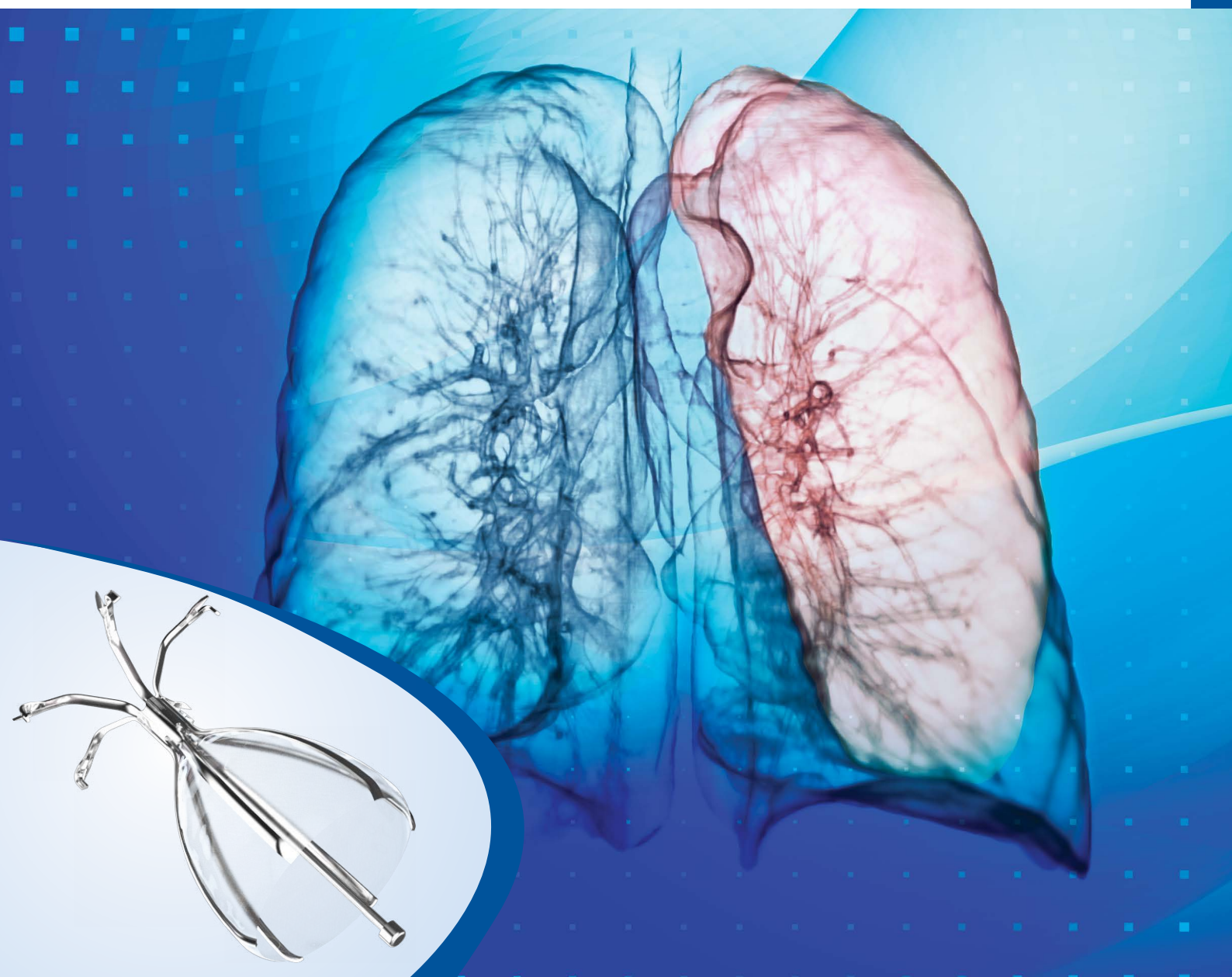


OLYMPUS[®]

