Instructions for Use...

6450 Series V2 Mask™
ORO-NASAL SINGLE PATIENT USE
Face Mask and Headgear for Custom Adapter & Valve Applications.
Large, Medium, Small, Extra Small, Petite

Intended Use:
The Hans Rudolph 6450 series V2 Mask face piece is designed for use with the Hans Rudolph Two-Way Non-Rebreathing Valves (NRBV) and other mask adapters designed for respiratory circuits with spontaneously breathing patients where the application requires a valve to separate the patient’s inspiratory and expiratory flows or a special connector to mate directly to a respiratory flow meter or other device. The typical mouthpiece and nose clip is replaced by this face mask assembly and headgear. The masks and valves are supplied clean, non-sterile. Typical applications are for pulmonary function testing, exercise testing and respiratory research.

Environment of Use:
This mask series is for use in hospitals and other clinical settings by individuals that have at least minimal instructions or training on the use of the mask as well as the device to which the mask are intended to connect.

Product Classification:
This mask and headgear are classified as disposable for single patient limited use. Sold clean non-sterile. There is no validated disinfection process.

Mask and Headgear Service Life:
Mask and headgear assembly may be cleaned and re-used on a single-patient basis for several test sessions as long as the fit continues to be leak free and comfortable.

Operational Temperature and Humidity Ranges for the Mask:
Temperature range: 5-40 C
Humidity range: 0-95% RH

Cautions:
1. Federal Law restricts this device to sale by or on the order of a physician.
2. Patients with facial hair, especially beards, may experience mask leakage which may require shaving the hair.
3. Do not use these masks and valves in a life support system such as a ventilator circuit.

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Recommended Headgear Sizes for each Mask Size

<table>
<thead>
<tr>
<th>Mask</th>
<th>L</th>
<th>M</th>
<th>S</th>
<th>XS</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Headgear</td>
<td>L</td>
<td>M</td>
<td>M</td>
<td>S</td>
<td>S</td>
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</tbody>
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Apply and Fitting Mask
1. Mask sizes: L (Large), M (Medium), S (Small), XS (Extra Small), P (Petite)
2. Headgear sizes: L (Large), M (Medium), S (Small)
3. Determine mask size of patient with a Mask Sizing Gauge (fig 1) provided to measure the patient’s face and aid in selecting the best mask size. For sizing the patient’s facial muscles should be relaxed and jaw closed. Fit the patient’s chin in the chin cup section of the mask and slightly press the mask on the face. The top of the mask should be slightly below the nasal root depression (where the nose meets the forehead).

Fitting the Mask
The mask and headgear is supplied fully assembled.
1. Place the mask over the patient’s nose and mouth. The patient’s chin should fit into the chin cup portion of the mask with the top of the mask sealing area on the bridge of the nose.
2. (a) Slide the headgear over the patient’s head. It may be easier for some patients if one of the lower headgear quick-release strap clips is disconnected before putting the headgear on the patient (b) Reconnect the headgear strap clip after the headgear is placed on. The bottom straps should be positioned below the ears and the top straps above the ears and below the eyes.
3. (a&b) Adjust the tension of the headgear Velcro™ straps by pulling back slightly on the straps. Tighten the lower two straps then the top two to achieve a comfortable fit. (c) Finally, adjust the two straps attached by the tri-glide connection at the crown of the head by pulling each in opposing directions until reaching the required tension and then reconnecting the Velcro™. Over-tightening can cause leaks.
4. Connect the mask to the patient circuit by following the equipment manufacturer’s operation instructions.
5. For functional test hold palm of hand over outlet of exhalation port or mask adapter.

Create a slight positive pressure inside the mask by exhaling gently. If you detect a leak around the mask sealing area, reposition the mask and or adjust the strap tension to eliminate the leak. If the leak continues regardless of your adjustments try another mask size.

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Disassembly for Cleaning
1. Detach mask from the valve assembly or adapter.
2. Separate the headgear from the mask.
3. Hand wash with a sponge or soft brush.
4. Rinse in clean tap water for 1 minute.
5. Air dry.

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Headgear
1. Submerge the headgear in warm soapy tap water and gently rub all the areas.
2. Rinse in clean tap water for 1 minute or until all signs of the soap are removed.
3. Air dry.
4. Precaution: Do not use bleach, chlorine or alcohol based solutions to clean any of the mask and headgear components. These solutions can damage this product. Direct sunlight exposure with the mask and headgear components can cause deterioration and reduce product life.

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Safety Information
Safety or technical information regarding this product can be obtained from Hans Rudolph, inc.

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Specifications subject to change without notice.