

# Aquablation Therapy Surgeon Training Course

## Part 1

- Aquablation Technique
- Science & Technology Overview
- Case Overview
- Hemostasis Protocol
- Clinical Data Summary

# Aquablation Technique

# Aquablation Procedure Overview

The screenshot displays the Aquablation software interface. The central panel shows a sagittal ultrasound view of the prostate with a treatment plan overlaid. The plan includes a green line for the treatment path, a blue vertical line for the trus, and a brown shaded area for the veru zone. The depth is 24.3mm and the angle is 172.5 degrees. The interface is divided into three main sections:

- Left Panel (TREATMENT PROFILE):** Contains a legend for zones (ML, BN, M), a profile, and treatment start/end markers. It includes a 'RESET' button and navigation buttons for 'BACK' and 'NEXT'. The view is labeled 'SAGITTAL' and shows a time of 13:23:58.
- Center Panel (PLAN):** Shows the ultrasound image with the treatment plan. A red warning text reads 'DO NOT MOVE TRUS OR HANDPIECE'. The depth is 24.3mm and the angle is 172.5 degrees. The plan includes a green line for the treatment path, a blue vertical line for the trus, and a brown shaded area for the veru zone. The zones are labeled ML, BN, and M. The profile is labeled 5. The treatment start and end points are marked with green and red diamonds respectively. The Veru Zone Start is marked with a pink diamond. The depth from the angle plan is 24.3mm. The view is labeled 'SAGITTAL' and shows a time of 13:23:58.
- Right Panel (PROCEDURE WALK THROUGH):** Contains a 'PROCEDURE WALK THROUGH' section with 'SETUP' (HANDPIECE, TRUS, ALIGNMENT) and 'PLAN' (ANGLE, REGISTRATION, PROFILE) sections. The 'TREAT' section has a 'TREATMENT' button. Below this are 'Nozzle Controls' for 'Neck' and 'Veru', a 'Probe Position: 53.9 mm' indicator, and 'System Status' (System Station, BK Cross Enabled).

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

- Anesthesia
- Good ultrasound image
- Alignment of the TRUS and AQUABEAM Handpiece
- Proper registration
- Irrigation of clots/tissue at the end of procedure

## Indications for Use

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

## Contraindications

- Active urinary tract or systemic infection
- Unable to safely stop anticoagulants or antiplatelet agents perioperatively
- Diagnosed or suspected cancer of the prostate

## No restriction of

- Prostate volume
- Prostate anatomy

## Indications for Use

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

## Contraindications

- Active urinary tract or systemic infection
- Unable to safely stop anticoagulants or antiplatelet agents perioperatively

## No restriction of

- Prostate volume
- Prostate anatomy

# Science & Technology Overview

# AQUABLATION THERAPY

ONLY IMAGE-GUIDED, HEAT-FREE, AUTOMATED ROBOTIC THERAPY FOR BPH



## REAL-TIME IMAGE GUIDANCE

Intraoperative ultrasound imaging combined with cystoscopic visualization provide a multidimensional view of the treatment area



## PERSONALIZED TREATMENT PLANNING

Advanced planning software allows the surgeon to map the treatment contour that precisely targets the resection area



## AUTOMATED ROBOTIC EXECUTION

The robot executes the treatment plan and guides the precisely calibrated waterjet with speed and accuracy while surgeon monitors



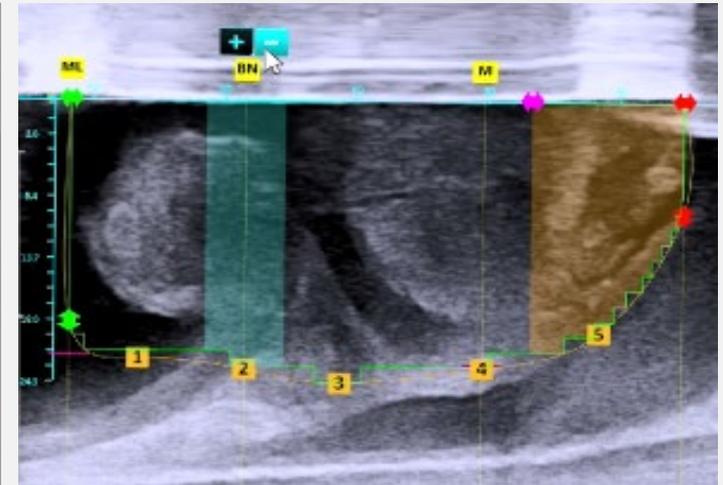
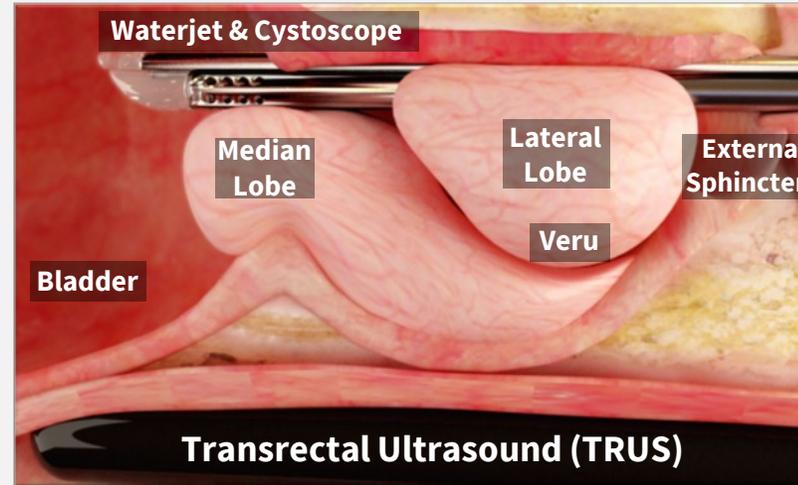
## HEAT-FREE WATERJET RESECTION

Utilizing the unique power of a pulsating waterjet near the speed of sound, Aquablation therapy removes prostatic tissue with a heat-free waterjet



**AQUABEAM**<sup>®</sup>  
— ROBOTIC SYSTEM —





**CYSTOSCOPY**

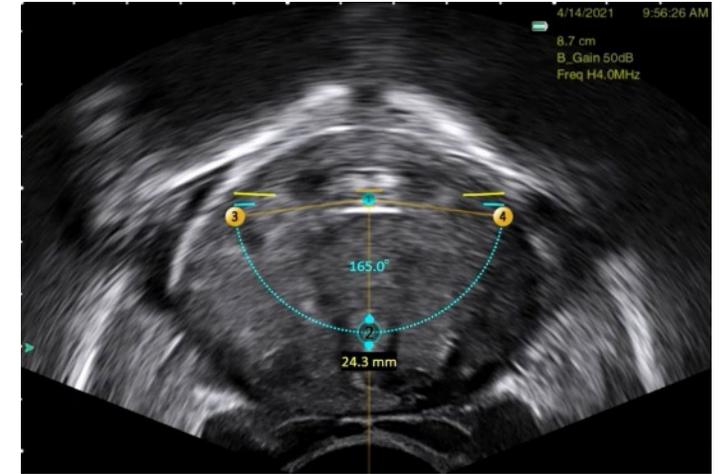


**TRANSRECTAL ULTRASOUND**

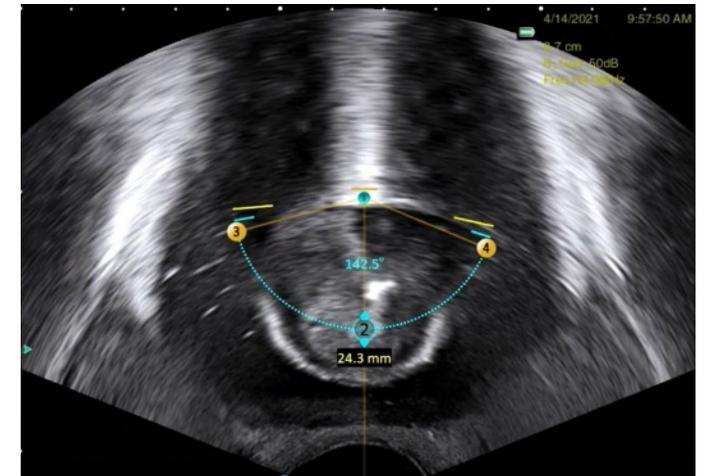
**MULTI-DIMENSIONAL IMAGING OF THE ENTIRE PROSTATE**



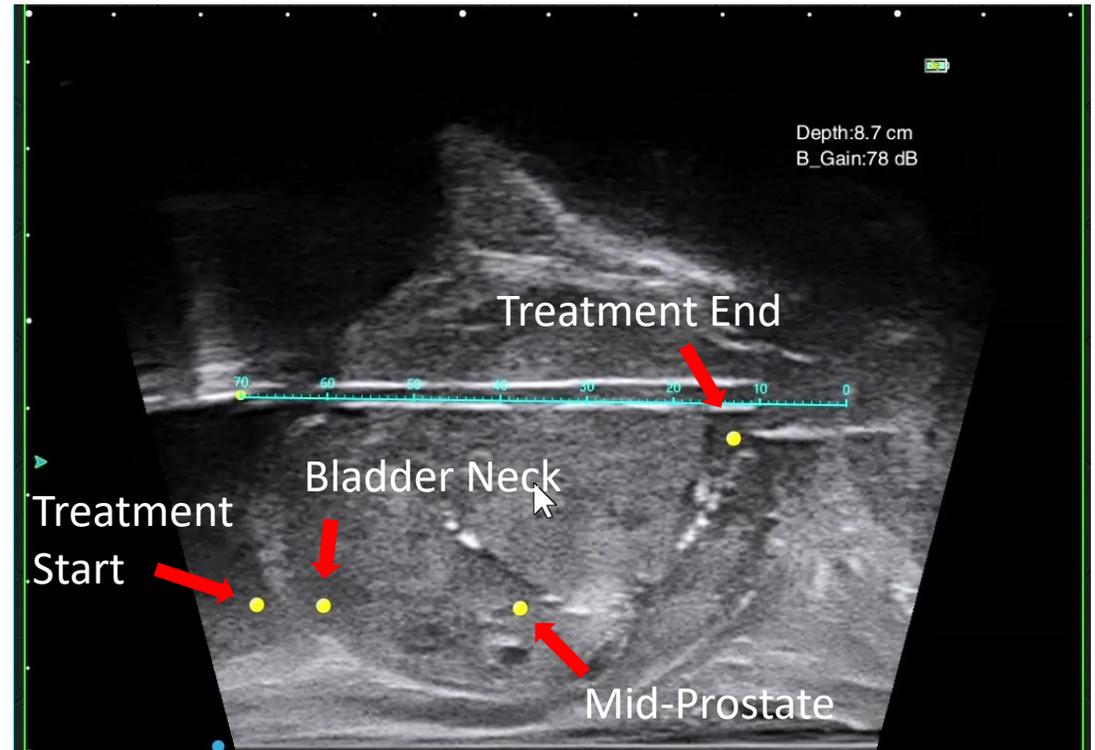
## Transverse View/Mid-Prostate Angle Planning



## Transverse View/Median Lobe Angle Planning



## Sagittal View/Contour Planning



# AQUABLATION THERAPY

ONLY IMAGE-GUIDED, HEAT-FREE, AUTOMATED ROBOTIC THERAPY FOR BPH



## REAL-TIME IMAGE GUIDANCE

Intraoperative ultrasound imaging combined with cystoscopic visualization provide a multidimensional view of the treatment area



## PERSONALIZED TREATMENT PLANNING

Advanced planning software allows the surgeon to map the treatment contour that precisely targets the resection area



## AUTOMATED ROBOTIC EXECUTION

The robot executes the treatment plan and guides the precisely calibrated waterjet with speed and accuracy while surgeon monitors



## HEAT-FREE WATERJET RESECTION

Utilizing the unique power of a pulsating waterjet near the speed of sound, Aquablation therapy removes prostatic tissue with a heat-free waterjet



