

edap | Focal·One[®]

The **Global Leader** in Therapeutic Ultrasound

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Important factors that could cause actual results to differ materially include, among others, the clinical status and market acceptance of the Company’s HIFU devices, the continued market potential for its lithotripsy and distribution businesses, and risks associated with global economic, political, and financial conditions, including inflationary pressures, geopolitical instability, climate-related events, and public-health crises. Additional risks are described in the Company’s filings with the Securities and Exchange Commission, including under the headings “Cautionary Statement on Forward-Looking Information” and “Risk Factors” in the Company’s Annual Report on Form 20-F.

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Strategic Company Focus

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

Large and Growing Market Opportunity In Urology and Prostate Cancer

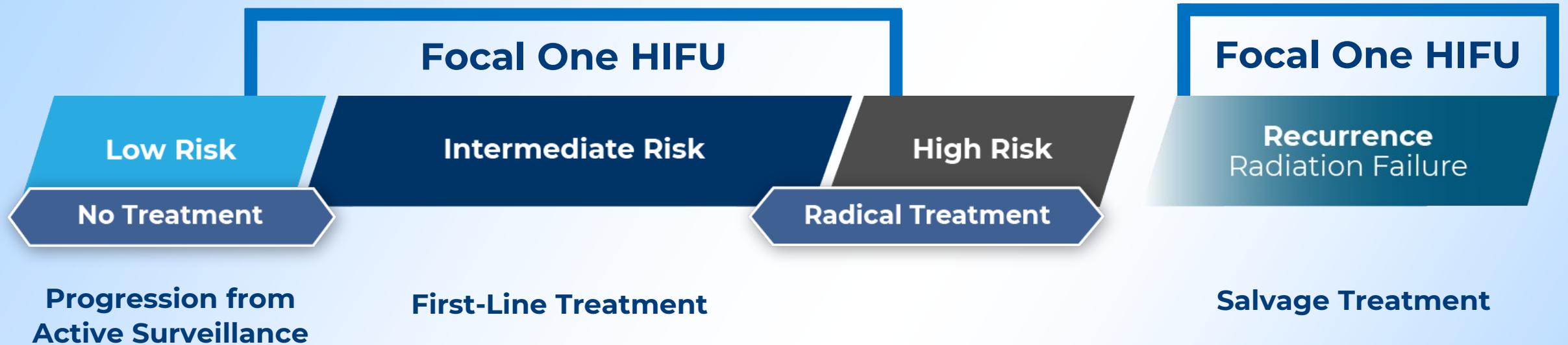
LARGE GLOBAL MARKET

Prostate Cancer Market Opportunity

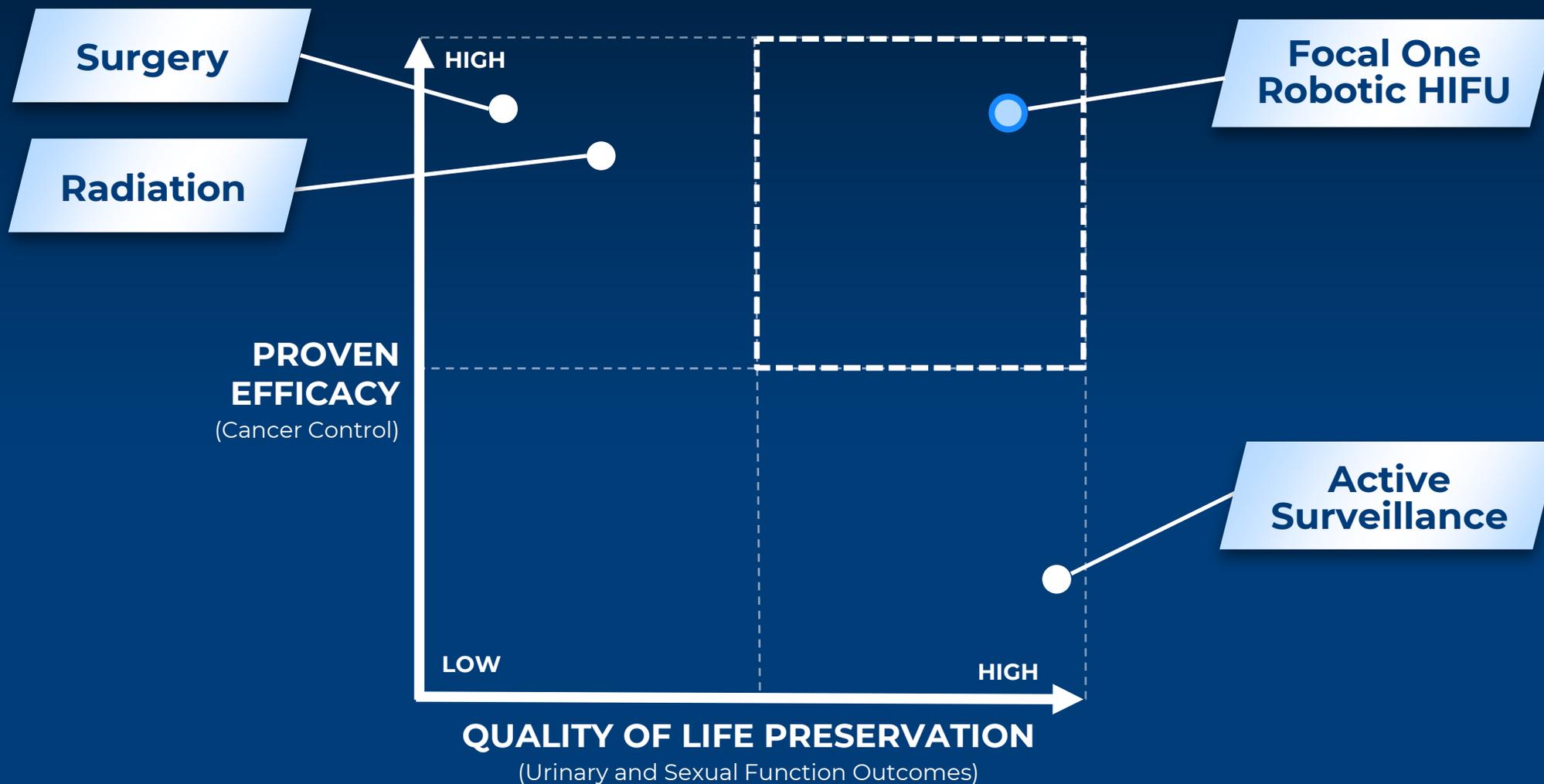
1.5 Million
New Prostate
Cancer Cases
Per Year

Region	Number of New Prostate Cancer Cases
Europe	473,011
Asia	386,424
North America	255,782
Latin America	225,985
Africa	103,050
Oceania	23,602
Total	<u>1,467,854</u>

