Clinical Protocol

NCT#02836990

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Prevena Incision Management System Versus Dermabond in the Prevention of Groin Wound Infections in Patients Undergoing Vascular Surgery

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Sponsor: Acelity

Clinical Protocol Acceptance

I have read this protocol and agree to adhere to the requirements. I will provide copies of this protocol and all pertinent information to the study personnel. I will discuss this material with them and ensure that they are fully informed regarding the conduct of this study, other applicable regulations, to applicable laws and the University of Buffalo Health Science Institutional Review Board (HSIRB) requirements.

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Principal Investigator Signature DD MM YY

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Principal Investigator Printed Name

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Investigational Site

Protocol Synopsis

Prevena versus Dermabond in the Prevention of Groin Wound Infections in Patients Undergoing Vascular Surgery	
Protocol Number	
Test Device	Prevena Incision Management System
Primary Objective	To evaluate the clinical efficacy and cost effectiveness of Prevena versus Dermabond in preventing groin wound infections in patients who undergo vascular surgery requiring a groin incision.
Study Design	A prospective randomized study comparing groin wound infection rates and costs of hospitalization for Prevena and Dermabond in patients who undergo vascular surgery which requires a groin incision
Eligibility Criteria	Adults 18-85 who are scheduled to undergo vascular surgery which requires a groin incision who are able to consent and are willing to comply with follow-up and are or have a responsible individual deemed able to take care of a wound.
Number of Subjects	140 patients: 70 in each arm of the study
Number of Sites	Buffalo Medical Center, Kaleida Health
Follow-up schedule	Clinical follow-up will be daily throughout hospitalization including day of discharge and within 30 days of surgery to evaluate healing of the groin incision.
Primary Safety Endpoint	Major adverse event rate at 30 days defined as: groin wound infection
Primary Effectiveness Endpoint	30 day healing of the groin wound
Secondary Effectiveness Endpoint	1. Cost of care including hospitalization and 30 day readmission for treatment of a groin wound. 2. Incidence of antibiotic use upon discharge for treatment of infected groin incision 3. Visiting Nurse home visits and physician office visits to assess/treat groin wound infection will also be evaluated.

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1.0 Introduction

1.1 Objective:

The purpose of this study is to evaluate the efficacy and cost of Prevena versus Dermabond in the prevention of groin wound infections in patient who undergo vascular surgery which requires groin incision.

1.1a Device Name:

Prevena Incision Management System by Acelity

1.1b Intended Use: Prevena Incision Management System is a negative pressure wound therapy device that maintains a closed environment over the surgical incision and removes exudate through use of negative pressure. It is intended to be used on surgical incisions that continue to drain following closure with sutures or staples to prevent infection and promote healing.

1.2 Hypothesis

Groin wound infection rates as graded per the Szilagyi score following vascular surgery will be lower in patients treated with the Prevena Incison Management System than in those treated with Dermabond. The cost of using Prevena will be lower than Dermabond due to lower groin wound infection rates, need for subsequent treatment or 30 day hospital readmission for groin wound infection.

2.0 Background

The incidence of infection in groin surgical incisions following vascular procedures ranges between 3% and 44%,[1-8] which is substantially higher than expected rates.[9] Groin incisions are particularly susceptible to complications such as infection, dehiscence, hematomas and lymphatic leaks.[7] In part this is due to incision location and body habitus. But additionally, use of sutures and staples creates tension points that can produce ischemia and potentially cause tissue necrosis.[Feinstein 10] Groin wound infections in vascular patients can be devastating. Graft infection may occur, particularly when prosthetic material is used, limb loss or death may even ensue. At the very minimum, infection contributes to significant increases in length of stay and cost. Surgical site infections have been estimated to cost an additional $20,000 per admission and increase LOS by 10 days.[11]

The purported benefits of negative pressure systems is the ability to hold incision edges together, remove exudate and debris from the site and protect the incision from other external infectious sources; attributes which would seem particularly beneficial for groin incisions. In addition to the features common to other negative pressure systems, Prevena, offers an interface layer of polyester knit fabric that functions similar to a non-adhesive dressing and protects the skin from contact with the foam bolster while delivering negative pressure and removing fluid. Moreover, Prevena is also noted for ease of use and portability.[12]

Prevena's efficacy has not yet been widely published, particularly in vascular patients, but studies which have been completed have been favorable. A small pilot study which included only 8 patients demonstrated a benefit to Prevena, however, the study was limited due to the comparator arm combining both Dermabond and Primapore dressings. [13]Matatov et al in a larger retrospective review of 90 vascular patients with groin incisions documented that infection rates were 5 times lower with Prevena than closure with skin adhesive (Dermabond) or absorbant dressing (Primapore) 6% vs. 30%. Costs were lower with Prevena because of decreased infection rates and need for subsequent treatment. [14] Unfortunately, this study is limited by its retrospective design, lack of randomization and reporting methods. Infection rates for Dermabond and Primapore were not reported separately, yet the efficacy of these two treatment groups could differ substantially.

Prevena use has become widespread despite the lack of data from larger randomized trials. It would be beneficial to establish its clinical and cost effectiveness in a prospective randomized trial. At our hospital, Prevena is substantially more costly than Dermabond (~$495 versus ~$57) but even minimal reductions in infection rates may be adequate to offset expense. It is not essential that the cost of Prevena be lower than Dermabond to support its use but rather decreased infection rates paired with comparable costs will be sufficient to demonstrate its advantage.

3.0 Inclusion and Exclusion Criteria

3.1 Inclusion Criteria

- Age 18-6
- In need of elective vascular procedure requiring $\geq$ 8cm groin incision
- Able to provide consent
- Willing to comply with follow-up

3.2 Eligibility screening

All referrals to vascular surgeons at Buffalo General Medical Center
for the vascular surgery that may
potentially require a groin incision will be monitored prospectively by the nurse coordinator through review of operating room schedules, and through communication with surgeons, their scheduling staff and Vascular Surgery residents. Those who meet eligibility requirements will be approached for consent and randomized accordingly.

3.3 Exclusion Criteria

- Individuals <18 years of age
- Adults unable to consent
- Subjects unable or unwilling to take care of the groin incision, use the Prevena Wound Management System or have a designated individual who is capable
- Subjects with hypersensitivity to adhesives or Silver
- Prisoners

3.4 Inclusion of non-English speaking individuals

- Every effort will be taken to include non-English speaking individuals

4.0 Study-wide Number of Subjects

4.1 Number of Subjects

A total of 140 subjects will be recruited.

There will be 70 subjects randomized to each arm.

