

A person in a red jacket stands on a rocky peak, looking out over a vast mountain valley. The sky is filled with large, white clouds, and the landscape below is a mix of green fields and blue mountains.

# PROFOUND

Customizable, Incision-Free Ablation Therapies

**PROFOUND**

CORPORATE PRESENTATION | 2019

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Market data and industry forecasts contained in this presentation have been obtained from industry publications, various publicly available 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. We have 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.

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“My life  
should  
not have  
to change”

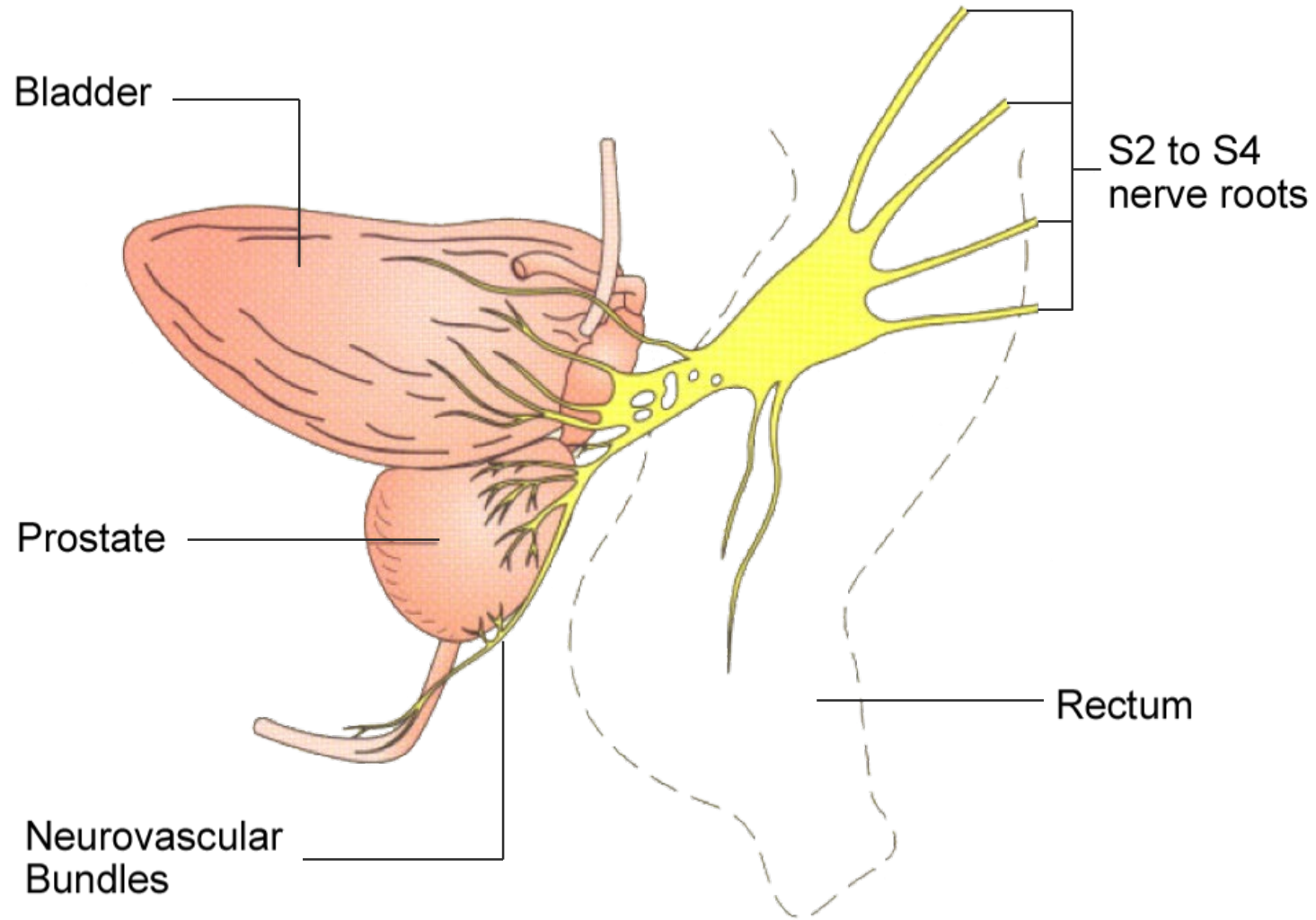


**TULSA-PRO<sup>®</sup>**

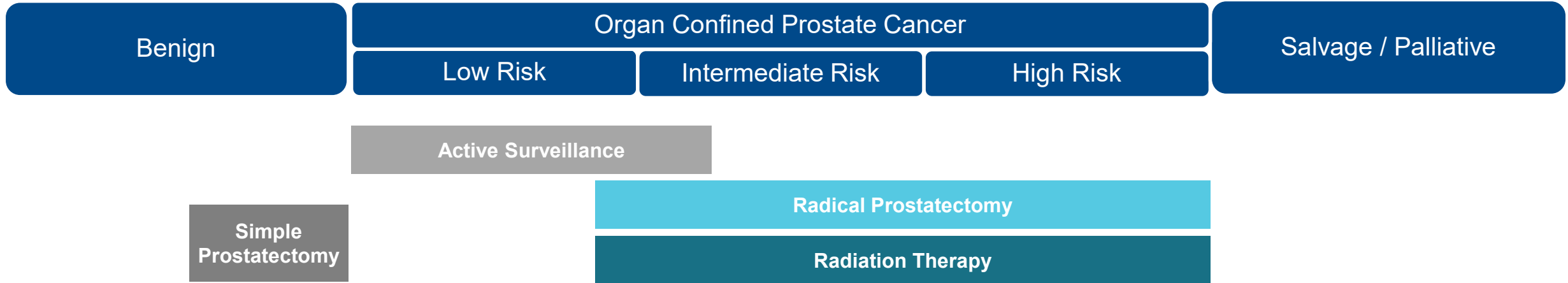
U.S. FDA Cleared, August 2019  
Ablation of Prostate Tissue

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# Prostate Anatomy



# Current Approaches to Prostate Disease



- 175,000 new prostate cancer patients diagnosed each year according to the American Cancer Society, 2.9 million US patients living with prostate cancer on active surveillance.
- 300,000 BPH surgeries per year in the US based upon CMS data. 10 million US patients living with BPH.
- Radiation failure and palliative patients have limited treatment options.
- Approx 10% of prostate cancer patients undergo other treatments such as HIFU, Laser and Cryo.

