

Endo-SPONGE for colorectal anastomotic leakage

Medtech innovation briefing

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Summary

- The **technology** described in this briefing is Endo-SPONGE. It is used for treating colorectal anastomotic leakage.
- The **innovative aspects** are that the technology uses a sponge, vacuum therapy and drainage in a minimally invasive way.
- The **intended place in therapy** would be in addition to endoscopic lavage and as an alternative to stents or reoperation in people with low rectal anastomotic leak after colorectal surgery.
- The **main points from the evidence** summarised in this briefing are from 7 non-comparative case series studies including a total of 277 adults with colorectal anastomotic leakage. They show that Endo-SPONGE may help improve healing of colorectal anastomotic leaks without the need for surgery.
- **Key uncertainties** around the evidence or technology are that there are no studies comparing Endo-SPONGE with other treatments for colorectal anastomotic leakage. There are no comparative studies available and no studies done in the NHS.
- The **cost** of Endo-SPONGE (plus Redyrob drainage bottle) is £271.11 per unit (exclusive of VAT). The **resource impact** may be less than standard care because of reduced length of stay and a reduced need for reoperations and stomas.

The technology

Endo-SPONGE (B. Braun) is a vacuum therapy, consisting of an open-pored polyurethane foam sponge inserted into the leakage cavity using a flexible endoscope. A drainage tube is connected to the sponge at 1 end. This leaves the body through the anus and is connected to a low-vacuum wound drainage system. The suction gives continuous drainage and avoids a build-up of secretion in the cavity. Secretions are drained into a Redyrob transplus bottle (B. Braun). The company claims the negative pressure leads to granulation of the tissues in contact with the sponge. Depending on the size of leakage cavity, 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 where the size of the cavity has reduced. The company claim that an average of 7 to 8 sponges are needed to complete treatment. Light sedation and analgesia may be needed for the procedure. It may be necessary to use an endoscopic dilation balloon to widen the entrance to the anastomotic cavity so that the Endo-SPONGE can be inserted.

Innovations

Endo-SPONGE is the only technology available that uses vacuum therapy to treat anastomotic leakage. An anastomotic leak is defined as a leak of luminal contents from a surgical join. Non-surgical treatment options for anastomotic leakage are limited and Endo-SPONGE is a minimally invasive endoscopic treatment. The company claims that using Endo-SPONGE reduces the risk of infection and over time reduces the size of the anastomotic cavity, through granulation of tissue caused by negative pressure, until it is healed. The company claims that if the area is already infected, Endo-SPONGE can be used to rapidly control the infection through active drainage. Endo-SPONGE can also be used to treat oesophageal leakages and perforations, however, the focus of this medtech innovation briefing is on colorectal anastomotic leakages only.

Current care pathway

NICE has not published guidelines on the treatment of colorectal anastomotic leakage. Guidance on [prevention, diagnosis and management of colorectal anastomotic leakage](#) from the Association of Surgeons of Great Britain and Ireland 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.

The guidance mentions that the Endo-SPONGE technology may be an effective treatment for low rectal anastomotic leakages but that evaluation of clinical and cost benefits of using the technology is needed.

The following publications have been identified as relevant to this care pathway: [Association of Coloproctology of Great Britain and Ireland, prevention, diagnosis and management of colorectal anastomotic leakage report \(March 2016\)](#).

Population, setting and intended user

Endo-SPONGE is intended for people with extraperitoneal rectal anastomotic leakage after colorectal surgery. The technology is intended for use in a hospital setting and will be used by colorectal surgeons, endoscopists and gastroenterologists.

Costs

Technology costs

The Endo-SPONGE kit costs £250.24 (excluding VAT) for a single sponge. The company estimates that complete treatment with Endo-SPONGE will need on average 7 to 8 sponges. The Redyrob transplus bottle is bought separately, costing £20.87 per bottle (excluding VAT). Any glycerol-based hydrogel can be used, this costs between £1 and £1.50 per tube. These costs do not include the cost of the procedure, however treatment with Endo-SPONGE is a minimally invasive, transanal, endoscopic procedure and is therefore expected to have lower resource impact than surgical reintervention.

Costs of standard care

A complex large intestine procedure costs between £6,248 and £12,534 from the national tariff 2019 to 2020. However, this does not include the cost of an anastomotic leak complication.

