Clinical Study Protocol

Title:	Vascular Positioning System G4 Algorithm ECG Data Collection for Model Training Study, A Single Center Prospective Clinical Study
Teleflex Product:	Product: Arrow Vascular Positioning System G4
Protocol Number:	2022-03
Version:	4.0
Date:	February 12 , 2024
Sponsor:	Arrow International LLC (an affiliate of Teleflex Incorporated)
ClinicalTrial.Gov NCT #	NCT05702515

GOOD CLINICAL PRACTICE (GCP)

This document is a protocol for a human clinical research study. This study is to be conducted in accordance with all applicable United States standards of Good Clinical Practice (FDA Title 21, parts 11,50,54,56 and 812) and International Clinical Harmonization (ICH) guidelines, applicable government regulations, institutional research policies and procedures and Teleflex standards, including, where applicable, the Declaration of Helsinki.

HIPAA

The Teleflex Incorporated is committed to protecting the privacy, security and integrity of individually identifiable health information provided to us. The Company follows the highest standards of integrity in the performance of its business to maintain compliance with the Health Insurance Portability and Accountability Act (HIPAA).

CONFIDENTIALITY

Protocol Approval Page

"Vascular Positioning System G4 Algorithm ECG Data Collection for Model Training Study, A Single Center Prospective Clinical Study"

Protocol #2022-03
V4.0 – February 12, 2024

Approved by:

_____ _____
Amy Bardin, Ed.D, RRT, FAARC, VA-BC™ Date
Vice President, Clinical and Medical Affairs, Vascular and Interventional
Director, Medical Affairs, Vascular

_____ _____
Adriann Taylor – Sr. Director, Date
Global Clinical Operations, CMA

_____ _____
Tatiana Puga - Associate Director, Date
Global Clinical Operations, CMA

Issued by:

_____ _____
Tolani Adebanjo, PhD – Clinical Trial Manager Date
Global Clinical Operations, CMA

<table>
<tr><th colspan="2">Synopsis</th></tr>
<tr><td rowspan="3">Sponsor: Arrow International LLC, an affiliate of Teleflex Incorporated</td><td>Protocol Number: 2022 – 03</td></tr>
<tr><td>Product: Teleflex Arrow Vascular Positioning System G4</td></tr>
<tr><td>Development Phase: Post Market</td></tr>
<tr><td colspan="2">Title: Vascular Positioning System G4 Algorithm ECG Data Collection for Model Training Study, A Single Center Prospective Clinical Study</td></tr>
<tr><td>Investigators:
Deborah Hutch Allen, PhD, RN
Duke University Hospital</td><td>Sponsor Management:
Teleflex Incorporated
Study Management: Tolani Adebanjo PhD, Clinical Trial Manager
Study Monitor: Aaron Cherry, Clinical Research Associate</td></tr>
<tr><td colspan="2">Study Design: Prospective Clinical Study</td></tr>
<tr><td colspan="2">Objective: The objective of this study is to collect and analyze intravascular and extravascular echocardiogram (ECG) data from subjects receiving peripherally inserted central catheters (PICC) while using the Vascular Positioning System G4 and a 12 lead ECG machine. The data obtained will be used to evaluate the correlation between intra- and extravascular ECG data and determine usability in updating the G4 algorithm.

Primary endpoint: The primary endpoint is synchronized digital data collected from the G4 and ECG machines during the PICC insertion procedure, including a photographic image documenting ECG lead placement, and a chest x-ray (post procedure).</td></tr>
<tr><td>Number of Subjects:30</td><td>Number of Study Centers: 1</td></tr>
<tr><td>Duration of Evaluation: Time required for PICC insertion</td><td>Estimated Duration of Study: 4 months</td></tr>
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Contents

1. Introduction

1.1. Background

A peripherally inserted central catheter (PICC) is an intravenous device that can be successfully utilized for medium- and long-course intravenous therapy in hospitalized and discharged patients.[i] Correct positioning of a PICC is essential to avoiding complications.[ii] The Arrow Vascular Positioning System G4 (here forth referred to as G4) (Teleflex, Morrisville, NC, USA) is designed for PICC navigation and tip confirmation. Using a combination of intravascular Doppler ultrasound, intravascular electrocardiogram (ECG) and advanced algorithmic logic, the system measures multiple physiological parameters and provides real-time navigation as the PICC advances through the patient's vasculature.[iii]

Like all medical devices, the AI ECG (algorithms) must be carefully vetted and validated in real-world clinical environments.[iv] Machine learning creates algorithms by building a model from a set of data points, then verifying its accuracy. Increasing data points allows the device to learn various circumstances and thus the ability to compare and respond appropriately.

