



Incision-free Surgery  
Real-Time MR Guided Ultrasound Therapies

CORPORATE PRESENTATION | August 2018

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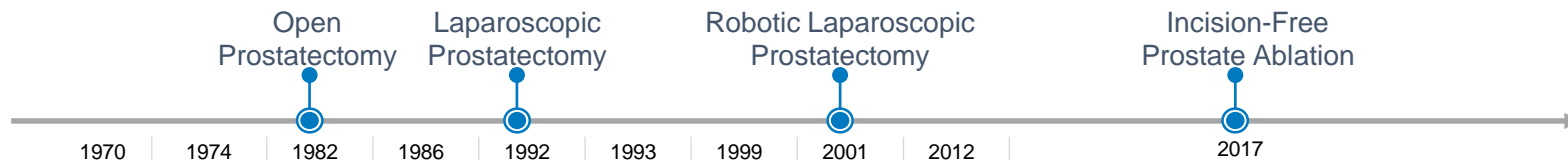
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# From open surgery to incision-free surgery



Whole gland removal, reduced hospital stay, faster patient recovery

- Incision-free ablative surgery
- Surgical planning with real time imaging
- Whole gland or disease targeted partial ablation of prostate

# TULSA-PRO®

Prostate Ablation

- CE Mark
- FDA Registration Study Recruited

**PROFOUND**  
MEDICAL





# Transurethral Ablation Using Thermal Ultrasound with Real-time MR Guided Controlled Dosimetry

## TULSA-PRO®

### Precise ablation with millimeter accuracy

- Real-Time MR Imaging, thermometry, automated process control

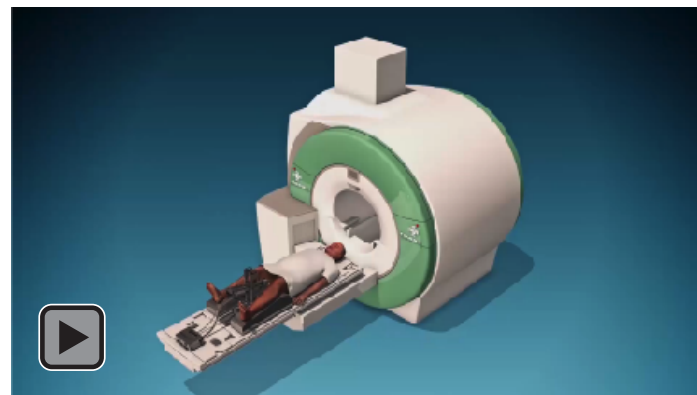
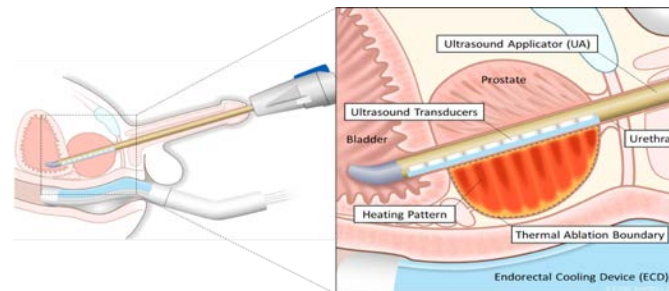
### Customized treatment to meet each patients particular need

- Urologist defines region of ablation
- Full gland or targeted therapy for localized cancer
- BPH

### Safety by design

- Ablate from Inside-prostate; safer than outside-through rectum, able to treat prostates >140 cc
- Actively protects urethra and rectum via cooling
- MR and Ultrasound heating are safe modalities

Two hour procedure time



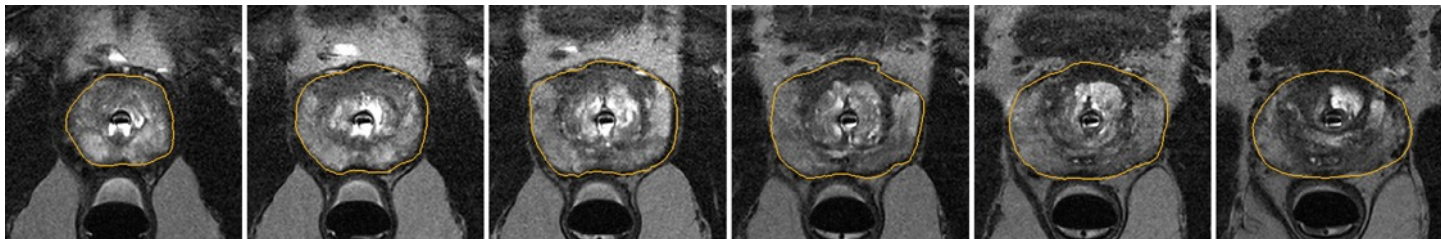
# TULSA Procedure Case Example (Axial Images)

