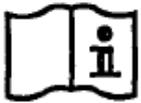


Single Use Rotatable and Repositionable Hemoclip



INSTRUCTIONS FOR USE

STERILE EO



Rx ONLY CAUTION: This device should be sold by or on the order of a physician.

WARNING:

1. Contents supplied STERILE using an ethylene oxide (EO) process. Do not use if sterile barrier is damaged. If damage is found, call your ANREI MEDICAL representative.
2. 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.
3. After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

【Device Name】

Single Use Rotatable and Repositionable Hemoclip

【Intended Use】

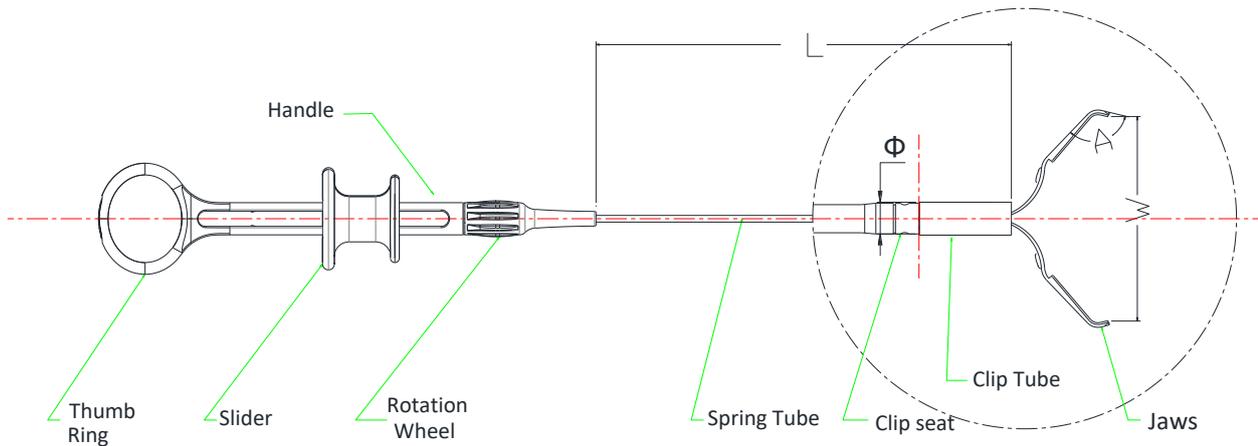
Single Use Rotatable and Repositionable Hemoclip is indicated for clip placement within the Gastrointestinal (GI) tract for the purpose of:

1. Endoscopic marking,
2. Hemostasis for:
 - Mucosal/sub-mucosal defects <3cm,
 - Bleeding ulcers,
 - Arteries < 2mm,
 - Polyps < 1.5cm in diameter,
 - Diverticula in the colon,
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.

【Structure】

Single Use Rotatable and Repositionable Hemoclip consists of a pre-loaded, rotatable, radiopaque, single-use clip, a flexible delivery system used to delivery, operate and deploy the clip. It is designed to be compatible with Gastrosopes and colonoscopes with working channels equal to or greater than 2.8 mm. In addition, the Single Use Rotatable and Repositionable Hemoclip 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 and closing capability may be limited by clinical circumstances and patient anatomy, among other factors.

Hemoclip Structure Diagram, as shown in Figure 1



W= Clip opening, A= Clip angle, L= Working length, Φ = Outside diameter

Figure 1: Single Use Rotatable and Repositionable Hemoclip Structure

【Specifications】

Type and specifications are shown in the following table

No.	Specification	Clip opening	Clip angle	Working length	Outside diameter	Plastic coated		
		$W \pm 1.5(\text{mm})$	$A \pm 20^\circ$	$L(\text{cm}) \pm 10\%$	$(\text{ØDmm} \pm 0.1\text{mm})$	(Yes or Not)		
1	HA- I -1	12	115	195	Ø2.6	No		
2	HA- I -2			230				
3	HA- I -3			165				
4	HA- I -4		90	195				
5	HA- I -5			230				
6	HA- I -6			165				
7	HA- I -7		115	270				
8	HA- I -8		90	270				
9	HA- I -1C	12	115	195		Ø2.6	Yes	
10	HA- I -2C			230				
11	HA- I -3C			165				
12	HA- I -4C		90	195				
13	HA- I -5C			230				
14	HA- I -6C			165				
15	HA- I -7C		115	270				
16	HA- I -8C		90	270				
17	HA- II -1	9	115	195			Ø2.6	No
18	HA- II -2			230				

