Important Announcement Regarding ISO 80369-3 Connectors

Dear Valued Customer,

The purpose of this communication is to provide you with an update on BD’s intent to implement the new ISO 80369-3 standard for enteral connectors, contingent on final ISO approval. BD is committed to providing safe and reliable oral and enteral solutions that do not introduce new patient risks and still meet customer requirements.

As discussed in BD’s October 2015 letter, BD and the clinical community identified a dosing inaccuracy risk with the new, reverse gender “female” enteral syringe option in ISO 80369-3. Patients of all ages, NICU, PICU, or adult, receiving low dose medications are particularly at risk. Putting patient safety first, BD has decided to launch an ISO-compliant traditional “male” enteral syringe that prevents misconnections without introducing dosing inaccuracies or requiring workarounds that alter established clinical practice. In addition, this solution allows clinicians to use the same syringe type for all enteral patients, regardless of dosage.

BD is actively working with industry partners to ensure that a complete enteral ecosystem is available for the male solution. Initial ecosystem launch focus will be on the NICU patient group, and roll out to other patient groups will occur once the clinical community’s feeding tube concerns are addressed.

BD is committed to the prevention of misconnections and actively supports the ongoing worldwide patient safety initiatives dedicated to reducing tubing misconnections by serving as U.S. Co-Chair of the ISO 80369-3 committee and by participating globally in the development of this and other ISO safety standards. Our commitment to launching a safe and accurate system is indicative that BD is focused on doing what’s right.

To ensure continuity of care, the ISO standard anticipates a phased transition to the new design over a 5-year period. Until BD’s ISO 80369-3 products become available, BD will continue to supply BD UniVia™ Oral/Enteral syringes to hospitals around the world. The BD UniVia™ Oral/Enteral syringes do not misconnect to Luer devices (e.g., IV devices) and comply with applicable U.S. medical device regulations.

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

Sincerely,

Martin Jacobsen, M.Sc. (Econ.)
Senior Global Product Manager, WW Anesthesia & -Enteral

1 BD Communication http://www.bd.com/hypodermic/products/enteral/
2 Applicable law or regulations in your location may require a more accelerated transition.

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