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Australia and New Zealand Horizon Scanning Network

ANZHSN

AN INITIATIVE OF THE NATIONAL, STATE AND
TERRITORY GOVERNMENTS OF AUSTRALIA
AND THE GOVERNMENT OF NEW ZEALAND

Horizon Scanning Technology Prioritising Summary

**Polyflex® oesophageal stent for patients with
oesophageal stenoses, fistulas and leakages**

August 2007



ASERNIP(S)

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



**Royal Australasian
College of Surgeons**

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PRIORITISING SUMMARY

REGISTER ID: S000045

NAME OF TECHNOLOGY: POLYFLEX® OESOPHAGEAL STENT

PURPOSE AND TARGET GROUP: PATIENTS WITH OESOPHAGEAL STENOSES,
FISTULAS AND LEAKAGES

STAGE OF DEVELOPMENT (IN AUSTRALIA):

- | | |
|---|---|
| <input checked="" type="checkbox"/> Yet to emerge | <input type="checkbox"/> Established |
| <input type="checkbox"/> Experimental | <input type="checkbox"/> Established <i>but</i> changed indication or modification of technique |
| <input type="checkbox"/> Investigational | <input type="checkbox"/> Should be taken out of use |
| <input type="checkbox"/> Nearly established | |

AUSTRALIAN THERAPEUTIC GOODS ADMINISTRATION APPROVAL

- | | | |
|---|-------------|-----|
| <input type="checkbox"/> Yes | ARTG number | N/A |
| <input checked="" type="checkbox"/> No | | |
| <input type="checkbox"/> Not applicable | | |

INTERNATIONAL UTILISATION:

COUNTRY	LEVEL OF USE		
	Trials Underway or Completed	Limited Use	Widely Diffused
Austria	✓		
Germany	✓		
Italy	✓		
United States	✓		

IMPACT SUMMARY:

Boston Scientific (Massachusetts, United States) provides the Polyflex oesophageal stent with the aim of relieving dysphagia in patients with oesophageal stenoses resulting from oesophageal cancer and treating oesophageal fistulas and leakages. The technology is currently not available in Australia.

BACKGROUND

Oesophageal cancer is a serious condition in which the most prominent symptom is difficulty swallowing (dysphagia) (Fisichella 2006). The cause of dysphagia is tumour growth in the oesophagus which obstructs the passage of food. The presence of dysphagia creates a knock-on effect resulting in un-intentional weight loss and malnutrition (Fisichella 2006). Initially patients experience difficulty swallowing solids, however progression to the inability to swallow liquids also occurs (Bethge and Vakil 2001). Dysphagia also increases the risk of aspiration pneumonia, airway obstruction and oesophageal fistula formation or enlargement (Paik 2006).

Oesophageal cancer can be either squamous cell carcinoma or adenocarcinoma. Adenocarcinoma is often associated with patients with chronic gastroesophageal reflux disease (GORD) who have also developed Barrett's oesophagus, while squamous cell carcinoma is often associated with tobacco smoking and alcohol use (Fisichella 2006).

Oesophageal cancer can be treated with surgery when the tumour is small and localised (Fisichella 2006). Surgery involves an oesophagectomy, a procedure in which all or part of the oesophagus is removed. Unfortunately, more than 50% of patients diagnosed with oesophageal cancer are not suitable for surgery (Siersema et al. 2001). Tumours that are not amenable to surgery may be treated with chemotherapy, radiotherapy, or a combination of the two in order to relieve symptoms or reduce the tumour to an operable size (Fisichella 2006).

Following surgical treatment of oesophageal cancer, septic complications including anastomotic leakage, wound infection and pneumonia may occur in up to 10 % of patients (Fisichella 2006 and Freeman 2007). Furthermore, stenoses of the oesophagus, requiring dilation may also occur in up to 20% of patients (Freeman 2007). Patients who experience these post operative complications as well as post operative oesophageal fistula formation or oesophageal perforation will most likely experience a prolonged hospital stay, delay in resumption of oral nutrition and hydration and potentially experience localised infectious complications and sepsis (Freeman 2007).

