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**Department of Health and Ageing**



Australia and New Zealand Horizon Scanning Network

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# Horizon Scanning Technology Prioritising Summary

## Stretta® procedure

October 2004



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



**Royal Australasian  
College of Surgeons**



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Enquiries about the content of the report should be directed to:

HealthPACT Secretariat  
Department of Health and Ageing  
MDP 106  
GPO Box 9848  
Canberra ACT 2606  
AUSTRALIA

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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:**

Stretta® procedure

**Purpose and Target Group:**

The Stretta® procedure is the minimally invasive endoscopic delivery of radiofrequency energy to the lower oesophageal sphincter and gastric cardia. This results in tissue constriction and muscle thickening and may therefore be applicable for the treatment of gastroesophageal reflux disease (GORD) (<http://www.curonmedical.com>).

**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 Stretta® system is registered in the Australian Register of Therapeutic Goods (ARTG number 69333).

**International Utilisation:**

| COUNTRY       | LEVEL OF USE    |             |                 |
|---------------|-----------------|-------------|-----------------|
|               | Trials underway | Limited use | Widely Diffused |
| United States |                 | ✓           |                 |
| Ireland       | ✓               |             |                 |

**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 gatekeeper reflux repair system, which involves implantation of expandable polyacrylonitrile-based hydrogel prostheses into the submucosa. 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 minimally invasive endoscopic delivery of radiofrequency energy (Stretta®) to the LOS is an alternative to surgery. It creates small thermal lesions in the LOS and gastric cardia, which causes tissue constriction (as the lesions heal thickening of the muscle occurs). This results in increased LOS pressure and hence reduces the incidence of refluxed acid into the oesophagus (<http://www.curonmedical.com>).

### ***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***

Multicentre use of the Stretta® system has been reported in the United States since February 1999. The Stretta® system manufactured by Curon Medical Inc, formerly Conway Stuart Medical Inc, received FDA approval for the device in April 2000. In 2001, the first commercial procedures involving the Stretta® system were completed in Greece, with additional centres in Italy, Belgium and Germany using the procedure. A publication by DiBaise *et al.* (2002) indicates its further diffusion into Ireland. The Stretta® procedure is also being used in Australia (Tam *et al.* 2003).

### ***Existing Comparators (apart from medication)***



- Bard EndoCinch system
- Enteryx implant
- Gatekeeper reflux repair system
- Nissen fundoplication

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

The Stretta® procedure is reported to be a 45-60 minute outpatient procedure which utilises the same anaesthetic as standard endoscopy. The minimally invasive technique requires only a brief recovery period of approximately 1-2 hours after the procedure. The costs associated with the Stretta® system have been reported to be one fifth of the cost of standard surgery (<http://www.staloisius.com/stretta.htm>). A 3-year cost analysis comparative study conducted by Harewood *et al.* (2003) reported that endotherapy (endoluminal plication and radiofrequency coagulation) was the most economical treatment option after 17 months for patients requiring a PPI twice daily. However, if uniform endotherapy failure rates were assumed over time (Stretta® 19% & endoluminal plication 20%), medication regained cost superiority after 29 months. For patients requiring PPIs once daily, medication remained to be the most economical option regardless of endotherapy failure rates. It should be noted that more invasive procedures such as the Stretta®, are usually done when medication fails, thus this a somewhat artificial comparison.

The costs associated with this procedure in Australia are not currently available. The cost of Nissen fundoplication 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 1279 claims to were processed between July 2002 to June 2003 for item numbers 31464, 31466 and 30527 (<http://www.hic.gov.au>).

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

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

|                                    |   |
|------------------------------------|---|
| Total number of studies            | 8 |
| Randomised controlled trials       | 1 |
| Non-randomised comparative studies | 2 |
| Case series studies                | 5 |

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

Significant improvements in GORD symptoms including heartburn were reported in Stretta® patients compared to sham patients in the RCT by Corley *et al.* (2003) (mean decrease in scores, -1.6 {95% confidence interval (CI)}, -1.1, -2.2 vs. -0.6 {95% CI, 0.1, -1.2} p=0.01), and these improvements were sustained at 12-month follow-up. Three case series also reported significant improvement in symptoms as early as one month post procedure (Wolfsen *et al.* 2002, Dibaise *et al.* 2002, Islam *et al.* 2004). However, one of the two non-randomised comparative studies reported that improvements in symptoms were



similar between patients who received the Stretta® ( $3.9 \pm 0.2$  to  $5.7 \pm 0.2$ ,  $p < 0.01$ ) and those who received laparoscopic fundoplication ( $4.1 \pm 0.2$  to  $6.2 \pm 0.1$ ,  $p < 0.01$ ) (Richards *et al.* 2003). An improvement of both general Quality of Life and GERD-specific Quality of Life scores was also reported (Corley *et al.* 2003, Dibaise *et al.* 2002, Tridafilopoulos *et al.* 2002). Medication usage for the relief of GORD was similar 6 months post procedure between Stretta® patients and sham patients in the RCT by Corley *et al.* (2003) ( $n=17$  {55%} vs.  $n=14$  {61%};  $p=0.67$ ). The other non-randomised comparative study (Richards *et al.* 2003) reported that 97% (72/75) patients who received laparoscopic fundoplication were off PPI compared to 58% (38/65) of Stretta® patients. Four case series reported a significant reduction in the daily use of medication (Islam *et al.* 2004, Tam *et al.* 2003, Tridafilopoulos *et al.* 2002, Wolfsen *et al.* 2002). The randomised controlled trial reported a median procedure time of 51 minutes (Corley *et al.* 2003), which is the same as the mean procedure time reported in the non-randomised comparative study (Wolfsen *et al.* 2003).

The randomised controlled trial conducted by Corley *et al.* (2003) reported one complication of delayed gastric emptying in Stretta® patients. In one of the non-randomised comparative studies, gastroparesis was the only reported complication in 1/65 (1.5%) Stretta® patients compared to major complications of enterotomies (2.6%), pneumothorax (1.3%), slipped-Nissen (1.3%), paraoesophageal hernia (1.3%) and incisional hernia (2.6%) reported in laparoscopic fundoplication (Richards *et al.* 2003). There were no reported complications in the non-randomised comparative study by Wolfsen *et al.* (2003). The most common complications reported amongst the case series were reported by Dibaise *et al.* (2002) and Tridafilopoulos *et al.* (2002). These were minor complications of mucosal tear 1/18 (5.5%) and 3/118 (2.5%), chest pain 12/18 (66.6%) and 2/118 (1.7%) and mild dysphagia 14/18 (77.7%) and 1/118 (0.8%) respectively.

In the randomised controlled trial 1/35 (2.8%) patients acquired an oesophageal ulcer after the Stretta® procedure compared to zero reported in the sham group (Corley *et al.* 2003). Five of 118 (4.2%) patients in a case series by Tridafilopoulos *et al.* (2002) were reported to have superficial mucosal ulcerations due to the thermal treatment.

### ***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:**

Some evidence exists on the safety and efficacy of the Stretta® procedure as an alternative to Nissen fundoplication. The available evidence suggests that the Stretta® may have favourable efficacy results with few serious complications.

**HealthPACT decision:**

It is recommended 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:**

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#### Sources of Further Information:

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#### 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 August 2004.

Search terms used were: 'Stretta', 'radio frequency and GERD or GORD' and 'radio frequency and gastroesophageal reflux disease'

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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



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