

## IBV<sup>®</sup> Valve System

The IBV Valve System is a minimally invasive treatment that has diverse applications in both acute and chronic conditions of the lung.

### FDA Approval for Prolonged Air Leaks

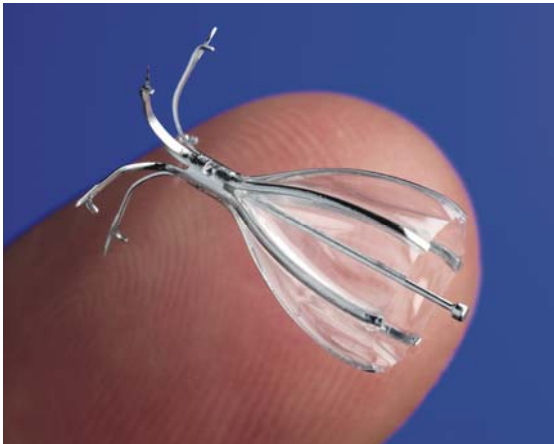
The device has received Humanitarian Device Exemption (HDE) approval from the U.S. Food and Drug Administration (FDA) to control prolonged air leaks of the lung, or significant air leaks that are likely to become prolonged, following lobectomy, segmentectomy, or lung volume reduction surgery. This HDE approval is the first for a bronchial valve. The effectiveness of this device for this use has not been demonstrated.

### Investigation in U.S. of IBV<sup>®</sup> Valve System as a Treatment Option for Severe Emphysema

The IBV Valve System is currently under investigation in the U.S. as a new treatment option for the many people with severe emphysema who do not respond well to current medical therapies or are not eligible for or elect not to undergo invasive surgery such as lung volume reduction or lung transplantation.

### Distribution Outside the United States

The IBV Valve System is marketed and distributed by Olympus in Europe, where the system has received market clearance through the CE Mark for the treatment of diseased and damaged lung, an indication that includes the treatment of emphysema and the resolution of prolonged air leaks. Olympus also has development and distribution rights for the IBV Valve System in Japan.



### Product Description

The IBV Valve is comprised of a Nitinol frame and a polymer membrane. The membrane is held against the airway mucosa by six elastic struts and will expand and contract with airway movement during breathing. The valve is designed to conform to the size and shape of the airways. The frame also has five flexible anchors that gently secure to the mucosal wall at a controlled depth. Valves are available in various sizes (5, 6 and 7mm diameters) appropriate for different airways. The valve is delivered through a custom deployment catheter.

### Procedure

During a minimally invasive procedure, a catheter is passed through a bronchoscope (a flexible tube passed into the bronchial tubes through the mouth or nose) to deploy the small umbrella-shaped valves into the airways of the lungs. Only flexible bronchoscopy equipment is required. The valves are designed to be removed via a similar bronchoscopic procedure if indicated.

**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 the HDE Approval in the U.S.:** [http://www.spiration.com/ibv\\_status.asp](http://www.spiration.com/ibv_status.asp)

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