JET Enhanced Thrombectomy Intervention Hong Kong Post Market Study

Study Protocol including Statistical Analysis Plan (SAP)

NCT06340763

August 26, 2024

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JETi Hong Kong Post Market Study (PMS)
Clinical Investigation Plan
JET Enhanced Thrombectomy intervention Hong Kong Post Market Study

Version Number	[redacted]
Date	[redacted]
Planned Number of Sites and Regions	Approximately 5 sites in Hong Kong
Planned Number of Subjects	Approximately 20
Clinical Investigation Type	A single-arm, multi-center study
Abbott Medical Expert	[redacted]
Sponsor	Abbott Medical [redacted]
Clinical Investigation Monitor	Abbott
Electronic Data Capture Software	Oracle Clinical
Core Laboratories	[redacted]
Clinical Event Committee Administration	[redacted]
CIP Author of Current Version	[redacted]

SITE PRINCIPAL INVESTIGATOR SIGNATURE PAGE

I have read and agree to adhere to the clinical investigation plan and all regulatory requirements applicable in conducting this clinical investigation.

Site Principal Investigator

Printed name:
Signature:
Date:

STUDY PRINCIPAL INVESTIGATOR
SIGNATURE PAGE

I have read and agree to adhere to the clinical investigation plan and all regulatory requirements applicable in conducting this clinical investigation.

Study Principal Investigator

Printed name:
Signature:
Date:

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COMPLIANCE STATEMENT:

This clinical investigation will be conducted in accordance with this Clinical Investigation Plan (CIP), the Declaration of Helsinki, applicable Good Clinical Practices (GCP) and regulations (ISO14155:2020) and the appropriate local legislation(s). The most stringent requirements, guidelines or regulations must always be followed. The conduct of the clinical investigation will be approved by the appropriate Institutional Review Board (IRB)/Ethics Committee (EC) of the respective investigational site and by the applicable regulatory authorities.

1 INTRODUCTION

The JET Enhanced Thrombectomy intervention (JETi) Hong Kong Post Market Study (PMS) is a post-market study designed to collect real-world data on the safety, performance, and clinical benefits of the JETi™ Hydrodynamic Thrombectomy System (HTS) (will be refer to as JETi System throughout this document) for the treatment of acute/subacute thrombosis in the peripheral vasculature.

The JETi System is a hydro-mechanical aspiration system manufactured by Abbott Medical, consisting of a catheter, pump set, and accessories. The system is intended to remove/aspirate fluid and break-up soft emboli and thrombus from the peripheral vasculature and to subselectively infuse/deliver diagnostics or therapeutics with or without vessel occlusion.

Several published studies have shown that the JETi System is safe and effective in the peripheral vasculature. In a retrospective study[1] of 18 consecutive patients with thrombus in the iliofemoral, axillosubclavian, and portal veins, mean thrombus reduction with JETi alone was 92%. Procedural success was 100%, and technical success with the JETi alone was 76%; 24% of procedures requiring subsequent catheter directed thrombolytics (CDT) overnight. One subsegmental pulmonary embolism (PE) event was reported. In another study, 30 patients with acute lower extremity deep vein thrombosis (DVT), including iliocaval, iliofemoral, and femoropopliteal) were treated with the JETi System.[2] Technical success was 93.3%, and mean thrombus removal was 74.0%. No major complications were observed. In a prospective pilot study conducted in 47 patients with thrombus in the iliocaval or iliofemoral veins treated in a single session with the JETi System, unobstructed flow was reestablished in 87% of patients with no major adverse events through 30 days.[3] In addition to these studies reporting on venous thromboses, a recent presentation by Dandu et al.[4] reported on a retrospective review of 27 patients treated for acute lower extremity ischemia. The success rate of all interventions in which the JETi System was used was 85%.

The JETi Hong Kong PMS is a single-arm, multi-center study registering approximately 20 subjects from up to 5 sites in Hong Kong. Both prospective and retrospective consent (if all assessments needed for primary endpoints are complete) are permitted. In cases of prospective consent, subject participation will be up to 30 days. If consent occurs after the procedure, duration of participation may vary given timing of consent but will not exceed 30 days.

This study will collect data on how the JETi System performs in the treatment of patients undergoing a percutaneous thrombectomy procedure for peripheral thrombosis. Subjects treated for arterial, venous, or arteriovenous thromboses, and subject with diagnoses such as acute limb ischemia (ALI), chronic limb ischemia/chronic limb threatening ischemia (CLI/CTLI), peripheral artery disease (PAD), deep vein thrombosis (DVT), hemodialysis access thrombosis, and others may be included. The details of data to

[1] Cournoyer-Rodrigue J, Bui TB, Gilbert P, et al. Percutaneous Thrombectomy with the JETi8 Peripheral Thrombectomy System for the Treatment of Deep Vein Thrombosis. *J Vasc Interv Radiol*. 2020;31(3):444-453.e2. doi:10.1016/j.jvir.2019.10.022
[2] Khalsa B., Luu K., Gilbert B., et al. Single-session treatment of lower extremity venous thrombosis using a novel thrombectomy device: results of a pilot study. *J Vasc Interv Radiol,* 2020; 31(3):S83. doi:10.1016/j.jvir.2019.12.217
[3] Razavi C, Khalsa B, Openshaw L, Razavi MK. Single-Session Treatment of Patients with Symptomatic Iliocaval and Iliofemoral Deep Vein Thrombosis: Technical Results of a Prospective Pilot Study. *J Vasc Interv Radiol*. 2022;33(2):183-188. doi:10.1016/j.jvir.2021.10.011
[4] Dandu C, Natour A, Onofrey K, et al. Single-Center Experience with JETi Aspiration Thrombectomy for Acute and Subacute Lower Limb Ischemia. Presented at the Vascular Annual Meeting (VAM), June 2022.

be collected and the timepoints for the purpose of this study are described in this plan. Each participating investigator will determine and implement the best treatment strategy for their patients based on the clinical situation and local physician practices. This study will be conducted in accordance with this CIP. All investigators involved in the conduct of the study will be qualified by education, training, and experience to perform their tasks and this training will be documented appropriately.

2 CLINICAL INVESTIGATION OVERVIEW

2.1 Clinical Investigation Objective

The objective of the JETi Hong Kong PMS is to collect real-world data on the safety, performance, and clinical benefits of the JETi System for the treatment of thrombosis in the peripheral vasculature.

2.2 Device Used in the Clinical Investigation

2.2.1 JETi Hydrodynamic Thrombectomy System

This post market study includes commercially available JETi Hydrodynamic Thrombectomy System at participating sites.

2.2.2 Indication for Use

The JETi Hydrodynamic Thrombectomy System is intended to remove/aspirate fluid and break-up soft emboli and thrombus from the peripheral vasculature and to subselectively infuse/deliver diagnostics or therapeutics with or without vessel occlusion.

2.2.3 Description of the Device

The JETi Hydrodynamic Thrombectomy System is a hydro-mechanical aspiration system intended for the removal of intravascular thrombus. The system is comprised of the JETi Catheter, JETi Pump Set, and JETi Saline Drive Unit (SDU), accessory cart, suction tubing, and non-sterile canister set. The JETi System is designed to simultaneously deliver a stream of high-pressure saline via a displacement pump to the distal tip of the JETi Catheter, while aspirating thrombotic material macerated by the saline stream. A thorough understanding of each component in the JETi System is required for proper operation. Please refer to the electronic Instructions for Use (eIFU) before attempting to use any part of the JETi System.

3 CLINICAL INVESTIGATION DESIGN

The JETi Hong Kong PMS is a single-arm, multicenter study to collect real-world data on the safety, performance, and clinical benefits of the JETi System for the treatment of acute and subacute thrombosis in the peripheral vasculature. This is a post-market study that will register approximately 20 subjects at approximately 5 centers in Hong Kong. Both prospective and retrospective consent (if all assessments needed for the primary endpoints are complete) are permitted. Subjects participating in this study will be followed for up to 30 days [redacted].

[redacted]

[redacted] After index procedure, subjects will be evaluated at discharge and 30 days in cases of prospective consent. [redacted]

The Sponsor has designed this study to involve as little pain, discomfort, fear, and any other foreseeable risks as possible for subjects. Refer to the Risks Analysis section (**Section 15.0**) of this clinical investigation plan for details.

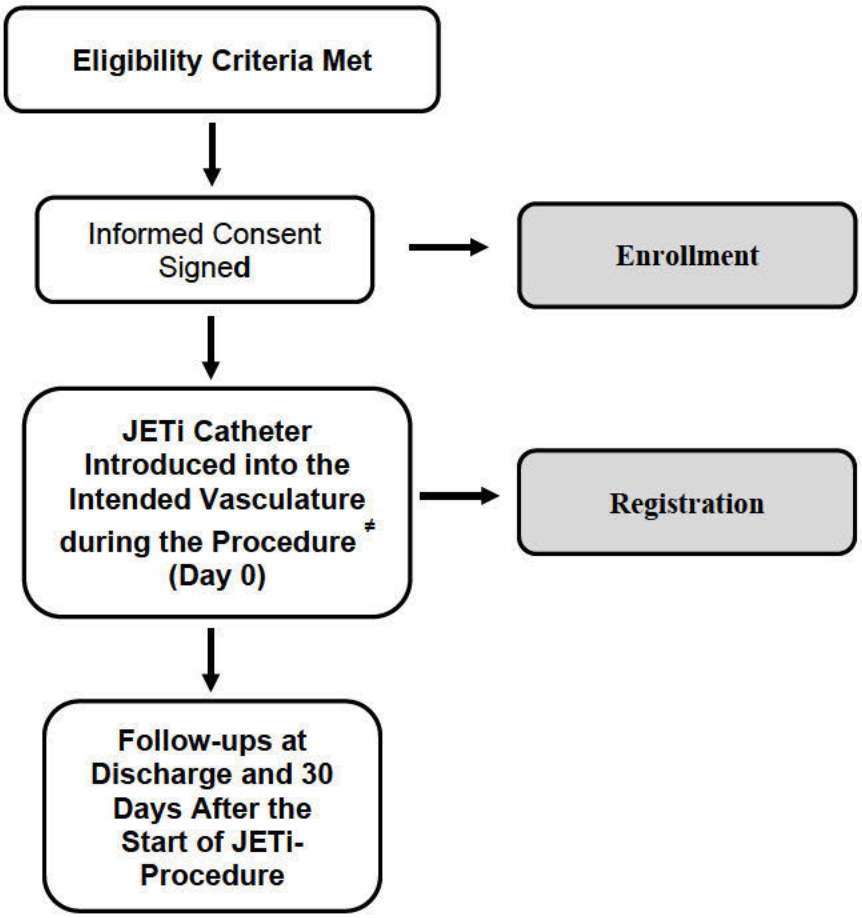
3.1 Clinical Investigation Procedures and Follow-up Schedule

The study flowchart is shown in **Figure 1,** and the follow-up requirements are described in this section. After meeting all eligibility criteria, a subject is considered enrolled in the study from the moment the subject provides written informed consent. The point of registration in the study is when a JETi Catheter is introduced into the intended vasculature of an enrolled subject during the procedure (Day 0).

A subject who is enrolled but not registered in this study will be considered a screen failure. Consenting after the JETi procedure is deemed acceptable if all assessments needed for primary endpoints were completed at baseline. In the cases of retrospective consent, the point of registration will be the same and any procedural information would be entered post-consent and defined adverse events (AEs) will be collected retrospectively from the point of registration. All registered subjects will be followed for up to 30 days in cases of perspective consent and will vary for retrospective consent. Registered subjects will be evaluated, and data will be collected at baseline, procedure, discharge, and at 30 days after Day 0.

