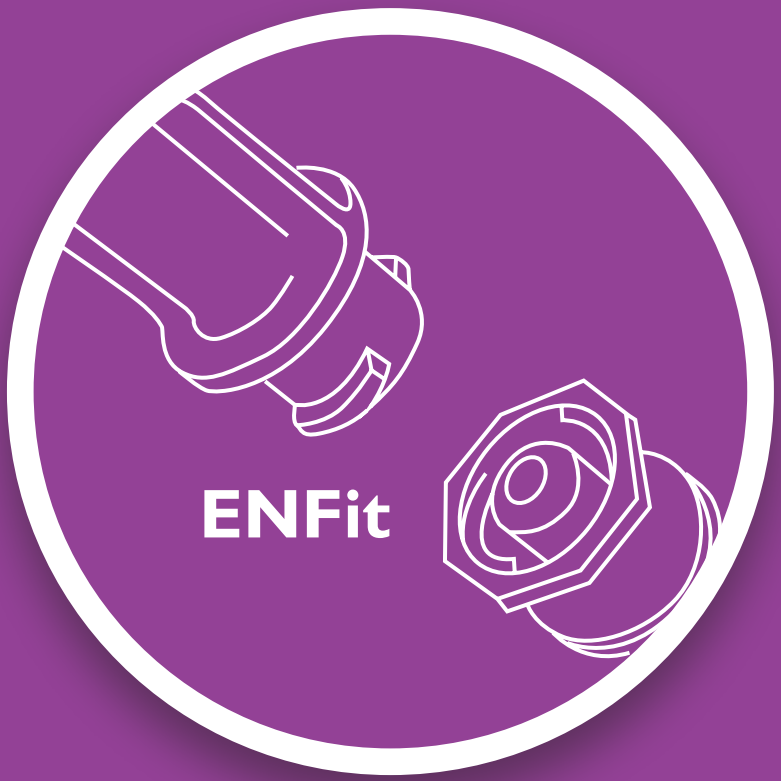
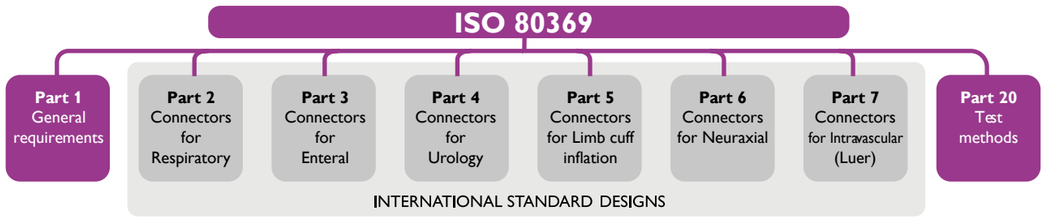
F.A.Q

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



• 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 intended to be non-interconnectable with each other.



• 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 and drawings 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.

• 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 ?

"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)

• What are the risks for a preterm infant ?

" Laboratory testing also shows a mid tolerance E1 [ENFit] connector pair in a female to male orientation displaces a mean average of 0.150ml…" (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 0.150ml over-delivery could multiply by 4 the expected volume administrated and therefore be detrimental for neonatal patients' health, especially for critical drugs such as morphine, digoxin, methadone, iron, caffeine citrate, etc.

• Is there a way to eliminate this risk of volume displacement ?

No, this risk cannot be eliminated. Even if you follow the draw-up protocol correctly, the tension surface effect or the viscosity of the medication will lead to a possible 0.150 ml mean over/under delivery.

• Is ENFit suitable in NICU ?

On behalf of the ISO working group, Vygon conducted a survey in 2014 to gather the clinical requirements for enteral medication deliver and evaluate the acceptability and suitability of ENFit for use in neonatal populations. 119 neonatal specialists from 11 countries were interviewed face-to-face in their hospitals. They expressed their daily need of high accuracy for enteral drug delivery, especially for digoxin, morphine, methadone, iron, caffeine citrate… With its potential over-delivery, ENFit was judged unacceptable for use in NICU.

• What is Vygon's solution ?

Vygon proposes nutri**safe**2®, a unique safe enteral feeding system specially designed for Neonatology. This 10-year experienced system is safe, small and accurate. It minimizes dramatically the risk of volume displacement, down to 0.029 ml(3). The neonatal specialists can use it with high confidence.

