

U.S. Pivotal Trial of IBV[®] Valve System for Severe Emphysema

The IBV[®] Valve Trial is a U.S. pivotal trial to evaluate safety and effectiveness of the IBV[®] Valve System for the treatment of severe emphysema.

Unmet Need: A Minimally Invasive Option for Patients with Severe Emphysema

More than four million Americans are living with emphysema, a condition that is chronic and severely impacts quality of life. People with severe emphysema struggle with each breath and therefore cannot do very simple things that most people take for granted, such as simultaneously walking and talking.

Currently available treatments for emphysema are generally palliative and include medications, home oxygen therapy, pulmonary rehabilitation, lung volume reduction surgery and lung transplantation.

Lung volume reduction surgery and lung transplantation are invasive procedures that are associated with substantial risks and long recovery periods. For many patients with severe emphysema, the risks of these treatments may be too great.

Encouraging Pilot Data

The IBV Valve Trial design is based on the results of a large U.S. IDE Pilot study. Data from more than 90 patients enrolled in this study indicate that the IBV Valves redirect air from diseased portions of the lungs to healthier areas and may enable more-efficient ventilation which likely results in improved disease-related health status. Furthermore, these data show that the design of the IBV Valve System provides the ease of use required in the intended clinical environment and allows the valves to be removed if needed.

The IBV Valve Trial

The IBV Valve Trial is a prospective, randomized, blinded clinical trial that will enroll up to 500 patients at up to 50 sites in the United States. The objective of the study is to demonstrate the safety and effectiveness of the IBV Valve treatment. The primary endpoints of the study will be measured at six months. Patients enrolled in the control arm of the study will be eligible to receive treatment with the IBV Valve System after completion of the six-month study period.

A Blinded Controlled Trial

The control for the study will be a “sham” treatment group: this group will be tested, treated and followed in a manner identical to the treatment group, except that no valves will be placed during the bronchoscopy procedure.

Safety and Effectiveness Endpoints

The primary safety endpoint will be the difference between the treatment and control groups in the incidence of a composite of serious adverse events during the six-month study period.

The primary effectiveness endpoint of the study will be the difference between responder rates of the treatment and control groups at six months. Responders are defined as subjects with clinically meaningful improvements in disease-related health status as measured by the St. George’s Respiratory Questionnaire (SGRQ) total score and regional lung volume changes as measured by quantitative CT scan at six months.

Inclusion Criteria

The study is open to men and women age 40 to 74 who have been diagnosed with predominantly upper lobe emphysema and shortness of breath with exertion. Eligible patients are able to participate in pulmonary function and standardized exercise tests, have not smoked for four months and are willing to not smoke during the trial, and will commit to visits to a medical center for initial health assessment tests. Additional criteria must be met for participation in the study. For more information visit www.emphysematrial.com or call (877) 547-8839.



Cautions: The IBV Valve is not yet approved for use in emphysema, but is subject to an ongoing clinical investigation in which approval for use in emphysema will be sought. The IBV Valve is a Humanitarian Use Device authorized by Federal (or United States) Law for the control of prolonged air leaks of the lung, or significant air leaks that are likely to become prolonged following lobectomy, segmentectomy, or lung volume reduction surgery. 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.

Instructions for Use and Approval Documents for HDE Approval in the U.S.: http://www.spiration.com/ibv_status.asp

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