Protocol for the Feasibility Study of the Kronos Electrocautery Device

NCT # 05593211

November 7th, 2022

Feasibility Study of the Kronos Electrocautery Device

Funding Sponsor:	Single Pass, Inc. 105 N. Pointe Drive, Ste B Lake Forest, CA 92630 +1 602-618-3377
Study Product:	Kronos Electrocautery Device
Short Name:	Kronos Study
Protocol Number:	SP-01
Version:	Version 2.0
Date:	October 4th, 2022

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1 Protocol Approval Form

Protocol Name**: Kronos Study**

I agree to conduct the study as detailed in this Clinical Investigational Plan and in accordance with all applicable regional laws and regulations. In addition, I agree to provide all the information requested in the case report forms presented to me by the sponsor in a manner to assure completeness, legibility and accuracy.

I agree to actively enroll patients into this study and confirm that I do not have any material conflicts including participation in any clinical investigations for similar types of medical devices. I will provide copies of this registry protocol and all necessary information about this registry to the registry staff under my supervision. I will discuss this material with them and ensure they are fully informed about the device under investigation as well as all aspects concerning the conduct of this registry.

I also agree that all information provided to me by the sponsor, including pre-clinical data, protocols, case report forms, and any verbal and written information, will be kept strictly confidential and confined to the clinical personnel involved in conducting the registry. It is recognized that this information may be relayed in confidence to the Ethics Committee or Institutional Review Board or to regulatory authorities.

In addition, no reports or information about the study or its progress will be provided to anyone not involved in the registry other than the sponsor, the Ethics Committee(s) or Institutional Review Board(s), the core labs, or the independent medical reviewer. Any such submission will indicate that the material is confidential.

I will supervise the conduct of the clinical investigation to be performed in compliance with the clinical investigational plan, Good Clinical Practice (GCP)/ICH, the Declaration of Helsinki, and all applicable regulatory and ethical requirements.

_____

Investigator Site Name

_____

Site Principal Investigator (Signature) Date

_____

Site Principal Investigator (Printed Name)

_____

Sponsor (Signature) Date

_____

Sponsor (Printed Name)

2 List of Abbreviations

AE	Adverse Event/Adverse Experience
CFR	Code of Federal Regulations
CRF	Case Report Form
DSMB	Data and Safety Monitoring Board
FDA	Food and Drug Administration
GCP	Good Clinical Practice
HER	Electronic Health Record
HIPAA	Health Insurance Portability and Accountability Act
IB	Investigator's Brochure
IRB	Institutional Review Board
Non-UPIRTSO	Non-Unanticipated Problems Involving Risk to Subjects or Others
PHI	Protected Health Information
PI	Principal Investigator
SAE	Serious Adverse Event/Serious Adverse Experience
SOP	Standard Operating Procedure
UPIRTSO	Unanticipated Problems Involving Risk to Subjects or Others

3 Study Summary

Title	Feasibility Study of the Kronos Electrocautery Device
Protocol Name	Kronos Study
Protocol Number	SP-01, Version 1.0
Phase	N/A
Methodology	Pilot Study, Non-Randomized
Overall Study Duration (Estimated)	4 months
Subject Participation Duration (Estimated)	14 Days post procedure
Number of Sites	Up to 5
Objectives	The primary objective for this study is to assess safety and performance of the Kronos Electrocautery Device for electrocautery procedures following coaxial biopsy procedures on areas that include, but are not limited to, liver, kidney, lungs, breasts, soft tissue, etc.
Intended Purpose	The Kronos Electrocautery Device is intended to be used in electrocautery procedures to control bleeding by use of electrical current to heat the device probe tip that is applied directly to the target tissue area of treatment.
Study Design	Prospective, multicenter, single arm study with consecutive, eligible subject enrollment at each site. Patients who require a coaxial biopsy procedures on areas that include, but are not limited to, liver, kidney, lungs, breasts, soft tissue, etc., will be eligible to participate in this study.
Number of Subjects	Up to 30 patients
Primary Endpoint	Assess rate of successful electrocautery procedure in absence of procedure related Adverse Events
Inclusion Criteria	1. Patients undergoing a scheduled elective coaxial biopsy procedures on areas that include, but are not limited to, liver, kidney, lungs, breasts, soft tissue, etc., 2. Patients have signed an informed consent 3. Patients who are ≥ 18 years of age.