**AQUABEAM**<sup>®</sup>  
— ROBOTIC SYSTEM —

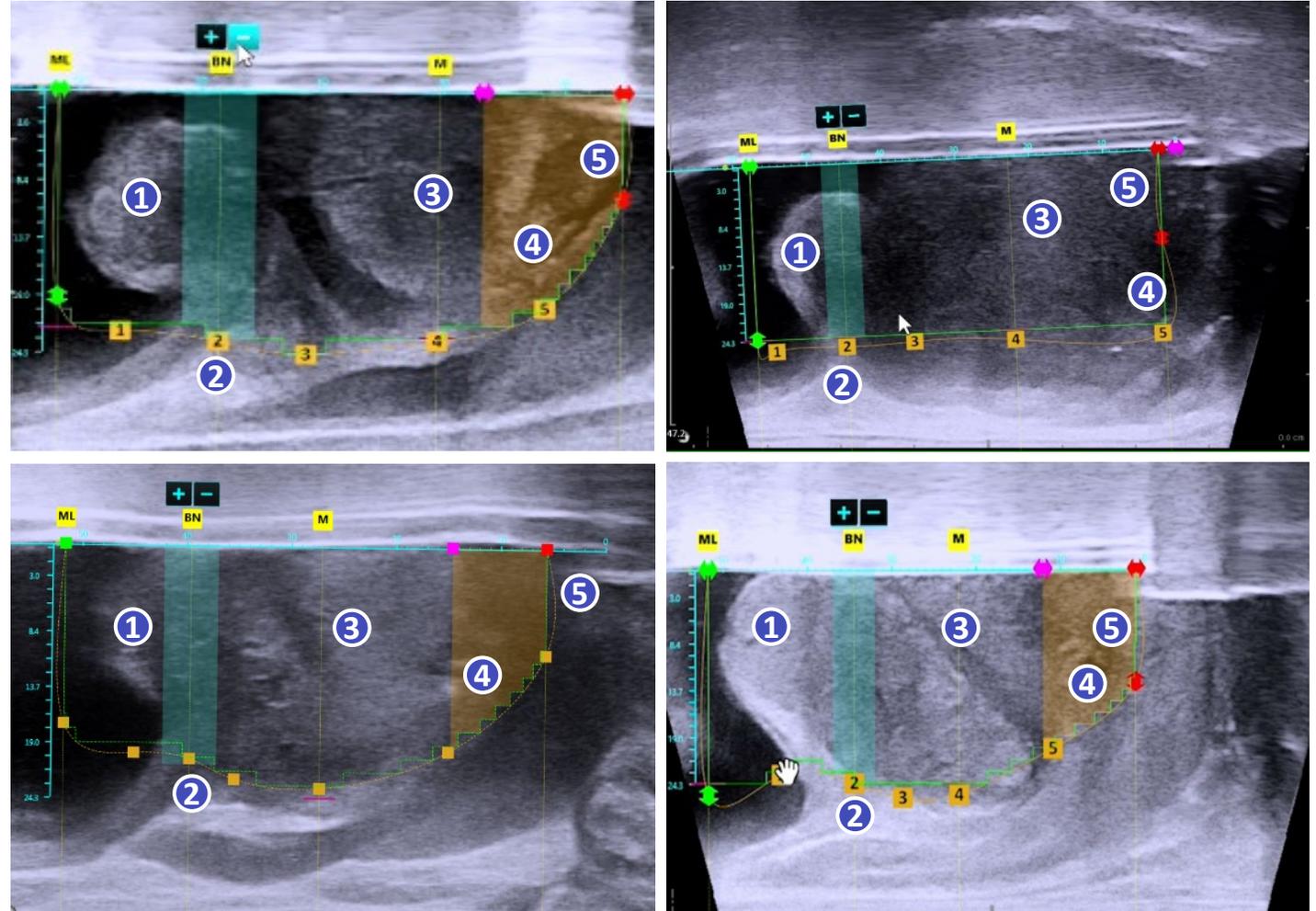


## FOUR UNIQUE TREATMENT PLANS

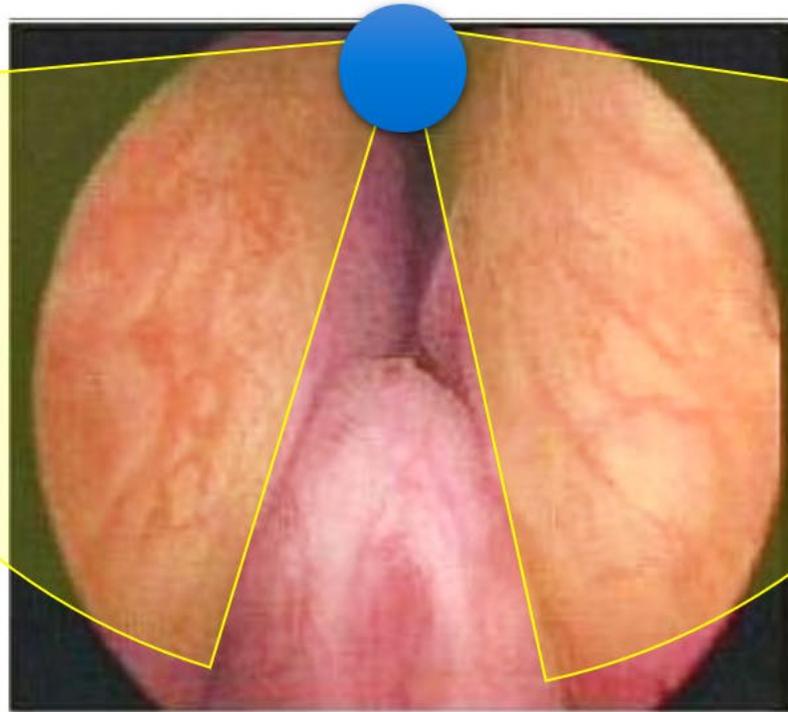
### IDENTIFY CRITICAL ANATOMY:

- 1 MEDIAN LOBE
- 2 BLADDER NECK
- 3 LATERAL LOBE
- 4 VERUMONTANUM
- 5 EXTERNAL SPHINCTER

### CREATE CUSTOMIZED TREATMENT PLAN



## Veru Protection Zone



The screenshot displays the AQUABLATION software interface. On the left, the 'TREATMENT PROFILE' section includes a legend for 'BN' (Bladder Neck Zone), 'M' (Mid-Prostate Zone), and 'Profile', along with markers for 'Treatment Start', 'Treatment End', 'Depth from Angle Plan', and 'Veru Zone Start'. The 'Estimated Aquablation Time' is shown as 04:50. The main display area shows a 'PLAN' view of an ultrasound image with a yellow circle around the Veru Protection Zone. The 'DEPTH' is 23 mm and the 'ANGLE' is 165 degrees. On the right, the 'PROCEDURE STEPS' section shows 'HANDPIECE', 'TRUS', and 'ALIGNMENT' as completed, and 'ANGLE', 'REGISTRATION', and 'PROFILE' as in progress. The 'TREAT' section shows the 'TREATMENT' button. The 'Nozzle Controls' section shows 'Neck' and 'Veru' buttons, with the 'Nozzle Position' set to 70.0 mm. The 'System Status' shows 'TRUS Connected'.

Veru protection start marker = 33% of the distance between bladder neck and end marker

# AQUABLATION THERAPY

ONLY IMAGE-GUIDED, HEAT-FREE, AUTOMATED ROBOTIC THERAPY FOR BPH



## REAL-TIME IMAGE GUIDANCE

Intraoperative ultrasound imaging combined with cystoscopic visualization provide a multidimensional view of the treatment area



## PERSONALIZED TREATMENT PLANNING

Advanced planning software allows the surgeon to map the treatment contour that precisely targets the resection area



## AUTOMATED ROBOTIC EXECUTION

The robot executes the treatment plan and guides the precisely calibrated waterjet with speed and accuracy while surgeon monitors



## HEAT-FREE WATERJET RESECTION

Utilizing the unique power of a pulsating waterjet near the speed of sound, Aquablation therapy removes prostatic tissue with a heat-free waterjet



**AQUABEAM**<sup>®</sup>  
— ROBOTIC SYSTEM —

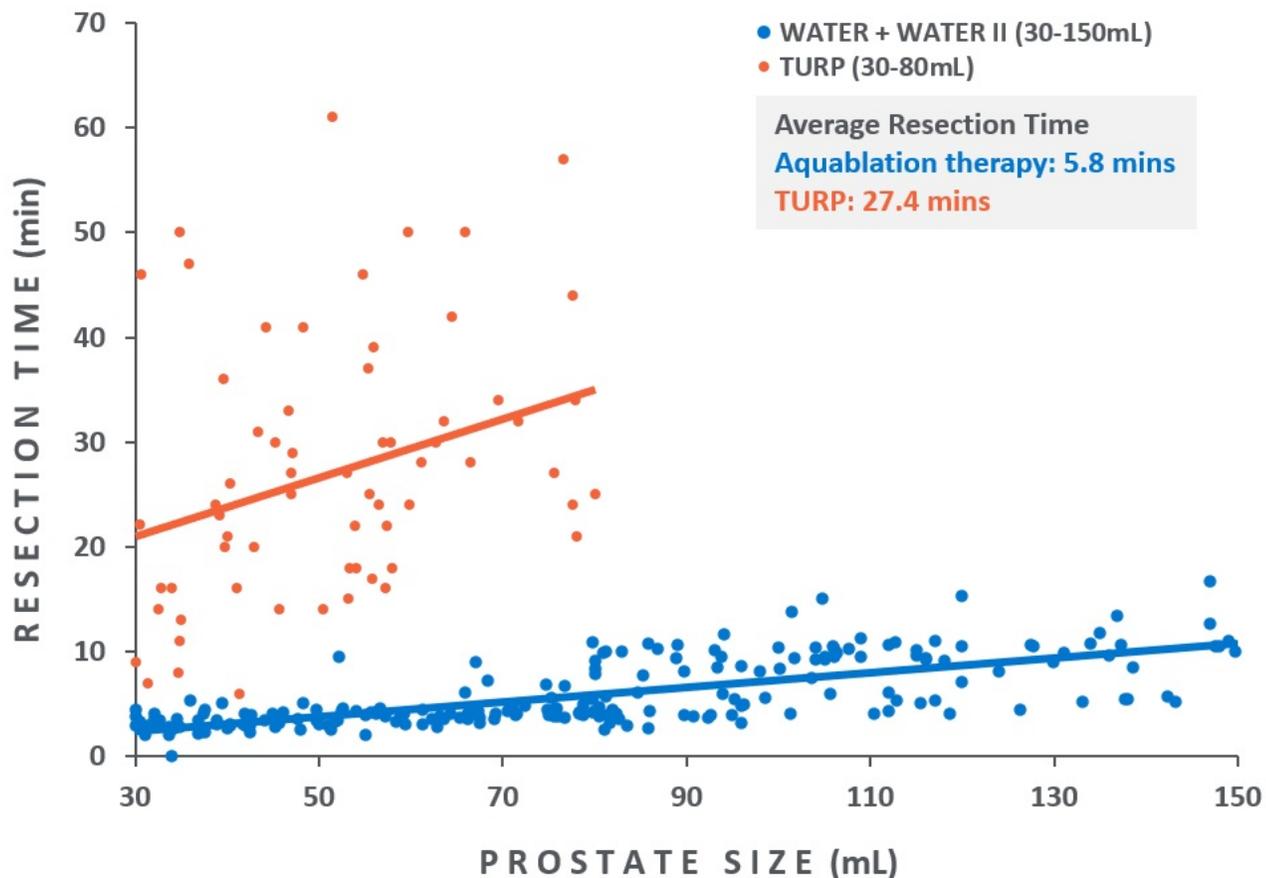


# AUTOMATED ROBOTIC EXECUTION

The screenshot displays the Aquablation software interface during a treatment session. The interface is divided into several sections:

- Top Left:** The Aquablation logo and "Therapy by PROCEPT BioRobotics".
- Top Center:** A yellow "TREAT" banner with a red warning "DO NOT MOVE TRUS OR HANDPIECE" and a "Main" label.
- Top Right:** A "SESSION ID:" field, a camera icon, and a power icon.
- Center:** A large ultrasound image showing a cross-section of the prostate. A green dashed line indicates the treatment area. A green padlock icon is visible on the image. Text on the right side of the image reads "Depth: 8.7 cm" and "B\_Gain: 78 dB".
- Bottom Left:** A gauge showing "100%" completion with "FLOW 220 mL/min". Below it is a blue progress bar and a timer showing "04:22" with "Aquablation Treatment Remaining". At the bottom, it says "SAGITTAL" and a clock showing "14:01:36".
- Bottom Center:** "Est. Contour Volume: 34.0".
- Right Panel:** A "PROCEDURE STEPS" section with "HANDPIECE", "TRUS", and "ALIGNMENT" all marked with green checkmarks. Below is a "PLAN" section with "ANGLE", "REGISTRATION", and "PROFILE" also marked with green checkmarks. The "TREAT" section has a "TREATMENT" button with a menu icon. At the bottom of the right panel are "Nozzle Controls" with "Neck" and "Veru" buttons, a "Nozzle Position: 60.4 mm" slider, and "System Status" and "TRUS Connected" indicators.

