PROFOUND

Customizable, Incision-Free Ablation Therapies

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CORPORATE PRESENTATION | SEPTEMBER 2019

 TSX: PRN | OTCQX: PRFMF

Forward-Looking Statements

Certain statements in this presentation and oral statements made during this meeting may contain “forward-looking statements” within the meaning of applicable securities laws, including the “safe harbour provisions” of the Securities Act (Ontario), with respect to Profound Medical Corporation (“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 statements 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 expectations regarding future clinical trials, expectations regarding regulatory approvals, expectations regarding the safety and efficacy of its products, expectations regarding the use of its products and its revenue, expenses and operations, plans for and timing of expansion of its product and service offerings, future growth plans, ability to attract and develop and maintain relationships with suppliers, manufacturers, physicians/clinicians, etc., ability to attract and retain personnel, expectations regarding growth in its product markets, competitive position and its expectations regarding competition, ability to raise debt and equity capital to fund future product development, and anticipated trends and challenges in Profound’s business and the markets in which it operates.

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, the risks and uncertainties discussed in the “Risk Factors” section in the Company’s Annual Information Form dated March 7, 2019, such as successful completion of clinical trial phases with respect to Profound’s device, obtaining regulatory approvals in relevant jurisdictions to market Profound’s device, risks related to the regulation of Profound (including the healthcare markets, lack of funding may limit the ability to commercialize and market Profound’s products, fluctuating input prices, international trade and political uncertainty, healthcare regulatory regime in relevant jurisdictions may affect the Company’s financial viability, reimbursement models in relevant jurisdictions may not be advantageous), competition may limit the growth of Profound, if the Company breaches any of the agreements under which it licenses rights from third parties, Profound could lose license rights that are key to its business, loss of key personnel may significantly harm Profound’s business and past performance is not indicative of future performance, 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. 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.

“My life should not have to change”

TULSA-PRO®

Ablative Treatment of Prostate Disease
U.S. FDA Cleared, August 2019

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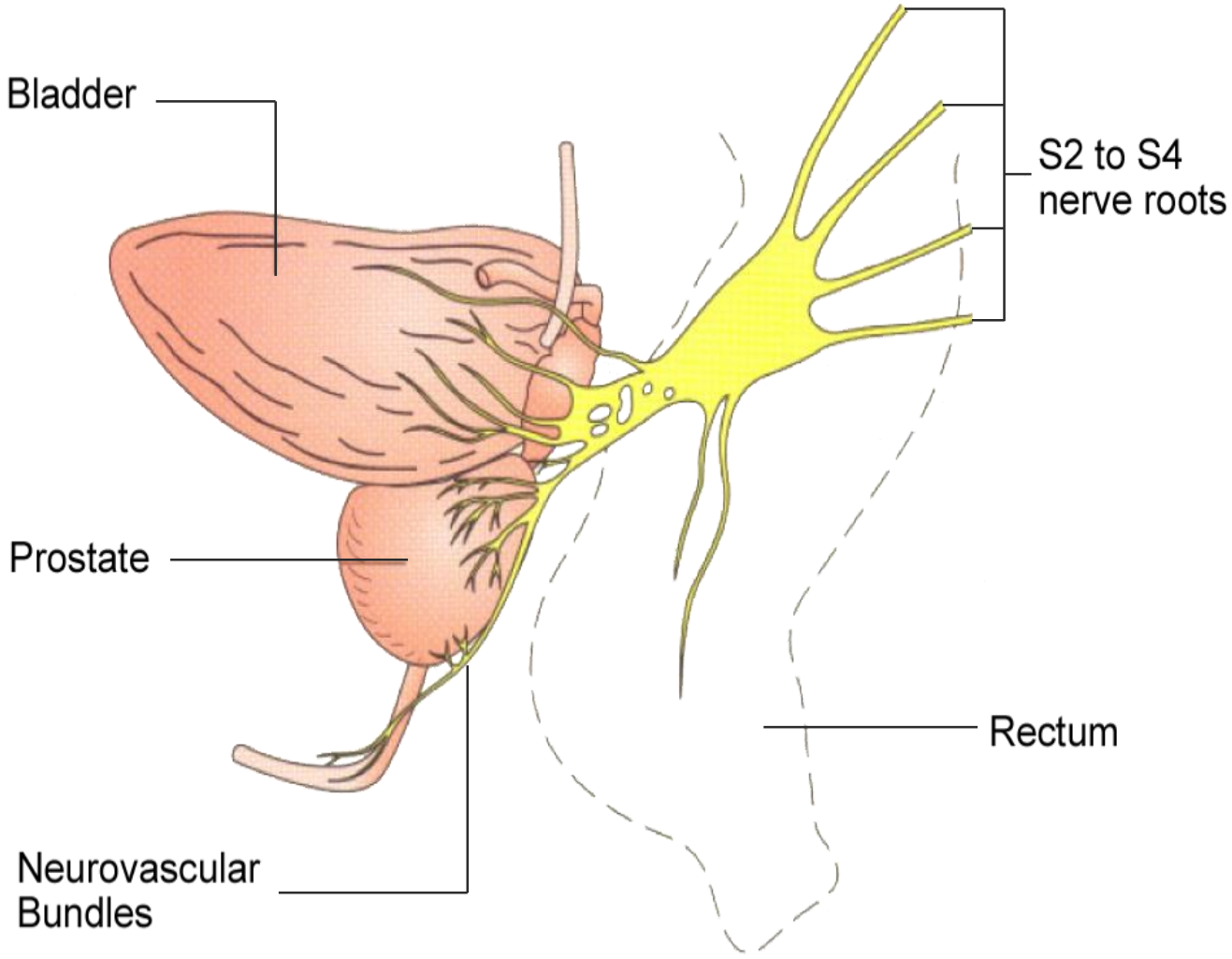
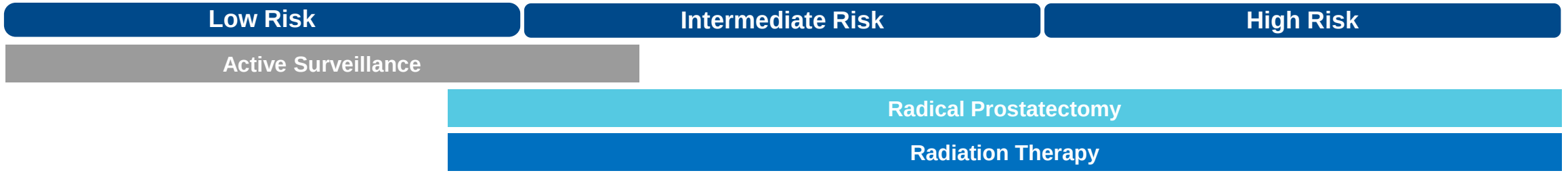
Prostate Disease and Management



Source: Kirby (1997) An Atlas of Prostatic Diseases, The Encyclopedia of Visual Medicine Series.

