Study Protocol and Statistical Analysis Plan Cover Page

NCT#0524097

Study Title: Mitigation of Major Hip Injury due to fall in an At-Risk, Older Adult Population with a Wearable Smart Belt

Document Date: 12/07/2023

Study Title: Mitigation of Major Hip Injury due to fall in an At-Risk, Older Adult Population with a Wearable Smart Belt

Short Title: Smart Belt Fall Injury Mitigation Study

Reference ID/Protocol#: COP-0001
Single Identification Number: Pro00061055 (Advarra Protocol ID)
Version: 2.0

Date: April 18, 2022 (Original version dated January 28, 2022)

Study Product: Tango® Belt

Study Type: Multi-center, comparative, non-significant risk study with retrospective controls

IDE Reference Number: N/A

Study Sponsor: Active Protective Technologies, Inc
580 Virginia Dr, Suite 230
Fort Washington, PA 19034

Sponsor Contact: Wamis Singhatat, CEO
580 Virginia Dr; Suite 230
Fort Washington, PA 19034

Rebecca J Tarbert, Director of Clinical Programs
580 Virginia Dr; Suite 230
Fort Washington, PA 19034

Protocol Approval on behalf of Active Protective Technologies, Inc by:
Wamis Singhatat, CEO Active Protective Technologies, Inc
580 Virginia Dr; Suite 230
Fort Washington, PA 19034

Date: 4/18/22 Signature: _____

The information contained herein is provided to you in confidence and should not be disclosed to others, without written authorization from Active Protective Technologies, Inc, except to the extent necessary to obtain informed consent from those persons to whom the device will be administered. Privacy and confidentiality of information about each subject shall be preserved in the reports and any publication of the clinical investigation data. Lists of subject's names and identifying information should, wherever possible, be maintained separately from Case Report Forms. All data shall be secured against unauthorized access.

List of Abbreviations and Definitions of Terms

ADE	Adverse device effect
AE	Adverse event
APT	Active Protective Technologies, Inc
BIMS	Brief Interview for Mental Status
CIB	Clinical Investigators Brochure
CIP	Clinical Investigation Plan (Protocol)
CRA	Clinical Research Associate
CRF	Case Record Form
EC	Ethics Committee
EMR	Electronic Medical Record
FDA	Food and Drug Administration
FES-I	Falls Efficacy Scale - International
GCP	Good Clinical Practice
ICF	Informed Consent Form
IRB	Institutional Review Board
ISO	International Organization for Standardization
LAR	Legally Authorized Representative
MDS	Minimum Data Set
QC	Quality Control
SADE	Serious Adverse Device Effect
SAE	Serious adverse event
SOC	Standard of care
STEADI	Stopping Elderly Accidents, Deaths, & Injuries
POA	Person Of Authority
UADE	Unanticipated Adverse Device Effect

Protocol Synopsis

Reference ID/Protocol Number: COP-0001

Title: Mitigation of Major Hip Injury due to fall in an At-Risk, Older Adult Population with a Wearable Smart belt

Sponsor: Active Protective Technologies, Inc

Regulatory Status: Non-significant risk pivotal study of medical device

Objectives: **Primary Objective:** To assess the performance of the Tango® Belt to mitigate fall-related major hip injuries in an at-risk of fall adult population as compared to the standard of care (SOC) only.

Secondary Objectives: To assess the performance of the Tango Belt to mitigate falls resulting in: (1) hip fractures, (2) emergency department visits or (3) hospitalizations.

Study Design: Multi-center, comparative, non-significant risk adaptive study with retrospective controls.

After providing informed consent and being screened for eligibility, intervention subjects will be prescribed and provided an appropriately sized Tango Belt. The subject must demonstrate a minimum of 64% adherence to the use of the Tango Belt within 14 days of initiation to fully enroll in the study. Upon demonstration of at least minimum adherence, the subject will be provided the Tango Belt to wear continuously for at least 6 months, except during bathing, device charging, and as deemed by clinical staff.

The study will investigate the safety and effectiveness of the Tango Belt with the primary and secondary endpoints being taken every 3 months and at the end of the study run time from the electronic medical record. Additionally, ancillary endpoints on adverse events and device performance will be gathered.

Study Population: Subjects must be older adults (≥65 years of age) who are at risk for fall with major hip-related injury as determined by the SOC for fall-risk management.

Number of Patients: Estimated up to 417 in the treatment group and up to 1688 in the control group. Final sample size to be determined from retrospective control data.

Study Duration:

Estimated enrollment time	3 months
Estimated in-study run time	6 months
Estimated total duration	12 months after 1st subject enrolled

Eligibility Criteria

Inclusion Criteria (ALL of the following criteria):

1. Age 65 years or older;
2. Have experienced a fall-related fracture after age 50
   -OR-
   Have experienced one or more falls in the 12-months prior to consent and have a diagnosis of osteoporosis, osteopenia, or prescribed osteoporosis medication.
3. Independently or with staff or caregiver assistance, able to transfer between surfaces (e.g., to or from a bed, chair, wheelchair, toilet, standing position) or walk or move between locations (use of an assistive device such as a walker is acceptable);
4. Have a waist circumference between 29 – 50 inches (63.5 – 127 cm);
5. Able to comply with required study procedures and follow-up schedule as determined by the Study Investigator;
6. Are under the care of the Investigational organization;
7. Provides consent or their legally authorized representative provides consent on subject's behalf

Exclusion Criteria (ANY of the following criteria):

1. Age 64 years or less;
2. Participation in a different clinical investigation that can conflict with this clinical study as determined by the Study Investigator and approved by the Sponsor;
3. Total dependence on staff or caregiver assistance to be able to transfer between surfaces (e.g. to or from a bed, chair, wheelchair, toilet, standing position) and walk and move between locations;
4. Use of other devices or interventions outside of SOC for fall risk management during study participation without Sponsor approval;
5. Unable to comply with required study procedures and follow-up schedule as determined by the Study Investigator;
6. Does not provide consent, or legally authorized representative does not provide consent

Investigational Device Tango® Belt

Route of Administration The Tango Belt is a device intended to be worn around the waist and is designed to:

- Recognize serious hip-impacting falls in progress
- Deploy an airbag upon detection of a serious hip-impacting fall in progress to protect the hip region from potential major injury
- Communicate fall and impact alerts to designated persons

Schedule of Visits

The study is composed of the following study intervals:

Baseline	Enrollment, screening, and provision of Tango Belt
14-day	Run-in for adherence screening
90-days	EMR screening for endpoints
180-days	EMR screening for endpoints and completion of participation

Table of Contents

Version Information

Revision	Date	Description
1.0	**28 Jan 2022**	**Original Protocol**
2.0	**18Apr2022**	**Protocol with simplification of adjudication process noted in sections 7.3 and 8.3 iii**

1. Key Roles

1.1 KEY ROLES

Sponsor	Active Protective Technologies, Inc 580 Virginia Ave Suite 230 Fort Washington, PA 19034
Sponsor Contact	Rebecca J Tarbert PT, DPT Director of Clinical Programs Active Protective Technologies, Inc 580 Virginia Dr Suite 230 Fort Washington, PA 19034 USA +1 267 242 6125 rebecca@activeprotective.com
Medical Monitor	Richard G. Stefanacci DO, MGH, MBA, AGSF, CMD 100 Maxis Dr Malvern, PA 19355 +1 610 386 2000 Richard.stefanacci@jefferson.edu

1.2 Investigator Signature

Study Title: Mitigation of Major Hip Injury due to fall in an At-Risk, Older Adult Population with a Wearable Smart belt

Reference ID/Protocol#: COP-0001
Version # & Date: 2.0, April 18, 2022

I have read, understood and agree to:

- Ensure that the study is conducted in accordance with this signed agreement, the investigational plan and applicable national regulations.
- Ensure that informed consent is obtained prior to entering patients into the study and only after required Ethics Committee approvals are obtained;
- Ensure that the requirements for obtaining informed consent are met
- Conduct the trial in accordance with this protocol, including applicable local/state laws and regulations
- Adhere to the publication policy of Active Protective Technologies, Inc as stated in the Clinical Trial Agreement, for data collected during this trial
- Ensure that all associates, colleagues, and employees assisting in the conduct of the trial are informed of their obligations in meeting the above commitments
- Supervise investigational device use and not supply the device to any person not authorized to receive it;
- Be accountable for devices under investigation;
- Return to the sponsor any remaining supply of the device upon termination of the investigation or my part of the investigation;
- Maintain accurate, complete and current records relating to my participation in the investigation;
- Permit inspections by Ethics Committee and national health and/or regulatory agencies;
- Submit complete, accurate and timely reports of:
  - unanticipated adverse events,
  - withdrawal of Ethics Committee approval,
  - deviation from the investigational plan,
  - inability to obtain informed consent, and
  - study progress and completion;
- Comply with any requirements imposed by the reviewing Ethics Committee;
- Discuss the investigational plan and study progress with a representative of Active Protective Technologies, Inc. and to permit the representative to inspect all records pertinent to the study;
- Obtain written permission from Active Protective Technologies, Inc before publishing or presenting information associated with this study;
- Not disclose confidential information regarding this study unless disclosure is required by national or other regulations;

- Inform clinical staff and other persons who have a "need to know" information to facilitate the study, that clinical study information is privileged and confidential;
- Not concurrently participate with the clinical evaluation of another wearable hip protection product during my period of involvement in this study.

I will ensure that the IRB review complies with governmental requirements and will be responsible for the initial and continuing review and approval of the clinical investigation. I also agree to promptly report to the IRB all changes in the research activity and all unanticipated problems involving risks to human subjects or others. Additionally, I will not make any changes in the research without sponsor and IRB approval of an amended protocol, except where necessary to eliminate apparent immediate hazards to human subjects. I agree to comply with all other requirements of this study in accordance with the protocol, ICH/GCP guidelines, applicable local and federal regulations, and to accept respective revisions conducted by the sponsor and by regulatory authorities.

Principal Investigator (printed):_____

Principal Investigator signature: _____

Date: _____

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2. Introduction

2.1 Background information

Every year in the United States there are approximately 3 million fall-related emergency room visits for geriatric adults. Of the 3 million emergency room visits, approximately 300,000 of those lead to hospital admissions due to hip fractures[i]. This coincides with the Centers for Disease Control (CDC) analysis that 1 out of 4 adults over the age of 65 (i.e., geriatric) will fall each year and those falls may occur more than once in a year[ii]. As a result of these high numbers, falls are the leading cause of injury-related deaths among the geriatric US population and cost over $50 billion in total medical costs[iii].

The standard of care (SOC) in the US for managing the fall risk of geriatric patients is the CDC's Stopping Elderly Accidents, Deaths, and Injuries (STEADI) initiative, which implements the America and British Geriatric Societies'' Clinical Practice Guidelines for fall risk management. The STEADI algorithm consists of tools and resources for healthcare providers for fall risk screening, assessment, and intervention[iv,v]. Screening and assessment includes identifying fall history and modifiable factors related to fall and fall injury risk (e.g. fear of falling, gait, strength, balance, medications, comorbidities, etc.); then interventions to reduce the fall and fall injury risk are applied based upon assessment findings, and can include physical therapy, medication adjustments, patient education, bed and chair alarms, bed rails, etc. [vi] Healthcare providers have also used passive hip protectors as an intervention to mitigate hip fracture for those identified with a fall risk. It has been shown that passive hip protectors are able to reduce hip fractures by over 80% when worn during the fall[vii,viii]. However, the clinical utility of passive hip protectors has been questioned, as compliance of wearing the hip protectors has proven to be low due to a variety of factors, most commonly related to comfort and difficulty taking them on and off .[ix,x]

Despite the broad adoption and utilization of the STEADI algorithm as the SOC for fall risk management, the number of older adults experiencing falls and fall related injuries has increased or remained unchanged since 2012[xi]. Furthermore, per the CDC, fall death rates in the U.S. have increased 30% from 2007 to 2026 among older adults. Lastly, multiple large clinical trials have recently shown that the aforementioned SOC for fall risk management was ultimately unsuccessful in reducing the rate of falls with injury. [xii, xiii] As such, there is a significant unmet need for new interventions for geriatric individuals who are at high risk of fall, as the existing SOC is not effective at reducing the overall rate of fall injuries.

2.2 Scientific Rationale

As a solution to the need for fall injury mitigation, Active Protective Technologies, Inc. ("APT") has developed the Tango® Belt, a wearable device primarily designed to protect geriatric individuals against major hip injuries due to a serious hip-impacting fall. Hip injuries are considered major if they are life-threatening, result in hospitalization or

emergency care, require medical intervention, or result in disability or permanent damage. A fall that results in major hip injury is described herein as a serious hip-impacting fall. The Tango Belt uses motion sensors and proprietary algorithms to determine if the wearer is experiencing a serious hip-impacting fall in progress and automatically deploys an automotive-grade cold-gas airbag around the hips to attenuate ground impact forces on the body. A longitudinal observational study by Yang et. al. analyzed recordings from thousands of real-world falls captured on closed-circuit video monitoring within the nursing home setting and determined that the vast majority of major hip injuries resulted from falls from standing height and ground-force impact to the lateral or posterolateral aspect of the hip. [xiv] Lastly, as referenced above, a randomized clinical trial of over 1200 subjects within nursing homes demonstrated that passive hip pads were able to reduce the incidence of hip fracture by over 80% when worn during the fall. These studies provide an evidence-based approach to mitigating fall-related major hip injuries via attenuation of ground impact forces and utilizing a belt-based form factor specifically designed to overcome common barriers to wear compliance.

2.3 Prior Investigations and Market Experience

The Tango Belt was previously marketed as a personal safety product and has been used in senior care facilities (including Skilled Nursing Facilities, Assisted Living Facilities, and Continuing Care Retirement Communities) and in-home environments. Following extensive laboratory testing, a pre-production version of the Tango Belt was initially introduced into multiple senior care facilities in a series of pilots beginning in 2017. The production version was then introduced into senior care facilities and in-home environments beginning in 2019. To date, the Tango Belt has been worn for over 80,000 hours of cumulative wear by over 100 older adults within home and senior care settings since its introduction as a personal safety product.

