

ORISE™ Gel

Submucosal Lifting Agent

**Boston
Scientific**

Advancing science for life™

PERFORMANCE.
EFFICIENCY.
CONVENIENCE.



ORISE Gel is designed to be used for submucosal lift of polyps, adenomas, early-stage cancers or other gastrointestinal mucosal lesions prior to excision with a snare or other endoscopic device.



PERFORMANCE. EFFICIENCY. CONVENIENCE.

- 1 READY TO USE**
Pre-filled, pre-dyed 10ml syringe kitted with delivery system 23ga Interject™ Injection Therapy Needle Catheter
- 2 VISCOUS SOLUTION**
Designed to provide a submucosal fluid cushion
- 3 DESIGNED TO HELP REDUCE PROCEDURAL RISK**
Provides clear differentiation between muscle and submucosa
- 4 INDICATED FOR ENDOSCOPIC PROCEDURES**
CE Marked, 510K K180068

PERFORMANCE

Viscous Solution in Complex Polypectomy

Results of a systematic review and meta-analysis demonstrate an **increase in en bloc resection rates** along with **low rates of residual lesions with the use of viscous solutions**, compared to normal saline as the agent for submucosal injection prior to Endoscopic Mucosal Resection (EMR)¹ Endoscopists should consider using viscous solutions for EMR.



Designed to reduce procedural risk

Contrast agent in viscous solutions serves multiple purposes:

- 1** For flat, conventional adenomas and serrated lesions, contrast provides delineation of lesion edges through resection
- 2** Contrast agent stains only the submucosa blue, and thereby facilitates identification of muscle injury²
- 3** May aid in the recognition of muscle injury (“target sign”) to avoid missed perforation diagnosis



The contrast agent chosen for ORISE Gel is a food grade blue dye

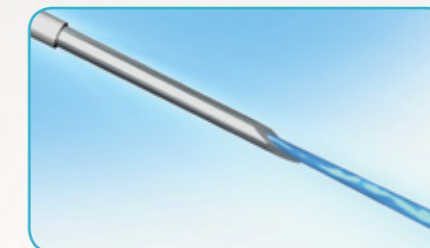
EFFICIENCY

ORISE™ Gel is a viscous solution with low injection force

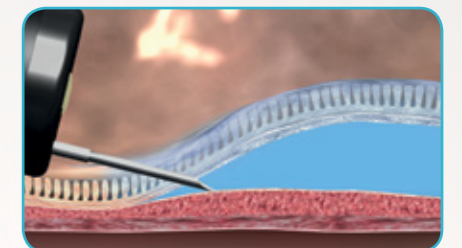
ORISE Gel is 3 times more viscous than Eleview™ Injection, but the force required to push through the syringe is similar to Eleview Injection.³



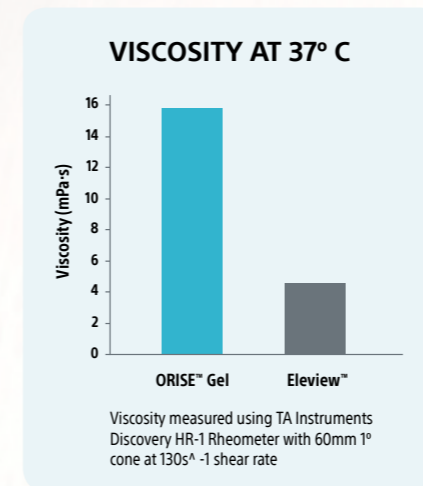
ORISE Gel viscosity, at rest in the pre-filled syringe, is significantly higher than Eleview Injection.³



