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

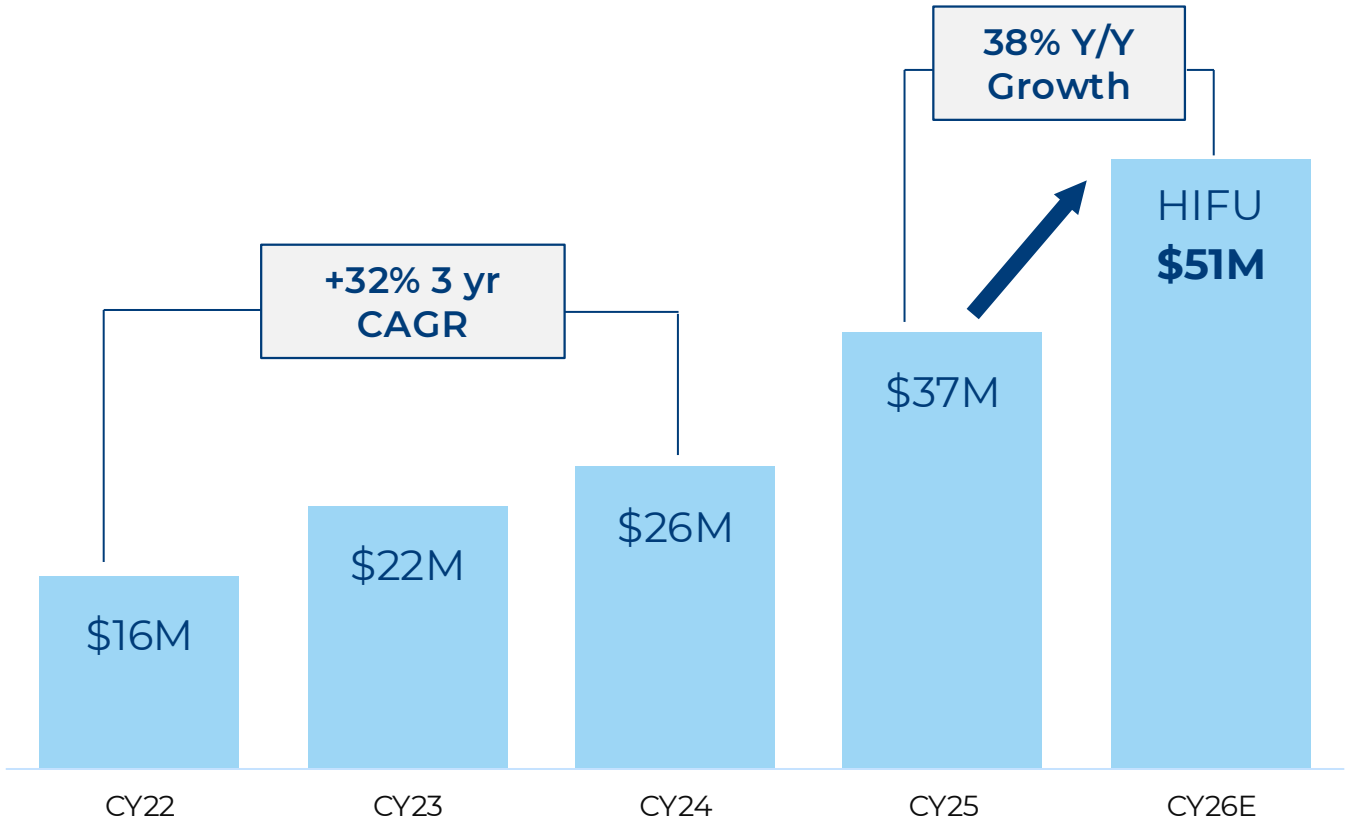


Redefining the Treatment of Cancer and Benign Disease through Organ Sparing, Function Preserving Focal Therapy

