Clinical Study of the WoundCare360 SiteSeal Adjunctive Compression Device Following Interventional Endovascular Procedures – NCT03234894

Informed Consent Form:
Document Date: April 23, 2015

Site Seal Adjunctive Compression Device

Protocol: 15-003 April23, 2015

Woundcare 360
10900 S. Clay Blair Blvd.
Olathe, KS 66061

Patient ID: _____ DOB _____ (mm/dd/yyyy)

Patient Initials: _____ Visit Date: _____ (mm/dd/yyyy)

Eligibility

Please enter responses in space provided.

1. Has this patient met all eligibility criteria according to the protocol?
   a. YES NO

Inclusion Criteria

All must be "YES" to qualify.

Is patient's age between19 to 90?	YES	NO
Has patient given written informed consent for participation prior to the procedure?	YES	NO
Is this procedure an interventional procedure?	YES	NO
Is patient willing to undergo all study procedures and adhere to data collection and follow-up requirements?	YES	NO
Is patient a candidate for elective, non- emergent cardiac or peripheral vascular catheterization from the femoral artery approach?	YES	NO
Is patient willing to have a pre/post procedure ultrasound?	YES	NO

Exclusion Criteria

All must be "NO" to qualify.

Is patient's age <19 years?	YES	NO
Is patient's age > 90years?	YES	NO
Did the patient receive GP IIb/IIIa inhibitors?	YES	NO
Is patient able to provide written informed consent on his/her own behalf?	YES	NO
Is patient unable or unwilling to adhere to data collection and follow-up requirements?	YES	NO
Is the procedure emergency PCI?	YES	NO
Is the patient on dialysis?	YES	NO
Does the patient have a known diagnosis of fibromyalgia?	YES	NO

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Does the patient have acute coronary syndrome (i.e., unstable angina or myocardial infarction) ≤ 48 hours before this catheterization procedure?	YES	NO
Was the patient's systolic blood pressure < 90 mm Hg at the end of this catheterization procedure?	YES	NO
Is the patient immunocompromised?	YES	NO
Does the patient have pre- existing systemic infection or local infections at this access site?	YES	NO
Is the patient known or suspected to be pregnant, or is lactating?	YES	NO
Has the patient undergone prior or recent use of an intra- aortic balloon pump through the arterial access site?	YES	NO
Has the patient undergone prior vascular closure device use in the ipsilateral common femoral artery ≤ 30 days before this catheterization procedure?	YES	NO
Has the patient undergone prior use of manual or mechanical compression for closure in the ipsilateral common femoral artery ≤ 30 days before this catheterization procedure?	YES	NO
Did the patient require a re- puncture at a site previously punctured within 48 hours of this catheterization procedure?	YES	NO
Did the patient have an antegrade puncture in this catheterization procedure?	YES	NO
Did the patient have a puncture site believed to be in the profunda femoris artery, superficial femoral artery, or at the bifurcation of these arteries in this catheterization procedure?	Yes	NO
Was the patient's puncture tract angle > 55° in this catheterization procedure?	YES	NO
Is the patient suspected to have experienced a femoral artery back wall puncture or who underwent > 1 femoral artery puncture during this catheterization procedure?	YES	NO

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Does the patient have significant anemia (hemoglobin < 10 g/dL, Hct < 30%)?	YES	NO
Does the patient have a known bleeding disorder, including thrombocytopenia (platelet count < 100,000 cells/μL), thrombasthenia, hemophilia, or von Willebrand's disease?	YES	NO
Did the patient have systolic blood pressure > 180 mm Hg or diastolic blood pressure > 110 mm Hg at the end of this catheterization procedure, unless systolic and/or diastolic pressure was lowered by pharmacological agents prior to the end of this catheterization procedure?	YES	NO
Did the patient have a baseline INR > 1.5 (e.g., on warfarin therapy)?	YES	NO
Was the patient's ACT > 300 seconds at the end of this catheterization procedure?	YES	NO
Did the patient undergo administration of low molecular weight heparin (LMWH) within 8 hours of this catheterization procedure?	YES	NO
Is continued heparin or other anticoagulant/antiplatelet therapy planned for this patient (with the exception of glycoprotein IIb/IIIa inhibitor therapy) during the first few hours following this catheterization procedure?	YES	NO
Did the patient have a complication or complications at the femoral artery access site during the catheterization procedure including bleeding, hematoma, intraluminal thrombus, pseudoaneurysm, or arteriovenous fistula?	YES	NO
Does the patient have an ipsilateral or bilateral lower extremity amputation(s)?	YES	NO
Is the patient known to require extended hospitalization (e.g., patient is undergoing cardiac surgery)?	YES	NO