This study seeks to collect and analyze synchronized digital data collected from the G4 and ECG machines during the PICC insertion procedure. De-identified G4 and ECG data will be submitted to the sponsor. Photographic data confirming ECG lead placement and radiographic imaging (chest x-ray) showing PICC placement will also be de-identified and submitted to the sponsor. Both the G4 and the ECG machine used for data collection in this study are FDA cleared.

1.2. Study Rationale

The purpose of this study is to collect and analyze synchronized intra- and extravascular ECG data from subjects requiring PICC insertion using the G4 system and an external 12-lead ECG machine. This study will serve to determine the feasibility of using the comparison data collected to evaluate the correlation between intra- and extravascular ECG data, and to determine usability of the data in refining the next generation G4 system algorithm.

1.3. Hypothesis

Data collected simultaneously from the G4 system and a 12-lead ECG machine during PICC insertion in adult subjects will be useful in evaluating the correlation between intra- and extravascular ECG recordings and refining the next generation G4 algorithm model.

1.4. Description of Device

The Arrow G4 system is an FDA cleared device (K123813) indicated for use as an alternative method to fluoroscopy or chest x-ray for central venous catheter tip placement confirmation in adult patients. The system consists of a base unit powered by a proprietary algorithm, a touch screen interface with remote control, a Doppler enabled ultrasonic stylet,

and a power supply; that are used together during PICC insertion to guide the inserter through the anatomy of the vasculature to the proper catheter tip location in the lower 1/3 of the superior vena cava – cavo-atrial junction.

An FDA cleared 12-lead ECG machine capable of collecting ECG data digitally with a sample resolution between 12-16 bit at a sample rate of 300 - 1000 Hz will be utilized for this study.

Photo documentation will be captured using a digital camera.

Radiographic image (lateral chest x-ray) will be captured using Duke Radiology services to document PICC tip placement.

2. Objective of Study and Study Design

2.1. Primary Objective

The objective of this study is to collect and analyze synchronized intra- and extravascular ECG data from subjects receiving PICC insertion while using the G4 and a 12-lead ECG machine. The data will be analyzed to evaluate the correlation between intra- and extravascular ECG data.

Primary Endpoint

The primary endpoint is the successful collection of the following data: synchronized digital data collected from the G4 and ECG machines during the PICC insertion procedure, photographic images documenting ECG lead placement, and a chest x-ray of the inserted PICC (post procedure). A copy of the data will be submitted to the sponsor.

2.2. Study Design

This is a single center prospective clinical feasibility study. All enrolled subjects will receive a 12-lead ECG during PICC insertion, a chest x-ray post insertion, and a photographic documentation of ECG lead placement.

2.3. Duration of Subject Study Participation

Each subject's participation will start at the time of signing the informed consent and terminate upon completion of the x-ray.

3. Selection of Subjects

3.1. Participant Population

Adult male patients scheduled to receive a PICC insertion using the G4 tip navigation system may be considered for participation in the study.

As this is a feasibility study, male and female patients will be recruited for participation in this study. As a means to limit female exposures to photographs, Images will only be captured for male subjects

3.2. Sample Size

A sample size of up to 30 adult subjects will be enrolled to obtain 20 evaluable subjects. Including a maximum of 10 subjects in whom the G4 system was used for tip navigation but the blue bull's eye was not achieved and 10 subjects where the blue bull's eye served as confirmation for tip placement. An adult subject per The Federal Food, Drug, and Cosmetic Act (FD&C Act) is persons 22 years of age and older at the time of treatment.[vi] To be considered an evaluable subject, data must be collected for the duration of the PICC insertion procedure on both the G4 and the ECG machines, the post-insertion chest x-ray completed, and photographic documentation of the ECG lead placement captured. Non-evaluable subjects will be replaced to meet the target sample size.

