

MIRUS Disposable Hemorrhoids Stapler Study

A study to evaluate safety and performance of MIRUS™ Disposable Hemorrhoids Stapler in the treatment of prolapsed hemorrhoids

Study Design

- Prospective, open-label, single-arm, multi-centre, post marketing surveillance study
- To evaluate the safety and performance of MIRUS™ Disposable Hemorrhoids Stapler in the treatment of prolapsed Hemorrhoids

Protocol No.	MES/MIRUS™-1
Study Objective	To evaluate safety and performance of MIRUS™ Disposable Hemorrhoids Stapler in the treatment of prolapsed hemorrhoids
Device	MIRUS™ Disposable Hemorrhoids Stapler
Sample Size	82 subjects
Clinical Sites	9 sites across India
Safety Endpoints	Immediate postoperative complications and short term outcomes. <ul style="list-style-type: none"> - Post-operative bleeding - Post-operative anal stenosis - Residual skin tags and prolapsed - Post-operative urine retention - Post-operative gas or fecal incontinence - Prolongation of hospitalization due to any other complication Number of AE/SAE related to study device Post-operative pain
Performance Endpoints	<ul style="list-style-type: none"> • Incidence of stapler malfunction or misfires [Time Frame: About 20 minutes for procedure] • Operation time [Time Frame: at baseline] Time of insertion of anoscope to time of anoscope removal after staple line evaluation • Length of Hospital Stay Length of time between time of admission and time of discharge
Other Endpoints	<ul style="list-style-type: none"> • Reapparition of the hemorrhoidal symptoms and/or Reoperations at 15 days, 3 months and 6 months • Standardized Stapled Hemorrhoidectomy Quality Of Life (QoL) at Baseline, 15 days, 3 months and 6 months • Overall QoL at Baseline, 15 days, 3 months and 6 months
Follow-Up	Clinical follow-up at 15 days, 3 months and 6 months
Study status as in September 2020	Study is completed.

Reference

Clinical Trial Registry- India (CTRI) number: CTRI/2017/05/008476

<http://ctri.nic.in/Clinicaltrials/pmaindet2.php?trialid=16968&EncHid=&userName=CTRI/2017/05/008476>