A. Intended Use

Inflatable Balloon-Type valves are designed for use as a directional flow control valve in a respiratory circuit. These valves can be assembled with two way non-rebreathing valves to provide additional functions as required by the application. These valves contain an inflatable silicone rubber balloon that when inflated occludes (closes off) a flow bore of the valve. When the balloon element is not inflated airflow is allowed through that flow bore of the valve. Valves are designed as one through five way configurations. Typical applications are pulmonary function testing, exercise testing and respiratory research.

WARNING: These valves are not designed to support systems such as a ventilator circuit. The inflatable balloon component of the valve is a replacement item that will rupture after several thousand inflations. Pneumatic controllers are available for these valves.

B. Directions for Use

1. Philips head screwdriver may be required on assemblies where screws are used.
2. Silicone lubricant (P/N 660170) may be required on assemblies where orings are used.
3. Use only approved liquid glutaraldehydes (see Section F, Step 6).
4. Attach the Two Way valve to the Inflatable Balloon valve. The threads of the knurled metal ring mate with the double threaded adapter of the Two Way valve. Orient the two valves to each other and thread them from each other. Be sure to install the two-way adapter in the correct orientation and fit 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 device materials. Do not use cleaning agents containing bleach or alcohol.

C. Reprocessing Instructions

1. Determine the required soak temperature and time of the sterilant/disinfectant and assure that these requirements are met.
2. Use the spanner wrench to attach the single threaded adapter with knurled metal ring to the Inflatable Balloon valve threaded outlet port. Hand tighten only slightly snug, do not over tighten.
3. Use the spanner wrench to thread the double threaded adapter into the Two Way valve body common port. Hand tighten only slightly snug, do not over tighten.
4. Remove orings from mating components where applicable.
5. Glutaraldehyde solutions are hazardous to humans. Enzymatic detergents with a neutral pH(7) are recommended when processing difficult-to-clean devices with dried-on matter. Soaking valve components in an enzymatic detergent solution can effectively remove visible debris except for lubricants thus providing an acceptable alternative to manual cleaning. Ringing is necessary to remove all traces of detergent and extraneous debris.

D. Decontamination

1. Cleaning Agents/Supplies for Hans Rudolph Components

Wild detergents (e.g., detergents containing glutaraldehyde) are recommended for cleaning Hans Rudolph Inflatable Balloon-Type valves. Enzymatic detergent with a neutral pH(7) are recommended when processing difficult-to-clean devices with dried-on matter. Soaking valve components in an enzymatic detergent solution can effectively remove visible debris except for lubricants thus providing an acceptable alternative to manual cleaning. Ringing is necessary to remove all traces of detergent and extraneous debris.

4. Attach the Two Way valve to the Inflatable Balloon valve. The threads of the knurled metal ring mate with the double threaded adapter of the Two Way valve. Orient the two valves to each other and thread them from each other. Be sure to install the two-way adapter in the correct orientation and fit 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 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 autoclaved or sheets on these products.

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

6. Care should be taken to ensure that all small parts (screws, rings, and shafts) are drained of liquid. Noninterchangeable components of assemblies should be kept together to ensure correct assembly.

7. Always reuse damaged components.

Where Inflatable Balloon valves incorporate a Two Way Non-Rebreathing valve refer to the two way valve instructions supplied for cleaning and disinfection recommendations.

C. Reprocessing Setup

1. Separate all port tube adapters by unthreading them from the valve body.
2. Remove the balloon assembly(s) from the carrier. The shoulder on the centerpiece determines the direction to push for removing the balloon from the pneumatic housing. Place your finger inside the balloon valve and push the balloon assembly out of the centerpiece assembly. Unthread the balloon assembly from the centerpiece. At the male thread end gently peel the silicone balloon off the silicone housing. Do not over tighten the balloon and be careful not to pull the exit bore of the centerpiece pin.
3. Use only approved liquid glutaraldehydes (see Section F, Step 6). This is to expose all surfaces in the disinfection and rinsing process.
4. Remove orings from mating components where applicable.
5. Use the spanner wrench to remove the retaining ring wrench (171218) to remove the retaining ring at each pneumatic housing location. Be very cautious while removing the retaining ring from the valve body, do not damage the component. Do not damage or round off the retaining ring or can flame the metal ring with a gas flame. Do not remove orings from mating components where applicable.
6. Care should be taken to ensure that all small parts (screws, rings, and shafts) are drained of liquid. Noninterchangeable components of assemblies should be kept together to ensure correct assembly.

