

FocalTherics™

# 2026 Investor Day

Nasdaq (FOCL)

June 1, 2026

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Certain physicians referenced in this presentation may have received consulting fees, research grants, or other compensation from FocalTherics.

# Agenda

1

**RYAN RHODES**  
CEO

**Transformation of EDAP | Focal One®**  
Our Next Chapter as FocalTherics™

**Commercial Leader in Robotic  
Focal Therapy:** Prostate Cancer

**Clinical Expansion of Our Focal  
Therapy Platform:** BPH and  
Endometriosis

2

**BEHFAR EHDAIE, MD, MPH**  
Memorial Sloan Kettering Cancer Center

**Clinical Experience with Focal One  
Robotic HIFU**

3

**STEVE ANNEN**  
EVP Product Management

**Innovation and Advanced Technologies**

4

**KEN MOBECK**  
CFO

**Financials: Positioned for Growth**

5

**ALL**

**Closing and Q&A**

# Transformation of EDAP | Focal One®

Our Next Chapter as FocalTherics™

Ryan Rhodes, CEO

**Focal Therapy**

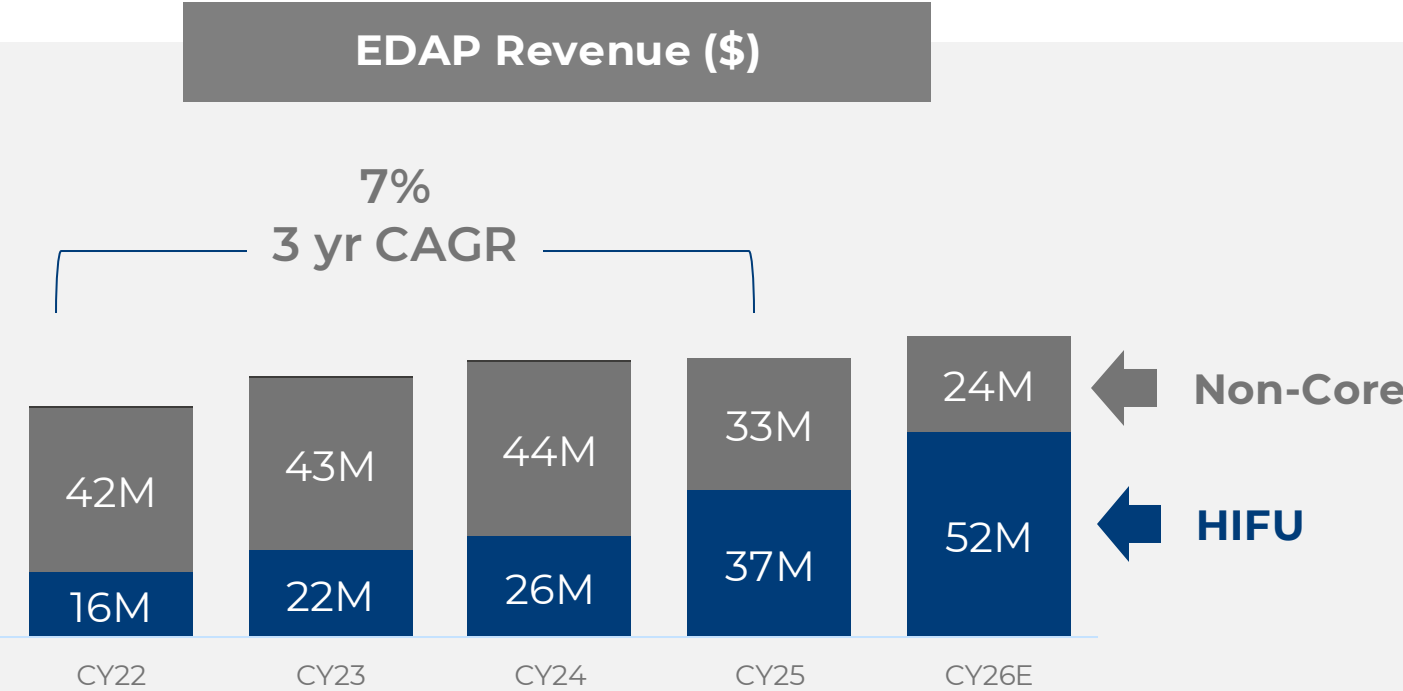
Therapeutics

**FocalTherics™**

We are Transforming into a High-Growth Pure-Play,  
Robotic Focal Therapy Company with a Leading Position in  
Both Large and Growing Markets

# Commitment to Focal Therapy

Focusing on Accelerating Our Growth Engine

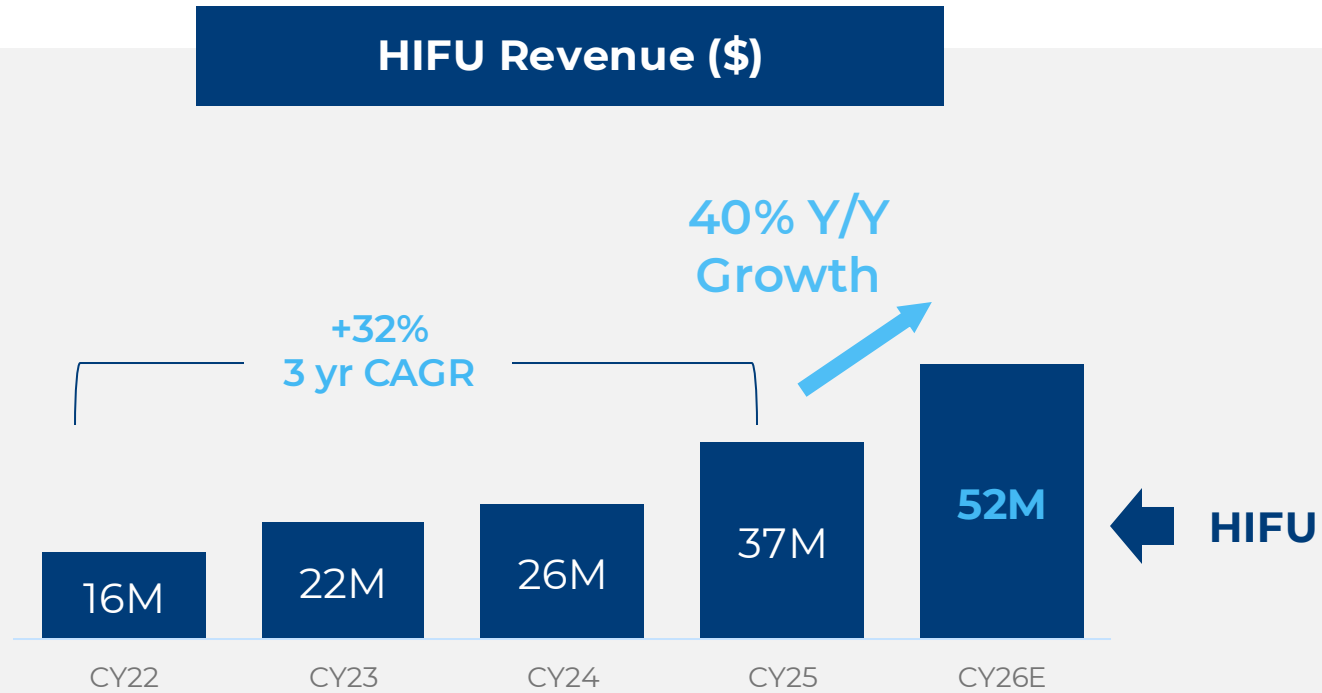


Moving Non-Core ESWL and Distribution Business to Discontinued Operations as of Q2 CY26

Note: CY26E = Midpoint of CY26 Guidance Range

# Commitment to Focal Therapy

Focusing on Accelerating Our Growth Engine



Note: CY26E = Midpoint of CY26 Guidance Range

# FocalTherics™

Global Leader in  
Therapeutic Ultrasound

Redefining the Treatment of Cancer and  
Benign Disease through Organ Sparing,  
Function Preserving Focal Therapy



# Driving Growth Across Three Strategic Pillars

Scaling Commercial  
Execution in  
Prostate Cancer

Expanding our Market  
Opportunity with Added  
Indications on the  
Focal One Platform

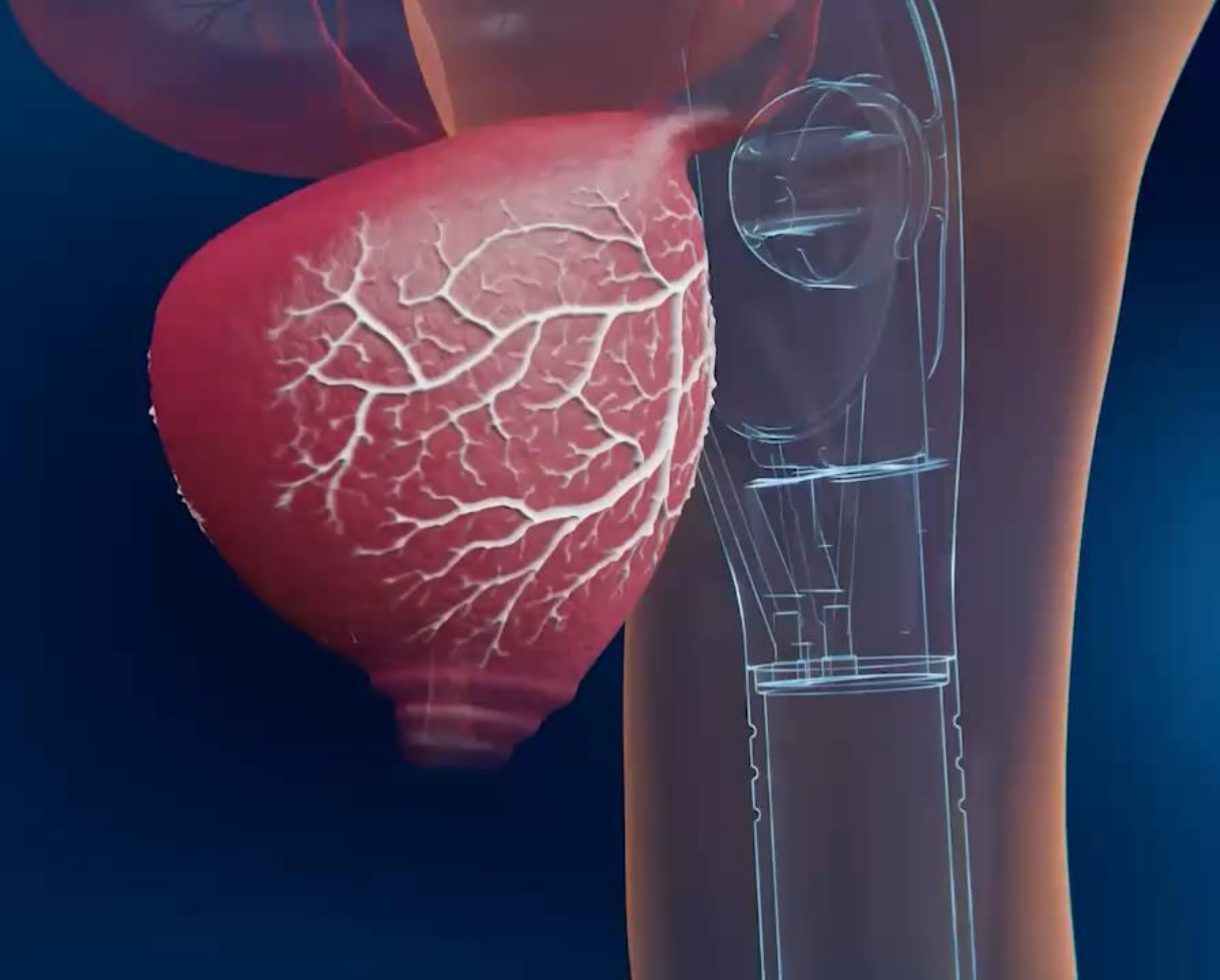
Advancing  
Technological  
Innovation in HIFU  
and Beyond

**Non-Invasive**

**No Surgery**

**No Cutting**

**No Radiation**





Advanced Imaging

High-Intensity Focused  
Ultrasound (HIFU)

Precise Robotic  
Energy Delivery



Organ Sparing,  
Function Preserving



# Defining, Building, and Leading the Category of Robotic Focal Therapy



# Driving Commercial Success in Current Markets

Prostate Cancer

# Prostate Cancer is the Most Common Cancer Among Men<sup>1</sup>

**>1.4 Million<sup>2</sup>**

New Cases Diagnosed Annually, Globally

**>330,000**

New Cases Diagnosed Annually in the U.S.

**>3.5 Million**

Men Living with Prostate Cancer in the U.S.



Annual Global Prostate Diagnoses Will

**DOUBLE**

by 2040<sup>3</sup>

1.4M  
Cases

2020

2.9M  
Cases

2040

[1] 2026 estimates from the American Cancer Society ([www.cancer.org](http://www.cancer.org))

[2] 2022 estimates from the World Health Organization ([www.who.int/](http://www.who.int/))

[3] James N, Tannock I, N'Dow J et al. The Lancet Commission on prostate cancer: planning for the surge in cases. *The Lancet*, 2024; 403, 1683-1722

# The Shift from Radical Treatment to Focal Therapy

*Surgery is Still Surgery...*

Open Surgery



Laparoscopic Surgery



Robotic Surgery



*Radiation is still Radiation...*

XRT Radiation



IMRT Radiation



SBRT Radiation

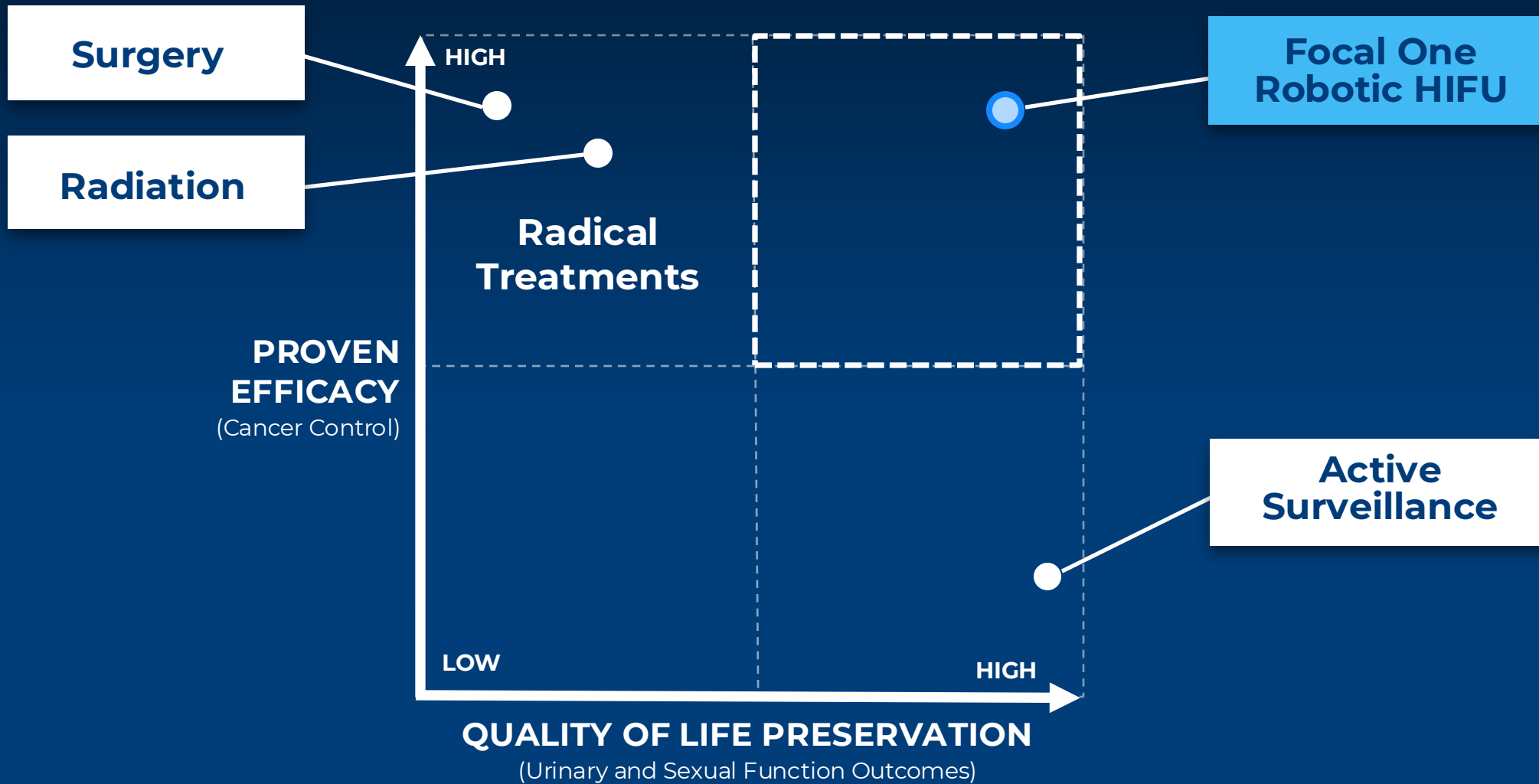


**Robotic Focal  
HIFU Ablation**

# The Prostate Cancer Patient's Dilemma



# Prostate Cancer Patient Value Equation



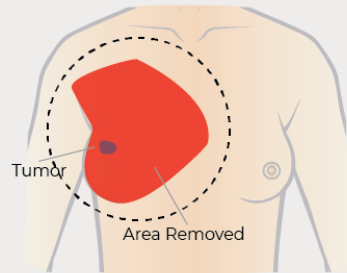
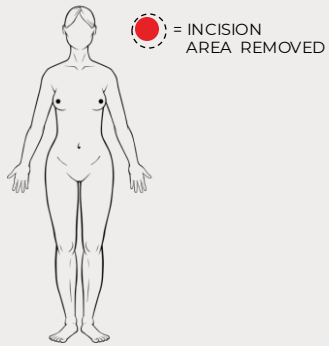
# From Radical To Organ-Sparing Treatments

The Evolution of Breast and Prostate Cancer Surgery

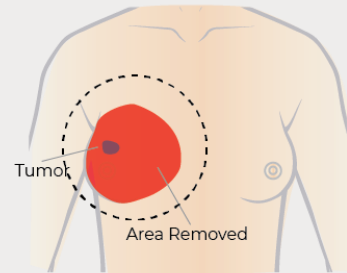
## Radical Surgery

## Organ-Sparing

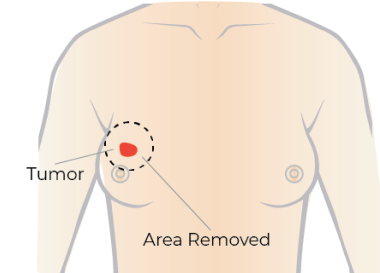
### Mastectomy



Radical Mastectomy

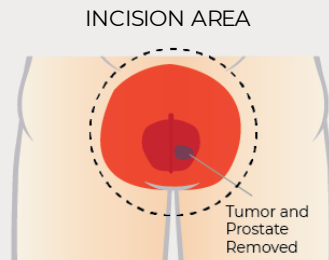
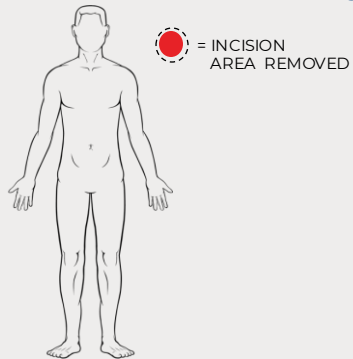


Modified Radical Mastectomy

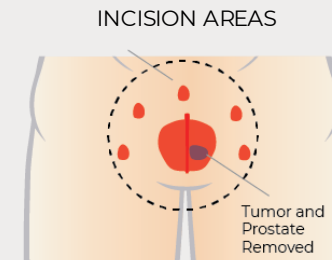


Lumpectomy

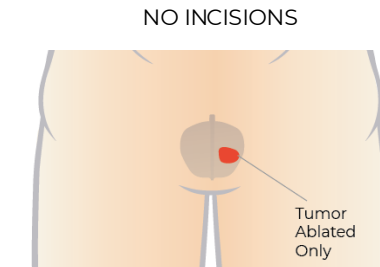
### Prostatectomy



Open Radical Prostatectomy

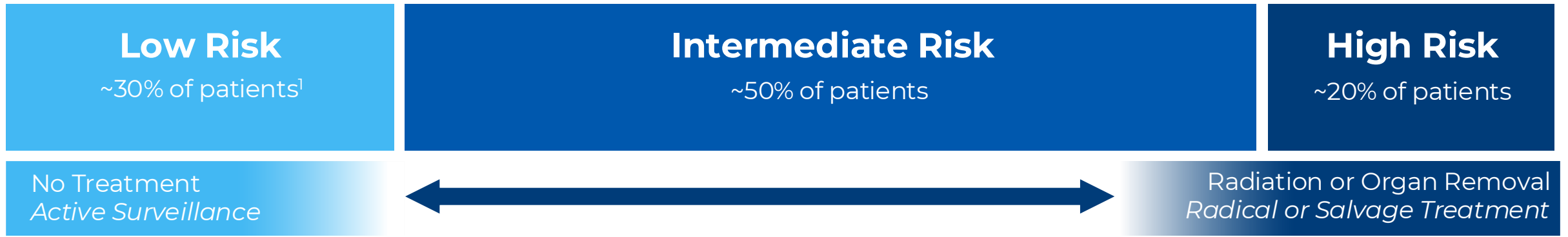


Robotic Radical Prostatectomy



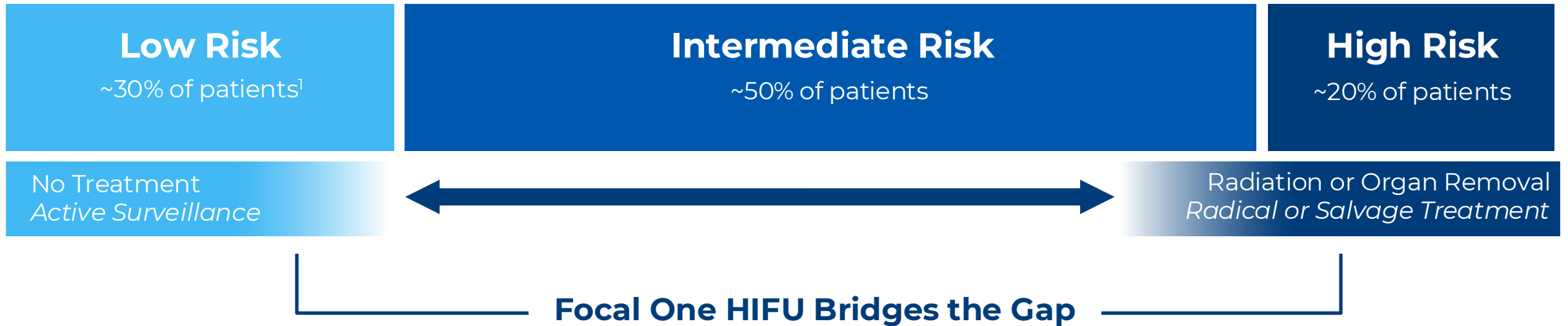
Robotic Focal HIFU Ablation

# The Large Gap Between No Treatment and Radical Treatment



Previously, There Have Been **No Options**, Other Than Active Surveillance or Radical Treatments, **to Address Intermediate Risk Patients**

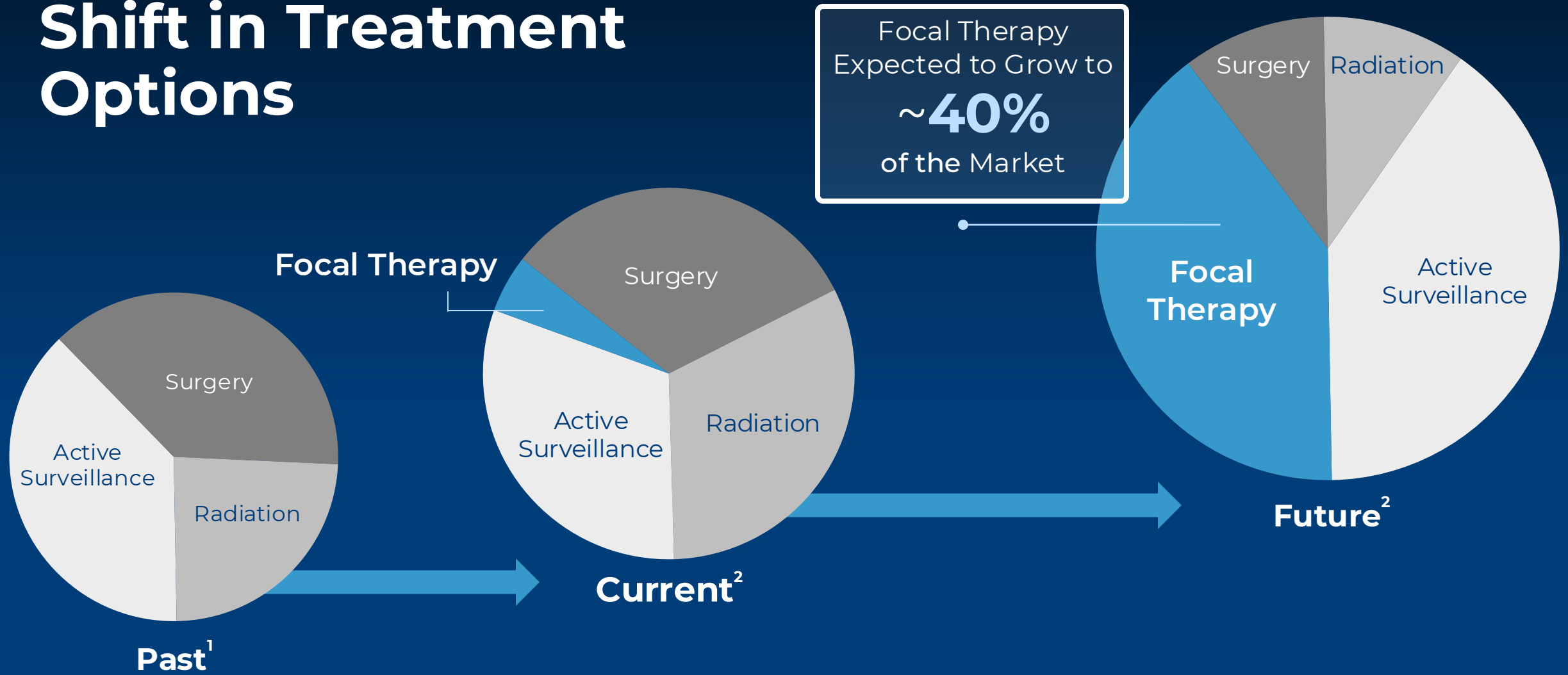
# The Large Gap Between No Treatment and Radical Treatment



Low and Intermediate Risk Patients **Represent a >\$4B TAM<sup>2</sup>**

<sup>[1]</sup> Fletcher, Sean A et al. "Contemporary national trends in prostate cancer risk profile at diagnosis." Prostate cancer and prostatic diseases vol. 23,1 (2020): 81-87. doi:10.1038/s41391-019-0157-y  
<sup>[2]</sup> Company Data on File

# Emerging Paradigm Shift in Treatment Options

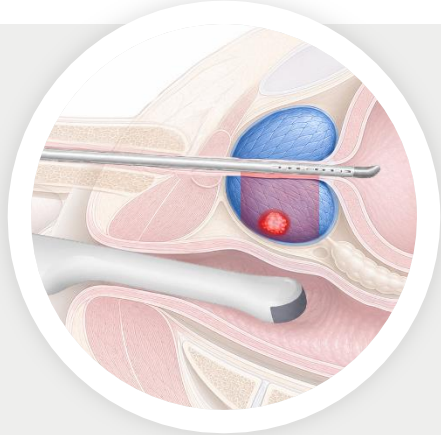


[1] As of 2013, Chen et al. National trends in the management of localized prostate cancer: A population-based analysis 2004-2013. Prostate.

