Spiration® Valve System

PRESCRIPTIVE INFORMATION

Caution: Humanitarian Device. Authorized by Federal law for use in the control of prolonged air leaks of the lung, or significant air leaks that are likely to become prolonged air leaks, following lobectomy, segmentectomy, or Lung Volume Reduction Surgery (LVRS). The effectiveness of this device for this use has not been demonstrated. Federal Law restricts this device to sale by or on the order of a physician.

Indication for Use

The Spiration Valve System is a device to control prolonged air leaks of the lung, or significant air leaks that are likely to become prolonged air leaks following lobectomy, segmentectomy, or Lung Volume Reduction Surgery (LVRS). An air leak present on post-operative day 7 is considered prolonged unless present only during forced exhalation or cough. An air leak present on day 5 should be considered for treatment if it is: 1) continuous, 2) present during normal inhalation phase of inspiration, or 3) present upon normal expiration and accompanied by subcutaneous emphysema or respiratory compromise. Spiration Valve System use is limited to 6 weeks per prolonged air leak.

Contraindications

- Patient is unable to tolerate a flexible bronchoscopy procedure.
- Patient is allergic to latex.
- Patients with known or suspected sensitivity or allergy to nickel.

General Warnings and Precautions

- Atelectasis may occur after the air leak seals; patients should be monitored for this possible complication.
- Use of the catheter requires bronchoscopy technical skills and adequate training. The operator must be a physician or medical personnel under the supervision of a physician and be trained in clinical bronchoscopy techniques and the use of the Spiration Valve System. The following instructions will give technical guidelines but do not obviate formal training in bronchoscopic procedures.
- 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 air leak isolation and airway sizing with the calibrated balloon catheter.
- 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 use the Spiration Valve System for other than its intended use.
- Do not reuse the catheter and loader for more than one patient procedure. The catheter and loader are not designed to be recleaned, 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 Adverse Effects

- Atelectasis
- Bleeding observed from an airway treated with a valve
- Bleeding due to valve removal and complications of such bleeding such as airway obstruction by blood clot
- Bronchitis
- Damage in the airway and/or tissue near a valve
- Death
- Infection in the tissue distal to a valve
- Local airway swelling or edema at site of valve placement
- Migration of valve out of the lung or within the lung
- Persistent cough
- Pneumothorax shortness of breath
- Tissue hyperplasia or other reaction at site of valve placement
- Valve fracture

MRI Information

The Spiration Valve was determined to be MR-Conditional according to the terminology specified in the American Society for Testing and Materials (ASTM) International, Designation: F2503. Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment. ASTM International, 100 Barr Harbor Drive, PO Box C700, West Conshohocken, Pennsylvania, 2005.

Non-clinical testing has demonstrated that the Spiration Valve is MR Conditional. A patient with this device can be scanned safely immediately after placement under the following conditions:

- Static magnetic field of 3-Tesla or less
- Spatial magnetic gradient field of 720-Gauss/cm or less
- Maximum MR system reported whole-body-averaged specific absorption rate (SAR) of 3-W/kg for 15 minutes of scanning

In non-clinical testing, the Spiration Valve produced a temperature rise of less than or equal to 0.5° C at a maximum MR system reported whole-body-average specific absorption rate (SAR) of 3-W/kg for 15 minutes of MR scanning in a 3-Tesla MR system (Excite, Software G3.0-052B, General Electric Healthcare, Milwaukee, WI).

MR image quality may be compromised if the area of interest is in the same area or relatively close to the position of the Spiration Valve. Optimization of MR imaging parameters is recommended.

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

The FDA has approved the Spiration Valve System under the Humanitarian Device Exemption (HDE) label. Under this approval, a physician at each site must complete a thorough training course before the site is approved for commercial use.

LITM-004851-02 Rev AA

OLYMPUS

Spiration, Inc. d/b/a
OLYMPUS RESPIRATORY AMERICA
6675 185th Ave NE, Redmond, Washington 98052