# FocalTherics™

The **Global Leader** in Therapeutic Ultrasound

FORWARD-LOOKING

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# FocalTherics™



## Global Leader in Therapeutic Ultrasound for the Treatment of Cancer and Benign Disease

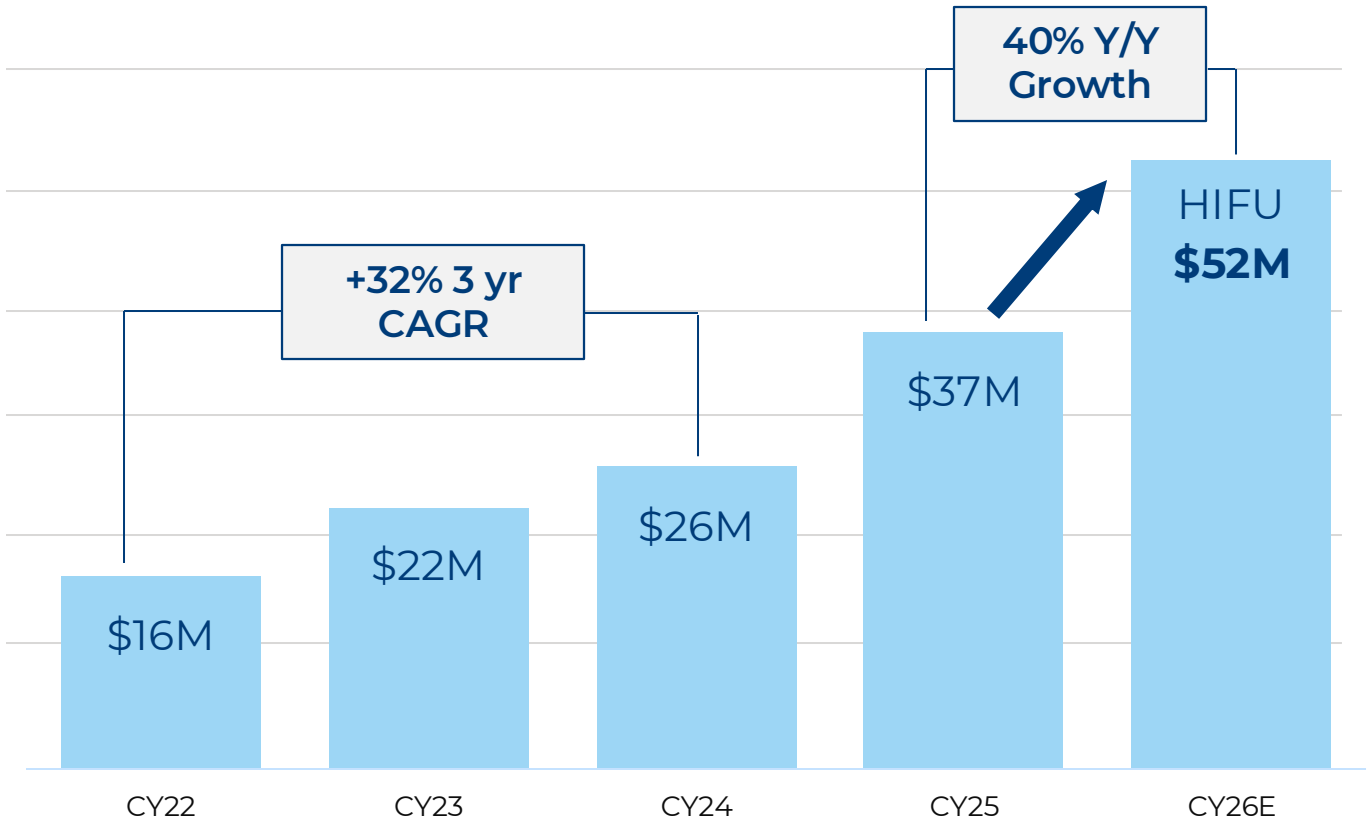


## Redefining the Treatment of Cancer and Benign Disease through Organ Sparing, Function Preserving Focal Therapy

FOCUSING ON ACCELERATING OUR GROWTH ENGINE

# Commitment to Focal Therapy

## HIFU Revenue ($)







Note: CY26E = Midpoint of CY26 Guidance Range Reiterated on August 13, 2026

# 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

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# Large and Growing Market Opportunity in Prostate Cancer

# Prostate Cancer is the Most Common Cancer Among Men[1]

## >1.4 Million[2]
New Cases Diagnosed Annually, Globally

## >330,000
New Cases Diagnosed Annually in the U.S.

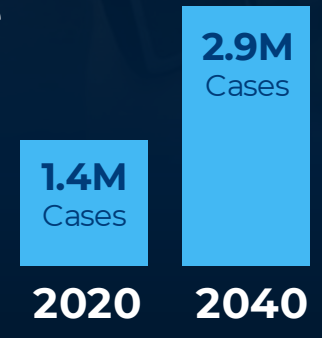
## >3.5 Million
Men Living with Prostate Cancer in the U.S.



Annual Global Prostate Diagnoses Will

**DOUBLE**

by 2040[3]




[1] 2026 estimates from the American Cancer Society (www.cancer.org)
[2] 2022 estimates from the World Health Organization [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 Prostate Cancer Patient's Dilemma

**Treatment**

Active Surveillance

Surgery

Radiation

**A Diagnosis that Demands a Difficult Choice**



**Outcomes**

Treatment Effectiveness

Complications & Recovery

Loss of Urinary Control

Loss of Sexual Function

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# 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

