



HANS RUDOLPH, inc.

MAKERS OF RESPIRATORY VALVES SINCE 1938

TEL: (913) 422-7788 U.S.A. & CANADA (800) 456-6695

FAX: (913) 422-3337 E-Mail: hri@rudolphkc.com

8325 COLE PARKWAY, SHAWNEE, KANSAS 66227 U.S.A.

EC|REP M. Devices Group

Marlborough House
Riding Street
Southport PR8 1EW, UK
P: 44 1704 544 944
F: 44 1704 544 050

**Recommended steps for
Cleaning, Disinfection,
Sterilization and Maintenance.**

**HANS RUDOLPH, INC. MOUTHPIECES, NOSECLIPS AND RESPIRATORY CONNECTORS
RECOMMENDED STEPS FOR CLEANING, DISINFECTION, STERILIZATION AND MAINTENANCE**

SILICONE RUBBER MOUTHPIECES

Standard Type



Small, Medium, & Large

Saliva Trap Type



Small, Medium, & Large

Reusable



9015 - Stainless Steel, Thermoplastic
Elastomer & Neoprene Foam

NOSECLIPS

Disposable



9014 - Plastic & Foam

MACHINED CONNECTORS



7004 - PET Plastic



7009 - PET Plastic

HANS RUDOLPH, INC. MOUTHPIECES, RESPIRATORY CONNECTORS, AND NOSECLIPS

RECOMMENDED STEPS FOR CLEANING, DISINFECTION, STERILIZATION AND MAINTENANCE

1. Intended Use

- Mouthpieces are designed for use in respiratory breathing circuits. Mouthpieces are available in a variety of sizes to accommodate patient and valve sizes. Mouthpieces are manufactured of a silicone rubber with comfortable bite geometry and an outlet diameter to mate with breathing valve ports. Typical applications are pulmonary function testing, exercise testing, spirometry, and respiratory research.
- Respiratory connectors are designed for connecting tubing, mouthpieces, valves and miscellaneous respiratory components together. Connector styles range from medical tapered o-ring slip sealing fit, coupler lock ring, low deadspace, shaped modular and custom designs. Typical applications are in pulmonary function testing and respiratory research.
- Noseclips are designed to mount on the outside of the nose and occlude the nasal passages to eliminate breathing through the nose. Noseclips are available as disposable and reusable types. Typical applications are pulmonary function testing, exercise testing, and respiratory research.

2. Directions for Use

Mouthpieces, respiratory connectors and noseclips are all simple, self explanatory devices that do not require instructions for use. For further information contact Hans Rudolph for data sheets on these products.

3. Reprocessing Instructions

Scope

This guidance document is directed to personnel responsible for decontamination of Hans Rudolph mouthpieces, respiratory connectors and noseclips.

Product Classification (Respiratory Components)

- | | |
|------------------------|---|
| Mouthpiece | - classified as a reusable device
- supplied clean, non-sterile |
| Respiratory Connector | - classified as a reusable device
- supplied clean, non-sterile |
| Noseclips (Reusable) | - classified as a reusable device
- supplied clean, non-sterile |
| Noseclips (Disposable) | - classified as a disposable, single patient use
- supplied clean, non-sterile |

Mouthpiece, and respiratory connector fall into the semi-critical device category based on potential risk of infection. Although sterilization is recommended whenever practical, High level disinfection is acceptable. High level disinfection of the mouthpieces, and respiratory connectors is recommended by using CIDEX™ liquid glutaraldehyde disinfection solution. Sterilization of the mouthpieces molded of silicone rubber, and respiratory connectors made of polysulfone plastic is recommended by steam autoclave. Procedures for these validated processes are listed below.

Noseclips are classified as non-critical which contacts only intact skin during routine use. For reusable noseclips intermediate level disinfection is recommended.

