



Black Eye

Black Eye™

Endoscopic Marker





Black Eye™

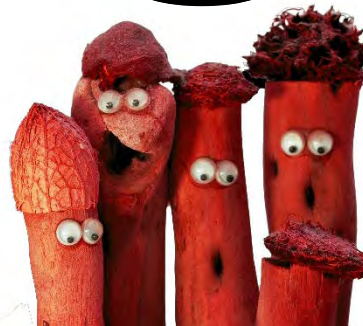
Endoscopic Marker

Permanent ink

Stable Suspension

Stable Emulsion

Proven in 45 countries



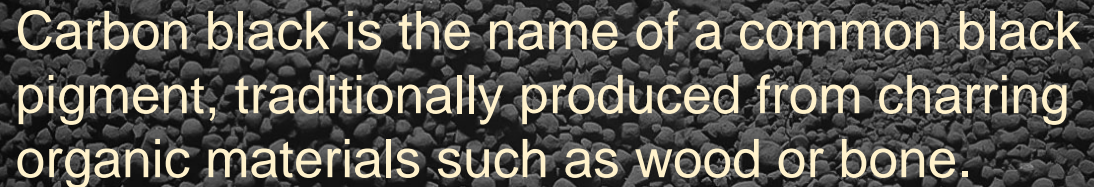
Black Eye™ is a sterile, non-pyrogenic ink designed to be used as an endoscopic marker for marking polyps and lesions in the gastrointestinal tract. It is supplied syringe contain 5ml of the marker.

“ Permanent ink ”

India ink preparations contain shellac, phenol, and ammonia that, even in dilute solutions, should be avoided. Black eye's biocompatible, non-toxic formulation contains no India ink.



Carbon black



Carbon black is the name of a common black pigment, traditionally produced from charring organic materials such as wood or bone.

Carbon black lasts for more than 10 years in the body !!!



- [1] Shatz, Burton A., et al. "Long-term safety of India ink tattoos in the colon." *Gastrointestinal endoscopy* 45.2 (1997): 153-156. *Summary: Tattoos on 55 patients did not disappear in the body for 117 months.*
- [2] Fennerty, M. Brian. "Tissue staining (chromoscopy) of the gastrointestinal tract." *Canadian Journal of Gastroenterology and Hepatology* 13.5 (1999): 423-429.
- [3] The establishment and clinical appliance of technique of mucosa marking targeting biopsy. Sun L, Si J, Chen S, Liu W, Zhao L, Wang L, *Hepatogastroenterology*. 2009 Jan-Feb; 56(89):59-62
- [4] Endoscopic marking: an adjunct to laparoscopic gastrointestinal surgery. Beretvas RI, Ponsky J., *Surg Endosc*. 2001 Oct; 15(10):1202-3
- [5] Safety of preoperation endoscopic tattoo with India ink for identification of colonic lesions. McArthur CS, Roayaie S, Wayne JD., *Surg Endosc*. 1999 Apr;13(4):397-400

“ Stable Emulsion ”

Emulsion

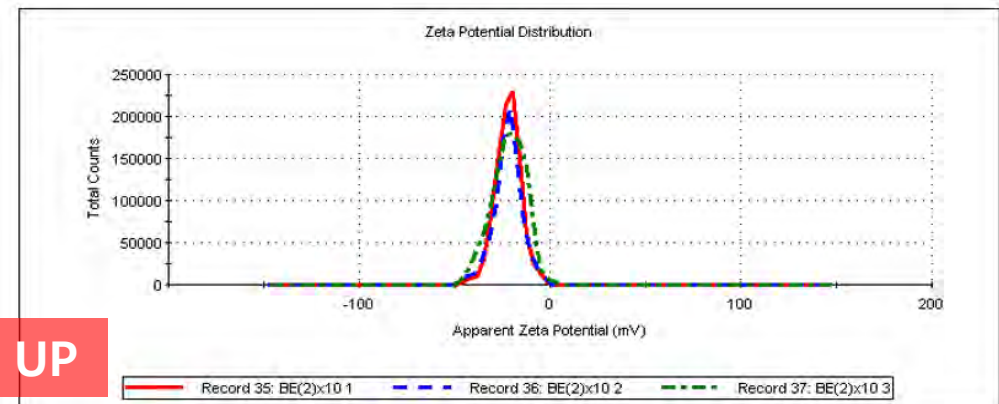
An emulsion is a mixture of two or more liquids that are normally unmixable. Milk is an emulsion of fat and water.



