PROFOUND

Customizable Incision-Free Ablation Therapies
Men's and Women's Health

CORPORATE PRESENTATION | AUGUST 2019

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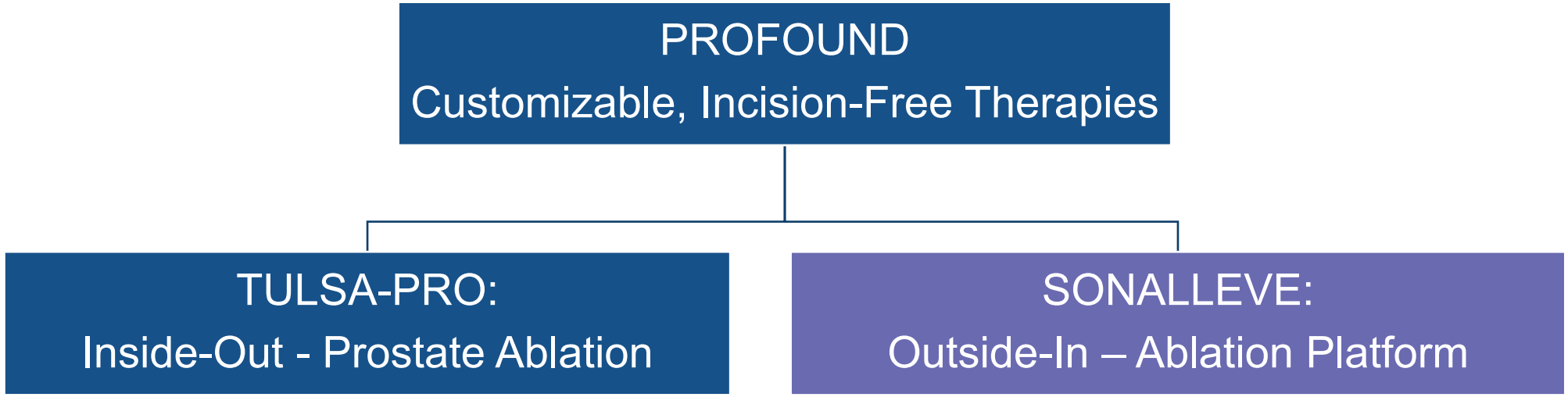
Creating Customizable Incision-Free Therapies By Combining **Three Powerful Modalities**

Real-time MRI imaging

Thermal ultrasound

Closed-loop temperature feedback control

Customizable Incision-Free Therapies



TULSA-PRO®

CE Marked

Filed For US FDA – May 2019

'My life should not have to change'

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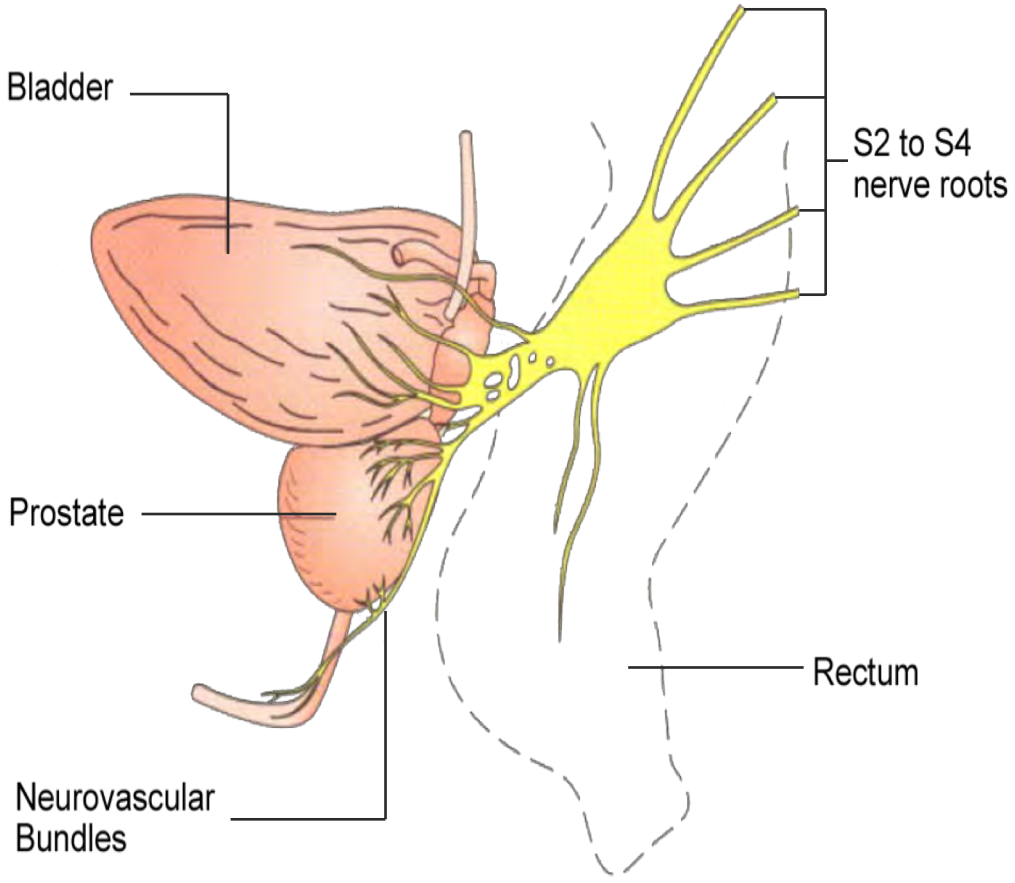
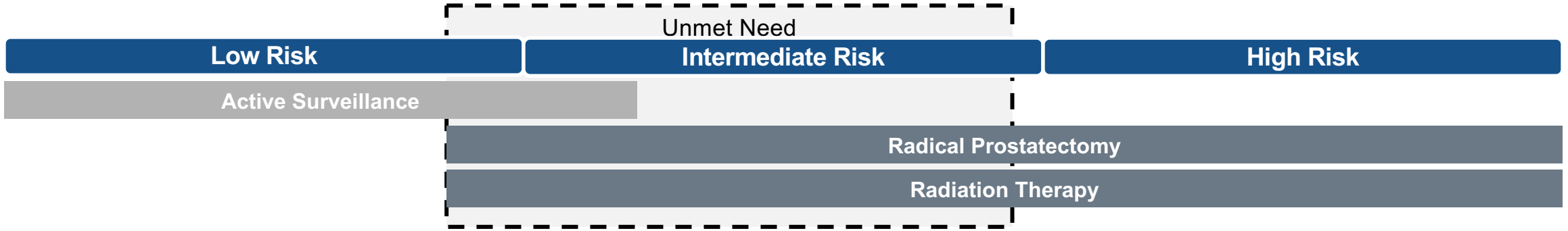
Prostate Disease and Management



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

Localized Prostate Cancer – **Unmet Need in Standard of Care**



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]
10 yr. cost: $29,000[2]	Surgery cost: $15,692[4]	Treatment cost: $27,564[4]

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

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MR-Guided TULSA – Closed Loop Temperature Control