Real-world evidence from this previous use provides insight into the belt's potential to mitigate the injury risk associated with hip-impacting falls. Published case series demonstrated that the belt appropriately detected falls in-progress and could discriminate between non-serious and serious hip-impacting falls. In addition, the belt successfully delivered automated fall notifications to designated caregivers when a fall occurred. [xv] Most notably, unpublished data of real-world evidence demonstrates the Tango Belt was able to reduce the overall rate of falls with major injury by 60% over 6 months in a pilot conducted in a large skilled nursing facility. Further, the ability of the airbag technology to mitigate fall-related injury in a serious hip-impacting fall without causing harm to the wearer has been demonstrated. Lastly, the belt has shown strong adherence to wear, with a previously published case series demonstrating that it could

be worn comfortably for prolonged durations with wear times exceeding 12 hours and with belt removal needed only for charging or for bathing. [xvi]

These initial case series demonstrate the utility of the Tango Belt in higher-fall-risk patients and warrant further investigation in a controlled study to specifically establish the safety and effectiveness of the Tango Belt for the mitigation of falls with major hip-related injury in an at-risk, older adult population.

2.4 Demonstration of the Safety and Effectiveness of study product

Laboratory performance testing of the serious hip-impacting fall-in-progress detection algorithm was conducted using APT's staged true-fall library and demonstrated sensitivity of 82%. This testing includes inertial data sensor recording, prototype sensor and airbag-disabled belt assemblies, and pre-production sensor and airbag-disables belt assemblies. Further, with respect to specificity, there were 10 false positives (i.e., false alarms) over 66,000 wear-hours. Laboratory testing includes extensive design verification testing to confirm safety and functionality of the hardware and software, including impact attenuation on crash test dummies, environment conditioning, out-of-position deployment, FCC certification, electromagnetic emissions and immunity, belt and companion app usability, etc. In conjunction with the real-world evidence noted above, testing performed to date has demonstrated that the Tango Belt is safe and performs as intended.

2.5 Potential Known Risks and Benefits

Risks to subjects in this study include, but are not limited to, the following: use error or ineffective intervention leading to impact-related injury, adverse tissue reactions and interference with other electrical equipment/devices.

Presently, there are no known adverse events associated with the Tango Belt itself that have arisen throughout the pre-clinical testing and real-world usage.

Potential benefits of the Tango Belt include mitigating major hip injuries due to falls and reducing emergency department visits and hospitalizations due to falls, thereby enabling safer mobility in older adults at risk of falls and fall injuries.

3. Purpose/Intended Use

Purpose:

The current comparative clinical study is intended to establish the safety and effectiveness of the Tango Belt as an adjunctive intervention to the standard-of-care (SOC) to mitigate major hip injuries due to falls in an older adult population at-risk for fall injury.

Intended Use:

The Tango Belt is intended to be worn around the waist by geriatric individuals (65+ years of age) at risk for fall injury in order to mitigate major hip injuries related to falls. The Tango Belt uses built-in sensors and algorithms to detect falls and impacts. The device can send an alert to the designated caregiver/healthcare providers upon detection of a fall or impact. When an in-progress serious hip-impacting fall is detected, an airbag will deploy to physically protect the hip region from potential major injury. The Tango Belt is for prescription use only.

4. Study Design, Duration, Objectives and Endpoints

4.1 Study Design

This is a multi-center, comparative, adaptive, non-significant risk clinical trial conducted in the United States to assess the safety and efficacy of the Tango Belt within senior care settings. Effectiveness of the Tango Belt will be determined by analysis of evidence for the Tango Belt as an adjunctive intervention to the standard-of-care (SOC) to mitigate major hip injuries from falls in an older adult population at-risk for fall injury as the primary endpoint. Performance of the Tango Belt to mitigate fall injuries that result in hip fracture, emergency room visits, and hospitalizations will be secondary endpoints. The performance of the device is determined by the comparison of the proportion of fall-related major hip injuries in the intervention group as compared to the proportion of fall-related major hip injuries in a retrospective control group utilizing only SOC. SOC utilization will be verified for each clinical site enrolled. An adaptive trial design will be utilized to allow an initial efficacy target to be evaluated at 6 months; if the initial target is not met, then a second cohort of sites and subjects will be enrolled for an additional 6 months to allow a lower efficacy target to be evaluated.

Safety of the device will be determined by analysis of adverse events as an ancillary endpoint.

4.2 Duration (per site)

Estimated enrollment time	3 months
Estimated in-study run time	6 months
Estimated total duration	12 months after 1st patient enrolled

4.3 Objectives

Primary Objective: To assess the performance of the Tango Belt to mitigate fall-related major hip injuries in an at-risk of fall adult population as compared SOC only.

Secondary Objective: To assess the performance of the Tango Belt to mitigate falls resulting in: (1) hip fractures, (2) emergency department visits or (3) hospitalizations.

4.4 Endpoints

Primary Endpoint: The primary outcome measure will be the proportion of major hip injuries due to fall in the subjects receiving SOC as compared to subjects receiving SOC plus the Tango Belt.

Secondary Endpoints: Secondary outcome measures include the proportion of each of the following:

- Hip fractures due to fall in the subjects receiving SOC as compared to subjects receiving SOC plus the Tango Belt.
- Emergency Department visits due to fall in the subjects receiving SOC as compared to subjects receiving SOC plus the Tango Belt.
- Hospitalizations due to fall in the subjects receiving SOC as compared to subjects receiving SOC plus the Tango Belt.

Ancillary Endpoints: Ancillary endpoints will include:

- Adverse events
- Major injuries due to fall
- Fall occurrence
- Device wear adherence
- Device fall alerts
- Device discrimination of serious hip-impacting vs. non-serious hip and non-hip impacting falls
- Airbag deployment
- FES-I short version

5. Selection of Subjects

5.1 Inclusion Criteria: All subjects are required to meet ALL of the following inclusion criteria to be considered eligible for participation in this study:

1. Age 65 years or older;

2. Have experienced a fall-related fracture after age 50
   -OR-
   Have experienced one or more falls in the 12-months prior to consent and have a diagnosis of osteoporosis, osteopenia, or prescribed osteoporosis medication.
3. Independently or with staff or caregiver assistance, able to transfer between surfaces (e.g., to or from a bed, chair, wheelchair, toilet, standing position) or walk or move between locations (use of an assistive device such as a walker is acceptable);
4. Have a waist circumference between 29 – 50 inches (63.5 – 127 cm);
5. Able to comply with required study procedures and follow-up schedule as determined by the Study Investigator;
6. Are under the care of the Investigational organization;
7. Provides consent or their legally authorized representative provides consent on subject's behalf

5.2 Exclusion Criteria: Subjects will be excluded from participating in this study if they meet ANY of the following exclusion criteria:

1. Age 64 years or less;
2. Participation in a different clinical investigation that can conflict with this clinical study as determined by the Study Investigator and approved by the Sponsor;
3. Total dependence on staff or caregiver assistance to be able to transfer between surfaces (e.g., to or from a bed, chair, wheelchair, toilet, standing position) and walk and move between locations;
4. Use of other devices or interventions outside of SOC for fall risk management during study participation without Sponsor approval;
5. Unable to comply with required study procedures and follow-up schedule as determined by the Study Investigator;
6. Does not provide consent, or legally authorized representative does not provide consent

5.3 Strategies for Recruitment and Retention

Control group: The investigator or designee will retrospectively review the site's EMR database to determine their long-term care patient population's initial eligibility for meeting the study inclusion criteria. The subjects in the clinical site census at the time frame 6 months prior to the IRB approval date will be screened for eligibility for study inclusion. Subjects eligible for the control group must meet the requirements of the inclusion and exclusion criteria except for the waist circumference and need for consent. Eligible subjects' electronic health records will be mined for the baseline, midpoint, and

final study metrics. If there is an insufficient number of eligible subjects to meet the control group target (defined as 4 times the expected number of intervention group subjects to be enrolled from the site) at 6 months prior to the intervention group start date, the EMR database screen will extend retrospectively in 6 month increments until the control group target is reached.

Intervention group: The investigator or designee will review the site's EMR database to determine their current long-term care patient population's initial eligibility for meeting all study inclusion and exclusion criteria, except for waist circumference, informed consent, and ability to comply. Subjects meeting initial eligibility will then have their waist circumference obtained, and those that meet inclusion criteria will then be offered the opportunity to participate in the study through the informed consent process utilizing IRB approved subject facing recruitment materials including a video introduction of the device, a flyer on the device and research study and verbal explanation of the study with access to study site investigator for addressing questions and/or concerns. If the subject agrees to be a participant in the study, the subject will be given a written informed consent to read, sign and date (Appendix 1 - Informed Consent). If the subject has a Legally Authorized Representative (LAR) or Person of Authority (POA) in place, the POA will receive notification regarding the eligibility for the subject to participate in the study with the IRB approved subject facing recruitment materials including video introduction of the device, a flyer on the device and research study and verbal explanation of the study with access to study site investigator for addressing questions and/or concerns with the written informed consent. The POA may offer consent verbally over the phone to the investigator/ designee with notation on the Informed Consent Form and subsequent receival of copy of the ICF via USPS or email. The ICF can also be signed electronically with a provided eSignature option to the POA. All subjects or POAs will be given the opportunity to discuss the technology, risks, potential benefits, alternative therapies, and the study requirements with the investigator prior to signing the informed consent. Subjects or their POAs that provide written or electronic consent will be preliminarily enrolled into the intervention group.

Upon preliminary enrollment, utilization of the Tango Belt will be prescribed by the site's physician and written into the subjects' plan of care at the care residence. A Tango Belt of appropriate size based upon waist measurement will be provided to the subject by the investigator or designee. The subject will be assigned to the Tango Belt ID located in the APT cloud electronically via Tango Belt companion app for data tracking. The Tango Belt size will be adjusted for most comfortable and appropriate fit using the sizing strap located in the left side zipper pocket of the Tango Belt. The Tango Belt will be prescribed to be worn up to 24 hours/ day with removal for bathing activities, dressing as needed, twice a week at minimum for charging and upon subject request. Baseline metrics will be obtained from the subjects' EMR. The enrolled participant will be

assessed for cognition level via the BIMS if this has not already been taken as part of the EMR. Assessment of balance confidence using the short version of the FES-I if they are cognitively capable of completing the survey with a BIMS Score of 13-15. (Appendix 2 – Study Questionnaire)

Enrolled subjects in the intervention group will then proceed through a run-in period of 14 days to assess adherence to utilization of the Tango Belt. At 14 days, if the subject is demonstrating adherence to use of the device of at least 64% as viewed by the investigator or designee in the Tango Belt companion app dashboard as "Compliance" (defined as wearing the device for at least 1 hour per day for at least 9 of 14 days), they will be fully enrolled into the study and proceed through the study duration. Subjects who do not meet the run-in period requirement will be withdrawn from the study.

Screen Failures in this study would include study candidates that:

- Do not meet inclusion criteria
- Meet any exclusion criteria
- Do not fit within the range of Tango Belt sizing available
- Do not comply with the minimum device utilization of 64% within the run-in period

To account for the relatively high morbidity and mortality of the target study population, we will assume a 20% in-study attrition rate, and thus will aim to over-recruit by this amount beyond the target sample size statistically required for the intervention group.

Lastly, after 6 months of in-study participation, intervention subjects may be given the option to continue wear of the Tango Belt in order to collect longer-term safety and efficacy data. In an effort to minimize potential for bias, this option will not be revealed to intervention subjects prior to study enrollment.

5.4 Participant Withdrawal/Discontinuation or Termination

All subjects will be followed for 6 months following enrollment in the study to ensure study inclusion and exclusion criteria continue to be met; any subject who no longer meets the study criteria during this timeframe will be withdrawn. Intervention subjects will be advised that they may voluntarily withdraw from the study at any time without jeopardy to any future medical care and will be instructed to notify the investigator or designee immediately should they wish to do so. If any intervention subject wishes to withdraw from the study, the reason(s) for discontinuation will be recorded in the subject's chart and on the appropriate Case Report Form (CRF). Intervention subjects

may choose to withdraw for any reason and are not obligated to reveal their reason(s) for withdrawal.

Any screen failure, withdrawal/discontinuation or termination of a subject from the study will be accompanied by the date, the reasoning specific to the removal from study and data captured prior to removal will be recorded on the CRF.

If a significant symptom or adverse event is associated with discontinuation, this will be recorded in the CRF and patients who are withdrawn due to adverse events will be followed until resolution or stabilization of the adverse event.

If an intervention subject is demonstrating adherence to utilization of the device under 64% during the initial 14-day run-in period, they will be withdrawn from the study.

It is also recognized that the investigator, at his or her discretion, may withdraw a subject from this trial to pursue other treatment modalities, if the subject no longer meets the study inclusion and exclusion criteria, or if the subject cannot continue in the trial for any medical reason(s). The sponsor is to be notified in a timely manner if the subject is to be withdrawn and a Study Termination Form will be completed.

5.5 Premature Termination, Suspension, or Extension of Study

It is agreed that either the investigator and/or APT may terminate this study at any time, provided written notice is submitted at a reasonable time in advance of intended termination. The study may be extended to obtain expanded efficacy and safety information as per the adaptive trial design and/or to obtain long-term safety information. Also, a decision on the part of the IRB/EC to suspend or discontinue testing, evaluation, or development of the product may lead to discontinuation/termination of a study subject's participation.

A study conducted at a single study site in a multicenter study may also warrant termination under the following conditions:

- Failure of the Investigator to enroll patients into the study at an acceptable rate
- Failure of the Investigator to comply with pertinent regulations of appropriate regulatory authorities
- Insufficient adherence to protocol requirements
- Submission of knowingly false information from the research facility to the sponsor, study monitor, or appropriate regulatory authority

6. Study Agent/Product

6.1 Device

The Tango Belt (the "Device") is a wearable belt designed to enable safer mobility of geriatric individuals (≥ 65 years of age) at risk for fall injury by mitigating major hip injuries due to falls. The Tango Belt is a patient-contacting electronic device made out of medical grade plastics and biocompatible fabrics. It is worn around the waist at the iliac crest, secured by a buckle. It comes in 5 sizes, XS, S, M, L, and XL, to accommodate wearers with a waist circumference between 29-50 inches (covering the 5^{th}-95^{th} percentile of older adults in the US); each belt is further adjustable to prevent sliding past the hips or elevating out of position.

