

Histotripsy: Delivering New Hope

"I feel more confident in my future after having histotripsy"

Marie,
USA



If you or a loved one have been diagnosed with tumors in the liver, histotripsy may be an option for you.

[Learn more.](#)

If you or a loved one have been diagnosed with tumors in the liver, there is hope for treatment and recovery that does not involve surgery or radiation. Harnessing the power of high-intensity sound waves. Histotripsy offers a non-invasive method to effectively destroy liver tumors.



What is Histotripsy?

Histotripsy is a cutting-edge form of ultrasound that utilizes pulsed sound waves to create “bubble clouds” from gases naturally found in targeted tissue.

These tiny bubble clouds form and collapse in microseconds, producing powerful mechanical forces that can effectively break down tissue at the cellular and sub-cellular levels.

Non-invasive



The procedure allows you to avoid incisions, needles, or other insertions through the skin which can help reduce the risk of infection, bleeding, long recovery times and other complications.

Single treatment

Histotripsy can be effective in destroying liver tumors in as little as one treatment, depending on the severity of your condition.



Targeted



Histotripsy can be used to precisely target and destroy unwanted tissue, such as tumors, without causing damage to surrounding healthy tissue.

Histotripsy has been studied in laboratories for over 20 years with clinical trials beginning in 2018.

Learn more >



www.myhistotripsy.com

The Procedure

The histotripsy procedure may be performed under general anesthesia and can be completed in as little as one treatment, depending on the severity of your condition.

Step 1: Consultation

If you are considering histotripsy, you will meet with your doctor who will answer your questions and discuss your eligibility for this procedure. If approved for histotripsy, you will schedule a date and time for the procedure.

Step 2: Prep

Your doctor may require you to follow some dietary restrictions before the planning histotripsy. Be sure to follow all instructions before your planned date.

Step 3: Day of Procedure

You will be guided into a room with a histotripsy system. Your doctor may perform an ultrasound for additional confirmation of your tumor location. General anesthesia will be administered and your doctor will place a histotripsy treatment head over the targeted tumor.

Step 4: Histotripsy Begins

During the procedure, the treatment head delivers acoustic energy to the targeted tissue while your doctor monitors the treatment area using ultrasound imaging.

Step 5: Duration of Therapy

The procedure time will vary depending on specific variables and the number of histotripsy treatments delivered in one session.

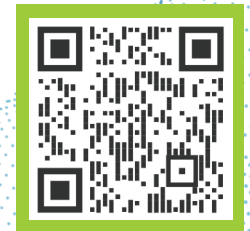
Step 6: Recovery

After the treatment, you may experience some pain depending on the treatment area. Many patients can return home on the day of the procedure or the day after and usually resume their normal activities quickly.

Is Histotripsy Right for Me?

Histotripsy is an innovative, non-invasive treatment option for patients with liver tumors. However, there are several factors that must be assessed and discussed with your doctor to determine if your clinical condition is suitable for a histotripsy procedure.

Find a Doctor
Performing
Histotripsy



"I would recommend it to any patient... you have no scar, nothing. It can't get any better than that."

-Eva, Germany



"After my histotripsy procedure, the first thing I did was go to breakfast with my family and then I went home because I didn't feel any discomfort. I felt very well."

-Juan, Spain



Questions?

Want more info?



< FAQ

All medical procedures involve risk. Patients should consult their physician for more information and to understand the risks and benefits of histotripsy of the liver. Histotripsy therapy procedures involve many patient-specific variables and conditions, including the size and location of the targeted tissue, that impact the length of procedure, anesthetic and other clinical aspects. Histotripsy results in the destruction of liver tissue, including liver tumors, which may impact overall liver function. Each patient experience will vary. During clinical trials, the most common side effects experienced were procedural pain, abdominal pain and fever.

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.

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Meet **Edison**[®]

System overview and
technical specifications



Edison treatment head with bubble cloud (enlarged).

