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**GLOBAL HEALTHCARE & BIOMEDICAL INTELLIGENCE**

**MLJC EXCLUSIVE | CHINA MEDICAL TECHNOLOGY WATCH**

**When the “Surgical Knife” Never Enters the Body**

**HIFU and the Evolution of Non-Invasive Tumour Ablation**

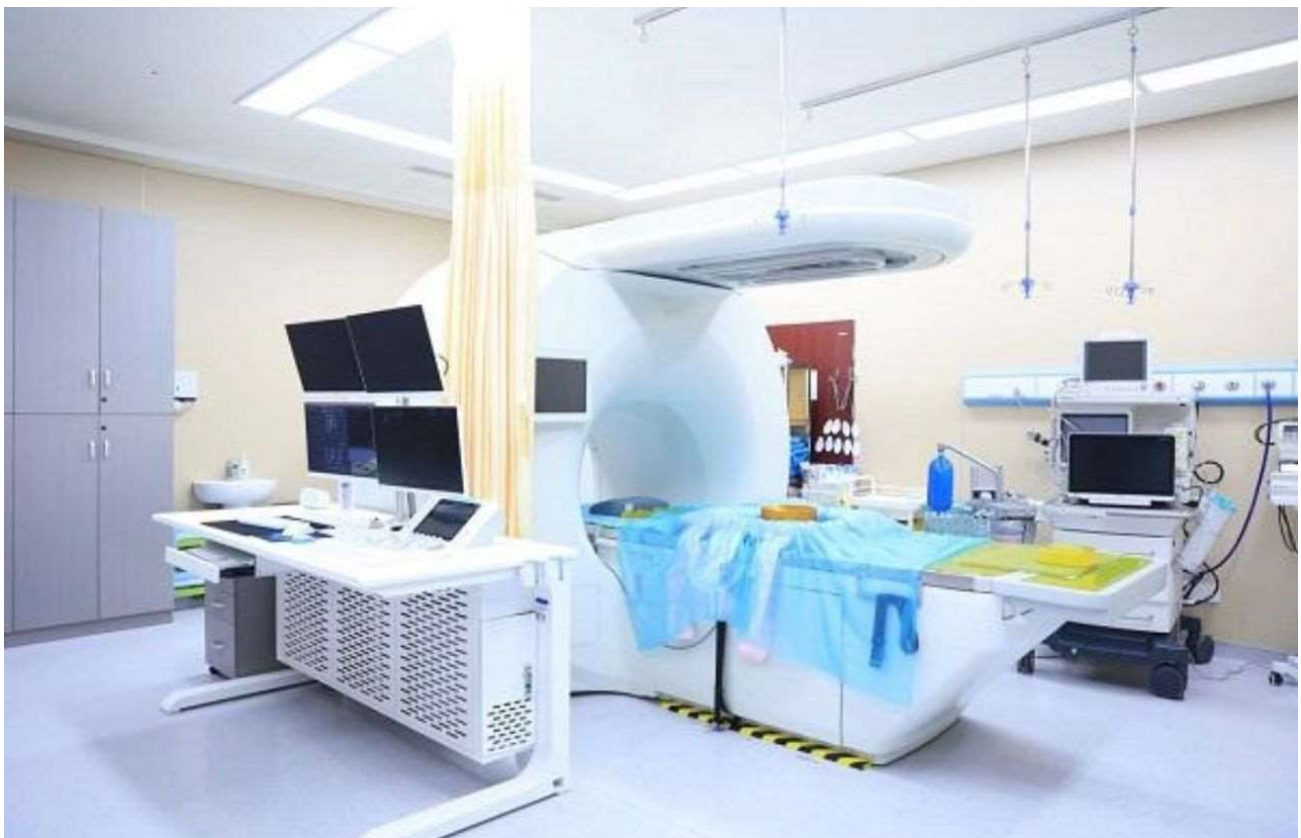
**High-Intensity Focused Ultrasound (HIFU) | Oncology | Medical Devices |**

**Precision Therapy | Biomedical Engineering | Translational Medicine**

**It is called a “knife”.**

**But there is no blade.**

**The tumour is treated not by cutting into the body, but by precisely delivering focused acoustic energy from outside the body.**



## HIFU and the Evolution of Non-Invasive Tumour Ablation

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### I. MLJC Executive Perspective

There are moments in medical history when innovation does more than improve an existing procedure.

It changes the underlying question:

**Does treating a tumour always require physically entering the body?**

Traditional surgery follows a familiar pathway:

**Incision → Exposure → Resection → Closure**

High-Intensity Focused Ultrasound, or **HIFU**, represents a fundamentally different approach:

**Imaging → Targeting → Focusing → Energy Delivery → Tissue Ablation**

The technology does not use a conventional surgical blade.

Instead, ultrasound energy generated outside the body is concentrated at a defined target within the body. At the focal region, the acoustic energy can produce thermal and mechanical effects capable of destroying targeted tissue.

This is the principle behind what is commonly known in China as “**Haifu Dao**” (**HIFU Knife**).

The name can be misleading.

It is not a knife.

It is an **image-guided focused-ultrasound energy platform**.



