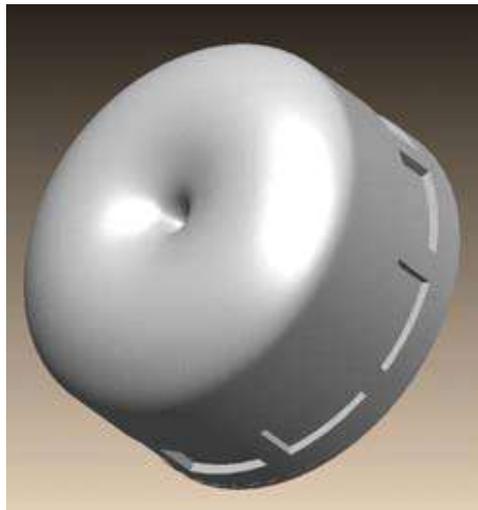


Instructions for Use

for the Shikani HME™

Breathe easily. Speak easily.



Contents of Shikani HME™ Patient Care Kit

This package contains a box that includes 25 (twenty-five) Shikani HMEs™ (Heat Moisture Exchangers) and an instruction booklet. For patients using the Shikani HME™ with oxygen, a lightweight oxygen tube (with a Luer lock mechanism to connect the HME to the oxygen tank) and tube clip (which secures the tube to the patient's clothing for comfort) are also included. The contents of this package are non-sterile. The HMEs do not contain any natural rubber latex.

Warnings prior to use of the Shikani HME™

- **Warning:** Prior to use, please read the instruction booklet thoroughly to ensure proper use of the Shikani HME™.
- **Warning:** Federal (USA) law restricts this device to sale by or on the order of a physician, speech language pathologist, respiratory therapist, or similar clinician. Patients using the Shikani HME™ should be evaluated and monitored by a trained clinical professional.¹
- **Warning:** The patient should be awake, alert, and have a patent airway before the Shikani HME™ is introduced.
- **Warning:** The patient should be observed with the Shikani HME™ in place to make sure that the patient's breathing and airway are adequate. The patient should be instructed to remove the HME **immediately** if shortness of breath or difficulty breathing is experienced.
- **Warning:** The Shikani HME™ is single patient use only, and each HME should be discarded after a **maximum of 24 hours of use** in order to minimize risk of infection. The Shikani HME™ should never be cleaned or reused given the risk of infection.
- **Warning:** The Shikani HME™ is not for use for laryngectomy patients.

- **Warning:** Store in a cool and dry place and protect from extreme heat.
 - **Warning:** When using the Shikani HME™ with oxygen, avoid use of oxygen around ignition sources.
 - **Warning:** When using the Shikani HME™ with oxygen, use care to avoid kinking or pinching the oxygen tubing.
 - **Warning:** When using the Shikani HME™ with oxygen, delivery of oxygen may differ from the delivery of oxygen via a trach collar. If clinically indicated, the treating provider should use methods such as pulse oximetry to ensure proper titration of oxygen while using the Shikani HME™.
1. The clinical evaluation should include the following basic measures: oxygen saturation levels, heart rate, and work of breathing for an appropriate duration (depending on the patient's medical condition). Secretion management, suctioning needs, alertness, the patient's subjective tolerance to the HME and ability to learn new information should also be assessed.

Indications for use

- To establish more normalized and uniform temperature and humidity levels in air that is inhaled by tracheotomized patients.
- To increase particle filtration from inhaled air.
- To reduce involuntary coughing and excessive mucus secretion.
- To increase resistance to airflow, which can have a positive effect on tissue oxygen saturation and lung ventilation.
- To reduce the risk of pulmonary infection and restore pulmonary conditions and health.
- To reduce discomfort following a tracheotomy.
- (For patients using the Shikani HME™ with oxygen) To provide portable, continuous, low-flow oxygen (typically <6L/min) to tracheostomy patients who require supplemental oxygen. For patients with resting hypoxemia, supplemental oxygen has a positive impact on breathlessness, exercise capacity and pulmonary health.

Description

Manufactured by The Airway Company[®], the Shikani HME[™] is the first true innovation in the field of tracheotomy heat moisture exchangers. The Shikani HME[™] functions as an artificial nose and is designed to restore some of the essential respiratory functions which are lost when the breathed air is directed away from the nose. In particular, the Shikani HME[™] filters airborne environmental particles from air inhaled by the tracheotomy patient; it retains moisture and heat from air that is exhaled out of the lungs; and upon re-inhalation by the patient, it efficiently filters, humidifies, and warms air returned to the lungs. The Shikani HME[™] can also be connected to an oxygen tank via a tube in order to provide supplemental oxygen to those patients who require it.

Placement of the Shikani HME™

The Shikani HME™ can be used with most standard (15mm) tracheostomy tubes and also directly with the Shikani Speaking Valve™ (SSV). Grasp the tracheostomy tube (or the SSV) in one hand and slide the open end of the Shikani HME™ over the inner cannula (or over the SSV) until a firm fit is achieved. When properly attached, the Shikani HME™ fits snugly onto the tracheostomy tube or onto the SSV. This is done through a simple coupling of the devices together. Proper placement of the HME will allow the patient to experience the most benefit from the HME.

