

# AQUABLATION<sup>®</sup>

Therapy by PROCEPT BioRobotics

## Minimizing Tradeoffs in BPH Surgical Treatment



# Historical BPH Surgical Treatment Landscape



**“Normal”**  
Walnut



**Small**  
Ping Pong Ball



**Medium**  
Golf Ball



**Large**  
Clementine



**Extra Large**  
Tennis Ball

TURP, GreenLight

HoLEP, Simple (Open, Robotic)

# Current BPH Surgical Treatment Landscape...



**“Normal”**  
Walnut



**Small**  
Ping Pong Ball



**Medium**  
Golf Ball



**Large**  
Clementine



**Extra Large**  
Tennis Ball

**Non-Resective**

UroLift, Rezum

**Resective Procedures**

TURP, GreenLight

HoLEP, Simple (Open, Robotic)

**Opportunity**

Predictable procedure for prostates of any size  
Minimal learning curve without highly specialized training  
Equivalent efficacy and superior safety to the existing standard<sup>1</sup>

<sup>1</sup>Gilling P. et al. WATER: A Double-Blind, Randomized, Controlled Trial of Aquablation® vs Transurethral Resection of the Prostate in Benign Prostatic Hyperplasia. J Urol. 2018 May;199(5):1252-1261



## Minimizing Tradeoffs in BPH Surgical Treatment

**Clarity**

**Consistency**

**Control**

**AQUABEAM®**  
— ROBOTIC SYSTEM —

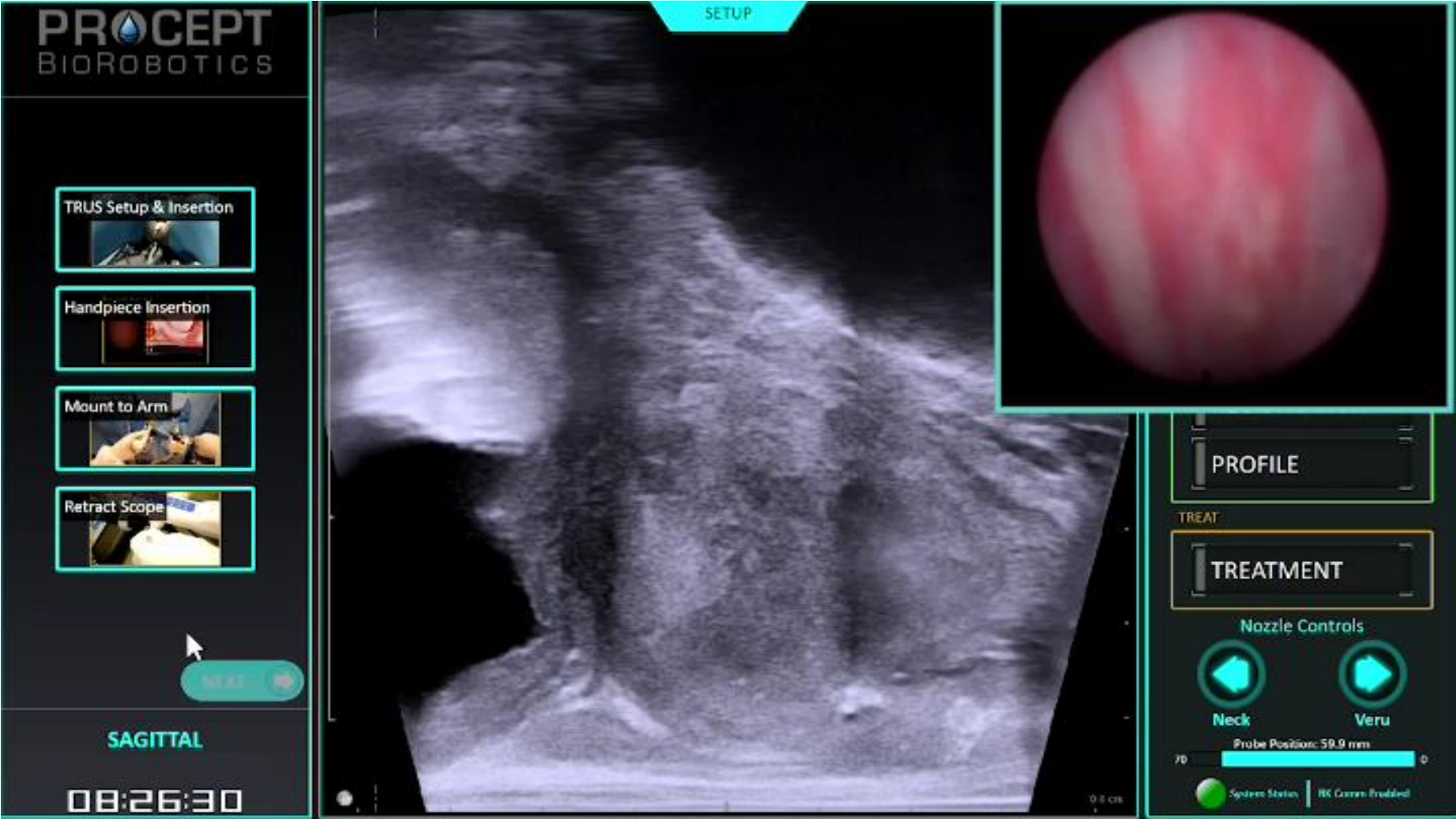
(Ultrasound and Articulating Arms not pictured)