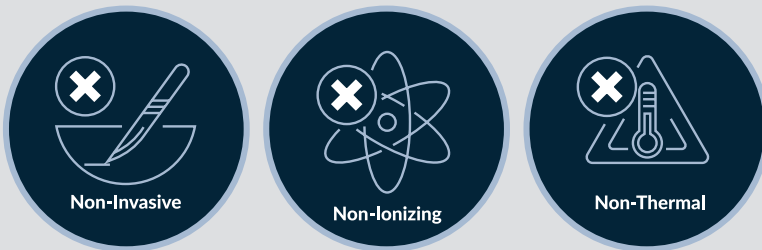
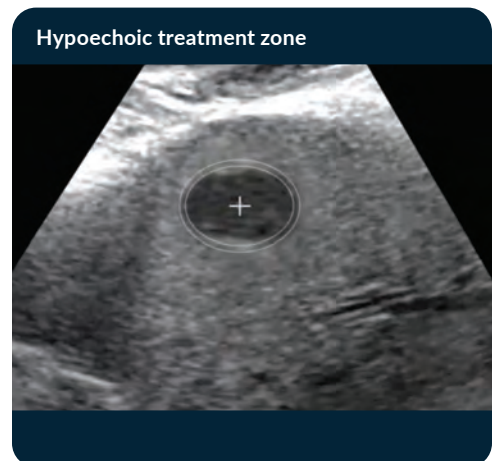
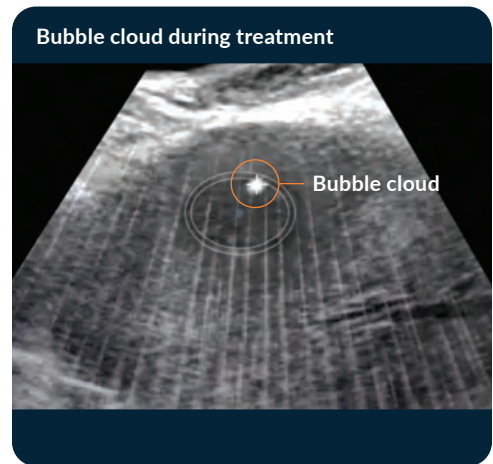
Histotripsy

Mechanism of Action

Histotripsy is a novel form of focused ultrasound that uses high amplitude, very short pulses designed to mechanically destroy and liquefy targeted tissue.

Specifically, as the focused ultrasound energy converges at a known focal point, high pressure causes extremely small, naturally occurring gas bubbles to expand many times larger through a phenomenon called acoustic cavitation.

During planning, the physician also establishes the minimum threshold voltage required to sustain the bubble cloud in the targeted tissue – this leverages histotripsy's "threshold effect" that removes targeted liver tumors, while tending to preserve collagenous vessels and ducts.¹



The histotripsy mechanism of action is non-thermal, non-ionizing and is designed to destroy only the targeted tissue in the planned treatment volume.

- The bubble cloud generally has a bright, visible echogenic appearance as seen with the Edison real-time ultrasound imaging.
- The Edison System automated treatment arm dynamically and precisely moves the treatment head and bubble cloud throughout the targeted treatment volume under the watchful eye of the treating clinician.

Edison Design Overview and Key Components



- A** User interface control panel
- B** Automated treatment arm
- C** Treatment head

Treatment Head Overview

The Edison System treatment head houses a concave therapy transducer which generates a localized bubble cloud at a known focal point to destroy targeted tissues and cells.

An integrated ultrasound imaging probe with encoded rotation and translation allows continuous visualization for localizing, planning and monitoring treatment.



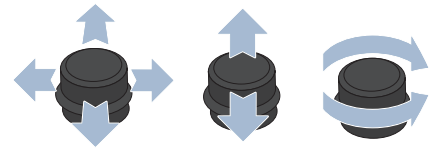
Imaging probe

Histotripsy therapy transducer

Freedrive button Imaging probe rotation lever



Freedrive handle buttons for load-assisted gross positioning.



Space mouse moves the treatment head in six degrees of freedom (x, y, z, pitch, roll and yaw) at the desired speed and allows precise, fine tune positioning of the treatment head.

OPTIONS

Treatment heads are designed and optimized for a specific treatment depth range.

Treatment heads are designed for quick and easy exchange.



2-12cm



8-14cm

Histotripsy Coupling Kit Overview

FEATURES

- Proprietary single-use design for easy setup and disposal.
- Ergonomic, easy fill and drain method to quickly couple the therapy transducer to the patient.
- Flexible membrane conforms to the patient's anatomy and allows uninterrupted ultrasound delivery.



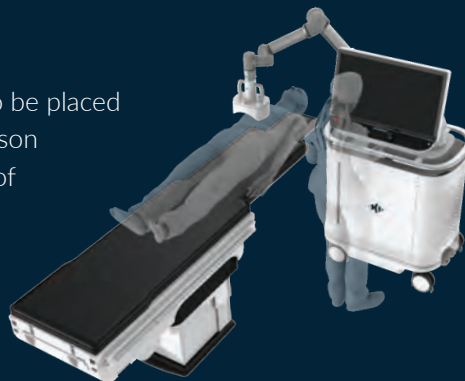
The Edison System patient membrane holds the ultrasound medium and contours to the patient, acoustically coupling the treatment head to the patient.