Focal One Answers an Unmet Need for a Large Underserved Patient Population

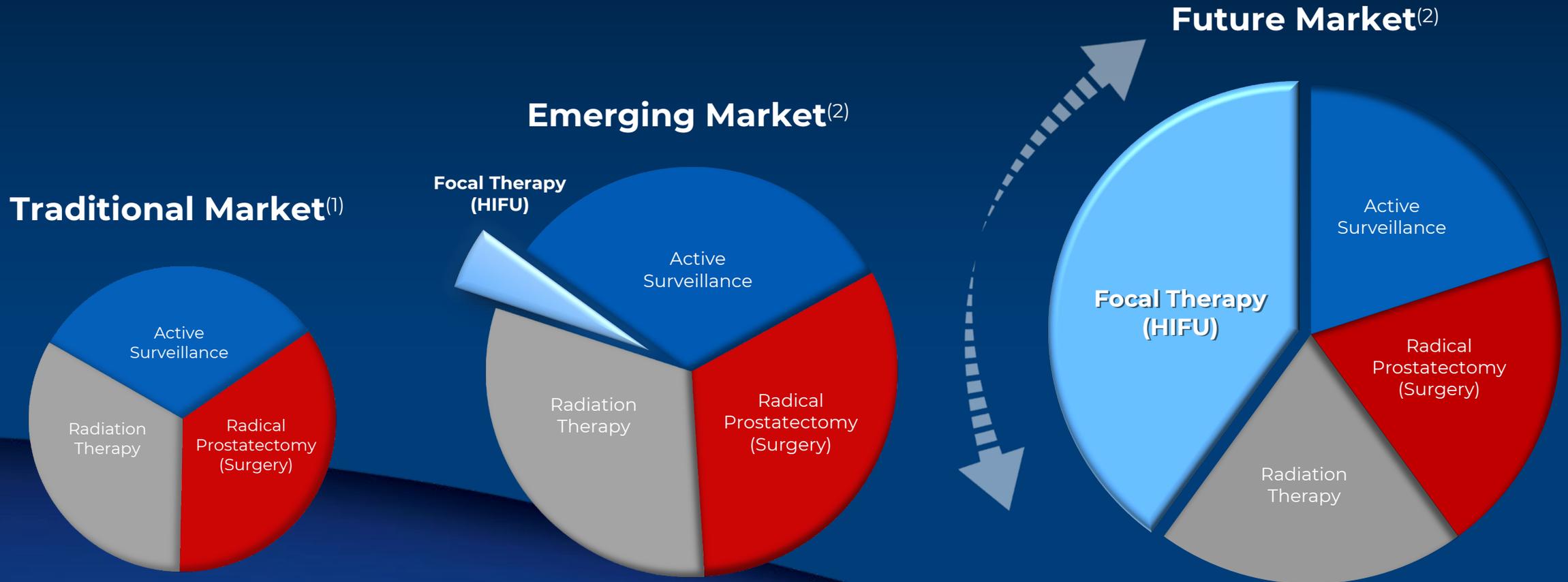


Prostate Cancer Patient Value Equation



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 management estimates

DRIVING A PARADIGM SHIFT IN PROSTATE CANCER

HIFU | The Fastest Growing Treatment Option



HIFU

Cryo

Brachytherapy

Radical
Prostatectomy

Based on Medicare claims data reported by CMS in the HOPPS Final Rules for FY2024–FY2026.
