

INSTRUCTION FOR USE

Product: Suction Irrigation Set

The Following information should be read before using this device.

Intended Use:

The Suction & Irrigation Set is a single-use medical device designed for endoscopic surgery for cleansing of the abdominal cavity and aspiration of fluids.

Device REF#:

REF#	Contents
ASI-A20000	5mm*330mm probe, Double spike, Transparent handle with Screw port, Buttons: Suction(White), Irrigation(Blue)
ASI-A20010	5mm*330mm Probe, Premier Suction Irrigation Set with Double spike
ASI-A25000	5mm*450mm Probe, Premier set with double spike
ASI-A27000	10mm*330mm probe, Double spike, Transparent handle with Screw port, Buttons: Suction(White), Irrigation(Blue)
ASI-A2700Z	10*330mm probe, Premier set with dual spike
ASI-B20000	5mm x 330mm Length Probe
ASI-B20030	5*330mm probe, Premier set with dual spike and flip top back cap
ASI-C20060	5mm*330mm Probe, Elite Suction Irrigation Set with Dual Spike
ASI-C2006Z	5mm*330mm Probe, Elite Suction Irrigation Set with Dual Spike

Device Description:

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

Item	Pressure Range	Suction Flow Rate	Irrigation Flow Rate
Value	-700~0 mmHg	2 L / min	0.7 L / min

Residual risks remain despite risk controls. When used as intended, potential residual risks are rare and may include: (a) irritation or allergic reaction; (b) infection related to contamination from reuse or compromised packaging; (c) procedure-related delay (prolonged surgery); (d) procedure-related complication; (e) skin abrasion from improperly operates; and (f) rare long-term toxicological effects evaluated under the ISO 10993 series.

Users should follow this IFU and good clinical practice to minimize these risks.

Intended User / Patient Target Group:

This device is intended to be used by healthcare professionals for laparoscopy in an operating theatre. This device is intended for use by adult patients only.

Contraindications:

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

Instruction for Use:

1. Examine the sterile pouch prior to use. If the packaging or device appears damaged or compromised, discard and replace with a new sterile unit.
2. Open the package within the sterile field using aseptic technique, starting from the V-shaped notch. Carefully remove the package without contaminating the contents.
3. For irrigation: Close both white tubing clamps before connecting to the irrigation system. Remove the spike caps and insert the spikes firmly to the desired irrigation system.
4. For suction: Follow the instructions provided by the suction machine manufacturer for details on connecting the suction adapter to the suction bottle.
5. To prime the tubing set, open both white tubing clamps, press the irrigation valve, and purge all air from the irrigation tubing until fluid flows continuously from the probe tip.
6. Insert the device through the trocar. The device is a 5mm instrument, and an appropriate trocar diameter must be selected. When using ASI-A2700Z, the diameter changes to 10mm, and a trocar of the same diameter should be used.
7. The suction and irrigation functions are operated by pressing the trumpet valve. Follow the instructions provided by the suction machine and irrigation pump manufacturers for operation details.

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 are sterile unless enclosed package has been opened or damaged. Do not use the device if the packaging or the device is broken or damaged.
 - If allergy or irritation occurs, stop use immediately.
 - If there is any abnormality in the appearance of the device or the device cannot be used, please replace the device with a new one. Recommend preparing a spare device.
 - If trocars or accessories from different manufacturers are used together in a procedure, verify compatibility prior to performing the procedure.
 - The product must be used exclusively by qualified medical staff. Thorough understanding of principles, instrumentation and techniques involving minimal invasive procedures is required to avoid possible injuries to both patients and medical staff.
 - Improper assembly or operation of the device may prolong surgical time, and even may lead to injury of the patient or operator.
 - The steel pipe and the cap of handle must be attached securely to prevent fluid leakage, as this may cause the device to lose function.
 - Only use AMD probes that are designated for AMD suction irrigation set to prevent possible patient injury resulting from loss of performance, leakage and inadvertent disassembly.
 - The suction function is intended for fluid aspiration only.
 - Do not place the probe too close to organ walls or tissues during irrigation or suction, as this may cause tissue injury or wall trauma.
 - Do not bend the tubing tighter than a radius of 2 cm, as this may reduce suction performance.
 - 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.
 - Do not use products beyond the expiry date.
 - Do not connect to the saline solution bag unless the button clip has been removed.
 - Do not use with a powered irrigation fluid supply systems.
 - 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.

Compatibility:

Please use with a normal saline solution bag and suction canister.

If using a 5mm probe, please use a 5mm trocar.

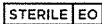
If using a 10mm probe, please use a 10mm trocar.

