

Spot[®] Ex

Endoscopic Tattoo

GASTROENTEROLOGY
Now MDR approved



Spot® Ex: Exhaustively assessed for MDR compliance

- Spot Ex is now approved for sale under the new European Union Medical Device Regulation (EU) 2017/745 (MDR)
- MDR certification provides you with assurance of the safety and efficacy of Spot Ex via a detailed review of the clinical evidence supporting the product's claims, and the use of post-market surveillance throughout the device's lifetime



Spot® Ex: Expanded Indications Support Adoption of Guidelines



Spot Ex is **long lasting**, enabling patient follow up for 36 months



Only tattoo indicated for use for both **Clinical Surveillance** and **Surgical Localisation**

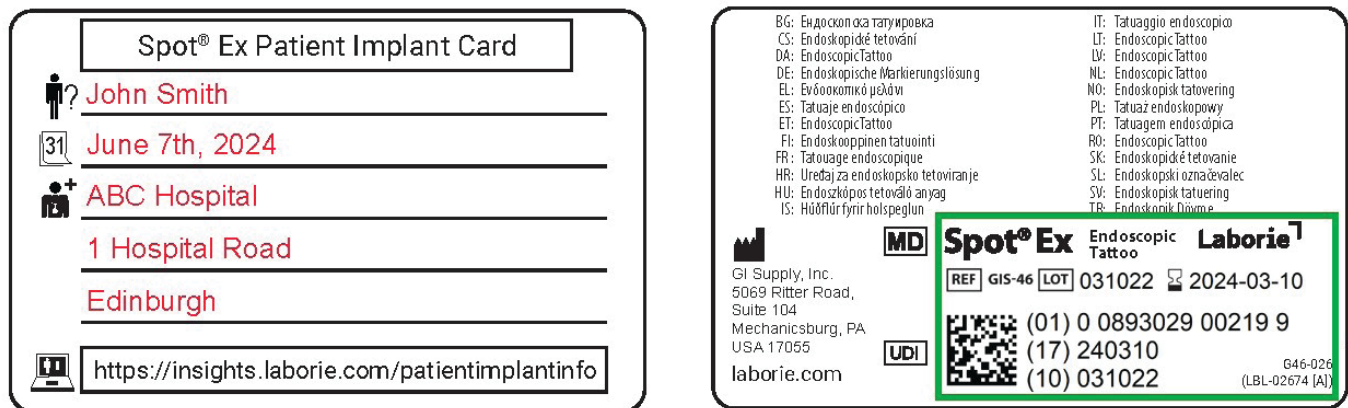


"ESGE recommends that lesions that may need to be located at future surgical procedures, polypectomy sites in cases where cancer is suspected, or where subsequent identification of the endoscopic scar location may be challenging, should be tattooed during colonoscopy, with the relationship between the tattoo and the lesion documented in photos and writing"

Ferlitsch, M. et al. Colorectal polypectomy and endoscopic mucosal resection: ESGE Guideline – Update 2024. Endoscopy 2024; 56

Spot® Ex: Explains Product Features to Patients

- Spot Ex now includes a Patient Implant Card and Informative Instruction Leaflet:
 - The EU Medical Device Regulations (MDR) requires manufacturers of implantable devices to provide a patient implant card, ensuring patients have convenient access to all essential information about their implanted device.
 - Each box of Spot Ex contains 10 Patient Implant Cards.



Patient Implant Card features

- Information to be completed by the healthcare provider (sample in **red** above):
 - Name of the patient or patient ID;
 - Date of implantation.
 - Name and address of the healthcare institution that performed the implantation;
- Information provided by the manufacturer, pre-printed on the implant card or patient label affixed to the implant card as featured in the **green** box depicted above:
 - Device name;
 - Device type;
 - Unique device identification (UDI);
 - Lot number;

