CLINICAL INVESTIGATION SYNOPSIS

EGLE study

Prospective clinical investigation on the evaluation of performance and safety of the EPIONE assisted CT-guided percutaneous procedures in the lungs

Clinical investigation plan: CA-LU-CIP-0019-Rev3

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Entity funding the study	Quantum Surgical SAS

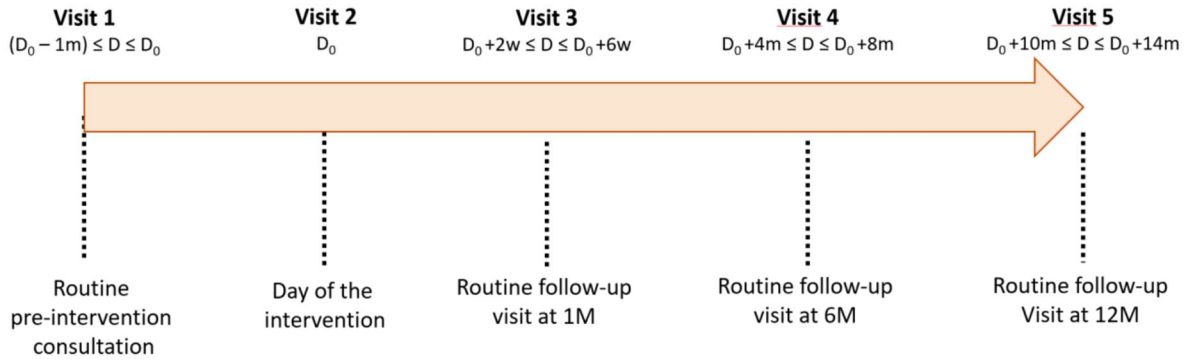
Revision History

Rev.	Description	Date	Author
A	Creation of the document in English from CA-LU-CIP-0019-Rev3	26-May-2025	Marion CHASSOUANT

Signatures

Role	Name	Date	Signature
Clinical Project Leader	Marion CHASSOUANT	26-May-2025	Signed on DocuSign
Clinical representative	Silène LAUNAY	26-May-2025	Signed on DocuSign

Full study title	Prospective clinical investigation on the evaluation of performance and safety of the EPIONE assisted CT-guided percutaneous procedures in the lungs
Brief study title	EGLE study
Study design	Clinical investigation of a CE marked device, used outside of its current indication, for an extension of the indication to the lungs. Interventional, prospective, non-randomized, non-comparative, single arm study
Study category	Category 1 according to ANSM categorization
Study centres	**Gustave Roussy Cancer Center** Therapeutic Imaging Department 114 rue Edouard Vaillant 94800 Villejuif FRANCE
Purpose of the clinical investigation	The Epione device is a robotic device that assists the physician during CT-guided percutaneous treatment. This device is validated in clinical practice for abdomen. The aim of this clinical investigation is to confirm in patients the accuracy and safety of the Epione device designed to assist radiologists during percutaneous procedures the lungs and thus, extend the Epione indication.
Primary objective and endpoint	**Primary objective**: Evaluation of the feasibility of the EPIONE device in assisting needles insertion in CT-guided intervention in the lungs. **Primary endpoint:** The primary feasibility endpoint is the technical success of the intervention per lesion.
Secondary objectives and endpoints	**Secondary objectives:** Evaluation of safety and performance parameters **Secondary criteria:** Safety • Adverse Event(s) (AE): all AEs (serious and non-serious, including deficiency or dysfunction) and AEs related to the device or the intervention. Performance • Assessment of the needle placement accuracy through an estimation of the distance from the needle inserted and the predefined planning; • Assessment of the number and the grade of needle adjustments to achieve technical success; • Assessment of post-intervention ablation success (ablation only); • Assessment of local tumor progression.
Eligibility criteria	Inclusion criteria • Patient ≥18 years, • Patient for whom a percutaneous CT-guided intervention in lung has been prescribed and agreed by a multidisciplinary team of radiologists, surgeons and clinicians, • Patient with a signed informed consent form. • Patient covered by a social security system.