[2] Company Data on File

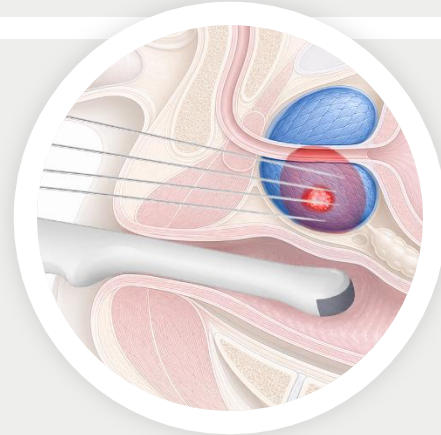
# Focal One Transrectal HIFU

Offers Superior Access, Precision, and Tissue Preservation



**Transurethral**

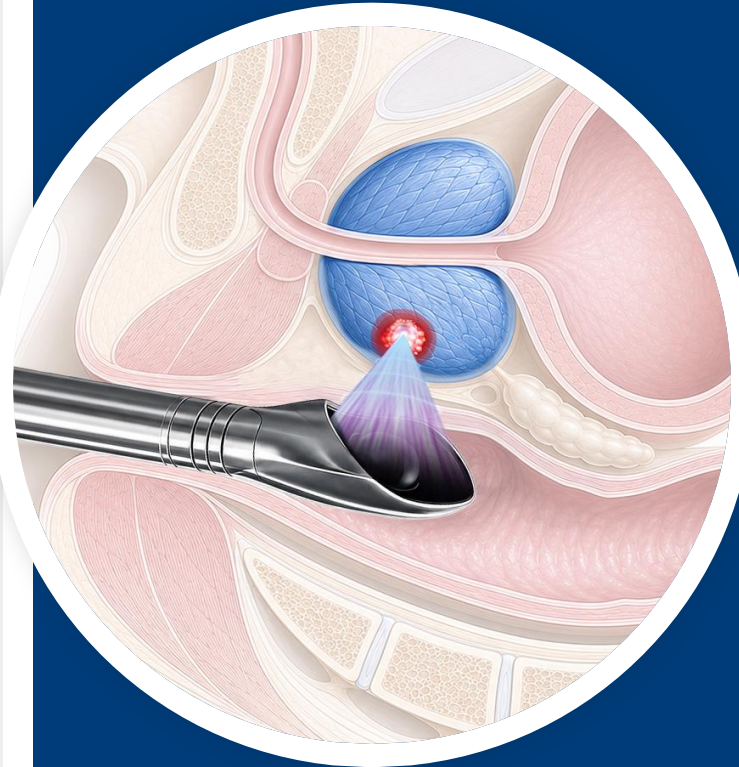
- × Requires MRI Suite and 2<sup>nd</sup> Physician
- × Non-Focused Energy
- × Bleeding from Urethra and Tissue Damage



**Transperineal  
(Needle-Based)**

- × Punctures Through Perineum
- × Manual Placement and Positioning
- × Bleeding from Tissue Damage

## Focal One Transrectal HIFU

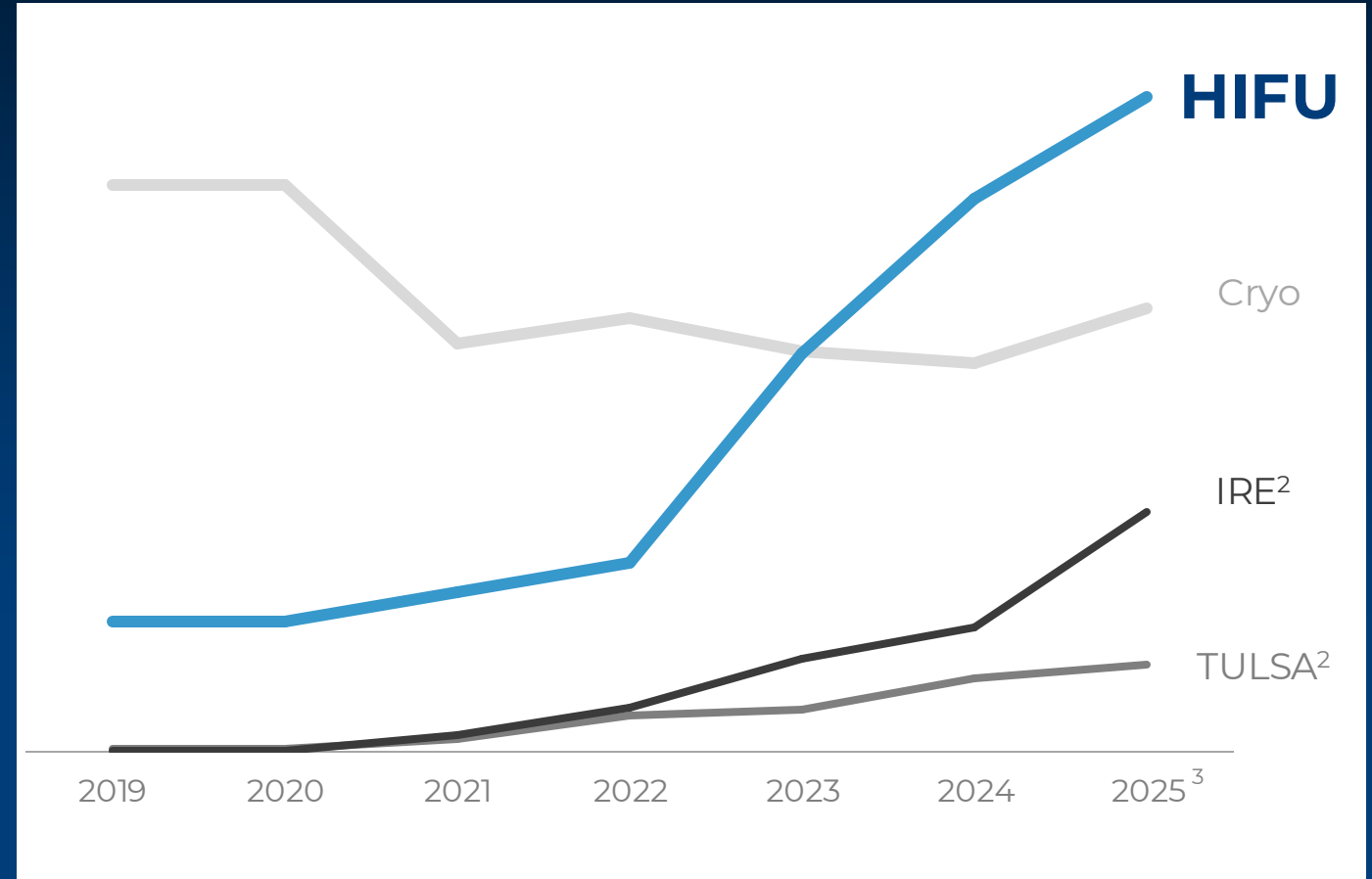


- ✓ Single Urologist
- ✓ Precise Focused Ultrasound
- ✓ Targeted Robotic Energy Delivery
- ✓ Closest Proximity To Target Tissue
- ✓ Urethra Sparing
- ✓ No Bleeding

# HIFU

**Fastest Growing  
Focal Therapy Treatment<sup>1</sup>**

**#1 Ablation Technology  
for Prostate Cancer**



[1] Based on Medicare claims utilization data published by CMS in connection with the Hospital Outpatient Prospective Payment System (HOPPS) Final Rules for CY 2021-CY 2026.

[2] IRE and TULSA treatment volumes may include procedures other than prostate cancer treatment, as applicable billing codes are not historically prostate-specific.

[3] Company Data on File

# Clinical Evidence Supports and Favors Focal One Robotic HIFU



# Landmark Studies Demonstrate Positive Clinical Outcomes Supporting Focal One HIFU Therapy

Prospective Comparative

**HIFI<sup>1</sup>**  
*European Urology*

## **HIFU vs Radical Prostatectomy**

HIFU Demonstrated High Cancer Control and Superior Continence and Erectile Function Preservation

Prospective Salvage

**HIFI-2<sup>2</sup>**  
*European Urology Oncology*

## **HIFU in Salvage Post Radiation**

HIFU Demonstrated High Cancer Control. 71% ADT-free Survival at 30 Months

Long-Term Retrospective

**CGRD<sup>3</sup>**  
*Int. Urology and Nephrology*

## **HIFU vs Radiation**

HIFU Demonstrated Higher Survival at 10 Years versus Radiation

RCT

**FARP<sup>4</sup>**  
Presented at AUA 2025

## **Focal Ablation vs Radical Prostatectomy**

Focal Ablation Demonstrated Equivalent Cancer Control

RCT

**HIFUSA<sup>5</sup>**  
Presented at AFU 2025

## **HIFU vs Active Surveillance**

HIFU Demonstrated Superior Progression-Free Survival compared to Active Surveillance

[1] Ploussard G et al. "Whole-gland or Subtotal High-intensity Focused Ultrasound Versus Radical Prostatectomy: The Prospective, Noninferiority, Nonrandomized, HIFI Trial." *European Urology*, November 2024. DOI: 10.1016/j.euro.2024.11.006, [2] Ploussard G et al. "HIFI-2: Prospective nationwide study across 32 centers in France, 531 patients. ADT-free survival 71% at 30 months." *European Urology Oncology*, 2025, [3] Yeh HT et al. "10-year oncological outcomes of EBRT versus HIFU for stage II prostate cancer: a multicenter Chang Gung Research Database (CGRD) study with inverse-probability-of-treatment weighting (IPTW) analysis." *International Urology and Nephrology*, 2025. DOI: 10.1007/s11255-025-04805-7, [4] Baco E et al. "Final 3-year outcome of Focal Ablation versus Radical Prostatectomy (FARP) Randomized Controlled Trial." Presented at 120th AUA Annual Meeting, April 27, 2025. NCT03668652, [5] S. Crouzet et al. Résultat préliminaire de l'étude randomisée HIFUSA, *Progrès en Urologie - FMC*, Volume 35, Issue 7, Supplement, 2025, Pages S114-S115, ISSN 1761-676X,

# Largest Prospective Comparative Multicenter Study in the Treatment of Prostate Cancer

**3,328** Patients

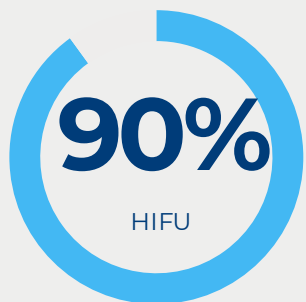
**46** Centers

**80+** Urologists

1

**Cancer Control**  
Primary Endpoint

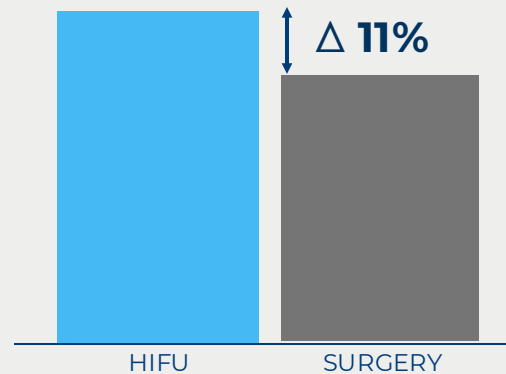
Patients Free from Salvage Treatment at 30 Months



2

**Maintain Urinary Control**  
Secondary Endpoint

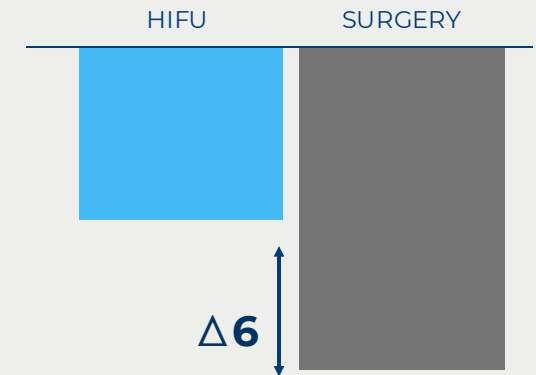
Pad-Free Continence at 12 Months



3

**Preserve Erectile Function**  
Secondary Endpoint

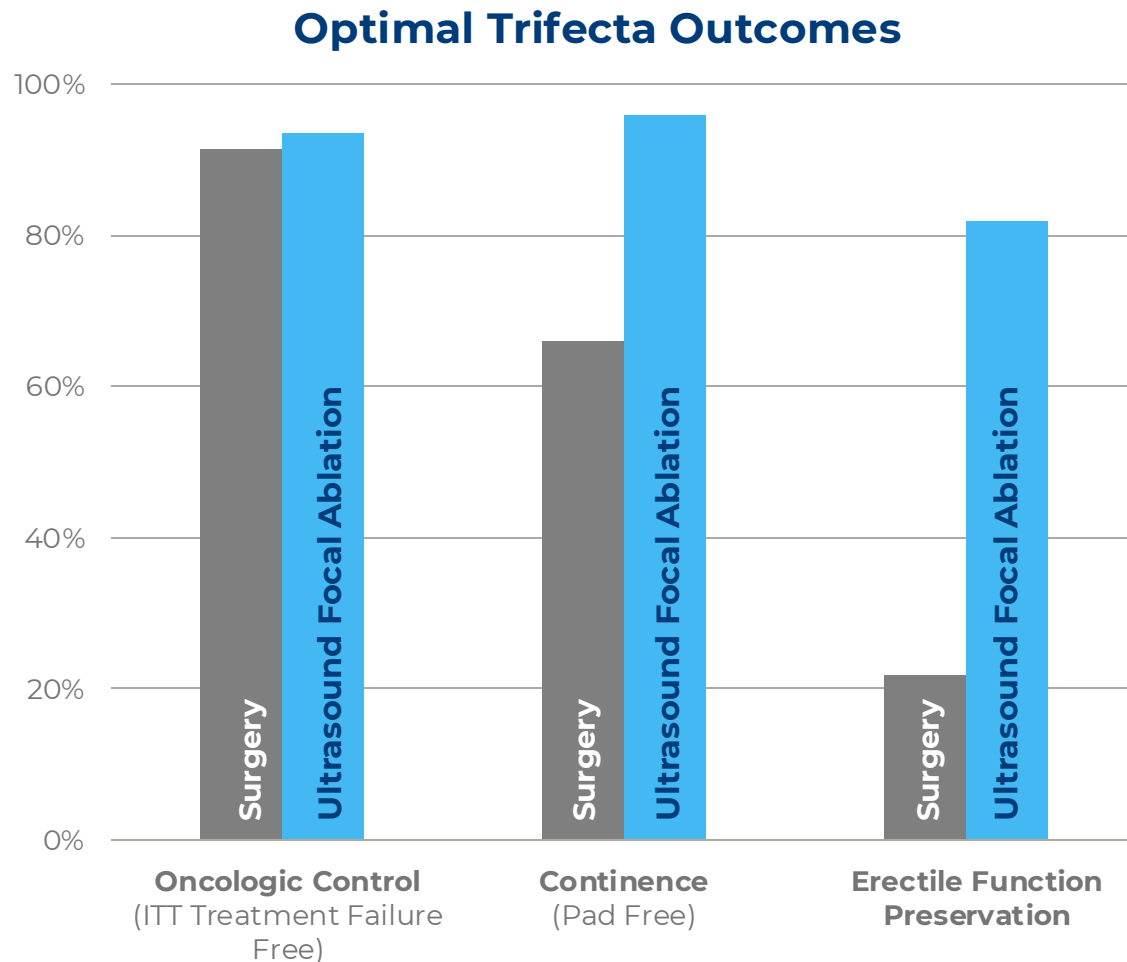
Decrease from Baseline at 12 Months



[1] Ploussard et al. "Whole-gland or Subtotal High-intensity Focused Ultrasound Versus Radical Prostatectomy: The Prospective, Noninferiority, Nonrandomized HIFI Trial." European urology vol. 87,5 (2025): 526-533. doi:10.1016/j.euro.2024.11.006

## FARP: Focal Ablation vs Radical Prostatectomy

# Level 1 Evidence from RCT Validates HIFI Study Outcomes<sup>1,2</sup>



### 213 Patients

Randomized Controlled Trial

**Equivalent Oncologic Control**  
at 3 years (93.5% TFF vs 91.5%)

**Superior Functional Outcomes**

### 25% of Patients

Refused Radical Prostatectomy  
after Randomization and Chose  
Focal Ablation

# Growing Global Adoption of Focal One Robotic HIFU



# FOCAL ONE ADOPTION ACCELERATING At Major U.S. Hospitals

91 Focal One Systems as of Mar. 31, 2026  
(43 Academic – 48 Community)



Focal One is the Leading Focal Therapy Technology

# Strong Adoption by the Highest Ranked Prostate Cancer Hospitals in the US



Best Hospitals  
for Urology

**70%**  
7 Out of 10



SUO Approved  
Programs

**66%**  
23 Out of 35



NCCN Member  
Institutions

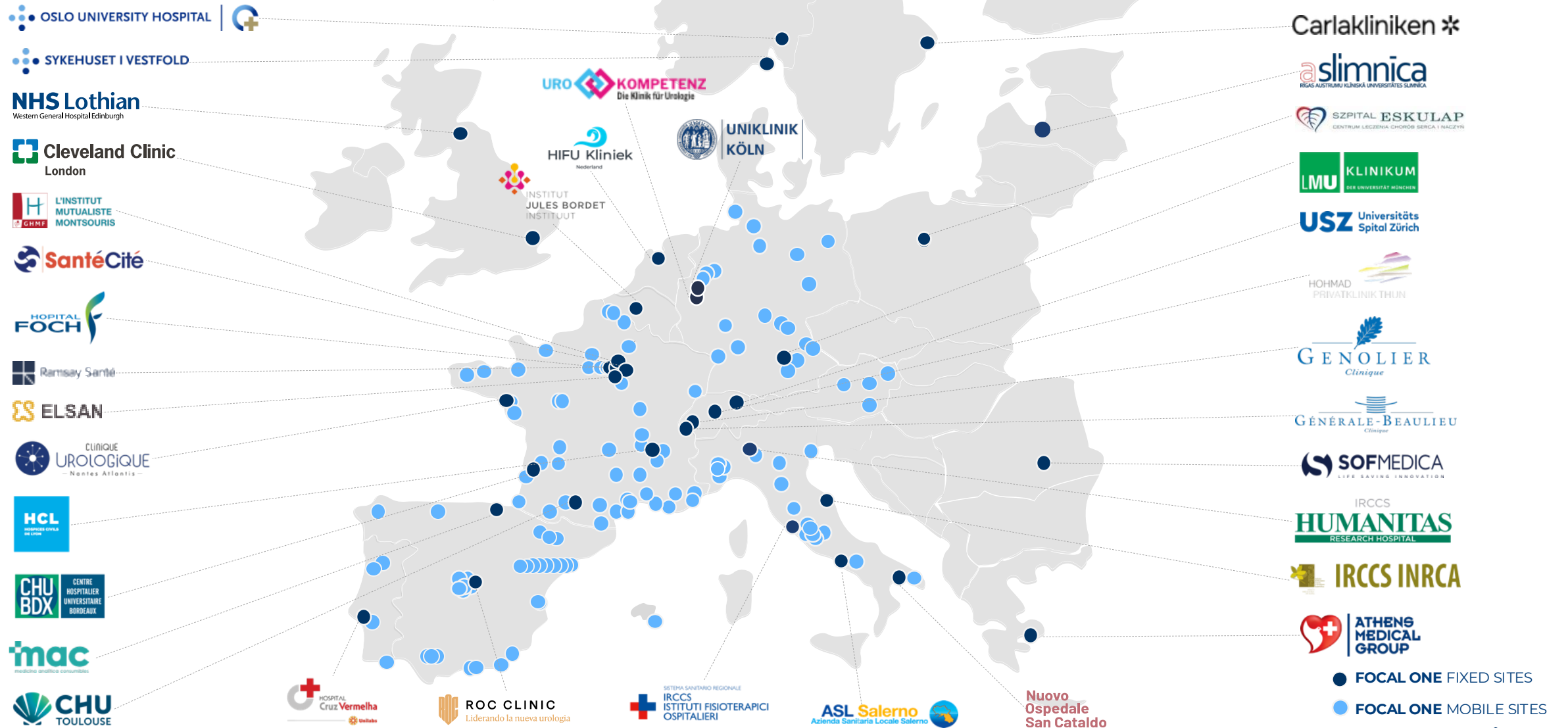
**58%**  
19 Out of 33





# FOCAL ONE ADOPTION ACCELERATING At Major European Hospitals

41 Focal One Systems as of Dec. 31, 2025  
254 Focal One Treatment Clinical Sites

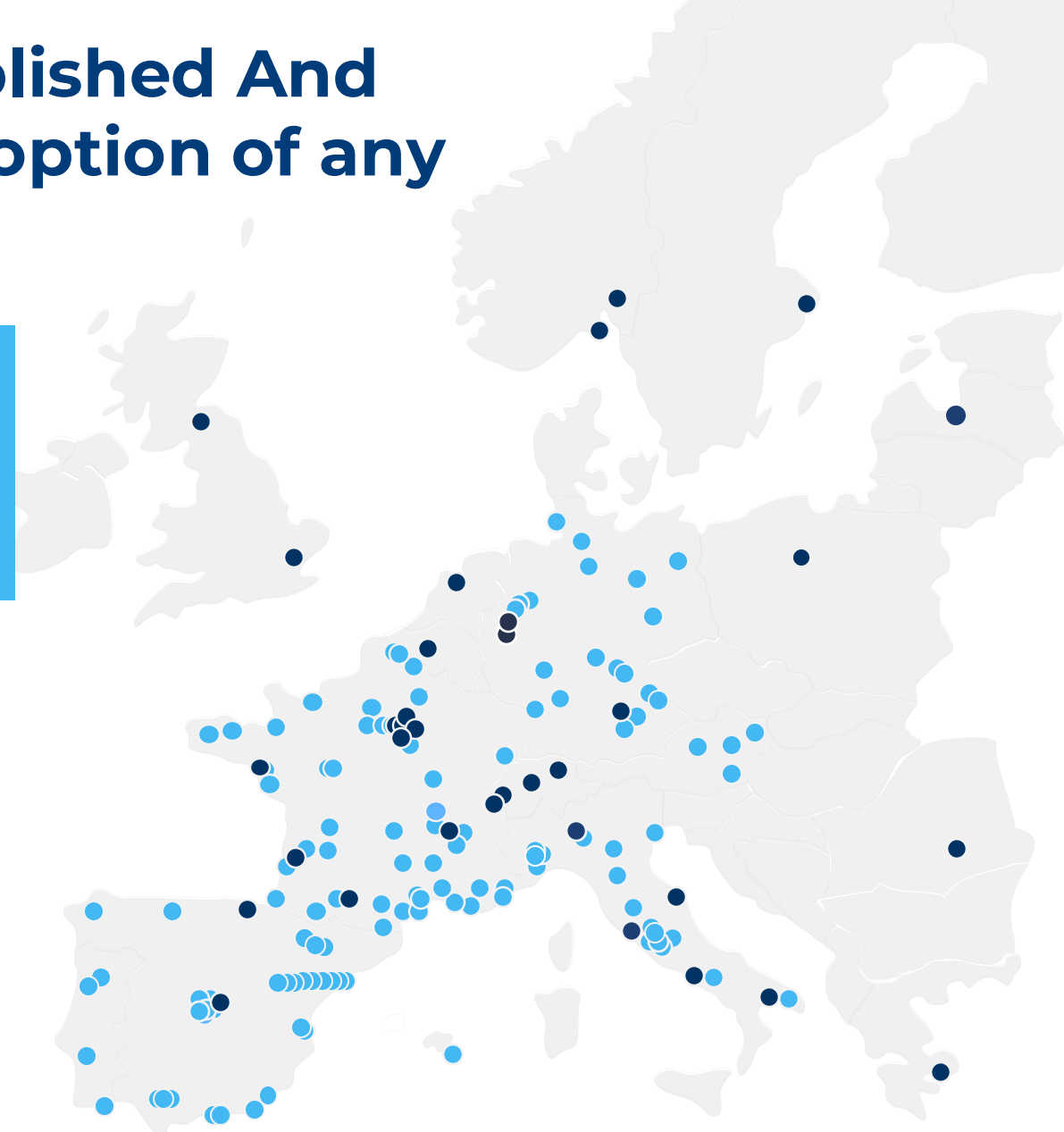
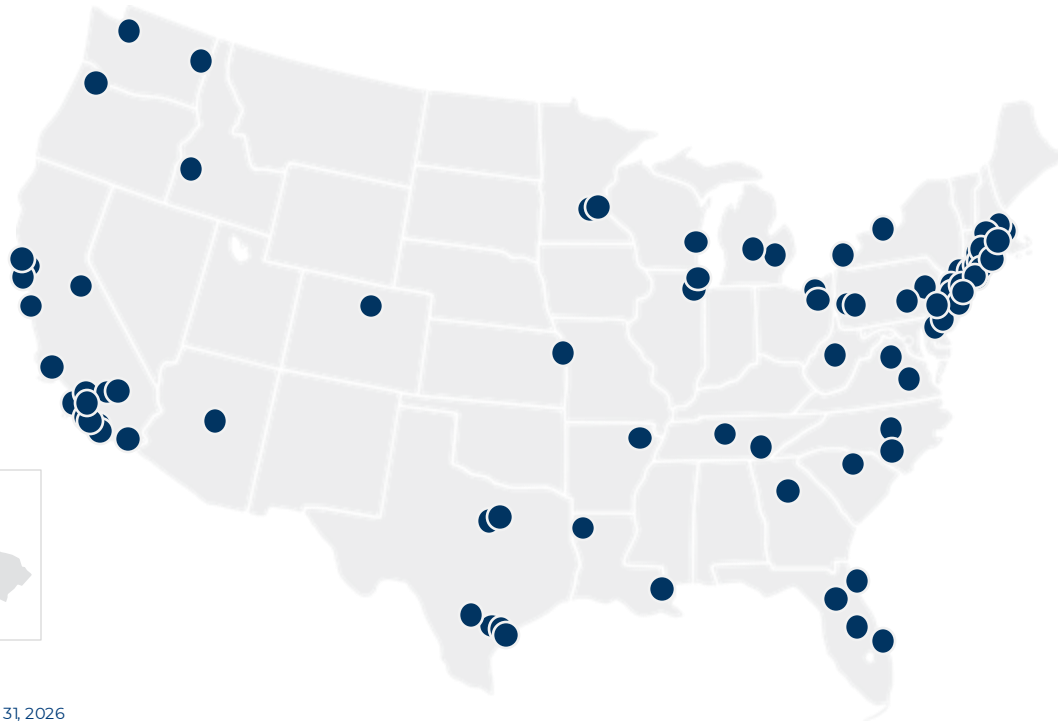


# FocalTherics has the Most Established And Growing Global Commercial Adoption of any Focal Therapy Company

**175+**

Installed Base<sup>1</sup>

Full Spectrum of  
**Academic** Centers, Large  
**Community** Hospitals &  
**Regional** Centers