Localized Prostate Cancer: **Significant Unmet Need Remains**



ACTIVE SURVEILLANCE	RADICAL PROSTATECTOMY	RADIATION THERAPY
Selected Delayed Treatment	**Invasive Surgery**	**Ionizing Radiation (multiple fractions, 8 weeks)**
• Serial monitoring: Biopsy, PSA, DRE, MRI • Psychological distress • Biopsies painful with 3% risk of sepsis	• Urinary incontinence (severe): 16% (4-31%)[5] • Urinary stricture (req. Tx): 9% (3-26%) • Erectile dysfunction: 79% (25-100%)	• Bowel dysfunction: 25% (0-40%) • Urinary incontinence (severe): 4% (2-15%) • Erectile dysfunction: 63% (7-85%)
• >50% patients undergo prostatectomy or radiation within 5 years[3]	• Success depends on surgeon skill • Inpatient & Weeks recovery time	• Risk of secondary cancers • Delayed response and assessment of treatment success (2 years) • 30% patients fail treatment[1]

Opportunity for patients with organ confined disease
- less invasive, function-preserving therapies
- do not preclude additional intervention if needed in future

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The TULSA **Treatment**

Customizable Incision-Free Therapy: Combining 3 Powerful Modalities

1. Real-time MR imaging

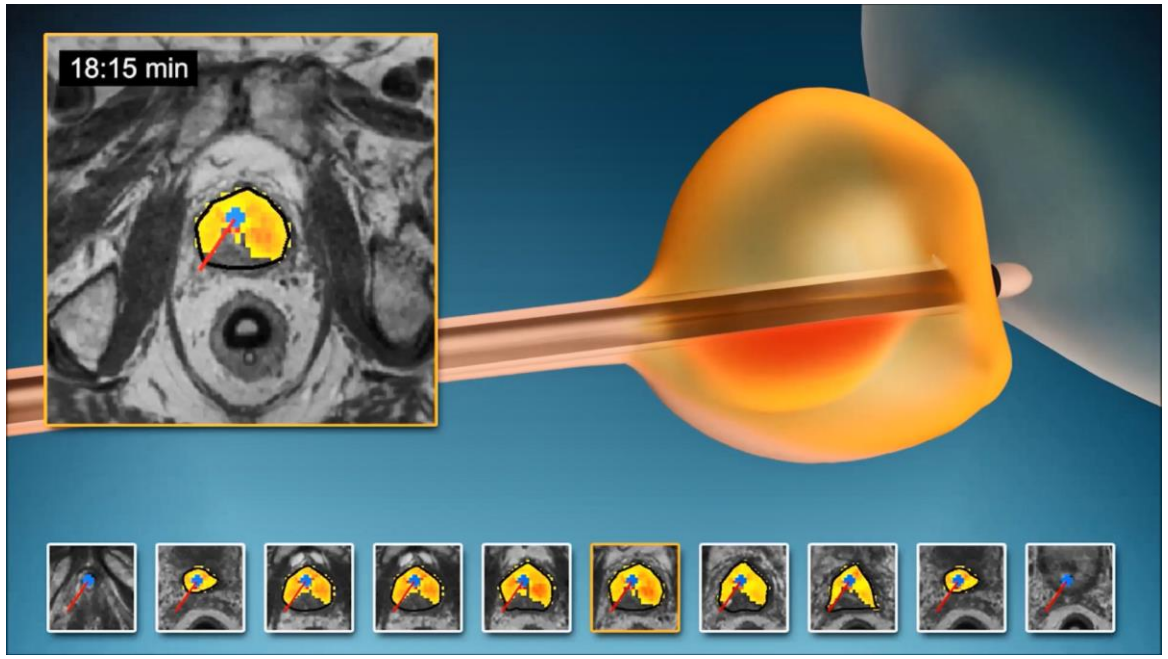
- Customizable, predictable treatment planning

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

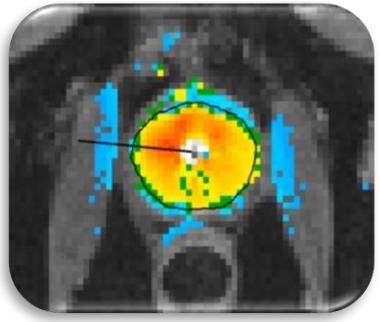
- Real-time temperature feedback provides for gentle and precise ablation



