



GEDSA StayConnected

Frequently Asked Questions

Blenderized Diets and other Concerns

All material provided is intended for informational purposes only and should not be used to replace regulatory or company-specific documents, nor should it replace the advice of a qualified professional. GEDSA is a 501(c)(6) Non-Profit Trade Association. GEDSA's mission is to promote initiatives surrounding safe and optimal delivery of enteral feeding and connectivity.

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Information provided does not imply endorsement of any specific product and is not intended to address any off label use. All products and product designs are the responsibility of each specific legal manufacturer, distributor or supplier. Products with these design features may be pending regulatory clearance or may not be available in a specific geography. Consult your supplier representative for product-specific use, availability, indications, contraindications, precautions, and warnings.

GEDSA would like to thank the Oley Foundation for gathering these questions from Home Enteral Nutrition consumers and working closely with GEDSA to provide answers.

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1. Why is a new enteral connector being introduced?

When enteral nutrition is accidentally delivered into a vein or other tube leading into any system in the human body other than gastrointestinal system, it is called a tubing misconnection. These misconnections can be fatal and possible as long as the connectors used in enteral, circulatory, respiratory, and other applications can physically connect to one another.

The purpose of the new connector is to help reduce the risk of enteral misconnections and improve patient safety. The new ISO standard, ISO-80369-3, has been established for connectors on the nutrition formula end (for example on extension and administration set and syringes) and the patient-access end (for example, a G-tube or PEG tube). The goal is to have one standard connector system utilized by many feeding set, tube, and syringe manufacturers and have it universally adopted into practice.

Home Enteral Nutrition patients should speak with their healthcare provider to determine if transitioning to an ENFit connector enteral system would be optimal for their nutritional requirements.

2. What is ENFit®?

ENFit is the registered trademark name commonly used for ISO 80369-3 connectors, with a specified reverse connector orientation when compared with legacy (current or existing) products. To help consumers easily identify compatibility, some manufacturers have adopted the ENFit name to use on devices that are made with the ENFit connector system with the ISO 80369-3 male connector on the patient side (feeding tubes and extension sets) and female connector on administration side (administration sets and syringes).

3. What is the purpose of GEDSA?

The Global Enteral Device Supplier Association (GEDSA) is a federal tax-exempt non-profit trade association established in part to help introduce the new ISO standard connector and facilitate adoption of the ENFit connectors in the healthcare community. GEDSA, which is comprised of leading manufacturers and distributors of enteral feeding devices, is united by a shared goal to improve patient safety and optimal delivery of enteral feeding and connectivity. GEDSA speaks in a singular industry voice to communicate with governing agencies, associations, and member suppliers, regarding issues that face enteral device manufacturers, suppliers and distributors.

GEDSA leads a joint communication effort on behalf of the industry to ensure consistency and avoid any confusion as new, safer connectors are introduced in the market

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- Develop and execute a coordinated joint communications initiative (StayConnected)
- Identify this new connector with a common name (ENFit) to be used by manufacturers
- Introduce enteral products with the ENFit connector within the same timeframe

4. Why should home users convert to using ENFit® connectors? Aren't misconnections more likely to happen in hospitals and nursing homes than at home?

Some consumers use both parenteral (IV nutrition) and enteral feeding systems at home. This creates situations where enteral feeding, solutions, and medications that are intended for the enteral feeding tube could potentially be inadvertently administered into a central venous catheter.

In addition, if a home user is using a feeding tube that does not have an ENFit connector and he or she is hospitalized in a facility that only has tubing and syringes with ENFit connectors available, he or she may experience a disruption in their enteral therapy or may potentially have to undergo a tube replacement procedure.

It is recommended for Home Enteral Nutrition patients speak with their healthcare provider if transitioning to using a system with the ENFit connector tube would be best suited for their current practice.

5. Will all GEDSA members produce devices with the ENFit connectors?

As part of GEDSA member companies are committing to roll out enteral devices which meet the ISO 80369-3 standard. There have been questions if syringe manufacturers which are GEDSA members have decided to not produce ENFit tip syringes. Their launch of ENFit is to coincide with ability to provide the low dose ENFit tip syringe to the market and satisfaction that there will be sufficient syringe supply in the market place to support an ENFit transition.

6. Will manufacturers benefit from changing their products to ENFit?

A positive benefit for the manufacturers will be introducing devices that reduces the risk of dangerous tubing misconnections to better serve all patient populations using small bore tubing, which includes enteral feeding.

The development work for the ISO 80369-3 began several years ago as nursing and other clinical associations asked for a device that would not connect with devices which it was not intended to connect with. The work has been supported by clinical, technical, regulatory and commercial experts volunteering their time and committing significant company resources. In addition to the resources committed to the collaborative effort each manufacturer in the

enteral delivery market is making significant capital investment in their production equipment needed to produce ENFit compatible products. These manufacturers are doing so because they believe the gains in patient safety merits this investment of resources.

