

FocalTherics™

The **Global Leader** in Therapeutic Ultrasound

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FocalTherics™

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

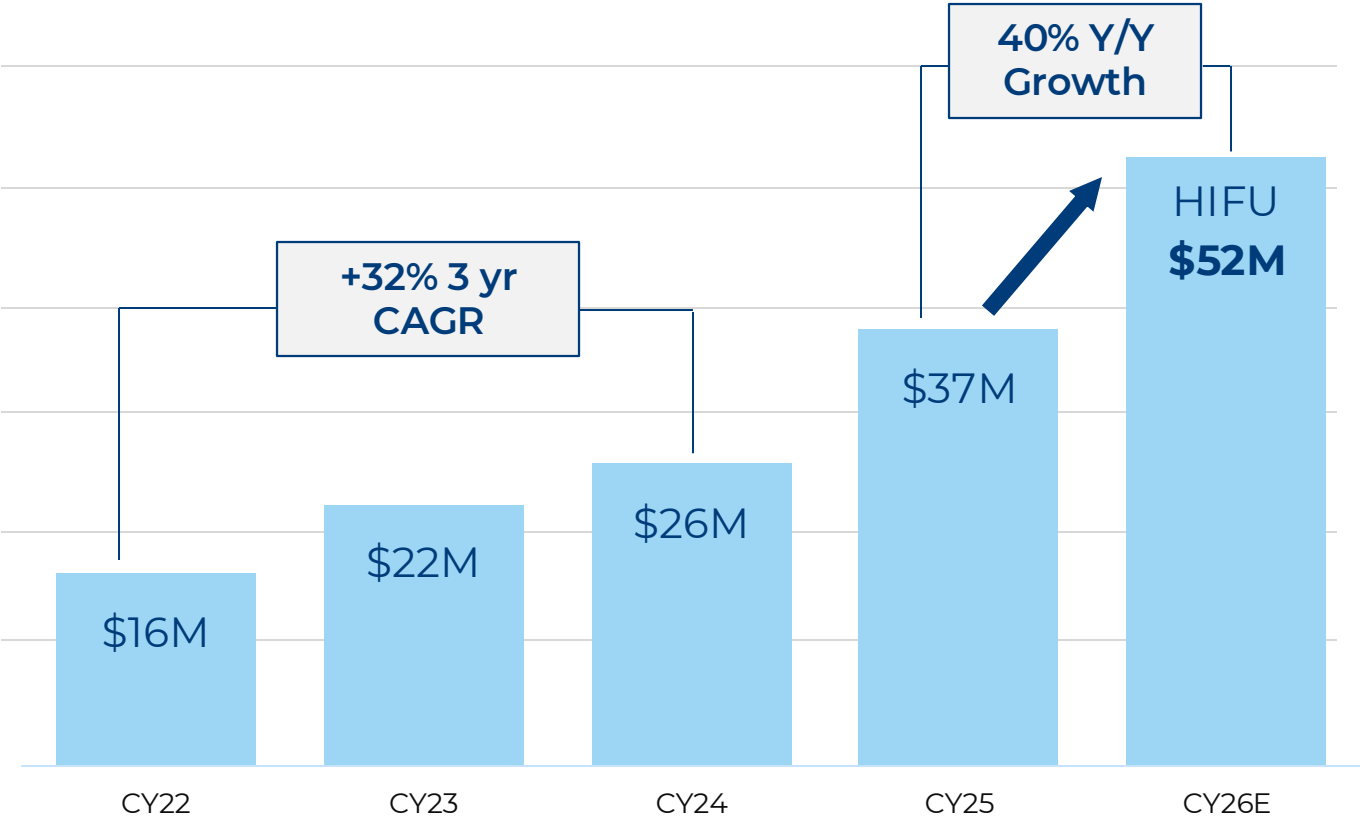
Redefining the Treatment of Cancer and
Benign Disease through Organ Sparing,
Function Preserving Focal Therapy