19	HA-II-3			165			
20	HA-II-4		90	195			
21	HA-II-5			230			
22	HA-II-6			165			
23	HA-II-7		115	270			
24	HA-II-8		90	270			
25	HA-II-1C	9	115	195			Yes
26	HA-II-2C			230			
27	HA-II-3C			165			
28	HA-II-4C		90	195			
29	HA-II-5C			230			
30	HA-II-6C			165			
31	HA-II-7C		115	270			
32	HA-II-8C		90	270			
33	HA-III-1	15	115	195			No
34	HA-III-2			230			
35	HA-III-3			165			
36	HA-III-4		90	195			
37	HA-III-5			230			
38	HA-III-6			165			
39	HA-III-7		115	270			
40	HA-III-8		90	270			
41	HA-III-1C	15	115	195			Yes
42	HA-III-2C			230			
43	HA-III-3C			165			
44	HA-III-4C		90	195			
45	HA-III-5C			230			
46	HA-III-6C			165			
47	HA-III-7C		115	270			
48	HA-III-8C		90	270			

No.	Specification	Clip opening	Clip angle	Working length	Outside diameter	Plastic coated
		W±1.5(mm)	A±20°	L(cm)±10%	(ØDmm±0.1mm)	(Yes or Not)
1	HE-I-1	5	115	195	Ø2.6	No
2	HE-I-2			230		
3	HE-I-3			165		
4	HE-I-4		90	195		
5	HE-I-5			230		
6	HE-I-6			165		
7	HE-I-7		115	270		
8	HE-I-8		90	270		
9	HE-II-1		9	115		

10	HE-II-2			230		
11	HE-II-3			165		
12	HE-II-4		90	195		
13	HE-II-5			230		
14	HE-II-6			165		
15	HE-II-7		115	270		
16	HE-II-8		90	270		
17	HE-III-1	11	115	195		
18	HE-III-2			230		
19	HE-III-3			165		
20	HE-III-4		90	195		
21	HE-III-5			230		
22	HE-III-6			165		
23	HE-III-7		115	270		
24	HE-III-8		90	270		
25	HE-IV-1	12	115	195		
26	HE-IV-2			230		
27	HE-IV-3			165		
28	HE-IV-4		90	195		
29	HE-IV-5			230		
30	HE-IV-6			165		
31	HE-IV-7		115	270		
32	HE-IV-8		90	270		
33	HE-V-1	13	115	195		
34	HE-V-2			230		
35	HE-V-3			165		
36	HE-V-4		90	195		
37	HE-V-5			230		
38	HE-V-6			165		
39	HE-V-7		115	270		
40	HE-V-8		90	270		
41	HE-VI-1	15	115	195		
42	HE-VI-2			230		
43	HE-VI-3			165		
44	HE-VI-4		90	195		
45	HE-VI-5			230		
46	HE-VI-6			165		
47	HE-VI-7		115	270		
48	HE-VI-8		90	270		
49	HE-VII-1	16	115	195		
50	HE-VII-2			230		

51	HE-VII-3			165		
52	HE-VII-4		90	195		
53	HE-VII-5			230		
54	HE-VII-6			165		
55	HE-VII-7		115	270		
56	HE-VII-8		90	270		
57	HE- I -1C	5	115	195	Ø2.6	Yes
58	HE- I -2C			230		
59	HE- I -3C			165		
60	HE- I -4C		90	195		
61	HE- I -5C			230		
62	HE- I -6C			165		
63	HE- I -7C		115	270		
64	HE- I -8C		90	270		
65	HE- II -1C	9	115	195		
66	HE- II -2C			230		
67	HE- II -3C			165		
68	HE- II -4C		90	195		
69	HE- II -5C			230		
70	HE- II -6C			165		
71	HE- II -7C		115	270		
72	HE- II -8C		90	270		
73	HE-III-1C	11	115	195		
74	HE-III-2C			230		
75	HE-III-3C			165		
76	HE-III-4C		90	195		
77	HE-III-5C			230		
78	HE-III-6C			165		
79	HE-III-7C		115	270		
80	HE-III-8C		90	270		
81	HE-IV-1C	12	115	195		
82	HE-IV-2C			230		
83	HE-IV-3C			165		
84	HE-IV-4C		90	195		
85	HE-IV-5C			230		
86	HE-IV-6C			165		
87	HE-IV-7C		115	270		
88	HE-IV-8C		90	270		
89	HE- V -1C	13	115	195		
90	HE- V -2C			230		
91	HE- V -3C			165		

