GEDSA Stay Connected
Enteral Feeding Device Connector Changes...
Introducing ENFit

June 2015
Objectives

• Explain why new tube feeding connectors are needed at home
• Outline timing and transition plan for new connectors
• Hands on experience with manufacturers and the new connectors
Stay Connected Initiative

• Global communications program to introduce new standard connectors
• An effort to improve patient safety by reducing the risk of medical device tubing misconnections
• Four phases—Aware, Prepare, Adopt & Measure to facilitate the transition
• Starting in 2014 with enteral devices
• Introduce new standard connectors for other delivery systems including neuraxial, and respiratory applications
• www.StayConnected.org
GEDSA/ Stay Connected Members

- Abbott
- AbbVie
- A. Hopf
- Alcor Scientific
- Amsino
- Baxter
- B Braun
- BD
- Boston Scientific
- Cair Lgl
- Cedic/Entek
- Cook Medical
- Corpak
- Covidien
- Dale Medical
- Degania
- Enteral UK
- Fresenius Kabi
- Halyard (formerly Kimberly Clark)
- VR Medical
- Medela
- Medicina
- Medline
- Moog
- NeoMed
- Nestle
- Nutricia
- Pajunk
- Smith’s Medical
- Teleflex
- Vygon
- Xeridiem
Stay Connected Partnership of Industry, Supply Chain, Clinician & Patient
The Luer connector is a classic type of a small-bore connector used commonly in the healthcare setting—a universal connector.
The Problem with Universal Luer Design

- Medicine
- Oxygen
- Fluids

One Connector Design
The Challenge: Connecting a System Designed Not to Connect

**CURRENT**

Male Stepped or “Christmas Tree” Connector from Administration Set

Female Feeding Tube Port

**NEW**

Female ENFit Connector from Administration Set

Male ENFit Connector for Feeding Tube
ENFit Transition Connector

Current: Female ENFit Connector from Administration Set

Temporary Transition: Female Feeding Tube Port

NEW:
US Enteral Patient Access Estimated Launch Timelines

ENFit Connector Transition

- **2014**
  - Q1 2015: Stay Connected Initiative Launched
- **Q1 2015**
  - FDA Recognized ANSI/AAMI Standard
- **Feb ‘15**
  - Transition Set Launch
- **May ‘15**
  - New ENFit Syringe Launch
- **July ‘15**
  - Launch ENFit Tubes
- **Aug ‘15**
  - ISO Standard Approval
- **Dec ‘15**
  - Estimated Launch Timelines
- **Q1 ‘16**
  - Stay Connected
• It is a TEMPORARY device allows fitment to current feeding ports until new enteral feeding tubes are available.

• Available Q4 2014 in all administration sets

• Used during year of transition.
ENFit transition connector: Tips

• For best performance wash tubes and connectors with warm soapy water and thoroughly dry between use

• Attach the transition connector with the ENFit set by turning clockwise

  • Note: Use only your hands to attach the transition connector. If you use tools the connector may become damaged
• Syringes to administer medicine, flushes, supplemental hydration, or bolus feeding through the enteral tubes.

• Will now require this Enteral Specific syringe with ENFit female connector

• Oral, Luer or cath-tip syringe will no longer fit

• Available Q1 - 2016
ENFit Feeding Tube

• Reversed orientation from female to male port

• Locking & forcing function features

• All enteral and multi-purpose ports will have an ENFit connector

• Available Q1 2016
Blenderized Diet Testing

- Flow rate testing was conducted to compare the performance of ENFit along with systems using current connectors.
- Testing was performed with commercially available viscous formulas and samples of blenderized diets similar to what is used in practice.
- Different feeding tube systems were tested including:
  - Low profile feeding tube system with “Bolus” extension set
  - G-Tube – Silicone balloon retained feeding tube
  - PEG – Initial placement feeding tube with solid silicone bolster and attachable feed head
  - GJ– Dual lumen, balloon retained, Jejunal feeding tube with gastric decompression lumen
Bore Size: System Cross-Section Drawings

ENFit Syringe
- Transition Connector
- Funnel Adapter
- Extension Set
- MIC-KEY Tube

Cath Tip Syringe
- Funnel Adapter
- Extension Set
- MIC-KEY Tube
The blenderized diet tests found:

• There are no significant differences between ENFit and Cath tip syringes with blenderized diets

• There is no significant difference between room temp and refrigerated blenderized diet in any of the tubes
What you can do:

• Spread the word
• Stay informed
• Sign Up for email updates at stayconnected.org
What you can do:
• Use current products as usual
• Use as directed
• Do not hoard
What you can do:

• Use all remaining current products before starting to use new connectors
• Use Transition Connector
• Replace feeding tubes when according to medical necessity,
• Do not replace prematurely just for new connector
Stay Connected: Enteral US, Canada and PR Timeline

Four Phased Approach

- AWARE: Through Summer 2014
- PREPARE: Fall 2014/Winter 2015
- ADOPT: Q3 2015; Q1 2016
- MEASURE: 2016
• Become a champion for change

• Spread the word

• Stay Connected - Go to www.StayConnected.org

• Adopt the new connectors
Sign Up to Stay Connected

www.StayConnected.org

- alerts and updates
- tools and information
- references
• FAQs, Brochures, Articles, References and Other Resources at: www.StayConnected.org
• EN Safety Campaign: A.S.P.E.N website: www.nutritioncare.org/ENToolkit
• AAMI website: http://www.aami.org/hottopics/connectors/index.html
• FDA Website: http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/TubingandLuerMisconnections/default.htm
• Thanks for your attention and participation

• Visit manufacturers to address your product specific questions

• Visit the GEDSA table as well as all our member manufacturers

Thank you again!
Questions?