

## 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.

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

#### If further information is required, please contact:



Advanced Medical Design Co., Ltd.  
 4F~5F, No29, Wuquan 5th Rd., Wugu Dist.,  
 New Taipei City, 24888 Taiwan R.O.C.  
 TEL: 886-2-22902627  
 FAX: 886-2-22988501  
<https://www.amdintl.com.tw/>  
 Email: sales@amdintl.com.tw



OBELIS S.A  
 Bd. Général Wahis, 53, 1030 Brussels, Belgium  
 TEL: +3227325954  
 FAX: +3227326003  
 E-mail: mail@obelis.net



Arazy Group Swiss GmbH  
 Bruderholzallee 53, 4059 Basel, Schweiz  
 swiss.ar@arazygroup.com

## 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.

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

#### If further information is required, please contact:



Advanced Medical Design Co., Ltd.  
 4F~5F, No29, Wuquan 5th Rd., Wugu Dist.,  
 New Taipei City, 24888 Taiwan R.O.C.  
 TEL: 886-2-22902627  
 FAX: 886-2-22988501  
<https://www.amdintl.com.tw/>  
 Email: sales@amdintl.com.tw



OBELIS S.A  
 Bd. Général Wahis, 53, 1030 Brussels, Belgium  
 TEL: +3227325954  
 FAX: +3227326003  
 E-mail: mail@obelis.net



Arazy Group Swiss GmbH  
 Bruderholzallee 53, 4059 Basel, Schweiz  
 swiss.ar@arazygroup.com