

FocalTherics™

The **Global Leader** in Therapeutic Ultrasound

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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

FocalTherics™

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

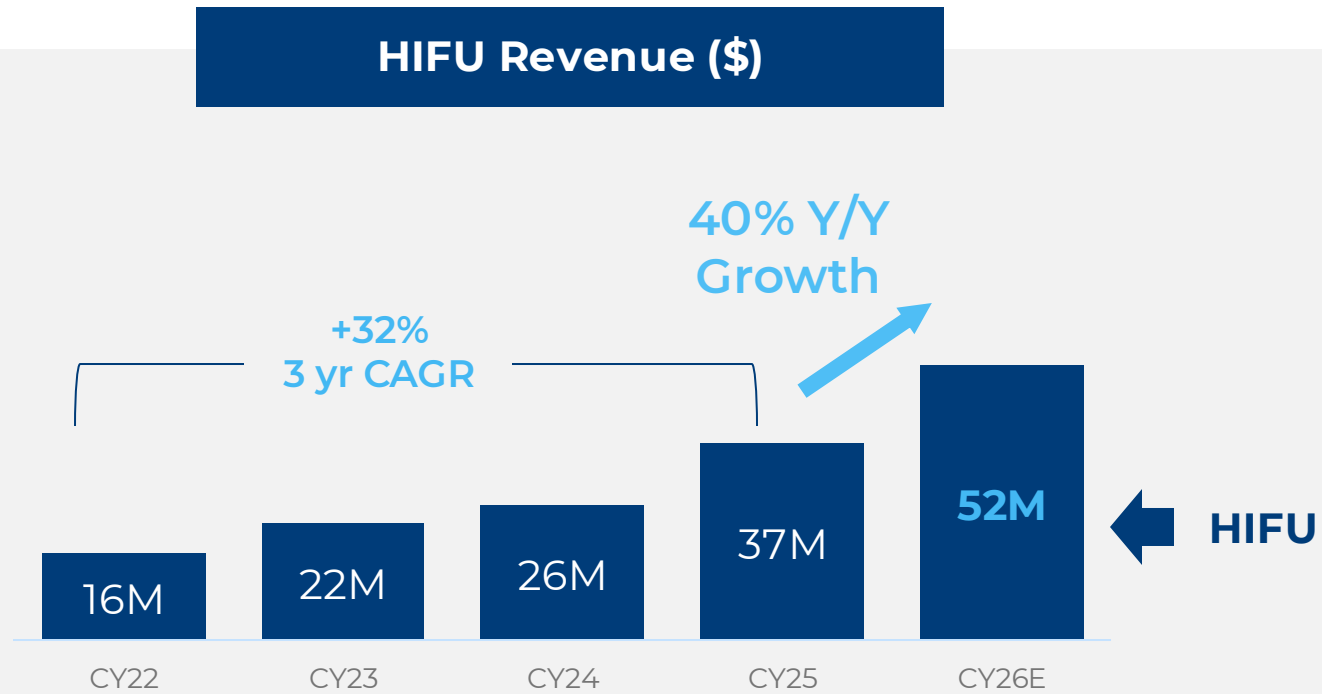
Redefining the Treatment of Cancer and
Benign Disease through Organ Sparing,
Function Preserving Focal Therapy



