

Instruction for Use

Product: Anti-Fog Solution

The Following information should be read before using this device.

Description:























The Anti-Fog Solution is a sterile, single use, disposable medical device intended to prevent condensation on the distal lens of endoscope and laparoscopes. The Anti-Fog consists of a 6ml vial of solution and a sponge applicator with adhesive backing.

Instructions for Use:

- Step 1. Examine sterile pouch, have a new pack if the package is damaged.
- Step 2. Place the Anti-Fog bottle on the sterile field.
- Step 3. Drop few into the sponge till the foam is moist.
- Step 4. Apply distal tip of rigid telescope to sponge till some bubbles on the foam surface.
- Step 5. Upon completion of the endoscopic procedure, dispose of this device in accordance with local regulation.

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 irradiation	 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
 Do not re-sterilize	 Use by	 Authorised representative in the European community
 Catalogue number	 Manufacturer	 Temperature limitation: 15°C~25°C
 Notified body: DNV Product Assurance AS, with CE2460	 Not made with natural rubber latex	 Federal law restricts this device to sale by or on the order of a physician
 Medical device	 Single sterile barrier system	 Single sterile barrier system with protective packaging outside
 Swiss Authorised Representative		

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: Anti-Fog Solution and Accessories

The Following information should be read before using this device.

Description:

Anti-fog solution and accessories is packaged in zip lock bag (non-sterile procedure pack) and manufactured for single patient use only. The non-sterile procedure contains the following items:

1. Sterile 6ml anti-fog solution
2. Sterile medical sponge with drawstring and radiopaque thread

Indications for Use:

Anti-fog solution and accessories is designed for using in warmer of endoscope/ laparoscope to prevent condensation and fogging of the scope.

Instructions for Use:

1. Open the sterile pouch of medical sponge and place onto the sterile field.
2. Fully loose the drawstring of medical sponge.
3. Open the sterile pouch of anti-fog solution and place onto the sterile field.
4. Unscrew the cap of anti-fog solution. Squeeze some solutions onto the medical sponge until the medical sponge is wet and soft completely.
5. Use the tip of the endoscope/ laparoscope to contact with medical sponge gently. Make sure the solution is fully spread on the lens. The endoscope/ laparoscope is ready for use.
6. Use 5mm instrument grasps the medical sponge, then put the medical sponge into abdominal cavity through the trocar (the ending position need to close to the distal cannula). The black drawstring needs to be placed outside of the body.
7. Using the medical sponge to wipe the endoscope/laparoscope in the abdominal cavity if the endoscope/ laparoscope starts with fog or any debris on the scope during the operation.
8. After operation, pulling the external drawstring of medical sponge to remove the medical sponge along with the cannula.
9. Disposed used product following standard procedure in the local government regulations.























If the operation procedure uses the trocar smaller than 10mm, the medical sponge can be used for external only. The following is the procedures:

1. Use the tip of the endoscope/ laparoscope to contact with medical sponge gently. Make sure the solution is fully spread on the lens. The endoscope/ laparoscope is ready for use.
2. Please remove the s endoscope/ laparoscope from the body if the endoscope/laparoscope starts with fog.
3. Check whether the surface of medical sponge is still wet and soft or not. If not, please squeeze anti-fog solution onto the medical sponge until the medical sponge becomes wet and soft.
4. Using the tip of the scope to contact with medical sponge gently.
5. Disposed used product following standard procedure in the local government regulations.

Cautions/Warnings:

1. 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.
2. Do not use grasper to remove the internal medical sponge through the cannula.
3. Do not insert the medical sponge into the abdominal cavity if the operation uses the trocar smaller than 10mm.
4. Store the procedure pack at room temperature 15°C~25°C.
5. If the medical sponge has a dry phenomenon (become harder) in the abdominal cavity, please do not pull out from the body.
6. Based upon different operation time, the medical sponge could dry in the abdominal cavity during the operation. Please make sure the medical sponge is wet and soft before removing the medical sponge. If dry, please apply the normal saline on the medical sponge to make it wet and soft, and then the medical sponge can be removed out of the body.

7. If the medical sponge has dried during the surgery, please apply the normal saline on the medical sponge to make it wet and soft, and then remove the medical sponge from the body. Take the new procedure kit and repeat the instruction to continue the surgery.
8. Do not use if the pouch of 6ml anti-fog solution is damaged or opened.
9. Do not use if the pouch of medical sponge with drawstring and radiopaque thread is damaged or opened.
10. Disposed used product following standard procedure in the local government regulations.

 Caution	 Sterilized using irradiation	 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
 Do not re-sterilize	 Use by	 Authorised representative in the European community
 Catalogue number	 Manufacturer	 Temperature limitation: 15°C~25°C
 Notified body: DNV Product Assurance AS, with CE2460	 Not made with natural rubber latex	 Federal law restricts this device to sale by or on the order of a physician
 Medical device	 Single sterile barrier system	 Single sterile barrier system with protective packaging outside
 Swiss Authorised Representative		

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