The Tango Belt contains a fall-in-progress detection algorithm which can detect a serious hip-impacting fall-in-progress using built-in sensors and deploy an automotive-grade cold-gas airbag to protect the hips from ground impact forces. When connected to Wi-Fi, the Tango Belt can send automated fall and impact alerts to caregivers and Healthcare Providers (HCPs) while recording motion and event data, which can then be analyzed for usage-based metrics viewable via a companion mobile app and/or desktop app. The Tango Belt can also send manually activated alerts for help, triggered by pressing a button on the belt buckle, when connected to Wi-Fi. Alerts are sent in the form of SMS texts and emails to alert recipients designated in the mobile or desktop Companion App. The Tango Belt can also detect non-serious hip-impacting or non-hip impacting falls in which the wearer may have incurred a minor injury (i.e., not a major hip injury) and/or may be unable to get up.

Additionally, the belt can be periodically surface disinfected using a germicidal wipe. Further, the belt contains a non-replaceable lithium-ion battery, which requires recharging via the included specially designed AC adapter every several days depending on wear duration. An optional Safety Latch can be installed by care staff on any belt to prevent inadvertent unbuckling. Lastly, if airbag deployment occurs, the Tango Belt cannot be reused.

The Tango Belt's Companion App (available in mobile and desktop versions) enables the following added functionality: 1) connecting the belt to Wi-Fi (mobile version only), 2) inputting contact information for alert recipients, 3) viewing dashboard metrics (e.g. Compliance and Daily Wear), 4) taking or administering the FES-I survey, and 5) managing a fleet of multiple belts within a facility setting.

6.2 Acquisition

The sponsor will provide the Tango Belts in numbers allocated to the sizes appropriate for enrolled subjects in the intervention group. The Tango Belts will be delivered to the clinical sites with chargers, instructional materials, and cleaning materials during the time of EMR screening in preparation for enrollment. Extra Tango Belts will be provided

to all clinical sites in sizes allocated for replacement in the case of device malfunction or airbag deployment.

6.3 Appearance and Labeling

The main component of the Tango Belt is the belt itself, which is shipped and stored in a custom foam-padded cardboard box also containing the Tango Belt Product Guide and Tango Belt charger. Each Tango Belt, including its individual box, is clearly labeled with its size and unique Serial Number (aka "ID number"), which is number located on the inside of the right zipper pouch and is uniquely tied to its lot manufacturing record and any digital data stored in the APT cloud. Physical labeling on the belt also includes graphical symbols to aid proper donning, warnings, and contact information. Further, the Product Guide includes instructions for use, warnings, cautions, and useful tips for operation. The Support page of the Tango Belt website also includes instructional videos covering the operation of the belt and companion app, as well as useful tips and cautions.

6.4 Product Storage and Stability

Tango Belt is designed to be shelf-stable for at least 12 months, in package, in climate-controlled storage. The Tango Belt should not be exposed to temperatures outside the range of -4° to 122° F (-20° to 50° C). If stored unused for a long period of time the belt should be recharged prior to use. For purposes of this clinical trial, no other special storage instructions apply. Product usage life of the Tango Belt is 3 years from the date of first use.

6.5 Preparation

The Tango Belt must be properly sized to the waist of each intervention subject. Determination of proper belt size and further adjustment of the built-in sizing strap is described in the Product Guide and online training videos. Prior to use, the Tango Belt should be charged using the included charger; charging time requires approximately 3 hours when the battery is fully depleted.

Additionally, the Tango Belt Companion App (running on a compatible mobile device) must be used to complete the following preparation steps prior to first use:

- Each belt must be connected to the site's Wi-Fi network using the Guided Setup

- A new "Wearer" should be created for each intervention and given a wearer name consistent with the subject naming scheme for the study
- Lastly, the sized belt should be ASSIGNED to the newly created Wearer via its unique Serial Number located on the belt and package labeling

Upon completion of the steps above, the Tango Belt can then be provided to the intervention subject to begin their 6-month study participation (subject to successful completion of their 14-day run-in period).

6.6 Device accountability procedures

An electronic data capture (EDC) platform will be custom-developed for this study and utilized by investigators or designees at each site for the purposes of electronically collecting and managing CRF data throughout the study. For each intervention subject, the investigator or designee will enter into the EDC platform the Tango Belt ID number along with a unique subject identifier obtained from APT to enable matching of EDC data with data stored in APT's cloud.

Labels will be provided for marking room numbers on the external aspect of the Tango Belt for easy identification of subject assigned device.

Inventory tracker sheets will be provided for quick reference of care team members and study investigators on-site for device allocation.

Lastly, metal rolling carts will be provided to each site to allow for secure storage and charging of belts provided for this study.

7. Study Procedures and Schedule

7.1 Investigator Training

All investigators involved in the clinical study will attend to the following training:

- Good Clinical Practices (GCP) and Research Ethics Training by an approved provider. Attendance certificates will be held at the clinical study sites
- Electronic Documentation System for recording of all data required on the CRF per this protocol
- Use and care of the Tango Belt
- Use of the Tango Belt mobile and desktop apps as appropriate

7.2 Evaluations and Scheduled Data Collection Flow Chart

Evaluation	Visit 1 Screening/ Baseline Visit (+/- 14 days)	Visit 2 14-day Run-In (+/- 2 days)	Visit 3 90-Days (+/- 10 days)	End of Study 180-days (+/- 30 days)	Unscheduled Visit /
Render Informed Consent	X				
Demographic information	X				
Medical / Fall history	X				
BIMS	X				
Fall mitigation plan of care	X		X	X	X
FES-I (short version)	X		X	X	X
Inclusion/Exclusion criteria review	X		X	X	X
Tango Belt adherence		X	X	X	X
Adverse Events (including Fall event information)			X	X	X
Device deficiencies			X	X	X

7.3 Study Visit Descriptions

Visit 1 Baseline:

- Informed Consent will include the provision of the Informed Consent Form (ICF) with overview of the clinical study proposed and informational materials that may include: video description, flyer and discussion of the Tango Belt technology. Informed consent will be obtained in person by qualified clinical study site personnel delegated to this task by the site investigator and before any study related procedures and/or assessments can be performed. If the subject has a legally authorized representative (LAR) documented as a person of authority (POA), that person identified in the EMR will be contacted with the same information and presented with the ICF. If there is telephonic agreement of study consent, this will be noted by the CRA on the ICF with date, time and indication of LAR, with tow (2)

copies sent via email or USPS to the LAR for final signature. An email including the ICF with explanation of the clinical study and inclusion of the noted information can also be shared with a LAR for electronic signature for subject informed consent. Contact information for the clinical site study investigator will be provided to the subject/LAR to offer communication in regard to any questions or concerns for consenting to participation in the clinical study. The subject will be provided the Short version of the FES-I if they have the cognitive capability to do so. BIMS score of 13-15 indicates ability to take the Short version of the FES-I.

- The subject will be assigned a Tango Belt of the correct size based on measuring their waist size and the belt will be introduced to the subject with specific fitting applied using the sizing strap for best comfort. The Tango Belt assignment will be performed using the Tango Belt Companion App to allow for data tracking for this subject. An order for wearing of the Tango Belt will be applied to the medical chart and the care team will be notified of the patient's inclusion in the study with attention for wear adherence and charging cycle.
- The baseline metrics of medical and fall history, fall mitigation plan, and mobility level will be taken directly from the MDS and/or EMR within the electronic documentation system utilized at the clinical study site.

Visit 2 Run-in period (14 days +/- 2):

- Metrics of the compliance to wear of the Tango Belt by the subject defined as at minimum 64% (at least 1 hour a day for 9 days out of 14) will be provided by sponsor to the CRA. If the subject is not utilizing the device for at least the minimum amount of time, they will be determined to be a screen failure and withdrawn.

Visit 3 Midterm (90 days +/- 10):

- Metrics of changes in fall mitigation plan, mobility level and fall events including falls, falls with major injury, adverse events (whether not pertaining to the Tango Belt), emergency department visits, and hospital admissions will be taken by the site - investigator or designee research assistant directly from the MDS and/or EMR within the electronic documentation system utilized at the clinical study site.
- Metrics of Tango belt wear days and wear hours/day will be provided to the site investigator or designee research assistant from the sponsor or obtained from the Tango Belt Companion App.
- Metrics of device deficiencies, device discrimination between types of falls, airbag deployments, and alerting will be provided to the site investigator or designee research assistant by sponsor from the Tango Belt cloud.

End of Study (180 days +/- 30):

- Metrics of changes in fall mitigation plan, mobility level and fall events including falls, falls with major injury, adverse events (whether or not pertaining to the Tango Belt), emergency department visits, and hospital admissions will be taken by the site -

investigator or designee research assistant directly from the MDS and/or EMR within the electronic documentation system utilized at the clinical study site.

- Metrics of Tango belt wear days and wear hours/day will be provided to the site investigator or designee research assistant by sponsor or obtained from the Tango Belt Companion App.
- Metrics of device deficiencies, device discrimination between types of falls, airbag deployments, and alerting will be provided to the site investigator or designee research assistant by sponsor from the Tango Belt cloud.
- Tango Belt will be collected by the sponsor for return to Active Protective Technologies, Inc.

Unscheduled Visit (AE, hospitalization, change in status in medical care plan):

- Metrics of changes in fall mitigation plan, mobility level and fall events including falls, falls with major injury, adverse events (whether or not pertaining to the Tango Belt), emergency department visits, and hospital admissions will be taken by the site investigator or designee research assistant directly from the MDS and/or EMR within the electronic documentation system utilized at the clinical study site.
- Metrics of Tango belt wear days and wear hours/day will be provided to the site investigator or designee by sponsor or obtained from the Tango Belt Companion App.
- Metrics of device deficiencies, device discrimination between types of falls, airbag deployments, and alerting will be provided to the site Investigator or designee research assistant by sponsor from the Tango Belt cloud

Major Hip Injury Adjudication: for 90-day and 180-day adverse event reporting of Fall with Major Injury:

- In the event of an identified Fall with Major Injury, the determination of Fall with Major Hip Injury will be independently assessed by a qualified medical expert in the field of geriatric medicine after receiving blinded data regarding the injury.

8. Assessment of Safety

8.1 Definition of Adverse Event (AE)

An Adverse Event (AE) is defined as:

Any untoward medical occurrences in a patient or subject receiving an investigational medical device and does not necessarily have to have a causal relationship with the device under investigation. An AE can therefore be any unfavorable and unintended sign (including abnormal laboratory finding), symptom, or disease temporally associated with the use of a medical device whether or not considered related to the medical

device. Any fall event is considered an AE for this study.

8.2 Definition of Serious Adverse Event (SAE)

A Serious Adverse Event (SAE) is defined as:

An AE that results in any of the following outcomes:

- Results in death;
- Is life-threatening;
- Requires in-patient hospitalization or prolongation of existing hospitalization;
- Results in persistent or significant disability/incapacity

8.3 Classification of AE

i. Severity of event

Each AE must be described as follows:

- the date of onset;
- date of resolution;
- severity;
- frequency of the event (single episode, intermittent, continuous);
- action taken (none, medical and/or surgical);
- relationship to study device;
- seriousness criteria must be recorded.

Each adverse event must be recorded separately.

AE Severity will be assessed using the following definitions:

Mild	Aware of sign or symptom, but easily tolerated
Moderate	Discomfort enough to cause interference with usual activity
Severe	Incapacitating with inability to work or do usual activity

ii. Relationship to Study Agent/Product

The relationship to study device will be assessed by the site investigator using the following definitions:

Not Related	Evidence exists that the adverse event definitely has a cause other than the study device (e.g., pre-existing condition or underlying disease, intercurrent illness, or concomitant medication) and does not meet any other criteria listed.

Possibly Related	A temporal relationship exists between the event onset and administration of study device. Although the adverse event may appear unlikely to be related to the study device, it cannot be ruled out with certainty, and/or the event cannot be readily explained by the patient's clinical state or concomitant therapies.
Probably Related	A temporal relationship exists between the event onset and administration of study device and appears with some degree of certainty to be related based on known mechanism of action of the device. It cannot be readily explained by the patient's clinical state or concomitant therapies.
Definitely Related	Strong evidence exists that the study device caused the adverse event. There is a temporal relationship between the event onset and administration of the study device. There is strong mechanistic evidence that the event was caused by the study device. The patient's clinical state and concomitant therapies have been ruled out as a cause.

Adverse events related to the Tango Belt could include the following:

- Discomfort, soreness, or injury due to normal wear of the belt, particularly in subjects who are very frail and thin and/or when the belt is not properly sized or fitted to the subject
- Discomfort, soreness, or injury caused by airbag deployment

iii. Adverse Event Reporting Procedures

Apparent Device malfunctions can be troubleshooted by site staff following provided materials, or by contacting sponsor for support, and should be recorded in patient files, along with initial date of occurrence, brief description, did it cause adverse events, whether damage is apparent. Malfunctions that impact essential performance, as defined in the Instructions for Use, should be recorded immediately and reported immediately to site-investigator. The site investigator may seek additional support from sponsor, but records in the EDC when a device is replaced due to malfunction, with date of replacement and start of malfunction. A device that doesn't maintain essential performance, as defined in the Instructions for Use, should be replaced (e.g. fails to power on, deploys without a fall, solid red light, blinking blue light). The site shall coordinate with the Sponsor Monitor for return and replacement, as needed.

All adverse events are to be evaluated for severity, relationship to product and whether they constitute an SAE, recorded in the EDC, to be reviewed by PI as described in section 8.4. PI continually monitors the enrolled study subjects for AEs and possible SAEs in the medical record.

PI should be notified immediately upon, Serious Adverse Event, fall event, or an AE that impacts utilization of the device.

