Dear Valued Customer,

September 7, 2016

**Important ISO 80369-3 Update: BD’s Concerns about the Proposed ENFit® Female and Low Dose Tip (LDT) Designs.**

This update is to inform you that on July 20, 2016, BD issued the below letter to GEDSA clearly outlining our ongoing concerns with the proposed ENFit® female design and Low Dose Tip (LDT) design for syringes. As we have openly communicated since May 2015, BD has concerns with the dose accuracy of the proposed ENFit female syringes, and BD has continued to evaluate available data and solicit opinions from leading clinical authorities on this important topic.

When filled at least halfway, the maximum hypodermic syringe performance variance¹ acceptable under ISO 7886-1 is +/-5% for syringes under 5 mL in size. For syringes 5 mL or greater in size the permitted variance when at least half-filled is even tighter at +/-4%. The allowable variance increases incrementally when a syringe is less than half full, but only when a syringe is filled far less than halfway, under 20% in 1, 3, 5 or 10 mL syringes, does the standard allow a variance of +/-10% or more. Although a hypodermic syringe standard by name, ISO 7886-1 is the standard that oral/enteral syringe manufacturers have used for years, and clinicians have accepted as a standard of care.

In BD’s view, increasing the delivered drug variance and adding extra steps to the workflow are not in alignment with The National Coordinating Council for Medication Error Reporting and Prevention (NCCMERP) guidelines for prevention of medication errors and The Joint Commission’s mission to increase safety.

Because of the dosing accuracy issues, especially in neonates, and additional workflow requirements, **BD has serious concerns about the current ENFit female and LDT designs.**

As part of BD’s continued commitment to manufacture safe and reliable oral and enteral syringes, **we have clearly outlined our concerns with the ENFit female and LDT designs along with our selected path forward.**

Sincerely,

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Amardeep Singh Chahal  
Senior Business Director, Injection Systems  
BD Medication & Procedural Solutions

¹ More formally referred to in ISO 7886-1 as the "tolerance on graduated capacity."