

edap | Focal·One®

The **Global Leader** in Therapeutic Ultrasound

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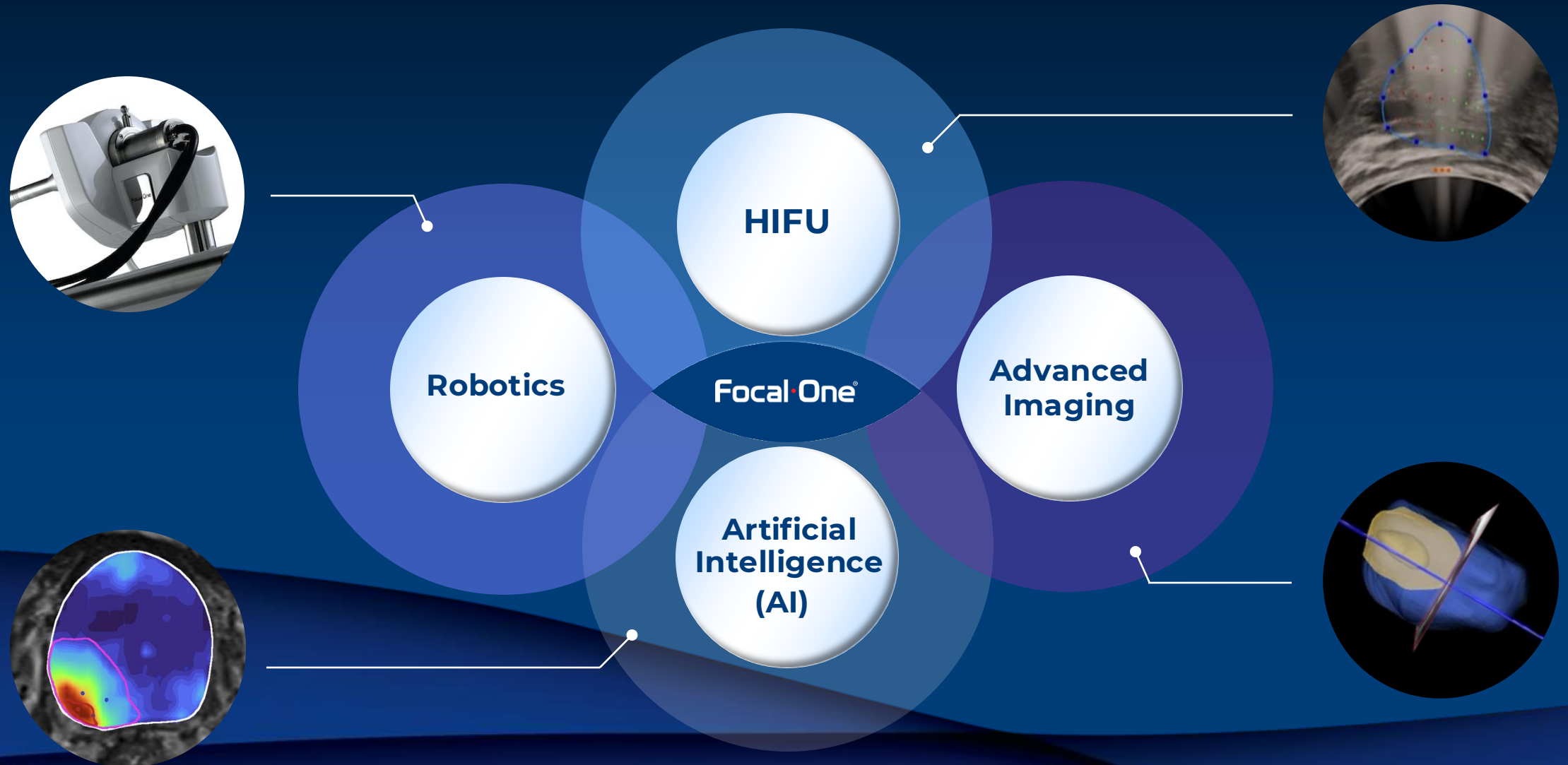
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Company Overview

The **Global Leader** in Innovation and Delivery of Advanced Ultrasound Technologies for both the **Diagnosis and Treatment of Disease**

Core Technologies of Focal One®



EDAP | FOCAL ONE

Global Market Presence

7 Global Subsidiaries and **350+ Clinical Sites**
Offering Our Advanced Ultrasound Technologies



- **EDAP Offices** – United States, France, Germany, Switzerland, South Korea, Japan and Malaysia
- **EDAP Customer Sites** – Over 350 Clinical Sites

GROWING MOMENTUM At Leading Hospitals

61 Focal One Systems in the U.S. at the end of Q3 2024
(32 Academic – 29 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



