NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

HealthTech Programme

GID-HTE10072 Endoscopic submucosal dissection knives for the resection of complex colorectal polyps with suspected submucosal invasion

Scope

1. Introduction

The technologies included in this NICE HealthTech evaluation are endoscopic submucosal dissection knives for the resection of complex colorectal polyps with suspected submucosal invasion. The technologies are to be assessed for existing use. Existing-use assessments consider HealthTech products that are already in established use within the NHS, to inform commissioning and procurement decisions.

This scope document describes the context and the scope of the assessment. The methods and process for the assessment follow the NICE HealthTech programme manual.

2. The condition

Polyps are abnormal growths that can occur anywhere in the body. Polyps and subepithelial tumours are types of gastrointestinal (GI) polyp that protrude from the GI wall. Most are not cancerous, although some may develop into cancer. Most people that have polyps are asymptomatic and are unaware that they have them. Polyps can be present anywhere in the GI tract but are found most frequently in the colorectal region. Around 15-20% of the UK population have colorectal polyps (NHS Inform, 2023) and incidence is associated with increasing age (CKS, 2024). Polyps occur in a wide range of sizes, shapes

and have different characteristics. Some polyps, such as colorectal polyps that are large or have characteristics suspicious of submucosal invasion are more difficult to remove and are often described as complex polyps. Appropriate removal of polyps is an important step in diagnosing and managing colorectal cancer. Colorectal cancer is the 4th most common cancer in the UK with around 44,000 new diagnoses each year in the UK (Cancer Research UK, 2025). It is the 2nd most common cause of cancer death in the UK, with around 17,400 deaths each year (Cancer Research UK, 2025).

3. Current practice

In the NHS, the treatment of colorectal polyps and colorectal cancer follows the:

- NICE colorectal cancer guideline (NG151)
- NICE suspected cancer guideline (NG12)
- Getting It Right First Time Best Practice Timed Cancer Pathways – Colorectal cancer diagnostic pathway

Engagement with experts has also identified that guidelines from The European Society for Gastrointestinal Endoscopy (ESGE), the British Society of Gastroenterology (BSG) and the Association of Coloproctology of Great Britain and Ireland (ACPGBI) are followed. A full list of the guidelines and consensus statements relevant to colorectal polyp and cancer care is included in Appendix A – External guidelines and consensus statements for colorectal polyps.

3.1 Referral

People may present to their GP with signs and symptoms of colorectal cancer. Symptoms include abdominal masses, changes in bowel habits, iron deficiency anaemia, rectal bleeding, and unexplained abdominal pain or weight loss. People presenting with symptoms are offered quantitative faecal immunochemical testing (FIT), as per the NICE Quantitative faecal immunochemical testing to guide colorectal cancer pathway referral in primary

care guidance. People with a FIT result of 10 micrograms or more of haemoglobin per gram of faeces are referred to gastroenterology services in line with the suspected cancer pathway referral. People with a FIT result of less than 10 micrograms haemoglobin per gram of faeces may still be referred to gastroenterology care services for further investigations if there is a strong clinical concern of cancer because of unexplained symptoms. People may also be referred directly to secondary care without presenting to their GP. This can happen following a FIT result of 10 micrograms or more of haemoglobin per gram of faeces as part of the NHS bowel cancer screening programme or as part of post polypectomy surveillance in patients that have previously had polyps resected. The screening programme is in place as most colorectal polyps do not cause any symptoms. Polyps may also be identified when the bowel is under investigation for another condition such as inflammatory bowel disease.

Where complex colorectal polyps are identified, people may be referred to regional complex polyp services. These are specialist services that contain multidisciplinary teams that may include experienced gastroenterologists, colorectal surgeons, histopathologists and colorectal nurse specialists. These healthcare professionals can make decisions regarding the most appropriate resection method for the polyp and have the appropriate skills and training to do the procedure.

3.2 Diagnosis

After referral to gastroenterology services, colorectal polyps are most frequently identified using optical colonoscopy that allows direct visualisation of the area. A colonoscopy involves a long flexible tube with a camera on the end being passed through the anus. They are typically done by endoscopists. Colonoscopies can be done with or without local anaesthetic. A bowel preparation regime is required beforehand, involving diet modification and laxatives to cleanse the bowel. In some patients a CT colonography or colon capsule endoscopy may be used for visualisation. Some polyps are easily

identifiable, whereas others may be more difficult and may only be identified by experienced endoscopists.