# Procedure Overview (Animation)



Note: Animation does not represent full draping required during Aquablation therapy.

# Aquablation Case Example (Video)

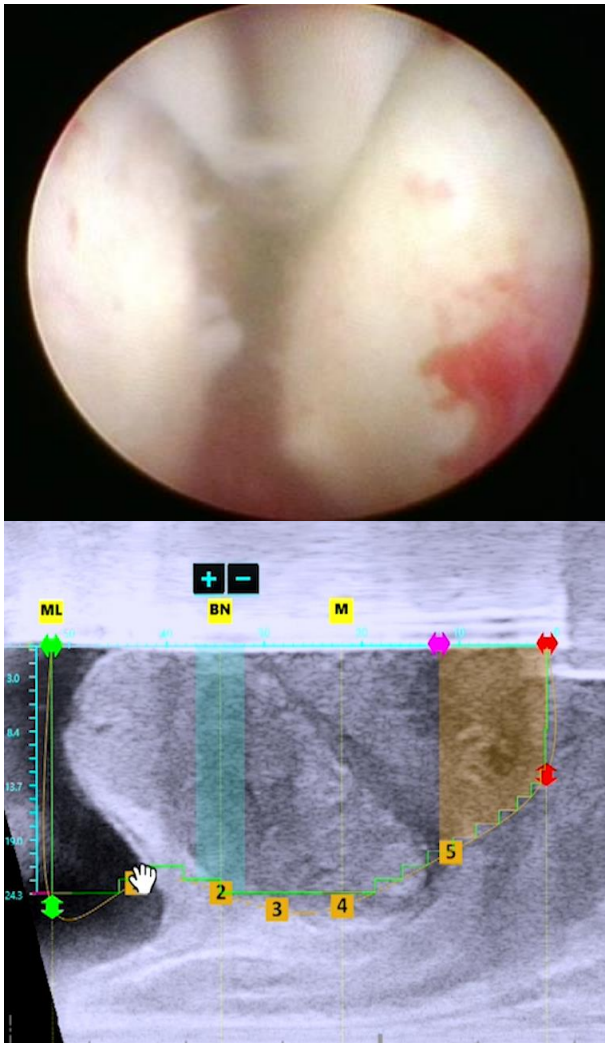


Video played at 6x speed

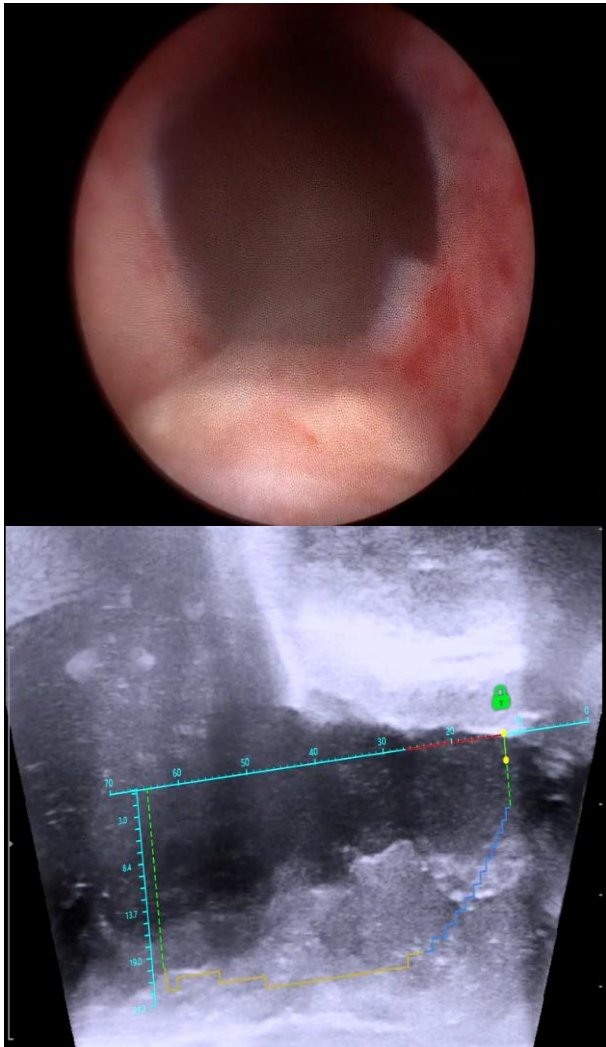


