

**Focal·One<sup>®</sup>**  
ROBOTIC FOCAL HIFU



The Global Leader in  
**Therapeutic Ultrasound**

**edap tms**  
(NASDAQ: EDAP)



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

(NASDAQ: EDAP)

**Focal·One®**  
ROBOTIC FOCAL HIFU

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# EDAP Business Model: Differentiated Solutions

3 Business Divisions | 3 Sources of Revenue



## HIFU

## Advanced Imaging

## ESWL

### HIFU Business Division:

Non-Invasive HIFU treatment for **Prostate Cancer** and therapeutic HIFU developments for other pathologies

### Distribution Business Division:

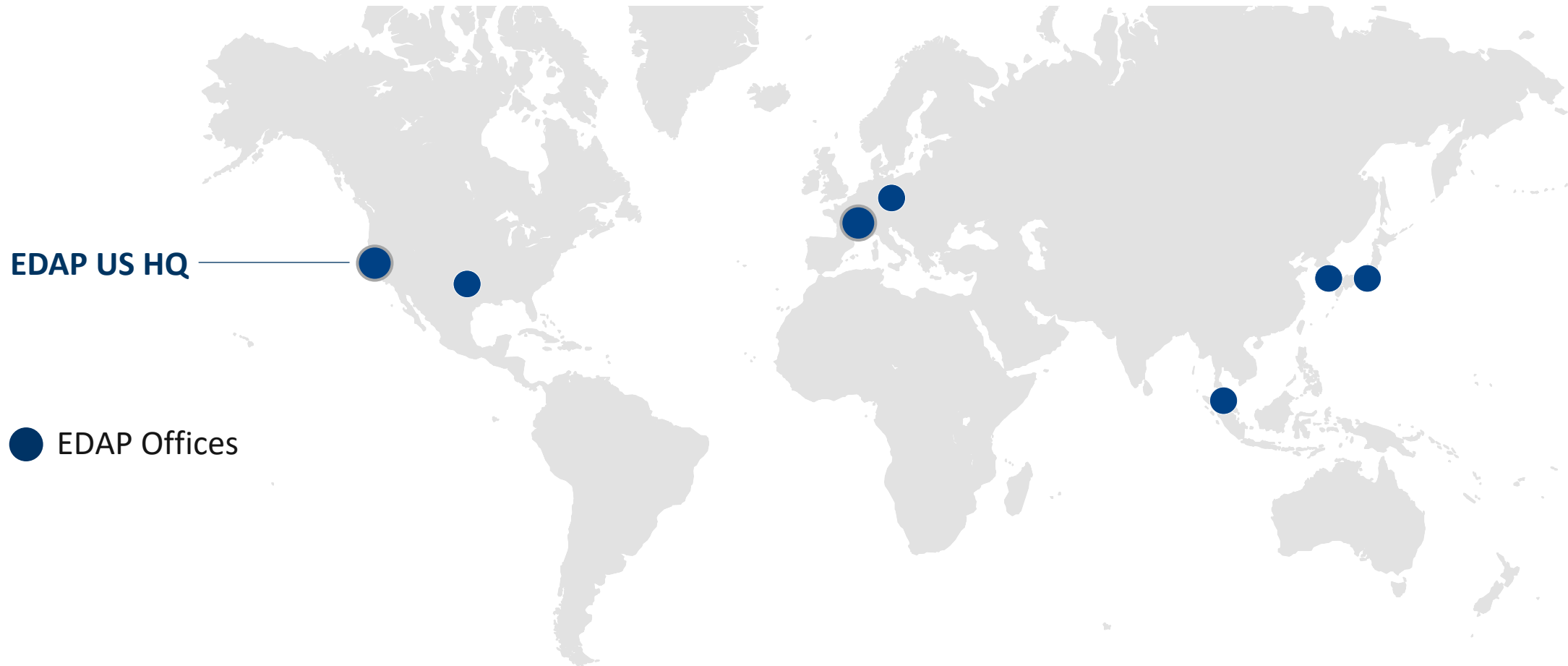
Micro-Ultrasound for imaging of the Prostate in the diagnosis of Prostate Cancer  
Lasers for the treatment of Benign Prostatic Hyperplasia (BPH) and Stones. Urodynamics

### ESWL Business Division:

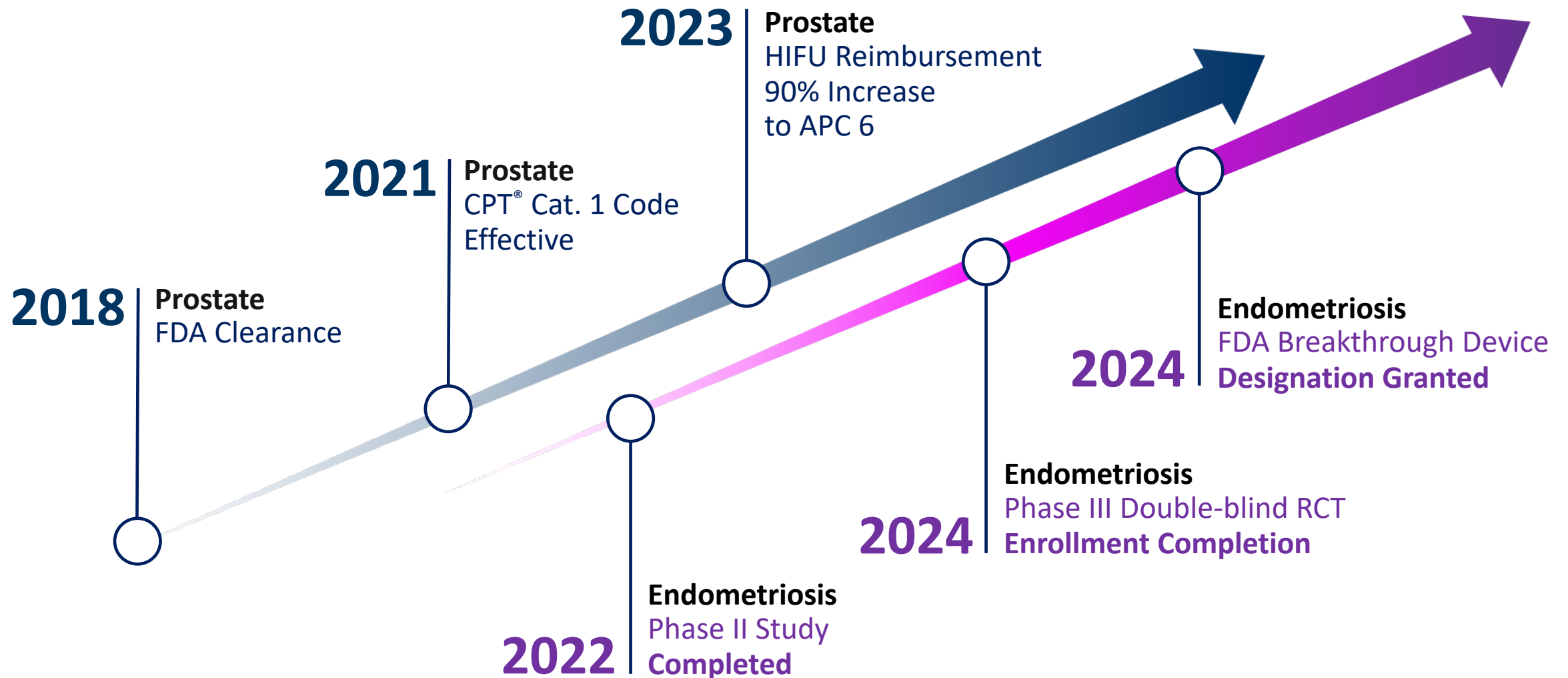
Shockwave technology for Urinary Stones (ESWL)  
Designed & Manufactured by EDAP TMS

