



Resolution™ 360 ULTRA Clip

Prescriptive Information

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.

Warning

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.

Intended Use/Indications for Use

The Resolution 360 ULTRA 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

- DO NOT FORCIBLY PULL BACK ON A CLIP THAT IS DEPLOYED AND HAS NOT DETACHED FROM THE COIL. THIS WILL TEAR THE TISSUE AND LIKELY RESULT IN SEVERE BLEEDING OR PERFORATION.
A wire-cutter should be available on the endoscopy cart and used to cut the coil near the device handle if needed. The endoscope can then be removed leaving the clip and coil intact. The patient may require URGENT SURGERY to separate the clip from the coil without tearing tissue or to manage bleeding resulting from manipulating the imbedded clip.
- If the clip detaches prematurely, there is a risk of re-bleeding, unsuccessful anchoring to affix jejunal feeding tubes, unsuccessful marking, or insufficient perforation closure.
- Although rates of occurrence are low, recurrent bleeding, ineffective clipping or endoscopic complications could result in the need for surgery.
- The use of clips in the presence of bacterial contamination may potentiate or prolong infection.
- Clipping hard or severely fibrotic lesions may result in ineffective hemostasis, unsuccessful anchoring to affix jejunal feeding tubes, unsuccessful marking, or insufficient perforation closure. Additional interventions may be required to control bleeding, successfully anchor to affix jejunal feeding tube, successfully mark, or sufficiently close the perforation.
- Contains nickel which may cause an allergic reaction in individuals with nickel sensitivity.
- The Resolution 360 ULTRA Clip is designed to be compatible with forward viewing endoscopes with working channels equal to or greater than 2.8 mm. Use with a side viewing scope may result in difficulty or inability to deploy, leading to patient injury.
- Failure to release the slider after separation could result in patient injury.
- Failure to follow the recommended MR Conditional labeling may result in a deployed GI hemoclip dislodging from tissue or heating of tissue at the GI hemoclip location. A GI hemoclip dislodgement may result in rebleeding requiring additional intervention or surgery, serious injury, or death.
- This clip contains ferromagnetic material. Follow your institutional protocols to determine whether or not an x-ray should be performed prior to an MRI exam. There may be a small potential risk of clip dislodgement and rebleeding if the clip is used in friable or healing tissues due to magnetic forces acting on the clip when in or near an MRI scanner.

Precautions

- It is recommended that healthcare providers distribute patient implant cards with the name of the clip and date it was placed.
- Passage of the Resolution 360 ULTRA 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.
- Do not advance an open clip through the endoscope working channel, otherwise endoscope working channel damage may result.
- Do not continue moving the slider proximally beyond the tactile resistance until you are ready to deploy the clip, otherwise you may not be able to re-open the clip. If you hear or feel a click, the clip cannot be re-opened, go to step 4 Option 2 to complete clip deployment.

Adverse Events

- Allergic reaction
- Burn
- Hemorrhage
- Infection
- Inflammation
- Pain
- Perforation
- Surgery
- Tissue Damage

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