# Aquablation Therapy Results

Before



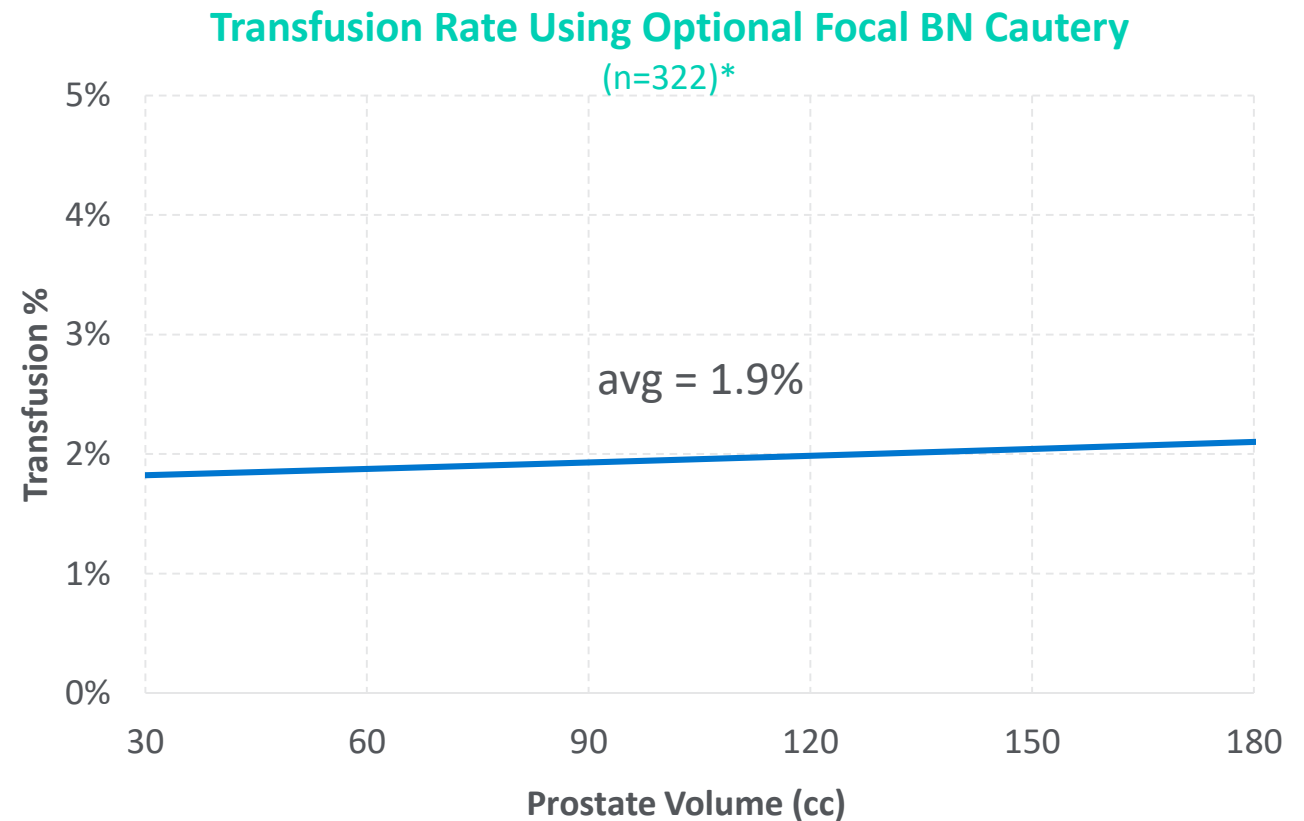
Post-Aquablation Therapy



Optional focal bladder-neck cautery with standard catheter tension resulted in an average transfusion rate of **1.9%** across all prostate volumes