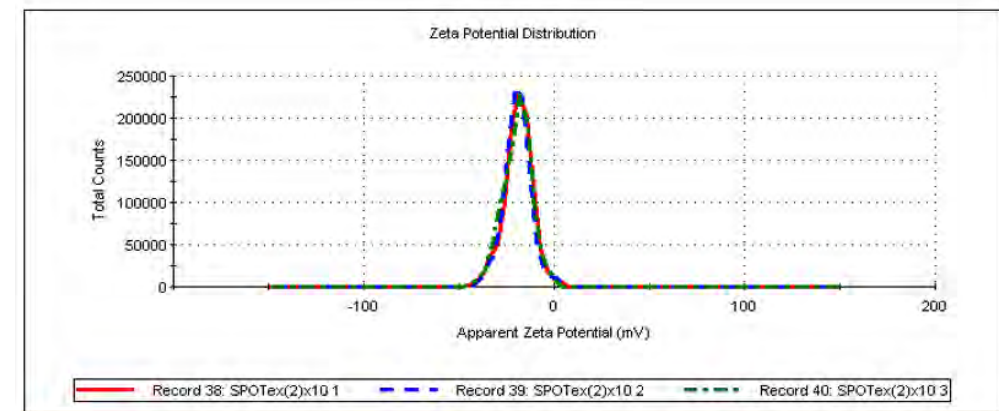
Poor emulsion can choke the tube of the syringe or body fluid !!!

Zeta potential Test

Performance 6.2% UP



	Mean(mV)	Area(%)	St Dev(mV)
Zeta Potential(mV): -21.6	Peak 1 : -21.6	100.0	8.85
Zeta Potential(mV): 8.85	Peak 2 : 0.00	0.0	0.00
Conductivity(mS/cm): 0.00595	Peak 3 : 0.00	0.0	0.00
Result quality : Good		Black Eye 20.7 mV	



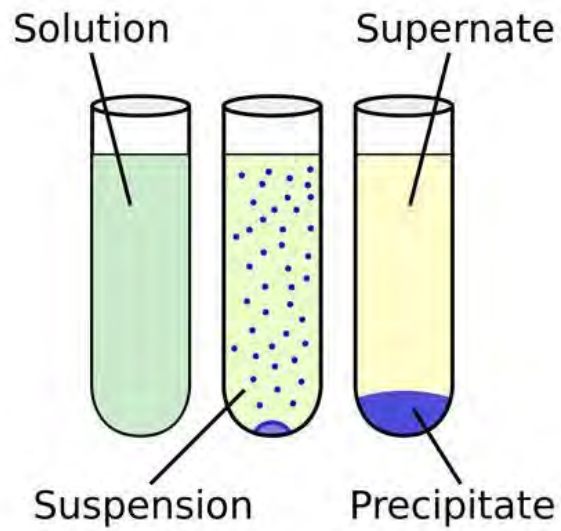
	Mean(mV)	Area(%)	St Dev(mV)
Zeta Potential(mV): -19.6	Peak 1 : -19.6	100.0	7.67
Zeta Potential(mV): 7.67	Peak 2 : 0.00	0.0	0.00
Conductivity(mS/cm): 0.00580	Peak 3 : 0.00	0.0	0.00
Result quality : Good		Predicate 19.5 mV	

“ Stable Suspension ”

