



NEONATOLOGY
Enteral nutrition



nutrisafe²

The safe enteral feeding
system for Neonatology

Compliant with
ISO 80369-1



Value Life

ISO standards

ISO 80369-3 - Annex A - THE CONCERN

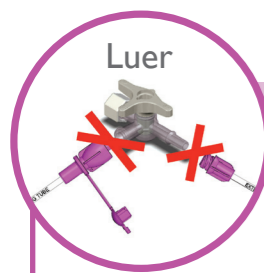
- “Concerns have been raised about the possible risks of delivering accurate doses of medicines in certain clinical practices across high risk subpopulations (e.g. neonatal patients) when using a reversed connection system (female to male). This orientation may introduce inadvertent displacement of fluid ...”⁽¹⁾
- “Laboratory testing also shows a mid tolerance E1 [ENFit™] connector pair in a female to male orientation displaces a mean average of 0.148ml...”⁽¹⁾

ISO 20695 - Annexes A & K - LOW DOSE TIP SYRINGE (here called "alternative enteral syringe tip")

- The ISO committee "has decided to propose [it] for information only as test results lead to contradictory conclusions on dose accuracy with this alternative enteral syringe tip."⁽²⁾
- "The design of this alternative enteral syringe tip may not ensure that the dose accuracy for enteral syringes is met; specific user information and education should accompany this alternative enteral syringe"⁽²⁾

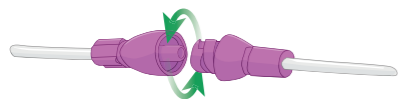
To provide the best possible care and safety for neonatal patients, Vygon will continue to provide the **nutrisafe2** system, which is compliant with **ISO 80369-1**.

In Neonatology, think **SAFE, SMALL & ACCURATE!**



SAFE...

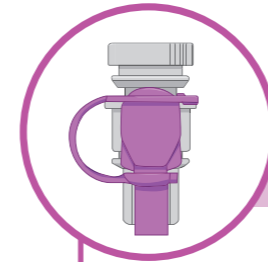
Specially designed for neonatal patients, **nutrisafe2** is a unique safe enteral feeding system incompatible with Luer and other small-bore connectors in accordance with ISO 80369-1 requirements. The risk of misconnection is minimized and the patient safety is increased.



The lockable system provides additional security. Accidental disconnection is practically impossible, ensuring precious nutrients are received.

(1) Extract of ISO 80369-3 : 2016

(2) Extract of ISO/DIS 20695.2:2018 (revision of EN1615/EN1618)



...SMALL...

Thanks to the compact design of **nutrisafe2**, the size, weight and deadspace of the connectors are minimized.



The tube displacement and kinking are therefore reduced.

nutrisafe2® reduces the deadspace by 70% compared to ENFit®

...and ACCURATE

The compact design of **nutrisafe2** connections ensures accurate delivery of small volumes of drugs, especially for critical drugs such as morphine, digoxin, caffeine citrate, iron, methadone, etc :

	nutrisafe2 (ISO 80369-1)	ENFit™ (ISO 80369-3)	Low Dose Tip (LDT)
Overdosing risk by Computational Fluid Dynamics simulation ^(3;4)	0.029ml	0.120ml*	0.120ml

*In ISO 80369-3:2016, the published results of laboratory testing show a 0.148ml volume displacement for ENFit™



Illustration of overdosing due to the feeding tube connection

www.safe-enteral.com

(3) Numerical measurements with Solidworks software - January 2014 - Internal data

(4) Study on the over-dosing risk of the « ENFit Low Dose Tip » syringe during its use, March 2018, Vygon & Andheo

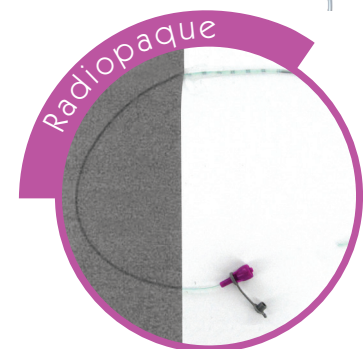
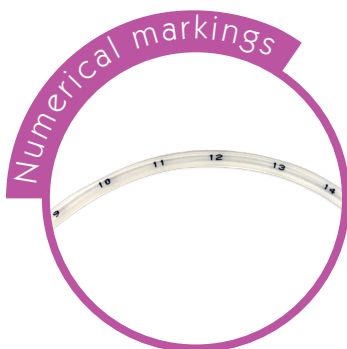
Worldwide proven system

>14 YEARS OF EXPERIENCE IN NEONATOLOGY !

- Created in 2005, **nutrisafe2** is the first enteral feeding system totally incompatible with Luer and specially designed for premature babies.
- No reported misconnection
- Satisfied customers from more than 30 countries

The Complete Solution for neonates

Syringes	0.5ml / 1ml / 2.5ml / 5ml / 10ml / 20ml / 35ml / 60 ml. Single-use and reusable Also amber-colored syringes available for UV reduction: 1ml / 2.5ml / 5ml / 10 ml
Feeding tubes	Available in PVC, polyurethane and silicone in a variety of lengths and sizes.
Extension lines	Available in a variety of lengths and sizes.
Sampling straws	Available in different sizes and types, to fill syringes with breast milk, formula or medication.
Accessories	Vented caps for syringe Y connector Male-male connector Oral medicine bottle caps for sampling ...
Syringe pump	Specifically designed for enteral feeding, this easy-to-use syringe pump is capable of more than 6 hours of continuous work and is compatible with all types of nutrisafe2 syringes (A-VY, C-GON, V-PY).



OBSTETRICS NEONATOLOGY ENTERAL

For further information, please contact: questions@vygon.com

The specifications given in this brochure are for information only and are not, under any circumstances, of a contractual nature.

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