92	HE-V-4C		90	195			
93	HE-V-5C		230				
94	HE-V-6C		165				
95	HE-V-7C		115	270			
96	HE-V-8C		90	270			
97	HE-VI-1C		15	115			195
98	HE-VI-2C						230
99	HE-VI-3C						165
100	HE-VI-4C	90		195			
101	HE-VI-5C			230			
102	HE-VI-6C			165			
103	HE-VI-7C	115		270			
104	HE-VI-8C	90		270			
105	HE-VII-1C	16	115	195			
106	HE-VII-2C			230			
107	HE-VII-3C			165			
108	HE-VII-4C		90	195			
109	HE-VII-5C			230			
110	HE-VII-6C			165			
111	HE-VII-7C		115	270			
112	HE-VII-8C		90	270			

No.	Specification	Clip opening	Clip angle	Working length	Outside diameter	Plastic coated
		W±1.5(mm)	A±20°	L(cm)±10%	(ØDmm±0.1mm)	(Yes or Not)
1	HG-I-1	5	115	195	Ø2.3	No
2	HG-I-2			230		
3	HG-I-3			165		
4	HG-I-4		90	195		
5	HG-I-5			230		
6	HG-I-6			165		
7	HG-I-7		115	270		
8	HG-I-8		90	270		
9	HG-II-1	9	115	195		
10	HG-II-2			230		
11	HG-II-3			165		
12	HG-II-4		90	195		
13	HG-II-5			230		
14	HG-II-6			165		
15	HG-II-7		115	270		

16	HG-II-8		90	270			
17	HG-III-1	11	115	195			
18	HG-III-2			230			
19	HG-III-3			165			
20	HG-III-4			90	195		
21	HG-III-5		230				
22	HG-III-6		165				
23	HG-III-7		115		270		
24	HG-III-8			90	270		
25	HG-IV-1	12	115	195			
26	HG-IV-2			230			
27	HG-IV-3			165			
28	HG-IV-4		90	195			
29	HG-IV-5			230			
30	HG-IV-6			165			
31	HG-IV-7			115	270		
32	HG-IV-8			90	270		
33	HG-V-1	13	115	195			
34	HG-V-2			230			
35	HG-V-3			165			
36	HG-V-4		90	195			
37	HG-V-5			230			
38	HG-V-6			165			
39	HG-V-7			115	270		
40	HG-V-8			90	270		
41	HG-VI-1	15	115	195			
42	HG-VI-2			230			
43	HG-VI-3			165			
44	HG-VI-4		90	195			
45	HG-VI-5			230			
46	HG-VI-6			165			
47	HG-VI-7			115	270		
48	HG-VI-8			90	270		
49	HG-VII-1	16	115	195			
50	HG-VII-2			230			
51	HG-VII-3			165			
52	HG-VII-4		90	195			
53	HG-VII-5			230			
54	HG-VII-6			165			
55	HG-VII-7			115	270		
56	HG-VII-8			90	270		

57	HG- I -1C	5	115	195	Ø2.3	Yes
58	HG- I -2C			230		
59	HG- I -3C			165		
60	HG- I -4C		90	195		
61	HG- I -5C			230		
62	HG- I -6C			165		
63	HG- I -7C		115	270		
64	HG- I -8C		90	270		
65	HG- II -1C	9	115	195		
66	HG- II -2C			230		
67	HG- II -3C			165		
68	HG- II -4C		90	195		
69	HG- II -5C			230		
70	HG- II -6C			165		
71	HG- II -7C		115	270		
72	HG- II -8C		90	270		
73	HG-III-1C	11	115	195		
74	HG-III-2C			230		
75	HG-III-3C			165		
76	HG-III-4C		90	195		
77	HG-III-5C			230		
78	HG-III-6C			165		
79	HG-III-7C		115	270		
80	HG-III-8C		90	270		
81	HG-IV-1C	12	115	195		
82	HG-IV-2C			230		
83	HG-IV-3C			165		
84	HG-IV-4C		90	195		
85	HG-IV-5C			230		
86	HG-IV-6C			165		
87	HG-IV-7C		115	270		
88	HG-IV-8C		90	270		
89	HG- V -1C	13	115	195		
90	HG- V -2C			230		
91	HG- V -3C			165		
92	HG- V -4C		90	195		
93	HG- V -5C			230		
94	HG- V -6C			165		
95	HG- V -7C		115	270		
96	HG- V -8C		90	270		
97	HG-VI-1C	15	115	195		

