

ORISE™ Gel Submucosal Lifting Agent

REFER TO THE DEVICE DIRECTIONS FOR USE FOR COMPLETE INSTRUCTIONS ON DEVICE USE. RX ONLY.
CAUTION: FEDERAL LAW (USA) RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

Warning

Contents supplied STERILE using a steam sterilization process. Visually inspect the package for any signs of damage. DO NOT USE if the package has any visible signs of damage. Failure to observe this warning may result in patient injury.

If damage is found, call your Boston Scientific representative. For single use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

Compatibility

Compatible with the 23ga Interject Injection Therapy Needle Catheter.

User Information

In a porcine study, ORISE Gel has not been shown to provide any additional benefit as compared to the use of saline prior to EMR and ESD procedures.

Intended Use/Indications for Use

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, and will be excised prior to excision with a snare or other suitable endoscopic device.

Contraindications

ORISE Gel - Those patients for whom endoscopic techniques are contraindicated.

Warnings

- The endoscopist using ORISE Gel must be experienced in the administration of submucosal injection fluid.
- No more than 10 syringes should be administered in a single procedure.

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Precautions

- ORISE Gel is a single use device provided in a glass syringe.
- ORISE Gel should not be reused after the packaging has been opened.
- ORISE Gel syringe contents not injected during the procedure should not be reused in another procedure.
- Do not use if the syringe tray is damaged before opening.
- Do not use if luer lock on syringe has been damaged.

Adverse Events

Rare, localized bleeding, perforation and/or an inflammatory reaction of the gastrointestinal lumen could occur which may or may not be associated with ORISE Gel.

Handling and Storage

Store in a cool, dry, dark place. Do not store below 4 °C.