FOCUSING ON ACCELERATING OUR GROWTH ENGINE

Commitment to Focal Therapy

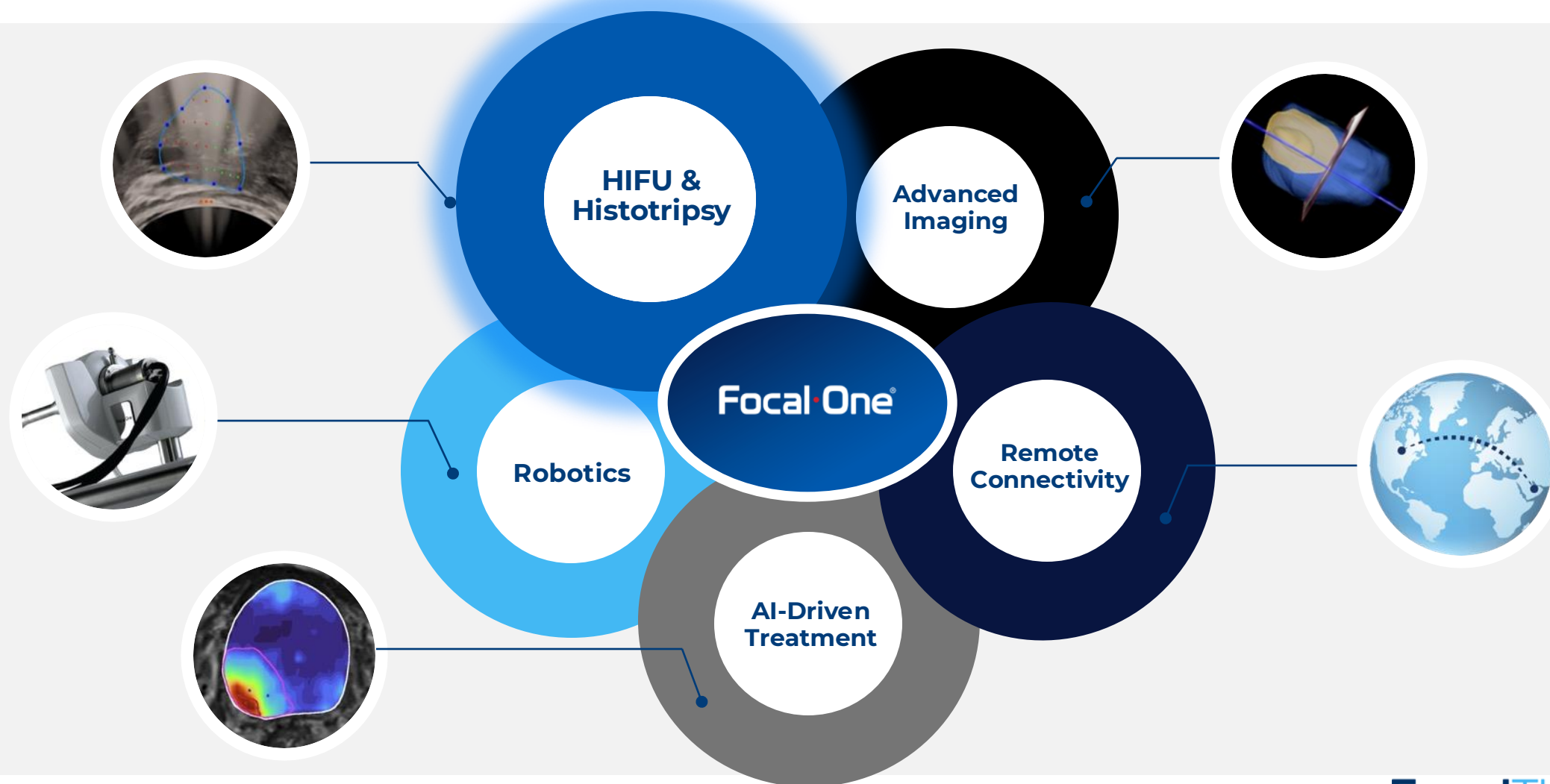
HIFU Revenue (\$)