51%

18 Out of 35
SUO Approved Programs



National
Comprehensive
Cancer
Network®

42%

14 Out of 33
NCCN Member Institutions

Prostate Cancer Addressable Market

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>

U.S. PROSTATE CANCER MARKET

3.3 Million

American Men Living with Prostate Cancer ⁽¹⁾

299,010

New Cases Diagnosed Every Year in the US ⁽¹⁾

1 Million

Prostate Biopsies Performed Annually in the US and Increasing Every Year ⁽²⁾

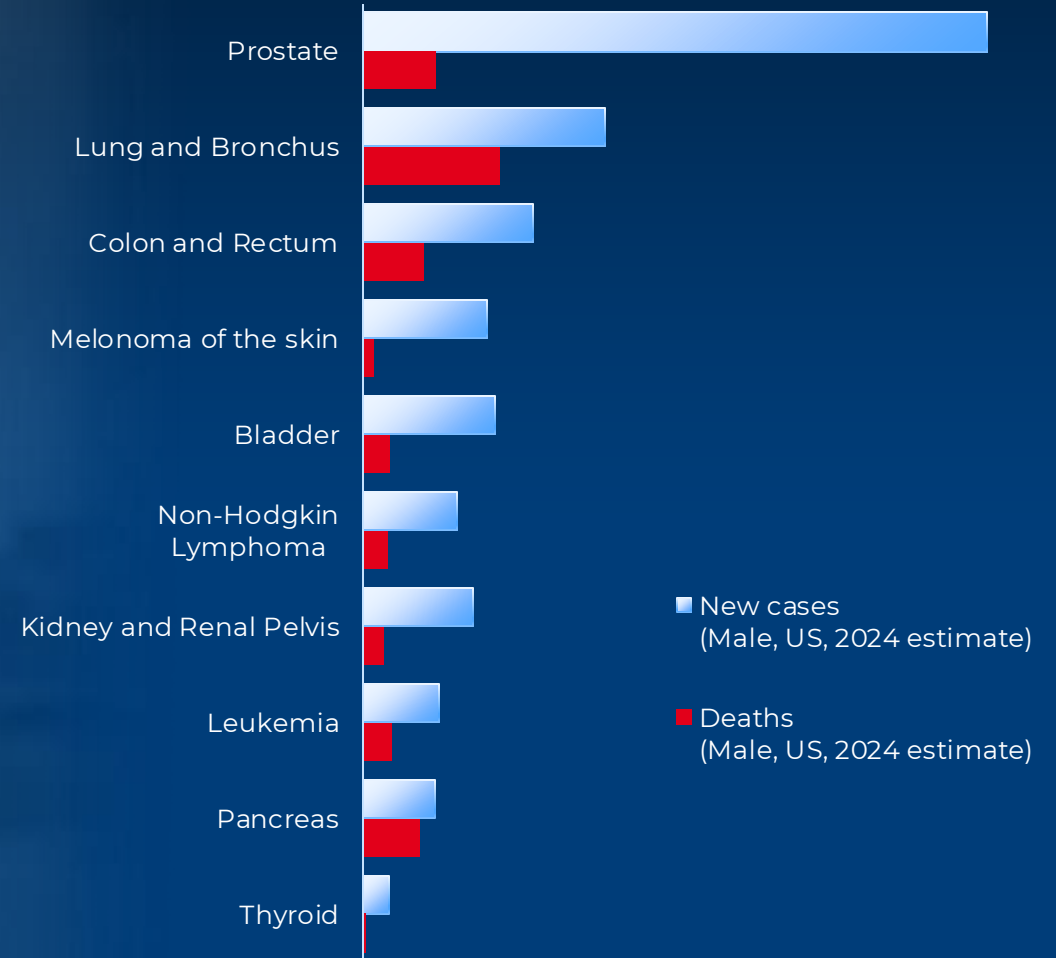
35,250

Deaths every year in the US ⁽¹⁾

⁽¹⁾ 2024 estimates from the American Cancer Society (www.cancer.org)

⁽²⁾ Bjurlin et al. Standards for prostate biopsy. Curr Opin Urol. 2014

Prostate Cancer is the Most Common Cancer Amongst Men In the US (2024)



95,000+

Prostate Cancer
Procedures Per Year

EXPANDING U.S. PROSTATE CANCER
Total Addressable Market

**First-Line
Treatment**



48,000+

Prostate Cancer
Procedures Per Year

**Progression from
Active Surveillance**



33,750+

Prostate Cancer
Procedures Per Year

**Salvage
Treatment**



13,500+

Prostate Cancer
Procedures Per Year

Global Prostate Cancer Addressable Market

465,000

Global Prostate Cancer Procedures Per Year



165,000
Europe

130,000
Asia

95,000
North America

75,000
South America

Prostate Cancer Treatment Trends

HISTORICAL TREATMENTS

Non-Organ Preserving Cancer Treatments

THE TREND TOWARDS

Organ Preserving Cancer Treatments

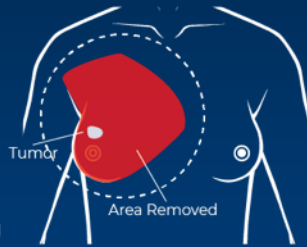
Radical Surgery

Progression To

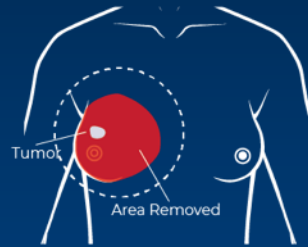
Organ-Sparing Treatments



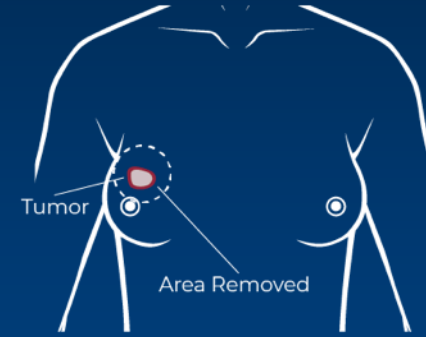
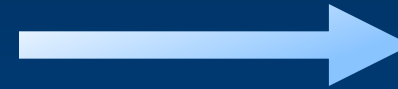
Incision Area
Area Removed



