ORISE Gel

- Pre-filled
- Pre-dyed
- Viscous gel
- Designed for easy injection
- Non toxic, food grade, biocompatible materials
Product Overview

**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**
510K K180068
Endoscopic Mucosal Resection (EMR)

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 EMR*

Endoscopists should consider using viscous solutions for EMR.

Dynamic Injection Using Viscous Solution
Presented by Douglas Rex, MD

- Viscous solution provides a mound that is concentrated underneath the lesion and has a dome shape
- A more viscous fluid provides longer duration of the mound


Video owned by Boston Scientific.
Endoscopic Mucosal Resection (EMR)

Designed to Reduce Procedural Risk – In EMR

**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 the submucosa blue,** and thereby facilitates identification of muscle injury.*

3. **May aid in the recognition of muscle injury** (“target sign”) to avoid missed perforation diagnosis.

*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. Gastroendonews.com 2017

The contrast agent chosen for ORISE Gel is a food grade blue dye.
En Bloc Resection / ESD

Viscous Solution in *En Bloc* Resection (EBR) / Endoscopic Submucosal Dissection (ESD)
Creating A Submucosal Fluid Cushion

**LIFTING ABILITY / VISCOUS SOLUTION**

1. *Saline dissipates quickly* when injected into the submucosal layer, resulting in rapid disappearance of the mucosal elevation.

2. *It is necessary to create a prominent and long-lasting mucosal elevation.* The duration of lesion lifting is crucial for successful results.

3. *The higher the viscosity,* the longer the submucosal fluid cushion lasts.

*Dynamic Injection Using Viscous Solution, presented by Douglas Rex, MD.*
### Benefits of a Viscous Solution

- A viscous solution may help to create a prominent, well-localized submucosal mound that does not spread laterally or dissipate
- Saline may spread beyond lesion borders and dissipate quickly

### ORISE GEL IS A VISCIOUS SOLUTION WITH LOW INJECTION FORCE

- Designed to push easily through a **23 gauge Interject™ Injection Therapy Needle Catheter** when shearing force is applied
- Additionally, the **23 gauge Interject Needle** has a larger inner catheter diameter than Carr Locke Needle*
- 30 minutes after initial injection, ORISE™ Gel demonstrates 32% better height maintenance† than Eleview™ Injection

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*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.

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

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

ORISE Gel has a 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.∗

Back at rest within the tissue, the solution recongeals to a more viscous state.∗

Viscosity & Injection Force

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*The testing was performed by or on behalf of ISC. Data on file. Bench Test results may not necessarily be indicative of clinical performance.
Benefits of a Viscous Solution

• A viscous solution may help to create a prominent, well-localized submucosal mound that does tend not to spread laterally or to dissipate.

While saline is often used for submucosal injection because of convenience, cost, and familiarity, it has a tendency to spread beyond lesion borders and dissipate quickly.

ORISE GEL IS A VISCOUS SOLUTION WITH LOW INJECTION FORCE

• Viscous solution with unique ergonomic injection force when shearing force is applied (pushed through a 23 gauge interject needle)

• Additionally, 23 gauge Interject Needle has a larger inner catheter diameter than Carr-Locke Needle

The combination of these properties allows for optimal injection force.

COMMONLY USED VISCOUS SOLUTIONS

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

While measuring the devices, the inner diameter catheter of the Interject Needle was found to be larger than the Carr-Locke 23g needle.*

Interject comes kitted with ORISE™ Gel for convenience.

Product Overview

• 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
This device is intended for use in gastrointestinal endoscopic procedures. It will be used for submucosal lift of polyps, adenomas, early-stage cancers or other gastrointestinal mucosal lesions, prior to excision with a snare or other suitable endoscopic device.
## Comparison to Eleview™ Injection

<table>
<thead>
<tr>
<th>ORISE Gel</th>
<th>Eleview*</th>
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<tbody>
<tr>
<td>Contains a food grade blue dye</td>
<td>Contains methylene blue</td>
</tr>
<tr>
<td>10 ml pre-filled syringe, no extra steps required</td>
<td>10 mL ampule, no syringe included</td>
</tr>
<tr>
<td>Packaged in a kit with an Interject™ Injection Therapy Needle Catheter</td>
<td>Requires separate needle purchase</td>
</tr>
<tr>
<td>Contains no emulsifier</td>
<td>Contains the emulsifier Polyoxyl-15-hydroxystearate. Emulsifiers may increase the lifetime of bubbles.***</td>
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</table>

*https://eleviewus.com

Endoscopic Submucosal Dissection, *in vivo* porcine. ORISE Gel and Eleview Injection were used with an Olympus Dual Knife, by the same physician on equal size resections.*
## ORISE™ Gel Ordering Information

<table>
<thead>
<tr>
<th>Order Number</th>
<th>Description</th>
<th>Packaging</th>
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<tbody>
<tr>
<td>M00519201</td>
<td>ORISE Gel Syringe Twin Pack (two 10mL Syringes per tray)</td>
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<tr>
<td>M00519210</td>
<td>ORISE Gel Syringe Twin Pack Kit with Interject Needle 23ga Clear (two 10mL Syringes per Kit)</td>
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### Other Devices for ESD Procedures

#### ORISE™ Tissue Retractor System

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<th>Reference</th>
<th>Diameter (mm)</th>
<th>Cage Length (cm)</th>
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<th># of Channels</th>
<th>Scope Compatibility (mm)</th>
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<td>8</td>
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#### ORISE Instrument Guides

