



Not made with natural rubber latex.

⚠ BEFORE USING PRODUCT, READ THE FOLLOWING INFORMATION THOROUGHLY.

DESCRIPTION

The LAGIS SUCTION IRRIGATION device consists of PVC 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. Devices could be categorized into different model numbers according to their lengths and function.

PRODUCT MODEL

Description	Model Numbers
Direct Flow™ Suction/Irrigation System for Dual Solution Bags.	SI-450C, SI-360C
Direct Flow™ Suction/Irrigation System without Probe	SI-360C-B
Direct Flow™ Suction/Irrigation Device without Tubing	SI-360E
Suction/Irrigation Tubing for Dual Solution Bags	SI-300P, SI-250P
Direct Flow™ Suction/Irrigation Device for use with 11cm Tubing	SI-110H
Suction/Irrigation 5mm Probe	SI-450S, SI-360S
Trumpet Suction/Irrigation System for Dual Solution Bags	SI-450CT, SI-360CT, SI-320CT
Trumpet Suction/Irrigation System without Probe	SI-360CT-B
Trumpet Suction/Irrigation Device without Tubing	SI-320ET
Trumpet Suction/Irrigation Handle	SI-070T
Trumpet Suction/Irrigation Device with Probe.	SI-360HT, SI-320HT
Trumpet Suction/Irrigation Device for use with 11cm Tubing	SI-T110

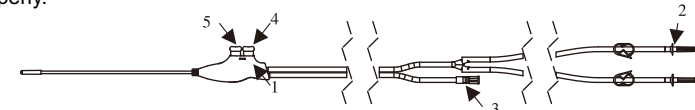
CONTRAINDICATIONS

This device is not intended for use except as indicated. It is not intended for use when endoscopic techniques are contraindicated.

INSTRUCTIONS FOR USE

- Pull the red guard tab located at the side of the housing (1) to relieve the buttons. (For Direct Flow™ devices.)
- For irrigation: insert the tubing spike (2) of the LAGIS SUCTION IRRIGATION device into a solution bag.

- For suction: attach the suction tubing (3) of the LAGIS SUCTION IRRIGATION device to a suction canister.
- Depress the blue button (4) to irrigate.
- Depress the red button (5) to evacuate fluids.
- Upon completion of the procedure, disconnect the tubes from the solution bag and the fluid collecting canister.
- Dispose of the used LAGIS SUCTION IRRIGATION device, solution bag, and the canister properly.




WARNING AND PRECAUTIONS

- Procedures for endoscopic surgery shall be performed only by qualified physicians familiar with endoscopic surgical technique.
 - This brochure is to assist clinicians in the use of the LAGIS SUCTION IRRIGATION device. This is not an instructional reference for laparoscopic surgery.
 - When endoscopic instruments and accessories from different manufacturers are used together in a procedure, verify compatibility prior to starting the procedure and ensure that electrical insulation or grounding is not compromised.
 - The probe and housing cap must be attached securely to prevent fluid leakage.
 - Sterile, non-toxic and non-pyrogenic unless unit package is opened, wet, or damaged.
 - Reprocessing and/or resterilization of this device may create the risk of contamination and patient infection. **DO NOT REUSE, REPROCESS OR RESTERILIZE.** For SINGLE use only.
 - CAUTION: For prescription only. Federal law (USA) restricts this device to sale by or on the order of a physician.
 - This medical device is made of material PVC, and it includes the plasticizer DEHP, so called Bis (2-ethylhexyl) phthalate. DEHP's effect to pregnant women and children is bigger than adult. When using this device, please pay attention to the risk result in the following possible complications, but are not limited to:
 - **Pregnant women:** Miscarriage and the deformity to embryo.
 - **Children:** The effects to the reproductive system including the decrease of the reproductive rate, the quantity of the sperm and the damage to the testis.
- Contact the trained doctor and nurses in advance to prevent the complications.

STORAGE CONDITIONS

- Suggestible storage temperature is room temperature (25°C) in a clean, cool and dry area away from sunlight.

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