As CMS publishes claims data on a retrospective basis, the CAGR shown reflects growth over the 2022–2024 claims period.

Focal One® Best-in-Class Technology

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

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

HIFU[®] 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

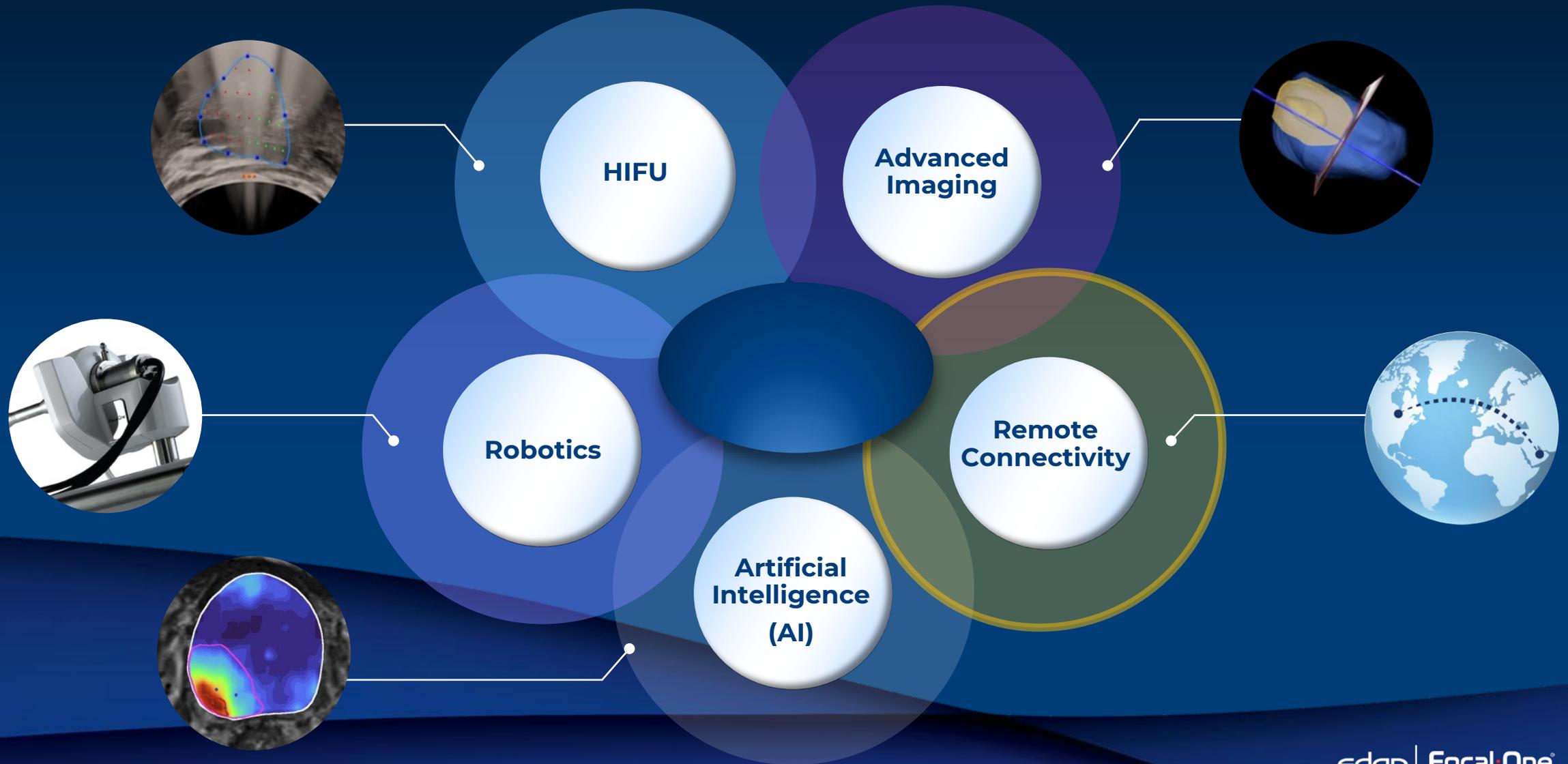
Auto-Adjusting Pinpoint Delivery
of HIFU Energy

