

TS-905 **Blue Eye**TM Submucosal Injection Agent



- Blue EyeTM is a medical device that is an injectable liquid composition intended for use in gastrointestinal endoscopic procedures for submucosal lift of polyps, adenomas, early stage cancers or other gastrointestinal mucosal lesions, prior to removal with a snare or endoscopic device.
- It facilitates endoscopic resection procedures during endoscopic examinations in the upper and lower gastrointestinal tract, such as the esophagus, the stomach.

1. Blue EyeTM is easy to use.

Unlike conventional ampoule products, Blue EyeTM is easy to use because it can be connected directly with the injection needle.

2. Blue EyeTM is safe from contamination.

Blue EyeTM is packaged in a ready-to-use syringe with steam-sterilized solution that connects directly to the injection needle with a Luer-lock to eliminate the risk of cross-contamination by preventing air exposure.

3. Blue EyeTM is effective.

Blue EyeTM has twice longer-lasting mucosal elevation than normal saline, which reduces entire procedure time and side effects such as perforation, which increases the success rate of the endoscopic procedure.

4. Blue EyeTM is biocompatible.

Blue EyeTM is biocompatible; it contains hyaluronic acid, a biopolymer naturally present in the human dermis.

TS-905 **Blue Eye™**

ready-to-use Submucosal Injection Agent with methylene blue



Blue Eye



Submucosal Injection Agent Comparison

Model Name	Blue Eye™	Predicate	Normal Saline
Cushioning agent	0.4% Sodium Hyaluronate	Poloxamer 188	None
Color	Blue	Blue	Transparent
Image			
Type	Syringe	Ampoule	Vinyl Pack
Direct Connection with endoscopic injection needle	O	X	X
Cross-contamination	X	O	O

Important Safety Information

▶ WARNINGS AND PRECAUTIONS

- The safety of Blue Eye™ has not been established in pregnant or lactating women, or in children under 18 years of age.
- The endoscopist injecting Blue Eye™ must be experienced in the administration technique.

▶ ADVERSE REACTIONS

- Rarely, local bleeding and/or inflammatory reaction could occur which may or may not be associated with Blue Eye™.

▶ CONTRADICTIONS

- Patients with known sensitivity to any of the components contained in Blue Eye™. Please see Instructions for Use for complete Important Safety Information.



THE STANDARD CO., LTD.

#120, Gunpocheomdansaneop 2-ro, Gunpo-si, Gyeonggi-do, 15880, Korea

Tel : 82-2-838-5533 Fax : 82-2-838-5523 E-mail : kn.kim@thetstd.co.kr www.thestandard.co.kr

LT0910(Rev. 1) 2019.04.19