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Incision-Free Ablative Intervention With Vision

TULSA – A real-time imaging guided therapy platform for ablation of prostate tissue malignant or benign

- FDA cleared in August 2019; first commercial site in January 2020, Al assistant cleared in May 2024
- Using patient cash pay business model installed >50 sites, >3,000 patients treated
- New reimbursement codes established by AMA, placed by CMS in urology Level 7, effective January 2025
- CAPTAIN peri-operative data announced at AUA 2025
- TULSA-AI Volume Reduction announced at AUA 2025

Corporate Presentation | May 2025

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Prostate Cancer – The Unmet Need

~299,010 Prostate Cancer Cases Diagnosed each year



Prostate Anatomy



Prostatectomy Outcomes:

Prospective Multicenter Comparison of Open vs Robotic Prostatectomy: The PROST-QA/RP2 Consortium

Peter Chang, Andrew A. Wagner, Meredith M. Regan et al.



Study & Outcomes:

Robotic Prostatectomy N=549, Open Prostatectomy N=545

- No difference in health-related quality of life (HRQOL) or in RALP pathological outcome (20% positive margins); Reduced perioperative complications, reduced hospital stay; Reduced blood loss
- >20% men incontinent, >50% lost erectile function

Radiation Outcomes:

- Similar complications profile to radical prostatectomy (RP) but delayed
- Limited salvage options, Increases risks of other cancers in future
- Multiple sessions required (5-40 treatments)

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MRI-Guided Transurethral Ultrasound Ablation of the Prostate (TULSA-PRO)

Transurethral Ultrasound:

- Incision and needle-free
- No energy through rectum
- Any region & size of prostate

Real-time MRI Robotics, with AI:

- Al-assisted treatment planning
- Physician-controlled robotics
- Closed-loop temperature imaging, millimeter precision

Gentle Prostate Heating:

- No blood loss, no overnight stay
- Urethra and rectal cooling



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TULSA-AI

Intelligent Modules with a Purpose

- Improve clinical outcomes
- Reduce treatment time
- Improve workflow
- Further improve ease of use
- Increase applicability of TULSA to variety of patients

TULSA-AI Modules Include:

- Thermal Boost increases heat to the outer edge of a specific region of the prostate where cancer resides. Used in 50% of TULSA patients.
- Contouring Assistant machine learning prostate segmentation to help define the target volume. Used in almost in every patient.
- **3. Alignment Assistant** automates and mimics typical user workflow under user guidance
- 4. NEW: Volume Reduction increases TULSA-PRO efficiency for patients with BPH

TULSA-AI – Thermal Boost



TULSA-AI – Contouring Assistant



70 Peer-Reviewed Publications & 200+ Conference Presentations Clinical Evidence in Unrivaled Variety of Prostate Indications

		Partial Gland Ablation	Whole Gland Ablation		
	Benign	Orga	In Confined Prostate Ca	ncer	Salvage / Palliative
>	Large prostate BPH, 200 cc treated successful	Hybrids with low grade ly cancer and BPH	Lesion-targeted ablation	Whole-gland, customized for QOL	Post radiation failure

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Number of segment specific clinical peer-reviewed publications:

2	3	13	16	7
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Sponsored and investigator-initiated clinical trials:

International CARE Registry							
TYKS-BPH	Elterman; Lumiani; Busch	FARP RCT CAPTAIN RCT		TYKS-sTULSA			
		ENFORCE RCT	ТАСТ	7			

TULSA-PRO Utilization Trends: Q4-2024

- 99% of patients treated are PCa, of those 28% had low grade PCa and BPH
- 53% of ablations are whole gland, providing flexibility to treat sub-total gland or focal
- Prostates treated as small as 7cc and as large as 283cc
- All grades of disease treated, including high risk, GG5; even palliative patients treated

Indication 0% 20% 40% 80% 60% 100% PCa PCa + BPH Salvage BPH Ablation 0% 20% 40% 100% 60% 80% Focal or Hemi Subtotal > 50% Whole-gland **Prostate Size** 0% 20% 40% 60% 80% 100% ■ < 20 cc ■ 20 – 40 cc ■ 40 – 60 cc ■ 60 – 100 cc > 100 cc Grade 0% 80% 20% 40% 60% 100% ■ GG4 + GG5 GG1 GG2 GG3



Prostate Diseases



Tripling the TAM:

- Ablation of malignant prostate tissue; approximately 200,000 patients per year
- Ablation of tissue due to BPH; approximately 400,000 patients per year
- Total TAM approximately \$ 5 B, about 70% in recurring revenue

TULSA Days: Surgeons can plan a day of TULSA patients; all cancer, all BPH or mix of both; maximizing productivity

CAPTAIN (NCT05027477): <u>Customized Ablation with TULSA vs. Prostatectomy in</u> <u>Intermediate-risk PCa</u>