7. Will ENFit misconnect with a tracheostomy tube?

All connectors within the ISO 80369 series are designed to reduce the risk of tubing misconnections. Tracheostomy connectors today do not specify dimensional requirements for the inside tube and as a result every connector or device smaller than a tracheostomy connector, including the connectors defined within the ISO 80369-3 standards, have the potential to misconnect with tracheostomy tubes. This potential is also inherent to existing or legacy devices. Until tracheostomy connectors are better defined, misconnection risks may still exist with these types of devices and many others, including almost all enteral proprietary connectors.

As a result of a careful survey of the tracheostomy tube market, dimensional changes have been made to ISO 80369-3 to reduce the risk of misconnections with a tracheostomy tube.

8. Will gastrostomy tube (G-tube) low profile devices be changed in any way? If so, how?

No. Connectors on skin-level feeding devices are not covered by the new ISO 80369-3 design standards, so the connectors on those specific devices should not change. Extension sets that attach to these devices will likely have the same (non-ENFit) connection at the point that it inserts into the device. However, the other end of the extension set (often called the proximal end) that connects to administration sets and syringes will have the ENFit connector(s).

9. Will the new connectors allow for venting?

Yes. ENFit connectors will allow for venting. With smaller French size tubes, venting should function the same as it does with current connectors. Additional testing is planned to better understand venting in larger French size tubes.

Venting a feeding tube with the ENFit connector will require an ENFit tip syringe or a venting bag with an ENFit connector.

Some companies may offer venting bags and tubing connectors that are ENFit compatible.

10. Will venting be possible through the G portion of a G-J tube?

Other than the connector, the design of G-J tubes are not likely to change and venting capability should be the same as it is today. Internal and external diameters of these tubes should stay the same.

To allow venting through the ENFit connector, some companies are developing venting systems that would be compatible with the G portion (see question number 10, above). For most procedures including venting, functionality should be consistent. Performance, however, may vary. Check with your supplier for device specific questions.

11. Will it be possible to hydrate with an ENFit tip syringe?

Yes. Hydration through a feeding tube with an ENFit connector will require the use of a syringe with an ENFit connector. Catheter-tip and oral-tip syringes will not fit into an ENFit connector. The ENFit connector was designed to be incompatible with catheter-tip and oral syringes in order to reduce the risks associated with possible misconnection among other medical delivery systems. Enteral specific syringes with the ENFit connector must be widely available before feeding tubes with ENFit connectors can be placed.

12. Will blenderized diets flow through the ENFit connector?

Currently there are no published professional standards for the use of blenderized foods for tube feeding, and there is great variability in viscosity and consistency of each individual blend being used. According to the American Society for Parenteral and Enteral Nutrition (A.S.P.E.N.) Standards for Nutrition Support: Home and Alternate Site Care, published in 2014, “EN formulas shall be prepared to prevent contamination. Commercially available EN formulations shall be used whenever possible,” and the use of home blenderized formulas “requires additional attention to safe food handling and storage practices.”¹

The ISO 80369-3 enteral connector design standard was developed with these A.S.P.E.N. guidelines in mind and specific requirements were established that would meet those needs in order to avoid any disruption of therapy for patients. The bore size (or size of the opening) in the ENFit connector was designed to be consistent with the current connector (commonly called “Christmas tree” or “stepped adapter”).

If you are currently using a blenderized diet with a pump set that has an ENFit connector and an ENFit transition connector, the flow rate will be consistent to what will be experienced with the complete system using the ENFit connector.

¹ Durfee, SM, Adams SC, Arthur E, Corrigan ML, Hammond K, Kovacevich DS, McNamara K, Pasquale JA Standards for Nutrition Support: Home and Alternate Site Care, American Society for Parenteral and Enteral Nutrition (A.S.P.E.N.). 2014 Jun 25.

13. What testing has been done on ENFit performance for blenderized diets?

Initial laboratory testing has been completed to show consistent flow rates between ENFit and legacy connectors using low profile devices with extension sets and 20Fr and smaller gastrostomy tubes. Additional performance testing with larger French size tubes and a variety of blenderized foods is planned for the future.

14. Will individuals with limited dexterity be able to manage ENFit connectors?

Limited dexterity is something each company factors into its designs. In preparation for FDA submission human factors and usability testing were completed using nurses and home caregivers and the ENFit connection has been found to be suitable. Many users found it easier to connect than current friction fitments. Twist lock systems, similar to the ENFit connector have been in use effectively for enteral feeding systems in the UK and around the world for more than 10 years.

In addition, while ISO 80369-3 defines certain parts of the connector (principally those which will affect the connector's compatibility with other devices), individual manufacturers are able to incorporate features into their devices to address dexterity issues, as they see necessary.

15. Will the old system become obsolete with the introduction of the new system?

As discussed above (see question 1) the goal of establishing an enteral connector design standard is to improve patient safety by reducing the risk of tubing misconnections, which are not common but are dangerous and sometimes fatal. The most effective way to comprehensively reduce the risk of misconnections is to ensure that connectors used in different delivery systems (e.g. enteral and IV) are not compatible. Leaving the legacy connectors in place means the possibility of misconnection would still exist.

