

Medtronic

Shiley™ speaking valve

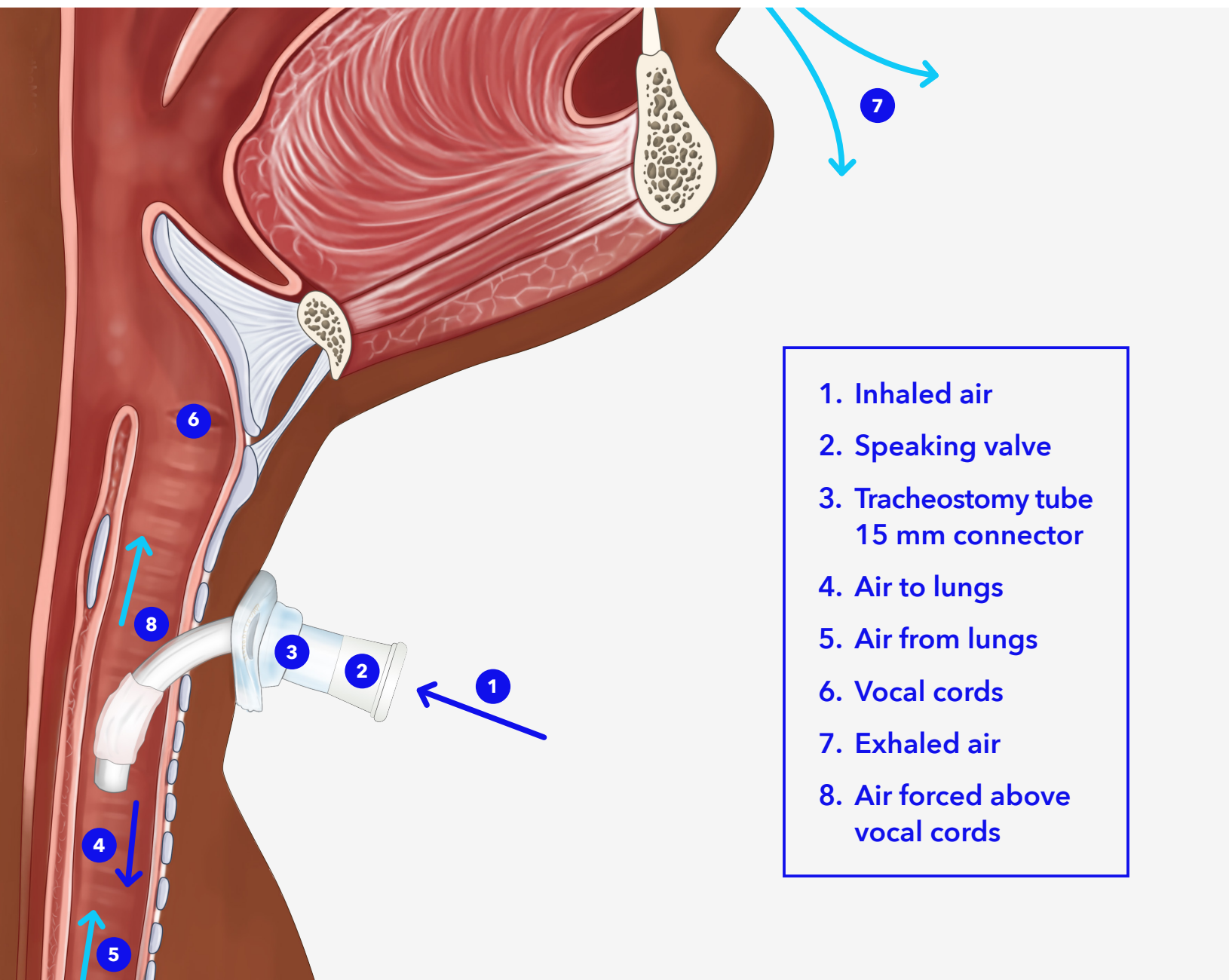
**Powering voice.
With a simple valve.**



Space to speak

A tracheostomy tube profoundly limits a patient's ability to communicate. The Shiley™ speaking valve is helping transform the lives of patients by restoring their voice.^{1,2}

Placed on the tracheostomy tube, the valve redirects airflow through the vocal cords, nose and mouth to deliver the most promising possibility – the power to speak.



