PleurX(TM) Catheter System Receives FDA 510(k) Clearance for Specific Non-Malignant Recurrent Pleural Effusions

Indication for Congestive Heart Failure on Display at the 2017 Society of Thoracic Surgeons (STS) Meeting

PR Newswire

FRANKLIN LAKES, N.J., Jan. 23, 2017 PRNewswire/ -- BD (Becton, Dickinson and Company) (NYSE: BDX), a leading global medical technology company, today announced its PleurX(TM) catheter system received U.S. Food and Drug Administration (FDA) 510(k) clearance for the use in specific non-malignant recurrent pleural effusions etiologies, including congestive heart failure, during the 53rd Annual Society of Thoracic Surgeons (STS) Meeting taking place Jan. 21-25 at the George R. Brown Convention Center in Houston, Texas.

A pleural effusion is a collection of fluid that accumulates in the pleural cavity that surrounds the lungs, leaving patients short of breath and affecting their quality of life. When this occurs, the PleurX catheter system provides patients with the option to drain pleural fluid in the comfort of their homes, which can help avoid the need for multiple hospital visits for thoracentesis procedures. The PleurX catheter system was initially approved in 1997 for managing malignant and recurrent pleural effusions. With the indication, the system is commercially available for patients suffering from certain non-malignant recurrent pleural effusion etiologies, including congestive heart failure and cardiogenic effusions.

Dr. David Sternberg, Beaumont Hospital, Farmington Hills, MI states, "The benefits of the PleurX catheter system when used for congestive heart failure patients with recurrent pleural effusions include the ability to drain at home and the option to be performed as an outpatient procedure, this may lead to less visits to the office and hospital and a shorter length of stay."

"This indication of the PleurX catheter system means BD can provide patients who suffer from recurrent pleural effusions due to congestive heart failure and other non-malignant recurrent pleural effusion etiologies with an option to manage their symptoms from the comfort of their home," said Jim Leitl, worldwide vice president and general manager for Infection Prevention, V. Mueller and Interventional Specialties at BD. "The system helps patients take control of their therapy by enabling them to manage fluid from pleural effusions outside of the hospital. Patients now have the option to potentially avoid the mental and physical toll of undergoing an additional hospital procedure."

"Our research found that the Pleurx catheter provided palliation of congestive heart failure patients' pleural effusions and freedom from re-intervention equal to that of talc pleurodesis using thoracoscopy while resulting in a shorter mean length of hospital stay," states Dr. Richard K. Freeman, Regional Chief Medical Officer, St Vincent Indianapolis. "Lower rates of operative morbidity and readmission related to the pleural effusion were also seen in the Pleurx catheter treatment group."

For more information on the PleurX catheter system visit the BD booth #147 during the 2017 Society of Thoracic Surgeons (STS) Meeting or go to bd.com/pleurx.

About BD

BD is a global medical technology company that is *advancing the world of health* by improving medical discovery, diagnostics and the delivery of care. BD leads in patient and health care worker safety and the technologies that enable medical research and clinical laboratories. The company provides innovative solutions that help advance medical research and genomics, enhance the diagnosis of infectious disease and cancer, improve medication management, promote infection prevention, equip surgical and interventional procedures, and support the management of diabetes. The company partners with organizations around the world to address some of the most challenging global health issues. BD has more than 40,000 associates across 50 countries who work in close collaboration with customers and partners to help enhance outcomes, lower health care delivery costs, increase efficiencies, improve health care safety and expand access to health. For more information on BD, please visit bd.com.

Contacts:

Matt Coppola Monique N. Dolecki

BD Public Relations BD Investor Relations

201.847.7370 201.847.5378

To view the original version on PR Newswire, visit http://www.prnewswire.com/news-releases/pleurx-catheter-system-receives-fda-510k-clearance-for-specific-non-malignant-recurrent-pleural-effusions-300394438.html

SOURCE BD (Becton, Dickinson and Company)

 $\underline{\text{https://news.bd.com/2017-01-23-PleurX-TM-Catheter-System-Receives-FDA-510-k-Clearance-for-Specific-Non-Malignant-Recurrent-Pleural-Effusions-1}$