Exclusion Criteria	1. Patients with known bleeding disorder 2. Significant congenital anomaly or medical problem that in the opinion of the investigator would preclude enrollment in this study. 3. Women of childbearing potential who are pregnant, lactating, or planning to become pregnant during the course of the clinical investigation. 4. Active systemic infection or sepsis.
Study Device	Kronos Electrocautery Device
Duration of Use	The Kronos Electrocautery Device is a single use probe that will be used during procedure only.
Statistical Methodology	No formal hypothesis is proposed in this protocol. All outcomes and analyses will be presented in descriptive manner only.
Applicable standards	The study will be conducted in compliance with this protocol and the following applicable regulations & Good Clinical Practices (GCPs): ISO 15444: 2020

4 Introduction

This document is a protocol for a human research study. This study will be carried out in accordance with the applicable United States government regulations, EU Regulation 2017/745 Chapter VI and Annex XV and enrolling research centers policies and procedures.

4.1 Purpose

The purpose of this feasibility study is to evaluate the safety and performance of the Kronos Electrocautery Device to verify the in-animal models evaluated optimal withdrawal parameters in humans to reduce or prevent bleeding following a coaxial biopsy procedures on areas that include, but are not limited to, liver, kidney, lungs, breasts, soft tissue, etc.

4.2 Background

Ultrasound-guided percutaneous liver and kidney biopsies are used widely for the diagnosis, staging and follow-up of hepatic and renal disease. Complications of these procedures include pain, bleeding, pneumothorax, bile peritonitis, arteriovenous fistula formation, glomeruli in kidney biopsies, hemorrhage, and others. Of the serious complications, bleeding is the most common, with an incidence ranging from 0.8 percent (%) to 1%, and subsequent fatality may occur in as many as three (3) out of 10,000 liver biopsies. Similarly, the bleeding complications from kidney biopsies have been reported as between 9% to 34%.[1,2,3] In addition, bleeding from breast biopsies have occurred in incidences ranging from 6.6% to 8.2%, and occurrences of bleeding from lung biopsies range from .6% - 17.6%.[5]

5 Risk Benefit Analysis

5.1 Risks to the Patient -FMEA

No additional risks are associated with the use of Kronos Electrocautery Device compared to existing electrocautery devices.

POTENTIAL ADVERSE EVENTS
Possible complications associated with the use of the Kronos device are similar to those associated with electrocautery devices and include, but may not be limited to:

Common (occurs in more than 10% of patients undergoing this type of procedure):

- Pain – study device or standard of care biopsy related
- Hemorrhage/Bleeding – study device or standard of care biopsy related
- Internal and external burn – study device related
- Scarring – study device or standard of care biopsy related

Less Common (occurs in 1-10% of patients undergoing this procedure):

- Reintervention - – study device or standard of care biopsy related

Rare (occurs in less than 1% of patients undergoing this type of procedure):

- Allergic Reaction – study device or standard of care biopsy related
- Inflammatory Response - – study device or standard of care biopsy related
- Infection - study device or standard of care biopsy related
- Death - study device or standard of care biopsy related
- Interference with implantable device – study device related

5.2 Potential Benefits to the Patient

Reduction or prevention of bleeding following a biopsy procedure could prevent the need of hospitalization, blood transfusion and sometimes surgery or another procedure to stop the bleeding.

6 Study Objectives

To objective of this study is to verify the in-animal models evaluated optimal withdrawal parameters in humans to reduce and control bleeding following a biopsy procedure and to assess preliminary usability evaluations of the Kronos Electrocautery Device.

7 Study Design

7.1 General Description

This is a multi-center, prospective, non-randomized feasibility study designed to evaluate the performance of the Kronos Electrocautery Device to verify the in-animal models evaluated optimal withdrawal parameters in humans to reduce or prevent bleeding following a biopsy procedure and to assess preliminary usability evaluations.

7.2 Number of Subjects

Up to 30 subjects

7.3 Duration of Participation

Up to 14 days

7.4 Primary Study Outcomes

Absence of Hematoma formation
Measure and categorize amount of blood loss from biopsy access site
Absence of the need for ultrasound examination due to observation of bleeding

7.4 Secondary Study Outcomes

Absence of secondary reintervention
Time to hospital discharge

7.6 Identification of Source Data

The study data will be captured and recorded on paper source documents.

