Assurance® Clip	**Reorder No. 00711881**
	Reorder No. 00711882
	Reorder No. 00711883
	Reorder No. 00711884
	Reorder No. 00711885
Assurance® Control Clip	**Reorder No. 00711887**
	Reorder No. 00711888

INSTRUCTIONS FOR USE

Manufactured for US Endoscopy
5976 Heisley Road
Mentor, OH 44060
1(800)/ 548-4873
www.steris.com
A subsidiary of STERIS Corporation

Assurance® Clip

Scan to watch the device set-up video or visit https://delivr.com/2bxpx_em

Assurance® Control Clip

Scan to watch the device set-up video or visit https://delivr.com/2abqt

This product is not made with natural rubber latex.

Intended Use:

The clip is compatible with endoscopes and is indicated for clip placement within digestive tract for the purpose of mechanical pressure treatment of bleeding of small arteries and pulsation. The device is intended for single use.

Indications for Use:

The Assurance® Clip and Assurance® Control Clip is indicated for endoscopic clip placement within the gastrointestinal tract for the purpose of:

1. Endoscopic marking,
2. Hemostasis for:
   - Mucosal/sub-mucosal defects <3cm
   - Bleeding ulcers
   - Arteries<2mm
   - Polyps<1.5cm 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<20mm that can be treated conservatively.

Device Description:

Product Name	Product Number	Outer Diameter (mm)	Opening Width (mm)	Working Length (cm)	Repositionable	Rotatable
Assurance® Clip	00711881	2.6	9	230	Yes	Yes
Assurance® Clip	00711882	2.6	11	230	Yes	Yes
Assurance® Clip	00711883	2.6	13	230	Yes	Yes
Assurance® Clip	00711884	2.6	16	230	Yes	Yes
Assurance® Clip	00711885	2.6	18	230	Yes	Yes

Product Name	Product Number	Outer Diameter (mm)	Opening Width (mm)	Working Length (cm)	Repositionable	Adjusted at Handle and Catheter
Assurance® Control Clip	00711887	2.6	11	230	Yes	Yes
Assurance® Control Clip	00711888	2.6	16	230	Yes	Yes

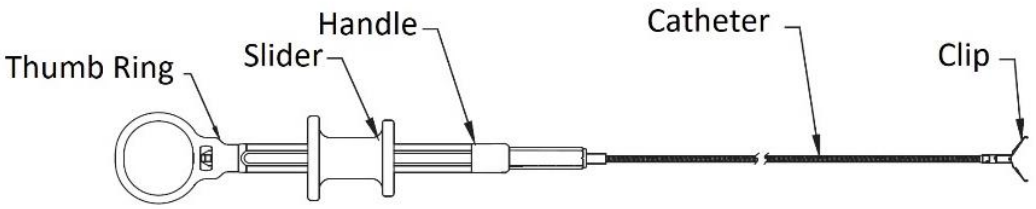

Figure 1

⚠ General Warning and Precautions

1. Follow universal precautions, use appropriate infection control principles, and wear appropriate PPE.
2. Consult the medical literature relative to techniques, technical principles, clinical applications, complications, risks, and hazards prior to the performance of any endoscopic procedure.
3. Endoscopic procedures should only be performed by persons having adequate training and familiarity with endoscopic techniques including those specific to endoscopic clips.
4. Lesions located in the esophagus and the lesser curvature of the stomach may be difficult to treat with a forward viewing endoscope.
5. Treatment of esophageal varices may require clipping in combination with a sclerosing agent, or other therapies.
6. Clipping hard or severely fibrotic lesions to achieve hemostasis may be more difficult.
7. The number of clips required for hemostasis may vary depending upon the anatomical site, histology, lesion type, and patient condition and history.
8. Re-bleeding may occur if clips detach within 24 hours.
9. In some cases, clips may have a relatively long retention time in vivo.
10. After 2 to 4 weeks the need for endoscopy or X-ray inspection may be warranted.
11. If the clip portion still has not fallen/sloughed off on its own, the need to remove the stranded clip portion to prevent the occurrence of symptoms may be warranted as well.
12. The use of clips in the presence of bacterial contamination may potentiate or prolong infection.
13. When the clip enters the working channel of endoscope, a doctor or nurse is required to pull the handle back a bit until the clip appears in the endoscopic view.
14. Although rates of occurrence are low, recurrent bleeding, ineffective clipping or endoscopic complications could result in the need for surgery.
15. When using clips, open surgery is possible as an emergency measure if the clip cannot be detached from the instrument or if any other unexpected circumstance take place.

