

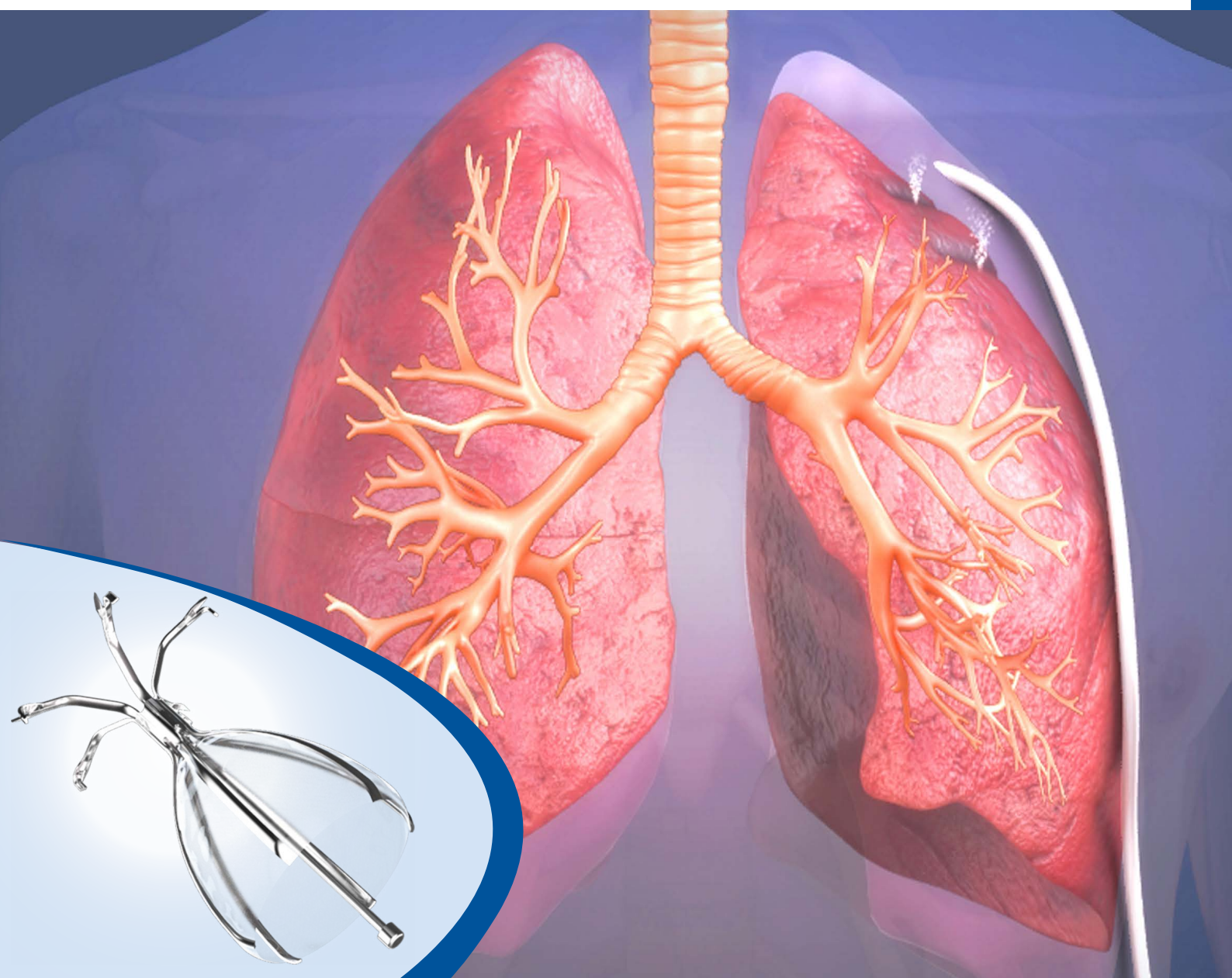
OLYMPUS[®]

