

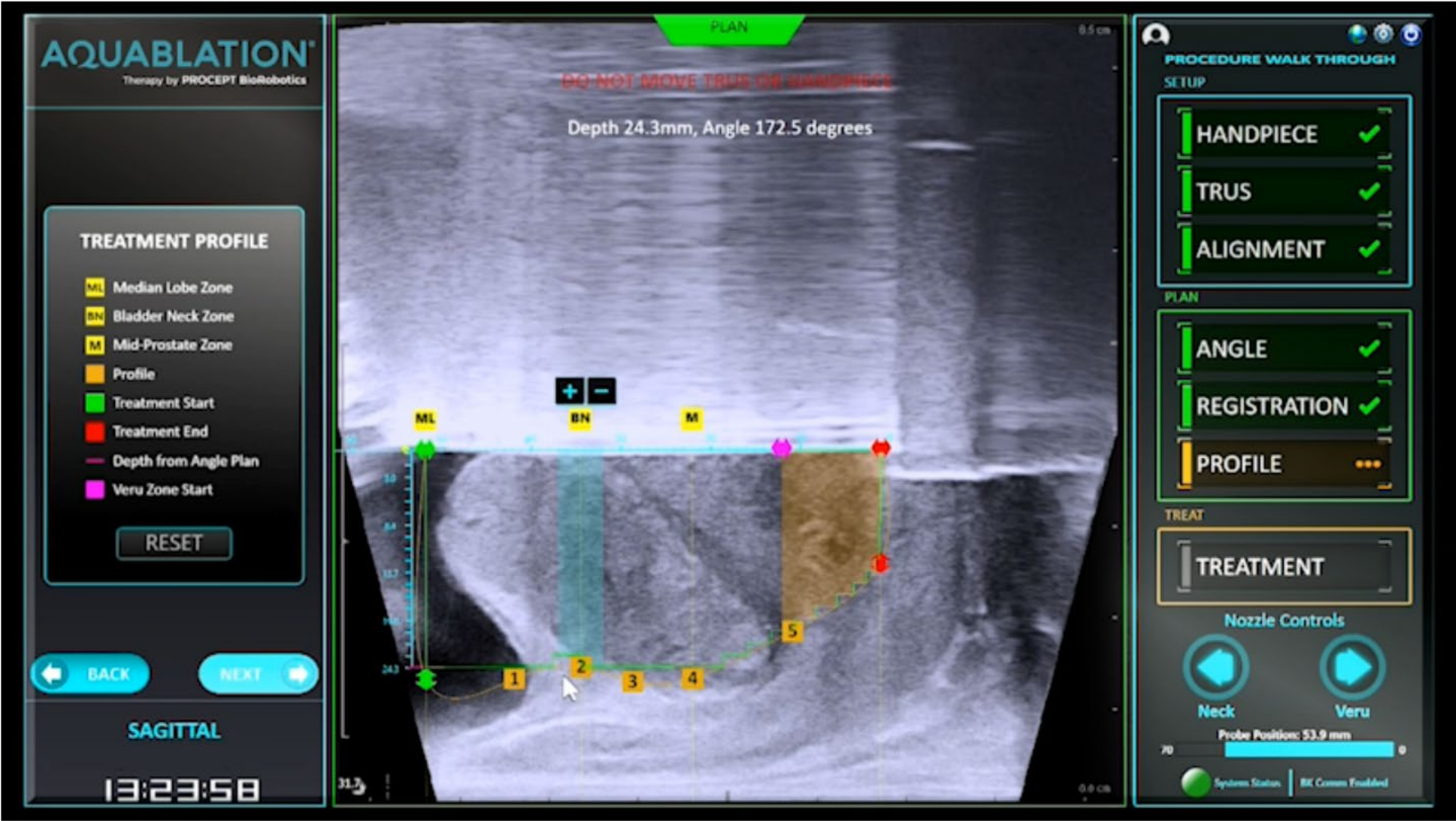
Aquablation Therapy Surgeon Training Course

Part 1

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

Aquablation Technique

Aquablation Procedure Overview



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® 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

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No restriction of

- Prostate volume
- Prostate anatomy

Science & Technology Overview

AQUABLATION THERAPY

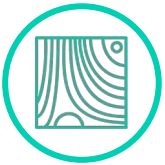
ONLY IMAGE-GUIDED, HEAT-FREE, AUTOMATED ROBOTIC THERAPY FOR BPH

AQUABLATION®
Therapy by PROCEPT BioRobotics



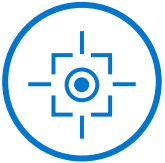
REAL-TIME IMAGE GUIDANCE

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

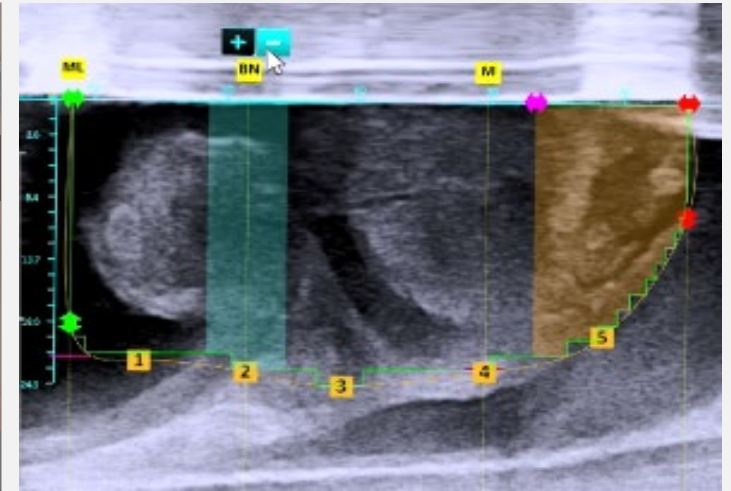
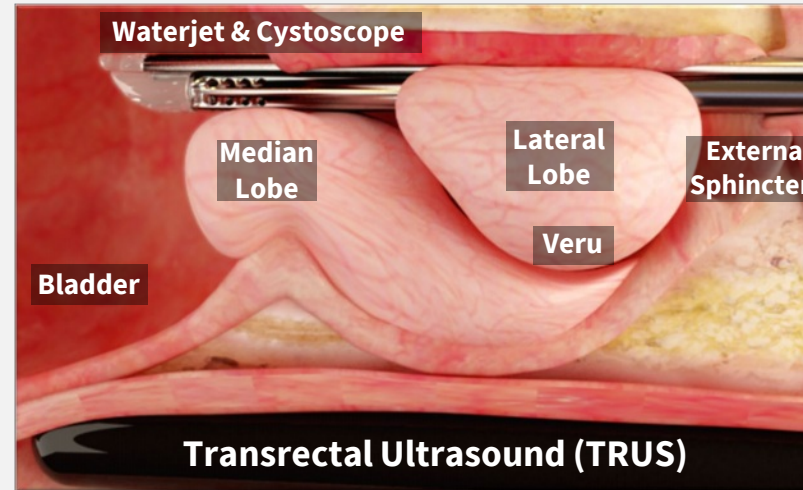


AQUABEAM®
— ROBOTIC SYSTEM —





CYSTOSCOPY

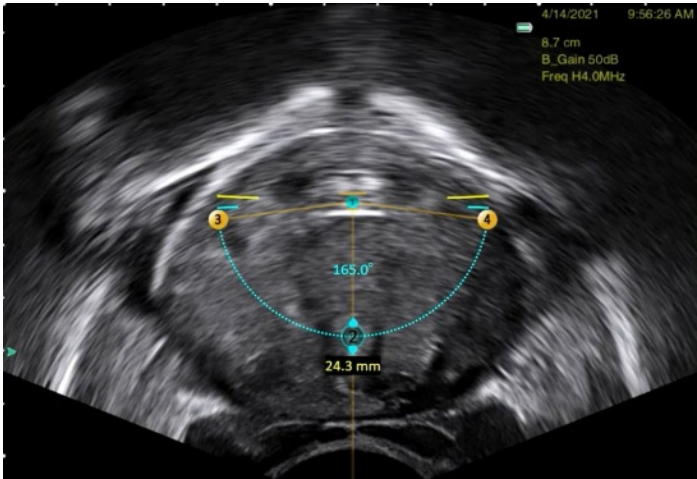


TRANSRECTAL ULTRASOUND

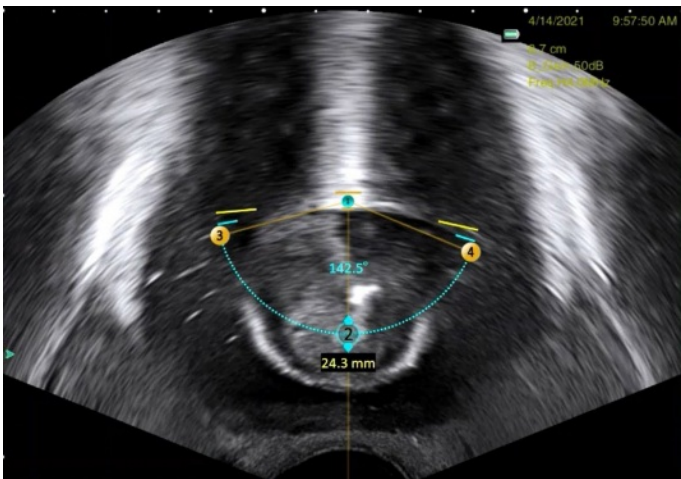
MULTI-DIMENSIONAL IMAGING OF THE ENTIRE PROSTATE



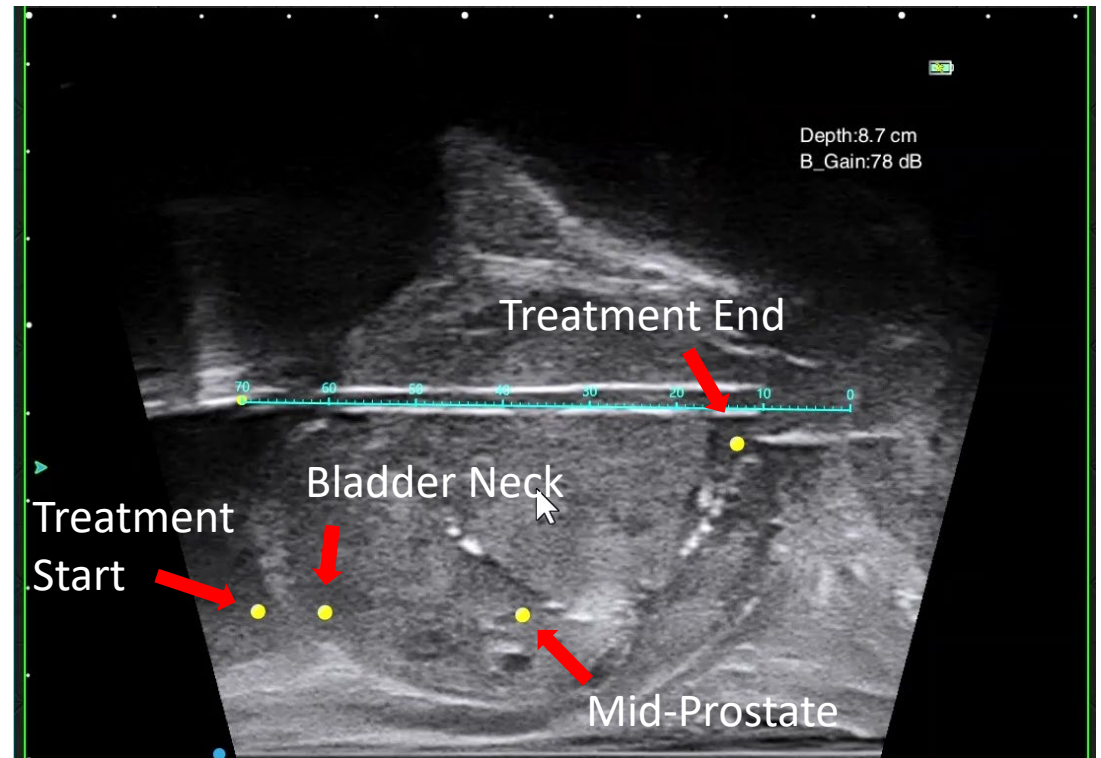
Transverse View/Mid-Prostate Angle Planning



Transverse View/Median Lobe Angle Planning



Sagittal View/Contour Planning



AQUABLATION THERAPY

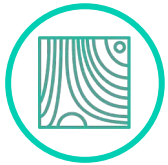
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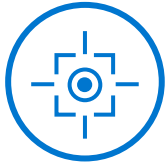
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AQUABEAM®
— ROBOTIC SYSTEM —

