

Enteral feeding connections are about to change. How and when will this affect your practice?



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Healthcare is littered with aphorisms and clichés, one of the best-known being 'first, do no harm'. Unfortunately, in any clinical setting it is a fact that 'accidents will happen'. When they do, it is the duty of all professionals to do what they can to ensure they do not recur.

The potential for incorrect administration of fluid lines, catheters and syringes has long been recognised. While misconnections are rare, where they occur they can be damaging and even life-threatening. They may arise due to confusion about a new patient's medical history or during the transfer of a patient between departments. They may also occur in treatment situations that require multiple tasks to be performed simultaneously and speedily. Such situations require action at the level of individual hospitals and professionals. 3.4

But where inadvertent connection of an enteral device and an IV line occurs as a consequence of the universal design of the Luer connector then device design changes are clearly needed,² requiring cooperation between healthcare professionals and industry. Such cooperation in the UK led to the development of the 'reverse Luer' system, which was introduced in 2007 (NPSA Alert 19) and has dramatically reduced the aforementioned risk. But addressing the problem in one country when usage is global, left a gap that needed filling.



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Addressing the problem globally

In an effort to improve patient safety, and partially as a result of the work carried out in the UK around the reverse Luer system in 2007, new international design standards are being rolled out for medical device tubing connectors globally.

In 2011, an International Standard (ISO 80369-1) was established setting general requirements for small-bore connectors for liquids and gases, making it difficult, if not impossible, for unrelated delivery systems to be connected. Subsequently, new nutrition ports and administration set connectors (covered under a sub-section of ISO 80369-1; that being ISO 80369-3) are being introduced to meet the new design standards. In practice, this will mean that all enteral plastics will have the same connection system, meaning that an enteral plastics device will only connect to another enteral device and cannot be connected to an IV device. For healthcare professionals this will promote patient safety; for the manufacturers it will allow for increased product competition. The collective name for the new global connector is ENFit.

Current UK practice and the introduction of ENFit

As mentioned previously and prior to the ISO initiative, manufacturers supporting the UK and Republic of Ireland worked with the National Patient Safety Agency (NPSA) on the introduction of the reverse Luer system. This followed a review of data from the NHS Reporting and Learning System in 2007, which showed 33 patient safety incidents involving intravenous administration of oral liquid medicines between 1st January 2005 and 31st May 2006. As a result, healthcare organisations were advised to review the design and supply of the oral/enteral syringes and enteral feeding systems being used, as well as the way in which they were used; and to review and make changes to organisational procedures, training and audit where necessary.

Today, the UK has an excellent safety record in enteral feeding. Nevertheless, the availability of adapters to change a reverse Luer back into a standard Luer, and with increasing numbers of patients travelling internationally, a single global solution is required to ensure patient safety and prevent possible misconnection or no connection of enteral tubes, sets, and syringes. So 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, but with a slightly larger bore size.

In the UK, the Enteral Plastics Safety Group (EPSG) – a group made up of the main companies and NHS stakeholder groups involved with the production, sale and use of enteral tube feeding devices – has been established to aid the transition of existing connectors found on enteral plastics, over to the new style of connector, and it is

anticipated that this will happen from March 2016, with transition giving sets and gravity sets being made available from September 2015 to support the change over.

How will this affect dietitians, nutrition nurses, gastroenterologists and gastroenterology nurses?

In practice, the new design standard will impact all feeding tubes (naso-gastric, naso-jejunal, percutaneous endoscopic gastrostomy tubes, G tubes, buttons and jejunostomies), enteral syringes, pump giving sets and enteral gravity sets. At the nutrition end, the ENPlus connector is already in place. From September 2015, enteral giving sets and enteral gravity sets will be supplied with ENFit transition connectors that facilitate compatibility between the existing feeding tube port and the new ENFit system. This will allow preparation for the introduction of the following in March 2016 (See Diagram 1)

- Patient-access end syringe the new connector requires a new ENFit syringe that can be used for medicine, flush, hydrate or bolus feed. The reverse Luer-tipped syringe will not fit the new ENFit male connector tube. (The transition sets will be used to facilitate connection to existing reverse Luer feeding tubes until new feeding tubes with ENFit are introduced)
- Patient-access end feeding tube new feeding tubes with the ENFit connector. Feeding tubes will change from the reverse Luer connector to the new ENFit connector, which will look similar to existing connectors, although the bore will be slightly larger.

Once these are in place, all transition connectors will be removed from the market. It is envisaged that the new ENFit connector will be rolled out across all enteral devices over an estimated 12 month period. The transition set will be removed from use after this period.

Key Facts:

- Following the introduction and success of the 'reverse Luer' system in the UK, there has been a move towards developing a safer system globally
- 2011 saw the International Standard, ISO 80369-1being established for small bore connectors – within which fell enteral plastic devices under the sub-heading ISO 80369-3
- ISO 80369-3 means the introduction of ENFit, a new global connector for all enteral plastic devices. ENFit will mean that an enteral plastics device will not connect to an IV device
- Transition giving sets and gravity sets will be made available from September 2015, with ENFit feeding tubes and syringes being introduced from March 2016
- The EPSG, made up of industry and NHS stakeholders, will be communicating the change extensively and working together to manage the change effectively.

