

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:

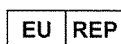
- This device was designed, tested and manufactured for single patient use only. Reuse or reprocessing of this device may lead to its failure and subsequent patient injury. Reprocessing and/or re-sterilization of this device may create the risk of contamination and patient infection. Do not reuse, reprocess 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