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<td>Left Colon</td>
<td>OTR-90G</td>
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#### Rescue™ Retrieval Devices

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<th>Description</th>
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<th>Sheath O.D. (mm)</th>
<th>Working Length (cm)</th>
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<tbody>
<tr>
<td>DGC-383-5</td>
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### Captivator COLD Single-use Snare

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<th>Min. Working Channel (mm)</th>
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### Single-Use Snares Rotatable Snares*

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*With Star Catheter™ Technology.
### Captivator II Single-Use Snares

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### Ordering Information

#### Other Devices for EMR Procedures

<table>
<thead>
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*Product with this symbol may be used in Magnetic Resonance environment according to the conditions described in Directions for Use.
# Ordering Information

## Other Devices for EMR Procedures

<table>
<thead>
<tr>
<th>Resolution™ Clip</th>
<th>Working Length (cm)</th>
<th>Minimum Working Channel (mm)</th>
<th>Clip Opening (mm)</th>
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</table>

1Product with this symbol may be used in Magnetic Resonance environment according to the conditions described in Directions for Use.
ORISE™ Gel

Submucosal Lifting Agent

**Frequently Asked Questions:**

1. **ORISE Gel: What is it and how is it used?**
   - ORISE Gel is a submucosal lifting agent designed to be used for submucosal injection prior to endoscopic mucosal resection or endoscopic submucosal dissection to lift the target lesion.

2. **How is the amount of ORISE Gel determined?**
   - The amount to be administered is determined based on the size and type of the lesion to be removed. Inject enough ORISE Gel to achieve a defined submucosal lift. The amount of injection will vary and will be at the discretion of the physician.

3. **How long does the submucosal lift last?**
   - The duration of the lift will be dependent on patient vasculature and lesion type and will vary from patient to patient.

4. **What is its viscosity and force?**
   - ORISE Gel is a pre-filled, pre-dyed viscous gel solution made with a non-vital dye, glass beads, and food-grade materials designed for ease of pushability. It is used to create a submucosal cushion to enable safe resection or dissection.

5. **Where is it used?**
   - ORISE Gel is used to lift gastrointestinal mucosal lesions prior to excision with a snare or other endoscopic device.

6. **Is it considered a pharmaceutical?**
   - No. ORISE Gel is a medical device.

7. **Is it made with any special technology or unique ingredients?**
   - Yes. ORISE Gel is made with glass beads that are non-vital, non-inflammatory, non-immunogenic, and non-sensitizing agents. Glass beads are used to customize viscosity and provide the submucosal lift needed for a successful procedure.

**Ordering Information:**

- **Availability:** ORISE Gel is currently available for limited launch evaluation.
- **Ordering:** For more information on ordering ORISE Gel, please contact your local Boston Scientific representative.
- **Product Codes and Pricing:**
  - ORISE Gel Syringe Twin Pack (two 10mL syringes per tray)
  - ORISE Gel Syringe Twin Pack Kit with Interject Needle 23 ga Clear (two 10mL syringes per kit)

**Coding Information:**

- **Coding:** 
  - CPT Code: 45381
  - M0051920
  - M0051921
  - M00519210
  - M00519211

**Physician Preference and Limited Launch Evaluation:**

- **510(k) Number:** K180068
- **Indicated For Endoscopic Procedures:** Provides clear differentiation of the muscle layer.
- **Designed to Help Reduce Procedural Risk:** ORISE Gel is designed to be used for submucosal lift of lesions to help reduce procedural risk.
- **Ergonomic Injection Force:** ORISE Gel is designed to be used for submucosal lift of polyps, adenomas, early-stage cancers or other gastrointestinal mucosal lesions prior to resection with standard endoscopic devices.

**Physician Preference and Limited Launch Evaluation:**

- **Product Overview:**
  - Endoscopic Mucosal Resection (EMR)
  - En Bloc Resection/ESD
  - Viscosity & Injection Force
  - Convenience
  - Indications
  - Comparison to Eleview
  - Ordering Information
  - Resources

- **Endoscopic Resection/ESD**
- **Viscosity & Injection Force**
- **Convenience**
- **Indications**
- **Comparison to Eleview**
- **Ordering Information**
- **Resources**

**Resources**

- **Previously Viewed:**
  - ORISE Gel

- **Home:**
  - CLICK / TAP TO VIEW

**FAQ**

**VAT**

**Physician Preference and Limited Launch Evaluation**

- **General Information:**
  - Product: ORISE Gel Syringe Twin Pack Kit with Interject Needle 23 ga Clear (two 10mL syringes per kit)
  - Description:
    - 23 ga Interject Injection Therapy Needle Catheter:
      - Pre-filled, pre-dyed 10mL syringe kitted with delivery system (23 ga Interject Injection Therapy Needle Catheter)

- **CPT Code:**
  - M0051921
  - M00519210
  - M00519211

- **UPN Used:**
  - [ ]

- **Today's Procedure:**
  - [ ]

- **Institution:**
  - [ ]

- **Order Number:**
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- **UPN**

- **Physician Preference and Limited Launch Evaluation:**
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- **Physician Preference and Limited Launch Evaluation:**
  - [ ]

- **Demographics:**
  - [ ]

- **Other:**
  - [ ]

- **Patient Populations:**
  - [ ]

- **CPT Code Descriptions:**
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