Integrated Workstation

Compatible With
Standard OR Beds



Focal One[®] Core Technologies



Strong Supporting Clinical Evidence

Proven Clinical Evidence Supporting Focal One Robotic HIFU



1000+ Peer-Reviewed Publications Supporting HIFU in the Treatment of Prostate Cancer⁽¹⁾

Optimizing **Trifecta Outcomes** for Prostate Cancer

1. Cancer Control

2. Maintain Urinary Control

3. Preserve Sexual Function

Functional Outcomes

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⁾	
	Continenence Preservation	96% ⁽³⁾	98% ⁽⁵⁾	96% ⁽³⁾	75% ⁽³⁾	
	Erectile Function Preservation	82% ⁽³⁾	93% ⁽⁵⁾	49% ⁽³⁾	69% ⁽³⁾	
QUALITY OF LIFE FUNCTIONAL OUTCOMES	Ejaculation Preservation	-	96% ⁽⁶⁾	28% ⁽⁴⁾	0%	
	Risk of Complications	Low	Low	Medium	High	
	Typical Complications	-	-	Radiation Toxicity, Risk of Secondary Cancers	Blood Loss and Other Surgical Complications	
PATIENT BURDEN	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.

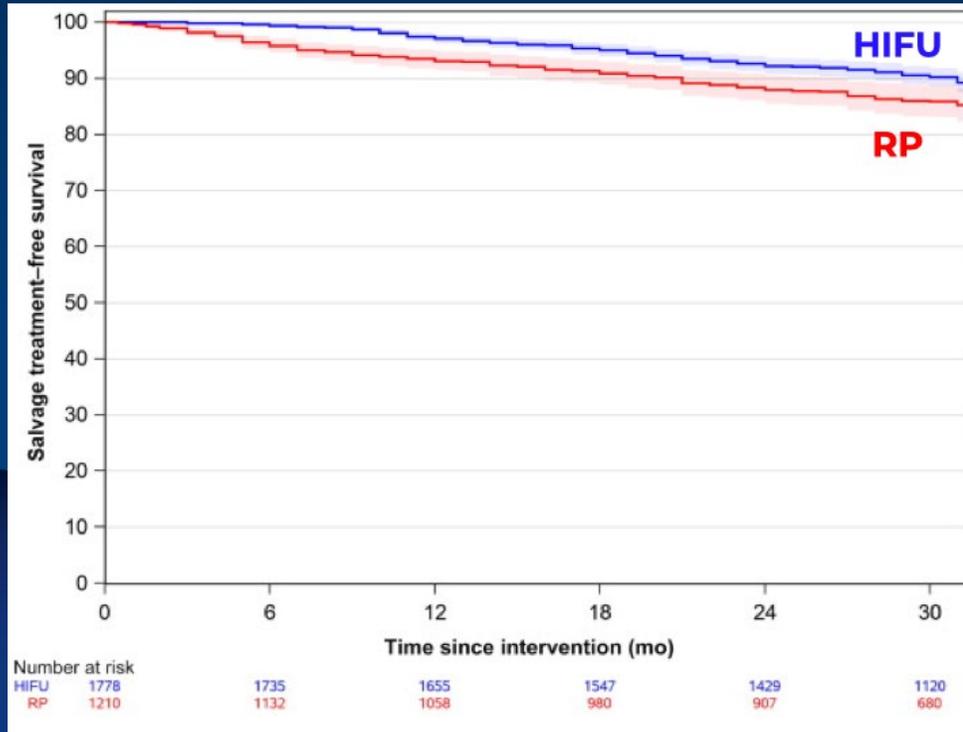
⁽⁴⁾ Sullivan JF et al. Ejaculation profiles of men following radiation therapy for prostate cancer. J Sex Med. 2013 May;10(5):1410-6.