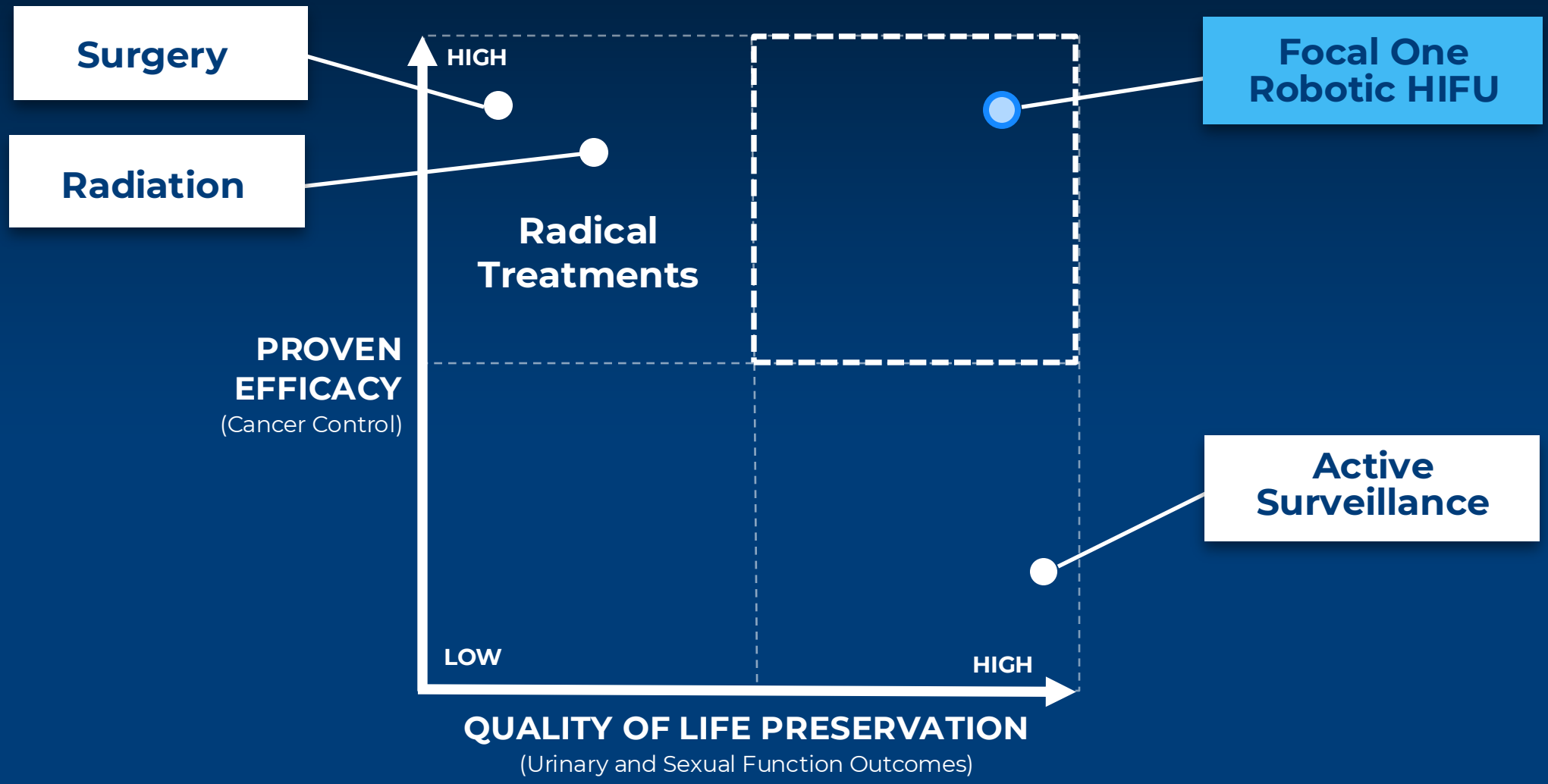




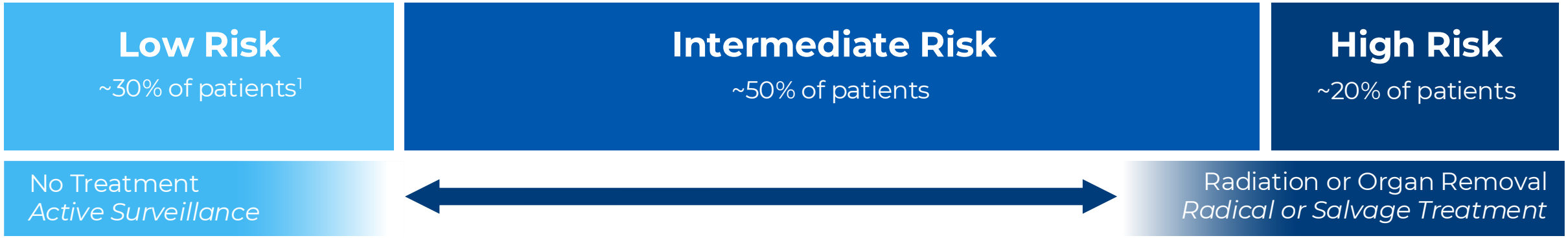
**Robotic Focal HIFU Ablation**

FOCAL ONE® ROBOTIC HIFU

# Prostate Cancer Patient Value Equation



# The Large Gap Between No Treatment and Radical Treatment

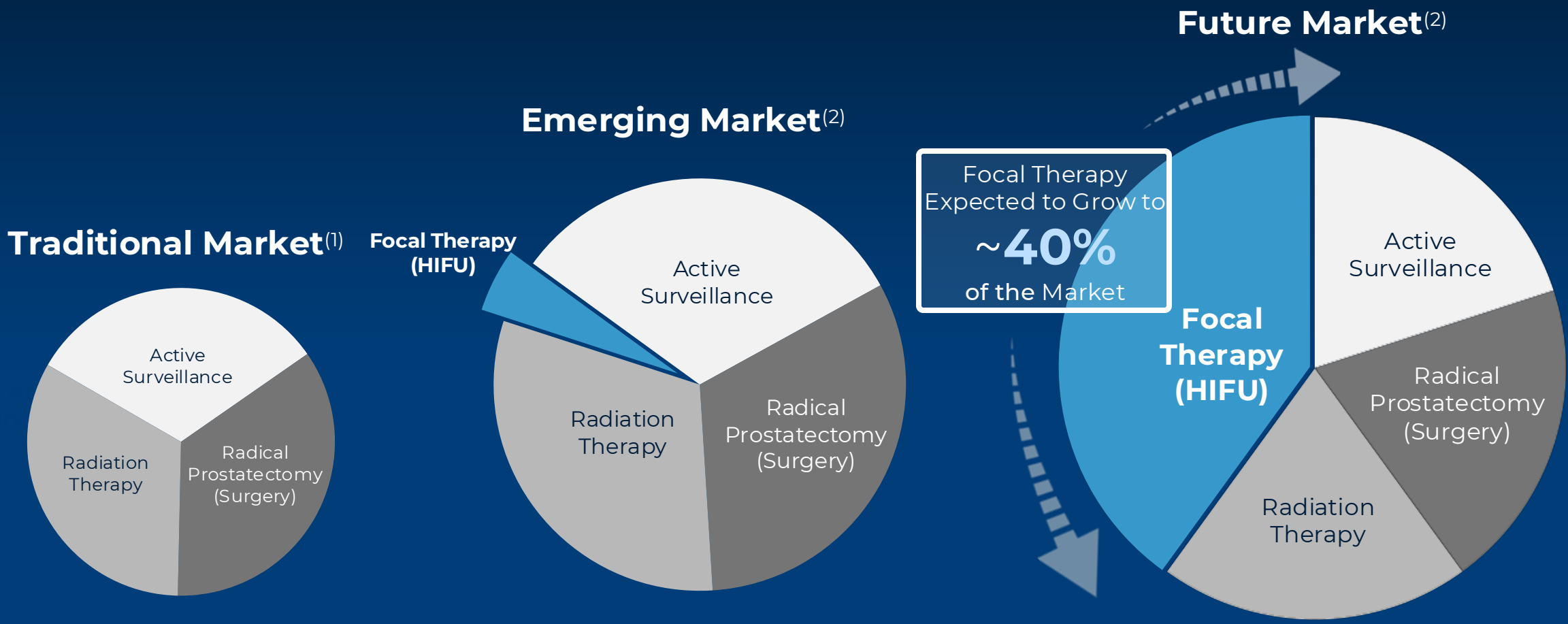



Previously, There Have Been **No Options**, Other Than Active Surveillance or Radical Treatments, **to Address Intermediate Risk Patients**

[1] 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

DRIVING A PARADIGM SHIFT IN PROSTATE CANCER

# Focal Therapy | The New Emerging Market



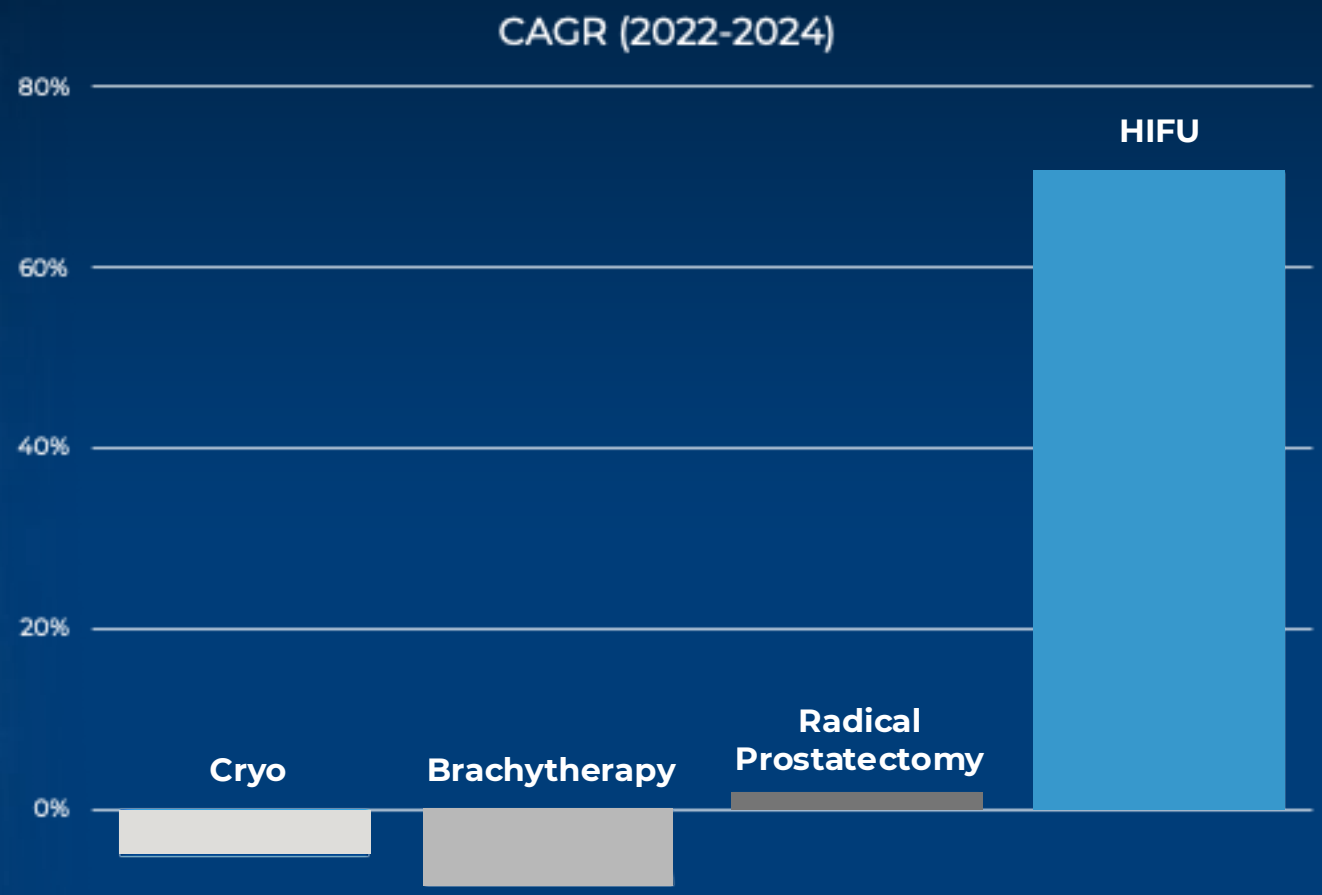

(1) As of 2013. Chen et al. National trends in the management of localized prostate cancer: A population-based analysis 2004-2013. Prostate.
(2) Source: Internal company estimates

