Customizable, Incision-Free Ablation Therapies

Corporate Presentation | January 2020

NASDAQ: PROF
TSX: PRN

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“My life should not have to change”

TULSA-PRO®

U.S. FDA Cleared, August 2019

Ablation of Prostate Tissue

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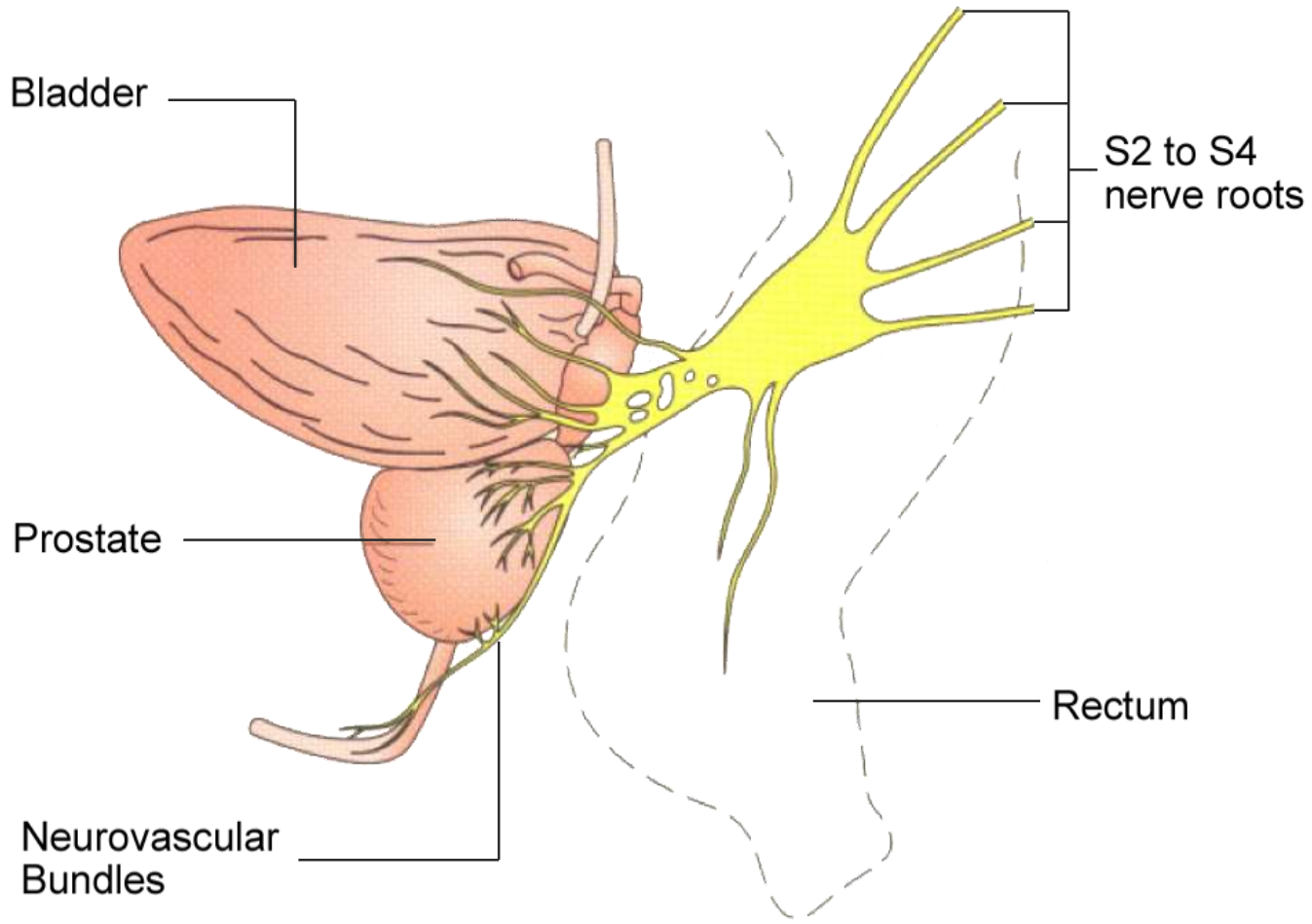
Prostate Anatomy



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

Current Landscape of Prostate Disease in the U.S.