98	HG-VI-2C		90	230			
99	HG-VI-3C			165			
100	HG-VI-4C			195			
101	HG-VI-5C			230			
102	HG-VI-6C			165			
103	HG-VI-7C			115			270
104	HG-VI-8C			90			270
105	HG-VII-1C			16			115
106	HG-VII-2C	230					
107	HG-VII-3C	165					
108	HG-VII-4C	195					
109	HG-VII-5C	90	230				
110	HG-VII-6C	165					
111	HG-VII-7C	115	270				
112	HG-VII-8C	90	270				

No.	Specificati on	Clip opening	Clip angle	Working length	Outside diameter	Over-Sheath or not			
		W±1.5(mm)	A±20°	L(cm)±10%	(ØDmm±0.1mm)				
113	HG- I -1S	5	115	195	Ø2.6	Yes			
114	HG- I -2S			230					
115	HG- I -3S			165					
116	HG- I -4S		90	195					
117	HG- I -5S			230					
118	HG- I -6S			165					
119	HG- I -7S		9	115			270		
120	HG- I -8S			90			270		
121	HG- II -1S	115		195					
122	HG- II -2S			230					
123	HG- II -3S			165					
124	HG- II -4S	90		195					
125	HG- II -5S			230					
126	HG- II -6S			165					
127	HG- II -7S	11	115	270					
128	HG- II -8S		90	270					
129	HG-III-1S		115	195					
130	HG-III-2S			230					
131	HG-III-3S			165					
132	HG-III-4S		90	195					
133	HG-III-5S			230					
134	HG-III-6S			165					

135	HG-III-7S		115	270			
136	HG-III-8S		90	270			
137	HG-IV-1S	12	115	195			
138	HG-IV-2S			230			
139	HG-IV-3S			165			
140	HG-IV-4S		90	195			
141	HG-IV-5S			230			
142	HG-IV-6S			165			
143	HG-IV-7S			115	270		
144	HG-IV-8S			90	270		
145	HG-V-1S	13	115	195			
146	HG-V-2S			230			
147	HG-V-3S			165			
148	HG-V-4S		90	195			
149	HG-V-5S			230			
150	HG-V-6S			165			
151	HG-V-7S			115	270		
152	HG-V-8S			90	270		
153	HG-VI-1S	15	115	195			
154	HG-VI-2S			230			
155	HG-VI-3S			165			
156	HG-VI-4S		90	195			
157	HG-VI-5S			230			
158	HG-VI-6S			165			
159	HG-VI-7S			115	270		
160	HG-VI-8S			90	270		
161	HG-VII-1S	16	115	195			
162	HG-VII-2S			230			
163	HG-VII-3S			165			
164	HG-VII-4S		90	195			
165	HG-VII-5S			230			
166	HG-VII-6S			165			
167	HG-VII-7S			115	270		
168	HG-VII-8S			90	270		

【Direction for Use】

1. Inspect the package to make sure it is intact, and then remove the Single Use Rotatable and Repositionable Hemoclip, Gently tighten the Slider and pull out the head Protector.
2. Gently tighten the Slider and make sure the clip closed. Carefully insert Single Use Rotatable and Repositionable Hemoclip through the biopsy channel of the endoscope with short, deliberate 2 to 3 centimeter strokes.

3. Once Single Use Rotatable and Repositionable Hemoclip can be observed exiting the tip of the endoscope under direct visualization, and the Clip is at the desired location, gentle move the Slider distally (away from the Thumb Ring) to open the Jaws, as shown in Figure 2.

