



RePlay™

Hemostasis Clip

*Instructions for use.
Read carefully prior to use.*

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

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Diversatek Healthcare RePlay™ Hemostasis Clip
Instructions for Use.
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INTENDED USE

The clip is compatible with an endoscope, which is indicated for clip placement within the digestive tract for purposes of mechanical pressure treatment of bleeding of small arteries and pulsation. The device is intended for single use.

INDICATIONS FOR USE

The Hemostasis Clip is used for endoscopic clip placement within the gastrointestinal (GI) tract for the purpose of:

1. Endoscopic marking
2. Hemostasis for:
 - a. Mucosal/sub-mucosal defects < 3cm
 - b. Bleeding ulcers
 - c. Arteries < 2 mm
 - d. Polyps < 1.5 cm in diameter
 - e. Diverticula in the colon
 - f. 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 for GI tract luminal perforation < 20 mm that can be treated conservatively

<u>Part Number</u>	<u>Description</u>
1170-01	11 mm wide, 230 cm
1170-02	16 mm wide, 230 cm

CONTRAINDICATIONS

1. Do not use this device when hemostasis cannot be verified visually within the endoscopic field of view.
2. Arteries greater than 2 mm.
3. Polyps greater than 1.5 cm in diameter.
4. Mucosal/submucosal defects greater than 3 cm.
5. Patients with a narrow upper digestive tract where endoscope cannot pass through.
6. Patients with serious coagulation disorders and hemorrhagic diseases.

WARNINGS AND PRECAUTIONS

1. Passage of clip through a retroflexed or tortuous path may result in clip separation from the catheter and potentially kinking or damaging the device. If the catheter or over-sheath becomes damaged during device insertion or passage, do not use.
2. Applying tangential pressure to an opened or closed clip may result in 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.
3. In a difficult endoscope position, it may be necessary to straighten the endoscope to facilitate the device passage and to reposition the endoscope for treatment. If the catheter or over-sheath kinks or becomes damaged during device insertion or passage, do not use.
4. The clip is intended for single use and supplied sterile. Carefully examine the unit prior to use to verify that neither the contents nor the sterile package has been damaged in shipment. Do not use if damaged.
5. Operation of this device is based on the assumption that open surgery is possible as an emergency measure if the clip cannot be detached from the device, or any other unexpected circumstances takes place.
6. Always have pliers and/or wire cutters ready to cut the delivery system at the handle if the clip cannot be detached.
7. The deployed hemostasis clip will be retained in vivo and will detach on its own with the excretion of waste. An x-ray or endoscopic inspection is recommended 2-4 weeks after the procedure. If devices are still found to be attached, remove them to prevent the occurrence of symptoms.
8. This product is only intended for adult populations.
9. This device must be used according to the IFU. If this device is not used in compliance with the IFU, infection control risk, perforation, or mucosal damage may occur which may harm or injure patients and users.

10. Do not use if the package is damaged.
11. Do not use if the device is expired.
12. This device is sterile and for single use only, and must be disposed of after use. Reuse is prohibited.
13. This device should only be used by a trained clinician.
14. Required operating environment: 10-40°C, relative humidity 30-80%.
15. Lesions located in the esophagus and the lesser curvature of the stomach may be difficult to treat with a forward viewing endoscope.
16. Treatment of esophageal varices may require clipping in combination with sclerosing agent.
17. Clipping hard or severely fibrotic lesions to achieve hemostasis may be more difficult.
18. The number of clips required for hemostasis may vary depending upon the anatomical site, histology, lesion type, and patient condition and history.
19. Re-bleeding may occur if clips detach within 24 hours.
20. The use of clips in the presence of bacterial contamination may potentiate or prolong infection.
21. The device is suitable for a minimum endoscope channel diameter of 2.8 mm.

INSTRUCTIONS FOR USE

1. Open the pouch and remove the device.
2. Inspect the device for kinks or damage. Do not attempt to repair nonfunctional or damaged devices.
3. Remove the device from the protective tube while slightly moving the slider to close the clip as shown in **figure 1**. Carefully insert the clip through the biopsy channel of the endoscope with short, deliberate 2-3 cm strokes as to avoid any breaking or damage if resistance is felt.

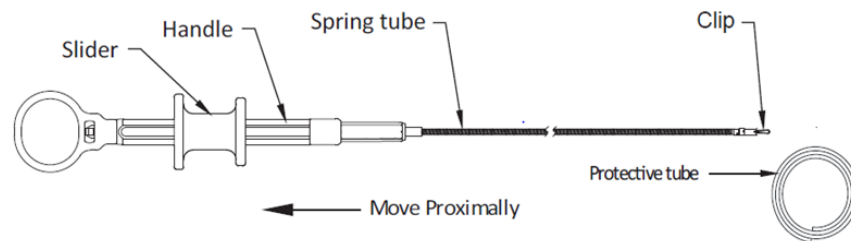


Figure 1

Note: When introducing the device through an endoscope in a tortuous position, straightening the endoscope may improve passage and exposure of the clip. With the clip in place, carefully reposition the endoscope for treatment.