# TULSA-PRO

Customizable, Predictable, Incision-Free

## 1. Real-time MR imaging

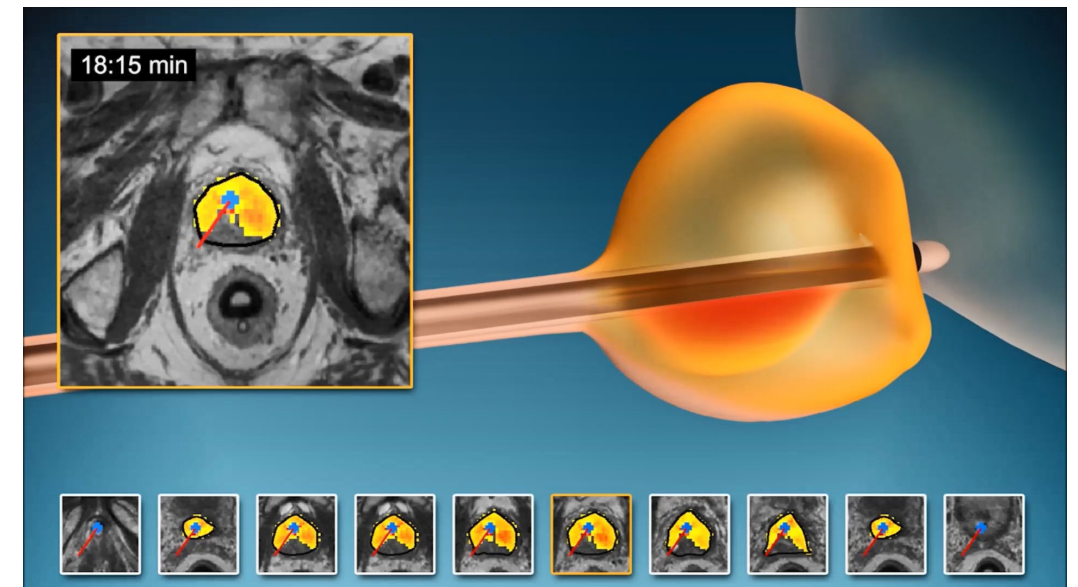
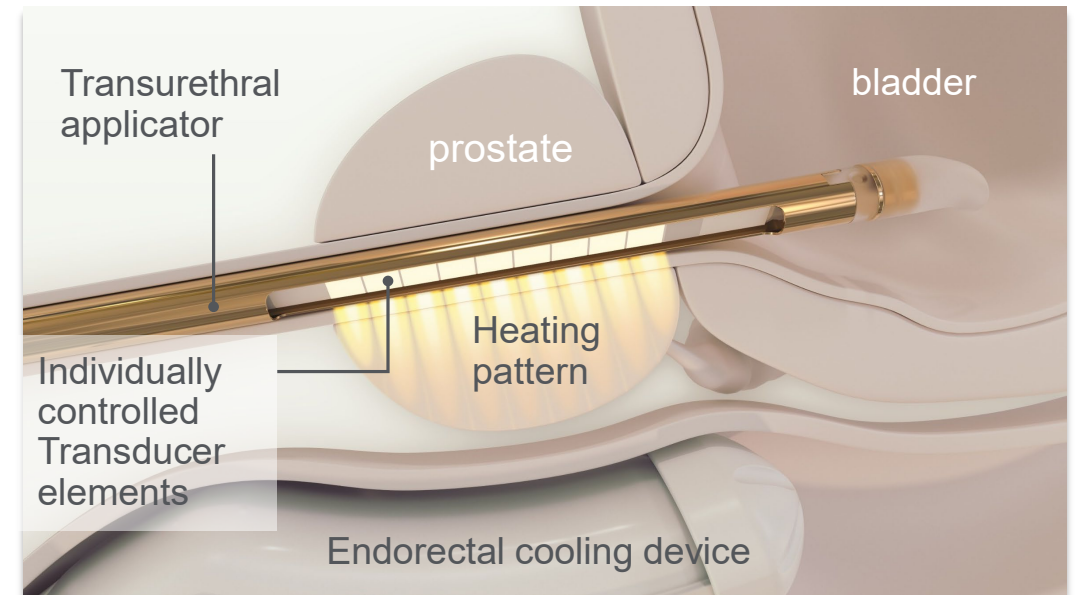
- Customized treatment plan

## 2. Transurethral directional ultrasound for thermal ablation; water cooling of urethra and rectum

- Sweeping ultrasound, continuous rotation (no risk of cold spots between discrete sonications)
- Capable of treating both large and small prostate volumes
- Thermal protection of important anatomy

## 3. Closed-loop process control software

- Real-time temperature feedback provides for gentle and precise ablation



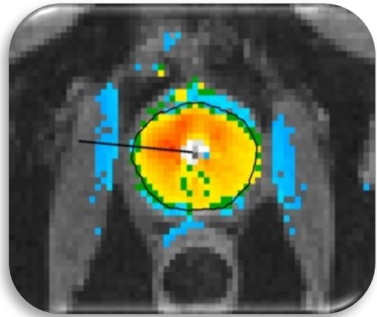


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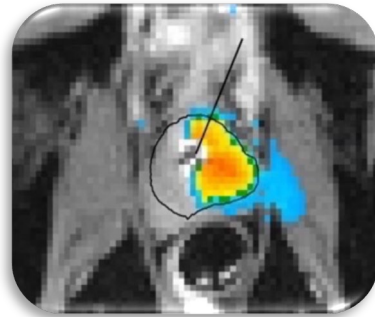
# TULSA Flexibility

Customizable, Predictable, Incision-Free

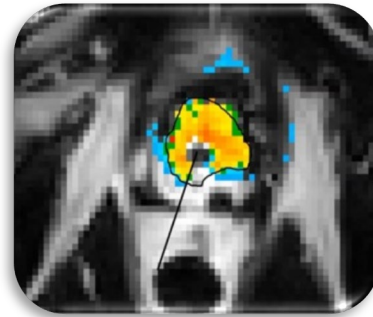
Whole gland  
ablation



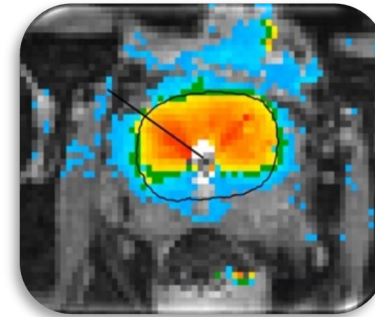
Targeted  
ablation



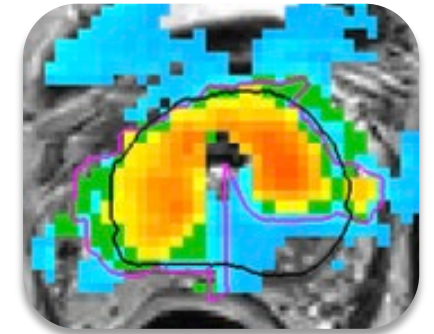
Post radiation  
failure ablative  
therapy



Targeted ablation  
of a benign large  
prostate



Targeted ablation of a  
benign large prostate  
with malignant lesion



# TACT: Clinical Trial Design

Pivotal study of whole-gland ablation in a clinically-significant patient population

## Study Population

- n = 115, 13 clinical sites, 5 countries
- 45 – 80 years old
- Low (33%) & intermediate risk (67%) prostate cancer