The insertion of self expanding metallic stents (SEMS) is a preferred treatment for patients with oesophageal cancer who require relief of dysphagia (Siersema et al. 2001). Stents may also be used in the treatment of oesophageal fistulas and oesophageal leak resulting from oesophagectomy or oesophageal perforation repair (Brinster et al. 2004). The stent may be inserted to maintain patency in the oesophagus or to occlude the fistula. Currently available endoluminal oesophageal stents are associated with various disadvantages including stent migration, malignant or granulomatous overgrowth, difficulties in removal or repositioning, high cost, bleeding, fistula formation and fistula enlargement (Baron 2001, Freeman et al. 2007).

The Polyflex oesophageal stent is a stent constructed of polyester netting fully covered with a silicone membrane (Bethge and Vakil 2001). The stent has a smooth inner surface that should protect against incrustation and a structured outer surface to help prevent stent migration (Conigliaro et al. 2007). Barium is incorporated into the stent material at the proximal and distal ends and the centre to aid stent placement under

fluoroscopic visualisation (Bethge and Vakil 2001). To aid placement of the stent under endoscopic control a blue line is present at the proximal end of the stent (Conigliaro et al. 2007). Delivery of the stent is performed by loading the stent into a delivery device provided with the kit (Bethge and Vakil 2001).

CLINICAL NEED AND BURDEN OF DISEASE

Worldwide, oesophageal cancer is the seventh leading cause of cancer death (Fisichella 2006). In Australia, the incidence of cancer of the oesophagus increased during the 1980s, peaked during the 1990s and is projected to decrease until 2011 (AIHW 2005). In 2001, there were 374 new cases of oesophageal cancer reported in Australia (AIHW 2005). This number is projected to increase to 461 new cases in 2011, an 18% increase from 2002 (AIHW 2005). These numbers translate to an age standardised incidence rate (per 100,000) of 3.4 in 2001 and 3.2 in 2011 (AIHW 2005).

The occurrence of anastomotic leaks following gastroesophageal resection for cancer is a major source of mortality and morbidity (Schubert et al. 2005). An Austrian study reported the incidence of this complication following oesophagectomy at approximately 33% (Langer 2005).

DIFFUSION

The Polyflex oesophageal stent is currently approved for use in Europe and the United States. The device is currently not available in Australia.

COMPARATORS

Comparators for the relief of dysphagia as well as the treatment of oesophageal leaks or fistulas because of perforation or oesophageal surgery (May and Ell 1998, Pross et al. 2000, Radecke et al. 2005):

- Fibrin glue injections
- Clips
- Self expanding metallic stents
- Covered self expanding metallic stents
- Self expanding, covered, plastic oesophageal stents
-

SAFETY AND EFFECTIVENESS ISSUES

The experience of sixty dysphagic patients treated with the Polyflex stent in a multi-centre trial in Italy, Germany and France was reported by Conigliaro et al. 2007. The patients suffered from unresectable oesophageal and oesophagogastric junction cancers which created inoperable malignant oesophageal stenosis.

Insertion of the Polyflex stent was performed under general anaesthesia under fluoroscopic or endoscopic guidance. The stent was successfully inserted in 59 out of 60 patients (98.3%). In the one patient where insertion was not achieved, the patient had undergone previous chemo-radiotherapy and experienced a tight stenosis of the mid oesophagus. The patient received a covered self expanding metallic stent instead.

The median length of hospitalisation was three days. Unfortunately, during the study period, all patients died. The median survival time was 4.6 months (95%CI: 4.1-5.0). No deaths however were attributed to the implantation of the Polyflex stent.

Prior to stenting, the mean baseline dysphagia score¹ was 2.8. The baseline dysphagia scores for all patients are outlined in Table 1.