C. Reprocessing Setup

1. Separate the Two Way Non-Rebreathing valve from the Inflatable Balloon valve. Hold the knurled metal ring and completely unthread the Two Way valve assembly counterclockwise. The double threaded adapter may either be left attached to the Two Way valve or the knurled metal ring. Use the spanner wrench to remove the double threaded adapter.
2. Remove the knurled metal ring and single threaded adapter from the Inflatable Balloon valve body by unthreading the single threaded adapter with the spanner wrench.
3. The threaded connector may remain attached to either the Two Way valve or the Inflatable Balloon valve. Unthread the connector counterclockwise.

C. Reprocessing Setup

1. Separate the Two Way Non-Rebreathing valve from the Inflatable Balloon valve. Hold the knurled metal ring and completely unthread the Two Way valve assembly counterclockwise. The double threaded adapter may either be left attached to the Two Way valve or the knurled metal ring. Use the spanner wrench to remove the double threaded adapter.
2. Remove the knurled metal ring and single threaded adapter from the Inflatable Balloon valve body by unthreading the single threaded adapter with the spanner wrench.

C. Reprocessing Setup

1. Separate the Two Way Non-Rebreathing valve from the Inflatable Balloon valve. Hold the knurled metal ring and completely unthread the Two Way valve assembly counterclockwise. The double threaded adapter may either be left attached to the Two Way valve or the knurled metal ring. Use the spanner wrench to remove the double threaded adapter.
2. Remove the knurled metal ring and single threaded adapter from the Inflatable Balloon valve body by unthreading the single threaded adapter with the spanner wrench.

C. Reprocessing Setup

1. Separate the Two Way Non-Rebreathing valve from the Inflatable Balloon valve. Hold the knurled metal ring and completely unthread the Two Way valve assembly counterclockwise. The double threaded adapter may either be left attached to the Two Way valve or the knurled metal ring. Use the spanner wrench to remove the double threaded adapter.
2. Remove the knurled metal ring and single threaded adapter from the Inflatable Balloon valve body by unthreading the single threaded adapter with the spanner wrench.

Step 4 Assembly (Inflatable Balloon-Type Valves)

Refer to the valve diagram.

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

Tools/Supplies

1. Philips head screwdriver may be required on assemblies where screws are used.
2. Silicone lubricant (P/N 660170) may be required on assemblies where orings are used.
3. Inflatable Balloon valve (P/N 171218) for removal of pneumatic housings in valve body.
4. Inflatable Balloon-Type valves: Two-Way Shut Off Three-Way Four-Way WARNING: These valves are not designed to support systems such as a ventilator circuit. The inflatable balloon component of the valve is a replacement item that will rupture after several thousand inflations. Pneumatic controllers are available for these valves.
5. Use only approved liquid glutaraldehydes (see Section F, Step 6). This is to expose all surfaces in the disinfection and rinsing process.
6. Care should be taken to ensure that all small parts (screws, rings, and shafts) are drained of liquid. Noninterchangeable components of assemblies should be kept together to ensure correct assembly.
7. Always reuse damaged components.

C. Reprocessing Setup

1. Separate the Two Way Non-Rebreathing valve from the Inflatable Balloon valve. Hold the knurled metal ring and completely unthread the Two Way valve assembly counterclockwise. The double threaded adapter may either be left attached to the Two Way valve or the knurled metal ring. Use the spanner wrench to remove the double threaded adapter.
2. Remove the knurled metal ring and single threaded adapter from the Inflatable Balloon valve body by unthreading the single threaded adapter with the spanner wrench.
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.
1. Manual cleaning of the valve 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 details. The rubber diaphragms and balloons should be washed gently by rubbing with the surfaces glazed with gloved fingers. Abrasive cleaning compounds and implements can damage these valve components and should not be used. Additional cleaning supplies may be required to clean stubborn stains or hard-to-reach areas.
2. Valve components must be thoroughly rinsed with clean water to remove the detergent residues and debris from the components. Use a flowing rinse cycle at a minimum of 12 minutes.
3. 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.

