NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Medical technology guidance scope

Endo-SPONGE for treating colorectal anastomotic leakage

1 Technology

1.1 Description of the technology

Endo-SPONGE (B. Braun) is a minimally invasive treatment for anastomotic leakage in the low colorectal area after colorectal surgery. The Endo-SPONGE system uses vacuum therapy, which is commonly used for the treatment of chronic and complex wounds.

The Endo-SPONGE system consists of an open pore sponge with a Redon drain, a sponge pusher, silicon overtube guides and a drainage set and system. It is designed to be used in conjunction with the Redyrob Trans Plus drainage bottle (B.Braun).

The sponge is inserted into the leakage cavity using a flexible endoscope or through open access via the anus. A drainage tube is connected to the sponge at one end and a drainage bottle at the other end. The bottle is a low-vacuum drainage container and exerts suction to provide continuous and constant negative pressure in the sponge. The system avoids the build-up of leaking discharge in the anastomotic leakage cavity and promotes the formation of granulation tissue and healing.

The size of the sponge in individual patients is cut according to the size of leakage cavity and up to 3 sponges may be placed into the cavity. The sponge is changed every 24 to 72 hours and is cut smaller with every application as the size of the cavity reduces. The number of sponges needed for completing treatment varies, ranging from 1 to 39. Sedation and analgesia may be needed for the insertion procedure. It may be necessary to use an

endoscopic dilation balloon to widen the entrance to the anastomotic cavity so that Endo-SPONGE can be inserted. Some potential risks associated with Endo-SPONGE are residual sponge particles, erosion of structures adjacent to sponge and injury to intestinal wall and bleeding.

The Endo-SPONGE system is not suitable when the following conditions are present: ileoanal or ileorectal cuff anastomotic leak, malignant tumour wound; necrotic tissue/gangrene; untreated osteomyelitis; anastomotic leakage directly adjacent to vessels; bladder or small bowels obstruction, non-drainable septic focus, systemic sepsis and clotting disorders.

1.2 Relevant diseases and conditions

The Endo-SPONGE system is intended for treating anastomotic leakage after colorectal surgery.

Anastomotic leakage refers to the escape of luminal bowel contents through a surgically created junction between two sections of bowel (McDermott et al., 2016). It is one of the most serious complications after colorectal surgery. Low anterior resections are associated with a leakage rate ranging from 1% to 24% (Kirchoff et al., 2010). Anastomotic leakage is associated with increased morbidity and mortality rates and can result in delayed wound healing, extended hospital stays and the need for a stoma (Clow et al., 2009, den Dulk et al., 2007). Anastomotic leakage also increases the need for reoperation, the risk of cancer recurrence and reduces both overall and disease free survival (Mirmezami et al., 2011).

In the UK, an analysis of the Hospital Episode Statistics database found that the rate of anastomotic leak following colorectal surgery was 6.4%, and anastomotic leakage was associated with higher rates of hospital mortality, 30-day readmission, and post-operative infection compared with no anastomotic leakage after colorectal surgeries (Wan et al., 2014). The study estimated that the hospitalisation associated with anastomotic leakage resulted in an additional cost of £2,651 and an extra length of stay of 9 days per patient compared with those without leakage after surgery.

Risk factors for anastomotic leakage can be broadly associated with patient and procedure related factors. Patient related factors include male gender, smoking, steroid use and nutritional status. Surgery related factors include longer operation time (i.e. longer than two hours), multiple blood transfusions, intraoperative contamination, and increased urgency of the operation (Khan et al., 2007). These risk factors are also noted in the guidance from the Association of Surgeons of Great Britain and Ireland on Prevention, Diagnosis and Management of Colorectal Anastomotic Leakage (March 2016) and are categorised as modifiable and non-modifiable risk factors as following:

- Modifiable risk factors:
  - Alcohol
  - Smoking
  - Obesity
  - Medication i.e. steroid, anti-TNF monoclonal anti-body, immunosuppressant, purine analogue immunosuppressant, VEGF inhibitor.
  - Nutrition and hypoalbuminaemia
  - Mechanical bowel preparation
  - Radiotherapy
  - Preoperative antibiotics and selective decontamination of the digestive tract
- Non-modifiable risk factors
  - Sex and age
  - History of radiotherapy
  - Diabetes
  - Emergency surgery
  - Tumour factors: distal anastomoses

1.3 Current management

Once a colorectal anastomotic leak has been diagnosed, the immediate principles in management relate to the treatment of potential contamination and resultant sepsis. Treatment choices available for anastomotic leakage

can be medical and conservative such as broad-spectrum antibiotics, parenteral nutrition, or nasogastric aspiration, with or without drainage of collected fluid and stoma formation. In addition, surgical approaches include, laparoscopy/laparotomy with anastomotic repair and de-functioning stoma, or abdominoperineal resection (Khan et al., 2008; Thomas and Margolin 2016).

