Abbott	Clinical Investigation Plan Cover Page

NCT Number: NCT04370691
JETi Registry
JET Enhanced Thrombectomy intervention Registry
Study Document No: [redacted]
Version [redacted]
Date: 16-Aug-2024

Sponsor Abbott

[redacted]

[redacted]

[redacted]

CRD 1063
JETi® Registry Clinical Investigation Plan
JET Enhanced Thrombectomy intervention Registry

Version Number	[redacted]
Date	[redacted]
Study Co-Principal Investigators:	[redacted]
Planned Number of Sites and Regions	Approximately 30 sites globally
Clinical Investigation Type	A prospective, single-arm, multi-center registry
Abbott Medical Expert	[redacted]
Sponsor	Abbott Vascular, Inc. [redacted]
Clinical Investigation Monitor	Abbott Cardiovascular Systems, Inc., [redacted]
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 (e.g., US 21 Code of Federal Regulations (CFR) Part 50, 21 CFR Part 56, 21 CFR Part 812 and OUS 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.

1.0 INTRODUCTION

The JET Enhanced Thrombectomy intervention (JETi) Registry is a post-market study to collect real-world data on the safety, performance, and clinical benefits of the JETi™ Hydrodynamic Thrombectomy System[1] (JETi System) for the treatment of acute/subacute thrombosis in the peripheral vasculature.

The JETi System is a hydro-mechanical aspiration system designed to continuously aspirate thrombotic material into the catheter, where a high-pressure stream of saline within the catheter tip macerates the thrombus as it is aspirated, allowing the safe removal of thrombus material from the vessel while minimizing risk of distal embolization and hemolysis. 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[2] 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.[3] 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.[4] In addition to these studies reporting on venous thromboses, a recent presentation by Dandu et al.[5] 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 Registry is the first Abbott-sponsored data collection on the JETi System. It is a prospective, single-arm, multicenter study registering approximately 280 subjects treated for thrombosis in the peripheral vasculature from approximately 30 sites globally. Subjects treated for arterial, venous, or arteriovenous thromboses, and subject diagnoses such as acute limb ischemia (ALI), chronic limb ischemia/chronic limb threatening ischemia (CLI/CTLI), peripheral artery disease (PAD), deep vein thrombosis (DVT), and others may be included. Subject participation will be through the 12-month post-

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[1] The JETi™ Hydrodynamic Thrombectomy System (HTS) was previously branded as the JETi All-in-one (AIO) Peripheral Thrombectomy System. The term "JETi System" will be used throughout the protocol to refer to all commercial versions of the JETi System covered in the Registry.

[2] 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

[3] 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

[4] 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

[5] 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.

procedure visit with data collection at baseline, during the procedure, discharge, 30-day, and 12-month visits.

This Registry will collect data on the use of the JETi System in the treatment of patients undergoing a percutaneous thrombectomy procedure for peripheral thrombosis. This Registry will be conducted in accordance with this CIP. All investigators involved in the conduct of the registry will be qualified by education, training, and experience to perform their tasks and this training will be documented appropriately.

2.0 CLINICAL INVESTIGATION OVERVIEW

2.1 Clinical Investigation Objective

The objective of the JETi Registry 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 System

This Registry may include any commercially available JETi System at participating sites.

2.2.2 Indication for Use

JETi Hydrodynamic Thrombectomy System (JETi HTS) – US

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.

JETi Peripheral Thrombectomy System – CE MDD

The JETi Peripheral Thrombectomy System is intended to remove/aspirate fluid and break-up soft emboli and thrombus from the peripheral vasculature and to sub selectively infuse/deliver diagnostics or therapeutics.
The JETi Peripheral Thrombectomy System is intended to be used for less than 30 days.

2.2.3 Description of the Device

The JETi System is a hydro-mechanical aspiration system, intended for the removal of intravascular thrombus. The system is comprised of the JETi Catheter (6F or 8F), JETi Pump Set, JETi Saline Drive Unit (SDU), JETi Accessory Cart, JETi Suction tubing, and JETi Non-sterile Canister Set. The JETi System is designed to continuously aspirate thrombotic material into the catheter, where a high-pressure stream of saline within the catheter tip macerates the thrombus as it is aspirated. Further information can be found in the Instructions for Use (IFU) supplied with the SDU.

3.0 CLINICAL INVESTIGATION DESIGN

The JETi Registry is a prospective, 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 280 subjects at approximately 30 centers globally. Subjects participating in this registry will be followed through their 12-month follow up visit. [redacted] After JETi procedure, subjects will be evaluated at discharge, 30 days, and 12 months.

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.

