

Beijing Surgerii Robotics Company Limited

Trocar Incision Protector

User Manual



Medical Device



©2026 SHURUI

 Beijing Surgerii Robotics Company Limited, 102, Floor 1, Building 7, Tiandilinfeng, No. 1 Yongtaizhuang North Road, Haidian District, Beijing 100192, China

 Surgerii Robotics (Netherlands) B.V., Herengracht 449A, 1017 BR, Amsterdam, Netherlands

 SHURUI® are trademarks or registered trademarks of Surgerii Robotics.

Number: H-15-000116

Version: V5

Date: 2026.01.30

Contents

Chapter 1 Cautions and Warnings	4
Chapter 2 Product Basic Information	6
Chapter 3 Instructions for use	13
Chapter 4 Manufacturing Information and Storage Condition	19
Chapter 5 Basic Information of Company	20
Chapter 6 Symbols and Instruction	21

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. 6) This product should only be used with SHURUI® Endoscopic Surgical System produced by Beijing Surgerii Robotics Company Limited. 7) 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. 8) 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 in 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 ethylene oxide (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) This product has been validated to ensure performance throughout a standard surgical procedure when used with the SHURUI® Endoscopic

	Surgical System. 5) Please use with care to prevent dropping. 6) This product should be stored at room temperature in a clean, well ventilated environment, free from corrosive gases and protected from light. 7) This product should be disposed of according to the relevant regulations on medical waste after use.
--	---

Chapter 2 Product Basic Information

2.1 Product Name

Product name: Trocar Incision Protector

2.2 Structure and Composition

The trocar incision protector is composed of a multi-channel trocar and an incision protector. The multi-channel trocar is composed of two or three surgical instrument channels, a 3D endoscope channel and trocar main body. The incision protector is composed of top cap, middle cap and retracting sleeve.

Multi-channel trocar is made of: thermoplastic polyurethane elastomer (TPU), polyisoprene, silicone rubber, polycarbonate, stainless steel, polyacrylamide; The incision protector is made of: thermoplastic polyurethane elastomer (TPU), polyisoprene, silicone rubber, polycarbonate, polyethylene.

The trocar incision protector was sterilized by EO and provided in sterility for single use only. Its shelf life is 2 years.

2.3 Product models

See the table below for product models and component models.

Table of product models

Product model	Component model
SR-TCIP-4-1	SR-TC-4-2、SR-IP-1
SR-TCIP-4-2	SR-TC-4-2、SR-IP-2
SR-TCIP-4-3	SR-TC-4-3、SR-IP-1
SR-TCIP-4-4	SR-TC-4-3、SR-IP-2
SR-TCIP-3-2	SR-TC-3-1、SR-IP-2
SR-TCIP-3-3	SR-TC-3-2、SR-IP-1

Table of component models

Component name	Component model	Component Description
Multi-channel trocar	SR-TC-4-2	Composed of 3 surgical instrument channels, a 3D endoscope channel and trocar main body.
	SR-TC-4-3	
	SR-TC-3-1	Composed of 2 surgical instrument channels, a 3D endoscope channel and trocar main body
	SR-TC-3-2	
Incision protector	SR-IP-1	Composed of top cap, middle cap (with insufflation valve) and retracting sleeve.
	SR-IP-2	Composed of top cap (with insufflation valve and auxiliary port), middle cap and retracting sleeve.

2.4 Intended use

This product is intended for use with SHURUI® Endoscopic Surgical System and is used to establish channels for endoscope and surgical instruments during surgery, protecting the incision from damage (without puncturing function).

2.5 Contraindication

If there are any contraindications for using SHURUI® Endoscopic Surgical System for assisted surgery, this product should not be used. The decision to use SHURUI® Endoscopic Surgical System for assisted surgery is at the discretion of the attending physician and should be based on individual risk-benefit analysis.

