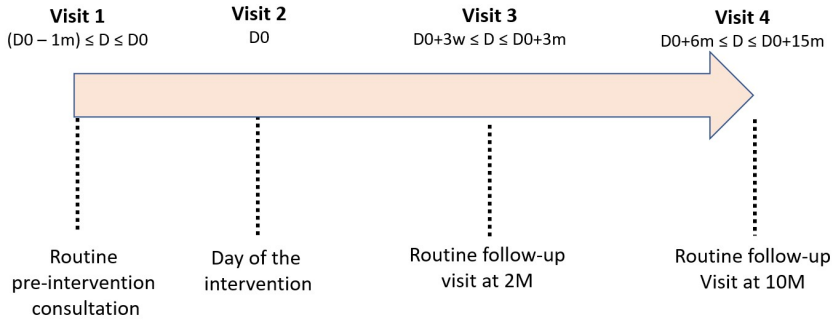
POST MARKET FOLLOW-UP STUDY OF A ROBOTIC DEVICE FOR IMAGE-GUIDED PERCUTANEOUS NEEDLE PLACEMENT IN THE ABDOMEN

Study title	Post Market Clinical Follow-up study of a robotic device for image-guided percutaneous needle placement in the abdomen
Study Number	QS-NIS-G-H-2101
Investigational product	EPIONE® device
Investigational product characteristics	The device is a user controlled, stereotactic accessory intended to assist in the planning and manual advancement of needle, as well as in verification of needle position during CT-guided percutaneous ablation procedures.
Investigational device administration	The operating principle of the investigational device is the following: pre-interventional CT-scan acquisition, planning with the device's software , needle's insertion according to the predefined planning, acquisition of a per-procedure CT-scan to evaluate the needle(s) placement.
Reference therapy/product	N/A
Study design	Post Market Clinical Follow-up study (PMCF) Non-interventional, prospective, non-comparative study
Number of sites & country	1 site in France
Sample size	Around 55 patients Around 55 CT-guided procedures in the abdomen
Indication	Percutaneous CT-guided procedures (tumor ablation, biopsy, …) in the abdomen (liver, kidney, …)

Primary objective	Evaluation of the technical success of the device
Primary endpoint	Number of targets reached; the target is considered to have been reached when the needle is positioned accurately enough to allow the planned procedure to be performed.
Secondary objective	Assessment of performance parameters and safety
Secondary endpoint	<u>Performance parameters</u> ○ Assessment of the needle placement accuracy ○ Assessment of the needle adjustments to reach the target ○ Assessment of post-intervention ablation success ○ Assessment of local tumor recurrence, ○ Operator satisfaction through a 5-points Likert scale question ○ Device dysfunction <u>Safety</u> ○ Adverse Event(s) (AEs)
Patient inclusion/exclusion criteria	<u>Inclusion criteria</u>: 1. Patient is >18 years old, 2. Patient for whom a CT-guided procedure in abdomen has been prescribed and agreed by a multidisciplinary team of radiologists, surgeons and clinicians, 3. Patient with a confirmed non-opposition. <u>Exclusion criteria</u>: 1. Patient unable to undergo general anesthesia, Pregnant or breast-feeding female
Visit schedule	<u>Schematic diagram of visit schedule:</u>  • <u>Visit 1: initial visit – patient screening (D0-1 month) ≤D≤D0</u> Review of inclusion and exclusion criteria, presentation of the study and the device (oral and written information for the patient). Paper information

	notice and non-opposition forms discussed with the patient allowing them sufficient time to consider the study's implications before deciding whether to participate. Next visit planned (day of the CT-guided intervention). • <u>Visit 2: inclusion visit – procedure day</u> <u>D0</u> - Confirmation of the non-opposition by the investigator, - Collection of demographic data, tumor data, primary cancer data as well as other medical history. Collection of concomitants pathologies/treatments. - Patient placed under general anesthesia. - Acquisition of the pre-interventional CT-guided image for the planning phase. - Insertion of the needle(s) to the targeted area with the subject device. - Acquisition of the per-procedure image under CT guidance. - Validation of the correct positioning of the needle(s). - Acquisition of the post-interventional CT-guided image. • <u>Visit 3: post-intervention follow-up visit at 2 months</u> <u>(D0+3 weeks≤D≤D0+3 months)</u> Acquisition of an image (CT-guided or MRI) of the organ to evaluate ablation site recurrence (local tumor recurrence) and possible AEs. • <u>Visit 4: post-intervention follow-up visit at 10 months</u> <u>(D0+6 months≤D≤D0+15 months)</u> Acquisition of an image (CT-guided or MRI) of the organ to evaluate ablation site recurrence (local tumor recurrence) and possible AEs.
Study duration per patient	From patient's information and non-opposition form signature to visit 4. From 6 months to 16 months, depending on the day of patient's non-opposition confirmation and the day of the visit 4.
Study schedule	Planned start: Q1 2022 Planned recruitment time: 18 months Planned last patient out: Q1 2024
Randomization/ blinding	No randomization, open label
DSMB	Non
GCP statement	This study will be conducted in compliance with the protocol, the current version of the Declaration of Helsinki, the ICH-GCP and ISO EN 14155 as well as all national legal and regulatory requirements.