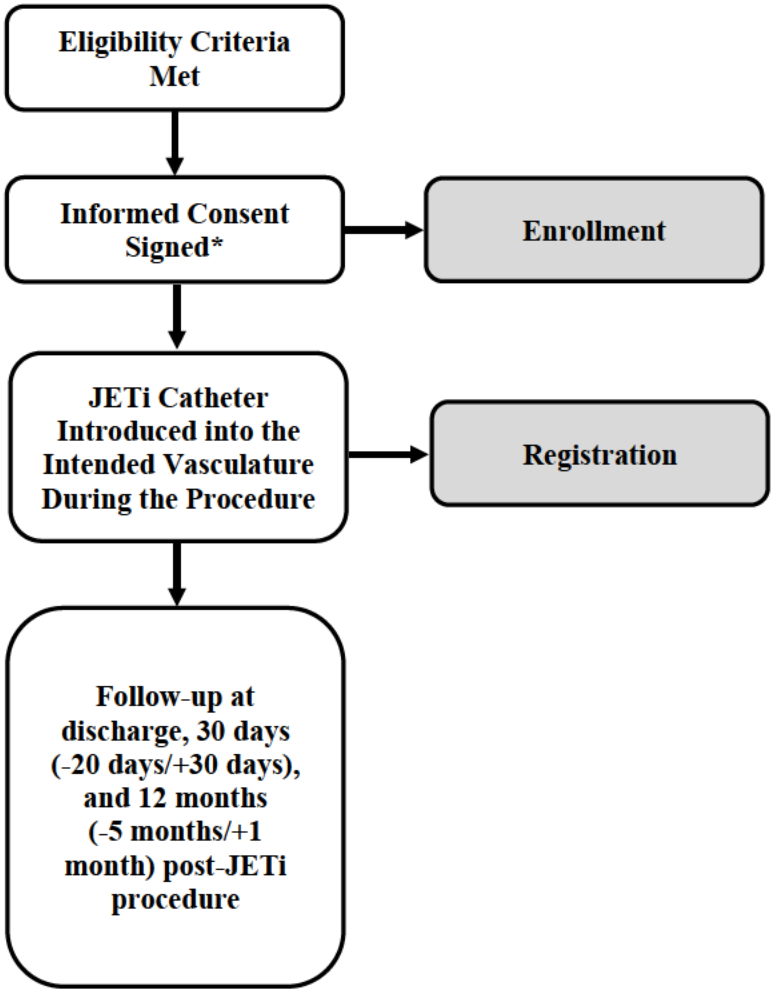
3.1 Clinical Investigation Procedures and Follow-up Schedule

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 registry from the moment the subject provides written informed consent. The point of registration in the registry 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 up to 5 days after the JETi procedure is acceptable. In these cases, the point of registration will be the same and any procedural information will be entered post-consent, and adverse events (AEs) will be collected retrospectively from the point of registration (Day 0). Any assessments performed prior to consent will be conducted per standard of care and data collection will occur after consent is obtained. Any assessment performed after consent will be conducted per the protocol's requirements. Registered subjects' data will be collected at baseline, procedure, and discharge, as well as at 30 days (-20 days/+30 days), and 12 months (-5 months/+1 month) after the JETi procedure.

For all follow-up visits, if all attempts to have the patient return to the office for an in-office visit are unsuccessful, a phone call or virtual follow-up will be allowed to collect available data. Protocol deviations must be reported for data that could not be collected via phone.

Refer to the detailed follow-up schedules in **Section 6.1.6** and **6.2.6**.

Figure 1: Study Flowchart



*Consenting up to 5 days after the JETi procedure is acceptable.

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, venograms and duplex ultrasound (DUS) imaging 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 Registry at any stage or reduce the follow-up period with suitable written notice to the investigator. Should the Sponsor discontinue the Registry, sites will follow subjects per routine hospital practice with device-related AEs reported to the Sponsor as per vigilance/commercial reporting requirements. The investigator shall return all Registry materials to the Sponsor and provide a written statement to the IRB/ EC (if applicable). All applicable Registry 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 Registry 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, and patients will continue to be treated per site standard of care. A Principal Investigator, IRB/EC, or regulatory authority may also suspend or prematurely terminate participation in the Registry at the investigational site(s) for which they are responsible. The investigators will follow the requirements specified in the Clinical Trial Agreement.

4.0 ENDPOINTS

4.1 Primary Endpoints

4.1.1 Arterial 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.

There will be no hypothesis testing, and there are no statistical power considerations. For subjects treated for arterial or arteriovenous thrombosis, the primary endpoints are:

- **Clot removal grade** for each JETi-treated target vessel(s) 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-JETi procedure and as adjudicated by a clinical events committee (CEC) (subject basis). 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 subjects treated for lower extremity DVT[6], 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. 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 event committee (CEC):
  1) death,
  2) symptomatic pulmonary embolism (PE),
  3) major bleeding
  4) re-thrombosis of JETi-treated vessel(s).

  Refer to **Appendix II** for definitions of major adverse events.

[redacted]

[6] Refer to Appendix II for definition of Lower Extremity Deep Venous Thrombosis

[redacted]

*Note, 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 at discharge, 30 days, and 12 months follow-up, and 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 only
    - JETi in combination with one or more of the following treatments:

[redacted]

- Short-Form Health Survey-12 (SF-12) at baseline, 30-day and 12-month follow-up.

4.2.2 Arterial 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 including device-related death, major amputation of treated limb (arterial subjects only), and major bleeding up to 30 days post-JETi as adjudicated by a CEC.
- Ankle Brachial Index* (ABI) of treated limb(s) at baseline and 30 days.
- Rutherford* classification at baseline and 30 days.
  ** only applicable to subjects with lower limb arterial thrombus*
- Rate of re-thrombosis of JETi-treated vessel at 30 days, and 12 months, as assessed by investigator/physician reported.

[redacted]

- Patency as determined by duplex ultrasound at baseline 30-day, and 12-month follow-up. 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)[7] (**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 TIPI score (**Table 3**):
    - Device success: Near complete or complete recanalization of occluded vessel, defined as post-JETi TIPI 2-3.
    - Technical success: Near complete or complete recanalization of occluded vessel, defined as final TIPI 2-3, where final TIPI 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 with ≥75% clot 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.
- For subjects not treated for lower extremity DVT as defined in Appendix II (i.e., upper extremity DVT (UE DVT)), Clot removal grade for each JETi-treated target vessel from pre-JETi venogram to final venogram (post-JETi thrombectomy and after any/all adjunctive therapies and prior to removal of the vascular sheath) per the grades in Table 1.