• CAPTAIN is an audacious trial that would be the first to generate Level 1 evidence demonstrating superior safety and non-inferior efficacy of ablative therapy vs. RP





TULSA-PRO Eliminates Blood Loss & Overnight Stay for the Patient & Hospital





TULSA-PRO Improves Post-treatment Patient Experience

Significantly less pain during first week post treatment

NRS pain scale after treatment (0 "no pain" to 10 "worst pain imaginable")



Significantly less extreme interference with mobility, self-care and usual activities

EQ-5D-5L Health Status after treatment (% reporting extreme problem / inability)



TULSA-PRO Patients are in Better Overall Health After Treatment

Significantly better overall health during first month post treatment

Change in EQ-5D-5L VAS overall health score after treatment



TULSA Patients:

Significantly less deterioration in overall health for all 30 days after TULSA vs. RP (p < 0.05).

Robotic Prostatectomy Patients:

Take > 2 weeks of recovery, on average, to feel like a TULSA patient does the day after their procedure.

By that time, TULSA patients are well back to their pre-treatment overall health.

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TULSA For BPH Relief

Alleviation of Lower Urinary Tract Symptoms

- TULSA addresses limitations of other volumereducing BPH treatments for large prostates:
 - MRI guidance allows complete targeting of enlarged transition zone, and accurate sparing of critical structures (possibly improving efficacy, durability, erectile / urinary / ejaculatory sparing)
 - Combined treatment of obstructive symptoms and low-grade / MRI-visible cancer
 - 360-degree capability enables treatment of anterior transition zone (TZ) and median lobe not addressed by some devices
 - No hospital stay, no post-operative bleeding, safe for patients on blood thinners
- BPH-specific TULSA of transition zone is even safer and simpler than TULSA for patients with prostate cancer



ΤZ

ΤZ

No need to treat posteriorly towards rectum, ejaculatory ducts, verumontanum, neurovascular bundles Calcifications at outer edge of TZ do not block BPH treatment



TULSA-AI Volume Reduction Uses Two New Features: Volume Customizer and the Treatment Arc

A fast and simple way to ablate any sub-total region of the prostate for relief from BPH symptoms



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Prostate Cancer Ablation

with TULSA-AI Contouring Assistant and Treatment Arc



Whole Gland Ablate 70cc in 55min



Partial Gland Ablate 45cc in 35min



Targeted Lesion Ablate 20cc in 16min

Benign Prostate Ablation

with TULSA-AI with Volume Customizer and Treatment Arc



Large Plan Ablate 53cc in 44min



Medium Plan Ablate 50cc in 29min



Small Plan Ablate 33cc in 16min



92% Volume Reduction with TULSA (TACT Pivotal Trial) Clinically Proven Prostate Volume Reduction¹

Gentle heating to kill temperatures collapses the tissue and the dead prostate cells are reabsorbed by the body **shrinking the prostate over time demonstrating effective & durable prostate ablative treatment.**



- TACT pivotal trial, n = 115
- Median perfused prostate volume decreased 91% from 37 cc to 3 cc, on MRI at 1 year

PROFICUND Prospective Phase I-II Study of TULSA-PRO for Men with BPH



IPSS Quality of Life 6 5 4 X 3 2 X X \mathbf{X} 0 Baseline 3 mo 9 mo 12 mo 24 mo 6 mo (n=28) (n=28) (n=28) (n=24) (n=24) (n=7)

Peak Flow Rate (mL/s)



Post-Void Residual (mL)



- Improved IPSS, QoL, flow, PVR, irritative/obstructive symptoms by 3 months post-TULSA
- Prostate volume decreased from 56 to 31 cc
- No change in erectile function or urinary continence
- Only 3 / 30 patients resumed alpha-blockers or 5ARIs
- 1 Grade 3 adverse event (GU infection); No Grade 4 AE's



TULSA Phase I-II Study in Context

		Symptoms (IPSS)		Bother (IPSS QoL)		Peak flow (Qmax, ml/s)				
Treatment	Ν	T=0	12m	-Δ	T=0	12m	-Δ	T=0	12m	+∆
TURP	1083	21.6	7.6	14.0 (65%)	4.1	1.4	2.7	7.4	21.2	13.8
Laser TURP (Greenlight)	100	23.7	8.1	15.6 (66%)	4.5	1.2	3.3	8.0	22.5	14.5
Urethral Lift (UroLift)	140	21.8	11.1	10.7 (44%)	4.5	2.2	2.3	8.1	12.1	4.0
Water Vapor (Rezum)	121	21.8	10.3	11.5 (52%)	4.4	2.1	2.3	10.0	15.5	5.5
Artery Embolization	114	24.3	10.9	13.4 (55%)	4.8	1.9	2.9	7.3	22.1	14.8
Water Jet (Aquablation)	117	22.9	7.8	15.1 (66%)	4.8	1.6	3.2	9.4	19.7	10.3
TULSA for BPH (Anttinen et al, 2024)	30	16.5	4.0	12.5 (73%)	4.0	1.0	3.0	11.1	17.0	8.1



