

# AAA-SHAPE Pivotal Trial: Abdominal Aortic Aneurysm Sac Healing and Prevention of Expansion

NCT06029660

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Status	RECRUITING
Phase	Not Applicable
Sponsor	Shape Memory Medical, Inc.
Enrollment	180 participants

## Key Eligibility Criteria

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### Inclusion (5)

- e18years of age
- A candidate for elective EVAR of an infrarenal fusiform aortic aneurysm e5.5 cm in diameter in men and e5.0 cm in women;
- Thrombus burden (percentage of the AAA sac occupied by thrombus) \<50%, based on pre-procedure CTA
- Maximum Lumen diameter within the AAA sac of e40mm.
- The predicted minimum number of IMPEDE-FX RapidFill Implants for the subject is d200.

### Exclusion (34)

- General
  - An inability to provide informed consent.
  - Enrolled in another clinical study that could interfere with the outcomes being studied in this trial.
  - Unable or unwilling to comply with study follow-up requirements.
  - Prisoner or member of other vulnerable population
- ... and 29 more (see full listing online)

## Locations (45 total)

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University of Alabama Birmingham, Birmingham, Alabama, United States  
Honor Health, Scottsdale, Arizona, United States  
USC Keck, Los Angeles, California, United States  
... and 42 more locations