3.2.1 Polyp classification

The ESGE guideline on colorectal polypectomy and endoscopic mucosal resection (EMR) defines polyps by size:

- Diminutive: 5 mm or less
- Small: 6 mm to 9 mm
- Intermediate: 10 mm to 19 mm
- Large: 20 mm or more

The shape of a polyp is most commonly defined according to the Paris endoscopic classification:

Polypoid:

- Type 0-Ip: protruded, pedunculated
- Type 0-Is: protruded, sessile

Non-polypoid:

- Type 0-IIa: superficial, elevated
- Type 0-IIb: flat
- Type 0-IIc: superficial shallow, depressed
- Type 0-III: excavated

The Paris endoscopic classification may also be used to predict malignancy of a polyp. Pedunculated polyps (0-Ip) grow away from the submucosa via a narrow stalk, providing separation between the GI tract wall and polyp. Flat (0-IIb) and sessile (0-Is) polyps have a wide base that connects directly to the GI tract wall. Compared to pedunculated polyps, malignant cells have less distance to travel between flat and sessile polyps and the submucosa, increasing the likelihood of cancer spreading into the submucosa. Larger polyps with submucosal invasion (0-IIc) are associated with a greater risk of cancer (Johnson, 2023). Nearly all ulcerated sessile or flat polyps that extend to the submucosa (0-III) are cancerous (Paris endoscopic classification,

2002). Superficial non-polypoid polyps >10 mm with a lateral growth pattern are broadly classified as laterally spreading tumours and have a risk of malignancy of 8.5% (Bogie, 2018). Increased polyp size is generally associated with increased risk of malignancy. The BSG/ACPGBI and ESGE guidelines recommend risk stratification based on the characteristics and number of polyps identified. Ascertaining the size of the polyp and the degree of invasion is an important stage in determining the subsequent resection approach.

3.2.2 Colorectal polyps

The ESGE recommends the prediction of submucosal invasiveness of colorectal polyps based on size, morphology, location, margin delineation and vascular and surface pattern. To do this, it recommends using chromoendoscopy and white light endoscopy to enhance polyp visualisation. It recommends the use of validated classification systems such as the Paris endoscopic classification, narrow-band imaging international colorectal endoscopic (NICE) classification or Japan narrow-band imaging Expert Team (JNET) classification. The guideline states that polyp evaluation should be done by an experienced endoscopist, such as those in complex polyp services.

The BSG/ACPGBI guidelines on the management of large non-pedunculated colorectal polyps defines categories of large colorectal polyp. Large non-pedunculated colorectal polyps (LNPCPs) refer to polyps with a flat or sessile base that are 20 mm or more in size. These polyps account for around 1% of all colorectal polyps (Cronin, 2023). An LNPCP may be referred to as complex if it has an:

- Increased risk of malignancy
- Increased risk of incomplete resection or recurrence
- Increased risk of adverse events
- Level 4 on the Size, morphology, site and access (SMSA) scoring system.

Around 11% of LNPCP's can be classified as complex due to containing submucosally invasive cells (O'Sullivan, 2024). The exact proportion of LNPCP's that can be classified as complex due to removal difficulty is more difficult to estimate. Removal difficulty is affected by endoscopist skill, individual risk of adverse events, and polyp characteristics. The BSG/ACPGBI guideline states that increased risk of malignancy is characterised by:

- Pit pattern type V
- Paris 0-IIc or 0-IIa+0-IIc morphology
- Non-granular laterally spreading type polyp
- Distorted surface pattern, colour and vessels (NICE NBI type III)
- Thick and irregular micro vessels (Sano capillary pattern type III)

Increased risk of incomplete resection or recurrence is characterised by:

- Size is 40 mm or more
- Location involving ileocecal valve, appendix, diverticulum or dentate line
- Within an inflamed segment of colitis
- Prior failed attempt at resection or recurrence at site of previous resection
- Non-lifting sign after submucosal injection
- Endoscopist concern about difficult location

Increased risk of adverse events is characterised by:

- Caecal location
- Size is 40 mm or more
- Endoscopist inexperience

Some centres may do additional tests to determine the depth of submucosal invasion and risk of malignancy. Biopsy sampling may be done to identify malignancy in cells. Also, MRI scans may be used to determine the degree of submucosal invasion. But MRI and biopsy sampling are not recommended in the ESGE guideline for endoscopic tissue sampling.

