

Laparoscopic insertion of a magnetic ring for gastro-oesophageal reflux disease

Interventional procedures guidance

Published: 11 January 2023

www.nice.org.uk/guidance/ipg749

Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account, and specifically any special arrangements relating to the introduction of new interventional procedures. The guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the [Yellow Card Scheme](#).

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful

discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties. Providers should ensure that governance structures are in place to review, authorise and monitor the introduction of new devices and procedures.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

This guidance replaces IPG585.

1 Recommendations

- 1.1 Evidence on the safety and efficacy of laparoscopic insertion of a magnetic ring for gastro-oesophageal reflux disease (GORD) is adequate to support using this procedure provided that standard arrangements are in place for clinical governance, consent and audit. Find out what standard arrangements mean on the NICE interventional procedures guidance page.
- 1.2 Patient selection, and the procedure, should be done by clinicians who have specific training in the procedure, and experience in upper gastrointestinal laparoscopic surgery and managing GORD.

2 The condition, current treatments and procedure

The condition

- 2.1 Gastro-oesophageal reflux disease (GORD) is a common condition in which acid from the stomach flows back up into the oesophagus. It is usually caused by the sphincter at the lower end of the oesophagus becoming weakened. Symptoms of GORD can be directly related to reflux episodes (such as heartburn, regurgitation, chest pain and nausea)

or be caused by complications of the disease (such as dysphagia and respiratory difficulties). Repeated episodes of GORD can damage the lining of the oesophagus and lead to oesophageal ulceration, oesophageal stricture and Barrett's oesophagus.

Current treatments

2.2 [NICE's guideline on GORD and dyspepsia in adults: investigation and management](#) describes managing GORD in adults. The standard treatments for symptomatic GORD are lifestyle modification and drug therapy. People may be offered anti-reflux surgery (usually laparoscopic fundoplication) if their symptoms do not improve, or if they develop complications despite medication or they have an intolerance to medication. Endoscopic interventions (such as endoscopic radiofrequency ablation at the gastro-oesophageal junction) and electrical stimulation of the lower oesophageal sphincter can also be used.

The procedure

- 2.3 The aim of laparoscopic insertion of a magnetic ring for GORD is to relieve reflux-related symptoms (such as heartburn or regurgitation) without impeding the ability to swallow, belch or vomit.
- 2.4 The procedure is done under general anaesthesia. Using a laparoscopic approach, a specially designed sizing tool is placed around the distal oesophagus to assess the size of implant needed. The sizing tool is then removed, and the implant is placed at the gastro-oesophageal junction, with the posterior vagus nerve trunk located outside the magnetic ring. The ends of the implant are secured together to hold it in place. Intraoperative endoscopy may be used to help identify the anatomic gastro-oesophageal junction and to assess device position.
- 2.5 The implant consists of a ring of interlinked beads, each with a weak magnetic force that holds the beads together and reduces reflux. When the person swallows, the magnetic force is overcome, allowing the ring to open. After swallowing, magnetic attraction brings the beads together

and the distal oesophagus is again closed.

3 Committee considerations

The evidence

- 3.1 NICE did a rapid review of the published literature on the efficacy and safety of this procedure. This comprised a comprehensive literature search and detailed review of the evidence from 10 sources, which was discussed by the committee. The evidence included 3 systematic reviews and meta-analyses, 1 randomised controlled trial, 3 non-randomised comparative studies, 2 case series, and a review of the MAUDE database and the Ethicon complaint database. It is presented in the [summary of key evidence section in the interventional procedures overview](#).
- 3.2 The professional experts and the committee considered the key efficacy outcomes to be: improved quality of life, reduced reflux symptoms and reduced need for medical therapy for reflux.
- 3.3 The professional experts and the committee considered the key safety outcomes to be: pain, dysphagia, oesophageal erosion and the need for device explantation and reoperation.
- 3.4 Two commentaries from people who have had this procedure and 1 patient organisation submission for this procedure were discussed by the committee.

Committee comments

- 3.5 The committee noted that the devices are intended to remain in place for life, so there should be arrangements to report complications in the long term.
- 3.6 The committee noted that this procedure has evolved, and the incidence of dysphagia and oesophageal spasm has reduced, over time.

- 3.7 The committee was informed that an MRI-compatible device is available.
- 3.8 The committee was informed that early postoperative management is important, including managing diet and encouraging normal eating after surgery.

ISBN: 978-1-4731-4935-9

Endorsing organisation

This guidance has been endorsed by [Healthcare Improvement Scotland](#).