The Management of Pilonidal Wounds with ACell MicroMatrix® and Cytal® Wound Matrix: A Case Series

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The Management of Pilonidal Wounds with ACell MicroMatrix® and Cytal® Wound Matrix: A Case Series

Protocol# CR2018-001

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Version: 1.0

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LIST OF ABBREVIATIONS

AE	Adverse Event
CFR	Code of Federal Regulations
CPT	Current Procedural Terminology
CRF	Case Report Form
FDA	Food and Product Administration
GCP	Good Clinical Practice
HIPAA	Health Insurance Portability and Accountability Act of 1996
ICD-10	International Classification of Disease, 10th Revision
ICF	Informed Consent Form
ICH	International Conference on Harmonisation
IRB	Institutional Review Board
PD	Pilonidal Disease
PI	Principal Investigator
PMS	Post-Market Surveillance
PQL	Postoperative Quality of Life Instrument
SAE	Serious Adverse Experience
SUB-I	Sub-Investigator

PROTOCOL SUMMARY

Title:	The Management of Pilonidal Wounds with ACell MicroMatrix® and Cytal® Wound Matrix: A Case Series.
Protocol Number:	CA2018-001
Study Design:	A case series involving the concomitant use of MicroMatrix® and Cytal™ Wound Matrix 2-Layer with standard of care negative pressure wound therapy (NPWT) during the management of pilonidal wound healing.
Objectives:	The purpose of this study is to examine the wound healing effect of MicroMatrix and Cytal Wound Matrix 2-Layer on pilonidal wound healing. All wounds will also receive standard of care negative pressure wound therapy. The study will measure the rate of wound closure within the 3 month time period. Patient reported outcomes as measured using the Visual Analog Pain Scale (VAS) and Katz Index of Independence in Activities of Daily Living (Katz ADL) will also be reported.
Number of Subjects:	A total of ten (10) subjects will be included in this series.
Study Criteria:	**Inclusion Criteria:** 1. Subject has a clinical diagnosis of pilonidal disease. 2. Subject is being scheduled for surgical excision of pilonidal disease. 3. Subject is at least 18 years of age. 4. Subject is willing and able to adhere to protocol requirements and agrees to participate in the study program and comply with the study follow-up regimen. 5. Subject is willing to provide written informed consent. **Exclusion Criteria:** 1. Subject has a known allergy to porcine-based materials. 2. Subject is pregnant.
Number of Sites:	One

Site Locations:	Florida Hospital Tampa 3100 Fletcher Avenue Tampa, FL 33613 Southeastern Center for Digestive Disorders and Pancreatic Cancer 3000 Medical Park Drive, Suite 500 Tampa, FL 33613
Study Product(s):	1. MicroMatrix® 2. Cytal™ Wound Matrix 2-Layer
Participant & Study Duration:	This study has an estimated overall duration of 6-8 months. Individual subject participation will be approximately 3 months..
Statistical Methodology:	Wound area will be analyzed for size and percentage closure during specified subject follow up period. The mean, median and standard deviations will be calculated and scatter plots developed to determine healing rates by application number, and days in treatment. The mean number of application of product will be tabulated. Safety will be assessed during the course of the study by collection of AEs as outlined in the Schedule of Events. All summaries of AEs will be based on treatment-emergent AEs and presented using the incidence and a tabulation of the number of events. The number and percentage of subjects experiencing AEs will be summarized by system organ class and description. Summaries by maximum severity and relationship to the study treatment will also be provided. SAEs and AEs leading to discontinuation from the study will be presented by system organ class and preferred term. Baseline demographic factors, patient characteristics and concomitant medications will be summarized. This summary will include the gender, age in years at the time of entry into the study, race, ethnicity, height (inches), weight (pounds) and BMI. Age, height, weight, and BMI will be summarized using descriptive statistics. The number and percent of each gender, race, and ethnicity category will be presented using counts and percentages. The medical and surgical history will be coded for each patient and summarized based on the body system description. The

patients will be summarized using counts and percentages for those patients who had a pre-study medical history.

Patient reported outcomes as measured using the Visual Analog Pain Scale (VAS) and Katz Index of Independence in Activities of Daily Living (Katz ADL) will be summarized.

