PRESCRIPTIVE INFORMATION

Resolution™ Clip Device

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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 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 infections 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.

Indications for Use

The Resolution 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,
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 open 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.

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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.

MRI Safety and Compatibility Information

MR conditional:
Non-clinical testing has demonstrated the Resolution™ Clip is MR Conditional according to ASTM F2503.

A patient with this clip(s) can be safely scanned under the following conditions:

Static magnetic field of 1.5 and 3 Tesla with:

- Spatial gradient field of 2500 Gauss/cm (value extrapolated) and less
- Maximum whole body averaged specific absorption rate (SAR) of 2 W/kg in Normal Operating Mode for a maximum scan time 15 minutes of continuous scanning at 1.5T and at 3T.

In non-clinical testing, the "Resolution Clips" produced a temperature rise of less than 1.4 °C at a maximum extrapolated WBA SAR of 2.0 W/kg for 15 min. of continuous MR scanning with body coil in a 1.5 Tesla Intera™, Philips Medical Systems (software: release 12.6.1.3, 2010-12-02) MR Scanner.

In non-clinical testing, the "Resolution Clips" produced a temperature rise of less than 4.0 °C at a maximum extrapolated WBA SAR of 2.0 W/kg for 15 min. of continuous MR scanning with body coil in a 3 Tesla Magnetom Trio™, Siemens Medical Systems (software: Numaris/4, syngo MRA30) MR Scanner.

MR image quality may be compromised if the area of interest is within approximately 80 mm of the clip(s) as found in non-clinical testing using a spin echo and gradient echo pulse sequence in a 3T MR system (Philips Medical Systems, Best, The Netherlands, Achieva, software 2.6.3.7 2010-11-24). Therefore, it may be necessary to optimize MR Imaging parameters in the presence of this implant.

Boston Scientific recommends that the patient register the MR conditions disclosed in this DFU with the MedicAlert Foundation (www.medicalert.org) or equivalent organization.

Precaution(s)—Prior to Use

Passage of the ResolutionTM Clip through a retroflexed or tortuous path, may result in the clip separating from the catheter and potentially kinking or damaging the device. If the catheter or over-sheath kinks or becomes damaged during device insertion or passage, do not use it. Call Boston Scientific Customer Service and return the product.

- 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. If the catheter or over-sheath kinks or becomes damaged during device insertion or passage, do not use it. Call Boston Scientific Customer Service and return the product.

- 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 catheter or over-sheath kinks or becomes damaged during device insertion or passage, do not use it. Call Boston Scientific Customer Service and return the product.
- In a difficult scope position, it may be necessary to straighten the endoscope to expose the clip from the over-sheath, then reposition scope for treatment. If the catheter or over-sheath kinks or becomes damaged during device insertion or passage, do not use it. Call Boston Scientific Customer Service and return the product.

The Resolution 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.

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