## HIFU and the Evolution of Non-Invasive Tumour Ablation

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According to Chongqing Haifu Technology's published history, its research team developed key technologies for extracorporeal focused ultrasound treatment of internal tumours and developed a large focused-ultrasound tumour-treatment system with independent intellectual property in 1999. Chongqing Haifu Technology — Official Website

### II. What Is HIFU?

#### High-Intensity Focused Ultrasound

HIFU is a form of focused acoustic-energy therapy that uses high-intensity ultrasound to create a precisely defined focal region inside tissue.

The basic concept can be understood through a familiar physical analogy:

#### Sunlight + Magnifying Glass

Sunlight itself does not necessarily burn a particular point.

But when optical energy is concentrated into a small focal area, the energy density increases dramatically.

HIFU applies a comparable principle using:

#### Sound energy rather than light.

Ultrasound waves are transmitted through tissue and focused at a selected target.

The objective is to create sufficient energy concentration within the target while limiting exposure to surrounding structures.

The U.S. FDA classifies focused ultrasound systems within the broader category of therapeutic ultrasound devices used to ablate soft tissue. FDA — Focused Ultrasound Device Classification

### III. What Actually Happens Inside the Body?

HIFU is not simply “burning a tumour”. Its biological effects involve several interacting mechanisms.

#### 01 | Thermal Effect

Acoustic energy is absorbed by tissue and converted into heat.

When the target tissue reaches a sufficiently high temperature for an appropriate duration, thermal injury can result in:

#### Protein denaturation

↓

#### Cellular structural damage

↓

#### Coagulative necrosis

↓

#### Loss of tissue viability

This is the fundamental basis of:

#### Thermal Ablation

Importantly, the actual temperature and treatment effect depend on the device, tissue characteristics, treatment parameters and clinical circumstances. It should not be presented as though every HIFU treatment simply reaches one fixed temperature.

### 02 | Cavitation Effect

Under appropriate acoustic conditions, microscopic gas bubbles can form, oscillate and collapse.

This can generate highly localised mechanical effects.

Therefore, HIFU is not merely a heating technology.

It represents an interaction between:

**Acoustic Energy**

→ **Thermal Effects**

→ **Mechanical Effects**

→ **Cavitation**

### 03 | Mechanical Effect

High-intensity ultrasound can also exert mechanical forces on tissue.

This distinguishes therapeutic high-intensity ultrasound from conventional diagnostic ultrasound.

## IV. The Real Engineering Challenge

The most important question is not:

**Can we heat tissue?**

We already know that we can.

The difficult question is:

**Can we deliver sufficient energy precisely to the intended target while minimising unwanted effects in surrounding tissue?**

This is why modern focused-ultrasound systems increasingly depend on:

**Imaging**

**Targeting**

**Treatment Planning**

**Energy Control**

**Real-Time Monitoring**

The Haifu JC200 system, for example, publicly describes three-dimensional treatment planning, positioning, treatment management and therapeutic-effect assessment functions. Haifu JC200 — Official Technical Information The deeper significance is therefore not simply:

**“High temperature kills the tumour.”**

It is:

**Precision energy delivery under image guidance.**

## V. Why Is HIFU Considered Non-Invasive?

Traditional surgery generally requires a physical pathway to the tumour:

**Skin incision**

↓

**Entry into the body**

↓

**Access to the lesion**

↓

**Resection**

HIFU attempts to create a different pathway:

**External energy source**

↓

**Ultrasound transmission**

↓

**Focal concentration**

↓

**Targeted tissue ablation**

In appropriate patients and under appropriate clinical conditions, this can avoid a conventional surgical incision.

It also does not rely on ionising radiation.

## HIFU and the Evolution of Non-Invasive Tumour Ablation

NICE describes ultrasound-guided HIFU for uterine fibroids as a technique in which high-intensity ultrasound is focused through the abdominal wall onto the fibroid. NICE — Ultrasound-guided HIFU for Uterine Fibroids

### VI. But “Non-Invasive” Does Not Mean “Risk-Free”

This distinction is essential.

A responsible medical publication should not present HIFU as a risk-free technology.

Potential adverse effects can include:

- Treatment-related pain
- Fever or inflammatory responses
- Skin burns
- Injury to adjacent tissues
- Nerve injury
- Organ-specific complications

Risk depends on:

**Tumour location**

**Lesion size**

**Depth**

**Adjacent anatomy**

**Acoustic pathway**

**Patient anatomy**

**Previous surgery**

**Treatment parameters**

and the expertise of the treating centre.

NICE specifically identifies potential complications such as skin burns and emphasises appropriate clinical governance, patient selection, informed consent and specialist expertise. NICE — Recommendations for HIFU in Uterine Fibroids

Therefore:

**Non-invasive is a description of the access route — not a guarantee of zero risk.**

### VII. Where Is HIFU Being Used or Investigated?

HIFU should not be described as a universal cancer treatment.

Its clinical indications vary according to:

- Device
- Country
- Regulatory approval
- Tumour type
- Clinical evidence
- Treatment centre
- Patient selection

Published clinical applications and research include areas such as:

**Uterine fibroids**

**Liver tumours**

**Soft-tissue tumours**

**Bone tumours**

**Breast lesions**

and other selected conditions.

The precise indication must always be determined according to the relevant regulatory approval and clinical protocol. Haifu Technology — Clinical Applications



### VIII. Uterine Fibroids — An Important Clinical Application

One of the most established areas of HIFU application is symptomatic uterine fibroids.