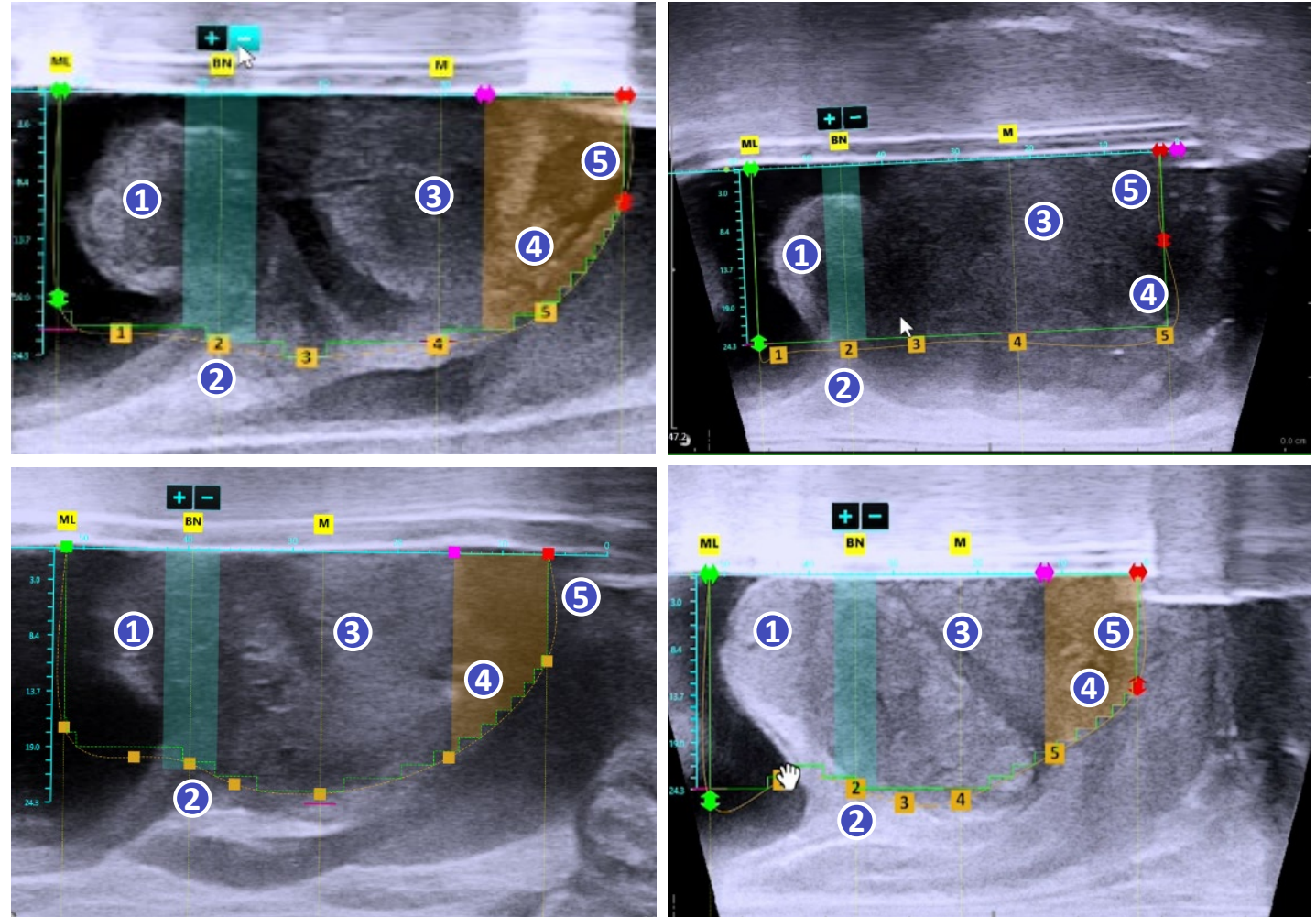


FOUR UNIQUE TREATMENT PLANS

IDENTIFY CRITICAL ANATOMY:

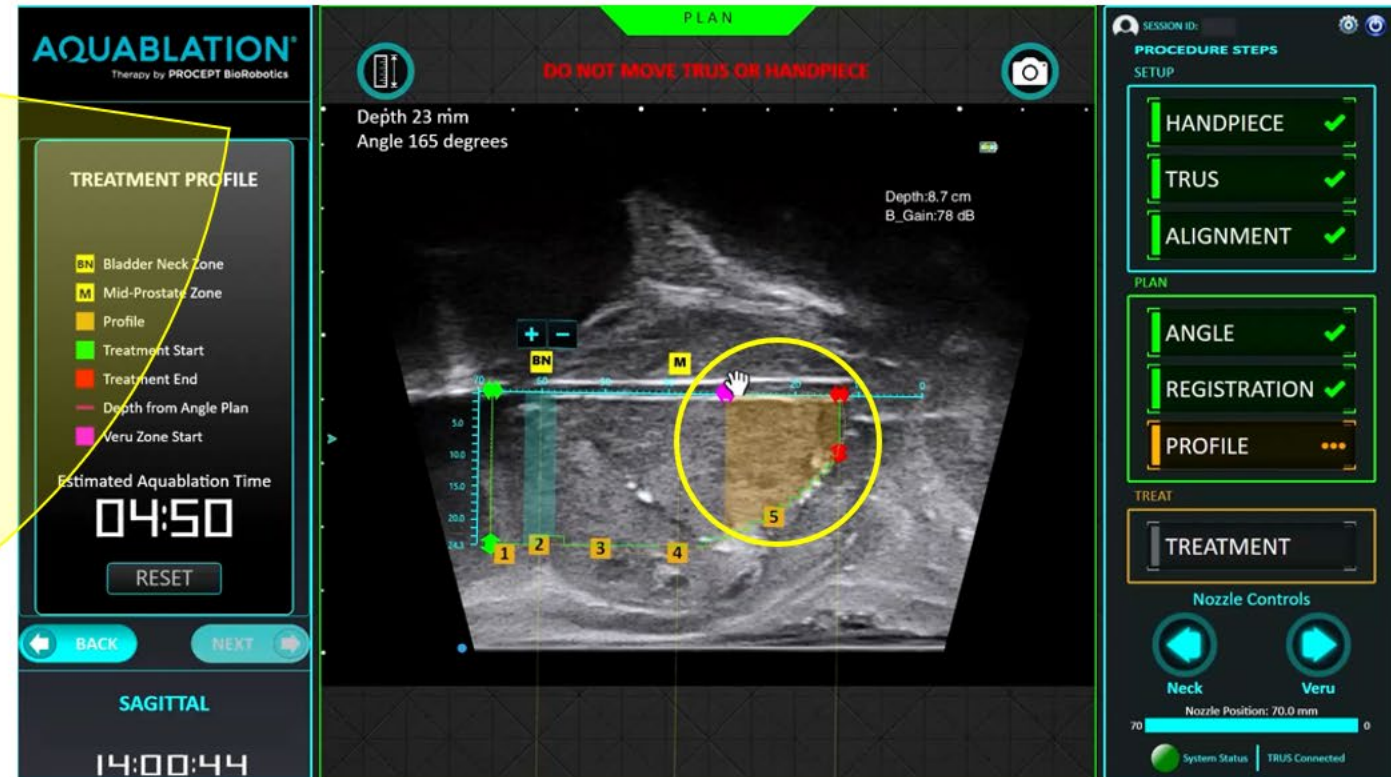
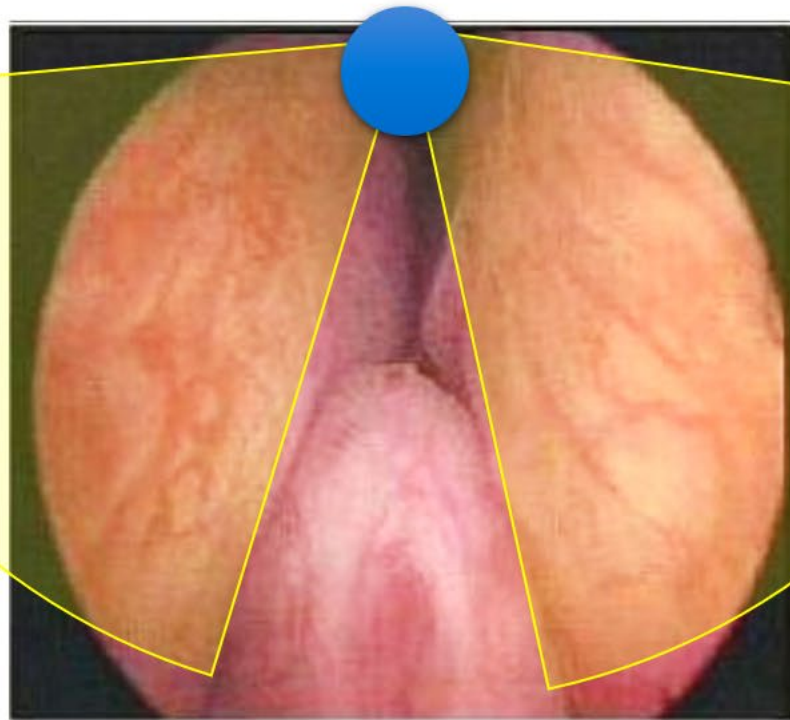
- 1 MEDIAN LOBE
- 2 BLADDER NECK
- 3 LATERAL LOBE
- 4 VERUMONTANUM
- 5 EXTERNAL SPHINCTER

CREATE CUSTOMIZED TREATMENT PLAN



Veru Protection Zone

Veru Protection Zone



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

AQUABLATION THERAPY

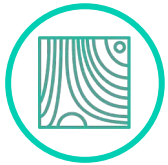
ONLY IMAGE-GUIDED, HEAT-FREE, AUTOMATED ROBOTIC THERAPY FOR BPH

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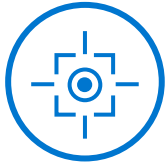
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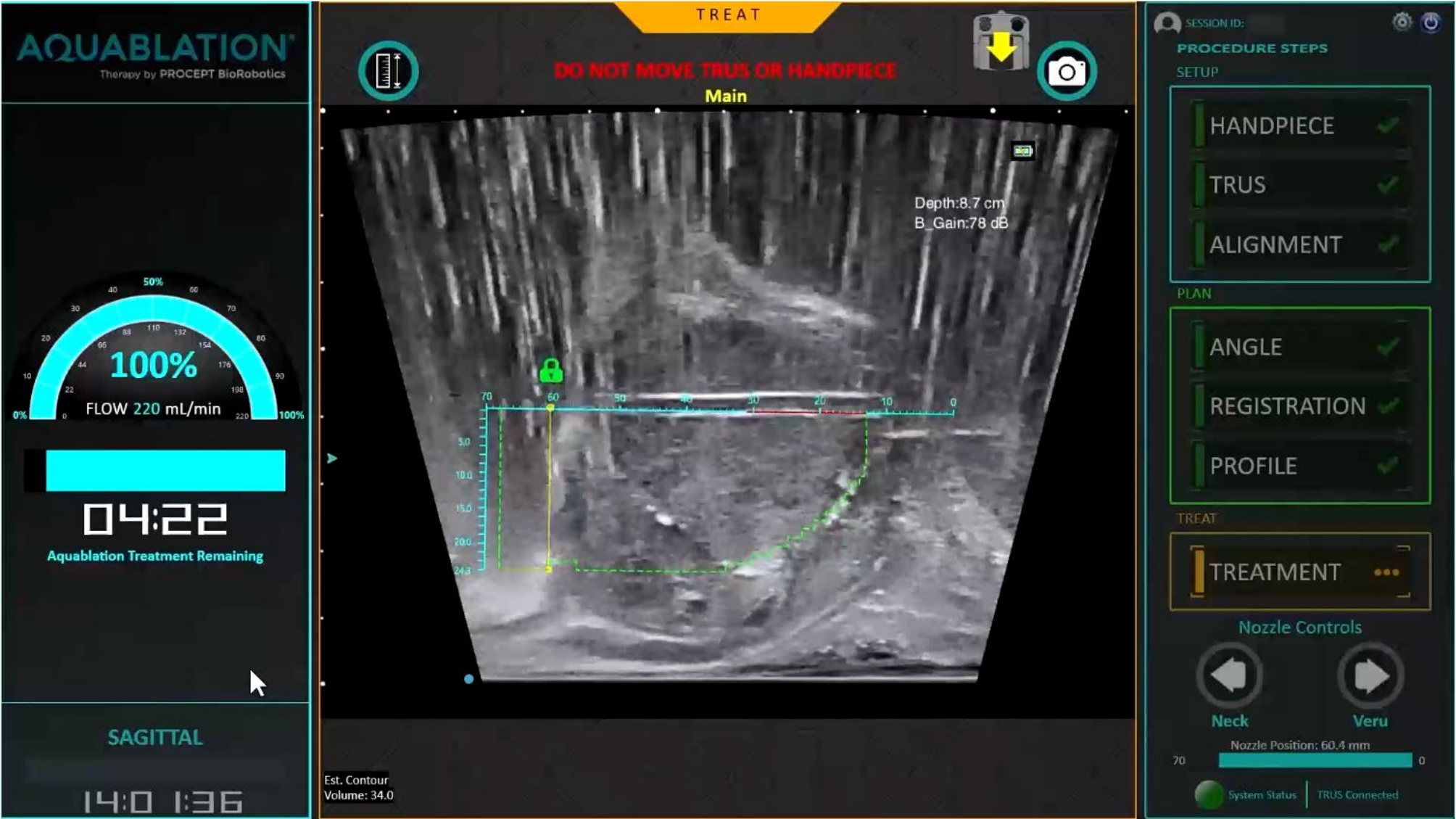
Utilizing the unique power of a pulsating waterjet near the speed of sound, Aquablation therapy removes prostatic tissue with a heat-free waterjet



