

Non-Invasive Cancer Treatment



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## Sonablate® vs. Ablatherm® Comparison Guide

**Sonablate®**  
*First prostate HIFU  
device cleared in the USA*

# Sonablate® vs. Ablatherm® Comparison Guide

## CLINICAL DATA

PRIMARY (Number of Subjects)	Sonablate® (219) <sup>1</sup>	Ablatherm® (131) <sup>2</sup>
Negative Biopsy	87%	68%
Urinary Incontinence (leak)	3%	39%
Rectal Fistula (surgical repair)	0%	0%
Urethral Stricture	18%	19%
Bladder Neck Contracture	1%	18%

FOCAL/HEMI (Number of Subjects)	Sonablate® Focal (41) <sup>3</sup>	Ablatherm® Hemiablation (111) <sup>4</sup>
Retained Sexual Function	89%	78%
Maintained Continence	100%	97%
Presence of Clinically Significant Disease on Biopsy	8%	12%
Rectal Fistula (surgical repair)	0%	0%



*After Sonablate HIFU  
treatment...*

94% of men (low risk)  
were disease-free after 4 years

92% of men had a PSA of  
.2ng/ML or lower after 3 months

*“I had absolutely no pain or discomfort.  
I just went about my normal life.”*

*~Barry W.*

## DEVICE DATA

SAFETY FEATURES	Sonablate®	Ablatherm®
Rectal Wall Distance Monitoring	Yes	Yes
Rectal Wall Temp. Monitoring	Yes	Yes
Patient Movement Sensor	No	Yes (External sensor on patient's hip)
Organ Movement Feedback	Yes (Current organ position compared to reference image)	No
Reflectivity Index Monitor (RIM)	Yes (Monitors echogenic change to prevent critical structure damage)	No

PATIENT SELECTION	Sonablate®	Ablatherm®
Rectal Wall Thickness (RWT)	No Restrictions	Must be between 3 mm - 8 mm
Gland AP Limit	AP + (RWT) < 37 mm	AP < 24 mm

PROBE CHARACTERISTICS	Sonablate®	Ablatherm®
Number of Transducers	4 (Two for imaging, two for therapy)	2 (One for imaging, one for therapy)
Imaging Frequency	6.3 MHZ	7.5 MHZ
Therapy Frequency	4 MHZ	3 MHZ
Transducer Focal Length	Dual focal lengths (4 cm and 3 cm)	4.5 cm
Robotic / Motorized	Yes (Transducer motion)	Yes (Transducer and probe motion)

<sup>1</sup> Uchida et al. *THE JOURNAL OF UROLOGY* Vol. 193, 103-110, January 2015

<sup>2</sup> EDAP PMA Data, 2014

<sup>3</sup> Ahmed et al. *Lancet* Vol. 13, 622-632, June 2012

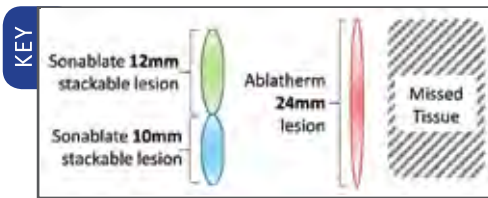
<sup>4</sup> EDAP Press Release Abstract 109th French Urology Congress, 2015

Sonablate® is a trademark of SonaCare Medical. Ablatherm® is a trademark of EDAP TMS.

Sonablate® 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.

# Ablation Method Comparison (shown on prostate with AP height of 2.8cm)

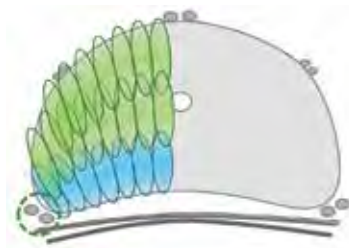


## Sonablate®

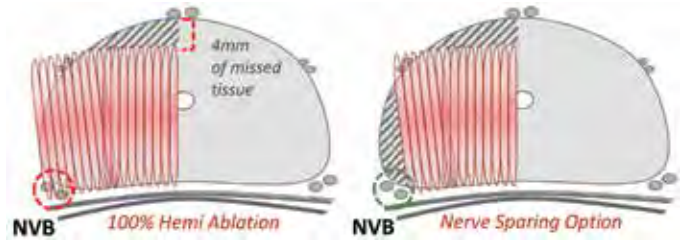
## Ablatherm®

HEMI GLAND

Due to the shorter length of a single lesion, the ablation zones can be stacked to conform to the shape of the gland.



Due to a greater length lesion and single-row treatment pattern, either the neurovascular bundle may be ablated or the gland may be under-treated.



## Sonablate®

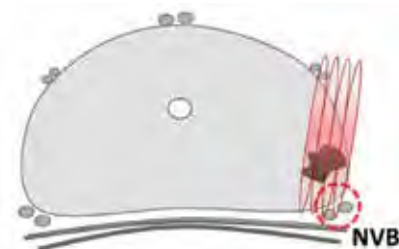
## Ablatherm®

FOCAL

Due to the shorter length of a single lesion, only the region of interest is ablated, resulting in a tissue sparing ablation.



Due to the greater length of a single lesion, there can be a large amount non-targeted tissue ablated.

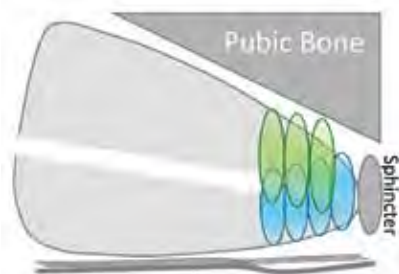


## Sonablate®

## Ablatherm®

APEX SPARING

Due to the shorter length of a single lesion, only the region of interest is ablated, resulting in an ablation that spares the sphincter and pubic bone.



A 4mm Safety Margin is "mandatory to avoid burning of the sphincter, and causing patient incontinence". Due to the longer length of a single lesion, the pubic bone remains at high risk of injury.