A major attraction is:

#### **Uterus-Sparing Treatment**

Instead of removing the uterus, HIFU may provide a non-invasive local treatment option for appropriately selected patients.

However, medical precision requires an important qualification:

**Uterus-sparing does not automatically mean fertility is preserved.**

NICE states that the effect of HIFU treatment of uterine fibroids on fertility and pregnancy remains uncertain. NICE — HIFU and Uterine Fibroids

This is exactly the distinction between:

**Medical Information**

and

**Medical Marketing.**

MLJC chooses the former.

### IX. Liver Cancer — A Different Treatment Paradigm

The liver is another important area of HIFU research.

The underlying attraction is straightforward:

**Can focused acoustic energy reach a deep tumour without inserting an instrument into the lesion?**

HIFU therefore belongs to the broader field of:

### **Local Ablative Oncology**

alongside established approaches such as:

- Surgical resection
- Radiofrequency ablation
- Microwave ablation
- Transarterial therapies
- Systemic therapies

HIFU should not currently be described as having replaced these established treatment modalities.

A 2024 meta-analysis comparing HIFU with radiofrequency ablation for primary liver cancer found no statistically significant differences across several evaluated outcomes, while also highlighting the need for larger, high-quality randomised trials. PubMed — HIFU versus RFA in Primary Liver Cancer

That is an important finding.

It means:

**HIFU is clinically significant and worthy of continued investigation — but evidence should determine its position relative to established therapies.**



### X. Pancreatic Cancer — Where the Technology Becomes Particularly Interesting

Pancreatic cancer presents a particularly difficult therapeutic environment.

Many patients are diagnosed at an advanced stage, and the tumour may be located close to critical vessels and organs.

This creates an important research question:

**Can non-invasive focused energy provide a local treatment option where conventional surgery is difficult or impossible?**

HIFU has therefore been investigated extensively in pancreatic cancer.

Systematic reviews have evaluated HIFU for advanced pancreatic cancer, while Chinese-European expert groups have developed consensus work around ultrasound-guided HIFU in pancreatic cancer. PubMed — HIFU in Pancreatic Cancer Systematic Review PubMed — Chinese-European HIFU Consensus Initiative

But again:

**Clinical investigation is not the same as proof of superiority.**

### XI. Why the Chinese HIFU Story Deserves International Attention

For MLJC, the most interesting part of this story is not simply the treatment itself.

It is the **innovation pathway**.

China's HIFU development demonstrates a potentially important model:

**Basic Science**



**Core Technology**



**Medical Engineering**



**Clinical Translation**



**Regulatory Development**



**International Deployment**

Haifu's published history describes decades of development in focused ultrasound research and clinical application, including the development of independently owned HIFU treatment systems and international deployment. Haifu Technology — Corporate & Technology History That makes HIFU more than a medical-device story.

It is also a case study in:

**China's Medical Technology Translation**

### XII. From “Made in China” to “Developed in China”

This distinction matters.

For decades, global perceptions of China’s healthcare industry were heavily associated with:

**Manufacturing**

**Cost efficiency**

**Generic pharmaceuticals**

**Medical-device production**

The more strategically important question today is whether China can consistently move further upstream:

**Scientific discovery**

→

**Original technology**

→

**Intellectual property**

→

**Clinical validation**

→

**Global regulatory recognition**

→

**International adoption**

HIFU is one case that deserves examination through this lens.

The objective is not to claim that every Chinese medical technology is globally superior.

It is to recognise that:

**China is increasingly producing technologies that deserve to be evaluated on scientific and clinical evidence rather than on manufacturing origin.**

### XIII. MLJC Strategic Questions

The most important questions for the next decade are not:

**“Is HIFU the world’s best cancer treatment?”**

They are much more consequential.

#### **Question 01**

Can HIFU generate stronger evidence through large-scale randomised clinical trials?

#### **Question 02**

Can next-generation imaging improve tumour segmentation and targeting?

#### **Question 03**

Can AI optimise treatment planning and energy delivery?

#### **Question 04**

Can real-time thermal monitoring improve treatment verification?

#### **Question 05**

Can HIFU be integrated with immunotherapy, targeted therapy, chemotherapy or interventional oncology?

#### **Question 06**

Can focused ultrasound become part of a broader precision-oncology platform?

If these questions are progressively answered, HIFU could evolve beyond being simply an ablation device.

It could become:

**A Precision Energy Oncology Platform**

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## HIFU and the Evolution of Non-Invasive Tumour Ablation

### XIV. The Next Convergence

MLJC sees a larger technological convergence emerging:

**Medical Imaging**

**Artificial Intelligence**

**Focused Energy**

**Robotics**

**Molecular Medicine**

**Biological Response**

This could eventually create treatment systems capable of:

**Detecting**

→

**Segmenting**

→

**Planning**

→

**Targeting**

→

**Treating**

→

**Monitoring**

→

**Verifying**

within a single integrated therapeutic workflow.

