



**PRO HITU**

**High Intensity Focused Ultrasound**

Non-Invasive Therapy

We lead the Future

**PRO**  **普罗**

PRO HITU Medical Co., Ltd

# CONTENT



# HISTORY



PRO HIFU(now  
“PRO HITU” is  
founded



First prototype  
**(Branded as PRO2008)**  
passed the type tests  
and began pre-clinical  
trial



PRO 2008 finished  
clinical trial with  
high efficacy and  
safety.



● PRO 2008 was approved by  
CFDA (Now NMPA) as the  
first benign gynecologic  
tumor treatment system.  
CE certificated in the same  
year.



National high-tech  
company



PRO300( Robotic  
treatment system) was  
approved by CFDA (Now  
NMPA) for benign  
gynecologic tumor  
treatment .



● PRO300 obtained CE  
certification  
● PRO300 began clinical trial  
for pancreatic cancer  
treatment .

# Team Leaders



## Chairman George Zhang

- Graduated from Shanghai Jiao Tong University, with a degree in Biomedical Engineering.
- Responsible for marketing work in large medical companies such as HP, Anke, Philips and GE, and has rich marketing practical experience.
- 2003 Founded Shenzhen Promedical Co., LTD
- Won the first prize and named "Top Ten inventors" in Shenzhen in the enterprise group of China Innovation and Entrepreneurship Competition
- Won the Best Clinical Medicine Transformation Award in the China Medical Industry Development and Innovation Competition

# Team Leaders



## Sun Fucheng :Chief Consultant

- Professor of Biomedical Engineering, Shanghai Jiao Tong University
- Member of Instrument Engineering Branch of Chinese Society of Ultrasonic Medical Engineering
- China' s ultrasonic practical technology research leader , A national well-known ultrasonic technology expert,
- As early as 1984, he presided over the development of China's first single-probe-focused ultrasound tumor hyperthermia equipment in Shanghai Jiaotong University
- Pro medical chief expert consultant

# Team Leaders



## Wang Rui : Senior Engineer

- Worked in Shenzhen Huada Technology Co., LTD., and Shenzhen Promedical Co., LTD
- Focusing on ultrasonic biology, ultrasonic transducer development and acoustic testing, she has developed transducers for the company's equipment. She has participated in the research and development of a number of products of the company, led development of the first ultrasonic directional air explosion treatment system in China which achieved good results in animal experiments.
- Obtained 3 authorized invention patents, and 4 utility model patents.

# Team Leaders

## Peng Lingling: Clinical Expert

- ❖ Degree in Clinical Medicine; Certified Doctor of Ablation of Benign and Malignant Tumors. Engaged in obstetrics and gynecology clinical professional for more than 20 years, and has worked in tertiary a-level hospital for nearly ten years.
- ❖ Senior Consultant of Obstetrics and Gynecology Application of Shenzhen Ultrasound Research Institute and the Manager of Clinical Training Department of Shenzhen Pro Medical Co. ,LTD
- ❖ Former Chief of Medical Department and Vice President at Chengdu Focused Ultrasound Hospital
- ❖ Teacher and Trainer of hospital clinical technology for ultrasound ablation therapy

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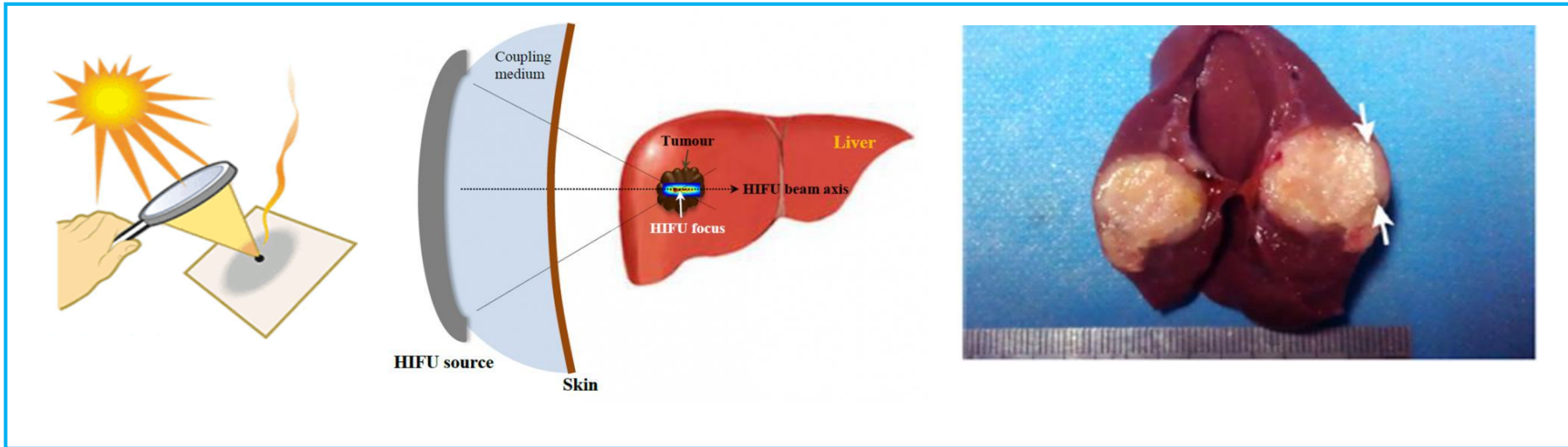
## Technical Principle

