UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934
Date of Report (Date of earliest event reported): May 3, 2024

PROCEPT BIOROBOTICS CORPORATION
(Exact name of registrant as specified in its charter)

Delaware	001-40797	26-0199180
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification Number)

150 Baytech Drive
San Jose, California 95134
(Address of principal executive offices, including Zip Code)

Registrant's telephone number, including area code: (650) 232-7200

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.00001 par value per share	**PRCT**	**The Nasdaq Stock Market LLC**

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 7.01 Regulation FD Disclosure

Beginning on May 3, 2024, representatives of PROCEPT BioRobotics Corporation (the "Company") intend to make presentations at investor conferences and in other forums. These presentations may include the information contained in Exhibit 99.1 furnished to this Current Report on Form 8-K. A copy of certain of the presentation slides containing such information that may be disclosed by the Company is furnished as Exhibit 99.1 to this report and is incorporated herein by reference and constitutes a part of this report.

The information included under Item 7.01 in this Current Report on Form 8-K, including Exhibit 99.1, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that Section, nor shall it be deemed to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.
(d) Exhibits

Exhibit No.	Description
99.1	Presentation of PROCEPT BioRobotics Corporation, dated May 3, 2024.
104	Cover Page Interactive Data File, formatted in Inline XBRL.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

PROCEPT BIOROBOTICS CORPORATION

Date: May 3, 2024

By: /s/ Alaleh Nouri
Alaleh Nouri
EVP, Chief Legal Officer and Secretary

Investor Event

2024 American Urological Association Annual Meeting

May 3, 2024

PROCEPT BioRobotics®

Safe Harbor Statement

This presentation and accompanying oral presentation contain "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, including the expected financial results of PROCEPT BioRobotics Corporation (the "Company"). Words such as "anticipates," "believes," "expects," "intends," "projects," "anticipates," and "future" or similar expressions are intended to identify forward-looking statements. Any forward-looking statements made by us in this presentation speaks only as of the date on which it was made and are based on management's current expectations of future events, assumptions, estimates, and beliefs, and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements. Factors that could cause actual results to differ materially from those described in the forward-looking statements include, among others: (i) the rate and degree of market acceptance of the AQUABEAM Robotic System and Aquablation therapy and descriptions of the Company's revenues, gross margin, profitability, operating expenses, or installed base growth, (ii) the establishment and maintenance of consistent and favorable payment policies for Aquablation therapy, (iii) the rate of growth of the commercial sales and marketing organization and the ability to manage this anticipated growth, (iv) the impact on volumes of elective procedures performed by health care providers and hospital medical device budgets, (v) the effects of increased competition as well as innovations by new and existing competitors in the market for treatments for benign prostatic hyperplasia, (vi) the ability to obtain the required regulatory approvals and clearances to market and sell the AQUABEAM Robotic System in certain other countries, (vii) the development and protection of future innovation, (viii) dependence on a limited number of third-party suppliers for components of the AQUABEAM Robotic System, (ix) the maintenance of intellectual property rights and the ability to operate the business without infringing the intellectual property rights and proprietary technology of third parties, (x) the successful completion of clinical trials and (xi) the adoption of our technology for additional indications.

This presentation and the accompanying oral presentation also contain estimates and other statistical data made by independent parties and by us relating to market size and growth and other data about our industry. This data involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates. In addition, projections, assumptions, and estimates of our future performance and the future performance of the markets in which we compete are necessarily subject to a high degree of uncertainty and risk.

Factors that could cause actual results to differ materially from those contemplated in this presentation can be found in the Risk Factors section of the Company's public filings with the Securities and Exchange Commission ("SEC"), including the Annual Report on Form 10-K filed with the SEC on February 28, 2024 and any current and periodic reports filed thereafter, available at www.sec.gov.

Because forward-looking statements are inherently subject to risks and uncertainties, you should not rely on these forward-looking statements as predictions of future events. All statements other than statements of historical fact are forward-looking statements. Except to the extent required by law, the Company undertakes no obligation to update or review any estimate, projection, or forward-looking statement. Actual results may differ from those set forth in this presentation due to the risks and uncertainties inherent in the Company's business. In light of the foregoing, investors are urged not to rely on any forward-looking statement or third-party data in reaching any conclusion or making any investment decision about any securities of the Company.

This presentation regarding the Company shall not constitute an offer to sell or the solicitation of an offer to buy any securities, nor shall there be any sale of these securities in any state or jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such state or jurisdiction. Sales and offers to sell PROCEPT BioRobotics securities will only be made in accordance with the Securities Act of 1933, as amended, and applicable SEC regulations, including prospectus requirements.

AGENDA

01 **Introduction**
Reza Zadno, CEO

02 **Financial Review**
Kevin Waters, CFO

03 **Commercial Update**
Sham Shiblaq, Chief Commercial Officer

04 **Georgia Urology Experience**
Dr. Lewis Kriteman

05 **BPH + Prostate Cancer Clinical Update**
Dr. Brian Helfand

06 **Prostate Cancer Fireside Chat**
Dr. Inderbir Gill + Barry Templin, EVP, Technology & Clinical Development

PROCEPT BioRobotics®

New Age of Innovation & Market Expansion

Mission

Revolutionize BPH treatment to improve patient lives

Vision

Become a Leading **Global Urology Company**

Patient First Culture

- **Highly Focused on BPH**
- **Expanding into Prostate Cancer**
- **Sustainable High Growth**

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Expansion into Adjacent Urology Market

