PROTOCOL STUDY SYNOPSIS	
Title:	Evaluation of the Rotation Medical Bioinductive Implant for Insertional Achilles Tendonopathy
Study Devices:	Rotation Medical Bioinductive Implant *(Cleared for commercial use by the U.S. Food and Drug Administration: K140300; K131637; K131635; K122048)*
Study Design:	Prospective, non-randomized
Enrollment:	Up to 10 subjects will be treated
Inclusion Criteria:	1. At least 21 years of age 2. Insertional Achilles tendonitis requiring surgery that has failed conservative management, which consist of: A. Shoe modification B. Nonsteroidal anti-inflammatory drugs C. Physical Therapy with/without modalities 3. Chronic Achilles tendon pain lasting longer than 3 months 4. MRI of the ankle within 60 days prior to the study procedure 5. Willing to comply with the prescribed post-operative rehabilitation program 6. Willing to be available for each protocol-required follow-up examination 7. Able to understand the informed consent process, including regulatory requirements such as HIPAA authorization, and document informed consent prior to completion of any study-related procedures 8. Ability to read, understand, and complete subject-reported outcomes in English
Exclusion Criteria:	1. Achilles tendon rupture 2. Previous Achilles tendon surgery on the index ankle 3. Genetic collagen disease 4. History of auto-immune or immunodeficiency disorders 5. History of chronic inflammatory disorders 6. Oral steroid use in last 2 months or injectable steroid use in last 4 weeks 7. History of heavy smoking (> 1 pack per day) within last 6 months 8. Hypersensitivity to bovine-derived materials 9. Hypersensitivity to Polylactic Acid (PLA) and Polyetheretherketone (PEEK) materials 10. Metal implants, fillings, shrapnel, and/or screws 11. Females of child-bearing potential who are pregnant or plan to become pregnant during the course of the study 12. Currently involved in any injury litigation or worker's compensation claims relating to the index ankle 13. Enrolled, or plans to enroll, in another clinical trial during this study that would affect the outcomes of this study 14. History of non-compliance with medical treatment, physical therapy/rehabilitation, or clinical study participation 15. History of cognitive or mental health status that interferes with study participation
Study Objective:	To evaluate bioinduction of new tissue and tendon healing after implantation of the Rotation Medical Bioinductive Implant used as adjunct to surgical repair in the treatment of insertional Achilles tendonitis.

Primary Outcomes:	MRI assessment of the following: 1. Increase in tendon thickness 2. Integration of induced tissue with the underlying tendon and maturation of the induced tissue 3. Amount of defect fill-in and characteristics of both the filled-in tissue within the tendon 4. Achilles tendon tear rate at surgical site
Secondary Outcomes:	1. Safety 2. Procedure parameters 3. Recovery 4. Subject satisfaction
Study Assessments	Baseline Procedure Post-procedure follow-up: 3 months, 1 year, 2 years
Sponsor:	Rotation Medical, Inc. 15350 25th Avenue North Plymouth MN 55447
Data Management and Monitoring:	Rotation Medical, Inc. 15350 25th Avenue North Plymouth MN 55447

1 INTRODUCTION & RATIONALE

Chronic insertional Achilles tendinopathy is a common ailment in the general population. It is traditionally described as a phenomenon of overuse in both athletic and nonathletic individuals. Non-operative management usually consists of activity and shoe modifications, nonsteriodal anti-inflammatory medications (NSAIDs), and some form of physical therapy, which can be successful. In patients in whom conservative interventions fail, operative intervention is the next step. This intervention intails open detachment and debridement of the diseased Achilles tendon, calcaneal osteotomy, and reattachment of the Achilles. Often the diseased Achilles debridement leaves the tendon compromised in terms of its integrity and the remaining tendon will need augementation with a tendon transfer using the flexor hallucis longus (FHL).

The Rotation Medical Bioinductive Implant is a bioabsorbable device that provides a layer of collagen over injured tendons. This device is indicated for the management and protection of tendon injuries in which there has been no substantial loss of tendon tissue and can be implanted during a the standard open treatment for insertional Achilles tendinopathy. The device was first evaluated in a preclinical study of 23 sheep that was approved by the Colorado State University Institutional Animal Care and Use Committee. The device did not elicit an inflammatory response or a foreign body reaction.Histological analysis confirmed the device was completely absorbed after six months with integration of the new tendinous tissue to the underlying host tendon and a fibrocartilagenous transition zone at the tendon-to-bone insertion site. Tendon thickness at the implant site increased by approximately 2.5 millimeters due to induction of new tendinous tissue and remained stable one year after surgery.

The Rotation Medical Bioinductive Implant was further evaluated in a clinical study of 24 subjects who underwent implantation of the device and completed a minimum of one year follow-up. This study was approved by the Northern Sydney Central Coast Ethics Committee and registered in the Australian New Zealand Clinical Trials Registry [#ACTRN12611001082998]. The procedure was performed arthroscopically in 14 subjects while the other 10 subjects underwent a mini-open procedure. The median implant time was 15 minutes and all subjects were successfully implanted with no intent-to-treat failures. One patient experienced a return to pain 12 months after surgery that was associated with significant bursitis and an arthroscopic clean-up procedure was performed to debride the bursa. Despite the bursal reaction in this patient, tendon healing and tissue induction were not compromised.

