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May 20, 2015

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.

Concerns have been raised about possible risks of delivering accurate doses of medication through syringes in certain clinical practices across high risk subpopulations (e.g. neonatal patients) when using a reversed gender connection system (female to male) like ENFit. GEDSA continues to work with the clinical community to further understand these clinical concerns.

Syringes are commonly used in enteral feeding, for hydration, flushing, bolus feeds and for administering medication. Feeding tubes and medication ports on feeding sets with new ENFit male connectors will require new ENFit tip syringes. ENFit tip syringes are appropriate for use in all healthcare settings for flushing, hydration, bolus feed and administering medication enterally. However, for precise dosing, draw up devices such as draw up straws or fill caps may be necessary.

When enterally delivering low dose liquid medications, which require high accuracy (within +/-0.15mL):

1. Use an ENFit tip Syringe
2. Attach Filling Device (Fill Cap, Draw up Straw, Transition Connector) to ENFit tip syringe
3. Withdraw desired dosage of medication
4. Remove any undesired air/bubbles from the ENFit syringe while syringe is still attached to the filling device
5. Disconnect filling device from ENFit tip syringe
6. Cap Syringe if filling in pharmacy according to hospital protocol
7. Disconnect the ENFit tip syringe cap (If syringe has been capped)
8. Administer Medication via ENFit feeding tube or ENFit medication port - Do not purge air from the tip of the ENFit tip syringe
9. Flush according to hospital protocol

Note: Medication delivery with the ENFit tip syringe will be most accurate when an ENFit compatible connector is used during filling, plunger operation, and delivery.

ENFit tip syringes were designed specifically for enteral and not for oral delivery of medications. For orally delivered medications which require high accuracy (better than +/- 0.15mL) GEDSA recommends the use of oral tip syringes according to current protocols, to ensure dose accuracy. If using ENFit tip syringes orally, consult your syringe supplier representative on the most appropriate filling and administration methods.

The Final Draft International Standard for 80369-3 does address these 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. It is therefore recommended that the ENFit connectors be used for all patients to reduce the risks of misconnection.

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The Global Enteral Device Supplier Association (GEDSA) is a 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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