Apex

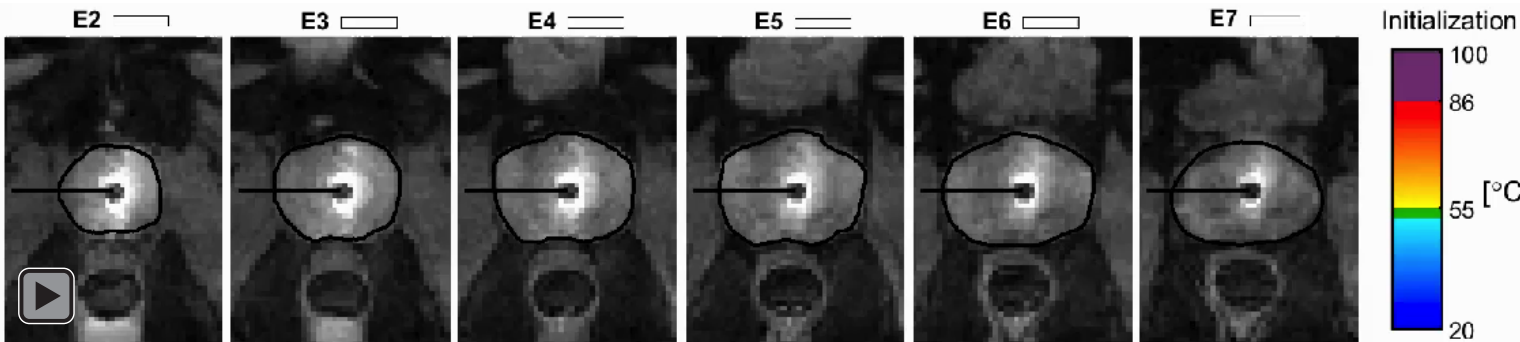
Mid-Gland

Base

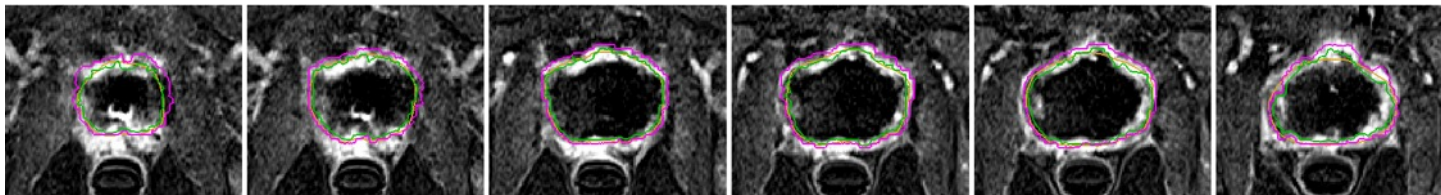
Treatment  
Planning



Maximum  
Temperature  
during  
Treatment



Post  
Treatment  
Contrast  
Enhanced  
MRI



# **Profound Medical:** Delivering incision free ablative therapies, customized to each patient, and delivered with precision

## Transurethral Thermal Ultrasound

Unobstructed ultrasound from inside the prostate, provides for high speed ablation with minimal impact to outer organs

## Real-time MR imaging

Real-time MR Imaging drives accurate treatment planning

## Real-time thermometry & Controlled Thermal Dosimetry

Real-time MR thermometry delivers an accurate map of the temperature of the prostate, allow closed loop software controlled heating

## Autonomous Robotics

Software guides the robotic arm - automated ablation based on real-time temperature feedback