AQUABEAM®
— ROBOTIC SYSTEM —

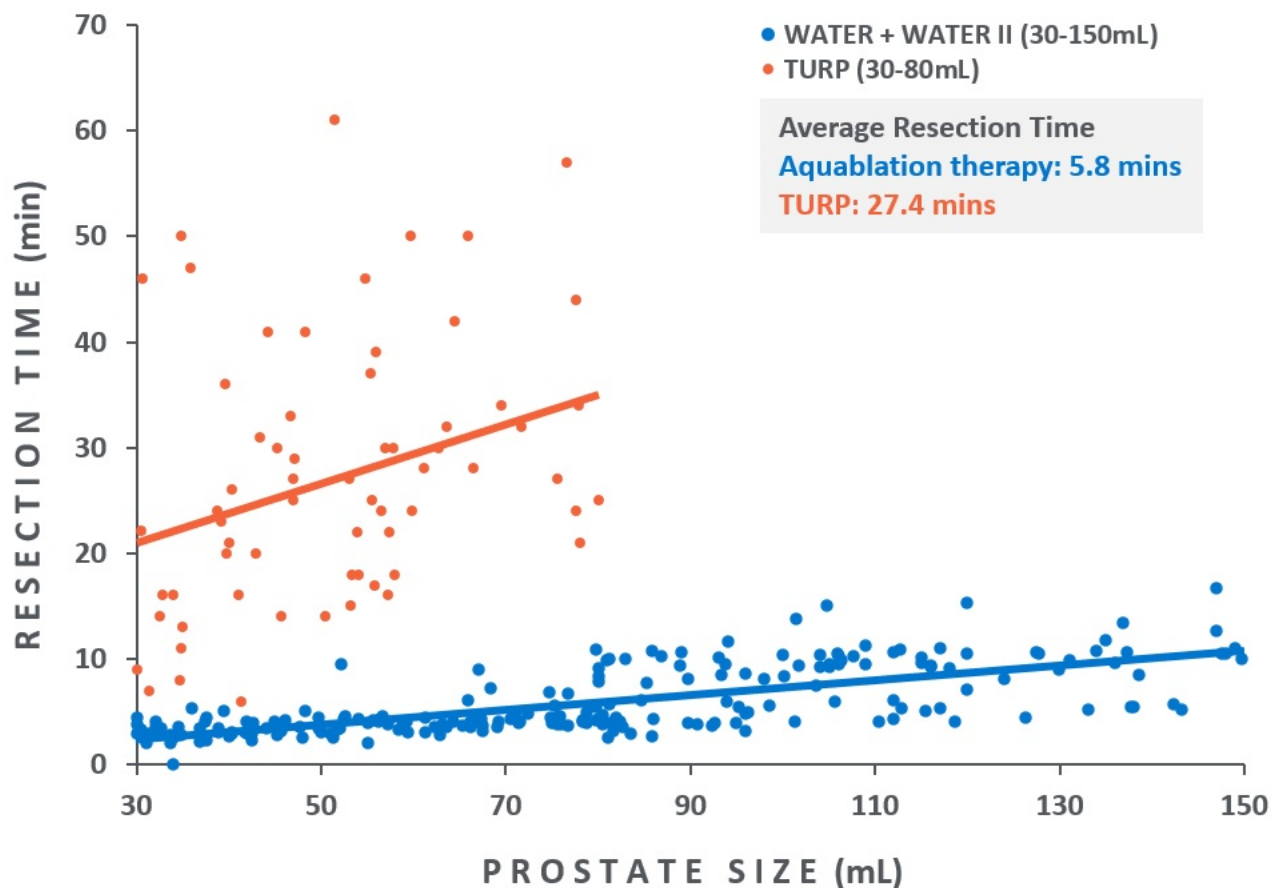


AUTOMATED ROBOTIC EXECUTION



AUTOMATED ROBOTIC EXECUTION

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

AQUABLATION®
Therapy by PROCEPT BioRobotics



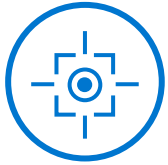
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AQUABEAM®
— ROBOTIC SYSTEM —