1 KEY ROLES

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2 INTRODUCTION: BACKGROUND INFORMATION AND SCIENTIFIC RATIONALE

2.1 BACKGROUND INFORMATION

Pilonidal disease is an inflammatory process affecting the skin and subcutaneous tissue of the lower back and intergluteal fold. The pathophysiology of pilonidal disease is not entirely clear. Pilonidal disease was originally believed to be congenital, secondary to abnormal skin in the gluteal cleft. However, the current widely accepted theory describes pilonidal disease as an acquired condition related to the presence of hair in the natal cleft skin; loose hairs create a foreign body reaction that leads to formation of midline pits, then secondary infection. Pilonidal disease typically presents in the second decade of life, and affects men three to four times more often than women. It is a common problem encountered by surgeons, with an incidence estimated at 26 patients per 100,000 people. In the United States alone, pilonidal disease is estimated to affect 70,000 patients annually. The disease creates a significant burden, as treatment costs entail not only the surgical procedure and hospital stay, but postoperative wound care and loss of earnings due to time taken off and chronicity of disease.

2.2 RATIONALE

Pilonidal disease is a chronic disease with a major impact on patient quality of life and productivity. Thus, improved wound healing would have a significant effect on patient quality outcomes, patient quality of life, and healthcare utilization, as well as societal benefits from allowing this vital population to return to productivity. There is no consensus on postoperative wound care after surgery for pilonidal disease. Negative pressure therapy is commonly used. However, this therapy is costly and cumbersome, and not evidence-based to optimize wound healing or postoperative patient or financial outcomes. Our goal is to examine the effect of the concomitant use of MicroMatrix® and Cytal™ Wound Matrix 2-Layer on pilonidal wound healing when used in combination with NPWT.

Our premise is that Cytal™ Wound Matrix 2-Layer and MicroMatrix® will demonstrate a positive trend on healing outcomes.

3 OBJECTIVES AND PURPOSE

Primary objective:

The purpose of this study is to examine the wound healing effect of MicroMatrix and Cytal Wound Matrix 2-Layer on pilonidal wounds. All wounds will also receive standard of care negative pressure wound therapy. The study will measure the rate of wound closure within the 3 month time period. Patient reported outcomes as measured using the Visual Analog Scale (VAS) and Katz Index of Independence in Activities of Daily Living (Katz ADL) will also be reported.

4 STUDY DESIGN

4.1 DESCRIPTION OF THE STUDY DESIGN

A prospective case series examining the concomitant use of MicroMatrix® and Cytal™ Wound Matrix 2-Layer with standard of care negative pressure wound therapy (NPWT) during the management of pilonidal wound healing. Wound healing will be evaluated at 2 weeks, 6 weeks and 3 months. If subjects heal prior to the 3 month visit, wound healing shall be documented at the visit.

A maximum of ten (10) subjects will be included in this series.

This study has an estimated overall duration of 6-8 months. Individual subject participation will be approximately 3 months.

5 STUDY ENROLLMENT AND WITHDRAWAL

5.1 PARTICIPANT INCLUSION CRITERIA

In order to be eligible to participate in this study, an individual must meet all of the following criteria:

Inclusion Criteria:

1. Subject has a clinical diagnosis of pilonidal disease.
2. Subject is being scheduled for surgical excision of pilonidal disease.
3. Subject is at least 18 years of age.
4. Subject is willing and able to adhere to protocol requirements and agrees to participate in the study program and comply with the study follow-up regimen.
5. Subject is willing to provide informed consent.

5.2 PARTICIPANT EXCLUSION CRITERIA

An individual who meets any of the following criteria will be excluded from participation in this study:

Exclusion Criteria:

1. Subject has a known allergy to porcine-based materials.
2. Subject is pregnant.

5.3 STRATEGIES FOR RECRUITMENT AND RETENTION

Subjects will be recruited from the medical offices of the Principal Investigator, Dr. Massarotti, and Co-Investigator, Dr. Chudzinski. A maximum of 10 subjects will be included in this series.

5.4 PARTICIPANT WITHDRAWAL OR TERMINATION

5.4.1 REASONS FOR WITHDRAWAL OR TERMINATION

A subject may be discontinued from the study at any time if the subject, the Investigator, or the Sponsor feels that it is not in the subject's best interest to continue. The following is a list of *possible* reasons for study treatment discontinuation:

1. Screen failure
2. Subject withdrawal of consent (or assent)
3. Subject is not compliant with study procedures
4. Adverse event that in the opinion of the Investigator would be in the best interest of the subject to discontinue study participation
5. Protocol violation requiring discontinuation
6. Lost to follow-up
7. Sponsor request for early termination of study
8. Subject death

All subjects are free to withdraw from participation at any time, for any reason, specified or unspecified, and without prejudice.