That is a much bigger story than the phrase:

**“HIFU Knife.”**

### XV. MLJC Evidence Position

| Area                               | MLJC Assessment                                                              |
|------------------------------------|------------------------------------------------------------------------------|
| Technology                         | <b>High-Intensity Focused Ultrasound (HIFU)</b>                              |
| Treatment principle                | <b>Focused acoustic-energy ablation</b>                                      |
| Conventional surgical incision     | <b>Generally not required for HIFU treatment</b>                             |
| Ionising radiation                 | <b>No</b>                                                                    |
| Core mechanisms                    | <b>Thermal, mechanical and cavitation effects</b>                            |
| Major clinical interest            | <b>Uterine fibroids and selected solid tumours</b>                           |
| Chinese technological contribution | <b>Significant and historically important</b>                                |
| Regulatory status                  | <b>Varies by country, device and indication</b>                              |
| Clinical positioning               | <b>A local ablative / non-invasive treatment option in selected settings</b> |
| Universal cancer cure              | <b>No</b>                                                                    |
| Risk-free treatment                | <b>No</b>                                                                    |
| Replacement for surgery            | <b>No</b>                                                                    |
| Future research potential          | <b>Significant</b>                                                           |

### XVI. MLJC's Recognition

There is something worth acknowledging.  
Medical innovation deserves recognition not because it comes from one particular country, institution or company.

It deserves recognition because researchers are willing to spend decades solving difficult problems that medicine could not previously solve.

The HIFU story represents that kind of persistence.

From physics,  
to engineering,  
to imaging,  
to clinical medicine,  
to international medical-device development.

That deserves respect.

But respect for innovation must exist alongside respect for evidence.

### XVII. MLJC's Medical Principle

At MLJC | JY HCG, our position is simple:

**Medicine is not marketing.**

**Medical technology is not mythology.**

**Innovation deserves recognition.**

**Evidence deserves discipline.**

**Patients deserve both.**

We believe the proper way to report emerging healthcare technologies is neither to exaggerate them nor to dismiss them prematurely.

Instead:

**Observe the innovation.**

**Examine the evidence.**

**Understand the limitations.**

**Follow the clinical outcomes.**

**Respect the patient.**

That is the standard we intend to maintain.

### XVIII. MLJC FINAL VIEW

The deeper significance of HIFU is not that:

**“A knife can treat a tumour without entering the body.”**

The deeper significance is that medicine is beginning to reconsider what the word “surgery” itself means.

From:

**Mechanical Surgery**

to

**Interventional Medicine**

to

**Image-Guided Energy Therapy**

and potentially toward:

**Precision Medicine**

The future operating room may not always be defined by scalpels.

It may increasingly be defined by:

**Imaging**

**AI**

**Energy**

**Robotics**

**Biology**

and **precision control.**

HIFU is one important part of that transition.

And the question for the global healthcare community is no longer simply:

**Can we remove the tumour?**

It is becoming:

**Can we treat the tumour with greater precision, less physical disruption, and better preservation of the patient?**

That is the question worth pursuing.

# HIFU and the Evolution of Non-Invasive Tumour Ablation

[https://www.haifu.com.cn/?utm\\_source=chatgpt.com](https://www.haifu.com.cn/?utm_source=chatgpt.com)

[https://www.nice.org.uk/guidance/htg523/chapter/2-The-condition-current-treatments-and-procedure?utm\\_source=chatgpt.com](https://www.nice.org.uk/guidance/htg523/chapter/2-The-condition-current-treatments-and-procedure?utm_source=chatgpt.com)

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[https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm?id=NRZ&utm\\_source=chatgpt.com](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm?id=NRZ&utm_source=chatgpt.com)

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The screenshot shows the FDA's Product Classification page for an MRI-guided focused ultrasound (HIFU) system. The page is titled "Product Classification" and includes a search bar and navigation links. The main content area displays the following information:

- Device:** Ablation System, High Intensity Focused Ultrasound (HIFU), MR-Guided
- Definition:** An MRI-guided focused ultrasound system is intended to use HIFU to ablate soft tissue. MRI imaging and thermal mapping are used to plan and monitor the use of ultrasound ablation before and during the procedure.
- Review Panel:** Obstetrics/Gynecology
- Product Code:** NRZ
- Premarket Review:** Office of Gastroenterology, Gynecology, and Urology Devices (DHT3)
- Submission Type:** PMA
- Device Class:** 3
- Total Product Life Cycle (TPLC):** TPLC Product Code Report
- GMP Exempt?** No
- Summary Malfunction Reporting:** Ineligible
- Implanted Device?** No
- Life-Sustain/Support Device?** No
- Recognized Consensus Standards:**
  - 12-280 IEC 62555 Edition 1.0 2013-11
  - 12-281 IEC 60601-2-62 Edition 1.0 2013-07
- Medical electrical equipment - Part 2-62: Particular requirements for the basic safety and essential performance of high intensity therapeutic ultrasound (HITU) equipment**
- Third Party Review:** Not Third Party Eligible

Page Last Updated: 08/17/2026  
Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.  
Language Assistance Available: Español | 繁體中文 | 中文 | 日本語 | Français | Polski | Português | Italiano | Ayisyen | Français | Polski | Português | Italiano

The screenshot shows the PubMed page for the article "US-guided high-intensity focused ultrasound in pancreatic cancer treatment: a consensus initiative between Chinese and European HIFU centers" by Kun Zhou et al. The page includes the NIH logo, the article title, the authors, and the publication year (2024). The article is marked as a "Free article". The page also features a "Show details" button and a "Full text links" button.

