



5 mm

SINGLE USE CLIP APPLIER

CE

0123

EN

Instruction For Use

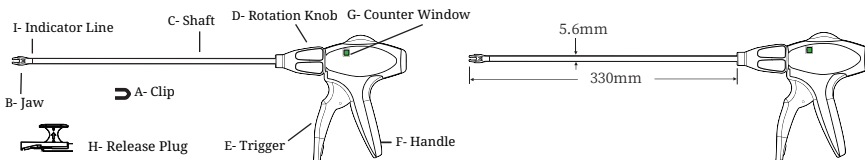
Before using the product, please read the following information thoroughly

Important: This package insert is designed to assist in using the SOLID CLIP™ Single Use Clip Applier. It is not a reference to surgical techniques.

① Description

1. The SOLID CLIP™ Single Use Clip Applier is a sterile, single patient use device designed for an appropriately sized trocar sleeve or larger sized trocar sleeve with the use of a converter and is intended for a long term use. Discard it after use, do not resterilize and reuse it.
2. The SOLID CLIP™ Single Use Clip Applier is available with the specification of the outer diameter of the shaft 5.6mm which contains 10 or 15 titanium clips in Medium-Large (ML) sizes. Please refer to the following schematic view and table to obtain more detailed specifications.
3. The ligating clips are applied using mechanical driving to deliver clips to a laparoscopic surgical site and using a mechanism of the trigger on the handle of the device to close the clip about the vessels and other tubular structures.

Code	Name
A	Clip
B	Jaw
C	Shaft
D	Rotation Knob
E	Trigger
F	Handle
G	Counter Window
H	Release Plug
I	Indicator Line



Drawing	W	H	L	Unit: mm
Size of Clip	W	H	L	
ML	3.5	8.2	9	

Model No.	Name	Outer Diameter of the shaft	Size of Clip	No. of Clips
CA567	5 mm Single Use Clip Applier ML Clip*10	5.6 mm	ML	10
CA568	5 mm Single Use Clip Applier ML Clip*15	5.6 mm	ML	15

② Intended purpose

The SOLID CLIP™ Single Use Clip Applier is intended for permanent closure and ligation of appropriately sized vessels and other tubular tissues.

③ Indications

Closure and ligation of appropriately sized vessels and other tubular tissues are required to achieve the tissue dissection of the following laparoscopic surgery.

④ Intended user

The Healthcare professionals such as surgeon, who are trained and skilled in performing surgical procedures.

⑤ Intended patient population

Patients requiring ligation of vessels or other structures, but not suitable for newborn infants or premature neonates. No limit for gender, weight range and nationality.

⑥ Clinical benefit

Effective closure or ligation of the tubular tissues and vessels such as veins, arteries and cystic duct, appendix stumps to achieve the dissection of the following commonly used laparoscopic surgery. The benefits of using ligation clips are safe and shorten the operation time and simplify the procedure compared to the conventional suture operation.

⑦ Contraindications

1. Do not apply in contraceptive tubal occlusion, but might be used to achieve hemostasis of blood vessels following transection of the fallopian tube.
2. Do not use the SOLID CLIP™ Single Use Clip Applier on renal artery, iliac artery, vessels of the central circulatory, other tissue structures or vessels upon which metal ligating clips would not normally be used.

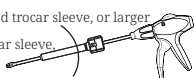
⑧ Instruction for Use

Step 1: Pull out the Release Plug



Remove the release plug following the arrow prior to use.

Step 2: Insert the Clip Applier



Insert the clip applier through an appropriately sized trocar sleeve, or larger sized trocar sleeve with the use of a converter.
Notice: Prior to insertion of this product from a trocar sleeve, please ensure that a clip is not preloaded into the jaw, to prevent an open clip from dropping into the body of the patient.

Step 3: Make sure that the jaw is fully visible



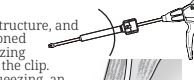
Make sure that the indicator line comes out of the trocar sleeve.
It is required to confirm that the indication line on the shaft is fully visible prior to firing the clip to prevent interference while the jaw is active.

Step 4: Rotate the rotation knob



Rotate the rotation knob can make the "Shaft" rotate 360° in either direction to adjust the visibility of the jaw.

Step 5: Occlude the clip



Insert the jaw to the target structure, and ensure that the clip is positioned within the jaw before squeezing the trigger firmly to occlude the clip.
Notice: When the trigger squeezing, an audible click will be felt / heard.

Step 6: Complete the occlusion of the clip



Release the trigger and remove the jaw from the target structure for completing the occlusion of the clip. Repeat Step 5 for subsequent application.

※Description of the Counter Window

The clip applier contains 15 (or 10) clips, the counter window will appear to be Green. When there are only 3 clips left, a green/red bar will begin to appear in the counter window to alert the user. When there are zero clips, the counter window will appear to be Red, and the safety interlock mechanism of the clip applier will be stuck so that the handle and the trigger cannot be squeezed again.

Attention:

To remove the clip applier with the presence of clip as shown through the counter window, one must make sure there are no clips at the jaw in order to prevent the clips from falling into the body of the patient.



When "A green/red bar" appears, it means that there are only three clips remaining



When "Red" appears, it means that there are no more clips and that the Handle cannot be squeezed again.

