GFCT Focal Therapy Limited

PROST8
Better treatments for prostate cancer

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The **Global Leader** in Innovative, Noninvasive Prostate Care

GFCT Focal Therapy Ltd. Proposal, March 2025

Joshua Darley, Regional Sales Director UKI and Nordics countries

Damien Desmedt, VP sales EMEIA & LATAM

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Our mission is to revolutionize prostate cancer treatment by leveraging Focal One® to deliver precise, non-invasive HIFU therapy that effectively eradicates tumors, all while preserving the quality of life for low to intermediate risk patients

Focal·One®

EDAP Focal One® 4 Core Pillars

Best-In-Class Technology

True Robotic Platform
- Robotic Positioning System
- 5 degrees of freedom

Dynamic Focusing Probe
- Advanced Contouring Capabilities
- Precise HIFU Energy Delivery
- Shortest Treatment Times

HIFUsion®
- Elastic Fusion of MRI or 3D Biopsy Maps
- Proprietary Open-Platform Software

Integrated Workstation
- Flexible Cart-Based System
- Compatible with Standard OR Tables

Comprehensive Training

Complete Training Offering
- Physicians
- Fellows
- Residents
- Clinical Staff

Focal One Practicum
- Online E-learning Modules
- Hands-on Procedure Simulation

Case Observation Sites

Physician-to-Physician Proctoring

Marketing Excellence

Full Marketing Resources
- Patient Education Videos
- Patient-Facing Tools

Customizable Assets
- Website
- Videos
- Social Media
- Brochures

Outreach Events
- Patient Education Seminars
- PCa Awareness Campaigns
- Referring Physician Seminars

World-Class Service & Support

Service Support

Dedicated Account Support Team
- Clinical Application Specialist
- Field Service Engineer
- Regional Clinical Manager

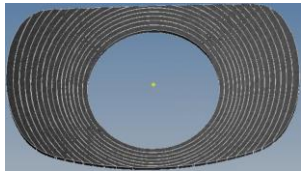

Focal·One®

Dynamic Focus Probe

Ultrasound common tranduscer

- Real Time Image
- 7,5 MHz
- 192 éléments
- B and CEUS Modes

Therapy tranduscers



- Treatment
- 3 MHz
- 16 rings
- 8 focal point of **Dynamic focused ultrasound**

Focal·One®

Fusion Platform – HIFUsion software

Focal One **elastic fusion technology** aligns MRI or biopsy data with real time ultrasound , enabling **precise cancer targeting** for more effective treatment.

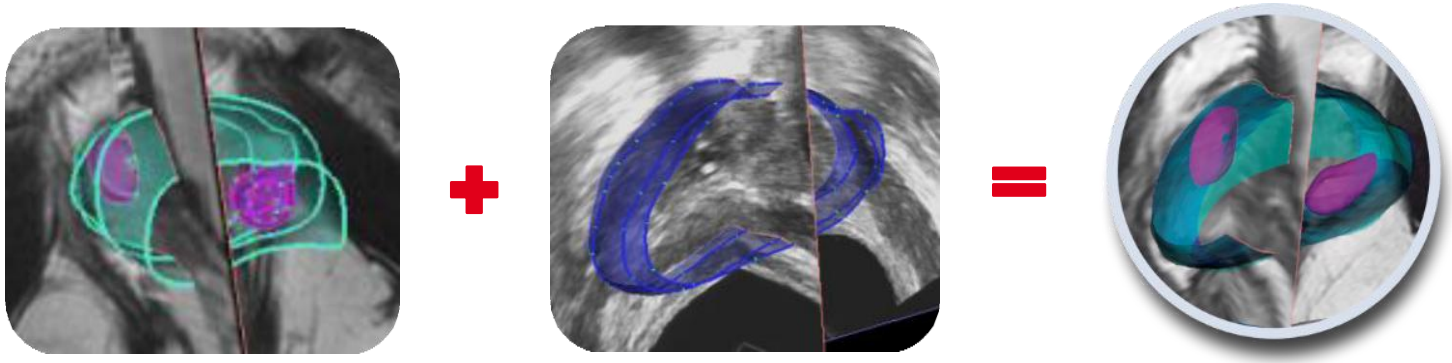
Focal·One®

Data Needed

The Focal One Fusion is performed with :