1. Transurethral directional ultrasound ablation

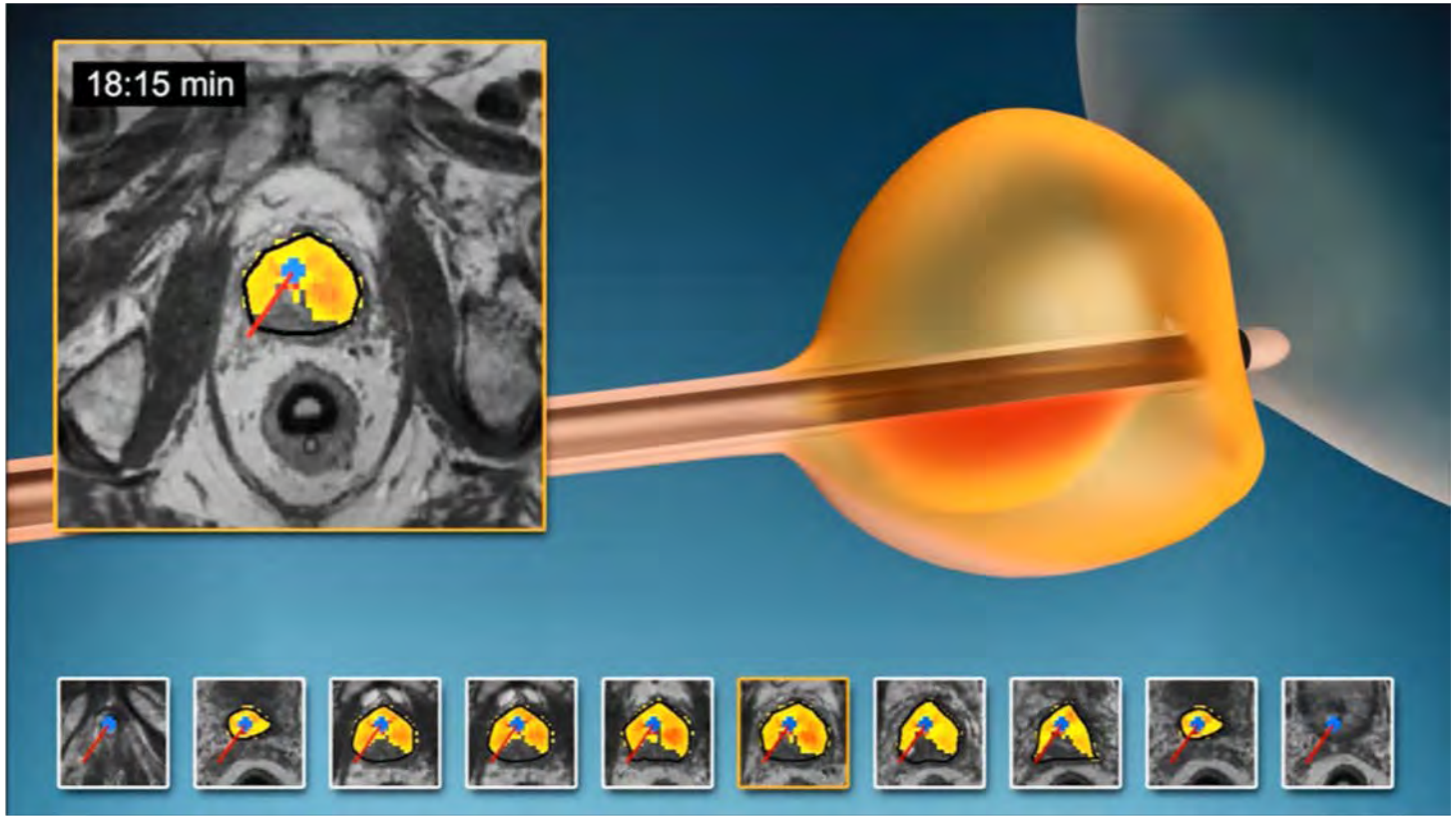
- Sweeping ultrasound, continuous rotation (no risk of cold spots between discrete sonications)
- Capable of treating large and small prostate volumes

2. Real-time MRI & Closed-loop thermal ablation

- Real-time temperature feedback provides millimeter accuracy

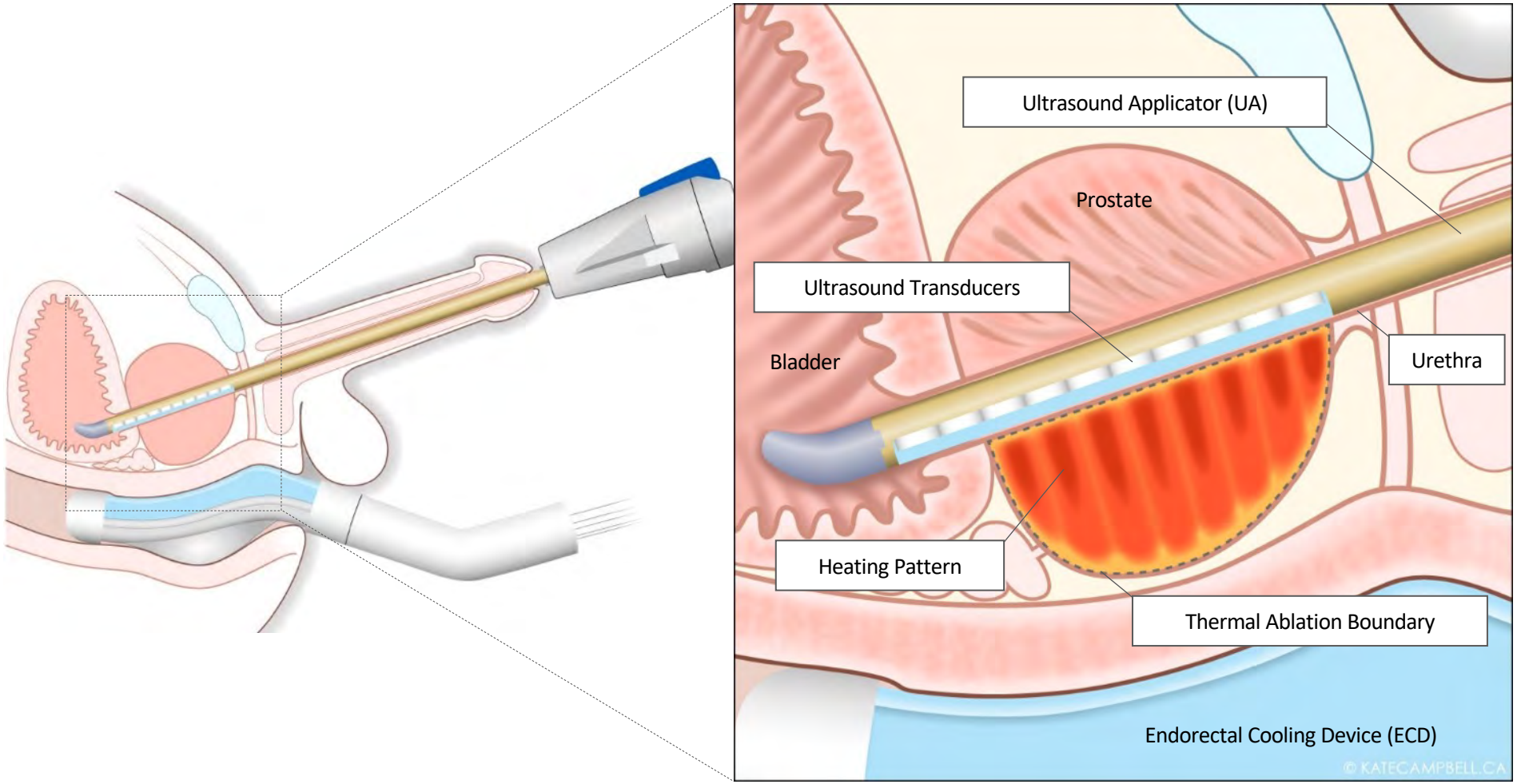
3. Urethra and rectum cooled

- Thermal protection of important anatomy



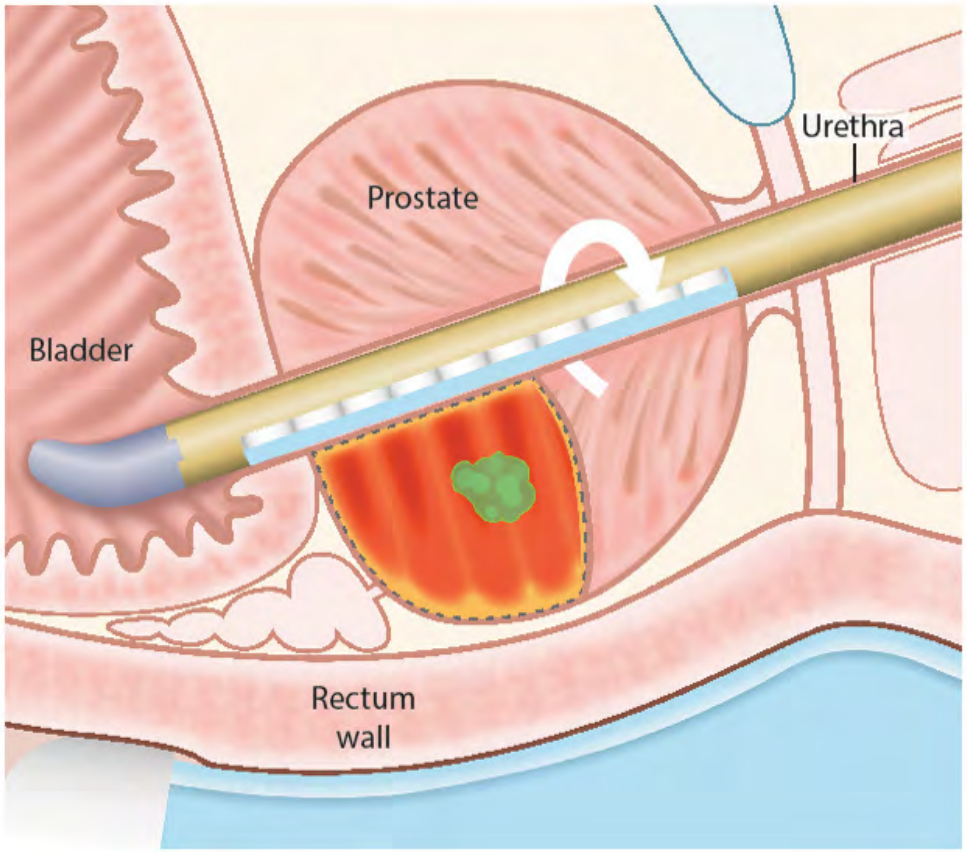
TULSA-PRO – Prostate Ablation From The Inside Out

