

Endoscopic Surgical System
(SR-ENS-600)
Instrument Reprocessing Instructions



Medical Device



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Notice: If any serious incident occurs concerning the device, please report it to Surgerii Robotics (Netherlands) B.V. and the regulatory authority in your jurisdiction.

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Safety Information

This document contains the following types of safety information.

 CAUTION	CAUTION symbol alerts reader to what needs attention when operating and using. Details of relevant scenarios are given in boxes similar to this box.
 WARNING	WARNING symbol alerts reader to a potentially hazardous situation that, if not avoided, may result in minor or moderate injury to the user or patient or damage to the equipment or other property. Details of relevant scenarios are given in boxes similar to this box.
 HAZARD	HAZARD symbol alerts reader to a situation that, if not avoided, could result in death, serious injury, or serious damage to patient, the equipment or other property. Details of relevant scenarios are given in boxes similar to this box.
 PROHIBITION	PROHIBITION symbol alerts reader to actions that are prohibited. Details of relevant scenarios are given in boxes similar to this box.

Chapter 1 Introduction

The instructions in this document contain the cleaning, disinfection and sterilization instructions and parameters recommended by Surgerii Robotics. These instructions apply to the SHURUI® instruments only. These instructions contain essential information for reprocessing. Read these instructions in their entirety carefully before any reprocessing activities. If there are any questions or comments about any information in these instructions, or if a problem occurs while reprocessing that cannot be resolved, contact Surgerii Robotics (Netherlands) B.V.

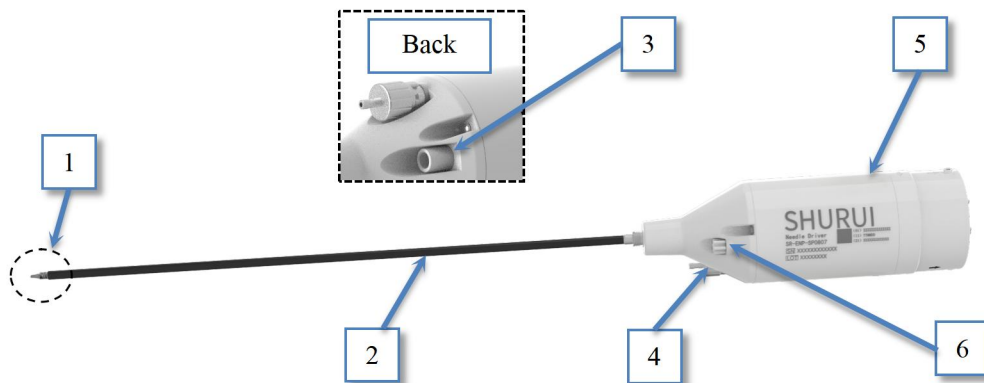
Chapter 2 Precautions and Warnings

 WARNING	1) No modifications to this device are permitted. 2) Reprocessing or reusing single-use products may lead to diminished instrument performance, loss of functionality, or exposure to viral, bacterial, fungal, or prion pathogens. 3) Only products and equipment that have undergone validated reprocessing should be utilized. Ensure that only validated parameter settings and cycles are applied. The use of non-validated parameters or cycles can result in damage, ineffective cleaning, or inadequate sterilization of instruments. 4) Use only validated packing for sterilization. The application of non-validated packing may cause damage or compromise the effectiveness of the sterilization process for instruments. 5) Devices must be handled, reprocessed, and operated exclusively by trained personnel. Insufficient training can lead to device damage or harm to patients and operators. 6) Please follow the validated cleaning process closely. Failing to follow the validated cleaning process can result in incomplete cleaning and sterilization. 7) Exercise caution when handling chemicals and contaminated solutions, as contact with skin, inhalation, or ingestion can cause injury. 8) Always inspect devices for any defects or damage before use, after use, and following reprocessing. Neglecting to perform these inspections could result in patient harm and/or further device damage. 9) Exercise caution when handling devices with sharp points or cutting edges. Failing to exercise the cautions can result in injury. 10) The cleaning processes, cleaning agents and disinfectant outlined in these instructions have been validated by Surgerii Robotics. Using alternative cleaning methods, cleaning agents, cleaning machines or disinfectants may result in incomplete reprocessing, potentially leading to patient harm and device damage. 11) The instruments must not be exposed to temperatures exceeding 95°C during processing to prevent potential device damage.
 CAUTION	1) Exposure of instruments to chemical disinfectants should be maintained to the specific contact time recommended by the manufacturer to achieve the validated disinfection level specified in this document. Longer exposure times could result in device damage. 2) Handle all devices with care to prevent mechanical shock or stress, as these can lead to device damage. 3) During installation or removal of the cleaning cage, care must be taken to prevent the internal threads of the cage from contacting the stem cover. Such contact may damage the seal integrity. 4) All hospital personnel working with contaminated or potentially contaminated devices should follow local guidelines. When handling or working with such devices, Personal Protective Equipment (PPE) must be worn. PPE includes gloves, gowns, masks, goggles or face shields, and shoe covers.