2.9 million patients currently living with prostate cancer on active surveillance*

10 million patients living with Benign Prostatic Hyperplasia ("BPH")**

Common treatment options associated with significant side effects such as incontinence and erectile disfunction

175,000 new prostate cancer patients diagnosed each year*

300,000 BPH surgeries per year**

Radiation failure and palliative patients have limited re-treatment options

*American Cancer Society

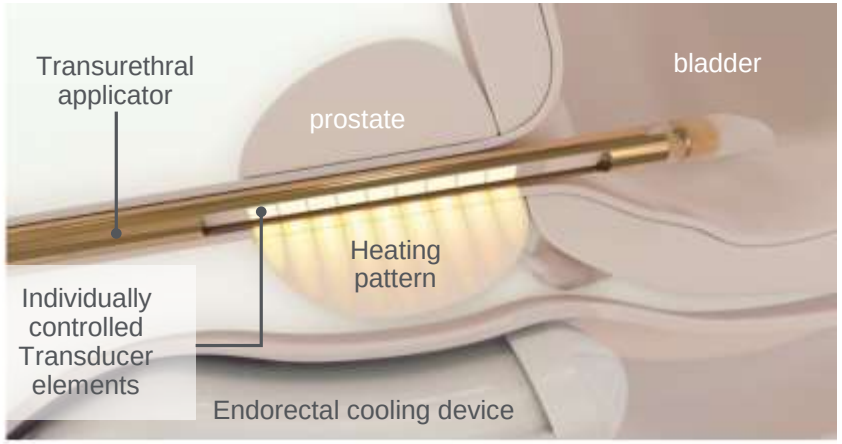
**Based upon CMS data

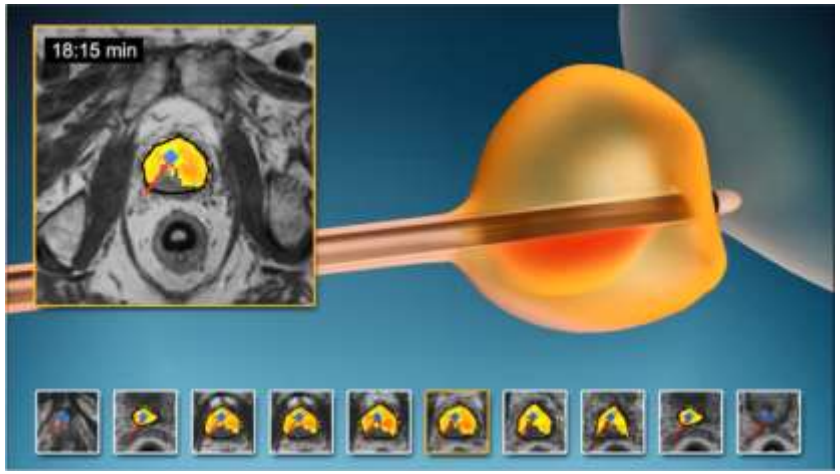
Todays Treatment Paradigm

BPH	Organ Confined Prostate Cancer			Salvage / Palliative
	Low Risk	Intermediate Risk	High Risk	
	Active Surveillance			
Simple Prostatectomy	**Radical Prostatectomy**			**Cryotherapy**
	Radiation Therapy			

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
- Capable of treating both large and small prostate volumes, anterior and posterior tissue
- Thermal protection of important anatomy

3

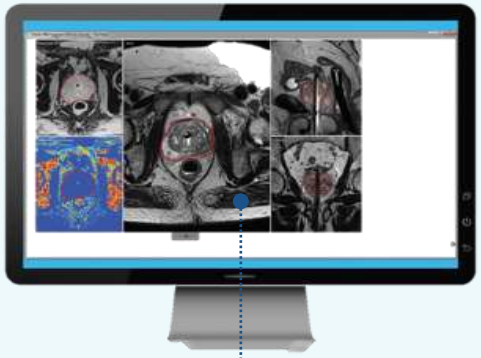
Closed-loop process control software

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

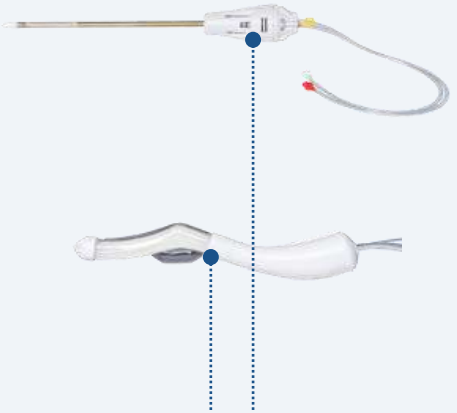
TULSA-PRO
System Components

Robotic Arm, Computer Hardware

Energy System



Surgeon Console Control Room



Disposable Applicators

Capital Equipment

One-Time Consumables

- Compatible with MR from leading companies, Philips and Siemens
- Recurring revenue business model