• Is nutri**safe**2® compliant with ISO 80369 ?

nutri**safe**2® is compliant with Part 1 of the ISO 80369. That means the design and dimensions of nutri**safe**2® were verified to prove that the risk of misconnection with the connectors used in the different applications (RESPIRATORY, NEURAXIAL, IV….) is eliminated or significantly reduced to reach an acceptable level. Therefore, nutri**safe**2® prevents misconnection with all connectors used within the ISO 80369.

The mission of Global Enteral Device Supplier Association (GEDSA) is to help health facilities to understand the new ISO standard and prepare for this change.
Vygon is a charter member of GEDSA and supports ENFit for old children and adults, but not for neonates.

(1) http://www.iso.org/sites/ConsumersStandards/1_standards.html
(2) ISO 80369-3
(3) Theoretical measurements - January 2014 - Internal Data

Vygon's solution for neonates

• In 1995, Vygon creates its first safety enteral feeding system to help prevent tubing misconnections. nutri**safe**1 was 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 system and in Neonatology, Vygon decides to maintain providing nutrisafe2® , which is a system compliant with ISO 80369-1 and provides the best care and safety for neonatal patients.

Think safe, small and accurate !

Accessories

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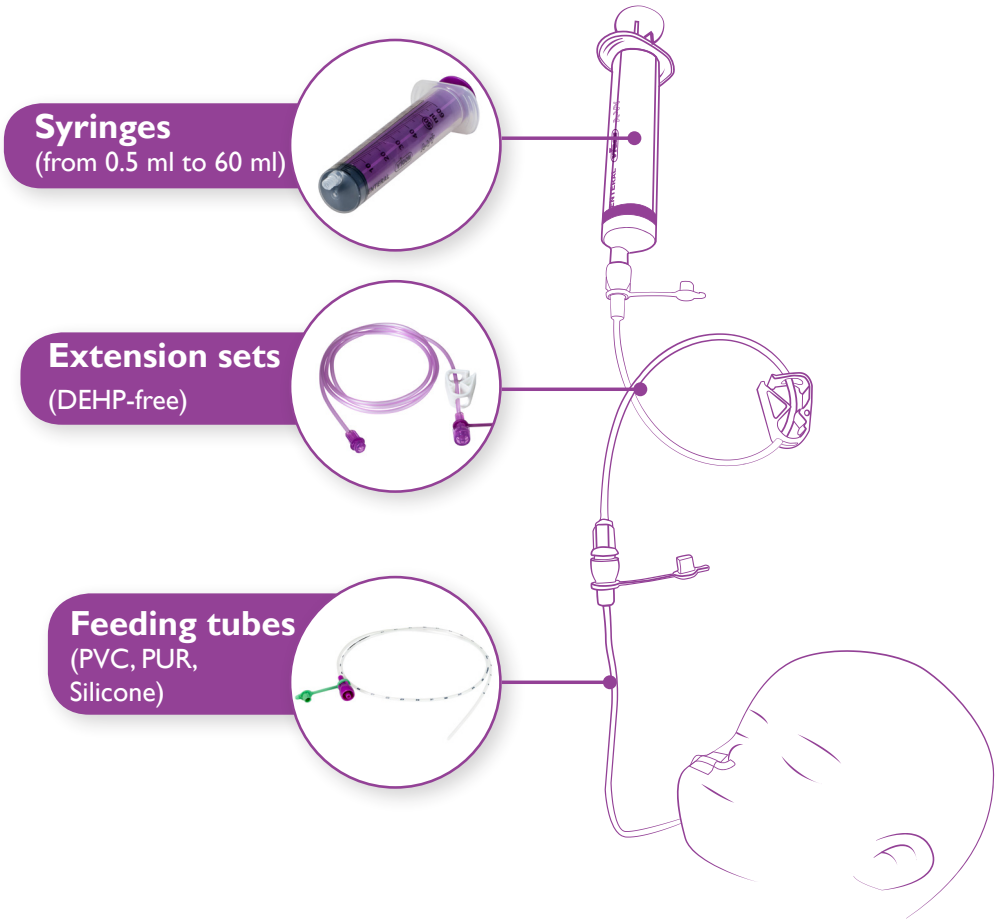
Syringe-driver



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