# EDAP Global Market Presence

6 Subsidiaries, Worldwide Network of Distributors



# Focal One | Growth Milestones Timelines



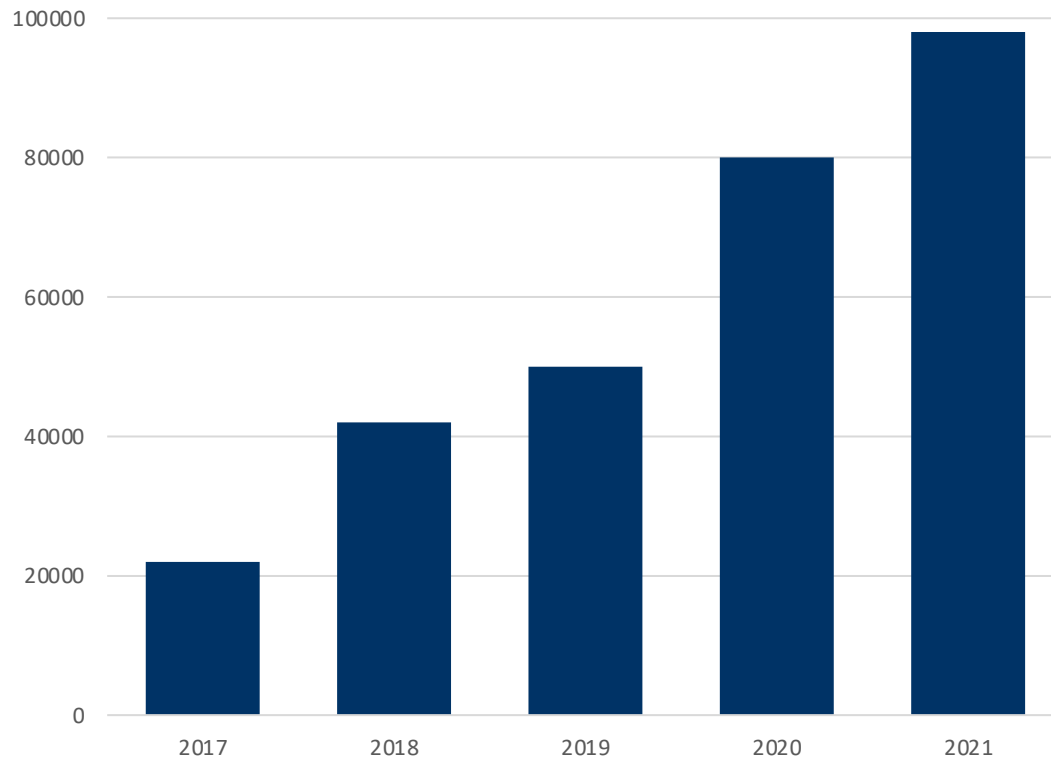


# The Potential of Therapeutic Ultrasound

A Fast-Growing Field for Research and Clinical Application

## 565,210

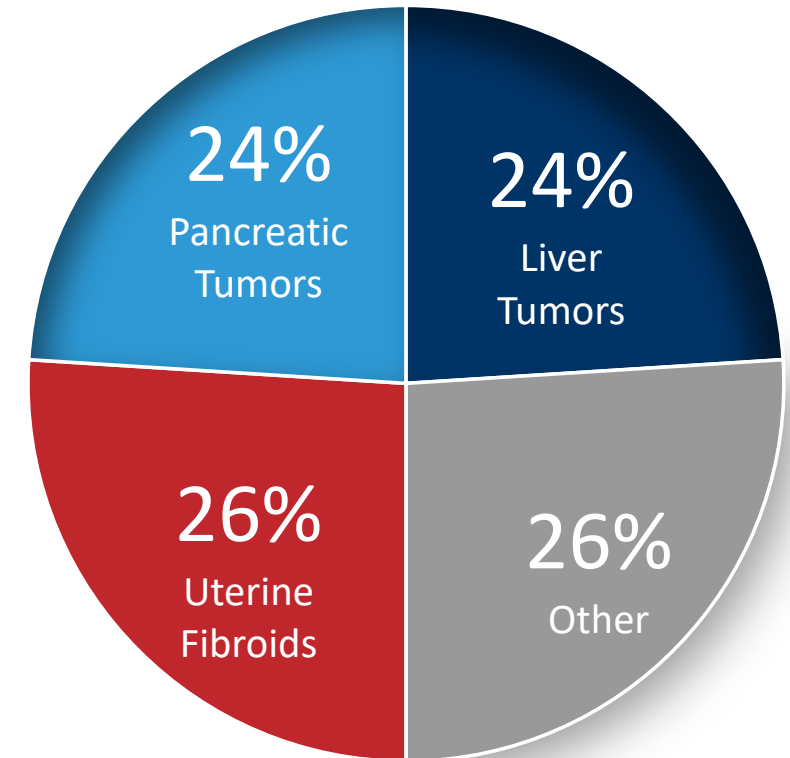
Cumulative WW Treatments as of End of 2022



