



**Australian Government**  
**Department of Health and Ageing**



Horizon Scanning Technology  
Prioritising Summary

Gatekeeper reflux repair system

September 2004



**Australian  
Safety  
and Efficacy  
Register  
of New  
Interventional  
Procedures -  
Surgical**



**Royal Australasian  
College of Surgeons**



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The production of this Horizon scanning prioritising summary was overseen by the Health Policy Advisory Committee on Technology (HealthPACT), a sub-committee of the Medical Services Advisory Committee (MSAC). HealthPACT comprises representatives from health departments in all states and territories, the Australia and New Zealand governments; MSAC and ASERNIP-S. The Australian Health Ministers' Advisory Council (AHMAC) supports HealthPACT through funding.

This Horizon scanning prioritising summary was prepared by staff from the Australian safety and Efficacy Register of New Interventional Procedures – Surgical (ASERNIP-S).



### Name of Technology:

Gatekeeper reflux repair system

### Purpose and Target Group:

The gatekeeper reflux repair system is the endoscopic delivery of expandable polyacrylonitrile-based hydrogel prostheses to the oesophageal submucosa. Augmentation of the lower oesophageal sphincter (LOS), creates a barrier restricting acid and other stomach contents from refluxing back up into the oesophagus. This procedure may therefore be applicable for the treatment of gastroesophageal reflux disease (GORD).

### Stage of Development (in Australia):

- Experimental
- Investigational
- Nearly established
- Established
- Established but changed indication or modification of technique
- Should be taken out of use

The Gatekeeper reflux repair system is not listed or registered in the Australian Register of Therapeutic Goods (ARTG).

### International Utilisation:

COUNTRY	LEVEL OF USE		
	Trials underway	Limited use	Widely Diffused
Netherlands		✓	
France	✓		
Italy	✓		
Germany	✓		
Norway	✓		
Switzerland	✓		
United Kingdom	✓		
United States	✓		

### Impact Summary:

#### *Background*

Gastroesophageal reflux disease (GORD) occurs when the lower oesophageal sphincter (LOS) does not close and stomach acids can flow back up, or reflux, into the oesophagus. When refluxed stomach acid touches the lining of the oesophagus, patients often report a burning sensation in the chest or throat, called heartburn. Heartburn that occurs more than



twice a week may be considered GORD, and can eventually lead to more serious health problems such as ulcers, Barrett's oesophagus or subsequent oesophageal cancer (<http://digestive.niddk.nih.gov>).

Depending on the severity of GORD, treatment may involve conservative lifestyle changes, medication or surgery. Lifestyle changes such as cessation of smoking, reducing alcohol intake and excess weight and eating small meals may reduce symptoms. Medications which involve antacids, foaming agents, H<sub>2</sub> blockers, proton pump inhibitors (PPI) or prokinetics are also recommended for GORD treatment. When GORD does not respond to conservative lifestyle changes or medications, more invasive alternatives are available. These include the Bard EndoCinch system, where stitches are placed in the LOS to help strengthen the muscle, Enteryx implants, a solution that becomes spongy and reinforces the LOS and the Stretta procedure where endoscopic delivery of radiofrequency to the LOS results in tissue constriction and muscle thickening. Nissen fundoplication is the standard surgical treatment for GORD, a laparoscopic technique where the upper part of the stomach is wrapped around the LOS in attempt to strengthen the sphincter (<http://digestive.niddk.nih.gov>).

The gatekeeper reflux repair system is a reversible treatment alternative that involves the endoscopic delivery of expandable polyacrylonitrile-based hydrogel prostheses to the oesophageal submucosa, designed to augment the LOS and inhibit reflux (Fockens *et al.* 2004).

### ***Clinical Need and Burden of Disease***

Gastroesophageal reflux disease is one of the most common disorders of the gastrointestinal tract. In the United States nearly half the population experience heartburn on a monthly basis and almost 10% of the population suffers from daily reflux (Lutfi *et al.* 2004). With 18.6 million cases of GORD reported per year, annual direct costs in the United States are approximately US\$9.3 billion. Antireflux medications are the largest component of the annual direct cost accounting for US\$5.8 billion (Richards *et al.* 2003). In 2000, the use of proton pump inhibitors, which is becoming a popular treatment for GORD, increased by 30%. Furthermore, oesophageal cancer, a complication of GORD has seen a dramatic increase in incidence within the last 10 years of 300% (Glenn *et al.* 2001).

Although there were no direct statistics found relating to the incidence of GORD within the Australian population, it is anticipated that rates are similar to that in the United States. The Commonwealth Department of Health and Ageing reported that in 1999-2000 approximately 3 million scripts were dispensed for proton pump inhibitors, used for treating peptic ulcers as well as GORD, costing AUS\$270 million (<http://www.health.gov.au>).

### ***Estimated Speed, Geographic and Practitioner Use Patterns of Diffusion in the Health System***

The gatekeeper reflux repair system, manufactured by Medtronic (MDT) Inc, was granted European Regulatory Approval on the 20<sup>th</sup> May 2003 (<http://www.biospace.com>). A



multicentre European study conducted by Fockens *et al.* (2003) utilised the procedure on a total of 69 GORD patients. On the 18<sup>th</sup> November 2003, Medtronic (MDT) Inc. announced the start of a randomised, single-blinded clinical trial to include 144 patients with a 12-month follow-up period. This U.S. trial is designed to measure the placebo effect prior to submission to the U.S. Food and Drug Administration (<http://www.heartburn.about.com>).

