



Incision-free Surgery  
Real-Time MR Guided Ultrasound Therapies

CORPORATE PRESENTATION | JANUARY 2018

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**TULSA-PRO<sup>®</sup>**

# Prostate Treatment

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# Emerging Prostate Care Dynamics

Precision Diagnosis will lead to Precise & Personalized Treatment with fewer side effects



## Enhanced Diagnosis and Targeted Identification

- MP-MRI
- MR Guided Biopsy
- Genomics

## Therapy capable of being:

- Personalized to each patient's anatomy and physiology
- Precisely planned
- Delivered with precision

# MR-Guided Transurethral Ablation of Prostate using ultrasound to provide thermal energy & real time process control software for precision

## TULSA-PRO®

### Precise ablation with millimeter accuracy

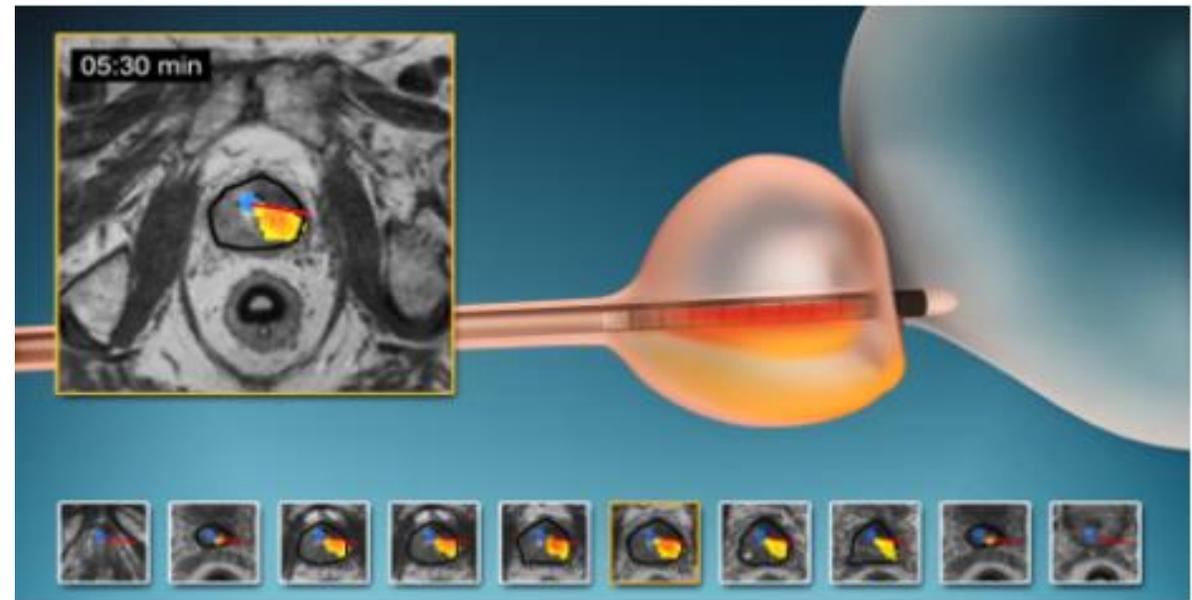
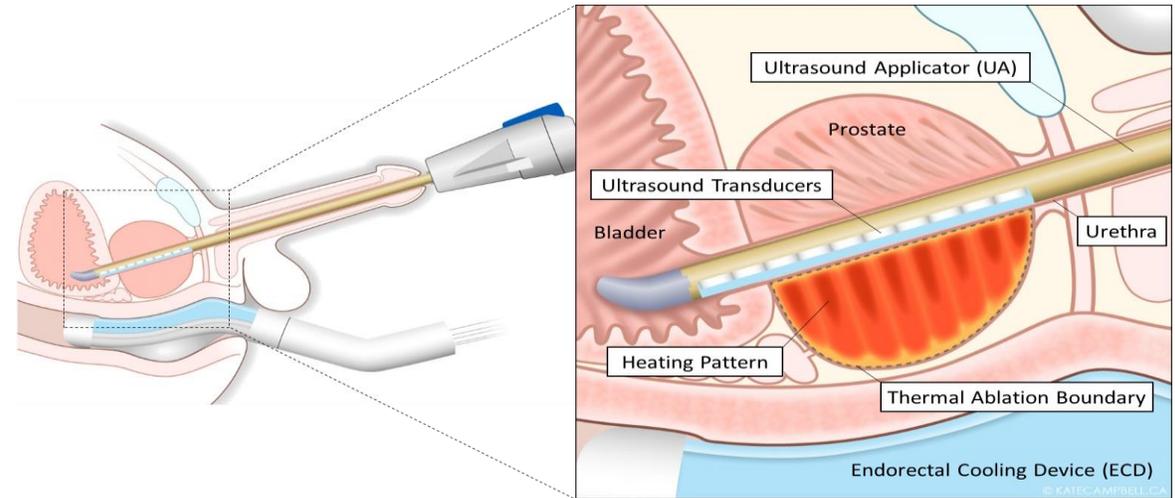
- Real-Time MR Imaging
- Real-Time process control of ablation using MR temperature map and robotically drive arm

