

## Instructions for Use

**BEFORE USING PRODUCT, PLEASE READ THE FOLLOWING INFORMATION THOROUGHLY.**

**IMPORTANT!**

- This Instruction for Use is to assist in using "Taiwan Surgical" Disposable Clip Applier, not a reference to surgical techniques.
- Do not reuse, reprocess or re-sterilize the device.
- The device is designed, tested and manufactured for single-use. Re-sterile or reuse the 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**

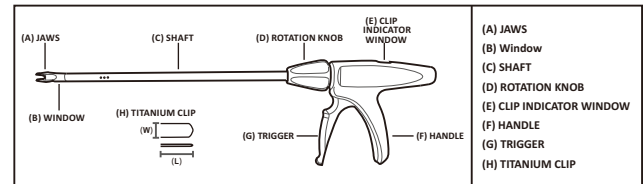
- When removing the clip applier through the applicable size trocar sleeve, or larger sized sleeve, be sure that a clip occludes the vessel well to avoid the open clip dropping in the body.
- Before squeezing the handle to place a clip, please be sure that it will be positioned free of other clips or 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 malfunction 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.
- Please do not twist the jaws excessively or try to lift excessive tissue when firing the device.

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- Please do not place an empty jaw or load a clip into the device while the jaw is around tissue.
- Please do not use the device for dissecting tissue.
- Please Store the device at room temperature. Avoid prolonged exposure to elevated temperatures.
- Do not expose to temperatures above 140°F, (60°C) when transporting.
- If need to use endoscopy device from difference companies in the same surgical procedure, please verify its compatibility before surgery.
- The device has sterilized, and is for single use, do not reuse and resterilize. Do not use if the package has been damaged or opened. Reuse or resterilize the device may result in clip malfunction and infection of patients.
- This device is obtainable only on a physician's prescription.
- It should be noted the magnetic fields influences when using this device.
- 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.
- Caution should be exercised when utilizing electrosurgical techniques such as electrocautery or electrocoagulation in the vicinity of any metallic clip. Inadvertent contact with a metallic clip by the energized electrosurgical device may cause unintentional cauterization or electrocoagulation at or around the clip site which may cause necrosis of the affected tissue. Dislodgement of the clip may occur, resulting in loss of hemostasis or leakage.
- The device is MR conditional. A patient with these devices can be safely scanned in an MR system meeting the following conditions:
  - Static magnetic field of 3 Tesla or less;
  - Maximum spatial field gradient of 3.25 Tesla/meter.

**DESCRIPTION**

The "Taiwan Surgical" Disposable Clip Applier is a medical device which consists of a handle piece and 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" Disposable 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**

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**OPERATION NOTE**

<p><b>STEP 1</b></p> <p>When inserting the clip applier through the trocar sleeve, please be sure that no clip is loaded in the jaw.</p>	
<p><b>Note:</b></p> <p>Upon insertion of the "Taiwan Surgical" 5mm Disposable 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.</p>	
<p><b>STEP 2</b></p> <p>The shaft is 360° rotatable in either direction. Please adjust the jaw for maximum visibility by turning the rotation knob.</p>	
<p><b>STEP 3</b></p> <p>Before placing the jaw around the vessel or structure to be occluded, please squeeze the handle gently to load.</p>	
<p><b>STEP 4</b></p> <p>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.</p>	
<p><b>STEP 5</b></p> <p>Release the handle to disengage the clip and remove the applier from the vessel or structure. Repeat the action above for subsequent application.</p>	
<p><b>STEP 6</b></p> <p>Once the cartridge is empty, the window will show "0", and the yellow indicator will appear to warn the surgeon. When the window show "0" and the yellow indicator appears, do not fire to avoid damage.</p>	
<p><b>STEP 7</b></p> <p>If desired, the clip applier could be used to secure a catheter for cholangiography.</p>	

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**SPECIFICATIONS**

MODEL	ILLUSTRATION	CLIP DIMENSIONS (W <sub>out</sub> /W <sub>in</sub> )	APPROXIMATE CLOSURE (L)	CLIP QUANTITY	APPROXIMATE SHAFT SIZE
TDC-10-ML		5.5/ 4.3 mm	9 mm	20 clips	Ø10* 300 mm
TDC-10-L		5.5/ 4.3 mm	11 mm	20 clips	Ø10* 350 mm
DCST1-B6		4.6/ 3.6 mm	9.1 mm	16 clips	Ø5.6* 330 mm
DCST1-BX		4.6/ 3.6 mm	9.1 mm	10 clips	Ø5.6* 330 mm

**Taiwan Surgical Corporation**

3F., No. 12, Sec. 2, Sheng Yi Rd., Zhubei City, Hsinchu County 30261, Taiwan  
 Tel: +886 3 6588129 Fax: +886 3 6588355  
<http://www.twsc.com.tw>

	Catalogue number		Batch code		Sterilized using irradiation
	Date of manufacture		Manufacturer		Caution
	Use-by date		Do not re-use		Do not re-sterilize.
	Temperature limit		Keep dry		Keep away from sunlight
	Do not use if package is damaged				Consult instructions for use
	The device is MR Conditional (no hazards in specified MRI environment)				This device to prescription only
		MDSS GmbH Schiffgraben 41, 30175 Hannover, Germany			
<b>0123</b>					

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