3.3. Inclusion Criteria

Subjects must meet the following criteria to be selected for participation in the study:

- 22 years of age or older
- Scheduled for PICC insertion using the G4 system
- ~~Willing to allow thoracic photos to be obtained after ECG lead placement~~

3.4. Exclusion Criteria

Subjects who meet any of the following criteria are not eligible for participation in the study:

- < 22 years of age
- Patient has a pacemaker
- Patient condition precludes ECG use and lead placement
- Patient condition precludes radiographic imaging
- ~~Unwilling to allow thoracic photos to be obtained after ECG lead placement~~

4. Study Procedures

4.1. Informed Consent

Subjects being scheduled to receive a PICC will be approached by clinical staff if deemed to meet the eligibility criteria for the study. Consent for participation in the study will be obtained from the subject using an Institutional Review Board (IRB) approved informed consent form (ICF) after study aims, methods, benefits and risks have been fully explained by the investigator or member of the study staff. Participation in the study is voluntary and the subject may withdraw at any time. Subjects will be told that electing not to participate in this study will not affect the care received for treatment. The subject will have a private room with sufficient time to read the informed consent form and ask any questions. A copy of the fully executed informed consent form will be given to the subject.

4.2. Screening and Enrollment

After the informed consent document has been signed, the subject will undergo screening procedures. All subjects screened for the study will be entered on the Screening/Enrollment Log and sequentially assigned a subject identification number. Present diagnosis requiring PICC placement and cardiovascular disease history, including pacemaker, and/or a history of arrhythmic heart conditions such as: atrial fibrillation, atrial flutter, severe tachycardia, or pacemaker driver rhythms will be captured for all subjects enrolled. Subjects who do not meet all inclusion/exclusion criteria will not be enrolled in the study. The reasons for screening failure will be documented on the screening/enrollment log.

4.3. ECG Lead Placement Image Capture

ECG lead will be placed according to the standardized ECG lead placement chart below. A second study team member will confirm and attest to the proper placement of the ecg lead in accordance with the ECG lead placement chart below. For some male subjects who consent, the placement of thoracic ECG leads will be documented by three photographs: one photo capturing the chest perpendicular to the xyphoid process, and one left and right oblique photograph. A ruler should be placed in the photograph, not obscuring any ECG leads, as a scale reference. Images captured will exclude portions of the body above the shoulders.

4.3.1. ECG Lead Placement and Procedure

The subject identification number will be entered into the ECG machine to ensure the correct subject data can be identified. (See below for ECG lead placement.)

ECG 12 lead placement:
Standardized placement of ECG leads is important. ECG lead placement must be consistent between subjects and performed according to the directions provided in this section below. Primary and secondary ecg lead placement attestation will be used to document the lead placement for each subject, to confirm the accuracy of the lead placement with the requirements of the protocol. Some consenting male subjects will undergo photographic documentation of ECG leads.

ECG Lead	Anatomical Placement
Lead 1	Fourth intercostal space on the right sternum
Lead 2	Fourth intercostal space on the left sternum
Lead 3	Midway between placement of Lead 2 and Lead 4 fifth intercostal space at the midclavicular line
Lead 4	Fifth intercostal space at the left and mid clavicular line
Lead 5	Anterior axillary line on the same horizontal level as Lead 4
Lead 6	Mid axillary line on the same horizontal level as Lead 4 and Lead 5
Right Arms (RA)	Anywhere between the right shoulder and right elbow
Right Leg (RL)	Anywhere between the right torso and the right ankle
Left Arm (LA)	Anywhere between the left shoulder and the left elbow
Left Leg (LL)	Anywhere between the left torso and the left ankle

Note: There will be three "duplicate" electrodes (RA / LA and RL) between the two systems (G4 and 12-lead ECG). Duplicate electrodes should be placed as close together as possible without interfering with the other electrode.

4.4. PICC Insertion, ECG, Chest X-ray, and Data Collection

The ECG recording and chest x-ray will be performed as described in the sections below. The ECG machine should start recording data prior to the first skin puncture and continue recording through catheter tip placement.

