Evaluating Clinical Hiatal Hernia Outcomes Using OviTex®

NCT07070115

Status	RECRUITING
Phase	Not Applicable
Sponsor	Tela Bio Inc
Enrollment	173 participants

Key Eligibility Criteria

Inclusion (5)

- Patient is a candidate for an elective robotic or laparoscopic primary hiatal hernia repair with the use of OviTex Core Resorbable or OviTex 1S Resorbable.
- Patient is willing and able to voluntarily sign the IRB-approved Informed Consent Form for the study.
- Patient is at least 22 years old at the time of surgery.
- Patient is not pregnant and not planning to become pregnant during the duration of the study (5 years).
- Patient is able and willing to comply with the study requirements including completion of patient questionnaires and clinic evaluations.

Exclusion (20)

- Patient has a Body Mass Index (BMI) of e 35.
- Patient meets the Centers for Disease Control (CDC) Surgical Site Infection (SSI) Wound Classification Class IV (Dirty-Infected) criteria.
- Patient has a Type I hiatal hernia (defined as only the esophagogastric junction is above the diaphragm).
- Patient has a life expectancy of less than five years making it unlikely that the subject will successfully achieve five-year follow-up.
- Patient is a current nicotine user (including smokeless, vaporized, etc.)

... and 15 more (see full listing online)

Locations (2 total)

University of South Alabama Health, Mobile, Alabama, United States
The University of Texas at Austin - Dell Medical School, Austin, Texas, United States