Large and Growing Market Opportunities In Prostate Cancer, BPH and Endometriosis

Commitment to Focal Therapy

Focusing on Accelerating Our Growth Engine



Note: CY26E = Midpoint of CY26 Guidance Range

Prostate Cancer is the Most Common Cancer Among Men¹

>1.4 Million²

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 2040³

1.4M
Cases

2020

2.9M
Cases

2040

[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



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

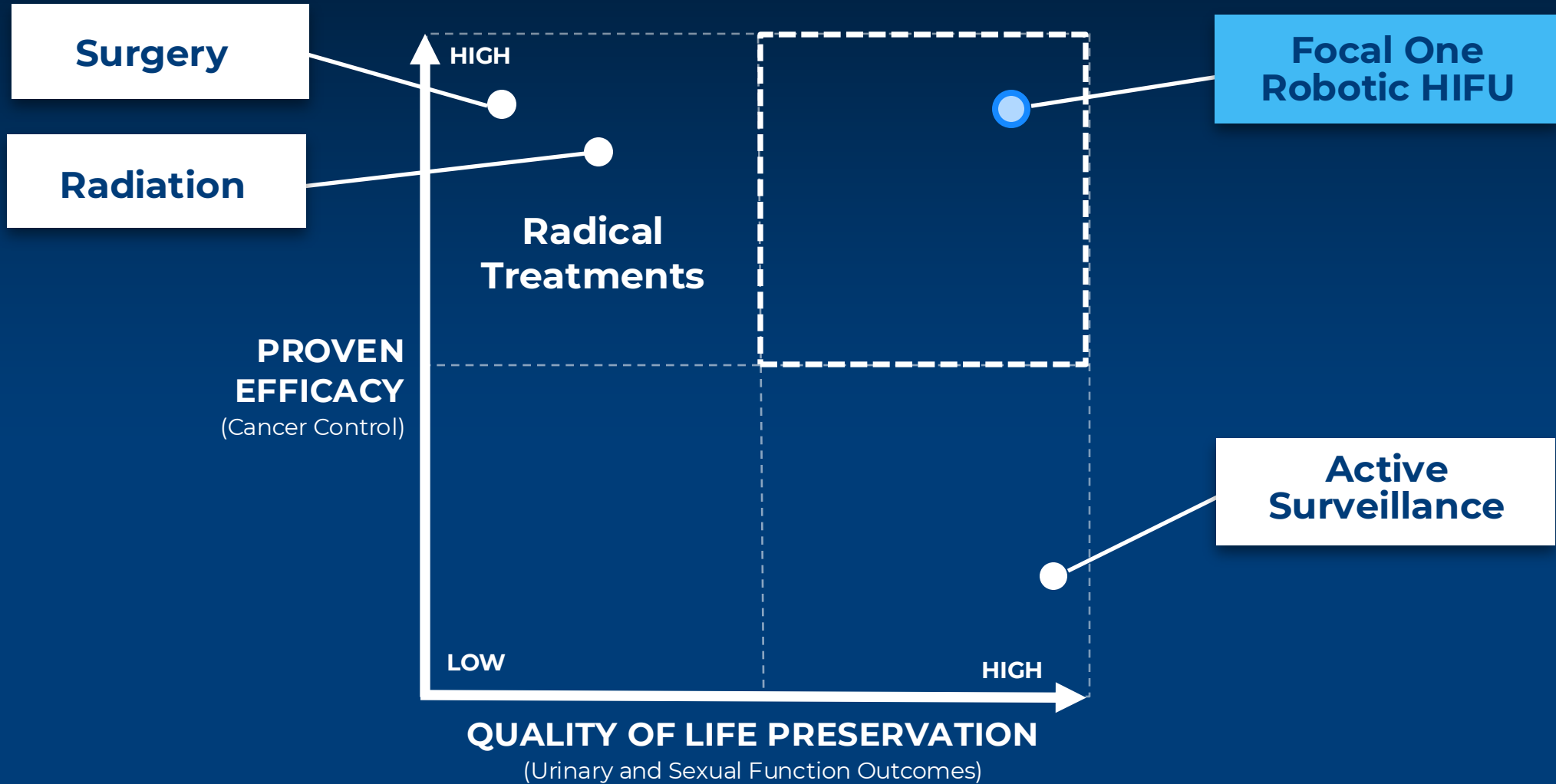


SBRT Radiation

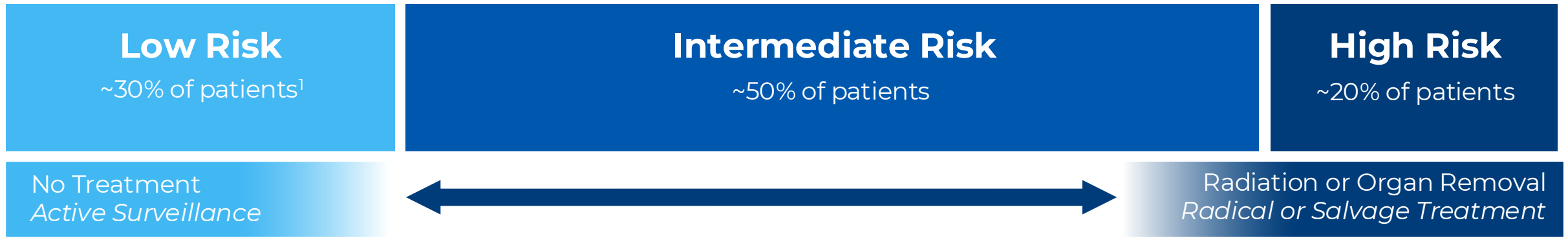


**Robotic Focal
HIFU Ablation**

Prostate Cancer Patient Value Equation



The Large Gap Between No Treatment and Radical Treatment

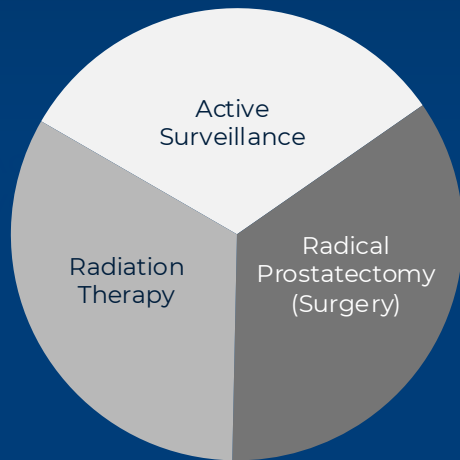


Previously, There Have Been **No Options**, Other Than Active Surveillance or Radical Treatments, **to Address Intermediate Risk Patients**

DRIVING A PARADIGM SHIFT IN PROSTATE CANCER

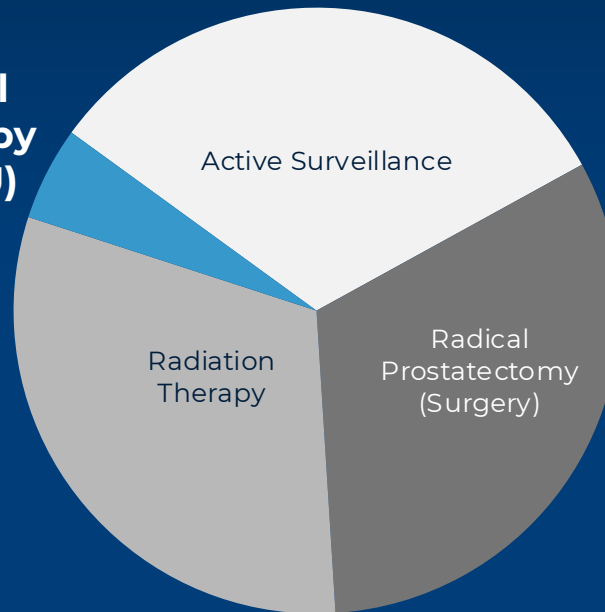
Focal Therapy | The New Emerging Market

Traditional Market⁽¹⁾



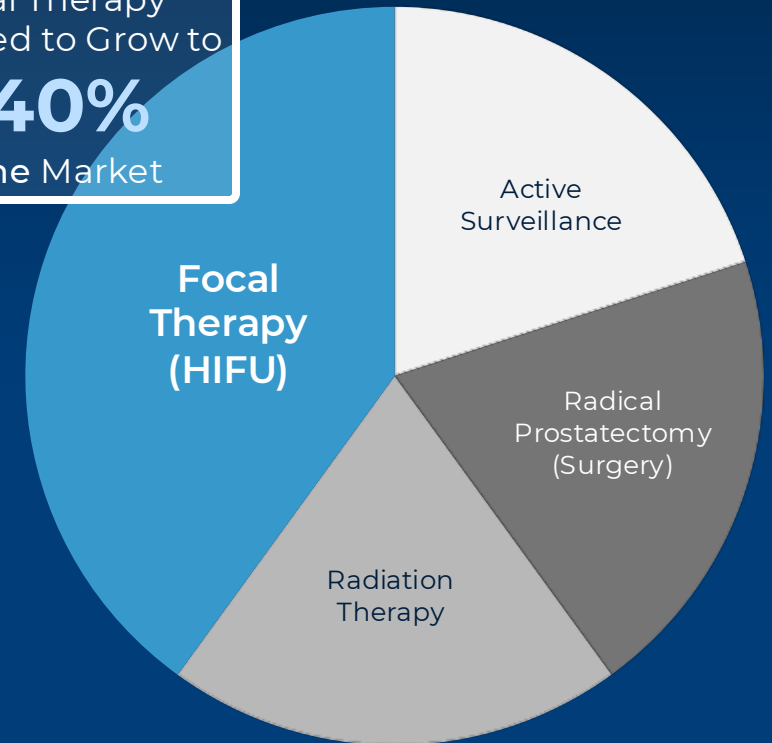
Emerging Market⁽²⁾

Focal Therapy (HIFU)



