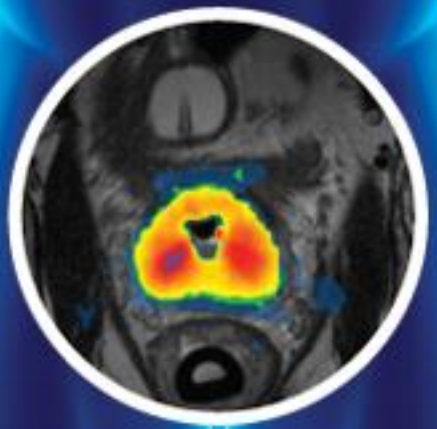
PROFOUND MEDICAL CORP.

Driving a new therapeutic standard in prostate cancer

September 2016



TSXV:PRN

Forward-Looking Statements

This presentation and oral statements made during this meeting regarding Profound and its business which may include, but are not limited to, the expectations regarding the efficacy of Profound's technology in the treatment of prostate cancer. Often, but not always, forward-looking statements can be identified by the use of words such as "plans", "is expected", "expects", "scheduled", "intends", "contemplates", "anticipates", "believes", "proposes" or variations (including negative variations) of such words and phrases, or state that certain actions, events or results "may", "could", "would", "might" or "will" be taken, occur or be achieved. Such statements are based on the current expectations of the management of each entity. The forward-looking events and circumstances discussed in this presentation may not occur by certain specified dates or at all and could differ materially as a result of known and unknown risk factors and uncertainties affecting the company, including risks regarding the pharmaceutical industry, economic factors, the equity markets generally and risks associated with growth and competition.

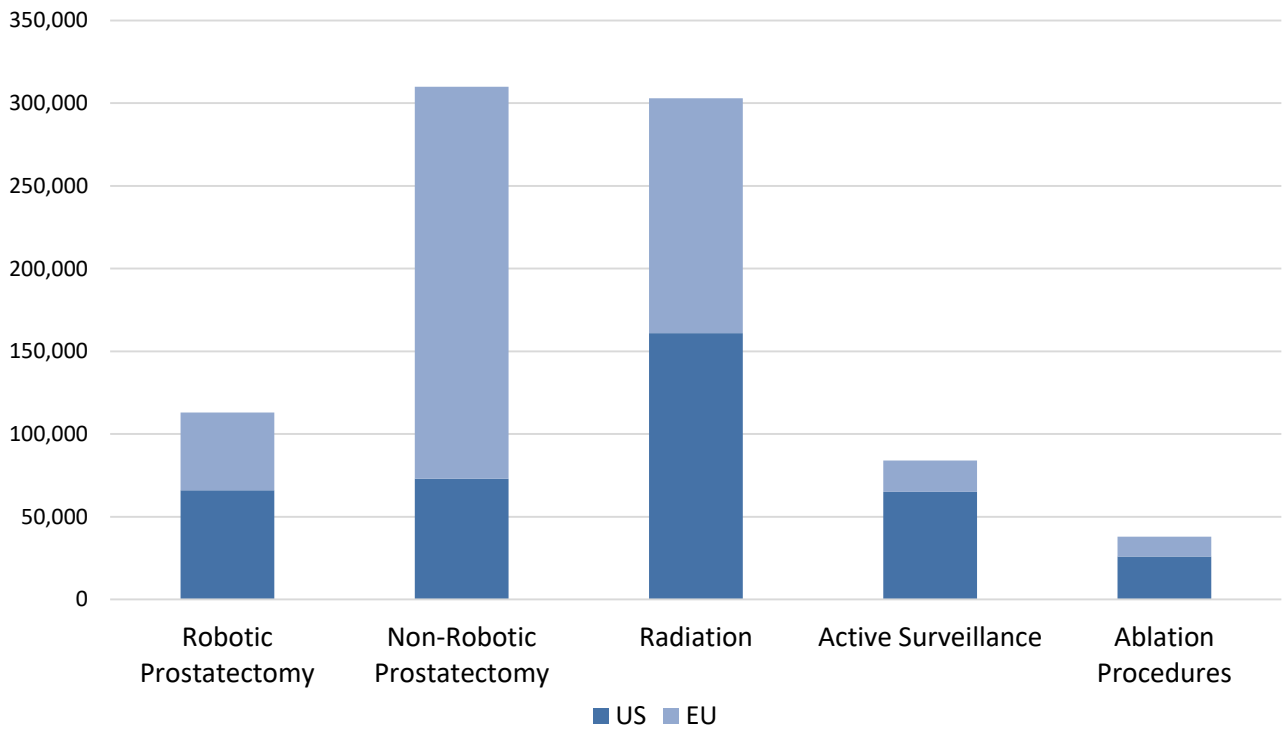
Although Profound has attempted to identify important factors that could cause actual actions, events or results to differ materially from those described in forward-looking statements, there may be other factors that cause actions, events or results to differ from those anticipated, estimated or intended. No forward-looking statement can be guaranteed. Except as required by applicable securities laws, forward-looking statements speak only as of the date on which they are made and Profound undertakes no obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future events, or otherwise, other than as required by law.