Precautions

- Mouthpieces, and respiratory connectors may become contaminated with patient secretions during use, thus they are cleaned and subjected to high level disinfection or sterilization between uses on different patients.
- Thorough cleaning of these components is required prior to the sterilization or disinfection process.
- Follow disinfection with appropriate rinsing, drying and packaging, taking care not to contaminate the devices in the process.
- Use good rinsing procedures on reusable semi-critical devices after they have been chemically disinfected. Introduction of detergents to the disinfectant solution, which can occur if the device is inadequately rinsed after cleaning, can alter the pH of the solution and reduce its effectiveness. Inadvertent dilution of the disinfectant solution by wash or rinse water on wet devices also will lower the disinfectant concentration. Organic matter left on the device can protect microorganisms or inactivate the active chemical agent in the disinfectant.
- Wash hands before and after contact with mucous membranes, respiratory secretions, or objects contaminated with respiratory secretions, whether or not gloves are worn.
- The responsibility for handling, cleaning and decontaminating reusable medical devices should be assigned to trained, qualified individuals.
- Appropriate protective clothing (gloves, masks, eye protection, gowns) will minimize the potential for personal exposure to blood borne and other disease-producing organisms.
- Immediately separate and contain soiled reusable devices at the point of use and transport to the decontamination area so as to minimize risk of personal contact with contaminants.
- The CIDEX™ disinfectant product label will include information on use-pattern, use-life and storage life of the product. Be sure you understand these terms and follow the manufacturer's instructions. These factors apply to the effectiveness of the disinfectant solution.
- A disinfectant solution is only effective if it can contact all surfaces of the items to be disinfected or sterilized.
- Adequate ventilation is required in the disinfection area to evacuate the chemical vapors from glutaraldehyde. Use lidded containers for the disinfectant solution when appropriate. The inhalation of fumes from disinfectant solutions or skin contact with liquid disinfectants can be hazardous to personnel.

4. Decontamination

Introduction

These recommended practices provide guidelines to assist the health care personnel in the decontamination, cleaning, maintenance, handling, storage and/or sterilization of Hans Rudolph mouthpieces, respiratory connectors and noseclips.

Decontamination is a multi-step process that includes preparation at point of use, thorough cleaning and rinsing and a microbicidal process. Thorough cleaning and rinsing are the first and most important steps in the reprocessing of any reusable medical device. Without thorough cleaning and rinsing it might not be possible to achieve high level disinfection or sterilization of the device. The purpose of cleaning and rinsing is to remove all adherent visible soil, to reduce the number of particulates and microorganisms, and to reduce the amount of pyrogenic and antigenic material. Any organic material, lubricants, or residual cleaning agents remaining on a device can inactivate liquid chemical disinfectants/sterilants as well as protect microorganisms from destruction.

The second step in decontamination is the microbicidal process which is defined as a process to provide a particular level of microbial lethality (kill). Hans Rudolph breathing components are classified as "semi-critical" items. Semi-critical devices at a minimum require a high-level disinfection procedure. Sterilization is not absolutely essential.

It is the responsibility of the user (health care personnel) for ensuring that the cleaning methods recommended by Hans Rudolph can be duplicated in their environment, that appropriate tools and replacement parts are available and that Hans Rudolph instructions are followed correctly.

5. Cleaning Agents/Supplies for Hans Rudolph Components

Mild detergents with a neutral pH(7) are recommended for cleaning Hans Rudolph breathing components. Grease cutting dishwashing detergent is helpful in removing the silicone lubricant found on many components. Use warm water (22°-43°C) with the mild detergent. To be effective, cleaning agents must assist in the removal of residual organic soil without damaging the device. Cleaning agents should be used in the correct dilution/concentration and at the correct temperature in accordance with the cleaning agents manufacturer's directions. It is ultimately the user's responsibility to choose the correct cleaning agent, based on the instructions of the device manufacturer and any recommendations of the cleaning manufacturer. Certain cleaning agents may damage metal or other device materials. Do not use cleaning agents containing bleach or alcohol.

Cleaning supplies are very basic, usually consisting of a surgical scrub brush, chenille pipe cleaners, cotton or foam tipped applicators, soft brushes, and soft cloths. Cleaning supplies should be cleaned and disinfected or sterilized daily.

Water Quality: Tap water is acceptable for use in cleaning Hans Rudolph reusable components. Hans Rudolph components should be soaked, cleaned and rinsed in tap water at 22°-43°C to prevent the coagulation of solid substances onto the device and thus facilitate the removal of debris.

Enzymatic detergents with a neutral pH(7) are recommended when processing difficult-to-clean devices with dried-on matter. Soaking components in an enzymatic detergent solution can effectively remove visible debris except for lubricants thus providing an acceptable alternative to manual cleaning. Rinsing is necessary to remove all traces of detergent and extraneous debris.

Silicone lubricant (P/N 660170) may be required on components where o-rings are used.

6. Cleaning Methods

Step 1 Preparation at Point of Use

The cleaning of reusable devices usually begins soon after use. At the point of use, personnel wearing gloves and other protective attire separate disposable items or components from reusable devices and discard them in appropriate receptacles. Soil is wiped from device surfaces with a moist sponge or towel. The soiled/contaminated items are then contained in a manner that will reduce the risk of personal exposure to pathogens. Breathing components are usually placed in a basket, tray or rigid container for transportation to the processing area, usually transported in or on a cart, as hand carrying of soiled items is discouraged.