Resource consequences

The company states that the device is being used in over 40 NHS centres in the UK.

The resource consequences of the technology are expected to be less than standard of care because of a reduced need for reoperations, permanent stomas and avoidance of sepsis.

Staff will need training to use the technology. The sponge needs to be changed every 48 to 72 hours, this will need to be done in an endoscopic room or operating theatre.

Regulatory information

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

No manufacturer field safety notices or medical device alerts for this technology have been identified. One specialist commentator stated that they had reported an issue to the MHRA concerning a loose ring on the lubrication gel tube. The specialist stated that they had received confirmation from the company that the gel tube had been replaced and no longer has a loose ring.

Equality considerations

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others.

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.

Clinical and technical evidence

A literature search was carried out for this briefing in accordance with the [interim process and methods statement](#). This briefing includes the most relevant or best available published evidence relating to the clinical effectiveness of the technology. Further information about how the evidence for this briefing was selected is available on request by contacting mibs@nice.org.uk.

Published evidence

This briefing summarises 7 studies, including a total of 277 adult patients with anastomotic leakage. These studies have been selected from a wider evidence base as the most relevant and informative. The studies are non-comparative case series and most have included low patient numbers; the longest follow up was 29 months.

Table 1 summarises the clinical evidence as well as its strengths and limitations.

Overall assessment of the evidence

The studies for Endo-SPONGE have low patient numbers and are non-comparative. This is likely to be because of the low incidence and severity of this complication. Comparative trial design is also challenging because it raises ethical issues around randomising patients at risk of infection and sepsis.

The studies suggest that Endo-SPONGE is a safe treatment for low rectal anastomotic leak and that it can lead to healing without the need for surgery. Several studies indicate that Endo-SPONGE is most effective when used soon after the anastomosis forms rather than in anastomotic leaks with delayed diagnosis. The studies have good length of follow up and indicate that the treatment effect is long lasting but that patients should be carefully monitored after healing because some studies reported abscess and sinus formation.

The studies include a range of patients and anastomotic leaks, however, further evidence on which patient groups would most benefit from Endo-SPONGE is desirable.

Table 1 Summary of selected studies

<u>Boschetti et al. (2018)</u>	
Study size, design and location	29 people with abscesses or fistulas from anastomotic leakage after rectal resection or colectomy in a retrospective case series. Location: France.
Intervention and comparator(s)	Endo-SPONGE. No comparator.
Key outcomes	Closure of the cavity happened in 27/29 patients (93%), which was sustained in 24/27 patients (89%) at 6 months. The treatment was well tolerated and done on an outpatient basis without sedation. In this study, anastomotic leakage was treated efficiently with Endo-SPONGE without sedation or stoma in 31% of cases.

Strengths and limitations	According to the authors, it is the first case series in which half of the patients did not have a diverting stoma. The authors note that patients without a diverting stoma tended to need a shorter duration of treatment with Endo-SPONGE. Around half of the people included in the study had been referred to the study after late failure of standard treatment for anastomotic leakage.
<u>Bortslap et al. (2018)</u>	
Study size, design and location	30 people with rectal cancer and leaking low colorectal anastomosis included in a prospective, multicentre, feasibility study. Location: Netherlands.
Intervention and comparator(s)	Endo-SPONGE. No comparator.
Key outcomes	22/30 patients had neoadjuvant radiotherapy during follow up (median 14 months, range 7 to 29 months). At 6 months, anastomosis was healed in 16 (53%) patients, 10/16 started treatment with Endo-SPONGE early (within 3 weeks of surgery), whereas the other 6 started treatment later. 7/8 patients who did not have neoadjuvant radiotherapy had healed at 6 months. At the end of follow up anastomosis had healed in 21/30 patients (11 had early treatment and 10 had later treatment), median time for the anastomosis to heal was 127 days (range 14 to 722). In 10 patients the anastomotic leak developed into a chronic sinus. 6 patients whose anastomotic leak did not heal needed further surgery.
Strengths and limitations	The authors noted that chronic sinus was more common in people who had started treatment late (21% early treatment versus 47% later treatment) and suggest that Endo-SPONGE is less effective when the anastomosis is diagnosis is delayed. The authors note that compared with previous studies reporting results for 'wait-and-see' cohorts time to healing and percentage of patients healed was improved using Endo-SPONGE.
<u>Jiménez Rodríguez et al. (2018)</u>	
Study size, design and location	22 people with low colorectal anastomosis leakage or opening of the rectal stump after anterior resection for rectal cancer in a case series. Location: Spain.

