Global Enteral Device Suppliers Association

PRESENTS

MythBUSTING

on ENFit® Enteral Feeding Connectors

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Mike Cusack

Executive Director

GEDSA

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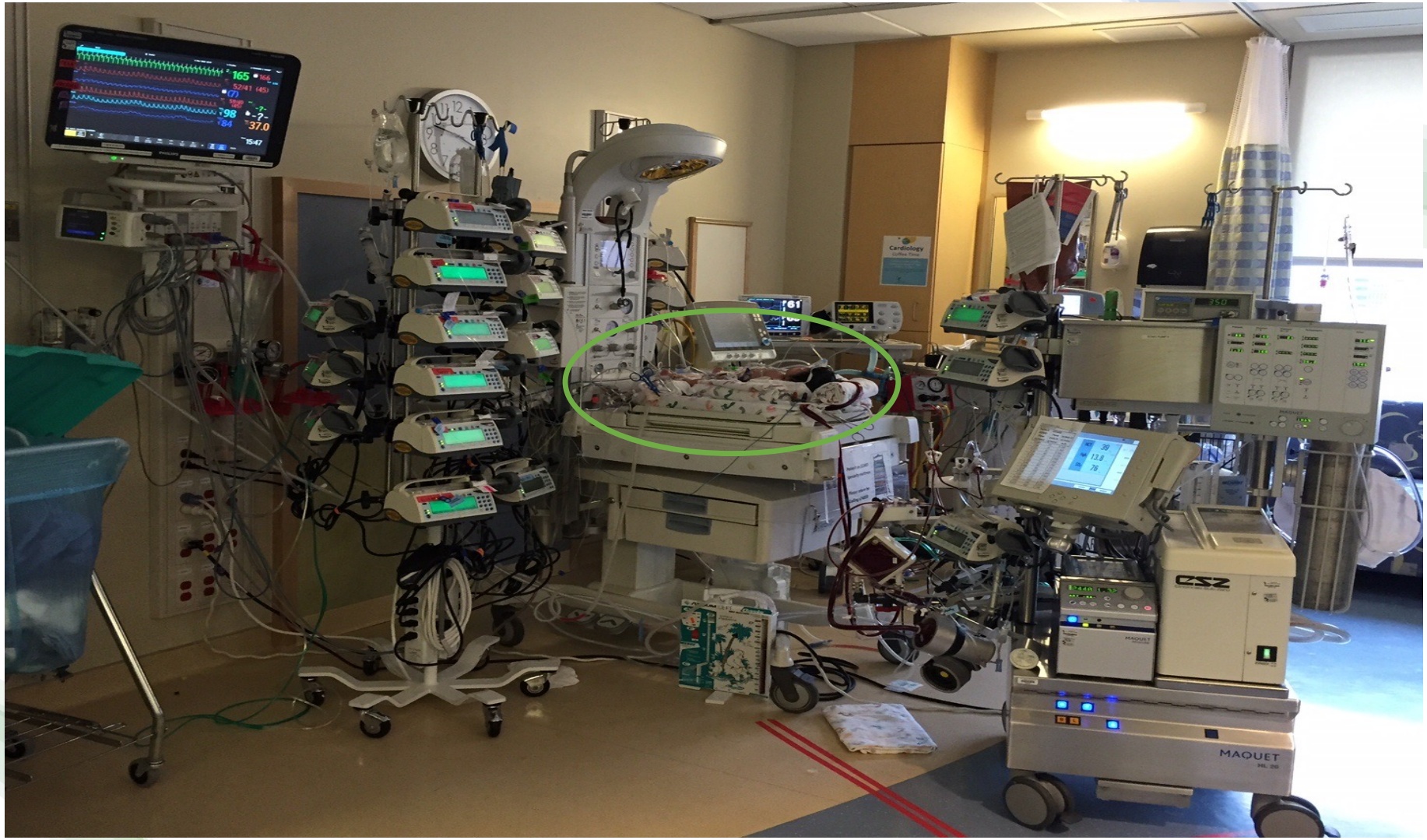
MAQUET

Christopher Falato, PharmD

Clinical Manager – Pediatric Pharmacy, University of North Carolina Children's Hospital

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Myth #1

The ENFit Low Dose Tip (LDT) syringe is not accurate enough for use in neonatal intensive care units where small variations in dosing accuracy can impact infants.

Development

- The LDT was developed after consultation with stakeholder groups including the Institute for Safe Medication Practices (ISMP), ASPEN, the American Society of Health-System Pharmacists (ASHP) and others.
- Together GEDSA & these organizations reached consensus that a +/-10% dose accuracy was accepted for a low-volume dose, such as a 0.2ml dose from a 1ml syringe.
- There is no global standardized test to evaluate dosing accuracy for syringes, so no baseline data exists.

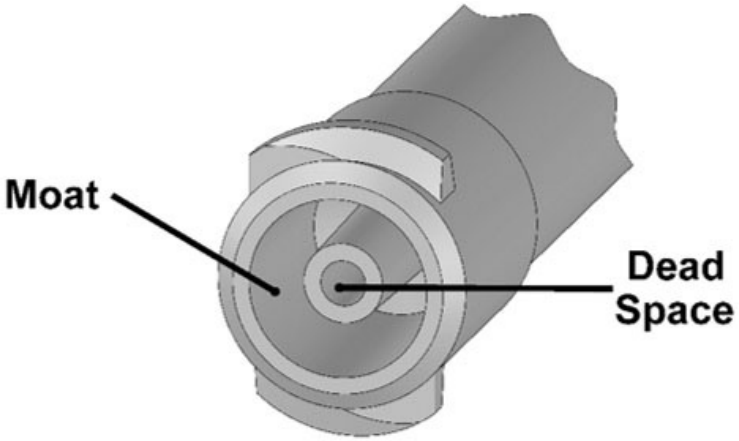
ISMP
Institute for Safe Medication Practices
An ECRI Affiliate

aspen
LEADING THE SCIENCE AND PRACTICE OF CLINICAL NUTRITION
American Society for Parenteral and Enteral Nutrition

ashp®

Regulatory Reviews & Accuracy

- The ENFit LDT syringe has passed all regulatory reviews, including the FDA as well as its counterparts in the European Union, Japan and Australia.
  - Reported +120 million sold.
- There is nothing more accurate on the market.
- LDT was substantially equivalent to legacy oral slip tip syringes and more accurate than reverse (female orientated) tip syringes.



