

⚠ 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.

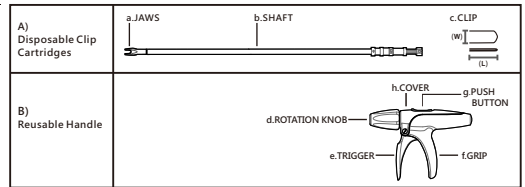
WARNINGS AND PRECAUTIONS

- The Reusable Handle of "Taiwan Surgical" Clip Applier is provided in a non-sterile condition. Be sure to clean and sterile 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.
- 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 140°F (60°C) when product in transportation condition.

PRODUCT DESCRIPTION

The "Taiwan Surgical" Clip Applier is a medical device which consists of a handle piece and the 10, 16 or 20 implantable titanium clips. There are two different outer diameters of shaft of 10mm and 5mm in the product line of "Taiwan Surgical" Clip Applier. Titanium clip size is 5.5 x 9.0 mm and 5.5 x 11 mm for 10mm clip applier, and 4.6 x 9.1 mm for 5mm clip applier respectively. The applier is designed for introduce through applicable trocar sleeves, 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 sterile before using.

Note:

- Other approved equivalent 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.



-Squeeze and release the trigger more than 5 times and rotate the rotational knob to confirm smooth operation of instrument. Inspect instruments for readability of device markings, as applicable, rust, pitting, cracking or burrs, staining or discoloration and worn or broken parts. If any trigger gets stuck or unsmooth rotation occurs, please stop using and contact the local distributor or the manufacturer. Repair or replace any instrument found not to be acceptable.

Manual Cleaning Process

- 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 soak in a solution containing 4ml of ENDOZIME® PREMIUM per Liter of water or 10 ml of Neodisher MediClean Forte per Liter of water for 2 min.
- After the soaking cycle, the reusable handle piece should be remove from the neutral enzymatic detergent or Neodisher MediClean Forte, and rinsed with regular tap water for 3~4min.
- Check the instrument to ensure it is thoroughly cleaned.

Automated Cleaning Process

****Note that the Manual Pre-Cleaning method documented herein is intended to reflect a minimum requirement, this should be conducted before the automated cleaning method.**

- Manual Pre-Cleaning

- Open the cover and remove the Disposable Clip Cartridge.
- Immerse the Reusable Clip Applier handle in cold tap water for at least 5 minutes.
- The surfaces and the inner tube of the Reusable Clip Applier handle must be brushed with a soft nylon brush until no residue is visible.

- Automated Cleaning:
Load the instrument into the automatic washing machine. And confirm the parameters of the automated cleaning method are as above:

Phase	Time (minutes)	Temperature	Detergent
PreWash	2:00	Cold tap water	N/A
Wash1	2:00	65°C	Enzymatic detergent or Neodisher MediClean Forte
Rinse1	00:15	Lukewarm tap water (22-43°C)	N/A
Rinse2	1:00	90°C	N/A
Dry	6:00	88 ± 2°C	N/A

Sterilization

Taiwan Surgical recommends the following validated sterilization method as a guideline:

- Prior to sterilization, a water-soluble lubricant should be used on all movable parts of the instrument.
- Recommended sterilization method:

Sterilizer Type	Pre-Vacuum
Minimum Temperature	270°F (132°C)
Cycle Time	4 minutes
Minimum drying time	30 minutes
Configuration	Wrapped

Check Before Assembly

- Check the reusable part for misalignment, bending or dislocation damage.
- Squeeze and release the trigger more than 5 times and rotate the rotational knob to confirm smooth operation of instrument. Inspect instruments for readability of device markings, as applicable, rust, pitting, cracking or burrs, staining or discoloration and worn or broken parts. If any trigger gets stuck or unsmooth rotation occurs, please stop using and contact the local distributor or the manufacturer. Repair or replace any instrument found not to be acceptable.