A refreshing change of direction

The Shiley™ speaking valve doesn't just help patients regain their voice. It also helps enhance their quality of life.

Equipped with a thin clear film, the one-way flutter valve harnesses the direction of airflow when connected to the tracheostomy tube.

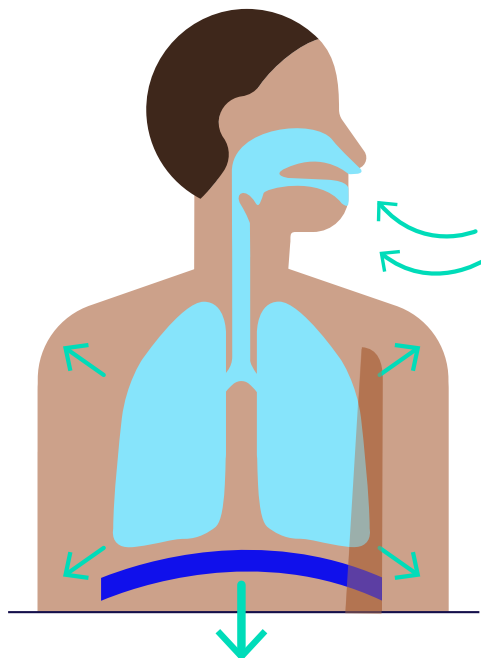
It opens when a patient breathes in allowing air to the lungs, then closes when a patient exhales, pushing air through the vocal cords and out of the mouth, thus enabling speech.

Those breakthroughs improve communication, pulmonary health, and most importantly – patient comfort.

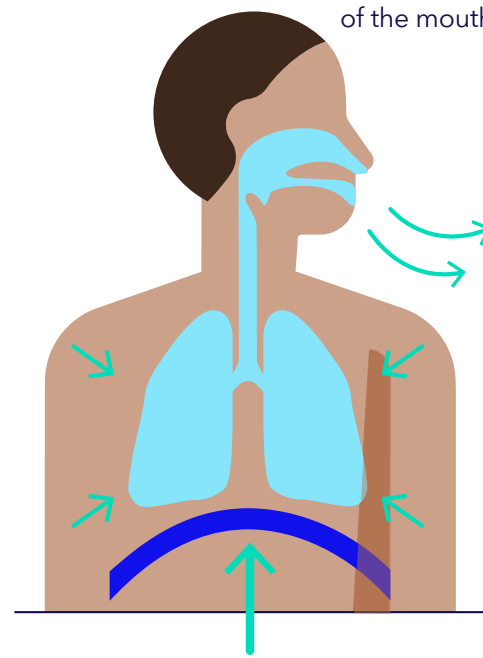


Shiley™ speaking valve (SSV or SSVO)

Natural inspiration:
One-way valve opens to breathe in air



Expiration:
One-way valve closes to force air across vocal cords and out of the mouth



Benefits that go beyond communication

Our speaking valve delivers significant benefits besides restoring speech. Discover how the Shiley™ speaking valve breathes new life into tracheostomy patient care.^{1,2}

Little valve, life-changing impact²

Improves

- Quality of life
- Breathing process
- Swallowing
- Core muscle strength

Restores

- Ability to communicate
- Potential return of sensation, taste, and smell
- Sub-glottic pressure

Reduces

- Aspiration
- Cough
- Suctioning needs

Eliminates

- Need for finger occlusion or chin dropping

Finding their voice: the first steps

Getting started with the Shiley™ speaking valve

The Shiley™ speaking valve is designed for patients who are alert, awake and can breathe independently. A speaking valve shouldn't be used with a cuffed tracheostomy tube because the patient may not be able to exhale air. Please refer to the Indications for Use for complete information regarding the use of the Shiley™ speaking valve.

Mobilizing patients to speak with our speaking valve begins with careful screening.