The study staff will defer to the institution's policy for confirming proper tip placement. After successful PICC tip placement , ECG data collection can be terminated. Up to a maximum of 10 subjects in whom the blue bull's eye was not achieved during PICC navigation will be included as evaluable subjects. Beyond, these 10 subjects, if the blue bull's eye is not achieved the subject's participation in the study will be terminated and no additional study procedures will be performed. If an ECG lead should fall off during the data collection period, the lead can be replaced, as long as, the G4 system is not displaying the orange caution indicator on the screen. If the caution indicator is displayed refrain from replacing the lead. If the ECG stops recording during the data collection period, it will not be resumed.

Data Collection Procedures

4.4.1. G4 and ECG Synchronization

The minutes and hour display on the G4 and the ECG clocks must be synchronized to within 1 second of variation prior to the start of PICC insertion data collection. This synchronization must be performed prior to each subject use.

4.4.2. PICC Placement Using G4

Standard PICC placement and G4 operating procedures will be followed according to institutional policy. The G4 data will be de-identified by replacing the MRN number with the subject ID number before transferring the data to the sponsor. The catheter selected, the final length inserted, exposed length of catheter, and location of lead placement for both devices will be recorded. Anatomical location of access site, including arm and vessel used for PICC insertion as well as the procedure start and stop time will also be documented. The data for each subject will be submitted to the sponsor.

4.4.3. Chest X-Ray: Image Capture and Radiology Review

PICC tip location in the lower one third of the superior vena cava/cavo-atrial junction will be documented by radiograph. Any patient items that may interfere with visualization, including jewelry, and ECG patches/wires, should be removed prior to capturing the image. Replace ECG patches/wires prior to the start of the data collection period. The image acquired should keep the arm with the PICC at the same angle from the patient's midline as performed during PICC insertion. Provide support for the arm during the X-ray procedure. X-ray beam should be 90° perpendicular to the film. Verify angle. The distance between the beam and the film should be maintained at 48 inches. Measure this to ensure that it is correct. X-ray should be shot at end-expiration during normal breathing. Do not

ask the patient to take a deep breath as this will move the PICC line and will not provide a proper assessment of the catheter tip.

ECG and G4 recording should be terminated before the x-ray. A de-identified copy of the x-ray image will be transferred to the study sponsor.

A designated radiologist will be selected to review and provided interpretation for all radiographs for this study to ensure consistency. The radiologist interpretation will be submitted to the sponsor.

4.4.4. Demographic and Procedural Data Collection

- The following demographic data will be collected: gender, age (in years), height in cm, weight in kg, and race/ethnicity will be collected.
- The following medical information will be collected: present diagnosis requiring PICC placement and cardiovascular disease history, including pacemaker, and/or a history of arrhythmic heart conditions such as: Atrial fibrillation, atrial flutter, severe tachycardia, or pacemaker driver rhythms will be captured for all subjects enrolled.
- The following procedural data will be collected: anatomic location of the access site (right/left arm and vein), catheter selected (number of lumens, length, and manufacturer), PICC insertion procedure start and stop times, lead placement (G4 and ECG machine), and final catheter length inserted and exposed.

4.5. Adverse Events (AE) Assessment
Adverse events will be assessed, documented, and reported to the Sponsor as outlined in Section 5.

4.6. End of Study Status: Subjects will be categorized based upon their end of study status as described below.

4.6.1. Completed Study
Subject is considered to have completed the study after completion of all study procedures.

4.6.2. Subject Initiated Early Termination from Study:
A subject's participation in the study will be immediately terminated upon subject withdrawal of consent. Upon termination a final AE assessment should be performed by the study staff.

4.6.3. Investigator Initiated Early Termination from Study:
If the Investigator feels that the subject can no longer fully comply with the requirements of the study, if any of the study procedures would not be in the best interest of the subject, or if any of the study procedures cannot be completed on the subject (data collection on 12-lead

ECG and/or chest x-ray) the investigator should withdraw the subject from the study. Upon termination a final AE assessment should be performed by the study staff.

5. Assessment of Safety

5.1. General

The safety of the subjects will be prioritized for this clinical study. Each participating Investigator has the responsibility for the safety of the subjects under their care. Since the only study procedures are the use of ECG during the PICC insertion and the chest x-ray post-insertion, only AEs related to the study procedures will be reported in the case report form (CRF) as described below. Incidences of device malfunction and adverse events related to the PICC device and G4 system should be reported to Teleflex in accordance with institutional policy and procedure and regulatory requirements.