Table 1: Baseline dysphagia scores for all patients

Dysphagia score	Number of patients
1	1
2	21
3	26
4	12

The mean dysphagia score following stent placement significantly improved to 1.0 ($p < 0.01$). This significant improvement was maintained at both 30 days and 90 days after stent placement in 86% and 81% of patients respectively ($p < 0.001$).

Before stenting, Eastern Cooperative Oncology Group² (ECOG) performance status was one or lower in 12% of patients and three or higher in 30%. The improvement in ECOG conferred by the Polyflex stent was limited in these patients with only ten percent experiencing an improvement in ECOG status of 10% after one week. This improvement remained present in only 5% and 3% of patients after 30 and 60 days respectively. Thirty six percent of patients experienced significant worsening ($p = 0.02$) in ECOG status at 60 days following stent placement. At this time approximately 30% and 9% of patients had scores of three and four respectively.

Prior to stent placement the median body weight was 58.8 kg (range: 31 to 89 kg). After seven days of stent placement, seven patients (12%) experienced weight loss. By the end of the first month, weight loss was reported in 21 patients (36%) and weight

¹ Dysphagia score: indicates the severity of dysphagia, where, 0 indicates no dysphagia, 1 indicates ability to swallow some solid foods, 2 indicates ability to swallow semisolid food, 3 indicates ability to swallow liquid only, 4 indicates complete dysphagia.

² ECOG classification: where 0 indicates fully active, able to carry on all predisease activities without restriction, 1 indicates restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, 2 indicates ambulatory and capable of all self care, but unable to carry out any work activities, up and about more than 50% of waking hours, 3 indicates capable of only limited self-care, contained to bed or chair 50% or more of waking hours, 4 indicates completely disabled, cannot carry on any self-care, totally confined to bed or chair.

gain was reported in 16 (27%). This finding is somewhat surprising considering the significant improvement in mean dysphagia score in patients.

Radiotherapy and/or chemotherapy prior to stent placement were required in 24 patients. This number was reduced to just three following stent placement indicating stent placement provides sufficient relief of symptoms to discontinue pre-stent treatment.

Several early³ minor⁴ complications were reported following stent placement. These included mild tolerable pain in 11 patients (18.6%) of which seven experienced regression of pain within seven days and four received analgesics. Incomplete stent deployment occurred in three patients (5.1%). In one of these patients the dysphagia score improved in the first week, however an oesophagorespiratory fistula developed two and a half months after stent placement, which was managed with a tracheal stent. This patient died two months later. The other two patients who experienced incomplete stent deployment also experienced an improvement in dysphagia score, but developed oesophageal strictures. Gastroesophageal reflux developed in one of them which was controlled with proton pump inhibitors. Finally, fever was reported in four patients.

Thirteen patients (22%) experienced early major⁵ complications. These included three deaths two days after stent placement owing to pulmonary embolism with infiltrative stricture of the upper oesophagus (one patient), and massive haemorrhage (two patients). Two patients experienced hematemesis and melaena. Atrial fibrillation occurred in a 75 year old patient with mid-oesophageal stricture. Recurrent dysphagia owing to early stent migration was observed in seven patients (11.9%). In two of these patients the stent was removed and replaced with another Polyflex stent, however migration of the second stent also occurred in both patients. Percutaneous endoscopic gastrostomy was placed in one whereas in the other no further stent was placed (age 72) as he was able to swallow semisolids. All patients died one to six months later owing to tumour progression.

A variety of late⁶ complications also occurred. Delayed stent migration was detected in five patients, after a median of 17 days (range: 14 days to 2.8 months). One of these patients refused further stenting and was treated with endoscopic dilation. In the remaining four patients the stent was removed and replaced in three, while in one an oesophagorespiratory fistula developed.

³ Early complication: complications were classified as early if they occurred within seven days of stent placement.

⁴ Minor complication: complications were defined as minor if mild or moderate discomfort or pain, gastroesophageal reflux or fever were present.