- ✓ MRI
- ✓ Biopsy data

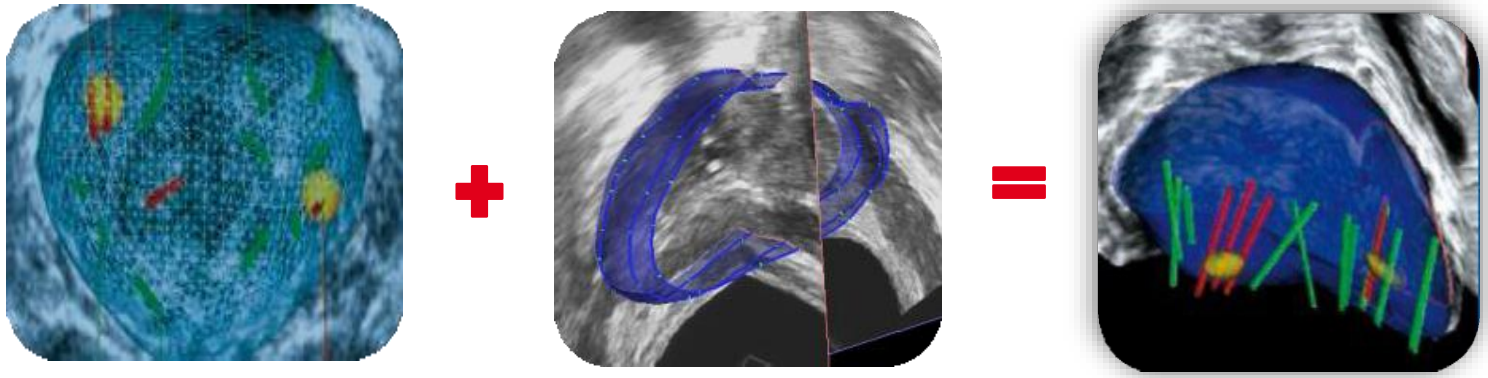
Fusion steps are quite the same for both fusions type.



Step 1
MRI contouring

Step 2
US contouring

Step 3
Elastic fusion



Step 1
Load biopsies data

Step 2
US contouring

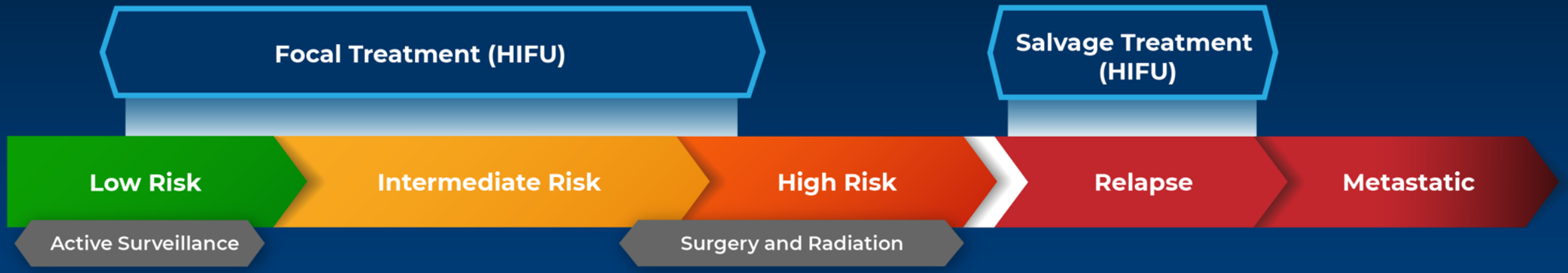
Step 3
Elastic fusion

Focal·One®

What type of patients are eligible to Focal One?