Reasonable attempts will be made by the Investigator to provide a reason for subject withdrawals. The reason for the subject's withdrawal from the study will be specified in the subject's source documents.

The Investigator must make every effort to contact subjects who are lost to follow-up. Attempts to contact such subjects must be documented in the patients' records (e.g., times and dates of at least 3 attempts via telephone/email, receipt for sending a registered letter).

If a subject is withdrawn from treatment due to an Adverse Event, the subject will be followed and treated by the Investigator until the abnormal parameter or symptom has resolved or stabilized.

5.4.2 HANDLING OF PARTICIPANT WITHDRAWALS OR TERMINATION

Although subjects may withdraw from the study at any time and for any reason (or may be withdrawn at the Investigator's discretion), subject withdrawal should be avoided as much as reasonably possible.

Subjects who prematurely discontinue are not to be replaced. For subjects considered lost to follow-up, the data collection forms must be completed up to the last visit performed.

5.5 PREMATURE TERMINATION OR SUSPENSION OF STUDY

This study may be temporarily suspended or prematurely terminated if there is sufficient reasonable cause. Written notification, documenting the reason for study suspension or termination, will be provided by the suspending or terminating party to the Investigator, Sponsor and Institutional Review Board (IRB), as appropriate. If the study is prematurely terminated or suspended, the PI will promptly inform the IRB and will provide the reason(s) for the termination or suspension.

Circumstances that may warrant termination or suspension include, but are not limited to:

* Determination of unexpected, significant, or unacceptable risk to participants
* Demonstration of efficacy that would warrant stopping
* Insufficient compliance to protocol requirements
* Data that are not sufficiently complete and/or evaluable
* Determination of futility

Study may resume once concerns about safety, protocol compliance, data quality are addressed and satisfy the Sponsor and/or IRB.

6 STUDY DEVICE

6.1 STUDY DEVICE DESCRIPTION

6.1.1 DEVICE DESCRIPTION

MicroMatrix®

MicroMatrix® is composed of a porcine-derived extracellular matrix known as urinary bladder matrix and is intended for the management of wounds including: partial and full-thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, tunneled/undermined wounds, surgical wounds (donor sites/grafts, post-Mohs surgery, post-laser surgery, podiatric, wound dehiscence), trauma wounds (abrasions, lacerations, second-degree burns, skin tears) and draining wounds. The device is intended for one-time use.

Cytal™ Wound Matrix 2-Layer

Cytal™ Wound Matrix 2-Layer is composed of a porcine-derived extracellular matrix also known as urinary bladder matrix. The device is intended for the management of wounds including: partial and full-thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, tunneled/undermined wounds, surgical wounds (donor sites/grafts, post-Mohs surgery, post-laser surgery, podiatric, wound dehiscence), trauma wounds (abrasions, lacerations, second-degree burns, skin tears) and draining wounds. The device is intended for one time use.

Negative Pressure Wound Therapy

The V.A.C.Via™ Negative Pressure Wound Therapy System is an integrated wound management system for use in acute, extended and home care settings. It is intended to create an environment that promotes wound healing by secondary or tertiary (delayed primary) intention by preparing the wound bed for closure, reducing edema, promoting granulation tissue formation and perfusion, and by removing exudates and infectious material. It is indicated for patients with chronic, acute, traumatic, subacute and dehisced wounds, partial-thickness burns, ulcers (such as diabetic, pressure or venous insufficiency), flaps and grafts.

6.1.2 ACQUISITION

MicroMatrix® and Cytal™ Wound Matrix 2-Layer are commercially available and will be obtained through ACell distribution methods.

6.1.3 STUDY DEVICE STORAGE

MicroMatrix® and Cytal™ Wound Matrix 2-Layer should be stored in a clean, dry environment at room temperature in the unopened and undamaged package. The products should be protected from freezing, excessive heat, and high humidity.