Investment Highlights

- Proprietary technology to ablate prostate cancer in a single, two hour treatment by urologists
- Reduction in side effect frequency compared to current treatments
- Large and growing market: >500,000 new patients/year
- Commercial stage in Europe (CE Mark received) and commencing TACT pivotal trial in U.S.
- Validated technology; relationships with Siemens and Philips
- Attractive razor/razor blade model with high-value, one-time use consumables

Over 5.8 Million Men Living with Prostate Cancer [4,5]

Procedures: US & EU[3]



2.8M US[4] men and 3M EU[5] men are living with prostate cancer

Over 524,000 **new patients** per year in initially targeted geographies: 181,000 US[1] and 343,000 in EU[2]

Annual number of **procedures** = 1.5x new patients

1. American Cancer Society
2. International Agency for Research on Cancer. WHO.
3.* iData Research and company assumptions
4. seer.cancer.gov
5. European Alliance for Personalized Medicine, 2015

Most Widely Used Therapies Today

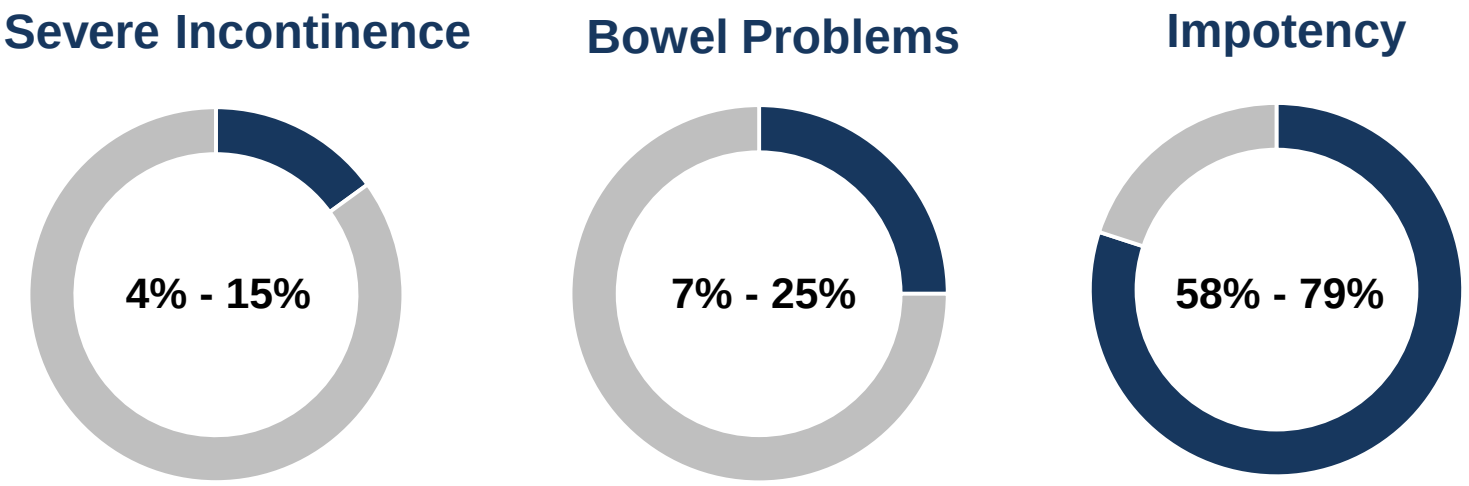
	PROCEDURES		MONITORING
	RADICAL PROSTATECTOMY	RADIATION	ACTIVE SURVEILLANCE
NO INCISION	✕	✓	Delayed Treatment Periodically monitored: biopsy, PSA tests, digital rectal exams, imaging
APPROACH	Outside-In	Outside-In	
PROTECTION OF CRITICAL ANATOMY	✕	✕	
COMPLICATIONS & SIDE EFFECTS	High rate of incontinence and impotency	High rates including damage to bowels	Expensive ($17-$29K over 5-10 yrs[2]) Impact on patients: psychological distress, periodic invasive and painful tests
LIMITATIONS	• Success related to skill of surgeon • Recovery time	• Damage to surrounding tissue • Risk of secondary cancers • Delayed onset of therapy & side effects • Multiple sessions over 30 to 60 days • 30% patients fail treatment[1]	

1. Rukstalis, DB. Treatment Options after Failure of Radiation Therapy – A Review. Rev Urolo. 2002; 4(Suppl 2): S12-S17.
2. Keegan et al. Active Surveillance for prostate cancer compared with immediate treatment. Cancer 2012; 118(14): 3512-3518.