### Personalized treatment

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

### Safety by design

- Ablate from Inside-Out; inherently safer than outside-in
- Actively protects urethra and rectum via cooling
- MR and Ultrasound heating are safe modalities



# TULSA-PRO Equipment

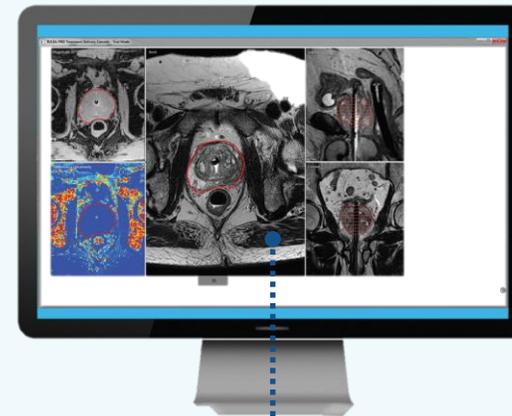
Compatible with MR from leading companies – Philips and Siemens



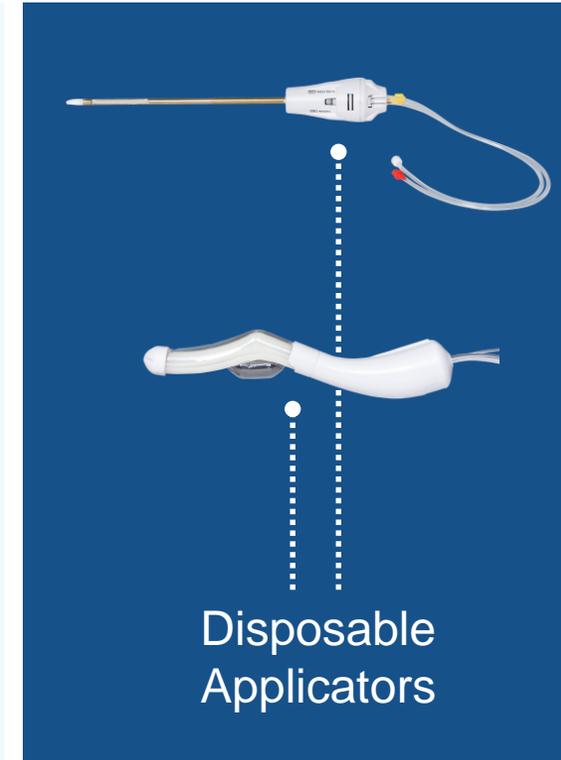
Robotic Arm,  
Computer Hardware



Energy  
System

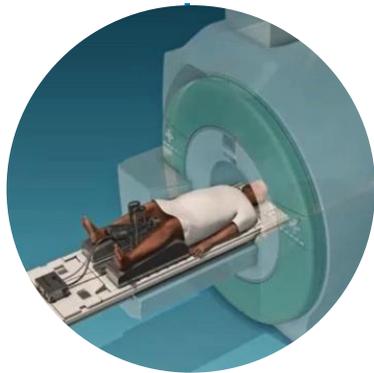


Surgeon Console  
Control Room

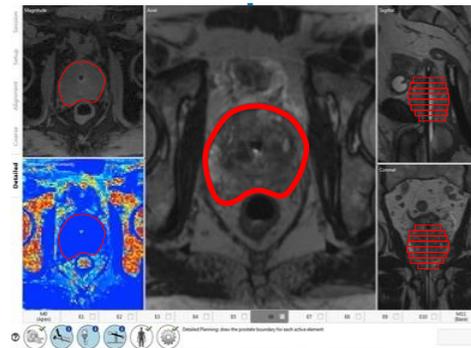


Disposable  
Applicators

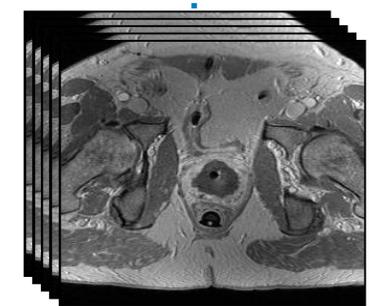
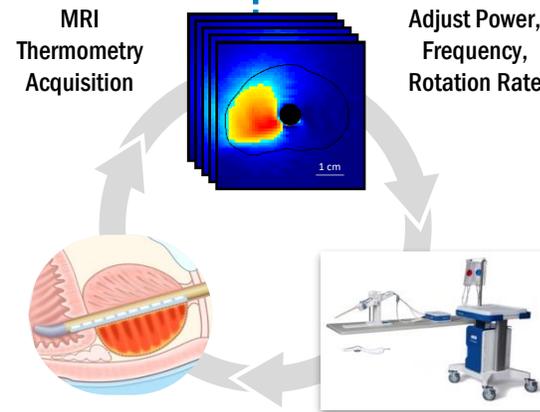
# Treatment Work Flow