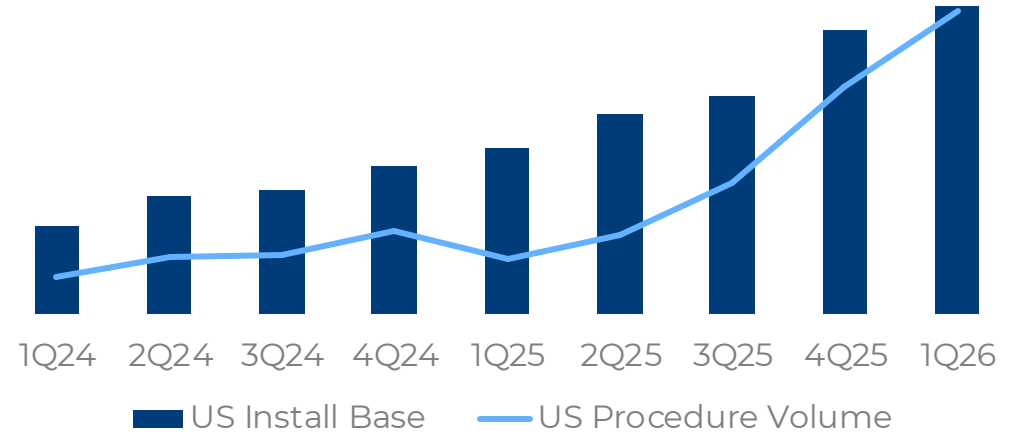
● FOCAL ONE FIXED SITES  
● FOCAL ONE MOBILE SITES

FocalTherics™

[1] As of March 31, 2026

# Consistent Execution Driving Durable Growth

## U.S. Market



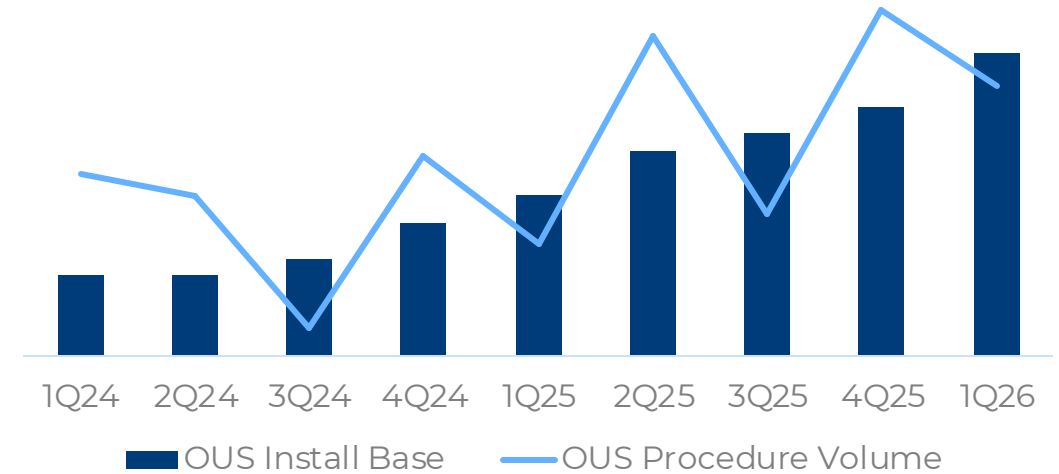
**91**  
Installed Base<sup>1</sup>

**53%**  
Procedure Volume Growth<sup>1</sup>

- Expanding Installed Base at Community Hospitals and Major Health Systems, Including Opportunities for Multi-System Sites
- Growing Physician Adoption Through Education, Training, and Clinical Evidence
- Driving Patient Demand for a Non-Invasive, Effective, Function Preserving Treatment Option

# Sharpened Commercial Strategy in Key Markets

## O.U.S Market



**84**  
Installed Base<sup>1</sup>

**30%**  
Procedure Volume Growth<sup>1</sup>

- Direct Commercial Model in Select Markets (UK, Nordic Countries, etc.)
- Reimbursement Established in France from HIFI Study
- Converting a Legacy Mobile System Service Model to Capital Sales
- Initial Entry into India and LatAm Countries
- Early Launch in Endometriosis Driving Multi-Specialty Sales

[1] As of March 31, 2026

# Executing Disciplined Commercial Strategy for Scalable Growth

## Targeting

### Account Activation

- Expand Installed Base through Sales to Greenfield High-Volume Centers
- Prioritize Accounts with Multi-System and Multi-Urologist Opportunities

**<10%**

Penetration into Initial Target Market Leaves Substantial Runway

## Building

### Program Building

- Drive Increased Utilization with Physician Training, Education & Clinical Evidence
- Develop Robust Patient Pipeline through Dedicated Hospital Marketing and Program Support

**53%**

YoY Procedure Growth in Q1 2026

## Scaling

### Program Independence

- Transition Sites to Clinically Autonomous Programs
- Reduce Reliance on Clinical Staffing as Programs Mature

**70%**

U.S. Procedures YTD Required No Clinical Application Support

**Non-Invasive Targeted Ablation**

**Don't Let Prostate Cancer Slow You Down**

**How Does HIFU Work?**  
HIFU technology targets prostate tissue by focusing high-intensity focused ultrasound waves on the affected area. This results in a localized effect that destroys only the targeted cells without damaging healthy surrounding tissue and critical structures.

**Find Out More About Robotic Focal One**  
Don't Let Prostate Cancer Slow You Down. Discover the power of Robotic Focal One and how you can change your prostate health without changing your life.

**Focal One Robotic HIFU is FDA Cleared and covered by many carriers by Medicare or commercial insurance providers.**



**Know Your Treatment Options for Prostate Cancer**

**Minimal Side-Effects**  
Focal Robotic HIFU has a low risk of side effects such as Erectile Dysfunction and Incontinence.

**A Non-Invasive Procedure**  
For most prostate cancer patients, Robotic Focal HIFU offers advantages over other options. Focal One is a non-invasive procedure that uses precise imaging and robotic technology to target and ablate only the affected prostate tissue while preserving surrounding critical structures.

**No Surgery, No Cutting, No Dissection**  
Robotic HIFU is a non-invasive procedure, which means there is no surgery, no cutting, no radiation. The treatment minimizes the impact on overall neighboring structures such as the urinary sphincter and erectile nerves. Unlike radical treatments such as surgery or radiation that affect the whole gland, HIFU may damage surrounding tissue and structures. Focal Robotic HIFU precisely targets only the diseased part of the gland.

**Ask About Robotic Focal HIFU**  
Your prostate health starts here. With Robotic Focal High-Intensity Focused Ultrasound (HIFU).



**Winning The Race Against Prostate Cancer.**

Change Your Prostate Health, Without Changing Your Life.

**Important Facts About Prostate Cancer**

1 in 8 Men will be diagnosed with Prostate Cancer in their lifetime.

Prostate Cancer is the 2nd most common Cancer in American men.

3,100,000 Over 3.1 Million Men in the United States are living with Prostate Cancer.

For more information, visit: [www.saintalphonsus.org/services/cancer-care/high-frequency-ultrasound](http://www.saintalphonsus.org/services/cancer-care/high-frequency-ultrasound)



**Offering a Non-Invasive Option for Prostate Cancer**

Using Robotic Focal HIFU Precision with Minimal Side Effects.



**WHAT IS HIGH-INTENSITY FOCUSED ULTRASOUND (HIFU)?**  
HIFU is a non-invasive, nonsurgical option offered to certain prostate cancer patients. This technology ablates prostate tissue by focusing high-intensity ultrasound waves on the affected area, causing localized heating that destroys the cells in the gland without damaging the healthy surrounding tissue. Focused ultrasound works in the same way as rays of sunlight that pass through a magnifying glass and are concentrated at a single point, equally causing a significant temperature to rise around the focal point.

**WHAT ARE THE ADVANTAGES OF HIFU TREATMENTS?**

**Non-Invasive Procedure**  
It is a non-invasive procedure with no surgery, no cutting, and no radiation.

**Quality of Life**  
Quality of life is preserved. Patients will be back to their day-to-day, regular activities shortly after the procedure.

**Outpatient Procedure**  
It is performed in an outpatient setting, meaning patients will go home the same day.

**Minimal Side Effects**  
There is a low risk of side effects such as incontinence and erectile dysfunction.

For more information, visit: [www.saintalphonsus.org/services/cancer-care/high-frequency-ultrasound](http://www.saintalphonsus.org/services/cancer-care/high-frequency-ultrasound)





**Saint Alphonbus Brings Latest in Non-Invasive Robotic Procedure for Prostate Cancer**

An estimated 1 in 8 men will be diagnosed with prostate cancer in their life, according to the American Cancer Society, and in Idaho, the rate of prostate cancer is higher than national averages, making access to technological solutions critical in earlier detection and diagnosis.

Saint Alphonbus is addressing this need with groundbreaking, non-invasive robotic technology for the treatment of prostate cancer patients known as the Focal One Robotic High-Intensity Focused Ultrasound (HIFU) technology. This is the only technology of its kind in the state of Idaho and within 400 miles of Boise.

"The procedure is non-invasive, meaning no blade, scar, radiation, or incision is involved," said Shelly Gorman, Saint Alphonbus Health System's Oncology and General Surgery Service Line Director. "HIFU is part of Saint Alphonbus's ongoing commitment to offer cutting edge and advanced minimally invasive and robotic surgical procedures to our patients. It supports in our mission to provide care close to home so patients will no longer need to leave the community to receive this care."

HIFU applies high-intensity ultrasound waves to remove prostate tissue. By focusing these waves on the affected area in one session under general anesthesia, HIFU causes localized heating that destroys the cells within the gland without harming healthy tissue nearby. The risk of side effects, such as incontinence and erectile dysfunction, following the treatment is low compared to



**WHAT TO EXPECT ON THE DAY OF YOUR HIFU PROCEDURE?**

- The patient arrives the morning of the treatment, and will have completed a bowel prep the night before.
- The patient is administered general anesthesia.
- The treating urologist will then perform the procedure with the Focal One robotic system with precision and accuracy, ablating only the targeted tissue.
- Typically, the patient is discharged shortly after the procedure with a Foley catheter.

**WHAT HAPPENS AFTER YOUR HIFU PROCEDURE?**  
At the end of the procedure, a temporary urinary catheter will be placed in order to limit the risk of urinary retention due to the temporary swelling. You will be discharged and can return home after the end of the procedure. The catheter will be removed at the first follow-up visit a few days later (5-7 days). Typical follow-up will include PSA testing at three months, six months, and one year, as well as an MRI image. This follow-up can be performed by the treating urologist, or if you travelled from a remote location, your local urologist.

**HOW TO CARE FOR YOUR CATHETER**

- Clean your catheter on a daily basis.
- Change your drainage bag two times a day.
- Wash your drainage bags every day.
- Keep hydrated, drinking one to two glasses of liquids every two hours.

**WHAT HAPPENS AFTER YOUR HIFU PROCEDURE?**  
Medications: Patients should consult with their physician regarding when to stop taking medications prior to the treatment. In some cases, patients can take their morning medications with a small sip of water. Certain blood thinning medications should be stopped several days before surgery. Diabetes medication and water pills should not be taken on the morning of procedure.

For more information, visit: [www.saintalphonsus.org/services/cancer-care/high-frequency-ultrasound](http://www.saintalphonsus.org/services/cancer-care/high-frequency-ultrasound)




**What is Focal One® HIFU?**


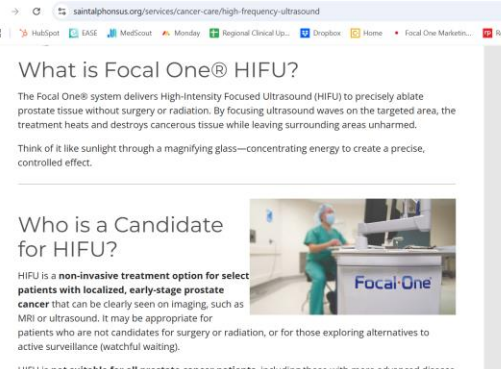
The Focal One® system delivers High-Intensity Focused Ultrasound (HIFU) to precisely ablate prostate tissue without surgery or radiation. By focusing ultrasound waves on the targeted area, the treatment heats and destroys cancerous tissue while leaving surrounding areas unharmed.

Think of it like sunlight through a magnifying glass—concentrating energy to create a precise, controlled effect.

**Who is a Candidate for HIFU?**

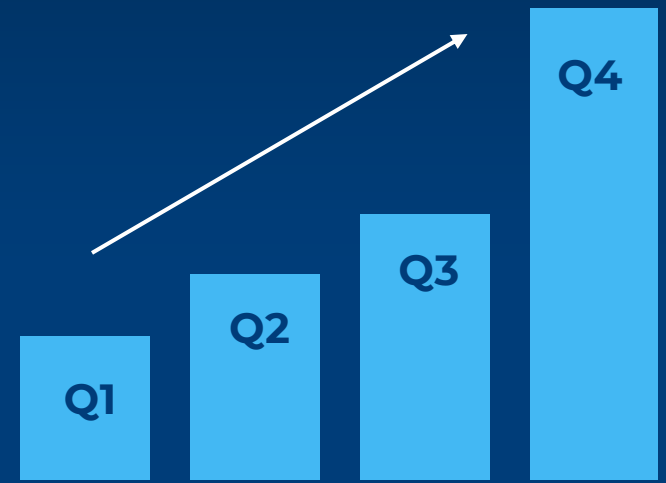
HIFU is a non-invasive treatment option for select patients with localized, early-stage prostate cancer that can be clearly seen on imaging, such as MRI or ultrasound. It may be appropriate for patients who are not candidates for surgery or radiation, or for those exploring alternatives to active surveillance (watchful waiting).

HIFU is not suitable for all prostate cancer patients, including those with more advanced disease.

# Program Launch Excellence

## Saint Alphonbus Medical Center: Boise, ID



Significant Case Volume Growth in First Year of Program Launch

STRONG REIMBURSEMENT  
**Creates Favorable  
Environment  
for Growth**



- 1. Cat. 1 CPT® Code at APC Level 6**
- 2. Favorable Physician Payment**
- 3. Growing Coverage**

# Hospital Outpatient Medicare Payment

Procedure	CPT® Code	2026 Payment	
Prostate Brachytherapy	55875	\$5,478	
Cryo Ablation	55873	\$9,671	
<b>HIFU</b>	<b>55880</b>	<b>\$9,671</b>	<b>+4.3%</b>
Laparoscopic/Robotic Prostatectomy	55866	\$10,860	

# Favorable Physician Payment

## Procedure

## CPT® Code

## Work RVU

(2026)

## Physician Payment

(Medicare - 2026)

MRI Transurethral Ultrasound Ablation

55882

11.21

\$530

Prostate Brachytherapy

55875

13.12

\$693

Cryo

55873

13.26

\$692

Irreversible Electroporation

55877

13.50

\$675

**HIFU**

**55880**

**17.29**

**\$884**

Laparoscopic/Robotic Prostatectomy

55866

21.90

\$1,087

# Expanding Patient Access

**Medicare Coverage:** Automatic for All Patients Nationwide

**National and Local Plans** may Provide Individual Payment According to their Coverage Policies and/or Local Arrangements

**Existing and Upcoming Positive Clinical Evidence** will Provide Broader and Expanded Coverage



# Clinical Expansion of our Focal One Platform

BPH and Endometriosis

# Benign Prostatic Hyperplasia (BPH) Market

**100+ Million<sup>1</sup>**

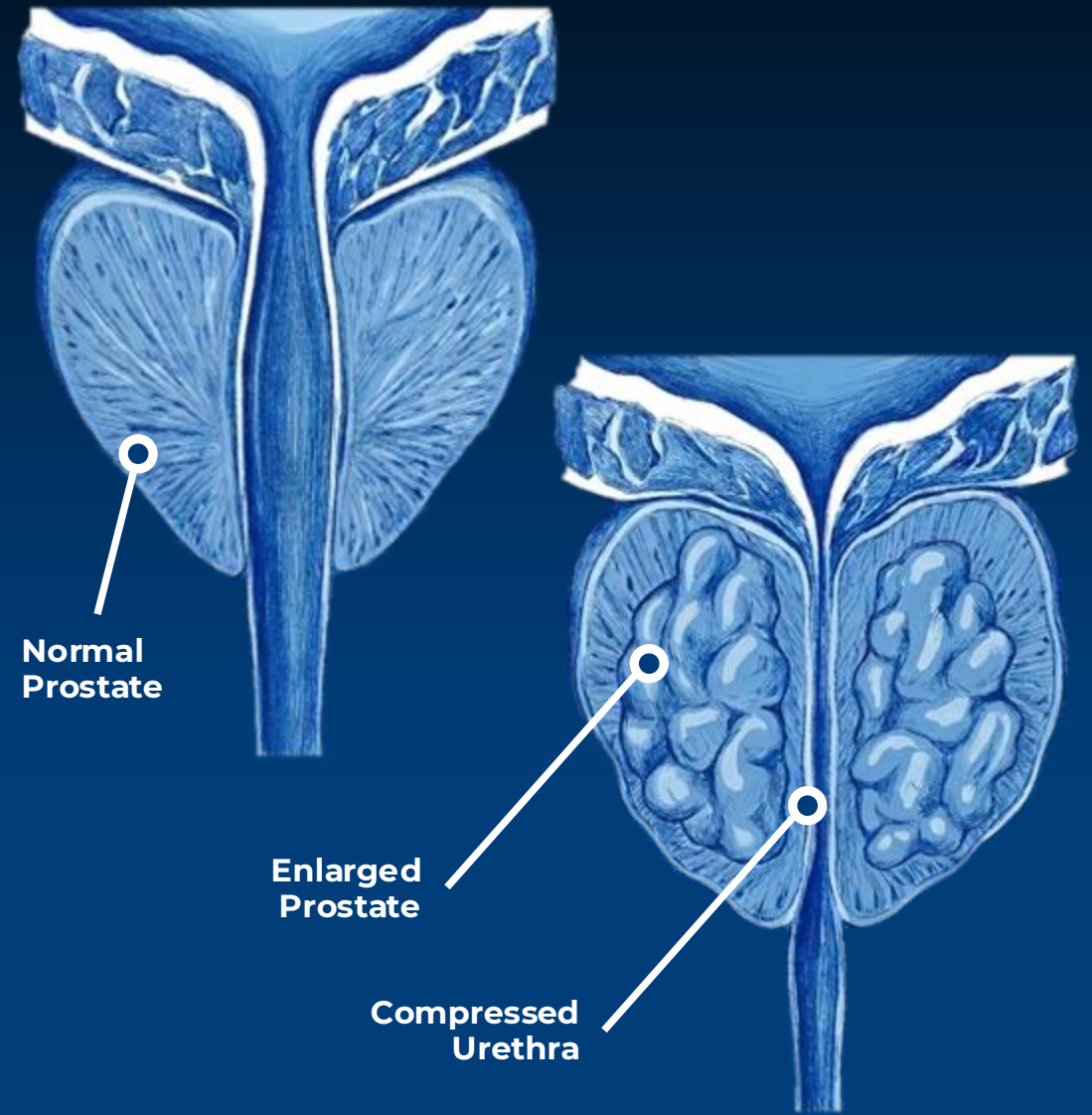
Men Living with BPH Globally

**13+ Million<sup>1</sup>**

New Cases Diagnosed Annually, Globally

**600,000+<sup>2</sup>**

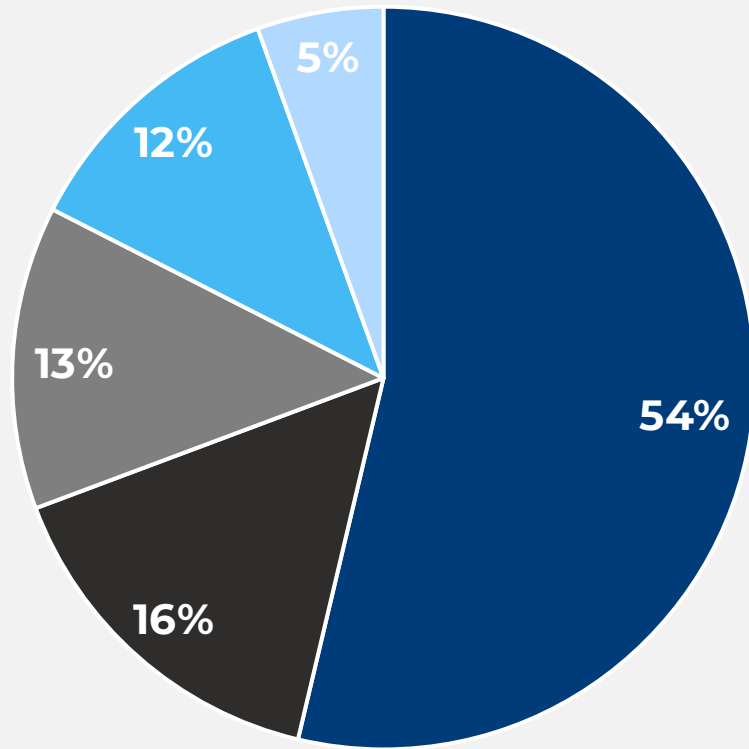
New Cases Diagnosed in the U.S.



[1] Chen X, Yang S, He Z, Chen Z, Tang X, Lin Y, Huang Y, Hou J, Wei X. Comprehensive analysis of the global, regional, and national burden of benign prostatic hyperplasia from 1990 to 2021. Sci Rep. 2025 Feb 15;15(1):5644. doi: 10.1038/s41598-025-90229-3. PMID: 39955408; PMCID: PMC11830103.

[2] Urologic Diseases in America. 2024. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases. 2024

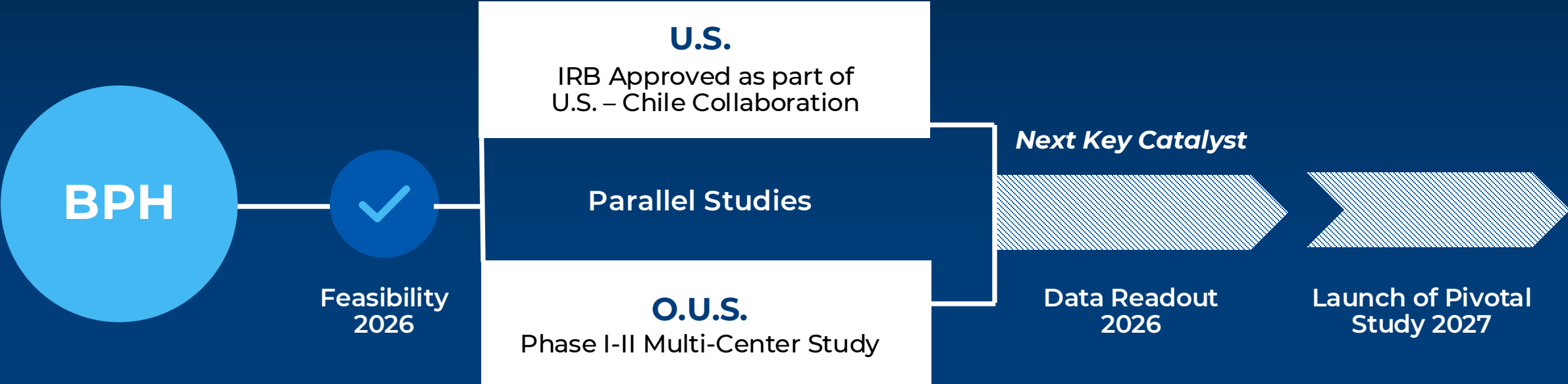
# BPH Treatment is a Highly Fragmented Market



■ TURP ■ Aquablation ■ Urolift ■ HoLEP ■ Rezum

Focal One will be the **ONLY Non-Invasive, Non-Surgical** Focal Therapy Solution

# BPH Indication Expansion Pipeline



# A BPH Solution Designed to Meet Patient Priorities

**Non-Invasive**

**No Bleeding**

**No Foreign Body**

**No Quality-of-Life Tradeoffs**



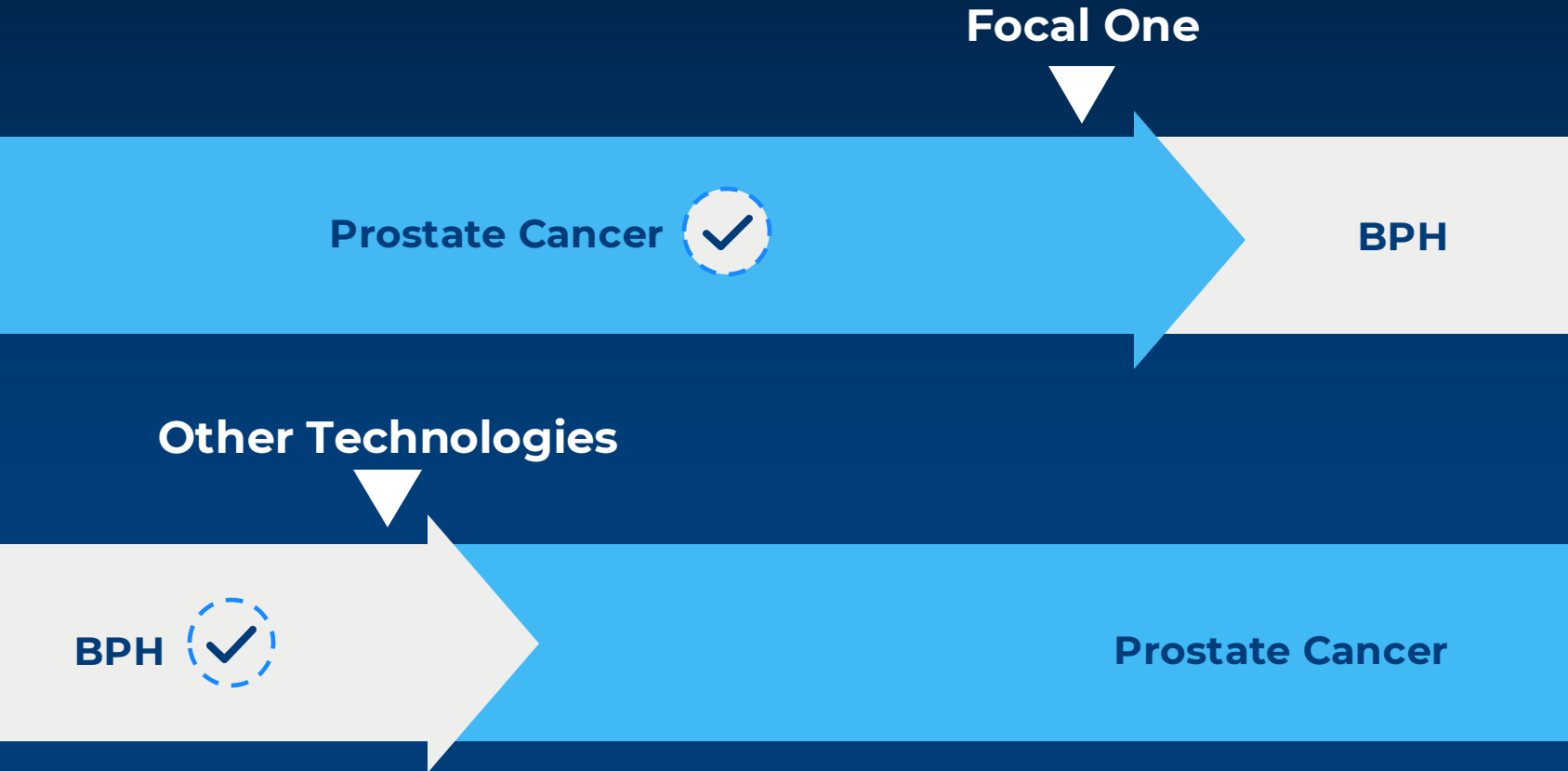
Particularly Compelling for the Growing Number of  
**BPH Patients on Anti-Coagulation Medication**  
who are at Risk of Bleeding Complications

# Ideally Suited to Capture Significant Portion of BPH Market



- **Same** Focal One Platform
- **Same** Installed Base
- **Same** Urology Call Point
- **Same** Physicians & Staff

