

Beijing Surgerii Robotics Company Limited

Sterile Drape

User Manual



Medical Device



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Chapter 1 Cautions and Warnings

 Warning	1) Please read this User Manual carefully before using this product. 2) Please check the package carefully before use. If it is damaged, do not use it. 3) Before use, please check whether the product is within the validity period. If it exceeds the validity period, do not use it. 4) The aseptic operation specification should be strictly followed when using this product. 5) This product is for single use, do not repeat disinfection, sterilization or reuse. This product should only be use with SHURUI® Endoscopic Surgical System produced by Beijing Surgerii Robotics Company Limited. 6) Reprocessing or reuse of products intended for single-use may result in degraded instrument performance, loss of functionality, or exposure to viral, bacterial, fungal, or prionic pathogens. 7) Any serious incident that has occurred in relation to this device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.
 Caution	1) The purpose of this User Manual is to assist the use of the product, not as a surgical technique reference. 2) The procedures, specifications, and illustrations related to the SHURUI® Endoscopic Surgical System provided in this document may vary based on the specific system configuration. Always refer to the actual system as the primary reference. 3) This product is sterilized by EO and is intended for use as a sterilized product by healthcare professionals qualified in the delivery, preparation, cleaning, sterilization and use of surgical equipment. 4) Please use with care to prevent dropping. 5) This product should be stored in an environment of room temperature, protected from light, clean, well ventilated and free from corrosive gases.

	6) This product should be disposed of according to the relevant regulations on medical waste after use.
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Chapter 2 Basic Product Information

2.1 Product Name

Product name: Sterile Drape

2.2 Structure and Composition

The Sterile Drape is differentiated by model according to its application position on the SHURUI® Endoscopic Surgical System. It is classified into the sterile drape for robotic arms (model SR-ENS-600-D1) and the sterile drape for the column (model SR-ENS-600-D2).

SR-ENS-600-D1 is composed of thermoplastic polyurethane elastomer film, thermoplastic polyurethane elastomer strap, initial positioning adhesive iron piece, instrument adapter and trocar adapter. SR-ENS-600-D2 is composed of thermoplastic polyurethane elastomer film, thermoplastic polyurethane elastomer strap and initial positioning adhesive iron piece.

The sterile drape is provided as sterile after ethylene oxide sterilization and is intended for single-use only. The product has a shelf life of 2 years.

2.3 Product Model

Sterile drape models table

No.	Product Name	Product Model	Description
1	Sterile Drape	SR-ENS-600-D1	Used to wrap around the robotic arm
2		SR-ENS-600-D2	Used to wrap around the column

2.4 Intended Use

This product is used to wrap around the robotic arm and column of SHURUI® Endoscopic Surgical System, to prevent doctors from directly coming into contact with these parts and then later with the patient's surgical site during surgery, thus avoiding potential infections.

2.5 Contraindication

None.

2.6 Product Performance

2.6.1 Appearance

The appearance of each component of the sterile drape should be neat, and the surface should be clean without any damages, odors, or stains. The joining tracks of the sterile drape should be even, firm, and free from wrinkles or folds. The indicative markings on the sterile drape should be clear and visible.

2.6.2 SR-ENS-600-D1 robotic arm sterile drape

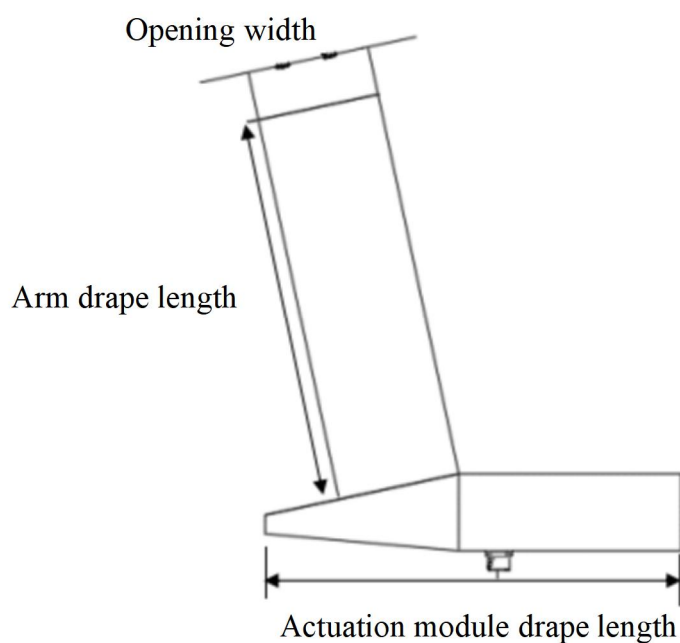


Figure 1 SR-ENS-600-D1 structure diagram

Opening width: 600mm.

