Frequently Asked Questions

Enteral Connectors (ISO 80369-3)

12 May 2015 (v6)

IMPORTANT NOTE

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. This information is based on the proposed ISO 80369-3 standard and does not imply or suggest any regulatory clearance of any specific product and may not be predictive of clinical outcomes. 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.

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.

Frequently Asked Questions

Enteral Connectors (ISO 80369-3)

1. **What is a small-bore connector?**
2. **What changes are coming to current connectors? And what are the implications of these new standards?**
3. **Are enteral devices impacted by the Stay Connected initiative?**
4. **Why are you introducing a new enteral connector?**
5. **Who developed the proposed new enteral ISO standard connector design?**
6. **When will the proposed standards be complete?**
7. **What guidance has the FDA provided on the adoption of these new standards?**
8. **Why should we adopt the new ENFit connector?**
9. **What makes the new ENFit connector different from the current system?**
10. **When will the new ENFit connector be available?**
11. **What is the timing of the new ENFit enteral connector transition?**
12. **How will the new ENFit connector be introduced?**
13. **If we use enteral administration sets from one manufacturer and feeding tubes from another manufacturer, how will we know if the products will work together?**
14. **Do we have to transition to the new ENFit connector?**
15. **What is the significance of the transition set?**
16. **How long will it take to be fully converted to the new ENFit connector?**
17. **When will the current sets, feeding tubes, and syringes be discontinued?**
18. **Will there be new item numbers or SKUs for the new ENFit sets, feeding tubes, and syringes?**
19. **If applicable, when will the new item numbers be available and how will we know when to order the new item numbers (SKUs)?**
20. **Will the transition connectors be available as a standalone item?**
21. **How long will the transition feeding/administration sets be available?**
22. **When can I get more information on pricing of new ENFit transition sets and tubes?**
23. **Will distributors have inventory of the current system and the ENFit system in stock?**
24. **Will there be a standard color for the new ENFit connector?**

25. **What is the role of GEDSA?**
26. **Will non-enteral new medical tubing connectors have distinct names?**
27. **Will gastrostomy tube (G-tube) skin-level devices be changed in any way? If so, how?**
28. **Will using a transition connector on a bolus extension set make the hole in the bolus extension–syringe connection smaller?**
29. **Will the new connectors allow for venting?**
30. **Will it be possible to hydrate with a catheter-tip or oral-tip syringe**
31. **Will thicker formulas and blenderized foods pass through the new ENFit connector?**
32. **Why does this new system require that the old system become obsolete?**
33. **Will the inclusion of the transition connector and the final ENFit connection make the hole in the bolus extension and syringe connection smaller?**
34. **Will bolus syringes used for feeding blenderized diets be available with the new enteral connections?**
35. **Will the smaller size of the hole leaving the syringe impact ability to feed?**
36. **Will there be color-coded enteral syringes available to manage medication administration?**
37. **Will pharmacies stock enteral syringes?**
38. **Once syringes are specifically enteral, will there be greater insurance coverage?**
39. **Will there be adaptors for different kinds of syringes?**

1. What is a small-bore connector?

A small-bore connector is a connector with an inner diameter of less than 8.5mm 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).

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. Unique international standard designs will promote better patient safety and help ensure that connectors for unrelated delivery systems are incompatible. The program that is helping introduce the new standards is called the Stay Connected initiative for using safer connectors.

3. Are enteral devices impacted by the Stay Connected initiative?

Yes, enteral devices, including feeding tubes, administration sets, and enteral syringes are impacted by the initiative. A new enteral-specific ISO standard connector design has been identified and awaits final approval prior to introduction.

New ISO standard connectors have already been implemented and universally adopted on the nutrition formula end of feeding/administration sets. All enteral device connectors including feeding tubes, administration sets, and medication, flush, and bolus feed syringes are anticipated to comply with the new ISO standard. Enteral-specific syringes will also be required to connect to the new enteral feeding connector for medication, flush, and bolus feed syringes.