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TULSA-AI Volume Reduction

Rapid Ablation of Large Prostate Volume

- No overnight stay, No blood loss, no fulguration
- No history of Grade 4 Adverse Events
- No need to discontinue anti-coagulants
- Treat any region including anterior, customizable
- Same indication for use, reimbursement codes
- Procedure time 60-90 minutes

Launch Plan

- New software release available, end of May 2025 to include Treatment Arc and updated Contouring Assistance
- Volume Reducer tool to be soft launched at 5-sites to collect clinical data and expect full launch in Q4



Contouring Assistant Physician prescribed 110 min ablation (99 cc) 20 min ablation (44 cc) 30 min ablation (67 cc)

Posterior sparing for NVB, EJD, Rectum Urethra notch for catheterization & recovery

Channel Reimbursement



Comparative Procedure Summary-2025 Final Rule (Medicare National Average)

TULSA Strongly Positioned Against Other Options

Procedure	CPT Code	Global	2025 APC Level	2025 Hospital HOPD	2025 ASC	2025 Non- Facility OBL	2025 Non- Facility OBL
		Penou		Payment	Payment	RVU	Dollar \$
TULSA	55882	0 Day	5377, Urology Level 7	\$12,992	\$10,728	272.21	\$8,773
Robotic RP	55866	90 Day	5362, Laparoscopy Level 2	\$10,411	N/A	N/A	N/A
Aquablation	0421T	90 Day	5376, Urology Level 6	\$9,247	\$6,756	Contract	or Priced
HIFU	55880	90 Day	5376, Urology Level 6	\$9,247	\$4,780	N/A	N/A
Cryo	55873	90 Day	5376, Urology Level 6	\$9,247	\$6,965	163.03	\$5,273
TURP	52601	90 Day	5375, Urology Level 5	\$5,084	\$2,522	N/A	N/A
Rezum/BPH	53854	90 Day	5374, Urology Level 4	\$3,449	\$1,336	47.95	\$1,551



TULSA + Siemens Interventional MR: Free.Max



Acquisition and operating costs approximately 50% lower than a standard high Field MR

Combining TULSA + MR to Create a Complete Interventional Suite for Personalized and Precise Ablative Procedures





Robotic Prostatectomy

- Demanded by patients and surgeons
- Reduced blood loss, reduced hospital stay
- Hospitals established robotic suites
- First widely used application Prostatectomy

iMRI Suite

- Patients are demanding it; leading surgeons see the vision
- iMRI moves robotics to autonomous potential:
 NO blood loss, NO hospital stay
- Leading hospitals budgeting for iMRI, starting with Prostate disease treatment
- First application Prostate ablation

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MR Centered Prostate Treatment Pathway Managed by Urologists





TULSA-PRO Opens Up MRI Feasibility in Urology

Cashflow Positive

	MRI Diagnostic Procedures Only	TULSA-PRO Procedures Only
Weekly	60	2
Monthly	239	8
First Year	2,862	99

*Example: ASC in Chicago, IL *50% Medicare / 50% Private Insurance

Profound Pipeline: SONALLEVE[®] For Solid Organs

Indications

FDA HDE Approved Indication

Osteoid Osteoma, pediatric application

Indications Approved Outside The U.S.

- Adenomyosis
- Uterine fibroids
- Pain palliation of bone metastases
- Benign desmoid tumors

MRI-guided Ablation Pancreatic Cancer

- Phase I underway in EU
- N=25 (5 treated to-date)



Clinical Trials

Histotripsy + Cancer Immunotherapy iFOCUS

 First patient treated Sept 2024 to address metastatic or unresectable cancers



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Paving the Way for the Future: Interventional MRI Suite





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TULSA-PRO[®] In Summary

Flexible & Precise Technology for whole or partial gland ablative treatment of prostate tissue – malignant or benign.

Large & Growing Body of Clinical Evidence 67 peer-reviewed clinical publications; 200 medical meeting presentations; 7-year outcomes data. CAPTAIN – AUA 2025 presentation: initial perioperative data demonstrate MRI-guided TULSA provides statistically significant improvement of post-operative experience vs. robotic RP. Clinical and side effect data will continue to read out over 10 years.

Volume Reduction Application for BPH relief announced at AUA 2025 Expands opportunity from 200,000 patients to 600,000 patients per year.

Agreement with Siemens in place to provide TULSA+MR as a total solution MR increasingly being used in prostate treatment journey - from patient screening to diagnosis and biopsy; TULSA adds treatment to the journey.

Medicare reimbursement effective Jan 2025; CMS Final Rule published in early November; classified TULSA treatment at Urology Level 7, above all other covered prostate disease treatment modalities.

TULSA reimbursement became effective as of January 1, 2025; Profound is building a larger sales team to drive mainstream adoption

