

EndoGuidance Suction Irrigation System Instruction for Use

The following information should be read before using this device.

PRODUCT DESCRIPTION:

The EndoGuidance Suction Irrigation System is a sterile, single-use and multifunctional instrument which achieves 2 functions in one device. EndoGuidance Suction Irrigation System is available both in a 5mm and 10mm instrumentation with double spike tubing.

INTENDED USE:

The Suction Irrigation System is intended for the delivery of solution/irrigate to, and aspiration of fluids/smoke from, the operative site during laparoscopic surgical procedures to aid visualization.

INDICATIONS:

The device is designed to provide controlled suction/irrigation during laparoscopic procedures with the help of medical suction equipment. The pulsatile action of the pump mechanism helps flush blood and tissue debris from the operative site during laparoscopy to aid visualization. It may also be used for resection of filmy adhesions (i.e., hydrodissection) and peritoneal lavage.

CONTRAINDICATIONS:

This product is indicated only for laparoscopic suction/irrigation. Use of this product in hysteroscopy or for cavity distention is contraindicated.

Use of this device for intra-abdominal irrigation is contraindicated whenever laparoscopy is contraindicated. See operator's manual of your laparoscope for absolute and relative contraindications.

DIRECTIONS FOR USE:

1. Remove the Suction Irrigation System from the package.
2. Remove Probe cap and insert the spike to the desired irrigation pump, please close the white clamp before inserting the irrigation pump.
3. Connect suction adapter (end of white tubing) to patient port of suction bottle machine, please follow instructions provided by suction machine manufacturer.
4. Insert the shaft through the desired 5mm trocar sheath.
5. The suction and irrigation functions are operated by white and blue trumpet valve. To operate the suction and irrigation feature, please follow instructions provided by suction machine and irrigation pump manufacturer.

6. When the smoke evacuation function is used, the suction power is adjusted by the blue button. When the button is adjusted to the ON, the biggest suction power will be got. When the button is adjusted to the OFF, the smoke evacuation is closed.
7. Once the Endoscopic procedure is complete, dispose this device in accordance with local regulations.

CAUTIONS/WARNINGS:

1. This device is single-used and can't be reused, reprocessed, re-packaging or resterilized.

Reuse, reprocessing, resterilization or re-packaging may compromise the structural integrity and/or essential material and design characteristics that are critical to the overall performance of the device and may lead to device failure which may result in injury to the patient.

Reuse, reprocessing, resterilization or repackaging may also create a risk of contamination of the device and/or cause patient infection or cross infection, including, but not limited to, the transmission of infectious diseases from one patient to another. Contamination of the device may lead to injury, illness or death of the patient or end user.
2. Do not used if package is opened or damaged.

The package damaged products create a risk of contamination of the device and/or cause patient infection.
3. Endoscopic procedures must be performed only by physicians with adequate training and knowledge of these procedures. In addition, medical literature should be consulted regarding techniques, hazards, contraindications and complications prior to the performance of these procedures. As with any surgical procedure where extensive irrigation is utilized, intravasation levels should be closely monitored by the attending physician.
4. Before using endoscopic instruments and accessories from different manufacturers in a procedure, verify compatibility and ensure that electrical isolation of grounding is not compromised.
 - 4.1 When using electrosurgical attachments or inserts, follow all instructions, warnings, precautions, and contraindications provided with these devices.
 - 4.2 Prior to insertion and during use of the irrigation probe in the peritoneal cavity, the operator must confirm through visualization that fluid exits the irrigation channel when the irrigation trigger is activated to ensure proper function and avoid excessive air entering peritoneal cavity.
 - 4.3 The absence of fluid exiting the irrigating channel on activation signifies either a depletion of fluid from the system and a need for re-priming or a system malfunction. This absence of fluid flow necessitates the immediate withdrawal of the irrigation probe from the peritoneum to troubleshoot the system outside the

peritoneal cavity. If the absence of flow is due to priming problems or line obstructions, after correction the probe can be re-introduced when the device is fully functional. Otherwise, the pump should be replaced.

4.4 The Suction Irrigation Set will provide gravity flow if the suction pipe is not properly connect to the medical suction pump.

4.5 If there is leakage of irrigation fluid out the exhaust line either while priming during set-up or during use, discard and replace the system as this may indicate pump malfunction.

5. A complete understanding of techniques and principles involved in electrosurgical procedures is necessary to avoid burn or shock hazard to patient and/or operator.

As with any surgical procedure, intravasation should be closely monitored by the attending physician in order to prevent reported complications associated with intravasation.

6. Federal (U.S.A) law restricts this device to sale, distribution, and use by, or on the order of a physician.

Maintenance and storage conditions:

The well packaged disposable flushing aspirator shall be stored in a room that is clean, free of corrosive gases, well ventilated and with a relative humidity of no more than 80% to avoid direct sunlight.

Transportation:

Transportation requirements shall be in accordance with the provisions of the order contract. Do not press heavily to avoid strong vibration and turbulence.

Shelf life:

The shelf life of the product is 3 years in full compliance with the use rules, transportation, storage and other conditions.





















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| Symbol | Definition | Symbol | Definition |
|---|-----------------------------------|---|---|
|  | No Latex |  | Expiry Date |
|  | EO Sterilized |  | unique device identifier |
|  | Do Not Reuse |  | Indicates the medical device manufacturer |
|  | Do not use if package is damaged. |  | DEHP Free |
|  | Do not reuse |  | Indicates a medical device is non-pyrogenic |
|  | Consult Instruction for Use |  | Indicates the item is a medical device |
|  | Model Number |  | This device is prescription only |
|  | Lot Number |  | Indicates a single sterile barrier. |
|  | Manufacture Date |  | Single sterile barrier system with protective packaging outside |