
User Manual

For

Disposable Laparoscopic Trocar Kits

Important Information to Customers

Important Tip

This user manual describes the correct operation and maintenance of the Disposable Laparoscopic Trocar Kits manufactured by Changzhou Tongchuang Medical Instrument Technology Co., Ltd. Any incorrect operation during use may cause instrument damage or personnel injury. Tongchuang will not be responsible for any personnel injury or instrument damage caused by incorrect use of the instrument. Please read all the instructions, warnings and precautions provided in this manual, and do not attempt to operate the instrument before fully reading and understanding the instructions.

Intended Use

The Disposable Laparoscopic Trocar Kits are used in minimally invasive surgery to create surgical channels for surgical instruments.

Intended Clinical Benefits

- Better maintenance of pneumoperitoneum during operation.
- The bladeless structure can effectively prevent tissue injuries in the affected area.
- Minimally invasive wound.

Indications

The Disposable Laparoscopic Trocar Kits are intended for use in a variety of gynecologic, general, and urologic endoscopic procedures to create and maintain a port of entry.

Contraindications

- This device is not intended for use when endoscopic techniques are contraindicated.
- This device is not intended for use except as indicated.

Potential side-effects

- Trocar site infection;
- Trocar site bleeding, or abdominal wall vessel bleeding;
- Intra-abdominal vascular or visceral injuries;
- perforation
- pneumothorax
- Wound seroma
- Chylothorax
- hemotomas

Device Description

Product Introduction

The Disposable Laparoscopic Trocar Kits contain multiple single Disposable Laparoscopic Trocar. Disposable Laparoscopic Trocar is a sterile single patient use instrument consisting of two main parts, a sleeve and an obturator in sizes 5 mm, 10 mm and 12 mm diameter. The obturators in sizes 10 mm and 12 mm contains a clear, tapered optical element, and accommodate an appropriately sized 0° endoscope and provide visibility of individual tissue layers during insertion. A stopcock valve is compatible with standard luer lock fittings and provides attachment for gas insufflation and desufflation. The stopcock is in the closed position when it is parallel to the sleeve.

Please see Table 1 for models of Disposable Laparoscopic Trocar Kits. The illustration of each parts are shown in Table 2. The dimensions are shown in Table 3.

Table 1 Models of Disposable Laparoscopic Trocar Kits

Model	Model of single Disposable Laparoscopic Trocar	Main parts	Quantity (pc/s)
A1 Model	TCCA5M	Obturator	1
		Sleeve	2
	TCCA10M	Obturator	1
		Sleeve	2
A2 Model	TCCA5M	Obturator	1
		Sleeve	2
	TCCA10M	Obturator	1
		Sleeve	1
A3 Model	TCCA5M	Obturator	1
		Sleeve	3
	TCCA10M	Obturator	1
		Sleeve	1
A4 Model	TCCA5M	Obturator	1
		Sleeve	1
	TCCA10M	Obturator	1
		Sleeve	2
A5 Model	TCCA5M	Obturator	1
		Sleeve	2
	TCCA12M	Obturator	1
		Sleeve	2
A6 Model	TCCA5M	Obturator	1
		Sleeve	2
A7 Model	TCCA10M	Obturator	1
		Sleeve	2
A8 Model	TCCA5M	Obturator	1
		Sleeve	1
	TCCA12M	Obturator	1
		Sleeve	2
A9 Model	TCCA5M	Obturator	1
		Sleeve	2
	TCCA10M	Obturator	1
		Sleeve	1
	TCCA12M	Obturator	1
		Sleeve	1

Table 2 Illustration of each part

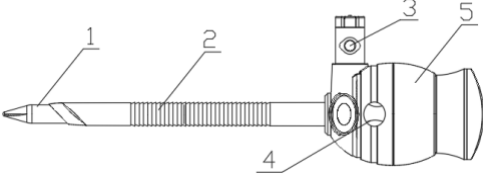
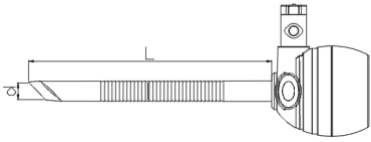
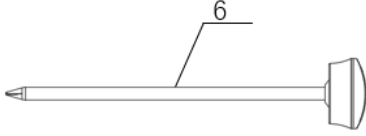
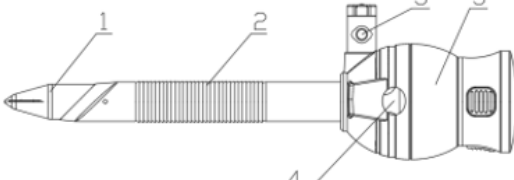
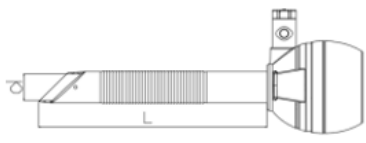
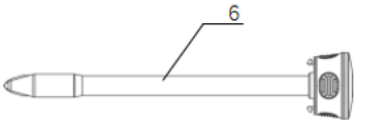
No.	Name	Drawings	Illustrations
1	TCCA5M		<ol style="list-style-type: none"> 1. Obturator 2. Sleeve 3. Gas injection valve 4. Choke valve 5. Sealing cap 6. Puncture rod
			
			
2	TCCA10M TCCA12M		<ol style="list-style-type: none"> 1. Obturator 2. Sleeve 3. Gas injection valve 4. Choke valve 5. Sealing cap 6. Puncture rod
			
			

Table 3 Basic dimensions of Disposable Laparoscopic Trocar (Unit: mm)

Model	Inner diameter of puncture sleeve	Length of puncture sleeve
TCCA5M	5.8+0.3	100±2.0
TCCA10M	10.8+0.3	108±2.0
TCCA12M	12.8+0.3	108±2.0

Shelf Life

3 years

Sterilization method

Ethylene Oxide Sterilized

Instruction for use

This device may be used with or without visualization for primary and secondary insertions.