Less Frequently Used Therapies

	HIFU	CRYOTHERAPY	ANDROGEN DEPRIVATION THERAPY (Hormone Therapy)
PROCEDURE	Focused ultrasound delivered via rectum Heats at up to >100^0 C	Under ultrasound guidance, hollow probes inserted into prostate; cold gases then passed through, creating ice balls that destroy prostate	Reduce production of testosterone and slow or reverse prostate tumor growth
LIMITATIONS	3+ hours Potential thermal damage to nerves and bowels; Obstructive urinary complications Limited to average or smaller sized prostates	Rarely utilized; second line therapy if radiation fails High rates of side effects, especially erectile dysfunction	Conjunctive & not curative Usually given in combination with other treatments

The Problem: Complication Rates & Side Effects



Current complication rates and variability may be correlated to lack of precision in treatment technologies available today

- Lack of direct ability to control potential damage to critical anatomy
- Experience of the surgeon

- Potosky et al, “Five-year outcomes after prostatectomy or radiotherapy for prostate cancer: the Prostate Cancer Outcomes Study (PCOS),” Journal of the National Cancer Institute, 96(18): 1358-1367 (2004)
- Thompson (Chair) et al for AUA Prostate Cancer Clinical Guideline Update Panel (2007) Guideline for the management of clinically localized prostate cancer: 2007 update. The Journal of Urology 177(6): 2106-31
- EDAP Technomed Inc., “EDAP Ablatherm® integrated imaging high intensity focused ultrasound (HIFU) indicated for the treatment of low risk, localized prostate cancer,” Sponsor Executive Summary (June 23) and Presentation Slides (July 30) from the Premarket Approval Application P130003 (2014)
- PMI 12-month Phase 1 Trial, GCP-10102 Table 10

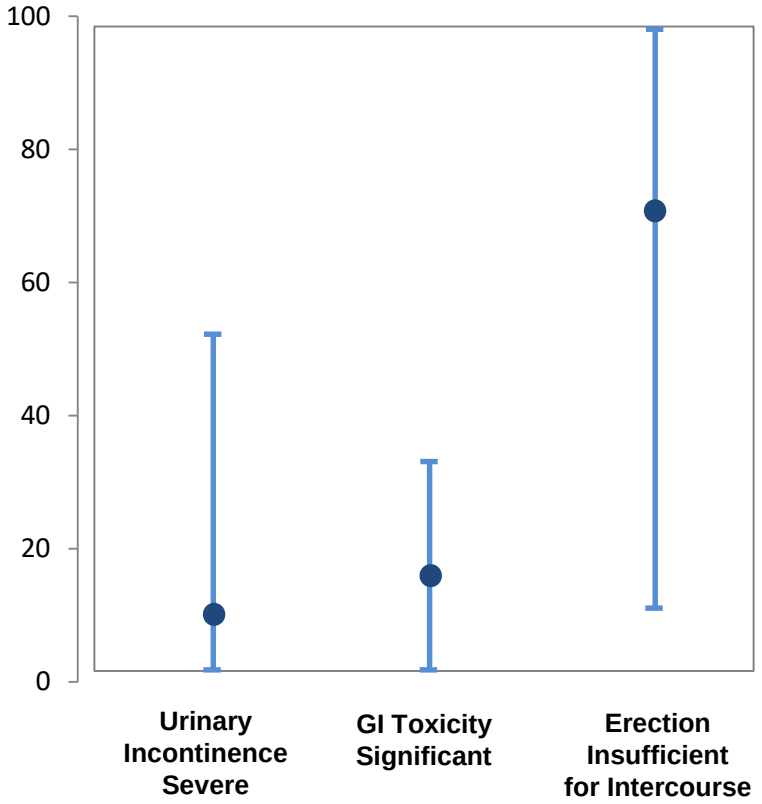
Functional Outcomes with Current Treatments

Functional Outcomes at 2 years[1]

	PROSTATECTOMY	RADIOTHERAPY
URINARY INCONTINENCE	No control or frequent urinary leakage	
	10%	3%
	Bothered by dripping or leaking urine	
	11%	2%
BOWEL FUNCTION	Bowel urgency	
	14%	34%
	Bothered by frequent bowel movements, pain, or urgency	
	3%	8%
SEXUAL FUNCTION	Erection insufficient for intercourse	
	79%	61%
	Bothered by sexual dysfunction	
	56%	48%

Rate of complications reported with radical prostatectomy & radiotherapy[2,3]

(Variation as reported in 436 publications)

