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August 9th, 2016

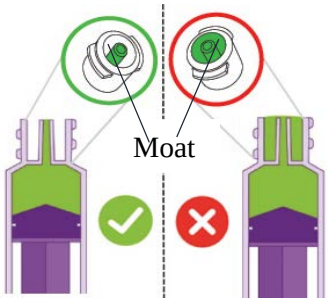
GEDSA Position Statement Supporting ENFit® Low Dose Tip Syringe

To reduce the risk of wrong route delivery of fluids and gases (tubing misconnections) there is an ongoing effort led by the International Organization for Standardization, ISO 80369, to address small-bore connectors for healthcare applications. The ISO 80369-3 standard for enteral applications has been approved and published to enable manufacturers to adopt a safer connector design which will be used on medical devices providing a safer enteral feeding system.

Prior to the introduction of ENFit Tip syringes and feeding tubes, concerns were raised regarding dose accuracy of low volume medications, when delivered with a standard ISO 80369-3 ENFit Tip Syringe. There is no recognized standard (ISO, AAMI, ASTM, EN) for enteral syringes that specifies design specifications or requirements for dose accuracy. After polling clinical experts, it was determined that the expected range for dosing accuracy among small volume doses (i.e., ±10% accuracy for a 0.2ml dose delivered with a 1mL syringe). A technical team of industry experts worked collaboratively to select and vet a solution to address small volume dose accuracy. This solution is known today as the ENFit Low Dose Tip (LDT) Syringe.

Performance testing conducted by an accredited third party lab and usability studies conducted throughout the world confirm the ENFit LDT syringe when used as instructed:

- Delivers an accurate dose substantially equivalent with current male orientated enteral/oral syringes.
- Outperforms existing female (reverse) orientated syringes.
- Fits into current practice and maintains compatibility with other ENFit devices.



ENFit LDT Syringes have been reviewed and obtained FDA 510(k) clearance for at least two manufacturers and are ready for market introduction to support the broader transition to ENFit. Other manufacturers are in the process of obtaining FDA 510(k) clearance for their ENFit LDT syringes. In order to obtain the requisite dose accuracy, manufacturers of ENFit LDT syringes should specify in their instructions for use and labeling that the syringe user should remove fluid that lies outside of the fluid path. The area between the male lumen and the outer ring (the "moat") is not part of the fluid path and should be free of fluid. For settings that require highly accurate low volume doses, an ENFit LDT Syringe is recommended. The ENFit LDT syringe tip design satisfies the performance expectations for dose accuracy, dead space, and tolerance on graduated capacity.

GEDSA and its supporting organizations including the Joint Commission, ISMP, ASHP, ASPEN, NHS, and EPSG encourage manufacturers to introduce enteral devices with ENFit connectors, and healthcare facilities to:

- Adopt feeding systems with ENFit connectors as soon as possible.
- Use ENFit LDT syringes to ensure accurate dose delivery of small volumes.
- Work with your supplier representative and distributor network to understand their specific timing and product availability for transition.
- Confirm syringe suppliers have adequate supplies of standard and LDT ENFit syringes before converting to ENFit feeding tubes.

Conversion to enteral devices with ENFit connectors impacts the entire enteral feeding system across all healthcare settings. To avoid disruption of therapy, a careful and methodical transition is recommended over the course of 2016 and 2017 throughout the world. Introduction of ENFit may vary depending on your supplier(s) timing.

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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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