Stay Connected – Where to find out more?

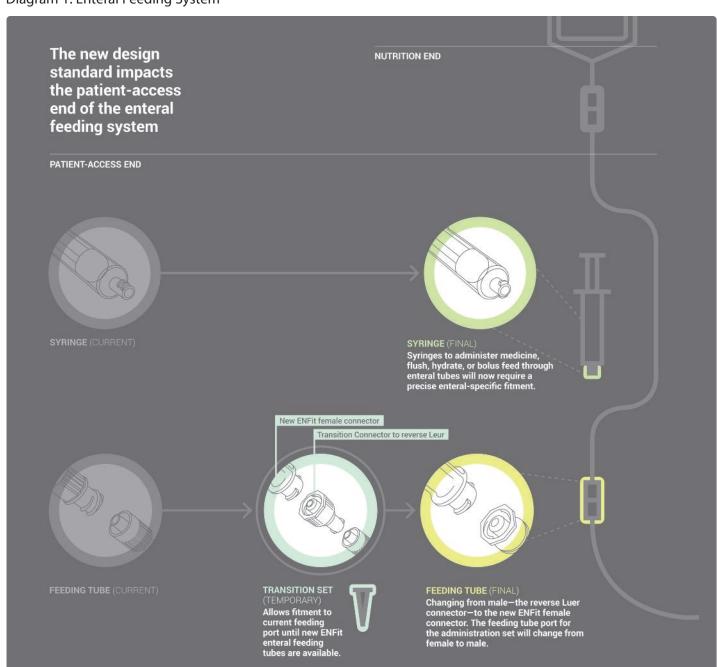
A growing platform of information is now available to support the introduction of ENFit. Globally, the introduction is being managed by GEDSA (Global Enteral Device Supplier Association www.stayconnected2014.org), a non-profit trade association. GEDSA is being supported in the UK by the Enteral Plastics Safety

Group (EPSG), which represents all leading UK enteral feeding device suppliers and is supported by clinical and patient representation from the PENG of the BDA, NNNG, BAPEN, BPNG and PINNT

Your current enteral feed/enteral feeding device supplier will be your first port of call for

information and support. In addition, the EPSG is supporting a comprehensive range of varying communications, from conference attendance, through advertising and direct mail/email to help ensure that UK health professionals are fully aware of the change and prepared for the introduction of ENFit.

Diagram 1: Enteral Feeding System



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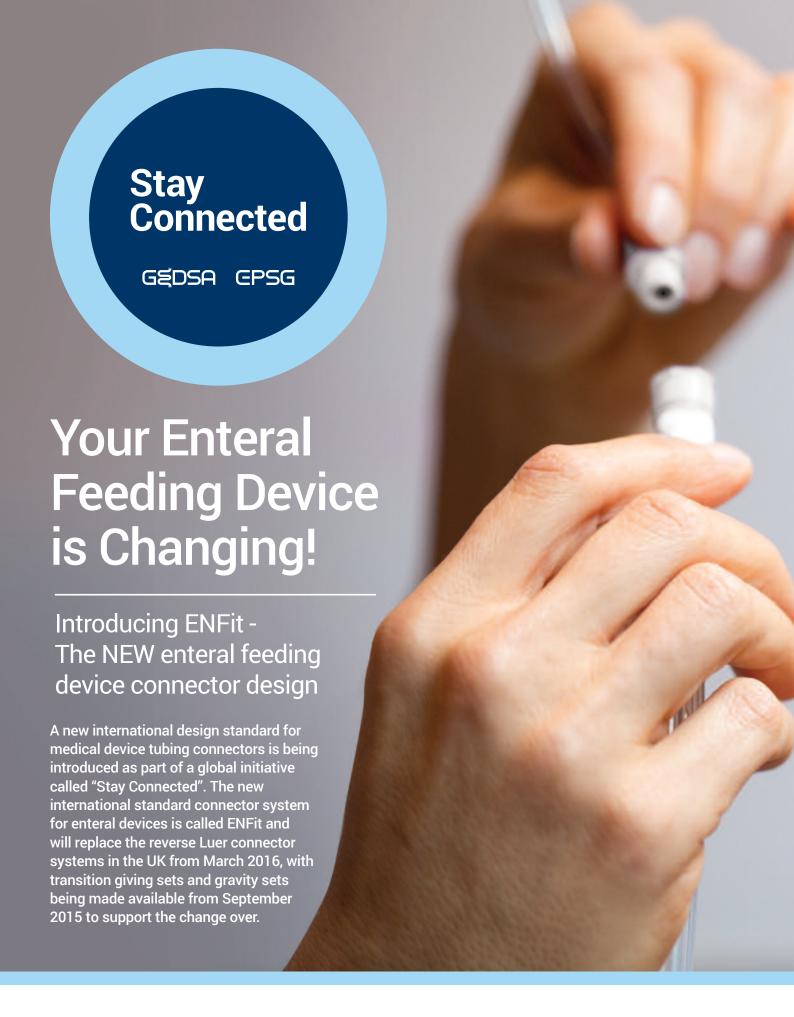












To find out what you need to know, contact your current enteral device supplier, or visit: www.stayconnected2014.org