TACT: Clinical Trial

Pivotal Study of Whole-Gland Ablation in a Clinically-Significant Patient Population

n = 115	**13**	clinical sites	**5**	countries	**45 - 80**	years old	**Prostate Cancer Risk**	Intermediate (67%) Low (33%)

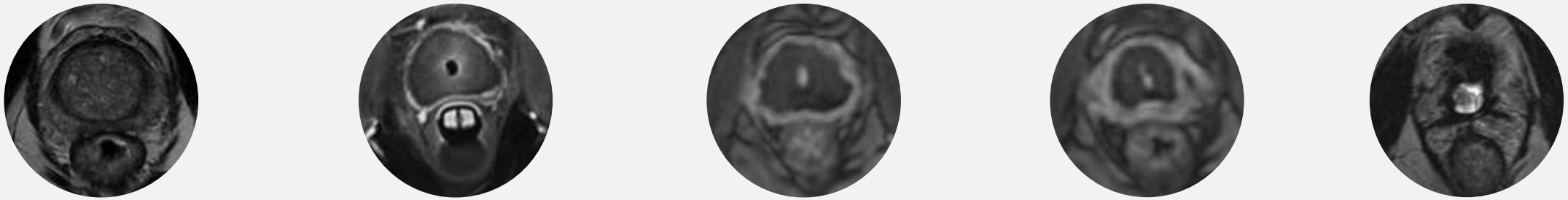
PSA primary efficacy endpoint resolutely met:

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

Prostate volume significantly reduced, demonstrating effective prostate ablation:

- Median perfused prostate volume decreased **91%**
  - from 37 cc to 3 cc
- Prostate ablation confirmed on Contrast Enhanced MRI

Prostate Volume Reduction



TACT Summary

Literature Review of Other Trials Provided for Context

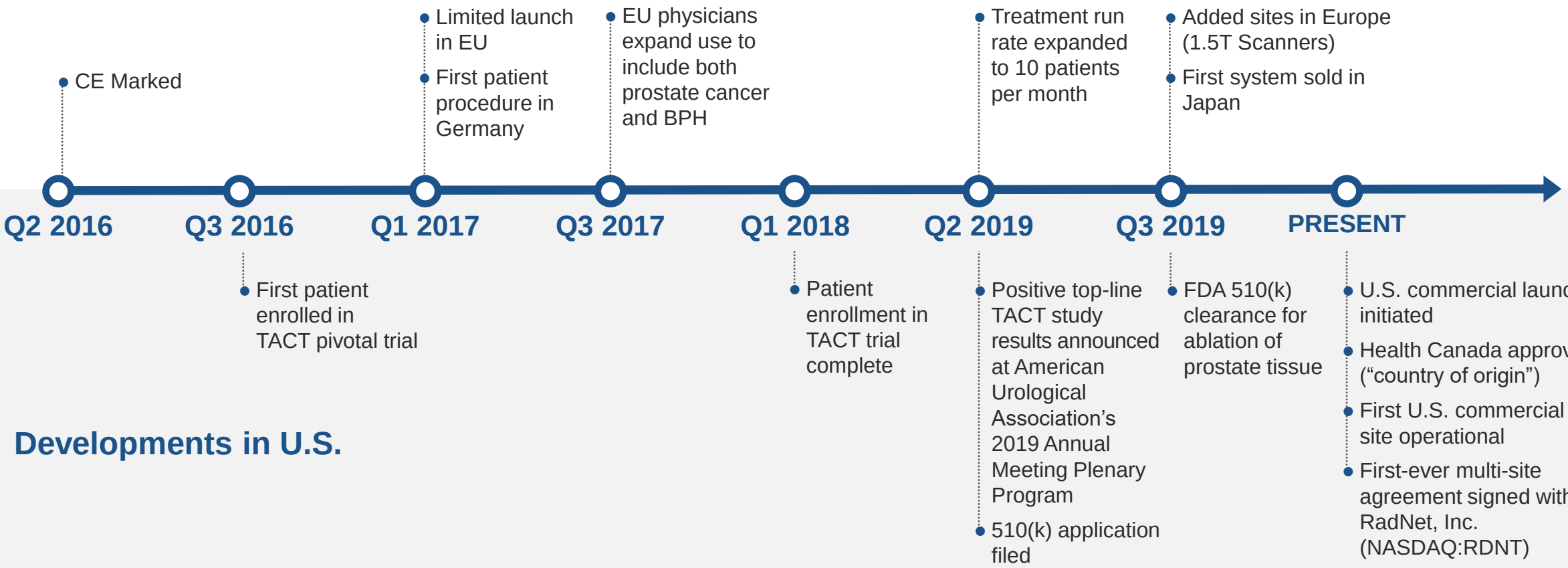
	TACT Study	Literature Review		
	TULSA	**Prostatectomy**	**Radiation**	**HIFU**
Biopsy / Histology	**21% Clinically Significant** **14% Insignificant Disease** (GG1, ≤2 cores, < 50% CCL) **65% Negative**	**16 – 24% +Margin** [1] (Meta-Analysis) **10 – 15% +Margin** [2] (RCT) **24% +Margin** [3] (ProtecT)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