Magnetic resonance imaging (MRI) at 3, 6, and 12 months after surgery provided evidence that the device consistently induced the formation of new, tendinous tissue that appeared well-integrated with each patient's native tendon tissue and showed progressive maturation over time. MRI observations were consistent with the histological results from prior sheep studies. Shoulder function and pain was also assessed at 3, 6 and 12 months after treatment using the ASES (American Shoulder and Elbow Surgery) and Constant (Constant-Murley) standard shoulder surveys. All of the scores at 12 months were significantly improved from baseline ($p < 0.05$) and improvement was comparable to published literature.

2 DEVICE DESCRIPTION

2.1 DEVICE DESCRIPTION

There are three implantable components in the Rotation Medical Bioinductive Implant™ (**Figure 1**).

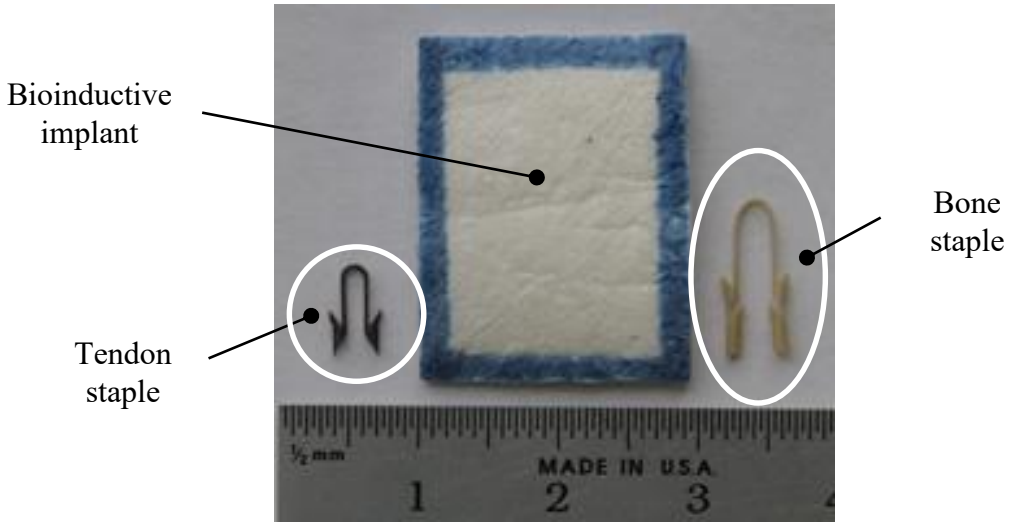
Bioinductive implant: The device is made from highly purified reconstituted collagen fibers derived from bovine tendon and manufactured for Rotation Medical, Inc. by Collagen Matrix, Inc. (Oakland, New Jersey, USA). It is contraindicated for use in patients with a history of hypersensitivity to bovine-derived materials and this is an exclusion criterion for study participation. The device is designed to completely absorb within six to 12 months.

Tendon staples: The tendon staples are made from poly(L-lactide-co-D,L-lactide) in a molar ratio of 70% L-lactide to 30% D,L-lactide. Polylactide materials have been used in a variety of medical devices, such as bone anchors, bone pins, screws, plates, and spinal fusion cages. The tendon staples are designed to completely absorb within approximately 12 months.

Bone staples: The bone staples are made from polyetheretherketone (PEEK), which is a common polymer used for bone anchors in orthopedic surgery. The bone staples are not bioabsorbable.

The Rotation Medical Rotator Bioinductive Implant has been cleared by the U.S. Food and Drug Administration (FDA) [K140300; K122048; K131635; K131637]. The purpose of this post-market study is to collect and analyze outcomes data under a common protocol.

Figure 1: Rotation Medical Implantable System Components



The tendon and bone staplers used to affix the bioinductive implant to tendon tissue and the calcaneus respectively are shown in **Figure 2**. These are designed as single-use devices.

Figure 2: Rotation Medical Single-Use Disposable Staplers

Tendon stapler Bone stapler

2.2 PRINCIPLES OF OPERATION

No investigational devices or procedures will be used in this post-market study and all devices will be used according to their indications for use. Operation, indication, and instructions for use are described in the Instructions for Use (IFUs).

3 STUDY OBJECTIVE

To evaluate bioinduction of new tissue and tendon healing after implantation of the Rotation Medical Bioinductive Implant used in the treatment of insertional Achilles tendonapathy.

4 STUDY DESIGN

This is a prospective, non-randomized, single-arm study conducted under a common protocol designed to evaluate long-term outcomes following open treatment and implantation of the Rotation Medical Bioinductive Implant to treat insertional Achilles tendinopathy.