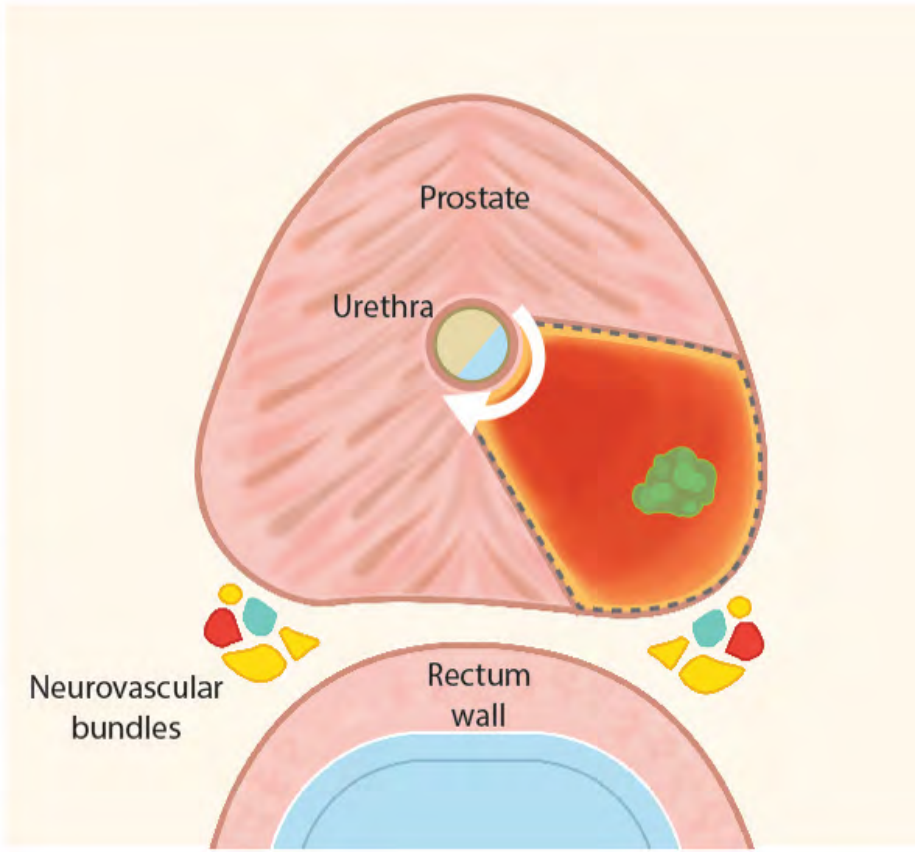
Whole Gland Ablation



TULSA-PRO – Targeted Ablation

Partial Gland Ablation

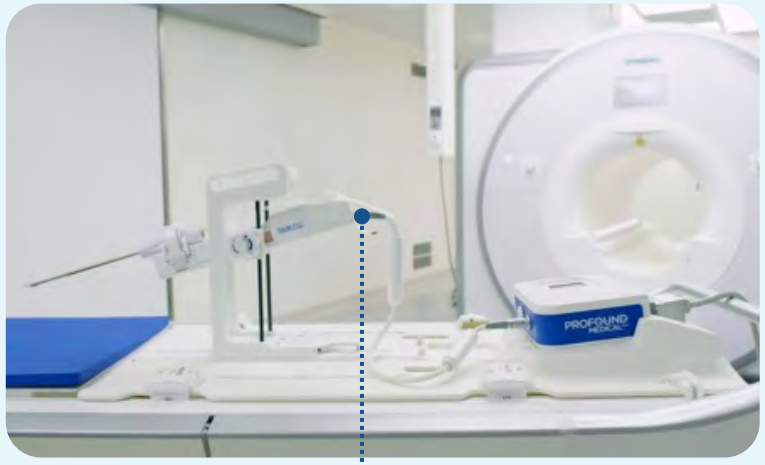




TULSA-PRO

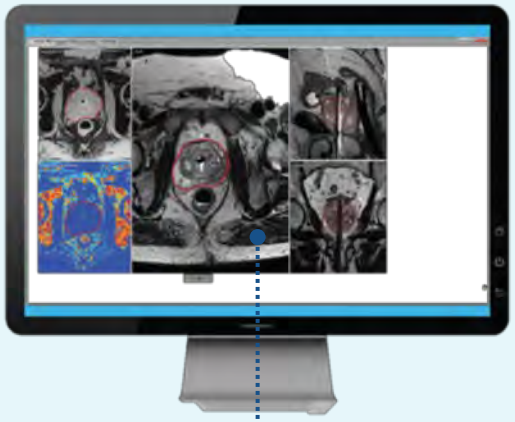
Equipment

Compatible with MR from leading companies – Philips and Siemens

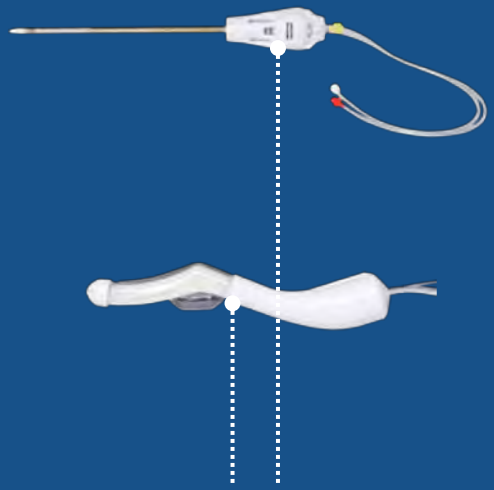


Robotic Arm,
Computer Hardware

Energy
System



Surgeon Console
Control Room

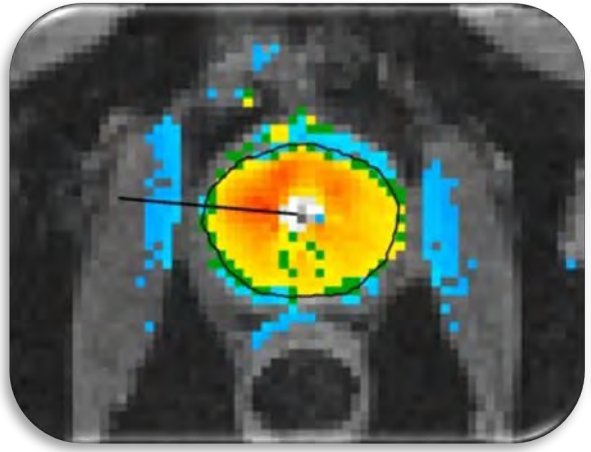


Disposable
Applicators

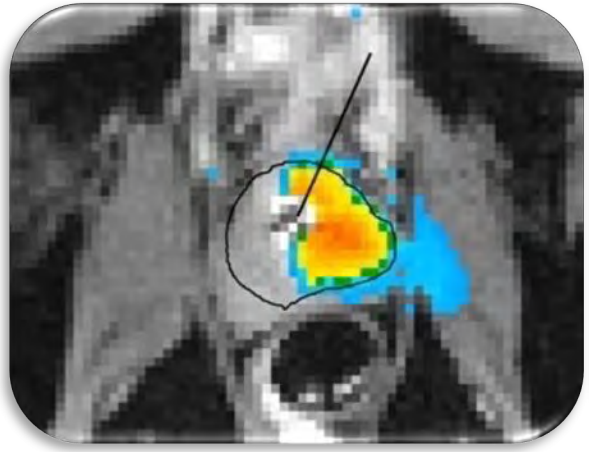
TULSA-PRO – A Three In One Device For Ablation