Current Treatment Challenges

BPH

Patients forced to make tradeoff between **safety** & **efficacy**

Surgeon skill can vary widely

Treatment options depend on **prostate size**

Prostate Cancer

Patients forced to make tradeoff between **safety** & **efficacy**

Treatment options have **high** rates of **morbidity** *(especially compared to BPH treatments)*

Many men suffer from both BPH and Prostate Cancer

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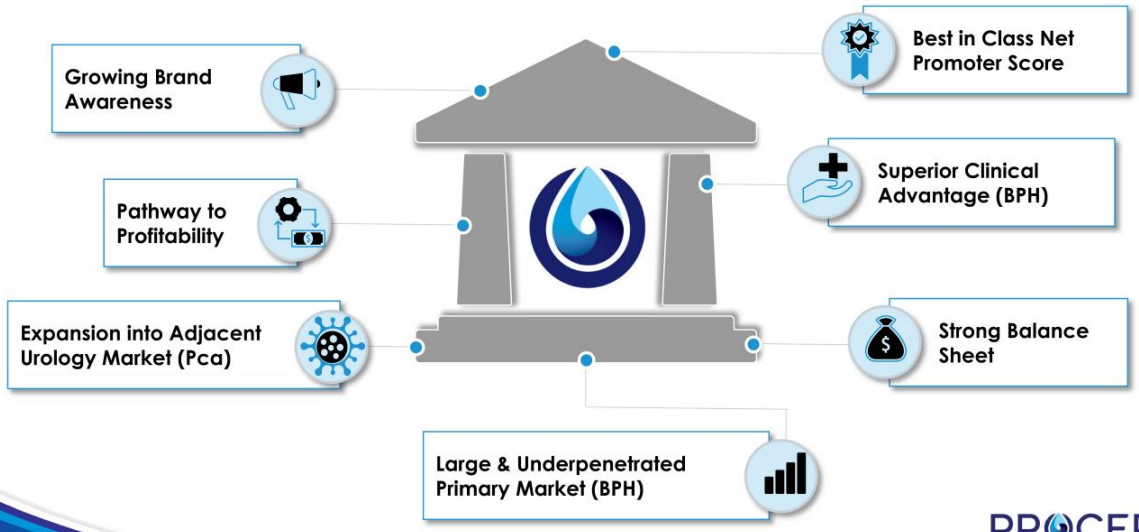
Strong Foundation for Continued Success



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FINANCIAL REVIEW

KEVIN WATERS
Chief Financial Officer

PROCEPT BioRobotics®

1Q24 Revenue Recap

$44.5M (+83% y/y)
Global Revenue

$4.3M (+65% y/y)
International Revenue

354 (+84% y/y)
U.S. Install Base

6,800 (+100% y/y)
U.S. Handpieces Sold

6.8 (+7% y/y)
U.S. Monthly Utilization

38 (+52% y/y)
U.S. Systems Sold

Leveraging Fixed Cost Infrastructure

New Headquarters

San Jose, CA
(160,000 Sq Ft)

Future Drivers of Gross Margin Expansion

1. Leverage fixed cost infrastructure with revenue growth
2. Improved efficiencies leading to lower scrap and improved yield

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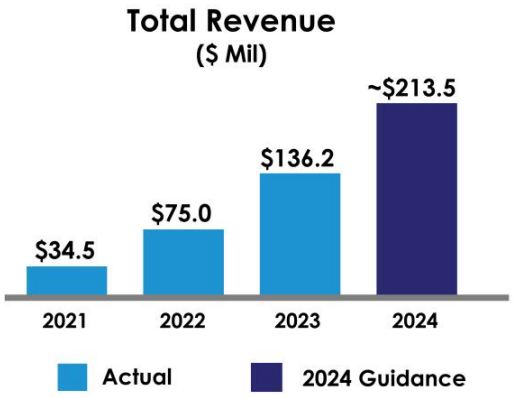
2024 Financial Guidance



	Actual 2023	Guidance FY24[1]
Revenue	**$136.2 million**	**~$213.5 million**
Revenue growth (y/y)	*82%*	*~57%*
Gross Margin	**52%**	**~58% to 59%**
Operating Expenses	**$180.2 million[2]**	**~$231.5 million[3]**
Revenue : OPEX Growth Ratio	*1.5x*	*~2.0x*
Adjusted EBITDA Loss	**$86.5 million[4]**	**~$70.0 million[4]**

TOTAL CASH & CASH EQUIVALENTS BALANCE OF $226M & DEBT BALANCE OF $52M AS OF MARCH 31, 2024

(1) 2024 financial guidance issued on May 1, 2024
(2) 2023 operating expenses included approximately $19.1 million in stock-based compensation expense
(3) 2024 operating expense guidance includes approximately $31.5 million in stock-based compensation expense
(4) See appendix for reconciliation of non-GAAP financial measures

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Non-GAAP Reconciliations

RECONCILIATION OF GAAP NET LOSS TO ADJUSTED EBITDA (in thousands) (unaudited)

	Three Months Ended March 31,	
	2024	2023
Net loss	$ (25,957)	$ (28,484)
Depreciation and amortization expense	1,184	793
Stock-based compensation expense	$ 6,256	3,724
Interest (income) and interest expense, net	(1,838)	49
Adjusted EBITDA	$ (20,355)	$ (23,918)

RECONCILIATION OF 2024 GAAP NET LOSS TO ADJUSTED EBITDA Guidance (in thousands) (unaudited)

	2024
Net loss	$ (100,000)
Depreciation and amortization expense	5,645
Stock-based compensation expense	31,500
Interest (income) and interest expense, net	(7,145)
Adjusted EBITDA	$ (70,000)