4.1 SAMPLE SIZE

Up to 10 subjects will be enrolled and treated with the Rotation Medical Bioinductive Impant at Union Memorial hospital and the associated Surgery Center.

4.2 STUDY DURATION

Enrollment is anticipated to take up to 12 months and all subjects will be followed for two years after surgery. Therefore, the overall study duration is estimated to be 36 months.

4.3 PRIMARY OUTCOME MEASURES

4.3.1 Increase in Tendon Thickness

Achilles tendon thickness will be measured pre-operatively (baseline) and the total thickness of the tendon and any newly induced tissue at the implant site will be measured at each follow-up visit using magnetic resonance imaging (MRI). The mean (± SD) change in post-operative Achilles tendon thickness will be calculated at each follow-up interval.

4.3.2 Integration and Maturation of New Tissue

Integration and maturation of the newly induced tissue will be assessed by MRI at each post-operative follow-up. This outcome will assess, at a minimum, the following characteristics of the newly induced tissue: (i) presence or absence of a clear boundary between the device and the underlying tendon; (ii) maturation of newly induced tissue to resemble characteristics of underlying tendon tissue (versus debris, artifact, or calcification).

4.3.3 Tear Rate

Tear rate following Achilles surgery will be assessed at each follow-up visit using MRI.

4.4 SECONDARY OUTCOME MEASURES

4.4.1 Safety

Safety will be evaluated by any of the following adverse events that occur over the duration of the study:

1. Any death
2. All serious adverse events (SAE) regardless of relation to the device or procedure
3. Any non-serious adverse event (AE) that is classified as either device or procedure-related
4. Any unanticipated adverse device effect (UADE)

Adverse events will be summarized by relation to the study devices or study procedure. Overall occurrence rate by event type will also be calculated.

4.4.2 Procedure Parameters

The following procedural parameters will be recorded on all subjects:

1. Device implant time: Mean (± SD) implant time defined as follows:

   Open procedure: Time from introduction of the bioinductive implant into the surgical field to completion of the last staple

2. Procedure technical success: The proportion of subjects where the device was successfully delivered and affixed to target tendon location.
3. Device implant position: An intra-operative photograph(s) or video recording showing the implant location of the device and all tendon and bone staples will be obtained.

4.4.3 Recovery

The following post-operative recovery parameters will be reported after discharge from the from study procedure:

1. CAM boot time: cumulative number of days spent in a CAM boot
2. Rehabilitation time: cumulative number of completed rehabilitation or physical therapy (PT) visits (mean ± SD) to treat index Achilles
3. Return to work: cumulative number of days (mean ± SD) between discharge and return to work (employed subjects only)
4. Return to normal daily activities (i.e. full, unrestricted activity): cumulative number of days (mean ± SD) between discharge and return to normal daily activity

4.4.4 Subject Satisfaction

Subject satisfaction is a self-reported measure of satisfaction with the outcome of the index surgery. The level of satisfaction is assessed with a 5-point Likert scale. Each subject will also be asked to indicate whether (s)he would recommend the study procedure to a friend ("yes/no").

5 STATISTICAL ANALYSIS PLAN

This is an initial feasibility study and not powered to address the hypotheses. Changes in tendon thickness over the time of the follow up visits will be assessed by a Repeated Measures ONEWAY ANOVA with a post hoc Scheffe. Indices of new tissue integration and maturation at each follow up visit will be assessed by Chi Square analyses.

6 ELIGIBILITY CRITERIA

Subjects who meet all inclusion criteria (**Section 6.1**) and none of the exclusion criteria (**Section 6.2**) will be eligible to participate in the study.

Enrollment in the study occurs upon intra-operative confirmation that the subject meets all of the inclusion criteria and none of the exclusion criteria. Subjects who meet eligibility criteria and are enrolled will be followed per protocol through the end of the study (i.e., intent-to-treat). Subjects who do not meet the study eligibility criteria at the time of surgery will not be enrolled.

6.1 INCLUSION CRITERIA

Subjects enrolled in the study **MUST meet** all of the following criteria:

1. At least 21 years of age
2. Insertional Achilles tendinopathy requiring surgery
3. Chronic insertional Achilles tendinopathy lasting longer than 3 months unresponsive to conservative therapy including, but not limited to, pain medication, physical therapy and shoe modification
4. MRI of the Achilles within 60 days prior to the study procedure
5. Willing to comply with the prescribed post-operative rehabilitation program
6. Willing to be available for each protocol-required follow-up examination
7. Able to understand the informed consent process, including regulatory requirements such as HIPAA authorization, and document informed consent prior to completion of any study-related procedures
8. Ability to read, understand, and complete subject-reported outcomes in English

6.2 EXCLUSION CRITERIA

Subjects enrolled in the study **MUST NOT meet** any of the following criteria:

1. Achilles tendon tear
2. Previous Achilles tendon surgery on the index ankle
3. Genetic collagen disease
4. History of auto-immune or immunodeficiency disorders
5. History of chronic inflammatory disorders
6. Oral steroid use in last 2 months or injectable steroid use in last 4 weeks
7. History of heavy smoking (> 1 pack per day) within last 6 months
8. Hypersensitivity to bovine-derived materials
9. Hypersensitivity to Polylactic Acid (PLA) and Polyetheretherketone (PEEK) materials
10. Metal implants, fillings, shrapnel, and/or screws
11. Females of child-bearing potential who are pregnant or plan to become pregnant during the course of the study
12. Currently involved in any injury litigation or worker's compensation claims relating to the index ankle
13. Enrolled, or plans to enroll, in another clinical trial during this study that would affect the outcomes of this study
14. History of non-compliance with medical treatment, physical therapy/rehabilitation, or clinical study participation
15. History of cognitive or mental health status that interferes with study participation

7 STUDY ASSESSEMENTS

The schedule of protocol-required study assessments is provided in **Table 7.1**. Adverse event (AE) reporting as required and defined in **Section 8** begins at the time of enrollment (i.e. intra-operative confirmation of eligibility) and concludes at the end of the study.

Table 7-1: Schedule of Study Assessments

Study Evaluation	Baseline	Procedure	3-Month	1 Year	2 Year
	Within 60 Days of Surgery	Within 60 Days of Baseline	± 15 days	± 45 days	± 90 days
Informed Consent	✓				
Medical History & Exam	✓				
Eligibility Assessment	✓	✓[1]			
Enrollment (Date of Surgery)		✓			
MRI	✓[2]		✓[2]	✓[2]	✓[2]
Procedure Data		✓			
Medications	✓[3]	✓[3]	✓[3]	✓[3]	✓[3]
Adverse Events		✓[4]	✓[4]	✓[4]	✓[4]
Recovery/Satisfaction Questionnaire			✓	✓	✓
Revision/Additional Achilles Surgery			✓[5]	✓[5]	✓[5]

[1]Eligibilty confirmation will be performed at the time of the study surgery to ensure the patient meets eligibility criteria. Patients who do not meet study eligibility criteria will not be enrolled in the study.
[2]Each study MRI must be performed in accordance with the MRI study guideline.
[3]Only prescription medications to treat the index Achilles will be recorded.
[4]Non-serious AEs will only be recorded if they are classified as either possibly or definitely related to either the study device or the study procedure.
[5]Any additional surgical intervention performed on the index Achilles will be reported.

7.1 ELIGIBILITY ASSESSMENT

Subjects are considered eligible for this study if they meet all of the inclusion criteria and none of the exclusion criteria as defined in **Section 6.1** and **Section 6. 2**. The Investigator, co-Investigator, or sub-Investigator performing the study surgery will confirm eligibility.

7.2 ENROLLMENT

Enrollment in the study occurs upon clinical confirmation that the subject meets all of the inclusion criteria and none of the exclusion criteria. **Patients who do not meet study eligibility criteria at the time of the study procedure will undergo tendon repair at the discretion of the surgeon (without use of the Rotation Medical Bioinductive Implant) and will not be enrolled in the study**. The date of the study surgery is defined as the enrollment date and all subjects who are enrolled in the study will be followed per protocol unless voluntary consent is withdrawn. All subjects enrolled into the study will be identified through a unique identifier.

7.3 BASELINE ASSESSMENT

During the baseline assessment, the following activities must be conducted within 60 calendar days prior to enrollment:

1. Obtain written informed consent

2. Obtain medical history
3. Perform an MRI per the Sponsor imaging guidelines
    - *Provide the Sponsor with a de-identified digital copy, or access to the MRI*
4. Assess subject eligibility based on inclusion/exclusion criteria defined in **Section 6.1 and 6.2**.
5. Record prescription medications
    - *Record any prescription medications the subject is taking at the time of the baseline visit to treat his/her index Achilles*
6. Administer VISA-A (Victorian Institute of Sports Assessment-Achilles questionnaire) form to assess Achilles tendon pain.

7.4 PROCEDURE ASSESSMENT

During the study procedure, use of any biological agents or implants aimed at augmenting tendon-to-bone healing, excluding the Rotation Medical Bioinductive Implant, are strictly prohibited. Intra-operative data along with the following study-specific procedure information will be documented on the Procedure CRF:

1. Device implant time
2. Procedure technical success
3. Device implant position
    - *After implantation of the device, an intra-operative photograph(s) or video recording showing the implant location of the device and all tendon and bone staples will be obtained.*
4. Intra-operative complication (if applicable; per **Section 8**)

7.5 PROCEDURE RULES

Subjects should be scheduled to undergo the study procedure within 60 days of baseline assessment. Device implantation will be performed in accordance with the Rotation Medical Bioinductive Implant System device and instrument Instructions for Use (IFUs) and may be performed as an open procedure.