Performance Testing

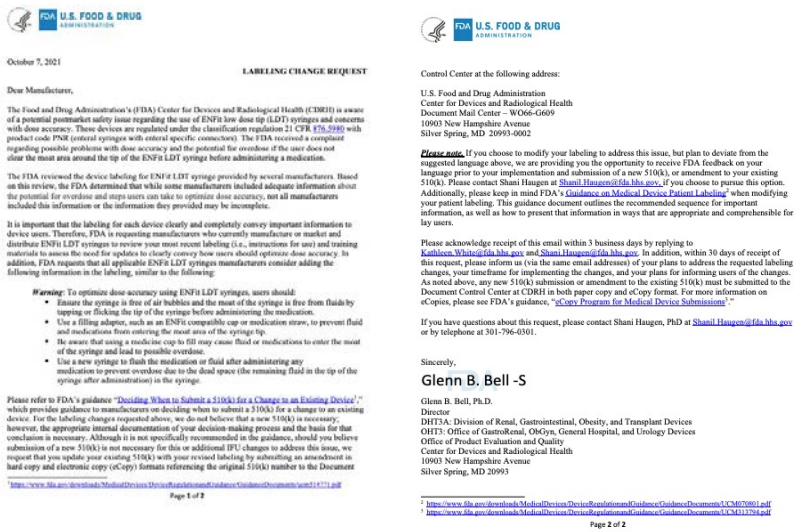
- Performance testing by an accredited third-party lab, together with usability studies conducted around the world, confirmed that the ENFit LDT syringe, when used as instructed:
  - Delivers an accurate dose substantially equivalent to current male enteral/oral slip-tip syringes
  - Outperforms existing female-oriented enteral syringes, including the reverse Luer system
- To maximize accuracy, the testing also found use of an adapter, such as a straw, delivers better performance than a cup fill.
- It is common practice to tap/flick a syringe to remove air bubbles. GEDSA and manufacturers recommend the same practice to remove any medication outside the fluid pathway.

Proven Results

- Beyond tests and studies, ENFit and the LDT syringe are proven to work in care settings around the world. They have been used with millions of patients across the European Union and other countries with no reported incidents.
- In the United States, these syringes and connectors have been used by leaders in patient centric care such as
  - Mayo Clinic
  - Rady Children's Hospital San Diego
  - Children's Mercy Hospital of Kansas City
  - Children's Hospital of Los Angeles
  - Lurie Children's Hospital of Chicago
  - Lucile Packard Children's Hospital Stanford
  - Children's Hospital of Orange County
  - UCLA Medical Centers.
  - Akron Children's Hospital
  - UNC Children's Hospital
  - *These organizations have done their own testing and concluded ENFit adoption was best for the safety of their patients.*

The FDA's Recent Safety Communication on Dosing Accuracy

- Important takeaway: no reports of overdose or injury, just reported concerns.
- As a result of the FDA's investigations, they "sent letters to manufacturers requesting they update their labeling and training materials" to include expanded instructions on proper product use (FDA, 2021).
- In support of their previous statement in 2017, "The FDA continues to recommend the use of enteral devices and syringes that reduce the risk of misconnections, such as ENFit LDT syringes." (FDA, 2021).



U.S. FOOD & DRUG ADMINISTRATION

October 7, 2021

LABELING CHANGE REQUEST

Dear Manufacturer,

The Food and Drug Administration's (FDA) Center for Devices and Radiological Health (CDRH) is aware of a potential postmarket safety issue regarding the use of ENFit low dose tip (LDT) syringes and concerns with dose accuracy. These devices are regulated under the classification regulation 21 CFR §76.5980 with product code PNR (enteral syringes with enteral specific connectors). The FDA received a complaint regarding possible problems with dose accuracy and the potential for overdose if the user does not clear the moat area around the tip of the ENFit LDT syringe before administering a medication.

The FDA reviewed the device labeling for ENFit LDT syringe provided by several manufacturers. Based on this review, the FDA determined that while some manufacturers included adequate information about the potential for overdose and steps users can take to optimize dose accuracy, not all manufacturers included this information or the information they provided may be incomplete.

It is important that the labeling for each device clearly and completely convey important information to device users. Therefore, FDA is requesting manufacturers who currently manufacture or market and distribute ENFit LDT syringes to review your most recent labeling (i.e., instructions for use) and training materials to assess the need for updates to clearly convey how users should optimize dose accuracy. In addition, FDA requests that all applicable ENFit LDT syringes manufacturers consider adding the following information in the labeling, similar to the following:

Warning: To optimize dose accuracy using ENFit LDT syringes, users should:

- Ensure the syringe is free of air bubbles and the moat of the syringe is free from fluids by tapping or flicking the tip of the syringe before administering the medication.
- Use a filling adapter, such as an ENFit compatible cup or medication straw, to prevent fluid and medications from entering the moat area of the syringe tip.
- Be aware that using a medicine cup to fill may cause fluid or medications to enter the moat of the syringe and lead to possible overdose.
- Use a new syringe to flush the medication or fluid after administering any medication to prevent overdose due to the dead space (the remaining fluid in the tip of the syringe after administration) in the syringe.

Please refer to FDA's guidance "Deciding When to Submit a 510(k) for a Change to an Existing Device[1]," which provides guidance to manufacturers on deciding when to submit a 510(k) for a change to an existing device. For the labeling changes requested above, we do not believe that a new 510(k) is necessary; however, the appropriate internal documentation of your decision-making process and the basis for that conclusion is necessary. Although it is not specifically recommended in the guidance, should you believe submission of a new 510(k) is not necessary for this or additional IFU changes to address this issue, we request that you update your existing 510(k) with your revised labeling by submitting an amendment in hard copy and electronic copy (eCopy) formats referencing the original 510(k) number to the Document

[1] https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm514771.pdf

Page 1 of 2

U.S. FOOD & DRUG ADMINISTRATION

Control Center at the following address:

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Please note. If you choose to modify your labeling to address this issue, but plan to deviate from the suggested language above, we are providing you the opportunity to receive FDA feedback on your language prior to your implementation and submission of a new 510(k), or amendment to your existing 510(k). Please contact Shani Haugen at Shanil.Haugen@fda.hhs.gov, if you choose to pursue this option. Additionally, please keep in mind FDA's Guidance on Medical Device Patient Labeling[2] when modifying your patient labeling. This guidance document outlines the recommended sequence for important information, as well as how to present that information in ways that are appropriate and comprehensible for lay users.