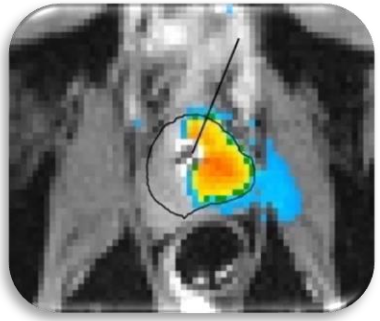
TULSA **Flexibility**

One device for many types of prostate diseases

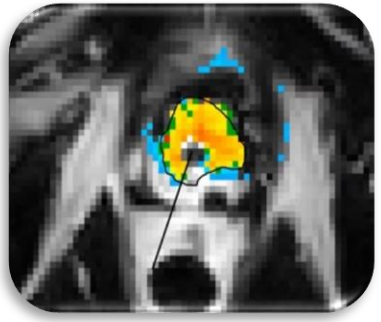
Whole Gland Ablation



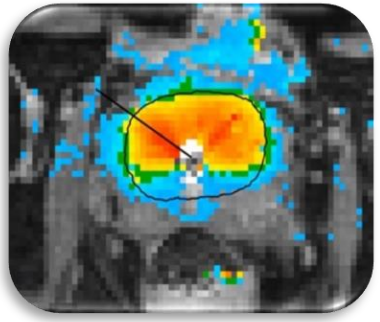
Targeted Ablation



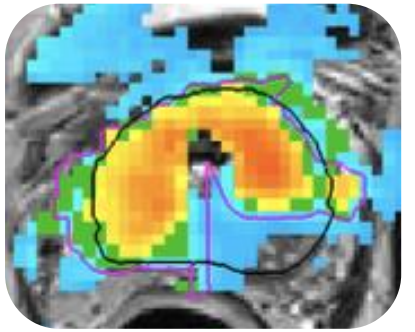
Salvage Therapy Post Radiation Therapy Failure



Benign Prostate Hyperplasia (BPH)



Patient with BPH and early-stage lesion



20% of men over 50,
60% of men over 60 have BPH

TULSA-PRO especially suitable for large prostates >80 CC

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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

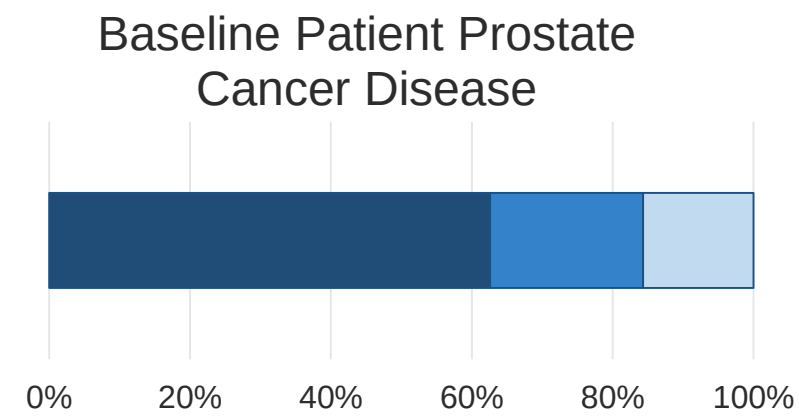
- Treatment intent was whole-gland ablation with sparing of the urethra and urinary sphincter
- Recommended by FDA to determine substantial equivalence with predicate devices and comparison with standard of care

Primary Endpoints (12 months)

- Safety: Frequency and severity of adverse events
- Efficacy: PSA reduction ≥ 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:

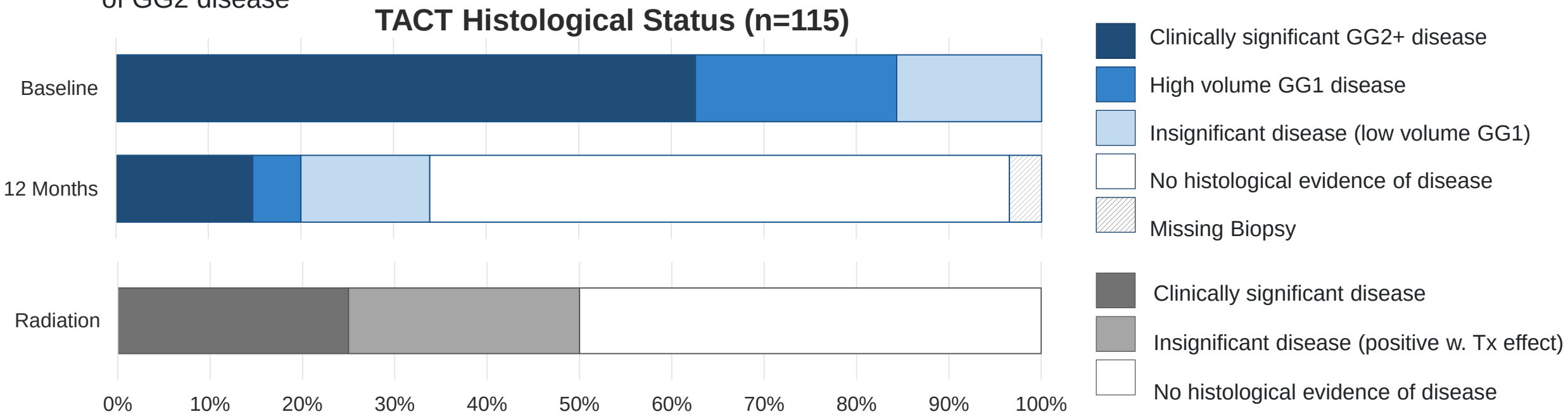
- Primary endpoint of PSA reduction ≥75% was achieved in 110 of 115 (96%)
- Median (IQR) PSA reduction was 95% (91-98%)
- Median PSA nadir was 0.34 (0.12-0.56) ng/ml

	Pre-Treatment	12 Month	PSA NADIR
N	115	115	115
Median	**6.26**	**0.53**	**0.34**
IQR	4.65 – 7.95	0.28 – 1.25	0.12 – 0.56
Average	**6.72**	**0.93**	**0.51**
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 disease
- 41% (16 of 39) of positive biopsies were clinically insignificant (Very Low Risk)
- Multivariate Analysis: Among men w. pre-Tx GG2 disease and w/o calcifications at screening, 51 of 60 (85%) were free of GG2 disease



1. Thompson (Chair) *et al,* AUA prostate cancer clinical guideline update panel, J Urol 2007
2. Resnick et al, Prostate Cancer Outcomes Study (PCOS), NEJM 2013
3. Potosky *et al*, Prostate Cancer Outcomes Study (PCOS), J NCI 2004
4. Elliott *et al*, CaPSURE database, J Urol 2007
5. Budaus et al, Review, Eur Urol 20012

