Dynarex Introduces New ENFit® Connectors in accordance with the FDA

Your Medical Products Partner

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Feeding Tube Erroneously Connected to Trach Tube An infant in the pediatric intensive care unit had both a feeding tube and a trach tube. The feeding tube was inadvertently placed in the trach tube and milk was delivered into the infant’s lungs, resulting in death.

Feeding tube connected to an in-line ventilator suction catheter A patient’s feeding tube was inadvertently connected to the instillation port on the ventilator in-line suction catheter. Tube feeding was delivered into the patient’s lungs, resulting in death.

A 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.
Changes being done to the current Universal connectors

What is being done?

1. FDA collaborated with International Organization for Standardization (ISO) and the Association for the Advancement of Medical Instrumentation (AAMI) to develop the ISO 80369 series of standards.

2. ISO 80369-3 specifies the dimensions and requirements for the design and functional performance of these small-bore connectors intended to be used as connections in enteral applications of medical devices and accessories to ensure non-inter-connectability.

3. California Senate Bill No.158: “Prohibit the use of intravenous, epidural, or enteral feeding connections that would fit into a connection port other than the type it was intended for…”. Mandate takes effect January 1, 2016

4. Global Enteral Device Supplier Association (GEDSA) is a nonprofit trade association made up of manufacturers, distributors, and suppliers —helps educate and introduce the new international standards in medical device tubing connectors to enhance patient safety.
Stay Connected

The **Stay Connected** initiative for using safer connectors is a three-phase program. Through the Aware, Prepare, and Adopt phases, GEDSA will help facilitate a successful transition to safer connectors.

**Website:** StayConnected.org
Be Aware of new up and coming changes in your medical environment

- Build awareness across the facility/provider to all impacted clinicians, administrators, supply chain and support staff.
- Communicate Who, What, Where, When, Why & How they will be Impacted
Be Prepared

- Approve product changes and prepare materials/inventory management
- Train Clinicians and Materials/Inventory Management Staff
- Assess processes and protocols that may need to change.
Adopting the Right Practice

• Introduce new connectors into work stream to reduce tubing misconnections and improve patient safety.
• Transition and integration into the medical practice.
• Remind the organization of the long-term benefits vs. the short-term hassles of transitioning to new connectors.
Current Enteral Feeding System

Phase 1: 2012
Change of proximal-end connector for closed system containers

New design for closed system containers compatible with the new proximal-end connector

Purpose: incompatible with IV ports
Phase 2:

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What is ENFit™ mean?

It’s a new enteral connector that will be phased in across the enteral device industry.

CHANGES

**Administrative Sets**

- **Tradition Male**
  - Stepped or “Christmas Tree” Connector.
- **Female ENFit Connector**

**Enteral Syringes**

- Traditional piston syringe
  - Syringe with ENFit Tip
- Traditional G-Tube Syringe

**Feeding Tubes**

- ENfit G-Tube

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ENFit™ connector unique design

Female distal connector
Enteral Feeding set

Male distal connector
Feeding tubes

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<table>
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<th>Phase 1</th>
<th>Phase 2</th>
<th>Phase 3 – TBD Coming at a later date</th>
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<td>Traditional Sets</td>
<td>Administration Kits*</td>
<td>Administration Sets**</td>
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<tr>
<td><strong>Item # 4272</strong> DynaSpike Enteral Delivery Pump Set</td>
<td><strong>Item # 4274</strong> (1) DynaSpike Enteral Delivery Pump set with ENFit Connector (1) Transition Connector</td>
<td><strong>Item # 4274</strong> DynaSpike Enteral Delivery Pump set with ENFit Connector</td>
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<td><strong>Item # 4277</strong> Enteral Delivery Gravity Bag set – 1200cc</td>
<td><strong>Item # 4280</strong> (1) Enteral Delivery Gravity Bag set with ENFit Connector (1) Transition Connector</td>
<td><strong>Item # 4280</strong> Enteral Delivery Gravity Bag set with ENFit Connector</td>
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* Kit will include 1 administrative set and 1 transition connector (Transition connector will not be pre-attached)

** Sets will no longer include transition connector

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**ENFit Connector And Transition Connector**

To attach transition connector for use with ENFit administration set, push and turn motion until the transition connector is firmly connected to the female connector.

- **Enenteral Administrative Kit will contain:**
  - (1) Enteral Administration Set (Spike, pump set or gravity)
  - (1) Transition Connector

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Enteral Feeding Tubes

**Traditional G-Tube**

- ENFit connector
- Transition connector

**ENFit G-Tube**

- Securely fit the transition connector into the enteral feeding tube funnel

Transition Connector will not work on ENFit G-Tubes

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# Dynarex® Syringe Product Line with ENFit™ Tip

Syringes will **not** include transition connector

<table>
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<th>Phase 1</th>
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<tr>
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<td>Syringes with ENFit Connector</td>
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<tr>
<td>Traditional Syringes</td>
<td>Item # 4264 Enteral feeding piston syringe</td>
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<td>Item # 4264 Enteral feeding piston syringe</td>
<td>Item # 4284 Enteral Feeding Piston syringe with ENFit Connector</td>
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<td>Item # 4265 IV Pole Kit enteral feeding piston syringe</td>
<td>Item # 4269 IV Pole Kit enteral feeding piston syringe with ENFit Connector</td>
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2015 GEDSA RECOMENDATION

• Manufactures commit to ENFit conversion:
  • ENFit Administrative Sets - Q2 2015 *(Now)*
  • ENFit Enteral Syringes – Q1 2016
  • ENFit Feeding Tubes –Q1 2016

CALIFORNIA MANDATE TAKES EFFECT JANUARY 1, 2016

• Senate Bill No. 158: “Prohibit the use of intravenous, epidural, or enteral feeding connections that would fit into a connection port other than the type it was intended for…”.

DYNAREX ENTERAL CONNECTORS

• Will offer both Traditional & ENFit Connector Administrative Sets/Syringes
• ENFit Administrative Kits & ENFit Syringes will be available third quarter of 2015

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Dynarex® is committed to patient safety and a smooth transition for our customers.