MRI Guided Device Positioning



Precise Treatment Planning



Confirmation of Ablation Margin with MRI

- 1. Controlled algorithm
- 2. Target temp 55° C
- 3. Ablation in 40 minutes

# Enables Targeted to Whole-Gland Treatment

- Over 90% of prostate cancers present with multi-focal lesions, and 20-40% of patients have their disease confined to one side of the prostate.<sup>1</sup>
- Multi-focal nature of prostate cancer requires that clinicians have tools that can provide them precise, safe and effective partial to whole gland range of treatment

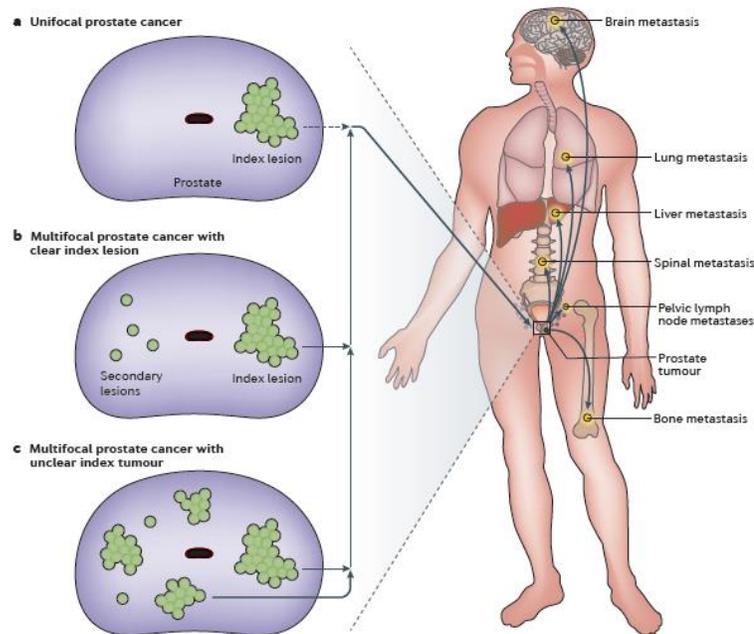
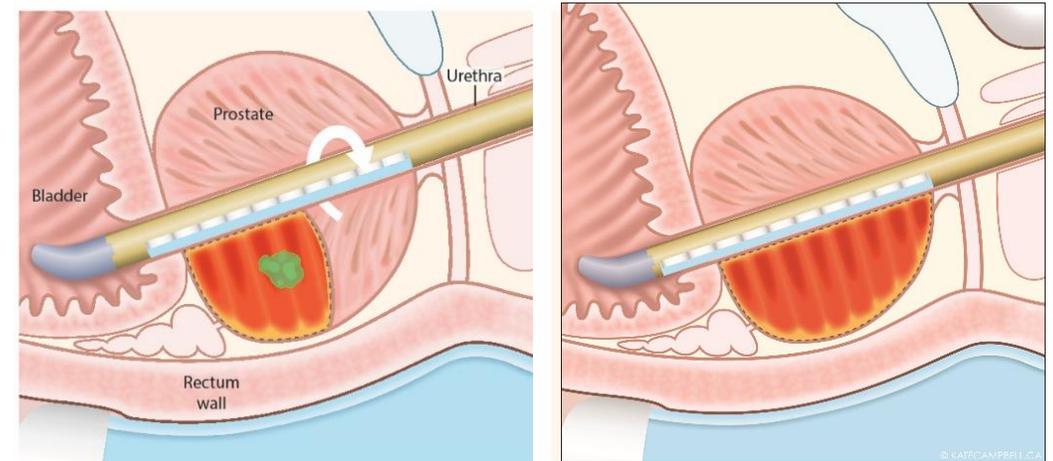


Figure 1 | Metastatic properties of prostate cancer. a | Unifocal prostate cancer. b | Multifocal prostate cancer with clear index lesion and one or more separate secondary tumour foci with smaller volumes (most common). c | Multifocal cancer with unclear index tumour.