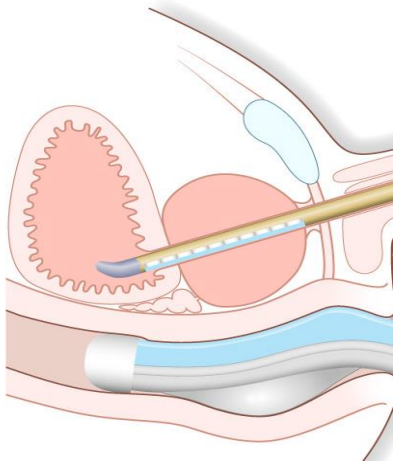


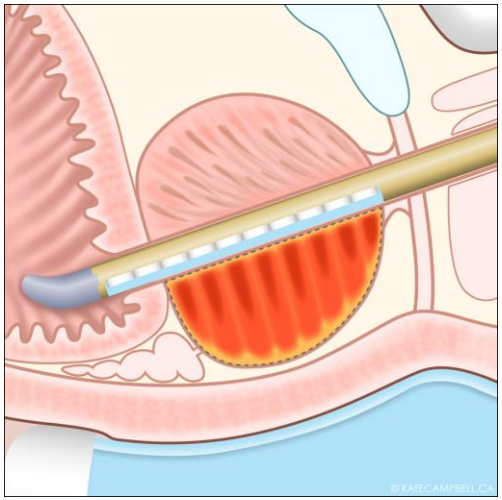
1. Resnick *et al.* Long-Term Functional Outcomes after Treatment for Localized Prostate Cancer; New England Journal of Medicine, 2013 (Jan): 368:436-445
2. Thompson (Chair) *et al* AUA prostate cancer clinical guideline update panel, "Guideline for the management of clinically localized prostate cancer: 2007 update," The Journal of Urology, 177: 2106-2331 (2007)
3. PMI 12-month Phase 1 Trial, GCP-10102 Table 10

Our Solution: TULSA, “One & Done”

Ablate cancerous prostate tissue in a single 2 hour procedure

- No incision: minimizing recovery time
- Ablate prostate from inside-out: inherently safer than outside-in
- Precise ablation: robotic applicator, real-time MRI Guidance, real-time temperature guidance and control
- Actively protect (via cooling) critical anatomy that normally gets damaged causing side effects