All subjects will be place in a supine position with a small bump under the contralateral hip. A tourniquet will be placed on the operative leg. A standard incision will be placed just medial to the Achilles tendon. The Achilles will be detached from the calcaneus, undergo debridement and assessed for integrity. The posterior aspect of the calcaneus will undergo exostectomy. At the surgeon's discretion the flexor hallucis longus tendon will be harvested. The Achilles tendon will be re-attached to the posterior aspect of the calcaneus using suture anchors. If the FHL is harvested a supplemental oblique tunnel will be created using a small burr. The FHL will be passed through the tunnel, woven through and attached to the remaining debrided Achilles tendon. Following the bioinductive implant will be attached to the Achilles tendon.

7.6 POST-OPERATIVE CARE

Post-operative care, including discharge instructions, pain management, and frequency/duration of physical therapy/rehabilitation regimen are at the discretion of the surgeon. To minimize the likelihood that the integrity or position of the device is compromised after implant, recommended rehabilitation guidelines are provided in **Table 7.2.**

Table 7-2: Post-operative Rehabilitation Guidelines

Study Procedure	Rehabilitation Guidelines
Device implant	• Remain in post mold splint until follow up • Remain nonweight bearing on operative leg with crutches or walker • **Follow up in one week for evaluation and placement into CAM boot with heel lift** • **Follow up at 2 weeks for suture removal** • **Follow up at 4 weeks for partial heel lift removal and progression to neutral foot** • **Follow up at 4 weeks for start of physical therapy** • **Fill out VISA-A (Victorian Institute of Sports Assessment-Achilles questionnaire) at 6 and 12 months**

7.7 FOLLOW-UP ASSESSMENTS

All subjects will undergo post-operative study assessments at 3 months, 1 year, and 2 years after discharge from the study procedure as described below and summarized in **Table 7.1**.

7.7.1 3-Month (± 15 Days) Follow-Up

1. Perform an MRI per the Sponsor Imaging guidelines.
    - *Provide the Sponsor with a de-identified digital copy of, or access to, the MRI*
2. Clinical Assessment
3. Record prescription medications
    - *Record any prescription medications the subject is taking at the time of the follow-up visit to treat his/her index Achilles.*
4. Record any new adverse events and update the status of any ongoing, previously-reported adverse events.
5. Report any new revision/additional Achilles surgeries performed on the index Achilles

7.7.2 1-Year (± 45 Days) Follow-Up

1. Perform an MRI per the Sponsor imaging guidelines.
    - *Provide the Sponsor with a de-identified digital copy of, or access to, the MRI.*
2. Clinical assessment
3. Administer the recovery/satisfaction questionnaire (VISA-A)
4. Record prescription medications.
    - *Record any prescription medications the subject is taking at the time of the follow-up visit to treat his/her index Achilles.*
5. Record any new adverse events and update the status of any ongoing, previously-reported adverse events.
6. Report any new revision/additional Achilles surgeries performed on the index Achilles.

7.7.3 2-Year (± 90 Days) Follow-Up

1. Perform an MRI per the Sponsor imaging guidelines.

- *Provide the Sponsor with a de-identified digital copy of, or access to, the MRI.*

2. Clinical assessment
3. Administer the recovery/satisfaction questionnaire.
4. Record prescription medications.
    - *Record any prescription medications the subject is taking at the time of the follow-up visit to treat his/her index Achilles.*
5. Record any new adverse events and update the status of any ongoing, previously-reported adverse events.
6. Report any new revision/additional Achilles surgeries performed on the index Achilles.

The results of all follow-up assessments will be documented on their respective CRFs. Each reportable adverse event (**Section 4.1.1**) will be documented on an Adverse Event CRF.

7.8 UNSCHEDULED FOLLOW-UP

Any unscheduled return visits to the study center/Principal Investigator for non-standard of care evaluation for ongoing Achilles-related issues will be documented. Visits required by the protocol or visits for routine post-operative follow-up are not considered unscheduled and do not need to be reported as an unscheduled visit.

7.9 REVISION/ADDITIONAL ACHILLES SURGERY

If the subject has additional or revision Achilles surgery on the index Achilles at any time during the follow-up period, the clinical site should make every effort to collect the procedure/operative notes for the procedure and complete the Revision/Additional Achilles Surgery.

7.10 EARLY WITHDRAWAL OR LOST TO FOLLOW-UP

If a subject wishes to withdraw from the study at any time, (s)he is able to do so voluntarily without having to justify it and without affecting her/his relationship with the Investigator.

Also, an Investigator may withdraw a subject from the study at any time if (s)he thinks it is in the subject's best interest.

The subject's future management will not be changed by a decision, voluntary or otherwise, to withdraw from the study.

All reasonable efforts should be made to retain the subject in this clinical study until completion of the clinical assessments at each follow-up visit. A subject will be considered "lost to follow-up" after a minimum of 2 documented phone calls to the subject were completed by a member of the study staff and a certified letter was sent to the last known address by a traceable method (e.g., certified mail; courier; commercial shipping/transport company).

7.11 END OF STUDY

Subjects will be exited upon successful completion of follow-up assessments or at the time of withdrawal or lost-to-follow-up.

8 ADVERSE EVENT DEFINITIONS AND REPORTING

Adverse events are to be reported from the time of enrollment through the last study follow-up visit.

