Reducing the Risk of Medical Device Tubing Misconnections
MISSION

Promote initiatives surrounding safe and optimal delivery of enteral feeding and connectivity
GEDSA Members

Abbott
A. Hopf
Alcor Scientific
Amsino
Bard
Baxter
B Braun
Boston Scientific
Cair Lgl
Cedic/Entek
Codan
Cook Medical
Corpak
Dale Medical
Degania
Enteral UK
Fresenius Kabi
Halyard
Intervene
Medela
Medicina
Medline
Medtronic
Moog
NeoMed
Nestle
Nutricia
Qosina
Smith’s Medical
UComfor
Vesco Medical
VYGON
VR Medical/Kentec
Xeridiem

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Supporting Organizations

AAMI
Advancing Safety in Medical Technology

AHRMM
Association for Healthcare Resource & Materials Management
Advancing the Healthcare Supply Chain

ASHRM
American Society for Healthcare Risk Management

ASHP
Pharmacists Advancing Healthcare

Aspen
Leading the Science and Practice of Clinical Nutrition

AV Anastacia

Vizient

Feeding Tube Awareness Foundation

HealthTrust

ISMP
Institute for Safe Medication Practices

The Joint Commission

Medication Safety Collaborative

NPSF
National Patient Safety Foundation

Oley Foundation

Premier
Tubing Misconnections Adverse Events

- **IV tubing misconnected to a nasal cannula** used to deliver oxygen — the patient survived after being treated for congestive heart failure.

- **Feeding tube to a tracheostomy tube**, delivering milk into an infant’s lung, resulting in death.

- **Epidural infusion set connected to a peripheral IV**, delivering epidural medication to bloodstream, resulting in patient death.

- **Feeding tube connected to an in-line ventilator suction catheter**, delivering feeding contents into the patient’s lungs, resulting in death.

- **Heparin lock (peripheral IV route) connected to an automatic blood pressure cuff**, delivering air to the bloodstream, causing death.
Robin was a young woman, 24, that was near term in her pregnancy. She had been having problems with vomiting and dehydration so they decided that they would emit her for hydration and tube feed her so she would be able to deliver her healthy baby girl.

But instead of connecting the liquid feed bag to the tube that entered her stomach, the nurse accidentally put the feed directly into her bloodstream, which is just like pouring concrete down a drain. Immediately, the fetus that was on fetal monitoring that was a healthy child, arrested, and Robin watched while the fetal monitor showed that her baby had died. Robin then began to go into respiratory distress and died within a few minutes.
ISO Design standards developed for system-specific applications

**80369 Series**
-1 General requirements

<table>
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<th>Respiratory</th>
<th>Enteral</th>
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<th>Limb Cuff</th>
<th>Neuraxial</th>
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Requirements:
- Not connectable with others in series
- Rigid or semi-rigid
- Passes Misconnection, Risk Analysis, Usability/Human Factors Testing
- Not connectable with Luer or needleless connector ports

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Design standards for system-specific applications start with enteral

ENFit®

80369-3

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Introducing ENFit®

As of July 1st 2016, ISO 80369-3 is a recognized published standard that is now ready for market introduction.

CURRENT
Male Stepped or “Christmas Tree” Connector from Administration Set

NEW
Female ENFit Connector from Administration Set

Female Feeding Tube Port

Male ENFit Connector for Feeding Tube

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GOAL: Eliminate the Long Term Need for adapters

TRANSITION SET
ENFit Transition Connector
• Temporary fitment
• From new ENFit connector to current feeding port
ADMINISTRATION SET
From Male Stepped Connector to Female ENFit:
• Pump Set
• Gravity Set
• Other Bolus Feed or Venting Devices

FEEDING TUBE
From Female Flexible Port to Male ENFit:
• NG Tubes
• G Tubes
• Low-Profile Extension Sets
• J-Tubes
SYRINGES
From oral, catheter, or Luer tip to enteral-specific fitment:
• Administer Medicine
• Flush
• Hydrate
• Bolus Feed
Dose Accuracy Concerns

- **Clinicians:**
  - Clinicians have raised concerns on dosing accuracy of small volume ENFit® syringes, due to their reverse gender orientation.
  - Clinicians and pharmacists indicated dosing accuracy expectation of ± 10% a target volume of 0.2 mL (*when delivered using a 1 mL syringe*).