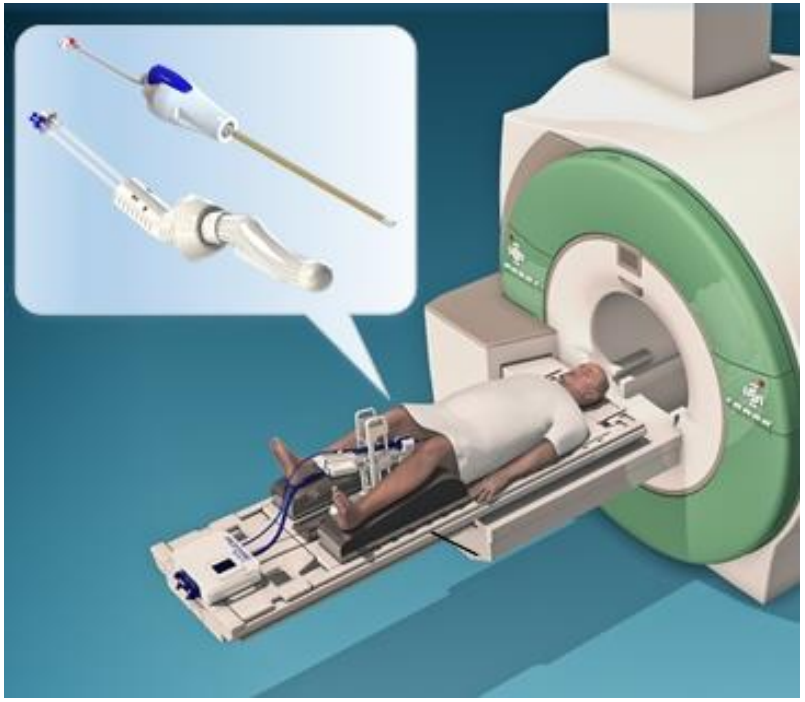
TULSA Procedure

Please click here to view video

TULSA-PRO™ Device Technology

CONTROL ROOM

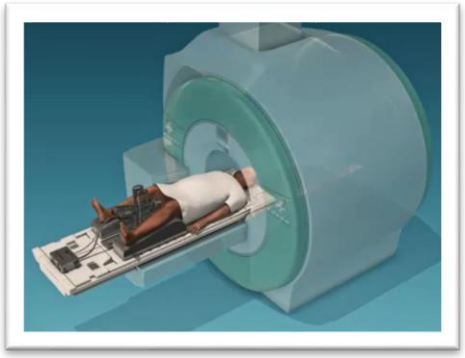
SCAN ROOM

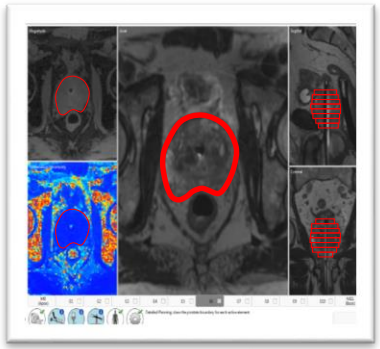


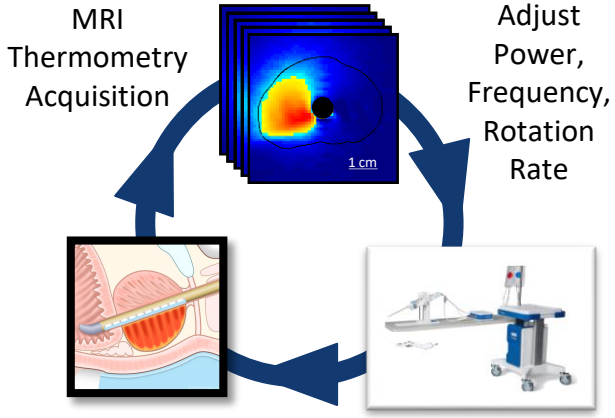
EQUIPMENT ROOM

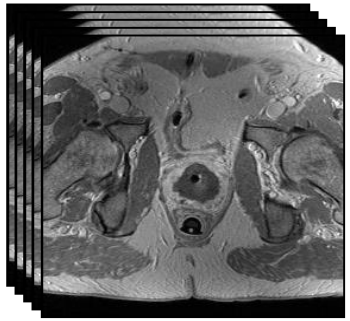
Automated, Precise Ablation from the Inside-Out

1 2 3 4









MRI Guided Device Positioning

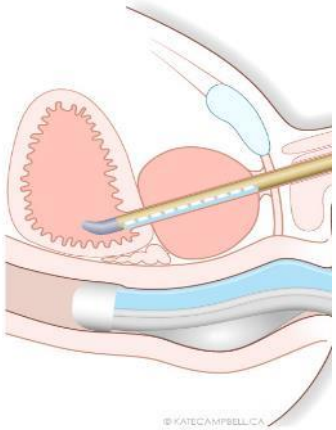
Precise Treatment Planning by Urologist

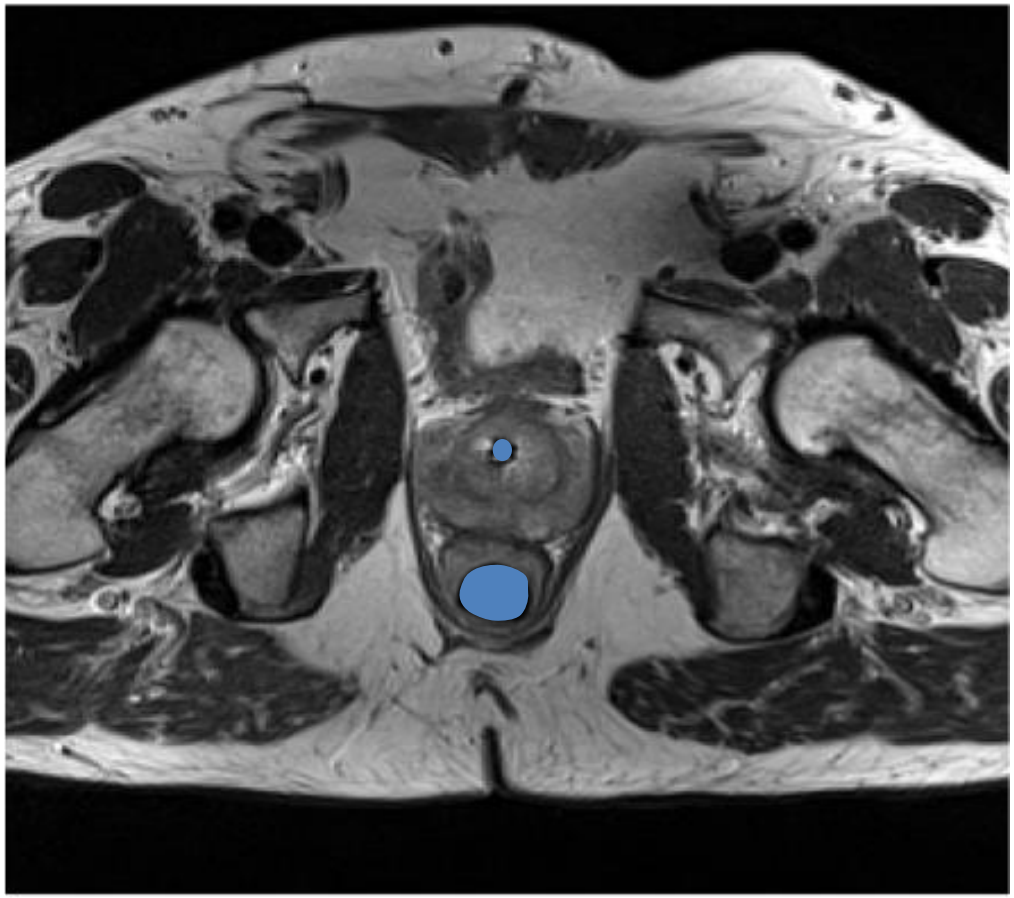
Automated Temperature Feedback Controlled, Robotically driven