8.1 DEFINITION OF ADVERSE EVENT (AE)

An Adverse Event (AE) is any undesirable clinical occurrence experienced by the subject. Any underlying disease that was present at the time of enrollment and prior to surgery that persists after surgery is not considered an AE.

8.2 SERIOUS ADVERSE EVENT (SAE)

A Serious Adverse Event (SAE) includes any of the following events:

- Results in death
- Is life threatening
- Requires subject hospitalization or prolongation of existing hospitalization
- Requires invasive surgical intervention to fix the problem
- Results in persistent or significant disability/incapacity
- Is considered an important medical event

An important medical event that may not meet one of the above definitions might be considered as an SAE if it jeopardizes the health of the subject or requires surgical intervention to prevent one of the outcomes listed in the above definition. Elective hospitalization after the procedure that was planned prior to subject enrollment is not to be considered as an SAE.

8.3 UNANTICIPATED ADVERSE DEVICE EFFECT (UADE)

An Unanticipated Adverse Device Effects (UADE) is any serious adverse effect on health or safety, or any life-threatening problem or death caused by, or associated with, a device, if that effect was not previously identified in nature, severity, or degree of incidence in protocol, subject informed consent form, or application, or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects. Anticipated adverse events are listed as known risks in **Section 12.1**.

8.4 ASSESSING, RECORDING AND REPORTING AEs, SAEs, AND UADEs

Only non-serious AEs that are classified by the Investigator as either device-related or procedure-related will be reported. All SAEs, regardless of relationship to the Rotation Medical Bioinductive Implant, and all UADEs will be reported.

An AE may be volunteered spontaneously by the subject or discovered as a result of questioning or physical examination by the Investigator or study staff. The following information should be reported on the Adverse Event CRF as soon as the Investigator becomes aware of the event and updated as needed until event resolves:

- Date of AE onset
- Date the Investigator became aware of the AE
- Main complaints/symptoms of the AE
- Relationship to the study device
- Relationship to the study procedure
- Status of the adverse event

Source documents (e.g., procedural notes, treatment notes, or a signed clinical summary) may be required as supporting documentation for the reported AE.

9 MALFUNCTIONS

Failure of the Rotation Medical Bioinductive Implant to meet its performance specifications or to perform as intended will be documented on the Malfunction CRF. In the event of a malfunction, every effort must be made to return the suspected Rotation Medical device or instrument to the Sponsor for analysis. Malfunctions will be evaluated for reportable requirements through the FDA medical device reporting (MDR) system.

10 PROTOCOL DEVIATIONS

Investigators are required to adhere to the study protocol, signed Clinical Trial Agreement (CTA), applicable national or local laws and regulations, and any conditions required by the appropriate IRB/EC or applicable regulatory authorities.

A protocol deviation is used to describe situations in which the protocol was not followed (this includes all activities at each scheduled visit or activities occurring outside of the study windows). All attempts should be made to obtain Sponsor approval of the deviation prior to their occurrence.

An Investigator must notify the Sponsor and the reviewing IRB/EC of any deviation from the Study Protocol that was done to protect the life or physical well-being of a subject (medical emergencies). Such notice should be given within 5 days of the occurrence. The Sponsor will determine if the subject affected is to continue in the study.

Documentation of deviations identified by the investigational center, the monitor, or other Sponsor representative(s) will be entered into the Protocol Deviation CRF for the purpose of tracking Investigator compliance with the protocol. The investigational center will be required to document actions taken to prevent recurrence of deviations. The Sponsor representative will initiate corrective actions based on individual deviations or trending reports as appropriate.

11 REPORTING REQUIREMENTS

Table 11-1 shows a summary of all reporting requirements. In addition to this list, individual IRBs may add additional reporting requirements and/or require a different notification time frame.

Table 11-1: Summary of Reporting Requirements

Type of Report	Prepared by Investigator FOR	Notification Time Frame
Death[1]	Sponsor & IRB	Within 24 hours of knowledge
Withdrawal of IRB approval	Sponsor	Within 5 working days of knowledge
Protocol Deviation to Protect Subject Life or Physical Well-Being	Sponsor & IRB	Within 5 working days of knowledge
Unanticipated Adverse Device Effect (UADE)	Sponsor & IRB	Within 10 working days of knowledge
[1]Copies of death records, medical records for the events that led to the subject's death, a death certificate (if available), and an autopsy report (if performed) should be requested.		

12 RISKS AND BENEFITS

12.1 RISKS AND RISK MITIGATION

Study patients will be informed of all known potential side effects and complications associated with the study assessments and study procedure prior to enrollment in the study.