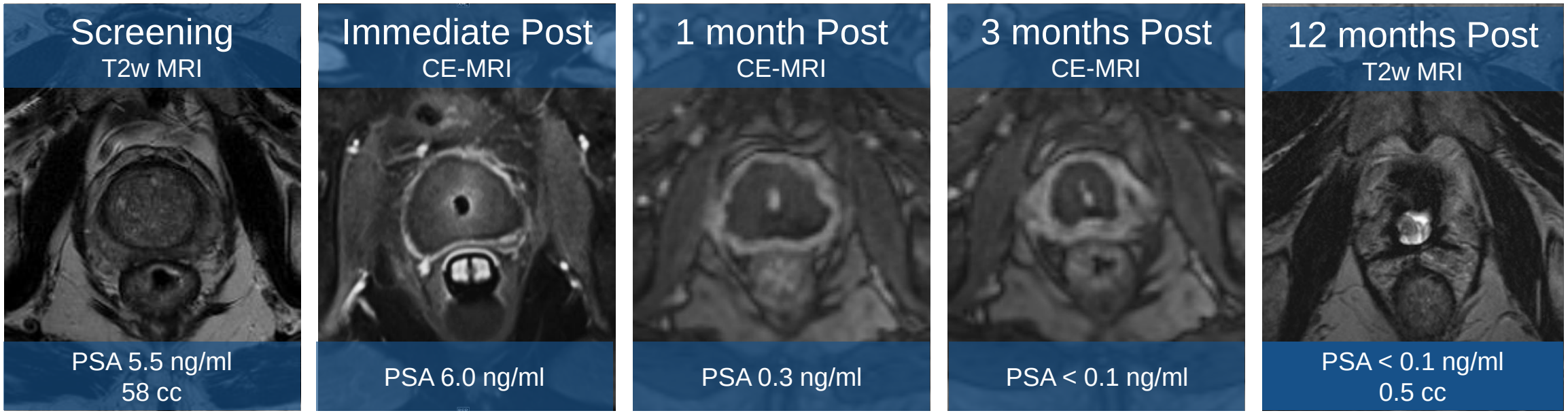
TACT: **Prostate Volume Reduction**

Prostate volume significantly reduced demonstrating effective prostate ablation

- Median perfused prostate volume decreased from 41 cc to 4 cc, on MRI at 1 year (interim analysis by local radiologists)
- Prostate volume reduction to be re-assessed by Central Radiology Core Lab, as per TACT protocol
- 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 ≥ 3 lesion at 1-year multi-parametric MRI has 92% Negative Predictive Value for absence of GG2 disease on 1-year biopsy (interim analysis by local radiologists, to be re-assessed by Central Radiology Core Lab)