Your Vision, Our Future

Spiration[®]
Valve System

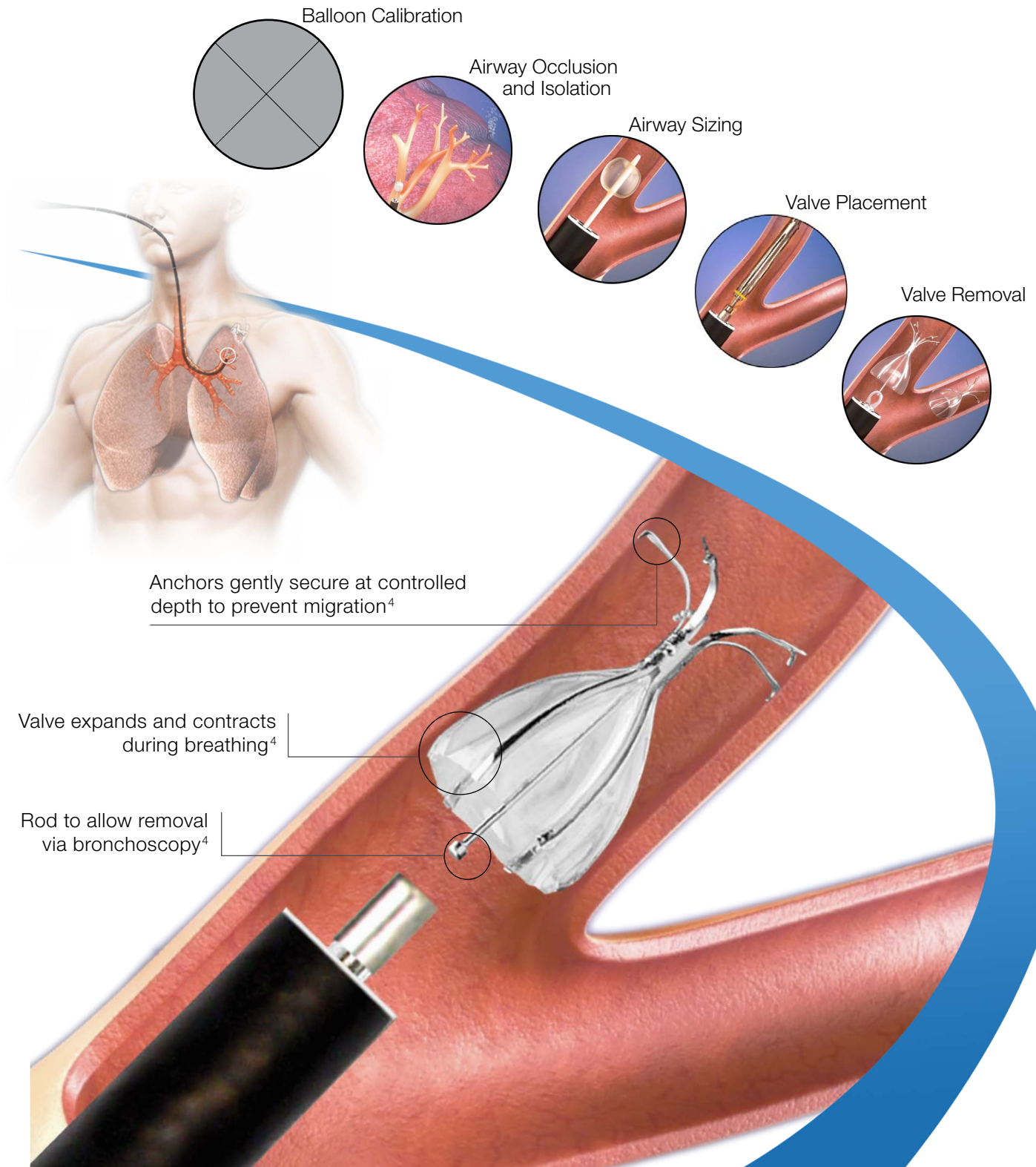
SPIRATION[®] VALVE SYSTEM

For the treatment of air leaks of the lung



A NOVEL INTERVENTIONAL APPROACH TO CONTROL PROLONGED AIR LEAKS

The Spiration Valve System is a minimally invasive device designed to limit air flow, which may accelerate resolution of an air leak.⁴