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DRIVING A PARADIGM SHIFT IN PROSTATE CANCER

# HIFU | The Fastest Growing Treatment Option



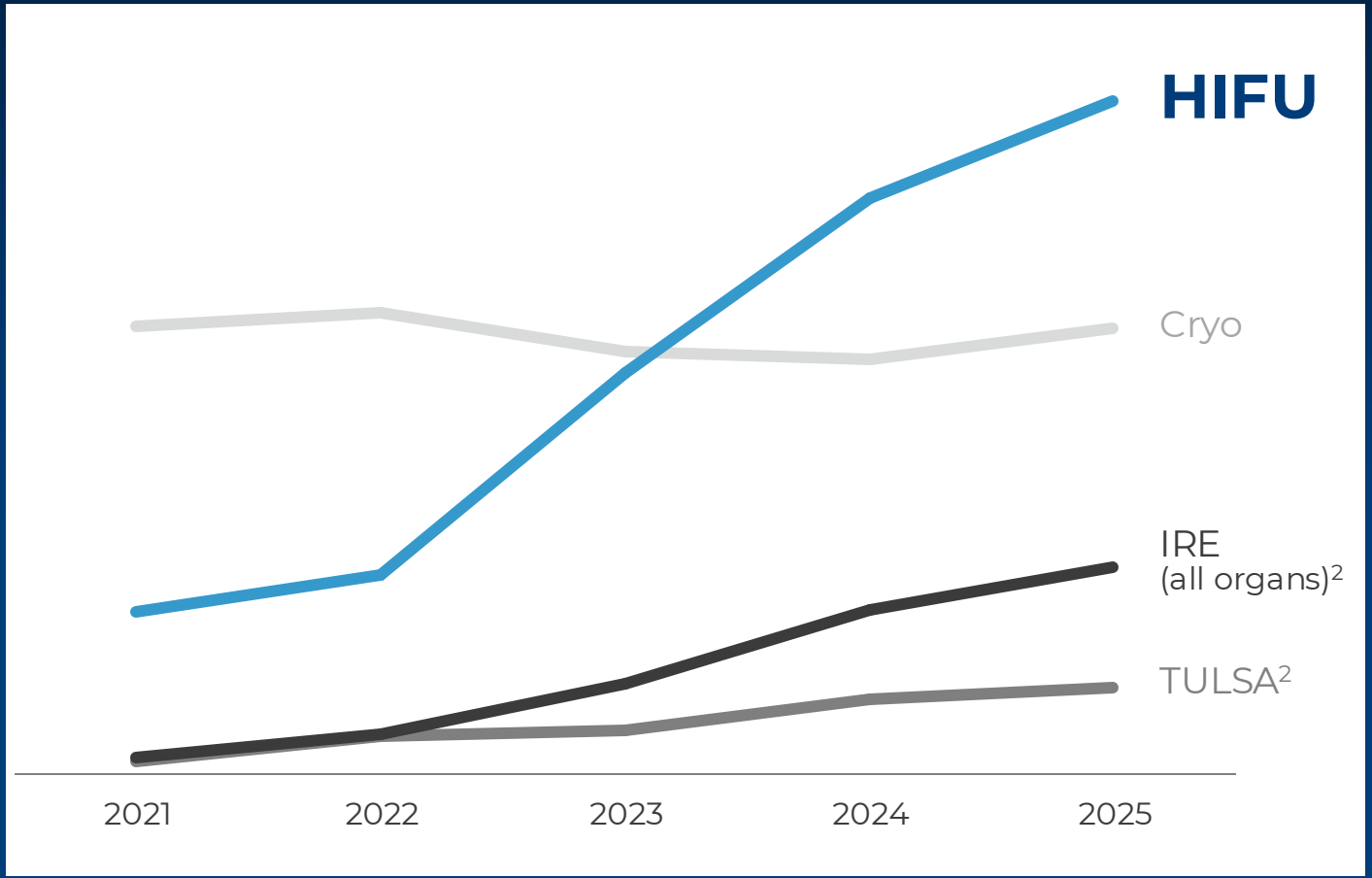



Based on Medicare Claims reported by CMS on HOPPS Final Rule for FY24, FY25 and FY26

# HIFU

## Fastest Growing
## Focal Therapy Treatment[1]

## #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) Proposed Rules for CY 2023–CY 2027.
[2] IRE and TULSA treatment volumes may include procedures other than prostate treatment, as applicable billing codes are not historically prostate-specific.

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# Favorable Facility & Physician Reimbursement

# Hospital Outpatient Medicare Payment

| Procedure | CPT® Code | 2027 Payment (Proposed) | |
|---|---|---|---|
| Prostate Brachytherapy | 55875 | $6,292 | |
| Cryo Ablation | 55873 | $10,797 | |
| **HIFU** | **55880** | **$10,797** | **+11.6%** |
| Laparoscopic/Robotic Prostatectomy | 55866 | $12,300 | |

Medicare Payment (National Average). From CMS Hospital Outpatient Prospective Payment System – CY27 Proposed Rule and CY26 Final rule

# 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 |

Based on CMS Physician Fee Schedule – CY 2026 Final rule

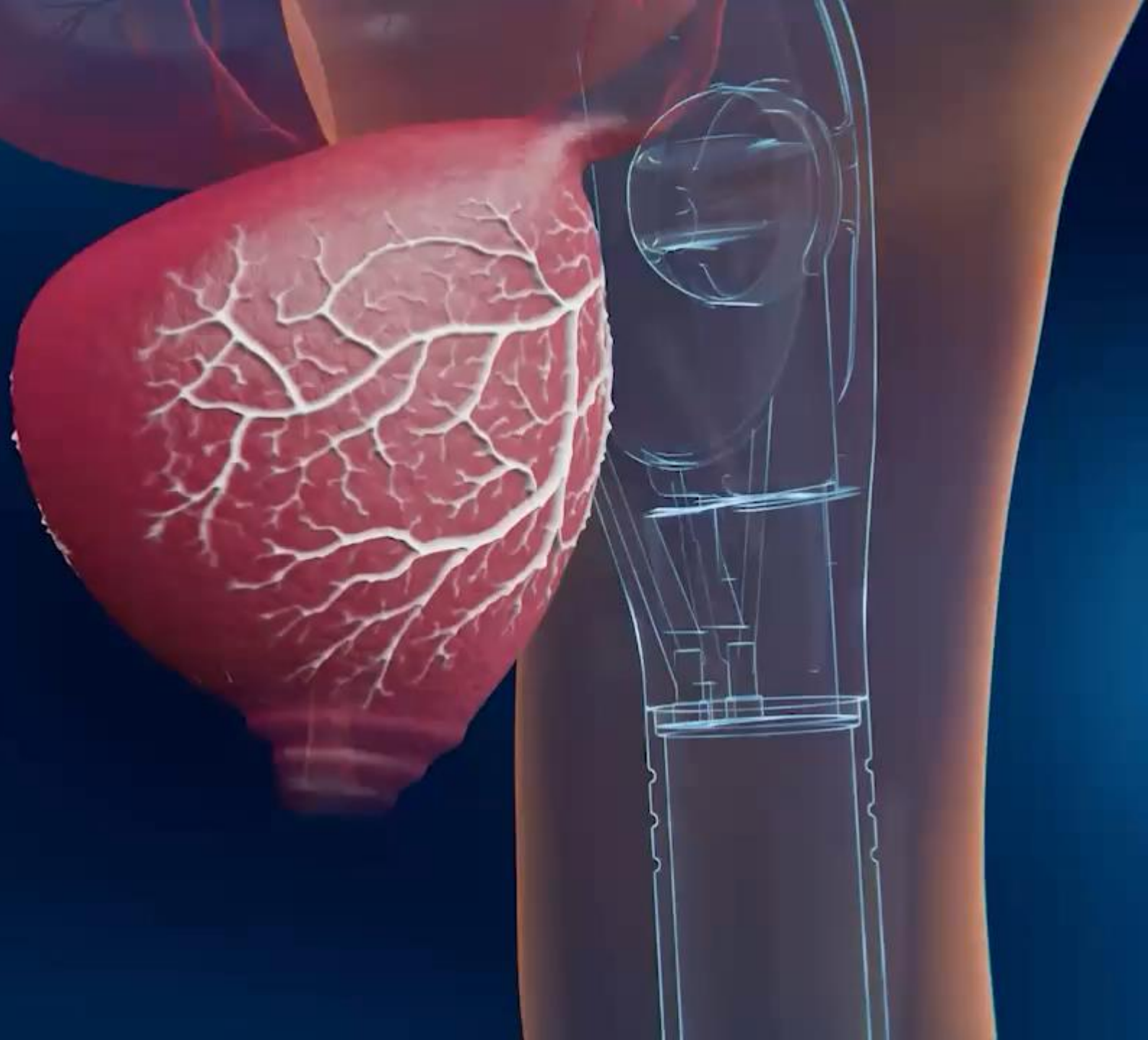
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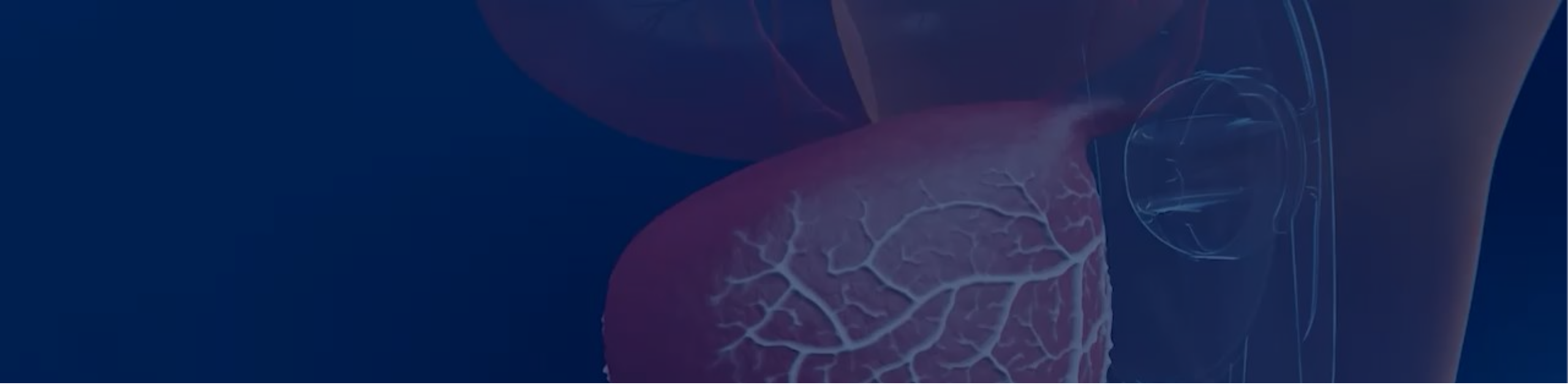
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# Technology Leadership & Innovation on the Focal One Platform