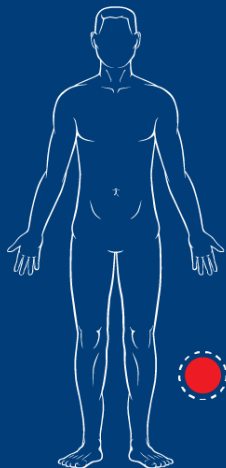
Radical
Mastectomy



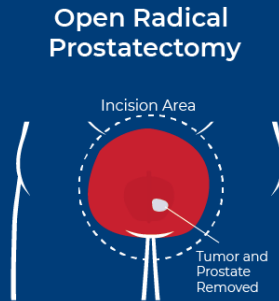
Modified Radical
Mastectomy



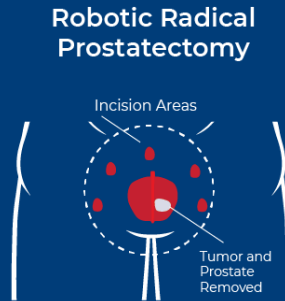
Lumpectomy



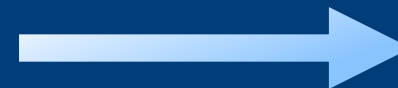
Incision Area
Area Removed



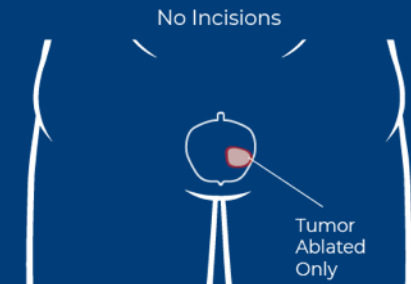
Open Radical
Prostatectomy



Robotic Radical
Prostatectomy



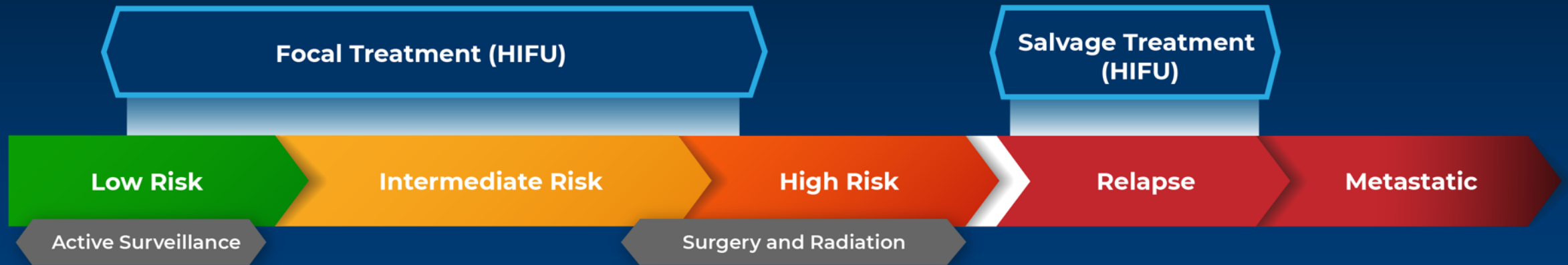
Robotic Focal HIFU Ablation



No Incisions

Tumor
Ablated
Only

Focal Therapy Fills an Important Treatment Gap in the Management of Prostate Cancer



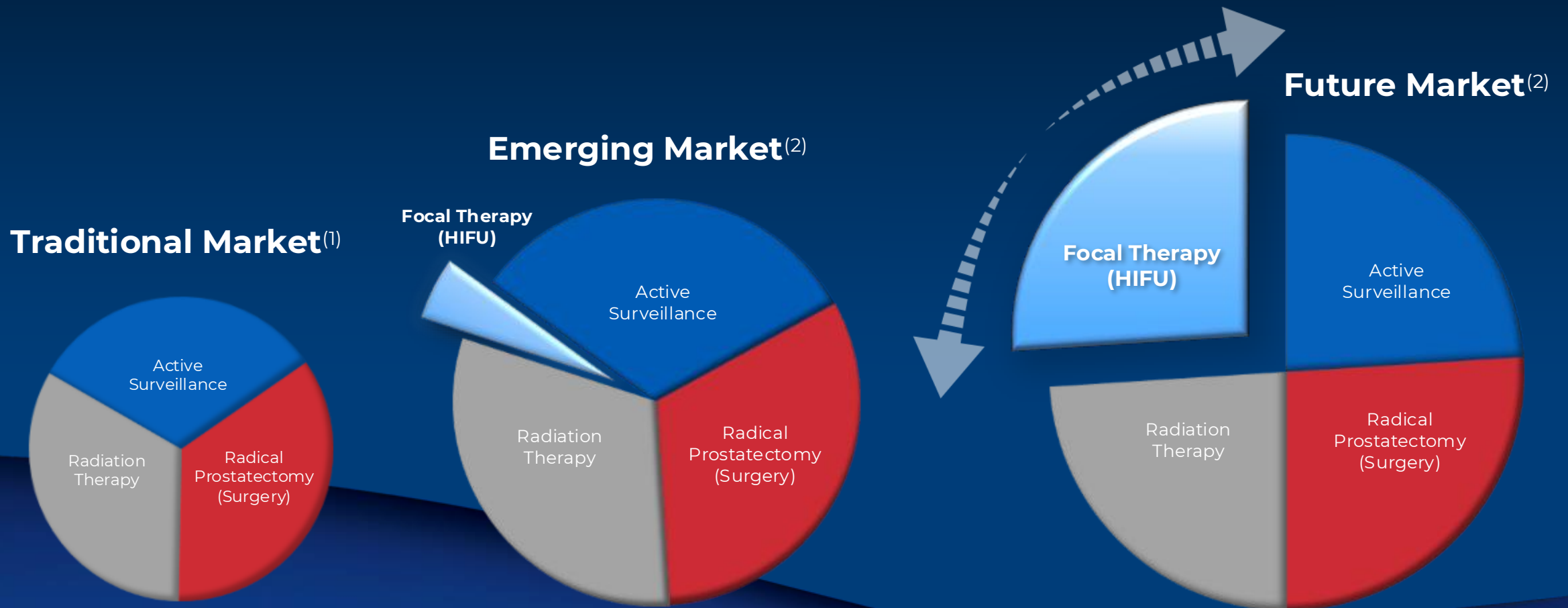
Advanced imaging, targeted biopsies, and genomic testing allow for **better risk stratification** of the prostate cancer patient.

