



Incision-free Surgery
Real-Time MR Guided Ultrasound Therapies

CORPORATE PRESENTATION | MAY 2018

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Profound Medical: Providing incision free surgery, customized to each patient and delivered with precision



Precision
Diagnosis

The diagram consists of two dark blue circles, one on the left and one on the right. Inside the left circle is the text 'Precision Diagnosis' and inside the right circle is the text 'Customized Therapy'. Between the two circles is a light blue plus sign. Below each circle is a list of bullet points. The left list is under the heading 'Enhanced Diagnosis and Targeted Identification' and the right list is under the heading 'Therapy capable of being:'.

Enhanced Diagnosis and Targeted Identification

- MP-MRI
- MR Guided Biopsy
- Genomics

Customized
Therapy

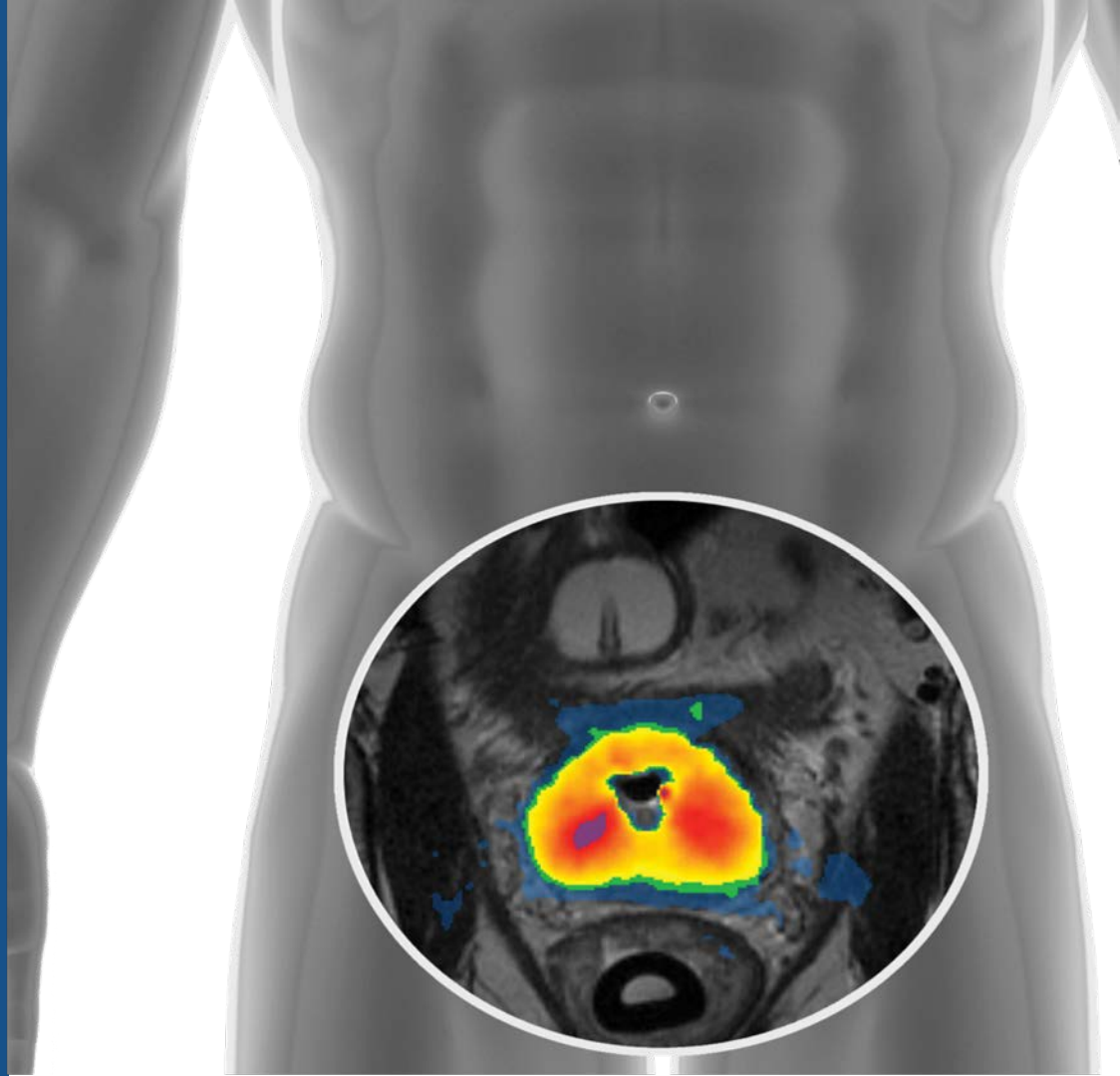
Therapy capable of being:

- Customized to each patient's anatomy and pathology
- Precisely planned
- Delivered with precision

TULSA-PRO®

Prostate Treatment

TSXV: PRN | OTCQX: PRFMF



MR-Guided Transurethral Ablation of Prostate

Ultrasound Thermal Energy & Precise Real Time Process Control

TULSA-PRO®

Precise ablation with millimeter accuracy

- Real-Time MR Imaging
- Real-Time process control of ablation using MR temperature map and robotically driven arm

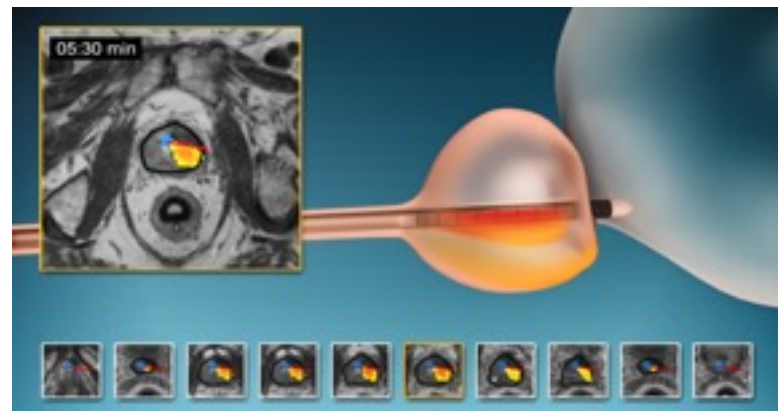
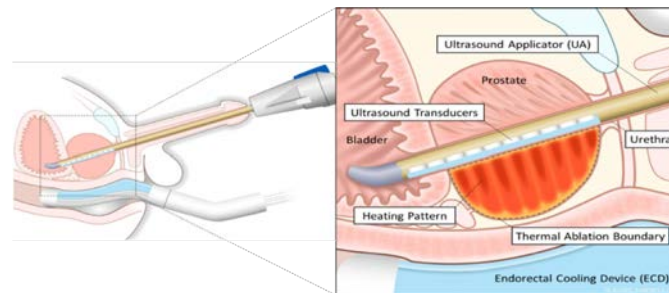
Customized treatment to meet each patients particular need

- Urologist defines region of ablation
- Full gland to targeted therapy for localized cancer
- BPH

Safety by design

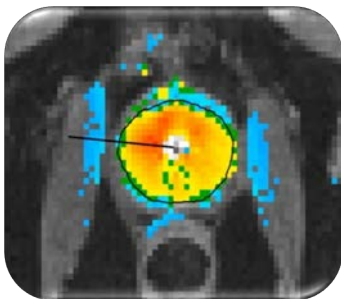
- Ablate from Inside-prostate; safer than outside-through rectum, able to treat prostates >140 cc
- Actively protects urethra and rectum via cooling
- MR and Ultrasound heating are safe modalities