3.3 Treatment

Current practice for the resection of complex polyps with suspected submucosal invasion in the NHS follows NICE, BSG/ACPGBI and ESGE guidelines. For complex polyps with a suspicion of submucosal invasion, endoscopic submucosal dissection (ESD) is recommended.

ESD for lower GI polyps has previously been assessed by NICE in 2010 under interventional procedures guidance (IPG335). It is currently recommended with special arrangements for clinical governance, consent and audit or research. Since 2010 it has been used by a small number of centres in the UK. The NICE colorectal cancer guideline recommends ESD as an option for the removal of early rectal cancer. ESD has not been assessed by NICE for early colon cancer. The ESGE guidelines recommend ESD more strongly for rectal than colonic polyps. This is due to the less certain safety profile in the colon, owing to thinner GI tract walls, presence of haustral folds and increased motility of this area.

3.3.1 Endoscopic submucosal dissection

ESD is a procedure that is done under direct visualisation from an endoscope. It involves injecting a solution into the submucosa, raising the polyp into the lumen and creating a thermal barrier between the submucosa and muscle. The solution often contains dye to aid visualisation of the polyp and adrenaline to reduce the risk of bleeding. The conventional technique uses an electrocautery knife to make a circumferential incision around the base of the polyp, followed by an incision parallel to the GI tract wall. This allows the polyp to be resected in 1 piece (referred to as en bloc). The knife can sometimes be used to achieve haemostasis. But sometimes endoclips are used to control bleeding and treat small perforations. There are several other ESD techniques that can be used, including pocket creation method, traction assisted and underwater ESD. The specific ESD technique used is beyond the scope of this evaluation, but has been summarised in a technical review by the ESGE.

By removing polyps en bloc, ESD provides a complete specimen for histopathological assessment, potentially improving diagnostic accuracy. But ESD is a technically challenging procedure that requires advanced training and skill development. ESD may also carry a risk of bleeding and perforation.

3.3.2 Histopathology

Once resected, most polyps are sent to histopathology services for cancer assessment. Complete polyps that have been removed en bloc improve the chances of accurate cancer diagnosis and staging, allowing informed clinical choices to be made on treatment.

3.4 Current NHS market for the technologies

NICE have been informed by NHS Supply Chain that there is a range of ESD knives available on the catalogue and that there is substantial price variation. ESD knives purchased through NHS Supply Chain are part of the Endoscopy, Endourology, and Oncology Framework, which commenced on 1st October 2025. There are also known to be additional knives that are not currently on the NHS Supply Chain catalogue but are available for purchase in the UK. Data from the UK ESD registry indicates that 568 colorectal ESDs were done in 6 tertiary referral centres between 2016 and 2023. But it is unclear whether this database captures all colorectal ESD procedures done in the NHS, and the number of knives used per procedure is not clear.

4. The technologies

This section describes the properties of the technologies based on information provided to NICE by manufacturers and experts, and publicly available information. NICE has not carried out an independent evaluation of these descriptions.

ESD knives are single use class IIb medical devices that are used to complete ESD procedures. They are used by endoscopists. They are used to incise polyps in the colorectal region under direct visualisation from an integrated endoscope. Many can also mark and inject polyps and provide haemostasis

after incision. Many ESD knives are designed to be used in a single entry, removing the need to use multiple devices for the ESD. All ESD knives require connection to a generator to provide electricity. Some knives require specific generators while others are cross compatible. The ESGE technical review defines three categories of ESD knife for different clinical presentations, based on the tip type.

- Insulated tip type – knives that are used when cutting from the far to near side of the polyp. Cutting is done with the shaft of the blade and occurs through lateral movements.
- Non-insulated tip type – knives that are used when cutting from the near to far side. Cutting is done with the tip of the blade.
  - The ESGE includes a subcategory of non-insulated tip type knives, referring to those with a hooked or L shaped tip. These knives may be used to retract the target tissue away from the muscularis propria to assist cutting, which can be done horizontally or vertically.
- Scissor type – knives that have a claw like pair of tips that can be used to grasp the polyp, allowing the polyp to be pulled whilst cutting.