⑨ Warnings

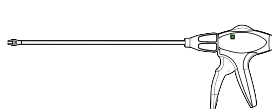
1. Remove the release plug before using this product.
2. Prior insertion or removal of the SOLID CLIP™ Single Use Clip Applier from a trocar sleeve (or with the aid of a converter), please ensure that the clip is not preloaded into the jaw, in order to prevent a clip from dropping into the body of the patient. If a clip appears on the jaw tip when removing the jaw from the targeted structure, please fully squeeze to close the jaw tip before removing the trocar sleeve and release the trigger to discard the formed clip outside the patient's body.
3. Prior squeezing the trigger to place a clip, please visually confirm that the clip is positioned free from other clips and obstructions. Firing a clip over an obstruction may result in malformed clips, which may cause a lack of hemostasis or damage to the jaw.
4. Ensure that the vessels or other tubular structures completely fit within the confines of the clip, otherwise may cause bleeding or damage.
5. When firing the device, squeeze the trigger firmly as far as it can go. Failure to squeeze the trigger can cause clip malformation, which may result in bleeding, leakage and/or tissue damage.
6. Confirm the closed clips are not applied across with others or obstructions when proceeding with the procedure of hemostasis. If minor bleeding and/or leakage is observed after successive application, electrocautery or surgical suture, etc.
7. Do not excessively twist the jaw or overload the tissue when firing the SOLID CLIP™ Single Use Clip Applier.
8. Do not apply too much lateral load to the jaw; otherwise, jaw deformation tends to occur and will result in the undesirable firing of the clip.
9. When the jaw is nearby the tissue, do not close the unloaded jaw.
10. When transecting the occluded structure, leave a sufficient margin of tissue to reduce the potential for the shift of the clip, which can result in bleeding and/or leakage.
11. Endoscopic procedures should be performed only by physicians that had adequate training and familiarity with endoscopic techniques. Before performing any endoscopic procedures, please consult the medical literature relative to techniques, complications, and hazards.
12. A thorough understanding of the principles and techniques involved in endoscopic laser and electrosurgical procedures is necessary to avoid shock and burn hazards to both patient and user(s) or damage to the instrument. Verify compatibility of instrumentation and ensure that electrical isolation or grounding is not compromised.
13. Caution should be exercised when utilizing electrosurgical techniques in the vicinity of any metallic clip. Inadvertent contact with a metallic clip by energized electrosurgical devices may cause unintentional cauterization or electrocoagulation at or around the clip position site which may cause necrosis of the affected tissue. Dislodgement of the clip could occur, resulting in bleeding and/or leakage.
14. SOLID CLIP™ Single Use Clip Applier is not suitable for newborn infants or premature neonates.
15. Do not use the SOLID CLIP™ Single Use Clip Applier if the package is opened or damaged. In case of product failure, please contact the distributor or the manufacturer.
16. The clip inside the device allows MRI and/or NMR performed at 3.0 Tesla or less strength after implantation.
17. The device is a sterile medical device manufactured by EO sterilization and is intended for single use only. Discard after using it; do not re-sterilize and use it again.
18. The device should be stored at room temperature away from sunlight and humidity.
19. If any serious incident has occurred in relation to the device, it should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.
20. This device should be disposed of in accordance with all applicable regulations including, without limitation, those pertaining to human health and safety and the environment.

⑩ MRI safety information

- MR conditional
- Static Magnetic Field Strength (B0): 3.0 T
- Maximum Spatial Field Gradient: 30 T/m (3,000 gauss/cm)
- Maximum Whole-Body SAR: 1.3 W/kg (Normal Operating Mode)
- Scan Duration: 1.3 W/kg whole-body average SAR for 20 minutes of continuous RF (a sequence or back to back series/scan without breaks)
- MR Image Artifact: The presence of this implant may produce an image artifact. In non-clinical testing, the image artifact caused by the device extends approximately 13mm from the SOLID CLIP™ Single Use Clip Applier when imaged with a gradient echo pulse sequence and a 3.0 T MRI system.
- MRI related heating information: At 3-Tesla, a whole body averaged SAR of 1.3 W/kg, 20 minutes of continuous MR scanning, the SOLID CLIP™ Single Use Clip Applier is expected to produce temperature increase of less than 0.5 °C in this non-clinical testing.

⑪ SSCP information:

Please download from <https://www.medscope.com.tw/en/downloadpublic/sscp-p1.pdf>


© Symbols glossary

Symbols	Description	Symbols	Description
	Manufacturer		Keep away from sunlight
	Authorized representative in the European Community		Keep dry
	Date of manufacture		Temperature limit
	Use-by date		Do not re-use
	Batch code		Consult instructions for use
	Sterilized using ethylene oxide / Single sterile barrier system		Caution
	Do not re-sterilize		Prescription only
	Do not use if package is damaged and consult instructions for use		Catalogue number
	Importer		Medical device
	Translation		Unique Device Identifier


Manufacturer:
Medscope Biotech Co., Ltd.

Add:2F, No. 8, Keyi Street, Guang Yuan Technology Park,
Zhunan Town, 35059 Miaoli County, TAIWAN
TEL:+886-37580055 FAX:+886-37585050
Website:www.medscope.com.tw

EU REP
MedNet EC-REP IIb GmbH
Borkstrasse 10, 48163
Muenster, Germany