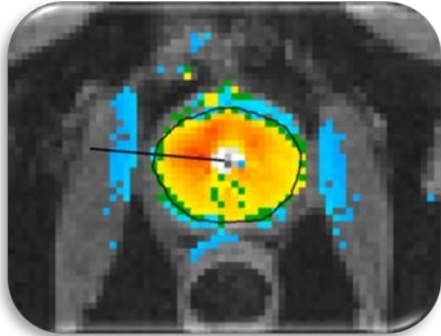
Precision

Flexibility

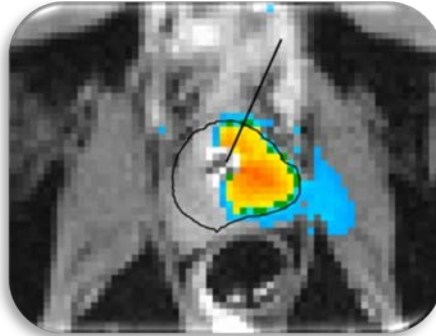
Safety by design

# TULSA Technology Offers **Flexibility**

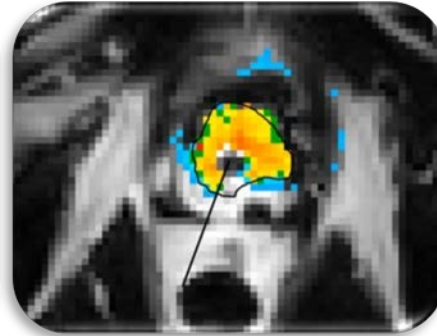
Whole Gland  
Ablation



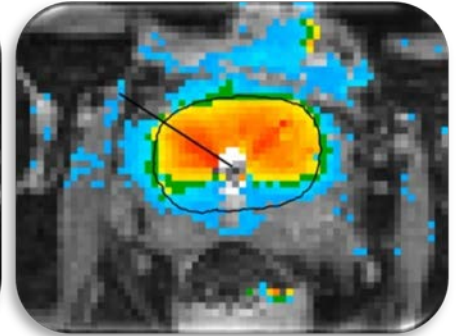
Targeted  
Ablation



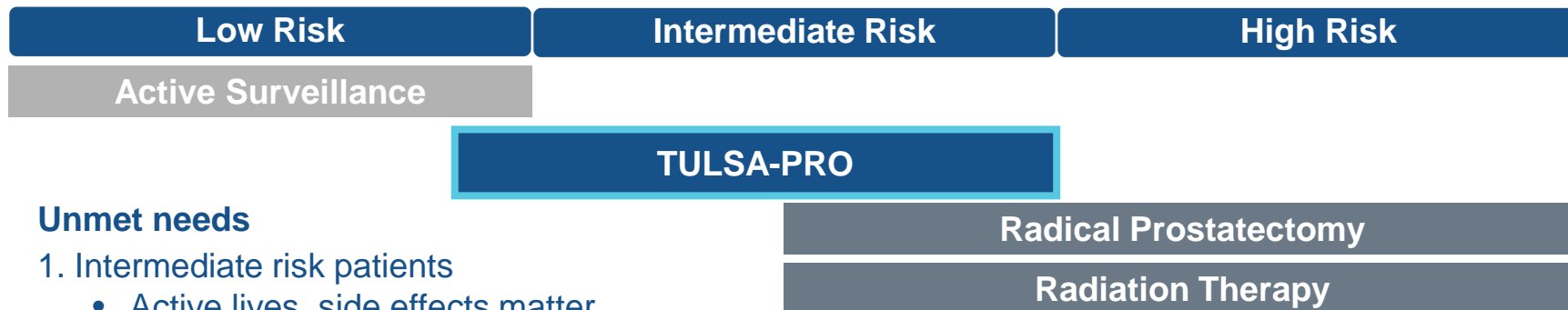
Salvage Therapy  
Post Radiation  
Therapy Failure



BPH



# TULSA-PRO Addressing Unmet Need



## Unmet needs

### 1. Intermediate risk patients

- Active lives, side effects matter
- Comorbid, surgery carries risks
- MR visible lesion

### 2. Low risk patients

- Also have BPH
- Want an intervention

### 3. Salvage therapy patients

### 4. Early stage disease, Gleason Score (GS) = 3+3 but genetic testing indicates aggressive disease

**TULSA does not preclude any additional intervention if needed in the future**

# TULSA Market Potential

## Estimated Annual Number of Newly Diagnosed Patients with Prostate Cancer

	Low Risk <sup>3,4</sup>	Intermediate Risk <sup>3,4</sup>	High Risk <sup>3,4</sup>	Total
US <sup>1</sup>	68,000	63,000	30,000	161,000
EU <sup>2</sup>	145,000	134,000	64,000	343,000
	213,000	197,000	94,000	504,000

Source:

(1) American Cancer Society 2018

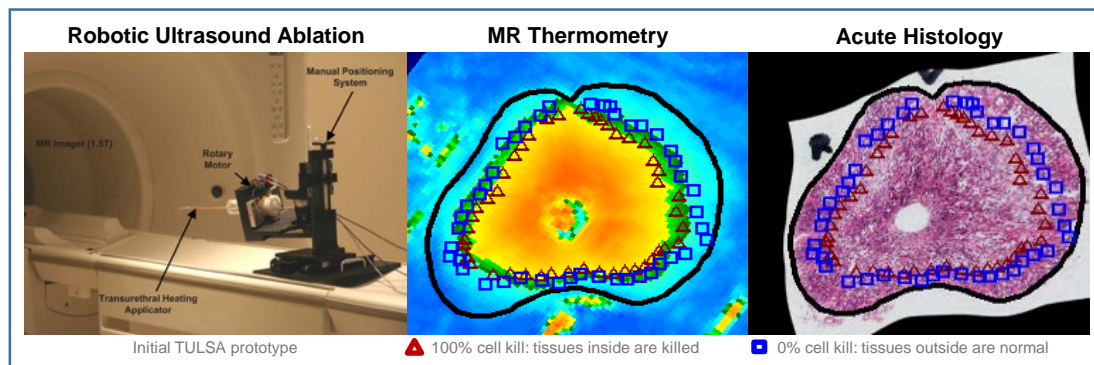
(2) International Agency for Research on Cancer. WHO.

(3) Wilt et al. The Prostate cancer Intervention Versus Observation Trial:VA/NCI/AHRQ Cooperative Studies Program #407 (PIVOT): design and baseline results of a randomized controlled trial comparing radical prostatectomy to watchful waiting for men with clinically localized prostate cancer. Contemp Clin Trials. 2009 Jan;30(1):81-7.

(4) Cooperberg M. et. Al. Time Trends and Local Variation in Primary Treatment of Localized Prostate Cancer. J Clin Oncol 28:1117-1123.

