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July 1, 2016

GEDSA Guidance Supporting ISO 80369-3 ENFit®

In an effort to prevent wrong route delivery of fluids and gases (tubing misconnections) there is an ongoing effort led by the International Organization for Standardization (ISO) to address small-bore connectors for healthcare applications. The overall objective of the ISO 80369 series of standards is to specify designs of small-bore connectors for various clinical applications to reduce the likelihood of tubing misconnections. The Final Draft International Standard 80369-3 has been approved and published. The published standard addresses dose accuracy, neonatal applications, improved connector usability, engineering assessments and other technical content supporting the common goal of improved patient safety. The ISO 80369-3 connector design in the reverse orientation as defined below is commonly 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 adoption of new ENFit connectors. This orientation significantly limits the ability to insert common male connectors into a female feeding port. While not mandated in the standard, adoption of these connectors in this female to male (reverse) orientation has been determined by a vast majority of industry to be in the best interest of improved patient safety and avoidance of any disruption in therapy. Because this change impacts the entire enteral feeding system across all health care settings, a careful and methodical transition to these new safer connectors is recommended, globally throughout 2016 and 2017.

A successful transition will include the use of ENFit compatible connectors on all 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.

For accurate enteral dosing for small doses, draw up devices such as straws or fill caps may be necessary to use during filling[1]. Additionally, to ensure small volume dosing accuracy, syringe sizes of 5 mL or smaller may require an ENFit Low Dose Tip Syringe design. Manufacturers have collaborated to validate the LDT through independent laboratory performance testing, usability studies and misconnection risk assessments. Testing has demonstrated with statistically significant confidence that the LDT syringes can provide dosing accuracy consistent with existing male (oral) tip syringes and better than other reverse gender solutions used today. The LDT syringe has been reviewed and gained FDA 510(k) clearance for two manufacturers and is now ready for market introduction and to support the broader transition to ENFit.

To comply with ISO 80369-3 and ensure patient safety, GEDSA is recommending to manufacturers and healthcare providers the adoption of new ENFit connectors in North America, Europe, Middle East, Africa, Australia and New Zealand as soon as possible with adequate supplies of enteral feeding tubes and ENFit tip syringes. This should include ENFit Low Dose Tip Syringes. It is recommended that Latin America and most of Asia begin to transition administration sets in the back half of 2016, followed by ENFit tip syringes and feeding tubes in the beginning of 2017. For China and Japan, the changes will most likely take place in 2018. Check with your supplier representative for more precise timing in your area. Visit www.StayConnected.org for up to date information on ENFit.

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[1] Mike Cohen, ISMP Medication Safety Alert: ENFit Enteral Devices are on their way…Important Safety Considerations for Hospitals: Published April 9, 2015.
http://www.ismp.org/newsletters/acutecare/showarticle.aspx?id=105

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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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