## Non-Invasive

**No Surgery**
**No Cutting**
**No Radiation**





Advanced Imaging

High-Intensity Focused Ultrasound (HIFU)

Precise Robotic Energy Delivery

**Organ Sparing, Function Preserving**



# The **Most Advanced Robotic HIFU** Platform Controlled by Urologists

## Focal One® *i*

- Expanded HIFUsion® Capabilities
- Streamlined Treatment Workflows
- Embedded Video Content Library
- Treatment Streaming and Recording*
- Remote Proctoring & Telecollaboration*
- Endometriosis Treatment Ready*

HIFUsion®
**Image-Guided Treatment Planning**

MRI, PSMA PET
Unfold AI*, OnQ Prostate*
Koelis* and DynaCAD* 3D Biopsy

**Precise Robotic Positioning**

Multi-Axis Sub-millimeter Robotic Movements

**Dynamic Focusing Probe**

Auto-Adjusting Pinpoint Delivery of HIFU Energy

**Integrated Workstation**

Compatible With Standard OR Beds

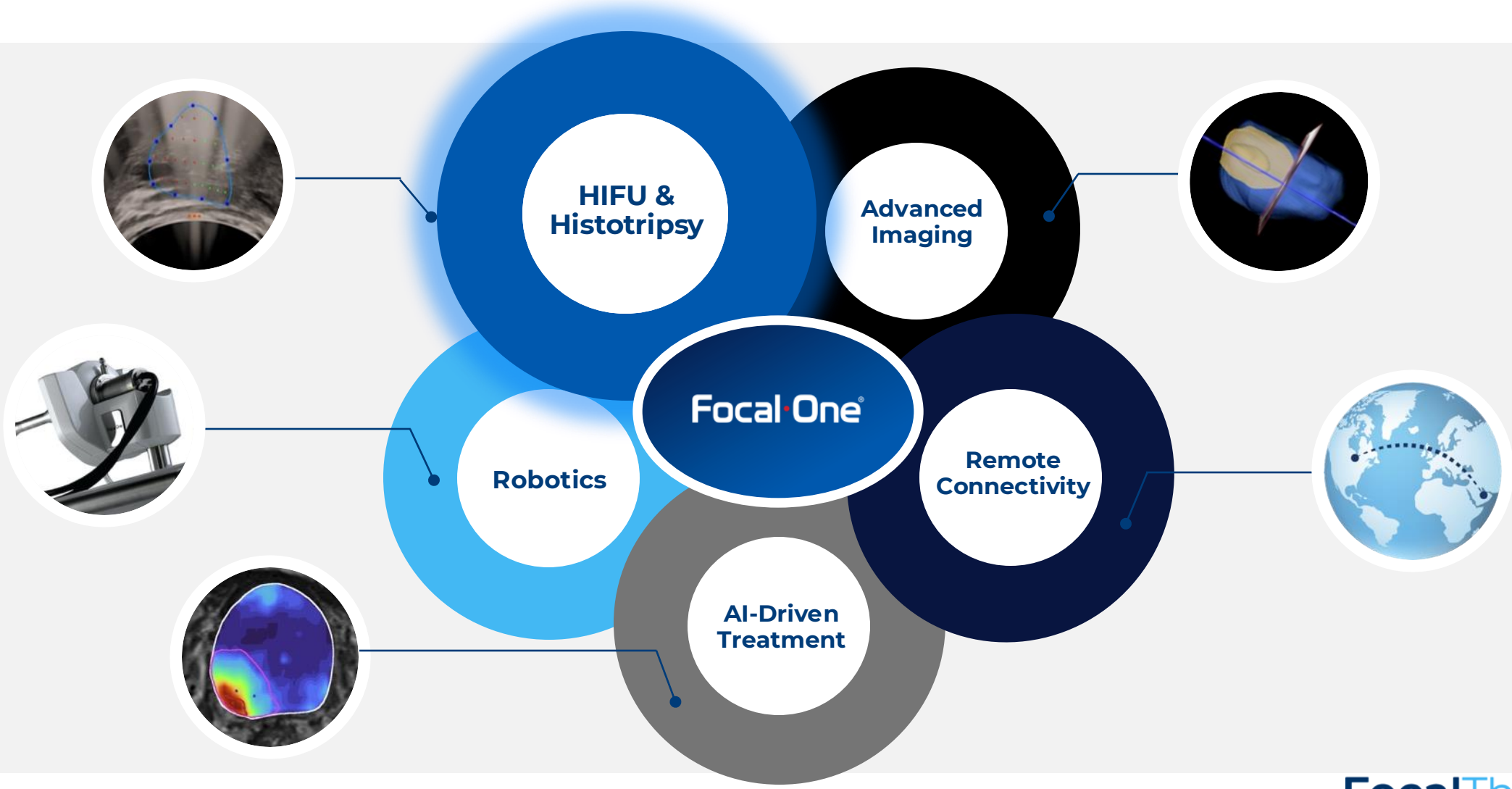



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* Not available in all markets. May require additional purchase

# Scalable Focal One Platform Enables Simultaneous Innovation



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# Strong Supporting Clinical Evidence

