Edison Histotripsy System

September 2024

Device Overview

Histotripsy is the use of focused ultrasound therapy, delivered externally through short bursts, to break down tissue into acellular debris that is reabsorbed by the body. [1] It is non-ionizing, non-invasive, and non-thermal, utilizing acoustic cavitation (expanding then collapsing pre-existing microbubbles) to fracture cells. [1,2] Research indicates this allows for more precise margins, higher predictability, more accurate tissue selection protecting surrounding organs, as well as potentially creating immune response and abscopal effect (shrinking tumors in other parts of the body not directly targeted). [1,2,3] While histotripsy is being investigated for numerous clinical applications, currently the U.S. Food and Drug Administration has approved it for tumors of the liver only. [4,5] According to the manufacturer, the Edison System "delivers pulsed sound energy into the body, without any incisions or needles, and has the ability to destroy tumors at the sub-cellular level, all while the treating physician continuously monitors the 'bubble cloud' and treatment effect in real-time." [6]

Actions for Consideration

PARTNER

ENGAGE SUBJECT MATTER EXPERTS

Utilize interdisciplinary team in decision making including interventional radiology, oncology, surgery, nursing, value analysis leaders, and administration.

CONSIDER GUIDELINES FOR USE

Assess integration into existing treatment pathways as well as Tumor Board evaluations and recommendations. Create procedural protocols.

UNDERSTAND CONCERNS

Listen actively and ensure to provide closed loop feedback to outstanding deliverables prior to decision making.

CONNECT

SEEK CLINICAL IMPACT

Compare current treatment options for target population(s) and potential to impact outcomes. Review available research.

CONDUCT ANALYSIS

Reimbursement specialists will be beneficial when determining cost and insurance approvals. Include both clinical and financial impacts when weighing options.

DETERMINE POPULATION

Work with stakeholders to determine appropriate patient population(s) & setting(s) for treatment.

COMMUNICATE

EDUCATE AND TRAIN

Coordinate technology training, mock patient selection, and mock procedures with end users (physicians, nurses, and technicians).

PLAN AHEAD

Engage supplier who advertises best practice sharing as well as clinical case, tumor board, simulation, and implementation support. [7]

FOLLOW-UP FOR FEEDBACK

Include expected metric tracking & committee/admin/department report out cadence. Outline pathway for questions/concerns.

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Professional Society Statements & Clinical Practice Guidelines

Focused Ultrasound Foundation

The foundation offers research, advocacy, best practice, clinical standard, collaborative, regulatory, and reimbursement programs. Their website includes guidelines regarding immune analysis during focused ultrasound research, treatment reporting, and data sharing. They also include the "state of research and regulatory approval of focused ultrasound for more than 170 medical conditions." Found here. [8]

Regarding the use of focused ultrasound for liver tumors, they state the following:

"For certain patients, focused ultrasound could provide a noninvasive alternative to surgery with less risk of complications – such as surgical wound healing or infection – at a lower cost. It can reach the desired target without damaging surrounding tissue and is repeatable, if necessary. Focused ultrasound can also enhance the chemotherapy dose for the target, with less impact to the rest of the patient." [9]

Clinical Evidence

There are limited studies with direct use of histotripsy for liver tumors in human subjects. A sample of the available evidence is provided.

A 2019 multicenter phase I trial, THERESA Study, by Vidal-Jove et al. aimed to evaluate the technical effectiveness and safety profile of histotripsy in primary and secondary liver tumors. Of note, the authors state this was the first in-human trial. They targeted 11 unresectable end-stage tumors in 8 patients. Technical effectiveness was measured by tissue destruction per planned volume 1 day post procedure [assessed by magnetic resonance imaging (MRI)]. Device-related adverse events were evaluated for 8 weeks post-therapy. With an average target of 1.4cm of tumor diameter, all procedures were successful in achieving their target, and there were no identified adverse events. Additionally, tumor markers continued to decline in two patients over 8 weeks.

They concluded that liver tissue was effectively destroyed correlating with planned targets, and the therapy had a high safety profile with additional extensive multicenter trials needed to validate results. Limitations included heterogeneity in population and tumor types, failure to account for the impact of other underlying liver conditions, and short follow-up period. [10]

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Clinical Evidence, continued

The HistoSonic System for Treatment of Primary and Metastatic Liver Tumors Using Histotripsy (#HOPE4LIVER US) clinical trial, ClinicalTrials.govID-NCT04572633, aimed to evaluate the system's safety and efficacy. The single arm, prospective, non-randomized trial assessed subjects at < 36 hours post-procedure, followed them for 30 days, evaluated them at 6 months, and then annually for 5 years (not yet completed).

The primary efficacy target was technical success, defined as complete tumor coverage and treatment volume equal or greater to tumor targeted. The primary safety measure was procedure-related major complications (including device related events), defined as "Common Terminology Criteria for Adverse Events (CTCAE) grade 3 or higher toxicities observed up to 30-days post index-procedure." Of 40 subjects included, the results indicated 95.5% efficacy [95% Confidence Interval (CI) 83.72-100%] with a 6.8% complication rate (95% CI 2.35-18.23%).

