

MYTHS VS FACTS

Dispelling 6 Myths About ENFIT® Enteral Feeding Connectors

Devices Meet Global ISO Standard That Improves Patient Safety

Hospital patients today are surrounded by technology. If a patient is in the hospital for more than three days, he or she may have connected with up to 14 devices for a variety of therapies. Many of these devices rely on the same type of connector. The Emergency Care Research Institute (ECRI) reported that enteral feeding misconnections are among the top 10 technology hazards found in hospitals.

That's why safer connectors are so important. Made to precise ISO 80369 standards established by experts around the world, they function as a system to prevent misconnections between devices that can result in patient injury or death. For instance, ENFit(R) enteral feeding connectors do not allow connectivity with devices for other clinical uses.



All ISO 80369 connectors are important because they function together as a system, not individual connectors.

While ENFit has been successfully adopted in countries around the world, several myths have slowed adoption in the United States. Here are the facts to set the record straight:

MYTH 1: The ENFit Low Dose Tip (LDT) syringe is not accurate enough for use in neonatal intensive care units where small variations in dosing accuracy can impact infants.

TRUTH: The ENFit LDT syringe addresses any dosing concerns for our smallest, most vulnerable patients. There is nothing more accurate on the market, and the ENFit LDT syringe has passed all regulatory reviews, including the FDA as well as its counterparts in the European Union, Japan and Australia. The LDT was developed after consultation with stakeholder groups including the Institute for Safe Medication Practices (ISMP), ASPEN, the American Society of Health-System Pharmacists (ASHP) and others. Together we reached consensus that a +/-10% dose accuracy was accepted for a low-volume dose, such as a 0.2ml dose from a 1ml syringe. It is important to note that there is no global standardized test to evaluate dosing accuracy for syringes, so no baseline data exists.



Performance testing by an accredited third-party lab, together with usability studies conducted around the world, confirmed that the ENFit LDT syringe, when used as instructed:

- Delivers an accurate dose substantially equivalent to current male enteral/oral syringes
- Outperforms existing female-oriented enteral syringes, including the reverse Luer system



To maximize accuracy, the testing also found use of an adapter, such as a straw, delivers better performance than a cup fill. It is common practice to tap/flick a syringe to remove air bubbles. GEDSA and manufacturers recommend the same practice to remove any medication outside the fluid pathway.

Beyond tests and studies, ENFit and the LDT syringe are proven to work in care settings around the world. They have been used with millions of patients across the European Union and other countries with no reported incidents. In the United States, these syringes and connectors have been used by leaders in patient-centric care such as the Mayo Clinic, Rady Children's Hospital San Diego, Children's Mercy Hospital of Kansas City, Children's Hospital of Los Angeles, Lurie Children's Hospital of Chicago, Lucile Packard Children's Hospital Stanford, Children's Hospital of Orange County, and the UCLA Medical Centers. These organizations have done their own testing and concluded ENFit adoption was best for the safety of their patients.

MYTH 2: ENFit's design does not allow venting and draining that is needed to fully convert facilities and support home feeding.

TRUTH: Members of the Global Enteral Device Supplier Association (GEDSA), a nonprofit organization formed to help introduce international standards in medical device tubing connectors, offer products that support venting and draining.

Cardinal Health is offering its **Kangaroo Salem Sump™ PVC Tubes** that offer the ability to decompress and feed with the added safety of ENFit to reduce risk of misconnections.

GBUK is offering **enteral drainage bags** that fit all ENFit-compliant tubes. Cardinal Health is also planning to introduce a Salem pump and anti-reflux valve in the near future.

This is not promotion of GEDSA members or vendors. These are simply products that are solutions to frequently asked questions and requests for more information.



Cardinal Health Salem Pump™ PVC Tubes



GBUK ENFit-Compatible Enteral Drainage Bags

MYTH 3: ENFit's moat design makes it hard to clean and creates unacceptable levels of bacteria.

TRUTH: GEDSA and others have developed job-specific sets of special brushes and training materials to help hospitals with the transition (standard cleaning materials like Kimwipes® and common brushes can also be used). Based on our experience in the U.S. and around the world, hospital staff are readily able to adapt to the cleaning process and ensure bacteria are removed.