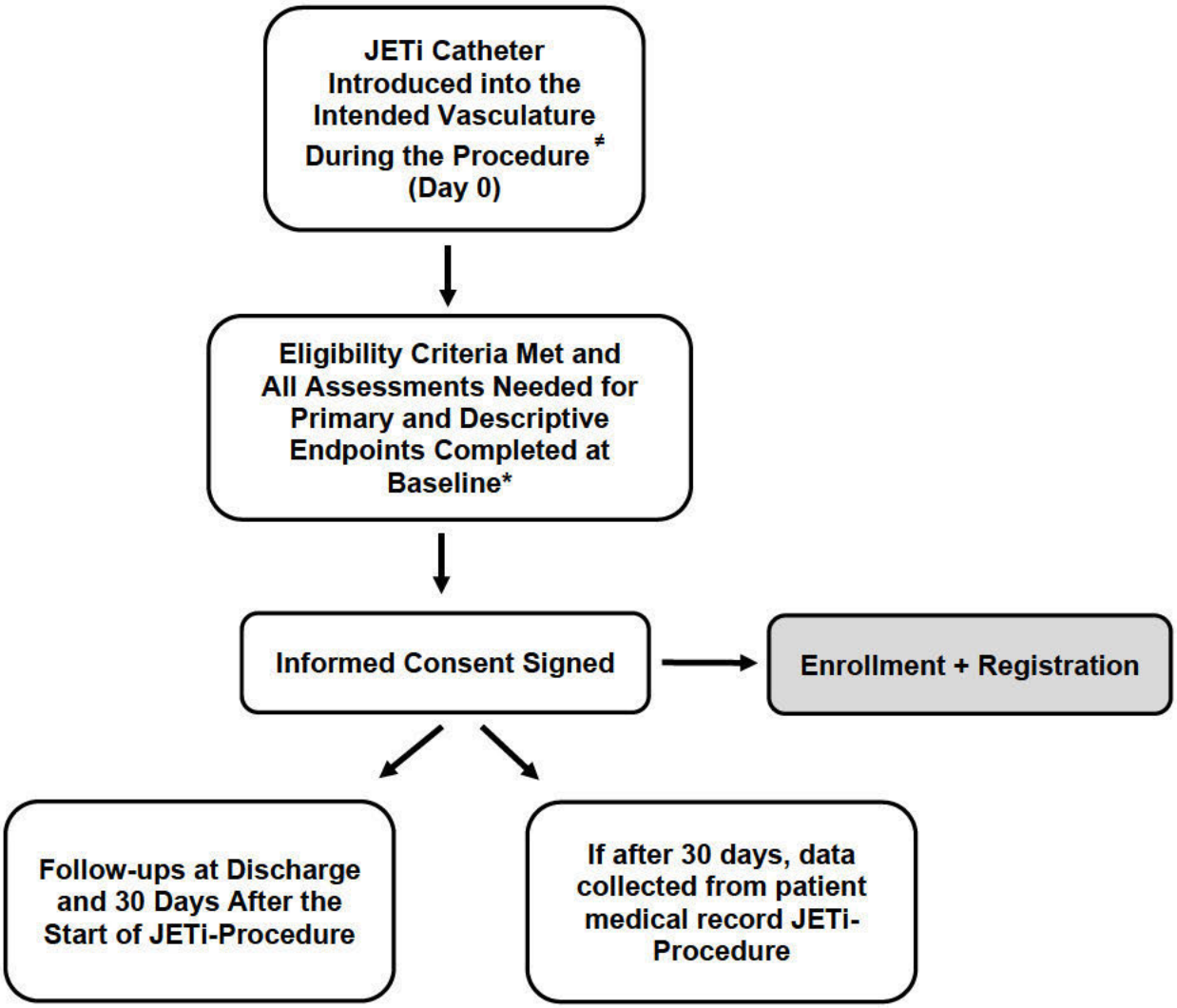
Figure 1: Study Flowchart

a) Prospective consent



≠ procedure performed in the treatment of patients undergoing a percutaneous thrombectomy procedure for peripheral arterial, venous, and arteriovenous thrombosis

b) Retrospective consent*



≠ procedure performed in the treatment of patients undergoing a percutaneous thrombectomy procedure for peripheral arterial, venous, and arteriovenous thrombosis

*Consenting after the index procedure is acceptable if all assessments needed for primary endpoints are complete

3.2 Measures Taken to Avoid and Minimize Bias

An independent core laboratory will be used for imaging data analysis to minimize bias. All angiograms and venograms (pre-JETi, post-JETi, and final) and duplex ultrasound (DUS) images will be sent to the core laboratory for analysis. See **Section 6.3** for details. In addition, a Clinical Events Committee (CEC will be included for adjudication of safety events.

3.3 Suspension or Early Termination of the Clinical Investigation

The Sponsor reserves the right to discontinue the study at any stage or reduce the follow-up period with suitable written notice to the investigator. Should the Sponsor discontinue the study, sites will follow subjects per routine hospital practice with device-, and procedure-related AEs reported to the Sponsor as per vigilance/commercial reporting requirements. The investigator shall return all study materials to the Sponsor and provide a written statement to the IRB/ EC (if applicable). All applicable study documents shall be subject to the same retention policy as detailed in **Section 11.5** of the CIP.

If the Sponsor suspends or prematurely terminates the study or suspends or prematurely terminates at an individual site in the interest of safety, the Sponsor will inform all other Principal Investigators. If suspension or premature termination occurs, the Principal Investigator or authorized designee will promptly inform the registered subjects at his/her site. A Principal Investigator, IRB/EC, or regulatory authority may also suspend or prematurely terminate participation in the study at the investigational site(s) for which they are responsible. The investigators will follow the requirements specified in the Clinical Trial Agreement.

4 ENDPOINTS

All endpoints are descriptive. There will be no hypothesis testing, and there are no statistical power considerations.

4.1 Primary Endpoints

4.1.1 Arterial and Arteriovenous Subjects

For subjects treated for arterial thrombosis (may include diagnoses such as acute limb ischemia, chronic limb ischemia/chronic limb threatening ischemia, peripheral artery disease, etc.) or arteriovenous (AV graft, AV fistula) thrombosis, all endpoints are descriptive.
For subjects treated for arterial or arteriovenous thrombosis, the primary endpoints are:

- **Clot removal grade** for each JETi-treated target vessel from pre-JETi angiogram to post-JETi angiogram (post-JETi thrombectomy and prior to any adjunctive therapies to treat underlying culprit lesions) per the grades in **Table 1** (vessel basis). The independent imaging core laboratory will be responsible for assessing this endpoint.
- **Composite of JETi-related major adverse events** (MAEs) up to 30 days post-JETi procedure, defined as the following JETi-related events adjudicated by a clinical events committee (CEC) (subject basis) death, major amputation of the treated limb, or major bleeding. Refer to **Appendix II** for definitions of major adverse events.

Table 1. Clot Removal Grade

Grade I	< 50% reduction
Grade II	50- <95% reduction
Grade III	95 - 100% reduction

4.1.2 Venous Subjects

For this study, lower extremity deep vein thrombosis or deep venous thrombosis is defined as lower extremity venous thrombosis involving the femoral, common femoral, iliac, popliteal, or inferior vena cava (IVC) alone or in combination.

For subjects treated for lower extremity DVT, the primary endpoints are:

- **Percent of treated vessel(s) with ≥ 75% venous thrombus reduction** from pre-JETi venogram to final venogram (post-JETi AND after any/all adjunctive therapies to treat underlying culprit lesions) via modified Marder score (limb basis). The independent imaging core laboratory will be responsible for assessing this endpoint.
  If no adjunctive therapies or devices are used after JETi, post-JETi modified Marder score is also final score.

  [redacted]

- **Composite of JETi-related major adverse events** (MAEs) up to 30 days post-JETi procedure, defined as the following JETi-related events adjudicated by a clinical events committee (CEC): death, symptomatic pulmonary embolism (PE), major bleeding, or re-thrombosis of JETi-treated vessel(s). Refer to **Appendix II** for definitions of major adverse events.

[redacted]

The effectiveness outcome for subjects treated for venous thrombosis that is not lower extremity DVT as defined in Appendix II (e.g., upper extremity DVT) will be assessed by clot removal grade, as defined in Section 4.1.1.

4.2 Descriptive Endpoints

4.2.1 All subjects

- Procedure-related death as adjudicated by a CEC.
- JETi-related AEs collected during JETi procedure, at discharge, and 30-day follow-up, as adjudicated by a CEC.
- Procedure-related access site complications such as hematoma, pseudoaneurysm (false aneurysm), perforation, as adjudicated by a CEC.
- **Treatment Used:** The number and percentage of patients having each of the following treatments:

- JETi mechanical thrombectomy (MT) only
- JETi in combination with one or more of the following treatments:

[redacted]

- **Short-Form Health Survey-12 (SF-12**) – score at baseline and 30-day visit.

4.2.2 Arterial and Arteriovenous Subjects

- Clot removal grade for each JETi-treated target vessel from pre-JETi angiogram to final angiogram (post-JETi thrombectomy and after any/all adjunctive therapies and prior to removal of the vascular sheath) per the grades in **Table 1**.
- Components of the MAE, up to 30 days post-JETi procedure, including device-related death, major amputation of treated limb, and major bleeding up to 30 days as adjudicated by a CEC.
- Ankle Brachial Index (ABI) of treated limb(s) at baseline and 30 days. Note this is applicable to lower extremity arterial subjects only.

[redacted]

- Rutherford classification of treated limb(s) at baseline and 30 days. Note this is applicable to lower extremity arterial subjects only.
- Re-thrombosis of JETi-treated vessel at 30-day follow-up, as assessed by investigator/physician reported.
- Patency as determined by duplex ultrasound at baseline and 30-day. Note that this endpoint will only apply to subjects treated for arteriovenous thrombus.
- Vessel patency**:** assessed by the independent imaging core laboratory using the Modified Thrombolysis in Myocardial Infarction (TIMI) classification called TIPI (Thrombo-aspiration in Peripheral Ischemia)[5] (**Table 3**) for each JETi-treated vessel, assessed using angiogram
  - At post-JETi timepoint (post-JETi thrombectomy and prior to any adjunctive therapies to treat underlying culprit lesions)
  - At final timepoint (post-JETi thrombectomy and after any/all adjunctive therapies and prior to removal of the vascular sheath)

  If no adjunctive therapies or devices are used after JETi, post-JETi TIPI score is also final TIPI score.

Table 3. Thrombo-aspiration in Peripheral Ischemia (TIPI)

Description	TIPI score
No recanalization of the thrombotic occlusion	0
Incomplete or partial recanalization of the thrombotic occlusion with no distal flow	1
Incomplete or partial recanalization of the thrombotic occlusion with any distal flow	2
Complete recanalization of the thrombotic occlusion with normal distal flow	3

- Acute success, as per [redacted] (**Table 3**):
  - Device success: Near complete or complete recanalization of occluded vessel, defined as post-JETi [redacted]
  - Technical success: Near complete or complete recanalization of occluded vessel, defined as final [redacted] where [redacted] evaluation occurs after JETi system and any other adjunctive device or procedures.
  - Procedural success: Technical success with no JETi-related MAEs within 5 days of registration or by discharge, whichever occurs first

4.2.3 Venous Subjects

- Percent of treated vessels (in lower extremity DVT) with ≥75% thrombus reduction from pre-JETi venogram to post-JETi venogram (post-JETi thrombectomy and before any adjunctive therapies to treat underlying culprit lesions) via modified Marder score. The independent imaging core laboratory will be responsible for assessing this endpoint. Note this is applicable to lower

[5] de Donato G, Pasqui E, Sponza M, et al. Safety and Efficacy of Vacuum Assisted Thrombo-Aspiration in Patients with Acute Lower Limb Ischaemia: The INDIAN Trial. *Eur J Vasc Endovasc Surg*. 2021;61(5):820-828. doi:10.1016/j.ejvs.2021.01.004

extremity DVT subjects only. The effectiveness outcome for subjects treated for venous thrombosis that is not lower extremity DVT as defined in Appendix II (e.g., upper extremity DVT) will be assessed by clot removal grade, as defined in Section 4.1.1.

