

## Enteral stents

To promote the appropriate use of new or emerging endoscopic technologies and those technologies that have an impact on endoscopic practice, the ASGE Technology Committee presents relevant information to practicing physicians in the form of technology reviews. Evidence-based methodology is employed wherein a MEDLINE literature search is performed to identify pertinent clinical studies on the topic, a MAUDE (Food and Drug Administration Center for Devices and Radiological Health) database search is performed to identify the reported complications of a given technology, and both are supplemented by accessing the “related articles” feature of PubMed and by scrutiny of pertinent references cited in the identified studies. Controlled clinical trials are emphasized, but in many cases data from randomized controlled trials are lacking; in such cases, large case series, preliminary clinical studies, and expert opinion are utilized. Technical data are gathered from traditional and Web-based publications, proprietary publications, and informal communications with pertinent vendors. Reviews are drafted by 1 or 2 committee members, reviewed in significant detail by the committee as a whole, and approved by the Governing Board of the ASGE. When financial guidance is appropriate, the most recent coding data and list prices at the time of publication are provided. For this review, the MEDLINE database was searched through April 2006 for articles related to enteral, esophageal, duodenal, and colonic stents.

### BACKGROUND

Stents are devices used to maintain or restore the lumen of hollow organs, vessels, and ducts. Current stents available for application in the alimentary tract include self-expanding metal stents (SEMS) for esophageal, gastroduodenal, and colonic malignant obstruction and a self-expanding plastic stent (SEPS) for benign or malignant esophageal strictures. This report will provide an update on the technical specifications, efficacy, safety, and finan-

cial considerations regarding stents for use in the esophagus, gastroduodenum, and colon.

### TECHNICAL CONSIDERATIONS

SEMS consist of woven, knitted, or laser cut metal mesh cylinders that exert self-expansive forces until they reach their maximum fixed diameter. They are generally packaged in a compressed form and constrained on a delivery device. SEMS are composed of either stainless steel (Z-stent) or alloys such as Nitinol (Ultraflex) or Elgiloy (Wall-stent). Nitinol, an alloy of nickel and titanium, yields increased flexibility that is helpful for stenting sharply angulated regions at the cost of lesser radial force relative to stents made with other metals. Elgiloy, an alloy composed primarily of cobalt, nickel, and chromium, is corrosion resistant and capable of generating high radial forces. All SEMS come in a variety of lengths and diameters. Most have a proximal and/or distal flare to prevent migration. The various stents that are commercially available in the United States, and their unique specifications and features, are outlined in [Table 1](#).

To prevent tumor ingrowth, the interstices between the metal mesh of esophageal SEMS may be wholly or partially covered by a plastic membrane. One specialized covered SEMS that is intended for tumors located near the gastroesophageal junction (Esophageal Z-stent with Dua Anti-reflux valve; Wilson-Cook Medical, Winston-Salem, NC) employs an extended polyurethane membrane 8 cm beyond the metal portion of the stent to prevent gastroesophageal reflux. Currently available enteral and colonic stents are noncovered.

An SEPS has been developed for esophageal strictures. This stent has a woven polyester skeleton and is completely covered with a silicone membrane. The silicone prevents tissue ingrowth through the mesh, and the polyester braids on the external surface anchor the stent to the mucosa to limit migration. Radiopaque markers positioned at the middle and ends of the stent facilitate visualization of this nonmetallic device during fluoroscopy. In contrast to most SEMS, which are sold in a constrained fashion, the SEPS requires mounting onto the delivery catheter just before use. The SEPS also come in a variety of lengths and diameters ([Table 1](#)).

