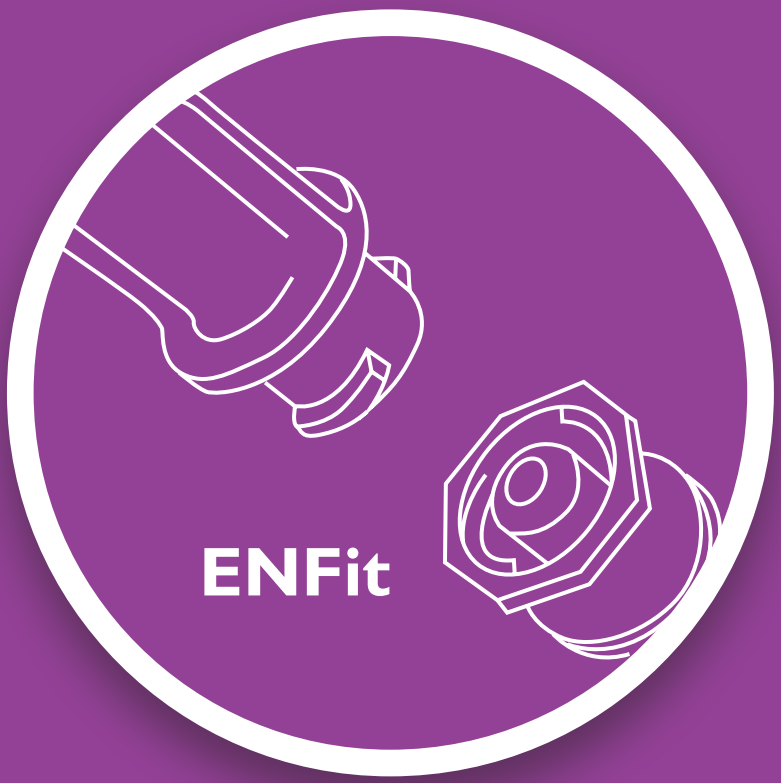
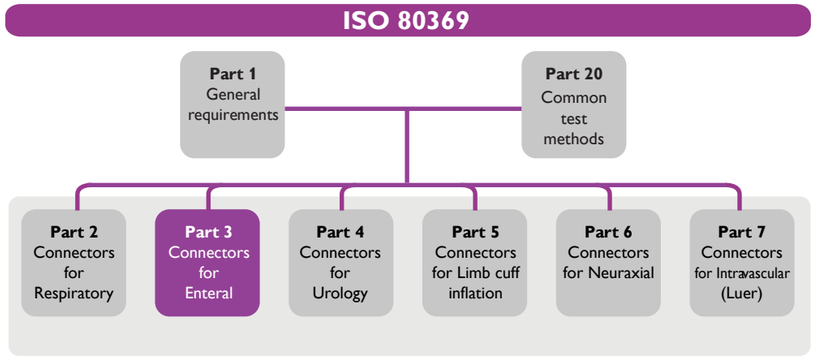
The New ISO Standard for enteral nutrition: ISO 80369-3

F.A.Q
for Neonatal Specialists



• What is ISO 80369?

A patient may be connected, via catheters or tubes, to several delivery systems to receive parenteral medication, oxygen, enteral nutrition, anesthesia, etc.
The ISO 80369 series of Standards aim to avoid misconnection between two unrelated delivery systems (e.g. enteral syringe connected to an IV catheter), which can cause patient injuries or deaths. To do so, ISO 80369 created unique international Standard designs of connectors for each application (Respiratory, Enteral, Urology…), which are non-interconnectable.



CONNECTORS' DESIGNS: dimensions and functional requirements

• What is ISO 80369-3?

ISO 80369-3 is part 3 of ISO 80369 series, which is dedicated to enteral applications. Part 3 describes all the dimensions, shape and functional requirements of the new proposed enteral standard connector, called ENFit™.

• What is "ENFit™"?

ENFit is the trade name of the new enteral standard connector compliant with ISO 80369-3, in the female to male orientation.

• Is it mandatory to implement the ISO 80369-3 (ENFit™) in my hospital?

No, an ISO standard is not a law, but an international recommendation. "The important distinction between standards and legislation is that standards are voluntary, whereas legislation is mandatory.
When regulatory authorities use standards as a basis for legislation, only then do they become mandatory, and then only within the jurisdiction covered by the legislation. […]" (1)

• Is ENFit™ suitable for the NICU environment?

"As written in the ISO 80369-3, the volume of the displacement when making a connection matters. In a 500 g newborn infant, enteral drugs are often prescribed in volumes as small as 0.1 ml or even 0.01 ml."(2)
"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 originally contained within […] " the syringe tip. (2)

The mission of Global Enteral Device Supplier Association (GEDSA) is to help health facilities to understand the new ISO80369 standard, prepare for this change and implement ENFit TM connectors.
Vygon is a charter member of GEDSA.

• What are the risks for a preterm infant with ENFit™?

"Laboratory testing also shows a mid tolerance E1 [ENFit™] connector pair in a female to male orientation displaces a mean average of 0.148ml…" (2)
As very low volumes of enteral drugs (0.05ml – 0.1ml) are administrated daily to patients in NICU, a high level of accuracy is required. This 0.148ml over-delivery could multiply by 4 the expected administrated volume and therefore be detrimental for neonatal patients' health, especially for critical rugs such as morphine, digoxin, methadone, captoril, caffeine ,etc.

• Does the use of a draw-up device eliminate this risk of volume displacement ?

No, this risk can't be eliminated. Even if you follow the draw-up protocol correctly, the tension surface effect and/or the viscosity of the medication may lead to a variation in the delivery (up to 0.148ml).