Flexible membrane

SETUP

With its small footprint and ability to be placed on either side of the patient, the Edison System is compatible with a variety of rooms and room configurations.



Workflow Overview

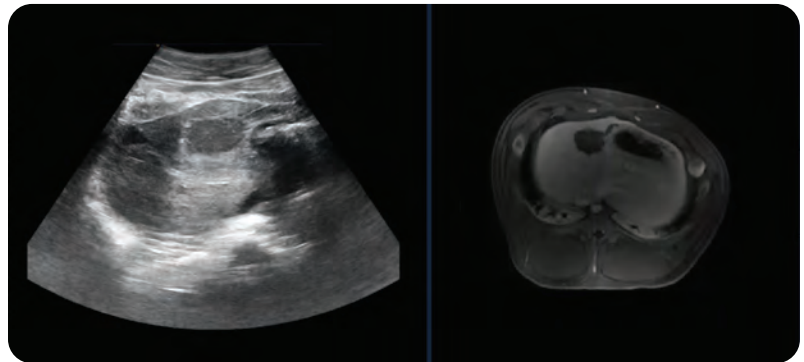
FOCUS

Designed around the three phases of the histotripsy procedure (Localize, Plan, Treat), the Edison System user interface provides step-by-step instructions and seamless workflow so that physicians can focus on the task at hand.

1 LOCALIZE

View MRI or CT imaging alongside real-time diagnostic ultrasound with 2D and 3D views.

- Evaluate both the target and other critical anatomy in the area of interest.
- Multi-planar viewing with the rotating and translating diagnostic ultrasound supports full volumetric targeting.



2 PLAN

Adjust the size, shape and location of the planned treatment volume with target and margin contours. Visual representation of the plan contours are overlaid onto real-time diagnostic ultrasound.

Edison's workflow allows the clinician to determine the precise amount of energy required to destroy the target. These measurements are performed inside each target at 7 discrete points and are used to determine the treatment parameters.