Two hour procedure time

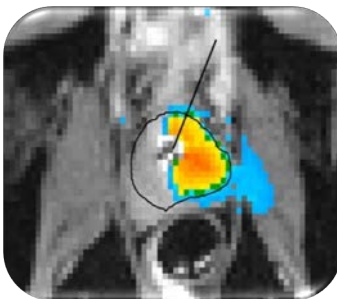


TULSA Technology Offers Ablative **Flexibility**

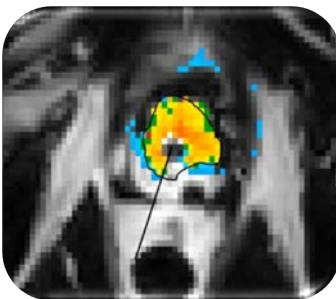
Whole Gland
Ablation



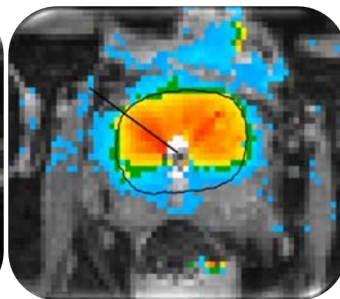
Targeted
Ablation



Salvage Therapy
post Radiation
Therapy Failure

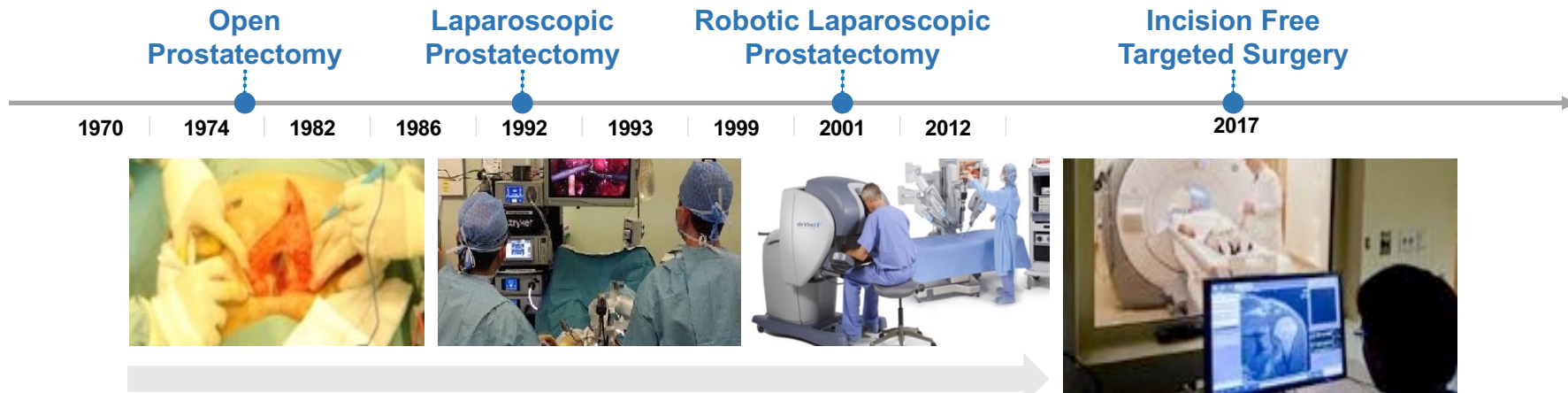


BPH



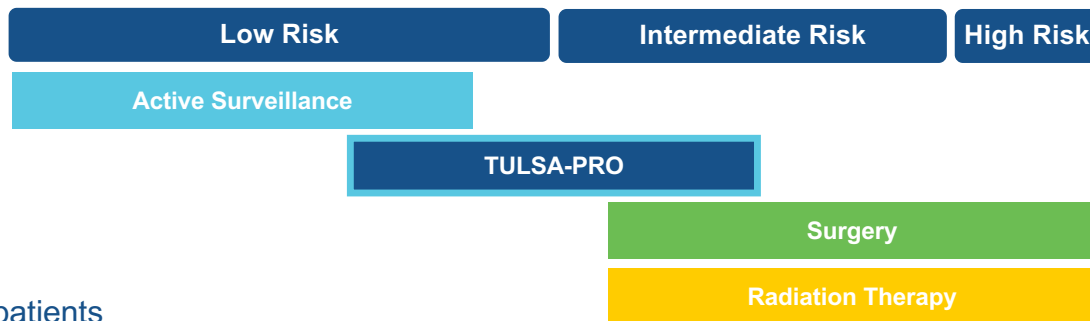
- Treatment – natural follow-on to MRI guided diagnosis and MRI guided biopsy to diagnose disease with precision
- Outpatient procedure – patients discharged within 24 hours
- Customized treatment plan to each prostate anatomy and pathology
- Real-time MRI guidance and control ensures accurate ablation to 1.3 mm precision
- Inside-Prostate approach allows for treatment of large prostates > 140 ml

From Open Surgery to Incision-Free Surgery



SURGERY TYPE	FULL PROSTATE REMOVAL	FLEXIBLE: FULL PROSTATE OR TARGETED CANCER ABLATION
Invasiveness	Reduced	Incision free
Recovery time	Reduced	Day surgery
Clinical outcome	Improved recovery time	Improved, Customized, Precise
Surgeon skill	Dependent	Closed loop process control automation
Cost of Surgery	Higher	Lower

