Joint MNI GEDSA position paper on ISO 20695 standard

15 April 2019

MNI, the Medical Nutrition International Industry, and GEDSA, the Global Enteral Device Supplier Association, support the ISO 20695 standard on the design and testing of enteral feeding systems (giving sets, feeding tubes, syringes and accessories).

The adoption of the standard will be an important and much-needed milestone to provide a unique set of rules at global level for enteral feeding devices and to strengthen safety of patients on enteral nutrition.

MNI and GEDSA welcome the positive vote in a majority of countries in favor of the draft standard on 11th March 2019 and invite national standardization bodies to confirm the ISO 20695 standard in the final vote.

Adoption of ISO 20695 provides clarity with a single and comprehensive set of rules at global level:

- The ISO 20695 standard being developed since 2015 will replace the European standards EN 1615 and EN 1618. Being an international standard, ISO 20695 defines the same state-of-the-art requirements for enteral feeding systems at the global level.
- The scope of the standard is extended to cover enteral feeding systems that were previously not standardized (e.g. balloon gastrostomy tubes).
- ISO 20695 also incorporates the new connection systems (ISO 80369-3 and ISO 18250-3)[1,2] which reduce risks linked to misconnections between medical devices for different medical applications.

[1] ISO 80369-3 :2016 Small-bore connectors for liquids and gases in healthcare applications – Part 3: Connectors for enteral applications

[2] ISO 18250-3 :2018 Medical devices – Connectors for reservoir delivery systems for healthcare applications- Part 3: Enteral applications

The ISO 20695 standard reflects current practice in the market. The standard refers to small bore connectors for enteral applications currently deployed in the market:

- ISO 80369-3 and ISO 18250-3 compliant connectors are implemented in most of the European countries and are being increasingly deployed around the globe[3].
- These connectors are adopted by a vast majority of enteral feeding devices manufacturers, including all MNI and GEDSA members, active in enteral feeding systems.
- Significant efforts have already been deployed to promote adoption and implementation of the standard. In anticipation of the adoption of the standard, various stakeholders including clinicians and enteral device manufacturers have launched a campaign to promote the implementation of the connection system worldwide: stayconnected.org.

The ISO 20695 standard further strengthens safety of patients on enteral feeding.

- With the adoption of the ISO 20695 standard, the risk of life-threatening misconnections between enteral feeding systems and devices for other medical applications (e.g. connection of enteral feeding tubes to intravenous nutrition systems) will be further reduced.
- To MNI and GEDSA knowledge, there has not been any adverse events linked to misconnections with devices complying with ISO 80369-3 or ISO 18250-3.

[3] See deployment map in Annex 2

The ISO 20695 standard brings clarity to users by creating the reference to the connector standard ISO80369-3 (known as ENFit®) and suggesting one standardized direction of flow for enteral feeding devices. Introducing a different design would create confusion among users:

- Users would need to be trained to the new design.
- Users would need to phase two or more different designs which might not be interchangeable between each other resulting in the impossibility to start a feeding therapy and the need to replace (parts of the) enteral feeding system or to use adapters to facilitate a connection. Using adapters should be avoided as this might cause confusion or even distress and opens the possibility for accidental misconnections again between connectors of systems from different healthcare applications.

About MNI:

MNI – the Medical Nutrition International Industry association – is the voice of the medical nutrition industry at international level.

MNI represent companies providing solutions for nutritional therapy: Oral Nutritional Supplements (ONS), Enteral Tube Feeding (enteral nutrition via the gastrointestinal tract), and Parenteral Nutrition (intravenous feeding) - as well as other actors operating in the medical nutrition market, such as ingredients and medical devices for nutritional care.

MNI works to achieve better care through better nutrition, across all ages and healthcare settings.

About GEDSA:

The Global Enteral Device Supplier Association (GEDSA) is a 501(c)6 nonprofit trade association formed to help introduce international standards for healthcare tubing connectors. Comprised of manufacturers, distributors, and suppliers of enteral nutrition devices worldwide, GEDSA facilitates information flow about the three-phase initiative, which is designed to increase patient safety and optimal delivery of enteral feeding by reducing the risk of tubing misconnections.

ENFit is a federally registered trademark of GEDSA in multiple jurisdictions throughout the world.

For more information, please visit StayConnected.org.

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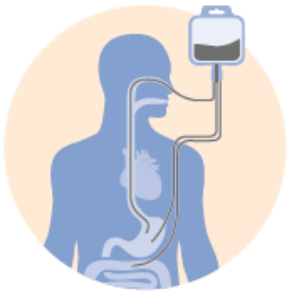
Annex 1 - GLOSSARY OF TERMS

What is enteral feeding?



Enteral Feeding – also called enteral tube feeding or nasogastric feeding - is administered into the gastrointestinal tract via a nasogastric, nasoenteric or percutaneous tube.

Enteral feeding is required when a patient is unable to consume sufficient nutrition via the oral route.

Examples include: severe cystic fibrosis, cerebral palsy, after a stroke or major surgery, such as head and neck surgery, and critical illness.

Enteral feeding can be supplementary to oral intake or parenteral nutrition or can be the sole source of nutrition.

What are enteral feeding systems?

Enteral feeding systems are the medical devices required to provide enteral nutrition solutions to patients: giving sets, feeding tubes, syringes, etc. All need to connect safely to each other.