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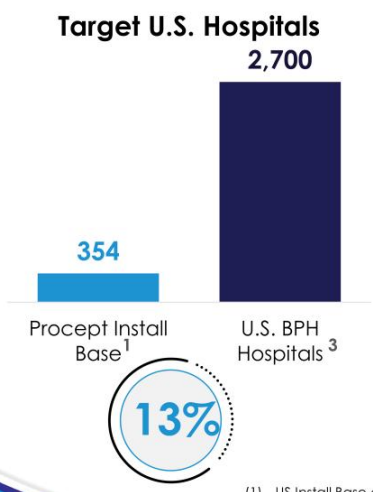
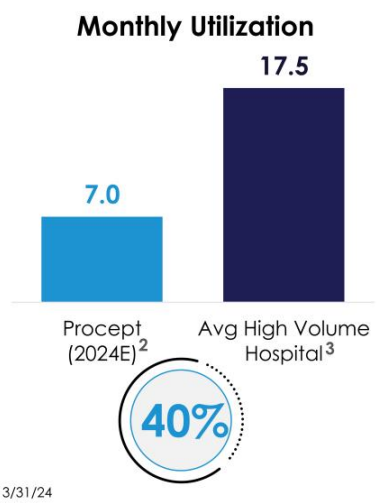
COMMERCIAL STRATEGY

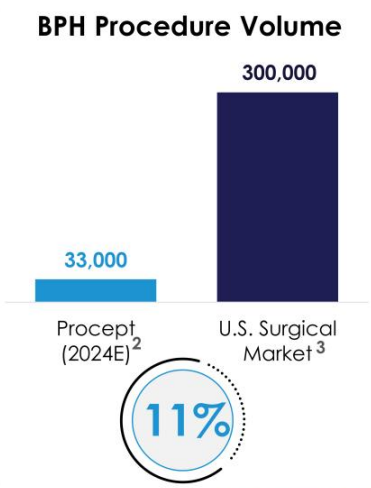
SHAM SHIBLAQ
Chief Commercial Officer

PROCEPT BioRobotics®

BPH Market Remains Underpenetrated







(1) US Install Base as of 3/31/24
(2) Based on 2024 guidance
(3) Hospitals and Procedures based on 2019 market data (data on file)

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Developing Winning Culture

Recruit & Develop

Hire highly experienced and tenured sales professionals

Commercial Execution

Clinical and sales excellence

Strong Partnerships

Outstanding clinical outcomes lead to increased demand

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Strong Momentum to Increase Utilization

Commercial Goal: Convert all resective BPH hospital-based procedures to Aquablation Therapy

Strong Foundation for Sustainable Growth

1. Largest & most tenured utilization team
2. >90% surgeon retention
3. Consistent & repeatable clinical outcomes
4. Standardizing treatment options

Educate

Host surgeon education and training events to identify surgeon champions

Accelerate

Increase utilization by training new surgeons at active hospitals

Target

Collaborate with hospitals to develop strategies to increase local patient volumes

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U.S. Capital in Position of Strength

1Q23		1Q24
~30	Sr Capital Reps	~40
~6 months	Sr Capital Rep Avg Tenure	~15 months
Zero	Jr Capital Reps	<10
Zero	Strategic Account Team	5
Deteriorating	Capital Environment	Stable-to-Improving
No	Signed Majority IDN Contracts	Yes
~70%	% U.S. Covered Lives	>95%

2024 Commercial Tailwinds

1

Improving Hospital CAPEX Environment

2

Largest & Most Tenured U.S. Sales Force

3

Strong & Growing U.S. Sales Funnel

4

Launching New Accounts with Multiple Surgeons

5

Robust Demand in United Kingdom

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GEORGIA UROLOGY ADOPTION

Dr. Lewis Kriteman
Partner and Executive VP, Georgia Urology

PROCEPT BioRobotics®

Disclosures

Dr. Lewis Kriteman
Partner and Executive VP, Georgia Urology

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Consulting disclosures: PROCEPT BioRobotics, Boston Scientific, SRS, Koelis, Laborie

Georgia Urology

GEORGIA UROLOGY

7
AquaBeam Systems

27
Aquablation Surgeons (today)

960
Aquablation Volume (2023)

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Challenges of Legacy Resective Procedures

Difficult & Steep Learning Curve
Optimal results depend on surgeon skill

Unpredictable Operating Room Time
Average procedure duration of medium to larger prostates can vary widely depending on patient anatomy and surgeon skill

Lack of Continuous Innovation
Resective technology is unchanged over the last decade and has not addressed clinical and procedural shortcomings

Failure to Preserve Sexual Function
Due to thermal energy, key anatomy is damaged by laser mechanism of action

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Aquablation Therapy is *Easy* Sell to….

Patients

- Customized treatment
- Superior clinical outcomes
- Sexual function preservation
- Improved post-op recovery

Surgeons

- Consistent outcomes
- Standardization across all prostate sizes & shapes
- Retain patients that were previously referred to area specialist
- Very flat learning curve regardless of experience

Hospitals

- Operating room efficiency
- First to market strategic advantage
- Patient satisfaction metrics lead to quality improvements
- Shorter length of stay
- Innovative solution draws surgeons + patients

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Dynamics Disrupting the Atlanta Market

Market Expansion

Surgeons now have viable option to offer drug failure patients

Competition from LVH[1]

Low Volume BPH Hospitals who have acquired an AquaBeam System are retaining patients

Local Marketing Initiatives

Hospitals are now marketing directly to patients highlighting the benefits of Aquablation Therapy

Improved Patient Outcomes

Higher levels of patient satisfaction improve trust in healthcare providers

Standardization

Hospitals are operating more efficiently offering Aquablation Therapy to all BPH patients