Chapter 3 Overview

3.1 Instrument Overview

The surgical instrument is composed of the instrument housing, instrument stem, end-effector, pressure valve, energy instrument cord port and grip release knob, as shown in the figure below.



1-End-effector, 2-Stem, 3-Energy instrument cord port (if it exist), 4-Pressure valve, 5-Instrument housing, 6-Grip release knob

3.2 Applicable Instruments

The instructions in this document apply to the SHURUI Surgical Instruments listed below.

Instrument	Model
Curved bipolar dissector	SR-ENT-SP0801
	SR-ENT-SP0801S
Maryland bipolar forceps	SR-ENT-SP0802
	SR-ENT-SP0802S
Monopolar curved scissors	SR-ENT-SP0803
	SR-ENT-SP0803S
Monopolar cautery hook	SR-ENT-SP0805
	SR-ENT-SP0805S
Bipolar forceps	SR-ENT-SP0806
	SR-ENT-SP0806S
Needle driver	SR-ENT-SP0807
	SR-ENT-SP0807S
Tissue forceps	SR-ENT-SP0808
	SR-ENT-SP0808S
Large tissue forceps	SR-ENT-SP0809
	SR-ENT-SP0809S
Large needle driver	SR-ENT-SP0810
	SR-ENT-SP0810S

3.3 Process Overview

Point-of-Use Preparation

1	Remove the Tip Cover and Energy Instrument Cords
2	Wipe
3	Keep Moist
4	Transport

Cleaning, Disinfection and Drying

Manual Cleaning		Automated Cleaning Using Washer Disinfector		Automated Cleaning Using MAG-120I	
1	Sealing Test	1	Sealing Test	1	Sealing Test
2	Remove the Pressure Valve Cap	2	Remove the Pressure Valve Cap	2	Remove the Pressure Valve Cap
3	Prepare Cleaning Solution	3	Manual Pre-Cleaning	3	Automated Cleaning Using MAG-120I
4	Soak		3.1 Prepare Cleaning Solution	4	Chemical Disinfection
5	Brush		3.2 Soak	5	Drying
6	Ultrasonic Cleaning		3.3 Brush	6	Inspect
7	Spray		3.4 Ultrasonic Cleaning	7	Transport
8	Rinse		3.5 Spray		-
9	Chemical Disinfection		3.6 Rinse		
10	Drying	4	Automated Cleaning and Thermal Disinfection Using Washer Disinfector		
11	Inspect	5	Inspection with Drying as Required		
12	Transport	6	Transport		

Sterilization

1	Final Inspect
2	Sealing Test
3	Pack
4	Sterilize
5	Store

3.4 Reprocessing Limits

The Endoscopic Surgical System's software will deactivate the instruments after they reach the intended number of uses. The system will display the remaining number of uses for the instruments and will remind the operator when the instruments are approaching or have reached the use limit. These use limits are described in the Endoscopic Surgical System User Manual.

Chapter 4 Reprocessing

The following tools are used for protection and support of surgical instruments during reprocessing.

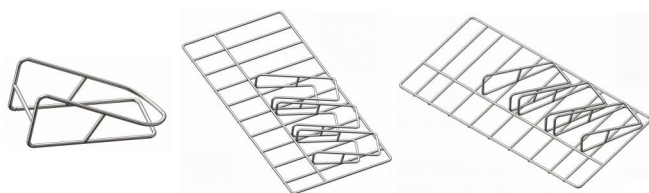
Surgical instrument cleaning cage	SR-ENT-CLN01
One-way valve	SR-ZSRH-3-5
Support rack	SR-WDRK-1-1
	SR-WDRK-2-1
	SR-WDRK-2-2
Basket	SR-WDBK-1-1
Transport container	SR-ENS-TRC01
	SR-ENS-TRC02



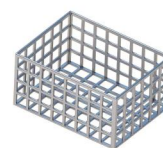
Surgical instrument cleaning cage



One-way valve



Support rack



Basket



Transport container

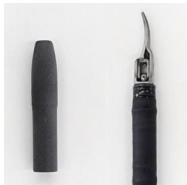
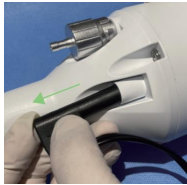
4.1 Point-of-Use Preparation

1	Remove the Tip Cover and Energy Instrument Cords
2	Wipe
3	Keep Moist
4	Transport

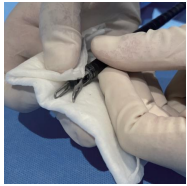
See the following sections for step-by-step instructions using the following materials:

- A proper basket, box, or bag for protective transportation
- Items to keep the instruments wet (one of the following):
 - Neutral pH solutions
 - Neutral pH spray
 - Water
- Moist cloth