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8 Subject Selection Enrollment and Withdrawal

8.1 Inclusion Criteria

1. Patients undergoing a scheduled elective coaxial biopsy procedures on areas that include, but are not limited to, liver, kidney, lungs, breasts, soft tissue, etc.,
2. Patients have signed an informed consent
3. Patients who are ≥ 18 years of age.

8.2 Exclusion Criteria

1. Patients with known bleeding disorder
2. Significant congenital anomaly or medical problem that in the opinion of the investigator would preclude enrollment in this study.
3. Women of child baring potential who are pregnant, lactating, or planning to become pregnant during the course of the clinical investigation.
4. Active systemic infection or sepsis.

8.3 Subject Recruitment, Enrollment and Screening

Subjects will be enrolled from the research centers. The study has an accrual target of at least 20 patients. The initial accrual period will last up to three months. Patients will be provided with an IRB approved Research Participant Informed Consent Form and Privacy Authorization Form describing the study devices, protocol, inclusion and exclusion criteria, as well as risks and benefits of participation.

8.4. Early Withdrawal of Subjects

Patients are free to withdraw at any time and for whatever reason. If patient withdraws consent prior to the biopsy procedure, the study data will not be collected. If patient withdraws consent after study data was already completed, the participant will need to provide instructions to the study team to remove his/her data from the data set. Pre-specified reasons for discontinuing include, but are not limited to, the following:

1. Patient Request: Patient decided that he/she did not want to continue (for any reason)
2. Adverse Event: Patient experienced a related or unrelated event that would interfere with the study objectives/evaluation
3. Inclusion/Exclusion Discrepancy/Violation: Patient should not have been enrolled
4. Other: Any other reason

8.4.1 When and How to Withdraw Subjects

The patient's participation in this clinical research study is voluntary. If patient decides to take part in this study, he/she will be asked to sign the Informed Consent Form showing that he/she has been informed about the clinical research study. A signed original of the Informed Consent Form will be provided to the patient and a signed second original will be retained in the patient's medical record.

The patient may decide to stop participating in this study at any time. If the patient decides to withdraw from this study, the patient will be asked to participate in a limited capacity allowing the patient's medical status to be followed by telephone contact, medical chart review, or by

other agreed upon method.

If the patient decides not to continue participation in a limited capacity, the doctor will not access patient's medical record or other confidential records for new purposes related to the study; however, study data collected prior to the patient's withdrawal may be reviewed and publicly available records may be consulted prior to or after your withdrawal. If the patient decides to stop taking part in this clinical research study, the patient shall tell his/her study doctor as soon as the patient decides to stop.

The patient's decision to not participate or withdraw or discontinue participation will not result in any penalty or loss of medical care or benefits to which the patient might be otherwise entitled.

The patient's study doctor may end the patient's participation in this clinical research study without the patient's consent. Some of the reasons for ending your participation may be:

The study doctor thinks it is necessary for the patient's health and safety;

1. If the patient becomes pregnant;
2. If the patient does not receive a device;
3. If the patient is unable to keep the his/her scheduled appointments;
4. If the study is stopped by the Sponsor, the Institutional Review Board or by a regulatory authority, such as the FDA.
5. If the patient does not consent to continue in the study after being told of changes in the clinical research study that may affect the patient, or
6. For administrative reasons

8.4.2 Data Collection and Follow-up for Withdrawn Subjects

If a participant withdraws from the study, no additional attempts will be made to contact the participant.

9 Study Device

9.1 Description

The Kronos Electrocautery Device (**Figure 1**) is a disposable electrocautery device that can cauterize deep tissue through a standard biopsy procedure guide needle. This device is intended to coagulate the tissue surrounding the core biopsy channel during withdrawal to reduce or eliminate significant post-procedural bleeding. Currently, the Kronos Electrocautery Device consists of one (1) size. As such, the existing Kronos Electrocautery Device is chosen as the worst-case condition.