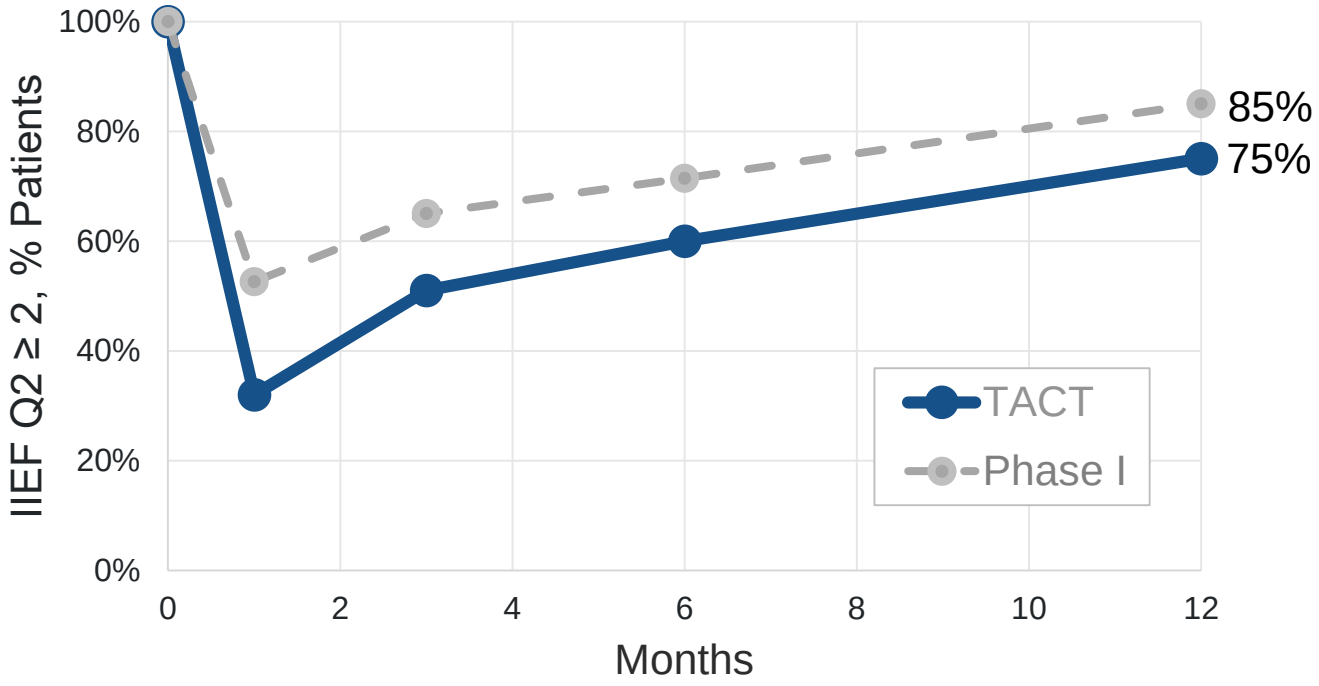


TACT: **Erectile Function**

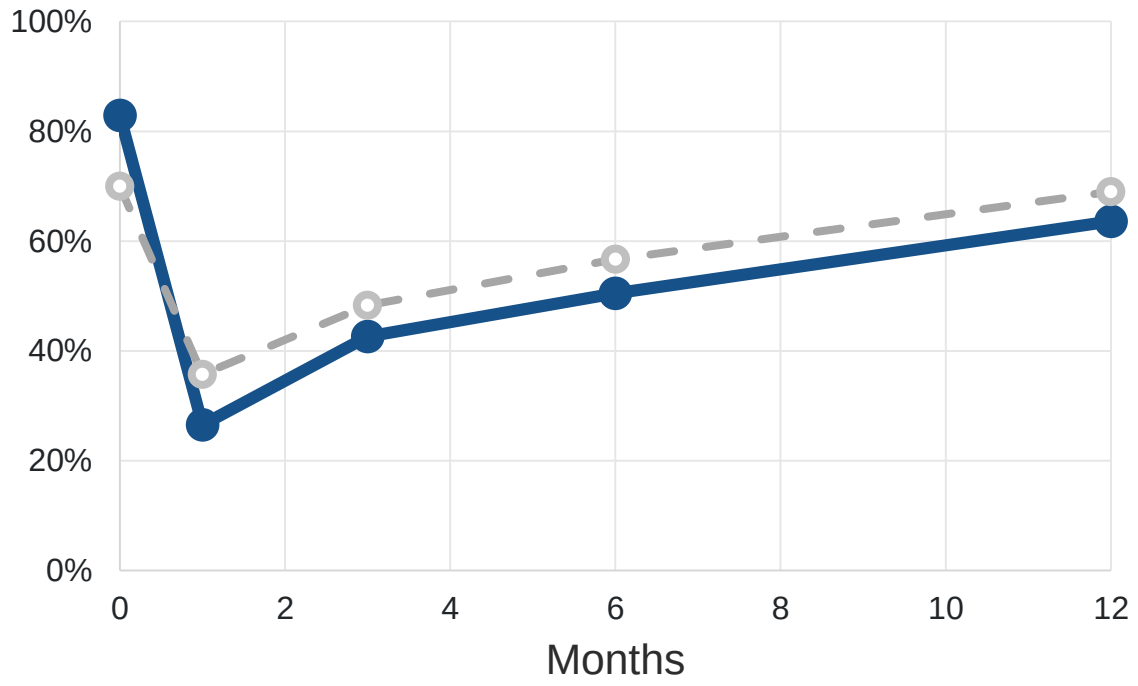
Erectile Function, at one year:

- 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
- Trend and recovery similar to Phase I

Patients Potent at Baseline (n=92)



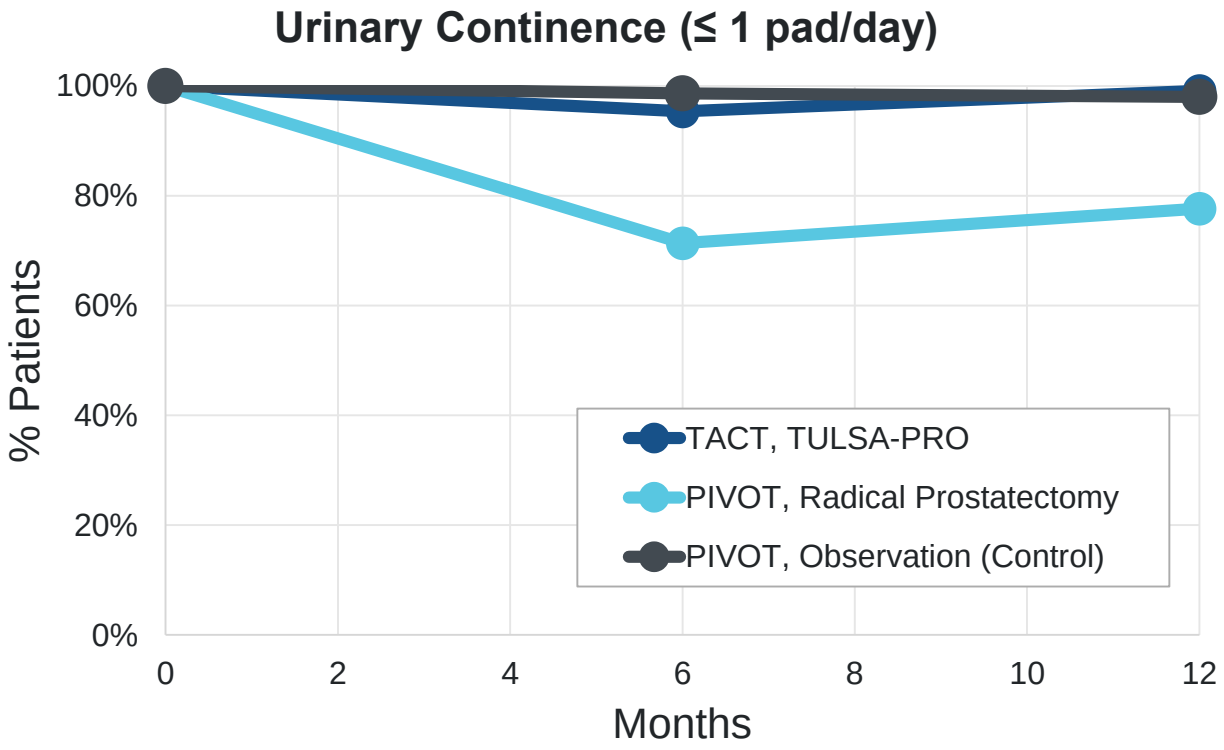
All Patients (n=110)