(1) Sleeve and obturator are packaged side by side. Prior to insertion of laparoscope, insert obturator into sleeve until the interlocking snap feature is engaged.

(2) Connect the appropriately sized 0° laparoscope to the light supply and monitor as directed in the manufacturer's instructions. Verify proper connection of the laparoscope and ensure the clarity of the picture on the monitor. Insert laparoscope into the obturator housing until it reaches the distal end of the obturator.

(3) To provide a clear image on the monitor, once the laparoscope is inserted into the obturator, touch the tip of the distal end of the obturator to a convenient soft sterile surface, and focus the camera.

(4) Insufflation of the abdomen prior to the insertion of the trocar is at the discretion of the surgeon as determined by the conditions of each case. The potential for abdominal adhesions or anatomical anomalies should be considered before using this device without first establishing pneumoperitoneum.

(5) Prepare the abdominal or for trocar insertion by making an incision adequate to accommodate the sleeve diameter.

An insufficient incision may cause increased penetration force which may reduce the surgeon's control during entry. An incision too large may increase the potential for port instability.

WARNING: The failure to make an adequate incision, the application of excessive force or incorrect insertion may increase the risk of injury to internal structures.

(6) Position the trocar assembly at the appropriate angle to the abdomen and while maintaining compression on the obturator, introduce the trocar assembly through the skin incision utilizing a clocking motion, applying continuous downward pressure.

(7) When the trocar assembly is in the desired position within the abdominal, remove the obturator from the trocar sleeve by depressing the interlocking snaps, leaving the sleeve in place, remove the laparoscope from the obturator.

(8) Reinsert the laparoscope through the port to facilitate visualization of secondary port entry into the abdominal cavity.

If no laparoscope is required, appropriately sized endoscopic instruments may now be inserted and removed through the trocar sleeve.

WARNING: To prevent damage to the seal system, follow manufacturer's instructions when inserting or removing instrumentation utilizing jaws or components that open and close, ensure that the instrument jaws or components are in the closed position (where applicable).

(9) When the procedure is complete, the abdomen may be desufflated by opening the stopcock. Remove the sleeve from the operative site. A twisting motion while pulling axially on the port will facilitate removal of the fixation sleeve.

WARNING: Before and after removal of the trocar from the abdominal, inspect the site for hemostasis. Bleeding may be controlled by electrocautery or manual sutures.

Warnings and Precautions

1. Failure to establish and maintain appropriate pneumoperitoneum in abdominal procedures may reduce available free space, increasing the risk of injury to internal structures.

2. Endoscopic procedures should be performed only by physicians having adequate training and familiarity with endoscopic techniques. Medical literature relative to techniques, complications and hazards should be consulted prior to use.

3. An insufficient skin incision may cause increased penetration force which may reduce the surgeon's control during entry. An incision too large may increase the potential for port instability.

4. The features in the distal end of the obturator are intended to minimize the likelihood of penetrating injury to intra-abdominal structures, however, standard precautionary measures employed in all obturator insertions must be observed.

5. Before and after removal of the trocar from the abdominal, inspect the site for hemostasis. Bleeding may be controlled by electrocautery or manual sutures.
6. Before endoscopic instruments and accessories from different manufacturers are used, verify compatibility and ensure that electrical isolation or grounding is not compromised.
7. A thorough understanding of the principles and techniques involved in laser laparoscopy and electrosurgical procedures is essential to avoid shock and burn hazards to both patient and operator(s), and damage to the instrument.
8. Closure of the fascia is at the discretion of the surgeon. Underlying fascia may be closed, e.g., by suturing to reduce the potential for incisional hernias.
9. Use care when introducing or removing sharp-edged or sharp-angled endoscopic instruments to minimize the potential of inadvertent damage to the seal.
10. In abdominal procedures, the incorrect perpendicular trocar insertion (depicted by the crossed-out trocar in the illustration) could result in an aortic puncture.
11. This device is provided STERILE and is intended for use in a SINGLE procedure only. DISCARD AFTER USE. DO NOT RESTERILIZE.
12. The user and/or patient that any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

Storage and Supplied

- Storage: Store in a well-ventilated room with relative humidity not higher than 90%, and no corrosive gas.
- Transportation: Properly packaged products can be transported by normal tools, and should be handled with care. Protected from direct sunlight, violent collision, rain and gravity extrusion.







Conditions	Transportation	Storage
Temperature	-35°C ~ +60°C (-31F ~ 140F)	-35°C ~ +60°C (-31F ~ 140F)
Humidity	≤ 90% RH	≤ 90% RH













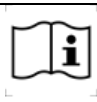






Disposal

For specific disposal methods, refer to the local laws and regulations on waste Disposable Laparoscopic Trocar Kits.

Symbol Description

The following is a list of the symbols used on the device and labels:

Symbol	Definition of Symbols
	Sterilized using Ethylene Oxide
	Catalogue Number
	Batch code
	Date of Manufacture
	Manufacturer
	Do not re-use

	Fragile, handle with care
	This way up
	Keep dry
	Keep away from sunlight
	Stacking limit
	Do not use if the packing is damaged
	Use-by date
	Caution
	Temperature Limit
	Humidity Limitation
	Do not re-sterilize
	Single sterile barrier system
	Consult instructions for use
	Medical Device
	Unique device Identifier
	European union approval
	Caution: Federal law prohibits dispensing without prescription
	Authorized representative in the European Community
	Manufacturer's serial number to identify a specific medical device



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