- Components of the MAE up to 30 days post-JETi procedure, including the following JETi-related events adjudicated by a CEC: device-related death, symptomatic pulmonary embolism (PE), major bleeding, and re-thrombosis of JETi treated vessel(s).
- The Villalta Post Thrombotic Syndrome (PTS) severity scale at baseline, and 30-day follow-up. Note this is applicable to lower extremity DVT subjects only.
    - Edema component score from the Villalta Post Thrombotic Syndrome (PTS) severity scale at baseline, and 30-day follow-up.
- A 7-point Likert Scale for leg pain at baseline, discharge, and 30-day follow-up. Note this is applicable to lower extremity DVT subjects only.
- Venous patency and compressibility as determined by duplex ultrasound at baseline, and 30-day follow-up. The independent imaging core laboratory will be responsible for assessing this endpoint.
- Acute success, [redacted], assessed by core laboratory:

o Device success: post-JETi thrombus removal grade II-III [redacted]

    o Technical success: Final thrombus removal grade II-III, [redacted] where final [redacted] evaluation occurs after JETi system and any other adjunctive device or procedures.

o Procedural success: Technical success with no JETi-related MAEs within 5 days of registration or by discharge, whichever occurs first.

    If no adjunctive therapies or devices are used after JETi, post-JETi [redacted] score is also final [redacted] score.

[redacted]

[redacted]	[redacted]	
[redacted]	[redacted]	
[redacted]	[redacted]	

5 SUBJECT SELECTION AND WITHDRAWAL

5.1 Subject Population

This study will register subjects of all genders from the patient population undergoing percutaneous treatment of thrombosis in the peripheral vascular system.

5.2 Subject Recruitment/Screening and Informed Consent

5.2.1 Subject Recruitment and Screening

A member of the site's study team previously trained to the CIP should evaluate patients for general study eligibility criteria. A patient who does not satisfy all general eligibility criteria prior to informed consent is considered a recruitment failure and should not be enrolled in the study.

Sites will ask patients meeting general inclusion criteria and no general exclusion criteria to sign an Informed Consent Form (ICF) following the established Informed Consent process (described in **Section 5.2.2**) if they wish to participate in the study.

Enrolled (consented) subjects who do not have a JETi Catheter introduced into the intended vasculature are considered a screen failure and should be withdrawn from the study. The Principal Investigator or the delegated study personnel will record the screen failure in the hospital records and on a recruitment/screening log as required.

5.2.2 Informed Consent

The Investigator or his/her authorized designee (if applicable) will conduct the Informed Consent process, as required by applicable regulations and the center's IRB/EC. This process will include a verbal discussion with the patient on all aspects of the study that are relevant to the patient's decision to participate, such as details of study procedures, anticipated benefits, and potential risks of study participation. Sites must inform patients about their right to withdraw from the study at any time and for any reason without sanction, penalty, or loss of benefits to which the patient is otherwise entitled. Withdrawal from the study will not jeopardize their future medical care or relationship with the investigator.

During the discussion, the Principal Investigator or his/her authorized designee will avoid any improper influence on the patient and will respect patient's legal rights. Financial incentives will not be given to patients. Patients may be compensated for time and travel directly related to the participation in the study. The site shall provide the patient with the Informed Consent form written in a language that is understandable to the patient and that has been approved by the center's IRB/EC. The patient shall have adequate time to review, ask questions, and consider participation. The Principal Investigator or his/her authorized designee will make efforts to ensure that the patient understands the information provided. If the patient agrees to participate, they must sign and date the Informed Consent form, along with the person obtaining the consent prior to any study-specific procedures. The site will file the signed original in the patient's hospital or research charts and provide a copy to the patient.

Sites should report any failure to obtain informed consent from a patient to the Sponsor within 5 working days and to the reviewing center's IRB/EC according to the IRB's/ EC's reporting requirements.

If, during the study, new information becomes available that can significantly affect a subject's future health and medical care, the Principal Investigator or his/her authorized designee (if applicable) will provide this information to the subject. If relevant, sites will ask the subject to confirm their continuing informed consent in writing.

5.2.2.1 Special Circumstances for Informed Consent

Sites may enroll individuals who are unable to make the decision to participate in a study on their own. Sites will obtain informed consent from the patient's legally authorized representative and will inform the patient about the study within his/her ability to understand. During the informed consent discussion, the Principal Investigator or his/her authorized designee will avoid any improper influence and make sure there is no manipulation of the patient and patient's legal rights are respected. Enrollment of these patients is important as data of comparable validity cannot be obtained from clinical research involving persons able to give informed consent or by other research methods. -

The legally authorized representative will represent the individual during the Informed Consent process, which will be performed according to the requirements in **Section 5.2.2**. Sites will respect the explicit wish of the individual to decline participation or withdraw from the study at any time. In addition, no incentives or financial inducements will be provided to these patients or their legally authorized representatives for their participation in the study.

This study excludes individuals under the age of 18.

Sites may enroll individuals unable to read or write in this study. Sites will obtain informed consent through a supervised oral process. An independent witness will be present throughout the Informed Consent process. A member of the site's study team previously trained to the CIP will read the written Informed Consent form and any other information aloud and explain to the prospective subject or his/her legally acceptable representative and will sign and personally date the Informed Consent form. The witness will also sign and personally date the Informed Consent form attesting that the information was accurately explained, and that informed consent was freely given. In addition, no incentives or financial inducements will be provided to these patients or their legally authorized representatives for their participation in the study.

Sites may enroll women who are pregnant or breastfeeding in this study. Informed consent must be obtained using the IRB/EC approved informed consent in accordance with IRB/EC requirements. The study is expected to produce a direct benefit to the woman or her embryo, fetus, or child, outweighing the risks and burdens involved. When breastfeeding women are included, care shall be taken to avoid any adverse impact to the health of the child. In addition, no incentives or financial inducements will be provided to these patients or their legally authorized representatives for their participation in the study. All other aspects of the Informed Consent process will follow **Section 5.2.2**.

Sites may enroll individuals admitted to the emergency units in this study in cases where emergent removal of life- or limb-threatening thrombi in the peripheral vasculature is required. When prior informed consent of the individual is not possible because of the patient's medical condition, sites will request the informed consent of the subject's legally acceptable representative, if present. When it is not possible to obtain prior informed consent from the subject, and the subject's legally acceptable representative is not available, sites will perform the informed consent process in accordance with **Section 5.2.2** as soon as possible. In addition, patients are able to enroll in the study post-procedure.

For live cases at congresses, the subject needs to sign a specific Live Case ICF, approved by the IRB/EC. The investigator must notify the Sponsor prior to performing a live case.

5.3 Eligibility Criteria

5.3.1 General Eligibility Criteria

Assessment for general eligibility criteria is based on medical records of the site and interview with a candidate patient. Patients must meet ALL general inclusion criteria to participate in the study. If ANY general exclusion criteria are met, the patient is excluded from the study and cannot be enrolled (recruitment failure).

5.3.2 Inclusion Criteria

5.3.2.1 General Inclusion Criteria

1. Subject was treated or is expected to be treated for acute/subacute thrombosis, as determined by investigator, in the peripheral vasculature with the JETi Hydrodynamic Thrombectomy System.
2. Subject or legally authorized representative must provide written informed consent
3. Subject must be ≥ 18 years of age and of Asian race.

5.3.3 Exclusion Criteria

5.3.3.1 General Exclusion Criteria

1. Subject has previously been registered in the JETi Hong Kong PMS in the last 12 months unless treated in the contralateral limb/different anatomy; patients treated in the contralateral limb/different anatomy within the last 12 months may re-enroll in the study**.**
2. Subject is currently participating in another drug or device clinical investigation.
3. Subject has active symptoms and/or a positive test result of COVID-19 or other rapidly spreading infectious agent within the past 20 days.

5.4 Subject Enrollment

A patient is considered enrolled in the study from the moment the patient provides written informed consent.

5.5 Subject Registration

An enrolled subject is considered registered in the study only after a JETi Catheter is introduced into the intended vasculature of the subject during the procedure (Day 0). Patients may be consented after the procedure if all assessments needed for the primary endpoints are complete. A subject who is enrolled but not registered in this study will be considered a screen failure. The sample size of the study is based on the number of registered subjects.

5.6 Subject Withdrawal and Discontinuation

Each registered subject shall remain in the study until completion of the required follow-up period; however, a subject's participation in any study is voluntary, and the subject has the right to withdraw at

any time without penalty or loss of benefit. Conceivable reasons for discontinuation may include, but not be limited to, the following:

- Subject death
- Subject voluntary withdrawal
- Subject lost-to follow-up as described below
- Subject's follow-up is terminated according to **Section 3.3**.

Sites must notify the Sponsor of the reason(s) for subject discontinuation. Investigators must also report this to their respective IRB/EC as defined by their institution's procedure(s).

No additional follow-up is required, or data recorded from subjects once withdrawn from the study, except for the status (deceased/alive).

However, if a subject withdraws from the study due to problems related to the safety or performance of the JETi System, the investigator shall ask for the subject's permission to follow his/her status/condition outside of the study.

In case of subject withdrawal of consent, the site should make attempts to schedule the subject for a final study visit. At this final follow-up visit, the subject will undergo clinical assessment.

Lost-to-Follow-up

If the subject misses the 30-day follow-up time point and the attempts at contacting the subject detailed below are unsuccessful, then the subject is considered lost-to-follow-up. Site personnel shall make all reasonable efforts to locate and communicate with the subject (and document these efforts in the source documents), including the following, at each contact time point:

- A minimum of two telephone calls on different days over the specified follow-up windows to contact the subject should be recorded in the source documentation, including date, time and initials of site personnel trying to make contact.
- If these attempts are unsuccessful, the site should send a letter (certified if applicable) to the subject.
- If a subject misses the 30-day follow up timepoint and the above-mentioned attempts at communicating with the subject are unsuccessful, the subject will be considered lost-to-follow-up.

Note: Telephone contact with General Practitioner, non-study cardiologist or relative without the presence of the subject or indirect documentation obtained via discharge letters will not be considered as subject contact.

5.7 Number of Subjects

The study will register approximately 20 subjects. [redacted]

[redacted]

5.8 Total Expected Duration of the Clinical Investigation

[redacted] The expected duration of each subject's participation is 30 days (in cases of prospective consent). [redacted] Subjects will exit the study at the end of their 30-day Follow-Up visit or 30 days after their procedure. [redacted]

6 TREATMENT AND EVALUATION OF ENDPOINTS

For this study, the following definitions apply:

- **Index procedure:** the entire intervention to treat the subject's peripheral vascular thrombosis. A subject's procedure may include more than one session if the subject is removed from the interventional suite and placed in a holding area with the intention of returning to the suite for additional treatments either the same day or following day (e.g., catheter placement or removal for CDT).
- **Treatment:** the individual techniques performed during a procedure to address the subject's peripheral vascular thrombosis (e.g., JETi thrombectomy, balloon angioplasty, stent placement, or catheter-directed thrombolysis (CDT)). Note that "JETi treatment" will refer to treatment during which the JETi Thrombectomy system is used.