⁽⁵⁾ 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

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

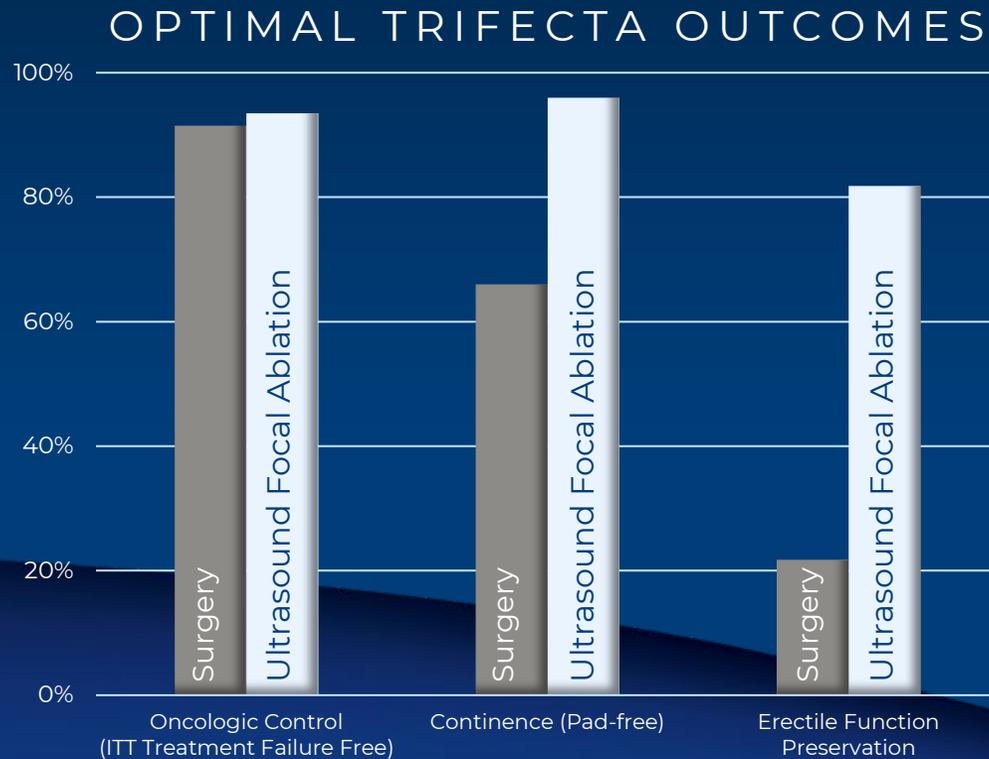
Comparable Cancer Control (Primary Endpoint):
90% STFS for HIFU vs **86%** for RP; $p = 0.008$

Superior functional outcomes for HIFU (Secondary Endpoint):

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

FARP - Randomized Controlled Trial Focal Ablation vs Radical Prostatectomy

Final Results Presented at AUA 2025



Randomized Controlled, Non-inferiority Clinical Trial comparing Focal Ablation (FA) to Robot-Assisted Radical Prostatectomy (RP)

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

Superior Functional Outcomes after Focal Ablation

213 Patients included in the Clinical Trial

25% of Patients refused radical surgery after randomized to RP and opted for FA

80+% of Focal Ablation patients treated with Focal One®

Baco et al. Final, three-year oncological results of a randomized clinical trial FARP comparing Focal Ablation and Radical Prostatectomy in patients with unilateral clinically-significant prostate cancer. Journal of Urology [Internet]. 2025 May 1;213(5S):e714.

