

The Efemoral Vascular Scaffold System (EVSS) for the Treatment of Patients With Symptomatic Peripheral Vascular Disease From Stenosis or Occlusion of the Femoropopliteal Artery

NCT04584632

Status	RECRUITING
Phase	Not Applicable
Sponsor	Efemoral Medical, Inc.
Enrollment	100 participants

Key Eligibility Criteria

Inclusion (11)

- Symptomatic peripheral vascular occlusive disease (Rutherford-Becker Clinical Category 2-4)
 - Patient with life expectancy >36 months
 - Females of childbearing potential must have negative pregnancy test
 - Patient is able to provide informed consent
 - Patient agrees to undergo all protocol-required follow-up examinations and requirements at the investigational site.
- ... and 6 more (see full listing online)

Exclusion (32)

- Hemoglobin <9.0 g/dL
 - WBC $<3,000$ cells/mm³
 - Platelet count $<80,000$ cells/mm³ or $>700,000$ cells/mm³
 - Acute or chronic renal dysfunction with creatinine >2.5 mg/dl (176 μ mol/L)
 - Severe liver impairment as defined by total bilirubin $e3$ mg/dl or two times increase over the normal level of SGOT or SGPT
- ... and 27 more (see full listing online)

Locations (8 total)

Northern Health, Sydney, New South Wales, Australia
Canberra Hospital, Canberra, Australia
The Alfred Hospital, Melbourne, Australia
... and 5 more locations