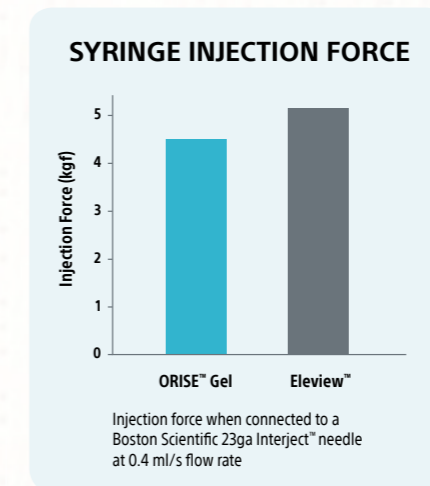
ORISE Gel has pseudo-plastic property, meaning its viscosity decreases under “shearing force” of being pushed through the syringe catheter and needle. It turns into a fluid gel.³



Back at rest within the tissue, the solution reconstitutes to a more viscous state.³



MORE VISCOUS...



LOWER FORCE NEEDED TO PUSH THROUGH SYRINGE...

30 minutes after initial injection, ORISE Gel demonstrates

32%

better height maintenance⁴ than Eleview Injection⁵

CONVENIENCE

Pre-dyed gel

Pre-filled 10ml syringe



Packaged with 23 gauge Interject™ Injection Therapy Needle Catheter



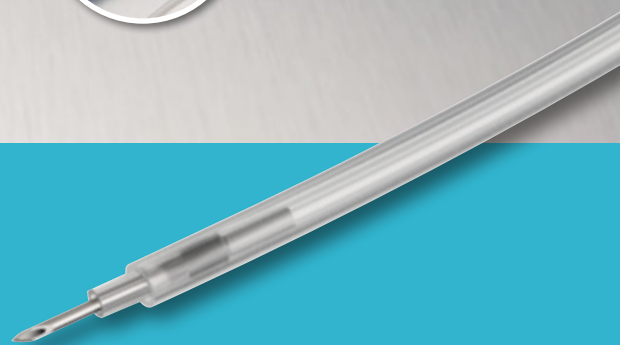
No extra set up required. Simply attach syringe to Interject needle's luer connection



INTERJECT INJECTION THERAPY NEEDLE CATHETER SPECIFICATIONS

Due to its large inner diameter catheter size, Interject Needle may be a more ideal endoscopic needle for a viscous injection solution.

Interject comes kitted with ORISE Gel for convenience.



ORDERING INFORMATION

Order Number	Description	Packaging
M00519201	ORISE Gel Syringe Twin Pack (two 10ml syringes per tray)	Box 10
M00519210	ORISE Gel Syringe Twin Pack Kit with Interject Needle 23ga Clear (two 10ml syringes per kit)	Box 1
M00519211	ORISE Gel Syringe Twin Pack Kit with Interject Needle 23ga Clear (two 10ml syringes per kit)	Box 10

1 Yandrapu et. Al., Normal Saline Versus Other Viscous Solutions for Submucosal Injection During Endoscopic Mucosal Resection (EMR) of Colorectal Polyps: a Systematic Review and Meta-Analysis. Gastrointestinal Endoscopy, Volume 81, Issue 5, Supplement, Page AB372, 2015.

2 Muscle injury is characterized by appearance of white parallel bands in the resection defect and by a circle or ring of white tissue on the cut surface of the EMR specimen Source Rex. 12 Tips for EMR in the Colon. Gastroendoneews.com 2017.

3 The testing was performed by or on behalf of BSC. Data on file. Bench Test results may not necessarily be indicative of clinical performance.

4 Height maintenance is defined as the average change in height of submucosal injections after 30 minutes in ex-vivo study. Sample sizes of ex-vivo study n=45 (15 per solution: ORISE Gel, Eleview Injection, and Saline).

5 Measurements taken by Boston Scientific. Data on file. Actual values may differ. Bench test results may not necessarily be indicative of clinical performance. The testing was performed by or on behalf of BSC.

Bench Test results may not necessarily be indicative of clinical performance and the testing was performed by or on behalf of BSC. Data on file.

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ENDO-644702-AA. Produced by Gosling.

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