Baco et al. Focal Ablation Versus Radical Prostatectomy for Intermediate-Risk Prostate Cancer: Interim Analysis of a Randomized Controlled Trial. The Journal of Urology. Vol. 206, No. 3S, Supplement, Sunday, September 12, 2021

HIFU Demonstrates Equivalent 10-year Survival to Radiation Therapy

HIFU

HIFU

Radiation

10-year Oncological Outcomes of HIFU vs EBRT⁽¹⁾

- **Lower Mortality** at 10 years post HIFU (9.2%) compared to EBRT (16.7%)
- **Lower Cancer-Specific Mortality** after HIFU (5.4%) compared to EBRT (9.2%)

Radiation

Strong Hospital and Physician Reimbursement

STRONG REIMBURSEMENT

Creates Favorable Environment for Growth



1. **APC Level 6** Under CMS for CY23, CY24 and CY25
2. **90% Increase** in Reimbursement in 2023
3. **APC Level 6** Maintained by CMS in 2026

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)
Prostate Brachytherapy	55875	13.12	\$693
Cryo	55873	13.26	\$692
MRI Transurethral Ultrasound Ablation	55882	11.21	\$530
HIFU	55880	17.29	\$884
Laparoscopic/Robotic Prostatectomy	55866	21.90	\$1,087