FOCUSING ON ACCELERATING OUR GROWTH ENGINE

Commitment to Focal Therapy

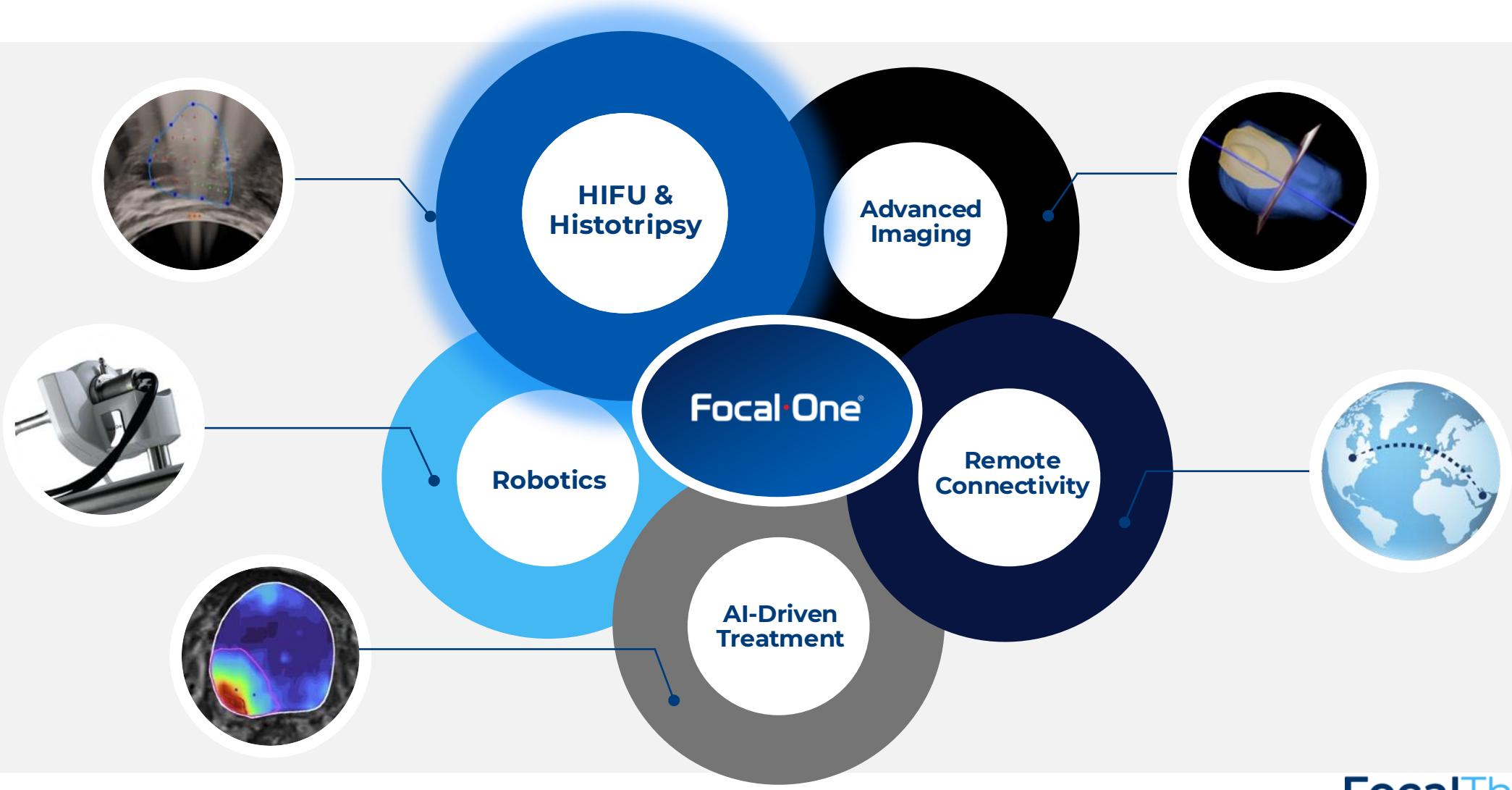
HIFU Revenue ($)





Note: CY26E = Midpoint of update CY26 Guidance Range on Nov. 5th, 2026

Focal One Platform Innovations Provide New Clinical Indications and Growth



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

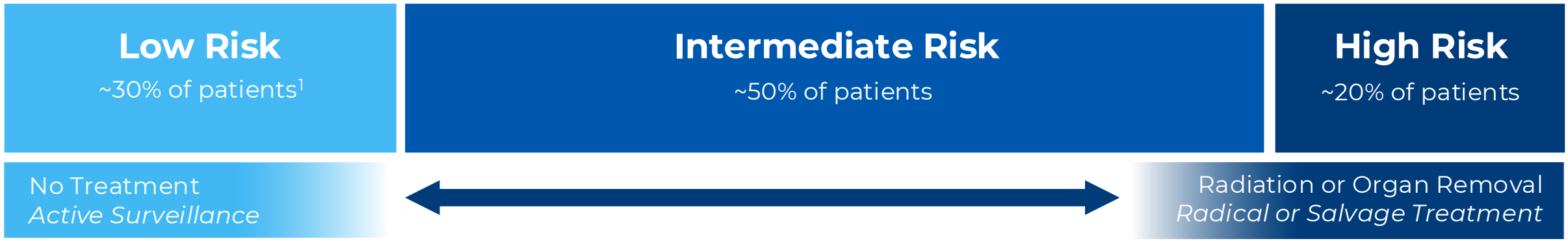
Men Living with Prostate Cancer in the U.S.



