

## Overtube use in gastrointestinal endoscopy

*The American Society for Gastrointestinal Endoscopy (ASGE) Technology Committee provides reviews of existing, new, or emerging endoscopic technologies that have an impact on the practice of GI endoscopy. Evidence-based methodology is used, with a MEDLINE literature search to identify pertinent clinical studies on the topic, and a MAUDE (Food and Drug Administration Center for Devices and Radiological Health) database search to identify the reported complications of a given technology. Both are supplemented by accessing the "related articles" feature of PubMed and by scrutinizing pertinent references cited by 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 opinions are used. Technical data are gathered from traditional and Web-based publications, proprietary publications, and informal communications with pertinent vendors.*

*Technology Status Evaluation Reports are drafted by 1 or 2 members of the ASGE Technology Committee, reviewed and edited by the committee as a whole, and approved by the governing board of the ASGE. When financial guidance is indicated, the most recent coding data and list prices at the time of publication are provided. For this review, the MEDLINE database was searched through March 2009 for articles related to overtube use in GI endoscopy by using the keywords overtube, intubation, enteral access, enteroscopy, and foreign bodies, paired with endoscopy, gastrointestinal. Practitioners should continue to monitor the medical literature for subsequent data about the efficacy, safety, and socioeconomic aspects of these technologies.*

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### BACKGROUND

An overtube is a sleeve-like device designed to facilitate endoscopy. All overtubes have an inner diameter larger than an endoscope, providing a conduit for passage of the device into the digestive tract. Overtubes are intended to protect the GI mucosa from trauma and limit the risk of aspiration. They also facilitate access in patients with challenging anatomy, increase the depth of insertion, and maintain access for repeated withdrawal and reinsertion. This overview covers the design and use of overtubes marketed for various general applications as well as overtubes designed for specific functions including those marketed with enteroscopes.<sup>1</sup>

### TECHNICAL CONSIDERATIONS

#### General overtubes

All overtubes are made of semi-rigid plastic with a tapered, soft, distal tip. Overtubes may have a proximal seal for the endoscope. The distal end of the overtube must be atraumatic and usually has an inner diameter closely matched with that of the endoscope to limit the potential of entrapment or pinching of mucosa between the 2 devices during insertion and exchanges. Endoscopic overtubes vary in length (23-135 cm) and caliber (outer diameters 14.4-21 mm) to correspond with intended applications and routes of entry. When the purpose is to protect the cricopharyngeal area or the airway, the overtube needs to be 20 to 25 cm in length. To protect the esophagus when objects are being removed from the stomach, the overtube should be at least 50 cm in length. Objects can be either extracted through the overtube or retracted into the overtube, with both overtube and endoscope being withdrawn simultaneously. Other important properties of commercially available overtubes are described in [Table 1](#).

One line of single-use overtubes (Guardus; U.S. Endoscopy, Mentor, OH) is designed to maintain insufflation and maximize the luminal diameter for removal of foreign bodies. A 2-tube system uses a tapered inner tube to provide a close fit between the endoscope and the device during intubation and a slightly shorter and larger-diameter, coil-spring-reinforced outer tube, thus reducing the potential for mucosal pinching. The outer and inner tubes are locked together by a threading mechanism at the proximal (external) portion of the tubes. This proximal

**TABLE 1. General overtubes**

Manufacturer & device name	Compatible endoscope diameter (OD, mm)	Length (cm)	Inner diameter (mm)	Outer diameter (mm)	Single use	List price (\$)
<b>U.S. Endoscopy, Mentor, OH</b>						
Guardus Overtubes*						
Esophageal	8.6-10.0	25	16.7	19.5	Yes	125
Esophageal	10.0-11.7	25	16.7	19.5	Yes	125
Gastric	8.6-10.0	50	16.7	19.5	Yes	150
Gastric	10.0-11.7	50	16.7	19.5	Yes	150
<b>ConMed, Utica, NY</b>						
ConMed Endoscopic Overtube	<13	23	15	20	No	130

OD, Outer Diameter.

\*OD measures refer to the outer of 2 sleeves. The inner sleeve facilitates insertion and dictates the caliber of the compatible endoscopes.

end of the inner tube also incorporates an insufflation seal to minimize leakage of air. There is a separate, larger insufflation seal attached by a plastic strap to the outer tube, which can be threaded in place once the inner tube is removed, again to minimize leakage of air. Adequate lubrication of all surfaces is necessary prior to assembly and backloading onto the endoscope. Once the desired location is achieved during endoscopy, the 2-tube system is advanced into position, and the inner tube is unlocked and simultaneously removed with the endoscope while the outer tube is maintained in position. The outer tube's dedicated insufflation seal is then threaded into position on the external portion of the tube before reinsertion of the endoscope. Models are available in various sizes for esophageal, gastric, and colonic indications (Table 1).