HIFU provides a safe, effective, and minimally invasive option for patients with low, intermediate-risk disease, as well as salvage treatment for failed radiotherapy

Patients are actively seeking an option **between active surveillance and radical therapy**

DRIVING A PARADIGM SHIFT IN PROSTATE CANCER

Focal Therapy | The New Emerging Market

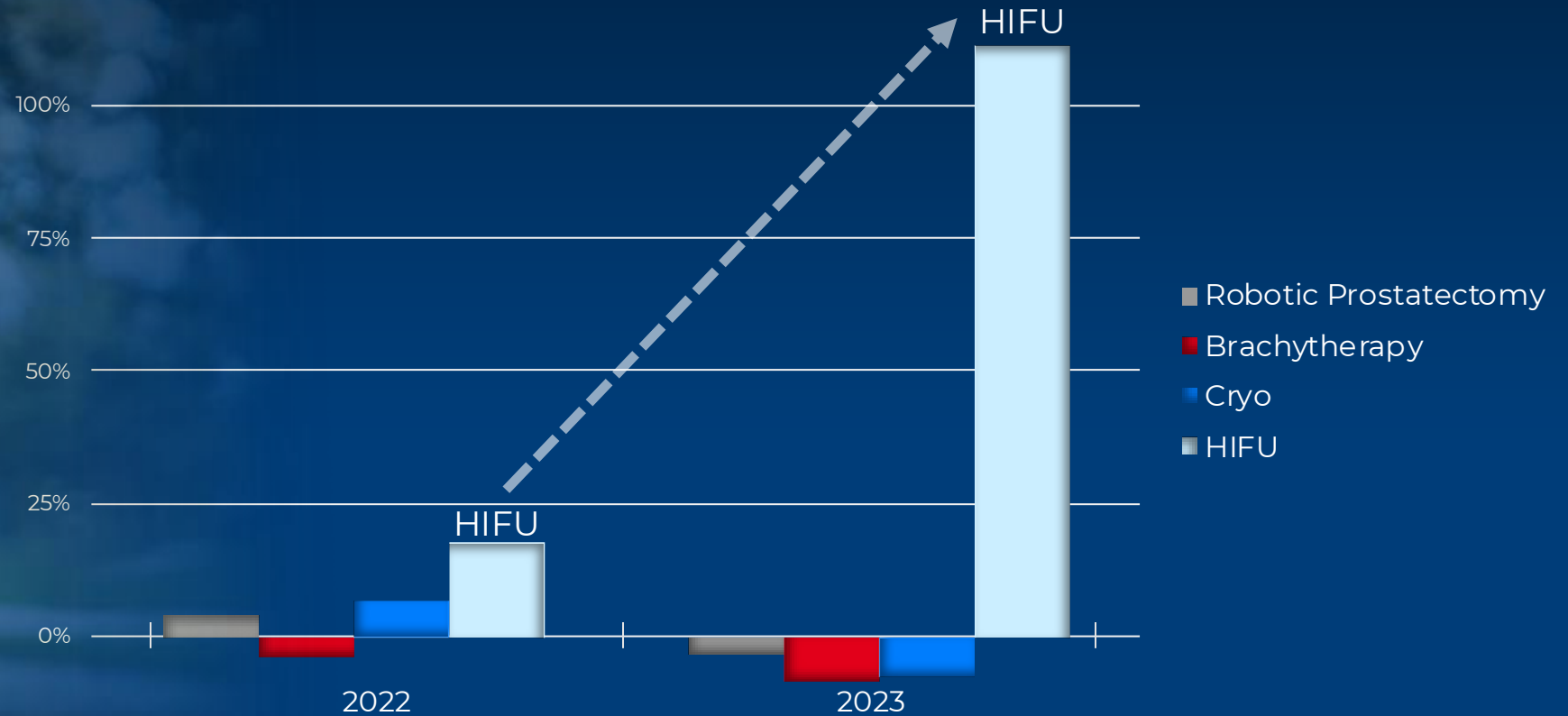


(1) As of 2013. Chen et al. National trends in the management of localized prostate cancer. A population-based analysis 2004-2013. Prostate.

(2) Internal market estimate

DRIVING A PARADIGM SHIFT IN PROSTATE CANCER

HIFU | The Fastest Growing Treatment Option



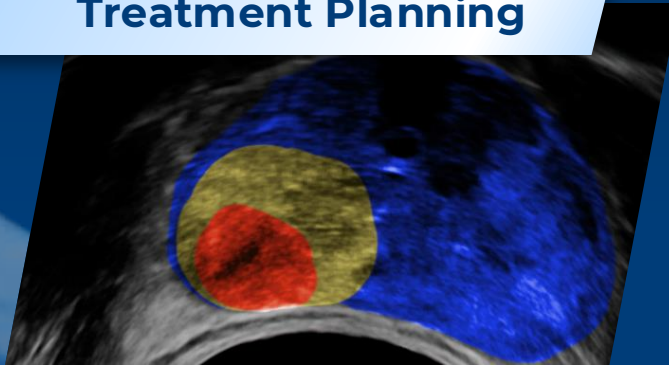
(1) Based on Medicare Claims reported by CMS on HOPPS Final Rule for CY 2024 vs CY 2023 and CY 2025 vs CY 2024