## 98,048

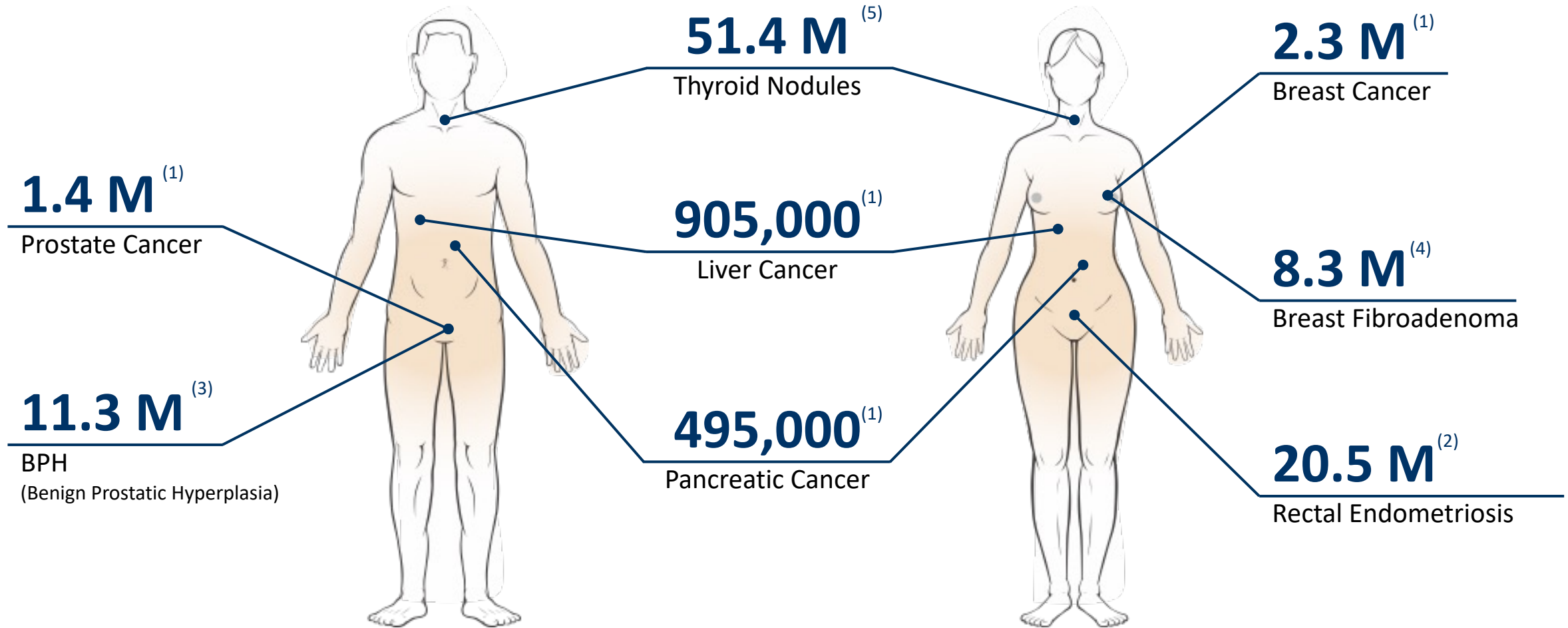
Treatments Performed WW in 2022

Clinical Conditions Treated by Focused Ultrasound in 2022



# The Breadth of Therapeutic Ultrasound

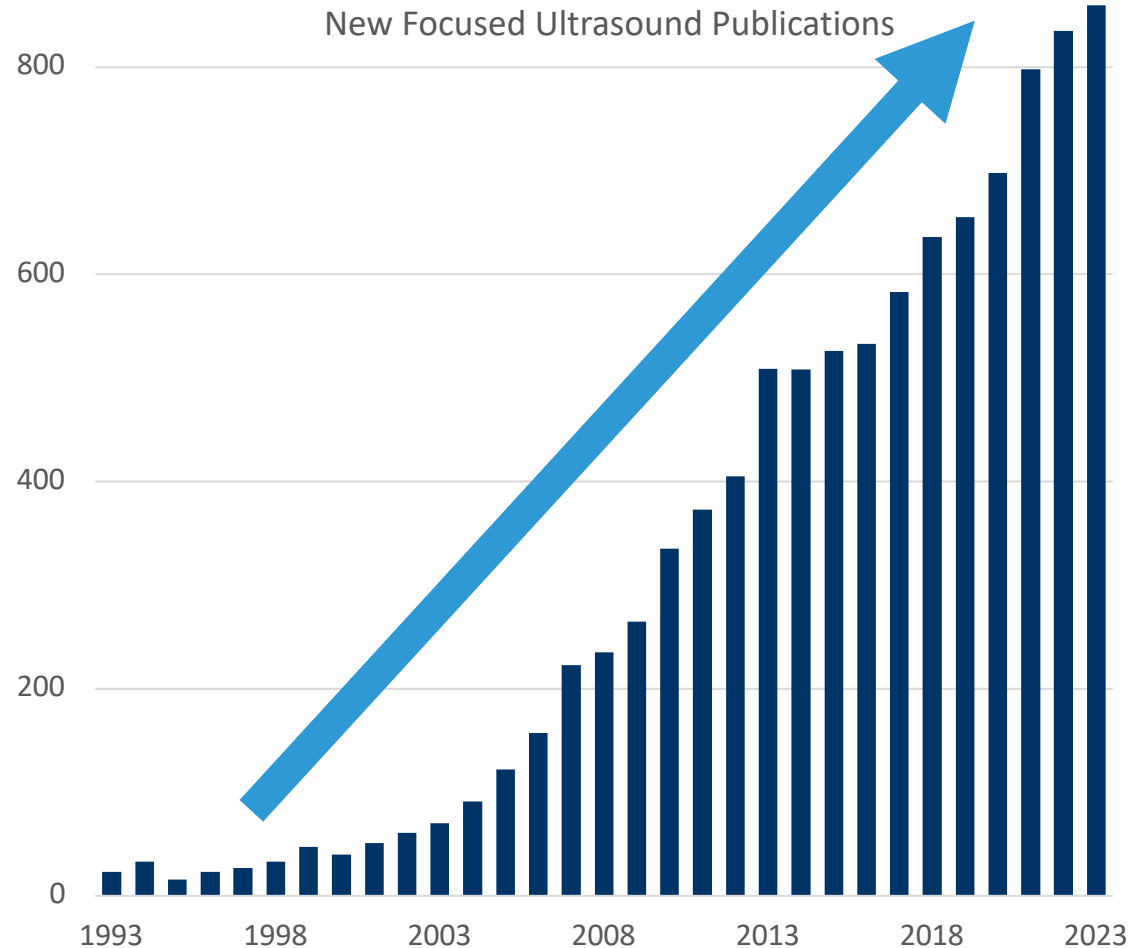
Targeting Large Incidence Cancer and Benign Conditions