- Controlled Algorithm Target Temp 57^0 Celsius
- Ablation in 40 minutes

Confirmation of Ablation Margin with MRI

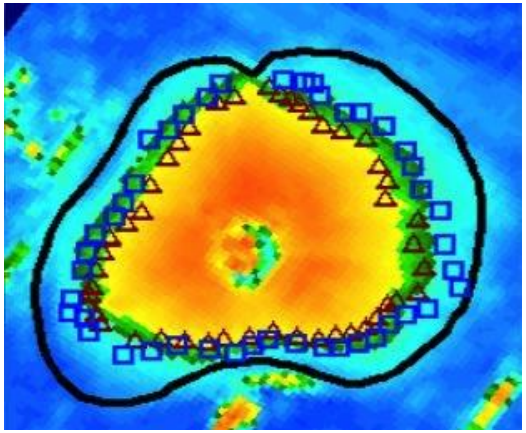
Unique Active Cooling Protects Critical Anatomy



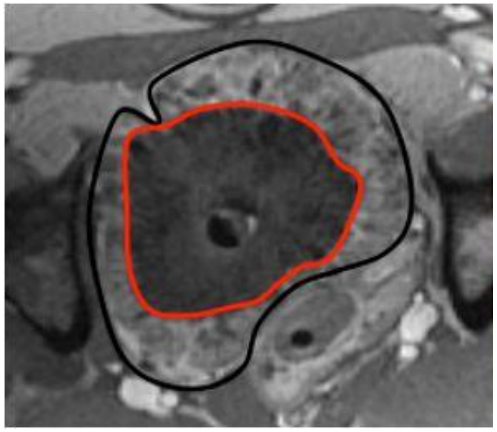


Precision of TULSA Has Been Validated

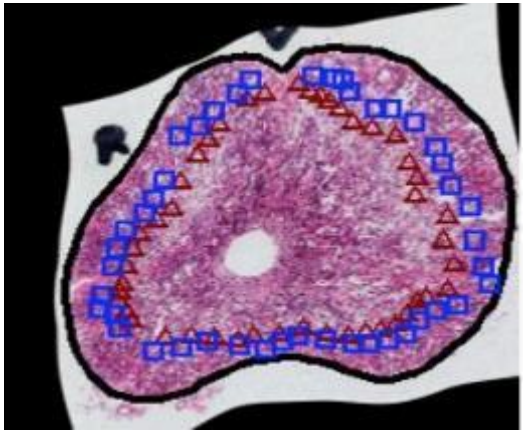
TULSA ablation is accurate to 1.3 mm, confirmed by contrast-enhanced MRI and histology in animal and human studies



Thermal MRI measurement from TULSA procedure



High resolution contrast MRI confirms ablation accuracy

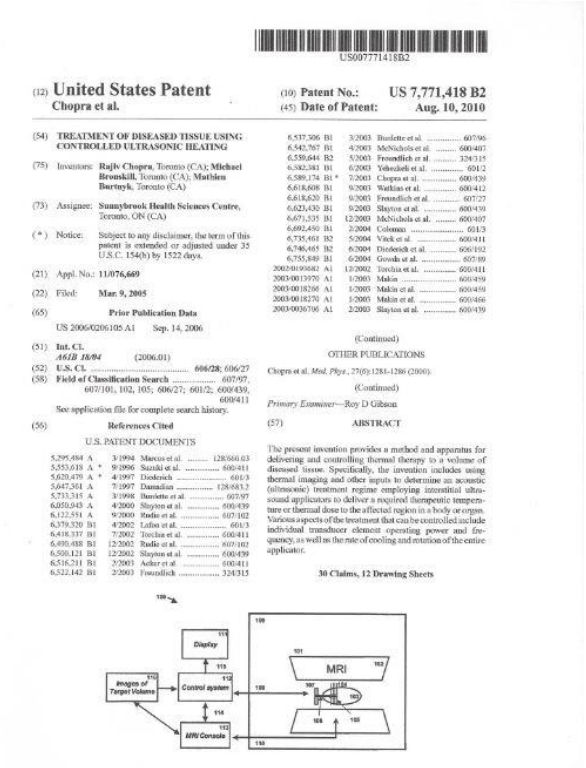


Also confirmed by gold standard whole-mount pathology

Chopra et al, Phys Med Biol. 2009; 54(9): 2615-33
Chin et al, European Urology (Sept 2016)

Opportunity is Well Protected by Strong IP

- Core patents focus on system and method to accurately treat tissue by measuring temperature and controlling ultrasound beam amplitudes and frequencies
  - Core claims include, but are not limited to, transurethral prostate treatment
  - Original core patents valid through 2026-2029
- Newer patents extend coverage to algorithms and devices used to deliver treatment
- United States: 6 patents issued, 6 pending
- PCT: 9 patents pending



US007771418B2

(12) **United States Patent**
Chopra et al.

(10) **Patent No.: US 7,771,418 B2**
(45) **Date of Patent: Aug. 10, 2010**

(54) **TREATMENT OF DISEASED TISSUE USING CONTROLLED ULTRASONIC HEATING**

(75) Inventors: **Rajiv Chopra**, Toronto (CA); **Michael Bronskill**, Toronto (CA); **Mathieu Burtnyk**, Toronto (CA)

(73) Assignee: **Sunnybrook Health Sciences Centre**, Toronto, ON (CA)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 1522 days.