## Ablation Treatment Plan

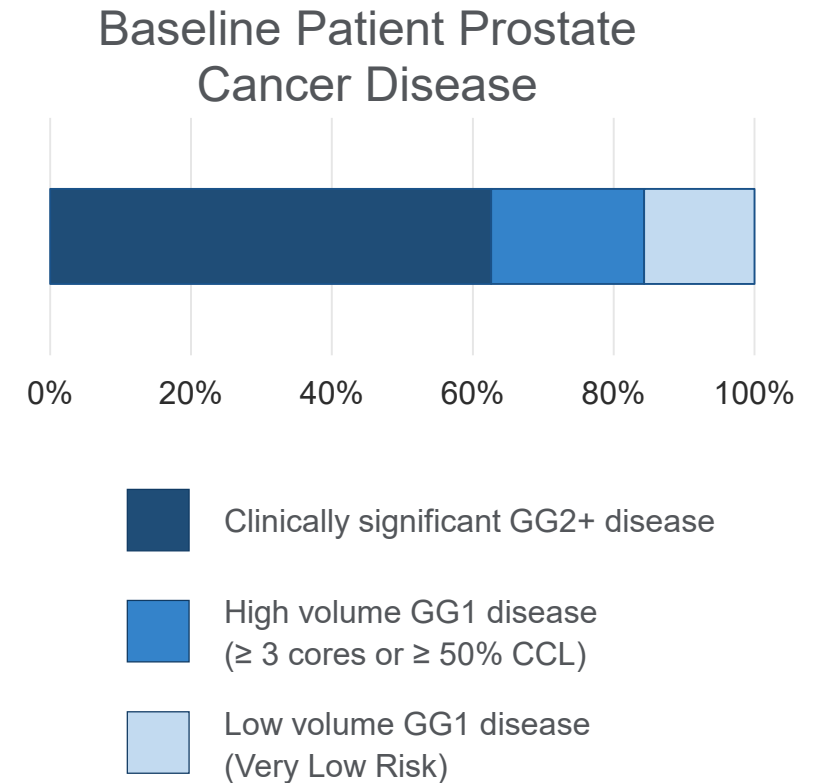
- Treatment intent was whole-gland ablation with sparing of the urethra and urinary sphincter
- Recommended by FDA to determine substantial equivalence with predicate devices and comparison with standard of care

## Primary Endpoints (12 months)

- Safety: Frequency and severity of adverse events
- Efficacy: PSA reduction  $\geq 75\%$  (in  $> 50\%$  of patients)

## Secondary Endpoints (to 5 years)

- Prostate volume reduction at 1 year
- Prostate biopsy at 1 year in all patients
- Multi-parametric MRI at 1 year (Central Radiology Lab, Cleveland Clinic)
- Functional Disability: EPIC, IIEF, IPSS



# TACT: Prostate Ablation Efficacy

## PSA primary efficacy endpoint resolutely met:

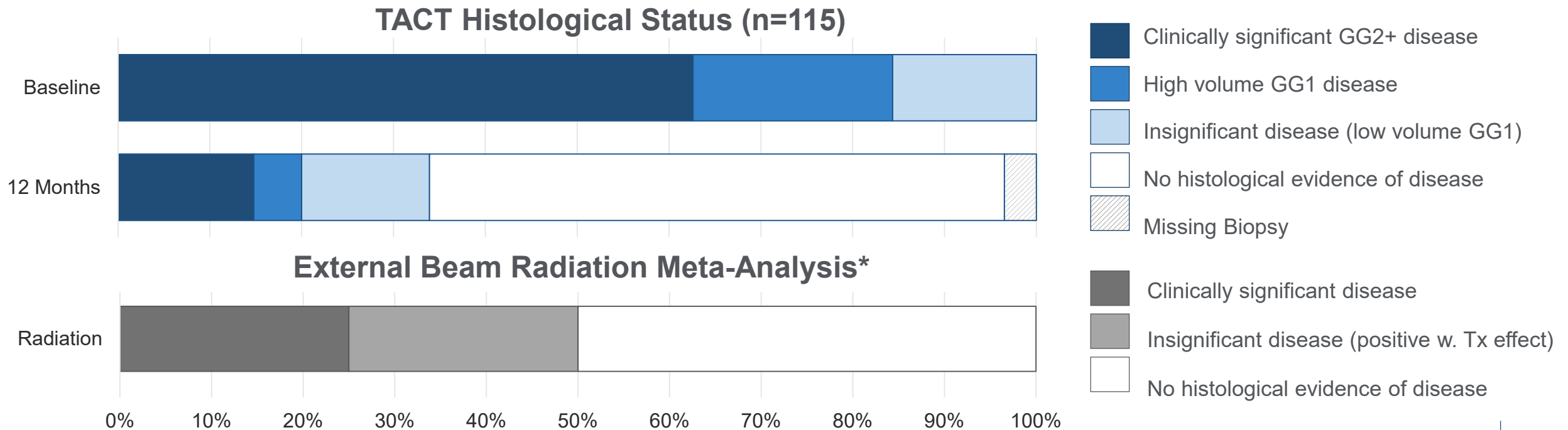
- Primary endpoint of PSA reduction  $\geq 75\%$  was achieved in 110 of 115 (96%)
- Median (IQR) PSA reduction was 95% (91-98%)
- Median PSA nadir was 0.34 (0.12-0.56) ng/ml

	Pre-Treatment	12 Month	PSA Nadir
N	115	115	115
<b>Median</b>	<b>6.26</b>	<b>0.53</b>	<b>0.34</b>
IQR	4.65 – 7.95	0.28 – 1.25	0.12 – 0.56
<b>Average</b>	<b>6.72</b>	<b>0.93</b>	<b>0.51</b>
T-Test against baseline		<0.001	<0.001

# TACT: Histological Response

## Biopsy Outcomes (1-year, 10-core TRUS, High Sampling Density 0.4 cc / core)

- Only 4 of 115 follow-up biopsies are missing, all due to patient refusal
- Among men with pre-treatment intermediate-risk GG2 disease, **54 of 68 (79%)** were free of GG2 disease
- Of men with one-year biopsy data, 72 of 111 (65%) had complete histological response and were free of any evidence of cancer
- 41% (16 of 39) of positive biopsies were clinically insignificant (Very Low Risk)
- Multivariate Analysis: Among men with pre-Tx GG2 disease and w/o calcifications at screening, **51 of 60 (85%)** were free of GG2 disease



\*GCP-10102 available upon request

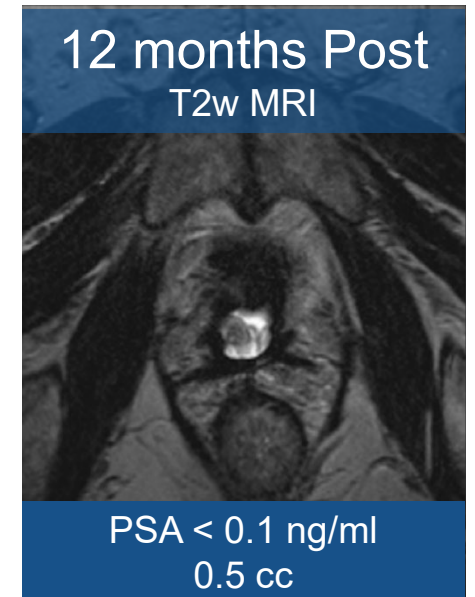
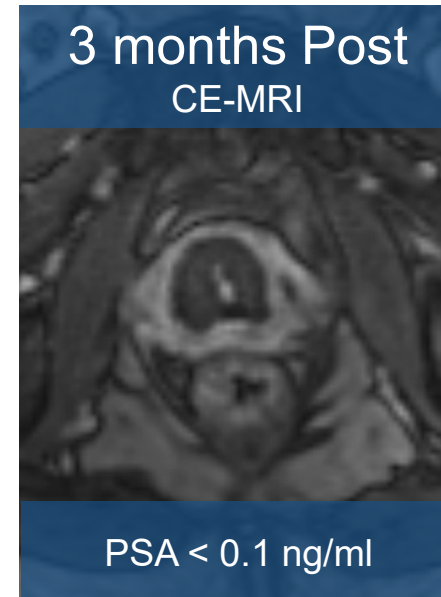
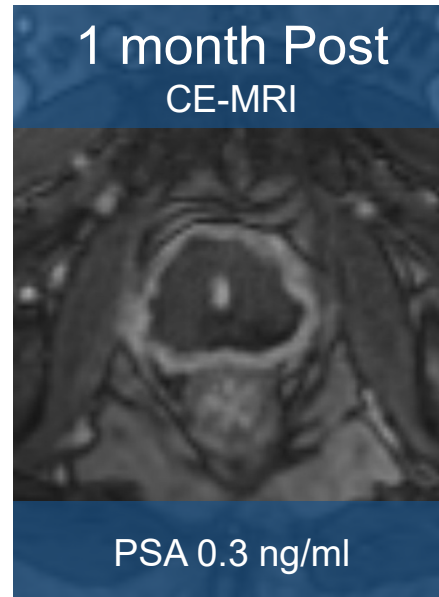
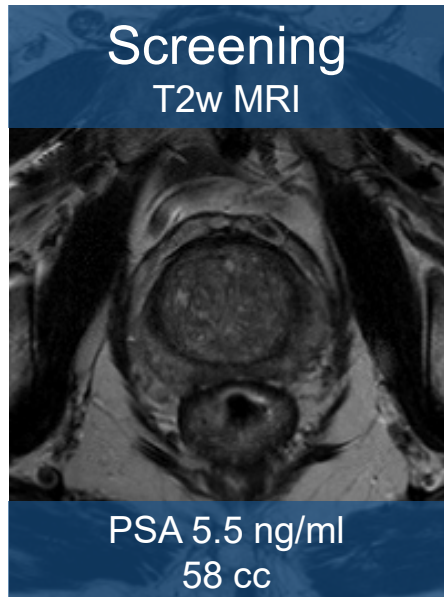
# TACT: Prostate Volume Reduction

