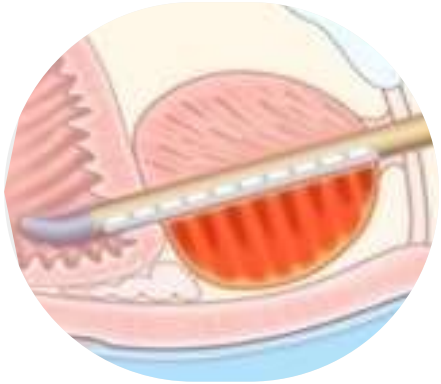
PROFOUND MEDICAL

Incision & Radiation-Free Surgery
Real-Time MR Guided Ultrasound Therapies

CORPORATE PRESENTATION | March 2019

 TSX: PRN | OTCQX: PRFMF

Profound Medical – The only company that can treat with real-time MR imaging, thermometry and energy source from the inside-out (catheter based) or from the outside-in



Inside out

TULSA-PRO®

Outside In

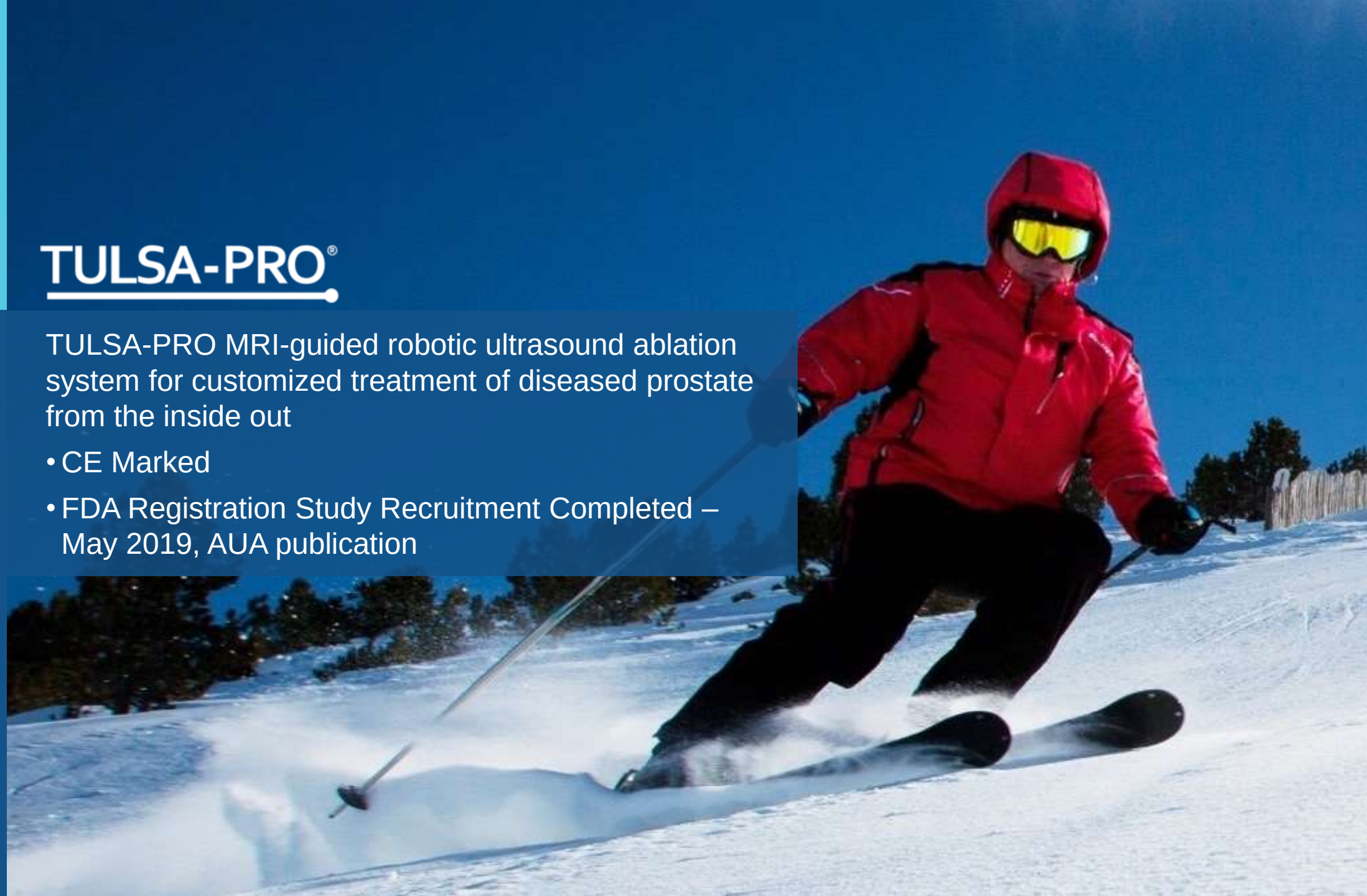
Sonalleve

- **Flexible, Customizable –** disease treatment to patient's exact need
- **Fast Patient Recovery –** from weeks to days
- **High Throughput –** four procedures in a routine day

TULSA-PRO®

TULSA-PRO MRI-guided robotic ultrasound ablation system for customized treatment of diseased prostate from the inside out

- CE Marked
- FDA Registration Study Recruitment Completed – May 2019, AUA publication