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



Scalable Focal One Platform Enables Simultaneous Innovation



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

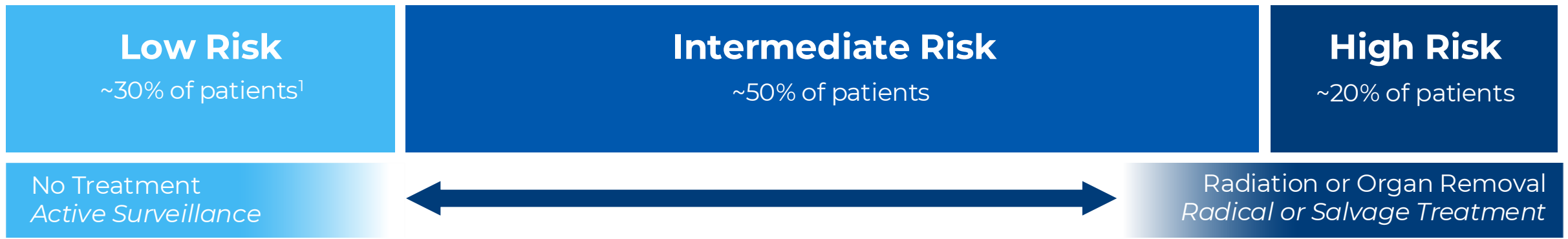
2040

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

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

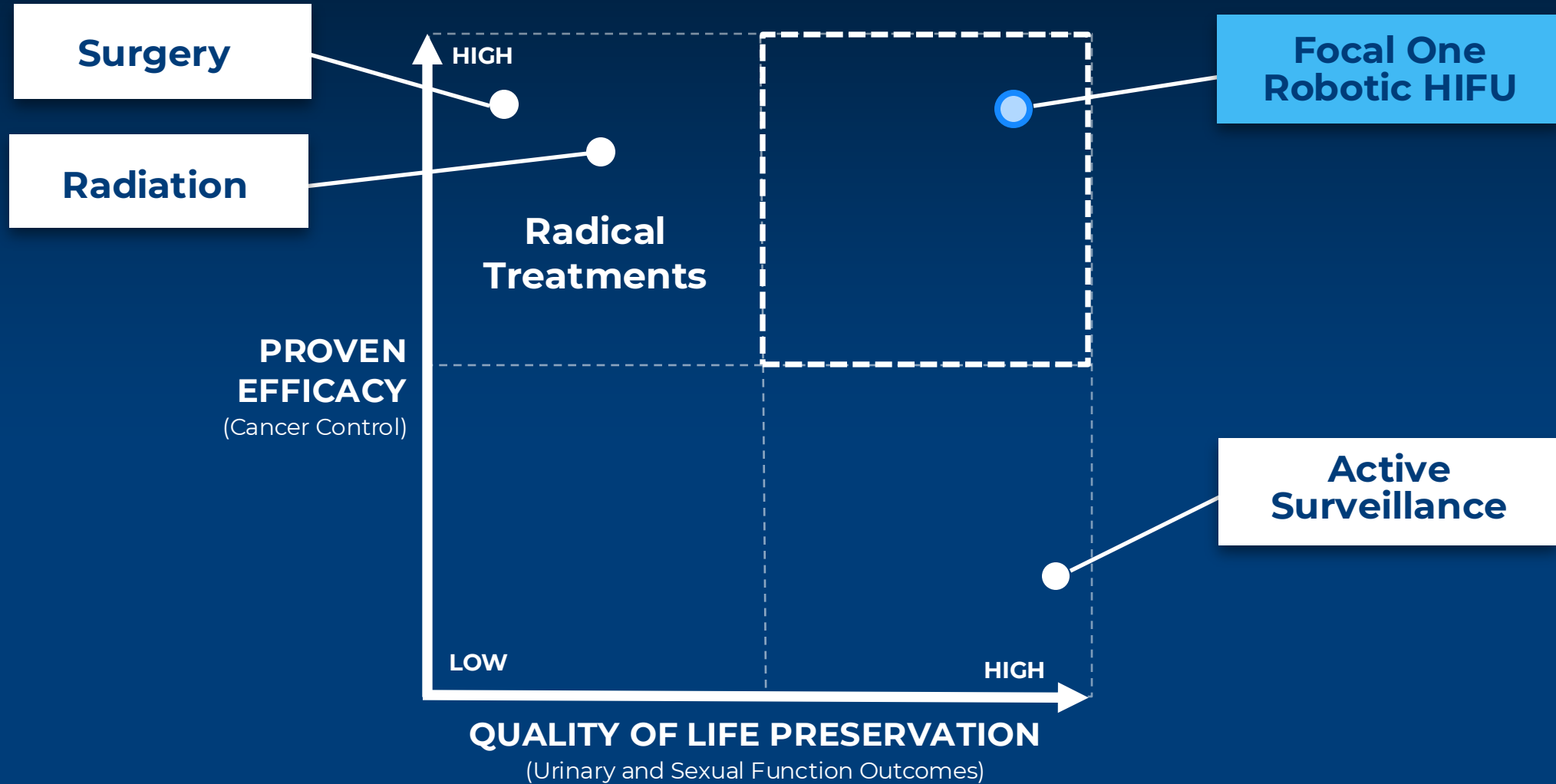
[3] James N, Tannock I, N'Dow J et al. The Lancet Commission on prostate cancer: planning for the surge in cases. *The Lancet*, 2024; 403, 1683-1722