TULSA-PRO Addressing Unmet Needs



Unmet needs

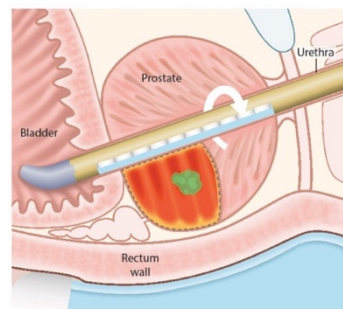
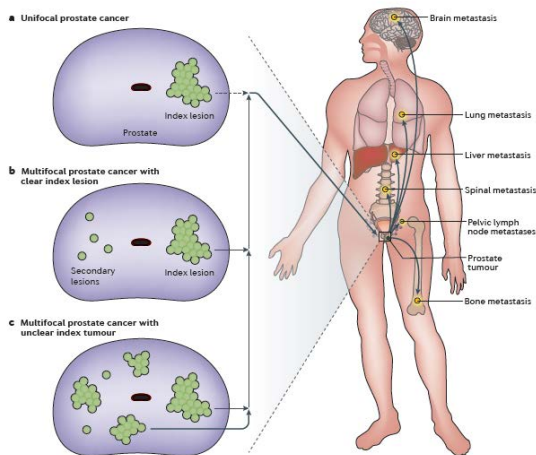
1. Intermediate risk patients
 1. Active lives, side effects matter
 2. Comorbid, surgery carries risks
 3. MR visible lesion
2. Low risk patients
 1. Also have BPH
 2. Want an intervention
 3. Active lives
3. Salvage therapy patients
4. Early stage disease, Gleason Score (GS) = 3+3 but genetic testing indicates aggressive disease

TULSA does not preclude any additional intervention if needed in the future

Enables Targeted to Whole-Gland Treatment

- Over 90% of prostate cancers present with multi-focal lesions
- 20-40% of patients have their disease confined to one side of the prostate

- Multi-focal nature of prostate cancer requires that clinicians have tools that can provide them precise, safe and effective partial to whole gland range of treatment



Focal Ablation



Whole Gland Ablation

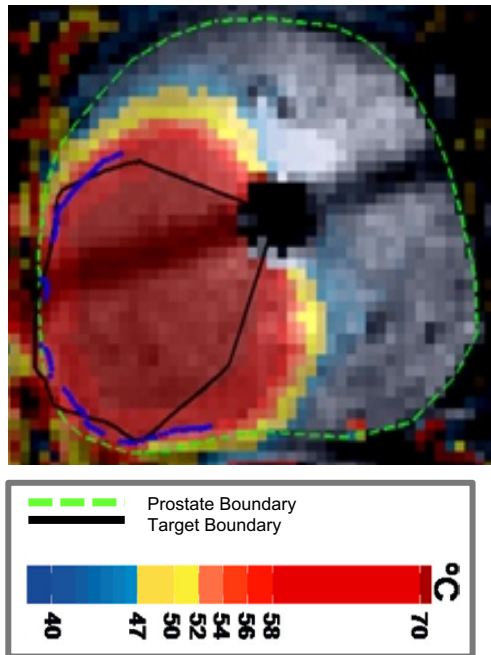
Perera M et al. An update on focal therapy for prostate cancer. Nature Reviews Urol 2016; 13:641-53.

Ablation Efficacy: Confirming Ablation of MR Visible Lesion

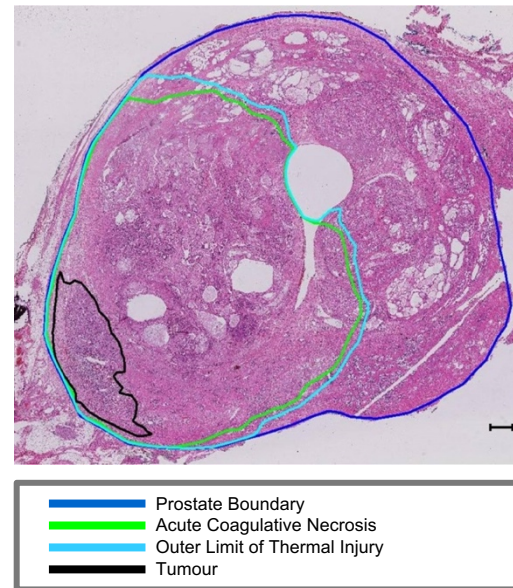
Clinical Histology (gold standard)

- Treat-and-resect clinical study, targeting MRI-visible lesion with TULSA (n=5)
- TULSA followed by Radical Prostatectomy on same day
- Histology confirmed complete ablation of target lesion to prostate capsule, accuracy 0.4 ± 1.7 mm