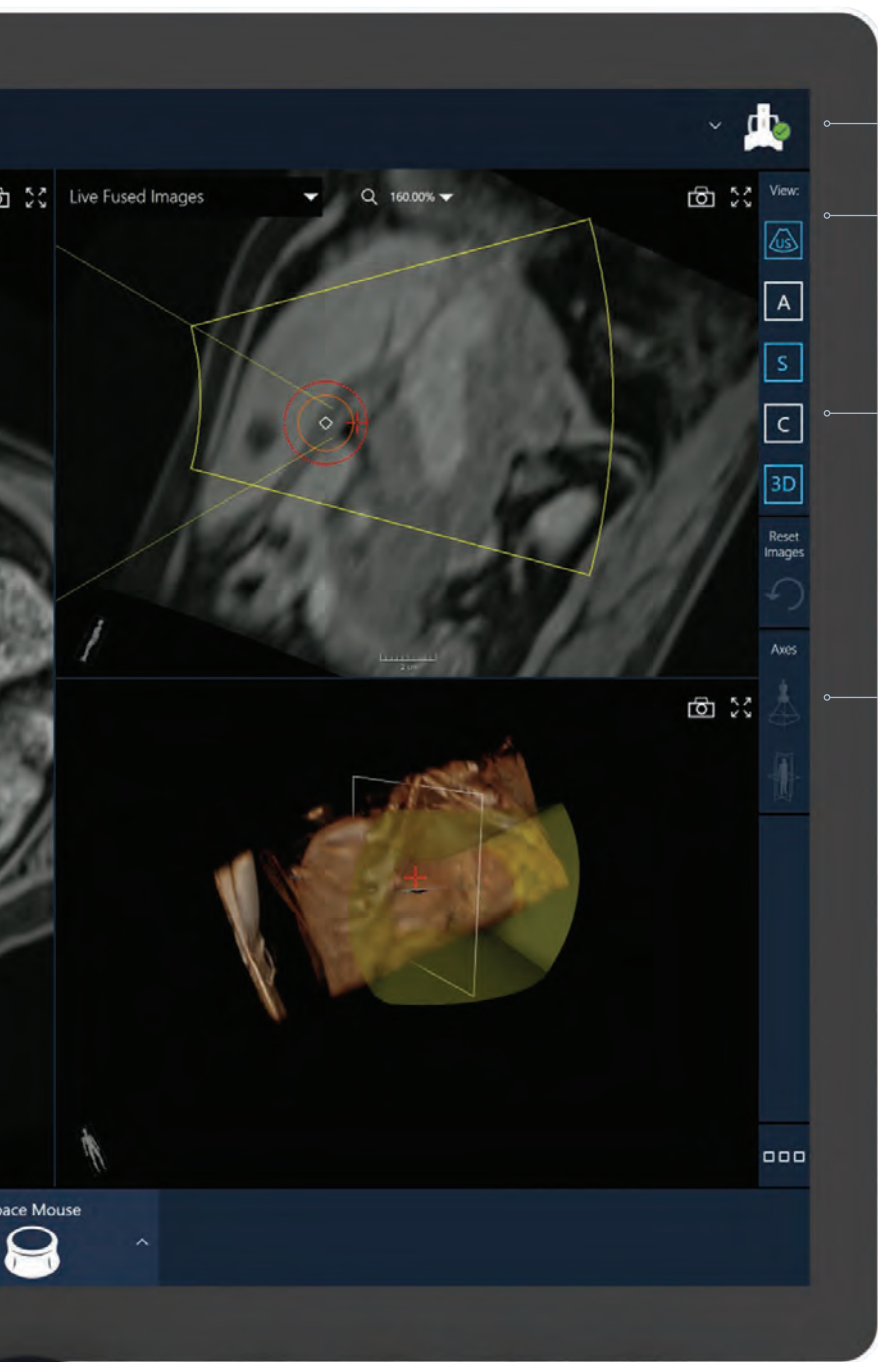
3 TREAT

During fully automated treatment, Edison dynamically and continuously moves the treatment head through the optimized pattern of the planned treatment volume and provides continuous real-time monitoring of imaging and treatment status.



User Interface Overview





SOFTWARE ELEMENTS

- A** Procedure phase (Localize, Plan, Treat)
- B** Current task and instructions
- C** Planning controls
- D** Treatment head identifier/status
- E** Image plane customization
- F** DICOM View (Axial, Sagittal, Coronal)
- G** Axis perspective controls

PHYSICAL CONTROLS

- 1** E-stop (emergency stop button)
- 2** Planning knobs (X, Y, Z)
- 3** Voltage adjustment
- 4** Trackpad
- 5** Space mouse
- 6** Power button



5

6

Specifications

THE EDISON SYSTEM



Features

- 32 inch touchscreen display with 16:9 aspect ratio, 3840 x 2160 pixels (4K), scratch-resistant AR glass, super wide 179 degree viewing angle (horizontal and vertical) and aluminum chassis
- Fully-adjustable display arm
- Detachable treatment head with integrated GE LOGIQ™* E10s imaging probe
- Automated treatment arm
- Physical control knobs for setting planning parameters
- Physical control knobs for controlling imaging probe translation/rotation
- E-stop button
- Track pad
- 3D space mouse and freedrive treatment arm control
- Uninterruptible power supply
- Full-surround aluminum handrail
- Swivel lock/full lock castors

Dimensions (Transport)

- Height: 166cm (65.5 inches)
- Width: 100cm (39 inches)
- Depth: 64.6cm (25 inches)

Weight

- 264kg/582lbs

Electrical

- 120 V (US)/240 V (Europe)

GE LOGIQ™* E10s



Features

- 22 inch high-resolution anti-glare OLED display
- 12.1 inch, high resolution, color touchscreen display
- Fully-adjustable monitor arm
- Next-generation cSound™* architecture
- High frequency imaging
- GE LOGIQ™* E10s imaging probe
- Ergonomic floating keyboard

Dimensions (Transport)

- Height: 130cm (51 inches)
- Width: 58.5cm (23 inches)
- Depth: 90cm (35.5 inches)