5.0 Study-wide recruitment methods

5.1 and 5.2 Recruitment of Subjects

All referrals to vascular surgeons at Buffalo General Hospital for vascular surgery that may require groin incision

will be monitored prospectively by the nurse coordinator through review of operating room schedules and through communication with surgeons, their scheduling staff and Vascular Surgery residents. Those who meet eligibility requirements will be approached for consent and randomized accordingly.

5.3 Advertisement

Advertisement will not be necessary for the recruitment process.

6.0 Multi-Site Research Communication

6.1 The clinical coordinator will ensure compliance in the following areas and will maintain electronic documentation of compliance.

- The most current version of the protocol, consent document and HIPAA authorization are on site and available for review
- All required approvals have been obtained at each site
- All modifications have been IRB approved and communicated to each site prior to implementation
- All data will be secured in a locked cabinet in the coordinators locked office. Electronic data will be stored on a PC in the coordinator's locked office and will be password secured. Patient data will be de-identified at the earliest possible date to prevent possible breach in confidentiality.
- The coordinator will be well versed on the protocol to ensure that investigators conduct the study appropriately
    - Noncompliance with the protocol will be reported to the PI at the site and remedied appropriately.

7.0 Study Timelines

7.1 Duration of subject's participation

Subjects will be evaluated throughout hospitalization including the day of discharge, and at at 30 days (25 - 40) following surgery. This will include clinical assessment (Szilagyi Scale) of the groin incision for presence of infection, need/use of antibiotics for groin

incision infection and need for visiting nurse home visits or surgeon office visit prior to scheduled follow-up to treat infection of the groin incision randomized to treatment.

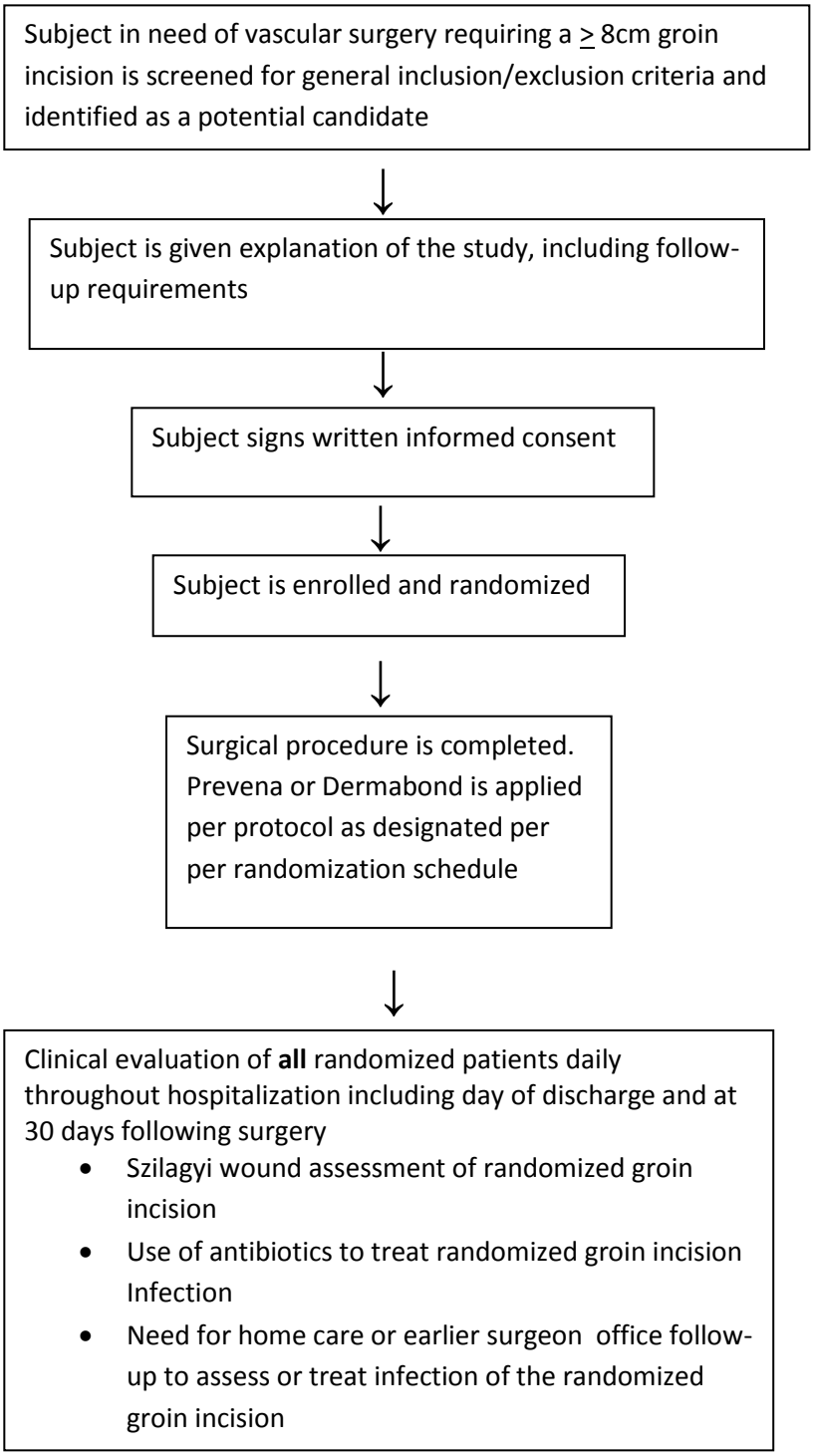
7.2 Duration of enrollment period

The expected enrollment phase is 12 months

7.3 Projected completion date

The anticipated completion date for the study enrollment, follow-up data analysis, report preparation is 05/31/17.

Figure1. **Study flow Diagram from Subject Screening to Follow-up**



8.0 Study Endpoints

8.1 Primary and Secondary Effectiveness Endpoints

The primary effectiveness endpoint is 30 day healing of the randomized groin incision, with any wound infection or failure to heal during that period representing an endpoint. All randomized patients will be followed out to 30 days regardless of developing an infection of the randomized groin incision

The secondary effectiveness endpoint is total hospital costs including 30 day readmission for treatment of infection of the randomized groin wound.

8.2 Primary Safety Endpoint

The primary safety endpoint is a major adverse event rate at 30 days defined as: device malfunction, Grade III Szilagyi Infection or any cause mortality.