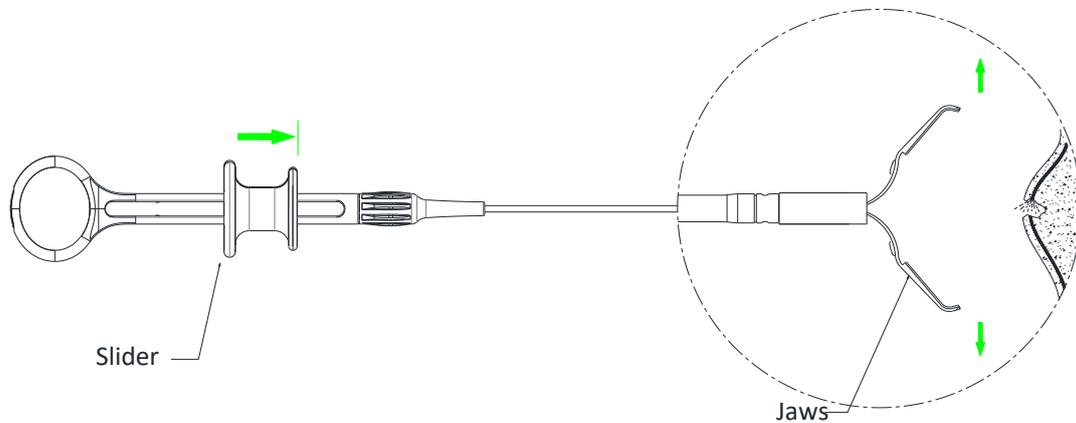


Figure 2: Open the Jaws

4. To rotate the Rotation Wheel to adjust the angle between the clip and the lesion, until the clip is in the proper position for clipping, as shown in Figure 3.

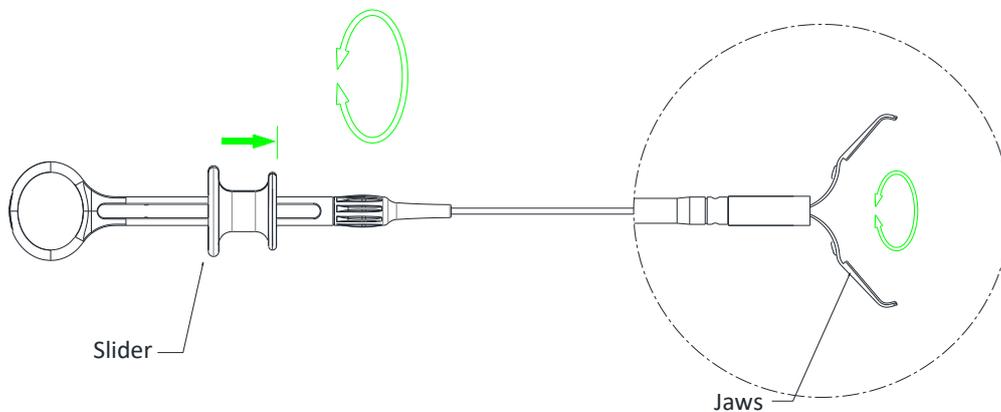


Figure 3: Rotating the Clip

5. To close the Jaws on the desired location, move the Slider proximally until tactile resistance is felt in the Handle, as shown in Figure 4. The Clip position may now be assessed prior to deployment.

At this point, there are 2 options:

Option 1, the clip can be re-opened and repositioned (See step 6). Option 2, the clip can be permanently deployed (See step 7).

Warning: Do not try to forcibly remove the clip if it become caught on the distal end of the coil sheath. Forcible removal of the clip could cause patient injury such as perforation, bleeding, or mucous

membrane damage.

