



**Stay  
Connected  
2015**

GEDSA

# Enhancing Patient Safety

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New global design standards  
for enteral device tubing connectors

GROUP 1

# Reducing the Risk of Tubing Misconnections

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*.

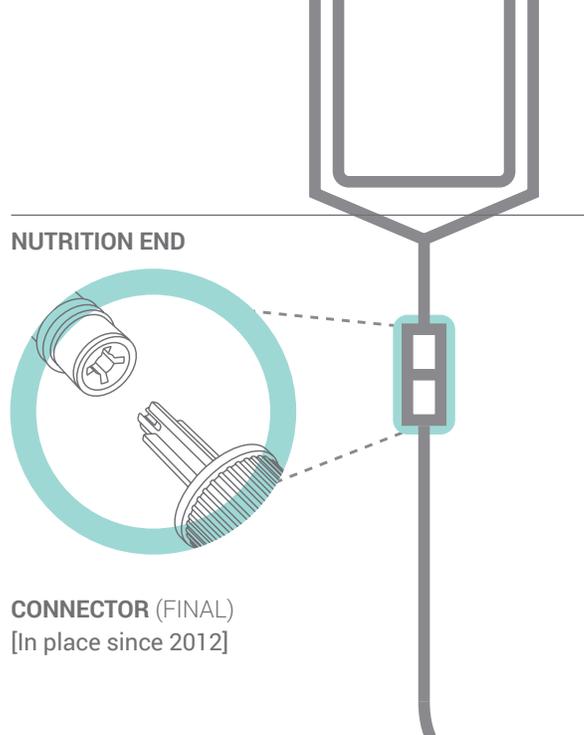
The universal design of the current Luer connector has allowed for the possibility of connections between devices that were not intended to connect. While misconnections are rare, they can be damaging and even life-threatening.

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.

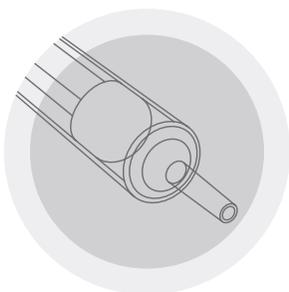
The *Stay Connected* initiative will help introduce new safer connectors related to the new design standards for specific clinical applications, including:

Enteral Feeding	2015
Neuraxial Applications	2015
Respiratory & Driving Gases	TBD
Limb Cuff Inflation Applications	
Intravascular and Hypodermic Applications	

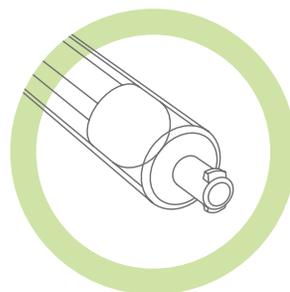
# The new design standard impacts the entire enteral feeding system



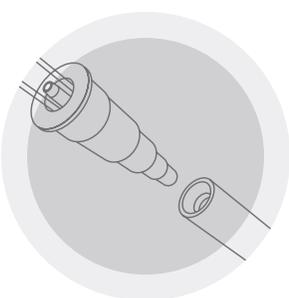
## PATIENT-ACCESS END



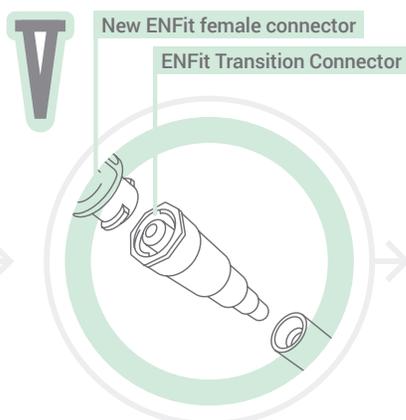
SYRINGE (CURRENT)



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



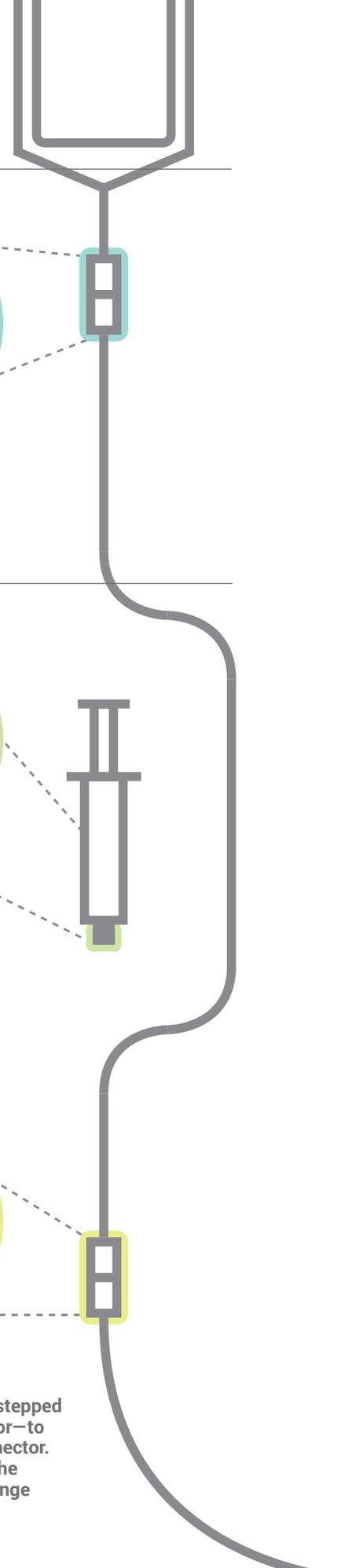
FEEDING TUBE (CURRENT)



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



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.



## GROUP 1

US, Canada, Puerto Rico

GROUP 2  
EMEA + ANZEurope, Middle East, Africa, Australia, and New Zealand  
The UK and Ireland will transition separately from the rest of Europe.

## GROUP 3

United Kingdom, Ireland

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# Timeline for New ENFit Connectors

2011

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

2012

## NUTRITION END CONNECTOR

Introduction of new nutrition end connectors.

2013

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

2014 Q1

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

## PATIENT-ACCESS END TRANSITION SET

Transition sets available.

2015 Q1

Administration 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.

## PATIENT-ACCESS END SYRINGE

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.

Q2

## PATIENT-ACCESS END FEEDING 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.

Q3

2016 Q1

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.

All dates are projected and subject to change due to timing of product-specific regulatory review and supplier discretion. Consult your supplier representative for product-specific availability, indications, contraindications, precautions, and warnings.

This transition to safer connectors is an international initiative. Europe and all other markets are anticipated to adopt these global design standards. For the most current information, visit [www.StayConnected2015.org](http://www.StayConnected2015.org).

# 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.

Aware	Prepare	Adopt
<p>Inform:</p> <ul style="list-style-type: none"> <li>• Clinicians</li> <li>• Administrators</li> <li>• Supply chain</li> <li>• Risk management</li> <li>• Quality and safety personnel</li> <li>• Healthcare technology management</li> <li>• Other support staff</li> </ul>	<ul style="list-style-type: none"> <li>• Assess and adapt existing systems, processes, and protocols</li> <li>• Work with supplier representatives</li> <li>• Train clinicians and inventory management staff</li> </ul>	<ul style="list-style-type: none"> <li>• Meet milestone transition dates</li> <li>• Reinforce long-term benefits over short-term inconvenience</li> </ul>

Supporting Organizations:



## Sign Up to Stay Connected

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

[www.StayConnected2015.org](http://www.StayConnected2015.org)