A-M Systems Mouthpieces and Respiratory Connectors Recommended Cleaning and Sterilization Instructions

WARNING: A-M Systems thermoplastic, reusable, products are supplied non-sterile and should be sterilized before first use and after each patient use.

Recommended Cleaning Instructions:

1. **Clean the products using one of the following validated processes:**

I. Method 1:

a) **Thoroughly rinse products under tap water for a minimum of one minute to remove gross soil and debris**

b) **Prepare cleaning solution using Enzol®*, or equivalent, and lukewarm tap water. Prepare the solution according to the manufacturer's recommendation.**

c) **Using a soft bristled brush, dip the brush into the prepared detergent and scrub products for a minimum of one minute each, paying particular attention to crevices and other hard to reach areas.**

d) **Once the products have been scrubbed, thoroughly rinse in reverse osmosis / deionized (RO/DI) water for a minimum of one minute to remove excess detergent.**

e) **Immediately after rinsing, drain off excess water from products.**

f) **Blow-dry the products using compressed air, especially in crevices and other hard to reach areas.**

g) **Wipe and thoroughly dry products using a clean, lint-free, cloth.**

h) **Visually inspect products to ensure all visible soil has been removed.**

II. Method 2:

a) **Thoroughly rinse products under tap water for a minimum of one minute to remove gross soil and debris.**

b) **Using a sonication unit, prepare a solution consisting of Renu-Klenz™**, or equivalent, and lukewarm tap water. Prepare the solution according to the manufacturer's recommendation.**

c) **Place products, fully immersed, in the detergent solution and allow to sonicate for ten minutes.**

d) **Remove products from sonication unit and thoroughly rinse in reverse osmosis / deionized (RO/DI) water for a minimum of one minute to remove excess detergent.**

e) **Immediately after rinsing, drain off excess water from products.**

f) **Blow-dry the products using compressed air, especially in crevices and other hard to reach areas.**

g) **Wipe and thoroughly dry products using a clean, lint-free, cloth.**

h) **Visually inspect products to ensure all visible soil has been removed.**

Recommended Sterilization Instructions:

1. **Manually clean the products before sterilization according to attached cleaning instructions.**
2. **Sterilize the products using the following validated process:**
   a) **Individually pouch the products**
   b) **Use a Prevacuum (Steam under Pressure) Cycle of 4 Minutes at 132° C with a minimum 20 Minute Drying Time and 3 Preconditioning Pulses.**
   c) **After completion of the Prevacuum Cycle, immediately remove the products from the autoclave and store them in a dry/contamination free environment prior to use.**

References:

1. **"Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: FDA Reviewer Guidance", Rockville, MD, FDA Center for Devices and Radiological Health, Office of Device Evaluation, April 1996**
2. **Association for the Advancement of Medical Instrumentation. "Designing, Testing, and Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: A Guide for Device Manufacturers". AAMI TIR No. 12-2004. Arlington (Vir.): AAMI Technical Information Report.**
3. **Association for the Advancement of Medical Instrumentation. "A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices". AAMI TIR No. 30-2003. Arlington (Vir.): AAMI Technical Information Report.**
4. **Association for the Advancement of Medical Instrumentation. "Safe Handling and Biological Decontamination of Medical Devices in Health Care Facilities and in Nonclinical Settings", ANSI/AAMI ST35-2003, Arlington (Vir.) AAMI, 2003 American National Standard.**

* **Enzol®** is a trademark of Johnson & Johnson Medical Products, Inc.
** **Renu-Klenz™** is a trademark of STERIS Corporation.

Revision History

Rev.	Date	Changes
1	8/10/10	DCR # 201300. Initial release.