

Spiration® Valve System

PRESCRIPTIVE INFORMATION

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

Indication for Use

Spiration Valves are one-way endobronchial valves indicated for adult patients with shortness of breath and hyperinflation associated with severe emphysema in regions of the lung that have evidence of low collateral ventilation.

Contraindications

- Patient is not an appropriate candidate for, or unable to tolerate, flexible bronchoscopy procedures.
- Patients with known or suspected sensitivity or allergy to nickel.
- Patients with evidence of active pulmonary infection.
- Patients who have not quit smoking.
- Patients with large bullae encompassing greater than 30% of either lung.
- Patients with diffuse homogenous emphysema.

General Warnings and Precautions

The following are general warnings:

The safety and effectiveness of the Spiration Valve System have not been studied in

- Prior major lung or chest surgery
 - Lung Volume Reduction Surgery (LVRS)
 - Transplant
 - Median sternotomy or thoracotomy
- Known cardiac history of myocardial infarction or congestive heart failure
- Implanted endobronchial valve currently treating a prolonged air leak

The following are general precautions:

- Do not use the Spiration Valve System for other than its intended use.
- The Spiration Valve System should not be used for patients who have active asthma, bronchitis or clinically significant bronchiectasis.
- Only use a bronchoscope with an instrument channel inner diameter of 2.6mm or larger.
- Valve placement should be done only after airway evaluation and sizing with the balloon catheter and Airway Sizing Kit (see Instructions for Use, Airway Sizing Kit).
- Valve placement and removal must be done under bronchoscopic observation with visualization of the target airway.
- Do not allow lubricants to contact the catheter, loader, or valve.
- Once a valve has been loaded and/or deployed, do not attempt to reuse or re-deploy the valve.
- The valve is not designed to be repositioned after it is deployed from the catheter. If the position of the deployed valve is not optimal or appropriate, the valve should be removed and discarded.
- Do not remove the valve from the cartridge.
- Do not reuse the catheter and loader for more than one patient procedure. The catheter and loader are not designed to be re-cleaned, reprocessed, or re-sterilized.
- Do not deploy more than 10 valves using the catheter and loader. If more than 10 valve deployments are needed, a new catheter and loader must be opened and used.

Potential Complications

Potential complications that may be associated with bronchoscopy and/or valve placement include, but are not limited to, the following:

- Altered arterial blood gas
- Anesthesia complications
- Arrhythmia
- Atelectasis
- Bronchial injury
- Bronchitis
- Bronchospasm
- Chest pain
- Chronic Obstructive Pulmonary Disease (COPD) exacerbation
- Death
- Dyspnea
- Empyema/lung abscess
- Hemoptysis (or bleeding)
- Hemothorax
- Hypoxemia
- Iatrogenic injuries
- Infection
- Migration of a valve out of the lung or within the lung
- Myocardial infarction
- Persistent cough
- Pleural effusion
- Pneumothorax
- Pneumonia
- Respiratory failure
- Sore throat
- Thoracic pain
- Tissue hyperplasia or other reaction at valve site
- Valve fracture
- Vocal cord injury
- Wheezing
- Other procedure-related adverse events may occur

Prior to using the Spiration Valve System, please review the Instructions for Use for additional information on indications, contraindications, warnings, precautions and potential complications.

Prior to ordering the Spiration Valve System, on-site product training with the treating physician(s) present must be completed.