All enteral SEMS are inserted and deployed over a guidewire during fluoroscopic and/or parallel

TABLE 1. Specifications and features of stents commercially available in the United States

	Composition	Delivery system diameter/length	Unconstrained outer diameter	Unconstrained lengths [covered length]	List price	Features
<b>Esophageal stents</b>						
<b>Boston Scientific</b>						
Ultraflex NG Covered	Nitinol	5 mm/87-95 cm	18 mm, 23 mm (proximal flare 23 mm and 28 mm respectively)	10 cm [7 cm] 12 cm [9 cm] 15 cm [12 cm]	\$1730	Available for distal or proximal release; suture removal release mechanism; 48%-54% foreshortening with deployment
Ultraflex NG Uncovered	Nitinol	5 mm/87-95 cm	18 mm (proximal flare 23 mm)	7 cm 10 cm 12 cm 15 cm	\$1650	Available for distal or proximal release; 48%-54% foreshortening with deployment
Wallstent II	Elgiloy	6 mm/74cm	20 mm center; 28 mm ends	10 cm [8 cm] 15 cm [13 cm]	\$2295	Restrained before completely deployed; free wire edges at ends of stent; 28% foreshortening with deployment
Polyflex®	Polyester/silicone	12-14 mm/70 cm	16 mm (proximal flare 20 mm) 18 mm (proximal flare 23 mm) 21 mm (proximal flare 25 mm)	9 cm 12 cm 15 cm	\$1950	Early studies have demonstrated safe removal weeks after placement; manual loading onto delivery system required; has radiopaque markers at ends and center; 36%-41% foreshortening with deployment
<b>Cook Medical</b>						
Z-Stent Fully Covered	Stainless steel	12 mm/70 cm	18 mm center; 25 mm flared ends	8 cm 10 cm 12 cm 14 cm	\$1298 \$1352 \$1407 \$1461	Preloaded in delivery system but some assembly required before deployment; no foreshortening with deployment
Z-stent Uncoated Flange	Stainless steel	12 mm/70 cm	18 mm center; 25 mm flared ends	8 cm 10 cm 12 cm 14 cm	\$1298 \$1352 \$1407 \$1461	Only portion of flanges on ends of stent are uncovered; same delivery mechanism as fully covered stent; no foreshortening
Z-stent with Dua Anti-reflux valve	Stainless steel	12 mm/70 cm	18 mm center; 25 mm flared ends	8 cm 10 cm 12 cm 14 cm	\$1505 \$1589 \$1672 \$1755	Required manual loading of stent into delivery system; windsock design reduces possibility of gastroesophageal reflux for stents placed at gastroesophageal junction; no foreshortening
<b>Endoventions</b>						
Alimaxx-E	Nitinol	7.3 mm/52 cm	18 mm center, 22 mm center (both with flared ends, proximal end 3 mm larger and distal end 5 mm larger)	7 cm 10 cm 12 cm	\$1900	Completely covered with polymer membrane; no foreshortening; limited clinical experience at time of writing
<b>Colon/enteral stents</b>						
<b>Boston Scientific</b>						
Ultraflex Colon stent	Nitinol	5 mm/100 cm	25 mm (proximal flare 30 mm)	57 mm 87 mm 117 mm	\$1775	Proximal (upstream) flare is larger than body and distal aspect to prevent migration; 23% foreshortening

TABLE 1 (continued)

	Composition	Delivery system diameter/length	Unconstrained outer diameter	Unconstrained lengths [covered length]	List price	Features
Wallstent	Elgiloy	3.3 mm/135 cm	20 mm	60 mm	\$1775	Through-the-scope deployment possible; reconstrainable before full deployment; 39%-49% foreshortening
Enteral®		and 230 cm	22 mm	90 mm		
<b>Cook Medical</b>						
Colonic Z-stent	Stainless steel	12 mm/35 cm	25mm	40 mm	\$1000	No foreshortening
				60 mm	\$1110	
				80 mm	\$1220	
				100 mm	\$1330	
				120 mm	\$1440	

endoscopic guidance. The only SEMS designed for gastro-duodenal and proximal colonic applications (Wallstent Enteral; Boston Scientific, Natick, Mass) employs both wire guidance and through-the-scope delivery, as its 10F delivery catheter can be placed through the working channel of a large caliber endoscope. When correctly positioned across a stricture, the stents are deployed by removal or release of the constraining mechanism. As the stent expands, radial forces anchor it at the site of obstruction. The main difference between delivery systems is in the design of the handles and their means of removing the constraining mechanism for deployment. Although the majority of deployment systems release the stent initially at the distal end of the catheter, the Ultraflex Esophageal NG stent (Boston Scientific) is available in both a proximal and distal release system.