• Does the Low Dose Tip (LDT) syringe solve the ENFit™ dosing inaccuracy risk in case of low volume deliveries?

No, an independent laboratory testing was performed to assess the accuracy of the LDT syringe and the results showed that, in case of using the current practices, the accuracy of the LDT syringe is equivalent to ENFit™ syringe(3), so inacceptable for neonates and newborns.
The results might appear acceptable only in case of implementation of a new strict syringe protocol (4). But this new protocol may lead to involuntary dosing errors due to human factors (inadequate training, forgetfulness, skipping a step…) and to microbial & chemical contamination risks.

• What is Vygon's solution?

Vygon proposes nutri**safe**2, a unique safe enteral feeding system specially designed for Neonatology. This 11-year experienced system is safe, small and accurate. It minimizes dramatically the risk of volume displacement, down to 0.029 ml(5). The neonatal specialists can use it with high confidence.

• Is nutrisafe2 compliant with ISO 80369?

Yes, nutri**safe**2 is compliant with Part 1 of the ISO 80369. That means the design of nutri**safe**2 connectors was assessed to mitigate risks of misconnection to the other connectors of the different applications (respiratory, neuraxial, IV….) within the ISO 80369.

• Why did Vygon decide to create ENFit™ range?

As the inventor of Nutrisafe, Vygon knows how safety in enteral therapy is important to patients and clinicians. Therefore, Vygon has been involved in the creation of the ISO 80369-3 from the beginning (in early 2000's). The creation and use of a universal safety enteral connector are essential for patients' health and ENFit™ meets the requirements for adults and children.

(1) http://www.iso.org/sites/ConsumersStandards/1_standards.html
(2) ISO 80369-3: 2016
(3) Analysis of «the report GEDSA Low Dose Syringe Accuracy test, dated 31 january 2016, by SMTL» - SELECT Report - 23 June 2016
(4) GEDSA ENFit® Low Dose Tip Review, Q2 2016
(5) Theoretical measurements - January 2014 - Internal Data

Vygon's solution for neonates

- In 1995, Vygon creates its first safety enteral feeding system to prevent tubing misconnections: nutri**safe**1, a reversed-Luer system.
- In 2005, Vygon improves its system and launches nutri**safe**2 : a complete non-Luer safety enteral feeding system, specially designed for preterm babies.

After 20 years of experience in safety enteral feeding systems in Neonatology, Vygon decides to maintain providing the nutri*safe*2 system to meet the intent of the ISO 80369-3 and provide the best care and safety for neonatal patients.

Think safe, small and accurate !

Accessories

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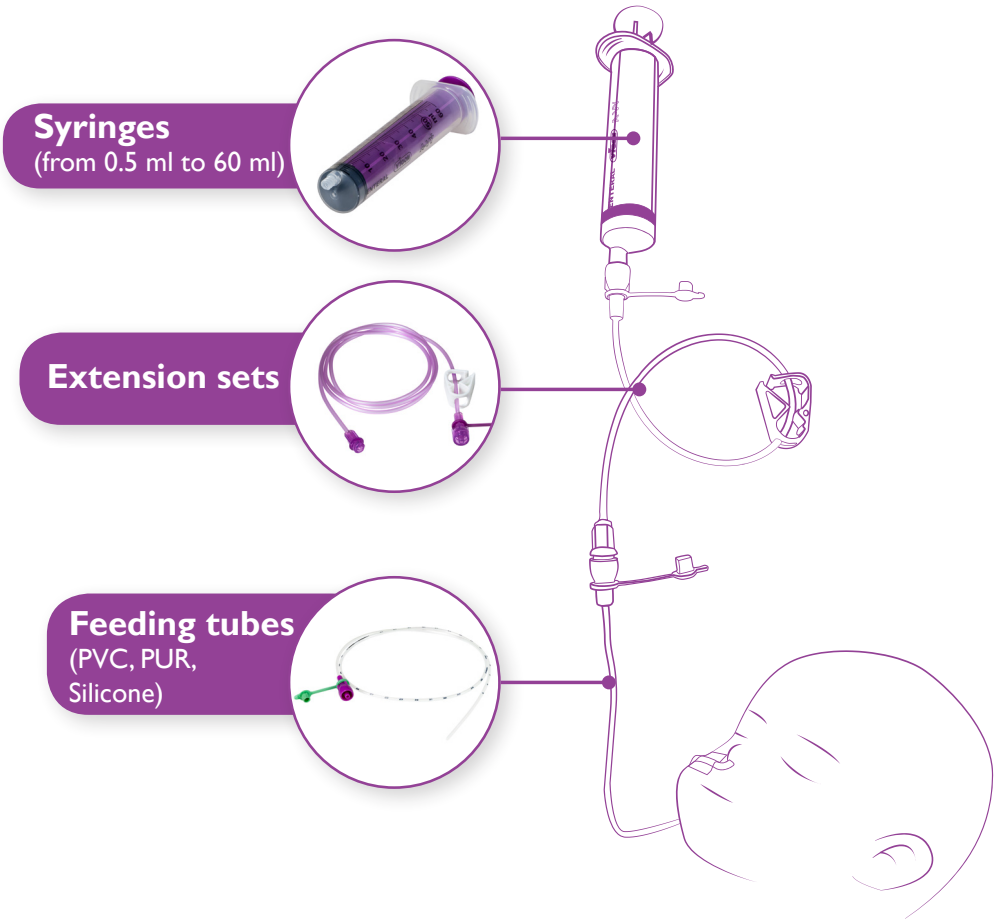
Syringe-driver



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

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