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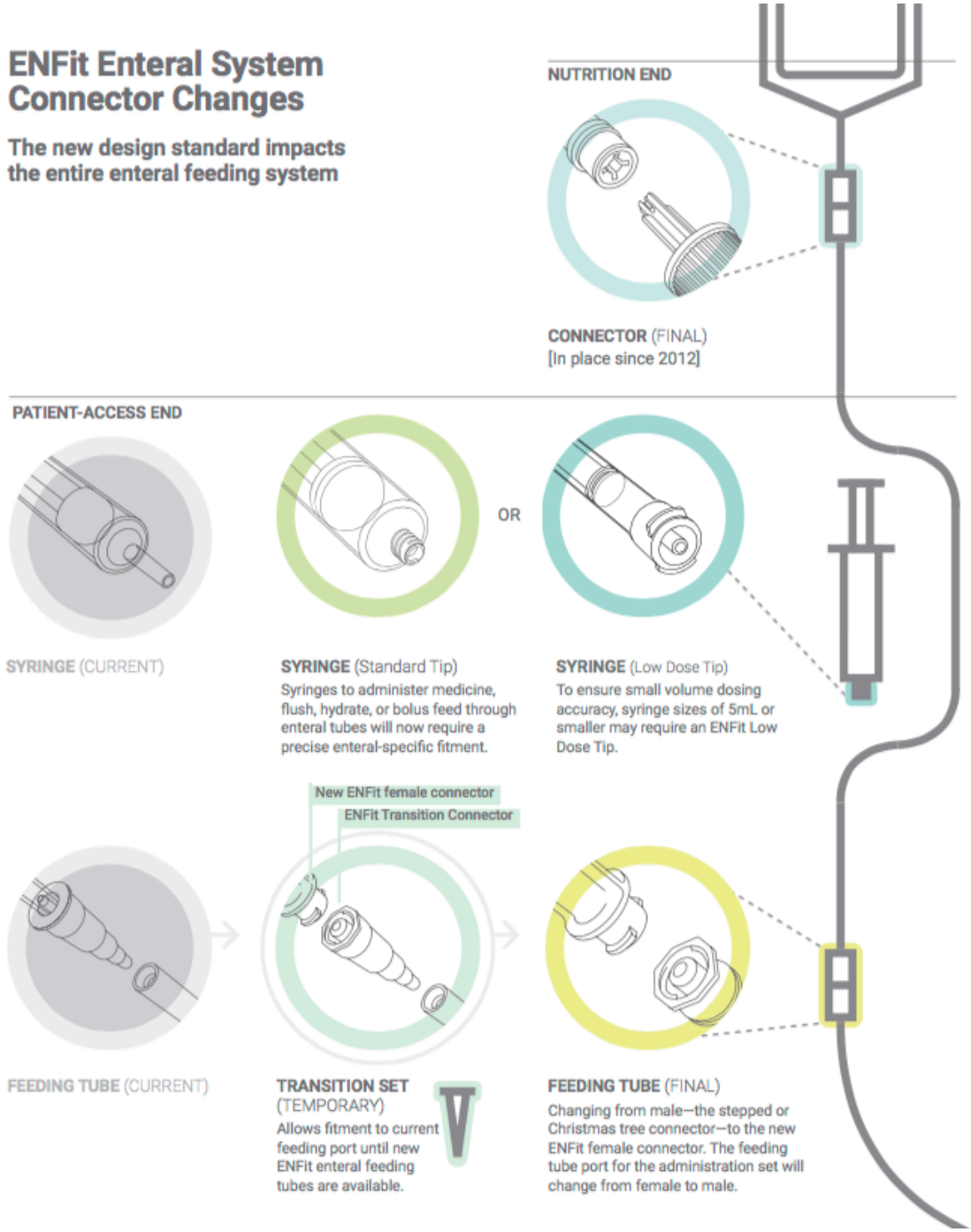
What are Enteral Feeding Systems Connectors?

Connectors are small components that connect the different elements of the feeding systems. Connectors are crucial to ensure an effective and safe connection between the different devices and allow a seamless flow of the nutritional solution from the container into the patient gastric system.



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Further information on enteral feeding can be found on MNI website:

- https://medicalnutritionindustry.com/medical-nutrition/about-medical-nutrition/enteral-tube-feeding/
- https://medicalnutritionindustry.com/medical-nutrition/medical-nutrition-dossier/

Further information on enteral feeding systems can be found on the GEDSA website:

- http://stayconnected.org/wp-content/uploads/2016/10/GEDSA-ENFit-LDT-Research-Poster.pdf
- http://stayconnected.org/wp-content/uploads/2017/02/medication-administration-poster.pdf
- http://stayconnected.org/wp-content/uploads/2016/08/GEDSA-Low-Dose-Tip-position-statement-817-FINAL.pdf

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Annex 2: DEPLOYMENT MAP

2019 ENFit Global Adoption Status

North America
- ~ 20%
- Law (AB444) in CA

South America
- ~ 5%
- Transition anticipated to commence in 2019
- Real push will follow US transition

Europe
- ~ 90% depending on market
- UK, Netherlands, France, Italy, Belgium, Ireland are 100% adopted

Eastern Europe, Middle East & Africa
- ~ 30%

Asia
- ~5% adoption
- China & Japan begin transition in 2019. Registration timelines take up to 2.5 years
- Southeast Asia countries will follow China & Japan

ANZ
- ~50% adoption

* Adoption rates are only rough estimates based on feedback from manufacturers, GPOs, hospitals and other stakeholders throughout the world