### Overtubes for enteroscopy

Several overtube devices are designed specifically to facilitate deep endoscope insertion with the goal of reaching portions of the digestive tract not traditionally accessible with standard upper or lower endoscopes. Two of these devices are specifically marketed as part of an entire enteroscopy system with an accompanying enteroscope. The double-balloon enteroscopy (DBE) system (Fujinon, Saitama, Japan) uses flexible, single-use overtubes that are matched to the caliber of the enteroscope. The overtubes are 1350 mm long and have a 1-mm-thick latex balloon permanently fixed to the distal end and a port for balloon inflation and deflation. The double-balloon enteroscopes have the second balloon attached to the distal tip. An external air pump is connected to the balloon ports of the endoscope and overtube. A control box for activation of balloon inflation and deflation is connected to the pump by a wire. Automated pressure control assures that the balloon inflation pressure does not exceed 45 mm Hg. The overtube contains a port for water instilla-

tion to activate a hydrophilic coating on the inner surface, which minimizes friction with the endoscope. When the apparatus is assembled, the balloons are deflated to begin the procedure. For the oral approach, the endoscope and overtube are inserted into the duodenum, and the balloon on the overtube is inflated to maintain a stable position. With its balloon deflated, the endoscope is inserted up to 40 cm beyond the overtube, the endoscope balloon is inflated, the overtube balloon is deflated, and the overtube is advanced to the tip of the endoscope. A circumferential white mark on the endoscope insertion tube 140 cm proximal to the endoscope balloon represents a stopping point beyond which the overtube should not be advanced or the endoscope withdrawn. This prevents the overtube from shearing off the endoscope balloon. The overtube balloon is then reinflated, so that the entire apparatus is secured in the intestine with both balloons inflated. The entire endoscope-overtube apparatus is then retracted, which pleats the intestine on to the overtube like a compressed concertina. This procedure is repeated, and the device is advanced through the intestine in increments of up to 40 cm.

The single-balloon enteroscopy (SBE) system uses a single-use, 140-cm long (working length 132 cm), 13.2-mm outer diameter, silicone (non-latex) overtube (ST-SB1, Olympus America, Inc., Center Valley, Pa) with a balloon at its distal end. The balloon is inflated and deflated by an electronic inflation control device with automatic pressure control to standardize balloon inflation pressures. This overtube is loaded onto the enteroscope, which has a working length of 200 cm and an outer diameter of 9.2 mm. The internal surface of the balloon overtube is hydrophilic, and lubrication between the outer sheath of the endoscope and the inner surface of the overtube is facilitated by flushing the internal surface of the overtube with water. The initial process of insertion into the small bowel is similar to that of the double-balloon

system, with the insertion of the endoscope system as far as possible in the deflated position. The balloon is then inflated and the entire system withdrawn to promote backloading of the small bowel onto the outer surface of the overtube. The endoscope is then advanced while the balloon is inflated, holding the proximal small bowel in the retracted position. When the endoscope cannot be advanced further, the balloon is deflated and the balloon overtube advanced over the scope to the tip of the endoscope. This sequence is repeated until the endoscope cannot be advanced further. The tip of the balloon sheath is radiopaque to facilitate fluoroscopic localization relative to the endoscope. Unlike the double-balloon system, the single-balloon system has no second balloon on the tip of the endoscope to secure the position while the sheath is inserted to meet the distal aspect of the endoscope. Whether this compromises insertion depth has not yet been defined in comparative studies.

Another set of overtube devices (Endo-Ease; Spirus Medical, Stoughton, Mass) is designed to facilitate endoscope intubation and increase depth of insertion through redundant anatomy. This overtube contains a leading helical-threaded portion that is designed to engage the mucosal folds of the small bowel or the colon as it is rotated, pulling itself and the endoscope through the lumen and pleating the bowel wall over the coupled devices. The endoscope is loaded into the overtube and advanced 25 cm beyond the tip of the overtube. The overtube is then clamped to the insertion tube of the endoscope by tightening the proximal nonrotating collar. A joint just distal to the collar allows free rotation of the distal portion of the overtube. The endoscope-overtube system is inserted orally and advanced into the small intestine. Using gentle pressure and clockwise rotation of the overtube, the physician advances the tip of the coupled system by pleating the small bowel onto the spiral overtube. Steering is accomplished by endoscopic visualization and tip deflection. Rotation continues until significant resistance is encountered or forward motion ceases. The overtube is then unlocked from the endoscope, allowing the physician to attempt further advancement of the endoscope. Withdrawal is accomplished with counter-clockwise rotation of the overtube. Although initially available in 3 configurations for colonoscopy and per oral or per anal enteroscopy, the device is now available in a single per oral enteroscopy version and a retrograde colonic version (Table 2). Recent changes in these newer versions intended to reduce mucosal trauma include incorporation of hollow rather than solid plastic threads and a more flexible distal end of the tube.