Customizable, Predictable, Incision-Free

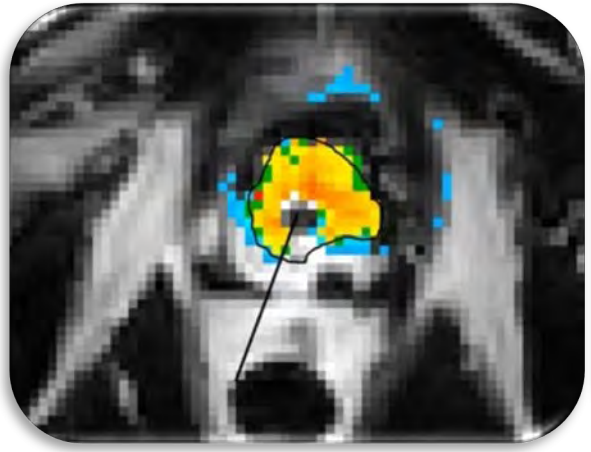
Whole Gland Ablation



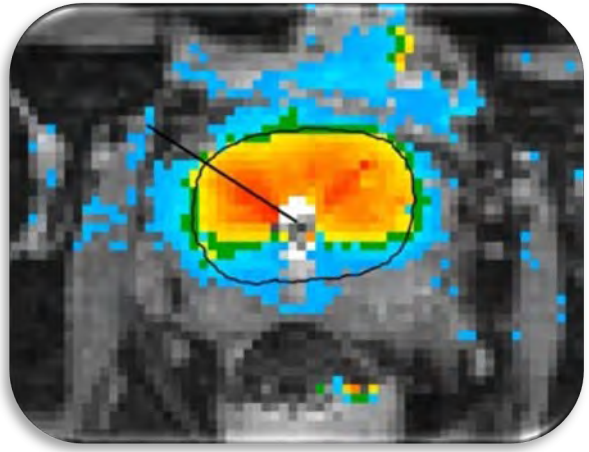
Targeted Ablation



Salvage Therapy Post Radiation Therapy Failure



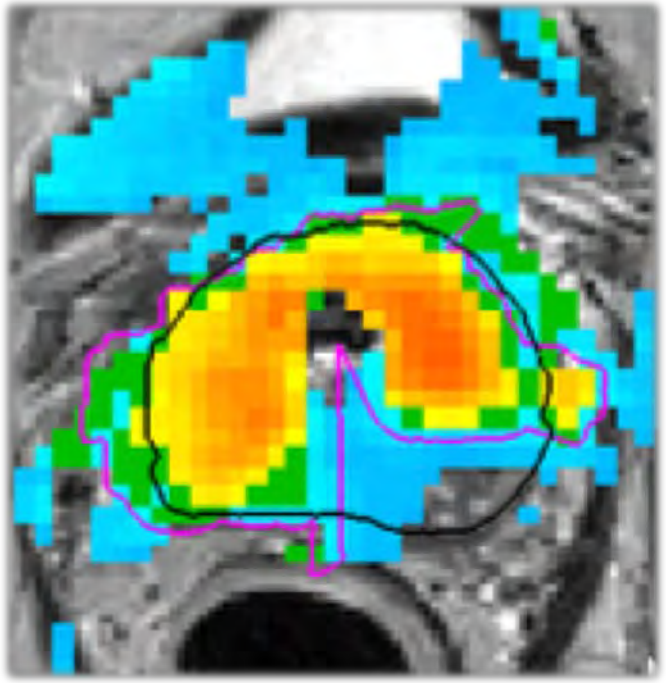
Benign Prostate Hyperplasia (BPH)



Example Prostate Tissue Ablation of Transition Zone & Suspicious Lesion

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

Profound technology specially suitable for large prostates >80 CC



Patient with BPH and early stage lesion

TACT – TULSA-PRO 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

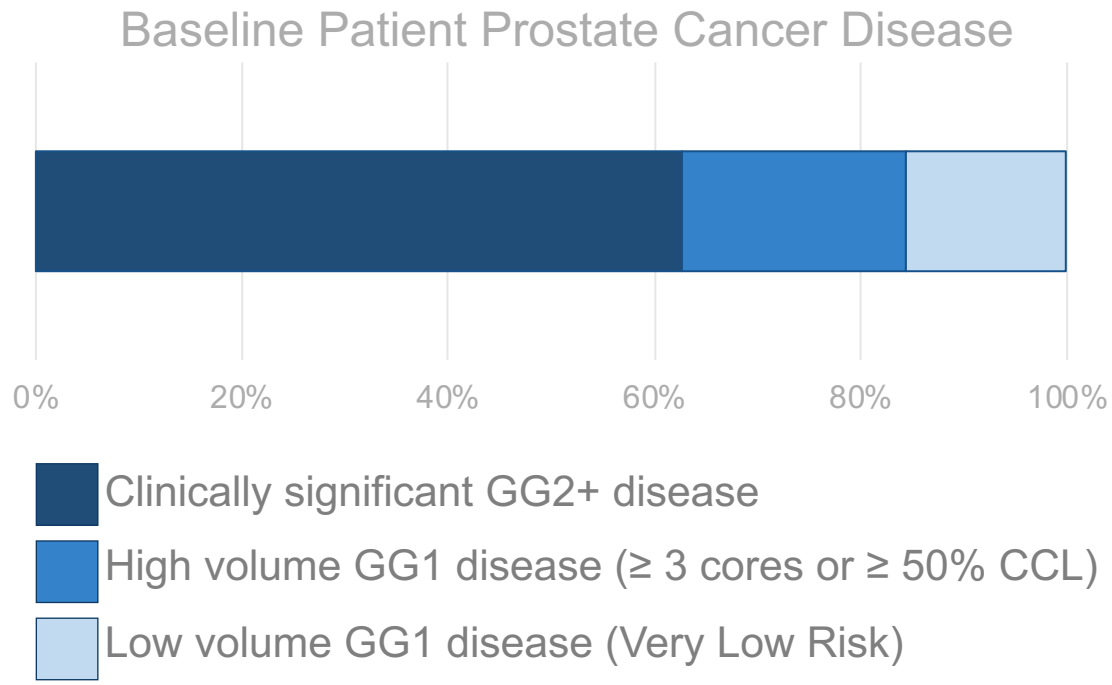
- Treatment intent was whole-gland ablation with sparing of the urethra and urinary sphincter
- Recommended by FDA to determine substantial equivalence with predicate devices and comparison with standard of care

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



Prostate **Ablation Efficacy** – PSA

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

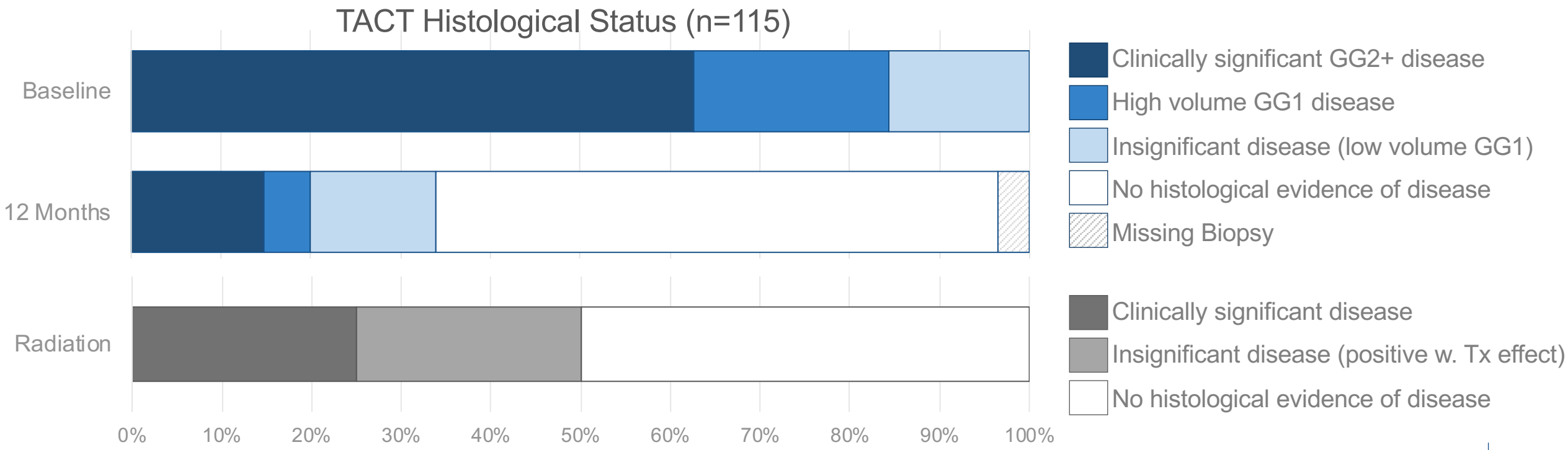
	Pre-Treatment	1 Month	3 Month	6 Month	12 Month	PSA NADIR
N	115	113	115	115	115	115
Median	**6.26**	**0.53**	**0.46**	**0.53**	**0.53**	**0.34**
IQR	4.65 – 7.95	0.30 – 1.19	0.17 – 0.95	0.20 – 1.00	0.28 – 1.25	0.12 – 0.56
Average	**6.72**	**0.90**	**0.77**	**0.77**	**0.93**	**0.51**
T-Test against baseline		<0.001	<0.001	<0.001	<0.001	<0.001

Missing values are interpolated using the LVCF method for the first time point after treatment.

