



Dear Valued BD Customer,

May 2015

Important Information Regarding the Industry Wide ENFit Connector

As you may be aware, the International Organization for Standardization (ISO) is in the process of finalizing part 3 of the ISO 80369 series entitled: *Small-bore connectors for liquids and gases in health care applications – Part 3: Connectors for enteral applications*. This standard specifies the dimensions and recommendations for the design and functional performance of small-bore connectors for enteral use. The design of the enteral connector has been designated as ENFit, by the Global Enteral Device Supplier Association (GEDSA).

Recently, there have been concerns expressed by some leading hospitals in the United States related to the use of the new industry wide ISO standard ENFit connector. A concern (particularly in the pediatric and neonatal population) is that using an ENFit connector may possibly result in inaccurate dosing using smaller syringe sizes.

As a global medical device manufacturer, BD is listening to these concerns and is actively working with the clinical community, ISO and GEDSA to gain further understanding and find clinically acceptable solutions within the ISO 80369-3 standard. BD recommends hospitals to make informed clinical decisions for patients receiving low dose medication prior to transitioning to the new ENFit connector design.

Until a solution to these low dose medication concerns is reached, BD will continue to supply the BD UniVia™ Oral/Enteral Non-Luer 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.

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

A handwritten signature in black ink, appearing to read 'Martin Jacobsen', written over a horizontal line.

Martin Jacobsen, M. Sc. (Econ.)
Senior Global Marketing Manager, WW Enteral

A handwritten signature in black ink, appearing to read 'Theresa Hermel-Davidock', written over a horizontal line. The date '5/26/2015' is written in small text below the signature.

Theresa Hermel-Davidock, PhD
Enteral Core Team Leader, WW R&D