Growing Global Install Base

FOCAL ONE ADOPTION ACCELERATING At Major U.S. Hospitals

87 Focal One Systems as of Dec. 31, 2025
(42 Academic – 45 Community)



FOCAL ONE IS THE LEADING FOCAL THERAPY TECHNOLOGY

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



70%

7 Out of 10
Best Hospitals for Urology



63%

22 Out of 35
SUO Approved Programs

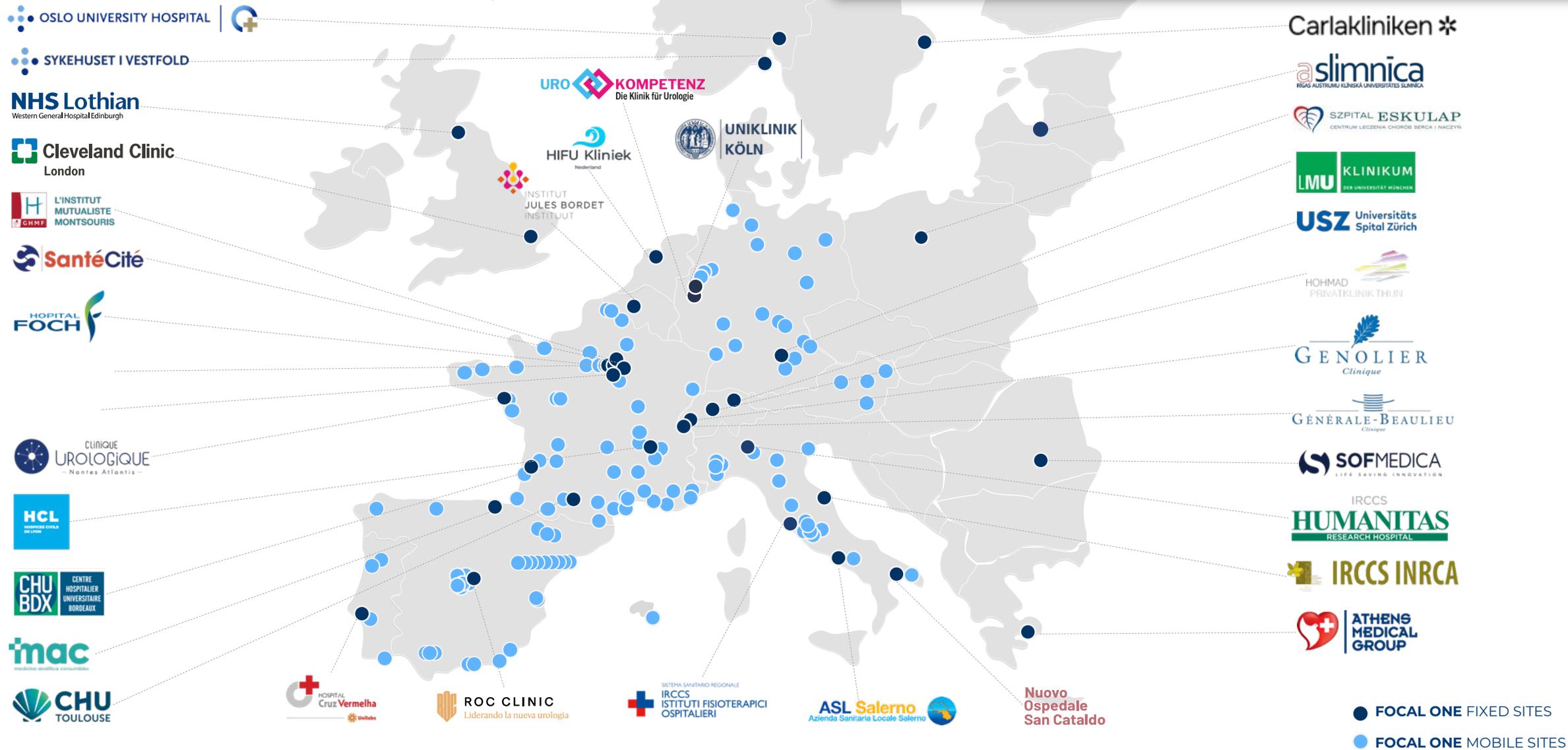


55%

18 Out of 33
NCCN Member Institutions

FOCAL ONE ADOPTION ACCELERATING At Major European Hospitals

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



BPH & Endometriosis

Large Market Opportunities For Expansion

BENIGN PROSTATIC HYPERPLASIA (BPH) MARKET

94 Million

Global cases of BPH in 2019 ⁽¹⁾

15 Million

U.S. men are affected by BPH/LUTS ⁽²⁾

600,000

U.S. men aged 65+ newly diagnosed annually ⁽³⁾

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

12.2 Million men actively managed for BPH/LUTS:

- 55% under Drug Management ⁽⁴⁾
- 35% under Watchful Waiting ⁽⁴⁾
- 300,000+ Active Surgical Treatments ⁽⁵⁾

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) Fentahun et al. The Lancet Healthy Longevity. 2022

(2) Egan K B. Urologic Clinics of North America. 2016

(3) Urologic Diseases in America. 2024. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases. 2024

(4) Vuichoud et al. Can J Urol. 2015

(5) Source: Internal company estimates

Building High-Level Evidence in the Treatment of Benign Prostate Hyperplasia

Feasibility Study

Completed



- Monocentric Feasibility Study (9 patients)
- Confirmed Safety and potential for improvement of BPH-related symptoms

Phase I-II Study

Recruiting



- First Patients Treated
- Phase I: Three-center study HIFU dose escalation
- Phase II: Multi-center Study Safety and Efficacy of Final HIFU Parameters as defined in Phase I

U.S. Study

IRB-Approved



- Protocol based on previous study findings

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

Building High-Level Evidence in the Treatment of Deep Infiltrating Rectal Endometriosis

Phase I Study

Completed



- Feasibility (20 patients)
- Published in the Journal of Ultrasound in Obstetrics and Gynecology in 2020

Phase II Study

Completed



- Multicenter Safety and Efficacy Study (60 patients)
- Completed in March 2022
- Published in Journal of Human Reproduction in 2024

Phase III Study

Completed Enrollment



- Multicenter Double-Blind Randomized Controlled Trial (RCT)
- Enrollment completed (60 patients)
- Follow-up of all patients in progress
- 85% of Sham Group patients elected and received HIFU Treatment

CE Mark

March 25, 2025



- Focal One received **CE mark certification** for the treatment of posterior deep endometriosis infiltrating the rectum

Key Business Trends

Focal One U.S. Momentum 2021 - 2025

(Compounded Annual Growth Rates)