Future Market⁽²⁾

Focal Therapy
Expected to Grow to
~40%
of the Market

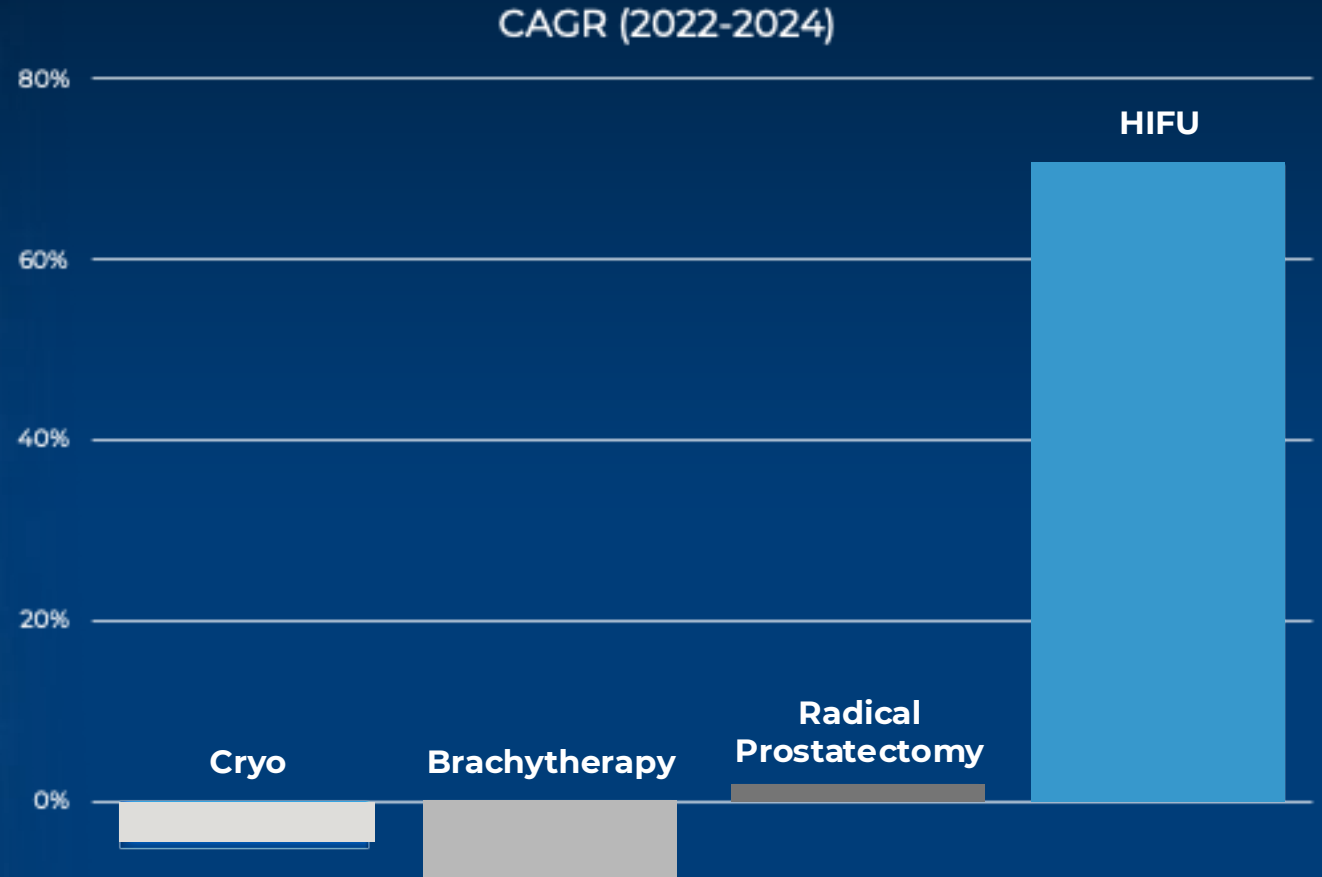


(1) As of 2013. Chen et al. National trends in the management of localized prostate cancer. A population-based analysis 2004-2013. Prostate.

