

Post-Market Registry for the Evaluation of RefluxStop in GERD Treatment

NCT05870163

Status	RECRUITING
Sponsor	Implantica CE Reflux Ltd.
Enrollment	2,500 participants

Key Eligibility Criteria

Inclusion (5)

- Willing and able to provide informed consent and to participate in the registry study,
- Patient's age \geq 18 years or according to local legal age of adulthood if older,
- Documented GERD present for \geq 6 months,
- Patient has a 24-hour pH monitoring proven GERD with pH and/or impedance pH measurement, off PPI therapy for at least 7 days prior to testing. (Total distal esophageal pH must be $<$ 4 for $>$ 4.5% of time during a 24-hour monitoring and/or total reflux episodes of acid \geq 55 or weakly acid \geq 26 for \geq 5 seconds at 5 cm above LES)
- Suitable to undergo general anesthesia and is a suitable laparoscopic surgery candidate as determined by the investigator.

Exclusion (7)

- Presence of para-esophageal hernia or sliding hernia \geq 3 centimeters,
- Known presence of delayed gastric emptying, if no other cause for acid reflux could be diagnosed,
- History of bariatric surgery wherein the stomach fundus has been extirpated,
- Female patients who are pregnant or nursing,
- Known sensitivity or allergies to silicone materials,
- ... and 2 more (see full listing online)

Locations (6 total)

Klinikum Friedrichshafen GmbH, Friedrichshafen, Germany
Ospedale IRCCS Saverio De Bellis, Bari, Italy
Ospedale Buon Consiglio Fatebenefratelli, Naples, Italy
... and 3 more locations