# The Potential of Therapeutic Ultrasound

A Fast-Growing Field for Research and Clinical Applications



# 8,800

Publications on Focused Ultrasound as of End of 2023<sup>(1)</sup>

- **+201%** Publications in 10 years<sup>(2)</sup>
- Number of Focused Ultrasound **Publications Continue to Grow Rapidly**
- Therapeutic Ultrasound Represents a Fast-Growing Market with Numerous and Expanding Clinical Applications

# Large Global Prostate Cancer Market Opportunity

**1.4 Million**  
New Cases Per Year

Area	Number of New Cases
Europe	473,344
Asia	371,225
North America	239,574
Latin America	214,522
Oceania	22,421
<b>Total</b>	<b>1,414,259</b>

**288,300**

New Cases Diagnosed Every Year in the US <sup>(1)</sup>

**34,700**

Deaths every year in the US <sup>(1)</sup>

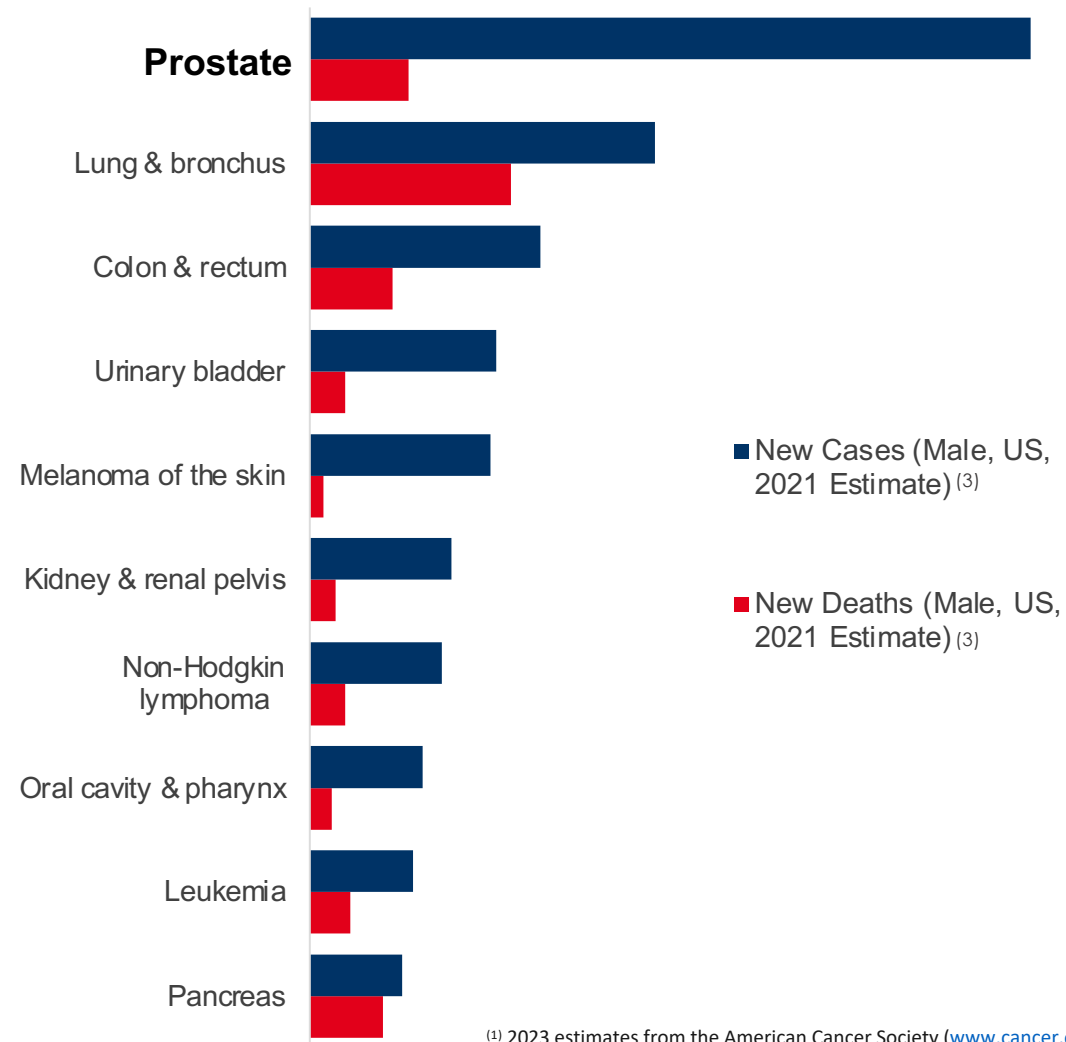
**1 Million**

Prostate Biopsies Performed Annually in the US and Increasing Every Year <sup>(2)</sup>

**3.1 Million**

American Men Living with Prostate Cancer <sup>(1)</sup>

## Prostate Cancer Is the Most Common Cancer Amongst Men in the US (2023)



<sup>(1)</sup> 2023 estimates from the American Cancer Society ([www.cancer.org](http://www.cancer.org))

<sup>(2)</sup> Bjurlin et al. Standards for prostate biopsy. Curr Opin Urol. 2014

<sup>(3)</sup> 2021 estimates from the American Cancer Society ([www.cancer.org](http://www.cancer.org))

# Expanding U.S. Addressable Market: 85,000+ Procedures / Year

## First-Line Treatment

### Primary Prostate Cancer Diagnosis Amenable to Focal Treatment:

- 288,300 new PCa cases every year<sup>(1)</sup>
- 80% are diagnosed at a localized stage
- 40% of the newly-diagnosed localized PCa are Intermediate-risk
- 50% of intermediate-risk PCa are favorable and amenable to Focal Therapy

**45,000 Procedures / Year**

## Active Surveillance

### Progression from Active Surveillance:

- 30% of the newly-diagnosed localized PCa elect Active Surveillance
- 50% of Active Surveillance patients get some form of treatment within 5 years
- 75% of Active Surveillance dropouts are Focal Therapy candidates

**30,000 Procedures / Year**

## Salvage Treatment

### Salvage Treatment for Failed Radiation:

- 30% of the newly-diagnosed localized PCa are treated with Radiation Therapy
- 30% of PCa treated with Radiation relapse and need a second-line Therapy
- We estimate 50% of radiotherapy failures to be eligible to Focal Therapy