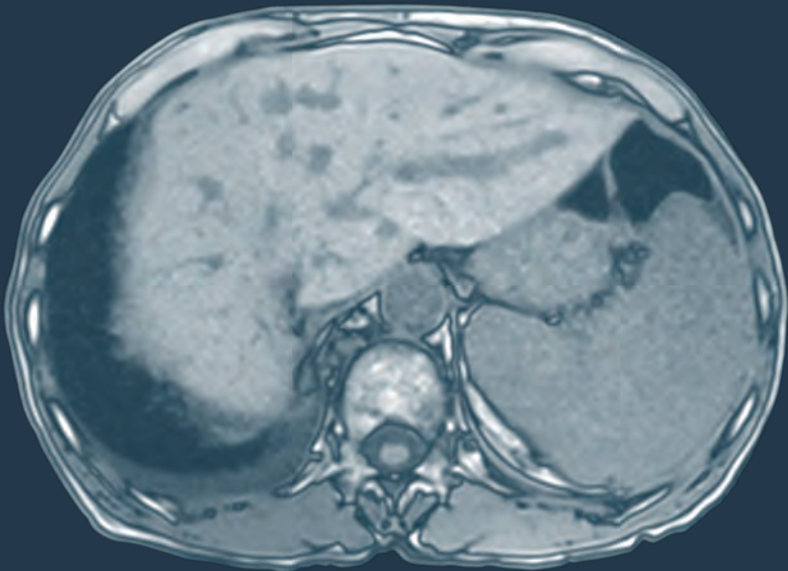
Weight

- 115kg (254 lbs)

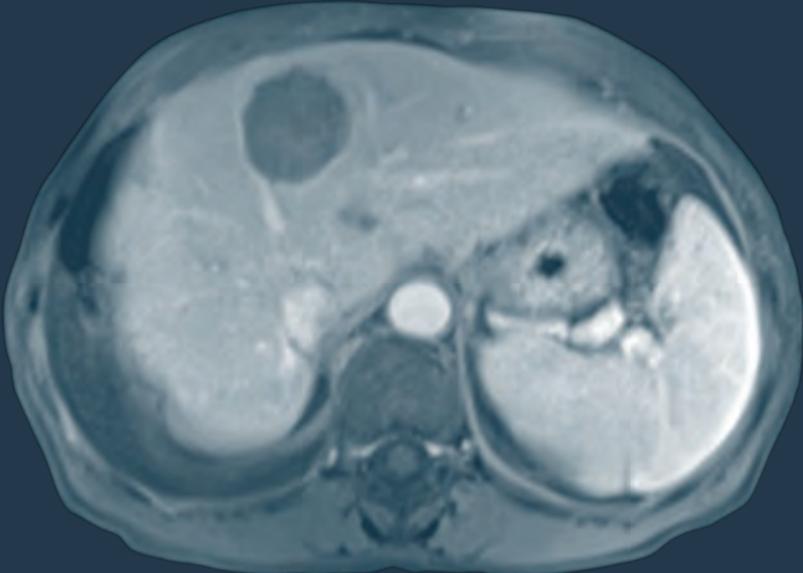
Electrical

- 120 V (US)/240 V (Europe)

Making the impossible, **possible.**



BEFORE



AFTER

*MRI series from a single patient in the THERESA Trial.
Vidal-Jove J, et al. Int J Hyperthermia. 2022;39(1):1115-1123.*

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1. Vlasisavljevich et al. Phys. Med. Biol. 2014;59(2): 253-70



16305 36th Ave N., Suite 300
Plymouth, MN 55446
877.740.0543 // histosonics.com

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FOCUS ON HISTOTRIPSY

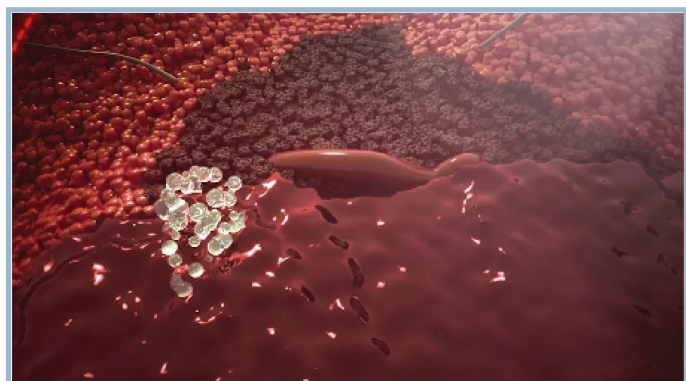
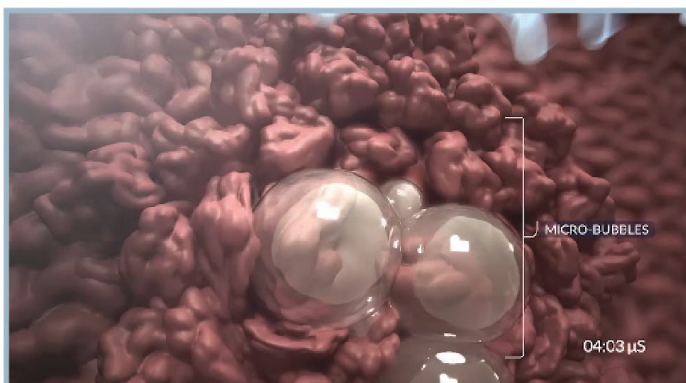
Bubbles have never been so powerful

THE SCIENCE

Histotripsy is a novel form of focused ultrasound that uses high amplitude, very short pulses designed to mechanically liquefy and destroy targeted tissue.