Arm drape length: 1700mm.

Actuation module drape length: 1630mm.

2.6.3 SR-ENS-600-D2 column sterile drape

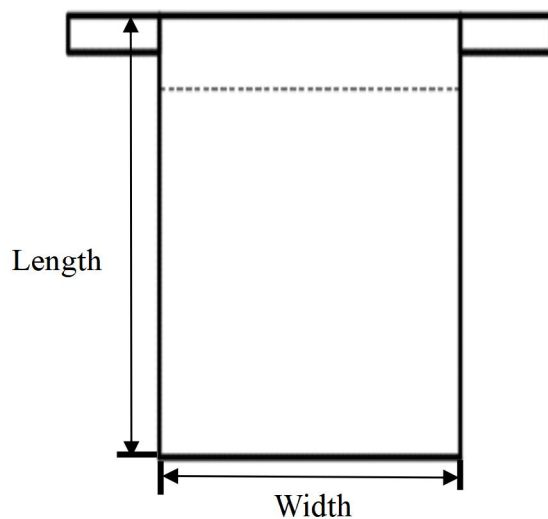


Figure 2 SR-ENS-600-D2 structure diagram

Length: 1350mm.

Width: 1320mm.

2.7 Disposal Information

Dispose following the hospital procedure for processing biologically contaminated materials and all applicable national and local laws and guidelines.

Chapter 3 Instructions for Use

3.1 SR-ENS-600-D1 Sterile Drape

Warning

Before use, inspect the sterile packaging for any damages. If there are any damages, do not use the product.

Please read the user instructions carefully before use.

Caution

The entire process should be performed by a sterile nurse following aseptic operating procedures. Non-sterile nurses can assist in hooking the closures during the process.

The images in this chapter are only intended to illustrate the installation procedure. When actually using the product, relevant personnel must take appropriate safety precautions before proceeding with the operation.

Caution

If the product accidentally drops on the ground during unpacking or installation, please replace it with a new product for use.

This product should only be use with Endoscopic Surgical System produced by Beijing Surgerii Robotics Company Limited. The robotic arm of the Endoscopic Surgical System is shown below:

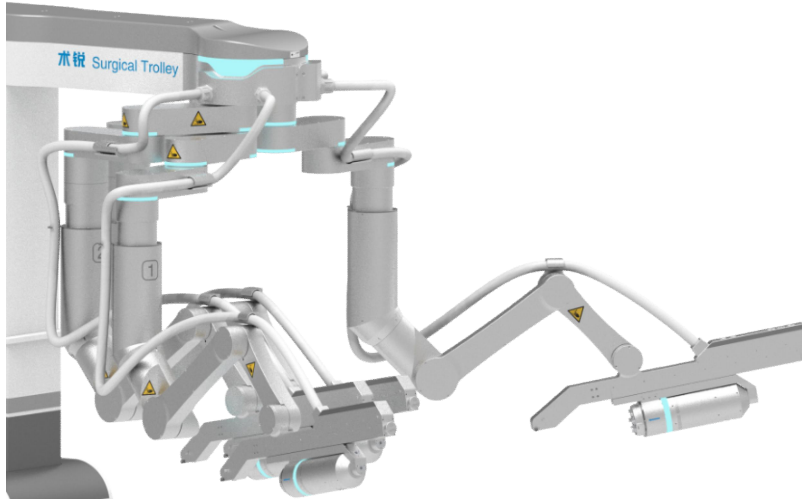


Figure 3 The robotic arm of the Endoscopic Surgical System

SR-ENS-600-D1 sterile drape needs to be installed on four robotic arms of the Endoscopic Surgical System. The installation sequence of the sterile drape is as follows: robotic arm 4, robotic arm 3, robotic arm 2 and robotic arm 1. It needs to be adjusted to the appropriate position before installation begins. The method of installing sterile drape on each arm is the same, so the following describes the installation method of one of the robotic arms.

1. Open the package and take the sterile drape out.



Figure 4 Take the sterile drape out

2. Unfold the sterile drape by tearing open the easy-tear label 1 first, then unfold it with the right hand palm facing upwards.



Figure 5 Tearing off the easy-tear labels and unfold

3. According to the instructions on the palm label, place your hands in the specified positions, and hold the upper and lower parts of the sterile drape with both hands. The right hand should be facing upwards. Slide the opening of the sterile drape over the actuation module at the tail end of the robotic arm.

