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Informational Product Bulletin

Applicable to:

X MGC Employee X Distributor X Customer

Product(s): All

Date: November 15, 2016

Subject: preVent®, DirectConnect™ Flow Sensor & Umbilical Inspection, cleaning, and disinfecting

Background: Medical Graphics recommends any of the following methods for infection control to minimize the risk of cross-contamination:

1. Discard the flow sensor after single use.
2. Use a pulmonary function barrier filter such as the preVent® Filter, P/N 536713-001 (The frequency of changing the flow sensor is up to the individual laboratory procedures or facilities infection control policies.)
3. Clean and disinfect the flow sensor between uses.

NOTE: preVent® Filter, P/N 536713-001 is only applicable for the preVent flow sensor

Medical Graphics has validated that the preVent and DirectConnect flow sensors may be cleaned and disinfected 10 times according to the procedures outlined below. Under NO circumstances may heat, >120°F/49°C be used to disinfect or to dry the flow sensors. The flow sensors are made of polystyrene, which can be damaged by heat.

NOTE: These items are received in a clean, but not sterile condition.

Purpose: To provide accurate cleaning instructions that will not damage the preVent or DirectConnect flow sensors.

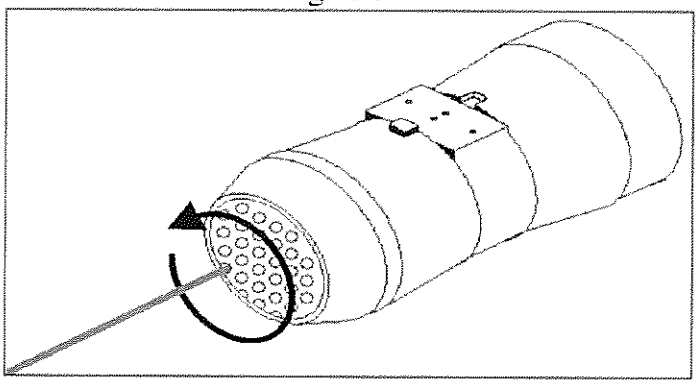
Procedure/Instructions:

Inspection

Before using any flow sensor, you must visually inspect each unit. Look for obvious signs of damage, including cracks, chips. On the ***preVent flow sensor only***, check for loose screens using the following steps:

1. Insert a rigid device, such as a small rod, into any hole near the edge of the screen (see Figure 1).
2. Hold the rod in the hole and perpendicular to the surface of the screen while you attempt to rotate the screen within its frame.
3. If the screen rotates or moves at all within its frame or if there are any obvious cracks or chips, dispose of the flow sensor immediately.

Figure 1



Cleaning

1. Rinse the flow sensor with warm tap water for two minutes, using a cleaning brush to loosen and remove any foreign matter.

Flow Sensor Disinfection:

1. Soak the flow sensor in a solution up to 10% bleach and water for 60 minutes; OR soak in a 2.4% glutaraldehyde solution for 45 minutes; OR use the Sterrad Sterilization (hydrogen peroxide) system.
2. Rinse flow sensor for five minutes using tap water.

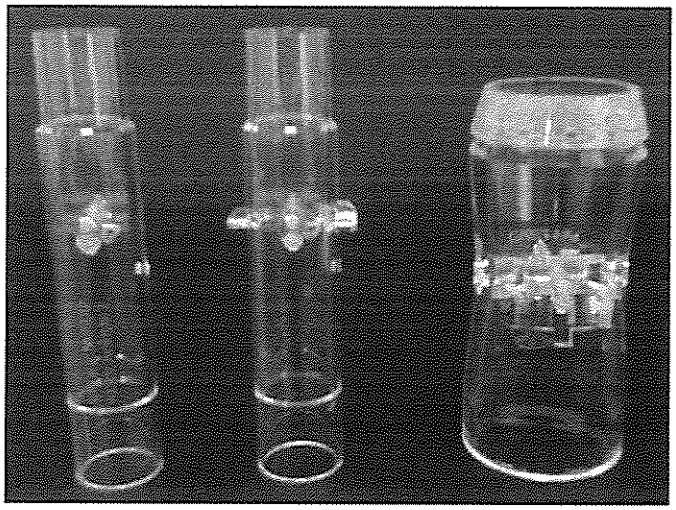
Note: To ensure test accuracy, no water may remain in the flow sensor or sample lines before using. Fan drying at room temperature or low pressure air through holes in the flow sensor may be used to hasten drying.