Intervention and comparator(s)	Endo-SPONGE. No comparator.
Key outcomes	Mean time to healing was 22.3±14.7 days. Full resolution was achieved in 19 patients (followed up to 1 year). Ileostomy closure was done in 5 patients (38.46%) during follow up. None of these patients showed leakage signs. Statistically significant differences were obtained depending on the onset of therapy, with better results in patients who had earlier vacuum-assisted therapy (before the sixth week after initial surgery), p=0.041.
Strengths and limitations	The authors noted that Endo-SPONGE is an alternative to surgery that can be safely administered in an ambulatory setting. The authors also note that colonic transit was only recovered in a few patients.
<u>Mussetto et al. (2017)</u>	
Study size, design and location	11 people recovering from anterior resection of the rectum for rectal cancer with colorectal anastomosis, included in a retrospective case series. Location: Italy.
Intervention and comparator(s)	Endo-SPONGE. No comparator.
Key outcomes	10/11 patients had closure of the anastomotic leakage after a mean of 16 sponge changes. Anastomotic stricture happened in 2 patients, 1 was treated with endoscopic dilation and the other with a 5-week stent placement. Treatment failure happened for 1 patient whose wound reopened after 23 Endo-SPONGE treatments despite having initially responded well.
Strengths and limitations	The follow up of this study was longer; mean 29 months, range 6 to 64 months. The authors noted that the size of anastomotic leakages included in this study were larger than those in other studies evaluating Endo-SPONGE (median 7.5 cm).
<u>Strangio et al. (2015)</u>	
Study size, design and location	149 people included in a case series and literature review. Location: Italy.

Intervention and comparator(s)	Endo-SPONGE. No comparator.
Key outcomes	131/149 patients had complete healing of presacral cavity. No studies reported any mortality relating to the procedure.
Strengths and limitations	This study combined data from a case series of 25 people with data from the studies identified in the literature review. These data were pooled together and analysed. It is not clear if the patient populations included in the literature review studies were comparable or not.
<u>Riss et al. (2010)</u>	
Study size, design and location	20 people who had had successful treatment with Endo-SPONGE (after rectal cancer surgery, 17 with anastomotic leakage and 3 with insufficiency of rectal stump) included in a multicentre consecutive case series. Location: Austria.
Intervention and comparator(s)	Endo-SPONGE. No comparator.
Key outcomes	Patients were followed up for a median of 17.1 months (range 1.5 to 29.8 months) after successful treatment with Endo-SPONGE. 5 patients died during follow up, 4 because of tumour progression and 1 because of liver cirrhosis. 1 patient developed anal stenosis which was improved with anal dilation. 5 patients (25%) developed recurrent symptomatic abscesses; 3 patients had abscesses needing surgical intervention (Hartmann's procedure), 1 needed CT-guided drainage and 1 had only minimal clinical signs that did not need treatment during the follow-up period. The authors noted that they were unable to identify any predictive factors for recurrent abscess formation because of the low patient numbers.
Strengths and limitations	The authors were unable to identify the cause of recurrent abscesses in 25% of patients because of the low patient enrolment and non-comparative design of the study. They suggest that this should be further investigated in a randomised trial with 2-year follow up.
<u>Koperen et al. (2009)</u>	

Study size, design and location	16 people (13 had had surgery for rectal cancer and 3 for ulcerative colitis) included in a multicentre case series. Location: Netherlands.
Intervention and comparator(s)	Endo-SPONGE. No comparator.
Key outcomes	8 patients had Endo-SPONGE treatment within 6 weeks of surgery, the remaining 8 had Endo-SPONGE more than 6 weeks after surgery. In the earlier treatment group Endo-SPONGE was in place for a median of 24 days and closure of the wound happened in 6 patients (75%). In the later treatment group, wound closure happened in 3 patients (38%). Median time to closure was 40 days with a median of 13 sponge replacements.
Strengths and limitations	The authors describe some differences between centres of how Endo-SPONGE was administered, for example with anaesthesia, sedation or without. The authors state that the follow-up (median 4 months) was not enough to evaluate the long-term effectiveness of Endo-SPONGE.