  NOTE: A subject's treatment is determined by the treating physician based on the clinical situation and institutional practices.
- **Session:** a session is the in and out period within an interventional suite that a subject is receiving treatment. A subject's procedure may include more than one session if the subject is removed from the interventional suite and placed in a holding area with the intention of returning to the suite for additional treatments either the same day or following day (e.g., catheter placement or removal for CDT).

  NOTE: Treatment for unexpected re-thrombosis is an adverse event and should not be considered as an additional session of the initial procedure. Refer to **Section 7.1.1**.

6.1 Arterial and Arteriovenous Subjects

At Baseline, demographic information, medications, clinical assessment, physical exam and a medical history will be collected. Laboratory assessments, up to 14 days prior to the procedure, will be recorded and may include estimated glomerular filtration rate (eGFR), serum creatinine (SCr), blood urea nitrogen (BUN), potassium (K), hemoglobin (Hgb), platelets (plt), prothrombin time (PT), international normalized ratio (INR) and activated partial thromboplastin time (aPTT).

The pre-JETi angiogram will be used to assess the initial degree of clot burden after catheter insertion into the vessel and prior to JETi Thrombectomy. The post-JETi Thrombectomy angiogram will be used to assess clot removal after JETi Thrombectomy and prior to any adjunctive therapies used to treat underlying culprit lesions. The final angiogram will be completed to assess clot removal after JETi Thrombectomy and any/all adjunctive therapies and prior to removal of the vascular sheath. All treated

vessels will be assessed using the provided clot removal grades (**Table 1**). All angiograms are requested to be transmitted to the core lab for analysis. Guidance from the imaging core laboratory will be provided for reference.

DUS will be collected at baseline and 30-Day Follow-Up for subjects with arteriovenous thrombosis. Refer to the DUS core laboratory guidelines for detailed information. All DUS completed are requested to be transmitted to the core lab for analysis.

An ABI examination is required at Baseline and 30 Days. Rutherford classification is required at Baseline and 30 Days. Note: baseline ABI (within 3 months prior to procedure) and Rutherford assessment (within 4 days prior to procedure) can be obtained via a non-study physician, including a referring physician; this will not be considered a protocol deviation. Note these are applicable to lower extremity arterial subjects only.

The Short Form (SF)-12 is a self-reported outcome quality of life measure. Its completion is requested at Baseline and at 30 days. For post-procedurally consented subjects, a baseline SF-12 will not be collected as the validity of this assessment is not supported when collected retrospectively.

Anticoagulants, and antiplatelet medications will be collected for this study at Baseline (medications that the patient was taking within the 30 days prior to admission and upon admission), Index Procedure, Discharge, and 30-day follow-up timepoint. Thrombolytics used during the index procedure will be collected.

AEs experienced by the patient during the study will be reported, starting as soon as the JETi catheter is introduced into the intended vasculature during the procedure. Please refer to AE reporting section 7.3.1 for additional details of event reporting.

The schedule of events for arterial subjects is located in **Section 6.1.6**

Data collection at each timepoint is discussed in the sections below.

6.1.1 Baseline

Subject preparation will occur in accordance with standard hospital policy for the care of interventional endovascular procedures. Note that no data will be recorded until consent is obtained. The following baseline data will be collected:

- Enrollment
- Demographics – including age, sex
- Medical history – subject medical history including general medical history, surgical history, vascular history, renal history, and thrombotic condition
- Medications: anticoagulant, antiplatelet, and thrombolytic medications (if applicable) taken within the 30 days prior to admission
- Laboratory assessments (within 14 days prior to the JETi procedure) such as:
    - eGFR

- Serum Creatinine (SCr)
- Blood urea nitrogen (BUN)
- Potassium (K)
- Hemoglobin (Hgb)
- Platelets (Plt)
- International normalized ratio (INR)
- Prothrombin time (PT)
- Activated partial thromboplastin time (aPTT)

- Clinical assessment (within 14 days prior to the JETi procedure) – clinical assessment information including height, weight, blood pressure, heart rate, temperature, and respiratory rate
- Physical exam (within 14 days prior to the index procedure
- Quality of life (QOL) questionnaire: SF-12 (not applicable for post-procedure consented subjects)
- ABI
- Rutherford classification *

  ** Note: ABI (done within 3 months prior to procedure) and Rutherford assessment (done within 4 days prior to procedure) can be obtained via a non-study physician, including a referring physician; this will not be considered a protocol deviation. ABI and Rutherford are applicable to lower extremity arterial subjects only.*
- Duplex ultrasound examination will be collected at Baseline (up to 14 days prior to the index procedure) for arteriovenous subjects. Guidance from the imaging core laboratory will be provided for reference. All DUS completed are requested to be transmitted to the core lab for analysis.

6.1.2 Index Procedure

The thrombectomy procedure with the JETi System should be conducted in accordance with standard of care practice and approved labelling. All consented subjects who have the JETi Catheter introduced into the intended vasculature will be considered registered subjects and will be entered into the study.

The following procedural data will be collected:

- **Procedure information:** Start and end dates/times, amount of contrast used during the entire procedure, total fluoroscopy time, access sites, obstruction location, and the number of sessions within the procedure (If multiple sessions were needed, the location of the subject in between the sessions is requested).
- **Treatment information:** The treatments performed during the index procedure will be captured in the order of performance with specific details for each treatment. The treatment options will include the following:
  - JETi mechanical thrombectomy (MT) only
  - JETi in combination with one or more of the following treatments:

- **Imaging Assessments:**
    - Pre-JETi arteriogram: The pre-JETi arteriogram will be used to assess the initial degree of clot burden after catheter insertion into the vascular system and prior to JETi thrombectomy.
    - Post-JETi arteriogram: The post-JETi thrombectomy arteriogram will be used to assess the degree of clot removal after JETi thrombectomy and prior to any adjunctive therapies used to treat underlying culprit lesions.
    - Final arteriogram: The final angiogram will be completed to assess the degree of clot removal after JETi thrombectomy and any/all adjunctive therapies and prior to removal of the vascular sheath.

  All treated vessels will be assessed using the provided grades in Table 1, per core lab assessment.

  All treated arterial vessels will be assessed using the provided TIPI grades in Table *3*, per core lab assessment.

- **Acute success**, as per [redacted] (**Table 3**), per core lab assessment:
    - Device success: Near complete or complete recanalization of occluded vessel, defined as post-JETi [redacted]
    - Technical success: Near complete or complete recanalization of occluded vessel, defined as [redacted] where [redacted] evaluation occurs after JETi system and any other adjunctive device or procedures (final).
    - Procedural success: Technical success with no JETi-related MAEs within 5 days of registration or by discharge, whichever occurs first.

- **Adverse Events and Device Deficiency assessment**
- **Medications:** Anticoagulant, antiplatelet, and thrombolytic medications administered during the procedure; anticoagulant and antiplatelet treatments within the peri-operative period should follow recommended societal guidelines.

6.1.3 Discharge

Discharge is defined as the subject leaving the treating hospital. The following discharge data will be collected:

- Adverse events and device deficiency
- Medications: Anticoagulant, and antiplatelet medications

6.1.4 30-day Follow-up (Office Visit)

A 7-day window is required for the 30-day follow-up visit (30 days ± 7 days). The following data will be collected at the follow-up visit:

- Adverse events and device deficiency
- Medications: Anticoagulant, and antiplatelet medications
- ABI*
- Rutherford classification*

* Note: ABI and Rutherford assessment can be obtained via a non-study physician, including a referring physician; this will not be considered a protocol deviation. ABI and Rutherford are only applicable to lower limb arterial thrombosis.

- QOL questionnaire (SF-12)
- Duplex ultrasound examination will be collected at 30 days for arteriovenous subjects. Guidance from the imaging core laboratory will be provided for reference. All DUS completed are requested to be transmitted to the core lab for analysis.

6.1.5 Unscheduled Visit

Unscheduled visits may occur as clinically warranted, and data will be collected if the unscheduled visit is related to the JETi procedure and/or investigational device (as determined by the physician). Data on any imaging, clinical assessment, medication (anticoagulant, antiplatelet, and thrombolytic medications), AEs, DDs and SAEs will be collected if applicable.

6.1.6 Schedule of Events

The schedule of assessments for Arterial Subjects is listed in ***Table 4***.

Table 5. Assessment Schedule for Arterial and Arteriovenous Subjects

CIP Activity	Baseline	Index Procedure	Discharge	30 Days Follow-up [1] (± 7 days)	Unscheduled Visit
Enrollment [2]	X				
Demographics	X				
Medical history	X				
Medications	X	X	X	X	X[3]
Laboratory assessments					
eGFR	X[4]				
Serum Creatinine (SCr)	X[4]				
Blood Urea Nitrogen (BUN)	X[4]				
Potassium (K)	X[4]				
Hemoglobin (Hgb)	X[4]				
Platelets (Plt)	X[4]				
International Normalized Ratio (INR)	X[4]				
Prothrombin Time (PT)	X[4]				
Activated Partial Thromboplastin Time (aPTT)	X[4]				
Clinical assessment	X[4]				
Physical exam	X[4]				
ABI	X[5, 6]			X[6]	
Rutherford classification	X[6,7]			X[6]	
Imaging assessment – Angiogram		X[8]			
Imaging assessment – DUS	X[9]			X[9]	
QOL (SF-12)	X[10]			X	
Adverse event assessment/Device Deficiency assessment		X[11]	X[11]	X[11]	X[11]
Procedure, treatment information		X			

[1] in-office visit is required at 30-day follow-up. A telephone contact or virtual visit is an option only for subject who would otherwise miss the visit due to being unable to complete an office visit
[2] retrospective consent is permitted
[3] unscheduled medications reported in Adverse Event form when applicable
[4] assessment done within 14 days prior to procedure is acceptable
[5] ABI done within 3 months prior to procedure is acceptable. In emergent ALI cases, missing ABI at baseline will not be considered a protocol deviation
[6] can be obtained via a non-study physician, including a referring physician; this will not be considered a protocol deviation
[7] Rutherford classification done within 4 days prior to JETi procedure is acceptable
[8] includes pre-JETi, post-JETi, and final (after JETi and all adjunctive device/treatment) angiograms
[9] only applicable for arteriovenous thrombosis
[10] not applicable for post-procedure consented subjects
[11] Serious adverse events (SAEs) and device deficiencies must be reported within 3 calendar days of Site becoming aware

6.2 Venous Subjects

At Baseline, demographic information, medications and a medical history will be collected. Laboratory assessments, up to 14 days prior to the procedure will be recorded and include eGFR, serum creatinine (SCr), blood urea nitrogen (BUN), potassium (K), hemoglobin (Hgb), platelets (Plt), prothrombin time (PT), international normalized ratio (INR) and activated partial thromboplastin time (aPTT).

Duplex ultrasound examination will be collected at Baseline (up to 14 days prior to procedure), and 30 Days. Thrombus obstruction and location will be assessed by venous compressibility with incomplete compression indicating the presence of thrombus in that venous segment. Guidance from the imaging core laboratory will be provided for reference. Refer to the DUS core laboratory guidelines for detailed information. All DUS completed are requested to be transmitted to the core lab for analysis.

The pre-JETi venogram will be used to assess the initial degree of clot burden after catheter insertion into the venous system and prior to JETi Thrombectomy. The post-JETi Thrombectomy venogram will be used to assess removal after JETi Thrombectomy and prior to any adjunctive therapies used to treat underlying culprit lesions. The final venogram will be completed to assess clot removal after JETi Thrombectomy and any/all adjunctive therapies and prior to removal of the vascular sheath. All venograms will be transmitted to the core lab for review and adjudication.