1. Perera M et al. An update on focal therapy for prostate cancer. Nature Reviews Urol 2016; 13:641-53.

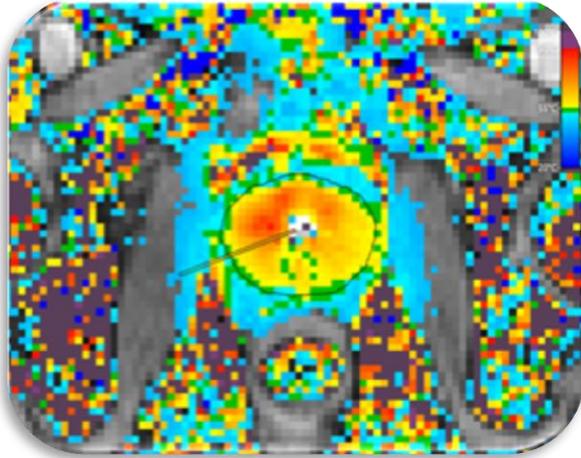


Focal Ablation

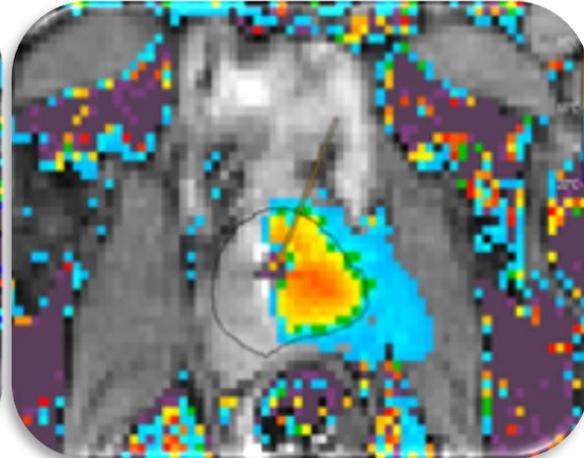
Whole Gland Ablation

# TULSA Technology: **Flexibility**

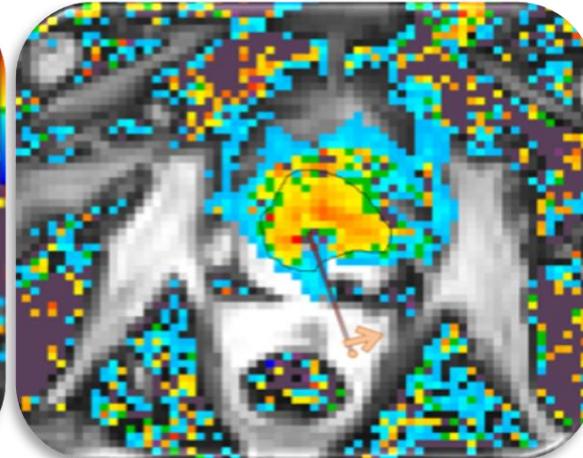
Whole Gland Ablation



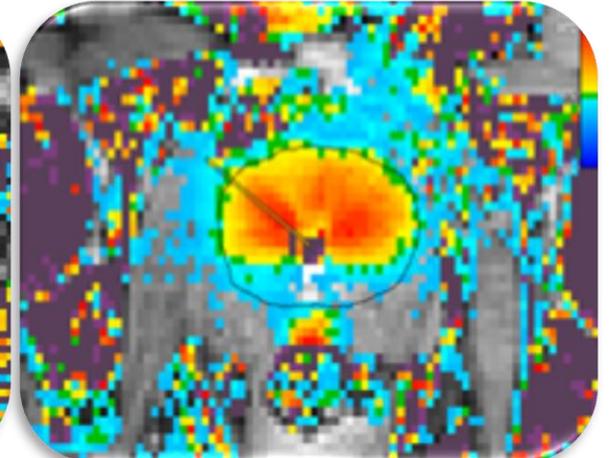
Targeted Ablation



Salvage Therapy post  
Radiation Therapy Failure



BPH



- Treatment – natural follow-on to MRI guided diagnosis and MRI guided biopsy to diagnose disease with precision
- Outpatient procedure – patients discharged within 24 hours
- Personalized treatment plan to each prostate anatomy and pathology
- Treated prostates as large as 120 ml
- Real-time MRI guidance and control ensures accurate ablation to 1.3 mm precision
- Phase I clinical trial demonstrated TULSA-PRO to be safe, feasible, well tolerated, with low side-effect profile

