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Vygon has launched a comprehensive ENFit™ range and maintains Nutrisafe2 for neonates and newborns

Dear Valued Customer,

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

Vygon has been part of the ISO 80369-3 creation as an expert member of this ISO working group for more than 10 years and supports the effort to mitigate the misconnection risk. That's why Vygon is charter member of GEDSA and launches a large and comprehensive range of ENFit™ products. This Vygon's ENFit™ range is named "nutrifit™" and includes administration sets for pumps, feeding tubes, syringes and numerous accessories.

However, being a GEDSA member should not impede Vygon from understanding that the introduction of the ENFit™ design could create a clinical issue for neonatal patients due to the requested high level of accuracy. Indeed, the moat of ENFit™ connection (in the classic or Low Dose Tip configurations) can hide unexpected volume of medicine and lead to an overdosing risk. Several organizations have raised this issue:

1. The ISO 80369-3 standard – Annex A – § Subpopulation - indicates:
   "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."

2. On March 2016, the French Society of Neonatology (SFN) relayed this information of 0,148ml ENFit™ overdosing risk and recommends the use of a safe but accurate enteral feeding system to the French neonatologists.

3. On April 2017, the Institute for Patient Access (IfPA) posted an article on this issue : "This places the baby at risk for overdosing and adverse drug reactions" (http://allianceforpatientaccess.org/tubing-mix-ups-pose-new-dangers-for-infants/)

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4. On September 2017, the draft of ISO 20695, which proposed the inclusion of the ENFit™ Low Dose Tip (LDT) syringe, has been disapproved. One of the main reasons is that the LDT efficacy has not been fully proven and is questioned. The misconnection risk assessments, the dose accuracy performance testing and the usability studies of the LDT syringe must be reviewed.

5. On November 2017, National Coalition for Infant Health (NCfIH) issued a letter to Joint Commission regarding ENFit™ tubing safety concerns in NICU (http://www.infanthealth.org/blog/2017/10/ncfih-issues-letter-to-joint-commission-regarding-nicu-tubing-safety-concerns)

Because of this inaccuracy concerns with ENFit™, Vygon decided to go further than the ISO 80369-3 standard and provide Nutrisafe2, a safe enteral feeding system designed and dedicated for neonates and newborns. This system has more than 10 years of experience in neonatology and offers two main advantages:

- Compliant with ISO 80369-1, Nutrisafe2 was assessed to prevent misconnection risks with the other clinical applications (respiratory, I.V,…), according to the ISO 80369 general requirements.
- Small and Accurate, Nutrisafe2 ensures high accuracy of drug administration with very low volumes thanks to its compact design and dramatically reduces the overdosing risk when compared to ENFit™ or Low Dose Tip connections.

If you want further information, please visit the website: www.safe-enteral.com or contact your Vygon representative.

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