bx @ 12m
- No change in IPSS, IIEF, EPIC SF / BF / UI @ 12m

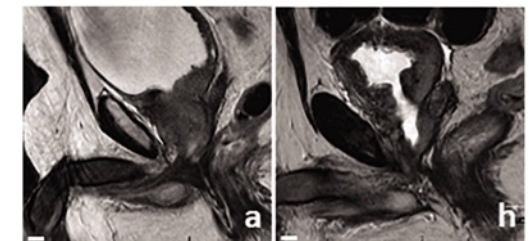
## Palliative locally advanced <sup>10</sup>

NCT03350529 to-date (n=10):

- 10/10 hematuria-free
- 7/10 catheter-free
- 1/10 improved
- 2/10 no change
- Hospitalization 7.3 → 1.4 days, within 6 months pre/post TULSA

1. Elterman *et al*, Journal of Endourology, 2020
2. Viitala *et al*, EAU 2020 (Conference presentation)
3. Ramsey *et al*, The Journal of Urology, 2017
4. Chin *et al*, European Urology, 2016
5. Bonekamp *et al*, European Radiology, 2018

6. Klotz *et al*, The Journal of Urology, 2020 (Accepted, pending publication)
7. Anttinen *et al*, International Journal of Hyperthermia, 2019
8. Anttinen *et al*, Scandinavian Journal of Urology, 2019
9. Anttinen *et al*, EU Open Science, 2020 (Submitted, not yet accepted)
10. Anttinen *et al*, Scandinavian Journal of Urology, 2020



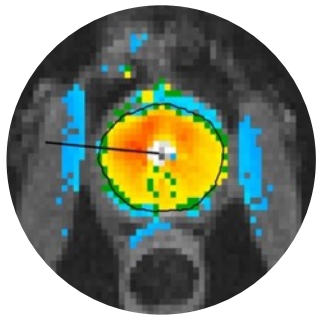
# TULSA-PRO

Flexibility to Treat Different Types of Patients

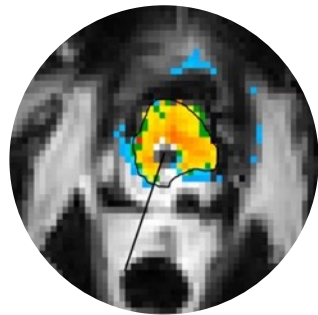
**Whole Gland Ablation**

**Unique Flexibility**

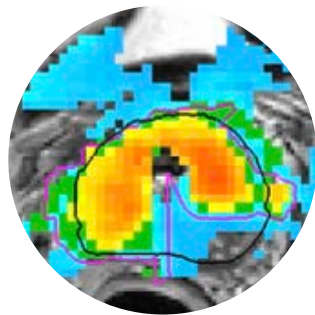
**Analogous to surgery and radiation**



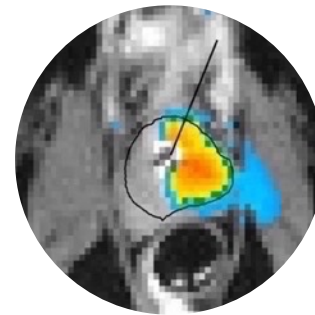
**Whole gland post radiation failure**



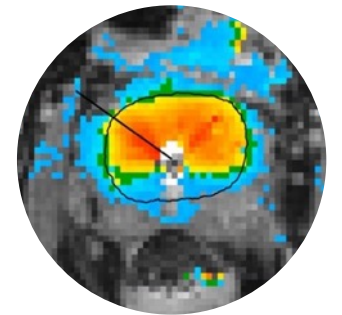
**Malignant lesion with lower urinary tract symptoms**