# Technical Principle

What is HIFU



# Technical Principle



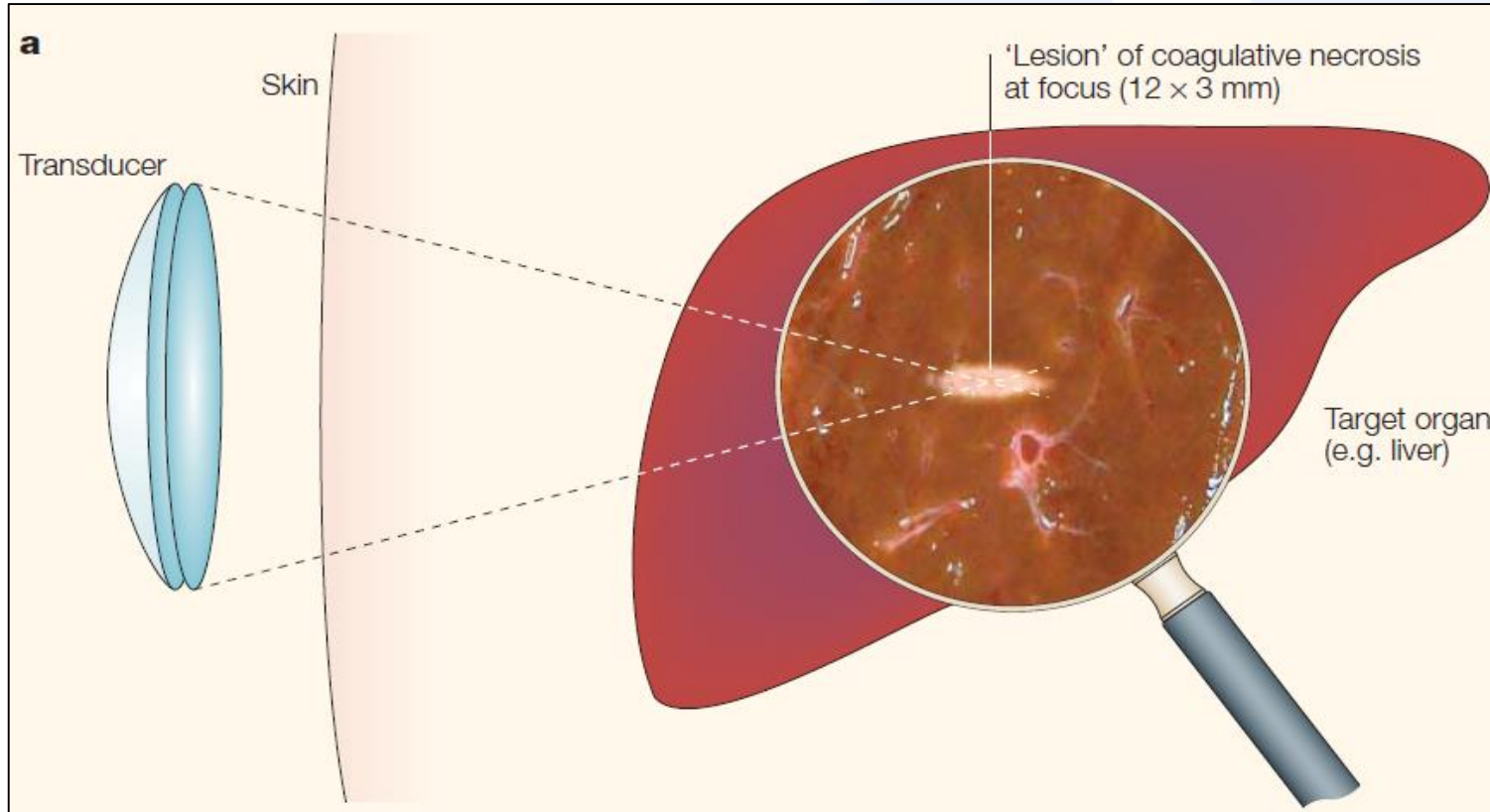
## Main feature

- **Nonradioactive**
- **Penetrability**
- **Focusable**

- The fundamental principle is analogous to using a magnifying glass to focus beams of sunlight on a single point to burn a hole in a paper.
- Using ultrasound as the therapeutic source, the physical characteristics of ultrasound, such as good tissue penetration and focusing ability, it can be focused deep in the body without incisions or radiation. When the ultrasound passes through the tissue, there is no effect. But, at the focal point, the focused ultrasound energy results in a high temperature above 65 °C in a very short time, and the tumor cells in the target area are instantly denatured.
- The ultrasound can be focused with extreme precision and accuracy, so the treatment only destroys the target without damage to the normal tissue. Thus, we can achieve **non-invasive** treatment.

# HIFU

## High Intensity Focused Ultrasound



- TISSUE PENETRATION
- FOCUS ABILITY
- THERMAL EFFECT



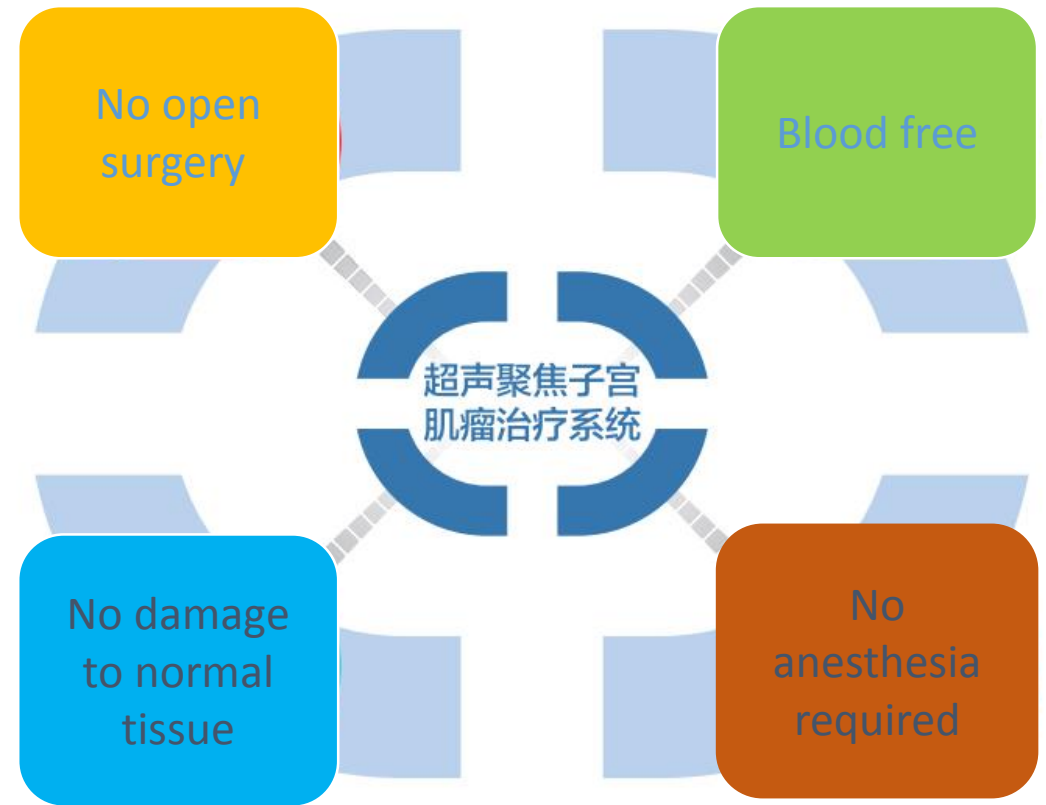
Adopted from JE. Kennedy, High-intensity focused ultrasound in the treatment of solid tumours, Nature Review Cancer, 2005 (18) : 321-327