MRI Thermometry



H&E Histology



Ramsay *et al* 2017, The Journal of Urology, 197(1):255-261

Phase I Clinical Trial Completed: **90%** Prostate Ablation

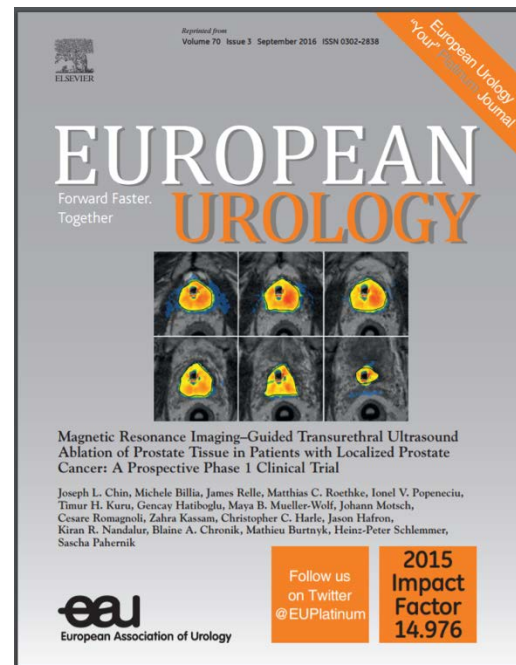
Study Population – Low & intermediate risk prostate cancer patients, ≥ 65 years old (n=30)

Well-tolerated favorable safety profile with minor impact on urinary, erectile and bowel function at 12 months

1. 0/30 urinary incontinence (pads) at 12 months
2. 0/30 rectal fistula or bowel urgency
3. 21/30 patients potent pre-treatment → 20/29 potent at 12 months (ED def: IIEF Q2 ≥ 2)
4. Prostate volume reduced 88%
5. PSA decreased 90%
6. Total cancer core length reduced by 75% - by prostate TRUS biopsy at 12 months

Treatment accuracy – Median thermal ablation accuracy & precision: 0.1 ± 1.3 mm

Ultrasound treatment time – Median 36 min for 44 cc prostate volume



Chin *et al*, European Urology (2016)
Bonekamp *et al*, European Radiology (submitted)

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

To support FDA application, enrollment completion Feb 2018

Study Population: Low & intermediate risk patients, 45 – 80 years old, n=110, 13 clinical sites

Primary Endpoints

- Safety – Frequency and severity of adverse events
- Efficacy – PSA reduction $\geq 75\%$
 - Proportion of patients achieving PSA nadir $\leq 25\%$ of the pre-treatment baseline value
 - Performance goal for the success proportion is 50% of patients

Secondary Endpoints

- Prostate volume reduction on MRI at 12 months, PSA nadir – % patients with PSA ≤ 0.5 ng/ml, PSA stability – % patients with PSA ≤ 0.5 ng/ml at 12 months
- Prostate TRUS biopsy – % patients with negative biopsy at 12 months
- Erectile function – Change in % patients with IIEF-5 ≥ 17 , Erection firmness sufficient for penetration – Change in % patients with IIEF Q2 ≥ 2
- Urinary incontinence – Change in % patients using ≥ 1 pad / day
- Quality of life – IPSS, IIEF-15 & EPIC-50
- Targeting accuracy – Accuracy and precision of conformal thermal ablation of target prostate volume

Based on a preliminary analysis performed by the Company, of the first 63 evaluable patients, the median PSA reduction to-date is 93%, and 92% (58 out of 63) have achieved the PSA reduction success proportion – January 2018