### ***Existing Comparators***

- Bard EndoCinch system
- Enteryx implant
- Nissen fundoplication
- Stretta procedure

### ***Estimated Cost Impact***

The costs associated with this procedure in Australia are not currently available. The cost of fundoplasty surgery in Australia is also not available. However, reimbursement fees for antireflux operation by fundoplasty as stated in the Medicare Benefits Schedule (Item numbers-31464, 31466 and 30527) are \$724.10, \$1086.15 and \$724.10 AUD respectively. According to the Health Insurance Commission a total of 1244 claims to were processed between July 2003 to June 2004 for item numbers 31464, 31466 and 30527 (<http://www.hic.gov.au>).

### ***Efficacy and Safety Issues***

#### **List of Studies Found**

Total number of studies	1
Randomised controlled trials	0
Non-randomised comparative studies	0
Case series studies	1
Conference abstracts	1

The studies included in this summary are highlighted in bold in the reference list.

Safety and efficacy data exists from one case series conducted by Fockens *et al.* (2004). Additional data was extracted from a conference abstract published in 2003 if the same set of patients (Fockens *et al.* 2003).

This multicentre trial involved 69 GORD patients with symptoms of heartburn, regurgitation and abnormal oesophageal acid exposure who responded to PPI therapy. A total of 77 procedures were performed in 67 patients, and a total of 270 prostheses placed. The mean procedural time was 26 minutes (range 6–50 mins) with patients reporting minimal postprocedural discomfort (Fockens *et al.* 2003). At 6 months, 24-hour pH-metry outcomes with pH <4.0 for >4.0% of the time decreased from 9.1% to 6.1% (n=45; p<0.05). Median LES pressure increased significantly from 8.8 mmHg at baseline to 13.8 mmHg at 6 months (n=42; p<0.01). Median GORD heartburn-related quality of life scores



also improved significantly (Fockens *et al.* 2004). Two of the 69 patients (3%), experienced serious adverse events. One patient suffered pharyngeal perforation and was treated conservatively. The other complained of nausea one week postprocedure; the prostheses were removed endoscopically, without any adverse events. Both patients recovered uneventfully (Fockens *et al.* 2003).

There is limited evidence for the safety and efficacy of the gatekeeper reflux repair system. Results from the single case series suggests that the procedure may effectively increase LOS pressure and decrease oesophageal acid exposure, which may reduce GORD symptoms and improve quality of life. However, the incidence of serious adverse events needs to be considered.

### ***Ethical Issues***

No issues were identified from the retrieved material.

### ***Cultural or Religious Considerations***

No issues were identified from the retrieved material.

### ***Other Issues***

No issues were identified from the retrieved material.

### **Conclusion:**

Limited evidence exists on the safety and efficacy of the gatekeeper reflux repair system. Long-term safety and efficacy data from randomised controlled trials may be required before this procedure can be widely accepted.

### **HealthPACT decision:**

It was decided that a further appraisal of the procedure be conducted and a horizon scanning report, which includes other treatments for GORD, be produced.

- |   |  |
|---|--|
| <input checked="" type="checkbox"/> Horizon Scanning Report | <input type="checkbox"/> Full Health Technology Assessment |
| <input type="checkbox"/> Monitor                            | <input type="checkbox"/> Archive                           |

### **References:**

Fockens P, Bruno MJ, Gabbrielli A, Odegaard S, Hatlebakk J, Allescher HD, Rosch T, Rhodes M, Bastid C, Rey J, Boyer J, Muehldorffer S, van den Hombergh U, Costamagna G. Endoscopic augmentation of the lower oesophageal sphincter for the treatment of gastroesophageal reflux disease: Multicenter study of the gatekeeper reflux repair system. *Endoscopy* 2004; 36(8):682-9.

Fockens P, Boechxstaens G, Costamagna A, Gabbrielli S, Odegaard J, Hattlebakk H, Allescher T, Roesch S, Muehldorffer J, Boyer J, Rey J, Bastid C. Gatekeeper reflux repair system: Multicenter European study. Madrid, Spain: (*Congress Review en*



***Gastroenterologia y Hepatologia* 2003) 11<sup>th</sup> United European Gastroenterology Week, 1<sup>st</sup> to 5<sup>th</sup> November 2003.**

Glenn TF. Esophageal cancer: Facts, figures and screening. *Gastroenterology Nursing* 2001;**24**(6): 271-75.

Lutfi RE, Torquati A, Richards WO. The endoscopic radiofrequency approach to management of GERD. *Current Opinion in Otolaryngology & Head and Neck Surgery* 2004;**12**(3): 191-6.

Richards WO, Houston HL, Torquati A, Khaitan L, Holzman MD, Sharp KW. Paradigm shift in the management of gastroesophageal reflux disease. *Annals of Surgery* 2003;**237**(5): 638-47.

#### **Sources of Further Information:**

Fockens P. Gatekeeper reflux repair system: technique, pre-clinical and clinical experience. *Gastrointestinal Endoscopy Clinics of North America* 2003; **13**(1):179-89.

#### **Search Criteria:**

A search of MEDLINE, PubMed and Cochrane Library, Current Controlled Trials metaRegister, UK National Research Register, International Network for Agencies for Health Technology Assessments, relevant online journals and the Internet was conducted in September 2004.

Search terms used were: 'gatekeeper reflux repair system', 'Polyacrylonitrile-based hydrogel and reflux', 'hydrogel prosthesis and reflux', 'protheses and oesophageal submucosa' and 'expandable protheses and reflux'.

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This Horizon Scanning Prioritising Summary was prepared by Ms Lynette Cufone from the NET-S Project, ASERNIP-S for the Health Policy Advisory Committee on Technology (Health PACT), on behalf of the Medical Services Advisory Committee (MSAC) and the Australian Health Ministers' Advisory Council (AHMAC).