6.2 POTENTIAL RISKS AND BENEFITS

6.2.1 POTENTIAL RISK AND PRODUCT WARNINGS

MicroMatrix® and Cytal® Wound Matrix 2-Layer

Complications and reactions are possible with any soft tissue repair, including but not limited to:

* infection
* increased chronic inflammation
* allergic reaction
* unexplained fever or chills
* excessive redness
* pain
* swelling

- odor associated with the use of products during the healing phase
- excessive drainage from the wound

Negative Pressure Wound Therapy

NPWT is contraindicated on the following situations:

- exposed organs, blood vessels, vascular grafts, or unexplored enteric fistulas
- active, untreated infection
- necrotic tissue
- malignancy tissue (within the wound)
- fragile skin
- active hemorrhage / coagulopathy / anticoagulation
- adhesive allergy

6.2.2 POTENTIAL BENEFITS

Benefits of study participation are unknown. This study may or may not directly benefit participants. However, the study may provide information that will benefit future patients.

7 STUDY PROCEDURES AND SCHEDULE

7.1 STUDY PROCEDURES/EVALUATIONS

7.1.1 STUDY SCHEDULE

A Schedule of Events representing the required testing procedures to be performed for the duration of the study is diagrammed in Appendix I. All follow-up visits will occur relative to the Treatment Visit, as outlined below:

7.1.2 BASELINE VISIT

The baseline visit may occur up to 5 days prior to the Treatment Visit.

1. Obtain informed consent of potential participant (or legally authorized individual).
2. Assign subject identification number (SID). SIDs will be assigned in consecutive order and not be re-used in the case of Screen Failures.
3. Obtain demographic information, medical history, height, weight and prior pilonidal wound procedures
4. Review medical history to determine eligibility based on inclusion/exclusion criteria.
5. Verify pregnancy test results if applicable
6. Obtain Subject Quality of Life Assessments (Visual Analogue Scale (VAS), Katz Index of Independence in Activities of Daily Living (Katz ADL))
7. Record each medication the subject is taking on the medication log.

7.1.3 TREATMENT VISIT

After all inclusion/exclusion criteria have been met, the patient becomes eligible for enrollment.

1. Confirm inclusion/exclusion criteria
2. Record procedure date, name of surgeon
3. Record surgical details (indication for surgery, procedure performed)
4. Obtain post-excisional images of wound area
5. Record wound measurements
6. Treat wound using Cytal® 2-layer and MicroMatrix®. Record study device details as required.

7.1.4 FOLLOW-UP VISITS (2 WEEKS ± 7 DAYS; 6 WEEKS ± 7 DAYS; 3 MONTHS ± 1 MONTH)

1. Obtain wound photograph and size measurements.
2. Perform wound assessment.
3. Record changes in medication.
4. Determine recurrence and necessitation for reoperation.
5. If wound requires retreatment with Cytal® 2-layer and MicroMatrix® record device application information
6. Obtain Visual Analogue Scale (VAS), Katz Index of Independence in Activities of Daily Living (Katz ADL))
7. Record any pilonidal wound related adverse events or serious adverse events.

7.1.5 UNSCHEDULED VISIT

Unscheduled visits may occur at any time after the treatment visit until the final study visit occurs. At an unscheduled visit, the patient will have their wound assessed and be evaluated for adverse events. The wound will also be photographed, measured, and documented

8 ASSESSMENT OF SAFETY

8.1 SPECIFICATION OF SAFETY PARAMETERS

8.1.1 DEFINITION OF ADVERSE EVENTS (AE)

Adverse event means any untoward medical occurrence associated with the use of an intervention in humans, whether or not considered intervention-related (21 CFR 312.32 (a)). Pilonidal wound related adverse events that occur post-treatment will be documented and evaluated under this protocol.

A pilonidal wound related medical condition that is present when the subject enters the study is not considered an AE unless the pilonidal wound related medical condition recurs after the subject had recovered from the pre-existing condition, or in the opinion of the Investigator, there is a clinically significant exacerbation in intensity or frequency during the study. If clinically significant worsening of the subjects' physical condition from screening is noted, the changes

will be documented as an AE. Clinical significance is defined as any pilonidal wound related variation in signs, symptoms, or testing that has medical relevance and may result in an alteration in medical care.