4. Why are you introducing a new enteral connector?

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

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

The new design was a group effort. AAMI/ISO assembled the ISO 80369–3 Project Group (PG-3). This group is a global representation of clinicians, practice experts, regulators, and industry participants. Through this open forum, any company interested in the ISO 80369 standard was allowed to participate. The PG-3 group identified, validated, and aligned to a global introduction of the new standard connector to systematically replace all prior enteral nutrition connector systems.

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 and AAMI/CN20:2014. The US Food and Drug Administration (FDA) now recognizes this standard and encourages all manufacturers to implement these standards on enteral devices.

These AAMI Provisional American National Standards cover Parts 3 of the International Standards Organization (ISO) 80369 series, which are currently in final development. Once the final version of ISO 80369-3 is approved by ISO, these provisional standards will be replaced by a parallel adoption of ISO 80369-3.

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

The FDA's newly released 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 AAMI/CN20:2014 (PS) to ensure that each proposed enteral connector is physically incompatible with non-enteral devices.
- Manufacturers of enteral connectors that do not meet AAMI/CN3:2014 (PS), 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 standard "Small-bore connectors for liquids and gases in health care applications"— Part 1: General requirements.

8. Why should we adopt the new ENFit connector?

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

- Addresses "patient side" connections between feeding tubes, administration sets, medication, flush and bolus feeding syringes, and other enteral devices
- Passes a rigorous validation process including computer aided design (CAD), human factors, and usability testing as part of the pathway to ISO standards

9. What makes the new ENFit connector different from the current system?

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

- Does not allow connectivity with any other connector for any other clinical use
- Provides a locking feature that signals the appropriate connection and stays in place
- Administration sets and syringes have a female connector end that fit into a male patient-access feeding tube port

10. When will the new ENFit connector be available?

Enteral products with the new ISO standard connector system are targeted to be implemented starting in Q2 2015 in the US, Canada, and Puerto Rico, and Q3 2015 for other markets. The ENFit connector will be transitioned into use with minimal disruption and allow clinicians to work through existing inventory. Timing is subject to change pending FDA 510(k) clearance. Check with your supplier representative for precise timing and product specific details.

11. What is the timing of the new ENFit enteral connector transition?

US, Canada, and Puerto Rico Implementation

Q1 2015 — Customers currently ordering sets with the stepped/Christmas tree connector will receive transition feeding/administration sets. These sets are compatible with both current feeding tube connections and the new ISO standard connector to ensure a smooth transition.

Q1 2016 — Flush and bolus feed syringes and enteral feeding tubes with the ENFit connector will be available.

2016 – Transition to new ISO standard connectors complete, at which point the current universal connector will no longer be available.

Timing is subject to change pending FDA 510(k) clearance. Check with your supplier representative for precise timing and product specific details.

Europe, Middle East, Africa, Australia, New Zealand Implementation

Q3 2015 — Customers currently ordering sets with the stepped/Christmas tree connector will receive transition feeding/administration sets. These sets are compatible with both current feeding tube connections and the new ENFit connector to ensure a smooth transition.

Q4 2015 — Enteral-specific syringes will also be available for fitment into new ENFit medication ports on feeding sets.

Q1 2016 — New enteral feeding tubes with the ENFit connector will be available.

2017 — Pending regulatory authority clearance and manufacturers' introduction dates, transition to new ISO standard connectors is anticipated to be complete, at which point the current universal connector will no longer be available.

United Kingdom, Ireland Implementation

September 2015 — Customers currently ordering sets with the stepped/Christmas tree connector will receive transition feeding/administration sets. These sets are compatible with both current feeding tube connections and new ENFit connector to ensure a smooth transition.

March 2016 — Enteral-specific syringes and new enteral feeding tubes with the ENFit connector will be available.

Introduction of new items are at the sole discretion of manufacturers. For precise timing of new item introductions, contact your supplier representative. In order to aid a smooth transition to the new ENFit connector, manufacturers are working to synchronize timing of transition feeding/administration sets with the new ENFit connectors to be available in Q1 2015 in the US, Canada, and Puerto Rico (Q3 2015 for EU and rest of world) for at least one (1) year while enteral feeding tubes are transitioned from current to new. Transition feeding/administration sets will allow fitment to both current feeding tube connectors as well as new ENFit connectors through the use of a dual compatible adapter.