[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

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The Large Gap Between No Treatment and Radical Treatment



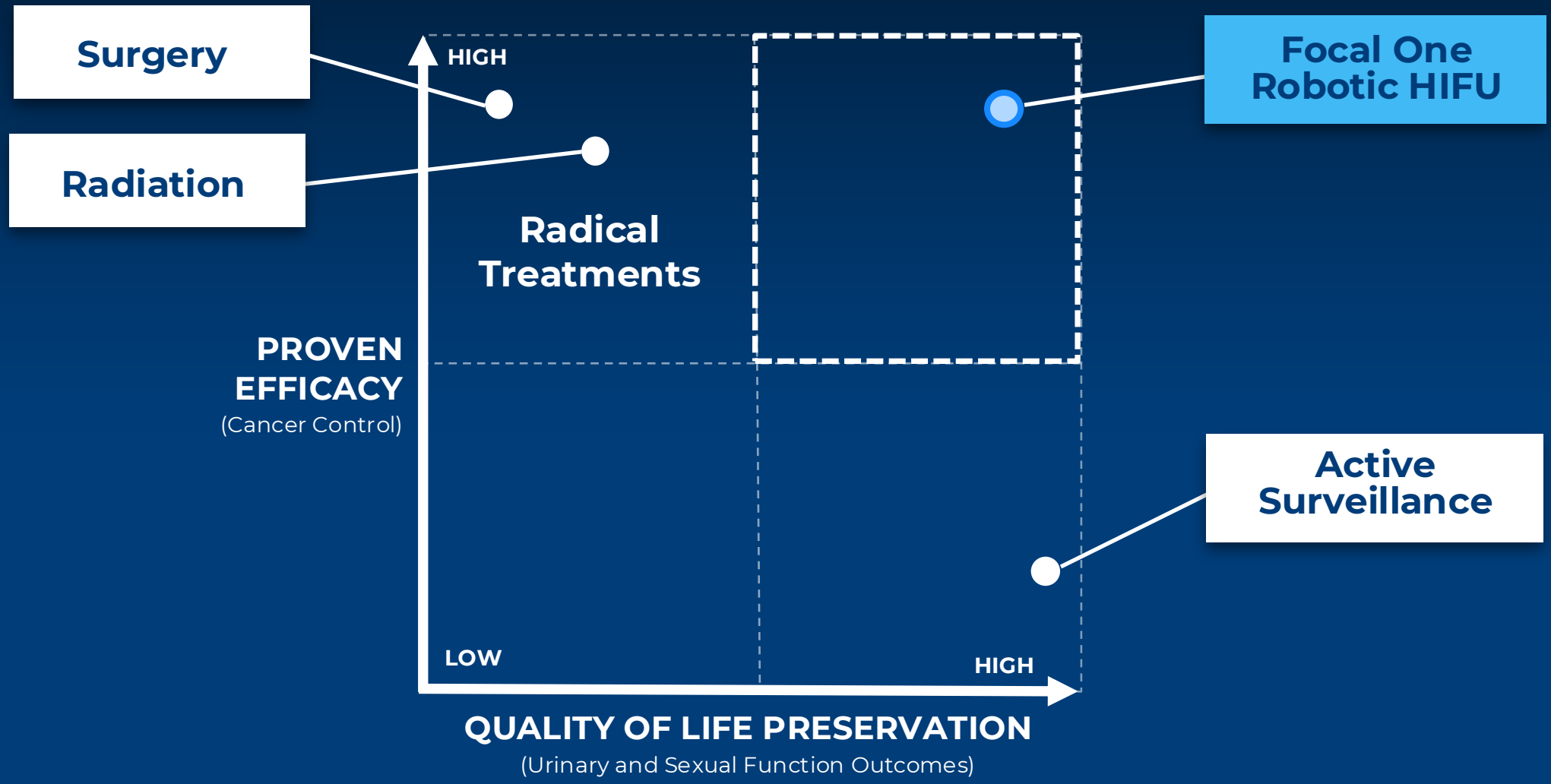
Previously, There Have Been **No Options**, Other Than Active Surveillance or Radical Treatments, **to Address Intermediate Risk Patients**

[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

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FOCAL ONE® ROBOTIC HIFU

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	
		Active Surveillance	**Focal One® Robotic HIFU**	**Radiation**	**Surgery** Radical Prostatectomy
CANCER CONTROL	**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 (*)