(2) Source: Internal company estimates

DRIVING A PARADIGM SHIFT IN PROSTATE CANCER

HIFU | The Fastest Growing Treatment Option

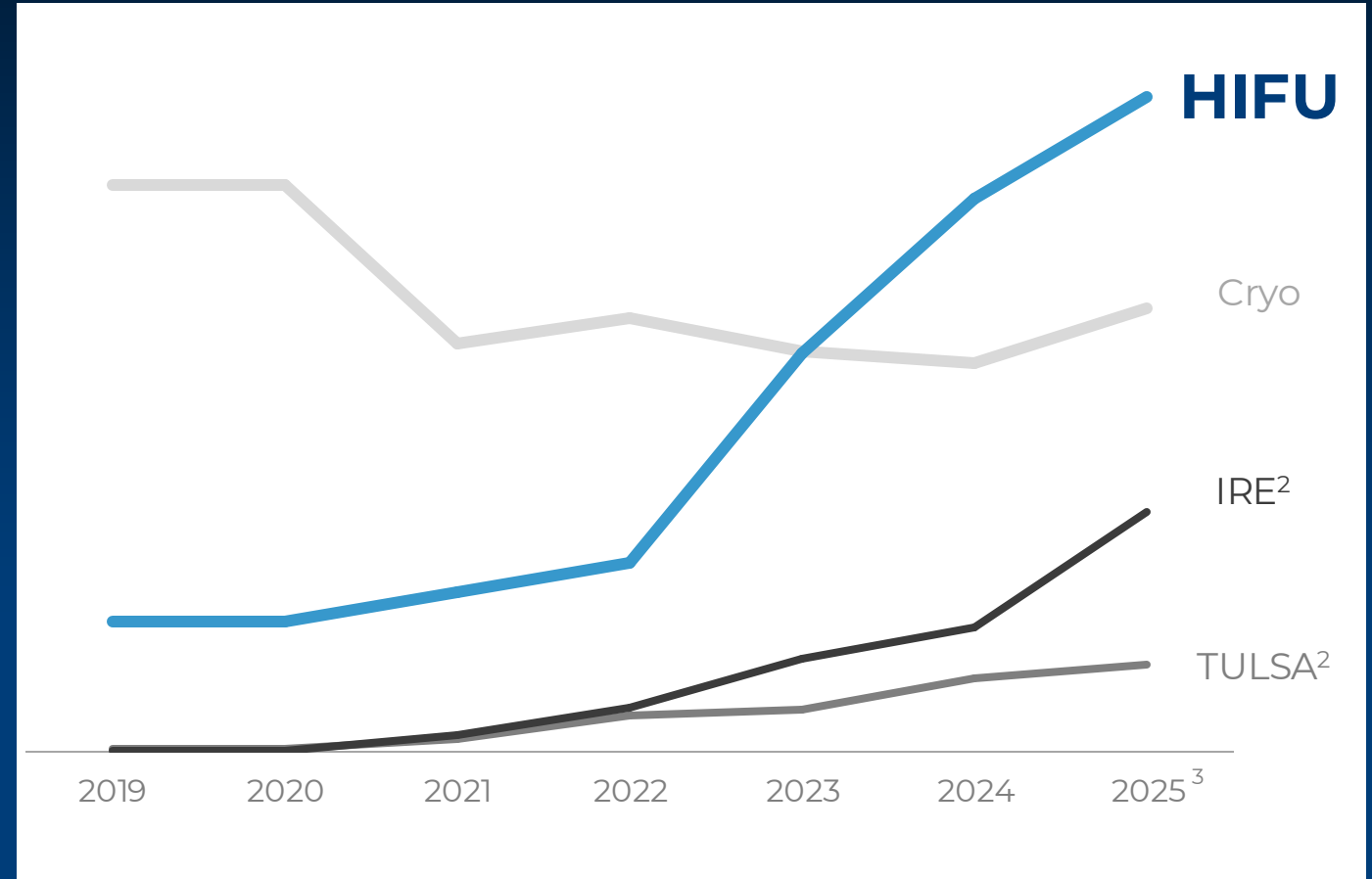


Based on Medicare Claims reported by CMS on HOPPS Final Rule for FY24, FY25 and FY26