The Villalta scale is a clinical severity score for the post-thrombotic syndrome (PTS).[6] The Villalta PTS assessment rates the severity of 5 patient-reported symptoms (pain, cramps, heaviness, paresthesia, pruritus) and 6 clinician-observed signs (edema, skin induration, hyperpigmentation, pain during compression, venous ectasia, redness) of PTS on a 4-point scale (0 = none, 1 = mild, 2 = moderate, 3 = severe) for treated limb(s). The assessment will be collected at Baseline and at 30 days and is applicable to lower extremity DVT patients only.

Severity of leg pain assessed using a 7-point Likert scale (1 = no pain, 2 = very mild pain, 3 = mild pain, 4 = moderate pain, 5 = severe pain, 6 = very severe pain, 7 = extremely severe pain) will be collected at Baseline, Discharge, and 30 days. Note this assessment is applicable to lower extremity DVT patients only.

The Short Form (SF-12) is a self-reported outcome quality of life measure. Its completion is required at baseline, and 30 days. For post-procedurally consented subject, a baseline SF-12 will not be collected as the validity of this assessment is not supported when collected retrospectively.

Anticoagulants, antiplatelet, and thrombolytic medications will be collected for this Study at Baseline (medications that the patient was taking within the 30 days prior to admission and upon admission), Index Procedure, Discharge, and 30-day follow-up timepoint. Thrombolytics used during the index procedure will be collected.

AEs experienced by the patient during the procedure through discharge will be assessed by the physician to determine if related to any portion of the procedure. If the event has been determined to be

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[6] Lattimer CR, Kalodiki E, Azzam M, Geroulakos G. Validation of the Villalta scale in assessing post-thrombotic syndrome using clinical, duplex, and hemodynamic comparators. *J Vasc Surg Venous Lymphat Disord*. 2014;2(1):8-14. doi:10.1016/j.jvsv.2013.06.003

related to the procedure, then a determination of relatedness to the JETi System is required. All events determined by the physician to be related to the JETi System will need to be assessed as to whether the event caused serious injury or death, and will be collected.

The schedule of events for venous subjects is located in **Section 6.2.6.**

Data collection at each timepoint is discussed in the sections below.

6.2.1 Baseline

Subject preparation will occur in accordance with standard hospital policy for the care of interventional endovascular procedures. Note that no data will be recorded until consent is obtained.

The following data will be collected:

- Enrollment
- Demographics – including age, sex
- Medical history – subject medical history including general medical history, surgical history, vascular history, renal history, and thrombotic condition
- Medications: anticoagulant, antiplatelet, and thrombolytic medications (if applicable) taken within the 30 days prior to admission
- Laboratory assessments (within 14 days prior to the JETi procedure) such as:
    - eGFR
    - Serum Creatinine (SCr)
    - Blood urea nitrogen (BUN)
    - Potassium (K)
    - Hemoglobin (Hgb)
    - Platelets (Plt)
    - International normalized ratio (INR)
    - Prothrombin time (PT)
    - Activated partial thromboplastin time (aPTT)
- Clinical assessment – clinical assessment information including height, weight, blood pressure, heart rate, temperature, and respiratory rate
- Physical exam
- Villalta PTS assessment (at baseline or within 4 days prior to the index procedure)*; note this is applicable to lower extremity DVT subjects only.

  ** can be obtained via a non-study physician, including a referring physician; this will not be considered a protocol deviation*
- DUS (within 14 days prior to the index procedure)*

  ** can be obtained via a non-study physician, including a referring physician; this will not be considered a protocol deviation*
- Quality of life (QOL) questionnaire: SF-12 (not applicable for post-procedure consented subjects)

- Leg pain assessment by 7-point Likert Scale; note this is applicable to lower extremity DVT subjects only.

6.2.2 Index Procedure

The thrombectomy procedure with the JETi System should be conducted in accordance with standard of care practice and approved labelling. All consented subjects who have the JETi Catheter introduced into the intended vasculature will be considered registered subjects and will be entered into the study.

The procedural data to be collected is described below:

- **Procedure information**: Start and end dates/times, amount of contrast used during the entire procedure, access sites, obstruction location, and the number of sessions within the procedure (If multiple sessions were needed, the location of the subject in between the sessions is requested).
- **Treatment information**: The treatments performed during the index procedure will be captured in the order of performance with specific details for each treatment. The treatment options will include the following:

  - JETi mechanical thrombectomy (MT) only
  - JETi in combination with one or more of the following treatments:

- **Imaging Assessments**
  - Pre-JETi venogram: The pre-JETi venogram will be used to assess the initial degree of clot burden after catheter insertion into the vascular system and prior to JETi thrombectomy.
  - Post-JETi venogram: The post-JETi thrombectomy venogram will be used to assess clot removal after JETi thrombectomy and prior to any adjunctive therapies used to treat underlying culprit lesions.
  - Final venogram: The final venogram will be completed to assess the degree of clot removal after JETi thrombectomy and any/all adjunctive therapies and prior to removal of the vascular sheath.

All treated lower extremity venous vessels will be assessed using Marder score, per core laboratory assessment. Any other venous treated vessels (i.e., upper extremity) will be assessed by clot removal grade (per Section 4.1.1).

- **Acute success**, [redacted] core laboratory assessed:
  - Device success: Thrombus removal grade II-III [redacted]

[redacted]

- Technical success: Thrombus removal grade II-III u[redacted]procedures (final), evaluated by [redacted]
- Procedural success: Technical success with no JETi-related MAEs within 5 days of registration or by discharge, whichever occurs first

- **Adverse Events and Device Deficiency assessment**
- **Medications:** Anticoagulant, antiplatelet, and thrombolytic medications administered during the procedure; anticoagulant and antiplatelet treatments within the peri-operative period should follow recommended societal guidelines.

6.2.3 Discharge

Discharge is defined as the subject leaving the treating or referral hospital. The following discharge data will be collected:

- Adverse events
- Medications: Anticoagulant, and antiplatelet medications
- Leg pain assessment by 7-point Likert Scale; note this is applicable to lower extremity DVT subjects only.

6.2.4 30-day Follow-up (Office Visit)

A 7-day window is required for the 30-Day visit (30 days ± 7 days). The following data will be collected at the follow-up visit:

- Adverse events
- Medications: Anticoagulant, and antiplatelet medications
- Leg pain assessment by 7-point Likert Scale; note this is applicable to lower extremity DVT subjects only.
- DUS*
- Villalta PTS assessment*; note this is applicable to lower extremity DVT subjects only.
- QOL questionnaire: SF-12*

** can be obtained via a non-study physician, including a referring physician. This will not be considered a protocol deviation*

6.2.5 Unscheduled Visit

Unscheduled visits may occur as clinically warranted, and data will be collected if the unscheduled visit is related to the JETi procedure and/or investigational device (as determined by the physician). Data on any imaging, clinical assessment, medication (anticoagulant, antiplatelet, and thrombolytic medications), AEs, DDs, and SAEs will be collected if applicable.

6.2.6 Schedule of Events

The schedule of assessments for Venous Patients is listed in ***Table 5***.

Table 6. Assessment Schedule for Venous Subjects

CIP Activity	Baseline	Index Procedure	Discharge	30 Days Follow-up (± 7 days) [1]	Unscheduled Visit
Enrollment[2]	X				
Demographics	X				
Medical history	X				
Medications	X	X	X	X	X[3]
Laboratory assessments					
eGFR	X[4]				
Blood Urea Nitrogen (BUN)	X[4]				
Serum Creatinine (SCr)	X[4]				
Potassium (K)	X[4]				
Hemoglobin (Hgb)	X[4]				
Platelets	X[4]				
International Normalized Ratio (INR)	X[4]				
Prothrombin Time (PT)	X[4]				
Activated Partial Thromboplastin Time (aPTT)	X[4]				
Clinical assessment	X[4]				
Physical assessment	X[4]				
Villalta PTS assessment	X[5]			X	
Leg pain assessment (7-point Likert scale)	X		X	X	
Imaging assessment					
Venogram		X[6]			
Duplex ultrasound	X			X	
QOL (SF-12)	X[7]			X	
Adverse event assessment/Device Deficiency assessment		X[8]	X[8]	X[8]	X[8]
Procedure, treatment information		X			

[1] *In-office visit is required. A telephone contact or virtual visit is an option only for subject who would otherwise miss the visit due to being unable to complete an office visit*
[2] *retrospective consent is permitted*
[3] *unscheduled Medications reported in Adverse Event form when applicable*
[4] *assessment done within 14 days prior to procedure is acceptable*
[5] *assessment done within 4 days prior to procedure is acceptable*
[6] *includes pre-JETi, post-JETi, and final venograms*
[7] *not applicable for post-procedure consented subjects*
[8] *Serious adverse events (SAEs) and device deficiencies must be reported within 3 calendar days of Site becoming aware*

6.3 Imaging Core Laboratories

An independent core laboratory will be used in this study to assess the arteriograms/venograms, and DUS imaging submitted by the sites.

7 ADVERSE EVENTS

To comply with worldwide standards and guidelines on clinical investigation adverse event reporting, the Sponsor has adopted uniform and worldwide applicable standard definitions and reporting timelines to be used and adhered to by the investigators.

7.1 Definition

7.1.1 Adverse Event

An adverse event (AE) is any untoward medical occurrence, unintended disease or injury, or untoward clinical signs (including abnormal laboratory findings) in subjects, users or other persons, whether or not related to the medical device under investigation.

As part of ISO14155 Section 3.2, the Adverse Event definition has the following notes:

Note 1: This definition includes events related to the medical device under investigation or the comparator.

Note 2: This definition includes events related to the procedures involved.

Note 3: For users or other persons, this definition is restricted to events related to medical devices under investigation.

7.1.2 Serious Adverse Event

If the AE meets any of the criteria below, it is regarded as a serious adverse event (SAE).

- Led to a death,
- Led to a serious deterioration in health of the subject, that either resulted in
    - a life-threatening illness or injury, or
    - a permanent impairment of a body structure or a body function, or
    - in-patient hospitalization or prolongation of existing hospitalization, or
    - medical or surgical intervention to prevent life threatening illness or injury or permanent impairment to a body structure or a body function.
    - chronic disease
- Led to fetal distress, fetal death or a congenital abnormality or birth defect.

Note: A planned hospitalization for a pre-existing condition, or a procedure required by the CIP without a serious deterioration in health, is not considered to be an SAE.

7.1.3 Device Deficiency/Device Malfunction

Device deficiency is defined as an inadequacy of a medical device related to its identity, quality, durability, reliability, safety or performance, such as malfunction, misuse or use error and inadequate labeling. This includes the failure of the device to meet its performance specifications or otherwise perform as intended. Note: performance specifications include all claims made in the labeling of the device.

A device malfunction is the failure of a device to meet its performance specifications or otherwise perform as intended, when used in accordance with the instructions for use or CIP.

7.2 Device Relationship

Determination of whether there is a reasonable possibility that the JETi System caused or contributed to an AE is to be **determined by the Investigator** and recorded on the appropriate case report (CRF) form. Determination should be based on the assessment of temporal relationships, evidence of alternative etiology, medical/biologic plausibility and patient condition (pre-existing condition).

7.3 Adverse Event and Device Deficiency/Device Malfunction Reporting

7.3.1 Adverse Event Reporting

Safety surveillance and reporting starts as soon as the JETi catheter is introduced into the intended vasculature during the procedure. Safety surveillance and reporting will continue until sites perform the last follow-up visit, the subject is deceased, the subject concludes participation in the clinical investigation, or the subject withdraws from the clinical investigation. Sites will collect all adverse event data, including deaths and device deficiency data (if applicable), throughout the period defined above. and will report these events to the Sponsor on a CRF. Sites should update additional information regarding an adverse event on the appropriate CRF.

Unchanged, chronic, non-worsening or pre-existing conditions are not AEs and should not be reported.

