HISTOTRIPSY PROCEDURE PLAN

HISTOSONICS®

Refer to the User Guide for important safety information and detailed operating instructions for the Histotripsy System (system).

MEDICAL CONSIDERATIONS

			IF YES: CONSIDER THE FOLLOWING
Does the Planned Treatment Volume (PTV) cover significant vasculature?	☐ Yes	☐ No	Need for anticoagulation—note whether the patient is already anticoagulated, or if intra-procedural anticoagulation (e.g., heparin 5,000 units) is planned
Does the patient have a compromised biliary sphincter? *(e.g., stent, prior sphincterotomy, or biliary-enteric anastomosis)*	☐ Yes	☐ No	Antibiotics (tailored approach based on risk factors)
Does the total volume of planned treatments or anticipated length of procedure warrant supportive measures?	☐ Yes	☐ No	Supportive measures (e.g., IV fluid hydration and/or Foley catheter)
On pre-op imaging, is bowel in the acoustic pathway and/or within or adjacent to the PTV?	☐ Yes	☐ No	Bowel preparation measures to reduce gas (e.g., bowel prep and/or gastric decompression)
Is the anticipated post-treatment liver reserve marginal or insufficient?	☐ Yes	☐ No	Reduce the number of treatment sessions and/or PTV dimensions, or stage treatment to preserve adequate liver reserve

PLANNED ANESTHESIA

(e.g., single lumen, double lumen, jet)

PLANNED TREATMENT SESSION OVERVIEW

Date

Imaging type ☐ CT ☐ MRI

Number of tumors planned

Tumor histology

How would you characterize the ultrasound appearance of the target tumor(s)? (Select all that apply)

☐ Hyperechoic ☐ Hypoechoic ☐ Isoechoic ☐ Poorly visualized/difficult to delineate ☐ Other (specify):

Will image fusion be used?

☐ Yes ☐ No ☐ Uncertain at this time

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TREATMENT SESSION DETAILS

This table outlines the planned treatment sessions, including treatment intent, tumor dimensions, required margin, and the resulting Planned Treatment Volume (PTV).
The PTV is calculated based on tumor dimensions plus the treatment margin, which includes both the planned margin and respiratory motion. |
The number of rows provided does not imply a maximum number of sessions.

	Intent		Segment	CT/MRI tumor size L x W x H (cm)	Ultrasound tumor size L x W x H (cm)	Target-muscle interface distance (cm)	Required margin (cm)	Residual respiratory motion (cm)	Total treatment volume (cm)
1	☐ Partial	☐ Complete							
2	☐ Partial	☐ Complete							
3	☐ Partial	☐ Complete							
4	☐ Partial	☐ Complete							
5	☐ Partial	☐ Complete							
6	☐ Partial	☐ Complete							

TREATMENT VOLUME CALCULATOR

TUMOR DIMENSIONS			TREATMENT MARGIN		TOTAL TREATMENT VOLUME (PTV + RESPIRATION)		
Length (cm)	Width (cm)	Height (cm)	Required margin (cm)	Residual respiratory motion (cm)	Length (cm)	Width (cm)	Height (cm)
					0	0	0

System-Enforced PTV Limitations

Limitations vary by version. Use the table below or the user guide to identify the applicable limits.

TREATMENT HEAD	MINIMUM PTV DIMENSIONS & VOLUME	MAXIMUM PTV DIMENSIONS & VOLUME	MAXIMUM DIMENSION RATIO
REF EDNTH0212 REF EDNTH0814	2.0 cm (4.19 cm^3)	4.0 cm (33.51 cm^3)	1.5:1
REF EDNTH12 REF EDNTH14	1.5 cm (1.80 cm^3)	4.0 cm (33.51 cm^3)	2:1

REGULATORY INFORMATION

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

The system is intended for the non-invasive mechanical destruction of liver tumors, including the partial or complete destruction of unresectable liver tumors via histotripsy.

The FDA has not evaluated the system for the treatment of any disease including, but not limited to, cancer or evaluated any specific cancer outcomes (such as local tumor progression, 5-year survival or overall survival). The system should only be used by persons who have completed training performed by HistoSonics or authorized provider, and its use guided by the clinical judgment of an appropriately trained physician. Refer to the device Instructions for Use for a complete list of warnings, precautions and a summary of clinical trial results, including reported adverse events.