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Data Sheet...

METRO SEAL™
SINGLE PATIENT USE
Adhesive Tube Securement

***Metro Seal*™ shown on face**

***Metro Seal*™ with Disposable 6500 V2 Mask™**

***Metro Seal*™**

Product Features:
- **Disposable, single patient use only**
- **Skin safe adhesive and thermoplastic elastomer**
- **Tube securement and sealing device**
- **Enables a seal between the mask, nasogastric tube and patient's skin**
- **Shipped clean, non- sterile**

SPECIFICATIONS

MATERIALS	
Metro Seal™	Skin Safe Adhesive & Biocompatible TPE (thermoplastic elastomer)

Intended Use:
- The Hans Rudolph Metro Seal™ is a disposable, medical adhesive and thermoplastic elastomer, tube securement device intended to hold securely in place on the patient's face an accessory tube which is routed under a face mask and to thus enable a seal between the mask, tube and patient's skin.The *Metro Seal* is intended to be used with any size Hans Rudolph oro-nasal mask when it is necessary to pass and secure an accessory tube (12 to 18 French) under the mask to the patient's nasal or oral orifices from somewhere outside of the mask. The accessory tubes involved may include but are not limited to nasogastric tubes and esophageal balloon catheters. The associated masks involve applications for single and bilevel CPAP, Non-Invasive Ventilation, and other clinical or research settings by individuals that have received at least minimal instruction or training on the use of the Metro Seal as well as the device and system with which the *Metro Seal* is associated.

Environment of Use:
- This seal is for use in hospitals and other clinical settings by individuals that have at least minimal instructions or training on the use of the seal as well as the device to which the seal is intended to be used with.

Service Life:
- The *Metro Seal* is a disposable single patient use device that must be disposed of following 24 hours continuous use and replaced with a new one.

Ambient Conditions:
- Temperature range: 5 °C to 40 °C
- Relative Humidity: 0-95% RH (non-condensing)

Caution: Federal Law restricts this device to sale by or on the order of a physician.
- After removal from packaging inspect each *Metro Seal* for damage prior to use.
- Patients with facial hair, especially beards, may experience excessive mask leakage even though the Metro Seal fitting instructions were followed. Facial hair may need to be shaved to assure mask and Metro Seal effectiveness.

Warnings: Refer to Instructions for Use 691246
- For continued biocompatibility each *Metro Seal* must be replaced after 24 hours of use.
- Do not place over open wounds.
- Do not attempt to sterilize, disinfect or clean the *Metro Seal*. Adhesive and sealing surfaces lose their adhesion and shape under these processes causing excessive leaks.
- Discontinue use and contact a physician if there is observation of patient skin irritation, infection, or an allergic reaction.
- In case of excessive leakage around *Metro Seal*, replace or refit Metro Seal OR replace, refit or clean mask.
- For use only on patient's skin.

Contraindications: The *Metro Seal* may not be suitable for use on patient's with the following conditions.
- Open wounds that are prone to infection.
- Claustrophobia, anxiety, or other discomfort with an adhesive device.
- Facial deformity, beard, or other inability for device adhesive to adhere to skin.
- Impaired cough reflex, hiatal hernia, or inability to swallow or clear secretions.
- Recent facial surgery.

Complications:
- Infection due to improper use over open wounds.
- Skin irritation after prolonged use.
- Nasal or dental pain.
- Some slight discomfort after prolonged use.

•Specifications subject to change without notice•

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Applying the Metro Seal™ (TUBE refers to nasogastric or catheter type tube)

- Identify and mark the location on the patient's face where the TUBE and mask sealing flange intersect.
- Clean the area of the patient's face where the *Metro Seal* will be installed.
- Remove the *Metro Seal* from the clam shell clear plastic package.
- Remove the clear plastic release film from the adhesive skin side of the *Metro Seal*.
- With the Metro Seal location identified on the patient's face, place the adhesive side of the *Metro Seal* directly on the patients face.
- The curvature of the *Metro Seal* should follow the curvature of the mask sealing flange.
- Place the TUBE in the exposed groove of the *Metro Seal* if necessary. The mask sealing flange should align over the *Metro Seal*, completely covering it.
- Install the mask and headgear on the patient as in normal use. Visually confirm that the *Metro Seal* is placed correctly and that there are no obvious leaks in this area.
- Make adjustments to the mask and or *Metro Seal* to reduce the leak potentials.

Disposal: Treat as conventional solid waste in accordance with local and federal regulations.

Ordering information: Ref 669353 is one *Metro Seal.*

Safety Information: Safety or technical information regarding the *Metro Seal*™ can be obtained from Hans Rudolph, inc. Phone 913-422-7788, Fax 913-422-3337, email hri@rudolphkc.com or by contacting your Hans Rudolph representative.

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