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

Clinical & Commercial Development

TULSA-PRO Timeline

Developments in Europe



Developments in U.S.

Clinical Application
Learnings From Limited EU Launch

Benign	Organ Confined Prostate Cancer			Salvage / Palliative
	Low Risk	Intermediate Risk	High Risk	

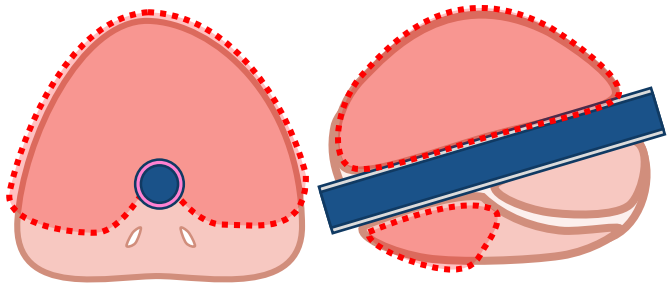
Large prostate BPH [1]
- Preservation of ejaculatory function
- Combined with targeted cancer ablation
- Prophylactic ablation of suspicious MRI lesion

Customized ablation [2-7]
- Targeted ablation (focal, or regional)
- Large ablation (wide margins)
- Whole gland ablation (with urethral sparing)

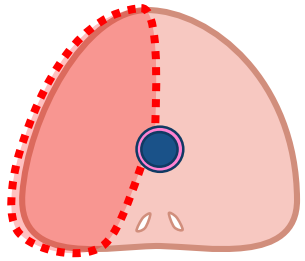
Recurrence after radiation [8]
- Localized recurrences have limited options, and morbidity is high

Palliative locally advanced [9]
- Severe urinary symptoms including BOO with retention and/or intractable hematuria

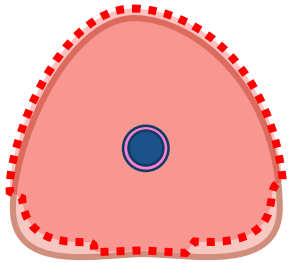
Oligometastatic [10]
- Benefit to locally treat prostate
- Often radio-recurrent



Ablation of benign prostate tissue



Targeted ablation of diseased prostate tissue

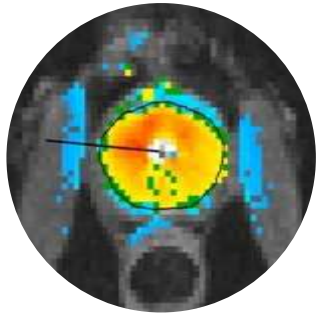


Whole gland ablation with bilateral nerve sparing

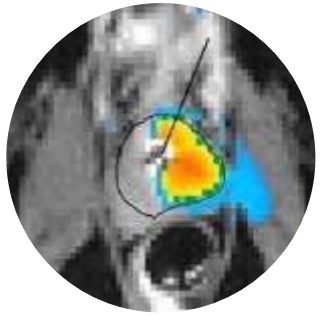
1. Elterman *et al*, Prostate Cancer and Prostate Diseases, 2019 *(Under Review)*
2. Ramsey *et al*, The Journal of Urology, 2017
3. Chin *et al*, European Urology, 2016
4. Bonekamp *et al*, European Radiology, 2018
5. Eggener *et al*, The Journal of Urology, 2019 *(AUA Abstract)*
6. Anttinen *et al*,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