1. Patients with thick abdominal walls that do not meet the specifications of this product are prohibited from using it to prevent dislocation or rupture of the incision protector.

2. The product should not be used for surgeries with incisions that are too small, making it difficult to place the incision protector.

3. In order to prevent the injury of the proximal ring, the distal ring and the retracting sleeve during surgical operation, it is forbidden to use the sharp instrument which may cause the scratch and rupture of the sleeve.

4. If it is found during operation that rings of the incision protector is not easy to be

flattened, or the deformation recovery after flattening is incomplete, or the rings fall off from the sleeve, or the sleeve is damaged, the use of this product is prohibited.

2.6 Product performance

2.6.1 Multi-channel Trocar Performance

1) Appearance

a) The surface of the product should be flat and smooth, without burrs, and should not have defects such as bubbles, impurities, cracks, pores, grooves, sintered materials, etc.

b) There should be no visible accumulation of lubricants on the surface of the product.

2) Basic dimension

a) Channel dimension

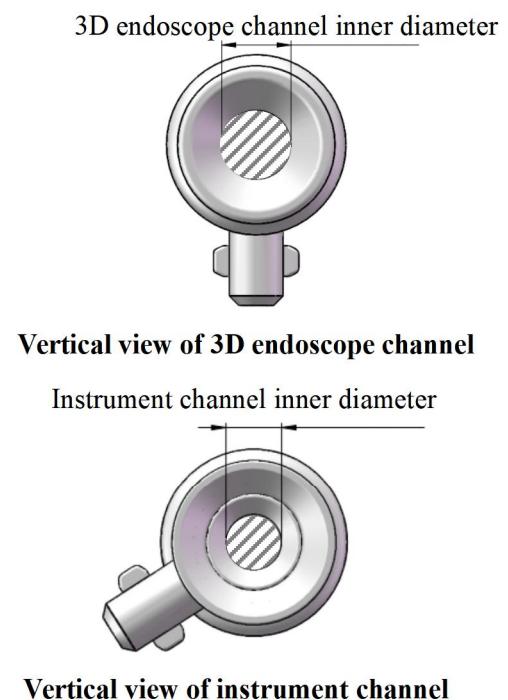
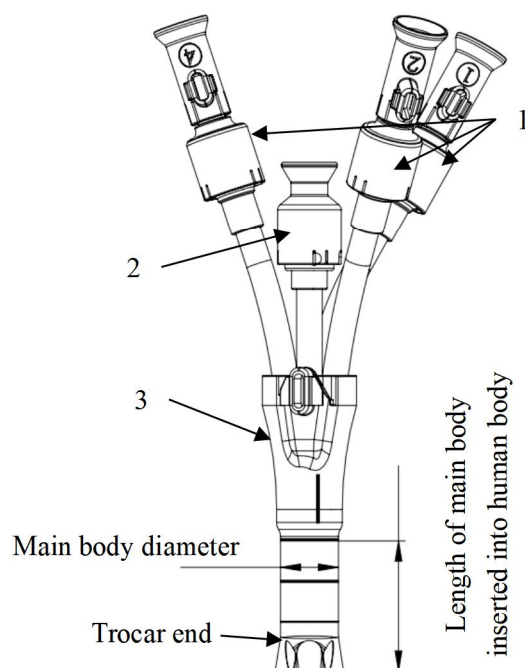
The inner diameter of the surgical instrument channel should be: 8.4mm with error range $+0.5\text{mm}; 0\text{mm}$.

The inner diameter of the 3D endoscope channel should be: 10.8mm with error range $+0.5\text{mm}; 0\text{mm}$.

b) SR-TC-4-2 multi-channel trocar dimension:

Main body diameter: $25.8\text{mm} \pm 0.5\text{mm}$.

The length of the trocar body inserted into the human body: $58\text{mm} \pm 2\text{mm}$.