Device malfunction-	Any case in which the device does not perform in its intended function when used in accordance with the instructions for use. All device malfunctions will be reported to the sponsor. Malfunctions that result in an adverse event must be reported as so. Malfunctions that do not result in an adverse event do not need to be recorded as an adverse event as they are not considered an adverse event. The malfunctioned device will be returned to Acelity.
All-Cause Mortality-	Death from any cause related or unrelated to surgery, use of Prevena or Dermabond. Any death will be reported to the Sponsor as soon as possible A written report of the death will be provided to the sponsor within 10 business days and will be provided to the IRB per guidelines. If requested, a copy of the death certificate and autopsy results be sent to the sponsor when available. Any other source documents related to the death should also be provided to the sponsor. If no source documents are available, the PI is submit a letter to the sponsor describing the circumstances of the subject's death.
Groin incision infection	Szilagyi Grade III infection of the randomized groin incision.

9.0 Procedures Involved

9.1 Study Design

This is a prospective multicenter randomized double arm study to evaluate the prevention of groin wound infections in patients undergoing vascular surgery which requires ≥ 8cm groin incision.

9.11 **Randomization Plan**:

We will employ a 1:1 randomization to either Prevena or Dermabond using a stratified blocked randomization plan with strata determined as a single incision or a bilateral incision with sequences of random block sizes of 4 or 8. Within the bilateral incision strata, one incision will be randomly chosen relative to defining a single endpoint measure, with site of incision essentially serving as a secondary substratum.

9.12 **Statistical Analysis Plan Outline**:

Primary Endpoint

The primary endpoint for this trial will be Szilagyi wound infection grade quantified on an ordinal scale (none, grade I: infection contained to the dermus, grade II: infection extending into the subcutaneous tissue but the arterial graft is not involved, grade III: infection of the arterial graft or native vessel underlying the incision). The primary analysis will be intent to treat and carried forth using an ordinal regression model with a stratified likelihood accounting for the primary randomization strata (incision number) and binary indicator variable for treatment arm with the primary test of treatment efficacy being the proportional odds different from 1. In the event of sparse data at the higher grades of infection (<2% at grade III), categories II and III will be combined. For the bilateral incision strata, the primary endpoint will be determined by randomly choosing a single incision as determined within the randomization scheme.

Secondary Endpoint

The secondary endpoint will be a comparison of cost of treatment between the two arms and will be considered an exploratory analysis. We will utilize regression approaches to account for potential selection bias and censored cost endpoints. We have completed a preliminary appraisal of the additional per patient hospital costs (dispersed over the entire sample) for treating groin wound infections using the following assumptions. The associated wound infection rate for Prevena would be 6%.[3] Groin wound infections for Prevena and Dermabond would require comparable care. Although lower wound severity grades have been reported for Prevena[3] which could potentially decrease the complexity, duration and cost of subsequent treatment of wound infection for this group, the finding was not statistically significant.[3] Therefore, we projected that treatment of groin wound infection in both groups would include an increased 10 day hospital length of stay,[1] seven days of IV antibiotics, daily CBC with or without differential and 2 cultures. We have estimated that the additional per patient cost of treating groin wounds if Prevena were used preemptively ($935- $1,114) would be similar to Dermabond ($869- $1,168) if the incidence of wound infection with Dermabond is ≤ 10%.

9.13 Sample size rationale:

Given N=140=70 +70 total subjects and setting the Type I error rate = 0.05, we will have the power of 0.88 to detect a proportional odds of 4.9 different from 1. For our calculations, we assumed a probability vector for the ordinal scale (none, grade I, grade II, grade III) of (0.90, 0.08, 0.019, 0.001) for the Prevena treatment arm and (0.70, 0.16, 0.11, 0.03) for the Dermabond arm respectively. The power estimate was carried forth using10,000 Monte Carl simulations. This volume should be easily attainable over a 12 month period because on average 484 lower extremity revascularizations and 100 Abdominal Aortic Aneurysm Repairs are performed annually at Kaleida Health. While most of these procedures (85%) are completed by endovascular approach, access by groin cutdown is necessary in 25% of EVAR and 10% of EVI in addition to the planned open lower extremity revascularizations, which should allow for adequate numbers. SPPS 22 will be used to perform the statistical analysis.

9.2 Research Procedures

- Baseline Requirements
    - Informed consent must be obtained from the subject prior to enrollment. The following is a list of all assessments and tests that are required during the baseline period. Assessment is based on data available to the investigator at time of enrollment.
        - Medical History- It is required that the subject's clinical history and pre-existing conditions be assessed and documented
        - Physical Exam- It is required that the subject undergo a pertinent arterial and venous physical exam and the results be documented
        - Concomitant Medication use- It is required that the subject's use of medications related to the study be provided and documented at baseline and throughout follow-up. Concomitant use includes antibiotics, NSAIDs, steroids, aspirin, anticoagulants and antiplatelet medications
        - Laboratory Testing- Routine laboratory testing performed prior to a surgical procedure will be documented: CBC without Differential, Electrolyte Panel
- Procedure Requirements
        - Concomitant Medication Use
        - Adverse Event (AE) evaluation- any undesirable medical occurrences in a subject related or unrelated to the study device, study procedure or study requirements that is identified or worsens during the clinical study. Adverse events must be assessed and documented by the investigator at the time of the procedure and at all follow-

ups (scheduled and unscheduled visits). All suspected AEs must be recorded and reported to the sponsor. See 12.0 **Data Safety Monitoring** for definitions of specific AEs and AE categorization.

- Post Procedure Requirements
    - Clinical Status Evaluation :
        - Sizalgyi Infection Score
            - Grade 0- No Infection
            - Grade I- Dermis only
            - Grade II- Subcutaneous tissue involvement
            - Grade III- Arterial Graft Involved
        - Lower extremity vascular assessment
            - Documentation of pulses, color, movement
            - Sensation, Ankle Brachial Index (ABI)
    - Concomitant Medical Use: Prophylactic antibiotics will be noted. Use of additional antibiotics along with indication will be recorded. Other medications such as NSAIDs, steroids, aspirin, anticoagulants and antiplatelet medications will also be recorded.
    - AE Evaluation: any infection of the randomized incision or other major postoperative morbidity related or unrelated to the surgical procedure/ wound treatment which may include but is not limited to: MI, CHF, CVA, Respiratory distress/failure, renal failure requiring dialysis, re-intervention for any reason, thrombosis, embolization, amputation, blood loss requiring treatment.

Table1. Study Assessment Requirements

Assessment Schedule (Time-Frame Window)	Baseline ≤45 days prior Labs ≤ 30 days prior	Procedure	Daily While Hospitalized	Day of Discharge	30 Day Follow-up 25-40 Days
Medical History	X				
Physical Exam	X				
Concomitant Medication Use	X	X	X	X	X
Laboratory Testing	X				
Clinical Status Evaluation	X	X	X	X	X
With ABI	X		X (x1)	X	X
Adverse Event Evaluation		X	X	X	X

9.3 Procedures to lessen the probability or magnitude of risks

- The randomized surgical incision will be irrigated copiously with a solution of saline and antibiotics
- Subjects and caretakers will be educated on the signs and symptoms of infection/allergic reaction, use of the Prevena.