4.1.1 Remove the Tip Cover and Energy Instrument Cords

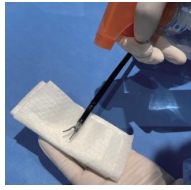
 WARNING	1) Before cleaning, the tip cover and energy instrument cords must be removed. Incomplete removal may lead to inadequate cleaning and sterilization of surgical instruments.
	Remove the disposable tip cover. (Applicable for Monopolar Curved Scissors)
	Remove the monopolar or bipolar energy instrument cord. (Applicable for monopolar or bipolar energy instruments)

4.1.2 Wipe

	With a moist cloth, wipe off excess soil from the ended procedure immediately after surgery.
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4.1.3 Keep Moist

 WARNING	1) When handling instruments in the operating room (or after surgery), preferably neutral pH solutions should be used.
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Spray pH-neutral solution on distal end of stem and end-effector and moisturize by wrapping with a moist cloth.

4.1.4 Transport



WARNING

- 1) The transportation shall be completed within 60 minutes to avoid the surface drying out.



When ready for the transport, remove the moist cloth. Screw the cleaning cage in clockwise direction to install it onto the instrument.

Transport the instruments for cleaning and sterilization. During transportation, please carefully use a proper basket, box, or bag to protect from damaging.

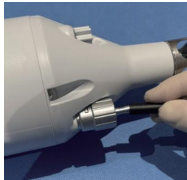
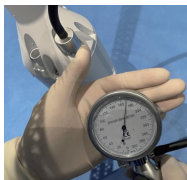
4.2 Manual Cleaning

1	Sealing Test
2	Remove the Pressure Valve Cap
3	Prepare Cleaning Solution
4	Soak
5	Brush
6	Ultrasonic Cleaning
7	Spray
8	Rinse
9	Chemical Disinfection
10	Drying
11	Inspect
12	Transport

See the following sections for step-by-step instructions using the following materials:

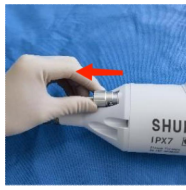
- Endoscope leak detector
- pH-neutral to mildly alkaline enzymatic solution (pH 7-11)
- A container capable of fully accommodating the items to be cleaned
- Spray gun
- Soft nylon brush
- Ultrasonic cleaning machine
- A proper basket, box, or bag for protective transportation
- Purified water
- Disinfectant
- Clean dry air
- MAG-120I Automated cleaning machine
- 4X magnifying glass

4.2.1 Sealing Test

	Install the pressure valve cap and connect the endoscope leak detector to the pressure valve of the instruments.
	Adjust the test pressure of the endoscope leak detector to 165mmHg (22KPa). Acceptance criteria: ● The pressure displayed $\geq 158\text{mmHg}$ (21kPa) after 3 minutes. Release the pressure of the endoscope leak detector to 0, and then remove the leak detector.

NOTE: If the test results are unsatisfactory, indicating a seal defect, please contact Surgerii Robotics.

4.2.2 Remove the Pressure Valve Cap



Unscrew the pressure valve cap in counterclockwise direction to remove it from the instruments.

NOTE: The removed pressure valve cap should be cleaned according to the Accessories Reprocessing Instructions.

4.2.3 Prepare Cleaning Solution

 WARNING	1) Be careful when handling chemicals and contaminated solutions, as skin contact, inhalation or ingestion may cause injury.
 CAUTION	1) Prepare and use the cleaning solution according to the instructions of enzyme cleaner, including temperature and concentration.

Prepare a sufficient amount of pH-neutral to mildly alkaline multi-enzyme solution (pH 7-11) in an appropriate container sufficient to completely immerse the entire instruments.

The following brand models and corresponding usage methods of the cleaning agents for manual cleaning and pre-cleaning have been validated:

Cleaning Agent	Concentration	Temperature
Metrex MetriZyme™	1:128	20°C to 40°C
Steris Prolystica® 2x Concentrate Enzymatic Presoak and Cleaner	1:1000	20°C to 40°C
DR.WEIGERT neodisher®MediClean forte	1:50 to 1:200	20°C to 40°C

4.2.4 Soak



Completely immerse the surgical instruments (along with the surgical instrument cleaning cage) in the cleaning solution for no less than 5 minutes.

NOTE: When soaking, ensure that the jaws (if present) of the surgical instrument are opened.

4.2.5 Brush

 CAUTION	1) Only use a soft nylon brush for cleaning. Clean with metal brushes or abrasive materials may cause damage to the device. 2) Before brushing, remove the cleaning cage, and then re-install it after brushing.
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 PROHIBITION	1) In the process of brushing and wiping, please do not hold the surgical instrument stem in the air. 
---	--

	Unscrew the cleaning cage in counterclockwise direction to remove it from the instrument.
	Use a soft nylon brush to scrub the end-effector and the stem of the surgical instruments for no less than 1 minute in the cleaning solution used during the soaking process.
	Screw the cleaning cage in clockwise direction to install it onto the instrument.