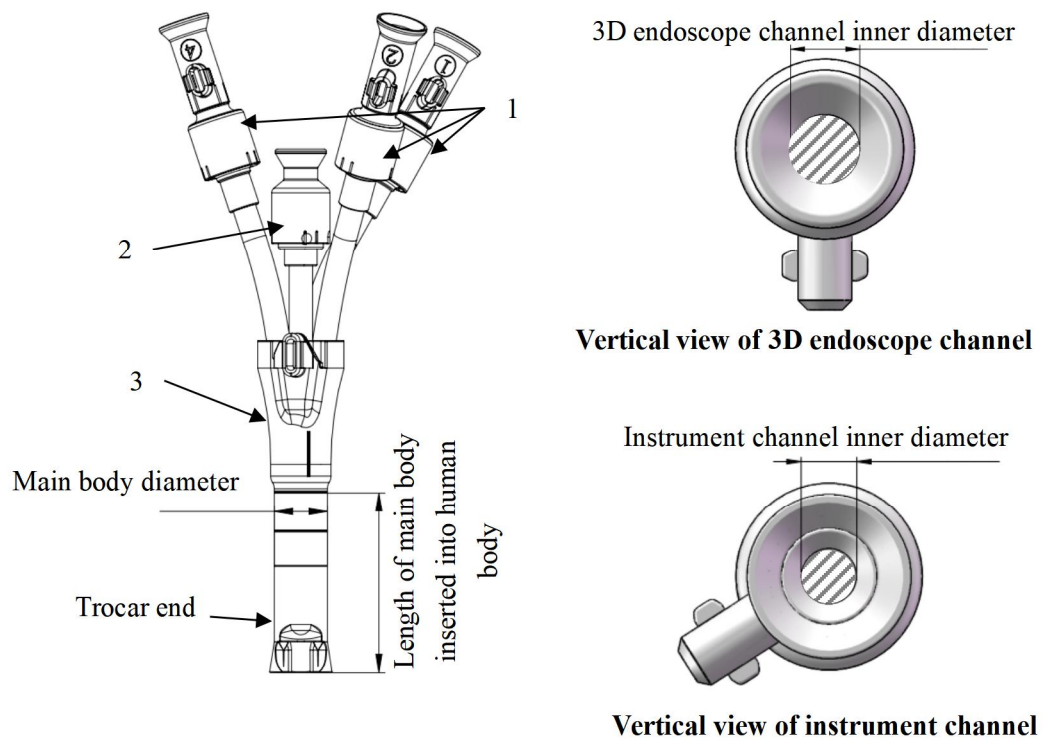
1-Instrument channel 2-3D endoscope channel 3-Trocar main body

Figure 1 Multi-channel trocar structure diagram (SR-TC-4-2)

c) SR-TC-4-3 multi-channel trocar dimension:

Main body diameter: $25.8\text{mm} \pm 0.5\text{mm}$.

The length of the trocar body inserted into human body: $88\text{mm} \pm 2\text{mm}$.



1-Instrument channel 2-3D endoscope channel 3-Trocar main body

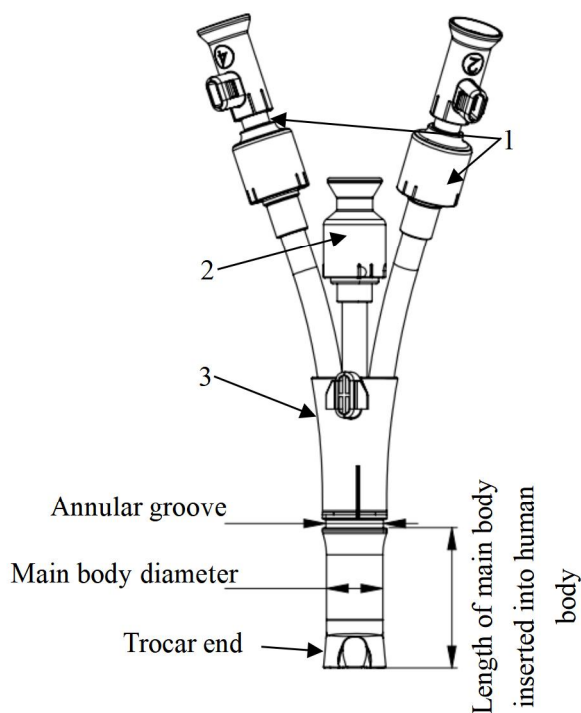
Figure 2 Multi-channel trocar structure diagram (SR-TC-4-3)

