

Endo-SPONGE for Treatment of Anastomotic or Hartmann's Stump Leakages in Lower Pelvic Area

NCT07035431

Status	RECRUITING
Phase	Not Applicable
Sponsor	Boston Scientific Corporation
Enrollment	66 participants

Key Eligibility Criteria

Inclusion (7)

- Confirmed grade B anastomotic leak as per the ISGRC (International Study Group of Rectal Cancer) grading system after colorectal surgery.
 - Subject is eligible for endoscopic intervention.
 - Subject has a transmural defect of at least 2 cm in diameter following colorectal surgery in the lower pelvic area.
 - Subject has an anastomotic or Hartmann's stump leak located within an extraperitoneal cavity.
 - Subject has pre-existing diverting ostomy or an ostomy created prior to the first Endo-SPONGE placement.
- ... and 2 more (see full listing online)

Exclusion (7)

- Subject is under 18 years of age.
 - Potentially vulnerable subject, including, but not limited to pregnant women.
 - Subject has undergone EVT or other similar interventions for the current colorectal indication.
 - Subject had colorectal surgery more than 60 days prior to the planned study procedure.
 - Subject has any necrotic tissue that would require endoscopic debridement prior to Endo-SPONGE placement.
- ... and 2 more (see full listing online)

Locations (6 total)

Mount Sinai, New York, New York, United States
Ohio State University Medical Center, Columbus, Ohio, United States
Penn State Health, Hershey, Pennsylvania, United States
... and 3 more locations