GEDSA
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GEDSA Position Statement Supporting ISO 80369-3 ENFit™
Enteral Connectors and Low Dose Medication Solutions

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 second Draft International Standard was voted on and approved by 96% of voting countries. The Final Draft International Standard 80369-3 is under review and anticipated to be approved, published and recognized by the early part of 2016. The latest draft addresses dose accuracy, direction of flow, and neonatal applications, including improved connector usability, engineering assessments and other technical content supporting the common goal of improved patient safety.

GEDSA and its supporting organizations strongly urge every manufacturer, distributor/supplier and health care provider to be an active participant in the adoption of new ISO 80369-3 standard connectors (ENFit™) in the female administration set & syringe to male patient access or feeding tube orientation. This orientation limits the ability to insert common male connectors into a female port, allows for a physical cue unique to enteral devices and provides a congruent solution to the reverse Luer successfully leveraged in the UK for enteral devices for over 10 years. While not mandated in the standard, adoption of these connectors in the same orientation is critical to 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 new safer connectors is recommended over the course of 2015 thru 2017 across the globe.

A successful transition will include the use of ENFit 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 in healthcare settings.

For precise enteral dosing, draw up devices such as straws or fill caps may be necessary to use during filling, plunger operation, and delivery[1]. Additionally, for highly accurate low volume doses (0.2mL within +/- 10% dose), an ENFit low dose syringe is proposed. GEDSA members are committed to introduce a common design, low dose solution during the first half of 2016 (pending required regulatory approvals) to support the broader transition to ENFit. Initial testing of this low dose ENFit syringe indicates that it will satisfy the performance requirements specified for dose accuracy, dead space and tolerance on graduated capacity in ISO 7886-1, as well as address concerns raised by videos now being distributed in the marketplace. Further validation of the low dose syringe is in progress.

GEDSA members align to introducing new ENFit connectors in the first half of 2016 and will make best efforts to introduce these devices in North America (Group 1), Europe, Middle East, Africa, Australia and New Zealand (Group 2), UK and Republic of Ireland (Group 3) as soon as manufacturers are ready with adequate supply of enteral feeding tubes and ENFit tip syringes, including low dose medication solutions. It is recommended that Latin America and most of Asia begin to transition administration sets 2016, followed by ENFit tip syringes and feeding tubes in 2017. For China and Japan, we recommend communicating these changes in 2016 with introduction of new ENFit enteral devices to be introduced starting 2017.

[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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