CLINICAL INVESTIGATION SYNOPSIS

EPIBONE study

Evaluation of the EPIONE robotic system for image-guided percutaneous bone procedures
A prospective study on feasibility, safety and accuracy

Clinical investigation plan: CA-BO-CIP-0060

Effective date	*05-JUN-2024*
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Entity funding the study	Quantum Surgical SAS

Revision History

Rev.	Description	Date	Author
A	Creation of the document	16-JUL-2024	Silène LAUNAY
B	Protocol amendment including: - Deletion of eligibility criterion number 5 - Addition of a note on eligibility criteria	08-OCT-2024	Silène LAUNAY

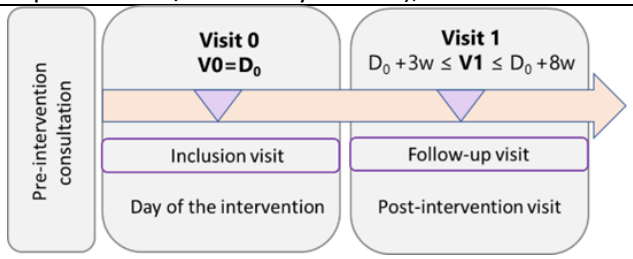
Signatures

Role	Name/Nom	Date	Signature
Clinical Project Leader	Silène LAUNAY	08-OCT-24	
Clinical Chief Operator	Laetitia MESSNER	08-OCT-24	

Full study title / Titre complet de l'étude	Evaluation of the Epione robotic system for image-guided percutaneous bone procedures A prospective study on feasibility, safety and accuracy
Brief study title Titre abrégé de l'étude	EPIBONE study
Study design / Design de l'étude	Multicentric, prospective, non-comparative study
Study category / Catégorie de l'étude	Category 1 according to ANSM categorization
Study centres / Centres investigateurs	**Gustave Roussy Cancer Center** Therapeutic Imaging Department 114 rue Edouard Vaillant 94800 Villejuif FRANCE **HCL Hospices Civils de Lyon** Medical Imaging Department Quai Celestins 69002 Lyon FRANCE **Institut Paoli Calmette** Medical Imaging Department 232 Boulevard de Sainte-Marguerite 13009 Marseille FRANCE
Purpose of the clinical investigation / Objectif de l'investigation clinique	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 and lung. The state of the art in percutaneous bone procedures and the observation of current practices highlighted the need to explore the use of the Epione device in this new indication. The aim of this clinical investigation is to confirm in patients the performance and safety of the Epione device designed to assist radiologists during percutaneous procedures in musculo-skeletal structures in view of the satisfactory results obtained during preclinical tests.
Primary objective and endpoint / Objectif et critère d'évaluation primaire	**Primary objective**: Evaluate the feasibility of the Epione robotic assistance for bone percutaneous procedures. **Primary endpoint:** successful instrument insertion with the Epione device
Secondary objectives and endpoints / Objectifs et critères d'évaluation secondaires	**Secondary objectives:** • Evaluate the safety of the Epione robotic assistance for bone percutaneous procedures • Evaluate the accuracy of the Epione robotic assistance for bone percutaneous procedures **Secondary criteria:**

	• Adverse event(s) (AE): all AEs (serious and non-serious, related and not-related to the device or the procedure(s))
	• Lateral and angular deviations:
	  ○ distance (mm) between the tip of the inserted instrument in its final position and its orthogonal projection on the first planned trajectory.
	  ○ and angle (°) between the tip of the inserted instrument in its final position and the first planned trajectory. (the special case of using a rod through the introducer is described in the protocol)

