

Refer to the device directions for use for complete instructions on device use.

Intended Use/Indications for Use

The Resolution™ Clip is used for endoscopic clip placement within the Gastrointestinal (GI) tract for the purpose of: Endoscopic Marking; Hemostasis for: Mucosal/sub-mucosal defects < 3 cm, Bleeding ulcers, Arteries < 2 mm, Polyps < 1.5 cm in diameter, Diverticula in the colon, Anchoring to affix jejunal tubes to the wall of the small bowel; and as a supplemental closure method of GI tract of luminal perforations <20mm that can be treated conservatively.

Contraindications

Do not use this device when hemostasis cannot be verified visually with an endoscopic field of view; Arteries greater than 2 mm; Polyps greater than 1.5 cm in diameter; and Mucosal/submucosal defects greater than 3 cm.

Warnings

Operation of this instrument is based on the assumption that open surgery is possible as an emergency measure if the clip cannot be detached from the instrument or in any other unexpected circumstances takes place; and always have pliers and/or wire cutters ready to cut the delivery system at the handle if the clip cannot be detached.

Contents supplied STERILE using an ethylene oxide (EO) process. Do not use if sterile barrier is damaged. 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.

Cautions can be found in the product labeling supplied with each device. CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

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Potential Adverse Events

Limited studies indicate that the use of clips in the presence of bacterial contamination may increase or prolong infection; Re-bleeding may occur if the clips detach within 24 hours; and although rates of occurrence are low, recurrent bleeding, ineffective clipping or endoscopic complications could result in the need for surgery.