Serious Adverse Events (SAE's) including status changes indicated in study subject medical records receive immediate attention of the Principal Investigator (PI) for consideration of device-related SAE. Serious AE (SAE) are to be reported to Sponsor and the IRB within 24 hours of the site becoming aware of the event. SAE notifications to the Sponsor are to be reported and completed via EDC.

Upon a fall event, site investigator is to initiate a Fall report, to gather evidence needed for the eventual adjudication of the Adverse Event, if required. Falls with Major Injury will be reviewed by the medical expert adjudicator as outlined in section 7.3. (Note, a Fall with Major Injury could *also* be considered a SAE for purposes of IRB reporting).

8.4 Safety Oversight

This trial is not conducted in an emergency setting and informed consent is being collected, so a Data Monitoring Committee is not required under regulation. The device poses non-significant risk and has been observed in a real-world setting (see section 2.3).

The Medical Monitor and Principal Investigator will oversee the safety of the study including any AEs and SAEs reported by the clinical Investigative Sites. Notification of any AEs will be obtained by the Principal Investigator via reporting from clinical site investigators in the shared CRO EDC system.

Adverse Events (AEs) that occur will be captured in the 90-day and 180-day visit reporting in the EDC for PI review.

9. Clinical Monitoring Procedures

Monitoring will be conducted by Sponsor and/or designee to ensure investigator and site personnel are in compliance with:

- The signed Clinical Trial Agreement,
- This Study Protocol,
- Adherence to applicable FDA regulations,
- Any conditions of approval imposed by the IRB or FDA,
- Ensuring the rights and well-being of the subjects are protected,
- Ensuring the reported study data are accurate, complete, and verifiable from source documents, and
- Ensuring the conduct of the study is in compliance with Good Clinical Practice.

Subject CRFs will be electronically completed and reviewed for completeness and accuracy as well as for any evidence suggesting subject risk. Risk can be anything that can affect subject safety and can be many factors including but not limited to: the reporting of false or inaccurate data, study visits and/or study procedures not being performed as required per protocol, misconduct or non-compliance by subject and/or site staff, and anything that can potentially harm or cause discomfort to the subject. Where any discrepancies are noted, they will be resolved with the investigator and/or an individual designated by the investigator. When the data are incomplete, attempts will be made to obtain the missing data.

Monitoring procedures and frequency will be conducted throughout the course of this study according to the Clinical Monitoring Plan. Monitoring visits will focus on the status of regulatory documents, adherence to the protocol, review of informed consents, adverse event reporting, device accountability, and a comparison of source documentation against electronic case report forms (eCRFs). Qualified site study personnel are expected to spend some time with the clinical monitor to resolve queries and review action items at each onsite monitoring visit.

The investigator(s)/institution(s) will permit trial-related monitoring, audits, IRB review, and regulatory inspection(s), providing direct access to source data/documents.

Representatives of the sponsor may request access to all study records, including source documents, for inspection and copying during normal business hours.

10. Statistical Considerations

10.1 Statistical Sample Size Determination and Analytical Plans

Historical control data will be utilized from data available in the medical record. Specifically, the rate of falls with major injury will be obtained and analyzed in 6-month retrospective periods from Investigational sites participating in the prospective enrollment of treatment subjects, beginning with the IRB approval date and extending back to 2018. Due to the COVID-19 pandemic restrictions, it is possible that some subjects at participating Investigational sites did not receive the SOC during this time

period. Therefore, if there is any evidence that the rate of falls resulting in major injuries is different for any portion of the 2018–present time frame, historical control data will not be utilized from the time frames with a different fall rate. The sample size for the control group, and therefore the allocation ratio, will be determined by the number of historical controls for which data is available during the selected time periods. It is anticipated that control data will be available to allow 2, 3, or 4 controls for each treatment subject. The annual rate of falls with major hip injury has been estimated between 6% and 10% in higher-risk populations within long-term care facilities. Since the fall rate is not exactly known in the study population, the fall rate observed in the historical control group, a nuisance parameter, will be used for sample size calculations.

To estimate performance of the Tango Belt, data on file from real-world use of the Tango Belt in the nursing home setting found airbag deployment in 6 of 6 total serious hip-impacting falls, resulting in no major hip injuries. Therefore, we are 95% confident that the Tango Belt will protect 66% of falls. However, it is possible that the Tango Belt may prove to be even more effective with a larger sample size. Therefore, a group sequential design (GSD) will be utilized. The GSD will include a planned interim analysis at a sample size to detect an 80% protective effect of the Tango belt at 80% power at a planned interim analysis. If a significant difference is found between the prospective Tango Belt subjects and historical controls at the interim analysis, the study will be completed early. If not, enrollment will continue until a final sample size is reached to detect a 60% protective effect of the Tango belt at 80% power and a 5% total level of significance. Exact sample sizes for the interim and final analysis will be calculated once the number of historical control subjects and the rate of falls with major hip injury in the control group are determined. The PASS GSD module will be used to simulate the sample sizes and power using the Pocock alpha-spending function. The steps to calculate the sample size will include:

1. Test the historical control time periods to determine if all the time periods can be used, depending on if any time periods differ in fall rate
2. From the remaining historical control data, find the fall rate and the total sample size available for the historical control group
3. Find the sample sizes for the historical controls and the prospective Tango Belt arm at the interim analysis.
4. Find the sample size for the prospective Tango Belt arm at the final analysis; the total sample of historical controls will be used at this look.

To demonstrate these calculations, we assumed subjects were followed for an average of 6 months, an annual fall-with-major-hip-injury rate of 8%, and sufficient historical control subjects to allow 1:4 allocation of subjects to treatment and control. This would require 176 subjects in the prospective Tango belt group and 704 subjects in the historical control group at the interim analysis. At the end of the study (should the

higher efficacy target not be achieved at interim analysis), 417 total subjects would be required in the prospective Tango belt group and 1688 subjects would be in the historical control group.

10.2 Analysis Datasets

Datasets to be used in the analysis include:

- EMR database of long-term care patient population at each site
- In-study CRF data collected within the EDC platform for intervention subjects
- Dashboard metrics (Compliance and Daily Wear) and alert data collected automatically by belts in the APT Cloud for intervention subjects
- FES-I data collected via Companion App for intervention subjects

10.3 Description of Statistical Methods

A test of proportions will be used to test the primary hypothesis that the proportion of subjects experiencing major hip injuries due to falls is lower in subjects receiving SOC plus the Tango Belt than in subjects receiving SOC alone, adjusting for propensity score. The hypotheses for the secondary endpoints will also be tested using propensity score adjusted test of proportions, and the type I error rate will be adjusted for multiple testing.

The primary outcome measure in this study is the proportion of major hip injuries from falls reported for intervention group as compared to the control group.

The secondary outcomes:

1. The proportion of subjects experiencing fall-related hip fractures is lower in subjects receiving SOC plus the Tango Belt than in subjects receiving SOC alone.
2. The proportion of subjects experiencing ED visits due to falls is lower in subjects receiving SOC plus the Tango Belt than in subjects receiving SOC alone.
3. The proportion of subjects experiencing hospitalizations due to falls is lower in subjects receiving SOC plus the Tango Belt than in subjects receiving SOC alone.

10.4 Measures to Minimize Bias

Bias in assessments shall be minimized through using established assessment procedures under experienced investigators, in addition, all screening data and ongoing assessments will be reviewed by an independent observer to ensure integrity. The clinical investigator(s) will permit trial-related monitoring, audits, EMR review and

regulatory inspection(s), providing direct access to the trial site and to source data/documents on request.

11. Access and Verification of Source Data

Unique password-protected logins will be provided to the investigator and/or designee at each site to access source data and databases outside of the EMR, including the EDC platform and Tango Belt companion app for completion of the CRFs. Secure access to subjects' EMR data will be provided to site-authorized Sponsor monitor(s) for source data verification and quality purposes.

Source data verification will be performed for 100% of the subjects for enrollment criteria, primary endpoint, as well as adverse events. Regulations require that all data in the clinical investigation are captured in the patient's medical records (i.e., source documentation). All information generated by patient evaluations/examinations/interviews pertinent to the study are to be transferred by the clinical investigator (or designee) into the EDC platform via the CRF. Note that the FES-I questionnaire can be completed by the intervention subjects or administered by the investigator (or designee) directly using the Tango Belt companion app and will not require additional transcription into the EDC platform. All source documentation must be made available for inspection by the monitor, sponsor's staff or other authorized sponsor representative.

Source documents are documents on which information regarding subjects is first recorded. They are used to verify the existence of the subject and to substantiate the integrity of the data that are collected during a clinical trial. Investigator subject files generally are the basis of source document information. This includes but is not limited to original subject files, operative reports, progress notes, clinic records, and original recordings. Any additional information relevant to the study should be included in source documents. In particular, any deviations from the study protocol or procedures should be recorded.

Information in the subject chart must be accurately reflected on the eCRFs. An Electronic Data Capture (EDC) system will be utilized by study site personnel to transfer study data from source records/medical records onto common eCRFs. This system is a web-based, secure electronic software application (iMedNet).

12. Quality Assurance and Quality Control

This clinical trial sponsored by APT will be conducted under Standard Operating Procedures. The CRAs serving as a representative of APT shall follow this study closely by visiting the investigator and the study facility regularly and maintaining necessary telephone, electronic and/or letter

communication so that any questions and problems that may arise can be promptly resolved. Such monitoring will also ensure that the clinical investigation is conducted in accordance with this CIP, including all amendments, per FDA Good Clinical Practice Guidelines. Monitoring will involve frequent virtual visits by the sponsor's representative to the investigation center to verify good management of subjects and the clinical investigation devices, to observe procedures and to audit the clinical investigation for quality control purposes (to check device supply, presence of required documents, informed consent and for comparison of CRF with source data). The monitor maintains current, personal knowledge of the study through observation, review of the records, comparison with source documents and discussion of the conduct of the study with the investigator. There will also be frequent telephone contact and written communication between monitor and clinical investigators.

During the periodic visits to the investigator, the monitor reviews the source documents used in the preparation of the CRFs to verify the accuracy and completeness of the information contained in those forms. All data generated during this study, and the source documents from which they originated, are subject to inspection by APT, Avania CRO and/ or other regulatory authorities. On-site audits may take place independent of and separate from routine monitoring or quality control functions. They may take place at various stages during the trial. The clinical investigator(s) will timely be informed in writing and/or by telephone that a QC audit is to take place and about the items for which the audit will be performed. Whenever possible, the QC auditor will be accompanied by the responsible monitor. The auditor may stay at the trial site as long as deemed necessary. The conduct of a QC audit will be confirmed by certification.

13. Ethics/Protection of Human Subjects

13.1 Ethical Standard

This study will be performed in accordance with the relevant parts of the Code of Federal Regulations, ICH Guidelines for Good Clinical Practice (GCP), the Belmont Report and any other applicable regional and/or national regulations.

This protocol has been prepared in accordance with FDA Good Clinical Practices (GCP). Both the Sponsor and the clinical investigators have to conduct this clinical investigation with strict adherence to the above-mentioned guidelines.

13.2 Institutional Review Board (IRB)

Each site will have a designated site investigator and potential co-investigators within the same practice. For each site, the site investigator must secure Institutional Review Board (IRB) approval from each hospital or medical facility where the clinical study will be conducted.

This approval will cover all physicians designated as co-investigators within that practice. A copy of such written approval must be forwarded to APT before medical devices can be shipped.

An independent IRB may be used by those facilities that do not have their own IRB, but use of such an IRB is subject to approval by APT.

The site must submit and, when necessary, obtain approval from the IRB for all subsequent protocol amendments and changes to the informed consent document. The PI should notify the IRB of deviations from the protocol or SAEs occurring at the site, as well as other adverse event reports received from the sponsor or its representatives, in accordance with local procedures. This documentation will be kept on file at the sponsor and each site.

The site will be responsible for obtaining annual IRB approval or renewal throughout the duration of the study, notifying the IRB of study completion, and providing the final study report, as required by the IRB. This documentation will be kept on file at the sponsor and each site.

APT must approve the drafted site-specific Informed Consent Form, which will be used for consenting subjects, prior to submitting the document to the IRB. If the IRB requires additional changes, these must be reviewed and approved by APT prior to resubmission to the IRB. A copy of the final, IRB-approved Informed Consent Form and all other IRB approved study documents must be submitted to APT.

13.3 ICF Process

The ICF process is generally described in Section 5.3; further details are provided below.

Consent Procedures and Documentation:

Before any non-standard of care study-related activity may occur, including recruitment and enrollment into the study, subject must provide written consent to participate in the study after the nature, scope and possible consequences of the clinical study have been explained in a form understandable to them. Each prospective candidate will be given a full explanation of the study. If the subject has an identified POA, that individual will be contacted with the consent information for proxy signature. After this essential information has been provided to the subject and the site investigator is assured that an individual candidate understands the implications of participating in this study, the subject will be asked to sign an informed consent form. Written informed consent must be obtained prior to enrollment in the study. The Informed Consent Form includes all the relevant elements currently required by GCP.

A notation that written informed consent has been obtained will be made on the subject's CRF. The original of the signed Informed Consent Form will be kept by the site investigator and a copy will be provided by the site investigator to the subject. If there is a POA for the subject, a copy of the POA documentation from source documentation will be obtained by the site investigator and notation of POA signature on behalf of the subject noted on the CRF.

Consent on behalf of a subject by a POA may be obtained with eSignature and/or verbal agreement with signature obtained via paper copies mailed or eSignature. Copies of signed ICF will be held by the site investigator and a copy shared with the POA.