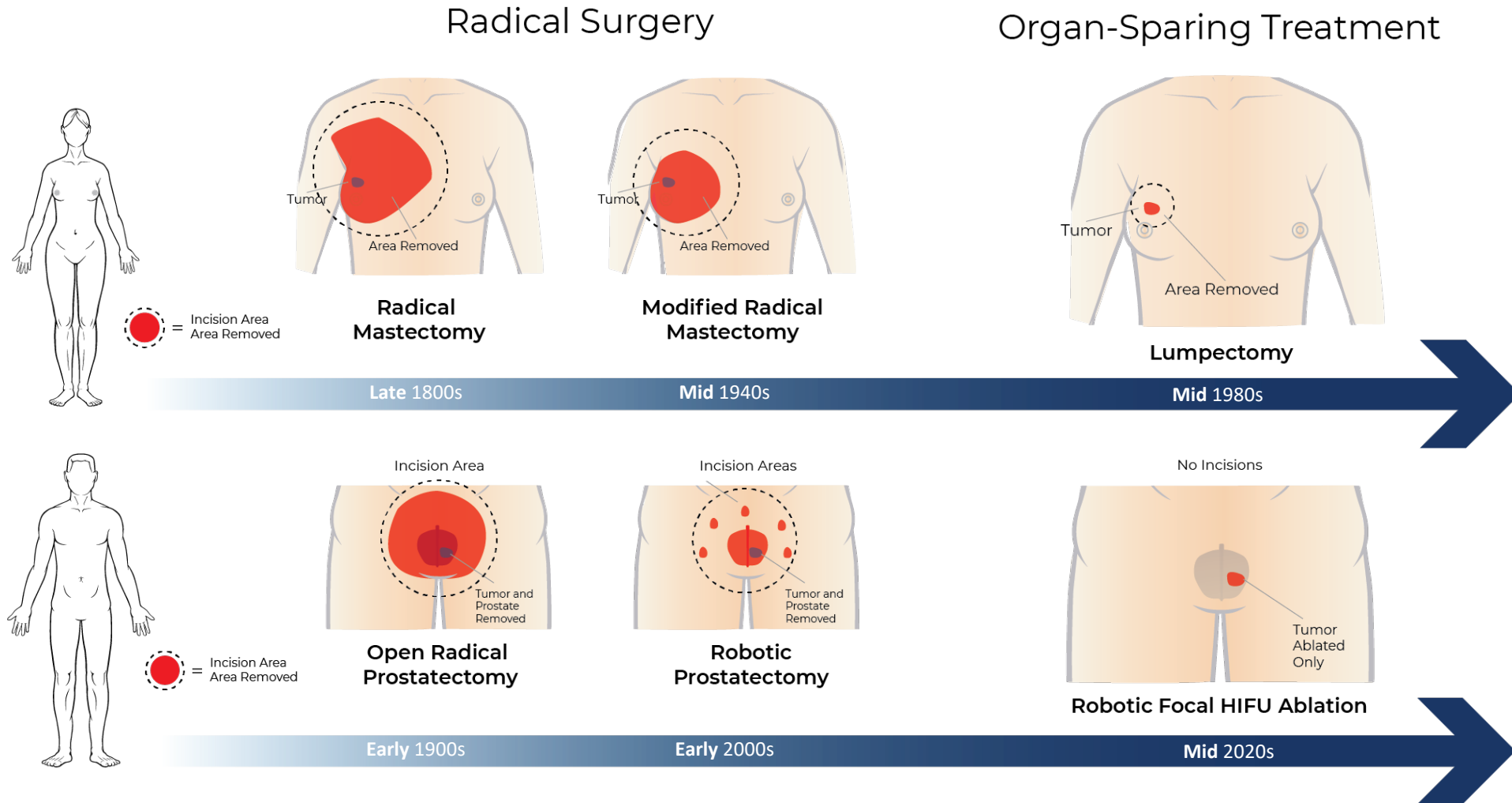
**10,000 Procedures / Year**

# EDAP Global Expanding Addressable Market



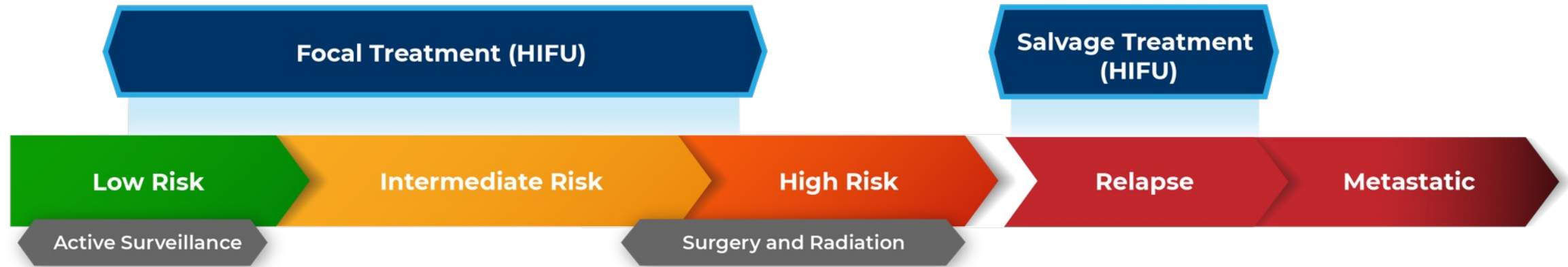
# Radical Surgery vs. Organ-Sparing Treatments

The Trend Toward Organ Preserving Cancer Treatments





# Why 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.

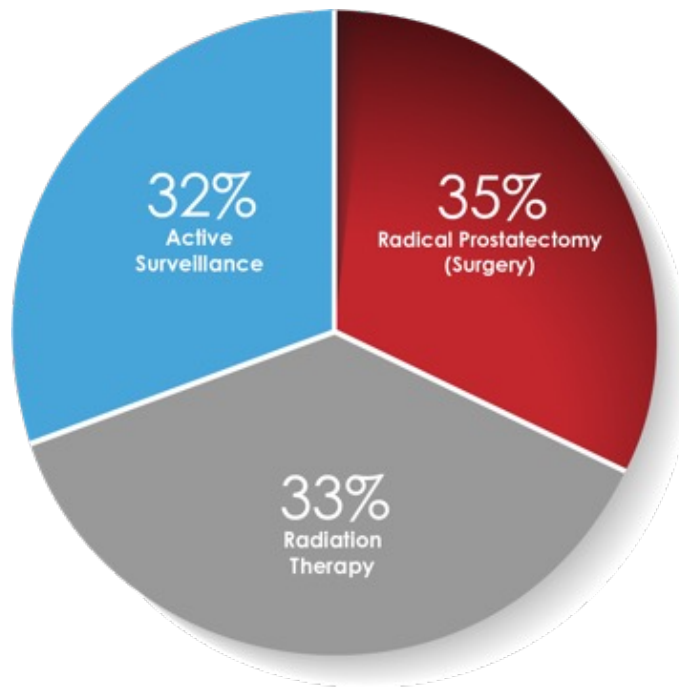
- HIFU provides a safe, effective and minimally invasive option for patients with low, intermediate-risk disease, as well as salvage treatment for failed radiotherapy