**Hemi-gland**



**Benign large prostate with lower urinary tract symptoms**



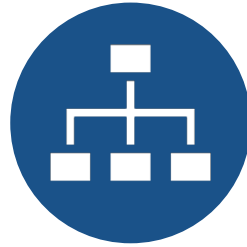
# U.S. Market Entrance Strategy

## TULSA-PRO



### Increase Awareness

- TACT clinical data presented at >10 conferences (AUA, EAU, RSNA)
- TULSA-PRO and TACT clinical data publications
- Low-cost / high-impact patient awareness initiatives
- TULSA patient website with center locator:  
[www.tulsaprocedure.com](http://www.tulsaprocedure.com)



### TULSA-PRO at Imaging Centers

- Early adopter Urologists focused on emerging technologies
- Independent Imaging service provider companies
- Opinion leading hospitals / Centers of Excellence



### Business Models

- Recurring revenue-only



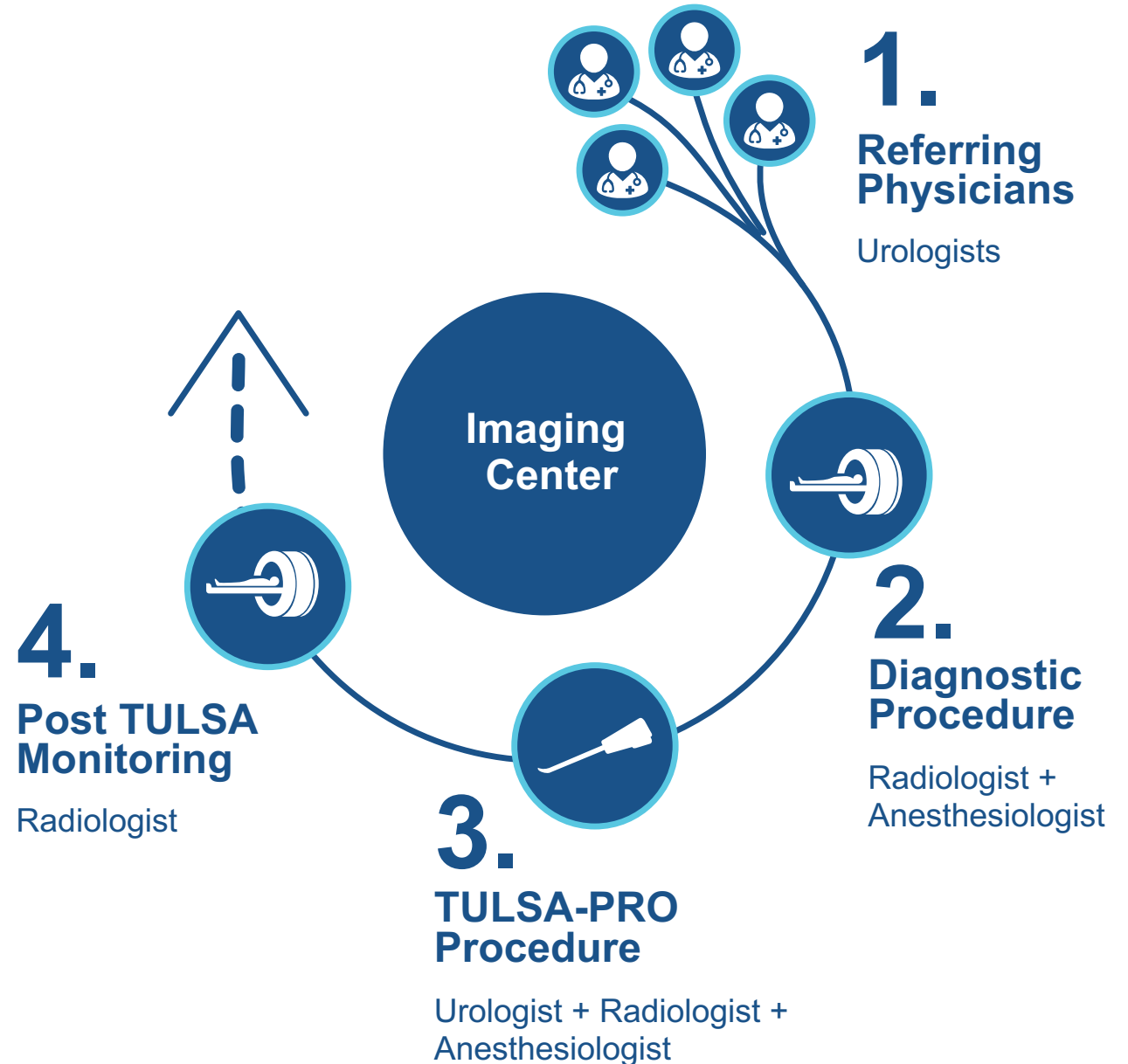
### 'Profound Genius Services'