## Hemostasis Method

- Clot Evacuation
- Optional focal bladder-neck cautery
- Catheter tension, as required
- Continuous bladder irrigation



\*Data on File. Publication pending. Elterman et al.





- **The only FDA pivotal study randomized to TURP (gold standard)**
- Prostates 30 – 80 (cc)
- N = 181 (Aquablation therapy = 116, TURP = 65)
- 17 sites in the United States, UK, Australia and New Zealand (14 sites: no prior experience with Aquablation therapy)

**Results: superior safety and non-inferior efficacy compared to TURP**

Gilling P. et al. WATER: A Double-Blind, Randomized, Controlled Trial of Aquablation® vs Transurethral Resection of the Prostate in Benign Prostatic Hyperplasia. J Urol. 2018 May;199(5):1252-1261



- **The only prospective multicenter study successfully completed for large prostates**
- Prostates 80 – 150 (cc)
- N = 101
- 16 sites in the United States and Canada (9 sites: no prior experience with Aquablation therapy)

**Results: Safe and effective in larger prostates, without significant increase in procedure or resection time**

Bhojani N. et al. Aquablation for Benign Prostatic Hyperplasia in Large Prostates (80-150 cc): 1-Year Results. BJUI 2019 July;129:1-7

## Real-World Single Center Data

- Prospective single-center, real-life experience from 180 consecutive, non-selected Aquablation therapy patients
- Prostates of all sizes
- N = 180
- Prof. Dr. Thorsten Bach (FEBU), Department of Urology, Asklepios Hospital Harburg, Hamburg, Germany

**Results: Safe and effective in a real-life setting, with a low perioperative complication profile**

Bach T. et al. Aquablation of the prostate: single-center results of a non-selected, consecutive patient cohort. World J Urol. 2019 Jul;37(7):1369-1375.