Eligibility criteria / Critères d'éligibilité	Inclusion criteria • Patient ≥18 years, • Patient approved for CT-guided percutaneous bone procedure under general anaesthesia at a multidisciplinary consultation meeting, • Patient who has signed an informed consent form, • Patient covered by a social security system • Patient who has already been included in the EPIBONE study for one or more given musculoskeletal disorders and for whom a new location is targeted for a CT-guided procedure that can be assisted again by the EPIONE device. Exclusion criteria • Patient unable to undergo general anaesthesia, • Patient offered a procedure without appropriate breathing control, • Patient approved for CT-guided percutaneous procedures on head and neck, including skull and cervical vertebrae • Patient unable to fully understand all relevant aspects of the clinical study necessary for his/her decision to participate, or who could be manipulated or unduly influenced as a result of a compromised position, expectation of benefits or fear of retaliatory response • Pregnant or breast-feeding women, • Patient subject to a legal protection measure, • Patient already participating in another interventional clinical study,
Device and comparator / Dispositif et comparateur	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 device is indicated for use with rigid straight instruments such as needles and probes used in CT-guided interventional procedures performed by physicians trained for CT procedures on musculoskeletal structures. 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). During the planning phase, the desired instrument placement and performance is defined relative to the target anatomy. During the guidance phase, the device enables to monitor respiratory levels and verify patient position prior to instrument advancement. During the assessment phase, the achieved instrument placement and performance are displayed relative to the previously defined plan through an overlay of the pre- and post-treatment image data.

	There is no comparator.
Procedures to use the device / Procédure d'utilisation du dispositif	The Epione device must be used in accordance with the instructions given in the study investigator brochure (CA-BO-IBR-0068). The device is a medical device reusable, non-sterile intended to be mobile. The 3 instruments of the system (guide to introduce, patient reference and navigation probe) are reusable and must be cleaned and sterilized after each use. The user of the device is a Doctor specialized and trained in CT-guided interventional procedures. Procedures that can be carried out using the instrument inserted into the human body with Epione's assistance include thermal ablations, biopsies and bone consolidation procedures (osteoplasties and/or osteosyntheses), either alone or in combination.
Study flowchart / Organigramme de l'étude	 The interventional radiologist will explain to the patient the planned procedure(s) and will present the response plan and its different steps during a pre-intervention consultation. The investigator: - will present the study and the device to the patient (oral and written information), -will review the inclusion and non-inclusion criteria of the study, and assess the patient's eligibility for the study, - Will provide the information letter and informed consent form to the patient, who must be able to read them and have time to think about his or her potential participation in the study prior to consent. . Demographics/medical data prior the intervention will be collected the day of the intervention if the patient returns a signed consent form and the investigator confirms the eligibility criteria. No data will be collected while prior intervention consultation, before signature of the written consentment.
Sample size / Taille de l'échantillon	The size of the sample of at least 67 insertions was calculated to assess the non-inferiority of the successful insertion rate of the introducer (with the help of EPIONE), using a reference proportion of 96% and with a non-inferiority threshold of 0.08 under the assumption of 97% of feasibility for the study. In line with centers practice, that is to say an average of 2 insertions per patient (different locations of possible musculoskeletal disorders, different possible treatments during the same procedure), it is planned to include a minimum of 34 patients in this study.
Randomisation and blinding / Randomisation et aveugle	Not applicable.

Statistical analysis methods / Méthode d'analyses statistiques	The statistical analysis will be performed at risk 0.05 and a power of 80%. The outcome of the primary endpoint will be assessed by a non-inferiority test compared to the results of the preclinical study. The primary endpoint analysis will be performed on the mITT population (modified Intention to Treat population). The security analysis will be carried out on the security population. A statistical analysis plan will be drafted and validated before the database is locked. Quantitative variables will be described using frequencies of missing and non-missing data, means, standard deviations, medians, quartiles, minimums and maximums. Qualitative variables will be described using the frequency of non-missing andof shortages, frequency and percentage by modality
Study duration per patient / Durée de l'étude par patient	The average duration of a patient's participation in the study is 1 month. The patient's participation will be of a minimum of 3 weeks or a maximum of 8 weeks.
Study schedule / Agenda de l'étude	Inclusion start time: Beginning of Q3 2024 Inclusion period: 6 months End of study visit of the last patient: end of Q1 2025/ Beginning of Q2 2025.