The screenshot shows the NICE website header, which includes the NICE logo and the text "National Institute for Health and Care Excellence". Below the logo, there is a navigation menu with the following items: Guidance, Standards and indicators, Clinical Knowledge Summaries (CKS), British National Formulary (BNF), BNF for Children (BNFC), Life sciences, and More from NICE.

## Temporary Service Interruption

**Error Code: 0x8133**

We're currently experiencing an unexpected technical issue that is preventing access to our website content.

We apologise for any inconvenience this may cause and want to assure you that we are working urgently to restore service.

Thank you for your patience while we resolve the issue.

We hope to be back online shortly.

The screenshot shows the NICE website footer, which includes the NICE logo and the text "National Institute for Health and Care Excellence". Below the logo, there is a navigation menu with the following items: Guidance, Standards and indicators, Clinical Knowledge Summaries (CKS), British National Formulary (BNF), BNF for Children (BNFC), Life sciences, and More from NICE. The footer also includes a section for "What NICE does" with links to "Implementing NICE guidance", "Get involved", "About us", "Careers", "News, blogs and podcasts", and "Newsletters and alerts". There is also a section for "Contact us" with links to "Leave feedback", "Reusing our content", "NICE UK Open Content", "Licence", "Syndicate our content", and "Events". The footer also includes social media links for Facebook, X, YouTube, and LinkedIn. At the bottom, there is a section for "Accessibility", "Freedom of information", "Glossary", "Terms and conditions", "Privacy notice", and "Cookies". The footer also includes the text "© NICE 2026. All rights reserved. Subject to Notice of rights."





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**GLOBAL HEALTHCARE & BIOMEDICAL INTELLIGENCE**

**MLJC EXCLUSIVE | CHINA MEDICAL TECHNOLOGY WATCH**

**当“手术刀”不再需要进入人体**

**海扶刀：从中国原创聚焦超声技术，到非侵入性肿瘤消融的全球医学探索**

**High-Intensity Focused Ultrasound | HIFU | Thermal Ablation | Oncology | Medical Devices | Precision Therapy**

**不是刀，却可以“切除”肿瘤。**

**不进入人体，却可以把能量送到人体深处。**



# 海扶刀：从中国原创聚焦超声技术，到非侵入性肿瘤消融的全球医学探索

## 一、MLJC 导读

医学史上，有一些技术的意义并不在于把传统手术做得更快。而在于：

**重新定义“手术”本身。**

传统外科的基本逻辑是：

打开人体 → 暴露病灶 → 切除病变 → 缝合组织。

而高强度聚焦超声（HIFU）提出了另一种思路：

不打开人体。

不把手术刀送入人体。

而是从体外发射超声能量，通过精确聚焦，把能量集中到体内目标组织。

这就是为什么“海扶刀”虽然被称为“刀”，实际上并没有传统意义上的刀刃。

它真正使用的是：

**Focused Ultrasound Energy**

即：

**聚焦超声能量。**

重庆海扶科技公开资料显示，其团队长期从事聚焦超声治疗技术，并在全球率先突破体外聚焦超声治疗体内肿瘤的关键技术；1999年研制出中国首台具有完全自主知识产权的大型医疗设备“海扶刀”聚焦超声肿瘤治疗系统。

这使它成为一个非常值得国际医疗产业重新审视的中国医疗器械案例。



## 二、首先：海扶刀究竟是什么？

海扶刀®是重庆海扶科技的注册商标。

它所对应的核心治疗技术属于：

High-Intensity Focused

Ultrasound

HIFU

中文：

高强度聚焦超声

在医学技术分类中，它属于一种：

Non-invasive / Non-ionizing  
Energy Ablation

即：

非侵入性、非电离辐射的能量消融技术。

FDA对HIFU类设备的定义同样强调，其基本用途是利用高强度聚焦超声对软组织进行加热和消融；MR引导型HIFU还可以利用磁共振成像及温度测绘进行治疗规划和监测。

所以：

“海扶刀”不是一把隐藏在人体里的刀。

而是一套：

成像 + 定位 + 聚焦 + 能量控制  
+ 消融

组成的医疗系统

## 三、它究竟是怎么“切”肿瘤的？

这里可以用一个非常直观的比喻：

太阳光 + 放大镜

太阳光本身不会把某一个点瞬间烧穿。

但是当放大镜把光线集中到一个焦点：

能量密度突然增加。

HIFU采用的是类似的物理思想。

不过，它不是光。

而是：

超声波。

设备从体外发出大量超声波。

这些超声波经过组织传播，并在目标区域形成：

高能量聚焦焦域

在焦点之外：

能量密度相对较低。

在焦点位置：

能量高度集中。

从而产生治疗效应。

海扶科技公开资料显示，其设备可在组织内形成高声强焦域，并利用热效应、机械效应及空化效应破坏目标组织。

因此，真正发生的不是：

“刀切掉肿瘤。”

而是：

“利用聚焦能量，在体内完成热消融。”