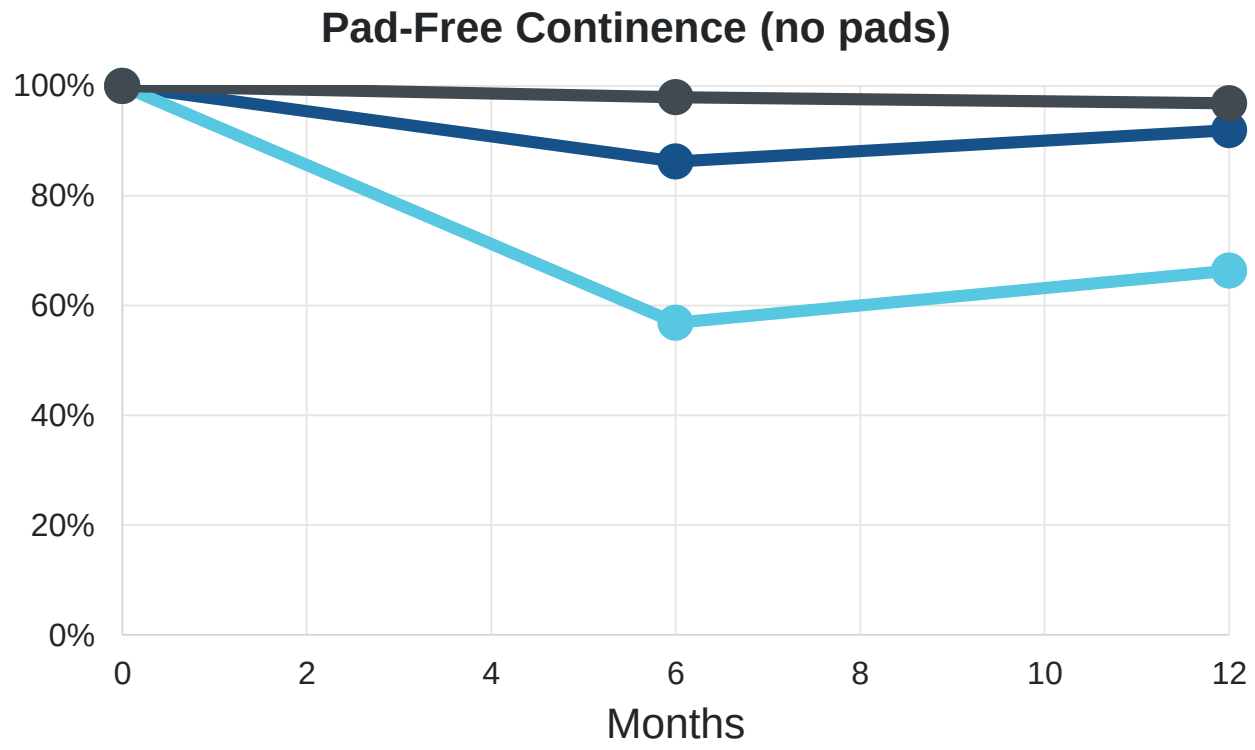


TACT: **Urinary Incontinence**

Urinary Incontinence (Pad use), at one year:

- TULSA Urinary Continence (≤ 1 pad/day) similar to Observation (control) arm of PIVOT study
- TULSA Pad-Free Continence (no pads) only 5%-points lower than Observation (control) arm of PIVOT study
- TULSA continence outcomes markedly superior to Radical Prostatectomy arm of PIVOT study
- PIVOT: Wilt *et al*, The *New England Journal of Medicine*, 2017





Real World Context & Outcomes

	Prostatectomy [1-4]	Radiation [1-5]	HIFU [6-8]	TULSA (TACT)
Biopsy / Histology	**16 – 24% Pos. Surg. Margin** (Meta-Analysis, Tewari *et al* 2012) **10 – 15% Pos. Surg. Margin** (RCT, Yaxley *et al* 2016) **24% Pos. Surg. Margin** (ProtecT, Hamdy *et al* 2016)	**50% Negative** (Complete response) **25% Insignificant disease** (Positive w. treatment effect) **25% Positive clinically significant Pca** (Meta-Analysis Page 5, Approx. No.)	**59 – 61% Negative** (Complete response, FDA IDE Studies DEN150011 & K153023, Intent to treat analysis) **63% Negative, after 40% having repeat HIFU and 39% ADT** (n=774, Crouzet *et al* 2013)	**65% Negative** (Complete response) **14% Insignificant disease** (GG1, ≤2 cores, < 50% CCL) **21% Positive clinically significant Pca**
Erectile Dysfunction erections insufficient for penetration	**79%** *(Range: 25 – 100%)*	**63%** *(Range: 7 – 85%)*	**58%** *(Range: 38 – 67%)*	**20% – 25%** Grade 2 medication indicated. No Grade 3 ED
Urinary Incontinence moderate to severe	**15%** *(Range: 0 – 50%)*	**4%** *(Range: 2 – 15%)*	**3%** *(Range: 3 – 22%)*	**2.6%** Grade 2 pads indicated. No Grade 3 Incontinence
Urethral Stricture moderate to severe	**9%** *(Range: 3 – 26%)*	**2%** *(Range: 1 – 9%)*	**35%** *(Range: 9 – 35%)*	**2.6%**
GI Toxicity, moderate to severe diarrhea, urgency, incontinence, fistula	**15%** *(Range: 0 – 24%)*	**25%** *(Range: 0 – 40%)*	**7%** *(Range: 1 – 21%)*	**No GI Toxicity**

References:

1. Thompson (Chair) *et al,* AUA prostate cancer clinical guideline update panel, J Urol 2007
2. Resnick et al, Prostate Cancer Outcomes Study (PCOS), NEJM 2013
3. Potosky *et al*, Prostate Cancer Outcomes Study (PCOS), J NCI 2004
4. Elliott *et al*, CaPSURE database, J Urol 2007
5. Budaus *et al*, Review, Eur Urol 20012
6. FDA IDE Study K153023
7. FDA IDE Study DEN150011
8. Crouzet *et al*, Whole-gland HIFU, Eur Urol 2014

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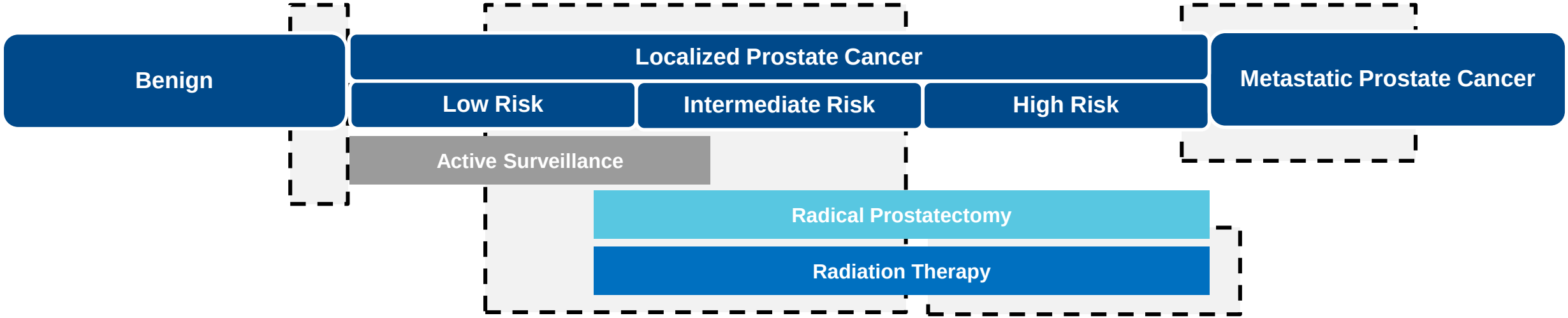
Broader & Deeper Use of TULSA for Prostate Disease