- Clinical proficiency – demonstrate TULSA flexibility by treating full variety of patients
- Productivity – number of patients per day
- Patient recruitment and satisfaction
- Reimbursement
- Innovation/publications

# Commercial Imaging Centers

## Recurring Revenue-Only

- 8,000 -10,000 imaging centers in U.S.; 40% owned by private equity or public companies
- Growing presence in urology due to MRI diagnostics, MRI-guided biopsy, MRI-guided follow-up
- Centers provide:
  - Service
  - Technology
  - In-house Radiologist(s)
  - Local Specialist Relationships (Urologists, Anesthesiologists)
  - Marketing
  - Payer Networks



# New TULSA-PRO Patient Website

## Growing Resource for Prostate Patients

TULSA Center Locator Page

---

Detailed Information to Help Patients Understand Their Options

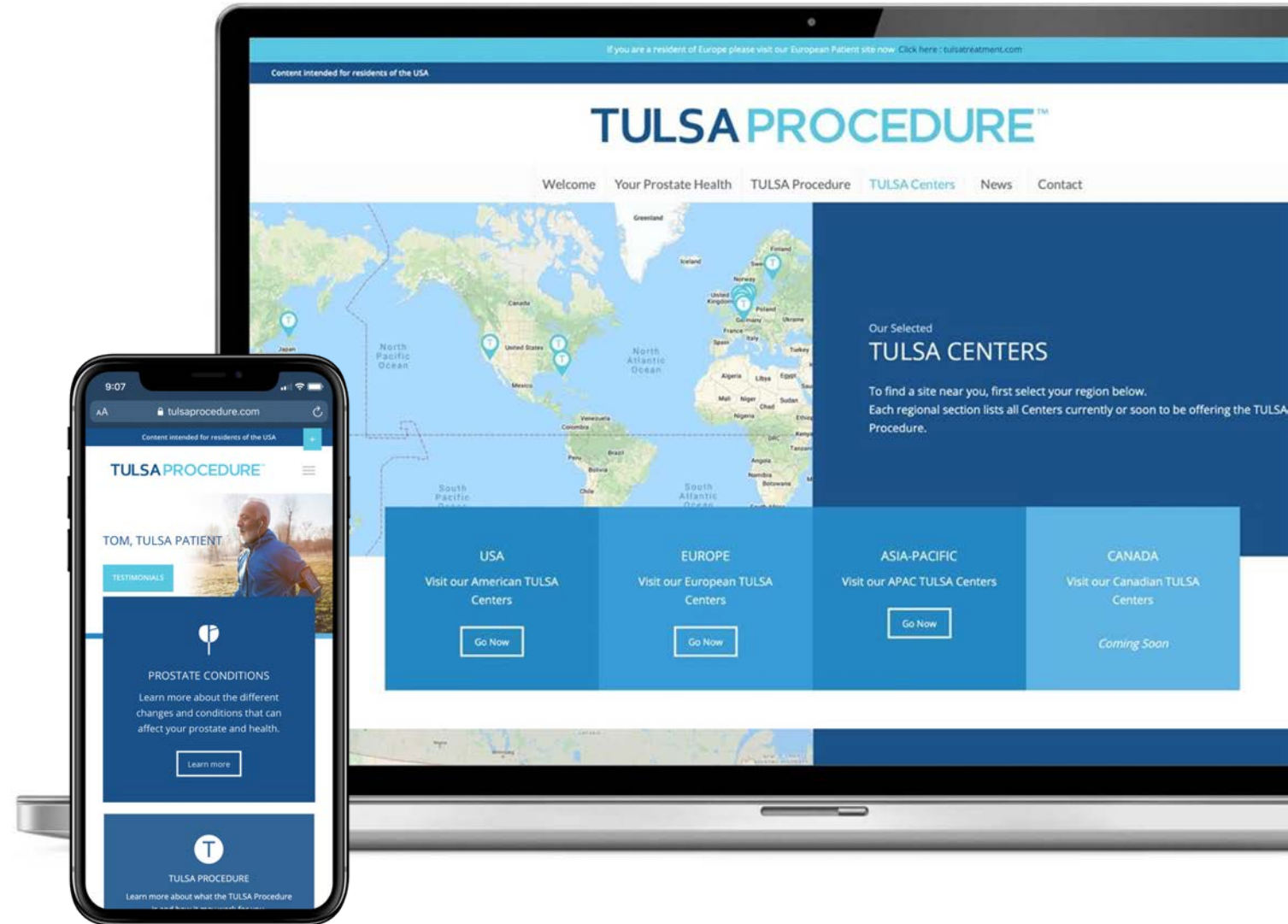
---

Contact Forms to Reach Out to Each Center Directly