## SIZE & SHAPE INDEPENDENT RESECTION



## CLINICAL OUTCOMES ARE EXPERIENCE AGNOSTIC

- ▶ **WATER study** - 14 of 17 participating surgeons had no previous experience with Aquablation therapy
- ▶ **WATER II study** - median previous experience of 0.5 procedures with Aquablation therapy



# AQUABLATION THERAPY

ONLY IMAGE-GUIDED, HEAT-FREE, AUTOMATED ROBOTIC THERAPY FOR BPH



## REAL-TIME IMAGE GUIDANCE

Intraoperative ultrasound imaging combined with cystoscopic visualization provide a multidimensional view of the treatment area



## PERSONALIZED TREATMENT PLANNING

Advanced planning software allows the surgeon to map the treatment contour that precisely targets the resection area



## AUTOMATED ROBOTIC EXECUTION

The robot executes the treatment plan and guides the precisely calibrated waterjet with speed and accuracy while surgeon monitors



## HEAT-FREE WATERJET RESECTION

Utilizing the unique power of a pulsating waterjet near the speed of sound, Aquablation therapy removes prostatic tissue with a heat-free waterjet



**AQUABEAM**<sup>®</sup>  
— ROBOTIC SYSTEM —



## Waterjets in Air

- Pressures: 30,000 - 90,000 PSI
- Aerospace, Mining, Medicine
- Cutting, Shaping, Reaming
- Metals, Stone, Food, Glass, Paper, Wood
- Tissue