Operational, Storage and Transportation Conditions:

- Operational temperature: 15°C to 25°C
- Storage temperature: 15°C to 25°C
- Transportation temperature: 5°C to 60°C

Notice to user and/or patients in EU:

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

 Medical device	 Catalogue number	 Batch code
 Manufacturer	 Date of manufacture	 Use-by date
 Sterilized using Ethylene Oxide	 Do not re-sterilise	 Do not use if package is damaged and consult instructions for use
 Caution	 Keep away from sunlight	 Keep dry
 Do not re-use	 Single sterile barrier system	 Unique device identifier



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Consult instructions for use



Authorised representative in the European Union



Notified body: DNV Product Assurance AS, with CE2460



Not made with natural rubber latex



Swiss Authorised Representative



Federal law restricts this device to sale by or on the order of a physician



Temperature limit



Distributor



Importer

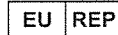
If further information is required, please contact:



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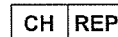
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INSTRUCTION FOR USE

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 set. 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.

Device REF#:

REF#	Contents
ASI-0X50X0	5mm*450mm probe
ASI-0X70X0	10mm*330mm probe
ASI-0X90X0	10mm*450mm probe with Triangular knob
ASI-1X00X0	5mm*330mm probe
ASI-1X50X0	5x450mm Probe for Elite Suction Irrigation set
ASI-1X70X0	10x330mm Probe for Elite Suction Irrigation set
ASI-2X10X0	5*330mm probe with knob
ASI-2X50X0	5*450mm probe with knob
ASI-3X00X0	5*330 mm probe

Device Description:

The AMD Suction Irrigation Probe is intended to be used as part of the AMD Suction Irrigation Set. For complete instructions for use, please refer to the IFU of the Suction Irrigation Set.

Residual risks remain despite risk controls. When used as intended, potential residual risks are rare and may include: (a) irritation or allergic reaction; (b) infection related to contamination from reuse or compromised packaging; (c) procedure-related delay (prolonged surgery); (d) procedure-related complication; (e) skin abrasion from improperly operates; and (f) rare long-term toxicological effects evaluated under the ISO 10993 series.

Users should follow this IFU and good clinical practice to minimize these risks.

Intended User / Patient Target Group:

This device is intended to be used by healthcare professionals for laparoscopy in an operating theatre. This device is intended for use by adult patients only.

Contraindications:

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

Instruction for Use:

1. Examine the sterile pouch prior to use. If the packaging or device appears damaged or compromised, discard and replace with a new sterile unit.
2. Hold the probe hub and screw it onto the front of the handpiece until both components are securely assembled.

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 are sterile unless enclosed package has been opened or damaged. Do not use the device if the packaging or the device is broken or damaged.
- If allergy or irritation occurs, stop use immediately.
- If there is any abnormality in the appearance of the device or the device cannot be used, please replace the device with a new one. Recommend preparing a spare device.
- The product must be used exclusively by qualified medical staff. Thorough understanding of principles, instrumentation and techniques involving minimal invasive procedures is required to avoid possible injuries to both patients and medical staff.
- Improper assembly or operation of the device may prolong surgical time, and even may lead to injury of the patient or operator.
- The steel pipe and the cap of handle must be attached securely to prevent fluid leakage, as this may cause the device to lose function.
- Only use AMD probes that are designated for AMD suction irrigation set to prevent possible patient injury resulting from loss of performance, leakage and inadvertent disassembly.
- Do not use products beyond the expiry date.
- 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.

Compatibility:

If using a 5mm probe, please use a 5mm trocar.

If using a 10mm probe, please use a 10mm trocar.

Operational, Storage and Transportation Conditions:

- Operational temperature: 15°C to 25°C
- Storage temperature: 15°C to 25°C
- Transportation temperature: 5°C to 60°C

Notice to user and/or patients in EU:

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

	Medical device		Catalogue number		Batch code
	Manufacturer		Date of manufacture		Use-by date
	Sterilized using Ethylene Oxide		Do not resterilise		Do not use if package is damaged and consult instructions for use
	Caution		Keep away from sunlight		Keep dry
	Do not re-use		Single sterile barrier system		Unique device identifier
	Consult instructions for use		Authorised representative in the European Union		Notified body: DNV Product Assurance AS, with CE2460
	Not made with natural rubber latex		Swiss Authorised Representative		Federal law restricts this device to sale by or on the order of a physician
	Temperature limitation: 15°C~25°C		Distributor		Importer

If further information is required, please contact:



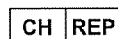
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