Reducing the Risk of Medical Device Tubing Misconnections

ENFit® Low Dose Tip Syringe Review

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ENFit and Dose Accuracy Background

- “Reducing the risk of (tubing) misconnection requires a complete design change with correlating standards established and adopted worldwide across the industry” (GEDSA website)
  - This is achieved through ISO 80369-3 for enteral connections
- Dose delivery accuracy *(which includes the entire system)* ensures that the correct dose is prepared and administered to the patient
- There is no standard to reference for dose delivery accuracy applicable to enteral syringes and/or administration systems
- Non-enteral reference points, such as hypodermic syringe performance standards (ISO 7886), provide information on container measurement accuracy, but not delivery accuracy
Dose Accuracy Concerns Raised

**Clinicians:**
- Raised concerns on the dosing accuracy of small volume ENFit® syringes, due to their reverse gender orientation
- Indicated a dosing accuracy expectation of ± 10% for a target volume of 0.2mL when delivered from a 1mL syringe

**Industry:**
- There is no global standardized test (ISO, AAMI, ASTM, EN, etc.) for manufacturers to use to evaluate dosing accuracy for syringes
- In absence of a standardized test, no baseline data existed for comparison
Performance Testing

- GEDSA members assessed the ability of the standard ENFit® syringe to meet a +/-10% delivery accuracy and determined that syringe sizes of 5 mL or smaller may require a “low dose tip” ENFit® connector design to meet this target.

- Performance testing was then conducted by a third-party, accredited test lab. The following enteral syringe types were evaluated to determine the performance of the low dose design and to establish a baseline for the performance of existing syringes:
  - Leading brands of existing enteral/oral syringes (*all male tip*)
  - Female Luer lock (*reverse system used in the UK*)
  - Proprietary reverse system syringes currently marketed
  - Standard ENFit® syringe tip
  - Proposed ENFit® low dose tip syringe

*OBJECTIVE:* Address delivery accuracy concerns raised by clinicians and determine the baseline performance of existing enteral syringes/systems

Results were submitted to the FDA to support 510(k) submissions for the low dose tip design.
Small Volume Dose Accuracy of Common Enteral/Oral Tip Syringes (*Delivering 0.2 mL in a 1 mL syringe*)

- **Standard ENFit®**
- **Existing enteral/oral**
- **Reverse Proprietary**
- **Reverse Female LL**

Note: Target is ±10% of a 0.2mL dose delivered in a 1mL syringe. Each box represents the 95% confidence interval of the data set.
ENFit® Dose Accuracy Solution

- The ENFit® Low Dose Tip (LDT) syringe was designed to specifically address the dose accuracy concerns
  - Design is proposed for inclusion into ISO 20695 standard and is under review by the committee

- LDT adds an internal male lumen to the standard ENFit® female syringe
  - This mimics the functionality of traditional male oral/enteral syringe designs

*Initial designs and samples used for testing and photography provided by NeoMed
Small Volume Dose Accuracy of Common Enteral/Oral Tip Syringes (Delivering 0.2 mL in a 1 mL syringe)

Note: Target is ±10% of a 0.2mL dose delivered in a 1mL syringe. Each box represents the 95% confidence interval of the data set.
Misconnection Risk Assessment

- The ENFit® Low Dose Tip provides a solution for accurate enteral dosing while maintaining a high level of mitigation to the risk of inadvertent tubing misconnections.
- The addition of the internal male feature to the standard female ENFit® connector was evaluated for tubing misconnections across the other small bore connector designs of the ISO 80369 series.
- The conclusion of this analysis was that the ENFit® LDT provides a solution for accurate enteral dosing while maintaining a high level of mitigation to the risk of inadvertent tubing misconnections.
148 respondents worldwide representing pharmacy, nursing and caregivers evaluated the ENFit® LDT using current practices and methods for filling and administering enteral doses.

The respondents were able to complete the filling or administering of water or thick liquids (Pepto Bismol®/Children’s Tylenol®/Paracare®) with the LDT successfully.

Responses about the LDT performance were consistent across all user groups, regardless of the tasks evaluated.

Overall, users found the ENFit® LDT design feature acceptable for filling and administering enteral doses.
Recommended Syringe Use

- **Method of filling the syringe** *(cup fill vs straw/adapter fill)*
  - Using a straw or adapter to fill the syringe will deliver higher accuracy for each dose, similar to how other reverse orientation syringes are filled currently.
  - The straw or adapter reduces the potential for excess residual fluid to be outside the fluid pathway.

- **Removal of Residual Fluid**
  - The LDT internal feature behaves similarly to the male tip of existing oral/enteral syringes.
  - LDT syringes, like standard syringes, should be tapped/flicked/wiped in order to move fluid that may be outside the fluid pathway.
Low Dose ENFit® Syringe Conclusion

**Performance Test Results** *(when used as instructed)*:
- Substantially equivalent to standard orientation (male) enteral/oral syringes
- Performs better than Reverse Orientation (female tip) syringes
- Use of an adaptor (such as a straw) provides better performance than a cup fill

**Misconnection Risk Assessment:**
ENFit®, including the Low Dose Tip, mitigates the risk of inadvertent tubing misconnections and provides a clinical benefit

**Usability:**
No significant difference between use of ENFit® LDT syringe and current practice when filling or administering different viscosity fluids or between respondents (Pharmacist, Nurses, or Caregivers)