BPH

- Large and Very Large Prostates
- Preservation of ejaculatory function
- Combined with targeted cancer ablation
- Prophylactic ablation of suspicious MRI lesion

Customized Targeted Ablation (25% - 99%)

- Targeted and customized to any size prostate and disease
- Large ablations (wide margins, not too focal, 25% - 99% ablation)

Recurrence after Radiation

- Localized recurrences have limited options, and morbidity is high

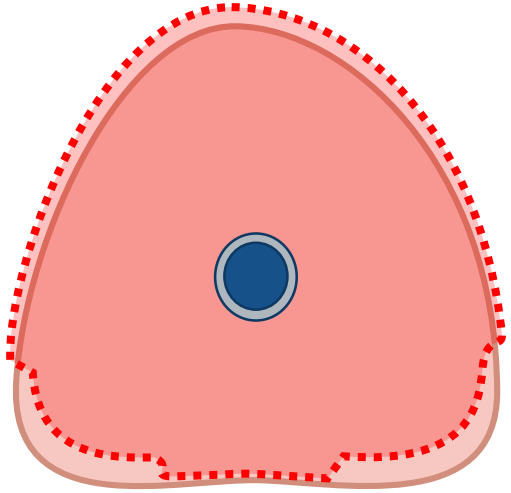
Palliative Locally Advanced

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

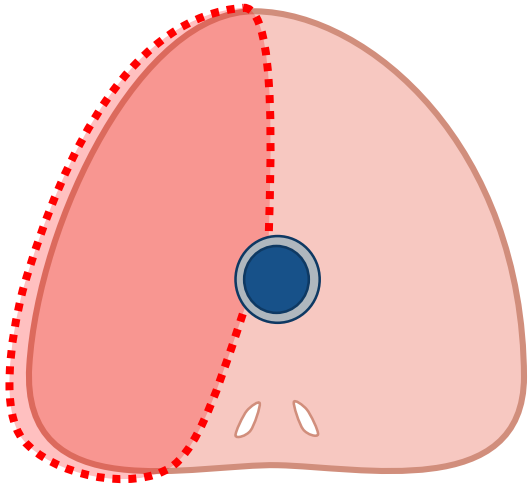
Oligometastatic

- Benefit to locally treat prostate
- Often radio-recurrent

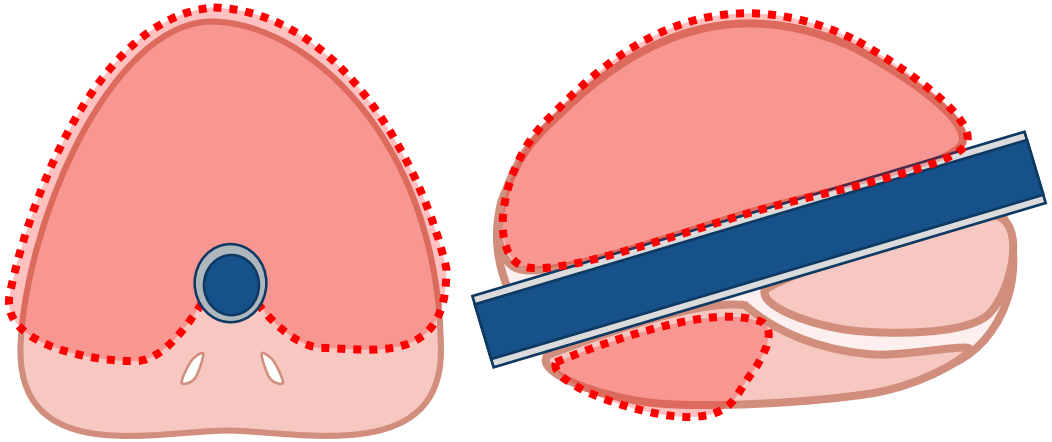
Optimizing Treatment Design to **Maximize Efficacy & Minimize Side Effects**



Bilateral Sparing
Ablation of cancerous prostate tissue



Targeted & Customized ablation of diseased prostate tissue



Ablation of benign tissue to treat BPH

Commercial Experience in **Europe**

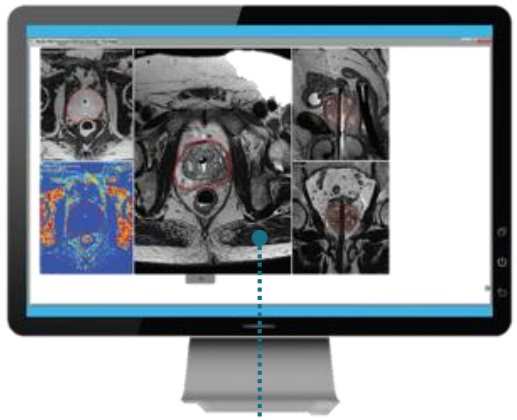
	Prostatectomy	Radiation	TULSA
Throughput, Procedures/Day	2 typically, 3 on a longer day	Multiple sessions: 5 to 40, 4 - 8 weeks	• 4 in a routine day • Consistent treatment times
Patient Recovery	Weeks	Deterioration over time	• 2 days • Minimal need for pain management

