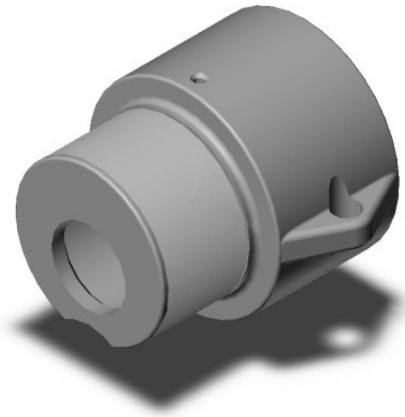
Instructions for Use

for the Shikani Speaking Valve™

One valve. Infinite possibilities.



The AirwayCompany

helping people breathe

Contents of Shikani Speaking Valve™ Patient Care Kit

This package contains a bag that includes 1 (one) Shikani Speaking Valve™ (SSV) inside of an SSV container, an instruction booklet, and a lanyard that attaches the speaking valve to the tracheostomy tube to prevent loss of the valve. The contents of this package are non-sterile. The SSV does not contain any natural rubber latex.

Warnings prior to use of the Shikani Speaking Valve™

- **Warning:** Prior to use, please read the instruction booklet thoroughly to ensure proper use of the Shikani Speaking Valve™.
- **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 SSV 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 SSV is introduced. The SSV should not be used when the patient is asleep.
- **Warning:** For cuffed tracheostomy tubes, ensure that the cuff is **fully deflated** prior to placing the Shikani Speaking Valve™ in order to allow airflow through the tracheostomy tube.
- **Warning:** The patient should be observed with the SSV in place to make sure that the patient's breathing and airway are adequate. The patient should be instructed to remove the SSV **immediately** if shortness of breath or difficulty breathing is experienced.

- **Warning:** While the SSV can improve swallowing and reduce aspiration in some patients, the risk of aspiration should be carefully evaluated for each individual patient to determine the appropriate usage of the SSV in addressing swallowing function.
- **Warning:** The SSV is single patient use only. **It is advisable to replace each SSV every 60 days**. Each SSV should be discarded after a **maximum of 90 days of use** in order to minimize the risk of infection. It is advisable to clean the SSV daily.
- **Warning:** The SSV is not for use for laryngectomy patients.
- **Warning:** Store in a cool and dry place and protect from extreme heat.

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 speaking valve and ability to learn new information should also be assessed.

Indications for use

- To allow airflow over the vocal cords for speaking function.
- To be used with a standard 15mm connection on tracheostomy tubes.

Description

Manufactured by The Airway Company®, the SSV is a true innovation in the field of tracheotomy speaking valves. It is a dynamic valve based on a *ball* design rather than the traditional flapper membrane design. The ball moves inside a chamber, where ramps act as a stop mechanism and act as a guide that

directs the ball towards the front or the back of the chamber, depending on the position of the valve. The patient can vary the position of the valve ("valve up" or "valve down") by rotating it 180°. Thus, the SSV gives the patient and clinician flexibility and full control over the use of the valve to preferentially allow the exhaled air to escape through the proximal opening of the valve or to redirect the air towards the larynx and speak. Depending on how the notch is turned, the valve has two modes of use – "**valve up**," ("biased open") or "**valve down**," ("biased closed") – each with its own unique benefits.