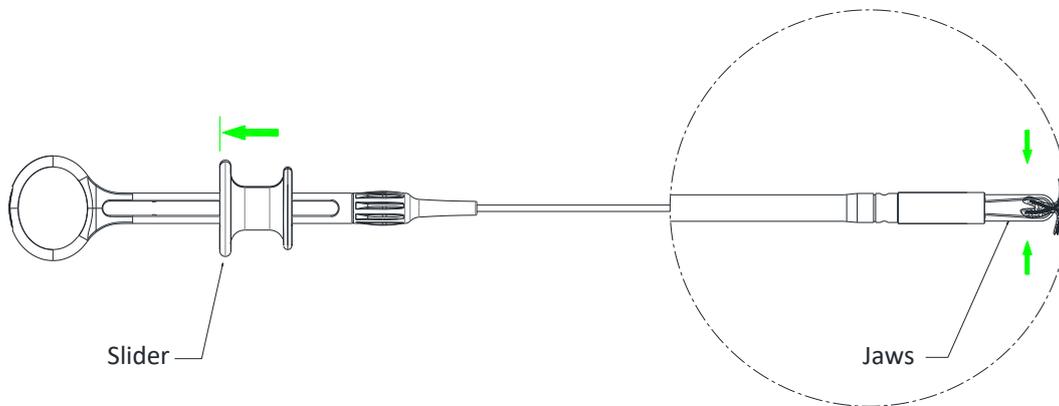


Figure 4: Close the Clip

6. To re-open and re-position the clip to another location, move the Slider distally to open the Jaws, to rotate the Rotation Wheel to adjust the angle between the Jaws and the lesion, and position the clip on the desired location (same as step 3.&4.).

7. To permanently deploy the clip, continue moving the Slider toward the Thumb Ring beyond the tactile resistance point, at this point a first click may be heard or felt. Continue moving the Slider toward the Thumb Ring until a second tactile resistance point and/or click is heard or felt. Continue moving the Slider until it reaches the Thumb Ring, as shown in Figure 5.

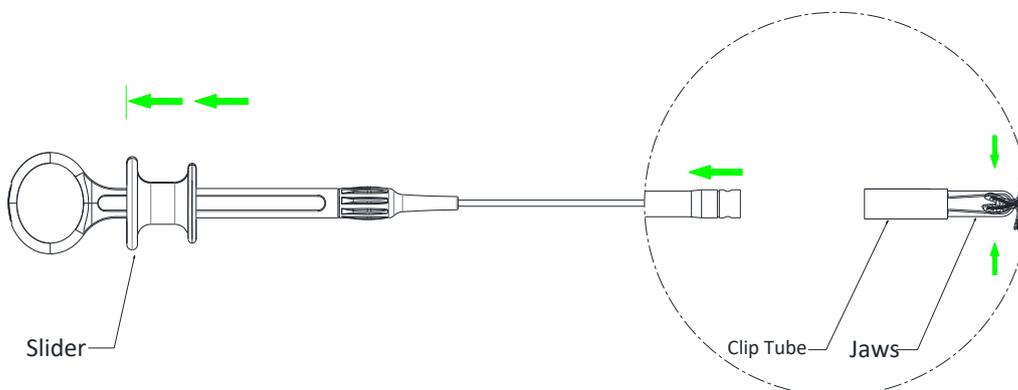


Figure 5: The Clip Permanently Deployed

【Contraindications】

1. Do not use this device when hemostasis cannot be verified visually with an endoscopic field of view.
2. Arteries greater than 2 mm.
3. Polyps greater than 1.5 cm in diameter.
4. Mucosal / Sub-Mucosal defects greater than 3 cm.

【MRI Safety Information】

Non-clinical testing demonstrated that the Hemoclip is MR Conditional according to ASTM F2503.A patient with this Hemoclip(s) can be safely scanned in an MR system under the following conditions:

Static magnetic field of 1.5-Tesla and 3-Tesla with;

- Spatial gradient field of 2,500-Gauss/cm(value extrapolated) and less
- Maximum 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 Hemoclip is expected to produce a maximum temperature rise of less than 1.5°C after 15-minutes of continuous scanning (i.e., per pulse sequence).In non-clinical testing, the image artifact caused by the Hemoclip extends approximately 60-mm from this implant when imaged using a gradient echo pulse sequence and a 3-Tesla MR system.

【Caution】

1. Do not use if the package is open or damaged when received.
2. Do not use if an abnormality is detected that would prohibit proper working condition.
3. Do not use if it is expired.
4. The device is a single-use sterile product. Destroy after use. Do not reuse.
5. The device must be operated by trained clinicians.

【Warning】

1. 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. In this case, refer to chapter “**Emergency Treatment**”.
2. It might be impossible to stop bleeding depending on the hemorrhage situation because the clip performance for hemostasis is limited .prepare more than one hemostatic device and select appropriate hemostatic device or use it together to respond to different hemorrhage situations appropriately.choose a surgical hemostasis if necessary.
3. Re-bleeding may occur on the clipping site depending on the local condition or the grasping condition .check the patient for any re-bleeding after the operation as appropriate
4. Use this instrument in an environment equipped to accommodate open surgery and have the hospitalization plan prepared in case any problem occurs that may not be resolved endoscopically.