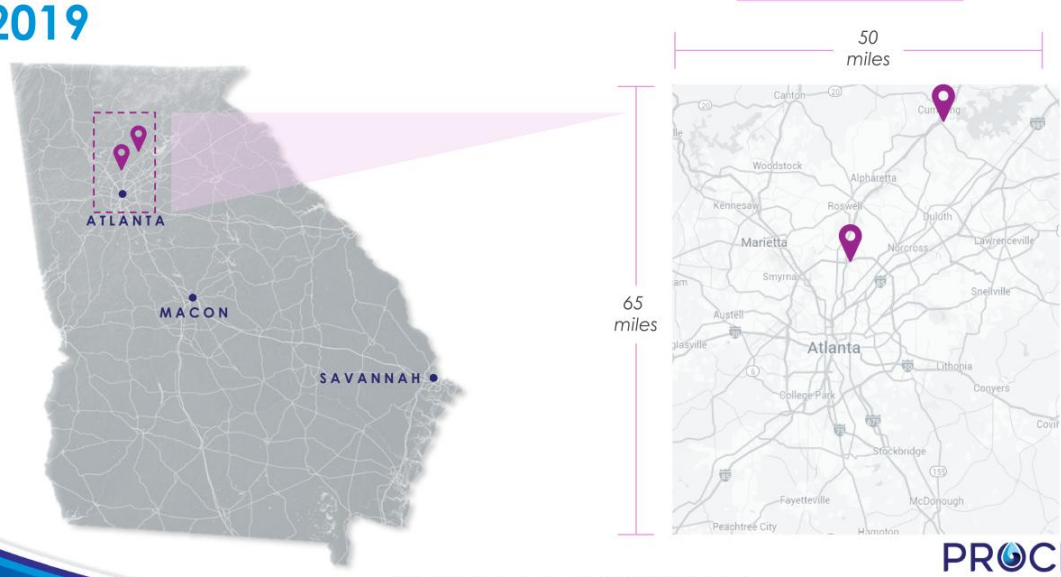
Increasing Brand Awareness

Patients are actively seeking out hospitals with AquaBeam Robot

1) LVH = Low Volume BPH Hospital

Northern Georgia + Atlanta Market
2019

Robot at Hospital



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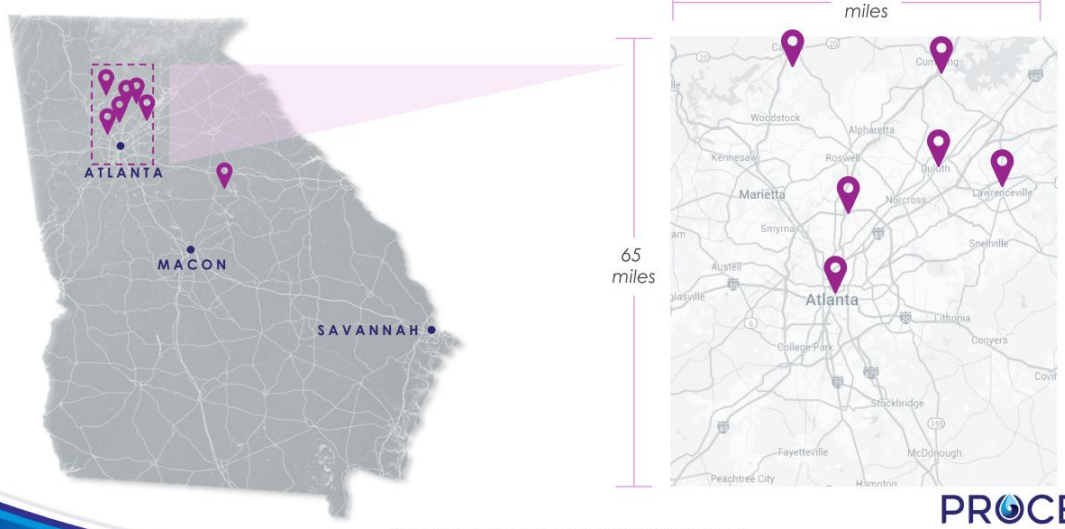
Northern Georgia + Atlanta Market

2019 >> **2021**

Robot at Hospital



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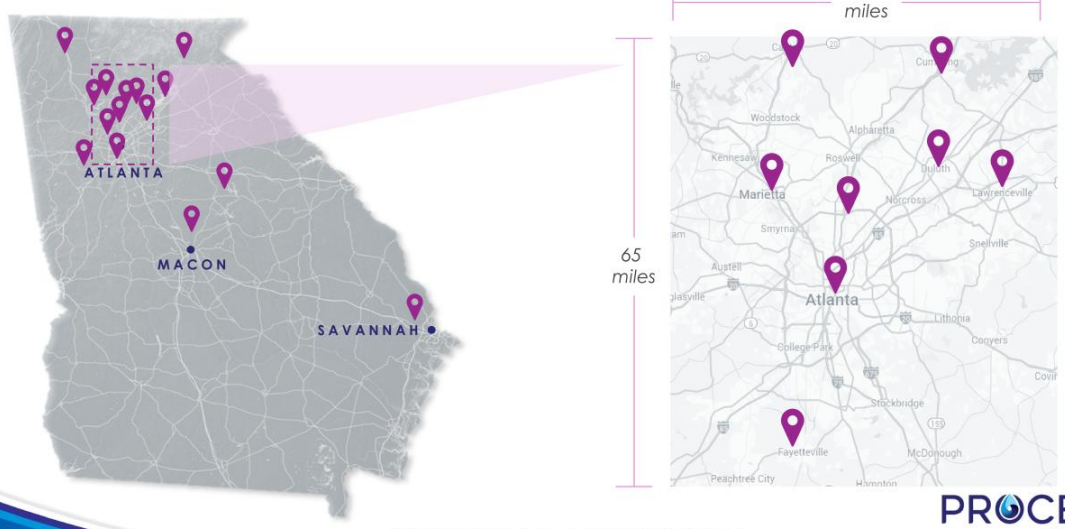
Northern Georgia + Atlanta Market