⁵ Major complication: complications were defined as major if they were life threatening or caused severe distress e.g. perforation, haemorrhage, stent migration, malignant or granulomatous tissue overgrowth, fistula formation and severe pain.

⁶ Late complication: complications were defined as late if they occurred seven days after stent placement.

Tumour overgrowth was reported in eight patients (13.6%) after a median of four months (range: 2.7 to 5.4 months). Oesophageal patency was successfully restored using a second stent (Ultraflex; Boston Scientific, Massachusetts, United States) in one patient, neodymium-doped yttrium aluminium garnet (Nd:YAG) laser in six, and endoscopic dilation in one.

One patient complained of severe dysphagia ten months after stent placement, caused by hyperplastic tissue reaction at the proximal end of the stent. After dilation with a through-the-scope balloon, the stent was pulled 1 cm above the granulomatous stenosis and resumption of a soft diet was possible.

Radecke et al. 2005 reported the use of the Polyflex stent in a German study of 39 patients with a variety of oesophageal conditions. These included malignant stenosis (n = 22), malignant fistula (n = 8), benign stenosis after treatment for malignant disease (n = 6), benign fistula (n = 2) and perforation or leakage after oesophageal surgery (n = 5). Fifty four Polyflex stents were successfully inserted into the 39 patients. The majority of patients (n = 29) received placement of one stent only, however eight patients received two stents, one patient received three stents and another patient received six stents. Stent placement was performed without fluoroscopy in 31 patients and with fluoroscopy in the remaining eight.

During the stent placement procedure, the initial stent had to be removed immediately after deployment in four patients due to intolerance (n = 1) or failure to cover the lesion completely (n = 3). In each case, the stent was removed and placed correctly during the same session. With the exception of a small proximal margin kink in six patients, which was not clinically apparent and resolved spontaneously, all remaining stents deployed adequately following insertion.

The median duration of stent therapy was 44.5 days (range: 1 to 438). A variety of adverse events were reported during this period, including stent migration in eight patients (20.5%) involving 13 stents (24%). Eight stents migrated within the first seven days while five migrated after the first seven days. Stent related bleeding was reported in three patients (7.7%) involving three stents (5.5%). Two of these patients required blood transfusion, and resulted from stent migration or tumour bleeding during stent deployment. Progressive fistula formation due to stent was reported in two patients (5.1%) involving two stents (3.7%) and mediastinal emphysema which spontaneously resolved occurred in one (2.6%) patient.

There were two cases of life threatening complications. Trachea compression from a tumour mass in one patient required placement of a separate tracheal stent. In the second case, a patient with a large tracheal bronchial fistula (due to Hodgkin's lymphoma) developed respiratory insufficiency and required immediate intubation.

A second look endoscopy was performed in 24 patients. Six minor erosions were discovered at the margin of the stent, and five benign hyperplastic lesions were discovered at the upper stent margin in five patients. There were also two cases of

obstructive tumour growth of the stent margin. Finally, in two patients, stent induced mucosal ulcers were discovered, but resolved spontaneously.

Bleeding was reported in four cases, however it was not attributed to the stent but instead to progressive tumour growth.

Reintervention for recurrent dysphagia was required in 14 patients. Stent correction due to migration was required in one patient while a second stent was implanted in four other patients (stent in stent) due to stent migration ($n = 2$) or fistula development at stent margin ($n = 2$). Removal of the stent was required in nine patients. The reason was stent migration in eight of these patients and ulcer formation behind the stent wall in the other. The stent was replaced in four of these patients, in another four the extremely proximal location of the stent was not tolerated so further stent therapy was considered inappropriate and not continued, and in the last patient, deep ulceration behind the stent prevented the placement of a new one.

Prior to stent placement 28/39 patients had oesophageal stenosis. In 26 of these, oesophageal passage was achieved by insertion of the Polyflex stent. In the other two patients oesophageal passage was achieved but stent migration occurred within 24 hours due to a very proximal location of the stenosis.