The Sponsor will provide an offline form to allow the investigator to report SAEs in the event the entry cannot be made in the electronic data capture (EDC). This does not replace the EDC reporting system. Sites must still enter all information in the EDC system as soon as feasible.

For the purposes of this study, the following adverse events will be reported for each subject through the 30-day follow-up visit.

- All device-and procedure-related AEs
- All SAEs

In addition, the following adverse events regardless of seriousness or relatedness will be collected:

- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

[redacted]

SAE Reporting

The investigator must report all SAEs to the Sponsor as soon as possible but no later than outlined below.

Clinical Site	Reporting timelines
All Sites	Sites must report SAEs to the Sponsor **no later than 3 calendar days** from the day the site personnel became aware of the event or as per the investigative site's local requirements, if the requirement is more stringent than those outlined.

Sites must record the date the site staff became aware that the event met the criteria of an SAE in the source document. The Investigator will further report the SAE to the local IRB/EC according to the institution's IRB/EC reporting requirements.

7.3.2 Device Deficiency/Malfunction Reporting

Sites should report all device deficiencies/malfunctions on the appropriate CRF form.

The investigator must report all device deficiencies/malfunctions to the Sponsor as soon as possible but no later than outlined below.

Clinical Sites	Reporting timelines
All Sites	Sites must report device deficiencies/malfunctions to the Sponsor **no later than 3 calendar days** from the day the site personnel became aware of the event or as per the investigative site's local requirements, if the requirement is more stringent than those outlined.

Sites must report device deficiencies/malfunctions to the IRB/EC per the investigative site's local requirements.

Sites should return the device to the Sponsor, if possible.

Sites will have access to an offline form to allow the investigator to report device deficiencies/malfunctions if sites cannot enter the information in the EDC system. This does not replace the EDC reporting system. Sites must still enter all information in the EDC system as soon as feasible.

In case a device deficiency/malfunction occurred before the patient ID has been assigned, sites should report the device deficiency to the Sponsor via the offline reporting form. This does not replace the EDC reporting system. Sites must still enter all information in the EDC system as soon as feasible.

7.3.3 Adverse Event Reporting to Country Regulatory Authorities by the Sponsor

The Sponsor will report SAEs and reportable device deficiencies/malfunctions to the country regulatory authority, per local requirements.

Note: Reportable device deficiencies/malfunctions include device deficiencies/malfunctions that might have led to an SAE if a) suitable action had not been taken or b) intervention had not been made or c) if circumstances had been less fortunate. These are handled under the SAE reporting system.

8 STATISTICAL CONSIDERATIONS

8.1 Analysis Populations

All registered subjects will be included in the analysis.

8.2 Statistical Analyses

The JETi Hong Kong PMS has not been powered to evaluate a hypothesis. Categorical variables will be summarized using frequency counts and percentages. Continuous variables will be summarized using means, standard deviation, median, min and max. Ninety-five percent confidence interval may be computed for exploratory purposes.

8.2.1 Primary Endpoints Analyses

The primary endpoints are:

Arterial and Arteriovenous subjects

For subjects treated for lower extremity arterial thrombosis, the primary endpoints are:

- **Clot removal grade** for each JETi-treated target vessel from pre-JETi angiogram to post-JETi angiogram (post-JETi thrombectomy and prior to any adjunctive therapies to treat underlying culprit lesions) per the grades in **Table 1** (vessel basis). The independent imaging core laboratory will be responsible for assessing this endpoint.
- **Composite of JETi-related major adverse events** (MAEs), defined as the following JETi-related events: device-related death, major amputation of the treated limb (arterial subjects only), or major bleeding up to 30 days post registration and as adjudicated by a clinical events committee (CEC) (subject basis). Refer to Appendix II for definitions of major adverse events.

Table 7. Clot Removal Grade

Grade I	< 50% reduction
Grade II	50- <95% reduction
Grade III	95 - 100% reduction

Venous Subjects

For this study, lower extremity deep vein thrombosis or deep venous thrombosis is defined as lower extremity venous thrombosis involving the femoral, common femoral, iliac, popliteal, or inferior vena cava (IVC) alone or in combination.

For subjects treated for lower extremity DVT, the primary endpoints are:

- **Percent of treated vessel(s) with ≥ 75% venous thrombus reduction** from pre-JETi venogram to final venogram (post-JETi AND after any/all adjunctive therapies to treat underlying culprit lesions) via modified Marder score (limb basis). The independent imaging core laboratory will be responsible for assessing this endpoint.

[redacted]

- **Composite of JETi-related major adverse events** (MAEs) up to 30 days post-JETi procedure, defined as the following JETi-related events adjudicated by a clinical events committee (CEC): death, symptomatic pulmonary embolism (PE), major bleeding, or re-thrombosis of JETi-treated vessel(s). Refer to **Appendix II** for definitions of major adverse events.

[redacted]

8.3 Sample Size Calculation

A total of approximately 20 subjects will be registered in this study. [redacted]

8.4 Timing of Analysis

Analysis will be performed after all registered subjects have reached their 30-day follow-up visit.

8.5 Subgroup Analysis

[redacted]

8.6 Multiplicity

[redacted]

8.7 Pooling Strategy

Analysis will be performed by pooling data [redacted]

8.8 Procedures for Accounting for Missing Data

Analysis will be based on available data with missing data excluded. Any unused or spurious data will be noted as appropriate in the final report.

9 DIRECT ACCESS TO SOURCE DATA/DOCUMENTS

The investigator/institution will permit direct access to source data/documents for performing study-related monitoring, audits, IRB/EC review and regulatory inspections.

Subjects providing informed consent agree to allow study monitors or regulatory authorities, including foreign countries, to review in confidence any records identifying the subjects in this study. This information may be shared with regulatory agencies; however, the Sponsor undertakes not to otherwise release the subject's personal and private information.

10 QUALITY CONTROL AND QUALITY ASSURANCE

10.1 Selection of Clinical Sites and Investigators

The Sponsor will select investigators qualified by training and experience to participate in the study. Sites will be selected based upon review of a recent site assessment, if applicable, and the qualifications of the investigators who will participate in the study.

10.2 CIP Amendments

The Sponsor will provide approved CIP amendments to the Investigators prior to implementing the amendment. The Principal Investigator is responsible for notifying the IRB/EC or equivalent committee of the CIP amendment (administrative changes) or obtaining IRB's/EC's approval of the CIP amendment (changes in subject care or safety), according to the instructions provided by the Sponsor with the CIP amendment.

Sites must document in writing acknowledgement/approval of the CIP amendment by the IRB/EC prior to implementation of the CIP amendment. Sites must also provide copies of this documentation to the Sponsor.

10.3 Training

10.3.1 Site Training

All Investigators and study personnel are required to attend Sponsor training sessions, which may be conducted at an Investigator's meeting, a site initiation visit, or other appropriate training sessions. Over-the-phone or self-training may take place as required. Training of Investigators and study personnel will include, but is not limited to, the CIP requirements, device usage, electronic case report form completion, and study personnel responsibilities. All Investigators and study personnel that are trained must sign a training log (or an equivalent) upon completion of the training.

10.4 Monitoring

Sponsor and/or designee will monitor the study over its duration according to the CIP-specific monitoring plan which will include the planned extent of source data verification.

Prior to initiating any procedure, the Sponsor monitor (or delegate) will ensure that the following criteria are met:

- The investigator understands and accepts the obligation to conduct the study according to the CIP and applicable regulations and has signed the Investigator Agreement or the Clinical Trial Agreement.
- The Investigator and his/her staff should have sufficient time and facilities to conduct the study and should have access to an adequate number of appropriate subjects to conduct the study.
- Sites must have source documentation (including original medical records) to substantiate proper informed consent procedures, adherence to CIP procedures, adequate reporting and follow-up of adverse events, accuracy of data collected on case report forms, and device information.
- The Investigator/site will permit access to such records and will maintain a monitoring visit sign-in log at the site. The Investigator will agree to dedicate an adequate amount of time to the monitoring process. The Investigator and/or research coordinator will be available for monitoring visits. It is expected that the Investigator will provide the monitor with a suitable working environment for review of study-related documents.

10.5 Deviations from CIP

The Investigator should not deviate from the CIP for any reason except in cases of medical emergencies when the deviation is necessary to protect the rights, safety, and well-being of the subject, or to eliminate an apparent immediate hazard to the subject. In that event, the Investigator will notify Sponsor immediately by phone or in writing.

All deviations will be collected, with the following exception:

- Baseline SF-12 in post-procedure consented subjects

The following deviations will be considered major:

- Late SAE, SADE, DD reporting
- Lack of patient informed consent
- Inclusion/exclusion criteria violations.

The Sponsor will not grant any waivers for CIP deviations. Sites must report all deviations to the Sponsor using the Deviation CRF. The Sponsor will monitor the occurrence of CIP for evaluation of investigator compliance to the CIP and regulatory requirements and handle according to written procedures. Investigators will inform their IRB/EC or equivalent committee of all CIP deviations in accordance with their specific IRB/EC or equivalent committee reporting policies and procedures.

In the event of repeated non-compliance, as determined by the Sponsor, a Sponsor's monitor or company representative will attempt to secure compliance by one or more of the following (and not limited to):

- Visiting the investigator and/or delegate
- Telephoning the investigator and/or delegate

- Corresponding with the investigator and/or delegate

Repeated non-compliance with the signed agreement, the CIP, or any other conditions of the study may result in further escalation in accordance with the Sponsor's written procedures, including securing compliance or, at its sole discretion, the Sponsor may terminate the investigator's participation in the study.

10.6 Quality Assurance Audit

A Sponsor representative or designee may request access to all study records, including source documentation, for inspection during a Quality Assurance audit.

If an investigator is contacted by a Regulatory Agency in relation to this study, the Investigator will notify Sponsor immediately. The Investigator and Research Coordinator must be available to respond to reasonable requests and audit queries made during the audit process. The Investigator must provide the Sponsor with copies of all correspondence that may affect the review of the current study (e.g., Form Food and Drug Administration (FDA) 483, Inspectional Observations, Warning Letters, Inspection Reports, etc.). The Sponsor may provide any needed assistance in responding to regulatory audits.

10.7 Clinical Events Committee (CEC)

The Clinical Events Committee (CEC) is an independent adjudication body comprised of qualified physicians who are not participants in the clinical investigation. The CEC will review and adjudicate pre-specified events reported by investigators or identified by Safety personnel for the clinical investigation as defined in the CEC charter and according to definitions provided in this CIP.

11 DATA HANDLING AND RECORD KEEPING

Sponsor and/or its affiliates will maintain documentation of the systems and procedures used in data collection for the duration of the study.

CRF data collection will be performed through a secure web portal and only authorized personnel will access the EDC system using a unique username and password to enter, review or correct data. Passwords and electronic signatures will be strictly confidential.

The data will be subjected to consistency and validation checks within the EDC system and supplemental review by the Sponsor.

At the end of the study, completed CRF images with the date-and-time stamped electronic audit trail indicating the user, the data entered, and any reason for change (if applicable) will be provided to the investigational sites, if requested.

For the duration of the study, the Investigator will maintain complete and accurate documentation including, but not limited to, medical records, study progress records, laboratory reports, CRFs, signed ICFs, correspondence with the IRB/EC, and study monitor/Sponsor, adverse event reports, and information regarding subject discontinuation or completion of the study.

11.1 Protection of Personally Identifiable Information

The Sponsor respects and protects personally identifiable information collected or maintained for this study.

The Sponsor implements technical and physical access controls to ensure that Personal Information is accessible only to and processed only on a 'need to know' basis, including periodic review of access rights, and revocation of access when an individual's employment is terminated or the individual transitions to a role that does not require access to Personal Information, and appropriate restrictions on physical access to premises, facilities, equipment, and records containing Personal Information.