Patients must:

- Be awake and fully alert
- Be medically stable and not require mechanical ventilation
- Be able to tolerate cuff deflation
- Have manageable or low secretions

Patients should:

- Be able to achieve full cuff deflation if using cuffed product
- Occlude the tracheostomy tube with gloved finger on exhalation
- Be asked to voice or cough



The right connection

Fitting the Shiley™ speaking valve to the tracheostomy tube

The Shiley™ speaking valve fits on the universal 15-mm tracheostomy tube connector. CAUTION: Prior to attaching the speaking valve, be sure the cuff is completely deflated or that an uncuffed product is used. To attach the product:

1. Wash hands thoroughly.
2. Carefully hold the tracheostomy tube with one hand while grasping the Shiley™ speaking valve with the opposite hand.
3. Attach the valve to the 15-mm connector using a gentle twisting motion.
4. Remove the valve if any respiratory distress or difficulty in breathing occurs.
5. To remove the valve, carefully hold the tracheostomy tube with one hand, while pulling the device from the tube with a gentle twisting motion.
6. If using the speaking valve for the first time, the patient's breathing should be observed by a home healthcare provider and/or speech pathologist for a period of time to make sure breathing and speaking can occur without difficulty.
7. Increase the wearing time as tolerated.

Overcome patient barriers

Inadequate exhalation or breath stacking, coughing, and weak voice are common conditions that hinder patient comfort. If these occur, we consider these treatment approaches. For more information, consult the product Instructions for Use included with the product.

Treating and troubleshooting

Inadequate exhalation or breath stacking

- Check for complete cuff deflation prior to placing speaking valve
- Suction tracheostomy tube and/or oropharynx
- Reposition patient and/or tracheostomy tube
- Retrain for normal breathing patterns
- Assess need for downsizing the tracheostomy tube
- Consider direct visual assessment for airway obstruction

Coughing

- Allow patient time to move secretions
- For persistent or dry cough, remove valve and reassess
- Educate and use relaxation techniques

Weak voice

- Consult your ENT or otolaryngologist
- Perform glottic closure exercises
- Perform diaphragmatic breathing exercises

Nurture and care

Using and maintaining the Shiley™ speaking valve

The valve should be cleaned daily. If mucous or secretions become attached to the device, it should be cleaned immediately:

- 1 Remove the valve by carefully holding the tracheostomy tube in position while gently pulling the device from the tracheostomy tube, with a slight twisting motion.
- 2 Disengage the valve cap from the main body for cleaning by pressing the cap away from the body at a position opposite the hinge. If an oxygen port is present, do not apply excess pressure to the side of the port during this step.
- 3 Prepare one of the following cleaning solutions:
 - a. Cool or lukewarm saline
 - b. Soapy water (a pure soap is recommended)
 - c. Diluted household strength hydrogen peroxide (one-part water and one-part peroxide)
 - d. Diluted household strength vinegar (one-part water and one-part vinegar)
- 4 Soak the opened valve in the cleaning solution for up to 15 minutes.
- 5 After the soaking period, agitate the valve in the cleaning solution and then drain.
- 6 Thoroughly rinse the speaking valve in cool or lukewarm tap water to remove any cleaning solution residue.
- 7 Examine the opened valve for remaining debris or encrustations. Ensure that the flexible diaphragm is clean, not torn or sticky, and lies flat in the valve cap. Check that the inner surface of the main body is smooth and undamaged. If an oxygen port is present, check for a clear and unobstructed passageway. If clean, go to step 9.
- 8 If necessary, use a moistened cotton tipped applicator to gently remove any remaining debris or encrustations. Repeat rinsing and examination, following steps 6 and 7 if required.
- 9 Close the speaking valve by firmly pressing the valve cap over the main body to engage the snap fitting.

Patient safety: criteria and constraints

Proper training and education must be completed prior to using this device outside of the hospital.

This device is not for use in patients who are being mechanically ventilated or who have a laryngeal stenosis, vocal cord paralysis, severe tracheal stenosis, airway obstruction, respiratory infection, or heavy pulmonary mucous secretions.

This product is intended for use with tracheostomy tubes only. The product is not made with natural latex and does not contain DEHP. The Shiley™ speaking valve should not be used during sleep.

For additional information, please refer to instructions for use included with every Shiley™ speaking valve product.

 For more information, please visit:
[medtronic.com/covidien](https://www.medtronic.com/covidien)



For trained personnel only. For specific indications and instructions for use, please refer to the product manual.

1. Marks, M. V. (2019, June 12). Power of the Speaking Valve [web log]. Retrieved November 4, 2021, from <https://www.chestnet.org/leadership/thought-leader-blog/2019/06/power-of-the-speaking-valve>.
2. Soneghet R, Toniolo J, Arevalo R. Benefits of the speaking valve according to patient perceptions. *Crit Care*. 2007;11(Suppl 3):P102. doi:10.1186/cc5889

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