

# Safety and Efficacy of Endovascular Repair of Complex Aortic Pathology With Physician-modified Endovascular Grafts (PMEGs)

NCT04746677

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Status	RECRUITING
Phase	Not Applicable
Sponsor	Beth Israel Deaconess Medical Center
Enrollment	180 participants

## Key Eligibility Criteria

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### Inclusion (35)

- Aortic pathology that fits one of the study arms (see below for detailed description)
  - Aortic pathology that cannot be treated within the Instructions for Use of an FDA- approved, commercially-available device
  - Aortic aneurysm that can be treated within the Instructions for Use of an FDA-approved, commercially-available custom-manufactured device but deemed unsafe to wait the required time for device manufacturing
  - Subject is at high-risk of morbidity and mortality with open surgical repair based on cardiopulmonary function, extent of comorbid disease, and anatomic complexity
  - Iliac and/or femoral access vessel morphology that is compatible with vascular access techniques, devices, or accessories, with or without use of a surgical or endovascular conduit
- ... and 30 more (see full listing online)

### Exclusion (16)

- Patient has prohibitive operative risk for open repair and no other viable endovascular treatment option
  - Estimated perioperative risk is lower than the estimated 1-year mortality without surgery
  - Subject is eligible for enrollment in a manufacturer-sponsored IDE at the investigational site
  - Subject is unwilling to comply with the follow-up schedule
  - Inability or refusal to give informed consent by subject or legal representative
- ... and 11 more (see full listing online)

## Locations (1 total)

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Beth Israel Deaconess Medical Center, Boston, Massachusetts, United States