2019 >> 2021 >> **TODAY**

Robot at Hospital



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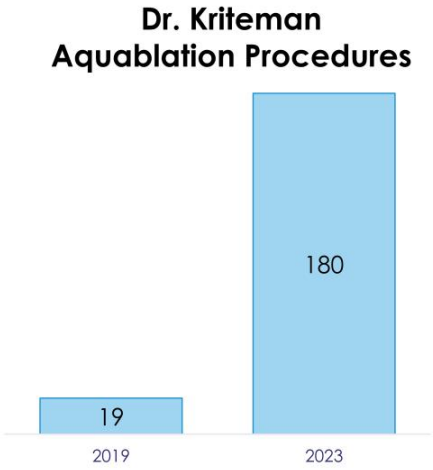
Aquablation Therapy is Expanding the Market



Aquablation Therapy cases have increased 9.5x since 2019

Averaging 15 monthly procedures in 2023

Total BPH procedures has grown significantly since 2019.

- *Resective procedures are biggest growth driver*
- *Non-Resective procedures have declined since 2019*

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Summary

Education Events

Hosted Aquablation therapy education events with >1,000 surgeon attendees

Learning Curve

Lower learning curve with Aquablation is game changer

Predictable Outcomes

Resecting tissue provides surgeons with more predictable outcomes

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BPH + PROSTATE CANCER CLINICAL UPDATE

Dr. Brian Helfand
Division of Urology, Northshore University Health System

PROCEPT BioRobotics®

Disclosures

Dr. Brian Helfand
Division of Urology, Northshore University Health System

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PROCEPT BioRobotics - consulting
GoPath diagnostics - advisor
Blue earth diagnostics - advisor and investigator
Olympus investigator
NIH LURN investigator

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Northshore Highland Hospital

NorthShore University HealthSystem

2 Robots at Single Site

8 AquaBeam Users

390 Aquablation Volume

Pioneers of *Same Day Discharge*

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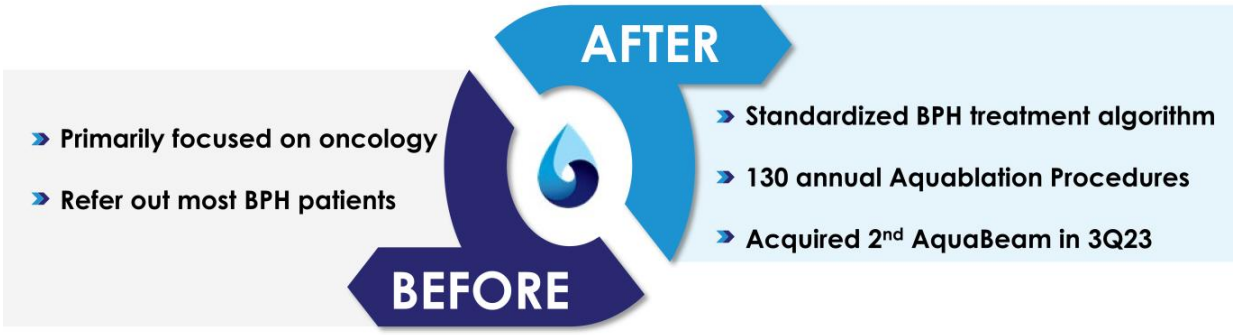
Before & After Aquablation Therapy



HEMOSTASIS EVOLUTION

2014-2019 (<2,000 patients)

FIM, WATER, WATER II, OPEN WATER, & early commercialization

Various hemostasis protocols investigated[1]

Electrocautery proved most effective and is now the standard

2020 & Beyond (>50,000 patients)

Introduction of Focal Bladder Neck Cautery

2,000 Patient Sample → <1% Transfusion Rate[2] <1% Takeback Rate[2]

>20,000 Patient Sample → Yearly decline & sustained transfusion & takeback risk <1%[3]

10 Years of Research & Data from Thousands of Patients

1. Elterman et al. 2020 British J Urol Int; 2. Elterman et al. 2021 Can J Uro; 3. Elterman et al. AUA 2023 MP51-02

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DAY CASE AQUABLATION GAINING ADOPTION

37 of **40 (93%)**
Patients Discharged Same Day

Prostates <150mL
Success with same day surgery.
Post-op day 3 void without catheter

- **Organically developed during COVID due to lack of bed space**
- **New data being presented at AUA 2024**
- **Numerous surgeons in US, UK, and Canada have adopted**

Ng et al BJI Int 2024 (in Press)
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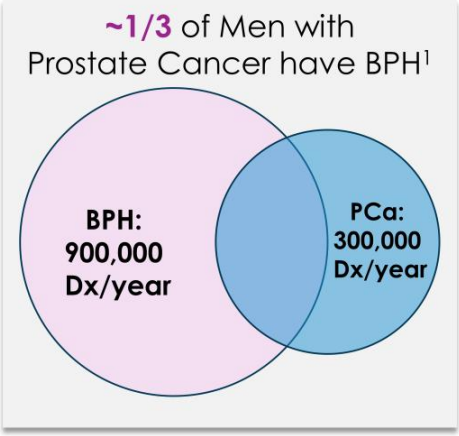
Aquablation Therapy for Prostate Cancer is a Natural Technology Evolution