# Straightforward Pathway to Additional Prostate Indications



## Payment and Coding

Freedom to Operate

CPT Category 3 Code  
(Transrectal HIFU Treatment,  
*Specifically* for BPH)

## Regulatory

Enrolling Parallel  
Studies

14 Patients Treated  
in Latin America

# Deep Infiltrating Endometriosis (DIE)

**38M**

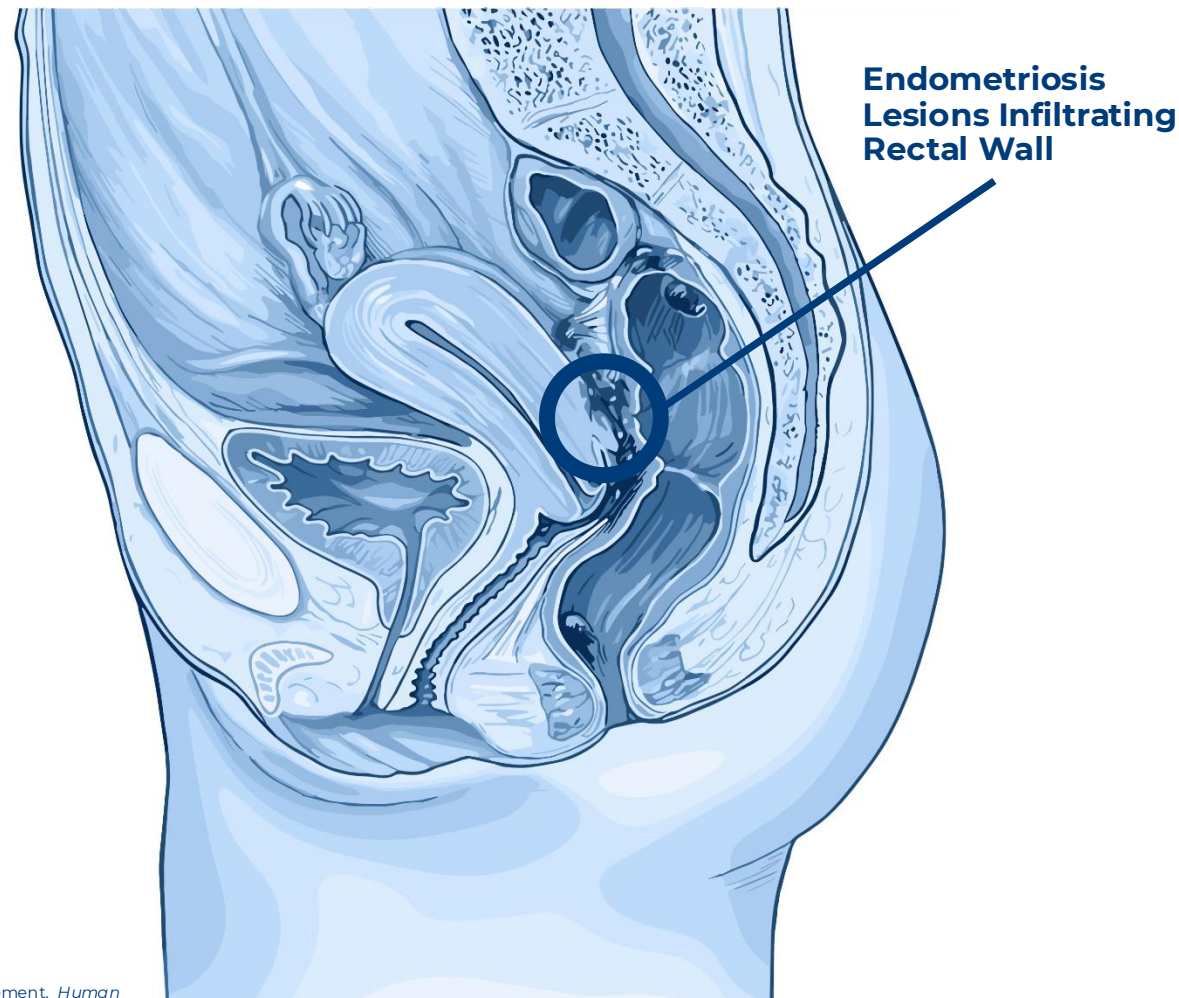
Women Living with Deep Infiltrating Endometriosis Globally<sup>1,2,3,4</sup>

**783,000+**

Patients Diagnosed with Deep Rectal Endometriosis Globally<sup>1,2,3,4</sup>

**225,000+**

Patients Diagnosed with Deep Rectal Endometriosis in U.S.<sup>1,2,3,4</sup>



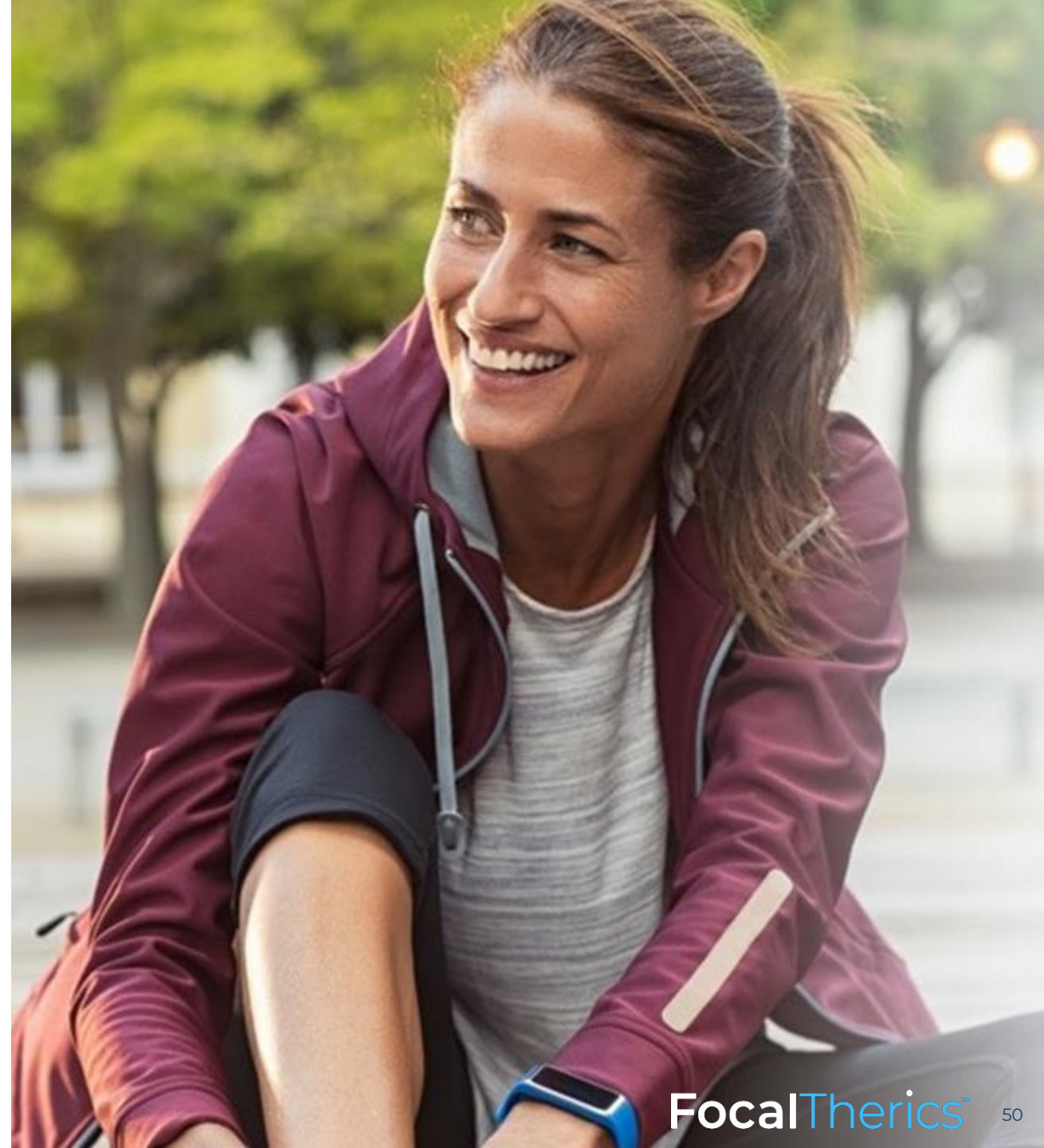
[1] Abrão MS, Petraglia F, Falcone T, Keckstein J, Osuga Y, Chapron C. Deep endometriosis infiltrating the recto-sigmoid: critical factors to consider before management. *Human Reproduction Update*, 2015; 21(3):329-339. [2] Wenwei Li, Huiyan Feng, Qingjian Ye. Factors contributing to the delayed diagnosis of endometriosis — a systematic review and meta-analysis. *Frontiers in Medicine*, 2025; doi: 10.3389/fmed.2025.1576490. [3] Agarwal SK, Chapron C, Giudice LC, et al. Clinical diagnosis of endometriosis: a call to action; underdiagnosis estimated at up to 60%. *Della Corte L et al, 2020; cited in scoping review 2024*. [4] United Nations, Department of Economic and Social Affairs, Population Division. *World Population Prospects 2024. Women aged 15-49 by country, 2024 mid-year estimates*. [5] Vercellini P, et al. Surgery versus hormonal therapy for deep endometriosis: hormonal treatment is ineffective or not tolerated in ~30% of women. *Minerva Ginecol*, 2016; PMID 27544308.

# Deep Infiltrating Endometriosis (DIE)

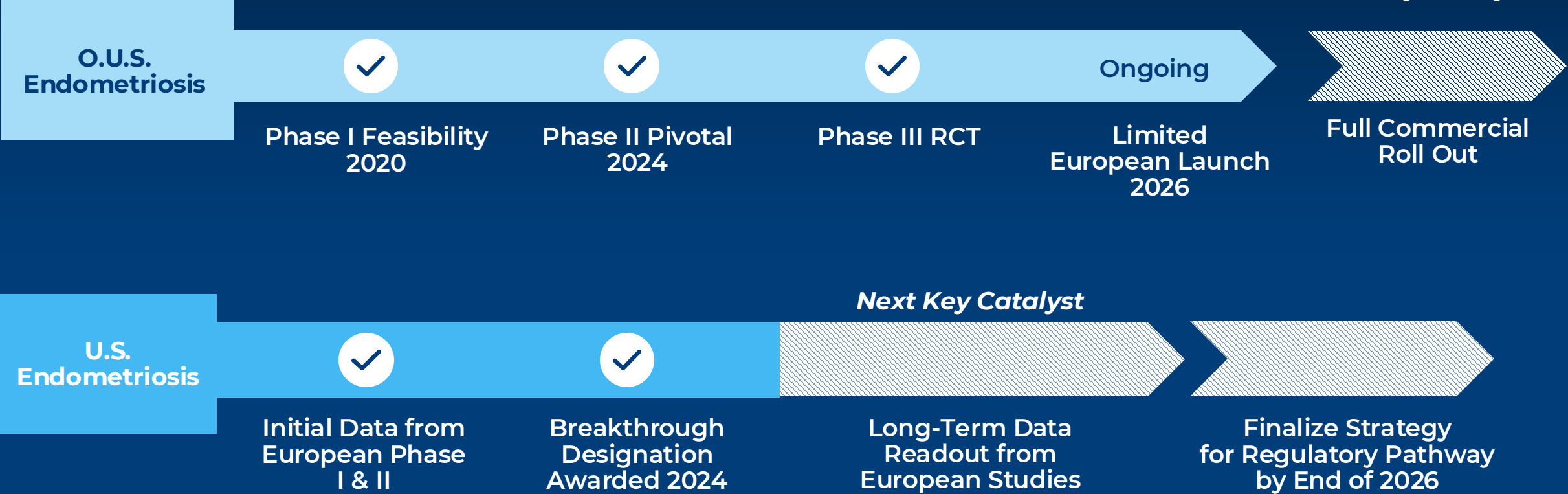
Characterized by Lesions that Penetrate >5mm Below the Peritoneal Surface, Invading Surrounding Structures like the Bowel, Bladder, and Rectum.

Current Treatment Options are Lacking and Limited to Hormonal and/or Surgical Management. When Offered the Choice, **91% of Women Prefer Non-Surgical Options<sup>1</sup>**

[1] Vercellini P, et al. Surgery versus hormonal therapy for deep endometriosis: hormonal treatment is ineffective or not tolerated in ~30% of women. Minerva Ginecol, 2016; PMID 27544308.

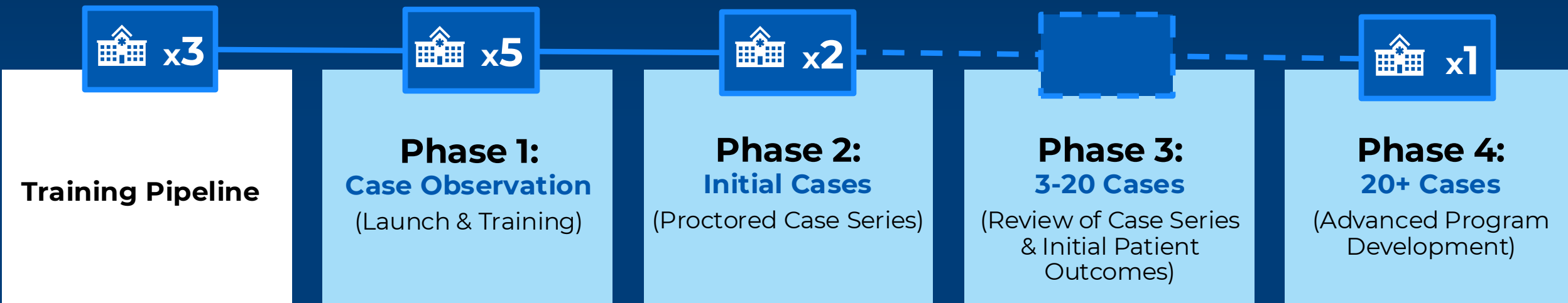


# Endometriosis Indication Expansion Pipeline

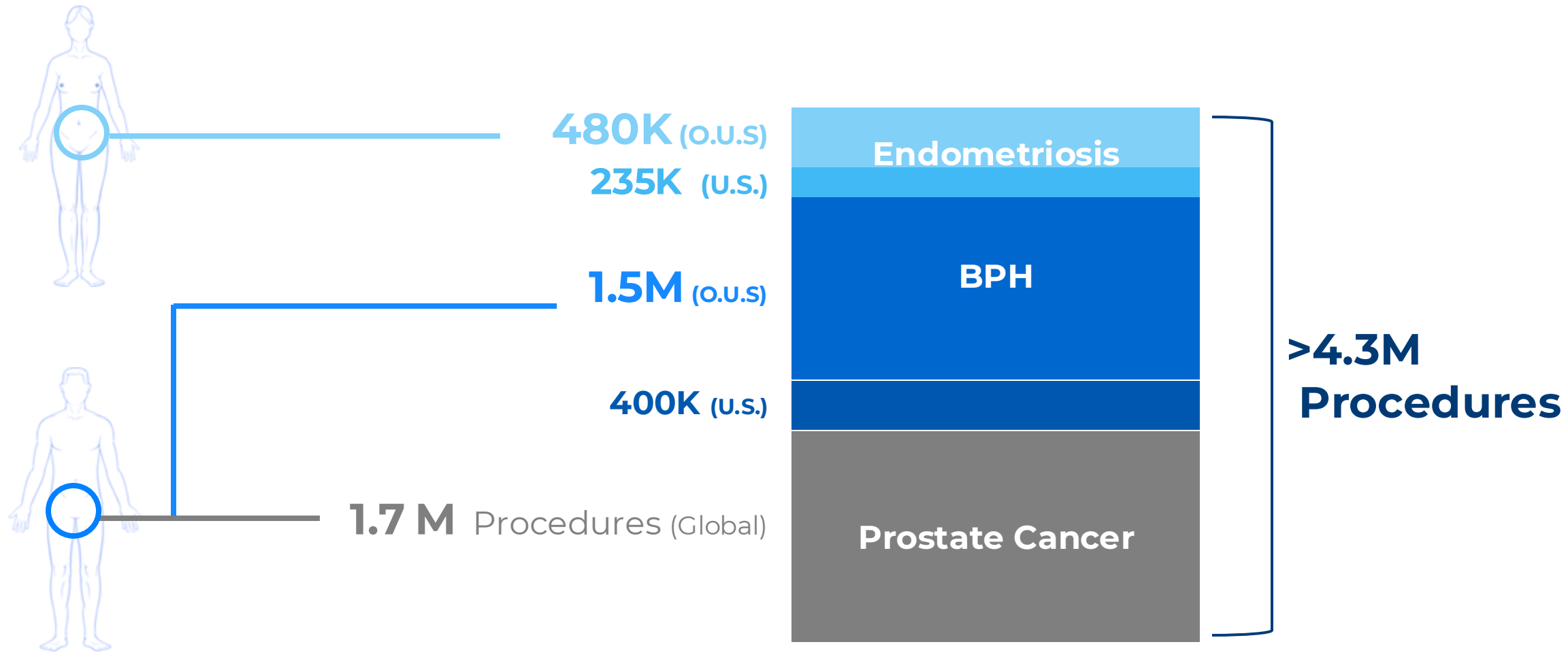


# Phased Launch Program Establishes Framework for Broad Commercial Rollout

Goal to end 2026 with Several Active Reference Centers with Influential Thought Leaders



# Focal One Platform Expansion Opportunity Represents a TAM of **4.3M+<sup>1</sup> Procedures** and **\$10B+ Revenue**



[1] Management Estimates; data on file.

**Behfar Ehdai, MD, MPH**  
Memorial Sloan Kettering Cancer Center



# Focal Therapy for Prostate Cancer and Urologic Oncology: A Paradigm Shift in Treatment

Behfar Ehdaie, MD, MPH  
Associate Member

Urology Service, Department of  
Surgery  
Department of Epidemiology  
and Biostatistics

Memorial Sloan Kettering  
New York, NY

Hello Dr. Ehdaie,

Thank you for getting back to me.

I say this every time I see you ->Thank you. While on long lines for the mens' rooms at sporting events or theaters, I "pee" on command quickly and efficiently like a teenager. I think my friends and husband are jealous. Listening to other guys my age (gay and straight) I think I have a better sex life than they do. I am never short of amazed about how my quality of life, while different, has remained so positive [REDACTED]... BUT I faired sooooo much better than other guys, [REDACTED]

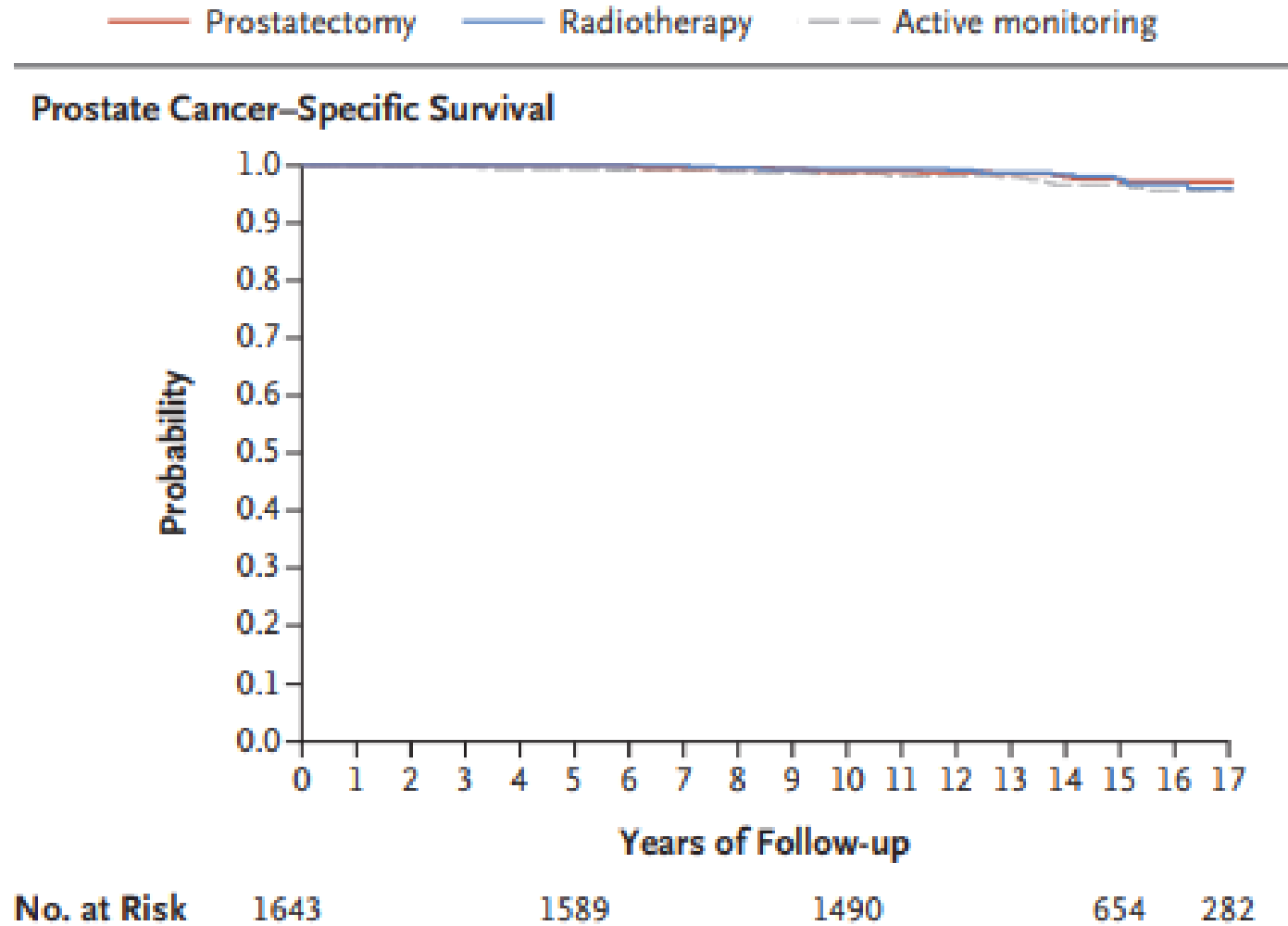
You remain a man who truly made my life better.

No need to reply - you are a busy man.

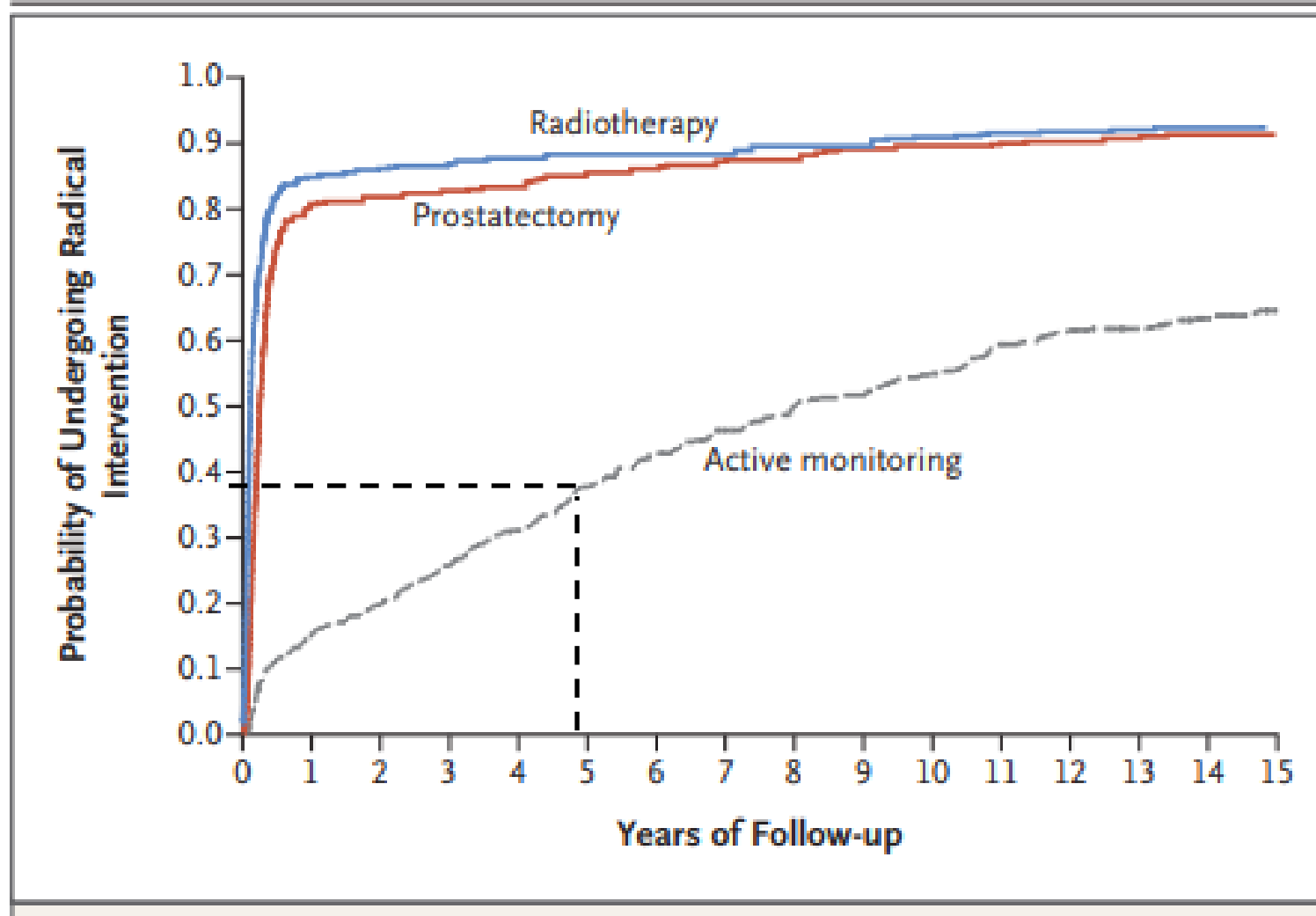
See you in a few months.