The informed consent process should include at minimum the following:

- Provide potential subjects with a complete copy of the correct version of the IRB informed consent document.
    - Revisions to the protocol based on new information or changes in study procedure may require new versions of the consent therefore it is important to ensure a complete copy of the correct consent be given to the subject for review.
    - Different sites may require different IRB approval and consent documents; therefore, it is important to use the proper consent version per subject if your site has multiple satellite sites and IRB reviews.
- Allow potential subjects plenty of time to review the informed consent document.
- Provide subjects ample opportunity to ask questions to the site investigator or appropriately trained and delegated study staff member to ensure the subject understands the study requirements, potential risks, and their rights as a research subject.
- If the subject agrees to participate, have the subject and study staff obtaining the consent, sign and date the Informed Consent Form.
    - Please be sure to review signatures so that the date added to the signature is the day the subject and person obtaining consent signed the ICF.
    - IRBs may require the subject to initial and date each page to show that he/she read the consent. It is best practice for the person obtaining the consent to review the document to ensure all pages are appropriately initialed as applicable.
- The original signed consent should be filed at the site and be made available for review to monitors. Document entire informed consent process in the subject's medical chart.

13.4 Participant and Data Confidentiality

Information about subjects will be kept confidential and managed according to the requirements of the Health Insurance Portability and Accountability Act of 1996

(HIPAA). Every reasonable effort will be made to protect the confidentiality of the subjects throughout the study. Participant confidentiality is strictly held in trust by the participating investigators, their staff, and the sponsor(s) and their agents. Therefore, the study protocol, documentation, data, and all other information generated will be held in strict confidence. No information concerning the study or the data will be released to any unauthorized third party without prior written approval of the sponsor. The study monitor, other authorized representatives of the sponsor, representatives of the IRB or regulatory bodies may inspect all documents and records required to be maintained by the investigator, including but not limited to, medical records (office, clinic, or hospital) for the participants in this study. The clinical study site will permit access to such records. The study participant's contact information will be securely stored at each clinical site for internal use during the study. In the event that a subject withdraws authorization to collect or use Personal Health Information, the investigator retains the ability to use all information collected prior to the withdrawal of authorization. At the end of the study, all records will continue to be kept in a secure location for as long a period as dictated by local IRB and Institutional regulations. The study data entry and study management systems used by clinical sites will be secured and password protected. At the end of the study, all study databases will be de-identified and archived at the sponsor.

The information contained herein is provided to you in confidence and should not be disclosed to others, without written authorization from APT, except to the extent necessary to obtain informed consent from those persons to whom the device will be administered. Identities of individuals participating in clinical research will be kept as confidential as is possible within the law. While the information obtained in clinical studies may be published in scientific journals or presented at scientific meetings, the identity of participants will not be revealed. Representatives of the sponsor may inspect study records to assess the results of this research. Avania CRO, a Contract Research Organization and monitor of the study will conduct source document verification to assure the accuracy of information collected.

Representatives of other applicable state and/or federal regulatory agencies may also inspect subject records. Due to the need to release information to these parties' absolute confidentiality of subject records is not guaranteed.

14. Data Handling and Record Retention

14.1 Data collection and Management Responsibilities

Data collection is the responsibility of the clinical trial staff at the site under the supervision of the site investigator. The investigator is required to maintain detailed source documents on all subjects who are screened and/or enrolled in the study. Source documents include subject records, investigator subject trial files, as well as the results of tests and assessments. The date the subject began and exited the trial and a notation as to whether the subject completed the trial or was discontinued, including the reason for discontinuation should be included in the subject file.

All source documents should be completed in a neat, legible manner to ensure accurate interpretation of data. Dark ink is required to ensure clarity of reproduced copies. When making changes or corrections, cross out the original entry with a single line, and initial and date the change. DO NOT ERASE, OVERWRITE, OR USE CORRECTION FLUID OR TAPE ON THE ORIGINAL.

The investigator is responsible for ensuring the accuracy, completeness, legibility, and timeliness of the data reported. Case Report Forms (CRFs) are used for the collection and recording of data at the Investigative Center. The investigator is responsible for the timely completion and updating of the CRF. Data reported in the CRF derived from source documents should be consistent with the source documents or the discrepancies should be explained and captured in a progress note and maintained in the participant's official study record.

Serious Adverse Events (SAEs) are to be reported within 24 hours of knowledge of the event.

Incoming data are reviewed to identify inconsistent or missing data and adverse events. Data issues will be addressed with the site and/or during site visits. All hard copy forms and data files will be secured to ensure confidentiality. Copies of the retrieved CRFs will be kept within the Trial Master File at the sponsor or the sponsor's designee.

Avania CRO will ensure the Final Study Report is completed within 3 calendar months following the locking of the clinical database and ensure that all necessary documents are available. Avania CRO will ensure that the Final Study Report is an accurate presentation of the study and will liaise with APT during its compilation and production.

Avania CRO will send a regular and prompt monthly report to APT containing details of study status. Copies of all monitoring reports are also to be sent to APT. CRF's will be used to record demographic, procedural and follow-up data. Adverse events, which may occur during this study, will be recorded on the Adverse Events form. The adverse events and incidence of morbidity and mortality will be reviewed with the clinical investigators to assess the safety of the investigational device and the surgical implantation procedure.

Statistical results such as confidence intervals and descriptive statistics for intervention safety and primary effectiveness outcomes will be presented by site and in aggregate. Likewise, incidence of adverse events will be presented by site and in aggregate.

Lastly, belt-collected data from intervention subjects will be securely maintained in APT's cloud for potential future development of new product features and enhancements by APT personnel or development partners.

14.2 Study Record Retention

Records will be held in the electronic trial master file with Avania CRO for the period of time consistent with GCP. No records will be destroyed without the written consent of the sponsor. It is the responsibility of the Sponsor to inform the investigator when these documents no longer need to be retained.

Records to be retained include: all study-related correspondence, documentation of device receipt and disposition, each subject's case history and record of exposure to the device, the protocol and amendments, IRB information pertaining to reviews and approvals, Investigator Agreements, and dates and reasons for any protocol deviations.

14.3 Protocol Deviations

A minor protocol deviation occurs when, with non-significant consequences, the activities on a study diverge from the Institutional Review Board-approved protocol or GCP requirements. The noncompliance may be either on the part of the participant, the investigator, or the study site staff.

A major protocol deviation is a divergence from the protocol that materially (a) reduces the quality or completeness of the data, (b) makes the Informed Consent Form inaccurate, or (c) impacts a subject's safety, rights, or welfare. Examples of major deviations may include the following:

- Inadequate or delinquent informed consent
- Inclusion/exclusion criteria not met
- Unreported serious adverse events or fall event
- Materially inadequate record keeping
- Intentional deviation from protocol, Good Clinical Practice, or regulations by study personnel

It is the responsibility of the site to use continuous vigilance to identify deviations and violations. Monitor also continually monitors for discrepancies, providing instructions where needed.

Site reports within 3 working days of identification of the protocol deviation, or within 5 working days of the scheduled protocol-required activity. All deviations must be addressed in study source documents and reported to the sponsor or designee. Corrective action at the site is initiated where a systemic or repeated deviation-type occurs.

Site reports major protocol deviations immediately, and corrective action is initiated.

Protocol deviations must be sent to the IRB per their required reporting guidelines. The site PI/study staff is responsible for knowing and adhering to their IRB requirements.

14.4 Publication and Data Sharing Policy

Prior to submitting for publication, presenting, using for instructional purposes, or otherwise disclosing the results of the study, the investigator agrees to allow APT a period of at least 60 days (or, for abstracts, at least 5 working days) to review the proposed publication or disclosure prior to its submission for publication or other disclosure. Publications or disclosures of study results shall not include other confidential information belonging to APT. If the proposed publication/disclosure risks APT's ability to patent any invention related to the study, the publication or disclosure will be modified or delayed, at the investigator's option, a sufficient time to allow APT to seek patent protection of the invention. For multicenter studies, the first publication or disclosure shall be a complete, joint multicenter publication or disclosure. This statement does not give APT any editorial rights over the content of a publication or disclosure, other than to restrict the disclosure of APT's confidential information. If a written contract for the conduct of the study which includes publication provisions inconsistent with this statement is executed, then that contract's publication provisions shall apply rather than this statement.

15. Investigator Reports

Study investigator(s) will provide monthly reports (verbal or written) to APT on the status of the study, including any concerns related to complying with study procedures, and any other matter which could potentially affect the successful execution and/or integrity of the study. Investigator reports will also include all related or non-related device malfunctions/deficiencies, any withdrawal of IRB approval and final IRB report (upon termination or completion of the study).

16. Termination of Study and Study Site Participation

The sponsor may terminate the study at any time. The sponsor reserves the right to terminate the study site participation and remove appropriate study materials at any time. Specific instances that may preciinvestigatortate such terminations include but are not limited to the following:

- Failure of the Investigator to enroll patients into the study at an acceptable rate
- Failure of the Investigator to comply with pertinent regulations of appropriate regulatory authorities
- Insufficient adherence to protocol requirements
- Insufficient adherence to GCP
- Submission of knowingly false information from the research facility to the sponsor, study monitor, or appropriate regulatory authority
- Demonstration of misconduct

The site Investigator may also discontinue study participation with suitable written notice to APT.

Refer to Section 5.5.

17. Regulatory Considerations

This study will be executed with the controls appropriate for non-significant risk studies as defined in FDA GCP guidelines.

18. Appendices

18.1 Informed Consent Form

RESEARCH SUBJECT INFORMED CONSENT FORM

PROTOCOL TITLE: Mitigation of Major Hip Injury due to fall in an At-Risk, Older Adult Population with a Wearable Smart belt

PROTOCOL ID: Tango® Study

SPONSOR: Active Protective Technologies, Inc

Facility:

PRINCIPAL INVESTIGATOR:

INVESTIGATOR CENTER & SATELLITE SITES:

CO-INVESTIGTOR(S):

CO-ADVISOR:

STUDY COORDINATOR:

STUDY-RELATED EMERGENCY PHONE NUMBER:

Introduction

You are being asked to take part in this research study to see if using the Tango Belt, a wearable smart belt, is effective in mitigating major hip injuries due to a fall. This clinical investigation will study the use of the Tango Belt in up to 20 senior care settings as an adjunctive intervention to standard-of-care (SOC) to mitigate injuries related to falls in an injury older adult population at-risk for fall injury.

This document is an Informed Consent Form and has important information about the reason for the study, what you will do if you choose to be in the study, and the way we would like to use information about you and your health. This form will give you detailed information about the study, so please ask your Study Doctor or someone from the Study Center Staff to explain any words or information that you do not clearly understand.

The Tango Belt, worn around the waist, can detect a serious hip-impacting fall-in-progress using built-in sensors and deploy an airbag to protect the hips from impact forces. When connected to Wi-Fi, the Tango Belt can send automated fall and impact alerts to caregivers. The airbags in the Tango Belt will only deploy when sensors indicate the fall motion is one in which a serious hip injury may occur. The Tango Belt will be sized and fit to you for comfortable wearing around the waist at all times with removal for charging at least 2 times a week and removal for showering. The Tango Belt is intended to be worn for at least 6 months during the trial.

Before you decide if you want to take part in this study, it is important for you to understand:

- why the research is being done,
- how your information will be used,
- what the study will involve, and
- the possible benefits, risks and discomforts for you when you take part.

Please take your time to make your decision about taking part in this research study. You may discuss your decision with your friends and family. You can also discuss it with your health care team. If you have any questions, you can ask your study doctor for more explanation.
After you are sure that you clearly understand the risks and benefits of taking part in this study and if you choose to take part in the study, you will be asked to sign the Informed Consent Form. You should not sign the Informed Consent Form if you have any questions that have not been answered. By signing the Informed Consent Form, you are confirming that the study has been explained to you, and that you give your permission to be a part of the study. You will be given a copy of this Patient Information Sheet and the signed and dated Informed Consent Form.

Why you are being invited to take part in a research study?

You are being invited to participate in this clinical study because you are at risk of falls and major injuries from falls. Participating in this study may reduce/avoid a major hip injury due to a fall and need for urgent medical treatment.

Who can you talk to about this research study?

If you have questions, concerns, or complaints, or think the research has hurt you, you can talk to the study team, which includes a physician and a researcher, or you may call Active Protective Technologies, Inc at 215-399-9763.

This research has been reviewed and approved by _____Institutional Review Board (IRB). An IRB reviews research projects so that steps are taken to protect the rights and welfare of human subjects taking part in research. You may talk to them at ( )___-_____ for any of the following:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research subject.
- You want to get information or provide input about this research.

Why is this study being done? Why are we doing this research?

Every year in the United States there are approximately 3 million fall-related emergency room visits for geriatric adults. Of the 3 million emergency room visits, approximately 300,000 of those lead to hospital admissions due to hip fractures . This coincides with the Centers for Disease Control (CDC) analysis that 1 out of 4 adults over the age of 65 (i.e., geriatric) will fall each year and those falls may occur more than once in a year . As a result of these high numbers, falls are the leading cause of injury-related deaths among the geriatric population and cost over $50 billion in total medical costs. Despite efforts made throughout healthcare settings in integration of standard of care for fall injury risk, the number of older adults experiencing falls and fall related injuries has increased or remained unchanged since 2012. Furthermore, fall death rates in the U.S. increased 30% from 2007 to 2026 for older adults. As such, there is a growing need for alternative care methods for geriatric individuals who are at high risk of fall as the existing standard of care is not effective at reducing the overall rate of fall injuries. As a solution to this problem, APT Technologies has developed the Tango Belt, a wearable belt designed to fill the need for protecting the hips during a serious, hip-impacting fall.

The Tango Belt device has amassed over 80,000 hours of wear time on real older adult users in the past several years and is currently being used in senior care living and independent living residences throughout the US. The belt has been shown to be safe in all real-world use to date, and no serious or life-threatening events related to the device have been reported.

How long will I be in the study? How long will the research last?

You will be in the study for a minimum of 6 months. This study consists of the following 4 Visits:

- Baseline/Screening Visit (Day 1):
  - Introduction to the device, measurement for the correct size and provision of the Tango Belt with sizing adjustments provided by care team.
  - A 7-question survey on balance confidence may be taken if appropriate
  - Any needed data will be taken from your electronic health record (EHR)
- Follow up Visit (14 days (+/- 2 days)
  - Data on wear compliance obtained from Tango Belt Companion App
  - If compliance is 64% or >, subject will continue with study enrollment
  - If compliance is < 64%, subject is excused from study enrollment
- Follow Up Visits (90 days (+/- 10 days) and Unscheduled
  - Data obtained from the EHR
  - 7-question balance confidence survey repeated if appropriate
- Completion Visit (180 days (+/-30 days):
  - Discharge use of the device
  - Data obtained from the EHR
  - 7-question balance confidence survey repeated if appropriate

How many people will take part in the study?

