Investigating the Safety and Clinical Performance of Eight iVascular Devices for Endovascular Intervention in Renal, Iliac or Femoral Arteries

NCT05902923

Status RECRUITING
Sponsor iVascular S.L.U.
Enrollment 209 participants

Key Eligibility Criteria

Inclusion (5)

- Corresponding to the CE-mark indications/contra-indications and according to the IFU of the device.
- Patient is \>18 years old.
- Patient understands the nature of the procedure and provides written informed consent prior to enrollment in the study.
- Target lesion(s) is/are located in renal, iliac or femoral arteries.
- Patient is eligible for treatment with the Oceanus 18 Balloon Dilatation Catheter and/or the Oceanus 35 Balloon Dilatation Catheter and/or the Luminor 18 Drug Coated Balloon and/or the Luminor 35 Drug Coated Balloon and/or the Restorer Peripheral Stent System and/or the iVolution pro Peripheral Self-Expanding Stent System and/or the iCover Covered Peripheral Stent System and/or the Sergeant Peripheral Support Catheter as described in IFU for each device.

Exclusion (6)

- Anatomy or size of vessels that will not allow appropriate usage of the investigational devices, following IFU of the investigational devices.
- Known contraindication and/or allergy to (a component of) an investigational device.
- Pregnant women and women with childbearing potential not taking adequate contraceptives or currently breastfeeding.
- Life expectancy of less than 12 months.
- Any planned surgical intervention/procedure within 30 days after the study procedure.

... and 1 more (see full listing online)

Locations (6 total)

CH Henri Duffaut, Avignon, France
Clinique Synergia Ventoux, Carpentras, France
Polyclinique Inkermann, Niort, France
... and 3 more locations