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

Prospective Comparative

**HIFI[1]**
*European Urology*

**HIFU** vs **Radical Prostatectomy**

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

Prospective Salvage

**HIFI-2[2]**
*European Urology Oncology*

**HIFU** in **Salvage Post Radiation**

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

Long-Term Retrospective

**CGRD[3]**
Int. Urology and Nephrology

**HIFU** vs **Radiation**

HIFU Demonstrated Higher Survival at 10 Years versus Radiation

RCT

**FARP[4]**
Presented at AUA 2025

**Focal Ablation** vs **Radical Prostatectomy**

Focal Ablation Demonstrated Equivalent Cancer Control

RCT

**HIFUSA[5]**
Presented at AFU 2025

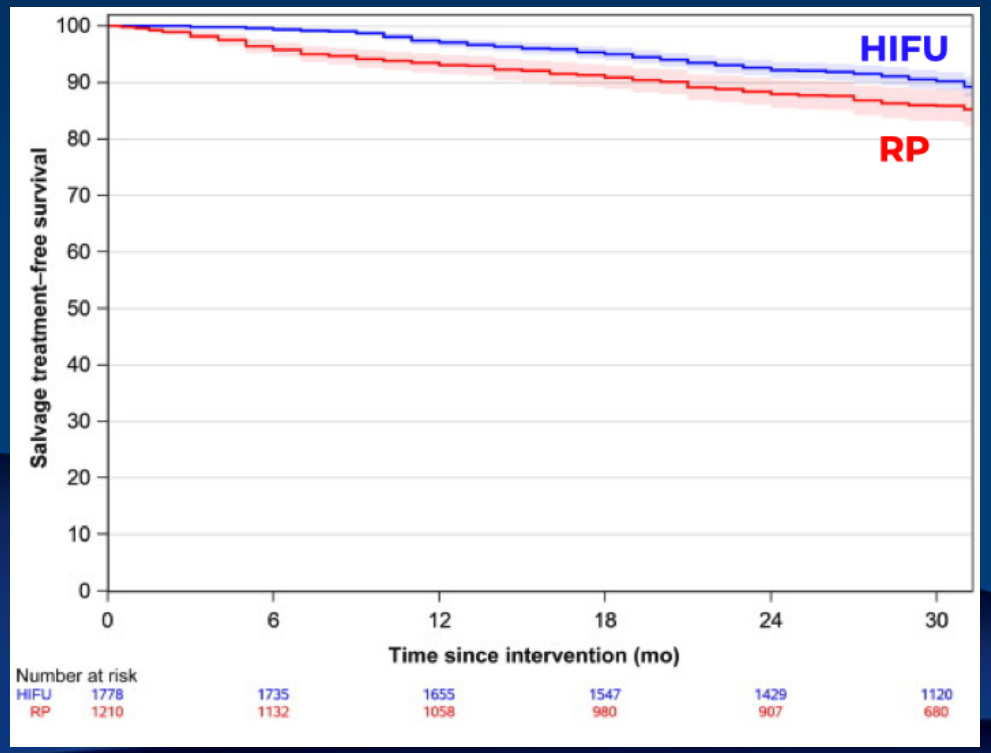
**HIFU** vs **Active Surveillance**

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.eururo.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,

# HIFI - Prospective Multicentric Comparative Study Focal One® HIFU vs Radical Prostatectomy

## **Published in European Urology** – December 2024




**Prospective, Comparative, Multicentric**, non-inferiority clinical trial comparing HIFU to Radical Prostatectomy (RP)

**3,328 patients** treated (1,967 HIFU - 1,361 RP) across **46 centers**

**90%** of HIFU patients treated with Focal One

**Comparable Cancer Control** (Primary Endpoint):
**90%** STFS for HIFU vs **86%** for RP; p = 0.008

**Superior functional outcomes for HIFU** (Secondary Endpoint):

- Urinary Continence significantly better after HIFU
- Significantly lower stress incontinence after HIFU
- Erectile Function less impaired

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.eururo.2024.11.006

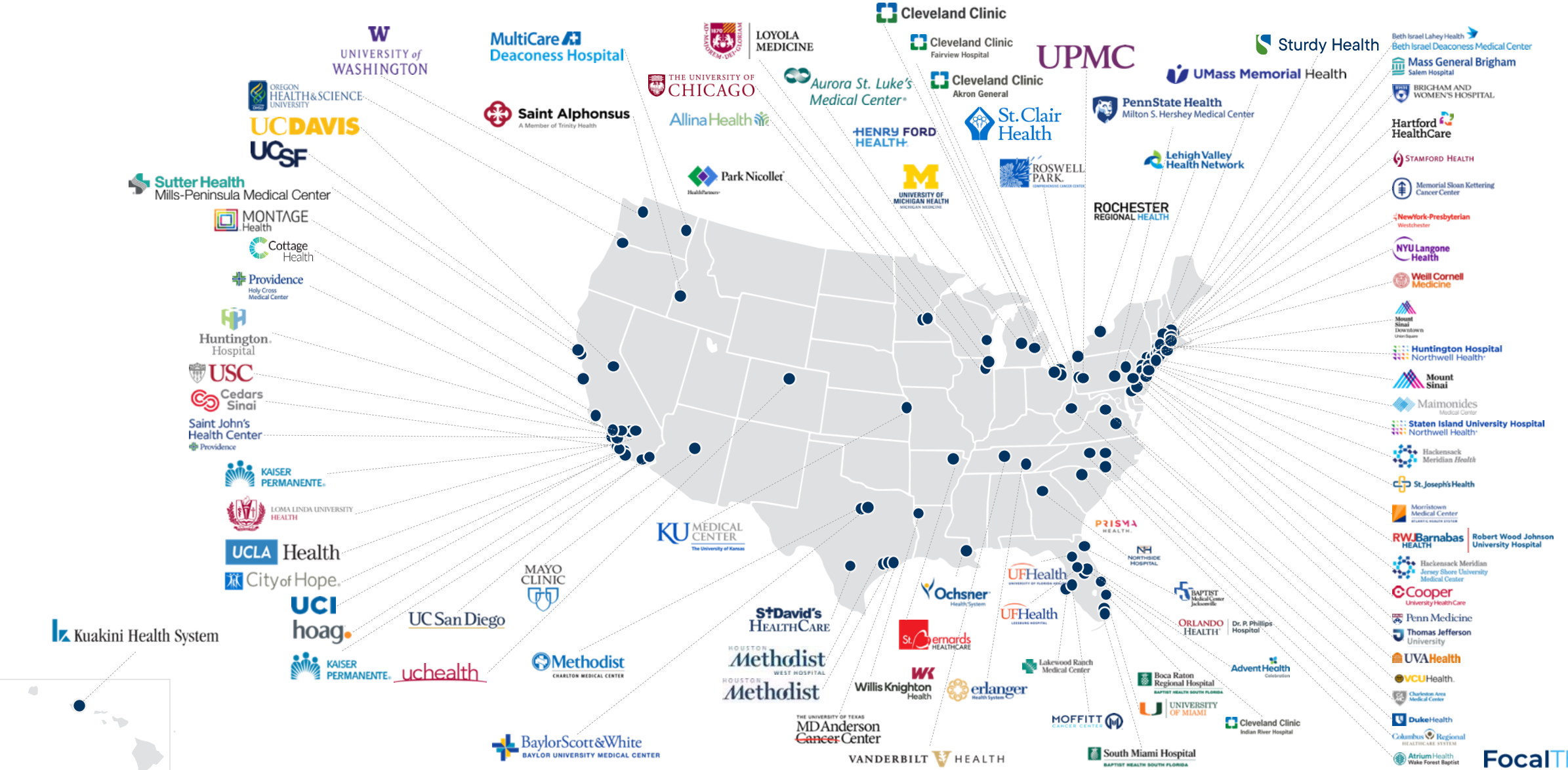
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# Growing Global Install Base

FOCAL ONE ADOPTION ACCELERATING

# At Major U.S. Hospitals

**96 Focal One Systems** as of Jun. 30, 2026
**(44 Academic – 52 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%**