Between 200 to 400 people will be included in treatment part of the study.

What will happen if I take part in this research study? What happens if I say yes, I want to be in this research?

Study Procedures:

This is what will happen if you take place in the study:

<u>Visit 1 - Baseline/Screening Visit (+/-14 days) – location of residence</u>

- A Medical and fall history (since age 50) will be collected via medical record review, this review will include:
  - Fall and fall injury history
  - Current fall risk factors and mitigation care plan as determined by the Stopping Elderly Accidents, Deaths & Injury (STEADI) algorithm
  - Current mental status as noted by most recent Brief Interview for Mental Status (BIMS) score
  - Current mobility level
- A waist measurement will be done with adjusting of size for comfort;
- A Tango Belt will be prescribed to be worn up to 24 hours/day with removal for charging, showers and upon request;

• You will be asked to complete a questionnaire if appropriate; Falls Efficacy Scale – International (short version) FES-I.

Visit 2 Run-in period (14 days +/- 2):

- Adherence to wearing of the device up to 24 hours/day with removal for charging and showers will be assessed for compliance to use of the device for decision of continuation in the study. Adherence to the compliance to wear of the Tango Belt is defined as at minimum 64% (at least 1 hour a day for 9 days out of 14). If the subject is not utilizing the device for at least the minimum amount of time, they withdrawn from the study at this time and the Tango Belt will be returned. If they demonstrate adherence to compliance, they will continue with enrollment in the study.

Visit 3 - Follow Up Visits (90-day +/- 10 day) and Unscheduled Visits – location of residence:

Midway through the study run time, approximately 3 months:

• Adherence to wearing of the device up to 24 hours/day with removal for charging and showers.

• Your medical record will be reviewed for obtaining the updated status on the following:

  - Any adverse events or unexpected medical problems you may have experienced since baseline
  - Any fall events that you may have experienced since baseline
  - Current level of mobility
  - Any changes to your fall mitigation plan of care since baseline

- Review of medical record for any changes of status;
  - You will be asked to complete a current FES-I short version (if appropriate)
  - Your smart belt will be assessed for any device deficiencies.

End of Study (180 Days +/- 30 days) – location of residence

At the end of the study run time, approximately 6 months:

- Adherence to wearing the device of the device up to 24 hours/day with removal for charging and showers.
- Your medical record will be reviewed for obtaining the updated status on the following:
  - Any adverse events or unexpected medical problems you may have experienced since baseline
  - Any fall events that you may have experienced since baseline
  - Current level of mobility
  - Any changes to your fall mitigation plan of care since baseline
- Review of medical record for any changes of status;
- You will be asked to complete a current FES-I short version (if appropriate)
- Your smart belt will be assessed for any device deficiencies. The Tango Belt will be collected for return to the sponsor.

What are my responsibilities if I take part in this research? What are my rights if I take part in this study?

Your participation in the study is voluntary. You may choose either to take part or not to take part in the study. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your regular benefits. Leaving the study will not affect your medical care. You can still get your medical care from our institution.

What happens if I do not want to be in this research? What other choices do I have if I do not take part in this study?

Our study team will refer you back to your Primary Care Physician to discuss alternative treatment options.

Can I stop being in the study? What happens if I say yes, but I change my mind later?

You can decide to stop at any time. You can tell a study team member if you are thinking about stopping or decide to stop. If you choose to discontinue the study at any time, the Study Evaluator will contact you.

What side effects or risks can I expect from being in the study? Is there any way being in this study could be bad for me?

Based on studies previously performed, the risks that could potentially occur from participation in this investigation are:

- Discomfort and moderate, reversible bruising and/or skin irritation underneath the belt;
- Soreness due to sustained wear caused by the weight of the belt;
- Pinching of fingers or belly skin which may be caught in-between buckle halves when putting on the belt;
- Falls and *fall-related* injuries may still occur, including injuries such as abrasion, contusion, concussion, whiplash, and/or fracture.

What are the reproductive risks?

This study is intended for individuals 65 years and older and thus has no reproductive risks.

Are there benefits to taking part in the study? Will being in this study help me in any way?

The benefits associated with the use of Tango Belt are the possible avoidance of incurring a major hip injury in the event of a serious hip-impacting fall while wearing the Tango Belt. The knowledge of the offered protection and alerting capabilities of the Tango Belt when worn may also improve the wearer's confidence and encourage mobility in the senior residence setting.

What are the costs of taking part in this study? Do I have to pay for anything while I am on this study?
There is no cost to you for being in the study or for receiving treatment. The use of the Tango Belt will be complimentary while being a participant in the study.

How is this study funded? Is anyone receiving compensation?
This study is funded by ActiveProtective Technologies, Inc. The sponsor will be providing all materials to the sites including the Tango Belts. Any time that the clinical team members including Principal Investigator, Site Investigators, and any Research Assistants of the clinical site or otherwise spend performing study activities will be reimbursed to them by Active Protective Technologies, Inc.

What happens to the information we collect? Will my medical information be kept private?
Protected Health Information is any health information or information in your medical record that can be used to identify you such as your name, address, telephone number, or identification numbers, or any other direct personal identifier.

During the study, the Study Doctor and Study Center staff will collect and record information about you and your health status. This may include your birthdate, sex, race, ethnic origins, medial history, and data obtained from study related visit assessments. The Tango Belt will also automatically collect data on usage, alerts, and motions while worn. This information along with results from study participation and follow-up is considered your "Study Data".

Your Study Data will not be identified on any study document by name, address, telephone number, or identification numbers, or any other direct personal identifier. Instead, you will be identified by an assigned code which will replace your Protected Health Information so that your Study Data cannot be easily linked to directly to you. The Study Doctor will keep the list that matches the assigned code to your name. That list will not be provided to the Sponsor, and only the Study Doctor and study center staff will have access to the list.

Your coded Study Data may be kept and shared by the Sponsor indefinitely or as long as required for business purposes related to the research study, applicable law, regulation, statute, or Sponsor's policy.

The Study Doctor also may share your coded Study Data with all applicable regulatory agencies in this country and in other countries where research studies involving Tango ® Belt are taking place. Information shared with these entities has the potential to be shared further and then may no longer be protected.

We will do our best to make sure that the personal information in your medical record will be kept private. Your data will be kept on a secure, HIPAA compliant server. However, we cannot guarantee total privacy. Your personal information may be given out if required by law. If information from this

study is published or presented at scientific meetings, or for the Sponsor to obtain FDA approval, your name and other personal information will not be used.

By signing this consent form, you grant permission for personal data and medical information about you obtained during this study (your Study Data) to be made available to authorized or approved representatives of the regulatory authorities and other government agencies. You also grant permission for your personal data to be made available to the Sponsor auditors, the study monitor, other study personnel, and ethics committees.

Organizations that may look at and/or copy your medical records for research, quality assurance, and data analysis include:

- Holy Redeemer Health System Institutional Review Board (IRB), a group of people who review the research study to protect your rights;
- Government agencies, including the Food and Drug Administration (FDA) and the Office for Human Research Protections (OHRP). These agencies may review the research to see that it is being done safely and correctly.

You have the right to withdraw your permission to use your Study Data at any time. In that case, you may be asked to communicate this in writing to your Study Doctor. In this case, you will be removed from the study.

You may decide not to give permission for collection of your Study Data in this study. In that case, you will not be able to participate. This is because the Study Doctor and study center staff would not be able to collect the information needed to evaluate the smart belt device.

If you withdraw your permission after you have started in the study, the Study Doctor and study center staff will stop collecting your Study Data. Although new information will no longer be collected, the information already collected will be kept and used as explained in this Informed Consent Form. Additional information will be gathered if you have a side effect related to the study.

Can I be removed from the research without my OK?
Yes, the study or your participation in the study may be stopped without your consent. Some reasons the Sponsor may stop the study or put the study on hold include:

- The smart belt has been shown unlikely to work
- Decisions made in the business or commercial interests of the Sponsor
- Decisions made by the regulatory authorities or ethics committees

Reasons the Study Doctor can stop your participation include:

- If you do not qualify for inclusion in the Treatment Period of the study, you are discontinued at that point.
- If you are unable to maintain the treatment schedule and utilize the device for the minimum of 6 months, or
- If you developed a medical condition that requires an intervention interfering with the use of the Tango Belt.

What else do I need to know? Where can I get more information?

The Sponsor and responsible party for reporting results of the study is ActiveProtective Technologies, Inc. Results from this research study will be available after the study research study is completed. Should you wish to see the results, please ask your Study Doctor. You will not be identified in any report or publication.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this website at any time.[1]

We will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

You have the right to look at your medical records during this research study. To request review of your medical records, Contact the Study Coordinator.

Informed Consent

Signatures

I have been given a copy of all 58 pages of this form. I have read the consent form, or it has been read to me. This information was explained to me and my questions were answered.

I have read (or someone has read to me) the information in the Informed consent in a language that I understand well, and the research study has been explained to me. I have been given ample time to ask questions and have been told whom to contact if I have more questions. All of my questions about the study and my participation in it have been answered to my satisfaction.

I voluntarily agree to be in the research study described in the Informed Consent Form and I understand that a copy of the complete Informed Consent Form will be provided to me after I sign it.

I authorize the use and disclosure of my Study Data as described in the Informed Consent Form.

I am free to stop taking part in this study at any time for any reason and my choice to stop taking part will not affect my future medical care. I agree to follow the Study Doctor's instructions and will tell the doctor as soon as possible if I have any changes in my health. By signing this document, I am not giving up any of my legal rights.

Name of Patient (please print) _____

Patient Signature_____ Date_____ Time_____

Is a Legally Authorized Representative (LAR) signing this consent? *Yes No*

Name of Patient (please print) _____

Name of Legally Authorized Representative (please print)_____

Legally Authorized Representative Signature _____

Date_____ Time_____

Was verbal consent offered by LAR pending above signature? *Yes No If Yes,*

Telephone number where LAR was reached: _____

I hereby declare that I have informed the above patient verbally and in writing about the nature, significance, implications, and risks of the study named above. The patient has been asked if any questions have arisen regarding these procedures, and these questions have been answered. A signed and dated second original of this Patient Information Sheet and Informed Consent Form have been provided to the patient.

Name of Person Obtaining Consent (please print) _____

Person Obtaining Consent

Signature_____Date_____ Time_____

Is the Impartial Witness Statement applicable? *Yes* *No*

If this document is read to the patient because the patient is unable to read the form, an impartial witness not affiliated with the research or Study Doctor must be present for the consent and sign the following statement. An impartial witness is a person, who is independent of the study, who cannot be unfairly influenced by people involved with the study, who attends the informed consent process if the

patient cannot read, and who reads the informed consent and any other written information provided to the patient.

I confirm that the information in this document and any other written information was accurately explained to, and apparently understood by, the patient. The patient freely consented to be in the research study.

Name of Witness and Relationship (please print) _____

Witness signature_____ Date_____ Time_____

18.2 Study Questionnaires

Short FES-I

Now we would like to ask some questions about how concerned you are about the possibility of falling. Please reply thinking about how you usually do the activity. If you currently don't do the activity, please answer to show whether you think you would be concerned about falling IF you did the activity. For each of the following activities, please tick the box which is closest to your own opinion to show how concerned you are that you might fall if you did this activity.

		Not at all concerned 1	*Somewhat concerned 2*	*Fairly concerned 3*	*Very concerned 4*
1	Getting dressed or undressed	*1* ☐	*2* ☐	*3* ☐	*4* ☐
2	Taking a bath or shower	*1* ☐	*2* ☐	*3* ☐	*4* ☐
3	Getting in or out of a chair	*1* ☐	*2* ☐	*3* ☐	*4* ☐
4	Going up or down stairs	*1* ☐	*2* ☐	*3* ☐	*4* ☐
5	Reaching for something above your head or on the ground	*1* ☐	*2* ☐	*3* ☐	*4* ☐
6	Walking up or down a slope	*1* ☐	*2* ☐	*3* ☐	*4* ☐
7	Going out to a social event (e.g. religious service, family gathering or club meeting)	*1* ☐	*2* ☐	*3* ☐	*4* ☐

Brief Interview for Mental Status (BIMS)

Repetition of Three Words

Ask resident: *"I am going to say three words for you to remember. Please repeat the words after I have said all three. The words are:* ***sock, blue*** *and* ***bed****. Now tell me the three words."*

Number of words repeated after first attempt:

☐ **0. None** ☐ **1. One** ☐ **2. Two** ☐ **3. Three**

After the resident's first attempt, repeat the words using cues *("sock, something to wear; blue, a color; bed, a piece of furniture")*. You may repeat the words up to two more times.

Temporal Orientation (orientation to month, year and day)

Ask resident: *"Please tell me what year it is right now."*

Able to report correct year

☐ **0. Missed by > 5 years**, or no answer
☐ **1. Missed by 2-5 years**
☐ **2. Missed by 1 year**
☐ **3. Correct**

Ask resident: *"What month are we in right now?"*

Able to report correct month

☐ **0. Missed by > 1 month**, or no answer
☐ **1. Missed by 6 days to one month**
☐ **2. Accurate within 5 days**

Ask resident: *"What day of the week is today?"*

Able to report correct day of the week

☐ **0. Incorrect**, or no answer
☐ **1. Correct**

Recall

Ask resident: *"Let's go back to the earlier question. What were the three words that I asked you to repeat?"*
If unable to remember a word, give cue *("something to wear," "a color," "a piece of furniture")* for that word.