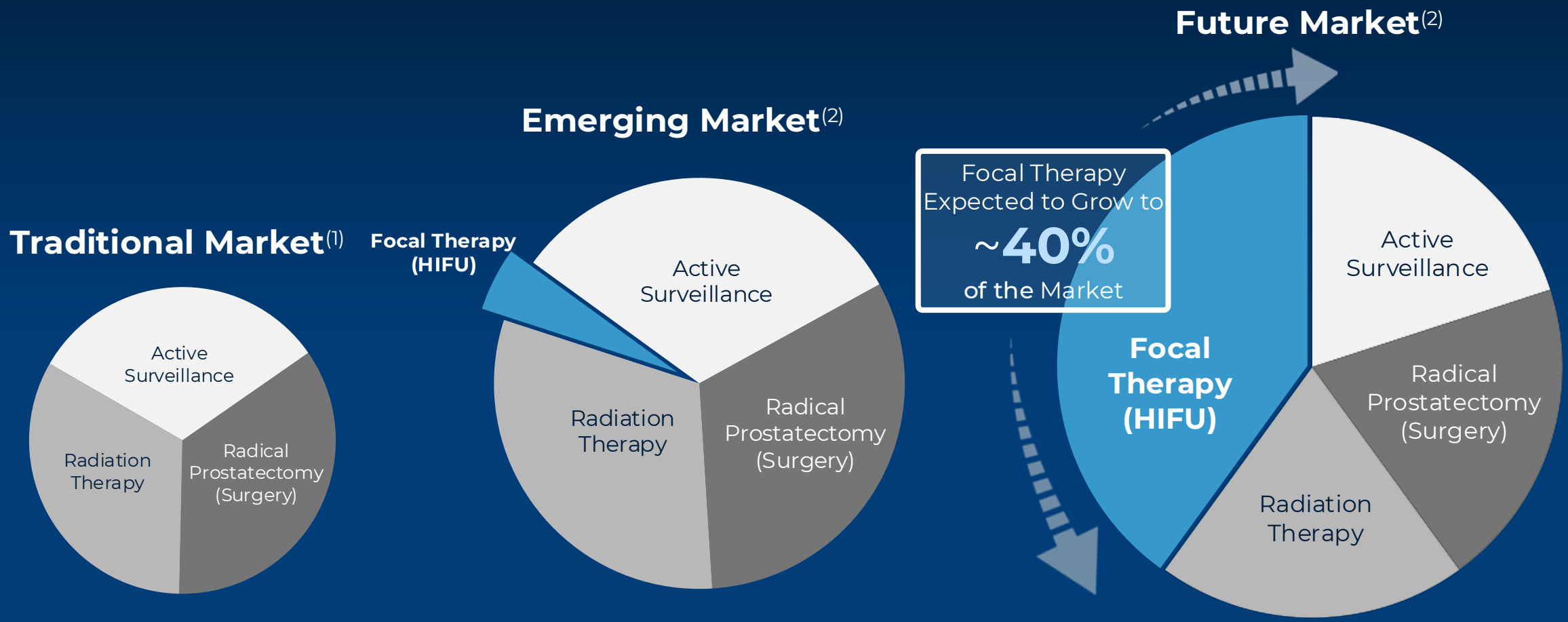
(*) Hospital stay duration for radical prostatectomy may vary

[1] Yeh, HT et al. 10-year oncological outcomes of EBRT versus HIFU for stage I 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] Arnouil, N., et al. "Traitement focal par HIFU versus prostatectomie radicale robot-assistée pour cancer de la prostate localisé: résultats carcinologiques 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

