Optcla®

Reusable Trocar

Instructions for Use

221-51215	221-01215	221-51225	221-51125	221-81225
221-81125	221-51235	221-01235	221-51135	221-01135
221-01245	221-81245	221-51145	221-01145	221-81145
221-01115	221-01225	221-01125	221-51245	221-51115

STATEMENT

Hangzhou Optcla Medical Instrument Co., Ltd. (Hereinafter referred to as Optcla) owns the intellectual property rights to this product and this manual. Disclosure of the information in this manual in any manner whatsoever without the written permission of Optcla is strictly forbidden. This manual provides the instructions necessary to operate the product in accordance with its function and intended use. Observance of this manual is a prerequisite for proper performance and correct operation, and ensures patient and operator safety. Optcla is responsible for safety, reliability and performance of this product only in the condition that:

- This product is operated under strict observance of this manual.
- This product is not damaged by human factors. Human factors refer to unintentional falling, intentional damaging, etc.

In the event that it becomes necessary to return a unit to Optcla, please contact the Optcla Service Department. Please provide the model number, batch code, and a brief description of the reason for return. The customer is responsible for freight charges when this product is shipped to Optcla for service (including any relevant customs fees or other freight related charges).

For this operator's manual, the issued date is 2021-01 (version:2.0)

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Intended Use

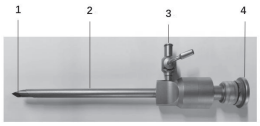
This instrument is used in clinical laparoscopic surgery in the hospital to establish access to the abdominal cavity for the instrument.

Contraindications for Use

Contraindications: coagulation function disorder, pregnant women and cardiac and pulmonary function disorder.

Product Description

- Structural diagram of the product appearance:



1.Trocar head 2. Casing tube 3. Gas injection valve 4.Needle file

- Specifications: φ5X95mm, φ10X95mm, φ12X95mm.
- The instruments are shipped non-sterile. To prevent infection, the instruments must be cleaned and sterilized by the user prior to use.

WARNING

- Please read this Instructions carefully before using this product.
- The violations against or deviations from the Instructions may bring harm to the patient.
- The instrument should only be used by medical practitioners or specialized medical staff that have received operational training.
- The instrument should be prevented from the compression, stacking impacting and bumping to avoid deformity and damage.
- Before each use, the instrument must be checked for the presence of a rough surface, sharp edges or protrusion causing injury in the part that is inserted in human body.
- Before each use, the instrument must be checked for the presence of a rough surface, sharp edges or protrusions causing injury in the part that is inserted into the human body.
- The accessories used in combination with the instrument must be compatible with the instrument.

CAUTION

- The product's tension tolerance is limited, and excessive force may cause the device to break or function damage and endanger the patient.

NOTE

- After the use for a year, the instrument is better checked and maintained once comprehensively by the manufacturer. In case of being unusable due to instrument aging, it is necessary to take measures to perform

maintenance, or discard as useless to avoid failure in surgery or endanger the patient.

- After being discarded as useless, the instrument is disposed of according to the waste disposal method of the hospital to avoid contamination to the environment.
- The surface and inner materials of the metal part of the device should be consistent.

Instructions for Use

- Make sure the product has been cleaned and sterilized prior to the first use and after every subsequent use.
- Inspect the instrument for overall condition and physical integrity. Do not use the instrument if any damage is noted.

Clean, Disinfection and Sterilization

- Clean: We recommend using the ultrasonic cleaning method to clean the instrument.
- Disinfection: It is recommended to be disinfected by 2% alkaline glutaraldehyde. Please follow the instruction of disinfectant manufacturer.
- Sterilization: We recommend using the steam sterilization. the sterilization parameter listed below:

Sterilization Method	Product Category	Temperature	The Minimum Time	Pressure
Gravity Cycle	Appliance	121℃	30 Min	102.9 Kpa
Pre Vacuum Steam Cycle	Appliance	132~134℃	4 Min	205.8 Kpa

Storage

- Stored in controlled environment, which is kept away from the sun, rats, fire, insects and caustic gas, as well as with good ventilation.
- Storage temperature range: -20℃～50℃, relative humidity range: 10%～80%.

Symbol Description

Table 1 Symbol Definition

Optcla®	Trademark of manufacture	LOT	Batch Code	50KG	Stacking limit by mass
	Manufacturer	EC REP	Authorized representative in the European		Keep away from sunlight
REF	Catalogue Number		Fragile,handle with care		Keep Dry
	Caution		Temperature limit		This way up
CE	Labelling for Class I products. Developed and marketed in compliance with medical device directive 93/42/EEC.				Consult instructions for use

Table 2 Definition of Safety Notes

Safety Notes	Meaning
WARNING	Read the statement below the symbol. The statement alerts you to an operating hazard that can cause personnel injury.
CAUTION	Read the statement below the symbol. The statement alerts you to possible damage to the device or other property.
NOTE	Read the statement below the symbol. The information is quite important that you should notice prior to the surgery.