Able to recall "sock"	☐ **0. No - could not recall**	☐ **1. Yes, after cueing ("something to wear")**	☐ **2. Yes, no cue required**
Able to recall "blue"	☐ **0. No - could not recall**	☐ **1. Yes, after cueing ("a color")**	☐ **2. Yes, no cue required**
Able to recall "bed"	☐ **0. No - could not recall**	☐ **1. Yes, after cueing ("a piece of furniture")**	☐ **2. Yes, no cue required**

Summary Score

Add scores for each question and fill in total score (00-15).
Enter 99 if the resident was unable to complete the interview. _____

18.3 Literary references

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Statistical Analysis Plan

For

[COP-0001] Smart Belt Fall Injury Mitigation Study

Active Protective Technologies, Inc

Mitigation of Major Hip Injury due to fall in an At-Risk, Older Adult Population with a Wearable Smart Belt

COP-0001

Version 2.0, dated 07 DEC 2023

SIGNATURE PAGE

The undersigned hereby jointly declare that they have reviewed the Statistical Analysis Plan and agree to its form and content.

Author			
Name	**Function**	**Signature**	**Date**
Patrick O'Connor	**Biostatistician**	DocuSigned by: Patrick O'Connor Signer Name: Patrick O'Connor Signing Reason: I am the author of this document Signing Time: 07-Dec-2023 | 11:55:11 AM EST E07A87B0206447B184581376106D8E0E	07-Dec-2023 | 11:55:18 AM EST

Approval by			
Name	**Function**	**Signature**	Date
Rebecca Tarbert	**Director, Clinical Operations**	DocuSigned by: Signer Name: Rebecca Tarbert Signing Reason: I approve this document Signing Time: 07-Dec-2023 | 9:10:20 AM PST BEAC2FEFD04948B2B3133D04E67829FB	07-Dec-2023 | 9:11:15 AM PST
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DOCUMENT HISTORY

Revision Date	Author	Version	Reason for Change
NA	Patrick O'Connor	1.0	NA – Initial Version
07DEC2023	Patrick O'Connor	2.0	Removed 90-day as a timepoint for the primary and secondary endpoints

1 ABBREVIATIONS

Abbreviation	Definition
AE	Adverse Event
CRF	Case Report Forms
CSR	Clinical Study Report
ED	Emergency Department
EMR	Electronic Medical Record
FDA	United States Food and Drug Administration
GSD	Group Sequential Design
ITT	Intent-To-Treat Population
IPTW	Inverse Probability of Treatment Weighted
NNM	Nearest Neighbor Matching
PP	Per-Protocol Population
PS	Propensity Score
PSM	Propensity Score Matching
PT	Preferred Term
SAE	Serious Adverse Event
SAP	Statistical Analysis Plan
SOC	System Organ Class
SSRE	Sample Size Re-estimation

2 SUMMARY

TITLE	Mitigation of Major Hip Injury due to fall in an At-Risk, Older Adult Population with a Wearable Smart Belt
PREFACE	This Statistical Analysis Plan (SAP) describes the planned analysis and reporting for Active Protective Technologies protocol COP-0001 (Mitigation of Major Hip Injury due to fall in an At-Risk, Older Adult Population with a Wearable Smart Belt). This study is being completed to assess the safety and efficacy of Tango® Belt for the treatment of the Tango Belt as an adjunctive intervention to the standard-of-care (SOC) to mitigate major hip injuries due to falls in an older adult population (65+ years of age) at-risk for fall injury. The following documents were reviewed in preparation of this SAP: • Clinical Research Protocol COP-0001 v2.0, issued 18APR2022 • Case report forms (CRFs) Casebook Rev 1.0, annotated Rev.01
PURPOSE	The purpose of this SAP is to outline the planned analyses in support of the Clinical Study Report (CSR) for protocol COP-0001. Exploratory analyses not necessarily identified in this SAP may be performed to support the clinical development program. Any post-hoc, or unplanned, analyses not identified in this SAP will be clearly identified in the respective CSR.
STUDY OBJECTIVES	**Primary Objective:** To assess the performance of the Tango® Belt to mitigate fall-related major hip injuries in an at-risk-of-fall-injury adult population as compared to the standard of care (SOC) only. **Secondary Objectives:** To assess the performance of the Tango Belt to mitigate falls resulting in: (1) hip fractures, (2) emergency department (ED) visits or (3) hospitalizations.
STUDY DESIGN	Multi-center, comparative, non-significant risk adaptive study with historical controls. After providing informed consent and being screened for eligibility, intervention subjects will be prescribed and provided an appropriately sized Tango Belt. The subject must demonstrate a minimum of 64% adherence to the use of the Tango Belt within 14 days of initiation to fully enroll in the study. Upon demonstration of at least minimum adherence, the subject will be provided the Tango Belt to wear continuously for at least 6 months, except during bathing, device charging, and as deemed by clinical staff. The study will Investigate the safety and effectiveness of the Tango Belt with the primary and secondary endpoints being taken every 3 months and at the end of the study run time from the electronic medical record. Additionally, ancillary endpoints on adverse events and device performance will be gathered.
ENDPOINTS	**Primary:**

	The study's **primary effectiveness endpoint** is the proportion of major hip injuries due to fall in the subjects receiving SOC as compared to subjects receiving SOC plus the Tango Belt. There is no primary safety endpoint for this study. This is a non-significant risk study. Safety of the device will be determined by analysis of adverse events as an ancillary endpoint. **Secondary:** The study's **secondary endpoints** include the proportion of each of the following: • Hip fractures due to fall in the subjects receiving SOC as compared to subjects receiving SOC plus the Tango Belt. • Emergency Department (ED) visits due to fall in the subjects receiving SOC as compared to subjects receiving SOC plus the Tango Belt. • Hospitalizations due to fall in the subjects receiving SOC as compared to subjects receiving SOC plus the Tango Belt. **Ancillary:** Ancillary endpoints will include: • Adverse events • Major injuries due to fall • Fall occurrence • Device wear adherence • Device fall alerts • Device discrimination of serious hip-impacting vs. non-serious hip and non-hip impacting falls • Airbag deployment • Falls Efficacy Scale - International (FES-I) short version
INTERIM ANALYSES	The study will incorporate a group sequential design (GSD) in which an interim analysis will be performed to detect an 80% protective effect of the Tango Belt at 80% power at a planned interim analysis. If a significant difference is found between the prospective Tango Belt subjects and historical controls at the interim analysis, the study will be completed early. If not, enrollment will continue until a final sample size is reached to detect a 60% protective effect of the Tango belt at 80% power and a 5% total level of significance. It was assumed subjects were followed for an average of 6 months, an annual fall-with-major-hip-injury rate of 15%, and sufficient historical control subjects

	to allow 1:2 allocation of subjects to treatment and control. This would require 94 subjects in the prospective Tango Belt group and 188 subjects in the historical control group at the interim analysis. Assuming a 30% attrition rate due to the fragile nature of this population, the samples sizes would increase to 134 and 268 in the prospective Tango Belt group and the historical control group, respectively. At the end of the study (should the higher effectiveness target not be achieved at interim analysis), 188 total subjects would be required in the prospective Tango Belt group and 376 subjects would be in the historical control group. Accounting for attrition, 268 and 536 in the prospective Tango Belt group and the historical control group, respectively.
FINAL ANALYSES	All final planned analyses identified in this SAP will be completed after the last subject has completed the End of Study visit and data entry has been finalized for all subjects used for analysis (including historical control subjects).

3 Study Objectives and Endpoints

3.1 Study Objective

The current comparative clinical study is intended to establish the safety and effectiveness of the Tango Belt as an adjunctive intervention to the standard-of-care (SOC) to mitigate major hip injuries due to falls in an older adult population at-risk for fall injury.

3.1.1 Primary Objective

To assess the performance of the Tango Belt to mitigate fall-related major hip injuries in an adult population at-risk of fall injury as compared SOC only.

3.1.2 Secondary Objective

To assess the performance of the Tango Belt to mitigate falls resulting in: (1) hip fractures, (2) emergency department (ED) visits or (3) hospitalizations.

3.2 Study Endpoints

3.2.1 Primary Endpoint

The study's **primary effectiveness endpoint** is the proportion of major hip injuries due to fall in the subjects receiving SOC as compared to subjects receiving SOC plus the Tango Belt, as reported between enrollment and the 180-day visit.

There is no primary safety endpoint for this study. Safety of the device will be determined by analysis of adverse events as an ancillary endpoint.

3.2.2 Secondary Endpoints

The study's secondary endpoints include the proportion of each of the following:

- Hip fractures due to fall in the subjects receiving SOC as compared to subjects receiving SOC plus the Tango Belt.
- Emergency Department (ED) visits due to fall in the subjects receiving SOC as compared to subjects receiving SOC plus the Tango Belt.
- Hospitalizations due to fall in the subjects receiving SOC as compared to subjects receiving SOC plus the Tango Belt.

The secondary endpoints will be assessed using data reported between enrollment and the 180-day visit.

3.2.3 Ancillary Endpoints

Ancillary endpoints will include:

- Adverse events
- Major injuries due to fall
- Fall occurrence
- Device wear adherence
- Device fall alerts
- Device discrimination of serious hip-impacting vs. non-serious hip and non-hip impacting falls
- Airbag deployment
- Falls Efficacy Scale - International (FES-I) short version

4 Sample Size

It is estimated that the sample size will include up to 268 subjects in the intervention group and up to 536 subjects in the historical control group. This estimated sample size includes the minimum sample size required to assess the primary endpoint with an additional 30% increase to account for possible subject attrition.

The sample size for the primary hypothesis will be calculated with 80% power. The annual rate of falls with major hip injury has been estimated between 6% and 10% in higher-risk populations within long-term care facilities. Since the fall rate is not exactly known in the study population, the fall rate observed in the historical control group, a nuisance parameter, will be used for sample size calculations. After roughly 70% of subjects were enrolled into the historical control group, the proportion of subjects who experienced a major hip injury due to a fall was calculated to be 15% and this rate was used in the sample size calculation.

The following steps were used to calculate the sample size (for further details, see section 10.1 of the Protocol):

1. Test the historical control time periods to determine if all the time periods can be used, depending on if any time periods differ in fall rate

2. From the remaining historical control data, the fall rate was calculated and the total sample size available for the historical control group
3. The sample sizes for the historical controls and the prospective Tango Belt arm at the interim analysis was calculated.
4. The sample size for the prospective Tango Belt arm at the final analysis was calculated using the total sample of historical controls.

This sample size determination was made based on the following specifications:

Primary Effectiveness Endpoint Assumptions:
The following assumptions were made for estimating sample size for the primary effectiveness endpoint:

1. Alpha of 0.025 (one-sided)
2. 80% power
3. Groups are independent

Based on the above assumptions, the minimum sample required for the intervention group for evaluation of effectiveness (unadjusted) is 94 subjects. At least 134 subjects will be enrolled to the intervention group to account for subject attrition and missing data (estimated to be 30%).

4.1 Interim Analyses

The study will incorporate a group sequential design (GSD) in which an interim analysis will be performed to detect an 80% protective effect of the Tango Belt at 80% power. If a significant difference is found between the prospective Tango Belt subjects and historical controls at the interim analysis, the study will be stopped, and the Tango Belt deemed superior to SOC alone. If not, sample size re-estimation will be completed, and enrollment will continue until a final sample size is reached to detect a 60% protective effect of the Tango Belt at 80% power and a 5% total level of significance.

Following the steps from section 4, we assumed subjects were followed for an average of 6 months, an annual fall-with-major-hip-injury rate of 15%, and sufficient historical control subjects to allow 1:2 allocation of subjects to treatment and control. This would require 134 subjects in the prospective Tango Belt group and 268 subjects in the historical control group at the interim analysis using the Pocock alpha-spending function as well as accounting for 30% attrition. At the end of the study (should the higher effectiveness target not be achieved at interim analysis), 268 total subjects would be required in the prospective Tango Belt group and 536 subjects would be in the historical control group.

4.1.1 Sample Size Re-Estimation

At the time of interim analysis, if the study is not stopped early for effectiveness, then sample size re-estimation (SSRE) will be performed to calculate the final analysis sample size. The SSRE will be calculated the same way as was performed prior to the trial with the addition of a propensity score matching rate. This rate will account for the percentage of subjects that were in the Tango Belt treatment group but were not able to match adequately with any subjects in the historical control

group. The annual fall-with-major-hip-injury rate will be updated using data from the 134 subjects in the Tango Belt treatment group as well.

4.2 Final Analyses and Reporting

All final, planned analyses identified in the protocol and in this SAP will be performed only after the last subject has completed the End of Study visit or if the stopping criterion is met at the interim analysis. Key statistics and study results will be made available following database lock. Any post-hoc, exploratory (ancillary) analyses completed to support planned study analyses, which were not identified in this SAP, will be documented, and reported as necessary. Any results from these unplanned analyses will also be clearly identified as post-hoc analyses.

The Final Study Report is to be completed within 1 calendar month following the locking of the clinical database.

5 Analysis Populations

5.1 Historical Control Population

The Historical Control Population (HC) for this study includes retrospective subjects that meet all inclusion and exclusion criteria except for the waist circumference and need for consent. Eligible subjects' electronic health records will be mined for the baseline, midpoint, and final study metrics.

The investigator or a designee will retrospectively review the site's electronic medical record (EMR) database to determine long-term care patient population's eligibility for meeting the study inclusion criteria. The subjects in the clinical site census at the time frame 6 months prior to the IRB approval date will be screened for eligibility for study inclusion.

If there is an insufficient number of eligible subjects to meet the control group target (defined as 2 times the expected number of intervention group subjects to be enrolled from the site) at 6 months prior to the intervention group start date, the EMR database screen will extend retrospectively in 6 month increments until the control group target is reached.

5.2 Intervention Population

Propensity score matching (described in section 7.1) will be used to match each treatment group subject with two subjects from the historical control group. If a subject from the treatment group is not included in any of the analysis populations described below, the historical control subjects they matched to using propensity scores will also not be included in any analysis comparing groups.

5.2.1 Intent to Treat Population (ITT)

The ITT population will consist of all intervention population subjects who demonstrate at least 64% adherence to use of device during run-in period (defined as wearing device for at least 1 hour per day for at least 9 of 14 days) and the propensity matched historical controls.

5.2.2 Per-Protocol Population (PP)

The per-protocol population (PP) will include all ITT subjects who additionally meet all study eligibility criteria, have available study data for the study endpoint and do not have a major protocol violation that affects primary effectiveness and the propensity matched historical controls. Major protocol violations are described in section 6.4.