## Prostate volume significantly reduced demonstrating effective prostate ablation

- Median perfused prostate volume decreased 91% from 37 cc to 3 cc, on MRI at 1 year (central radiology)
- Prostate ablation confirmed on Contrast Enhanced MRI immediately after TULSA and during follow-up

## Follow-up prostate MRI predicts clinically significant disease on biopsy

- Multivariate Analysis: Absence of PIRADS  $\geq 3$  lesion at 1-year post-treatment MRI has 92% Negative Predictive Value for absence of GG2 disease on 1-year biopsy (local radiologists, same as diagnostic PIRADS)
- Ongoing work: Adjusting PIRARDS for post-ablation setting, MRI has **96% Negative Predictive Value** for absence of GG2 disease on 1-year biopsy (central radiology)

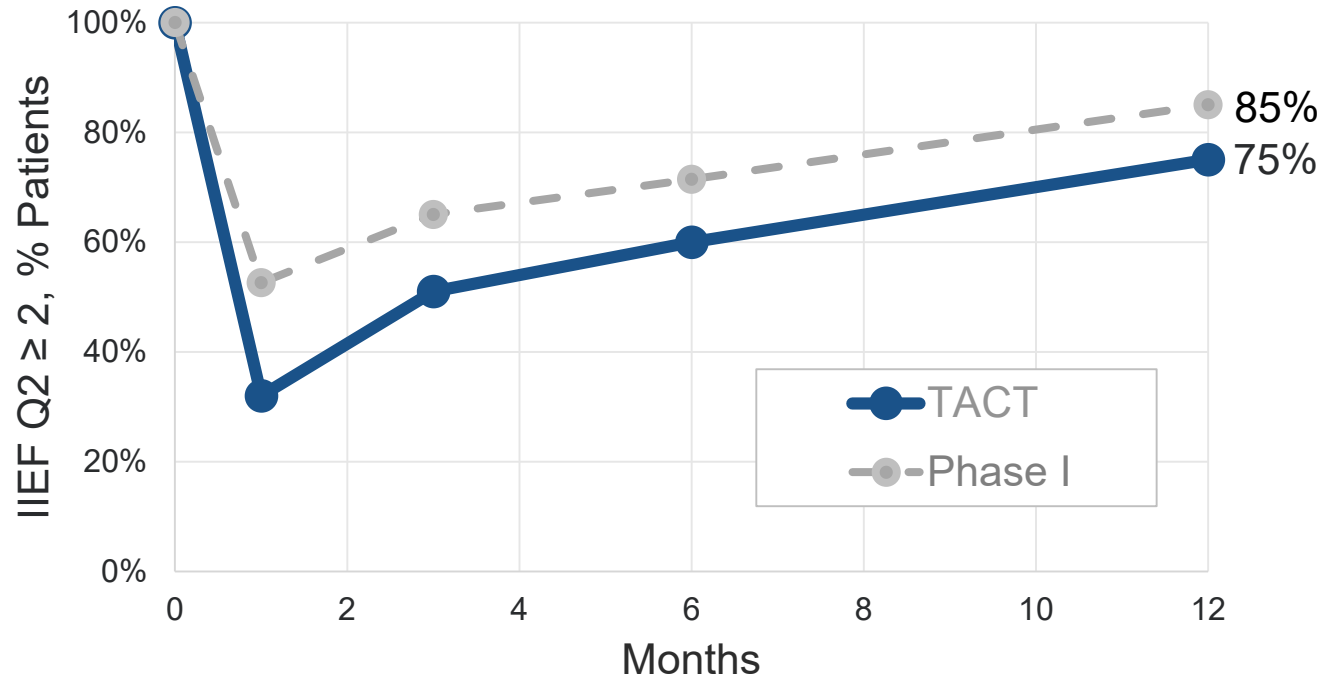


# TACT: Erectile Function

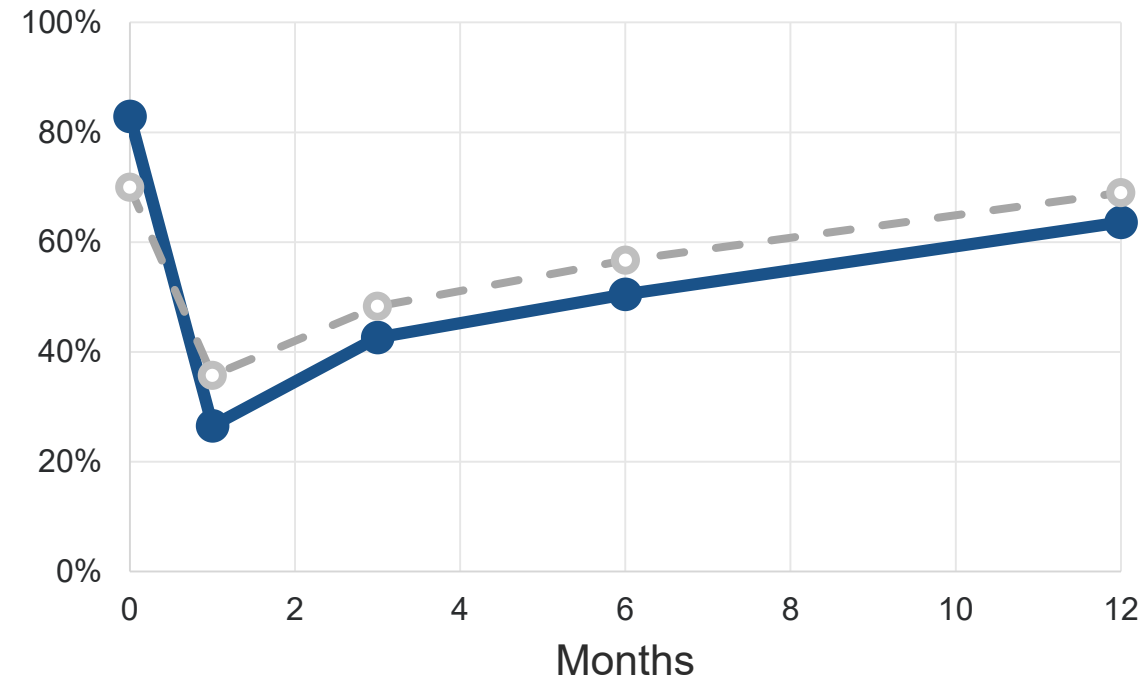
## Erectile Function, at one year:

- 23% surgeon-assessed moderate erectile dysfunction (CTCAE Grade 2, intervention such as medication indicated)
- 0% any occurrence of severe erectile dysfunction (CTCAE Grade 3, intervention such as medication not helpful)
- 75% (69/92) of previously potent patients maintained erections sufficient for penetration
- Phase I 90% ablation, TACT whole gland ablation

Patients Potent at Baseline (n=92)



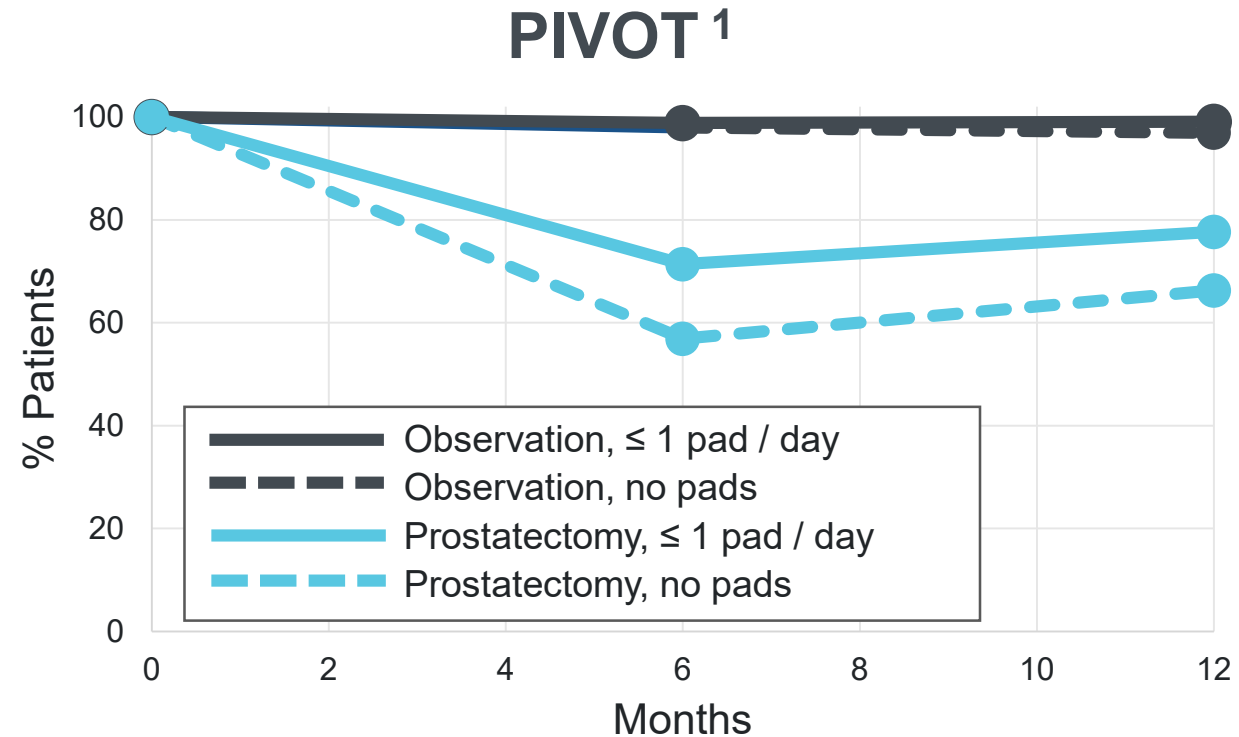
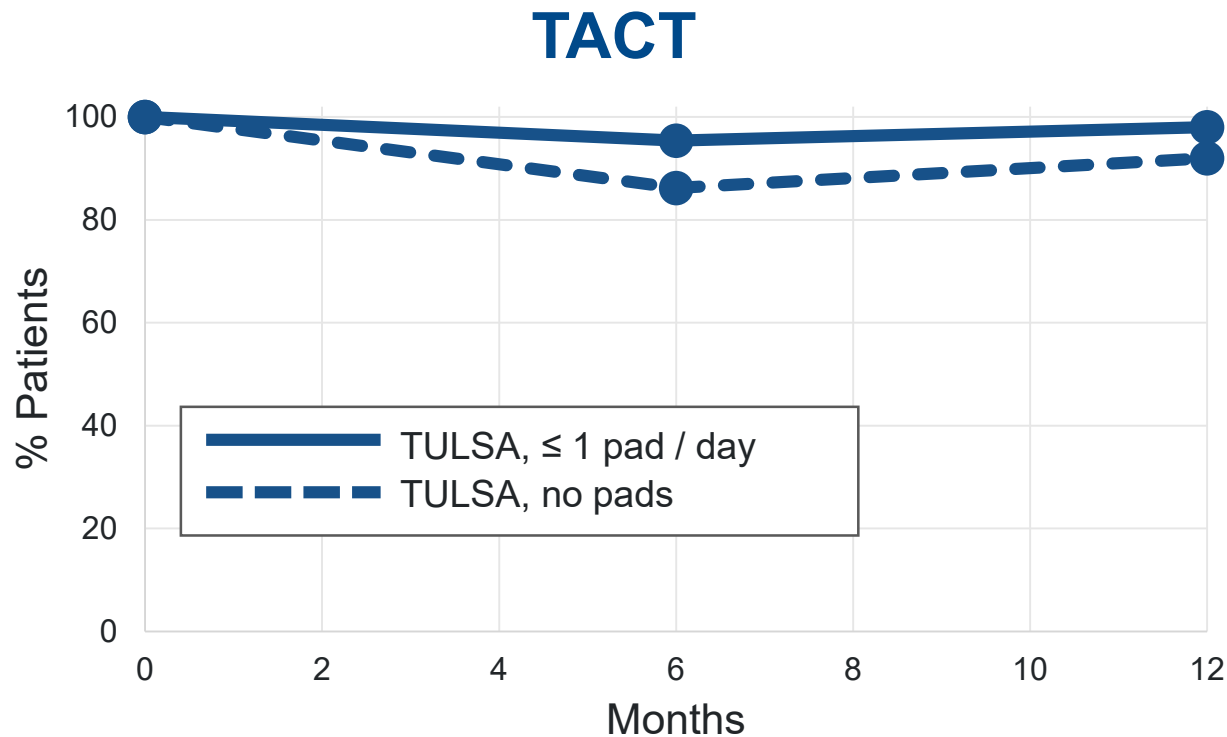
All Patients (n=110)



# TACT: Urinary Incontinence

## Urinary Incontinence, at one year:

- 2.6% surgeon-assessed moderate urinary incontinence (CTCAE Grade 2, pads indicated)
- 0% any occurrence of severe urinary incontinence (CTCAE Grade 3, operative intervention indicated)
- TACT Urinary Continence (pad use) similar to Observation arm of PIVOT study