[REDACTED]

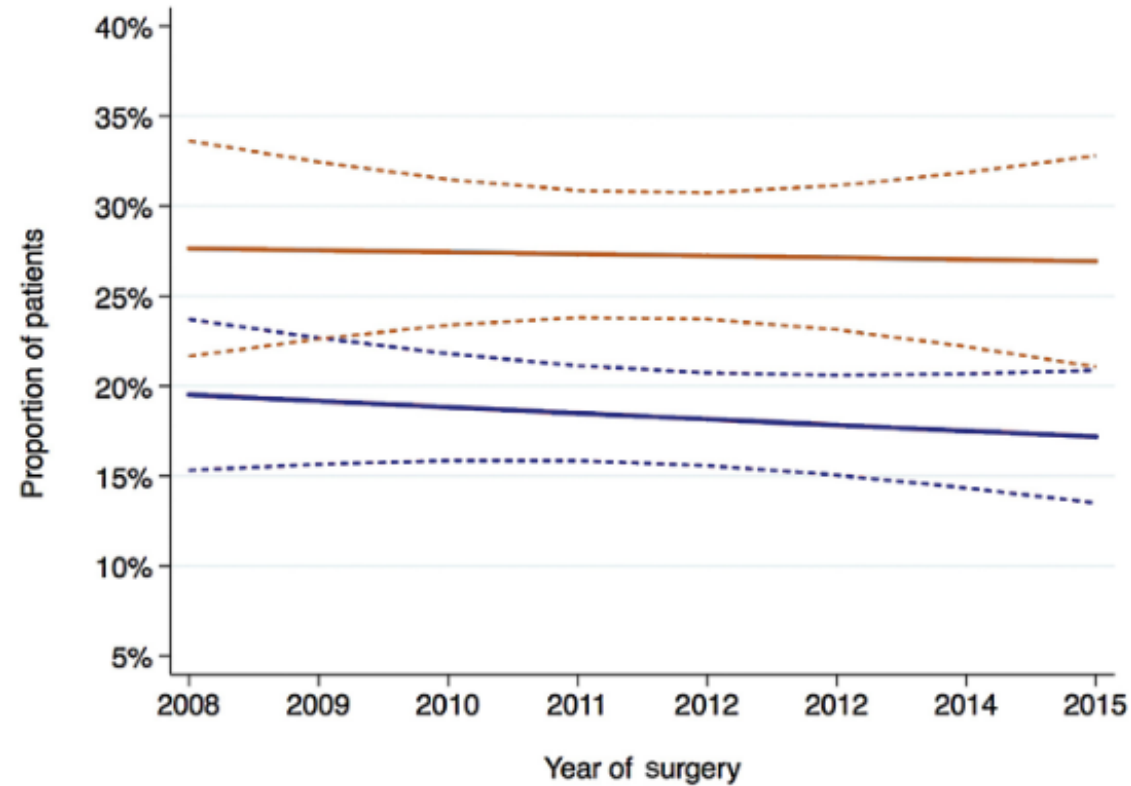
# Overall Prostate Cancer Survival In All Men In The PROTECT Trial: 2.7% At 15 Years



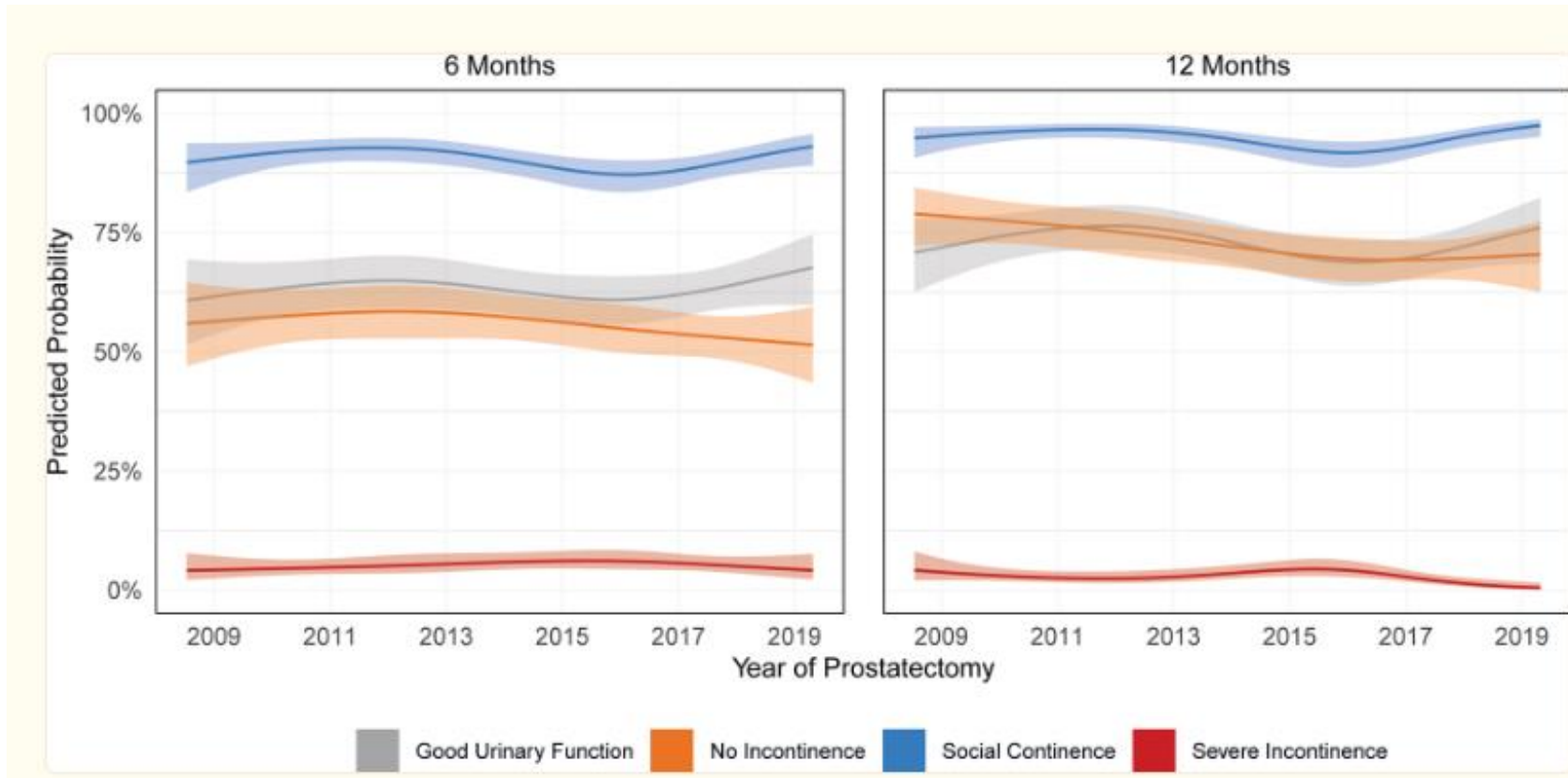
# Approximately 40% Of Men Randomized To Active Monitoring Underwent Radical Prostatectomy Or Radiation Therapy Within 5 Years



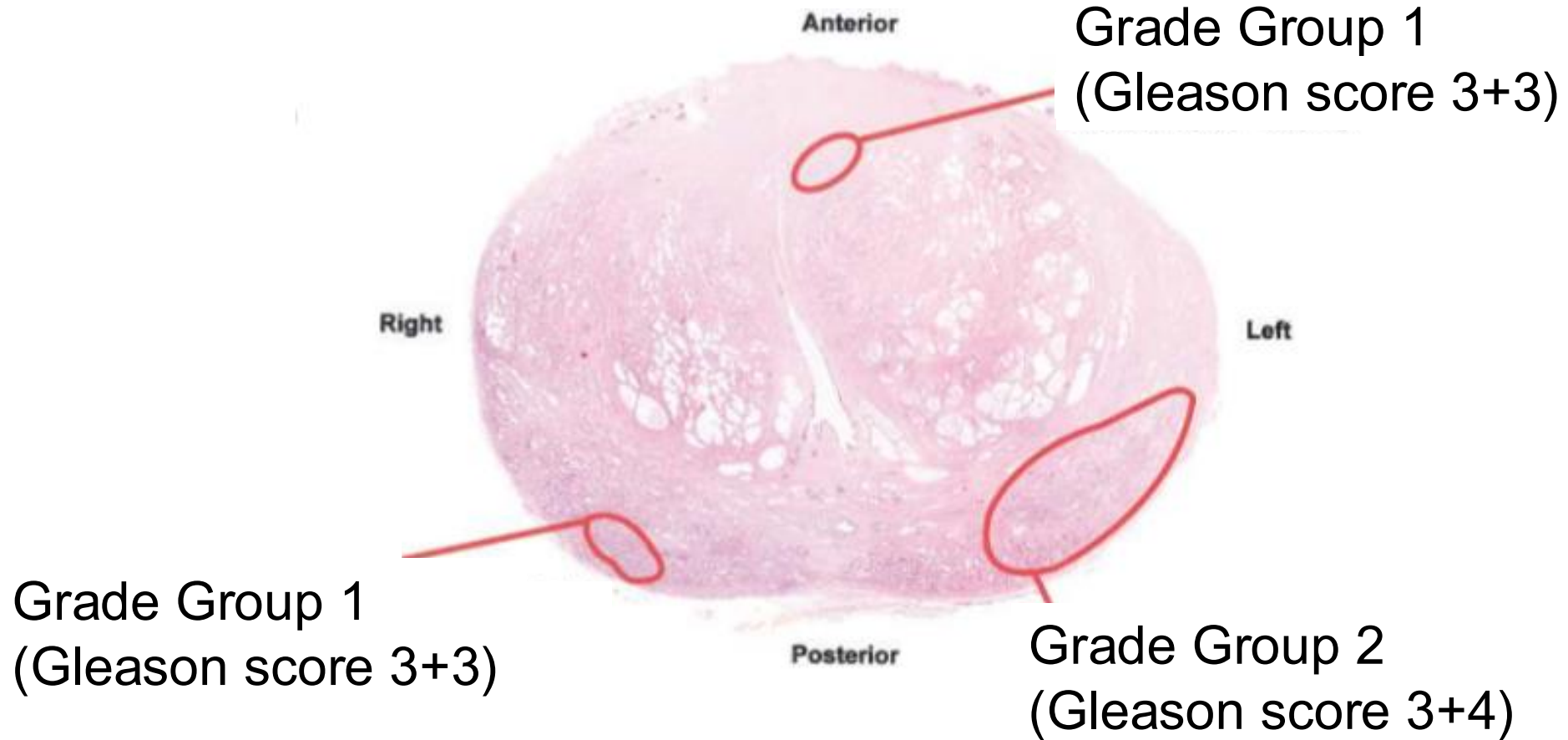
# Has The Probability Of Regaining Sexual Function After Prostate Cancer Surgery Improved Over The Last Decade?



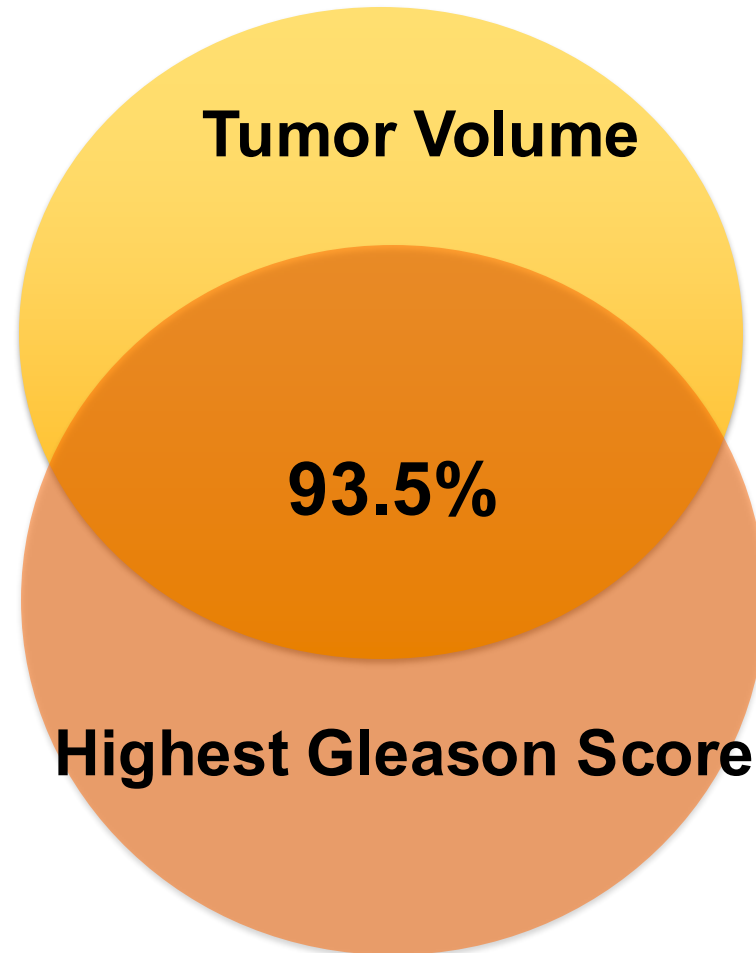
# Similarly, We Have Not Observed Improvements In The Probability Of Regaining Urinary Function After Surgery



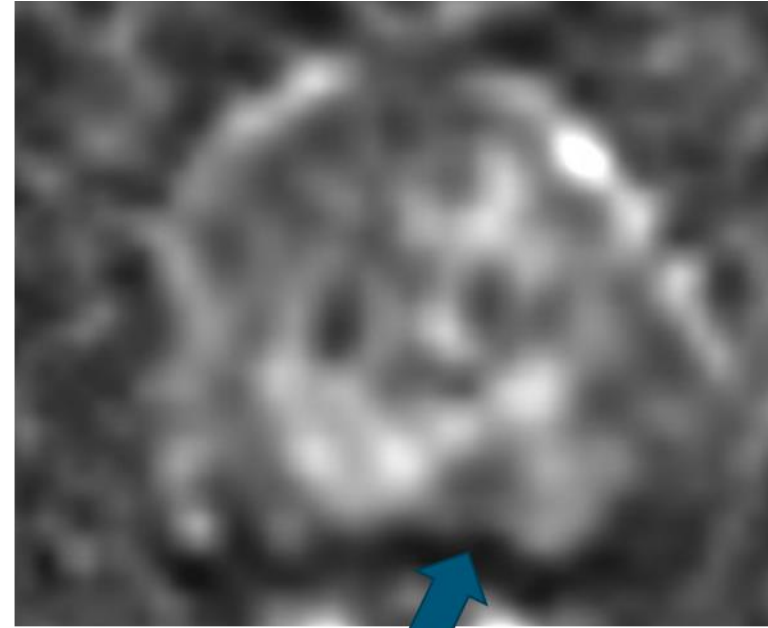
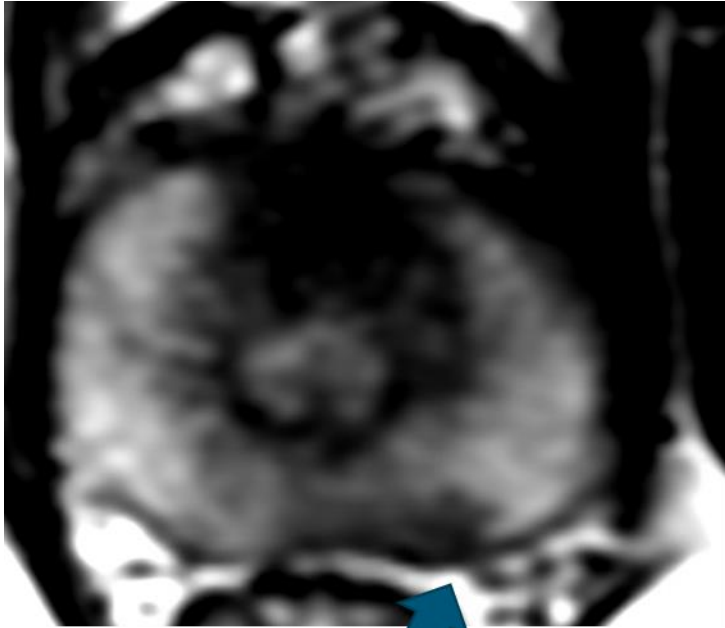
# Overcoming The Problem Of Tumor Multifocality Within The Prostate Has Been Key To The Emergence of Focal Therapy



# Adverse Pathologic Features, Including Highest Stage, Gleason Score, And Tumor Volume Converge To Define The *Index* Lesion



# Multiparametric MRI Is Enabled Physicians To Detect The Index Lesion And Map The Prostate Gland



# Patient Selection Criteria

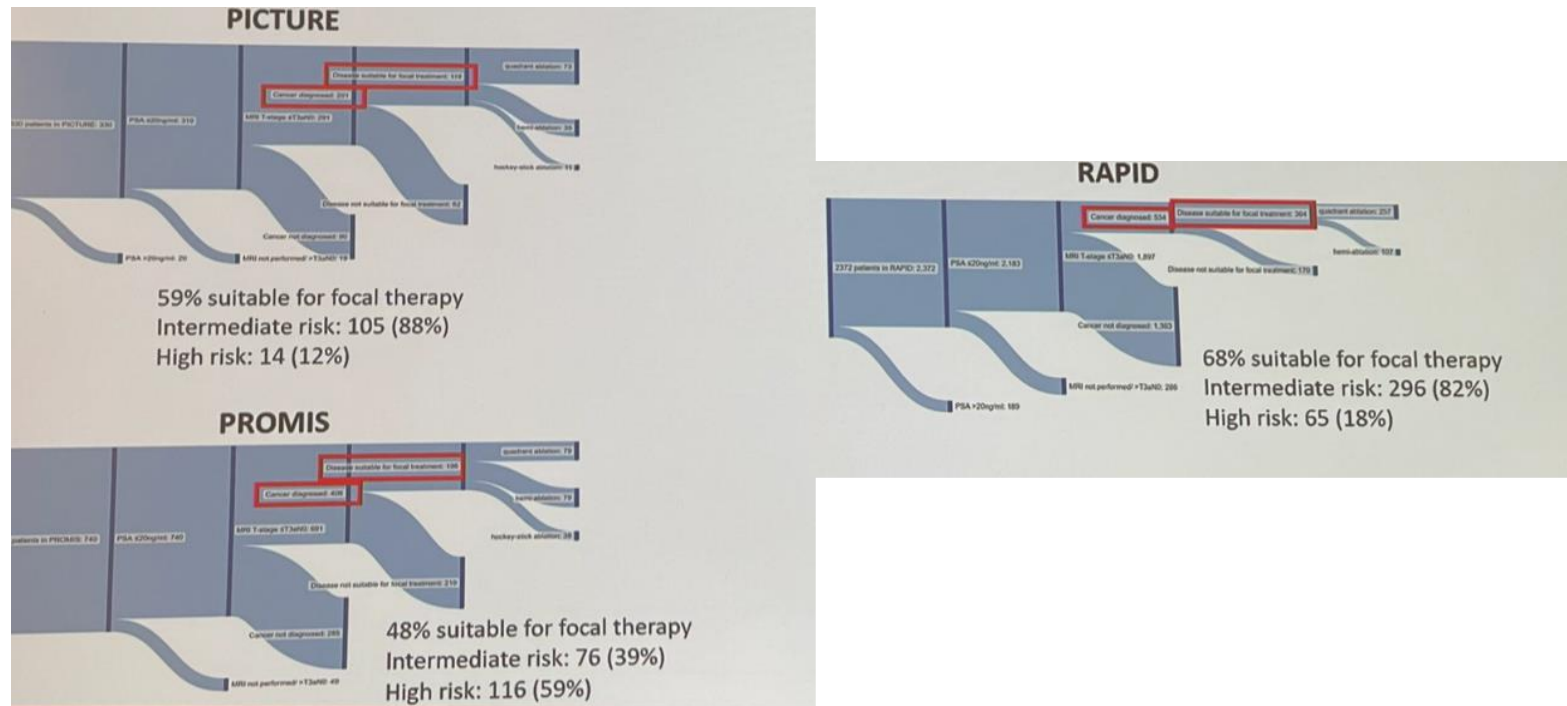
## Preferred Focal Therapy Candidates:

- GG 2 or GG 3 prostate cancer in a single lesion visible on MRI
- Concomitant GG1 prostate cancer elsewhere in the gland is allowed and observed
- PSA  $\leq$ 20 if prostate gland size <100gm
- No evidence of extraprostatic extension (MRI)
- HIFU:
  - Anterior margin of treatment  $\leq$ 4cm from the rectal wall
  - No treatment plans crossing midline anterior to the urethra

# Who Is A Candidate For Focal Therapy?

Across 3 prospective prostate cancer diagnostic and screening clinical trials in the UK (total accrual >700 patients)

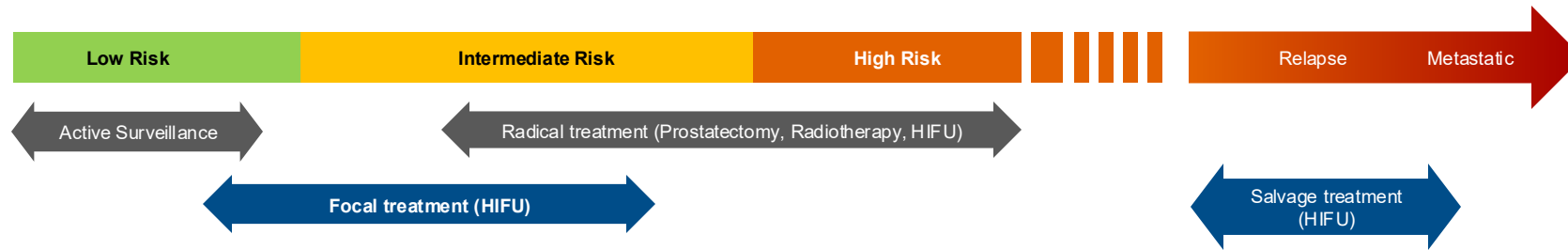
- **48-68%** of patients suitable for focal therapy



# Key Trends In Patient Selection Expanding Focal Therapy Eligible Patients

- A. >60% of patients in the United States with low grade prostate cancer are enrolled in active surveillance and approximately **20% of these patients** have higher grade cancer detected within 24 months
- B. MRI targeted prostate biopsies have enabled detection of low volume 'high risk' prostate cancer in a single lesion visible on MRI
- C. Utilization of MRI in post radiation patients have enabled **detection of recurrence earlier** and localized stage making them candidates for salvage focal treatment

# Focal Therapy Fills An Important Treatment Gap In Prostate Cancer



- Advanced imaging and MR-targeted biopsies have improved the ability to localize disease and risk stratify prostate cancer
- Patients are seeking an option between active surveillance and radical therapy
- Patients are more accepting of less invasive treatments to optimize quality of life as they seek to expand their own interests instead of seeing prostate cancer as only a life or death decision

# Where Is Focal Therapy For Prostate Cancer Today?

- Inclusion in guidelines
- Rapid increase in scientific publications
- Participation in focal therapy instructional courses at national meetings

# European Association Of Urology Has Changed Their Guidelines To Include Offering Focal Therapy (HIFU/Cryo) For Prostate Cancer Outside Of Clinical Trails – Now Within Prospective Registries.

EAU Guidelines on Focal Therapy for Prostate Cancer

2022

**6.1.6 General guidelines for the treatment of prostate cancer**  
Offer focal therapy within a clinical trial setting or well-designed prospective cohort setting.

**HOW IT WAS APPLIED TO YOUR PRACTICE**

Research ethics committee, legally sponsored trial only

2023

**Section 6.1.5.3**  
Currently, focal therapy using HIFU or cryotherapy should be performed within the context of a prospective registry. All other ablative modalities should only be offered in a well-designed prospective trial setting.

**6.1.6 General guidelines for the treatment of prostate cancer**  
Only offer focal therapy with high-intensity focused ultrasound or cryotherapy within a clinical trial or prospective registry.

**HOW TO APPLY TO YOUR PRACTICE**

HIFU or cryotherapy within prospective registry  
ALL other modalities: research ethics committee, legally sponsored trial only

# Annual Scientific Publications Have *Quadrupled* In The Last 2 Decades

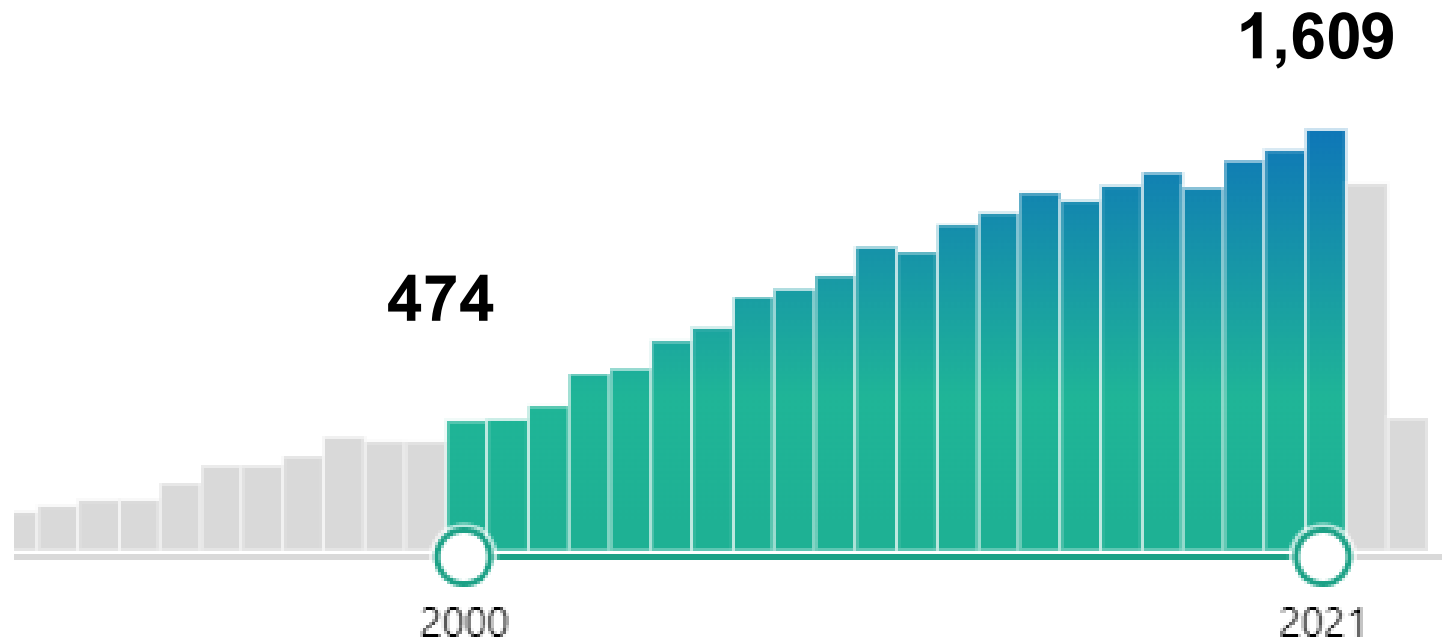
NIH National Library of Medicine  
National Center for Biotechnology Information

PubMed®

focal therapy prostate cancer

Search

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# American Urological Association Offered 2 Courses In Focal Therapy For Prostate Cancer And Both Sessions Were Fully Registered



# My Experience With The Commercial Utilization Of The Focal One<sup>®</sup> Device

## Advantages

- Leading technology among competition in efficiency and decreased treatment time per treatment
- The robotic positioning system provides highly reproducible targeting with submillimeter accuracy and automated treatment planning thereby reducing operator variability
- Ease of workflow: OR device without requirement of the MRI suite
- State of the art:
  - 1) Real-time treatment modification to adjust treatment boundaries and update plans if anatomy shifts
  - 2) MRI/ultrasound fusion software to improve identifying and targeting the tumor



## Data: Oncologic Efficacy

---

**No evidence of clinically significant prostate cancer in the targeted area in 93% of patients at 12 months**

	Whole gland 12-month biopsy	In-field (12-month biopsy)
<b>Oncological efficacy</b>		
No evidence of GG $\geq$ 2	54 (89%)	57 (93%)
<b>Biopsy Outcome</b>		
NED	41 (67%)	57 (93%)
GG1	13 (21%)	0 (0%)
GG2	6 (9.8%)	3 (4.9%)
GG3	1 (2%)	1 (1.6%)
GG4-5	0 (0%)	0 (0%)

## Data: Quality of Life

---

- **Good or moderate erectile function reported in 90% of patients with or without medications at 12 months.**
- **No incontinence requiring pads reported at 12 months.**

Characteristic	N	Baseline N = 76	3-month (2-4 months) N = 56	6-month (4-9 months) N = 44	12-month (9-15 months) N = 18
MSHQ (Range 1-15; Higher Indicates Better Ejaculatory Function)	55	--	9 (4, 12)	7 (4, 10)	8 (4, 11)
IPSS (Range 0-35; Higher Indicates worse urinary symptoms)	184	6 (4, 12)	6 (3, 9)	5 (3, 10)	7 (5, 10)
IIEF (Range 1-30; Higher indicates better erectile function)	180	26 (19, 30)	20 (6, 26)	24 (7, 28)	21 (8, 29)