NOTE: For surgical instruments equipped with a grip, simultaneously rotate the grip release knob while brushing to open and close the jaws, ensuring that the interior of the jaws is thoroughly cleaned. Take care to prevent the bristles from becoming embedded in the jaws.



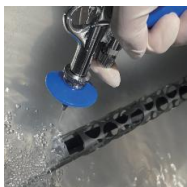
4.2.6 Ultrasonic Cleaning

	Immerse at least the distal 270mm of the surgical instruments with the surgical instruments cleaning cage into the ultrasonic cleaning machine containing the cleaning solution, using the support rack as needed.
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NOTE: Use ultrasonic cleaning with a power setting of no less than 14W/L and ensure that the ultrasonic cleaning time is no less than 10 minutes. The cleaning temperature should be set according to the cleaning solution being used.

4.2.7 Spray

	Immerse the surgical instruments and cleaning cage completely or in sections in room-temperature tap water.
	Using a spray gun (pressure: 0.30–0.35 MPa), spray the instruments thoroughly while they are submerged, for at least 1 minute.

NOTE: For the grip-type surgical instruments, simultaneously rotate the grip release knob to open and close the jaws, ensuring that the inside of the jaws is thoroughly sprayed.



4.2.8 Rinse

	Rinse the entire instruments (along with the surgical instrument cleaning cage) under purified water at room temperature for no less than 1 minute.
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NOTE: Ensure that there are no visible residues or solution on the surface.

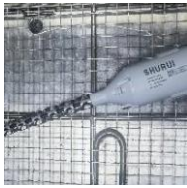
4.2.9 Chemical Disinfection

The necessity and required level of disinfection may vary according to hospital policies and regional guidelines. If disinfection is not needed, proceed to "Drying" to complete the drying step.

 WARNING	1) Disinfection is not a substitute for cleaning or sterilization. 2) Check with the hospital's policy and regional guidelines to determine if disinfection is needed.
 CAUTION	1) After chemical disinfection, always rinse the instrument. Failure to rinse may expose patients to disinfectant chemicals, which may lead to patient harm.

NOTE:

- Follow the manufacturer's instructions for the preparation and use of disinfectants, including temperature and concentration.
- Disinfection of the instrument has been validated using a compound peroxyacetic acid surface chemical disinfectant.

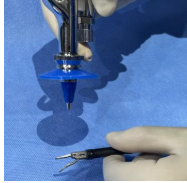
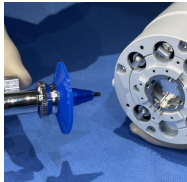
	Completely immerse the surgical instruments (with the cleaning cage) in the disinfectant. Follow the disinfectant manufacturer's instructions for preparation and use.
	Rinse the entire instruments (with the cleaning cage) under purified water at room temperature for no less than 1 minute.

4.2.10 Drying (Manual / Automated)

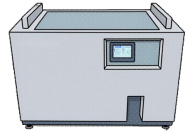
According to the actual operating environment conditions, either manual drying or automated drying may be selected.

 CAUTION	1) After drying, the surface of surgical instruments must be free of moisture, otherwise the low-temperature plasma sterilization process will be interrupted.
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4.2.10.1 Manual Drying

	Unscrew the cleaning cage in counterclockwise direction to remove it from the instrument.
	Thoroughly air-dry the entire end-effector to ensure that there is no visible water stain on the surfaces or in any corner.
	Thoroughly air-dry the stem and the housing to ensure that there is no visible water stain on the surfaces or in any corner.
	Thoroughly air-dry the entire back of housing to ensure that there is no visible water stain on the surfaces or in any corner.

4.2.10.2 Automated Drying Using MAG-120I

	Use the drying function of the automated cleaning machine. Follow the reprocessing instructions of the cleaning machine manufacturer.
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For the information of validated machines, drying parameters, load capacity and method of item placement, please refer to Appendix A "MAG-120I Automated Cleaning Machine."

4.2.11 Inspect

	Under a 4x magnifying glass, inspect for soil. If soil is present, repeat the entire cleaning process.
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	Screw the cleaning cage in clockwise direction to install it onto the instrument.
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NOTE: If the instruments still do not meet the standards after repeated cleaning, please contact Surgerii Robotics.

4.2.12 Transport

Transport the surgical instruments for sterilization. During transportation, please carefully use a proper basket, box, or bag to protect from damaging.