---

Patient Testimonials

---





# Longer Term

## Building an Incision- & Radiation-Free Ablative Therapeutic Platform

Oncology, Highly Symptomatic  
Chronic Diseases



# SONALLEVE



## Current Approvals

Europe: CE Marked

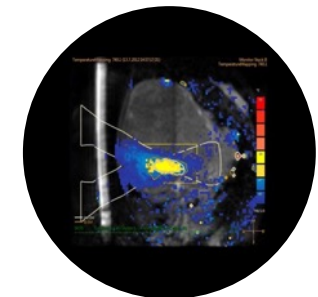
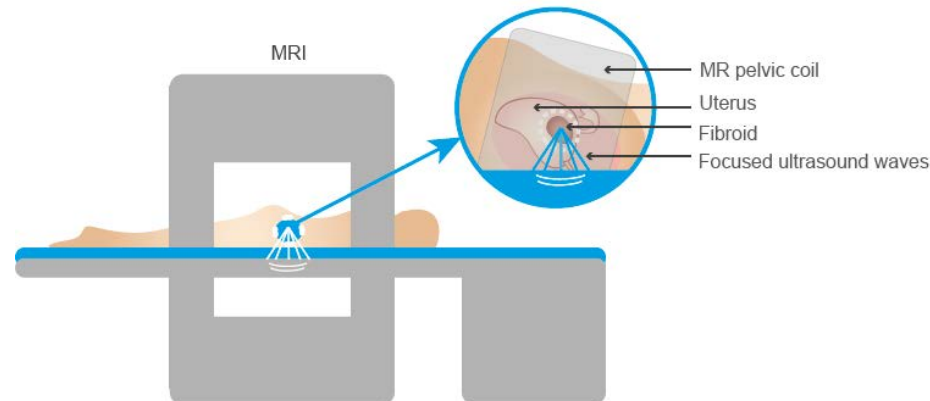
China: CNMPA Approved



## Over 200 Publications

from leading U.S. & European clinicians and hospitals

- Uterine Fibroid Treatment
- Pain Management
- Pediatric Bone
- Hyperthermia
- Abdominal Cancer



## In Summary



### **Business Model Capital Efficient**

- TULSA-PRO: focus on U.S.
- Sonalleve: focus on Asia with larger distribution partner

### **Future Investments**

- Expand sales team
- Increase manufacturing capacity
- Support additional clinical trials with TULSA-PRO for reimbursement
- Continue further product enhancements