[7] 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

- Components of the JETi-related MAE up to 30 days post-JETi adjudicated by a CEC including death, symptomatic pulmonary embolism (PE), major bleeding, and re-thrombosis of JETi treated vessel(s).
- Re-thrombosis of the JETi-treated vessel(s) at 30-day, and 12-month follow up, as assessed by investigator/physician reported, and as adjudicated by CEC.
- The Villalta Post Thrombotic Syndrome (PTS) severity scale at baseline, 30-day, and 12-month follow-up. Note that this assessment will apply only to subjects with lower extremity DVT.
    - Edema component score from the Villalta Post Thrombotic Syndrome (PTS) severity scale at baseline, 30-day, and 12-month follow-up
- A 7-point Likert Scale for leg pain at baseline, discharge, 30-day, and 12-month follow-up.
- Venous patency and compressibility as determined by duplex ultrasound at baseline 30-day, and 12-month follow-up.
- Acute success, [redacted] assessed by core laboratory:
    - Device success: post-JETi thrombus removal grade II-III [redacted]
    - Technical success: Final thrombus removal grade II-III, [redacted] where final [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.

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

[redacted]

5.0 SUBJECT SELECTION AND WITHDRAWAL

5.1 Subject Population

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

[redacted]

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 the 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 Registry.

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 Registry.

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 Registry.

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 Registry that are relevant to the patient's decision to participate, such as details of registry procedures, anticipated benefits, and potential risks of registry participation. Sites must inform patients about their right to withdraw from the Registry at any time and for any reason without sanction, penalty, or loss of benefits to which the patient is otherwise entitled. Withdrawal from the Registry 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 Registry. 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 registry-specific procedures. The site will file the signed original in the patient's hospital or research charts and provide a copy to the patient. The dated signatures can be electronic. The site will follow local hospital and local EC/IRB provisions for documenting electronic ICF signature.

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 Registry, 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 registry on their own. Sites will obtain informed consent from the patient's legally authorized representative and will inform the patient about the Registry 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. Additionally, the Registry directly relates to a medical condition from which the individual suffers, and the Registry is expected to produce a direct benefit to the individual, outweighing the risks and burdens involved.

The legally acceptable 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 Registry 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 Registry.

This Registry excludes individuals under the age of 18 or age of legal consent from the Registry population.

Sites may enroll individuals unable to read or write in this Registry. 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 Registry.

Sites may enroll women who are pregnant or breastfeeding in this registry. Informed consent must be obtained using the IRB/EC approved informed consent in accordance with IRB/EC requirements. The Registry 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 Registry. 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 Registry 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 Registry up to 5 days post-procedure.

In addition, sites must obtain an authorization for use and disclosure of the subject's protected health information, in accordance with the Health Insurance Portability and Accountability Act (HIPAA), from the subject or their legally acceptable representative.

For live cases at congresses, the patient 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 Registry. If ANY general exclusion criteria are met, the patient is excluded from the Registry 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 the 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.

5.3.3 Exclusion Criteria

5.3.3.1 General Exclusion Criteria

1. Subject has previously been registered in the JETi Registry 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 novel infectious agent within the past 20 days.

5.4 Subject Enrollment

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

All patients treated with the JETi System and for which study consent is obtained, will be consecutively enrolled in the study.

5.5 Subject Registration

An enrolled subject is considered registered in the Registry only after a JETi Catheter is introduced into the intended vasculature of the subject during the procedure (Day 0). Patients may be consented up to 5 days post-JETi procedure. A subject who is enrolled but not registered in this study will be considered a screen failure. The sample size of the Registry is based on the number of registered subjects.

5.6 Subject Withdrawal and Discontinuation

Each registered subject shall remain in the Registry until completion of the required follow-up period; however, a subject's participation in any registry 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 Registry, except for the status (deceased/alive).

However, if a subject withdraws from the Registry 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 Registry.

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

Lost-to-Follow-up

If the subject misses both scheduled follow-up time points 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 one follow-up contact time points, it will be considered a missed visit. The subject may then return for subsequent visits. If the subject misses two consecutive time points

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-Registry cardiologist or relative without the presence of the subject or indirect documentation obtained via discharge letters will be considered as subject contact for the purpose of collecting vital status information. The center shall retain records of the contact.

5.7 Number of Subjects

The Registry will register approximately 280 subjects. [redacted]

5.8 Total Expected Duration of the Clinical Investigation

[redacted] The expected duration of each subject's participation is approximately 12 months, including the scheduled visits and data collection for this registry that will occur at 30 days, and 12 months. Subjects will exit the registry at the end of their 12-Month Follow-Up visit. [redacted]

6.0 TREATMENT AND EVALUATION OF ENDPOINTS

For this Registry, 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). An index procedure can start with JETi or any other treatment first.
- **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 device 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).

[8] Specifically Lower Extremity DVT subjects as defined in Appendix II

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

6.1 Arterial 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 JETi procedure will be recorded and include estimated glomerular filtration rate (eGFR), LMWH), 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 venous system 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 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, 30-Day and 12-Month 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 JETi procedure) and Rutherford assessment (within 4 days prior to JETi procedure) can be obtained via a non-study physician, including a referring physician; this will not be considered a protocol deviation. In emergent acute limb ischemia (ALI) cases, missing ABI at baseline will not be considered a protocol deviation.

The Short Form (SF-12) is a self-reported outcome quality of life measure. Its completion is required at baseline, 30 days, and 12 months. 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, and antiplatelet medications will be collected for this Registry at Baseline, Index Procedure, Discharge, and all follow-up timepoints. Thrombolytics used during the procedure will be collected. At Baseline, the medications taken within the 30 days prior to the admission and those medications that the patient was taking upon admission will be documented.

AEs experienced by the patient during the study will be reported, 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 data will be collected:

- Enrollment
- Demographics – including date of birth (US subjects only)/age, sex, race/ethnicity
- Medical history – subject medical history including general medical history, surgical history, vascular history, renal history, DVT 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):
    - 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 JETi procedure)
- Quality of life (QOL) questionnaire: SF-12 (not applicable for post-procedure consented subjects)
- ABI *
- Rutherford category *

  ** Note: ABI (done within 3 months prior to JETi procedure) and Rutherford assessment (done within 4 days prior to JETi procedure) can be obtained via a non-study physician, including a referring physician; this will not be considered a protocol deviation. In emergent ALI cases, missing ABI at baseline will not be considered a protocol deviation.*

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 that have a successful or attempted (with at least the JETi Catheter being introduced into the intended vasculature) procedure with the JETi System will be considered registered subjects and will be entered into the study.