Two-Way Mode of Use

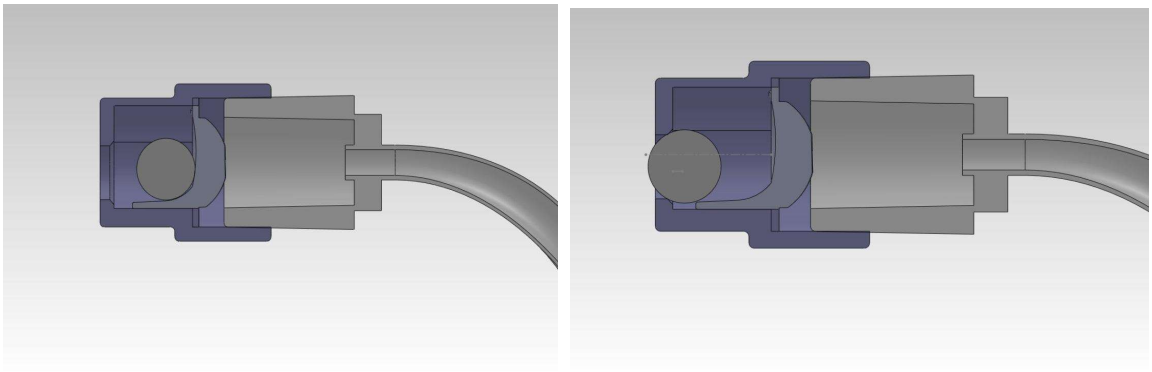
Mode 1: Valve Up ("Biased Open"): Many patients start with the valve with the notch up in the 12:00 o'clock position ("biased open"). In this position, the ball has a tendency to sit away from the frontal opening, closer to the posterior opening of the chamber, providing a more open airflow passage. When the patient uses the valve in this position at rest, he or she is breathing through the tracheostomy tube almost as if there is no valve in place. A soft "natural" breathing pattern does not push the ball forward; hence air can be exhaled through the valve freely and with no obstruction. When attempting to voice, the patient should exhale with a little more force. This force seats the ball into the frontal circular opening, closing the valve and redirecting air through the upper airway, thereby allowing vocalization and speech. The use of the valve quickly becomes intuitive for the patient. The patient will learn

instinctively how to choose between breathing and speaking as needed in this position. This flexibility offered by the SSV allows an easier and quicker first-time introduction to and acceptance of the speaking valve by the tracheotomized patient.

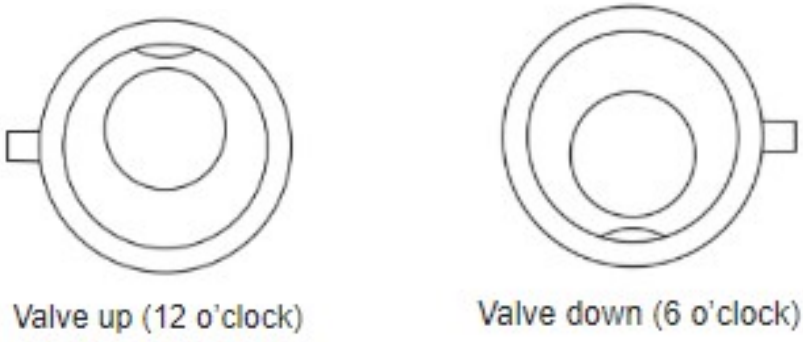
Example candidates for the "biased open" position: Patients with unique anatomy (e.g. stenosis, partial airway obstruction) that cannot tolerate every breath going through the upper airway, patients with severely compromised respiratory function, and patients that are anxious about using a speaking valve are good candidates for the biased open position. This position is also excellent for pediatric patients, because it allows for easier introduction to the valve. This position is often an ideal starter position for any patient to get used to the valve. That said, a doctor or clinician should always be consulted to determine which position is best for the patient.

Mode 2: Valve Down ("Biased Closed"): With the notch down in the 6:00 o'clock position ("biased closed"), every single breath is going through the upper airway. "Positive closure" is generated in this position as the ball naturally rolls forward along a ramp and closes the frontal opening of the SSV. This opening remains closed until a sufficient amount of inhalation pressure is applied. The valve opens easily with inspiration and closes readily at the end of the inspiratory cycle, without any air leak. This feature allows the patient to create positive airway pressure and restore a more normalized "closed respiratory system." It also allows secretions to be coughed up around the

tracheotomy tube and expectorated or suctioned from the mouth.