Step 2 Inspection

Inspect the components for damage at all stages of handling. If damage is detected on any of the components it should be identified and documented. Complete the disinfection/sterilization process and contact Hans Rudolph for guidance on replacement components.

Step 3 Presoak

Protective attire is required of personnel handling contaminated devices. At the processing area soak or rinse the device in tap water 22°-43°C. If an enzyme product is required, soak for one to two minutes. Remove and examine, extend the soak time for components with dried-on matter. Prolonged soaking of components may be detrimental, causing damage to the component surfaces.

Step 4 Disassembly (Respiratory Connectors)

Remove o-rings from components where applicable.

Step 5 Manual Cleaning

Protective attire is required for personnel handling contaminated devices. Manual cleaning must be done in a manner that protects personnel handling the devices from aerosolization and splashing of infectious material.

- Submerge the device in a mild neutral pH detergent (Neutrad). Prepare the detergent according to the manufacturer's recommendations. Soak the device for five (5) minutes in the mild detergent.
- Scrub the submerged device with a soft bristled brush. Agitate the device in the solution while scrubbing. Use a small cytology brush to clean the internal channels.
- Rinse the device with warm (38-49° C) tap water. Place the device into a bath containing warm (38-49° C) water. Agitate the device by hand for at least one (1) minute. Repeat this process two (2) additional times.
- Rinse the device with clean, tap water for at least one (1) minute.
- Dry the exterior of the device with a clean, lint free cloth.

7. High Level Disinfection (mouthpieces, & respiratory connectors)

- a. Mouthpieces, and respiratory connectors should be disinfected (high level) or sterilized between multiple patient uses.
- b. Mouthpieces, and respiratory connectors must be thoroughly cleaned, in accordance with the cleaning instructions prior to disinfection.
- c. The disinfectant/sterilizing agent must contact all surfaces to ensure disinfection or sterilization.
- d. For high level disinfection use CIDEX™ liquid glutaraldehyde disinfection solution.
- e. Adequate ventilation of glutaraldehyde chemical vapors is required. Use lidded containers for the disinfection solution when appropriate. The inhalation and direct skin contact of the disinfectant chemicals can be hazardous to personnel. Gloves should be worn made of butyl or nitrile rubber.
- f. **Liquid disinfection technique:**
 1. Submerge the device components in the liquid chemical (CIDEX™ glutaraldehyde) solution. Prepare the solution according to manufacturer's recommendation.
 2. Soak the device for 45 minutes.
 3. Remove the device from the solution and submerge in 1500 ml of sterile water for at least one (1) minute (first rinse).
 4. Remove the device from the sterile water and submerge in 1500 ml of sterile water for at least one (1) minute (second rinse).
 5. Dry the device with a clean (preferably sterile), lint free cloth.
- g. **Inspection**

All components should be visually inspected for cleanliness, proper function and freedom of defects. Visual inspection provides evidence of thorough cleaning and proper functioning of all the components. Respiratory components in poor working condition are hazardous to personnel and patients.

 1. Visually inspect all components for cleanliness. If there are signs of residue from the detergent or disinfectant repeat the previous steps. If there are any signs of remaining stains or organic debris repeat the previous steps. If the cleaning and disinfection steps have been repeated with no improvement eliminating residual or stains etc. then dispose of the components and replace.
 2. Visually inspect all components for defects. Check the rubber parts for tears, nicks, hardening or stiffening, deformation or distortion. Check the plastic parts for crazing, cracking or stripped threads. Any defective parts should be discarded and replaced.
 3. Visually inspect all metal components for corrosion. Replace any metal components showing rust or chipped plated surfaces.
- h. **Reassembly (Respiratory Connectors)**

Use appropriate personal protective clothing to assure that you do not recontaminate the components.

 1. O-rings should be lubricated with an approved silicone lubricant (HRI P/N 660170). Apply a light film of lubricant with your fingers to all surfaces of the o-ring. Place o-ring(s) in the appropriate groove(s) of the respiratory connector.
- i. **Functional Test**

Confirm that the respiratory components function as intended before storage. There is no functional test for these respiratory components. A visual test is specified to evaluate the components for tears, nicks, deformations, deterioration or discoloration.
- j. **Storage**

Confirm that the respiratory components are completely dry prior to storage. Respiratory components should be stored in a way that prevents recontamination or damage between uses.

