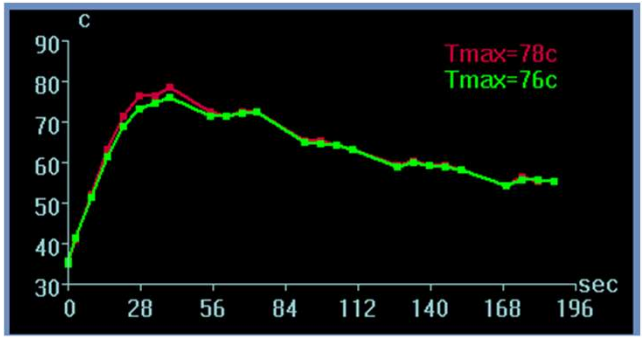
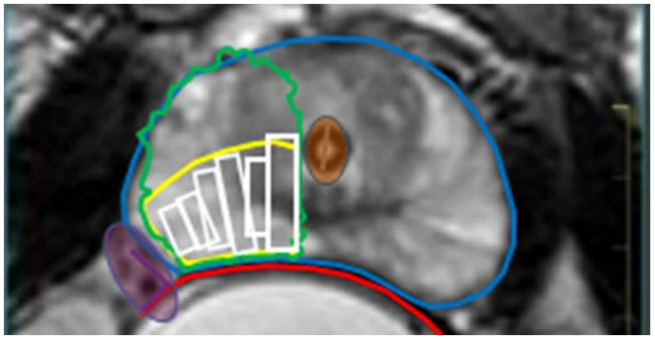
Exablate Prostate

Designed for Optimal Precision and Control

EXABLATE PROSTATE IS DESINGED FOR OPTIMAL **PRECISION** AND **CONTROL**





MR-Guidance

- Real-time thermometry
- Real-time anatomical imaging
- Contrast-enhanced confirmation of final ablated volume

Transrectal Transducer

- Flexible spot size and location enabled by 2.3MHz frequency & high elements density (990)
- Sharp beam edge near NVB's, sphincters and urethra
- Rectal cooling system
- Automatic electrical & robotic steering

Sophisticated Software

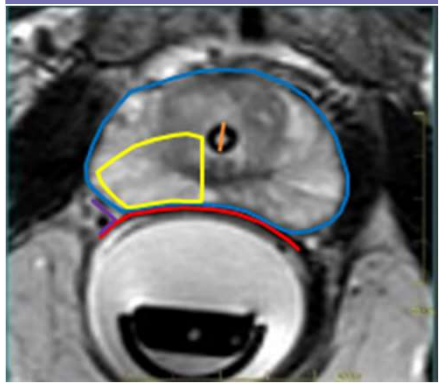
- Automatic & editable beam sculpting according to treatment plan
- Immediate and cumulative visualization of thermal response
- Motion detection & correction

EXABLATE PROSTATE TREATMENT FLOW

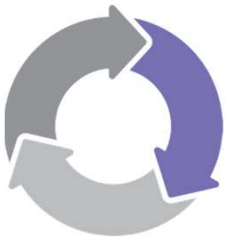
Define

Identify anatomical landmarks and define target area

DEFINE

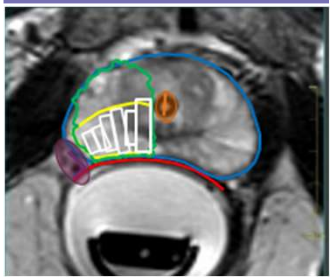


PLAN → Treat & Assess → Adjust

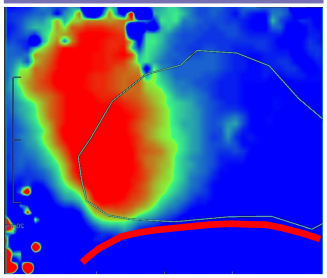


- Plan sonications according to treatment goals
- Sonicate & assess thermal response during and after sonication
- Adjust treatment parameters, as needed, to optimize response