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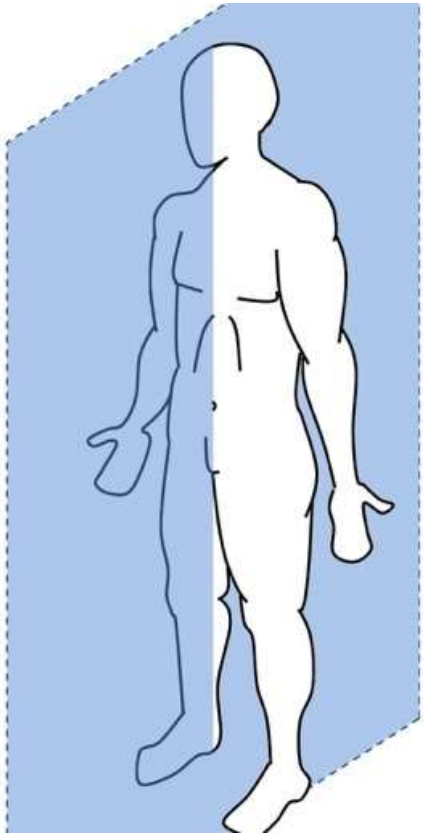
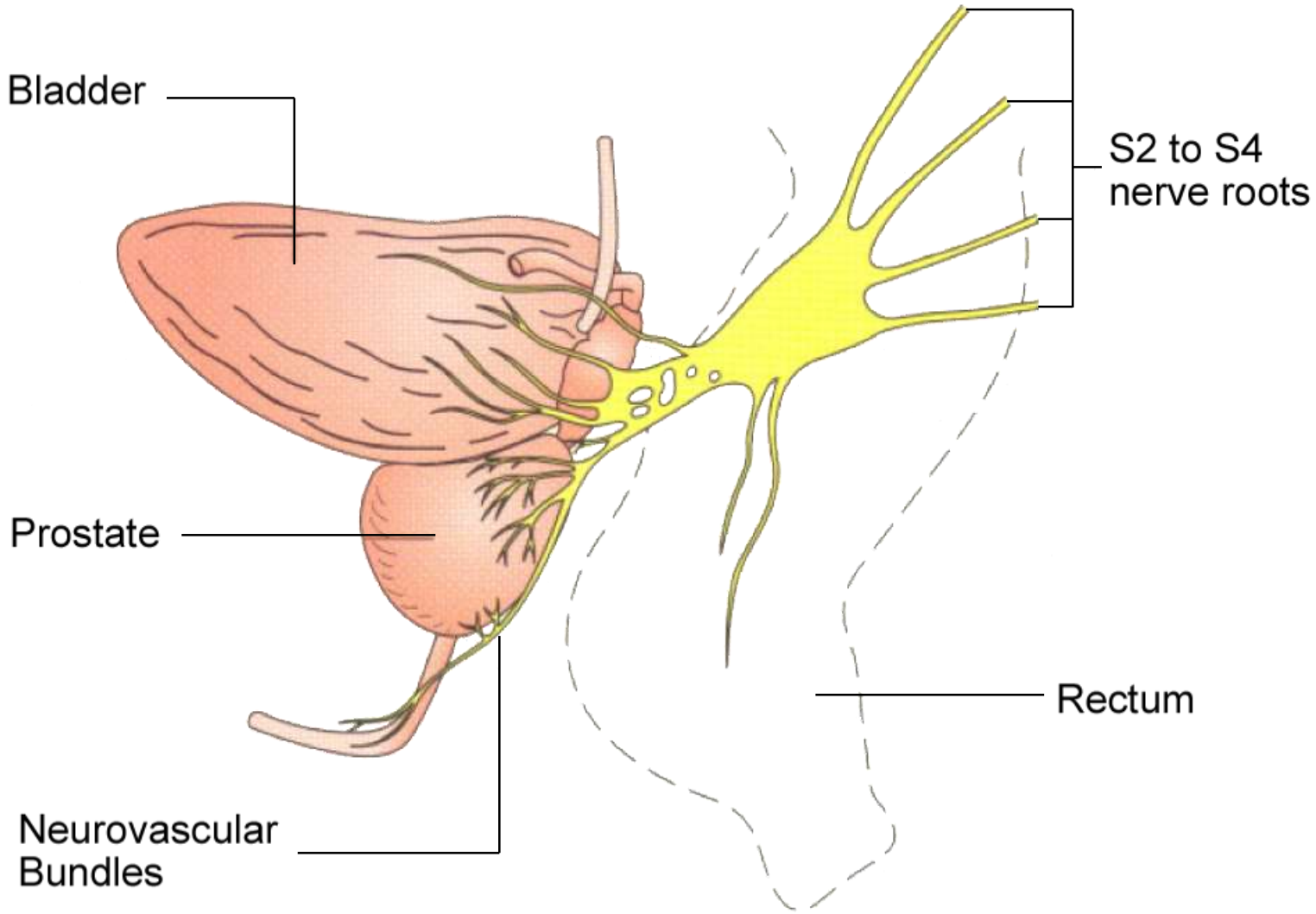
The Prostate





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

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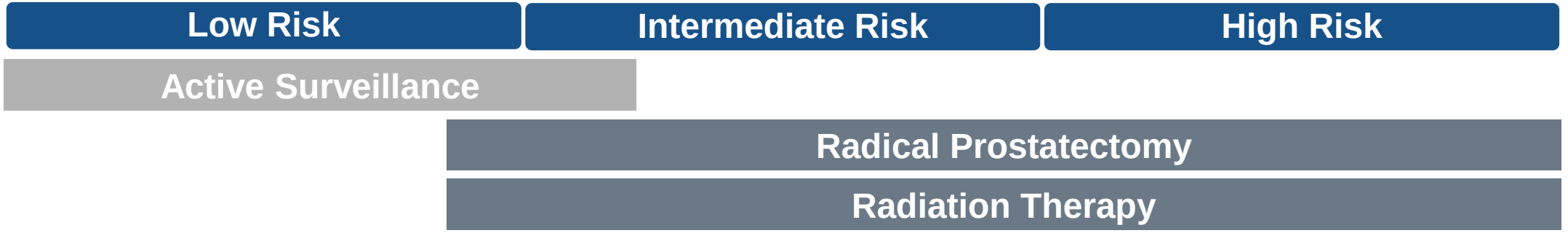
Localized Prostate Cancer – **Unmet Need**

Disease Staging - Today



Incontinence (10-30%),

Erectile dysfunction (20-80%)

Proctitis (5-25%)

Acceptable for patients with life threatening disease, but overtreatment for prostate localized disease specially low & intermediate risk

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

MR-Guided TULSA – **Closed Loop Temperature Control**

1. Transurethral directional ultrasound ablation

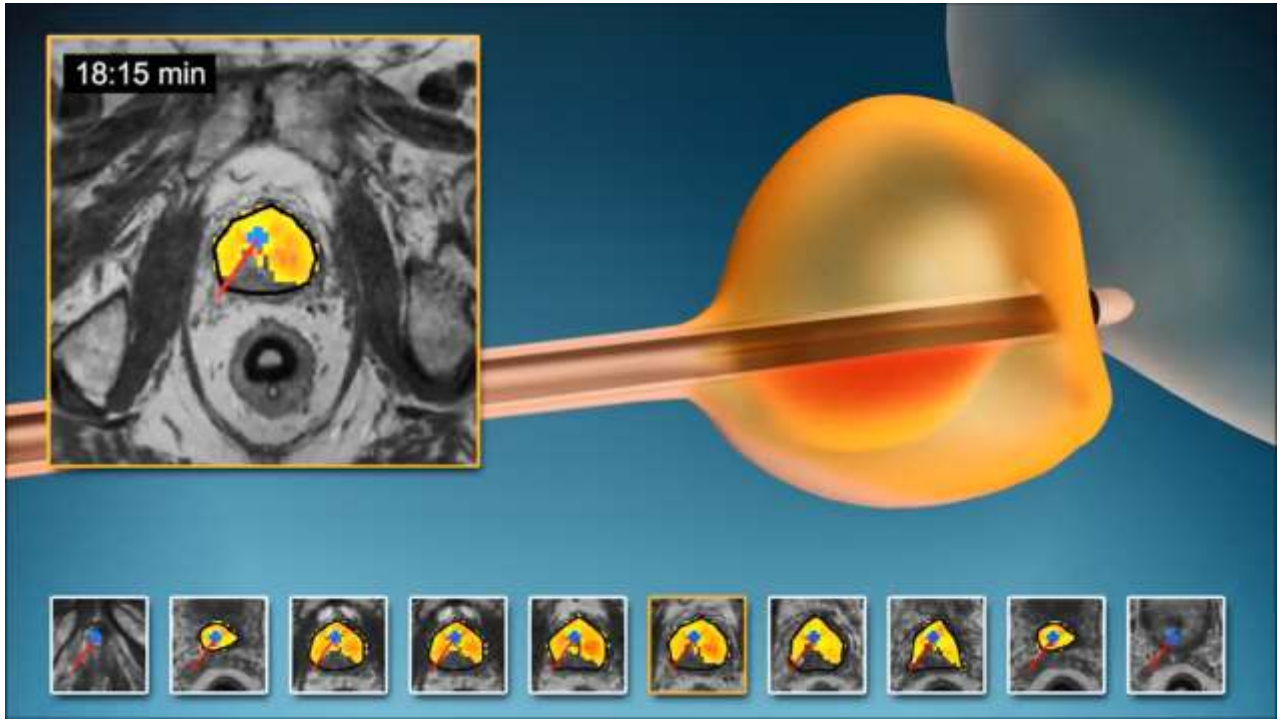
- Sweeping ultrasound, continuous rotation (no risk of cold spots between discrete sonications)
- Capable of treating large and small prostate volumes