5.2. Adverse Events

An adverse event (AE) is any unfavorable medical occurrence affecting a clinical investigation Subject, which does not necessarily have a causal relationship with the treatment or procedure. An AE can therefore be any unfavorable and unintended sign, symptom, or diagnosis associated with the use of the study device, whether or not it is considered related to the device. Adverse events should be reported in accordance with International Conference on Harmonization (ICH) guidelines.

For all adverse events, the investigator must pursue and obtain information adequate to determine the severity, causality (e.g., study procedure or other cause), and outcome of the event and to assess whether it meets the criteria for classification as a serious adverse event. Follow-up of the event is required until the event or its sequelae resolve or stabilize at a level acceptable to the investigator and the study sponsor/monitor. Adverse event evaluation will begin from the start of data collection through completion of the chest x-ray. Adverse events reported to the investigator subsequent to the subject's participation will also be evaluated.

5.2.1. Relationship to Study Device/ Procedure

Adverse events will be assessed for relationship to the study procedures and categorized as follows:

Not Related
Possibly Related
Definitely Related

5.2.2. Unanticipated Adverse Device Effect

An unanticipated adverse device effect (UADE) is a serious adverse effect that is possibly caused by or related to a study device or procedure not previously identified in nature, severity or degree, or any other unanticipated serious problem associated with a device. UADEs associated with use of the 12-lead ECG should be reported to the sponsor on the eCRF and to the ECG manufacturer in accordance with institutional policy and procedure and regulatory requirements.

5.2.3. Non-serious Adverse Events

Non-serious adverse events determined by the principal investigator (PI) to have at least a possible relationship to the 12-lead ECG use, or the chest x-ray study procedures will be reported to the sponsor on the eCRF.

5.2.4. Serious Adverse Events (SAE)

A serious adverse event is any adverse event that:

- Results in death
- Is life-threatening: A life-threatening adverse event is defined as any adverse experience that places the subject at immediate risk of death from the reaction as it occurred.
- Results in inpatient hospitalization or prolongation of existing hospitalization: Hospitalization is defined as any inpatient or outpatient/short-stay admission as a result of a precipitating, device or treatment-related emergent adverse event. For chronic or long-term patients, inpatient admission also includes transfer within the hospital to an intensive care inpatient unit.
    - Hospitalization for administrative reasons or a non-worsening pre-existing condition should not be considered adverse events (e.g., admission for workup of a persistent pretreatment lab abnormality, yearly physical exam, protocol-specified admission, elective surgery). Preplanned treatments or surgical procedures should be noted in the baseline documentation. However, if a hospitalization due to an unknown event occurs, it should be considered as a serious adverse event.
    - Prolongation of hospitalization is defined as any extension of an inpatient hospitalization beyond the stay anticipated/required for the original reason for admission, as determined by the investigator or treating physician.
- Results in persistent or significant disability/incapacity: Disability is a substantial disruption of a person's ability to conduct normal activities of daily living.
- An adverse event that is not fatal, life-threatening, or requires hospitalization may be considered medically significant and therefore serious when, in the opinion of the investigator, it could jeopardize the subject and may require medical or surgical intervention to prevent any of the above outcomes.

5.2.5. SAE Reporting

Serious adverse events must be reported to the sponsor immediately, within 24 hours of knowledge of the event, if it occurs or comes to the attention of the investigator any time a subject is on study or reported to the investigator subsequent to the subject's participation. SAEs may be reported by emailing the SAE documents to:

Teleflex Incorporated
Global Clinical Operations
Email: TeleflexVPSstudy@teleflex.com

An SAE report form and relevant documentation (if any) should be submitted electronically to Teleflex and to the IRB, in accordance with IRB reporting requirements. The initial report should include at minimum the following information:

- Subject ID number, sex, age
- Study device/procedure suspected relationship to the SAE

• SAE term and date of event

Follow-up information including causality, severity, outcome, action taken, and concomitant medications should be communicated to the sponsor as soon as possible.