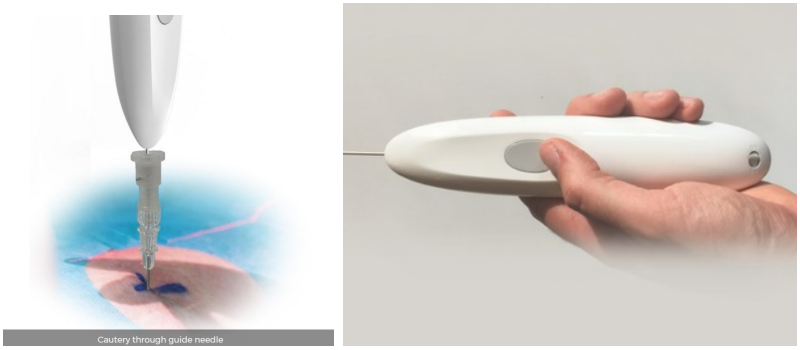

Figure 1: Kronos Electrocautery Device

10 Study Procedures

10.1 Visit 1 (Screening and Enrollment up to the day of Biopsy)

1. Review of the medical record to confirm the patient meets study enrollment criteria
2. Informed Consent - Patients will be identified during their preoperative appointment and introduced to the study; they will be provided with a copy of the consent document and information about the study. The consenting will take place after additional discussion on the day of procedure.
3. Screening will include past and current medical history, a physical examination, blood labs (including Platelet account, INR, Fibrinogen, aPTT and other tests may be considered as needed), and history of current medications. Lab testing is performed prior, as standard of care, to determine if someone may have an undiagnosed bleeding disorder related to their current medical condition prior to participation.

10.2 Visit 2 (Treatment – Day of Biopsy procedure)

1. Ultrasound guided percutaneous biopsy will be performed as per standard of care
2. Placement of the desired core biopsy needle and guide needle will be as per standard of care
3. The needle will be removed, leaving the guide needle in place.
4. Biopsy forceps will be advanced through the guide needle to obtain the tissue
5. The biopsy forceps will be removed with the tissue
6. Remove Kronos Electrocautery Device from packaging and visually inspect. Record Device Condition score per Attachment 1 – Kronos Scoring Criteria
7. Using the current Instruction for Use (IFU), the Kronos Electrocautery Device will be advanced to a predetermined length (recorded) to ensure that it protrudes into the biopsy track. Record Maneuverability to Target Tissue score per Attachment 1 – Kronos Scoring Criteria. If Guide needle was used, record Compatibility with guide needle score per Attachment 1 – Kronos Scoring Criteria
8. The Kronos Electrocautery Device will be activated, and the device and guide needle will

be withdrawn simultaneously at controlled speed. The total time of withdrawal (recorded). Record Withdrawal Force score per Attachment 1 – Kronos Scoring Criteria

9. Any blood or fluids from the access site will be soaked up with a dry gauze without placing any pressure on the access site.
10. Blood or other fluids will be collected for a minimum of five minutes, or until all bleeding has stopped (if applicable). The gauze will be weighed (recorded)to estimate the blood loss with results. Record Device Performance (Blood control) score per Attachment 1 – Kronos Scoring Criteria.
11. This procedure will be performed a single time, on areas that include, but are not limited to, liver, kidney, lungs, breasts, soft tissue, etc.,.. The biopsy procedure is being performed as a standard of care, which may require multiple passes.

10.3 Schedule of Events

	Schedule of Events		
Study Activity	Screening/Baseline	Procedure	Follow-up
Informed consent	X		
Medical History	X		
Eligibility criteria	X		
Index data collection		X	X
Adverse event evaluation		X	X

11 Statistical Plan

11.1 Sample Size

No formal statistical hypothesis is proposed for this study. A non-statistically driven sample size of 30 patients is considered sufficient for this pilot study.

11.2 Handling of Missing Data

This is a prospective acute outcomes study and therefore we do not anticipate any missing data. In the event of any unexpected missing data, no attempt to impute this missing data will be made. Missing data will simply be treated as missing in the statistical analysis.