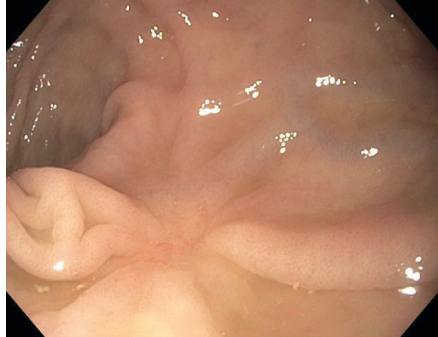
Further product details are provided on the Patient information website:

insights.laborie.com/patientimplantinfo

Spot® Ex: Expedites Localization at Follow Up Procedures¹

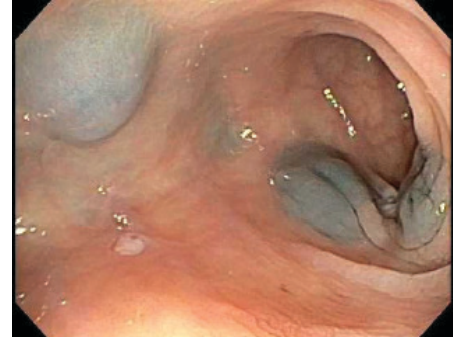
• Follow-Up Procedure Post-Polypectomy³

Scar tissue healed at 4 months without endoscopic tattoo.



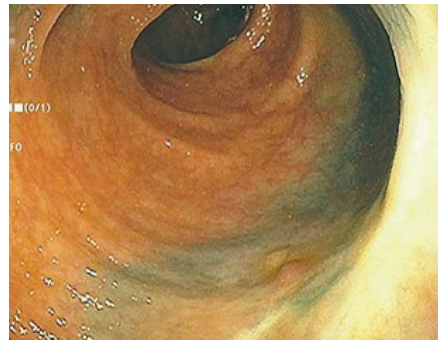
• Polypectomy Procedure with Spot Ex

Spot Ex is indicated for clinical surveillance ensuring you will be able to locate the area of interest at follow up procedures.



• Clinical Surveillance

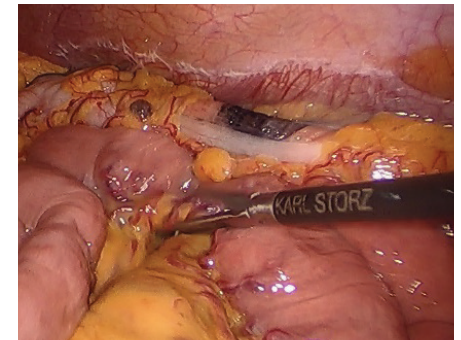
Tattooing is recommended to facilitate localization at follow-up².



► Endoscopic Follow-up of Piecemeal EMR

• Surgical Localization

Tattooing reduces OR time by up to 40 minutes by improving localization¹.



► Laparoscopic Follow-Up at Colorectal Surgery

Spot® Ex: Extra Efficiency From Additional Features

Roll-Proof Pop-Proof Cap

2D Barcode

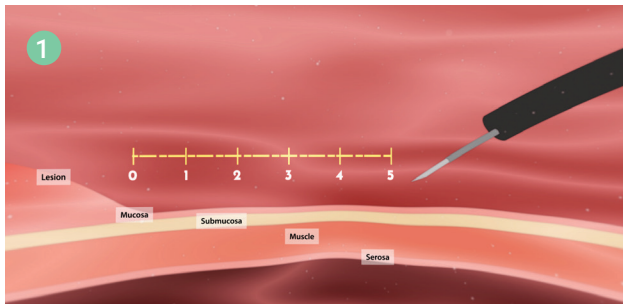


Zero-Step Prep™ Syringe

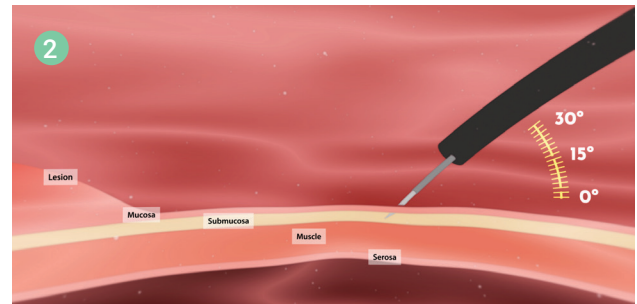
Sustainable Packaging

Four Patient Labels

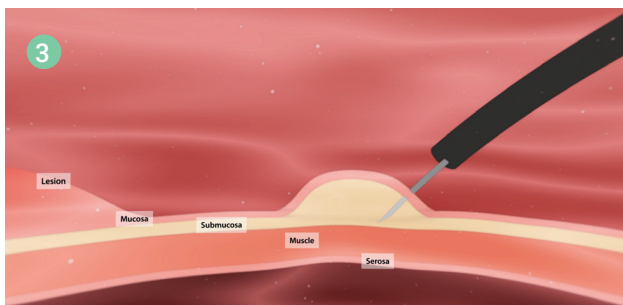
Submucosal Injection - with the bleb technique⁴