- Prostate cancer & BPH effect similar populations
- Waterjet resection can be planned up to prostate capsule
- Aquablation resects tissue as opposed to in-situ ablation

Bell KJ, et al., Int J Cancer. 2015

Prostate Cancer Treatment Patient (PRCT002)

62yo Latino-American
- Family history of PCa
- Family history of BPH

- Prostate Volume: 96ml
- AUA-SI: 22, QoL: 5
- Qmax: 10mL/sec

	PSA (ng/ml)	Stage	MRI	Positive Cores	Pathology
Diagnostic Bx 3/22 OSH	5.8	T1c	Not done	3/12 Rt Apex	GG2
Confirmatory Bx 7/22	7.6	T1c	PIRADS 5 1.1cc Rt Apex	3/15 Rt Apex	GG2 Target only
Surveillance Bx 8/23	13.6	T1c	PIRADS 5 1.5cc Rt Apex	4/15 Rt Apex	GG2 Target + 1 random

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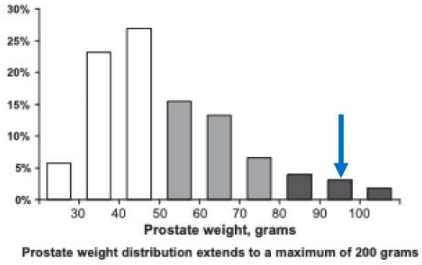
Prostate Size Perspective

62yo Latino-American
- Family history of PCa
- Family history of BPH

- Prostate Volume: 96mL
- AUA-SI: 22, QoL: 5
- Qmax: 10mL/sec

- **50mL** is average prostate size for prostatectomy in New York City[1]
- This specific **96mL** prostate is very large for prostate cancer case



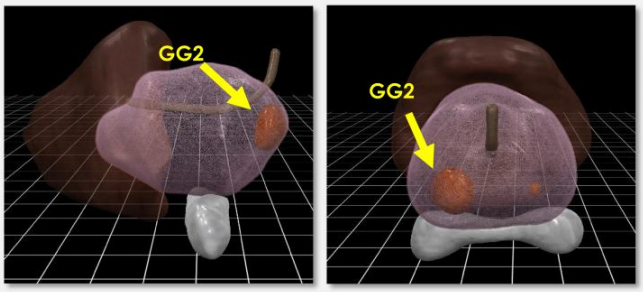
Prostate weight distribution extends to a maximum of 200 grams

1. Olsson et al Ar J Urol 2011

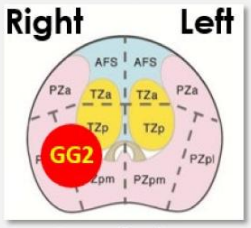
Surgical Pre-Planning

Final Diagnosis

3D MRI



Sagittal View | Transverse View



Prostate Apex

- Systematic biopsy
  - Right apex (GG2)
- Targeted biopsy
  - Right apex lesion (GG2)
  - Left apex lesion (benign)

CAUTION Investigational device. Limited by United States law to investigational use." However, since that may make it sound like the device is completely investigational & may be confusing, I'd recommend - "Aquablation therapy for the ablation of abnormal prostate tissue is limited by United States law to investigational use

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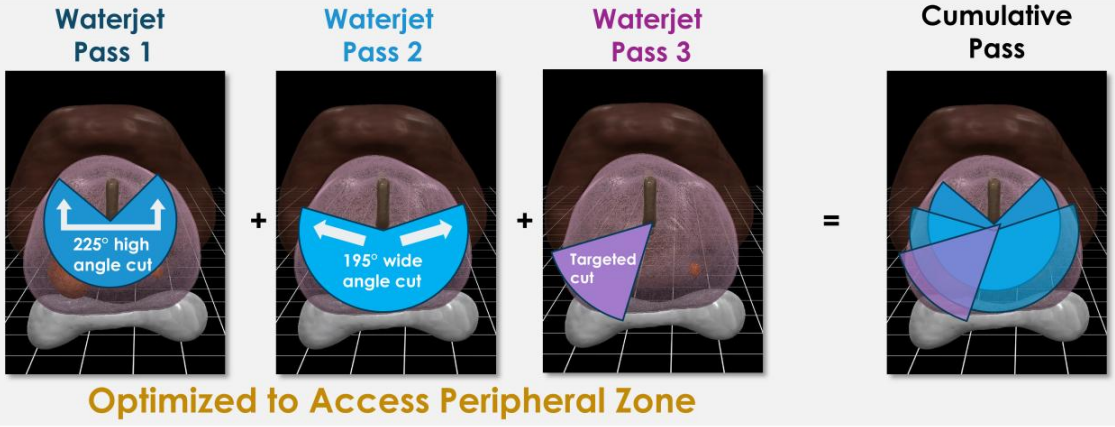
Surgical Pre-Planning

Treatment Plans



Optimized to Access Peripheral Zone

CAUTION Investigational device. Limited by United States law to investigational use." However, since that may make it sound like the device is completely investigational & may be confusing, I'd recommend - "Aquablation therapy for the ablation of abnormal prostate tissue is limited by United States law to investigational use

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Actual Treatment: Pass #1

Transverse View

Sagittal View

225° high angle cut

CAUTION Investigational device. Limited by United States law to investigational use." However, since that may make it sound like the device is completely investigational & may be confusing, I'd recommend - "Aquablation therapy for the ablation of abnormal prostate tissue is limited by United States law to investigational use