Focal One® Best-in-Class Technology

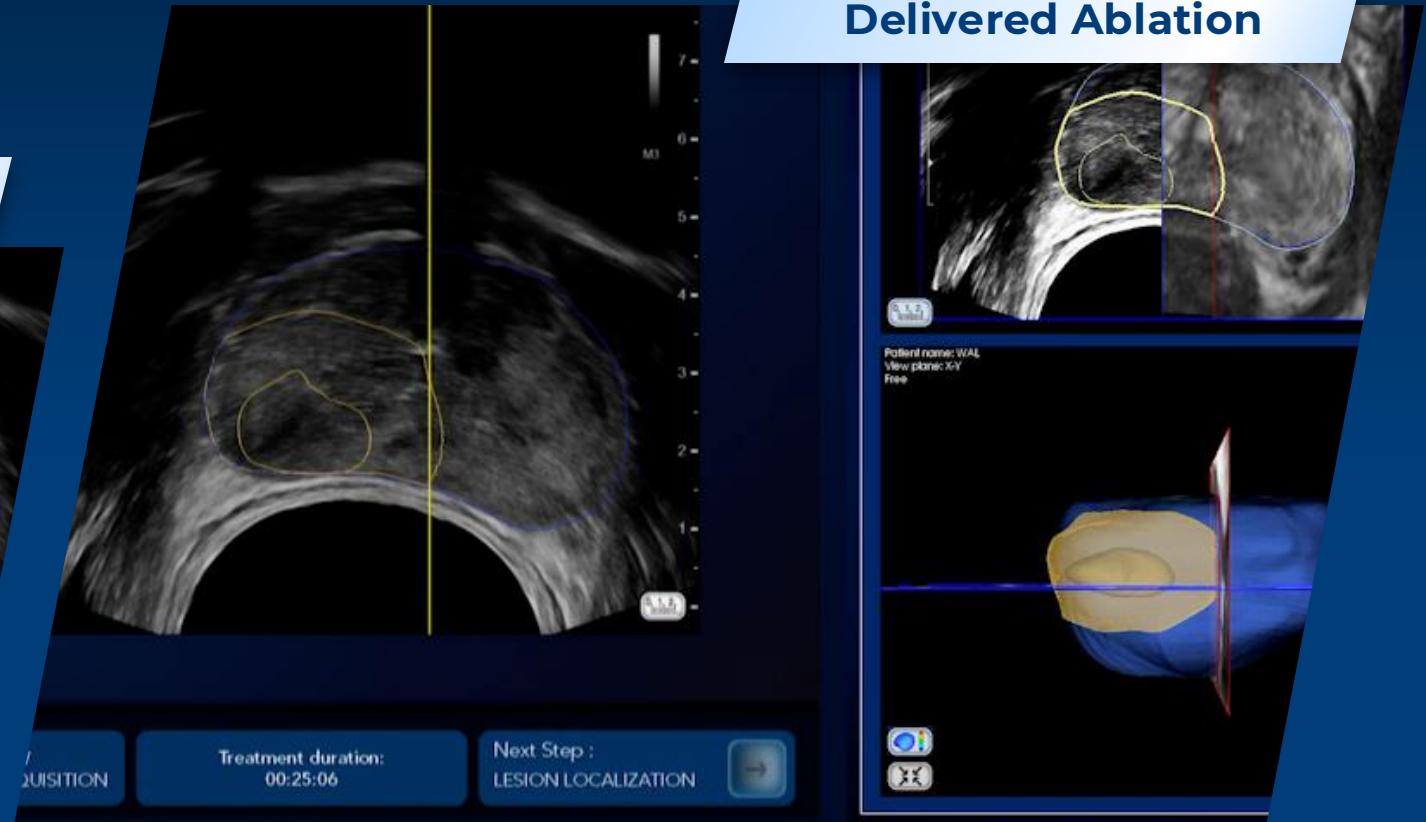
THE LEADING FOCAL THERAPY TECHNOLOGY

Targeting and Imaging

Image Guided
Treatment Planning



Precise Robotic
Delivered Ablation



The **Most Advanced Robotic HIFU**
Platform In the Hands of Urologists

The Leading Platform for Focal Ablation of Prostate

Fusion

HIFusion® MRI /
3D Biopsy Fusion

Robotic Positioning System

Dynamic Focusing Probe

Integrated Workstation

Compatible With
Standard OR Beds



Focal One®



Favorable Reimbursement

STRONG REIMBURSEMENT
**Creates Favorable
Environment
for Growth**



1. **APC Level 6** Under CMS for CY23 and CY24 ^(1,3)
2. **90% Increase** in Reimbursement in 2023 ^(1,2)
3. **APC Level 6** Maintained by CMS in 2025 ⁽³⁾

(1) CMS Hospital Outpatient Prospective Payment System - 2023 Final rule
(2) CMS Hospital Outpatient Prospective Payment System - 2022 Final rule
(3) CMS Hospital Outpatient Prospective Payment System - 2025 Final rule

Hospital Outpatient Medicare Payment

Procedure	CPT® Code	2024	2025	% Change
Prostate Brachytherapy	55875	\$4,930 ⁽¹⁾	\$5,084 ⁽²⁾	3.1%
Cryo	55873	\$8,777 ⁽¹⁾	\$9,247 ⁽²⁾	5.4%
MRI Transurethral Ultrasound Ablation	C9734 / 55882	\$12,553 ⁽¹⁾	\$12,992 ⁽²⁾	3.5%
HIFU	55880	\$8,777⁽¹⁾	\$9,247⁽²⁾	5.4%
Laparoscopic Prostatectomy	55866	\$9,808 ⁽¹⁾	\$10,411	6.1%

(Laparoscopic Prostatectomy with or without Robotic Assistance and/or nerve-sparing)