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DRIVING A PARADIGM SHIFT IN PROSTATE CANCER

Focal Therapy | The New Emerging Market



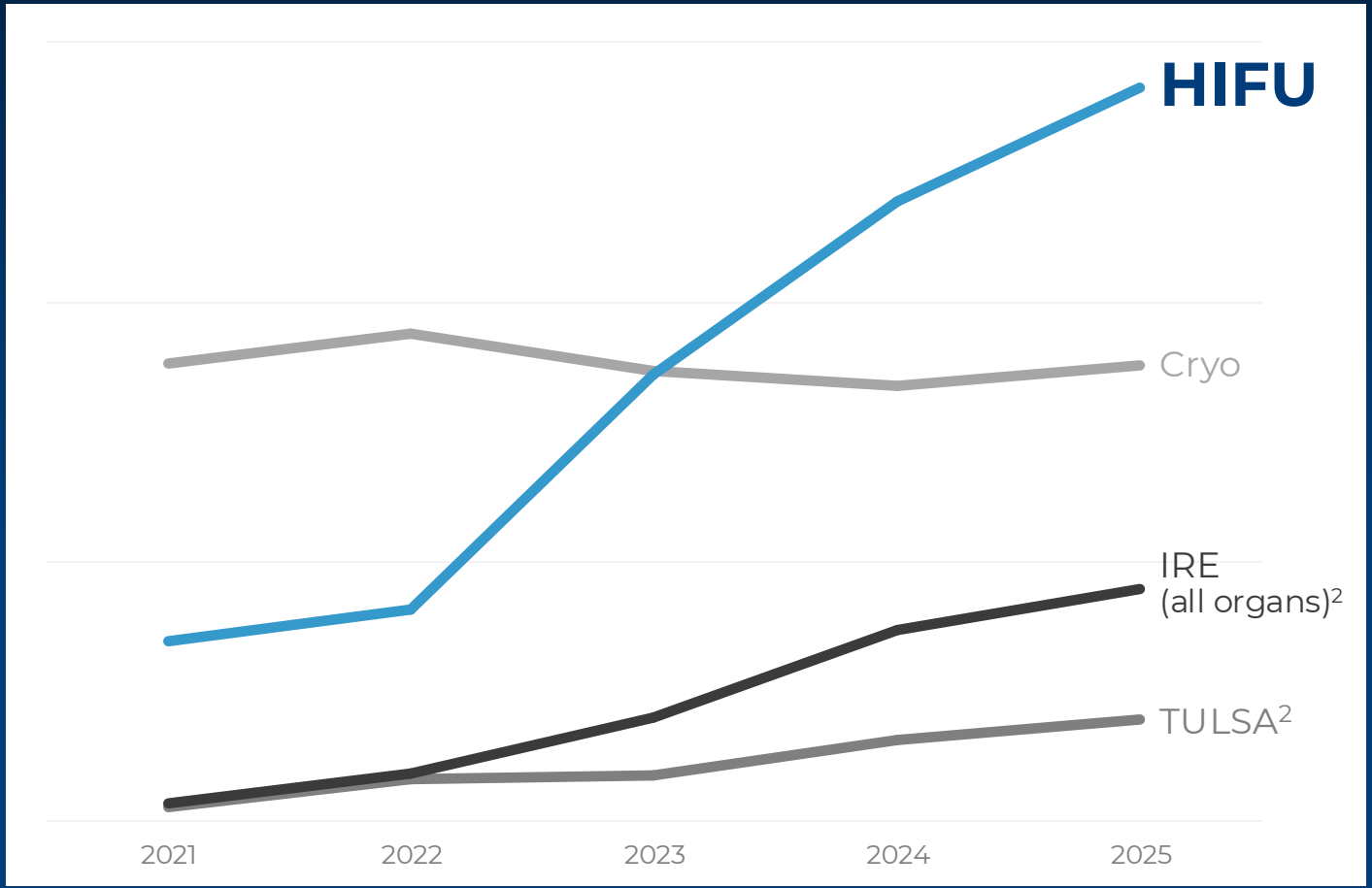
(1) As of 2013. Chen et al. National trends in the management of localized prostate cancer: A population-based analysis 2004-2013. Prostate.
(2) Source: Internal company estimates

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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) Final 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	
Prostate Brachytherapy	55875	$6,191	
Cryo Ablation	55873	$10,688	
HIFU	**55880**	**$10,688**	**+10.5%**
Laparoscopic/Robotic Prostatectomy	55866	$12,126	

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

Favorable Physician Payment

Procedure	CPT® Code	Work RVU (2027)	Physician Payment (Medicare - 2027)
Prostate Brachytherapy	55875	13.12	$667
Cryo	55873	13.26	$672
MRI Transurethral Ultrasound Ablation	55882	11.21	$510
Irreversible Electroporation	55877	13.50	$670
HIFU	**55880**	**17.29**	**$859**
Laparoscopic/Robotic Prostatectomy	55866	21.90	$1,058