TULSA-PRO
Unique Flexibility

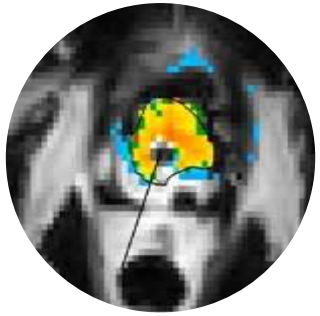
Whole Gland Ablation



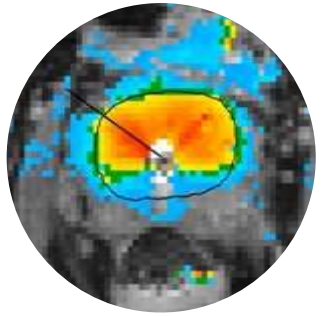
Targeted Ablation



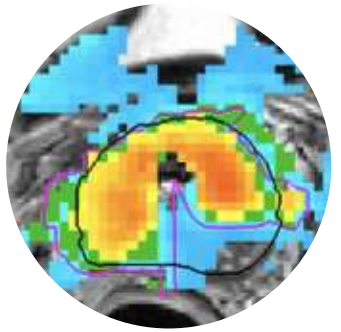
Post Radiation Failure Ablative Therapy



Targeted Ablation
of a benign large prostate



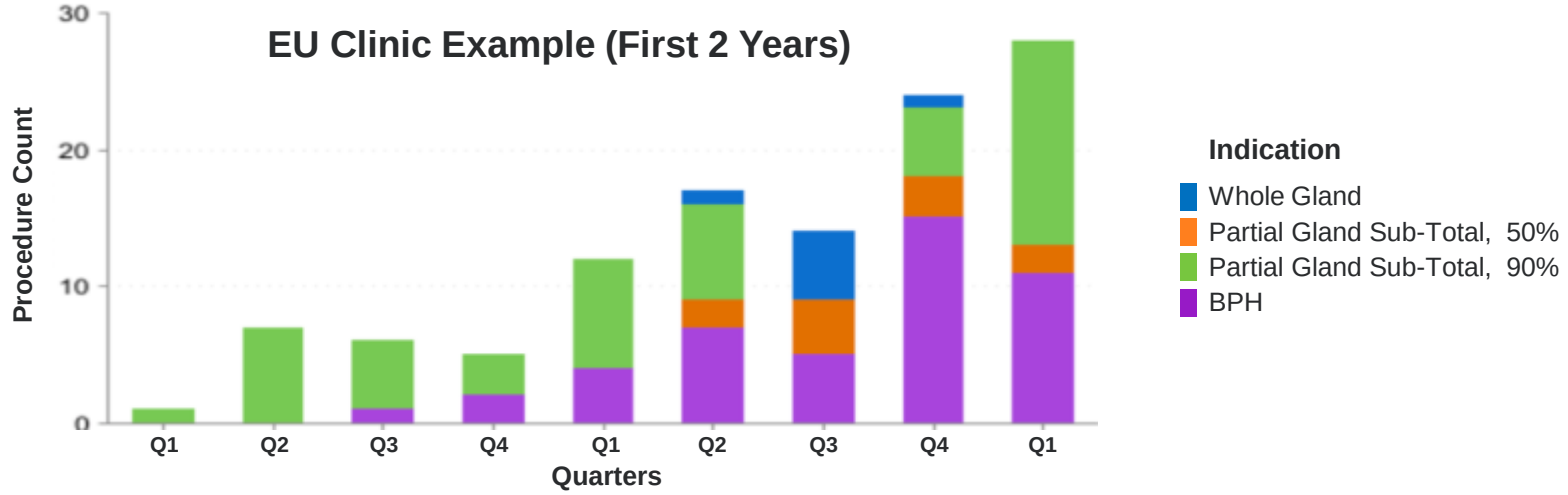
Targeted Ablation
of a benign large prostate with malignant lesion



Clinical Application & Adoption

Learnings From Limited EU Launch

	Prostatectomy	Radiation	TULSA
Throughput: Procedures/Day	• 2 typically • 3 on a longer day	• Multiple sessions: 5-to-40 over 4-to-8 weeks	• 4 in a day • Consistent treatment times
Patient Recovery	• Weeks	• Deterioration over time	• Outpatient procedure for most patients • Generic analgesic needed for pain management after procedure



U.S. Market Entrance Strategy
TULSA-PRO

Increase Awareness

- TACT clinical data presented at >10 conferences (AUA, EAU, RSNA)
- TULSA-PRO and TACT clinical data presented to multiple institutions
- Low-cost / high-impact patient awareness initiatives