Suspension

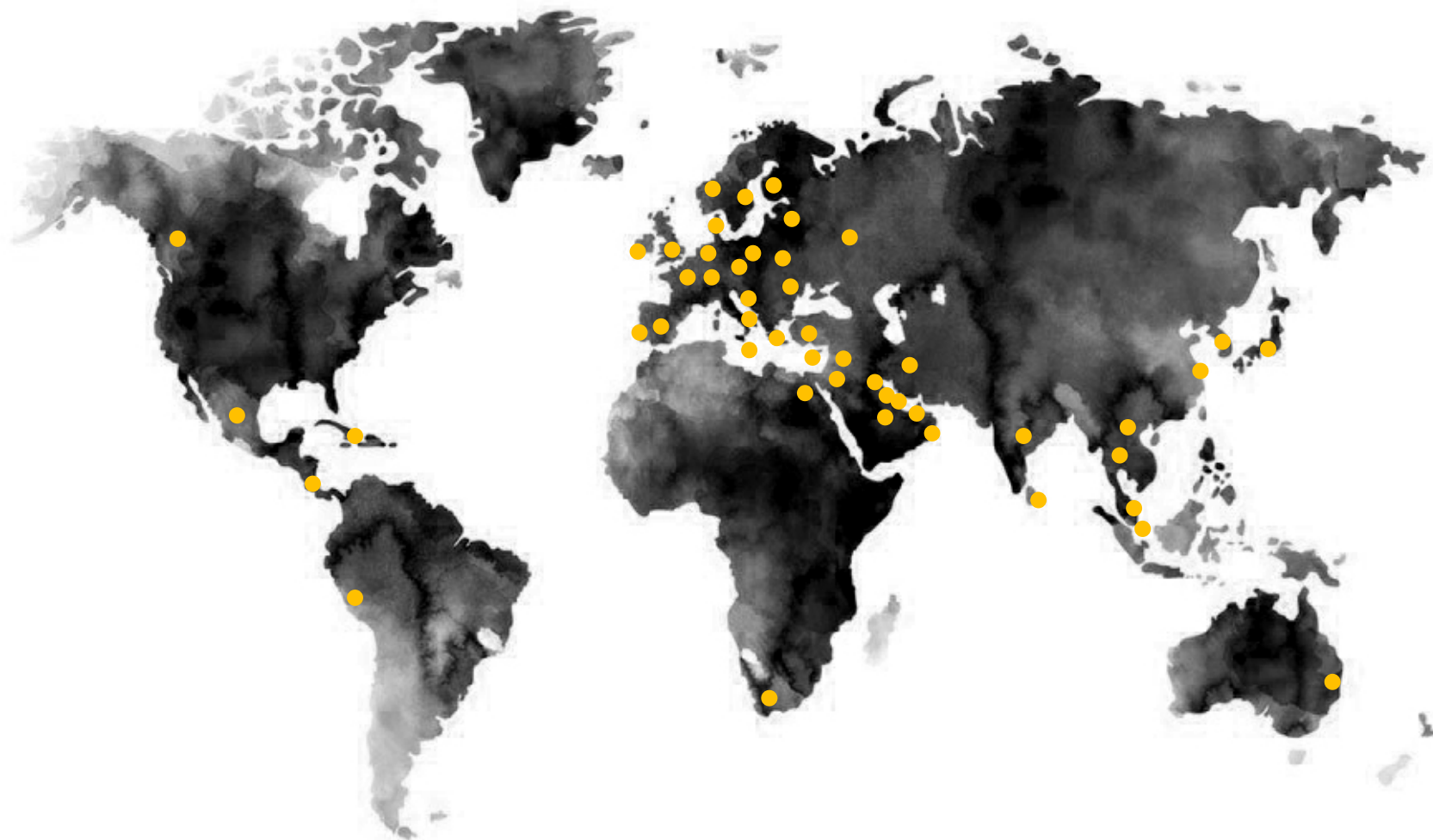
Suspension is a heterogeneous mixture that contains solid particles sufficiently large for sedimentation.

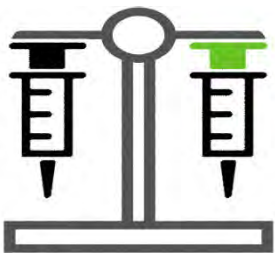
Poor suspension can make the solution separated, which leads to unstable marking !!!



You do not need shake well before use !!!

“ Proven in 45 countries ”





Improved Endoscopic Marker!

Particle Size Distribution



Test report (BE & Spot) by
The Standard / Lee SeungHee

Black Eye 0.85%
Predicate 1.96%

The particle of Carbon black not more than 50nm can be toxic in the body !!!

[1] Sahu, Devashri, G. M. Kannan, and R. Vijayaraghavan. "Carbon black particle exhibits size dependent toxicity in human monocytes." *International journal of inflammation* 2014 (2014).

Intended Use

Black Eye™ is indicated for endoscopically marking lesions in the GI tract when the endoscopist anticipates the lesion will require surgical removal.



Store at room temperature

Two year shelf life

Instructions for Use

Packaging 5 ml syringe, box of 12

Black Eye™ Applications

An anatomical illustration of the human digestive system, including the stomach, liver, pancreas, and large and small intestines, overlaid on a blue-tinted human torso. The system is highlighted in a light pinkish-orange color. Eight green callout boxes with white text are arranged around the system, pointing to specific areas. The callouts are: 'Marking Pancreatic Lesions' (pointing to the pancreas), 'Marking Areas of Suspicion' (pointing to the upper small intestine), 'Double Balloon Endoscopy' (pointing to the small intestine), 'Barrett's Esophagus' (pointing to the esophagus), 'Marking Colon Resections' (pointing to the colon), 'Marking Stomach Lesions' (pointing to the stomach), 'Highlight Lymph Nodes' (pointing to the lymph nodes in the abdominal region), and 'Post Polypectomy Surveillance' (pointing to the colon).

Marking Pancreatic Lesions

Marking Areas of Suspicion

Double Balloon Endoscopy

Barrett's Esophagus

Marking Colon Resections

Marking Stomach Lesions

Highlight Lymph Nodes

Post Polypectomy Surveillance



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