Kansas City Children's Mercy Hospital developed and tested the ENFit cleaning protocol that forms the basis for the ENFit instructions. In addition, this data was submitted to the FDA as part of the normal product review process. Finally, the FDA specifically instructed Children's Mercy not to include bioburden testing in the review process. The GI tract standard is not sterile, so the relevant standard under FDA guidelines is cleanliness – roughly equivalent to dish washing – not sterility.

MYTH 4: ENFit doesn't meet the needs of the home-feeding community because the connectors have a narrower opening that slows feeding.

TRUTH: Many people on home-feeding prefer a blenderized diet so they can participate in the same meals as their families. To ensure ENFit meets the needs of these patients, the Mayo Clinic has studied this issue and concluded that ENFit can support blenderized meals, though it may take slightly longer to complete a feeding. Extended blending time can provide the right consistency for use with ENFit. Use of a higher-end blender can also help, though extended blending time with lower-cost models has the same effect. The [FDA](#) also compared ENFit performance in using pre-packaged formula and found that ENFit does not clog more frequently than the Legacy connectors and does not require more force. However, we understand that many people in the tube feeding community prefer a blenderized diet and ENFit can meet their needs by following the tips we outlined above.

ENFit also offers a better option for home feeding because legacy connectors are prone to leaks and disconnections that can prevent a patient from receiving their full meal. "Feeding the bed" is a common term related to disconnections that cause the contents of an entire meal to spill before the patient can consume it. By comparison, ENFit offers a secure connection that ensures the feeding schedule is maintained and prescribed calorie counts are achieved.

MYTH 5: ENFit does not really fix the problem of misconnections.

TRUTH: The ENFit design is supported by the FDA as an important step for improving patient safety. To quote from a September 2018 FDA letter: "The FDA recommends hospitals and clinicians use enteral devices with connectors that meet the International Organization for Standardization (ISO) 80369-1 or ISO 80369-3 standard, or that are otherwise designed to reduce the risk of misconnections."



It's important to keep the big picture in mind. Only a complete system of ISO standard connectors will prevent all misconnections from occurring. One connector alone won't fix the problem. Compare it to the making of an umbrella – ENFit is the first pane, but that's not enough to keep you dry. We need a comprehensive system of ISO connectors to fully protect patients. Only after the entire range of ISO 80369 connectors is in the market will the problem be fully addressed. ENFit is the first step. [NRFit](#), a solution for neuraxial connectors, is the second, and others will follow. The ISO standard provides a unified global standard to improve patient safety that reduces complexity and risk.

MYTH 6: ENFit is a solution in search of a problem so manufacturers can profit.

TRUTH: Manufacturers did not lead the effort to develop the international standards. This effort is led by clinical, technical and regulatory experts under the auspices of the International Organization for Standardization (ISO). Tubing misconnections pose a serious threat to patient safety. A Sentinel Alert from The Joint Commission states “Tubing misconnections continue to cause severe patient injury and death.”



That risk is the reason hospitals around the world have adopted ENFit. They are doing the right thing because EVEN one near miss, injury or death is one too many. GEDSA members funded the development, production, and testing of safer connectors themselves and are not taking a price increase. We are not reacting to any government mandate but taking this action because we think it is the right thing to do.

About GEDSA

The Global Enteral Device Supplier Association (GEDSA) is a nonprofit trade association formed to establish a voice for addressing issues that face enteral device manufacturers, suppliers, and distributors, and to help introduce international standards for healthcare tubing connectors. Comprised of manufacturers, distributors, and suppliers 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.

For more information, visit StayConnected.org

For more information:

Dose Accuracy – Performance Testing of Enteral, Oral, ENFit and ENFit LDT Syringe, by Ashley Deken, Ben Davis, Andy Giles, Crystal Koelper, Don McMichael, Pete Phillips

Sentinel Event Alert: The Joint Commission, August 20, 2014

ENFit Implementation: Pharmacy Keys to Success, Valley Children’s Healthcare (Video)

Reducing the Risk of Medical Device Tubing Misconnections, GEDSA, 2014