(1) Medicare Payment (National Average. From on CMS Hospital Outpatient Prospective Payment System – 2024 Final rule
 (2) Medicare Payment (National Average. From on CMS Hospital Outpatient Prospective Payment System – 2025 Final rule

Favorable Physician Payment

Procedure	CPT® Code	Work RVU (2024) ⁽¹⁾	Physician Payment (Medicare - 2024)	Work RVU (2025) ⁽²⁾	Physician Payment (Medicare - 2025)
Prostate Brachytherapy	55875	13.46	\$776	13.46	\$763
Cryo	55873	13.60	\$760	13.60	\$744
MRI Transurethral Ultrasound Ablation	55882	-	-	11.50	\$579
HIFU	55880	17.73	\$972	17.73	\$951
Laparoscopic Prostatectomy	55866	22.46	\$1,183	22.46	\$1,157

(Laparoscopic Prostatectomy with or without Robotic Assistance and/or nerve-sparing)

(1) CMS Physician Fee Schedule – CY 2024 Final rule
 (2) CMS Physician Fee Schedule – CY 2025 Final rule

Strong Supporting Clinical Evidence

CLINICAL EVIDENCE SUPPORTS HIFU

Proven Clinical Evidence Supporting HIFU

Published Results Confirm Reproducible Outcomes for Prostate Cancer with HIFU

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

The **Trifecta Outcome** for Prostate Cancer Management

1. Cancer Control

2. Maintaining Urinary Control

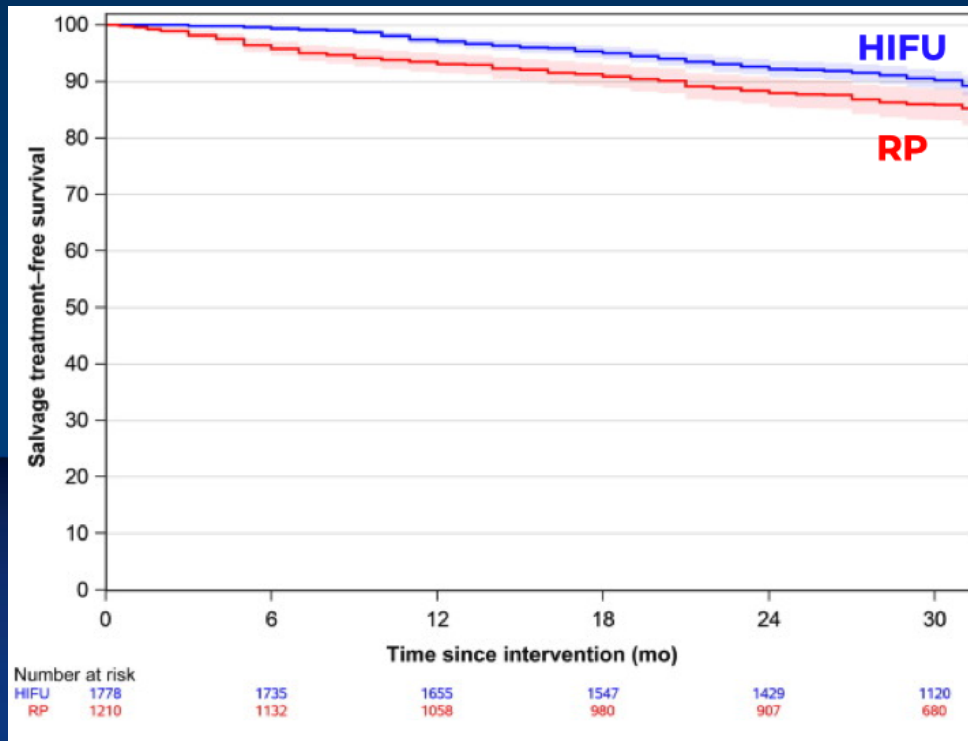
3. Preservation of Sexual Function



CLINICAL EVIDENCE SUPPORTS HIFU

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

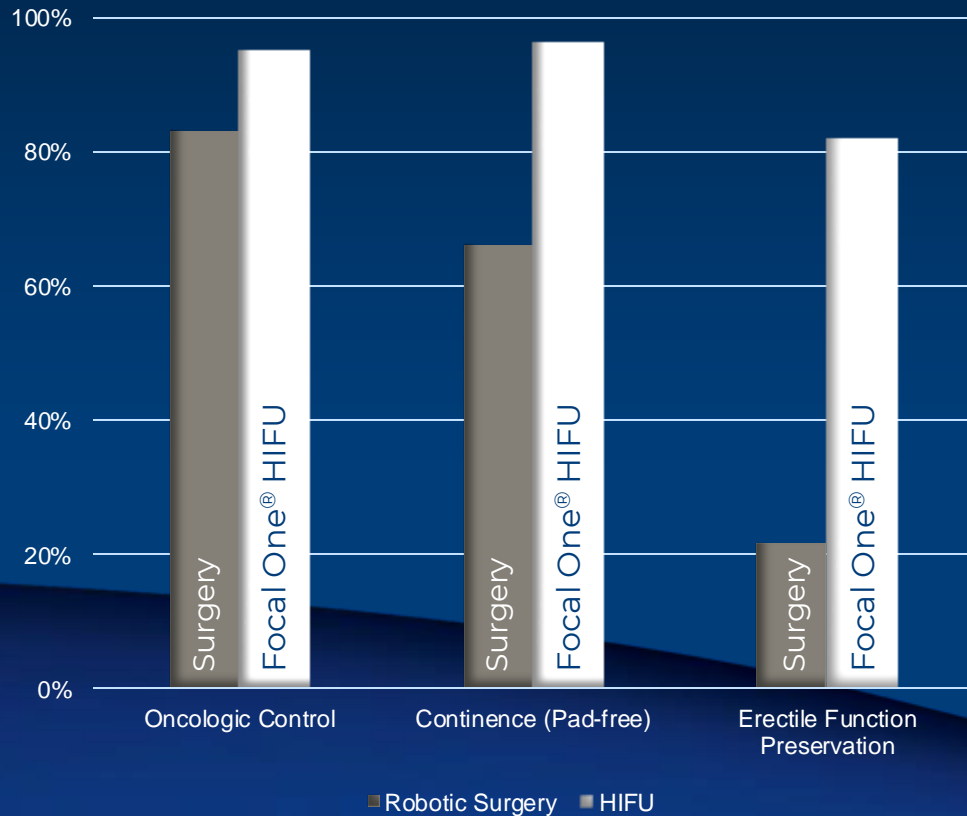
Comparable Cancer Control (90% STFS for HIFU vs 86% for RP; p = 0.008)