The 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**

Prostate Cancer Patient Value Equation



Treatment Comparison

Focal One HIFU Provides the Optimal Organ-Preserving Patient Treatment

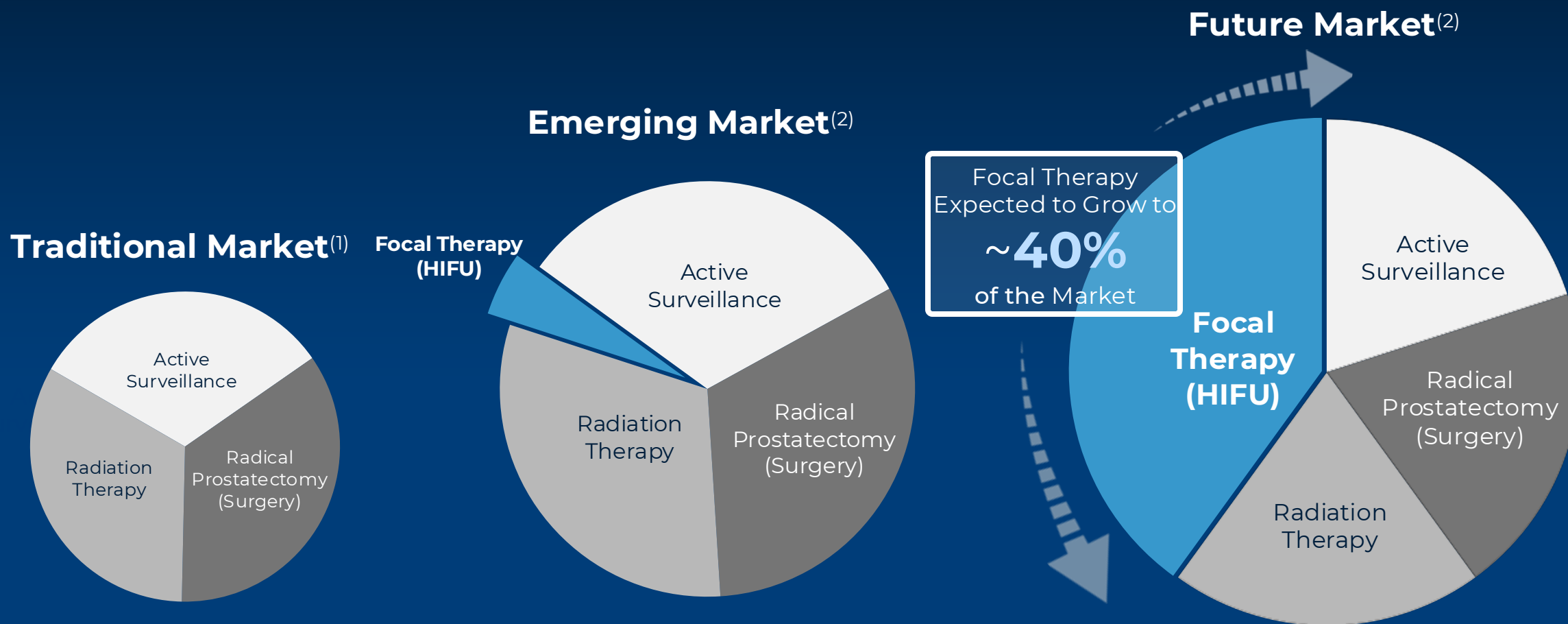
ORGAN-PRESERVING STRATEGY			WHOLE-GLAND RADICAL TREATMENT STRATEGY		
CANCER CONTROL		Active Surveillance	Focal One [®] Robotic HIFU	Radiation	Surgery Radical Prostatectomy
	10-year Cancer Specific Survival	N/A	95% ⁽¹⁾	91% ⁽¹⁾	99% ⁽²⁾
QUALITY OF LIFE FUNCTIONAL OUTCOMES	Continence Preservation	96% ⁽³⁾	98% ⁽⁵⁾	96% ⁽³⁾	75% ⁽³⁾
	Erectile Function Preservation	82% ⁽³⁾	93% ⁽⁵⁾	49% ⁽³⁾	69% ⁽³⁾
	Ejaculation Preservation	-	96% ⁽⁶⁾	28% ⁽⁴⁾	0%
PATIENT BURDEN	Risk of Complications	Low	Low	Medium	High
	Typical Complications	-	-	Radiation Toxicity, Risk of Secondary Cancers	Blood Loss and Other Surgical Complications
	Treatment Process	-	1 Session, Same Day Outpatient Procedure	45 Sessions 45 Visits	1 Session 1-Day Hospital Stay ^(*)

