



MAKERS OF RESPIRATORY VALVES SINCE 1938

HANS RUDOLPH, inc.

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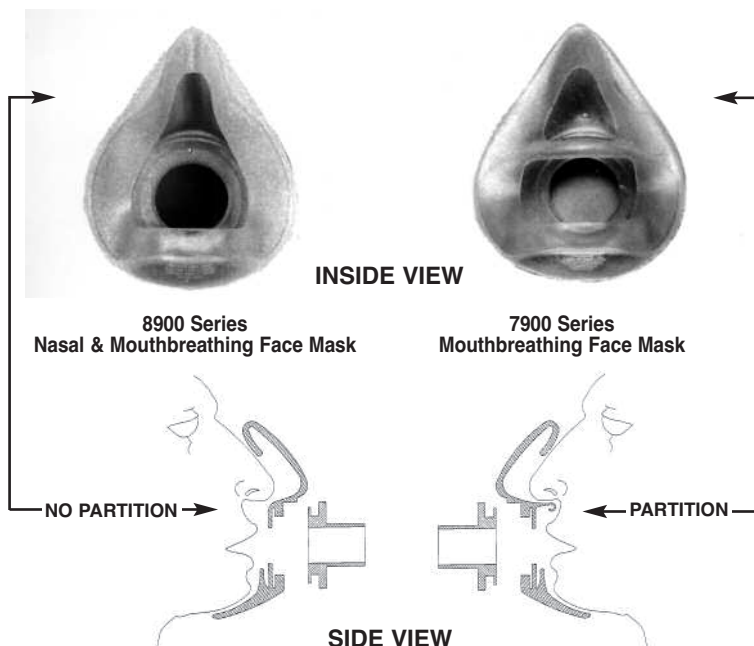
Recommended steps for
Cleaning, Disinfection,
Sterilization and Maintenance.

HANS RUDOLPH, INC FACE MASKS, (FACE PIECE ONLY) SILICONE RUBBER
RECOMMENDED STEPS FOR CLEANING, DISINFECTION/STERILIZATION AND MAINTENANCE
VENTILLOSE ATEMASKEN AUS SILIKONGUMMI, HANS RUDOLPH, INC.
EMPFOHLENE MAßNAHMEN ZUM REINIGEN, DESINFIZIEREN, STERILISIEREN UND INSTANDHALTEN
MASQUE FACIAL, (PIECE FACIALE UNIQUEMENT) CAOUTCHOUC DE SILICONE, HANS RUDOLPH, INC
ETAPES RECOMMANDEES POUR LE NETTOYAGE, LA DESINFECTION/STERILISATION ET L'ENTRETIEN
MASCHERE FACCIALI, (SOLO PARTE MASCHERA) IN GOMMA DI SILICONE, HANS RUDOLPH, INC
PROCEDURE CONSIGLIATE PER LA PULIZIA, DISINFEZIONE/STERILIZZAZIONE E MANUTENZIONE
MASCARILLAS, (SÓLO PIEZA FRONTAL) DE CAUCHO SILICONADO, HANS RUDOLPH, INC.
PROCEDIMIENTOS RECOMENDADOS DE LAVADO, DESINFECCIÓN/ESTERILIZACIÓN Y MANTENIMIENTO
INGEZICHTSMASKERS, (ENKEL GELAATSTUK) SILICONRUBBER, HANS RUDOLPH, INC
AANBEVOLEN STAPPEN VOOR HET REINIGEN, ONTSMETTEN/STERILISEREN EN ONDERHOUD
ANSIKTSMASKER (ENDAST ANSIKTSDELEN) SILIKONGUMMI, HANS RUDOLPH, INC.
REKOMMENDERAT FÖRFARANDE VID RENGÖRING, DESINFEKTION/STERILISERING OCH UNDERHÅLL.



REFER TO
LAST PAGE FOR
ADDITIONAL
PRODUCTS

MASK AND HEAD CAP ASSEMBLY WITH CUSTOM ADAPTERS



HEAD CAP
AND
HARNESS

HANS RUDOLPH, INC FACE MASKS, (FACE PIECE ONLY) SILICONE RUBBER

RECOMMENDED STEPS FOR CLEANING, DISINFECTION/STERILIZATION AND MAINTENANCE

A. Intended Use

Respiratory face masks (face piece only) that are molded of silicone rubber. These face masks consist of models covering the nose and mouth and models covering the nose only. The masks are designed to be used with Hans Rudolph head cap assemblies. The masks have optional plastic port adapters that mate the mask to other systems such as tubing assemblies, non-rebreathing valves, CPAP blowers and anesthesia equipment. Applications range from pulmonary function testing, exercise testing, anesthesia and respiratory research.