# Conclusions

- Data supports offering focal therapy as a viable treatment option for select (and growing population) of patients with prostate cancer
- Rapid adoption in academic hospitals enables a pipeline of residents and medical students exposed to focal therapy
- Inclusion of focal therapy in academic meetings (courses, research sessions, panels) will positively influence specialty and national guidelines
- Focal therapy has reduced the burden of prostate cancer for patients without compromising oncologic outcomes

**Thank you for your attention**



# Innovation & Advanced Technologies

Steve Annen, EVP Product Management



# The **Focal One** Robotic HIFU Advantage

Validated by Surgeons,  
Proven in Practice

Accurate Treatment  
Targeting

Precision HIFU  
Energy Ablation

Easy-To-Use  
Workflow with  
Treatment Versatility

Ongoing Commitment  
to Invest in Clinician-  
Driven Innovation

# Purpose Built for Precision Focal Therapy: Seamless Integration of Technologies

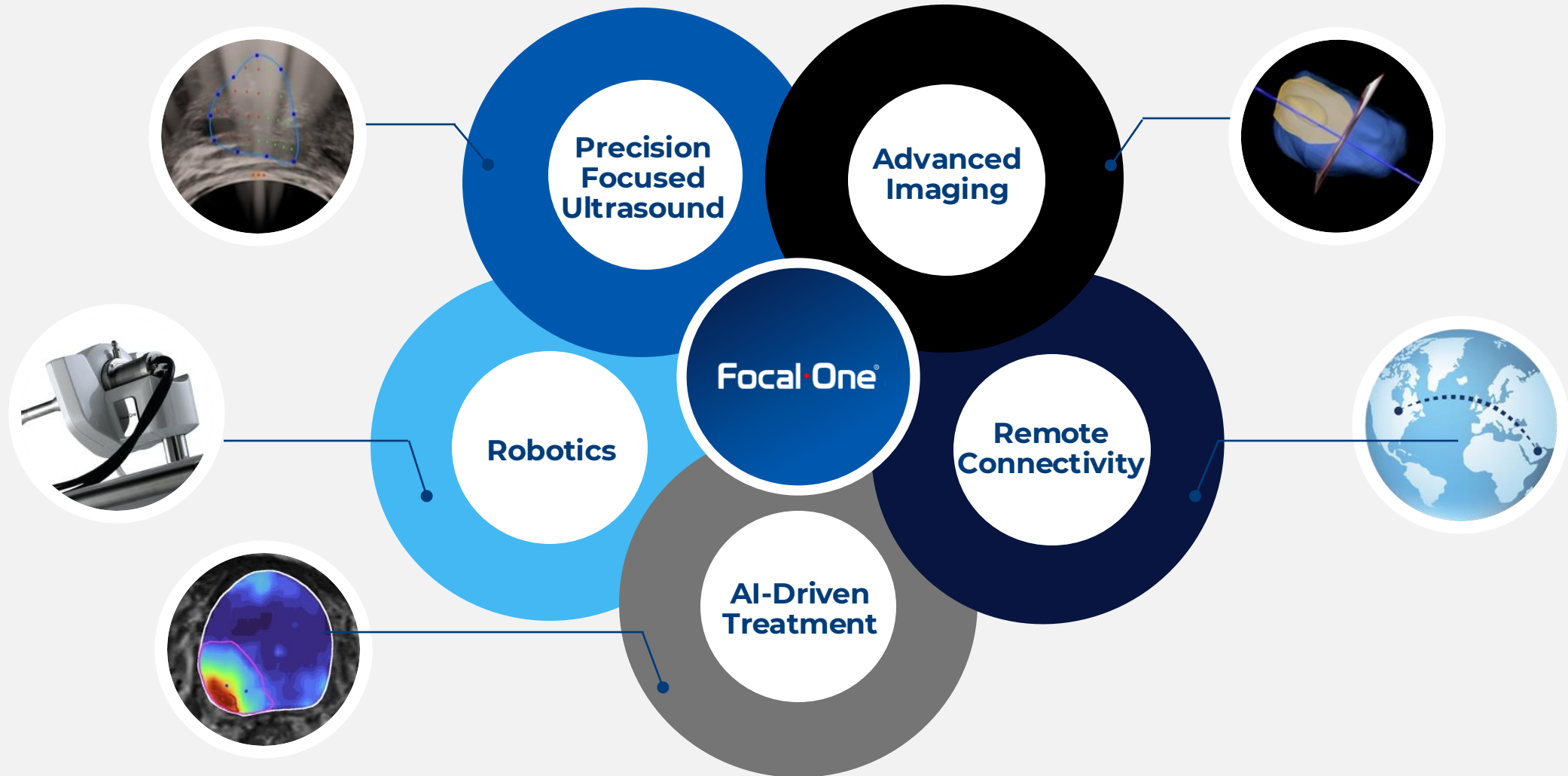
Precision  
Robotics

Dynamic  
Focusing  
Probe

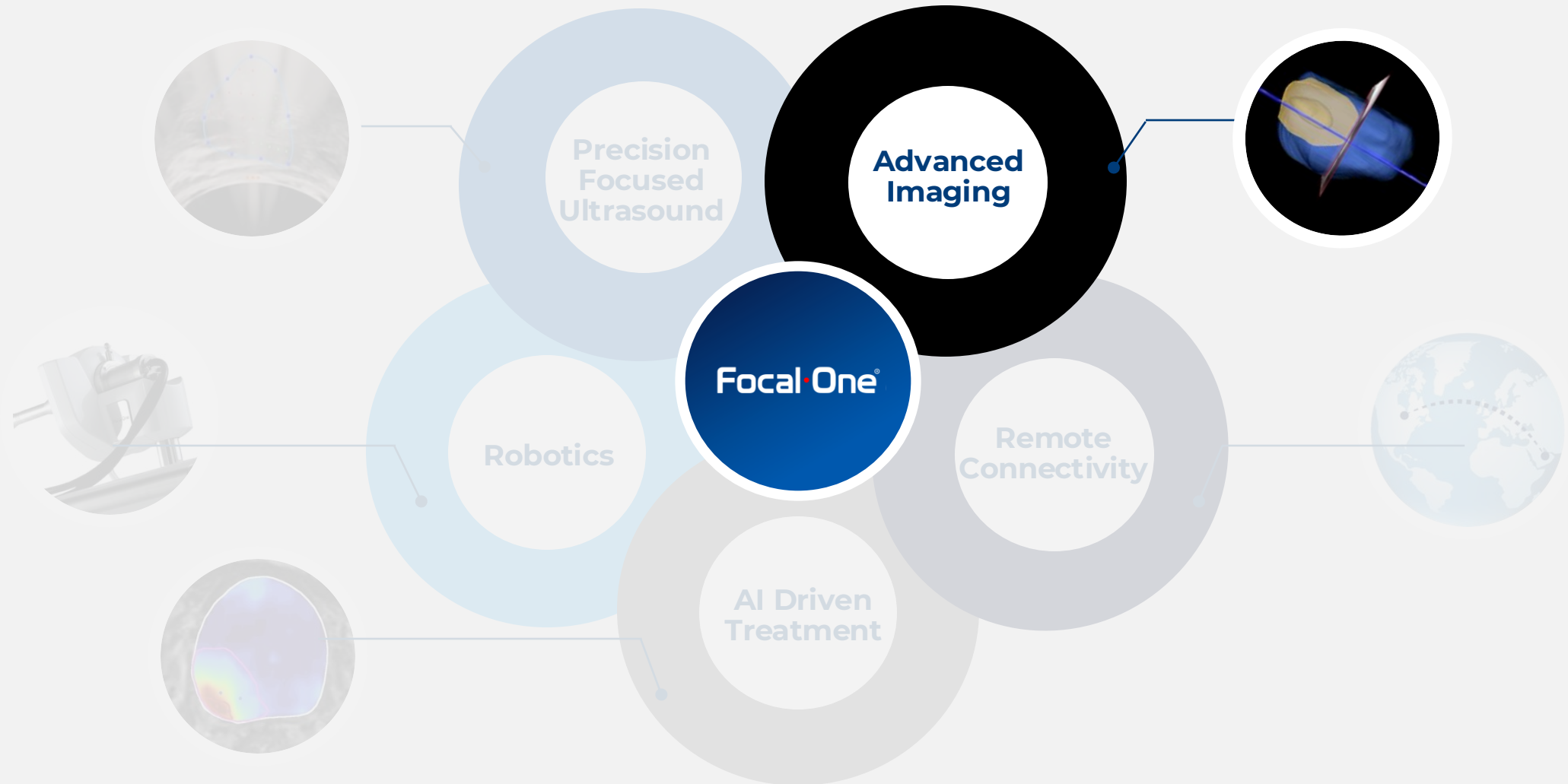
High  
Resolution  
Imaging

Mature  
Software  
Driven  
Workflow

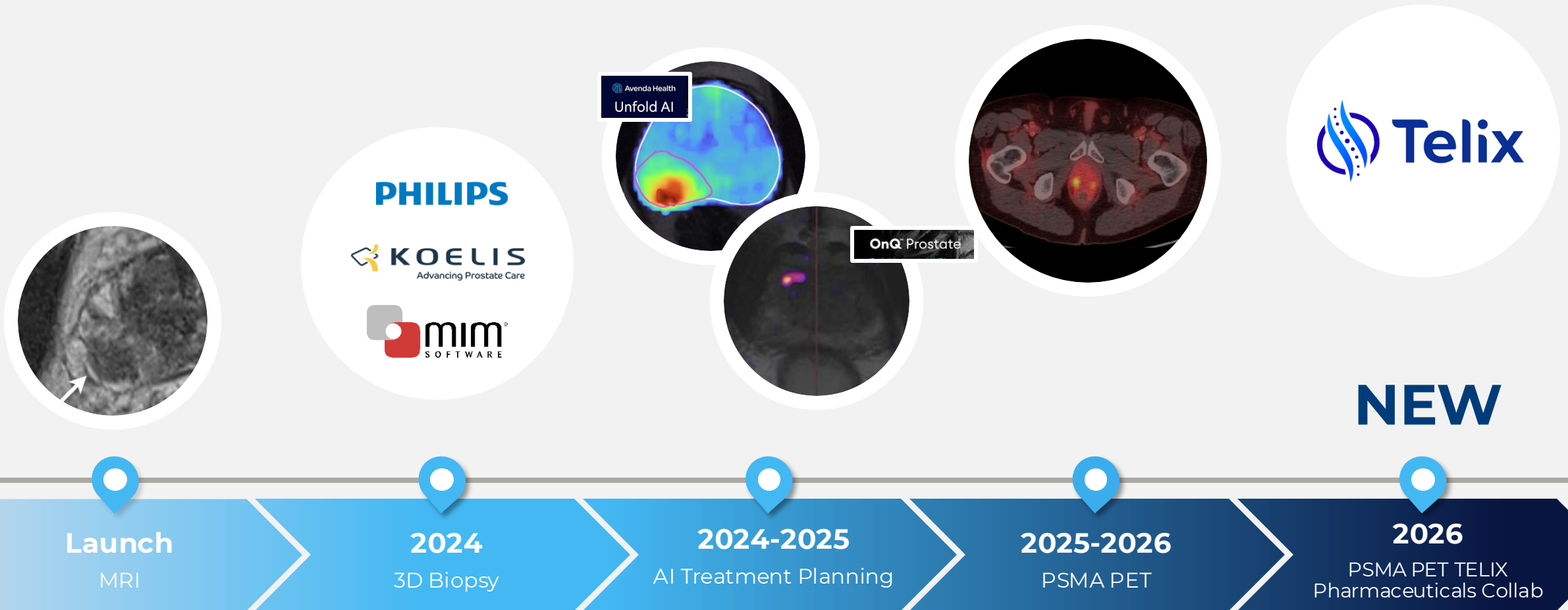
# Scalable Focal One Platform Enables Simultaneous Innovation



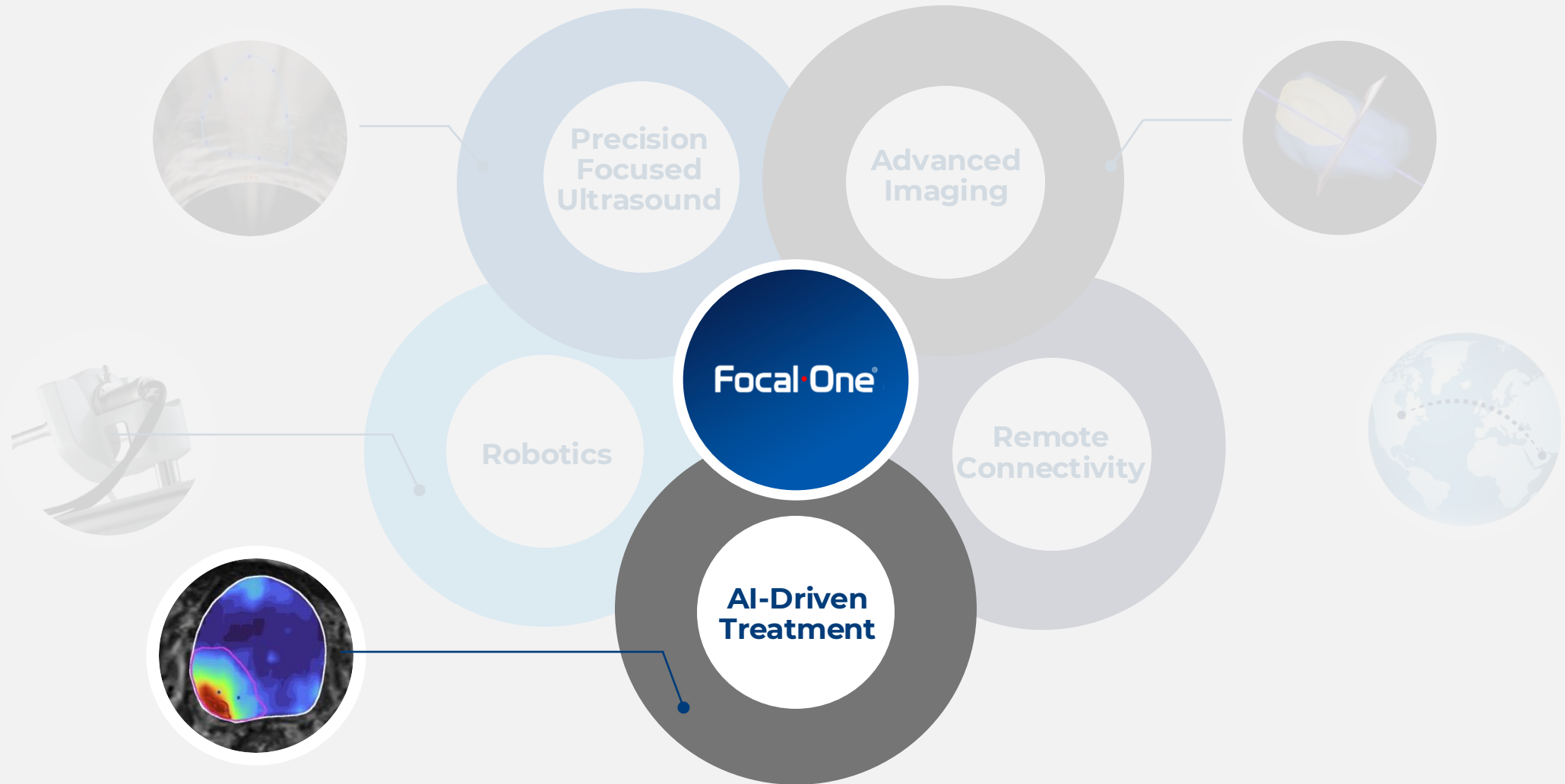
# Scalable Focal One Platform Enables Simultaneous Innovation



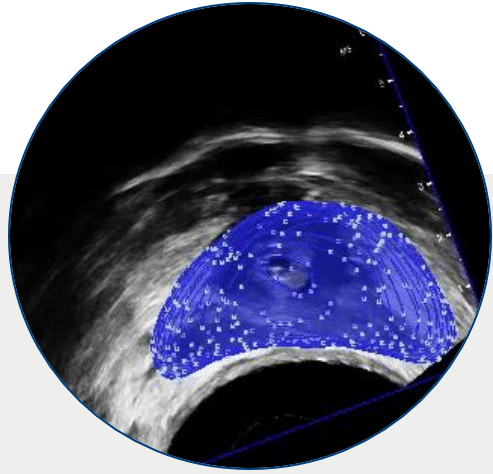
# Open Platform for Advanced Imaging Driven Treatment



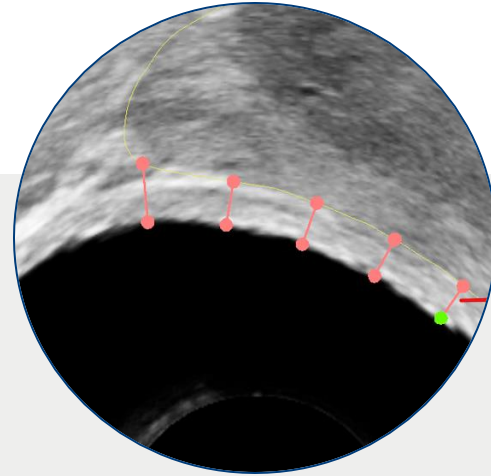
# Scalable Focal One Platform Enables Simultaneous Innovation



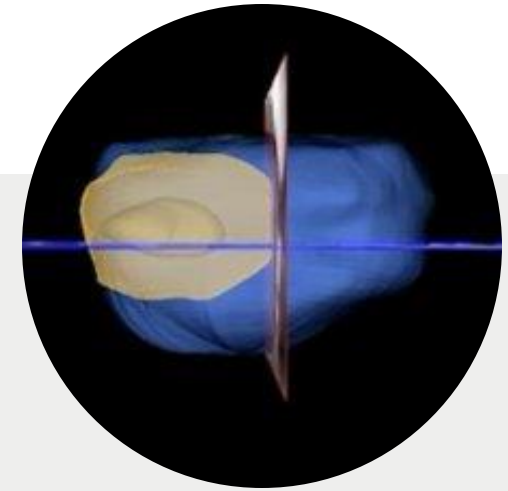
# AI Integration Shaped by Clinician Feedback



**Mapping of  
Cancer & Critical  
Structures**

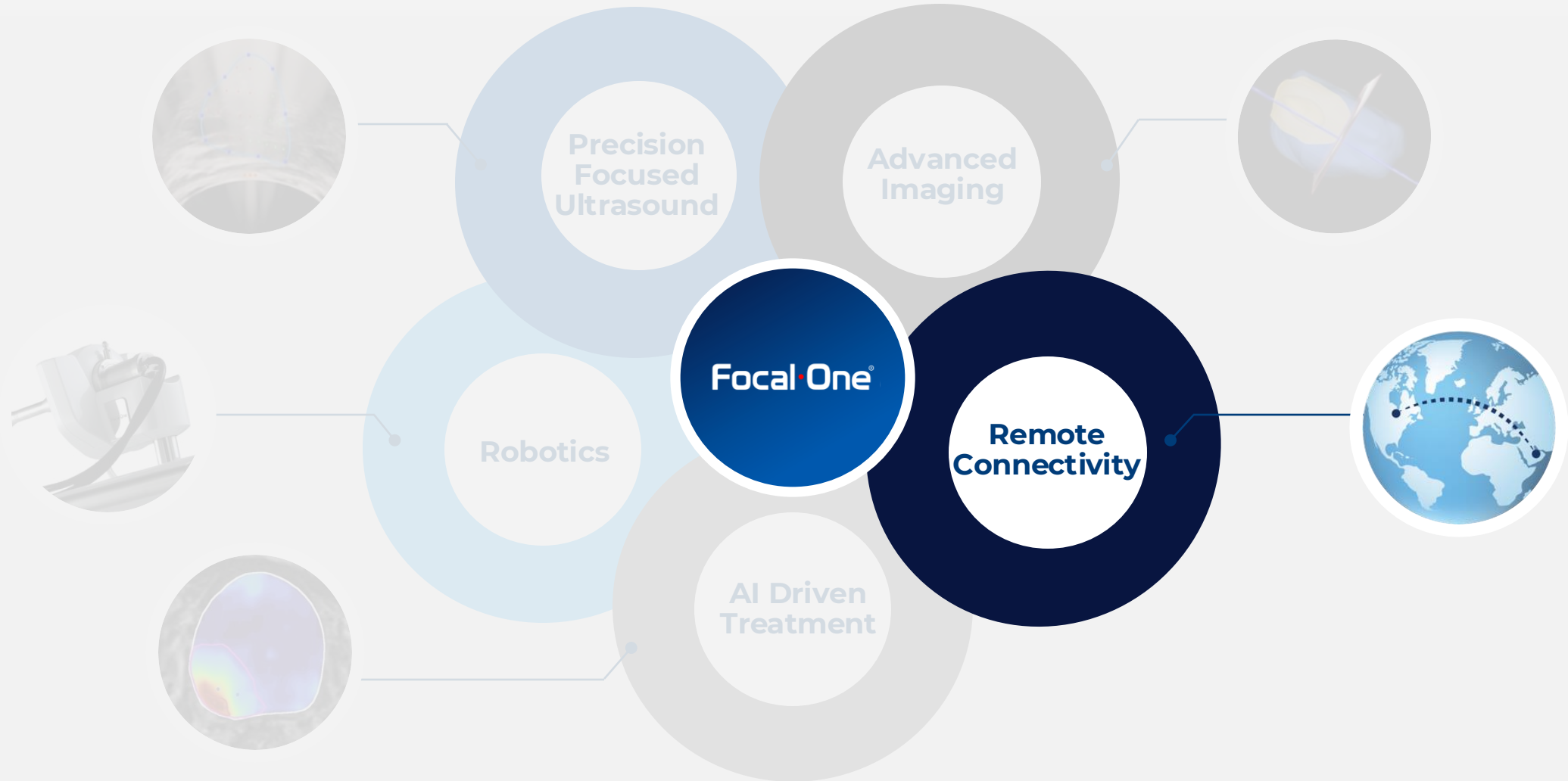


**Real-Time  
Monitoring of  
Anatomy**



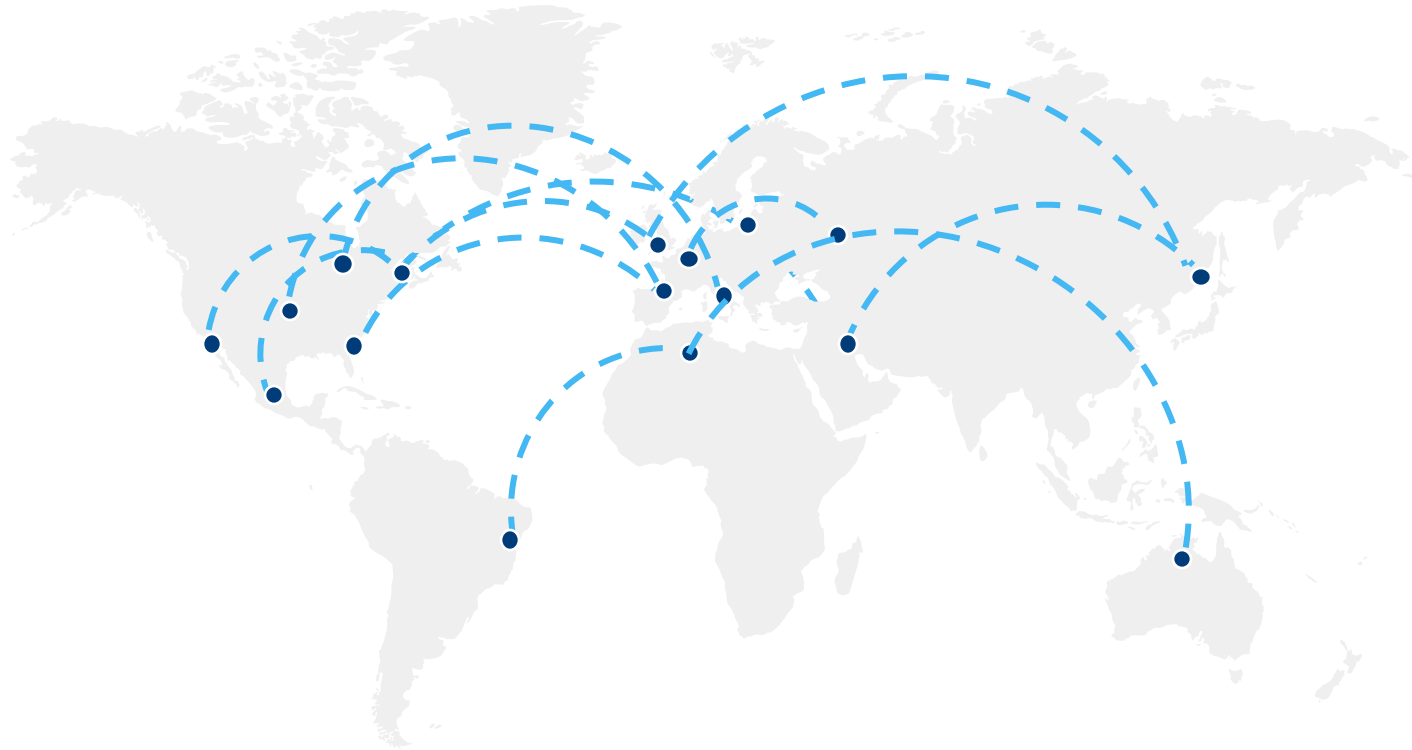
**Ability to  
Assess Tissue  
Ablation**

# Scalable Focal One Platform Enables Simultaneous Innovation



# FocalConnect™

Focal One Uniquely Designed for High-Fidelity Focal Therapy Telecollaboration



Completely **Integrated Digital** Platform

Leveraging **Existing Hospital Networks**

**Broadens Patient Access** to Focal Therapy

# World's First Transcontinental Focal One HIFU Telecollaboration



Cleveland

7,000+ miles

Abu Dhabi



UroToday

EUS 2025: The First-in-Human Transcontinental Telesurgery Collaboration for High-Intensity Focused Ultrasound: A New Era in Globalizing Focal Cancer Treatment for Prostate...

The first reported case of transcontinental telesurgery using High-Intensity Focused Ultrasound (HIFU) for the treatment of localized prostate cancer.

