

B-SAFER: Branched Stented Anastomosis Frozen Elephant Trunk Repair

NCT04747626

Status	RECRUITING
Phase	Not Applicable
Sponsor	Eric Roselli, M. D.
Enrollment	590 participants

Key Eligibility Criteria

Inclusion (4)

- At least 18 years of age
- Subject is willing and able to give written informed consent to participate in the study or the subject's legally authorized representative has given written informed consent for the subject to participate in the study.
- Expected life expectancy of greater than two years after repair
- Subject has aortic pathology and requires repair or replacement of multiple damaged or diseased segments of the thoracic aorta (at least one of the following condition): Thoracic aortic aneurysm considered at increased risk for rupture or complications, Acute aortic dissection requiring urgent repair, Congenital aortic disease requiring repair

Exclusion (8)

- Subject is unfit for open surgical repair involving circulatory arrest
- Subject is comatose or suffering from irreversible severe brain malperfusion
- Subject has known sensitivity to components of the devices
- Subject has an active systemic infection that, in the opinion of the investigator, would compromise the outcome of the surgical procedure
- Subject is enrolled in another active study and has received an investigational product (device, pharmaceutical or biologic) within 6 months prior to the date of the implant or has not reached the primary endpoint of the study
- ... and 3 more (see full listing online)

Locations (1 total)

Cleveland Clinic, Cleveland, Ohio, United States