## 四、三个核心物理机制

### 01 | Thermal Effect

#### 热效应

这是HIFU最核心的机制之一。

焦点区域的超声能量被组织吸收并转化为热能。

当局部组织达到足够高的温度并持续一定时间，就会发生：

蛋白质变性



细胞膜及细胞结构破坏



凝固性坏死



目标组织失去活性

这就是：

Thermal Ablation

热消融。

### 02 | Cavitation Effect

#### 空化效应

在特定声学条件下，超声可以引起组织液体中的微气泡形成、振荡甚至塌陷。

这一过程会产生局部机械效应。

因此HIFU并不仅仅是“加热”。

它实际上涉及：

Acoustic Energy → Thermal + Mechanical Effects

### 03 | Mechanical Effect

#### 机械效应

高强度超声能够对组织产生机械作用。

这也是现代HIFU技术与普通诊断超声之间的重要区别之一。

## 五、真正高级的地方：不是“烧”，而是“控制烧在哪里”

这也是MLJC认为HIFU最值得关注的地方。

真正的挑战并不是：

能不能把组织加热？

而是：

能不能只把目标区域加热到足够程度，同时尽可能降低对周围组织的影响？

因此现代HIFU系统越来越强调：

Imaging

成像

Targeting

靶点定位

Treatment Planning

治疗规划

Energy Control

能量控制

Real-time Monitoring

实时监测

海扶科技目前公开的JC200系统资料显示，其系统包括三维模拟定位、治疗计划、位置记录、治疗及疗效检测等软件模块，并采用多维适形定位及实时超声影像监控。

所以：

HIFU不是简单的“高温治疗”。

而是一套：

Image-Guided Precision Energy Therapy

影像引导精准能量治疗。

## 六、为什么说它是“无创”？

传统手术通常需要：

切开皮肤

↓

进入体腔或组织

↓

到达病灶

↓

切除

HIFU则尝试改变这条路径：

体外

↓

超声穿透组织

↓

聚焦

↓

目标区域消融

因此在合适的患者和合适的病灶条件下，可以实现：

不切开皮肤

不需要传统手术切口

不产生传统外科切口

不使用电离辐射

这也是它最重要的临床吸引力之一。

NICE对经皮超声引导HIFU治疗子宫肌瘤的描述，同样明确其能量是通过腹部皮肤聚焦到肌瘤进行消融。

## 七、但“无创”不等于“没有风险”

这是MLJC必须特别强调的一点。

真正专业的医疗报道，不应该只讲优点。

HIFU仍然可能出现：

- 治疗区域疼痛
- 发热
- 皮肤灼伤
- 邻近组织损伤
- 神经损伤
- 炎症反应
- 个别器官相关并发症

具体风险取决于：

肿瘤位置

病灶大小

病灶深度

周围血管与神经

声通道条件

既往手术史

患者体型

以及设备和治疗经验。

NICE目前关于子宫肌瘤HIFU的指导明确指出，皮肤灼伤等并发症是已知风险，同时认为部分疗效证据质量仍有限，因此要求适当的临床治理、知情同意、审计及专业团队实施。

## 八、它到底可以治疗什么？

这里必须避免把“HIFU”与某一台设备的获批适应症混为一谈。

不同国家：

设备不同

监管批准不同

适应症不同

临床证据不同

因此不能简单说：

“HIFU可以治疗所有癌症。”

这是错误的。

海扶科技目前公开的JC200系统适应症包括：

- 肝脏肿瘤
- 软组织肿瘤
- 骨肿瘤
- 乳腺癌
- 乳腺纤维腺瘤
- 子宫肌瘤

具体适应症仍应以相应设备的注册证、说明书及所在国家/地区监管要求为准。



## 九、子宫肌瘤：HIFU最重要的应用之一

子宫肌瘤是HIFU非常重要的临床应用领域。

其核心优势之一是：

**Uterus-Sparing Treatment**

即：

保留子宫结构的治疗选择。

传统治疗可能包括：

药物

子宫动脉栓塞

肌瘤切除

子宫切除

而HIFU提供另一种：

通过体外聚焦超声能量消融肌瘤组织

的治疗路径。

FDA已经批准MR引导聚焦超声系统用于特定条件下的症状性子宫肌瘤消融。

但这里必须再次强调：

**保留子宫 ≠ 已证明不影响生育。**

NICE明确指出，患者如果未来考虑怀孕，应被告知HIFU治疗后对生育及未来妊娠的影响仍存在不确定性。

这就是我们坚持：

**Evidence before Promotion**

的原因。

### 十、肝癌：从“切除”走向“局部能量消融”

肝癌是HIFU研究的重要方向。

HIFU的潜在优势在于：

可以从体外将聚焦能量送入深部组织。

但在肝癌治疗中，HIFU不能简单被理解为取代：

手术切除

射频消融

微波消融

TACE

系统治疗

等成熟治疗方式。

它更准确的定位是：

局部消融技术体系中的一种选择。

一项2024年的Meta-analysis比较了HIFU与射频消融治疗原发性肝癌，纳入304名患者，结果没有发现两者在疗效、长期生存或并发症方面存在统计学显著差异；作者同时强调需要更大规模、高质量随机临床试验。