B. Directions for Use

Based on the mask application a selection process should take place that considers all the factors:

- mask type
- mask size
- outlet adapter type and size
- valve type and size
- head cap type and size

The health care provider is responsible for selecting the appropriate mask and accessory components for the patient. Proper use of these masks will ensure their effectiveness. Masks that function ineffectively can cause delays in a procedure and increase the risk of infection and patient injury. For further information contact Hans Rudolph for data sheets on these products.

C. Reprocessing Instructions

Scope

This guidance is directed to personnel responsible for decontamination of Hans Rudolph face masks.

Product Classification

These face masks are classified as reusable devices.

These masks are supplied clean, non sterile.

These masks fall into the semi-critical device category based on potential risk of infection. This device will come into contact with intact mucous membranes but will not penetrate body surface. Although sterilization is recommended whenever practical, high level disinfection is acceptable. High level disinfection is recommended by using liquid glutaraldehyde disinfectants approved as sterilant/disinfectants by the Environmental Protection Agency and cleared for marketing for use on medical instruments by the office of Device Evaluation, Center for Devices and Radiologic Health, Food and Drug Administration. High level disinfectants are simply sterilants used at a shorter exposure time. Sterilization is recommended with steam or liquid chemical glutaraldehydes.

Precautions

- Face masks 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 valves is required prior to the sterilization or disinfection process.
- Follow disinfection with appropriate rinsing, drying and packaging, taking care not to contaminate the valves in the process.
- Use sterile water for rinsing reusable semi-critical devices used on the respiratory tract after they have been chemically disinfected. The 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.
- Liquid chemical disinfectants product label must 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.

D. 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 face masks. 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 face masks valves are classified as "semi-critical" items which are devices that come into contact with intact mucous membranes. Semi-critical devices at a minimum require a high-level disinfection procedure. Sterilization is not absolutely essential.

All Hans Rudolph face masks require complete or partial disassembly for cleaning and disinfection. 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.

E. Cleaning Agents/Supplies for Hans Rudolph Components

Mild detergents with a neutral pH(7) are recommended for cleaning Hans Rudolph face mask assemblies. 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 face masks. Hans Rudolph masks and valves 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 mask and adapter or valve 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.

F. Cleaning Methods (High Level Disinfection and Sterilization)

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. Mask and valve devices 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 mask 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 (Mask Assemblies)

Protective attire is required of personnel handling contaminated devices. The person(s) to whom the job of reprocessing mask assemblies is given should have the opportunity to become completely familiar with the mechanical aspects of these assemblies. The mask assemblies must be completely disassembled to expose all surfaces to the cleaning process.

Tools/Supplies

- Phillips head screwdriver may be required on assemblies where screws are used.
- Silicone lubricant (P/N 660170) may be required on assemblies where orings are used.

Instructions

- Separate head cap assembly and any valve or outlet adapters from the face mask.
- Valve and outlet adapters should be disassembled completely.

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.

- Manual cleaning of the mask and components should be done under water in cool to lukewarm water (43°C maximum). Use a neutral pH(7) mild detergent. Typical concentration of detergent is one ounce to 3.8 liters of water. Water hardness, temperature and the type of soil affect the effectiveness of the detergents; the detergent manufacturer's instructions should be consulted. Use a small soft brush to scrub all detachable parts. Use a small brush to clean the inner groove of the mask outlet adapter location. Abrasive cleaning compounds and implements can damage these mask and valve components and should not be used. Additional cleaning supplies may be required to clean stubborn stains or hard-to-reach areas.
- Mask and valve components must be thoroughly rinsed with clean water to remove the detergent residuals and debris from the components. Use a flowing triple rinse cycle at a minimum with tap water.
- Dry all components thoroughly using soft clean cloths or disposable paper towels. Components should be dry to prevent dilution of the disinfectant used in subsequent steps.
- Clean the head cap assembly (with strap clips) by hand washing with a mild detergent. Do not use bleach. Remove the head cap from the mask, leaving the strap clips attached to the straps. Machine or line dry. Do not iron the head cap assembly.

Step 6 Manual Disinfection with Liquid Glutaraldehyde Solution

High level disinfection of all mask and valve components must be performed after each use. The disinfectant/sterilizing agent must contact all surfaces to ensure disinfection or sterilization. High level disinfection of mask and valve components ensures patient safety and minimizes the risk of infection.

Use only liquid glutaraldehyde disinfectant solutions approved as sterilants/disinfectants by the Environmental Protection Agency and cleared for marketing use on medical devices by the Office Device Evaluation, Center for Devices and Radiologic Health, Food and Drug Administration. For a list of approved products contact Hans Rudolph, inc.

