Beijing Surgerii Robotics Company Limited

Endoscopic Surgical System

(SR-ENS-600)

Safety and Performance Information

Number: H-15-000104
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Purpose of the Document

According to the requirements of "ANNEX I GENERAL SAFETY AND PERFORMANCE REQUIREMENTS" of the MDR Regulation, "Each device shall be accompanied by the information needed to identify the device and its manufacturer, and by any safety and performance information relevant to the user, or any other person, as appropriate."

The basic safety and performance information contained in this document will be displayed on the official website (https://en.surgerii.com/) in order to provide users with sufficient information and at the same time meet the relevant regulatory requirements of the MDR.

Safety and Performance

1.1 Performance

1.1.1 Essential Performance of the System

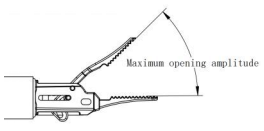
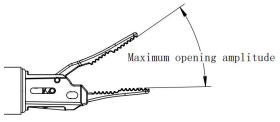
The following essential performance information is in compliance with IEC 60601-1.

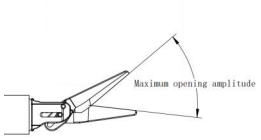
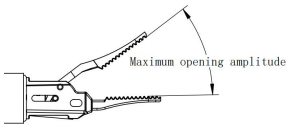
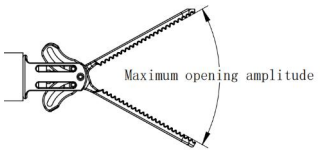
•The Endoscopic Surgical System allows real-time acquisition of surgical field images on the side of surgical instruments through a 3D endoscope. Surgical field can be displayed normally on 2D display and 3D viewer with no interruption or blackout in image transmission.

•The Endoscopic Surgical System provides motion control of the surgical instruments and 3D endoscope loaded on the Surgical Trolley through the Surgeon Console with master-slave teleoperation accuracy and master-slave teleoperation time delay within the claimed range: master-slave teleoperation distance accuracy ≤2mm, master-slave teleoperation distance repeatability ≤2mm, master-slave teleoperation time delay ≤200ms.

•The Endoscopic Surgical System have no unintended motion during preoperative preparation and intraoperative manipulation.

1.1.2 Performance of Surgical Instruments

Surgical Instrument	Working Length	End-effector Length	Schematic diagram of the end-effector	End-effector open angle
Curved bipolar dissector	529mm±3%	24.4mm±2mm		43°±20%
Maryland bipolar forceps	529mm±3%	22.2mm±2mm		34°±20%

Surgical Instrument	Working Length	End-effector Length	Schematic diagram of the end-effector	End-effector open angle
Monopolar curved scissors	530mm±3%	23mm±2mm		50°±20%
Monopolar cautery hook	518mm±3%	15.8mm±2mm	N.A	N.A
Bipolar forceps	529mm±3%	22.7mm±2mm		35°±20%
Needle driver	522mm±3%	15mm±2mm		25°±20%
Tissue forceps	535mm±3%	28.4mm±2mm		58°±20%

The effective working space of surgical instruments is a truncated cone. Its axis coincides with the axis of the instrument channel of the trocar, and the base of the truncated cone is 60mm away from the front end of the trocar. The height is 120mm, the radius of the base is 85mm, and the radius of the top surface is 50mm.