All disease signs and symptoms experienced by the subject and related to the pilonidal disease and wound will be recorded on the Adverse Event Form from the time of the index procedure until study completion. During each visit, each subject will be asked “Since your last clinic visit, have you had any new pilonidal wound related medical problems or any pilonidal wound related medical problems that have worsened since your last visit?” The Investigator/authorized designee shall record all directly observed pilonidal wound related AEs, all pilonidal wound related AEs as a response to the open question to the subject, and all pilonidal wound related AEs spontaneously reported by the subject during the study. Subjects will be told to notify their physician if they suspect they are experiencing an AE outside of the visit windows. All pilonidal wound related AEs shall be recorded and described in detail, recording the diagnosis, onset date, treatment, and resolution date. If the event is not resolved, a resolution date shall not be recorded and the event shall be recorded as “ongoing”.

8.1.2 DEFINITION OF SERIOUS ADVERSE EVENTS (SAE)

An AE or suspected adverse reaction is considered "serious" if, in the view of either the Investigator or Sponsor, it results in any of the following outcomes:

- Death
- A life-threatening adverse event
- Inpatient hospitalization or prolongation of existing hospitalization
- A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions
- A congenital anomaly/birth defect

Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered serious when, based upon appropriate medical judgment, they may jeopardize the patient or subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition.

8.1.3 DEFINITION OF UNANTICIPATED ADVERSE DEVICE EFFECT (UADE)

Unanticipated adverse device effect is any serious adverse effect on health or safety, any life-threatening problem or death caused by, or associated with a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the application; or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects.

8.2 CLASSIFICATION OF AN ADVERSE EVENT

8.2.1 SEVERITY OF EVENT

The Investigator will be asked to assess the severity of the AE using the following categories:

Mild: Events require minimal or no treatment and do not interfere with the participant's daily activities.

Moderate: Events result in a low level of inconvenience or concern with the therapeutic measures. Moderate events may cause some interference with functioning.

Severe: Events interrupt a participant's usual daily activity and may require systemic drug therapy or other treatment. Severe events are usually potentially life-threatening or incapacitating.

8.2.2 RELATIONSHIP TO STUDY DEVICE

For all collected AEs, the clinician who examines and evaluates the participant will determine the AE's causality based on temporal relationship and his/her clinical judgment. The degree of certainty about causality will be graded using the categories below.

Definitely: The relationship of the AE and the study device or the study procedure can definitely be established.

Probably: While a clear relationship to the study device or to the study procedure cannot be established, the AE is associated with an expected AE or there is no other medical condition or intervention, which could explain the occurrence of such an event.

Possibly: There is no clear relationship between the AE and the study device or study procedure; however, one cannot definitely conclude that there is no relationship.

Unrelated: There is no relationship between the AE and the study device or study procedure. This may include but is not limited to the incident being an expected outcome of a previously existing or concurrent disease, concomitant medication or procedure the subject experienced.

8.2.3 EXPECTEDNESS

The Investigator will be responsible for determining whether an AE is expected or unexpected. An AE will be considered unexpected if the nature, severity, or frequency of the event is not consistent with the risk information previously described for the study products.

8.3 TIME PERIOD AND FREQUENCY FOR EVENT ASSESSMENT AND FOLLOW-UP

The occurrence of an AE or SAE may come to the attention of study personnel during study visits or upon review by a study monitor. All AEs (per Investigator discretion) that are

possibly impactful to the development or healing of a pilonidal wound will be captured on the appropriate data collection form. Information to be collected includes event description, time of onset, clinician's assessment of severity, relationship to study device (assessed only by those with the training and authority to make a diagnosis), and time of resolution/stabilization of the event. All AEs will be followed to adequate resolution.

Any medical condition that is present at the time that the participant is screened will be considered as baseline and not reported as an AE. However, if the study participant's condition deteriorates at any time during the study, it will be recorded as an AE. UADEs will be recorded throughout the study.

Changes in the severity of an AE will be documented to allow an assessment of the duration of the event at each level of severity to be performed. AEs characterized as intermittent require documentation of onset and duration of each episode.

8.4 REPORTING PROCEDURES

8.4.1 ADVERSE EVENT REPORTING

Adverse events will be documented on the appropriate data collection form as the Investigator learns of the event. The Investigator will follow all AEs until adequate resolution is achieved. If the event has not resolved by the end of the study, the status of the event should be documented as of study closure. The IRB should be notified of all AEs according to their notification policies.

8.4.2 SERIOUS ADVERSE EVENT REPORTING

In the case of a SAE, the Investigator must immediately notify (within 1 working day) the Sponsor (contact information is provided in **Section 1, Key Roles).** The IRB must also be notified according to their notification policies.