d) SR-TC-3-1 multi-channel trocar dimension:

Main body diameter: $25.8\text{mm} \pm 0.5\text{mm}$.

The length of the trocar body inserted into the human body: $64\text{mm} \pm 2\text{mm}$.

Annular groove diameter: $26.5\text{mm} \pm 0.5\text{mm}$.

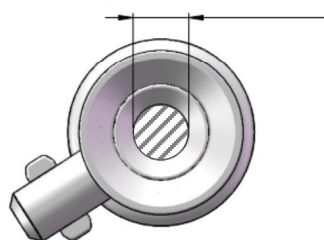


3D endoscope channel inner diameter



Vertical view of 3D endoscope channel

Instrument channel inner diameter



Vertical view of instrument channel

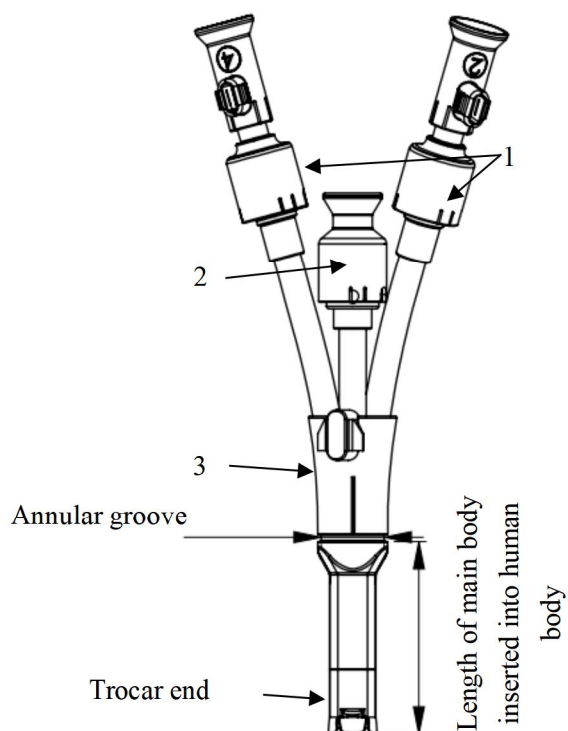
1-Instrument channel 2-3D endoscope channel 3-Trocar main body

Figure 3 Multi-channel trocar structure diagram (SR-TC-3-1)

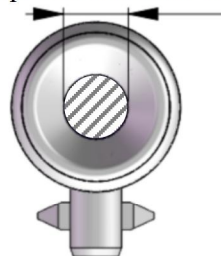
e) SR-TC-3-2 multi-channel trocar dimension:

The length of the trocar body inserted into the human body: $80\text{mm} \pm 2\text{mm}$.

Annular groove diameter: $26.5\text{mm} \pm 0.5\text{mm}$.