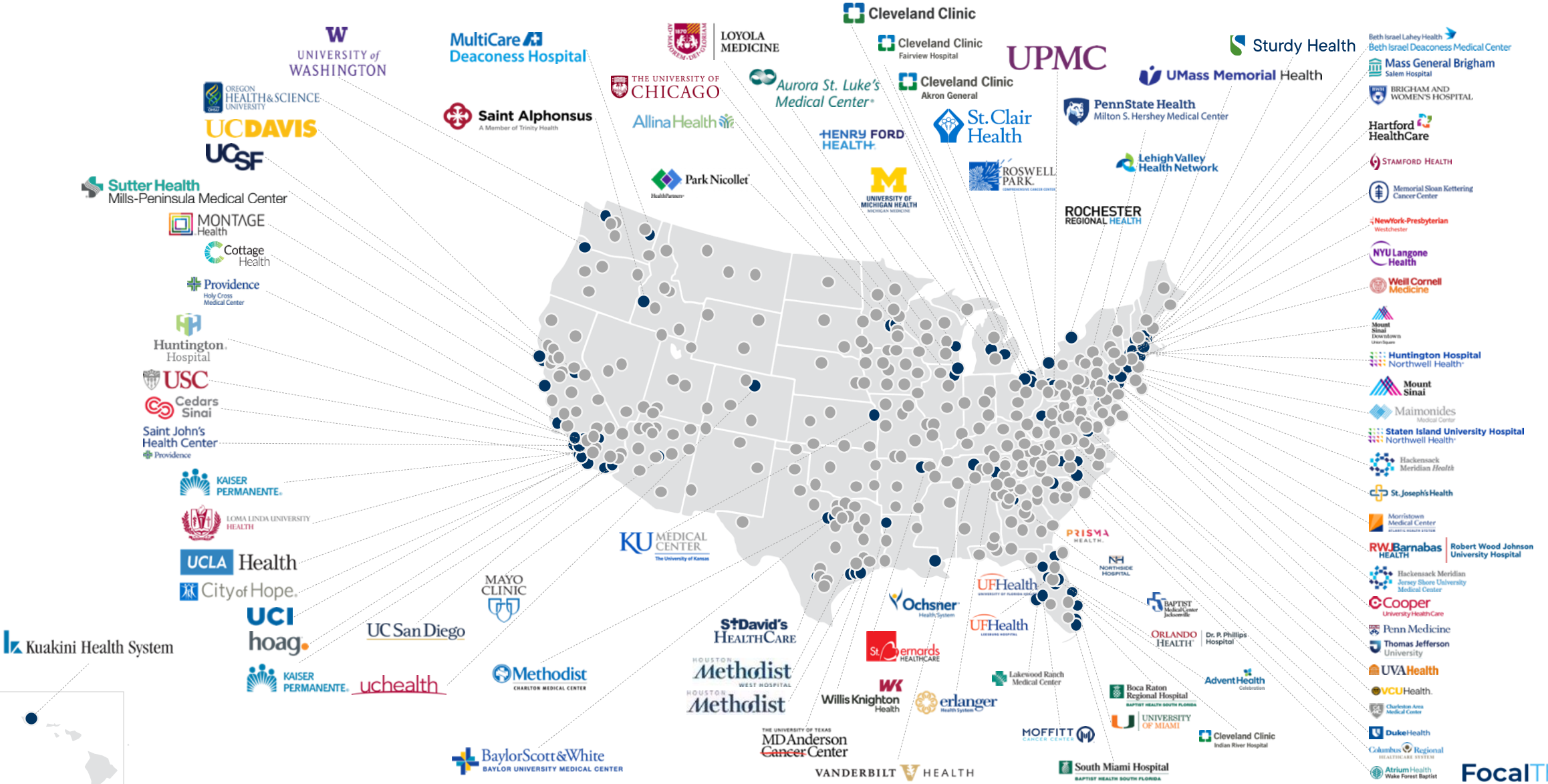
19 Out of 33



FOCAL ONE ADOPTION ACCELERATING

# At Major U.S. Hospitals

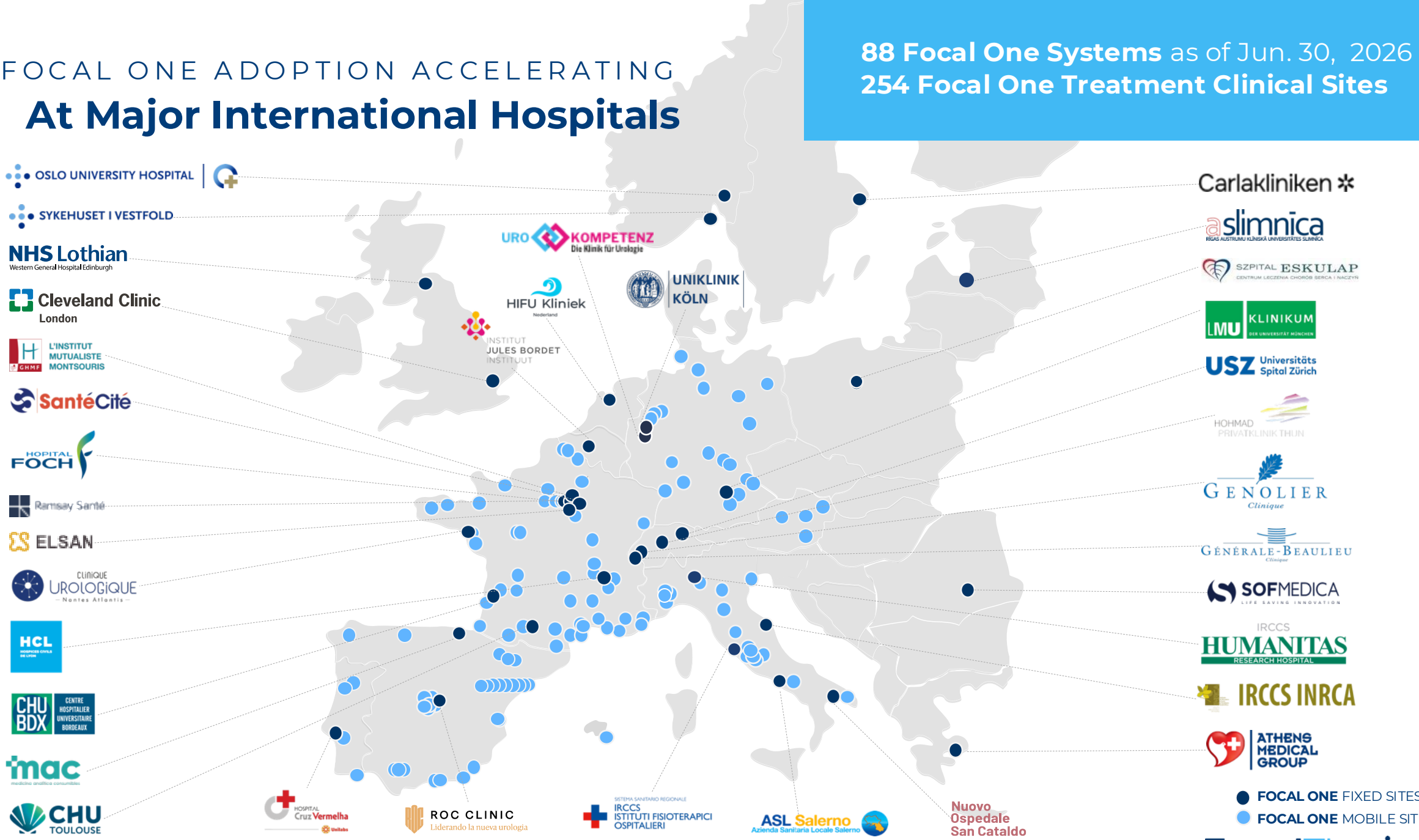
**96 Focal One Systems** as of Jun. 30, 2026
300+ Hospitals in Sales Pipeline



FOCAL ONE ADOPTION ACCELERATING

# At Major International Hospitals

**88 Focal One Systems** as of Jun. 30, 2026
**254 Focal One Treatment Clinical Sites**




**FOCAL ONE** FIXED SITES
**FOCAL ONE** MOBILE SITES

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# Expanding Clinical Indications