EARLY INTERVENTION FOR FASTER RESOLUTION OF AIR LEAKS

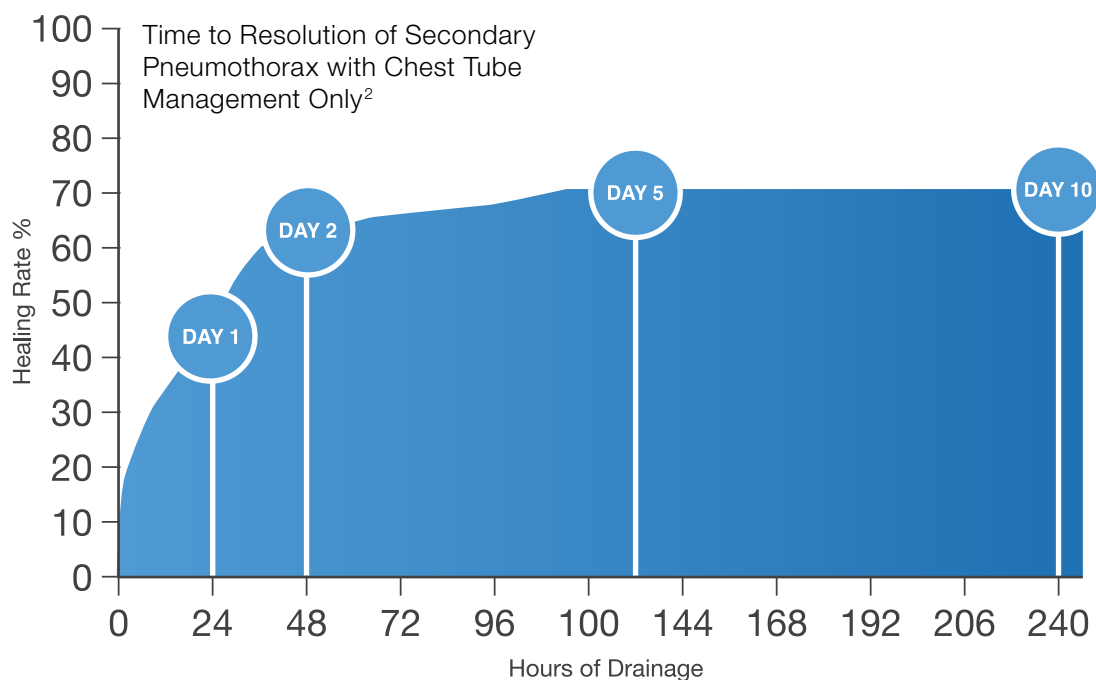
“It [Prolonged Air Leak] increases the frequency of inpatient and outpatient resources utilization, having a major impact on hospital costs.”¹

“Patients with Prolonged Air Leaks demonstrated an increased rate of postoperative morbidity, such as empyema, fever and pneumonia.”¹

Alessandro Brunelli M.D.

“Considering their efficacy and the low incidence of complications, the early use of invasive procedures such as surgical pleurectomy, after 48 hours of persistent gas leaking, seems justified. Shorter in-patient care and lower recurrence rates may result.”²

Ronald Andreas Schoenenberger, M.D.



“...if there was an airleak on postoperative day 4, there was a good chance (83%) that it would not seal by postoperative day 7.”³

“Any technology that helps to increase our ability to treat alveolar pleural fistulas or air leaks in a scientific, objective manner has enormous clinical as well as cost-saving potential.”⁵

Robert J. Cerfolio, M.D.