There are no known incremental risks to the subject for participating in the study. The risks associated with participating in this study are the same as if the patient is treated outside of the study using the same commercially-available device and include the following potential risks of Achilles Tendinopathy surgery performed under general or regional anesthesia:

- Tissue inflammation
- The need for repeated surgery because tendons do not heal properly or tears
- Pain or stiffness that won't go away
- Fever and/or infection
- Complication from anesthesia
- Nerve or blood vessel damage
- Adverse reaction to device

In addition, subjects will be required to undergo MR imaging. MRI is generally a well-tolerated procedure and there is no ionizing radiation involved with MR imaging The potential risks are minimal and include claustrophobia, coil element heating and peripheral nerve stimulation, although the latter two are considered highly unlikely, given that the subjects will be imaged within preset safety guidelines to eliminate peripheral nerve stimulation. Coil element heating ranges from a mild sensation of heat to a potential burn. This is considered highly unlikely, as the coils have all undergone extensive testing and clinical use, and special pads are placed surrounding all contact points.

All Investigators will undergo training and subjects will be screened and evaluated for medical histories/conditions that may compromise safe, successful completion of any of the study assessments or performance of the device. Subjects with a known hypersensitivity to bovine-derived materials will not be enrolled in the study.

12.2 BENEFITS

Participation in this study is voluntary. Subjects can obtain the same treatment without participating in this study. However, information gathered from this study will help the Sponsor to continue to evaluate long-term performance of the device.

13 DATA MANAGEMENT

13.1 DATA COLLECTION

Report forms will be completed by the Investigator (or authorized study personnel) for each subject enrolled in the study. Data queries and edit checks will be used to reconcile discrepancies between data on the source documents and data entered on the CRFs. The Investigator must assure the accuracy and completeness of the recorded data. For the purpose of this study, the ASES and Constant shoulder surveys, as well as the Recovery/Satisfaction form, may act as their own source data.

13.2 DATA PROCESSING

All study documentation will be entered and maintained in a central database by the Sponsor or Sponsor-authorized representatives. Automatic and/or manual edit checks will be issued as necessary to correct discrepant data. Appropriate quality control measures will be established to ensure accurate and complete transfer of information from the study documentation to the central database. Data files will be exported from the central database for statistical analyses.

14 ADMINISTRATIVE RESPONSIBILITIES

14.1 SITE AND INVESTIGATOR SELECTION

Each site and Investigator selected to participate will be evaluated to ensure each has the capacity, volume of surgical candidates, and capability to comply with all informed consent and protocol requirements. Each study site and Investigator are required to comply with applicable local legal and regulatory requirements and applicable U.S. federal regulations.

14.2 TRAINING

The principal investigators must be Board Certified orthopaedic surgeons with experience performing surgery for insertional Achilles tendinopathy. Prior to first enrollment, each participating surgeon will complete Sponsor-provided training on the Rotation Medical Bioinductive implant System.

The Sponsor will also be responsible for ensuring each site and Investigator are properly trained on the study protocol and applicable regulatory requirements.

To insure uniform data collection and protocol compliance, the Sponsor or Sponsor-authorized representatives will train the Study Coordinator(s) and study staff on all

components of the study including the study protocol, techniques for the identification of eligible subjects, instructions for data collection during the procedure, and schedules for follow-up.

14.3 INSTITUTIONAL REVIEW BOARD (IRB) / ETHICS COMMITTEE (EC)

It is the Investigator's responsibility to obtain and maintain written approval of the final study protocol and Informed Consent from the appropriate IRB or Ethics Committee. Investigators are responsible for submitting and obtaining initial and continuing review of the trial by their IRB/EC. It is also the Investigator's responsibility to notify the IRB/EC of any amendments to these documents. A copy of the written approval must be forwarded to the Sponsor prior to first device shipment. The written approval must identify the study and document the date of review.

The Investigators must keep on file all study-related correspondence with the IRB/EC and forward copies of such correspondence to the Sponsor.

14.4 INFORMED CONSENT FORM (ICF)

Informed consent must be obtained in accordance with the applicable guidelines or local regulations and laws, whichever represents the greater protection of the individual. The subjects must be informed about their right to withdraw from the study at any time and for any reason without sanction, penalty, or loss of benefits to which the subject is otherwise entitled and also informed that withdrawal from the study will not jeopardize their future medical care. The institutional standard subject consent form does not replace the study informed consent form (ICF).

The Sponsor will provide a study-specific template ICF to each site for IRB/EC submission. This template may be modified to suit the requirements of the individual study site. The Sponsor must pre-approve all changes to the ICF prior to initial submission to the IRB/EC. The Informed Consent Form must be approved by the IRB/EC prior to device shipment and a copy must be retained at the investigational site along with the other investigational forms. A signed copy of the consent form must be given to each subject enrolled in the study and a signed copy of the consent form must be retained for each subject at the investigational site.

Modifications to the study-specific Informed Consent Form and/or any written information distributed to subjects must be approved by the Sponsor, and the IRB/EC as necessary.

14.5 CONFIDENTIALITY

All information and data sent to the Sponsor concerning subjects or their participation in this study will be considered confidential. All data used in the analysis and reporting of this evaluation will be used in a manner without identifiable reference to the subject. The Investigator consents to visits by the staff of the Sponsor and its authorized representatives and the U.S. FDA or any other local governmental body to review the study subjects' medical records, including any test or laboratory data that might have been recorded on diagnostic test media (e.g., MRI scan).