12. How will the new 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 all manufacturers
- Introduce enteral products with the new ENFit connector within the same timeframe

13. If we use enteral administration sets from one manufacturer and feeding tubes from another manufacturer, how will we know if the products will work together?

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 new ENFit connector system.

14. Do we have to transition to the new ENFit connector?

Adoption is mandatory in California after the implementation of Assembly Bill 1867 that prohibits 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. In rest of the United States, all manufacturers are planning to adopt the new ENFit connector to be compliant with the new ISO standard design. These transitions are expected to be complete sometime in 2016, in the US, Canada, and Puerto Rico, at which point the current universal connector will no longer be available.

In Europe and other markets throughout the world, all major manufacturers and suppliers are planning to adopt the same new global standard connector system. Introduction will be on a different timeline than in the US, Canada, and Puerto Rico, but the goal remains the same—to align to a common enteral connector across the globe to improve patient safety. Transition is anticipated to be complete by 2017, pending manufacturer launch timing.

15. What is the significance of the transition set?

Transition feeding/administration sets allow fitment to both current feeding tube connectors as well as new ENFit connectors through the use of a dual compatible adapter. 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.

16. How long will it take to be fully converted to the new ENFit connector?

Enteral transition sets began rolling into the supply chain Q1 2015 however depending on your supplier and your facility's inventory management, conversion from the current connector system to the new connector system could take up to several months. By some time in 2016, the transition to new ENFit connectors should be complete in the US, at which point the current universal connector will no longer be available for enteral feeding tubes or feeding/administration sets. For Europe and all other markets, transition is anticipated to be complete by 2017, pending manufacturer launch timing.

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

Discontinuation of items is at the sole discretion of manufacturers. For precise timing of item discontinuation, contact your supplier representative. Products with current connectors that allow fitment into a connection port other than the type for which it was intended will be prohibited after January 1, 2016, in the state of California.

18. Will there be new item numbers or SKUs for the new 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.

19. 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.

20. Will the ENFit Transition Connectors be available as a standalone item?

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

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

Transition feeding/administration sets will most likely be made available for at least one year, allowing time for healthcare facilities and providers to work through their inventory of feeding tubes with the current connector system. 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.

22. When can I get more information on pricing of new 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.

23. Will distributors have inventory of the current system and the new ENFit system in stock?

As devices with the new ENFit connector are introduced in the market, distributors will have both the current and new ENFit systems in stock until inventories of the older model are depleted. Members of GEDSA (Global Enteral Device Suppler Association) have been working diligently to establish a transition plan to shift customers from the current system to the new ENFit connector. The transition plan that manufacturers and suppliers are working on 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. Manufacturers are prepared to provide transition sets for the period of at least a year in order to ensure the ability to connect to tubes with either the current or new ENFit connectors.

24. Will there be a standard color for the new ENFit connector?

Color coding is not included in the 80369 standards. The standards will only address the new 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.

25. 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 new ENFit connectors with the healthcare community. GEDSA, which is composed of leading manufacturers and distributors of enteral feeding devices, is united by a shared desire to increase 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.

26. Will non-enteral new medical tubing connectors have distinct names?

Connector naming will most likely not be included in the ISO 80369 standards. However to establish conformity many supplier companies are encouraged to use a common trademarked name for 80639 connectors as long as their product meets standards. Other delivery system working groups will align on a common name for the established standard connector.

27. Will gastrostomy tube (G-tube) skin-level devices be changed in any way? If so, how?

No. Connectors on skin-level feeding devices are out of scope of the new ISO 80369-3 design standards, so those specific device connectors will not change. At the point that extension sets attach to these devices the connection will likely remain the same since those connection points are not affected by the standard. However, the other end of the extension set (often called the proximal end) that connects to administration sets and syringes will have the new ENFit male connector.

28. Will using a transition connector on a bolus extension set make the hole in the bolus extension–syringe connection smaller?