1. Wilt *et al*, The New England Journal of Medicine, 2017

# TACT summary, Literature review of other trials provided for context

	TACT Study	Literature Review		
	TULSA	Prostatectomy	Radiation	HIFU
<b>Biopsy / Histology</b>	21% Clinically significant 14% Insignificant disease (GG1, ≤2 cores, < 50% CCL) 65% Negative	16 – 24% +Margin <sup>1</sup> (Meta-Analysis) 10 – 15% +Margin <sup>2</sup> (RCT) 24% +Margin <sup>3</sup> ( ProtecT)	28% Clinically significant <sup>4</sup> 20% Insignificant disease <sup>4</sup> (Positive w. treatment effect) 52% Negative <sup>4</sup>	59 – 61% Negative <sup>5-6</sup> (Intent to treat) 63% Negative, after 40% having repeat HIFU and 39% ADT <sup>7</sup>
<b>Erectile Dysfunction</b> erections insufficient for penetration	<b>23%</b> Grade 2 medication indicated. No Grade 3 ED	<b>79%</b> <sup>9</sup> (Range: 25 – 100%) <sup>1-4</sup>	<b>63%</b> <sup>9</sup> (Range: 7 – 85%) <sup>1-5</sup>	<b>58%</b> <sup>7</sup> (Range: 44 – 67%) <sup>6-8</sup>
<b>Urinary Incontinence</b> moderate to severe	<b>2.6%</b> Grade 2 pads indicated. No Grade 3 Incontinence	<b>15%</b> <sup>9</sup> (Range: 0 – 50%) <sup>1-4</sup>	<b>4%</b> <sup>9</sup> (Range: 2 – 15%) <sup>1-5</sup>	<b>3%</b> <sup>5</sup> (Range: 3 – 22%) <sup>6-8</sup>
<b>Urethral Stricture</b> moderate to severe	<b>2.6%</b>	<b>9%</b> <sup>11</sup> (Range: 3 – 26%) <sup>1-4</sup>	<b>2%</b> <sup>11</sup> (Range: 1 – 9%) <sup>1-5</sup>	<b>35%</b> <sup>5</sup> (Range: 9 – 35%) <sup>6-8</sup>
<b>GI Toxicity,</b> moderate to severe diarrhea, urgency, incontinence, fistula	<b>No GI Toxicity</b>	<b>15%</b> <sup>9</sup> (Range: 0 – 24%) <sup>1-4</sup>	<b>25%</b> <sup>9, 12</sup> (Range: 0 – 40%) <sup>1-5</sup>	<b>7%</b> <sup>5</sup> (Range: 1 – 21%) <sup>6-8</sup>

1. Tewari et al 2012 (Meta-Analysis)  
 2. Yaxley et al 2016 (RCT)  
 3. Hamdy et al 2016 (ProtecT)  
 4. Radiation Meta-Analysis (publication pending)  
 5. FDA IDE Study K153023

6. FDA IDE Study DEN150011  
 7. Crouzet et al, Eur Urol 2014 (1000+ patients, Whole-gland HIFU)  
 8. Thompson (Chair) et al, AUA prostate cancer clinical guideline update panel, J Urol 2007  
 9. Resnick et al, Prostate Cancer Outcomes Study (PCOS), NEJM 2013

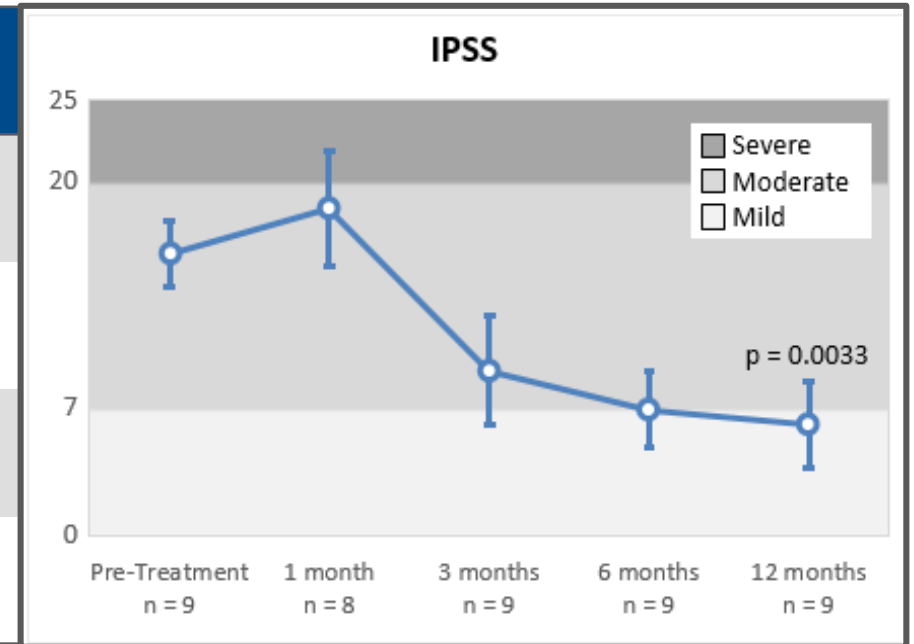
10. Potosky et al, Prostate Cancer Outcomes Study (PCOS), J NCI 2004  
 11. Elliott et al, CaPSURE database, J Urol 2007  
 12. Budaus et al, Review, Eur Urol 20012



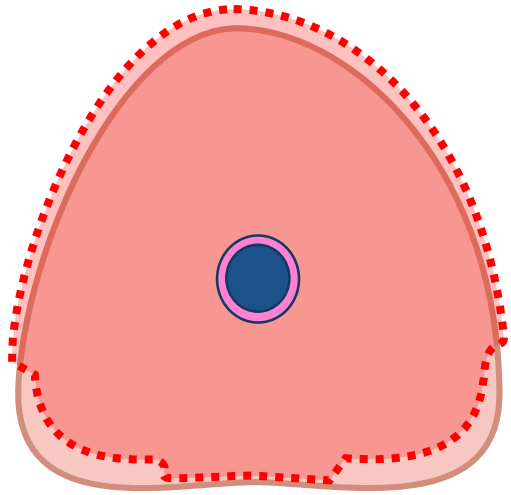
# BPH Subgroup Analysis of Phase I Study

- Subgroup analysis of Phase I patients with baseline IPSS  $\geq 12$  (n = 9/30)
- No Grade 3 adverse events, erectile function (IIEF) stable from  $15 \pm 9$  to  $16 \pm 9$
- Elterman *et al*, Prostate Cancer and Prostate Diseases, 2019 (*Under Review*)