Additional data to be presented at AUA on May 19, 2018

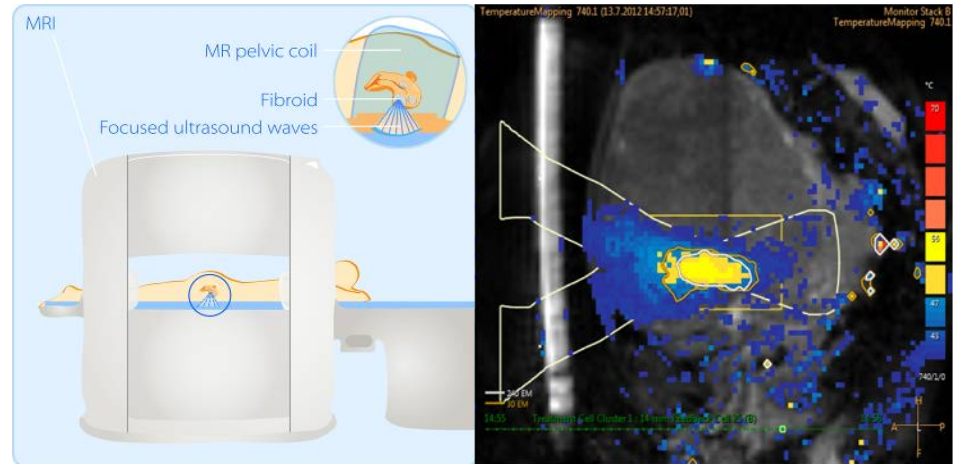
SONALLEVE

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



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

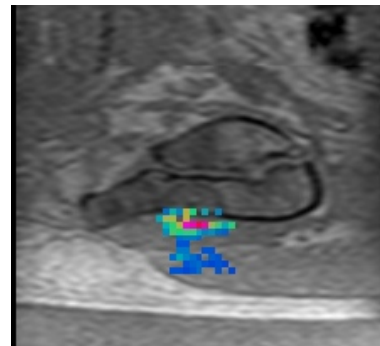
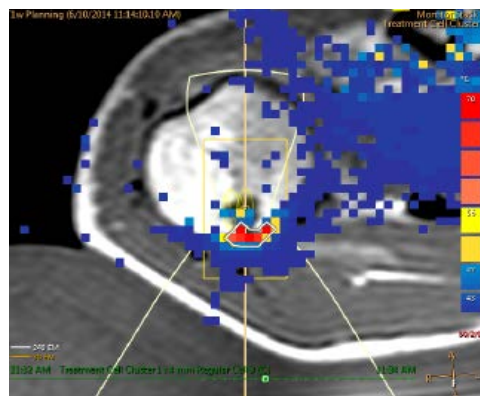
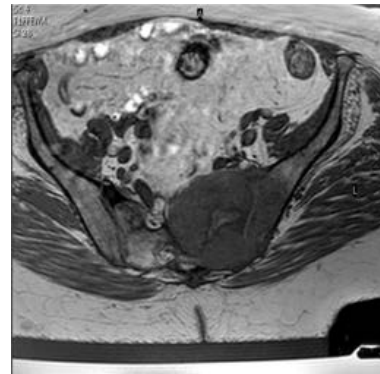
"Volumetric MR-guided high-intensity focused ultrasound ablation of uterine fibroids: treatment speed and factors influencing speed," M. J. Park, Y. S. Kim, B. Keserci, H. Rhim, and H. K. Lim, Eur Radiol, vol. 23, no. 4, pp. 943–950, Apr. 2013. 1. Gorny KR, Woodrum DA et al. Magnetic resonance-guided 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. Rossetti 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

Sonalleve: Bone Metastasis Pain Therapy

Non-invasive alternative to radiotherapy

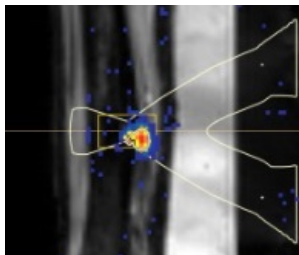
Most patients with slow growing tumors develop bone metastasis in the later stage of the disease. Bone changes and malformations irritate nerve endings creating significant pain for patients.

