July 18, 2019

Vygon's Nutrisafe2® Continuation of Supply

Dear Valued Customers,

Vygon will continue to manufacture and sell the complete Nutrisafe2® Safe Enteral Feeding System without interruption and without ramp down.

As you may know, a press release was distributed Thursday, July 18th by GEDSA (Global Enteral Device Suppliers Association) on the ENFit® Connector Conversion Schedule for the U.S. This communication states that GEDSA member manufacturers have aligned to only produce ISO 80369-3 compliant devices with ENFit® connectors according to specific deadlines.[1] While Vygon continues to be a founding GEDSA member, we do not support this schedule, nor will we follow it.

While ISO 80369-3, also known as ENFit®, protects against misconnections which can occur from existing slip-fit legacy enteral feeding devices to non-enteral devices, an unintended consequence has been documented within ISO 80369-3 specifically related to the neonatal patient population. ENFit® introduces the risk of inadvertent fluid displacement (mean average of 0.148mL) which can lead to an overdose of enteral medication.[2] Additionally, the second draft of ISO 20695 removed the Low Dose Tip (LDT) ENFit® syringe from the normative requirements of the standard and further, changed its term from "Low Dose Tip" to "alternative enteral syringe tip" due to its inability to reliably demonstrate an increase in dose accuracy.[3]

Nutrisafe2® is not only FDA-cleared, but it is also compliant with the most rigorous international standards for non-interconnectability. Specifically, Nutrisafe2® complies with ISO 80369-1[4], which provides a framework for testing connectors of different medical applications against each other to ensure non-interconnectability and also establishes specific misconnection testing methods. ISO 80369-1 was recognized by the FDA on March 14, 2011, as noted on the FDA's Recognized Consensus Standards webpage.[5] Additionally in their guidance on September 7, 2018, the FDA recommends hospitals and clinicians use enteral devices with connectors that meet the ISO 80369-1 or ISO 80369-3 standard, or that are otherwise designed to reduce the risk of misconnections.[6] Testing has established Nutrisafe2® compliance with ISO 80369-1.

Vygon has expressed their concerns with the ENFit® and LDT ENFit® designs with GEDSA. GEDSA is and has always been aware despite our membership that we will continue to manufacture and sell Nutrisafe2®. The Nutrisafe2® Safe Enteral Feeding System has been in neonatal clinical use for over 14 years in more than 30 countries with zero reported misconnections and zero reported dosing inaccuracies. Vygon is proud to utilize our working knowledge and provide a product offering to ensure patients remain safe from misconnections with a high dosing accuracy. More and more NICUs trusts Nutrisafe2® to feed their neonatal patients worldwide.

If you have any questions, please do not hesitate to contact your local representative or myself.

Best Regards,

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[1] Available at http://stayconnected.org/wp-content/uploads/2019/07/ENFit-Connector-Conversion-Schedule-for-US.pdf

[2] ISO 80369-3: 2016; Available at https://www.iso.org/standard/50731.html

[3] ISO/DIS 20695.2; Available at https://www.iso.org/standard/68853.html

[4] ISO 80369-1:2010; Available at https://www.iso.org/standard/45976.html

[5] Available at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfstandards/results.cfm

[6] FDA. (2018). The FDA Encourages Use of Enteral Device Connectors that Reduce Risk of Misconnection and Patient Injury. Retrieved from https://www.fda.gov/downloads/MedicalDevices/ResourcesforYou/Industry/UCM619782.pdf