Frequently Asked Questions

Blenderized Diet and Other Patient/Caregiver Concerns (ISO 80369-3)

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IMPORTANT NOTE

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Frequently Asked Questions

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1. **Will gastrostomy tube (G-tube) skin-level devices be changed in any way? If so, how?**
2. **Will using a transition connector on a bolus extension set make the hole in the bolus extension-syringe connection smaller?**
3. **Will the new connectors allow for venting?**
4. **Will it be possible to hydrate with a catheter-tip or oral-tip syringe?**
5. **Will thicker formulas and blenderized foods pass through the new ENFit connector?**
6. **Why does this new system require that the old system become obsolete?**
7. **Will the inclusion of the transition connector and the final ENFit connection make the hole in the bolus extension and syringe connection smaller?**
8. **Will bolus syringes used for feeding blenderized diets be available with the new enteral connections?**
9. **Will the smaller size of the hole leaving the syringe impact ability to feed?**
10. **Will there be color-coded enteral syringes available to manage medication administration?**
11. **Will pharmacies stock enteral syringes?**
12. **Once syringes are specifically enteral, will there be greater insurance coverage?**
13. **Will there be adaptors for different kinds of syringes?**

1. **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. Extension sets that attach to these devices will likely have the same connection at the point that it inserts into the device 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 connector.

2. **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, but 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.

3. **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.

4. **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.

5. **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.

6. **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.

7. 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.

8. 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.

9. 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.

10. 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.

11. 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.

12. 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.

13. 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 207
Columbus, OH 43215 USA

gedsa.org

Prepared by GEDSA

Contact:
Tom Hancock
m (614)716-8971
tom@gedsa.org