Your Vision, Our Future

Spiration[®]
Valve System

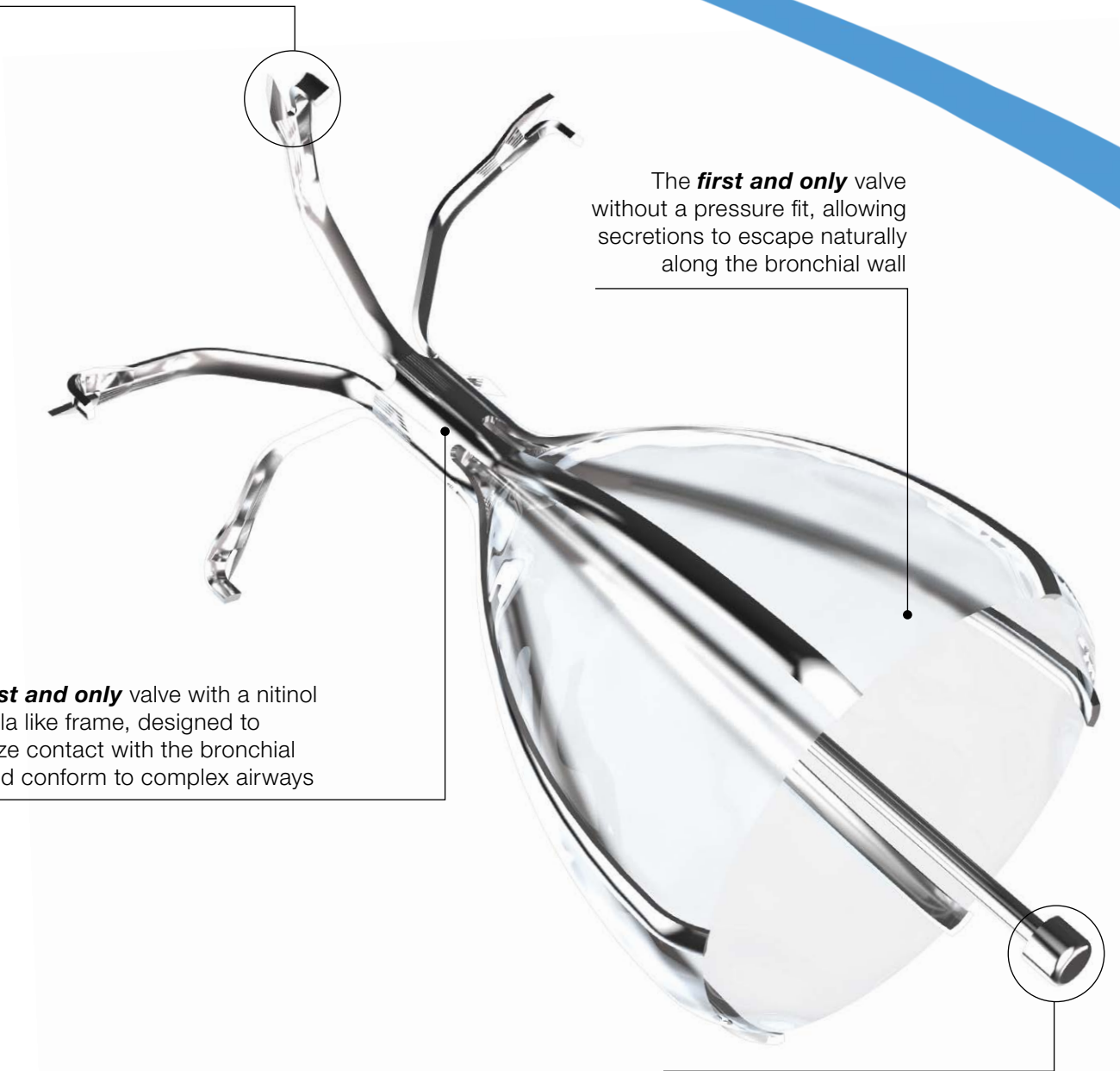
SPIRATION[®] VALVE SYSTEM
For the treatment of emphysema



A NOVEL BRONCHIAL VALVE SYSTEM TO TREAT EMPHYSEMA

A state-of-the-art design for complex airways.

The **first and only** valve with anchors for 0% migration and expectoration^{1, 2, 3}



The **first and only** valve without a pressure fit, allowing secretions to escape naturally along the bronchial wall

The **first and only** valve with a nitinol umbrella like frame, designed to minimize contact with the bronchial wall and conform to complex airways

The **first and only** valve with a center rod to facilitate removal

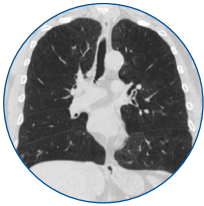
¹Sterman. Respiration 2010;79:222-223.

²Ninane. Eur Respir J 2012; 39:1319-1325.

³Spiration IDE Annual Safety Report 2010.

MINIMALLY INVASIVE TREATMENT FOR EMPHYSEMA

The Spiration Valve System procedure is considered minimally invasive and can be performed through a flexible bronchoscope.



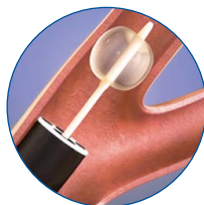
Patient Selection & Treatment Approach

- Bronchial valve treatment with complete occlusion of a single lobe is a promising treatment for selected patients with severe emphysema.^{6,7}
- Target lobe will have severe, highly heterogenous emphysema with complete fissures.^{4,5,6}



Balloon Calibration

Prior to the procedure, a balloon is calibrated to size the airways.



Airway Sizing

The calibrated balloon is used to determine the appropriate valve size for placement.



Valve Placement

Multiple valves are placed to occlude all the airways leading to the targeted lobe and enable atelectasis or significant lobar reduction.



Lobar Volume Reduction

Significant lobar reduction can relieve hyperinflation, enable healthier tissue to expand, and make breathing easier.⁶

⁴Sciurba. NEJM 2010; 363:1233-1244.


⁵Springmeyer. Thorac Surg Clin 2009; 19(2):247-253.

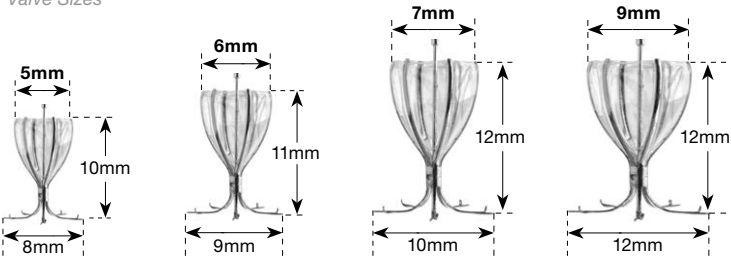

⁶Eberhardt. CHEST 2012; 142(4): 900-908.


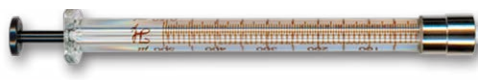
⁷Wood. J Bronchol Intervent Pulmonol 2014; 21(4): 288-297.

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.

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

<i>Valve Sizes</i>		<i>Cartridge</i>		
				
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	

<i>Gauge Hole</i>		<i>Glass Syringe</i>		
				
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



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



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