



10mm

SINGLE USE CLIP APPLIER

CE
0123

EN

Instruction For Use

Summary:

- Before using SOLIDCLIP™ CA16 Series (hereinafter referred to as "This Product"), read the following information thoroughly.
- "This Product" should be used only by Physicians having adequate training of Endoscopic techniques.
- This Manual is designed to assist in using "This Product". It is not a reference to surgical techniques.
- "This Product" contains Eight (8) Models (CA162, CA163, CA164, CA165, CA166, CA167, CA168, CA169), read the following information thoroughly with regard to the specification of each Model.
- The titanium Clips may be implanted for a while or permanently. Biocompatibility testing has been performed to a level appropriate for permanent implant with no adverse effects.

Contraindications:

- "This Product" is not intended for contraceptive tubal occlusion, but may be used to achieve hemostasis following transection of the fallopian tube.
- "This Product" is not intended to renal artery, aorta, arteria intestinalis, vessels of the central circulatory/ nervous system or other vessels upon which metal ligating clips would not normally be used.
- Do not use "This Product" on the tissue of aortic dissective aneurysm.

Description:

- Indication:
 - "This Product" has application in many types of endoscopic procedure to achieve occlusion of "Vessels and other Tubular Structures" (hereinafter referred to as "Target") and for Radiographic marking.
 - "This Product" is designed for the introduction and use through all appropriately sized Trocar Sleeve, or larger sized Trocar Sleeve with the use of an appropriate converter.
- "This Product" is provided STERILE and designed, tested and manufactured for Single Patient Use only. Discard after use, DO NOT Resterilize.
- Schematic view and component: please refer to the following Figure and Table 1.

Table 1

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

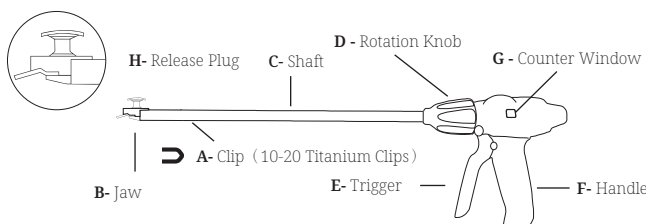


Table 2

Series Model No.	CA							
	162	163	164	165	166	167	168	169
Description	M	M	M	L	L	ML	ML	ML
Specification	M	M	M	L	L	ML	ML	ML
Pre-Load Quantity	15	20	10	10	15	15	20	10
Size of Clip	M: Medium Size			L: Large Size		ML: Medium Large Size		

- Specification and Quantity of the Clip: "This Product" contains 10-20 Titanium Clips.
 - Table 2 describes the Specification and Quantity of the Clip.
 - Table 3 describes the span of Clip before closure and the length of Clip when closed.
 - The shape of the closed Clip changes for thickness of the target tissue.
- The length of shaft in "This Product" is 330 mm (13 inches), outer diameter of shaft is 10 mm (0.394 inch)

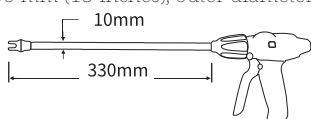


Table 3

Drawing Dimension	Unit: mm		
	W	H	L
Size of Clip			
M	4.5	4.8	6
ML	4.5	7.8	9
L	4.5	9.8	11

Instruction for Use

<p>Step 1: Pull out the Release Plug</p> <p>Use fingers to pull up the Release Plug from the Shaft.</p>	<p>Step 2: Insert the Clip Applier</p> <p>Insert "This Product" through an appropriately sized trocar sleeve, or larger sized trocar sleeve with the use of a converter. Notice: Ensure that a Clip is not preloaded into the Jaw, to prevent an open Clip from dropping into the body of patient.</p>	<p>Step 3: Rotate the Rotation Knob</p> <p>Rotate the Rotation Knob can make the shaft rotating 360° in either direction to adjust the visibility of Jaw.</p> <p>The Rotation Collar rotates 360° in either direction.</p>
<p>Step 4: Place the Clip</p> <p>Insert the Jaw of "This Product" to the "Target", and ensure that the Clip is positioned within the Jaw before squeezing the Trigger firmly to close the Clip. (When the Trigger squeezing, an audible click will be felt/ heard.)</p>	<p>Step 5: Complete the Closure of the Clip</p> <p>Release the Trigger and remove the Jaw from "Target" for completing the closure of Clip. Repeat the Step 4 for subsequent application.</p>	
<p>※Description of the Counter Window</p> <p>The Counter Window shows Yellow Block to warn the user that there are only 5 Clips left in "This Product". When there are no Clips left in "This Product", the Counter Window will show "0" indicating the Clip Quantity is ZERO (0). A safety interlock feature will prevent the Handle and Trigger from being squeezed. Notice: If the Counter Window shows that there are Clips left in while removing "This Product", ensure that there is no Clip in the Jaw, to prevent the Clip from dropping into the body of patient.</p> <p>The number "5" shown on the Yellow Block means that there are Five (5) Clips left in "This Product".</p> <p>"0" means that there are ZERO Clips in "This Product" and the Handle cannot be squeezed.</p>		

Warnings and Precautions

- Prior to insertion or removal of "This Product" from a trocar sleeve (or with the use of a converter), please ensure that the Clip is not preloaded into the Jaw, to prevent a Clip from dropping into the body of patient.
- Prior to squeezing the Trigger to place a Clip, visually confirm that the Clip is positioned free of other clips and obstructions. Firing a Clip over another may result in malformed of Clips, which may cause lack of hemostasis or damage the Jaw.
- Ensure that the "Target" completely fits within the confines of the Clip or bleeding/ damage may result in.
- When firing the Clip, squeeze the Trigger firmly as far as it will go. Failure to squeeze the Trigger can cause the malformed Clip which results in bleeding or damage of the tissue.
- Confirm the closed Clips which are not applied across with others or obstructions and carry out the procedure of hemostasis. If minor bleeding and/or leakage is observed after successive application, electrocautery or surgical suture...etc., are suggested to complete the occlusion.
- Do not excessively twist the Jaw or overload with the tissue when firing "This Product".
- When the jaw is nearby the tissue, do not close the unloaded Jaw.
- When transecting the occluded structure, leave a sufficient margin in the end of tissue to avoid the shift of the Clip, which can cause the bleeding and/ or leakage.
- Endoscopic procedures should be performed only by physicians having adequate training and familiarity with endoscopic techniques. Prior to performance of any endoscopic procedures 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 dip by energized electrosurgical devices may cause unintentional cauterization or electrocoagulation at or around the Clip site which could affect the tissue. Dislodgement of the Clip could occur, resulting in bleeding and/or leakage.
- Some surgeons believe that titanium Clip should not be used in the brain.
- DO NOT Use if the package is opened or damaged.
- It should be noted the magnetic fields influences when using "This Product".
- Please contact the local distributor or the manufacturer if "This Product" is malfunction.
- "The Product" is not suitable for newborn infants or premature neonates.
- The clip inside this device allows MRI and/or NMR performed at 3.0 Tesla or less strength after it is implanted.



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