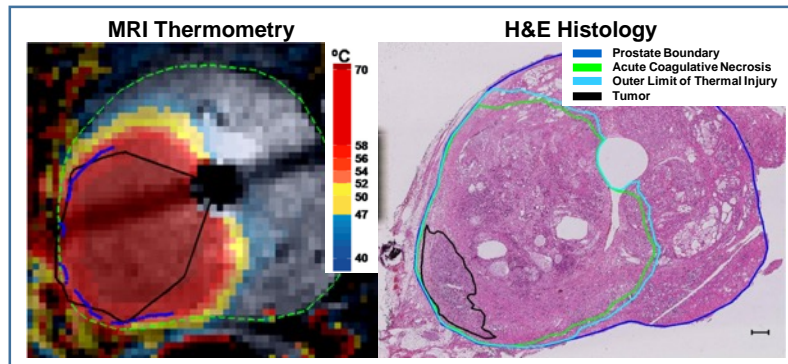


# TULSA – Technical & Canine Studies



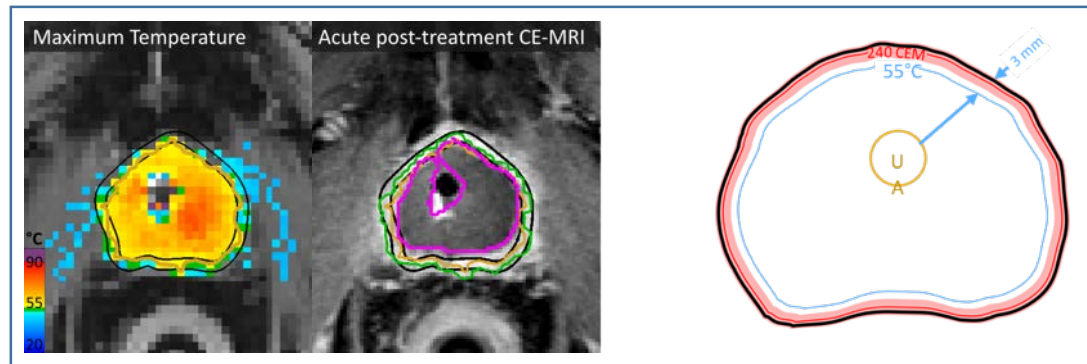
- In vivo evaluation of MRI-compatible robotics, directional US applicators, MRI thermometry, and feedback control algorithm
- Millimeter ablation accuracy on histology
- Urethra spared, no unintended damage on 28d histology

# TULSA – Treat & Resect for Targeted Ablation



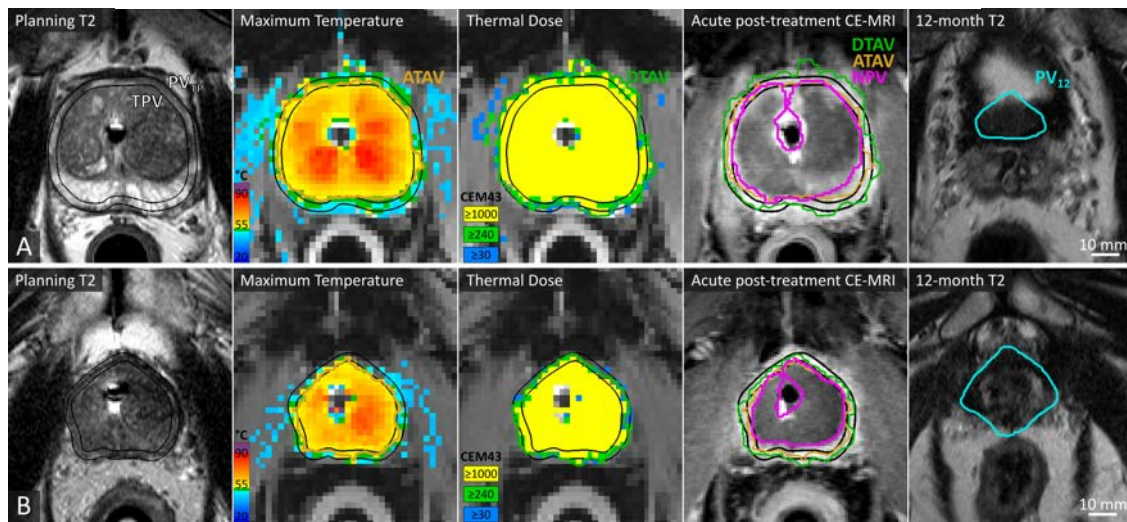
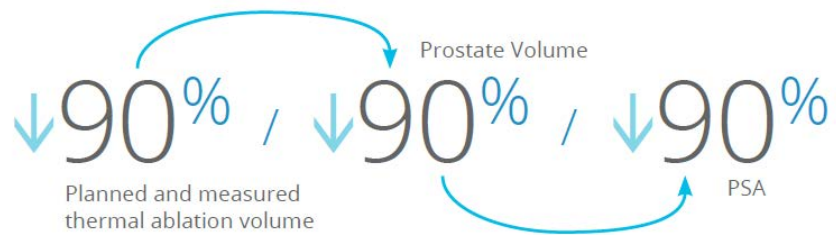
- 5 treat-and-resect patients with whole-mount histology
- Targeting to mpMRI-visible lesion identified during TULSA treatment
- Millimeter ablation precision on histology
- All index tumors within complete tissue ablation zone