Focal·One®

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

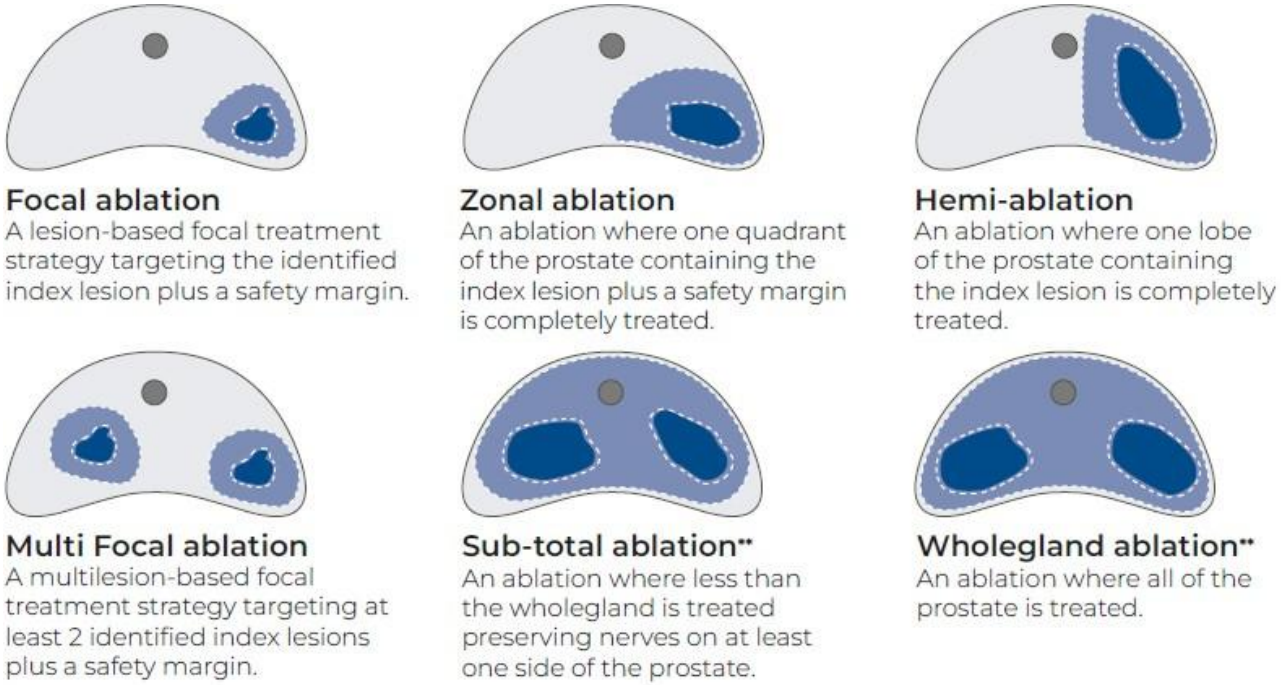
Patients are actively seeking an option **between active surveillance** and **radical therapy**

Focal Therapy with Focal One

The Focal One procedure can be tailored or personalized to every patient and clinical condition.

Focal therapy does not necessarily mean ablating a very small area of the prostate.

Ablating a quadrant, a lobe (hemi ablation) or both lobes sub-totally would be defined as "focal therapy".



Focal ablation
A lesion-based focal treatment strategy targeting the identified index lesion plus a safety margin.

Zonal ablation
An ablation where one quadrant of the prostate containing the index lesion plus a safety margin is completely treated.

Hemi-ablation
An ablation where one lobe of the prostate containing the index lesion is completely treated.

Multi Focal ablation
A multilesion-based focal treatment strategy targeting at least 2 identified index lesions plus a safety margin.

Sub-total ablation**
An ablation where less than the wholegland is treated preserving nerves on at least one side of the prostate.

Wholegland ablation**
An ablation where all of the prostate is treated.

Standardized Nomenclature and Surveillance Methodologies After Focal Therapy and Partial Gland Ablation for Localized Prostate Cancer: An International Multidisciplinary Consensus - Eur Urol. 2020 September ; 78(3): 371–378. doi:10.1016/j.eururo.2020.05.018.

** The examples below are not intended to be exhaustive, but are merely illustrative. ** A TURP should be considered for sub-total and wholegland ablations.*

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Growing Momentum of Focal One at Leading US Hospitals