5.2.3 Adherence Population

The adherence population includes all subjects in the PP population excluding those subjects who were not actually wearing Tango Belt when the primary effectiveness endpoint was experienced.

5.2.4 Safety Population

The safety population includes all subjects who were assigned a Tango Belt and attempted the run-in period.

6 General Issues for Statistical Analysis

Descriptive statistics for continuous variables will be summarized using descriptive statistics (number of subjects, mean, median, quartiles, standard deviation [SD], minimum, and maximum). Categorical variables will be summarized using frequencies and percentages of subjects in each category. All results will be presented by treatment and appropriate subject populations.

Statistical results such as confidence intervals and descriptive statistics for intervention primary effectiveness outcomes will be presented by site and in aggregate. Likewise, incidence of adverse events will be presented by site and in aggregate.

P-values will be one-sided and considered significant at the 0.025 level, or two-sided and considered significant at the 0.05 level of significance.

6.1 Analysis Software

Analysis data sets, statistical analyses and associated output generated by Avania will be generated using SAS® Software version 9.4 or later and/or R version 4.2.0 or later.

6.2 Disposition of Subjects and Withdrawals

6.2.1 Intervention Population

The number and percent of subjects in each analysis population will be presented, with percentages based on the ITT population for the intervention group. The frequency and percent of subjects who

completed each scheduled assessment will be presented in a table. The number and percentage of ITT subjects prematurely withdrawing will be presented overall and by reason of discontinuation.

6.2.2 Historical Control Population

Due to the retrospective nature of the control group, only observed data will be used in analyses. Control subjects missing information will not be used in the Propensity Score (PS) analysis as there will be no imputation of missing data for the HC population.

6.3 Methods for Withdrawals and Missing Data

All practical monitoring and follow-up steps will be taken to ensure complete and accurate data collection. Since endpoints are assessed at the 180-day visit, it is anticipated that there will be approximately 30% attrition. Given the disproportionately high rate of death and other loss-to-follow up reasons within this population, multiple imputation approaches will be carried out for missing primary endpoint data on the ITT population. The primary effectiveness analysis will be performed on data that has the primary outcome multiply imputed.

6.3.1 Multiple Imputation

Prior to propensity score matching, the intervention group may have missing information on the primary endpoint (i.e. major hip injury due to a fall), primarily due to premature withdrawal from the study.

At the time of the final analysis, if more than 20% of data is missing for the primary endpoint reported at the 180-day visit, then the primary endpoint will be multiply imputed and the analysis from section 7.2 will be repeated using both observed and multiply imputed data.

For the multiple imputation, a total of 50 imputed datasets will be calculated (Graham et al.). Fully conditional specification (FCS) logistic regression will be used to impute missing major hip injury due to a fall status (primary endpoint) using the baseline covariates of age, sex, ethnicity, race, mobility level (Independent, Limited Assist, Supervision, Extensive Assist, or Total Dependence), BIMS Score, and FES-I score.

The analysis for the primary endpoint will be carried out utilizing 50 datasets and then results will be combined using PROC MIANALYZE in SAS to obtain one overall test of significance.

6.4 Protocol Deviations

Subjects with such non-compliance will be determined prior to database lock. Major protocol deviations will be summarized in the CSR. This summary will include the number and percent of subjects (overall and by site) with each deviation type.

Major deviations in this study include, but not limited to the following:

- Inadequate or delinquent informed consent
- Inclusion/exclusion criteria not met
- Unreported serious adverse events or fall event

- Materially inadequate record keeping
- Intentional deviation from protocol, Good Clinical Practice, or regulations by study personnel

6.5 Multiple Comparisons and Multiplicity

There is one primary effectiveness endpoint, and it will be compared between treatment groups at a one-sided 0.025 level of significance, adjusting for propensity score (PS). There are three secondary endpoints that will also be tested using propensity score adjusted test of proportions, and the type I error rate will be adjusted for multiple testing.

To control type I error, the three secondary endpoints will be tested in a hierarchical, gatekeeping manner in the order specified below, each at a one-sided 0.025 level of significance, and only after the primary study effectiveness endpoint has been achieved in favor of the test treatment. Further, each secondary endpoint numbered 2 through 3 below will be tested for significance between treatments only if the previous secondary endpoint in the list has been shown to be significantly beneficial for the test treatment.

This hierarchical closed test procedure is used to account for multiple testing with the goal of controlling the "maximum overall Type I error rate", which is the maximum probability that has been prespecified that one or more null hypotheses are rejected incorrectly, at a one-sided 0.025 level of significance.

1. The proportion of Hip fractures due to fall in the subjects receiving SOC as compared to subjects receiving SOC plus the Tango Belt.
2. The proportion of ED visits due to fall in the subjects receiving SOC as compared to subjects receiving SOC plus the Tango Belt.
3. The proportion of Hospitalizations due to fall in the subjects receiving SOC as compared to subjects receiving SOC plus the Tango Belt.

There will be no adjustment for multiple comparisons across any remaining effectiveness endpoints, nor will there be adjustment for multiple comparisons across ancillary endpoints.

6.6 Demographics

Subject demographics and baseline characteristics for the Safety, ITT, and HC populations will be summarized in a table. Sex, race, ethnicity, and mobility level will be summarized with frequency and percent.

Age will be summarized with number of observations, mean, median, minimum, maximum, and standard deviation.

7 Effectiveness Analyses

Given that subjects in the two comparison groups (Tango Belt vs. SOC) are not randomized and thus may not have balanced baseline characteristics, Propensity Score (PS) matching will be carried out to adjust for measured baseline confounders prior to any statistical test(s) comparing treatments on effectiveness endpoints at the interim and final analysis.

7.1 Propensity Score Method

For each subject, a PS (i.e., predicted probability between 0 and 1) of intervention group membership (Tango Belt vs. SOC) will be calculated using a logistic regression, with "intervention group" as the outcome and the following baseline variables as the predictors: Age, mobility level, sex, and whether the subject fell in the past year.

Once propensity scores are calculated, propensity score matching (PSM) without replacement will be performed.

Subjects in the intervention group (i.e., Tango Belt) will be matched to controls with a similar PS using nearest neighbor matching (NNM) at a ratio of 1:2.

The PS modeling and design will be performed by a statistician who will be blinded to the endpoint data for each subject to avoid introducing bias into the analysis. The blinded endpoint data includes the primary and three secondary endpoints listed in section 3.2.

Balance of baseline variables (e.g., continuous variable, dichotomous variable, interaction terms, or squares of continuous variable) will be assessed by comparing the pre-matched and post-matched datasets.

Adequacy of propensity balance will be assessed by examination of standard differences between groups to confirm standard difference in post-matched dataset does not exceed 10%. Additionally, a comparison of the baseline covariate variables between groups after adjusting for propensity subgroup will be carried out as in D'Agostino et al. If the propensity matching is adequate, this will result in non-significant p-values ($p>0.05$) for the baseline characteristics.

Additional PS methods may be employed if group balance is not achieved by NNM, examples include covariate adjustment, inverse probability of treatment weighted (IPTW), etc.

Since enrollment may be ongoing at the time of interim analysis, propensity score modeling and matching will be conducted at the interim analysis and subjects will be rematched at the time of the final analysis to ensure the best PS match possible. With PS matching possibly occurring twice the following differences in PS modeling and design may occur:

1. Subjects may be matched to different control subjects.
2. The number of matches (1:1 or higher – to a maximum of 1:4) may change based upon enrollment ratios.

3. The technique used to match (i.e., NNM) may change to another PS method to ensure adequacy of propensity balance.

7.2 Primary Effectiveness Analysis

The primary effectiveness endpoint for this study is the proportion of subjects experiencing major hip injuries due to falls, as reported at the 180-day visit and will be presented for the Tango Belt and control groups using the ITT and adherence populations.

The proportion of subjects experiencing major hip injury due to falls is defined as the total number of subjects who experience a major hip injury due to a fall divided by the total number of subjects.

The primary effectiveness hypotheses are:

$$H_0: \pi_T \geq \pi_C$$
$$H_1: \pi_T < \pi_C$$

where π_T and π_C are the proportion of subjects experiencing major hip injuries due to falls in the Tango Belt and control group, respectively.

The null hypothesis (H_0) for this endpoint states that the true proportion of subjects using Tango Belt and experiencing major hip injuries due to falls is greater than or equal to the true proportion of subjects in the control group who experience major hip injuries due to falls. The alternative hypothesis (H_1) states that the true proportion of subjects using Tango Belt and experiencing major hip injuries due to falls is less than the true proportion of subjects in the control group who experience major hip injuries due to falls.

The proportion of major hip injuries by treatment group will be presented along with a 95% confidence interval using the Clopper-Pearson method. H_0 will be tested at a one-sided 0.025 level of significance using a logistic regression analysis to compare treatment groups while controlling for propensity score.

7.3 Secondary Effectiveness Analysis

The secondary endpoints will also be tested using propensity score adjusted test of proportions with a hierarchical gate-keeping method to preserve the type I error rate (see section 6.5).

The secondary effectiveness endpoints for this study include the following:

1. The proportion of subjects experiencing fall-related hip fractures will be presented for the Tango Belt and control groups.
2. The proportion of subjects experiencing ED visits due to falls will be presented for the Tango Belt and control groups.
3. The proportion of subjects experiencing hospitalizations due to falls will be presented for the Tango Belt and control groups.

The secondary endpoints will be assessed using data reported at the 180-day visit using the ITT population.

The proportion of subjects experiencing a secondary event will be assessed separately following the methodology in section 6.5 and are defined as follows:

1. The proportion of subjects experiencing fall-related hip fractures is defined as the total number of subjects who experience fall-related hip fractures divided by the total number of subjects.
2. The proportion of subjects experiencing fall-related ED visits defined as the total number of subjects who experience fall-related ED visits divided by the total number of subjects.
3. The proportion of subjects experiencing fall-related hospitalizations defined as the total number of subjects who experience fall-related hospitalizations divided by the total number of subjects.

The secondary effectiveness hypotheses are:

$$H_0: \pi_T \geq \pi_C$$
$$H_1: \pi_T < \pi_C$$

where π_T and π_C are the proportion of subjects experiencing a secondary event (i.e., hip fractures, ED visits & hospitalizations) due to falls is greater than or equal to the true proportion of subjects in the control group who experience a secondary event due to falls. The alternative hypothesis states that the true proportion of subjects using Tango Belt and experiencing a secondary event (i.e., hip fractures, ED visits & hospitalizations) due to falls is less than the true proportion of subjects in the control group who experience a secondary event due to falls.

The proportion of secondary events (i.e., hip fractures, ED visits & hospitalizations) by treatment group will be presented separately along with a 95% confidence interval using the Clopper-Pearson method. H_0 will be tested at a one-sided 0.025 level of significance using a logistic regression analysis to compare treatment groups while controlling for propensity score.

8 Adverse Events

8.1 All Adverse Events

The occurrence of all adverse event (AEs) will be documented for all subjects from the time of enrollment. Adverse Events will be categorized into three groups based on frequency: Single episode, Intermittent, or Continuous. This categorization is in lieu of other formal coding strategies (i.e., MedDRA). The final categorization of all AE's will be performed by the Sponsor but general definitions are as follows:

- Single Episode: Any AE's that occurred only once (Fall, death, etc.) as well as the first occurrence of an AE that occurs more than once.
- Intermittent: Subsequent AE's beyond the first of each type. If a subject had more than one of the same AE (i.e., fall), all occurrences of that AE after the first one will be included in the Intermittent category.

- Continuous: Any AE's that are ongoing and not resolved. Also, any AE that the subject lives with daily but doesn't result in death.

Summaries of incidence rates of individual AEs by frequency will be prepared. Because a subject may experience more than one AE per frequency, summaries will provide both the number of subjects experiencing at least one event and the number of events. Percentages provided will be the percent of subjects experiencing one or more adverse events. In addition, incidence of AEs will be presented by severity (mild, moderate, severe) and relationship to study device.

Subjects experiencing an event within a given frequency more than once will be counted under the maximum severity/relationship experienced.

A listing of all adverse events will include the subject number, date of onset, date of resolution, severity, AE type, the severity of AE, frequency of the event, the action taken, relationship to device, seriousness, and the outcome.

An additional listing will be provided that includes both site reported and adjudicated information for AEs that are adjudicated.

8.2 Serious Adverse Events

Summaries of incidence rates and relationship to the investigational device of individual Serious Adverse Events (SAEs) by frequency will be prepared. Summaries will provide both the number of subjects and the number of events within the reporting period. Percentages provided will be the percent of subjects experiencing one or more serious adverse events. A data listing of SAEs will also be provided, displaying details of the event(s) captured on the CRF.

8.3 Device Related Adverse Events

Summaries of incidence rates of device related AEs by frequency will be prepared. Summaries will provide both the number of subjects and the number of events within the reporting period. Percentages provided will be the percent of subjects experiencing one or more device or procedure related adverse events. Data listings of device and procedure related AEs will also be provided, displaying details of the event(s) captured on the CRF. Relationship of the AE to the device will be judged by the investigator. Device relatedness categories include, not related, possibly related, probably related, and definitely related.

8.4 Deaths

Should any subjects die during the course of the trial, relevant information will be supplied in a data listing.

9 Summary of Changes from the Protocol

The following table provides a list of changes from the protocol to the SAP, and the justification for each change.

Section	Description	Justification
4. Sample Size	Estimated attrition was changed from 20% to 30%	After roughly half the subjects in the Tango Belt group were exited, the attrition rate was reexamined and adjusted upwards to account for the higher-than-expected loss.
4. Sample Size	Historical Control rate of major hip injury estimate changed from 8% to 15%	The sample size estimate was revisited after it was clear that the expected 1:4 allocation ratio was not attainable. The HC rate of major hip injury was also examined and deemed to be much higher than estimated at the beginning of the trial.

10 Reporting Conventions

All reporting will meet the standards of SOP-68 AS Data Analysis Reporting and SOP-83 AS Programming Standards.

11 References

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