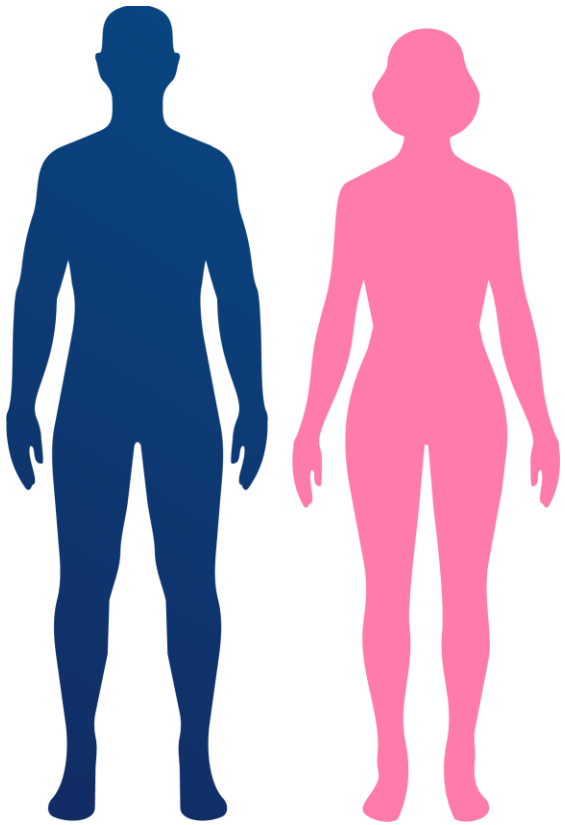
SINGLE PLATFORM, MULTIPLE INDICATIONS

# Expanded Indications of Focal One

## Benign Prostatic Hyperplasia (BPH)

**100+ Million**[1]
Men Living with BPH Globally

**13+ Million**[1]
New Cases Diagnosed Annually, Globally



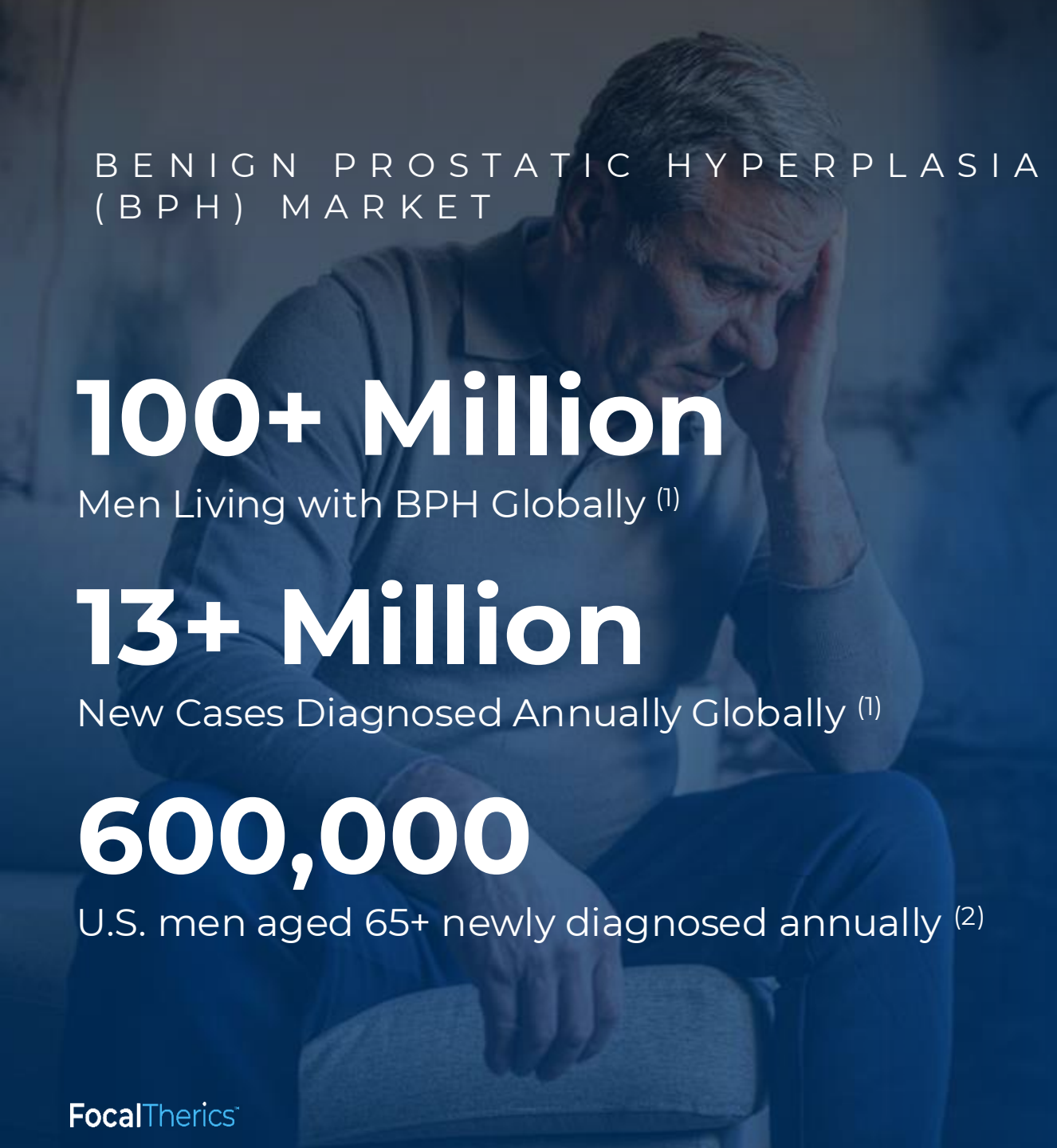
## Deep Infiltrating Endometriosis

**38M**
Women Living with Deep Infiltrating Endometriosis Globally[2,3,4,5]

**783,000+**
Patients Diagnosed with Deep Rectal Endometriosis Globally[2,3,4,5]

[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] 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. [3]* 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. [4]* 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. [5]* United Nations, Department of Economic and Social Affairs, Population Division. World Population Prospects 2024. *Women aged 15-49 by country, 2024 mid-year estimates.*

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BENIGN PROSTATIC HYPERPLASIA (BPH) MARKET

# 100+ Million

Men Living with BPH Globally [1]

# 13+ Million

New Cases Diagnosed Annually Globally [1]

# 600,000

U.S. men aged 65+ newly diagnosed annually [2]

## Leveraging Expertise in **Robotic HIFU** and Prostate for **BPH**

12.2 Million men actively managed for BPH/LUTS:

- 55% under Drug Management [3]
- 35% under Watchful Waiting [3]
- 300,000+ Active Surgical Treatments [4]

**Focal One** Robotic HIFU technology has the potential to provide a **non-invasive** option that can safely treat BPH-related symptoms while avoiding the side effects of standard surgical treatments.

10,000s PCa treatments constitute a robust foundation to build upon for a BPH strategy

[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
[3] Vuichoud et al. Can J Urol. 2015
[4] Source: Internal company estimates

# A BPH Solution Designed to Meet Patient Priorities

**Non-Invasive**

**No Bleeding**

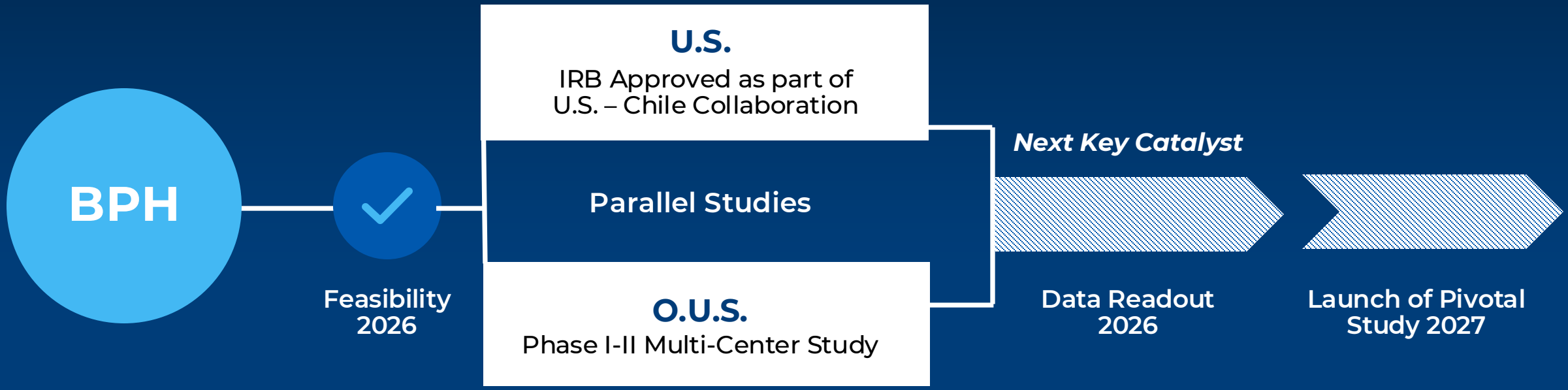
**No Foreign Body**

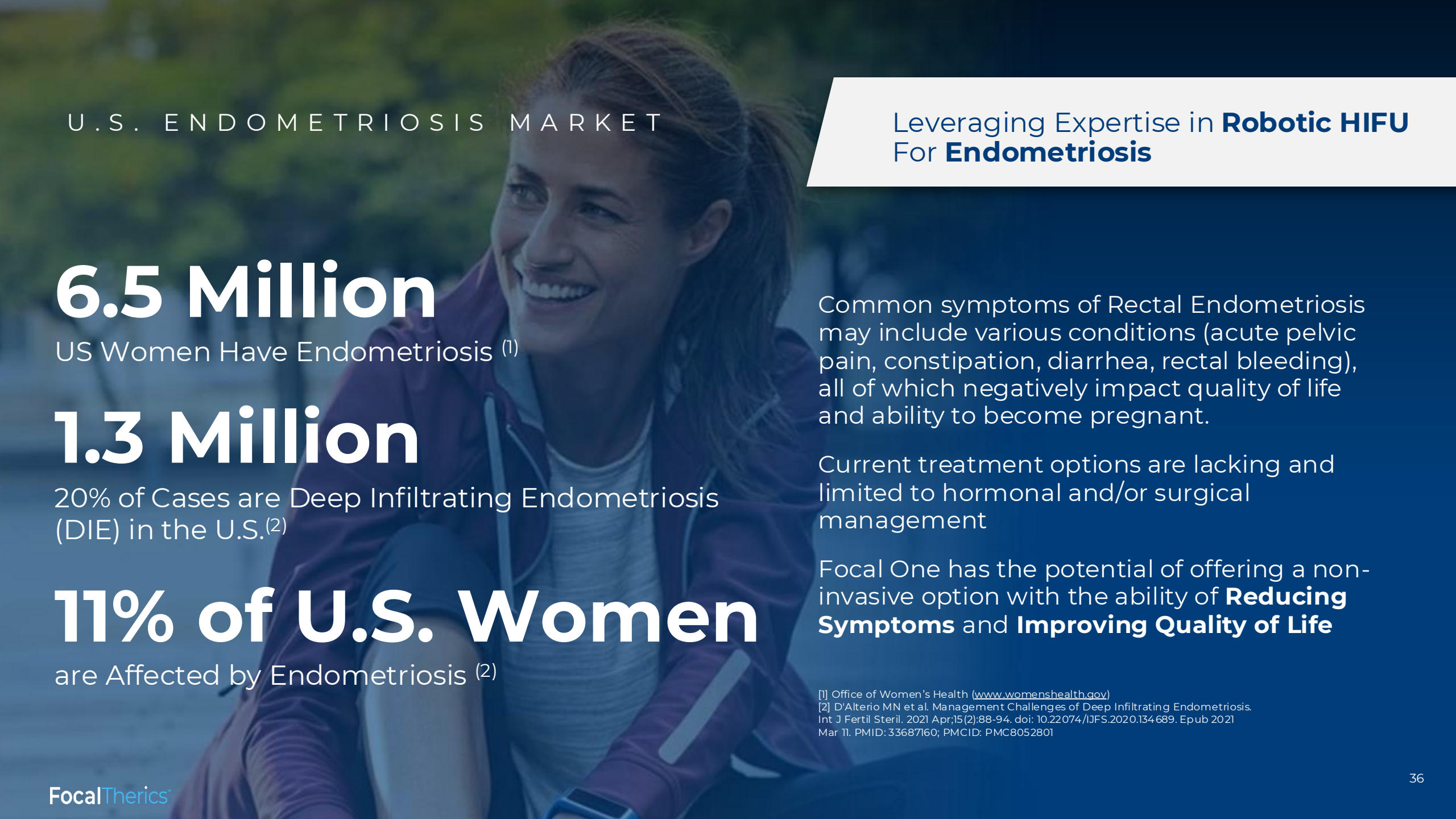
**No Quality-of-Life Tradeoffs**



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

# BPH Indication Expansion Pipeline





U.S. ENDOMETRIOSIS MARKET

## Leveraging Expertise in **Robotic HIFU** For **Endometriosis**

# 6.5 Million

US Women Have Endometriosis [1]