Focal·One®

Growing Momentum of Focal One at Leading Hospitals

7 Focal One installed in the US at the end of 2019 (**4** Academic – **3** Community)

Growing Momentum of Focal One at Leading Hospitals

12 Focal One installed in the US at the end of 2020 (**8** Academic – **4** Community)

Growing Momentum of Focal One at Leading Hospitals

19 Focal One installed in the US at the end of 2021 (**32** Academic – **31** Community)

Growing Momentum of Focal One at Leading Hospitals

34 Focal One installed in the US at the end of 2022 (**18** Academic – **16** Community)

Growing Momentum of Focal One at Leading Hospitals

50 Focal One installed in the US at the end of 2023 (**27** Academic – **23** Community)

Growing Momentum of Focal One at Leading Hospitals

63 Focal One installed in the US at the end of Q4 2024 (**32** Academic – **31** Community)

FOCAL ONE IS THE LEADING FOCAL THERAPY TECHNOLOGY

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

BEST HOSPITALS U.S.News & WORLD REPORT RANKINGS

70%

7 Out of **10**

Best Hospitals for Urology

SUO Society of Urologic Oncology, Inc. — Defining Excellence in Urologic Cancer

FELLOWSHIP PROGRAM

49%

17 Out of **35**

SUO Approved Programs

NCCN National Comprehensive Cancer Network®

42%

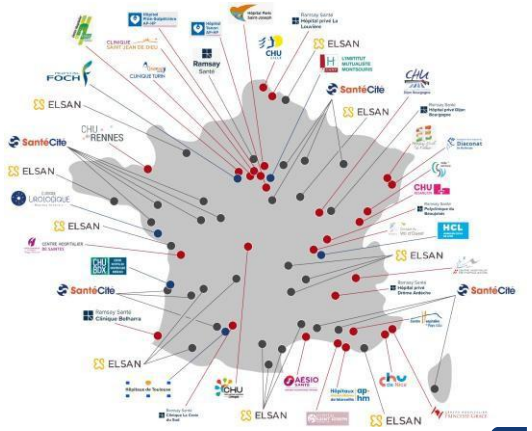
14 Out of **33**

NCCN Member Institutions

What about OUS ?

Focal·One®

Focal One - Worldwide presence



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Why this growing momentum ?

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Meeting the Demand for Noninvasive Cancer Care

30 to 50% of patients in active surveillance will need treatment over 5 years

12,000+ eligible focal treatments per year in the UK

The growing demand ask for non invasive, safer alternatives to surgery and radiation

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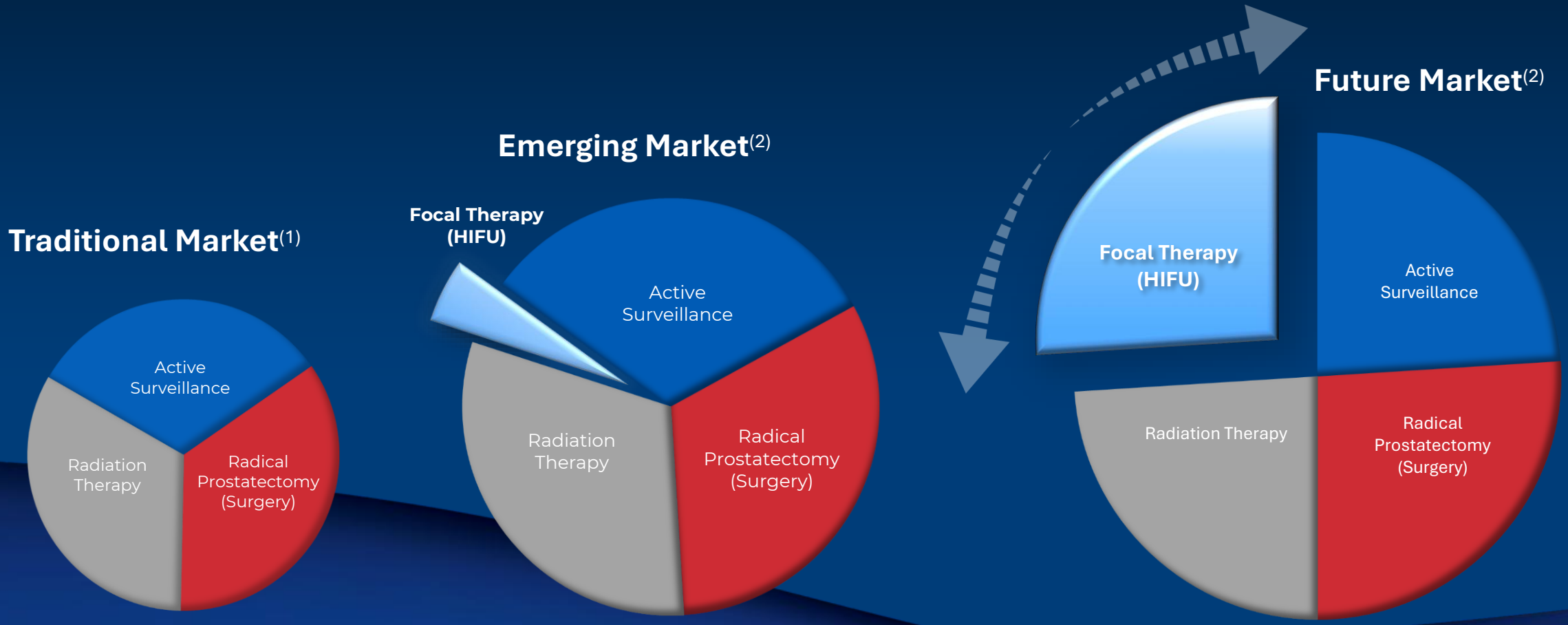
DRIVING A PARADIGM SHIFT IN PROSTATE CANCER

