

BEFORE USING PRODUCT, PLEASE READ THE FOLLOWING INFORMATION THOROUGHLY.

IMPORTANT!

- This Instruction for Use is to assist in using "Taiwan Surgical" Clip Applier, not a reference to surgical techniques.
- Do not reuse, reprocess or re-sterilize a single-use unit of this unit.
- The disposable component of this device is designed, tested and manufactured for single-use. Re-sterile or reuse the disposable component of this device may cause the device failure and cause harm to the patient and may also pose a risk of contamination and infection.

INTENDED USE

The use of the product is indicated in endoscopic procedures, including laparoscopic surgical procedures where instruments are introduced into the body through a cannula for the purpose of ligating vessels and tubular structures.

CONTRAINDICATIONS

- Do not apply in contraceptive tubal occlusion, but might be used to achieve hemostasis following transection of the fallopian tube.
- Do not use the clip applier on the renal artery, iliac artery, aorta or other vessels where metal ligating clips could not be used normally.
- Do not apply in any central circulatory system, and central nervous system related surgery.

WARNINGS AND PRECAUTIONS

- The Reusable Handle of "Taiwan Surgical" Clip Applier is provided in a non-sterile condition. Be sure to clean and sterilize before using.
- Use neutral detergent to clean the Reusable Handle of the device.
- The Disposable Clip Cartridges of the device has sterilized, and is for single use, do not reuse and re-sterilize. Do not use if the package has been damaged or opened. Reuse or re-sterilize the clip applier may result in clip malfunction and infection of patients.
- When inserting or removing the clip applier through the applicable size trocar sleeve, or larger sized sleeve, be sure that a clip occludes the vessel well to avoid the open clip dropping in the body.
- Before squeezing the handle to place a clip, please be sure that it will be positioned free of other clips or other obstructions. Firing a clip over a clip might lead to bleeding, lack of hemostasis and/or destroy to the jaws.
- Please be sure that the tissue to be occluded fits completely within the confines of the clip to avoid bleeding and leakage.
- When firing the device, press the handle firmly as far as it will go. Failure to squeeze the handle completely can lead to clip malformation and bleeding and/or leakage.
- Please do check all clips to confirm that none has been applied across another clip or obstruction and that hemostasis or occlusion has been made. If minor bleeding and/or leakage appears, electro cautery or manual sutures could be used to ensure hemostasis.
- When transecting an occluded structure, please leave an enough margin of distal tissue to reduce the possibility of clip dislodgement. Bleeding and/or leakage could happen due to dislodgement of a clip.
- Endoscopic surgery should be performed only by physicians who have professional training and familiarity with endoscopic techniques. Prior to performance of any endoscopic procedures, please consult the medical literature relevant to techniques, complications, and hazards.
- The titanium clips may be implanted for a while or permanently. Biocompatibility testing has been performed to a level appropriate for permanent implant on titanium clips with no adverse effects noted.
- Please do not twist the jaws excessively or try to lift excessive tissue when firing the device.
- Please do not place an empty jaw or load a clip into the device while the jaw is around tissue.
- Do not use this device in dissecting aneurysm tissue.
- Please Store the Disposable Clip Cartridges part of the device at room temperature, 25°C.
- If need to use endoscopy device from difference companies in the same surgical procedure, please verify its compatibility before surgery.
- This device is obtainable only on a physician's prescription.
- It should be noted the magnetic fields influences when using this device.
- Remove and discard the disposable Clip Cartridges immediately after operation to avoid cross infection.
- The temperatures must under 130°F (54°C) when product in transportation condition.

SPECIFICATIONS

Model	Description	SHAFT Spec.(D*L)	CLIP Spec.(W*L, Qty)
TRC-TM120	Titanium Clip Cartridge, 20 Clip, ML 10mm	Φ10*309mm	5.5*9mm, 20Clips
TRC-TM121	Titanium Clip Cartridge, 20 Clip, ML 10mm	Φ10*309mm	5.5*9mm, 20Clips
TRC-TL120	Titanium Clip Cartridge, 20 Clip, L 10mm	Φ10*359mm	5.5*11mm, 20Clips
TRC-TL121	Titanium Clip Cartridge, 20 Clip, L 10mm	Φ10*359mm	5.5*11mm, 20Clips
TRC-TM110	Titanium Clip Cartridge, 10 Clip, ML 10mm	Φ10*309mm	5.5*9mm, 10Clips
TRC-TM111	Titanium Clip Cartridge, 10 Clip, ML 10mm	Φ10*309mm	5.5*9mm, 10Clips
TRC-TL110	Titanium Clip Cartridge, 10 Clip, L 10mm	Φ10*359mm	5.5*11mm, 10Clips
TRC-TL111	Titanium Clip Cartridge, 10 Clip, L 10mm	Φ10*359mm	5.5*11mm, 10Clips
TRC-HTM12	Reusable Clip Applier Handle with Titanium Clip Cartridge, 20 Clip, ML 10mm	Φ10*309mm	5.5*11mm, 20Clips
TRC-HTM13	Reusable Clip Applier Handle with Titanium Clip Cartridge, 20 Clip, ML 10mm	Φ10*309mm	5.5*11mm, 20Clips
TRC-HTL12	Reusable Clip Applier Handle with Titanium Clip Cartridge, 20 Clip, L 10mm	Φ10*359mm	5.5*9mm, 20Clips
TRC-HTL13	Reusable Clip Applier Handle with Titanium Clip Cartridge, 20 Clip, L 10mm	Φ10*359mm	5.5*9mm, 20Clips
TRC-HTM11	Reusable Clip Applier Handle with Titanium Clip Cartridge, 10 Clip, ML 10mm	Φ10*309mm	5.5*11mm, 10 Clips
TRC-HTM14	Reusable Clip Applier Handle with Titanium Clip Cartridge, 10 Clip, ML 10mm	Φ10*309mm	5.5*11mm, 10 Clips
TRC-HTL11	Reusable Clip Applier Handle with Titanium Clip Cartridge, 10 Clip, L 10mm	Φ10*359mm	5.5*9mm, 10Clips
TRC-HTL14	Reusable Clip Applier Handle with Titanium Clip Cartridge, 10 Clip, L 10mm	Φ10*359mm	5.5*9mm, 10Clips
Model	Description	Handle Spec.(L*W*H)	
TRC-H0000	Reusable Clip Applier Handle	190*130*40mm	