Early Adopter Pipeline

- Already visited about 75 potential users
- Includes top teaching hospitals, companies owning imaging centers with large footprint, and specialty urology practices

Potential Delivery Channels

- Opinion leading hospitals / Centers of Excellence
- Imaging centers
- Urology practice co-ops that focus on emerging technologies

Business Models

- Recurring revenue-only
- Capital + consumables sales

'Profound Genius Services'

- Start-up clinical support
- Flexibility – ablation of range of patients
- Productivity
- Patient awareness
- Reimbursement

Centers of Excellence

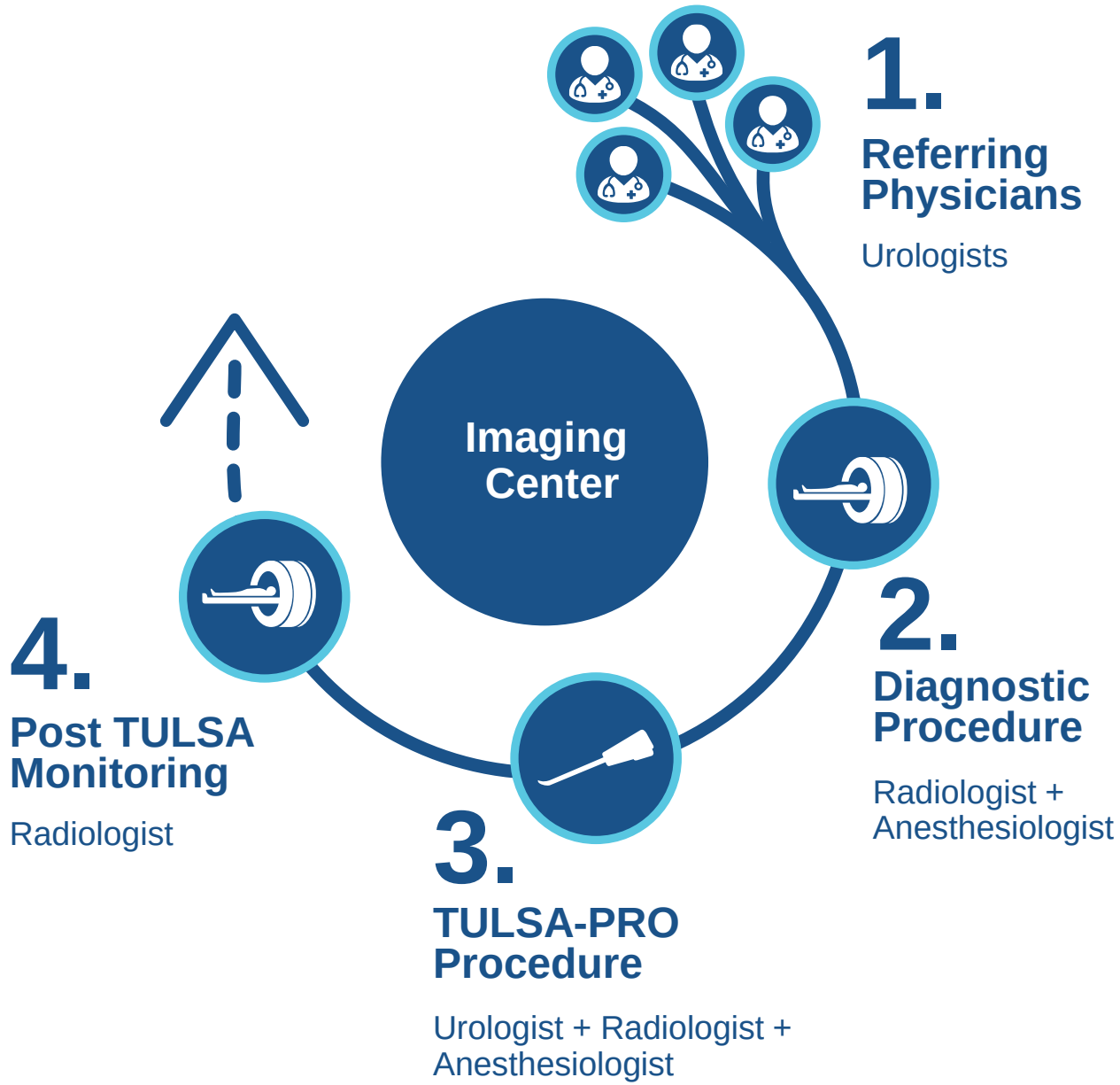
- Includes many of the TACT study sites
- Will likely be relatively low volume while TULSA is a patient self-pay procedure
- Best positioned to help drive long-term adoption by:
  - Participate in additional trials designed to support reimbursement
  - Training next generation of urologists
  - Presenting at medical conferences
  - Publish papers in relevant journals