8.4.3 UADE REPORTING

The Investigator must immediately notify the study Sponsor and the reviewing IRB as soon as possible, but in no event later than 10 working days after the Investigator first learns of the effect. The study Sponsor is responsible for conducting an evaluation of an UADE and shall report the results of such evaluation to the reviewing IRB and the Investigator within 10 working days after the Sponsor first receives notice of the effect.

8.4.4 REPORTING OF PREGNANCY

If a female patient becomes pregnant during the trial, she must be followed up until the outcome of the pregnancy is known.

9. STATISTICAL CONSIDERATIONS

9.1 STATISTICAL AND ANALYTICAL PLANS

Primary Endpoint:

Wound area will be analyzed for size and percentage closure during specified subject follow up period. The mean, median and standard deviations will be calculated and scatter plots developed to determine healing rates by application number, and days in treatment. The mean number of application of product will be tabulated.

Safety will be assessed during the course of the study by collection of AEs as outlined in the Schedule of Events. All summaries of AEs will be based on treatment-emergent AEs and presented using the incidence and a tabulation of the number of events. The number and percentage of subjects experiencing AEs will be summarized by system organ class and description. Summaries by maximum severity and relationship to the study treatment will also be provided. SAEs and AEs leading to discontinuation from the study will be presented by system organ class and preferred term.

Baseline demographic factors patient characteristics and concomitant medications will be summarized. This summary will include the gender, age in years at the time of entry into the study, race, ethnicity, height (inches), weight (pounds) and BMI. Age, height, weight, and BMI will be summarized using descriptive statistics. The number and percent of each gender, race, and ethnicity category will be presented using counts and percentages.

The medical and surgical history will be coded for each patient and summarized based on the body system description. The patients will be summarized using counts and percentages for those patients who had a pre-study medical history.

Patient reported outcomes as measured using the Visual Analog Scale (VAS) and Katz Index of Independence in Activities of Daily Living (Katz ADL) will be summarized.

10 SOURCE DOCUMENTS AND CASE REPORT FORMS

Data collection is the responsibility of the clinical trial staff at the site under the supervision of the site Principal Investigator. The Investigator is responsible for ensuring the accuracy, completeness, legibility, and timeliness of the data reported. Study data will be collected on data collection forms and in the subject medical records.

All source documents should be completed in a neat, legible manner to ensure accurate interpretation of data. 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 ANY ORIGINAL DOCUMENTS.

Study personnel at each site will enter data from source documents corresponding to a subject's visit into the protocol-specific CRF when the information corresponding to that visit is available. Subjects will not be identified by name on any study documents to be collected by the Sponsor (or designee), but will be identified by a subject number and initials.

The handling of the data by the Sponsor after receipt of the CRFs may generate additional requests to which the Investigator is obliged to respond by confirming or modifying the data questioned.

11 ETHICS/PROTECTION OF HUMAN SUBJECTS

11.1 ETHICAL STANDARD

The Investigator will ensure that this study is conducted in full conformity with Regulations for the Protection of Human Subjects of Research codified in 45 CFR Part 46, 21 CFR Part 50, 21 CFR Part 56, and/or the ICH E6.

11.2 LAWS AND REGULATIONS

This clinical study will be conducted in compliance with all national laws and regulations of the countries in which the clinical trial is performed, as well as any applicable guidelines. The trial will be registered on www.clintrials.gov and on other sites, as appropriate.

11.3 INSTITUTIONAL REVIEW BOARD

The protocol, informed consent form(s) and all participant materials will be submitted to the IRB for review and approval. Approval of both the protocol and the consent form must be obtained before any participant is enrolled. Any amendment to the protocol will require review and approval by the IRB/IEC before the changes are implemented to the study. All changes to the consent form will be IRB approved; a determination will be made regarding whether previously consented participants need to be re-consented.

