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GEDSA Guidance Supporting ISO 80369-3 ENFit®

The International Organization for Standardization (ISO) has established ISO 80369 series of standards specifying designs of small-bore connectors for various clinical applications to reduce the likelihood of tubing misconnections. ISO 80369-3 standard for enteral devices in the female (admin set & syringe) to male (feeding tube) orientation addresses dose accuracy, neonatal applications, improved connector usability, engineering assessments and other technical content supporting the common goal of improved patient safety and global standardization. This connector is known by its federally registered trademarked name, ENFit.

GEDSA and its supporting organizations urge manufacturers, distributors/suppliers and health care providers to be an active participant in the immediate adoption of new ENFit connectors. The female to male orientation significantly limits the ability to insert common male connectors into any female patient access port such as current legacy feeding tubes. Therefore, the vast majority of industry worldwide supports ENFit adoption as a singular system to be in the best interest of improved patient safety and ensure connectivity between any enteral devices supplied worldwide. This change impacts the entire enteral feeding system across all neonatal, pediatric and adult health care settings, therefore an expeditious and methodical transition to new safer connectors is recommended, globally throughout 2017 and 2018. To ensure compatibility without the long-term use of adapters, GEDSA **does not** support the use of proprietary connectors or any current or proposed male to female connectors.

A successful transition will include the use of ENFit compatible connectors on all neonatal, pediatric and adult components of an enteral feeding system. Feeding tubes and medication ports on feeding sets with new ENFit male connectors will require new female ENFit tip syringes. Syringes for flushing, hydration, bolus feeding and enteral administration of medication are critical to support the introduction of feeding tubes with the ENFit connectors. Using a feeding system other than ENFit for neonatal or pediatric use is strongly discouraged due to potential compatibility issues with changing patient settings.

For accurate enteral dosing of small doses, syringe sizes of 5 mL or smaller require an ENFit Low Dose Tip (LDT) Syringe design. Validated through independent laboratory performance testing, usability studies and misconnection risk assessments, LDT syringes deliver dosing accuracy statistically consistent with existing male (oral) tip syringes and better than other reverse gender solutions used today. Several manufacturers have gained FDA 510(k) clearance for their ENFit LDT Syringe and are readily available to support the broader transition to ENFit. Other obstacles to adoption have been resolved as follows:

Obstacle	Background/Concern	Resolution
Disconnection & Leakage	98% of enteral patients experience disconnections due to legacy stepped connectors[1]. Administration sets with ENFit Transition Connectors (TCs) used for 2+ years with sub-optimal connectivity, causing disconnections, leakage and cracking ENFit components.	Transition connectors were only intended to be temporary. ENFit to ENFit connections are designed with a locking feature to keep tubes connected, avoiding disconnections that may cause hospitalization and other complications. Full scale adoption of ENFit will eliminate disconnection concerns.
Flow Rates & Pressure	ENFit feeding tubes appear to have a smaller inner diameter than legacy feeding tube funnels. The smaller inner diameter may cause delays in feeding, particularly with home blenderized diets.	Independent testing conducted by the FDA and The Mayo Clinic demonstrate flow rates and pressure required to feed with an ENFit system are consistent with legacy tubes.[2]

[1] Feeding Tube Awareness Foundation *ENFit Survey* 2017 June 2nd Available from: http://stayconnected.org/wp-content

[2] Suvajyoti Guha PhD, Matthew R. Myers PhD, Joshua Silverstein PhD, Mark J. Antonino MS, Jeffrey Cooper DVM, MS, Food & Drug Administration *Feeding tubes and transition to ENFit: creating science around infinite user variables*. 2017 July 26th Available from: http://stayconnected.org/wp-content/uploads/2017/08/FDA.Blenderized-Update-upload.pdf

Cleaning Procedures	Male ENFit connectors by design have a moat outside of the fluid path where fluid can build up. ENFit feeding tubes may be hard to keep clean.	As with any feeding tube, proper tube maintenance is essential. GEDSA is working with the clinical community to assess the cleanliness of tubes and to develop cleaning procedures.
Training/ Education	Transitioning to ENFit involves many departments and functions including nursing, pharmacy and supply chain. Such changes require proper training & education for all departments/functions.	GEDSA has developed training manuals, patient discharge materials, in-service presentations, tool kits, FAQs and many other resources to aid in training. Visit stayconnected.org to learn more.
Component Supply	The number one obstacle to transition to ENFit has been the perception that product is not available for every component of a feeding system.[3]	GEDSA member manufacturers have confirmed adequate supply is available in aggregate. It is highly recommended that healthcare facilities communicate demand 8-12 weeks ahead of a "Go-Live" date. Facilities may need to rely on multiple suppliers/distributors to meet future ENFit demand.

To comply with ISO 80369-3 and ensure patient safety the majority of healthcare facilities in Europe, Middle East, Africa, Australia and New Zealand have successfully adopted ENFit. While other markets are currently lagging behind, GEDSA strongly recommends healthcare facilities throughout the world adopt ENFit as soon as possible. Check with your supplier representative for more precise timing in your area. Visit www.StayConnected.org for up to date information on ENFit.

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.

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[3]Global Enteral Device Supplier Association *ENFit Adoption Survey* 2017 July 26th
Available from: http://stayconnected.org/wp-content/uploads/2017/08/ENFit-Advocacy-Meeting-uploadv2.pdf