4. When the clip is at the desired location, gently move the slider distally to open the clip jaws as shown in **figure 2**. The clip may be rotated clockwise or counterclockwise by turning the handle until correct position is achieved.

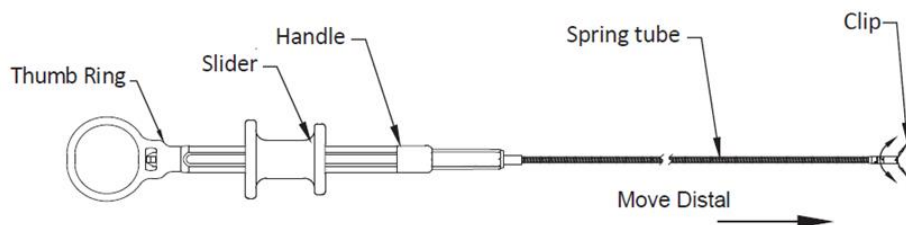


Figure 2

5. With clip in desired location, pull back on the slider until tactile resistance is felt in the handle as shown in **figure 3**. Clip position can be assessed prior to deployment. **Caution:** Do not continue to pull back on the slider further beyond

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.

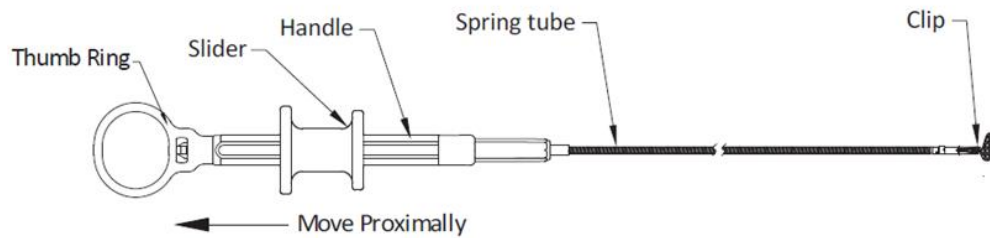


Figure 3

6. If necessary, re-open and reposition the clip as shown in **figure 2**. **Note:** The clip is engineered to enable opening and closing an unlimited amount of times prior to deployment, aiding in repositioning of the clip at the lesion site. Reopening and closing capability may be limited by clinical circumstances and patient anatomy, among other factors.
7. Permanently deploy the clip by continuing to pull back on the slider beyond the tactile resistance point as shown in **figure 3**. **Note:** Sudden loss of resistance followed by an audible click while moving the slider indicates that the clip is fully deployed from the delivery system.
8. Once the clip separates from the delivery device, release the slider and withdraw the delivery system from biopsy channel of the endoscope.
9. If the clip has not been deployed, move slider proximally to close the jaw as shown in **figure 3**, and observe through the endoscope confirming that the clip is closed. Withdraw the device slowly through the endoscope while keeping slight force on the slider.

Note: Endoscope must remain as straight as possible while withdrawing the device. If the clip did not immediately detach from the catheter, apply gentle movement of the catheter or endoscope to unseat the clip.

Caution: Do not remove an unsheathed open clip through the endoscope working channel as it will result in damage to the endoscope.

POTENTIAL COMPLICATIONS

1. The use of clips in the presence of bacterial contamination may increase or prolong infection.
2. Re-bleeding may occur if the clips detach within 24 hours.
3. 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 demonstrated that the hemostasis clip is MR conditional. A patient with this device can be scanned safely in an MR system under the following conditions:

1. Static magnetic field of 1.5 T or 3.0 T
2. Maximum special field gradient of 2,000 gauss/cm (20 T/m)
3. Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2 W/kg (normal operating mode).
















Under the scan conditions defined, the hemostasis clip is expected to produce a maximum temperature rise of 2°C after 15 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by the hemostasis clip extends approximately 30 mm from the hemostasis clip when imaged using a gradient echo pulse sequence and a 3.0 T MRI system.

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DESCRIPTION OF SYMBOLS USED ON LABELS

	Manufactured for
	Use-by date (YYYY-MM-DD)
	Lot Number
	Part number
	Sterilized using ethylene oxide
	Temperature limit
	Humidity limitation
	Atmospheric pressure limitation
	Do not use if package is damaged
	Keep dry
	Keep away from sunlight
	Do not re-use
	MR conditional
	Consult instructions for use
	Not made with natural rubber latex