Some knives have multiple purchase options with different tips. This means services are required to stock a range of knives to allow operators to choose the most appropriate tip type for the polyp. The type of tip used is dependent on the location, size and characteristics of the polyp. Multiple tips may be used in the same procedure to allow the operator to make incisions from different angles. Knives do not have interchangeable tips, meaning the use of multiple tips requires multiple knives to be used.

Sections 4.1 to 4.21 describe the thirty included technologies. All the included technologies were available to purchase in the UK at the time of writing this scope.

4.1 AqaNife (Ovesco)

The AqaNife is an insulated tip type ESD knife that is indicated for the marking of polyps, delivery of submucosal lifting agent, incision and coagulation of

tissue within the GI tract. It has a waterjet function that allows submucosal fluid to be topped up during the procedure. It is compatible with endoscopes with a minimum working channel of 2.8 mm.

4.2 ClutchCutter (FujiFilm Healthcare Europe)

The ClutchCutter is a scissor type ESD knife that is indicated for the marking of polyps, delivery of submucosal lifting agent, incision and coagulation of tissue within the GI tract.

4.3 DualKnife (Olympus Medical Systems)

The DualKnife is a non-insulated tip type ESD knife that is indicated for the marking of polyps, delivery of submucosal lifting agent, incision and coagulation of tissue within the GI tract. It is compatible with Olympus electrosurgical units ESG-100 and ESG-400 and endoscopes with a minimum working channel of 2.8 mm.

4.4 DualKnife J (Olympus Medical Systems)

The DualKnife J is a non-insulated tip type ESD knife that is indicated for the marking of polyps, delivery of submucosal lifting agent, incision and coagulation of tissue within the GI tract. It is a modification of the DualKnife, with a waterjet function that allows submucosal fluid to be topped up during the procedure. It is compatible with Olympus electrosurgical units ESG-100 and ESG-400 and endoscopes with a minimum working channel of 2.8 mm.

4.5 FlushKnife NS and FlushKnife BTS (FujiFilm Healthcare Europe)

The FlushKnife NS and FlushKnife BTS are non-insulated tip type ESD knives that are indicated for the marking of polyps, delivery of submucosal lifting agent, incision and coagulation of tissue within the GI tract.

4.6 GOLDKNIFE Type I, GOLDKNIFE Type T, GOLDKNIFE Type O and GOLDKNIFE Type IT (Micro-Tech)

The GOLDKNIFE Type I and GOLDKNIFE Type T are non-insulated tip type ESD knives. The GOLDKNIFE Type O and GOLDKNIFE Type IT are insulated tip type ESD knives. They are indicated for the marking of polyps, delivery of submucosal lifting agent, incision and coagulation of tissue within the GI tract. They have a waterjet function that allows submucosal fluid to be topped up during the procedure.

4.7 HookKnife (Olympus Medical Systems)

The HookKnife is a non-insulated tip type ESD knife with a hooked tip. It is indicated for the incision of tissue within the GI tract. It is compatible with endoscopes with a minimum working channel of 2.8 mm.

4.8 HookKnife J (Olympus Medical Systems)

The HookKnife J is a non-insulated tip type ESD knife with a hooked tip. It is a modification of the HookKnife, with a waterjet function that allows submucosal fluid to be topped up during the procedure. It is indicated for the incision of tissue within the GI tract. It is compatible with endoscopes with a minimum working channel of 2.8 mm.

4.9 HybridKnife I-type, HybridKnife O-type and HybridKnife T-type (Erbe Elektromedizin GmbH)

The HYBRIDknife O-type is an insulated tip type ESD knife. The HybridKnife I-type and HybridKnife T-type are non-insulated tip type ESD knives. They are indicated for the marking of polyps, delivery of submucosal lifting agent, incision and coagulation of tissue within the GI tract. They use a high pressure water jet to inject fluid into the submucosa and lift the polyp into the lumen. They are monopolar knives that are compatible with ERBEJET 2 and VIO electrosurgical units and endoscopes with a minimum working channel of 2.8 mm.