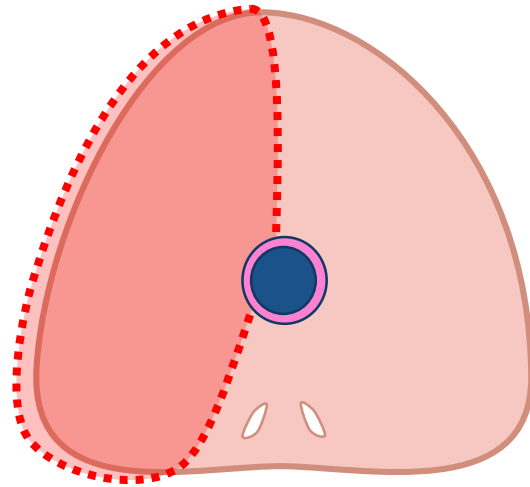
Characteristics (n=9)	Baseline	12 months	Change (%)
IPSS	$16.1 \pm 3.8$	$6.3 \pm 5.0$	$\Delta -9.8 \pm 7.1$ (-58%)
IPSS QoL	$2.8 \pm 1.1$	$0.8 \pm 1.0$	$\Delta -2.0 \pm 1.7$ (-66%)
Prostate Volume (cc)	$54 \pm 23$	$14 \pm 5$	$\Delta -40 \pm 24$ (-70%)
Peak flow (Qmax, ml/s)	$14.5 \pm 4.1$	$21.9 \pm 12.7$	$\Delta +7.4 \pm 13$ (+60%)



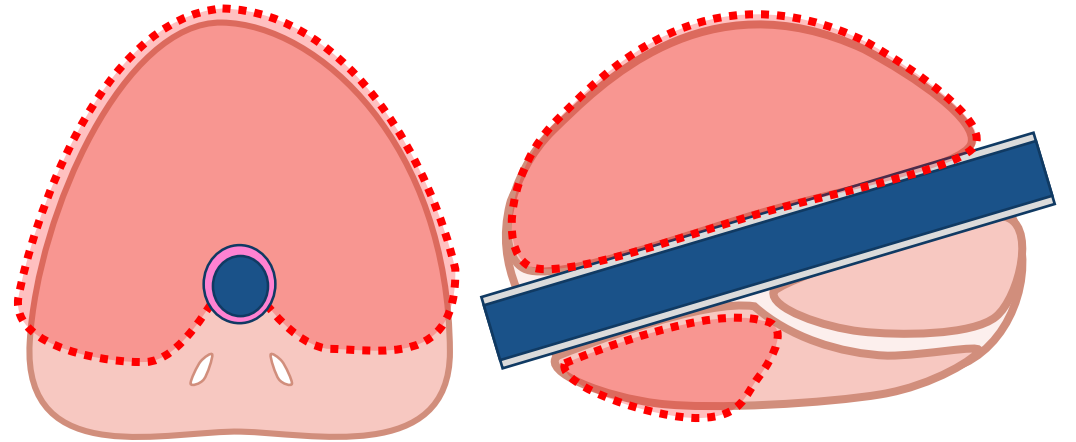
# Predictable and Targeted Ablation



Bilateral sparing  
ablation of cancerous  
prostate tissue



Targeted & customized  
ablation of diseased  
prostate tissue



Ablation of benign tissue

# Clinical Application of TULSA

Benign

Organ Confined Prostate Cancer

Salvage / Palliative

Low Risk

Intermediate Risk

High Risk

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

- Preservation of ejaculatory function
- Combined with targeted cancer ablation
- Prophylactic ablation of suspicious MRI lesion

## Customized ablation <sup>2-7</sup>

- Targeted ablation (focal)
- Large ablation (wide margins)
- Whole gland ablation (with urethral sparing)

## Recurrence after radiation <sup>8</sup>

- Localized recurrences have limited options, and morbidity is high

## Palliative locally advanced <sup>9</sup>

- Severe urinary symptoms including BOO with retention and/or intractable hematuria

## Oligometastatic <sup>10</sup>

- Benefit to locally treat prostate
- Often radio-recurrent

1. Elterman *et al*, Prostate Cancer and Prostate Diseases, 2019 (*Under Review*)  
2. Ramsey *et al*, The Journal of Urology, 2017  
3. Chin *et al*, European Urology, 2016  
4. Bonekamp *et al*, European Radiology, 2018  
5. Eggener *et al*, The Journal of Urology, 2019 (*AUA Abstract*)

6. Anttinen *et al*, International Journal of Hyperthermia, 2019  
7. Anttinen *et al*, Scandinavian Journal of Urology, 2019 (*Under Review*)  
8. Suomi *et al*, ISTU Barcelona, Spain, 2019 (*Conference*)  
9. Sainio *et al*, ISTU Barcelona, Spain, 2019 (*Conference*)  
10. *Physician interest*

# Commercial Application of TULSA



	Prostatectomy	Radiation	TULSA
<b>Throughput, Procedures/Day</b>	2 typically, 3 on a longer day	Multiple sessions: 5 to 40, 4 - 8 weeks	<ul style="list-style-type: none"> <li>• 4 in a routine day</li> <li>• Consistent treatment times</li> </ul>
<b>Patient Recovery</b>	Weeks	Deterioration over time	<ul style="list-style-type: none"> <li>• 2 days</li> <li>• Minimal need for pain management</li> </ul>

# TULSA-PRO System Components

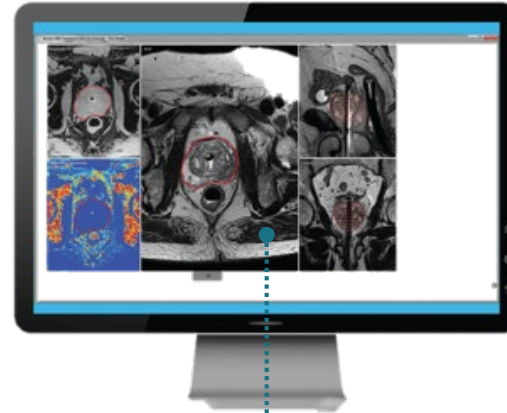
Compatible with MR from leading companies, Philips and Siemens



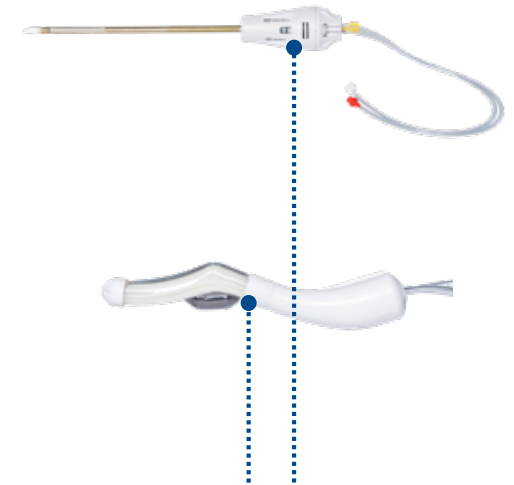
**Robotic Arm,  
Computer Hardware**



**Energy  
System**



**Surgeon Console  
Control Room**



**Disposable  
Applicators**

**Capital Equipment**

**One-Time Consumables**

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# U.S. Market Entrance Strategy

## 1. Increasing awareness of TULSA-PRO technology and the TACT clinical data

- TACT clinical data presented at >8 conferences (AUA, EAU, RSNA)
- TULSA-PRO and TACT clinical data presented to >50 institutions

## 2. Early adopter pipeline developed through interest from clinical presentations

## 3. Potential delivery channels for TULSA-PRO

- Imaging centers
- Urology practice co-ops who focus on new technologies
- Large opinion leading hospital-based practices

## 4. Recurring revenue business model

## 5. 'Profound Genius Services' launched to support early adopters

# Building Our Brand: **Low-Cost / High-Impact Patient Awareness Initiatives**

## **Profound Branded Patient Marketing**

### **A. TULSA Patient Website**

- EU/APEC site launched
- U.S. site in development
- Global TULSA-PRO site locator

### **B. Corporate Website enhancement**

- Language accessibility
- Blog development with patient-focused material
- TULSA clinical data webpage