(21) Appl. No.: **11/076,669**

(22) Filed: **Mar. 9, 2005**

(65) **Prior Publication Data**

US 2006/0206105 A1 Sep. 14, 2006

(51) **Int. Cl.**
A61B 18/04 (2006.01)

(52) **U.S. Cl.** **606/28**; 606/27

(58) **Field of Classification Search** 607/97, 607/101, 102, 105; 606/27; 601/2; 600/439, 600/411

See application file for complete search history.

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(Continued)

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(Continued)

Primary Examiner—Roy D Gibson

(57) **ABSTRACT**

The present invention provides a method and apparatus for delivering and controlling thermal therapy to a volume of diseased tissue. Specifically, the invention includes using thermal imaging and other inputs to determine an acoustic (ultrasonic) treatment regime employing interstitial ultrasound applicators to deliver a required therapeutic temperature or thermal dose to the affected region in a body or organ. Various aspects of the treatment that can be controlled include individual transducer element operating power and frequency, as well as the rate of cooling and rotation of the entire applicator.

30 Claims, 12 Drawing Sheets

Safety & Feasibility Clinical Trial: Completed

OBJECTIVE	**Determine safety and feasibility of MRI-TULSA for whole-gland prostate ablation in a primary treatment setting of localized prostate cancer**
SUBJECTS	30 Patients (Inclusion criteria: Men ≥ 65 yr, organ confined PCa, PSA ≤ 10 ng/ml, Gleason score 3+3 or 3+4)
OUTCOMES	• 30 patients treated with at least 12 month follow-up • No intraoperative complications, no rectal injury or fistula • Erectile dysfunction rate of 8% (IIEF item 2 ≥ 2) • At 12 months, only 1 patient (3%) with Grade 1 urinary incontinence (no pads) • Functional quality-of-life outcomes back to baseline levels • Accuracy of thermal ablation +/- 1.3 mm

Chin *et al*, "Magnetic Resonance Imaging-Guided Transurethral Ultrasound Ablation of Prostate Tissue in Patients with Localized Prostate Cancer: A Prospective Phase 1 Clinical Trial," European Urology (2016)

TACT Pivotal Trial: IDE Approved

OBJECTIVE	**Further evaluate safety and efficacy of TULSA-PRO™ intended to ablate prostate tissue of patients with localized, organ-confined prostate cancer**
SUBJECTS	110 Patients (Inclusion criteria: Males, age 45-80 yrs, organ confined PCa, PSA ≤ 15 ng/ml, Gleason score ≤ 3+4)
SITES	15 Sites, first patient September 2016
OUTCOMES	**Primary Endpoints** • Safety • Efficacy **Secondary Endpoints** • Frequency and Severity of Adverse Events • Rate of Erectile Dysfunction • Rate of Urinary Incontinence • PSA Levels and Stability • Procedure Efficiency • Resource Requirements for Reimbursement Purposes

Changing the Therapeutic Prostate Paradigm

Safe, Fast & Accurate

- No need to wait, reducing psychological distress
- Single treatment; quick 2 hour procedure
- No incision (minimally invasive) leads to a quick recovery
- Leveraging existing infrastructure and precision of MRI

Dr. Chin and world's first TULSA-PRO™ patient

Favorable Reimbursement Environment

Multiple treatment approaches, including infrequently performed procedures, are already reimbursed

PROCEDURE	CODE	PAYMENT 2016	CODE	PAYMENT 2016
LAPAROSCOPIC RADICAL PROSTATECTOMY WITH CC	DRG 666	$9,775	CPT 55866	$1,443
LAPAROSCOPIC RADICAL PROSTATECTOMY WITH MCC	DRG 665	$17,022	CPT 55866	$1,443
RADIATION THERAPY (IMRT SIMPLE, 40 SESSIONS)	APC 5623	$19,816	CPT 77387	Fee bundled into primary APC
BRACHYTHERAPY	APC 5532, 5613, 5374, 5614, 5624	$4,324[1]	CPT 76873, 77318, 55875,55876, 77778	$2,206[1]
CRYOABLATION	DRG 666	$9,775	CPT 55873	$793

1. Payment is the sum of the indicated APC/CPT codes
The payments included in this worksheet are for Medicare patients, private payers payments for these procedures will vary and may result in higher payments than published Medicare rates.