Please acknowledge receipt of this email within 3 business days by replying to Kathleen.White@fda.hhs.gov and Shani.Haugen@fda.hhs.gov. In addition, within 30 days of receipt of this request, please inform us (via the same email addresses) of your plans to address the requested labeling changes, your timeframe for implementing the changes, and your plans for informing users of the changes. As noted above, any new 510(k) submission or amendment to the existing 510(k) must be submitted to the Document Control Center at CDRH in both paper copy and eCopy format. For more information on eCopies, please see FDA's guidance, "eCopy Program for Medical Device Submissions[3]."

If you have questions about this request, please contact Shani Haugen, PhD at Shanil.Haugen@fda.hhs.gov or by telephone at 301-796-0301.

Sincerely,

Glenn B. Bell -S

Glenn B. Bell, Ph.D.
Director
DHT3A: Division of Renal, Gastrointestinal, Obesity, and Transplant Devices
OHT3: Office of GastroRenal, ObGyn, General Hospital, and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health
10903 New Hampshire Avenue
Silver Spring, MD 20993

[2] https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM070801.pdf
[3] https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM311754.pdf

Page 2 of 2

https://www.fda.gov/medical-devices/safety-communications/potential-medication-overdose-enfit-low-dose-tip-syringe-fda-safety-communication?utm_medium=email&utm_source=govdelivery

Truth #1

The ENFit LDT syringe has been tested and proven safe when used as instructed & addresses any dosing concerns for our smallest, most vulnerable patients.

Barbara Fleming, MS, APN, RNC-NIC, C-ELBW

Clinical Nurse Specialist- NICU,
Ann & Robert H. Lurie Children's Hospital of Chicago

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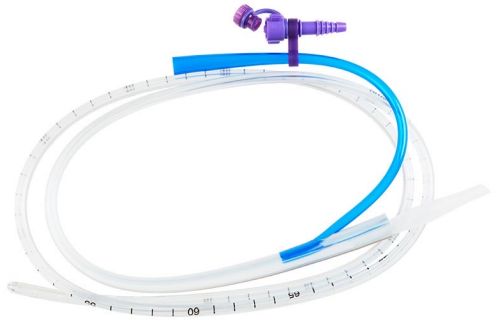
Myth #2

ENFit’s design does not allow venting and draining that is needed to fully convert facilities and support home feeding experience.

Clinical Nurse Specialist Perspective

- Feeding tubes are designed to feed and are subject to the ISO Standard for ENFit® connectors. Decompression tubes are intended to drain and vent and not intended for feeding.
- But the clinical reality is sometimes feeding tubes need to vent and sometimes drainage tubes are used to feed or administer medications.
- Whatever the clinical need, there are SAFE options.

Products that address concerns



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Disclaimer: The products & details mentioned in the next slides are shared based on personal use & experience . These are intended to be examples of what is currently available in the healthcare market and not an exhaustive list. This is in no way endorsement or promotion of any mentioned products by the presenters or GEDSA. The goal is to share knowledge of available resources & help with concerns of products and availability.

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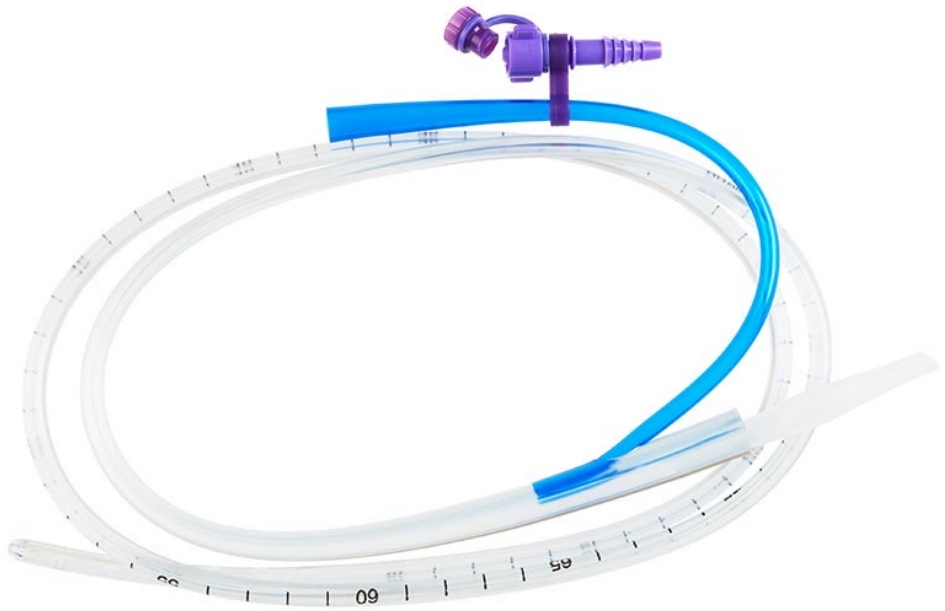
Salem Sump

Cardinal Health offers a Kangaroo™ Salem Sump™ PVC tube with ability to decompress or feed with the added safety of ENFit® to reduce risk of misconnections.



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Multi-Functional Port with Safe Enteral Connections

Cardinal Health offers Kangaroo™ Salem Sump™ Silicone Tube with a multifunctional port and ARV

All-in-one enteral system that allows for feeding, medication, irrigation, checking residuals and suction all through one closed port.

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Hybrid GT Extension Sets

AMT offers a Hybrid GT extension set in which the medication port is ENFit® but the drainage port is a funnel shaped connector

Supports gastric decompression by gravity or suction via a low profile button type GT or GJT.

Drainage Bags

GBUK offers DEHP & Latex Free Enteral Drainage bags (Variety of sizes 50-1000 ml) that fit all ENFit® compliant tubes.

Cardinal Health is planning to introduce an ENFit® compliant gastric drainage bag.

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Closed Venting System

Avanos offers a FARRELL Valve System in which the vented bag allows the escape of gas, while also providing a reservoir to retain excess formula in a closed system.

The FARRELL Valve supports continual decompression of stomach, while allowing the stomach to fill at its own pace

Transition Adaptors: BE AWARE!

Connects an ENFit Feeding set or ENFit syringe to a legacy feeding tube

Initial need for transition adaptors during “transition” but then develop a planned timeline for the discontinuation of routine use of these adaptors.

