Evaluation of the MAGNITUDE® Bioresorbable Drug-Eluting Scaffold in the Treatment of Patients With Below the Knee Disease in Australia

NCT06075940

Status	RECRUITING
Phase	Not Applicable
Sponsor	R3 Vascular Inc.
Enrollment	30 participants

Key Eligibility Criteria

Inclusion (28)

- Subject (or their legally authorized representative) has provided written informed consent prior to any study-related procedure, using the form approved by the Human Research Ethics Committee.
- Subject agrees not to participate in any other investigational device or drug study for a period of at least 12 months following the index procedure.
- Note: Questionnaire-based studies, or other studies that are non-invasive and do not require investigational devices or medications are allowed.
- Subject has symptomatic chronic limb-threatening ischemia, determined as Rutherford categories 4 or 5.
- Subject is e 18 years and d 90 years of age.

... and 23 more (see full listing online)

Exclusion (34)

- Subject with Body Mass Index (BMI) \< 18.
- Subject is pregnant or nursing. Subjects who plan pregnancy during the clinical investigation follow-up period may not be enrolled.
- Note: Subjects of child-bearing potential must have a negative pregnancy test d 28 days prior to the index procedure and agree to use contraception for 6 months.
- Estimated life expectancy \<1 year, in the opinion of the Investigator at the time of enrollment.
- Subject is permanently bedridden.

... and 29 more (see full listing online)

Locations (1 total)

Prince of Wales Hopsital, Randwick, New South Wales, Australia