# Phase I – 90% Ablation for Safety & Precision



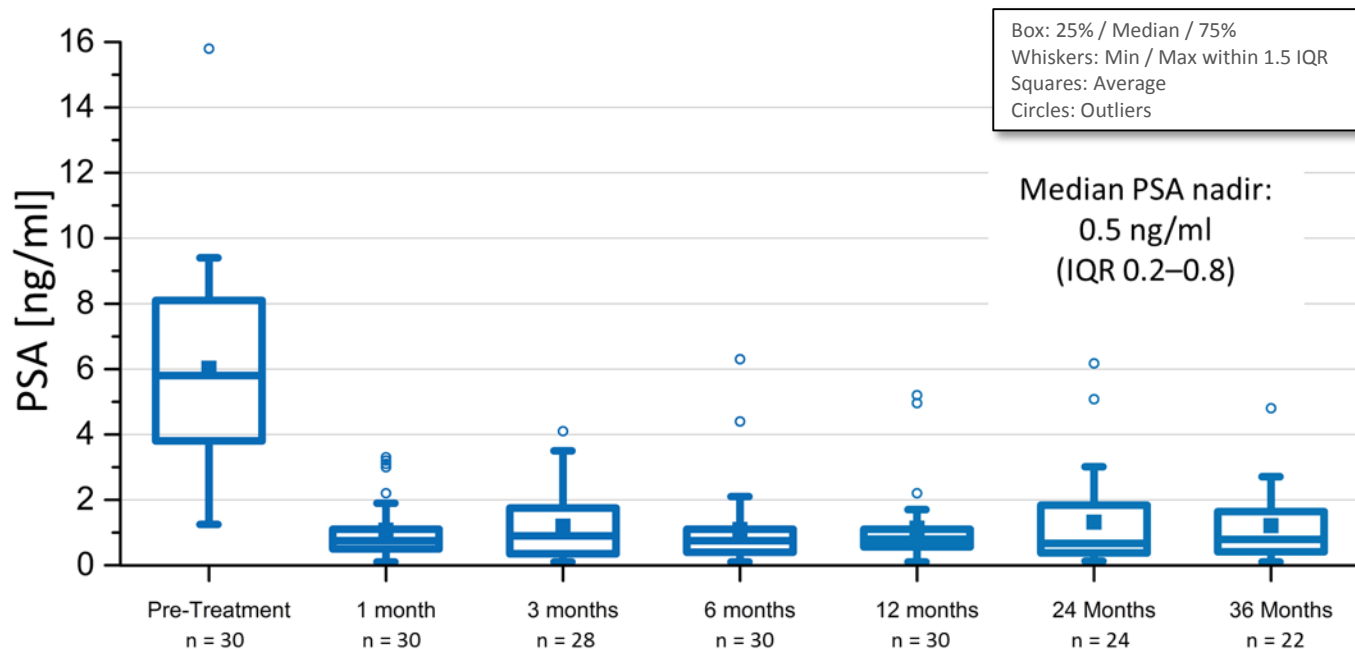
- 30 patients with 3-year follow-up
- 90% ablation with 3 mm margin designed to measure precision
- Demonstrated favorable safety profile with minor impact on QOL
- Millimeter ablation precision on MR thermometry
- **PSA and prostate volume reduction** match **planned** target volume and **measured** thermal ablation volume (90% of the gland)

## Phase I: Correlation of Thermal Ablation to Prostate Volume & PSA reduction



# Phase I Ablation Efficacy: PSA

- PSA reduction in agreement with treatment plan
- Decreased 90% to nadir and stable to 36 months



# TULSA – TACT – Pivotal Study, Whole Gland Ablation to Capsule



- 115 patients, Gleason 3+3 & 3+4, 45 - 80 years old
- 13 clinical sites
- Millimeter ablation precision on MR thermometry
- Expected 12 month full data release Q1 2019



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# TACT Pivotal Trial: Full Prostate Volume Ablation (99%)

To support FDA application, enrollment completion Feb 2018

**Study Population:** Intermediate and low risk patients, 45 – 80 years old, n=115, 13 clinical sites

## Primary Endpoints

- Safety – Frequency and severity of adverse events
- Efficacy – PSA reduction  $\geq 75\%$ 
  - Proportion of patients achieving PSA nadir  $\leq 25\%$  of the pre-treatment baseline value
  - Performance goal for the success proportion is 50% of patients

## Secondary Endpoints

- Prostate volume reduction on MRI at 12 months, PSA nadir – % patients with PSA  $\leq 0.5$  ng/ml, PSA stability – % patients with PSA  $\leq 0.5$  ng/ml at 12 months
- Prostate TRUS biopsy – % patients with negative biopsy at 12 months
- Erectile function – Change in % patients with IIEF-5  $\geq 17$ , Erection firmness sufficient for penetration – Change in % patients with IIEF Q2  $\geq 2$
- Urinary incontinence – Change in % patients using  $\geq 1$  pad / day
- Quality of life – IPSS, IIEF-15 & EPIC-50
- Targeting accuracy – Accuracy and precision of conformal thermal ablation of target prostate volume

## TACT Pivotal Trial – Study Population

Characteristics	Planned	Actual
Enrollment	110	115
Age (years)	45 – 80 y	64 (IQR 59 – 69) y
PSA (ng/ml)	≤ 15	6.4 (IQR 5.0 – 8.3) ng/ml
Gleason Score 6 (3 + 3) 7 (3 + 4)	≤ 3 + 4	45 (39%) 3+3 70 (61%) 3+4
D'Amico Risk Low risk Intermediate risk	Low to Intermediate	39 (34%) Low-risk 76 (66%) Intermediate-risk
Targeted Prostate Volume		34 (range 15 – 88) cc
Actual Treatment Time		55 (IQR 41 – 70) min

# PSA – TACT Primary Efficacy Endpoint **Successful**

**Primary Efficacy Endpoint:** Proportion of patients achieving PSA nadir  $\leq 25\%$  of pre-tx baseline value

**Hypothesis:** TULSA-PRO would be of clinical interest if  $> 50\%$  of patients had a PSA reduction  $\geq 75\%$

**N=115**

- Median PSA reduction to-date is 95%
- Median PSA nadir to-date 0.36 ng/ml
- 95% of pts (109/115) meeting endpoint of  $\geq 75\%$  PSA reduction
- Number of patients with 12-month QoL data is not yet large enough to assess

