



August 2016

Update on the new ENFit™ Enteral connection (ISO 80369-3) and its adoption by Vygon

Dear Valued Customer,

As the inventor of Nutrisafe2, the first safe enteral feeding system incompatible Luer and designed for neonates, Vygon knows how the safety in enteral therapy is important to patients and clinicians.

In July 2016, the International Standards Organization published the ISO 80369-3, which creates a standardized safety enteral feeding connection. This new connection, named ENFit™, prevents the likelihood of tubing misconnections (e.g. inject milk in the intravenous line) by its specific design.

Vygon, who has been involved in the creation of the ISO 80369-3 for years, is proud to **launch a complete product range integrating ENFit™ connectors, named Nutrifit®**, for adults and children. This Nutrifit® range proposes:

- administration sets for enteral nutrition pumps: from September 2015,
- syringes: from June 2016,
- feeding tubes and accessories: from September 2016.

However, while ENFit™ meets the needs for adults and children, ENFit™ syringes may result in inaccurate dosing errors particularly unacceptable in neonatology. **Therefore, Vygon decided to maintain its ISO 80369-1 compliant enteral feeding system, called Nutrisafe2, for neonates and newborns.** This Nutrisafe2 system provides the required accuracy for these tiniest patients and experiences 10 years of success in more than 30 countries.

Our decision was based on two main facts:

1. as indicated in the ISO 80369-3 – Annex A – § Subpopulation:

“Concerns have been raised about the possible risks of delivering inaccurate doses of medicines in certain clinical practices across high risk subpopulations (e.g. neonatal patients) if using a reversed connection system (female to male). [...] Laboratory testing also shows a mid-tolerance E1 connector pair in a female to male orientation displaces a mean average of 0,148 ml [...] of fluid.”

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2. A new syringe design, called Low Dose Tip (LDT) syringe, is currently proposed to address those concerns. But, according to laboratory testing ^(1,2), the results are inconclusive:

- by following the current practices, the accuracy of the LDT syringe is equivalent to ENFitTM ⁽¹⁾, so unacceptable for Neonatology.
- by following a new strict syringe protocol, the accuracy seems acceptable ⁽²⁾. But this protocol may lead to involuntary dosing errors due to human factors and chemical/microbial contamination risks of the dispenser and syringe preparation area.

So, in the aim to offer a safe and secure enteral feeding system for every patient, Vygon proposes:

- Nutrisafe2 for neonates and newborns
- Nutrifit[®] for adults and children,

as ENFitTM connectors and LDT syringe meet the adults and children requirements but not the neonatal requirements.

For further information do not hesitate to contact your Vygon representative or email questions@vygon.com

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(1) Analysis of "Report GEDSA low Dose Syringe Accuracy test, dated 31 January 2016, by STML", by SELECT, June 2016

(2) GEDSA ENFit[®] Low Dose Tip Review, Q2 2016

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