Boston Scientific

Resolution 360™ Clip

Clip

Tổng giám đốc

CÔNG TY TNHH BOSTON SCIENTIFIC VIỆT NAM

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Boston Scientific (Master Brand DFUTemplate 3in x 9in Global, 90106040AS), DFU, MB, Resolution 360 Clip, Global, 51065688-01A

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℞ 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 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.

HOW SUPPLIED

The device is supplied sterile by ethylene oxide gas and is intended for single use only. Do not use if package is opened or damaged. Do not use if labeling is incomplete or illegible.

PRODUCT DESCRIPTION

The Resolution 360 Clip consists of a radiopaque, single-use clip with an 11mm clip opening , pre-loaded on a flexible, rotatable delivery system.

The Resolution 360 Clip is designed to be compatible with forward viewing endoscopes with working channels equal to or greater than 2.8 mm.

The radiopaque Resolution 360 Clip is engineered to enable opening and closing no more than five times prior to deployment, aiding in repositioning of the clip at the lesion site. Re-opening, closing and rotation capability may be limited by clinical circumstances and patient anatomy, among other factors.

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

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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.
  A wire-cutter should be available on the endoscopy cart and be used to cut the coil where it exits the endoscope. The endoscope can then be removed leaving the clip and coil intact. The patient will require URGENT SURGERY to remove the imbedded clip from the tissue.
- Contains nickel, which may cause an allergic reaction in individuals with nickel sensitivity.

NOTES

Limited studies indicate that:

- Lesions located in the esophagus and the lesser curvature of the stomach may be difficult to treat with a forward viewing endoscope.
- Treatment of esophageal varices may require clipping in combination with a sclerosing agent.
- Clipping hard or severely fibrotic lesions to achieve hemostasis may be more difficult.
- The number of clips required for hemostasis may vary depending upon the anatomical site, histology, lesion type, and patient condition and history.
- Re-bleeding may occur if clips detach within 24 hours.
- The use of clips in the presence of bacterial contamination may potentiate or prolong infection.
- Limited studies indicate that the clips used to anchor feeding tubes remain in place for a mean of 18 days.

Note: There is no clinical evidence to support the use of this device for clipping the neck of the diverticulum to treat bleeds.

There is no clinical evidence to support the use of this device for clipping GI tract luminal perforations >20mm.

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 INFORMATION

MR CONDITIONAL

Non-clinical testing has demonstrated the Resolution 360™ 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 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.

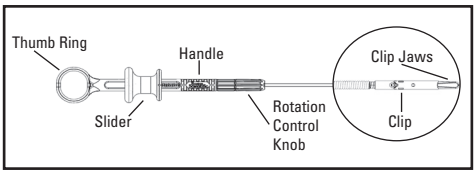

Figure 1. Resolution 360 Clip

PREPARATION

1. Open the pouch and remove the device.
2. Inspect the device for kink or damage.

Note: If the device shows any sign of damage, do not use it, call Boston Scientific Customer Service and return the product. Do not attempt to repair nonfunctional or damaged devices.

DIRECTION FOR USE

Device Insertion

1. Carefully insert the Resolution 360 Clip Device through the biopsy channel of the endoscope with short, deliberate 2 to 3 centimeter strokes.

Caution: Do not advance an open clip through the endoscope working channel, otherwise endoscope working channel damage may result.

Note: The Resolution 360 Clip and this Directions For Use are intended for use by physicians with adequate experience with endoscopic procedures.

Note: 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. 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 attempt to repair nonfunctional or damaged devices.

PROCEDURE

Note: 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. Prior to permanently deploying the Resolution 360 Clip , visually confirm that the device has not kinked, separated from the catheter, or become damaged in any way. If the device shows any sign of damage, DO NOT USE IT. Call Boston Scientific Customer Service and return the product.

1. When the Resolution 360 Clip is at the desired location, gently move the slider distally (away from the thumb ring) to open the Resolution 360 Clip jaws, as shown in Figure 2.

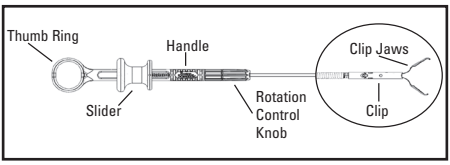

Figure 2. Open the Resolution 360 Clip Jaws

2. If additional positioning is desired, the clip may be rotated in either of the following two methods (see Figure 3):
   a. The clip can be rotated by turning the rotation control knob in either direction. Typically, this is done by the nurse, technician, or assistant. Because the rotation control knob is separate from the handle, the user can keep his/her hand on the handle while rotating the knob with the other hand.
   b. The clip can be rotated by spinning the catheter between your fingers in either direction where it enters the scope channel. Typically, this would be done by the physician.

