MIRUS Disposable Haemorrhoids Stapler Study

A study to evaluate safety and performance of MIRUS Disposable Haemorrhoids Stapler in the treatment of prolapsed haemorrhoids

Study Design

- Prospective, open-label, single-arm, multi-centre, post marketing surveillance (PMS) study
- 82 subjects at 9 sites across India

CTRI No.	CTRI/2017/05/008476
Study Objective	To evaluate safety and performance of MIRUS™ Disposable Haemorrhoids Stapler in the treatment of prolapsed haemorrhoids.
Safety Endpoints	1. Immediate postoperative complications and short term outcomes. - Post-operative bleeding - Post-operative anal stenosis - Residual skin tags and prolapse - Post-operative urine retention - Post-operative gas or fecal incontinence - Prolongation of hospitalization due to any other complication 2. Number of AE/SAE related to study device 3. Post-operative pain
Efficacy Endpoints	1. Incidence of stapler malfunction or misfires [Time Frame: About 20 minutes for procedure] 2. Operation time [Time Frame: at baseline] Time of insertion of anoscope to time of anoscope removal after staple line evaluation. 3. Length of Hospital Stay Length of time between time of admission and time of discharge
Other Endpoints	1. Reapparition of the hemorroidal symptoms and/or Reoperations : [Time Frame: at 15 days (±7 days), 3 months (±28 days) and 6 months (±28 days)] 2. Standardized Stapled Hemorrhoidectomy Quality Of Life (QoL) [Time Frame: at Baseline, 15 days (±7 days), 3 months (±28 days) and 6 months (±28 days) 3. Overall QoL [Time Frame: at Baseline, 15 days (±7 days), 3 months (±28 days) and 6 months (±28 days)
Clinical Sites	Nine sites across India
Sample Size	82 subjects [MIRUS Disposable Haemorrhoids Stapler]
Follow-Up	Clinical follow-up at 15 days (±7 days), 3 months (±28 days) and 6 months (±28 days)
Study Duration	Study started in May, 2017 Study completed in July, 2018

❖ **Reference:**

1. Clinical Trial Registry- India (CTRI): CTRI/2017/05/008476 http://ctri.nic.in/Clinicaltrials/showallp.php?mid1=16968&EncHid=&userName=CTRI/2017/05/008476