One important aspect of deployment is the variable degree of foreshortening that occurs with many of the SEMS and SEPS during the transition from the compressed to fully expanded state. The endoscopist must anticipate and allow for this foreshortening to ensure appropriate placement. Table 1 indicates the foreshortening for each device. The labeled stent length always indicates the length at full expansion.

Dilation to  $\geq 36F$  is often required to enable passage of the esophageal SEMS, depending on stent type and the character and location of the stricture. In contrast, predeployment dilation is generally not required during gastroduodenal stenting and should be avoided during colonic SEMS placement. Technical details of stent placement and general reviews have been previously published.<sup>1,2</sup>

Noncovered SEMS cannot be easily repositioned or removed once fully deployed. Covered SEMS can often be repositioned, removed, or inadvertently displaced early after placement before ingrowth into their uncovered portions. The available SEPS has been designed and demonstrated to be removable, although the manufacturer

warns that the safety of removal beyond 9 months has not been demonstrated.

## EFFICACY/COMPARATIVE ANALYSIS

### Esophageal stents

Esophageal SEMS are indicated for palliation of malignant strictures and tracheo-esophageal fistulas. SEMS have largely replaced the use of rigid plastic stents in the esophagus as a result of the lower complication rate with their use.<sup>3-6</sup> SEMS improve dysphagia in  $> 90\%$  of patients with esophageal cancer.<sup>4,6</sup> SEMS also improve dysphagia due to extrinsic malignant compression; however, outcomes are less optimal in this setting.<sup>7</sup> In a randomized study, SEMS were associated with more rapid restoration of oral intake and lower hospital mortality compared with palliative bypass surgery.<sup>8</sup> A Dutch cooperative study comparing SEMS to brachytherapy found that SEMS more rapidly improved dysphagia but brachytherapy yielded better long-term control of dysphagia and better overall quality of life with fewer complications.<sup>9</sup> A randomized controlled trial suggested SEMS were more effective than LASER therapy and required fewer reinterventions.<sup>10</sup> In trials comparing various available SEMS, no single device is consistently associated with improved outcomes or fewer complications.<sup>11-13</sup>

Placement of stents for tumors near the upper esophageal sphincter (UES) is often technically difficult and may cause tracheal compression, globus sensation, or interfere with the swallowing mechanism. It is recommended to avoid stenting when the tumor involves the UES or hypopharynx.<sup>14</sup> One case series suggests stents can be successfully placed for tumors within 1 cm of the UES, but the authors recommended avoiding large caliber stents in this region.<sup>15</sup>

Covered SEMS help prevent tumor ingrowth. In one randomized controlled study, during 6 months of

observation, covered stents decreased the necessity of re-intervention for tumor ingrowth from 27% to 0%.<sup>16</sup> In vitro studies, animal data, and clinical series suggest that the coated Esophageal Z-stent with Dua Anti-reflux valve (Wilson-Cook Medical) successfully prevents significant reflux,<sup>17,18</sup> when stent placement across the esophago-gastric junction is required. Randomized controlled trials of similarly designed windsock anti-reflux stents have demonstrated both no benefit<sup>19</sup> and significant improvement<sup>20</sup> in prevention of esophageal acid reflux as determined by reflux scores and 24-hour pH monitoring.

Covered SEMS are effective for palliation of malignant tracheoesophageal fistulas with successful closure of the fistula in 66% to 100% of patients.<sup>21-24</sup> When fistulae persist despite esophageal stent placement, bronchoscopic placement of a parallel tracheal stent can facilitate closure.<sup>25</sup>

The currently available silicone-covered SEPS is approved for treatment of malignant and benign esophageal strictures. Preliminary reports indicate similar efficacy for malignant strictures to SEMS.<sup>26,27</sup> Although not approved as a removable stent, the complete silicone coating facilitates removal even after it is in place for several months. There are several reports of its use for benign strictures; however, they are uncontrolled and include only small numbers of heterogeneous patients.<sup>28,29</sup> In one series, temporary SEPS placement for anastomotic leaks after esophagectomy resulted in more rapid oral intake, shorter average hospital stay, and improved mortality compared to surgery or conservative therapy.<sup>30</sup>