TACT Clinical Data As Presented At AUA – May 2019

TACT 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



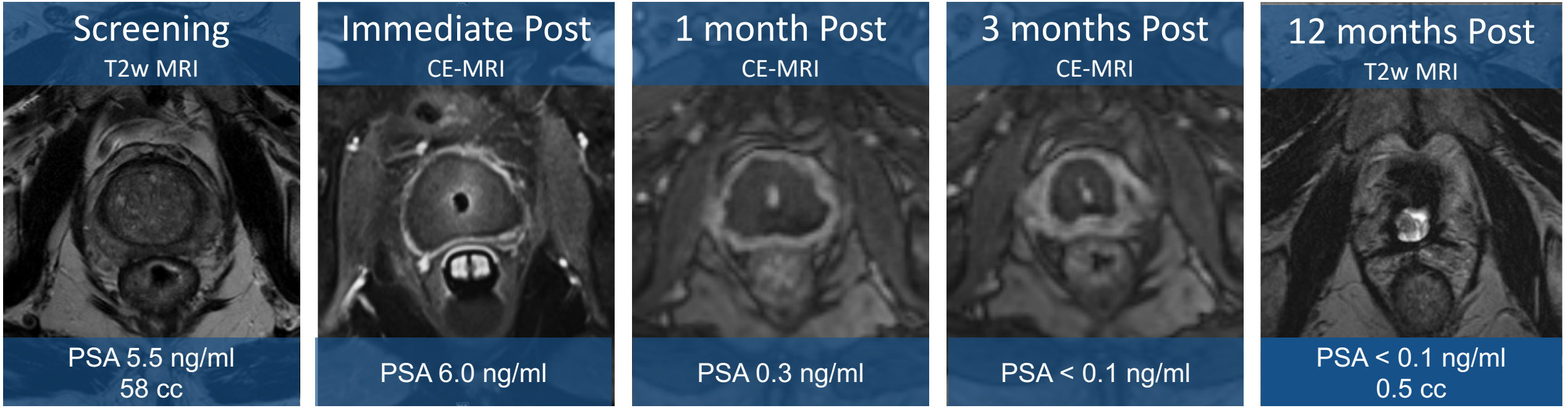
Prostate **Ablation Efficacy** – Volume Reduction on MRI

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

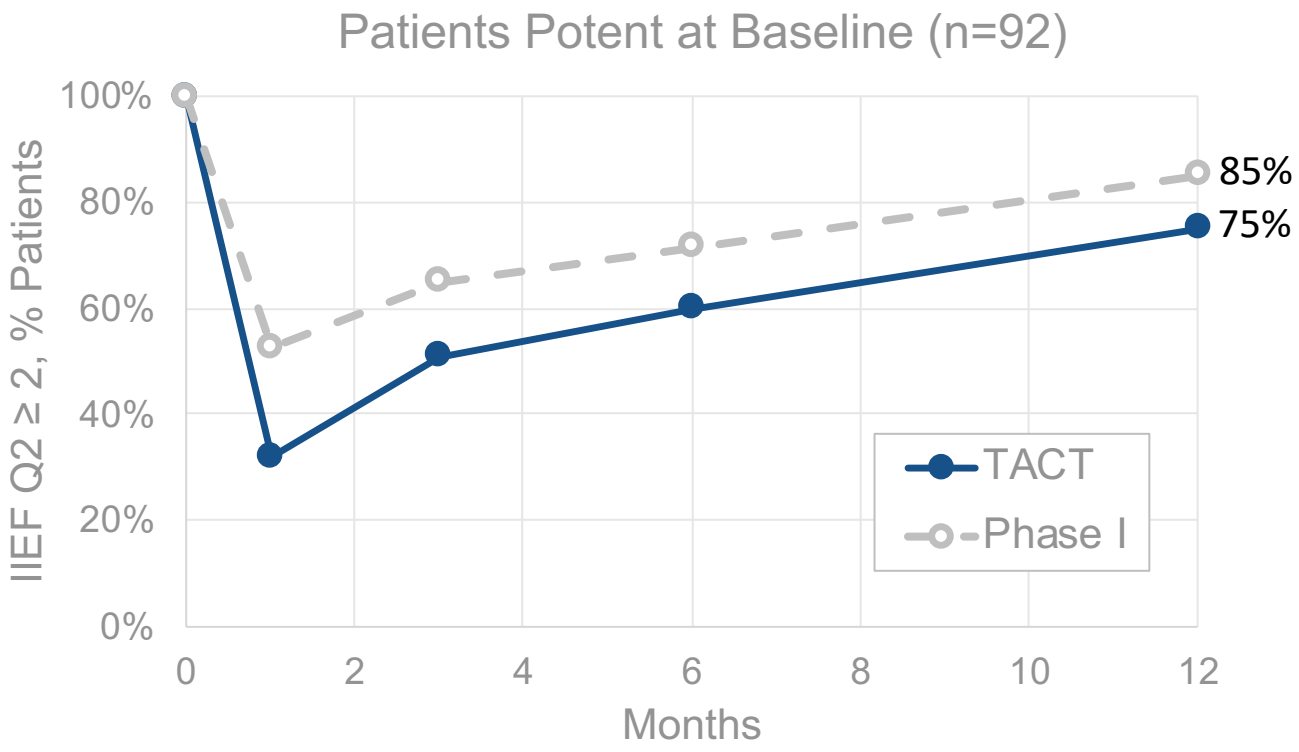
- Multivariate Analysis: Absence of PIRADS ≥ 3 lesion at 1-year multi-parametric MRI has **92% Negative Predictive Value** for absence of GG2 disease on 1-year biopsy (interim analysis by local radiologists, to be re-assessed by Central Radiology Core Lab)