(*) Hospital stay duration for radical prostatectomy may vary

⁽¹⁾ 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. Int Urol Nephrol. (2025).
⁽²⁾ Stensland KD et al. National Long-term Survival Estimates After Radical Prostatectomy for Prostate Cancer. Urology. 2024 Feb;184:135-141.
⁽³⁾ Donovan JL, et al. Patient-Reported Outcomes after Monitoring, Surgery, or Radiotherapy for Prostate Cancer. N Engl J Med. 2016 Oct 13.
⁽⁴⁾ Sullivan JF et al. Ejaculation profiles of men following radiation therapy for prostate cancer. J Sex Med. 2013 May;10(5):1410-6.
⁽⁵⁾ Arnoult N, et al. "Traitement focal par HIFU versus prostatectomie radicale robot-assistée pour cancer de la prostate localisé: résultats cardiologiques et fonctionnels à 1 an." Progrès en Urologie 28.12 (2018) : 603-610.
⁽⁶⁾ von Hardenberg J et al. Prostate cancer treatment by the latest focal HIFU device with MRI/TRUS-fusion control biopsies: A prospective evaluation. Urologic Oncology: Seminars and Original Investigations, Volume 36, Issue 9, 2018, Pages 401.e1-401.e9

DRIVING A PARADIGM SHIFT IN PROSTATE CANCER

Focal Therapy | The New Emerging Market



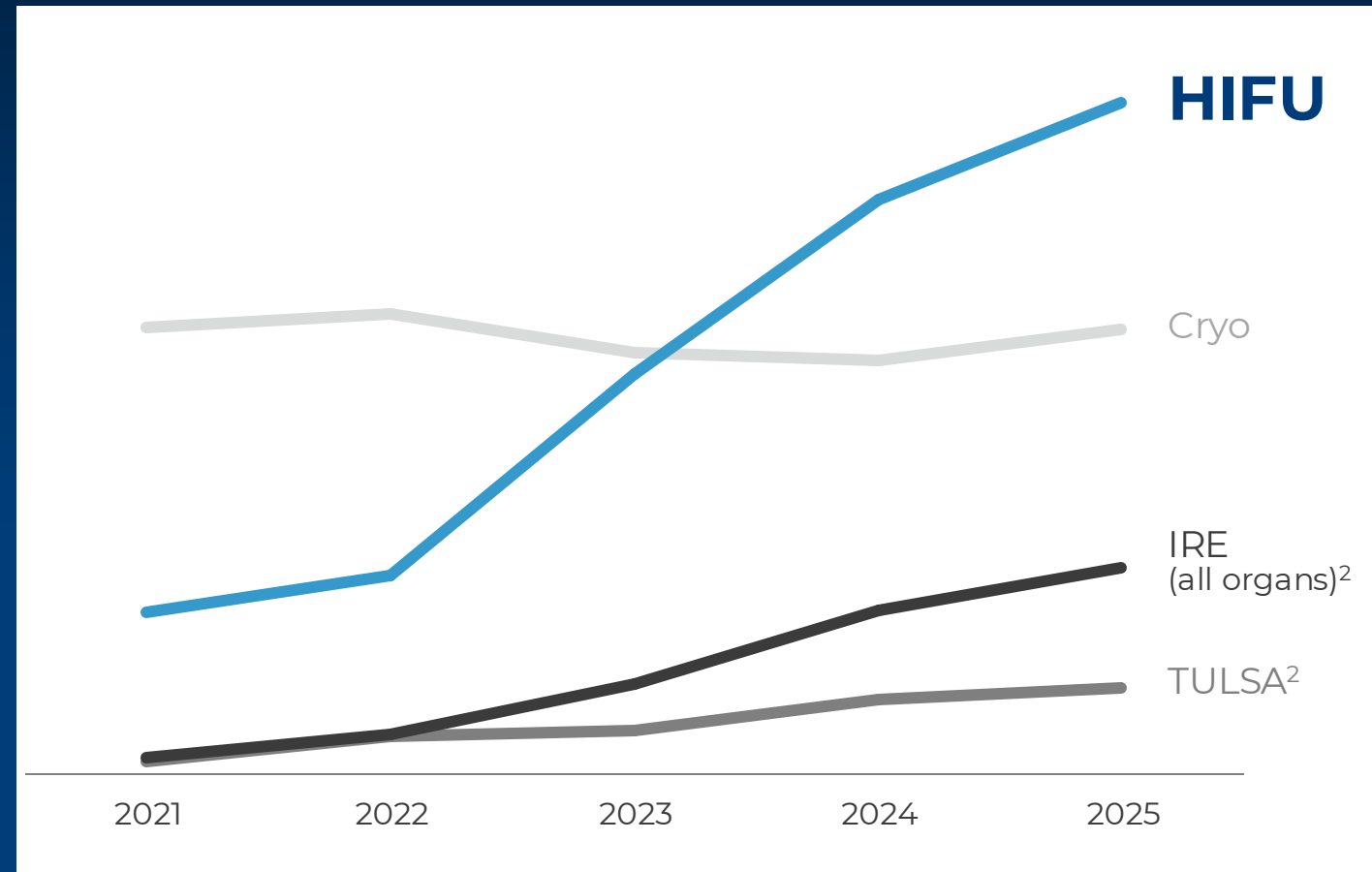
[1] As of 2013, Chen et al. National trends in the management of localized prostate cancer: A population-based analysis 2004-2013. Prostate.

[2] Source: Internal company estimates

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) 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.

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

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

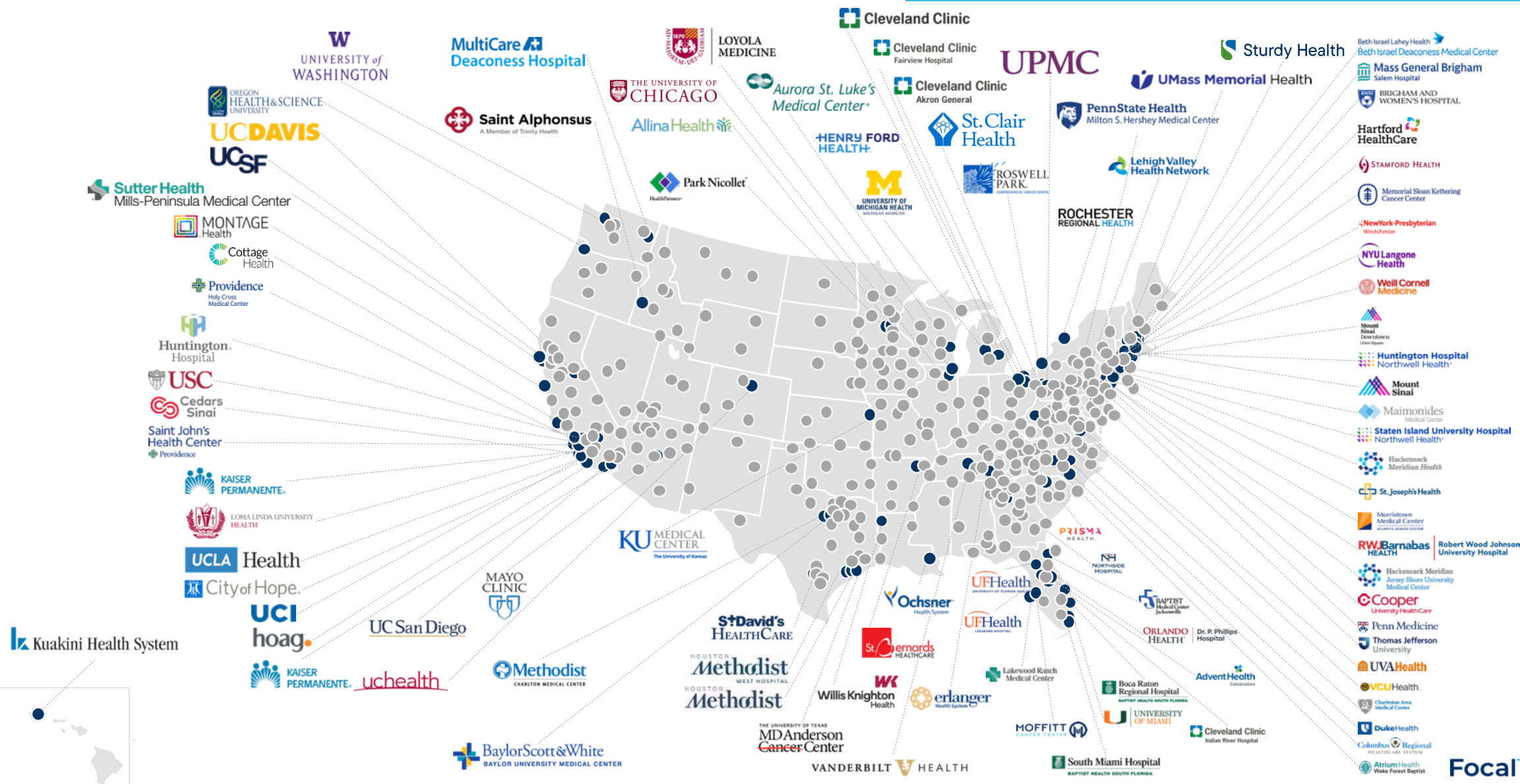
\$1,087