4.10 HYBRIDknife flex I-type and HYBRIDknife flex T-type (Erbe Elektromedizin GmbH)

The HYBRIDknife flex I-type and HYBRIDknife T-type are non-insulated tip type ESD knives. They are a modification of the HybridKnife, with increased shaft flexibility, reduced electrode length and a shorter distal shaft segment. They are indicated for the marking of polyps, delivery of submucosal lifting agent, incision and coagulation of tissue within the GI tract. They use a high pressure water jet to inject fluid into the submucosa and lift the polyp into the lumen. They are monopolar knives that are compatible with ERBEJET 2 and VIO electrosurgical units and endoscopes with a minimum working channel of 2.8 mm.

4.11 ITknife2 (Olympus Medical Systems)

The ITknife2 is an insulated tip type ESD knife. It is indicated for the incision of tissue within the GI tract. It is compatible with endoscopes with a minimum working channel of 2.6 mm.

4.12 ITknife nano (Olympus Medical Systems)

The ITknife2 is an insulated tip type ESD knife. It is a modification of the ITknife2, with a smaller tip. It is indicated for the incision of tissue within the GI tract. It is compatible with endoscopes with a minimum working channel of 2.8 mm.

4.13 ORISE ProKnife (Boston Scientific Corporation)

The ORISE ProKnife is a non-insulated tip type ESD knife that is indicated for the marking of polyps, delivery of submucosal lifting agent and incision of tissue within the GI tract. It is a monopolar knife that is compatible with ERBE VIO 200D/300D electrosurgical generators and endoscopes with a minimum working channel of 2.8 mm.

4.14 Speedboat Inject (Creo Medical Ltd.)

Speedboat Inject is a non-insulated tip type ESD knife that is indicated for the marking of polyps, delivery of submucosal lifting agent, incision and

coagulation of tissue within the GI tract. It is a dual modal knife that simultaneously delivers bipolar radiofrequency and high frequency microwave energy using Creo Medical's Kamaptive™ platform. It is designed to be used with the Creo Medical CROMA Electrosurgical Generator endoscopes with a minimum working channel of 3.7 mm.

4.15 Speedboat Notch (Creo Medical Ltd.)

Speedboat Notch is a non-insulated tip type ESD knife. It is a modification of Speedboat UltraSlim, with a notch in the blade to allow traction procedures to be done. It is indicated for the marking of polyps, delivery of submucosal lifting agent, incision and coagulation of tissue within the GI tract. It is a dual modal knife that simultaneously delivers bipolar radiofrequency and high frequency microwave energy using Creo Medical's Kamaptive™ platform. It is designed to be used with the Creo Medical CROMA Electrosurgical Generator and endoscopes with a minimum working channel of 2.8 mm.

4.16 Speedboat UltraSlim (Creo Medical Ltd.)

Speedboat UltraSlim is a non-insulated tip type ESD knife that is indicated for the marking of polyps, delivery of submucosal lifting agent, incision and coagulation of tissue within the GI tract. It is a dual modal knife that simultaneously delivers bipolar radiofrequency and high frequency microwave energy using Creo Medical's Kamaptive™ platform. It is designed to be used with the Creo Medical CROMA Electrosurgical Generator and endoscopes with a minimum working channel of 2.8 mm.

4.17 SpydrBlade Flex (Creo Medical Ltd.)

SpydrBlade Flex is a pincer shaped ESD knife that is indicated for the incision and coagulation of tissue within the GI tract. It is a dual modal knife that simultaneously delivers bipolar radiofrequency and high frequency microwave energy using Creo Medical's Kamaptive™ platform. It is designed to be used with the Creo Medical CROMA Electrosurgical Generator and endoscopes with a minimum working channel of 3.2 mm.

4.18 Splash-M-Knife (PENTAX Medical)

The Splash-M-Knife is a non-insulated tip type ESD knife that is indicated for the marking of polyps, delivery of submucosal lifting agent, incision and coagulation of tissue within the GI tract. It has a waterjet function that allows submucosal fluid to be topped up during the procedure.

4.19 TriangleTipKnife (Olympus Medical Systems)

The TriangleTipKnife is a non-insulated tip type ESD knife that is indicated for the marking, incision and coagulation of tissue within the GI tract. It is compatible with endoscopes with a minimum working channel of 2.8 mm.

4.20 TriangleTipKnife J (Olympus Medical Systems)

The TriangleTipKnife J is a non-insulated tip type ESD knife. It is a modification of the TriangleTipKnife, with a with a waterjet function that allows submucosal fluid to be topped up during the procedure. It is indicated for the marking, incision and coagulation of tissue within the GI tract. It is compatible with endoscopes with a minimum working channel of 2.8 mm.

