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TS-205

Black Eye

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TS-205 Black Eye[™] Endoscopic Marker

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.

Black Eye Non-India-ink-based product for marking the GI tract.

CE 0120

TS-205 Black Eye[™] Endoscopic Marker

Intended Use

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

Technological Characteristics and Substantial Equivalence

Black Eye[™] is substantially equivalent to the predicate colon marker. The Black Eye[™] and the predicate device have same indications for use. Both are carbon black formulations that are used for endoscopically tattooing or marking the colon.

The Black Eye[™] Endoscopic Marking System provides a method of marking cancerous lesions on the wall of a patient's stomach or colon during an endoscopic procedure. The mark provides a reference point for subsequent removal of the tissue. The inexpensive packaging solution turned the technology into a product, by creating a whimsical brand identity that uses color and simple iconography that make it appear less threatening, thereby reducing user anxiety.

Why it's better for your patients

It's safe.

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.

It's sterile.

Black Eye $^{\rm m}$ is a single-use product, so sterility is easily maintained. Each syringe is sterilized prior to packaging and shipping.

Each syringe is prefilled.

Preparation is simplified thanks to Black Eye's ready-to-use product design. Each syringe comes with 5ml of the marking fluid. Just shake it vigorously prior to use.

It's easy to work with.

Black Eye $^{\rm m}$ is easier to use than India-ink-based markers, and it has a shelf life of two years.



Packing 5ml syringe, box of 12



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