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

- Real-time temperature feedback provides millimeter accuracy

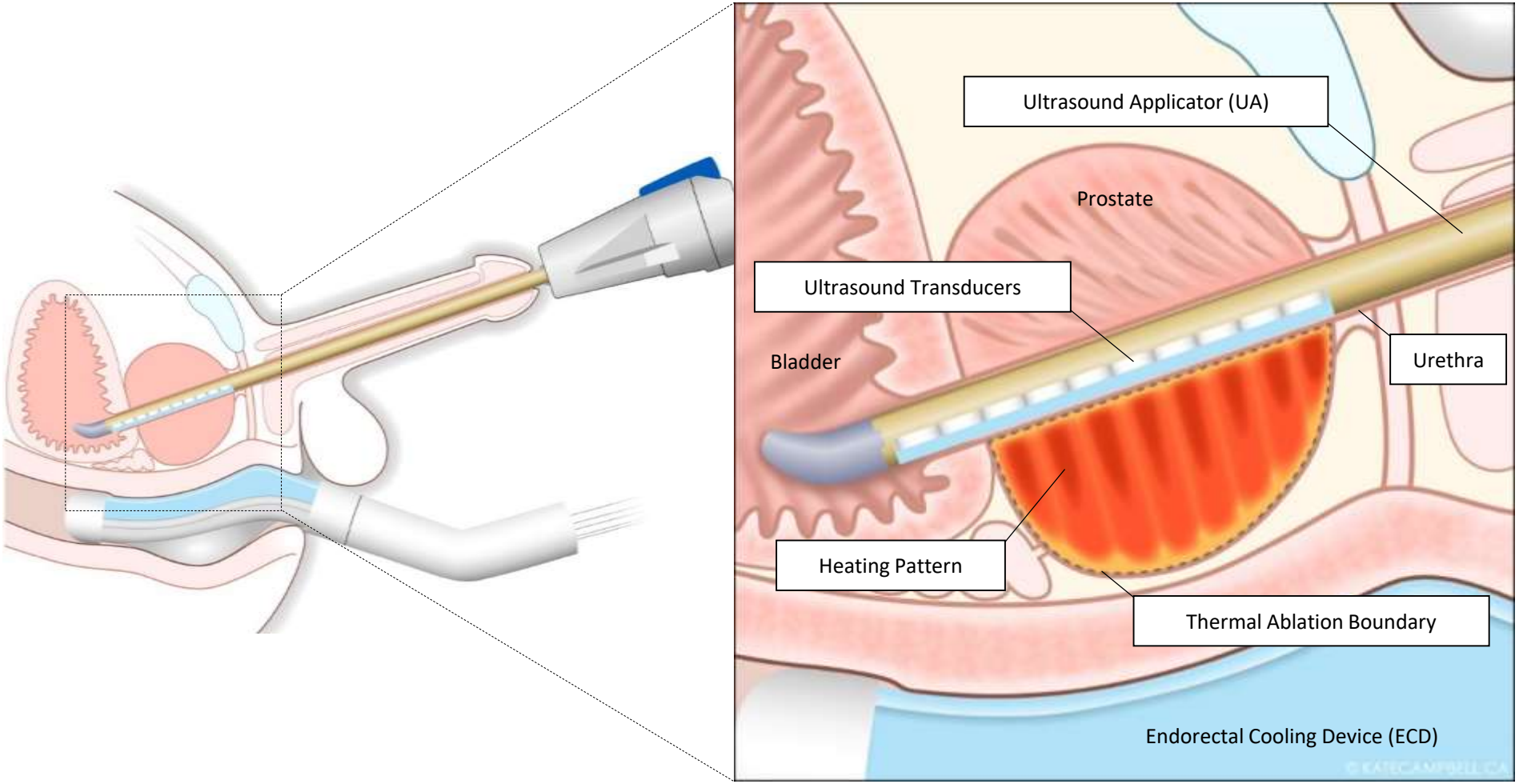
3. Urethra and rectum cooled

- Thermal protection of important anatomy



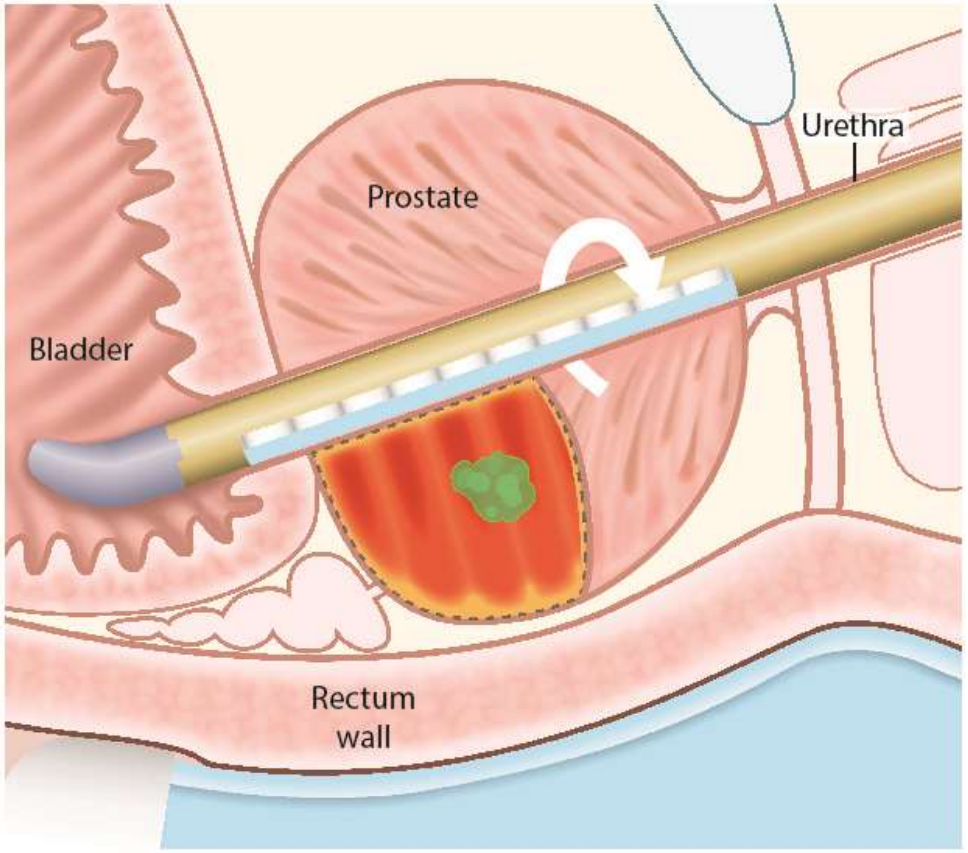
TULSA-PRO – **Prostate Ablation From The Inside Out**

