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This Technique Guide was developed by consensus of the authors according to standards of the American College of Surgeons, in collaboration with Clinical Education personnel from Covidien.

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COVIDIEN

Hemorrhoidopexy with Covidien EEA™ Hemorrhoid Stapler: Technique Guide

Developed by a consensus council of colorectal surgeons,
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Stapled Hemorrhoidopexy was initially introduced by Antonio Longo, MD in the mid-1990s as a surgical treatment for symptomatic hemorrhoids, with less post-operative pain than conventional surgical procedures. Since that time, significant clinical data has been published to show efficacy of the procedure for certain patient populations.

The introduction of a new commercial device by Covidien in 2009 warrants re-examination of the standard method for performing Hemorrhoidopexy, in order to assure the best practice with this device by surgeons new to the procedure. This Technique Guide outlines and details the recommendations of an international consensus council comprised of colorectal surgeons with extensive experience in the procedure and with the new Covidien device.

This Guide is not intended to substitute for proper medical education, nor to address every possible situation facing a surgeon performing hemorrhoidopexy. It is supplemental to the Instructions for Use of the device. This Guide is strictly intended as a tool for teaching and a guide for learning the key steps and criteria for safe and effective outcomes of hemorrhoidopexy with the Covidien EEA™ Hemorrhoid Stapler.

INDICATIONS AND CONTRAINDICATIONS

Indications

Grades 2 and 3 (and in some cases, Grade 4) hemorrhoids.

Absolute Contraindications

Anal stenosis of severity to prevent proper insertion of the anoscope and device

Relative Contraindications

- Grade 4 hemorrhoid
- Previous anorectal surgery
- Previous radiation of the immediate area
- Inflammatory Bowel Disease
- Anal incontinence
- Anal-receptive sexual practice

QUALIFICATIONS OF PERSONNEL

Surgeon

Current, appropriate certification to practice surgical medicine, and extensive specialty-level knowledge of ano-rectal anatomy. Hemorrhoidopexy is most safely performed by well-trained colorectal and general surgeons whose regular clinical practice incorporates that aspect of surgery.

Operating Room Staff

All staff must be properly certified to support anorectal surgery, and adequately in-serviced on the Covidien device.

SPECIFICATIONS OF THE PROCEDURE

Pre-operative Preparation of Patient

According to the surgeon's preference, the patient may have pre-operative preparation: full bowel prep, enema or rectal washout.

Anesthesia

Prior to start of surgery, the patient should be given spinal block anesthesia, or conscious sedation and a local anesthetic. In some cases, the patient may be treated under general anesthesia.

Patient Positioning

The patient may be positioned either prone ("jack-knife") or supine (lithotomy), according to surgeon preference. The surgical table should be at a height appropriate for the surgeon to be seated during rectal suturing and standing during implementation of the stapler.

Suturing

Prior to suturing and throughout the procedure, the suture port must be in place. It may be sutured into place, at the surgeon's preference. The anoscope should be used throughout the suturing process.

With the suture port in place, the surgeon must suture a fully circumferential purse string with no gaps between sutures, at 2 cm to 3 cm above the hemorrhoid pedicle, approximately 4 cm from dentate line. Suturing closer to the hemorrhoid pedicle is not

recommended for hemorrhoidopexy. Suturing too high in the rectal canal may not resolve prolapse.

The depth of the sutures should not extend beyond the sub-mucosal layer.

Upon completion, a careful manual and/or visual inspection of the purse string is required, to assure the suture line is complete and not spiraled within the rectum. If the purse string is not correct, it should be removed and resutured.

DEVICE INSERTION AND APPLICATION

Follow the Instructions for Use and training materials provided by the manufacturer for further details on the application of the device.

Prior to insertion of the anvil, surgical lubricant should be applied to the anvil; using a clamp on the anvil post will facilitate insertion.

The anvil should be inserted gently at an angle; the anvil post should be straightened within the canal when the anvil head is past the purse string.

In female patients, a digital and visual vaginal exam must be done to confirm the vagina is not involved in the sutured tissue. Gentle movement of the anvil during the manual exam can help determine vaginal involvement.

Prior to anchoring the anvil, the purse string should be inspected for location and accuracy of suturing. If the purse string is not correct, it should be removed and resutured.

The purse string may be cinched prior to anchoring, at the surgeon's preference, and then should be anchored to the center rod by tying 3 or 4 tight square knots

Both ends of the suture line should be inserted, in opposite directions, through the center rod hole that is proximal to the tissue to be removed. Gentle tension on the anvil may facilitate placement of the sutures into the best hole for optimal tissue removal. In most patients, the second hole on the anvil post is the correct hole for optimal tissue removal.