# HIFU Advantage

## The treatment is safe and reliable

- The traditional treatments for tumors, surgery, chemotherapy, and etc, are invasive and the risk of side effects are high. In the United States 600,000 uterine fibroids are removed by surgery per year. In China, this number is no less than 1.5 million.
- Hifu provides the patient with a new option: to treat these diseases with the following drawbacks addressed: Normal tissue damage, bleeding, and use of anesthesia.

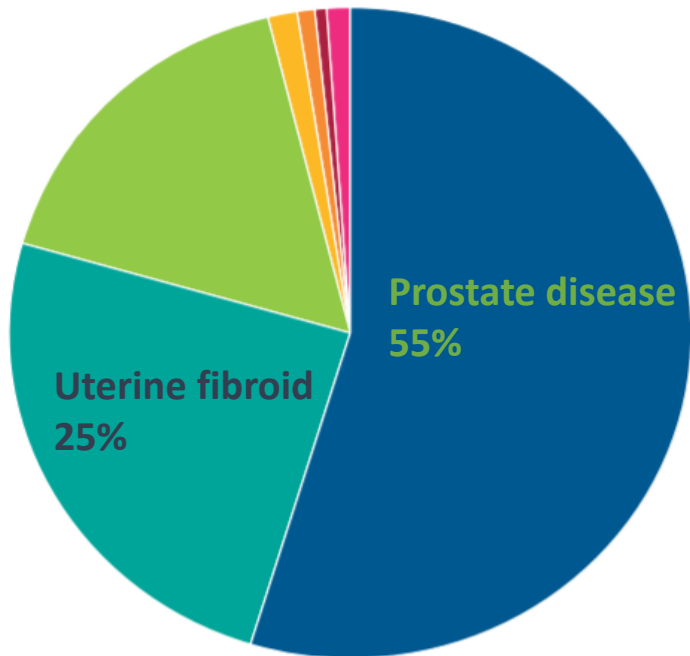
Our device uses focused US therapy and has the following advantages:



# Uterine fibroids became the main treatment indication

## Treatments by Indication

Up to 2014



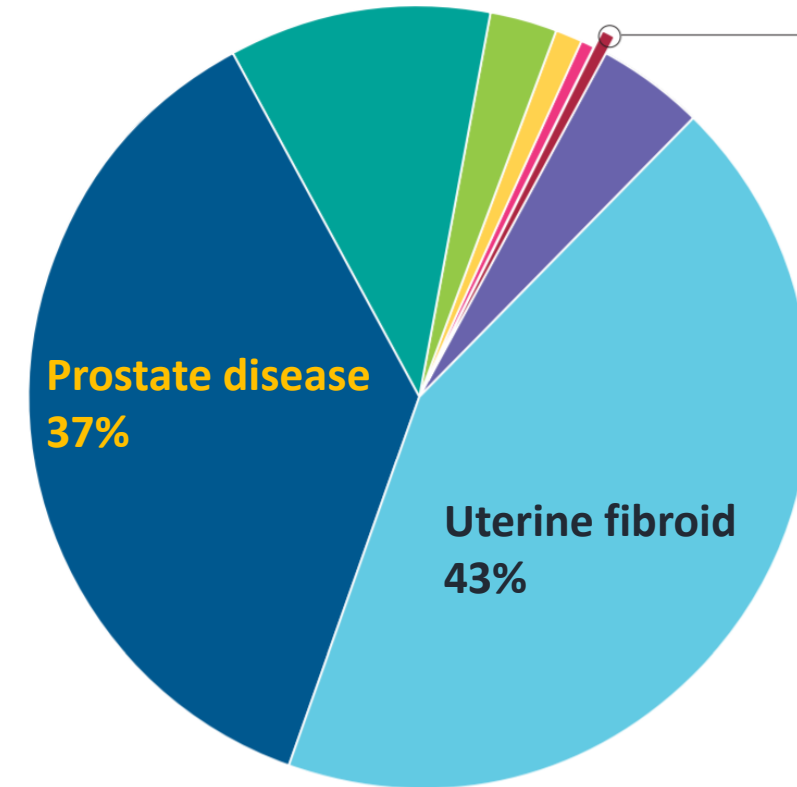
89,544 Treatments

Prostate cancer	49,010	55%
Uterine fibroids	22,144	25%
Liver cancer	15,000	17%
Bone metastases	1,256	1%
BPH	725	>1%
Breast cancer	520	>1%
Others*	889	>1%

- Uterine fibroids ranked 1st in number of cases among all focused ultrasound treatments, accounting for **43%** (2017)
- Of all treatment by Focused ultrasound, Uterine fibroids is the fastest growing indication: (**25% to 43%** from 2014 to 2017)
- 3-year increase in the number of uterine fibroids treated by focused ultrasound increased by: **227%** (72,488 cases in 2017)

Up to 2017

All Indications



167,993 Total Treatments

Uterine fibroids	72,488	43%	Bone metastases	1,602	>1%
Prostate diseases	61,749	37%	Breast cancer	1,269	>1%
Liver cancer	18,000	11%	Brain	868	>1%
Glaucoma	4,900	3%	Others*	7,117	4%

