



10mm

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.

Intended Purpose

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

Intended user

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

Indications

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

Intended patient population

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

Clinical benefit

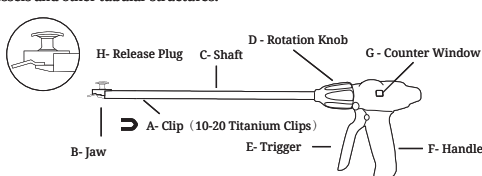
Effective closure or ligation of the tubular tissues and vessels such as veins, arteries and cystic duct, appendix stumps to achieve the dissection of the following commonly used laparoscopic surgery. The benefits of using ligation clips are safe and shorten the operation time and simplify the procedure compared to the conventional suture operation. On the other hand, it also benefits the patient not just by means of a safer procedure but also in terms of decreased morbidity, a faster recovery, and decreased hospital stay.

Description

- 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.
- The SOLID CLIP™ Single Use Clip Applier is available in the specification of the outer diameter of the shaft 10 mm which contains 10, 15 or 20 titanium clips in two sizes, Medium-Large (ML) and Large (L).
- Please refer to the following schematic view and table to obtain more detailed specifications. 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.

Table 1

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



Series	Model No.	Shaft Length (mm)	Shaft Diameter (mm)	Clip Size	Clip Q'ty.	Clip Specification (mm)		
						W	H	L
CA16	CA165	330	10	L	10	4.5	9.8	11
	CA166	330	10	L	15	4.5	9.8	11
	CA167	330	10	ML	15	4.5	7.8	9
	CA168	330	10	ML	20	4.5	7.8	9
	CA169	330	10	ML	10	4.5	7.8	9

Contraindications

- Do not apply in contraceptive tubal occlusion, but might be used to achieve hemostasis of blood vessels following transection of the fallopian tube.
- Do not use the device 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.

Instruction for Use

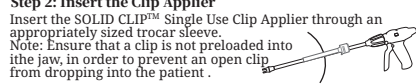
Step 1: Pull out the Release Plug

Remove the release plug from the jaw.



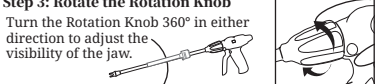
Step 2: Insert the Clip Applier

Insert the SOLID CLIP™ Single Use Clip Applier through an appropriately sized trocar sleeve. Note: Ensure that a clip is not preloaded into the jaw, in order to prevent an open clip from dropping into the patient.



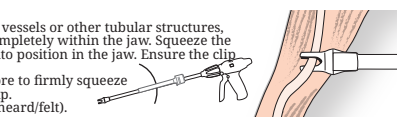
Step 3: Rotate the Rotation Knob

Turn the Rotation Knob 360° in either direction to adjust the visibility of the jaw.



Step 4: Place the Clip

Place the jaw around the vessels or other tubular structures, ensure it is positioned completely within the jaw. Squeeze the trigger to push the clip into position in the jaw. Ensure the clip is properly positioned before to firmly squeeze the trigger to close the clip. (An audible click will be heard/felt).



Step 5: Complete the Closure of the Clip

Release the trigger and remove the jaw from the vessels and other tubular structures to complete the closure of the clip. Repeat Step 4 for subsequent applications.



Description of the Counter Window

The counter window shows a yellow block to warn the user when there are only 5 clips left in the SOLID CLIP™ Single Use Clip Applier. When there are no clips left in the SOLID CLIP™ Single Use Clip Applier, the counter window will show "0", indicating the clip quantity is zero. A Safety Interlock feature will prevent the handle and trigger from being squeezed.



The number "5" shown on the yellow block means there are 5 clips left in the device.



"0" means there are 0 clips left in the device and handle cannot be squeezed.

Warnings

- Remove the release plug before using this product.
- 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.
- 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.
- Ensure that the vessels or other tubular structures completely fit within the confines of the clip, otherwise may cause bleeding or damage.
- 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.
- 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.
- Do not excessively twist the jaw or overload the tissue when firing the SOLID CLIP™ Single Use Clip Applier.
- 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.
- When the jaw is nearby the tissue, do not close the unloaded jaw.
- 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.
- 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.
- 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.
- 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.
- SOLID CLIP™ Single Use Clip Applier is not suitable for newborn infants or premature neonates.
- 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.
- The clip inside the device allows MRI and/or NMR performed at 3.0 Tesla or less strength after implantation.
- 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.
- The device should be stored at room temperature away from sunlight and humidity.
- 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.
- 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.

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 average 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.

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