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Actual Treatment: Pass #2

Transverse View

Sagittal View

195° wide angle cut

CAUTION Investigational device. Limited by United States law to investigational use." However, since that may make it sound like the device is completely investigational & may be confusing, I'd recommend - "Aquablation therapy for the ablation of abnormal prostate tissue is limited by United States law to investigational use

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Actual Treatment: Pass #3

Transverse View

Sagittal View

Targeted cut

CAUTION Investigational device. Limited by United States law to investigational use." However, since that may make it sound like the device is completely investigational & may be confusing, I'd recommend - "Aquablation therapy for the ablation of abnormal prostate tissue is limited by United States law to investigational use

PROCEPT BioRobotics®

Initial Aquablation Impressions for Prostate Cancer

Real Time Imaging

Surgical planning with ultrasound and 3D MRI reconstruction

Surgeon Confidence

Waterjet resection provides confidence to carry out comprehensive treatment plan

Post-op Recovery

Postop recovery similar to BPH treatment experience

1. **Attractive to Patients when Consenting Given Surgical Attributes**
2. **Resects Obstructive Tissue (BPH), Prostate Cancer Lesion(s), and Non-Obstructive Tissue that may Harbor Cancer**

PROCEPT BioRobotics®

Active Surveillance & Focal Therapy

Both Aim to Delay or Avoid Radical Treatment and Its Respective Morbidities

	Strategy	Cost to Patient	Failure Rate
Active Surveillance ***(watch)***	No immediate action. Regular testing & radical treatment if progression occurs	No treatment morbidity	50%-60% radical treatment within 10-15 years[1]
Focal Therapy ***(disrupt)***	Disrupt natural course of disease by ablating known cancer up to half the prostate	4% incontinence[2] 10-25% erectile dysfunction[2]	~35% residual actionable GG≥2 disease after 1-2 years[3-9] *(MRI Era Intermediate risk)*

Following Focal Therapy, 35% of patients Still Have Untreated Significant Disease

1. Hamdy et al NEJM 2023; 2. Weighted averages based on the totality of the ablation literature; reference available upon request; 3. Mortezavi et al J Urol 2019; 4. Abreu et al J Urol 2020; 5. Nahar et al J Urol 2020; 6. Ehadie et al 2022; 8. Wysock et al J Urol 2023; 8. Zhu et al E Urol Open 2023; 9. Dixon et al J Endo 2023

Data reported in each category is not head-to-head

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Radical Therapy Leads to Substantial Morbidity

	Strategy	Cost to Patient	Failure Rate
Active Surveillance ***(watch)***	No immediate action. Regular testing & radical treatment if progression occurs	No treatment morbidity	50%-60% radical treatment within 10-15 years[1]
Focal Therapy ***(disrupt)***	Disrupt natural course of disease by ablating known cancer up to half the prostate	4% incontinence[2] 10-25% erectile dysfunction[2]	~35% residual actionable GG≥2 disease after 1-2 years[3-9] *(MRI Era Intermediate risk)*
Surgery & Radiation ***(radical)***	Radical treatment prostatectomy or radiation therapy	**Surgery:**[10] Incontinence 21%; ED: 81% **Radiation:**[10] Incontinence: 4%; ED: 66%	Intermediate-risk disease Biochemical Failure[11] **Surgery:** 15%(5yrs), 24%(10yrs) **Radiation:** 13%(5yrs), 21% 10yrs)

1. Hamdy et al NEJM 2023; 2. Weighted averages based on the totality of the ablation literature; reference available upon request; 3. Mortezavi et al J Urol 2019; 4. Abreu et al J Urol 2020; 5. Nahar et al J Urol 2020; 6. Ehadie et al 2022; 8. Wysock et al J Urol 2023; 8. Zhu et al E Urol Open 2023; 9. Dixon et al J Endo 2023; 10 Donovan et al NEJM 2016; 11. Falagario et al Jama Net Open 2023

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PROSTATE CANCER OVERVIEW

Barry Templin
EVP, Technology & Clinical Development

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Prostate Cancer in U.S.

3.3 Million

Men in the U.S. living with prostate cancer today[1]

Low Mortality

Prostate cancer is a serious disease, but most men diagnosed do **not** die from it[2]

Active Surveillance

Common treatment recommendation given low disease lethality and high risk of treatment morbidity

>2 million Men Living With Low to Intermediate Risk Disease

1. American Cancer Society 2024; 2. Hamdy et al NEJM 2023; Donovan et al NEJM 2016

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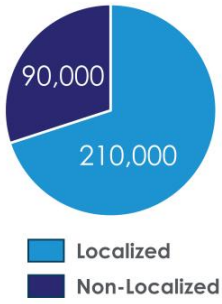
U.S. Prostate Cancer Market

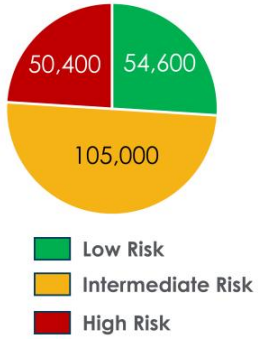
Annual Incidence[1]

