GEDSA StayConnected

Frequently Asked Questions

ISO 80369-3 Enteral Specific for Clinicians and Supply Chain Professionals

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This material is provided by GEDSA for informational purposes only. 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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1. **What is a small-bore connector?**

   A small-bore connector is a connector with an inner diameter of less than 8.5 mm that is used to link or join medical devices, components, and accessories for the purposes of delivering fluids or gases. A Luer connector is a classic type of a small-bore connector used commonly in the healthcare setting. The current universal design of the Luer connector allows for medical tubing misconnections—connections between unrelated delivery systems that have different intended uses (e.g., vascular, enteral, respiratory, epidural, and intrathecal). The ISO 80369-3 standard deals with enteral connectors. The ISO 80360-3 connector in the reverse direction is commonly known as the trademarked name ENFit®.

2. **What changes are coming to current connectors? And what are the implications of these new standards?**

   To reduce the frequency of medical tubing misconnections, an international group of clinicians, manufacturers and regulators, such as the FDA, is collaborating with the International Organization of Standardization (ISO) and the Association for the Advancement of Medical Instrumentation (AAMI) to develop ISO 80369 standards.

   Connectors will now have unique international standard dimensions which are designed to promote improved patient safety and help ensure that connectors for unrelated delivery systems are incompatible.

3. **What is the role 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 connector with the healthcare community. GEDSA, which is comprised of leading manufacturers and distributors of enteral feeding devices, is united by a shared desire to improve patient safety and optimal delivery of enteral feeding and connectivity. GEDSA speaks in a singular industry voice to communicate with the governing agencies, associations, and member suppliers, regarding issues that face enteral device manufacturers, suppliers, and distributors. GEDSA will lead a joint communication effort on behalf of the industry to ensure consistency and avoid any confusion as new, safer connectors are introduced in market.
   - Develop and execute a coordinated joint communications initiative
   - Identify this connector with a common name (ENFit) to be used by all manufacturers
   - Introduce enteral products with the ENFit connector within the same timeframe

4. **Why is a new enteral connector being introduced?**

   The purpose of the new connector is to help reduce the risk of enteral tube feeding misconnections and improve patient safety. The new ISO standard, ISO-80369-3, has been

established for Luer connectors on the nutrition formula end and the patient-access end. There is just one standard connector that will be utilized by all feeding set manufacturers and universally adopted into practice.

5. **Who developed the proposed new standard for enteral connector design?**

The new design was a group effort. Developed by ISO/TC 210/JWG 4Project Group (PG-3). This group is a global representation of clinicians, practice experts, regulators, and industry participants. Through this open forum, any company, National Standard organization or health care group interested in the ISO 80369-3 standard was allowed to participate. The PG-3 group identified, validated, and aligned to a global introduction of the new standard connector.

6. **When will the proposed standards be complete?**

In an effort to expedite the transition to safer connectors, the Association for the Advancement of Medical Instrumentation (AAMI) established a Provisional American National Standards AAMI/CN3(PS):2014 "Small-bore connectors for liquids and gases in health care applications" – Part 3: Connectors for enteral applications". The US Food and Drug Administration (FDA) recognizes this standard and encourages all manufacturers to implement it on enteral devices.

The Final Draft International Standard ISO 80369-3 is under review and anticipated to be approved with a published and recognized standard due mid-2016. The latest draft addresses dose accuracy, improved connector usability, engineering assessments and other technical content supporting the common goal of improved patient safety.

7. **What guidance has the FDA provided on the adoption of these standards?**

The FDA's final guidance: Safety Considerations to Mitigate the Risks of Misconnections with Small-bore Connectors Intended for Enteral Applications provides recommendations to manufacturers, FDA reviewers, and others involved in manufacturing devices that use small-bore connectors for enteral feeding. This guidance also provides direction for those submitting or reviewing premarket notification submissions [510(k)] for these types of devices.

The FDA's final guidance recommends:

- Devices with connectors that are part of, or form connections to, enteral feeding tubes conform to AAMI/CN3:2014 (PS) Part 3. However, conformance to the standard is not a requirement.
- Manufacturers design and test enteral connectors based upon AAMI/CN3:2014 (PS) and ISO 80369-20:2015 (formerly AAMI/CN20(PS):2014) to ensure that each proposed enteral connector is physically incompatible with non-enteral devices.
- Manufacturers of enteral connectors that do not meet AAMI/CN3 (PS):2014 also known as proprietary connectors or transition connectors, continue to design and test the

devices based upon the AAMI/American National Standards Institute (ANSI)/International Organization for Standardization (ISO) 80369-1:2010 standard "Small-bore connectors for liquids and gases in health care applications— Part 1: General requirements."