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## Product Introduction

# Current status of HIFU industry in China



- supine position treatment
- Integrated self-focusing transducer
- Treatment head: 360 rotation.
- Indications: Uterine fibroids
- 2021.8.23-2026.8.22
- 2018.9.18-2023.9.17

PRO2008 HIFU treatment system



- Supine Position
- 6 Primitive self-focusing transducer
- Treatment head: Angle flip
- Indications: Specific for uterine fibroids
- 2015.7.9-2020.7.8

HY2900 Focused Ultrasound tumor system



- Supine position
- Multicomponent double focusing transducer
- Treatment head: Angle swing
- Indications: Tumors of bone and soft tissue of extremities, trunk, breast, and liver
- 2015.11.2-2020.11.1

HIFUNIT9000 high intensity focused ultrasound tumor treatment system



- prone position treatment
- Piezoelectric ceramic+ lens, secondary focus
- Treatment head: Angle rotation
- Indications: Uterine fibroids and soft tissue tumors
- 2019.3.20-2024.3.19



JC200 focused Ultrasound tumor treatment system



- Prone Position
- Multicomponent double focusing transducer
- Treatment head :Angle flip
- Indications: Tumors of bone and soft tissue of extremities, trunk, breast, and liver
- 2021.4.13-2026.4.12

HIFU2001 high intensity focused ultrasound tumor treatment system



- Both prone and supine position
- Multicomponent flat panel transducer, secondary focusing
- Treatment head: Angle flip
- Indications: Specific for uterine fibroids
- 2020.1.14-2025.1.13

FEP-BY02 focused ultrasound tumor treatment system

## Shenzhen VS Chongqing

Chongqing HaiFu	1.Poor comfort	①Lower position (prone position), abdomen immersed in water ② Enema is required, with strict fasting and no drinking. ③Need for anesthesia.
	2.High cost	①Device occupies lots of space② Limited mobility of treatment head limits ultrasound pathway options.
	3.Difficult to operate	The operation is complex, doctors require extensive training and experience.
	4.High risk	①Prone type, easy to cause intestinal injury, medical accidents are common ②The design of the transducer adopts acoustic lens focusing, which has energy loss, large focal area and imprecise accuracy resulting in damage to surrounding normal tissue. ③For Chongqing, a single treatment head is not specialized in treating uterine fibroids. This often leads to side effects or complications such as nerve damage and surrounding tissue damage as surrounding tissues are not taken into consideration in it's design.

# Shenzhen VS Chongqing

PRO HIFU	1.Experience comfort <b>C</b>	① supine position ②No enema required , No anesthesia ③Dry treatment.
	2.Economical and practical <b>E</b>	①Compact device ②Multi-angle treatment, resulting in a wider range of treatable cases.
	3.Easy to operate <b>E</b>	①Artificial intelligence with intelligent software operating systems is easy to learn. ②The positioning ultrasound image is the upper type, the same position as the normal abdominal B-ultrasound detection, thus easy for doctors to read.
	4.Treatment safety <b>S</b>	①With the upper position, the intestine is out of the way and creates an ultrasound pathway.② 3D, 360-degree rotation, preferred sound channel ③self-focusing, one focus, energy concentration, to achieve accurate focusing treatment ④Professional gynecological machine: The design fully considers the physiological structure of the human body, especially the sensitive tissues around the lesion, such as sacral nerve, rectum and other parts of the safety protection measures are relatively perfect.