TACT Trial Sites

Commercial Imaging Centers

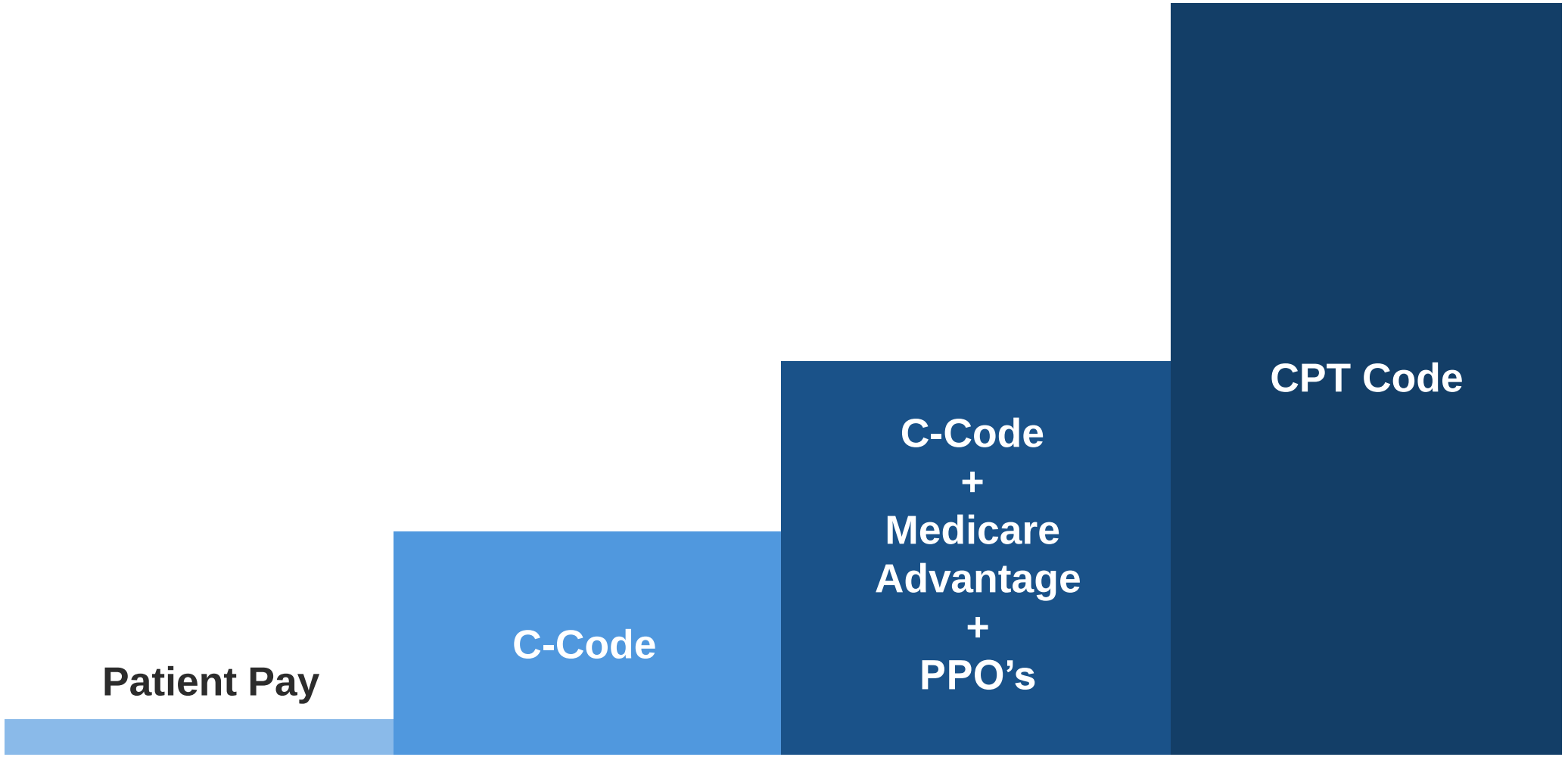
- 8,000 -10,000 imaging centers in U.S.; 40% owned by private equity or public companies
- Growing presence in urology due to MRI diagnostics, MRI-guided biopsy, MRI-guided follow-up
- Centers provide:
  - Service
  - Technology
  - In-house Radiologist(s)
  - Local Specialist Relationships (Urologists, Anesthesiologists)
  - Marketing
  - Payer Networks