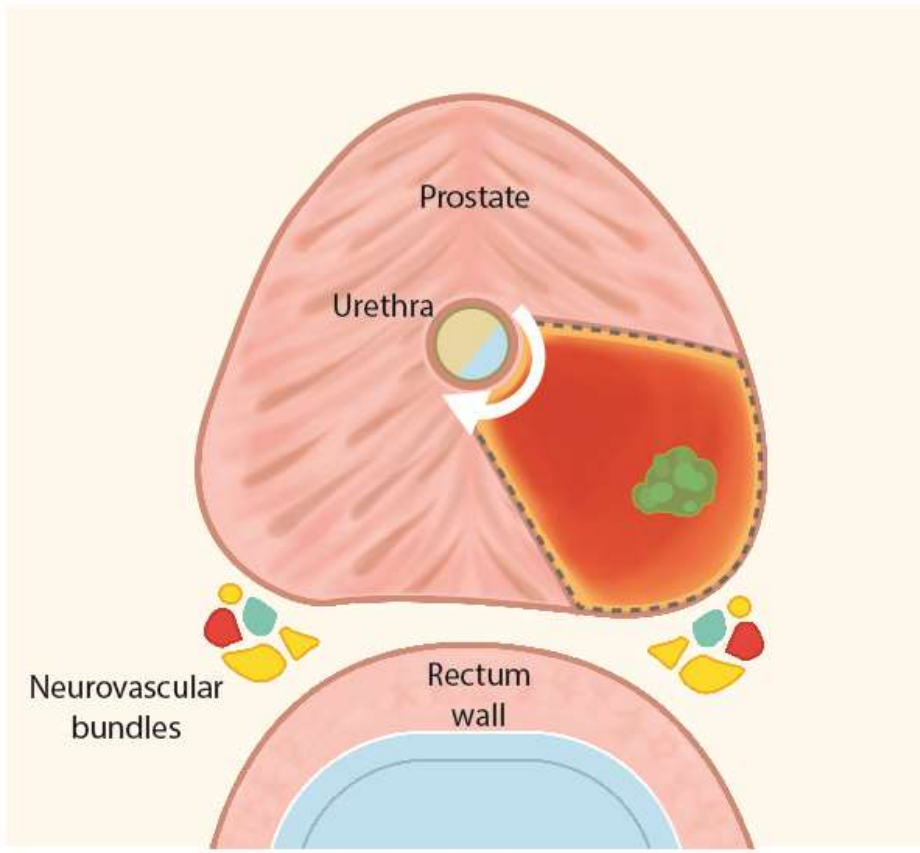
Whole Gland Ablation



TULSA-PRO – **Targeted Ablation**

Partial Gland Ablation





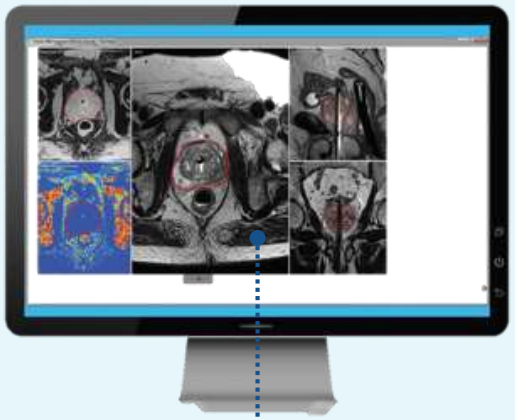
TULSA-PRO

Equipment

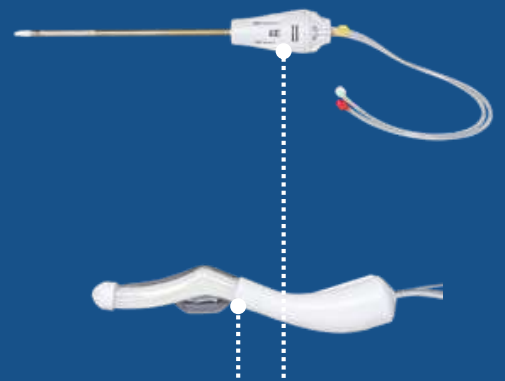
Compatible with MR from leading companies – Philips and Siemens

