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ORISE™ ProKnife
Value Analysis Brief

Designed with Cutting Precision and Injection Capabilities with Efficient, Safe, and Economically Viable Endoscopic Submucosal Dissection Procedures in Mind.

Endoscopic submucosal dissection (ESD) is an advanced endoscopic technique that allows complete resection of early-state lesions throughout the gastrointestinal tract to achieve an accurate histological diagnosis and prevent tumor recurrence.[1] ESD represents an advance in therapeutic endoscopy, which was developed in Japan in the 1990s. ESD adoption has been slower in Western countries, however, primarily because of its association with greater technical difficulty, longer procedure times and potentially high risks of perforation and adverse outcomes.[2]

The ORISE ProKnife is a soft tissue cutting and dissection tool engineered to address these concerns. For use in ESD and other endoluminal surgery procedures in the GI tract, its innovative features are designed to facilitate precise cutting and injection of submucosal lifting agents by clinicians. ProKnife supports procedure efficiency and economic value by enabling more hospitals, surgery centers and physicians to perform ESD as a safe[4], economic[3] alternative to surgical resections.

Key Benefits

Procedural Efficiency

Designed for cutting performance and precision

Facilitates injection of submucosal lifting agent through the electrode during the procedure without exchanging the device

Electrode locking feature secures the electrode in place throughout the entire procedure

Clinical and Economic Value

Enhances the viability of ESD as a practical, economical alternative to surgical resections[4]

Eliminates the capital investments needed since its universal luer lock adapter does not require the purchase of a pump for injection capabilities[3]

In a meta-analysis of 13,603 patients with colorectal tumors across multiple studies in 15 countries, researchers found that, although marginally significant, over time with increasing expertise the rates of ESD treatment success increased and the lengths of the procedure decreased.[1**]

** Length of procedure also dependent on size of tumor.

ESD Benefit

Over 90% of complex non-malignant colorectal polyps, regardless of size, can be safely resected endoscopically with an outpatient procedure.[5]

ESD is a less invasive endoscopic procedure that can be used to replace surgical resections. This approach may avoid unnecessary bowel resections and is increasingly being used to remove large as well as complex lesions from the colon and rectum. This procedure is less invasive and costly and provides faster recovery time for patients.[6]*

A single-center, retrospective, cohort study of 359 patients who underwent either endoscopic resection (ER) or primary surgical resection (SR) for complex polyps found that:

- The ERs had a lower rate of adverse events than SRs (10% vs 18%; p=.09)

Hospitals that replace surgery with ESD may enhance patient satisfaction and realize clinical and economic benefits, such as improvements in reducing:

Patients' hospital stays by allowing an outpatient resection and avoiding 5 days patient length of stay (p<.0001)[4]

A study[4] comparing outcomes for ESD and surgical modalities to remove complex polyps found:

12-month mortality (1.4% v. 0% for surgical and ESD modalities, respectively; p=.2694)

Significant adverse events (17.8% v. 10.1% for surgical and ESD modalities, respectively; p =.0852)

According to a recent study, gastric ESD has gained favorability in the last decade due to faster recovery, lower costs, and a superior quality of life compared to gastrectomy.[6]**

* Despite the efficacy of endoscopic resection, surgical resection remains a viable treatment option for patients with complex polyps.
** According to the same study, five year OS, DSS and DFS were similar between ESD and surgery groups. However, recurrent, synchronous and metachronous cancers were more prevalent in patients treated by ESD compared to patients treated by surgery, resulting in a lower RFS. Adequate surveillance with upper endoscopy is crucial after ESD to detect early recurrence and metachronous lesions.

An analysis[7] of 18 retrospective studies involving 5,993 patients found that ESD had considerable clinical and economic advantages over surgery, including the following statistics:

ESD had higher rates of en bloc resection and complete resection and lower risk of local recurrence (p <0.00001)

ESD operations were 128.38 minutes shorter in duration than surgeries (p=0.001)

The hospital stays for ESD patients were 7.13 days shorter than those for surgical patients (<0.00001)

In a recent study of 596 patients[8] comparing esophageal ESD to the surgical alternative of esophagectomy, researchers found that disease-specific mortality was lower among patients who received ESD (3.4%) than with who received esophagectomy (7.4%) (P = .049).

Digestive cancers (stomach[9], esophagus[10], colorectal[11])

Account for more than 10% of cancers diagnosed in the US

Account for approximately 13% of all cancer deaths

Nearly 200,000 new cases a year in the US

Potential benefits of precision cutting

Designed to limit the risk of thermal damage to the mucosa and submucosa

May provide cleaner samples to pathology to facilitate accuracy of diagnoses

ORISE ProKnife's T-shaped electrode and innovative features were designed for cutting precision, procedural efficiency and safety[3]:

Focal injection of saline/submucosal lifting agent through the tip of the electrode during dissection is designed to create a sustained lift without a device exchange for ESD procedures.

Electrode locking feature secures the electrode in place to ensure a fixed length of the electrode throughout the entire procedure, even in tortuous anatomy; allows the assistant to have free hands during the resection for procedural efficiency[3]

Boston Scientific Endoscopy is a world leader in less invasive medical devices for **treating gastrointestinal and pulmonary conditions.**

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