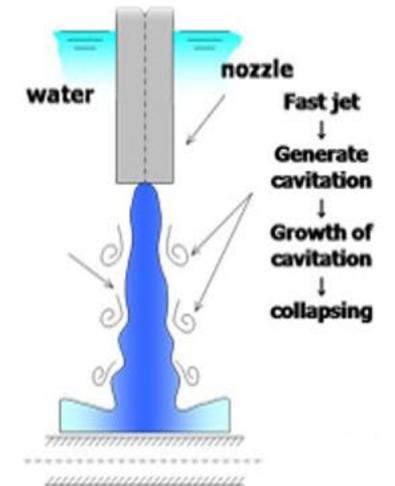


## Submerged Waterjets

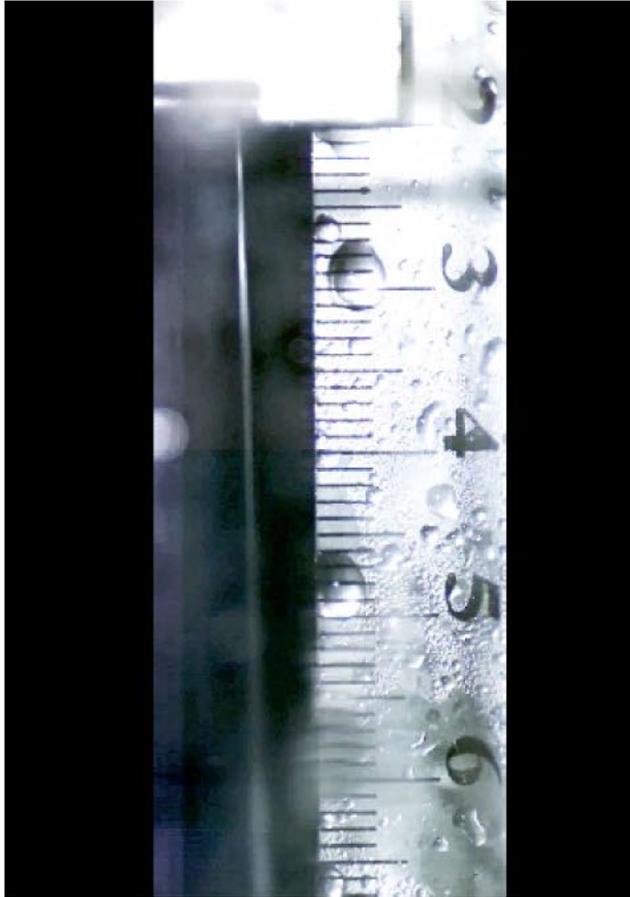
Non-cavitating

Cavitating

- Pressures: 500 - 10,000 PSI
- Highly erosive and self-limiting



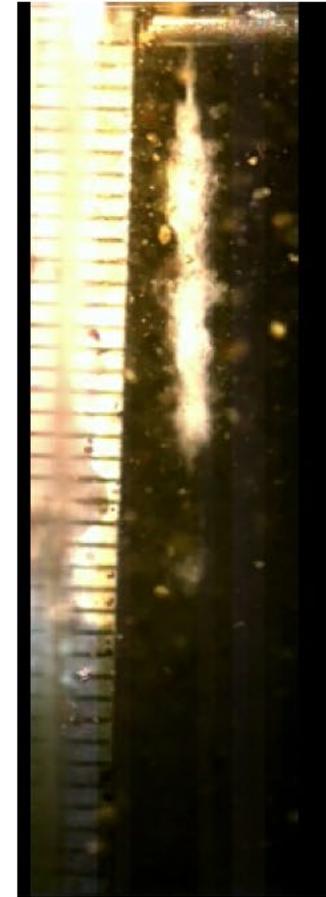
AQUABEAM Jet in Air



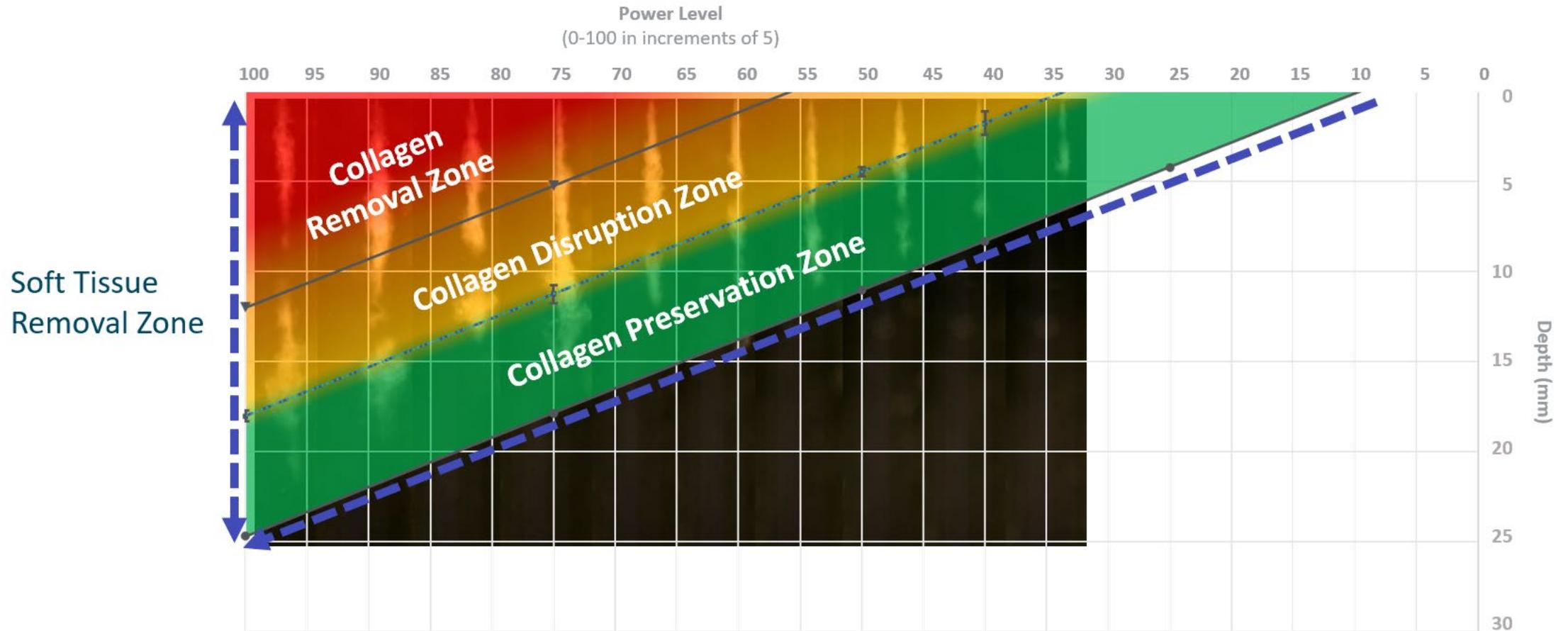
AQUABEAM Jet Submerged



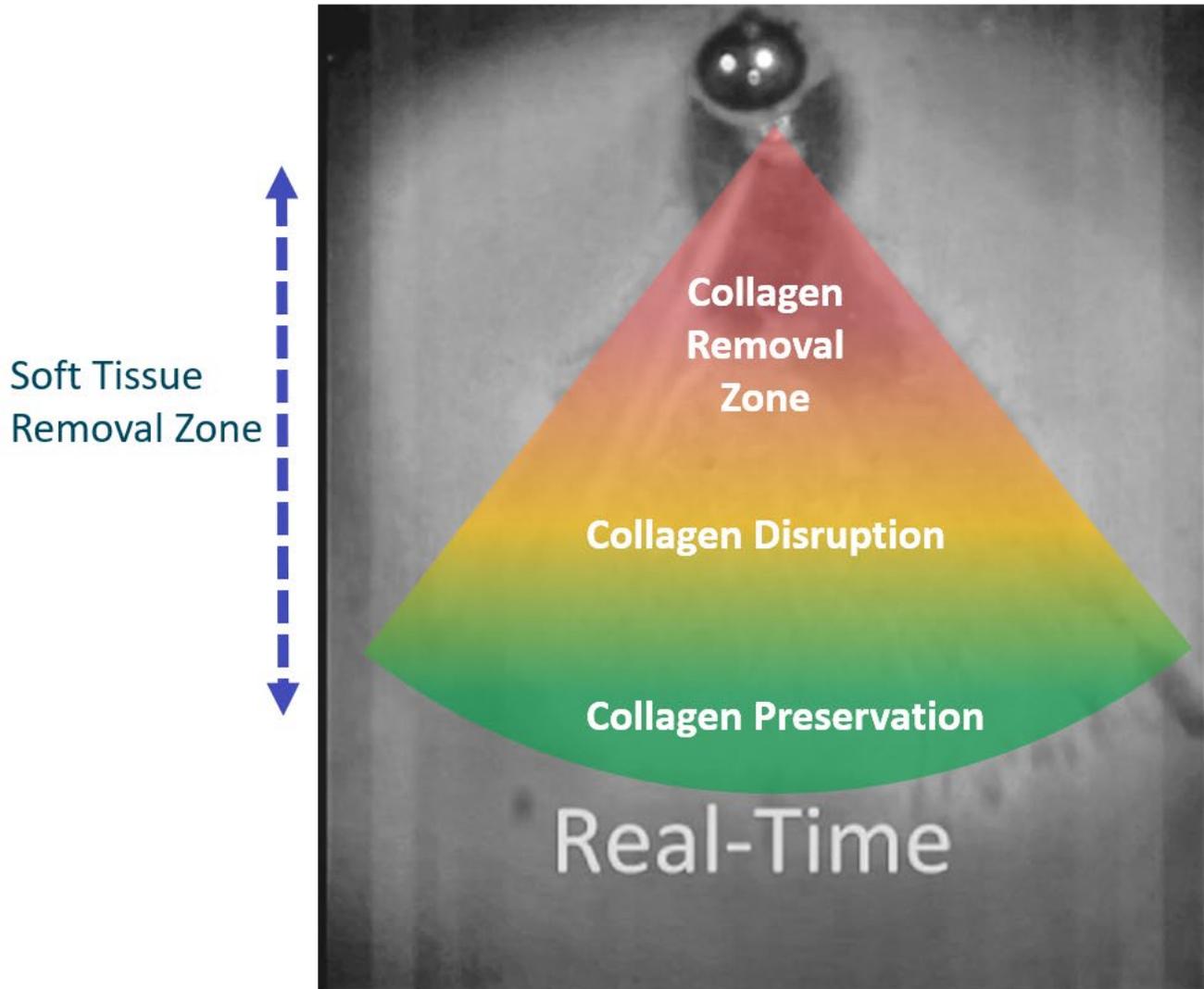
Targeted Resection



# Tissue Selective Zones



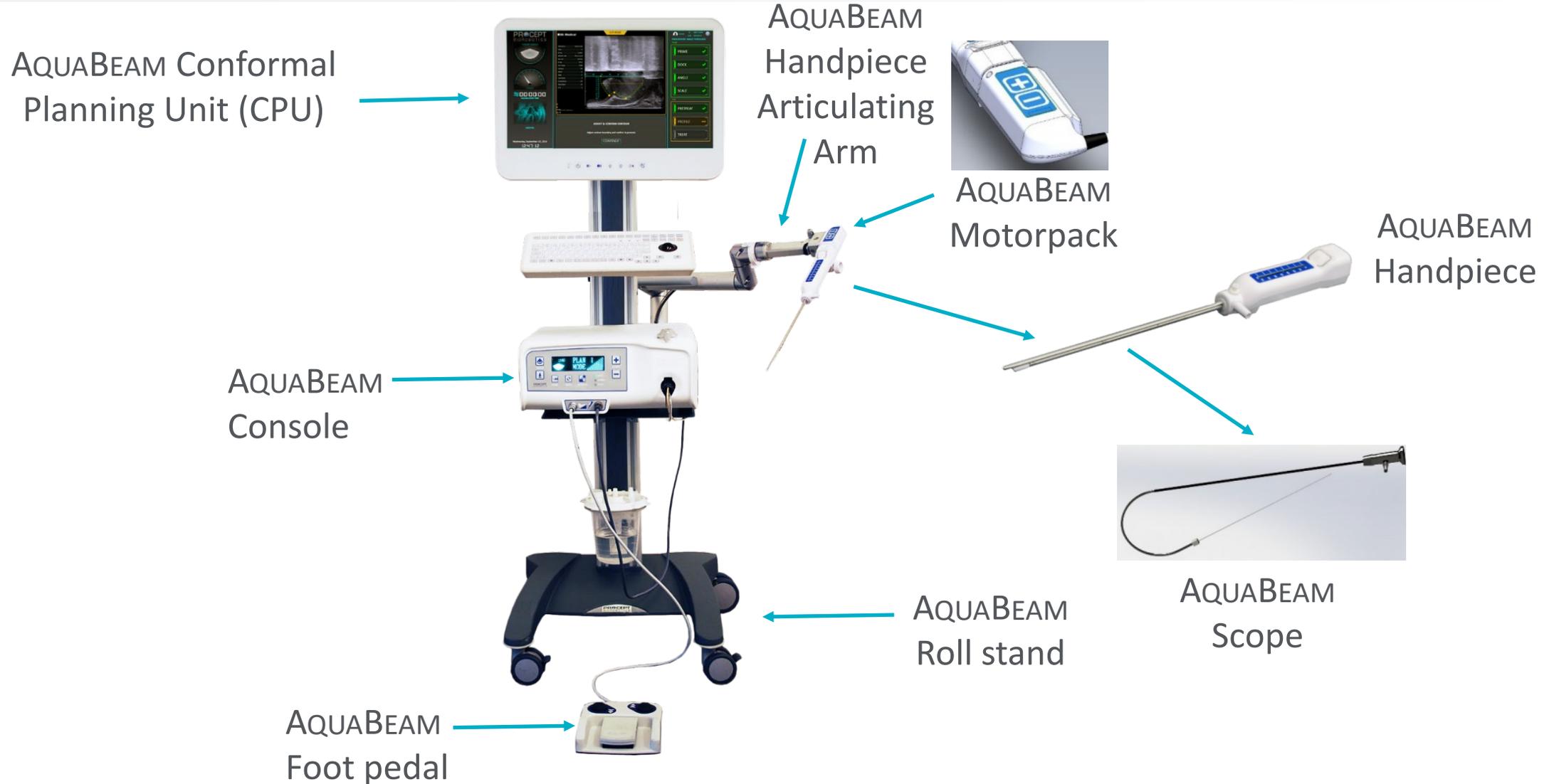
# Tissue Selective Zones



**AQUABLATION**<sup>®</sup>  
Therapy by PROCEPT BioRobotics

# AQUABEAM Robotic System & Components

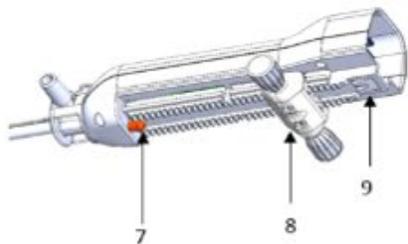
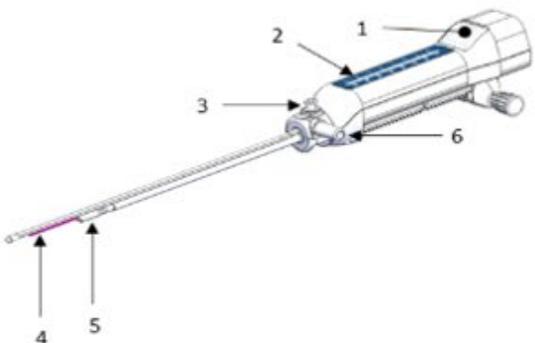
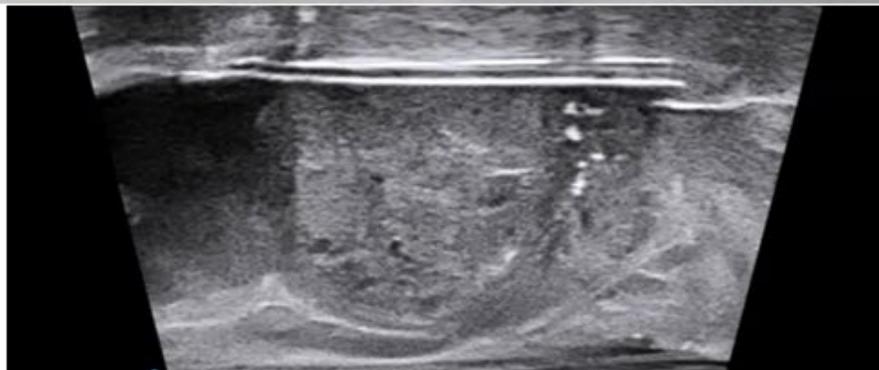
# The AQUABEAM Robotic System Components



AQUABEAM TRUS Articulating Arm not pictured

## Handpiece

- Aspiration tube
- AQUABEAM nozzle
- Scope tip
- Scope carriage

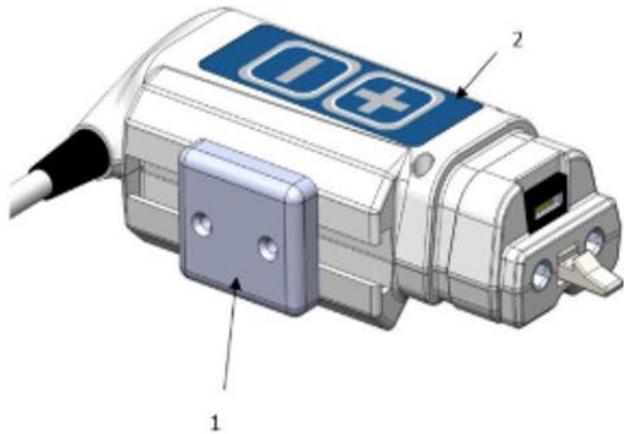


- 1 Handpiece Release Button
- 2 Handpiece Position Indicator
- 3 Irrigation Luer
- 4 High Pressure Probe
- 5 Scope Tube tip

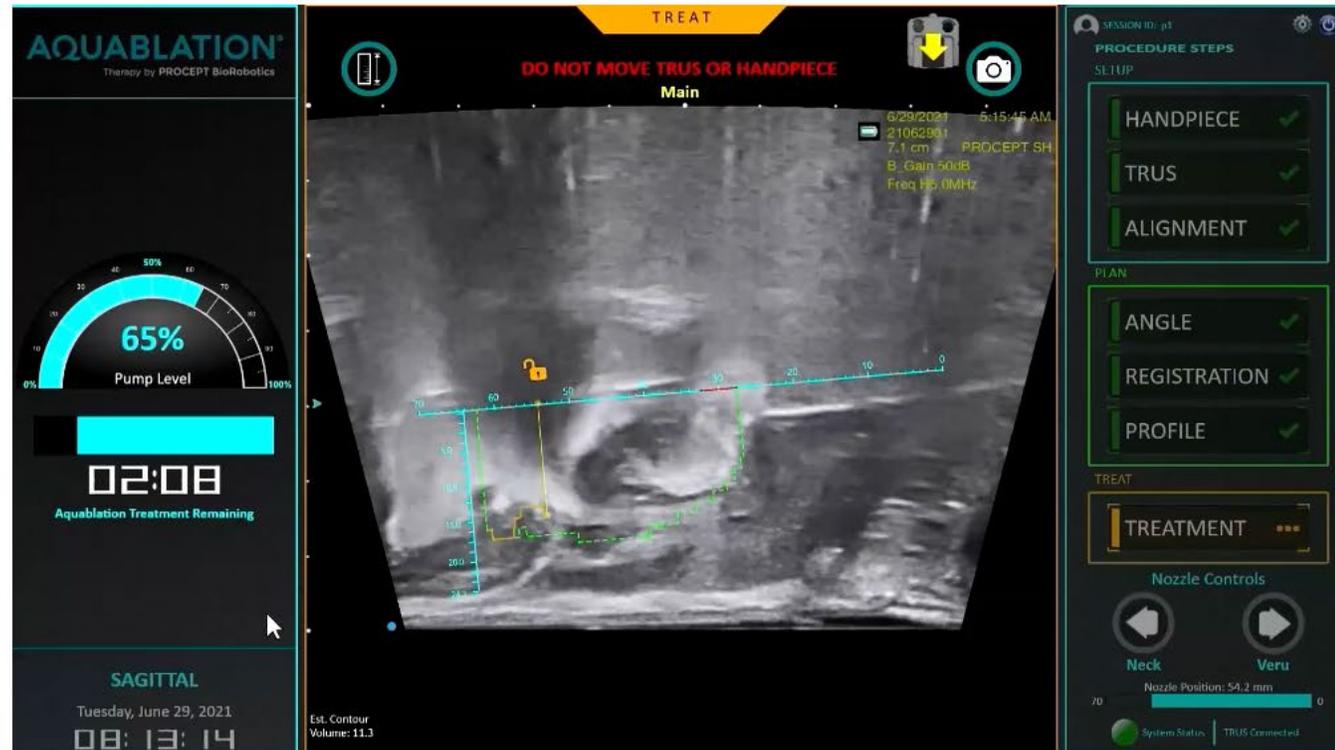
- 6 Aspiration Port
- 7 Scope Port
- 8 Scope Carriage
- 9 Scope Carriage Stop

## Motorpack

- Magnetic plate
- Pump power buttons

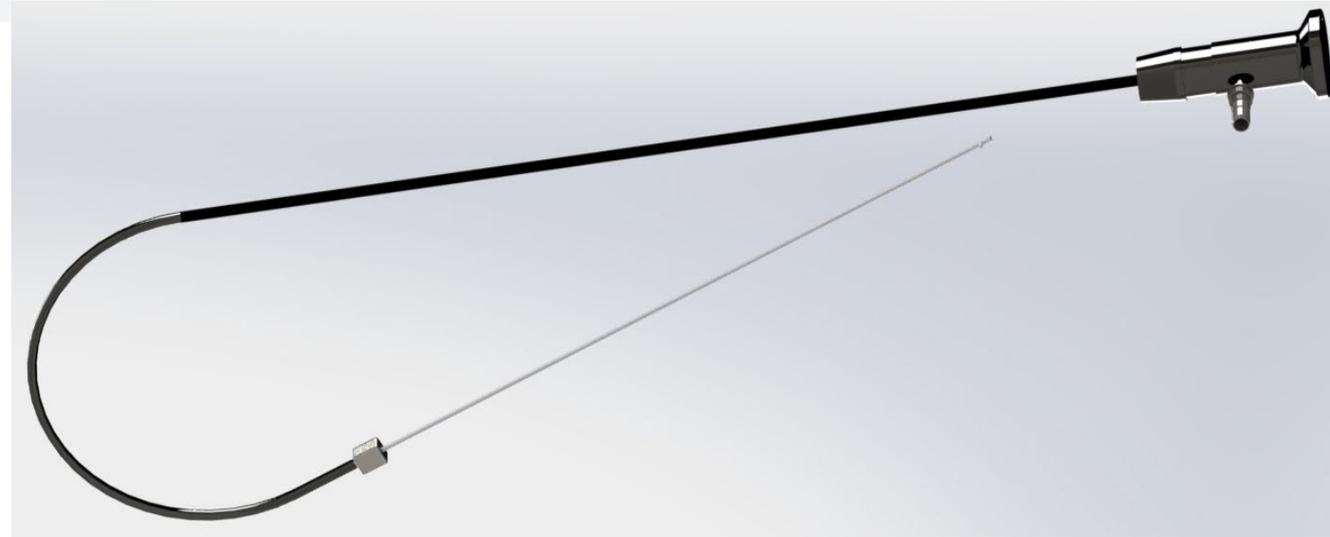


1. Motorpack Magnetic Strike Plate for Handpiece Articulating Arm
2. Pump Power Control Buttons (+/-)
  - - decrease pump power (active during Aquablation)
  - + increase pump power (active during Aquablation)



## AQUABEAM Scope Assembly

- Telescope – 0° angle
  - Camera port
    - Compatible with standard camera system
  - Light port
    - Compatible with standard light guide cable
- Scope clamp