【Note】

1. 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.
2. Limited studies indicate that the treatment of esophagus varices may require clipping in combination with a sclerosing agent.
3. Limited studies indicate that clipping hard or severely fibrotic lesion to achieve hemostasis may be more difficult.
4. Limited studies have shown that the number of clips required for hemostasis may vary depending

upon the anatomical site, histology, lesion type, and patient condition and history. A sufficient quantity of clips should be prepared in consideration of all of these factors prior to the procedure.

5. Limited studies indicate that the hemostasis clips remain in place for an average of 9.4 days; re-bleeding may occur if the clips detach within 24 hours.
6. Limited studies indicate that the use of clips in the presence of bacterial contamination may potentiate or prolong infection.

【Emergency Treatment】

Withdrawing the instrument from the endoscope if the clip cannot be detached

Warning: Do not try to forcibly withdraw the instrument from endoscope if the clip cannot be detached from the instrument. Forcibly withdrawing the instrument could cause patient injury such as perforation, bleeding, or mucous membrane damage.

If the clip cannot be detached from the instrument, follow the procedures described in this section. If the distal end of the coil sheath or clip pipe is crushed or deformed, it may not be possible to detach the clip from the instrument.

Step 1: Straighten out the portion of the endoscope that extends from the patient.

Straighten out the portion of the endoscope that extends from the biopsy valve.

Straighten out the coil sheath that extends from the distal end of the endoscope. At the same time, the distal of clips keep as straight as possible.

Step 2: Confirm that the slider has been pulled out as far as possible,

Step 3: Push the slider to release the clip.

If when the clip cannot be detached from the instrument.

Step 4: Cut the coil sheath, tube sheath and operation wire using pliers and/or wire cutters.

Step 5: A certain amount of force is sometimes required to withdraw the endoscope

Step 6: Carry out open surgery or other possible treatment. And Leave the clip in place until tissue necrosis occurs and the clip comes free. This may take some time

Removal of an aspirated clip

If a clip is accidentally aspirated into the endoscope, follow the procedure below to remove it.

Step 1: Withdraw the endoscope from the body cavity, keeping the insertion portion and bending section straight. Leave the biopsy valve mounted on the endoscope.

Step 2: Remove the suction tube and connect a syringe filled with tap water to the endoscope's suction connector.

Step 3: While gently pressing the suction valve, inject the tap water into the endoscope's suction

Step 4: Irrigation should discharge the clip from the endoscope. If one injection is not enough to discharge the clip, repeat Step 2 and 3 until the clip is discharged.

NOTE: If the clip cannot be discharged after Step 4 has been repeated, pass a channel cleaning brush from the suction cylinder up to the distal end of the endoscope and repeat Step 2 and 3.

【Packaging】

Pouch: One set per pouch

Box: 10 pouches per box

Carton: 10 boxes per carton

【Date of Manufacture】

Please refer to the label on pouch.

【Storage conditions】

Store the device in a dry, cool (room temperature), clean place and protect it from direct sunlight, heat and/or aggressive chemical substances. Relative Humidity applicable range is less than 80%, temperature applicable range is 10°C - 40°C.

【Sterilization Method】

EO Sterilization

【Symbol Instruction】

	Manufacturer		Authorized representative in the EC
	Date of manufacture		Use-by date
	Batch code		Catalogue number
	Sterilized using ethylene oxide		Do not use if package is damaged
	Fragile, handle with care		Keep away from sunlight
	Protect from heat and radioactive sources		Keep dry
	This way up		Stacking limit by number
	Temperature limit		Do not re-use

	Consult instructions for use		Caution
	Contains or presence of natural rubber latex		EC notified body identification number
	No Natural rubber latex		Diameter
	Colonic device		ERCP device
	Bronchial device		Gastric device

【Shelf Life】 3 years after sterilization.

【Manufacturer】 Anrei Medical (HZ) Co., Ltd

【Address】 No.3 Ave. 8, Hangzhou Economic Development Area, Hangzhou, People's Republic of China

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【Telephone Number】 400-8096118

【Fax Number】 86-571-87603502

【Website】 www.anrei.com.cn

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