Robotic Arm,
Computer Hardware

Energy
System



Surgeon Console
Control Room

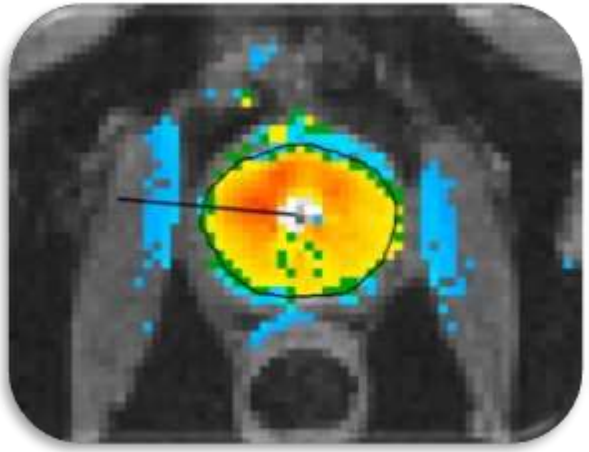


Disposable
Applicators

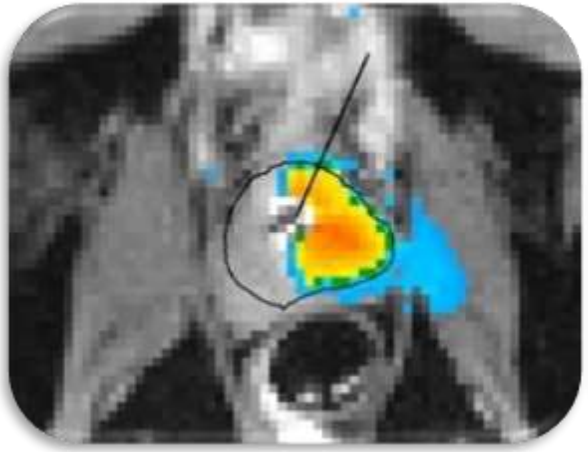
TULSA Flexibility

Precise Whole Gland or Customized Partial Gland Ablation

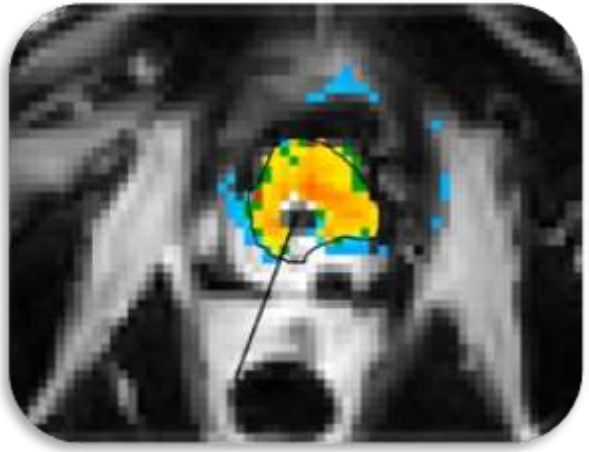
Whole Gland Ablation



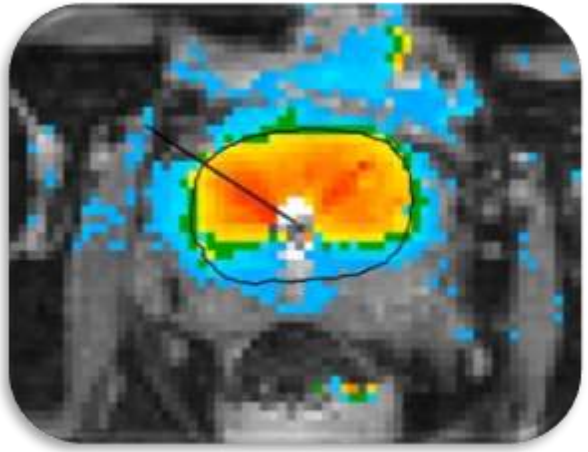
Targeted Ablation



Salvage Therapy Post Radiation Therapy Failure



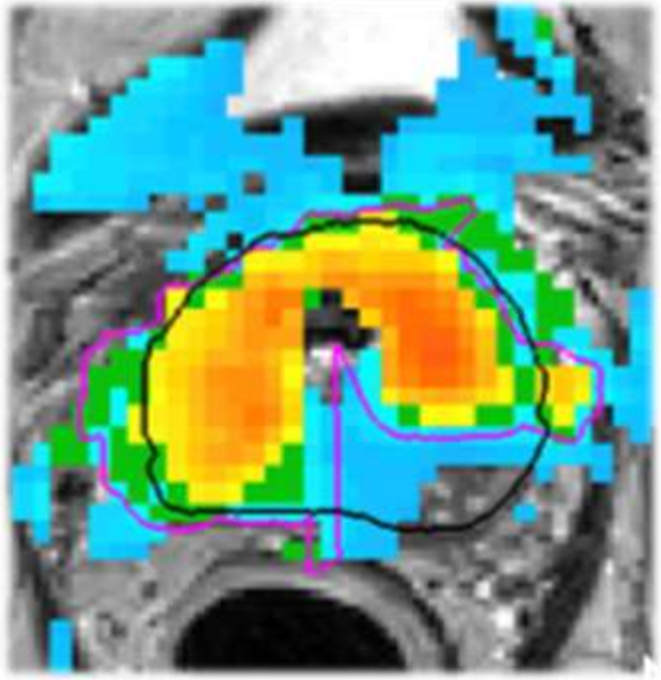
Benign Prostate Hyperplasia (BPH)



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

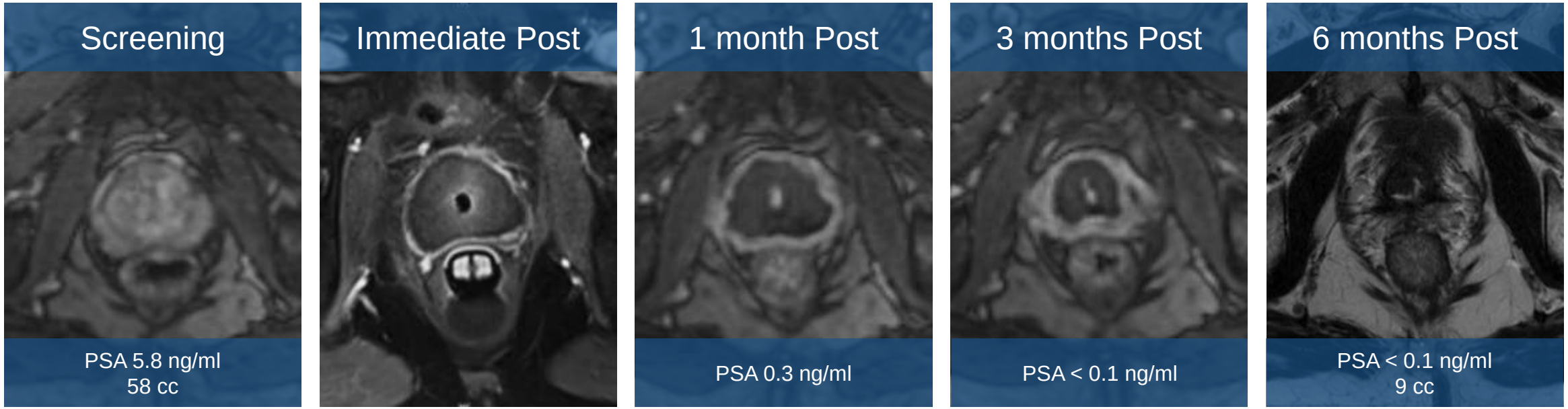


Patient with BPH and early stage lesion

Example – **Ablation on MRI**

Ablation & Volume Reduction on MRI

- 67 years old, multi-focal GS 3+4 disease (biopsy), 1x PIRADS 3 Left Mid Anterior (MRI)
- Complete ablation confirmed on CE-MRI immediately after TULSA and during follow-up
- MRI and PSA show ablation of almost entire prostate, with no evidence of complications
- 12-month prostate “size of raisin” and negative for adenocarcinoma on biopsy



Courtesy Dr. Steve Raman, University of California Los Angeles (UCLA)

Adding Incision & Radiation-Free Intervention – A New Paradigm To Treat The Disease

Whole gland removal

Whole gland radiation, multiple sessions

Disease targeted ablation

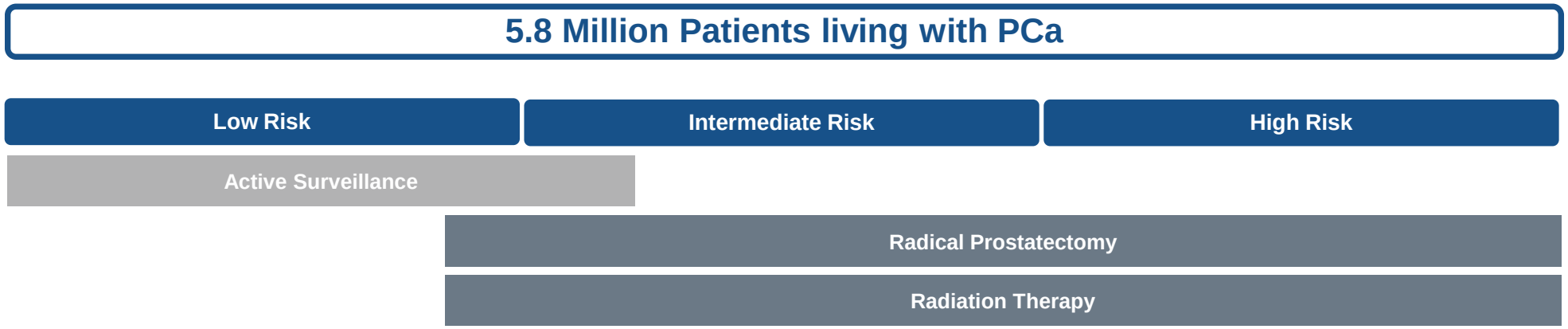
Potential to Expand Urologist Practice

- Potential to keep radiation candidates “in practice”
- Treat patients - large prostates, BPH, high volume disease
- TULSA-PRO – significantly less intervention time