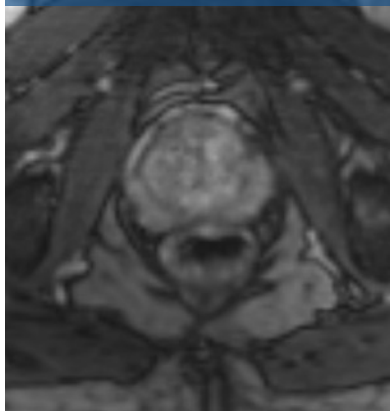
## Case Study: TACT Pivotal Trial:

67 year old

Gleason 3+4 (L mid, R apex, R anterior)

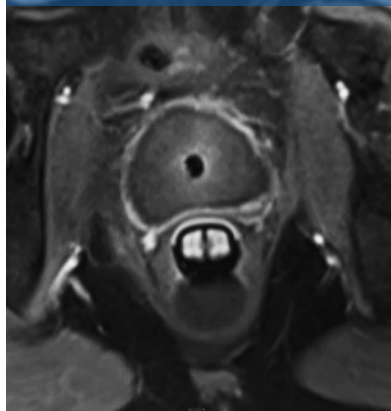
MRI-visible L mid anterior 14mm

Screening

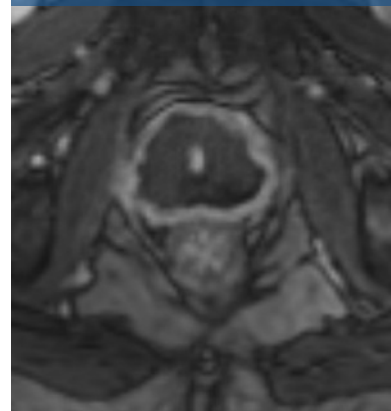


PSA 6.0 ng/ml

Immediate Post

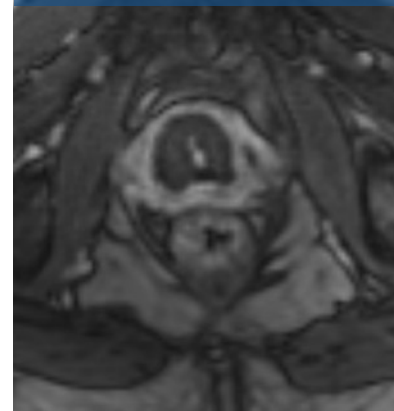


1 month Post



PSA 0.28 ng/ml

3 months Post



PSA 0.09 ng/ml

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A photograph of a family in a nursery. A man and a woman are sitting on a grey shag rug, holding a baby who is wearing a striped onesie. The man is holding a colorful ring toy above the baby's head. The woman is holding the baby's feet. In the background, there is a white crib, a white dresser, and a large colorful wall decal of a tree with flowers and birds. A blue semi-transparent banner is overlaid on the left side of the image.

Sonalleve®

PROFOUND  
MEDICAL

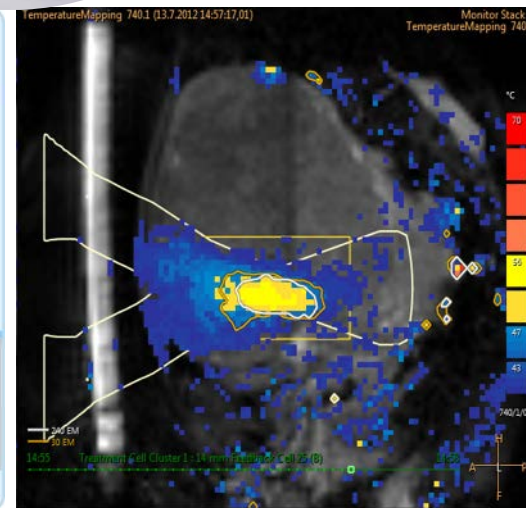
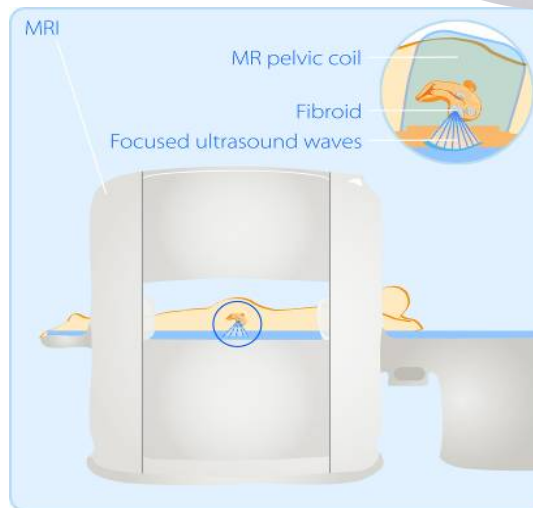
# SONALLEVE

## Technology platform for:

- Uterine Fibroid Treatment
- Bone Metastasis Pain
- Pediatric bone
- Hyperthermia

Over 200 publications from leading US and European clinicians and hospitals

CE Marked  
CFDA Approved





# Uterine Fibroid: Symptom Relief & Durability

In normal commercial use, over 85% of patients experienced sustained symptom improvement

Months post-procedure	Patients available for follow-up	Symptom improvement		
		Improved	No relief	Worse
3 months	105	90 (85.7%)	14 (13.3%)	1 (1%)
6 months	99	92 (92.9%)	7 (7.1%)	0
12 months	89	78 (87.6%)	11 (12.4%)	0

Durability of the therapeutic effect compared to other uterine preserving treatments