 1. Place the component in a clean plastic bag and heat seal the end.
 2. Label the bag documenting that it has been disinfected, date, initials, component part number and description.

8. Steam Sterilization (Mouthpieces molded of silicone rubber)

- Sterilization of the silicone mouthpieces can be achieved with steam sterilization
- a. The devices should be disinfected (high level) or sterilized between multiple patient uses.
 - b. The devices must be thoroughly cleaned and dry in accordance with the cleaning instructions prior to sterilization.
 - c. Gloves should be worn to prevent contamination of sterile packages.
 - d. It is the user's responsibility to validate any deviations from this recommended method of processing.
 - e. **Steam sterilization cycle parameters (pre-vacuum and gravity displacement)**
 - Pre-vacuum Cycle type**
 1. Sterilization temperature: 132.2 +3/-1 C
 2. Sterilization time: 4 minutes
 3. Dry time: 10 minutes
 4. Packaging: Double pouched or wrapped in CSR (Cellulose Sterilization Wrap)
 - Gravity Displacement Cycle type**
 1. Sterilization temperature: 132.2 +3/-1 C
 2. Sterilization time: 10 minutes
 3. Dry time: 10 minutes
 4. Packaging: Tyvek® sterilization pouch
 - f. **Packaging system should:**
 1. allow adequate air removal and steam penetration of the package
 2. adequate barrier to microorganisms and resist tearing and puncturing
 3. proven seal integrity and low linting
 4. provide removal of the contents without contamination
 - g. **Loading/Unloading the sterilizer**
 1. Allow for free circulation of steam around each package.
 2. Position devices to allow for adequate air elimination and draining of condensate without wetting other items.
 3. Items removed from the sterilizer should not be touched until adequately cooled otherwise they can absorb moisture-carrying bacteria.
 4. Visually inspect for torn packaging, compressed packaging, or wet packaging. These packages should be returned for reprocessing.
 5. Sterilizers differ in design and each manufacturer's written instructions should be carefully followed.
 - h. **Storage**
 1. Plastic dust covers should be applied soon after sterilization but only to packages that are thoroughly cool and dry.
 2. Dust cover should be sealed to be an effective barrier to moisture.
 3. Label the package with the appropriate identity and traceability information.

9. Operating Temperature and humidity ranges for these products

Temperature Range: 5-40° C
Humidity Range: 0-95% RH

10. Service Life

All reusable devices are expected to stay in service for a minimum of 100 high level disinfection cycles or 50 autoclave (steam sterilization) cycles or 2 years of operation under normal operational and environmental conditions, whichever occurs first.

11. Warnings

- a. Use only approved high level disinfectant (see Section 7F, Step 1). Do not use alcohol or bleach solutions.
- b. Liquid high level disinfectant solutions may be hazardous to humans.
 1. Do not get into eyes, on skin or on clothing.
 2. Use in well ventilated area in closed containers.
 3. For emergency, safety or technical information about the glutaraldehyde solution contact the manufacturer.
- c. Appropriate personal protective clothing should be worn when cleaning and sterilizing/disinfecting soiled devices.
- d. Contaminated, reusable devices must be thoroughly cleaned prior to disinfection or sterilization, since residual contamination will decrease effectiveness of the glutaraldehyde solution.
- e. It is the user's responsibility to validate any deviations from this recommended method of processing.

12. Safety Information

Safety or technical information regarding Hans Rudolph respiratory components can be obtained from Hans Rudolph, inc., Phone 913-422-7788, USA & Canada 800-456-6695, Fax 913-422-3337, or by contacting your Hans Rudolph representative.

13. References

- a. "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
- b. 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. 12-1994. Arlington (Vir.): AAMI, 1194c. AAMI Technical Information Report
- c. 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 ST35-1196, Arlington (Vir.) AAMI, 1996 American National Standard.
- d. Centers for Disease Control. "Guidelines for Handwashing and Hospital Environmental Control". Section 2: "Cleaning, Disinfecting, and Sterilizing Patient Care Equipment." Atlanta: CDC, 1985
- e. Centers for Disease Control. "Guideline for Prevention of Nosocomial Pneumonia." Infection Control and Hospital Epidemiology 1194; 15:587-627
- f. Rutala, WA. APIC "Guideline for Selection and Use of Disinfectants." American J. INFEC. Control, 1190, Vol. 18 No. 2, pp 99-117.

14. Credits

- a. Cidex™ is a trademark of Johnson & Johnson Medical Products, Inc.
- b. Tyvek® is a trademark of DuPont.