



Blue EyeTM

Submucosal Injection Agent



Blue EyeTM is

Easy to use

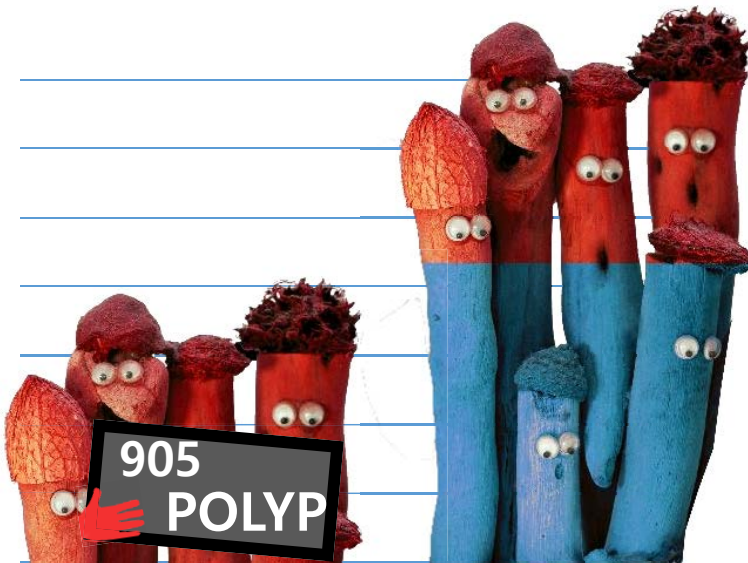
Safe from contamination

Effective

Biocompatible



- 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.



“Ease to use”

Unlike conventional ampule products, Blue Eye™ comes prefilled in a syringe.



“safe from contamination”






Blue Eye™ 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.

“ Effective ”

Mucosal elevations has been shown to last two times longer with Blue Eye than normal saline. This may reduce the procedure time and side effects such as perforation. The success rate of the endoscopic procedure is potentially greatly increased.



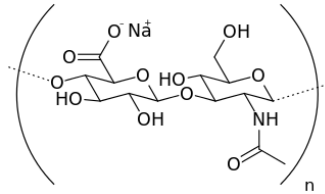
Elevation Test

	Normal Saline	Predicate	Blue Eye
Injection			
30 minutes Later			

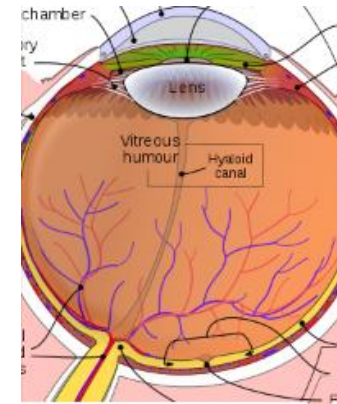
“ Biocompatible ”

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

Sodium Hyaluronate



Sodium hyaluronate is the sodium salt of hyaluronic acid, a glycosaminoglycan found in various connective tissue of humans





Biocompatibility Test



- Cytotoxicity
- Intracutaneous Test
- Sensitization
- Systemic toxicity
- Genotoxicity
- Implantation
- Subchronic toxicity
- Pyrogen





Bubbles Test

Many bubbles associated with predicate device.



Vortex mixer 3,000 r.p.m. 5 sec.



Too much bubble on predicate!!!

Blue Eye™

Submucosal **Injection** Agent





**THE
STANDARD**

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