The following procedural data will be collected:

- Procedure information (including, but not limited to): 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), procedure outcome.
- Treatment information (including, but not limited to): 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 [redacted]

[redacted]

- 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 TIPI score (**Table 3**), per core lab assessment:
  - Device success: Near complete or complete recanalization of occluded vessel, defined as post-JETi TIPI 2-3.
  - Technical success: Near complete or complete recanalization of occluded vessel, defined as final TIPI 2-3, where final TIPI 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
- Adverse events

[redacted]

- 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 or referral hospital. Discharge will be performed per standard of care. The following data will be collected:

- Adverse events
- Medications: Anticoagulant and antiplatelet medications

6.1.4 Follow-up

A window of 10 days to 60 days post JETi procedure is allowed for the 30-day follow-up visit (30 days -20 days/+30 days), and a window of 5 months to 13 months is allowed for the 12-month (12 months -5 months/+ 1 month) follow-up visit.

- An in-office visit is required for 30-day follow-up visit. If all attempts to have the patient return to the office for an in-office 30-day follow-up visit are unsuccessful, a phone call follow-up will be allowed to collect SF-12 and adverse event data. Protocol deviations will need to be reported for data that could not be collected via phone.
- While an in-person visit is strongly recommended, the follow-up assessments at 12 months may be collected by phone call or virtual visit. Protocol deviations will need to be reported for data that is not collected via phone.

The following data will be collected at the follow-up visit:

- Adverse events
- Medications: Anticoagulant and antiplatelet medications
- ABI* (30-day visit only)
- Rutherford classification* (30-day visit only)

* 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)

6.1.5 Health Care Utilization

Data on resource utilization will be collected prospectively for the index hospitalization and the full follow-up period using standardized case report forms.

6.1.6 Unscheduled Visit

Unscheduled visits may occur as clinically warranted, and data will be collected if the unscheduled visit is related to the procedure (as determined by the physician). Data on any imaging, medication (anticoagulant, and antiplatelet medications), AEs and SAEs will also be collected if applicable.

6.1.7 Schedule of Events

The schedule of assessments for Arterial Subjects is listed in **Table 3**.

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Table 5: Assessment Schedule for Arterial Subjects

CIP Activity	Baseline	Index Procedure	Discharge	30 Days Follow-up [1] (-20 days/+ 30 days)	12 Months Follow-up [2] (-5 months/+ 1 month)	Unscheduled Visit
Enrollment [3]	X					
Demographics	X					
Medical history	X					
Medications	X	X	X	X	X	X[4]
Laboratory assessments						
eGFR	X[5]					
Serum Creatinine (SCr)	X[5]					
Blood Urea Nitrogen (BUN)	X[5]					
Potassium (K)	X[5]					
Hemoglobin (Hgb)	X[5]					
Platelets (Plt)	X[5]					
International Normalized Ratio (INR)	X[5]					
Prothrombin Time (PT)	X[5]					
Activated Partial Thromboplastin Time (aPTT)	X[5]					
Clinical assessment	X[5]					
Physical exam	X[5]					
ABI	X[6,7]			X[7]		
Rutherford category	X[7, 8]			X[7]		
Imaging assessment - Angiogram		X[9]				
Imaging assessment – DUS	X[10]			X[10]	X[10]	
QOL (SF-12)	X[11]			X	X	
Adverse event assessment		X[12]	X[12]	X[12]	X[12]	X[12]
Healthcare utilization		X				X
Procedure, treatment information, procedure outcome		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] *in-office visit is strongly recommended*
[3] *retrospective consent within 5 days of JETi-procedure is permitted*
[4] *unscheduled Medications reported in Adverse Event form when applicable*
[5] *assessment done within 14 days prior to procedure is acceptable*
[6] *ABI (only applicable to lower extremity arterial thrombosis) done within 3 months prior to procedure is acceptable. In emergent ALI cases, missing ABI at baseline will not be considered a protocol deviation*
[7] *can be obtained via a non-study physician, including a referring physician; this will not be considered a protocol deviation*
[8] *Rutherford assessment (only applicable to lower extremity arterial thrombosis) done within 4 days prior to procedure is acceptable*
[9] *includes pre-JETi, post-JETi, and final angiograms*
[10] *only applicable for arteriovenous thrombosis*
[11] *not applicable for post-procedure consented subjects*
[12] *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 JETi procedure will be recorded, and 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).

Duplex ultrasound examination will be collected at baseline (up to 14 days prior to JETi procedure), at 30-Day and 12-Month Follow-Up. A vascular ultrasound lab that routinely performs compressibility and venous flow on venous cases is recommended. Thrombus obstruction and location will be assessed by venous compressibility with incomplete compression indicating the presence of thrombus in that venous segment. 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 treated vessels will be assessed using the grades in **Table 1**. 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).[9] 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 Villalta PTS assessment will follow standard scoring completed by the physician. In addition, several patient outcomes will be assessed, including patient-reported Villalta PTS (same timepoints as physician-scored Villalta). The assessment will be collected at baseline (up to 4 days prior to JETi procedure), 30 days, and 12 months.

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, 30 days, and 12 months.

The Short Form (SF-12) is a self-reported outcome quality of life measure. Its completion is required at baseline, 30 days, and 12 months. 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, and antiplatelet medications will be collected for this Registry at Baseline Discharge, and all follow-up timepoints. Thrombolytics used during index procedure will be collected. At Baseline, the

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[9] 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

medications taken within the 30 days prior to the admission and those medications that the patient was taking upon admission will be documented.

AEs experienced by the patient during the study will be reported, please refer to AE reporting section 7.3.1 for additional details of event reporting.