Waterjets in Air

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

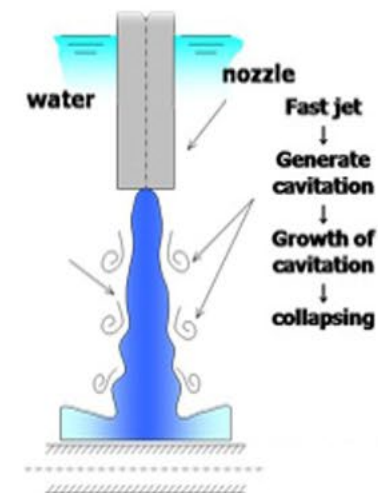


Submerged Waterjets

Non-cavitating

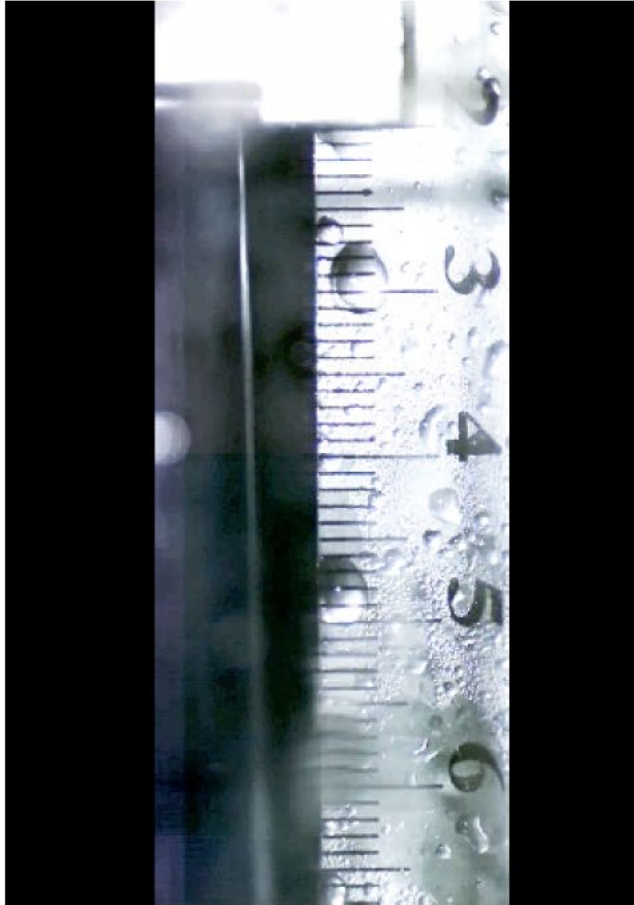
Cavitating

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

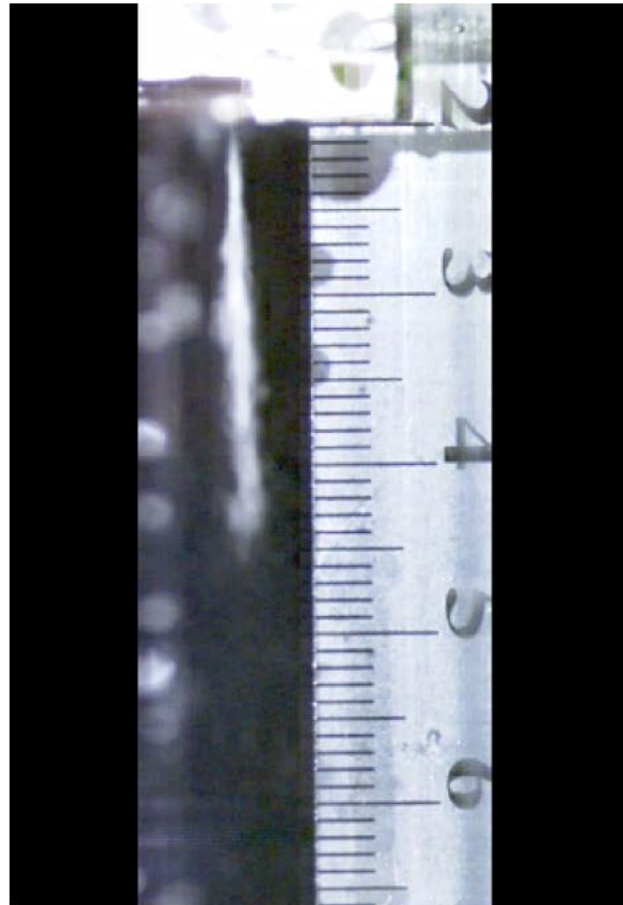


Waterjet Types

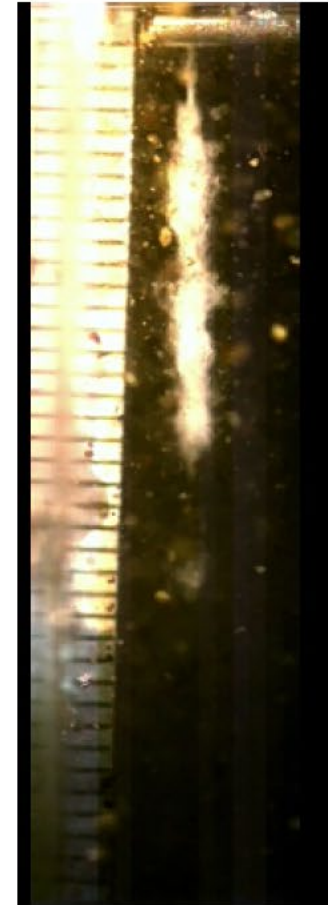
AQUABEAM Jet in Air

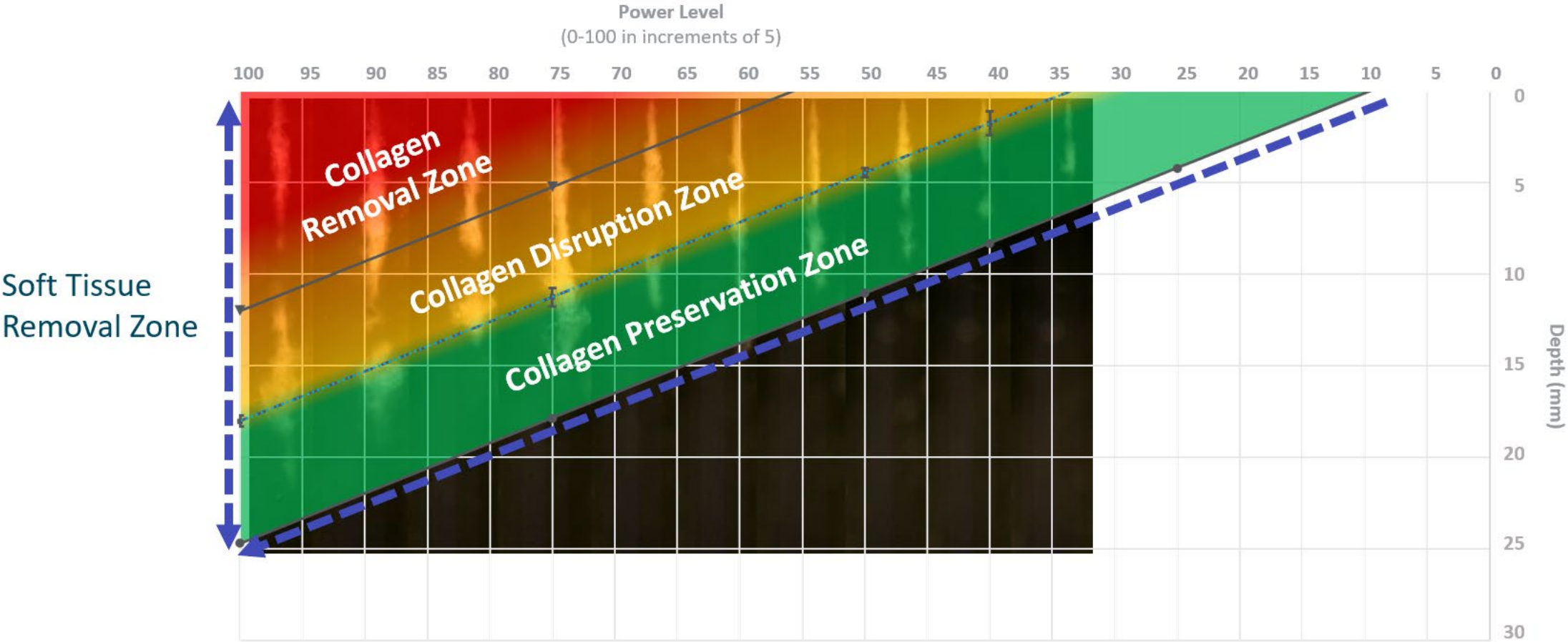


AQUABEAM Jet Submerged

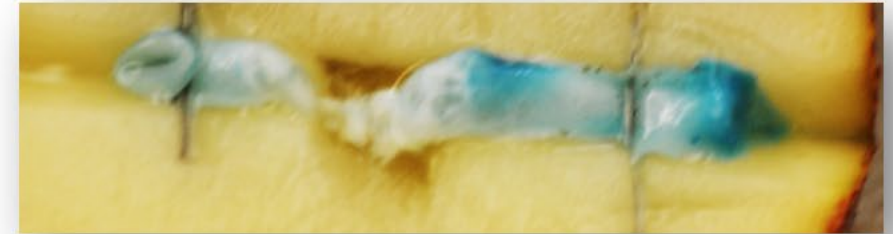
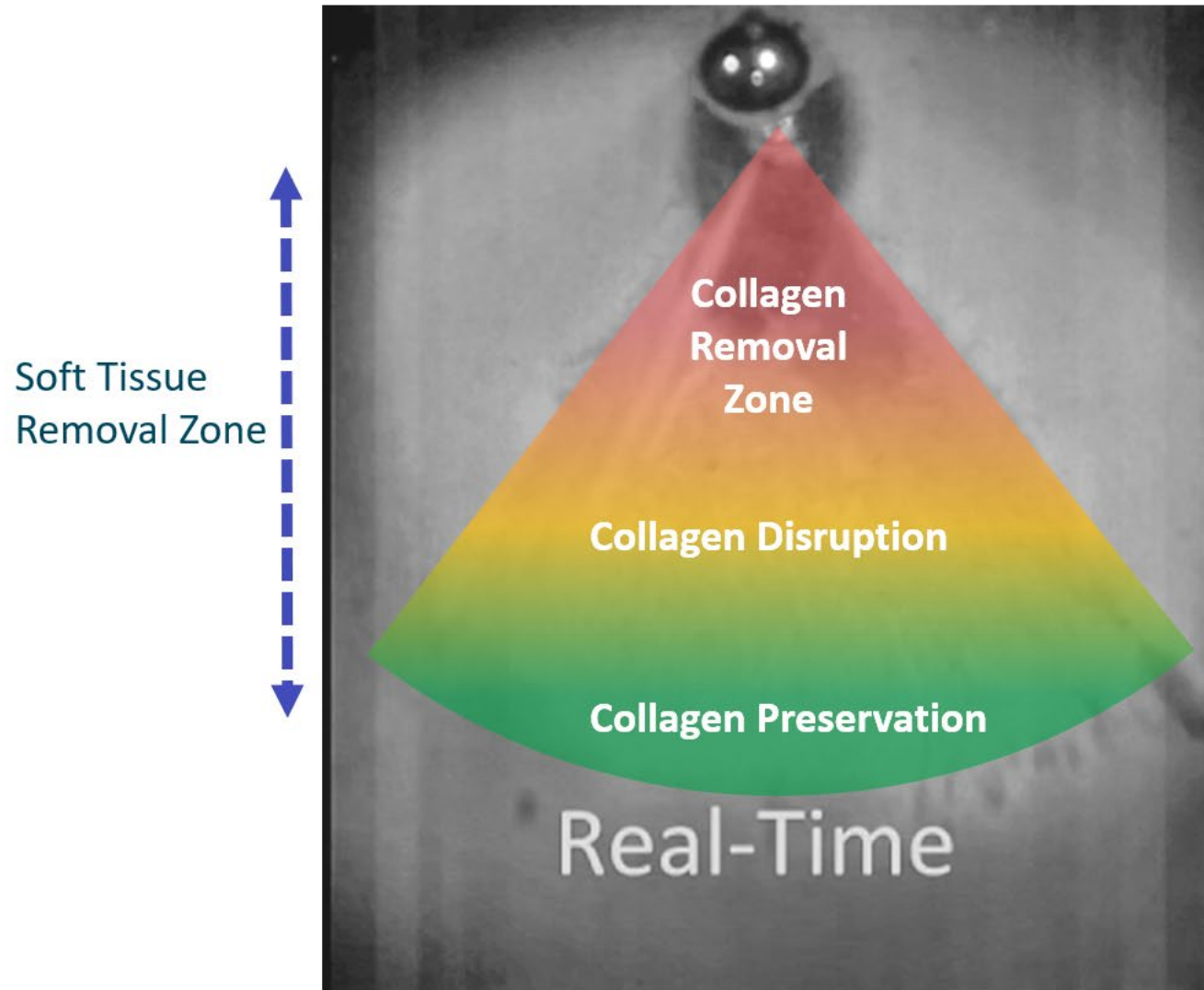


Targeted Resection



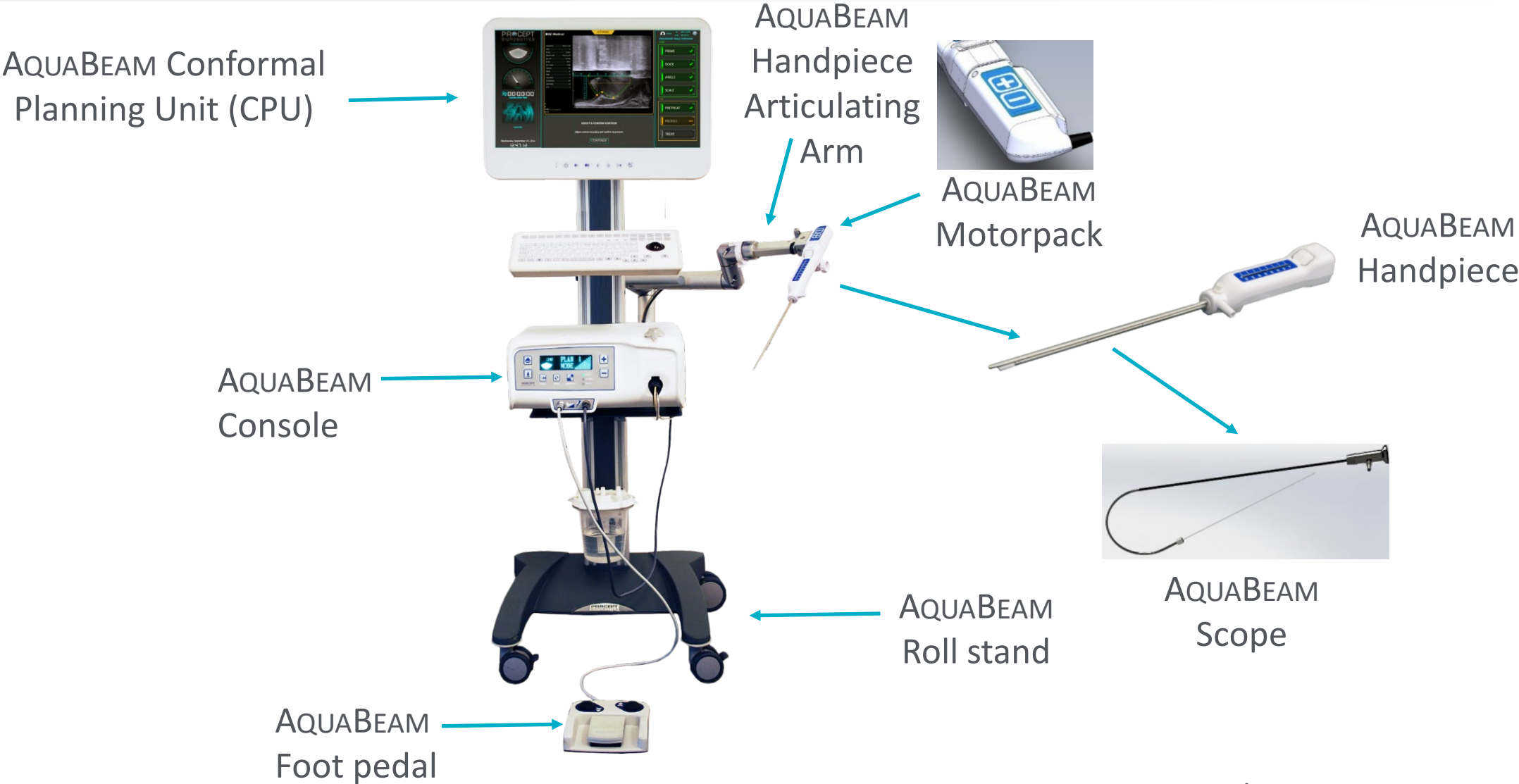


Tissue Selective Zones



AQUABEAM Robotic System & Components

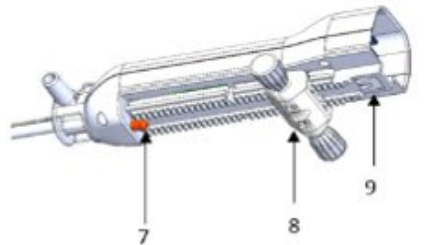
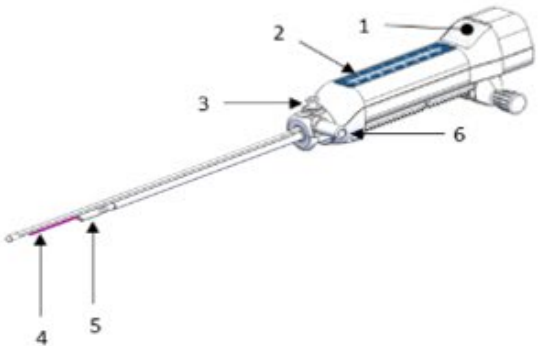
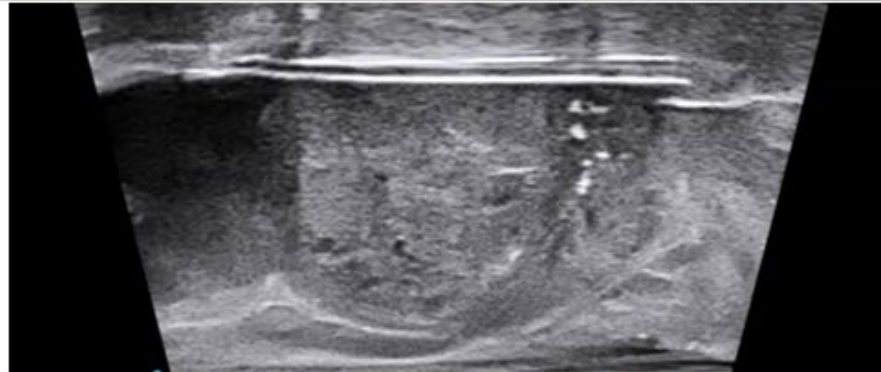
The AQUABEAM Robotic System Components



AQUABEAM TRUS Articulating Arm not pictured

Handpiece

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

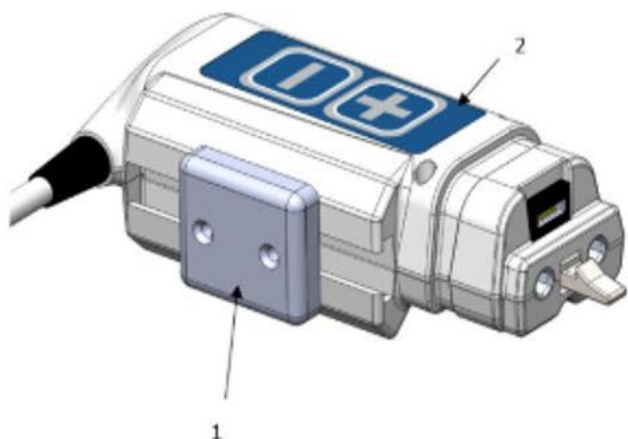


- | | |
|---|------------------------------|
| 1 | Handpiece Release Button |
| 2 | Handpiece Position Indicator |
| 3 | Irrigation Luer |
| 4 | High Pressure Probe |
| 5 | Scope Tube tip |