The Sponsor requires the investigational sites to enter only pseudonymous Personal Information (key-coded) necessary to conduct the study, such as the patient's medical condition, treatment, dates of treatment, etc., into Sponsor's data management systems. The Sponsor discloses as part of the study informed consent process that some Sponsor representatives still may see Personal Information at the participating sites for technical support of the participating physicians on the device implant or procedures, monitoring and quality control purposes. All parties will observe confidentiality of Personal Information always throughout the study. All reports and data publications will preserve the privacy of each subject and confidentiality of his/her information.

The Sponsor data management systems and processes were designed, developed, and tested according to industry standards to appropriately safeguard Confidential Information (including any Personal Information) against unauthorized access and/or interference by third parties, intrusion, theft, destruction, loss or alteration. Study data are encrypted in transit and at rest.

The Sponsor maintains a Privacy Incident procedure that complies in all respects with Applicable Law and industry best practices.

11.2 Data Management Plan

A Data Management Plan (DMP) will describe procedures used for data review, data cleaning, and issuing and resolving data discrepancies. If appropriate, the Sponsor may update the DMP throughout the duration of the study. The Sponsor will track and document control all revisions.

11.3 Source Documentation

Regulations and GCP require the Investigator to maintain information in the subject's original medical records that corroborates data collected on the CRFs. To comply with these regulatory requirements/GCP, sites should include the following information in the subject record at a minimum and if applicable to the study:

- Medical history/physical condition of the subject before involvement in the study sufficient to verify CIP entry criteria
- Dated and signed notes on the day of entry into the study referencing the Sponsor, CIP number, subject ID number, and a statement that informed consent was obtained
- Dated and signed notes from each subject visit (for specific results of procedures and exams)

- AEs reported and their resolution, including supporting documents, such as discharge summaries, catheterization laboratory reports, ECGs, and lab results including documentation of site awareness of SAEs and of investigator assessment of device relationship for SAEs.
- CIP-required laboratory reports, reviewed and annotated for clinical significance of out of range results (if applicable).
- Notes regarding CIP-required and prescription medications taken during the study (including start and stop dates)
- Subject's condition upon completion of or withdrawal from the study
- Any other data required to substantiate data entered into the CRF
- Patient reported outcome measures may be completed using CRF worksheets. This serves as source documentation.

11.4 Case Report Form Completion

Site research personnel trained on the CIP and CRF completion will perform the primary data collection clearly and accurately based on source-documented hospital and/or clinic chart reviews. The investigator will ensure accuracy, completeness, legibility, and timeliness of the data reported to the Sponsor on the CRFs and in all required reports.

Sites will collect data on all subjects registered into the study. Only authorized site personnel will be permitted to enter the CRF data through the EDC system deployed by the Sponsor. The Sponsor will use an electronic audit trail to track any subsequent changes of the entered data.

11.5 Record Retention

The Sponsor and Investigator/Site will archive and retain all documents pertaining to the study as per the applicable regulatory record retention requirements. The Investigator must obtain permission from Sponsor in writing before destroying or transferring control of any study records.

12 ETHICAL CONSIDERATION

12.1 Institutional Review Board/Medical Ethics Committee Review and Approval

The Principal Investigator at each investigational site will obtain IRB/EC approval for the CIP and ICF/other written information provided to the patient prior to consenting and enrolling patients in this study. The site must receive the approval letter prior to the start of this study and provide a copy to the Sponsor.

Sites will submit any amendments to the CIP as well as associated ICF changes to the IRB/EC and written approval obtained prior to implementation, according to each institution's IRB/EC requirements.

No changes will be made to the CIP or ICF or other written information provided to the patient without appropriate approvals, including IRB/EC, the Sponsor, and the regulatory agencies (if applicable).

Until the study is completed, the Investigator will advise his/her IRB/EC of the progress of this study, per IRB/EC requirements. Written approval must be obtained from the IRB/EC yearly to continue the study, or according to each institution's IRB/EC requirements.

Sites will not perform any investigative procedures, other than those defined in this CIP, on the enrolled subjects without the written agreement of the IRB/EC and the Sponsor.

13 CLINICAL INVESTIGATION CONCLUSION

The study will be concluded when:

- All sites are closed AND
- The final report has been provided to investigators or the Sponsor has provided formal documentation of study closure.

In addition, the Sponsor will submit the study report within one year of the end of the study to the investigational sites, competent authorities, and reviewing IRBs and ECs.

14 PUBLICATION POLICY

The data and results from the study are the sole property of the Sponsor. The Sponsor shall have the right to access and use all data and results generated during the study. The Investigators will not use this study-related data without the written consent of the Sponsor for any purpose other than for study completion or for generation of publication materials, as referenced in the Clinical Trial Agreement. Single-center results are not allowed to be published or presented before the multi-center results. The Sponsor must review and approve any proposals for publications or presentations by the investigators in a timely manner in compliance with the Sponsor's publication policy set forth in the Clinical Trial Agreement.

The Sponsor will be responsible for determining whether to register the study on www.clinicaltrials.gov or any other clinical trials, in accordance with the International Committee of Medical Journal Editors guidelines, or any other applicable guidelines. In the event the Sponsor determines that the study should be registered, the Sponsor shall be responsible for any such registration and results posting as required by the ClinicalTrials.gov website. Institution and/or Principal Investigator(s) shall not take any action to register the study.

15 RISK ANALYSIS

15.1 Anticipated Clinical Benefits

JETi is similar in development and design to other mechanical thrombectomy devices that aspirate and remove thrombus in the peripheral vasculature. The JETi System functions by delivering a stream of high-pressure saline through a catheter to aspirate the thrombus and remove the material from the vessel. Use of the JETi System for mechanical thrombectomy may allow for thrombus removal without the use of thrombolytic drugs with an acceptable device-related serious adverse event rate.

15.2 Foreseeable Adverse Events and Anticipated Adverse Device Effects

Risks associated with the JETi Thrombectomy System and the procedure, together with their likely incidence, are described in the instructions for use (IFU) and **Appendix V**. There may be risks related to the device under investigation that are unknown at present. Likewise, the exact frequency of the risk may be unknown.

15.3 Residual Risks Associated with the Device Under Investigation, as Identified in the Risk Management Report / Risk Analysis Report

Risk analysis of the JETi System has been performed in accordance with the Risk Management File (including Risk Management Plan, Failure Mode Effect Analysis (FMEA), and Hazard Analysis (HA)) [redacted] to systemically identify potential hazards associated with the design and use of this device. Based upon bench testing and prior clinical study data, all risks have been identified and mitigated as far as possible through application of appropriate controls and inspections and determined to be within acceptable levels.

Residual risks are likewise disclosed in the IFU in the form of clear instructions of what actions to take or to avoid, to avoid a hazardous situation of harm from occurring (contra-indications, warnings, and precautions). The anticipated AEs disclosed in the IFU [redacted] provide further information to enable the user, and potentially the patient, to make an informed decision that weighs the residual risk against the benefit of using the device.

15.4 Risks Associated with Participation in this Clinical Investigation

There are no additional risks related to the participation in this clinical investigation: risks related to the procedure have been included in the product IFU, all study procedures are considered standard of care.

15.5 Steps Taken to Control or Mitigate Risks

In-depth recommendations, special precautions and instructions for use related to the device and device performance are included in the IFU. Patient selection, [redacted] evaluated in this trial are included within this document (**Section 5.3** Eligibility Criteria; [redacted]

The sponsor conducted a comprehensive risk analysis for the device and per ISO 14971 - "Medical devices – Application of risk management to medical devices". In order to ensure the highest probability of safety for the device design, the sponsor implemented design features, preventive steps, or completed pre-clinical evaluations to address and reduce the risks identified wherever possible.

The JETi System is made of materials known to be safe for human use and the device is already cleared for removal of intravascular thrombus.

The risk to the subjects is mitigated by selection of investigators with proficient knowledge and experience in the removal of intravascular thrombus. Investigators will receive comprehensive training by the sponsor on device handling prior to use during this study.

Investigator Selection and Training: It is also stated in the IFU that the devices can only be used by physicians who have received appropriate training on how to use the device. This statement is interpreted to mean that the physician users are expected to be aware of the known and foreseeable safety risks associated with the use of the devices including the surgical and/or non-surgical treatment of these conditions.

Ensuring strict adherence to the clinical investigation protocol: The clinical investigation will be carefully monitored by the Sponsor monitor (or designee) to ensure adherence to the CIP. Adverse events and device deficiencies will be reported to Abbott/designee and will be monitored internally for safety surveillance purposes.

15.6 Risk to Benefit Rationale

A thorough risk assessment was completed, applicable control measures were applied, and analysis confirmed that there are no unacceptable residual risks. Based on the risk management review and with management approval of the residual risks, the device design, device usability, and manufacturing process of the JETi Peripheral Catheter has an acceptable level of risk for its intended use.
The JETi system is an FDA-cleared device and a part of the current standard of care for clot removal in the peripheral vasculature. [redacted]. Use of the JETi System for mechanical thrombectomy may allow for thrombus removal without the use of thrombolytic drugs with an acceptable device-related serious adverse event rate. Taking these into consideration, the clinical benefits that may be expected from the removal of emboli and thrombus from the peripheral vasculature with the JETi System outweigh the possible risks that patients may experience when participating in this clinical investigation.

APPENDIX I: ABBREVIATIONS AND ACRONYMS

Acronym or Abbreviation	Complete Phrase or Definition
AE	Adverse Event
ABI	Ankle Brachial Index
BUN	Blood Urea Nitrogen
CDT	Catheter-Directed Thrombolysis
CFR	Code of Federal Regulations
CIP	Clinical Investigation Plan
CRF	Case Report Form
EC	Ethics Committee
EU	European Union
eGFR	Estimated Glomerular Filtration Rate
EDC	Electronic Data Capture
FDA	Food and Drug Administration
GCP	Good Clinical Practice
HIPAA	Health Insurance Portability and Accountability Act Intersocietal Commission for the Accreditation of Vascular
ICF	Informed Consent Form
IFU	Information for Use
INR	International Normalized Ratio
IRB	Institutional Review Board
IVC	Inferior Vena Cava
JETi	JET Enhanced Thrombectomy intervention
LMWH	Low Molecular Weight Heparin
PT	Prothrombin Time
PTS	Post Thrombotic Syndrome
aPTT	Activated Partial Thromboplastin Time
QOL	Quality of Life
SAE	Serious Adverse Event
SDU	Saline Drive Unit
SF-12	Short Form-12

APPENDIX II: DEFINITIONS

Amputation

The removal of a body extremity by surgery. For this study, the definition of amputation will only apply to amputations of the limb that was treated.

Minor amputation: amputation below the ankle
Major amputation: amputation above the ankle

Ankle Brachial Index (ABI)

The ABI is the ratio of the ankle to arm pressure, and it is calculated by dividing the higher systolic blood pressure of the two arteries (Dorsalis pedis or Posterior tibial) at the ankle of the assessed leg by the higher of the two brachial systolic blood pressures.

Calculation of the Ankle Brachial Index:

ABI = Highest Ankle Systolic Pressure/Highest Brachial Systolic Pressure

Death (per ARC 1)

When possible, death will be classified according to underlying cause. Death within 30 days of the study procedure will be classified as procedure related unless medical history or autopsy findings demonstrate otherwise.

Cardiac death:

Any death due to proximate cardiac cause (e.g., MI, low-output failure, fatal arrhythmia), unwitnessed death, or death of unknown cause.

Vascular death:

Death caused by noncoronary vascular causes, such as cerebrovascular disease, pulmonary embolism, ruptured aortic aneurysm, dissecting aneurysm, or other vascular diseases.