这类证据非常重要。

因为它告诉我们：

HIFU值得研究，并不等于HIFU已经证明全面优于其他消融技术。

### 十一、胰腺癌：为什么国际医学界一直关注？

胰腺癌最大的困难之一，是：

位置深

周围重要血管和器官密集

很多患者确诊时已经无法手术

因此，非侵入性局部治疗一直具有研究价值。

HIFU能够从体外聚焦深部组织，因此成为研究方向之一。

系统综述和Meta-analysis已经报道HIFU用于晚期胰腺癌的研究，但不同研究质量存在差异，仍需要更高质量的随机临床试验。

2023/2024年发表的中国与欧洲HIFU中心共识也专门讨论了超声引导HIFU在胰腺癌中的应用。

因此MLJC更准确的判断是：

HIFU在胰腺癌领域具有重要临床研究价值，但不应被包装成已经取代标准治疗的“万能疗法”。



## 海扶刀：从中国原创聚焦超声技术，到非侵入性肿瘤消融的全球医学探索

### 十二、一个值得国际医疗界重新观察的问题

过去：

**Surgery**

打开人体。

后来：

**Interventional Oncology**

通过针、导管等进入人体。

现在：

**Non-invasive Energy Therapy**

开始尝试：

不进入人体，也能在体内完成精准组织破坏。

这代表医学治疗技术的一条重要演进路线：

**CUT → PUNCTURE → FOCUS**

从：

切开

到：

穿刺

再到：

聚焦能量。

这正是HIFU真正值得关注的战略意义。

### 十三、海扶为什么是中国医疗器械产业值得研究的案例？

海扶科技公开资料显示：

**1997**

完成利用HIFU治疗骨肿瘤、乳腺癌等恶性肿瘤的早期临床突破。

**1999**

研制中国首台具有完全自主知识产权的大型“聚焦超声肿瘤治疗系统”。

**2001**

获得国家技术发明二等奖。

**2002**

设备出口至英国牛津大学丘吉尔医院。

**2005**

通过欧盟CE认证；海扶方面称其为当时全球首个获得该认证的超声监控、体外聚焦超声肿瘤治疗设备。

这条路径值得关注：

**Research → Engineering → Medical Device → Clinical Application → International Deployment**

这正是一个国家医疗科技产业从科研成果走向国际市场的重要途径。

## 海扶刀：从中国原创聚焦超声技术，到非侵入性肿瘤消融的全球医学探索

### 十四、一个非常值得赞赏的地方

MLJC认为，中国医疗科技真正值得国际社会关注的，不只是：

“中国制造。”

而是：

“中国创造。”

海扶案例值得研究的地方，是它不是简单把国外已有设备做得更便宜。其企业公开历史显示，团队长期投入聚焦超声的基础研究、设备工程化、临床方案和国际培训体系，并形成完整产业链。

这体现了一种非常重要的医疗产业逻辑：

原创科学 → 核心设备 → 临床验证 → 医生培训 → 国际推广  
对于中国高端医疗器械产业，这是比单纯“出口一台机器”更重要的能力。

### 十五、MLJC提出的核心问题

真正值得问的不是：

“海扶刀是不是世界第一？”

而是：

#### Question 01

中国原创的非侵入性治疗技术，能否持续通过更多国际随机临床试验验证？

#### Question 02

HIFU能否进一步进入更多国家的临床指南与医保体系？

#### Question 03

能否通过MRI、超声、AI和实时温度监测进一步提高靶区精准度？

#### Question 04

能否把HIFU与：

免疫治疗

靶向治疗

化疗

介入治疗

形成更加成熟的联合治疗体系？

#### Question 05

未来能否通过AI自动规划：

Tumour Segmentation

→

Treatment Planning

→

Energy Delivery

→

Real-time Monitoring

→

Treatment Verification

如果这些问题逐步得到解决：

HIFU可能不再只是一个“无创消融设备”。

它可能成为：

Precision Energy Oncology Platform

精准能量肿瘤治疗平台。

# 海扶刀：从中国原创聚焦超声技术，到非侵入性肿瘤消融的全球医学探索

## 十六、MLJC对“海扶刀”的最终判断

我们不会把它称为：

- ✗ “癌症终结者”
- ✗ “不开刀就能治愈所有癌症”
- ✗ “世界上最先进的癌症治疗”

这些都超出了现有证据。

我们更愿意把它定义为：

A Chinese-origin, image-guided non-invasive focused-ultrasound ablation technology with significant clinical and translational relevance.

即：

一种源自中国原创技术体系、以影像引导为基础的非侵入性聚焦超声消融技术，在实体肿瘤及部分良性疾病治疗领域具有重要的临床与转化价值。

这句话更专业。

也更经得起国际医学界审阅。

## 十七、MLJC | JY HCG Evidence Matrix

| 领域        | MLJC判断                                |
|-----------|---------------------------------------|
| 技术类别      | HIFU / Focused Ultrasound Ablation    |
| 是否需要传统切口  | 通常不需要                                 |
| 是否使用电离辐射  | HIFU本身不使用电离辐射                         |
| 核心机制      | 热效应 + 机械效应 + 空化效应                     |
| 核心目标      | 精准消融目标组织                              |
| 中国原创体系    | 海扶团队形成自主知识产权的聚焦超声肿瘤治疗系统               |
| 主要研究/应用领域 | 子宫肌瘤、肝脏肿瘤、软组织肿瘤、骨肿瘤、乳腺等，具体取决于设备及监管适应症 |
| 全球监管情况    | 不同国家适应症和设备不同                          |
| 临床定位      | 局部消融/非侵入性治疗技术之一                       |
| 是否适合所有癌症  | 否                                     |
| 是否完全没有风险  | 否                                     |
| 是否已经取代手术  | 否                                     |
| 是否值得长期研究  | 是                                     |