Please see “The Shikani Speaking Valve™ and Shikani HME™ Combination” section at the end of this booklet for more information on using the HME with the valve simultaneously.

- **Breathing:** Breathing through the HME should be comfortable and easy. If it isn't, remove the HME and consult a medical professional for assistance.

When a patient begins using the HME, a slight feeling of increased airflow resistance may initially be felt. This resistance is a normal function of the device, and the patient will quickly become accustomed to it, typically after a few days. The Shikani HME™ contains side airflow vents, which should allow for easier breathing as well.

- **Coughing:** It is usually recommended that the HME be removed prior to coughing. However, most patients will be able to cough with the HME in place without significant problems.

For those patients using the Shikani HME™ with oxygen, prior to connecting the HME tube to the oxygen tank, connect the tube onto the side port connector of the HME using the Luer lock mechanism, and ensure that the attachment is secure. The tube will feed the HME with oxygen that is supplied from the oxygen tank. Also included in the box is a tube clip that can be used to secure the oxygen tube to the patient's clothing (e.g. shirt) for comfort.

Removing the Shikani HME™

The Shikani HME™ can either be disconnected from the Shikani Speaking Valve™ or from the tracheostomy tube. To remove the Shikani HME™, grasp the HME in one hand and the valve (or the tracheostomy tube, depending on which device the HME is connected to) in the other, and simply rotate and pull to loosen the friction fit. To also then remove the valve from the tracheostomy tube, grasp the valve in one hand and the tracheostomy tube in the other, and simply rotate and pull to loosen the friction fit.

For those patients using the Shikani HME™ with oxygen, the lightweight oxygen tube is a simple attachment that can be easily disconnected from the HME and from the oxygen tank when not in use.

Cleaning instructions and when to replace/change the HME

The Shikani HME™ has a life expectancy of a **maximum of 24 hours of use**. The Shikani HME™ is disposable and designed for daily, **one-time use only**. Discard the HME when it is clogged with mucus or after 24 hours of use to maintain proper function of each HME and to decrease the risk of infection. Replace the HME with a new one at least once a day; some patients may need to go through two or more HMEs per day.

Never clean or remove the foam media from its cartridge. Never wash the HME with water, soap or cleaning agents.

Benefits of the Shikani HME™

By using the HME consistently, tracheotomy patients can achieve:

- More normalized and uniform temperature levels from inhaled air
- More normalized and uniform humidity levels from inhaled air
- Substantially increased particle filtration from inhaled air
- Improved oxygenation (for those patients who require supplemental oxygen)
- Reduced mucus secretion and thickening
- Reduced risk of pulmonary infection
- Restored pulmonary conditions and health

The Shikani HME™ is more discreet and lighter than other comparable HMEs and has an intricate design that allows for optimal airflow and enhanced heat transfer and moisture/humidity retention.

For more information regarding the benefits of the Shikani HME™, please visit www.theairwaycompany.com.



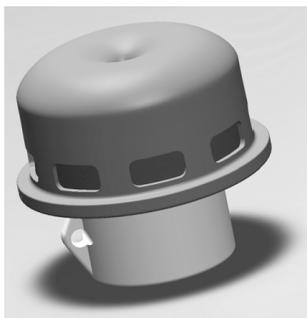
Shikani HME™ with oxygen port

The Shikani Speaking Valve™ and Shikani HME™ Combination

A unique feature of the Shikani Speaking Valve™ is the fact that it can be used in unison with the Shikani HME™, allowing effective speech and humidification, warming, and filtration of air at the same time. In contrast, flapper speaking valves cannot be coupled with HMEs as their membranes close 100% upon exhalation, and therefore exhaled air cannot bypass the flapper valve and reach the HME.

The Shikani HME™ can be used with the Shikani Speaking Valve™ during the day in order to achieve both improved speech and pulmonary health; afterwards, the same HME can be placed directly onto any standard 15mm tracheostomy tube cannula at night. Patients can therefore realize the benefits of the Shikani HME™ for a full 24 hours before replacing it with a new one the next day.

The combination use of the valve and HME quickly becomes intuitive for the patient. The patient will learn instinctively to choose to breathe and speak as needed.



To place the two devices together, first grasp the tracheostomy tube in one hand and slide the open end of the SSV over the inner cannula (15mm hub) until a firm fit is achieved. Then, turn the valve

so that the small, half-moon-shaped notch (and the dark-green line) on the front is positioned **upwards (at 12 o'clock position, i.e. "biased open")**. Then grasp the SSV in one hand and slide the open end of the Shikani HME™ over the SSV until a firm fit is achieved. When properly attached, the Shikani HME™ fits snugly onto the SSV, which in turn fits snugly onto the tracheostomy tube. Proper placement of the SSV and Shikani HME™ will allow the patient to experience the most benefit from both devices.

Please refer to www.theairwaycompany.com and/or the Shikani Speaking Valve™ instruction booklet for additional information regarding The Airway Company's products.

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The Shikani HME™ is manufactured in the USA.