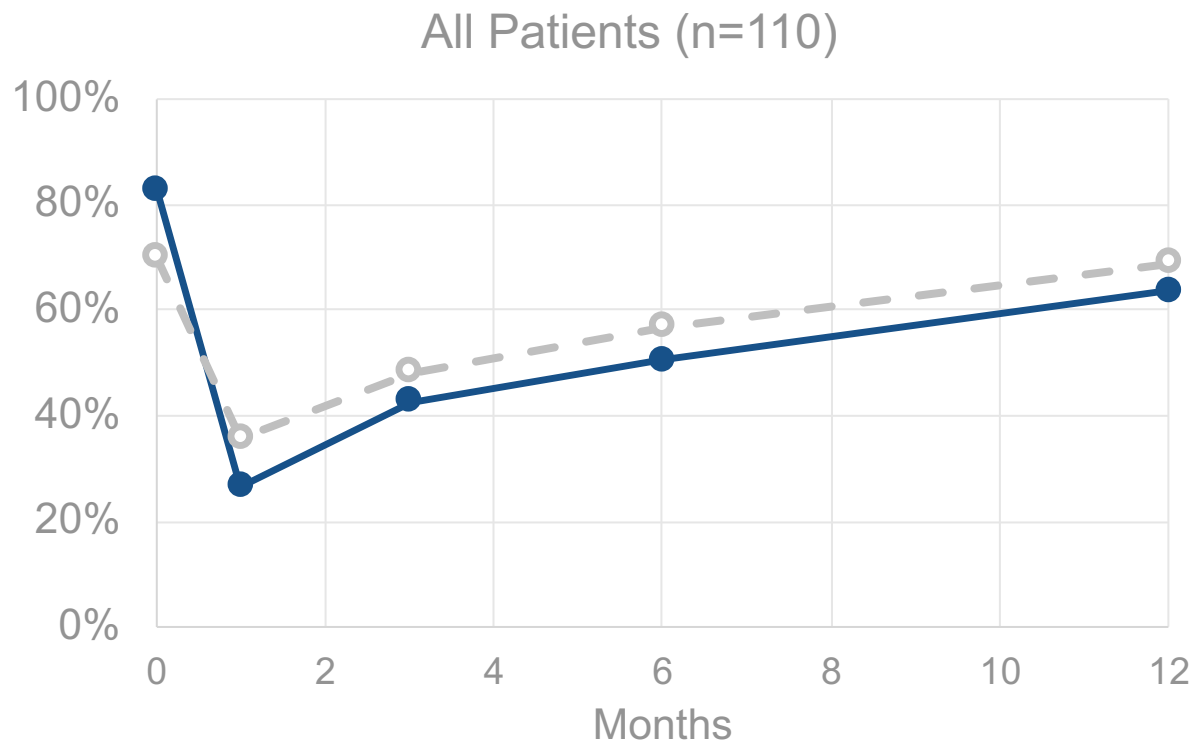


TACT **Erectile Function** – As Presented At AUA – May 2019

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

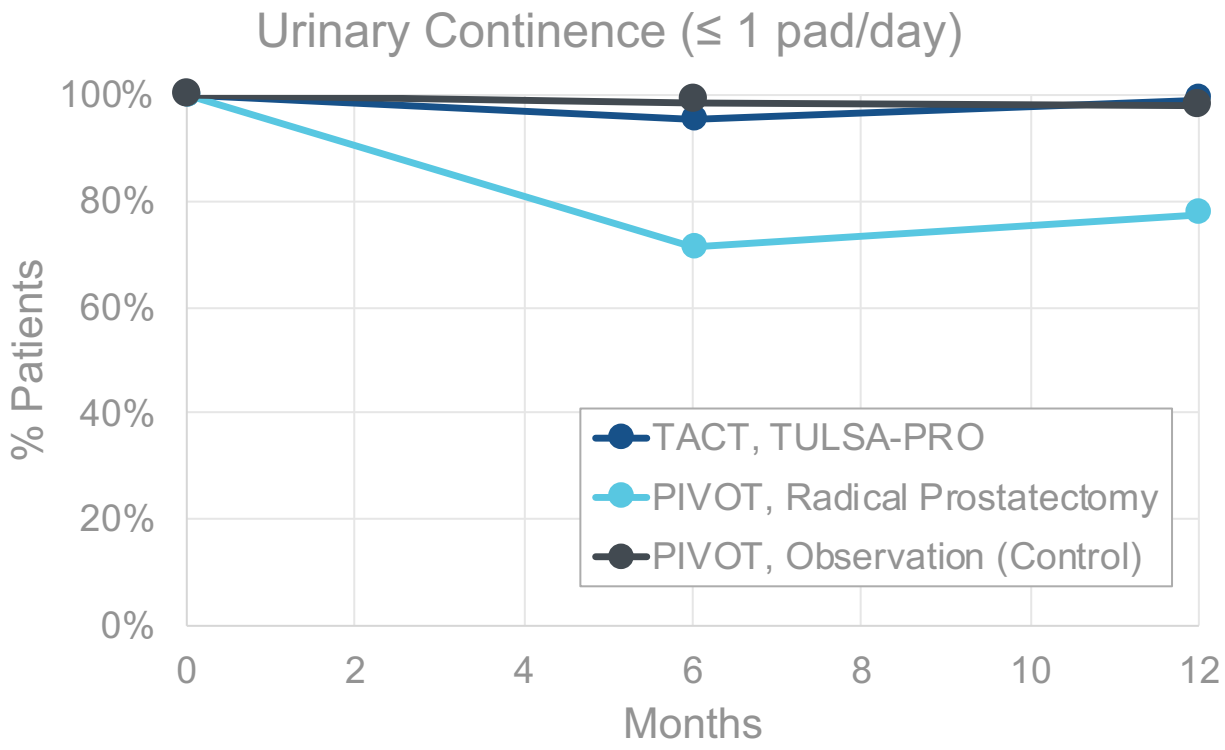


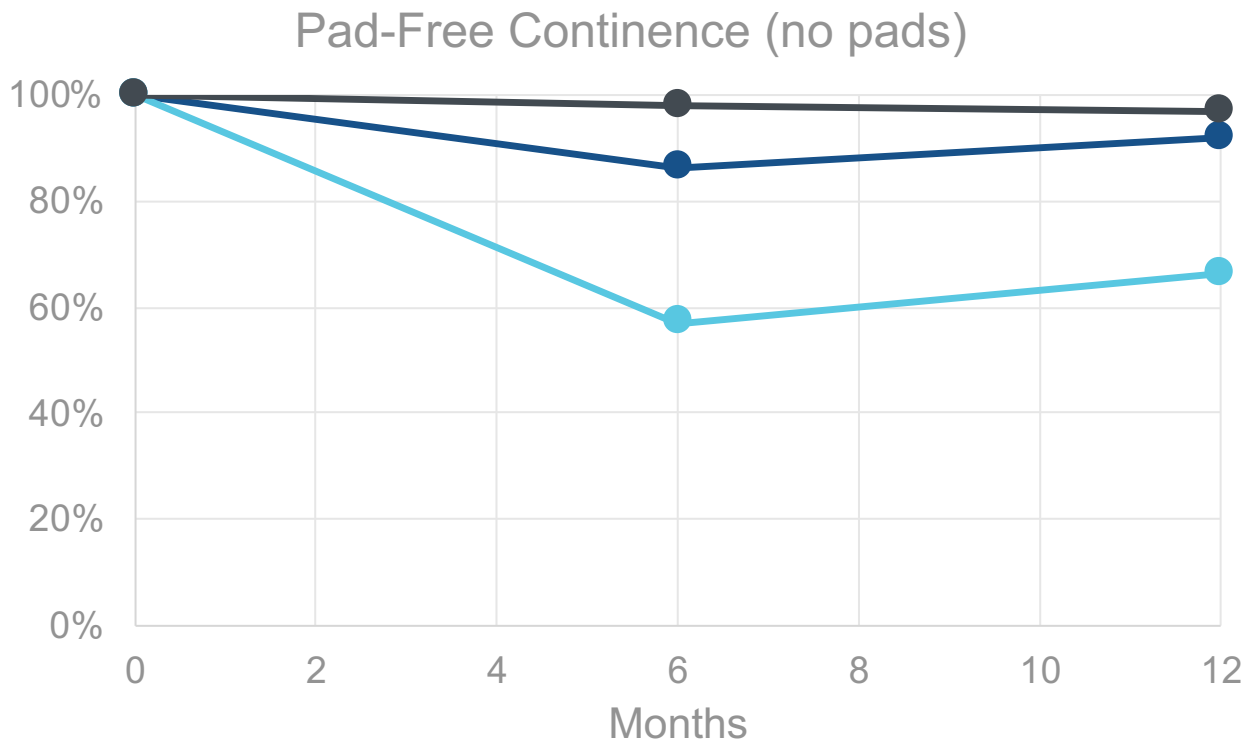


Urinary Incontinence – Context to PIVOT

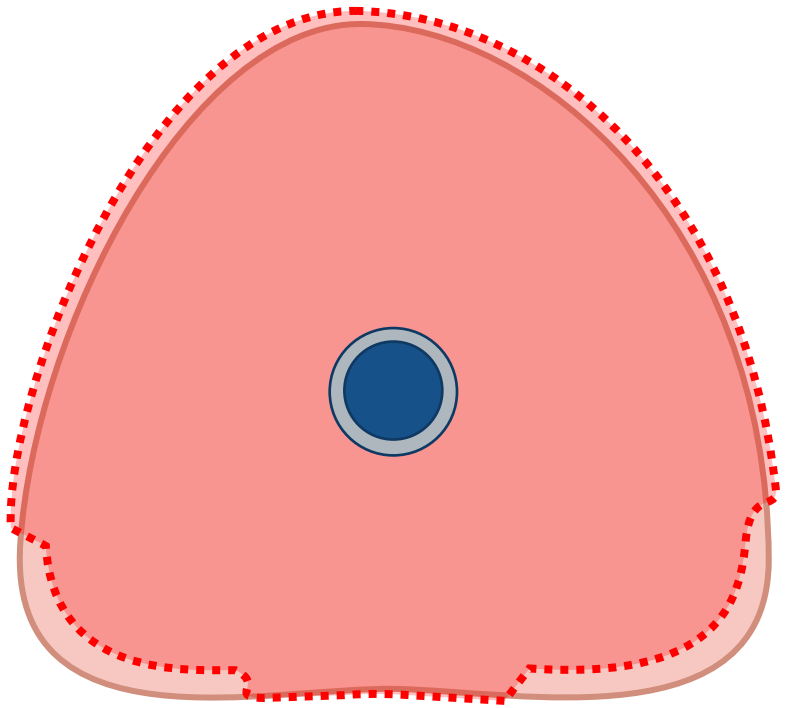
Urinary Incontinence (Pad use), at one year:

- 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

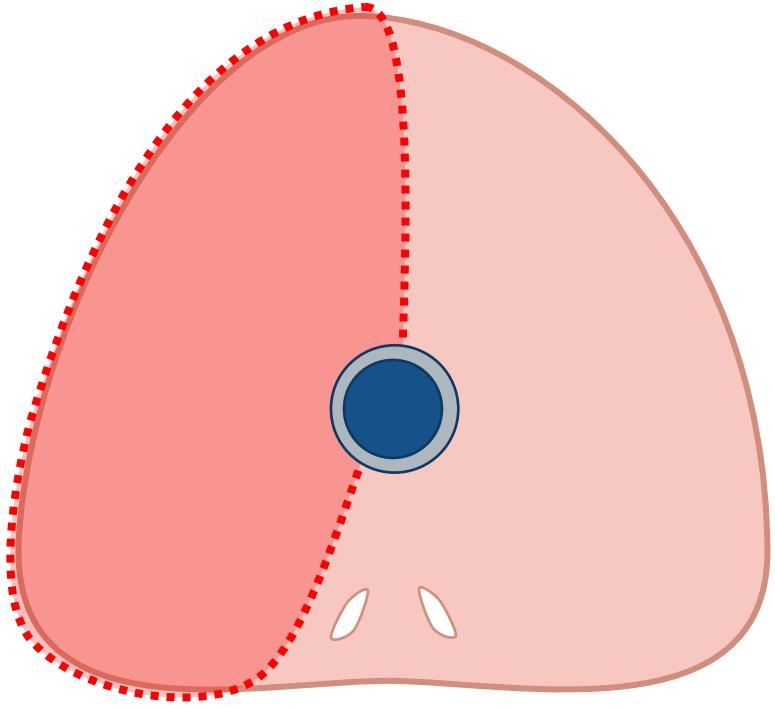




TULSA-PRO – Optimize Treatment Design – Maximize Efficacy, Minimize Side Effects

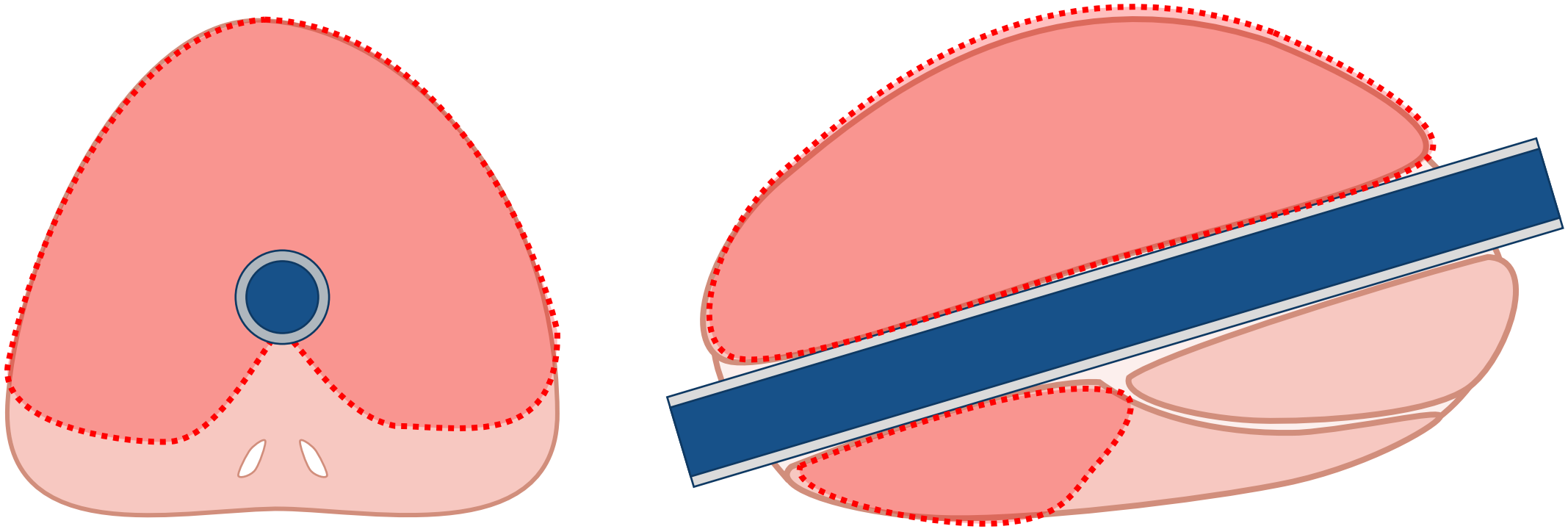


Bilateral Sparing



Targeted & Customized to disease and anatomy

TULSA-PRO – Real World Clinical Approach



BPH

Real World Context and 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

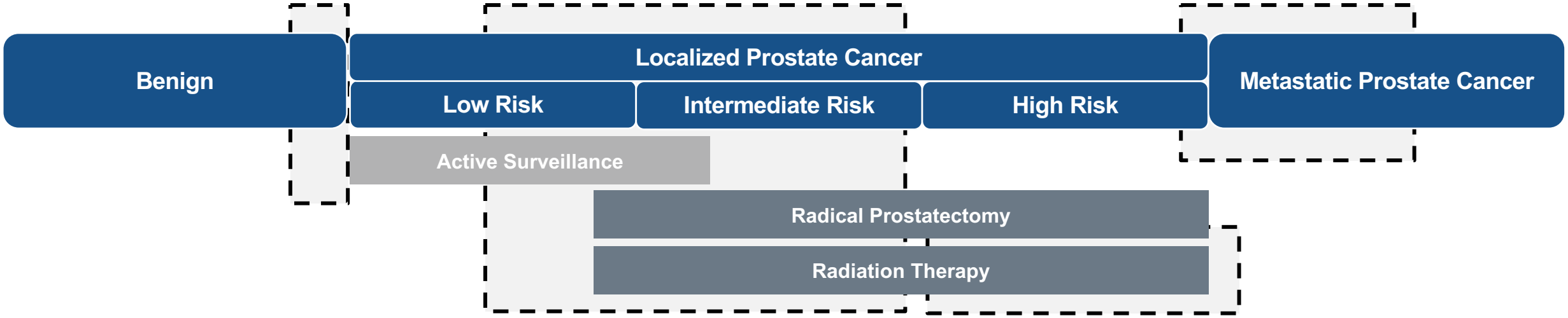
References

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

TULSA-PRO – **Customizable, Predictable, Incision-free**

	Prostatectomy	Radiation	TULSA
Outcome	Predictable	2 year follow-up required	Predictable, NPV 95%
Treatment type	Whole gland	Whole gland, Limited customization	Customized
Throughput, Procedures/day	2 typically, 3 if longer day	Multiple sessions - 5 to 40 over 4 - 8 weeks	4 in a routine day, Consistency, higher possible
Patient recovery	Weeks	Deterioration over time	2 days