⚠ Hemoclip Warning and Precautions

1. The device is suitable for endoscopes with a minimum channel diameter of 2.8mm.
2. If the device is used in a non-forward viewing endoscope, the device may malfunction, or it may not be possible to detach the clip from the catheter.

3. The passage of the clip through a retroflexed or tortuous path, may result in the clip separating from the delivery system and potentially kinking or damaging the device. If the delivery system or clip part kinks or becomes damaged during device insertion or passage, do not use it.
4. Applying tangential pressure to an opened or closed clip may result in the clip separating from the delivery system and potentially kinking or damaging the device. If the delivery system or clip part kinks or becomes damaged during device insertion or passage, do not use the device.
5. When introducing the device in an endoscope in a tortuous position, straightening the distal tip of the endoscope may improve passage and exposure of the clip. After the clip exits the instrument channel, carefully reposition the endoscope for treatment. If the catheter kinks or becomes damaged during device insertion or passage, remove device from endoscope and do not use the device.
6. If the clip has not been deployed, move the slider proximally to close the jaws, as shown in Figure 4, and endoscopically observe that the clip is closed. Then, withdraw the device slowly from the endoscope by using a slight pull force.

   Note: Endoscope must remain as straight as possible when withdrawing the device.
7. If the clip does not immediately detach from the delivery system, then apply gentle movement to the delivery system or endoscope to detach the clip.

   Caution: Do not remove an unsheathed open clip through the endoscope working channel, otherwise endoscope working channel damage may result.
8. If the clip has not been deployed, but the tissue has been already clipped and the slider continues moving proximally, the clinician can still move the slider distally to open the clip again, to release the tissue from the clip. Then moving the slider proximally to close the clip, withdraw the device slowly through the endoscope, and change to another device.
9. If the tissue has been already clipped, but the clip has not been deployed, bleeding may be caused when the device is removed.
10. For an area left with what is deemed a small amount of bleeding, the clinician can change to another hemoclip to treat the bleeding area immediately.
11. For an area left with what is deemed a large amount of bleeding, injecting adrenalin in that area to stop the bleeding may be necessary, and then allow the clinician to manage further with additional clips or other means.
12. The device is only intended for adult populations.
13. Please use this device according to this IFU. If the end user does not comply with this IFU, there may be an increased risk related to infection control, perforation, or mucosal damage, which may harm the patient(s) or effect the safety of the end user(s).
14. Operating Environment Requirement: ambient environment:10—40℃, Relative humidity:30—85%.
15. Do not attempt to reuse, reprocess, refurbish, remanufacture, or resterilize this device. This device is not intended to be reused, reprocessed, refurbished, remanufactured, or resterilized. Performing such activities on this disposable medical device presents a safety risk to patients (e.g., compromised device integrity, cross-contamination, infection).
16. It is recommended that healthcare providers distribute patient implant cards with the name of the clip and date it was placed.

MRI Safety Information:

MR Conditional

Non-clinical testing demonstrated that the Hemoclip is MR Conditional. A patient with this device can be scanned safely in an MR system under the following conditions:

- Static magnetic field of 1.5 Tesla or 3.0 Tesla.
- Maximum spatial field gradient of 2,000 Gauss/cm (20 T/m).
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2 W/kg for 15 minutes of scanning (i.e., per pulse sequence) in the Normal Operating Mode.

Under the scan conditions defined, the clip is expected to produce a maximum temperature rise of 1.9°C after 15 minutes of continuous scanning.

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

Warning:

1. 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.
2. 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.

Contraindications:

- Do not use this device when hemostasis cannot be verified visually with an endoscopic field of view.
- Arteries greater than 2mm.
- Polyps greater than 1.5 cm in diameter.
- Mucosal/Submucosal defects greater than 3 cm.
- The patient has a serious narrow upper digestive tract where the endoscope cannot pass through.
- The patient has serious coagulation disorders and hemorrhagic diseases.

Directions for Device Usage:

Prior to Use:

3. The clip is intended for single use and supplied sterile. The device is sterilized by Ethylene Oxide. Carefully examine the unit before use to verify that neither the contents nor the sterile package has been damaged in shipment. Do not use if damaged.