American  
Urological  
Association

## AUA 2019 Surgical Practice Guidelines

**NICE** National Institute for  
Health and Care Excellence

## NICE 2019 Guidance



Canadian  
Urological Association

## CUA 2018 Surgical Practice Guidelines



## Minimizing Tradeoffs in BPH Surgical Treatment

**Clarity**

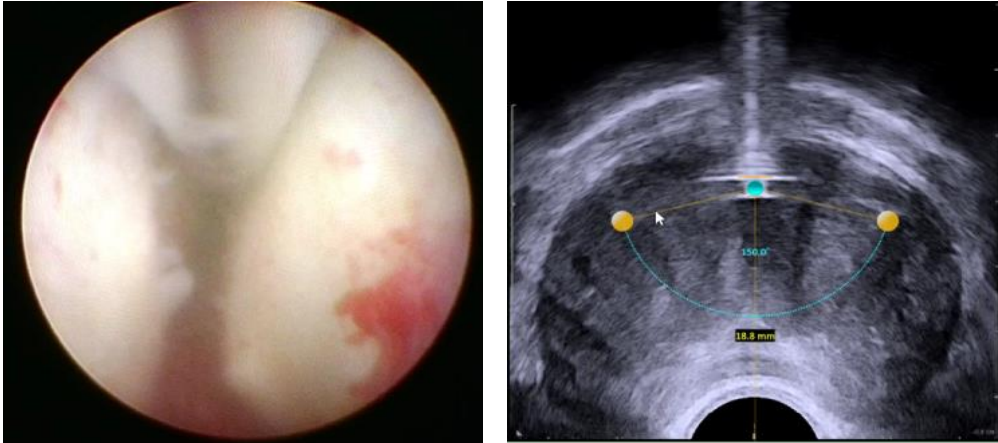
**Consistency**

**Control**

**AQUABEAM®**  
— ROBOTIC SYSTEM —

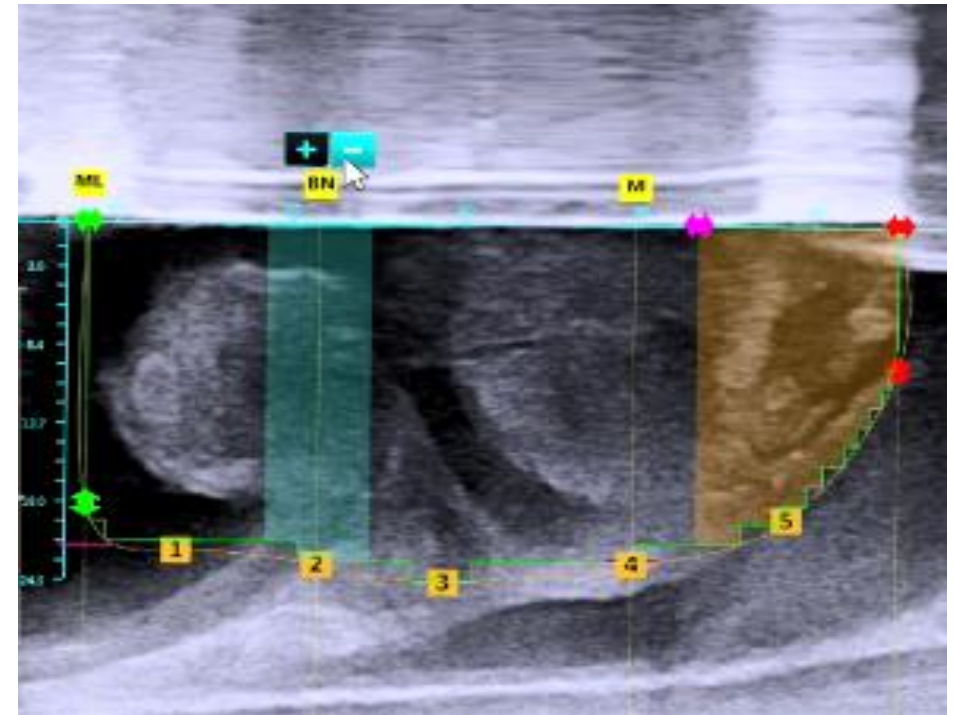
(Ultrasound and Articulating Arms not pictured)

## Intraoperative Surgical Planning



Improved ability to optimize resection

## Anatomical Preservation



Spare critical anatomies, like the bladder neck, verumontanum & external sphincter



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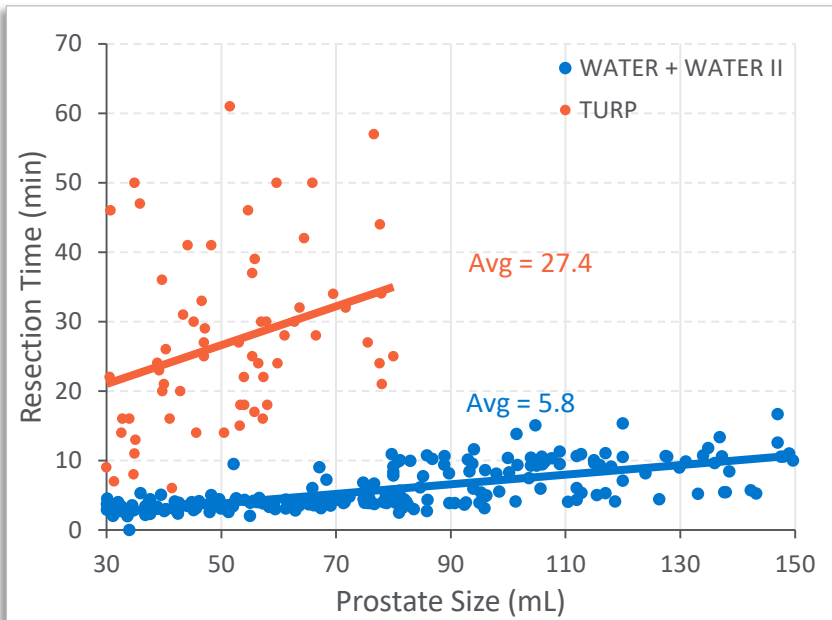
**AQUABEAM®**  
— ROBOTIC SYSTEM —

(Ultrasound and Articulating Arms not pictured)