HIFU

**Fastest Growing
Focal Therapy Treatment¹**

**#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.

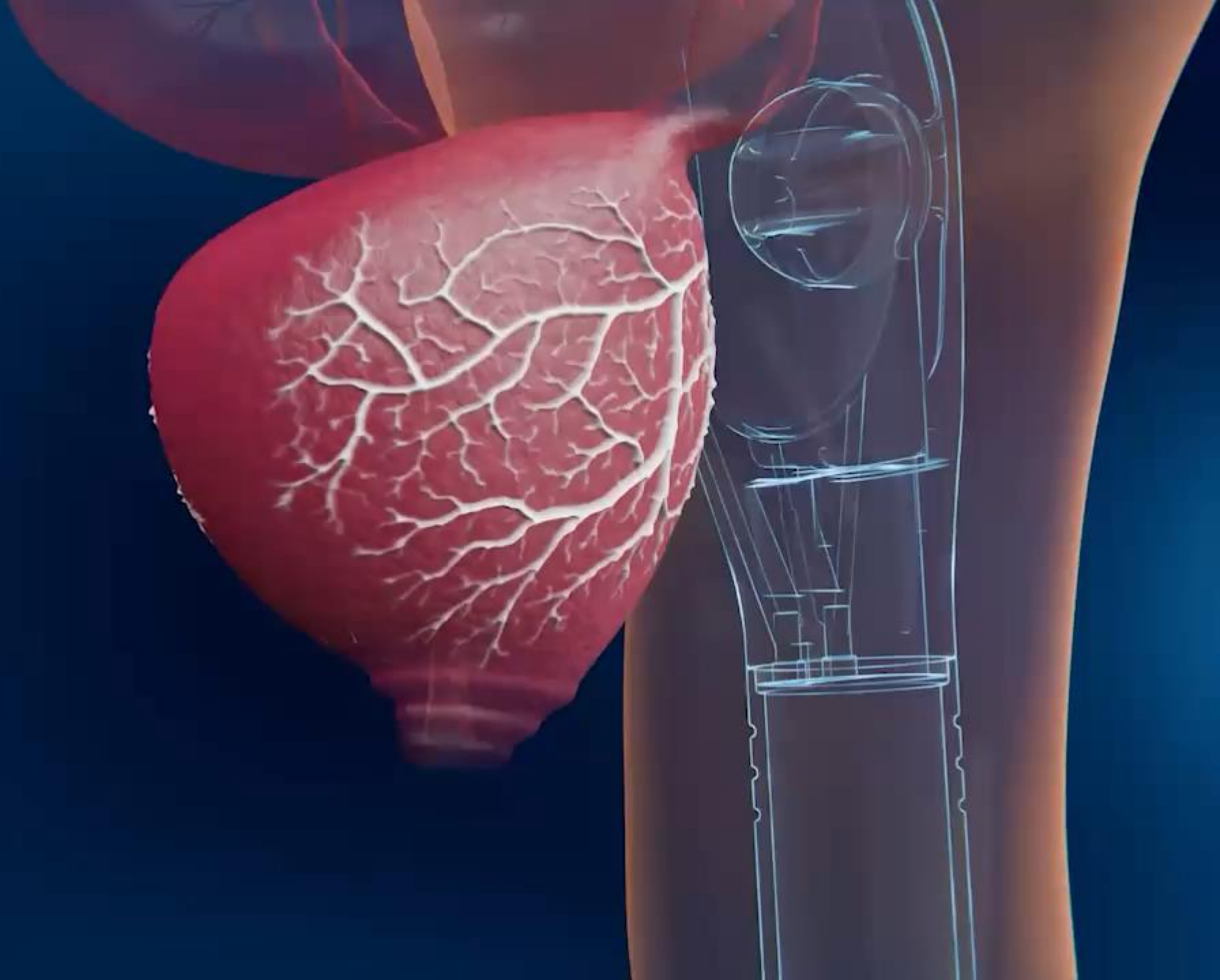
[3] Company Data on File

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

HIFUson® 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

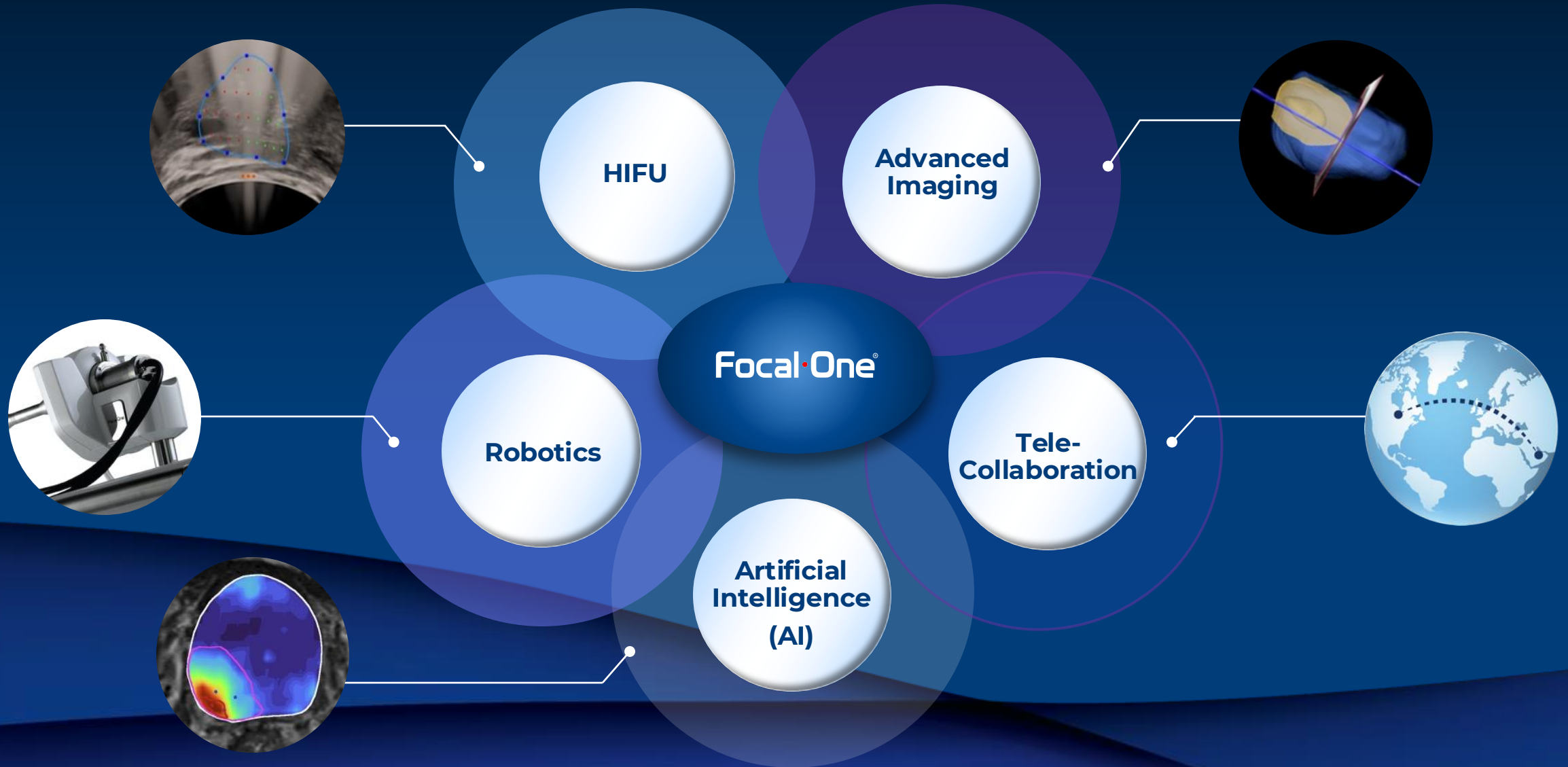
Auto-Adjusting Pinpoint Delivery
of HIFU Energy

