

IBS Titan™ Sirolimus-eluting Iron Bioresorbable Peripheral Scaffold System Clinical Trial

NCT05971394

Status	RECRUITING
Phase	Not Applicable
Sponsor	Biotyx Medical (Shenzhen) Co., Ltd.
Enrollment	100 participants

Key Eligibility Criteria

Inclusion (12)

- General criteria
- Subject between 18 and 85 years old.
- Subject who can understand the purpose of the trial, voluntarily participate in, and sign the informed consent form, and who are willing to participate until the 12 months follow-up.
- Subject has symptomatic Critical Limb Ischemia, Rutherford category 3-5.
- Subject requires primary treatment of de novo infrapopliteal lesions.
- ... and 7 more (see full listing online)

Exclusion (26)

- General criteria
- Severe renal insufficiency, hepatic dysfunction (Cr $>$ 2 times normal limit or renal dialysis, ALT or AST $>$ 5 times normal limit).
- Major amputation before index procedure or plan for major amputation.
- Any coagulation disorder.
- Lower extremity arteries surgery or thrombolytic therapy in the ipsilateral extremity in the past 6 weeks.
- ... and 21 more (see full listing online)

Locations (1 total)

Azienda Ospedaliero Universitaria Careggi, Florence, Italy