Reimbursement For TULSA

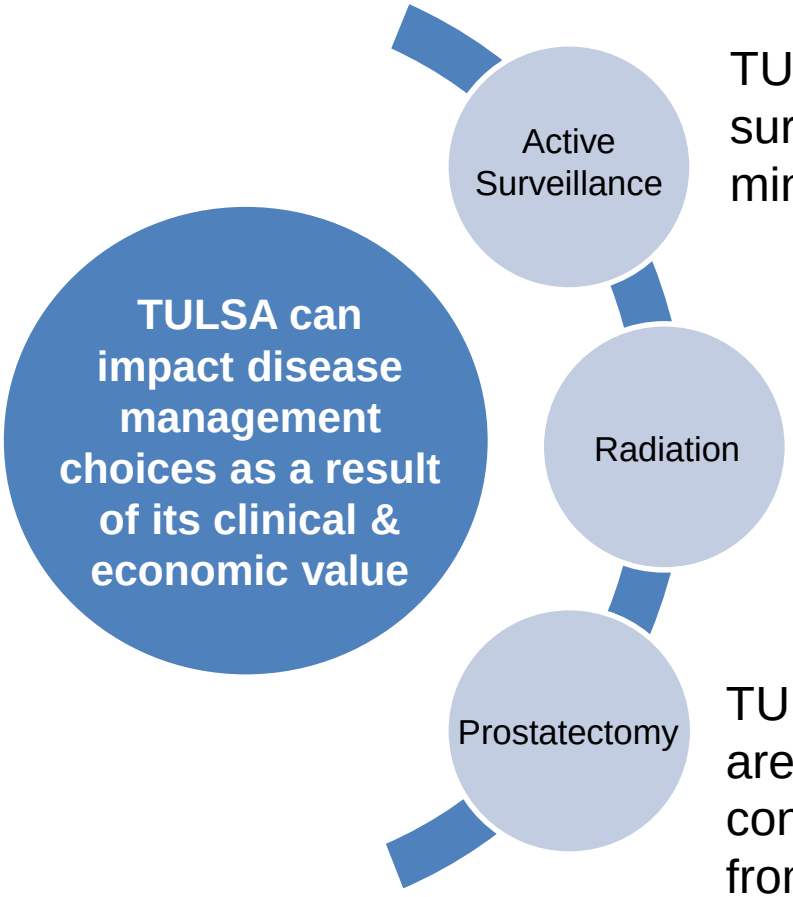
- Positive feedback from reimbursement experts who have communicated with payers: “Clinical and economic and survival data from the TACT study may be sufficient to submit for reimbursement consideration”
- Simultaneously, plan to work with American Medical Association (AMA) and the American Urological Society (AUA) to directly apply for a category 1 CPT code using the data from TACT
- CMS has approved payment of approximately $8,200 for the procedure per patient for the TACT trial

TULSA Well-Suited for Accountable Care

TULSA is inherently less expensive than other therapies

- Cost of using the MR suite is significantly less than that of an operating room or a radiation therapy room
- Treatment time for TULSA is significantly shorter than that of other therapies
- TULSA is potentially a one time day therapy

TULSA: Clinical & Economic Value



TULSA potentially reduces costs of active surveillance and total cost of prostate care by minimizing the need to wait

TULSA potentially less expensive, one-time treatment, with minimal concern of therapy failure

TULSA potentially an alternative for patients who are candidates for radical prostatectomy but are concerned about side effects and recovery time from co-morbidities

Delivering Benefits Across Continuum

PATIENTS	UROLOGISTS	PAYERS
• Single procedure • Short duration ~ 2 hours • Significant reduction of side effects and complications • Faster recovery and return to normal activities	• Ability to treat patients who might otherwise go to radiation • Computer-driven procedure enables standardization across doctors • Enables urologist to use innovative/cutting-edge therapies remotely, in “control room” setting	• Faster procedure and shorter time in hospital • Favorable side effect and complication profile • Change in risk-benefit analysis may cause patients on active surveillance to act earlier, reducing total/ongoing cost

Solid Path to Commercialization

- Co-marketing agreements signed with leading MR companies, Philips and Siemens, even prior to CE Mark
- Leverage brand, scale & installed base and co-market with partners
  - TULSA-PRO™ base units (robotic system & treatment delivery console) can be sold bundled with new MR sales or as a follow-on sale to broaden utility of MR installed base by Siemens and Philips
- Profound sales team to co-sell TULSA-PRO™ base units with MR companies and independently drive utilization (~$3,000 USD per patient) after the sale
- Establishing Centers of Excellence & reference hospitals
- Developing country-specific market entry strategies, with initial focus on Germany and opinion-leading sites

Key Upcoming Milestones

TACT Trial:

- First patient treated – September 2016
- Recruitment completed – End of Q2 2017
- Reporting Interim data (6 months) – End of Q4 2017
- Reporting Interim data (12 months) – End of Q2 2018
- FDA 510k submission – Early Q3 2018

Commercial – Europe:

- First revenue recognized – Q4 2016
- Focus on Germany & EU opinion leading sites
- Establishing Centers of Excellence & reference hospitals
- Market access and digital marketing to drive momentum

Capitalization

Exchange & Ticker		TSXV: PRN
Cash (@ June 30, 2016)		$12.9MM
Debt:	FedDev	$0.8MM
	HTX	$1.3MM
	Knight	$4.0MM
Common Shares (@ March 31, 2016)		
Basic, Fully Diluted		39.5MM; 43.8MM
Significant Shareholders:	BDC	24.8%
	Genesys	23.1%
	Knight	7.7%