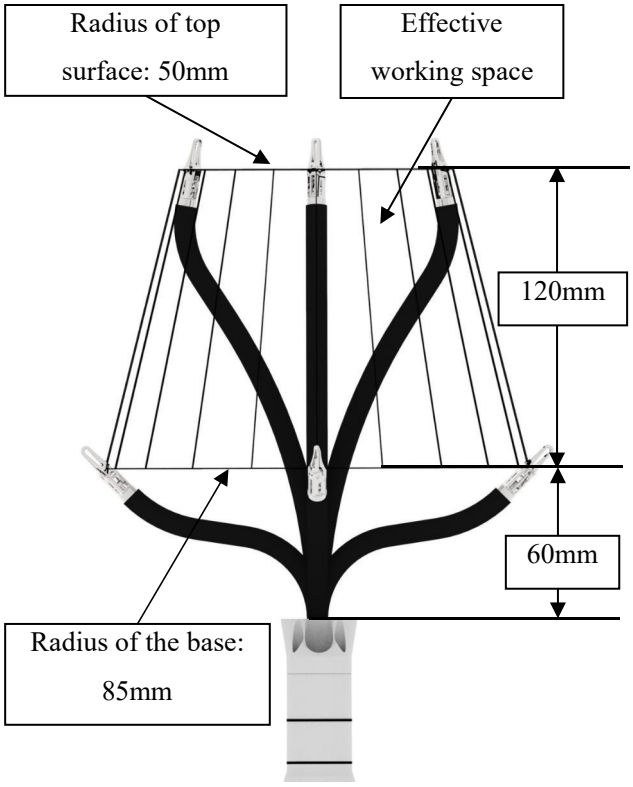


Figure: Effective working space of surgical instruments

1.1.3 Performance of 3D Endoscope

Working length	480mm
Maximum diameter (inserted in the patient cavity during surgery)	ϕ 10.8mm
Imaging performance	Resolution: 1920×1080 Field of View: 85°

1.2 Intended Purpose

The SHURUI® Endoscopic Surgical System is intended to assist in the accurate control of the SHURUI® instruments during urologic laparoscopic surgical procedures, gynecologic laparoscopic surgical procedures, general laparoscopic surgical procedures, and thoracoscopic surgical procedures. It is intended for use by trained surgeons in an operating room environment in accordance with the representative, specific procedures set forth in the User Manual.

The SHURUI® Instruments are controlled by the SHURUI® Endoscopic Surgical System, and include flexible endoscopes, blunt and sharp endoscopic dissectors, scissors, forceps, needle drivers, endoscopic retractors, electrocautery and accessories for endoscopic surgical operations, including grasping, cutting, blunt and sharp dissection, approximation, ligation, electrocautery, and suturing through a single port. They are intended for use by trained surgeons in an operating room environment in accordance with the representative, specific procedures set forth in the User Manual.

1.3 Indications for Use

The system is indicated for adult and pediatric patients eligible for minimally invasive surgeries, indicated for benign or malignant conditions, performed intra-thoracically or intra-abdominally in specialties such as urological, gynecological, general and thoracic surgical procedures.

1.4 Intended Users

The system is intended to be used by trained surgeons in the operating room environment in accordance with the representative, specific procedures set forth in the User Manual.

1.5 Intended Patients

The system is indicated for adult and pediatric use and applicable to people who need laparoscopic or thoracoscopic surgery.

1.6 Complications and Side-effects

Common complications, side-effects and residual risks associated with the use of robotically assisted surgical devices, such as the SHURUI Endoscopic Surgical System, includes, but is not limited to, the followings:

- Bleeding

- Tissue damage
- Infection
- Abdominal pain/wound pain
- Nausea and vomiting
- Ileus
- Ascties / Pleural effusion
- Incision hernia / Impaired healing
- Anastomotic leak
- Urinary retention / Obstruction / Occlusion
- Urine leak
- Delayed gastric emptying / Abdominal distention
- Pneumonia / Respiratory tract infection
- Atelectasis / Respiratory failure
- Pneumothorax
- Deep vein thrombosis

1.7 Benefit-risk

When used as indicated, the SHURUI Endoscopic Surgical System is safe and effective in urological laparoscopic surgical procedures, gynecologic laparoscopic surgical procedures, general laparoscopic surgical procedures, and thoracic surgical procedures, for both adult and pediatric use. The potential clinical benefits to patients undergoing surgical procedures with the SHURUI Endoscopic Surgical System include the benefits of minimally invasive surgery, such as lower blood loss, reduced complication rates, lower postoperative pain, improved cosmesis, and shorter length of hospital stay, during normal conditions of use. These clinical benefits are similar to those expected with traditional laparoscopic surgical techniques or other commercially available robotic systems. Clinical risks, including intraoperative and postoperative complications, have been identified and reviewed against the available

clinical evidence and treatment alternatives. The risks associated with the use of the SHURUI Endoscopic Surgical System are acceptable when weighed against the evaluated benefits to the patient, during normal conditions of use.