Superior functional outcomes for HIFU

- Urinary Continence significantly better after HIFU
- Significantly lower stress incontinence after HIFU
- Erectile Function less impaired (IIEF-5: $\Delta = -7$ vs -13)

LEVEL 1 EVIDENCE

FARP - Randomized Control Trial Comparing Focal Ablation vs Robotic Prostatectomy



Prospective, Comparative, Randomized, non-inferiority clinical trial comparing Focal Ablation to Robot-Assisted Radical Prostatectomy

213 patients included

Equivalent Oncologic Control at 2 years (94% TFF vs 92%)

Superior Functional Outcomes after HIFU

25% of patients refused surgical treatment after being randomized to RP and opted for FA

Baco et al. A Randomized Clinical Trial Comparing Focal Ablation and Radical Prostatectomy in Patients with Unilateral Clinically Significant Prostate Cancer. Intention to Treat Analysis at Two-Year Follow-Up. [PD39-06]. J. Urol. 2024; Vol. 211, No. 5S, Supplement, Sunday, May 5, 2024.

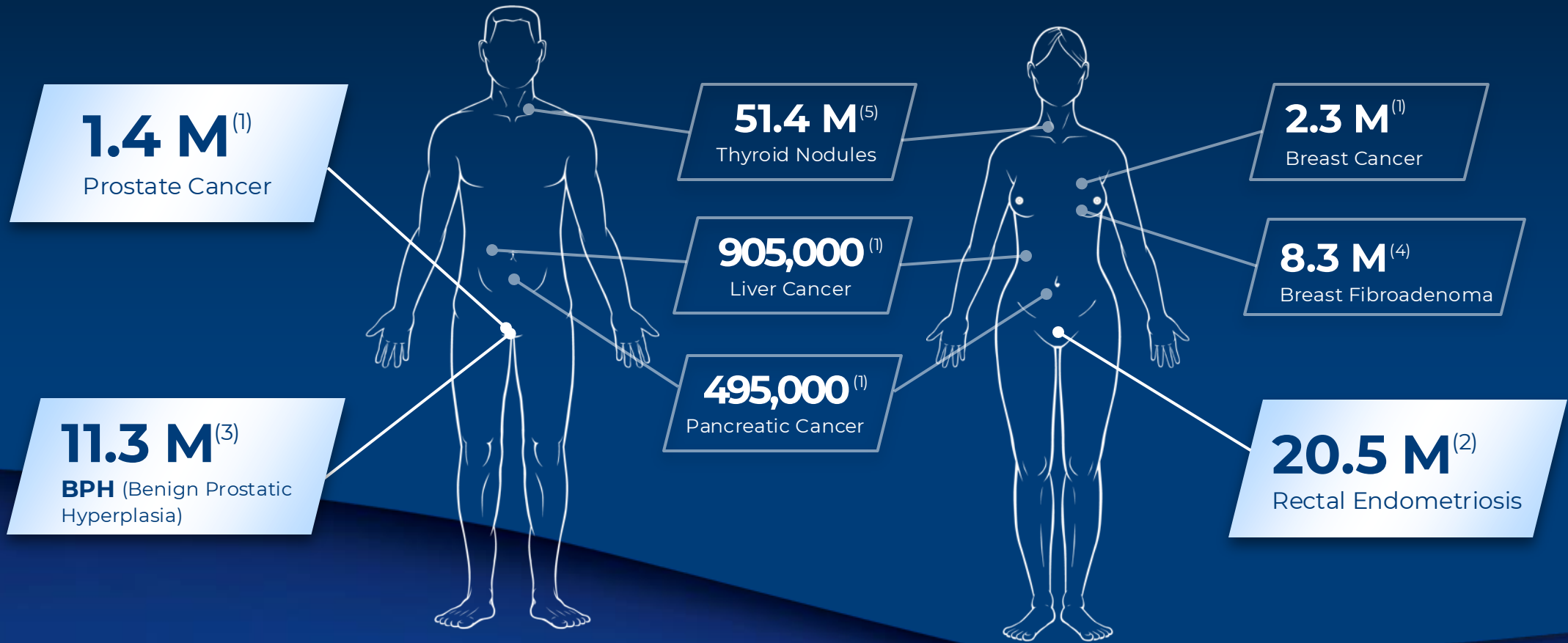
Baco et al. Focal Ablation Versus Radical Prostatectomy for Intermediate-Risk Prostate Cancer: Interim Analysis of a Randomized Controlled Trial. The Journal of Urology. Vol. 206, No. 3S, Supplement, Sunday, September 12, 2021

BPH & Endometriosis

Large Market Opportunities For Expansion

THE BREADTH OF THERAPEUTIC ULTRASOUND

Targeting Large Incidence Cancer and Benign Conditions



⁽¹⁾ Newly Diagnosed Cases per year From World Health Organization – Globocan 2020