First multi-site imaging center commercial agreement signed with RadNet in January 2020



Reimbursement Pathway

From “Cleared” to “Covered”



TULSA-PRO: Pre-Reimbursement “Patient Paid”

Significant Market Opportunity, Even With Low Single-Digit Initial Penetration Levels

New Prostate Cancer Diagnosis (U.S. + Canada)	**180,000[1]**
BPH, Prostates, surgical candidates, Unusual shapes (U.S. + Canada)	**400,000[2]**
Total Opportunity, # of patients	**580,000**
Total Addressable Market, assuming patient paid is 5% of total opportunity	**29,000[3]**
Add selected International markets (UK, Germany, Japan)	**14,500[3]**
Total patient pay addressable market # of patients	**43,500[3]**
Addressable market, $6,000 per patient (includes: disposable + amortized capital + service)	**$261,000,000[3]**
Achievable share in X years, 25% (<11,000 patients per year) TULSA Installed base = 110 at treatment rate 100 patients/year	**$65,250,000[3*]**

* Represents approximately 1% of total current annual prostate surgery and/or radiation treatment market

PROFOUND

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
3. Figures are not Profound projections. Rather, they are being provided for illustration purposes only.

“C-Code”

- Applied for a new technology “C-Code” in November 2019
- Typically takes 6 months to obtain a decision from CMS
- If approved, would provide for a 3-year period of coding and billing methodology for facility costs
  - Patients may only be required to personally cover $2,000-$4,000 in related physician fees

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“CPT Code”
Publication Package

		Rationale	Level	N	US %	Start
1.	TACT 2.0 5-year	• TULSA U.S. 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	1b	144 in 2:1 96 TULSA	~100%	2020
3.	Salvage 1-year	• Strong clinical value and 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, U.S.?)	• 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

AMA Requirements for Category I CPT Code

- FDA-cleared
- Performed widely by many physicians across U.S. (warrants new CPT code)
- Frequency consistent with intended clinical use 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)

Longer Term

Building an Incision- & Radiation-Free Ablative Therapeutic Platform

Oncology, Highly Symptomatic Chronic Diseases

PROFOUND

SONALLEVE

Current Approvals

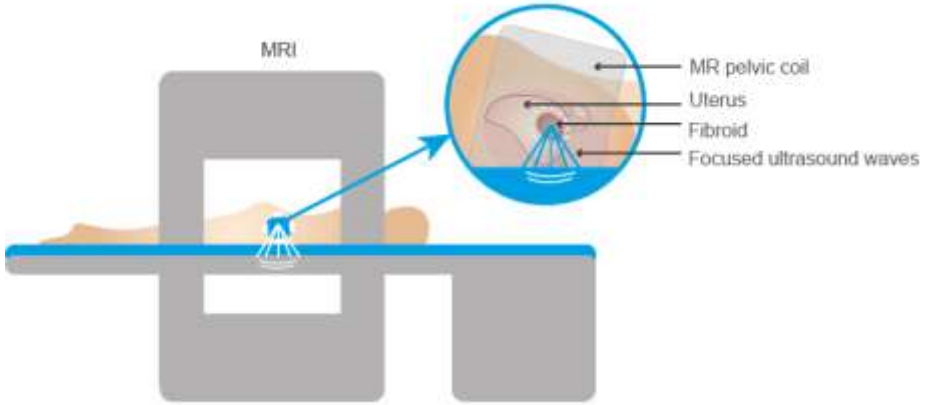
Europe: CE Marked

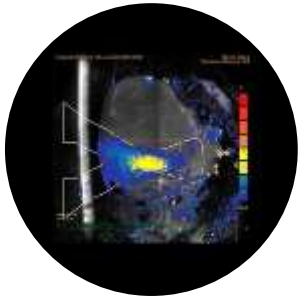
China: CNMPA Approved

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

U.S. & Western Markets

Partnered with Cologne University Hospital to develop critical clinical data for cancer and highly symptomatic chronic diseases

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

Long term business model – recurring revenue

China

Philips as distribution partner

- Small Profound direct sales team

Marketing for treatment of uterine fibroids

Reference site in S. Korea, treating 200 patients/year

Potential applications include:

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

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, continue work with MRI partners
- Additional clinical trials for TULSA-PRO for reimbursement
- Product enhancements