

The Flexible Design of the Shikani Speaking Valve

This two-way valve gives tracheostomy patients complete control over how airflow is directed into the upper airway depending on how they position the valve.

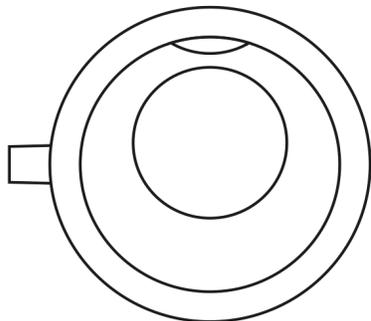


Bias Open

This position allows patients to breathe through the tracheostomy tube as if there were no valve in place until they go to voice. This position allows patients to utilize a speaking valve earlier in the recovery period and is ideal for patients with a unique anatomy (narrowing of the airway or partial airway obstruction).

Bias Open is achieved by placing the valve so that the small, half-moon-shaped notch on the front is positioned at 12 o'clock or "up." See Figure 1 below.

FIGURE 1



Positioning the valve as pictured 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. In this position, patients will only exhale through the upper airway when they voice. At rest, they will exhale through the tracheostomy tube as if there was no valve at all. 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.

In the 12 o'clock or "Bias Open" or "up" mode, 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 ("biased-open" position) hence allowing the patient to breathe easier. The exhalation force that is normally used for voicing allows the valve to seat in the frontal hole, seal off airflow, hence redirecting air through the upper airway.

Alternately, the tracheotomized patient may breathe more softly and allow exhaled air to exit through the valve rather than being redirected through the patient's upper airway.

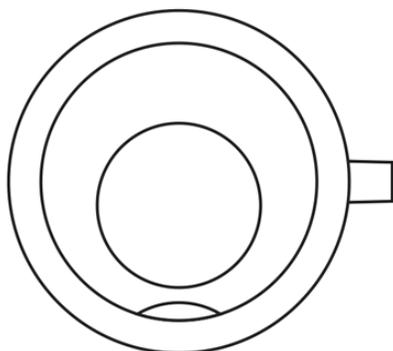
The use of the valve becomes intuitive and requires little to no instruction. The patient will learn instinctively how to alternate between breathing and speech as needed. In the "bias open" position, exhaled air flows freely through the valve when patient is not voicing, hence allowing the improved tracheostomy speaking valve to be coupled with the Shikani Heat Moisture Exchange (HME). THE HME fits over the Shikani Speaking Valve as a cap, and helps restore some of the moisturizing and warming roles played by the nose, and nasopharynx.

Bias Closed

This position is recommended for patients who can tolerate every single breath going into the upper airway.

Bias Closed is achieved by placing the valve so that the small, half-moon-shaped notch on the front is positioned at 6 o'clock or "down." See Figure 2 below.

FIGURE 2



Positioning the valve as pictured will allow the ball to seat and seal instantly on exhalation with no additional effort. Using the valve in Bias Closed 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.

In this mode, with the valve oriented "down", the ball automatically rolls forward along a 2.5 degree ramp towards the frontal opening of the valve, closing the valve opening and maintaining a positive closure until a sufficient amount of inhalation pressure is applied. This

innovation allows the ball to sit inside the frontal opening of the valve body, when the patient is breathing regularly at rest, and provide a leak free seal to the valve with no expiratory air required to seat the ball in the opening ("biased-closed position"). The valve opens easily with inspiration and closes more readily at the end of the inspiratory cycle, without air leak.

In addition to restoring speech with greater naturalness, the benefits of this "Positive Closure" include enhanced ability to cough, swallow and smell.

ADDITIONAL IMAGERY:

