Summary of the SFN newsletter - N°07 (dated on March 2016)

> New enteral nutrition connector of ISO 80369-3: a system presenting a real risk in premature infants and young children

The International Standards Organization (ISO) decided to create a new standard dedicated to the conception of medical devices connectors for enteral nutrition (feeding tubes, syringes, extension lines, etc). The publication is expected for 2016. This new connector, called ENFit™, is currently proposed to all patients, from premature infant to adults.

Although this connector is well adapted for adults, concerns within the standard itself have been documented around "the possible risks of delivering accurate doses of medicines in certain clinical practices across high risk sub-populations (e.g. neonatal patients)."

The sampling and administration of a small dose of medication, in the range of tenth of milliliters, using a syringe equipped with the ENFit™ connector is not precise enough, due to the important dead space generated by the large internal diameter of the connector.

Since 2012, the French Society of Neonatology warned AFNOR (French National Standard Body) and ISO committee around the real risk that the connector represented, and asked that the project would not be accepted as it was. Unfortunately, devices equipped with ENFIT™ connectors are now on the market, without taken into account the clinical risks for premature infants and young children.

What are the risks related to the ISO 80369-3 connector?
As indicated in the standard (annex A), "Laboratory testing also shows a mid tolerance E1 [ENFit] connector pair in a female to male orientation displaces a mean average of 0.150ml…"
The common dosage for oral drugs administrated to neonatal patients is very low, so this volume displacement can multiply the expected dose by 2, 3, 4… which can lead to medication overdosing risk.

Oral drugs	Prescribed dose *(1kg infant)*	With a 0.150ml overdosing linked to the ENFit™ system
Morphine	Starts from 0.03 ml	x 6
Methadone	0.05 ml – 0.1 ml	x 4 – x 2.5
Digoxin	0.07 ml	x 3
Corticosteroid	0.1 ml	x 2.5

Is it mandatory to use enteral devices compliant with ISO 80369-3?
No, because an ISO Standard is not a law, but a recommendation.

The French Society of Neonatology recommends a neonatal enteral feeding system as follows:

> Safe

- Incompatible with Luer and other small-bore connectors used in other applications (e.g. I.V)
- Allowing to connect components without leakage or cracking

> Accurate

- Having an internal dead space inferior to 0.1ml
- Generating a volume displacement inferior to 0.05ml

> Small, adapted to preterm infants

- incorporating the smallest possible connectors
- incorporating the lowest possible weight connectors