Yes, the hole will likely be smaller than that of the current catheter-tip syringes, however it won't be smaller than the end of the extension set that connects to a low-profile device. As long as the end of the extension set remains the smallest hole in the system, the flow rate properties are not expected to change from the current configuration.

29. Will the new connectors allow for venting?

Yes. Venting will work in the same manner. Venting a feeding tube with the new standard ENFit connector will require a syringe with the new ENFit connector.

30. Will it be possible to hydrate with a catheter-tip or oral-tip syringe?

No. Hydration through a feeding tube with the new standard ENFit connector will require the use of a syringe with the new ENFit connector. Catheter-tip and oral-tip syringes will not fit the new connector. The connector was designed specifically to prevent the use of catheter-tip syringes in order to reduce the risks associated with possible misconnection among other medical delivery systems. Enteral-specific syringes with the ISO 80369-3 connector will be available in advance of the feeding tubes with the new ENFit connector.

31. Will thicker formulas and blenderized foods pass through the new ENFit connector?

The ISO 80369-3 enteral feeding design standards were developed with current practice in mind and specific requirements to avoid any disruption of therapy. The bore size (or hole) in the ENFit connector was designed to be consistent with the current connector (commonly called "Christmas tree" or "stepped adapter"). Therefore, feeding through devices with the ENFit connector is intended to be consistent with current practice. For more information, contact the manufacturer of the enteral device directly.

32. Why does this new system require that the old system become obsolete?

The goal of establishing an enteral connector design standard is to improve patient safety by reducing the risk of a tubing misconnection, which is rare but dangerous and can even be fatal. The most effective way to comprehensively reduce the risk of misconnections and enhance patient safety is to ensure that connectors of different delivery systems (i.e., enteral and IV) are not compatible. Leaving the current connectors in place means the possibility of misconnection would still exist. Today patients are typically quite mobile, moving between hospital, post-acute facilities, and home. If each channel has enteral feeding devices with either old or new connectors then there is a strong likelihood of disruption of therapy due to incompatibility as well as the potential for a misconnection with the current system.

33. Will the inclusion of the transition connector and the final ENFit connection make the hole in the bolus extension and syringe connection smaller?

Yes. The hole will likely be smaller than the catheter-tip syringe but not smaller than the patient access end of the (bolus) extension set opening on the low-profile device. As long as the end of the extension set remains the smallest hole in the system, the flow rate properties are not expected to change from the current configuration.

34. Will bolus syringes used for feeding blenderized diets be available with the new enteral connections?

Yes. All syringes intended for use through the enteral feeding tube in the future will require the new ENFit connector.

35. Will the smaller size of the hole leaving the syringe impact ability to feed?

These enteral-specific syringes with the new ENFit connector will likely have a smaller hole than the catheter-tip syringe. However the hole will not likely be smaller than the patient access end of the (bolus) extension set opening on most low-profile devices. As long as the end of the extension set remains the smallest hole in the system, the flow rate properties are not expected to change from the current configuration. For other devices, the industry is currently evaluating the impact of a smaller size of the hole.

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

There are no color-coding requirements in the standards. Therefore, syringe manufacturers may offer enteral-specific ENFit syringes in one or more colors. Check with your manufacturer or distributor of syringes for additional details as products become available.

37. 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 to carry these items. Check with either your local pharmacy or your home medical equipment company for the availability of enteral-specific syringes.

38. 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. Check with your insurance provider for their specific policy.

39. Will there be adaptors for different kinds of syringes?

During the transition period there will be a transition connector that will be compatible with the new enteral syringe with ENFit connector and allow fitment to the current feeding ports. After the transition period, it will not be necessary to have an adapter to fit an ENFit syringe to the ENFit feeding tube. You may need to have an enteral-specific ENFit syringe to connect to the feeding tube. Catheter-tip or oral-tip syringes will not work with the new ENFit connector feeding tube.

Non-Traditional Use of Enteral Patient Access Devices

GEDSA advises against and cannot comment on 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.

692 N. High St. Suite 304
Columbus, OH 43215 USA

gedsa.org

Prepared by GEDSA

Contact:
Tom Hancock
m (614)947-0041
tom@gedsa.org