Prior to stent insertion 15/39 patients had leakage of the oesophagus. In 11 (73.3%) of these, the leakage was successfully sealed by stent placement. Leakage persisted in the other four. In one the stent did not completely seal around the oesophageal wall due to an enlarged oesophagus, in another development of an enlarging fistula occurred despite correct stent position, in the third patient the distal oesophageal leakage could not be completely covered by stent. The fourth patient experienced rapid tumour progression preventing successful sealing of the leakage.

In six patients with benign leakage or stenosis, elective stent removal was performed. Three patients, two with prior oesophageal perforation and one with prior anastomotic leakage after oesophageal cancer surgery showed complete healing after elective stent removal. One patient with a benign stenosis at the upper oesophageal stricture after radiotherapy for laryngeal cancer required regular oesophageal bougienage after elective stent removal. In the last two patients (one with aorto-oesophageal fistula and one with oesophageal perforation) stents were electively removed because of lack of therapeutic success.

Dysphagia improved and oral feeding could be resumed in 27/39 (62.9%) of patients after stent placement. In six patients, although stent placement was technically successful (achievement of oesophageal passage and ability to swallow saliva), oral nutrition could not be started due to progressive tumour disease. In another six patients oral feeding was not possible because of clinical non-function of the stent.

Thirty six patients died during follow-up (median 56 days) as a result of underlying disease. Median duration after stent placement to death was 54 days (range: 6 to 340 days).

Freeman et al. 2007 reported their experience treating refractory postoperative oesophageal fistulae using the Polyflex oesophageal stent. Twenty one patients with post-operative oesophageal leak (owing to the presence of an oesophageal fistula) and at least one operative repair attempt were recruited across two tertiary care hospitals in the United States. The Polyflex stents were implanted by a thoracic surgeon under general endotracheal anaesthesia and fluoroscopy guidance. Implantation occurred at a mean number of 12 ± 8 days (range: 3 to 31 days) following initial surgical repair of oesophageal leakage. In addition to Polyflex stent implantation, 12 patients underwent additional procedures, the most common being for enteral feeding access. There were no intraoperative complications reported. According to the protocol, patients were intended to have repeat oesophagraphy a minimum of 48 hours after stent placement, however this occurred at a mean (\pm standard deviation) of $6 (\pm 7)$ days (range: 2 to 29 days) after stent placement. The most common reason for this was requirement for continued mechanical ventilation.

Occlusion of the oesophageal fistula was demonstrated in the initial oesophagram in 20 (95%) patients. In addition, patients were also able to resume oral nutrition. After a mean of 51 ± 43 days (range: 15 to 175 days) stents in 20 (95%) patients were removed under general anaesthesia without evidence residual oesophageal leak or fistula. In these patients no further operations were required for treatment of oesophageal fistula.

One patient experienced dehiscence of oesophageal perforation repair two days after stent placement and required operative repair. Other morbidities reported included stent migration in five patients (24%), respiratory failure in three patients (14%), pneumonia in two patients (10%), deep venous thrombosis in one patient (5%) and an enterocutaneous fistula in one patient (5%). In one patient (5%) endoscopic dilation was required to relieve an oesophageal stricture following stent removal. One death was reported resulting from rupture of an infected thoracic aortic dissection complicated by oesophageal perforation after stent removal. Migration of the stent occurred in five patients (seven stents) and required repositioning or replacement.

COST IMPACT

The cost of the Polyflex stent was reported in two separate studies. Bethge and Vakil (2001) report the Polyflex stent to cost approximately USD\$400, this compared favourable to the reported cost of self expanding metal stent at USD\$1000.

Conigliaro et al. (2007) reported the cost of the Polyflex stent in Italy to be approximately €50.

The Medicare Benefits Schedule reimbursement fees for procedures related to the surgical treatment of oesophageal strictures are listed in Table 2.