# Prostate Cancer Therapies Today – US + Europe

5.8 Million Patients living with PCa

Low Risk, PSA <10 ng/ml, GS 6  
New diagnosed 200,000/year

Intermediate Risk, PSA 10-20, GS 7  
New diagnosed 200,000/year

High Risk, PSA>20, GS>7  
New 95,000/Yr

Active Surveillance

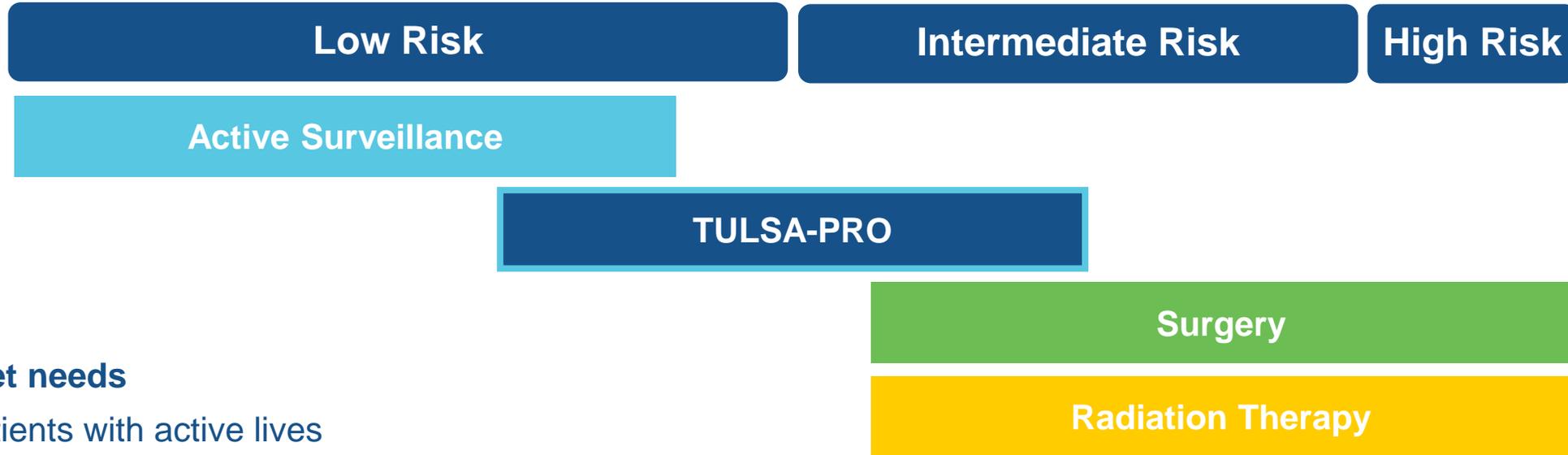
Surgery

Radiation Therapy

## Unmet needs

1. Patients with active lives
2. Patients under active surveillance but don't want to wait, or also have BPH
3. Patients with co-morbidities preventing surgical intervention
4. Salvage patients who failed radiation treatment
5. Patients with early stage disease, Gleason Score (GS) = 3+3 but genetic testing indicates aggressive disease
6. Patients with mid stage disease with MRI visible disease pattern
7. BPH patients who value erectile and ejaculatory functions

# TULSA-PRO Addressing Unmet Needs



## Unmet needs

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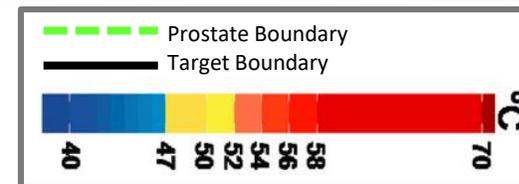
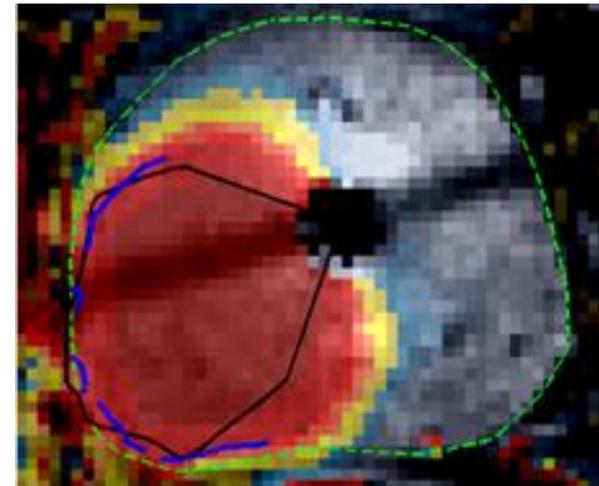
**TULSA does not interfere with any additional intervention if needed in the future**

# Ablation Feasibility – Confirming ablation of MR visible lesion

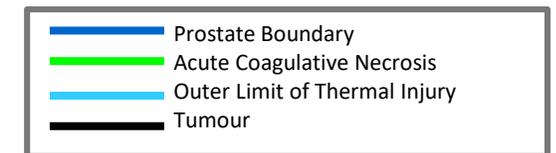
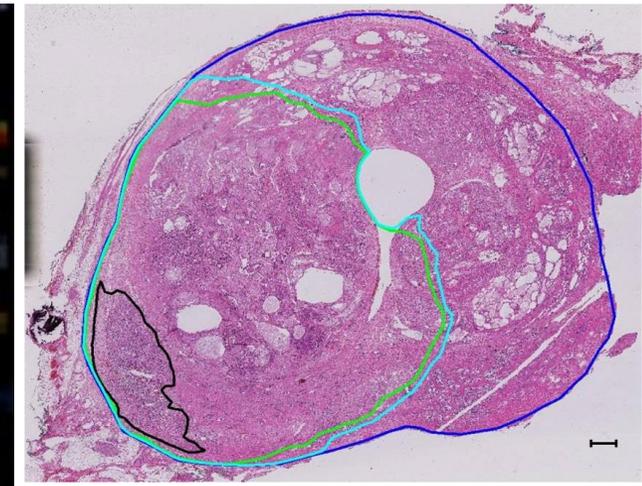
## Clinical Histology (gold standard)