9.4 Device description, purpose and regulatory approval status

Prevena Incision Management System by Acelity

Prevena is a negative pressure wound therapy device intended for use on surgical incisions that continue to drain following closure with either staples or sutures. Prevena promotes healing by maintaining a closed environment which protects the incision from external infectious sources. Through the application of negative pressure, Prevena removes fluids, and potentially infectious exudate from the surgical site. Prevena is lightweight and portable.

Dermabond

Dermabond by Ethicon is a cyanoacrylate adhesive that forms bonds across wound edges to promote healing. When Dermabond comes in contact with moisture on the skin surface, it binds to the top epithelial layer and bridges the edges of the incision together, allowing healing to occur beneath. It has been marketed to replace sutures ≤ 5.0 in diameter for repair of lacerations or incisions. The multiple benefits of Dermabond include an antimicrobial water resistant coating that protects against external sources of infection, application time is shorter than suture placement, need for suture removal is eliminated and long term cosmetic outcomes are comparable. When Dermabond is used in the extremity or torso, placement of subcutaneous sutures is usually recommended as this tends to improve healing. When used in moist areas of high tension or mobility such as the groin, the incision must be kept dry and mobility restricted. [15]

9.5 Source Records and Data Collection Sheets

Source records will include the subjects hospital electronic/paper medical and financial records, surgeons office records and home health care records.

Data collection sheets will include patient demographics, co-morbidities, available preoperative vascular testing, operative data, operative, postoperative complications, reintervention, clinical assessment as per table II, antibiotic use and other concomitant medications, hospital LOS, 30 day hospital readmission for infection, total, direct and indirect hospital costs, reimbursement, contribution margin, discharge and 30 day (25-40) clinical assessment (see table II) antibiotic use, use of home health services for wound assessment/care of the randomized incision, or unscheduled office appointments for evaluation or treatment of the randomized incision.

9.6 Data/Long term Follow-up

Patients will be assessed at 30 days (25 -40) following vascular surgery with groin

incision to evaluate healing.

10.0 Data Banking

10.1 Data will not be stored for future use

11.0 Data Management

11.1 Data analysis plan and 11.2 Power Analysis

Study Design

This is a prospective multicenter randomized double arm study to evaluate the prevention of groin wound infections in patients undergoing vascular surgery which requires ≥ 8cm groin incision.

Randomization Plan:

We will employ a 1:1 randomization to either Prevena or Dermabond using a stratified blocked randomization plan with strata determined as a single incision or a bilateral incision with sequences of random block sizes of 4 or 8. Within the bilateral incision strata, one incision will be randomly chosen relative to defining a single endpoint measure, with site of incision essentially serving as a secondary substratum.

Statistical Analysis Plan Outline:

Primary Endpoint

The primary endpoint for this trial will be Szilagyi wound infection grade quantified on an ordinal scale (none, grade I, grade II, grade III). The primary analysis will be intent to treat and carried forth using an ordinal regression model with a stratified likelihood accounting for the primary randomization strata (incision number) and binary indicator variable for treatment arm with the primary test of treatment efficacy being the proportional odds different from 1. In the event of sparse data at the higher grades of infection (<2% at grade III), categories II and III will be combined. For the bilateral incision strata, the primary endpoint will be determined by randomly choosing a single incision as determined within the randomization scheme.

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infection in both groups would include an increased 10 day hospital length of stay,[1] seven days of IV antibiotics, daily CBC with or without differential and 2 cultures. We have estimated that the additional per patient cost of treating groin wounds if Prevena were used preemptively ($935- $1,114) would be similar to Dermabond ($869- $1,168) if the incidence of wound infection with Dermabond is $\leq$ 10%.

Sample size rationale:

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11.3 Securing the Data

The data will be collected by a single nurse coordinator with vascular surgery experience, who has received training on the case report forms developed for use in this study. The coordinator will also be trained to enter information from the case report form into a database set up in SPSS on a password protected PC kept in a locked office. All protected health information on the database will be de-identified. Subjects will be assigned a study number at time of randomization. The case report forms which contain patient identified protected health information will be kept in a locked cabinet within the coordinator's locked office. These will be retained for the required 3 year period following the study and the disposed of per institutional HIPPA policy. A master list of the patient name, DOB, hospital medical record number and study number to allow accurate linking of follow-up data to the index case will also be kept in a locked cabinet in the locked coordinator's office.

11.4 Quality Control of Collected Data – 11.11 Handling and Transmission of Data

All appropriate sections of the case report form (CRF): (See appendix) will be completed by the coordinator, viewed and signed by the prinicipal investigator and entered into the database within two weeks following the subject's discharge for the index procedure. The follow-up forms will be completed within a timely fashion after follow-up.

Study monitors designated by the sponsor will review the information documented in the CRF to verify that the recorded information is consistent with the medical record or other source documents and that input of this information into the data base is accurate. Errors or incomplete data will be rectified. All information will be treated as confidential. The following individuals will have full access to the data: Principal investigator, clinical

coordinator, statistician Co-investigators, vascular technicians, Core Lab personnel and study monitors will have access on an as needed basis.

Table 2. Adverse Event Definitions and Categorizations

Adverse Event	Any undesirable medical occurrences in a subject whether or not it is related to the study device, procedure or study requirements that is identified or worsens during the clinical study	
Major Adverse Event	A primary safety endpoint adverse event defined as Sizlagyi Grade III infection of the randomized incision and all-cause mortality	Grade III Szilagyi infection of the randomized incision All-cause mortality
Serious Adverse Event	Any adverse event that results in death, is life threatening, requires > 24 hour in-patient hospitalization, or prolongation of an existing hospitalization, requires intervention to prevent permanent impairment/damage or results in persistent or significant disability/incapacity	Myocardial Infarction Congestive Heart Failure Pulmonary Embolus Respiratory Failure Stroke Cardio/Pulmonary Arrest Thirty day hospital readmission for Grade II or III Szilagyi infection of the randomized incision
Unanticipated Adverse Event	Any serious adverse event leading to injury, illness or death of a subject not previously identified in nature, severity or degree of incidence in this protocol, literature or application (including a supplementary plan or application) that may be directly related to use of the device	