	Exclusion criteria • Patient unable to undergo general anesthesia, • Pregnant or nursing female, confirmed before the intervention • Patient already participating in another clinical study
Device and comparator	The Epione investigational device is a user controlled, stereotactic accessory intended to assist in the planning and manual advancement of one or more instruments, as well as in verification of instrument position during Computed Tomography (CT) guided percutaneous procedures. The Epione device is composed of 3 main components (Robot cart, Display cart with software and Navigation cart) and 3 instruments (Introducer guide, Patient reference and Navigation probe). There is no comparator.
Procedures to use the device	The operating principle of the subject device is the following: • pre-interventional CT-scan acquisition • planning with the device's software (choice of the needle's trajectory to reach the targeted point) • needle's insertion according to the predefined planning • acquisition of an per-intervention CT-scan to evaluate the needle(s) placement.
Study flowchart	Schematic diagram of visit schedule:  • **Visit 1: initial visit – patient screening (D0-1 month) ≤D≤ D0** Prior to the intervention, interventional radiologists perform a pre-intervention consultation with the patient. During the consultation, a review of inclusion and exclusion criteria is performed, presentation of the study and the device (oral and printed information for the patient). Paper information notice and informed consent forms are read and given to the patient with sufficient time to consider the study's implications before deciding whether to participate. Next visit planned (day of the CT-guided intervention). • **Visit 2: inclusion visit –Day of the intervention D0** Retrieval of the signed informed consent form by the investigator (signed by the patient and the investigator), confirmation of enrollment and validation of screening (inclusion and non-inclusion criteria are confirmed), 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-intervention CT-guided image of the lungs. Confirmation of the prescribed CT-guided intervention realization (if the intervention is not maintained, the patient's exit from the study, for screening failure). Planning with the subject device to visualize the path of needle(s) to the target. Planning validation by the investigator and then insertion of the needle(s) to the targeted area with the subject device. Acquisition of the per-intervention image under CT guidance. Validation of the correct positioning of the needle(s). Completion of the CT-guided intervention with a needle routinely used by the investigator. Acquisition of the post-intervention CT-guided image and evaluation of possible adverse events. in case of interventions on multiple lesions, the absence of a non-reduced major pneumothorax must be confirmed to use the device again for the next intervention. In case of interventions performed on different days on or both lungs treated on two different days, the additional intervention day will be added to the D0 sheet. • **Visit 3: post-intervention follow-up visit at 1 month (D0+2 weeks ≤ D ≤ D0+6 weeks)** Follow-up of AEs related to the intervention and record of possible new AE/SAEs. Review of the acquired image (CT-scan or equivalent) of the lungs to evaluate for ablation the ablation site local tumor progression and establish a baseline situation of the treated tumor. • **Visit 4: post-intervention follow-up visit at 6 months (D0+4 months ≤ D ≤ D0+8 months)** Review of the acquired image (CT-scan or equivalent) of the lungs to evaluate ablation site local tumor progression and evaluation of possible AE/SAEs. • **Visit 5: post-intervention follow-up visit at 12 months (D0+10 months ≤ D ≤D0+14 months)** Review of the acquired image (CT-scan or equivalent) of the lungs to evaluate ablation site, local tumor progression and evaluation of possible AE/SAEs.
Sample size	25 patients
Randomisation and blinding	Not applicable.
Statistical analysis method	The statistical analysis will be performed by an external CRO (Delta Data Consultants, Eybens, France). All statistical analyses will be produced using SAS® 9.4 software (Cary, NC, USA).).
Study duration per patient	From patient's informed consent form signature to visit 5. From 10 months to 15 months, depending on the day of patient's signed informed consent retrieval and the day of the visit 5: • 10 months if the patient informed consent form is collected the day of the intervention, and the last visit is performed at the beginning of the time window (10 months) • 15 months if the patient informed consent form is collected at the initial visit 1 month before the intervention, and the last visit performed at the end of the time window (15 months)
Study schedule	Planned start: October 2022 Planned recruitment time: 6 months Planned last patient out: Q1 2024