4.21 VedKnife D-Type, VedKnife L-Type and VedKnife T-Type (Vedkang)

The VedKnife D-Type and VedKnife T-Type are insulated tip type ESD knives. The VedKnife L-Type is a non-insulated tip tip ESD knife with a hooked tip. They are indicated for the marking of polyps, delivery of submucosal lifting agent, incision and coagulation of tissue within the GI tract. They have a waterjet function that allows submucosal fluid to be topped up during the procedure They are compatible with endoscopes with a minimum working channel of 2.8 mm.

4.22 Innovative aspects

Some ESD knives provide heat to the electrocautery blade through novel modalities. Single source energy delivery systems require users to switch between radiofrequency and microwave to prioritise incision or cauterisation, reducing the efficacy of the function not selected. Some technologies provide

heat via dual modality energy delivery, simultaneously delivering bipolar radiofrequency and high frequency microwave energy. Simultaneous dual modality energy delivery of radiofrequency and microwave energy allows both incision and cauterisation to be done at the same time without the need to prioritise either function. This may reduce collateral damage to nearby healthy tissue when incising polyps while providing timelier cauterisation of small bleeds. This may allow the user to make deeper incisions into the submucosa by reducing the risk of perforation, allowing polyps with deeper invasion to be resected en bloc. But, bipolar ESD knives cannot be used for underwater ESD.

Some ESD knives contain a waterjet function. This is primarily used to top up submucosal injection fluid, which can deplete over time during the ESD procedure. The waterjet can also be used to wash away obstacles such as mucus, saliva and blood, to allow a clearer view of the polyp.

Most ESD knives can be used for the ESD underwater technique where water or saline solution is used instead of CO2 for insufflation. This technique may improve the visibility of the polyp. The thermal properties of water may reduce collateral thermal damage to the surrounding tissue by distributing heat more evenly, reducing the likelihood of concentrated heat spikes that can damage healthy tissue. Due to the buoyancy of tissue, underwater ESD may also make resection more accurate by lifting the tissue flap away from the submucosa, allowing easier access to the submucosa and clearer differentiation of margins between the polyp and healthy tissue.

5. Comparator

ESD is established practice in tertiary complex polyp services for complex colorectal polyps that have suspected limited submucosal invasion. This assessment will compare ESD knives that have a similar tip type to each other.

6. Healthcare professional issues and preferences

Clinical experts have identified a preference among gastroenterologists to use the ESD knife that they have been trained to use. Transferability of skills acquired with one knife to another is unclear. Different types of knife may be suitable for polyps with different characteristics. The ESGE technical review recommends the use of dedicated ESD knives with size adequate to the location of the polyp thickness of the GI wall. These factors mean that operators are required to maintain competencies with multiple ESD knives.

7. Potential equality issues

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with protected characteristics (Equality Act 2010) and others. People with cancer are protected under the Equality Act 2010 from the point of diagnosis. The following potential equality issues have been identified.

- The risk of colorectal cancer increases with age. Most cases occur in people over 50 years of age (Cancer Research UK, 2025).
- Men are more likely to get colorectal cancer than women. Forty four percent of UK cases are in women, compared to 56% in men (Cancer Research UK, 2025).
- Variation in the incidence of colorectal cancer by ethnic group is reported. But, some studies suggest that people in the White ethnic group have an increased risk (Birch, 2023), whilst others suggest that people from Non-White ethnic groups do (Delon, 2022).
- People in the Black and Asian ethnic groups have the highest rates of late stage and emergency cancer diagnosis (Birch, 2023).
- People with learning disabilities are less likely to receive NHS screening tests for bowel cancer (Public Health England).

The following potential inequality issues have been identified:

- People who are overweight or obese have an increased risk of bowel cancer (Ma, 2013).
- ESD is a specialist endoscopic procedure that requires extensive training. It is currently offered in a small number of regional centres and may not be accessible for all people in the UK. People that live further from gastroenterology specialist services are typically diagnosed with cancer at a later stage (Dobson, 2022).
- People with a low socioeconomic status have higher colorectal cancer incidence rates and are typically diagnosed with cancer at a later stage. People living in the most deprived areas have a higher probability of death compared to those in the least deprived (Sturley, 2023).
- Genetic conditions such as familial adenomatous polyposis and Lynch syndrome, and chronic inflammatory bowel conditions such as ulcerative colitis and Crohn's disease may increase the risk of bowel cancer (Cancer Research UK, 2025). Inflammatory bowel conditions may also increase the difficulty of resection which may affect the choice of technique used.