Table 3. Procedure Related Categories for Adverse Events

Procedure Related Adverse Event	AE that have a strong temporal relationship to the procedure and an alternative etiology is unlikely
Probably Procedure Related Adverse Event	AE that have a strong temporal relationship to the procedure and an alternative etiology is less likely than the potential relationship to the procedure
Probably–Not Procedure Related Adverse Event	AE that have minimal or no temporal relationship to the procedure and/or a more than likely alternative etiology
Not Procedure –Related Adverse Event	AE is due to the underlying disease state or concomitant medication or therapy and not caused by the procedure

Criteria for MAE and SAE

Serious Infection- Grade III Sizlagyi infection of the randomized incision

Myocardial Infarction- Per the ESC/ACC definition for acute, evolving or recent MI
Typical rise and gradual fall of Troponin or more rapid rise and fall of (CK-MB) biomarkers or myocardial necrosis with at least one of the following:

- Ischemic symptoms
- Development of pathologic Q weave on ECG
- ECG changes indicative of ischemia (ST segment elevation or depression) or coronary artery intervention (ie: coronary angioplasty
- Pathologic findings of an acute MI

Congestive Heart Failure- New or worsening shortness of breath confirmed by chest x-ray findings consistent with CHF and/or requiring unscheduled dialysis or fluid restriction

Cerebrovascular Accident- A neurologic deficit lasting more than 24 hours, or lasting less than 24 hours with a brain imaging study showing infarction.

Pulmonary Embolus- Embolus in the pulmonary vascular documented by CT findings

Respiratory Failure- Respiratory difficult requiring intubation

Cardio-Pulmonary Arrest- Loss of pulse and respiration. Need for cardio-pulmonary resuscitation to prevent impending death

Interim analysis will be performed of the primary and secondary endpoints after half of the subjects are enrolled and again when all subjects are enrolled. Anova will be used to determine differences in infection rates between the two treatment arms. The PI will verbally communicate the findings to Acelity with recommendations to continue, stop the study or make changes to the protocol if additional patients are needed to achieve statistical significance. These will be provided in writing within 4 weeks.

13.0 Withdrawal of Subjects

13.1 Circumstances under which subjects would be withdrawn without their consent

All study subjects have the right to withdraw their consent at any time during the study. However, withdrawal of a subject from the study can occur at the direction of the PI or the sponsor. Reasons for physician directed withdrawal could include but are not limited to: the subject's not adhering to the study follow-up protocol, the subject enrolls in another study which conflicts with this study's primary or secondary endpoints, or if the physician deems it is in the patients best interest for safety or welfare of the subject to withdraw.

13.2 Procedures for Termination

When possible the coordinator should obtain written documentation from the subject that wishes to withdraw his/her consent for future follow-up and contacts. If written documentation is unable to be obtained, all information regarding the subject's withdrawal

must be recorded in the subject's medical record. In addition, the appropriate CRF's must be completed for the subject and clear documentation of the subject's withdrawal be provided to the sponsor.

13.3 Procedures for partial withdrawal

Subject withdrawal is unlikely because other than randomization to intra-operative wound treatment, all care will be provided in the standard fashion and follow-up requirements (30 day follow-up with the surgeon or his/her designee) will be the same regardless of participation in the study. However, if the subject for any reason chooses to withdrawal from the study, procedure will be followed as in 13.2.

13.4 Lost to Follow-up

Every attempt will be made to have all subjects complete the follow-up schedule. A subject will not be considered lost to follow-up unless efforts to obtain compliance are unsuccessful. At minimum, three attempts by telephone via the most recent contact number should be made. If these efforts are unsuccessful, a certified letter from the PI should be sent to the subject's last known address. Attempts to contact the subject should be noted in the his/her medical record and on the study case report form.

14.0 Risks to Subjects

14.1 Foreseeable risks

Subjects in this study will be exposed to anesthetic, operative, and postoperative risks inherent to vascular surgery that requires groin incision.

- Anesthetic risk
  Anesthesia will be provided per the surgeon's preference and will not expose subjects to additional risk beyond that experienced during routine vascular surgery.
- Procedural risks
  Additional procedural risks will be nominal.
- Postoperative Risks
  Routine postoperative care will be provided and will pose no additional risk to subjects in either arm of the study.
- Follow-up Risks
  Standard intervals for follow-up will be employed and will pose no additional risk for subjects in either arm of the study
    - Clinical evaluation will be required at 30 days (25 -40) after surgery

14.2 Unforeseeable risks

Any serious adverse event leading to injury, illness or death of a subject not previously identified in nature, severity or degree of incidence in this protocol, literature or application (including a supplementary plan or application) that may be directly related to use of the device

15.0 Potential Benefits to Subjects

15.1 Potential benefits may be experienced in subjects randomized to:

Prevena Incision Management System

Patients randomized to Prevena may have lower rates of groin incision infection and and be less likely to require additional wound care treatment or longer hospital length of stay, or readmission to the hospital within 30days to manage infection. Need for home health care to manage wound infection may be lower and recuperation period shorter than if infection was to occur.

15.2 Potential benefits to hospital

Premptive use of Prevena may lower surgical incision infection rates and 30 day readmission rates for treatment of infected surgical incisions, key outcomes measures by which hospitals are evaluated. The associated reduction in surgical site infection rates may result in decreased spending, thus improving hospital contribution margin.

16.0 Vulnerable populations

16.1 Safeguards to protect the rights and welfare of vulnerable populations

Minors, pregnant women, prisoners or cognitively impaired adults will not be included in the study.

17.0 Community-Based Participatory Research

17.1 Community involvement in the design and conduct of the Study

The concept and design of the study was developed by the Principal Investigator in collaboration with members of the research team including co-investigators, study coordinators and a biostatistician. This project has the potential to change current standards of practice for surgical wound management in subjects who undergo vascular surgery that requires a groin incision. To the individual, this translates to a hospitalization less likely to be complicated by infection which equates to quicker recovery and positive hospital experience. Image is critical to hospitals in this competitive health care market as are quality outcomes such as low surgical infection rates and reduced hospital readmission. Both are likely to be associated with substantial financial savings and improved utilization of resources.

18.0 Sharing of Results with Subjects

18.1 Individual results of the clinical endpoint will be obvious to the subject and will be shared via verbal communication from the surgeon or his designee (resident, nurse practitioner, physician assistant). Results will be shared with the subject's primary care physician through written correspondence. Results of the study when available will be

shared verbally with the subject upon request.

19.0 Setting

19.1 Description of study site locations

The study will be conducted at 2 sites: Buffalo General Medical Center, Kaleida Health, and Erie County Medical Center (ECMC). The Veteran's Administration Medical Center of Buffalo (VAMC) may be added with an addendum if there is a need for additional numbers. This would require a separate IRB submission.