14.6 AMENDING THE PROTOCOL

The Sponsor must write amendments in order to alter the protocol. Administrative changes that do not affect the subject benefit/risk ratio (e.g., editorial changes for clarity) may be

implemented without any further approvals. Any change that would require alteration of the Informed Consent form must receive approval from all persons who approved the original protocol and from the IRB/EC prior to implementation. Following approval, the protocol amendment(s) will be distributed to all protocol recipients with instructions to append them to the protocol.

14.7 CRITERIA FOR TERMINATING STUDY

The Sponsor reserves the right to terminate the study early but intends only to exercise this right for valid scientific or administrative reasons or reasons related to the protection of study subjects. Investigators and associated IRB/EC will be notified in writing in the event of termination. Reasons for study termination include but are not limited to:

- The discovery of an unexpected, significant, or unacceptable risk to the study subjects.
- A decision on the part of the Sponsor to suspend or discontinue commercial distribution of the Rotation Medical Bioinductive Implant.

14.8 CRITERIA FOR TERMINATING AN INVESTIGATIONAL CENTER

The Sponsor reserves the right to stop enrollment of subjects at an investigational center at any time for any of the following reasons including but not limited to:

- Repeated failure to complete case report forms (CRFs)
- Failure to obtain Informed Consent
- Failure to report any study subject deaths, SAEs, or UADEs within the timeframes specified in **Table 11-1**
- Repeated protocol deviations
- Lack of study enrollment or study activity

14.9 SPONSOR RESPONSIBILITIES

The Sponsor's responsibilities for this study are to:

- Provide sufficient training to support study activities per agreements executed with the study sites
- Select all clinical Investigators, study sites, and consultants (e.g., the study monitors) who participate in the study
- Provide financial support to each study site per agreements executed with the study sites
- Follow all regulatory standards per federal regulations for clinical study sites, core laboratories, and other participants, and ensure regular site monitoring to assure compliance with them
- Retain ownership of all clinical data generated in this study
- Work collaboratively with Investigators to present and publish study results

14.10 INVESTIGATOR RESPONSIBILITIES

The Investigator for each site is responsible for ensuring the study is conducted according to:

- All signed agreements

- The study protocol
- IRB/EC guidelines
- Applicable FDA regulations

The Investigator for each site may not begin enrollment until the Sponsor receives and approves (when necessary) required documents, including the complete signed Investigator Agreement, Protocol Signature Page, IRB/EC and ICF approvals.

It is acceptable for the Investigator to delegate one or more of the above functions to an associate or Co-Investigator or trained Study Coordinator; however, the Investigator remains responsible for the proper conduct of the clinical investigation, including obtaining the ICF, collecting all required data, submitting accurate and complete CRFs, etc.

At each site, appropriate procedures must be followed to maintain subject confidentiality according to HIPAA (Health Insurance Portability Accountability Assurance) regulations. Each site may have its own internal procedures or requirements for use and release of subject medical information in research studies. Each Investigator is responsible for obtaining appropriate approvals, consents or releases of medical information as dictated by their relevant subject privacy regulations.

The study is not transferable to other sites attended by the Investigator unless prior approval is obtained from the appropriate IRB and the Sponsor.

15 MONITORING AND AUDITING

Monitoring visits to the investigational centers will be made frequently during the study to ensure that all aspects of the current approved protocol/amendment(s) are followed. Source documents will be reviewed for verification of agreement with data entered on the CRFs and all regulatory documents will be checked for accuracy including but not limited to IRB/EC approvals, study-related correspondence, and subject informed consent. The Investigator/institution guarantees direct access to source documents by designated Sponsor personnel and appropriate regulatory authorities. The site staff must agree to be available to meet with the Sponsor during each visit.

The study may also be subject to a quality assurance audit by the Sponsor or its designees as well as inspection by appropriate regulatory authorities.

16 REPORTS AND RECORDS

16.1 REPORTS

Adverse events and Rotation Medical Bioinductive Implant malfunctions will be evaluated for reportable requirements through the FDA medical device reporting (MDR) system.

16.2 RECORDS

All records pertaining to the clinical study will be kept for a minimum of 3 years following the date on which the study is terminated or completed.

17 USE OF INFORMATION AND PUBLICATION

Any previously unpublished information provided to the Investigators by the Sponsor, such as patent applications, manufacturing processes and basic scientific data, is considered confidential and will remain the sole property of the Sponsor. The Investigator agrees to use this information only in accomplishing this study and will not use it for other purposes without the Sponsor's written consent.

An Investigator may publish the study experience from his/her site subject to approval by the Sponsor. The Sponsor will work collaboratively with Investigators to support data analyses for publication of study results. The Sponsor reserves the right to review all publications in order to verify accuracy of the data. The Investigator may proceed with the publication when notified by the Sponsor.

For any multi-center publications (if applicable), the number, names, and order of the authors will be determined by the Sponsor with input from the Investigators.