Integrated Workstation

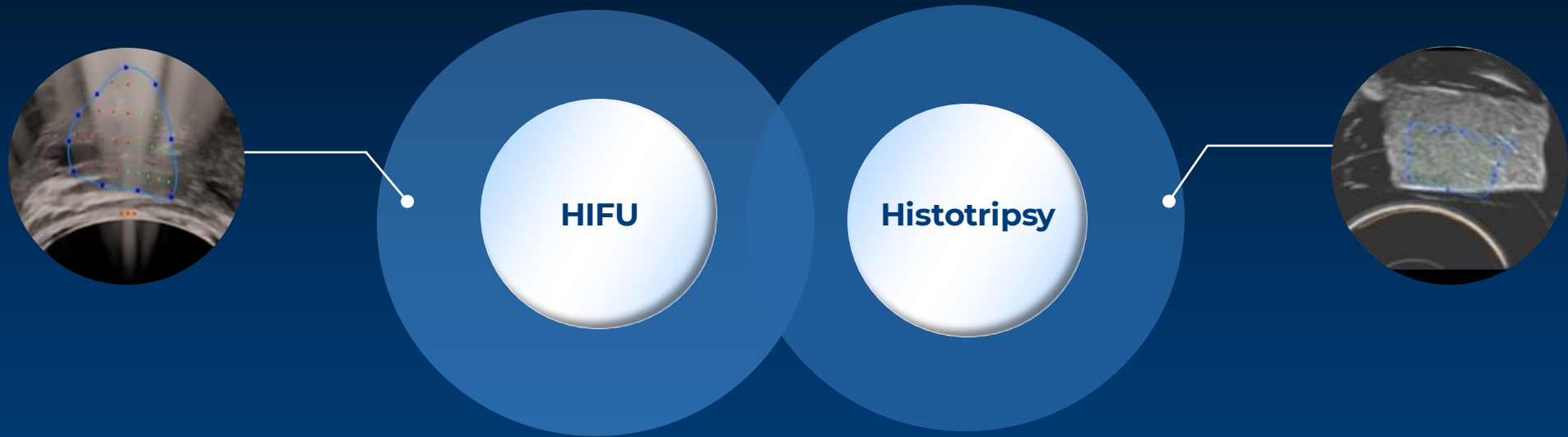
Compatible With
Standard OR Beds



Focal One Core Technologies

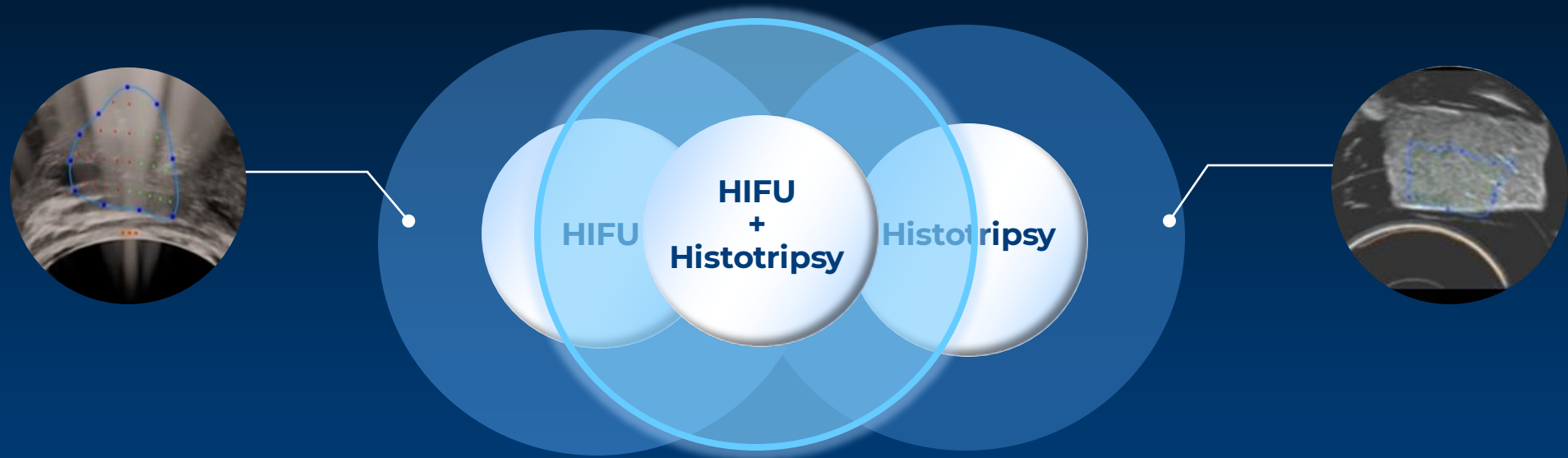


Leading in Therapeutic Ultrasound



Expanding Ultrasound Energy Delivery Capabilities
With the **FocalOne** [®] *i* Platform

Leading in Therapeutic Ultrasound



Expanding Ultrasound Energy Delivery Capabilities
With the **FocalOne[®]** *i* Platform

Landmark Studies Demonstrate Positive Clinical Outcomes Supporting Focal One HIFU Therapy

Prospective Comparative

HIFI¹
European Urology

HIFU vs Radical Prostatectomy

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

Prospective Salvage

HIFI-2²
European Urology Oncology

HIFU in Salvage Post Radiation

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

Long-Term Retrospective

CGRD³
Int. Urology and Nephrology

HIFU vs Radiation

HIFU Demonstrated Higher Survival at 10 Years versus Radiation

RCT

FARP⁴
Presented at AUA 2025

Focal Ablation vs Radical Prostatectomy

Focal Ablation Demonstrated Equivalent Cancer Control

RCT

HIFUSA⁵
Presented at AFU 2025

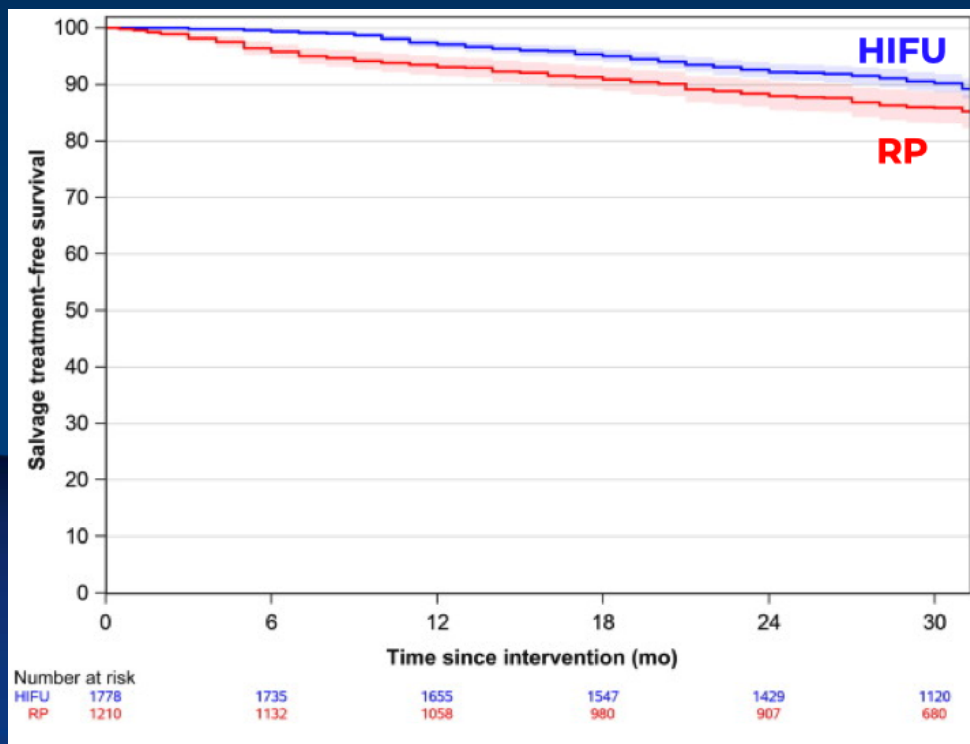
HIFU vs Active Surveillance

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,

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

Hospital Outpatient Medicare Payment

Procedure	CPT® Code	2026 Payment	
Prostate Brachytherapy	55875	\$5,478	
Cryo Ablation	55873	\$9,671	
HIFU	55880	\$9,671	+4.3%
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