When used according to the manufacturer's instructions a high level disinfectant destroys all microorganisms, but not necessarily all bacterial spores. The chemical agent should be sporicidal when used in recommended concentrations, temperatures and contact time. Manufacturer's instructions will include information on monitoring chemical concentration of the disinfection solution for use-life effectiveness. Disinfectants can become diluted with water that is retained in the mask and valve components or accessories.

The fumes of glutaraldehyde can irritate the mucous membranes of eyes, nose and throat. Some people develop allergic reactions to glutaraldehyde that can cause skin rashes, headaches and breathing difficulties. Containers of glutaraldehyde should be kept closed and in a well ventilated area. Gloves should be worn made of butyl or nitrile rubber. Do not use latex rubber gloves. The concentration of glutaraldehyde in the air should not exceed .2 ppm.

1. Determine the required soak temperature and time of the sterilant/disinfectant and assure that these requirements are met.
2. Activate the glutaraldehyde solution by mixing the components per the manufacturer's instructions. Use the concentration testing devices sold by the manufacture to determine that the solution is above the minimum effective concentration.
3. Pour the activated glutaraldehyde solution into an appropriate sized basin.
4. Completely immerse the mask and valve components in the basin. Assure that all channels and cavities are filled with disinfectant and that no air pockets remain within the components.
5. Cover the disinfectant soaking basin with a tight fitting lid to minimize chemical vapor exposure.
6. Soak the valve components for the time specified by the disinfectant solution manufacturer to achieve high level disinfection. Use a timer to ensure adequate soaking time.

Step 7 Rinse After Manual Disinfection

Adequate rinsing must follow disinfection to remove all traces of the toxic residues of the disinfectant left on the mask and valve components. Sterile water rinse is preferred over tap water. Tap water may contain a variety of micro-organisms which could recontaminate the valve components.

1. Rinse 1: Fill a basin with 7-8 liters of water (preferably sterile water). Place the mask and valve components into the basin and thoroughly rinse all the components for a minimum of one minute. Empty basin.
2. Rinse 2: Fill a basin with 7-8 liters of water (preferably sterile water). Place the mask and valve components into the basin and thoroughly rinse all the components for a minimum of one minute. Empty basin.

Step 8 Drying

To prevent the growth of waterborne organisms, the mask and valve components should be thoroughly dried prior to reassembly and storage.

1. Dry thoroughly using a soft cloth (preferably sterile) or disposable paper towels.

Step 9 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 mask and valve components. Mask assemblies 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.

Step 10 Reassembly

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

1. Attach valve or outlet adapter assembly to the mask if applicable.
2. Head cap may be assembled on the mask or at the time of installing on the patient.

Step 11 Functional test

Confirm that the mask assembly functions as intended before storage.

There is no functional test for the face mask. A visual test is specified to evaluate the face mask for tears, nicks, deformation, deterioration or discoloration.

Step 12 Storage

Confirm that the mask assembly is completely dry prior to storage. Masks should be stored in a way that prevents recontamination or damage between uses.

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

G. Steam Sterilization (Silicone Rubber Face Mask Only)

Sterilization of the silicone rubber face masks can be achieved with steam sterilization.

Type of Cycle:	Gravity Displacement
Type of Load:	Wrapped Method
Temperature:	132°-135°c
Cycle Time:	10-15 minutes

Special Notes:

1. Follow cleaning procedures as instructed prior to steam sterilization. Since the degree of sterility assurance depends on the amount of contamination of items to be sterilized, thorough cleaning procedures are essential.
2. All lubricants should be removed from components because this will interfere with steam contact.
3. Dry devices (components) reduce the potential for wet device packs after sterilization.
4. Sterilization container systems should be cleaned after each use.

1. Package Material Requirements

Allow adequate air removal from and steam penetration of the package

Provide adequate barrier to microorganisms

Resist tearing or puncturing

Have proven seal integrity

Be free of toxic ingredients

Be low linting

Maintain sterility of the contents until the package is opened

Provide for removal of the contents without contamination

2. Preparation of Devices

All devices should be disassembled into component parts. Mask face pieces should be individually packaged in an acceptable packaging material and sterilized in a position that ensures adequate steam contact with all surfaces.

3. Loading the Sterilizer

Allow for free circulation of steam around each pack and each item. Position devices in the sterilizer to allow for adequate air elimination and drainage of condensate without wetting of other items in the load.

Sterilizers differ in their design and operating characteristics, so it is important that the manufacturer's written instructions be carefully followed.