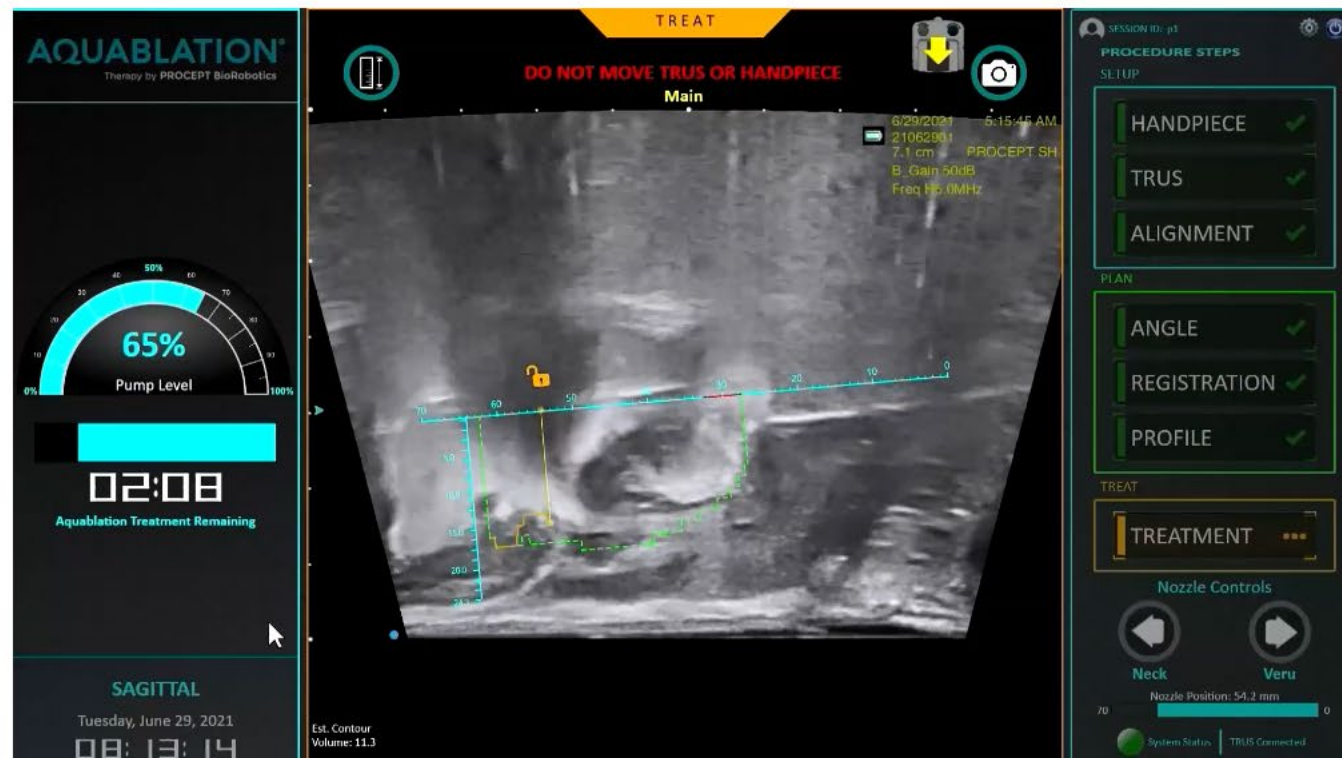
- | | |
|---|---------------------|
| 6 | Aspiration Port |
| 7 | Scope Port |
| 8 | Scope Carriage |
| 9 | Scope Carriage Stop |

Motorpack

- Magnetic plate
- Pump power buttons

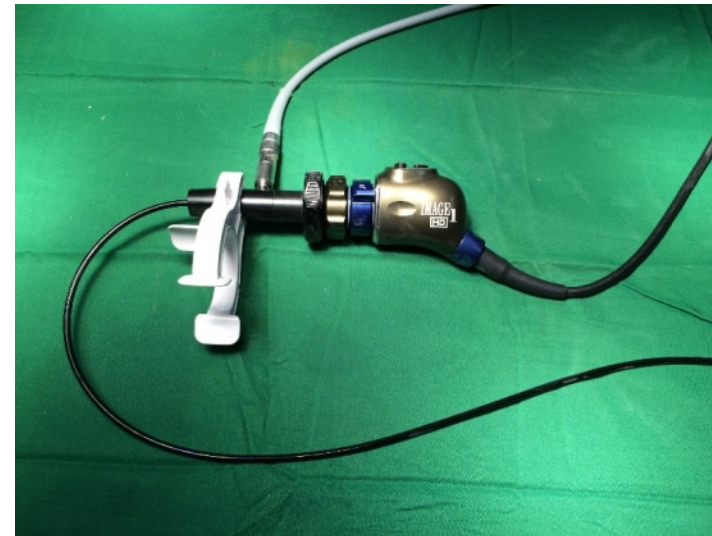
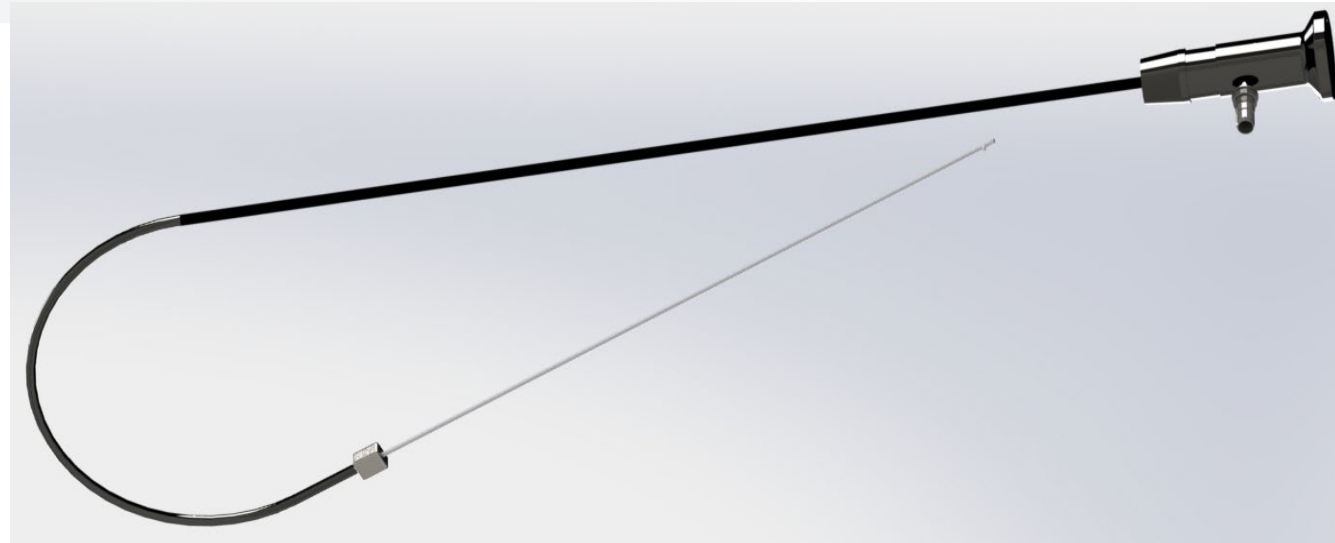


1. Motorpack Magnetic Strike Plate for Handpiece Articulating Arm
2. Pump Power Control Buttons (+/-)
 - - decrease pump power (active during Aquablation)
 - + increase pump power (active during Aquablation)