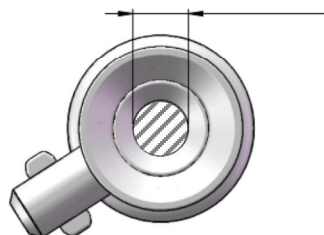


3D endoscope channel inner diameter



Vertical view of 3D endoscope channel

Instrument channel inner diameter



Vertical view of instrument channel

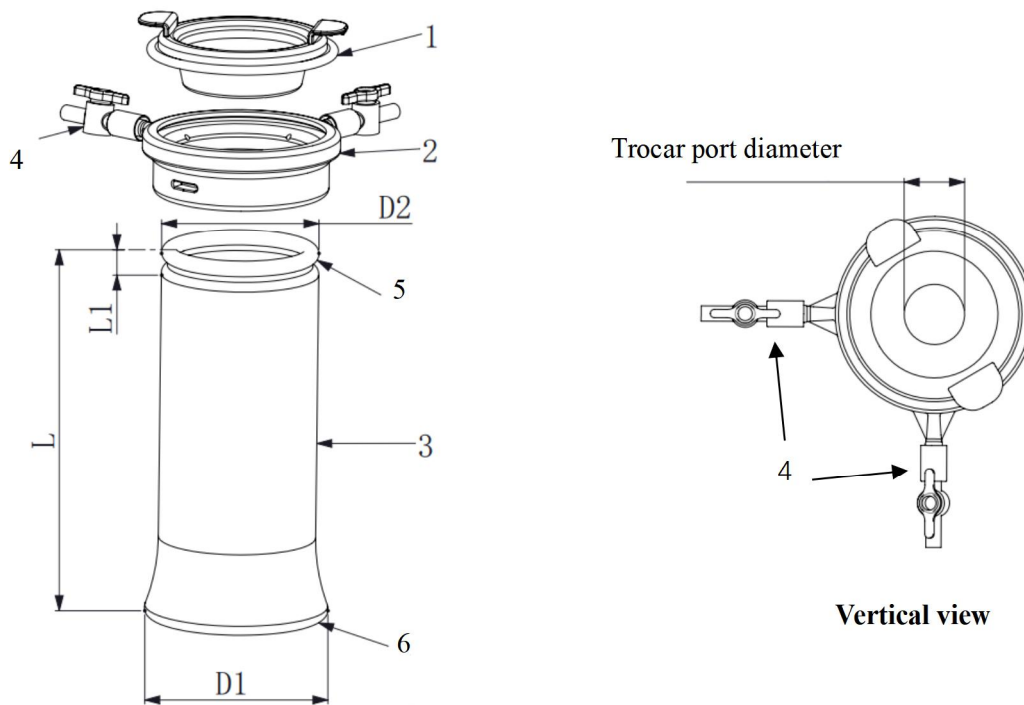
1-Instrument channel 2-3D endoscope channel 3-Trocar main body

Figure 4 Multi-channel trocar structure diagram (SR-TC-3-2)

2.6.2 Incision Protector Performance

- 1) Appearance: the rings of the product should be free of burrs and sharp angles; The channel should be smooth, soft, no cracks, no obvious defects.
- 2) Basic dimension

a) SR-IP-1 basic dimension



1-Top cap 2-Middle cap 3-Retracting sleeve 4-Insufflation valve
5- Proximal ring 6-Distal ring

Figure 5 Incision protector structure diagram (SR-IP-1)