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



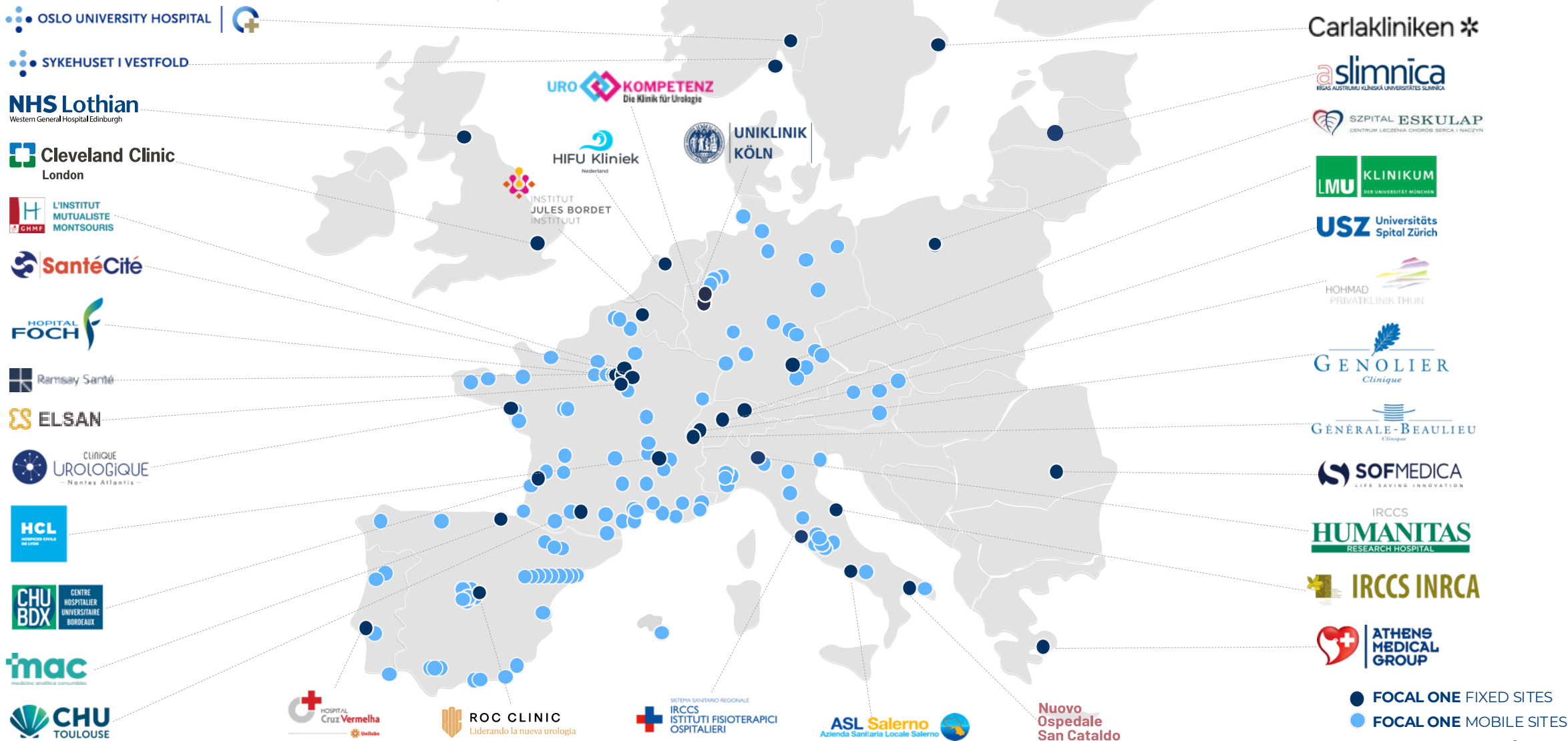
FOCAL ONE ADOPTION ACCELERATING At Major U.S. Hospitals

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



SINGLE PLATFORM, MULTIPLE INDICATIONS

Expanded Indications of Focal One

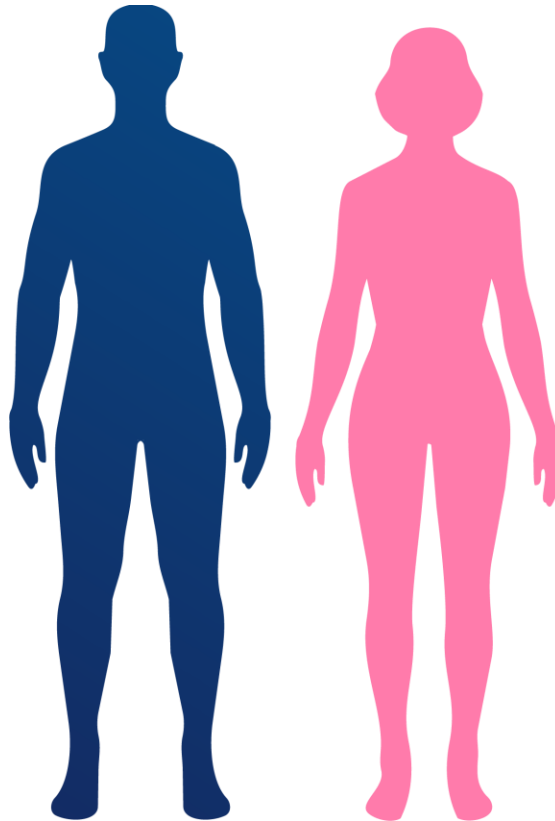
Benign Prostatic Hyperplasia (BPH)

