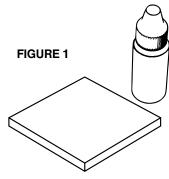
# **INSTRUCTIONS FOR USE:** ANTI-FOG SOLUTION | NON-STERILE

# BEFORE USING PRODUCT, READ THE FOLLOWING INFORMATION THOROUGHLY.

#### **DESCRIPTION**

The Antifog with Pad is a single use, non-sterile device that is designed to apply an antifogging solution to the scope when used prior to and during procedures that utilize an endoscope or laparoscope. Included with the system is the Antifog bottle with solution and a foam pad with an adhesive bottom. See *Figure 1*.



#### **INDICATIONS**

The Antifog with Pad is a single use, non-sterile device to be used prior to and during endoscopic and laparoscopic procedures to prevent fogging of the scope lens.

#### INTENDED PURPOSE AND USER

This device is intended for use by trained healthcare professionals only.

#### **CONTRADICTIONS**

This device is not designed, sold, or intended for use except as indicated.

#### **KNOWLEDGE AND USE**

Device is to be used by prescription only. Professional use requires knowledge of this instruction for use. Device use limited to surgical operating room in a hospital or surgery center.

#### **CLINICAL BENEFITS**

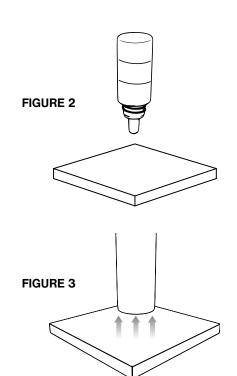
Provides a clean field & vision for professionals during surgical procedures.

#### PREPARATION AND USE

- 1. Dispense pouch contents onto sterile field.
- 2. Remove paper backing from foam pad and adhere foam pad onto sterile drape in a convenient location.
- 3. Remove cap and apply 5 or 6 drops of Anti-Fog solution to sponge. See *Figure 2*.
- 4. Touch distal end of scope to sponge, blot dry (do not wipe dry) with sterile sponge. *See Figure 3.*
- 5. Alternatively, apply solution directly to laparoscope lens.
- 6. Repeat as needed.

#### **DISPOSAL**

 After use, the Antifog with Pad should be disposed of in accordance with hospital policy



#### WARNINGS

- This device must be sterilized prior to use
- This device was designed, test and manufactured for single patient use only. Reuse or reprocessing of this device may lead to its failure or subsequent injury
- Reprocessing and/or resterilization of this device may create the risk of contamination and patient infection
- Do not reuse, reprocess or resterilization this device
- After use, the Antifog with Pad should be disposed of in accordance with hospital policy
- The Antifog with Pad should be stored in a clean, dry location at room temperature prior to use. Avoid prolonged exposure to elevated temperatures
- Please visually inspect for breaches of packaging integrity prior to use. Do not use if damaged, opened or breached as sterility cannot be guaranteed
- US Federal law restricts this device to sale by or on the order of a physician.

### **PRECAUTIONS**

- The solution should be used in accordance with the instructions for use and any contraindications, warnings or precautions provided by the manufacturer of the associated instrument.
- Notice to the User and/or patient that any serious incident that has occurred in relation to the device should be reported and the competent authority of the Member State in which the user and/or patient is established, as well as, Xodus Medical and its Authorized Representative.

#### **TECHNICAL SPECIFICATIONS**

- Xodus Medical recommends the use of gamma radiation for sterilization
- Materials of manufacture include:
  - Bottle: polyethylene
  - Foam Pad: Polyurethane foam, synthetic adhesive, radiopaque barium cord
  - Solution: Water, Isopropyl Alcohol, Sufactant
- Shelf-life 2 years

## STORAGE, TRANSPORT, AND OPERATIONAL CONDITIONS

Antifog with Pad should be stored in a clean, dry location at room temperature prior to use. Avoid prolonged exposure to elevated temperatures.



Do Not Re-use



Do Not



**Use-by Date** 



Consult instructions for use or consult electronic instructions for use









Not Made with Natural



Do Not Use If The Package Is Damaged Or Opened





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