NICE has not published guidelines on the treatment of colorectal anastomotic leakage. Guidance from the Association of Surgeons of Great Britain and Ireland on Prevention, Diagnosis and Management of Colorectal Anastomotic Leakage (March 2016) states that people with anastomotic leakage who are considered clinically stable may be treated conservatively using fluids, antibiotics and oxygen, with close clinical observation. However, for people showing signs of sepsis, steps must be taken to remove the source of the leak within 3 to 18 hours, depending on the underlying condition and severity of infection. In less severe cases of sepsis associated with extraperitoneal rectal anastomotic leakage, proximal defunctioning of the anastomosis with transanal or transperitoneal drainage may be considered. If there is radiological evidence that the anastomotic cavity is separate from the bowel, or if there are multiple sites of anastomotic leakage, surgical intervention is needed.

1.4 Regulatory status

Endo-SPONGE is a CE marked class (class IIb) medical device.

1.5 Claimed benefits

The benefits to patients claimed by the company are:

- Faster healing compared with conventional treatment
- Reduced risk of subsequent infection if the area is not infected
- Rapid control of the infection if the area is infected
- Reduced size of the anastomotic cavity
- Improvement in quality of life
- Reduced reoperation
- Reduced number of permanent stomas

The benefits to the healthcare system claimed by the company are:

- Reduced length of hospital stay after colorectal surgery
- Reduced healthcare utilisation through reversal of stomas
- Reduced resource use (i.e. fewer staff needed)
- Treatment in an outpatient clinic

2 Decision problem

Population	People with an anastomotic leakage in the low colorectal area (extraperitoneal) after colorectal surgery.
Intervention	Endo-SPONGE
Comparator(s)	• Non-surgical interventions including antibiotics and/or percutaneous drainage • Surgical interventions (i.e. open drainage, laparoscopy with anastomotic repair, defunctioning stoma (i.e. loop ileostomy, loop transverse colostomy)) It should be noted that the type of treatment a person receives is dependent on the severity of an anastomotic leakage.
Outcomes	The outcome measures to consider include: • the rate of anastomotic healing (i.e. closure of the cavity) • the percentage of cavity size reduction • time to heal • antibiotic usage (in defined daily doses) • the rate of re-operation, stoma formation and stoma reversal for anastomotic leakage • the rate of recurrent abscess formation • mortality rate • health related quality of life • length of hospital stay • length of intensive care stay • the rate of sepsis • the rate of complications (e.g. bleeding) • device-related adverse events.
Cost analysis	Costs will be considered from an NHS and personal social services perspective. The time horizon for the cost analysis will be long enough to reflect differences in costs and consequences between the technologies being compared.

	Sensitivity analysis will be undertaken to address uncertainties in the model parameters, which will include scenarios in which different numbers and combinations of devices are needed.	
Subgroups to be considered	• The severity of anastomotic leakage (moderate versus severe) • Time to anastomotic leakage diagnosis and treatment (early versus delayed) • With versus without protective stoma • Distance of anastomosis from anal verge	
Special considerations, including those related to equality	People having colorectal surgery will have an underlying condition such as inflammatory bowel disease or colorectal cancer. People who have been diagnosed with cancer and chronic diseases may be considered disabled under the Equality Act. Colorectal anastomotic leakage is more common in men; gender is a protected characteristic under the equality act.	
Special considerations, specifically related to equality	Are there any people with a protected characteristic for whom this device has a particularly disadvantageous impact or for whom this device will have a disproportionate impact on daily living, compared with people without that protected characteristic?	No
	Are there any changes that need to be considered in the scope to eliminate unlawful discrimination and to promote equality?	No
	Is there anything specific that needs to be done now to ensure the Medical Technologies Advisory Committee will have relevant information to consider equality issues when developing guidance?	No
Any other special considerations	Endo-Sponge may be particularly useful in people with significant co-morbidity because further surgery would be high risk for them.	

3 Related NICE guidance

There is no related guidance for this technology.'

4 External organisations

4.1 Professional

The following organisations have been asked to comment on the draft scope:

- Association for Cancer Surgery
- Association of Laparoscopic Surgeons of Great Britain and Ireland
- Association of surgeon of Great Britain and Ireland

- Bladder and Bowel Foundation
- Royal College of surgeon
- The Association of coloprotology of Great Britain and Ireland

4.2 Patient

NICE's Public Involvement Programme identified the following organisations for patient commentary on the use of the technology during the guidance development:

- Beating Bowel Cancer
- Bowel Cancer UK
- Bladder and Bowel UK
- Colostomy UK
- Patient Liaison Group (ACPGBI)
- Pelican Cancer Foundation