Recent and ongoing studies

- [Endosponge Vacuum Therapy \(E-VAC\) Registry of Intestinal Anastomotic Leaks and Perforations](#). ClinicalTrials.gov identifier: NCT02477930. Status: recruiting. Indication: anastomotic leaks and perforations. Devices: Endo-SPONGE.

Specialist commentator comments

Comments on this technology were invited from clinical specialists working in the field and relevant patient organisations. The comments received are individual opinions and do not represent NICE's view.

All 3 specialists were familiar with his technology, 2 have used the device and the third specialist would like to use the technology.

Level of innovation

All specialists agreed that the technology was innovative and that it had not been superseded or replaced by another treatment.

Potential patient impact

All specialists stated the technology can be helpful in managing extra peritoneal rectal anastomotic leakage when it can be accessed by the transanal route in patients with no sepsis or sepsis with contained leakage. One specialist noted that the technology may be particularly useful when the cavity is located in the posterior, low presacral area. Another expert noted that the technology may also be useful after gynaecological surgery.

One specialist noted that using Endo-SPONGE can reduce the need for immediate surgery at a time when the patient is most unwell, allowing time for nutrition and physical health to improve. Two specialists stated that further surgical procedures might be avoided altogether. One specialist noted that using Endo-SPONGE could reduce the need for long-term and permanent stomas and stated that the technology was less invasive than other treatment options. One specialist stated that using the technology would lead to enhanced recovery rates and improved outcomes for patients.

Only 1 of the specialists had experience of a healed anastomosis after treatment with Endo-SPONGE, in 1 out of a total of 3 patients treated.

Potential system impact

All specialists agreed that using Endo-SPONGE could lead to substantial cost savings for the NHS compared with standard care. One specialist noted that using Endo-SPONGE could reduce the need for high-risk surgery and associated costs. One specialist stated that the technology can be used in an inpatient or an outpatient setting, noting that the sponge would need changing every 2 to 3 days. All specialists agreed that using Endo-SPONGE could lead to quicker healing of anastomosis and quicker discharge from hospital. One specialist noted that in their experience the technology had helped in the control of sepsis.

All specialists stated that knowledge of the technology is not widespread in the NHS and that it is only used in a few hospitals. Two specialists noted that adopting the technology will need availability of endoscopy services and equipment and training for endoscopists. One specialist noted that in their experience, adopting the technology had been a simple process and treatment could be administered by a nurse specialist. Another specialist noted the importance of assistance from a nurse specialist. One specialist advised that an approved certification system for competence in using Endo-SPONGE should be set up in the UK.

The specialists noted that extraperitoneal leakage of rectal anastomosis with contained sepsis

amenable to Endo-SPONGE therapy is a rare complication, happening in 2 to 4 patients per hospital per year, in their experience. One specialist who has been using Endo-SPONGE for 5 years has used it in 3 patients out of a total of 40 to 50 rectal resections per year.

General comments

Two specialists noted some practical problems with using the technology and warned that it can cause damage to the healthy adjacent bowel if not used carefully. One specialist also stated that the technology may not be suitable for people taking anticoagulants because of the risk of excess bleeding from the negative suction effect. One specialist noted that some patients may not tolerate treatment with the technology because of its transanal administration.

One specialist advised that use of Endo-SPONGE would be classified as a source control for grade 1 anastomotic leakage (no sepsis) and in grade 2 anastomotic leakage (sepsis with contained leak/ abscess). Two specialists advised that audit data should be collected on using Endo-SPONGE. One specialist noted that it would not be possible to do randomised studies in this population but that case series studies would provide further evidence.

Specialist commentators

The following clinicians contributed to this briefing:

- Biju Aravind, consultant colorectal surgeon, East Kent Hospital University Foundation Trust, did not declare any interests.
- Mr Venkatesh Shanmugam, consultant colorectal surgeon, University Hospital of North Tees, did not declare any interests.
- Dr Ray Georges Shidrawi, consultant physician and gastroenterologist, Homerton University Hospital NHS Foundation Trust, did not declare any interests.

Development of this briefing

This briefing was developed by NICE. The [interim process and methods statement](#) sets out the process NICE uses to select topics, and how the briefings are developed, quality-assured and approved for publication.

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