- Treat-and-resect clinical study, targeting MRI-visible lesion with TULSA (n=5)
- TULSA followed by Radical Prostatectomy on same day
- Histology confirmed ablation of target lesion to prostate capsule, accuracy  $0.4 \pm 1.7$  mm

### MRI Thermometry



### H&E Histology



Ramsay *et al* 2017, The Journal of Urology, 197(1):255-261

# Phase I Clinical Trial Completed – 90% Prostate Ablation

**Study Population** – Low & intermediate risk prostate cancer patients,  $\geq 65$  years old (n=30)

**Well-tolerated favorable safety profile with minor impact on urinary, erectile and bowel function at 12 months**

1. 0/30 urinary incontinence (pads) at 12 months
2. 0/30 rectal fistula or bowel urgency
3. 21/30 patients potent pre-treatment → 20/29 potent at 12 months (ED def: IIEF Q2  $\geq 2$ )
4. Prostate volume reduced 88%
5. PSA decreased 90%
6. Total cancer core length reduced by 75% - by prostate TRUS biopsy at 12 months

**Treatment accuracy** – Median thermal ablation accuracy and precision:  $0.1 \pm 1.3$  mm

**Median ultrasound treatment time** – 36 min for 44 cc prostate volume



Chin *et al*, European Urology (2016)  
Bonekamp *et al*, European Radiology  
(submitted)

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# TACT Pivotal Trial – Full Prostate Volume Ablation (99.7%)

To Support FDA Application, Enrollment Completion Feb 2018

## Study Population

- Low & intermediate risk prostate cancer patients, 45 – 80 years old, n=110, 13 clinical sites

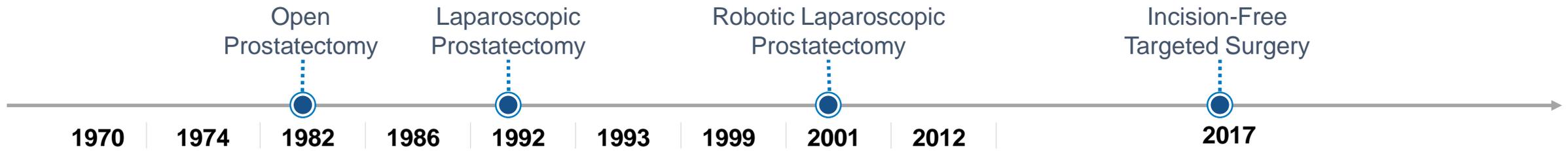
## Primary Endpoints

- 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 & stability – % patients with PSA  $\leq 0.5$  ng/ml at nadir & 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 item 2  $\geq 2$
- 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

# From Open Surgery to Incision-Free Surgery



SURGERY TYPE	FULL PROSTATE REMOVAL	FLEXIBLE: FULL PROSTATE OR TARGETED CANCER ABLATION
Invasiveness	Reduced	Incision free
Recovery time	Reduced	Day surgery
Clinical outcome	Unchanged	Superior
Surgeon skill	Dependent	Closed loop process control
Cost of Surgery	Higher	Lower