Brittany Detrick

Enteral Feeding Patient

paralyzed gastrointestinal tract

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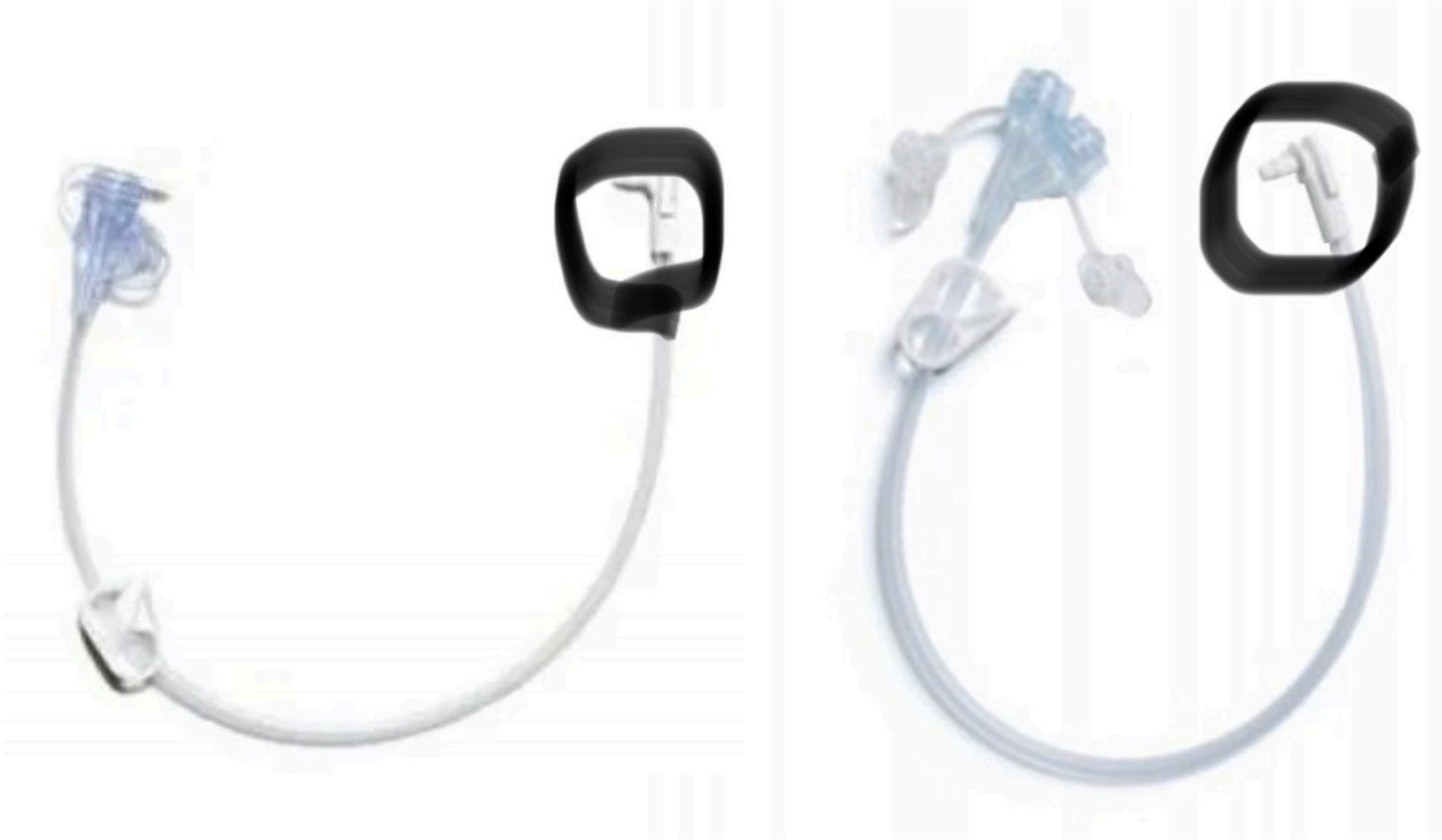
Home Feeding Patient Perspective

- Being able to use ENFit to drain means the extension will **not** come apart
  - No leakage or spilling of contents or formula
- With the use of ENFit, you don't need extra connectors, etc. it just screws in (i.e. no AMT clamps)
  - This eliminates all additional products I used to have to have on hand

Home Feeding Patient Perspective

Legacy vs. ENFit Bayonet

- People say you can’t drain out of ENFit because the “bayonet” is small, but it’s the same size as legacy & works just fine



Truth #2

ENFit's design **does** allow for proper venting and draining that is needed to fully convert facilities.

ENFit not only supports but has improved the venting and drainage experience for the home feeding consumer.

Ruba Abdelhadi, MD

Professor of Pediatrics, UMKC School of Medicine; Director, Nutrition Support, Kansas City's Children's Mercy Hospital, Associate Director for Education and Staff Development

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Myth #3

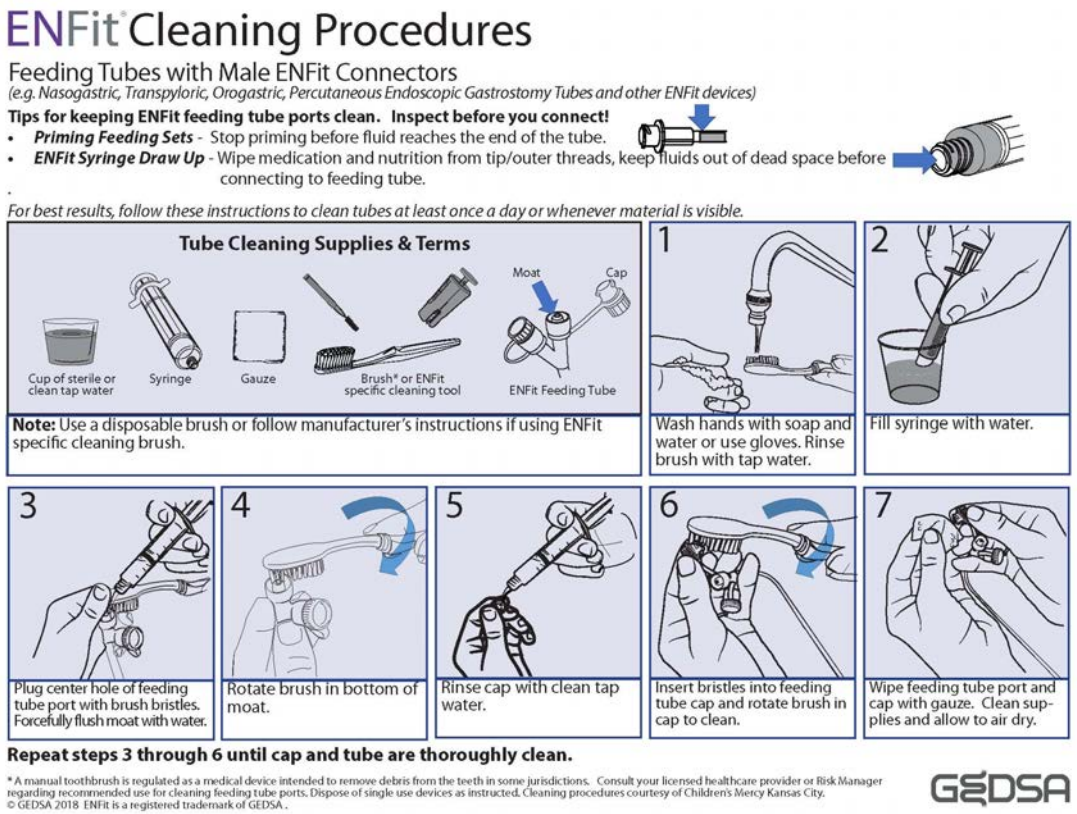
ENFit’s moat design makes it hard to clean and creates unacceptable levels of bacteria.