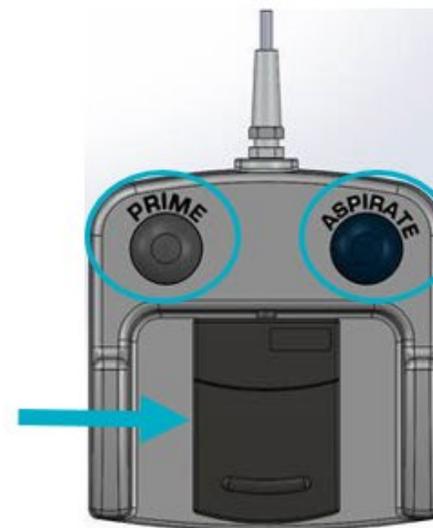
## Handpiece Articulating Arm

- Rotational adjuster
- Arm trigger



## Foot pedal

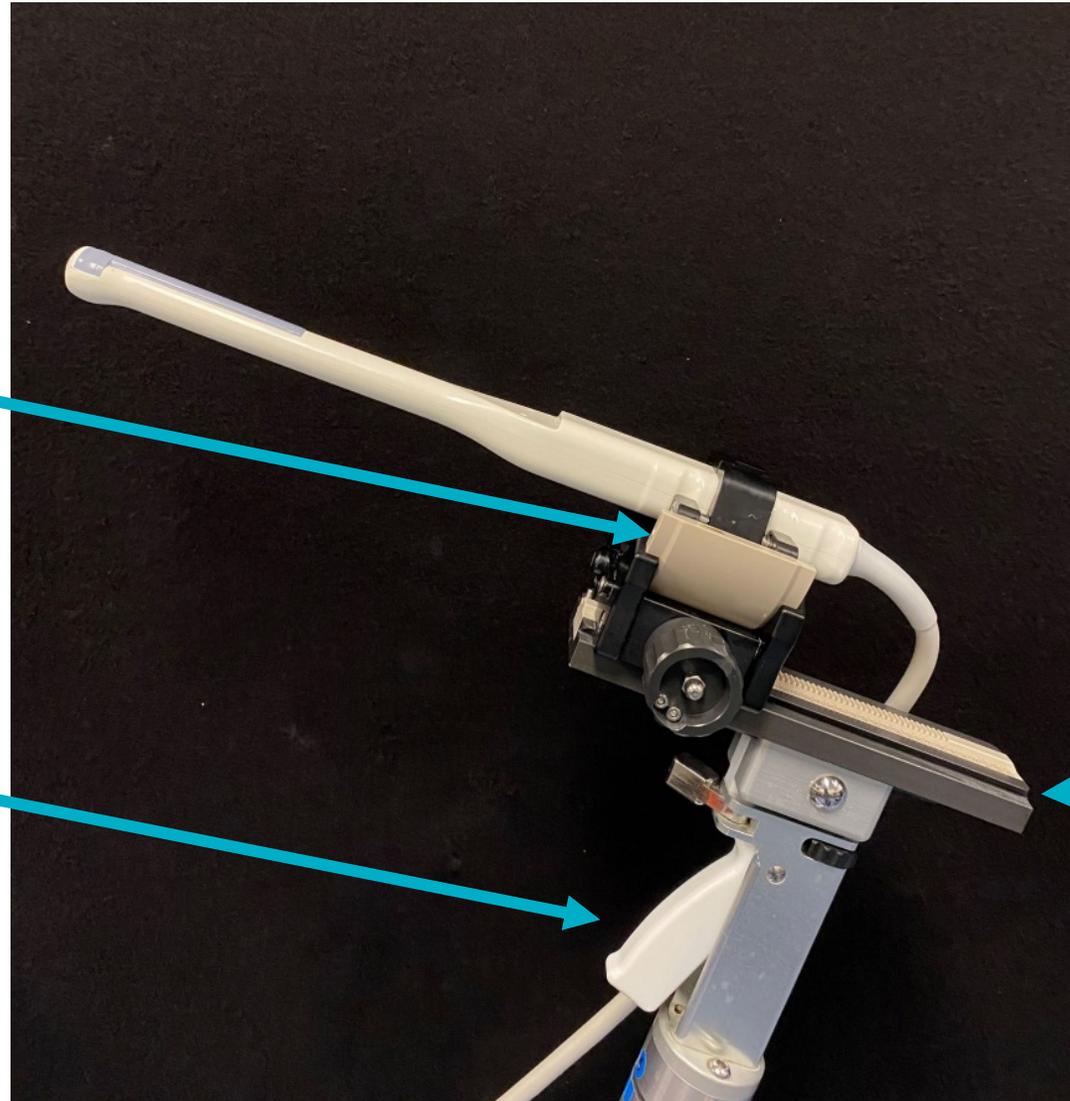
- Aspiration
- Prime
- Aquablate pedal



TRUS  
Cradle/Receptacle

TRUS  
Articulating  
Arm

TRUS Stepper



# Case Overview

# Contour Planning

## AQUABLATION<sup>®</sup>

Therapy by PROCEPT BioRobotics

### TREATMENT PROFILE

- BN** Bladder Neck Zone
- M** Mid-Prostate Zone
- Profile**
- Treatment Start**
- Treatment End**
- Depth from Angle Plan**
- Veru Zone Start**

Estimated Aquablation Time

# 04:07

RESET

BACK NEXT

SAGITTAL

# 11:57:57

PLAN

DO NOT MOVE TRUS OR HANDPIECE

20072701  
7.9 cm PROCEPT SH  
B\_Gain 74dB  
Freq 15.0MHz

50  
100  
150  
200  
243

30  
0

BN M

2 3 4 5

### TRUS

ALIGNMENT

PLAN

### ANGLE

### REGISTRATION

### PROFILE

TREAT

### TREATMENT

Nozzle Controls

Neck Veru

Nozzle Position: 70.0 mm

70 0

System Status TRUS Connected

System Status TRUS Connected

# Clot Evacuation and Focal Bladder Neck Cautery

**AQUABLATION<sup>®</sup>**  
Therapy by PROCEPT BioRobotics

**COMPLETE**

7/23/2020 9:44:34 AM  
20072301 PROCEPT SH  
7.9 cm  
B\_Gain 70dB  
Freq 15.0MHz

**TREATMENT PASS COMPLETE**

ADDITIONAL PASS

AQUABLATION COMPLETE

**SAGITTAL**

09:44:27

**PROCEDURE STEPS**

**SETUP**

- HANDPIECE ✓
- TRUS ✓
- ALIGNMENT ✓

**PLAN**

- ANGLE ✓
- REGISTRATION ✓
- PROFILE

**TREAT**

- TREATMENT**

Nozzle Control

Neck

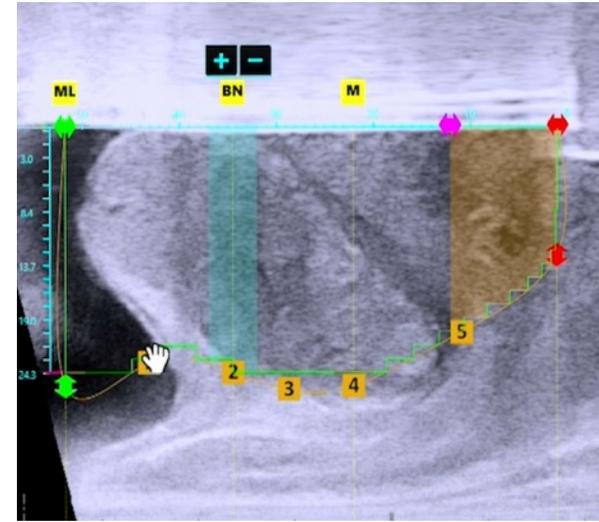
Needle Position: 23.9 cm

System Status | TRUS C

# AQUABLATION THERAPY RESULTS

## BEFORE

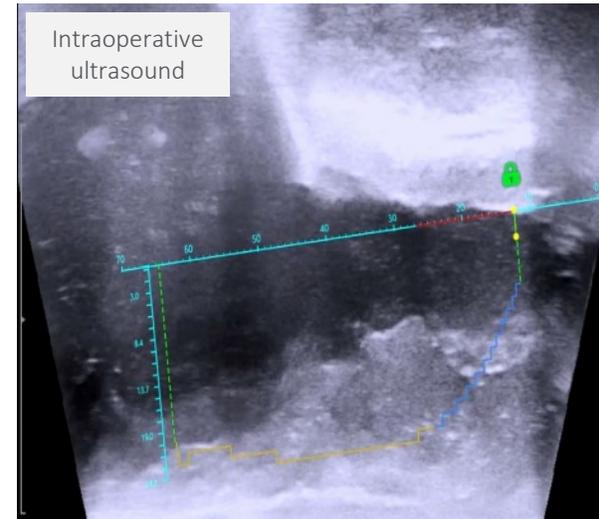
Obstructed Prostatic Urethra



3 months  
post-op

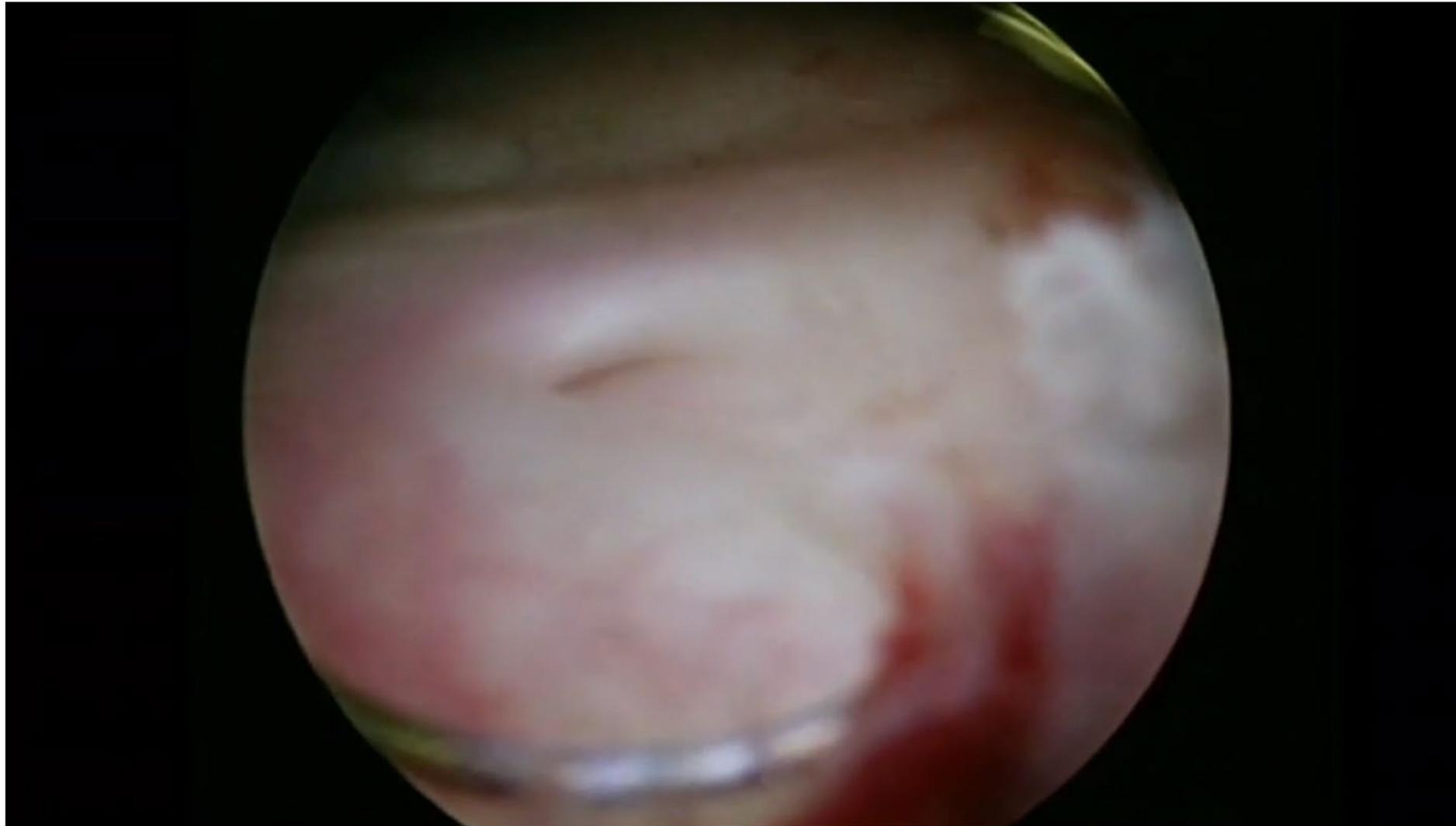


Intraoperative  
ultrasound



## AFTER

Open Prostatic Urethra

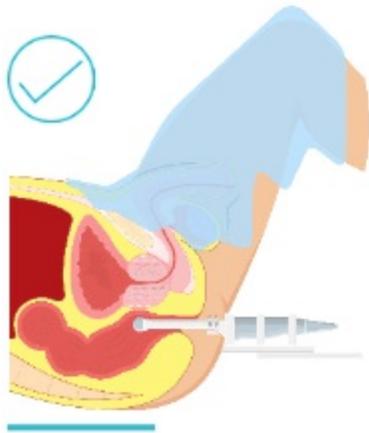


- 1) The transrectal ultrasound probe placement slightly elevates the posterior aspect of the bladder, tenting up the trigone and the UO's fall off to an atypical lateral positioning, further away from waterjet.
- 2) Careful consideration is given when planning the depth of resection along the posterior bladder wall.
- 3) This was a big concern for all WATER II clinical investigators. Over 90% of patients with a median lobe had an intravesical protrusion. Immediate cystoscopic visualization of UO's immediately post-treatment yielded no UO damage.