AQUABEAM Scope Assembly

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



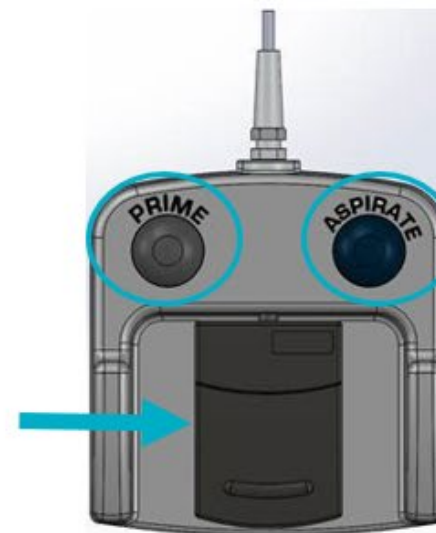
Handpiece Articulating Arm

- Rotational adjuster
- Arm trigger



Foot pedal

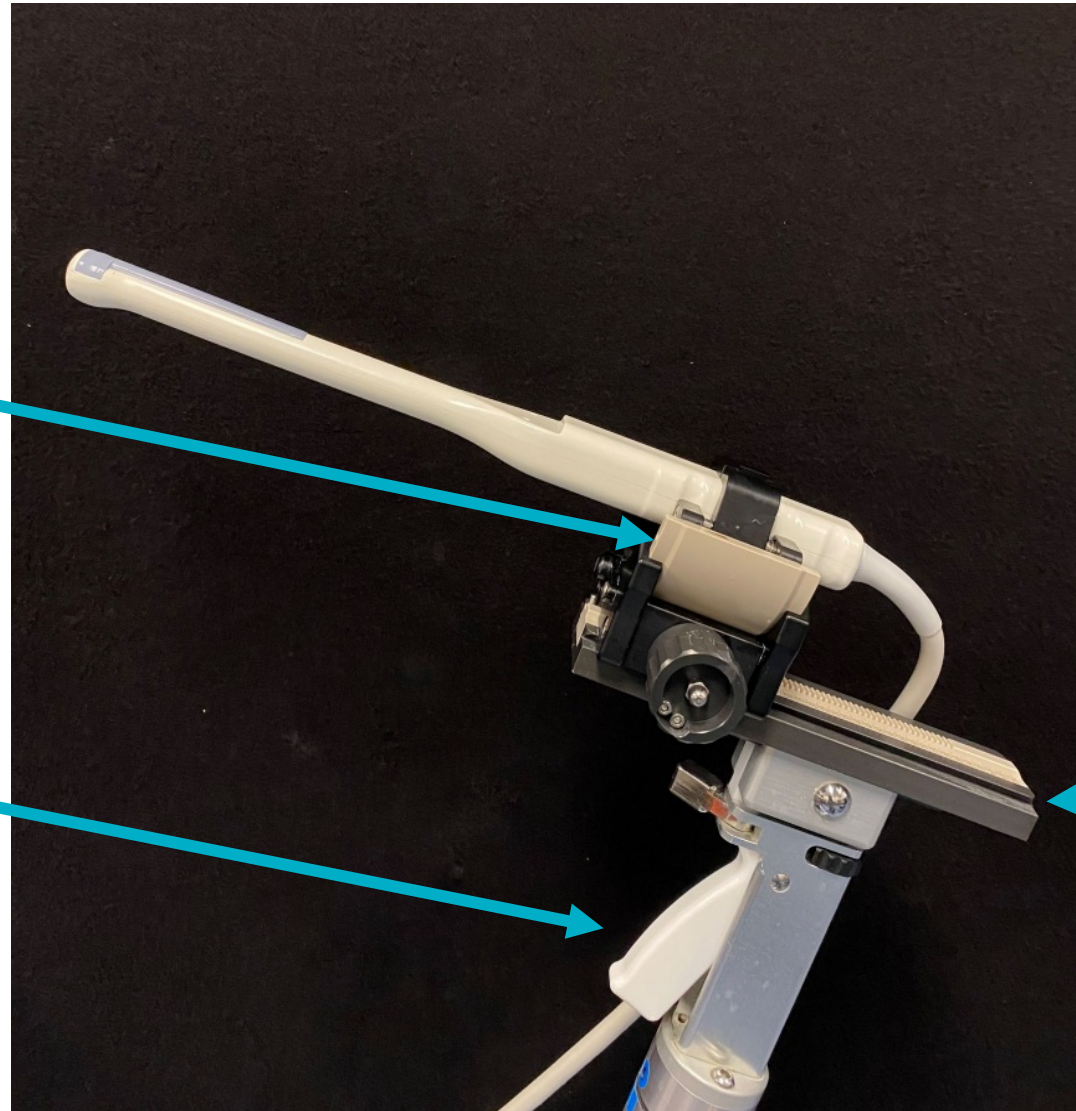
- Aspiration
- Prime
- Aquablate pedal



TRUS
Cradle/Receptacle

TRUS
Articulating
Arm

TRUS Stepper



Case Overview

AQUABLATION®
Therapy by PROCEPT BioRobotics

- 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

SAGITTAL

11:57:57

PLAN

DO NOT MOVE TRUS OR HANDPIECE

20072701

7.9 cm

PROCEPT SH

B_Gain 74dB

Freq H5.0MHz

TRUS

ALIGNMENT

PLAN

ANGLE

REGISTRATION

PROFILE

TREAT

TREATMENT

Nozzle Controls

Neck

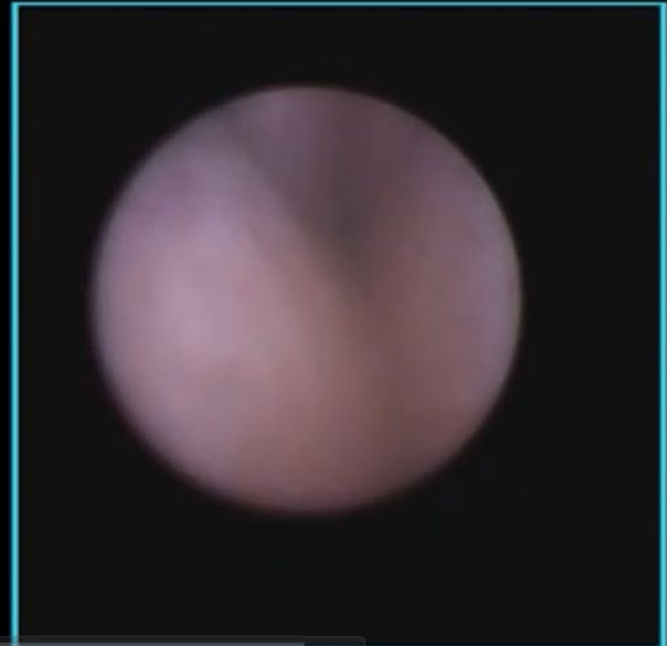
Veru

Nozzle Position: 70.0 mm

70



System Status TRUS Connected



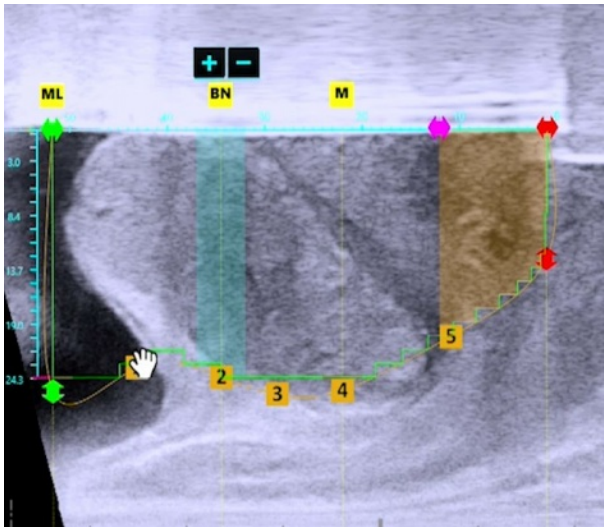
Clot Evacuation and Focal Bladder Neck Cautery



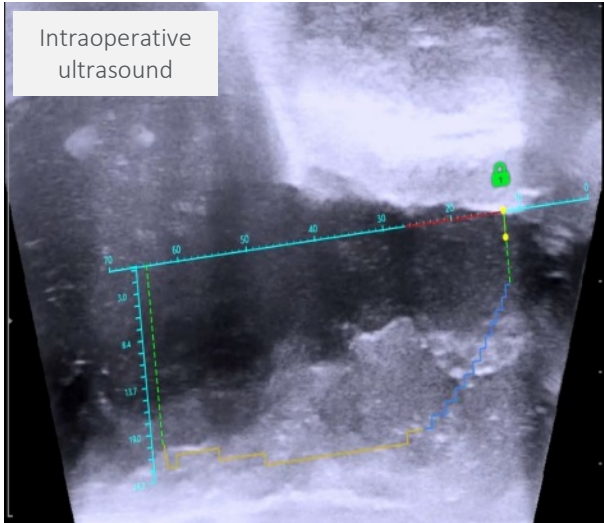
AQUABLATION THERAPY RESULTS

BEFORE

Obstructed Prostatic Urethra



3 months
post-op

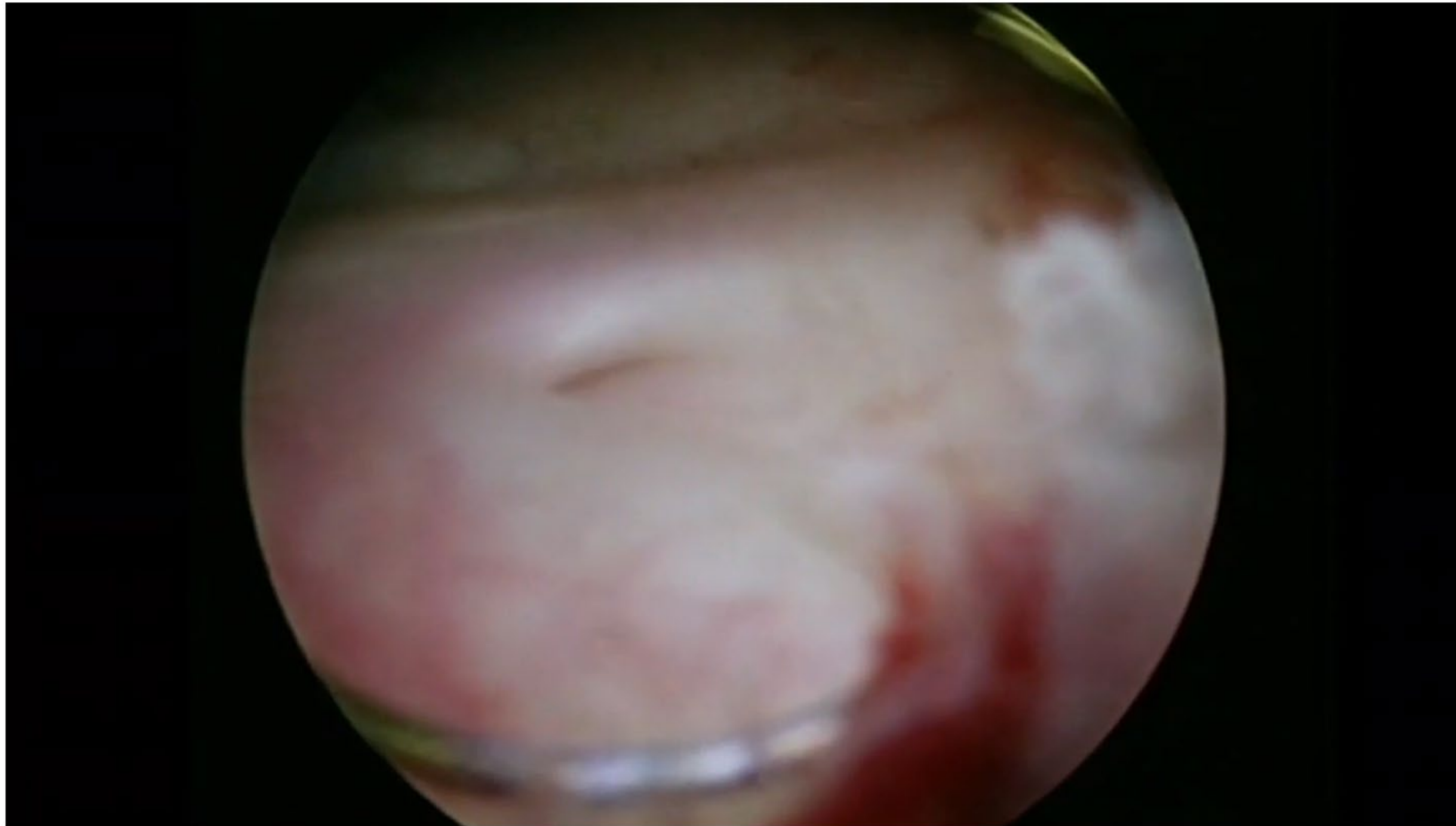


Intraoperative
ultrasound

AFTER

Open Prostatic Urethra

Sample results shown here

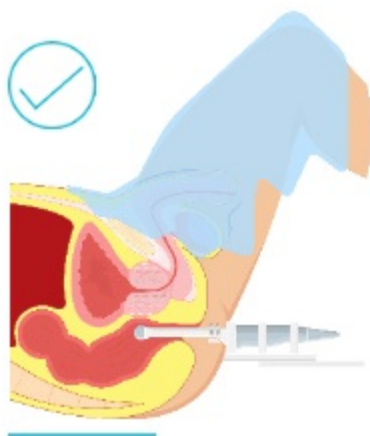


- 1) The transrectal ultrasound probe placement slightly elevates the posterior aspect of the bladder, tenting up the trigone and the UO's fall off to an atypical lateral positioning, further away from waterjet.
- 2) Careful consideration is given when planning the depth of resection along the posterior 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.

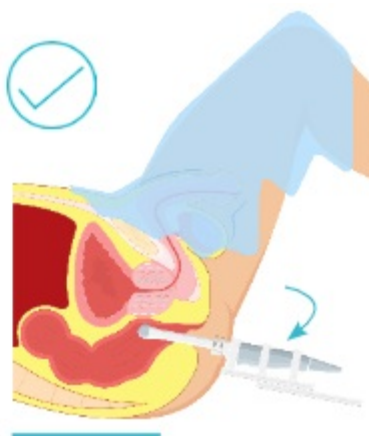
Best Practices for Transrectal Ultrasound

STEP	RECOMMENDATION	REASON
PATIENT PREPARATION	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
PRE-INSERTION	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
INSERTION	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
PROCEDURE	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
POST-OPERATIVE	Inspect the TRUS probe and anus for blood	Indicates potential injury

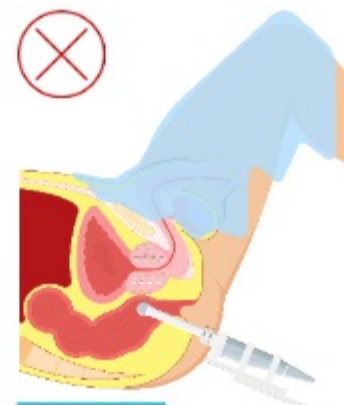
This material has been developed with, reviewed by, and approved by independent surgeons who are not PROCEPT BioRobotics employees. These surgeons received compensation from PROCEPT BioRobotics for consultation services.



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.



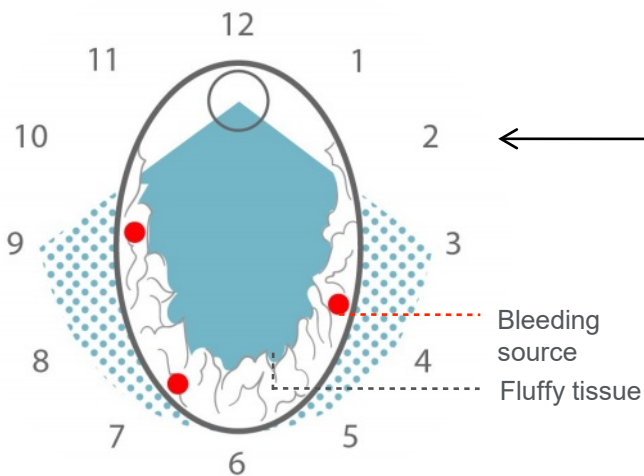
3. Do not angle the TRUS probe steeply. If angling is required to create space for other instruments, consider removing the TRUS probe.

