Enhancing Patient Safety

New global design standards for enteral device tubing connectors
In an effort to improve patient safety, new international design standards for medical device tubing connectors are anticipated to be released in 2015 as part of a phased initiative called *Stay Connected*.

The universal design of the current Luer connector has allowed for the possibility of connections between devices that were not intended to connect. While misconnections are rare, they can be damaging and even life-threatening.

The *Stay Connected* initiative for using safer connectors is led by an international group of clinicians, manufacturers, and regulators, which together developed ISO 80369-1. This standard establishes requirements for small-bore connectors for liquids and gases, making it difficult, if not impossible, for unrelated delivery systems to be connected.

The *Stay Connected* initiative will help introduce new safer connectors related to the new design standards for specific clinical applications, including:

<table>
<thead>
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<th>Application</th>
<th>Year</th>
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<tr>
<td>Enteral Feeding</td>
<td>2015</td>
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<td>Neuraxial Applications</td>
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<td>Respiratory &amp; Driving Gases</td>
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<td>Limb Cuff Inflation Applications</td>
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<td>Intravascular and Hypodermic Applications</td>
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The new design standard impacts the entire enteral feeding system

**CONNECTOR (FINAL)**
In place since 2012

**SYRINGE (CURRENT)**

**FEEDING TUBE (CURRENT)**

**TRANSITION SET (TEMPORARY)**
Allows fitment to current feeding port until new ENFit enteral feeding tubes are available.

**NEW ENFit female connector**

**ENFit Transition Connector**

**SYRINGE (FINAL)**
Syringes to administer medicine, flush, hydrate, or bolus feed through enteral tubes will now require a precise enteral-specific fitment.

**FEEDING TUBE (FINAL)**
Changing from male—the stepped or Christmas tree connector—to the new ENFit female connector. The feeding tube port for the administration set will change from female to male.

**NUTRITION END**
Completion and adoption of foundational standard ISO 80369-1 that sets general requirements for safer connectors.

Introduction of new nutrition end connectors.

Formation of the Global Enteral Device Supplier Association (GEDSA) to introduce new standard connectors.

The Stay Connected initiative for using safer connectors is launched and the Awareness phase of the enteral connector transition begins.

Transition sets available.

Adminstration sets will have the new ENFit female connector and the limited-use ENFit Transition Connector to facilitate compatibility between the new ENFit system and the existing port.

Enteral-specific syringes available.

The new connector requires the new enteral-specific syringe that can be used for medicine, flush, and bolus feeding. The oral-tipped syringe will not fit the new ENFit male connector tube.

New enteral feeding tubes with ENFit connector available.

The final step of the transition will be the proliferation of the new ENFit male connector port. After the new ENFit male connectors are in place and have been fully adopted in the market, the transition adapters may not be needed.

Transition to new ENFit connectors complete. California mandate takes effect.

Effective Jan. 1, 2016, a California law (HB 1867) will prohibit general acute care, acute psychiatric, and special hospitals from using an epidural, intravenous or enteral feeding connector that fits into a connection port other than the type for which it was intended.

For the most current information, visit www.StayConnected2015.org.

This transition to safer connectors is an international initiative. Europe and all other markets are anticipated to adopt these global design standards.
Stay Connected with GEDSA: Aware, Prepare, Adopt

The Global Enteral Device Supplier Association (GEDSA) is a nonprofit trade association formed to help introduce international standards for healthcare tubing connectors. Comprised of manufacturers, distributors, and suppliers of enteral nutrition devices worldwide, GEDSA facilitates information flow about the three-phase initiative, which is designed to increase patient safety and optimal delivery of enteral feeding by reducing the risk of tubing misconnections.

<table>
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<th>Aware</th>
<th>Prepare</th>
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<tr>
<td>Inform:</td>
<td>• Assess and adapt existing systems, processes, and protocols</td>
<td>• Meet milestone transition dates</td>
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<td>• Clinicians</td>
<td>• Work with supplier representatives</td>
<td>• Reinforce long-term benefits over short-term inconvenience</td>
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<td>• Administrators</td>
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<td>• Supply chain</td>
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<td>• Risk management</td>
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<td>• Quality and safety personnel</td>
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<td>• Healthcare technology management</td>
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<td>• Other support staff</td>
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Supporting Organizations:

![AAMI](image1)
![ashp](image2)
![aspen](image3)
![ISMP](image4)
![The Joint Commission](image5)
![MedAssets](image6)
![Novation](image7)
![Qley Foundation](image8)
![PREMIER](image9)

**Sign Up to Stay Connected**

To sign up for email updates with the latest information and tools to help you with this transition, visit