SPECIFICATIONS

Model	Description	SHAFT Spec.(D*L)	CLIP Spec.(W*L, Qty)
TRC-TM120	Titanium Clip Cartridge, 20 Clip, ML 10mm	ø10*300mm	5.5*9 mm, 20 Clips
TRC-TM121	Titanium Clip Cartridge, 20 Clip, ML 10mm	ø10*300mm	5.5*9 mm, 20 Clips
TRC-TL120	Titanium Clip Cartridge, 20 Clip, L 10mm	ø10*350 mm	5.5*11 mm, 20 Clips
TRC-TL121	Titanium Clip Cartridge, 20 Clip, L 10mm	ø10*350 mm	5.5*11 mm, 20 Clips
TRC-TM110	Titanium Clip Cartridge, 10 Clip, ML 10mm	ø10*300mm	5.5*9 mm, 10 Clips
TRC-TM111	Titanium Clip Cartridge, 10 Clip, ML 10mm	ø10*300mm	5.5*9 mm, 10 Clips
TRC-TL110	Titanium Clip Cartridge, 10 Clip, L 10mm	ø10*350 mm	5.5*11 mm, 10 Clips
TRC-TL111	Titanium Clip Cartridge, 10 Clip, L 10mm	ø10*350 mm	5.5*11 mm, 10 Clips
RCST1-86	Titanium Clip Cartridge, 16 Clip, ML 5mm	ø5.6*330 mm	4.6*9.1 mm, 16 Clips
RCST1-8X	Titanium Clip Cartridge, 10 Clip, ML 5mm	ø5.6*330 mm	4.6*9.1 mm, 10 Clips
TRC-HTM12	Reusable Clip Applier Handle with Titanium Clip Cartridge, 20 Clip, ML 10mm	ø10*300mm	5.5*9 mm, 20 Clips
TRC-HTM13	Reusable Clip Applier Handle with Titanium Clip Cartridge, 20 Clip, ML 10mm	ø10*300mm	5.5*9 mm, 20 Clips
TRC-HTL12	Reusable Clip Applier Handle with Titanium Clip Cartridge, 20 Clip, L 10mm	ø10*350 mm	5.5*11 mm, 20 Clips
TRC-HTL13	Reusable Clip Applier Handle with Titanium Clip Cartridge, 20 Clip, L 10mm	ø10*350 mm	5.5*11 mm, 20 Clips
TRC-HTM11	Reusable Clip Applier Handle with Titanium Clip Cartridge, 10 Clip, ML 10mm	ø10*300mm	5.5*9 mm, 10 Clips
TRC-HTM14	Reusable Clip Applier Handle with Titanium Clip Cartridge, 10 Clip, ML 10mm	ø10*300mm	5.5*9 mm, 10 Clips
TRC-HTL11	Reusable Clip Applier Handle with Titanium Clip Cartridge, 10 Clip, L 10mm	ø10*350 mm	5.5*11 mm, 10 Clips
TRC-HTL14	Reusable Clip Applier Handle with Titanium Clip Cartridge, 10 Clip, L 10mm	ø10*350 mm	5.5*11 mm, 10 Clips
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.	
Clousure	
Step 4: When inserting or removing the clip applier through the trocar sleeve, please be sure that no clip is loaded in the jaw.	
Note: Upon insertion of the "Taiwan Surgical" Clip Applier through the trocar sleeve and prior to loading a clip into the jaw, ensure that the demarcation printed on the distal end of the applier shaft is fully visible. This indicates that the device jaws are clear of interference from the trocar sleeve.	
Step 5: The shaft is 360° rotatable in either direction. Please adjust the jaw for maximum visibility by turning the rotation knob.	

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: Withdraw the clip applier through the trocar sleeve.	
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-sterilize the reusable handle.	
Step 15: Discard the disposable Clip Cartridge after using.	

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REF	Catalogue number	LOT	Batch code	SN	Serial Number	⚠	Caution
	Date of manufacture		Manufacturer		Sterilized using irradiation		Do not re-sterilize
	Use-by date		Keep dry		Keep away from sunlight		Do not re-use
	Do not use if package is damaged			Consult instructions for use			Temperature limit
		MDSS GmbH Schifflgraben 41, 38175 Hannover, Germany Tel.: +49 511 6582 9830 Fax: +49 511 6242 8623					