FOCAL ONE ADOPTION ACCELERATING At Major U.S. Hospitals

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



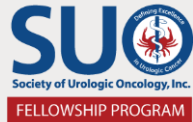
Focal One is the Leading Focal Therapy Technology

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



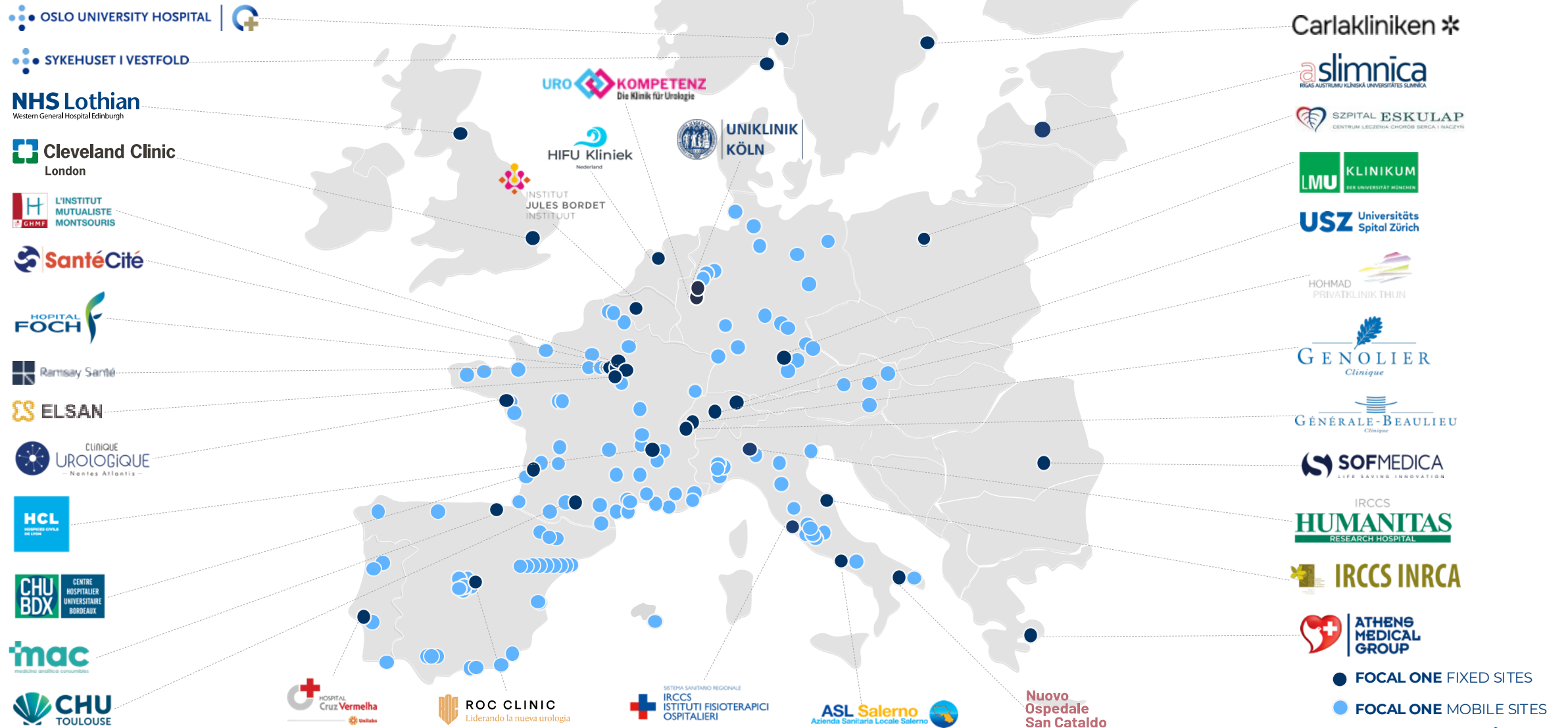
NCCN Member
Institutions

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



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

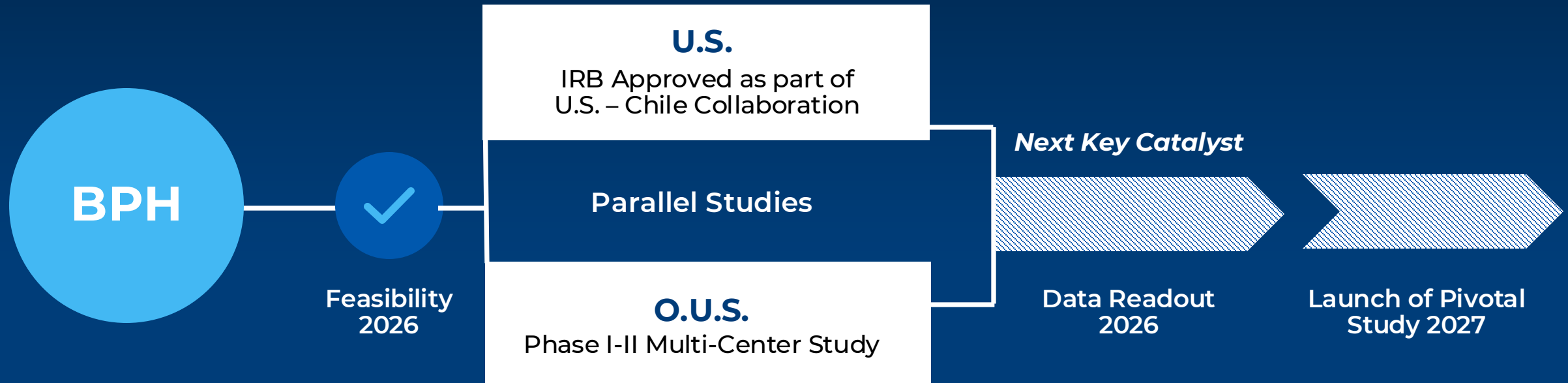
No Foreign Body

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



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.

