Document No.: BR-CCQ-J-30, Version: A

Safety and Performance Information for:

Disposable Laparoscopic Trocar

Model: BR-CCQ-05-10, BR-CCQ-08-10
BR-CCQ-10-10, BR-CCQ-12-10

1. Important Note for Users

1.1 General Description of the Product

The disposable laparoscopic trocar is a sterile single use instrument consisting of a sleeve and trocar pin in sizes 5mm, 8mm, 10mm and 12mm diameter. All the trocars are available with standard lengths of 100mm.

1.2 Principles of operation

During the operation, the trocar sleeve and the trocar pin are used together. A skin incision is cut in the appropriate position of the abdomen, the surgeon uses the trocar pin to insert into the incision of the abdomen and penetrates the trocar sleeve through the abdominal surface of the human body into the abdominal cavity, thereby delivering gas to the abdominal cavity and establishing a path of entry for endoscopic instruments.

The trocar sealing system includes sealing cap and choke valve, which can prevent gas leakage when the device inserted or removed, and maintain the pressure stabilizer system in the abdominal cavity.

The trocar air injection valve is intended to be used together with the insufflator to inject air, replenish air or stabilize pressure during surgery.

1.3 Intended use/Indication for Use

The disposable laparoscopic trocar has applications in abdominal, thoracic, and gynecologic minimally invasive surgical procedures to establish a path of entry for endoscopic instruments.

1.4 Contraindications

This device is not intended for use when minimally invasive techniques are contraindicated.

1.5 Patient Target Group

Abdominal, thoracic, and gynecologic minimally invasive surgery patients.

1.6 Intended Users

A professional doctor who has experienced formal professional and technical training and has

operational qualifications.

1.7 Clinical Benefits

Work as an auxiliary path for endoscopes and endotherapy devices to enter into the body.

1.8 Combinations of Other Devices and Equipment

The air injection valve is equipment with a standard female Luer lock connector, which can be used in combination with a gas insufflator through a pneumoperitoneum tube equipped with a standard male Luer connector to inject gas, replenish gas or stabilize pressure during clinical application.

2. Safety Information

2.1 Warnings and Precautions

1. Please read this IFU carefully before use, and operate according to this IFU!

2. Minimally invasive procedures should be performed only by persons having adequate training and familiarity with minimally invasive techniques. Consult medical literature relative to techniques, complications, and hazards prior to performance of any minimally invasive procedure.

3. A thorough understanding of the principles and techniques involved in laser, electrosurgical, and ultrasonic procedures is essential to avoid shock and burn hazards to both patient and medical personnel and damage to the device or other medical instruments. Ensure that electrical insulation or grounding is not compromised. Do not immerse electrosurgical instruments in liquid unless the instruments are designed and labeled to be immersed.

4. This device must be used only by professional persons with formal professional technical training and operating qualifications. Non-medical staffs are strictly forbidden to open the package or use this device!

5. Please confirm that there is no damage or abnormality in the product before use. It is strictly prohibited to use if the sterile package is damp, damaged or unintentionally opened!

6. Before using this device, the outer surface of device should be checked to ensure that there are no unintended foreign objects, rough surfaces, sharp edges or protrusions which may cause harm.

7. Minimally invasive instruments may vary in diameter from manufacturer to manufacturer. Before using this device, it is necessary to confirm that all devices and its accessories are compatible. There is no guarantee that instruments selected solely using working length and minimum instrument channel width will be compatible in combination.

8. Using minimally invasive instruments with a diameter smaller than specified for the trocar may result in desufflation of the abdominal cavity.

9. Before inserting this device, please prepare the surgery according to the correct surgical method, the standard precautionary measures employed in all trocar insertions must be observed.

10. Although this device has a blunt tip, care must still be taken, as with all trocars, to avoid damage to major vessels and other anatomic structures (such as bowel or mesentery). To minimize the risk of such injury, be sure to:

- Establish adequate pneumoperitoneum;
- Properly position the patient to help displace organs out of the area of penetration;
- Note important anatomical landmarks;
- Direct the trocar tip away from major vessels and structures;
- Do not use excessive force.

11. Once partial entry has been accomplished, very little pressure may be required to complete entry. Excessive pressure could cause injury to intra-abdominal or intra-thoracic structures.

12. Once complete entry has been made into the abdominal or thoracic cavity, the trocar should not be advanced for additional penetration. Continued entry of the device at this point could cause injury to intra-abdominal or intra-thoracic structures.

13. Use caution when introducing or removing instruments or prosthetic mesh through the trocar sleeve in order to prevent inadvertent damage to the seals which could result in loss of pneumoperitoneum. Special care should be used when inserting sharp or angled edged endoscopic instruments to prevent tearing the seal.

14. After removing the trocar from the cavity, always inspect the site for hemostasis. Bleeding can be controlled by electrocautery or surgical sutures.

15. Instruments or devices which come into contact with bodily fluids may require special disposal handling to prevent biological contamination.

16. Dispose of all opened instruments whether used or unused according to local medical waste disposal methods.

17. This device is sterilized by EO, and for single use only. Do not reuse, reprocess or resterilize this device. Reuse, reprocessing or resterilization may alter the structural and/or functional integrity of this device which may result in patient injury, infection, illness or death. Risk of residual contamination and resterilization failure may leas to patient injury, infection, illness or death.

18. Please do not use after the expiration date!

19. User and the patient to report any serious incident that has occurred in relation to this device to the manufacturer and the authority having jurisdiction in their locale.

20. The user can contact to the manufacturer to obtain authorized service.

2.2 Storage and Transport

The product should be stored in a indoor environment with room temperature, a relative humidity of no more than 80%, no corrosive gas, good ventilation and avoiding high temperature, humidity, direct sunlight.

The product should be transported at a temperature of -10°C to 45°C, a relative humidity of no more than 90%, and keep away from heavy pressure, direct sunlight, rain and snow during transportation.

3. Performance Characteristics

1. The air injection valve connector meets the requirements specified in EN ISO 80369-7:2021.

2. The basic dimension of the trocar meets the requirements specified in the following table:

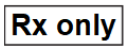
Basic dimension of trocar Unit: mm

Model/ specification	Trocar sleeve nominal diameter Φ	Trocar sleeve inner diameter d (Minimum instrument channel)	Trocar sleeve working length L
BR-CCQ-05-10	5	6.00~6.30	100±2.0
BR-CCQ-08-10	8	9.00~9.30	100±2.0
BR-CCQ-10-10	10	11.00~11.30	100±2.0
BR-CCQ-12-10	12	13.00~13.30	100±2.0

3. The match between trocar sleeve and trocar pin should be good, and there should be no stuck during interaction.

4. Symbols Description

Medical device



This device to sale by or on the order of a physician

Model number

Batch code

Unique device identifier


Date of manufacture


Use-by date


Caution


Consult Instructions for Use


Manufacturer

Authorized representative


Do not re-use


Do not use if package is damage


CE marking


Key dry


Keep away from sunlight


Humidity limitation

Stacking limit by number

Sterilized using ethylene oxide, single sterile barrier system