The schedule of events for venous subjects is located in **Section 6.2.7**
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 date of birth (for US subjects only)/age, sex, race/ethnicity
- Medical history – subject medical history including general medical history, surgical history, vascular history, renal history, deep vein thrombosis 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):
    - 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 JETi procedure)*
- DUS (within 14 days prior to JETi 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

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 that have a successful or attempted (with at least the JETi Catheter being introduced into the intended vasculature) procedure with the JETi System will be considered registered subjects and will be entered into the study.

The following procedural data will be collected:

- **Procedure information** (including, but not limited to): 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.), procedure outcome.
- **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 [redacted]

      [redacted]
- **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 venous vessels for lower extremity DVT will be assessed using Marder score, per core lab assessment.
- **Acute success**, [redacted], core laboratory assessed:
    - Device success: Post-JETi thrombus removal grade II-III, [redacted]
    - Technical success: Final thrombus removal grade II-III, [redacted] where final [redacted] evaluation occurs after JETi system and any other adjunctive device or procedures.

[redacted]

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

- **Adverse events**
- **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. Discharge will be performed per standard of care. The following data will be collected:

- Adverse events
- Medications: Anticoagulant, and antiplatelet medications
- Leg pain assessment by 7-point Likert Scale

6.2.4 Follow-up (Office Visit)

A window of 10 days to 60 days post JETi procedure is allowed for the 30-day follow-up visit (30 days -20 days/+30 days), and a window of 7 months to 13 months is allowed for the 12-month (12 months -5 months/+1 month) follow-up visit.

- An in-office visit is required for 30-day and 12-month follow-up visit. If all attempts to have the patient return to the office for an in-office visit are unsuccessful, a phone call follow-up will be allowed to collect applicable data. Protocol deviations will need to be reported for data that could not be collected via phone.

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
- DUS *
- Villalta PTS assessment *
- 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 Health Care Utilization

Data on resource utilization will be collected prospectively for the index hospitalization and the full follow-up period, including any unscheduled visits, using standardized case report forms.

6.2.6 Unscheduled Visit

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

6.2.7 Schedule of Events

The schedule of assessments for Venous Patients is listed in **Table *6***.

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Table 6. Assessment Schedule for Venous Subjects

CIP Activity	Baseline	Index Procedure	Discharge	30 Days Follow-up [1] (-20d days/+ 30 days)	12 Months Follow-up [1] (-5 months/+1 month)	Unscheduled Visit
Enrollment [2]	X					
Demographics	X					
Medical history	X					
Medications	X	X	X	X	X	X[3]
Laboratory assessments						
eGFR	X[4]					
Creatinine	X[4]					
Blood Urea Nitrogen (BUN)	X[4]					
Potassium	X[4]					
Hemoglobin	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 exam	X[4]					
Villalta PTS assessment	X[5]			X	X	
Leg pain assessment (7-point Likert scale)	X		X	X	X	
Imaging assessment						
Venogram		X[6]				
Duplex ultrasound	X			X	X	
QOL (SF-12)	X[7]			X	X	
Adverse event assessment		X[8]	X[8]	X[8]	X[8]	X[8]
Health care utilization		X				X
Procedure, treatment information, procedure outcome		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 within 5 days of JETi-procedure 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
[6] Serious adverse events (SAEs) and device deficiencies must be reported within 3 calendar days of Site becoming aware

6.3 Imaging Core Laboratory

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

7.0 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).

a) Led to a death,

b) Led to a serious deterioration in health of the subject, that either resulted in
   1. a life-threatening illness or injury, or
   2. a permanent impairment of a body structure or a body function, or
   3. in-patient hospitalization or prolongation of existing hospitalization, or
   4. medical or surgical intervention to prevent life threatening illness or injury or permanent impairment to a body structure or a body function.
   5. chronic disease

c) 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. AEs will not be collected for screen failure subjects. Safety surveillance and reporting will continue until sites perform the last follow-up visit, the subject is deceased, the subject concludes participation in the registry, or the subject withdraws from the registry. Sites will collect all serious adverse events, all JETi device related adverse events, including deaths and device deficiency data 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 Registry, the following adverse events will be reported for each subject through the 12-month 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]

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.

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.

8.0 STATISTICAL CONSIDERATIONS

8.1 Analysis Populations

All registered subjects will be included in the analysis.

8.2 Statistical Analyses

8.2.1 Primary Endpoint(s) Analyses

For subjects treated for lower extremity DVT, the primary effectiveness endpoint is the 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.

[redacted]

The primary safety endpoint is the composite of JETi-related MAEs (death, symptomatic pulmonary embolism (PE), major bleeding, or re-thrombosis of JETi treated vessel(s)) up to 30 days post-JETi procedure for subjects treated for lower extremity DVT and as adjudicated by a clinical events committee (CEC).

[redacted]

8.3 Sample Size Calculation

[redacted]

. A total of approximately 280 subjects will be registered in this Registry.

[redacted]

8.4 Timing of Analysis

Analysis for the primary endpoints will be performed after all registered subjects (within arterial or DVT groups) have reached their 30-day follow-up visit. Analysis for final report will be conducted after all registered subjects have completed the 12-month follow-up visit.

8.5 Subgroup Analysis

Details can be found in the SAP.

8.6 Multiplicity

Details about multiplicity adjustment can be found in the SAP.

8.7 Pooling Strategy

Details on pooling strategy can be found in the SAP.

8.8 Procedures for Accounting for Missing Data

Every effort will be made to collect all required 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. However, impact of missing data may be assessed in the sensitivity analysis. Details can be found in the SAP.

[redacted]

8.9 Success Criteria

[redacted]

8.10 Deviations from Statistical Plan

The Sponsor will document any major changes to the SAP in an amendment to the SAP and any less significant changes to the planned analyses in the final report.

9.0 DIRECT ACCESS TO SOURCE DATA/DOCUMENTS

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

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

10.0 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 registry. 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 registry.