11.4 INFORMED CONSENT PROCESS

Informed consent is a process that is initiated prior to the individual's agreeing to participate in the study and continues throughout the individual's study participation. Extensive discussion of risks and possible benefits of participation will be provided to the participants and their families. Consent forms will be IRB approved and the participant will be asked to read and review the document. The Investigator will explain the research study to the participant and answer any questions that may arise. All participants will receive a verbal explanation in terms suited to their comprehension of the purposes, procedures, and potential risks of the study and of their rights as research participants. Participants will have the opportunity to carefully review the written consent form and ask questions prior to signing. The participants should have the opportunity to discuss the study with their surrogates or think about it prior to agreeing to participate. The participant will sign the informed consent document prior to any procedures being done specifically for the study. The participants may withdraw consent at any time throughout the course of the trial. A copy of the informed consent document will be given to the participants for their records. The rights and welfare of the participants will be protected by emphasizing to them that the quality of their medical care will not be adversely affected if they decline to participate in this study.
If a consent document is revised due to changes in study procedures, subjects who were enrolled prior to the change, but are affected by the change, will be informed of the changes and will sign the amended consent document. If a consent document is revised due to changes in the risks or safety of the study, all active participants must sign the revised consent.

11.5 PARTICIPANT AND DATA CONFIDENTIALITY

Participant confidentiality is strictly held in trust by the participating Investigator(s), their staff, the Sponsor and their agents. 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, and/or representatives of the IRB may inspect all documents and records required to be maintained by the Investigator 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. 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.

12 DATA HANDLING AND RECORD KEEPING

12.1 STUDY RECORDS RETENTION

All study documents (patient files, signed informed consent forms, Study Regulatory Binder, etc.) must be kept secured for a period of two years following completion of the study. There

may be other circumstances for which the Sponsor is required to maintain study records and, therefore, the Sponsor should be contacted prior to removing study records for any reason. It is the responsibility of the Sponsor to inform the Investigator when these documents no longer need to be retained.

12.2 PROTOCOL DEVIATIONS

Protocol deviation is any noncompliance with the clinical trial protocol or GCP requirements (with the exception of proposed subject follow up outlined in Section 7). The noncompliance may be either on the part of the participant, the Investigator, or the study site staff. As a result of deviations, corrective actions are to be developed by the site and implemented promptly.

All protocol deviations/violations should be documented using the Protocol Deviations/Violations data collection form and submitted to the IRB according to their reporting guidelines.

12.3 PUBLICATION AND DATA SHARING POLICY

The preparation and submittal for publication of manuscripts containing the study results shall be in accordance with a process determined by mutual written agreement among the study Sponsor and participating institutions. The publication or presentation of any study results shall comply with all applicable privacy laws, including, but not limited to, the Health Insurance Portability and Accountability Act of 1996.

13 CONFLICT OF INTEREST POLICY

The independence of this study from any actual or perceived influence, such as by the device industry, is critical. Therefore any actual conflict of interest of persons who have a role in the design, conduct, analysis, publication, or any aspect of this trial will be disclosed and managed. Furthermore, persons who have a perceived conflict of interest will be required to have such conflicts managed in a way that is appropriate to their participation in the trial. The study leadership has established policies and procedures for all study group members to disclose all conflicts of interest and will establish a mechanism for the management of all reported dualities of interest.

14 LITERATURE REFERENCES

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APPENDIX I: SCHEDULE OF EVENTS

PROCEDURES	BASELINE	INITIAL TREATMENT	SCHEDULED FOLLOW-UP VISITS		
			2 WEEKS ± 7 DAYS	6 WEEKS ± 7 DAYS	3 MONTHS ± 1M
Written Informed Consent	X				
Assign Subject ID Number	X				
Inclusion/Exclusion Criteria	X				
Demographic information	X				
Medical/SurgicalHistory	X				
Physical Examination (height and weight)	X				
Wound Imaging and Measurement		X	X	X	X
Wound Assessment			X	X	X
Surgical Procedure Details		X			
Subject questionnaires (VAS, Katz ADL)	X		X	X	X
Adverse Events		X (As necessary)			
Additional Treatment			X (As necessary)		

APPENDIX II: STATEMENT OF COMPLIANCE

The trial will be conducted in accordance with the ICH E6, the United States (US) Code of Federal Regulations (CFR) applicable to clinical studies (45 CFR Part 46, 21 CFR Part 50, 21 CFR Part 56, and 21 CFR Part 812.

The Principal Investigator will assure that no deviation from, or changes to the protocol will take place without prior agreement from the Sponsor and documented approval from the Institutional Review Board, except where necessary to eliminate an immediate hazard(s) to the trial participants. All personnel involved in the conduct of this study have completed Human Subjects Protection Training.

I agree to ensure that all staff members involved in the conduct of this study are informed about their obligations in meeting the above commitments.

Signature of Principal Investigator	**Date (mm/dd/yy)**
Printed Name	
Name of Institution	