



Helping all people
live healthy lives

October 2015

Dear Valued Customer,

Important Update Regarding the Availability of ENFit™ Connectors

This letter is to provide an update on the status of the heightened concerns with the proposed ISO 80369-3 ENFit™ design, and to reinforce BD's continued commitment to manufacture safe and reliable oral and enteral syringes.

As a follow up to our May 2015 communication in which we identified the potential low dose medication risk with the new ENFit™ design, we are writing to let you know that at this time BD has decided not to launch the ENFit™ connectors in its current configuration (female syringe) given these potential safety implications.

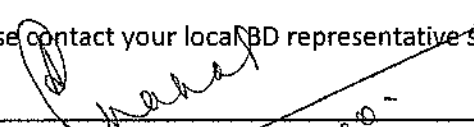
Using an ENFit™ connector with smaller syringe sizes, may result in inaccurate dosing for some NICU, PICU & Adult patient groups, leading to a potentially critical impact to patients receiving low dose medications.

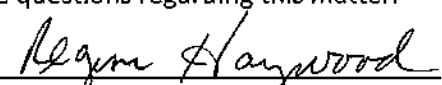
Over the past several months, BD has been working closely with the healthcare community to better understand these concerns and to share them with the broader industry. However, due to fundamental differences in the approach to delivering a safe ENFit™ solution that works for all patients groups, BD has withdrawn from the Global Enteral Device Suppliers Association (GEDSA), effective September 19, 2015.

BD will continue to supply the BD UniVia™ Oral/Enteral syringes to hospitals around the world. The BD UniVia™ Oral/Enteral syringes do not connect to Luer devices and comply with U.S. medical device regulations.

BD will continue to work with the clinical community and the International Organization for Standardization (ISO) to find a data driven solution not only to address the low dose concerns but also to ensure a safe and reliable syringe, while remaining within the upcoming ISO 80369-3 standard.

Please contact your local BD representative should you have questions regarding this matter.


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MSS0905-1 10/15