4. Familiarize yourself with the Figures contained in this Instructions for Use.
5. Review labeling to ensure that product is not expired**. If expired, do not use. Save the device and packaging and contact your local Product Specialist.**
6. Inspect the package and device(s) for shipping and handling damage.
7. Open the package and remove the device.
8. Do not use this device if there is any evidence of damage (e.g. bent or cracked catheter, clip broken or missing, damaged packaging). **Save the device and packaging and contact your local Product Specialist.**
9. Familiarize yourself with the device.

Procedural Use:

1. Remove the protective tip from the clip.
2. Confirm that the Clip is in the closed position by moving the Slider towards the Thumb Ring as shown in **Figure 2**. Continuous light pressure may be needed to keep the clip closed.

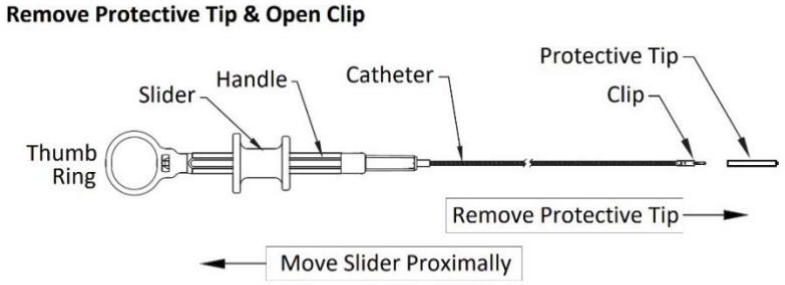

Figure 2

3. Endoscopically confirm the desired tissue site for clip closure.
4. Using short strokes, 1"-1.5" (2.5cm – 3.8cm) in length, advance the device through the instrument channel.

⚠ **Warning:** When introducing the device in an endoscope in a tortuous position, straightening the distal tip of the endoscope may improve passage and exposure of the clip. After the clip exits the instrument channel, reposition the endoscope for treatment. If the catheter kinks or becomes damaged during device insertion or passage, remove device from endoscope and do not use the device.

5. When the clip is at the desired location, gently move the slider away from the thumb ring to open the clip jaws, as shown in **Figure 3**.

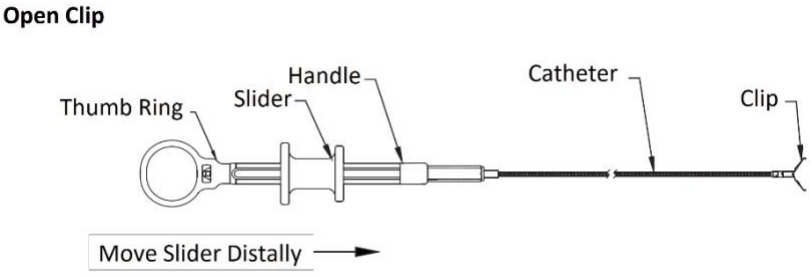

Figure 3

6. For Assurance® Clip (00711881, 00711882, 00711883, 00711884, 00711885) the Clip may be rotated clockwise or counterclockwise by turning the entire handle as one unit until correct position is achieved.
7. For Assurance® Control Clip (00711887, 00711888), if the angle of the distal clip is not in the correct position for deployment, it can be adjusted by rolling the whole product, which can be accomplished by rotating the handle or twisting the catheter.

   Note: Rotation may be limited by patient anatomy, endoscope position, or other factors
8. Additionally, the clinician may need to adjust the endoscope to a suitable angle to clip the desired area more easily.
9. Close the clip slowly by moving the slider towards the thumb ring until tactile resistance is felt in the handle. Endoscopically observe to confirm that the tissue is closed by the clip, as shown in **Figure 4**.

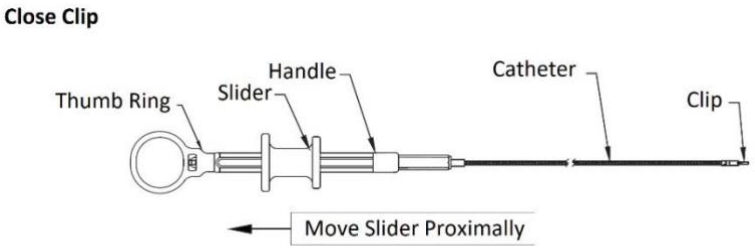

Figure 4

10. If the clip is not in the desired position, the clip can be re -opened and repositioned.
    Note: The 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. Reopening and closing capability may be limited by clinical circumstances and patient anatomy, among other factors.
11. **To permanently deploy the clip, pull the slider proximally towards the thumb ring using a forceful and secure squeeze (two hands may be necessary to perform maneuver in a more controlled fashion).** Audible and tactile feedback along with a sudden loss of resistance will be noted. This indicates that the clip has been released and disengaged from the inner drive wire.
12. Once the 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 and withdraw the delivery system from biopsy channel of endoscope.
13. Do not forcibly pull back on a clip that is deployed and has not detached from the delivery system. This will tear the tissue and likely result in severe bleeding.
14. A wire-cutter should be available on the endoscopy cart and be used to cut the sheath where it exits the endoscope. The endoscope can then be removed leaving the clip and sheath intact. The patient may require an URGENT SURGICAL intervention if there is active bleeding from the site.