**First-generation product**

**PRO2008 High intensity therapeutic  
ultrasound treatment device**

The first HIFU device specialized for uterine fibroids

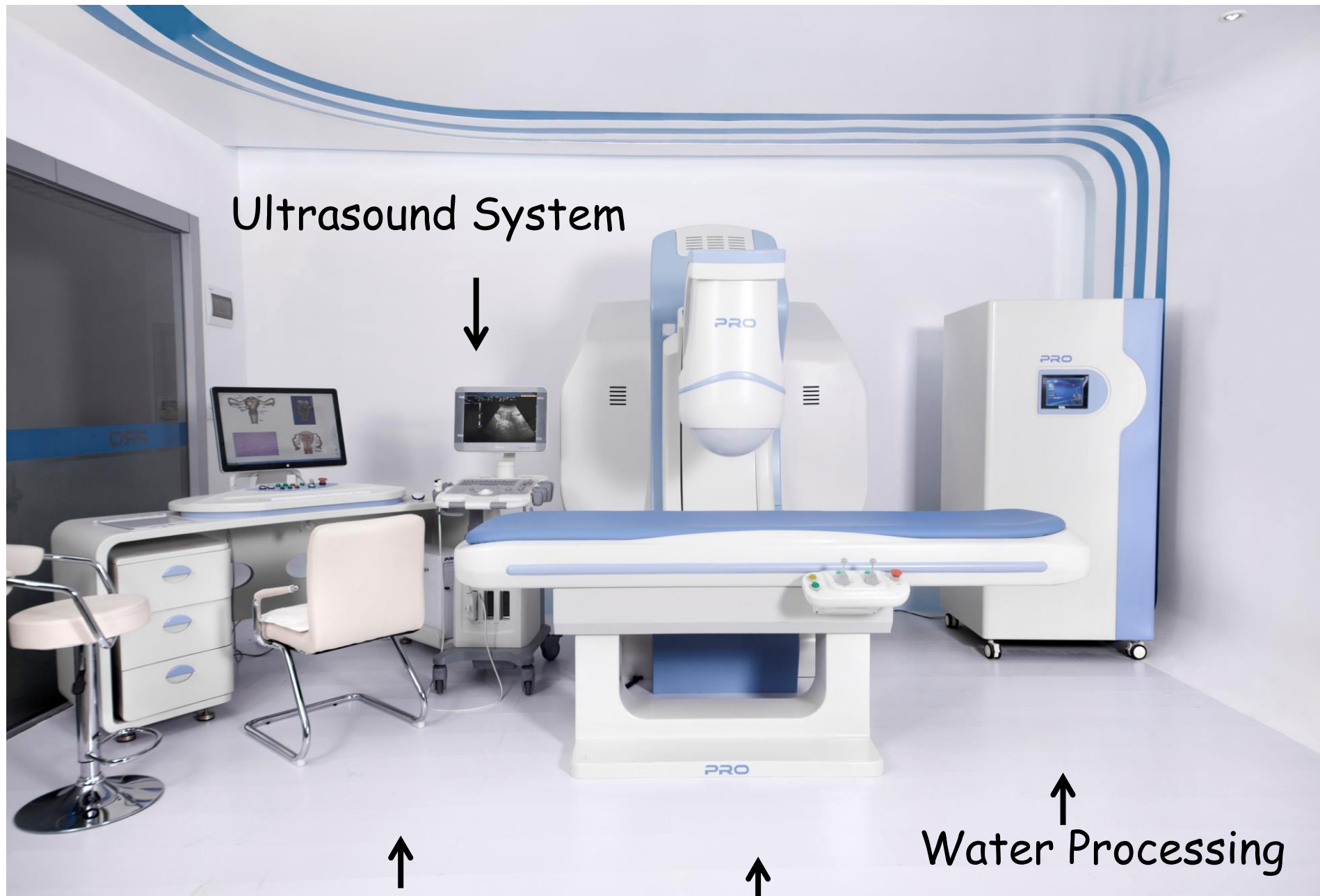
# PRO HIFU For Uterine Fibroids



**PRO2008 HIFU treatment system**



**PRO300 robotic HIFU treatment system**



Ultrasound System



Water Processing

PRO+ 普罗医学 Operation WS

Main HIFU system 无创治疗的引领者·让治疗更有尊严

# New Product

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After continuous improvement and innovation,  
In 2018, our second generation HIFU treatment  
product obtained NMPA certification.

# Second-generation product

## PRO300 High intensity therapeutic ultrasound treatment device

The first HIFU device to use a robot arm

# Clinical indications and advantages

Gynecology - Obtained CFDA Class III registration certificate in September 2018, obtained CE certification in May 2021

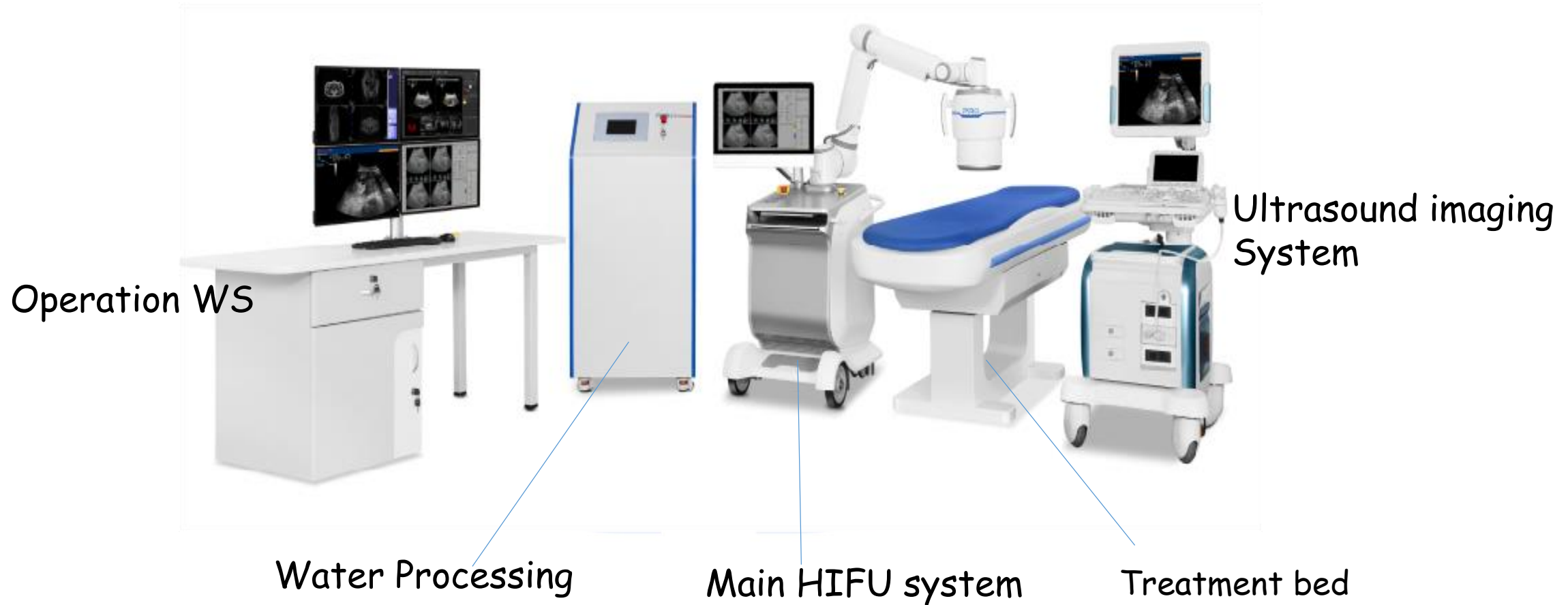


## Clinical indication

- It is used for the treatment of **Uterine fibroids, Adenomyosis, Cesarean scar pregnancy, Placenta accreta**

无创治疗的引领者·让治疗更有尊严

# Treatment scene



# PRO 300 ROBOTIC HIFU system



## Accurate and safe

- 6 axis robotic-arm positioning system with high accuracy
- Touch automatic alarm, improve surgical safety



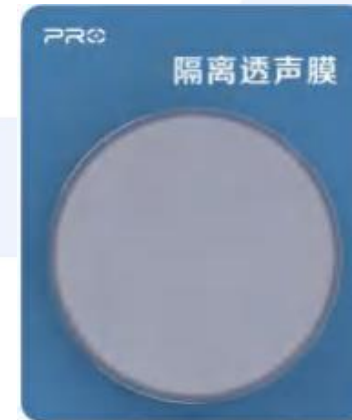
## Intelligent drainage system

- Intelligent automatic loading/draining
- Semiconductor temperature control system



## Compact design and moveable

- Smaller than its predecessor
- Easily transportable with wheels



## Safe and effective

- sound transmitting film, sound transmitting effect is good
- One person a membrane, prevent contact cross infection prevention

# PRO 300 ROBOTIC HIFU system

- **Supine position + treatment head/deaerated water results in a sound channel with the intestine out of the way and preoperative enema is not required**
- **Food can be injected right after surgery.**
- **Less stressful to the patient in comparison to surgery.**



# Cloud and big data system PRO 300



## Traceable System

- After-sale equipment operating status and malfunction alerts  
Remote initial malfunction diagnosis.