# 海扶刀：从中国原创聚焦超声技术，到非侵入性肿瘤消融的全球医学探索

## 十八、MLJC的医学原则

我们特别希望这一点成为  
MLJC | JY HCG 的长期标准。

医学不是宣传。

医疗科技不是神话。

创新需要赞赏，证据需要尊重。

我们赞赏中国科研人员和医疗工程团队几十年来在聚焦超声领域的持续探索。

同时，我们也尊重：

随机临床试验

长期随访

监管批准

指南评价

真实世界数据

以及：

Patient Safety

因为医疗技术真正的价值，最终不是：

它看起来有多先进。

而是：

它是否能够让患者获得更安全、更有效、更有尊严的治疗选择。

## 十九、MLJC FINAL VIEW

“海扶刀”这个名字容易让人产生误解。

它不是一把刀。

它代表的是一种完全不同的治疗思想：

不一定要进入人体，才能治疗人体内部的病变。

这背后，是现代医学从：

Mechanical Surgery

逐渐走向：

Image-Guided Energy Medicine

再进一步走向：

Precision Medicine

的一个缩影。

未来的医疗器械，可能越来越不像传统意义上的“工具”。

它可能是：

Imaging

AI

Energy

Robotics

Biology

的综合系统。

而HIFU正处于这个技术交叉点上。

# 海扶刀：从中国原创聚焦超声技术，到非侵入性肿瘤消融的全球医学探索

[https://www.haifu.com.cn/?utm\\_source=chatgpt.com](https://www.haifu.com.cn/?utm_source=chatgpt.com)

[https://www.nice.org.uk/guidance/htg523/chapter/2-The-condition-current-treatments-and-procedure?utm\\_source=chatgpt.com](https://www.nice.org.uk/guidance/htg523/chapter/2-The-condition-current-treatments-and-procedure?utm_source=chatgpt.com)

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[https://pubmed.ncbi.nlm.nih.gov/38517812/?utm\\_source=chatgpt.com](https://pubmed.ncbi.nlm.nih.gov/38517812/?utm_source=chatgpt.com)

The screenshot shows the FDA's Product Classification page for the 'Ablation System, High Intensity Focused Ultrasound (HIFU), MR-Guided'. The page is part of the 'Medical Devices' section. It includes a 'New Search' button and a 'Back to Search Results' link. The 'Device Definition' section states: 'An MR-guided focused ultrasound system is intended to use HIFU to ablate soft tissue. MRI imaging and thermal mapping are used to plan and monitor the use of ultrasound ablation before and during the procedure.' The 'Review Panel' is 'Obstetrics/Gynecology'. The 'Product Code' is 'NRZ'. The 'Premarket Review' is 'Office of Gastroenterology, Gynecology, and Urology Devices (DHT3)'. The 'Submission Type' is 'PMA'. The 'Device Class' is '3'. The 'Total Product Life Cycle (TPLC)' is 'PLC Product Code Report'. The 'GMP Exempt?' is 'No'. The 'Summary Malfunction Reporting' is 'Ineligible'. The 'Implanted Device?' is 'No'. The 'Life-Sustain/Support Device?' is 'No'. The 'Recognized Consensus Standards' are listed: '12-280 IEC 62555 Edition 1.0 2013-11' (Ultrasound - Power measurement - High intensity therapeutic ultrasound (HITU) transducers and systems) and '12-281 IEC 60601-2-62 Edition 1.0 2013-07' (Medical electrical equipment - Part 2-62: Particular requirements for the basic safety and essential performance of high intensity therapeutic ultrasound (HITU) equipment). The 'Third Party Review' is 'Not Third Party Eligible'. The page was last updated on 08/17/2026. A note states: 'If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.' Language assistance is available in Spanish, French, Polish, and Portuguese.

The screenshot shows the PubMed page for the article 'US-guided high-intensity focused ultrasound in pancreatic cancer treatment: a consensus initiative between Chinese and European HIFU centers' by Kun Zhou et al. The article is published in 'Int J Hyperthermia' in 2024. The page includes a 'Log in' button, a search bar, and a 'Show details' button. The article is marked as a 'Free article'. The page also features a 'Full text links' button, a 'Cite' button, and a 'More' button.

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The screenshot shows the NICE website footer. It includes a navigation menu with links to 'Guidance', 'Standards and indicators', 'Clinical Knowledge Summaries (CKS)', 'British National Formulary (BNF)', 'BNF for Children (BNFC)', 'Life sciences', and 'Library and knowledge services'. There is also a 'What NICE does' section with links to 'Implementing NICE guidance', 'Get involved', 'About us', 'Careers', 'News, blogs and podcasts', and 'Newsletters and alerts'. A 'Contact us' section includes links to 'Leave feedback', 'Reusing our content', 'NICE UK Open Content Licence', 'Syndicate our content', and 'Events'. Social media links for Facebook, X, YouTube, and LinkedIn are provided. The footer also includes links to 'Accessibility', 'Freedom of information', 'Glossary', 'Terms and conditions', 'Privacy notice', and 'Cookies'. The copyright notice states: '© NICE 2026. All rights reserved. Subject to Notice of rights.'