4. Sterilization Cycle for Wrapped Items

Gravity displacement cycle: 10-15 minutes

Exposure time at 132°-135°c

5. Unloading the Sterilizer

All items removed from the sterilizer after sterilization must remain in the sterilizer cart until adequately cooled. They should not be touched during the cooling process, because hot packs absorb moisture, hence bacteria from hands.

Visually inspect all packs for torn packaging, compressed packaging or with packaging that appears to be wet, such items should be returned to the decontamination area for reprocessing.

6. Storage

Plastic dust covers should be applied soon after sterilization but only to packages that are thoroughly cool and dry. Placing a dust cover on a wet item may result in condensation inside the dust cover causing contamination of the package contents.

The dust cover should be sealed using a heat sealer or similar method to be an effective barrier to moisture.

The cover should be clearly designated as a dust cover to prevent it being mistaken for a sterile wrap.

Label the package (dust cover) with the appropriate identity and and traceability information.

Sterile items should be stored away from floors, ceilings or outside walls. They should be positioned so that the packaging is not crushed, bent, compressed or punctured. Closed or covered cabinets are recommended for storage of sterile packages.

Gloves should be worn to prevent contamination of sterile packages.

H. Service Life

Hans Rudolph face masks when maintained properly and reprocessed per these instructions should function within specifications a minimum of 25 reuses. Visual inspection of all the components during each reprocessing cycle will identify any defects. The functional test as described in Section F, Step 11 will determine if the masks functioning properly.

I. Warnings

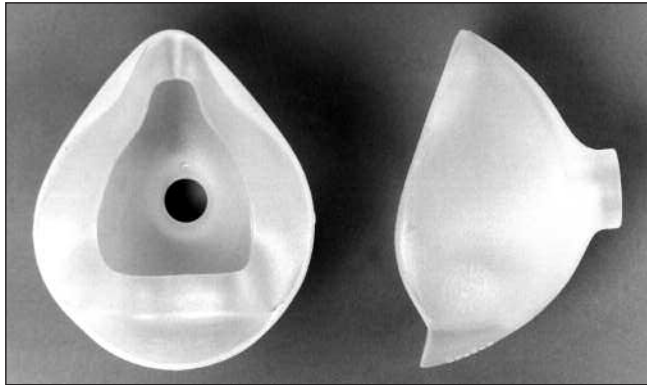
1. Do not ethylene oxide, steam sterilize or pasteurize the valves, outlet adapters or head cap components.
2. Do not expose the valves, outlet adapters or head caps to heat at or above a temperature of 45°c (113°F).
3. Use only approved liquid glutaraldehydes (see Section F, Step 6). Do not use alcohol or bleach solutions.
4. Glutaraldehyde solutions are 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.
5. Appropriate personal protective clothing should be worn when cleaning and sterilizing/disinfecting soiled devices.
6. Contaminated, reusable devices must be thoroughly cleaned prior to disinfection or sterilization, since residual contamination will decrease effectiveness of the glutaraldehyde solution.
7. It is the user's responsibility to validate any deviations from this recommended method of processing.
8. Federal (USA) law restricts this device to sale by or on the order of a physician.

J. Safety Information

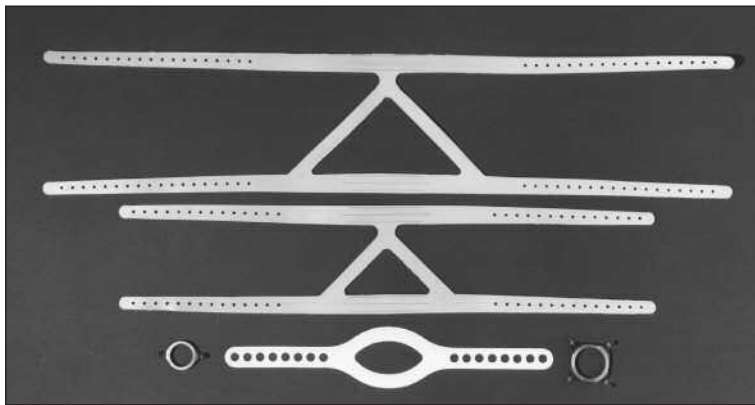
Safety or technical information regarding Hans Rudolph mask assemblies can be obtained from Hans Rudolph, inc., Phone 913-422-7788, USA & Canada 800-456-6695, Fax 913-422-3337, or by contacting your Hans Rudolph representative.

K. References

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5. Centers for Disease Control. "Guideline for Prevention of Nosocomial Pneumonia." Infection Control and Hospital Epidemiology 1194; 15:587-627
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6990 SERIES ANESTHESIA MASK



HEAD CAP & HEAD HARNESS