Provides treatment plans by analyzing big data in the cloud.



## Real-time Monitoring System

- With the current feedback module that collects the operating status of the device, the system automatically notifies the person in charge when the output of device is abnormal. Users can check in real time whether each device is in normal use from the terminal. Support is available and accessible online or in person.

# Cloud big data system PRO 300



## Intelligent Expert System

- The system provides the most superior and simplified treatment plan, at an expert level aiding less experienced doctors in complex treatments. The treatment plan is chosen using previous successful treatment data.

# AI robot arm PRO 300



- The robot arm is precise to 0.1mm, and the high flexibility perfectly meets precision needs and angles of attack of up to 15 degrees in the treatment process
- Touch automatic alarm function, greatly improves the safety of the treatment.

# Present Status of international FUS

The NEW ENGLAND JOURNAL of MEDICINE

## CLINICAL PRACTICE

Caren G. Solomon, M.D., M.P.H., *Editor*

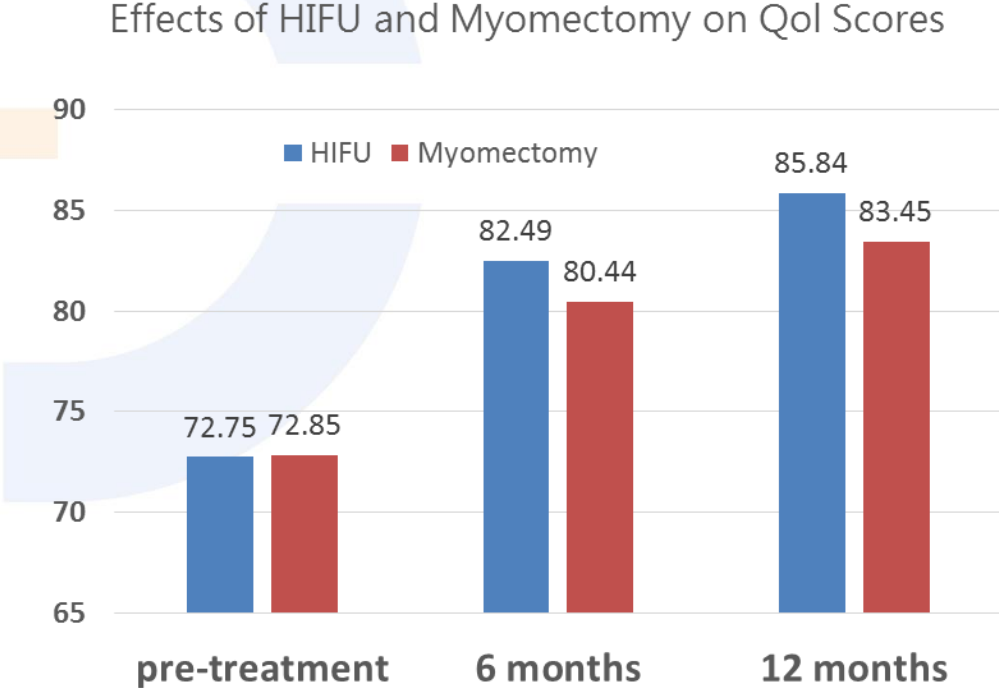
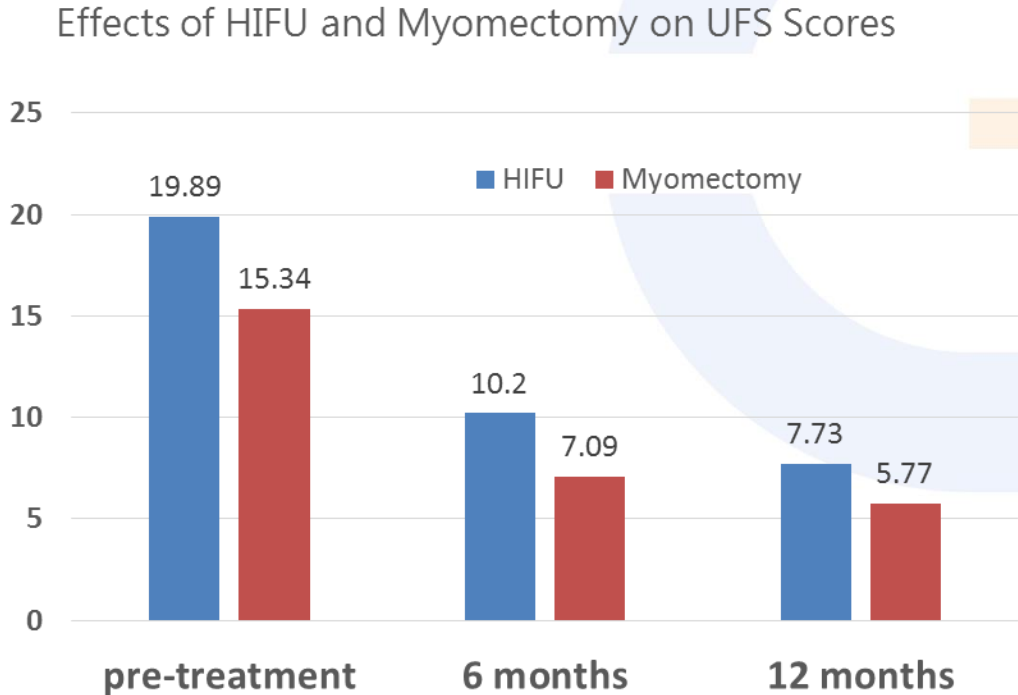
## Uterine Fibroids

Elizabeth A. Stewart, M.D.