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Does the patient have a planned endovascular procedure within the next 30 days after this catheterization procedure?	YES	NO
Is the patient currently participating in another investigational study that has not concluded the follow- up period?	YES	NO
Has the patient already participated in this IDE study?	YES	NO
Is it known that the patient cannot adhere to or complete the study for any reason including but not limited to geographical residence or life- threatening disease?	YES	NO

Signature Date (mm/dd/yyyy)

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Patient ID: _____ DOB _____ (mm/dd/yyyy)

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Demographics

1. Date of Birth: _____ (dd/mm/yyyy)
2. Gender: MALE FEMALE
3. Race
    a. Caucasian
    b. Hispanic
    c. Asian
    d. Black
    e. Other
4. Height: _____ (ft/inches)
5. Weight: _____ (lbs)
6. BMI: _____

Procedure-Related Data

1. Procedure Type:
    a. CARDIAC PERIPHERAL VASCULAR
2. Access Site Location
    a. RIGHT LEFT
3. Size of the introducer sheath:
    a. _____Fr.
4. Intra-procedure anticoagulants:
    a. _____
5. Intra-procedure antiplatelet agents:
    a. _____
6. Previous arterial puncture site in the ipsilateral common femoral artery >30days before this catheterization procedure:
    a. YES NO
7. Systolic blood pressure
    a. _____ mm Hg

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8. Diastolic blood pressure:
    a. _____ mm Hg
9. Peripheral arterial disease:
    a. YES NO
10. Activated clotting time (ACT) at the end of this catheterization procedure:
    a. _____ seconds
11. Pre-procedural anticoagulants:
    a. _____
12. Pre-procedure antiplatelet agents (including GP IIb/IIIa inhibitors):
    a. _____
13. Post-procedural GP IIb/IIIa inhibitors
    a. _____

MEDICATION HISTORY

PREVIOUS DIAGNOSTIC/INTERVENTIONAL ENDOVASCULAR PROCEDURES

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Catheterization Procedure Data

1. Procedure Date: _____ (mm/dd/yyyy)
2. Pre-procedure Duplex Ultrasound?
    a. YES NO
3. Procedure Start Time:
    a. _____ (24hour)
4. Procedure End Time:
    a. _____ (24hour)
5. Post procedure Duplex Ultrasound?
    a. YES NO
6. Time of SiteSeal removal:
    a. _____ (24hour)
7. Calculated time to deploy device without visible bleeding at the access site (TTH):
    a. _____
8. Time of first standing & walking 20ft without evidence of arterial re-bleeding from the access site (TTA):
    a. _____ (24hour)
9. Calculated Time To Ambulation (TTA):
    a. _____ (24hour)
10. Adverse events:
    a. YES NO
    b. _____
11. Patient Discomfort:
    a. Patient discomfort @ discharge from the catheterization lab:
        i. _____ Patient comfort level (1-10) with 10 being intense pain
    b. Patient discomfort @ 24 hours after this procedure:
        i. _____ Patient comfort level (1-10) with 10 being intense pain

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Primary Post Procedure Endpoints

1. **Nerve Puncture**
    a. Was there an involuntary leg muscle contraction and an auditory response at the time of placing the device?
        i. YES NO
2. **Femoral Artery Laceration**
    a. Was there common femoral artery laceration (or needle penetration) with resultant bleeding or hematoma > 6 cm diameter?
        i. YES NO

Secondary Endpoints

Major Complications @ 30day follow-up

1. Vascular repair or the need for vascular repair (via surgery, ultrasound-guided compression, transcatheter embolization, or stent-graft) – Y N
2. Access site-related bleeding requiring transfusion – Y N
3. Any new ipsilateral lower extremity ischemia documented by patient symptoms, physical exam, and/or decreased or absent blood flow on lower extremity angiogram - Y N
4. Surgery or the need for surgery for access site-related nerve injury – Y N
5. Permanent (lasting > 30 days) access site-related nerve injury – Y N
6. Access site-related infection requiring intravenous antibiotics and/or extended hospitalization – Y N

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Minor Complications @ 30day Follow-up

1. Non-treated pseudoaneurysm documented by ultrasound – Y N
2. Non-treated arteriovenous (AV) fistula documented by ultrasound – Y N
3. Pseudoaneurysm treated with ultrasound-guided thrombin injection or ultrasound-guided fibrin adhesive injection – Y N
4. Access site hematoma greater than or equal to 6 cm – Y N
5. Access site-related bleeding requiring greater than 30 minutes to achieve hemostasis – Y N
6. Late (following hospital discharge) access site-related bleeding – Y N
7. Ipsilateral lower extremity arterial emboli – Y N
8. Transient loss of ipsilateral lower extremity pulse – Y N
9. Ipsilateral deep vein thrombosis – Y N
10. Access site-related vessel laceration – Y N
11. Transient access site-related nerve injury – Y N
12. Access site wound dehiscence – Y N
13. Localized access site infection treated with intramuscular or oral antibiotics – Y N