Initial Feasibility Study of the STENTiT Resorbable Fibrillated Scaffold (RFS). The RFS is Intended to Restore Lumen Patency and Blood Flow to Infrapopliteal Arteries. The RFS is a Fully Electrospun Tubular Device With a Fibrillated Microarchitecture and Designed for Transcatheter Delivery

NCT07006467

Status	RECRUITING
Phase	Not Applicable
Sponsor	Stentit
Enrollment	10 participants

Key Eligibility Criteria

Inclusion (12)

- Subject must provide written informed consent prior to any clinical investigation related procedures.
- Subject is willing and able to comply with the study procedures, and follow-up schedule.
- Subject has Critical Limb Ischemia (CLI), Rutherford Becker Clinical Category 4 or 5
- Subject must be at least 18 years of age.
- Target lesion located in the tibioperoneal trunk, or 2/3 proximal part of the anterior tibial artery, posterior tibial artery or peroneal artery.

... and 7 more (see full listing online)

Exclusion (28)

- Subject is currently participating in another clinical investigation that has not yet reached the primary endpoint.
- Pregnant or nursing subjects or with planned pregnancy during the clinical investigation follow-up period.
- Presence of other anatomic or comorbid conditions, or other medical, social, or psychological conditions that, in the investigator's opinion, could limit the subject's ability to participate in the clinical investigation or to comply with follow-up requirements.
- Incapacitated individuals, as defined as persons who are mentally ill, mentally handicapped, or individuals without legal authority, are excluded from the study population.
- Subject has known hypersensitivity or contraindication to device material and its degradants (poly (L-lactide), poly (glycolic acid), lactic acid, and glycolic acid) that cannot be adequately pre-medicated. Subject has known contrast sensitivity that cannot be adequately pre-medicated.

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

Locations (1 total)

Medical Universiteit Graz, Graz, Austria