1.8 Contraindications

Any and all relative and absolute contraindications to endoscopic surgical technique applicable to the use of conventional endoscopic surgical instruments apply to the use of the SHURUI Endoscopic Surgical System. Generally, non-procedure specific contraindications to endoscopic surgery include bleeding diathesis, morbid obesity and pregnancy. Do not use the SHURUI Endoscopic Surgical System for procedures involving the circulatory system or central nervous system.

1.9 Precautions and Warnings

1.9.1 Training

Only trained and qualified operators may use this product.

The training provided by Surgerii Robotics is limited to using the system and does not replace the necessary medical training and experience required to perform surgery.

 **CAUTION**	1) Operators should have adequate medical expertise and surgical skills.

1.9.2 Product Use

 **WARNING**	1) Reprocessing or reusing the products intended for single use may result in degraded performance, loss of functionality, or exposure to viral, bacterial, fungal, or prionic pathogens.

 **CAUTION**	1) The user should check that the current alarm preset (alarm volume) is appropriate for the usage environment before using the product and that the alarm volume is not too high or too low. 2) During use, the user should pay attention to the system undergoing unexpected motions. If such a situation occurs, immediately press the emergency stop button on the Surgeon Console or Surgical Trolley, remove all components in contact with the patient, and then proceed with the corresponding treatment. If necessary, the system can be rebooted, and the surgical operation process can continue. Relevant feedback information should be provided to Surgerii Robotics's customer service department in time after the surgery. Only after Surgerii Robotics confirms that the system is functioning properly can it be used for future surgical operations. 3) In case of a serious system failure during the use of this product, the system should be stopped immediately and handled following the user manual. The relevant feedback information should be reported to the customer service department of Surgerii Robotics immediately. 4) This product is not suitable for use with movable multi-outlet sockets. 5) Unless otherwise specified, one button should not be pressed multiple times within a short period of

	time. 6) This product's Standard Operating Procedure (SOP) should be strictly followed during surgery. 7) This product is a delicate medical device. Do not apply force to the moving components or use these components to hang any object that does not belong to this product. 8) When using the system, avoid damaging the casing, which may cause electric shock and safety risks. 9) Failure to comply with the user manual's requirements may damage the surgical instruments or the 3D endoscope. 10) This product should not be used near strong electromagnetic interference sources such as nuclear magnetic imaging equipment and high-voltage cables. 11) This product has not been tested in environments with specific electromagnetic safety requirements, such as computed tomography, diathermy therapy machines, and argon gas electro knives. 12) An uninterruptible power supply (UPS) cannot be used to complete a surgery but can be used for instrument removal and patient release during an emergency removal of this product from the patient. System alarms will not be affected by the UPS usage. 13) Excessive gas injection during pneumoperitoneum

	can be dangerous and may cause a gas embolism. 14) Only CO_2 should be used as the insufflating gas when using the system with insufflation. Insufflation should only be performed by personnel having adequate training and experience with this technique. 15) The haptic force feedback associated with the system differs from that in traditional laparoscopic surgical instruments. Similar to laparoscopic surgery, the operating surgeons should rely on visual feedback to guide their operation. 16) The system is not suitable for use in the presence of a flammable anesthetic mixture of air, oxygen, and nitrous oxide. 17) The demonstration of safety and effectiveness for the representative specific procedures did not include evaluation of outcomes related to the treatment of cancer (overall survival, disease-free survival, local recurrence) or treatment of the patient's underlying disease/condition. Device usage in all surgical procedures should be guided by the clinical judgment of an adequately trained surgeon.

1.9.3 Conversion to Non-Minimally Invasive Surgery

CAUTION	1) Anatomical characteristics of a patient may preclude using the minimally invasive techniques. Environmental or equipment failures may cause

	the system to be unavailable. The surgical team should always have backup devices available and be prepared to convert to alternative surgical techniques. The potential risk of such conversion should be communicated to the patient.