8. Guidance type

The endoscopic submucosal dissection knives for the resection of complex colorectal polyps with suspected submucosal invasion will be assessed as existing use guidance. This is because:

- the assessed group of technologies (interventions) comprise similar technologies, at least some of which would be considered established practice in the NHS (NICE HealthTech programme manual provides more detail on how established practice is determined)
- the technologies are potential incremental innovations, continuous improvements or copycat devices, as defined by the Department of Health and Social Care's medical technology innovation classification framework
- there is variation in price between alternative technologies in the assessed group of technologies.

9. Decision problem

The key decision questions for this assessment are:

- Do differences in clinical and cost-effectiveness between alternative ESD knives for the resection of complex colorectal polyps with suspected submucosal invasion justify price variation?
- Are there other factors that can inform decisions about which technology to purchase?

Table 1: Decision problem

Type of assessment	Existing use
Population	• People with 1 or more complex colonic polyp with suspected submucosal invasion • People with 1 or more complex rectal polyp with suspected submucosal invasion
Interventions	• ESD knives stratified by tip type <u>Insulated tip type knives</u> • AqaNife (Ovesco) • ITknife nano (Olympus Medical Systems) • ITknife2 (Olympus Medical Systems) • GOLDKNIFE Type IT (Micro-Tech) • GOLDKNIFE Type O (Micro-Tech) • HybridKnife O-type (Erbe Elektromedizin GmbH) • VedKnife T-Type (Vedkang) • VedKnife D-Type (Vedkang) <u>Non-insulated tip type knives</u> • DualKnife (Olympus Medical Systems) • DualKnife J (Olympus Medical Systems) • TriangleTipKnife (Olympus Medical Systems) • TriangleTipKnife J (Olympus Medical Systems) • FlushKnife BTS (FujiFilm Healthcare Europe) • FlushKnife NS (FujiFilm Healthcare Europe) • GOLDKNIFE Type I (Micro-Tech)

	• GOLDKNIFE Type T (Micro-Tech) • HybridKnife I-type (Erbe Elektromedizin GmbH) • HybridKnife T-type (Erbe Elektromedizin GmbH) • HYBRIDknife flex I-type (Erbe Elektromedizin GmbH) • HYBRIDknife flex T-type (Erbe Elektromedizin GmbH) • ORISE ProKnife (Boston Scientific Corporation) • Speedboat Inject (Creo Medical Ltd.) • Speedboat Notch (Creo Medical Ltd.) • Speedboat UltraSlim (Creo Medical Ltd.) • Splash-M-Knife (PENTAX Medical) <u>Non-insulated tip type subgroup – hook shaped knives</u> • HookKnife (Olympus Medical Systems) • HookKnife J (Olympus Medical Systems) • VedKnife L-Type (Vedkang) <u>Scissor type knives</u> • ClutchCutter (FujiFilm Healthcare Europe) • SpydrBlade Flex (Creo Medical Ltd.)
Comparator	• ESD knives with a similar type of tip
Setting	• Tertiary referral centres (complex polyp services)
Outcomes and costs (may include but are not limited to)	Intermediate outcomes: • Length of hospital stay • Mortality • Adverse events (bleeding, perforation) • Procedure duration • R0 resection rate • Number of cancer diagnoses Clinical outcomes: • Polyp recurrence • Cancer progression • Need for additional surgery Patient-reported outcomes: • Health related quality of life

	Costs and resource use: • Cost of knife and associated equipment (for example, dyes, endoclips, generators) • Number of knives needed due to durability issues or device failure • Cost of staff • Cost of follow-up testing for recurrent polyps • Costs of treating cancer • Length of hospital stay A user preference assessment will be conducted to determine the preferences of people that use ESD knives when choosing a knife.
Economic analysis	A health economic model will be developed comprising a cost utility or cost-comparison analysis. Costs will be considered from an NHS and Personal Social Services perspective. Sensitivity and scenario analysis should be undertaken to address the relative effect of parameter or structural uncertainty on results. The time horizon should be long enough to reflect all important differences in costs or outcomes between the technologies being compared.

