CareFusion Receives Two 510(K) Clearances for Spine Products

FRANKLIN LAKES, N.J., Dec. 10, 2015 /PRNewswire/ – CareFusion, a BD company (NYSE:BDX), today announced the U.S. Food and Drug Administration (FDA) has cleared two 510(k)s for its spine augmentation devices.

The new 13-gauge AVA*max*® Vertebral Balloon system expands the company's offerings in devices to treat vertebral compression fractures. The balloon fits down a 13-gauge cannula, which has a cross-sectional area that is 37 percent smaller than the 11-gauge cannula and 50 percent smaller than the 10-gauge cannula. The smaller size creates a smaller access point, resulting in less trauma than larger cannulas. This will be the smallest straight-line vertebral balloon in the industry to date, enabling vertebral augmentation higher in the spine than with current offerings. The 13-gauge balloon will be offered in 10mm, 15mm and 20mm lengths.

The new 11-gauge AVA*flex*® Vertebral Balloon System will enable targeted balloon placement across the midline of the vertebral body through a unipedicular, lateral approach, but higher in the spine through a smaller cannula than current products. The AVA*flex* needle then allows targeted cement placement for an optimal fill. Once commercially available, the 11-gauge AVA*flex* balloon will be the smallest curved balloon in the industry and will also have the benefits of a smaller access point and less trauma to the patient. The 11-gauge AVA*flex* will be available in 15mm, 20mm and 30mm lengths.

"We are committed to investing in research and development to create new innovations that benefit patients and providers," said Jim Leitl, worldwide vice president and general manager of Infection Prevention, V. Mueller and Interventional Specialties for BD. "We are proud to offer a wide variety of minimally invasive vertebral augmentation devices for providers to choose the right treatment for their patients."

CareFusion expects a full commercial launch within a year. With this launch, CareFusion will maintain the most comprehensive portfolio of vertebral balloon products in the industry.

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, optimize respiratory care 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 45,000 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.

About CareFusion

CareFusion, a BD company, serves the health care industry with products and services that help hospitals measurably improve the safety and quality of care. The company develops industry-leading technologies including Alaris® infusion pumps and IV sets, MaxPlus® and MaxZero™ IV connectors and sets, Pyxis® automated dispensing and patient identification systems, AVEA®, LTV® series and AirLife® ventilation and respiratory products, ChloraPrep® products, MedMined services for data mining surveillance, V. Mueller® surgical instruments, and an extensive line of products that support interventional medicine. For more information please visit www.carefusion.com.

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