Disposable Endoscopy Surgical Instruments

Disposable LESS Port Instructions for use

STATEMENT

Hangzhou Mindray Medical Technology Co., Ltd. (Hereinafter called Mindray) owns the intellectual property rights to this product and this manual. Disclosure of the information in this manual in any manner whatsoever without thewrittenpermission of Mindray is strictly forbidden. This manual provides the instructions necessary to operate the product in accordance with its function and intended use. Observance of th0is manual is a prerequisite for proper performance and correct operation, and ensures patient and operator safety. Mindray 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 Mindray, please contact the Mindray Service Department. Please provide the model number, batchcode, and a brief description of the reason for return. The customer is responsible for freight charges when this product is shipped to Mindray for service (including any relevant customs fees or other freight related charges).

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- **Product model and specification**

Number	Model	Specification
1	191-JQST4C635	φ60
2	191-JYST4C635	φ60
3	191-JQST4C835	φ80
4	191-JGST4C825	φ80
5	191-JGST4C815	φ80
6	191-JYST4C835	φ80
7	191-JQGJ4C835	φ80
8	191-JGGJ4C825	φ80
9	191-JGGJ4C815	φ80
10	191-JYGJ4C835	φ80

- **Intended purpose**

Disposable LESS Port: It is a single-use auxiliary device for surgical treatment. It applies to the minimally invasive single-incision endoscopic surgery, and supplies paths for endoscope, clamp and scissors to enter into or out from the incision and for surgical operations and transporting CO2 gas into abdominal cavity. And it is intended for patients who undergo laparoscopic surgery.

- **Intended users**

The instrument should only be used by medical practitioners or specialized medical staff who have received operational training.

- **Intended patient population**

It is mainly used for patients undergoing laparoscopic surgery. Adults and children are intended patient population.

- **Intended medical conditions**

It is mainly used in medical institutions for patients undergoing laparoscopic surgery.

Operational Conditions:

Ambient temperature: 5℃~ + 40℃

Relative humidity: 10%~80% (no condensation)

Atmospheric pressure: 700 hPa~1060 hPa

- **Indications**

It is suitable for patients who requiring endoscopic surgery.

- **Contraindications**

1. Patients with severe cardiovascular disease, or with cardiac dysfunction，or with low lung function.

2. Patients with disturbance of blood coagulation, or with hematologic disease, or with predominant ascites, or with entorrhagia.

3. Patients with severe intestinal inflation, or with obesity, or with a history of several laparotomy.

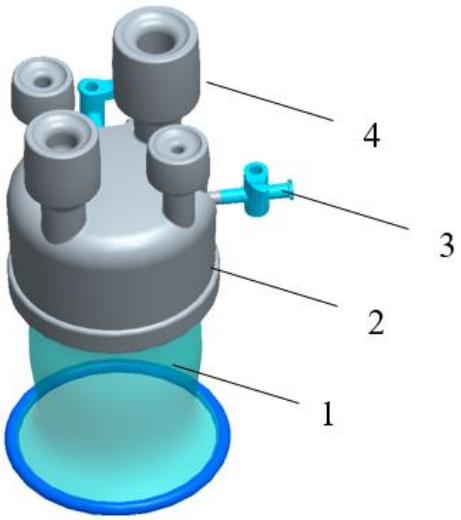
- **Side-effects**

Incisional hernia .

- **Intended Clinical Benefits**

The main clinical benefit of LESS port is the reduction of wound infection.

- **Structural composition of product**



1. Protective sleeve(include wandering ring)
2. Porous operating platform (include hoop knob,hoop connecting rod, hoop body)
3. smoke exhaust pipe
4. puncture cannula

■ **Product performance**

1. The product is sterile and disposable.
2. EO residual：The average daily dose for the patient should not exceed 0.6mg.
3. The materials in contact with the patient should comply with the requirements for biocompatibility.

■ **Sterilization method**

This product is sterilized with ethylene oxide.

■ **Method of application (**191-xxSTxxxx5, 191-xxGJxxxx5**)**

1. Preparation before operation

1) Inspect the product packaging and confirm that the packaging is free from damage before use;

2) Inspect the appearance, model and specification of the product;

3) Take out the product from the package according to the sterile operating procedures;

2. Operation

1) Placement of incision protective sleeve

① Knead the inner ring of the incision protective sleeve flat and in long-tongue shape and pushed it into the incision and the elastic inner ring will automatically expand and stick to the inner wall of the incision. (If there is a transvaginal ring, install it on the incision protective casing before accessing the incision)