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 Registry 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. Training of Investigators and Registry personnel will include, but is not limited to, the CIP requirements, electronic case report form completion, and Registry personnel responsibilities. All Investigators and Registry personnel that are trained must sign a training log (or an equivalent) upon completion of the training.
Note that JETi operators contributing to the Registry need not be included on the Delegation of Authority (DOA).

10.4 Monitoring

Sponsor and/or designee will monitor the Registry 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 registry 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 registry and should have access to an adequate number of appropriate subjects to conduct the registry.
- 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 registry-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
- Baseline ABI in cases of emergent ALI

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 registry 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 registry.

10.6 Quality Assurance Audit

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

If an investigator is contacted by a Regulatory Agency in relation to this registry, 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 registry (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.

11.0 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 Registry.

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

11.1 Protection of Personally Identifiable Information

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

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 registry, 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 registry 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 registry. 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. Registry 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 Registry. The Sponsor will track and document control all revisions.

11.3 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 Registry. 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.

11.4 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 Registry:

- Medical history/physical condition of the subject before involvement in the Registry sufficient to verify CIP entry criteria
- Dated and signed notes on the day of entry into the Registry 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)
- Outside records, including referring physician follow-up visits to support data from baseline throughout the follow-up period as permitted per local regulation
- 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 Registry (including start and stop dates)
- Subject's condition upon completion of or withdrawal from the Registry
- 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.

11.5 Record Retention

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

12.0 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 Registry. The site must receive the approval letter prior to the start of this Registry 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 Registry is completed, the Investigator will advise his/her IRB/EC of the progress of this Registry, per IRB/EC requirements. Written approval must be obtained from the IRB/EC yearly to continue the Registry, 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.

13.0 CLINICAL INVESTIGATION CONCLUSION

The Registry 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 Registry closure.

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

14.0 PUBLICATION POLICY

The data and results from the Registry are the sole property of the Sponsor. The Sponsor shall have the right to access and use all data and results generated during the Registry. The Investigators will not use this Registry-related data without the written consent of the Sponsor for any purpose other than for Registry 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 Registry 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 Registry 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 Registry.

15.0 RISK ANALYSIS

15.1 Anticipated Clinical Benefits

JETi is commercially available and 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 III**. 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

The risks related to the procedure have been included in the product IFU.

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 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
aPTT	Activated Partial Thromboplastin Time
BUN	Blood Urea Nitrogen
CDT	Catheter-Directed Thrombolysis
CEAP	Clinical-Etiologic-Anatomic-Pathologic
CFR	Code of Federal Regulations
CIP	Clinical Investigation Plan
CRF	Case Report Form
DVT	Deep Vein Thrombosis/Deep Venous Thrombosis
EC	Ethics Committee
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
QOL	Quality of Life
SAE	Serious Adverse Event
SAP	Statistical Analysis Plan
SDU	Saline Drive Unit
SF-12	Short Form-12
US	United States

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

- **BARC IIIa:** Overt bleeding plus hemoglobin drop of 3 to < 5 g/dL (provided hemoglobin drop is related to bleed); transfusion with overt bleeding or
- **BARC IIIb:** 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
- **BARC Va:** Probable fatal bleeding; no autopsy or imaging confirmation but clinically suspicious or
- **BARC Vb:** 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)

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 III: RATES OF FORESEEABLE ADVERSE EVENT

[redacted]

[redacted]

[redacted]

APPENDIX IV: LABELING

Device labeling is available under separate cover.