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

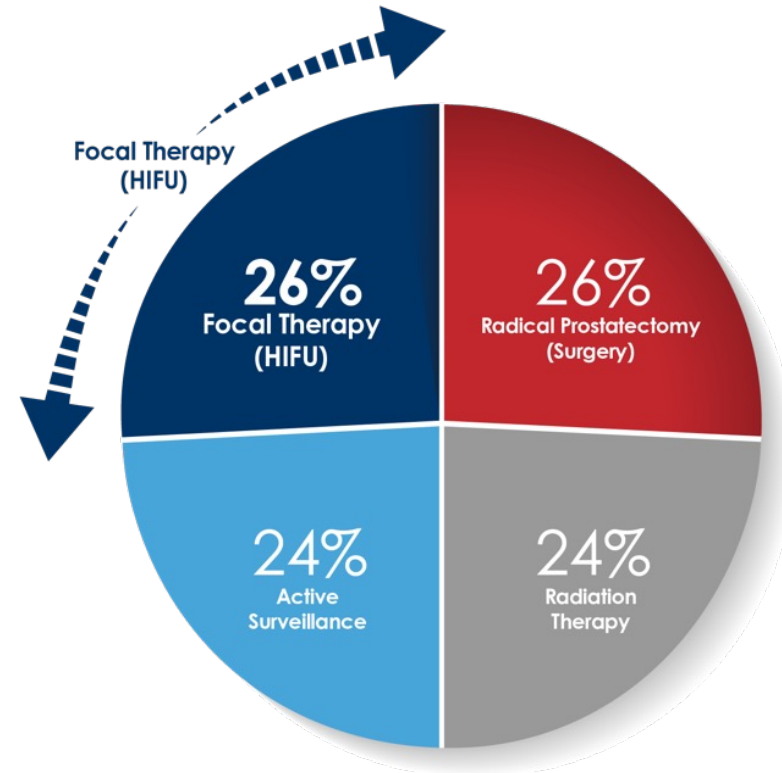
# Management of Prostate Cancer | Driving a Paradigm Shift

HIFU Treatment Market Taking Share from Radiation and Surgery

Previous Typical Treatment Patterns  
for Localized PCa<sup>(1)</sup>



Shifting of Potential Treatment Patterns  
for Localized PCa<sup>(2)</sup>

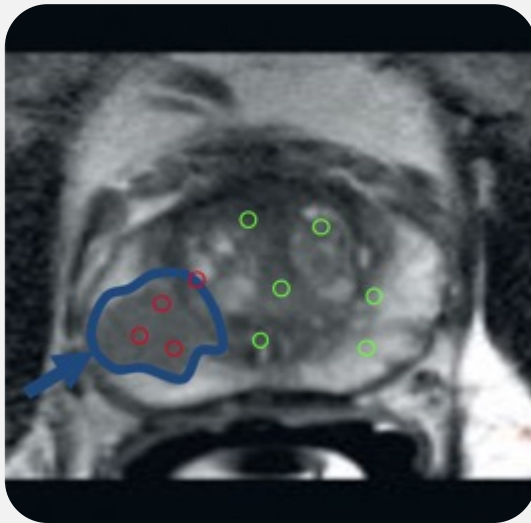


# Core Fundamentals of Focal One

Advanced Imaging & Robotic Ablation

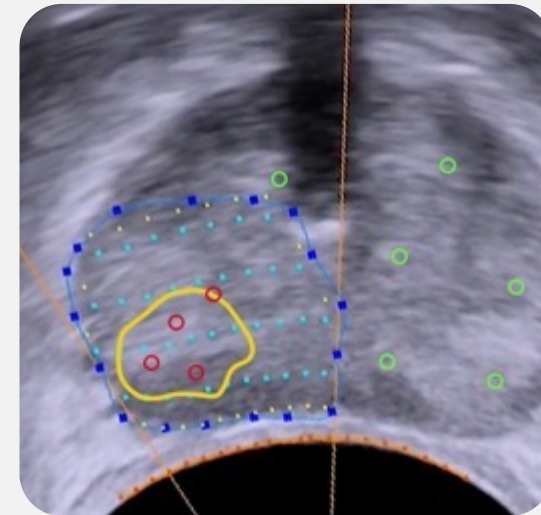
1

## Advanced Imaging



2

## Robotic Ablation



# Only Platform Specifically Designed for Focal Ablation of Prostate



# Focal One Video



# 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**



**49%**

**17 Out of 35**

**SUO Approved Programs**



**National  
Comprehensive  
Cancer  
Network®**

**39%**

**13 Out of 33**

**NCCN Member Institutions**



# Growing Momentum at Both Academic and Community Hospitals



# Strong Global Reimbursement Creates Favorable Environment for Growth

Increase in Medicare APC Payment Level in 2023 and 2024

1. **APC Level 6 Under CMS for CY23 and CY24** <sup>(1,3)</sup>
2. **90% Increase in Reimbursement in 2023** <sup>(1,2)</sup>
3. **APC Level 6 Maintained by CMS in 2024** <sup>(3)</sup>



# Hospital Outpatient Medicare Payment

## (2023 vs. 2022)

Procedure	Code	2022 Payment	2023 Payment	% change
Prostate Brachytherapy	55875	\$4,506 <sup>(1)</sup>	\$4,702 <sup>(2)</sup>	+4.3%
Cryo	55873	\$8,429 <sup>(1)</sup>	\$8,558 <sup>(2)</sup>	+1.5%
<b>HIFU</b>	<b>55880</b>	<div> <div>\$4,506<sup>(1)</sup></div> <div>➔</div> <div>\$8,558<sup>(2)</sup></div> </div>		<b>+90%</b>
Laparoscopic Prostatectomy (with or without Robotic Assistance and/or nerve sparing)	55866	\$9,096 <sup>(1)</sup>	\$9,087 <sup>(2)</sup>	-0.1%

# Favorable Physician Payment (2024)

Procedure	CPT	RVU (Total Facility)	Physician Payment (Medicare)
Prostate Brachytherapy	55875	23.31 <sup>(1)</sup>	\$763
Cryosurgical ablation of Prostate	55873	22.84 <sup>(1)</sup>	\$748
<b>HIFU</b>	<b>55880</b>	<b>29.21<sup>(1)</sup></b>	<b>\$956</b>
Laparoscopic Prostatectomy (with or without Robotic Assistance and/or nerve sparing)	55866	35.53 <sup>(1)</sup>	\$1,163