② Pinch the positions on both sides of the outer ring with both hands, gently lift the outer ring upward to expand the protective sleeve at the incision and then roll the outer ring inward with both hands to gradually shorten the sleeve until it is difficult to continue, which will increase the radial expansion force of the sleeve continuously. Then lift it upward slightly and roll it once so that the incision is fully expanded and protected. The outer ring is used as positioning of the multi-channel sealing member. (For the 191-JGGJxxxx5 model, the installation of the protective sleeve is completed by placing the inner ring into the incision)

2) Multi-channel Seal to Sleeve Nest

① Place the porous operation platform of the multi-channel sealing member on the outer ring of the incision protection sleeve, and press and embed it by hands along the circumference of the platform, and then close the ring for reinforcement;

② Connect the insufflator through the vent valve (inlet);

③ Mediate the abdominal pressure according to the surgical requirements and perform instrument operation;

3) Post-operative disassembly

Removal of the multi-channel sealing body: open the hoop to the maximum, and then uncover the circumference of the porous operation platform, and the multi-channel sealing member and the outer ring will be separated.

Removal of incision protective sleeve: If there is a pulling rope, the sleeve can be taken out from the incision by directly pulling the rope until the inner ring is deformed; if without a pulling rope, it can be taken out by pulling out the internal ring with fingers inserted into the incision and clasped on it or by pushing the inner ring from outside of the pipe until it is displaced or by using a hooked appliance to pull out.

- **Combination devices**

This product is applicable to the connection with insufflator for the establishment of insufflator or smoke evacuation. The insufflator interface should meet the luer connector requirements.

- **Date of manufacture:**

see the label.

- **Service life**

3 years.

- **Warning**

1. Do not use it if the primary package is damaged or the shelf life of sterilization is expired.
2. The product is a sterilized disposable product. It is not allowed to be used for a second time. It is prohibited from re-use, re-sterilization and repeated use.
3. Once the product is unpacked, it can only be used in the in-person operation and should not to be used in the next operation.
4. This product can only be used by licensed physicians and trained medical professionals. Violation or deviation of this product may cause harm to patients.

- **Precautions**

1. Please read the manual carefully before use.
2. Prior to surgery, please determine the compatibility of the product with other supporting equipment or accessories.
3. Ensure that the incision protective sleeve and multi-channel sealing body are well connected and ensure the tightness of their chimeras;
4. When the insufflation pressure is too high, adjust it through the vent valve.
5. Prior to each use, it is necessary to inspect whether the part of device inserted into human body has rough surface, sharp edge or protrusion which may cause safety hazard.
6. Do not prematurely open sterile packaging prior to surgery to avoid product sterility failure.
7. Use with caution when introducing or removing instruments through the disposable single-port trocar cannula to avoid inadvertent damage to the sealing system resulting in deflation of the abdomen. When inserting endoscopic instruments with sharp or angled edges, exercise caution to avoid tearing the sealing system.

- **Storage conditions**

The product shall be stored in a clean room which is dark, cool, fire-proof, rat-proof, insect-proof and free from corrosive gas, with good ventilation and relative humidity of not more than 80%.

- **Transportation conditions**

Temperature range: -20℃ ~ 50℃; relative humidity range: 10% ~ 80%; atmospheric pressure: 500hpa-1060hpa.

- **Use environment**

Temperature range: 10℃ ~ 40℃ , relative humidity range: 30% ~ 80%; Atmospheric pressure: 700hpa-1060hpa.

- **Notification of Incident**

As a health care provider, you may report the occurrence of certain events to Hangzhou Mindray Medical Technology Co., Ltd. and possibly to the competent authority of the member state in which the user and / or patient is established.

These events include device-related death and serious injury or illness. In addition, as part of our Quality Assurance Program, Hangzhou Mindray Medical Technology Co., Ltd. requests to be notified of device failures or malfunctions. This information is required to ensure that Hangzhou Mindray Medical Technology Co., Ltd.. provides

only the highest quality products.

- **Disposal**

The products must be decontaminated prior to disposal.

The products must be disposed of in compliance with the local regulations. If you have any questions concerning disposal of the equipment, please contact Mindray.

- **Symbol description**

	Operating instructions		Do not use if package is damaged		Medical Device
	Do not re-use		Do not resterilize		Catalogue Number
	Batch Code		Date of manufacture		Use-by date
	Manufacturer		Authorized representative in the European Community		Sterilized using ethylene oxide
	Temperature Limit		Humidity limitation		Atmospheric pressure limitation
	This way up		Fragile, handle with care		Keep Dry
	Stacking weight limit 50 kg		Keep away from sunlight		Packaging Recycling Label
	Single sterile barrier system		Unique device identifier	mindray	Trademark of manufacture, authorized by Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
	The product is provided with a CE marketing in accordance with regulations stated in Regulation(EU)2017/745 concerning Medical Devices.				