10. Other issues for consideration

10.1 Potential implementation issues

10.1.1 Training

ESD is an advanced endoscopic technique that requires extensive specialist training. Accreditation of endoscopy services in the UK is overseen by the Royal College of Physician's Joint Advisory Group on GI Endoscopy. The Joint Advisory Group consensus statements for training and certification in colonoscopy do not currently include ESD, but is developing a framework for the procedure. The ESGE acknowledges that ESD is an advanced endoscopic procedure that requires extensive training to become competent in.

10.1.2 Generator compatibility

Most ESD knives are cross compatible with generators that are available in most hospitals for other procedures. But, knives delivering simultaneous bipolar currents require specific generators that may require additional purchase for the knife to be adopted. This may present a barrier to implementation in lower volume centres where the purchase of specialist equipment for a fewer case is less viable.

10.1.3 Determining depth of submucosal invasion

Some centres may use MRI scanning to determine the degree of submucosal invasion. By doing an MRI scan, invasion can be more accurately determined than by estimation based on polyp characteristics alone. But MRI is also not recommended in the ESGE guideline for endoscopic tissue sampling. Instead, the ESGE invasion depth is estimated using the Paris, NICE or JNET classification. But clinical experts have stated that the ability to accurately classify polyps is associated with the skill and experience of the gastroenterologist. It is unclear which approach is followed in practice in the NHS.

10.2 Environmental considerations

Some ESD knives may have environmental benefits. Many ESD knives can complete the ESD procedure with a single device, reducing the number of devices required for the procedure. ESD knives that have lower adverse event rates may also require fewer additional devices that are typically used to manage bleeds and perforations. Some knives may facilitate higher complete resection rates. Successfully resecting polyps in a single ESD procedure would reduce the need for patients to return to gastroenterology services for repeat investigations, mitigating the emissions of travel that are known to be a major contributor to the overall environmental impact of healthcare. But ESD requires specialist training and can only be done by skilled endoscopists in tertiary centres. People with polyps may have to travel further to access specialists that are able to do the procedure.

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Appendix A – External guidelines and consensus statements for colorectal polyps

European Society of Gastrointestinal Endoscopy

- Colorectal polypectomy and endoscopic mucosal resection: European Society of Gastrointestinal Endoscopy (ESGE) Guideline – Update 2024
- Endoscopic submucosal dissection for superficial gastrointestinal polyps: European Society of Gastrointestinal Endoscopy (ESGE) Guideline – Update 2022
- Endoscopic tissue sampling – Part 2: Lower gastrointestinal tract. European Society of Gastrointestinal Endoscopy (ESGE) Guideline (2021)
- Diagnosis and management of iatrogenic endoscopic perforations: European Society of Gastrointestinal Endoscopy (ESGE) Position Statement – Update 2020
- Post-polypectomy colonoscopy surveillance: European Society of Gastrointestinal Endoscopy (ESGE) Guideline – Update 2020
- Endoscopic management of Lynch syndrome and of familial risk of colorectal cancer: European Society of Gastrointestinal Endoscopy (ESGE) Guideline (2019)
- Bowel preparation for colonoscopy: European Society of Gastrointestinal Endoscopy (ESGE) Guideline – Update 2019
- Endoscopic surveillance after surgical or endoscopic resection for colorectal cancer: European Society of Gastrointestinal Endoscopy (ESGE) and European Society of Digestive Oncology (ESDO) Guideline (2019)

The British Society of Gastroscopy, The Association of Coloproctology of Great Britain and Ireland and Public Health England

- JAG consensus statements for training and certification in colonoscopy (2023)
- FIT in patients with signs or symptoms of suspected CRC: A joint guideline from ACPGBI and BSG (2022)

- BSG-ACPGBI guidelines for the management of large non-pedunculated colorectal polyps (2021)
- BSG/ACPGBI/PHE Post-polypectomy and post-colorectal cancer resection surveillance guidelines (2021)
- The Association of Coloproctology of Great Britain and Ireland consensus guidelines in emergency colorectal surgery (2021)
- Public Health England NHS Bowel Screening Programme: Guidance on reporting polyps (2021)