TULSA-PRO **System Components**

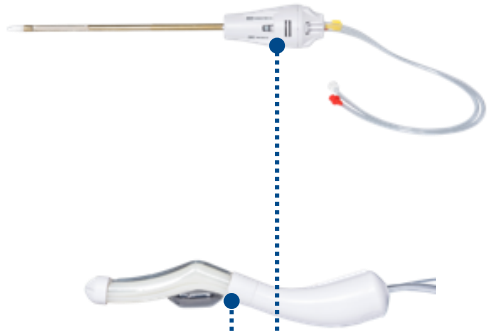
Compatible with MR from leading companies, Philips and Siemens

Robotic Arm, Computer Hardware

Energy System



Surgeon Console Control Room



Disposable Applicators

Capital Equipment

One-Time Consumables

Total Addressable Market: **Pre-reimbursement**

# of U.S. prostate cancer + BPH patients requiring intervention	**575,000[1,2]**
Pre-reimbursement addressable market in U.S: 5% -10% of total	**29,000 – 58,000**
Add selected international markets (UK, Germany, Canada, Japan)	**14,500 – 29,000**
Total addressable market, selected countries	**43,500 – 87,000**
Addressable market, $4,000/patient ($ disposable revenue only)	**$174 – $348 Million**
Achievable – capturing 25% of addressable market (<11,000 patients per year)	**$44 – $87 Million**

Upside potential – 5.5 million patients currently diagnosed with prostate cancer remain on Active Surveillance. The low side effect profile of the TULSA treatment may prompt this patient population for TULSA instead of waiting. Just 1% of the population could represent an additional revenue opportunity of $220 Million.

References:
1. Prostate cancer: 175,000 new prostate cancer diagnosed each year in US according to American Cancer Society
2. BPH: 300,000 surgeries based upon CMS data, + 1% of 10 Million BHP patients in United Stated

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U.S. Market Entrance Strategy

1. **Educating Urologists on TACT clinical data and the TULSA-PRO technology**
   - Presented to >100 urologists at >50 institutions
2. **Creating a pipeline of early adopters based upon feedback from presentations**
3. **Developing TULSA-PRO installed base and delivery channels**
   - Imaging centers
   - Co-ops of urology practices who specifically focus on new technologies
   - Large opinion leading hospital-based practices
4. **Recurring revenue business model**
   - Disposable kit priced at $4,000/patient
   - Early adopter program for upfront capital costs – monthly rental fee or a fixed charge/treatment for use of device
   - Longer-term program – Capital sale or monthly rental for the device
5. **Supporting early-stage adoption with ‘Profound Genius Services’**

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

Profound Branded Patient Marketing

A. TULSA Treatment Patient Website
- EU/APEC launched TulsaTreatment.com
- U.S. site in development
- Global treatment site locator pages

B. Corporate Website
- Patient Page
- Language accessibility
- Blog development with patient-focused material
- TULSA clinical data webpage

C. Video Patient & Physician Testimonials
- Cross platform promotion across
  - New YouTube channel
  - Patient Page
  - TULSA treatment site
  - Social media

Customer Branded Patient Marketing

A. TULSA Patient Marketing Print Material (Kit)
- Patient value brochure
- Patient procedure overview pamphlet
- 'Could TULSA be for me?'

B. TULSA Marketing Digital Material
- Site branded testimonials
- Digital marketing collateral as required
  - Ad campaigns
  - Social media banners

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)

SourceL https://www.ama-assn.org/practice-management/cpt/criteria-cpt-category-i-and-category-iii-codes

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

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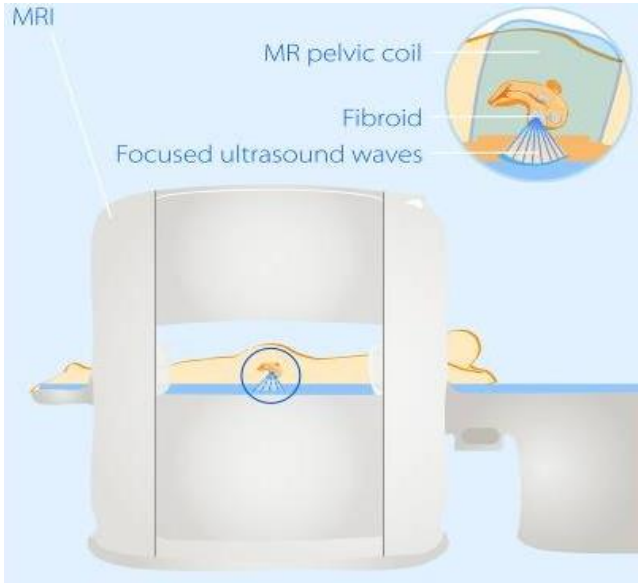
SONALLEVE

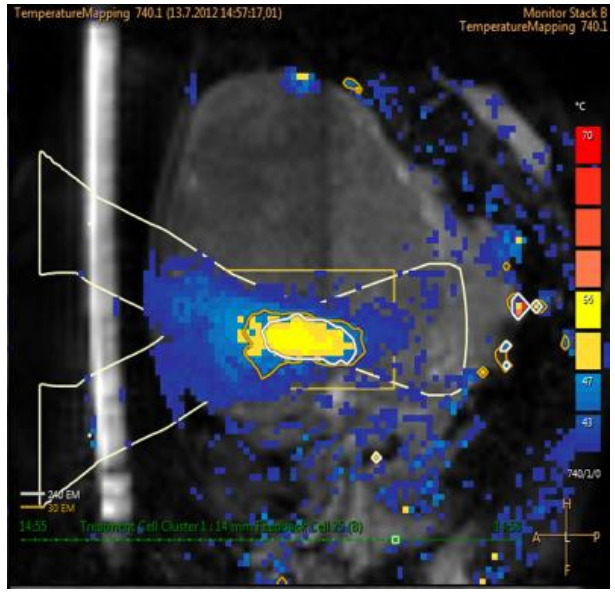
CURRENT APPROVALS

- 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





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

In **Summary**

Introducing TULSA-PRO to U.S. market

- Pre-reimbursement TAM $50 - $100 million/year
- Potential to expand TAM by 10X or more following reimbursement

Business model is 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