- The Buffalo General Medical Center is a___ bed University of Buffalo Medical School affiliated Tertiary Care Center. The Medical center boasts a new state of the art Global Vascular Institute and is a key provider of vascular care to Western New Yorkers. Over _____ vascular procedures are completed annually by five board-certified vascular surgeons, including 2 academic surgeons and the Division Chief of the Division of Vascular Surgery, Department of Surgery, University of Buffalo Medical School, and an internationally known vascular surgeon, trained internationally. The medical center is the premiere training site for the University's Vascular Fellowship and Integrated Vascular Residency Programs accredited through the Accreditation Council of Graduate Medical Education.

19.2 Identification of potential study subjects

The nurse coordinator will identify potential study subjects through multiple- sources.

- The coordinator will monitor the office schedules of participating surgeons and identify patients having vascular surgery that requires groin incision as potential candidates.
    - The office staff of participating surgeons will be asked to notify the coordinator when scheduling a patient office visits for lower extremity intervention or aortic aneurysm repair likely to require a groin incision
- The coordinator will review the operating room schedule daily to identify potential subjects
- The coordinator will collaborate daily with the Vascular Fellow/resident to identify potential candidates on the Vascular Service or referred to the Vascular Service for surgery that may require groin incision.
    - Vascular Fellows/residents will be asked to notify the coordinator of potential study subjects

19.3 Location of Research procedures

Research procedures will be completed in the following areas

- Surgeon's exam room, patient hospital room or other private room in the hospital Patients may be screened for eligibility, consent obtained and randomized to a study arm in the surgeon's office, patient hospital room or other private room in the hospital.
- Operating Room

- Prevena (3 units) and Dermabond are both readily available in the OR supply area. The coordinator will ensure that there continues to be an adequate supply to allow for randomization. Both products are also used for other procedures, both vascular and other surgical interventions.

- The Clinical coordinator's office, participating surgeon's office, medical record department, hospital surgical unit
  These areas may be used for collecting and in-putting data.
  The aforementioned precautions will be used to assure patient confidentiality

19.4 Community Advisory Board
There will be no community advisory board

19.5 Research conducted outside of the organization and its affiliates
This study will not involve any research outside of the designated participating sites.

20.0 Resources Available

20.1 Qualifications of staff:

Lead Principal Investigator:	Linda M. Harris, MD FACS, Division Chief: Division of Vascular Surgery, University of Buffalo Medical School.
Co-Investigator:	Maciej L. Dryjski, MD, PhD, FACS, Director
Sub-Investigators:	Gregory S. Cherr, MD, FACS: Attending Vascular Surgeon Buffalo General Medical Center James Lukan, MD, FACS: Director AV Access Center, ECMC Raphael Blochle, MD: Attending Vascular Surgeon, ECMC G Richard Curl, MD Sonya Noor, MD Ivan Dominguez, MD
Study Consultant Protocol, Case Form Data Base Development Statistical Assistance	Monica S. O'Brien-Irr, MS, RN; Vascular Research NP Department of Surgery
Biostatistician:	Alan Hutson, PhD, Founding and Current Chairman; Department of Biostatistics, School of Public Health and Health Related Professions; University of Buffalo
Study Coordinator:	A medical health professional with experience in coordinating the daily operations of clinical research trials and oversight of research assistants will be assigned

Research Assistant: A medical health professional with experience in assisting the clinical coordinator with daily operations of clinical trial will be assigned

20.2 Feasibility of recruiting subjects

One hundred and forty subjects will be enrolled in this study: seventy in each arm. Recruitment should be achievable over a 12 month period because on average 484 lower extremity revascularizations and 100 abdominal aortic aneurysm repairs are performed annually at Buffalo General Medical Center. While most of these procedures are completed by endovascular approach (EVAR, EVI), access by groin cut-down is necessary in 25% of EVAR and 10% of EVI which would provide approximately 204 potential candidates, nearly a third more subjects than necessary to meet study enrollment requirements.

20.3 Time necessary to conduct the research project

The projected completion time for the study is 18-24 months allowing a minimum recruitment period of 12 months with an additional 6-9 months if necessary and 3-6 months for data analysis, write-up and study closure.

Anticipated Personnel time requirements

- 1/4 FTE Study Consultant for development of protocol and case report forms, statistical analysis, preparation of manuscript and slide presentation
- 1/2 FTE clinical coordinator for project oversight
- 1 FTE research assistant for start-up, patient screening, data collection , entering of data and maintenance of the data base, study closure
- 10-20 hours Bio-statistical consultation

20.4 Facilities

Please refer to 19.1

20.5 Availability of medical or psychological resources for study subjects.

It is anticipated that psychological counseling will be not be required due to subject participation in the study since additional psychological risk associated with study involvement should be none or minimal.

The surgeon performing the vascular surgery will be available to subjects for evaluation and treatment of any surgical or postoperative complication that may arise from the procedure, or during the follow-up period.

20.6 The sponsor or a representative of the sponsor will conduct a training session with each Principal investigator and his/her staff to review the protocol, instructions for use of the Prevena Incision Management System, case report forms (CRFs), the informed consent process, IRB/EC involvement and guidelines, responsibilities and obligations, reporting requirements and general guidelines for good clinical practice.

21.0 Prior Approvals

21.1 Prior to enrolling subjects at the investigational site, the following documents will be provided to the sponsor:

- IRB/EC approval for the Clinical Protocol
- IRB/EC approval for the Principal Investigator to conduct the study
- IRB/EC and sponsor approved Consent Form for the study
- Investigators Curriculum Vitae (CV)
- Financial Disclosures of the Principal Investigators and sub-investigators
- Signed Investigator Agreement and if applicable, Sub-Investigaors Agreements
- Training log documenting each participating surgeon has been trained on the Prevena Incision Management System.
- Training log documentation to verify that appropriate study staff have been trained on the protocol, system, CRFs and study conduct.

22.0 Recruitment Methods

22.1- 22.4 Details of Patient Recruitment

The nurse coordinator will identify potential study subjects through multiple- sources.

- The coordinator will monitor the office schedules of participating surgeons and identify patients referred for lower extremity revascularization or AAA repair as potential candidates.
    - The office staff of participating surgeons will be asked to notify the coordinator when scheduling patient office visits or surgery for lower extremity revascularization or AAA repair
- The coordinator will review the operating room schedule daily to identify potential subjects
- The coordinator will collaborate daily with the Vascular Fellow/resident to identify potential candidates on the Vascular Service or referred to the Vascular Service for lower extremity revascularization or AAA repair.
    - Vascular fellows/residents will be asked to notify the coordinator of potential study subjects

22.5 Payments to Subjects

Subjects will not receive monetary compensation for this study.