Inclusion criteria, secondary outcomes measures, and other technical specifications can be found here. [11]

Systematic search terms: histotripsy, targeted ultrasound therapy, histonics, focused ultrasound therapy

Databases: Pubmed, CINAHL
Studies published from 2019-2024

Clinical Insights: Healthtrust Physician Advisors

A panel of general surgeons, oncologists, and interventional radiologists within our HealthTrust Physician Advisor Network offered the following insights with regard to use of the Edison Histotripsy System. [12]

Physician Insights

Utilized in primary & metastatic solid organ neoplasms.

Benefits include nonsurgical, noninvasive, and has the potential to change multiple treatment algorithms, replacing external beam radiation, proton beam, and laser systems in certain populations.

Risks include uncertain safety profile, bleeding, perforation of hollow viscus, embolism, increased imaging for serial follow-up, and potential for metastatic seeding.

Considerations for adoption include volume, cost, cure rate, demonstration of efficacy, safety, and peer acceptance.

There is a need for further safety, efficacy, and non-inferiority trials.

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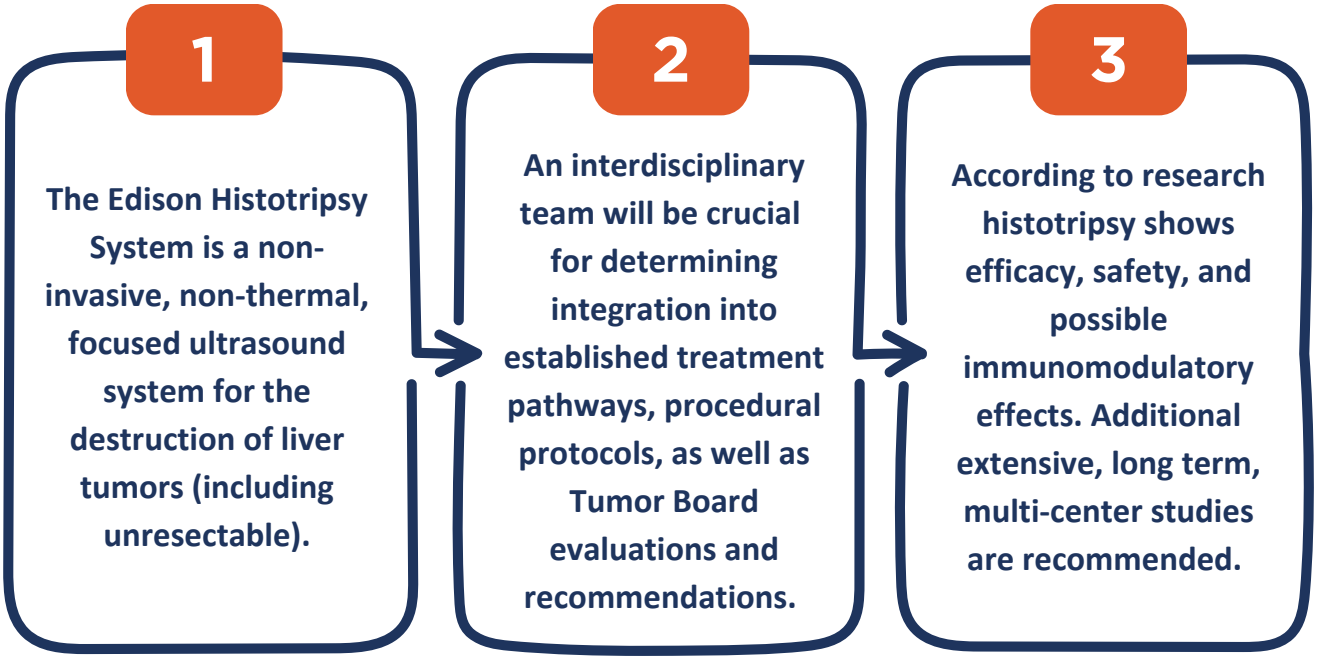
FDA Approval

The Edison Histotripsy System has FDA 510k approval (#K233466) as indicated for:

"...the non-invasive destruction of liver tumors, including unresectable liver tumors, using a non-thermal, mechanical process of focused ultrasound." Found here. [13]

The predicate device listed is the Edison System's prior Denovo classification (DEN220087) found here. [14]

Summary



HealthTrust Clinical Resources

Allow us to connect you with the resources you need. Examples for this category include resources on value analysis, physician engagement, and product trials.

ASK A QUESTION | PROVIDE YOUR FEEDBACK | SHARE YOUR VOICE | NETWORK WITH PEERS

PERSONALIZED REQUEST SERVICE & RESOURCE LIBRARY

www.hpginsights.com

PEER NETWORKING

www.huddle.healthtrustpg.com
App store: "HealthTrust Huddle"

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