- 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



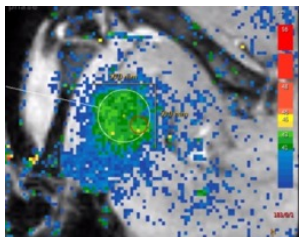
Pediatrics: Osteoid osteoma

- 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



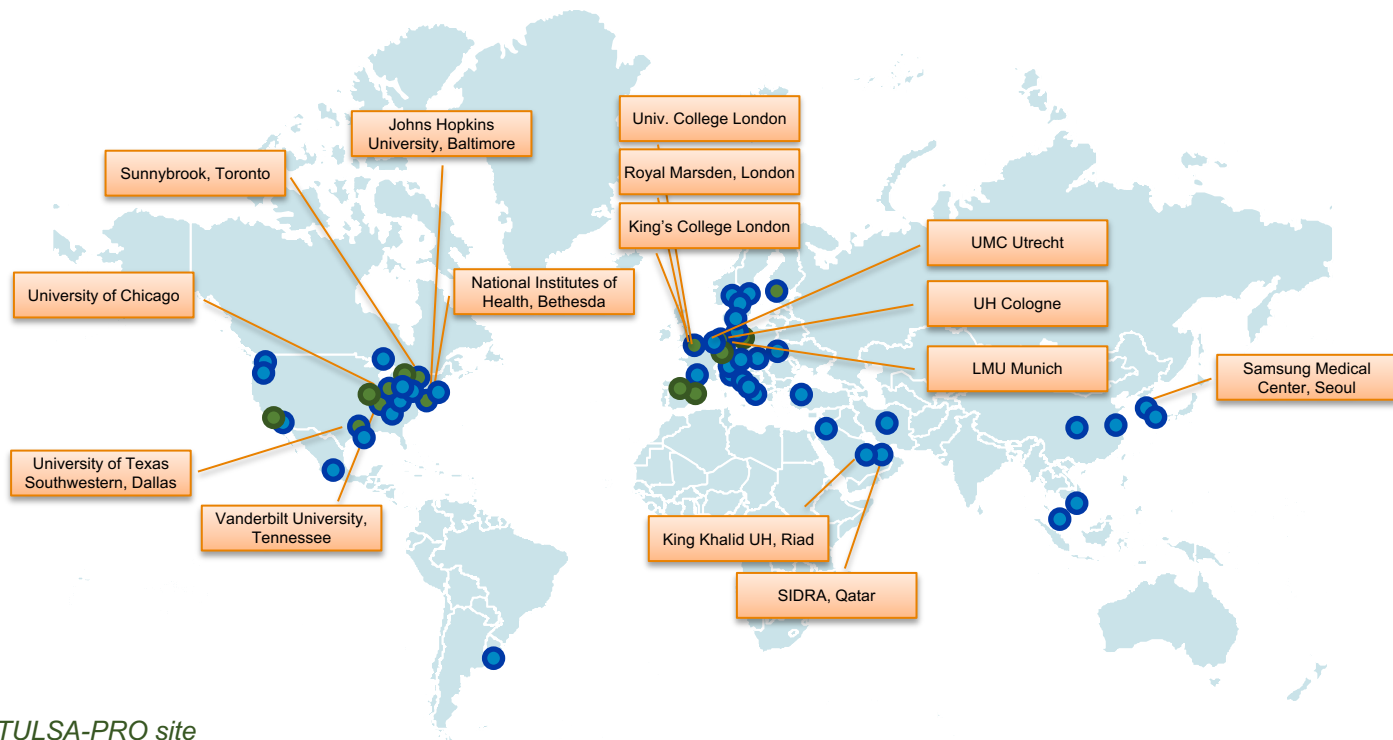
Hyperthermia

- 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



Commercialization

Strong Global Network of Clinical Partners

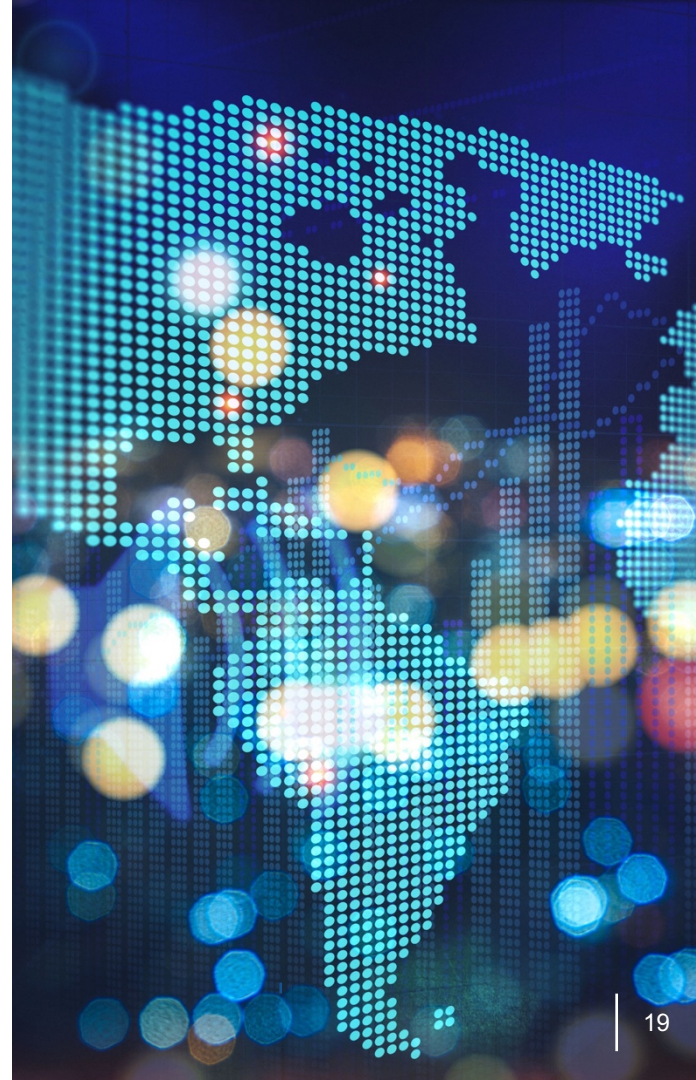


- Indicates TULSA-PRO site
- Indicates Sonalleve site
- Indicates Sonalleve & TULSA-PRO site

