

# ORISE™ Tissue Retractor System

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 NON-STERILE. Do not use if damaged. If damage is found, call your Boston Scientific representative. For single use only. Do not reuse, reprocess or sterilize. Reuse, reprocessing or sterilization 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 or reprocessing 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.

## Intended Use/Indications for Use

The ORISE Tissue Retractor System is indicated for use in conjunction with an endoscope in the gastrointestinal tract for tissue or foreign body manipulation and/or where multiple removal and reinsertions of the endoscope are required.

## Contraindications

- Contraindications include but are not limited to:
- Active bleeding from any source
- HIV-positive or immunocompromised patient
- Pregnancy
- Liver cirrhosis
- End stage renal disease
- Receiving chemotherapy
- Advanced malignancy
- Coagulopathy
- Treatment with an investigational drug or medical device in the past 30 days
- Recent stroke
- Not well-compensated systemic disorder

## Warnings

- This product should only be used by physicians adequately trained in therapeutic interventions.
- Interventional procedures have been associated with perforation and bleeding. Such complications should be monitored for during and after the procedure and treated appropriately if detected.
- Do not use any equipment that is observed to be damaged or excessively worn. Doing so could lead to patient injury and/or further damage to the equipment.
- Never insert/withdraw, advance and maneuver the ORISE™ Tissue Retractor assembly, or perform dissection without direct visualization. Patient injury may occur.

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## Caution

- Never drop or subject the equipment to severe impact as this can compromise the functionality or safety of the equipment.
- ORISE Tissue Retractor System is provided non-sterile. Use care in handling the device once the device is removed from packaging in order to prevent any inadvertent contamination.

## Adverse Events

Possible adverse events include, but are not limited to:

- Tissue Damage
- Perforation
- Bleeding
- Infection
- Pain