



**Stay
Connected**

GEDSA

Enhancing Patient Safety

New global design standards
for enteral device tubing connectors

Reducing the Risk of Tubing Misconnections

A new international design standard for medical device tubing connectors is anticipated to be released in 2015 as part of a phased initiative called *Stay Connected*.

Stay Connected 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 introduction of this standard will mark a new milestone in the global effort to improve patient safety, starting with enteral feeding systems. Prior to the ISO initiative, as an interim step toward enhancing patient safety, manufacturers supporting the UK and Republic of Ireland met customer demand for a safer connector with a reverse Luer system. However, with the availability of adapters to change a reverse Luer back into a standard Luer and with increasing patient mobility, a single global solution is required to ensure patient safety and prevent possible misconnection or no connection of enteral tubes, sets, and syringes.

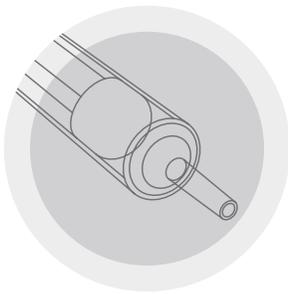
The new ISO standard connector system—called ENFit—will replace the reverse Luer connector systems in the UK, to ensure one global enteral connector. The ENFit connector will look very similar to the existing connector, however the bore size is slightly larger.

The new design standard impacts the entire enteral feeding system

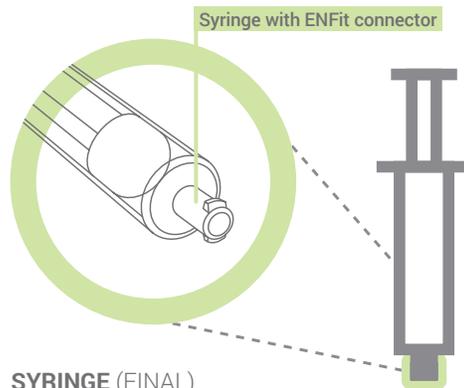
NUTRITION END

ENPLUS OR
40mm SCREWCAP CONNECTOR
(Proposed ISO 18250)

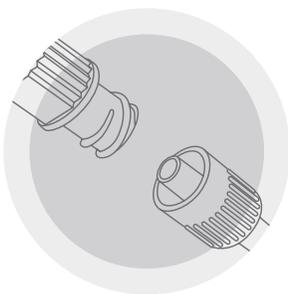
PATIENT-ACCESS END



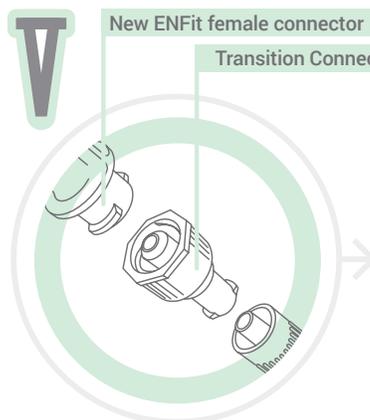
SYRINGE (CURRENT)



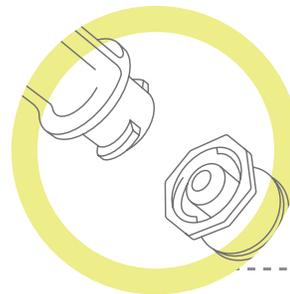
SYRINGE (FINAL)
Syringes to administer medicine, flush, hydrate, or bolus feed through enteral tubes will now require a precise enteral-specific fitment.



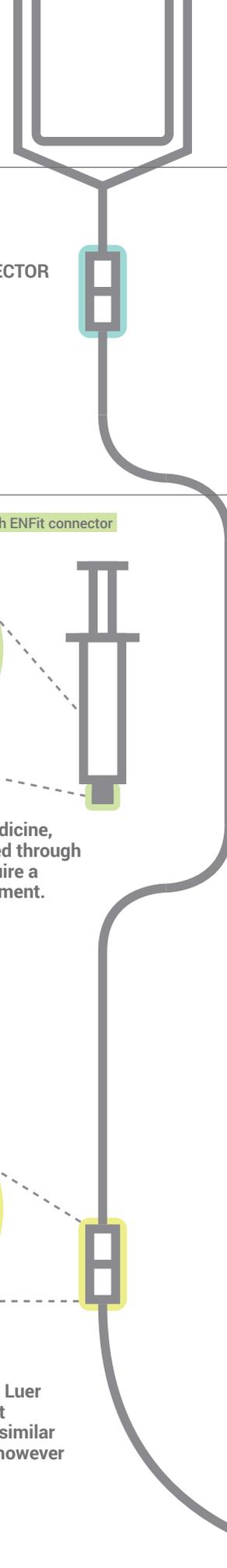
FEEDING TUBE (CURRENT)



TRANSITION SET (TEMPORARY)
Allows fitment to current port until new ENFit enteral feeding tubes are available. Estimated conversion and phase out of transition connector is one year.



FEEDING TUBE (FINAL)
Changing from the reverse Luer connector to the new ENFit connector, which will look similar to the existing connector, however the bore is slightly larger.



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

Proposed ISO 18250 standard to include ENPlus connector and existing 40mm Screwcap.

2013

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

2014

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

2015 Sept.

PATIENT-ACCESS END TRANSITION SET

Transition sets available.

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.

2016 March

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.

PATIENT-ACCESS END SYRINGE

Enteral-specific syringes available.

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

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.

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