⁽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

BENIGN PROSTATIC HYPERPLASIA (BPH) MARKET

94 Million

Global cases of BPH in 2019 ⁽¹⁾

15 Million

US men are affected by BPH/LUTS ⁽²⁾

600,000

US 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⁾ Internal market estimate

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

US FDA Study

Scoping



- Multi-center Study to be defined based on Phase I-II Study findings

6.5 Million

US Women Have Endometriosis ⁽¹⁾

1.3 Million (20%)

Cases are Deep Infiltrating Endometriosis (DIE)
in the US ⁽²⁾

11% of US 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**

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
- Manuscript Accepted for Publication

Phase III Study *Completed Enrollment*



- Multicenter Double-Blind Randomized Controlled Trial (RCT)
- Enrollment completed (60 patients) in less than 9 months

Phase III Study *Follow-up*



- Follow-up of all patients in progress
- 85% of Sham Group patients elected and received HIFU Treatment

Key Financial Data

Financial Highlights as of September 30, 2024

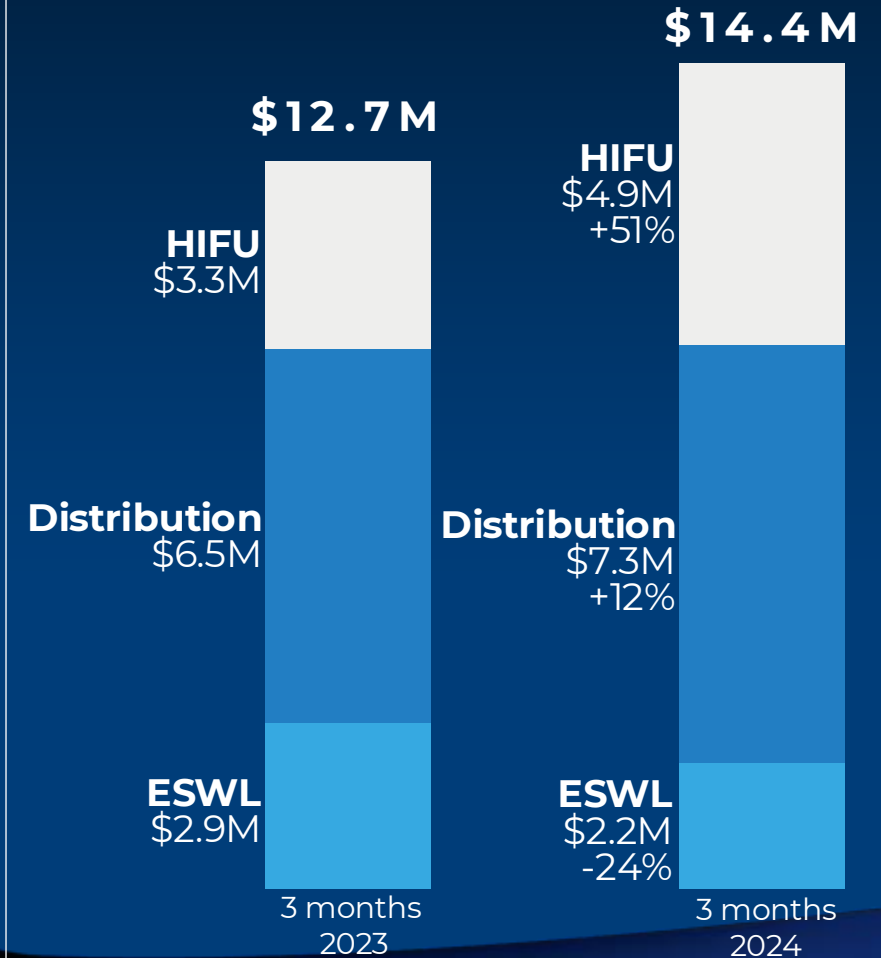
THREE MONTHS ENDED SEPTEMBER 30TH

(in \$Million USD except per share data)

	2023	2024
Revenue	12.7	14.4
Gross Profit	4.5	5.7
Gross Margin	35.5%	39.4%
Operating Profit (Loss)	(6.0)	(6.4)
Net Income (Loss)	(4.3)	(7.0)
Earnings (Loss) Per Share	(0.12)	(0.19)

Year to Date 2024

\$47.6 Million Total Revenue (+7.7% YoY)
+14.9% HIFU Growth



NOTE: Translated for convenience of the reader to U.S. dollars at the 2024 average three months' exchange rate of 1 Euro = 1.1010 USD, and 2023 average three months' exchange rate of 1 Euro = 1.0814 USD

Balance Sheet Highlights as of September 30, 2024

Balance Sheet As Of:

(in \$Million USD)

	September 30, 2024	September 30, 2023
Cash and Cash Equivalents	28.4	50.5
Other Current Assets	42.9	34.5
Fixed and Other Non-Current Assets	16.8	13.8
	88.1	98.7
Current Liabilities	32.7	27.5
Non-Current Liabilities	7.8	7.7
Shareholders' Equity	47.5	63.6
	88.1	98.7

Note: Translated for convenience of the reader to U.S. dollars at the exchange rate of 1 Euro = 1.1145 USD, on September 30, 2024 and at the noon buying rate of 1 euro = 1.0584 USD on September 30, 2023.

SUMMARY

Positioned for Growth

- Large Addressable Markets in Men's and Women's Health
- Growing 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

Johnson & Johnson

ACCURAY

MAKO
stryker

Mazor
Robotics
Medtronic

Boston
Scientific

edap | Focal·One[®]

The **Global Leader** in Therapeutic Ultrasound