BD Receives FDA Clearance for a Novel Infusion Set with BD FlowSmart™ Technology to Enhance the Use of Insulin Pumps

Unique Side-Ported Catheter Designed to Offer Consistent Insulin Delivery and Fewer Flow Interruptions including Silent Occlusions
Infusion Set Developed in Collaboration with JDRF and Helmsley Charitable Trust

FRANKLIN LAKES, N.J., May 13, 2015 – BD Medical, a segment of leading global medical technology company BD (Becton, Dickinson and Company) (NYSE: BDX), announced today it has received 510(k) clearance from the U.S. Food and Drug Administration for a new insulin infusion set with BD FlowSmart™ technology. Insulin infusion sets connect the insulin pump to the body. The new product is BD's first within the diabetes infusion set category. BD FlowSmart features a unique side-ported catheter designed to improve insulin flow, potentially reducing the number of flow interruptions – defined as a continuous rise in pressure lasting at least 30 minutes. Without triggering an occlusion alarm, these events are known as silent occlusions, which could lead to unexplained hyperglycemia in some patients[i,ii]. This infusion set also features the smallest insertion needle, designed to reduce insertion pain and trauma. The product is expected to launch in the U.S. in fiscal year 2016.

BD collaborated with JDRF and The Leona M. and Harry B. Helmsley Charitable Trust on the research and development of the new infusion set to enhance the use of insulin pumps and improve the treatment of type 1 diabetes. Approximately two thirds of current insulin pump users have been shown to experience insulin flow interruptions that often go undetected by the pump occlusion alarm system.

"We believe that our new infusion set with BD FlowSmart technology is a ground-breaking innovation in diabetes technology that redefines the role of infusion sets in pump therapy by reducing the incidence of silent occlusions," said Kenneth Miller, Worldwide President, BD Medical-Diabetes Care. "We are especially pleased to achieve this milestone in collaboration with JDRF and the Helmsley Charitable Trust, and that our work together may help people better control their diabetes." "JDRF is excited to see the potential of BD's new infusion set for people with type 1 diabetes," said Derek Rapp, JDRF President & CEO. "Experiencing hyperglycemia for even a short period of time can lead to disastrous consequences such as ketoacidosis, and over long periods of time, concerns of serious complications are a major part of living with type 1 diabetes for many people. Having the assurance of this new technology in the arsenal of tools to help relieve the daily burden of type 1 diabetes is very encouraging. It's a privilege to work with such dedicated organizations like the Helmsley Charitable Trust and BD in helping to change the understanding and treatment of this disease."

"Now more than ever before, we believe that philanthropy is uniquely positioned to partner with industry to help incentivize and catalyze the development of new therapies and treatments for people with type 1 diabetes," said David Panzirer, trustee of the Helmsley Charitable Trust. "We are thrilled that, together with JDRF, our support for BD has helped move this important infusion technology from the early conceptual stages to an FDA-approved device that can have a real, tangible impact on those living with type 1 diabetes every day."

In a previously presented head-to-head clinical study with a leading infusion set, subjects using the infusion set with BD FlowSmart technology had significantly fewer flow interruptions and less time spent with interrupted flow.[ii] Three studies featuring the new infusion set with BD FlowSmart technology will be presented during the American Diabetes Association's annual meeting in Boston from June 5-9, 2015.

The infusion set with BD FlowSmart technology received approval for sale in Canada (January 2015) and United States (April 2015). An application has been submitted for CE marking and a response is anticipated from the Notified Body in May 2015.

Product availability is expected in fiscal year 2016. To register for more information, please visit www.bd.com/infusionset.

About BD

BD is one of the largest global medical technology companies in the world and is advancing the world of health by improving medical discovery, diagnostics and the delivery of care. The company supports the heroes on the frontlines of health care by developing innovative technology, services and solutions that help advance both clinical therapy for patients and clinical process for health care providers. BD and its 65,000 employees have a passion and commitment to help enhance the safety and efficiency of clinicians' care delivery process, enable laboratory scientists to accurately detect disease and advance researchers' capabilities to develop the next generation of diagnostics and therapeutics. BD has a presence in virtually every country and partners with organizations around the world to address some of the most challenging global health issues. By working in close collaboration with customers, BD can help enhance outcomes, lower costs, increase efficiencies, improve safety and expand access to health care. For more information on BD, please visit bd.com

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[i] Bolick, Natasha, et al. "Reduction of Silent Occlusion Occurrence During Continuous Subcutaneous Insulin Infusion." ATTD. Paris, France, 2015.

ii For the presentation at ATTD: Gibney M, et al. Continuous Subcutaneous Insulin Infusion (CSII) sets – Reduced flow interruptions with a novel investigational catheter infusion set. Diab Tech Ther 2015 (Suppl 1);17:A-8

[iii] van Bon A, et al. Insulin glulisine compared to insulin aspart and to insulin lispro administered by continuous subcutaneous insulin infusion in patients with type 1 diabetes: A randomized controlled trial. Diab Tech Ther 2011;13(6):607-614

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