GEDSA
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GEDSA Position Statement in support of ISO 80369-3 (ENFit enteral connector)

There is an ongoing effort led by the International Organization for Standardization (ISO) to address small-bore connectors for healthcare applications in an effort to prevent wrong route delivery of fluids and gases (tubing misconnections). 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 (FDIS) 80369-3 is under review and anticipated to be approved, published and recognized by the fall of 2015. The latest draft does address potential concerns for dose accuracy, direction of flow, and neonatal applications, including improved connector usability, engineering assessments and other technical content that adds to support 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 standard connectors (ENFit) as adoption of these connectors is critical to the best interest of improved patient safety. 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 and 2016.

A successful transition will include the use of ENFit connectors on all components of an enteral feeding system including administration sets, syringes and feeding tubes along with ENFit Transition Connectors. Syringes with ENFit tips are critical for the introduction of feeding tubes with the ENFit connectors and must be available to provide appropriate therapy for the tube fed patient. Unexpected delays in production and capacity constraints has caused syringe manufacturers to require incremental time to ensure adequate supply of enteral syringes with ENFit tips for access to feeding tubes with ENFit connectors. GEDSA and its members recommend that the introduction of feeding tubes with ENFit connectors in the United States, Canada and Puerto Rico be delayed as follows:

Second Quarter 2015	Administration sets with ENFit connector and Transition connector
First Quarter 2016	Enteral-specific syringes with ENFit Tip and Enteral feeding tubes with ENFit connectors

Timing subject to each manufacturer's FDA 510(k) pre-market clearance and or formal declaration of conformance. Check with your supplier representative on precise timing and product availability.

The unexpected delay of syringe supply in the US, Canada & PR does not impact the introduction of new connectors elsewhere throughout the globe. New connectors and temporary use of Transition Connectors are anticipated to take a full year to transition and are expected in Europe, Middle East, Africa, Australia and New Zealand along the following stepwise introduction timeline:

From late Q3 2015:	Administration sets with new ENFit connectors & Transition connectors
Q4 2015	Enteral-specific syringes with ENFit connector
Q1 2016	Enteral feeding tubes with ENFit connector

Timing subject to each manufacturer's for CE mark and other regulatory approval. For suggested introduction timelines in the UK, Ireland and other regions not listed above, check with your supplier representative on precise timing and product availability.