



Prairie

EDUCATION & RESEARCH COOPERATIVE

326 North 7th Street, Suite 101, Springfield, IL 62701 • (217) 544-6464 X 66044 • Fax: (217) 522-1206

VIABAHN

<u>Trial Sponsor:</u>	W.L.Gore & Associates
<u>Principal Investigator:</u>	Jeffrey Goldstein, MD
<u>Trial Name:</u>	GORE VIABAHN Endoprosthesis Versus Bare Nitinol Stent in the Treatment of Long Lesion (>8cm) Superficial Femoral Artery Occlusive Disease
<u>Purpose:</u>	To evaluate the performance of the GORE VIABAHN® Endoprosthesis compared to a bare nitinol stent for the treatment of SFA occlusive disease in long lesions.
<u>Details:</u>	This is a multicenter, prospective, randomized study with clinical and radiographic follow-up for three years post-procedure. Approximately one hundred fifty subjects will be enrolled and randomized into one of two study treatment groups.
<u>Phase:</u>	Phase IV
<u>Study Type:</u>	Interventional
<u>Study Design:</u>	Treatment, Randomized, Open Label, Active Control, Parallel Assignment
<u>Study Arms:</u>	2
<u>Expected Enrollment:</u>	150
<u>Study Start:</u>	September 2005

Primary Outcome Measures:

- Efficacy: Primary patency at three years post-procedure
- Safety: Composite of major procedural (30-day) adverse events

Secondary Outcome Measures:

- Primary assisted patency
- Secondary patency
- Technical success
- Target vessel revascularization
- Target lesion revascularization



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- Clinical Success
- Primary composite safety and efficacy endpoint
- Quality of Life subject self-assessments
- Change in ankle-brachial index (ABI)
- Alternate Peak Systolic Velocity Ratios
- Quantitative angiographic assessment of patterns of restenosis
- Occurrence of stent fracture

Eligibility:

Ages Eligible for Study: 21 years and above

Genders Eligible for Study: Both

Inclusion Criteria:

- Lifestyle-limiting claudication or rest pain
- Subject (or their legal guardian) has read, understood and provided written informed consent
- At least 21 years of age.
- Quality of life questionnaires completed
- Noninvasive lower extremity arterial studies within 45-days prior to study procedure
- If applicable, staged ipsilateral vascular procedure \geq 14-days prior to study procedure.
- If applicable, vascular treatment on non-study leg for bilateral claudication \geq 14-days prior to study procedure
- Male, infertile female, or female of child bearing potential practicing an acceptable method of birth control with a negative pregnancy test
- Projected life expectancy of greater than three years.
- The ability to comply with protocol
- Angiographic and Lesion Requirements meets protocol criteria

Exclusion Criteria:

- Untreated flow-limiting aortoiliac occlusive disease.
- Any previous stenting or surgery in the target vessel.
- Subjects with arterial lesions requiring treatment with device diameters other than 6, 7, or 8 mm.
- Severe ipsilateral common femoral/profunda disease requiring surgical intervention.
- Femoral or popliteal aneurysm.
- Non-atherosclerotic disease resulting in occlusion
- Tibial artery disease requiring treatment.
- Prior ipsilateral femoral artery bypass.
- Severe medical comorbidities
- Popliteal artery vascular access at any time during procedure.



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- Antegrade and retrograde vascular access on the same common femoral artery at the time of the SFA intervention.
- Serum creatinine > 2.5 mg/dL within 45 days prior to study procedure.
- Major distal amputation
- Septicemia.
- Any previously known coagulation disorder
- Morbid obesity or operative scarring that precludes percutaneous approach (physician's discretion).
- Contraindication to anticoagulation or antiplatelet therapy.
- Known allergies to stent/stent-graft components.
- History of prior life-threatening reaction to contrast agent.
- Currently participating in another clinical research trial
- Current peritoneal or hemodialysis