GORE® ENFORM Biomaterial Product Study

NCT04718168

Status	RECRUITING
Phase	Not Applicable
Sponsor	W.L.Gore & Associates
Enrollment	245 participants

Key Eligibility Criteria

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 \>40.

... and 23 more (see full listing online)

Locations (9 total)

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