23.1 Local Accrual of Subjects

All subjects will be accrued locally

23.2 Screen Failures

Screen failure will not be an issue with subject recruitment as there are few exclusion criteria for this study. The most likely reason for nonparticipation would be patient refusal. All screen failures will be noted on a log with the reason documented

24.0 Confidentiality

24.1 - 24.5 Procedures to assure maintenance of confidentiality, storage, access and transmission of data

The data will be collected by a single nurse coordinator with vascular surgery experience, who has received training on the case report forms developed for use in this study. The coordinator will also be trained to enter information from the case report form into a database set up in SPSS on a password protected PC kept in a locked office. All protected health information on the database will be de-identified. Subjects will be assigned a study number at time of randomization. The case report forms which contain patient identified protected health information will be kept in a locked cabinet within the coordinator's locked office. A master list of the patient name, DOB, hospital medical record number and study number to allow accurate linking of follow-up data to the index case will also be kept in a locked cabinet in the locked coordinator's office. Only personnel listed in the study protocol will have access to the data which will be restricted to an as needed basis. The subjects' CRF will be retained for the required 3 year period following the study and the disposed of per institutional HIPPA policy.

25.0 Provisions to Protect the Privacy Interests of Subjects

25.1 Steps to protect subject's privacy interest

At time of recruitment, potential subjects will be made aware of the need for study personnel to review their medical record, surgeon office record, vascular laboratory results for pertinent medical information following enrollment in the study through 30 days (25-40) following surgery but the review will be restricted to an as needed basis. Subjects will be informed of efforts to maintain confidentiality of protected health information. Only subjects who are agreeable to these terms will be enrolled. If during the study period, the subject wishes to restrict interaction with a particular study member or limit that individual's access to his/her protected health information and the situation can not be resolved, the subject should submit a written request to the PI. This will be noted in the subject's medical record and be included in his/her CRF. Every reasonable effort will be made to comply with the subjects request. If this is not feasible, the subject will be withdrawn from the study and missing data will be censored.

25.2 Assuring the Subjects Ease

Study enrollment is unlikely to cause any greater patient uneasiness beyond that which would be naturally experienced when an individual requires lower extremity revascularization or repair of AAA. Documentation of the patients pertinent past medical history would be the same regardless of study enrollment as would preoperative testing and physical examination. The study will be explained in understandable terms. The subject will be assured that participation is voluntary and decision not to participate will not in any way impact his/her care. The subject will be treated respectfully at all times and given ample opportunity to ask questions. Study personnel will assure that all questions are adequately answered prior to enrollment.

25.3 The research team will be permitted to access any source of information on a subject (ie. medical record, hospital financial record, surgeon office record, vascular laboratory results) on an as needed basis.

26.0 Research Related Injury: Compensation

26.1 This research poses only minimal risk to patients beyond that associated with routine lower extremity revascularization or AAA repair. Both Prevena and Dermabond are currently being used in vascular patients with groin incisions. Allergic reaction which is uncommon for either Prevena or Dermabond could be a potential risk. We will limit this through thorough screening of allergies to adhesives, formaldehyde, cyancoacetate and silver prior to enrollment. If the subject does incur a research related injury, care related to that injury will be provided, but there will be no additional compensation, as both are commercially available, and FDA approved for the planned procedures.

27.0 Economic Burden to Patient

27.1 Subjects will incur no additional expense as a result of participation in the study. Hospitalization and first postoperative follow-up will be covered by the subject's insurer.

28.0 Consent Process

28.1- 28.20

Informed consent will be obtained from all subjects prior to enrollment by one of the following study personnel: coordinator, participating surgeon, co-investigator or PI. SOP: Informed Consent Process for Research (HRP-090) will be used. The subject may be consented in the surgeon's office, patient hospital room or another private room within the hospital. Consent will be obtained after the subject has been provided information concerning the study and has had all questions satisfactorily answered. Subjects who are uncertain regarding participation will be given additional time to deliberate. The study coordinator will contact the individual within three days to ascertain the subject's decision. Non-English speaking individuals will be recruited. The likely language would be Spanish, due to the Hispanic population in Western New York. A certified Spanish speaking hospital interpreter will be used to provide information on the study and assist in obtaining informed consent. The consent form and other written materials will be provided in Spanish. Minors, cognitively impaired adults, prisoners and adults unable to give consent will not be included in the study.

29.0 Process to document Consent in Writing

29.1 Consent Process

SOP: Written Documentation of Consent (HRP -091) will be used to document consent.

30.0 Drugs and Devices

30.1 Storage and Handling of study device

The Prevena Incision Management System and Dermabond will be stored in the Operating Room. All participating surgeons will be trained on the system and study protocol.

30.2 IND/IDE/Abbreviated IDE

The Prevena Incision Management system received FDA approval for Use. Additional FDA approval is not required for this study

31.0 Protocol Amendments

31.1 Procedure for amending the protocol

This protocol is to be followed exactly and will only be altered by written amendments. Administrative changes that do not affect the patient benefit/risk ratio (ie: editorial changes for clarity) may be made without further approvals. Any change that would require alteration in the Informed Consent form must receive approval from Acetily and the IRB at the respective study sites prior to implementation. Following approval, the protocol amendments will be distributed to all protocol recipients with instructions to amend the protocol.

32.0 Definitions

Adverse Event Definitions

Adverse Event	Any undesirable medical occurrences in a subject whether or not it is related to the study device, procedure or study requirements that is identified or worsens during the clinical study
Major Adverse Event	A primary safety endpoint adverse event defined as thrombosis of the AV fistula, fistula re-intervention and all-cause mortality
Serious Adverse Event	Any adverse event that results in death, is life threatening, requires > 24 hour in-patient hospitalization, or prolongation of an existing hospitalization, requires intervention to prevent permanent impairment/damage or results in persistent or significant disability/incapacity
Unanticipated Adverse Event	Any serious adverse event leading to injury, illness or death of a subject not previously identified in nature, severity or degree of incidence in this protocol, literature or application (including a supplementary plan or application) that may be directly related to use of the device

Allergic Reaction: Allergic reaction which could result in nausea, rash, wheezing, edema induced thrombotic events, urticarial or shock.

Aneurysm: A localized, pathologic, blood filled dilation of a blood vessel caused by weakening in the vessel wall.

Artery Perforation: Extravasation of a small quantity of blood outside the arterial adventitial layer.

Artery Rupture: Large transmural disruption of a vessel with gross extravasation and hemorrhage.