Need for alternative treatment	@ 12 month	@ 24 month	References
<b>Myomectomy</b>	10.6 %	13-16.5 %	1,2,3,4
<b>UAE (Uterine Artery Embolization)</b>	7-10 %	12.7-23.7 %	5,6,7
<b>MR-HIFU/MRgFUSNPV &gt;60%</b>	6 %	13 %	8

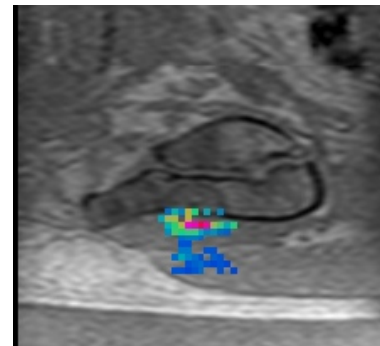
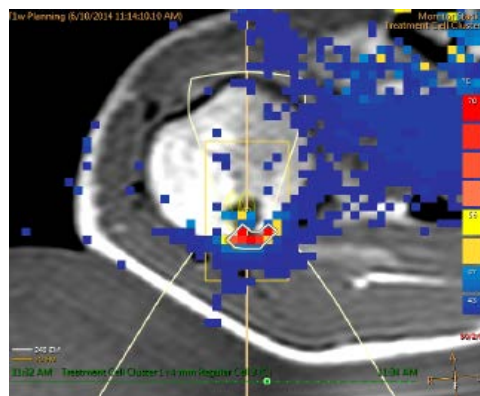
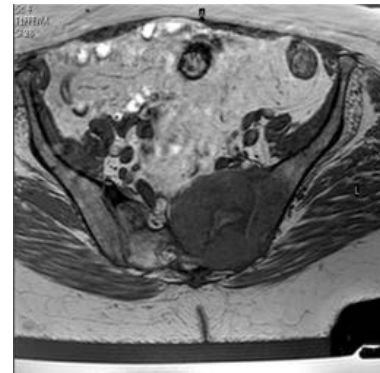
"Volumetric MR-guided high-intensity focused ultrasound ablation of uterine fibroids: treatment speed and factors influencing speed," M. J. Park, Y. S. Kim, B. Keserci, H. Rhim, and H. K. Lim, Eur Radiol, vol. 23, no. 4, pp. 943-950, Apr. 2013. 1. Gorny KR, Woodrum DA et al. Magnetic resonance-guided focused ultrasound of uterine leiomyomas: review of a 12-month outcome of 130 clinical patients. J Vasc Interv Radiol 2011 2. Subramanian S, Clark MA, Isaacson K. Outcome and resource use associated with myomectomy. Obs & Gyn.2001; 98: 583-587 3. Nezhat FR, Roemisch M, et al. Recurrence rate after laparoscopic myomectomy. Am Assoc Gynecol Laparosc. 1998;5: 237-240 4. Rossetti et al. Long term results of laparoscopic myomectomy: recurrence rate in comparison with abdominal myomectomy. Hum Reprod. 2001;16:770-774 5. Doridot et al. Recurrence of leiomyomata after laparoscopic myomectomy. J Am Assoc Gynecol Laparosc. 2001;8: 495-500 6. Spies JB, Bruno J, et al. Long-term outcome of uterine artery embolization of leiomyomata. Obstet Gynecol. 2005; 106: 933-939 7. Goodwin SC, Spies JB, et al. Uterine artery embolization for treatment of leiomyomata: long-term outcomes from FIBROID registry. Obstet & Gynecol. 2008; 111: 22-32 8. Sharp HT. Assessment of new technology in the treatment of idiopathic menorrhagia and uterine leiomyomata. Obstet Gynecol. 2006;108: 990-1003

# Sonalleve: Bone Metastasis Pain Therapy

Non-invasive alternative to radiotherapy

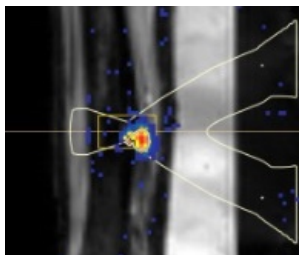
Most patients with slow growing tumors develop bone metastasis in the later stage of the disease. Bone changes and malformations irritate nerve endings creating significant pain for patients.

- Radiotherapy standard of care for bone mets, but 20-30% of patients do not respond
- Sonalleve as non-invasive alternative to radiotherapy
- Heating of bone surface, ablation of periosteal nerves
- Quick pain relieve in 2-3 days, vs. radiotherapy typical 3 weeks



# Exploring **Further Indications** on Current Platform

## Pediatrics, Hyperthermia



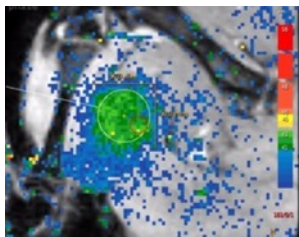
### **Pediatrics: Osteoid osteoma**

- Very painful, benign bone tumor in children and young adults
- MR-HIFU very effective, immediate pain relief and bone restructuring
- Standard of care is radiofrequency ablation (RFA, invasive)



### **Pediatrics: Desmoid tumors (Fibromatosis)**

- Benign aggressively growing tumors, everywhere in the body
- Can cause severe (bulk) symptoms
- Surgery (+/- radiotherapy) is standard of care, but high risk of recurrence
- Successful MR-HIFU treatments presented as individual case studies