A reusable overtube designed specifically to facilitate small-bowel push enteroscopy (ST-S2 Splinting tube; Olympus America) is intended for use with the SIF-Q140 enteroscope but can be used with any instrument with a compatible diameter. (Table 2). This semirigid overtube prevents gastric looping, thus straightening the endo-

scopic path from the esophagus through the stomach to the descending part of the duodenum. The proximal portion of this overtube contains a drain pipe for venting the air. When the physician inserts this system into the patient, slow rotation is needed to prevent mucosal pinching between the endoscope and overtube. The endoscope should never be removed prior to removal of the overtube.

### Emerging overtube systems

A novel device designed to enhance the depth of insertion uses an overtube that can be converted from a flexible to a rigid state (ShapeLock; USGI Medical, San Clemente, Calif) (Table 2). An inner metallic reusable component of this system is made of multiple nested titanium links, which are held together by 4 cables. A lever in the handle is used to apply tension to the cables, squeezing the links together and fixing the device in its present configuration. A disposable sterile sleeve covers the metallic components. The overtube (in a lax state) is back-loaded onto the endoscope, which is then inserted through the mouth or rectum. The rigidity of the overtube can be enabled or disabled at any time during the procedure, but conversion to the rigid state is ideally used after negotiating and reducing redundant bowel loops. Although this device is not commercially available at the time of this writing, it has received 510 k clearance by the Food and Drug Administration, and the manufacturer expects to market the device in the near future. In addition, this technology is being incorporated into an endosurgical platform that is designed for natural orifice transluminal endoscopic surgery (NOTES) or laparoscopic procedures. This single-use device (TransPort Multilumen Operating Platform; USGI Medical Inc) is commercially available but is far more than an overtube, with special design features including 4 lumens (including 1 for a 6-mm endoscope), 4-way tip deflection, wheel and tool locks, and a means for carbon dioxide insufflation.

There are several other overtube devices that are currently in development by other manufacturers (Apollo Endosurgery Inc, Austin, Tex; Ethicon Endo-Surgery Inc, Cincinnati, OH) to serve as potential platforms for NOTES. These overtubes are intended to serve as ports providing access from the natural orifice (mouth, vagina, etc) to the peritoneal cavity for repeated insertion and withdrawal of the endoscopes. Some of the overtubes designed for NOTES have additional channels allowing passage of other endoscopic instruments (grasping forceps, suturing devices, etc), articulating distal ends to facilitate endoscope orientation within the peritoneal cavity, and mechanisms (balloons, etc) to anchor the distal end of the overtube in the wall of the organ used for transluminal passage. These devices will require further study and clearance by the Food and Drug Administration before they can be marketed in the United States.

**TABLE 2. Overtubes for enteroscopy and specialized therapeutic applications**

Manufacturer & device name	Compatible endoscope diameter (OD, mm)	Length	Inner diameter	Outer diameter	Single use	List price
<b>Fujinon, Wayne, NJ</b>						
TS-12140	8.5 mm (EN-450P5/20 double-balloon enteroscope)	135 cm	10 mm	12.2 mm	Yes	\$208
TS-13140	9.4 mm (EN-450T5 double-balloon enteroscope)	135 cm	10.8 mm	13.2 mm	Yes	\$208
<b>Olympus, Cedar Valley, Penn</b>						
ST-S2	≤12 mm	100 cm	12.4 mm	14.4 mm	No	\$2234
ST-SB1	9.2 mm (SIF-Q180 single-balloon enteroscope)	132 cm	12.4 mm	14.4 mm	Yes	\$232
<b>Spirus Medical, Stoughton, Mass</b>						
Endo-Ease Discovery SB	9.1-9.4 mm (only specialized enteroscopes SIF-Q180 and EN-450T5)	118 cm	9.8 mm	16 mm + 4.5 mm (low profile) or 5.5 mm (standard profile) hollow helical thread at distal 22 cm	Yes	\$495
Endo-Ease Vista Retrograde	10.5-11.6 mm (enteroscopes and pediatric colonoscopies)	90 cm	13 mm	18 mm + 5.5 mm hollow helical thread at distal 25 cm	Yes	\$395
<b>USGI Medical, San Clemente, Calif</b>						
TransPort Incisionless Operating Platform	4 lumens: endoscope lumen accommodates ≤6 mm	100 cm	4 lumens: Two 6.8 mm Two 4.5 mm	18 mm	Yes	\$1150
Colonoscopy ShapeLock*	≤13.5 mm (adult colonoscope)	60 cm or 80 cm		21 mm	No	Reusable mechanism: \$3200 (expected)
	≤11.8 mm (pediatric colonoscope)	60 cm or 80 cm		21 mm	No	Disposable sleeve: \$110
Enteroscopy ShapeLock*	≤10.5 mm	100 cm		16 mm	No	Reusable mechanism: \$3200 (expected) Disposable sleeve: \$300