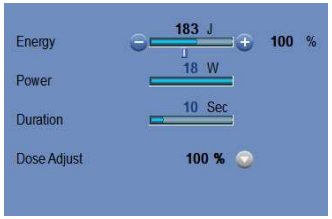
PLAN



TREAT & ASSESS



ADJUST



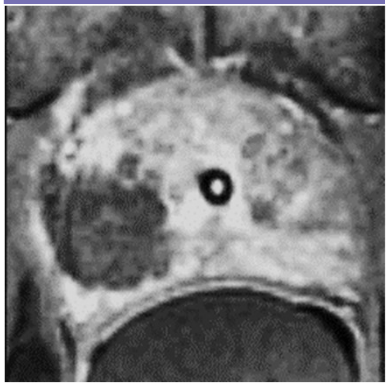
Repeat Slice-By-Slice

Repeat in same/next slice on **updated anatomical position**

CONFIRM

Confirm treatment outcome as non-enhancing volume

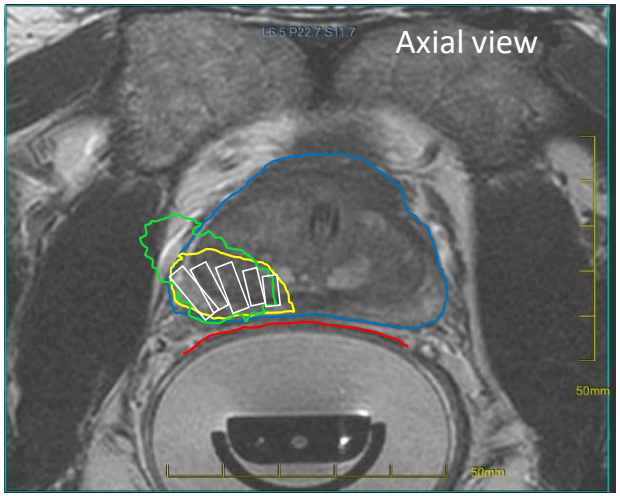
CONFIRM



INSIGHTEC

CASE REVIEW: SAFELY TREAT NEAR NVB AND RECTAL WALL

Treatment plan

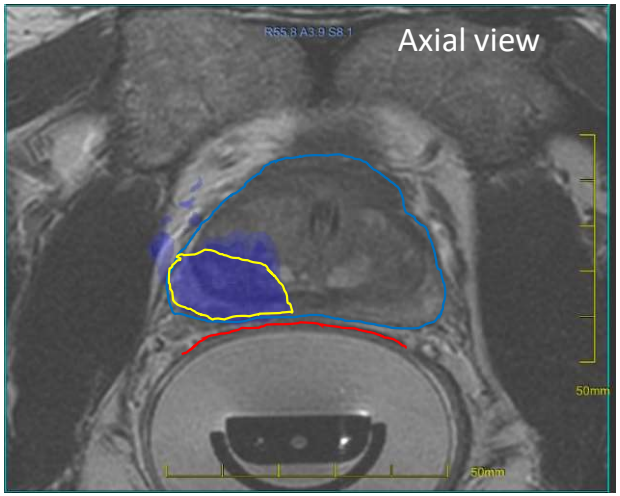


Target area

Planned sonications

Estimated thermal effect

Cumulative thermal response

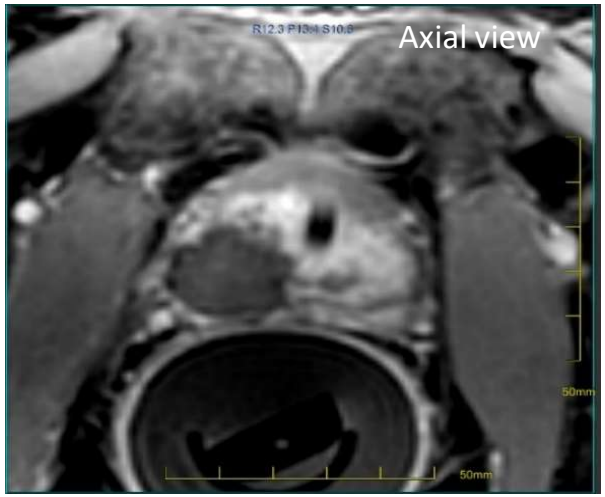


Target area

Equivalent to 43°c for 8,000 minutes

Equivalent to 43°c for 240 minutes *the threshold for ablation of soft tissue*

Final ablated volume



Case 43009

INSIGHTEC

CLINICAL TRIAL

- Completed 101 treatments (@2 year follow up)
- GG2-3 MR visible tumors
- Luminary, leading sites