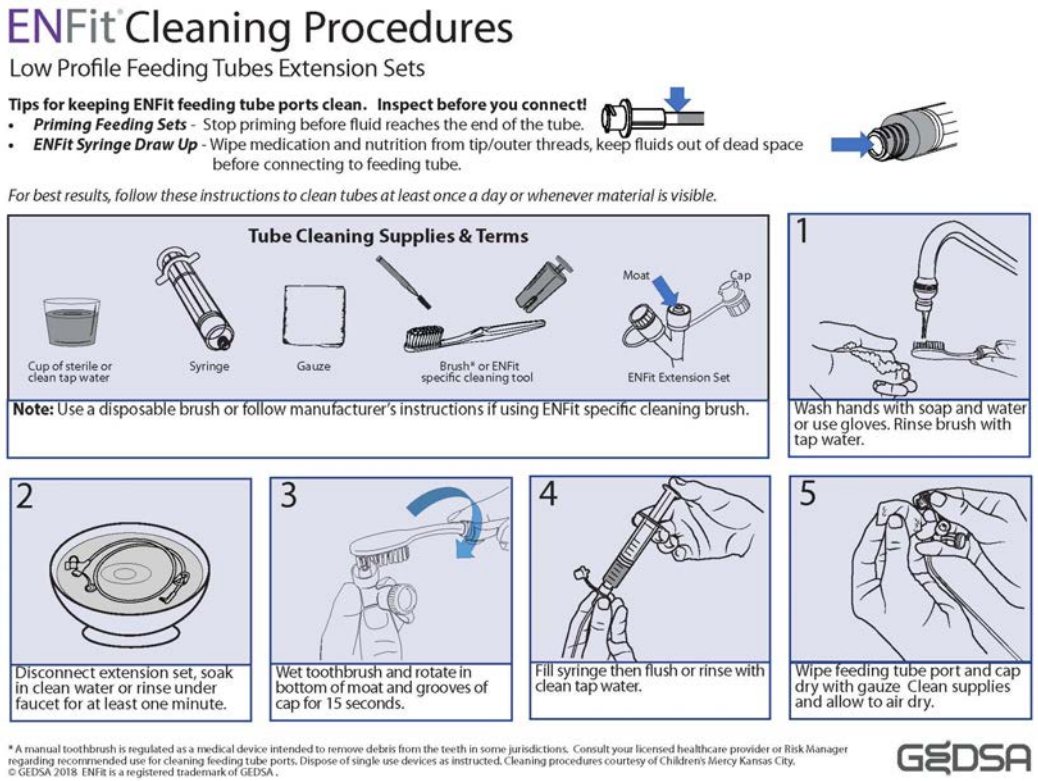
Cleaning Materials

- GEDSA and others have developed job-specific sets of special brushes and training materials to help hospitals with the transition (standard cleaning materials like Kimwipes® and common brushes can also be used).
- Based on our experience in the U.S. and around the world, hospital staff are readily able to adapt to the cleaning process and ensure residual is removed and the tubes are safe to use.

Cleaning Procedures

Establish local procedures on how to clean tubes/moats.





Trial Assessment of the effectiveness of cleaning regimens for ENFit® Connectors: *https://stayconnected.org/wp-content/uploads/2021/01/Randomized-Controlled-Trial-Assessing-the-Effectiveness-of-Two-Cleaning-Regimens-for-ENFit-Connectors.pdf*

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Cleaning Procedures

- Kansas City Children's Mercy Hospital developed and tested the ENFit cleaning protocol that forms the basis for the ENFit instructions. In addition, this data was submitted to the FDA as part of the normal product review process.

- The FDA specifically instructed Children's Mercy not to include bioburden testing in the review process. The GI tract standard is not sterile, so the relevant standard under FDA guidelines is cleanliness – roughly equivalent to dish washing – not sterility.

Truth #3

ENFit’s moat is no more difficult to clean than any other. With the tested and proven cleaning procedures and tools you can ensure ENFit is ready to use and all the residual is removed.

Cynthia Reddick, RD, CNSC

National Tube Feeding Manager, Coram/CVS Specialty Infusion Services

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Myth #4

ENFit doesn’t meet the needs of the home-feeding community because the connectors have a narrower opening that slows feeding.

Home-Feeding with ENFit

- Standard and Blenderized Tube Feeding (BTF)

  Mayo Clinic study concluded that ENFit vs. Legacy syringe compression force and gravity feeds showed no significant difference except with 14 Fr tubes*.

  - BTF Blender selection
  - BTF Blending time
  - BTF Recipe/Formula choice

- Gravity Flow Rate Comparison

  FDA Study of performance concluded that flow rates of ENFit vs. Legacy was not strongly correlated with formula choice.

  - On average, the 20 minute feeding increased to 25 minutes
  - 70% of ENFit devices had lower flow rates than Legacy counterpart
  - Estimated that 30% of the difference in flow rate would be noticeable
  - No increase in tube clog frequency

Mundi, Manpreet S et al. Comparison of Syringe Compression Force Between ENFit and Legacy Feeding Tubes. *JPEN. Journal of parenteral and enteral nutrition* vol. 43,1 (2019): 107-117. doi:10.1002/jpen.1174

Mundi MS, Duellman W, Epp L, Davidson J, Hurt RT. Comparison of Gravity Flow Rates Between ENFit and Legacy Feeding Tubes. JPEN J Parenter Enteral Nutr. 2018 Mar;42(3):522-528.