\*Devices are Food and Drug Administration cleared but not currently marketed. Expected release 2009-2010.

## INDICATIONS, EFFICACY, AND EASE OF USE

Potential indications for the use of an overtube during GI endoscopy are listed in Table 3. More common indications are described. Prior to overtube placement, a diag-

nostic endoscopy is often required because the overtube may be an encumbrance and obscure the markings on the endoscope. Preloading the overtube onto the endoscope promotes procedural efficiency by avoiding reinsertion of the endoscope into the patient. An overtube

**TABLE 3. Indications for overtube use in GI endoscopy**

Removal of foreign bodies (eg, airway protection during oral extraction, mucosal protection from sharp objects) <sup>4,6-8,39-41</sup>
Conduit for endoscopic intubations (eg, endoscopic mucosal resections, variceal banding, endoscopic suturing, NOTES) <sup>2,9,42-45</sup>
Reduce looping (eg, small bowel enteroscopy, difficult colonoscopy) <sup>27,29,36,46-49</sup>
Protect altered anatomy (eg, bypass Zenker's diverticulum) <sup>50,51</sup>
Incorporation with specialized endoscopes (eg, double-balloon or single-balloon enteroscopes) <sup>1</sup>
Access for larger devices (eg, stent removal, capsule endoscopy delivery, transesophageal echocardiography) <sup>51-54</sup>
Colonic decompression (eg, sigmoid volvulus, pseudo-obstruction) <sup>46,55</sup>
Reduce infection or malignant seeding during PEG tube placement <sup>56,57</sup>

NOTES, Natural orifice transluminal endoscopic surgery.

should be introduced and guided into the GI tract either over an endoscope or a bougie.<sup>2</sup> Liberal lubrication of the inner and outer surfaces of the overtube and endoscope is critical prior to insertion, and resistance to passage of the overtube warrants reassessment.

Foreign body removal represents one of the most common indications for overtube use. Most published studies are retrospective descriptive reports of techniques used to remove foreign bodies with an endoscope and overtube system.<sup>3-8</sup> The major advantages of an overtube include prevention of esophageal mucosal injury and aspiration. In addition, if numerous objects need to be extracted, the overtube provides a conduit for repeated endoscope insertion and withdrawal.

Overtubes were frequently used to facilitate repeated intubation and withdrawal during esophageal variceal band ligation with individually loaded bands<sup>9,10</sup>; however, this practice has largely been obviated by currently available multiband ligators.<sup>11</sup>

Another major indication for overtube use is facilitation of deeper access during small bowel enteroscopy. Two prospective randomized trials of standard push enteroscopy, with and without an enteroscopy overtube, demonstrated that the use of an overtube yielded a 12-to-15-cm greater depth of insertion; however, there was no improvement in the yield of pathological findings.<sup>12,13</sup>

Overtubes specifically designed for balloon enteroscopy systems do appear to enhance depth of insertion. A prospective paired-design series of 52 patients with GI bleeding compared DBE to push enteroscopy with an overtube. The depth of jejunal intubation (230 cm vs

