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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.

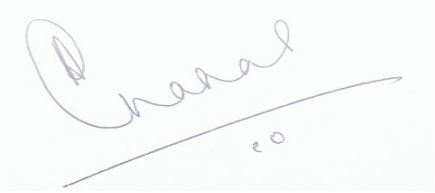
When filled at least halfway, the maximum hypodermic syringe performance variance[1] acceptable under ISO 7886-1 is +/-5% for syringes under 5 mL in size. For syringes 5 mL or greater in size the permitted variance when at least half-filled is even tighter at +/-4%. The allowable variance increases incrementally 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,



Amardeep Singh Chahal
Senior Business Director, Injection Systems,

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

BD Medication & Procedural Solutions

Thomas J. Hancock, Executive Director
Global Enteral Device Supplier Association
692 N. High St., Suite 304
Columbus, OH 43215

July 20, 2016

Dear Mr. Hancock:

BD stays committed to provide safe and reliable oral and enteral solutions that are safe for all patient populations and have continued to evaluate available data and solicit opinions from leading clinical authorities and device experts on this important topic. Based on the information available, BD is concerned with safety risks posed by the female ENFit® syringe and Low Dose Tip (LDT) designs. We outline some of these risks below and would like to reinforce our commitment to arrive at the best solution for patients—one that prevents misconnections and delivers reliably accurate doses to the most vulnerable patients.

BD is aligned with GEDSA on the critical mission to improve patient safety and to ensure a 'careful and methodical' adoption of a new connector; however, clinicians and researchers have found dosing inaccuracies with the proposed female ENFit and Low Dose Tip (LDT) syringe designs. In BD's opinion, both of these proposed designs fail to meet the accepted syringe dose accuracy standards on which clinicians around the world have come to rely.

Dosing Inaccuracy Concerns

1. The existing standard for syringe accuracy (ISO 7886-1) has been in place since 1993 and establishes the maximum acceptable performance variance of +/- 5% for syringes.
    - According to the performance data summary and clinical feedback that have been made public by GEDSA, the ENFit female syringe design performs at +/- 20% dose accuracy and the Low Dose Tip (LDT) design performs at +/- 10% dose accuracy[2]. Neither meets the standard of ISO 7886-1.
2. Based on the information available to BD, the new female ENFit design does not perform to the level of other syringes already on the market. The ENFit LDT variance of +/- 10% is not equal to the performance of current oral and enteral syringes in use today, including syringes manufactured by BD.
3. Low dose accuracy is imperative, especially for neonates, and potentially for other patient populations including those patients weighing less than 10 kg, critically ill or immuno-compromised patients and the elderly. As they are currently proposed, GEDSA's ENFit female syringe and LDT can put vulnerable patient populations in harm's way.

[2] GEDSA Presentation: "Reducing the Risk of Medical Device Tubing Misconnections, ENFit® Low Dose Tip Syringe Review, Q2 2016"

Workflow Concerns

A switch to the new female ENFit syringe will require a new standard of practice. In BD's opinion, this change increases the potential for human error and necessitates additional training for both pharmacists and clinicians administering patient care.

- Nurses administering medication using the LDT may have to manipulate the syringe to obtain the appropriate dosage, which involves manual wiping of fluid[3] from the syringe. This presents a risk of human error in dosage.
- Drawing up medication using female ENFit or LDT syringes requires extra steps like using straws to obtain the claimed accuracy.

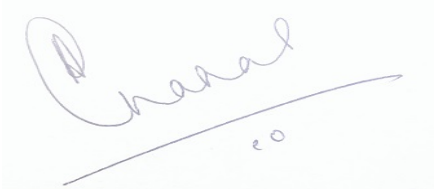
In BD's view, increasing the delivered drug variance and adding extra steps to the workflow is not in alignment with the NCCMERP guidelines for prevention of medication errors or The Joint Commission's mission and standards to increase safety.

A Path Forward

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.**

BD is currently pursuing a male enteral syringe design that complies with the ISO 80369-3 standard that will also meet the standard for dosage accuracy defined in ISO 7886-1. However, BD remains very open to **re-evaluating alternate solutions as long as they comply with the existing standards for dosage accuracy to ensure patient safety.**

Respectfully,



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

Bruce Culleton, MD, MBA
VP WW Medical Affairs
BD Medication and Procedural Solutions

CC: J. Martin

[3] GEDSA Presentation: "Reducing the Risk of Medical Device Tubing Misconnections, ENFit® Low Dose Tip Syringe Review, Q2 2016"