4.3 Automated Cleaning Using Washer Disinfector

1	Sealing Test	
2	Remove the Pressure Valve Cap	
3	Manual Pre-Cleaning	
	3.1	Prepare Cleaning Solution
	3.2	Soak
	3.3	Brush
	3.4	Ultrasonic Cleaning
	3.5	Spray
	3.6	Rinse
4	Automated Cleaning and Thermal Disinfection Using Washer Disinfector	
5	Inspection with Drying as Required	
6	Transport	

See the following sections for step-by-step instructions using the following materials:

- Endoscope leak detector
- pH-neutral to mildly alkaline enzymatic solution (pH 7-11)
- A container capable of fully accommodating the items to be cleaned
- Spray gun
- Soft nylon brush
- Ultrasonic cleaning machine
- A proper basket, box, or bag for protective transportation
- Purified water
- Clean dry air
- Non-woven wipes
- Washer disinfectant
- 4X magnifying glass

4.3.1 Sealing Test

Please refer to Section 4.2.1 "Sealing Test" and follow the provided instructions.

4.3.2 Remove the Pressure Valve Cap

Please refer to Section 4.2.2 "Remove the Pressure Valve Cap" and follow the provided instructions.

4.3.3 Manual Pre-Cleaning

4.3.3.1 Prepare Cleaning Solution

Please refer to Section 4.2.3 "Prepare Cleaning Solution" and follow the provided instructions.

4.3.3.2 Soak

Please refer to Section 4.2.4 "Soak" and follow the provided instructions.

4.3.3.3 Brush

Please refer to Section 4.2.5 "Brush" and follow the provided instructions.

4.3.3.4 Ultrasonic Cleaning

Please refer to Section 4.2.6 "Ultrasonic Cleaning" and follow the provided instructions.

4.3.3.5 Spray

Please refer to Section 4.2.7 "Spray" and follow the provided instructions.

4.3.3.6 Rinse

Please refer to Section 4.2.8 "Rinse" and follow the provided instructions.

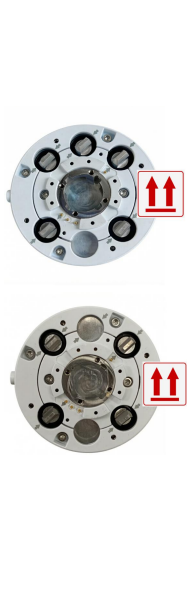
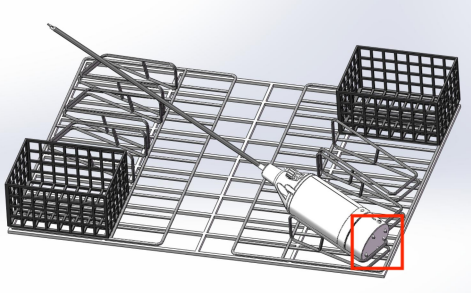
4.3.4 Automated Cleaning and Thermal Disinfection Using Washer Disinfector

 WARNING	1) Disinfection is not a substitute for cleaning or sterilization. 2) Check with the hospital's policy and regional guidelines to determine if disinfection is needed.
 CAUTION	1) Before automated cleaning and thermal disinfection using washer disinfector, ensure that the pressure valve cap and the one-way valve are properly installed. Failure to install them may result in damage to the instrument.

NOTE:

- Refer to Appendix B "Washer Disinfector" to find validated washer disinfector cycle parameters. An example diagram illustrating item placement within the washer-disinfector is also provided in Appendix B "Washer Disinfector".
- Disinfection may be performed as required by hospital policy and regional guidelines.
- Thermal disinfection should be done in accordance with ISO 15883-2.
- Each washer-disinfector provides its own manufacturer-specified drying program (see ISO 15883-1). Follow the drying instructions of the washer disinfector manufacturer.

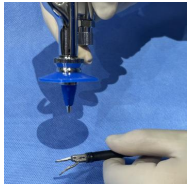
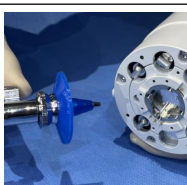
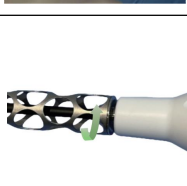
	Unscrew the cleaning cage in counterclockwise direction to remove it from the instrument.
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	Screw the pressure valve cap in clockwise direction to install it onto the instruments.
	To install the one-way valve, attach the hose of the one-way valve to the air nozzle of the pressure valve cap.
	Securely load the instrument into the washer disinfector, using the support rack as needed. Ensure the instrument is uninstalled with the cleaning cage and load them separately. For an example of item placement, refer to the diagram in Appendix B "Washer Disinfector." Follow the instructions of the washer disinfector manufacturer. NOTE: place the instrument in the orientation as shown for effective drainage of any residual water. 
	Set parameters and run the washer disinfector cycle. The cycle should include the parameters shown in Appendix B "Washer Disinfector". Perform disinfection per hospital policy and regional guidelines. Follow the instructions of the washer disinfector manufacturer.