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) Internal market estimate

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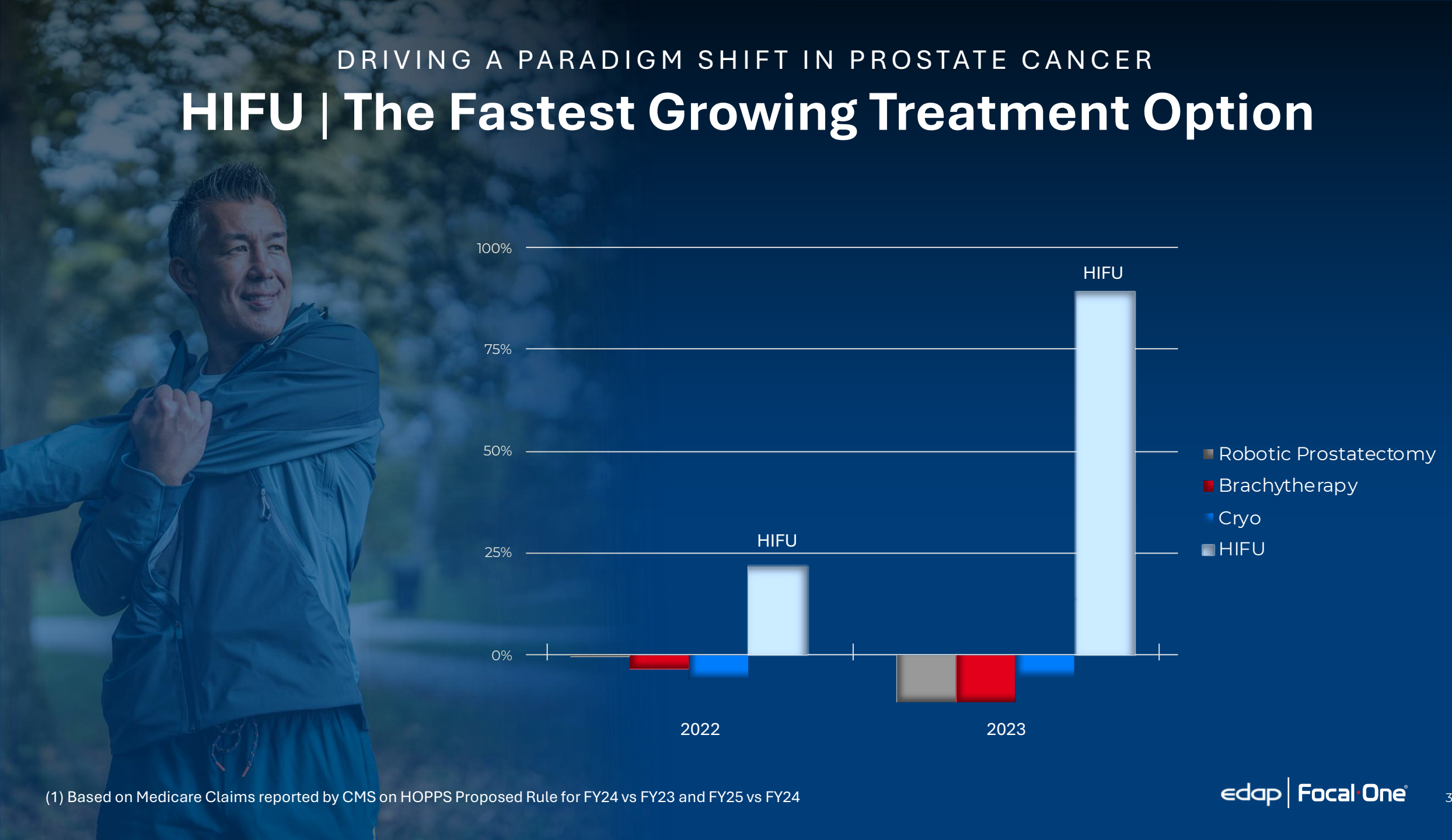
DRIVING A PARADIGM SHIFT IN PROSTATE CANCER