8. **What makes the ENFit connector different from the current system?**

The ENFit connector has a unique enteral-specific design that:

- Does not allow connectivity with connectors for any other clinical use
- Provides a locking feature for a secure, leak free connection
- Administration sets and syringes have a female connector end that fit onto or over a male patient access feeding tube port

9. **Why should we adopt the ENFit connector?**

The ENFit connector provides a simple way to reduce the risk of enteral tube feeding misconnections and improve patient safety. The ENFit connector:

- Addresses "patient side" connections between feeding tubes, administration sets, medication, flush and bolus feeding syringes, and other enteral devices
- Has been tested using a rigorous validation process including performance testing, misconnections assessment, computer aided design (CAD), human factors, usability and risk analysis testing.
- Provides the added benefit of providing a connection that stays connected much like a Luer lock system for IV/hypodermic applications

10. **What is syringe dead space and how does dead space relate to the ENFit connector?**

Dead space is the volume which is leftover in the tip of a syringe which remains undelivered after the gradient marking is at zero. Dead space occurs in all syringes and there are existing standards in place for some specific applications which identify ranges for acceptable levels of dead space in some syringes.

Because there is placement of the male patient access side into the female ENFit tip syringe there is a potential for the fluid inside the tip of the syringe to be displaced. GEDSA members have established an ENFit tip syringe protocol which addresses fluid displacement in the dead space.

In addition, a technical team of industry experts have worked collaboratively to identify a new ENFit low dose tip design that has demonstrated the ability to deliver highly accurate doses while appropriately fitting into current practice. The device design which is ISO 80369-3 ENFit compliant is progressing through final validation and anticipated to be ready for market introduction in 2016 pending regulatory clearance.

11. **Is ENFit appropriate for medication dosing?**

Yes. For accurate enteral dosing, draw up devices such as straws or fill caps may be necessary to use during filling. Additionally, to ensure dosing accuracy with doses of ≤ 1 mL and for syringes of sizes 5 mL and less, an ENFit Low Dose Tip (LDT) syringe is recommended.

A technical team of industry experts have worked collaboratively to identify a solution to address dose accuracy with a new ENFit low dose tip that has demonstrated the ability to deliver highly accurate doses while appropriately fitting into current practice. The device design solution which is ISO 80369-3 ENFit compliant is progressing through final validation and anticipated to be ready for market introduction in 2016 pending regulatory clearance.

12. **How will the ENFit connector be introduced?**

With guidance from regulatory authorities, practice experts, and the industry, healthcare facilities and providers will be guided through a careful transition plan from the current system to the new connector. Each company will follow its own product and market launch timeline. To avoid confusion and reinforce a common enteral connection, the global industry group has aligned to:

- Develop and execute a coordinated joint communications initiative
- 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

13. **If we use enteral administration sets with an ENFit connector from one manufacturer and feeding tubes with an ENFit connector from another manufacturer, will the products work together?**

Standard connection systems means interoperability; all major enteral device manufacturers are expected to comply with the proposed new ISO standards to help ensure compatibility between feeding tubes and feeding/administration sets. Manufacturers have worked together to develop an enteral-specific plan including transition connectors to allow cross-compatibility for the introduction period and to synchronize the introduction of the ENFit connector system.

14. **Can smaller size ENFit tip syringes be used without the low dose tip design?**

The low dose ENFit tip design has been created to address concerns with displacement of fluid in the tip and dosing accuracy. To ensure dosing accuracy with doses of ≤ 1 mL and for syringes of sizes 5 mL and less, an ENFit Low Dose Tip (LDT) syringe is recommended. In larger syringe

sizes, the amount of fluid displaced maintains an acceptable dosing amount. However for smaller syringe sizes, the low dose tip design may provide a more suitable dosing amount.

15. **Can ENFit tip syringes and the low dose ENFit tip design be used for oral route administration?**

The ISO 80369-3 connector standard is designed to address enteral route administration. Oral administration is not included in the scope of the standard. Work with your supplier representative to determine the best solution for oral administration of medication.

16. **Is it mandatory to adopt the new ENFit connector?**

Within the United States, California Assembly Bill 444 makes adoption mandatory for hospitals and skilled nursing facilities in the State of California, prohibiting the use of an epidural, intravenous, or enteral feeding connector which fits into a connection port other than the type for which it was intended.