### Gastroduodenal stents

Many uncontrolled case series have reported effective palliation of malignant gastric outlet obstruction in the antrum, proximal small bowel, and gastro-enteral anastomoses by endoscopic SEMS placement.<sup>31-35</sup> Only the Wallstent Enteral (Boston Scientific) is approved for treatment of malignant gastroduodenal obstruction; however, some series include cases using esophageal stents with introducer systems long enough to reach the duodenum. Technical success rates are generally >90%, and 60% to 80% of patients are able to eat at least soft mechanical diets. A comprehensive review of 32 case series including 606 patients unable to take oral intake reported successful stent deployment in 97% of patients, and oral intake was possible in all successful cases, with 87% of patients capable of eating at least a mechanical soft diet.<sup>36</sup>

There are limited reports comparing stenting of the gastric outlet or small intestine with surgical bypass. A small randomized prospective study of 18 patients comparing SEMS placement to surgical bypass found no difference in survival, complication rates, or gastric emptying at 3 months, but the SEMS group had more rapid restoration of oral intake and a shorter mean hospitalization.<sup>37</sup> Similarly, a retrospective comparison of a cohort of 27 patients with pancreatic cancer causing duodenal obstruction treated with endoscopic stenting or surgical bypass found

no difference in survival but a median hospital stay of 4 days in the stent group versus 14 days in the surgical group.<sup>34</sup> A prospective nonrandomized study of 36 patients found no difference in overall survival or ability to tolerate food 1 month after stent placement or surgical bypass.<sup>38</sup>

### Colonic stents

Currently available colonic stents are uncovered but many have reported using both uncovered and covered esophageal stents in the colon, and the latter may lower the rate of tissue ingrowth and aid with fistula closure.<sup>39,40</sup> While most reports include patients primarily with left-sided colonic malignancies, some have employed stenting of right-sided obstructing malignancies using devices with a longer delivery system.<sup>41,42</sup> Available reports suggest the success rate for stenting of right-sided colon obstruction may be lower than stenting of left-sided colorectal obstruction.<sup>40,43</sup>

Overall technical success rates have exceeded 95%, with approximate clinical success rates, defined as relief of obstructive symptoms, of 85% to 90% for palliative stenting. When SEMS have been used for temporary preoperative decompression, success rates for completion of a single stage elective operation are 70% to 85%.<sup>1,40,44-47</sup>

There are currently no randomized trials comparing colonic stenting with surgery in either the palliative setting or for emergent decompression before curative surgery. One retrospective study found a primary anastomosis was possible in 84.6% of patients decompressed with colonic SEMS compared with 41.4% of patients treated with emergency surgery.<sup>47</sup> Total hospital stay, complications, and need for re-intervention were also lower in the group treated with SEMS before surgery. Similarly, a recent decision model of colonic stent placement versus emergency surgery for obstructing left-sided colon cancer estimated preoperative colonic SEMS placement would decrease operative procedures by 23% and reduce the need for a stoma from 43% to 7%.<sup>48</sup>

### SAFETY

In addition to the standard risks of endoscopy, SEMS placement in the esophagus is associated with several severe, life-threatening complications, including perforation, hemorrhage, and airway compression.<sup>2,3</sup> Whereas perforation and hemorrhage may be immediate or delayed, airway compression is an immediate complication, and some have advocated bronchoscopy and possible tracheal stent placement simultaneously or before esophageal stent placement for bulky lesions in the upper esophagus involving or compressing the airways.<sup>25,49,50</sup> It has been suggested that smaller diameter stents should be chosen for upper esophageal tumors to avoid excessive compressive forces, which can lead to unpleasant symptoms and