# 1.3 Million

20% of Cases are Deep Infiltrating Endometriosis (DIE) in the U.S.[2]

# 11% of U.S. Women

are Affected by Endometriosis [2]

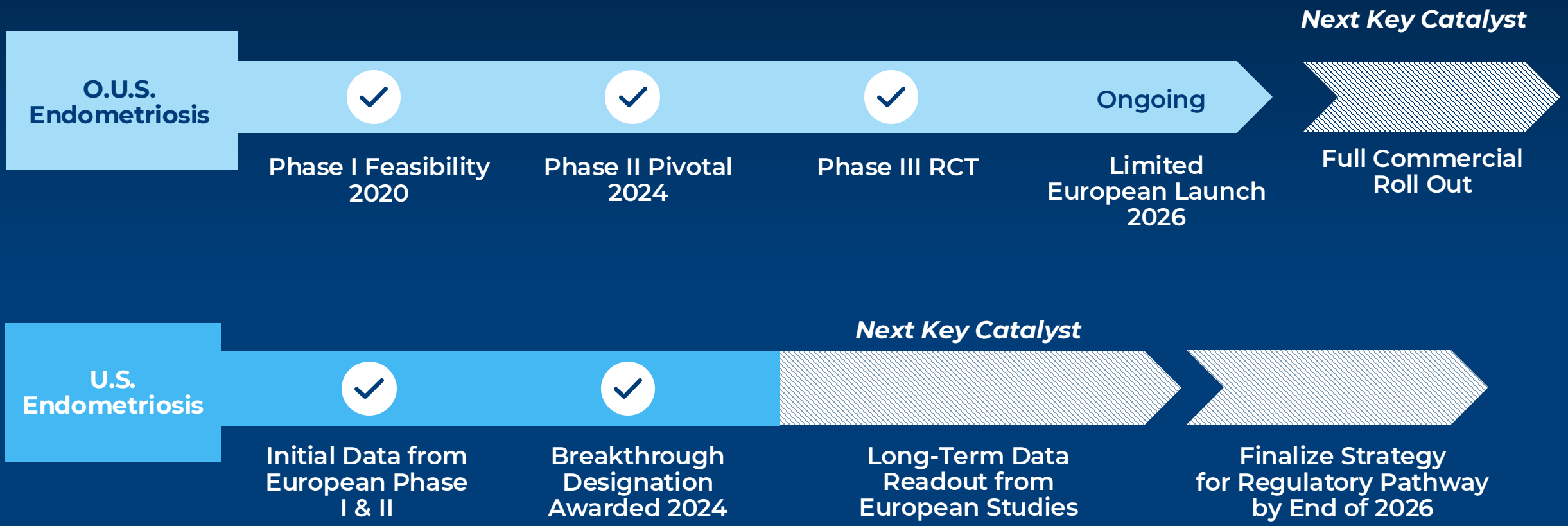
Common symptoms of Rectal Endometriosis may include various conditions (acute pelvic pain, constipation, diarrhea, rectal bleeding), all of which negatively impact quality of life and ability to become pregnant.

Current treatment options are lacking and limited to hormonal and/or surgical management

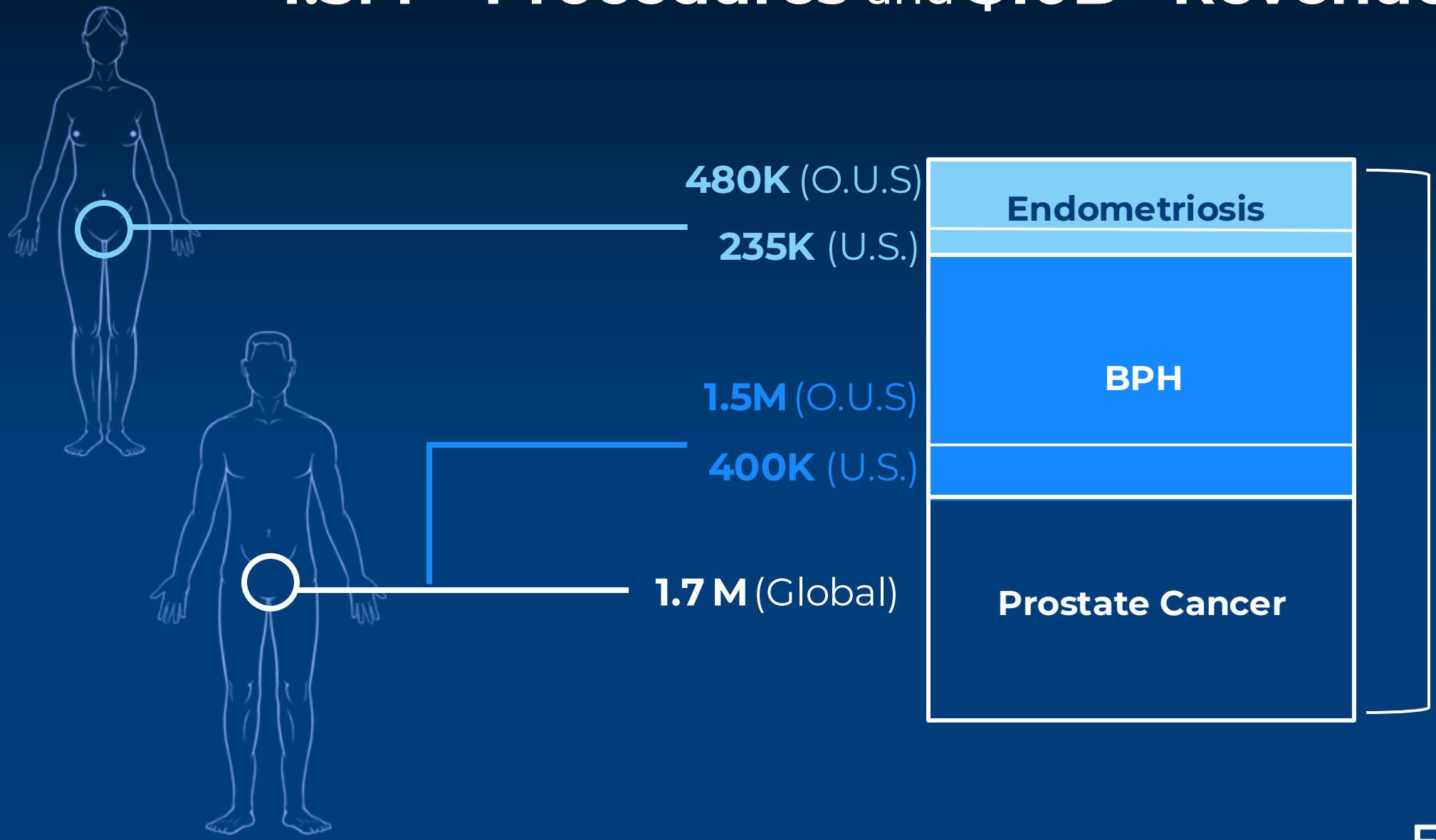
Focal One has the potential of offering a non-invasive option with the ability of **Reducing Symptoms** and **Improving Quality of Life**

[1] Office of Women's Health (www.womenshealth.gov)
[2] D'Alterio MN et al. Management Challenges of Deep Infiltrating Endometriosis. Int J Fertil Steril. 2021 Apr;15(2):88-94. doi: 10.22074/IJFS.2020.134689. Epub 2021 Mar 11. PMID: 33687160; PMCID: PMC8052801

# Endometriosis Indication Expansion Pipeline



# Focal One Platform Expansion Opportunity Represents a TAM of **4.3M+[1] Procedures** and **$10B+ Revenue**




[1] Management Estimates; data on file.

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# Key Business Trends & Financial Highlights

# Q2 2026 Financial Highlights

**$13.2M**
HIFU Revenue
39% Y/Y Growth

**44%**
Y/Y Growth
13 Focal One System Sales

**184**
Global Installed Base

**47%**
Y/Y Procedure
Volume Growth

**55.6%**
Gross Margin
+444 bps Y/Y

ESWL & DISTRIBUTION NOW CLASSIFIED
UNDER DISCONTINUED OPERATIONS

# 2028E Target Model Financial Framework

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

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

Supported by Recent $43M+ Equity Raise (Aug. 2026) to Fund Execution

Note: E = Estimate

# 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**

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