Based on CMS Physician Fee Schedule –CY 2027 Final Rule

FOCAL ONE ADOPTION ACCELERATING

At Major U.S. Hospitals

98 Focal One Systems as of September 30, 2026
(43 Academic – 55 Community)

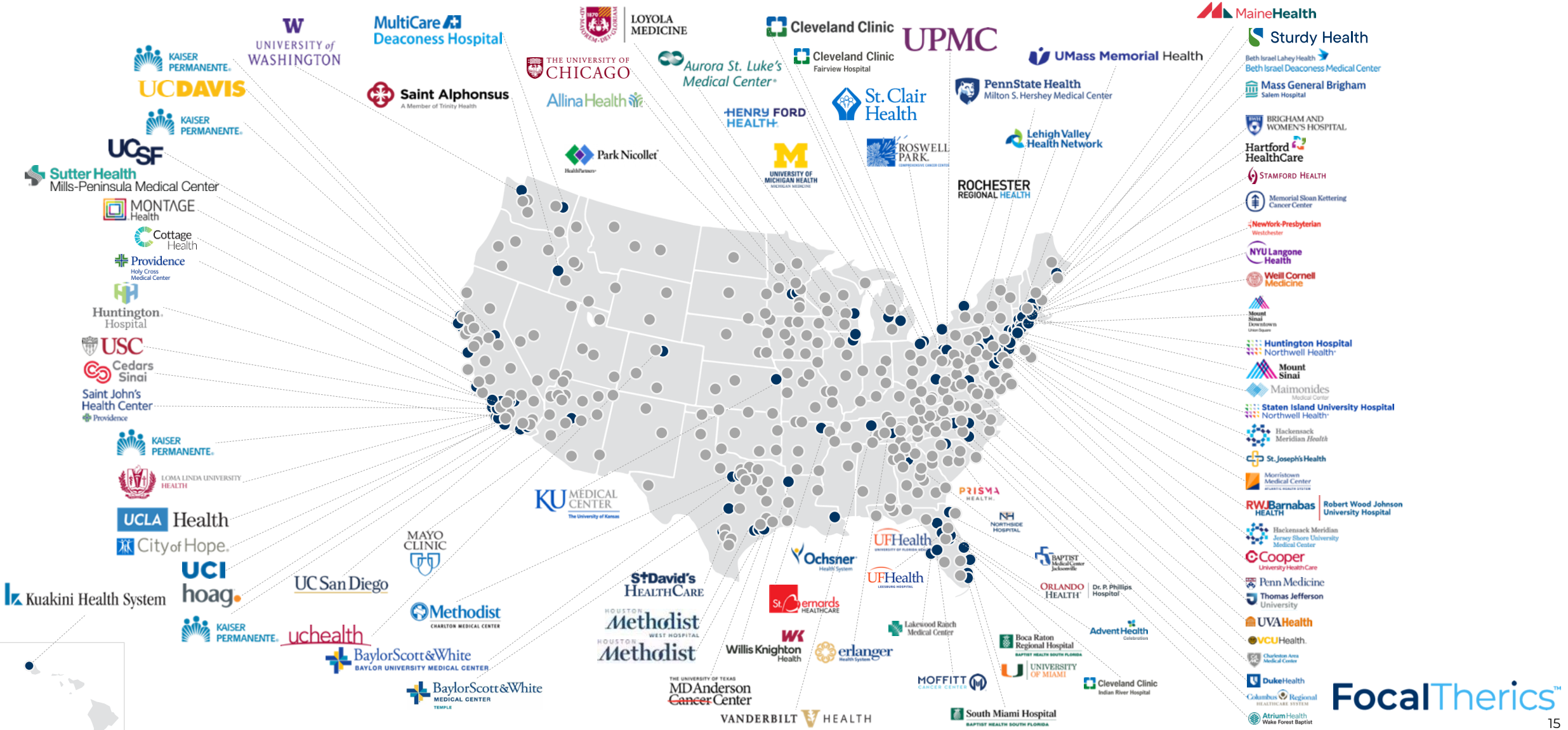


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FOCAL ONE ADOPTION ACCELERATING