Umbilical Clip Assembly Disinfection:

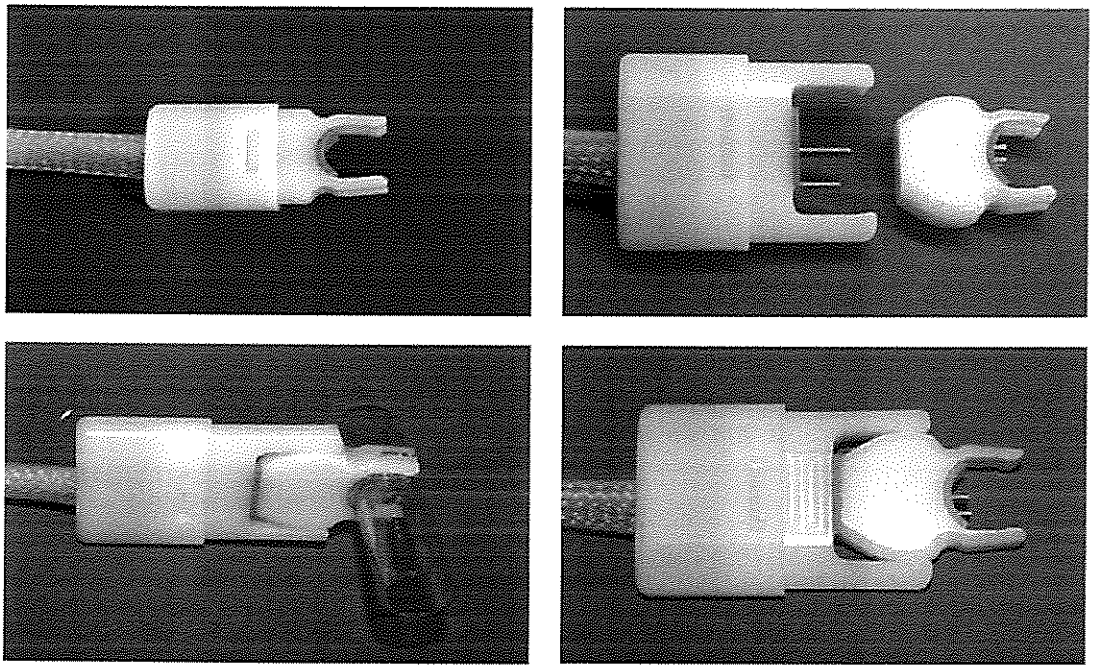
1. Disconnect the preVent or DirectConnect flow sensor
2. Assure the vacuum pump is off
3. Wipe down the umbilical sheath with a disinfectant wipe (example: CaviWipes by Metrex)
4. Wipe down the stainless steel tubes, clip & DirectConnect Adapter if applicable
5. The stainless steel tubes are pressure sensing only but for the purpose of ensuring that there is no moisture in the umbilical lines you may consider blowing compressed air into the back of the gas sample line to remove any moisture that may have been introduced. (Important: Sample line must be disconnected from the system; blow air from the end connected to the system towards the flow sensor connector. Place connector toward a paper towel to capture any moisture.
6. In the event that secretions or moisture get aspirated into the gas sample line you can disinfect the DirectConnect adapter and proximal end of the sampling tubing by rinsing it and immersing in the bleach solution. This step will require flushing with compressed air to dry the tubing before it can be used.

WARNING:

Failing to comply with these cleaning procedures or exceeding recommended cleaning time will degrade the accuracy, safety, and product integrity. The flow sensors, plugs or honeycomb screens may loosen or dislodge.



DirectConnect and preVent flow sensors



DirectConnect and Standard preVent Umbilical Connections

For more information, please visit our website www.mgcdiagnostics.com.