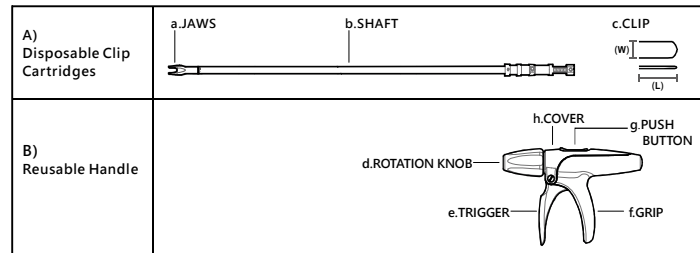
OPERATION NOTE

Assembly	
Step 1: Pull the push button forward and open the cover on the handle.	
Step 2: Insert the cartridge through the Rotation Knob, then close the cover horizontally. During cartridge insertion, do not push the trigger to avoid getting stuck.	
Step 3: Rotate the Clip Cartridges to lock into the rotation knob.	
In Use	
Step 4: When inserting or removing the clip applier through the trocar sleeve, please be sure that no clip is loaded in the jaw.	
Step 5: The shaft is 360° rotatable in either direction. Please adjust the jaw for maximum visibility by turning the rotation knob.	

PRODUCT DESCRIPTION

The "Taiwan Surgical" Clip Applier contains 10 or 20 pieces large or medium titanium clips in total. The applier is designed for introduction and use through all applicably sized trocar sleeve, or larger sized trocar sleeve with the use of a fitted converter.

SCHEMATIC VIEW



RE-STERILIZATION NOTE

The Reusable Handle of "Taiwan Surgical" Clip Applier is provided in a non-sterile condition. Be sure to clean and sterilize before using.

Clean

- Remove the disposable Clip Cartridges immediately after the operation.
- Open the cover and rinse the reusable handle piece thoroughly for 1 min. And then the handle should be sock in a neutral enzymatic solution containing 4ml of ENDOZIME® PREMIUM per Liter of water for 2 min.
- After the soaking cycle, the reusable handle piece should be remove from the neutral enzymatic detergent, and rinsed with regular tap water for 3~4min.
- Check the instrument to ensure it is thoroughly cleaned.

Note:

- Other approved equivalent neutral enzymatic solution may be used. Always follow the manufacturer's instructions regarding concentration of the clean solution, temperature and exposure time.
- Water-soluble Lubricating Agents should be used to preserve the articulation and action of all movable part of the instrument before sterilization.



Sterilization

The Reusable Handle of the product is designed as a reusable function. Taiwan Surgical recommends the following validated sterilization method as a guideline.

-Warning! Make sure that the cartridge is removed before sterilization.

-Suggestion Sterilization Method:

Sterilizer Type	Pre-Vacuum
Minimum Temperature	270°F (132°C)
Cycle Time	4 minutes
Minimum drying time	NA
Configuration	Unwrapped or in sterilization case

Check Before Use

- Check the reusable part for misalignment, bending or dislocation damage.
- Before loaded the Clip Cartridges, squeeze and release handle 5 plus times to check for damage.
- If any breakage of the handle occurs, please contact the local distributor or the manufacturer.

Step 6: Before placing the jaw around the vessel or structure to be occluded, please squeeze the handle gently to fire.	
Step 7: Place the jaw around the vessel or structure to be occluded, please be sure that the vessel or structure fits completely within the confines of the jaw, and close the clip on the vessel or structure.	
Step 8: Release the handle to disengage the clip and remove the applier from the vessel or structure. Repeat the action above for subsequent application.	
Step 9: Once the Cartridge is empty, the yellow Indicator will appear to warn the surgeon. When the yellow indicator appears, do not fire to avoid damage.	
Step 10: Sequence of closure.	
Step 11: If desired, the clip applier could be used to secure a catheter for cholangiography. At a point during closure, the handle is released to allow the clip being remained on the cystic duct. By releasing pressure on the handle, the clip is released from the jaw.	
Disassembly	
Step 12: Pull the push button forward and open the cover on the handle.	
Step 13: Remove the Clip Cartridges from the handle and close the cover.	
Step 14: Be sure to follow the RE-STERILIZATION NOTE to clean and re-sterile the reusable handle.	
Step 15: Discard the disposable Clip Cartridge after using.	

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REF	Catalogue number	LOT	Batch code	STERILE	Sterilized using irradiation	Caution
	Date of manufacture		Manufacturer		Do not re-use	
	Use-by date		Temperature limit		Keep away from sunlight	
	Do not use if package is damaged				Consult instructions for use	
	EC REP Wellkang Ltd. Suite B, 29 Harley Street, LONDON, W1G 9QR, England, United Kingdom Tel: +44(20)32876300 Fax: +44(20)7681874					