Guha, Suvajyoti et al. In Vitro Performance Testing of Legacy and ENFit Gastrostomy Tube Devices Under Gravity Flow Conditions. JPEN JPEN J Parenter Enteral Nutr. 2018 Nov;42(8):1334-1341.

*Dr. Mundi's later research negates this.

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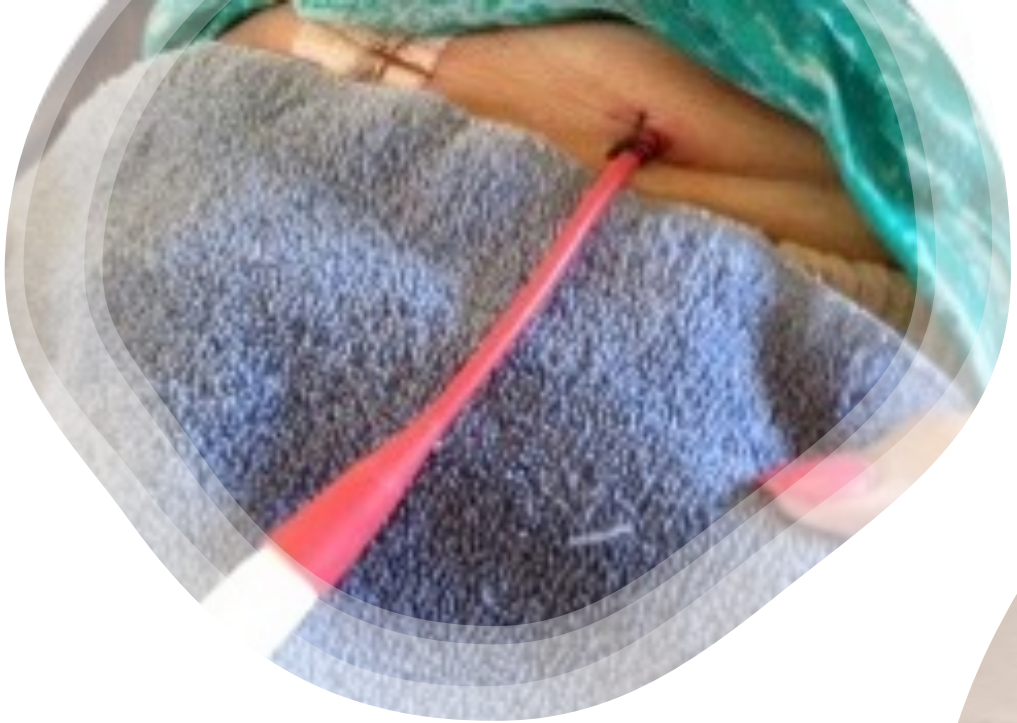
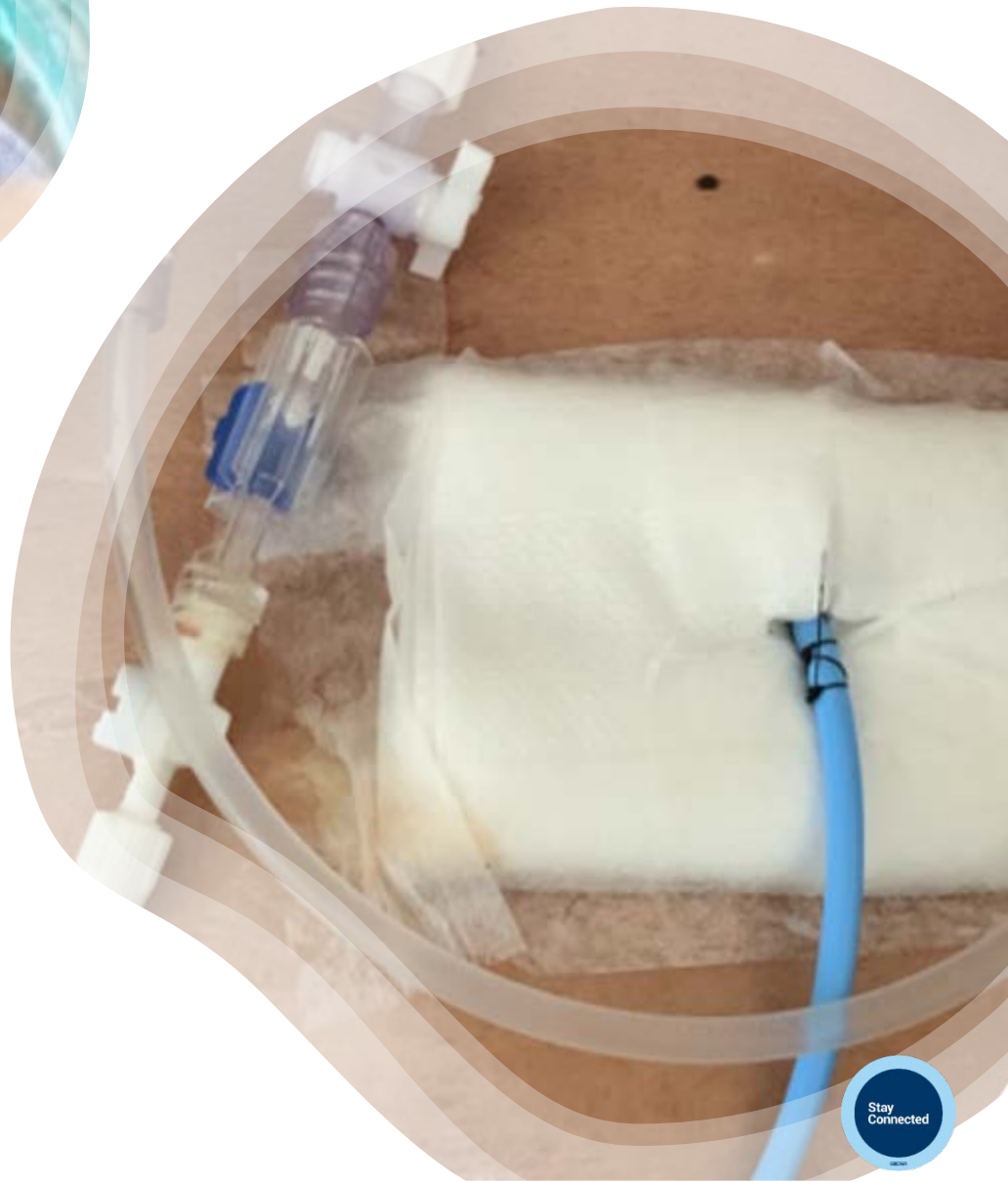
Home-Feeding without *"Feeding the Bed"*

"Feeding the bed" is a common term used to describe unintended disconnections that result in infusion of formula or spills that go unnoticed.

