

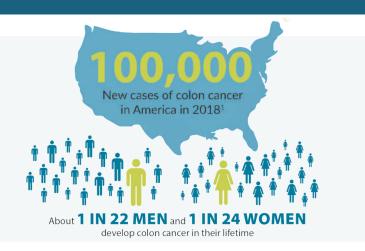
A Gastroenterologist's Guide to Endoscopic Tattooing Methods





Brief Overview

As the third most common cancer diagnosis among both men and women, with nearly 100,000 new cases expected in 2018,¹ according to the American Cancer Society, the fight against colon cancer is far from over. However, significant ground has been gained in colon cancer prevention as awareness for this preventable disease has grown.



The American Cancer Society recently updated their guidelines for colorectal cancer screening, and now recommend that adults begin screening at age 45, lowered from age 50.² This is a meaningful step in the fight against this disease. Earlier screening and increased use of long-term clinical surveillance — through procedures like endoscopic tattooing — can be vital tools to utilize in the fight against colon cancer.

Endoscopic tattooing of suspicious lesions or confirmed tumors, is an important tool for surgical localization and to enable identification of malignant or suspicious lesions at a future colonoscopy. Tattooing has also been shown to decrease time spent in the operating room³ and greatly improve tumor localization.⁴ That time saved in the OR is good news for both doctors and patients.⁵

New clinical guidelines have also been released from the European Society of Gastrointestinal Endoscopy (ESGE) that recommend tattooing all lesions that need to be followed-up at future colonoscopy or surgery.⁶

Given the number of studies and reports on the clinical benefits of endoscopic tattooing, not to mention its inclusion in the ESGE's Guidelines for EMR and Polypectomy, it might surprise you to learn that the methods for endoscopic tattooing are not part of the core surgical curriculum at most medical schools.

Even when taught, it's rarely reinforced with additional training after medical school. Add a lack of standardized guidelines for the procedure, and it becomes clear why a lot of questions remain about when and why physicians should tattoo.

In this guide you'll find answers to frequently asked questions about endoscopic tattooing, take a closer look at the most common methods for tattooing, and learn more about an effective tool in the fight against colon cancer.

 $^{^1 \,} Key \, Statistics \, for \, Colorectal \, Cancer. \, American \, Cancer \, Society. \, https://www.cancer.org/cancer/colon-rectal-cancer/about/key-statistics.html.$

² Wolf AMD, Fontham ETH, Church TR, et al. Colorectal cancer screening for average-risk adults: 2018 guideline update from the American Cancer Society. CA: A Cancer Journal for Clinicians. 2018. doi:10.3322/caac.21457.

³ Arteaga-Gonzalez I, et. al., The use of preoperative endoscopic tattooing in laparoscopic colorectal cancer surgery for endoscopically advanced tumors: a prospective comparative clinical study. World J Surg. 2006. 30(4):605—611.

Askin MP, Waye JD, Fiedler L, Harpaz N. Tattoo of colonic neoplasms in 113 patients with a new sterile carbon compound. Gastrointestinal Endoscopy. 2002;56(3):339-342. doi:10.1067/mge.2002.126905.

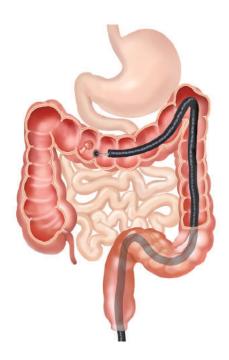
⁵ Arteaga-Gonzalez I, et. al., The use of preoperative endoscopic tattooing in laparoscopic colorectal cancer surgery for endoscopically advanced tumors: a prospective comparative clinical study. World J Surg. 2006. 30(4):605—611.

⁶ Ferlitsch M, Moss A, Hassan C, etal. Colorectal polypectomy and endoscopic mucosal resection (EMR): ESGE Clinical Guideline. 2017.

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FA-ET-Qs (Frequently Asked Endoscopic Tattoo Questions)



What are the benefits of endoscopic tattooing?

By tattooing lesions with dark, permanent endoscopic tattoos, localization in colon resection surgery or post-polypectomy for follow-up colonoscopy can be fast and easy. When a surgeon cannot locate a lesion during surgery, the potential risks include:⁷

- Longer surgical times while the surgeon attempts to locate the lesions
- Additional colonoscopies to identify the site
- The need for the surgeon to convert from a laparoscopic to an open procedure
- The need for an intraoperative colonoscopy
- Wrong site surgery the potential for the surgeon to remove the wrong section of bowel

Endoscopic tattooing has also been proven to:

- Decrease time spent in the operating room⁸
- Greatly improve tumor localization⁹

Why would a doctor not tattoo?

