

Prospective, Multicenter, Single-Arm Observational Study to Confirm the Safety and Clinical Performance of the Oscar Peripheral Multifunctional Catheter for the Dilatation of Lesions in the Femoral, Popliteal and Infrapopliteal Arteries (BIO-OSCAR First)

NCT06758921

Status	RECRUITING
Sponsor	Biotronik AG
Enrollment	200 participants

Key Eligibility Criteria

Inclusion (13)

- Subject ≥18 years old
- Subject has provided written informed consent
- Subject has Rutherford classification 2 to 6
- Reference vessel diameter ≥2 and ≤7 mm
- Target lesion(s) has stenosis >70% by visual assessment
- ... and 8 more (see full listing online)

Exclusion (12)

- Subject has a single target lesion that involves both ATK and BTK segments.
- Subject not suitable for receiving endovascular procedures of lower limb arteries.
- Prior planned major amputation in the target limb (i.e., above the ankle).
- Subject with previous bypass surgery of target vessel.
- History of any open surgical procedure within the past 30 days.
- ... and 7 more (see full listing online)

Locations (16 total)

LKH Univ. -Klinikum Graz, Ambulanz für Angiologie, Graz, Austria
Onze Lieve Vrouweziekenhuis, Aalst, Belgium
AZ Saint Blasius, Dendermonde, Belgium
... and 13 more locations