- **Legacy connections can 'pop out' or disconnect** with gastric pressure, coughing, or movement.
- **Legacy connections sometimes require the use of a clamp or tape** to secure the connection.
- **ENFit connections are secure** and reduce or eliminate accidental disconnection.
- **ENFit connections reduce or eliminate accidental spills** from venting with a syringe or bag





Portability of Care and Standardizing Connections

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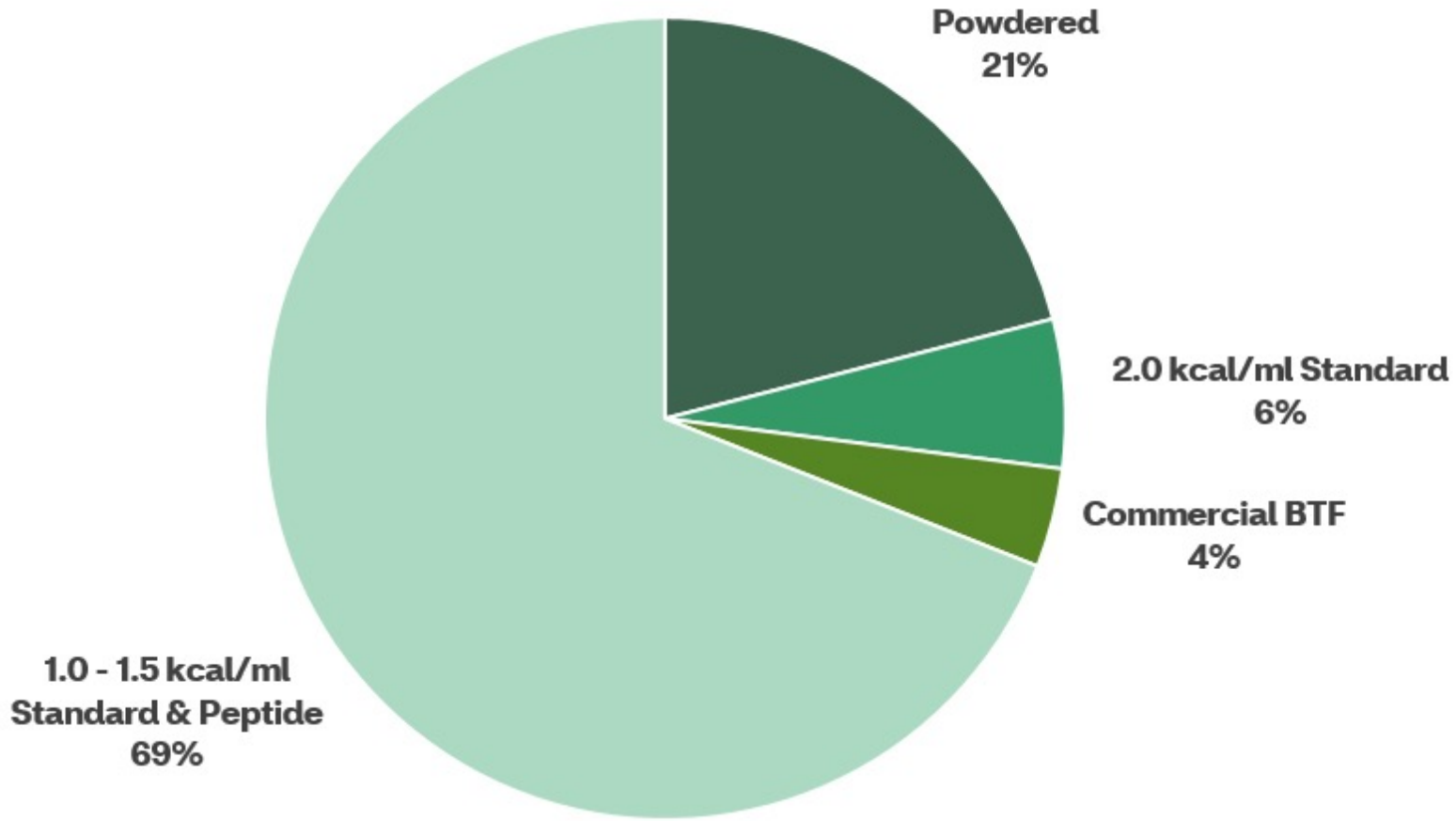
ENFit Consumers by Formula Type



Data Source: Coram/CVS Specialty Infusion Services

ENFit Consumers by Tube Type

Tube Type n = 1703 (14%)		
Gastric	55%	Long Term Tube 68%
GastroJejunostomy	4%	
Jejunal	9%	
NasoGastric	25%	Short Term Tube 32%
NasoJejunal	7%	

Data Source: Coram/CVS Specialty Infusion Services

Truth #4

ENFit meets the needs of the home-feeding community while also preventing disconnections & avoiding feeding the bed (or ‘vomiting’).

Mike Cusack

Executive Director

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Myth #5

ENFit does not really fix the problem of misconnections.

Luer Connector in Widespread Use

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ECRI Top 10 Technology Hazards

- ECRI published “Top 10 Technology Hazards for 2012”, a practical guide to identifying technology risks at health care facilities.
- The guide addresses 10 medical technologies that most frequently lead to patient injuries (and historically, malpractice lawsuits):
  - Alarm hazards
  - Exposure hazards from radiation therapy and CT
  - Medication administration errors using infusion pumps
  - Cross-contamination from flexible endoscopes
  - **Inattention to change management for medical device connectivity**
  - **Enteral feeding misconnections**
  - Surgical fires
  - Needlesticks and other sharps injuries
  - Anesthesia hazards due to incomplete pre-use inspection
  - Poor usability of home-use medical devices

http://www.krogerlaw.com/blog/2012/02/medical-technology-risk-management-ecri-institute-releases-top-10-hazards-guide/

Simmons et al. 2010 Literature Review

- 116 Cases
  - 21 Died (18%)
  - 95 Survived (82%)
  - 84 of the 95 had at least 1 diagnosis reported 37/84 respiratory conditions including arrest (44%)
  - 16/84 had sepsis (19%)
  - 11/84 had neurological harm (13%)
  - 8/84 had renal impairment (9.5%)
  - 1/84 had hypersensitivity/hypercoagulopathy