HIFU | The Fastest Growing Treatment Option



(1) Based on Medicare Claims reported by CMS on HOPPS Proposed Rule for FY24 vs FY23 and FY25 vs FY24

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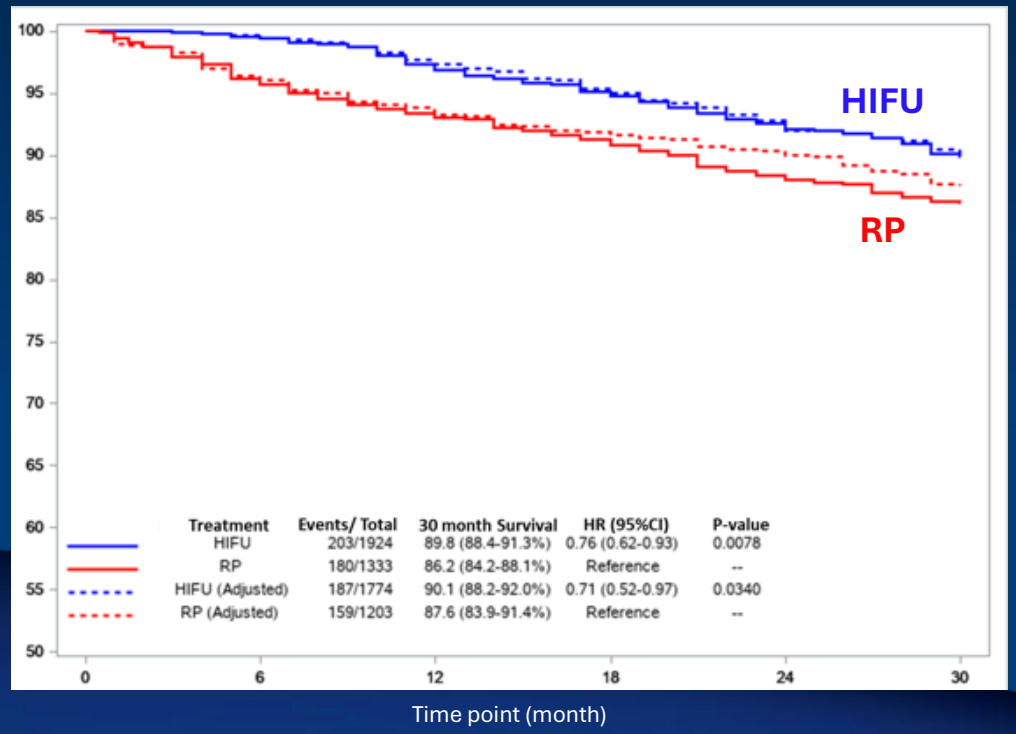
EUROPEAN UROLOGY

HIFI - Prospective Multicentric Comparative Study Focal One HIFU vs Radical Prostatectomy



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**

Non inferior Cancer Control (**90.1%** STFS for HIFU vs **87.6%** 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: Δ = -4 vs -9)