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Focal Bladder Neck Caution

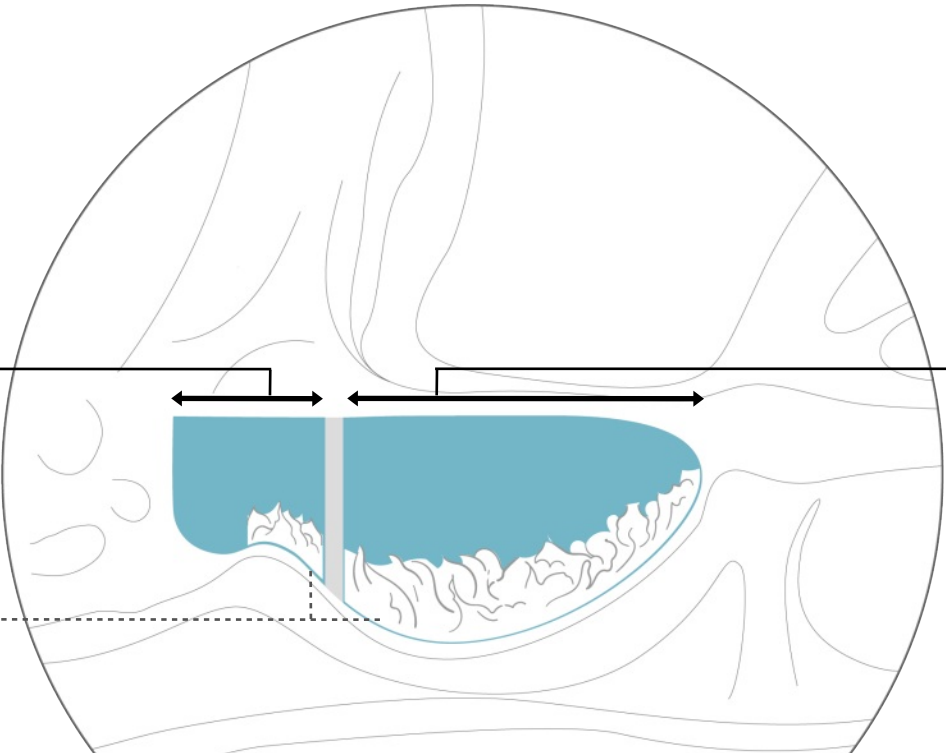
STEP 1

Irrigate bladder



STEP 2

Focus at the Bladder Outlet
Systematically work
around the bladder outlet



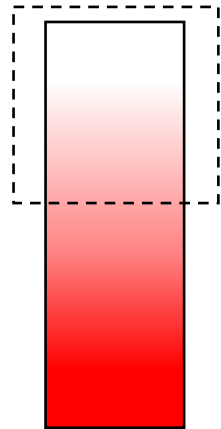
STEP 3

Inspect

Turn off irrigation
and inspect for bleeders
under normal blood pressure

STEP 4

Effluent Color Goal



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

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

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Alexander Kugler, MD,⁴ Vincent Misrai, MD,⁵ Angelo Porreca, MD,⁶
Dominik Abt, MD,⁷ Kevin C. Zorn, MD,⁸ Naeem Bhojani, MD,⁸
Lewis Kritek, MD,⁹ Rahul Mehan, MD,¹⁰ Michael McDonald, MD,¹¹
Steven A. Kaplan, MD¹²

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

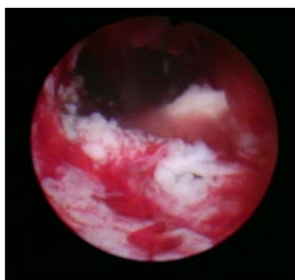
Conclusions: In prostates sizes averaging 87cc (range 20 cc-363 cc), Aquablation procedures performed with focal bladder neck cauterization that required a transfusion postoperatively occurred in a remarkably low number of cases.

Focal bladder neck cautery

associated with low rates of post operative bleeding

FOCAL BLADDER NECK CAUTERY

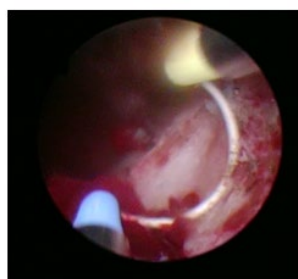
- Clot Evacuation
- Removal of “fluffy tissue”
- Cauterize around bladder neck



FLUFFY TISSUE



USE LOOP TO REMOVE
FLUFFY TISSUE

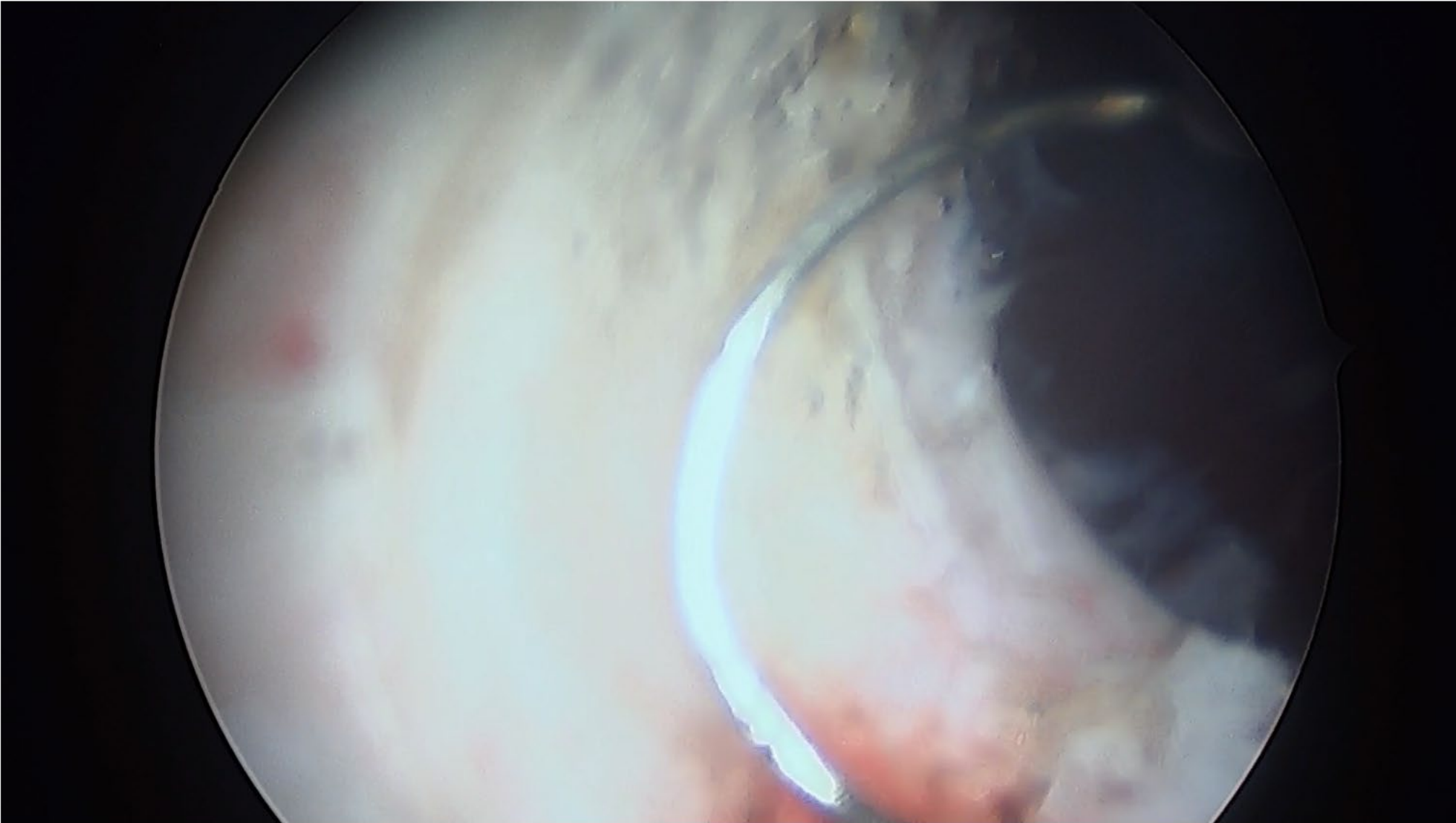


FOCAL CAUTERY
AT BLEEDERS

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



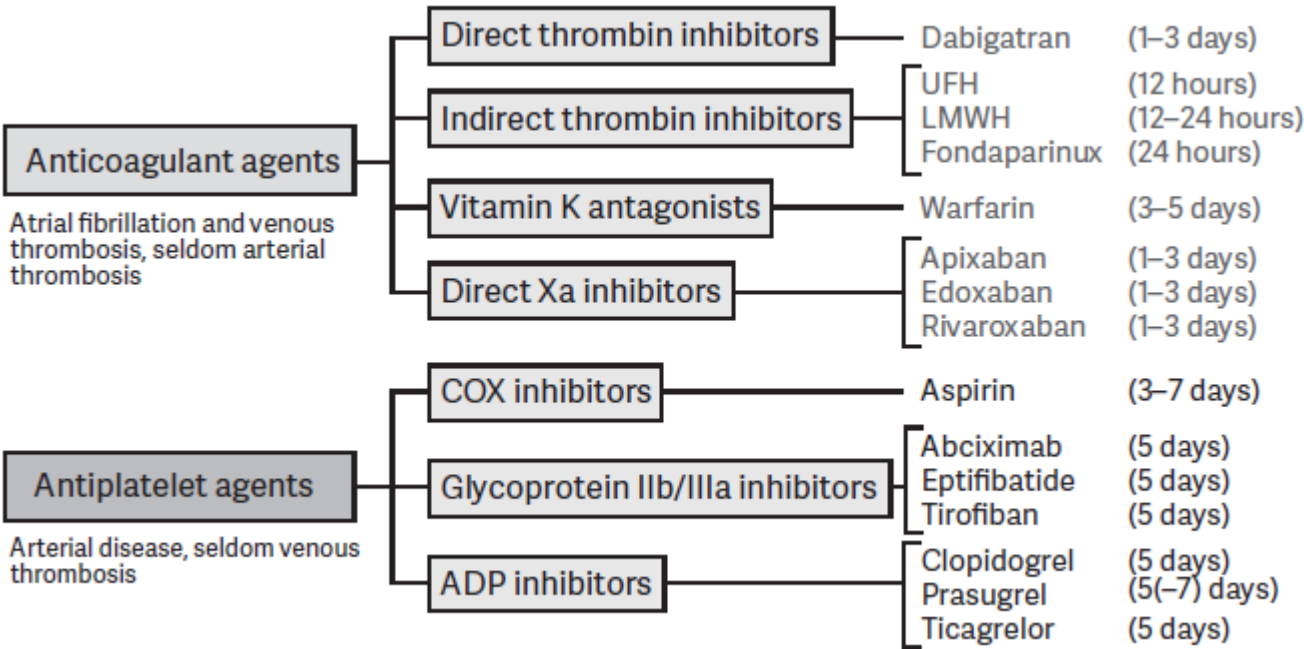
Anticoagulant / Antiplatelet Contraindications for Aquablation

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

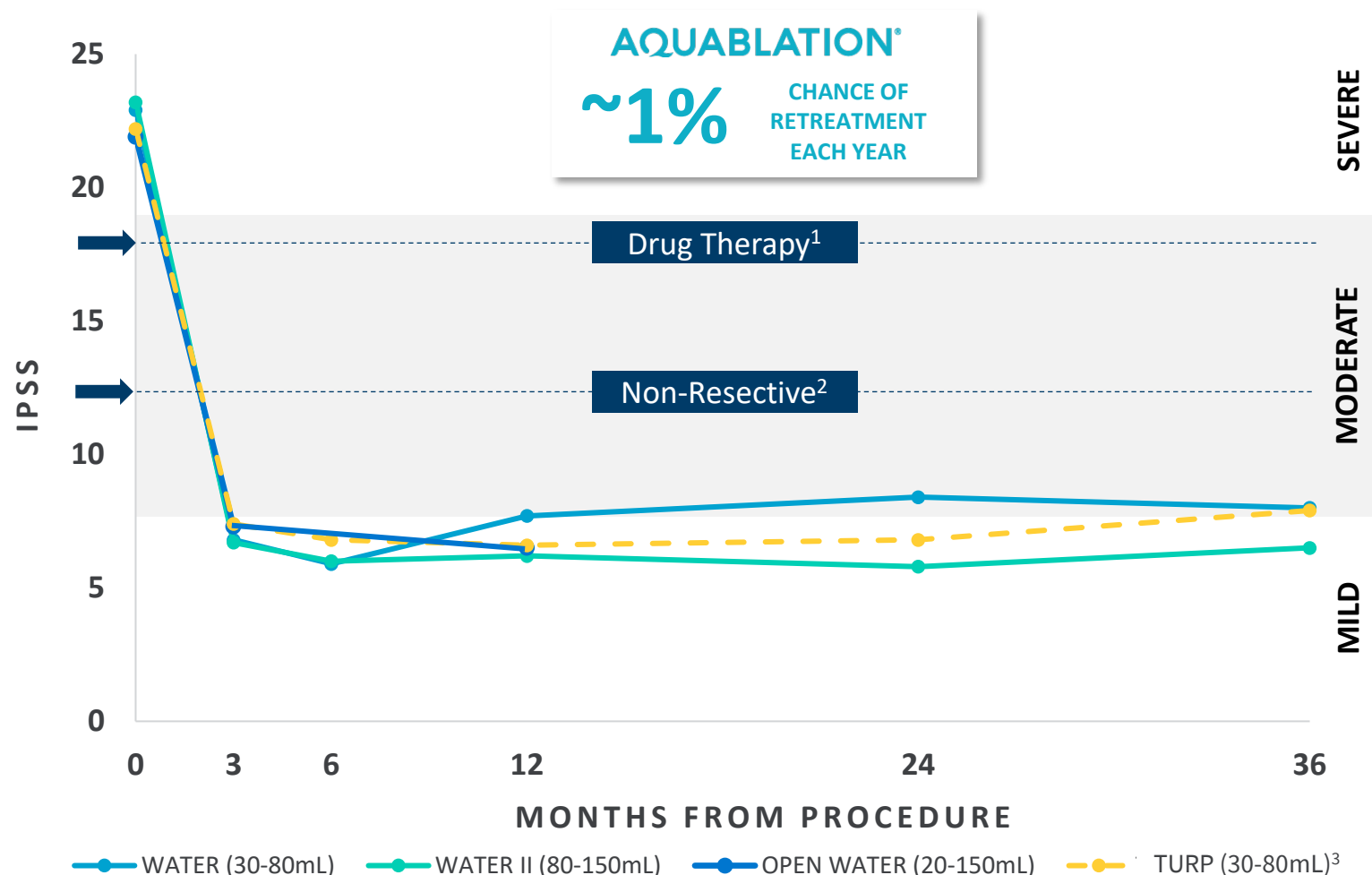
Bach T. et al. First Multi-Center All-Comers Study for the Aquablation Procedure. J Clin Med. 2020 Feb;9(2): 603.

