

Instruction for Use

Product: Suction Irrigation Set

The Following information should be read before using this device.

Description:

The Suction & Irrigation Set is a single-use medical device designed for endoscopic surgery for cleansing of the abdominal cavity and aspiration of debris. Suction & Irrigation set is available both in a 5 mm and 10 mm instrumentation with double spike tubing.

Contraindications:





















This device is not intended for use when endoscopic techniques are contraindicated.

Preparation:

1. Remove the sleeve containing the Suction & Irrigation set from the package.
2. To remove spike's cap and insert the spike to the desired irrigation pump, please close the white clamp before inserting the irrigation pump.
3. To 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 5 mm 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.

Cautions/Warnings:

- This device was designed, tested and manufactured for single patient use only. Reuse or reprocessing of this device may lead to its failure and subsequent patient injury. Reprocessing and/or re-sterilization of this device may create the risk of contamination and patient infection. Do not reuse, reprocess or re-sterilize this device.
- Contents sterile unless enclosed package has been opened or damaged. Store at 15°C~25°C.
- Dispose used product following local state or federal guidelines.
- Federal (U.S.A) law restricts this device to sale, distribution, and use by, or on the order of a physician.

 Caution	 Sterilized using Ethylene Oxide	 Consult instructions for use
 Do not use if package is damaged	 Batch code	 Do not reuse
 Keep away from sunlight	 Date of manufacture	 Keep dry
 Catalogue number	 Manufacturer	 Authorised representative in the European community
 Do not re-sterilize	 Use by	 Temperature limitation: 15°C~25°C
 Medical device	 Single sterile barrier system	 Single sterile barrier system with protective packaging outside
 Swiss Authorised Representative	 Notified body: DNV Product Assurance AS, with CE2460	

If further information is required, please contact:



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Instruction for Use

Product: Suction Irrigation Probe

The Following information should be read before using this device.

Intended Use:

The AMD Suction Irrigation Probe is an accessory to the AMD Suction Irrigation systems. The probes are intended for evacuation and aspiration of fluids during general laparoscopic procedure.

Note: Single use only, Sterile (Unless package is damaged or opened). All contents are ETO sterilized.

Instruction for Use:

Open in a sterile environment; aseptically assemble the probe onto the suction irrigator. Hold the hub of the probe and screw it onto the front of the hand piece until the two components are fully assembled.

Cautions:

- This device was designed, tested and manufactured for single patient use only. Reuse or reprocessing of this device may lead to its failure and subsequent patient injury.
- Reprocessing and/or re-sterilization of this device may create the risk of contamination and patient infection. Do not reuse, reprocess or re-sterilize this device.
- Federal (U.S.A) law restricts this device to sale, distribution, and use by, or on the order of a physician.
- Do not apply excessive lateral force on the distal end. This may cause the probe crack, break and bend.

Warnings:

- Inspect the device prior to each use for cracks or breaks. Discard the product if there is any damage. Cracks or breaks may lead to inadvertent flow of electricity, shocks or saline leakage. Store at 15°C~25°C.
- Do not use the probe or other laparoscopic instrument as laser backstops. Absorbed radiation may cause excessive heating of laparoscopic instruments. Reflected radiation may cause inadvertent burns.
- The device is suit to AMD Suction Irrigation system only. Assemble the device to other system may lead to saline leakage, tube block, or system dysfunction.
- Before endoscopic instruments and accessories from different manufacture are utilize together in a procedure, verify compatibility and ensure that electrical isolation of grounding is not compromised.
- Dispose used product following local state or federal guidelines.



Caution



Sterilized using Ethylene Oxide



Consult instructions for use



Do not use if package is damaged



Batch code



Do not reuse



Keep away from sunlight



Date of manufacture



Keep dry



Catalogue number



Manufacturer



Authorised representative in the European community



Do not re-sterilize



Use by



Temperature limitation: 15°C~25°C



Medical device



Single sterile barrier system



Single sterile barrier system with protective packaging outside



Swiss Authorised Representative



Notified body: DNV Product Assurance AS, with CE2460

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