A lack of common guidelines for endoscopic tattooing leaves many doctors (and nurses who frequently assist with the procedure as well) in limbo on when they should tattoo. Tattooing methods are rarely taught in medical schools and even when training happens it's rarely reinforced with additional follow-up training. Other common obstacles include not having the right tools (or running out), timing pressures, or simply overlooking.

How many tattooing methods are there (and what are they)?

There are two widely used tattooing techniques, that are considered by most physicians as the most reliable methods — saline bleb and direct.

Does it matter which method is used?

Proper placement of the tattoo is an important part of ensuring it is visible during follow-up colonoscopy and/or surgery, so using proper technique and a reliable method is important.

Who recommends endoscopic tattooing?

Endoscopic Tattooing is society-recommended by the American College of Gastroenterology,¹⁰ European Society of Gastrointestinal Endoscopy,¹¹ British Society of Gastroenterology,¹² and Society of American Gastrointestinal Endoscopic Surgeons.¹³

⁷ Acuna SA, et. al., Preoperative localization of colorectal cancer: a systematic review and meta-analysis. Surg. Endosc. 2017; 31:2366-2379.

⁸ Arteaga-Gonzalez I, et. al., The use of preoperative endoscopic tatiooing in laparoscopic colorectal cancer surgery for endoscopically advanced tumors: a prospective comparative clinical study. World J Surg. 2006. 30(4):605—611.

⁹ Acuna SA, et. al., Preoperative localization of colorectal cancer: a systematic review and meta-analysis. Surg. Endosc. 2017; 31:2366-2379.

¹⁰ Rex D, Schoenfeld P, Cohen J, et al. Quality Indicators for Colonoscopy. Am J Gastroenterol. 2014: 1-19.

¹¹ Ferlitsch M, Moss A, Hassan C, et al. Colorectal polypectomy and endoscopic mucosal resection (EMR): ESGE Clinical Guideline. 2017.

¹² Rees C, Bevan R, Zimmerman-Fraedrich K, et al. Expert opinions and scientific evidence for colonoscopy key performance indicators. Gut BMJ. 2016.

¹³ SAGES. Guidelines for laparoscopic resection of curable colon and rectal cancer. 2012.

The Methods Explained 14,15

Having a firm grasp of the available methods is important to ensure the endoscopic tattoo provides the greatest benefit as a surgical localization and clinical surveillance tool. While the precise process may vary between occurrences, these are the two most widely used methods for effective endoscopic tattooing.

Two Techniques

Physicians can choose to use either a saline bleb or a direct method to tattoo a lesion for either surgical localization or clinical surveillance. No matter the technique, an effective endoscopic tattoo requires these things:

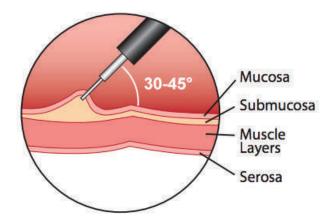
Careful insertion of the needle tangentially, not *en face*, into the submucosal plane at a 30-45° angle.

A closely monitored and controlled injection to avoid accidental injection into the peritoneal cavity and diffuse intraabdominal staining, which can be potentially misleading during surgery.

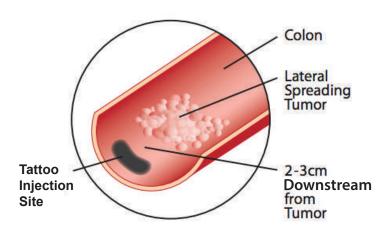
If the lesion is being marked for surgical resection, mark the lesion on the downstream side and place the tattoo's 2-3 cm from the lesion in 3-4 quadrants.

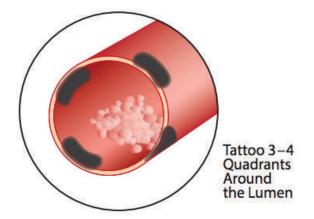
Do NOT tattoo directly into or underneath the lesion.

If the lesion is being marked after endoscopic resection for colonoscopy follow up, place the tattoo after completion of the resection. Place the tattoo 2 cm downstream of the resection defect.



Endoscopic Tattoo for Surgical Localization





¹⁴ Spot Ex Instructions For Use. Rev 03. May 2018.

¹⁵ Rex DK. Driving patient safety with endoscopic tattooing. Gastroenterology and Endoscopy News. 2015 May.

