

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

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

Cautions can be found in the product labeling supplied with each device.

Warning

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 packaging in accordance with hospital, administrative and/or local government policy.

Indications For Use/Intended Use

The Resolution 360 Clip is indicated for clip placement within the Gastro-intestinal (GI) tract for the purpose of:

1. Endoscopic marking,
2. Hemostasis for: Mucosal/sub-mucosal defects <3 cm, Bleeding ulcers, Arteries <2 mm, Polyps <1.5 cm in diameter, Diverticula in the colon, Prophylactic clipping to reduce the risk of delayed bleeding post lesion resection,
3. Anchoring to affix jejunal feeding tubes to the wall of the small bowel,
4. As a supplementary method, closure of GI tract luminal perforations <20 mm 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
- Mucosal/Submucosal defects greater than 3 cm

Warnings

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

Possible Complications

- 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.
- Although rates of occurrence are low, recurrent bleeding, ineffective clipping or endoscopic complications could result in the need for surgery.

Precaution(s) - Prior to Use

- Passage of the Resolution 360™ Clip through a retroflexed or tortuous path, may result in the clip separating from the catheter and potentially kinking or damaging the device.
- Applying tangential pressure to an opened or closed clip may result in the clip separating from the catheter and potentially kinking or damaging the device.
- In a difficult scope position, it may be necessary to straighten the endoscope to facilitate the device passage, then reposition scope for treatment.
- If the device kinks or becomes damaged during insertion or passage, do not use it. Call Boston Scientific Customer Service and return the product.

How Supplied

The Resolution 360 Clip is supplied sterile. Carefully examine the unit to verify that neither the contents nor the sterile package has been damaged in shipment. DO NOT USE if damaged. Immediately return damaged product to Boston Scientific Corporation.