Step 6 Manual Disinfection
High level disinfection of all Inflatable Balloon-Type 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 balloon portion of valve components ensures patient safety and minimizes the risk of infection.
Use only liquid glutaraldehyde disinfectant products approved as sterilants/disinfectants by the Environmental Protection Agency and cleared for marketing use on medical devices by the Office of Device Evaluation, Center for Devices and Radiological Health and Food and Drug Administration. For a list of approved products contact Hans Rudolph, Inc.
When used according to the manufacturers 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 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 2.5 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 manufacturer to determine that the solution is above the minimum effective concentration.
3. Pour the activated glutaraldehyde solution into an appropriate sized basin.
4. Completely submerge the Inflatable Balloon-Type 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 substances of the disinfectant left on the valve components. Sterile water rinse is preferred over tap water. Tap water may contain a variety of microorganisms which could contaminate the valve components.
1. Rinse 1: Fill a basin with 7-8 liters of water (preferably sterile water). Place the 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 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 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 valve components.
Valves in poor working condition are hazardous to personnel and patients. Valves in poor working condition are hazardous to personnel and patients. Listing of items to visually inspect:
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 prongs 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
Refer to the previous valve diagrams. Use appropriate personal protective clothing to assure that you do not recontaminate the components.
1. Install orings on all components as required. Orings should be lubricated with approved silicone lubricant (HR4 660170). Apply a light film of lubricant with your fingers to all surfaces of the oring.
2. Install the balloon assembly onto the centerpiece. Return the balloon membrane back to its original position into the grove on the carrier. Thread the balloon assembly into the centerpiece. Do not over tighten, hand tighten only slightly snug.
3. Install pneumatic housing(s) into the valve body. Push the pneumatic housing through the square hole in the valve body until the oring is compressed and the retaining ring groove is visible. Note the orientation of the long narrow hole in end of pneumatic housing for the balloon assembly. Install retaining ring (wrench 171218) into the groove directly above the top of the pneumatic housing. Be very cautious while installing the retaining ring. If not done properly, the ring can release from the wrench dangerously fast and injure someone close by. Wear eye protection.
4. Thread the common and port tube adapters into the appropriate ports of the valve body. Do no over tighten, hand tighten only slightly snug.

CO2 Rebreathing Setup
1. Attach the Two Way Non-Rebreathing valve to the Inflatable Balloon-Type valve with the single and double threaded adapters and knurled metal ring.
2. Use the spanner wrench to attach the single threaded adapter and knurled metal ring to the Inflatable Balloon valve threaded outlet port. Hand tighten only slightly snug, do not over tighten.
3. Use the spanner wrench to thread the double threaded adapter into the Two Way valve body component port. Hand tighten only slightly snug, do not over tighten.
4. Attach the Two Way valve to the threads of the knurled metal ring male with the double threaded adapter of the Two Way valve. Orient the two valves to each other and thread (clockwise) the knurled metal ring with the double threaded adapter. Hand tighten snug. Do not over tighten.

Inspiratory Occlusion Setup
1. Attach the Inflatable Balloon-Type valve to the Two Way Non-Rebreathing valve. The threaded connector of the Inflatable Balloon valve threads (clockwise) into the inspiratory port of the Two Way valve body. Do not over tighten, hand tighten only slightly snug. Confirm that the diaphragm and ring assembly in the inspiratory port of the Two Way valve body are positioned correctly in the body counter bore.

Step 11 Functional test
Confirms that the Inflatable Balloon valve functions as intended before storage. Inflate all of the balloons and confirm visually or with air flow that the balloon completely occludes the flow path of the valve. The time it takes to completely inflate the balloon should be less than one second.

Step 12 Storage
Confirm that the valve is completely dry prior to storage. Valves should be stored in a way that prevents recontamination or damage between uses.
1. Place valve assembly in a clean plastic bag and heat seal the end.
2. Label the bag documenting that it has been disinfected, date, initials, valve part number and description.

L. References
5. Centers for Disease Control. "Guideline for Prevention of Nosocomial Pneumonia." Infection Control and Hospital Epidemiology 1194; 15:567-627