Stanford Hospital & Clinics

Memorial Sloan Kettering Cancer Center

MAYO CLINIC

City of Hope

Weill Cornell Medicine

BWH BRIGHAM AND WOMEN'S HOSPITAL

UHN Toronto General Hospital

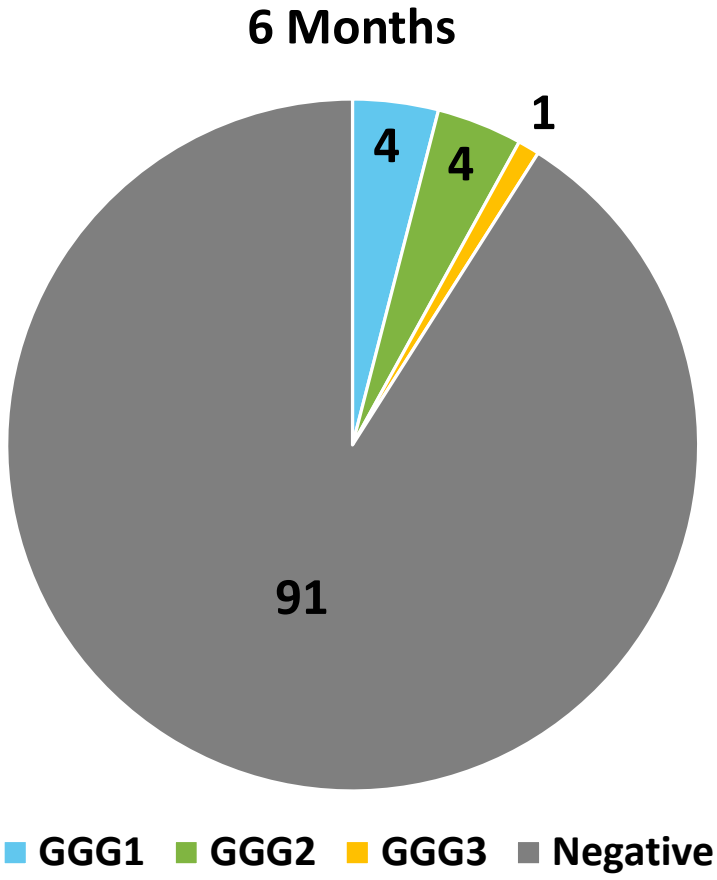
SPERLING PROSTATE CENTER

UCLA Health

INSIGHTEC

BIOPSY RESULTS

Positive Biopsy Results Within the Planned ROT by Gleason Grade at 6 Months			
Positive Biopsy Results Within the Planned ROT / Gleason Grade Group		Exablate	
		N	%
Yes	Gleason ≤ 6 (3+3) / GGG 1	4	4.0
	Gleason 7 (3+4) / GGG 2	4	4.0
	Gleason 7 (4+3) / GGG 3	1	1.0
	Total	9	8.9
No	Total	92	91.1
Totals	**Total**	**101**	**100.0**



INSIGHTEC

EXABLATE vs. FT FDA LABELING & SOC DATA

	Prostatectomy[1-4]	Whole-Gland HIFU[5-7]	FOCAL ONE[8]	TULSA-PRO[9]	Exablate
Positive Biopsy / Histology	16-24% (Surgical margin)	39-41% (@12 months)	37% (@12 months)	35% (@12 months)	~20% (@24 months)
Erectile Dysfunction (Erections insufficient for penetration)	79% (Range: 25-100%)	58% (Range: 38-67%)	45%	20-25% (Grade 2 medication indicated; no grade 3)	21%
Urinary Incontinence (Moderate to severe)	15% (Range: 0-50%)	3% (Range: 3-22%)	12%	2.6% (Grade 2 pads indicated; no grade 3)	1%
Urethral Stricture (Moderate to severe)	9% (Range: 3-26%)	15% (Range: 9-35%)	N/A	2.6%	1%
GI Toxicity (Moderate to severe)	15% (Range: 0-24%)	7% (Range: 1-21%)	N/A	None	None

References:

1. ProtecT, Hamdy *et al* 2016
2. RCT, *Yaxley et al Lancet* 2016
3. Thompson (Chair) et al, AUA prostate cancer clinical guideline update panel, J Urol 2007
4. Resnick *et al*, Prostate Cancer Outcomes Study (PCOS), NEJM 2013
5. FDA IDE Study DEN15001 (Sonablate 450)
6. FDA IDE Study K153023 (Ablatherm)
7. Crouzet *et al*, Whole-gland HIFU, Eur Urol 2014
8. FDA IDE Study K172721 (FOCAL ONE)
9. TACT – TULSA-PRO Ablation Clinical Trial for FDA 510(k)

INSIGHTEC

SITE REQUIREMENTS

- Treatment team: Radiologist/IR, Urologist, Anesthesiologist, Nurse, MR technician
- GE MR meeting Exablate System requirements, and
  - Screening – 3T mp-MRI *or 1.5T MRI with an endorectal coil*
  - Treatment - 3T *or* 1.5T with GE cardiac coil
- MR-compatible anesthesia equipment
- Access to CT scanner
- Access to mapping biopsy and localization pathology reading
- Urinary catheter (Foley or SPC - in certain cases)


Mayo Clinic
Rochester, USA
Stanford Hospital
SF, USA
UCLA Health
LA, USA
City of Hope Medical
LA, USA
Cornell Medicine
NYC, USA
Toronto General Hospital
Toronto, Canada
Brigham & Women's Hospital
Boston, USA
Memorial Sloan Kettering Cancer Center
NYC, USA
Sperling Clinic
FL, USA
Radiology Im Triamedis
Frankfurt, Germany
VKO
Ust-Kamenogorsk, Kazakhstan
Beijing Hospital
Beijing, China
Changhai Hospital
Shanghai, China

INSIGHTEC

Thank You!

STEPUP.
Make a Difference.

INSIGHTEC