Trocar port diameter: 23mm with error ± 1 mm

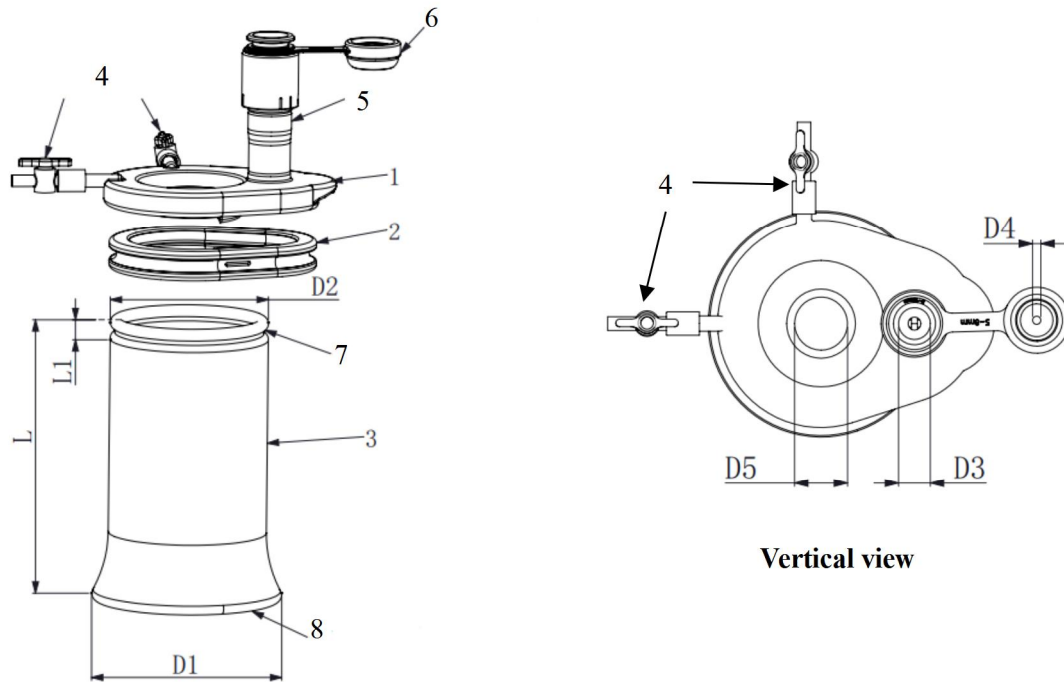
Outer diameter of distal ring D1: 70mm with error ± 10 mm

Proximal ring height L1: 12mm with error ± 2 mm

Outer diameter of proximal ring D2: 60mm with error ± 10 mm

Retracting sleeve length L: 150mm with error ± 30 mm

b) SR-IP-2 basic dimension



1-Top cap 2-Middle cap 3-Retracting sleeve 4-Insufflation valve
5-Auxiliary port 6-Adapter 7-Proximal ring 8-Distal ring

Figure 6 Incision protector structure diagram (SR-IP-2)

Trocar port diameter D5: 23mm with error ± 1 mm

Adapter port diameter D4: 3.5mm with error ± 1 mm

Auxiliary port diameter D3: 13mm with error ± 1 mm; 0mm

Outer diameter of distal ring D1: 90mm with error ± 20 mm

Proximal ring height L1: 12mm with error ± 2 mm

Outer diameter of proximal ring D2: 80mm with error ± 20 mm

Retracting sleeve length L: 150mm with error ± 30 mm

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

Warning

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

Please read the User Manual carefully before use.

Caution

The entire process is used by medical professionals in accordance with aseptic procedures.

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

The SR-IP-2 model of the incision protector comes with an auxiliary port. If the diameter of the auxiliary instrument is 5 to 8mm, it can enter the auxiliary port through adapter. If the diameter of the auxiliary instrument is 8 to 13mm, before entering the auxiliary port, the adapter should be removed first.

Caution

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

The trocar incision protector is composed of a multi-channel trocar and a incision protector. The multi-channel trocar has four models, and the incision protector has two models. Take the product model SR-TCIP-4-4 as an example, that is, the combination of SR-TC-4-3 multi-channel trocar and SR-IP-2 incision protector to explain the operation procedure, and the

same applies to other types.