Table 2: Medical Benefits Schedule of fees for procedures related to the oesophagus (Department of Health and Ageing 2007)

Category	Item Number	Benefit (AUD)	Number of Claims (July 2005 to June 2006)
Insertion of oesophageal prosthesis including endoscopy and dilation	30490	\$465.10	347
Repair of oesophageal perforation by thoracotomy	30560	\$834.00	9
Dilatation of oesophageal stricture without oesophagoscopy	41828	\$46.15	26
Division and repair of tracheo-oesophageal fistula without atresia	43900	\$982.60	7
Local excision for tumour of oesophagus	30559	\$750.70	21
Intrathoracic operation on heart, lungs, great vessels, bronchial tree, oesophagus or mediastinum, or on more than 1 of those organs	38456	\$1353.75	349
Balloon dilation of oesophagus using interventional imaging techniques	41832	\$201.90	24
Oesophagus, resection of congenital, anastomotic or corrosive stricture and anastomosis	43096	\$1432.85	0

ETHICAL, CULTURAL OR RELIGIOUS CONSIDERATIONS

No issues were identified from the retrieved material.

OTHER ISSUES

No issues were identified from the retrieved material.

SUMMARY OF FINDINGS

The evidence available on the Polyflex oesophageal stent suggest that the stent is safe to insert and safe to use under a variety of medical conditions including oesophageal stenoses, fistulas and leakages. However similar to other oesophageal stents, the Polyflex stent has been reported to migrate once implanted.

Use of the Polyflex stent has been demonstrated to improve certain symptoms associated with stenoses, fistulas and leakages of the oesophagus. However, this was not supported by weight gain and ECOG performance status in patients. Therefore, further randomised comparative studies with other oesophageal stents are required to establish the safety and efficacy of this stent.

HEALTHPACT ACTION:

The current evidence on the Polyflex oesophageal stent reports the occurrence of various safety issues. The device appears to provide relief of symptoms to patients suffering dysphagia, oesophageal leaks or oesophageal fistulas however randomised controlled trials are necessary to determine its safety and effectiveness. Based on the low level of evidence currently available, it is therefore recommended that the Polyflex stent is archived.

NUMBER OF STUDIES INCLUDED

Total number of studies	3
Level IV intervention evidence	3

REFERENCES

AIHW, AACR & NCSG: Ian McDermid 2005. Cancer incidence projections, Australia 2002 to 2011. Canberra: Australian Institute of Health and Welfare (AIHW), Australasian Association of Cancer Registries (AACR) and the National Cancer Strategies Group (NCSG).

Baron TH. A practical guide for choosing an expandable metal stent for GI malignancies: is a stent by any other name still a stent? *Gastrointestinal Endoscopy* 2001; 54(2): 269-272.

Bethge N and Vakil N. A prospective trial of a new self-expanding plastic stent for malignant esophageal obstruction. *The American Journal of Gastroenterology* 2001; 96(5): 1350-1354.

Brinster CJ, Singhal S, Lee L, Marshall MB, Kaiser LR, Kucharczuk JC. Evolving options in the management of esophageal perforation. *Annals of Thoracic Surgery* 2004; 77(4): 1475-1483.

Conigliaro R, Battaglia G, Repici A, De Prestis G, Ghezzo L, Bittinger M, Messmann H, Demarquay JF, Togni M, Bianchi S, Filiberti R, Conio M. Polyflex stents for malignant oesophageal and oesophagogastric stricture: a prospective, multicentric study. *European Journal of Gastroenterology and Hepatology* 2007; 19(3): 195-203.

Costamagna G, Shah SK, Tringali A, Mutignani M, Perri V, Riccioni ME. Prospective evaluation of a new self-expanding plastic stent for inoperable esophageal strictures. *Surgical Endoscopy* 2003; 17(6): 891-895.

Department of Health and Ageing. Medicare Benefits Schedule. Last updated 2007. <http://www9.health.gov.au/mbs/> [Accessed June 2007].