Market Introduction Strategy

- Strategic Partnerships: expanded and existing collaborations with MR partners will drive revenue:
 - Capital Sales
 - Co-selling
 - Co-marketing
- Build direct sales to drive procedure adoption and disposable sales
- Focus Sonalleve sales in Asian market and academic hospitals in North America and Europe. Focus TULSA-PRO in Europe

PHILIPS
SIEMENS



Reimbursement Environment

US

PROCEDURE	APPROXIMATE HOSPITAL PAYMENT	APPROXIMATE SURGEON PAYMENT
Laparoscopic Radical Prostatectomy	\$10,000	\$1,450
Radiation Therapy (IMRT Simple, 40 Sessions)	\$20,000	Fee bundled into primary APC
Brachytherapy	\$8,000	\$2,200
Cryoablation	\$10,000	\$800

Germany

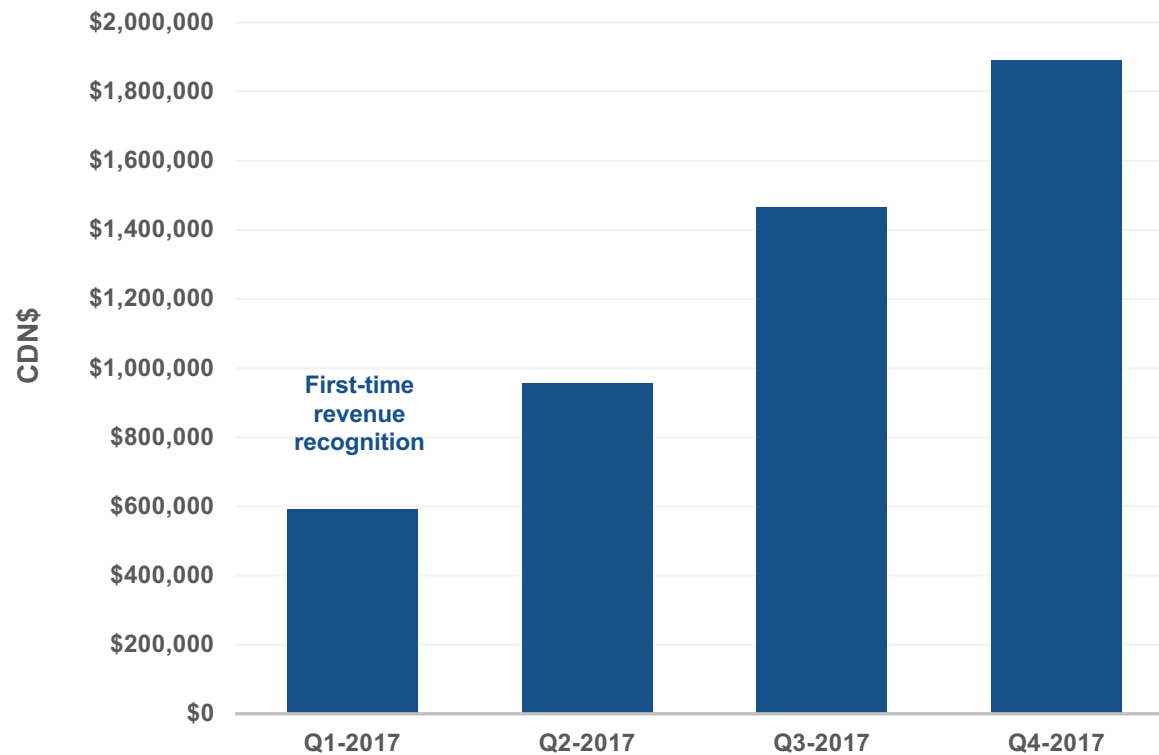
TULSA-PRO part of DRG payment to the hospital 3,963 Euros as of January 2018

* Payment is the sum of the indicated APC/CPT codes

** Payments are for Medicare patients. Private payer payments for these procedures will vary and may result in higher payments than published Medicare rates.

European Pilot Commercial Launch

Revenue Ramp



Profound Medical

Summary

Incision-free Procedures

Real-Time MR guided treatments

1

Precise

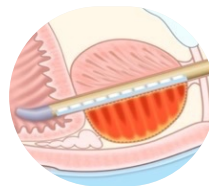
2

Customized

3

Safe

TULSA-PRO®

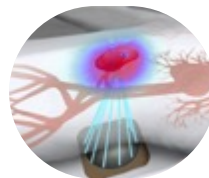


Prostate disease treatment from 'Inside-Prostate'

- CE marked
- FDA expected 2019



Sonalleve



Treatment from 'Outside-In'

- Uterine Fibroids
- Bone Metastasis
 - CE marked
 - China FDA expected in 2018