80 cm,  $P < .0001$ ) and rate of lesion detection (63% and 44%,  $P < .0001$ ) were superior in the DBE group.<sup>14</sup> A retrospective comparison of 118 patients with a variety of indications demonstrated that intubation to about 92 cm beyond the ligament of Treitz was achieved with DBE, compared to 22 cm using push enteroscopy with an overtube ( $P < .0001$ ).<sup>15</sup> In both of these studies, the DBE system required more than double the procedure time relative to standard push enteroscopy (60-70 minutes vs 21-30 minutes). The SBE overtube system has been less well studied, but procedure times and depth of insertion appear similar to those of the DBE system.<sup>16,17</sup> There are currently no published studies directly comparing the depth of insertion of DBE and SBE systems. Use of a pediatric colonoscope with the Endo-Ease overtube system for per oral enteroscopy has recently been demonstrated in 27 patients to achieve a mean insertion depth of 176 cm beyond the ligament of Treitz.<sup>18</sup> This technique for enteroscopy has also been reported via a retrograde per anal approach in a limited number of patients.<sup>19</sup> This overtube enteroscopy system appears safe, with minimal mucosal trauma, but published experience remains limited. In addition, these studies used an older, larger version of the spiral overtube. There are no published reports with the newer version, which has a smaller internal and external caliber and will accommodate only standard-size enteroscopes and not pediatric colonoscopes.<sup>1</sup>

A small case series using the ShapeLock device for push enteroscopy in patients with normal and surgically altered anatomy suggested an improved depth of insertion relative to enteroscopy without an overtube.<sup>20</sup> In a study of 9 patients with a Roux-en-Y gastric bypass who underwent failed attempts at examination of the stomach with enteroscopy without an overtube, the ShapeLock overtube was used to provide enteroscopy access for successfully examining the excluded stomach and duodenum in 8 of 9 patients.<sup>21</sup>

Both the SBE and DBE systems have been used to perform ERCP in altered anatomy.<sup>22,23</sup> The ShapeLock system has also been used to access the ampulla for ERCP by facilitating insertion of the endoscope through a prolonged segment of altered upper GI anatomy.<sup>24</sup>

Overtubes have also been used to facilitate completion of colonoscopy. In a study of 54 patients undergoing colonoscopy with the ShapeLock device, users subjectively rated the device as easy to use and resulting in minimal trauma, but no detail on the ease of cecal intubation was reported.<sup>25</sup> In a preliminary series of 8 patients who had failed colonoscopy secondary to excessive loop formation, the ShapeLock device was used for successful cecal intubation.<sup>26</sup> A case report demonstrated the use of the ShapeLock device in a patient with multiple large colonic polyps and a redundant sigmoid colon to provide a stable platform for repeated intubations of the proximal colon.<sup>27</sup> Use of the Endo-Ease spiral leading edge colonic overtube system has been reported only in abstract form.<sup>28</sup> When this system was used for routine

colonoscopy, in 18 of 168 patients the overtube was unsuccessful because of patient and physician factors. There were no major complications, and mucosal trauma was noted in only 3% of patients. In a historical case series of 119 patients who failed colonoscopy, 117 patients had a complete examination, with the majority being accomplished with standard techniques, but various overtubes were used in 13 patients to assist in completion.<sup>29</sup>

## SAFETY

The most commonly reported complications during overtube use are mucosal abrasions and tears secondary to the large diameter of the overtube or pinching of mucosa between the endoscope and overtube.<sup>30,31</sup> Previously described insertion techniques may reduce these risks. Other significant complications including pharyngeal and esophageal perforation, variceal rupture, overtube separation, transient vocal cord paralysis, pneumomediastinum, and tracheal compression have been described.<sup>31-35</sup> When overtubes are used in enteroscopy, pancreatitis has been reported, presumably related to prolonged compression or trauma to the ampulla during small-bowel manipulation.<sup>36-38</sup>

## FINANCIAL CONSIDERATIONS

List prices for reusable and disposable overtubes are presented in [Tables 1 and 2](#). There is no specific CPT\* code for overtube use. Codes relevant to enteroscopy are reviewed in the enteroscopy Technology Status Evaluation Report.<sup>1</sup>

## AREAS FOR FUTURE RESEARCH

Given the limited amount of comparative analysis, there is a need for studies examining the impact of overtube use in various endoscopic techniques. Particular needs include direct comparisons of DBE, SBE, and the spiral enteroscopy overtube system. Further studies examining multifunctional overtubes, which may become platforms for more complex transluminal endosurgical procedures, are also needed.

## SUMMARY

Several overtubes are available for use in GI endoscopy, some intended for specific endoscopic systems. Overtubes have expanded from their role as simple endoscopic ac-

cessories to more complex and specialized designs that facilitate endoscope insertion and bowel wall manipulation. Overtubes can be associated with serious adverse events, and it is important to follow proper insertion techniques. Based on their ability to facilitate luminal access, overtubes will likely play an important role as endoscopic surgical techniques expand.

*Abbreviations: DBE, double-balloon enteroscopy; NOTES, natural orifice transluminal endoscopic surgery; SBE, single-balloon enteroscopy.*

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