TULSA Unique **Benefits**

- **Flexible, Customized to Individual Patient's Disease/Need**
  Real-time MRI guidance and control, quantitative thermal dosimetry allows Interventionist to ablate only the diseased part of the prostate potentially preserving healthy tissue
- **Actively Protect Urethra and Rectum**
  Water-cooled Ultrasound Applicator (UA) and Endorectal Cooling Device (ECD), single-use disposable
- **Large Prostate Ablation Capable**
  Transurethral approach inherently safer than outside-in, no energy directed through rectal wall.
  Capable of ablating any size prostate
- **High Patient Throughput, well tolerated by patients**
  Four cases per day
- **Possibility of Future Treatments**
  Repeatable ablation, and does not prevent future treatment with standard of care therapies

Target TULSA-PRO Market Segment



TULSA-PRO Target Patients

1. Palliative patient care
2. Radio recurrent salvage therapy
3. Organ confined prostate cancer disease
   a. Patients with active lives
   b. Patients under active surveillance but don't want to wait, or also have BPH
   c. Patients with co-morbidities preventing surgical intervention
   d. Patients with early stage disease, Gleason Score (GS) = 3+3 but genetic testing indicates aggressive disease
   e. Patients with MRI visible disease pattern
4. BPH patients with very large prostates

TACT Pivotal Trial: Full Prostate Volume Ablation (99%)

To Support FDA Application, Enrollment Completion Feb 2018

Trial Design

- 65% intermediate risk. 35% low risk PCa
  45-80 y, PSA ≤ 15, GS ≤ 3+4
- n = 115, 13 clinical sites, 5 countries

Primary endpoints (12 months)