4.3.5 Inspection with Drying as Required

	1) After drying, the surface of surgical instruments must be free of moisture, otherwise the low-temperature plasma sterilization process will be interrupted. 2) Keep the pressure valve cap and the one-way valve installed until the instrument is completely dry, to prevent moisture ingress.
---	---

	Under a 4x magnifying glass, inspect for soil. If soil is present, repeat the entire cleaning process.
---	---

	Inspect the entire end-effector for any residual moisture. If present, thoroughly wipe and air-dry until no visible moisture remains on any surface or in corners.
	Inspect the stem and the housing for any residual moisture. If present, thoroughly wipe and air-dry until no visible moisture remains on any surface or in corners.
	Inspect the entire back of housing for any residual moisture. If present, thoroughly wipe and air-dry until no visible moisture remains on any surface or in corners.
	Remove the one-way valve from the pressure valve cap.
	Screw the cleaning cage in clockwise direction to install it onto the instrument.

NOTE: If the instruments still do not meet the standards after repeated cleaning, please contact Surgerii Robotics.

4.3.6 Transport

Please refer to Section 4.2.12 "Transport" and follow the provided instructions.

4.4 Automated Cleaning Using MAG-120I

1	Sealing Test
2	Remove the Pressure Valve Cap
3	Automated Cleaning Using MAG-120I
4	Chemical Disinfection
5	Drying
6	Inspect
7	Transport

See the following sections for step-by-step instructions using the following materials:

- Endoscope leak detector
- A container capable of fully accommodating the items to be cleaned
- Spray gun
- A proper basket, box, or bag for protective transportation
- Disinfectant
- Purified water
- Clean dry air
- MAG-120I automated cleaning machine
- 4X magnifying glass

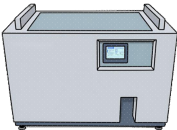
4.4.1 Sealing Test

Please refer to Section 4.2.1 "Sealing Test" and follow the provided instructions.

4.4.2 Remove the Pressure Valve Cap

Please refer to Section 4.2.2 "Remove the Pressure Valve Cap" and follow the provided instructions.

4.4.3 Automated Cleaning Using MAG-120I

	Unscrew the cleaning cage in counterclockwise direction to remove it from the instrument.
	Follow the reprocessing instructions of the cleaning machine manufacturer.
	Screw the cleaning cage in clockwise direction to install it onto the instrument.

For validated cleaning machines, detergents, load capacity, and parameters please

refer to Appendix A "MAG-120I Automated Cleaning Machine".

4.4.4 Chemical Disinfection

The necessity and required level of disinfection may vary according to hospital policies and regional guidelines. If disinfection is not needed, proceed to "Drying".

 WARNING	1) Disinfection is not a substitute for cleaning or sterilization. 2) Check with the hospital's policy and regional guidelines to determine if disinfection is needed.
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Please refer to Section 4.2.9 "Chemical Disinfection" and follow the provided instructions.

4.4.5 Drying (Manual / Automated)

According to the actual operating environment conditions, either manual drying or automated drying may be selected.

 CAUTION	1) After drying, the surface of surgical instruments must be free of moisture, otherwise the low-temperature plasma sterilization process will be interrupted.
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Please refer to Section 4.2.10 "Drying (Manual / Automated)" and follow the provided instructions.

4.4.6 Inspect

Please refer to Section 4.2.11 "Inspect" and follow the provided instructions.

4.4.7 Transport

Please refer to Section 4.2.12 "Transport" and follow the provided instructions.

4.5 Sterilization

1	Final Inspect
2	Sealing Test
3	Pack
4	Sterilize
5	Store

See the following sections for step-by-step instructions using the following materials:

- Endoscope leak detector
- Lubricant (legally marketed)
- Pouches for packing
- Non-woven wrapping material
- Chemical monitoring indicator card, biological indicator, label, sterilization indicator tape
- Sterilizer

4.5.1 Final Inspect

	Unscrew the cleaning cage in counterclockwise direction to remove it from the instrument.
	Under a 4x magnifying glass, inspect for soil. If soil is present, repeat the entire cleaning process. Inspect the instruments for any damage or scratches on the stem cover. Check the end-effector for any damage to the jaws, and inspect the housing for any cracks or damage. If any issues are found, please contact Surgerii Robotics.
	Screw the cleaning cage in clockwise direction to install it onto the instrument.

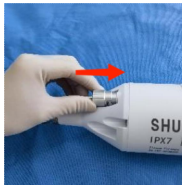
4.5.2 Sealing Test

Repeat the procedure specified in Section 4.2.1. If the sealing test results are unsatisfactory, indicating a seal defect, please contact Surgerii Robotics.