Specifically, as the focused ultrasound energy converges at a known focal point, high pressure causes extremely small, naturally occurring gas bubbles to expand many times larger through a phenomenon called acoustic cavitation.

As the ultrasound waves converge on the targeted tissue, the rapid expansion and collapse of the micro-bubbles forms a “bubble cloud” which imparts mechanical forces on the cells, resulting in instantaneous cell destruction and leaving behind an acellular lysate.



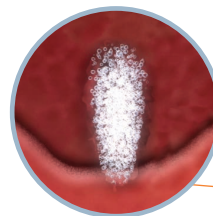
Histotripsy’s unique mechanism of action destroys targeted tissue only within the bubble cloud, which enables highly precise treatments while avoiding damage to non-targeted tissue. Histotripsy is performed non-invasively, and it does not use ionizing radiation or heat to destroy targeted tissue.



HARNESSING THE POWER

Using the Edison® System, the physician views real-time diagnostic ultrasound to localize the targeted tissue and to plan the treatment volume (including any margin the physician determines appropriate). During planning, the physician also establishes the minimum threshold voltage required to sustain the bubble cloud in the targeted tissue – this leverages histotripsy’s “threshold effect” that removes targeted liver tumors while tending to preserve collagenous vessels and ducts.¹

During treatment, the physician monitors treatment via real-time diagnostic ultrasound as the precision treatment arm continuously moves the bubble cloud automatically to encompass the entire planned treatment volume. The destructive effects of histotripsy is confined to the tissue within the planned treatment volume.



Rendering of histotripsy bubble cloud



POST-TREATMENT

After treatment has concluded, the physician uses live ultrasound to confirm treatment. The volume where soft tissue was mechanically destroyed will typically appear hypoechoic (dark). The images below demonstrate histotripsy results in (A1) a patient MRI and contrast-enhanced ultrasound demonstrating precision treatment and (A2) an immediate tissue response with preserved patent vessel traversing the treatment zone. The final images (A3) are of an ex-vivo animal model and are representative of collagen structures and larger vessels which tend to remain preserved after histotripsy.

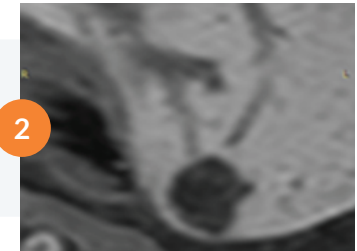
A1

Theresa Trial²

MRI images of pre and post liver tissue treatment.



Red circle designates the planned treatment area.



The treatment zone encompasses the planned treatment area but does not impact other tissue, including the adjacent liver capsule.

A2

Theresa Trial

Contrast-enhanced ultrasound (CEUS) pre and post liver tumor and tissue treatment.



Red circle designates the planned treatment area.

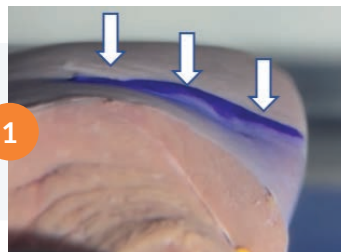


Hypoechoic appearance post-treatment.

A3

Benchtop Bovine Liver

Post liver tissue treatment.



Histotripsy treatment completed just below liver capsule, which remains intact.



Patent vessels traversing through treatment zone visualized after washout of acellular lysate.

REFERENCES

1. Vlaisavljevich E, et al. Effects of tissue mechanical properties on susceptibility to histotripsy-induced tissue damage. *Phys Med Biol.* 2014;59(2):253-270. doi:10.1088/0031-9155/59/2/253
2. Vidal-Jove J, et al. First-in-man histotripsy of hepatic tumors: the THERESA trial, a feasibility study. *Int J Hyperthermia.* 2022;39(1):1115-1123. doi:10.1080/02656736.2022.2112309

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