A Study to Evaluate the Safety and Effectiveness of the Rapidlink Device When Used in Patients Undergoing an Open Surgical Procedure to Repair the Aorta

NCT07078383

Status	RECRUITING
Phase	Not Applicable
Sponsor	Vascutek Ltd.
Enrollment	150 participants

Key Eligibility Criteria

Inclusion (6)

- Patient is aged 18 years or over on date of consent
- Written informed consent (from patient or a legally authorized representative) to participate in study, documenting willingness and ability to comply with all study procedures and study visits (unless an exemption for emergency cases has been IRB / EC approved)
- Patient's need for open surgical repair of the thoracic aorta using a Gelweave graft or a Thoraflex Hybrid device (AnteFlo or Plexus) in line with the applicable IFU
- Anticipated need to use Rapidlink for the repair or replacement of the LSA, LCCA and/or IA during the open surgical repair
- Patient has an 8-15 mm inner diameter (target SAV)

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

Exclusion (20)

- Patient does not have a clear landing zone equal to the implantable stent length which is free from stenosis, calcification or thrombus.
- Patient does not have a sealing zone free from tortuosity.
- Patient has significant angulation (\>79° with an internal radius of less than 6mm) for the full implantable stent length
- Patient cannot receive anticoagulation / antiplatelet therapy during or after the index procedure as per the protocol
- Patient has uncontrolled hypercoagulation

... and 15 more (see full listing online)

Locations (23 total)

Keck Medicine of USC, Los Angeles, California, United States
Cedars-Sinai Medical Center, Los Angeles, California, United States
University of Colorado Anschutz Medical Campus, Aurora, Colorado, United States
... and 20 more locations

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