**TABLE 2. CPT codes used when performing stent placement in the alimentary tract**

CPT	Procedure
43219	Esophagoscopy with insertion of plastic tube or stent
43256	Upper GI endoscopy with stent placement, includes predilation
44370	Small-bowel endoscopy with stent placement, includes predilation
44397	Colonoscopy through stoma with stent placement, includes predilation
45345	Flexible sigmoidoscopy with stent placement, includes predilation
45387	Colonoscopy proximal to splenic flexure with stent placement, includes predilation
76000	Fluoroscopy (separate procedure), up to 1 hour physician time
<b>Device codes</b>	
C-1874	Stent covered/coated, with delivery system
C-1876	Stent noncovered/noncoated, with delivery system
<b>APC codes</b>	
0384	Used for all non-ERCP GI stenting procedures

potentially cause airway compression or pressure necrosis with fistula formation.<sup>51</sup> The overall death rate from palliative stenting of the esophagus has been estimated at 0.5% to 3.3% on the basis of retrospective surveys and reports including both SEMS and rigid plastic stents.<sup>3,52,53</sup> Prior radiation or chemotherapy may be associated with an increased rate of complications. One series reported stent-related mortality of 8.5% in this setting, while another revealed no increase in mortality or life-threatening complications with esophageal in this setting.<sup>54-56</sup> Other complications of esophageal stent placement include stent occlusion due to tissue hyperplasia or tumor ingrowth (11%), stent migration (7%), chest pain (12%), gastroesophageal reflux and aspiration pneumonia (8%), and delayed tracheoesophageal fistula due to pressure necrosis (2%).<sup>33</sup>

As with SEMS placement in the esophagus, perforation and bleeding are the most serious complications of gastro-duodenal stent placement, occurring in 0.7% and 0.5% of patients, respectively.<sup>36</sup> Stent migration (5%) and restenosis (18%) are typically late complications, and the majority of these complications can be managed with insertion of an additional stent.<sup>36</sup> One unique complication for gastro-duodenal stent placement is precipitation of cholangitis or biliary obstruction due to compression of the papilla.<sup>2,32,36</sup> Because the papilla cannot typically be accessed after duodenal SEMS placement, a biliary SEMS should be placed

before duodenal SEMS when biliary obstruction is present or impending.

Perforation is the most severe complication of colonic SEMS and occurred in 3.8% of patients from a pooled analysis of all reported studies or case series.<sup>40</sup> Predeployment dilation has been associated with an increased risk of perforation and hence is discouraged.<sup>57</sup> Other potential factors contributing to perforation include puncture of the colonic wall during guidewire passage and erosion of the colonic wall by free wires at the end of the stent.<sup>58</sup> Stent migration and obstruction are generally delayed complications reported in 11.8% and 7.3% of patients, respectively.<sup>40</sup> Stent placement low in the rectum can lead to severe tenesmus.<sup>59</sup>

## FINANCIAL CONSIDERATIONS

The list prices of the available enteral stents are provided in Table 1. Several cost analyses have suggested that stent costs are offset by the relative reduction in number of surgical procedures and hospital days when compared with alternative therapies. In a cost-minimization analysis from the United Kingdom, endoscopic palliation of esophageal cancer with SEMS placement yielded a lower cost per day-of-survival compared with alternative modalities.<sup>60</sup> Similarly, gastroduodenal stent placement yields 30% lower hospital costs compared to surgical palliation, while colonic stenting for palliation or preoperative decompression is associated with a 10% to 20% cost reduction.<sup>38,48,61</sup>

As of 2005 there are specific CPT codes that must be used when performing stent placement in the alimentary tract, and facilities must include a separate code for the stent itself (Table 2). Although CMS does not provide additional payment for the device, facilities are required to report these codes to permit cost tracking for future rate determinations. These requirements change frequently and each facility should check with its local payers. Dilation of the stricture prior to stent placement is included in the stent procedure code. Fluoroscopic supervision when done by the physician inserting the stent is separately reported using CPT 76000.

## SUMMARY

Obstruction of the digestive tract is a frequent cause of morbidity in patients with gastrointestinal malignancies. The role of palliative stenting in the management of these patients has expanded in recent years to include the esophagus, the gastroduodenal region, and the colon. Stent placement also serves as an adjunct to definitive surgical therapy for obstructing colonic lesions, as endoscopic decompression facilitates formal bowel cleansing and subsequent single-stage elective surgery. Stenting has also expanded into the realm of benign esophageal

disease, with limited data demonstrating the use of an SEPS for benign strictures and anastomotic leaks. Endoscopic capabilities are likely to expand with the advent of innovative stenting devices and techniques.

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