### **C. Video Patient & Physician Testimonials**

- Cross platform promotion across
  - YouTube channel
  - Patient resources
  - Social media

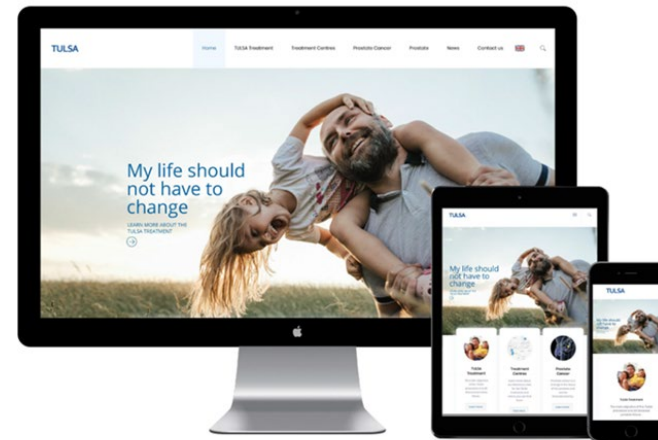
## **Customer Branded Patient Marketing**

### **A. TULSA Patient Marketing**

- Patient brochure
- Patient procedure pamphlet

### **B. TULSA Digital Marketing**

- Site branded testimonials
  - Ad campaigns
  - Social media collateral



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# Reimbursement: **AMA Requirements for Category I CPT Code**

- FDA cleared
- Performed widely by many physicians across United States (warrants new CPT code)
- Frequency consistent with intended clinical use (common conditions have higher volume)
- Consistent with current medical practice (mentioned in guidelines/policies)
- Clinical Efficacy (documented in “top 5” peer-reviewed publications, judged by CPT Panel)
  - 1+ reference in a majority US patient population
  - 2+ references with no overlapping patients or authors
  - 1+ reference with Level of Evidence IIa (review of large long-term cohort studies) or Level I (randomized controlled trials)



# Reimbursement: Clinical Evidence Plan

## Publication Package

	Rationale	Level	N	US %	Start
1. TACT 2.0 5-year	TULSA US Momentum at key teaching sites Increase US patient % Re-treat TACT 1.0 patients	2b	115 (+35=150)	48% (60%)	Started
2. BPH RCT 6-month	Anchor study for Level 1 data Backup plan (next slide)	1b	144 in 2:1 96 TULSA	~100%	2020
3. Salvage 1-year	Strong clinical value & entry into guidelines Need to sponsor or too slow with patient pay	2b	68	~100%	2020
4. Primary Cancer Meta-Analysis (Phase I, EU, Registry)	% Ablation vs. Outcomes	2a			
5. Single/Small-center Cancer RCT TULSA vs. Radiation (Turku, UWO, US?)	Small RCT, 50+ pts, good chance to randomize Level 1 data in cancer, even if not traditional Offloads sponsor requirements from Profound	1b	50 minimum	0% (more)	2020

## Why This is a Good Plan

- Unify device indication with coding and TULSA value proposition (1 CPT for multiple prostate diseases)
- Level 1b data in both BPH and Cancer
- Meet CPT & payer requirements (level of evidence, US patients, exclusive authors, exclusive patients)
- Sponsor: TACT 2.0 (n=35), BPH (n=96), Salvage (n=68) = 199 TULSA-PRO Treatments
- Registry: FLEX protocol (and/or SPARED) to get more data at low cost to Profound
- Minimize company-paid procedures, while also providing runway for teaching sites as we motivate them to perform patient pay

Longer  
Term

## Building an Incision- and Radiation-free Ablative Therapeutic Platform

Oncology, Highly Symptomatic Chronic Diseases

**PROFOUND**



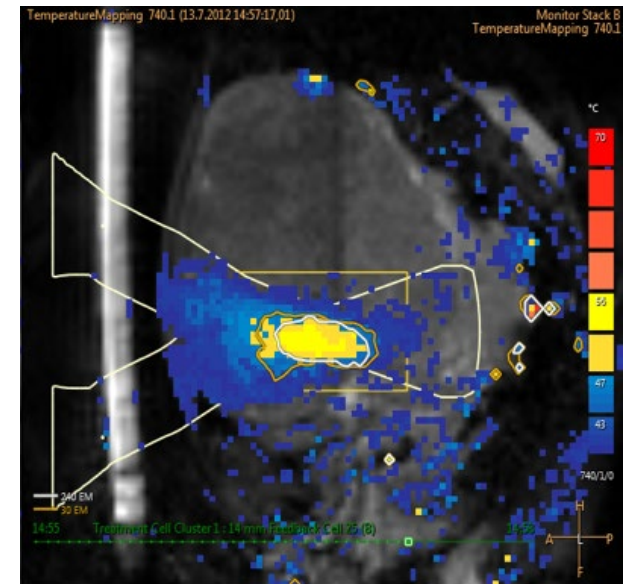
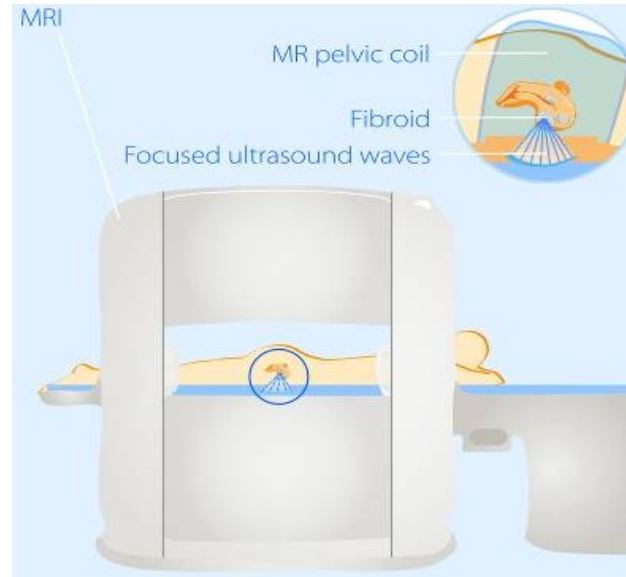
# SONALLEVE

## CURRENT APPROVALS

- Europe: CE Marked
- China: CFDA Approved

## Over 200 publications from leading U.S. & European clinicians and hospitals

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



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# SONALLEVE: Market Development Strategy

## 1. U.S. & Western Markets

- Partner with Cologne to continue to develop critical clinical data for cancer and highly symptomatic chronic diseases
- Deploy recurring revenue business model for all new clinical applications
- Enter U.S. market with Humanitarian Device Exemption indication (similar to orphan drug indication for rare diseases)
  - Application filed with FDA
  - FDA manufacturing site inspection completed successfully
- Potential applications include:
  1. Pain management
  2. Osteoid Osteoma
  3. Pancreatic cancer
  4. Hyperthermia
  5. Neuro-modulation

## 2. China

1. Continue working with Philips as distribution partner, in concert with a small Profound direct sales team
2. Marketing for treatment of uterine fibroids
3. Reference site in S. Korea, treating 200 patients/year

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## In Summary

Introducing TULSA-PRO to U.S. market

Business model designed to be capital efficient

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

Future investments:

- Strategically expand U.S.-based sales team as we continue to work with MRI partners, Philips and Siemens
- Clinical trials for TULSA-PRO for reimbursement
- Continued product evolution

PROFOUND