

## Sonablate<sup>®</sup> HIFU vs Focal One<sup>®</sup> Comparison Guide

Type of Treatment	Sonablate <sup>®</sup> HIFU	Focal One <sup>®</sup>	Treatment Planning	Sonablate <sup>®</sup> HIFU	Focal One <sup>®</sup>
Focal	✓	✓	3D Representation	✓	✓
Repeatable	✓	✓	Automatic Variable Planning Margins	✓	
Robotic	✓	✓	Variable Dosing	✓	
<b>Intra-Treatment</b>			<b>Outcomes</b>		
Highest Quality Imaging		✓	Contrast Imaging Assessment of Intervention	✓	✓
Most Useful Imaging	✓		Best Disease Control	✓	
Adaptive Dosing	✓		Lowest Incidence Incontinence	✓	✓
Adjustment to Changing Organ Position	✓	✓	Lowest Incidence Erectile Dysfunction	✓	✓
Automatic Real Time Assessment of Tissue Effect	✓		Lowest Incidence Ejaculatory Dysfunction	✓	✓
Real Time Visual Assessment of Tissue Effect	✓		<b>Activities of Daily Living</b>		
Pre/Post Treatment Effect Comparison	✓		Drive Next Day	✓	✓
Nontarget Volume Dose Assessment	✓		Early Return to Work	✓	✓
Control of Power During Treatment	✓		Early Return to Physical Activity	✓	✓
Control of Pulse Sequence During Treatment	✓		<b>Clinical</b>		
Variable Shot Distribution	✓		Extensive Clinical Experience	✓	✓
Rectal Wall Distance Monitoring	✓	✓	Strong Peer Reviewed Clinical Publication	✓	✓
Patient Movement Assessment	✓	✓	Registry	✓	✓
Prostate Movement Assessment	✓		Standardized Treatment Protocols	✓	
<b>Case Support</b>			Intensive Training and Certification	✓	
Dedicated Nursing Team > 5,000 Case Hours	✓				
Dedicated Tech Support Team > 20,000 Case Hours	✓				

Sonablate<sup>®</sup> has 510(K) clearance in the U.S. under a De Novo regulatory grant for the ablation of prostate tissue. Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.

## Clinical Comparison Partial Gland Ablation Studies

<i>Patient Details</i>	<i>Sonablate<sup>®</sup> HIFU</i>	<i>Focal One<sup>®</sup></i>
Median F/U	36-56 months	12-17 months
Number of Patients	1821 (164-1032)	147 (24-74)
Intermediate/High Risk	85-88%	49%
Patients with Gleason Score $\geq 7$	69-80% 2,5,9	16-92% 1,3,4,6,7,8
<i>HIFU Ablation Outcomes</i>		
Clinically Significant Disease	6-25%	10-33%
Failure Free Survival	91-98%	80-92%
Salvage Procedures*	6.6-8%	8-20%
Repeat Focal Procedures	9-19% 2,5,9	13%** 1,3,4,6,7,8
<i>HIFU Side Effect Profile</i>		
Urethral Stricture	2%	2%
Urinary Tract Infection	9%	6-18%
Post HIFU TURP	0%	3%
Pad-Free	98%	96-97%
Retain Sexual Function	85% 2,5,9	70-87% 1,3,4,6,7,8

### Partial Gland Ablation Comparative Data Notes

- Table compares most recent Sonablate and Focal One data.
- Sonablate biopsies were for cause only, Focal One biopsies were routine follow up
- Sonablate studies include significantly more patients, a higher percentage of intermediate/high risk disease, and longer follow up period
- Sonablate studies report higher rates of failure free survival and lower rates of post-HIFU whole gland or systemic salvage therapy for recurrent disease

\*Salvage defined as requiring whole gland and/or systemic therapy for recurrent disease

\*\*Repeat procedures increase with time. Therefore the percentage of repeat Focal One procedures may become greater when follow up equals that of Sonablate

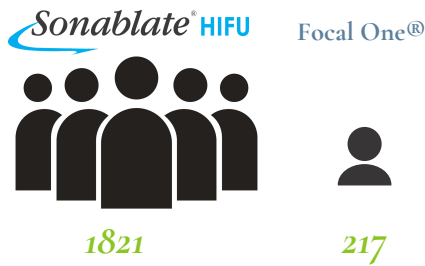
### Bibliography

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- 2 Hindley et al. Journal of Urology Apr 2017;2287
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- 5 Guillamier et al. Eur Urol. 2018; 74(4):422-419
- 6 Mortezaei et al. PP31. Focal Therapy/Imaging Meeting.2018
- 7 Ganzer et al. Journal of Urology 2019; 100(4):983-989
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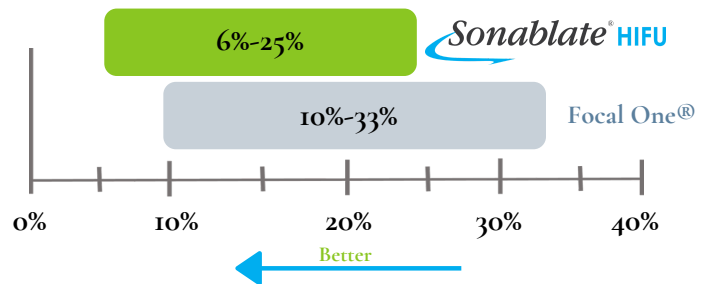
## Sonablate<sup>®</sup> HIFU vs Focal One<sup>®</sup>