100+ Million¹

Men Living with BPH Globally

13+ Million¹

New Cases Diagnosed Annually,
Globally



Deep Infiltrating Endometriosis

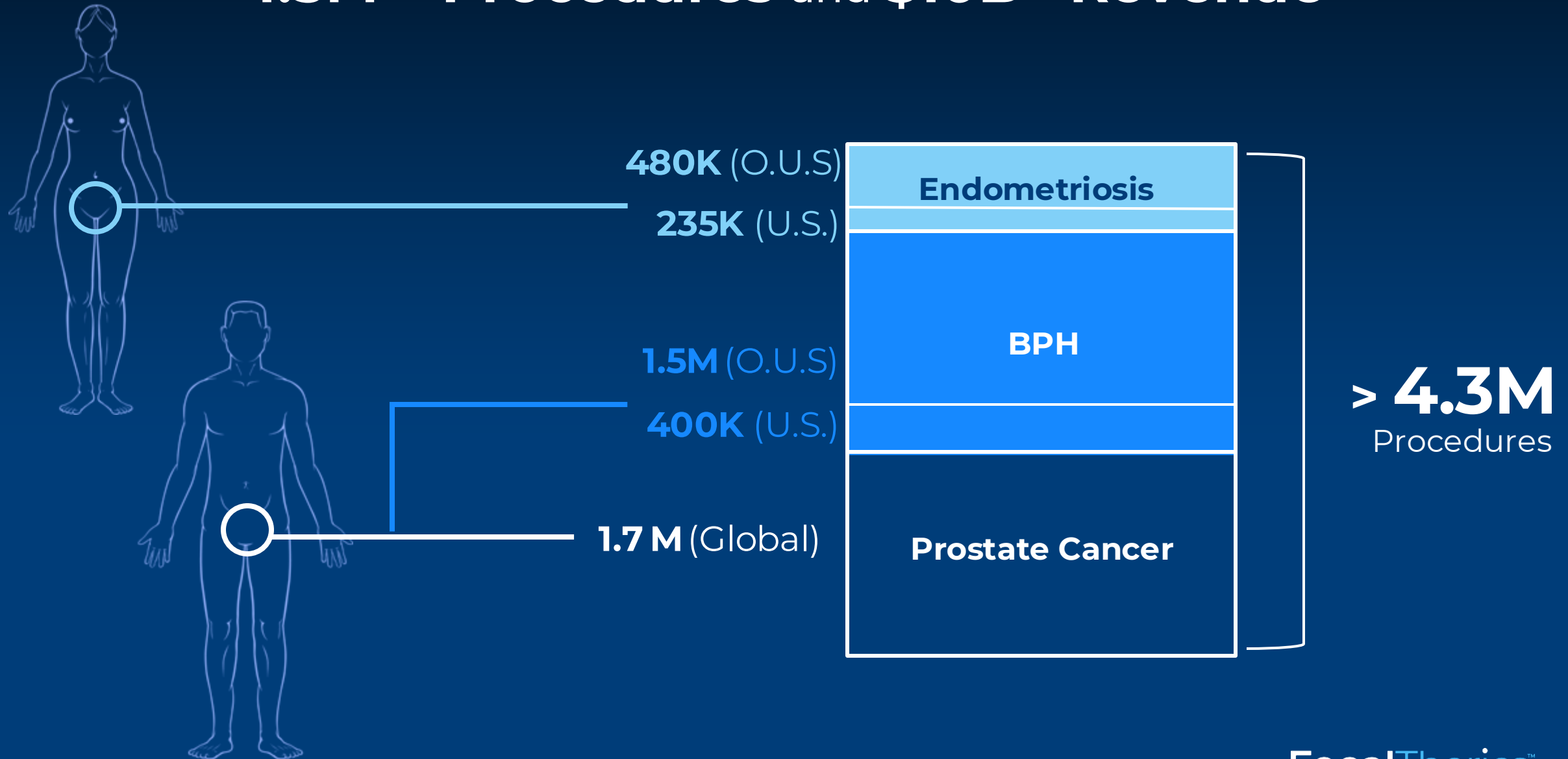
38M

Women Living with Deep
Infiltrating Endometriosis
Globally^{2,3,4,5}

783,000+

Patients Diagnosed with Deep
Rectal Endometriosis Globally^{2,3,4,5}

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



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

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