The Methods Explained (continued)

BLEB METHOD



Dr. Douglas K. Rex demos bleb technique. 17

The bleb technique is recommended. In this method, a bleb of saline (1 mL) is first injected into the submucosa in four quadrants. The tattoo is then injected (0.5 to 0.75 mL) into each of the blebs.

This allows for a more certain injection of the tattoo into the submucosa.

A four-quadrant injection around the circumference of the bowel is recommended to optimize localization during surgery.¹⁶

This multi-step approach allows doctors and nurses to more reliably inject the tattoo in the proper spot (the submucosa), and avoid transmural injection.

In the direct method, the tattoo is injected directly into the submucosa, without the use of a saline bleb.

The key is to get tangential (30° - 45°) to the wall of the colon, and 2-3 cm downstream of the lesion. Do not place the tattoo directly into or underneath the lesion.

The needle is then inserted directly into the submucosal space, starting slowly to make sure a bleb forms, then injecting the tattoo (0.5 to 0.75 mL).

This is repeated four times, circumferentially.

This approach requires less prior prep than the bleb technique, and is a common technique for doctor's who are experienced with the tattooing process.

DIRECT METHOD



Dr. Douglas K. Rex demos direct technique. 18

¹⁶ Hyman N, Waye JD. Endoscopic four quadrant tattoo for the identification of colonic lesions at surgery. Gastrointest Endosc 1991;37:56-8.

^{17.18} GI Supply (2017). Methods to Inject Endoscopic Tattoo into the Submucosal Space with Dr. Douglas K. Rex. [video] Available at: https://www.youtube.com/watch?v=0vEGAx0IHwM.

The Methods Explained (continued)



Which is preferred?

As would be the case with any medical procedure, each of these methods has its own list of pros and cons. That's why awareness of possible complications at every step is important. With both of these two methods, the maximum recommended dose of tattoo is 8 mL.¹⁹ You can find demonstrations of both of these methods on the GI Supply YouTube channel.

It is very important that whichever method is used, that the tattoo is not injected directly into or underneath the lesion.

Don't Forget to Document²⁰

As important as the method, it is also important to properly document the tattoo. Here are a few best practices to keep in mind:

- Use text and photo documentation in your reports with unambiguous terminology
- Document location of the tattoos in relation to the lesion
- Indicate where and how many tattoos were placed at each area of interest
- Don't specify the colonic segment unless you are 100% certain
- If there are other tattoos in the colon you should describe those and their relationship to the lesion marked for surgery

¹⁹ Spot® Ex Endoscopic Tattoo Instructions for Use. Rev 03. May 2018.

²⁰ Rex DK. Driving Patient Safety with Endoscopic Tattooing Gastroenterology and Endoscopy News. May 2015.

The Next Step in the Fight Against Colon Cancer



As the medical community battles this disease, the need for earlier detection and long term clinical surveillance will increase and the right tools and procedures are needed for the job. It's clear patients, surgeons, and gastroenterologists all benefit from having suspicious lesions tattooed to improve future endoscopic and surgical procedures.

GI Supply is proud to provide an effective endoscopic tattoo solution for clinical surveillance and surgical localization, **Spot® Ex Endoscopic Tattoo**. It's indicated for 36 months²¹ and darker than Spot²² which enables expedited localization at follow-up procedures. Spot Ex also has expanded indications that support the ESGE's updated clinical guidelines:²³

"Colonoscopic tattooing is performed to enable future identification, at colonoscopy or surgery, or malignant lesions (proven or suspected), polypectomy, EMR, or ESD sites, difficult-to-detect polyps, or dysplactic areas. All such lesions, other than those definitely located in the cecum, adjacent to the ileocecal valve, or in the low rectum, should be tattooed."

Properly performed and documented endoscopic tattooing is the standard of care to convey definitive disease localization information between practitioners or to facilitate long-term clinical surveillance post-polypectomy. Easy to use and easy to find Spot Ex enables both surgical localization and clinical surveillance. Learn more about tattooing at spotextattoo.eu.

²¹ Spot Ex Indication. Instructions For Use. Rev 03. May 2018

²² Spot Ex Luminosity Lab Results. Northwestern Biological Imaging Facility. Nov 2017.

²³ Ferlitsch M, Moss A, Hassan C, et al. Colorectal polypectomy and endoscopic mucosal resection (EMR): ESGE Clinical Guideline. 2017.

Questions about Spot®Ex?

Please contact your local distributor for further information

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