6. Potential Risks and Benefits

For the purpose of this study, subjects will have continuous 12-lead ECG tracings performed during PICC insertion and one chest x-ray of the inserted catheter at the end of the procedure. The chest x-ray and 12-lead ECG are not part of the routine PICC insertion procedures. These risks are outlined further but are considered to be minimal risk procedures. There is no perceived clinical benefit to subjects from participation in this study.

There are standard risks of participating in a research study, for example given the potential of accidental disclosure of subject's confidential information. Every effort will be made to ensure that subject personal information remains confidential at all times, including application of Subject ID and redacting personally identifying information before submitting to the Sponsor.

Since subjects participating in the study will be receiving PICC insertion per standard of care, and the G4 is within the standard procedures for use during PICC device placement at this institution, these are not considered study procedures. Consent for PICC placement will be obtained as part of the standard of care and will not be associated with this study.

The internal G4 device records ECG data during the central catheter line insertion that is used to detect correct placement. This ECG recording will be de-identified of the subject PHI and replaced with subject number prior to being sent to Teleflex.

Risks associated with 12-lead ECG:
The risks associated with use of the ECG machine include:

Minor discomfort during electrode removal
Skin irritation, itching, rash or redness from the ECG electrode pads.

Hair that may prevent an adequate tracing will be removed via shaving, pending the subject approval.
No PHI will be inputted into the ECG machine (only subject number) to maintain subject confidentiality.

Risks associated with photographic images:
A thoracic photograph will be taken to document the placement of the ECG leads. The risk associated with the photographic images is the risk of loss of privacy. Pictures of the body above the shoulder i.e., the face will not be included in the photographic images. Stored images will not contain PHI (only subject number) to maintain subject confidentiality.

Risks associated with chest x-rays:

Radiation exposure from the x-rays needed for this study is about the same as the average person receives from normal radiation sources, such as sunlight and TV during a 10-day period. There is a slight chance of cancer from excessive exposure to radiation from x-rays.

Minimization of risk
There are no significant risks associated with the study related procedures of this clinical protocol.

7. Statistical Consideration

7.1. Sample Size Justification

The sample size is not intended to be statistically justified. Data will be collected from 20 evaluable subjects and analyzed to support the determination of feasibility of this synchronized data for the algorithm refinement process.

7.2. Study Populations for Analysis

7.2.1. Safety Analysis Population (Intent to Treat/ITT)

All subjects on whom the G4/ECG data collection procedure was started shall be included in the assessment of safety (ITT population). Subjects who withdraw or are withdrawn from the study prior to study completion will be included through the point that they exited the study. All available data will be included in the analysis.

7.2.2. Feasibility Analysis Population

Non-evaluable subjects will be excluded from the feasibility analysis population. See Section 3.2 - Sample Size for definition of evaluable subject.

7.3. Outcome Analysis

Data collected for this study will be used to assess the feasibility of refining the next generation G4 algorithm model.

8. Quality Control and Quality Assurance

8.1. Sponsor

The Sponsor will confirm that the study meets GCP guidelines and all applicable regulatory requirements. The Sponsor will be allowed direct access to all study related sites, source documents, and reports for the purpose of monitoring and auditing by the Sponsor, and the inspection by regulatory agencies.

8.2. Investigators

Investigators will be responsible for implementing and maintaining quality assurance and quality control systems to ensure that the data is generated, recorded, and reported appropriately. Additionally, investigators are responsible for ensuring that the study is conducted according to this clinical study protocol. Investigators assume full responsibility for performance of the clinical study in accordance with this protocol, Good Clinical Practice, and all regulatory requirements applicable to the jurisdiction in which the study

sites are located. The Investigators will apply quality control measures to all stages of data handling to ensure reliability and accuracy and will confirm that the data is processed correctly.

9. Study Monitoring

9.1. General

Both the Investigators and the Sponsor of this study are responsible for taking all reasonable steps to ensure the proper conduct of the study regarding ethics, protocol compliance, integrity, and validity of the data recorded on the CRFs. At regular intervals during the study, the Investigator and Sponsor will communicate, through site visits, letters, or telephone calls to review study progress, compliance to protocol requirements, and any problems or issues.

Onsite Monitoring visits will be made periodically during the study to ensure that all aspects of the current, approved protocol are being followed. Original source documents will be reviewed for verification of selected data captured on the eCRF. Digital files will be reviewed and submitted to the sponsor.