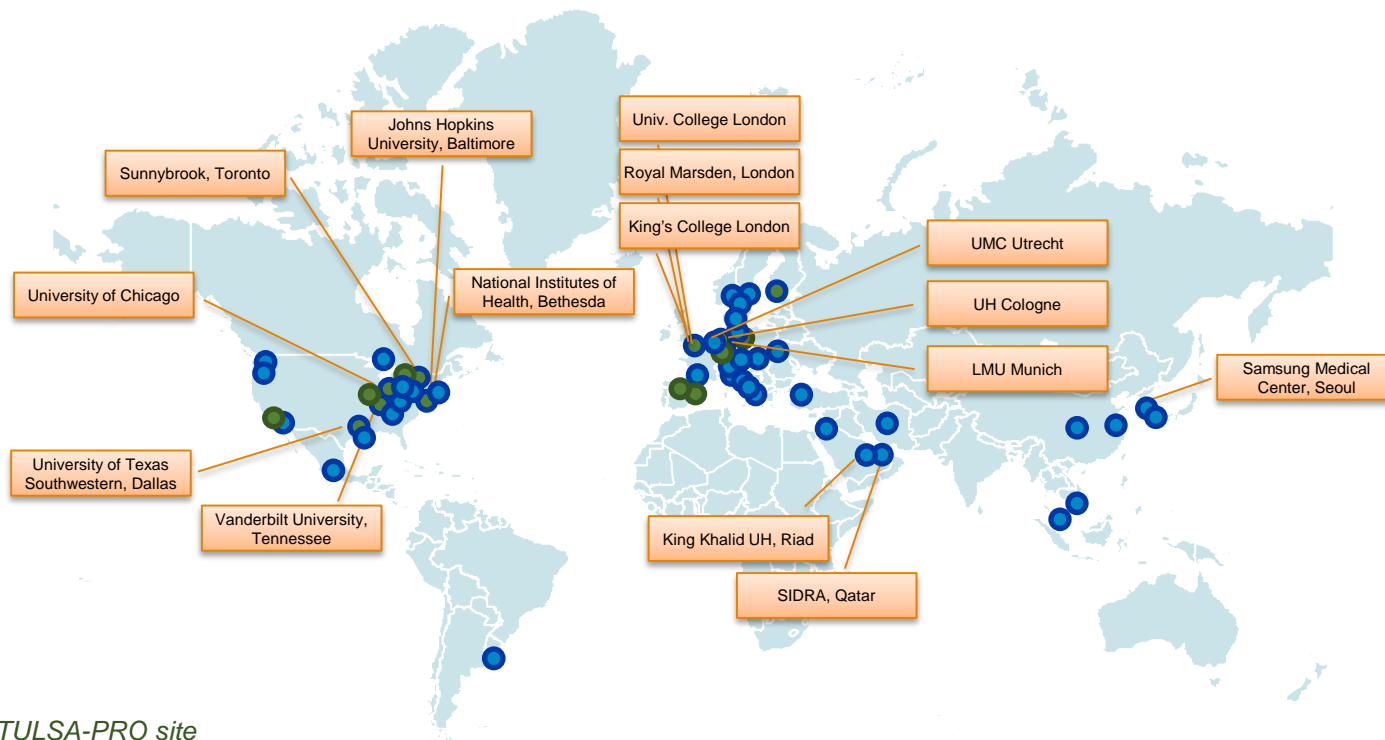


### **Hyperthermia**

- Increase tumor sensitivity to Radiation and Chemo Therapy
- Local heating to 40 – 43°C, precise control of temperature and lesion size
- Adjuvant therapy to chemotherapy or radiation therapy
- Enabling technology for Local Drug Delivery

# Commercialization

# Strong Global Network of Clinical Partners



- Indicates TULSA-PRO site
- Indicates Sonalleve site
- Indicates Sonalleve & TULSA-PRO site

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# Market Introduction Strategy

- Philips and Siemens catalog
  - Capital Sales
  - Co-selling
  - Co-marketing
- Direct sales to drive procedure adoption and disposable sales
- Sales geography focus
  - Sonalleve – Asian market and academic hospitals in North America and Europe
  - TULSA-PRO – Europe





# Reimbursement

## US

PROCEDURE	APPROXIMATE HOSPITAL PAYMENT	APPROXIMATE SURGEON PAYMENT
Laparoscopic Radical Prostatectomy	\$10,000/\$20,000	\$1,450
Radiation Therapy (IMRT Simple, 40 Sessions)	\$40,000	Fee bundled into primary APC
Cryoablation	\$10,000	\$1,000

Initiation of clinical trial for salvage patients – Q4-2018, to support inclusion in NCCN guidelines as a recommended alternative

## Germany

TULSA-PRO part of DRG payment to the hospital 3,963 Euros as of January 2018

\* Payment is the sum of the indicated APC/CPT codes

\*\* Payments are for Medicare patients. Private payer payments for these procedures will vary and may result in higher payments than published Medicare rates.

# Profound Medical

– About disease treatment not organ removal

## Incision-free Procedures

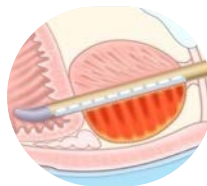
Real-Time MR guided

1 **Precise**

2 **Flexible**

3 **Safe**

## TULSA-PRO®

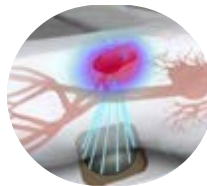


### Treatment for prostate disease

- CE marked
- FDA expected H2-2019



Sonalleve



### Treatment for uterine fibroids, bone metastasis, pediatric

- CE marked
- China FDA approved for uterine fibroids