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

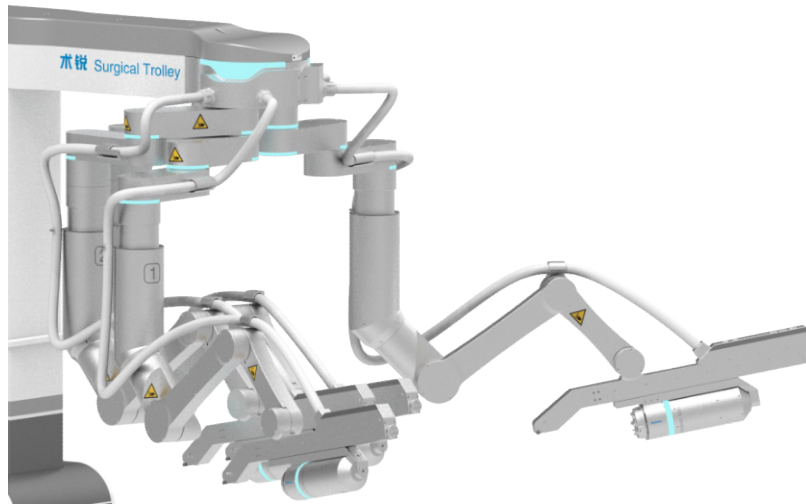


Figure 7 The robotic arms of the Endoscopic Surgical System

1. Based on the size of the incision at the clinical surgical site, determine and select the size specifications of the incision protector (suitable incision size and incision protector size can maintain good air-tightness)
2. Open the package and take the incision protector out.