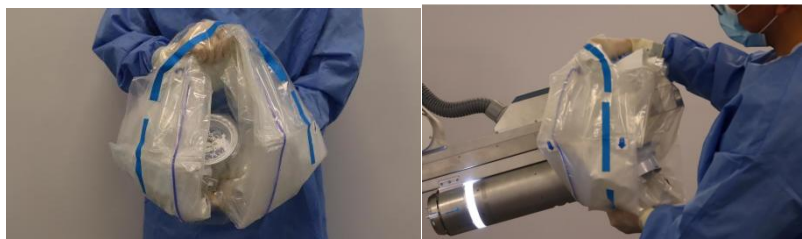


Figure 6 Place the sterile drape over the robotic arm according to the label instructions

4. Push the sterile drape along the actuation module, robotic arm, and small column until it reaches the end, and then fasten the plastic hook at the end closure.



Figure 7 Push the sterile drape and fasten the hook on the end

5. Engage the metal disk on the drape with the magnet on the actuation module

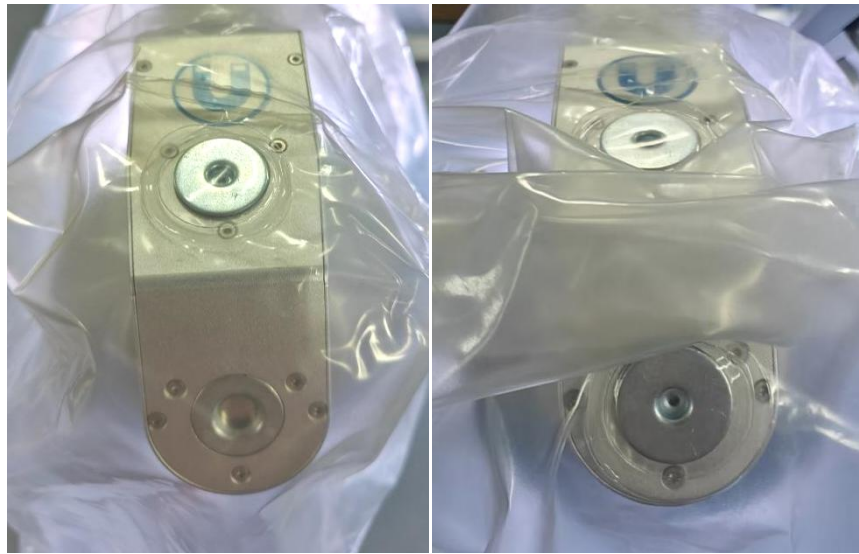


Figure 8 Engaging the metal disk with the magnet

6. Push the trocar adapter into the front slot of the linear module to the bottom (be careful not to clip the film into the gap), then tighten the screws on both sides.

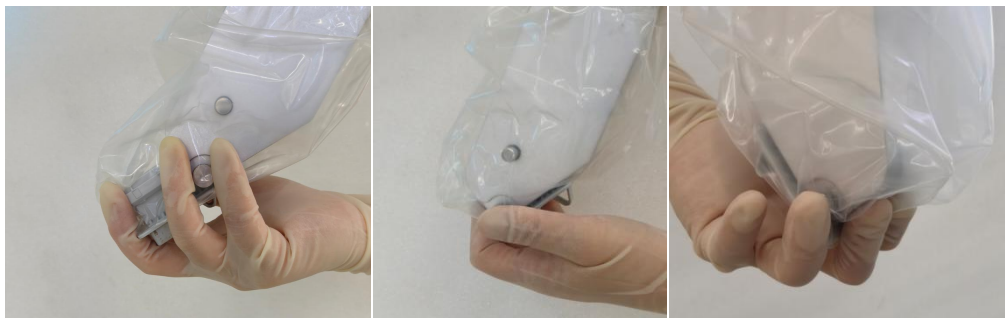


Figure 9 Installing the trocar adapter

7. Adjust the robotic arm to a proper posture, and buckle the instrument adapter into the rotary module according to the direction indicated by the sign. After installation, the actuation module's LED status indicator will have a green flashing prompt. Then remove the positioning clamp and zero position holder. and finally long press the button below the rotating module to lock the instrument adapter.