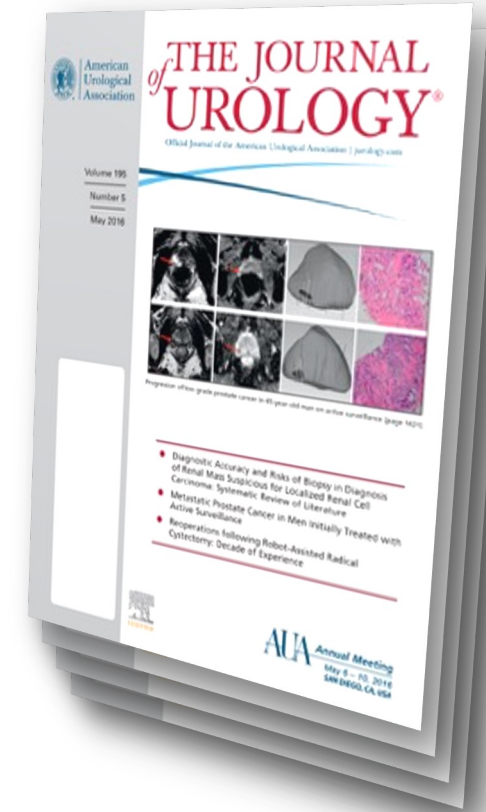
# Strong Clinical Evidence Supporting HIFU

## Reproducible Published Results for the Treatment of Prostate Cancer with HIFU

**1000+ Peer-Reviewed Publications Supporting HIFU**  
in the Treatment of Prostate Cancer <sup>(1)</sup>

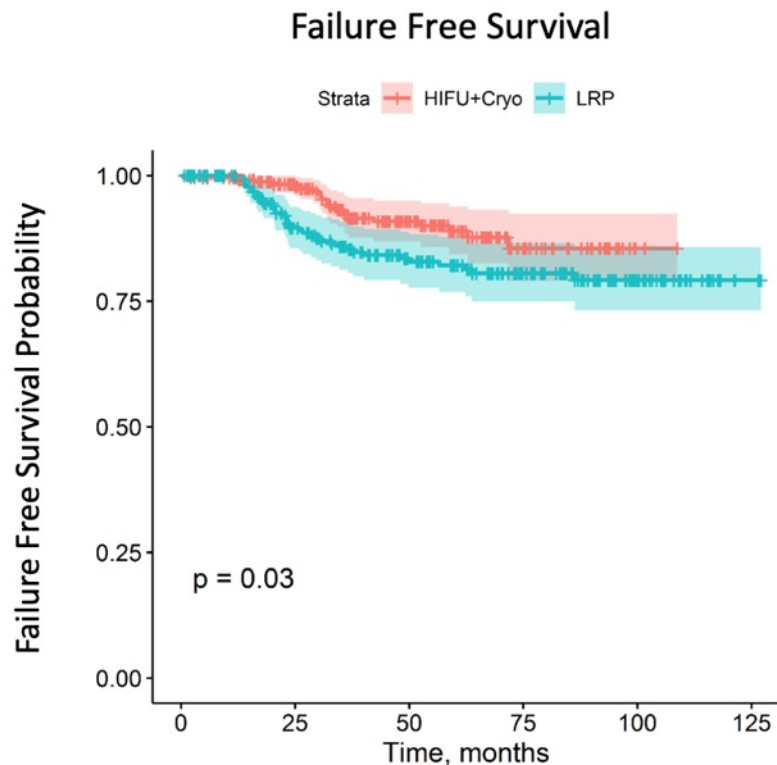
## Trifecta Criteria of Prostate Cancer Management

1. Cancer Control
2. Maintaining Urinary Control
3. Preservation of Sexual Function



# Strong Clinical Evidence Driving Adoption of Focal Therapy with HIFU

Clinical Evidence Supporting Focal One and HIFU as the Leading Technology in Focal Therapy

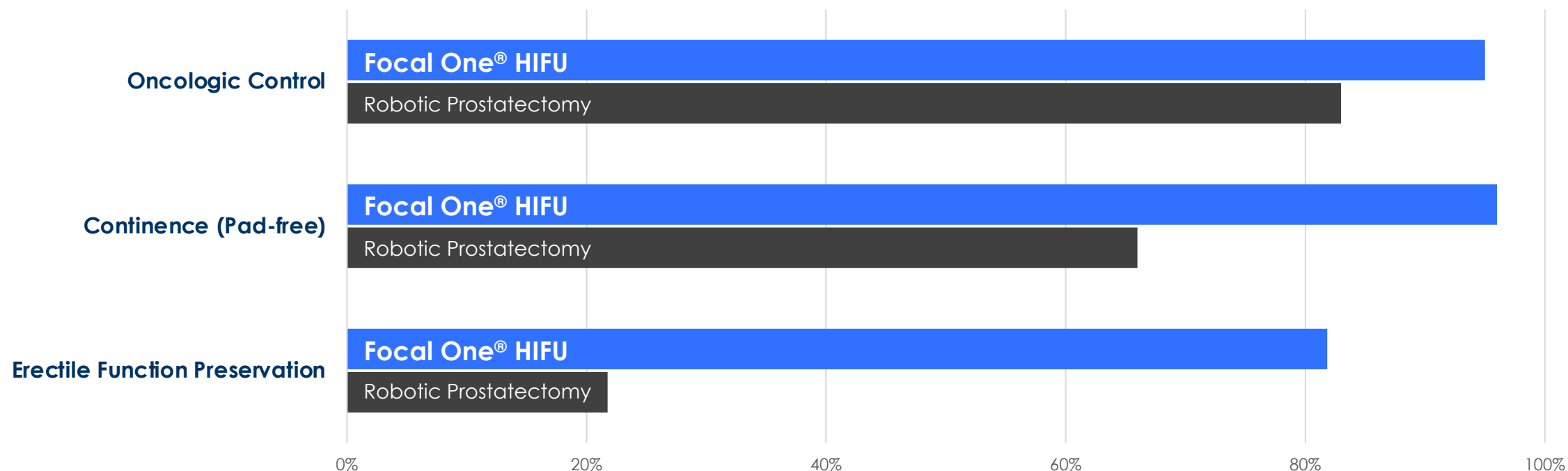


- **Systematic Review** including **4,209** patients from 20 studies treated with Focal HIFU<sup>(1)</sup>
  - ✓ **78% - 95%** absence of clinically significant cancer found on follow-up biopsy at 1 year
  - ✓ **98%** urinary continence (pad-free) at 6 months
  - ✓ **80%** preservation of potency without drugs at 6 months
- **Long-term follow-up** “*in patients with non-metastatic low-intermediate prostate cancer, oncological outcomes over 8 years were similar between focal therapy and prostatectomy*” <sup>(2)</sup>



# Level 1 Evidence Study

Focal Ablation versus Radical Prostatectomy for Intermediate-Risk Prostate Cancer  
Interim Analysis of a Randomized Controlled Trial



## CONCLUSION

One year post-treatment, HIFU Focal Ablation (Focal One®) achieved **good oncological efficacy** and **preserved erectile function and urinary continence better than Robotic Prostatectomy**.