After attaching the anvil to the stapler, the device may be closed. Before firing the device, the surgeon should be positioned appropriately for single-squeeze firing. For most surgeons, this means shifting from a seated position (during suturing and insertion) to standing for firing the stapler. The device handle must be closed completely in one uninterrupted squeeze.

After firing, the stapler can be removed following one full turn of the black handle. After removal of the fired stapler, the surgeon should carefully inspect the stapled suture line. The sutures anchoring the port may then be removed.

ANTIBIOTICS

Antibiotics may be administered pre- or peri-operatively according to surgeon preference and/or institutional protocol. Peer-reviewed literature shows no preference for prophylactic use of antibiotics.

PATIENT INSTRUCTIONS

Pre-procedural Care and Instructions

Patients who take medications such as Plavix™* or Coumadin™* may need to cease medications in advance of surgery and for an appropriate post-operative period. Ceasing and restarting medications is at the judgment of the surgeon based on the specific needs and co-morbidities of the patient.

Post-Procedural Care

Patients should be monitored appropriately according to the anesthesia administered. In most cases, patients can be discharged within 12-24 hours based on local institution protocols. Upon discharge, patients should be advised to follow a high fiber diet, and use stool softeners and sitz baths. Analgesics should be provided for the immediate recovery period, with specific instructions to continue fiber and stool softeners for the duration of the analgesics. General recommendations for patient activity include limiting activity for at least two to three days, and advising against travel for two weeks.

A follow-up visit should be scheduled according to the surgeon's preference, within 2-4 weeks of surgery.

REFERENCES

Burch J, Epstein D, et al., Stapled haemorrhoidopexy for the treatment of haemorrhoids: a systematic review, Colorectal Dis 2009; 11: 233-44.

Chew M, Kam M, et al., The evaluation of CEEA 34 for stapled hemorrhoidectomy: results of a prospective clinical trial and patient satisfaction, Am J Surg 197(6):695-701.

Corman ML., Gravie JF. et al., Stapled haemorrhoidopexy: a consensus position paper by an international working party – indications, contra-indications and technique, Colorectal Disease, 5, 304–310.

Ganio E, Altomare D, et al., Long-term outcome of a multi-centre randomized clinical trial of stapled haemorrhoidopexy versus Milligan-Morgan haemorrhoidectomy, Brit J Surg 94(8):1033-1037.

Gerjy R, Lindhoff-Larson, et al., Randomized clinical trial of stapled haemorrhoidopexy performed under local perianal block versus general anaesthesia, Brit J Surg 95(11):1344-1351.

Giordano P, Gravante G, et al., Long-term outcomes of stapled hemorrhoidopexy vs conventional hemorrhoidectomy: a meta-analysis of randomized controlled trials, Arch Surg, 144 vol3 March 2009, 266-272.

Gravié JF et al., Stapled Hemorrhoidopexy versus Milligan-Morgan hemorrhoidectomy: a prospective, randomized, multi-center trial with 2-year postoperative follow-up, Ann Surg, 2005 July; 242(1): 29–35.

Jayarman S, Colquohoun P, Malthaner R, Stapled hemorrhoidopexy is associated with a higher long-term recurrence rate of internal hemorrhoids compared with conventional excisional hemorrhoid surgery, Dis Colon Rectum 50(9):1297-1305.

Laughlan K, Jayne D, et al., Stapled haemorrhoidopexy compared to Milligan-Morgan and Ferguson haemorrhoidectomy: a systematic review, Int J Colorectal Dis (2009) 24:335-344.

Longo A, Treatment of hemorrhoids disease by reduction of mucosa and hemorrhoidal prolapse with a circular suturing device: a new procedure, Proceedings of the 6th World Congress of Endoscopic Surgery, Rome, Italy, June 1998: 777-784.

Ortiz H, Marzo J, et al., Stapled hemorrhoidopexy vs diathermy excision for fourth-degree hemorrhoids: a randomized, clinical trial and review of the literature, Dis Colon Rectum 48(4):809-815.

Plocek M, et al., Hemorrhoidopexy staple line height predicts return to work, Dis Colon Rectum 2006; 49:1905-1909.

Shao W, Li G, et al., Systematic review and meta-analysis of randomized controlled trials comparing stapled haemorrhoidopexy with conventional haemorrhoidectomy, Brit J Surg 95(2):147-160.

Sileri P, Stolfi V, et al., Stapled hemorrhoidopexy: a prospective study from pathology to clinical outcome, J Gastrointestinal Surg 11(12):1662-1668.

Tjandra J and Chan M, Systematic review on the procedure for prolapsed and hemorrhoids (stapled hemorrhoidopexy), Dis Colon Rectum 50(6):878-892.

Williams R. et al., Stapled hemorrhoidopexy height as outcome indicator, Am J Surg 2007; 193:336-340.