# Consistency

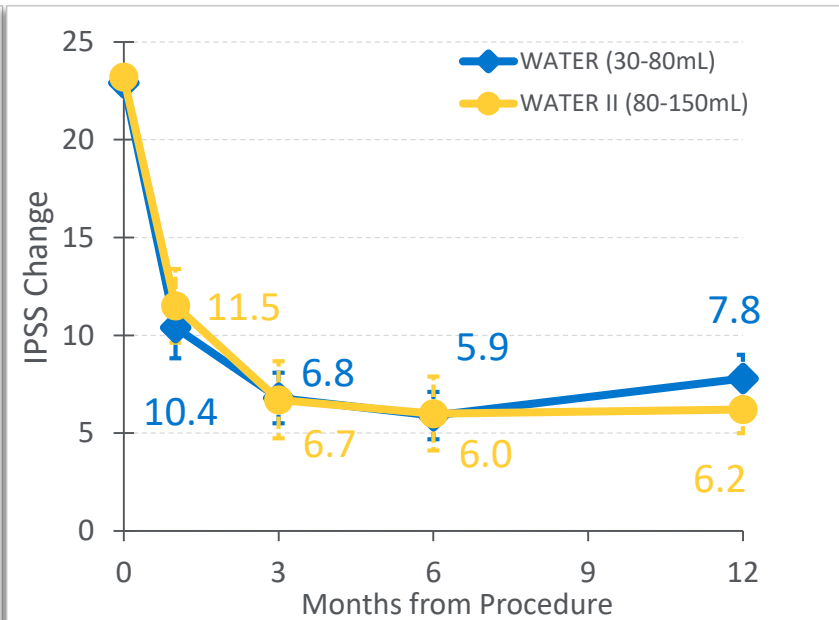
Robotic execution delivers predictable clinical excellence across prostates of all sizes