12.Safety and Adverse Events

12.1 Definitions

12.1.1 Unanticipated Problems Involving Risk to Subjects or Others (UPIRTSO)

Any unanticipated problem or adverse event that meets the following three criteria:

- Serious: Serious unanticipated problems or events that result in significant harm, (which may be physical, psychological, financial, social, economic, or legal) or increased risk for the subject or others (including individuals who are not research subjects). These include: (1) death; (2) hemorrhage or life threatening adverse experience; (3) hospitalization - inpatient, new, or prolonged; (4) disability/incapacity - persistent or significant; (5) birth defect/anomaly; (6) breach of confidentiality and (7) other problems, events, or new information (i.e. publications, DSMB reports, interim findings, product labeling change) that in the opinion of the local investigator may adversely affect the rights, safety, or welfare of the subjects or others, or substantially compromise the research data, **AND**
- Unanticipated: (i.e., unexpected) problems or events are those that are not already described as potential risks in the protocol, consent document, not listed in the Investigator's Brochure, or not part of an underlying disease. A problem or event is "unanticipated" when it was unforeseeable at the time of its occurrence. A problem or event is "unanticipated" when it occurs at an increased frequency or at an increased severity than expected, **AND**
- Related: A problem or event is "related" if it is possibly related to the research procedures.

12.1.2 Adverse Event

An untoward or undesirable experience associated with the use of a medical product (i.e. drug, device, biologic) in a patient or research subject.

12.1.3 Serious Adverse Event

Adverse events are classified as serious or non-serious. Serious problems/events can be well defined and include:

- death
- hemorrhage
- life threatening adverse experience
- hospitalization
- inpatient, new, or prolonged; disability/incapacity
- persistent or significant disability or incapacity
- birth defect/anomaly

All adverse events that do not meet any of the criteria for serious, should be regarded as non- serious adverse events.

12.1.4 Adverse Event Reporting Period

For this study, the follow-up period is defined as up to 30 days post-procedure.

12.1.5 Preexisting Condition

A pre-existing condition is one that is present before the start of the study. A pre-existing condition should be recorded as an adverse event if the frequency, intensity, or the character of the condition worsens during the study period.

12.2 Recording of Adverse Events

At each contact with the subject, the study team must seek information on adverse events by specific questioning and, as appropriate, by examination. Information on all adverse events should be recorded immediately in the source document, and also in the appropriate adverse event section of the electronic case report form (CRF). All clearly related signs, symptoms, and abnormal diagnostic, laboratory or procedure results will be recorded in the source document.

All adverse events occurring during the study period must be recorded. The clinical course of each event should be followed until resolution, stabilization, or until it has been ultimately determined that the study treatment or participation is not the probable cause. Serious adverse events that are still ongoing at the end of the study period must be followed up, to determine the final outcome. Any serious adverse event that occurs during the Adverse Event Reporting Period and is considered to be at least possibly related to the study treatment or study participation should be recorded and reported immediately.

12.3 Reporting of Serious Adverse Events and Unanticipated Problems

When an adverse event has been identified, the study team will take appropriate action necessary to protect the study participant and then complete the appropriate documentation. The site's Principal Investigator will evaluate the event and determine the necessary follow-up and reporting required.

12.3.1 Principal Investigator reporting notifying the IRB

The site's Principal Investigator will report to the IRB any UPIRTSOs and Non-UPIRTSOs according to the IRB Policy and Procedures. Any serious adverse event (SAE) which the Principal Investigator has determined to be a UPIRTSO will be reported to the IRB as soon as possible but no later than 5 working days after the investigator first learns of the problem/event.

The following information will be collected on the adverse event worksheet (and entered in the research database):

- Study ID
- Disease
- The date the adverse event occurred
- Description of the adverse event
- Relationship of the adverse event to the research device*
- Determination if the adverse event was expected
- The severity of the adverse event (severity scale described below**)
- If any intervention was necessary
- Resolution (was the incident resolved spontaneously, or after discontinuing treatment)
- Date of Resolution

The site's Principal Investigator will review all adverse event reports to determine if specific reports need to be made to the IRB and FDA. The site's Principal Investigator will sign and date the adverse event report when it is reviewed. For this protocol, only directly related SAEs/UPIRTSOs will be reported to the IRB.

* Relationship Index

The relationship of an AE to the Investigational Device is a clinical decision by the site's Principal Investigator based on all available information at the time of the completion of the CRF's and is graded as follows:

1. Not related: a reaction for which sufficient information exists to indicate that the etiology is unrelated to the study device.

2. Unlikely: a clinical event, including laboratory test abnormality, or underlying disease provide plausible explanations.