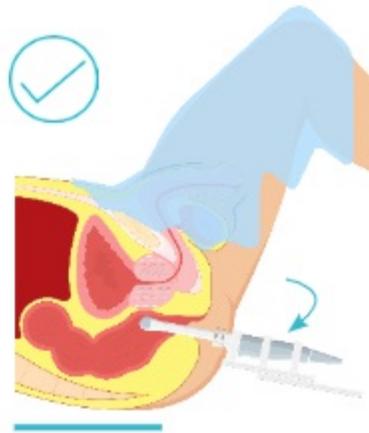
# Best Practices for Transrectal Ultrasound

STEP	RECOMMENDATION	REASON
<b>PATIENT PREPARATION</b>	Review patient history for any rectal pathology such as hemorrhoids, history of radiation therapy in the rectum, etc.	Informs safe introduction of the TRUS probe
	Center patient on the surgical bed with buttocks suspended beyond the edge by a few inches	Allows for easier manipulation of the TRUS probe and to prevent TRUS stepper from hitting the bed
<b>PRE-INSERTION</b>	Prepare the TRUS probe in the cover, mount the TRUS probe in stepper, and advance stepper all the way to the end	Ensures the TRUS probe is in the most advanced position upon insertion
	Perform a rectal examination prior to any insertion	Relaxes sphincter and reduces force needed to insert the TRUS probe
	Insert 60cc of ultrasound gel in the rectum	Lubricates rectum and optimizes imaging
<b>INSERTION</b>	Insert in transverse view and switch to sagittal view to advance further as needed	Maintains midline position and helps prevent over-insertion of TRUS probe
	Ensure the TRUS probe is parallel to the floor	Prevents anterior pressure points
	If met with any resistance, stop advancing the TRUS probe. Retract and aim the TRUS probe posteriorly before advancing	Prevents tenting of tissue
	Minimize angled anterior compression. Keep the TRUS probe parallel to floor as much as possible, while allowing for handpiece insertion	Prevents anterior pressure points
<b>PROCEDURE</b>	Consider removing the TRUS probe and replanning if there is significant patient movement during the procedure	Ensures ultrasound image is accurate
	Prior to introducing the resectoscope to start the hemostasis protocol, reduce TRUS compression and ensure there is no steep angling of the TRUS probe	Prevents anterior pressure points
	Note: In the rare instance of patients with a high bladder neck where the Handpiece cannot reach the bladder and a resectoscope may be needed to resect tissue, remove the TRUS probe while the resectoscope is in use	Avoids undesired angling of the TRUS probe when addressing external instrument clashing between the resectoscope and the TRUS probe. Avoids interaction between resectoscope and TRUS probe in the patient
<b>POST-OPERATIVE</b>	Inspect the TRUS probe and anus for blood	Indicates potential injury

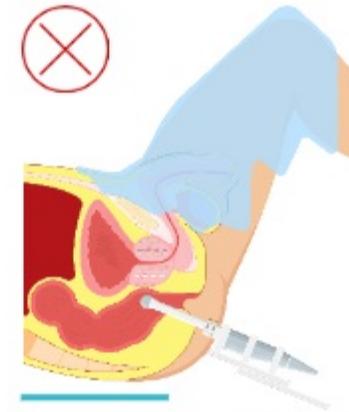
This material has been developed with, reviewed by, and approved by independent surgeons who are not PROCEPT BioRobotics employees. These surgeons received compensation from PROCEPT BioRobotics for consultation services.



**1. Introduce the TRUS probe parallel to the floor.**



**2. Once the TRUS probe is introduced far enough, tilt at a slight angle to allow for Handpiece insertion.**



**3. Do not angle the TRUS probe steeply. If angling is required to create space for other instruments, consider removing the TRUS probe.**

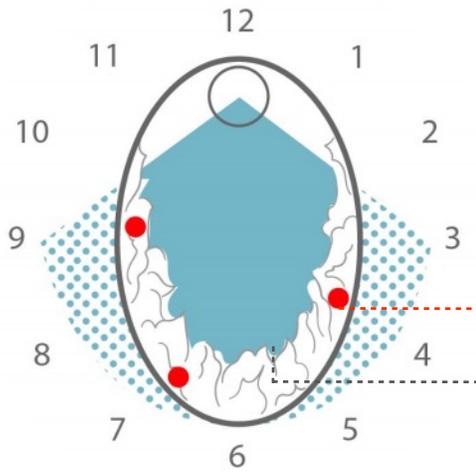
This material has been developed with, reviewed by, and approved by independent surgeons who are not PROCEPT BioRobotics employees. These surgeons received compensation from PROCEPT BioRobotics for consultation services.

# Focal Bladder Neck Caution

# Hemostasis Protocol

## STEP 1

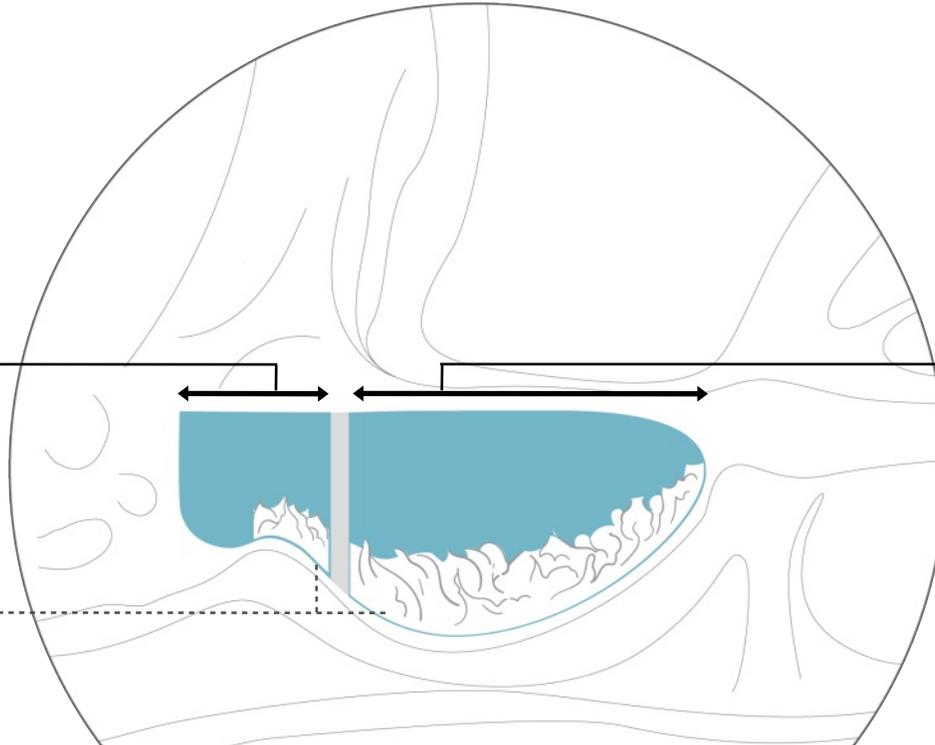
Irrigate bladder



## STEP 2

Focus at the Bladder Outlet

Systematically work around the bladder outlet



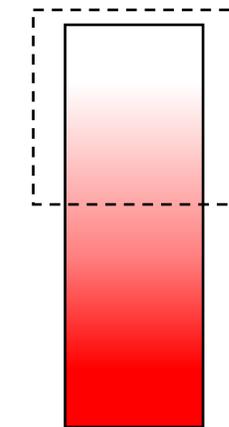
## STEP 3

Inspect

Turn off irrigation and inspect for bleeders under normal blood pressure

## STEP 4

Effluent Color Goal



FLUFFY TISSUE

USE LOOP TO REMOVE  
FLUFFY TISSUE

FOCAL CAUTERY  
AT BLEEDERS

Resect the fluffy tissue to smooth tissue, then cauterize as required

## *Focal bladder neck cauterization associated with low rate of post-Aquablation bleeding*

Dean S. Elterman, MD,<sup>1</sup> Susan Foller, MD,<sup>2</sup> Burkhard Ubrig, MD,<sup>3</sup>  
Alexander Kugler, MD,<sup>4</sup> Vincent Misrai, MD,<sup>5</sup> Angelo Porreca, MD,<sup>6</sup>  
Dominik Abt, MD,<sup>7</sup> Kevin C. Zorn, MD,<sup>8</sup> Naeem Bhojani, MD,<sup>8</sup>  
Lewis Kritek, MD,<sup>9</sup> Rahul Mehan, MD,<sup>10</sup> Michael McDonald, MD,<sup>11</sup>  
Steven A. Kaplan, MD<sup>12</sup>

<sup>1</sup>Division of Urology, University Health Network, University of Toronto, Toronto, Ontario, Canada; <sup>2</sup>Universitätsklinikum Jena, Jena, Germany; <sup>3</sup>Witten/Herdecke University, Augusta-Kranken-Anstalt, Bochum, Germany; <sup>4</sup>Klinikum Fichtelgebirge Marktredwitz gGmbH, Marktredwitz, Germany; <sup>5</sup>Clinique Pasteur, Toulouse, France; <sup>6</sup>Policlinico Abano Terme, Abano Terme PD, Italy; <sup>7</sup>Kantonsspital St. Gallen, Switzerland; <sup>8</sup>University of Montreal, Montreal, Quebec, Canada; <sup>9</sup>Northside Forsyth Hospital, Atlanta, Georgia, USA; <sup>10</sup>East Valley Urology Center, Mesa, Arizona, USA; <sup>11</sup>AdventHealth Celebration, Celebration, Florida, USA; <sup>12</sup>Mount Sinai Medical Center, New York, New York, USA

ELTERMAN DS, FOLLER S, UBRIG B, KUGLER A, MISRAI V, PORRECA A, ABT D, ZORN KC, BHOJANI N, KRITEMAN L, MEHAN R, MCDONALD M, KAPLAN SA. Focal bladder neck cauterization associated with low rate of post-Aquablation bleeding. *Can J Urol* 2021;28(2):10610-10613.

**Introduction:** To determine if focal bladder neck cauterization is effective in reducing bleeding following prostate tissue resection for benign prostatic hyperplasia using Aquablation.

**Materials and methods:** Consecutive patients at 11 countries in Asia, Europe and North America who underwent Aquablation for symptomatic benign prostatic hyperplasia between late 2019 and January 2021 were

**Results:** A total of 2,089 consecutive Aquablation procedures were included. Mean prostate size was 87 cc (range 20 cc to 363 cc). Postoperative bleeding requiring transfusion occurred in 17 cases (0.8%, 95% CI 0.5%-1.3%) and take-back to the operating room for fulguration occurred in 12 cases (0.6%, 95% CI 0.3%-1.0%). This result compares favorably ( $p < .0001$ ) to the previously published hemostasis transfusion rate of 3.9% (31/801) using methods performed in the years 2014 to 2019.

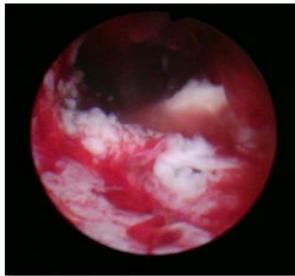
**Conclusions:** In prostates sizes averaging 87cc (range 20 cc-363 cc), Aquablation procedures performed with focal bladder neck cauterization that required a transfusion postoperatively occurred in a remarkably low number of cases.

# Focal bladder neck cautery

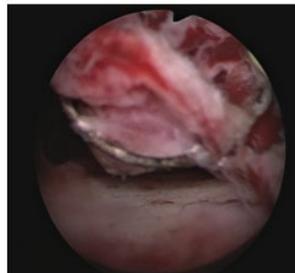
associated with low rates of post operative bleeding

## FOCAL BLADDER NECK CAUTERY

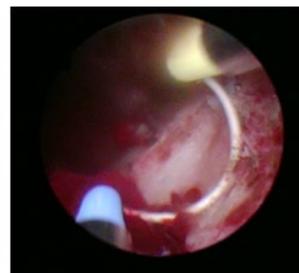
- Clot Evacuation
- Removal of “fluffy tissue”
- Cauterize around bladder neck



