



ECRI UPDATE

Navigating the Transition to ENFit Enteral Connectors

ENFit enteral tubing connectors were introduced more than five years ago to prevent misconnections involving enteral feeding tubing – misconnections that have had fatal consequences. While ENFit connectors have been widely adopted in Europe, their adoption has lagged in the United States and elsewhere. In 2022, that should change.

Traditional enteral feeding tubing – tubing that incorporates “legacy connectors” – can be inadvertently connected to patient lines intended for other purposes, sometimes with fatal consequences. In one deadly incident, enteral nutrition was delivered into a patient’s lungs when feeding tubing was misconnected to a ventilator suction catheter. In another, nutrition was delivered through an IV line directly into the patient’s bloodstream; the patient did not survive.

Severe incidents such as these are rare, but enteral tubing misconnections with the potential to cause significant harm have occurred. To prevent such misconnections, health care industry groups developed a standards-based connector design for enteral feeding systems. Known by the trademarked name ENFit, these enteral connectors fit only with each other, not with other connector types. “It’s an engineering control that eliminates the misconnec-

tion hazard,” explains Juuso Leinonen, a principal project engineer in ECRI’s device evaluation group. “That’s what makes this design so important.”

The ENFit connector design won’t prevent harm, however, if the connectors aren’t used. Despite being introduced more than five years ago, these connectors have not gained full adoption yet in the United States, or in many other regions. (In contrast, the connectors are widely used in the European Union, Australia and New Zealand.)

The landscape is changing, however. Some of the roadblocks that have slowed the conversion process have been resolved, and access to legacy (i.e., nonprotective) products is about to become more difficult. As a result, health care organizations will not be able to delay the change much longer.

Efforts to drive the adoption of ENFit connectors have been spearheaded by the Global Enteral Device Supplier Association (GEDSA), a nonprofit trade association. In July 2021, members of GEDSA stopped manufacturing legacy (i.e., non-ENFit) feeding tubes, as well as the cross-application adapters that had been made available to help facilities through the transition. And in January 2022, many will stop manufacturing transition sets and adapters sold separately from other devices. (Note, however, that some manufacturers are not part of GEDSA

and may continue to market legacy enteral products.)

THE BENEFITS OF ENFIT CONNECTORS

Unlike traditional Luer-lock connector designs, ENFit connectors have a female-to-male orientation; administration devices have a female connector that fits around the male connector on the feeding tube, reversing the traditional orientation. Thus, it’s impossible to directly connect, for example, an ENFit administration device to legacy IV tubing, since both connectors are female. ENFit connectors also have a locking feature to provide a more secure connection and minimize leaks.

The use of ENFit connectors will standardize connections among all enteral devices (e.g., enteral syringes, nasogastric tubes), helping to ensure that enteral connectors will fit only with each other, and not with other connector types.

ENFit is part of the International Organization for Standardization (ISO) 80369 family of standards, which was developed by ISO to reduce misconnections by specifying different small-bore connector designs for different health care applications, such as intravascular, limb cuff, and breathing system and driving gas connectors. Each application has its own distinct connector design. ENFit connectors meet the dimensional requirements of the standard for enteral applications, ISO 80369-3.



Figure: ENFit enteral connectors. The female end on the administration set (top) fits around the male end on the feeding tube (bottom). An ENFit administration device cannot be connected to a legacy (non-ENFit) connector. ENFit has a locking feature for a more secure, leak-free connection.

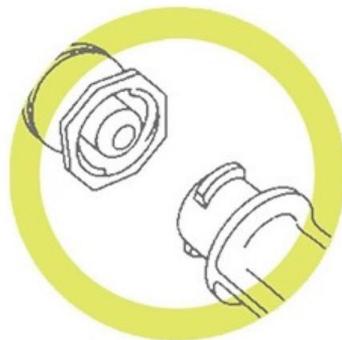


Image courtesy of GEDSA

THE BARRIERS, AND BREAKING THROUGH THEM

Transition challenges. Perhaps the chief deterrent to ENFit conversion is the significant time and expense associated with rolling out an organization-wide transition of all enteral connectors. The effort includes providing staff education and training, adjusting to new workflows and coordinating with suppliers. The implementation process requires substantial resources (e.g., supply chain management, project management personnel, training) – especially given the fact that ensuring the best and safest transition calls for making the switch in all areas simultaneously, rather than in phases, to avoid a mix of legacy and ENFit products.

“The cost and effort of the transition will always be an issue,” advises ECRI’s Leinonen. “But eventually you’ll need to make the switch” as legacy products become harder to find. Plus, by reducing the risk of misconnections, an ENFit-equipped facility will save on the costs associated with misconnection incidents.

Product availability. Another obstacle has been the perception that the ENFit market is not sufficiently mature, and that product availability may be limited. When ENFit connectors first appeared on the market, early adopters were unable to maintain an adequate supply, due to supply chain gaps caused by factors such as low demand and the lack of adoption of the

standard by some manufacturers. The situation has improved significantly.

Today, over 30 manufacturers offer ENFit products worldwide, and more syringe sizes are available to suit a wider range of patients. In addition, manufacturers now offer a wider array of accessories, such as bottle adapters to facilitate syringe preparation, and caps to support syringe transportation, storage and security.

Product quality. Facilities may also have lingering concerns that product design improvements are needed. Initial ENFit connectors had design flaws that in some cases actually introduced safety concerns. However, recent design improvements have addressed several of the flaws that originally caused concern.

For example, the dead space in the original ENFit syringe was high, meaning that a larger-than-desired amount of fluid would be left in the syringe and tip after the plunger is fully depressed. The excess dead space could lead to underdosing or overdosing, which could have a particularly significant impact with low-volume doses.

This dead-space issue has been remediated in two ways: (1) Through the introduction of medicine transfer straws; these attach to the syringe tip and allow medication to be drawn directly into the syringe barrel, reducing accumulation in the dead space. And (2) through the introduc-

tion of an ENFit low-dose tip (LDT) for small-volume (i.e., <6 mL) syringes; the LDT has less dead space, and thus minimizes drug retention after oral administration, increasing dosing accuracy.

Another concern was that early cap designs were prone to both falling off during transport and leakage. Manufacturers redesigned the caps to remedy these issues.

MOVING FORWARD

ECRI strongly encourages organizations to convert to the ENFit connectors to eliminate the risk of enteral misconnections. Refer to ECRI’s guidance on the topic, as well as GEDSA’s www.stayconnected.org website. The GEDSA site is a rich source of information about the ENFit products, as well as other connectors designed to reduce medical tubing misconnections. ✨

To Learn More

This article is adapted from ECRI’s “Adopting ENFit Enteral Connectors: Guidance for the Coming Transition” (Device Evaluation 2021 Oct 27). The complete article is available to members of ECRI’s Capital Guide, Device Evaluation, and associated programs. To learn more about membership, visit www.ecri.org/solutions/evaluation-and-comparison, or contact ECRI by telephone at (610) 825-6000, ext. 5891, or by e-mail at clientservices@ecri.org.