This bill does not apply to home care use and while the standard is optional in the United States, several manufacturers are planning to adopt the ENFit connector design to be compliant with the new ISO standard. These transitions are expected to be complete sometime in 2017, in the US, Canada, and Puerto Rico, Europe, Middle East, Africa, Australia & New Zealand at which point the current universal connector will no longer be in wide circulation.

17. **What is the significance of the transition set?**

Transition feeding/administration sets allow fitment to both current feeding tube connectors as well as ENFit connectors through the use of a dual compatible connector. Transition feeding/administration sets will minimize disruption to supply and clinical practice and allow distributors and facilities to work through existing inventory of feeding tubes and feeding/administration sets.

18. **How long will it take to be fully converted to the ENFit connector?**

GEDSA recommends the introduction of new ENFit connectors in the first half of 2016 as soon as manufacturers are ready with adequate supply of feeding tubes and ENFit tip syringes including LDT syringes subject to design verification and regulatory approval in the following regions:

- North America (Group 1)
- Europe, Middle East, Africa, Australia and New Zealand (Group 2),
  The transition for these markets is anticipated to be completed sometime in 2017.

The UK (Group 3) introduction commences in June with targeted transition complete December, 2016.

It is recommended that Latin America and most of Asia begin to transition administration sets in 2016, followed by ENFit tip syringes and feeding tubes in 2017 where the transition will be completed sometime in 2018. For China and Japan, we recommend communicating these changes in 2016 with introduction of new ENFit enteral devices to be introduced starting 2017. Visit www.StayConnected.org for up to date information of ENFit timing.

19. **When will the current sets, feeding tubes, and syringes be discontinued?**

Discontinuation of items is at the sole discretion of manufacturers. In the State of California, enteral products with current connectors that allow fitment into a connection port other than the type for which it was intended will be prohibited in hospitals and skilled nursing facilities after July 1, 2016.

The California mandate does not include home use therefore current systems may still be used in home care. Check with your healthcare professional to determine which connector system would be most appropriate for use. Several GEDSA manufacturers have indicated that in addition to supplying feeding tubes with the ENFit connector they will continue to supply feeding tubes with the current connector until further notice. For precise timing of item discontinuation, contact your supplier representative.

20. **Will there be new item numbers or SKUs for the ENFit sets, feeding tubes, and enteral specific syringes?**

Introduction of new items and related issues such as new item numbers are at the sole discretion of manufacturers. For precise answers relative to new item introductions, contact your supplier representative.

21. **If applicable, when will the new item numbers be available and how will we know when to order the new item numbers (SKUs)?**

Introduction of new items and related issues, such as new item numbers, are at the sole discretion of manufacturers. For precise answers relative to new item introductions, contact your supplier representative.

22. **Will the ENFit transition connectors for the administration set be available as a standalone item?**

    Yes, the ENFit Transition Connectors are anticipated to be available by manufacturers. For timing, pricing, item numbers, and other details, please contact your supplier representative.

23. **How long will the transition feeding/administration sets be available?**

    Patients will need to consult their healthcare providers to understand if and when transition to a system with ENFit connectors is recommended. GEDSA recommends that the administration sets with transition connectors be made available for a period of one year after the introduction of ENFit tip syringes. Existing devices with the current connector will continue to be available to home use patient populations which use of ENFit will not be most suitable.

    Enteral feeding tubes may also have a transition period where ENFit Transition Connectors would be made available for cross-compatibility between current and the new ENFit connector. Introduction and availability of new items are at the sole discretion of manufacturers. For precise timing and availability of new item introductions, contact your supplier representative.

24. **Where can I get more information on pricing of ENFit transition sets and tubes?**

    Pricing is at the sole discretion of device manufacturers. You should work directly with your supplier to identify the best solution for your patients.

25. **Will distributors have inventory of the current system and the ENFit system in stock?**

    As devices with the ENFit connector are introduced in the market, distributors will have both the current and ENFit systems in stock. The transition plan that manufacturers and suppliers are developing will take into account inventory on hand for manufacturers, distributors, and end users. The plan does assume that it will take time to work through remaining inventory of the current products with the current connectors on them and then offer a flow-through of products with the new connector.

26. **Will there be a standard color for the ENFit connector?**

    Color coding is not included in the ISO 80369-3 standard. The standard will only address the ENFit connector's shape and size. These newly developed engineering controls (forcing functions) make it highly unlikely to bring two unintended connectors together, a development that seems more secure as opposed to relying on memorization of a specific color scheme. While you might see a consistent color used for enteral connectors, it is not a requirement.

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