300,000

New Cases of Prostate Cancer Annually

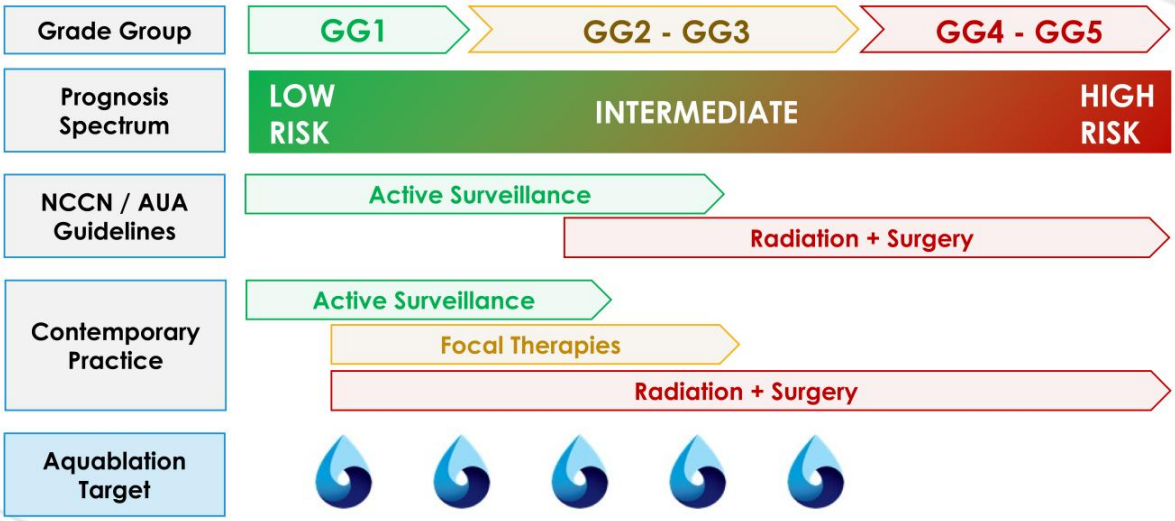


Localized Diagnoses by Risk[2]



1. American Cancer Society 2024; 2. Rasul et al CUAJ 2020

Localized Prostate Cancer Treatment Landscape



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Initial Prostate Cancer Research

PRCT001 Objective

Evaluate **safety** & **efficacy** of Aquablation therapy for patients with BPH & localized prostate cancer.

Step 1

Feasibility performed in **5 patients**

Key Inclusion
IPSS ≥ 8
Grade Group 1-3
PIRADS 3-4
PSA < 20 ng/ml

Data Presented

Step 2

Modified protocol to include ….
- up to125 patients
- up to15 global sites

PRCT001 Design

Single Arm on-label study of BPH patients with…
- Localized prostate cancer
- Grade Group 1-3
- Candidates for Active Surveillance or Observation

Cancer Progression

- MRI Visibility is cause for concern[1,2,3]
- MRI progression is a cause for biopsy[1,2,3]
- Grade group progression is usually a trigger for radical treatment[4]

	Active Surveillance (6-13m Bx)
MRI Invisibility (PIRADS ≤ 2)	12%[1]
Progression Metrics	
MRI Progression	30%[1]
Grade Group Progression	32-46%[1,2]

1. Stavrinides et al 2019; 2. Omil-Lima et al 2022; 3.Osses et al 2020; 4. Weinstock et al 2020

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Aquablation Cancer Progression Data

- MRI Visibility is cause for concern[1,2,3]
- MRI progression is a cause for biopsy[1,2,3]
- Grade group progression is usually a trigger for radical treatment[4]

	Active Surveillance (6-13m Bx)	AQUABLATION® (n=5; 6m f/u)[5]
MRI Invisibility (PIRADS ≤ 2)	**12%**[1]	**100%**
Progression Metrics		
MRI Progression	30%[1]	**0%**
Grade Group Progression	32-46%[1,2]	**0%**

Data ★ Presented

1. Stavrinides et al 2019; 2. Omil-Lima et al 2022; 3.Osses et al 2020; 4. Weinstock et al 2020 5. Data on file

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FDA Prostate Cancer Research

PRCT002 Objective

Evaluate **safety** & **efficacy** of Aquablation therapy for localized prostate cancer.

PRCT002 Design

Single-arm FDA IDE Study

- Localized prostate cancer
- Grade Group 1-2

20 patients 5 US Sites

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Treatment Strategy Categories

	Strategy	Cost to Patient	Failure Rate
Active Surveillance *(watch)*	No immediate action. Regular testing & radical treatment if progression occurs	No morbidity from active treatment	50%-60% radical treatment within 10-15 years[1]
Focal Therapy *(disrupt)*	Disrupt natural course of disease by ablating known cancer up to half the prostate	4% incontinence[2] 10-25% erectile dysfunction[2]	~35% residual actionable GG≥2 disease after 1-2 years[3-9] *(MRI Era Intermediate risk)*
AQUABLATION® THERAPY *(resect)*	Near total resection of prostate, including all known disease	**Early results (n=5):** 0% incontinence 0% erectile dysfunction	**Early results (n=5):** 0% actionable disease 0% residual tumor on MRI
Surgery & Radiation *(radical)*	Radical treatment prostatectomy or radiation therapy	**Surgery:**[10] Incontinence 21%; ED: 81% **Radiation:**[10] Incontinence: 4%; ED: 66%	Intermediate-risk disease Biochemical Failure[11] **Surgery:** 15%(5yrs), 24%(10yrs) **Radiation:** 13%(5yrs), 21%(10yrs)

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PCa Summary for Aquablation Therapy

1

Near Whole Gland Treatment

2

~3 Million Patients

3

Enrolling Patients in Two Trials

GOALS

- **Stop or delay progression of cancer** in low & intermediate risk patients
- **Reduce rates of unnecessary morbidity** to low & intermediate risk patients
- **Offer safe & effective treatment** for prostate cancer

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PROSTATE CANCER FIRESIDE CHAT

Dr. Inderbir Gill
Founding Executive Director for USC Urology.
Chairman of Urological Cancer Surgery at Keck School of Medicine of USC

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Disclosures

Dr. Inderbir Gill
Keck School of Medicine of USC

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