## Size-Independent Resection Time



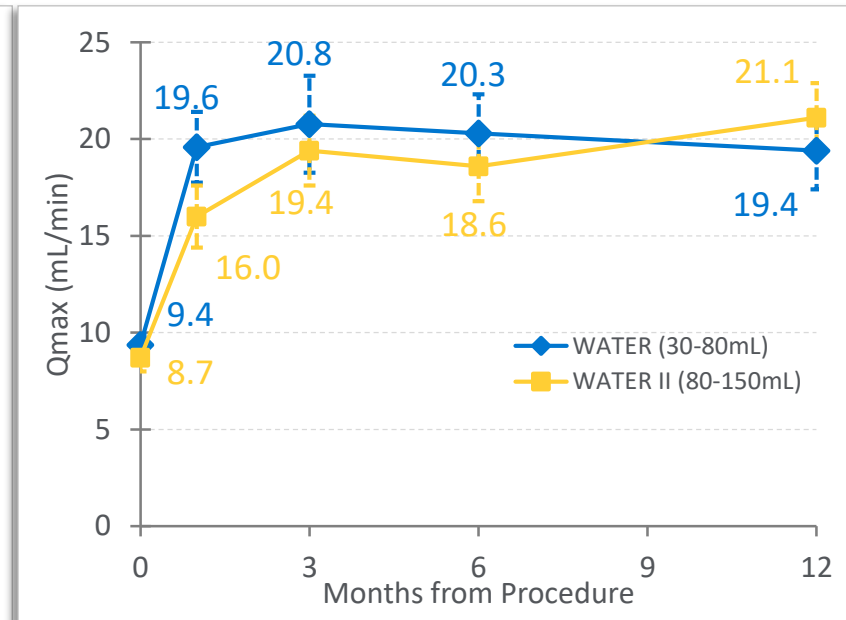
Average resection time of 5.8 minutes

## Effective Symptom Relief



Average IPSS improvement  
at 12 months = 16

## Immediate Flow Improvement



Average Qmax improvement  
at 12 months = 11.2 mL/min





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**Clarity**

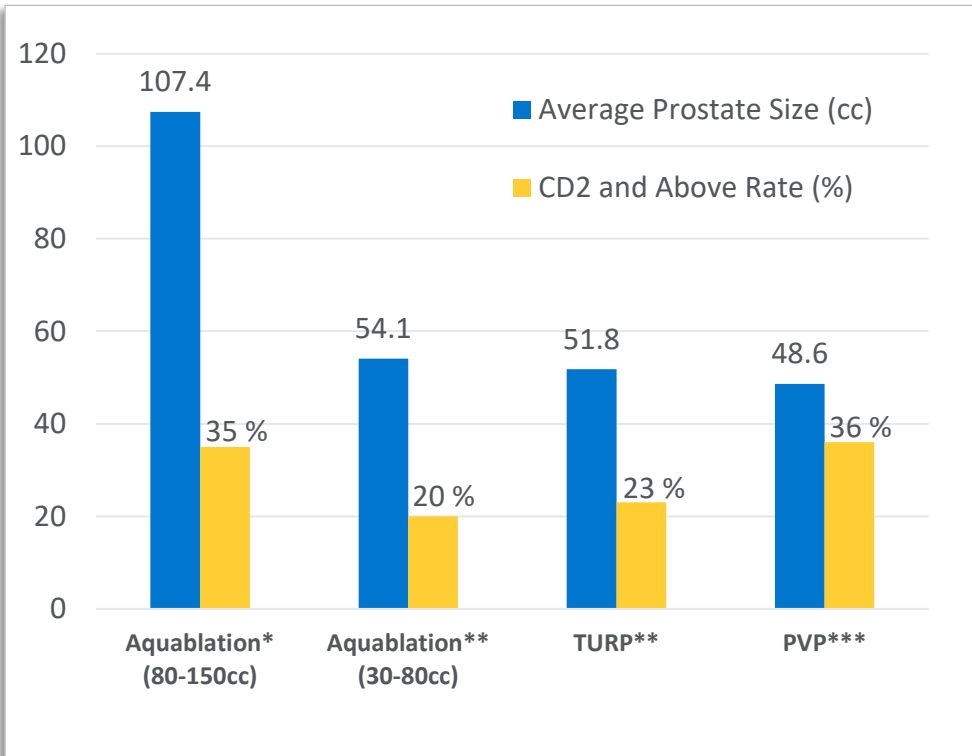
**Consistency**

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(Ultrasound and Articulating Arms not pictured)

### Low Surgical Complications



### Reduced Irreversible Complications

12 Month Complication Rates (Pooled Studies: WATER & WATERII)	Aquablation (30-150mL)
Incontinence	0.9%
Erectile Dysfunction	0.0%
Ejaculatory Dysfunction	14.0%

\*Desai M. et al. Aquablation for Benign Prostatic Hyperplasia in Large Prostates (80-150 cc): 1-Year Results. Urology, Volume 129, 1 - 7

\*\*Gilling P. et al. WATER: A Double-Blind, Randomized, Controlled Trial of Aquablation® vs Transurethral Resection of the Prostate in Benign Prostatic Hyperplasia. J Urol. 2018 May;199(5):1252-1261

\*\*\*Bachmann, A, et al. 180-W XPS GreenLight Laser Vaporisation Versus Transurethral Resection of the Prostate for the Treatment of Benign Prostatic Obstruction: 6-Month Safety and Efficacy Results of a European Multicentre Randomised Trial—The GOLIATH Study. Eur Urol. 2014 May;65(5):931-42.

NOTE: CD grade definitions: CD1P (ejaculatory dysfunction, incontinence), CD2 (requiring pharmacological treatment, blood transfusions), CD3 (endoscopic or surgical interventions), CD4 (complications requiring ICU management). CD2 and Above rate calculated by summing CD2+CD3a+CD3b



Therapy by PROCEPT BioRobotics

## **RISK AND SAFETY INFORMATION**

All surgical treatments have inherent and associated side effects. The most common side effects are mild and transient and may include mild pain or difficulty when urinating, discomfort in the pelvis, blood in the urine, inability to empty the bladder or a frequent and/or urgent need to urinate, and bladder or urinary tract infection. Other risks include ejaculatory dysfunction and a low risk of injury to the urethra or rectum where the devices gain access to the body for treatment. For more information about potential side effects and risks associated with Aquablation therapy, speak with your urologist or surgeon. No claim is made that the AQUABEAM® Robotic System will cure any medical condition, or entirely eliminate the diseased entity. Repeated treatment or alternative therapies may sometimes be required. For more detailed information on risks, side effects, and contraindications refer to the IFU.

### **Indications for Use: United States, Canada, and Hong Kong**

The AQUABEAM® Robotic System is intended for the resection and removal of prostate tissue in males suffering from lower urinary tract symptoms due to benign prostatic hyperplasia.

### **Indications for Use: Rest of World**

The AQUABEAM® Robotic System is intended for the resection and removal of prostate tissue in males suffering from lower urinary tract symptoms.



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