Fisichella PM. Esophageal cancer. Last updated 2006. <http://www.emedicine.com/med/topic741.htm> [Accessed June 2007].

Freeman RK, Ascoti AJ, Wozniak TC. Postoperative esophageal leak management with the Polyflex esophageal stent. *The Journal of Thoracic and Cardiovascular Surgery* 2007; 133(2): 333-338.

Langer FB, Wenzl E, Prager G, Salat A, Miholic J, Mang T, Zacherl J. Management of postoperative esophageal leaks with the Polyflex self-expanding covered plastic stent. *Annals of Thoracic Surgery* 2005; 79(2): 398-404.

May A, Ell C. Palliative treatment of malignant esophagorespiratory fistulas with Gianturco-Z stents. A prospective clinical trial and review of the literature on covered metal stents. *American Journal of Gastroenterology* 1998; 93(4): 532-535.

Paik NJ. Dysphagia. Last updated 2006. <http://www.emedicine.com/pmr/topic194.htm> [Accessed June 2007].

Pross M, Manger T, Reinheckel T, Mirow L, Kunz D, Lippert H. Endoscopic treatment of clinically symptomatic leaks of thoracic esophageal anastomoses. *Gastrointestinal Endoscopy* 2000; 51(1): 73-73.

Radecke K, Gerken G, Treichel U. Impact of a self-expanding, plastic esophageal stent on various esophageal stenoses, fistulas, and leakages: a single-center experience in 39 patients. *Gastrointestinal Endoscopy* 2005; 61(7): 812-818.

Schubert D, Scheidbach H, Kuhn R, Wex C, Weiss G, Eder F, Lippert H, Pross M. Endoscopic treatment of thoracic esophageal anastomotic leaks by using silicone-covered, self-expanding polyester stents. *Gastrointestinal Endoscopy* 2005; 61(7): 891-896.

Siersema PD, Hop WC, van Blakestein M, van Tilburg AJ, Bac DJ, Homs MY, Kuipers EJ. A comparison of 3 types of covered metal stents for the palliation of patients with dysphagia caused by esophagogastric carcinoma: a prospective, randomized study. *Gastrintestinal Endoscopy* 2004; 54(2): 145-153.

SOURCES OF FURTHER INFORMATION:

Decker P, Lippler J, Decker D, Hirner A. Use of the Polyflex stent in the palliative therapy of esophageal carcinoma. *Surgical Endoscopy* 2001; 15(12): 1444-1447.

Dormann AJ, Eisendrath P, Wigglinghaus B, Huchzermeyer H, Deviere J. Palliation of esophageal carcinoma with a new self-expanding plastic stent. *Endoscopy* 2003; 35(3): 207-211.

Gelbmann CM, Ratiu NL, Rath HC, Rogler G, Lock G, Scholmerich J, Kullman F. Use of self-expandable plastic stents for the treatment of esophageal perforations and symptomatic anastomotic leaks. *Endoscopy* 2004; 36(8): 695-699.

Pungpapong S, Raimondo M, Wallace MB, Woodward TA. Problematic esophageal stricture: an emerging indication for self-expandable silicone stents. *Gastrointestinal Endoscopy* 2004; 60(5): 842-845.

Scileppi T, Li JJ, Iswara K, Tenner S. The use of a Polyflex coated esophageal stent to assist in the closure of a colonic anastomotic leak. *Gastrointestinal Endoscopy* 2005; 62(4): 643-645.

Siddiqui AA, Loren D, Dudnick R, Kowalski T. Expandable polyester silicon-covered stent for malignant esophageal strictures before neoadjuvant chemoradiation: a pilot study. *Digestive Diseases and Sciences* 2007; 52(3): 823-829.

SEARCH CRITERIA TO BE USED:

esophageal stenosis/therapy*
esophageal stenosis/surgery*
esophageal perforation/surgery*
esophageal neoplasm/therapy*
Stents*
Polyflex
esophageal