At Major U.S. Hospitals

98 Focal One Systems as of September 30, 2026
300+ Hospitals in Sales Pipeline

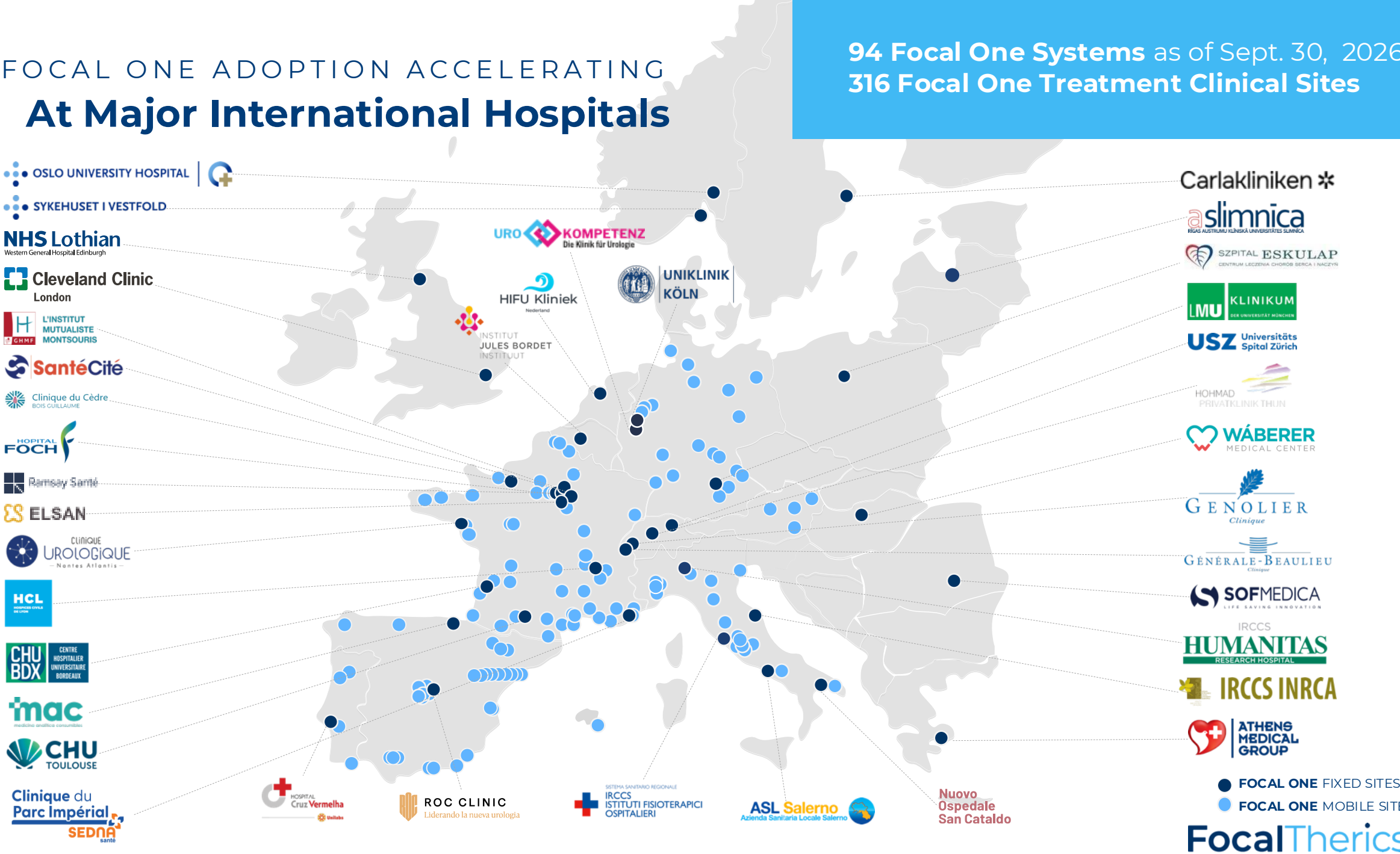


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FOCAL ONE ADOPTION ACCELERATING

At Major International Hospitals

94 Focal One Systems as of Sept. 30, 2026
316 Focal One Treatment Clinical Sites



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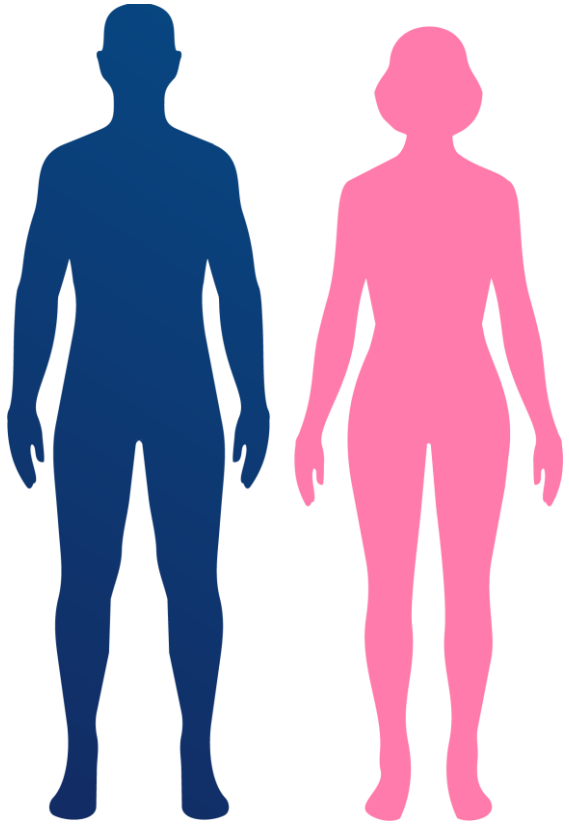
SINGLE PLATFORM, MULTIPLE INDICATIONS