### Data Analysis Sonablate Study Differences

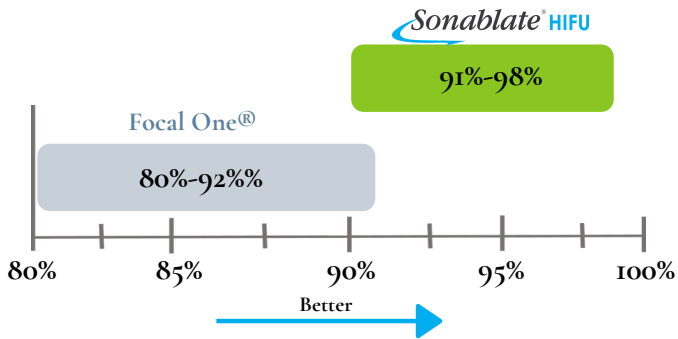
5.5X More Patients



Lower incidence of clinically significant disease detected on follow up



Higher Incidence of Failure Free Survival

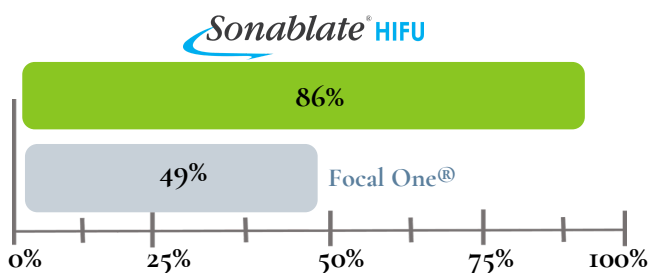


3.8X Longer Follow up

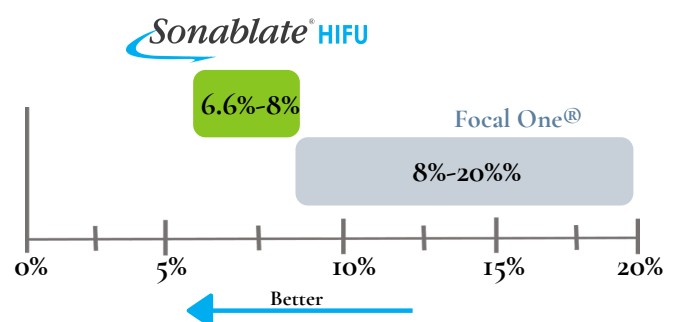


45 Months vs. 14 Months  
Mean Follow Up

1.8x Higher Risk Percent



Fewer Incidence of Salvage Procedures



## Unique Sonablate Features *(Not Available With Focal One)*

### Large Variety Of Commercial MR/US Fusion Provider Software Licenses

A broad choice of commercially validated MR/US fusion software options are compatible with Sonablate.

### Customizable Automatic Planning Margins

Provides the ability to automatically and differentially target specific regions of interest, set margins and spare

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Provides the ability to automatically and differentially target specific regions of interest, set margins and spares sensitive structures, including the prostate capsule, urethra and neurovascular bundles.

### Tissue Change Monitoring (TCM)

Used to guide energy delivery, TCM assesses energy delivery adequacy of each elemental HIFU lesion.

### Reflectivity Index Monitoring (RIM)

Used to guide energy delivery, RIM monitors echogenic changes that may indicate increased near field heating.

### HIFU Power Adjustment

The total acoustic power (TAP) control provides the ability to make real-time power level adjustment specific to the needs of each prostate region under treatment.

### Duty Cycle Adjustment

Provides the ability to adjust the duty cycle and thereby change energy delivery levels specific to each prostate region under treatment.

### Reference Ultrasound Images

Provides ability to compare treatment and reference images to help assess changes during the HIFU procedure.

### Detection of Prostate Movement

Comparing reference images to live images provides information on prostate organ movement.

### Multiple Sonablate Probes

Two Sonablate probes provide uninterrupted system uptime during probe servicing and additional backup protection should a probe be damaged.

### Smaller Mobile Unit

Smaller system footprint provides easier transport and increased mobility within operating rooms, doorways, elevators, corridors and storage spaces.

### Multiple Modality Platform

Single system operates both the Sonablate and Sonatherm probes.

### Experienced / Dedicated Staff

SonaCare utilizes a skilled, experienced and dedicated USA team for Sonablate manufacturing, training, service and support.