- **Industry:**
  - There is no current standard (ISO, AAMI, ASTM, EN) dosing accuracy requirement or specification for oral/enteral syringes.
  - Dosing accuracy is not a standard test performed by syringe manufacturers, therefore no baseline data exists for comparison.
Proposed ENFit® Low Dose Tip Syringe

- Designed to specifically address dose accuracy concerns.
- Standard ENFit female syringe tip with an internal tip lumen.
- Orientation/configuration is similar to Luer lock syringes*
Dose Accuracy of ENFit® Low Dose Tip vs. Common Enteral/Oral Tip Syringes

ENFit LDT
E/O Overall
Reverse E
Reverse F

% Dose Accuracy (95% CI)

-2.9 10.47
-7.37 9.69
-11.2 18.00
-3.96 21.22

Note: Target is ±10% of a 0.2mL dose delivered in a 1mL syringe.
GEDSA ENFit usability study participants information

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</table>
Usability testing top level summary

• No significant differences for syringe use when filling or administering water or a thicker liquid (Pepto-Bismol)
• No significant difference for syringe use between responses of pharmacist, nurses, or caregivers
• No significant difference for syringe use when filling from a dose cup when:
  - Capping
  - Doing nothing
  - Wiping the syringe tip or
  - Tapping the syringe tip
Low Dose ENFit® Syringe Conclusion

Performance Test Results (when used as instructed):
- Dose Accuracy range of -2.90% to +10.47% (95% CI)
- 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
Mitigates risk of tubing misconnections and provides a clinical benefit that outweighs the risk of its use.

Usability:
No significant difference vs. current practice when filling or administering different viscosity fluids or between respondents (Pharmacist, Nurses, or Caregivers)

FDA Clearance:
The FDA has thoroughly reviewed and cleared two 510(k) submissions for ENFit Low Dose Tip Syringes
Best practices

- The LDT male lumen behaves similarly to the male nozzle on a standard (male) syringe.
  - LDT syringes, like standard syringes, should be tapped/flicked/wiped in order to remove fluid or air

- Method of filling the syringe (cup fill vs straw/adapter fill)
  - The straw/adapter fill method is more accurate than the cup fill method because there is less potential for excess residual fluid on the syringe to transfer to the feeding tube.
GEDSA Members have confirmed their commitment to ENFit and the introduction of syringes and feeding tubes in 2016.
Global Introduction of ENFit – NOW!

North America
Global Introduction of ENFit

Europe, Middle East, Africa, Australia & New Zealand
Global Introduction of ENFit - 2017

South America, Asia
Recommendations

- Work with your Cross Functional Team within your provider system
  - Determine the transition plan and timing that meets your needs
  - Partner with your suppliers

- Work with your Supplier Representative:
  - Understand what products available when
  - Item Number Changes? – Obtain Crosswalk
  - Make sure they have the right components you need

- Syringes:
  - Key components to ENFit Transition
  - Smaller sizes (< 3mL, possibly 5mL) should have an ENFit Low Dose Tip
  - Verify adequate supply to meet your needs

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Brochures, Presentations, FAQs & Checklists all at www.stayconnected.org

Provisional American National Standard Published

AAMI/CN3 (PS): 2014 Published

The Association for the Advancement of Medical Instrumentation (AAMI) published AAMI/CN3 (PS): 2014 on Friday, December 12, 2014. This US provisional standard is a result of the work completed on the second Draft International Standard (DIS) 80369-3 through the International Organization of Standardization (ISO) process. With the adoption of ISO 80369-3 published standard the US provisional standard will be replaced by a parallel adoption of ISO 80369-3 and the text will be aligned to the ISO standard.

The next step in the process is for the US Food and Drug Administration (FDA) to recognize this US Provisional Standard. Along with this recognition, the FDA also intends to provide additional guidance and assist in a clear regulatory pathway for all manufacturers impacted by the ISO 80369 small bore connections. This marks a significant step forward in the introduction of new, safer connectors starting with the new ENF connector external administration sets in Q1, 2015. Click here for the US, Canada, and Puerto Rico timeline and additional details on the introduction.