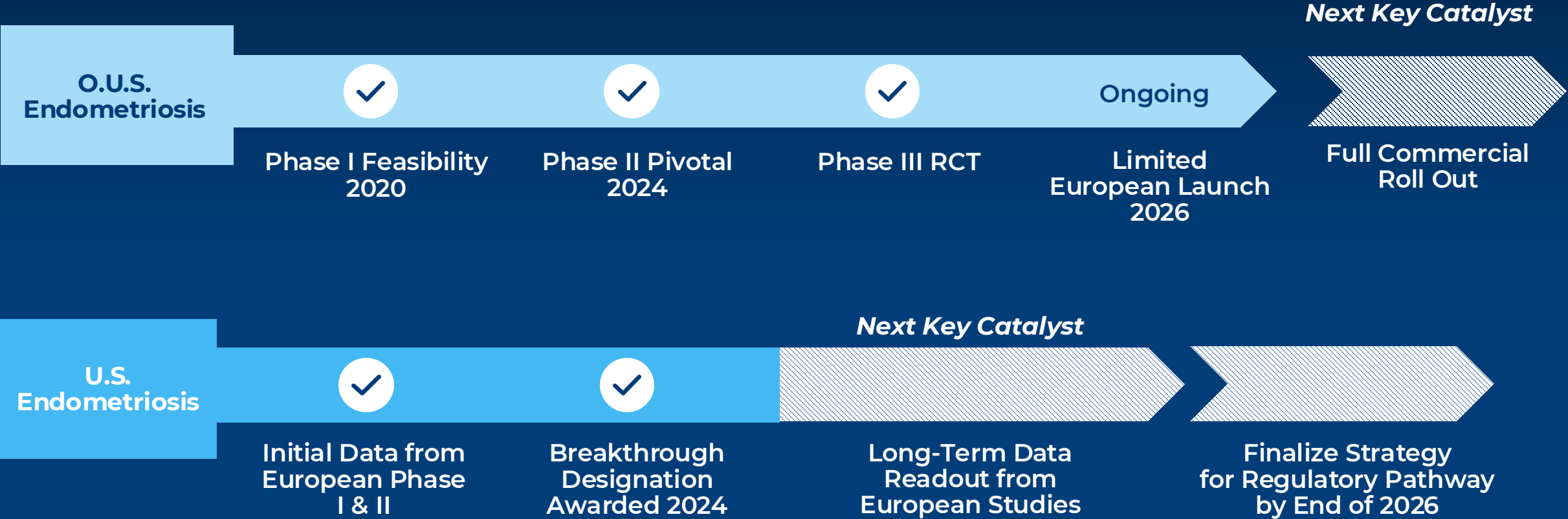
Current treatment options are lacking and limited to hormonal and/or surgical management

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

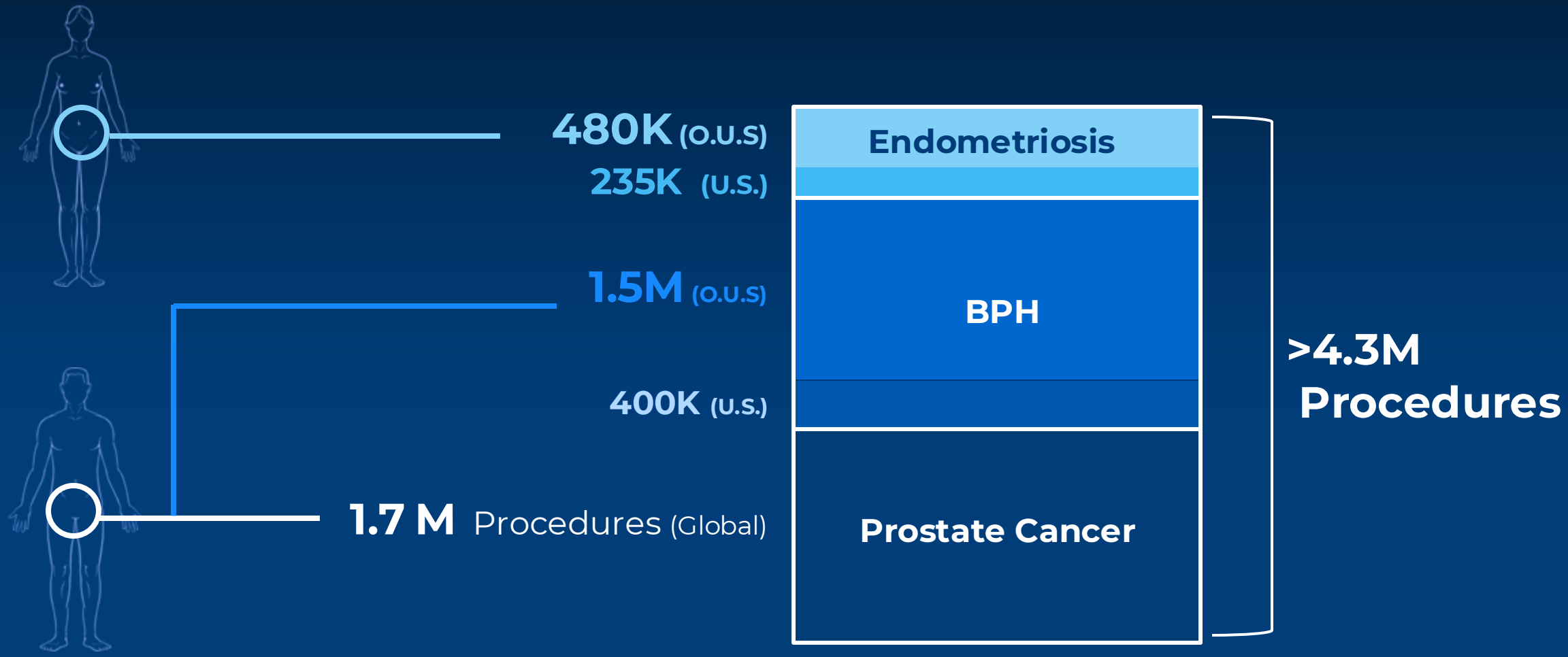
Endometriosis Indication Expansion Pipeline



Next Key Catalyst

Next Key Catalyst

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



[1] Management Estimates; data on file.

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%)

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**

FocalTherics™

The **Global Leader** in Therapeutic Ultrasound