Example candidates for the "biased closed" position: Patients who can tolerate every breath going through the upper airway, patients who are weaning from their tracheostomy tube, patients who are receiving nutrition by mouth, and patients who wish to speak for extended periods of time are good candidates for the biased closed position. Again, a doctor or clinician should always be consulted to determine which position is best for the patient.



Placement of the Shikani Speaking Valve™ in the "biased open" and "biased closed" positions

The SSV can be used with most standard (15mm) tracheostomy tubes. 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 of the valve is positioned either upwards (at 12 o'clock position, i.e. "biased open") or downwards (at 6 o'clock position, i.e. "biased closed"). See above figures.

The clinical professional and patient can experiment with the two orientations to determine which is most comfortable and beneficial for the patient. The valve can also be oriented anywhere in between the two main settings noted above, for example in the 3 o'clock or 9 o'clock positions. The SSV can therefore provide the optimal combination of airflow and closure performance, depending on each individual patient's needs. Proper placement of the SSV will allow the patient to experience the most benefit from the valve.

Removing the Shikani Speaking Valve™

To remove the valve, grasp the SSV in one hand and the tracheostomy tube in the other, and simply rotate and pull to loosen the friction fit.

Cleaning instructions

It is advisable to clean the SSV daily. Do not clean the valve while it is still attached to the tracheostomy tube. Once the

valve has been removed from the tube, it may be cleaned with hydrogen peroxide or with soap and water for 10 minutes. The hydrogen peroxide should be completely flushed off with tap water when done cleaning. The valve may also be cleaned in any proteolytic enzyme cleaner (e.g. contact lens solution). The SSV can be cleaned with a cotton swab without fear of damage. Dry thoroughly after cleaning is complete. It is recommended to have a second SSV available, so that the second SSV can be used while the first SSV is being cleaned.

WARNING: Only use the cleaning solutions identified above. Do not use a sharp object to assist in cleaning. Do not leave the valve in hydrogen peroxide for more than 10 minutes, as doing so can decrease the life expectancy of the valve.

When to replace/change the valve

It is advisable to replace each SSV every 2 months or 60 days. The SSV has a life expectancy of a **maximum of 3 months or 90 days of use**. Discard the valve after at most 90 days of use. Replace the valve either 90 days after it was first put into use or when any of the following occur prior to the 90-day mark: 1) there is a noticeable change in color of the valve or the inside ball, 2) there is an increase in the amount of thick mucus that has adhered to the ball or the inside of the valve and that cannot be removed with cleaning, or 3) there are any visual indentations to the valve body or any changes in its shape (caused by accident, misuse, etc.).

Sterilization

The valve should never be autoclaved, ETO sterilized, boiled, or used with any cold or chemical sterilization methods.

Retaining lanyard

Included within each SSV package is a flexible retaining lanyard for attaching the valve to the tracheostomy tube to prevent loss of the valve.

Benefits of the Shikani Speaking Valve™

As compared to existing flapper membrane valves, the SSV offers patients many advantages and benefits that can improve their overall quality of life. In addition to restoring speech, studies have shown that users of the SSV can benefit from:

- Significantly lower airflow resistance, resulting in increased comfort, tolerance, and ease of breathing.
- Superior voice quality and speech naturalness.
- Superior olfaction.
- More effective cough.
- Improved swallowing.
- The valve's discreet, low-profile design (smaller than flapper valves).
- The valve's ability to be used with a heat moisture exchanger (HME), allowing speech and humidification, warming, and filtration of air at the same time.

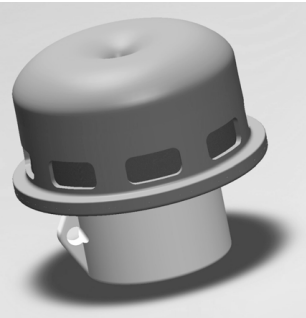
For more information regarding the benefits of the Shikani Speaking Valve™, please visit www.theairwaycompany.com.

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 HME™ instruction booklet for additional information regarding The Airway Company's products.

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The Shikani Speaking Valve™ is manufactured in the USA.