The Investigator and site personnel will guarantee direct access to original source documents by Sponsor and their designees. In the event original medical records cannot be obtained for a subject who is seen by a non-study physician at a non-study institution, copies of original source documents must be made available for review. Copies of original source documents related to SAEs (from either the study site or a non-study institution, if applicable) must also be made available for submission to the Sponsor.

9.2. Protocol Deviations

A protocol deviation is any noncompliance with the clinical study protocol. As a result of deviations, corrective actions are to be developed by the site and implemented promptly. The study site is responsible for assuring that the protocol is followed, that subjects are included and assessed in accordance with the inclusion and exclusion procedures and that the subjects are seen and followed at designated times.

10. Institutional Review Board Review

10.1. Ethical Principals

This study will be conducted in accordance with GCP, as defined by the International Conference on Harmonization (ICH) guidelines, and all applicable regulations.

10.2. Institutional Review Board/Independent Ethics Committee

This study protocol will be reviewed and approved by an IRB prior to study implementation. A copy of the approval will be collected by the Sponsor.

10.3. Protocol Amendments

During the clinical trial, any amendment or modification to the protocol must be reviewed and approved by the IRB prior to implementation. The board or committee should also be informed of any event likely to affect the safety of subjects or the conduct of the study, in particular any change in safety and all updates to the IRB.

10.4. Progress Reports

As applicable, Investigator must send a report to the IRB, at least annually. A study closure report, including a summary of the trial's outcome will be reported at the end of the study.

11. Data Handling and Recording

11.1. Record Storage and Retention

The F.D.A. requires that essential documents be retained at the site for at least 2 years after the latter of the following two dates: The date on which the investigation is terminated or completed, or the date that the records are no longer required for purposes of supporting a premarket approval application, a notice of completion of a product development protocol, a humanitarian device exemption application, a premarket notification submission, or a request for De Novo classification.[v]

11.2. Investigator Responsibilities

The Investigator will maintain all study documentation and institute measures to prevent accidental or premature destruction of any data and/or documents related to the study. After the formal discontinuation of the clinical study, the Investigator will retain the study documentation produced by the investigator for at least 2 years after the completion of the study (see 10.1). The Investigator will allow Sponsor and/or Sponsor's representatives to have access to the essential study documents.

11.3. Sponsor

The Sponsor will maintain all study documentation and institute measures to prevent accidental or premature destruction of any data and/or documents related to the study. The Sponsor will retain the study documentation permanently in accordance with Teleflex Record Control Global S.O.P. D0003064.

11.4. Data ownership

The Sponsor shall retain sole ownership of all data, results, reports, findings, and any other information collected during this study.

11.5. Early Termination of Study

This study may be terminated earlier than anticipated if, in the opinion of the investigator or the sponsor, there is sufficient reasonable cause. Written notification, documenting the reason for study termination, will be provided to the investigator or sponsor by the terminating party. Circumstances that may warrant termination include, but are not limited to:

- Insufficient adherence to protocol requirements
- Data that is not sufficiently complete and/or evaluable
- Plans to modify, suspend, or discontinue the study

If the study is terminated earlier than anticipated, the IRB will be informed promptly and provided the reason(s) for the early termination.

12. Confidentiality

All materials, information (oral or written) and unpublished documentation provided to the Investigators (or any company/institution acting on their behalf), inclusive of this protocol and the Subject CRFs, are exclusive property of the Sponsor and may not be given or disclosed, either in part or in whole, by the Investigator or by any person under his/her authority to any third party without written approval from the Sponsor. The submission of this protocol and other necessary documentation to the IRB is expressly permitted. The IRB members have the same obligation of confidentiality.

The Investigator will consider all information, results, discoveries, records accumulated, acquired, or deduced in the course of the study, other than that information to be disclosed by law, as confidential and will not disclose any such results, discoveries, records to any third party without written notification to the Sponsor.

13. Publication Policy

The Sponsor and Investigator agree that it is not anticipated that any publication will result from the Study, however each party retains the right to publish the Study Data and results of the Study in a manner compliant with the Protocol and the International Committee of Medical Journal Editors Recommendations for the Conduct, Reporting, Editing and Publication of Scholarly Work in Medical Journals in effect as of the date of initiation of the Study.

References

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