3. Possible: a clinical event, including laboratory test abnormality, with a reasonable time sequence to use of study device but which could also be explained by concurrent disease or other drugs/devices or chemicals.

4. Probable: a clinical event including laboratory test abnormality, with a reasonable time sequence to use of the device, unlikely to be attributed to concurrent disease or other devices or chemicals.

5. Definite: a reaction that follows a reasonable temporal sequence from use of the device.

** Severity Scale

The maximum intensity of an AE should be graded according to the definitions below and recorded in detail as indicated on the CRF. If the intensity of an AE changes over a number of days, then separate entries should be made having distinct onset dates.

1. Mild: AEs are usually transient, requiring no special treatment, and do not interfere with patient's daily activities.

2. Moderate: AEs typically introduce a low level of inconvenience or concern to the patient and may interfere with daily activities but are usually ameliorated by simple therapeutic measures.

3. Severe: AEs interrupt a patient's usual daily activity and traditionally require systemic drug therapy or other treatment.

12.4 Medical Monitoring

It is the responsibility of the Principal Investigator to oversee the safety of the study at his/her site. This safety monitoring will include careful assessment and appropriate reporting of adverse events as noted above, as well as the construction and implementation of a site data and safety-monitoring plan, medical monitoring will include a regular assessment of the number and type of serious adverse events.

13 Data Handling and Record Keeping

13.1 Confidentiality

Information about study subjects will be kept confidential and managed according to the requirements of the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Those regulations require a signed subject authorization informing the subject of the following:

- What protected health information (PHI) will be collected from subjects in this study
- Who will have access to that information and why
- Who will use or disclose that information
- The rights of a research subject to revoke their authorization for use of their PHI.

In the event that the subject revokes authorization to collect or use PHI, the investigator, by regulation, retains the ability to use all information collected prior to the revocation of subject authorization. For subjects that have revoked authorization to collect or use PHI, attempts should be made to obtain permission to collect at least vital status (long term survival status that the subject is alive) at the end of their scheduled study period.

13.2 Source Documents

Source data is all information, original records of clinical findings, observations, or other activities in a clinical trial necessary for the reconstruction and evaluation of the trial. Source data are contained in source documents. Examples of these original documents and data records include hospital records and any forms completed specifically for this study.

13.3 Case Report Forms

CRFs will be developed to collect study-specific data points.

13.4 Data Management

Study data to be collected and managed using EHR and transcribed into electronic CRFs in an electronic data capture system that is a secure, web-based application designed to support data capture for research studies.

13.5 Data Processing

All study data will be stored within the electronic data capture system. The principal investigator will be responsible for overseeing the analysis of the data. De-identified data will be shared with the study sponsor.

13.6 Data Security and Confidentiality

All source documents including clinical findings, observations or other activities will be stored in an electronic database and overseen by the Investigator. Access to the database will be limited to the Principal Investigator, Investigators, Study Team members, and Statistician.

13.7 Data Quality Assurance

Once the study is completed, the Principal Investigator will randomly select 1 participant and compare the data documented in the EHR with what is entered into the electronic database. If there is any discrepancy, the Principal Investigator and/or Investigators will cross-reference all patients to ensure accuracy.

13.8 Data Clarification Process

For any data query, the site's Principal Investigator and Sub-Investigators will meet to clarify the data queried and make corrections based on consensus.

13.9 Records Retention

The site's Principal Investigator will maintain records and essential documents related to the conduct of the study. These will include subject case histories and regulatory documents. The site's Principal Investigator will retain the specified records and reports.

14 Study Monitoring, Auditing, and Inspecting

14.1 Study Monitoring Plan

The site's Principal Investigator will allocate adequate time for such monitoring activities. The Principal Investigator will also ensure that the compliance or quality assurance reviewer is given access to all the study-related documents.

14.2 Auditing and Inspecting

The investigator will permit study-related monitoring, audits, and inspections by the IRB, the sponsor, and government regulatory agencies, of all study related documents (e.g. source documents, regulatory documents, data collection instruments, study data etc.). Participation as a Principal Investigator or Sub-Investigator in this study implies acceptance of potential inspection by government regulatory authorities and applicable compliance offices.

