

# **National Trials** **VIVA III - FORTRESS**

## **FORTRESS**

**Trial Sponsor:** VIVA Physicians, Inc.

**National  
Principal Investigator:** John Laird, MD

**Trial Name:** Renal Artery Embolic Protection Study; A Prospective, single-arm feasibility trial of renal artery distal protection using the Lumen Biomedical FiberNet® Embolic Protection System in patients with atherosclerotic renal artery stenosis

**Purpose:** To evaluate the procedural safety and filter efficiency of the FiberNet® Embolic Protection System when used in conjunction with the Boston Scientific Express SD Stent System for primary stenting of ostial atherosclerotic renal lesions in patients with atherosclerotic renal artery stenosis.

**Details:** This trial is a prospective, multi-center, non-randomized, single-arm study to demonstrate the safety and filter efficiency of the Lumen Biomedical FiberNet® Embolic Protection System during the performance of primary renal stenting in the treatment of patients with a high grade (> 70%) ostial atherosclerotic renal lesion(s). A total of up to 20 subjects will be enrolled at up to 10 U.S. sites. Follow-up visits will be at 30 days, 3 months and 6 months.

## **Eligibility**

**Ages Eligible for Study:** 18 – 85 years old

**Genders Eligible for Study:** Both

### **Clinical Inclusion Criteria**

1. Age  $\geq$  18 and  $\leq$  85 years.
2. 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.
3. Subject understands the duration of the study and it's follow up visit requirements.
4. Unilateral or bilateral atherosclerotic de novo renal artery stenosis (RAS) associated with any or all of the following:
  1. SBP >140 despite  $\geq$ 3 anti-hypertensive medications
  2. Estimated Glomerular Filtration Rate (eGFR)  $\geq$ 30- $\leq$ 70 cc/min calculated using the Modified Diet in Renal Disease (MDRD) formula
  3. Recurrent episodes of decompensated heart failure
  4. Recurrent episodes of "flash" pulmonary edema

### **Angiographic Inclusion Criteria**

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1.  $\geq 70\%$   $< 100\%$  renal artery stenosis (by visual estimate) involving unilateral, bilateral renal arteries or solitary renal artery.
2. Renal pole-to-pole length  $> 7\text{cm}$ .
3. Lesion  $\leq 15\text{ mm}$  from the aorto-ostial junction.
4. Renal artery reference lumen diameter  $\geq 3.5 - \leq 7\text{ mm}$  for FiberNet placement.

### **Clinical Exclusion Criteria**

1. Estimated life expectancy  $< 12$  months.
2. Estimated Glomerular Filtration Rate (eGFR)  $< 30\text{ cc/min}$ .
3. Renal pole-to-pole length  $< 7\text{cm}$  on side of diseased kidney.
4. No history of transplanted kidneys or polycystic kidney disease.
5. Uncontrolled hypercoagulability.
6. Known allergies or sensitivities to heparin, aspirin, other anti-coagulant/antiplatelet therapies, nitinol and stainless steel.
7. Known allergy to contrast media that cannot adequately be pre-medicated prior to study procedure.
8. Patient refuses possible temporary or permanent hemodialysis.
9. Refuses possible surgery for repair of access site or renal artery.
10. Known severe coronary or carotid disease likely to require surgical treatment after enrollment or during follow-up period.
11. Uncompensated congestive heart failure.
12. Current enrollment in any investigational study wherein patient participation has not been completed.
13. Cardiovascular surgical or cardiovascular interventional procedures (including, but not limited to, aortic, renal, cardiac, carotid, femoro-popliteal, and below the knee) within 30 days prior to enrollment in this study.
14. Planned or predicted cardiovascular surgical or interventional procedures outside of the affected renal artery (including, but not limited to, aortic, renal, cardiac, carotid, contralateral femoro-popliteal, and contralateral below the knee) within 30 days after entry into this study and prior to completion of the 30 day follow-up.
15. Pregnancy, breast-feeding or plans to become pregnant in female of child bearing potential.
16. Any patient who in the opinion of the investigator would not be a good candidate for enrollment.

### **Angiographic Exclusion Criteria**

1. Early bifurcation of the main renal artery preventing complete embolic protection of the kidney with the FiberNet.
2. Fibromuscular Dysplasia.
3. Presence of thrombus at the lesion site.
4. Non-ostial atherosclerosis (lesion  $> 15\text{mm}$  from the renal ostium).
5. Subintimal guidewire placement resulting in dissection of the renal artery or aorta, or perforation of the renal artery or aorta prior to deployment of the device.

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6. Severe calcification likely to prevent the passage of the device. -