

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:



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◆ INSTRUCTION FOR USE◆

(Anti-Fog Solution with Sponge)(REF# FC00013/FC00013-100AD)

◆ Description:

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◆INSTRUCTIONS FOR USE

Step 1. Examine sterile pouch. Discard and use a new pack if the package is damaged.

























Step 2. Place the Anti-Fog bottle on the sterile field.

Step 3. Place a few drops into the sponge until moist.

Step 4. Apply moist sponge to distal tip of rigid laparoscope, until some bubbles are observed on the foam surface.

Step 5. Upon completion of the endoscopic procedure, dispose of this device in accordance with local regulation.

Explanation of symbols:

	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		Authorized 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		Distributor		Flammable




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


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Instruction for Use

Product: Anti-Fog Solution

The Following information should be read before using this device.

Description:
























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 Medical device	 Single sterile barrier system	 Single sterile barrier system with protective packaging outside
 Swiss Authorised Representative	 Importer	

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Plasmatica Ltd
 HaTaasiya 25 Raanana 4365413 Israel

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