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
- **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
- **Feeding tube was coupled with a peripheral line of a pregnant woman**, resulting in enteral nutrition delivered directly into the bloodstream; neither the 35-week-old fetus nor the woman survived


A Global Effort to Enhance Patient Safety
Technical Experts
ISO 80369
Small-bore connectors
Clinical Experts
Regulatory/ Standards Experts
Stay Connected 2015
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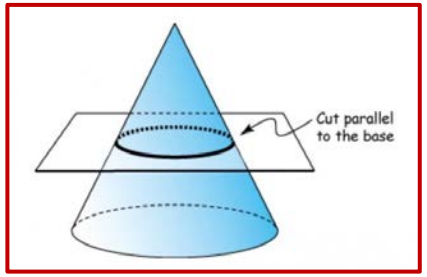
The Big Picture
A Family of Connectors

80369 Series

Respiratory	*Enteral*	Urological	Limb Cuff	*Neuraxial*	Intravascular
-2	**-3**	-4	-5	**-6**	-7

- **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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Regulatory Support

- FDA letter " Encourages Use of Enteral Device Connectors that Reduce Risk of Misconnection and Patient Injury"
- TJC Sentinel Alert and Physician Leaders Communication
  - March *Still Relevant* Release
- CMS Alert on Luer Misconnection Adverse Events
- ASPEN Position Statement
- ISMP/ECRI Statement

FDA

The Joint Commission

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

ISMP
Institute for Safe Medication Practices
An ECRI Affiliate

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American Society for Parenteral and Enteral Nutrition

Truth #5

ENFit is one connector out of a family of connectors that when completely converted to, will prevent small-bore misconnections.

Ben Davis

President, Adavation LLC

Acting/Interim Chairman of the GEDSA BOD

Expert in Enteral Device Engineering & Product Development

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Myth #6

ENFit is a solution in search of a problem so manufacturers can profit.

Creation of the new standard

- The popularity of the Luer connection resulted in it being used very universally, beyond just IV applications. This created the opportunity for misconnection between incompatible bodily systems. In 2006 the Joint Commission issued a Sentinel Event Alert on tubing misconnections*.
- A Working Group within ISO's Technical Committee 210 was established to resolve misconnections between small-bore connectors. This resulted in the ISO 80369 series of standards.
- This effort is led by clinical, technical and regulatory experts, and manufacturers, within the framework of the International Organization for Standardization (ISO).

What ENFit means for Manufacturers

- R&D costs
  - Engineering / Product Development
  - Performance Verification
  - Usability/Validation
  - Intellectual Property
  - Syringe Pump Characterization
- Regulatory costs
  - FDA 510(k) packet assembly and submission costs
  - MasterFile Costs
  - Possible Remediation Work

What ENFit means for Manufacturers

- New Tooling Costs
  - Syringe Barrels (0.5/1/3/5/12/12v/20/20v/60/100mL)
  - Syringe Tip Caps
  - Male tubing connectors/hubs
    - Closures for male hubs/connectors
    - Dual Port Connectors
  - Female tubing connectors/hub
    - Dust covers/closures for female hubs
  - Accessories
    - Temper Evident Syringe Caps
    - Specialized oral administration products
    - Medication Bottle Adapters
      - Screw On (A/B/C/D/E/G/I)
      - Press-In Bottle Adapters (up to 7 sizes)
      - Bung Adapters (2 sizes)
      - Fill Cap Coupler
    - Female/Female Adapter
    - Milk Transfer Lids
    - Specialized Cleaning Tools

What ENFit means for Manufacturers

- Increased Manufacturing Capacity Costs
  - New Injection Molding Machines
  - Parallel Syringe Barrel Print Lines
  - Increased Tubing Extrusion Capacity
  - Parallel Packaging Lines and Materials
  - Increased sterilization capacity
  - Increased Clean Room Manufacturing Space
- Increased Warehousing and Logistical Costs
  - Additional warehousing space to accommodate dual product lines
  - Increased logistical/freight costs for carrying two product lines.
- Business Costs
  - Marketing of new products
  - Training of sales reps

Truth #6

This is a patient safety initiative that was born from the clinical community and then spearheaded by clinical, technical and regulatory experts, and manufacturers, within the framework of the International Organization for Standardization (ISO).

There actually have been enormous costs associated with this initiative, yet there has not been a noted uptick in product pricing.

Q&A

Thank You!

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Supporting Articles & Recommendations

For full references and articles visit StayConnected.org

1. The Joint Commission issues “Sentinel Event Alert, Issue 36: Tubing misconnections- a persistent and potentially deadly occurrence to increase awareness of tubing misconnection errors”
2. Association for the Advancement of Medical Instrumentation (AAMI) publishes “ISO 80369-1 Small bore connectors for liquids and gases applications” and is recognized by the FDA
3. The Food and Drug Administration (FDA) publishes a guidance on “Safety Considerations to Mitigate the Risks of Misconnections with Small bore Connectors Intended for Enteral Applications”
4. Institute for Safe Medication Practices (ISMP) publishes Medication Safety Alert” ENFit Enteral Devices are on their way… Important safety considerations for hospitals”
5. Center for Medicare & Medicaid Service (CMS) addresses State Survey Agency Directors on “Luer Misconnection Adverse Events”
6. ECRI Institute releases “Critical Notice–Avoid Fatal Misconnections with ENFit-compliant Feeding Tube Connectors”
7. American Society for Parenteral and Enteral Nutrition (ASPEN) publishes “A.S.P.E.N. Supports Major Medical Device Changes for Improved Patient Safety”
8. American Journal of Health-System Pharmacy (ASHP) publishes “Transition to ENFit enteral devices: Special challenges for pediatric institutions”
9. British Association for Parenteral and Enteral Nutrition (BAPEN) published “ISO 80369-3: IMPORTANT UPDATE – ENFit Implémentation“
10. National Health Services (NHS) publishes a patient safety alert “Stage One: Warning Managing risks during the transition period to new ISO connectors for medical devices “
11. Dose Accuracy – Performance Testing of Enteral, Oral, ENFit and ENFit LDT Syringe, by Ashley Deken, Ben Davis, Andy Giles, Crystal Koelper, Don McMichael, Pete Phillips
12. Sentinel Event Alert: The Joint Commission, August 20, 2014
13. ENFit Implementation: Pharmacy Keys to Success, Valley Children’s Healthcare (Video)
14. Reducing the Risk of Medical Device Tubing Misconnections, GEDSA, 2014
15. ENFit Cleaning Procedures, GEDSA, 2018

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