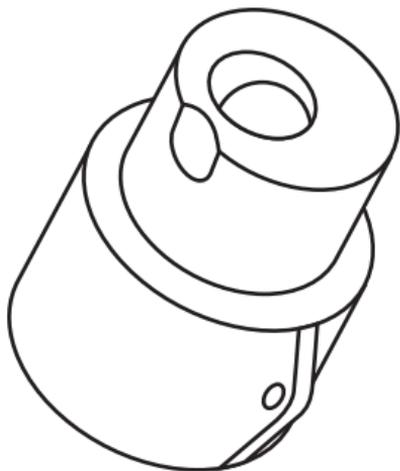


Instructions for Use

The Shikani Speaking Valve

One valve. Infinite possibilities.™



The
AirwayCompany
helping people breathe

Description

The Shikani Speaking Valve™ is produced in the USA of a polymer material holding a USP class VI rating for biocompatibility. This rating requires the most stringent testing of the materials used in order to be listed as Class VI. The stainless steel pin retains the ball. It is to be applied for single patient use only with a maximum service period of 90 days.

Indications for use

To enable airflow through the vocal cords for speaking function.

To be used with a standard 15mm hub on tracheostomy tubes.



Precautions

Patient should be awake, alert, and have a patent airway before the Shikani Speaking Valve™ is introduced.

Not for use when the patient is asleep.

Patient should be evaluated by a trained clinical professional for tolerance of the Shikani Speaking Valve™. The 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, and patient's subjective valve tolerance, alertness, and ability to learn new information should also be addressed. The patient should be instructed to remove the valve immediately if shortness of breath is experienced.

For cuffed tracheostomy tubes, ensure that the cuff is fully deflated prior to placing the valve to allow airflow around the tracheostomy tube.

Caution

Federal (USA) law restricts this device to sale by or on the order of a physician.

Introduction to use

Please read these instructions thoroughly to fully understand the Shikani Speaking Valve's™ adaptable design and ability to be adjusted to accommodate individual patient needs. By doing so you may find quicker acceptance of the valve, even in patients who have previously encountered problems using a speaking valve. Proper placement of this valve may enable more consistent and extended use, allowing the patient to experience the maximum benefit of a speaking valve.

Applying the Shikani Speaking Valve™

Placement of the valve is accomplished with the open end of the valve attaching via friction fit to the standard 15mm hub found on tracheostomy tubes and inner cannulas.

Placing the Valve

Some patients being introduced to a speaking valve for the first time find it difficult to sustain use of a bias-closed valve and the resulting airflow through the upper airway with each exhalation.

The Shikani Speaking Valve's™ unique design allows the clinical professional and patient control over how airflow is handled.

Based on the patient's needs, the valve can be attached in two different modes as follows.

A) Bias Open / Two-Way Mode:

Place the valve so that the small, half-moon-shaped notch on the front is positioned at 12 o'clock or "up." See Figure 1.

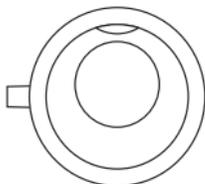


Figure 1

Grasp the tracheostomy tube in one hand and slide the speaking valve over the 15mm hub until a firm fit is achieved. Positioning the valve as pictured in Figure 1 requires more force on exhalation to seat the ball and close the valve. This allows the patient to exhale back through the valve when desired without being forced to redirect airflow into the upper airway with each breath.

With the valve in this Bias Open / Two-Way mode, a slightly stronger exhalation will seal the valve, redirecting airflow into the upper airway. The patient will then be able to produce sound for vocalization.

Patients may choose to always wear the valve in this two-way position taking advantage of the flexibility offered. For instance, when at rest and not vocalizing, it may be beneficial to the patient's comfort to exhale out through the valve. And then

when desired, a stronger exhalation will close the valve, redirect airflow into the upper airway, and allow vocalization.

B) Bias Closed / One-Way Mode:

Place the valve so that the small, half-moon-shaped notch on the front is positioned at 6 o'clock or "down." See Figure 2.

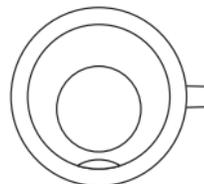


Figure 2

Grasp the tracheostomy tube in one hand, and slide the speaking valve over the 15mm hub until a firm fit is achieved. Positioning the valve as pictured in Figure 2 will allow the ball to seat and seal instantly on exhalation with no additional effort.

Using the valve in Bias Closed / One-Way mode provides a closed respiratory system on exhalation, redirecting air through the vocal cords into the upper airway with every breath. The patient will then be able to produce sound for vocalization.

This setting is appropriate for patients who can comfortably sustain a fully closed position with exhalation through their upper airway during each breath.

Placement Summary

Regardless of the orientation selected, the Shikani Speaking Valve's™ ball-valve design will provide low airflow resistance during inhalation.

The clinical professional and patient can experiment with the two orientations to determine which is most comfortable and beneficial for each individual. The valve can even be used oriented anywhere in between the two main settings noted above. This may provide the perfect combination of flow/closure performance, depending on the patient.

The Shikani Speaking Valve's™ design should be taken advantage of to allow each patient to adjust its closure performance to accommodate his or her individual needs.

Proper placement of the valve for an individual can result in quicker acceptance, longer periods of use, and better compliance.

Retaining Lanyard

Included with each Shikani Speaking Valve™ is a flexible retaining lanyard for attaching the valve to the tracheostomy tube to prevent loss of the valve.

Removing the Shikani Speaking Valve™

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

Cleaning Instructions

Do not clean the valve while it is still attached to the tracheostomy tube.

Once the valve is removed from the inner and/or outer cannula, it may be cleaned in any proteolytic enzyme cleaner. Proteolytic enzyme cleaner is readily available packaged as contact lens cleaner. The valve should then be placed in hydrogen peroxide for 10 minutes. Clean the valve of any residual secretions by swishing it in the hydrogen peroxide. The Shikani Speaking Valve™ can be cleaned with a cotton swab without fear of damage. The hydrogen peroxide should be completely flushed off with tap water. Dry thoroughly after cleaning is complete.

WARNING

Only use the solutions identified above. Do not use a sharp object to assist 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

The valve has a life expectancy of 3 months/90 days of use. Replace the valve 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 are any visual indentations to the valve body, or any change of shape (caused by accident, abuse, misuse, etc.).

Sterilization

Under no circumstances is the valve to be autoclaved, ETO sterilized, boiled, or used with any cold or chemical sterilization methods.



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