A Clinical Practice Review, published in the April 23th 2015 issue of the [New England Journal of Medicine](#) by Mayo Clinic Ob/Gyn Elizabeth Stewart, MD, recommends **focused ultrasound** as an important **uterine-conserving treatment** that should be an option for **women with symptomatic uterine fibroids**.

# Clinical Recognition

A 20-Centre non-randomized controlled study of treatments for uterine fibroids  
Both groups saw improvements in mean UFS scores from pre-treatment to 6 and 12 months post-treatment.  
The QoL scores for both groups improved. Notice that HIFU patients see slightly greater QoL scores after 6 and 12 months



# Case Report

## Subject Info

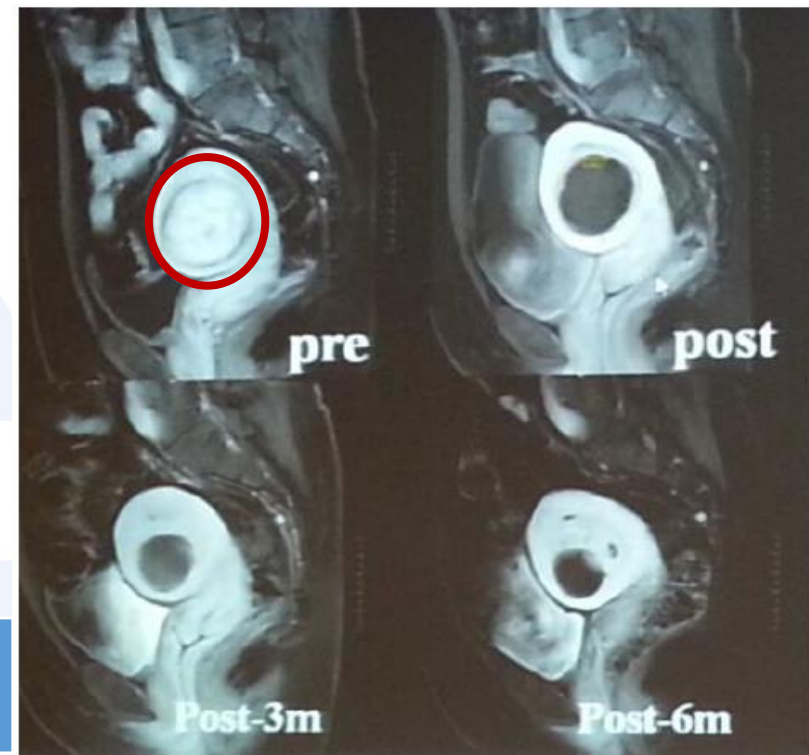
• 45 year-old female with dysmenorrhea shows an approximately 5-cm well-defined myoma in the anterior wall of the uterus.

## Treatment

PRO - Ultrasound-guided FUS system

## Date

	$V_{UF}(cm^3)$	Symptom	Non-perfused Rate
Pre-procedure	73.56	Dysmenorrhea, frequent urination, urinary urgency	
3 month	38.04	symptomatic relief	<b>95%</b>
6 months	26.96	Normal during period	



# PRO Taiwan Teaching Center



**Jeng, Cherng-Jye (鄭丞傑)**

**(also known as Jeng, C. Jay)**

President, Taiwan Association Gynecologic  
Tumor Ablation

1. Fellow, International College of Surgeons  
國際外科學院院士
2. Fellow, American College of Sexologists  
美國性學學院院士
3. Vice President, International Society for  
Minimally-invasive and Noninvasive  
Medicine (ISMINIM) 國際微無創醫學學  
會全球副主席
4. President, International College of  
Surgeons, Taiwan Section.  
國際外科學會中華民國總會理事長

# User Experience (domestic)



Gui Zhou Provincial Hospital of Traditional Chinese Medicine

PRO2008 installation since **Feb 2016**

**675** Clinical reports on HIFU treatment Until May 2017

**40** +HIFU UF patients per month

**US\$1,200** Local treatment fee for HIFU

**US\$860,000** Direct return, **US\$100,000** Indirect return

Successful use of our device enhances the hospital's local reputation,  
a win-win for the hospital, physician, and patients



无创治疗的引领者·让治疗更有尊严

# End User Experience (International)



Gangnam St. Peter hospital

A Private hospital in Korea known for large myoma ablation.