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%
Irreversible Complications	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

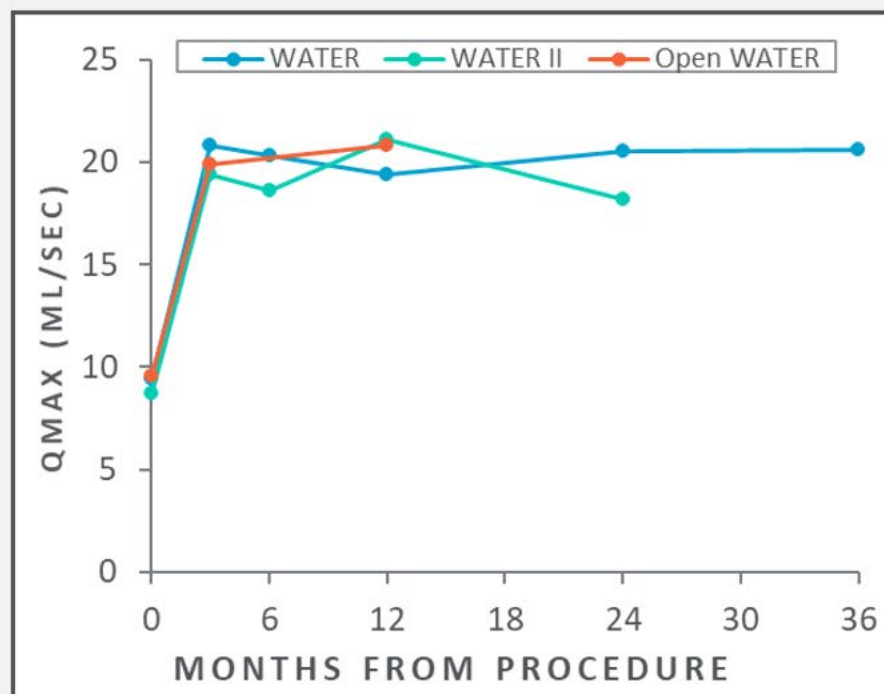
Roehrborn CG, et al. Five year results of the prospective randomized controlled prostatic urethral L.I.F.T. study. Can J Urol. 2017 Jun;24(3):8802-8813.

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

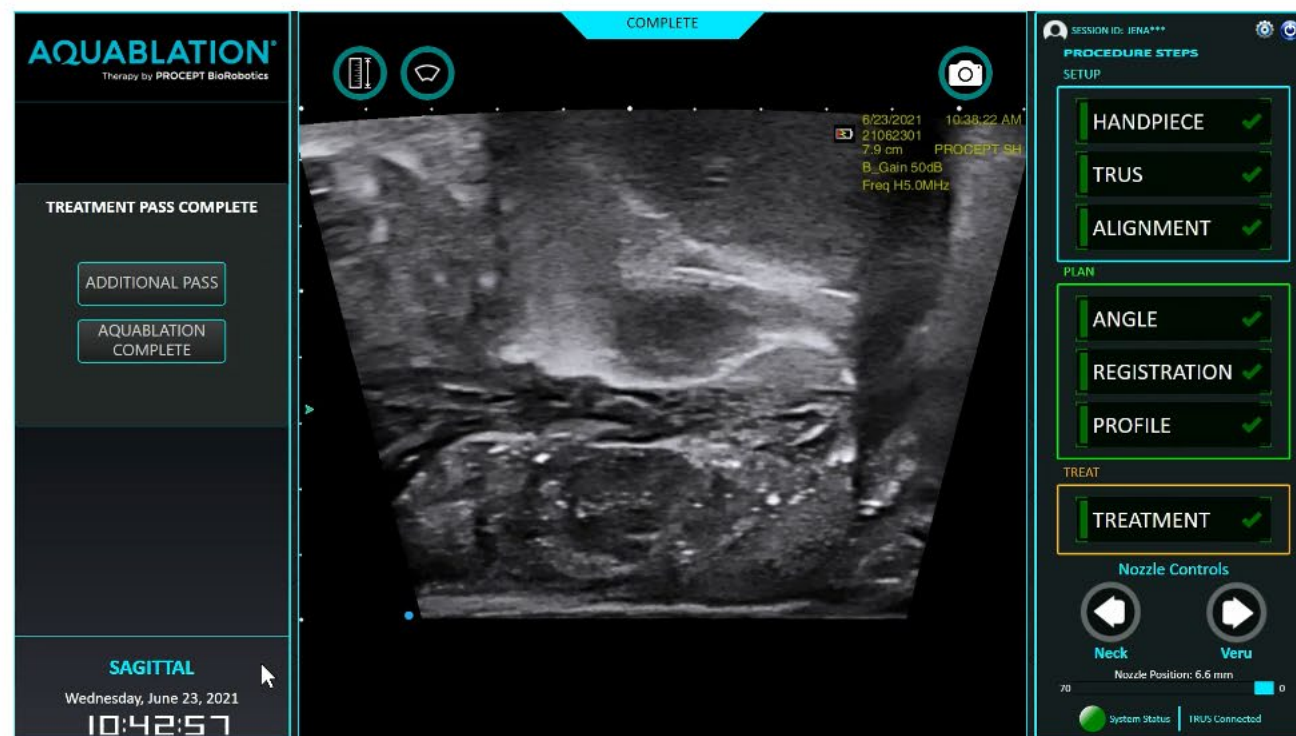
Data on file. WATER, WATER II, and OPEN WATER clinical studies.
McVary KT, et al. Final 5-Year Outcomes of the Multicenter Randomized Sham-Controlled Trial of a Water Vapor Thermal Therapy for Treatment of Moderate to Severe Lower Urinary Tract Symptoms Secondary to Benign Prostatic Hyperplasia. J Urol.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

Immediate and sustained flow improvement

FLOW IMPROVEMENT
Average Qmax improvement = 11 mL/sec



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
VOLUME	<100 mL 57 mL average	350
	>100 mL 126 mL average	75
MEDIAN LOBE	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	16 points
Peak Flow Rate (Qmax)	20.5 mL/sec
QoL Improvement	3.3 points
PVR Improvement	62 mL
Ejaculatory Function Preservation	89.2%
Erectile Function Preservation	100%
Continence Preservation	99.5%

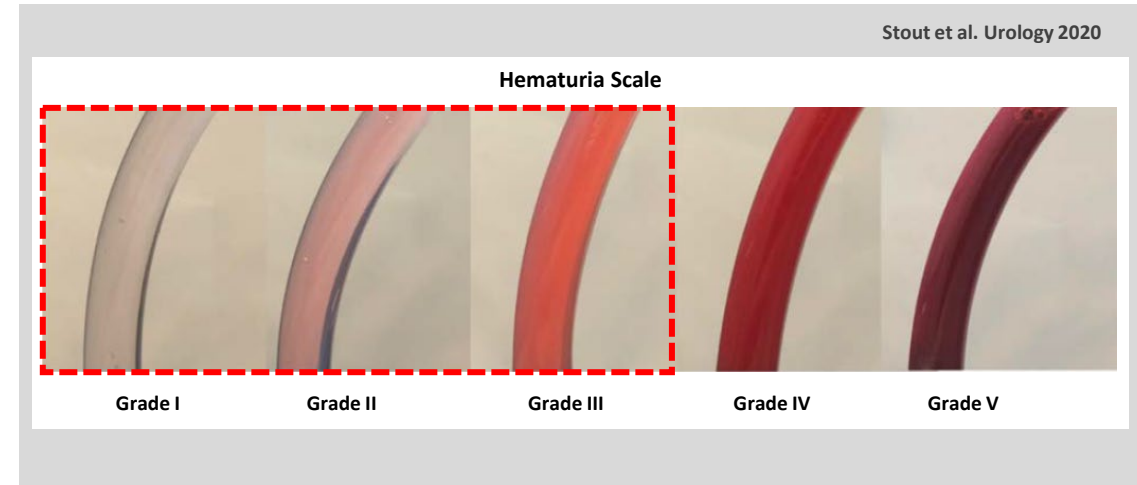
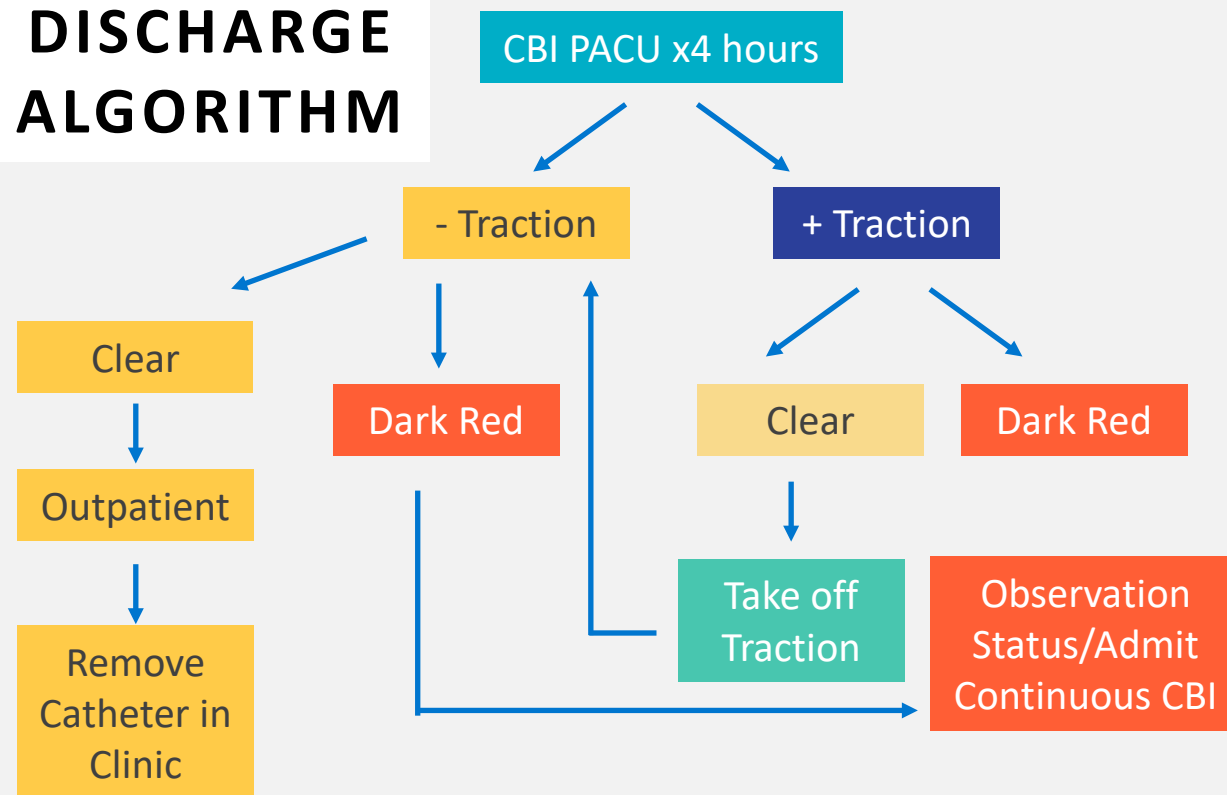
Elterman D. et al. Meta-analysis with individual data of functional outcomes following Aquablation for lower urinary tract symptoms due to BPH in various prostate anatomies BMJ Surg Interv Health Technologies 2021

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

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)	99.87 (50.69)	180.67 (158.35)
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.

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

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® 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.



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