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

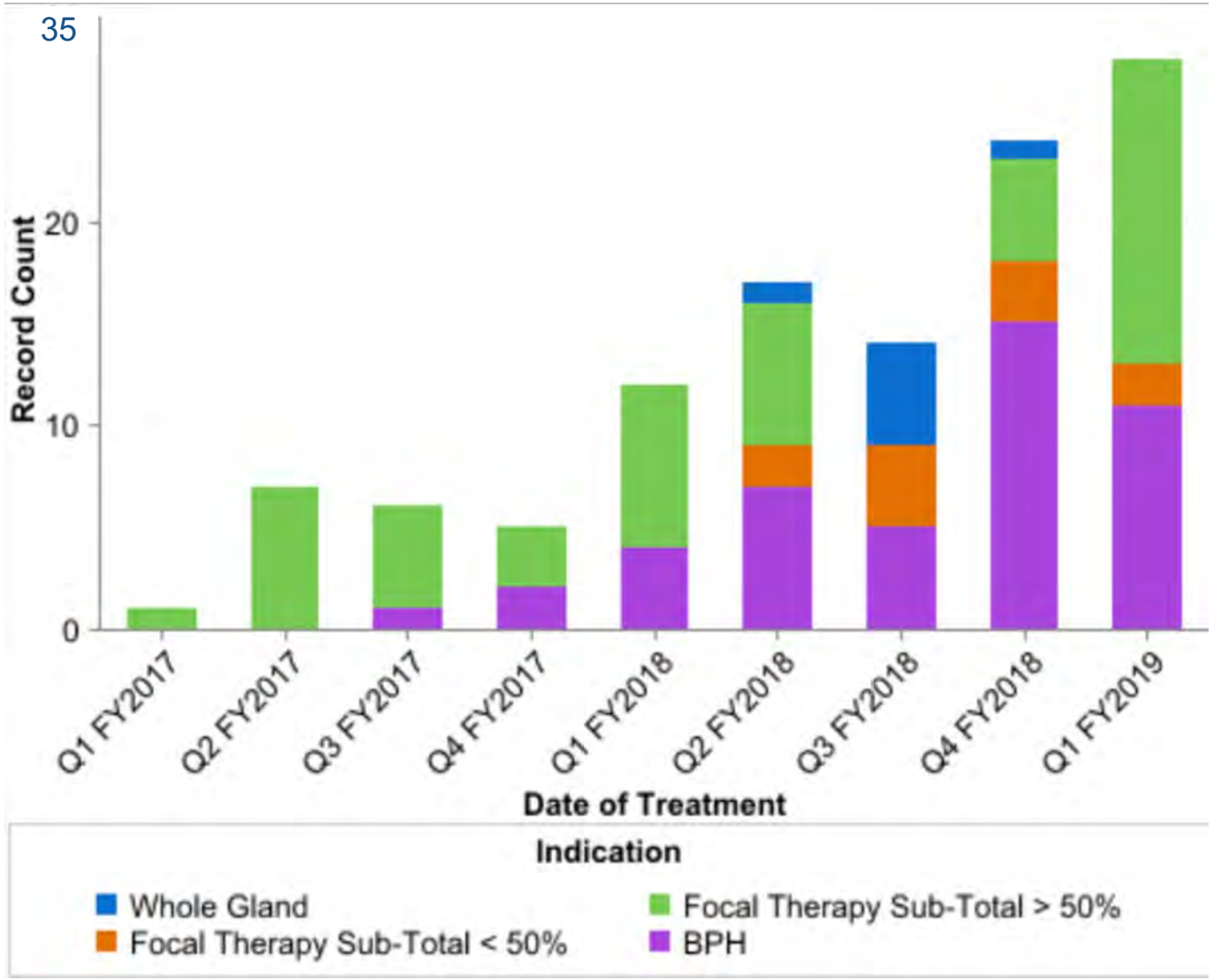
Palliative Locally Advanced

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

Oligometastatic

- Benefit to locally treat prostate
- Often radio-recurrent

TULSA-PRO In Commercial Use – Example From Europe



- Initiated Q1-2017
- Methodically increased usage
- Discovered potential to treat BPH patients – Q3-2017
- Streamlined procedure – routinely 4 patients per day
- Increased utilization rate in 2019

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TULSA-PRO Total Addressable Market: Pre-reimbursement

• New Prostate Cancer Diagnosis (US + Canada)	180,000[1]
• BPH, Prostates, surgical candidates, Unusual shapes (US + Canada)	400,000[2]
• Total Opportunity, # of patients	580,000
• Total Addressable Market, patient paid is 5 -10% of total opportunity	29,000 - 58,000
• Add selected International markets (UK, Germany, Japan)	14,500 - 29,000
• Total patient pay addressable market # of patients	43,500 - 87,000
• Addressable market, $4,000 per patient (includes: disposable + amortized capital + service)	$174 – 348 M
• Achievable share in X years, 25% (<11,000 patients per year) TULSA Installed base = 110 at treatment rate 100 patients/year	$43.5 – 87 M

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 + Canada

Prevalence Market Opportunity – Prostate Cancer

Estimated Active Surveillance (AS) Population	5.5 million			
Addressable AS Market – Patient Pay (5%)	~ 275,000			
Penetration of AS Patient Pay Population	5%	10%	20%	30%
Patient Pay AS Market	**$55 M**	**$110 M**	**$220 M**	**$330 M**

TULSA-PRO Total Addressable Market – Additional Clinical Studies

Title	Purpose	Status/Comments
Radio-Recurrent Cancer/Palliative Care	Inclusion in NCCN guidelines	• EU validation trial in progress • US study in H1-2020
Prostate Cancer: Focal/Disease Targeted Therapy. MR visible tumors	Adoption, Reimbursement	• Registry – EU H2-2019 • Active discussions with Advisory Board in US
Prostate Cancer	Reimbursement	• Active discussions with Advisory Board in US now that TACT is complete
BPH, focus on surgical candidates	Adoption, Reimbursement	• Validation studies – TURKU, ALTA. • Initiate US study in H1-2020

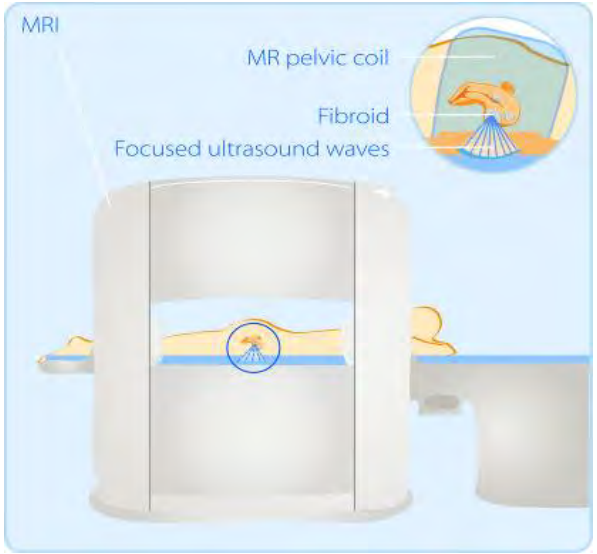
SONALLEVE

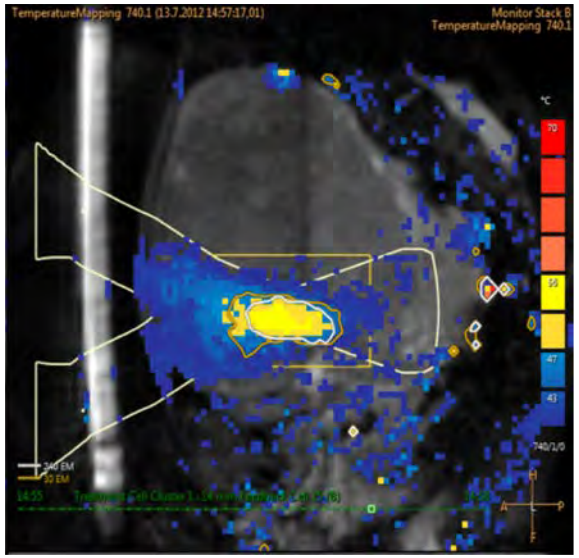
Technology platform for:

- 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
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

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Sonalleve – Uterine Fibroid

1. Data compelling as presented

2. Focus on Asia
   - Reference site in S. Korea, treating 200 patients per year
   - Top tier hospitals in China. First site led by the President of Radiological Society of China

Sonalleve – Platform

- Additional applications
  1. Pain management
  2. Osteoid Osteoma
  3. Pancreatic cancer
  4. Hyperthermia
  5. Neuro-modulation

- Strategy – Partner with Cologne and the FUS Foundation to continue to develop clinical data. **Deploy recurring revenue business model for all new clinical applications**

Summary

1. TULSA – Applied for US FDA 510(k) clearance
2. Business model is capital efficient
   - Tulsa focus on US at key teaching hospitals and private clinics
   - Sonalleve focus on Asia
3. Patient-pay TAM $50 - 100 Million per year
4. Potential to expand TAM by 10X following reimbursement
5. Future investments
   - Efficient sales team
   - Market expanding clinical trials
   - Continued product evolution

PROFOUND

Customizable Incision-Free AblationTherapies

Men’s and Women’s Health | Oncology

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