FLUFFY TISSUE



USE LOOP TO REMOVE  
FLUFFY TISSUE

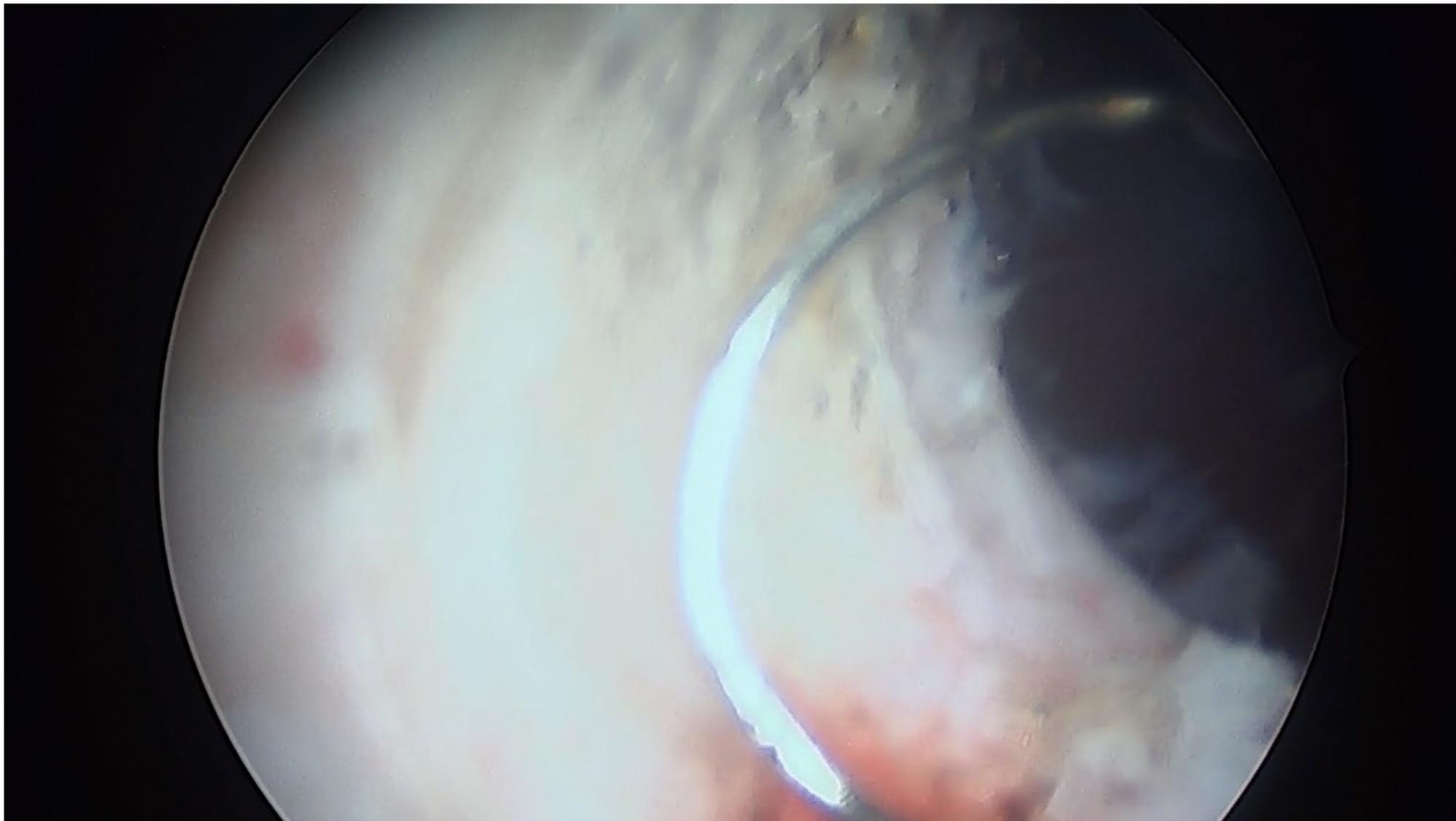


FOCAL CAUTERY  
AT BLEEDERS

## RESULTS

FOCAL BLADDER NECK CAUTERY	MEAN (N = 2,089)
Transfusion Rate (%)	0.8 (95% CI: 0.5-1.3)
Prostate Size (mL)	87 (20-363)
FBNC Time (min) (handpiece removal to catheter insertion)	19.9

# Effective Cautery: Proper Demonstration of Technique



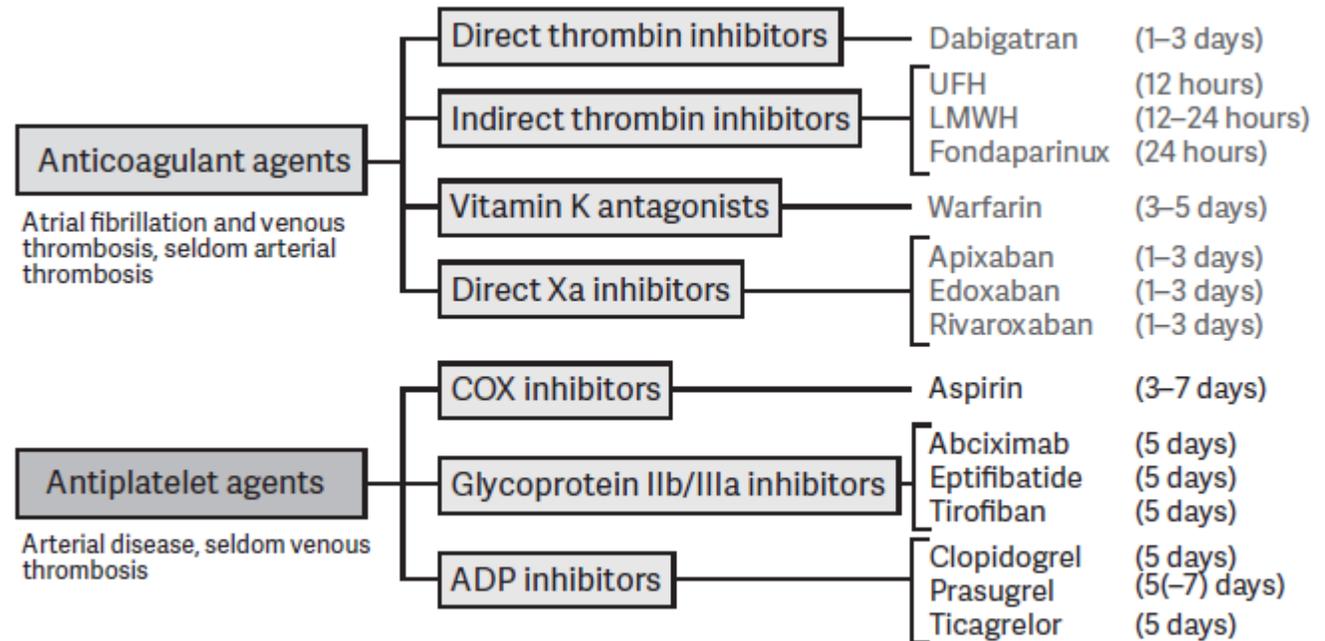
## Anticoagulant / Antiplatelet Contraindications for Aquablation

Do not use the AQUABEAM Robotic System in patients who do not meet the indication for the system's intended use. In addition, do not use the system in the following:

- Active urinary tract or systemic infection
- Known allergy to device materials (nickel)
- Unable to safely stop anticoagulants or antiplatelet agents perioperatively

## Guideline Recommendations for BPH Prostate Surgery

- Stop antiplatelet and anticoagulant agents per the figure details →
- Do not initiate any alternative antithrombotic therapy (i.e. bridging)
- Restarting when bleeding risk is no longer a serious risk – typically 4 days



*Tikkinen (Chair) et al. EAU Guidelines: Thromboprophylaxis in Urological Surgery*

# Clinical Data Summary

# CLINICALLY PROVEN OUTCOMES



**OUTCOMES**

Superior safety and non-inferior efficacy compared to TURP  
Sub-group of prostates over 50 mL were SUPERIOR in safety AND efficacy over TURP

Safe and effective without significant increase in procedure or resection time

Safe and effective without significant increase in procedure or resection time

**DESCRIPTION**

Only FDA pivotal study randomized to the gold standard

Only successful FDA multicenter study for large prostates

Largest commercial trial evaluating safety and efficacy

**DESIGN**

Prospective, double-blind, randomized controlled clinical trial

Prospective, multicenter clinical trial

Prospective, multicenter, all-comer trial

**POPULATION**

Prostates 30 – 80 mL  
N = 181  
17 Sites | US, UK, AU, NZ

Prostates 80 – 150 mL  
N = 101  
16 Sites | US and CA

Prostates 20 – 150 mL  
N = 178  
6 Sites | DE, AU, NZ, UK, LB

Gilling P. et al. Three-year outcomes after Aquablation® therapy compared to TURP: results from a blinded randomized trial. Can J Urol. 2020 Feb;27(1):10072-10079

Desai M, et al. Aquablation for benign prostatic hyperplasia in large prostates (80-150 cc): 2-year results. Canadian Journal of Urology. 27(2):10147-10153. Apr 2020

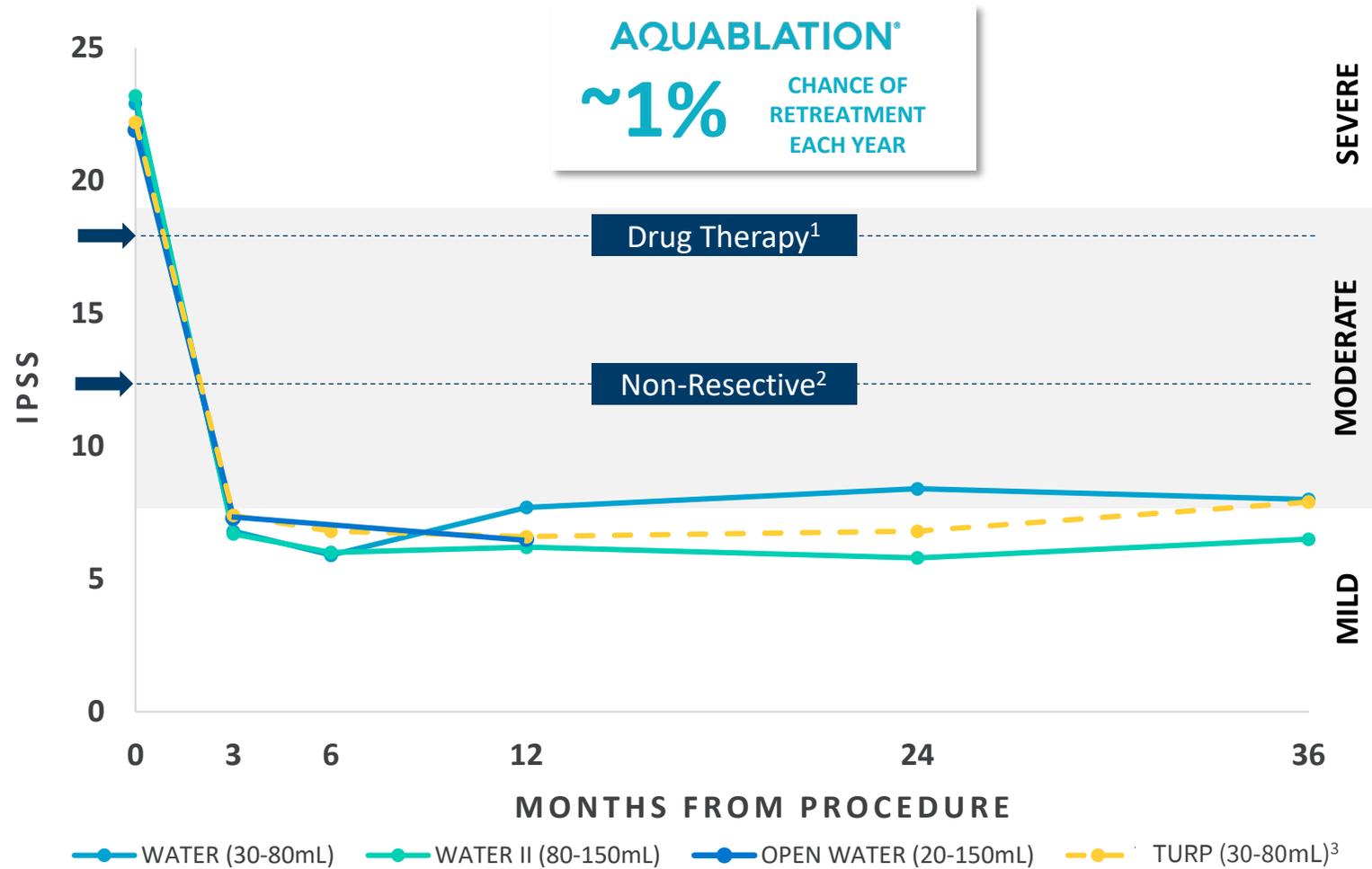
Bach T. et al. First Multi-Center All-Comers Study for the Aquablation Procedure. J Clin Med. 2020 Feb;9(2): 603.