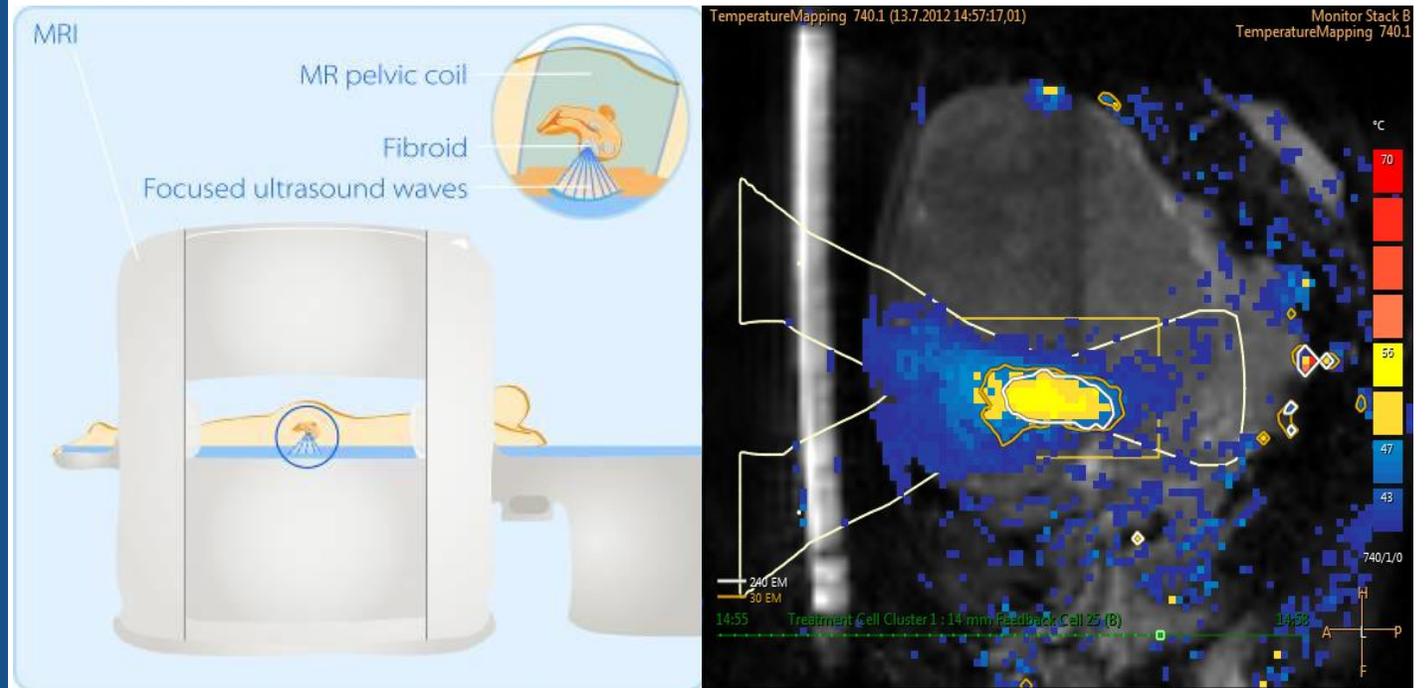
# SONALLEVE

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



# 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
Myomectomy	10.6 %	13-16.5 %	1,2,3,4
UAE (Uterine Artery Embolization)	7-10 %	12.7-23.7 %	5,6,7
MR-HIFU/MRgFUSNPV >60%	6 %	13 %	8

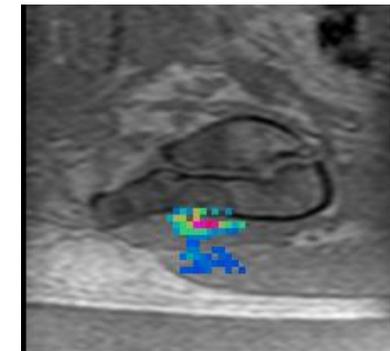
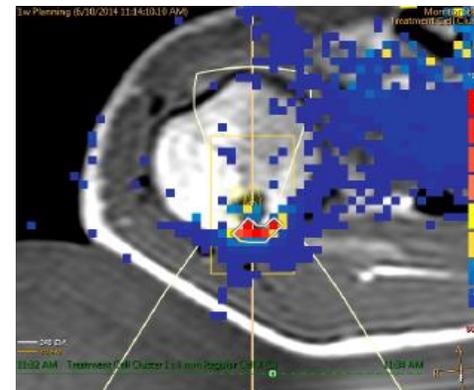
"Volumetric MR-guided high-intensity focused ultrasound ablation of uterine fibroids: treatment speed and factors influencing speed," M. J. Park, Y. S. Kim, B. Keserci, H. Rhim, and H. K. Lim, Eur Radiol, vol. 23, no. 4, pp. 943–950, Apr. 2013. 1. Gorny KR, Woodrum DA et al. Magnetic resonance-guided 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. Rossseti 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

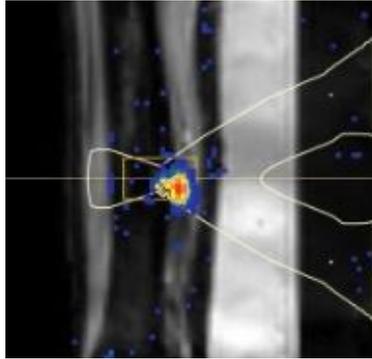
Most patients with slow growing tumors develop bone metastasis in the later stage of the disease. Bone changes and malformations irritate nerve endings creating significant pain for patients.

