Ventral or Inguinal Hernia, Robotically Repaired With OviTex Mesh

NCT04779918

Status	RECRUITING
Phase	Not Applicable
Sponsor	Tela Bio Inc
Enrollment	160 participants

Key Eligibility Criteria

Inclusion (8)

- Subject suffers from a ventral or inguinal hernia that requires surgical repair with the use of an implant to reinforce or replace weakened or missing tissue.
- The patient is scheduled for an elective robotic approach with the use of OviTex LPR, OviTex Core Permanent, or OviTex 1S Permanent.
- The size of the implant needed for repair is expected to be less than or equal to 15 x 25 cm for OviTex LPR and 25 x 40 cm for OviTex Core Permanent and OviTex 1S Permanent.
- Subject meets CDC/SSI Wound Classification Class I (Clean), Class II (Clean-Contaminated) or Class III (Contaminated) criteria.
- Subject is willing and able to sign an informed consent for the study and has signed the IRB approved Informed Consent form for this study.

... and 3 more (see full listing online)

Exclusion (10)

- Subject has a BMI of \> 40
- Subject meets CDC/SSI Wound Classification Class IV (Dirty-Infected) criteria
- Subject is female and is pregnant or plans to become pregnant during the course of the study.
- Subject has a life expectancy of \< 2 years making it unlikely that the subject will successfully achieve two-year follow-up.
- Subject has recent history of drug or alcohol abuse (in last 3 years).

... and 5 more (see full listing online)

Locations (10 total)

University of South Alabama, Mobile, Alabama, United States
SurgOne, Denver, Colorado, United States
GenesisCare, Destin, Florida, United States
... and 7 more locations