https://www.europeanurology.com/article/S0302-2838(24)02701-5/abstract

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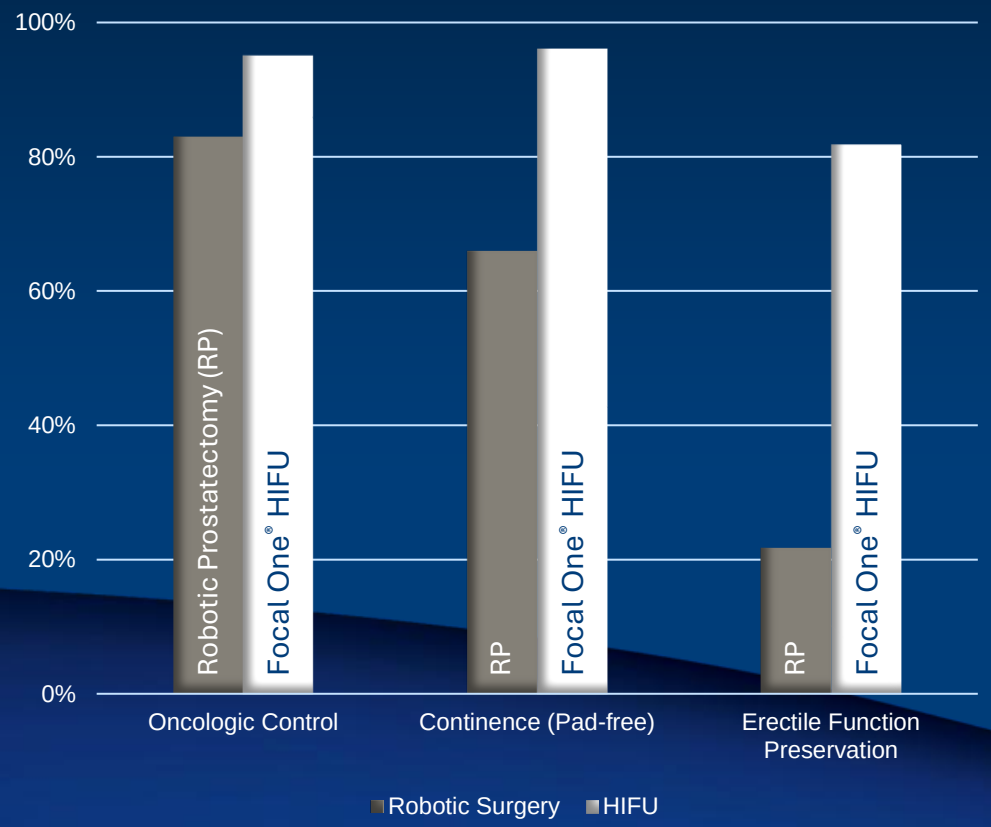
LEVEL 1 EVIDENCE

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

Is Focal Therapy the right path?

I P

Imperial College Healthcare NHS
NHS Trust

Summary of treatments for men with intermediate or high risk prostate cancer suitable for radical and focal therapy

Type of treatment	Mechanism	Number sessions	Urine leakage (any pad use)	Urinary symptoms (frequency, nocturia, urgency)	Erectile dysfunction	Dry orgasm	Back-passage symptoms	Rectal injury	Need for another type of cancer treatment (5-10 years)	Need for another type of cancer treatment (10 -15years)	Cancer-specific survival (5-10 years)	Cancer specific survival (10-15 years)
Prostatectomy 	Whole prostate removal using surgery	Once	10-25%	5-15%	30-60%	100%	1%	Rare	5-10%	10-15%	99-100%	>97%
Radiotherapy (external beam) 	Whole prostate from outside	20 to 37 weekdays	5%	5-15%	30-60%	100%	5-15%	Rare	5-10%	10-15%	99-100%	>97%
Radiotherapy (brachytherapy) 	Whole prostate irradiation from inside	Once	5%	5-15%	30-60%	100%	5%	Rare	5-10%	10-15%	99-100%	>97%
Focal Therapy 	Heat (HIFU) or freeze (cryotherapy) cancer area	70-80% once. 20-30% twice	1-2%	5%	5-20%	50%	<1%	Rare	5-10%	Not known	99-100%	Not known

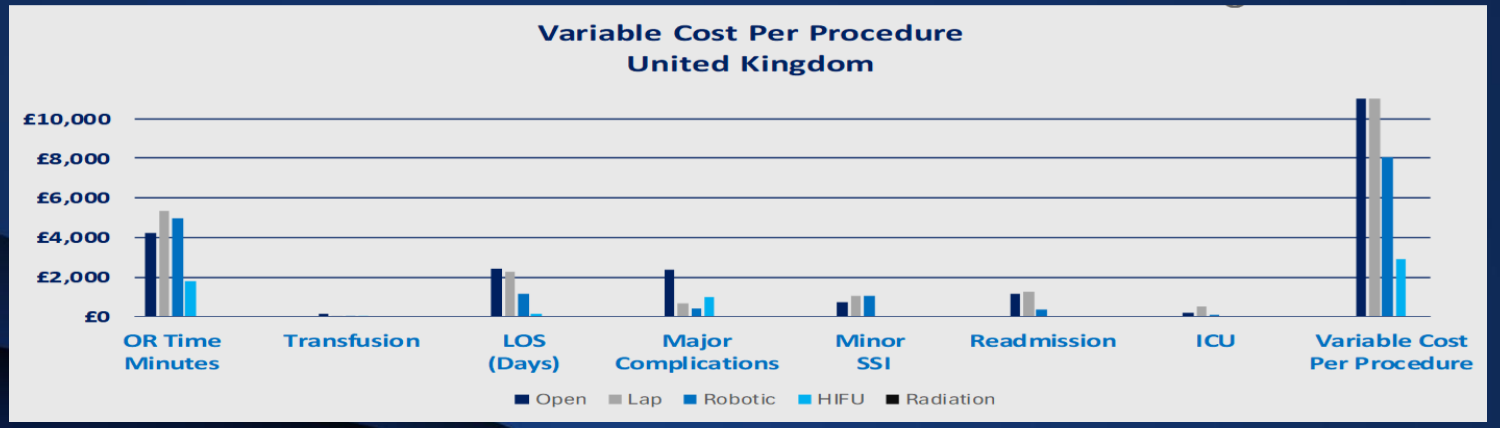
These are overall estimates based on a number of sources. Specific rates for each patient may be different and quoted as such by clinicians depending on baseline risk
Radical Therapy data based on PROTECT RCT, CHIPP trial and UK National Prostate Cancer Audit
Focal Therapy data based on UK HEAT and UK ICE registry approved by UK NICE and published 2018/2019

Focal One meets the Quadruple Aims

A Strategic Investment for Superior Patient Outcomes and Financial Return

Reduced costs from shorter recovery times and fewer complications compared to surgery.

Increased revenue from attracting more patients seeking advanced focal therapy and noninvasive treatment.



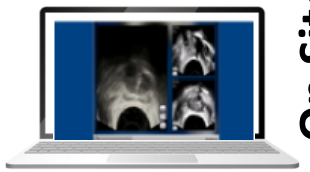
Approach	N	OR Time Minutes	Transfusion	LOS (Days)	Major Complications	Minor SSI	Readmission	ICU	Variable Cost Per Procedure	Annual Variable Cost
Open	7,837	£4,250	£167	£2,412	£2,364	£734	£1,154	£174	£11,254	£88,201,438
Lap	5,225	£5,350	£57	£2,291	£695	£1,048	£1,270	£521	£11,233	£58,690,936
Robotic	13,062	£5,000	£18	£1,166	£417	£1,048	£346	£78	£8,073	£105,449,787
HIFU	250	£1,800	£9	£121	£974	£0	£0	£0	£2,903	£725,733
Radiation	5000									

Variable Costs							
Variable	Operative Time	Transfusion	LOS	Major Complication	Minor SSI	Readmission	ICU
Cost	£25 [24]	£877 [6,7]	£402 [#]	£13,908 [#]	£5,240 [27]	£11,541 [28]	£1,738 [23]

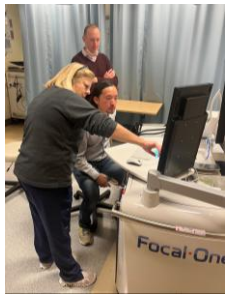
Implementation of the Best-in-Class Clinical Program

Best in Class Patients Outcomes Customized Learning Journey

Case Obs



On Site Proctoring



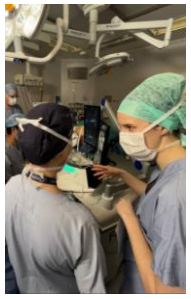
Case support

Follow Up Cases Reveiw

Masterclass

E Learning

Peer to Peer



Workshops

Expert Certification

Webinars and educational Videos

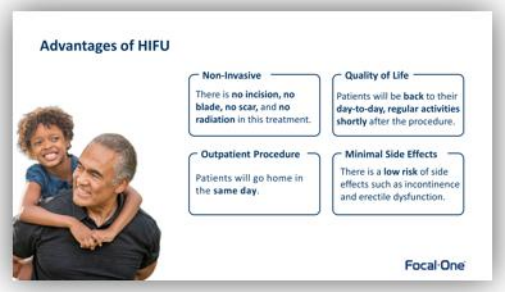
Focal·One®

Implementation of the Best-in-Class Communication and Education Campaign

W.E.A.R. program over 6 Months

Website

Patient Education Video



Patient Seminar Presentation

Social Media Asset

Patients Trifold Brochure

Waiting Room Poster

Customizable Mailers for Referrals

Video Testimonial

Focal·One®

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ROBOTIC FOCAL HIFU

Focal One is a clinically essential and strategically recommended solution, attracting more patients and surgeons while driving hospital revenue growth and maximizing economic rewards

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THANK YOU!