Safety and Feasibility Study of the CELLSPAN Esophageal Implant (CEI) in Patients Requiring Short Segment Esophageal Replacement

NCT05877300

Status	RECRUITING
Phase	Phase 1
Sponsor	Harvard Apparatus Regenerative Technology, Inc.
Enrollment	10 participants

Key Eligibility Criteria

Inclusion (26)

- Subject e18 years of age
- The patient has medical conditions requiring esophageal reconstruction, such as, but not limited to:
- Refractory benign esophageal strictures (RBES)
- Esophageal perforation (full thickness)
- Chronic/persistent esophageal fistula

... and 21 more (see full listing online)

Exclusion (23)

- Subject requires or undergoes an esophageal segmental excision \>6 cm in length
- Esophageal segment extends below the diaphragm or \<4 cm below larynx
- Pre-existing implants/structures adjacent to target surgical location for implant that could cause abrasion of the scaffold/regenerated tissue (e.g., pacemaker lead, vascular clips, vascular grafts).
- Known clinical contraindication that would obfuscate the use of the covered metallic stent to be used as an adjunct to the procedure
- Post ablation stricture for Barrett's esophagus treated less than 1 year prior to planned procedure

... and 18 more (see full listing online)

Locations (3 total)

Keck Medical Center of University of Southern California, Los Angeles, California, United States
University of Michigan, Ann Arbor, Michigan, United States
Mayo Clinic, Rochester, Minnesota, United States