APPENDIX V: CASE REPORT FORMS

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

APPENDIX VI: INFORMED CONSENT FORM

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

APPENDIX VII: MONITORING PLAN

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

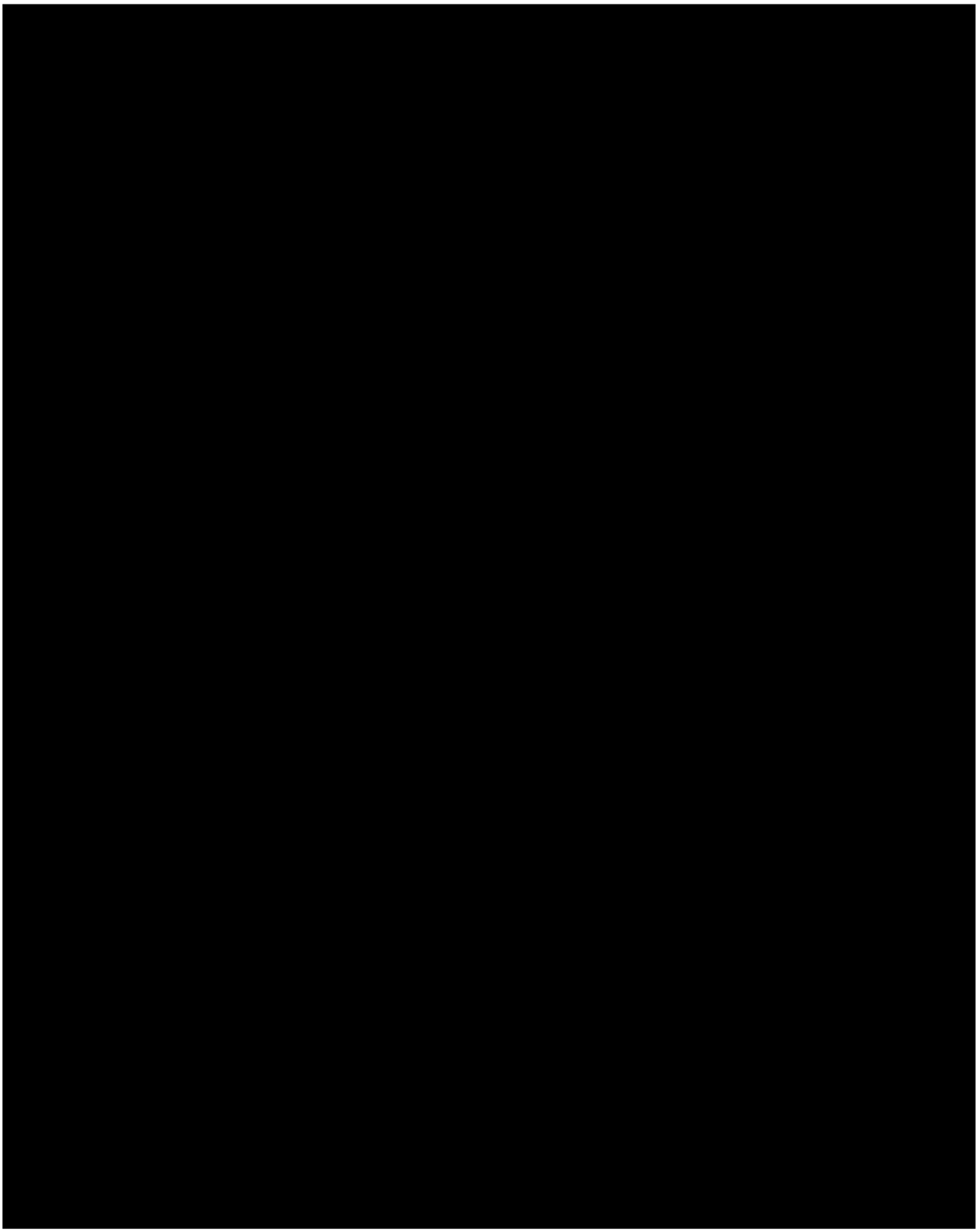
APPENDIX VIII: ADDITIONAL DOCUMENTS

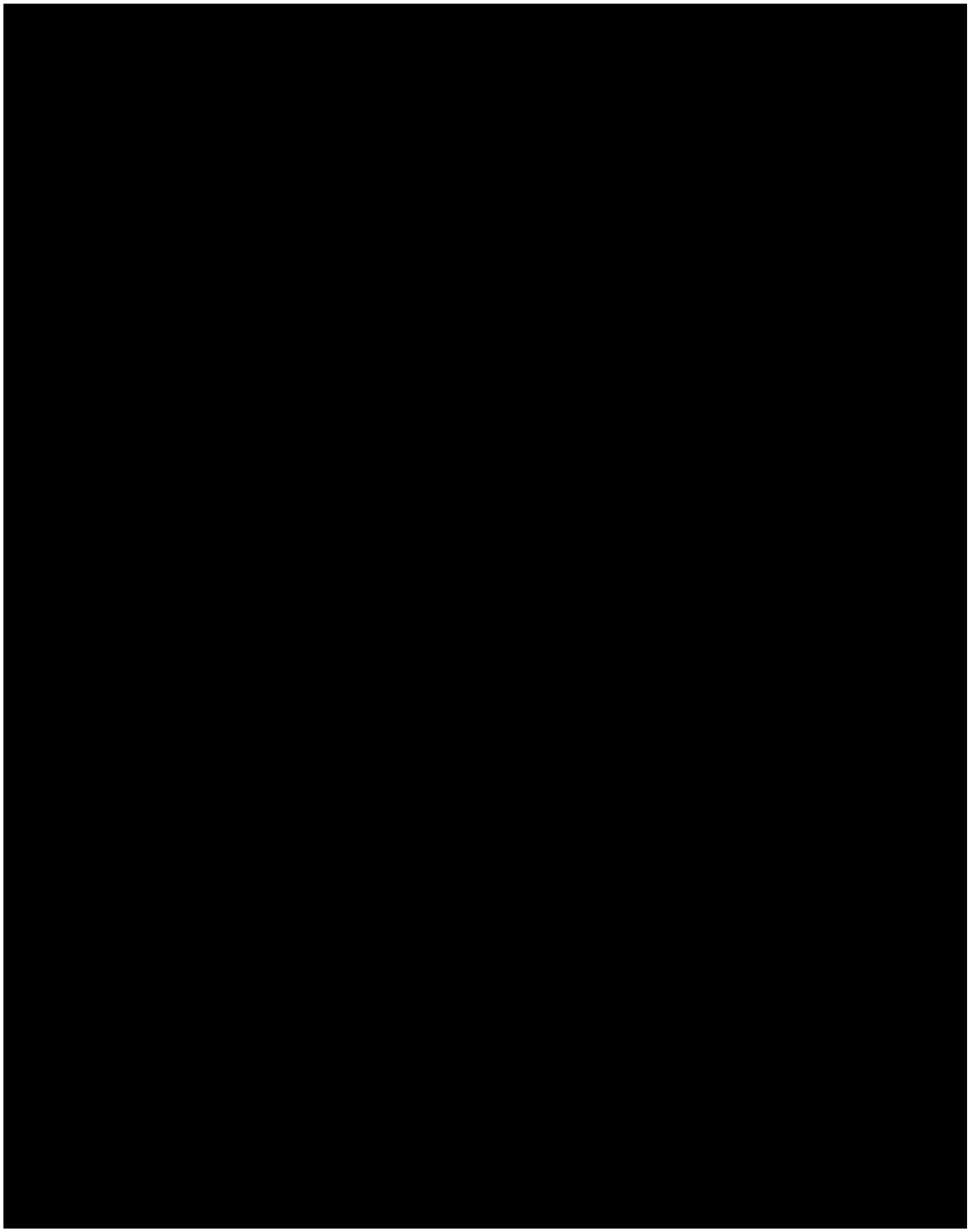
The following documents will be provided separately:

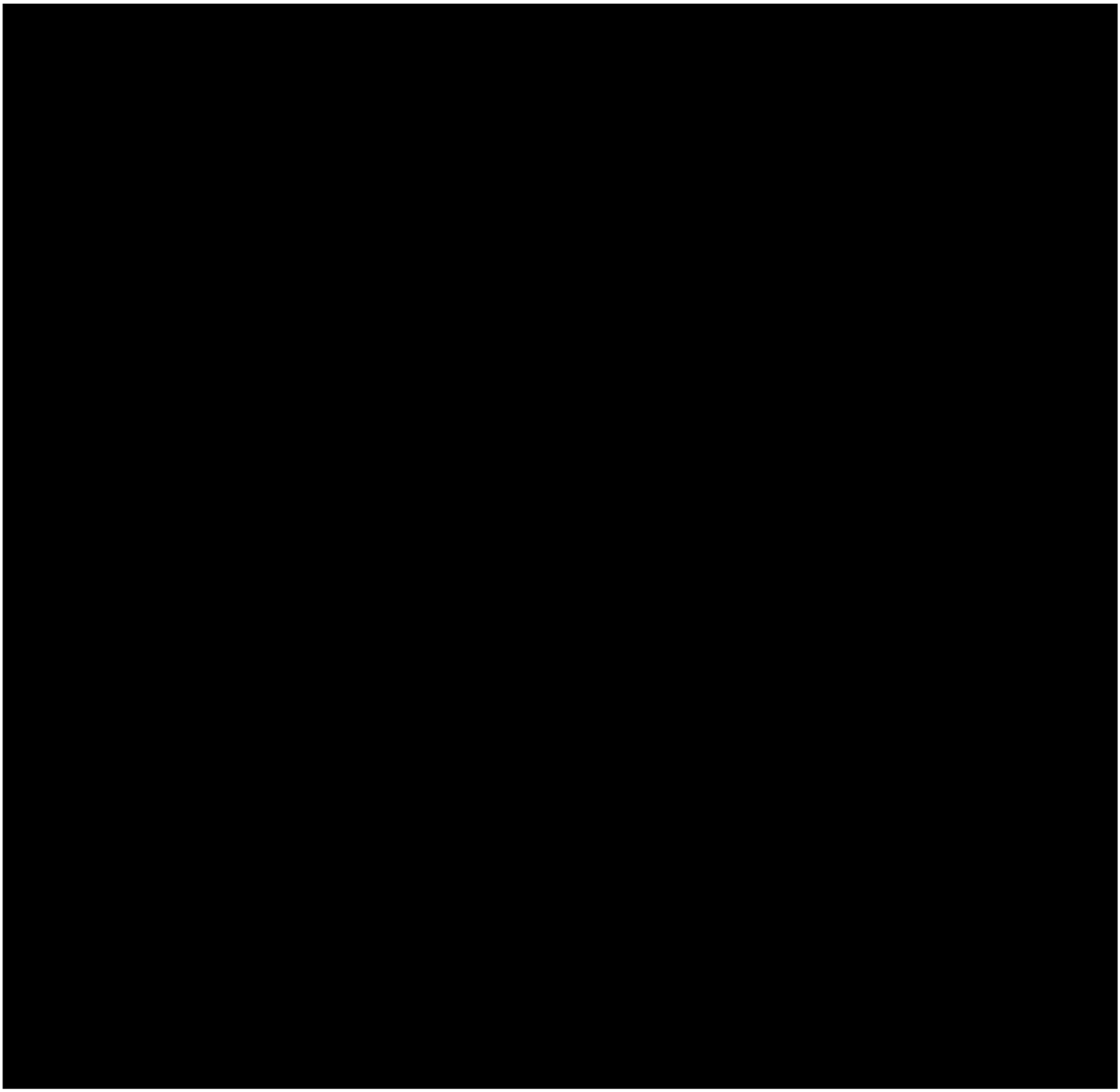
1. Quality of Life Survey (SF- 12)
2. Villalta Score for PTS Assessment
3. Core laboratory imaging guidelines

APPENDIX VIII: REVISION HISTORY

[redacted]







APPENDIX IX: CIP SUMMARY

Clinical Investigation Name	JETi Registry
Title	JET Enhanced Thrombectomy intervention Registry
Objective	To collect real-world data on the safety, performance, and clinical benefits of any JETi System for the treatment of thrombosis in the peripheral vasculature
Device	JETi System
Number of Subjects	Approximately 280 subjects
Clinical Investigation Design	A prospective, single-arm, multi-center, registry
Primary Endpoint(s)	For subjects treated for arterial thrombosis: • **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. 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-JETi procedure and as adjudicated by a clinical events committee (CEC). 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-JETi venogram to final venogram (post-JETi AND after any/all adjunctive therapies to treat underlying culprit lesions) via modified Marder score.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 event committee (CEC): death, symptomatic pulmonary embolism (PE), major bleeding, 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, and 12 months post JETi procedure
Inclusion Criteria	1. Subject was treated or is expected to be treated for acute/subacute thrombosis as determined by the investigator in the peripheral vasculature with any of the JETi Peripheral Thrombectomy System. 2. Subject must provide written informed consent. 3. Subject must be ≥ 18 years of age.

Exclusion Criteria	1. Subject has previously been registered in the JETi Registry in the last 12 months unless treated in the contralateral limb/different anatomy; patients treated in the contralateral limb/different anatomy may be included when treated within the last 12 months. 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 novel infectious agent within the past 20 days.

APPENDIX X: EXCEPTIONS FROM ISO 14155 COMPLIANCE

Minimal exceptions to ISO 14155:2020 compliance are expected, though these exceptions do not affect the safety and protection of the clinical investigation subjects and do not compromise data quality and security.

- This clinical investigation provides market approved devices, which will be used within their intended purpose, thus clinical investigation labelling will not be applied, a separate investigator Brochure will not be created, and clinical device accountability will not be set up.
- The study will not be submitted for review to the Competent Authority, only standard vigilance reporting will be observed. Local and/or regional requirements might be still applicable and will be tracked in a study specific Safety Plan.
- Financial disclosures will not be collected from the Investigators.