Apr 29, 2025



**Dr. Oliveras**

*"After a while I forgot I was doing a remote surgery."*

**Dr. Hassen**

*"[Dr. Oliveras] was enabled to seamlessly perform the procedure from beginning to end without my intervention."*

Leveraged Hospital Network with No Delays or Interruptions

# FocalConnect

Enabling a New Paradigm in Focal Therapy Telecollaboration



Dual Console (Operating Room)



Across Hospital Campus



Regional Hospital Network

# FocalConnect

Enabling a New Paradigm in Focal Therapy Telecollaboration



Dual Console  
(Operating Room)



Across Hospital Campus



Regional Hospital  
Network

# FocalConnect

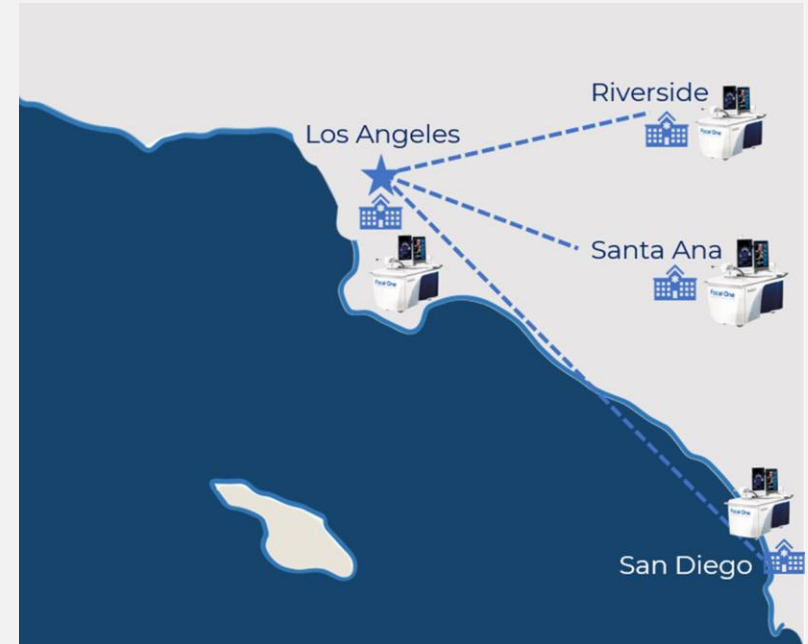
Enabling a New Paradigm in Focal Therapy Telecollaboration



Dual Console  
(Operating Room)



Across Hospital Campus



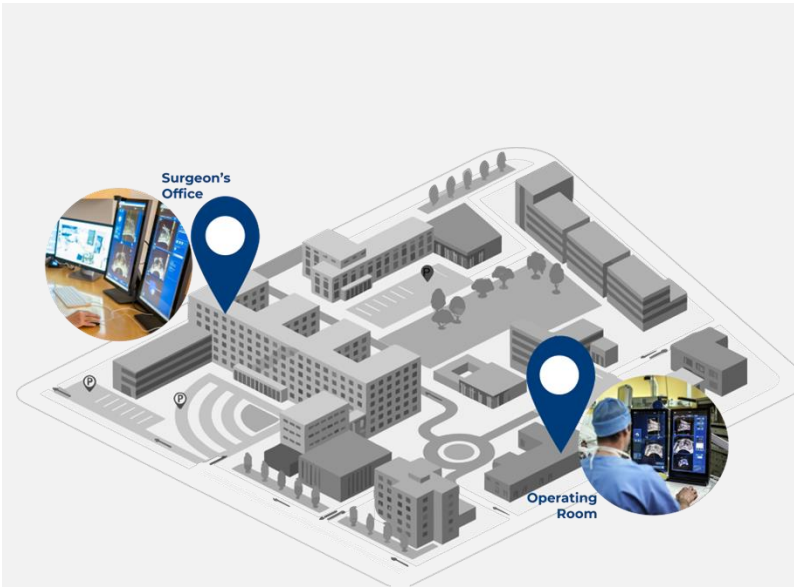
Regional Hospital Networks

# FocalConnect

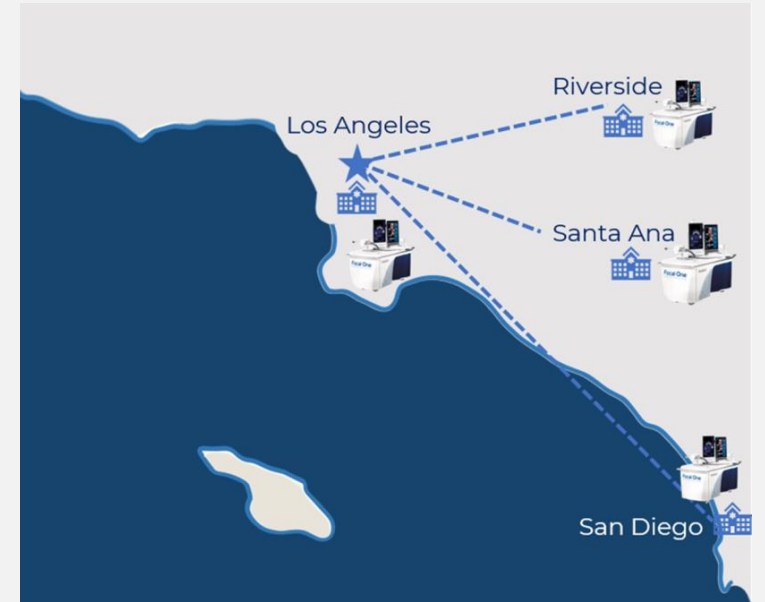
Enabling a New Paradigm in Focal Therapy Telecollaboration



Operating Room



Across Hospital Campus



Regional Hospital Networks



Dr. Jihad Kaouk, MD  
Enterprise Chair of Urology



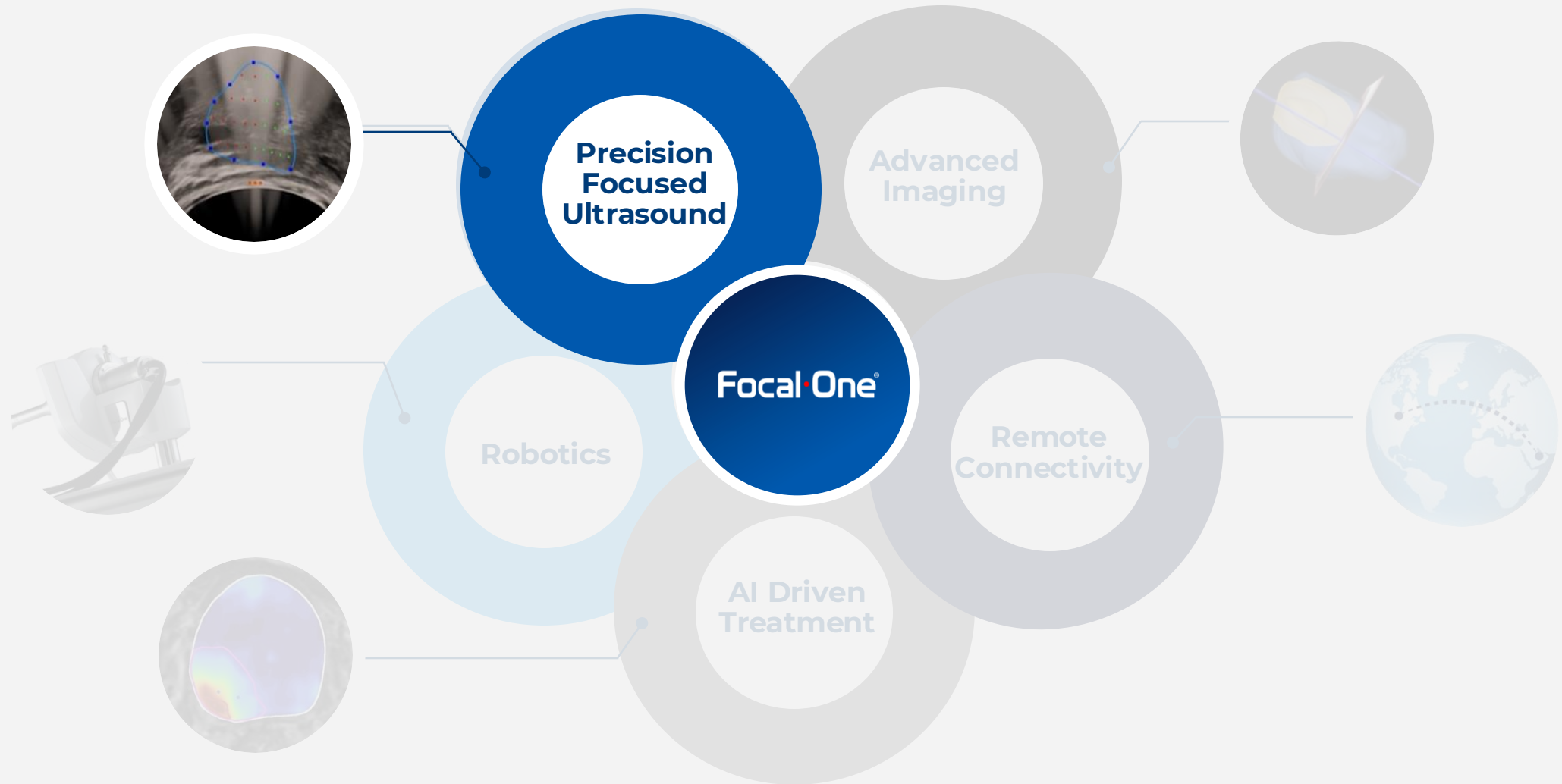
# FocalConnect™ Accelerates the Sharing of Best Practices in Broadening Patient Access to Expert Care



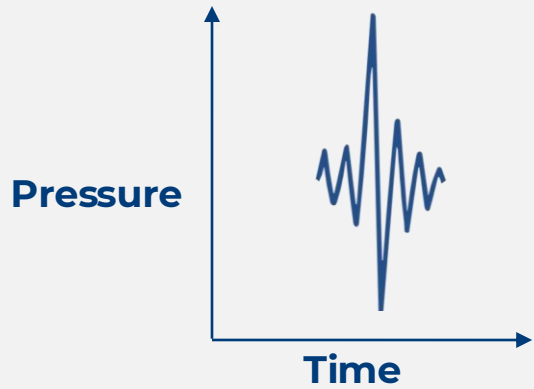
“This innovative approach [with Focal One Robotic HIFU] not only allows us to **share expertise across Cleveland Clinic’s locations** but also **expands access to specialized care for patients**, no matter where they are.”

# FocalConnect™

# Scalable Focal One Platform Enables Simultaneous Innovation



# Lithotripsy

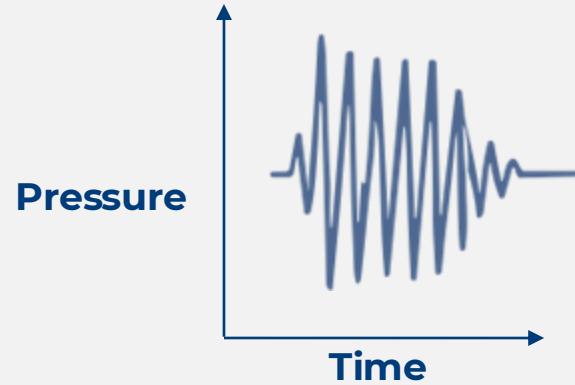


- Very Short Shock Pulse

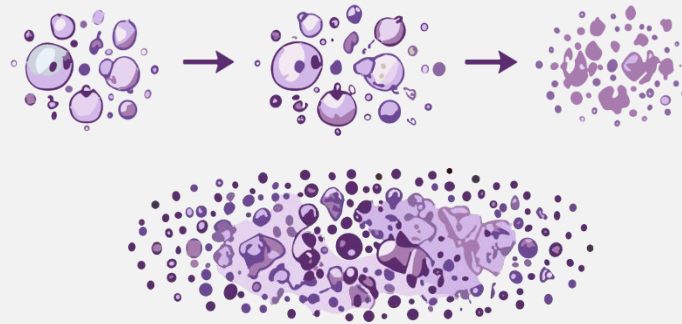


**Mechanism & Tissue Effect:**  
Mechanical Stress Causes Cracks and Fragmentations of Calcified Structures

# Histotripsy

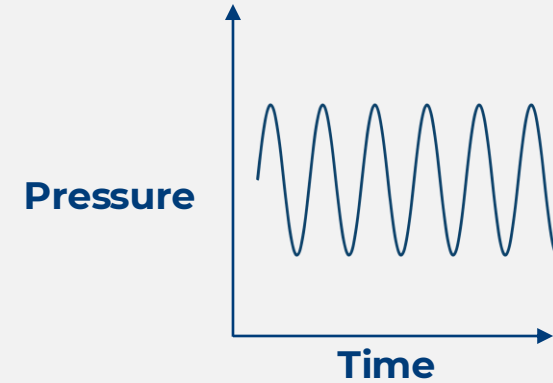


- Short Pulse Bursts

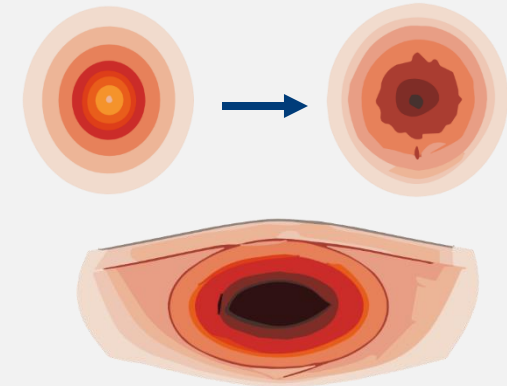


**Tissue Effect:** Non-Thermal Mechanical Fractionation of Tissue into Microparticles, Tissue is Liquified

# HIFU



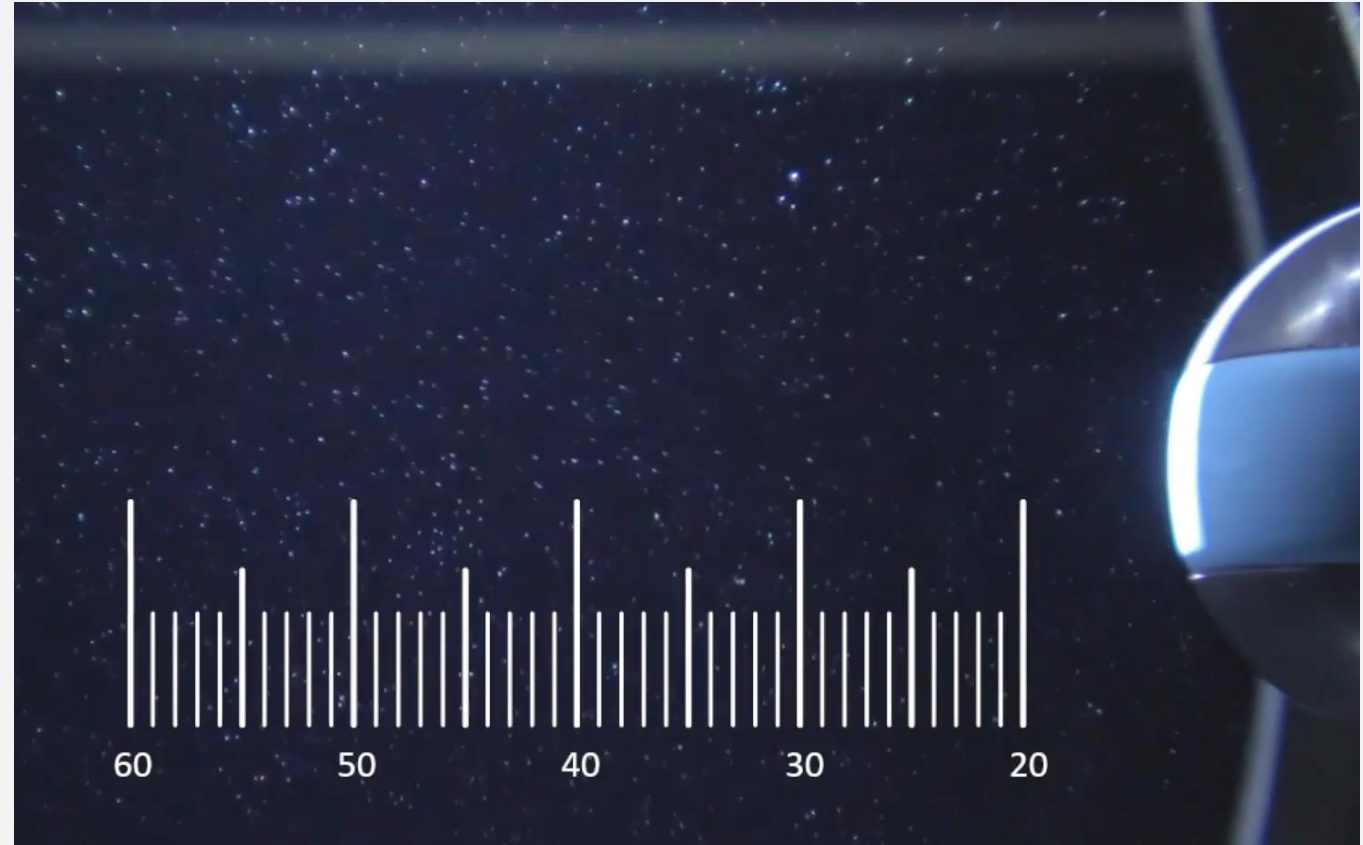
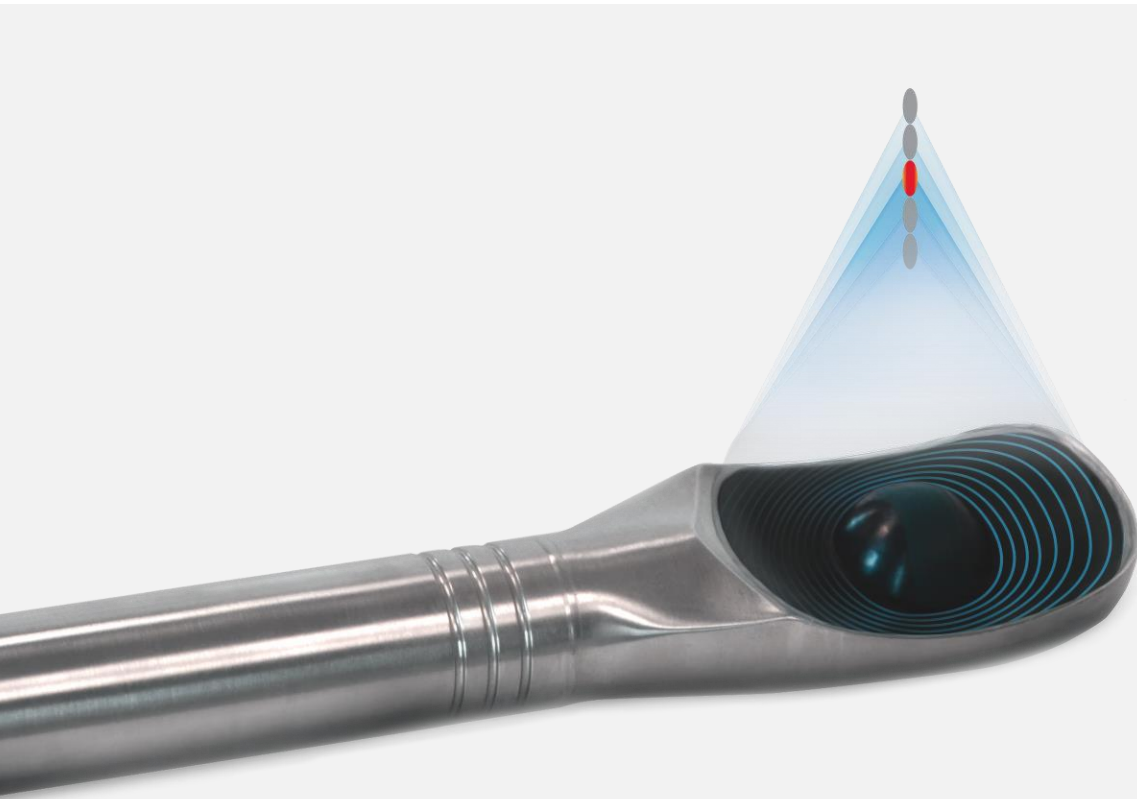
- Long Pulse (Continuous Wave)



**Tissue Effect:** Thermal Coagulative Necrosis in the Focal Zone; Surrounding Tissue Largely Spared

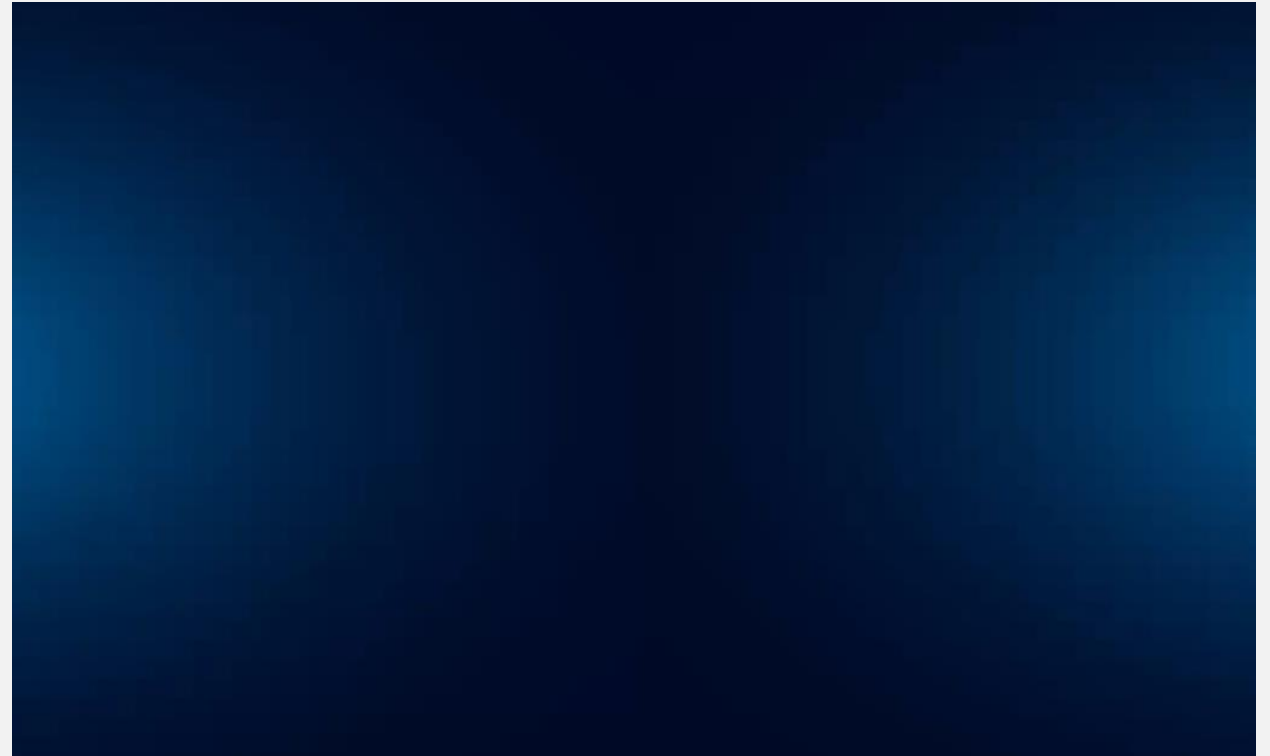
# Histotripsy

Leveraging Focal One HIFU Transducer

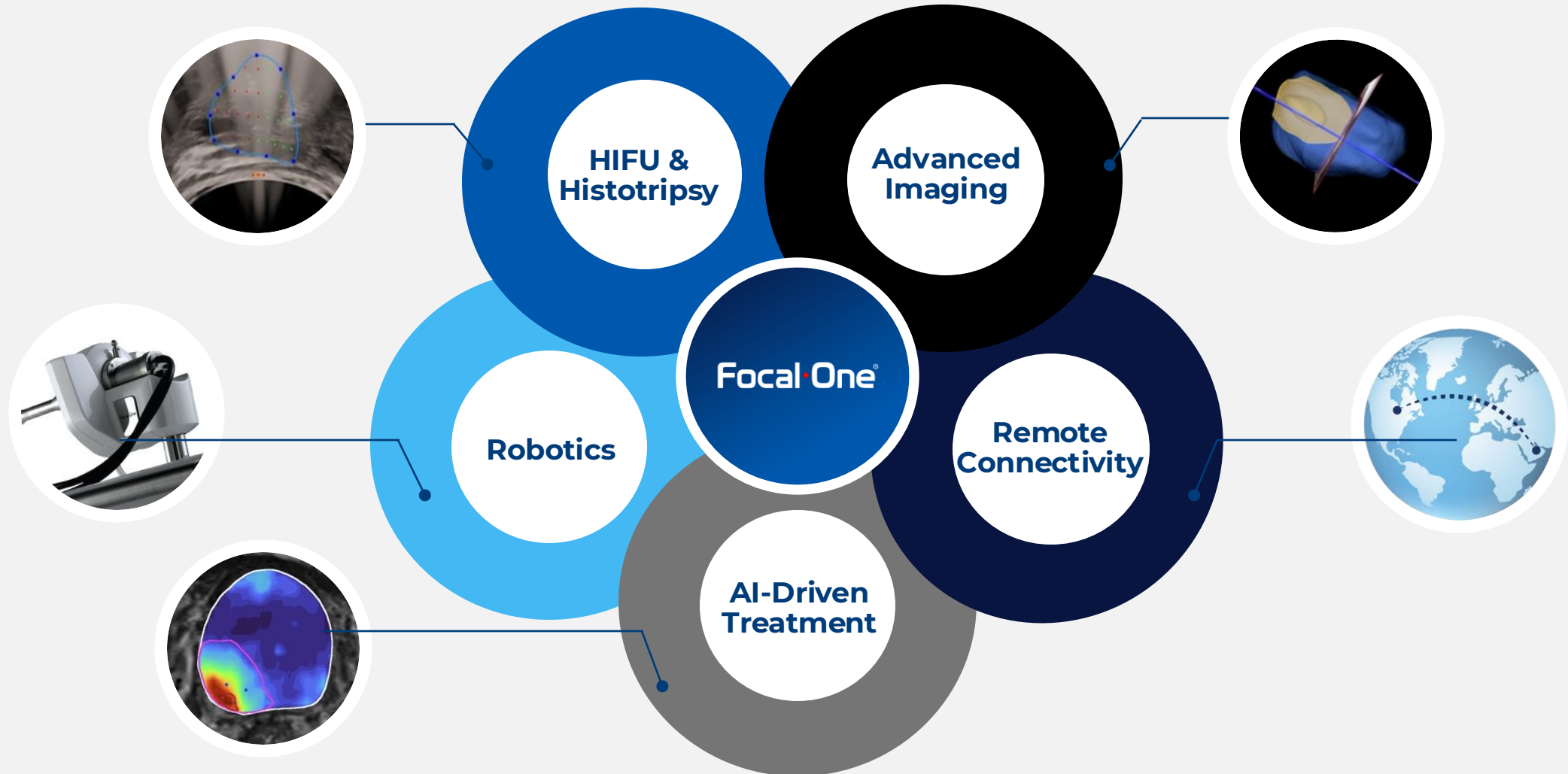


# Histotripsy

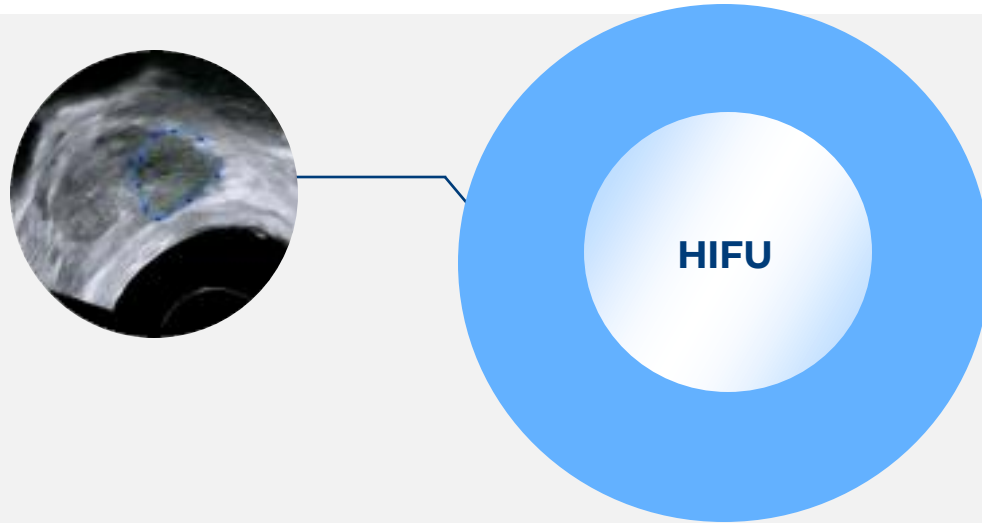
## Leveraging Focal One Treatment Workflow