Figure 8 Open the package

3. Flatten the distal ring of the retracting sleeve and insert it into the incision.



Figure 9 Put the distal ring into the incision

4. Flip the proximal ring inward and adjust the retracting sleeve to the appropriate height.



Figure 10 Adjust the retracting sleeve to the appropriate height

5. Install the middle cap on the proximal ring.

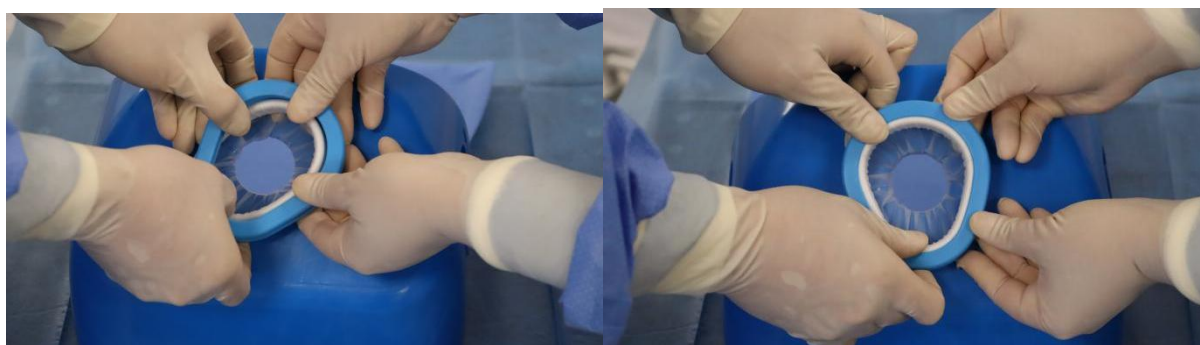


Figure 11 Install the middle cap on the proximal ring

6. Install the top cap on the middle cap.



Figure 12 Install the top cap on the middle cap

7. Open the package and take out the multi-channel trocar.

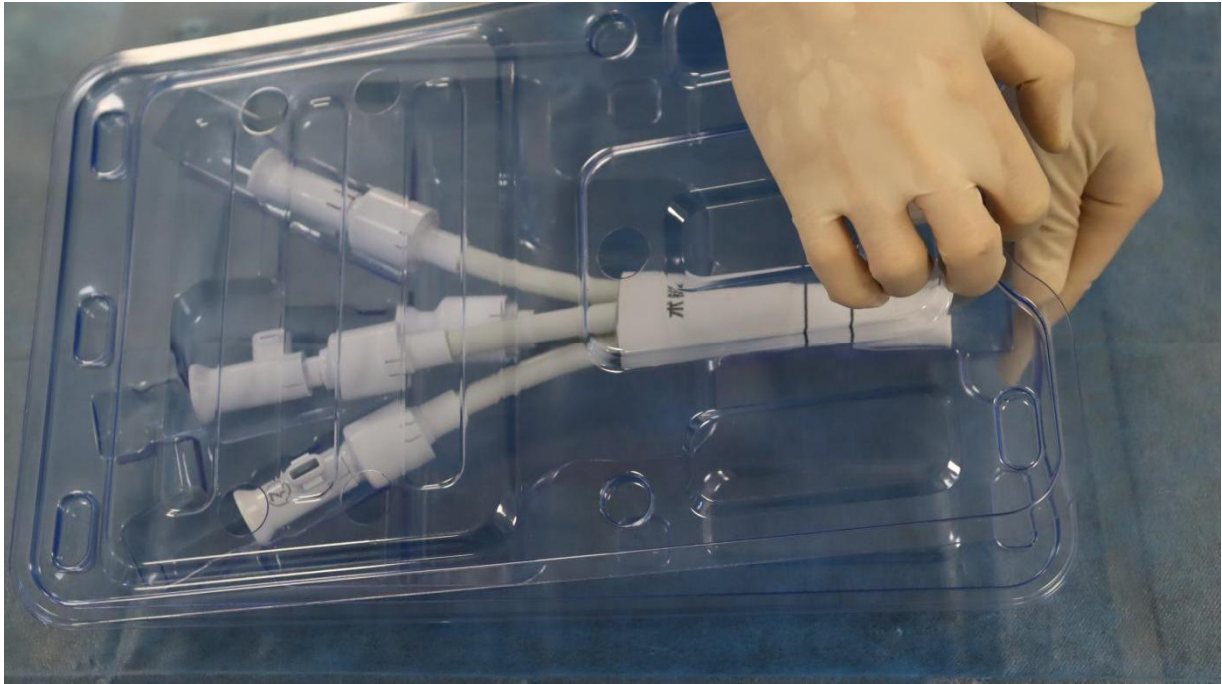


Figure 13 Open the package

8. The multi-channel trocar is inserted into the incision protector according to the required orientation of the operation.
9. According to the surgical requirements and orientation, insert the multi-channel trocar into the trocar port on top cap.



Figure 14 The multi-channel trocar is inserted into the trocar port

10. Push the Surgical Trolley of Endoscopic Surgical System that already installed with sterile drape and sheath connector to the operation table, adjust robotic arm 3 of the trolley, and

connect the 3D endoscope channel to robotic arm 3 with sheath connector.



Figure 15 Connect robotic arm 3 of the Surgical Trolley to the 3D endoscope channel

11. Then adjust the robotic arm 2, 1 and 4 successively, and connect instrument channel 2, 1 and 4 of the multi-channel trocar to the sheath connector respectively.



Figure 16 Adjust robotic arm 2, 1 and 4 successively, and connect instrument channel 2, 1 and 4

12. After the surgery is completed, remove the multi-channel trocar and the incision protector, and dispose them according to the requirements for medical waste. To remove the multi-channel trocar, first loosen the sheath connector, release each channel, and then take out the trocar from the trocar port.



Figure 17 Remove the multi-channel trocar

13. Remove the incision protector: remove them in the reverse order of installation.



Figure 18 Remove the top cap



Figure 19 Remove the middle cap, flip the proximal ring and adjust the tightness.



Figure 20 Reach into the incision and take the distal ring out

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

2 years.

4.4 Storage Condition

Store at room condition, 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 of Company

Manufacturer

Beijing Surgerii Robotics Company Limited

102, Floor 1, Building 7, Tiandilinfeng, No. 1 Yongtaizhuang North Road, Haidian District,
Beijing 100192, China

Contact: +86-10-62841863

EU Representative

Surgerii Robotics (Netherlands) B.V

Herengracht 449A, 1017 BR, Amsterdam, Netherlands

Contact: +31-850643988

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 with protective packaging inside
14		In conformance with Regulation (EU) 2017/745 European Medical Devices Regulation (MDR)