Note: It is not recommended to utilize both rotation methods at the same time, as the rotation performance may be compromised.

Note: If there is no rotation response, do not continue to rotate the device more than three full rotations. Failure to do so may result in difficulty removing and/or scope damage.

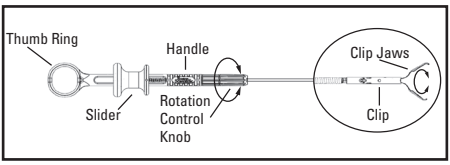

Figure 3. Rotating the Handle

3. To close the Resolution 360™ Clip on the desired location, move the slider proximally until tactile resistance is felt in the handle, as shown in Figure 4. Clip position may now be assessed prior to deployment.

Caution: 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.

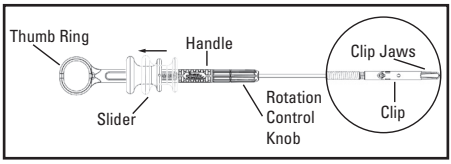

Figure 4. Resolution 360 Clip Closed

4. At this point, there are 2 options:
   - Option 1: The Resolution 360 Clip can be re-opened, rotated, and repositioned to the desired location. (See steps 1-3).

     Note: The Resolution 360 Clip is engineered to enable opening and closing up to five times prior to deployment, aiding in repositioning of the clip at the lesion site. Re-opening, closing, and rotation capability may be limited by clinical circumstances and patient anatomy, among other factors.

   - Option 2: The Resolution 360 Clip can be permanently deployed. To permanently deploy the Resolution 360 Clip, continue moving the slider proximally beyond the tactile resistance point, at which point a first click may be heard or felt. Continue moving the slider proximally until a second tactile resistance point and/or click is heard or felt. Continue moving the slider proximally until it reaches the thumb ring, as shown in Figure 5.

     Note: Do not attempt to reopen the clip once the initial tactile resistance point has been passed and/or the first click has been heard or felt. Reopening the clip may result in the clip separating from the catheter and potentially kinking or damaging the device. After the first tactile resistance point is passed and/or click is observed, do not attempt to move the slider distally until both clicks are observed and/or the slider has been pulled against the thumb ring.

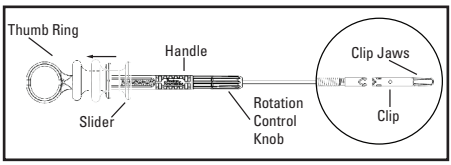

Figure 5. Resolution 360 Clip Permanently Deployed

5. Once the Resolution 360 Clip has been deployed, gently move the slider distally to separate the clip from the delivery device. Once the clip separates from the delivery device, release the slider.

Warning: Failure to release the slider after separation could result in patient injury.

If the Resolution 360 Clip has not been deployed, close the jaws, and withdraw the device slowly through the endoscope.

DEVICE REMOVAL

Withdraw the device slowly through the endoscope.

For partially deployed clip, attempt to fully deploy the clip. If unable to deploy clip, withdraw the scope and clip together.

STORAGE

Store in a cool, dry, dark place. Do not expose to organic solvents, ionizing radiation or ultraviolet light. Rotate inventory so that products are used prior to the expiration date on package label.

CAUTION: Do not crush device or store devices on sharp objects. Failure to comply may cause device damage or user injury.

WARRANTY

Boston Scientific Corporation (BSC) warrants that reasonable care has been used in the design and manufacture of this instrument. **This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether express or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness for a particular purpose.** Handling, storage, cleaning and sterilization of this instrument as well as other factors relating to the patient, diagnosis, treatment, surgical procedures and other matters beyond BSC's control directly affect the instrument and the results obtained from its use. BSC's obligation under this warranty is limited to the repair or replacement of this instrument and BSC shall not be liable for any incidental or consequential loss, damage or expense directly or indirectly arising from the use of this instrument. BSC neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this instrument. **BSC assumes no liability with respect to instruments reused, reprocessed or resterilized and makes no warranties, express or implied, including but not limited to merchantability or fitness for a particular purpose, with respect to such instruments.**