15 Ethical Considerations

This study is to be conducted according to United States government regulations and Institutional research policies and procedures and the requirements of the Regulation (EU) 2017/745 Chapter VI and Annex XV.

This protocol and any amendments will be submitted to a properly constituted local Institutional Review Board (IRB)/EC, in agreement with local legal prescriptions, for formal approval of the study. The decision of the IRB concerning the conduct of the study will be made in writing to the site's Principal Investigator before commencement of this study.

All subjects for this study will be provided a consent form describing this study and providing sufficient information for subjects to make an informed decision about their participation in this study. This consent form will be submitted with the protocol for review and approval by the IRB/EC for the study. The formal consent of a subject, using the Approved IRB/EC consent form, must be obtained before that subject undergoes any study procedure. The consent form must be signed by the subject and the individual obtaining the informed consent.

16 Study Finances

16.1 Funding Source

Single Pass, Inc. is the funding sponsor of this study.

16.2 Conflict of Interest

Any study team member who has a conflict of interest with this study (patent ownership, royalties, or financial gain greater than the minimum allowable by their institution, etc.) will have the conflict reviewed by a properly constituted Conflict of Interest Committee with a Committee-sanctioned conflict management plan that has been reviewed and approved by the study site's Principal Investigator prior to participation in this study.

16.3 Subject Stipends or Payments

Subjects may receive a stipend payment for participation, but only within a fair and reasonable amount.

17 Publication Plan

The primary responsibility for publication of the study results is with the Primary Investigator. After the completion of study and prior to publication, the study results will be shared with all Investigators. The study will be registered at ClinicalTrials.gov prior to subject recruitment along with the posting of the results within 12 months of final data collection for the primary outcome measure if required by Compliance Office and applicable laws and regulations.

18 References

1. Whittier WL, Korbet SM. Timing of complications in percutaneous renal biopsy. J Am Soc Nephrol. 2004;15(1): 142–7.
2. Manno C, Strippoli GF, Arnesano L, Bonifati C, Campobasso N, Gesualdo L, et al. Predictors of bleeding complications in percutaneous ultrasound-guided renal biopsy. Kidney Int. 2004;66(4):1570–7
3. Mahal AS, Knauer CM, Knauer M, Gregory PB. Bleeding after Liver Biospy. West J Med 1981;134:11-14.
4. Sanghyeok Lim, Hyunchul Rhim, Min Woo Lee, Kyoung Doo Song, et al. New Radiofrequency Device to Reduce Bleeding after Core Needle Biopsy: Experimental Study in a Porcine Liver Model. Radiol 2017;18(1):173-179.
5. *Pub Med review of 156 published articles detailing 371,947 biopsy procedures

19 Attachments

1. Attachment A: Kronos Scoring Criteria

Attachment A: Kronos Scoring Criteria

Attribute	Score				
	1 Unacceptable	2 Unsatisfactory	3 Acceptable	4 Good	5 Excellent
Device Condition (Visual Inspection)	Device was unable to prepare. Device was unable to connect for use	Device was difficult to prepare. Device was difficult to connect to fittings with insecure connection	Device was easy to prepare. Device was able to connect to fittings with some issues	Device was easy to prepare. Device was able to connect to fittings with slight issue	Device was easy to prepare. Device was able to connect to fittings without issue
Maneuverability to Target Tissue	Device was unable to maneuver to target tissue	Device was difficult to maneuver to target tissue	Device was able to maneuver to target tissue with some issue	Device was able to maneuver to target tissue with slight issue	Device was able to maneuver to target tissue without issue
Device Performance (Blood Control)	Device was unable to cease blood at target vessel	Device was able to cease blood at target vessel with great difficulty	Device was able to cease blood at target vessel with some issue	Device was able to cease blood at target vessel with slight issue	Device was able to cease blood at target vessel without issue
Compatibility with Guide Needle	Device was unable to track through guide needle	Device was able to track through guide needle with a lot of friction	Device was able to track through guide needle with some friction	Device was able to track through guide needle with slight friction	Device was able to track through guide needle without friction
Withdrawal Force	Device was unable to be removed from target vessel	Device was able to be removed from target vessel with a lot of friction	Device was able to be removed from target vessel with some friction	Device was able to be removed from target vessel with slight friction	Device was able to be removed from target vessel without friction