Storage:

After packaging, the device shall be stored in an environment of relative humidity below 80%, temperature of -10℃ - 40℃, and noncorrosive gases and well-ventilated room.

Product Disposal:

After use, this product may be a potential biohazard which presents a risk of cross-contamination. Handle and dispose of in accordance with accepted medical practice and applicable local, state, and federal laws and regulations.

Issued Date: May 2022

Warning: An issued or revision date for these instructions is included for the user's information. In the event two years has elapsed between this date and product use, the user should contact STERIS to determine if additional information is available.

Serious incidents that have occurred in relation to this medical device should be reported to the manufacturer and competent authority in the country where the incident occurred.

US Endoscopy, a wholly owned subsidiary of STERIS Corporation.

Explanation of symbols used on Labels and Instructions for Use

SDO (if applicable)	Symbol and Reference	Title of Symbol	Meaning of Symbol
ISO 15223-1 Medical Devices – Symbols to be used with medical device labels, labelling, and information	5.1.3 	Date of Manufacture	Indicates the date when the medical device was manufactured
	5.1.4 	Use By	Indicates the date after which the medical device is not to be used.

to be supplied	**5.1.5** 	**Batch Code**	**Indicates the manufacturer's batch code**
	5.1.6 	**Catalog Number**	**Indicates the manufacturer's catalogue number**
	5.1.11 	**Country of manufacture - China**	**To identify the country of manufacture of products**
	5.2.3 	**Sterilized by Ethylene Oxide**	**Indicates a medical device that has been sterilized using ethylene oxide**
	5.2.6 	**Do Not Re-Sterilize**	**Indicates a medical device that is not to be resterilized**
	5.2.8 	**Do not use if package is damaged**	**Do not use if the product sterile barrier system or its packaging is compromised**
	5.2.11 	**Single sterile barrier system**	**Indicates a single sterile barrier system**
	5.2.14 	**Single sterile barrier system with protective packaging outside**	**Indicates a single sterile barrier system with protective packaging outside**
	5.3.1 	**Fragile, handle with care**	**Indicates a medical device that can be broken or damaged if not handled carefully**
	5.3.2 	**Keep away from sunlight**	**Indicates a medical device that needs protection from light sources**
	5.3.4 	**Keep dry**	**Indicates a medical device that needs to be protected from moisture**

	5.3.7 	**Temperature limit**	**Indicates the temperature limits to which the medical device can be safely exposed**
	5.3.8 	**Humidity limitation**	**Indicates the range of humidity to which the medical device can be safely exposed**
	5.3.9 	**Atmospheric pressure limitation**	**Indicates the range of atmospheric pressure to which the medical device can be safely exposed**
	5.4.1 	**Biological Risks**	**Indicates that there are potential biological risks**
	5.4.2 	**Do not reuse**	**Indicate a medical device that is intended for a single procedure**
	5.4.3 	**Consult instructions for use**	**Indicates the need for the user to consult instructions for use**
	5.4.4 	**Caution**	**Consult instructions for use for cautionary information**
	5.7.10 	**Unique Device Identifier**	**Indicates a carrier that contains unique device identifier information**
21 CFR 801.109 (b) (1)	**N/A** 	**Caution: Federal law (U.S.A.) restricts this device to sale and use by or on the order of a physician.**	
N/A	**N/A** 	**Length**	**Indicates length measurement**
ASTM F2503 – 13 Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment	**7.4.6.1** 	**MR Conditional**	

N/A	**N/A** 	**Contents**	**Number of devices/kits within packaging**
ISO 780:2015(E) Graphical symbols used for both transport and storage	**No.13** 	**This way up**	**This is the correct upright position of the distribution pack-ages for transport and/or storage**
	No.16 	**Stacking limit by 6**	**Maximum number of identical transport packages/items which may be stacked on the bottom package, where "6" is the limiting number**

File No.: AGQWLUA2022001

Version: V001

Issued date: 2022/6/2