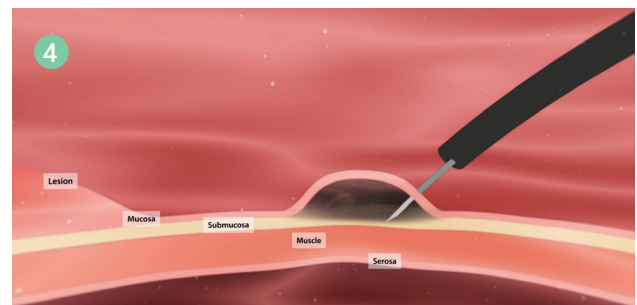
1. Place injection 3-5 cm distal (anal side) of the area of lesion.



2. Inject tangentially, at a 30-45° angle to the mucosa.

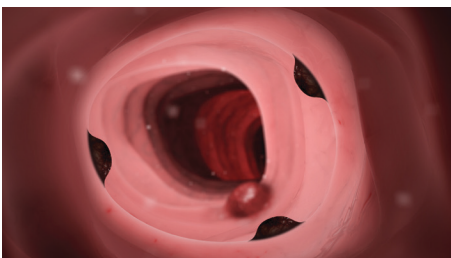


3. Create a saline bleb to find the submucosal plane prior to injecting Spot Ex to reduce risk of transmural injection.



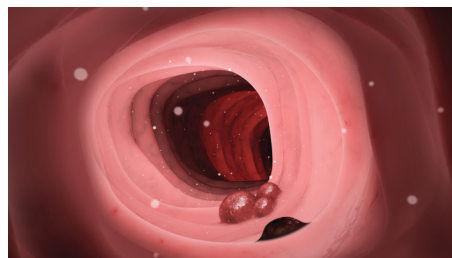
4. Use 0.5-0.75 mL of Spot Ex per injection site, and no more than 8 mL per patient.⁵

Tattoo Placement⁴



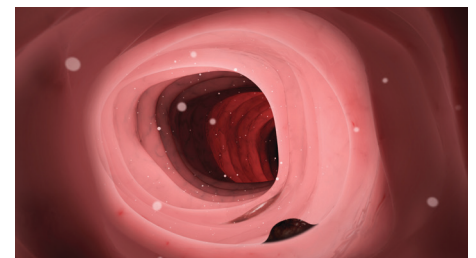
For Surgical Resection

- Place the tattoos in 2-3 quadrants, circumferentially;
- 3-5 cm from the lesion on the distal (anal) side



For Future Endoscopic Resection

- Place a single tattoo;
- 3-5 cm from the lesion on the distal (anal) side



For Surveillance of Large/ Piecemeal Resected Lesions

- Place a single tattoo after resection of the lesion;
- 3-5 cm from the lesion on the distal (anal) side



Scan the QR code to watch an animation on how to correctly inject & place endoscopic tattoos.

Preparation



Shake it



Attach it



Prime it

Storage

Keep at room temperature



2-year shelf life



Store upright or on its side



Documentation Best Practices³

- Use text and photo documentation in your reports with unambiguous terminology.
- Document both the depth of scope and anatomic location of each tattoo.
- Indicate where and how many tattoos were placed at each area of interest.

Your Polypectomy Partner:

Following the resection of polyps with EverLift® Submucosal Lifting Agent, use Spot Ex for clinical surveillance

EverLift: The Lift you’ve been waiting for:

- Reliable Lift
- For Everyday Use
- Conveniently Packaged



Endoscopic Resection and Tattooing Ordering Information

Item No.	Description	Unit
GIS-46	Spot Ex Endoscopic Tattoo	10 syringes per box
GIS-55	EverLift Submucosal Lifting Agent, 5 mL syringe	10 syringes per box
GIS-59	EverLift Submucosal Lifting Agent, 10 mL syringe	10 syringes per box

1. Arteaga-Gonzalez, 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: 605–611

2. Ferlitsch, M. et al. Colorectal polypectomy and endoscopic mucosal resection: ESGE Guideline – Update 2024. Endoscopy 2024; 56

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

4. L. Medina-Prado et al, When and How To Use Endoscopic Tattooing in the Colon: An International Delphi Agreement. Clinical Gastroenterology and Hepatology 2021;19:1038–1050

5. Spot Ex IFU G46-006 (LBL01906 [K])

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Laborie⁷

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