

# GORE® ENFORM Biomaterial Product Study

NCT04718168

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<b>Status</b>	RECRUITING
<b>Phase</b>	Not Applicable
<b>Sponsor</b>	W.L.Gore & Associates
<b>Enrollment</b>	245 participants

## Key Eligibility Criteria

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### Inclusion (10)

- The subject is / has:
  - At least 18 years old at the time of informed consent. Minimum age required by state regulations (as applicable).
  - An expected scored Class I (Clean) surgical wound using CDC Surgical Wound Classification system.
  - A planned implant with GORE® ENFORM Biomaterial for a single site ventral or hiatal hernia repair as suture line reinforcement.
  - An expected scored Grade 1 or Grade 2 using the Ventral Hernia Working Group Grading system.
- ... and 5 more (see full listing online)

### Exclusion (28)

- The subject is / has:
  - Treated in another drug or medical device study within 1 year of study enrollment.
  - Implanted with GORE® ENFORM Biomaterial in the reconstruction of cardiovascular defects.
  - Hernia repair expected to be performed as part of a bridged procedure (i.e., expected inability to perform primary closure of fascia or crura, patients requiring permanent support from the device).
  - A BMI  $\geq 40$ .
- ... and 23 more (see full listing online)

## Locations (9 total)

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University of California - San Diego, San Diego, California, United States  
Institute of Esophageal and Reflux Surgery, Denver, Colorado, United States  
Sarasota Memorial HealthCare System, Sarasota, Florida, United States  
... and 6 more locations

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<https://clinicaltrials.gov/study/NCT04718168>

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