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

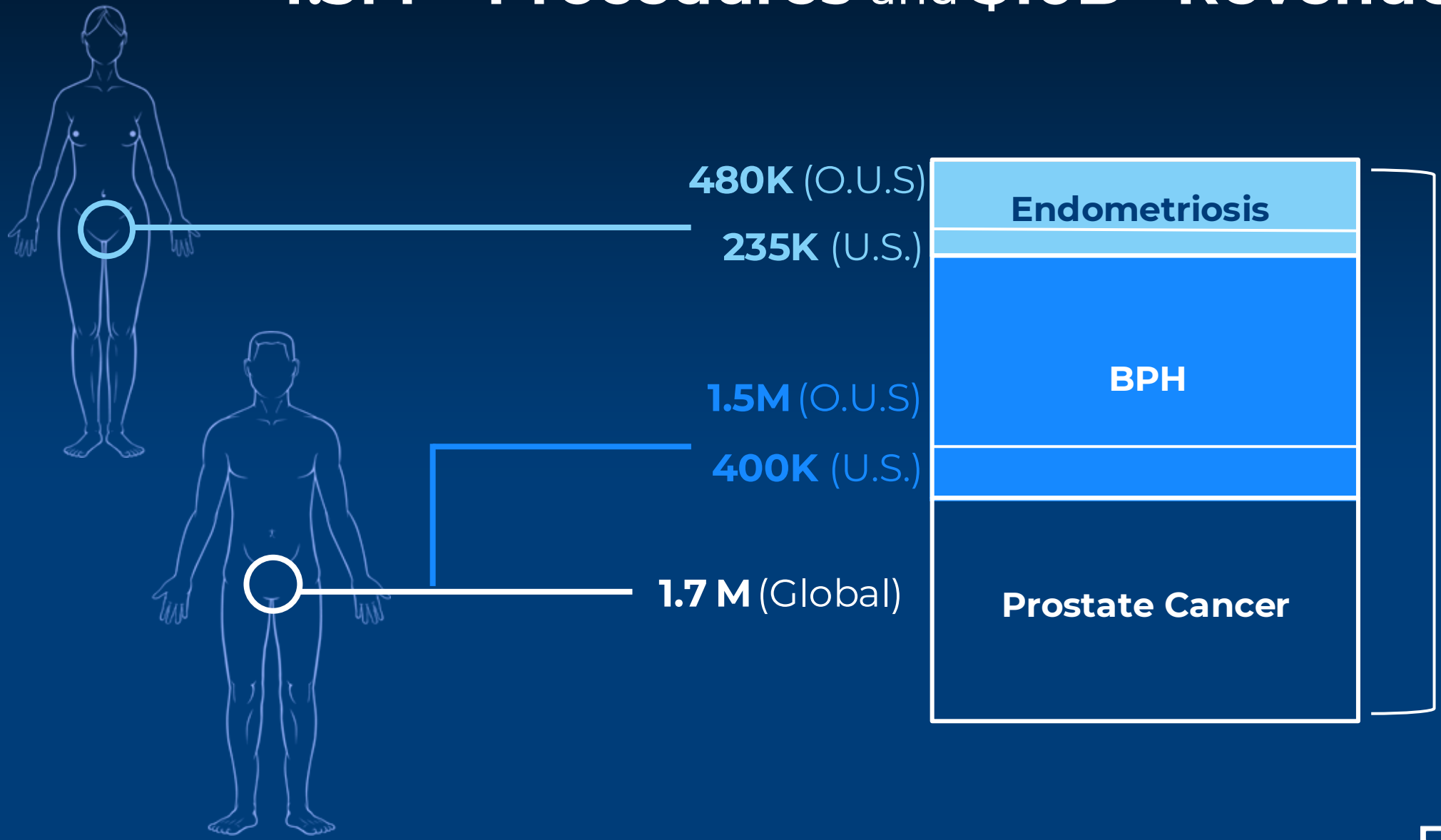
38 Million
Women Living with Deep Infiltrating Endometriosis Globally[2,3,4,5]

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



[1] Management Estimates; data on file.

Q3 2026 Financial Highlights

$9.8M
HIFU Revenue
26% YoY Growth

17%
Focal One Systems
Sales Growth YoY

192
Global Installed Base

32%
YoY U.S. Procedure
Volume Growth

51.4%
Gross Margin
+482 bps YoY

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 as presented at investor day event on June 1st 2026

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