Stay Connected 2014

GEDSA

Enhancing Patient Safety

New global design standards
for medical device tubing connectors

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 2014 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.

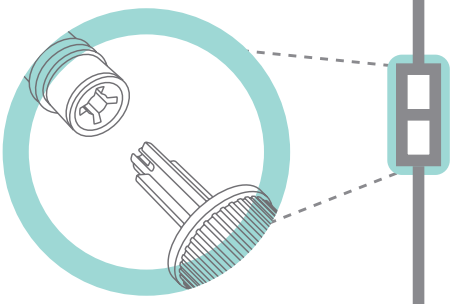
The *Stay Connected* initiative for using safer connectors is led by an international group of clinicians, manufacturers, and regulators, which together developed ISO 80369-1. This standard establishes requirements for small-bore connectors for liquids and gases, making it difficult, if not impossible,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

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

Enteral Feeding	2014
Neuraxial Applications	2015
Respiratory & Driving Gases	
Limb Cuff Inflation Applications	
Intravascular and Hypodermic Applications	

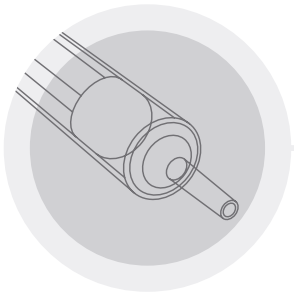
The new design standard impacts the entire enteral feeding system

NUTRITION END

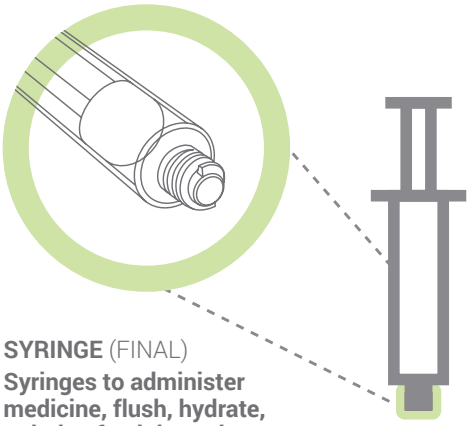


CONNECTOR (FINAL)
[In place since 2012]

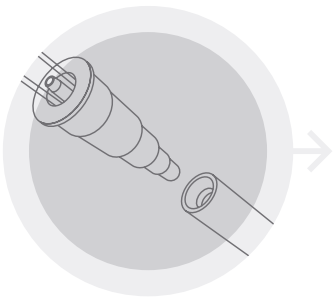
PATIENT-ACCESS END



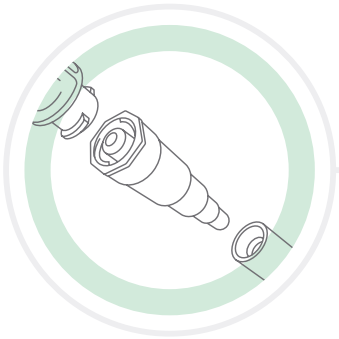
SYRINGE (CURRENT)



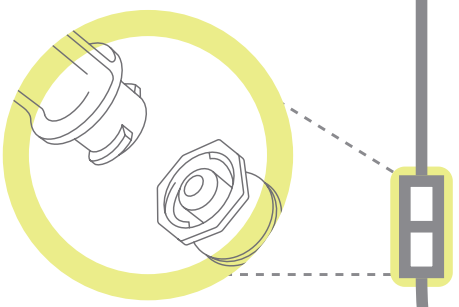
SYRINGE (FINAL)
Syringes to administer medicine, flush, hydrate, or bolus feed through enteral tubes will now require a precise enteral-specific fitment.



FEEDING TUBE (CURRENT)



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



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

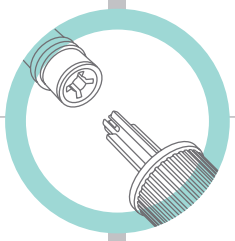
Stay Connected 2014

Timeline for New Enteral Connectors

US, Canada, Puerto Rico

2011

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



NUTRITION END CONNECTOR

2012

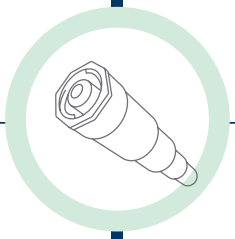
Introduction of new nutrition end small-bore connectors.

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.

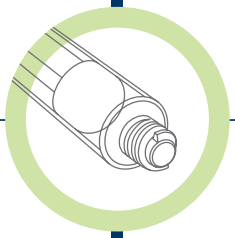


PATIENT-ACCESS END TRANSITION SET

Q4

Transition sets available.

Administration sets will have a transition adapter to facilitate compatibility between the new standard designs with existing designs.

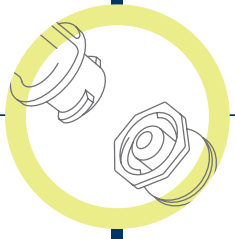


PATIENT-ACCESS END SYRINGE

2015 Q1

Enteral-specific syringes available.

The new connector requires the new standard syringe that can be used for medicine, flush, and bolus feeding. The oral-tipped syringe will not fit the new female connector.



PATIENT-ACCESS END FEEDING TUBE

Q2

New enteral feeding tubes with ISO standard connector available.

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

2016 Q1

Transition to new ISO standard 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 estimates 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 other markets are anticipated to adopt these global design standards. For the most current information, visit **www.StayConnected2014.org**.

Stay Connected with GEDSA: Aware, Prepare, Adopt

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

GEDSA partnered with leading industry organizations to devise a three-phase communications program to help you make this transition.

Aware

Inform clinicians, administrators, supply chain, risk management, quality and safety personnel, healthcare technology management, and other support staff about the transition.

Prepare

Assess and adapt existing systems, processes, and protocols that may need to change.

Adopt

Meet milestone dates and reinforce long-term benefits over the short-term inconvenience.

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.StayConnected2014.org