- 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



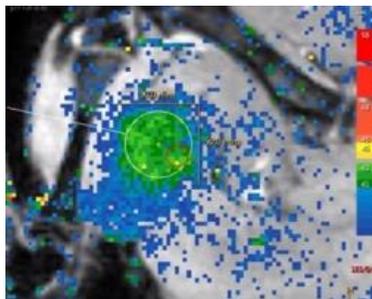
### **Pediatrics: Osteoid osteoma**

- 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

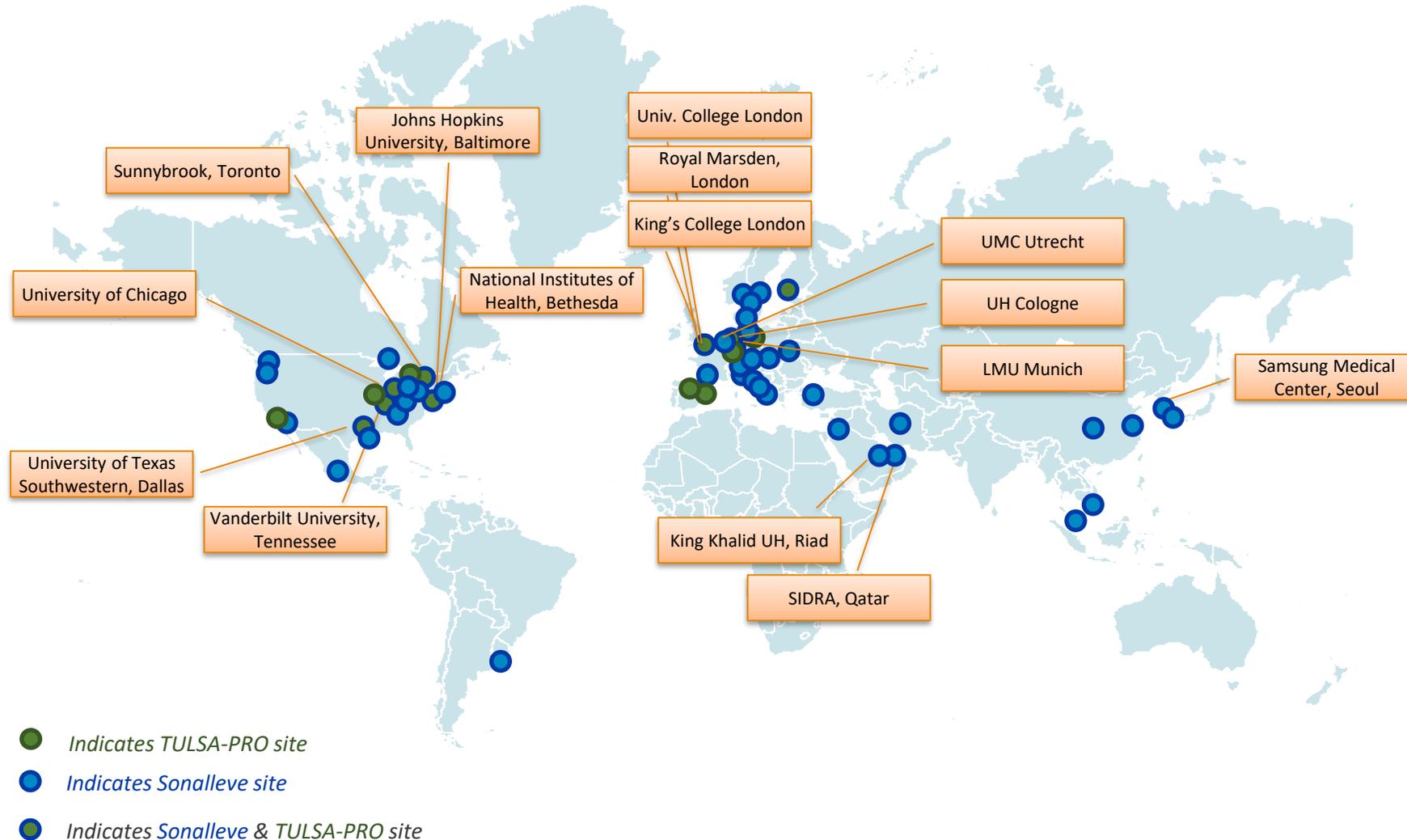


### **Hyperthermia**

- 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



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# Market Introduction Strategy

- Strategic Partnerships: expanded and existing collaborations with MR partners will drive revenue:
  - Capital Sales
  - Co-selling
  - Co-marketing
- Build direct sales to drive procedure adoption and disposable sales
- Focus Sonalleve sales in Asian market and academic hospitals in North America and Europe, until a US strategy is developed by end of 2018

**PHILIPS**  
**SIEMENS**

# Reimbursement Environment

## US

PROCEDURE	APPROXIMATE HOSPITAL PAYMENT	APPROXIMATE SURGEON PAYMENT
Laparoscopic Radical Prostatectomy	\$10,000	\$1,450
Radiation Therapy (IMRT Simple, 40 Sessions)	\$20,000	Fee bundled into primary APC
Brachytherapy	\$8,000	\$2,200
Cryoablation	\$10,000	\$800

## 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.

# European Pilot Commercial Launch Revenue Ramp



# Profound Medical

## Summary

### INCISION-FREE PROCEDURES

REAL-TIME MR GUIDED TREATMENTS

**1** Precise

**2** Personalized

**3** Safe

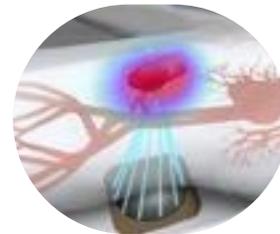
### TULSA-PRO®



Ultrasound 'Inside-Out'  
- Prostate Disease  
- CE marked  
- FDA expected 2019



Sonalleve



Ultrasound 'Outside-In'  
- Uterine Fibroids  
- Bone Metastasis  
- CE marked  
- Extending indications