Enhancing Patient Safety

New global design standards
for enteral device tubing connectors

American English

GROUP 2

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.

This ISO 80369-1 standard will define among other small-bore connectors, the new connector for enteral applications: ENFit. Introduction of this standardized enteral connector will impact the current marketed connectors, including stepped/funnel, ENLock, reverse Luer and other proprietary connectors, and will mark a new milestone in the international effort to improve patient safety. With increasing patient mobility and portability, a single global solution is required to ensure patient safety and prevent either a misconnection or no connection.

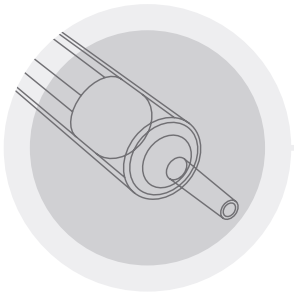
To ensure one global enteral connector, a transition phase is needed. For this transition, suppliers will provide you with ENFit transition connectors that allow fitment to the current feeding port. As illustrated, there are different ENFit transition connectors for your specific feeding port.

The new design standard impacts the entire enteral feeding system

NUTRITION END

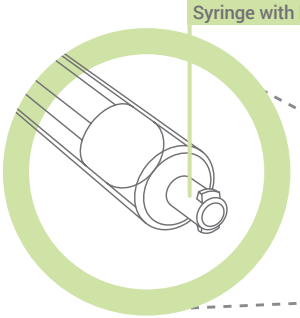
ENPLUS OR
40mm SCREWCAP CONNECTOR
(Proposed ISO 18250)

PATIENT-ACCESS END



SYRINGE (CURRENT)

Syringe with ENFit connector



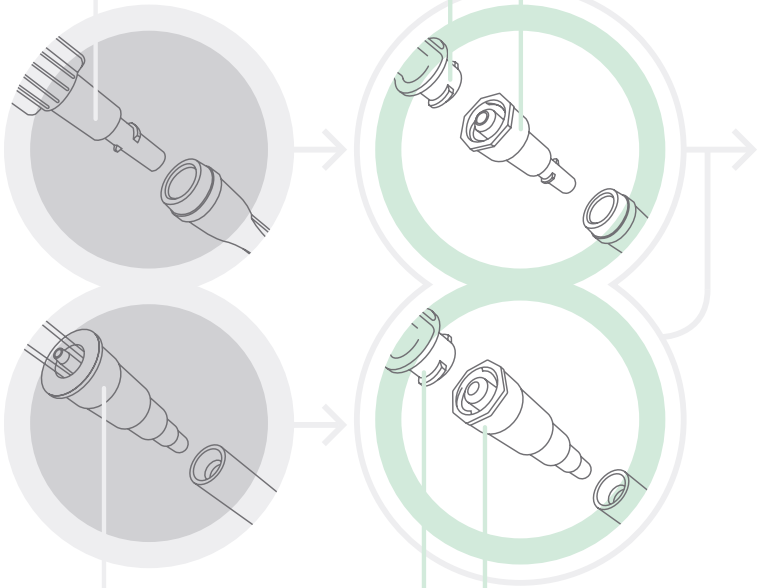
SYRINGE (FINAL)
Syringes to administer medicine, flush, hydrate, or bolus feed through enteral tubes will now require a precise enteral-specific fitment.

MEDICATION PORT
Administration sets with medication ports will have the male ENFit connector.

Example of proprietary connection system: ENLock

New ENFit female connector

ENFit Transition to ENLock



FEEDING TUBE (FINAL)
Changing from the stepped or proprietary connectors (e.g. ENLock) to the new ENFit female connector. The feeding tube port for the administration set will change to the new ENFit male connector.

Stepped or Christmas tree/funnel connector

ENFit Transition Connector

New ENFit female connector

FEEDING TUBE (CURRENT)

TRANSITION SET (TEMPORARY)
Suppliers will provide transition connectors, like the two pictured above, to allow fitment to current feeding port until new ENFit enteral feeding tubes are available. Estimated conversion and phase out of transition connector is one year.

Stay Connected

GEDSA

Timeline for New ENFit Connectors

GEDSA LAUNCH GROUPS

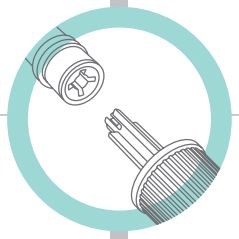
GROUP 1
US, Canada, Puerto Rico

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

GROUP 3
United Kingdom, Ireland

2011

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



NUTRITION END CONNECTOR

2012

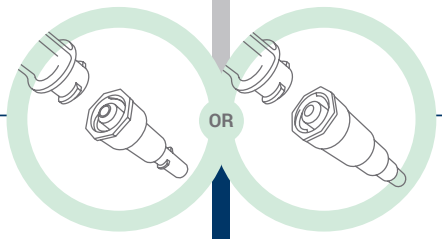
Introduction of new ENPlus connection system. Proposed ISO 18250 standard to include ENPlus connector and existing 40mm Screwcap.

2013

Formation of the Global Enteral Device Supplier Association (GEDSA) to 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.

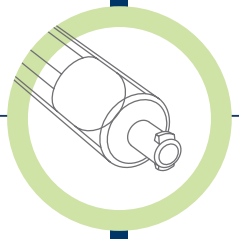


2015 Q3

PATIENT-ACCESS END TRANSITION SET

Transition sets available.

Administration sets will have the new ENFit female connector and the limited-use transition connector to facilitate compatibility between the new ENFit system and the original stepped/funnel port or proprietary ports like ENLock.

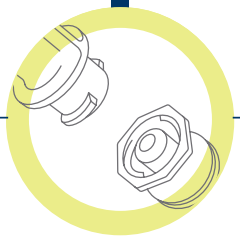


Q4

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 luer-tipped syringe will not fit the new ENFit male connector tube.



2016 Q1

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.

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. For the most current information, visit **www.StayConnected.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
Inform: • Clinicians • Administrators • Supply chain • Risk management • Quality and safety personnel • Healthcare technology management • Other support staff	• Assess and adapt existing systems, processes, and protocols • Work with supplier representatives • Train clinicians and inventory management staff	• 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