4.5.3 Pack

 WARNING	1) Only use validated pouches and non-woven wrapping material for packing. Using materials that have not been validated could result in damaging or ineffective sterilization of instruments.
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 CAUTION	1) Before packing, ensure that the pressure valve cap is installed properly, the one-way valve is removed, and confirm that the jaws (if present) are open.
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	Ensure the pressure valve cap is installed properly. If it is not installed, screw the pressure valve cap in clockwise direction to install it onto the instruments.
	Before packing, it is recommended to apply an appropriate amount of lubricants to the end effector of the surgical instrument, especially to the jaws of the needle driver, to ensure the surgical instrument function properly in its next use. Use a legally marketed lubricant. Refer to lubricant manufacturer's labeling instructions for use.
	If a sterilization pouch is used, cut the pouch to 100 cm * 20 cm and pack the instrument. If non-woven wrapping material is used, select an appropriately sized non-woven sheet and double-wrap the instrument.

According to the relevant regulations and guidelines of the hospital, place chemical indicator cards, biological indicators, labels, and other items in the corresponding positions.

4.5.4 Sterilize

 WARNING	1) Only use validated reprocessing products and equipment. Only use validated the parameter settings and cycles. Parameter settings or cycles that have not been validated could result in damaging, ineffective cleaning, or ineffective sterilization of the instruments.
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Put the packed instruments into the hydrogen peroxide low temperature plasma sterilizer. Instruments should be placed without squeezing and stacking. Refer to the sterilizer manufacturers' instructions for loading methods, proper use of the sterilizer and recommendations for sterilization.

Validated Sterilizer	Validated Cycle	Sterilization Parameters*
STERIS® V-PRO max 2	Non Lumen	● Vacuum setpoint (factory setting): 1.0 Torr ● STERIS Hydrogen Peroxide Sterilant (VAPROX HC) concentration: 59% ● Chamber temperature during sterilization: 48.5°C - 51.5°C (119°F - 125°F) ● Cycle time: approx 28 minutes
STEELCO PL130	FLEX	● Vacuum setpoint (factory setting): 0.8 hPa ● Cartridge: liquid solution of concentrated hydrogen peroxide (58%) ● Chamber temperature during sterilization: 50°C -

		55°C ● Cycle time: 37 minutes
STERRAD 100NX	FLEX	● Vacuum setpoint (factory setting): 500 mTorr ● Cassette: 58% hydrogen peroxide ● Chamber temperature during sterilization: 50°C (47°C - 56°C) ● Cycle time: 42 minutes
*Note: The sterilization parameters are all originated from the instructions for use of the sterilizer. For more details, please refer to the instructions for use of the sterilizer.		

The validated maximum load capacity per sterilization cycle is as follows:

Sterilizer	Item	Quantity
STERIS® V-PRO max 2 STEELCO PL130 STERRAD 100NX	Surgical instrument or 3D endoscope	4
	Disposable tip cover	4
	Monopolar energy instrument cord or Bipolar energy instrument cord	4
	Sheath connector	4
	Instrument release wrench	1

4.5.5 Store

Store sterilized surgical instruments under appropriate conditions as specified in the Endoscopic Surgical System User Manual.

Appendix A MAG-120I Automated Cleaning Machine

Validated Cleaning Machine		
Manufacturer	Model	Compatible Detergent
Marge	MAG-120I	Choose either one: ● Metrex MetriZyme™ ● Steris Prolystica® 2x Concentrate Enzymatic Presoak and Cleaner ● DR.WEIGERT neodisher® MediClean forte

Cleaning Parameters for Marge MAG-120I				
Items		Metrex MetriZyme™	Steris Prolystica® 2x Concentrate Enzymatic Presoak and Cleaner	DR.WEIGERT neodisher®MediClean forte
Pre-wash	Temperature	Room temperature	Room temperature	Room temperature
	Time	Not less than 60s	Not less than 60s	Not less than 60s
Enzyme wash (spray)	Temperature	20°C - 40°C	20°C - 55°C	35°C - 55°C
	Wash time	Not less than 180s	Not less than 180s	Not less than 180s
	Enzyme dosing time	68s - 272s	35s	175s
	Alkali dosing time	0s	0s	0s
Ultrasonic cleaning	1 st ultrasonic time	Not less than 300s	Not less than 300s	Not less than 300s
	2 nd ultrasonic time	0s	0s	0s
	3 rd ultrasonic time	0s	0s	0s
	Enzyme dosing time	0s	0s	0s
	Alkali dosing time	0s	0s	0s
Rinse	Rinse time	Not less than 60s	Not less than 60s	Not less than 60s
	Temperature	Room temperature	Room temperature	Room temperature
	Number of rinse cycles	3 times	2 times	2 times

Drying Parameters for Marge MAG-120I		
Rinse	Rinse time	Not less than 60s
	Temperature	Room temperature
	Number of rinse cycles	1 time
Drying	Drying time	Not less than 5400s
	Drying temperature	58°C - 60°C
	Cooling time	Not less than 60s

Validated Maximum Load Capacity per Cleaning or Drying cycle			
Model	Item	Quantity	Place
Marge MAG-120I	3D endoscope	2	Upper basket
	Monopolar energy instrument cord or Bipolar energy instrument cord	4	
	Surgical instrument cleaning cage or Endoscope cleaning cage	8	