Great experiences with HIFU

**2300+** Clinical reports on HIFU treatment

**80+** HIFU UF patients per month

**US\$3,000** national healthcare insurance per HIFU procedure

**\$240,000+** realized revenues per month



无创治疗的引领者·让治疗更有尊严

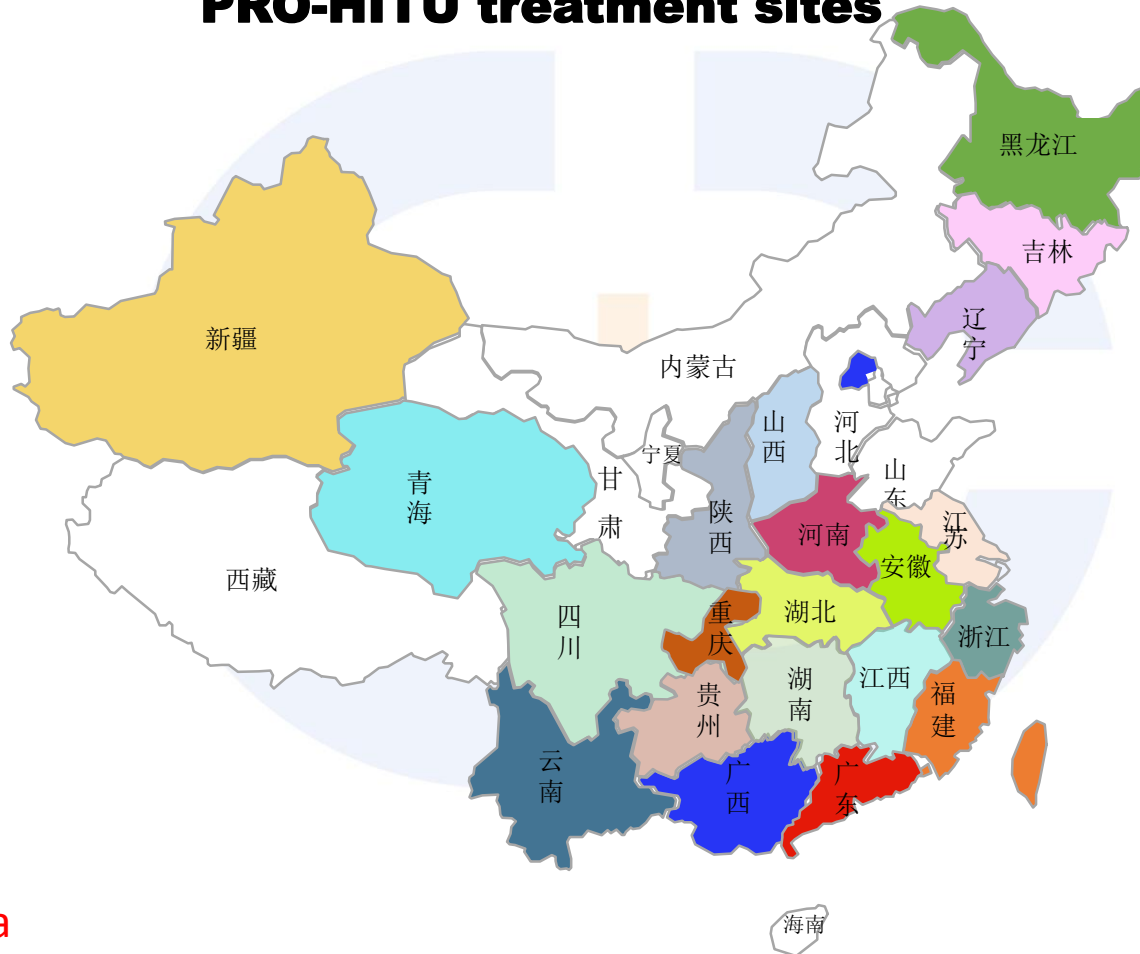
# Treatment Sites

**Current PRO installations:**

**China : > 150 sites**

**Outside China : > 20 sites**

## PRO-HITU treatment sites



**Taiwan (7) from 2019**

Tainan Guo General H (2019)

China University H (2020)

Show Chun H (2020)

E-DA DACHANG H (2021)

Kaohsiung Veterans H (2021)

TUNGS' Taichung MetroHarbor H (2021)

Taiwan Adventist H (2022)

**Korea (15) from 2016**

Jamsil Joen Woman's Hospital

Gangnam St.peters hospital

Uijeongbu peters hospital

Kwons womens clinic

Daegu Hyosung Hospital

THE jouen hospital

kimhae jungang hospital

**Total 40 HIFU systems in Korea**

**Total 16 HIFU systems in Taiwan**

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## Development Direction

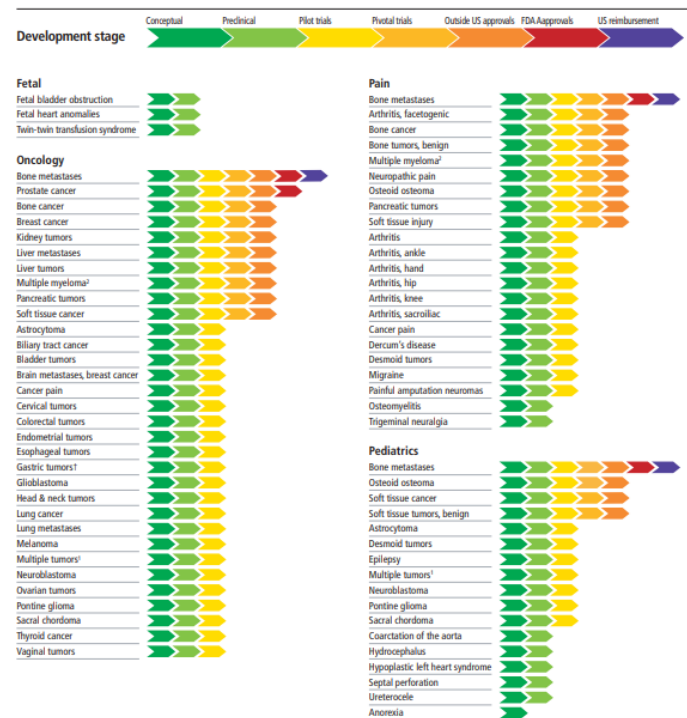
# HIFU Research Field



Ultrasonic focusing, as a technology platform, is widely used for at least 136+ indications



State of Research and Regulatory Approvals by Area of Interest



<sup>1</sup> Protocols inclusive of more than one indication  
<sup>2</sup> Multiple myeloma approval is based on bone metastases.  
<sup>3</sup> New in 2019

2020 FUS field report: 136+ clinical indications worldwide, with at least 9 new indications annually and 2 new indications approved

# Clinical application of HIFU technology

## Gynecological

- Uterine myoma
- Scar pregnancy
- Adenomyosis of uterus
- Ectopic pregnancy
- .....



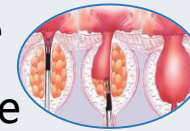
## Malignant tumor

- Liver cancer
- Breast cancer
- Bone tumor
- Soft tissue tumor
- Renal tumor
- Pancreatic cancer
- .....



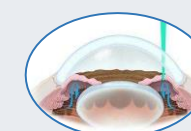
## Urinary system

- Hyperplasia of prostate
- Enlargement of prostate
- Chronic prostatitis
- Chyluria
- .....



## Other fields

- HIFU Skin Beauty
- HIFU fat ablation
- HIFU for glaucoma
- .....



PRO+ 普罗医学

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