Non-cardiovascular death:

Any death not covered by the above definitions, such as death caused by infection, malignancy, sepsis, pulmonary causes, accident, suicide, or trauma.

Dissection

National Heart, Lung, and Blood Institute (NHLBI) Dissection Classification System:

A. Minor radiolucencies within the lumen during contrast injection with no persistence after dye clearance.
B. Parallel tracts or double lumen separated by a radiolucent area during contrast injection with no persistence after dye clearance.
C. Extraluminal cap with persistence of contrast after dye clearance from the lumen.
D. Spiral luminal filling defects.
E. New persistent filling defects.
F. Non-A-E types that lead to impaired flow or total occlusion.

Note: Type E and F dissections may represent thrombus.

Lower Extremity Deep Vein Thrombosis or Deep Venous Thrombosis (DVT)

DVT occurs when a blood clot forms in a deep vein, usually in the lower leg, thigh, or pelvis, but it can also occur in the arm.

For this study, the definition of Lower Extremity Deep Vein Thrombosis will apply to lower extremity venous thrombosis involving the femoral, common femoral, or iliac veins, or popliteal, or inferior vena cava (IVC) alone or in combination.

Acute clot for this study is defined based on signs and symptoms of onset of <2 weeks

Subacute clot for this study is defined based on signs and symptoms of onset of 2-6 weeks

Chronic clot for this study is defined based on signs and symptoms of onset of >6 weeks.

Major Bleeding (per BARC)

- BARC 3a: Overt bleeding plus hemoglobin drop of 3 to < 5 g/dL (provided hemoglobin drop is related to bleed); transfusion with overt bleeding or
- BARC 3b: Overt bleeding plus hemoglobin drop ≥ 5 g/dL (provided hemoglobin drop is related to bleed); cardiac tamponade; bleeding requiring surgical intervention for control; bleeding requiring IV vasoactive agents or
- BARC 5a Probable fatal bleeding; no autopsy or imaging confirmation but clinically suspicious or
- BARC 5b Definite fatal bleeding; overt bleeding or autopsy, or imaging confirmation

Pulmonary Embolism (per AHA)

Low-risk Pulmonary Embolism: Acute PE and the absence of the clinical markers of adverse prognosis that define massive or submassive PE

Massive Pulmonary Embolism: Acute PE with sustained hypotension (systolic blood pressure <90 mm Hg for at least 15 minutes or requiring inotropic support, not due to a cause other than PE, such as arrhythmia, hypovolemia, sepsis, or left ventricular [LV] dysfunction), pulselessness, or persistent profound bradycardia (heart rate <40 bpm with signs or symptoms of shock).

Sub-massive Pulmonary Embolism: Acute PE without systemic hypotension (systolic blood pressure ≥90 mm Hg) but with either RV dysfunction or myocardial necrosis.

- RV dysfunction means the presence of at least 1 of the following:
  - RV dilation (apical 4-chamber RV diameter divided by LV diameter >0.9) or RV systolic dysfunction on echocardiography
  - RV dilation (4-chamber RV diameter divided by LV diameter >0.9) on CT
  - Elevation of BNP (>90 pg/mL)
  - Elevation of N-terminal pro-BNP (>500 pg/mL); or
  - Electrocardiographic changes (new complete or incomplete right bundle-branch block, anteroseptal ST elevation or depression, or anteroseptal T-wave inversion)
- Myocardial necrosis is defined as either of the following:
  - Elevation of troponin I (>0.4 ng/mL) or
  - Elevation of troponin T (>0.1 ng/mL)

Renal Failure

Acute renal failure, also known as acute kidney injury (AKI), definition as per Kidney Disease Improving Global Outcomes (KDIGO):

- Increase in serum creatinine of ≥0.3 mg/dL within 48 hours or ≥50% within 7 days OR
- Urine output of <0.5 mL/kg/hour for >6 hours

Symptomatic Pulmonary Embolism

Define as per Society of Interventional Radiology (SIR) Quality Improvement Guidelines for the Treatment of Lower-Extremity Deep Vein Thrombosis with Use of Endovascular Thrombus Removal:

Episodes of DVT or PE can be symptomatic (the patient had symptoms and/or signs that prompted evaluation for DVT or PE) or asymptomatic (DVT or PE was detected on an imaging study in a patient without symptoms)

Recurrent Deep Venous Thrombosis (DVT)
Deep Vein Thrombosis that recurs in the treated limb.

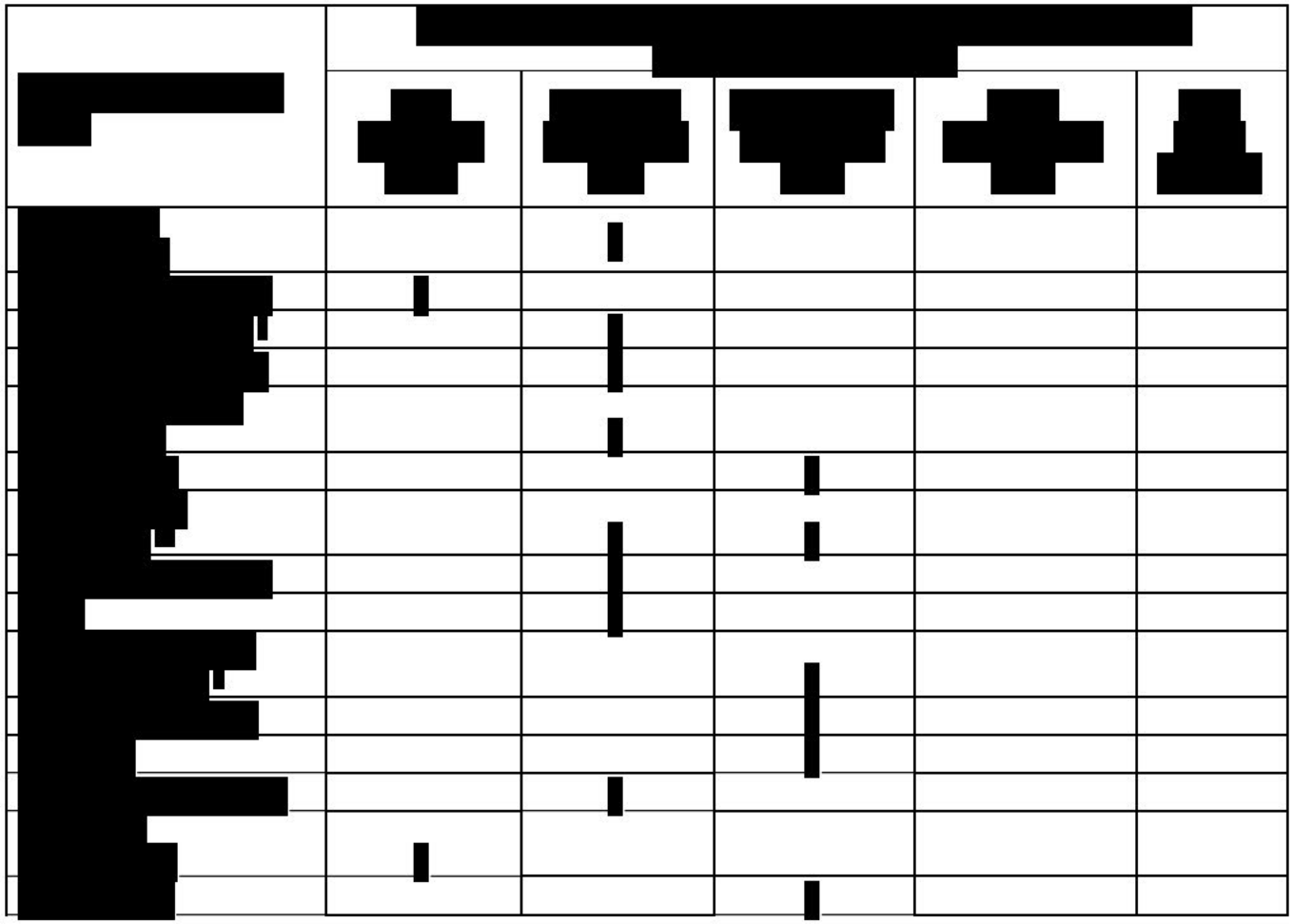
APPENDIX III: SITE CONTACT INFORMATION

Contact information for each participating clinical site is available under separate cover by contacting the Sponsor at:

Contact Name
Contact Address
Contact Email
Contact Phone

APPENDIX IV: RATES OF FORESEEABLE ADVERSE EVENT

[redacted]



[redacted]

[redacted]					

[redacted]

APPENDIX V: IFU AND LABELING

Device IFU and labeling is available under separate cover.

APPENDIX VI: CASE REPORT FORMS

The Case Report Forms (CRF) will be provided under a separate cover.

APPENDIX VII: INFORMED CONSENT FORM

A template Informed Consent Form (ICF) will be provided separately.

APPENDIX VIII: MONITORING PLAN

A copy of the Monitoring Plan can be obtained upon request from the Sponsor Clinical Project Manager for the study.

APPENDIX IX: ADDITIONAL DOCUMENTS

The following documents will be provided separately:

1. Quality of Life Survey (SF- 12)
2. Villalta Score for PTS Assessment
3. Core laboratory imaging guidelines

APPENDIX X: REVISION HISTORY

[redacted]

[redacted]

APPENDIX XI: CIP SUMMARY

Clinical Investigation Name	JETi Hong Kong Post Market Study
Title	JET Enhanced Thrombectomy intervention Hong Kong Post Market Study
Objective	To collect real-world data on the safety, performance, and clinical benefits of the JETi System for the treatment of thrombosis in the peripheral vasculature
Device	JETi™ Hydrodynamic Thrombectomy System
Number of Subjects	Approximately 20 subjects
Clinical Investigation Design	A single-arm, multi-center study
Primary Endpoint(s)	For subjects treated for arterial thrombosis: • **Clot removal grade** for each JETi-treated target vessel from pre-JETi angiogram/venogram to post-JETi angiogram/venogram (post-JETi thrombectomy and prior to any adjunctive therapies to treat underlying culprit lesions) per the grades in Table 1. The independent imaging core laboratory will be responsible for assessing this endpoint. • **Composite of JETi-related major adverse events** (MAEs) up to 30 days post-JETi procedure, defined as the following JETi-related events adjudicated by a CEC: death, major amputation of the treated limb (arterial subjects only), or major bleeding. Refer to **Appendix II** for definitions of major adverse events. For subjects treated for venous thrombosis: • **Percent of treated vessel(s) with ≥ 75% venous thrombus reduction** from pre-procedure venogram to final venogram (post-JETi AND after any/all adjunctive therapies to treat underlying culprit lesions) via modified Marder score. • **Composite of JETi-related major adverse events** (MAEs) up to 30 days post-JETi procedure, defined as the following JETi-related events adjudicated by a clinical events committee (CEC): death, symptomatic pulmonary embolism (PE), major bleeding, or re-thrombosis of JETi-treated vessel(s). Refer to Appendix II for definitions of major adverse events.
Subject Follow-up	Office visits at 30 days after the start of JETi procedure (Day 0).
Inclusion Criteria	1. Subject was treated or is scheduled to be treated for acute/subacute thrombosis as determined by the investigator in the peripheral vasculature with any of the JETi System. 2. Subject must provide written informed consent. 3. Subject must be ≥ 18 years of age and of Asian race.
Exclusion Criteria	1. Subject has previously been registered in the JETi Hong Kong Study in the last 12 months unless treated in the contralateral limb/different anatomy; patients treated in the contralateral limb/different anatomy within the last 12 months may re-enroll in the study. 2. Subject is currently participating in another drug or device clinical investigation.

	3. Subject has active symptoms and/or a positive test result of COVID-19 or other rapidly spreading infectious agent within the past 20 days.