As-Treated Analysis: An "As Treated" analysis is one in which all participants in a study are analyzed according to the treatment received , regardless of the initial assignment and regardless of the amount of follow-up.

Bleeding: Blood loss resulting from surgery that may require transfusion of blood products.

Cardio-Pulmonary Arrest: Loss of pulse and respiration. Need for cardio-pulmonary resuscitation to prevent impending death

Concomitant Medication: Medication use related to the study, including antibiotics aspirin, NSAIDs, steroids.

Congestive Heart Failure:

Acute: New or worsening shortness of breath confirmed by chest x-ray findings consistent with CHF and/or requiring unscheduled dialysis or fluid restriction.

Established or History of CHF: New York State Heart Failure Classification

Class	Description
Class I	No physical limitations and is Asymptomatic
Class II	Mild symptoms while doing light exercise or activities of daily living
Class III	Difficulty doing simple activities of daily living
Class IV	Frequently bed or chair ridden for most of the day and is too weak and short of breath to do simple activities

Death: Termination of Life

Device Malfunction: Defined as a malfunction in the Prevena Incision Management System such that it did not perform its intended function when used in accordance with the *Instructions for Use.*

Device-Relatedness Categories of Adverse Events:

Device Related Adverse Event	AE that have a strong temporal relationship to the presence or performance of the device/system and an alternative etiology is highly unlikely
Probably Device Related Adverse Event	AE that have a strong temporal relationship to the presence or performance of the device/system and an alternative etiology is less likely than the potential relationship to the device/system
Probably–Not Device Related Adverse Event	AE that have minimal or no temporal relationship to the presence or performance of the device/system and/or a more than likely alternative etiology exists
Not Procedure –Related Adverse Event	AE is due to the underlying disease state or concomitant medication or therapy and not caused by the device/system

Device Success: Ability to deploy the Prevena Incision Management System as intended at the treatment site.

Diabetes (History of): Defined as subjects who have been diagnosed with either Type I or Type II diabetes and are currently diet controlled, taking oral hypoglycemic or insulin.

Discharge: The time-point in which the subject is released from the admitting hospital, transferred to another facility or expired.

Dissection: Intimal disruption of the vessel wall.

Embolus/Embolization: Obstruction of a blood vessel by a foreign substance (air, plaque debris or blood clot).

Emergent Surgical Revascularization: Surgery performed on an urgent or emergent basis.

Enrollment: The subject is enrolled after he/she has signed the informed consent and has been determined to meet all the inclusion criteria and no exclusion criteria.

Fever: An increase in internal body temperature to levels above normal: (37° C or 98.6° F).

Hematoma: Localized mass of extravasated blood.

Hemorrhage: Bleeding requiring hospitalization, repeat procedure, operation or Transfusion.

Hypertension: Increase in the systolic blood pressure over 140 mm Hg or a diastolic blood pressure above 90 mm Hg.

Hypotension: Fall in systolic blood pressure that requires treatment with vasopressors, inotropic agents or fluid resuscitation.

Infection: Caused by bacterial or viral sources and produces an immunologic response resulting in inflammation, redness, swelling heat, pain or dysfunction of the organ involved and elevation of the white blood count. Infection in this study will be classified according to Szilagyi wound grade: 0= No signs of infection, I= Infection limited to the dermis, II= Infection involving the subcutaneous tissue, but not the arterial graft, III= Infection which involves the arterial graft.

Intention-to-treat Analysis: An intention to treat analysis is one in which the data from all participants in the study are analyzed according to the allocated treatment regardless of the treatment received.

Myocardial Infarction (MI): Per the ESC/ACC definition

Acute, evolving or recent MI

Typical rise and gradual fall of Troponin or more rapid rise and fall of (CK-MB) biomarkers or myocardial necrosis with at least one of the following:

- Ischemic symptoms
- Development of pathologic Q weave on ECG
- ECG changes indicative of ischemia (ST segment elevation or depression) or coronary artery intervention (ie: coronary angioplasty
- Pathologic findings of an acute MI

Established MI or History of MI

Pathologic findings of a healed or healing MI

Physician directed subject withdrawal: Withdrawal of the subject from the study at the direction of the principle investigator. Reasons for physician directed subject withdrawal include but are not limited to: the subject not adhering to the study protocol requirements, the subject enrolls in another study that conflicts with this study's primary endpoints, or if the PI deems it is in the best interest for safety and welfare of the subject to withdraw.

Principal Investigator: Physician responsible for the overall clinical management of subjects enrolled at his/her institution. Assumes responsibility and accountability for the clinical team and for data obtained from each subject participating in the study. Assures compliance with the protocol, applicable laws and applicable regulations; ensure informed consents are signed and reviews an signs case report forms indicating that documents are accurate and complete.

Procedure-Relatedness Categories for Adverse Events:

Procedure Related Categories for Adverse Events

Procedure Related Adverse Event	AE that have a strong temporal relationship to the procedure and an alternative etiology is unlikely
Probably Procedure Related Adverse Event	AE that have a strong temporal relationship to the procedure and an alternative etiology is less likely than the potential relationship to the procedure
Probably–Not Procedure Related	AE that have minimal or no temporal

Adverse Event	relationship to the procedure and/or a more than likely alternative etiology
Not Procedure –Related Adverse Event	AE is due to the underlying disease state or concomitant medication or therapy and not caused by the procedure

Protocol Deviation: Any divergence from the study protocol.

Pulmonary Embolus: Embolus in the pulmonary vascular documented by CT findings.

Reintervention: Any surgery or radiologic intervention on the index procedure.

Respiratory Failure: Respiratory difficult requiring intubation

Sepsis: Systemic inflammatory response to infection.

Shock: A condition in which the cells of the body receive inadequate amounts of oxygen to changes in perfusion most commonly secondary to blood loss or sepsis.

Stroke: A neurologic deficit lasting more than 24 hours, or lasting less than 24 hours with a brain imaging study showing infarction.

Study Coordinator: Employee at investigational site that assists the PI with study activities as delegated by the PI, including tracking subjects involved in the study, scheduling tests and follow-up visits, maintaining study records, completing and providing the CRF to the sponsor in a timely fashion.

Sub-Investigators: Physicians responsible for the study activities in coordination with the PI and in accordance with the protocol. A site is not required to have a co-investigator.

Thrombosis: Formation or development of blood clots that lead to occlusion of the artery or bypass graft

Transient Ischemic Attack: A neurologic deficit that lasts < 24 hours and if an imaging study is performed, there is no evidence of infarction.

Appendix A: Contacts

Sponsor:
Acelity

Principal Investigator (PI):
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Appendix B: References

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Appendix C: Consent Form