

National Trials **VIVA 1 - XCELL**

XCELL

<u>Trial Sponsor:</u>	VIVA Physicians, Inc.
<u>National Principal Investigator:</u>	James D. Joye, DO
<u>Trial Name:</u>	Xpert™ nitinol stenting for Critically ischemic Lower Limbs
<u>Purpose:</u>	To evaluate the safety and performance of the Xpert™ stent in below-the-knee lesions as part of an overall treatment for infrapopliteal lesions in patients undergoing percutaneous intervention for chronic critical limb ischemia (CLI).
<u>Details:</u>	The study is a prospective, single-arm, multi-center registry to evaluate the Xpert™ stent in chronic CLI. Consenting subjects with chronic CLI, after meeting eligibility criteria, will have a baseline assessment including demographics, medical history, a baseline HRQoL and angiogram to document their baseline status. Obstructions in proximal segments may be treated according to local norms, however, all inflow vessels treated must have antegrade flow with adequate or rapid clearance of dye, via visual estimate, prior to study stent placement in the target vessel. When all anatomic criteria are met, a single infrapopliteal vessel and target lesion is treated with an Xpert™ stent(s). Enrollment will be n=140 from up to 20 sites in the United States, with a maximum of 60 subjects in Rutherford Category 4 and the balance from Rutherford Category 5 and 6. Follow up visits at 30 days, 3, 6, and 12 months. The 6 month visit will include a follow up angiogram of the target vessel.

Eligibility

Ages Eligible for Study: Greater than 18 years and less than 90 years

Genders Eligible for Study: Both

Clinical Inclusion Criteria

- Age > 18 years and < 90 years
- Subject or subject's legal representative have been informed of the nature of the study, agrees to participate and has signed an IRB approved consent form.
- Female subjects of childbearing potential have a negative pregnancy test ≤7 days before the procedure and are willing to use a reliable method of birth control for the duration of study participation.
- Subject understands the duration of the study and its follow up visit requirements.
- As applicable, subject has documented wound care ≥ 2 weeks prior to enrollment, specifically where and/or who is performing the wound care and the type of wound care performed.

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- Subject has documented chronic critical limb ischemia in the target limb for two weeks with Rutherford Category 4, 5 or 6.
- Subject must have **one** of the following non-invasive test results of the target limb within two weeks of enrollment:
 - ❑ Pulse Volume Recording (PVR) of 0, 1 or 2 or
 - ❑ Pulse Plethysmography (PPG) non-pulsatile or
 - ❑ TcPO₂ < 30mmHg or
 - ❑ Ankle pressure < 40mmHg

Anatomic Inclusion Criteria

- Stenotic (> 50%) or occlusive atherosclerotic disease of the infrapopliteal arteries
- Reference vessel diameter between 2.0 and 5.0 mm
- Target lesion access must be trans-femoral approach (no popliteal or pedal)
- Inflow is unobstructed between the iliac and distal popliteal artery, generally characterized by no stenoses > 50% [Assessment may be made after interventions proximal to the target lesion.]
- All inflow vessels treated in the target limb, via visual estimate, have antegrade flow with adequate or rapid clearance of dye.
- Target solitary infrapopliteal vessel, stenotic or occluded, with angiographically visible above-the-ankle reconstitution (proximal to the inferior cortical margin of the talus bone) and with a total estimated stented length ≤15 cm. In the event of a patent non-index tibial vessel, the index artery must directly perfuse the foot or the wound area (i.e., anterior or posterior tibial artery)

Clinical Exclusion Criteria

- Life expectancy < 12 months
- CVA or MI within < 3 months prior to enrollment
- Inability to walk (walking with assistance is acceptable)
- Previous bypass surgery to target limb < **30 days prior to study procedure**
- Known allergies or sensitivities to heparin, aspirin, other anti-coagulant/antiplatelet therapies, and nitinol
- Known allergy to contrast media that cannot adequately be pre-medicated prior to study procedure
- Serum Creatinine ≥ **2.5 mg/ dL**
- Untreatable bleeding diatheses
- Hypercoagulable state
- Systemic infection present or suspected
- Untreatable osteomyelitis present or which may be so severe that limb salvage is unlikely
- Enrolled in another investigational device, drug, or biologic study
- Subject is breast-feeding or plans to become pregnant
- Acute thrombus at the lesion site(s)

Anatomic Exclusion Criteria

- Target lesion can only be accessed via popliteal or pedal approach
- Previously implanted stent in target infrapopliteal vessel
- Target lesion is within or adjacent to an aneurysm
- Inflow limiting lesions untreatable in this procedural setting
- Angiographic evidence of intra-arterial thrombus or atheroembolism from inflow treatment

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- A segment/portion of a study stent will be deployed distal to the inferior cortical margin of the talus bone
- A segment/portion of a study stent will be deployed in a pedal vessel
- No angiographic evidence of a patent pedal artery
- No angiographically identifiable patent distal tibial artery