



BEFORE USING PRODUCT, READ THE FOLLOWING INFORMATION THOROUGHLY.

◆ **DEVICE DESCRIPTION :**

The LAGIS Suction Irrigation System consists of flexible tubing attached to a plastic housing/handle with a spring activated valve/stopper. Attached distally is a stainless steel probe and proximally is a plastic housing cap. When properly connected and operated, the device irrigates and evacuates fluids during laparoscopic procedures.

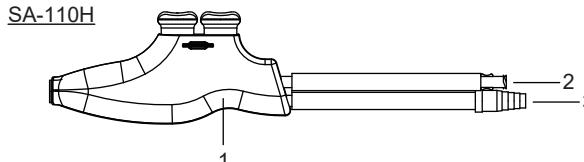
| Item | Pressure range | Flow rate |
|-------|----------------|-----------|
| Value | 0~1000 mmHg | >10L/min |

PRODUCT MODEL

| Models Numbers | Description | Probe Length (cm) |
|----------------|--|-------------------|
| SA-450C | | 45 |
| SA-360C | | 36 |
| SA-520C | | 52 |
| SA-360C-B | Direct Type Suction Irrigation for Dual Solution Bags without Probe | — |
| SA-360E | Direct Type Suction Irrigation with 11cm Tubing | 36 |
| SA-300P | 280cm Tubing for Dual Solution Bags | — |
| SA-250P | 250cm Tubing for Dual Solution Bags | — |
| SA-110H | Direct Type Suction Irrigation Handle with 11cm Tubing | — |
| SA-450CT | | 45 |
| SA-360CT | | 36 |
| SA-320CT | | 32 |
| SA-520CT | | 52 |
| SA-360CT-B | Trumpet Type Suction Irrigation for Dual Solution Bags without Probe | — |
| SA-320ET | Trumpet Type Suction Irrigation with 11cm Tubing | 32 |
| SA-T110 | Trumpet Type Suction Irrigation Handle with 11cm Tubing | — |

◆ **ILLUSTRATION AND NOMENCLATURE :**

1. Handle



2. Female Luer

Compatible with Male Luer connectors that comply with ISO 80369-7.

3. Barbed Connector

Connectable to Suction Tubing Connectors with an inner diameter greater than 8.3mm.

4. Male Luer

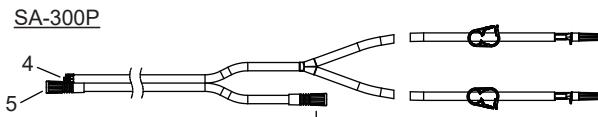
Compatible with Female Luer connectors that comply with ISO 80369-7.

5. Suction Tubing Connector

Connectable to Barbed Connector with an outer diameter smaller than 8.8mm.

6. Suction Tubing Connector

Connectable to Suction Canister Connector or Suction Pump Connector with an outer diameter smaller than 8.8mm.



◆ **INDICATIONS/INTENDED PURPOSE :**

- The LAGIS Suction Irrigation System has applications in laparoscopic procedures to provide suction and irrigation functions to help flush blood and tissue debris from the operative site during laparoscopy to aid visualization.

◆ **INTENDED PATIENT POPULATION :**

- Patient target group: the LAGIS Suction Irrigation System is intended for adults who need laparoscopic procedures.

◆ **CONTRAINDICATIONS :**

The LAGIS Suction Irrigation System is not intended for use when endoscopic techniques are contraindicated.

◆ **INSTRUCTIONS FOR USE :**

Prior to use, inspect the contents of the packaging and the packaging itself to ensure the integrity is not compromised.

- Pull the red guard tab located at the side of the housing to relieve the buttons. (For Direct Type.)
- For irrigation: insert the tubing spike of the LAGIS Suction Irrigation System into a normal saline solution bag.
- For suction: attach the suction tubing of the LAGIS Suction Irrigation System to a suction canister.
- Depress the blue button to irrigate.
- Depress the red button to evacuate fluids.
- Upon completion of the procedure, disconnect the tubes from normal saline solution bags and the fluid collecting canister.
- Dispose of the used the LAGIS Suction Irrigation System, normal saline solution bags, and the canister properly and safely by healthcare professionals in accordance with the national waste management regulation.

◆ **WARNINGS AND PRECAUTIONS :**

- Do not use if the device or the sterile packaging is open or damaged, as this may cause an increase in the incidence of wound infections.
- This brochure is to assist clinicians in the use of the LAGIS Suction Irrigation System. This is not an instructional reference for laparoscopic surgery.
- If trocars or accessories from different manufacturers are used together in a procedure, verify compatibility prior to performing the procedure.
- The probe and housing cap must be attached securely to prevent fluid leakage, as this may cause the device to lose function.
- This device is packaged and sterilized for single patient use only. Do not reuse, reprocess, or resterilize. Reuse, reprocess, or resterilization may create contamination, infection, cross-infection, or even compromise the integrity of the device and lead to device failure which in turn may result in patient injury, illness or death.
- The normal saline solution only shall be used for irrigation solution.
- This device should be operated only by surgeons with adequate training and familiarity with surgical techniques. Consult medical literature for further information regarding techniques, hazards, contra-indications, and complications prior to performing the procedures.
- Return the device and packaging to the distributor or implement safe disposal handling by the healthcare professionals if the sterile packaging is damaged or unintentionally opened before use.
- The used device which comes into contact with bodily fluids should be considered as biomedical waste and safely dispose of by healthcare professionals in compliance with the national waste management regulation to prevent patients, users, and other persons from biological contamination or infection.

- In the event of malfunction of the device, changes in performance that they may affect safety, or even any serious incident, please report to the manufacturer, the competent authority of the Member State, and the authorized representative immediately according to the contact information provided on the label or in this instruction for use.
- Do not suck foreign objects or a large amount of tissue in a short period of time, as this may cause the device to lose suction function.
- Improper assembly or operation of the device may result in tissue or organ injuries from mechanical damage to the patient or operator.

Compatibility:

Please use LAGIS Suction Irrigation System with a normal saline solution bag and suction canister or irrigation/suction pump, tubing, 5 mm probe and 5 mm Trocar.

◆ ENVIRONMENTAL CONDITIONS FOR STORAGE :

Appropriate storage environment is a clean and dry area away from sunlight with a temperature range of 13~30°C (55.4~86°F).

◆ EXPLANATION OF SYMBOLS :

| | | | | | |
|----------------|---|--|---|--|---|
| | Temperature limit | | Caution | | Not made with natural rubber latex |
| | Do not re-sterilize | | Manufacturer | | Do not use if package is damaged and consult instructions for use |
| | Do not re-use | | Consult instructions for use or consult electronic instructions for use | | Sterilized using ethylene oxide |
| | Date of manufacture | | Single sterile barrier system | | Medical device |
| Rx only | Caution: Federal (USA) law restricts this device to sale by or on the order of a physician. | | | | |