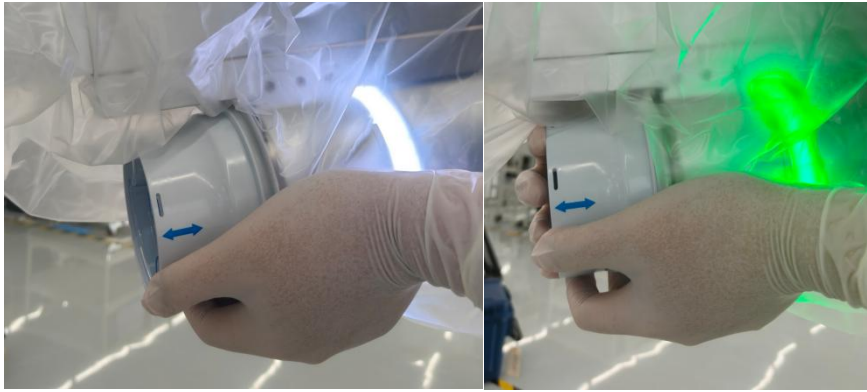


Figure 10 Clap the trocar adapter into the rotating module (the green light will flash when the trocar adapter is in the right position)



Figure 11 Remove the clamp and zero-position holder

8. Fasten the straps. Adjust the tightness of the straps so that the film hanging below does not obstruct the line of sight, but do not fasten the straps tightly around the robotic arm to avoid affecting the arm's movement.



Figure 12 Fasten the straps

9. After the surgery completed, the sterile drape needs to be removed and disposed of as medical waste. Removal method: After loosening the screws on both sides of the trocar adapter, press the button in the circle below to pull out the adapter module and remove the trocar adapter; After the UI is switched to the sterile drape installation interface, long press the button below the rotating module to unlock the instrument adapter, and then pull

out the instrument adapter; Unfasten the straps, unhook the closure at the end, and then remove the entire sterile drape from the arm.



Figure 13 Press the button in the circle below to pull out the trocar adapter

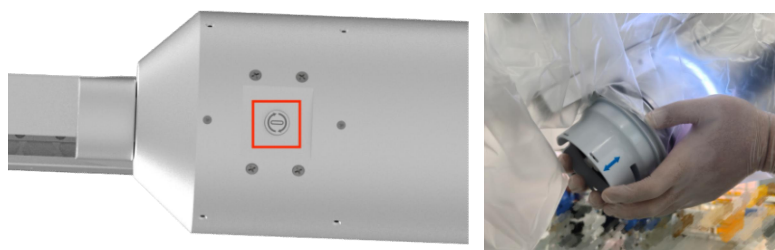


Figure 14 Long press the button below the rotating module to unlock the instrument adapter



Figure 15 Remove the entire sterile drape

3.2 SR-ENS-600-D2 Sterile Drape

Warning

Before use, inspect the sterile packaging for any damages. If there are any damages, do not use the product.

Please read the user instructions carefully before use.

Caution

The entire process should be performed by a sterile nurse following aseptic operating procedures. Non-sterile nurses can assist in hooking the closures during the process.

The images in this chapter are only intended to illustrate the installation procedure. When actually using the product, relevant personnel must take appropriate safety precautions before proceeding with the operation.

Caution

If the product accidentally drops on the ground during unpacking or installation, please replace it with a new product for use.

1. Open the paper-plastic bag, and place the sterile drape with the right palm label facing upwards.



Figure 16 Take the sterile drape out

2. Tear off the easy-tear labels 1 and 2.
3. Put hand into the sterile drape according to the palm label, and then unfold the sterile drape.



Figure 17 Unfold the sterile drape

4. Attached one side of the iron piece to the column and then attached the other side, fasten the straps and complete the installation.



Figure 18 Attach the iron piece to the column



Figure 19 Fasten the straps

5. After the operation is completed, the sterile drape needs to be removed and disposed of as medical waste.

Chapter 4 Manufacturing Information and Storage Condition

4.1 Batch Code

See package label for details.

4.2 Date of Manufacture

See package label for details.

4.3 Validity Period

Two years.

4.4 Storage Condition

Store at room temperature, protected from light, clean, well ventilated and free from corrosive gases.

4.5 Transportation Condition

Temperature of -10~50°C. Relative humidity of 10~95%.

4.6 Product Maintenance

Single-use sterile products, not applicable.

4.7 List of Accessories

This product has no accessories.

Chapter 5 Basic Information about Company

Manufacturer

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Chapter 6 Symbols and Instruction

No.	Symbols	Description
1		Batch code
2		Country and date of manufacture
3		Use by date
4		Read the user manual before use
5		Sterilized using ethylene oxide
6		Do not re-sterilize
7		Do not re-use
8		Do not use if package is damaged
9		Medical Device
10		Manufacturer
11		Authorized representative in the European Union
12		Catalogue number
13		Single sterile barrier system
14		In conformance with Regulation (EU) 2017/745 European Medical Devices Regulation (MDR)