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BD Launches Ergonomic Pen Needle Technology to Help Optimize Injection Technique

BD Nano™ Second Generation Pen Needle Receives 510(k) Clearance from U.S. Food and Drug Administration

FRANKLIN LAKES, N.J., Jan. 24, 2019 /PRNewswire/ -- BD (Becton, Dickinson and Company) (NYSE: BDX), a leading global medical technology company, announced the U.S. Food and Drug Administration 510(k) clearance of its second generation BD Nano™ pen needle, designed for more reliable subcutaneous injection depth.

BD Nano™ 2nd gen pen needles offer people who inject diabetes medications a more reliable subcutaneous delivery of their medication, designed to help people better manage their diabetes.¹ Recent updates to the 2019 American Diabetes Association (ADA) [Standards of Care](#) highlight the importance of proper injection technique as part of good diabetes management.² Proper injection technique is critical to insulin's consistent absorption and there are several factors that can inhibit predictable insulin uptake, including accidental intramuscular injections, which can be caused by greater than required injection force.

BD Nano 2nd gen pen needles help mitigate the risks resulting from user injection force variability through its contoured needle base and compensate for variable injection forces by first concentrating, then distributing pressure closely around the injection site (to support more reliable 4 mm target injection depth compared to other 4mm pen needles^{1,3}). The new design has demonstrated more reliable subcutaneous injection depth resulting in up to an 8-fold reduction in calculated intramuscular injection risk.^{1,4} Additionally, the new ergonomic design of BD Nano 2nd gen makes it easier to use, from attachment to disposal, compared to other pen needles, and results in a more comfortable injection experience.^{5,6}

"The launch of BD Nano 2nd gen pen needles reinforces BD's commitment to providing the most advanced solutions possible for people with diabetes to help achieve better clinical management of insulin use," said Stanislav Glezer, MD, MBA, global vice president of Medical Affairs for BD. "In addition to the added clinical benefits the latest BD innovation brings, the new ergonomic pen needle features can help people feel more comfortable with their injection experience."

This latest advancement to the BD Nano portfolio includes all the benefits its predecessor pen needle has, including BD's 32G x 4 mm pen needle with 5-bevel PentaPoint™ comfort, which has been clinically shown to enter the skin more easily than other 3-bevel needles, providing a smoother and more comfortable injection, and extra thin wall EasyFlow™ technology that increases the medication flow rate, making injections easier.^{7,8} FDA 510(k)

clearance will enable BD Nano 2nd gen pen needles to be commercially available in mid-2019.

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 healthcare by developing innovative technology, services and solutions that help advance both clinical therapy for patients and clinical process for healthcare 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 healthcare. In 2017, BD welcomed C. R. Bard and its products into the BD family. For more information on BD, please visit bd.com.

¹Results from a BD conducted, non-blinded, randomized, study measuring the depth of 1200, 90° injections comparing to several brands of 4 mm posted-hub pen needles across several pre-specified target injection force ranges; test performed on swine.

²American Diabetes Association. 9. Pharmacologic approaches to glycemic treatment: Standards of Medical Care in Diabetes—2019. *Diabetes Care* 2019;42(Supp. 1):S90-S102.

³(Target injection depth reliability defined as injection percentage within 4.0 mm to 4.5 mm inclusive).

⁴Demonstrated range between 2x-8x across recommended injection sites: Abdomen, thigh, arm, buttock, pooled across gender and BMI.

⁵Results from a BD-sponsored, non-blinded, randomized, home-use, 2-period crossover, patient preference study with patients currently using 32G pen needles. Total of 226 paid participants; superiority was established with each subgroup.

⁶Results from a BD-sponsored, non-blinded, randomized, home-use, 2-period crossover, patient preference study comparing 32G pen needles. Total of 226 paid participants. Superiority/preference not demonstrated with some subgroups.

⁷Hirsch L, Gibney M, Berube J, Manocchio J. The impact of a modified needle tip geometry on penetration force as well as acceptability, preference and perceived pain in subjects with diabetes, *J Diab Sci Tech* 2012;6(2):328-35.

⁸Aronson R., et al. (2013). *Insulin pen needles. Effects of extra thin-wall needle technology on preference, confidence, and other patient ratings. Clinical Therapeutics, In Press, Corrected proof, Available online 20 June 2013.*

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