Patients are typically quite mobile, moving between hospital, post-acute facilities, and home. Further, HEN patients also travel across state lines and country borders. If there are multiple enteral connectors and feeding systems available, as patients move between facilities and home or travel it is likely they will experience disruption in their nutrition therapy at some point due to incompatibility, as well as the potential for a misconnection.

Some manufacturers have committed to continue to offer feeding tubes with the current female funnel port until further notice. Please check with your supplier representative to understand your tube manufacturers' plans for transition and availability of current feeding tubes.

16. Will the final ENFit connection make the inner diameter of the low profile extension sets and syringe connection smaller?

Yes. The inner diameter of the ENFit connector on the extension set will likely be smaller than the catheter-tip syringe tip inner diameter. The ENFit connector inner diameter is still equivalent to the inner diameter of the connector on the patient access end of the extension set which is used to connect to the low-profile device. As long as the patient end connector of the extension set remains equivalent in diameter to the ENFit connector, the flow rate properties are not expected to change from the current configuration.

17. Will bolus syringes used for feeding blenderized diets be available with the ENFit connectors?

Yes. All syringes intended for use with enteral feeding tubes will have an ENFit connector. The diameter in the outlet of the syringe will be the same size or larger than the patient access end of most feeding tubes 20Fr or smaller, or the opening on most low-profile devices.

For larger French size feeding tubes (>20Fr), the industry is currently evaluating the impact of ENFit on overall performance. Until more is understood regarding performance with common blenderized diets, several existing (legacy) larger French size feeding tubes (> 20 Fr) will remain available from some manufacturers. This will allow consumers to continue using catheter tip syringes to deliver blenderized diets.

Check with your supplier representative for company specific plans for transition and availability of legacy devices.

18. Will there be more clogging with ENFit connectors?

It is not anticipated that clogging incidences will increase for feeding tubes with inner diameters smaller than the inner diameter of the ENFit connector (20Fr and smaller). Additional performance testing with larger French sizes is planned for the future.

Individual flow rates may vary depending on the device and the patient's feeding and medication regimen. The adoption of correct clinical practice with proper flushing has shown to prevent clogging in tubes smaller than the ENFit inner diameter and is recommended.

19. What is recommended to keep ENFit connectors clean?

A reverse Luer system with a very similar design has been in place in the United Kingdom and initially this subject was a concern. This issue was resolved quickly, however, as consumers became familiar with using the system. When connecting or disconnecting the tubing, the

ENFit connector portion of the tubing and syringe should be kept free of fluid. Some have suggested using a toothbrush and warm water to clean the ENFit connector daily. Additionally there are products on the market being promoted for the cleaning of ENFit connectors.

20. Will color-coded enteral syringes be available to manage medication administration?

There are no color-coding requirements in the ISO standard. Therefore, syringe manufacturers may offer enteral-specific ENFit tip syringes in one or more colors. Check with the syringe manufacturer or your home care supplier for additional details.

21. Will the cost of syringes increase and will it be more difficult to obtain syringes?

GEDSA cannot comment on pricing or insurance coverage. Pricing is at the sole discretion of the manufacturer.

22. Will tubes need to be replaced more often, either due to clogs or being accidentally dislodged?

For most feeding tubes, it is anticipated that performance will be consistent. This is a subject you should address with your healthcare provider, home care supplier or the manufacturer. Manufacturers have considered this aspect of use in their risk analysis as they have designed their new devices and will be able to answer this question in regard to your specific device.

23. Can a J-tube be repaired if the ENFit connector cracks?

For device specific quality issues please work with your supplier/manufacturer.

24. Will pharmacies stock enteral syringes?

Distributors and pharmacies will be alerted of this potential need but ultimately it is up to the pharmacy to decide whether to carry these items. Consumers should check with their local pharmacy or their home care supplier for the availability of ENFit tip syringes.

25. Once syringes are specifically enteral, will there be greater insurance coverage?

GEDSA is not in a position to address issues related to insurance coverage or reimbursement. Consumers should check with their insurance provider for their specific policy.

26. Will there be adapters for different kinds of syringes?

Once an ENFit compatible feeding tube is used, only ENFit compatible syringes can be used for feeding, flushing, and medication delivery. To facilitate a smooth transition, some manufacturers may offer a transition connector for a limited period of time to introduce ENFit tube sets with the current syringes. Refer to individual manufacturers for their products and availability.

Check with your supplier representative for products and availability.

27. Will a Lopez® Valve, Farrell® Valve bag and CoriSafe® be compatible?

Check with your supplier representative of enteral device manufacturer to confirm ENFit connection compatibility

28. What should you do if formula is leaking out behind the transition connector?

For device specific quality issues please work with your supplier/manufacturer.

Non Traditional Use of Enteral Patient Access Devices

GEDSA cannot comment or address any off label use. All products and product designs are the responsibility of each specific legal manufacturer, distributor or supplier. Products with these design features may be pending regulatory clearance or may not be available in a specific geography. Consult your supplier representative for product-specific use, availability, indications, contraindications, precautions, and warnings.