## Low Rates of Irreversible Complications in ALL Prostates

	WATER		WATER II	OPEN WATER	
	Aquablation	TURP			
Mean Prostate Size	54 ml	52 ml	107 ml	59 ml	
Obstructive Median Lobe	50%	52%	83%	59%	
<b>Irreversible Complications</b>	Incontinence	0.0%	0.0%	2.0%	0.0%
	Erectile dysfunction	0.0%	0.0%	0.0%	0.0%
	Ejaculatory dysfunction	6.9%	24.6%	14.9%	8.4%
		Statistical Significance: p<0.05			

# EFFICACY AND DURABILITY

SIMILAR OUTCOMES TO TURP, ACROSS ALL PROSTATES IN CLINICAL AND COMMERCIAL STUDIES



1. Drug therapy generally provides IPSS reduction of approximately 5 points.

2. Non resective surgery generally provides IPSS reduction of approximately 10 points

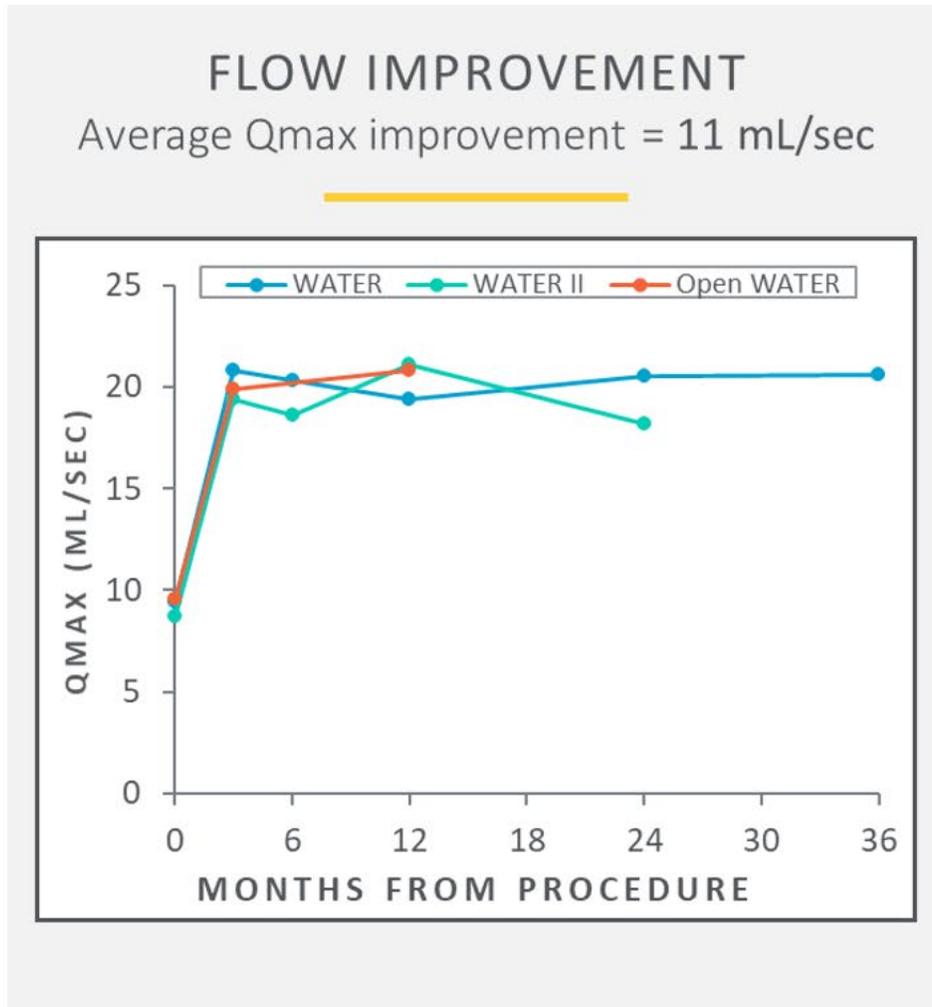
3. TURP results from WATER study

Roehrborn CG, et al. Five year results of the prospective randomized controlled prostatic urethral L.I.F.T. study. Can J Urol. 2017 Jun;24(3):8802-8813.

MTOPS study, NEJM December 2003, Vol.349, No.25

Data on file. WATER, WATER II, and OPEN WATER clinical studies.  
McVary KT, et al. Final 5-Year Outcomes of the Multicenter Randomized Sham-Controlled Trial of a Water Vapor Thermal Therapy for Treatment of Moderate to Severe Lower Urinary Tract Symptoms Secondary to Benign Prostatic Hyperplasia. J Urol. 2021 Apr 19

# Immediate and sustained flow improvement



## 183% Flow Improvement at 3 years



Data on file. Pooled percent change of Qmax from WATER and WATER II

# META-ANALYSIS OF FUNCTIONAL OUTCOMES

Remarkable Improvements across prostates of all sizes and shapes

425 PATIENTS   20-150 mL WATER, WATER II, OPEN WATER, FRANCAIS WATER		
GROUP	SUBGROUP	N
<b>VOLUME</b>	<100 mL 57 mL average	350
	>100 mL 126 mL average	75
<b>MEDIAN LOBE</b>	Absent	144
	Present	264

## ANALYSIS

IPSS, uroflowmetry, post-operative incontinence, and surgical retreatment

## RESULTS

Remarkable functional improvements across prostates of all sizes & shapes

IPSS Improvement	<b>16 points</b>
Peak Flow Rate (Qmax)	<b>20.5 mL/sec</b>
QoL Improvement	<b>3.3 points</b>
PVR Improvement	<b>62 mL</b>
Ejaculatory Function Preservation	<b>89.2%</b>
Erectile Function Preservation	<b>100%</b>
Continence Preservation	<b>99.5%</b>

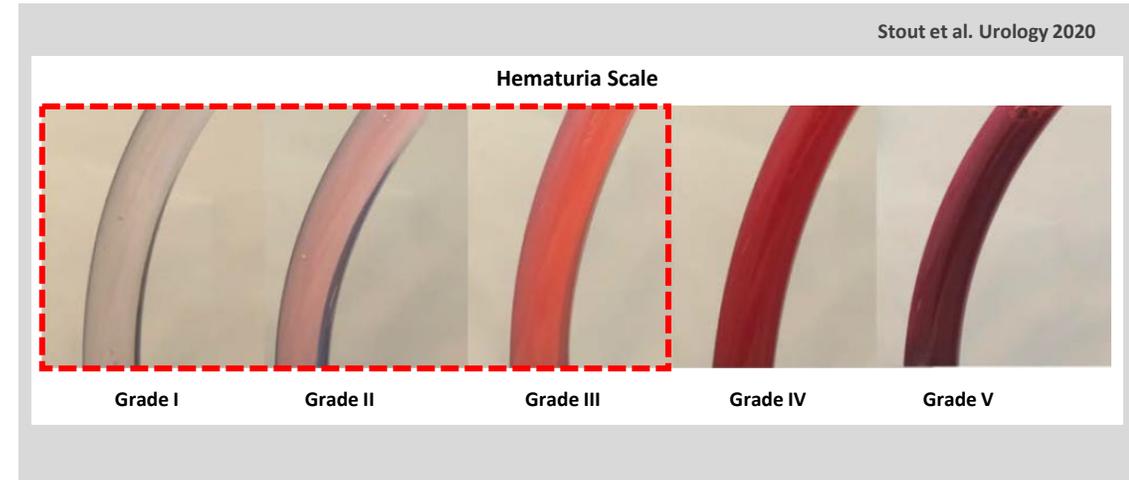
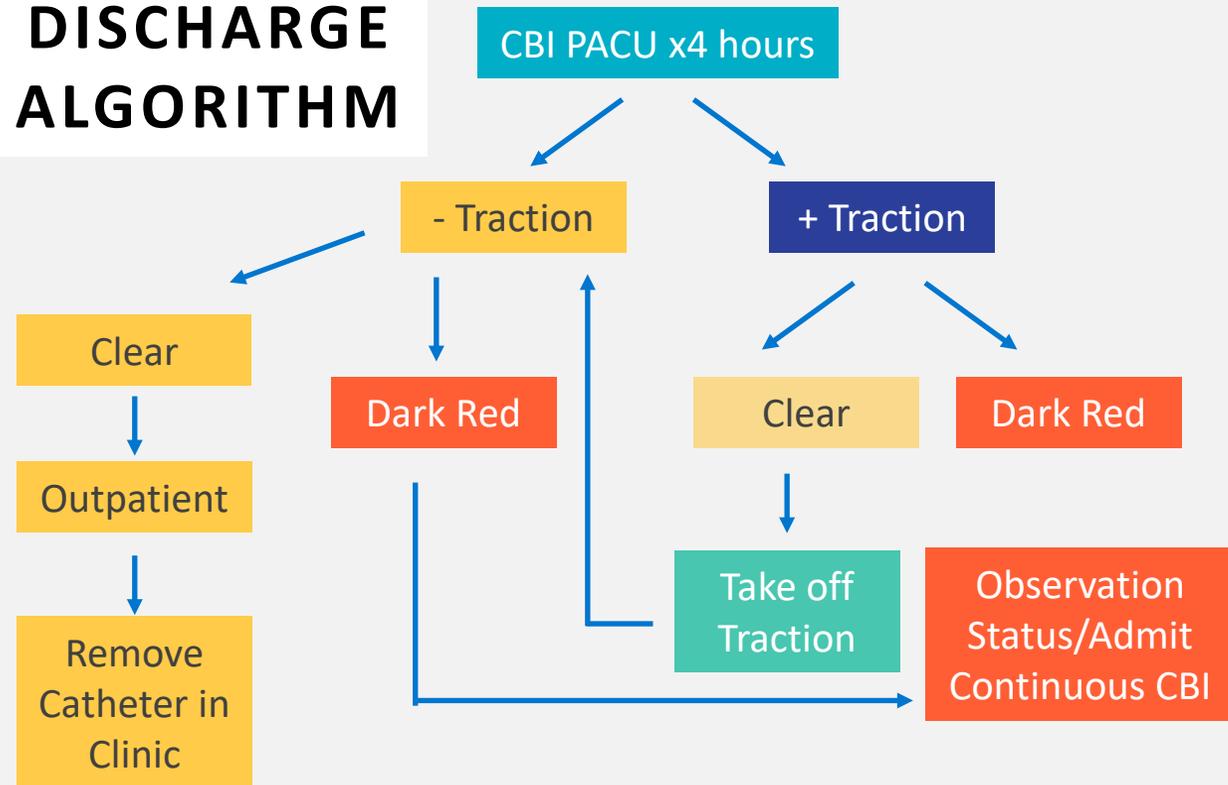
Elterman D. et al. Meta-analysis with individual data of functional outcomes following Aquablation for lower urinary tract symptoms due to BPH in various prostate anatomies BMJ Surg Interv Health Technologies 2021

# Same Day Discharge

# Same day discharge with Aquablation therapy

- 1 Well-established hemostasis method resulting in **0.8% transfusion rate** in over 2,000 patients
- 2 Confidence in hemostasis and need for COVID outpatient resulted in studying **same day discharge**
- 3 Consecutive patients from Dec 1, 2020 to April 15, 2021 were offered Aquablation on outpatient basis

## DISCHARGE ALGORITHM



Helfand. (2021). Aquablation Therapy Day Case Feasibility [White Paper] PROCEPT BioRobotics

# Same day discharge with Aquablation therapy

## RESULTS

- 87% successfully underwent day-case Aquablation therapy
- 0% readmissions and transfusions
- 0% of patients required home irrigation

	Day-Case (n=20)	23-Hour Observation (n=3)
Average Age (SD)	64.8 (4.8)	65.3 (6.65)
Average TRUS Volume (SD)	<b>99.87 (50.69)</b>	<b>180.67 (158.35)</b>
Average Intraprostatic Protrusion Length mm (SD)	5.07 (9.40)	8.41 (11.17)
Average AUA-SI Score (SD)	18.5 (9.2)	17.8 (6.4)
Average QoL Score (SD)	3.7 (0.9)	3.0 (1.7)
Average PSA ng/ml (SD)	5.22 (6.51)	8.85 (3.78)
Average Resection Time (SD)	8.22 (1.33)	14.50 (5.62)

## CONCLUSION

While there is a trend for 23-hour hospital observation for men with very large prostates, **Aquablation therapy is feasible for most men as a day-case procedure** when they meet the noted hematuria criteria and medication considerations.

### **IMPORTANT SAFETY INFORMATION**

All surgical treatments have inherent and associated side effects. Individual's outcomes may depend on a number of factors, including but not limited to patient characteristics, disease characteristics and/or surgeon experience. 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. Further, there may be other risks as in other urological surgery, such as anesthesia risk or the risk of infection, including the potential transmission of blood borne pathogens. For more information about potential side effects and risks associated with Aquablation therapy for Benign Prostatic Hyperplasia (BPH) treatment, speak with your urologist or surgeon. No claim is made that the AQUABEAM<sup>®</sup> Robotic System will cure any medical condition, or entirely eliminate the diseased entity. Repeated treatment or alternative therapies may sometimes be required.

As with any surgical urologic procedure, potential perioperative risks of the Aquablation procedure include but are not limited to the following, some of which may lead to serious outcomes and may require intervention: Anesthesia risk, Bladder or prostate capsule perforation, Bladder neck contracture, Bleeding or blood in the urine, Bruising, Penile or pelvic pain, Irritative symptoms, which may include dysuria, urgency or frequency, Infection, Transurethral resection (TUR) syndrome, Electric shock/burn, Urethral damage causing false passage or stricture, Rectal incontinence / perforation, Sexual dysfunction, including ejaculatory and erectile dysfunction, Incontinence or overactive bladder, Embolism, Urinary Retention  
Rx Only

**Indications for Use:** Please review the Instructions for Use and any accompanying documentation for a complete listing of indications, contraindications, warnings, precautions, and potential adverse event.

### **Medical Information**

All of the content provided by PROCEPT BioRobotics is intended for informational purposes only, DOES NOT CONSTITUTE THE PROVISION OF MEDICAL ADVICE, and is not intended to be a substitute for independent professional medical judgment, advice, diagnosis, or treatment.



900 Island Drive, Suite 210 / Redwood City, CA 94065 / [PROCEPT-BioRobotics.com](https://www.procept-biorobotics.com)