	Surgical instrument	6	Lower basket
	Disposable tip cover	17	
	Sheath connector	5	
	Instrument release wrench	1	

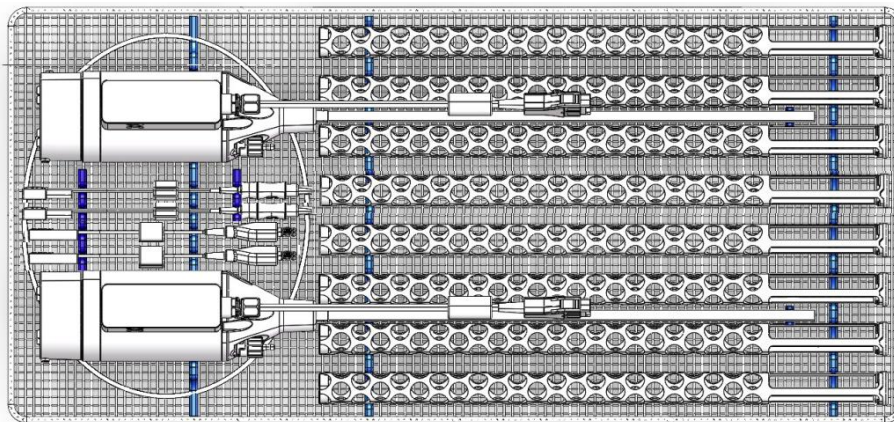


Diagram of item placement in Marge MAG-120I (upper basket)

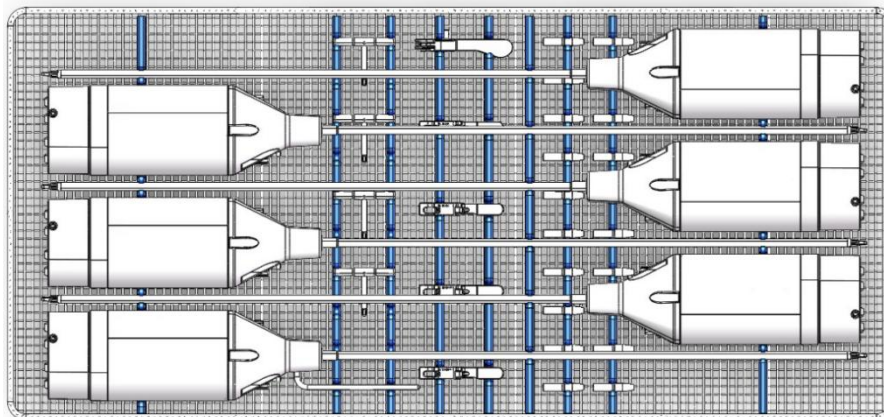


Diagram of item placement in Marge MAG-120I (lower basket)

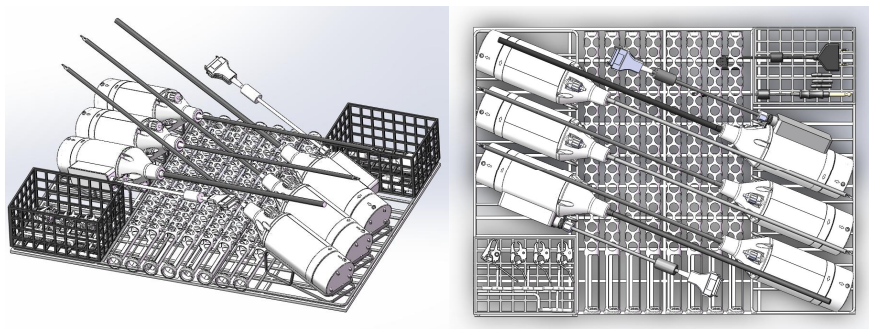
Appendix B Washer Disinfector

NOTE:

- Use only a washer disinfector that has been validated for efficacy in accordance with ISO 15883-1 and ISO 15883-2.
- Follow the instructions provided by the washer disinfector manufacturer and that of the process-chemistry manufacturer.
- The washer disinfector features a thermal disinfection cycle that follows cleaning. The thermal disinfection process complies with national regulatory requirements for the requisite A₀-value, as specified in ISO 15883-1. An A₀-value of 3000 is recommended.

Typical Washer Disinfector Parameters		
Stage of cycle	Parameters	Comments
Pre-wash	4 minutes with cold water	-
Wash	10 minutes detergent wash at 45°C using a 0.5% concentration of DR.WEIGERT neodisher MediClean forte	Use a detergent concentration and temperature range recommended by the detergent manufacturer Use tap water*
Rinse	4 minutes with water	Use DI water
Thermal Disinfection	Up to 93°C with a duration of 5 minutes	Use DI water
Drying	Up to 90°C with a duration of 20 minutes	-

* Tap water: Of drinking water quality or above.



Example diagram illustrating item placement in a washer-disinfector