52% Focal One
Installations CAGR

Focal One
Procedures
Focal One
Installations

44% Focal One
Procedures CAGR

Focal One HIFU Accelerated Revenue Growth

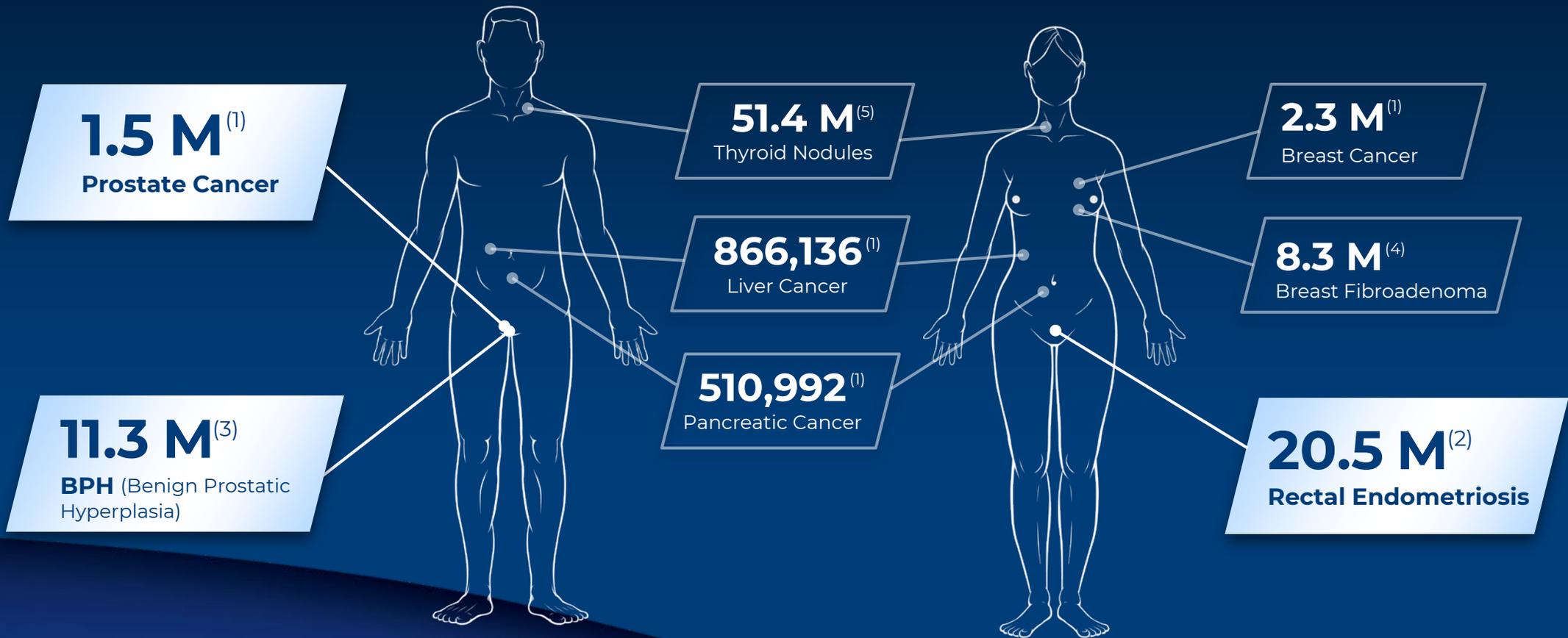
Capital Sale + Recurring Revenue

- Capital Sales
- Disposables & Treatment-Driven Revenue
- Service



(1) Based on preliminary, unaudited Company results for 2025
 (2) Source: 2026 financial guidance as disclosed in the Company's preliminary, unaudited earnings release (as of January 12, 2026)

HIFU Unlocks a Large Market Opportunity



⁽¹⁾ Newly Diagnosed Cases per year From World Health Organization – Globocan 2022

⁽²⁾ From WHO and Habib N et al. Bowel Endometriosis: Current Perspectives on Diagnosis and Treatment. Int J Womens Health. 2020

⁽³⁾ Xu et al.. Global, Regional, and National Incidence and Year Lived with Disability for Benign Prostatic Hyperplasia from 1990 to 2019. Am J Mens Health. 2021

⁽⁴⁾ Based on UN Population Division and Goehring et al. Epidemiology of benign breast disease, with special attention to histologic types. Epidemiol Rev. 1997

⁽⁵⁾ Based on UN Population Division and Bomeli et al. Evaluation of a thyroid nodule. Otolaryngol Clin North Am. 2010

SUMMARY

Positioned for Growth

- **Large Addressable Markets** in Men's and Women's Health
- **Growing Global Install Base** of Leading Tier 1 Academic and Community Hospitals
- **Differentiated Non-Invasive Robotic HIFU Technology Solving Unmet Needs** for Prostate Cancer, BPH and Endometriosis
- **Strong Clinical Evidence** with **Favorable Reimbursement** in Place
- **Proven Management Team** from Industry-Leading MedTech Companies

INTUITIVE

Medtronic

stryker

Boston
Scientific



GE HealthCare

Johnson & Johnson

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The **Global Leader** in Therapeutic Ultrasound