## Endometriosis is a Large Market Opportunity

**6.5 Million**

US Women Have Endometriosis <sup>(1)</sup>

**1.3 Million (20%)**

Cases are Deep Infiltrating Endometriosis (DIE) in the US <sup>(2)</sup>

## Endometriosis

Leveraging Expertise  
in Robotic HIFU

- Affects **11%** of All American Women <sup>(1)</sup>
- **Most Prevalent** Among Women in their **30s and 40s** <sup>(1)</sup>
- Treatment can help **Manage Symptoms** and **Improve Pregnancy Chances.** <sup>(1)</sup>

<sup>(1)</sup> Office of Women's Health ([www.womenshealth.gov](http://www.womenshealth.gov))

<sup>(2)</sup> 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

# Endometriosis: Focal One Clinical Study Progress

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 Draft in Progress

## Phase III Study *Completed Enrollment*



- Multicenter Double-Blind Randomized Controlled Trial (RCT)
- Enrollment completed (60 patients) in less than 9 months
- Results expected second half of 2024

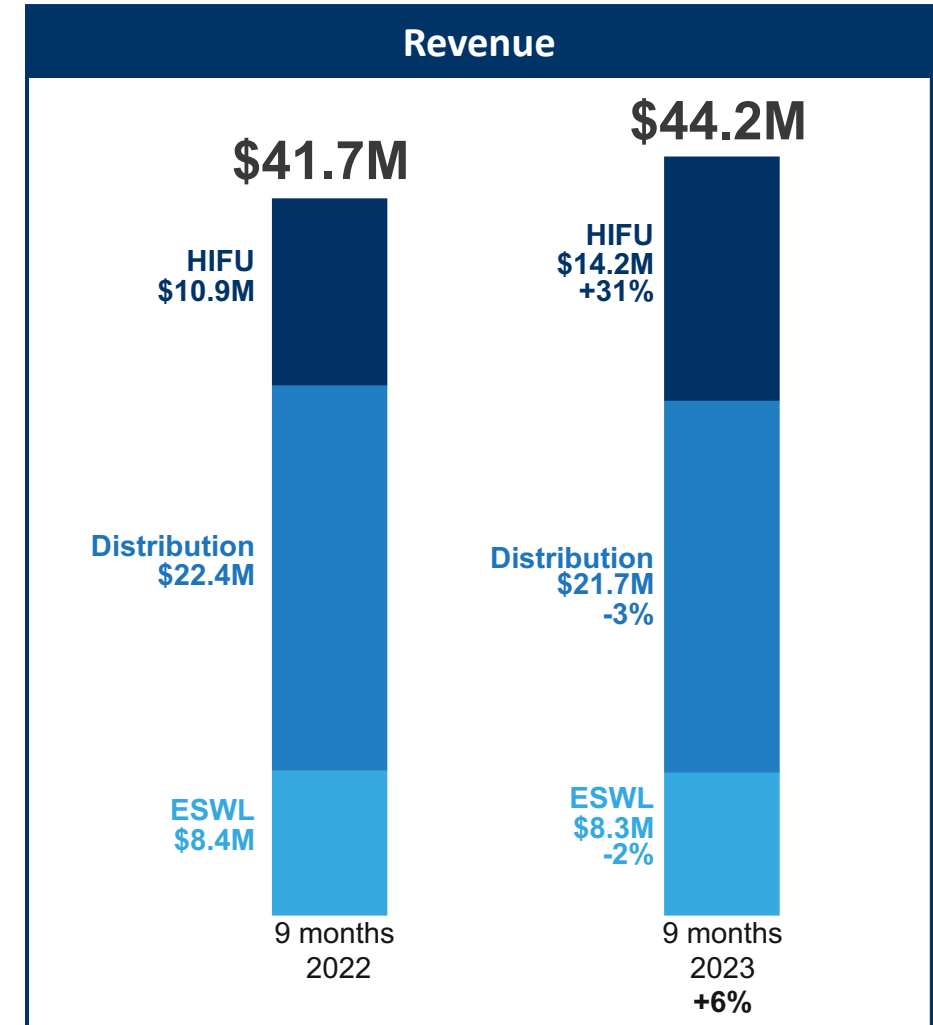
# Key Financial Data

(in \$Million USD except per share data)

	Nine Months Ended September 30th	
	2023	2022
Revenue	44.2	41.7
Gross Profit	17.2	18.0
Gross Margin	38.8%	43.1%
Operating Profit (Loss)	(17.7)	(2.8)
Net Income (Loss)	(17.5)	2.3
Earnings (Loss) Per Share	(0.47)	0.07

## 2023 Full Year - Preliminary Unaudited <sup>(1)</sup>

**\$65.4 Million USD Total Revenue (+9.6% YoY)**  
**+31.7% HIFU Revenue Growth YoY**



# Balance Sheet Highlight

Strong Cash Position of **\$50.5 Million** as of September 30, 2023

	Balance Sheet As Of:	
<i>(in \$Million USD)</i>	September 30, 2023	September 30, 2022
Cash and Cash Equivalents	50.5	66.8
Other Current Assets	34.5	25.1
Fixed and Other Non-Current Assets	13.7	10.5
	<b>98.7</b>	<b>102.5</b>
Current Liabilities	27.5	21.1
Non-Current Liabilities	7.6	8.8
Shareholders' Equity	63.6	72.6
	<b>98.7</b>	<b>102.5</b>

# Summary | Poised for Growth

- Large and Growing Addressable Market
- Differentiated Non-Invasive Robotic Technology
- Solves Unmet Need for Prostate Cancer Patients with Expansion Potential for Endometriosis and Beyond
- Strong Clinical Evidence
- Favorable Reimbursement in Place
- Strong Balance Sheet Enabling Growth and Investments
- Proven Management Team from Industry-Leading MedTech Companies

INTUITIVE

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# Thank You