Author conclusions pertain to the treatment of air leaks and do not necessarily constitute an endorsement of the Spiration Valve System.

¹Brunelli et al. Predictors of prolonged air leak after pulmonary lobectomy. Ann Thorac Surg 2004; 77:1205-1210

²Schoenenberger RA et al. Timing of Invasive Procedures in Therapy for Primary and Secondary Spontaneous Pneumothorax. Arch Surg, Vol 126, June 1991


³Cerfolio RJ et al. A Prospective Algorithm for the Management of Air Leaks After Pulmonary Resection. Ann Thorac Surg 1998; 66: 1726-1730

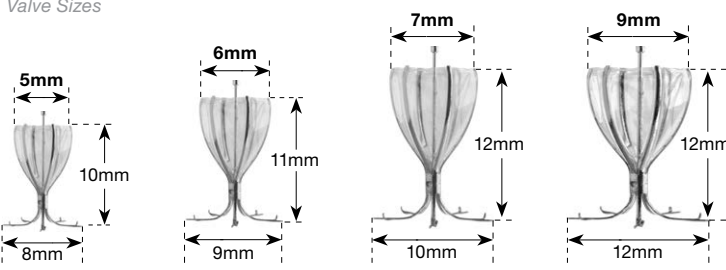

⁴Instructions for Use, Humanitarian Device Use for the control of air leaks, Spiration Valve System



⁵Cerfolio RJ et al. The Benefits of Continuous and Digital Air Leak Assessment After Elective Pulmonary Resection: A Prospective Study. Ann Thorac Surg 2008; 86: 396-401

THE SPIRATION VALVE SYSTEM

A device placed in the lung airway intended to treat severely diseased lung in patients with heterogeneous emphysema and evidence or markers of low collateral ventilation such as complete fissures, or damaged lung resulting in air leaks, by limiting airflow to selected areas.

 Spiration Valve System Deployment Catheter				
Model Name	Article Number	Catheter Working Length	Bronchoscope Channel Inner Diameter	Number Required per Procedure
IBV-C26N	N5381300	1020mm	2.6mm or greater	1

 Valve Sizes		 Cartridge		
Model Name	Article Number	Valve Size	Cartridge Color	Valves Required per Procedure
IBV-V5	N3495330	5mm	Blue	Determined by number of target locations
IBV-V6	N3495430	6mm	Yellow	
IBV-V7	N3495530	7mm	Green	
IBV-V9	N5381200	9mm	Grey	

 Gauge Hole		 Glass Syringe		
Model Name	Article Number	Gauge Hole	Glass Syringe	Number Required per Procedure
IBV-SK	N3495630	Sized for appropriate valve selection	500 microliters	1

Required ancillary equipment needed for each procedure

- Flexible bronchoscope with a working channel inner diameter of 2.6mm or greater
- Olympus balloon catheter B5-2C
- Bronchoscopy forceps appropriate for valve removal
- Sterile Luer-lock 3-way stop-cock
 - Important:** Luer-lock must have tight threads to provide the necessary "lock"
- Standard 10cc sterile syringe with Luer-lock for use in preparing the balloon catheter
- Sterile saline



Copyright © 2015 Spiration, Inc. d/b/a Olympus Respiratory America
ARTG Identifiers: 188455, 182553, 181950

WAND Reference Nos: 110725-WAND-6BJ53E, 110505-WAND-6B1TDA, 110509-WAND-6B2O34



Manufactured by
OLYMPUS RESPIRATORY AMERICA
6675 185th Ave NE, Redmond, Washington 98052 USA

Distributed by
OLYMPUS EUROPA SE & CO. KG
Wendenstrasse 14-18, 20097 Hamburg, Germany

KEYMED LTD.

KeyMed House, Stock Road, Southend-on-Sea, Essex, SS2 5QH, UK

OLYMPUS AUSTRALIA PTY. LTD.

3 Acacia Place, Notting Hill, VIC 3168 Australia