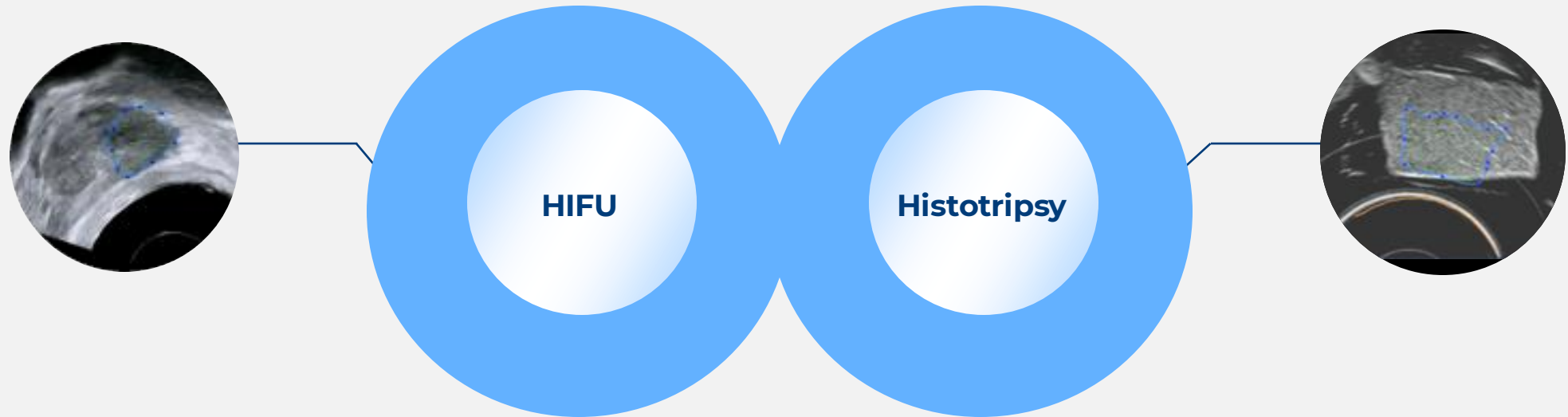
# Scalable Focal One Platform Enables Simultaneous Innovation



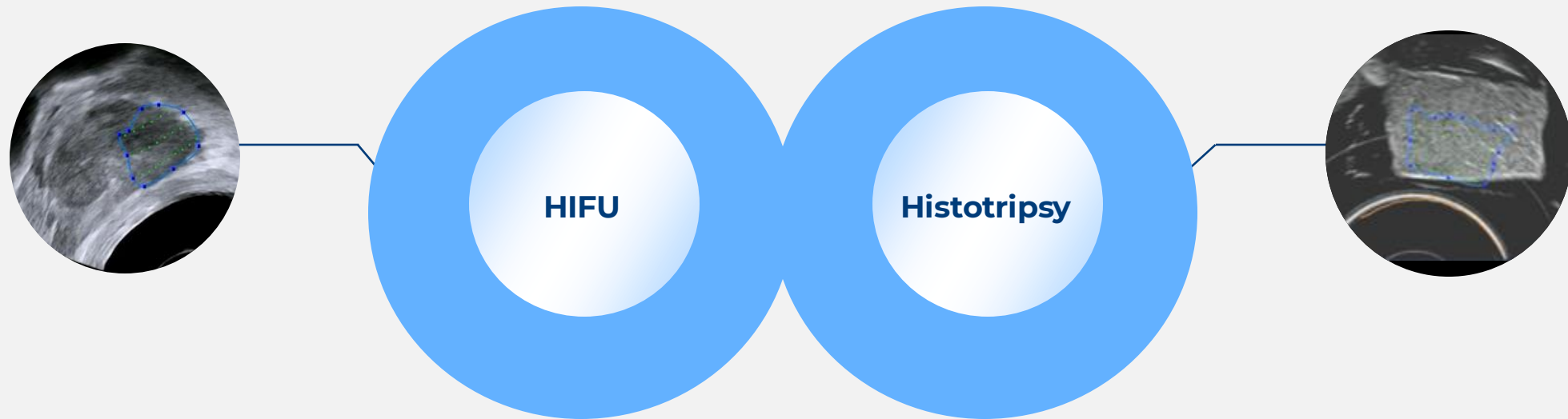
# Focal One HIFU and Histotripsy



# Focal One HIFU and Histotripsy

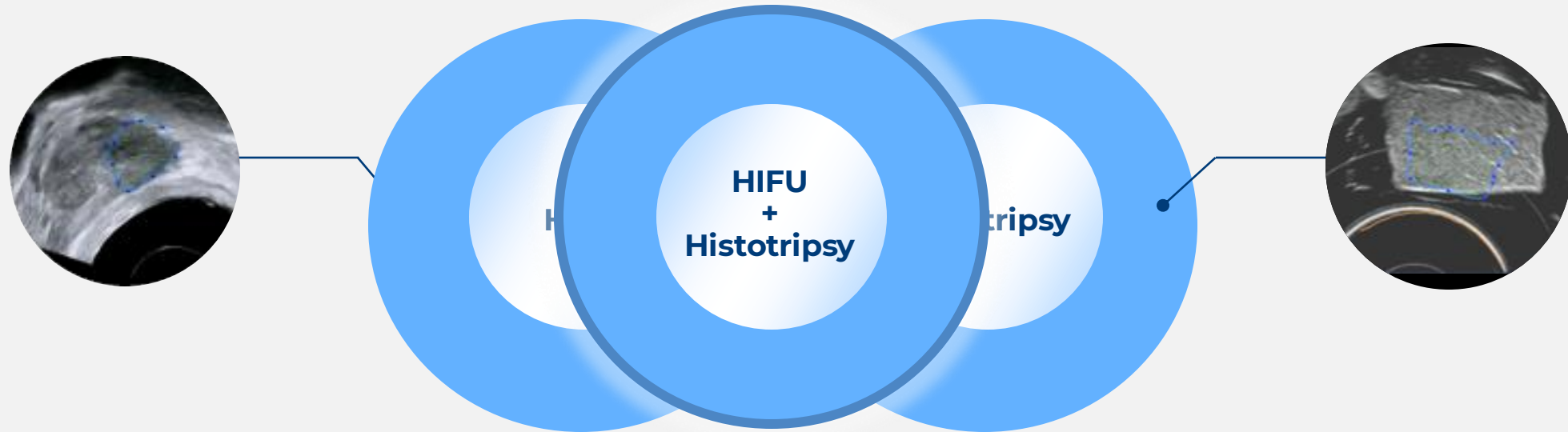


# Focal One HIFU and Histotripsy

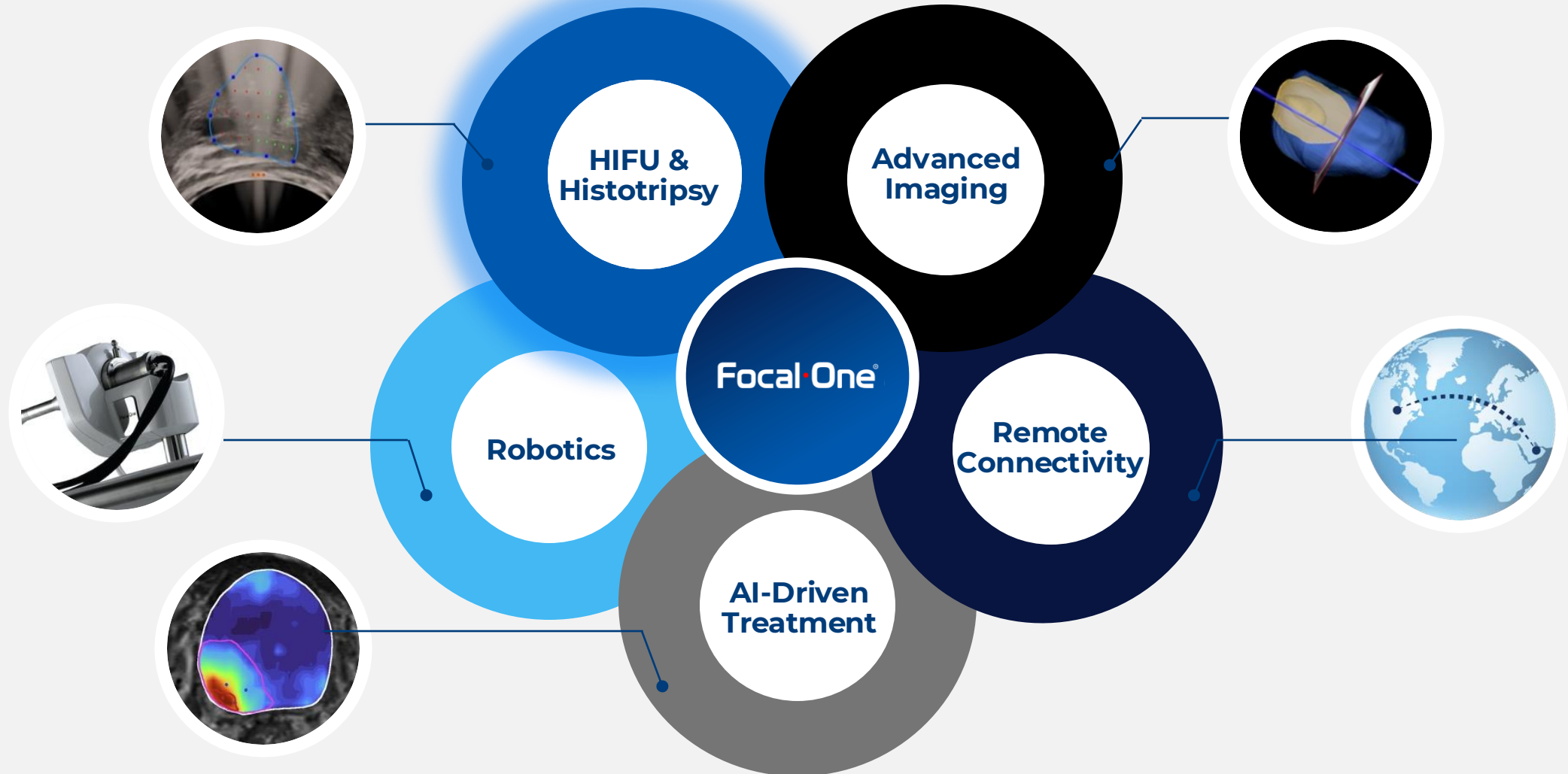


# Focal One HIFU and Histotripsy

Actively Developing and Filing Novel Intellectual Property Covering The Unique Combination of HIFU and Histotripsy to Strengthen our IP Portfolio



# Scalable Focal One Platform Enables Simultaneous Innovation



# Focal One Robotic Focal Therapy Difference

**Most Compatible**

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**Precise Energy Delivery**

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**Easiest to Learn, Use & Teach**

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**Minimal OR Staffing**

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**Shortest Treatment Times**

**Advanced Imaging with PSMA PET**

**Training and Telecollaboration via FocalConnect**

**AI-Assisted Treatment & Ablation Assessment**

**Expanding Focal One to a Single Platform to Treat Multiple Indications with a Combination of HIFU and Histotripsy**

# Positioned for Growth

FocalTherics™

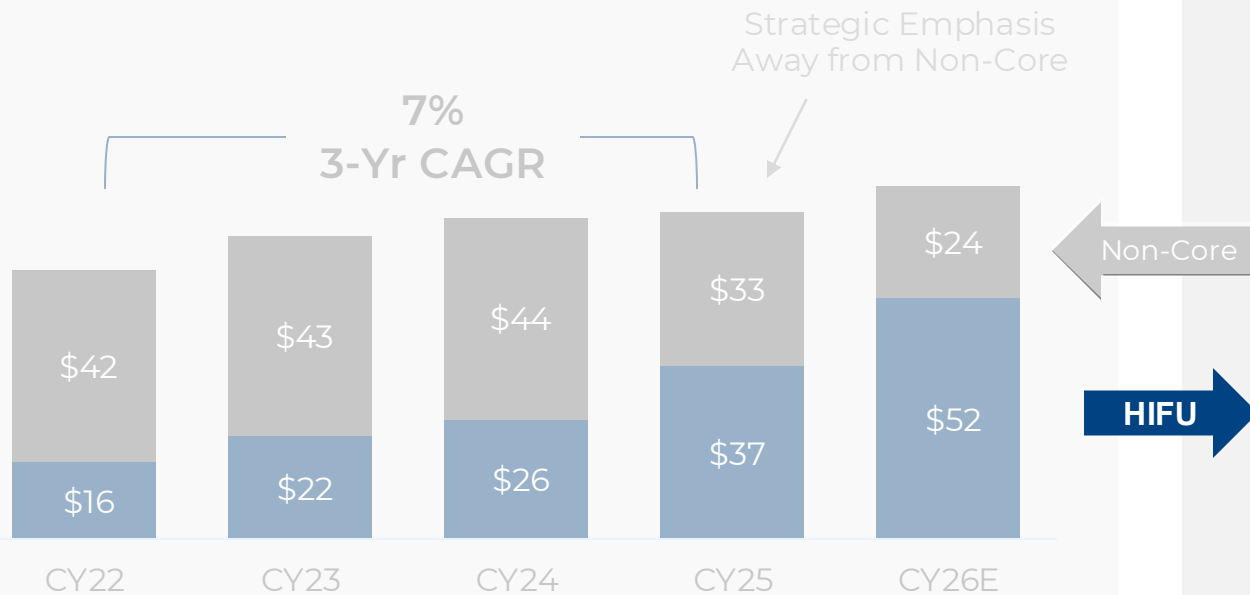
A Pure-Play HIFU Company

Ken Mobeck, CFO

# Commitment to HIFU Portfolio

Accelerating Our Growth Engine

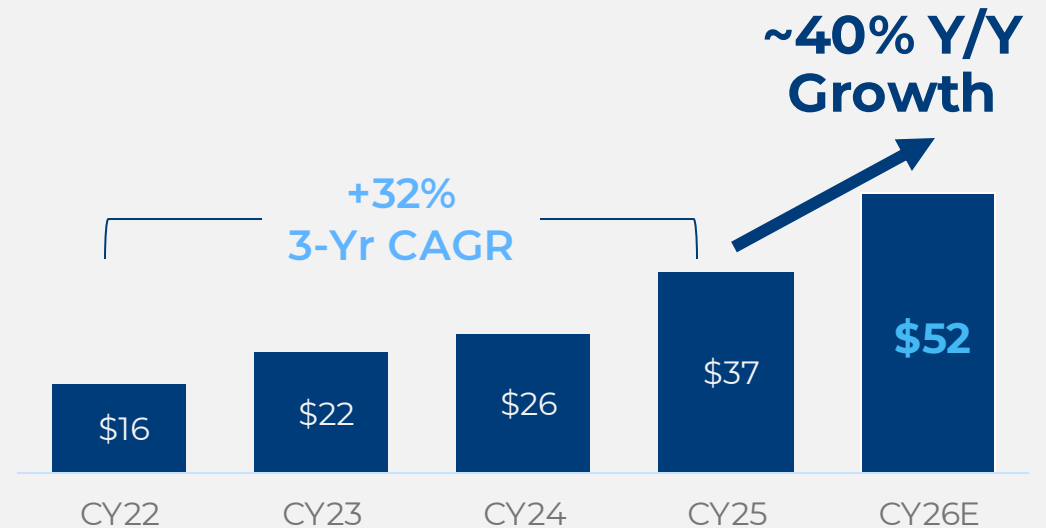
EDAP Revenue (\$M)



Moving Non-Core ESWL and Distribution Business to Discontinued Operations as of Q2 CY26

Note: CY26E = Midpoint of CY26 Guidance Range

HIFU Revenue (\$M)

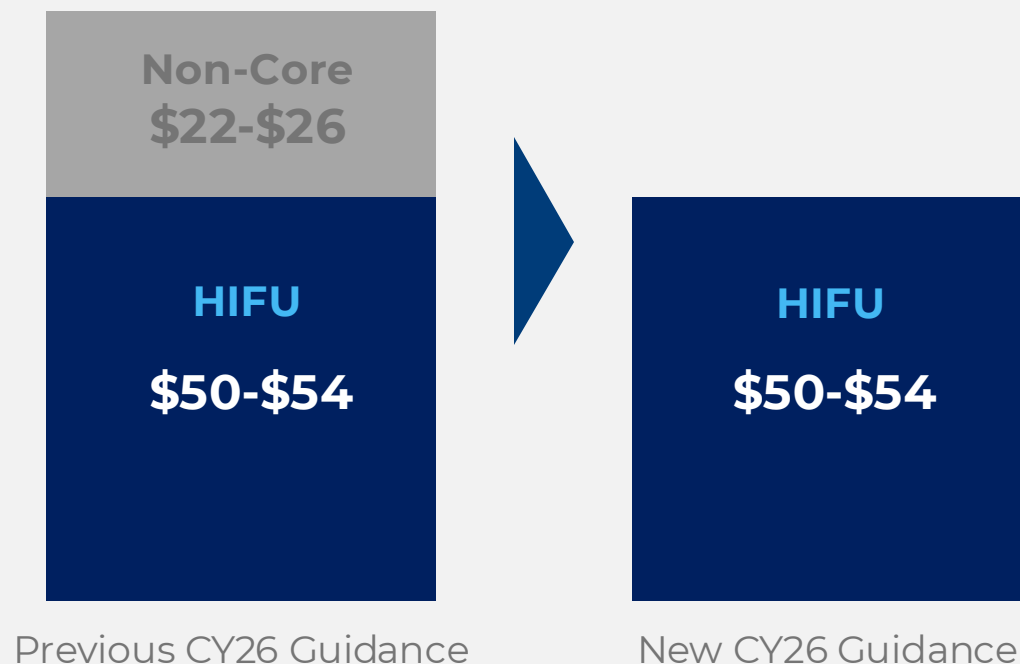


# CY 2026 Updated Revenue Guidance

Reiterating HIFU Only Guidance (Non-Core Classified to Discontinued Operations)

## Revenue Guidance (\$M)

## Benefits of HIFU Focus

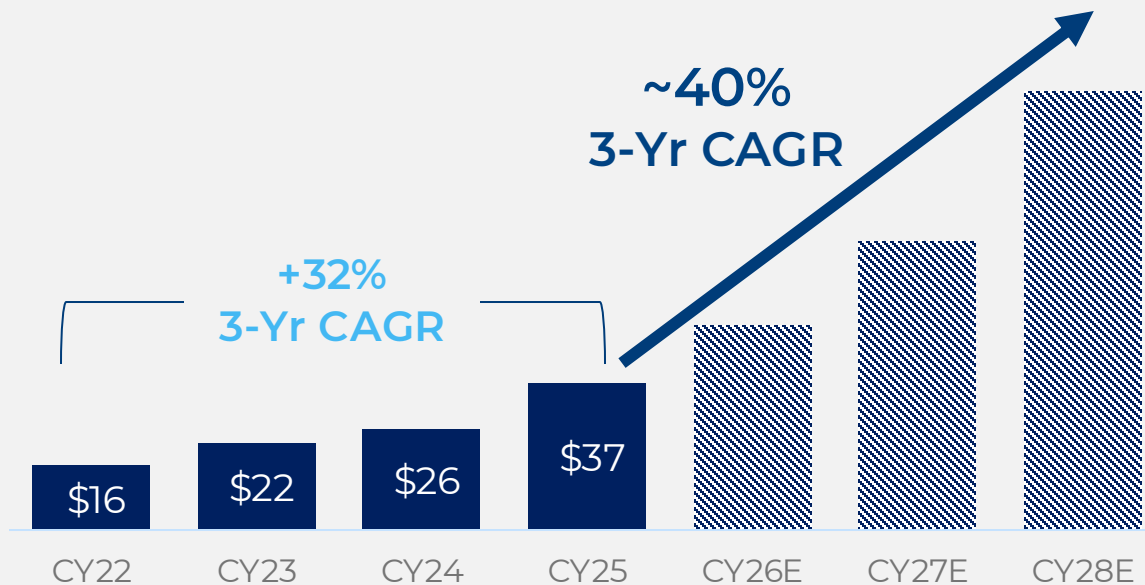


- **Accelerated** Revenue Growth
- **Higher** Gross Margins
- **Lower** Operating Expenses
- Pathway to **Operating Income Breakeven** in CY28

# Long-Term Target Revenue Growth Model

Focal One System Placements & Procedure Volumes Remain Primary Catalysts

## HIFU Revenue (\$M)



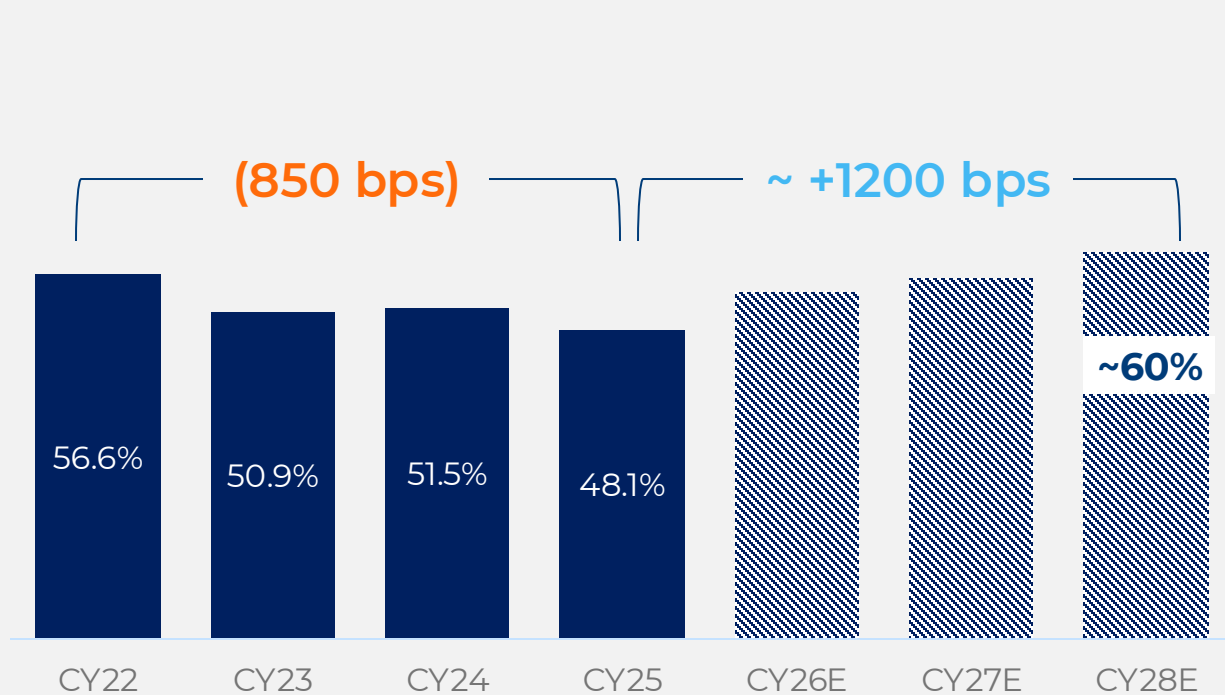
## Growth Drivers

- Continued **Penetration** into Core U.S. Markets
- **International Expansion** into New Markets
- **Procedure** Volumes Growth
- Continued **Marketing Program** Development
- **New Indications** will Boost Procedures
- **Installed Base** Growth

# Opportunities to Drive Operating Leverage

Levers to Drive HIFU Target Gross Margin to ~60%

## HIFU Gross Margin (%)



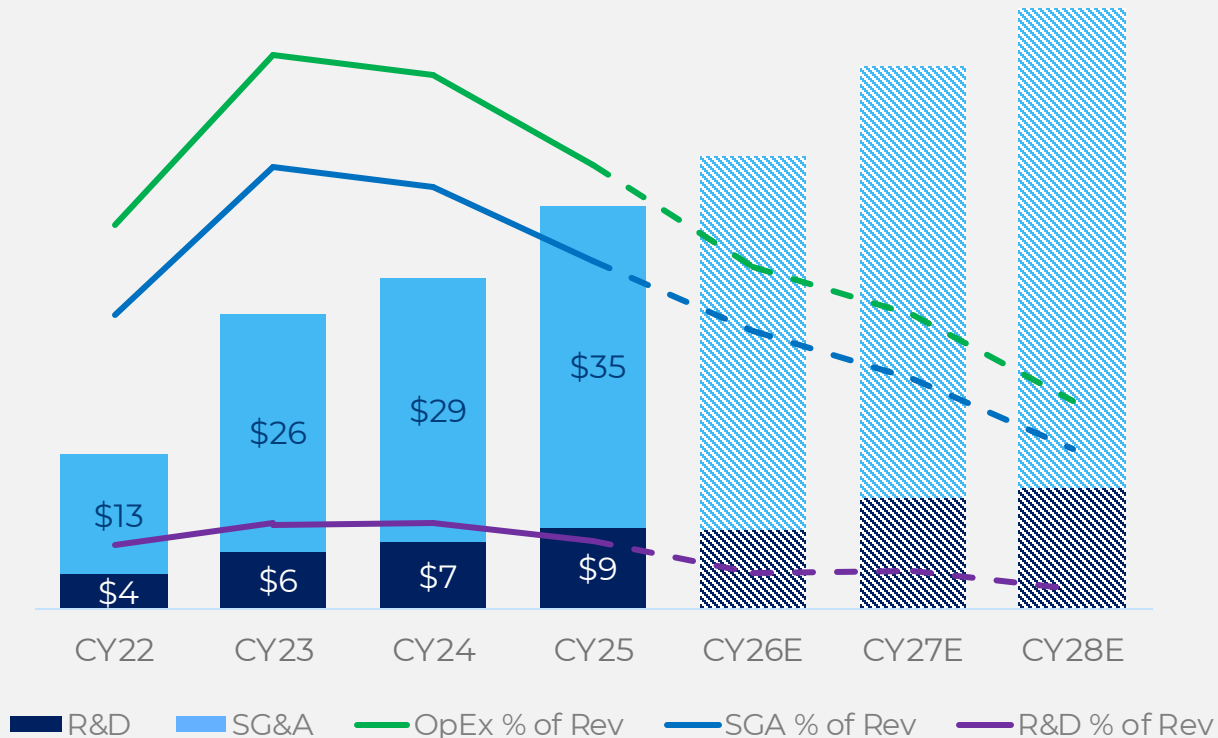
## Levers

- Bill of Materials **Optimization**
- Continued Strong **Capital Unit** Growth
- **Procedure** Volumes Driving **Consumables**
- Maintain **Pricing** Discipline
- Enhanced **Capacity Utilization**

# Disciplined Operating Expense Investment

Operating Leverage Driven by Revenue Growth, Efficiency Gains and Platform Extensibility

## HIFU Operating Expenses (\$M)



## Priorities

- **R&D Investments** to Expand Indications and Unlock New Markets
  - **BPH**
  - **Artificial Intelligence**
  - **Histotripsy**
- **High Evidence Clinical Studies**
- SG&A Investment to Complete **Global Commercialization** Build-Out

# 2028E Target Model Financial Framework

Focused on Driving Positive EBITDA and Breakeven Operating Income to Deliver Shareholder Value

	CY25 Actual	CY28E Target Range
<b>Revenue</b>	\$37M	~ 40%+ 3-Yr CAGR (+/- 3%)
<b>Gross Margin</b>	48.1%	~60% (+/- 200 bps)
<b>Operating Income</b>	(\$21M)	<b>Breakeven</b>
<b>EBITDA</b>	(\$19M)	<b>Positive</b>
<b>Installed Base</b>	166	~ 30%+ 3-Yr CAGR (+/- 5%)

# Closing Remarks

# FocalTherics: Positioned For Strong Growth

**Large, Underserved  
Growing Market**

**Differentiated Technology  
Leading the Category of  
Robotic Focal Therapy**

**Expanding Favorable  
Reimbursement**

**Robust Clinical Evidence**

**Accelerated Global  
Commercial Execution**

**Growing Revenue and  
Pathway To Profitability**

# Thank You

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