- Efficacy: PSA reduction ≥ 75%
- Safety: Frequency & severity of adverse events

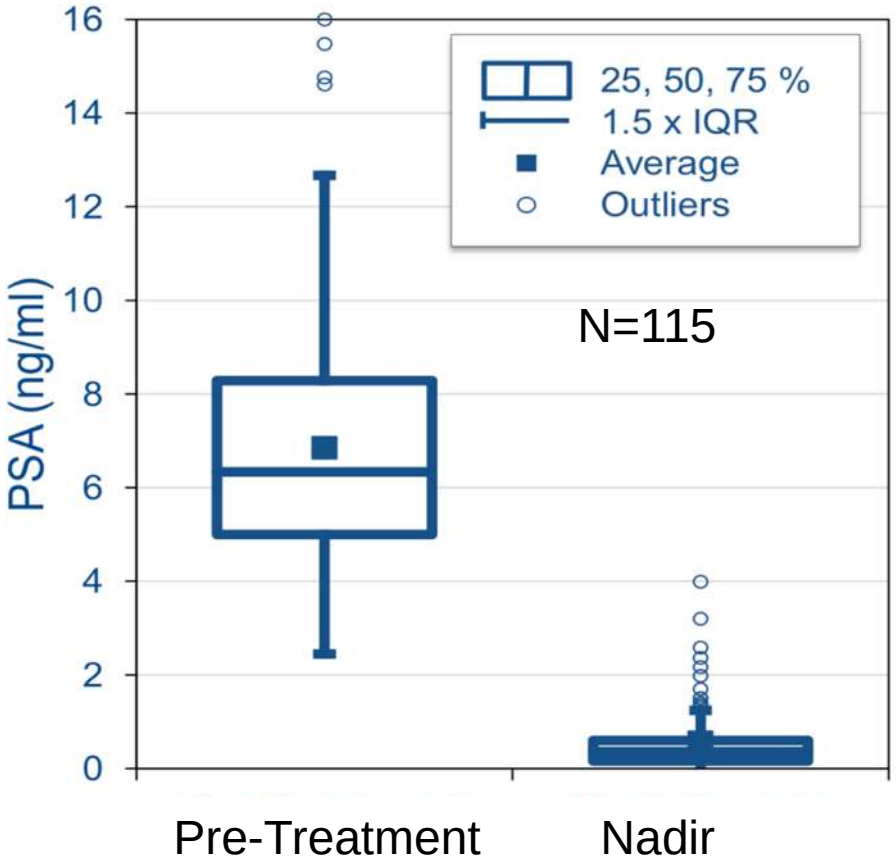
Secondary endpoints

- 12 month MRI and biopsy in all patients
- QoL: EPIC, IIEF, IPSS

TACT Pivotal Trial

Safety and PSA Outcomes

Full data expected in Spring 2019



Primary efficacy endpoint

- PSA nadir ≤ 25% of pre-tx baseline

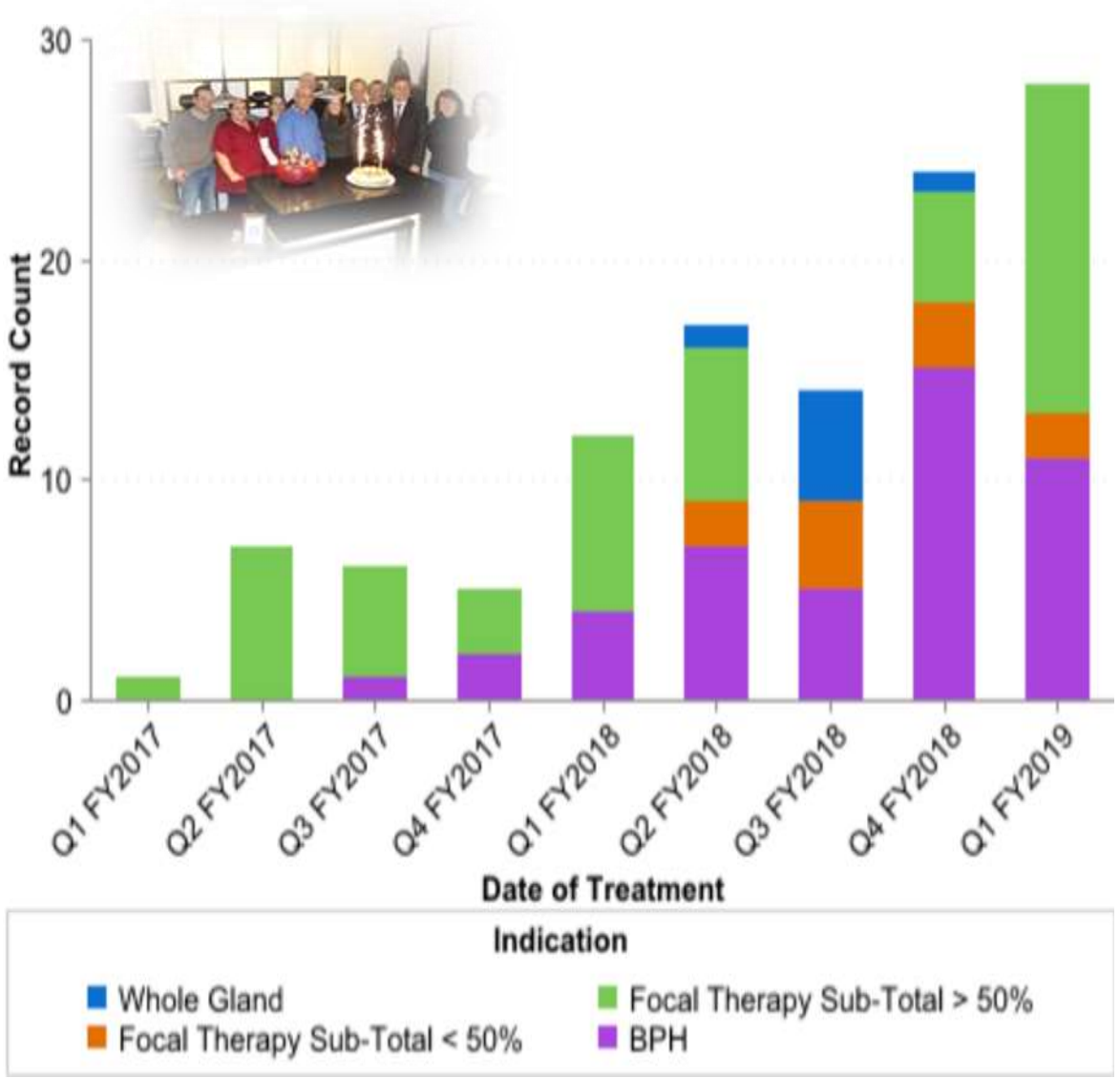
Results to-date

- 95% of patients met PSA endpoint
- PSA reduction 95% (91 – 97%)
- PSA nadir 0.36 (0.16 – 0.60) ng/ml

Safety

- No rectal injury, No Grade ≥ 4 AE,
  No incontinence > Grade 1
- Attributable Serious AE in 7% of patients, all resolved: 3 G2 retention, 3 GS infection, 1 urinoma, 1 ileus, 1 DVT

TULSA-PRO In Commercial Use – Example From Europe



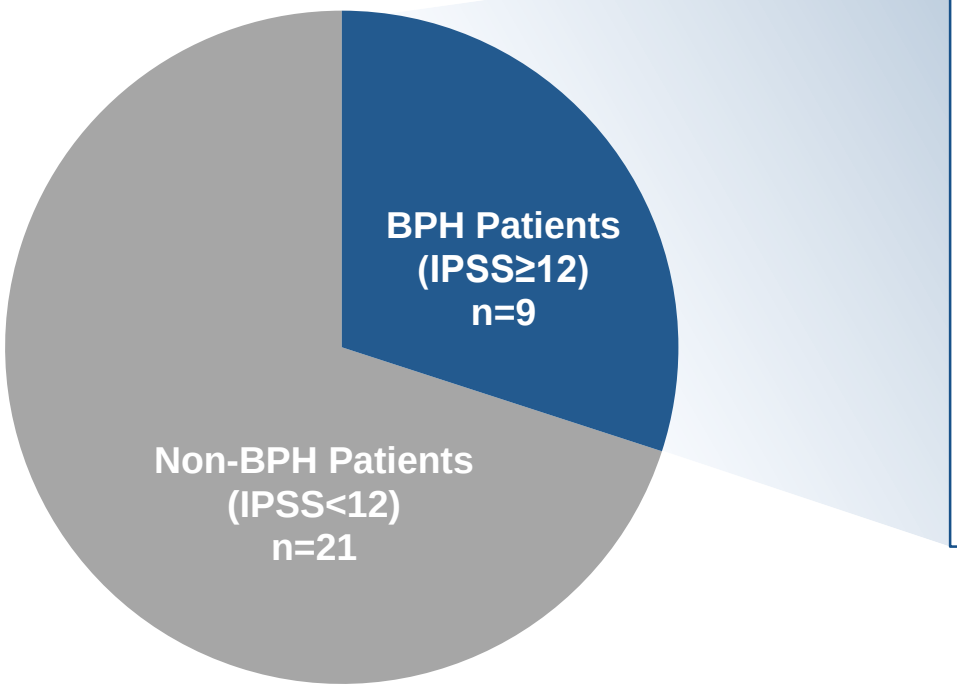
- Initiated Q1-2017
- Methodically increased usage
- Discovered potential to treat BPH patients – Q3-2017
- Streamlined procedure – routinely 4 patients per day
- Increased utilization rate in 2019

TULSA-PRO For BPH

Retrospective Analysis

- Physicians involved in the TULSA trial observed strong anecdotal results in patients with BPH
- A retrospective examination of the quantitative results has shown a consistent trend

TULSA Phase 1 Study (n=30)



BPH Patients in Prior Study

- There were 9 patients in the Phase 1 study who had at least moderately symptomatic BPH
- Determined by International Prostate Symptoms Score (IPSS) ≥ 12, in addition to cancer at baseline

Feasibility

of TULSA-PRO for BPH

Retrospective subgroup analysis of 9/30 Phase I patients with IPSS ≥12 suggests similar urinary symptom relief as other surgical techniques

Characteristics	Baseline	12 months	Change (%)
IPSS	16.1 ± 3.8	6.3 ± 5.0	-9.8 ± 5.0 (58 ± 34%)
IPSS QoL	2.8 ± 1.1	0.8 ± 1.0	-2.0 ± 1.7 (66 ± 48%)
Prostate Volume (cc)	54 ± 23	14 ± 5	-40 ± 24 (70 ± 19%)
Peak flow (Qmax, ml/s)	14.5 ± 4.1	21.9 ± 12.7	+7.4 ± 13 (60 ± 93%)

No Grade 3 adverse events, erectile function (IIEF) stable from 15±9 to 16±9,
% Patients with erections sufficient for penetration (IIEF Q2 ≥2): from 7/9 to 8/9 men

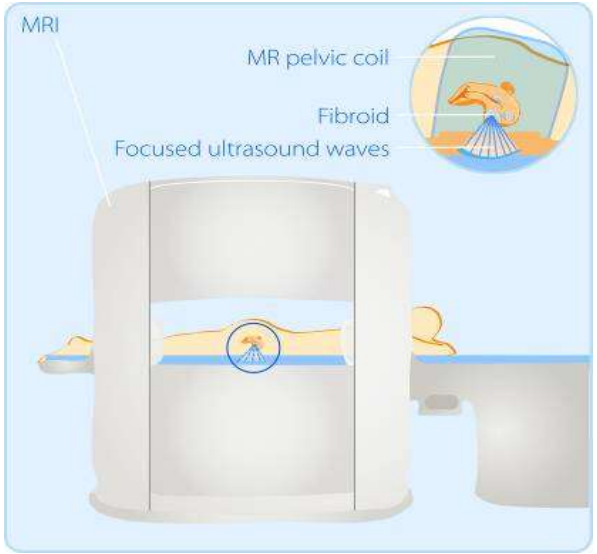
SONALLEVE

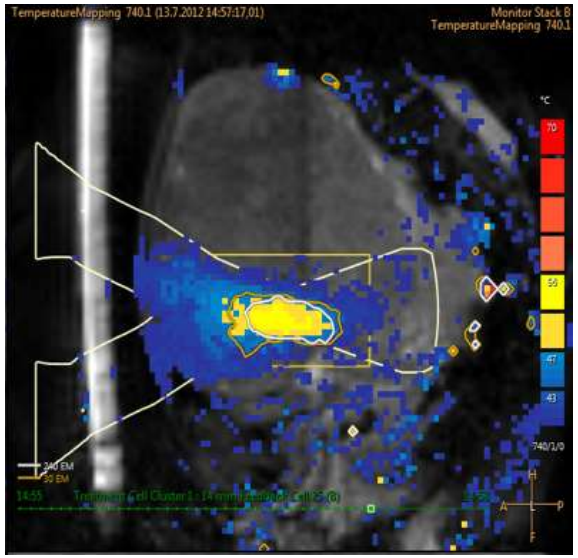
Technology platform for:

- 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

PROFOUND MEDICAL

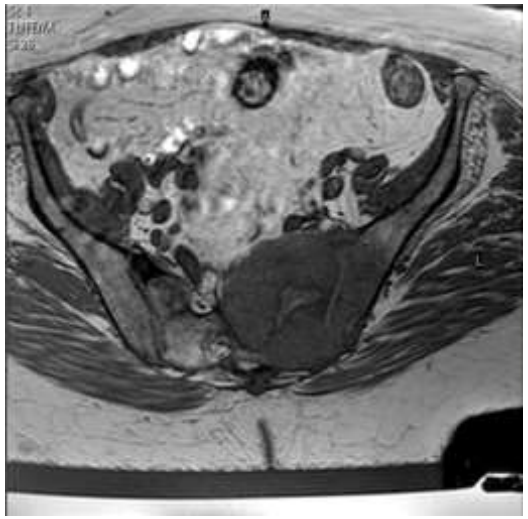
Sonalleve: Bone Metastasis Pain Therapy

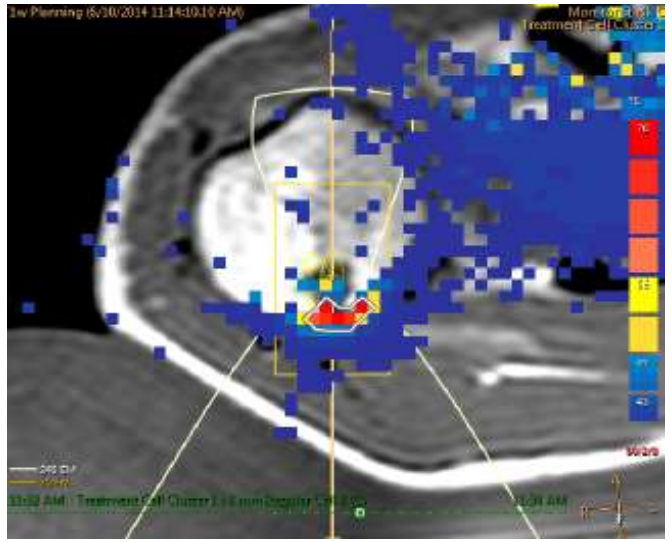
Non-invasive alternative to radiotherapy

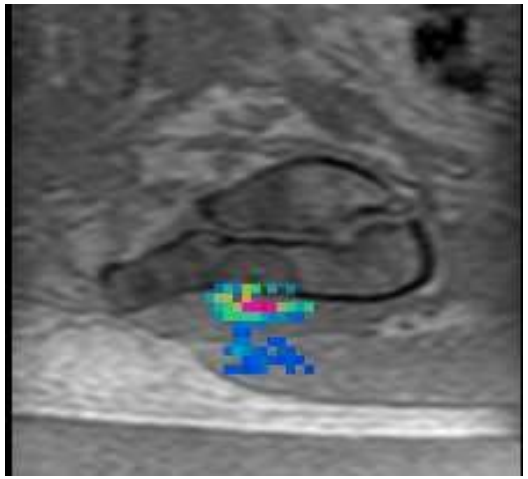
Most patients with slow growing tumors develop bone metastasis in the later stage of the disease.

Bone changes and malformations irritate nerve endings creating significant pain for patients.

- Radiotherapy standard of care for bone mets, but 20-30% of patients do not respond
- Sonalleve as non-invasive alternative to radiotherapy
- Heating of bone surface, ablation of periosteal nerves
- Quick pain relieve in 2-3 days, vs. radiotherapy typical 3 weeks

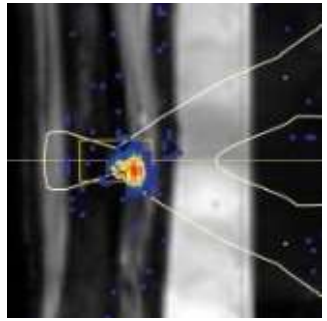






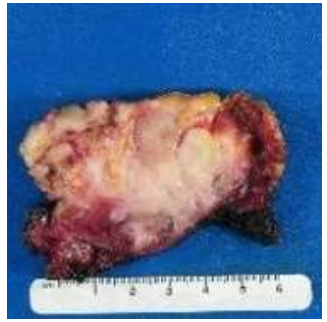
Exploring Further Indications on Current Platform

Pediatrics, Hyperthermia



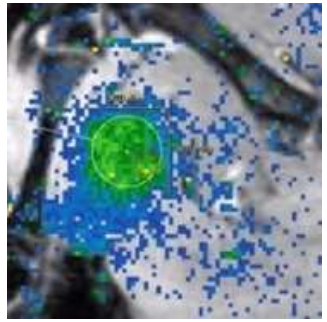
Pediatrics: Osteoid osteoma

- Very painful, benign bone tumor in children and young adults
- MR-HIFU very effective, immediate pain relief and bone restructuring
- Standard of care is radiofrequency ablation (RFA, invasive)



Pediatrics: Desmoid tumors (Fibromatosis)

- Benign aggressively growing tumors, everywhere in the body
- Can cause severe (bulk) symptoms
- Surgery (+/- radiotherapy) is standard of care, but high risk of recurrence
- Successful MR-HIFU treatments presented as individual case studies



Hyperthermia

- Increase tumor sensitivity to Radiation and Chemo Therapy
- Local heating to 40 – 43°C, precise control of temperature and lesion size
- Adjuvant therapy to chemotherapy or radiation therapy
- Enabling technology for Local Drug Delivery

Adoption Strategy

TULSA-PRO

1. Limited launch in Europe
   - Confirmation of business model, value proposition & additional clinical data generation
2. US– 510(k) file – Q2-2019
   - TACT complete data release at podium presentation at AUA – May 5-2019
3. Full launch in US and Europe – H2, 2019
   - Leverage agreements with Philips and Siemens for capital sales
   - Direct sales to build recurring revenue model – per patient kit

Sonalleve

1. Pilot launch in China
   - CFDA approved in May 2018, launched in September 2018
   - Leverage distribution agreement with Philips and its installed base of MR's in China
   - Initial focus – key opinion leading reference sites

Combining Two Powerful Modalities – real time MR and thermal ultrasound to create incision and radiation free intervention

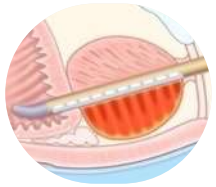
Disease Treatment

Not

Organ Removal

1. Precise
2. Flexible
3. Safe

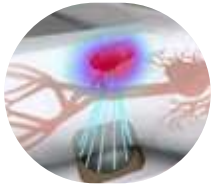
TULSA-PRO®



Treatment for prostate disease

- CE marked
- FDA expected H2-2019

Sonalleve



Treatment for uterine fibroids, bone metastasis, pediatric

- CE marked
- China FDA approved for uterine fibroids